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Clinical Research

Clinical Effectiveness of a Hydrophobic Coating Used in Conjunction With a One-step Self-etch Adhesive: An 18-month Evaluation

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Clinical Relevance

This 18-month clinical evaluation showed that the use of a hydrophobic resin coat over a one-step self-etch adhesive does not improve clinical performance in noncarious cervical lesions.

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SUMMARY

The purpose of this randomized clinical trial was to evaluate the clinical performance of a one-step self-etch adhesive in noncarious cervical lesions with inclusion of a hydrophobic bonding layer not included in the original bonding system as a test of potentially improved bonding. Patients with noncarious cervical lesions received two or four restorations after being randomly assigned to two adhesive technique protocols (n=32): EB, application of Adper Easy Bond (3M ESPE) following manufacturer's instructions; and EB+B, application of Adper Easy Bond, immediately followed by the application of a hydrophobic resin coat (Scotchbond Multi-Purpose Bonding Agent, 3M ESPE). All restorations were restored with a microhybrid composite (Filtek Z250, 3M ESPE). Clinical effectiveness was recorded in terms of retention, marginal discoloration, marginal integrity, postoperative sensitivity,

recurrent caries, periodontal health, and pulpal vitality, according to the modified USPHS criteria, for 18 months. Data were analyzed using chi-square, Fisher exact, and McNemar tests at α=0.05. Two restorations of each group were debonded after six months, leading to an overall clinical success rate of 93.8% for both groups. At the 18-month evaluation period, no new restoration was debonded. However, one restoration of the EB group displayed recurrent caries at the dentin margin, decreasing the overall success rate to 90.6% in comparison to 93.8% of EB+B. The success rate between EB and EB+B was not statistically significant (p=0.5). The application of a hydrophobic resin coat over EB did not increase bonding effectiveness in noncarious cervical lesions after 18 months.

INTRODUCTION

One-step self-etch adhesives are produced from a complex blend of hydrophilic and hydrophobic monomers, solvents, and water in order to combine etching, priming, and bonding application steps into a one-bottle solution.[1] One-step self-etch adhesives are hydrophilic in nature, allowing water to flow from dentin into the adhesive up to the adhesive/composite interface even after polymerization.[2,3] By evaporative, osmotic, and convective processes, water is attracted into the adhesive during gelation phase and travels through interconnecting channels to bind to polar groups of hydrophilic and ionic monomers through hydrogen bonding and van der Waal's forces.[4] The water affinity of this category of dentin adhesive can result in negative consequences to marginal sealing and bond strengths to dentin. Water tends to accumulate on the top surface of the hybrid layer, inhibiting copolymerization within the adhesive, modifying the polymers and accelerating degradation of the adhesive.[5–7] The adverse effect of one-step self-etch adhesive hydrophilicity on bonding to dentin has been reported.[8–12] *In vitro* dentin bond strength tests indicate that the hydrophilicity of one-step self-etch adhesives is a contributive cause for reduced short-term[13] and medium-term values.[14]

As much as *in vitro* evidences are used to predict general clinical outcomes of dental materials through mechanical testing and aging simulations,[15] only well-controlled randomized clinical trials can supply definitive statements on the effectiveness of a given material. The clinical performance of one-step self-etch adhesive systems has been shown to have inferior clinical success rates when compared with two-step or three-step self-etch and etch-and-rinse systems.[16] *In vivo* evidence of water blistering within and protruding from the one-step self-etch adhesive layer has also been documented,[8,17] especially for HEMA-containing formulations. The water diffusion channels are made visible in cross-sectional images by ammonical silver nitrate tracing,[18] revealing geometries that imply the outward fluid flow from a moist substrate and dentinal tubules. When dehydrated dentin was used as substrate, one-step self-etch adhesives failed to show such water blister formation.[19]

The application of an additional layer of hydrophobic resin over unpolymerized one-step self-etch adhesives has been suggested as an alternative procedure to prevent such thoroughgoing water sorption.[20] An additional supply of hydrophobic cross-linking monomers (eg, Bis-GMA) would increase its concentration within the hydrophilic layer, reduce its affinity to water, and enhance its physical properties.[21] The beneficial effect of converting one-step self-etch adhesives into two-step self-etch adhesives by applying an additional coat of a hydrophobic resin has been proven under laboratory conditions,[21–23] and only scarce clinical evidence has been made available.[24]

Therefore, the purpose of this study was to evaluate the clinical performance of a novel one-step self-etch adhesive in noncarious cervical lesions with and without the application of an additional layer of hydrophobic resin.

