©Operative Dentistry, 2014, **39-3,** 228-238

Clinical Research

Clinical Performance of One-step Self-etch Adhesives Applied Actively in Cervical Lesions: 24-month Clinical Trial

C Zander-Grande • R C Amaral • AD Loguercio
LP Barroso • A Reis

Clinical Relevance

The active application mode seems to be an easy and effective clinical alternative to improve the retention rates and reduce marginal staining of one-step self-etch adhesives in noncarious cervical lesions.

SUMMARY

Objectives: To evaluate the clinical performance of two one-step self-etch adhesives in noncarious cervical lesions (NCCL) under active or passive application mode.

Methods: Thirty-one patients with four NCCL were enrolled in this study. One hundred and twenty-four restorations were placed according to one of the following conditions: 1) Adper Prompt L-Pop (AP), active application (APA); 2) AP, passive application (APP); 3) Xeno III (XE), active application (XEA), or 4) XE, passive application (XEP). The restorations were evaluated by the FDI World Dental Federation criteria at baseline and after six, 12, and 24 months of clinical service. The effects of adhesive, mode of application, and recall period were assessed via mixed generalized linear model (α=0.05).

Results: The adhesive AP and the passive application mode showed significantly higher marginal staining than did XE and active application, respectively ($p<0.05$). With regard to the retention rates, the active application mode yielded higher retention rates at the 24-month recall compared to the passive application, regardless of the material. The individual

Christiana Zander-Grande, DDS, DMD, PhD, clinician at the Brazilian Army (Ponta Grossa, Paraná, Brasil)

Roberto César do Amaral, DDS, DMD, professor, School of Dentistry, University of Oeste de Santa Catarina, Joaçaba, SC, Brasil

Alessandro Dourado Loguercio, DDS, DMD, PhD, professor, Department of Restorative Dentistry, State University of Ponta Grossa, Ponta Grossa, Paraná, Brasil

Lúcia Pereira Barroso, PhD, professor, Statistics Department, Mathematics and Statistics Institute, University of São Paulo, São Paulo, São Paulo, Brasil

*Alessandra Reis, DDS, PhD, professor, Department of Restorative Dentistry, State University of Ponta Grossa, Ponta Grossa, Paraná, Brasil

*Corresponding author: Universidade Estadual de Ponta Grossa, Avenida General Carlos Cavalcanti, 4748, CEP 84030-900, Ponta Grossa, Paraná, Brasil; e-mail: reis_ale@hotmail.com

DOI: 10.2341/12-286-C

retention rates (95% confidence interval) of both adhesives in the active application mode were the same, 96.8% (83.8-99.4%), while in the passive application rates were 87.1% (71.2-94.9%) and 80.7% (63.7-90.8%) for XE and AP, respectively.

Conclusions: The active application improved the retention rates of both adhesives after 24 months and minimized the marginal staining at enamel margins.

INTRODUCTION

The etiology of noncarious cervical lesions (NCCL) is quite variable, but their prevalence is increasing as the adult population continues to age.[1,2] Often, these lesions need to be restored as a result of sensitivity or for esthetic reasons or in such a way as to prevent further loss of dental structure. In general, the retention of resin-based composites in NCCL has shown considerable increase;[3,4] however, as reported by Van Dijken,[3] there is a vast range of adhesives available from which to choose, including the older three-step version to the most recent one-step self-etch systems.

One-step self-etch adhesive systems require shorter clinical application times and they are less technique sensitive.[5,6] The elimination of separate etching and rinsing steps has simplified the bonding technique and has been responsible for the increased popularity of these systems in daily practice. These systems do not require removal of the smear layer and smear plugs, as they are incorporated into the hybrid layer complex.[4]

Unfortunately, different studies[7,8] have shown that some one-step self-etch adhesives produce relatively low bond strength values and inferior marginal adaptation to both enamel and dentin when compared to two-step self-etch or etch-and-rinse systems, findings confirmed in a recent systematic review of clinical studies.[9] The authors have reported that the clinical effectiveness of one-step self-etch adhesives was the least efficient among all classes of available adhesives. This may be partially attributed to the acidity of the adhesive system, since the interaction of the material with the underlying substrate may be quite superficial[10] for low acidic materials, which may preclude an adequate retention of the restorative resin-based composite.

In vitro studies have reported that the bond strength of self-etch adhesives to enamel[11-13] and the dentin[12,14-16] can be improved by vigorous agitation. This clinical approach was shown[15,17] to increase the durability of adhesive interfaces produced with one-step self-etch adhesives when applied to dentin. It has been suggested[8,18] that the active primer application may improve smear layer dissolution and improve micromechanical interlocking and chemical interaction with dentin.

Despite the favorable laboratory findings with this technique, only one study[19] evaluated this approach clinically, but a conventional etch-and-rinse system was employed. To the extent of the authors' knowledge, no study has so far addressed the benefits of active application under a clinical scenario using self-etch adhesives. Though *in vitro* testing methodology with aging protocols tends to predict clinical performance,[20,21] clinical trials remain necessary to evaluate the ultimate clinical efficacy of adhesives and/or clinical techniques. Thus, the aim of this randomized clinical trial was to evaluate the influence of the application method of two one-step self-etch adhesives placed in NCCL after 24 months of clinical service. The null hypothesis tested was that the retention rates of both materials will be similar after 24 months of clinical service, regardless of the application mode.

MATERIALS AND METHODS

Study Design and Participant Selection

The study was reported following the CONSORT statement.[22] This was a randomized, double-blind clinical trial. The local Ethics Committee on Investigations Involving Human Subjects reviewed and approved the protocol and consent form for this study (protocol 6291/06).

