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Five-year Randomized Clinical Trial on the Performance of Two Etch-and-rinse Adhesives in Noncarious Cervical Lesions

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Clinical Relevance

The two adhesive systems tested, a polyalkenoic acid-containing adhesive or an MDP-containing adhesive, had comparable clinical performance, at 60 months, when used to restore noncarious cervical lesions.

SUMMARY

Objectives: To evaluate the 5-year clinical performance of two-step etch-and-rinse adhesives in noncarious cervical lesions (NCCL).

Methods and Materials: The sample comprised 35 adults with at least two similar-sized NCCL. Seventy restorations were placed, according to one of the following groups: Adper Single Bond 2 (SB) and Ambar (AM). The restorations were placed incrementally using a resin composite (Opallis). The restorations were evaluated at baseline and after 6 and 18 months and 5 years using some items of the FDI criteria. The differences in the ratings of the two materials after 6 months, 18 months, and 5 years were performed with Friedman repeated measures ANOVA by rank and McNemar test for significance in each pair (α=0.05).

Results: Five patients did not attend the 60-month recall. No significant differences were observed between the materials for any criteria evaluated.

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Twenty-one restorations failed (12 for SB and 9 for AM) after 60 months. Thus, the retention rate for SB at 60 months were 55.6% for SB and 71% for AM (p=0.32). After 60 months, 12 restorations (6 for SB and 6 AM) showed some loss of marginal adaptation (p=1.0). Slight marginal discoloration was observed in 10 restorations (6 for SB and 4 AM; p=0.91). Five restorations (2 for SB and 3 for AM) showed recurrences of caries (p=1.0).

Conclusions: Both two-step etch-and-rinse adhesives—Adper Single Bond 2, a polyalkenoic acid-containing adhesive, and Ambar, a 10-methacryloyloxydecyl dihydrogen phosphate (MDP)-containing adhesive—showed acceptable clinical performance after 60 months.

INTRODUCTION

A noncarious cervical lesion (NCCL)—a frequent and challenging condition to treat—is described as the loss of hard tooth tissue at the cementoenamel junction.[1] Data from the literature regarding prevalence of NCCLs show a high prevalence of NCCLs, ranging from 35.4%[2] up to 77.3%.[3] Besides compromising esthetics and function, up to 92.1% of NCCLs result in dentin hypersensitivity, as reported in the systematic review of prevalence studies.[4] A restorative procedure is the main way to reestablish the lost dental substrate and minimize dental sensitivity.[5]

Unfortunately, NCCLs are difficult to restore, because the margins of these lesions are located in the cementum or dentin, jeopardizing moisture control and access to the gingival margins.[6] Furthermore, they present a high index of sclerotic dentin,[7,8] which reduces bonding efficacy when compared to sound dentin.[7] Due to these adverse conditions, NCCLs are the best model to test the clinical effectiveness of adhesives.[9] Additionally, due to the presence of NCCLs in several teeth of the same patient, it is easy to compare adhesive systems in a split-mouth study design.[9,10]

Although several adhesive strategies have been developed, one of the most used currently is the application of phosphoric acid associated with an adhesive system. This technique was launched in the mid-1980s,[11] and it was originally called "total-etch," because the enamel and dentin are etched simultaneously with phosphoric acid.[12,13] However, the term "etch-and-rinse" has been used, because it better represents the technical procedure.[14] The etch-and-rinse strategy is divided according to the number of bottles in a two-step or three-step system.[11] After etch-and-rinse, hydrophilic and solvent-based adhesives are applied, and are responsible for infiltration into the demineralizing dentin. Afterward, the polymerization is performed, and the adhesive becomes micromechanically bonded into dentin to form the hybrid layer.[15] However, in the etch-and-rinse adhesives, the micromechanical interlocking is a prerequisite for achieving a strong mechanical bond.[10]

