Effect of an additional bonding resin on the five years performance of a universal adhesive: a randomized clinical trial

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Research Article

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Abstract

Objectives

To evaluate the effect of the application of an additional hydrophobic bonding resin on the clinical performance of a universal adhesive applied in etch-and-rinse (ER) or self-etch adhesive (SE) strategy in non-carious cervical lesions (NCCLs) after 5 years.

Materials and Methods

Scotchbond Universal Adhesive (3M Oral Care) was applied in 134 NCCLs of 39 subjects using different adhesive approaches: 3-step ER (3-ER), 2-step ER (2-ER), 2-step SE (2-SE), and 1-step SE (1-SE). An extra layer of a hydrophobic bonding resin was applied for groups 3-ER and 2-SE. All lesions were restored with Filtek Supreme XTE resin composite (3M Oral Care). Restorations were evaluated at baseline and at 5 years using the modified USPHS criteria. Mann-Whitney U and Wilcoxon tests were performed, and the survival rates (retention/fracture) were analyzed using Kaplan-Meier and Log-rank tests ($p < 0.05$).

Results

The recall rate was 66.7% at 5 years. The cumulative survival rate was 96.9% for 3-ER, 96.8% for 2-ER, 71.4% for 2-SE and 81.3% for 1-SE strategies. Log-rank-test was statistically significant ($p = 0.006$). Retention rates were 100% for both ER groups, 75% for 2-SE and 81.3% for 1-SE. At 5 years, 2- and 1-SE approaches showed similar retention rates, but lower than those for 3- and 2-ER. A significant decrease in retention rate was detected for 2-SE ($p = 0.007$) and 1-SE ($p = 0.014$) groups between baseline and 5 years. All groups, except 2-ER, showed an increase in marginal discoloration. This parameter was statistically significant difference between 2-ER and 1-SE ($p = 0.004$).

Conclusions

The addition of a hydrophobic bonding resin to the recommended application sequence of Scotchbond Universal Adhesive did not improve its clinical performance in NCCLs after 5 years. Higher retention rates were found when this adhesive was applied in ER mode.

Trial registration

This manuscript is a 5-year follow-up of a randomized clinical trial that started in 2012 when there was no strong recommendation for registration in clinicaltrials.gov. The results after 36 months of clinical service were previously published in this journal.

Introduction

The interest for more versatile materials, simpler and less technique-sensitive strategies has led manufacturers to develop dental adhesives that are more user-friendly [1–3]. The recent family of universal or multi-mode adhesives can be applied with different adhesion strategies according to the dentist´s personal preference: Etch-and-rinse (ER), self-etch (SE) or selective enamel etching [2, 4, 5]. The optional ER or SE application strategy has been made possible through the inclusion of hydrophilic specific carboxylate and/or phosphate functional monomers [2]. The most common functional monomer added to universal adhesives is 10-methacryloyloxydecyl dihydrogen phosphate (MDP), that has a proven potential to chemically interact with hydroxyapatite creating a nano-layered structure of MDP-Ca salts at the interface that appears to be hydrolytically stable and improves adhesion strength [6–7].

The first universal adhesive system launched into the market was Scotchbond Universal Adhesive. It is currently the most prevalent universal adhesive in the peer-reviewed literature [2–4, 8–10]. The adhesion mechanism of this adhesive is achieved by means of the incorporation of 10-MDP and also polyalkenoic acid copolymer that bonds chemically to $Ca2+$ in dentin hydroxyapatite [11, 12].

There is a consensus that previous etching of enamel improves the clinical performance of this adhesive as increases the micromechanical interlocking and enhances the chemical bonding potential of the functional acid monomer 10-MDP [4, 10, 13, 14]. Conversely, in dentin, two recent meta-analysis conclude that the bond strength and sealing ability of universal adhesives seem not to be influenced by the adhesion strategy, ER or SE [8, 15]. The bonding mechanism of these adhesives used in ER strategy would be mainly micromechanical as calcium depletion would hamper its interaction with 10-MDP and polyalkenoic acid copolymer [5]. However, in medium and long-term clinical trials performed on NCCLs, the application of Scotchbond Universal Adhesive in ER or selective enamel etching approach provides more predictable retention [16–19], although more long-term studies are warranted.

Moreover, universal adhesives were simplified by incorporating hydrophilic monomers, such as HEMA (15–25%) in the case of Scotchbond Universal, and water as solvent, and by removing the final hydrophobic resin layer of traditional adhesives [20]. These modifications make adhesive-dentin interfaces prone to hydrolytic degradation over time [21, 22] regardless of the adhesive strategy used. Therefore, the addition of a non-solvated hydrophobic resin coating has been proposed to decrease the relative concentration of retained solvents and unreacted monomers in the adhesive layer [23] and increasing the polymerization efficiency [24]. Also, this extra layer of adhesive would avoid water ingress from dentin tubules and water sorption from oral environment improving the long-term durability of the adhesive interface [25, 26]. This application protocol has been tested in several laboratory studies with favorable results in dentin for both, ER and SE adhesion strategies [24, 27–29], even after 18 months of water aging [20], although aging stability could be material dependent [30]. Accordingly, several manufacturers have recently launched universal adhesives that include a last hydrophobic bonding resin, turning the 2-ER mode into 3-ER one and the 1-SE mode into a 2-SE mode.

