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Two-year clinical evaluation of Class I composite resin restorations using three adhesive systems: A double-blind randomized clinical trial

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Abstract

Aim: The purpose of this randomized split-mouth clinical study was to assess the effect of three adhesive systems on the 2-year clinical success of Class I composite resin restorations.

Methodology: In the treatment of the Class I carious lesions of 20 participants aged 18–24 years with at least three similar carious lesions, three adhesives—Clearfil SE Bond (CSE; Kuraray, Osaka, Japan), Single Bond 2 (SB2; 3M ESPE, St. Paul, MN, USA), and Tri-S Bond (TSB; Kuraray, Osaka, Japan)—and a Filtek Z550 nanohybrid composite resin (3M ESPE, St. Paul, MN, USA) were cured. The baseline and 2-year results of the restorations were assessed according to the World Dental Federation (FDI) and the United States Public Health Service (USPHS) criteria. The chi-square test was used to analyze the data obtained.

Results: There was no loss of restoration in any group at 2 years. No significant differences were observed in any criteria (marginal staining, fracture retention, secondary caries, and postoperative sensitivity) evaluated except marginal adaptation, in accordance with FDI and USPHS criteria ($p > 0.05$). At 2 years, SB2 showed the best marginal adaptation, followed by CSE and TBS. There was a statistically significant difference between SB2 and TSB ($p < 0.05$).

Conclusion: All three adhesive systems can be used successfully in the restoration of Class I carious lesions.

Keywords: Adhesive system, clinical follow-up, composite resin, Class I restoration, USPHS, FDI

Introduction

Today, most composite resins used in the treatment of Class I carious lesions require the prior application of an adhesive material. Self-etch (SE) and etch-and-rinse (ER) systems have long been employed for this purpose (1).

Most dentists continue to show a preference for conventional ER systems over SE systems, which are streamlined, simple to operate, and require less technical precision (1, 2). The results of recent studies suggest that ER systems, as opposed to SE systems, have superior effects on enamel than dentin (1-3). However, by eliminating the administration of acid and the subsequent washing process, SE systems minimize the chance of application and manipulation errors. In addition, the simultaneous occurrence of demineralization and resin infiltration in SE systems is a significant benefit in terms of speeding up application time (4). Therefore, most current adhesive systems involve SE adhesives.

Two-step SE systems were common when clinicians began searching for one-step bonding agents that eliminated the need for a separate acidic priming application. Subsequently, "all in one" single-step SE systems that combine pickling, priming, and adhesive agent application have been developed in recent years. Unfortunately, studies have found that these systems do not perform as well as two-step SE systems (5, 6). Some studies concluded that single-step SE systems were more hydrophilic and permeable (7), while others found single-step SE systems to be more acidic (4). Single-step SE systems also have other disadvantages, such as short shelf life, weakening of bonding over time, phase separation, and excessive absorption of water in dentin before polymerization, causing bonding weakness in complex surfaces where the dentin is not dry (1).

The literature contains a large number of in vitro studies comparing adhesive systems. However, the number of clinical studies is insufficient. Hence, the aim of the current study was to determine how three adhesives often used in clinics affect the performance of Class I composite restorations based on the criteria of the USPHS and FDI. Thus, our hypothesis is as follows: Adhesive system differences do not affect the clinical behavior of composite restorations in Class I restorations.

Materials and Methods

The present study followed the Consolidated Standards of Reporting Trials (CONSORT) and was confirmed by the Erciyes University's University Clinical Research Ethics Committee (2015/281). All volunteer participants read and signed a consent form after being informed of the protocol and potential issues.

Participant Selection and Randomization

Two pre-calibrated dentists used a mouth explorer, mirror, and periodontal probe to evaluate 78 participants between the ages of 18 and 24 with similar oral hygiene habits. After examination of radiographic data, a total of 20 volunteers (11 females and 9 males) were chosen for the study based on the exclusion and inclusion criteria. Figure 1 lists the study's exclusion criteria.

