

# ONE YEAR CLINICAL PERFORMANCE OF UNIVERSAL ADHESIVE APPLIED IN THREE MODES IN NON-CARIOUS CERVICAL LESIONS (A RANDOMIZED CONTROLLED TRIAL)

Karam M. Abdel Hamid<sup>1\*</sup> BDS Waleed A. El Mahy<sup>2</sup> PhD,  
Dina M. Nasr<sup>3</sup> PhD

## ABSTRACT

**INTRODUCTION:** Universal adhesives can be applied in self-etch, selective enamel etch, or etch-and-rinse modes. Universal adhesives can also provide adhesion to multiple substrates other than tooth surfaces, including resin composites, metals, zirconia, and silica-based ceramics.

**OBJECTIVES:** To evaluate the one-year clinical performance of a universal adhesive applied in three application modes in comparison to other self-etch and etch and rinse adhesives (control groups) in the restoration of non-cariou cervical lesions with composite resin.

**MATERIALS AND METHODS:** Seventy-five restorations in fifteen patients were randomly allocated to five groups (n = 15) according to adhesives and application modes: group I: etch-and-rinse adhesive; group II: self-etch adhesive; group III: universal adhesive in self-etch mode; group IV: universal adhesive in selective enamel etch mode; and group V: universal adhesive in etch-and-rinse mode. The same composite resin (Charisma Diamond) was placed incrementally, finished, and polished. The composite restorations were assessed at baseline, 3, 6, and 12 months using the World Dental Federation (FDI) criteria. Groups were compared at each time point regarding all criteria using the Kruskal-Wallis test.

**RESULTS:** All subjects were recalled after one year, with 100% retention rates in all groups. Using the Kruskal-Wallis test, there were no significant differences between all groups at any recall time regarding fracture, marginal adaptation, marginal staining, and postoperative sensitivity (P > 0.05). None of the five groups showed secondary caries.

**CONCLUSION:** The three application modes of the universal adhesive and the two control adhesives perform similarly without significant difference between them after one year.

**KEYWORDS:** Universal adhesive, application modes, retention, clinical trial, cervical restorations.

**RUNNING TITLE:** Different application modes of universal adhesive in cervical restorations.

1 Instructor of Operative Dentistry, Faculty of Dentistry, Kafr Elsheikh University, Kafr Elsheikh, Egypt

2 Professor of Operative Dentistry, Conservative Dentistry Department, Faculty of Dentistry, Alexandria University, Alexandria, Egypt

3 Lecturer in Operative Dentistry, Conservative Dentistry Department, Faculty of Dentistry, Alexandria University, Alexandria, Egypt

\* Corresponding Author:

E-mail: [karamviii@gmail.com](mailto:karamviii@gmail.com)

## INTRODUCTION

Adhesion to either dentin or enamel can be achieved using etch-and-rinse (ER) adhesives, which require phosphoric acid etching before bonding, or self-etch (SE) adhesives, which bond to dental substrates using acidic primers. Phosphoric acid etching improves enamel adhesion due to the predominance of hydroxyapatite crystals. Dentin, on the other hand, is made up mainly of organic components, making bonding a more difficult procedure (1). The main drawback of the ER adhesives when bonding to dentin is the difficulty of maintaining effectively hydrated collagen fibers after demineralization of the dentin with phosphoric acid.

This complicated bonding process results in clinical errors, which may manifest clinically as post-operative

sensitivity or adhesive failure. On the other hand, ER adhesives remain the gold standard for bonding to enamel (2).

One of the major clinical challenges of SE adhesives when bonding to dentin is their difficulty in etching enamel as effectively as with phosphoric acid etch (3). To overcome this drawback, a selective enamel etch (SEE) technique has been proposed, in which enamel margins are selectively etched using phosphoric acid before applying self-etch adhesives. However, accidental dentin etching may occur during selective

enamel etching, compromising the bonding strength to the dentin (4).

Dental manufacturers have developed a new class of multi-use dental adhesives known as universal adhesives. These multi-mode systems can be applied in SE, ER, or SEE bonding strategies, thus allowing clinicians to make their own judgment for each of their cases. Despite the increased popularity of these new universal adhesives, only a few randomized clinical studies assessed their performance when applied in different adhesion modes (5).

Non-carious cervical lesions (NCCLs) are described as the cervical loss of tooth structure without bacterial involvement, which can be caused by erosion, abrasion, abfraction, or a combination of multiple factors. Because of their good aesthetic and physio-mechanical characteristics, composite resins are commonly used in the restoration of these lesions. Adhesive systems are frequently clinically evaluated using these lesions because bonding to them is challenging due to the overall lack of macro-mechanical retention and the inclusion of both enamel and dentin margins, which demand different adhesive techniques (6).

Therefore, the aim of this study was to determine the clinical effectiveness of different application modes of universal adhesive in NCCLs restored with a nanohybrid composite resin after a one-year follow-up period. The null hypothesis is that there is no difference in the clinical performance of the universal adhesive applied in three application modes (ER, SE, or SEE modes) in comparison to other SE and ER adhesives in NCCLs restoration with dental composite using the FDI criteria regarding retention, marginal fracture, marginal adaptation, marginal staining, postoperative sensitivity, and the presence of caries.

**MATERIALS AND METHODS**

**Materials**

The materials used in this study are shown in table 1.

