

A New Universal Simplified Adhesive: 6-Month Clinical Evaluation

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ABSTRACT

Statement of the Problem: Multimode adhesives, which can be used as etch-and-rinse or as self-etch adhesives, have been recently introduced without clinical data to back their use.

Purpose of the Study: To evaluate the 6-month clinical performance of Scotchbond Universal Adhesive (SU; 3M ESPE, St. Paul, MN, USA) in noncarious cervical lesions (NCCLs) using two evaluation criteria.

Methods/Materials: Thirty-nine patients participated in this study. Two hundred restorations were assigned to four groups: SU-TE_m: etch-and-rinse + moist dentin; SU-TE_d: etch-and-rinse + dry dentin; SU-SE_{et}: selective enamel etching; and SU-SE: self-etch. The composite resin Filtek Supreme Ultra (3M ESPE) was placed incrementally. The restorations were evaluated at baseline and after 6 months using both the World Dental Federation (FDI) and the United States Public Health Service (USPHS) criteria. Statistical analyses were performed with Friedman repeated measures analysis of variance by rank and McNemar test for significance in each pair ($\alpha = 0.05$).

Results: Only four restorations (SU-SE: 3 and SU-TE_m: 1) were lost after 6 months ($p > 0.05$ for either criteria). Marginal discoloration occurred in one restoration in the SU-SE group ($p > 0.05$ for either criteria). Only 2/200 restorations were scored as bravo for marginal adaptation using the USPHS criteria (one for SU-SE and one for SU-SE_{et}, $p > 0.05$). However, when using the FDI criteria, the percentage of bravo scores for marginal adaptation at 6 months were 32%, 36%, 42%, and 46% for groups SU-TE_m, SU-TE_d, SU-SE_{et}, and SU-SE, respectively ($p > 0.05$).

Conclusions: The clinical behavior of the multimode adhesive does not depend on the bonding strategy at 6 months. The FDI evaluation criteria are more sensitive than the USPHS criteria.

CLINICAL SIGNIFICANCE

At 6 months, the clinical behavior of the new multimode adhesive Scotchbond Universal was found to be reliable when used in noncarious cervical lesions and may not depend on the bonding strategy employed.

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INTRODUCTION

One of the disadvantages of etch-and-rinse adhesives is their susceptibility to variations in the degree of dentin moisture.^{1,2} The complete filling of the interfibrillar spaces by resin monomers is unfeasible, and an area of exposed demineralized dentin may remain within

the bonded interface.^{3–5} Consequently, interfacial degradation may occur as a result of the incomplete infiltration of resin monomers into the dentin collagen network.^{6,7} In vivo morphological evidence of hydrolysis of collagen has been reported in human primary teeth with bonded restorations.⁸ Elution of resin from the bonded

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interface as a result of hydrolysis has also been reported *in vitro*.⁹

Self-etch adhesives dissolve the smear layer only partially and do not demineralize dentin as deep as etch-and-rinse adhesives.⁷ The incorporation of smear layer, resin, collagen, and mineral¹⁰ into the hybrid layer and the superficial portion of the resin tags may prevent postoperative sensitivity that occurs with etch-and-rinse adhesives because of incomplete infiltration of resin monomers into the collagen network.^{11,12} On the other hand, self-etch adhesives do not etch enamel to the same depth that phosphoric acid does, resulting in lower enamel bond strengths and frequent occurrence of enamel marginal discrepancies in clinical studies.^{11,13} To overcome this limitation, selective etching of enamel margins has been recommended prior to the application of self-etch adhesives.^{14,15} For some self-etch adhesives, bond strengths may decrease when they are applied on acid-etched dentin compared with the same adhesive applied in the self-etch mode.^{16–18}

Clinically, it is difficult to apply phosphoric acid on enamel without overflowing to dentin, especially if dentists use low-viscosity gels or liquid etchants. Some dentists even dry the enamel surface to check for a frosty aspect of the etched enamel, which would result in air-drying the dentin surface as well. Overdrying acid-etched dentin may prevent collagen fibers from being completely enveloped by resin monomers leading to degradation by hydrolysis and decreased durability of the bonding.^{8,19}

In spite of compromised *in vitro* and clinical longevity associated with ultrasimplified adhesives compared with that of adhesives that rely on several steps,^{7,20} several one-step self-etch adhesives have been recently developed to simplify and shorten the application time, making the clinical procedure more user-friendly.²¹ Manufacturers have recently launched universal or multimode one-bottle adhesives that can be used as self-etch or as etch-and-rinse adhesives.^{22,23} These materials, and the respective concept behind them, are novel; hence, only immediate ultramorphological and bond strength studies have been published.^{22,23} Clinical studies are needed to back the use of these new

adhesives as suggested by the respective manufacturers, *i.e.*, evaluating the same adhesive under two adhesive strategies: self-etch and etch-and-rinse.