Actually, the addition of functional monomers with the potential capacity for chemical adhesion to the tooth structure could be beneficial in terms of durability, because it ensures an intimate adaptation of the substrate and biomaterial components, thereby preventing nanoleakage.[16] Two monomers with this chemical potential are polyalkenoic acid copolymer (PAC) and 10-methacryloxydecyl dihydrogen phosphate (MDP).[11] The former was first used in the composition of Vitrebond (3M Oral Care) and more recently has been used in several adhesive formulations from the same manufacturer.[17,18] Due to PAC's ability to chemically bond to the calcium in hydroxyapatite, a good clinical performance has been observed when PAC-containing etch-and-rinse adhesives are used.[19-21] On the other hand, it is well documented that, due to the formation of highly hydrolytically stable MDP-Ca salts,[22] the presence of MDP promotes a stable chemical bond with dental substrates.[22] Despite only recent use, the clinical performance of MDP-containing etch-and-rinse adhesives has been evaluated and has shown good results.[23-25]

However, to the extent of the author's knowledge, only a short-term (18-month) randomized clinical trial was found that compared an adhesive containing-PAC versus an adhesive containing-MDP, with similar results between both the materials.[26] Thus, the objective of this randomized clinical trial was to compare the 5-year failure rate of an adhesive-containing PAC versus an adhesive-containing MDP, with both applied in the etch-and-rinse mode, in a paired-tooth study design. The null hypothesis was that the failure rate of the composite restorations were placed with both the adhesive systems will be same after 60 months of clinical service.

METHODS AND MATERIALS

Study Design

This was a randomized, double-blind clinical trial, and it was described following the Consolidated Standards of Reporting Trials (CONSORT) statement.[27] The restorations were placed in the clinic of the School of Dentistry at the local university from July 2010 to July 2011. 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.

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Participant Recruitment

Written informed consent was obtained from all participants prior to starting the treatment. A total of 51 participants were examined by two calibrated dentists to check if the subjects met the inclusion and exclusion criteria. The evaluations were performed using a mouth mirror, an explorer, and a periodontal probe.

The inclusion criteria were the following: participants between 20 and 70 years old had to be in good general health, have an acceptable oral hygiene level, and present at least 20 teeth under occlusion. Participants were required to have at least two NCCLs to be restored in two 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 cavosurface margin could not involve more that 50% of enamel.[20,21] All the patients were given oral hygiene instructions before the operative treatment was performed. Patients with extremely poor oral hygiene, severe or chronic periodontitis, or more than two wear facets on the occlusal surface of posterior teeth were excluded from the study.

Sample Size Calculation

The sample size calculation was based on the failure rate of the predecessor of the Adper Single Bond 2 (SB) (Adper Single Bond; 3M Oral Care, St. Paul, MN, USA; also known as Single Bond, Scotchbond 1 and Adper Scotchbond 1 in some countries) reported in earlier studies.[19-21] Using an α of 0.05, a power of 90%, and a equivalence limit of 20%, a minimum of 35 participants with two similar-sized NCCL were required. Taking that into consideration, 51 participants were evaluated, 15 subjects were excluded.

Randomization and Allocation Concealment

The randomization process was performed (using software available at http://www.sealedenvelope.com) by a staff member not involved in the research protocol. The allocated group's details were recorded on cards in sequentially numbered, opaque, and sealed envelopes. These were prepared by a staff member not involved in any of the clinical trial phases. The allocation assignments were revealed by opening the envelope immediately before the restorative procedure to guarantee the concealment of the random sequence and prevent selection bias. The allocation assignment was revealed by opening the envelope on the day of the restorative procedure, which ensured the concealment of the random sequence. In all cases, the tooth with the highest FDI tooth number received the treatment described first, while the tooth with the next number in sequence received the treatment mentioned second. The participants and the examiners were blinded to the group assignments.

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 (Table 1).[28] 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, the distribution of enamel in the cervical margin was 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 4 years of clinical experience in operative dentistry, placed four restorations, two in each

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,[39] with permission from Elsevier.*

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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 two restorations, one of each experimental group, in different lesions previously selected according to the inclusion criteria.

Before the 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 Vita Classical (VITA Zahnfabrik, Bad Säckingen, Germany). Following the guidelines of the American Dental Association (ADA),[29] no additional retention or bevel was prepared.

A rubber dam was placed, and then the NCCLs received the Adper Single Bond 2 (3M Oral Care; also known as Single Bond 2, Adper Single Bond Plus and Adper Scotchbond 1XT in some countries) or Ambar (FGM, Joinville, SC, Brazil) adhesive system, which defined the two different groups. The compositions and application modes are described in Table 2.