Nevertheless, information regarding the clinical effectiveness of this additional hydrophobic adhesive layer is scarce and controversial [26, 31] and, specifically for Scotchbond Universal, this benefit was not confirmed in NCCLs after 36 months of clinical performance [18].

Therefore, the aim of this randomized clinical study was to evaluate the effect of the application of an additional hydrophobic bonding resin on the clinical performance of the Scotchbond Universal Adhesive applied in ER or SE strategy in NCCLs after 5 years. The null hypothesis to be tested is that adding an extra step of a hydrophobic bonding resin to the recommended application sequence of a universal adhesive would not improve the respective clinical performance after 5 years in NCCLs regardless of the adhesion strategy.

Materials And Methods

Study design and subject selection

This randomized parallel clinical trial began in May 2012 and the evaluation period concluded in November 2019. The CONSORT guidelines were followed as far as possible. All the interventions were performed in the dental clinic of the Fundación Rey Juan Carlos University (Madrid, Spain).

Once the research protocol was approved by the Ethics Committee of Rey Juan Carlos University, the subjects participating in the study signed a specific written informed consent, which had been previously endorsed by the same organism. Based on pre-established criteria, 39 volunteers with ages ranging from 27 to 77 (average 52.4) were selected for this study (Table 1).

Table 1
Distribution of participants and restorations according to the sex and age group of the participants.

Characteristics of subjects	Number of lesions
Gender distribution	
Male	14
Female	25
Age distribution (years)	
20–29	3
30–39	6
40–49	10
50–59	13
60–69	6
> 70	1

Inclusion criteria included at least two NCCLs that required restoration in individuals who were at least 18 years old and had a minimum of 20 teeth under occlusion. Exclusion criteria considered oral situations like poor oral hygiene, uncontrolled caries and/or periodontal disease, xerostomia, severe bruxism, undergoing bleaching or orthodontic treatment, non-vital, fractured or supporting teeth for fixed or removable prostheses, and teeth that had undergone periodontal surgery in the preceding three months. General health status was also contemplated so potential candidates with serious medical problems, known allergy to resin-based materials, pregnant or breast feeding were also discarded. Thus, twenty-eight persons were excluded as they did not match the inclusion criteria (Fig. 1).

The randomization process within subject was performed by assigning a number from 1 to 4 to each NCCL and then asking each patient to pick a piece of paper from an opaque envelope, containing numbers from 1 to 4, corresponding to 4 different adhesive approaches. This process was carried out by a volunteer not involved with the study and kept all subjects blinded to group assignation. However, the operators could not be blinded to this information to ensure the proper application of the materials.

Restorative procedures

Before starting the restorative procedures, the characteristics of the NCCLs were recorded. The NCCL dimensions in mm (height, width, and depth) were determined with a periodontal probe PCP 12 and the angle of the cavity was registered from a proximal view, classifying the respective geometry into four groups (< 45°, 45°-90°, 90°-135°, > 135°) (Table 2). The degree of dentinal sclerosis was evaluated according to the UNC dentin sclerosis scale (Swift et al., 2001) and the presence of attrition facets was also recorded. Afterwards, clinical photographs of the teeth to be restored were taken (Nikon D80 camera and a 105-mm Micro-Nikkor lens, Nikon USA, Melville, NY, USA).

Table 2 Distribution of the restorations according to the tooth type, characteristics of the NCCLs and adhesion strategy.

Characteristics of NCCLs		Number of lesions				
		Adhesive strategy				Total
		3-ER	2-ER	2-SE	1-SE	
Tooth	Upper canine	1	2	0	3	6
	Lower canine	1	1	0	0	2
	Upper premolar	15	14	11	11	51
	Lower premolar	11	10	14	15	50
	Upper molar	4	5	3	4	16
	Lower molar	2	2	3	2	9
Degree of sclerotic dentin	None	17	9	17	15	58
	Less than 50%	13	19	10	13	55
	More than 50%	1	5	4	6	16
	Present	3	1	0	1	5
Shape (degree of angle)	<45	3	5	2	5	15
	45-90	17	17	14	18	66
	90-135	8	7	8	8	31
	>4	6	5	7	4	22
Marginal enamel	<25%	0	1	1	1	3
	25-50%	25	21	15	21	82
	>50%	9	12	15	13	49
Height (mm)						
	Median	2,5	2,5	2,5	2	2
	Interquartile range	1	1	1	1	1
	Minimum	1	1	1	1	1
	Maximum	4	5	5	3	5
Width (mm)						
	Median	3	3	3	3	3
	Interquartile range	0	2	1	1	1
	Minimum	1	2	1	2	1
	Maximum	7	7	6	7	7
Depth (mm)						
	Median	1	1,5	1	1,3	1
	Interquartile range	1	1	1	1	1
	Minimum	1	1	1	1	1
	Maximum	3	3	3	3	3
Attrition facet	No	20	21	18	21	80
	Yes	14	13	13	14	54
Gingival status	Normal	29	30	28	28	115
	Gingivitis	5	4	3	7	19
Number of NCCLs per group	----	34	34	31	35	134

