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A 36-month Clinical Evaluation of Ethanol/Water and Acetone-based Etch-and-Rinse Adhesives in Non-carious Cervical Lesions

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Clinical Relevance

Based on the findings of this clinical trial, one may conclude that non-carious cervical lesions should be restored with the ethanol/water-based two-step etch-and-rinse adhesive Single Bond, instead of the acetone-based One Step, as the latter presents a high number of debonded restorations after short- and long-term recalls. However, other literature findings should also be taken into account before reaching a clinical decision.

SUMMARY

This double-blind randomized clinical trial compared different ethanol/water and acetone-based systems in non-carious cervical lesions over 36 months. Materials and Methods: Eighty-four patients having at least one non-carious cervical lesion [NCCL] under occlusion were enrolled in this study. A total of 84 restorations were placed, half for each group (Adper Single Bond [SB] + Filtek A110 or One Step [OS] + MicroNew). All the materials were placed by two calibrated operators. Two other independent examiners evaluated the restorations at baseline, 6, 12, 18 and 36 months, according to slightly modified USPHS criteria. Statistical analysis between materials in each period was conducted using the Fisher's exact test (α=0.05), and performance of the materials in the baseline in comparison to each period was evaluated by McNemar's test (α=0.05). Results: The 12-, 18- and 36-month retention rates for SB were 95.2% (12 and 18 months) and 92.3% (36 months). For OS, the retention rates were 83.3%, 73.8% and 56.4%, respectively, for each recall period. After 36 months, 10 OS restorations (25.7%) and seven SB restorations (17.9%) were rated as Bravo in the marginal discoloration item. Conclusions: The ethanol/water-based adhesive (Single Bond) that was evaluated showed a higher retention rate than the acetone-

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based system (One Step) after 36 months of clinical service.

INTRODUCTION

Successful adhesion to hard tissues, including enamel and dentin, is a fundamental requirement prior to the insertion of tooth-colored materials, such a direct resin composites.[1] Contemporary resin-based adhesive systems can be classified based on the underlying strategy as an "etch-and-rinse" or "self-etch" approach. In the etch-and-rinse strategy, the tooth is first etched (37% phosphoric acid) and rinsed off. This conditioning step is followed by a priming step and application of the adhesive resin, resulting in a conventional three-step application procedure.

Although the three-step etch-and-rinse strategy has been considered to be the "gold standard," the most frequently used adhesive system from this category is the two-step version, which combines the primer and adhesive resin into one bottle. However, these systems still require a preliminary conditioning and rinsing step.[1] The technique sensitivity of the etch-and-rinse systems and the likely discrepancy between the extent of demineralization and monomer infiltration[2] has been blamed for the degradation of these adhesives systems when exposed to a water environment.[3] Although their clinical performance has clearly improved over earlier systems,[1,4] there are still randomized clinical trials showing varying retention rates of commercial systems over a period of one to five years,[5-12] which might be related to their chemistry and solvent content.

Thus, the aim of this randomized controlled study was to evaluate the performance of an ethanol/water and acetone-based two-step etch-and-rinse adhesive for the restoration of non-carious cervical lesions over 36 months, mainly in terms of retention and marginal integrity discoloration.

METHODS AND MATERIALS

The materials employed in the current study were: Adper Single Bond, an ethanol/water-based two-step, etch-and-rinse adhesive system (3M ESPE, St Paul, MN, USA) and One Step (BISCO Inc, Schaumburg, IL, USA). Each material was employed with the respective microfilled resin composite from its manufacturer (Filtek A110, 3M ESPE and MicroNew, BISCO Inc). Detailed compositions and mode of application are described in Table 1.

The protocol and consent form for the current study were reviewed and approved by the University of Oeste of Santa Catarina Committee on Investigations Involving Human Subjects. Patient screening and pretreatment selection of teeth, with cervical lesions identified visually or tactilely, were performed by two clinical investigators. The investigators screened the patients initially to determine if they met the study entry criteria (described below). The investigators enrolled the qualified patients in the study for the evaluation visit. Qualified patients were recruited in the order in which they reported for the screening session, thus forming a convenience sample. The investigators carried out the evaluations using a mouth mirror, an explorer and a periodontal probe. They used air from an air-water syringe to administer the thermal sensitivity test. They were asked to report the pain on a scale of 0 to 4. In the instance where the investigators reported a 3 or 4, the patients were not included in the study.