Inclusion and Exclusion Criteria

A total of 48 participants were examined to determine if they met the inclusion and exclusion criteria (described below) (Figure 1) by three calibrated dental students. The evaluations were performed using a mouth mirror, an explorer, and a periodontal probe. Participants had to be healthy and at least 18 years old. They had to have an acceptable oral hygiene level and present with at least 20 teeth under occlusion. They were required to have at least four NCCL to be restored in four different teeth. These lesions had to be noncarious and nonretentive (greater than 1 mm deep) and involve both the enamel and dentin of vital teeth without mobility. The cavo-surface margin could not involve more that 50% of the enamel.[4]

All patients were given oral hygiene instructions before operative treatment was performed. Patients

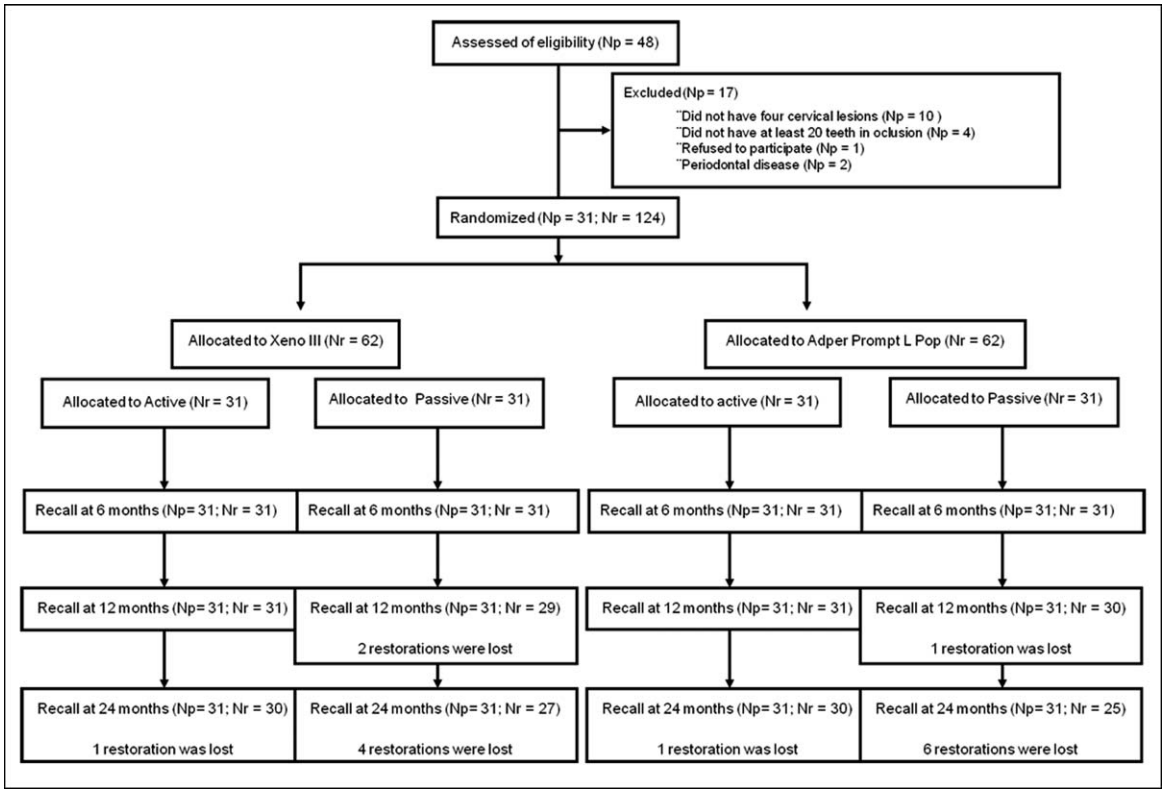

Figure 1. *Flow diagram. Np, number of patients; Nr, number of restorations.*

with extremely poor oral hygiene, severe or chronic periodontitis, or heavy bruxism habits were excluded from the study.

Interventions: Restorative Procedure

Two weeks before the restorative procedures, all of the volunteers received a dental screening and a dental prophylaxis with pumice and water in a rubber cup and signed an informed consent form.

Before restoration placement, some features of the NCCL were evaluated. The degree of sclerotic dentin was measured according to the criteria described by Swift and others[23] (Table 1). The cavity dimensions in millimeters (height, width, and depth) and the geometry of the cavity (evaluated by photograph profile and labeled at $<45°$, 45-90°, 90-135°, and $>135°$) were also recorded. Other features, such as the presence of antagonist and attrition facet, were observed and recorded. These features were recorded to allow comparison of the baseline features of the dentin cavities among experimental groups.

The previously calibrated dental students who participated in the patient screening selection restored all teeth under the supervision of an experienced clinician.[19] All participants received four restorations, one of each experimental group in different teeth with similar characteristic, such as depth, shape, dentin sclerosis, and others.

