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Clinical Evaluation of Self-etch and Total-etch Adhesive Systems in Noncarious Cervical Lesions: A Two-year Report

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Clinical Relevance

This two-year clinical trial evaluated three adhesive systems to restore noncarious cervical lesions with composite resin restorations. No significant differences were observed between restorations bonded with a one-bottle total-etch, a one-bottle self-etch, or a two-bottle self-etch adhesive.

SUMMARY

Objective: The purpose of this study was to compare the clinical performance of two self-etch dental adhesives with Single Bond Plus, a traditional one-bottle total-etch dental adhesive, for the restoration of noncarious cervical lesions.

Materials and Methods: A total of 156 restorations were placed in noncarious cervical lesions with a minimum depth of 1.5 mm. Patients had no chronic periodontal disease and had normal salivary function. Each patient received restorations on three teeth, each bonded with either Adper Single Bond Plus, Adper Easy Bond, or Adper Scotchbond SE dental adhesive. All lesions were restored with Filtek Supreme Plus composite resin. All teeth were isolated with a rubber dam, received a short enamel bevel, and were cleaned with flour of pumice. The adhesives and resin composite were applied following the manufacturers' instructions. Restorations were clinically evaluated at baseline, six months, one

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year, and two years using modified US Public Health Service criteria.

Results: Two-year retention was recorded as 97.3%, 90.5%, and 95.2%, for Single Bond Plus, Scotchbond SE, and Easy Bond, respectively. Statistical analysis did not show a significant difference ($p>0.05$) in clinical performance between any of the three adhesives after a period of two years.

INTRODUCTION

Noncarious cervical lesions (NCCLs) are slowly progressing clinical conditions with multiple etiologies that offer unique challenges to adequate dental restoration.[1-3] The incidence of NCCLs ranges from 5% to 85%, and the number, size, and depth of the lesions increase with patient age.[4] The main etiologies of NCCLs are abrasion, erosion, or abfraction. Although many authors claim a single etiology for these lesions, their pathogeneses appear to be multifactorial.[5-8] Treatment for NCCLs may include restorations, occlusal adjustment, and oral hygiene instructions.[9] Primary indications for treating NCCL are sensitivity, esthetics, plaque retention, and the need for the affected tooth to abut a removable partial denture.[9,10] It has been suggested that restoring NCCLs may reduce tooth flexure during occlusal load, thereby strengthening the teeth and perhaps slowing the progression of the NCCLs.[11] To preserve tooth structure, NCCLs are generally restored with tooth-colored materials, such as resin composite, glass ionomer, or compomer. Of these materials, resin composites are used most often because of their excellent esthetic and physical properties.

The success of composite resin Class V restorations depends in large part on the properties of the bonding agent used. Residual stress resulting from polymerization shrinkage and long-term durability may be affected by external factors, such as multidirectional loading during mastication, thermal stress by cold and hot stimuli, and wear from tooth brushing.[12-15] In particular, repetitive compressive and tensile stresses caused by tooth flexure in cervical lesions can contribute to restoration loss.[16,17] In addition, the surface of NCCLs typically consists of sclerotic dentin, which is resistant to acid etching due to hypermineralized intertubular and peritubular dentin and may prevent maximum adhesion.[18]

In the evolution of adhesive technology from one generation to the next, the impetus has been to improve bond strength while simplifying application procedures. The first clinically successful bonding agents had separate conditioning, priming, and bonding steps. Most modern adhesives combine these functions into one or two bottles. Although many simplified adhesives perform adequately in laboratory studies compared with their traditional multistep counterparts,[19-23] simplified systems generally display poor clinical performances.[24] Clinical trials are necessary to verify laboratory results and to evaluate long-term adhesive performance.

The aim of this prospective randomized controlled clinical trial was to evaluate the performance of a one-bottle self-etch adhesive, a two-bottle self-etch adhesive, and a well-established one-bottle total-etch adhesive in Class V resin-based composite restorations on NCCLs over two years. The null hypothesis was that the total-etch adhesive would provide better clinical performance than the self-etch adhesives.

