

A new universal simplified adhesive: 6-month randomized multi-center clinical trial

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ABSTRACT

Objective: the objective of this multi-center double-blind, randomized clinical trial was to evaluate the clinical performance of a new universal adhesive system (Futurabond U, Voco GbmH, Germany) when applied using different application strategies over a period of six months. **Material and Methods:** for this, 200 restorations were performed on non-carious cervical lesions using the adhesive Futurabond U according to four adhesive strategies (n = 50 per group): self-etch without previous conditioner (SEE); self-etch associated with selective enamel etching (SET); etch-and-rinse with dry dentin (ERDry) and; etch-and-rinse with wet dentin (ERWet). After hybridization, cavities were restored using Admira Fusion composite resin (Voco GmbH). After 6 months of clinical performance, these restorations were evaluated according to FDI criteria in the following items: retention/fracture, marginal adaptation, marginal staining, postoperative sensitivity and caries recurrence. **Results:** seven restorations were lost/fractured after six months of clinical evaluation (2 in the SEE group, 1 in the SET group, 1 in the EDRdry group, and 3 in the ERWet group). The retention rates for six months (95% confidence interval) were 96% (86%-98%) for the SEE group, 98% (89%-99%) for the SET group, 98% (89%-99%) for the EDRdry group and 94% (83%-97%) for the ERWet group, with no statistical difference identified between any pair of groups (p > 0.05). Twenty-four restorations presented small marginal adaptation defects at the six-months evaluation recall, and all of them were considered clinically acceptable. **Conclusion:** the clinical performance of the universal adhesive Futurabond U associated to Admira Fusion unidoses resin composite was found to be promise after 6-month of clinical evaluation when applied in non-carious cervical lesions and it was not depending on the bonding strategy employed.

Keywords: Adhesive techniques; Self etching; Dental restorations; Clinical longevity.

Introduction

The simplification of daily clinical procedures in dental practice represents an excellent gain for the dentist.¹ Based on this idea, the evolution of the adhesive systems was also conceived with the objective of reducing the operative steps, reducing clinical time, and facilitating the application technique without impairing the stability of the adhesive interface over time.²

A good example of simplification is the development of self-etch adhesive systems that allowed, through partial infiltration and/or modification of the smear layer, the penetration of resinous monomers into the intra- and inter-tubular dentin, forming a hybrid layer with fewer defects compared to etch-and-rinse adhesive systems,³ therefore making this layer more resistant to degradation.⁴ This is only possible due to the fact that self-etch adhesives eliminate the acid etching of dentin in a separate step. However, the enamel conditioning pattern is lower when using a self-etch adhesive.⁵ To overcome this situation, the selective enamel-etching technique is recommended when self-etch adhesives are recommended.⁶ Unfortunately, when phosphoric acid is applied to the enamel and inadvertently flows into the dentin, the dentin-bonding results of the self-etch adhesive could be affected.^{7,8}

Trying to improve the versatility during the application of adhesive systems, especially considering the different clinical situations (for example, cavities with or without the presence of enamel), universal adhesive systems have recently been developed, with the proposal that the same adhesive bottle could be used

associated or not with the previous application of phosphoric acid⁹⁻¹¹ without compromising the effectiveness of bonding when applied to dentin or enamel^{12,13} and, thus, can replace the existing simplified adhesives (one-step self-etch and two-step etch-and-rinse). This is only possible because universal adhesives contain monomers that promote chemical adhesion to enamel and dentin in their composition.^{9,10,12} So, they can be used as self-etch adhesives with and without the association of selective enamel etching. In addition, manufacturers have also asserted that, whenever the dentist choose the etch-and-rinse technique, after acid is rinsed out of dentin, and dentin is dried, adhesion may be made on wet or dry dentin, which is certainly another interesting simplification for dentists when this process is used in the etch-and-rinse strategy.

