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Clinical Research

Two-year Randomized Clinical Trial of Self-etching Adhesives and Selective Enamel Etching

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Clinical Relevance

Selective enamel etching in combination with self-etching adhesives does not affect the overall clinical performance of composite restorations.

SUMMARY

Objective: The aim of this randomized, controlled prospective clinical trial was to evaluate the clinical effectiveness of restoring noncarious cervical lesions with two self-etching adhesive systems applied with or without selective enamel etching.

Methods: A one-step self-etching adhesive (Xeno V$^+$) and a two-step self-etching system (Clearfil SE Bond) were used. The effectiveness of phosphoric acid selective etching of enamel margins was also evaluated. Fifty-six cavities were restored with each adhesive system and divided into two subgroups (n=28; etch and non-etch). All 112 cavities were restored with the nanohybrid composite Esthet.X HD. The clinical effectiveness of restorations was recorded in terms of retention, marginal integrity, marginal staining, caries recurrence, and postoperative sensitivity after 3, 6, 12, 18, and 24 months (modified United States Public Health Service).

Results: The Friedman test detected significant differences only after 18 months for marginal staining in the groups Clearfil SE non-etch (p=0.009) and Xeno V$^+$ etch (p=0.004). One restoration was lost during the trial (Xeno V$^+$ etch; $p>0.05$).

Conclusions: Although an increase in marginal staining was recorded for groups Clearfil SE non-etch and Xeno V$^+$ etch, the clinical effectiveness of restorations was considered acceptable for the single-step and two-step self-etching systems with or without selective enamel etching in this 24-month clinical trial.

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INTRODUCTION

Adhesive systems have gone through several changes in recent years in an attempt to simplify bonding procedures without compromising adhesion to tooth substrates.[1,2] A few years ago, most adhesives were available in three application steps, which were combined into two steps (etch-and-rinse or self-etching), and later, into one single self-etching application step. One-step self-etching adhesives present a shorter clinical application time, reduction in technique sensitivity, and are user-friendly. Despite the simplified approach of all-in-one adhesives, early formulations did not promote an effective seal of dentin.[1] However, manufacturers claim that the chemistry behind newer all-in-one self-etching adhesives have been changed for improved performance.[3,4]

Self-etching systems have been widely accepted as a good alternative for bonding resin composite to dentin. However, controversy still remains regarding their use for bonding composite to enamel.[5,6] This concern centers around the shallower demineralization pattern produced by mild self-etching systems compared with etch-and-rinse systems.[7,8] Therefore, selective enamel etching with phosphoric acid has been routinely indicated when self-etching systems are to be used. A long-term clinical study has demonstrated only minor benefits of selective etching of enamel margins when a two-step self-etching system was used.[9] However, there is no information on whether selective etching is necessary for newer single-step self-etching formulations.

Laboratory-based studies are important for predicting the clinical performance of adhesive procedures, whereas randomized clinical trials are the ultimate tests to evaluate the clinical efficacy of adhesive materials and techniques.[10-12] Noncarious cervical lesions (NCCLs) are widely available and are normally used because they present no macromechanical retention, they present margins in enamel and dentin, and are subjected to high stress during masticatory function.[13,14]

The null hypotheses of this randomized, controlled prospective clinical trial were that 1) there is no difference in the long-term clinical performance of NCCLs restored with a two-step and a one-step self-etching system; and 2) selective etching of enamel margins produces no difference in the long-term clinical performance of restorations.

METHODS AND MATERIALS

Two self-etching adhesives were evaluated in the present investigation: a one-step, XENO V$^+$ (Dentsply De Trey, Konstanz, Germany), and a two-step, Clearfil SE Bond (Kuraray Noritake, Tokyo, Japan). Clinical effectiveness of adhesive systems was evaluated when they were applied following the manufacturers' recommendations, abbreviated as XV-NE (non-etch) and CSE-NE, and when applied after selective etching of enamel margins with 36% H_3PO_4, abbreviated as XV-E (etch) and CSE-E. Composition, manufacturers, and application technique of materials are presented in Table 1.