In 2007, several journals published new criteria for evaluation of dental restorations called the “World Dental Federation (FDI) criteria” as a result of the efforts of FDI to organize them.^{24,25} Since then, results have so far been only partly published,²⁵ and only one study compared the FDI criteria with the United States Public Health Service (USPHS) criteria²⁶ for the evaluation of restorations in primary teeth.²⁷ This study²⁷ concluded that the FDI criteria were more sensitive for identifying differences in the restorations. However, this paper²⁷ is an abstract and has not been published in full article format.

Thus, the aim of this randomized, double-blind clinical trial was to study the influence of different application strategies of a new universal multimode adhesive (Scotchbond Universal Adhesive [SU], 3M ESPE, St. Paul, MN, USA) placed in noncarious cervical lesions (NCCLs) over the course of 6 months using two evaluation criteria (FDI and USPHS criteria). The null hypotheses tested were (1) that bonding to NCCLs using the self-etch strategy, associated or not to enamel etching (selective etching), or using the etch-and-rinse strategy applied on dry or moist dentin, would not result in similar clinical performance over 6 months of clinical service, and (2) that 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.²⁸ This was a randomized, double-blind, clinical trial. The study took place in the clinic of the State University of Ponta Grossa School of Dentistry from January 2011 to November 2011. All participants were informed about the nature and objectives of the study; however, they were not aware of what lesion received the treatments under evaluation.