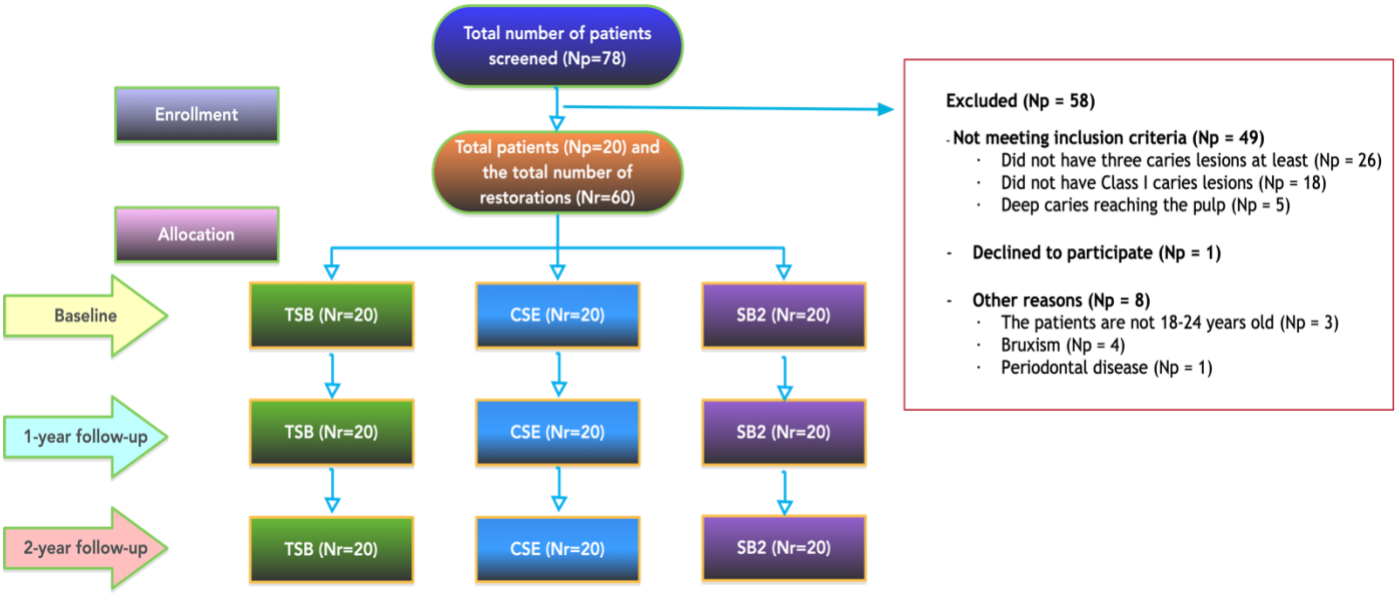

Figure 1. Schematic representation of inclusion and exclusion criteria.

Np, Number of patients; Nr, Number of restorations; TSB, Tri-S Bond; CSE, Clearfil SE Bond; SB2, Single Bond 2

The included participants had a minimum of three Class I carious lesions, were generally in good health, and had adequate oral hygiene. Bite-wing radiographs were obtained from all participants to assess the approximal decay of their carious lesions. Before performing the operative procedures, the patients were provided with oral hygiene guidelines to ensure that the study conditions were uniform.

A researcher not included in the experimental processes determined the teeth allocation for all groups using a random list. The number associated with each treatment was noted on cards, which were then placed inside sequentially numbered, sunproof, stamped envelopes. Intra-individual randomization was carried out. To avoid disclosure, the envelopes were unsealed immediately before the restoration procedure. One skilled and experienced operator performed all the restorations.

Groups-restorative method

The materials, components, and application methods used in the current research are presented in Table 1. Patients who received 30 sec with 2% chlorhexidine solution (Klorhex, Drogsan, İstanbul, Türkiye) were advised to gargle with it. A rubber dam was placed following local anesthesia. All cavities were prepared with high-speed, rotating, water-cooled diamond round burs (Diamir, srl Resia UD, Italy). Hand tools and moderate rotating tungsten carbide burs (Meisinger, Düsseldorf, Germany) were used to clean up the soft caries. The cavity floors were evaluated using a sharp explorer for probing and visual examination of the color of the underlying dentin. The cavities were standardized as follows: There was no tubercle in any of the cavity preparations, and the width of the cavity was one-third of the intercuspal space. Preparation margins had no bevels.

