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Eighteen-month Clinical Study of Universal Adhesives in Noncarious Cervical Lesions

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Clinical Relevance

Some of the currently available universal adhesives may present similar clinical performance when applied in the self-etch and etch-and-rinse modes. Yet clinicians should be aware that use in the etch-and-rinse application mode tends to result in fewer stained margins when compared to the self-etch application mode.

SUMMARY

Objective: To evaluate the clinical performance of Scotchbond Universal (3M Oral Care) and Prime & Bond Elect (Dentsply Sirona) in the restoration of noncarious cervical lesions (NCCLs).

Methods and Materials: This was a randomized controlled clinical trial involving 63 subjects. Two hundred and three NCCLs were restored using Scotchbond Universal and Prime & Bond Elect using both an etch-and-rinse and a self-etch technique. Lesions were notch-shaped NCCLs, and the restorations were placed without any mechanical retention. Restorations were finished immediately after placement and scored with regard to retention, marginal discoloration, marginal adaptation, and secondary caries. Similar assessment of the restorations was performed 18 months after placement. Logistic regression was performed for each outcome separately with a compound symmetric variance-covariance structure assumed to consider a correlation of restorations within subjects. All analyses were conducted using SAS version 9.4 (SAS Inc).

Results: One hundred and fifty-eight teeth (77.8% of the restorations placed) in 46 subjects (73% of subjects enrolled) were available for the 18-month follow-up. A statistically significant difference was reached only for the comparison Scotchbond Universal/self-etch (SU_SE) and Prime & Bond Elect/etch-and-rinse (PBE_E&R) groups (p=0.01), where

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a restoration with SU_SE was 66% less likely to maintain a score of Alpha for marginal discoloration than a restoration performed with PBE_E&R.

Conclusions: Scotchbond Universal and Prime & Bond Elect presented acceptable clinical performance after 18 months of clinical service. However, Scotchbond Universal, when applied with a self-etch approach, did demonstrate a relatively high level of marginal discoloration when compared to the other groups.

INTRODUCTION

Adhesion of varying degrees to both dentin and enamel can be accomplished by using etch-and-rinse and self-etch techniques.[1,2] Etch-and-rinse adhesive systems rely on the initial application of phosphoric acid to demineralize dentin and enamel. After rinsing, the demineralized surfaces that remain allow for subsequent infiltration of a low-viscosity resin to achieve micromechanical retention.[1] This approach is common to both two-step etch-and-rinse adhesives (primer and adhesive in one bottle) and three-step etch-and-rinse adhesives (primer and adhesive applied separately).

Clinical challenges that may compromise the longevity of restorations performed with etch-and-rinse adhesive systems include 1) the potential for errors during application because of the multiple steps (particularly for three-step materials) and 2) maintenance of an adequately hydrated collagen network after the dentin is demineralized by phosphoric acid.[3-5] To allow for optimal resin infiltration into the demineralized collagenous network, dentin must not be overdried and desiccated.[5]

Meanwhile, self-etch adhesive systems, which do not include phosphoric acid pretreatment of dentin and enamel, can be found in one- or two-step application modes.[2] Two-step self-etch adhesive systems have been available for many years and have been shown to be clinically reliable.[6,7] On the other hand, one-step self-etch adhesive systems, which normally combine all adhesion steps in one single bottle, have demonstrated questionable clinical success.[7-9] In order to provide adequate conditioning of the tooth structures, one-step adhesive systems require significant amounts of water to ionize their acidic monomers. An inverse correlation between hydrophilicity of materials and stability of adhesive interfaces has been continuously demonstrated in *in vitro* studies, thereby raising concerns for longevity of the bonds.[6,8-11]