Although several universal adhesives have already been evaluated in in vitro tests to establish the best application protocol for universal adhesives, and though these studies showed reliable results,^{9,12-14} it is known that only clinical evaluations are the ultimate proof of clinical efficacy.¹⁵ Unfortunately, clinical studies with universal adhesive systems have shown controversial results, and they are still restricted to two universal adhesives, which shows that other universal adhesives and their different application techniques still have to be evaluated.¹⁶⁻¹⁹ Therefore, the objective of this multi-center, double-blind, randomized clinical trial was to evaluate the clinical behavior of a new universal adhesive (Futurabond U, Voco GbmH, Cuxhauer, Germany) when applied using different application strategies during six months of clinical evaluation. The null

hypothesis tested was that bonding to NCCLs using the SE strategy - regardless of whether or not it is associated with selective enamel etching or using the ER strategy - applied on dry or moist dentin would result in similar retention levels over six months of clinical service.

Material and Methods

Study Design

The description of the experimental design followed the Consolidated Standards of Reporting Trials (CONSORT) statement.²⁰ The Universidade Estadual de Ponta Grossa (protocol 165.357; 2016) and the Universidade Federal Fluminense – Polo de Nova Friburgo (protocol 1.618.895; 2016), ethics committees reviewed and approved the protocol and issued a consent form for this study. Written informed consent was obtained from all participants prior to starting the study. This clinical trial was registered in clinicaltrials.gov clinical registry (#NCT03244124). 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.

This was a multi-center double-blind randomized clinical

trial that used a superiority, method. The study was carried out in the clinics of the School of Dentistry at Universidade Federal Fluminense (Nova Friburgo, RJ, Brazil) and Universidade Estadual de Ponta Grossa (Ponta Grossa, PR, Brazil) between October 2016 and November 2016. The authors decided to form a sample of convenience, and no advertisement was made for participant recruitment. While patients were searching for treatment in the clinics of both universities, they were informed about the research and, once they understood the objectives of the study, and signed the informed consent, they were recruited to the study.

Eligibility Criteria

A total of 120 participants were examined by two calibrated dental residents to check if they met the inclusion and exclusion criteria at each university (Figure 1). Clinical examination was performed with a mouth mirror, a number 5 explorer, and a periodontal probe. Participants had to be in good general health, be at least 18 years old, have an acceptable oral hygiene level, and present at least 20 teeth under occlusion.

To be included in the study, participants had to have at least four non-carious cervical lesions (NCCLs), that should