All participants were healthy and had at least 20 teeth. According to the treatment rules from the School

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

Material	Composition	Mode of Application
Adper Single Bond (3M ESPE St Paul, MN, USA)	1 Scotchbond acid – 37% phosphoric acid 2 Adhesive–Bis-GMA, HEMA, dimethacrylates, polyalkenoic acid copolymer, initiators, water and ethanol	**a**–acid-etch (15 seconds); **b**–rinse (15 seconds); **c**–air-dry (30 seconds); **d**–dentin left visibly moist; **e**–two coats of adhesive systems brushed for 10 seconds each; **f**–air-dry for 10 seconds at 20 cm; **g**–light-cure (10 seconds–600 mW/cm^2)
One Step (BISCO Inc Schaumburg, IL, USA)	1 Uni-etch–32% phosphoric acid 2 Adhesive–Bis-GMA, BPDM, HEMA, initiators and acetone	**a**–acid-etch (15 seconds); **b**–rinse (15 seconds); **c**–air-dry (30 seconds); **d**–dentin left visibly moist; **e**–two coats of adhesive systems, brushed for 10 seconds each; **f**–air-dry for 10 seconds at 20 cm; **g**–light-cure (10 seconds 600 mW/cm^2)
Filtek A110 (3M ESPE)	1 Microfilled resin composite. Silica filler, particle size distribution: 0.01–0.09 microns and approximately 56% wt or 40% vol filler load. Matrix: Bis-GMA and TEGDMA, stabilizers, catalysts and pigments	**A**–incremental placement (<1.5 mm each layer); **b**–light-cure (40 seconds–600 mW/cm^2)
Micronew (BISCO Inc)	1 Reinforced microfilled resin composite. Amorphous silica, filler load 70% wt Matrix: Ethoxylated BisGMA and TEGDMA, stabilizers, catalysts and pigments	**a**–incremental placement (<1.5 mm each layer); **b**–light-cure (40 seconds–600 mW/cm^2)

of Dentistry, University of Oeste de Santa Catarina, all patients were given oral hygiene instructions before operative treatment was performed. Patients with poor hygiene, severe or chronic periodontitis or heavy bruxism were not included in the study group. At least one cervical lesion (erosion/attrition/abfraction) under occlusion was required for each patient. Only non-retentive cavities were included; no undercuts and no more than 50% of the cavosurface margin could involve enamel.[13] The cervical wall had to be located in cementum. Lesions not classified as criteria 2 and 3 of dentin sclerosis that exhibited hypersensitivity (self-reported by the patients as score 3 or 4 on a 0-4 scale) were excluded from the study.[6] Other details about the lesions are described in Table 2.

All participants were informed of the nature and objectives of the current study; however, they were unaware of where each material originated from. Written informed consent was also obtained from all participants prior to starting the treatment.

The retention rate of Adper Single Bond at 36 months was considered to be 86%.[9-12] Using an α of 0.05, a power of 80% and a one-sided test, the minimal sample size was 41 restorations in each group in order to detect a difference of 24% among the groups.

Restorations Procedures

All the lesions were restored by the same two investigators who participated in the patient screening. For calibration purposes, one experienced clinician placed

Table 2: *Distribution of non-carious cervical lesions according to 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 Lesions
Shape (degree of angle)	
<45	12
45-90	16
90-135	26
>135	30
Cervico-incisal height (mm)	
<1.5	12
1.5-2.5	36
>2.5	36
Degree of sclerotic dentin	
1	0
2	32
3	52
4	0
Presence of antagonist	
Yes	84
No	0
Attrition facet	
Yes	40
No	44
Pre-operative sensitivity (spontaneous)	
Yes	20
No	64
Tooth distribution	
Anterior	
Incisor	14
Canines	10
Posterior	
Premolar	60
Molar	0
Arch distribution	
Maxillary	45
Mandibular	39

four restorations for each adhesive. Then, each study operator placed four restorations for each material under the direct supervision of the experienced clinician. These restorations were not included in the current study.

Each patient received one restoration. Randomization of the material was determined by tossing a coin. The lesions were prepared as follows: 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 (Filtek A-110 shade guide/3M ESPE); 4) rubber dam isolation (SS White Prod Odontol Ltda); 5) cleaning with water/air spray. No additional retention or bevel was performed.

The adhesives were then applied according to the description in Table 1. Lesions bonded with Adper Single Bond were incrementally filled with Filtek A110 (3M ESPE) and those bonded with One Step were filled with Micronew (BISCO Inc) (± 3 increments). Each increment was light cured for 40 seconds using a VIP light unit set at 600 mW/cm^2 (BISCO Inc).

All restorations were finished with fine grain diamond burs (#1190F and #2135F, KG Sorensen). After one week, the restorations received a final polishing with Sof-Lex Pop-On disks (3M ESPE).