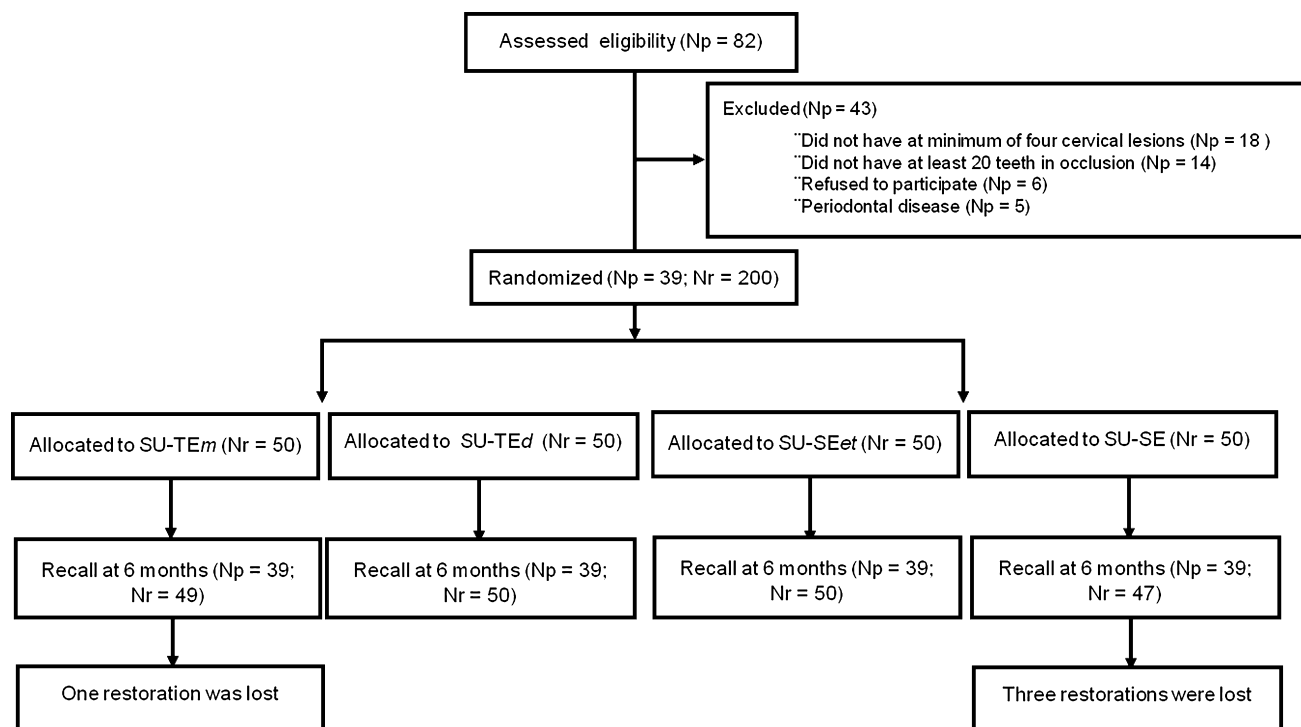


FIGURE 1. Flow diagram. Np = number of patients; Nr = number of restorations; SU-SE = self-etch; SU-SE_{et} = selective enamel etching; SU-TE_d = etch-and-rinse, dry dentin; SU-TE_m = etch-and-rinse, moist dentin.

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 before starting 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 to check if they met the inclusion and exclusion criteria (Figure 1) by two precalibrated operative dentistry residents. The qualified patients were recruited in the order in which they reported for the screening session, 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 and at least 18 years old.

They needed to have an acceptable oral hygiene level and present at least 20 teeth under occlusion. They were required to have at least four NCCLs in four different teeth with a maximum of six lesions that needed to be restored. These lesions had to be noncarious, nonretentive, and deeper than 1 mm, and involve both the enamel and dentin of vital teeth without mobility. The cavosurface margin could not involve more than 50% of enamel.²⁹

All patients were given oral hygiene instructions before 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 the volunteer participants received a dental prophylaxis with pumice and water in a rubber cup and signed an informed consent form 2 weeks before the restorative procedures.

TABLE 1. Dentin sclerosis scale*

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
*Adapted from Swift and colleagues. ³⁰	

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 *et al.*³⁰ (Table 1). The cavity dimensions in millimeters (height, width, and depth) and the geometry of the cavity (evaluated by photograph profile and labeled at <45°, 45–90°, 90–135°, >135°) were also recorded. Other features such as the presence of antagonist and 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 over 5 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 by 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 person 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 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 selection guide, the proper shade of the composite was determined. Following the American Dental Association (ADA) guidelines,³¹ the operators did not prepare any additional retention or bevel.

Then, the NCCLs received the SU system applied in different modes: the etch-and-rinse approach, keeping the dentin moist (SU-TE_m) or dry (SU-TE_d), and in the self-etch approach with (SU-SE_{et}) or without selective enamel etching (SU-SE). The compositions, application modes, and batch numbers are described in Table 2.

In the SU-TE_m group, dentin was kept visibly moist, whereas in the SU-TE_d group, dentin was air-dried for 5 seconds, but not overdried. In the SU-SE_{et} group, the lesion was air-dried after rinsing the etchant from the enamel. Dentin was kept dry in both 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 on the dentin surface under manual pressure (equivalent to approximately 45 g or more) followed by gentle air thinning for 5 seconds and finally light-curing (Radii Cal, SDI, Bayswater, Victoria, Australia) for 10 seconds (1,000 mW/cm²).

TABLE 2. Adhesive system: composition and application mode

Adhesive systems	Composition	Application mode*			
Scotchbond Universal Adhesive (3M ESPE, St. Paul, MN, USA)	1. Scotchbond Universal Etchant: 34% phosphoric acid	Etch-and-rinse	Apply etchant for 15 seconds. Rinse for 10 seconds. Air dry to remove excess water.	Keep dentin moist.	Apply the adhesive for 20 seconds with vigorous agitation. Gently air thin for 5 seconds. Light-cure for 10 seconds.
	2. Adhesive: methacryloyloxydecyl dihydrogen phosphate, phosphate monomer; dimethacrylate resins, hydroxyethyl methacrylate, methacrylate-modified polyalkenoic acid copolymer; filler; ethanol, water; initiators, silane	Selective etching	Apply etchant only on enamel for 15 seconds. Rinse for 10 seconds. Air dry to remove excess water.	Keep dentin dry; do not overdry.	
	Self-etch	Do not use etchant.	Keep dentin dry; do not overdry.		
*According to the manufacturer's instructions.					

