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Six-month Follow-up of Cervical Composite Restorations Placed With a New Universal Adhesive System: A Randomized Clinical Trial

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Clinical Relevance

At six months the universal adhesive Xeno Select didn't fulfill the American Dental Association criteria for full approval when using all of the bonding strategies suggested by the manufacturer. Its behavior depends on the bonding strategy used.

SUMMARY

Purpose: The objective of this double-blind, randomized clinical trial was to evaluate the six-month clinical performance of a new universal adhesive (Xeno Select, Dentsply) in non-carious cervical lesions (NCCLs) using two evaluation criteria: World Dental Federation (FDI) and the US Public Health Service (USPHS).

Methods and Materials: A total of 124 restorations were randomly placed in 31 patients according to the following groups: ER-D = etch-and-rinse/dry dentin; ER-M = etch-and-rinse/moist dentin; SE-et = selective enamel etching; and SET = self-etch. The composite resin EVOLUX (Dentsply) was placed incrementally. The restorations were evaluated after one week (baseline) and at six months using the FDI and USPHS criteria. Statistical analyses were performed using appropriate tests (α=0.05).

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Results: Fifteen restorations were lost or fractured at six months (one for ER-D, three for ER-M, five for SE-et, and six for SET) ($p>0.05$ at six-month recall). When ER (ER-D and ER-M) was compared with SE (SE-et and SET) there was a significant difference in the retention rate after six months ($p=0.001$). Marginal staining and postoperative sensitivity to air were only observed in three (one for ER-M and two for SET) and two restorations (two for ER-D) in both evaluation criteria ($p>0.05$), respectively. Forty-seven restorations were considered to have minor discrepancies in marginal adaptation at the six-month recall using the FDI criteria (13 for ER-D, 10 for ER-M, 11 for SE-et, and 13 for SET; $p>0.05$ between groups). However, for all groups, a significant difference was detected when baseline and six-month data were compared ($p<0.05$).

Conclusions: The six-month clinical behavior of Xeno Select Universal Adhesive depends on the bonding strategy used. The universal adhesive did not fulfill the American Dental Association criteria for full approval when used in the self-etch mode.

INTRODUCTION

Adhesive systems led to a significant revolution in restorative dentistry, which has provided dentists with the opportunity to offer pleasing, direct esthetic restorations, which are typically able to be completed during a single clinical appointment and with satisfactory mechanical properties.[1]

Etch-and-rinse (ER) adhesive systems require previous dissolution of the mineral components in enamel and dentin with phosphoric acid before monomer infiltration into the dental substrates. For most dental adhesives, the depth and pattern of the etching play a significant role in the enamel bond strength values,[2,3] and in dentin, prior dentin demineralization with phosphoric acid is essential to expose collagen fibrils for resin infiltration.[4,5] Three-step and two-step ER adhesive systems have been extensively evaluated *in vitro* and *in vivo*, and, in general, the results have been quite satisfactory.[6-8] Regardless of the number of steps, the main disadvantage of the ER system is that there is a risk of collagen fibril collapse during drying of the demineralized dentin, which leads to a consequent decrease in bond strength.[1] To avoid this, demineralized dentin should be kept moist, which is a difficult task clinically since adequate moisture depends on the solvent employed in the material[9] and on the individual's interpretation of the manufacturer's directions.[10] This complex bonding protocol of ER adhesives may lead to clinical mistakes,[1,9,10] which may be clinically translated as postoperative sensitivity or adhesive failure after some years of function.

On the other hand, self-etch (SE) adhesive systems have a simpler bonding protocol.[11] The demineralization of the dental substrates is produced by a non-rinsing acidic primer, and except in the case of some SE systems,[12] the whole extension of the demineralized dentin depth is impregnated by resin monomers. Unfortunately, SE adhesives produce relatively low bond strength values and inferior marginal adaptation to enamel when compared to ER systems.[13,14] SE adhesives do not produce a retentive etching pattern on enamel, such as that produced by phosphoric acid, which may produce restorations with higher rates of marginal discoloration—a clinical problem in anterior restorations. Although selective etching of enamel margins prior to the application of SE adhesives[15,16] can minimize this limitation, an accidental dentin etching may occur and jeopardize bonding efficacy to dentin.[17,18]

Considering that both adhesive strategies have advantages and limitations, their selection may vary depending on the clinical scenario. In light of this fact, more versatile adhesives, called multimode or universal adhesives, were developed recently. Theoretically, these universal adhesives are indeed SE adhesives that can be used with or without acid etching in both enamel and dentin.[19-23] Different research centers have shown that universal adhesives applied on dentin in both ER or SE strategies have high bond strength values,[20,21] and this can be attributed to the acidic monomers that promote chemical bonding to a tooth.[21,22]

As these materials are relatively new in the literature, few clinical trials have been conducted to evaluate their clinical performance.[19,24,25] Most of the clinical data available are related to 10–methacryloyloxydecyl dihydrogen phosphate10-MDP–containing adhesives. According to an *in vitro* study,[23] only universal adhesives that contain 10-MDP showed high and stable dentin bonding after six months of water storage, but such a finding warrants clinical validation.

To the authors' knowledge, no clinical study has so far evaluated the clinical performance of a universal adhesive that contains functional monomers other than 10-MDP. Therefore, the objective of this double-blind, randomized clinical trial was to evaluate the

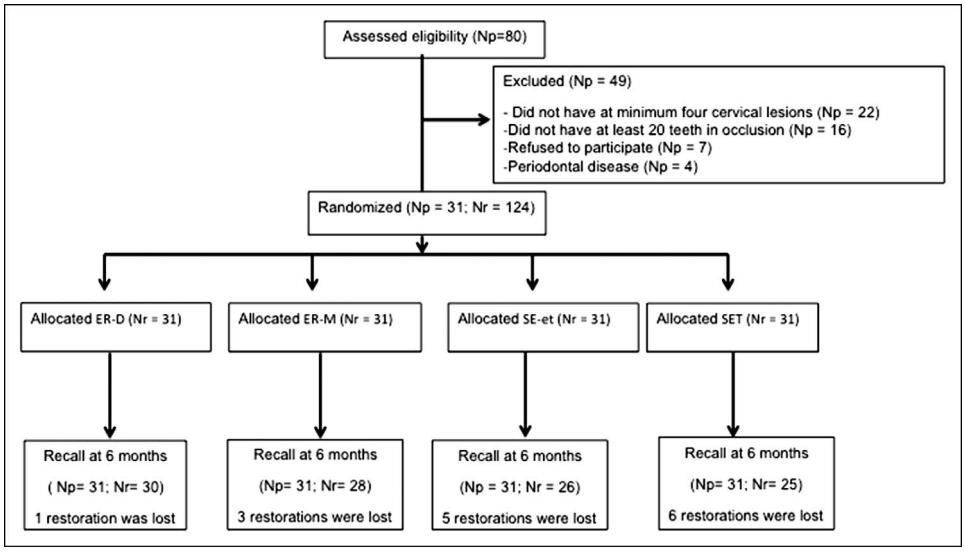

Figure 1. *Flow chart of the study design.*

influence of different application strategies on the clinical behavior of a new universal multimode adhesive (Xeno Select adhesive system) placed in noncarious cervical lesions (NCCLs) over the course of six months using the evaluation criteria of the World Dental Federation (FDI) and the US Public Health Service (USPHS). The null hypothesis tested was that bonding to NCCLs using the SE strategy—regardless of whether or not it is associated with selective enamel etching or using the ER strategy—applied on dry or moist dentin would result in similar retention levels over six months of clinical service.