Recently, adhesive systems that can be applied using either the etch-and-rinse or the self-etch technique, namely, universal adhesives, have been developed.[12] These materials can be used with or without pretreatment of dentin and enamel with phosphoric acid, even though selective etching of enamel is often recommended, and the adhesive system can be applied to dry or wet dentin.[13] Universal adhesives contain functional monomers in their compositions that may enhance bonding through chemical adhesion to tooth structures. One of these monomers, namely, 10-methacryloyloxydecyl dihydrogen phosphate (10-MDP), has been part of the composition of dental adhesives for decades.[14] Its affinity for calcium in hydroxyapatite, which is amplified and stabilized by the low solubility of the calcium salt of the acidic molecule, makes it a desirable component for adhesive systems.[14-17] However, the ability of functional monomers to properly condition the enamel structure in order to have restorations free of marginal staining has been questioned.[13,18] The pH of universal adhesives is directly related to the ability of the material to sufficiently demineralize tooth structure and is in the mild range.[19,20] This feature makes it ideal for adhesion to dentin but sometimes inadequate for optimal enamel bonding.[19-22] Clinical data demonstrating that universal adhesives can be applied without phosphoric acid pretreatment of enamel are needed despite favorable *in vitro* data suggesting that they do adhere well to both dentin and enamel substrates.[12,23-26]

Clinical evaluation of adhesive systems is often performed using noncarious cervical lesions (NCCLs).[7] The inherent characteristic of NCCLs. including increased sclerosis of the dentin substrate, occlusal forces that stress the cervical third of teeth, minimal retention form, and margins that not only are in enamel but also extend to dentin, make them the ideal substrate to challenge the retention ability of adhesive systems.[27] A recent clinical trial where restorations bonded with a universal adhesive system (Scotchbond Universal, 3M Oral Care, St Paul, MN, USA) in the etch-and-rinse, self-etch, or selective etching mode showed no difference in retention after 18 months of service.[18] Similarly, no difference in clinical behavior was found when the same universal adhesive was bonded to moist or dry dentin using the etch-and-rinse technique or using the self-etch or selective etching techniques after 36 months.[13] Contradicting results were found when Scotchbond Universal was applied in etch-and-rinse and self-etch modes and compared to Scotchbond

Multi-Purpose (3M ESPE).[28] In this study, Scotchbond Universal showed superior performance with regard to marginal discoloration when applied in the etch-and-rinse mode after 24 months of function.[28] Differences in clinical performance between etch-and-rinse and self-etch techniques also have been reported for Xeno Select (Dentsply Sirona, York, PA, USA). In a recent published study, Xeno Select did not fulfill the American Dental Association (ADA) criteria for full approval when used in the self-etch or the selective etching mode after six months of clinical service.[29]

The limited clinical data available and the increased popularity of universal adhesives have led us to the design of this clinical trial. The clinical performance of two universal adhesives, namely 10-MDP-containing Scotchbond Universal and Prime & Bond Elect (Dentsply Sirona) placed in NCCLs was evaluated over a period of 18 months. The null hypothesis tested was that there is no difference in clinical performance between etch-and-rinse and self-etch techniques for Scotchbond Universal and Prime & Bond Elect with regard to retention, marginal discoloration, marginal adaptation, and secondary caries.

METHODS AND MATERIALS

This study was a randomized controlled clinical trial that evaluated the clinical performance of two universal adhesives used with a bis-GMA–free nanohybrid composite resin (Kalore, GC Corporation, Tokyo, Japan) in NCCLs. The Institutional Review Board of the Federal University of Santa Catarina, Brazil, approved the study, protocol 745.430/14. Subjects were recruited via mass e-mail to faculty, staff, and students at the Federal University of Santa Catarina.

A single operator (VCR) screened all candidates in the operative dentistry postgraduate clinic at the Federal University of Santa Catarina. Adults who were in need of restoration of at least one notch-shaped NCCL and who fulfilled the inclusion/exclusion criteria were included in the study. Excluded were candidates with fewer than 20 teeth and with poor oral hygiene, uncontrolled periodontal disease, xerostomia, or known allergy to resin-based materials or who were medically compromised, pregnant, or breast-feeding. Teeth that had saucer-shaped lesions or that were nonvital, not in occlusion, or previously restored also were excluded.