Filtek Supreme Ultra (3M ESPE) resin composite was used in three increments, each one being light-cured for 30 seconds. The restorations were finished immediately with fine-grain diamond burs (KG Sorensen, Barueri, SP, Brazil). Polishing was performed with rubber points (Astropol, Ivoclar Vivadent, Schaan, Liechtenstein) 1 week after placement of the restorations.

Sample Size Calculation

The retention rate of SU in the etch-and-rinse approach was considered based on the retention rate of Adper single bond (3M ESPE). It was considered 94% at 18- to 24-month follow-up.^{32–37} Using an α 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.³⁸

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 subjects each on 2 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 the beginning of the evaluation.²⁶

All parameters during evaluation were recorded using a standardized paper case report form. The evaluation paper had to be sent after each observation to the research auxiliary, so that evaluators were blinded to group assignment during follow-up recalls.

The restorations were evaluated by two criteria: the FDI criteria^{24,25} and the classical USPHS criteria adapted by Dalton Bittencourt *et al.*³⁹ and Perdigão *et al.*³⁷ at baseline and after 6 months of clinical service.

For either of the two criteria, only the clinically relevant measures of performance of adhesives were evaluated. For example, wear and color match were not considered as relevant parameters (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 1 week after the restorative procedure by applying air for 10 seconds from a dental syringe placed 2 cm from the tooth surface.

TABLE 3. World Dental Federation (FDI) criteria used for clinical evaluation^{24,25}

	Esthetic property	Functional properties		Biological properties	
	1. Marginal staining	2. Fractures and retention	3. Marginal adaptation	4. Postoperative (hyper) sensitivity	5. Recurrence of caries
1. Clinically very good	1.1 No marginal staining.	2.1 Restoration retained, no fractures/cracks.	3.1 Harmonious outline, no gaps, no discoloration.	4.1 No hypersensitivity.	5.1 No secondary or primary caries.
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 μ m). 3.2.2 Small marginal fracture removable by polishing.	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)	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 μ m not removable. 3.3.2 Several small enamel or dentin fractures.	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)	1.4 Pronounced marginal staining; major intervention necessary for improvement.	2.4 Chipping fractures that damage marginal quality; bulk fractures with or without partial loss (less than half of the restoration).	3.4.1 Gap >250 μ m or dentin/base exposed. 3.4.2 Chip fracture damaging margins. 3.4.3 Notable enamel or dentin wall fracture.	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)	1.5 Deep marginal staining not accessible for intervention.	2.5 Partial or complete loss of restoration.	3.5 Filling is loose but in situ.	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.
Acceptable or not acceptable (N, % and reasons)	Esthetic criteria.	Functional criteria.		Biological criteria.	

These variables were ranked according to the criteria in the following scores: 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 *et al.* was used.^{24,25} Each evaluator outlines the extent of the observed event on the sketch of each restoration using

a pen according to defined criteria (marginal staining and marginal adaptation); after that, each margin is 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.

TABLE 4. Modified United States Public Health Service (USPHS) criteria according to Dalton Bittencourt *et al.*³⁹ and Perdigão *et al.*³⁷

	Marginal staining	Retention	Fracture	Marginal adaptation	Postoperative sensitivity	Recurrence of caries
<i>Alfa</i>	No discoloration along the margin	Retained	None	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>	Slight and superficial staining (removable, usually localized)		Small chip, but clinically acceptable	Detectable V-shaped defect in enamel only. Catches explorer going both ways	–	–
<i>Charlie</i>	Deep staining cannot be polished away	Missing	Failure due to bulk restorative fracture	Detectable V-shaped defect to dentin-enamel junction	Sensitivity present at any time during the study period	Evidence of presence of caries

The restoration retention rates were calculated according to the ADA guidelines.³¹ Cumulative failure percentage = $[(PF + NF)/(PF + RR)] \times 100\%$, where PF is the number of previous failures before the current recall, NF is the number of new failures during the current recall, and RR is the number of currently recalled restorations.³¹

Statistical Analysis

The statistical analyses followed the intention-to-treat protocol according to CONSORT suggestion.²⁸ This protocol includes all participants in their originally randomized groups, even those that 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 property. The differences in the ratings of the four groups after 6 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 6 months were evaluated using the McNemar test ($\alpha = 0.05$). SQUACE was evaluated for Kruskal–Wallis and Mann–Whitney tests ($\alpha = 0.05$). Cohen's kappa statistic was used to test interexaminer agreement.

