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Clinical Research

A Randomized Clinical Evaluation of a One- and Two-step Self-etch Adhesive Over 24 Months

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Clinical Relevance

The application of an extra hydrophobic bond layer over the self-etch adhesive system improved clinical performance over a 24-month period, mainly in terms of retention rate.

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DOI: 10.2341/09-241-C

SUMMARY

Objective: To evaluate the performance of All Bond SE used in a one- or two-step protocol in a 24-month randomized clinical study.

Methods: Thirty-three patients with two similarly sized non-carious cervical lesions participated in this study. A total of 66 restorations were placed, half using the one-step All Bond SE protocol (SE-1) and the other half using the two-step All Bond SE protocol (SE-2). The restorations were evaluated at baseline and after 6, 12 and 24

months following the modified USPHS criteria and analyzed by the McNemar's test and Fisher's exact test (α=0.05).

Results: After 24 months, six SE-1 and four SE-2 restorations were rated as Bravo in marginal discoloration The retention rates for SE-1 and SE-2 were 84.8% and 90.9%, respectively, after 24 months. Compared to baseline, the retention rate for SE-1 was statistically lower.

Conclusions: All Bond SE used in the one- or two-step protocol resulted in high retention rates after 24 months.

INTRODUCTION

Contemporary adhesive systems can be explained based on management of the smear layer. The etch-and-rinse system removes the smear layer, while self-etch systems modify the smear layer. The self-etch approach has changed the traditional concept of bonding, eliminating the need for a separate acid-etching step. However, it is necessary to use acidic primers composed of non-rinse acidic monomers that etch and prime the dental substrate simultaneously, followed by a second layer of hydrophobic resin in the two-step process of self-etching. When both components of the acidic primer and adhesive resin are mixed and applied together to the tooth, a one-step procedure is used.[1]

An immediate consequence of adhesive simplification is sacrifice of the universality of multi-bottle adhesives.[1-2] Most simplified versions are capable of bonding only to light-cured composites.[3-4] Based on this assumption, it would be of clinical interest to have versatile systems capable of being used either in complete or simplified version. A recent systematic review of clinical studies[5] has reported that the clinical effectiveness of one-step self-etch adhesives was the least efficient among all classes of available adhesives. The lower effectiveness of one-step self-etch systems has been attributed to the lack of a non-solvated resin layer that makes the adhesive a very permeable membrane.[2]

Several *in vitro* studies have demonstrated that placement of a hydrophobic resin coating improves the performance of one-step self-etch adhesives in terms of resin-dentin bond strengths.[6-8] Clinical evidence demonstrating that one-step systems perform less favorably compared to two-step self-etch systems is, to date, confined to the use of materials with very different compositions. This precludes the conclusion that improved performance of two-step versions is mainly due to the hydrophobic coating.

Recently, a versatile self-etch system (All Bond Self-Etch, BISCO, Inc, Schaumburg, IL, USA) was released. According to the manufacturer, this adhesive can be used in both the one- and two-step version. The only difference between the one- and two-step version is that, in the latter, an extra coat of a relatively hydrophobic resin is applied over the primed surface.[9] This characteristic permits direct investigation of the effect of the protective coating on clinical performance of the adhesive.

The current study conducted a 24-month randomized controlled prospective study in non-carious cervical lesions in order to evaluate the performance of All Bond Self-Etch used as a one- or two-step self-etch system. The null hypothesis tested was that clinical performance would not be affected by the different bonding approaches after 6, 12 and 24 months of evaluation.

METHODS AND MATERIALS

The materials employed in the current study were the nanohybrid resin composite Aelite (BISCO, Inc) and All-Bond SE, a self-etch adhesive system (BISCO, Inc). The adhesive was used in a two-step or one-step protocol. Detailed composition and mode of application of the adhesive are described in Table 1.

