Research Article

Eighteen-month randomized clinical trial on the performance of two etch-and-rinse adhesives in non-carious cervical lesions

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ABSTRACT: Purpose: An 18-month randomized, controlled prospective study evaluated, in an intra-individual comparison, the clinical performance of two-step etch-and-rinse adhesives in non-carious cervical lesions (NCCL). **Methods:** 35 subjects, with at least two similar sized NCCL participated in this study. After sample size calculation, 70 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 according to the FDI criteria. The differences in the ratings of the two materials after 6 and 18 months were tested with Fisher's exact test ($\alpha = 0.05$), and the performance of the each material at baseline and after 6 and 18 months was evaluated by Wilcoxon test ($\alpha = 0.05$). **Results:** All subjects attended the 18-month recall. No significant differences were observed between the materials for any criteria evaluated. Only four restorations (two from each material) were lost after 18 months. Thus, the retention rates of both materials at 18 months were 94.2% (95% CI 81-98%). Nine restorations (four Ambar and five Adper Single Bond 2) showed marginal discoloration which was solved with a polishing procedure. Both adhesive systems showed acceptable clinical retention rates after 18 months. (*Am J Dent* 2014;27:312-317).

CLINICAL SIGNIFICANCE: The new two-step etch-and-rinse adhesive Ambar showed retention rates similar to Adper Single Bond 2 after 18 months of clinical service.

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Introduction

Dentistry has seen ongoing changes since the development of adhesive systems. More conservative approaches with reduced chair-side time are now possible because of such materials. However, clinicians are exposed to a variety of different materials on the market, making selection of the right material quite difficult.

Manufacturers usually promote their products by presenting laboratory data. However, the reliability of such tests to predict the longevity of adhesive restorations has been recently under debate,[1,2] without reaching a clear consensus. For instance, Van Meerbeek et al[1] found a significant correlation between "aged" laboratory bond strength and medium-term clinical retention rates of Class V restorations. However, another author[2] reported that this correlation would be clinically significant only if data from different test institutes were pooled together.

In the face of this debate, clinical trials are still required to ultimately evaluate the efficacy of new adhesives.[1,2] Although clinical trials are complicated, expensive and the results tend to be available only several years later, no laboratory testing can simulate the challenging conditions of the oral cavity. For this purpose, non-cervical carious lesions (NCCL) are the best model to test the clinical effectiveness of adhesives since these lesions do not have any macro-mechanical retention with margins located in enamel and dentin. Additionally, prevalence of NCCL is high and presented in several teeth in the same patient, which facilitates patient selection and enables split-mouth study designs.[1,3]

Recently, a new two-step etch-and-rinse adhesive (Ambar[a]) was launched in the Brazilian market. Several laboratory studies[4-8] showed that this material has properties similar to the Adper Single Bond 2.[b] A short-term clinical study also reported high retention rates of Ambar after 12 months. However, to the extent of our knowledge, clinical performance of this newest material has not been compared for periods longer than 12 months with any successful adhesives available.

Therefore, the objective of this article was to compare the 18-month retention/fracture rate (primary outcome) of this new released adhesive (Ambar) with the gold standard Adper Single Bond 2 in a paired-tooth study design. The null hypothesis was that the retention rate of composite restorations placed with this new material will be similar to those obtained with Adper Single Bond 2 after 18 months of clinical service.

Materials and Methods

Trial design - This study and the informed consent form was approved by the Committee on Investigations Involving Human Subjects of the State University of Ponta Grossa (Paraná, Brazil) under protocol number 14918/10. This research was a double-blind, randomized equivalence clinical trial and it was described following the CONSORT guidelines.[9]

Sample size - Sample size was based on the mean retention rate (95%) of the comparative adhesive (Adper Single Bond 2) reported in earlier studies at 18 or 24 months.[10-12] Using a α of 5%, a power of 90%, and an equivalence limit of 20%, a minimum of 26 participants with two similar-sized NCCL were required.