METHODS AND MATERIALS

Study Design

The experimental design followed the Consolidated Standards of Reporting Trials (CONSORT) statement.[26] This was a randomized, double-blind clinical trial, registered in the REBEC clinical registry under protocol RBR-4wh4sh. The study was carried out in the clinic of the School of Dentistry at the local university from June 2014 to November 2014. All participants were informed about the nature and objectives of the study, but they were not aware of which tooth received the specific treatments under evaluation.

Participant Recruitment

The local Ethics Committee on Investigations Involving Human Subjects reviewed and approved the protocol and issued a consent form for this study (protocol 800.273/14). Written informed consent was obtained from all participants prior to starting the treatment.

Sample Size Calculation

The sample size calculation was based on the retention rate of Xeno III, IV, and V, and predecessors of the Xeno Select adhesive system from the same manufacturer (Dentsply, DeTrey, Konstanz, Germany). The retention rate was reported to be 96% at 18- to 24-month follow-up.[27-30] Using an α of 0.05, a power of 80%, and a two-sided test, the minimal sample size was 31 restorations in each group in order to detect a difference of 25% among the tested groups.[31]

Eligibility Criteria

A total of 80 participants were examined by two calibrated dental students to determine if they met the inclusion and exclusion criteria (Figure 1). Those who qualified for the study 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, at least 18 years of age, have an acceptable oral hygiene level, and present with at least 20 teeth under occlusion. Participants were required to have at least four NCCLs to be restored in four different teeth. These lesions had to be noncarious, nonretentive, and deeper than 1 mm and had to involve both the enamel and dentin of vital teeth without mobility. The cavo-surface margin could not involve more that 50% of enamel.[32]

Table 1: *Dentin Sclerosis Scale*[33]

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

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.

Randomization and Allocation Concealment

A staff member not involved in the research protocol performed the randomization process with computer-generated tables. Details of the allocated groups were recorded on cards contained in sequentially numbered, opaque, sealed envelopes. Opening the envelope on the day of the restorative procedure revealed the allocation assignment. The operator was not blinded to group assignment when administering interventions; however, participants and evaluators were blinded to the group assignment.

Interventions: Restorative Procedure

All of the patients selected for this study 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 were initiated.

The degree of sclerotic dentin from the NCCLs was measured according to the criteria described by Swift and others[33] (Table 1). The cavity dimensions in millimeters (height, width, and depth), the geometry of the cavity (evaluated by profile photograph and labeled at $<45°$, 45°-90°, 90°-135°, and $>135°$), the presence of an antagonist, and the presence of attrition facets were observed and recorded. Preoperative sensitivity was also evaluated by applying air for 10 seconds from a dental syringe placed 2 cm from the tooth surface and with an explorer. These features were recorded to allow comparison of the baseline features of the dentin cavities among experimental groups.

In order to calibrate the restoration procedure, the study director placed one restoration of each group in order to identify all steps involved in the application technique. Then the two operators, who were resident dentists with more than five years of clinical experience in operative dentistry, placed four restorations, one in each group, under the supervision of the study director in a clinical setting. The restoration failures were shown to the operators prior to starting the study. At this point, the operators were considered calibrated to perform the restorative procedures.

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

Before restorative procedures, 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. Then shade selection was made using a shade guide. Following the guidelines of the American Dental Association (ADA),[34] no additional retention or bevel was prepared.

A rubber dam was placed, and then the NCCLs received the Xeno Select adhesive system (also known in some countries as Prime & Bond One Select, Dentsply) applied in different modes: an ER approach, keeping the dentin dry (ER-D) or moist (ER-M), and a SE approach with (SE-et) or without (SET) selective enamel etching, which defined the four different groups. The compositions, application modes, and batch numbers are described in Table 2. Some details of the restorative procedures include the following:

- Etch-and-rinse/dentin dry group (ER-D)—The 37% phosphoric acid (Dentsply, Rio de Janeiro, Brazil) was applied on enamel (30 seconds) and dentin (15 seconds). Then cavities were rinsed thoroughly for 30 seconds and slightly air-dried for five seconds to dry dentin without causing dentin dehydration. The adhesive system was applied sufficiently, wetting all cavity surfaces uniformly, and was gently agitated on the entire enamel and dentin

Table 2: *Materials (Batch No.), Compositions, and Application Mode*

Materials (Batch No.)	Composition	Application Mode[a]
Xeno Select; Dentsply, DeTrey, Konstanz, Germany (1401001212)	Bifunctional acrylate, acidic acrylate, functionalized phosphoric acid ester, water, tertiary butanol, initiator, stabilizer	Etch & Rinse (ER-D and ER-M) 1. Apply etchant in enamel (30 s) and dentin (15 s), rinse for 30 s, air-dry to remove excess water; 2. Keep dentin dry (ER-D)[b] or moist (ER-M); 3. Apply the adhesive for 20 s with vigorous agitation, gently air thin for 5 s. Light-cure for 10 s.
		Selective enamel etching (SE-et) 1. Apply etchant for 15 s in enamel, rinse for 15 s, air-dry to remove excess water; 2. Keep dentin dry (do not overdry); 3. Apply the adhesive for 20 s with vigorous agitation, gently air thin for 5 s. Light-cure for 10 s.
		Self-etching (SET) 1. Do not use etchant; 2. Keep dentin dry (do not overdry); 3. Apply the adhesive for 20 s with vigorous agitation, gently air thin for 5 s. Light-cure for 10 s.
37% Tooth Conditioner Gel; Dentsply, Rio de Janeiro, Brazil (941685F)	Phosphoric acid, surfactant, Aerosil 200, deionized water, and pigment	With the aid of the applicator tip, apply the acid conditioner to the dental structures in question, keeping it in contact with enamel for at least 15 s and with dentin for no more than 15 s. After conditioning, wash the surfaces with plenty of water for at least the same amount of time as used for the conditioning, vacuuming with a saliva sucker.
EvoluX; Dentsply, Rio de Janeiro, Brazil (Shade A3–681887E; Shade A3.5–697997E; Shade A1–673729E)	Silanized barium aluminum borosilicate glass, silanized barium fluoro aluminum boro silicate glass, dimethacrylate Bis-GMA and Bis-EMA, nanoparticulated silica, dyes, photoinitiators, inhibitors	Insert in the cavity increases of up to 2 mm and light-cure each area of the surface of the restoration with a dental curing light appliance light power of 1200 mW/cm^2) for 30 s.