The protocol and consent form for this study were reviewed and approved by the local university review board (protocol #159/2006). The current protocol is in accordance with Needleman and others.[10] Four calibrated operators performed the patient screening and pretreatment selection of teeth with cervical lesions identified visually or tactily. The patients were screened initially to determine if they met the study entry criteria. Qualified patients were recruited in the order that they reported for the screening session, forming a convenience sample. The investigators carried out the evaluations using a mouth mirror, an explorer and a periodontal probe. The operator recorded the sensitivity of each tooth to applications of compressed air based on the patient's spoken response to a visual analogue scale from 0 to 10 (continuous measurements). The clinicians applied compressed air from a three-way dental unit syringe at a distance of approximately 2 cm. They timed the applications of each stimulus until the subject responded by raising his or her left hand with a maximum application lasting for 15 seconds.[11]

All the participants were healthy and had at least 20 teeth. According to local regulations, the patients were given oral hygiene instructions prior to performing the operative treatment. Patients with very poor oral hygiene, severe or chronic periodontitis or heavy bruxism were not included in the research study, as these conditions would require treatment before restorative intervention. Patients with at least two similar-sized cervical lesions (erosion/attrition/abfraction) in normal occlusion were selected. The lesions had to be non-retentive, with no undercuts and no more than 50% of

Table 1: *Material, Batch Number, Composition and Mode of the Application of the Materials*

Adhesive Systems	Composition/Batch #	Application Mode
All Bond SE (BISCO, Inc) [SE]	**Part I**–Ethanol, sodium benzene sulfinate dihydrate [0600010907]. **Part II**–Bis(glyceryl 1,3 dimethyacrylate) phosphate; hydroxyethyl methacrylate, biphenyl dimethacrylate [0600007324]. **All Bond SE Liner** Bisphenol A diglycidylmethacrylate, urethane dimethacrylate, hydroxyethyl methacrylate, glass frit [0600007395].	***1-step self-etch [SE-1]*** 1. Mixing of Part I and Part II(1:1) until uniformly pink; 2. Application of one coat of the adhesive under finger pressure (15-20 seconds); 3. Air thinning of the adhesive using a strong air stream for 15 seconds; 4. In case the substrate was not shiny, procedures 1 and 2 were repeated; 5. Light-activation (10 seconds–600 mW/cm^2). ***2-step self-etch [SE-2]*** 6. After steps 1 to 5, an additional thin layer of All Bond SE liner was applied; 7. Light-activation (10 seconds–600 mW/cm^2).

the cavosurface margin involving enamel.[12] The cervical wall had to be located in dentin/cementum.

The degree of sclerotic dentin was measured according to the criteria described by Swift and others.[12] The lateral visualization of the cavity allowed for its classification into four groups according to the angle of the cavity (<45°; 45°-90°; 90°-135°; >135°). The gingival-incisal height of the cavity was measured using a periodontal probe. Other features, such as the presence of an antagonist or an attrition facet, were also observed and recorded.

All patients were informed of the nature and objectives of the current study and they were blinded to material selection. Written informed consent was obtained from all participants prior to starting treatment.

Restorative Procedures

All lesions were restored by three operators who participated in the patient screening. One experienced clinician carried out the calibration. Operators first observed the detailed application procedures in laboratory models (3x for each protocol). They then performed four repeated restorations (for each protocol) under direct supervision in a clinical setting. The operators' questions were addressed and consensus was obtained during the calibration session.

In the clinical phase of the current study, each patient received at least one restoration using the one-step protocol and one restoration using the two-step protocol. Randomization of the materials was performed on each patient by tossing a coin. The lesions were prepared as follow: 1) anesthesia (Citanest, Dentsply, Petrópolis, RJ, Brazil); 2) cleaning with pumice and water (SS White Prod Odontol Ltda, Petrópolis, RJ, Brazil) in a rubber cup (#8040RA and #8045RA, KG Sorensen, Barueri, SP, Brazil) followed by rinsing and drying; 3) shade selection; 4) rubber dam isolation (SS White Prod Odontol Ltda); 5) rinsing with a water/air spray. No additional retention or bevel was performed.

The adhesives were applied according to the description featured in Table 1. The lesions were incrementally filled with Aelite (BISCO, Inc) in approximately three increments. Each increment was light cured for 30 seconds using a VIP light unit set at 600 mW/cm^2 (BISCO, Inc). All the restorations were finished with diamond finishing burs (Ultradent, South Jordan, UT, USA). After one week, the restorations received a final polishing with finishing discs (Superfix, TDV Dental, Pomerode, SC, Brazil).

Clinical Evaluation

The categories evaluated were: retention (primary outcome), color match, anatomic form, marginal adaptation, marginal discoloration, postoperative sensitivity and recurrent caries according the United States Public Health Service (USPHS)[13] criteria adapted at baseline and after 6, 12 and 24 months.