The materials used in the study are listed in Table 3. Restorations were performed by three operators with advanced expertise in Operative Dentistry and full knowledge about the application of all the materials in this trial, resulting in a similar number of NCCLs restored by each clinician. For each subject, all NCCLs were restored by the same operator and at the same moment (2 to 4 lesions).

Table 3
Composition of different materials used in the current study.

Material	Composition
Scotchbond Universal Etchant (3M Oral Care)	32% phosphoric acid; water; synthetic amorphous silica, polyethylene glycol, aluminum oxide.
Scotchbond Universal Adhesive (3M Oral Care)	BisGMA[a] (15–25 Wt%); HEMA[c] (15–25 Wt%); water (10–15 Wt%); ethanol (10–15 Wt%); silane-treated silica (5–15 Wt%); decamethylene dimethacrylate (10-MDP) (5–15 Wt%); 2-propenoic acid, 2-methyl-, reaction products with 1,10-decanediol and phosphorous oxide (P_2O_5) (1–10 Wt%); copolymer of acrylic and itaconic acid (Vitrebond Copolymer) (1–5 Wt%); dimethylamino-benzoat(-4) (< 2 Wt%); camphorquinone (< 2 Wt%); (dimethylamino) ethyl methacrylate(< 2 Wt%); methyl ethyl ketone (< 0.5 Wt%); silane
Adper Scotchbond Multi-Purpose Adhesive (*Bottle 3*) (3M Oral Care)	BisGMA[a] (60–70%); HEMA[c] (30–40%); Triphenylantimony (< 0.5%); photoinitiator
Filtek Supreme XTE (also called Filtek Supreme Ultra or Filtek Supreme Z350 XT) (3M Oral Care)	Silane treated ceramic (60–80%), silane treated silica (1–10%); UDMA[f] (1–10%); BisEMA[b] (1–10%); BisGMA[a] (1–10%); silane treated zirconia (1–5%); PEGDMA[d] (< 5%); TEGDMA[e] (< 1%); photoinitiator.
a. BisGMA - Bisphenol A diglycidyl ether dimethacrylate;	
b. BisEMA- Bisphenol A polyethylene glycol diether dimethacrylate;	
c. HEMA – 2-hydroxyethyl methacrylate;	
d. PEGDMA - Polyethylene glycol dimethacrylate;	
e. TEGDMA - Triethylene glycol dimethacrylate;	
f. UDMA - Diurethane dimethacrylate	

Lesions were cleaned using a cotton pellet with pumice, washed with water, and dried without desiccating prior to the adhesive procedures. They were all conducted under isolation with cotton rolls and retraction cord. The experimental groups and the application procedures are listed above and described in Table 4:

Table 4
Adhesion strategies tested and application procedure of each experimental group. ER = Etch-and rinse. SE = Self-etch.

Experimental groups	Adhesives	Application procedure
3-ER	Scotchbond Universal Adhesive in ER mode + Scotchbond Multi-Purpose Adhesive (bottle 3)	Scotchbond Universal Etchant was applied for 15 s to enamel and dentin. Then, the NCCL was rinsed thoroughly with water, and gently air-dried for 5 s keeping dentin visibly moist. One coat of adhesive Scotchbond Universal Adhesive, was scrubbed on the entire enamel and dentin surfaces for approximately 20 s. The adhesive was evaporated with a gentle air stream for 5 s and light-cured for 10 s at 1100 mW/cm2 (Bluephase). A coat of a hydrophobic bonding resin (Scotchbond Multi-Purpose Adhesive, bottle 3) was then applied and light-cured for 10 s.
2-ER	Scotchbond Universal Adhesive in ER mode	Enamel and dentin were etched with 32% phosphoric acid (Scotchbond Universal Etchant) and SBU was applied as explained above.
2-SE	Scotchbond Universal Adhesive in SE mode + Scotchbond Multi-Purpose Adhesive (bottle 3)	One coat of SBU was applied and light-cured in the same manner, followed by one coat of Scotchbond Multi-Purpose Adhesive.
1-SE	Scotchbond Universal Adhesive in SE mode	one coat of SBU was applied and light-cured as described for the other groups.

– 3-step ER strategy (3-ER): Scotchbond Universal Adhesive (SBU) (3M Oral Care) was applied in ER mode according to manufacturer´s instructions, followed by application of a hydrophobic bonding resin Scotchbond Multipurpose Adhesive, bottle 3 (3M Oral Care).