Participants - Thirty-five participants in clinical attendance at the School of Dentistry, State University of Ponta Grossa (Paraná, Brazil), who met the inclusion and exclusion criteria, were consecutively enrolled in this study. A written consent form was signed for all participants before enrollment in this clinical trial.

Healthy participants, between 20-70 years old, were recruited. They had an acceptable oral hygiene level and presented with at least 20 teeth under occlusion. They were required to have at least two NCCL to be restored in two vital teeth without mobility. These lesions had to be non-carious and non-retentive with more than 1 mm deep with incisal margin in enamel and gingival margin in dentin. The cavo-surface margin could not involve more than 50% of enamel.[10,13] Participants with a compromised medical history (hypertension, diabetes, cancer and other chronic diseases), a severe or active periodontal or carious disease, or with poor oral hygiene were excluded from the study.

Randomization - All participants received one restoration from each group, in different teeth, with similar characteristics, such as depth, shape, dentin sclerosis, and others. To determine which lesion would receive the new material, a coin was tossed immediately before the restoration placement.

Interventions: Restorative procedure - Before restoration placement, some features of the NCCL were evaluated. The degree of dentin sclerosis[10] was evaluated (Table 1). The cavity dimensions were measured in millimeters (height, width and depth) with a probe millimeter, and the geometry of the cavity (evaluated by photograph profile and labeled at < 45°, 45°-90°, 90°-135°, > 135°) was also recorded. Other features such as the presence of cervical border in dentin, the presence or absence of occlusal wear facets, presence or absence of pre-operative tooth sensitivity to stimuli (spontaneous, to water jet, air blast, and the pressure of the explorer) were also evaluated (Table 3).

Restorative procedures were carried out by two trained and calibrated dental residents with 4 years of clinical practice, who screened patients and selected teeth with NCCL. A preliminary cleaning of the tooth surface was performed with pumice and water to remove the salivary pellicle and dental biofilm, followed by rinsing and drying. The proper shade of composite, by means of comparison with a shade guide (Vita Lumin[c]), was determined. The patients were given local anesthesia if required to prevent discomfort during the intervention. All restorations were placed under rubber dam isolation.

In the control group, the adhesive Adper Single Bond 2 (also known as Adper Single Bond Plus and Adper Scotchbond 1XT) was applied according to the manufacturer's instructions (Table 2). Briefly, the cavity was etched (CondAc 37[a]) 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, the solvent was evaporated, and the adhesive layer was light-cured (LED Radii-Cal[d]) for 10 seconds at 1200 mW/cm^2. In the experimental group, the adhesive Ambar was applied following the protocol described in Table 2.

Three increments of resin composite (Opallis[a]) with less than 2 mm were placed, and each one light-cured for 40 seconds. Finally, the restorations were finished and polished using fine-grit diamond burs (#3195F and #3195FF[e]) and flexible abrasive disks (Diamond Pro[a]).

Blinding - The examiners who carried out all evaluations at baseline, 6, 12, and 18 months were blinded to group assignment. All parameters during each recall evaluation were recorded using a new standardized paper case report form, so the evaluators were also blinded to the previous evaluations.

Table 1. Distribution of non-carious cervical lesions according to characteristics and degree of dentin sclerosis (Zander-Grande et al[10]).

Characteristics	Number of lesions	
	Adper Single Bond 2	Ambar
Shape (degree of angle)		
< 45°	2	1
45 - 90°	3	3
90 - 135°	18	17
> 135°	12	14
Inciso-gingival height (mm)		
< 1.5	3	3
1.5 – 2.5	14	17
> 2.5	18	15
Score on dentin sclerosis scale*		
1	28	24
2	1	5
3	5	2
4	1	4
Pre-operative sensitivity		
Yes	16	18
No	19	17
Attrition facet		
Yes	9	10
No	26	25
Enamel in cervical margin		
<25%	1	1
25-50%	34	34
Tooth distribution		
Incisor	2	2
Canine	5	9
Premolar	25	21
Molar	3	3
Arch distribution		
Maxillary	20	24
Mandibular	15	11

* 1 (No sclerosis present; dentin is light yellowish or whitish, with little discoloration; dentin is opaque, with little translucency or transparence).
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]; dentin has a glassy appearance, with significant translucency or transparency evident).