Abbreviations: Bis-EMA, bisphenol A dimethacrylate; Bis-GMA, bisphenol A glycidyl dimethacrylate.
[a] *According to the manufacturer's instructions.*
[b] *Manufacturer does not indicate application in dry dentin.*

surface for approximately 20 seconds, according to the manufacturer's recommendations (Table 2). Then the adhesive was evaporated by gentle air thinning for five seconds and light-cured (Radii Cal, SDI, Victoria, Australia) for 10 seconds (1200 mW/cm^2).

- Etch-and-rinse/dentin moist group (ER-M)—All of the restorative procedures were similar to those described for the ER-D group. The only difference was that after acid rinsing, dentin was kept visibly moist.
- Selective enamel etch group (SE-et)—The 37% phosphoric acid (Dentsply) was applied for 15 seconds only on enamel. Then it was rinsed thoroughly for 15 seconds and air-dried for five seconds, until the dentin was dried but not over dried. Following this, the adhesive was applied similarly to the way it was applied to the ER-D group.
- Self-etch group (SET)—The adhesive system was applied as described in the ER-D group, without any previous acid etching. Then the adhesive was evaporated by gentle air thinning for five seconds and light-cured (Radii Cal, SDI) for 10 seconds (1200 mW/cm^2).

After adhesive application, EvoluX (Dentsply) resin composite was used in up to three increments, each one being light cured (Radii Cal, SDI) for 30 seconds. The restorations were finished immediately with fine and extra-fine #2200 diamond burs (KG Sorensen, Barueri, SP, Brazil). Polishing was performed with rubber points (Enhance, Dentsply) one week after placement of the restorations.

Clinical Evaluation

Two experienced and calibrated dentists, not involved with the restoration procedures 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 but were not part of this project. An intraexaminer and interexaminer agreement of at least 85% was necessary before beginning the

Table 3: *World Dental Federation (FDI) Criteria Used for Clinical Evaluation*[36]

	Esthetic Property	Functional Properties		Biological Properties	
	1. Staining Margin	**2. Fractures and Retention**	**3. Marginal Adaptation**	**4. Postoperative Hyper-Sensitivity**	**5. Recurrence of Caries**
1. Clinically very good (A)	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 (B) (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	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 (C) (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	4.3.1 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 (D) (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 μm 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 (E) (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 dentine that is not accessible for repair of restoration
Acceptable or not acceptable (n, %, and reasons	Esthetic criteria	Functional criteria		Biological criteria	

evaluation.[35] After recording the parameters during evaluation using a standardized paper case report form, the evaluation paper had to be sent back to the research staff, so that evaluators were blinded to group assignment during follow-up recalls.

The restorations were evaluated by FDI[36] and the classical USPHS criteria (adapted by Bittencourt and others[37] and Perdigão and others[7]) at baseline and after six months of clinical service. Only the clinically relevant measures for evaluation of the performance of adhesives were used and scored (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 spontaneous postoperative sensitivity was performed one week after the restorative procedure.

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[36] was used. Each evaluator outlined 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

Table 4: *Modified US Public Health Service (USPHS) Criteria According to Perdigão and Others[7] and Bittencourt and Others[37]*

	Marginal Staining	Retention	Fracture	Marginal Adaptation	Postoperative Sensitivity	Recurrence of Caries
Alfa	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
Bravo	Slight and superficial staining (removable, usually localized)	Partially retained	Small chip, but clinically acceptable	Detectable V-shaped defect in enamel only Catches explorer going both ways	—	—
Charlie	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

margin was assessed quantitatively as a proportion of the total length of the margin.

Both examiners evaluated all of 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[34] 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.

Statistical Analysis

The statistical analyses followed the intention-to-treat protocol according to the CONSORT (Consolidated Standards of Reporting Trials) suggestion.[26] Descriptive statistics were used to describe the distributions of the evaluated criteria. Statistical analysis for each individual item was performed for each evaluation criteria (FDI and USPHS criteria).

Two different statistical analyses were performed after we had collected data for six months. We used the Friedman repeated-measures analysis of variance by rank to compare the differences in the ratings of the four groups at six months, and we used the Fisher exact test to compare the differences in the ratings of ER vs SE groups. In this case, the data of the ER-D and ER-M were merged, as were those from the SE-et and SET groups.

We compared the baseline vs the six-month finding within each group using the McNemar test. The Cohen kappa statistic was used to test for interexaminer agreement. Data from SQUACE were categorized into three scores, as follows: 1) marginal discrepancies involving less than 10% of the total length of the restoration; 2) those involving between 10% and 30%; and 3) those involving more than 30%,[19,24] and the groups were compared with Kruskal-Wallis and Mann-Whitney tests. In all statistical tests, we pre-set the level of significance to 5%.

RESULTS

The restorative procedures were implemented exactly as planned, and no modification was performed. Forty-nine out of 80 patients examined for eligibility were not enrolled in the study because they did not fulfill the inclusion criteria. Thus, a total of 31 subjects (15 men and 16 women) were selected. One hundred and twenty-four restorations were placed, 31 for each group (Figure 1).

All baseline details relative to the research subjects and characteristics of the restored lesions are displayed in Table 5. The overall Cohen kappa statistics showed excellent agreement between the examiners in the six-month (0.94) follow-up. All research subjects were evaluated at baseline and at the six-month recall.

Retention/Fracture

Fifteen restorations were lost or fractured after six months (one for ER-D, three for ER-M, five for SE-et, and six for SET). According to both evaluation criteria, the six-month retention rates (95% confidence interval [CI]) were 96.8% (83.8%-99.4%) for ER-M, 90.3% (75.1%-96.7%) for ER-D, 83.9% (67.4%-92.9%) for SE-et, and 80.7% (63.7%- 90.8%) for SET,

Table 5: *Characteristics of the Research Subjects and the Noncarious Cervical Lesions (NCCLs) per Group*

Characteristics of Research Subjects	**No. of Lesions**			
Gender distribution				
Male	15			
Female	16			
Age distribution, y				
20-29	0			
30-39	1			
39-49	6			
>49	24			
Characteristics of NCCL Lesions	**No. of Lesions**			
	ER-D	**ER-M**	**SE-et**	**SET**
Shape, degree of angle				
<45	1	1	1	0
45-90	6	6	10	7
90-135	16	18	11	17
>135	8	6	9	7
Cervico-incisal height, mm				
<1.5	4	5	4	3
1.5-2.5	12	10	12	12
2.5-4.0	11	13	10	12
>4.0	4	3	5	4
Degree of sclerotic dentin				
1	15	16	15	15
2	7	8	5	10
3	6	6	8	4
4	3	1	3	2
Presence of antagonist				
Yes	29	28	30	29
No	2	3	1	2
Attrition facet				
Yes	16	15	20	19
No	15	16	11	12
Preoperative sensitivity (spontaneous)				
Yes	0	1	0	1
No	31	30	31	30
Preoperative sensitivity (air dry)				
Yes	7	9	12	9
No	24	22	19	22
Preoperative sensitivity (touch)				
Yes	7	11	14	9
No	24	20	17	22
Tooth distribution				
Anterior				
Incisor	7	5	3	4
Canines	4	4	4	3
Posterior				
Premolar	19	22	21	19
Molar	1	0	3	5

Table 5: Continued.