MATERIALS AND METHODS

A total of 64 restorations were placed in noncarious cervical lesions of vital teeth (assessed through the sensitivity test) of 17 patients, 6 male and 11 female, with a mean age of 42 years (range 22–68). All patients signed an informed consent under a protocol approved by the Federal University of Santa Catarina Ethics Committee. The selection criteria excluded participants with compromised medical history, moderate or chronic periodontitis, lesions with associated caries, absence of antagonist teeth, severe bruxism, and active orthodontic treatment, teeth with cracks, premature contact, or previously placed restorations. The noncarious cervical lesions to be restored were typical V- or U-shaped abrasion/erosion/abfraction lesions in the buccal surface of the maxillary and mandibular incisors, canines, and premolars. Lesions less than 1.0 mm in depth were also excluded from the study. All lesions had incisal/occlusal margins in enamel and gingival margins in dentin. Carious lesions were not included due to a

possible retentive geometry after decayed tissue removal. The lesions were preoperatively categorized according to sensitivity, shape, angle, cervicoincisal height and depth, presence of wear facets, and degree of dentinal sclerosis (Table 1). "No sclerosis" referred to lesions with normal dentin color and spontaneous or provoked sensitivity reported by the patient after the application of a high-pressure air-blow for 3 seconds at a distance of 3.0 cm. "Slightly sclerotic" was used to classify lesions with more opaque or yellow discoloration with spontaneous or provoked sensitivity; these lesions usually presented less severe sensitivity. Lesions classified as "moderate sclerotic" were those that had an opaque or yellow dentin and no sensitivity at all, spontaneous or provoked. The lesions classified as having "severe sclerosis" presented transparent dentin without sensitivity. Noncarious cervical lesions with severe sclerosis (according to the classification above) were also excluded from the study since this condition would theoretically prevent outward dentinal fluid flow.

For a direct comparison of the different bonding approaches, a split-mouth design was selected, in which the same patient received both restorative groups according to the adhesive technique used. The selection of the bonding technique of the first lesions to be restored was determined by flipping a coin. The same calibrated operator, familiar with the adhesive procedures, restored 64 lesions, 32 restorations per group. Six patients received two restorations, and 13 patients received four restorations per group. The distribution of the restorations is shown in Table 2.

The teeth were cleaned with a pumice-water slurry and rubber cup to remove salivary pellicle and any bacterial plaque in a gentle way to prevent gingival dilacerations, which could provoke bleeding and bias during baseline sensitivity evaluation. No local anesthesia was given in order to maintain normal pulpal pressure during the bonding procedure. The field isolation was accomplished by using a labial retractor, cotton rolls, and saliva aspirator. Retraction cords (Ultrapack #00 or #000, Ultradent, South Jordan, UT, USA) were used to retract the gingiva, expose the dentin margins, and prevent gingival fluid from contaminating the lesion. No enamel bevel or dentin roughening was performed. The bonding procedures followed the two experimental adhesive techniques: a group restored with the all-in-one adhesive Adper Easy Bond (3M ESPE, St Paul, MN, USA) according to the manufacturer's instructions (EB) and a group restored with the all-in-one adhesive Adper Easy Bond (3M ESPE) followed by the application of an additional hydrophobic adhesive layer, without rubbing movements (Scotchbond Multi- Purpose Bonding Agent, 3M ESPE) over the unpolymerized all-in-one adhesive (EB+B). The adhesive was then light-polymerized for 40 seconds using a LED light-curing unit (Blue-Phase, Ivoclar Vivadent, Schaan, Liechtenstein) with 1200 mW/cm^2 output intensity, checked using a radiometer (Bluephase meter, Ivoclar Vivadent). Details of the bonding procedures are shown in Table 3.