**Study Design, Ethics approval, Setting and location**

The study was a randomized, double-blind (subjects and evaluators) clinical trial that followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines (7).

The clinical trial was carried out in the postgraduate clinic of the department of Conservative Dentistry, Faculty of Dentistry, Alexandria University, after receiving ethical approval from the Alexandria University Faculty of Dentistry's Research Ethics Committee. All subjects were aware of the study's purpose and objectives, but they were not informed about which teeth received the particular treatments under investigation.

**Sample size calculation**

The minimum sample size was determined based on a previous study by Oz et al. (8). Based on the results of

that study, and by assuming a power of 80% to distinguish a standardized outcome size in retention (d = 0.4482) (medium-sized standardized outcome size), and a level of significance of 95% ( $\alpha=0.05$ ), the minimum essential sample size was calculated to be 12 teeth per group (number of groups = 5) (total sample size = 60 teeth). The sample size was increased to 15 teeth per group (a total of 75 teeth) to control for dropout bias (9).

**Table 1:** Classification, composition, and manufacturers of the materials used in the study.

Material	Classification	Composition	Manufacturer
Gluma Bond Universal	Single Component Universal Dental Adhesive	UDMA, 10-MDP, 4-META, HEMA, acetone, water, photo initiators, stabilizers	Heraeus Kulzer, Hanau, Germany
Gluma Self Etch	One bottle Self-Etch Dental Adhesive	UDMA, 4-META/Acidic monomer, acetone, water, fillers, photo initiators, stabilizers	
Gluma Bond5	One bottle etch and dental adhesive	UDMA, 4-META, HEMA, glutaraldehyde (trace), silica (trace), ethanol, camphor quinone (trace), water	
Charisma Diamond	Nano-hybrid composite resin	Matrix: TCD-DI-HEA, UDMA Filler: Barium aluminum fluoride glass and colloidal silica filler (64vol% filler, 5nm - 20µm)	
Gluma Etch 35 Gel	Etchant	35% Phosphoric acid, Blue Dye, Pyrogenic Silica (Aerosil), water	

**Abbreviation:** UDMA: Urethane dimethacrylate ;10-MDP: 10-Methacryloyloxydecyl dihydrogen phosphate; 4 META, 4methacryloxyethyl trimellitate anhydride; HEMA: 2-Hydroxyethyl methacrylate;TCD-DI-HEA: Bis-(acryloyloxymethyl) tricyclodecane.

**Participants and lesion selection**

Fifteen patients were enrolled in that study. Each patient submitted a written informed consent before the start of the treatment.

**A-Inclusion criteria**

- 1) All subjects must be at least 18 years old and have no behavioral or medical issues that could prevent them from completing the recall visits.
- 2) All participants should have good oral hygiene.

- 3) All participants should have at least five NCCLs (abrasion, erosion, or abfraction) in canines and premolars.
- 4) The selected lesions should be at least 1.5 mm deep (determined by a periodontal probe).
- 5) The selected lesions should have their incisal/occlusal margins in enamel and their cervical margins in dentin.

#### B-Exclusion criteria

- 1) Advanced untreated periodontal disease or severe para-functional habits.
- 2) Pregnancy during screening or teeth restoration.
- 3) Patients undergo desensitizing therapy or medical treatment, including chronic anti-inflammatory and analgesic use.
- 4) Patients undergoing orthodontic treatment or bleaching of teeth.
- 5) Teeth that have been restored or that have had root canal treatment.
- 6) Teeth that were used as abutments in fixed and removable dentures.
- 7) Teeth that showed hypersensitivity, mobility, or were without an antagonist.

#### Randomization and allocation concealment

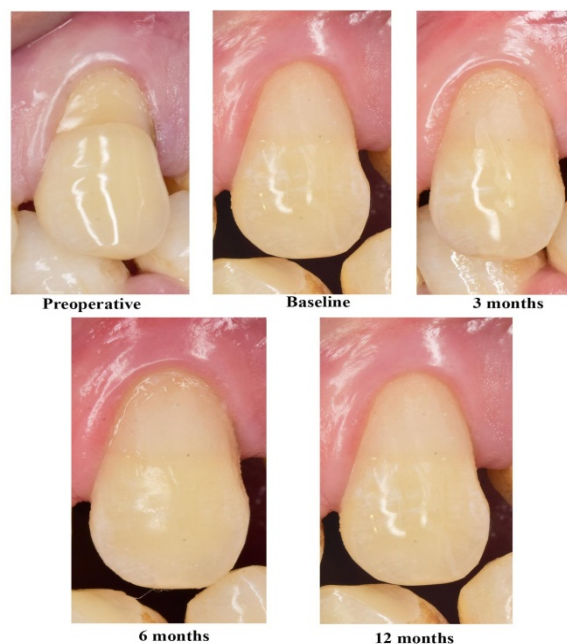
The randomization was done on an intra-individual basis so that each subject ended up with five restorations, each one resulting from one of all possible combinations of adhesive strategy. A staff member not involved in the research protocol performed the randomization process with computer-generated tables.

Details of the allocated groups were recorded on cards contained in sequentially numbered, opaque, sealed envelopes. Opening the envelope on the day of the restorative procedure revealed each participant's allocation assignment. The operator was not blinded to group assignment when administering interventions; however, participants and evaluators were blinded to the group assignments.