– 2-step ER strategy (2-ER): SBU was applied in ER mode according to manufacturer´s instructions.

– 2-step SE strategy (2-SE): SBU was applied in SE mode according to manufacturer´s instructions, followed by Scotchbond Multipurpose Adhesive (bottle 3).

– 1-step SE strategy (1-SE): SBU was applied in ER mode according to manufacturer´s instructions.

All lesions were restored with Filtek Supreme XTE (3M Oral Care) resin composite, which was placed in 2-mm increments using an incremental layering technique, and light-curing each one for 40 s (Bluephase, Ivoclar Vivadent, Schaan, Liechtenstein). The restorations were contoured with finishing multi-blade tungsten carbide burs (H134.314 and H134F.314, Komet-Brasseler, Lemgo, Germany) and then polished with aluminum oxide Sof-Lex discs (3M Oral Care).

Recall evaluations

All restorations were evaluated at baseline, after 18, 36 months and 5 years using the modified United States Public Health Service (USPHS) criteria *alfa*, *bravo*, and *charlie* as described by Swift et al. [32]. The primary clinical endpoint was retention or fracture of the restoration. Secondary end points included color match, marginal discoloration, recurrent caries lesion, marginal adaptation, and post-operative sensitivity. Two calibrated evaluators, who had not placed the restorations, performed the clinical analysis blindly and separately at each recall. Discrepancies between them were resolved immediately at chair side before dismissing the patient. Clinical photographs of each restoration were taken in every evaluation appointment.

Statistical analysis

Descriptive statistics was used to describe the distributions of the evaluated USPHS criteria. The survival rates (retention and fracture as primary outcome) of each adhesion strategy tested were calculated by Kaplan-Meier procedure and compared using the log-rank test. Kruskal-Wallis and Mann-Whitney U non-parametric tests were used to compare the behavior of the four adhesion strategies applied at 5-year follow-up period. Friedman and Wilcoxon non-parametric tests were used to compare the data obtained for each adhesion strategy among recall times. The level of significance was set at $\alpha < 0.05$. The software used was IBM SPSS 27 for Windows (IBM Corporation, Armonk, NY, USA).

Results

Thirty-nine subjects were treated at the baseline. The patient recall rate at the 5-year evaluation was 66.7%. Thirteen patients did not complete the 5-year recall because of the following reasons: two patients died, four patients dropped out (three of them never attended a recall visit), and seven patients could not be contacted or failed to attend the appointment (Fig. 1). The distribution of UPSHS criteria obtained by NCCLs according to each adhesion strategy at different recall periods is summarized in Table 5.

Table 5

Number and percentage of evaluated restorations for each experimental group. classified according to the modified USPHS criteria (A = *alfa*; B = *bravo*

Criteria	Modified USPHS criteria	Baseline				18 months				36 months				5 years	
Adhesion strategy		3-ER	2-ER	2-SE	1-SE	3-ER	2-ER	2-SE	1-SE	3-TE	2-TE	2-SE	1-SE	3-TE	2-TE
Retention	A	34	34	31	35	28	27	22	27	28	27	19	25	24	22
		100%	100%	100%	100%	100%	100%	88.0%	90.0%	100%	100%	76.0%	86.2%	100%	100
	B	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	C	0	0	0	0	0	0	3	3	0	0	3	1	0	0
		0%	0%	0%	0%	0%	0%	12.0%	10.0%	0%	0%	13.6%	3.8%	0%	0%
Fracture	A	34	34	31	35	28	27	21	28	28	26	19	25	23	22
		100%	100%	100%	100%	100%	100%	95.5%	100%	96.6%	96.3%	100%	100%	95.8%	95.7
	B	0	0	0	0	0	0	1	0	0	1	0	0	1	0
		0%	0%	0%	0%	0%	0%	4.5%	0%	0%	3.7%	0%	0%	4.2%	0%
	C	0	0	0	0	0	0	0	0	1	0	0	0	0	1
		0%	0%	0%	0%	0%	0%	0%	0%	3.4%	0%	0%	0%	0%	4.3%
Marginal discoloration	A	34	33	31	35	21	22	15	16	19	21	11	13	14	17
		100%	97.1%	100%	100%	75.0%	81.5%	68.2%	59.3%	67.9%	77.8%	57.9%	52.0%	58.3%	77.3
	B	0	1	0	0	6	5	5	10	8	5	8	9	8	4
		0%	2.9%	0%	0%	21.4%	18.5%	22.7%	37.0%	28.6%	18.5%	42.1%	36.0%	33.3%	18.2
	C	0	0	0	0	1	0	2	1	1	1	0	3	2	1
		0%	0%	0%	0%	3.6%	0%	9.1%	3.7%	3.6%	3.7%	0%	12.0%	8.3%	4.5%
Marginal adaptation	A	34	34	31	35	28	26	21	26	28	27	19	25	23	22
		100%	100%	100%	100%	100%	96.3%	95.5%	96.3%	100%	100%	100%	100%	95.8%	100
	B	0	0	0	0	0	1	1	1	0	0	0	0	1	0
		0%	0%	0%	0%	0%	3.7%	4.5%	3.7%	0%	0%	0%	0%	4.2%	0%
	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Recurrent caries	A	34	34	31	35	27	27	22	27	27	27	19	25	23	22
		100%	100%	100%	100%	96.4%	100%	100%	100%	96.4%	100%	100%	100%	95.8%	100
	C	0	0	0	0	1	0	0	0	1	0	0	0	1	0
		0%	0%	0%	0%	3.6%	0%	0%	0%	3.6%	0%	0%	0%	4.2%	0%
Sensitivity (question)	A	34	32	31	34	28	27	22	25	28	25	18	25	23	22
		100%	94.1%	100%	97.1%	100%	100%	100%	92.6%	100%	92.6%	94.7%	100%	95.8%	100
	C	0	2	0	1	0	0	0	2	0	2	1	0	1	0
		0%	5.9%	0%	2.9%	0.0%	0%	0%	7.4%	0%	7.4%	5.3%	0%	4.2%	0%
Sensitivity (air)	A	32	31	29	33	26	26	21	25	27	25	18	24	22	22
		94.1%	91.2%	93.5%	94.3%	92.9%	96.3%	95.5%	82.6%	96.4%	92.6%	94.7%	96.0%	91.7%	100
	C	2	3	2	2	2	1	1	2	1	2	1	1	2	0
		5.9%	8.8%	6.5%	5.7%	7.1%	3.7%	4.5%	7.4%	3.6%	7.4%	5.3%	4.0%	8.3%	0%
Color match	A	29	32	29	30	21	23	15	19	18	19	13	20	12	17
		85.3%	94.1%	93.5%	85.7%	75.0%	85.2%	68.2%	70.4%	64.3%	70.4%	68.4%	80.0%	50.0%	77.3
	B	5	2	2	5	7	4	7	8	10	8	6	5	12	4