After the bonding procedures the lesions were restored with a microhybrid composite (Z250, 3M ESPE) in two or three incremental layers, beginning with the gingival margin increment. Each composite increment was light-polymerized for 40 seconds using the same LED light-curing unit at 1200 mW/cm^2. Final contouring and polishing of the restorations were performed at the same appointment, using a fine-grit diamond bur (Komet, Lemgo, Germany), silicon carbide polisher (Jiffy polishers cups, Ultradent, Salt Lake City, UT, USA), flexible discs (Sof-Lex, 3M ESPE), and polishing pastes (Diamond polish 1 μm and 0.5 μm, Ultradent).

Two previously calibrated evaluators (κ=0.893), fully blinded to the adhesive techniques used, evaluated the restorations at baseline (one day after placement of restorations), after six and 18 months using modified USPHS criteria.[25] The criteria evaluated were: retention, postoperative sensitivity, marginal discoloration, marginal integrity, recurrent caries, periodontal health, and pulpal vitality (measured through the sensitivity test). Retention, marginal integrity, marginal discoloration, and occurrence of caries were used as key parameters determining the overall clinical success. Severe marginal defects and marginal discoloration that needed repair or replacement of the restorations were considered as failure.

The chi-square and Fisher exact tests were used to evaluate the association between groups, and McNemar test was used to verify the alpha ratings variation time within the same group ($p \leq 0.05$). For all statistical analyses a 5% significant level was adopted (α=0.05).

RESULTS

Recall results are summarized in Table 4. All patients and restorations were examined in the first and second recalls (recall rate 100%). After six months, the overall retention rate was 93.8% for

Table 1: *Evaluation Methods and Number of Lesions According to Their Characteristics*

Characteristics of the Treated Lesions	Evaluation Method	Number of Lesions
Sensitivity	Anamnesis and high-pressure air-blow for 3 sec at a distance of 3 cm	
Provoked (nonspontaneous)		8
Spontaneous (nonprovoked)		17
Spontaneous and provoked		10
No sensitivity		29
Lesion shape	Visually and tactilely (probe)	
U-shaped		24
V-shaped		40
Lesion angle, degrees	Visually and tactilely (probe)	
<45		4
45–90		24
90-135		21
>135		15
Cervicoincisal height, mm	Periodontal probe	
<1.5		6
1.5-2.5		28
>2.5		30
Lesion depth, mm	Periodontal probe	
≥ 1 < 1.5		44
≥ 1.5		20
Degree of sclerosis	Visually and high-pressure air-blow	
No sclerosis	Normal dentin with spontaneous or provoked sensitivity	21
Slightly sclerotic	Opaque (or yellow) dentin with spontaneous or provoked sensitivity	14
Moderately sclerotic	Yellow (or opaque) dentin without provoked sensitivity	29
Severely sclerotic	Transparent dentin without provoked sensitivity	0
Presence of wear facets	Visually (after air drying)	
Wear facets		21
No wear facets		43
Tooth distribution		
Upper incisor		5
Lower incisor		0
Upper canine		13
Lower canine		2
Upper premolar		15
Lower premolar		29
Upper molar		0
Lower molar		0

both groups due to full debonding of four restorations in total, being two restorations lost per group. Between six and 18 months no full debonding was observed, but one of the restorations of EB presented with a carious lesion at the dentin margin, decreasing the overall success rate for this group to 90.6%. However, statistical analysis revealed no significant differences between the 18-month and baseline evaluations for both groups for the retention criteria. The four debonded restorations were from different patients, which indicate a low influence of patient

Table 2: *Distribution of Noncarious Cervical Lesions*

Adhesive Technique	Arch	Right Quadrants (34)			Left Quadrants (30)		
		Incisor	Canine	Premolar	Incisor	Canine	Premolar
EB	Maxilla	0	2	4	1	5	2
	Mandible	0	1	6	0	2	9
EB+B	Maxilla	3	3	5	1	2	4
	Mandible	0	0	10	0	0	4

factor. Moreover, these lost restorations were bonded to shallow lesions (<1.5 mm), presenting with slight or moderate sclerosis levels, all in lower premolars presenting wear facets. Two of them belonged to U-shaped lesions and the other two to V-shaped lesions.