The selected teeth were allocated into four groups to be restored according to the following protocols: 1) Scotchbond Universal, etch-and-rinse mode (SU_E&R); 2) Scotchbond Universal, self-etch mode (SU_SE); 3) Prime & Bond Elect, etch-and-rinse mode (PB_E&R); and 4) Prime & Bond Elect, self-etch mode (PB_SE). A member of the study team not involved with the insertions performed the randomization. The very first restoration was restored according to protocol 1. Subsequently, the randomization followed the Universal Numbering System (1-32) with the next lowest numbered tooth being restored following protocol 2 and so on. Always following in ascending order, the first tooth for the next subject was restored following the next protocol in queue. Prior to restoration, the amount (percentage) of enamel margins; restoration volume determined by height, width, and depth of the NCCL; presence of stress occlusion; gingival condition around the tooth to be restored; preoperative sensitivity; and degree of dentin sclerosis as measured by the UNC Sclerosis Scale were recorded.[30]

A total of 63 subjects with 203 NCCLs were enrolled. Subjects were 34 females and 29 males ranging from 21 to 67 years of age (42.6±12.7). A trained operative dentistry operator (VCR) performed all restorative procedures. After shade selection, moisture control was performed with retraction cord, cotton rolls, lip retractor, and low-speed suction. The internal aspect of the lesion was roughened with a round diamond (#1014, KG Sorensen, Cotia, Brazil), and no bevel or mechanical retention features were placed. Anesthesia was used as needed. The adhesive systems were applied according to the manufacturer's directions as detailed in Table 1 and the preparations restored with three increments of up to 2 mm in thickness of Kalore (GC Corporation). See Figure 1 for insertion technique. Finishing and polishing procedures were immediately performed using carbide finishing burs, Jiffy Composite Adjusters and Polishers (Ultradent Products, Inc, South Jordan, UT, USA), and Astrobrush (Ivoclar Vivadent AG, Schaan, Liechtenstein). Light-curing procedures were performed using Translux Blue (Heraeus Kulzer, Hanau, Germany) at a consistent output of 800 mW/cm^2.

Two independent and calibrated evaluators (SS and SCS) assessed the restorations immediately after placement and after 18 months of clinical service using the criteria in Table 2. Evaluations were performed using an intraoral mirror and a number 23 explorer and under operatory light. Disagreements were discussed, and a consensus rating was developed.

Table 1: *Materials, Compositions, and Application Techniques for the Universal Adhesive Systems Used*

Adhesive	Composition	Application Technique	
		Self-Etch	Etch-and-Rinse
Scotchbond Universal (3M Oral Care, St Paul, MN, USA)	10-MDP phosphate monomer, dimethacrylate resins; HEMA; methacrylate-modified polyalkenoic acid copolymer; filler; ethanol; water; initiators; silane	1. Apply adhesive with a microbrush with rubbing motion for 20 s 2. Evaporate solvents with gentle stream of air until adhesive movement no longer can be noticed 3. Light cure for 10 s	1. Apply etchant for 15 s 2. Rinse for 10 s 3. Air-dry for 5 s 4. Apply adhesive as detailed in self-etch technique
Prime & Bond Elect (Dentsply Sirona, York, PA, USA)	Mono-, di-, and trimethacrylate resins; PENTA diketone; organic phosphine oxide; stabilizers; cetylamine hydrofluoride; acetone; water	1. Apply adhesive agitating for 20 s 2. Gently dry for 5 s 3. Light cure for 10 s	1. Apply etchant for 15 s 2. Rinse for 15 s 3. Air-dry for 5 s 4. Apply adhesive as detailed in the self-etch technique

Abbreviations: 10-MDP, 10-methacryloyloxydecyl dihydrogen phosphate; HEMA, 2-hydroxyethyl methacrylate; PENTA, dipentaerythritol penta-acrylate monophosphate.

