

Two-year Clinical Performance of Self-etching Adhesive Systems in Composite Restorations of Anterior Teeth

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Clinical Relevance

Clinical studies evaluating the clinical performance of one-step self-etching adhesives are scarce. In this study, one-step self-etching adhesives showed good clinical performance at the end of 24 months compared with a two-step etch-and-rinse adhesive.

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SUMMARY

Objective: The aim of this study was to evaluate the two-year clinical performance of Class III, IV, and V composite restorations using a two-step etch-and-rinse adhesive system (2-ERA) and three one-step self-etching adhesive systems (1-SEAs).

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Material and Methods: Two hundred Class III, IV, and V composite restorations were placed into 50 patients. Each patient received four composite restorations (Amaris, Voco), and these restorations were bonded with one of three 1-SEAs (Futurabond M, Voco; Clearfil S3 Bond, Kuraray; and Optibond All-in-One, Kerr) or one 2-ERA (Adper Single Bond 2/3M ESPE). The four adhesive systems were evaluated at baseline and after 24 months using the following criteria: restoration retention, marginal integrity, marginal discoloration, caries occurrence, postoperative sensitivity and preservation of tooth vitality. After two years, 162 restorations were evaluated in 41 patients. Data were analyzed using the χ^2 test ($p < 0.05$).

Results: There were no statistically significant differences between the 2-ERA and the 1-SEAs regarding the evaluated parameters ($p > 0.05$).

Conclusion: The 1-SEAs showed good clinical performance at the end of 24 months.

INTRODUCTION

The advantages of self-etch adhesives are less postoperative sensitivity, fewer operative steps, faster technique, less technique sensitivity, and clinical time savings.¹ In the self-etching systems, acid monomers are combined with water, and hydrophilic solvents can condition the dental structure while simultaneously promoting the infiltration of resinous monomers, diminishing the risk of postoperative sensitivity and reducing the chances of having demineralized dentin that has not been impregnated.^{1,2} Additionally, there are no concerns about the total removal of the acid and overdrying of dentin in these systems.^{2,4}

Although self-etching adhesives have demonstrated good performance in dentin,^{5,6} some studies have suggested that their performance in enamel is lower and that their use may lead to low bond-strength values.^{7,8} Another shortcoming of self-etching adhesives is that *in vitro* studies have shown that they are more susceptible to microleakage in enamel because of the lower bond strength.^{9,10} Self-etching adhesive systems are also subject to hydrolysis caused by the high permeability of the adhesive layer (osmosis), which generates nanoleakage at the adhesive interface.¹¹⁻¹³

Some clinical studies have showed good clinical performance of two-step self-etching systems.¹⁴⁻¹⁸ Recently, one-step self-etching adhesive systems

(1-SEAs) were introduced as the seventh generation of etching systems, which combine acid conditioning, primer, and adhesive in one bottle. Some *in vitro* studies showed that these systems demonstrated a similar impregnation in dentin compared with two-step self-etching systems¹⁹ or total-etch systems,²⁰ although these experiments were conducted *in vitro*. However, clinical studies evaluating the clinical performance of the 1-SEAs are scarce.^{1,2,21-24}

Because of those concerns, the objective of this study was to evaluate the clinical behavior of anterior composite restorations bonded with three 1-SEAs compared with their bonding behavior in a two-step etch-and-rinse adhesive system (2-ERA).

MATERIALS AND METHODS

The São Paulo State University Committee on Investigations Involving Human Subjects reviewed and approved the protocol and consent form used for this study.

Two clinical investigators selected 50 patients according to the following inclusion criteria: presence of four Class III, IV, and/or V carious lesions or unsatisfactory restorations; teeth with pulp vitality; a good general state of health; age between 18 and 65 years; absence of periodontal disease; appropriate oral hygiene; nonsmoker; and absence of parafunctional habits.

Before participating in the study, all patients signed an informed consent. According to the treatment rules from the São José dos Campos School of Dentistry, São Paulo State University, São Paulo, Brazil, all subjects received oral hygiene instructions before treatment.

Restoration Procedures

The restorations were performed by three master's degree students under the supervision of two professors, according to a predetermined procedure that included prophylaxis using rubber cup with pumice and water, shade selection before isolation, rubber dam isolation, and cavity preparation by removing preexisting restorations or excavating carious tissue with carbide spherical burs in a slow-speed headpiece. A bevel was made at the labial cavosurface angle of the anterior teeth using a diamond bur.²⁵ The cavities were cleaned with pumice and water in a rubber cup, rinsed, and dried.