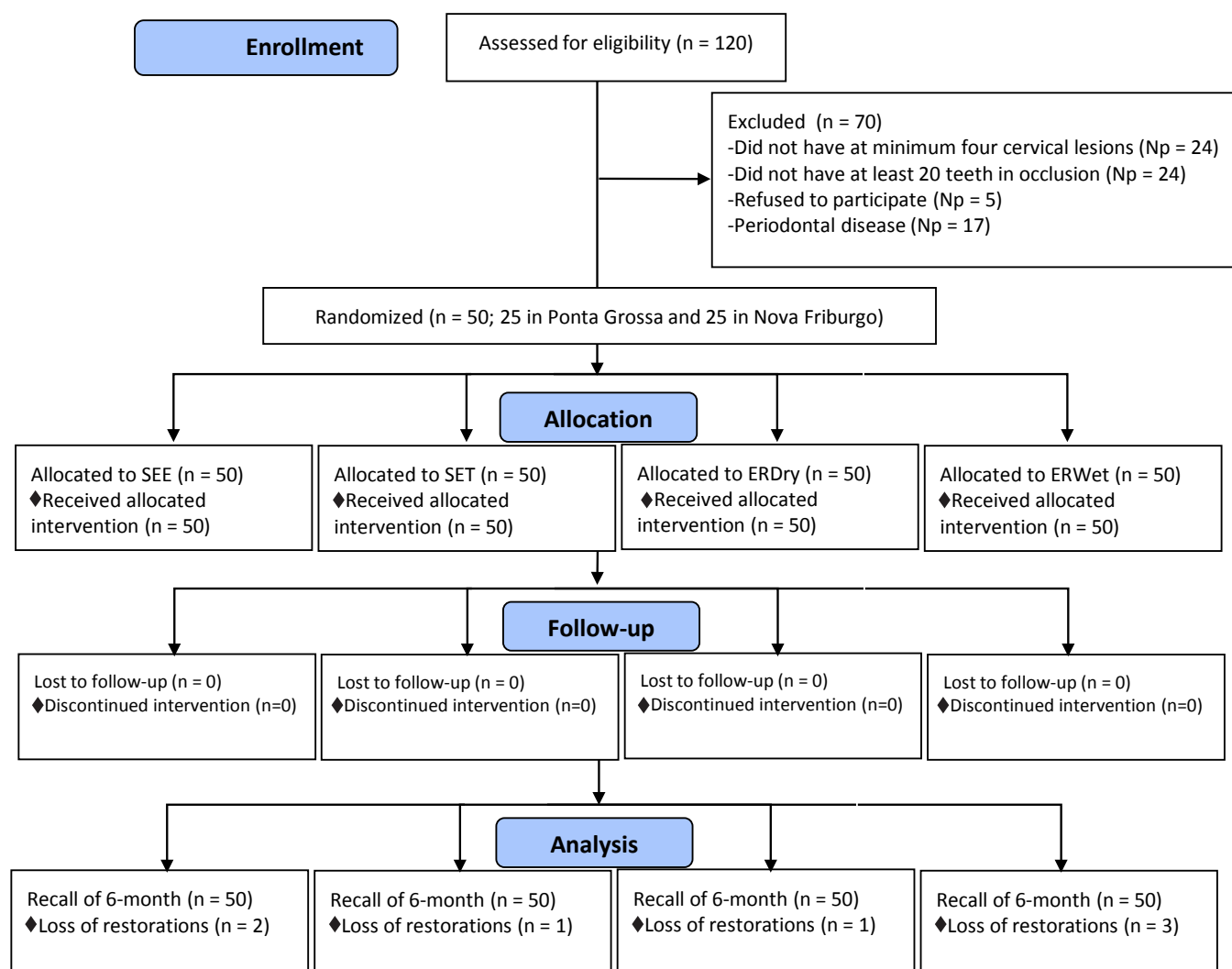


Figure 1. Flow chart of the study design

be non-retentive, deeper than 1 mm, and involve both the enamel and dentin of vital teeth without mobility, in four different teeth. The cavosurface margin could not involve more than 50% of enamel,²¹ as shown in Figure 2a e 2b. Patients with extremely poor oral hygiene or who used orthodontic devices, had severe or chronic periodontitis, or had heavy bruxism habits were excluded from the study, as they would receive other treatments before restorative intervention. Also, participants with known allergies to resin-based materials or any other material used in this study, who were pregnant or breastfeeding women, or participants under chronic use of anti-inflammatory, analgesic, and psychotropic drugs were not included in the study. After the screening sessions, 50 patients were selected, and 200 teeth were randomized into four different groups.



Figure 2. Initial aspect of non-carious cervical lesion: A. Vestibular view. B. Lateral view

Sample Size Calculation and Randomization

In a recent systematic review,²² the annual retention failure rate to one-step self-etch adhesives in NCCLs was reported to be 4.4%. Considering that this data follows a linear trend, the overall retention rate of these adhesive systems will be of approximately 78% after five years of clinical service. Then, considering an Type I error of 5% ($\alpha = 0.05$), a type II error of 20% ($\beta = 80\%$), and a two-sided test, the minimal sample size was calculated to be of 50 restorations in each group to detect a difference of 25% among the test groups.

The randomization was done on an intra-individual basis so that each subject ended up with four restorations, each one resulting from one of all possible combinations of adhesive strategies. These randomization schemes were performed using the software available at <http://www.sealedenvelope.com>.

A staff member not involved in the research protocol performed the randomization process with computer-generated tables.

Interventions: Restorative Procedure

All 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. The degree of sclerotic dentin from the NCCLs was measured according to the criteria described by Swift *et al.*²³ and was classified in categories 1 (no sclerosis present) to 4 (significant sclerosis present). The cavity dimensions in millimeters (height, width, and depth), the geometry of the cavity (evaluated by profile photograph and labeled at $< 45^\circ$, 45° - 90° , 90° - 135° , and $> 135^\circ$),²⁴ the presence of an antagonist, and the presence of attrition facets were observed and recorded. Pre-operative sensitivity was also evaluated by applying air for 10 s from a dental syringe placed 2 cm from the tooth's surface and by applying it with an explorer. These features were recorded to allow comparison of the baseline features of the dentin cavities among experimental groups.