Retention rates were calculated using the following equation (ADA Guidelines, 2001)[14]:

Cumulative failure %= [(PF+NF)/(PF+RR)] x 100%

PF is the number of previous failures before the current recall; NF represents the number of new failures during the current recall and RR is the number of restorations recalled for the current recall. Photographs were also taken prior to starting treatment at baseline and after 6, 12 and 24 months. Five photographic representatives of each score in each criterion were observed.

Two experienced and calibrated examiners performed the evaluation using a mirror and an explorer after dental prophylaxis. The examiners were unaware of which adhesive protocol was used, as they were not the ones who placed the restorations. Each examiner evaluated the restoration independently. When disagreements occurred between evaluators during the

evaluation, a consensus had to be achieved before dismissing the patient.

Statistical Analysis

The retention rate of Clearfil SE Bond (Kuraray Co, Ltd, Tokyo, Japan) at 24 months (100%)[15] was used as a parameter for sample size calculation. This system was chosen because Clearfil SE Bond is a two-step system as the two-step All Bond SE used in the present investigation. In order to detect a difference of 20% between groups, using an α of 0.05, a power of 80% and a two-tailed test, the minimal sample size should be 32 restorations in each group.

Descriptive statistics were used to describe the frequency distributions of the evaluated criteria. The differences in ratings of the two materials after 6, 12 and 24 months were tested with the Fisher's exact test (α=0.05) and performance of the materials at baseline and after each recall (6, 12 and 24 months) was evaluated using the McNemar test (α=0.05). Weighted Cohen's Kappa statistic was used to test the inter- and intra-examiner agreement.

RESULTS

Thirty-three of 72 evaluated patients met the inclusion criteria. A total of 66 restorations were placed, 33 in each treatment group. Thirty-six restorations were placed in maxillary teeth and 30 were placed in mandibular teeth. Forty-two restorations were placed in premolars and molars and 24 in anterior teeth. Details of the distribution of the restorations can be found in Table 2.

The Cohen's Kappa statistics for the inter- and intra-examiner agreement was over 80% in all criteria, showing excellent agreement between examiners. The weighted kappa was 0.91. All patients attended the 6, 12 and 24-month recall.

The overall results are shown in Table 3. There were excellent results in regards to the items of anatomic

Table 2: *Distribution of Non-carious Cervical Lesions According to Age and Gender Distribution, Shape, Cervico-incisal Size of the Lesion, Degree of Sclerotic Dentin, Presence of Antagonist, Presence of Attrition Facets, Presence of Preoperative Sensitivity and Tooth and Arch Distribution*

Characteristics of Class V Lesions	Number of Research Subjects	Number of Lesions
Gender Distribution		
Male	18	36
Female	15	30
Age Distribution (years)		
20-29	4	8
30-39	5	10
39-49	12	24
> 49	12	24
Shape (degree of angle)		
< 45		8
45-90		18
90-135		18
> 135		22
Cervico-incisal Height (mm)		
< 1.5		20
1.5-2.5		22
> 2.5		24
Degree of Sclerotic Dentin		
1		15
2		21
3		13
4		17
Presence of Antagonist		
Yes		66
No		0
Attrition Facet		
Yes		44
No		22
Pre-operative Sensitivity (spontaneous)		
Yes		26
No		40
Tooth Distribution		
Anterior		
Incisor		19
Canines		5
Posterior		
Premolar		28
Molar		14
Arch Distribution		
Maxillary		36
Mandibular		30

form, marginal adaptation and post-operative sensitivity throughout the 6- and 12-month evaluation period. Marginal discoloration was observed in a few restorations (n=5): four cases were observed for SE-1 and one for SE-2. These differences were not statistically significant ($p>0.05$). Regarding item retention rate, only one restoration from group SE-1 debonded after 6 and 12 months, and this single failure did not lead to any statistical difference between the groups investigated at the 12-month recall ($p>0.05$).

After 24-months, no secondary caries was observed and no restorations were scored as Bravo for the item post-operative sensitivity. Nine restorations were scored Bravo for anatomical form, six being SE-1 and three being SE-2 throughout the 24-month evaluation period. The SE-1 group had significantly more restorations scored Bravo for anatomic form in the 24-month recall ($p<0.05$). Significant differences between baseline and 24-months were observed for anatomic form only for SE-1 ($p<0.05$). Bravo scores for marginal adaptation were observed in nine restorations (four SE-1, five SE-2) and no significant difference was observed between groups at the 24-month period and between 24-months and baseline ($p<0.05$).