RESULTS

The restorative procedures were implemented exactly as planned, and no modification was performed. The performed analyses had been prespecified in the protocol. No subgroup analysis was done. Forty-three out 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 details regarding the research subjects and characteristics of the restored lesions are presented in Table 5. The overall Cohen's kappa statistics (0.94) showed good agreement between the examiners. All research subjects were evaluated at the baseline and at 6 months (Figure 1).

Nine restorations had postoperative sensitivity 1 week after the restorative procedures using both the FDI and USPHS criteria (1 for SU-TE_m, 4 for SU-TE_d, 3 for SU-SE_{et}, and 1 for SU-SE), with no statistical difference when compared with different groups ($p > 0.05$) (Tables 6 and 7). None of the restorations showed postoperative sensitivity under both the FDI and USPHS criteria at the 6-month recall evaluation.

Four restorations were lost at 6 months (1 for SU-TE_m and 3 for SU-SE) according to FDI and USPHS criteria. Six-month retention rates were 98%

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 antagonistic, presence of attrition facets, presence of preoperative sensitivity, and tooth and arch distribution)

Characteristics of research subjects	Number of lesions			
Gender distribution				
Male	24			
Female	15			
Age distribution (years)				
20–29	05			
30–39	12			
39–49	12			
>49	10			
Characteristics of Class V lesions	Number of lesions SU-TE _m	SU-TE _d	SU-SE _{et}	SU-SE
Shape (degree of angle)				
<45				
45–90	14	14	12	12
90–135	34	34	38	38
>135	02	02		
Cervicoincisal 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	0	0	0	0
No	50	50	50	50
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
Molar	12	14	08	12
Arc distribution				
Maxillary	25	26	30	28
Mandibular	25	24	20	22
SU-SE = self-etch; SU-SE _{et} = selective enamel etching; SU-TE _d = etch-and-rinse, dry dentin; SU-TE _m = etch-and-rinse, moist dentin.				

TABLE 6. Number of evaluated restorations for each experimental group according to the adhesive (SU-TE_m, SU-TE_d, SU-SE_{et}, and SU-SE) classified according to the World Dental Federation (FDI) criteria^{24,25}

Time FDI criteria		Baseline				6 Months			
		SU-TE _m	SU-TE _d	SU-SE _{et}	SU-SE	SU-TE _m	SU-TE _d	SU-SE _{et}	SU-SE
Marginal staining	VG	50	50	50	50	50	50	50	49
	GO	–	–	–	–	–	–	–	01
	SS	–	–	–	–	–	–	–	–
	UN	–	–	–	–	–	–	–	–
	PO	–	–	–	–	–	–	–	–
Fractures and retention	VG	50	50	50	50	49	50	50	47
	GO	–	–	–	–	–	–	–	–
	SS	–	–	–	–	–	–	–	–
	UN	–	–	–	–	–	–	–	–
	PO	–	–	–	–	01	–	–	03
Marginal adaptation	VG	50	50	50	50	34	32	29	27
	GO	–	–	–	–	16	18	21	23
	SS	–	–	–	–	–	–	–	–
	UN	–	–	–	–	–	–	–	–
	PO	–	–	–	–	–	–	–	–
Postoperative (hyper) sensitivity	VG	49	46	47	49	50	50	50	50
	GO	–	–	–	–	–	–	–	–
	SS	01	04	03	01	–	–	–	–
	UN	–	–	–	–	–	–	–	–
	PO	–	–	–	–	–	–	–	–
Recurrence of caries	VG	50	50	50	50	50	50	50	50
	GO	–	–	–	–	–	–	–	–
	SS	–	–	–	–	–	–	–	–
	UN	–	–	–	–	–	–	–	–
	PO	–	–	–	–	–	–	–	–

SU-SE = self-etch; SU-SE_{et} = selective enamel etching; SU-TE_d = etch-and-rinse, dry dentin; SU-TE_m = etch-and-rinse, moist dentin; GO = clinically good; PO = clinically poor; SS = clinically sufficient/satisfactory; UN = clinically unsatisfactory; VG = clinically very good.

for SU-TE_m, 100% for SU-TE_d, 100% for SU-SE_{et}, and 94% for SU-SE, with no statistical difference between any pair of groups at each recall ($p > 0.05$) (Tables 6 and 7).