#### Interventions: restorative procedure

Before starting the restorative processes, the subject's demographics (gender and age) and tooth type (canine/premolar) were recorded. The criteria of Swift et al. were used to estimate the degree of dentin sclerosis (10). The height (cervico-occlusally), width (mesio-distally), and cavity depth of NCCLs were measured in millimeters using a periodontal probe. The angle of each lesion was measured from a profile photograph using Windows software (ImageJ, USA) and labelled as (45°, 45°–90°, 90°–135°, and > 135°; Figure 1) (11). An air stream from a dental unit syringe was applied for 10 seconds, 2 cm away from the tooth surface, while cotton rolls were placed on the adjacent teeth to test preoperative sensitivity. The cervical margins of NCCLs were classified as supra-gingival, gingival level, or sub-gingival. These features were recorded to allow comparison of the

baseline features of the cavities among experimental groups. Patients received dental prophylaxis and oral hygiene instructions one week before treatment.



**Figure (1):** An example of NCCLs restoration in upper left canine bonded with Gluma bond5 at different evaluation recalls. The restoration obtained a score of 1 for all the evaluated criteria.

The teeth were polished with pumice and water in a rubber cup. The selected teeth were anaesthetized with Articaine 4% with epinephrine 1:100.000 (Artinibsa 4%, Inibsa, Barcelona, Spain). Charisma diamond shade guide (Heraeus Kulzer GmbH, Germany) was used to select the right shade of the composite. All teeth to be restored were isolated with rubber dam isolation and a 212 clamp (Dentech KSK, Tokyo, Japan) was used on the tooth to be restored for better gingival retraction. The incisal/occlusal margins of lesions were beveled with a 0.5 mm bevel using a contra-angled high-speed handpiece and a flame-shaped diamond stone (Komet Dental, Gebr, Germany) under water spray.

All subjects received five composite restorations, one for each group, on five lesions in canines and premolars bonded with Gluma bond 5, Gluma self-etch, and Gluma bond universal system applied in three modes (SE, SEE, and ER modes). All adhesives and composite restorations were cured with an LED light-curing unit (Demi Ultra, Kerr) with a light intensity of 1100-1300 mW/cm<sup>2</sup>.

**Group I: Gluma Bond 5 (GB5-ER):** Gluma Etch was applied for 30 seconds on enamel and 15 seconds on dentin, then lesions were rinsed off for 20 seconds with water spray and dried with an oil-free air stream. Gluma Bond 5 was applied using a soft brush to the complete

surface of the cavity, then solvent and residual moisture were carefully evaporated under a gentle air stream until no movement of liquid could be detected. The adhesive was polymerized for 20 seconds.

**Group II: (Gluma Self Etch) (GSE-SE):** Gluma self-etch was applied to the whole surface of the cavity with a soft brush, then light-cured for 20 seconds.

**Group III: Gluma Bond Universal in the SE mode (GBU-SE):** Gluma Bond Universal was applied to the cavity with a soft brush and gently brushed for 20 seconds, then dried with an air stream (oil-free) until no movement of liquid could be detected, then polymerized for 10 seconds.

**Group IV: Gluma Bond Universal in SEE mode (GBU-SEE):** Gluma Etch 35 Gel was applied only to the enamel for 30 seconds. Then rinsed off with water spray and dried with an air flow (oil-free). The universal adhesive was then used in the manner mentioned in group III.

**Group V: Gluma Bond Universal in the ER mode (GBU-ER):** Gluma Etch 35 Gel was applied for 30 seconds (enamel) and 15 seconds (dentin). Then rinsed thoroughly with water and dried with an oil-free air flow. The universal adhesive was then used in the manner mentioned in group III.

**Placement of composite restorations:** After application of the different adhesives with the different modes as per the assigned group, the Charisma Diamond restorative material (Heraeus Kulzer GmbH, Germany) was used to restore NCLs. It was applied in increments with a plastic filling instrument and adapted carefully to the cavity surfaces, and each increment was polymerized for 20 seconds. The composite restorations were finished with fine and extra-fine diamond stones (Komet Dental, Germany) in a contra-angled high-speed handpiece under water spray. For polishing, rubber points (Kenda AG, Vauz, Liechtenstein) and polishing discs (Soflex, 3M ESPE) with decreasing grit sizes were used. Patients received individualized instruction for the mechanical control of dental biofilm, including guidance on brushing technique and flossing.

**Calibration procedures for clinical evaluation**

The clinical evaluation was carried out by two calibrated and skilled evaluators who were not participating in the restoration processes. Intraexaminer reliability on observation was achieved through Cohen’s kappa test.

**Clinical evaluation**

Clinical performance of the composite resin was assessed after one week after the restoration procedure (baseline), 3, 6, and 12 months according to the FDI criteria (12). Only significant clinical parameters that measure the adhesive performance, such as 1) retention/fracture, 2) marginal adaptation, 3) marginal staining, 4) postoperative hypersensitivity, and 5) caries presence, were evaluated (Table 2). The evaluation was achieved by two calibrated examiners through visual and tactile examination using a mouth mirror and an explorer. To keep evaluators blind to previous evaluations during follow-up recalls, a standard case sheet was used for each evaluator in the

four recall periods. Restorations were scored using a scale of 1 to 5, where a score of 1–3 represented a clinically acceptable restoration and 4 or 5 represented failures.