After 24 months, 10 restorations (six SE-1 and four SE-2) were rated Bravo for marginal discoloration. This difference was not statistically different between materials ($p>0.05$) at this period of evaluation. Significant differences were only observed in the item marginal discoloration for the group SE-1 when the 24-month findings were compared to their respective baseline recordings ($p<0.05$).

Retention rates at the 24-month recall were 84.8% and 90.9% for SE-1 and SE-2, respectively. When both adhesive strategies were compared to one another at the 24-month period ($p>0.05$), no significant difference was detected between groups. When compared to baseline recordings, the retention rate of the SE-1 group was statistically lower ($p<0.05$), while no significant difference was observed between baseline and the 24-month recall for the SE-2 group.

DISCUSSION

The clinical performance of adhesives in general has improved significantly, allowing adhesive restorations to be placed with a highly predictable level of clinical success. Most of the modern adhesive systems are superior to their predecessors, especially in terms of retention, which no longer is the main cause of premature clinical failure.[16]

The All Bond SE system is a new two-component, self-etch material capable of being used either in a one- or two-step procedure. Although similar microtensile bond strength values could be found for one- and two-step All-Bond SE,[9] they differed slightly under this clinical evaluation. The clinical significance of bond strength results has been discussed in many papers,[17-19] and some authors doubt if they are really important, especially considering that studies failed to find any correlation between bond strength results and clinical outcome.[18]

The chemistry of one-step self-etch systems is very challenging. The incorporation of hydrophilic and hydrophobic monomers, along with organic solvents and water into a single bottle, results in the high hydrophylicity of these systems. Hydrophilic chemistry

Table 3: *Number of Evaluated Restorations Classified in Alfa, Bravo and Charlie in Each Item According to the USPHS Criteria*

Criteria (*)	↓	Baseline		6 Months		12 Months		24 Months	
		SE-1	SE-2	SE-1	SE-2	SE-1	SE-2	SE-1	SE-2
Retention	A	33	33	32	33	32	33	28	30
	C	--	--	1	--	1	--	5	3
Anatomic Form	A	33	33	32	33	32	33	22	27
	B	--	--	--	--	--	--	6	3
	C	--	--	--	--	--	--	--	--
Marginal Adaptation	A	33	33	32	33	32	33	24	25
	B	--	--	--	--	--	--	4	5
	C	--	--	--	--	--	--	--	--
Marginal Discoloration	A	33	33	28	32	28	32	22	26
	B	--	--	4	1	4	1	6	4
	C	--	--	--	--	--	--	--	--
Secondary Caries	A	33	33	32	33	32	33	28	30
	C	--	--	--	--	--	--	--	--
Postoperative Sensitivity	A	33	33	32	33	32	33	28	30
	C	--	--	--	--	--	--	--	--

creates permeable membranes, resulting in water diffusion from the underlying dentin across the adhesive layer.[20] A more far-reaching consequence of the high intrinsic permeability of these simplified self-etch systems is that they are more prone to water sorption, which causes water swelling and reduces frictional forces between the polymer chains in a process known as plasticization. This water-driven process can, therefore, decrease the mechanical properties of the polymer matrix.[21] The retention of water, either from residual water that is incompletely evaporated from the adhesive or from the underlying dentin as the result of the high osmolarity of the hydrophilic adhesive mixture, creates water-filled channels within the adhesive.[20] These water-filled channels can work as stress raisers, inducing early adhesive failure. Permeability to water and its consequences could be regarded as the leading reasons for inferior performance of one-step All Bond SE compared to the two-step version after 24 months of clinical service.