Characteristics of Research Subjects	No. of Lesions			
Arc distribution				
Maxillary	17	15	15	10
Mandibular	14	16	16	21

Abbreviations: ER-D, etch-and-rinse, dry dentin; ER-M, etch-and-rinse, moist dentin; SE-et, self-etch with selective enamel etching; SET, self-etch without selective enamel etching.

with no statistical difference identified between any pair of groups ($p>0.05$; Tables 6 and 7).

When the data from the six-month results from each group were compared with their baseline findings, a significant difference was found only for SET ($p=0.03$; Tables 6 and 7). Also, when the overall retention rate of the ER approach (93.6%, 95% CI 84.5%-97.5%) was compared with the overall retention rate of the SE approach (82.2%, 95% CI 70.9%-89.8%), significant differences in the retention rates were detected after six months ($p=0.001$; Tables 6 and 7).

Postoperative Sensitivity

Only two restorations had postoperative sensitivity to air at the six-month recall using both criteria (two for ER-D). No significant difference was detected between any pair of groups at the six-month mark or when the six-month findings of each group were compared to the baseline data. The

Table 6: *Number of Evaluated Restorations for Each Experimental Group Classified According to the World Dental Federation (FDI) Criteria*[36]

FDI Criteria	(*)	Baseline				6 mo			
		ER-D	ER-M	SE-et	SET	ER-D	ER-M	SE-et	SET
Marginal staining	A	31	31	31	31	31	27	26	23
	B	—	—	—	—	—	1	—	2
	C	—	—	—	—	—	—	—	—
	D	—	—	—	—	—	—	—	—
	E	—	—	—	—	—	—	—	—
Fractures and retention	A	31	31	31	31	30	28	25	25
	B	—	—	—	—	—	—	—	—
	C	—	—	—	—	—	—	1	—
	D	—	—	—	—	1	—	—	—
	E	—	—	—	—	—	3	5	6
Marginal adaptation	A	31	31	31	31	17	18	15	12
	B	—	—	—	—	13	10	11	13
	C	—	—	—	—	—	—	—	—
	D	—	—	—	—	1	—	—	—
	E	—	—	—	—	—	—	—	—
Postoperative (hyper-) sensitivity	A	31	31	31	31	29	28	26	25
	B	—	—	—	—	2	—	—	—
	C	—	—	—	—	—	—	—	—
	D	—	—	—	—	—	—	—	—
	E	—	—	—	—	—	—	—	—
Recurrence of caries	A	31	31	31	31	31	28	26	25
	B	—	—	—	—	—	—	—	—
	C	—	—	—	—	—	—	—	—
	D	—	—	—	—	—	—	—	—
	E	—	—	—	—	—	—	—	—

Abbreviations: ER-D, etch-and-rinse, dry dentin; ER-M, etch-and-rinse, moist dentin; SE-et, self-etch with selective enamel etching; SET, self-etch without selective enamel etching.

Table 7: *Number of Evaluated Restorations for Each Experimental Group According to the Modified US Public Health Service (USPHS) Criteria*[7,37]

USPHS Criteria	Baseline				6 mo			
	ER-D	ER-M	SE-et	SET	ER-D	ER-M	SE-et	SET
Marginal staining								
Alfa	31	31	31	31	31	27	26	23
Bravo	—	—	—	—	—	1	—	2
Charlie	—	—	—	—	—	—	—	—
Retention								
Alfa	31	31	31	31	31	28	26	25
Bravo	—	—	—	—	—	—	—	—
Charlie	—	—	—	—	—	3	5	6
Fracture								
Alfa	31	31	31	31	30	28	25	25
Bravo	—	—	—	—	—	—	1	—
Charlie	—	—	—	—	1	—	—	—
Marginal adaptation								
Alfa	31	31	31	31	30	28	26	25
Bravo	—	—	—	—	—	—	—	—
Charlie	—	—	—	—	1	—	—	—
Postoperative sensitivity								
Alfa	31	31	31	31	29	28	26	25
Bravo	—	—	—	—	2	—	—	—
Charlie	—	—	—	—	—	—	—	—
Recurrence of caries								
Alfa	31	31	31	31	31	31	31	31
Bravo	—	—	—	—	—	—	—	—
Charlie	—	—	—	—	—	—	—	—

Abbreviations: ER-D, etch-and-rinse, dry dentin; ER-M, etch-and-rinse, moist dentin; SE-et, self-etch with selective enamel etching; SET, self-etch without selective enamel etching.

overall postoperative sensitivity of ER vs SE was also not statistically significant ($p>0.05$; Tables 6 and 7).

Marginal Adaptation

Forty-seven restorations were considered to have minor discrepancies in marginal adaptation at the six-month recall using the FDI criteria (13 for ER-D, 10 for ER-M, 11 for SE-et, and 13 for SET). No significant difference was detected between any pair of groups at the six-month recall for either evaluation criteria ($p>0.05$). In addition, the overall ER data were not statistically different from the overall SE at the six-month evaluation for marginal adaptation ($p>0.05$).

Despite these minor discrepancies, only one restoration was considered to have clinically relevant discrepancies in marginal adaptation (one for ER-D; Table 6). When the USPHS criteria were used, one restoration was scored as "charlie" for marginal adaptation (one for ER-D; Table 7). However, for all groups, a significant difference was detected when baseline and six-month data were compared ($p=0.0001$), as well as when the overall ER data and overall SE data were compared with their baseline data ($p=0.0001$).

No significant difference was detected between any pair of groups (ER-D, ER-M, SE-et, and SET) or ER (ErD and ErM) vs SE (SE-et and SET) at the six-month recall for either criteria ($p>0.05$).