Both adhesives were applied according to the manufacturer's instructions (Table 2). Briefly, the cavity was etched with 37% phosphoric acid (CondAc 37, FGM) for 15 seconds, then rinsed with water for 15 seconds, and gently dried with an oil-free air stream, leaving the dentin surface slightly moist. The adhesive was scrubbed for 10 seconds on the cavity surfaces, and the solvent was evaporated with an air stream for 20 seconds. Another coat of adhesive was applied for 10 seconds, the solvent was evaporated for 20 seconds, and the adhesive layer was light cured (Radii-Cal, SDI, Victoria, Australia) for 10 seconds at 1200 mW/cm^2.

Two or four increments of resin composite (Opallis, FGM) with less than 2 mm were placed, and each one was light cured for 40 seconds. Finally, the restorations were finished and polished using fine-grit diamond burs (#3195F and #3195FF, KG Sorensen, Barueri, São Paulo, Brazil.) and flexible abrasive disks (Diamond Pro, FGM).

Clinical Evaluation

Two experienced and calibrated dentists, not involved with the restoration procedures and therefore blinded to the group assignment, performed the evaluations. For training purposes, the examiners observed 10 photographs that were representative of each score for each criterion. They evaluated from 10 to 15 patients each on two consecutive days. These subjects had cervical restorations but were not part of this project. An

Table 2: *Materials, Compositions, and Application Mode*

Materials (Batch Number)	Compositions	Application Mode[a]
Adper Single Bond 2	Acid: phosphoric acid 37% Adhesive: bisphenol glycidyl dimethacrylate, hydroxyethyl methacrylate, dimethacrylates, polyalkenoic acid copolymer (PAC), initiators, water, ethanol	Acid etch for 15 seconds; Rinse with water for 15 seconds; Dry the tooth surfaces for 5 seconds, but avoid excessive drying of the dentin; Apply one coat of adhesive system under vigorous agitation for 10 seconds; Evaporate the solvent for 20 seconds; Apply a second coat of adhesive system under vigorous agitation for 10 seconds; Evaporate the solvent for 20 seconds; Light cure for 10 seconds;
Ambar	Acid: 37% silica-thickened phosphoric acid gel Adhesive: 10-methaclyloxydecyl dihydrogen phosphate, urethane dimethacrylate (UDMA), 2-hydroxyethyl methacrylate, and other hydrophilic and acid methacrylate monomers, ethanol, silanated silica, photo-initiators, co-initiators, and stabilizers	1-8 (Same as for Adper Single Bond 2)

[a]*According to the manufacturer's instructions.*

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intraexaminer and interexaminer agreement of at least 85% was necessary before beginning the evaluation.[21,22] 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[30] criteria (Table 3) at baseline and after 6, 12, 18 and 60 months of clinical service. Only the clinically relevant measures for evaluation of the performance of adhesives were used and scored (Table 3). The primary clinical outcome was restoration retention/fractures, but the following secondary outcomes were also evaluated: marginal staining, marginal adaptation, postoperative sensitivity, and recurrence of caries. The evaluation of the spontaneous postoperative sensitivity was performed 1 week after the restorative procedure. These variables were ranked according to the FDI criteria in the following scores: VG = clinically very good; GO = clinically good; SS = clinically sufficient/satisfactory; UN = clinically unsatisfactory; PO = clinically poor.

Both the 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[29]: Cumulative failure percentage = [(PF + NF)/(PF + RR)] × 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.[27] Descriptive statistics were used to describe the distributions of the evaluated criteria. For all outcomes (retention/fracture, marginal staining, marginal adaptation, postoperative sensitivity, and recurrence of caries), the differences between the two groups' ratings after 60 months were tested by Friedman's repeated measures analysis of variance rank (α=0.05). Cohen's kappa statistics were used to test the interexaminer agreement (α=0.05) (Statistica for Windows 7.0, StatSoft Inc., Tulsa, OK, USA).

RESULTS

Thirty-five subjects (18 male and 17 female), with a mean age of 45 years, were enrolled in this study. Seventy restorations were placed (35 for each group). All baseline details relative to the research subjects and characteristics of the restored lesions are displayed in Table 4.

The overall Cohen's Kappa statistics (0.87) showed good agreement between the examiners. All research subjects were evaluated at baseline and the 6-, 12-, and 18-month recalls. Five patients did not attend the 60-month recall, because they moved to other cities (Figure 1).