**Table 2:** The FDI Criteria Used for Clinical Evaluation (12).

	Esthetic Property	Functional Properties		Biological Properties	
	1. Marginal Staining	2. Fracture 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 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 shortcoming 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 Several small enamel or dentin fractures	4.3.1 Premature/ slightly more intense. 4.3.2 Delayed/ weak sensitivity; no subjective complaints, no treatment needed	5.3 Larger areas of demineralization, but only preventive measures necessary (dentin not exposed)
4. Clinically unsatisfactory (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 Chip fracture damaging margins 3.4.2 Notable enamel or dentin wall fracture	4.4.1 Premature/ very intense 4.4.2 Extremely delayed/weak with subjective complaints 4.4.3 Negative sensitivity; intervention necessary but not replacement	5.4 Caries with cavitation (localized and accessible and can be repaired)
5. Clinically poor (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 dentin that is not accessible for repair of restoration

**Statistical analysis**

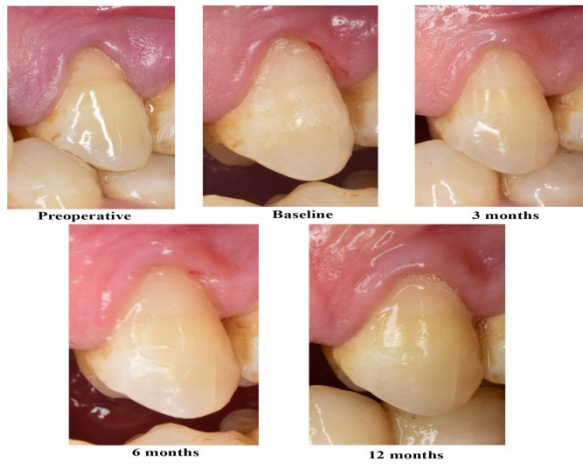
The statistical analysis followed the CONSORT-recommended intention-to-treat protocol (7). The distributions of the evaluated criteria were analyzed using descriptive statistics. Using the FDI criteria, a statistical analysis was done for the five tested criteria and for each overall criteria.

Data was presented using frequency and percentage. Groups were compared at each time point regarding all criteria by the Kruskal-Wallis test. Within group comparisons were done using the Friedman test and followed by pairwise comparisons with Bonferroni adjustment. The level of significance was set at a p value ≤0.05. Data was analyzed by SPSS IBM version 25 (IBM Corporation, Armonk, NY, USA).

**RESULTS**

There were no dropouts in this trial, so all subjects were evaluated at baseline, 3, 6, and 12 months. Example images of restorations are shown in Figures 1, 2, 3, 4, and 5.

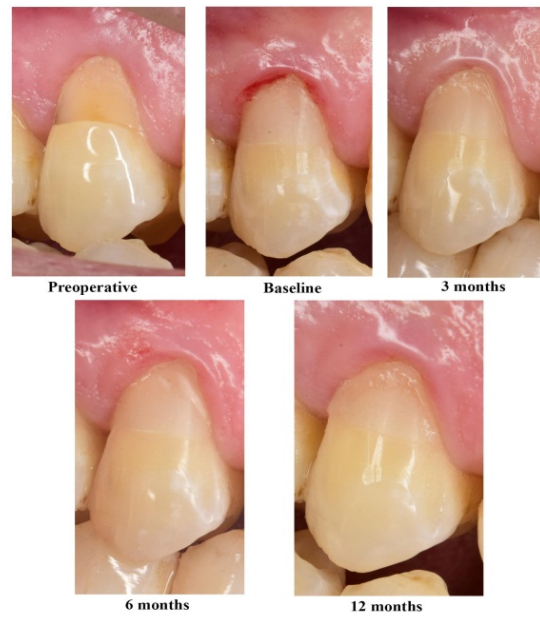




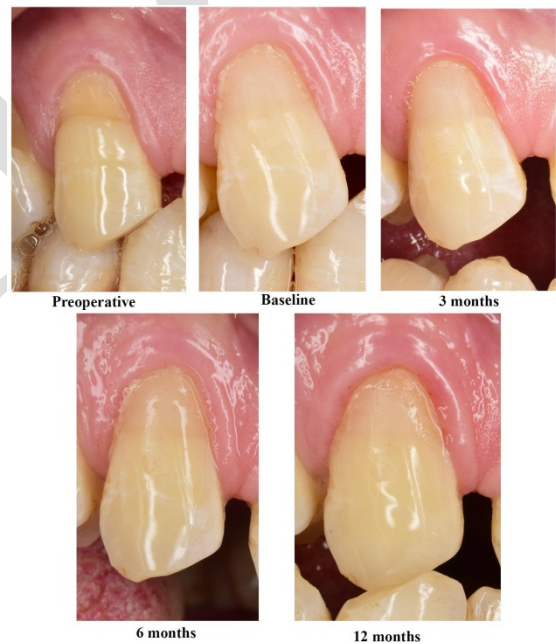
**Figure (2):** An example of NCCLs restoration in upper left first premolar bonded with Gluma self-etch at different evaluation recalls. The restoration obtained a score of 1 for all evaluated criteria, except it was scored 2 for marginal discoloration at 12 month follow up.