Clinical Evaluation

The categories evaluated were: retention, color match, anatomic form, marginal adaptation and marginal discoloration, postoperative sensitivity and recurrent caries, according to the United States Public Health Service (USPHS)[14] criteria adapted by Barnes and others[15] and Loguercio and others[13] at baseline and after 6, 12, 18 and 36 months.

Restoration retention rates were calculated using the following equation (ADA Guidelines, 2001)[16]: Cumulative failure %= [(PF+NF)/(PF+RR)] x 100%.

PF is the number of previous failures before the current recall; NF is the number of new failures during the current recall and RR is the number of restorations recalled for the current recall.

Two other experienced examiners performed the evaluation. For training, five photographs representative of each score in each criterion were observed. Then, both investigators examined approximately 10-15 teeth together (they were not included in the sample) on two different occasions. An initial intra-examiner and inter-examiner agreement of at least 85% was necessary before beginning the evaluation.[14]

The examiners performed the evaluation using a mirror and a double-ended probe after tooth prophylaxis with water and pumice in a low-speed handpiece. Each examiner independently evaluated the restoration once. They were unaware of which material had been used, creating a double-blind study.

An initial agreement of at least 85% among examiners was necessary.[17] When disagreement occurred during an evaluation, a consensus had to be made among the evaluators before the patient was dismissed.

Statistical Analysis

Descriptive statistics were used to describe the frequency distributions of the evaluated criteria. The differences in the ratings of the two materials after 6, 12, 18 and 36 months were tested with the Fisher's exact test (α=0.05), and performance of the materials at the baseline and after each occurrence (6, 12, 18 and 36 months) was evaluated by the McNemar's test (α=0.05). As a measurement of agreement among the examiners, the Cohen's Kappa statistic was used.

RESULTS

Eighty-four research subjects were selected and 84 restorations were placed, 42 for each group. The reasons for treatment were prevention of further wear and/or for esthetic reasons. Forty-five restorations were placed in the maxillary arch and 39 were placed in the mandibular arch. Approximately 73% of the restorations were placed in premolars and 27% were placed in anterior teeth. The age and gender distribution of the research subjects are presented in Table 3.

Table 3: *Distribution of Treated Research Subjects and Non-carious Cervical Lesions According to Gender and Age*

Characteristics of Research Subjects	Number of Research Subjects	Number of Lesions
Gender distribution		
Male	41	41
Female	43	43
Age distribution (years)		
20-29	30	30
30-39	19	19
39-49	20	20
> 49	15	15

The Cohen's Kappa statistics (0.90) showed excellent agreement among the examiners. All research subjects were evaluated in the 6-, 12- and 18-month recalls. After 36 months, 78 restorations (39 for each material) in 60 research subjects were available for evaluation. One reason for teeth not being available for evaluation was non-attendance at the 36-month recall. The results are shown in Figures 1 and 2.

No restorations presented secondary caries and loss of anatomic form throughout the evaluation period. After six months, seven teeth restored with One Step/Micronew presented post-operative sensitivity.

Two restorations from the Adper Single Bond group were lost after 12 months and another restoration was lost after 36 months. Using the ADA guidelines formula, the authors of the current study calculated the 12-, 18- and 36-month retention rates to be 95.2% (12 and 18 months) and 92.3% (36 months) for Adper Single Bond. For One Step, seven restorations were lost after 12 months, another four after 18 months and eight after 36 months. The retention rates were 83.3%, 73.8% and 51.4%, respectively, for each recall period (Figure 1).

After 6 and 12 months, no significant difference in the retention rate was found among Adper Single Bond and One Step ($p>0.05$). When the retention rates of the materials at 6 and 12 months were compared with the baseline recordings, again, no significant difference was detected ($p>0.05$). However, after 18 and 36 months, significant differences in retention rates were found among adhesives ($p<0.001$). The comparison of the 18- and 36-month measurements with those of the baseline detected statistical differences only for the One Step system ($p<0.0001$). All restorations that debonded during the 36-month period for both adhesives showed an adhesive failure.

The restorations preserved marginal adaptation and no interfacial staining was found at the six-month recall. Marginal integrity and discoloration were observed after 12, 18 and 36 months. After 36 months, 10 One Step restorations (25.7%) and seven Adper Single Bond restorations (17.9%) were rated as Bravo in the marginal discoloration item (Figure 2). This difference was not statistically different between materials ($p>0.05$), but it was statistically different among periods of evaluation for each adhesive (baseline and 36 months, $p<0.05$). This discoloration occurred at the enamel margin in the majority of the restorations.