Evaluation criteria and procedure - Restorations were evaluated at baseline and after 6, 12, and 18 months of clinical service by two independent examiners who were trained and calibrated to evaluate FDI criteria.[14,15] These examiners were not involved in the participants' selection or placement of the restorations.

Only the most relevant items from the FDI criteria for testing the adhesive performance were evaluated (Table 3). The primary endpoint was retention/fractures, but the following secondary endpoints were also evaluated: marginal staining, marginal adaptation, postoperative sensitivity, and caries lesions adjacent to the restoration. These items were ranked in the following scores: very good, good, sufficient/satisfactory, unsatisfactory and poor (Table 3). The two examiners evaluated all restorations once and independently. When disagreements occurred during the evaluations, a consensus was reached before the participant was dismissed.

Statistical analysis - The differences in the ratings of the two

Table 2. Materials used, composition and mode of application.

Material	Composition	Application mode
Adper Single Bond 2	Acid: phosphoric acid 37% Adhesive: bisphenol glicydyl dimethacrilate, hydroxyethyl methacrylate, dimethacrylates, polyalkenoic acid copolymer,initiators, water, ethanol	1. Acid etch for 15 seconds; 2. Rinse with water for 15 seconds; 3. Dry the tooth surfaces for 5 seconds, but avoid excessive drying of the dentin; 4. Apply one coat of adhesive system under vigorous agitation for 10 seconds; 5. Evaporate the solvent for 20 seconds; 6. Apply a second coat of adhesive system under vigorous agitation for 10 seconds; 7. Evaporate the solvent for 20 seconds; 8. Light-cure for 10 seconds.
Ambar	Acid: 37% silica-thickened phosphoric acid gel Adhesive: 10-methacryloxydecyl dihydrogen phosphate, urethane dimethacrylate, 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)

Table 3. World Dental Federation (FDI) criteria used for clinical evaluation (proposed by Hickel et al[14]).

	Esthetic Property	**Functional Properties**	
Rating	**1. Marginal Staining**	**2. Fractures and Retention**	**3. Marginal Adaptation**
1. Clinically very good	1.1 No marginal staining	2.1 Restoration retained, no fractures/ cracks	3.1 Harmonious outline, no gaps, no discoloration.
2. Clinically good (after correction very good)	1.2 Minor marginal stining, easily removed by polishing	2.2 Small hairline crack.	3.2.1 Marginal gap (50 μm). 3.2.2 Small marginal fracture removable by polishing
3. Clinically sufficient/ satisfactory (minor shortcomings with no adverse effects but not adjustable without tooth damage)	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. Clinically unsatisfactory (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 dentin/base exposed 3.4.2 Chip fracture damaging margins 3.4.3 Notable enamel or dentin wall fracture
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*

	Biological Properties	
Rating	**4. Postoperative (Hyper-) Sensitivity**	**5. Recurrence of Caries**
1. Clinically very good	4.1 No hypersensitivity	5.1 No secondary or primary caries
2. Clinically good (after correction very good)	4.2 Low hypersensitivity for a limited period of time No operative treatment required	5.2 Very small and localized demineralization
3. Clinically sufficient/ satisfactory (minor shortcomings with no adverse effects but not adjustable without tooth damage)	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 (repair for prophylactic reasons)	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)	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 dentin that is not accessible for repair of restoration

groups after each time (6, 12 and 18 months) were tested with the Fisher's exact test ($\alpha = 0.05$), and differences in the ratings of each group at baseline, 6, 12 and 18 months were evaluated using the McNemar's test ($\alpha = 0.05$). Cohen's Kappa statistic was used to test the inter-examiner agreement.