To calibrate the restorative procedure, the study director in each center placed one restoration of each group in one patient to identify all steps involved in the application technique. Then, the four operators, who were resident dentists with more than five years of clinical experience in operative dentistry-two in each center-placed four restorations, one of each group, under the supervision of the study director in a clinical setting. The restoration failures were shown to the operators prior to starting the study. At this point, the operators were considered calibrated to perform the restorative procedures. The operators restored all teeth included in the study. All participants received four restorations, one of each experimental group in different lesions previously selected according to the inclusion criteria.

Before restorative procedures, the patients received dental local anaesthesia using 3% mepivacaine solution (Mepisv, Nova DFL, Rio de Janeiro, RJ, Brazil). Operators cleaned all lesions with pumice and water in a rubber cup (ref #8040RA and #8045RA, KG Sorensen, Barueri, SP, Brazil), followed by rinsing and drying. Then, shade selection was made using a shade guide. After a rubber dam was placed, the new universal adhesive system Futurabond U (Voco, GmbH, Cuxhaven, Germany) was applied as described below. The compositions, application modes, and batch numbers are described in Table 1 and Table 2.

Table 1. Composition and batch number of materials used in the restorative procedures

Material (Manufacturer)	Batch Number	Composition
Futurabond U (VOCO GmbH, Cuxhaven, Germany)	1609415	35% Phosphoric acid (Vocacid): 35% Phosphoric Acid Adhesive: HEMA, Bis-GMA, HEDMA, acidic adhesive monomer (*), urethane dimethacrylate, catalyst, silica nanoparticles, ethanol
Admira Fusion (VOCO GmbH, Cuxhaven, Germany)	- shade A2: 1607524; - shade A3: 1606252; - shade A3,5: 1605482	Resin matrix: aromatic and aliphatic dimethacrylates, methacrylate-functionalized polysiloxane Inorganic filler: Ba-Al-glass, pyrogenic SiO ₂ , filler load: 78% mass. Photoinitiator: camphorquinone. Synergist: NI

Abbreviations: HEMA: 2-hydroxyethyl methacrylate; Bis-GMA: Bisphenol-A-glycidyl dimethacrylate; HEDMA: 1,6-hexanediol dimethacrylate; (*) Acidic adhesive monomer in the composition of Futurabond U is 10-MDP: 10-methacryloyloxydecyl dihydrogen phosphate according to personal communication with Dr. Martin Danebrock

Table 2. Application mode of the adhesive system in the groups (*)

Group	Application mode			
	Etch		Adhesive	Resin composite
Self-etch (SEE)	No	Keep dentin dry (do not overdry)	1. Activate single dose adhesive package; 2. Apply adhesive to the cavity surface with Voco Single Tim Brush for 20s with vigorous agitation; 3. Gently air thin for 5s; 4. Light cure for 10 s at 1200 mW/cm ² .	Insert in the cavity increases of up to 1 mm and light-cure each area of the surface of the restoration with a dental curing light appliance (wavelength of 470 nm, light power of 1200 mW/cm ²) for 30s.
Self-etch associated to selective enamel etching (SET)	Apply etchant ONLY in enamel (30s), rinse for 30s, air dry to remove excess of water			
Etch-and-rinse, dentin dry (ERDry) (**)	Apply etchant in enamel (30s) and dentin (15s), rinse for 30s, air dry to remove excess of water			
Etch-and-rinse, dentin wet (ERWet)		Keep dentin wet		

(*) According to the manufacturer's instructions.

(**) Manufacturer does not indicate application in dry dentin.

- *Self-etch associated with selective enamel etching group (SET)* – The 35% phosphoric acid (Vocacid, Voco GmbH, Cuxhaven, Germany) was applied for 30 s only in enamel (Figure 3a). Then, cavities were rinsed and air dried, keeping the dentin visibly dry (Figure 3b). The single-dose adhesive system package was activated (Figure 3c and 3d),

and then one coat of adhesive was gently scrubbed on the entire enamel and dentin surface for approximately 20 s, according to the manufacturer's recommendations (Table 2) (Figure 4a). The adhesive was then evaporated by gentle air stream for 5 s and light cured for 10 s at 1200 mW/cm² (Bluephase, Ivoclar Vivadent, Schaan, Liechtenstein).