The operator classified the order of the teeth to be restored. After that, the groups were described in

Table 1: *Dentin Sclerosis Scale*[a]

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

[a] *Adapted from Swift and others.*

Table 2: *Adhesive Systems: Composition and Application Mode*

Adhesive Systems	Composition	Mode of Application	Application Mode[a]
Adper Prompt L-Pop (AD; 3M ESPE, St Paul, MN, USA)	Liquid 1 (red blister): methacrylated phosphoric esters, bis-GMA, initiators based on camphorquinone and stabilizers Liquid 2 (yellow blister): water, HEMA, polyalkenoic acid and stabilizers	Active (manufacturer's recommendation)	a, b1, c, b1, c, d
		Passive	a, b2, c, b2, c, d
Xeno III (XE; Dentsply Caulk, Milford, DE, USA)	Liquid A (green cap): HEMA, purified water, ethanol, UDMA, BHT, highly dispersed silicon dioxide Liquid B (black cap): phosphoric acid modified polymethacrylate resin, PEM-F, modified methacrylate resin, UDMA, camphorquinone, ethyl-4-dimethylaminobenzoate	Active	a, b3, c, d
		Passive (manufacturer's recommendation)	a, b4, c, d

Abbreviations: BHT, butylated hydroxy toluene; Bis-GMA, bisphenol A diglycidyl methacrylate; HEMA, 2-hydroxyethyl methacrylate; MDP, 10-methacryloyloxydecyl dihydrogen phosphate; PEM-F, pentamethacryloyloxyethylcyclohexaphosphazene monofluoride; UDMA, urethane dimethacrylate.
[a] a: Dispense equal amounts of Liquid A or 1 and Liquid B or 2 and mix them in mixing well thoroughly (five seconds); b1: Apply one coat with agitation for 15-20 seconds; b2: Apply one coat passively and leave undisturbed for at least 15-20 seconds; b3: Apply one coat with agitation for 20 seconds; b4: Apply one coat passively and leave undisturbed for at least 20 seconds; c: air-dry for 10 seconds at 20 cm; d: light-cure (10 seconds, 600 mW/cm^2).

opaque papers that were folded and randomly selected by a third person not involved in the research protocol. The allocation assignment of the four groups was revealed by opening these folded papers on the day of the restorative procedure. The operator was not blinded to group assignment when administering interventions; however, participants were blinded to the group assignment.

Before rubber dam placement, the operators anesthetized the teeth (Mepisv 3%, NovaDFL, Rio de Janeiro, RJ, Brazil) and cleaned all lesions with pumice and water in a rubber cup (reference #8040RA and #8045RA, KG Sorensen, Barueri, SP, Brazil); this step was followed by rinsing and drying. With a shade selection guide, the proper shade of the composite was determined. According to the American Dental Association (ADA) guidelines,[24] the operators did not prepare any additional retention or bevel.

Next, the cavities received the self-etch adhesive systems Adper Prompt L-Pop (AP; 3M ESPE, St Paul, MN, USA) or Xeno III (XE; Dentsply Caulk, Milford, DE, USA) applied under active or passive application. Their composition, application mode, and batch number are described in Table 2.

1. Passive application (P): In these groups, the adhesive was only spread over the entire surface for approximately three to five seconds and was left undisturbed for 15 to 20 seconds (Table 2). Then an airstream was applied for 10 seconds at a distance of 20 cm. The air-dry pressure used was 40 psi (0.27 MPa).
2. Active application (A): The adhesive was rigorously agitated on the entire dentin surface for approximately 15 to 20 seconds (Table 2). The microbrush was scrubbed on the dentin surface under manual pressure (equivalent to approximately 34.5 $\pm$ 6.9 *g*, tested in an analytical balance before the beginning of the clinical trial). An airstream was applied for 10 seconds at a distance of 20 cm. The air-dry pressure used was 40 psi (0.27 MPa).

The resin-based composites Esthet X (Dentsply Caulk) and Filtek Z250 (3M ESPE) were used in combination with XE or AP, respectively. The cavities were restored in three increments, and each increment was light-cured for 40 seconds (VIP light-curing unit, Bisco Inc, Schaumburg, IL, USA; 600 mW/cm^2). The restorations were finished with fine-grit diamond burs, and the polishing procedure was performed with abrasive discs (Sof-Lex Pop-On discs, 3M ESPE) one week after placement of the restorations.

Sample Size Calculation

The retention rate of the antecessor of AP, commercially available as Prompt L-Pop, was reported[25] to be 69% after 12 months of clinical service. With 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.[26]

Clinical Evaluation

Two experienced and calibrated examiners who were not involved in the placement of the restorations and who were 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

Table 3: *FDI Criteria Used for Clinical Evaluation (Hickel and others[28,29])*

	Esthetic Property	Functional Properties		Biological Properties	
	1. Staining Margin	**2. Fractures and Retention**	**3. Marginal Adaptation**	**4. Postoperative Sensitivity**	**5. Secondary Caries**
1. Clinically very good	1.1. No marginal staining	2.1. Restoration retained, no fractures/cracks	3.1. Harmonious outline, no gaps, no discoloration	4.1. No hypersensitivity	5.1. No secondary or primary caries
2. Clinically good (after correction very good	1.2. Minor marginal staining, easily removable by polishing	2.2. Small hairline crack	3.2.1. Marginal gap (50 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 (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 11.3.2. Delayed/ weak sensitivity; no subjective complaints, no treatment needed..	5.3. Larger areas of demineralization, but only preventive measures necessary (dentine not exposed)
4. Clinically unsatisfactory (repair for prophylactic reasons)	1.4. Pronounced marginal staining; major intervention necessary for improvement	2.4. Chipping fractures that damage marginal quality; bulk fractures with or without partial loss (less than half of the restoration)	3.4.1. Gap >250 μm or dentine/base exposed 3.4.2. Chip fracture damaging margins 3.4.3. Notable enamel or dentine wall fracture	4.4.1. Premature/ very intense 4.4.2. Extremely delayed/weak with subjective complaints 4.4.3. Negative sensitivity; intervention necessary but not replacement	5.4. Caries with cavitation (localized and accessible and can be repaired)
5. Clinically poor (replacement necessary)	1.5. Deep marginal staining not accessible for intervention	2.5. (Partial or complete) loss of restoration	3.5. Filling is loose but *in situ*	4.5. Very intense, acute pulpitis or nonvital Endodontic treatment is necessary and restoration has to be replaced	5.5. Deep secondary caries or exposed dentine that is not accessible for repair of restoration
Acceptable or not acceptable (n, %, and reasons)	Esthetic criteria	Functional criteria		Biological criteria	

evaluated 10 to 15 teeth in two different clinical appointments to allow intraexaminer agreement. The intraexaminer and interexaminer agreement of at least 85% was necessary before the beginning of the evaluation.[27] The evaluation paper form of each recall was not available for the next evaluation, so that evaluators were blinded to group assignment during follow-up recalls.