Each subject received at least four restorations in which the adhesive systems were allocated randomly using a coin toss. The adhesive systems used in this

Table 1: *Materials, pH, Compositions, and Application Mode*

Material	pH	Composition	Application Mode
37% Phosphoric acid/ Adper Single Bond 2 (3M ESPE)	0.6	BIS-GMA, HEMA, diurethane dimethacrylate, polyalcenoic acid copolymer, camphorquinone, water, ethanol, glycerol, nanoparticles of silica	Acid etch (15 seconds); rinse (15 seconds); air dry (30 seconds); remove excess moisture with absorbent paper; apply two coats of adhesive systems (15 seconds each); air dry (5 seconds at 20 centimeters); light cure (10 seconds at 600 mW/cm ²)
Futura Bond M (Voco)	2.0	Organic acids, UDMA, HEMA, camphorquinone, and BHT	Apply one coat actively (20 seconds); air dry (5 seconds at 20 cm); light cure (10 seconds at 600 mW/cm ²)
Clearfil S3 Bond (Kuraray, Tokyo)	2.5	MDP, BIS-GMA, HEMA, hydrophobic dimethacrylate, camphorquinone, ethanol, water, silanized colloidal silica	Apply one coat actively (20 seconds); air dry (5 seconds at 20 cm); light cure (10 seconds at 600 mW/cm ²)
Optibond All-in-One (Kerr Corporation)	2.7	Glycerol phosphate dimethacrylate, mono- and dimethacrylate, water, acetone, ethanol, camphorquinone, nanoparticles	Apply two coats actively (20 seconds); air dry (5 seconds at 20 cm); light cure (10 seconds at 600 mW/cm ²)
Bis-GMA, bisphenol A glycidyl methacrylate; HEMA, 2-hydroxyethyl methacrylate; UDMA, urethane dimethacrylate; MDP, 10-Methacryloyloxydecyl dihydrogen phosphate; BHT, Butylated hydroxy toluene.			

study were one 2-ERA, Adper Single Bond 2 (3M ESPE, St Paul, MN, USA), and three 1-SEAs, Futurabond M (Voco, Cuxhaven, Germany), Optibond All-in-One (Kerr Corporation, Orange, CA, USA), and Clearfil S3 Bond (Kuraray, Tokyo, Japan). The adhesive systems were used according to manufacturer's instructions and are described in detail in Table 1.

After the adhesive procedures, resin restorations were completed using a Mylar matrix band and wood wedges. The teeth were restored incrementally with the microhybrid composite, Amaris (Voco). After seven days, the restorations were finished with a sequential protocol using fine grit diamond burs and polishing discs (Soflex, 3M ESPE) under water cooling (Figures 1A,B and 2A,B).

Clinical Evaluation

Evaluations were performed by the operator and at regular time intervals by other evaluators with a kappa agreement of 80%. The restorations were evaluated at baseline, 12 months, and 24 months with regard to (1) restoration retention, (2) enamel and dentin marginal integrity, (3) marginal discoloration, (4) caries occurrence, (5) postoperative sensitivity, and (6) preservation of tooth vitality. The restorations were evaluated according to the criteria introduced by Vanherle and others,²⁶ as shown in Table 2.

Statistical Analysis

Descriptive statistics were used to describe the frequency distributions of the evaluated US Public Health Service criteria. Clinical success between the adhesive systems was determined using the χ^2 test at a significance level of 5% ($p < 0.05$).

RESULTS

Baseline Data

Fifty subjects were enrolled. The mean age of the patients was 38.5 (± 11.1) years. Two hundred composite restorations were placed, 50 with Futura-Bond M, 50 with Optibond All-in-One, 50 with Clearfil S3 Bond, and 50 with Single Bond 2. The distribution of the adhesive systems according to Black's classification is listed in Table 3.

Recall Rate

At the one-year and two-year recalls, the recall rates were 86.0% (43 patients with 172 restorations) and 80.0% (41 patients with 162 restorations), respectively (Table 4). Table 5 summarizes the number of restorations evaluated at each recall period. A cumulative number of two restorations failed during the two years; two restorations with Single Bond 2 were lost.