Criteria	Modified USPHS criteria	Baseline			18 months			36 months				5 years		
		14.7%	5.9%	6.5%	14.3%	25.0%	14.8%	31.8%	29.6%	35.7%	29.6%	31.6%	20.0%	50.0%	18.2
	C	0	0	0	0	0	0	0	0	0	0	0	0	0	1
		0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	4.5%

The survival rate of the restorations at the 5-years recall was 87%, considering as failures *charlie* scores for retention and fracture criteria. The total number of failed restorations was 16 (13 for retention criterion and 3 for fracture). The cumulative survival for the 3-ER adhesion strategy was 96.9% (one fractured restoration) and 96.8% for 2-ER (one fractured restoration). The application of a hydrophobic layer after SBU in SE mode (2-SE) resulted in a cumulative survival of 71.4% (7 retention failures and one fracture), while for the 1-SE mode was of 81.3% (6 retention failures) (Fig. 2). The log rank test revealed significant differences among adhesion strategies after 5 years of clinical service ($p = 0.006$). The survival rate was significantly higher for 3-ER adhesion strategy in comparison with 2-SE ($p = 0.006$) and 1-SE ($p = 0.047$), and for 2-ER vs 2-SE ($p = 0.006$) and 1-SE ($p = 0.049$).

Retention

The overall cumulative failure rate was 10.6% at 5 years. Ten restorations had been already lost in previous recalls (3 restorations at 18 months and another 3 at 3 years for 2-SE strategy; and 3 restorations at 18 months and 1 at 3 years for 1-SE) and three additional restorations after 5 years of clinical service (1 for 2-SE, 2 for 1-SE).

The 5-year retention rates were 100% for both ER strategies, 75% for the 2-SE strategy, and 81.3% for the 1-SE strategy. Retention was statistically influenced by the adhesion strategy ($p < 0.001$). Both self-etch strategies showed lower retention rate after 5 years in comparison with both etch-and-rinse strategies (3-ER vs 2-SE $p = 0.001$; 3-ER vs 1-SE $p = 0.013$; 2-ER vs 2-SE $p = 0.002$; 2-ER vs 1-SE $p = 0.017$). In contrast, no statistical differences were observed in retention rates between both ER groups, and between both SE groups ($p > 0.05$).

When retention rate was compared at baseline versus 5 years for each of the four adhesion strategies, a significant decrease was observed for the restorations inserted using the 2-SE ($p = 0.007$) and 1-SE strategies ($p = 0.014$). In addition, in 2-SE group, the loss of retention was also significant between 18 months and 5-year recalls ($p = 0.034$).

Fracture

No differences were found among the four adhesion strategies at 5-year evaluation ($p > 0.05$) for this parameter. Three restorations were fractured at 5 years (1 for 2-SE and 1 for group 2-ER, both recorded at this recall; and 1 for 3-ER, recorded at 36-month recall).