The restorations were evaluated by the FDI World Dental Federation criteria[28,29] at baseline and after six, 12, and 24 months of clinical service. Only the most relevant items for testing the adhesive performance were selected (Table 3). The primary measurable variable was restoration retention/fractures, but the following secondary measurable variables were also evaluated: marginal staining, marginal adaptation, postoperative sensitivity, and recurrence of caries. Those measurable variables were ranked with the following scores: clinically very good, clinically good, clinically sufficient/satisfactory, clinically unsatisfactory, and clinically poor. Both examiners evaluated all the restorations once and independently. When disagreements occurred during the evaluations, the examiners had to reach a consensus before the participant was dismissed. The restoration retention rates were calculated according to the ADA guidelines.[24]

Statistical Analysis

Descriptive statistics were used to describe the distributions of the evaluated criteria. Statistical analysis was performed for each item as well as for

each property. The effects of adhesive, mode of application, and time were assessed via mixed generalized linear model[30] associated to a link function. This was required because the items marginal adaptation and caries recurrence had only two responses, and, thus, a binary model should be used for this analysis. For all others items, a multinomial model was used. As the four groups were always placed in the same patient, the patient was considered the repeated measure.

Two different statistical analyses were run. One followed the intention-to-treat protocol, which included all teeth in their originally randomized groups, even those that were not able to be analyzed during the scheduled recall visits. In this case, we filled in the missing data by carrying the last observed value of such teeth. The second approach followed the per-protocol or on-treatment approach, in which the participants with missing data were excluded from the statistical analysis. The first approach is more conservative and less open to bias than the second one and is recommended by the CONSORT statement.[22]

RESULTS

The restorative procedures were implemented exactly as planned and no modification was performed. No subgroup analysis was done. Seventeen out of 48 participants initially screened were excluded from the study because they did not fulfill the inclusion criteria. Thus, a total of 31 subjects (12 men and 19 women), with a mean age of 48 years, were enrolled. One hundred and twenty-four restorations were placed, 31 for each group (Figure 1). All details regarding the research subjects and characteristics of the restored lesions are presented in Table 4.

Table 4: *Demographic Characteristic of Research Subject and Features of Noncarious Cervical Lesions (NCCL)*

Characteristics	Number of Lesions			
Research subjects				
Gender distribution				
Male	48			
Female	76			
Age distribution, y				
20-29	04			
30-39	36			
39-49	40			
>49	44			
	XEA	XEP	APA	APP
NCCL				
Shape, degree of angle				
<45	01	01	01	01
45-90	08	08	09	10
90-135	12	14	10	12
>135	10	08	11	08
Cervico-incisal height, mm				
<1.5	02	02	02	02
1.5-2.5	09	03	09	06
>2.5	20	26	20	23
Degree of sclerotic dentin				
1	10	09	11	08
2	18	19	17	20
3	02	02	01	01
4	01	01	02	02
Presence of antagonist				
Yes	29	29	30	28
No	02	02	01	03
Attrition facet				
Yes	26	26	25	25
No	05	05	06	06
Preoperative sensitivity, spontaneous				
Yes	15	15	17	15
No	16	16	14	16
Tooth distribution				
Incisors	02	02	02	02
Canines	05	06	08	09
Premolars	21	20	20	19
Molars	03	03	01	01
Arch distribution				
Maxillary	15	15	13	13
Mandibular	16	16	18	18

Abbreviations: APA, Adper Prompt L-Pop, active application; APP, Adper Prompt L-Pop, passive application; XEA, Xeno III, active application; XEP, Xeno III, passive application.

Both statistical analyses (intention-to-treat and per-protocol) led to similar conclusions (data not shown), and the *p*-values reported in this section are from the intention-to-treat analysis. All research subjects were evaluated at baseline and in the six-, 12-, and 24-month recalls. When a restoration was lost, the other criteria could not be evaluated as the restoration was no longer in place. In the intention-to-treat protocol, we filled in this missing data by carrying the last observed value of such teeth.

Esthetic Properties

With regard to the marginal staining, only the main factors of adhesive ($p=0.011$), application mode ($p=0.008$), and recall period ($p<0.001$) were statistically significant. At the 24-month recall, four

Table 5: *Number of Restorations for Each Experimental Group Classified According to the FDI Criteria (Hickel and others[28,29])*

Hickel Criteria [a]		Baseline				Six Months				12 Months				24 Months			
		XEA	XEP	APA	APP	XEA	XEP	APA	APP	XEA	XEP	APA	APP	XEA	XEP	APA	APP
1. Marginal staining	VG	31	31	31	31	31	31	31	31	28	23	24	20	26	18	22	12
	GO	—	—	—	—	—	—	—	—	03	06	07	09	04	08	08	12
	SS	—	—	—	—	—	—	—	—	—	—	—	—	—	01	—	01
	UN	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
2. Fractures and retention	VG	31	31	31	31	31	31	31	31	31	27	30	26	28	19	26	15
	GO	—	—	—	—	—	—	—	—	—	02	01	03	02	06	04	08
	SS	—	—	—	—	—	—	—	—	—	—	—	—	—	02	—	02
	UN	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	—	—	—	—	—	—	02	—	02	01	04	01	06
3. Marginal adaptation	VG	31	31	31	31	31	31	31	31	27	27	28	23	24	19	23	16
	GO	—	—	—	—	—	—	—	—	04	02	03	06	06	08	07	09
	SS	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	UN	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
4. Postoperative sensitivity	VG	29	31	30	30	31	31	31	31	31	29	31	29	30	27	30	25
	GO	02	—	01	01	—	—	—	—	—	—	—	—	—	—	—	—
	SS	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	UN	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
5. Secondary caries	VG	31	31	31	31	31	31	31	31	29	31	27	28	28	26	29	22
	GO	—	—	—	—	—	—	—	—	02	—	01	01	02	01	02	03
	SS	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	UN	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—