**Figure (3):** An example of NCCLs restoration in upper right second premolar bonded with Gluma bond universal in SE mode at different evaluation recalls. The restoration obtained a score of 1 for all the evaluated criteria.



**Figure (4):** Example of NCCLs restoration in upper right first premolar bonded with Gluma bond universal in SEE mode at different evaluation recalls. The restoration obtained a score of 1 for all the evaluated criteria.



**Figure (5):** Example of NCCLs restoration in upper right canine bonded with Gluma bond universal in ER mode at different evaluation recalls. the restoration obtained score 1 for all criteria.

**1. Retention and fracture**

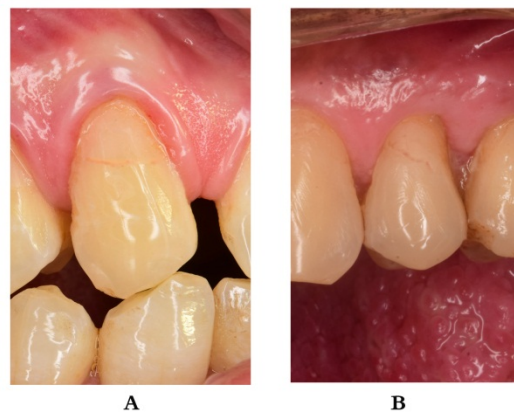
The retention rates of all groups at different follow-up periods were 100% with no loss of any restoration according to FDI criteria (Table 3).

Two restorations (one for GBU-SE and one for GBU-ER; Table 3) showed minor chip fractures after one year, but this did not affect the marginal integrity (score 2).

**Table 3:** Number of evaluated restorations for each experimental group scored according to the FDI in different follow-up periods.

Criteria	score	Baseline				3 Months				6 Months				12 Months				p value
		GB-ER	GSE-SE	GBU-SE	GBU-ER	GB-ER	GSE-SE	GBU-SE	GBU-ER	GB-ER	GSE-SE	GBU-SE	GBU-ER	GB-ER	GSE-SE	GBU-SE	GBU-ER	
Fracture and retention	VG	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	1.00
	GO	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0.551
	SN	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	PN	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Marginal adaptation	VG	15	15	15	15	15	15	15	15	14	13	14	13	13	12	13	14	0.709
	GO	-	-	-	-	-	-	-	-	1	1	1	1	1	1	1	1	0.795
	SN	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	PN	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Marginal staining	VG	15	15	15	15	15	15	15	15	14	13	14	13	13	12	13	14	0.644
	GO	-	-	-	-	-	-	-	-	1	2	1	1	1	2	1	1	0.954
	SN	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	PN	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Post-operative sensitivity	VG	15	15	15	15	15	15	15	15	15	15	15	15	14	13	15	14	1.00
	GO	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0.551
	SN	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	PN	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Secondary caries	VG	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	1.00
	GO	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1.00
	SN	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	PN	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	

Abbreviations: GB-ER: GE/MA Bond (etch and prime adhesive); GSE-SE: GE/MA Self Etch (self-etch adhesive); GBU-SE: GE/MA Bond Universal in the self-etch mode; GBU-ER: GE/MA Bond Universal in the adhesive etched mode; GB-ER: GE/MA Bond Universal in each and time mode; VG: clinically very good; GO: clinically good; SN: clinically sufficient/satisfactory; PN: clinically unsatisfactory; PO: clinically poor.



**Figure (6):** Examples of different obtained marginal discoloration scores at 12 months' follow up. A: Composite restoration in maxillary right canine bonded with Gluma Self Etch showed minor marginal discoloration that can be easily removed by polishing (score 2); B: Composite restoration in maxillary left first premolar bonded with the self-etch mode of Gluma Bond Universal showed moderate marginal staining that cannot be removed without damaging the tooth (score 3).

**2. Marginal adaptation**

Five restorations (one for GB5-ER, two for GSE-SE, one for GBU-SE, and one for GBU-ER) were reported with marginal gaps (scores 2 and 3) at the 6-months recall using the FDI criteria (Table 3).

Nine restorations (two for GB5-ER, three for GSE-SE, two for GBU-SE, one for GBU-SEE, and one for GBU-ER) were reported with marginal gaps (scores 2 and 3) at the 12-month recall using the FDI criteria, with no significant difference between the five groups. When the baseline and 12-month data were compared, no significant difference (Table 3) was found.

**3. Marginal staining**

Six restorations (one for GB5-ER, two for GSE-SE, two for GBU-SE, and one for GBU-SEE) were presented with minor marginal discoloration (score 2) at the 6-month evaluation using the FDI criteria (Table 3). After 12 months of clinical evaluation, 12 restorations (two for GB5-ER, three for GSE-SE, three for GBU-SE, two for GBU-SEE, and two for GBU-ER) were evaluated with minor and moderate acceptable marginal discoloration (scores 2 and 3) using the FDI criteria without significant difference between the five groups. Examples of composite restorations scored with different marginal staining scores are shown in figure 6. When the baseline and 12-month data were compared, no significant difference (Table 3) was found.

**4. Postoperative sensitivity**

Using the FDI criteria, two restorations (one for GB5-ER and one for GBU-ER) demonstrated mild postoperative sensitivity to air at the 12-month recall without a significant difference between the five groups (Table 3).