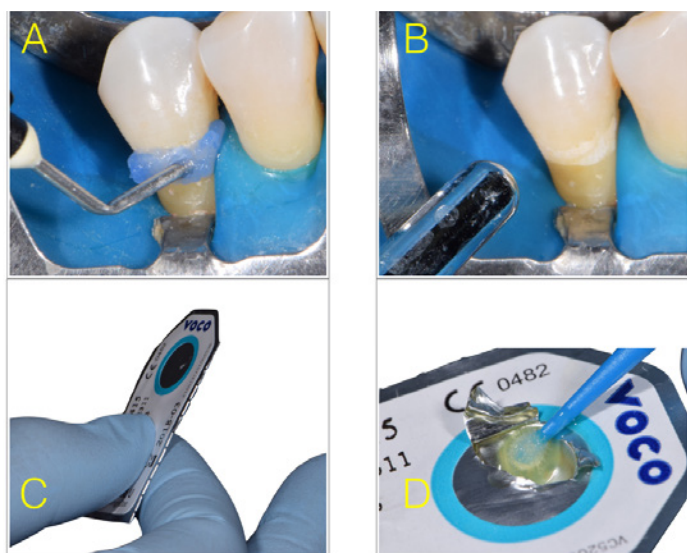


Figure 3. Restorative procedure: A. Selective enamel etching. B. After rinsed and air-dried cavity. C. Single dose adhesive system package being activated. D. Adhesive system ready to be applied

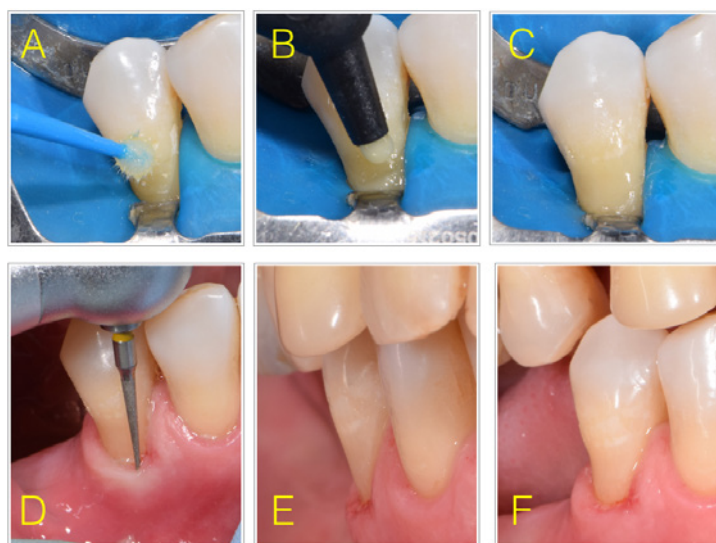


Figure 4. Restorative procedure: A. Adhesive system being applied for 20 s with vigorous agitation on enamel and dentin. B. Composite resin unidose being applied in the cavity. C. Composite resin restoration after place last increment and light cured. D. Restoration being finished. E. Restoration finished; Immediate aspect; Lateral view. F. Restoration finished; Immediate aspect; Vestibular view

- *Self-etch without previous etching group (SEE)* – One coat of adhesive was gently scrubbed on the entire enamel and dentin surface for approximately 20 s, according to the manufacturer's recommendations (Table 2). Solvent-evaporation and light-curing procedures were similar to the sequence described in the SET group.

- *Etch-and-rinse dry dentin group (ERDry)* – The 35% phosphoric acid (Vococid) was applied for 30 s (enamel) and 15 s (dentin). Then, cavities were rinsed and air dried, keeping the dentin visibly dry. The adhesive system was applied as described in the SET group (Table 2). Solvent evaporation and light curing procedures were also the same.

- *Etch-and-rinse wet dentin group (ERWet) [CONTROL GROUP]* – The 35% phosphoric acid (Vococid) was applied for 30 s (enamel) and 15 s (dentin). Then, cavities were rinsed and slightly air dried, keeping the dentin visibly moist. The adhesive system was applied as described in the SET group (Table 2). Solvent evaporation and light curing procedures were also the same.