Clinical effectiveness of restoration was determined according to the following parameters: retention rate, marginal integrity, marginal staining, secondary caries, postoperative sensitivity, and pulp vitality. Clinical performance of restorations was evaluated at baseline and at 3, 6, 12, 18, and 24 months of clinical service. Clinical success was recorded according to the modified United States Public Health Service (USPHS) criteria.[10]

Fifty-six class V restorations were performed with each adhesive and were divided into two subgroups (n=28; with or without selective enamel etching).

Inclusion and Exclusion Criteria

Previous to patient recruitment, the research protocol was approved by the Ethics Committee in Clinical Research. This clinical trial was registered at ClinicalTrials.gov. Patients were examined by a single investigator and needed at least four NCCLs, independent of tooth location. Patients with a compromised medical history, severe or chronic periodontitis, extreme caries sensitivity, heavy bruxism, under orthodontic treatment, having poor oral hygiene and smokers were excluded from the study. Based on these criteria, 25 patients were included in the present investigation and signed the informed consent.

Prior to restoration, lesions were classified in terms of shape, depth, cervico-incisal size, degree of dentin sclerosis, presence of antagonist, preoperative sensitivity, and type of tooth.

Restorative Procedure

Operative procedures were performed by an experienced dentist from the Department of Operative Dentistry. Each patient received at least four restorations, in which groups were randomly allocated (using randomization tables). Four restorations were placed in one appointment. Three patients had eight lesions, which were restored in two appointments. After shade selection, teeth were restored using cotton roll and retraction cord (Ultra-

Table 1: *Materials, Manufacturers, Lot Number, Composition, and Application Technique*

Materials	Composition	Application procedure
Clearfil SE (Kuraray-Noritake) Lot# Primer 00954A; Bond 01416A	Primer: 10-MDP, HEMA, hydrophilic dimethacrylate, CQ, *N,N*-diethanol p-toludine, water	Apply primer for 20 seconds; gently air-blow
	Bond: 10-MDP, Bis-GMA, HEMA, hydrophilic dimethacrylate, CQ, *N,N*-diethanol p-toludine, silanized colloidal silica	Apply adhesive and light-cure for 10 seconds
Xeno V^+ (Dentsply DeTrey) Lot# 00751	Bifunctional acrylate, acidic acrylate, functionalized phosphoric acid ester, water, tertiary butanol, initiator, stabilizer	Apply adhesive for 20 seconds, gently air-blow and light-cure for 10 seconds
DeTrey Conditioner 36 (Dentsply DeTrey) Lot# 1004002386	Phosphoric acid, highly dispersed silicon dioxide, detergent, pigment, water	Apply etchant selectively on enamel and leave for 15 seconds; thoroughly rinse and gently air dry (only for CSE-E and XV^+-E)
Esthet.X HD (Dentsply Caulk) Lot# 100726	Bis-GMA, Bis-EMA, triethylene glycol dimethacrylate, CQ, Stabilizer, pigments, barium fluoroborosilicate glass, nanofiller silica	Apply increments (maximum thickness of 2 mm) and light cure for 20 seconds

Abbreviations: Bis-GMA, bisphenol-A glycidyl dimethacrylate; Bis-EMA, bisphenol-A ethoxylated dimethacrylate; CQ, di-camphorquinone; HEMA, hydroxyethyl methacrylate; 10-MDP, 10-methacryloyloxydecyl dihydrogen phosphate.

pack #000 or 00, Ultradent, Salt Lake City, UT, USA) isolation. Lesions were cleaned with pumice and water in a rubber cup followed by rinsing and drying. An enamel bevel of 1 to 2 mm was prepared with a fine diamond bur (#1190F, FG 314 ISO no. 890, 010, grit size 45 μm, KG Sorensen, Cotia, São Paulo, Brazil) operated in a high-speed handpiece under air-water spray.