Retention/fracture

After 60 months, 21 restorations were lost (12 for Adper Single Bond 2 and 9 for Ambar; Table 5). According to ADA guidelines,[29] the 60-month retention rates were 55.6% for Adper Single Bond 2 and 71% for Ambar. The risk ratio for both the groups was 0.58 (95% CI, 0.29-1.18). The 95% CI interval of the risk ratio crosses the null value of 1, meaning the groups were not different from each other (p=0.32). In addition, after the 60-month recall, 6 restorations for each group showed some small fractures (Table 5). No significant difference was detected between groups at the 60-month recall (p=1.0; Table 5).

Marginal Adaptation

According to the FDI criteria, after 60 months, 12 restorations (3 classified as "B" and 3 classified as "C" for SB, and 3 classified as "B" and 3 classified as "C" for AM) showed some marginal discrepancy (Table 5). No significant difference was detected between both the groups at the 60-month recall (p=1.0; Table 5).

Marginal Staining

The evaluated restorations showed a slight increase in the marginal staining after 60-months of clinical evaluation (3 classified as "B" and 3 classified as "C" for SB, and 3 classified as "B" and 1 classified as "C" for AM). No significant difference was found between the groups at the 60-month recall time (p=0.91; Table 5).

Recurrence of Caries

After 60 months, five restorations (2 for Adper Single Bond 2 and 3 for Ambar) showed a very small and localized demineralization around restorations that suggested recurrence of caries. However, no operative treatment was required. No difference was observed for this parameter when both adhesives were compared (p=1.0; Table 5).

Postoperative Sensitivity

Six restorations showed postoperative sensitivity in the baseline (3 for Adper Single Bond 2 and 3 for Ambar), but this occurrence was not reported in the

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Table 3: *World Dental Federation (FDI) Criteria Used for Clinical Evaluation*[37,38]

	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 (dentine not exposed)
4. Clinically unsatisfactory (D) (repair for prophylactic reasons)	1.4 Pronounced marginal staining; major intervention necessary for improvement	2.4 Chipping fractures which 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 (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 non vital. 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	Aesthetic criteria	Functional criteria		Biological criteria	

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Table 4: *Characteristics of the Research Subjects and the Noncarious Cervical Lesions (NCCLs) Per Group*

Characteristics of Research Subjects	**Number of Lesions**	
Gender distribution		
Male	18	
Female	17	
Characteristics of NCCLs	**Number of Lesions**	
	SB	**AM**
Shape (degree of angle)		
<45	2	1
45-90	3	3
90-135	18	17
>135	12	14
Cervico-incisal height (mm)		
<1.5	3	3
1.5-2.5	14	17
>2.5	18	15
Degree of sclerotic dentin		
1	28	24
2	1	5
3	5	2
4	1	4
Attrition facet		
Yes	9	10
No	26	25
Enamel in cervical margin		
<25%	4	5
25%-50%	31	30
Preoperative sensitivity (spontaneous)		
Yes	16	18
No	19	
Tooth distribution		
Incisor	2	2
Canines	5	9
Premolar	25	21
Molar	3	3
Arch distribution		
Maxillary	20	24
Mandibular	15	11

Abbreviations: SB, Adper Single Bond 2 (3M Oral Care, St. Paul, MN, USA); AM, Ambar (FGM, Joinville, SC, Brazil).

following recall times. No difference was observed for this parameter when both the adhesive were compared (p=1.0; Table 5).

DISCUSSION

The simplification of technique in contemporary dental adhesives has occurred at the expense of an increasing incorporation of hydrophilic monomers.[10] According to a systematic review of clinical trials published by Peumans and others,[31] two-step etch-and-rinse adhesives perform clinically less favorably than other adhesive strategies in NCCL restorations. Two-step etch-and-rinse adhesives showed an average annual failure rate of 6.2%, which means that after 5 years of clinical evaluation, an average failure rate of 31.0% will be expected. Therefore, some manufacturers added functional monomers, such as PAC (Adper Single Bond 2) and MDP (Ambar), in an attempt to significantly improve the bonding results for simplified etch-and-rinse adhesives.