For the FDI criteria, 78 restorations were considered to have minor discrepancies with marginal adaptation (16 for SU-TE_m, 18 for SU-TE_d, 21 for SU-SE_{et}, and 23 for SU-SE, $p = 0.001$) (Table 6). These discrepancies were

TABLE 7. Number of evaluated restorations for each experimental group according to the adhesive (SU-TE_m, SU-TE_d, SU-SE_{et}, and SU-SE) classified according to the adapted United States Public Health Service (USPHS) criteria^{37,39}

Time	USPHS modified criteria	Baseline				6 Months			
		SU-TE _m	SU-TE _d	SU-SE _{et}	SU-SE	SU-TE _m	SU-TE _d	SU-SE _{et}	SU-SE
Marginal staining	<i>Alfa</i>	50	50	50	50	50	50	50	49
	<i>Bravo</i>	—	—	—	—	—	—	—	01
	<i>Charlie</i>	—	—	—	—	—	—	—	—
Retention	<i>Alfa</i>	50	50	50	50	49	50	50	47
	—	—	—	—	—	—	—	—	—
	<i>Charlie</i>	—	—	—	—	01	—	—	03
Fracture	<i>Alfa</i>	50	50	50	50	50	50	50	50
	<i>Bravo</i>	—	—	—	—	—	—	—	—
	<i>Charlie</i>	—	—	—	—	—	—	—	—
Marginal adaptation	<i>Alfa</i>	50	50	50	50	50	50	50	48
	<i>Bravo</i>	—	—	—	—	—	—	—	02
	<i>Charlie</i>	—	—	—	—	—	—	—	—
Postoperative sensitivity	<i>Alfa</i>	49	46	47	49	50	50	50	50
	—	—	—	—	—	—	—	—	—
	<i>Charlie</i>	01	04	03	01	—	—	—	—
Recurrence of caries	<i>Alfa</i>	50	50	50	50	50	50	50	50
	—	—	—	—	—	—	—	—	—
	<i>Charlie</i>	—	—	—	—	—	—	—	—

SU-SE = self-etch; SU-SE_{et} = selective enamel etching; SU-TE_d = etch-and-rinse, dry dentin; SU-TE_m = etch-and-rinse, moist dentin.

easily removed. No significant difference was detected among groups at the 6-month recall ($p > 0.05$). Also, there was no statistical difference among groups when SQUACE^{24,25} was compared ($p > 0.05$; Table 8). In this specific item, only overcontour in the enamel margins was observed. For the USPHS modified criteria, only two restorations in the SU-SE group were classified as *bravo* for marginal adaptation, and no significant difference was found among groups at the 6-month recall ($p > 0.05$) (Table 7).

Marginal staining was only observed in one restoration for the SU-SE group according to FDI criteria, and no significant difference was found between groups and at 6 months ($p > 0.05$). No restoration had clinical

problems related to fracture, postoperative sensitivity, and recurrence of caries at 6 months for either the FDI or the USPHS criteria. Thus, no statistical differences were noted for any of the other parameters.

When the FDI criteria for “acceptable” versus “not acceptable” restorations were applied, only the four lost restorations were ranked as “not acceptable” (Table 9).

DISCUSSION

We failed to reject both null hypotheses, as there were no statistical differences in the clinical parameters for the different bonding strategies tested in this study and

TABLE 8. Number of evaluated restorations for each experimental group according to the adhesive classified for semiquantitative score (SQUACE)^{24,25}

FDI criteria*		SU-TE _m	SU-TE _d	SU-SE _{et}	SU-SE
SQUACE	Less than 10%	10	09	13	08
	Between 10% and 20%	03	05	05	05
	Between 21% and 30%	03	04	03	08

SU-SE = self-etch; SU-SE_{et} = selective enamel etching; SU-TE_d = etch-and-rinse, dry dentin; SU-TE_m = etch-and-rinse, moist dentin.
 *No significant difference was found between groups (Kruskal–Wallis, $p = 0.45$).