All outcomes were evaluated as Alpha at baseline; thus, the focus of the statistical analyses was on the change of outcome overtime, that is, A vs B and C outcomes. The primary goal of the statistical analyses was to identify the effect of adhesive protocol on the outcome of the restorations. The effects of sclerosis degree and volume of the restoration on the outcome of the restorations were also considered. Descriptive statistics were performed. Logistic regression was performed for each outcome separately, where a compound symmetric variance-covariance structure was assumed to consider a correlation of restorations within subjects. All analyses were conducted at a significance level of 5% ($p \leq 0.05$), using SAS version 9.4 (SAS Inc, Cary, NC, USA).

RESULTS

One hundred and fifty-eight teeth (77.8% of the restorations placed) in 46 subjects (73% of subjects enrolled) were available for the 18-month follow-up. Table 3 shows the descriptive statistics and Table 4 shows the logistic regression results. The outcomes retention and secondary caries were not considered due to a small number of Bravo or Charlie scores at 18 months. Likewise, protocol was not included in the model for marginal adaptation. Significant statistical difference was reached only for the comparison SU_SE and PBE_E&R ($p=0.01$), where a restoration with SU_SE is 66% less likely to maintain a score of Alpha for marginal discoloration than a restoration performed with PBE_E&R. Four of 38 and 10 of 37 restorations placed with

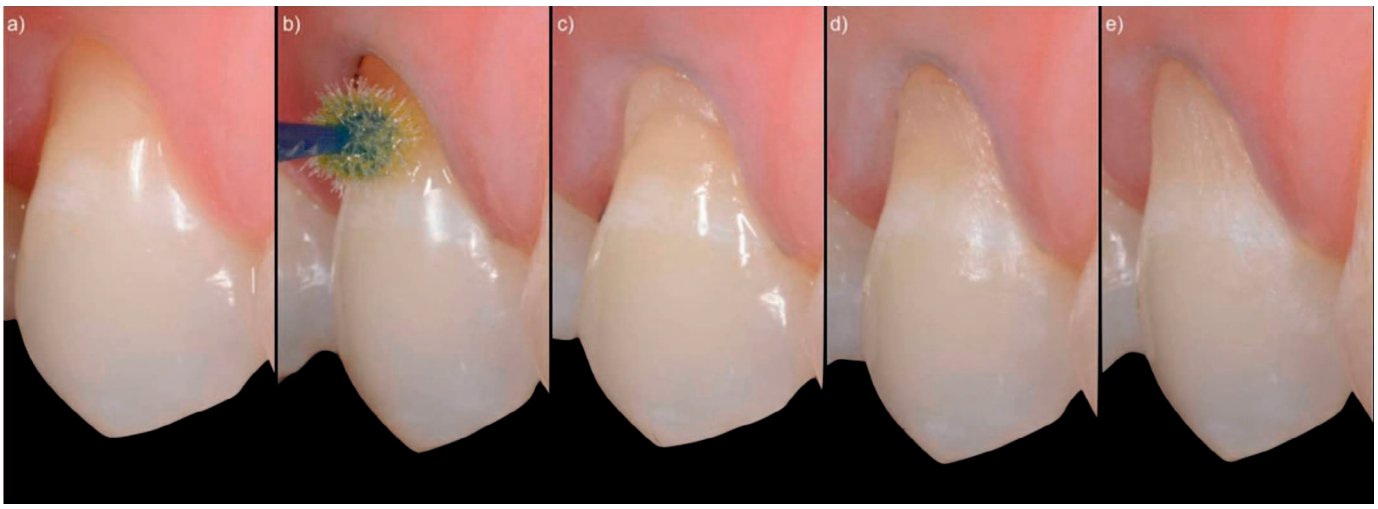

Figure 1. *Stratification of the composite resin restoration. (a): Preoperative view of the class V cavity. (b): Application of adhesive system in the self-etch mode. (c): Insertion of the first dentin increment. (d): Insertion of the second dentin increment. (e): Insertion of the enamel increment. Note that no enamel shade of composite resin was used.*