PAC is a component of several adhesive systems by 3M Oral Care available in the market, among them is Adper Single Bond (also known as Single Bond, Scotchbond 1 and Adper Scotchbond 1 in some countries)—an antecessor of Adper Single Bond 2. Initially, the rationale for the use of the PAC was to provide better moisture stability.[42] However, due to the high molecular weight of PAC, some authors indicated that PAC prevents a complete infiltration of the collagen mesh, resulting in a nonuniform adhesive–dentin interface formation.[33,34] More recently, it was observed that the carboxyl groups present in polyalkenoic acids replace the phosphate ions in hydroxyapatite, establishing ionic bonding with calcium.[18] This chemical bonding mechanism followed the same adhesion–decalcification reaction described by self-etch adhesives.[11]

Only a few years ago, Sezinando and others[18] evaluated the interaction between PAC and hydroxyapatite using high-technological spectroscopy methods. The authors showed that Adper Single Bond-containing PAC chemicals interact with hydroxyapatite, in comparison to an experimental Adper Single Bond PAC-free adhesive. It is worth mentioning, this chemical interaction depends on the abundance of PAC polar carboxyl groups, which may provide a high affinity for binding.[18] According to the manufacturer, Adper Single Bond contains from 5 wt% to 10 wt% of PAC.[17,18] This fact should be responsible for the higher immediate and long-term bond strength values of the Adper Single Bond-containing PAC when compared to the experimental Adper Single Bond PAC-free adhesive.[17,18]

Among the two-step etch-and-rinse adhesives, a systematic review of *in vitro* bond strength studies

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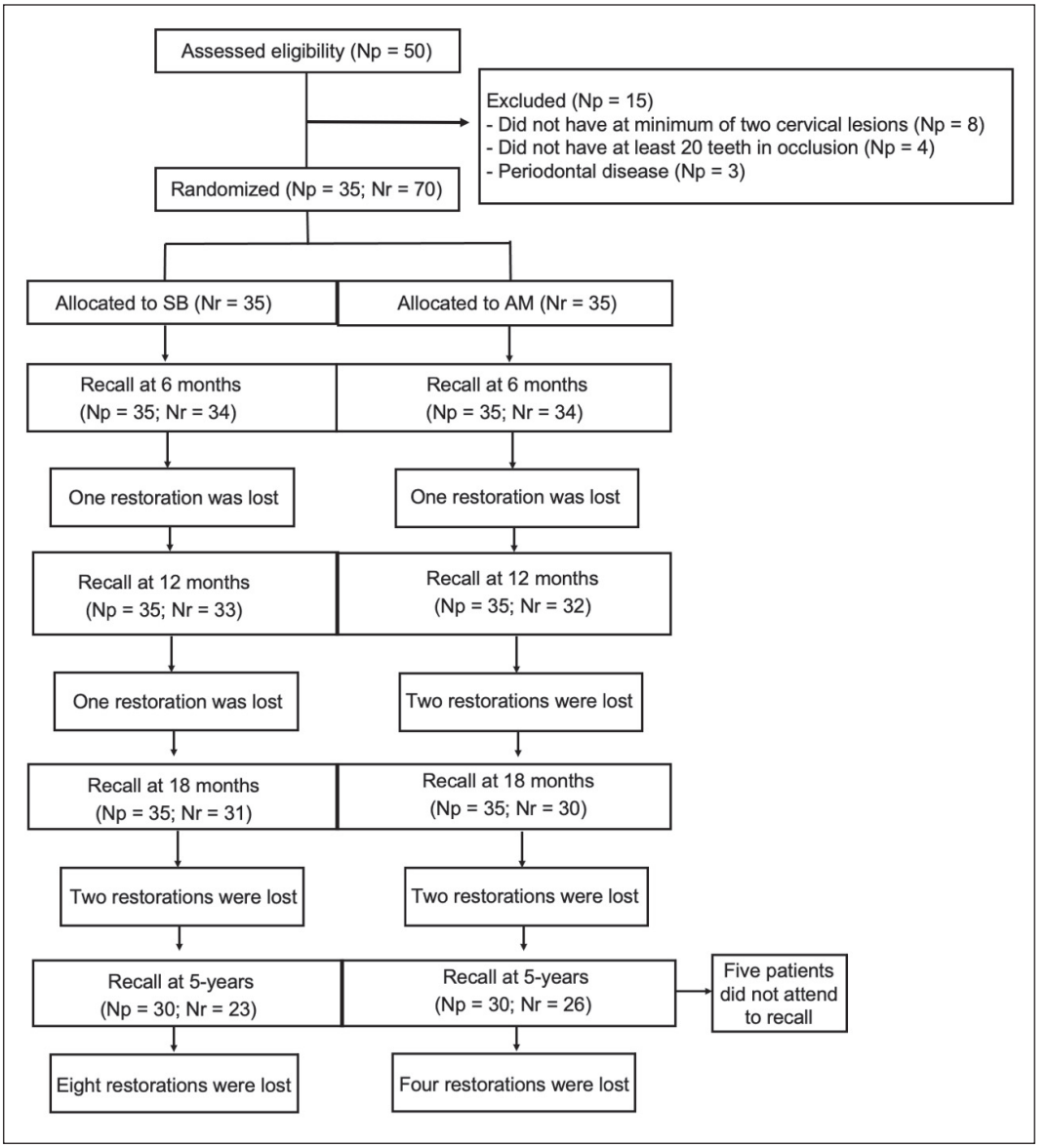