TABLE 9. Restorations acceptable or not acceptable according to the World Dental Federation (FDI) criteria after 6 months^{24,25}

Properties	Esthetic				Functional				Marginal adaptation				Biological				Recurrence of caries			
	Staining margin				Fractures and retention								Postoperative (hyper) sensitivity							
	SU-TE _m	SU-TE _d	SU-SE _{et}	SU-SE	SU-TE _m	SU-TE _d	SU-SE _{et}	SU-SE	SU-TE _m	SU-TE _d	SU-SE _{et}	SU-SE	SU-TE _m	SU-TE _d	SU-SE _{et}	SU-SE	SU-TE _m	SU-TE _d	SU-SE _{et}	SU-SE
Acceptable	50	50	50	50	49	50	50	47	50	50	50	50	50	50	50	50	50	50	50	50
Not acceptable	00	00	00	00	01	00	00	03	00	00	00	00	00	00	00	00	00	00	00	00
Reasons		Total loss of the restorations																		

SU-SE = self-etch; SU-SE_{et} = selective enamel etching; SU-TE_d = etch-and-rinse, dry dentin; SU-TE_m = etch-and-rinse, moist dentin.

there was no difference among the four bonding strategies when evaluated with the FDI and the USPHS criteria. In the present study, the behavior of SU in self-etch mode (SU-SE) suggests that SU may possess an intrinsic ability to bond chemically to dentin and enamel. SU differs from Adper Single Bond Plus adhesive primarily in the partial replacement of the dimethacrylate monomers with the 10-methacryloyloxydecyl dihydrogen phosphate (MDP) monomer to provide acidity for its self-etching capability. Chemical bonding between 10-MDP and enamel and dentin may play an important role in providing stable and durable interfaces.^{15,40} The chemical bonding provided by the 10-MDP molecule in the primer, combined with the excellent mechanical properties and high conversion rate of its filled hydrophobic resin,^{41,42} resulted in very good clinical behavior of Clearfil SE Bond (CSE; Kuraray, Osaka, Japan) at 8 years.¹¹ CSE, a 10-MDP-based two-step self-etch adhesive, is considered the reference for all other self-etch adhesives.^{11,43,44}

Although SU contains less 10-MDP than CSE,⁴⁰ SU also contains a polyalkenoic acid copolymer. This copolymer was first used in the composition of Vitrebond (3M ESPE), also known as Vitrebond copolymer or VCP. This copolymer bonds chemically to the calcium in hydroxyapatite.⁴⁵ Clinical studies have shown a good performance of VCP-containing etch-and-rinse adhesives,^{39,46} which may be attributed, at least partially, to chemical bonding. For self-etch adhesives, chemical bonding between polycarboxylic monomers (such as VCP) and hydroxyapatite plays a crucial role in their bonding mechanism.^{47,48} Over 50% of the carboxyl groups in the polyalkenoic acid copolymer are capable of bonding to hydroxyapatite.⁴⁷ Carboxylic groups replace phosphate ions on the substrate and make ionic bonds with calcium.⁴⁷ With these two chemical bonding mechanisms in mind, the clinical behavior of SU-SE in our study may have been a result of: (1) the chemical bonding ability of both the 10-MDP monomer^{49–51} and VCP⁴³ to hydroxyapatite; (2) the protective effect of the calcium-MDP (Ca-MDP) salt,¹¹ as the Ca-MDP salt is

one of the most hydrolytically stable salts⁴⁹; and (3) the formation of a submicron micromechanical interlocking at the dentin surface by SU.⁴⁰ The monomer 10-MDP is adsorbed onto hydroxyapatite in a regularly layered structure at the hydroxyapatite surface (nano-interaction)^{40,51} and at the same time decalcifies hydroxyapatite.⁴⁹ However, SU does not form nanolayered structures with the same frequency as CSE on the dentin surface. This difference may be related to the presence of the VCP and 2-hydroxyethyl methacrylate (HEMA) in SU, which may compete with 10-MDP.⁴⁰