Each cavity was cleaned by rinsing with water and air-drying for 5 seconds before enforcement of the adhesives. Using three adhesive systems in accordance with the manufacturer's directions, a total of 60 restorations (20 restorations with each adhesive) were performed using the split-mouth method.

The participants were divided into groups based on the type of adhesive used, as follows:

1. **Single Bond 2 (3M ESPE, St. Paul, MN, USA)**
2. **Tri-S Bond (Kuraray, Osaka, Japan)**
3. **Clearfil SE Bond (Kuraray, Osaka, Japan)**

Following the completion of the adhesive applications, a nanohybrid composite (Filtek Z550, 3M ESPE, St. Paul, MN, USA) and an LED gleam source (Valo, 1000 mW/cm^2, Ultradent Products Inc., South Jordan, UT, USA) were used to layer all cavities for 20 seconds. After the restorations were finished with fine diamond finishing burs (Finishing diamond 858-018, Diatech Dental Ac, Heerbrugg, Switzerland), they were polished with spiral discs (3M ESPE, St. Paul, MN, USA).

Table 1. Materials, composition, and application modes used in the present study.

Materials	Composition	Application mode
Filtek Z550 Nano Hybrid composite (3M ESPE, St. Paul, MN, USA). Batch # N623045	Bis-GMA, UDMA, Bis-EMA, PEGDMA, TEGDMA	1. Apply resin composite to surface, 2. Light polymerize for 20 s
Clearfil SE Bond (Kuraray, Osaka, Japan). Primer Batch # 01041A Bond Batch # 01552A	Primer: MDP, HEMA, hydrophilic dimethacrylate, dl-camphorquinone, N, N-diethanol-p-toluidine, water. Bond: MDP, Bis-GMA, HEMA, hydrophobic dimethacrylate, dl- camphorquinone, N,N-diethanol-p-toluidine, silanated colloidal silica.	1. Apply primer to tooth surface and leave in place for 20 s 2. Dry with air stream to evaporate the volatile ingredients 3. Apply bond to the tooth surface and then create a uniform film using a gentle air stream 4. Light polymerize for 10 s
Adper Single Bond 2 (3M ESPE, St. Paul, MN, USA). Batch # N151635	HEMA, Bis-GMA, ethanol, dimethacrylate, methacrylate functional copolymer of polyacrylic and polytaconic acid, water, photoinitiator.	1. Apply etchant for 15 s 2. Rinse for 10 s 3. Blot excess water 4. Apply 2–3 consecutive coats of adhesive for 15 s with gentle agitation 5. Gently air dry for 5 s 6. Light polymerize for 10 s
Clearfil Tri-S Bond (Kuraray Medical Inc., Osaka, Japan). Batch # 000004	MDP, Bis-GMA, HEMA, Colloidal silica, Ethanol, Water, dl-Camphorquinone, Initiators, Accelerators, Others	1. Apply adhesive for 20 s 2. Air dry for more than 5 s 3. Light polymerize for 10 s

Abbreviations: Bis-GMA, bis-phenol A diglycidylmethacrylate; HEMA, 2-hydroxyethyl methacrylate; TEGDMA, triethyleneglycodimethacrylate; MDP, 10-methacryloyloxydecyl dihydrogen phosphate; UDMA, Urethane Dimethacrylate; HEDMA, PEGDMA, Polyethylene glycol dimethacrylate; 1,6-hexanediol dimethacrylate; Al2O3, aluminium oxide.

Clinical assessment

Two impartial adjusted scorers who were blind to the study's goal evaluated all restorations at baseline, one year, and two years. Evaluations were conducted according to the FDI (8) and USPHS criteria modified by Perdigão et al. (9). In case of inconsistency between the raters, restorations were reassessed by both inspectors and the ultimate consensus was reached. A standardized paper case form was used to record the data obtained. Because parameters such as color change and wear are connected to the composite resin itself in the assessment of adhesive performance, these parameters were not taken into account while evaluating marginal adaptation, fracture, retention, postoperative sensitivity, marginal discoloration, and secondary caries (10).

