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ORIGINAL RESEARCH

FIVE-YEAR CLINICAL PERFORMANCE OF UNIVERSAL ADHESIVES IN NON-CARIOUS CERVICAL LESIONS: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: The complicated nature of Non-cariou cervical lesions together with their characteristic substrate impacts the adhesive restoration process in detrimental ways. The versatility of universal adhesives led to their increased popularity as a suitable solution for restoring NCCLs. The research examined the long-term clinical success of three universal adhesives which received three distinct bonding methods.

Materials and Methods: This clinical trial treated 60 patients with 240 NCCLs using three universal adhesive systems: SBU as well as PBE and FBU. Experimental groups totaled six through the application of the three adhesives using both self-etch SE and etch-and-rinse ER protocols. Two trained examiners conducted USPHS modified criteria evaluation of restorations at baseline through 6, 12, 24, 36, 48, and 60 month points regarding retention and marginal adaptation as well as marginal color changes and secondary tooth decay and post-treatment sensitivity features.

Results: For 5-year follow-up the retention rates reached 93.6% in the ER mode group which proved superior to the retention rates achieved with the SE mode at 83.0% ($p < 0.05$). number of SBU restorations remained in place at (94.6%) which was higher than PBE (89.2%) and FBU (85.6%). Among different experimental groups the marginal adaptation and discoloration worsened progressively until reaching unacceptable limits yet self-etch mode presented the most severe marginal defects. Every group displayed similar rates when it came to postoperative sensitivity and secondary caries development.

Conclusion: Results indicated that universal adhesives functioned well throughout five years in treatment of non-cariou cervical lesions. The bonding strategy with etch-and-rinse manifestation produced better retention and better marginal quality when compared to self-etch bonding. The clinical durability was influenced by the adhesive type where SBU produced the best results.

Keywords: Universal adhesives; Non-cariou cervical lesions; Etch-and-rinse; Self-etch; Randomized controlled trial; Retention; Marginal adaptation

INTRODUCTION

The definition of non-cariou cervical lesions (NCCLs) establishes these conditions as tissue wasting at tooth cervical areas that develops independently from bacteria. The cemento-enamel junction area experiences a continuous degradation that results in wedge-shaped or notch-shaped tissue loss¹. The rates of Non-cariou cervical lesions (NCCLs) have undergone rising trends throughout recent years based on reporting between 5% and 85% prevalence across diverse population variables

and diagnostic standards². Multiple factors lead to the development of NCCLs and these factors include abrasion combined with erosion along with abfraction and occlusal stress³.

The treatment of NCCLs demands special attention because cervical lesions exist in a difficult-to-access region while affecting both enamel and dentin structures with sclerotic dentin being stubborn to acid etching solution and subject to cervical biomechanical strain⁴. Medical experts agree that adhesive restorations made from resin composite materials stand as the preferred

dental treatment for NCCLs because they solve both functional and aesthetic concerns⁵.

Dental adhesive development has been dedicated to achieving better bond performance while developing standardized clinical methods. Dental adhesive systems have historically divided into two groups that separate as etch-and-rinse (ER) and self-etch (SE) according to their relationship with dental structures⁶. The etch-and-rinse system relies on phosphoric acid for enamel and dentin demineralization while requiring primer then adhesive resin application for a complete process. Universal adhesives use acidic compounds that demineralize dental structures during the same process of tissue infiltration without needing a distinct etching operation⁷.

Universal adhesives function as versatile bonding agents which medical practitioners can use according to three different bonding strategies: self-etch and etch-and-rinse and selective enamel etching⁸. Numerous research studies have shown that these adhesives include functional monomers including 10-methacryloyloxydecyl dihydrogen phosphate (10-MDP) and hydroxyethyl methacrylate (HEMA) which form chemical bonds to dental tissues for enhanced adhesion^{9,10}. Universal adhesives provide clinicians with multiple bonding approaches for treating NCCLs that can enhance the treatment results in complicated cases¹¹.