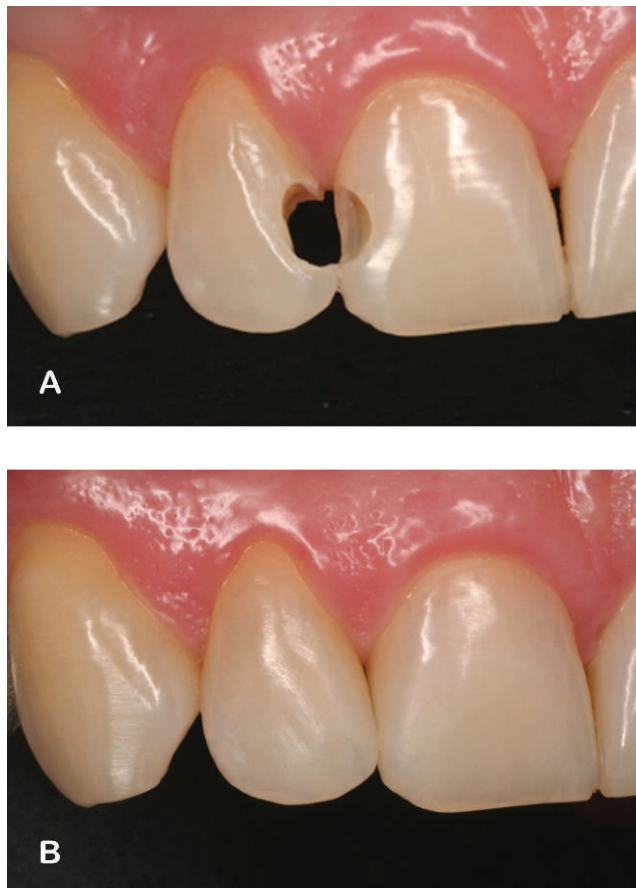


Figure 1. A. Some examples of Class III cavities; B. Class III restorations bonded with Single Bond (central incisor) and Clearfil S3 Bond (lateral incisor).

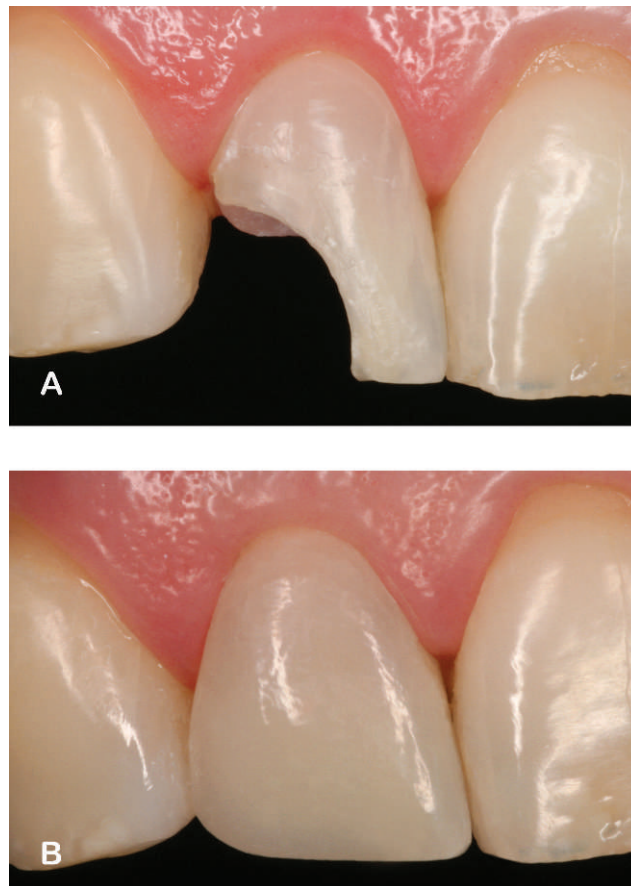


Figure 2. A. An example of Class IV cavity; B. Class IV restoration bonded with Futurabond M (central incisor).

Restoration Retention

At the two-year recall, the restoration alpha retention rate was 95.0% because of the loss of two restorations bonded with Single Bond 2. No statistical differences between the 2-ERA and the 1-SEAs were observed for retention rate ($p > 0.05$).

Marginal Integrity

At the one-year recall, the marginal integrity rates for Single Bond 2 were 97.0%. At the two-year recall, the marginal integrity rates for Single Bond 2 were 97.5%, Clearfil S3 Bond 97.5% and Optibond All-in-One 97.5%. No significant differences in marginal integrity rates were observed between the systems ($p > 0.05$).