The patient's postoperative sensitivity was assessed seven days following the restorative operation by questioning how stimuli such as cold and warm temperatures and occlusal force (chewing) affected them. After two years, bitewing radiographs were taken to determine secondary caries. The parameters used in the variables were ranked as follows (Table 2) (8, 9):

Table 2. FDI and USPHS evaluation criteria

FDI criteria	USPHS criteria
• Clinically very good	• Alpha (clinically ideal)
• Clinically good	• Bravo (clinically acceptable)
• Clinically sufficient/satisfactory	• Charlie (clinically unacceptable)
• Clinically unsatisfactory	
• Clinically poor	

Regardless of how severe the sensitivity was, it was evaluated according to the USPHS criteria: "Charlie" indicated sensitivity, and "alpha" indicated no sensitivity. The term "secondary caries" was assessed in a similar manner. Each patient's restoration was assessed individually and once by each examiner using a uniform paper case report form per FDI and USPHS standards (8, 9).

Statistical analysis

Analyses were performed by using SPSS software (IBM SPSS Statistics version 26, IBM Inc., Armonk, NY, USA).

The chi-square test was used to assess the parameter changes between the baseline and two years. The significance level was established at $\alpha = 0.05$.

Results

All of the 20 volunteers who were evaluated in the initial session of the study came to their controls two years later. In accordance with the USPHS and FDI criteria, all 60 restorations of 20 patients who were evaluated at the initial session were re-evaluated at the end of two years without any loss. The initial, 1-, and 2-year findings of the evaluations are presented in Table 3 and 4.

Fractures and retention

All restorations made at baseline were rated "alpha" according to USPHS criteria and "very good" according to FDI criteria. After two years, all restorations could be evaluated, and no fracture or loss of retention was observed in any restoration. Therefore, at the end of two years, whole restorations were rated as "clinically very good" according to FDI criteria and "alpha" according to USPHS criteria ($p > 0.05$).

Postoperative sensitivity

After two years, without any loss, when all restorations were evaluated, postoperative sensitivity was not detected, so it was rated "clinically very good" according to FDI criteria and "alpha" according to USPHS criteria ($p > 0.05$).

Marginal adaptation

At baseline, 60 restorations were considered "very good" according to FDI criteria. Two years later, small differences were determined in 23 restorations according to FDI criteria and in 20 restorations according to USPHS criteria. Ten restorations in the TSB, eight in the CSE, and five in the SB2 were deemed "good" according to FDI criteria.

When the same groups were evaluated according to USPHS criteria, ten restorations in the TSB, seven in the CSE, and three in the SB2 were scored as "bravo." When each adhesive was evaluated at baseline and at the end of two years, there was a statistically significant difference in marginal integrity only in TSB ($p < 0.05$). After two years, SB2 showed the best marginal adaptation, followed by CSE and TBS. The difference between SB2 and TSB was statistically significant ($p < 0.05$).

Marginal staining

At baseline, all restorations were deemed "very good" according to FDI criteria. After two years, small differences in marginal staining were detected in ten restorations according to FDI criteria and in five restorations according to USPHS criteria. When the groups were assessed according to FDI criteria—six restorations in the TSB and four restorations in the CSE were evaluated according to USPHS criteria—two restorations in the TSB and three in the CSE were scored as "bravo."

According to the statistical analysis, when each adhesive was evaluated within itself, the differences in

marginal coloration at the baseline and at the end of two years according to both FDI and USPHS criteria were not statistically significant ($p > 0.05$).

In addition, there was no significant difference ($p > 0.05$) seen at the end of the two-year evaluation period, when the adhesives were compared against one another using both evaluation criteria (FDI and USPHS).

Secondary caries

At the conclusion of the two years, secondary caries had not been found in any of the groups. All studied restorations received "clinically very good" ratings according to FDI criteria and "alpha" ratings according to USPHS criteria at the end of the two-year assessment period ($p > 0.05$).

Table 3. The findings at baseline 1 year and 2 years recall according to FDI criteria.