For groups with selective enamel etching, margins were etched with 36% H_3PO_4 (De Trey Conditioner, Dentsply De Trey, Konstanz, Germany) for 15 seconds and subsequently thoroughly rinsed and air-dried. Adhesive systems were applied according to the manufacturers' instructions and light-cured with a light emitting diode (LED) having a power output of 1500 mW/cm^2 for 10 seconds (Radii Plus, SDI, Bayswater, Australia). NCCLs were restored incrementally with a microhybrid composite resin (Esthet.X HD, Dentsply Caulk, Milford, DE, USA). Increments were light cured for 20 seconds. Afterward, the retraction cord was removed, and finishing/polishing was performed with rubber points under water spray (Enhance/PoGo, Dentsply Caulk).

Evaluation Criteria

Restorations were evaluated at baseline and 3, 6, 12, 18, and 24 months of clinical service for retention, marginal integrity, marginal staining, postoperative sensitivity, caries recurrence, and pulp vitality according to the modified USPHS criteria.[10,15] High-resolution photographs were made preoperatively, at baseline, and at each recall (DSLR Camera EOS Rebel T4i, Macro lens EF 100 mm, Flash Twin Lite MT-24EX, Canon Inc, Tokyo, Japan). Two independent examiners blinded to the adhesive systems and technique carried out all evaluations. Any discrepancy between examiners was resolved at chair side.

The statistical analyses followed the intention-to-treat protocol according to the Consolidated Standards of Reporting Trials.[16] 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.[2] The Friedman test was used for statistical analysis of retention rate, marginal integrity, marginal pigmentation, caries recurrence, postoperative sensitivity, and pulp vitality at the 5% confidence level.

RESULTS

A description of NCCL classification and distribution is presented in Table 2. The majority of lesions (61.6%) presented a cervico-incisal height >2.5 mm. Most of the cavities presented some degree of dentin sclerosis (83.9%). In addition, patients reported preoperative sensitivity in 52.7% of lesions. The clinical data for the different parameters evaluated at different time intervals are presented in Table 3. The recall rate at 3 and 6 months was 100%. At the 12- and 18-month evaluation periods, the recall rate was 96.4% (one patient having one restoration allocated in each group had all teeth extracted for implant placement). At the 24-month evaluation, the recall rate dropped to 92.9% (one patient moved to another city and through telephone contact related that no restoration was lost).

Table 2: *Distribution of Noncarious Class V Lesions According to Patient Sex; Shape, Depth, and Cervico-Incisal Size of the Lesion; Degree of Sclerotic Dentin; Presence of Antagonist; Presence of Preoperative Sensitivity; and Type of Tooth*

Characteristic of class V lesions	Number of lesions	%
Total	112	100
Patient sex		
Male 13	60	53.5
Female 12	52	46.5
Shape and depth		
Wedge-sharp, ≤1 mm depth	34	30.4
Wedge-sharp, >1 mm depth	36	32.1
Saucer-rounded, ≤1 mm depth	33	29.5
Saucer-rounded, >1 mm depth	9	8
Cervico-incisal height		
<1.5 mm	5	4.5
1.5–2.5 mm	38	33.9
>2.5 mm	69	61.6
Degree of sclerotic dentin		
No sclerosis	18	16.1
Slight sclerotic dentin (opaque)	47	42
Moderate sclerotic dentin (yellow)	24	21.4
Severe sclerotic dentin (transparent)	23	20.5
Presence of antagonist		
Antagonist present	105	93.8
Antagonist not present	7	6.3
Pre-operative sensitivity (to air and/or tactile contact)		
Yes	59	52.7
No	53	47.3
Tooth distribution		
Lower incisor	2	1.8
Lower canine	3	2.7
Lower premolar	29	25.9
Lower first molar	2	1.8
Upper incisor	13	11.6
Upper canine	11	9.8
Upper premolar	47	42
Upper first molar	5	4.5

For retention rate, no significant differences were observed among groups ($p>0.05$). One restoration was lost, from a patient in group XV-E at the 12-month recall. No significant differences were observed for marginal integrity among groups ($p>0.05$). However, a few minor superficial marginal defects were observed on enamel margins for group CSE-NE (3.6%) at the 12-, 18-, and 24-month recalls; for group XV-E (3.7%) at the 18- and 24-month recalls; and for group XV-NE (3.6%) at the 18- and 24-month recalls. Group CSE-E did not present any marginal defects throughout the study.