Figure 1. *Flow diagram of the study phases.*

published by De Munck and others[35] showed that Adper Single Bond (described as Scotchbond 1) had a better bond strength performance. It is worth mentioning that Adper Single Bond 2 contains nanofillers and Adper Single Bond does not. Unfortunately, the addition of nanofiller in Adper Single Bond 2 did not show improvement in terms of bonding ability.[36] However, all of these features could be responsible for the good retention rate and lower marginal discoloration of Adper Single Bond 2 in the present study, as well as the observations in the medium- and long-term clinical trial in NCCLs for their predecessor Adper Single Bond.[19-21]

Regarding the two-step etch-and-rinse adhesive, Ambar is a nanofiller- and MDP-containing adhesive. Functional monomers have already been ranked based on their chemical bonding potentials, and 10-MDP (10-methacryloyloxydecyl dihydrogen phosphate) has been identified as capable of establishing a very intensive and stable chemical interaction with hydroxyapatite. The MDP–Ca water-insoluble salts contribute to the protection of the collagen fibers. The atomic relation of the 10-MDP molecule favors the chemical interaction.[22]

Considering the chemical bonding between MDP and hydroxyapatite, dissolving the smear layer and the hydroxyapatite on the dentin surface through phosphoric acid etching, as indicated by the manufacturer of Ambar, may reduce chemical interactions mainly in the dentin surface.[37] Although

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Table 5: *Number of Evaluated Restorations for Each Group Classified According to the World Dental Federation Criteria[30] in Different Follow-up Times*

Time	Baseline			6 Months		12 Months		18 Months		60 Months	
Criteria	**SB[a]**		**AM**	**SB**	**AM**	**SB**	**AM**	**SB**	**AM**	**SB**	**AM**
Fractures/Retention	VG	35	35	27	29	31	30	26	25	20	23
	GO	—	—	5	5	2	2	2	1	1	1
	SS	—	—	2	—	—		3	4	2	2
	UN	—	—	—	—	—	—		—	—	—
	PO	—	—	1	1	1	2	2	2	8	4
Marginal adaptation	VG	35	35	34	34	29	28	24	22	17	20
	GO	—	—	—	—	4	4	3	3	3	3
	SS	—	—	—	—	—	—	4	5	3	3
	UN	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	—	—	—	—	—	—	—
Marginal staining	VG	35	35	34	34	33	32	26	26	17	22
	GO	—	—	—	—	—	—	4	3	3	3
	SS	—	—	—	—	—	—	1	1	3	1
	UN	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	—	—	—	—	—	—	—
Recurrence of caries	VG	35	35	34	34	33	32	31	30	21	23
	GO	—	—	—	—	—	—	—	—	2	3
	SS	—	—	—	—	—	—	—	—	—	—
	UN	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	—	—	—	—	—	—	—
Postoperative sensitivity	VG	32	32	34	34	33	32	31	30	23	26
	GO	3	3	—	—	—	—	—	—	—	—
	SS	—	—	—	—	—	—	—	—	—	—
	UN	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	—	—	—	—	—	—	—

Abbreviations: SB, Adper Single Bond 2 (3M Oral Care, St. Paul, MN, USA); AM, Ambar (FGM, Joinville, SC, Brazil).