Abbreviations: APA, Adper Prompt L-Pop, active application; APP, Adper Prompt L-Pop, passive application; XEA, Xeno III, active application; XEP, Xeno III, passive application.

[a] *VG, clinically very good; GO, clinically good; SS, clinically sufficient/satisfactory; UN, clinically unsatisfactory; and PO, clinically poor.*

restorations from XEA, nine from XEP, eight from ADA, and 13 from APP showed marginal staining (Table 5). The adhesive AP and the passive application mode showed significantly higher marginal staining than did XE and active application, respectively. The overall marginal staining in the active and passive groups was 19.4% (95% confidence interval [CI], 11.4-30.9%) and 35.5% (95% CI, 24.7-47.9%) (Figure 2). The marginal staining was statistically higher in the 12- and 24-month recall in comparison with the baseline and six-month findings.

Functional Properties

For marginal adaptation, only the main factor of recall period was statistically significant ($p<0.001$), meaning that lack of marginal adaptation was more often observed in the 12- and 24-month recalls compared to baseline and six-month findings. Although at the 24-month recall a total of 30 restorations showed a lack of marginal adaptation in the enamel margins, they were all considered clinically good (Table 5).

With regard to the retention rates, only the main factors of application mode ($p<0.0001$) and recall

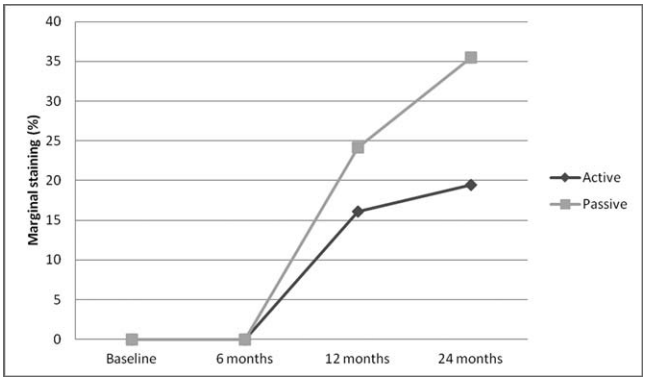

Figure 2. *Overall marginal staining for active and passive application groups.*

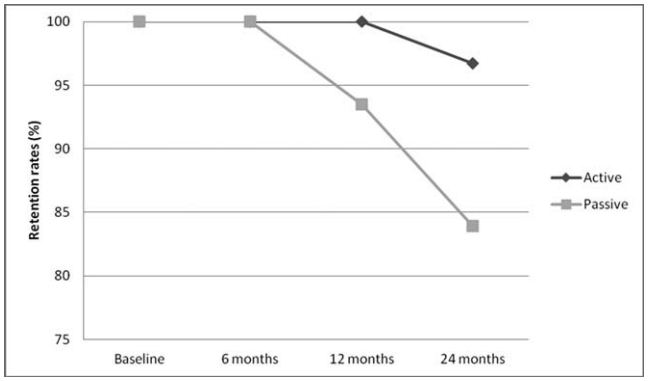

Figure 3. *Overall retention rates for active and passive application groups.*

period ($p<0.0001$) were statistically significant. The active application mode yielded higher retention rates at the 24-month recall compared to the passive application, regardless of the material. A total of two and 10 restorations from the active and passive application modes, respectively, were lost and considered clinically not acceptable (Table 5). The overall retention rates for the active and passive groups were 96.8% (95% CI, 89.0-99.1%) and 83.9% (95% CI, 72.8-91.0%), respectively. The individual retention rates of XE and AD in the active application mode were the same, 96.8% (95% CI, 83.8-99.4%). In the passive application, the rates were 87.1% (95% CI, 71.2-94.9%) and 80.7% (95% CI, 63.7-90.8%) for XE and AD, respectively (Table 5; Figure 3).

For the item fracture, the main factors of adhesive ($p<0.01$) and recall period ($p<0.001$) were statistically significant. More fractures were observed for the passive application group (eight for XEP and 10 for APP) than for the passive application (two for XEA and four for APA). The adhesive AP showed significantly more fractures than did XE, and this was shown to increase in the latter recall periods (12- and 24-month recall vs baseline and six-month recall). These 24 small fractures detected at the 24-month recall were all considered clinically good (Table 5).

Biological Properties

For the item secondary caries only the main factor of recall time ($p=0.003$) was statistically significant. After 24 months, a total of eight restorations showed signs of secondary caries, but they were all ranked as clinically good. With regard to postoperative sensitivity, no difference was detected among groups since no report of postoperative sensitivity was recorded throughout the study period.

Overall Analysis

The overall analysis of the study results (Table 6) demonstrated that only the lack of retention of the clinical restorations were considered clinically unacceptable, and this loss of Class V restorations could be significantly improved by the active adhesive application.