Table 2: *Modified US Public Health Service Direct Evaluation Criteria*

Criteria	Classification
Retention	Alpha = retained
	Charlie = mobile or missing
Marginal discoloration	Alfa = No discoloration at margins
	Bravo = Shallow discoloration (localized or generalized)
	Charlie = Deep discoloration (localized or generalized)
Marginal adaptation	Alpha = no visible evidence of a crevice along the margin into which the explorer will penetrate
	Bravo = visible evidence of a crevice along the margin, dentin not exposed, clinically acceptable
	Charlie = explorer penetrates into crevice, dentin exposed, clinically unacceptable
Secondary caries	Alpha = no
	Charlie = yes

PBE_E&R and SU_SE, respectively, received a score of Bravo at 18 months. Other comparisons that did not reach significant statistical differences for marginal discoloration were that 1) PB_SE is 10% less likely to maintain a score of Alpha than PB_E&R, 2) SU_SE is 42% less likely to maintain a score of Alpha than SU_E&R, 3) SU_E&R is 41% less likely to maintain a score of Alpha than PB_E&R, and 4) SU_SE is 62% less likely to maintain a score of Alpha than PBE_SE. In addition, restorations were more likely to present marginal discoloration in teeth with greater levels of dentin sclerosis, but that comparison also was not statistically significant.

DISCUSSION

The null hypothesis that there is no difference in the clinical performance between etch-and-rinse and self-etch techniques for Scotchbond Universal and Prime & Bond Elect with regard to retention, marginal discoloration, marginal adaptation, and secondary caries was accepted. Scotchbond Universal and Prime & Bond Elect had similar clinical performance, the only statistically significant difference being found for the comparison between SU_SE and PB_E&R, in which the former had a 66% less chance to maintain ideal margins with regard to marginal discoloration over time than the latter.

Overwhelming *in vitro* literature suggesting that degradation of resin-dentin bonding may affect the longevity of composite resin restorations exists.[6,31] It is believed that the collagen matrix at the adhesive interface is only partially infiltrated by the bonding resin after phosphoric acid treatment of dentin.[1,6,12,13,32] The exposed collagen would then be susceptible to degradation by matrix metalloproteinases,[33,34] ultimately resulting in failure of the adhesive interface by fatigue.[1,6,31] The clinical implications of the resin-dentin bonding degradation are somewhat unclear, as cavity preparations often have enamel margins, which do not undergo the same degradation process. Recently, the degradation of the resin-dentin bonding was disregarded as a clinical problem when the overall caries risk of the patient is under control.[35] Studies evaluating the effects of aging on the dentin bond strength of universal adhesives applied in the etch-and-rinse mode have shown no deterioration of the adhesive interface.[26,36]

On the other hand, the major issue related to self-etch adhesives seems to be enamel marginal discoloration due to the mild acidity of these adhesives when compared to phosphoric acid.[2] Several *in vitro* studies have demonstrated that the enamel bonding created by self-etch adhesives is inferior to that created by etch-and-rinse materials.[37-39] The two universal adhesives tested in this study have similar pH values (PBE=2.5 and SU=2.7).[19-21] Ultramild self-etch adhesives (pH>2.5) have limited interaction with dentin, resin tags are hardly formed, smear plugs get slightly demineralized and resin-infiltrated, and there is less potential for enamel etching with lower chemical reactivity with hydroxyapatite in enamel.[2] A meta-analysis of *in vitro* studies demonstrated that phosphoric acid etching of enamel increases the bond strength of universal adhesives to that substrate.[21]