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

this is the most plausible possibility, several *in vitro* studies found the resin–dentin bond strength values of MDP-containing adhesives did not diminish during water storage, even when the dentin was etched with phosphoric acid before adhesive application.[38,39] Unfortunately, there are important open questions concerning the dentin bond durability of MDP-containing adhesives when applied in the etch-and-rinse system.

Actually, a recent study published by Hidari and others[40] evaluated the effect of phosphoric acid on dentin before the application of an MDP-containing adhesive (Clearfil Universal Bond, Kuraray, Noritake Dental, Tokyo, Japan) in comparison to an MDP-free adhesive (experimental Clearfil Universal Bond). The results showed higher immediate and long-term degradation after artificial aging when a MDP-containing adhesive was used, even after phosphoric acid application. Actually, Hiraishi and others[41] speculated that a certain interaction might occur between exposed collagen fibrils and MDP. On the other hand, it is more plausible that the association of the methacrylate group with the long carbon spacer group effectively provides hydrophobicity,[42] and it might contribute to bond durability *in vivo*.[43] All of these descriptions justify the acceptable retention rate

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and lower marginal discoloration for Ambar adhesive observed in the present study.

In the specific case of two-step etch-and-rinse Ambar, several *in vitro* studies showed an optimal laboratory performance, such as a higher degree of conversion inside the hybrid layer and immediate bond strength values, as well as, reduced water sorption and solubility and nanoleakage, similar to the Adper Single Bond 2.[44-48]

Actually, it is worth mentioning that an MDP-containing Ambar adhesive showed a higher retention rate (71%) in comparison to a PAC-containing Adper Single Bond 2 adhesive (55.6%). However, a closer view regarding 5-year clinical studies in NCCL when two-step etch-and-rinse adhesives were evaluated, showed that, the retention rate varied from 51.5% to 77%.[19,49-53] For instance, Van Dijken and others[50] evaluated the performance of a single two-step etch-and-rinse material, and, after 5 years, the retention rate of 62.3% was observed. In a recent paper published by Torres and others,[52] after 5 years of clinical service, a retention rate of 77% was observed when a single two-step etch-and-rinse adhesive was evaluated. Therefore, an overall analysis of clinical trials that evaluated two-step etch-and-rinse in comparison with the results of the present study does not allow us to conclude the superiority of one over the other. This clearly indicates that no significant improvement in the clinical performance of two-step etch-and-rinse adhesives were observed when PAC (Adper Single Bond 2) or MDP (Ambar adhesive) were added.

Although the two tested adhesives have several differences in their chemistry, they share important features. The Adper Single Bond 2 and Ambar adhesive system both contain ethanol as the solvent. Usually, acetone-based systems have been reported to be more sensitive to the dentin moisture than ethanol and ethanol/water adhesives.[54] If dentin is not kept sufficiently moist, the acetone-based systems cannot infiltrate within the collagen fibrils leading to reduced bond strengths.[54] This is the main reason that the majority of adhesive systems available in the market, at the present moment, are ethanol-based systems.

Although the two products differ in the kind of structural monomer employed, with Ambar containing urethane dimethacrylate (UDMA) and Adper Single Bond 2 containing the less flexible *Bis*-GMA (bisphenol A-glycidyl methacrylate),[26] this difference did not appear to produce important variances in the performance of either of the materials, at least in the evaluation period, as well as also shown in several clinical studies.[19,49-53]

Finally, although the FDI criteria was launched in 2007 for evaluating dental restorations,[30] few publications have used it.[55,56] However, at least two studies suggested that the FDI criteria is more sensitive for identifying differences in restorations than the traditional United States Public Health Service (USPHS) criteria when evaluating restorations in NCCLs. [55,56] This is the reason why the FDI criteria were used in the present study instead of the traditional USPHS criteria.

CONCLUSION

The present study demonstrated that both two-step etch-and-rinse adhesives, Adper Single Bond 2—a polyalkenoic acid-containing adhesive, and Ambar—an MDP-containing adhesive, had comparable clinical performances after 60 months of clinical evaluation.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the human subjects' oversight committee guidelines and policies of The Ethics Committee on Investigations Involving Human Subjects by State University of Ponta Grossa. The approval code issued for this study is 14918/10.

Conflict of Interest

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

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