METHODS AND MATERIALS

Fifty-two patients were recruited from subjects attending the BioHorizons Research Clinic at the University of Alabama at Birmingham. The local Institutional Review Board approved the clinical trial protocol, and all subjects gave informed consent by signing a consent form. During the screening examination, inclusion and exclusion criteria were used to evaluate acceptable subjects (Table 1). The procedure was thoroughly explained to each patient and their questions were answered. Each patient had at least three NCCLs with at least a 1.5-mm depth measured by a periodontal probe. Each patient received three Filtek Supreme Plus (3M ESPE, St Paul, MN, USA) restorations bonded with Adper Single Bond Plus, Adper Scotchbond SE, and Adper Easy Bond (3M ESPE). The adhesive materials, compositions, and mode of application are described in Table 2.

Restoration Procedure

All lesions were restored following protocol by two calibrated and experienced investigators. Each patient received three restorations, and each tooth was randomly assigned an adhesive for a total of 156 restorations.

The teeth were cleaned with flour of pumice and a prophylaxis cup (Whip Mix Corporation, Louisville, KY, USA) followed by rinsing and drying. Shade selection was performed using the Vita shade guide to select the appropriate Filtek Supreme Plus resin

Table 1: *Inclusion and Exclusion Criteria*

Inclusion Criteria	Exclusion Criteria
• Is aged 19 years and older	• Is taking part in an evaluation of other restorative materials/ systems
• Has a minimum of three noncarious Class V lesions >1.5 mm in depth	• Does not have three noncarious lesions or the lesions are <1.5 mm deep
• Is a regular dental attendee who is able to return for assessments	• Is not able to tolerate the time required to place the restorations
• Is in good medical health and able to tolerate the dental procedure	• Has a history of adverse reaction to any materials used in the study
• Does not have rampant caries	• Is an irregular dental attendee
• Does not have chronic periodontitis or carious lesions	• Maintains an unacceptable standard of oral hygiene
• Is able to tolerate the dental procedure	• Has chronic periodontitis or rampant caries
• Has normal salivary function	• Has severe salivary gland dysfunction
	• Is unable to return for recall appointments

Table 2: *Adhesives and Composite Used in the Study*

Materials	Classification	Composition	Application
Adper Single Bond Plus	Ethanol/water-based, one-bottle, etch-and-rinse adhesive	Scotchbond acid: 37%; Phosphoric acid adhesive: silica nanofiller, Bis-GMA, HEMA, dimethacrylates, ethanol, water, copolymer (polyacrylic-polyitaconic acids), camphorquinone	a) Acid-etch for 15 s; b) Rinse for 15 s; c) Air-dry for 30 s; d) Leave dentin visibly moist; e) Apply two coats of adhesive for 10 s; f) Air-dry for 10 s at 20 cm; g) Light-cure for 10 s
Adper Scotchbond SE	Water-based, two-bottle, self-etch adhesive	Liquid A: water, HEMA, rose bengal dye; Liquid B: UDMA, TEGDMA, TMPTMA, HEMA; phosphate, MHP, zirconia nanofiller, camphorquinone	a) Apply liquid A; b) Apply liquid B on top for 20 s; c) Air-dry 10 s; d) Apply another coat of liquid B; e) Air thin; f) Light-cure for 10 s
Adper Easy Bond	Ethanol/water-based, one-bottle, self-etch adhesive	Silica nanofiller, HEMA, Bis-GMA, methacrylated phosphoric esters, dimethacrylate, polyalkenoic acid, ethanol, water, camphorquinone	a) Apply two coats of adhesive for 20 s; b) Air thin for 5 s; c) Light-cure for 10 s
Filtek Supreme Plus	Nanocomposite	Silica/zirconia filler: non-agglomerated/non-aggregated nanosilica filler and loosely bound agglomerated zirconia/silica nanocluster, consisting of agglomerates of primary zirconia/ silica particles; Matrix: Bis-GMA, Bis-EMA, UDMA, TEGDMA	a) Use incremental placement (dentin shade <1.5 mm, others <2 mm each layer); b) Light-cure 40 s for dentin shade and 20 s for others