After 36 months, four Adper Single Bond restorations (10.3%) and five One Step restorations (12.8%) were rated as Bravo in the item marginal adaptation. No significant difference was detected between these materials and between the baseline and 36-month recall period ($p<0.05$). This lack of adaptation occurred at the enamel margin.

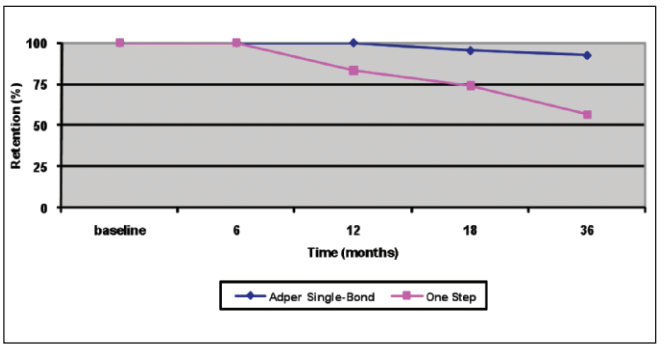

Figure 1: *Retention rates from the two adhesive systems over the evaluation period.*

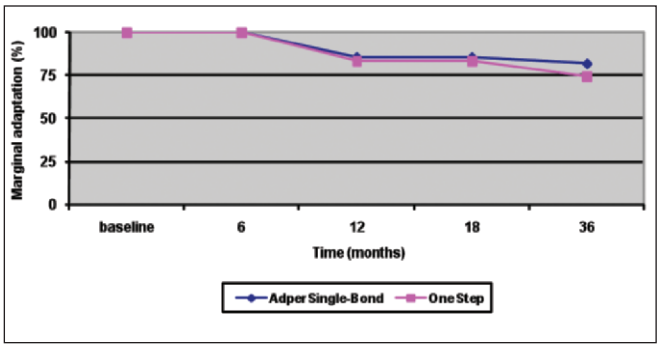

Figure 2: *Percentages of Alpha scores in the item marginal discoloration for the two adhesive systems over the evaluation period.*

DISCUSSION

All restorations in the current investigation were performed using rubber dam isolation. However, there is available data evaluating whether or not use of a rubber dam can improve the performance of Class V restorations. A closer look at the literature findings allow the authors of the current study to observe that many clinical trials were conducted without using rubber dam isolation,[5-6,9,18] but many others employed this type of isolation.[8,12,19-20] The authors of the current study prefer the employment of rubber dam isolation in Class V cavities because, once you get accustomed to placing it, the risk of contamination is much lower than using cotton rolls and retraction cord, primarily during the adhesive steps of acid etching, rinsing and drying. But, this is not an evidence-based dentistry statement, just a clinician preference. Only one clinical trial employing old versions of adhesive systems was found[21] that compared both isolation approaches; future studies using more contemporary adhesive systems should be conducted in order to evaluate the influence of this variable on the performance of Class V restorations.

Another important variable about the methodology of the current clinical trial that deserves mentioning is the delay in the polishing procedure. Some authors

indicated that delaying the polishing procedure can allow for better marginal adaptation in restoration margins, primarily when microfilled composite restorations are employed, similar to the one in the current investigation.[22-23] The effect of this variable on the clinical performance of Class V restorations is yet to be addressed.

Non-carious lesions at the cervical area are used as clinical models to evaluate the efficacy of dentin bonding agents in non-retentive tooth cavities, as recommended by the American Dental Association.[16] This is due to the fact that cervical lesions present no macromechanical undercuts, and they are widely available in research subjects who have better than average oral hygiene. These lesions require at least 50% bonding to dentin, and they are usually found in anterior teeth and premolars with good clinical access. Ineffective bonding commonly results in restoration loss, which is the most objective evaluation parameter of clinical studies.[24]

According to the American Dental Association,[16] for provisional acceptance, dentin and enamel adhesive materials require no more than 5% of the restorations be lost, with no more than 5% of the restorations showing microleakage at the six-month recall. In two independent clinical studies, in order to obtain full acceptance, the cumulative incidence of clinical failures after 18 months had to be lower than 10% for retention and 10% for microleakage. Considering these figures, one could say that only Adper Single Bond met the ADA full-acceptance requirements, as its retention rate at 18-months was 95.2%. One Step, on the other hand, demonstrated a statistically lower retention rate at the same recall period, which was only 73.8%. This situation got worse after 36 months of clinical service. Only 56.4% of One Step restorations were in place, compared to 92.3% of restorations bonded with Adper Single Bond.