Time		Baseline			1 Year			2 Years		
FDI Criteria		TSB	CSE	SB2	TSB	CSE	SB2	TSB	CSE	SB2
Marginal staining	Very good	20	20	20	19	19	20	14	16	20
	Good	–	–	–	1	1	–	6	4	–
	Satisfactory	–	–	–	–	–	–	–	–	–
	Unsatisfactory	–	–	–	–	–	–	–	–	–
	Poor	–	–	–	–	–	–	–	–	–
Fractures and retention	Very good	20	20	20	20	20	20	20	20	20
	Good	–	–	–	–	–	–	–	–	–
	Satisfactory	–	–	–	–	–	–	–	–	–
	Unsatisfactory	–	–	–	–	–	–	–	–	–
	Poor	–	–	–	–	–	–	–	–	–
Marginal adaptation	Very good	20	20	20	20	20	20	10	12	15
	Good	–	–	–	8	5	2	10	8	5
	Satisfactory	–	–	–	–	–	–	–	–	–
	Unsatisfactory	–	–	–	–	–	–	–	–	–
	Poor	–	–	–	–	–	–	–	–	–
Postoperative sensitivity	Very good	20	20	20	20	20	20	20	20	20
	Good	–	–	–	–	–	–	–	–	–
	Satisfactory	–	–	–	–	–	–	–	–	–
	Unsatisfactory	–	–	–	–	–	–	–	–	–
	Poor	–	–	–	–	–	–	–	–	–
Recurrence of caries	Very good	20	20	20	20	20	20	20	20	20
	Good	–	–	–	–	–	–	–	–	–
	Satisfactory	–	–	–	–	–	–	–	–	–
	Unsatisfactory	–	–	–	–	–	–	–	–	–
	Poor	–	–	–	–	–	–	–	–	–

Table 4. The findings at baseline 1 year and 2 years recall according to USPHS criteria.

Time		Baseline			1 Year			2 Years		
USPHS Criteria		TSB	CSE	SB2	TSB	CSE	SB2	TSB	CSE	SB2
Marginal staining	Alfa	20	20	20	19	19	20	18	17	20
	Bravo	–	–	–	1	1	–	2	3	–
	Charlie	–	–	–	–	–	–	–	–	–
Fractures and retention	Alfa	20	20	20	20	20	20	20	20	20
	Bravo	–	–	–	–	–	–	–	–	–
	Charlie	–	–	–	–	–	–	–	–	–
Marginal adaptation	Alfa	20	20	20	12	15	18	10	13	17
	Bravo	–	–	–	8	5	2	10	7	3
	Charlie	–	–	–	–	–	–	–	–	–
Postoperative sensitivity	Alfa	20	20	20	20	20	20	20	20	20
	Bravo	–	–	–	–	–	–	–	–	–
	Charlie	–	–	–	–	–	–	–	–	–
Recurrence of caries	Alfa	20	20	20	20	20	20	20	20	20
	Bravo	–	–	–	–	–	–	–	–	–
	Charlie	–	–	–	–	–	–	–	–	–

Discussion

In this study, three conventional adhesives were used, and their effects on the clinical behavior of class I restorations were tested comparatively. Baseline and two-year findings were presented by evaluating the USPHS and FDI criteria. According to the outcomes of the present study, no significant difference was determined with regard to any criteria assessed (marginal staining, postoperative sensitivity, fracture and retention, and secondary caries), except for marginal integrity. However, there was a difference between the baseline and two-year values when TBS was examined. The difference between the groups with regard to marginal integrity was statistically significant. Therefore, the study's hypothesis was partially rejected.

For the assessment of restorations in clinical research, researchers usually employ the FDI and USPHS criteria. Both methods are simple to use and describe the qualities of a restoration that is clinically acceptable. For long-term clinical follow-up studies, the USPHS criteria may be sufficient. However, because there are more scoring possibilities in short-term research, the FDI criteria may provide more accurate results (9). This may be because of the detailed criteria and the higher scoring values of the FDI. In the current study, the 2-year clinical performance of adhesives was investigated with both FDI and modified USPHS criteria.

Clinical studies evaluating the behavior of adhesives are generally performed on class I and class II cavities and on carious and non-carious cervical lesions (11,12). In this study, class I cavities were preferred for ease of application.