When SU was applied on dentin in the self-etch mode, with (SU-SE*et*) or without (SU-SE) selective enamel etching, the clinical behavior of SU was similar to that of the etch-and-rinse groups, SU-TE*m*, and SU-TE*d*. Besides the chemical bonding between enamel and both 10-MDP and VCP, etching may have provided micromechanical enamel retention. Enamel microtensile bond strengths are higher when two multimode one-bottle adhesives, SU and G-Bond Plus (GC Corporation, Tokyo, Japan), are applied on etched enamel.^{20,52} The benefits of enamel selective etching may be only apparent after a few years. Enamel marginal defects were more prevalent in clinical studies up to 8 years when a 10-MDP-based adhesive was applied as a self-etch adhesive.^{11,13,53}

The amount of resin impregnation within the hybrid layer for water-free adhesives with dry bonding is significantly lower than when dentin is left moist.⁵⁴ In our study, when dentin and enamel were etched with phosphoric acid, the amount of surface moisture (moist versus dry dentin) did not influence the clinical behavior of SU. This adhesive is ethanol- and water-based (10–15% by Wt of each).⁵⁵ In spite of the dryness of the dentin surface, the water contained in SU may be able to plasticize the collapsed collagen network, allowing for reexpansion and reopening of the interfibrillar spaces for the infiltration of resin monomers.⁵⁶ This phenomenon was deemed responsible for the hybrid layer formed with SU-TE*d* in a recent *in vitro* investigation.²³ Additionally, a dynamic application of the adhesive on dry dentin may have contributed to the indistinguishable behavior between

moist and dry dentin, as *in vitro* and clinical research has shown that rubbing the adhesive continuously on dry dentin results in similar performance.^{57,58}

Despite 92 teeth that showed preoperative sensitivity to air, only 9 teeth had postoperative sensitivity after the restorations were inserted, which disappeared at the 6-month recall. Clinical studies have shown no difference in postoperative sensitivity between self-etch and etch-and-rinse adhesives.³⁷ For self-etch adhesives, they use part of the smear layer as the bonding substrate; therefore, the monomer-impregnated smear plugs serve as barrier to prevent the fluid shift inside the tubules. For SU used as etch-and-rinse adhesive on moist or on dry dentin, resin tags were found to be profusely branched out into dentin tubules and able to seal the tooth-resin interface,²³ which may explain that no tooth showed postoperative sensitivity.

Recent studies have shown water sorption of adhesive resin as proportional to its hydrophilic characteristics.^{59,60} The self-etching ability of one-bottle adhesives is commonly achieved by incorporation of water in resin monomers that enables ionization of acidic monomers. In addition to the water in the compounds, the ionizable moieties of acidic monomers are also hydrophilic. The presence of such a more hydrophilic layer may thus induce water sorption and water uptake, in turn jeopardizing the stability of the polymer network. Accordingly, other studies should focus on 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. In fact, a systematic review⁶¹ of clinical studies published between 1998 and 2009 found that two-step self-etch adhesives and glass-ionomer cement-based materials resulted in the lowest failure rate when used to restore NCCL. Besides the proven chemical affinity between 10-MDP and hydroxyapatite, 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.^{62,63} The addition of a hydrophobic resin layer to the new multipurpose adhesive systems is a clinically relevant topic of future research. Besides 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 into the clinical behavior of SU over 5 years.

Although laboratory studies cannot always predict the clinical durability of bonded restorations, the dentin bond strengths of aged specimens seem to correlate with 5-year clinical data.⁶¹ Another research group found evidence that dentin microtensile bond strength, especially after water storage for 6 months, showed a good correlation with marginal discoloration in short-term clinical Class V restorations.⁶⁴

This clinical study has limitations, as 6 months may sound like a very short period to evaluate the long-term clinical behavior of dental adhesives. However, the fact that SU belongs to a novel family of simplified multimode dental adhesives, which lack clinical data and are indicated for use under different application strategies, warranted this short-term evaluation. Another limitation is that more than four restorations were placed in several patients (11). In spite of being a common situation in the dental literature,^{11,29,35,39,46,53} this may have caused a clustering effect. The impact of this clustering effect on the final results was not considered, and it should be considered in the future studies.

CONCLUSIONS

Within the limitations of this study, the 6-month clinical behavior of SU does not depend on the bonding strategy used. The FDI evaluation criteria are more sensitive to small variations in the clinical outcomes than the USPHS criteria when evaluating restorations of NCCLs.

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