Marginal Discoloration

At the one-year recall, the marginal discoloration rates for Single Bond 2 were 93.0%, Clearfil S3 Bond 90.0%, Futurabond M 95.0% and Optibond All-in-

One 90.0%. At the two-year recall, Single Bond 2 was 90.0%, Clearfil S3 Bond 90.0%, Futurabond M 97.5% and Optibond All-in-One 92.5%. No statistical differences were observed between the total etch and the self-etching adhesives systems for marginal discoloration rates ($p > 0.05$).

Caries Occurrence

Caries occurrence was observed for only one restoration bonded with Clearfil S3 Bond after the two-year recall (2.5%). No statistical differences between the total etch and the 1-SEAs for caries occurrence rate were observed ($p > 0.05$).

Postoperative Sensitivity

At the one-year recall, one restoration bonded with Clearfil S3 Bond, one with Single Bond 2 and one with Optibond All-in-One showed postoperative sensitivity (2.5%). At the two-year recall, the postoperative sensitivity rates were 2.5% for Clearfil S3 Bond and 2.5% for Optibond All-in-One. No

Table 2: <i>Criteria for Assessing Composite Restorations</i>		
Criteria	Score and Definition	Evaluation Method
Marginal discoloration	<p>Alpha: There is no visual evidence of marginal discoloration. There is no difference between restorative material color and the adjacent structure color.</p> <hr/> <p>Bravo: There is visual evidence of marginal discoloration between the tooth structure and restoration, but the discoloration does not penetrate the interface in a pulpal direction.</p> <hr/> <p>Charlie: There is visual evidence of marginal discoloration between the tooth structure and restoration, and the discoloration penetrates along the restoration in a pulpal direction.</p>	Visual inspection with a mirror at 18 inches
Caries occurrence	<p>Alpha: There is no visual evidence of dark and deep discoloration adjacent to the restoration.</p> <hr/> <p>Charlie: There is visual evidence of dark and deep discoloration adjacent to the restoration, but it is not directly related to the cavosurface margin.</p>	Visual inspection
Marginal integrity	<p>Alpha: The explorer does not stick when it is passed from the restoration surface to the tooth, or, if the explorer sticks, there is no visible fracture along the restoration margin.</p> <hr/> <p>Bravo: The explorer sticks and there is no clear and visible fracture where the explorer enters, indicating that the margin of the restoration is not adapted closely with the structure of the tooth. The dentin and/or the base are not exposed, and the restoration has no mobility.</p> <hr/> <p>Charlie: The explorer enters a mass defect of the fracture that extends to the dentoenamel junction.</p> <hr/> <p>Delta: The restoration is totally or partially fractured, mobile, or missing.</p>	Visual inspection with an explorer
Postoperative sensitivity	<p>Alpha: No postoperative sensitivity.</p> <hr/> <p>Bravo: Postoperative sensitivity is present.</p>	Blowing a stream of compressed air for 5 s
Retention	<p>Alpha: The restoration is completely retained.</p> <hr/> <p>Bravo: The restoration is partially retained.</p> <hr/> <p>Charlie: The restoration is completely lost.</p>	Visual inspection with an explorer
Tooth vitality	<p>Alpha: Vital.</p> <hr/> <p>Bravo: Non-vital with retracted pulp.</p> <hr/> <p>Charlie: Non-vital; endodontic treatment is needed.</p> <hr/> <p>Delta: Non-vital due to restoration.</p>	Thermal sensitivity test

Table 3: Distribution of the Adhesive Systems According to Black's Classification

Adhesive System	Black's Classification		
	Class III	Class IV	Class V
Single Bond 2	26	8	16
Futurabond M	24	9	17
Clearfil S3 Bond	22	8	20
Optibond All in One	24	7	19

significant differences in postoperative sensitivity rates were observed between the systems ($p>0.05$).

Preservation of Tooth Vitality

One hundred percent of teeth with retained restorations preserved tooth vitality at the two-year recall.

Overall Clinical Success Rate

Because two restorations with Single Bond 2 were lost, the overall clinical success rate was 95.0% after the two-year recall. There was no significant difference between the five adhesives at the two-year recall ($p>0.05$).

DISCUSSION

The 1-SEAs were developed following the recent trend of simplifying the clinical steps and saving operator time. Yet it is important to determine the longevity of these restorations and provide evidence of the safety and efficacy of the new 1-SEAs. Therefore, to that end, the current clinical study evaluated the short-term clinical effectiveness of three of the newest generation of 1-SEAs and compared them to a two-step etch-and-rinse adhesive (2-ERA).