DISCUSSION

Although one-step self-etch adhesive systems are marketed as simplified materials, a more complex chemistry is required to blend hydrophilic and hydrophobic monomers, water, solvents, and additives.[5,31] Water is essential, because it provides the ionization medium for the self-etch activity. Other solvents, such as acetone and ethanol, are necessary to dissolve both hydrophilic and hydrophobic monomers into one single phase[32] and to assist water to evaporate upon completion of the self-etch process. Because of these features, one-step self-etch adhesives are reported[33,34] to behave as permeable membranes after polymerization, allowing the diffusion of water from the hybridized dentin to the adhesive surfaces.[35] Altogether these factors have been blamed for the lower retention rates of one-step

Table 6: *Restorations Acceptable or Not Acceptable According to the FDI Criteria at the 24-Month Recall (Hickel and others[28,29])*

	Esthetic				Functional								Biological							
	1. Staining Margin				2. Fractures and Retention				3. Marginal Adaptation				4. Postoperative (Hyper-)Sensitivity				5. Recurrence of Caries			
	XEA	XEP	APA	APP	XEA	XEP	APA	APP	XEA	XEP	APA	APP	XEA	XEP	APA	APP	XEA	XEP	APA	APP
Acceptable	31	31	31	31	30	27	30	25	31	31	31	31	31	31	31	31	31	31	31	31
Not acceptable	00	00	00	00	01	04	01	06	00	00	00	00	00	00	00	00	00	00	00	00
Reasons					Total loss of the restorations															

Abbreviations: APA, Adper Prompt L-Pop, active application; APP, Adper Prompt L-Pop, passive application; XEA, Xeno III, active application; XEP, Xeno III, passive application.

self-etch systems in clinical trials when compared to the two-step version.[9,36,37]

In the present investigation, the retention rates of both adhesives investigated were increased by active adhesive application, and this led us to reject the anticipated null hypothesis. Retention rates of 96.8% were observed for both adhesives under active application. Other studies[25,38-42] reported retention rates varying from 75% to 90% for AP after one to two years of clinical service and rates varying from 90% to 93% for XE (Dentsply). Compared with existing literature, the retention rates of XE and AP applied actively in the present study were the highest already reported after 24 months of clinical service, resembling those achieved with three-step etch-and-rinse systems.[9,43]

The active application may accelerate solvent evaporation and increase the diffusion rate of monomer inside the smear layer, carrying fresh acidic resin monomers to the basal part of the etched dentin. This may produce a more aggressive demineralization[44] and promote a better interaction with the smear layer and underlying dentin.[16,18] This method can also increase the moieties' kinetics and allow for better monomer diffusion inward, while solvents are diffusing outward. Laboratory tests investigating the active application of the etch-and-rinse adhesives[45,46] and the self-etch adhesives[12,14-16] have also reflected good results. This was also confirmed in *in vitro* longevity studies for the one-step self-etch[15,17] and in one recent clinical trial[19] that employed an acetone-based two-step etch-and-rinse adhesive system.

With regard to the marginal staining, this began to be observed in the present study after 12 months, mainly for the passive application groups. Marginal staining is primarily the result of infiltration of colored molecules into the interface and/or inside the adhesive layer. Simplified one-step self-etch adhesives are much more hydrophilic than their two-step counterparts.[47] The hydrophilic nature of methacrylate copolymers allows increased water sorption,[47-49] and this is a time-driven process, meaning that the more the contact of the adhesive with water, the higher the water sorption ratio.[47-49]

As a consequence of polymer swelling caused by water, the frictional forces between the polymer chains are reduced,[50] leading to solubility of residual monomers and oligomers, which makes the adhesive interface even more porous and prone to marginal staining over time. The prevalence of marginal staining was similar to that described in previous clinical studies[19,41,51-53] and in most of the cases would be easily solved by re-polishing the restoration margins.[40] The lower marginal staining rates in the active application groups may be attributed to the improved quality of the polymer. This could be achieved as a result of the higher water/solvent evaporation and also as a result of deeper etching of the enamel margins and, consequently, better resin infiltration.[54]

In terms of marginal adaptation, all groups were similar to one another, but lack of marginal adaptation was increasingly seen in the later recall periods. These findings can also justify the increase of the marginal staining, as it has already been demonstrated[39,55] that marginal adaptation is usually correlated with marginal staining.

The intervention and control groups were implemented in participants of both sexes who were older than 18 years of age. Therefore, the results of the present trial apply for an adult population having NCCL with similar features to the ones selected to be included in this clinical trial. Further long-term evaluations should be carried out in order to detect if the positive findings of the active application still remain after a longer clinical service period.

CONCLUSIONS

Within the limitations of the present study, we can conclude that the active application of one-step self-etch systems improved the retention rates of Class V restorations and minimized the marginal staining in the enamel margins. As long as one-step self-etch systems are employed actively, retention rates similar to those reported in the literature for three-step etch-and-rinse systems can be achieved.

Acknowledgements

This study was performed by Christiana Zander-Grande in partial fulfillment of her PhD degree at the State University of Ponta Grossa (UEPG), Ponta Grossa, PR, Brazil. This study was partially supported by the National Council for Scientific and Technological Development under grants 301937/2009-5; 301891/2010-9 and 301291/2010-1.

Conflict of Interest

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

(Accepted 18 October 2012)

REFERENCES

1. Bartlett DW, & Shah P (2006) A critical review of non-carious cervical (wear) lesions and the role of abfraction,

erosion, and abrasion *Journal of Dental Research* **85(4)** 306-312.