Marginal discoloration and marginal adaptation

At 5 years, marginal discoloration was statistically different according to the adhesion strategy used ($p = 0.039$), specifically between 2-ER and 1-SE strategies ($p = 0.004$). For the latter, 65% of the restorations were scored as *bravo* and 5% as *charlie*, while restorations of 2-ER strategy exhibited a better performance for this criterion, with 77.3% of *alfa* scores (Fig. 3). A significant deterioration in marginal discoloration was detected from baseline to 5-year recall for restorations performed with 3-ER, 2-SE, and 1-SE strategies (3-ER $p < 0.001$; 2-ER $p > 0.05$; 2-SE $p = 0.001$; 1-SE $p < 0.001$). This worsening was also found in the period between 36 months and 5 years for the 3-ER strategy.

Regarding marginal adaptation, no significant differences among adhesion strategies or over time for each of them were detected. After 5 years of clinical service only three restorations were scored as *bravo*, for the 3-ER, 2-SE and 1-SE adhesion strategies.

Other parameters

After 5 years, only one secondary caries was detected, which had been recorded at 18 months for the 2-ER strategy group. At 5 years, restorations showing hypersensitivity to air or question were scarce and without statistical significance among adhesion strategies.

In relation to color match, although one restoration in the 2-ER group was classified as *charlie* at 5 years, no statistical differences among the adhesion strategies were found ($p > 0.05$). However, it was observed a significant increase in *bravo* values in restorations of 3-ER (50%) and 1-SE (40%) groups with respect to baseline values ($p = 0.007$ and $p = 0.014$, respectively). For 3-ER group, the differences were also significant between 18 months and 5 years ($p = 0.025$).

Discussion

In the current study, the application of an additional hydrophobic resin after SBU did not improve retention nor other clinical parameters evaluated in NCCLs after 5 years, regardless of the adhesion strategy applied. Therefore, the results lead us to accept the null hypothesis and corroborate the trend observed in our previous paper at 36 months follow-up [18].

The incorporation of an extra hydrophobic resin layer in the sequence of simplified adhesives application has been consistently related with a retardation in dentin bond degradation in laboratorial studies [27, 33, 34], also for SBU [20, 24, 27, 28]. The reasons mainly attributed to this beneficial effect are a higher hydrophobicity, a better polymerization efficiency and a thicker film thickness that may protect the adhesive interface against hydrolytic degradation [24, 25, 27, 30, 34, 35]. Therefore, according to our results, we can state that this improvement obtained *in vitro* studies with SBU does not seem extrapolate to clinical

behavior, at least using Scotchbond Multipurpose bonding agent as hydrophobic resin. Two clinical studies also evaluated the application of the same hydrophobic resin coat over one-step self-etch adhesives after 18 months of clinical service, reporting a beneficial effect on the clinical performance, mostly in terms of retention rate in one of them [26] and no effect in the other [31]. As far as we know, no other studies have evaluated this topic using universal adhesives nor in a long-term period.

In the current clinical trial, Adper Scotchbond Multipurpose was selected as hydrophobic resin layer, based on the two clinical studies cited above [26, 31], instead of Heliobond, a non-solvated bonding resin used in several laboratorial studies [20, 24, 28, 29]. Thus, the composition of the resin used as an extra layer may have influenced the results obtained, as Adper Scotchbond Multipurpose contains HEMA in higher levels than SBU (30–40 wt% vs 15–25% in SBU). Although HEMA promotes the penetration of the resin monomer into demineralized dentin [21], [22, 36], also leads to water sorption and the formation of poly-HEMA hydrogels that are highly prone to degradation over time [37]. Furthermore, the thicker adhesive layer produced by Scotchbond Multipurpose, might induce greater dimensional alterations due to expansion and contraction from temperature changes, resulting in the deterioration of the bonded interface [38]. In agreement with this, marginal discoloration was not prevented in NCCLs restorations for 3-ER and 2-SE adhesion strategies after five years of clinical service in the present study, despite the fact that the universal adhesive was light-cured separately, as recommended by Ermis et al. [27].

This absence of clinical benefit on the application of a hydrophobic bonding resin after a universal adhesive should be confirmed using other coatings, such as a non-solvated one or a highly filled resin [34], instead of a less silica-filled adhesive resin as it was used in the present study.

According to our results, it seems that the adhesion strategy may have been more clinically relevant than an additional hydrophobic layer since a worse performance of NCCL restorations was detected when SBU was applied using the SE strategy. This fact was mainly evidenced by a lower retention rate when the adhesive was applied with both SE strategies compared to ER strategies (75% for 2-SE and 81% for 1-SE strategies vs 100% for both ER strategies), regardless of the application of hydrophobic coating, in accordance with the 36-month recall observations [18]. These results are in agreement with the other 5-year clinical trial testing SBU, in which Matos et al. reported higher retention rate in ER modes (moist and dried dentin) (93%) compared to SE mode (81.4%) [19]. And also, with the results of a meta-analysis comprising clinical studies using universal adhesives in NCCLs with up to 36 months of follow-ups [9].