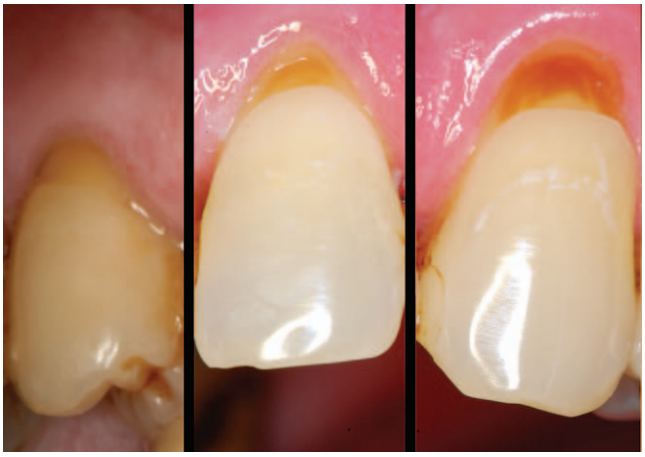

Figure 1. *Preoperative NCCLs on teeth #4, #5, and #12 from left to right.*

shade. After providing local anesthesia, the teeth were isolated using a rubber dam and appropriate retainers. A 0.5-mm bevel was prepared on the occlusal margin of the lesion on the enamel using an OS 2 bur (Brasseler USA, Savannah, GA, USA). The order of the adhesives was determined by drawing slips from a box containing the names of the three adhesives. Starting with the lowest numbered tooth, the adhesives were applied in the order drawn. The assigned adhesive was applied to the lesion following the manufacturer's instructions (Table 1). Filtek Supreme Plus Restoratives were placed according to manufacturer's instructions and cured using a G Light (GC America, Chicago, IL, USA). The output of the curing light was assessed daily using a LASER power meter (FieldMate, Coherent Inc, Santa Clara, CA, USA) to ensure proper output (>700 mW/cm^2). The restorations were finished and polished using an

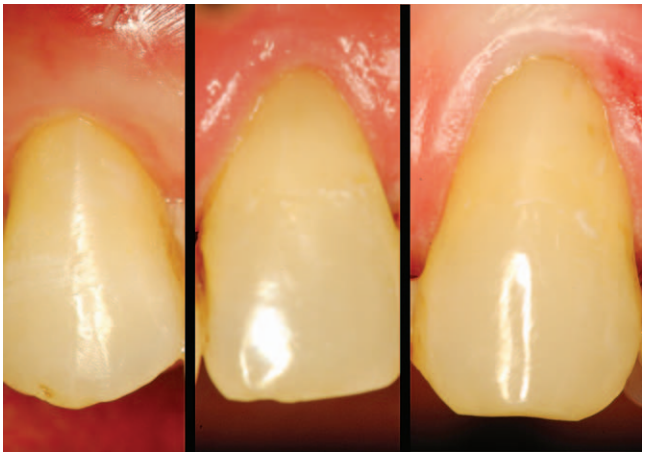

Figure 2. *Class V restorations at baseline on teeth #4 (Scotchbond SE), #5 (Easy Bond), and #12 (Single Bond Plus) from left to right.*

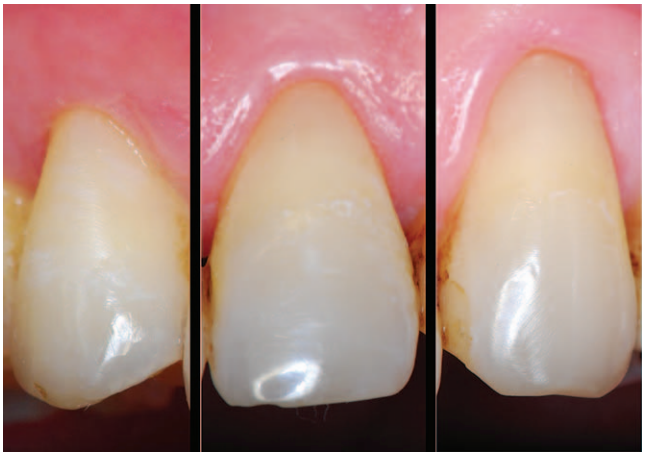

Figure 3. *Class V restoration at the six-month follow-up on teeth #4 (Scotchbond SE), #5 (Easy Bond), and #12 (Single Bond Plus) from left to right.*

established protocol with 7901 and OS 2 finishing burs (Brasseler USA), Enhance Finishing, and PoGo Polishing Systems (Dentsply/Caulk, Milford, MA, USA). Digital images of the lesions were taken before and after preparation at baseline and at the six-month, one-year, and two-year recall visits. Figures 1 through 5 show NCCLs and the Class V restorations in a subject at before the procedure, at baseline, and at the six-month, one-year, and two-year recall visits.