2. Wood I, Jawad Z, Paisley C, & Brunton P (2008) Non-carious cervical tooth surface loss: A literature review *Journal of Dentistry* **36(10)** 759-766.
3. Van Dijken J (2001) Durability of new restorative materials in Class III cavities *Journal of Adhesive Dentistry* **3(1)** 65-70.
4. 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 non-carious cervical lesions *Journal of Adhesive Dentistry* **5(4)** 323-332.
5. Tay FR, & Pashley DH (2003) Have dentin adhesives become too hydrophilic *Journal of the Canadian Dental Association* **69(11)** 726-731.
6. Perdigão J (2007) New developments in dental adhesion *Dental Clinics of North America* **51(2)** 333-357.
7. Frankenberger R, & Tay FR (2005) Self-etch vs etch-and-rinse adhesives: Effect of thermo-mechanical fatigue loading on marginal quality of bonded resin composite restorations *Dental Materials* **21(5)** 397-412.
8. Can Say E, Nakajima M, Senawongse P, Soyman M, Özer F, Ogata M, & Tagami J (2006) Microtensile bond strength of a filled vs unfilled adhesive to dentin using self-etch and total-etch technique *Journal of Dentistry* **34(4)** 283-291.
9. Heintze SD, Ruffieux C, & Rousson V (2010) Clinical performance of cervical restorations—A meta-analysis *Dental Materials* **26(10)** 993-1000.
10. Moura SK, Pelizzaro A, Dal Bianco K, De Goes MF, Loguercio AD, Reis A, & Grande RHM (2006) Does the acidity of self-etch primers affect bond strength and surface morphology of enamel *Journal of Adhesive Dentistry* **8(2)** 75-83.
11. Ando S, Watanabe T, Tsubota K, Yaoshida T, Irokawa A, Takamizawa T, Kurokawa H, & Miyazaki M (2008) Effect of adhesive application methods on bond strength to bovine enamel *Journal of Oral Science* **50(2)** 181-186.
12. Velasquez LM, Sergent RS, Burgess JO, & Mercante DE (2006) Effect of placement agitation and placement time on the shear bond strength of 3 self-etching adhesives *Operative Dentistry* **31(4)** 426-430.
13. Torres CR, Barcellos DC, Pucci CR, Lima G de M, Rodrigues CM, & Siviero M (2009) Influence of methods of application of self-etching adhesive systems on adhesive bond strength to enamel *Journal of Adhesive Dentistry* **11(4)** 279-286.
14. Chan K, Tay FR, King NM, Imazato S, & Pashley DH (2003) Bonding of mild self-etching primers/adhesives to dentin with thick smear layers *American Journal of Dentistry* **16(5)** 340-346.
15. Amaral RC, Stanislawczuk R, Zander-Grande C, Michel MD, Reis A, & Loguercio AD (2009) Active application improves the bonding performance of self-etch adhesives to dentin *Journal of Dentistry* **37(1)** 82-90.
16. Amaral RC, Stanislawczuk RG, Zander-Grande C, Gagler D, Reis A, & Loguercio AD (2010) Bond strength and quality of the hybrid layer of one-step self-etch adhesives applied with agitation on dentin *Operative Dentistry* **35(2)** 211-219.
17. Loguercio AD, Stanislawczuk R, Mena-Serrano A, & Reis A (2011) Effect of 3-year water storage on the performance of one-step self-etch adhesives applied actively on dentine *Journal of Dentistry* **39(8)** 578-587.
18. Miyazaki M, Platt JA, Onose H, & Moore BK (1996) Influence of dentin primer application methods on dentin bond strength *Operative Dentistry* **21(4)** 167-172.
19. Loguercio AD, Raffo J, Bassani F, Balestrini H, Santo D, Amaral RC, & Reis A (2011) 24-Month clinical evaluation in non-carious cervical lesions of a two-step etch-and-rinse adhesive applied using rubbing motion *Clinical Oral Investigation* **15(4)** 589-596.
20. 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.
21. Heintze SD, & Rousson V (2011) Pooling of dentin microtensile bond strength data improves clinical correlation *Journal of Adhesive Dentistry* **13(2)** 107-110.
22. Schulz KF, Altman DG, Moher D, & CONSORT Group (2011) CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials *International Journal of Surgery* **9(8)** 672-677.
23. 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 filed and unfilled dentin adhesive *Journal of Dentistry* **29(1)** 1-6.
24. American Dental Association Council on Scientific Affairs (2011) *Acceptance Program Guidelines: Dentin and Enamel Adhesive Materials* American Dental Association, Chicago, Ill.
25. Brackett WW, Covey DA, & St Germain HA Jr (2002) One year clinical performance of a self-etching adhesive in Class V resin composites cured by two methods *Operative Dentistry* **27(3)** 218-222.
26. Pocock SJ (1983) The size of a clinical trial In: Pocock SJ (ed) *Clinical Trials: A Practical Approach* John Wiley & Sons, Chichester, UK 123-141.
27. Cvar JF, Ryge G, & Schmalz G (2005) Reprint of criteria for the clinical evaluation of dental restorative materials *Clinical Oral Investigations* **9(4)** 7-24.
28. Hickel R, Roulet JF, Bayne S, Heintze SD, Mjör IA, Peters M, Rousson V, Randall R, Schmalz G, Tyas M, & Vanherle G (2007) Recommendations for conducting controlled studies of dental restoratives materials. Science committee project 2/98—FDI World Dental Federation study design (Part I) and criteria for evaluation (Part II) of direct and indirect restoration including onlays and partial crowns *Journal of Adhesive Dentistry* **9(1)** 121-147.
29. Hickel R, Peschke A, Tyas M, Mjör 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.