The clinical efficacy of the systems tested was determined by evaluating the restorative retention, marginal integrity, marginal discoloration, caries occurrence, and tooth vitality.^{23,26} In most of the restorations evaluated, few changes were noted from baseline to the two-year evaluation visit. No statistically significant differences were observed between the 2-ERA and the 1-SEAs in terms of retention or any of the other evaluation criteria.

The American Dental Association requires a retention rate of at least 90% of the restorations

Table 4: Number of Restorations Evaluated After Each Recall

Adhesive Systems	No. of Restorations Evaluated		
	Baseline	12 months	24 months
Single Bond 2	50	43	40
Futurabond M	50	43	41
Clearfil S3 Bond	50	43	41
Optibond All in One	50	43	40
Total	200	172	162

placed after 18 months to obtain full acceptance.²⁷ Because of the retention loss of two Class IV restorations belonging to the Single Bond 2, the overall clinical success rate was 95.0% for Single Bond 2 after two years. Therefore, all systems evaluated in this study demonstrated good clinical performance and full acceptance. It is possible that the Single Bond 2 restorations failed because large resin composite restorations have a higher failure rate.²⁸ Additionally, Moura and others²⁹ observed that Class IV restorations had a high prevalence of failures in a three-year clinical performance of composites. With regards to bonding performance and longevity, *in vitro* investigations found that 1-SEAs presented similar tensile bond strengths to dentin when compared with two-step self-etching systems¹⁹ or total-etch systems.²⁰

Corroborating the current results, Zhou and others²⁴ and Brackett and others,²¹ at one-year and two-year recalls, respectively, evaluated the clinical performance of two-bottle and one-bottle self-etching adhesives and observed no statistically significant differences between the systems. Van Landuyt and others²³ and Ermis and others,²² after one-year and two-year clinical evaluations, respectively, found that a one-step self-etch adhesive and a three-step etch-and-rinse adhesive were equally clinically successful. Fron and others¹ observed that the effectiveness of a one-step self-etch adhesive was very good after two years of clinical service.

Slightly more restorations exhibited marginal discoloration at the two-year recall when bonded with Single Bond 2 (10%) than when bonded with Optibond All-in-One (7.5%) and Futurabond M (2.5%), but no statistically significant differences

Table 5: Summary of Restorations Evaluated

Adhesive System and Criteria	Restorations with an Alpha Score/Recalled Restorations (% with Alpha Score) per Evaluation Period		
	Baseline	1 year	2 years
Single Bond 2	Baseline	1 year	2 years
Restorative retention	50/50 (100%)	43/43 (100%)	38/40 (95%)
Marginal integrity	50/50 (100%)	42/43 (97%)	39/40 (97.5%)
Marginal discoloration	50/50 (100%)	40/43 (93%)	36/40 (90%)
Caries occurrence	50/50 (100%)	43/43 (100%)	40/40 (100%)
Postoperative sensitivity	50/50 (100%)	42/43 (97%)	40/40 (100%)
Tooth vitality	50/50 (100%)	43/43 (100%)	40/40 (100%)
Futurabond M	Baseline	1 year	2 years
Restorative retention	50/50 (100%)	43/43 (100%)	41/41 (100%)
Marginal integrity	50/50 (100%)	43/43 (100%)	41/41 (100%)
Marginal discoloration	50/50 (100%)	41/43 (95%)	40/41 (97.5%)
Caries occurrence	50/50 (100%)	43/43 (100%)	41/41 (100%)
Postoperative sensitivity	50/50 (100%)	43/43 (100%)	41/41 (100%)
Tooth vitality	50/50 (100%)	43/43 (100%)	41/41 (100%)
Clearfil S3 Bond	Baseline	1 year	2 years
Restorative retention	50/50 (100%)	43/43 (100%)	41/41 (100%)
Marginal integrity	50/50 (100%)	42/43 (97%)	40/41 (97.5%)
Marginal discoloration	50/50 (100%)	39/3 (90%)	37/41 (90%)

Table 5: Continued.