Despite the *in vitro* evidence that enamel etching may be critical for maintenance of restorations without marginal discoloration, a recent 13-year randomized clinical trial comparing a self-etch adhesive applied to NCCLs with and without the use of selective etching of enamel showed only a minor positive effect of selective etching of enamel on marginal integrity and absence of marginal discoloration. The differences were not statistically significant.[40] Our study showed no significant difference in clinical performance between universal adhesives applied using the etch-and-rinse and self-etch technique in the short term. Yet 10 of 37 restorations placed with SU_SE showed marginal discoloration after 18 months, which may be considered a high incidence in such a short period of time. Despite the fact that 16.6% (26 of 157) and 5.7% (9 of 157) of the restorations presented a Bravo score for marginal discoloration and marginal adaptation, respectively, at 18 months, the use of phosphoric acid on the

Table 3: *Descriptive Statistics for a Total Number of 158 Restorations Placed in 46 Subjects. Data Are Listed as Percentage After 18 Months for the Outcomes of Retention, Marginal Discoloration, Marginal Adaptation, and Secondary Caries and Frequency for the Covariates of Tooth Type, Dentin Sclerosis, and Mean Volume (±SD) and for Restorations Evaluated for Each Adhesive. Missing Restorations (Unavailable for Evaluation) Were Excluded From the Calculations of the Percentage Shown*

Type	Variable	Total (n=203)	SU_E&R (n=52)	SU_SE (n=50)	PBE_E&R (n=50)	PBE_SE (n=51)
Outcome	Retention					
	Alpha	157 (99.4%)	42	37	38	40
	Charlie	1 (0.6%)	0	0	0	1
	Missing	45	10	13	12	10
	Marginal discoloration					
	Alpha	131 (83.4%)	35	27	34	35
	Bravo	26 (16.6%)	7	10	4	5
	Charlie	0 (0.0%)	0	0	0	0
	Missing	46	10	13	12	11
	Marginal adaptation					
	Alpha	148 (94.3%)	38	35	38	37
	Bravo	9 (5.7%)	4	2	0	3
	Charlie	0 (0.0%)	0	0	0	0
	Missing	46	10	13	12	11
	Secondary caries					
	Alpha	157 (100%)	42	37	38	40
	Charlie	0 (0.0%)	0	0	0	0
	Missing	46	10	13	12	11
Covariate	Tooth type					
	Canine	23	9	5	2	7
	Incisor	9	2	2	2	3
	Molar	19	6	5	4	4
	Premolar	107	25	25	30	27
	Dentin sclerosis					
	1	73	19	14	22	18
	2	68	21	19	13	15
	3	15	1	4	2	8
	4	2	1	0	1	0
	Volume (mm^3)	11.0 ± 8.7	10.1 ± 5.8	12.8 ± 11.0	11.5 ± 10.5	9.8 ± 6.5

Abbreviations: SU_E&R, Scotchbond Universal/etch-and-rinse; SU_SE, Scotchbond Universal/self-etch; PBE_E&R, Prime & Bond Elect/etch-and-rinse; PBE_SE, Prime & Bond Elect/self-etch.

preparation failed to alter the outcome of the restorations. PB_SE was 10% less likely to maintain a score of Alpha than PB_E&R, while SU_SE was 42% less likely to maintain a score of Alpha than SU_E&R with regard to marginal discoloration. It should be pointed out that marginal discoloration often occurs due to excess material at the margins of the restoration and can be solved by repolishing.[41]

Previous clinical studies with longer follow-up periods than our study have shown inferior marginal discoloration or adaptation over time. In 2015, Lawson and others[28] showed no statistical differences between Scotchbond Universal applied in the etch-and-rinse and self-etch techniques with regard to secondary caries and marginal adaptation. However, the etch-and-rinse application of the adhesive resulted in fewer cases of marginal discoloration at 24 months. Likewise, increased marginal staining was found for Scotchbond Universal when applied using the self-etch technique compared to the etch-and-rinse technique after 36 months of service in another controlled clinical trial.[13]

Studies evaluating the performance of dental restorative materials have used for decades some variation of the US Public Health Service (USPHS) criteria.[42-44] These criteria, which have shown to be effective in determining the clinical performance of restorative materials over time, may not be specific