**5. Recurrence of caries**

Using the FDI criteria, no restoration exhibited the presence of caries at any recall time (Table 3).

**DISCUSSION**

In this randomized controlled trial, the universal adhesive was evaluated in restoring NCCLs in different application modes compared to ER and SE adhesives. Even though the USPHS has been more commonly used for evaluating the clinical performance of dental adhesives, the FDI criteria have been the method of choice in the current study. The FDI criteria were shown to be more sensitive to minor differences in clinical outcomes (13). The retention is considered the most important parameter to evaluate in NCCLs restorations, as none of the other criteria can be evaluated if the restorations are not retained (14). The retention rate of restorations bonded with Gluma Bond Universal is similar (100%) regardless of the application mode. The same universal adhesive was tested in another 24-month clinical trial, showing retention rates of 72.2% in SE mode, 93.7% in SEE mode and 100% in ER mode (8). When comparing the retention rate of this study to that in other clinical studies, similar retention rates (100%) were found for Adhese Universal with both SE and SEE protocols after 24 months (15), and for

Clearfil Universal Bond and G-Premio Bond in SEE after 18 months (16), and also for Scotchbond Universal Adhesive in both ER and SE mode after 6 months (17).

The success rates of the tested universal adhesive have shown similarity to those of other universal adhesives containing 10-MDP (18). This functional monomer forms a stable calcium salt with the hydroxyapatite of dentin in a process called nano layering. This nano layering is important for bonding to dentin and enamel as well, which might clarify why this adhesive performs well on enamel even without selective enamel etching (5). Other adhesives containing monomers other than 10-MDP, such as dipentaerythritol penta acrylate monophosphate (PENTA), showed inferior results in comparison to MDP-containing adhesives, especially when used in self-etch mode (17).

The beveling procedure could be another explanation for the great retention rate (100%). In the current study, all restorations were beveled with a 0.5-mm bevel. Lawson et al. (2015) and Canali et al. (2019) performed enamel beveling (19,20) because the reason for failures due to decreased retention with the ER technique might be the omission of bevel (21). However, because beveling can inhibit adhesives from demonstrating their actual performance, beveling is not performed in the majority of clinical trials. (17,21,22). Perdigao et al. showed that enamel beveling, or enamel etching, had no effect on the clinical performance of the adhesive (23). Lawson et al. found better marginal adaptation for the SE mode when compared to the ER of universal adhesive with no significant differences between the three modes (19). These findings agree with the present study, in which two restorations in SE mode and only one restoration in ER mode showed marginal gaps after 12 months. This may be related to the relatively high pH (1.8) of Gluma Bond Universal and therefore its lower etching potential compared to the phosphoric acid etchant. Oz et al. found that the marginal adaptation was not affected by the pH of three universal adhesives with different pH values (16). Söderholm et al. also found the same results (24).

Marginal discoloration was observed with all techniques but was more (with three restorations after 12 months) in restorations bonded with SE adhesive and universal adhesives in SE mode. However, universal adhesive in ER and SEE mode and the ER adhesive showed less marginal discoloration (only two restorations in each group). Kose et al. also found a more marginal discoloration of universal adhesive when applied in SE mode (25). The discoloration was superficial and mostly found at the enamel margin, which may indicate the significance of SEE with phosphoric acid to achieve a good marginal seal for restorations as recommended by Van Meerbeek et al. (26). Although this superficial

marginal discoloration may predict restoration failure, it is not necessary to replace the whole restoration as polishing may be enough (25).

The solvent included in the used adhesive (Gluma Bond Universal) is acetone, which has a lower film thickness in comparison to ethanol or water-based universal adhesives. This means that this adhesive is more liable to polymerization inhibition by oxygen. Also, this adhesive may be more sensitive to air drying during the rinsing phase because acetone has a relatively high vapor pressure (27). This could have been one of the reasons for the post-operative sensitivity and marginal discolorations shown in ER mode. Oz et al. found that after 36 months, acetone-based adhesives showed lower retention rates than ethanol-based adhesives (16). However, another study demonstrated no significant difference between acetone ethanol and water-based universal adhesives during the 24-month clinical evaluation (8).

There was no secondary caries in this study. Most NCCLs trials showed no secondary caries after different evaluation periods (21). This may be because caries does not often occur in NCCLs clinical trials because the majority of patients with NCCLs have excellent oral hygiene and brush thoroughly in this region (28).

Cruz et al. did not find a significant difference in post-operative sensitivity between application strategies, which is similar to the findings of the current study (16). Two restorations (one in the ER mode of universal adhesive and one in the ER adhesive) showed postoperative sensitivity after 12 months. However, the other groups did not show any postoperative sensitivity. This is likely due to the phosphoric acid etchant removing the peri-tubular dentin and entirely opening the dentinal tubules (2). Patients with hypersensitivity were excluded from this trial. This could have influenced the better post-operative sensitivity results. Similarly, subjects with extreme hypersensitivity were excluded from another clinical trial comparing 18-month results for three different universal adhesives in NCCLs restorations (18).