By applying a non-solvated hydrophobic bonding layer over the surface previously treated with one-step self-etch systems (using the two-step All Bond SE protocol), the concentration of the hydrophobic monomers is increased.[2,6-8,22] This fact may explain the higher retention rates in this clinical trial for All-Bond SE two-step after 24-months. In addition, this leads to a thicker, more uniform adhesive layer, with lower concentration of retained water and solvent, which is known to reduce the detrimental effects of polymerization shrinkage of composites.[23] These results are in agreement with previous laboratory investigations, which reported that the conversion of one-step into two step self-etch systems could yield improved microtensile bond strength results[2,6-8] and increased clinical retention rates for one-step self-etch systems.[22]

Although the retention rates for one-step All Bond SE were inferior to the two-step version, the retention rates of this simplified material are within those rates published in the literature for similar one-step materials. Retention rates of 75% to 90% have been reported for Adper Prompt L-Pop after one to two years of clinical service, 77%-100% for Clearfil S3 (Kuraray) and 90%-93% for Xeno III (Dentsply).[23-25] Retention rates were respectively reported by previous studies after the same period of time.[22,27-30] When comparing different studies, it should be noted that factors, such as the study population, inclusion and exclusion criteria, technical procedures and operators' experience, will vary among studies. For instance, the inclusion and exclusion criteria[28,30-31] and the operator or evaluator calibration procedure, was not reported in some clinical studies.[27-28,30-31] Enamel beveling was used in other clinical protocols.[28-30] Some investigators placed more than one restoration per group in each patient in an attempt to enhance the power of the study; however, most of them[26-28,30] have not used appropriate statistical methods to take the clustered measurements into account, as it was properly done in the study by Van Landuyt and others.[32]

Retention is a very objective criterion; whereas evaluation of marginal staining is much more subjective.[16] Adhesive systems should keep the restoration in place for a significant time and also completely seal the restoration margins against the ingress of oral fluids and microorganisms. Incomplete marginal sealing will result in post-placement sensitivity, marginal staining and, eventually, recurrent caries, which are still the most common symptoms associated with clinical failure of adhesive restorations.[19]

Marginal staining is thought to be one of the first clinical signs that a resin composite restoration is prone to failure. Marginal discoloration may be caused by three factors, such as the presence of excess filling materials (positive marginal adaptation), a deficit of filling materials at the margin (negative marginal adaptation) and the formation of gaps.[33-34] It is thought that these mild discolorations are due to the retention of microscopic pigments derived from colored beverages and food at marginal defects.

As it is often described in the literature, marginal defects usually correlate with marginal adaptation and marginal discoloration.[15,35] In the current investigation, 14% (SE-1) and 17% (SE-2) of the restorations received Bravo scores for marginal adaptation. Marginal discolorations were observed in 13% and 21% of the cases, respectively, for SE-1 and SE-2, which correspond to imperfect restoration margins showing a surplus of the material. This is evidence that the increase in Bravo scores for marginal adaptation is usually accompanied by an increase in Bravo scores for marginal discoloration.

However, as pointed out by Türkün,[35] excess material at the margins may not be considered to be a clinical failure. The Bravo records for marginal discoloration were similar to what was reported in previous clinical evaluations dealing with one-step self-etch systems,[22,26-27,29-30,32] indicating that the material, regardless of the bonding protocol, performed reasonably well in this short-term evaluation. This discoloration occurred at the enamel margins for the majority of the restorations, which seems to be a common finding in clinical studies.[22,26-27,29-30,32] The enamel marginal discoloration found for both procedures may have been due to the inferior etching pattern of these systems.[32,36-38] The clinical performance on enamel margins can be improved by beveling and/or acid etching, two suggested approaches to reduce the rate of marginal discoloration of these materials at the enamel margins.[15,39] Therefore, the percentage of Bravo scores for marginal discoloration should be carefully interpreted, as they do not

necessarily mean defective restorations. Most of the marginal staining observed in the current study appeared to be superficial and could be easily removed by a new finishing and polishing procedure.

CONCLUSIONS

One-step All Bond SE exhibited good performance after 24 months of clinical service. Two-step All Bond SE exhibited excellent performance. The application of an extra hydrophobic bond layer over the self-etch adhesive system improved clinical performance mainly in terms of retention rate. All Bond SE using the two-step protocol meets the ADA guidelines for full acceptance as an adhesive dental material.

Acknowledgements

This study was partially supported by BISCO, Inc and funds from the National Council for Scientific and Technological Development (CNPq) under grants 305075/2006-3 and 303933/2007-0.

Disclaimer

Drs Manso and Carvalho were employed at BISCO, Inc when the study started but were no longer involved with the company when the 12- and 24-month evaluations were carried out.

(Received 10 August 2009)

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