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Effect of Surface Sealant Reapplication on Clinical Performance of HEMA-containing and HEMA-free Self-etch Adhesives: Two-year Results

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Clinical Relevance

The application of a surface sealant on Class I restorations is promising for decreasing marginal discoloration and particularly for improving marginal adaptation.

SUMMARY

Purpose: To evaluate the clinical performance of one-step self-etch adhesives over two years with and without the application of a surface sealant.

Methods and Materials: In total, 160 restorations in 40 patients were performed for occlusal caries. Each patient received four Class I restorations, which included a 2-hydroxyethyl methacrylate (HEMA)–containing (Clearfil S3 Bond) and HEMA-free (G-aenial Bond) one-step self-etch adhesive system with and without surface sealant. Half of the restored teeth received Fortify Plus (Bisco) surface sealant material, and the other half were polished with Sof-Lex discs only. Two experienced calibrated examiners clinically evaluated the restorations at baseline and at one- and two-year recalls according to the modified US Public Health Service criteria. The filled surface sealant material was reapplied at each evaluation period.

Results: After two years, none of the restorations had failed. There were no significant differences between the two dentin adhesives with or without a surface sealant application among the evaluation periods. Each dentin adhesive with and without surface sealant showed significant changes from the clinically ideal (Alfa) to clinically acceptable (Bravo) with regard to marginal discoloration, marginal adaptation, and surface texture. Sealed restorations exhibited lower ideal restoration rates with regard to color matching and surface texture and higher ideal restoration rates

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with respect to marginal adaptation compared with unsealed restorations. In addition, the surface sealant application reduced the marginal discoloration of the HEMA-free one-step self-etch adhesive.

Conclusions: The two-year success rates of HEMA-containing and HEMA-free self-etch adhesives with and without surface sealing application were excellent. Although the surface sealant application was not effective with regard to changes in color matching and surface texture, it improved the marginal adaptation of the dentin adhesive and the marginal discoloration of a HEMA-free adhesive.

INTRODUCTION

Shrinkage stresses compete with resin-dentin bonds during resin composite polymerization in such a way that bond failure can be caused, depending upon the configuration and depth of the cavity and the restorative technique used.[1] The configuration factor (C) affects dentin adhesion.[2] The restoration shape is defined by C-factor, which is the proportion of the bonded to the unbonded surface in a restoration.[3] This proportion is greatest in box-like cavities in which there are five bound walls and a single free surface.[4] For clinical circumstances, the proportion of bonded to nonbonded (free) surfaces can reach a maximum C = 5. The increased shrinkage stress rate that develops with an increasing C-value leads to a decrease in the stress-relieving flow capacity of the restorations.[3] Composites are bonded to more than two dentin walls in three-dimensional Class V cavity models in bovine teeth. Flow is significantly restricted in this situation, and contraction stress values can exceed bond strength, which leads to separation.[5] For this reason, in Class I cavities with a high configuration factor, a certain amount of stress is caused when the resin composite is bonded.[2]

Marginal adaptation becomes an important clinical sign of adhesive degradation in composite restorations.[6,7] Sealing marginal gaps through rebonding requires an unfilled resin bonding agent to cover the margins of finished restorations to eliminate the adverse effect of polymerization shrinkage and to ensure better quality and more durable marginal adaptation.[8-11] Unfilled resin seals marginal gaps and decreases microleakage by penetrating into interfacial microgaps.[10,12]

One-step self-etch or so-called "all-in-one" adhesives are accepted as user-friendly materials because the number of steps required in the bonding protocol is reduced. With this system, etching, priming, and adhesive application stages are combined, and, therefore, technique sensitivity diminishes.[13,14] A hydrophilic monomer, 2-hydroxyethyl methacrylate (HEMA), is especially incorporated in adhesive formulations.[15] Current all-in-one adhesives commonly contain HEMA, a well-known co-monomer, that functions as a wetting agent and diffusion promoter of resin into the exposed collagen and prevents phase separation between hydrophilic and hydrophobic monomers.[16,17] However, HEMA makes it difficult to remove water from the adhesive by decreasing the vapor pressure, and this residual water may interfere with the polymerization of adhesive monomers, thereby affecting the quality of the hybrid layer.[18] This negative effect was overcome by introducing HEMA-free self-etch adhesives, which isolate water.[17] HEMA-free self-etch adhesives are a mixture of hydrophilic and hydrophobic contents, solvent, and water. These adhesives are prone to phase separation, which partially accounts for their lower bonding effectiveness. However, strongly air-drying the phase-separated adhesive might be an appropriate clinical technique for removing substantial interfacial water for HEMA-free adhesives, which, when applied accurately, are expected to result in a less hydrophilic (no HEMA) and thus more hydrolysis-resistant adhesive interface in the long term.[16,19,20] The omission of HEMA from adhesive formulations is considered an advantage for removing most of the water that would otherwise weaken the bond.[20] Very strong air-drying appeared sufficient to remove the water droplets.[20]

Acceptable clinical results were reported with sealed restorations that had been maintained after three and 10 years.[6,21] Sealing restorations improved marginal adaptation and staining.[6] A three-year clinical study[21] showed that marginal sealing of defective resin-based composite and amalgam Class I and Class II restorations were conservative and simple procedures that increased the longevity of restorations. Therefore, it is important to understand the clinical success of surface sealing on composite restorations with HEMA-containing or HEMA-free all-in-one self-etch adhesives.