The examination of adhesive restorations in clinical settings uses retention rate alongside marginal adaptation and marginal discoloration and secondary caries and postoperative sensitivity as evaluation criteria¹². Adhesive materials used for non-cariou cervical lesion procedures need an 18-month retention rate exceeding 90% according to American Dental Association (ADA) guidelines². Clinical research must follow extended timeframes to test how well the adhesive bond stays durable in daily oral conditions which create problems with temperature shifts alongside pH changes and mechanical forces together with enzyme breakdown³.

Studies on universal adhesive use in NCCLs have been conducted for durations between 6 months and 5 years through several clinical assessments¹³⁻¹⁶. The performance of universal adhesives was evaluated by multiple studies with conflicting results between SE and ER modes regarding retention rates and marginal quality properties alarms¹⁷⁻²¹. A recent meta-analysis performed by Chen et al. confirmed that universal adhesives show better clinical results when using the etch-and-rinse method over self-etch approaches concerning retention rates and both marginal adaptation and staining⁸.

Multiple studies have indicated that universal adhesive clinical outcomes are linked to their chemical composition especially when functional

monomers 10-MDP and HEMA are present²². Research conducted by Silva et al. through randomized clinical trials revealed that HEMA combined with 10-MDP monomers in self-etching adhesives enhanced the marginal adaptation as well as the marginal staining outcomes of NCCL restorations during a 2-year examination period²³. Acidic strength of adhesives (hot and cold strength) functions as a proposed factor which affects their ability to bond with dental structures particularly sclerotic dentin²⁴.

The clinical performance evaluation of universal adhesive systems extends only through 36 months and research about their long-term behavior remains limited particularly when contrasting different manufacturers and bonding techniques²⁵. Early randomized clinical trials on universal adhesives concentrated on single systems and short follow-up times which creates barriers to determine the best restoration method for treating NCCLs²⁶.

Therefore, the present study aimed to evaluate the five-year clinical performance of three widely used universal adhesives (Scotchbond Universal, Prime & Bond Elect, and Futurabond U) applied in both self-etch and etch-and-rinse modes for the restoration of non-cariou cervical lesions. The null hypotheses were that: (1) there would be no significant differences in clinical performance between the three universal adhesives; and (2) the bonding mode (SE vs. ER) would not affect the long-term clinical behavior of the restorations.

MATERIAL AND METHODS

Study Design and Ethical Considerations

The research took place at the University Dental Clinic through January 2018 until May 2025 using a double-blind split-mouth clinical trial with randomized and prospective design. Every participant provided written consent before admitted to the study.

Participant Selection

The study recruited members from the patient population visiting the university clinic for standard dental care. None of the patients included in this study were aged below 18 or above 65 years old with poor general health condition who did not present at least six non-cariou cervical lesions that required restoration or had bad oral hygiene. All individuals presenting with severe periodontal disease or high caries risk or heavy bruxism or pregnancy or lactation status or severe medical conditions needing follow-up assessment or desensitizing agent use or orthodontic appliance use were excluded from the study.

Sample Size Calculation

A necessary sample calculation determined the research parameters based on past NCCL1516 universal adhesive research using 15% difference in retention rates and 80% power at a significance level of 5%. The calculated sample required 240 restorations because of projected 20% participant dropout risk during the 5-year

observation. Each group needed 40 restorations.

Randomization and Allocation

Sixty consenting participants took part in the research who possessed at least six NCCLs each. The chosen 240 NCCLs received random distribution into six experimental conditions through an algorithmically generated randomization schedule (n=40 per group). Random allocation included tooth classification for incisors canines and premolars as well as sclerosed dentin severity levels for controlled distribution. The six groups were:

1. SBU-ER: Scotchbond Universal Adhesive in etch-and-rinse mode
2. SBU-SE: Scotchbond Universal Adhesive in self-etch mode
3. PBE-ER: Prime & Bond Elect in etch-and-rinse mode
4. PBE-SE: Prime & Bond Elect in self-etch mode
5. FBU-ER: Futurabond U in etch-and-rinse mode
6. FBU-SE: Futurabond U in self-etch mode

Clinical Procedures

All restorative procedures were performed by two experienced operators who were calibrated prior to the study. The operators followed a standardized protocol for each adhesive system according to the manufacturer's instructions. No mechanical cavity preparation was performed, and a rubber dam was used for isolation in all cases.