Marginal Staining

Marginal staining was observed in three restorations (one for ER-M and two for SET) in both evaluation criteria. No significant difference was found between groups at six months or when the overall ER data were compared to the SE data. It was not detect any significant differences within each group when baseline and six-month data were compared for both criteria ($p>0.05$; Tables 6 and 7). When SQUACE[36]

Table 8: *Number of Evaluated Restorations for Each Experimental Group According to the Semiquantitative Score (SQUACE)*[36]

Classification	ER-D	ER-M	SE-et	SET
Less than 10%	17	18	15	12
Between 10% and 30%	13	9	9	11
Between 31% and 50%	1	1	2	2
Statistical analysis[a]	A	A	A	A

Abbreviations: ER-D, etch-and-rinse, dry dentin; ER-M, etch-and-rinse, moist dentin; SE-et, self-etch with selective enamel etching; SET, self-etch without selective enamel etching.
[a] *Different letters indicate significant differences between groups (Kruskal-Wallis,* $p>0.05$*).*

was used, we did not detect a statistical difference among groups at the six-month evaluation ($p>0.05$; Table 8).

Other Parameters

No restoration showed recurrence of caries after six months for either criteria. One restoration had clinical problems related to fracture at six months for both criteria. When the FDI criteria for "acceptable" vs "not acceptable" restorations were applied, 16 restorations were ranked as "not acceptable" (14 restorations were lost, one restoration fractured, and one showed severe lack of marginal adaptation). Among these 16 restorations, only five were placed with the ER approach, while the remaining 11 restorations were placed with the SE approach (Table 9).

DISCUSSION

Most of the studies using universal adhesives found in the literature were laboratory tests, although it is known that the validity of bond strength testing is questionable.[38,39] Clinical studies in NCCLs provide the ultimate proof for the evaluation of the performance of adhesive systems, mainly because the most important parameter for evaluation of restorations in NCCLs is retention.[6] This is considered a true endpoint, because if restorations are lost, none of the other parameters can be evaluated.

The results of the present study showed that after six months of clinical service a total of 15 restorations failed as a result of debonding—11 bonded with the SE approach and four bonded with the ER approach (ER-M and ER-D)—which highlighted a poor bonding efficacy of the Xeno Select when used in the SE strategy. This poor bonding ability may be related to the kind of chemical bond produced by this adhesive with the dental substrates.

In general, SE adhesives differ from one another in many aspects, especially in their resin monomer composition, water content, and acidity.[40] They usually dissolve the smear layer and do not remove the dissolved calcium (Ca) phosphates.[41] According to the manufacturer of the Xeno Select, two acidic monomers are responsible for the interaction of this adhesive with the dentin surface: an "inverse" functionalized phosphoric acid ester and an acryloylamino alkylsulfonic acid, which was also present in the predecessor Xeno V.[42]

The manufacturer claims that the presence of a phosphoric acid ester group in the functionalized monomer makes it very similar to dipentaerytritol-pentacrylate–phosphoric acid–monomer (PENTA). There is evidence (by Raman spectroscopy findings) that the ester group of PENTA can establish a covalent bond with the Ca from dentin and enamel.[43] However, not only chemical bonding is essential to provide a strong bonded interface; the Ca salt produced by this chemical interaction should also be stable in an aqueous environment,[44,45] which ultimately depends on the stability of the formed

Table 9: *Restorations Acceptable or Not Acceptable According to the World Dental International (FDI) Criteria After Six Months*[36]

	Esthetic				Functional								Biological							
	Staining Margin				Fractures and Retention				Marginal Adaptation				Postoperative (Hyper-) Sensitivity				Recurrence of Caries			
	ER-D	ER-M	SE-et	SET	ER-D	ER-M	SE-et	SET	ER-D	ER-M	SE-et	SET	ER-D	ER-M	SE-et	SET	ER-D	ER-M	SE-et	SET
Acceptable	31	28	26	25	30	28	26	25	30	28	26	25	31	28	26	25	31	28	26	25
Not acceptable	0	0	0	0	1	3	5	6	1	0	0	0	0	0	0	0	0	0	0	0
Reasons	14 restorations were lost, one restoration fractured, and one restoration showed severe lack of marginal adaptation																			

bond to Ca, according to the "adhesion-decalcification" concept.[41,46-48]

Different functional monomers, such as "inverse" functionalized phosphoric acid ester and acryloylamino alkylsulfonic acid from Xeno Select, initially bond to Ca of hydroxyapatite, but they readily debond.[41,49] This debonding was recently confirmed by Zhou and others[50] Through the use of attenuated total reflection (ATR) spectroscopy, the authors evaluated the chemical interaction of functional monomers with dentin. The authors did not observe any signal of chemical bonding of the Xeno V monomers to dentin surfaces, indicating low affinity of Xeno V (the predecessor of Xeno Select) to this substrate.[50]

It is also known that during interaction with the hydroxyapatite surface mild and ultramild SE adhesives leach little Ca, as they bind strongly enough to mineral content. On the other hand, intermediary strong or strong SE adhesives also bind to Ca ions from the hydroxyapatite, but they also demineralize the substrate more and tend to produce more soluble Ca salts.[46,47] According to the Xeno Select data, this adhesive system can be considered to be of intermediate strength (pH<2.0, manufacturer instructions), along with the predecessor Xeno V, which was classified as a strong SE adhesive system (pH=1.38 for Xeno V).[50,51]

The PENTA ester group is considered a weak acid, but this low pH is likely obtained after addition of the acryloylamino alkylsulfonic acid to the adhesive formulation. According to the manufacturer's instruction, this second acidic monomer was added to the formulation to adjust the acidity of Xeno Select.[42] Compared to other mild SE adhesives, the Xeno V produced cleaner dentin surfaces with more exposition of dentin tubules, likely due to the lower pH of Xeno V in comparison to that of the other mild SE adhesives tested.[50] Using field-emission scanning electron microscopy and ATR findings, these authors[50] also observed that the mild SE adhesives contained functional monomers with a higher affinity to dentin, likely due to the type of functional monomers presented in their composition.

This was also confirmed by a systematic review[51] of clinical studies in NCCLs. The authors showed that the mild and ultramild SE systems contained functional monomers with the chemical potential to produce restorations with higher quality and durability in cervical lesions.[51] This was also confirmed by the few clinical studies[19,24,25,52] that evaluated ultramild universal adhesives in NCCLs. Mena-Serrano and others[24] showed that after six months of clinical service, only three restorations were lost (94% retention rate), and this feature was very similar to the more recent publication of Lawson and others[52] (one restoration lost; 97% retention rate). Even after two and three years of clinical service, retention rates as high as 89% to 93% were observed.[25,52]

The good performance of composite restoration in cervical lesions from these studies[19,24,25,52] is likely due to the presence of the acidic functional monomer 10-MDP in the SE adhesives.[41,46-48] This functional monomer is responsible for the formation of a stable salt with the Ca in hydroxyapatite. The stability of this Ca salt has been correlated[40] with the high bond strength of MDP to enamel and dentin immediately and after long-term water storage.