A significant increase in marginal discoloration was observed after 18 months of clinical service for groups CSE-NE ($p=0.009$) and XV-E ($p=0.004$). Small areas of discoloration were observed on enamel margins for XV-E, which increased with time (3.6% at 6-month, 7.4% at 12-month, 11.1% at 18-month, and 14.8% at 24-month recalls). The same trend was observed for CSE-NE (3.6% at 12-month, 10.7% at 18-month, and 14.3% at 24-month recalls) as shown in Figure 1. No significant differences were detected in marginal discoloration for CSE-E ($p>0.05$). Also, no significant difference was detected for XV-NE ($p>0.05$), although a trend toward increased marginal discoloration was observed (7.1% at 24-month recall).

For postoperative sensitivity, 100% of patients reported no sensitivity in any recall period ($p>0.05$). Secondary caries were not observed in any group ($p>0.05$). The overall clinical success was not significantly different among groups ($p>0.05$). Loss of one restoration was recorded for group XV-E at the 12-month recall (96.4% overall clinical success); for the other groups, overall clinical success was 100%.

DISCUSSION

Despite being considered user-friendly, single-step adhesive systems were often criticized due to low clinical performance. Acidity (pH) adjustment of adhesive solution and incorporation of new functional monomers to promote clinical performance stability over time were the main changes proposed to improve these materials. In this study, Clearfil SE Bond (CSE) was chosen as the control, because it is considered the gold standard for self-etching adhesives and demonstrates a clinical performance similar to the three-step etch-and-rinse.[9,17,18]

CSE acidic primer contains 10-methacryloyloxydecyl-dihydrogen-phosphate (10-MDP) dissolved in water, with a pH of around 2. This promotes a mild dentin surface etching, resulting in a thin but uniform and stable hybrid layer.[19] In addition, an interaction occurs between 10-MDP and hydroxyapatite crystals present around and within collagen fibrils of the hybrid layer.[18,20] Results of this study corroborate data obtained by Peumans and others,[18] who also evaluated CSE for 13 years, with the same