Table 4: *Results of Logistic Regression for Marginal Discoloration and Marginal Adaptation Modeling the Probability of Maintaining Alpha Scores, With Compound Symmetry Correlation Structure*

Outcomes	Covariates	Effect	OR	95% CI		z	p
Marginal discoloration	Protocol	PBE_SE vs PBE_E&R	0.90	0.24	3.36	−0.16	0.87
		SU_E&R vs PBE_E&R	0.59	0.20	1.76	−0.94	0.35
		SU_SE vs PBE_E&R	0.34	0.15	0.79	−2.53	0.01
		SU_E&R vs PBE_SE	0.66	0.18	2.42	−0.62	0.53
		SU_SE vs PBE_SE	0.38	0.11	1.27	−1.57	0.12
		SU_SE vs SU_E&R	0.58	0.25	1.33	−1.29	0.20
	Sclerosis	2 vs 1; 3 vs 2; 4 vs 3	0.56	0.29	1.08	−1.73	0.08
		3 vs 1; 4 vs 2	0.31	0.08	1.17		
		4 vs 1	0.17	0.02	1.27		
	Volume		1.001	0.95	1.05	0.04	0.97
Marginal adaptation	Sclerosis	2 vs 1; 3 vs 2; 4 vs 3	0.70	0.23	2.11	−0.64	0.52
		3 vs 1; 4 vs 2	0.49	0.05	4.46		
		4 vs 1	0.34	0.01	9.40		
	Volume		1.04	1.06	0.66	−0.42	0.67

Abbreviations: OR, odds ratio; CI, confidence interval; PBE_SE, Prime & Bond Elect/self-etch; PBE_E&R, Prime & Bond Elect/etch-and-rinse; SU_E&R, Scotchbond Universal/etch-and-rinse; SU_SE, Scotchbond Universal/self-etch.

enough to identify minor differences among the very similar and extensively developed modern restorative materials. This observation led to the development of the Federation Dentaire Internationale (FDI) criteria in 2007.[45] The current study, which used the USPHS modified criteria, failed to demonstrate significant differences when comparing the application techniques, namely, etch-and-rinse and self-etch techniques, of two universal adhesives. Similarly, no differences in marginal adaptation and discoloration were found in another recently published controlled clinical trial comparing Scotchbond Universal applied following different techniques. Interestingly, a significant increase in marginal discrepancies when the material was used in the self-etch technique was found when the FDI criteria were applied in that study.[18]

Aside from containing 10-MDP, which may enhance adhesion to tooth structures through chemical adhesion to hydroxyapatite in a process called nanolayering,[14,15,18,46,47] SU contains polyalkenoic acid copolymer in its composition. The ionic bond between the carboxyl groups in the polyalkenoic acid and hydroxyapatite in enamel and dentin may have aided the adhesion of SU to the NCCLs in this study, as demonstrated in an *in vitro* study.[24] Prime & Bond Elect, on the other hand, contains dipentaerythritol penta-acrylate monophosphate (PENTA) in its composition. To the best of the authors' knowledge, there is no *in vitro* study demonstrating the effects of PENTA on adhesion. In a recently published *in vitro* study, PB presented the lowest dentin bond strengths when adhesives were applied according to the manufacturers' instructions.[48]

Some limitations of this study that are worth mentioning are 1) the relatively low sensitivity of the modified USPHS evaluation criteria used and 2) the placement of all restorations by the same operator. Further evaluation of the restorations placed in this study is planned, and an updated report should be available in the near future.

CONCLUSIONS

Scotchbond Universal and Prime & Bond Elect presented acceptable clinical performance after 18 months of clinical service. However, it should be noted that Scotchbond Universal used with a self-etch approach did exhibit a fairly high incidence of marginal discoloration for this short clinical time period.

Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the Federal University of Santa Catarina. The approval code for this study is 745.430/14.

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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