Clinical Evaluation

Two calibrated examiners evaluated the restorations at one week (baseline), six months, one year, and two years. The examiners and the subjects were blind to which adhesive was used for each of the restorations. The restorations were evaluated using a modified US

Figure 4. *Class V restoration at the 12-month follow-up on teeth #4 (Scotchbond SE), #5 (Easy Bond), and #12 (Single Bond Plus) from left to right.*

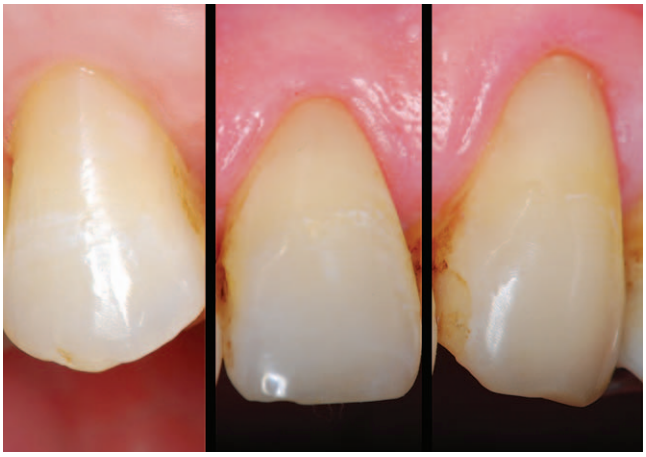

Figure 5. *Class V restoration at the 24-month follow-up on teeth #4 (Scotchbond SE), #5 (Easy Bond), and #12 (Single Bond Plus) from left to right.*

Public Health Service[25] criteria adapted by Loguercio and others[26] and Barnes and others.[27] In the event that the examiners differed in their evaluation outcome, a consensus was reached before the subject was dismissed.

Clinical evaluation of each restoration was performed with magnification, a mouth mirror, an explorer, and a periodontal probe. Retention, anatomic form, marginal discoloration, marginal integrity, surface roughness, color match, and staining were all measured on a three-tiered scale: alpha, bravo, and charlie. Secondary caries was measured using a two-tiered scale: alpha and charlie. Endo ice (Coltene/Whaledent, Cuyahoga Falls, OH, USA) was used to assess postoperative thermal sensitivity. Endo ice was applied to a cotton pellet that was placed on the restoration for three seconds; the patient was then asked to indicate their pain level from on a scale from 1 to 10, with 1 representing no pain and 10 representing the worst pain they could imagine (eg, childbirth, kidney stones, major surgery). Then the gingival index around the restorations was recorded using the criteria of Loe and Silness and ranked 0-3.[28]

Statistical Analysis

Descriptive statistics were used to describe the frequency distribution of the evaluated criteria. The difference in performance of the three adhesives was assessed at the baseline and after each recall visit (six months, one year, and two years) by the McNemar's test (α=0.05). Postoperative pain level was evaluated by a paired *t*-test (α=0.05). The Friedman test was used to compare the gingival index around each restoration followed by the paired sign post-hoc test (α=0.05).

Table 3: *Restorations Distribution With Different Adhesives*

Materials	Anterior	Premolar	Molar	Total
Adper Single Bond Plus	18	28	7	52
Adper Scotchbond SE	17	29	5	52
Adper Easy Bond	16	30	6	52
Total number of restorations	51	87	18	156

RESULTS

Table 3 shows the distribution of restorations in anterior, premolar, and molar teeth. The table shows that the restorations were placed mostly on premolars and distributed evenly. Of the 156 restorations at baseline, 96%, 83%, and 75% were available for assessment at six months, one year, and two years, respectively. Recall percentage was computed based on the number of observations recorded at each time interval as a percentage of total observations evaluated at baseline. Retention of the restorations was 97%, 90%, and 95% for Single Bond Plus, Scotchbond SE, and Easy Bond, respectively at two years (Table 3).