For marginal integrity criteria, two restorations from both groups showed bravo scores in enamel. In dentin, one restoration from EB+B and four restorations from EB were assigned bravo, but no significant differences were found (p=0.177). For all other criteria, no statistical differences could be detected between groups and evaluation periods, including overall clinical success (p=0.500).

DISCUSSION

The present clinical trial showed that the application of a hydrophobic resin coat over a one-step self-etch hydrophilic adhesive did not increase bonding effectiveness in noncarious cervical lesions after 18 months. The degradation of the bonded interfaces with one-step self-etch adhesives is linked to its high hydrophilic nature. Thus, in order to maximize the water supply at the interface during and after the restorative procedures, the study design involved the exclusion of lesions presenting severely sclerotic dentin and the maintenance of normal pulpal pressure by not using anesthesia of any kind. Severe

Table 3: *Application Procedures of the Adhesive Technique Protocols Used in This Study*

Adhesive Technique	Code	Manufacturer	Composition	Batch Number	Application Procedure
Adper Easy Bond	EB	3M ESPE, St Paul, MN, USA	HEMA, Bis-GMA, methacrylated phosphoric esters, 1,6 hexanediol dimethacrylate, methacrylate functionalized polyalkenoic acid, silica fillers (7 nm), ethanol, water, initiators based on CQ, stabilizers	301394	1. Apply adhesive for 20 sec in both enamel and dentin. 2. Air-dry with high-pressure for 10 sec at a distance of 10 cm. 3. Light-cure for 10 sec
Adper Easy Bond + Adper Scotchbond Multi-Purpose Bonding Agent (SBMP)	EB+B	3M ESPE, St Paul, MN, USA	Easy Bond: see above. SBMP adhesive: Bis-GMA, HEMA, tertiary amines, photoinitiator	301394 (Adper Easy Bond) 8RF (Adper SBMP)	1. Apply Easy Bond for 20 sec in both enamel and dentin. 2. Air-dry with high-pressure for 10 sec at a distance of 10 cm. 3. Apply SBMP in enamel and dentin. 4. Apply air spray until no more adhesive movement on the surface. 3. Light-cure for 20 sec

Abbreviations: Bis-GMA, bisphenol A diglycidyl ether dimethacryalate; HEMA, 2-hydroxyethyl methacrylate.

Table 4: *Evaluation Results in Percentage of Alpha Score at Each Evaluation Period*[a]

	Recall Period						*p* Value at 18 Months
	Baseline		6 Months		18 Months		
	EB	EB+B	EB	EB+B	EB	EB+B	
Recall rate	100	100	100	100	100	100	0.999
Retention rate	100	100	93.8	93.8	93.8	93.8	0.999
Spontaneous sensitivity	100	100	100	100	100	100	0.999
Provoked sensitivity	100	100	100	100	93.3	96.7	0.500
Marginal discoloration in enamel	100	100	100	100	86.7	86.7	0.999
Marginal discoloration in dentin	100	100	100	100	86.7	86.7	0.999
Marginal integrity in enamel	100	100	96.7	96.7	93.3	93.3	0.999
Marginal integrity in dentin	100	100	93.3	96.7	86.7	96.7	0.177
Absence of caries occurrence	100	100	100	100	96.7	100	0.500
Periodontal health	100	100	100	100	100	96.7	0.500
Pulpal vitality	100	100	100	100	100	100	0.999
Overall clinical success rate	100	100	93.8	93.8	90.6	93.8	0.500

Abbreviations: EB, Adper Easy Bond; EB+B, Adper Easy Bond plus Scotchbond Multi-Purpose Bonding Agent.
[a] *Percentages of all parameters evaluated refer to retained restorations, except for recall rate, retention rate, and overall clinical success rate. Baseline percentages for sensitivity refer to evaluation after the restorations were placed. Number of lesions with sensitivity prior to restoration is shown in Table 1.*

dentin sclerosis is known to result in tubule occlusion by physiologic mineralization preventing the outward flow of fluid. Indeed, water absorption and water tree formation in one-step self-etch adhesives seemed to be minimized when they were applied to transparent sclerotic carious dentin.[26]