Results

A total of 35 subjects (18 male and 17 female), with a mean age of 45 years were enrolled in this study. Seventy restorations were placed, 35 per group. Table 1 shows all baseline details and characteristics of the NCCL.

Table 4. Number of evaluated restorations for each experimental group according to the adhesive classified according to the World Dental Federation (FDI) criteria (Hickel et al[14,15]).

		Baseline		6 months		12 months		18 months	
Criteria*		SB	AM	SB	AM	SB	AM	SB	AM
Fractures/Retention	VG	35	35	27	29	32	31	28	28
	G	--	--	5	5	2	2	2	1
	S	--	--	2	--	--	--	3	4
	P	--	--	1	1	1	2	2	2
Marginal adaptation	VG	35	35	34	34	30	29	26	25
	G	--	--	--	--	4	4	3	3
	S	--	--	--	--	--	--	4	5
Marginal discoloration	VG	35	35	34	34	34	33	28	29
	G	--	--	--	--	--	--	4	3
	S	--	--	--	--	--	--	1	1
Caries lesions adjacent to the restoration	VG	35	35	34	34	34	33	33	33
Postoperative sensitivity	VG	32	32	34	34	34	33	33	33
	G	3	3	--	--	--	--	--	--

(*) VG = clinically very good; G = clinically good; S = clinically sufficient/satisfactory and; P = clinically poor.
SB = Adper Single Bond 2 ; A = Ambar.

Performance of adhesive restorations - The overall Cohen's Kappa statistics (0.93) showed good agreement between the examiners. All restorations were evaluated at the baseline, and 6, 12, and 18-month recalls.

Retention - Two restorations were lost at 6 months (one for each adhesive). Three restorations were lost by the 12-month recall (one for Adper Single Bond 2 and two for Ambar), and four restorations were lost by the 18-month recall (two for each adhesive). The 18-month retention rates (95% confidence interval) of both adhesives were 94.2% (95%CI 81-98%), with no statistical difference between any pair of groups at 6, 12, and 18-month recalls or for each group when baseline was compared with 6, 12, and 18-month data (P> 0.05) (Table 4).

Fracture - Some minor shortcomings were detected in the item fracture (seven for Adper Single Bond 2 and five for Ambar after 6 months; two for Adper Single Bond 2 and two for Ambar after 12 months, and five for Adper Single Bond 2 and five for Ambar after 18 months) (Table 4). No significant difference was detected between any pair of groups at the 6-, 12-, and 18-month recall and for each group when baseline was compared with 6-, 12-, and 18-month data (P> 0.05).

Marginal staining - Few restorations showed marginal staining. After 18 months, five restorations from Adper Single Bond 2 and four from Ambar were not scored as clinically very good (Table 3). No significant difference was found between groups at each recall time or for each group when baseline was compared with 6-, 12-, and 18-month data (P> 0.05) (Table 4).

Marginal adaptation - Eight (four for Adper Single Bond 2 and four for Ambar) and 15 (seven for Adper Single Bond 2 and eight for Ambar) restorations were considered to have minor shortcomings in the item marginal adaptation at the 12- and 18-month recalls, respectively. No significant difference was detected between any pair of groups at 6 and 12 months. A significant difference was detected when the 18-month data was compared with baseline records (P= 0.03) for both adhesives.

Other parameters - Caries lesions adjacent to the restoration at 6, 12, and 18 months were not observed. Only six restorations showed postoperative sensitivity in the baseline (three for Adper Single Bond 2 and three for Ambar), but this occurrence was not detected in the other recall times. No difference was observed for this parameter when the adhesives were compared.