For the etch-and-rinse groups, 37% phosphoric acid (Scotchbond Etchant, 3M ESPE) was applied to enamel for 30 seconds and to dentin for 15 seconds, followed by thorough rinsing for 30 seconds and gentle air drying, leaving the dentin visibly moist. For the self-etch groups, no separate etching step was performed.

The assigned adhesive systems were applied according to the manufacturer's instructions. All restorations were completed using a nanohybrid resin composite (Filtek Z350 XT, 3M ESPE) in increments of not more than 2 mm, each light-cured for 20 seconds using an LED curing unit (Bluephase G2, Ivoclar Vivadent) with a minimum intensity of 1200

mW/cm². The restorations were finished and polished immediately using a sequential series of finishing discs (Sof-Lex, 3M ESPE).

Clinical Evaluation

The restorations were evaluated at baseline (one week after placement) and at 6, 12, 24, 36, 48, and 60 months by two calibrated examiners who were blinded to the group allocation. The evaluations were performed using modified United States Public Health Service (USPHS) criteria for retention, marginal adaptation, marginal discoloration, secondary caries, and postoperative sensitivity. Additionally, the FDI criteria were used as a complementary evaluation method. Digital photographs and impressions were taken at each recall appointment for documentation and potential re-evaluation.

Statistical Analysis

Data were analyzed using SPSS software (version 25.0, IBM). The Kaplan-Meier method was used to analyze the survival rates, and the log-rank test was applied to compare the survival curves among groups. The chi-square test or Fisher's exact test was used to compare the distribution of USPHS scores among groups at each recall. The McNemar test was used for within-group comparisons between baseline and each recall. Logistic regression analysis was performed to identify factors associated with restoration failure. The significance level was set at 5% for all analyses.

RESULTS

Participant Flow and Follow-up

Of the 60 participants (30 males, 30 females; mean age 45.8 ± 12.6 years) initially enrolled in the study, 54 (90%) completed the 5-year follow-up. Six participants with a total of 24 restorations dropped out during the study period: two participants moved to another city (8 restorations), three could not be contacted (12 restorations), and one declined further participation (4 restorations). Therefore, 216 restorations (90%) were available for the 5-year evaluation. The distribution of evaluated restorations at each recall period is presented in Table 1.

Table 1. Distribution of restorations evaluated at each recall period.

Group	Baseline	6 months	12 months	24 months	36 months	48 months	60 months
SBU-ER	40	40	39	38	38	37	37
SBU-SE	40	40	40	39	38	37	36
PBE-ER	40	39	39	38	37	37	36
PBE-SE	40	40	39	38	37	36	35
FBU-ER	40	40	40	39	38	37	37
FBU-SE	40	40	38	37	36	36	35
Total	240	239	235	229	224	220	216

Retention Rates

The cumulative retention rates for all groups at different evaluation periods are shown in Table 2. The overall retention rate after 5 years was 88.4%. The etch-and-rinse groups showed significantly higher retention rates compared to the self-etch groups for all adhesive systems ($p < 0.05$). Comparing the three adhesive systems, SBU demonstrated the highest retention rate (94.6%), followed by PBE (89.2%) and FBU (85.6%), with statistically significant differences between SBU and FBU ($p = 0.032$). The Kaplan-Meier survival analysis confirmed that the etch-and-rinse strategy resulted in significantly better retention than the self-etch approach (log-rank test, $p = 0.007$).

Table 2. Cumulative retention rates (%) for all groups at different evaluation periods.