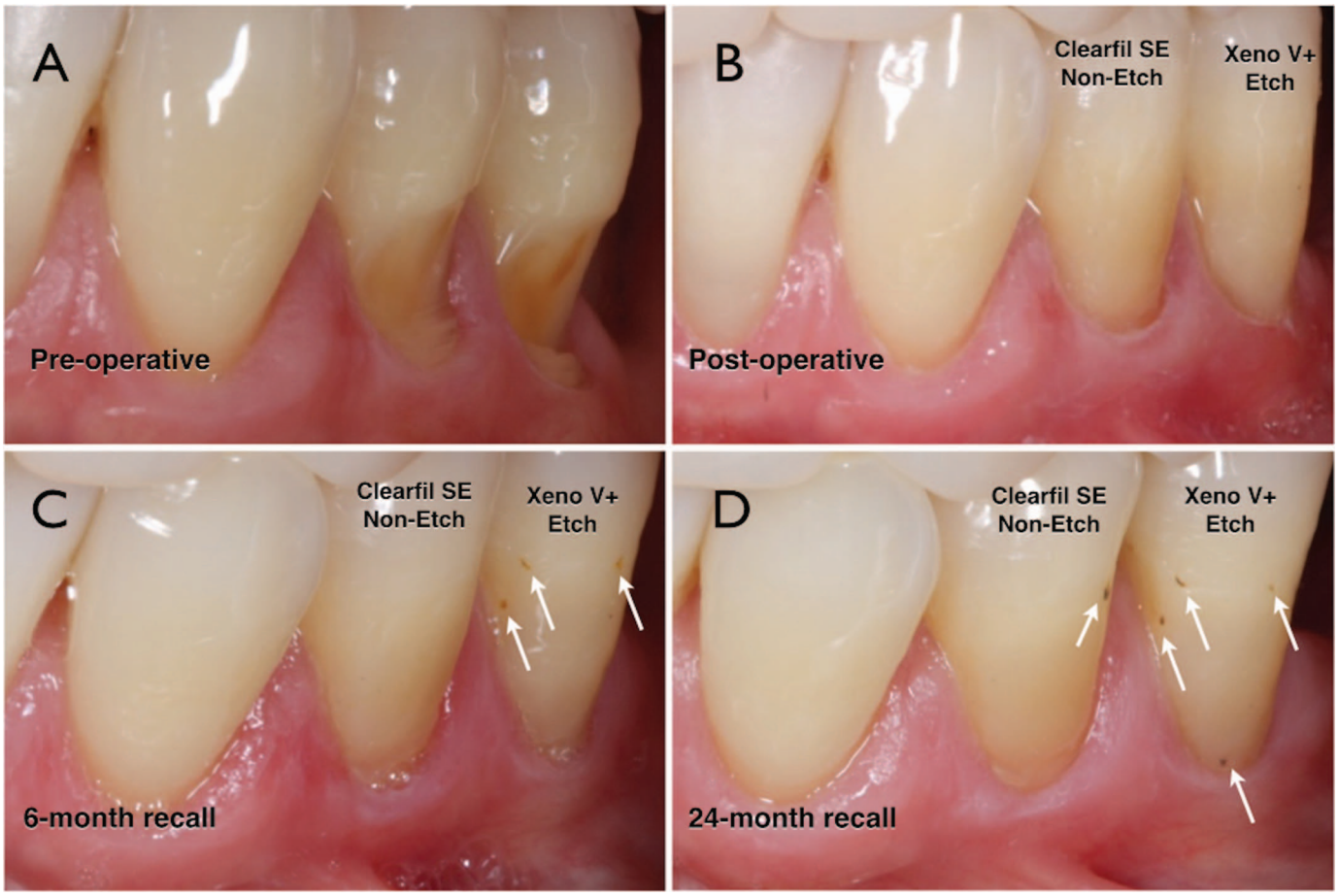

Figure 1. *(A) Preoperative view of noncarious cervical lesions. (B) Aspect immediately after placement of restoration. (C) After 6 months, regions of marginal discoloration were observed for XENO V+ E. (D) After 24 months, marginal discoloration was also observed for CSE-NE. Arrows point to regions of marginal discoloration.*

enamel treatment. Selective enamel etching produced only minor positive effects on NCCLs.[18] Another factor that contributes to satisfactory performance of CSE is the application of a separate hydrophobic-filled adhesive layer. This layer may also contribute to withstand stresses generated in the composite/dentin interface during polymerization.[21,22]

Van Meerbeek and others[11] showed a 100% retention rate for CSE after 24 months, with marginal staining in enamel being the only difference found in the group that did not receive selective etching after 24 months (there was no assessment at 18 months). However, according to the authors, this finding did not determine the need for restoration replacement. Similar findings were obtained in this study; however, a significant increase was observed for marginal staining after 18 and 24 months. The highest marginal enamel staining for CSE-NE is probably due to the moderate CSE pH, which was not sufficient to produce an adequate etching pattern compared with phosphoric acid.[11,23]

XENO V^+ is an evolution of the adhesive family XENO III (Dentsply DeTrey), XENO IV (Dentsply Caulk), and XENO V (Dentsply DeTrey). This latest version (XENO V^+) contains a phosphonated pentaacrylate ester (PENTA)-modified monomer, reduced the curing time and the aroma to a softened butyl alcohol odor. In the present study, there was no statistical difference in most of the parameters studied. Restorations performed with XENO V^+ showed promising results in NCCL restorations after 2 years of clinical follow-up. XENO V^+ is a recent material with few clinical and laboratory tests available comparing it with other adhesives.[24,25] Therefore, comparison with the gold standard self-etching adhesive (CSE) in a 2-year clinical trial produces relevant clinical data. XENO V^+ presents a