When the six-month data of this material are compared with that of other 10-MDP–containing universal adhesives in the SE strategy, we clearly show that 10-MDP adhesives show higher retention rates (94%-97%)[19,24,25,52] than are reported in this clinical trial (80.7%), which reinforces that MDP might have an important role on the bonding performance of universal adhesives when used in the SE mode. Future studies comparing universal adhesives with and without MDP should be conducted.

It is also interesting to observe that even when the SE was applied after selective enamel etching (SE-et), the retention pattern did not improve significantly.[53,54] The clinical trials[53,54] that compare the benefits of selective enamel etching before application of SE adhesives do not report improved retention rates of composite resin restorations in NCCLs, and this finding has also been observed for one universal adhesive.[19,24,25] On the other hand, selective enamel etching with SE adhesives (SE-et) can reduce marginal discoloration at the restoration interface after medium/long-term clinical service.[53,54]

The better performance of Xeno Select with the ER approach may be related to the fact that after phosphoric acid etching, the adhesive is no longer dependent on the chemical bonding produced by the acidic monomers with the dental substrates.[55] In this case, micromechanical bond is responsible for the good retention of the adhesive so long as the material produces a well-impregnated hybrid layer[55] and a strong polymer inside the hybrid layer.[1]

In the present investigation, the results of Xeno Select when applied in wet (ER-M) and dry (ER-D)

conditions showed similar results in terms of retention rates, as well as all other parameters evaluated. The similar results of the ER-M and ER-D groups were not surprising, as other clinical trials that compared wet and dry bonding with ER systems did not report higher retention rates for the wet bonding protocol,[56,57] mainly if the adhesive was applied actively,[57,58] as was done for Xeno Select (manufacturer's recommendation).

In the case of Xeno Select, this new adhesive system contains a special solvent named tert-butanol (2-methyl-2-propanol), which is able to re-expand collapsed collagen fibrils produced by air-drying. Indeed, during microscopic analysis of resin-dentin interfaces produced by an adhesive system (XP-Bond) containing tert-butanol, the formation of very similar hybrid layers and resin tags in dentin under dry and moist conditions was observed.[59] Although tert-butanol has a higher molecular weight than ethanol, the evaporation rate is almost the same, with a latent heat of vaporization of 41 kJ/mol for tert-butanol and of 42 kJ/mol for ethanol.[60] The vapor pressure of the different kinds of solvents at 20°C is given as 2330 Pa for water, 4133 Pa for tert-butanol, 5900 Pa for ethanol, and 23,300 Pa for acetone.[61]

Regardless of the bonding strategy used, the present study observed a significant deterioration of the marginal adaptation even at the short-term evaluation. These results are similar to those of earlier published articles[19,24,25] that compared universal adhesives using ER and SE approaches using a more sensitive criteria for evaluation (SQUACE). Although different clinical trials have shown that marginal discrepancies of a composite restoration usually develop rather rapidly,[19,24,25,52] most of the marginal defects were small and clinically acceptable.[51]

While there is a general consensus that marginal defects can affect the final performance of resin composite restorations, to the extent of our knowledge no study has so far observed an association between marginal defects and loss of retention. These defects can cause early marginal discoloration, which may jeopardize the restoration esthetics. Fortunately, restoration re-polishing can amend these discrepancies without causing any damage to the integrity of the restoration.[62]

As a result of the efforts of the FDI, new criteria for evaluating dental restorations were published in 2007 and named the "FDI criteria."[36] Since then, only a few publications have used the FDI criteria,[19,24,25,63,64] as most clinical studies on NCCL restorations continue using the USPHS criteria.[6-8,52] Recent publications[19,24,25,63] that compared the six-month clinical behavior of several adhesion strategies using both FDI and USPHS-modified criteria concluded that the FDI criteria are more sensitive than the USPHS-modified criteria to small variations in the clinical outcomes 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. We opted to keep both criteria in the present study to allow comparison of the present results with those of studies that used both criteria.

Clinical trials have greater value when published after long-term follow-ups. However, the large number of failures in such a short-term follow-up justifies the publication of these data, as this can provide clinicians with further evidence before selecting a universal adhesive for purchase and use in their clinical offices. Additionally, these findings may also stimulate further studies based on this material, improving when they use the SE approach in their formulation, as Xeno Select did not fulfill the criteria for provisional acceptance according to the ADA guideline of having a failure rate of less than 5% after six months of clinical performance.[34] Future clinical recalls are already scheduled in order to assess the long-term performance of Xeno Select in NCCL restorations.

CONCLUSIONS

Within the limitations of this study, the six-month clinical behavior of Xeno Select Universal Adhesive (Dentsply) depends on the bonding strategy used. The universal adhesive did not fulfil the ADA criteria for full approval when used in the SE mode.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subject's oversight committee guidelines and policies of: Fluminense Federal University. The approval code for this study is: 800.273/14.

Conflict of Interest

The authors 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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REFERENCES