Nominal variables (retention, anatomic form, marginal discoloration, marginal integrity, surface roughness, color match and staining, secondary caries) were analyzed with McNemar's test for correlated proportions (Table 4). Because of the relatively small numbers of Bravo and Charlie ratings, the scale was modified to "A" and "not A" (NA). Counts of two case/control discordant combinations—A/NA and NA/A—were determined for each nominal variable using the outcome matched by the patient. Three separate analyses were used to compare the outcomes between each material investigated. Because of the small numbers of discordant cells, the normal approximation of the binomial distribution could not be used, and the *p* values were determined using the exact binomial probability. The alpha level was set at a Bonferroni-adjusted level of 0.0166. The null hypothesis for testing these parameters was that the same number of discordant combinations was equally likely (p=0.5) for each pair of materials tested. Analysis of each nominal

Table 4: *Nominal Variables (% Alpha) for Each Adhesive*

	% Alpha			Exact Binomial *P*-value		
	Easy Bond	**Scotchbond SE**	**Single Bond Plus**	**Easy Bond vs Scotchbond SE**	**Easy Bond vs Single Bond SE**	**Single Bond vs Scotchbond SE**
Retention						
Baseline	100.00%	100.00%	100%	NA	NA	NA
6 mo	100.00%	98.08%	98.04%	NA	NA	1.0000
1 y	97.78%	93.33%	86.67%	0.0625	0.5000	0.3281
2 y	95.24%	90.48%	97.30%	NA	0.5000	0.7500
Anatomic form						
Baseline	92.59%	94.23%	94.44%	0.7500	0.7500	1.0000
6 mo	94.23%	96.15%	92.31%	0.6250	0.7500	0.5000
1 y	95.56%	95.45%	84.78%	0.1094	0.7500	0.2188
2 y	90.48%	87.50%	91.89%	0.7500	0.5000	0.5000
Color match						
Baseline	92.59%	94.34%	96.30%	0.5000	0.6250	0.7500
6 mo	94.23%	94.23%	90.38%	0.5000	0.7500	0.5000
1 y	91.30%	88.89%	86.67%	0.3125	0.4688	0.5469
2 y	90.70%	85.37%	92.11%	0.7500	0.1875	0.4375
Marginal integrity						
Baseline	98.15%	98.11%	98.15%	1.0000	1.0000	1.0000
6 mo	100.00%	94.23%	94.23%	0.2500	0.2500	0.7500
1 y	76.09%	68.89%	75.56%	0.3867	0.2417	0.3867
2 y	55.81%	63.41%	73.68%	0.1074	0.4375	0.2344
Marginal discoloration						
Baseline	100.00%	100.00%	100.00%	NA	NA	NA
6 mo	98.08%	96.15%	96.15%	0.7500	NA	0.7500

Table 4: *Nominal Variables (% Alpha) for Each Adhesive (cont.)*

	% Alpha			Exact Binomial *P*-value		
	Easy Bond	**Scotchbond SE**	**Single Bond Plus**	**Easy Bond vs Scotchbond SE**	**Easy Bond vs Single Bond SE**	**Single Bond vs Scotchbond SE**
1 y	91.11%	84.44%	84.09%	0.2188	0.3281	0.4102
2 y	76.74%	78.05%	78.95%	0.4512	0.5469	0.4922
Surface roughness						
Baseline	98.15%	100.00%	100.00%	NA	NA	NA
6 mo	96.15%	94.23%	98.08%	0.7500	0.7500	0.5000
1 y	82.61%	77.78%	84.44%	0.4922	0.3281	0.4102
2 y	30.23%	35.59%	39.47%	0.2500	0.5000	NA
Secondary caries						
Baseline	100.00%	100.00%	100.00%	NA	NA	NA
6 mo	100.00%	98.08%	98.08%	NA	NA	1.0000
1 y	95.56%	93.33%	93.33%	0.6250	0.5000	0.6250
2 y	95.35%	95.12%	97.37%	NA	0.7500	0.7500
Staining						
Baseline	100.00%	100.00%	98.15%	NA	NA	NA
6 mo	100.00%	98.08%	98.04%	NA	NA	1.0000
1 y	95.65%	93.33%	93.33%	0.6250	0.5000	0.6250
2 y	95.35%	95.12%	97.37%	NA	0.7500	0.7500

Abbreviation: NA, not A.

variable revealed no statistical difference at any time period between any two material combinations.