Clinical trials are one of the most effective methods for evaluating the performance of a material. While laboratory studies simulate clinical conditions and should be performed under ideal conditions, the clinical behavior of the material cannot be determined exactly due to the variable parameters of the mouth. Nonetheless, laboratory studies are important for the improvement and initial assessment of restorative materials. For this reason, it is the most valid method to evaluate harmless materials that have been adequately tested at the cellular level in clinical studies. Additionally, long-term clinical studies are needed for a complete evaluation. While there are many in vitro studies comparing three adhesive systems in the literature, there are few adequate clinical studies on this topic.

Retention rate is the most important criterion for the clinical performance of a restoration. According to the American Dental Association, a restoration should be in place two years after the procedure, with a retention rate of at least 90%, to be fully accepted. In the current study, the 2-year survival rate of the groups was 100%, and no fractures were observed in the 2-year evaluation in any restoration. Therefore, the adhesive systems did not differ from one another evaluated at the end of the 2-year period. Other studies investigating adhesive systems have reported no differences between adhesive systems in terms of retention (13, 14).

Some properties of the adhesive and dental tissues are essential for successful adhesion; important tooth characteristics include tooth surface, surface roughness, surface tension value, correct surface angle, and good wettability, and important adhesive properties include low viscosity with sufficient fluidity, chemical content, and polymerization (15). According to previous studies, adhesives containing polyalkenoic acid copolymers and 10-MDP monomers have shown more successful clinical performance. Polyalkenoic acid copolymer was first used in the Vitrebond (3M-ESPE) composition (10); therefore, it is also known as Vitrebond copolymer (VCP) (16, 17). More than half of the polyalkenoic acid copolymer's carboxyl groups can be attached to Hydroxyapatite (Hap). Carboxyl groups form an ionic bond with calcium by exchanging phosphate ions on the substrate (17). These may enable the adhesive to display better clinical behavior in the long term. Otherwise, a 10-MDP monomer is a hydrolysis-resistant monomer that was first synthesized and patented by Kuraray. One study showed that this monomer has the capacity to form strong ionic bonds with calcium (18). Among the adhesives tested in the current study, SB2 contains VCP in its content, while CSE and TSB contain the 10-MDP monomer in its structure. This clinical performance of adhesives may be related to the chemical bonding of VCP and 10-MDP with HAp and the protective impact of Ca-MDP salt.

Brackett et al. (14) reported that the Clearfil SE bond and Clearfil Tri-S bond exhibited acceptable clinical performance, and similar to our study, there was no significant difference between them at the end of 2 years.

Similar to the present study, in Zanatta et al.'s study (19) with Adper Single Bond 2, there was no significant difference between the adhesive systems and techniques, except for the marginal deterioration in TBS. It has been determined that the type of bonding agent and polymerization shrinkage of the composites have an effect on the marginal adaptation of composite restorations. (20). In this study, there was no difference in marginal adaptation between the two adhesives (CSE and TSB) belonging to the same company after two years. However, according to the initial and 2-year results, only the difference in TBS is significant. This can be explained by the higher pH value of TSB compared to CSE. A study conducted by Moretto et al. (21) supported our research in terms of marginal adaptation, and the results reported in other studies were similar (22, 23).

In addition, SB2 produced significantly better marginal adaptation values than TSB, which may be due to differences in adhesive strategies. Researchers have determined that etching enamel tissue with acid creates more effective and permanent bonds (1, 2); however, this enamel bonding has been shown to preserve the resin–dentin interface opposite degradation in vitro (24) and clinically (1).

Frankenberger et al. (25) also reported that acid etching of enamel tissue improves the bonding performance of adhesives. Furthermore, according to

some studies, etching enamel with acid before adhesive application reduces gap formation (25, 26).

Conclusion

Given the limitations of this investigation, the following conclusions were drawn:

1. Despite the few variations between them, all adhesives were detected to be clinically successful at the 2-year recall.

2. The 2-year clinical behavior of conventional adhesives is not dependent on the adhesive system.

3. When evaluated only in terms of marginal adaptation, SB2, followed by CSE, showed the best clinical performance.

4. Two years is a short amount of time to assess and compare the long-term clinical performance of any adhesive.

Disclosures

Ethical Approval: Ethics committee approval was received for this study from Erciyes University, Faculty of Dentistry, Research Ethics Committee, in accordance with the World Medical Association Declaration of Helsinki, with the approval number: 2015/281).

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