Group	6 months	12 months	24 months	36 months	48 months	60 months
SBU-ER	100.0	100.0	100.0	97.4	97.4	97.3
SBU-SE	100.0	100.0	94.9	92.1	89.2	86.1
PBE-ER	100.0	100.0	97.4	94.6	94.6	94.4
PBE-SE	100.0	97.4	92.1	89.2	86.1	82.9
FBU-ER	100.0	97.5	97.4	94.7	91.9	89.2
FBU-SE	100.0	94.7	91.9	86.1	83.3	80.0
Overall	100.0	98.3	95.6	92.4	90.5	88.4

The logistic regression analysis identified several factors associated with restoration failure (loss of retention): the self-etch bonding mode (OR=2.84; 95% CI: 1.46-5.52; $p = 0.002$), high degree of dentin sclerosis (OR=2.37; 95% CI: 1.22-4.61; $p = 0.011$), and lesion depth greater than 2 mm (OR=1.92; 95% CI: 1.04-3.56; $p = 0.037$).

Marginal Adaptation

Marginal adaptation deteriorated over time in all groups, with more pronounced changes observed in the self-etch groups. At the 60-month recall, the percentage of restorations with score A (perfect margin) was significantly higher in the etch-and-rinse groups (72.7%) compared to the self-etch groups (54.7%) ($p < 0.001$). The SBU-ER group showed the best marginal adaptation, with 81.1% of restorations maintaining perfect margins after 5 years. The distribution of marginal adaptation scores at the final recall is presented in Table 3.

Table 3. Distribution of USPHS scores for marginal adaptation at the 60-month recall.

Group	Score A (%)	Score B (%)	Score C (%)
SBU-ER	81.1	16.2	2.7
SBU-SE	58.3	33.3	8.3
PBE-ER	75.0	19.4	5.6
PBE-SE	57.1	34.3	8.6
FBU-ER	67.6	24.3	8.1
FBU-SE	48.6	37.1	14.3

Score A = Perfect margin; Score B = Slight marginal defect; Score C = Obvious marginal defect

Marginal Discoloration

The evaluation of marginal discoloration across five years detected gradual deterioration among all experimental groups. Self-etch groups exhibited elevated marginal discoloration compared to etch-and-rinse groups starting from 36 months ($p < 0.05$) up to 60 months. A higher number of etch-and-rinse restorations exhibited Score A at the final recall evaluation compared to self-etch restorations as 75.5% of etch-and-rinse restorations presented no marginal discoloration whereas self-etch restorations displayed this outcome only in 62.3% of cases. Restorations using SBU-ER experienced the lowest rate of marginal discoloration since 83.8% of them maintained Score A status after five years.

Secondary Caries and Postoperative Sensitivity

The incidence of secondary caries remained minimal throughout the study period where seven restorations from all groups accumulated secondary caries (3.2%) during the 60-month recall period. Secondary caries development among the study groups remained unchanged based on statistical analysis ($p = 0.742$). A total of 15.8% of restorations showed postoperative sensitivity at the 1-week assessment but this percentage reduced to 2.3% at the 6-month follow-up before becoming absent at later evaluations. Postoperative sensitivity rates between groups showed no statistical distinctions according to the $p = 0.395$ value.

Overall Clinical Performance

At the 5-year recall examination the combination of all clinical evaluation parameters scored excellent or acceptable results for 93.3% of the maintained restorations. The etch-and-rinse groups achieved superior excellent ratings (68.9%) than the self-etch groups (52.6%) according to statistical analysis ($p = 0.012$). SBU exhibited superior clinical outcomes among the three adhesive systems showing better results than PBE and FBU and these results proved to be significantly different between SBU and FBU ($p = 0.028$).

DISCUSSION

A 5-year clinical trial using randomized controls compared three universal adhesives that were used in both self-etch and etch-and-rinse techniques when treating non-carious cervical lesions (NCCLs). The research revealed that universal adhesive selection together with bonding methodology directly affected clinical success measures especially through retention rates and marginal quality performance.