Pain in response to thermal stimulation was recorded using a visual analog scale for each tooth at each time interval, with 1 being no pain and 10 being severe pain. The null hypothesis was that there is no difference in pain between the materials tested. These data were analyzed for normality and equality of variance. Logarithmic transformation $\ln(x+1)$ was applied to stabilize the variance. A paired *t*-test was used to test each possible pair of mean values. The results are given in Figure 6. Statistically different mean pain values were noted at baseline and at one year between Easy Bond and Single Bond Plus, with Single Bond Plus showing the greater pain level ($p=0.0166$), but no statistical difference was observed at the six-month and two-year recall visits ($p>0.05$).

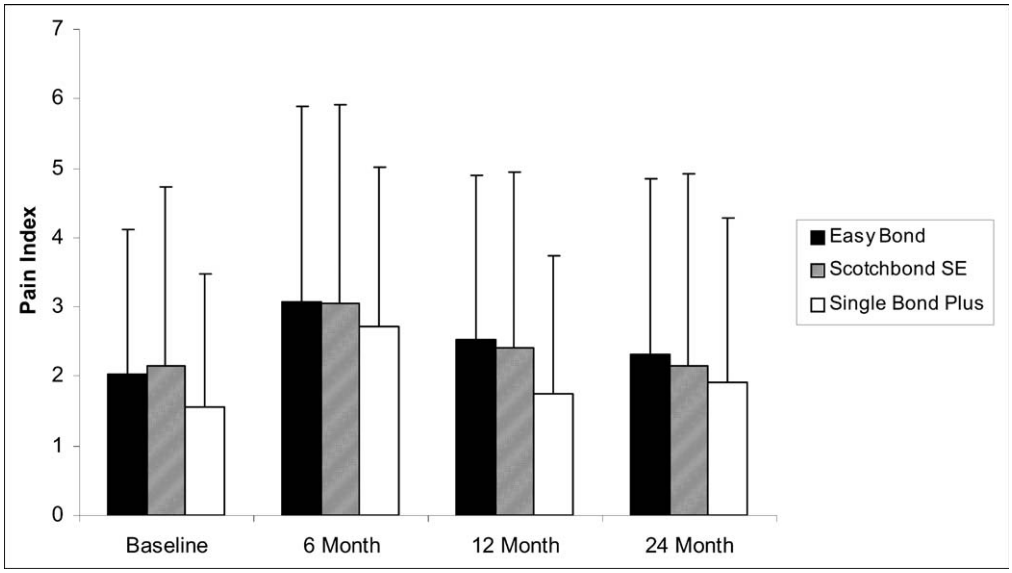

Figure 6. *Mean pain index for three adhesives at baseline and recall visits.*

Table 5: *Gingival Index (Median and Range) for Each Adhesive at Each Recall*

Time	Material	Gingival Index	
		Median	Range
Baseline	Easy Bond	0	0-1
	Scotchbond SE	0	0-1
	Single Bond Plus	0	0-1
6 mo	Easy Bond	0	0-2
	Scotchbond SE	0.5	0-2
	Single Bond Plus	0	0-1
1 y	Easy Bond	0	0-1
	Scotchbond SE	0	0-1
	Single Bond Plus	0	0-1
2 y	Easy Bond	1	0-1
	Scotchbond SE	1	0-2
	Single Bond Plus	1	0-1

The gingival index (Table 5) data were analyzed using Friedman's analysis of variance (ANOVA) at each time interval. At the two-year time point, Friedman's ANOVA was <0.05; therefore, each material combination was examined with a paired sign post-hoc test. No significant difference in gingival indices for any material combination was noted ($p=0.0166$).

DISCUSSION

This study used three adhesives (Single Bond Plus, Scotchbond SE, and Easy Bond) to bond composite resin (Filtek Supreme Plus) to three NCCLs in each patient. This prospective double-blind, randomized, controlled clinical trial was conducted to measure the clinical effectiveness of adhesive bonding resin on composite restorations in NCCLs. Regarding the clinical effectiveness of the adhesives at two years, no significant difference between the three adhesives was seen. Previous studies have reported, however, that three-step etch-and-rinse adhesives have superior clinical performance compared with simplified adhesives, especially if longer evaluation times are taken into consideration.[22,29-31]

In the current study, the restoration retention for Single Bond Plus, Scotchbond SE, and Easy Bond adhesives were 97%, 90%, and 95%, respectively, at two years, suggesting long-term durability. The guidelines for dentin and enamel adhesive materials put forth by the American Dental Association (ADA) suggest that the retention rate at six months must

be at least 95% for provisional acceptance, whereas the retention rate at 18 months must be at least 90% for full acceptance.[32] Although an 18-month recall was not performed in this study, the two-year data show that each of these adhesives fulfills the permanent adhesive acceptance criterion.