Therefore, excellent retention rates were observed when SBU was applied after acid etching, with 3-ER or 2-ER adhesion strategies. In fact, this performance was expected as the application of phosphoric acid of the enamel produces a deeper and more pronounced etch pattern compared to SE mode, resulting in an increased micro-mechanical retention and consequently an optimal bond to enamel [39]. In contrast, the poor etching in enamel margin in SE modes due to less acidic composition of SBU (pH = 2.7), is correlated with the significant differences in marginal discoloration noticed between 2-ER and 1-SE groups at 5-year follow-up period. Again, these results are in line with those reported by Matos et al., [19] with SBU. They found less discoloration for the ER strategy compared to the SE strategy after 5 years of clinical function, using both USPHS and FDI criteria. Contrary to these findings, a meta-analysis did not find differences in marginal discoloration in NCCLs restorations according to the strategy applied (SE or ER) in universal adhesives [9], although only short and medium-term clinical trials were included.

The absence of acid etching of dentin has also been related with a higher retention loss when NCCLs treated with SBU were evaluated after 5 years, even when the enamel was selectively etched [19]. The better long-term performance of this adhesive in dentin using the ER mode contrasts with *in vitro* reports [11, 40], which may be attributed to the different substrates used in those *in vitro* studies. Clinical trials are performed in NCCLs, whose main substrate is sclerotic dentin that differs from the healthy (sound) dentin used in laboratory studies. Exposed dentin in such NCCLs contains an hypermineralized layer with denatured collagen and bacteria, and crystalline deposits into the tubules [41]. Acid etching of sclerotic dentin seems to enhance the limited micromechanical interlocking without hampering the chemical interaction of the 10-MDP and carboxyl groups of the polyalkenoic acid with the partially dissolved mineral content as a chemical interaction of SBU in ER mode also has been described in sound dentin as a thin density layer below the hybrid layer, the so-called reaction layer [38].

There were no significant changes in marginal adaptation among groups in the current study along the time. However, minor marginal defects at the enamel margins were observed in all groups, which could be due to excess adhesive flashes or chipping fractures that were considered as alfa under USPHS criteria, although could have been detected with FDI criteria as they are more sensitive and accurate for the marginal adaptation parameter [42].

Finally, another limitation of the present long-term study is that the dropout is higher than 20% and that only one universal adhesive was tested, therefore, more clinical studies are warranted to confirm our results.

Conclusion

The application of an extra layer of hydrophobic bonding resin did not improve the clinical performance of Scotchbond Universal Adhesive after 5 years of service. Besides, phosphoric acid etching was crucial for the 5-year retention rate of Scotchbond Universal.

Declarations

Author contribution

Conceptualization: JP and LC; Methodology: VF, BB, IG, LC; Formal analysis and investigation: VF, LC, BB, IG; Writing-original draft preparation: VF; Writing-original draft review and editing: LC and JP. Supervision: VF, LC. All authors approved the final manuscript.

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Conflict of Interests

The authors declare no competing interests.

Ethics Approval and Consent to Participate

The research protocol was approved by the Ethics Committee of Rey Juan Carlos University in Madrid, and the procedures involving human participants were in accordance with Declaration of Helsinki. Written informed consent was obtained from all participants prior to starting the treatment.