1. Pashley DH, Tay FR, Breschi L, Tjäderhane L, Carvalho RM, Carrilho M, & Tezvergil-Mutluay A (2011) State of the art etch-and-rinse adhesives *Dental Materials* **27(1)** 1-16.
2. Zafar MS, & Ahmed N (2015) The effects of acid etching time on surface mechanical properties of dental hard tissues *Dental Materials Journal* **34(3)** 315-320.
3. Li N, Nikaido T, Alireza S, Takagaki T, Chen JH, & Tagami J (2013) Phosphoric acid-etching promotes bond strength and formation of acid-base resistant zone on enamel *Operative Dentistry* **38(1)** 82-90.
4. Nakabayashi N, Nakamura M, & Yasuda N (1991) Hybrid layer as a dentin-bonding mechanism *Journal of Esthetic Dentistry* **3(4)** 133-138.
5. Salvio LA, Hipolito VD, Martins AL, & de Goes MF (2013) Hybridization quality and bond strength of adhesive systems according to interaction with dentin *European Journal of Dentistry* **7(3)** 315-326.
6. Van Dijken JW (2013) A randomized controlled 5-year prospective study of two HEMA-free adhesives, a 1-step self etching and a 3-step etch-and-rinse, in non-carious cervical lesions *Dental Materials* **29(11)** e271-e280.
7. Perdigão J, Dutra-Corrêa M, Saraceni CH, Ciaramicoli MT, Kiyan VH, & Queiroz CS (2012) Randomized clinical trial of four adhesion strategies: 18-Month results *Operative Dentistry* **37(1)** 3-11.
8. Reis A, Mânica D, Ferneda F, Amaral R, Stanislawczuk R, Manso A, De Carvalho RM, & Loguercio AD (2010) A 24-month randomized clinical trial of a two- and three-step etch-and-rinse technique *American Journal of Dentistry* **23(4)** 231-236.
9. Reis A, Loguercio AD, Carvalho RM, & Grande RH (2004) Durability of resin dentin interfaces: Effects of moisture and adhesive solvent component *Dental Materials* **20(7)** 669-676.
10. Sano H, Kanemura N, Burrow MF, Inai N, Yamada T, & Tagami J (1998) Effect of operator variability on dentin adhesion: Students vs. Dentists *Dental Materials Journal* **17(1)** 51-58.
11. Perdigão J (2007) New developments in dental adhesion *Dental Clinics of North America* **51(2)** 333-357.
12. Carvalho RM, Chersoni S, Frankenberger R, Pashley DH, Prati C, & Tay FR (2005) A challenge to the conventional wisdom that simultaneous etching and resin infiltration always occurs in self-etch adhesives *Biomaterials* **26(9)** 1035-1042.
13. Erhardt MC, Cavalcante LM, & Pimenta LA (2004) Influence of phosphoric acid pretreatment on self-etching bond strengths *Journal of Esthetic and Restorative Dentistry* **16(1)** 33-40.
14. Rotta M, Bresciani P, Moura SK, Grande RH, Hilgert LA, Baratieri LN, Loguercio AD, & Reis A (2007) Effects of phosphoric acid pretreatment and substitution of bonding resin on bonding effectiveness of self-etching systems to enamel *Journal of Adhesive Dentistry* **9(6)** 537-545.
15. Van Meerbeek B, Kanumilli P, De Munck J, Van Landuyt K, Lambrechts P, & Peumans M (2005) A randomized controlled study evaluating the effectiveness of a two-step self-etch adhesive with and without selective phosphoric-acid etching of enamel *Dental Materials* **21(4)** 375-383.
16. Frankenberger R, Lohbauer U, Roggendorf MJ, Naumann M, & Taschner M (2008) Selective enamel etching reconsidered: Better than etch-and-rinse and self-etch? *Journal of Adhesive Dentistry* **10(5)** 339-344.
17. Erickson RL, Barkmeier WW, & Latta MA (2009) The role of etching in bonding to enamel: A comparison of self-etching and etch-and-rinse adhesive systems *Dental Materials* **25(11)** 1459-1467.
18. Van Landuyt KL, Peumans M, De Munck J, Lambrechts P, & Van Meerbeer B (2006) Extension of a one-step self-etch adhesive into a multi-step adhesive *Dental Materials* **22(6)** 533-544.
19. Perdigão J, Kose C, Mena-Serrano AP, De Paula EA, Tay LY, Reis A, & Loguercio AD (2014) A new universal simplified adhesive: 18-Month clinical evaluation *Operative Dentistry* **39(2)** 113-127.
20. Hanabusa M, Mine A, Kuboki T, Momoi Y, Van Ende A, Van Meerbeek B, & De Munck J (2012) Bonding effectiveness of a new 'multi-mode' adhesive to enamel and dentine *Journal of Dentistry* **40(6)** 475-484.
21. Muñoz MA, Luque I, Hass V, Reis A, Loguercio AD, & Bombarda NH (2013) Immediate bonding properties of universal adhesives to dentine *Journal of Dentistry* **41(5)** 404-411.
22. Loguercio AD, Muñoz MA, Luque-Martinez I, Hass V, Reis A, & Perdigão J (2015) Does active application of universal adhesives to enamel in self-etch mode improve their performance? *Journal of Dentistry* **43(9)** 1060-1070.
23. Muñoz MA, Luque-Martinez I, Malaquias P, Hass V, Reis A, Campanha NH, & Loguercio AD (2015) In vitro longevity of bonding properties of universal adhesives to dentin *Operative Dentistry* **40(3)** 282-292.
24. Mena-Serrano A, Kose C, De Paula EA, Tay LY, Reis A, Loguercio AD, & Perdigão J (2013) A new universal simplified adhesive: 6-Month clinical evaluation *Journal of Esthetic and Restorative Dentistry* **25(1)** 55-69.
25. Loguercio AD, de Paula EA, Hass V, Luque-Martinez I, Reis A, & Perdigão J (2015) A new universal simplified adhesive: 36-Month randomized double-blind clinical trial *Journal of Dentistry* **43(9)** 1083-1092.
26. Schulz KF, Altman DG, Moher D, & CONSORT (2011) Group CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials *International Journal of Surgery* **9(8)** 672-677.
27. Sugizaki J, Morigami M, Uno S, & Yamada T (2007) Clinical evaluation and interfacial morphology observation of Xeno III self-etching resin bonding and restorative system *Dental Materials Journal* **26(4)** 602-607.
28. Heintze SD, & Cavalleri A (2010) Retention loss of Class V restorations after artificial aging *Journal of Adhesive Dentistry* **12(6)** 443-449.

29. van Dijken JWV, Sunnegårdh-Grönberg K, & Sörensson E (2007) Clinical bonding of a single-step self-etching adhesive in noncarious cervical lesions *Journal of Adhesive Dentistry* **9(Supplement 2)** 241-243.

30. Zander-Grande C, Amaral RC, Loguercio AD, Barroso LP, & Reis A (2013) Clinical performance of one-step self-etch adhesives applied actively in cervical lesions: 24-Month clinical trial *Operative Dentistry* **39(3)** 228-238.

31. Pocock SJ (1983) *Clinical Trials: A Practical Approach* Wiley, New Jersey, USA.

32. Loguercio AD, Reis A, Barbosa AN, & Roulet JF (2003) Five-year double-blind randomized clinical evaluation of a resin-modified glass ionomer and a polyacid-modified resin in noncarious cervical lesions *Journal of Adhesive Dentistry* **5(4)** 323-332.

33. Swift EJ Jr, Perdigão J, Heymann HO, Wilder AD Jr, Bayne SC, May KN Jr, Sturdevant JR, & Roberson TM (2001) Eighteen-month clinical evaluation of a filled and unfilled dentin adhesive *Journal of Dentistry* **29(1)** 1-6.

34. American Dental Association Council on Scientific Affairs (2001) *Acceptance Program Guidelines: Dentin and Enamel Adhesive Materials* American Dental Association, Chicago.

35. Cvar JF, & Ryge G (2005) Reprint of criteria for the clinical evaluation of dental restorative materials *Clinical Oral Investigations* **9(4)** 215-232.

36. Hickel R, Peschke A, Tyas M, Mjor I, Bayne S, Peters M, Hiller KA, Randall R, Vanherle G, & Heintze SD (2010) FDI World Dental Federation: Clinical criteria for the evaluation of direct and indirect restorations—Update and clinical examples *Journal of Adhesive Dentistry* **12(4)** 259-272.

37. Bittencourt DD, Ezecelevski IG, Reis A, Van Dijken JW, & Loguercio AD (2005) An 18-months' evaluation of self-etch and etch & rinse adhesive in non-carious cervical lesions *Acta Odontologica Scandinavica* **63(3)** 173-178.