To assess the bonding efficacy of both bonding techniques used (EB and EB+B), no bevel or selective etching of enamel was performed. The no-preparation approach allowed assessment of whether the low etching capacity of self-etch systems to unground enamel compromises the establishment of micromechanical retention and marginal sealing.[27] Retention of such poorly bonded noncarious cervical composite restorations to the enamel margin would then rely mainly on dentin bond quality. At 18 months, only two restorations were not rated alpha for enamel marginal integrity, but marginal discoloration was evident in four restorations for both groups. Between six and 18 months, marginal discoloration in enamel increased from 0% to 13.3% for both groups. In a randomized clinical trial evaluating the effect of selective enamel etching prior to the application of a mild self-etch system, unfavorable results for marginal integrity and discoloration were already obtained for the non-etched group at two years.[28] Abdalla and Garcia-Godoy[29] found more marginal discrepancies and discoloration when a self-etching adhesive was applied to mandibular premolars without selective enamel etching following a period of one and two years in cervical lesions.

Studies have demonstrated that all-in-one adhesives form structures that can act as semipermeable

membranes after polymerization, permitting bidirectional water movement across the adhesive layer.[3,4,12,17] However, the hydrophobic bonding applied over the noncured one-step self-etch adhesive creates a thicker and more uniform layer with lower concentrations of retained water and solvent.[21] The additional resin coating applied over a noncured all-in-one adhesive system provides additional free radicals to enhance the rate and extent of polymerization of the self-etching primers with an expected increase in the bond strength to dentin.[20] Furthermore, thickening the adhesive layer has also shown to bring advantages to dentin bonding, once the interface permeability is reduced.[30,31] Clinically, the encouraging results of adding a hydrophobic layer over a one-step self-etch adhesive showed improved retention rates when Clearfil S3 Bond and iBond Gluma were sealed with a hydrophobic resin coat.[24]

Belli and others[32] reported an increased resistance to bond degradation for Adper Easy Bond after one year of storage under simulated pulpal pressure in comparison to other simplified adhesives. Adper Easy Bond showed to be less permeable to dentin humidity.[33] From the present 18 month study of retention rate results, it was not possible to affirm whether Adper Easy Bond is resistant to water sorption or whether the application of an additional coat of hydrophobic resin improved the bond effectiveness. Therefore, hydrolytic degradation of one-step self-etch adhesive is still a concern.

The only restorations to debond were placed in mandibular premolars presenting with wear facets and moderate sclerosis. Although it is early at this stage of the present investigation to correlate these clinical covariables to retention loss, one cannot overlook the potential effect of excessive occlusal loading on cervical stress concentration,[34,35] which can challenge the bond between tooth and restoration.[36,37] Early restoration debonding in allegedly higher loaded teeth may be a sign of bond fragility of the tested adhesive, irrespective of the application method. Teeth with wear facets usually are not excluded from Class V clinical trials, and even so, many adhesives have shown excellent retention rates after six months.[38–40] The fact that all lost restorations were bonded to moderate sclerotic dentin, and therefore, theoretically less subjected to water degradation, may indicate occlusal factors as the main cause of retention loss. Since none of the four lost restorations were from different patients, patient-related factors may be considered minimal in this case.

The use of a hydrophobic resin coat over one-step self-etch adhesive makes bonding procedures more complex, increasing clinical chairside time. Moreover, this clinical approach did not improve clinical performance of the composite resin restorations in noncarious cervical lesions over 18 months of clinical trial. Longer periods of observation and additional studies will be indispensable to further evaluate the clinical performance of one-step self-etch adhesive.

CONCLUSION

From the results of this clinical study, the application of a hydrophobic resin coat over an uncured one-step self-etch adhesive did not statistically improve bonding effectiveness over the 18-month trial period.

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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