In a systematic review of adhesive clinical trials, Peumans and others[24] reported that although 79% of the two-step etch-and-rinse adhesives fulfilled the provisional acceptance of the ADA guidelines (95% retention at six months), only 51% fulfilled the full acceptance criterion (90% retention at 18 months). The suggested reasons for the inconsistent retention rate of two-step etch-and-rinse adhesives are their propensity to form an optimal hybrid layer and their tendency to leave more residual solvent in the adhesive layer, which can result in increased hydrolytic degradation over time.[33,34] In this study, each of the adhesives fulfilled the ADA guideline with 97% (Single Bond Plus), 90% (Scotchbond SE), and 95% (Easy Bond) retention at two years.

The ADA guideline for adhesives asks for less than 10% charlie for marginal integrity at 18 months.[35,36] In this study, the two-year data showed 3%, 5%, and 5% charlie scores in Single Bond Plus, Scotchbond SE, and Easy Bond, respectively. The adhesives used in this clinical trial also appear to meet the guidelines for marginal quality of composite resin restorations.

The current study compared three adhesives: a one-bottle self-etch adhesive, a two-bottle self-etch adhesive, and a two-bottle etch-and-rinse adhesive. Similar comparisons have previously been made in the laboratory, with the self-etch adhesives producing significantly lower bond strengths to enamel, but the results for dentin are not consistent.[37-44] In this clinical study the overall clinical performance did not differ between the three adhesives after two years. This suggests that the two-bottle self-etch adhesives used in this study may have potential for decalcifying NCCLs, thereby creating a clinically acceptable bond that withstands occlusal forces for two years as well as the one-bottle total-etch adhesive does, but a longer clinical study is needed to confirm this hypothesis.

In this study, the self-etch adhesives showed clinically acceptable retention rates (90% and 95% for Scotchbond SE and Easy Bond, respectively) at two years. Other studies have reported various retention rates for Class V restorations using self-etch adhesives. Friedl and others[45] and Van Dijken[46] reported retention rates of 84% and 79.8% for self-etch adhesives, after two years. On the other hand, Kim and others[47] reported a 100% retention rate for self-etch adhesives after 2 years. In a study similar to this clinical trial, Perdigão and others[48] reported retention rates similar to ours but their last follow-up was 18-months. They reported retention rates of 100%, 90.9% and 92.3% for restored NCCLs using Single Bond Plus, Scotchbond SE, and Easy Bond, respectively. In their clinical trial, the adhesives were applied in two coats and attention was paid to solvent removal before curing. The high retention rates in our study might be related to this careful two-coat application. Such a protocol would prevent the formation of a dry spot, which could produce an area without optimal hybridization and a lack of sufficient resin saturation in the upper hybrid layer.[31,49,50] Another reason for the high retention rate of self-etch may be attributed to the enamel bevel. The bevel may facilitate the self-etching effect of the adhesive on unground enamel which is somewhat resistant to etching.[51]

The retention for Single Bond Plus, Scotchbond SE, and Easy Bond at 24 months was 97%, 90%, and 95%, respectively. The lower retention value for Scotchbond SE might be due to being a water based adhesive, while the other two are ethanol based. This is supported by Carvalho and others who reported that a mixture of 35% 2-hydroxyethyl methacrylate (HEMA) in 65% ethanol produced greater resin infiltration than 35% HEMA in 65% water.[52] They determined that when the ethanol evaporated, there was less matrix collapse, allowing more HEMA to remain in the matrix, where it protected the collagen fibrils and strengthened the hybrid layer.[52]

CONCLUSION

Within the limitation of this study, the three adhesives tested presented acceptable clinical performance with no statistical differences between them in a two-year period. The null hypotheses that the total-etch adhesive would have better clinical performance was rejected. This study continues as longer-term evaluations will be performed to compare the long-term performance of these self-etch adhesives.

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Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature

or kind in any product, service, and/or company that is presented in this article.

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