Table 3: *Results of Evaluated Parameters in Percentage at Each Recall Period*

Evaluated parameters	Recall period											
	3 months				6 months				12 months			
	CSE		XenoV+		CSE		XenoV+		CSE		XenoV+	
	E	NE	E	NE	E	NE	E	NE	E	NE	E	NE
Recall rate	100				100				96.4			
Retention rate	100	100	100	100	100	100	100	100	100	100	96.4	100
	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(27)	(28)
Absence of marginal defects	100	100	100	100	100	100	100	100	100	96.4	100	100
	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(27)	(27)	(28)
Enamel marginal defect	0	0	0	0	0	0	0	0	0	3.6 (1)	0	0
Small enamel marginal defect	0	0	0	0	0	0	0	0	0	3.6 (1)	0	0
Severe enamel marginal defect	0	0	0	0	0	0	0	0	0	0	0	0
Dentin marginal defect	0	0	0	0	0	0	0	0	0	0	0	0
Small dentin marginal defect	0	0	0	0	0	0	0	0	0	0	0	0
Severe dentin marginal defect	0	0	0	0	0	0	0	0	0	0	0	0
Absence of marginal discoloration	100	100	100	100	100	100	96.4	100	96.4	96.4	92.6	100
	(28)	(28)	(28)	(28)	(28)	(28)	(27)	(28)	(27)	(27)	(25)	(28)
Superficial localized marginal discoloration	0	0	0	0	0	0	3.6 (1)	0	3.6 (1)	3.6 (1)	7.4 (2)	0
Deep generalized marginal discoloration	0	0	0	0	0	0	0	0	0	0	0	0
Absence of sensitivity	100	100	100	100	100	100	100	100	100	100	100	100
	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(27)	(28)
Absence of caries occurrence	100	100	100	100	100	100	100	100	100	100	100	100
	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)
Overall clinical success rate	100	100	100	100	100	100	100	100	100	100	96.4	100
	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(27)	(28)

Number of noncarious cervical lesions is presented between parentheses.
[a] *Underlined values are significantly different by Friedman test at the 95% confidence level.*

pH of approximately 1.3, being considered more aggressive compared with SE Bond. Thus, the indication of selective etching with this material must be questioned.

Groups CSE-E, CSE-NE, and XV-NE presented a 100% retention rate after 24 months, whereas the XV-E group had a retention rate of 96.4%, due to the loss of one restoration at the 12-month evaluation recall. This small difference after 2 years did not result in statistically significant differences between materials ($p>0.05$). Results obtained by XENO V^+ may be due to the change of the ester group by an amide group that provided these monomers higher stability in acidic and aqueous medium.[25] It has been suggested that hydrogen bonds can occur between amide-based monomers and collagen carboxyl groups.[26,27]

Relative to marginal integrity, CSE-E presented 100% of intact margins, whereas CSE-NE, XV-E, and XV-NE presented approximately 96%. Marginal problems detected were only small surface enamel defects (24 months), requiring finishing and repolishing of restorations. There was no statistical difference between groups. Similar findings were observed by Van Meerbeek and others,[11] in which CSE was the subject of study.