30. McCullagh J, & Nelder PA (1989) *Generalized Linear Models* Chapman and Hall, London.

31. Van Meerbeek B, De Munck J, Yoshida Y, Inoue S, Vargas M, Vijay P, Van Landuyt K, Lambrechts P, & Vanherle G (2003) Buonocore Memorial Lecture. Adhesion to enamel and dentin: Current status and future challenges *Operative Dentistry* **28(3)** 215-235.

32. Furukawa M, Shigetani Y, Finger WJ, Hoffmann M, Kanehira M, Endo T, & Komatsu M (2008) All-in-one self etch model adhesives: HEMA-free and without phase separation *Journal of Dentistry* **36(6)** 402-408.

33. Tay FR, Pashley DH, Suh B, Carvalho R, & Miller M (2004) Single-step, self-etch adhesives behave as permeable membranes after polymerization. Part I. Bond strength and morphologic evidence *American Journal of Dentistry* **17(4)** 271-278.

34. Tay FR, Pashley DH, Garcia-Godoy F, & Yiu CK (2004) Single-step, self-etch adhesives behave as permeable membranes after polymerization. Part II. Silver tracer penetration evidence *American Journal of Dentistry* **17(5)** 315-322.

35. Tay FR, Pashley DH, & Yoshiyama M (2002) Two modes of nanoleakage expression in single-step adhesives *Journal of Dental Research* **81(7)** 472-476.

36. Reis A, Leite TM, Matté K, Michels R, Amaral RC, Geraldeli S, & Loguercio AD (2009) Improving clinical retention of one-step self-etching adhesive systems with an additional hydrophobic adhesive layer *Journal of the American Dental Association* **140(7)** 877-885.

37. Loguercio AD, Mânica D, Ferneda F, Zander-Grande C, Amaral R, Stanislawczuk R, Carvalho RM, Manso AP, & Reis A (2010) A randomized clinical evaluation of a one- and two-step self-etch adhesive over 24 months *Operative Dentistry* **35(3)** 265-272.

38. Van Dijken JW (2004) Durability of three simplified adhesive systems in Class V non-carious cervical dentin lesions *American Journal of Dentistry* **17(1)** 27-32.

39. 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.

40. Van Dijken JW, Sunnegardh-Grönberg K, & Sörensson E (2007) Clinical bonding of a single-step self-etching adhesive in non-carious cervical lesions *Journal of Adhesive Dentistry* **9(Supplement 2)** 241-243.

41. Loguercio AD, Bittencourt DD, Baratieri LN, & Reis A (2007) A 36-month evaluation of self-etch and etch-and-rinse adhesives in non-carious cervical lesions *Journal of the American Dental Association* **138(4)** 507-514.

42. Schattenberg A, Werling U, Willershausen B, & Ernst CP (2008) Two-year clinical performance of two one-step self-etching adhesives in the restoration of cervical lesions *Clinical Oral Investigations* **12(3)** 225-232.

43. Peumans M, Kanumilli P, De Munck J, Van Landuyt K, Lambrechts P, & Van Meerbeek B (2005) Clinical effectiveness of contemporary adhesives: A systematic review of current clinical trials *Dental Materials* **21(9)** 864-881.

44. Azevedo Manhães L, Cerqueira Oliveira D, Martins Marques M, & Bona Matos A (2005) Influence of er: YAG laser surface treatment and primer application methods on microtensile bond strength self-etching systems *Photomedicine and Laser Surgery* **23(3)** 304-312.

45. Jacobsen T, & Söderholm KJ (1998) Effect of primer solvent, primer agitation, and dentin dryness on shear bond strength to dentin *American Journal of Dentistry* **11(5)** 225-258.

46. Dal-Bianco K, Pellizzaro A, Patzlaft R, de Oliveira Bauer JR, Loguercio AD, & Reis A (2006) Effects of moisture degree and rubbing action on the immediate resin-dentin bond strength *Dental Materials* **22(12)** 1150-1156.

47. Ito S, Hoshino T, Iijima M, Tsukamoto N, Pashley DH, & Saito T (2010) Water sorption/solubility of self-etching dentin bonding agents *Dental Materials* **26(7)** 617-626.

48. Yiu CK, King NM, Carrilho MR, Sauro S, Rueggeberg FA, Prati C, Carvalho RM, Pashley DH, & Tay FR (2006) Effect of resin hydrophilicity and temperature on water sorption of dental adhesive resins *Biomaterials* **27(9)** 1695-1703.

49. Malacarne J, Carvalho RM, de Goes MF, Svizero N, Pashley DH, Tay FR, Yiu CK, & Carrilho MRO (2006) Water sorption/solubility of dental adhesive resins *Dental Materials* **22(10)** 973-980.

50. Kalachandra S, & Turner DT (1987) Water sorption of polymethacrylate networks: bis-GMA/TEGDMA copolymers *Journal of Biomedical Materials Research* **21(3)** 329-338.

51. 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.

52. Gallo JR, Burgess JO, Ripps AH, Walker RS, Ireland EJ, Mercante DE, & Davidson JM (2005) Three-year clinical evaluation of a compomer and a resin composite as Class V filling materials *Operative Dentistry* **30(3)** 275-281.

53. Burrow MF, & Tyas MJ (2007) Clinical evaluation of three adhesive systems for the restoration of non-carious cervical lesions *Operative Dentistry* **32(1)** 11-15.

54. Cehreli SB, & Eminkahyagil N (2006) Effect of active pretreatment of self-etching primers on the ultramorphology of intact primary and permanent tooth enamel *Journal of Dentistry for Children* **73(2)** 86-90.

55. Peumans M, De Munck J, Van Landuyt K, Lambrechts P, & Van Meerbeek B (2007) Five-year clinical effectiveness of a two-step self-etching adhesive *Journal of Adhesive Dentistry* **9(1)** 7-10.