After adhesive application, the resin composite Admira Fusion unidoses (Voco GmbH, Cuxhaven, Germany) was used in up to three increments, inserted directly in the cavity with Centrix device, and each one was light cured for 10 s at 1200 mW/cm² (Bluephase, Ivoclar Vivadent, Schaan, Liechtenstein) (Figure 4b and Figure 4c). The restorations were finished immediately with fine and extra-fine #2200 diamond burs (KG Sorensen, Barueri, SP, Brazil) (Figure 4d) and polished with Jiffy polisher (Ultradent, South Jordan, Utah, USA) under constant water cooling (Figures 4e and Figure 4f).

Blinding

The two examiners, who performed the clinical evaluation, were not involved or present during the clinical procedures, which means that they were blinded to group assignment. Patients were also blinded to group assignment, and didn't know which teeth received each treatment. So, this study followed a double-blind randomized clinical trial design.

Clinical Evaluation

The examiners evaluated the restorations following the World Federation criteria (FDI)^{25,26} at baseline and after six months. Examiners were kept blind to earlier evaluations during the follow-up recalls.

Following the FDI criteria, the primary outcome was restoration retention and fracture, and the secondary outcomes were marginal staining, marginal adapta-

tion, postoperative sensitivity, and recurrence of caries. Spontaneous postoperative sensitivity evaluation was performed seven days after the restorative procedure. Patients were asked if they experienced any pain during the seven days period.

These variables were ranked according to FDI criteria and placed into categories: clinically very good, clinically good, clinically sufficient/satisfactory, clinically unsatisfactory but repairable, and clinically poor (replacement required).^{25,26} 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 ADA guidelines.²⁷ Cumulative failure percentage = [(PF + NF) / (PF + RR)] X 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 CONSORT's (Consolidated Standards of Reporting Trials) suggestion.²⁰ Descriptive statistics were used to describe the distributions of the evaluated criteria. A statistical analysis for each individual item was performed for FDI evaluation criteria. The differences in the ratings of the four groups after 6 months were tested with the Friedman repeated-measures analysis of variance by rank ($\alpha = 0.05$). Cohen's kappa statistics were used to test inter-examiner agreement. In all statistical tests, the authors pre-set the level of significance to 5%.

Results

The restorative procedures were implemented exactly as planned, and no modification was performed. Seventy out of 120 patients examined for eligibility were not enrolled in the study because they did not fulfill the inclusion criteria. Thus, a total of 50 subjects (23 men and 27 women) were selected. Two hundred restorations were placed: 50 for each group (Figure 1). All baseline details relative to the research subjects and characteristics of the restored lesions are displayed in Table 3. The overall Cohen kappa statistics showed excellent agreement between the examiners during the six-month (0.94) follow-up recall. All research subjects were evaluated at baseline and at the six-month recall.

Table 3. Characteristics of the research subjects and the non-carious cervical lesions (NCCL) per each experimental group (*)

Characteristics of research subjects	Number of patients			
Gender distribution				
Male	23			
Female	27			
Age distribution (years)				
20-29	3			
30-39	3			
39-49	20			
> 49	24			
Characteristics of NCCLs lesions		Number of lesions		
	SEE	SET	ERDry	ERWet
Shape (degree of angle)				
< 45	0	0	0	0
45-90	8	10	13	6
90-135	17	13	15	17
> 135	25	27	22	27
Cervico-incisal height (mm)				
< 1.5	14	17	17	15
1.5-2.5	15	13	14	17
2.5-4.0	12	8	12	11
> 4.0	9	12	7	7
Degree of sclerotic dentin				
1	29	28	28	31
2	13	14	11	11
3	6	7	9	6
4	2	1	2	2
Presence of antagonist				
Yes	41	39	42	44
No	9	1	8	6
Attrition facet				
Yes	37	38	40	43
No	13	12	10	7
Pre-operative sensitivity (spontaneous)				
Yes	13	11	11	13
No	37	39	39	37
Pre-operative sensitivity (air dry)				
Yes	17	13	13	15
No	33	37	37	35
Tooth distribution				
Anterior				
Incisor	9	12	10	11
Canines	8	5	10	9
Posterior				
Premolar	21	24	23	21
Molar	12	9	7	9
Arc distribution				
Maxillary	25	27	24	26
Mandibular	25	23	26	24

(*) SEE, self-etch without any previous etching; SET, self-etch with selective enamel etching; ERWet, etch-and-rinse, wet dentin; EDRDry, etch-and-rinse, dry dentin

Retention/Fracture

Seven restorations were lost or fractured after six months of clinical evaluation (two for SEE, one for SET, one for ERDry, and three for ERWet; Table 4). According to FDI evaluation criteria, the six-month retention rates (95% confidence interval [CI]) were 96% (86%-98%) for SEE, 98% (89%-99%) for SET, 98% (89%-99%) for ERDry, and 94% (83%-97%) for ERWet, with no statistical difference identified between any pair of groups ($p > 0.05$; Table 4).