Adhesive System and Criteria	Restorations with an Alpha Score/Recalled Restorations (% with Alpha Score) per Evaluation Period		
	Baseline	1 year	2 years
Caries occurrence	50/50 (100%)	43/43 (100%)	40/41 (97.5%)
Postoperative sensitivity	50/50 (100%)	42/43 (97%)	40/41 (97.5%)
Tooth vitality	50/50 (100%)	43/43 (100%)	41/41 (100%)
Optibond All-in-One	Baseline	1 year	2 years
Restorative retention	50/50 (100%)	42/43 (97%)	40/40 (100%)
Marginal integrity	50/50 (100%)	43/43 (100%)	40/40 (100%)
Marginal discoloration	50/50 (100%)	39/43 (90%)	37/40 (92.5%)
Caries occurrence	50/50 (100%)	43/43 (100%)	40/40 (100%)
Postoperative sensitivity	50/50 (100%)	42/43 (97%)	39/40 (97.5%)
Tooth vitality	50/50 (100%)	43/43 (100%)	40/40 (100%)

were observed. The differences among all of the adhesive systems were not statistically significant. All restorations that exhibited marginal discoloration were classified with a bravo score, “the visual evidence of marginal discoloration between tooth structure and restoration, but the discoloration does not penetrate in the interface in pulp direction” (Table 2). Rates were high for this short period of time. These results could be due to the fact that the patients enrolled have great difficulty in finding access to dental services because they have low incomes and probably have worse oral health than the general population.

Marginal discoloration usually results from defects present between the tooth-colored restoration and the cavity margins and walls, and the etiology can be inadequate restoration placement, finishing procedures, and unsatisfactory bonding.³⁰ According

to some studies, 1-SEAs are more susceptible to microleakage in enamel tissue because of their lower bond strength.^{9,10} However, the current results showed good clinical performance of 1-SEAs compared with a 2-ERA, as also observed by Van Landuyt and others²³ and Ermis and others.²²

At the one-year recall, alpha scores for marginal integrity were 97.0% for restorations bonded with Single Bond 2. At the two-year recall, alpha scores for marginal integrity (marginal adaptation) were 97.5% for restorations bonded with Single Bond 2, Clearfil S3 Bond, and Optibond All-in-One. Statistical differences between the adhesive systems were not significant. These results demonstrate that the tested adhesive systems showed good marginal integrity during the evaluated period, which is desirable, because restorations with deteriorating margins are more likely to fail than restorations with ideal margins.³¹ However, *in vitro* studies have shown that 1-SEAs are subject to hydrolysis, which is caused by the high water content of the dentin surface, which can generate a phenomenon called water treeing.³² Water trees are water canals at the adhesive interface created by the highly osmolarity of the adhesive solution generating nanoleakage.¹¹⁻¹³ *In vivo* studies are in agreement with the current results, showing good results of 1-SEAs for marginal integrity.^{1,21,22,24}

With regards to postoperative sensitivity, one restoration bonded with Clearfil S3 Bond, one with Single Bond 2, and one with Optibond All-in-One showed postoperative sensitivity at the one-year recall. At the two-year recall, one restoration bonded with Clearfil S3 Bond and one with Optibond All-in-One showed sensitivity. One of the advantages of the self-etching adhesives is a reduction of postoperative sensitivity, as they are less technique sensitive, which reduces possible failures caused by imperfections in the adhesion that result from overetching or drying of the dentin.^{1,22,33} However, the current results showed no significant differences in postoperative sensitivity between the systems, corroborating the findings of Van Landuyt and others²³ and Ermis and others.²² According to Van Landuyt and others,²³ the reduction of postoperative sensitivity can be explained by the protective effect of the restoration combined with the passage of time.

The excellent short-term clinical performance of 1-SEAs in the present study can be attributable to (1) the experience of the operators in performing adhesive dentistry; (2) the presence of a bevel at the labial cavosurface angle, which can improve retention and reduce marginal discoloration of restorations;^{3,34} and (3) the low pH of the systems and functional

monomers in their composition (ie, manufacturers have developed products with lower pH, which increases their acidity, and consequently, they produce an acceptable enamel etching pattern.)⁶

In conclusion, after a two-year recall, the 1-SEAs Clearfil S3 Bond, Futurabond M, and Optibond All-in-One performed similarly to a 2-ERA (Single Bond 2) in terms of restorative retention, marginal integrity, marginal discoloration, caries occurrence, and tooth vitality. However, further studies are necessary to evaluate the long-term clinical performance of these systems.

CONCLUSIONS

There were no statistically significant differences between the 2-ERA and the 1-SEAs with regards to the evaluated parameters. The 1-SEAs showed good clinical performance at the end of 24 months.

Conflict of Interest

The authors 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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