The mechanical characteristics of the composite used in the restoration of NCCLs are less significant than the adhesive's actual performance (29). Several clinical trials demonstrated that the type of composite (nano hybrid, micro-filled, or flowable) is not as important as the choice of a composite with tested and predictable efficiency (29). Many clinical trials used the adhesive and composite from the same manufacturer (30). In the current trial, a nano hybrid composite resin (Charisma Diamond) was used, which has been reported in a recent study to be the most mechanically stable among seven tested composite materials (31).

The other secondary variables evaluated in this study (patient age, gender, tooth type, degree of sclerotic dentin, depth, width, height, and lesion angle) did not



affect the failure rate of restorations. These findings are consistent with previous trials (25, 32), as well as a meta-analysis of twenty-four clinical studies (33).

Each patient received five NCCLs composite restorations to confirm that they had a restoration from each approach and to control different environmental factors such as oral hygiene, saliva composition, and diet (34) and to enhance the power of the study (35). In some studies, more than one lesion was restored in the same patient (36). However, a prior study found that patient variables had no effect on retention or clinical performance of adhesives (25).

One shortcoming of this trial was that it had a fairly low number of subjects, despite the power analysis accomplished. A more extensive statistical analysis was not possible due to the small number of tested restorations. Another shortcoming may be due to the placing of all restorations in ideal settings, which do not always mimic everyday clinical practice. Most NCCLs clinical trials excluded patients with poor dental hygiene, a high caries risk, significant bruxism, and erosive problems. The clinical lifetime of resin composite materials in such scenarios has yet to be studied.

## CONCLUSIONS

After 12 months, all restorations were clinically acceptable with no significant difference in aesthetic (marginal staining), functional (retention/fracture and marginal adaptation) or biological (post-operative sensitivity and caries recurrence) criteria. The way the universal adhesive was applied (SE, SEE, and ER) did not have an effect on the clinical performance of NCCLs restorations. None of the cavity's features influenced the restoration's performance.

## CONFLICT OF INTEREST

The authors state that they do not have any conflicts of interest.

## FUNDING STATEMENT

There was no specific funding given to the authors for this work.

## REFERENCES

1. Van Meerbeek B, Yoshihara K, van Landuyt K, Yoshida Y, Peumans M. From Buonocore's Pioneering Acid-Etch Technique to Self-Adhering Restoratives. A Status Perspective of Rapidly Advancing Dental Adhesive Technology. *J Adhes Dent.* 2020;22:7–34.
2. Pashley DH, Tay FR, Breschi L, Tjäderhane L, Carvalho RM, Carrilho M, et al. State of the art etch-and-rinse adhesives. *Dent Mater.* 2011;27:1–16.
3. Łukomska-Szymańska M, Sokołowski J, Łapińska B. Current views on adhesive bonding systems. *J Stomatol.* 2017;70:384–93.
4. Szesz A, Parreiras S, Reis A, Loguercio A. Selective enamel etching in cervical lesions for self-etch adhesives: A systematic review and meta-analysis. *J Dent.* 2016;53:1–11.
5. Yoshihara K, Hayakawa S, Nagaoka N, Okihara T, Yoshida Y, Van Meerbeek B. Etching efficacy of self-etching functional monomers. *J Dent Res.* 2018;97:1010–6.
6. Peumans M, Politano G, Van Meerbeek B. Treatment of noncarious cervical lesions: when, why, and how. *Int J Esthet Dent.* 2020;15:16–42.
7. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials. *Int J Surg.* 2011;9:672–7.
8. Oz FD, Ergin E, Canatan S. Twenty-four-month clinical performance of different universal adhesives in etch-and-rinse, selective etching and self-etch application modes in NCCL - a randomized controlled clinical trial. *J Appl oral Sci.* 2019;27:e20180358.
9. Pannucci CJ, Wilkins EG. Identifying and avoiding bias in research. *Plast Reconstr Surg.* 2010;126:619–25.
10. Swift EJ, Perdigão J, Heymann HO, Wilder AD, Bayne SC, May KN, et al. Eighteen-month clinical evaluation of a filled and unfilled dentin adhesive. *J Dent.* 2001;29:1–6.
11. Costa TRF Da, Loguercio AD, Reis A. Effect of enamel bevel on the clinical performance of resin composite restorations placed in non-carious cervical lesions. *J Esthet Restor Dent.* 2013;25:346–56.
12. Hickel R, Peschke A, Heintze SD, Tyas M, Mjör I, Bayne S, et al. FDI World Dental Federation: clinical criteria for the evaluation of direct and indirect restorations-update and clinical examples. *Clin Oral Investig.* 2010;12:349–66.
13. Lopes L, Calazans F, Hidalgo R, Buitrago L, Gutierrez F, Reis A, et al. Six-month follow-up of cervical composite restorations placed with a new universal adhesive system: A randomized clinical trial. *Oper Dent.* 2016;41:465–80.
14. Marquillier T, Doméjean S, Le Clerc J, Chemla F, Gritsch K, Maurin JC, et al. The use of FDI criteria in clinical trials on direct dental restorations: A scoping review. *J Dent.* 2018;68:1–9.
15. Rouse MA, May JT, Platt JA, Cook NB, Capin OR, Adams BN, et al. Clinical evaluation of a universal adhesive in non-carious cervical lesions. *J Esthet Restor Dent.* 2020;32:691–8.
16. Oz FD, Kutuk ZB, Ozturk C, Soleimani R, Gurgan S, Oz FD, et al. An 18-month clinical evaluation of three different universal adhesives used with a universal flowable composite resin in the restoration