Marginal Adaptation

Twenty-four restorations were considered to have minor discrepancies in marginal adaptation at the six-month recall using the FDI criteria (8 for SEE, 9 for SET, 4 for ERDry, and 3 for ERWet; Table 4). No significant difference was detected between any pair of groups at the six-month recall ($p > 0.05$; Table 4).

Table 4. Number of evaluated restorations for each experimental group (*) classified according to the World Dental Federation (FDI) criteria^{25,26}

FDI Criteria	(**)	Baseline				Six months			
		SEE	SET	ERWet	ERDry	SEE	SET	ERDry	ERWet
Marginal staining	A	50	50	50	50	48	49	49	47
	B	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	--
	E	--	--	--	--	--	--	--	--
Fractures and retention	A	50	50	50	50	48	49	49	47
	B	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	01
	E	--	--	--	--	02	01	01	02
Marginal adaptation	A	50	50	50	50	40	40	45	44
	B	--	--	--	--	08	09	04	03
	C	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	--
	E	--	--	--	--	--	--	--	--
Post-operative (hyper-) sensitivity	A	50	50	50	50	48	49	49	47
	B	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	--
	E	--	--	--	--	--	--	--	--
Recurrence of caries	A	50	50	50	50	48	49	49	47
	B	--	--	--	--	--	--	--	--
	C	--	--	--	--	--	--	--	--
	D	--	--	--	--	--	--	--	--
	E	--	--	--	--	--	--	--	--

(*) SEE, self-etch without any previous etching; SET, self-etch with selective enamel etching; ERWet, etch-and-rinse, wet dentin; ERDry, etch-and-rinse, dry dentin.

(**) A = Clinically very good; B = Clinically good; C = Clinically sufficient / satisfactory; D = Clinically unsatisfactory; E = Clinically poor.

Other Parameters

No restorations had postoperative sensitivity to air at the six-month recall using FDI criteria. Marginal discoloration was not observed in any restorations in FDI criteria. No restoration showed recurrence of caries after six months for FDI criteria. Usually, the restorations showed a very good clinical performance, which can be seen in Figure 5, after 6 months of clinical performance.



Figure 5. Restoration after 6-month of clinical evaluation

Discussion

Adhesion to dental tissues is one of the greatest challenges still present in adhesive dentistry, and manufacturers of dental materials are continually seeking solutions to increase the clinical longevity of adhesive restorations.²

Two-step etch-and-rinse adhesive systems have been used for many years, and several problems are associated with their application technique. During dentin acid etching, the demineralized collagen fibers may collapse after air drying, leading to a decrease in bond strength.²⁸ Therefore, the maintenance of moist or wet dentin is necessary, but without water excesses, which could also prevent the correct infiltration of the resinous monomers.²⁹ However, methods for moisture control of the dentin surface and for maintaining the original structure of collagen fibrils are highly subjective and technique sensitive,³⁰ which leads to a large number of failures during the formation of the hybrid layer.³¹ These failures may lead to accelerated degradation of the adhesive layer and may thereby undermine the longevity of adhesive restorations.^{32,33}

However, no significant difference was observed when the ERDry and ERWet groups were compared. Although this fact seems novel, in fact, no previous clinical study comparing dentin moisture with the older two-step etch-and-rinse adhesives found any difference when dentin was kept moist or dry during an evaluation period of up to two years.^{21,34,35} Same results were also recently demonstrated for two universal adhesive systems.^{16,18,19} This fact may lead us to conclude that dentin moisture does not appear to in-

fluence clinical outcomes. However, longer studies (at least five years) are necessary to draw more informed conclusions about this clinical situation. It is worth to note the extremely low percentage of restorations that showed failures in these two groups (ERDry and ERWet), similar to two other recently evaluated universal adhesive systems (Single Bond Universal, 3MESPE^{16,17} and Xeno Select, Dentsply¹⁹). This testifies to the quality of the Futurabond U system when applied in conjunction with acid etching of the dentin.