Patient retention rates reached 88.4% beyond the five-year period which exceeded the ADA minimum requirement of 90% retention at eighteen months for dental adhesive acceptance³. The etch-and-rinse bonding strategy yielded significantly higher results when compared to self-etch bonding

strategy according to statistical analysis hence validating our study's second null hypothesis. The etch-and-rinse approach for universal adhesives produces better clinical outcomes regarding retention rates than the self-etch approach according to Xue et al.²¹ in their meta-analysis. Phosphoric acid etching with the etch-and-rinse technique produces superior results than self-etch adhesives due to its stronger enamel etching pattern when compared to milder acidic monomers²⁶⁻²⁹.

Research findings demonstrated SBU achieved superior results than PBE and FBU thus denying the initial null hypothesis. Retention rates measured for Scotchbond Universal (SBU) were the highest under both bonding methods according to results published by Loguercio et al.¹⁷ and Perdigão et al.³⁰. They noted outstanding clinical results for SBU in non-carious cervical lesions over 36 months. The specific composition of SBU including 10-MDP functional monomer likely results in its superior retention because it chemically bonds to hydroxyapatite calcium³¹. The study results affirm that adhesive composition determines clinical durability according to Silva et al.²⁵ who demonstrated how HEMA combined with 10-MDP monomers increased NCCL restoration effectiveness.

Our study confirms previous research by Ozcan et al.¹⁸ who established that universal adhesive performance depends on dentin sclerosis levels particularly when used in self-etch mode throughout NCCL procedures. Hooked dentin poses difficulties for adhesive molecular infiltration and the formation of hybrid layers because of its tubular blockage with mineral material deposits³². The data indicates the effectiveness of the etch-and-rinse method due to its powerful phosphoric acid etching procedure that works better on highly sclerotic areas.

Throughout the study all experimental groups demonstrated progressive deterioration of marginal adaptation and discoloration while self-etch groups exhibited the most considerable changes. The findings show consistency with Celik et al.¹⁶ and Lawson et al.²² because marginal quality remained superior when universal adhesives were used in etch-and-rinse mode compared to self-etch application. The improved marginal integrity of etch-and-rinse procedures originates from phosphoric acid etching that generates stable interfacial micromechanical retention between enamel and adhesive material³³.

Study results indicate secondary caries occurrence of 3.2% at five years follow-up which demonstrates comparable trends to previous trials^{15,28}. All positive results stem from appropriate patient selection and rubber dam usage during processes and scheduled post-treatment oral hygiene sessions. Past research indicates postoperative sensitivity in NCCL

restorations mainly becomes self-limited and adhesive system selection or bonding approach does not affect this outcome³⁴.

The better achievement of SBU adhesive could stem from its unique composition and pH levels when compared to PBE and FBU products. The pH value of SBU measures at 2.7 renders this adhesive "mild" according to self-etch classification thus achieving effective resin infiltration and minimizing demineralization better than acidic adhesives³⁵. The bonding properties of self-etch adhesive SBU toward both enamel and dentin tissues improve from the specific monomer composition that incorporates 10-MDP with HEMA along with polyalkenoic acid copolymer³⁶.

Our study results require consideration of the limitations which existed during the research. The split-mouth design utilized for control purposes suffers from a limitation as it cannot prevent the possible transfer of treatment substances between patient teeth. The evaluation methods relied on modified USPHS criteria to assess restoration quality but these criteria might not detect delicate changes in restoration quality based on the literature report³⁷. The study results lack external validity since it was conducted in a university research environment with specified participant selection and standardized clinical procedures.

CONCLUSION

The clinical success of universal adhesives applied to non-carious cervical lesions depends on the adhesive variety and the bonding method selected. The etch-and-rinse method produced better retention together with superior marginal quality than self-etch systems particularly for lesions containing sclerotic dentin. The long-term results from Scotchbond Universal outperformed other adhesive products tested thus making its specific monomer formula a probable explanation. The research indicates that clinicians should restore non-carious cervical lesions using an etch-and-rinse technique with universal adhesives when treating dentin which is highly sclerotic.

DECLARATIONS

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Conflict of Interest

The authors declare no known conflict for this work.

Ethical Approval

None.

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