Discussion

The adhesive system Adper Single Bond 2 is considered a good two-step etch-and-rinse adhesive due to optimal laboratory performance, such as high immediate microtensile bond strength values,[16,17] reduced solubility,[7] nanoleakage,[16] and a high degree of conversion[17] inside the hybrid layer. Van Meerbeek et al[1] found a significant correlation between "aged" laboratory bond strength and medium-term clinical retention rates of Class V restorations and this may explain its good clinical performance in previous studies.[18,19]

This adhesive contains hydroxyethyl methacrylate (HEMA), which improves dentin wetting and increases bond strength[20] by preventing hydrophobic and hydrophilic phase-separation.[21] Another important component of this material is the polyalkenoic acid copolymer. Despite the controversy regarding the benefits of its inclusion on dentin bonding,[20,22] recent studies showed that polyakenoic acid was capable of chemically bonding with hydroxyapatite[23] and enhanced the bond strength with the dentin substrate.[24]

Based on that, a high retention rate of Adper Single Bond 2 observed in this clinical trial (94.2%) was not surprising. It was similar to retention rates published in other 18- and 24- month clinical studies[10-12] where this material and its predecessor (Adper Single Bond) was used.

Different from its predecessor, Adper Single Bond 2 has 10 wt% of 5 nm spherical silica fillers that may allow the formation of a uniform adhesive film,[25] and may reinforce the mechanical properties of the adhesive layer.[26] As the ultimate tensile strength of the adhesive layer is positively correlated with bond strength,[27] this may play an important role on the performance of the adhesive system.[28] Nonetheless, we cannot omit the fact that some laboratory studies have found no difference in bonding and mechanical properties between the filled and unfilled versions of the Adper Single Bond.[29,30]

The newest two-step etch-and-rinse adhesive (Ambar)

showed similar retention rates to the control adhesive employed (94.2%). This finding is in agreement with a shorter clinical trial, which reported that the 12-month retention rate of the Ambar was 92.6%.[31] Apart from that, Ambar and Adper Single Bond 2 were similar in other evaluated aspects: fracture, marginal staining, marginal adaptation, caries lesions adjacent to the restorations and postoperative sensitivity.

The good clinical performance of this new material was somewhat expected, based upon the results from earlier laboratory studies.[4-8] Similar resin-dentin bond strength values were reported for Ambar and Adper Single Bond Plus.[4,8] Both adhesives produced bonded interfaces that were resistant to thermal fatigue.[4] Under in situ micro-Raman analysis, the degree of conversion of Ambar was statistically similar to Adper Scotchbond 1XT.[5,8] An even higher monomer conversion was reached after prolonged solvent evaporation.[6] Additionally, Ambar showed the lowest water sorption/solubility and the highest ultimate tensile strength when compared to other two-step etch-and-rinse adhesives.[7]

Although the two tested adhesives have several differences in their chemistry, they share several important features. Adper Single Bond 2 and Ambar both contain ethanol as the solvent. Compared to water, ethanol has a higher vapor pressure, which allows better solvent evaporation with air-drying.[20] Ambar is also nanofilled and contains HEMA that prevents phase separation. Both adhesives benefit from chemical bonding with hydroxyapatite. Instead of polyalkenoic acid presented in the Adper Single Bond 2, Ambar contains a 10-methacryloxydecyl dihydrogen phosphate (10-MDP) monomer, which produces stable chemical bonding with dental substrates.[32,33]

The two products differ, however, in the kind of structural monomer employed. While Ambar contains urethane dimethacrylate (UDMA), the Adper Single Bond 2 contains the less flexible Bis-GMA. This difference, however, did not appear to produce important variances in the performance of either material, at least in the evaluation period.

In 2007, the FDI launched new criteria as the standards for evaluating dental restorations.[14,15] Nonetheless, few publications have used the FDI criteria since then.[24,34,35] Two recent studies[24,35] that employed the traditional United States Public Health Service (USPHS) criteria and the FDI criteria suggested that the second are more sensitive for identifying differences in restorations than the first when evaluating restorations in NCCLs. This is the reason why the FDI criteria were used in the present study instead of the traditional USPHS criteria.

In conclusion, the newest two-step etch-and-rinse adhesive Ambar was equivalent to the Adper Single Bond 2 in this 18-month clinical trial.

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d. SDI Limited, Bayswater, Victoria, Australia.
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