However, using the universal adhesive systems, such as self-etch adhesives, is one way of making the technique more simplified and, consequently, less sensitive to the operator.² A well known problem of self-etch adhesives over time is the low bonding rate to the enamel, which can be solved with the selective enamel-etching technique.^{5,6} For this reason, the majority of the manufacturer's recommendations for universal adhesive systems indicate the technique of selective enamel etching prior to the application of the adhesive to the enamel and dentin.

The clinical results in terms of the retention of Futurabond U in these two groups (SEE and SET) were very good after 6 months of clinical evaluation, with a success rate of 96%-98%. Despite the short clinical evaluation, a recently published clinical study that evaluated the universal adhesive system Xeno Select (Dentsply)¹⁹ demonstrated a retention percentage of 80%-85% when applied in these same techniques, lower than the result of the present investigation. In other words, the good clinical results of the present study could not be attributed to the short clinical evaluation, but to the composition of Futurabond U.

In fact, the success rates of Futurabond U have shown similarity to those of another universal adhesive system (Single Bond Universal, 3M ESPE) after six months of clinical performance.^{16,17} In the Mena-Serrano's¹⁶ study, the percentage of success ranged from 94%-100% for SEE and SET and in Lawson's one;¹⁷ it was 97% (only SEE group was evaluated). These results are probably related to the presence of the 10-MDP acidic functional monomer (10-methacryloyloxydecyl dihydrogen phosphate).³⁶ This functional monomer is responsible for the formation of a stable salt with hydroxyapatite calcium from dentin. The stability of this calcium salt has been correlated with the high bond strength of 10-MDP to enamel and dentin immediately and after storage in water.³⁷ Although the safety data sheet of Futurabond U does not make clear the presence of 10-MDP in its composition, the chemical responsible for the development of the material (Danebrock M, personal communication) has already been described; this monomer is present in the Futurabond U composition (Table 1). It is noteworthy that the lack of this monomer was pointed out by Lopes *et al.*¹⁹ as the main cause for the lower results found in their study.

Because few clinical studies have been found in the literature with the use of universal adhesives—with or without this 10-MDP monomer—it cannot be stated that this was the real reason for the differences found, and therefore, the authors believe that more clinical studies with different universal adhesive systems with different formulations need to

be performed. This is also to prove the clinical quality of these new adhesive systems.

Another important finding of the present study were the marginal adaptation data. Although these data are still initial and there is no difference between the four different techniques of application of the Futurabond U adhesive system, the low percentage of marginal failures found in this study (12%) is remarkable in comparison with previous studies (38% in Mena-Serrano *et al.*¹⁶ and 39% in Lopes *et al.*¹⁹). Several factors may be involved in the good marginal adaptation of a resin composite to the cavity.³⁸ However, in this specific case, the resin composite Admira Fusion was used in caps and was applied directly (with the aid of a Centrix syringe) to the cavity and not in syringes as in previous studies,^{16,17,19} thereby facilitating their insertion into the cavity and consequently decreasing the presence of voids and porosities in the final restorations.³⁹

Although, to the best of our knowledge, the effects of the insertion of resin composites in caps or syringes on the

clinical performance of composite resin restorations are not known, this is the only plausible explanation for the lower percentage of marginal adaptation problems in the present study in which Admira Fusion was used.

It is important to mention that these percentages of marginal adaptation failures have been increasingly observed due to the use of a more specific evaluation criteria, known as FDI, as in the present study.^{16,40} Most of these defects are clinically acceptable and easily solved with a re-polishing of the restorations.⁴¹ Future long-term clinical follow-up studies are still necessary to prove the initial results obtained.

Conclusion

The clinical performance of the Universal Adhesive Futurabond U associated with the Admira Fusion unidoses was found to be safe and shows promise after six months of clinical evaluation when applied in non-carious cervical lesions; Within the limitations of this study, the six-month clinical behavior of Futurabond U (VOCO) was not dependent on the bonding strategy employed.

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