For marginal staining, CSE-E (96.4%) and XV-NE (92.9%) presented no statistically significant difference; however, they differed significantly from CSE-NE (85.7%) and XV-E (85.2%), which were similar after 24 months. Enamel staining was small and superficial, without the need for restoration replacement. Despite some improvement with regard to marginal staining for CSE, selective enamel etching

Table 3: *Results of Evaluated Parameters in Percentage at Each Recall Period (ext.)*

Evaluated parameters	Recall period							
	18 months				24 months			
	CSE		XenoV+		CSE		XenoV+	
	E	NE	E	NE	E	NE	E	NE
Recall rate	96.4				92.9			
Retention rate	100	100	96.4	100	100	100	96.4	100
	(28)	(28)	(27)	(28)	(28)	(28)	(27)	(28)
Absence of marginal defects	100	96.4	96.3	96.4	100	96.4	96.3	96.4
	(28)	(27)	(26)	(27)	(28)	(27)	(26)	(27)
Enamel marginal defect	0	3.6 (1)	3.7 (1)	3.6(1)	0	3.6(1)	3.7(1)	3.6(1)
Small enamel marginal defect	0	3.6 (1)	3.7 (1)	3.6(1)	0	3.6(1)	3.7(1)	3.6(1)
Severe enamel marginal defect	0	0	0	0	0	0	0	0
Dentin marginal defect	0	0	0	0	0	0	0	0
Small dentin marginal defect	0	0	0	0	0	0	0	0
Severe dentin marginal defect	0	0	0	0	0	0	0	0
Absence of marginal discoloration	96.4	89.3	88.9	96.4	96.4	85.7	85.2	92.9
	(27)	(25)	(24)	(27)	(27)	(24)	(23)	(26)
Superficial localized marginal discoloration	3.6	10.7	11.1	3.6	3.6	14.3	14.8	7.1
	(1)	(3)	(3)	(1)	(1)	(4)	(4)	(2)
Deep generalized marginal discoloration	0	0	0	0	0	0	0	0
Absence of sensitivity	100	100	100	100	100	100	100	100
	(28)	(28)	(27)	(28)	(28)	(28)	(27)	(28)
Absence of caries occurrence	100	100	100	100	100	100	100	100
	(28)	(28)	(28)	(28)	(28)	(28)	(28)	(28)
Overall clinical success rate	100	100	96.4	100	100	100	96.4	100
	(28)	(28)	(27)	(28)	(28)	(28)	(27)	(28)

did not promote additional benefits for XENO V^+ after 24 months. Differences in marginal staining between CSE-E and CSE-NE have been attributed to a shallower enamel-etching pattern obtained due to the mild self-etching primer pH.[11,28] The highest marginal staining observed in enamel margins for the XV-E group may be due to exacerbated enamel etching with phosphoric acid combined with the acidic adhesive solution (pH $\sim$ 1.3). A variation in etching time and acidity produces a series of phenomena, weakening enamel structure and not providing an effective etching pattern.[29]

Patients reported preoperative sensitivity in 52.7% of lesions. However, after placement of restorations, none of the groups presented postoperative sensitivity at any recall. It can be speculated that CSE and XENO V^+ provided good sealing of dentinal tubules, confirming that self-etching adhesives perform well in preventing postoperative sensitivity.[9,11] However, as most of the NCCLs presented some level of dentin sclerosis (83.9%), which could cause many of the dentin tubules to be occluded at the start of the study, the insulating effect of the composite resin can also account for the reduction in sensitivity.

Although the degree of dentin sclerosis has been reported to affect restorations in NCCLs,[30] our results corroborate with several studies that found no correlation between longevity of restorations and dentin sclerosis.[9,11,12,31] Also, no correlation has been found between performance of NCCL restorations and patient age, tooth type, size and shape of lesion, location, and occlusal load.[9,11,12,31] Both adhesive systems, with and without enamel selective etching, reached the American Dental Association (ADA) parameters for clinical use (less than 10% of

restoration loss or deep marginal staining in 18 months). Other parameters, such as secondary caries and pulp vitality, were considered excellent in all groups at all evaluation times.

CONCLUSION

Overall clinical success of the two self-etching adhesive systems tested in this study was not affected by selective enamel etching in the 24-month evaluation. There was no significant difference between groups tested for retention rate, marginal integrity, secondary caries, and postoperative sensitivity.

Acknowledgement

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of: Guarulhos University Ethics Committee. The approval code for this study is: #636.726.

Conflict of Interest

The authors of this manuscript 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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