38. Sudsangiam S, & van Noort R (1999) Do dentin bond strength tests serve a useful purpose? *Journal of Adhesive Dentistry* **1(1)** 57-67.

39. Van Meerbeek B, Peumans M, Poitevin A, Mine A, Van Ende A, Neves A, & De Munck J (2010) Relationship between bond-strength tests and clinical outcomes *Dental Materials* **26(2)** e100-e121.

40. Van Landuyt KL, Snauwaert J, De Munck J, Peumans M, Yoshida Y, Poitevin A, Coutinho E, Suzuki K, Lambrechts P, & Van Meerbeek B (2007) Systematic review of the chemical composition of contemporary dental adhesives *Biomaterials* **28(26)** 3757-3785.

41. Van Meerbeek B, Yoshihara K, Yoshida Y, Mine A, De Munck J, & Van Landuyt KL (2011) State of the art of self-etch adhesives *Dental Materials* **27(1)** 17-28.

42. Van Loghum BS (2014) Xeno Select fact file *Tandartspraktijk* **35(5)** 50-51.

43. Latta MA (2007) Shear bond strength and physicochemical interactions of XP BOND *Journal of Adhesive Dentistry* **9(Supplement 2)** 245-248.

44. Yoshida Y, Nagakane K, Fukuda R, Nakayama Y, Okazaki M, Shintani H, Inoue S, Tagawa Y, Suzuki K, De Munck J, & Van Meerbeek B (2004) Comparative study on adhesive performance of functional monomers *Journal of Dental Research* **83(6)** 454-458.

45. Yoshida Y, Van Meerbeek B, Nakayama Y, Snauwaert J, Hellemans L, Lambrechts P, Vanherle G, & Wakasa K (2000) Evidence of chemical bonding at biomaterial-hard tissue interfaces *Journal of Dental Research* **79(2)** 709-714.

46. Yoshida Y, Van Meerbeek B, Nakayama Y, Yoshioka M, Snauwaert J, Abe Y, Lambrechts P, Vanherle G, & Okazaki M (2001) Adhesion to and decalcification of hydroxyapatite by carboxylic acids *Journal of Dental Research* **80(6)** 1565-1569.

47. Yoshioka M, Yoshida Y, Inoue S, Lambrechts P, Vanherle G, Nomura Y, Okazaki M, Shintani H, & Van Meerbeek B (2002) Adhesion/decalcification mechanisms of acid interactions with human hard tissues *Journal of Biomedical Materials Research* **59(1)** 56-62.

48. Fu B, Sun X, Qian W, Shen Y, Chen R, & Hannig M (2005) Evidence of chemical bonding to hydroxyapatite by phosphoric acid esters *Biomaterials* **26(25)** 5104-5110.

49. Maeda T, Yamaguchi K, Takamizawa T, Rikuta A, Tsubota K, Ando S, & Miyazaki M (2008) pH changes of self-etching primers mixed with powdered dentine *Journal of Dentistry* **36(8)** 606-610.

50. Zhou L, Wang Y, Yang H, Guo J, Tay FR, & Huang C (2015) Effect of chemical interaction on the bonding strengths of self-etching adhesives to deproteinised dentine *Journal of Dentistry* **43(8)** 973-980.

51. Peumans M, De Munck J, Mine A, & Van Meerbeek B (2014) Clinical effectiveness of contemporary adhesives for the restoration of non-carious cervical lesions. A systematic review *Dental Materials* **30(10)** 1089-1103.

52. Lawson NC, Robles A, Fu CC, Lin CP, Sawlani K, & Burgess JO (2015) Two-year clinical trial of a universal adhesive in total-etch and self-etch mode in non-carious cervical lesions *Journal of Dentistry* **43(10)** 1229-1234.

53. Can Say E, Yurdaguven H, Ozel E, & Soyman M (2014) A randomized five-year clinical study of a two-step self-etch adhesive with or without selective enamel etching *Dental Materials Journal* **33(6)** 757-763.

54. Peumans M, De Munck J, Van Landuyt K, & Van Meerbeek B (2015) Thirteen-year randomized controlled clinical trial of a two-step self-etch adhesive in non-carious cervical lesions *Dental Materials* **31(3)** 308-314.

55. Taschner M, Nato F, Mazzoni A, Frankenberger R, Krämer N, Di Lenarda R, Petschelt A, & Breschi L (2010) Role of preliminary etching for one-step self-etch adhesives *European Journal of Oral Science* **118(5)** 517-524.

56. Perdigão J, Carmo AR, & Geraldeli S (2005) Eighteen-month clinical evaluation of two dentin adhesives applied on dry vs moist dentin *Journal of Adhesive Dentistry* **7(3)** 253-258.

57. Zander-Grande C, Ferreira SQ, da Costa TR, Loguercio AD, & Reis A (2011) Application of etch-and-rinse adhesives on dry and rewet dentin under rubbing action: A 24-month clinical evaluation *Journal of the American Dental Association* **142(7)** 828-835.

58. Loguercio AD, Raffo J, Bassani F, Balestrini H, Santo D, do Amaral RC, & Reis A (2011) 24-Month clinical evaluation in non-carious cervical lesions of a two-step etch-and-rinse adhesive applied using a rubbing motion *Clinical Oral Investigations* **15(4)** 589-596.

59. Machado LS, Oliveira FG, Guinossi TA, Sundfeld Neto D, Alexandre RS, Reis AF, & Sundfeld RH (2013) Effects of dentin dry/moist condition on the immediate adhesive performance of different solvent-based etch-and-rinse adhesive systems *International Journal of Adhesion & Adhesives* **43(1)** 1-6.

60. Oktavian R, Amidelsi V, Rasmito A, & Wibawa G (2013) Vapor pressure measurements of ethanol-isooctane and 1-butanol-isooctane systems using a new ebulliometer *Fuel* **107(1)** 47-51.

61. Neumüller O (1981) *Römpps chemie lexikon* Franckh-Fachlexikon, Stuttgart, Germany.

62. Hickel R, Brüshaver K, & Ilie N (2013) Repair of restorations—Criteria for decision making and clinical recommendations *Dental Materials* **29(1)** 29-50.

63. Paula EA, Tay LY, Kose C, Mena-Serrano A, Reis A, Perdigão J, & Loguercio AD (2015) Randomized clinical trial of four adhesion strategies in cervical lesions: 12-Month results *International Journal of Esthetic Dentistry* **10(1)** 122-145.

64. Da Rosa Rodolpho PA, Donassollo TA, Cenci MS, Loguércio AD, Moraes RR, Bronkhorst EM, Opdam NJ, & Demarco FF (2011) 22-Year clinical evaluation of the performance of two posterior composites with different filler characteristics *Dental Materials* **27(10)** 955-963.