Several other investigations have already reported low retention rates with One Step after short- and long-term clinical function in the oral cavity,[5,7-8,25] which is in agreement with the current investigation. According to a recent systematic review of current clinical trials,[24] this material did not meet the ADA guidelines[16] in most clinical trials.

Several factors may account for the differences observed between the materials evaluated in the current investigation. For instance, it is known that the characteristics of the adhesive resin play an important role in the performance of adhesive systems, since the mechanical properties of the polymer formed within the hybrid layer are relevant for the integrity of the adhesive interface.[26] Some authors have shown that One Step contains an excessive amount of acetone (52-81wt%),[27-28] and this can affect the performance of the adhesive in several ways.

First, as acetone has a lower boiling temperature (56.5°C) and higher vapor pressure (200 mmHg) when compared to ethanol (78.3°C/43.9 mmHg) and water (100°C/17.5 mmHg),[27] it is likely that, after evaporation, the adhesive layer of the acetone-based system can be thinner than that formed by the ethanol/water-based material. The thinner the adhesive layer, the more susceptible it is to polymerization inhibition by oxygen, which could have been one of the reasons for the higher failure rates of this material. Some authors suggested 20 µm as the minimum adhesive thickness to avoid polymerization inhibition by oxygen.[29]

Second, it is probable that the high amount of acetone present in the One Step system directly affects its ultimate tensile strength [UTS] when tested as bar-like specimens[30-32] and its degree of conversion [DC][32] compared with other solvent-based materials. This was, in fact, demonstrated in a recent laboratory study in which the ultimate tensile strength and modulus of elasticity of experimental adhesives decreased with an increase in solvent content.[33]

A recent study has reported UTS means of 12.8 (± 3.1) and 7.6 (± 1.0) for Adper Single Bond and One Step, respectively, and a DC means of 59.9 (± 5.1) and 36.6 (± 5.7), respectively.[32] This could again be attributed to the high proportion of solvent/monomer concentration that prevents the monomers from contacting each other and forming a high cross-linking polymer, despite the fact that it was already demonstrated that One Step adhesive is capable of penetrating to a deeper extent in the demineralized dentin surface due to its reduced viscosity.[34]

However, retention failure can occur, owing to cohesive failure of the adhesive layer or adhesive failure. As One Step can penetrate deeper into the demineralized dentin, one may suppose that a cohesive failure might have caused the premature failure of restorations bonded with this material. This should be a matter of future investigations, as the condition of polymerization inside the hybrid layer is still unclear for some materials.

Another important finding of the current investigation is that both materials presented some restorations rated as Bravo in the category of marginal discoloration. Marginal staining occurs primarily because of the infiltration of colored molecules into the interface and/or inside the adhesive layer. Simplified two-step etch-and-rinse adhesives are much more hydrophilic than three-step etch-and-rinse adhesives. The hydrophilic nature of methacrylate copolymers facilitates water sorption[35-37] from the oral environment when exposed externally to salivary fluids and internally from the underlying hydrated dentin.

Water sorption swells the polymer and reduces the frictional forces between the polymer chains, causing a decrease in their mechanical properties.[38-39] This poly-

mer swelling could be the reason for the discoloration at the marginal interface. There is a general belief that the progression of adhesive degradation can lead to interfacial gaps, microleakage and secondary caries of the restoration. However, this correlation was not found in the current study. After 36 months of clinical service, 10 One Step restorations (25.7%) and seven Adper Single Bond restorations (17.9%) were classified as Bravo in the item marginal discoloration, whereas no secondary caries was diagnosed. This occurrence of marginal discoloration was similar to previous clinical studies[5-12] and is usually solved by repolishing the restoration margins.[5]

One cannot rule out the fact that marginal discoloration is a very common finding in cases where there is a lack of marginal adaptation. If composite flash is left on the enamel, the operator also leaves the restoration prone to marginal discoloration in a similar pattern to what occurs when a lack of marginal adaptation occurs over time. This was diagnosed in the baseline assessment in order to avoid misinterpretation of the other data collection. Despite the fact that 17.9% and 25.7% of marginal discoloration after 36 months was detected for SB and OS, respectively, only 13% of the restorations for each adhesive showed a lack of marginal adaptation. However, all were also rated as Bravo in the item marginal discoloration.

CONCLUSIONS

Within the limitations of this investigation, one must conclude that the acetone-based system evaluated in the current study (One Step [BISCO Inc]) should be avoided in Class V restorations, due to the limited retention rate after three years of clinical service.

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