- of non-cariou cervical lesions. *Clin Oral Investig.* 2019;23:1443–52.
17. Follak AC, Ilha BD, Oling J, Savian T, Rocha R de O, Soares FZM. Clinical behavior of universal adhesives in non-cariou cervical lesions: A randomized clinical trial: Six-month follow up of two universal adhesives on NCCLs. *J Dent.* 2021;113:103747.
  18. Josic U, Maravic T, Mazzitelli C, Radovic I, Jacimovic J, del Bianco F, et al. Is clinical behavior of composite restorations placed in non-cariou cervical lesions influenced by the application mode of universal adhesives? A systematic review and meta-analysis. *Dent Mater.* 2021;37:503-21.
  19. Lawson NC, Robles A, Fu C-C, Lin CP, Sawlani K, Burgess JO. Two-year clinical trial of a universal adhesive in total-etch and self-etch mode in non-cariou cervical lesions. *J Dent.* 2015;43:1229–34.
  20. Canali GD, Ignácio SA, Rached RN, Souza EM. One-year clinical evaluation of bulk-fill flowable vs. regular nanofilled composite in non-cariou cervical lesions. *Clin Oral Investig.* 2019;23:889–97.
  21. Atalay C, Ozgunaltay G, Yazici AR. Thirty-six-month clinical evaluation of different adhesive strategies of a universal adhesive. *Clin Oral Investig.* 2020;24:1569–78.
  22. Manarte-monteiro P, Domingues J, Teixeira L, Gavinha S, Conceiç M. Universal adhesives and adhesion modes in non-cariou cervical restorations: 2-year randomized clinical trial. *Am J Dent.* 2022;14:33.
  23. Perdigão J, Carmo ARP, Anauate-Netto C, Amore R, Lewgoy HR, Cordeiro HJD, et al. Clinical performance of a self-etching adhesive at 18 months. *Am J Dent.* 2005;18:135–40.
  24. Söderholm K-JM, Ottenga M, Nimmo S. Four-year clinical evaluation of two self-etching dentin adhesives of different pH values used to restore non-retentive cervical lesions. *Am J Dent.* 2013;26:28–32.
  25. Kose C, Mena-Serrano AP, De Paula EA, Tay, LPerdigão J, Y. ., Reis A, et al. A new universal simplified adhesive: 18-month clinical evaluation. *Oper Dent.* 2014;39:113–27.
  26. Van Meerbeek B, De Munck J, Yoshida Y, Inoue S, Vargas M, Vijay P, et al. Buonocore memorial lecture. Adhesion to enamel and dentin: current status and future challenges. *Oper Dent.* 2003;28:215-35.
  27. Pashley DH, Carvalho RM, Tay FR, Agee KA, Lee K-W. Solvation of dried dentin matrix by water and other polar solvents. *Am J Dent.* 2002;15:97–102.
  28. Yaman BC, Doğruer I, Gümüştaş B, Efes BG. Three-year randomized clinical evaluation of a low-shrinkage silorane-based resin composite in non-cariou cervical lesions. *Clin Oral Investig.* 2014;18:1071–9.
  29. Stojanac IL, Premovic MT, Ramic BD, Drobac MR, Stojsin IM, Petrovic LM. Noncariou cervical lesions restored with three different tooth-colored materials: two-year results. *Oper Dent.* 2013;38:12–20.
  30. Peumans M, De Munck J, Mine A, Van Meerbeek B. Clinical effectiveness of contemporary adhesives for the restoration of non-cariou cervical lesions. A systematic review. *Dent Mater.* 2014;30:1089–103.
  31. Gomes de Araújo-Neto V, Sebold M, Fernandes de Castro E, Feitosa VP, Giannini M. Evaluation of physico-mechanical properties and filler particles characterization of conventional, bulk-fill, and bioactive resin-based composites. *J Mech Behav Biomed Mater.* 2021;115:104288.
  32. Zanatta RF, Silva TM, Esper MALR, Bresciani E, Gonçalves SEP, Caneppele TMF. Bonding performance of simplified adhesive systems in noncariou cervical lesions at 2-year followup: A double-blind randomized clinical trial. *Oper Dent.* 2019;44:476–87.
  33. De Oliveira Correia AM, Bresciani E, Borges AB, Pereira DM, Maia LC, Caneppele TMF. Do Tooth- and Cavity-related Aspects of Noncariou Cervical Lesions Affect the Retention of Resin Composite Restorations in Adults? A Systematic Review and Meta-analysis. *Oper Dent.* 2020;45:124–40.
  34. Tuncer D, Yazici AR, Özgünaltay G, Dayangac B. Clinical evaluation of different adhesives used in the restoration of non-cariou cervical lesions: 24-month results. *Aust Dent J.* 2013;58:94–100.
  35. Van Landuyt K, Fieuws S, Van Meerbeek B. Sample size considerations for restoration-longevity randomized controlled trials. *J Adhes Dent.* 2008;10:247.
  36. De Albuquerque EG, Warol F, Calazans FS, Poubel LA, Marins SS, Matos T, et al. A new dual-cure universal simplified adhesive: 18-month randomized multicenter clinical trial. *Oper Dent.* 2020;45:255–70.