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Figures

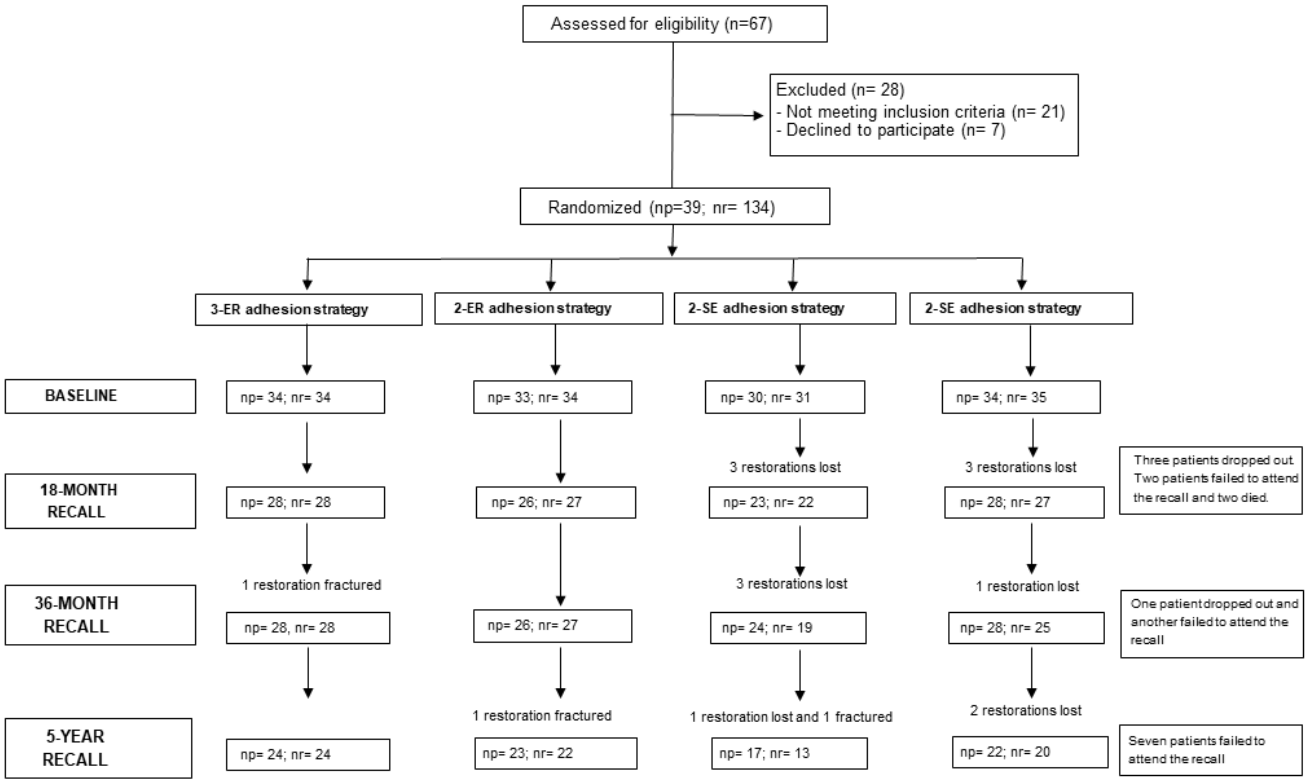

Figure 1

Flow diagram. np number of patients; nr, number of restorations.

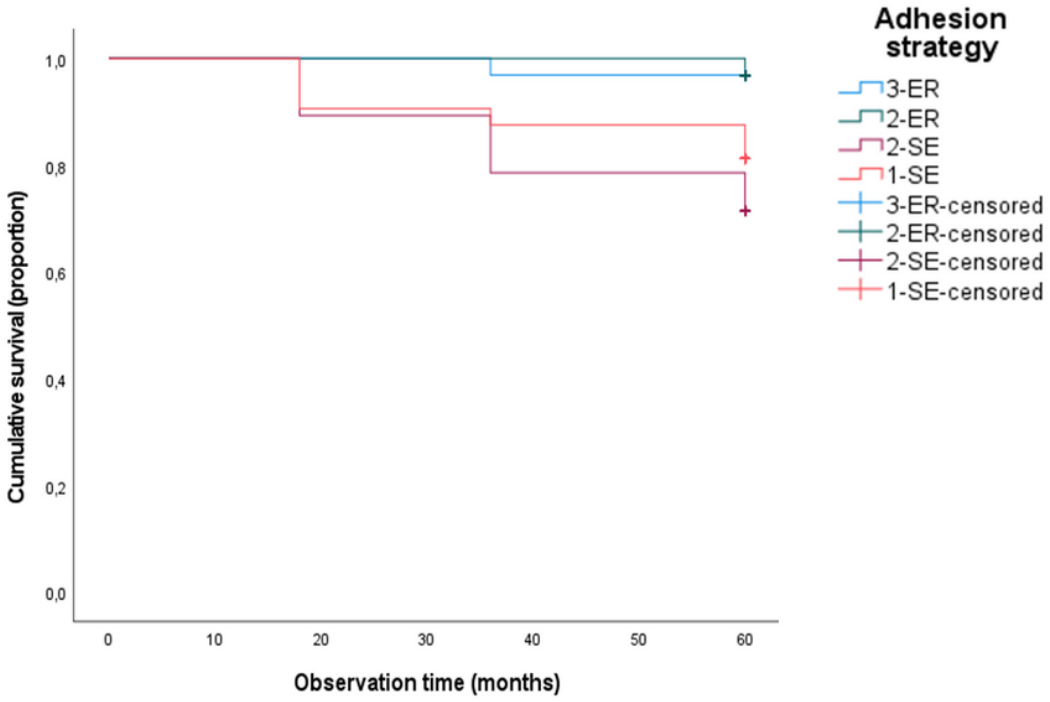

Figure 2

Kaplan Meier survival rate at 5 years.

Figure 3

Clinical images of the cervical restorations after 5 years of clinical service. *NCCL*, initial cervical lesion; *B*, baseline; *5Y*, 5-year recall. **a, b, c** Cervical lesion in 34 restored with 3-ER strategy that exhibits superficial marginal discoloration in occlusal margin that was rated as *bravo*. **d, e, f** Cervical lesion in 45 restored with 2-ER strategy and rated *alfa* for all parameters. **g, h, i** Cervical restoration in 44 belonging to group 2-SE, and rated *charlie* in marginal discoloration. **j, k, h** 44 restored with 1-SE strategy and rated *bravo* for marginal discoloration.