Our aim was to evaluate the clinical performance of HEMA-containing and HEMA-free all-in-one self-etch adhesives with and without a surface sealing process in Class I cavities. The first null hypothesis was that there would be no significant differences between the clinical performance of HEMA-containing and HEMA-free all-in-one self-etch adhesives in

Table 1: *The Brand Names, Chemical Compositions, and Manufacturers' Instructions for Application*

Material (Manufacturer)	Type	Composition	Manufacturers' Instructions
G-aenial Bond (GC Corp, Tokyo, Japan)	HEMA-free one-step self-etch adhesive	4-MET, UDMA, phosphate monomer, DMA component, fumed silica filler, acetone, water, photoinitiator	Shake adhesive bottle. Apply adhesive. Leave for 10 s. Dry thoroughly for 5 s with oil-free air under maximum air pressure. Light-cure for 10 s.
Clearfil S3 Bond (Kuraray Medical Inc, Tokyo, Japan)	One-step self-etch adhesive with HEMA	10-MDP, HEMA, Bis-GMA, water, ethanol, silanated colloidal silica, camphorquinone, photoinitiator	Apply adhesive. Leave for 20 s. Dry by high-pressure blowing for more than 5 s. Light-cure for 10 s.
Fortify Plus Filled Surface Sealant (Bisco, Schaumburg, IL, USA)	Microfilled surface sealant material	Bis-EMA, UDMA, 17.3 vol % 0.4 μm amorphous silica filler	Etch the surface of the restoration and approximately 1-2 mm beyond the tooth/restoration margin for 15 s. Apply a thin layer to previously etched surfaces using a scrubbing motion. Air-thin by blowing a gentle stream of air over this layer to assure an even distribution. Light-cure sealant for 10 s.
Clearfil Majesty Posterior (Kuraray Medical Inc, Tokyo, Japan)	Superfilled nanohybrid composite	Organic content: Bis-GMA, TEGDMA, hydrophobic aromatic dimethacrylate	Place the chosen shade product into the cavity in 1.5-mm increments. Light-cure the resin for 20 s.
		Inorganic content: Glass ceramics, surface-treated alumina microfiller (1.5 μm), silica filler (20 nm)	
		Filler (wt/vol %): 92/83	

Abbreviations: Bis-EMA, ethoxylated bisphenol A dimethacrylate; Bis-GMA, bisphenol glycidyl methacrylate; DMA, dimethacrylate; 4-MET, 4-methacryloxyethyl trimellitic acid; HEMA, 2-hydroxyethyl methacrylate; PENTA, dipentaerythritol penta-acrylate phosphate; TEGDMA, triethylene glycol dimethacrylate; 10-MDP, 10-methacryloyloxydecyl dihydrogen phosphate; UDMA, urethane dimethacrylate.

Class I cavities. The second null hypothesis was that annual surface sealant reapplication would not significantly affect the clinical performance of HEMA-containing and HEMA-free all-in-one self-etch adhesives in Class I cavities.

METHODS AND MATERIALS

Study Design

The study was approved by the Ethics Committee of Kocaeli University, Faculty of Dentistry (KOU KAEK 2014/239). Table 1 shows the materials used in the study. The restorations were performed between July and December 2014 in the Department of Restorative Dentistry, Faculty of Dentistry at Kocaeli University. In total, 40 patients (15 males and 25 females) aged 18-55 years (mean age: 23.3 years) were included in the study (Figure 1). The inclusion criteria were patients who needed four direct Class I composite restorations, those with good oral hygiene and with no active pulpal or periodontal diseases, whose permanent first or second molars/premolars required restorations because of the presence of occlusal carious lesions and were in occlusion with antagonist teeth.[22-24] Patients were excluded according to the following criteria: patients with uncontrolled parafunction, those presenting with poor oral hygiene and those disinterested in or refusing of oral hygiene instructions, those with molars and premolars with carious lesions on a surface other than the occlusal surface or with pulp exposure during carious tissue excavation, those having sensitivity to percussion or spontaneous pain from the related tooth, and patients with periodontal or gingival disease.[22-24] Each patient received four restorations for primary caries on occlusal surfaces. All teeth had opposing and adjacent tooth contacts. The distribution of Class I restorations with sealing and without sealing according to dentin adhesives, composite material type, and teeth numbers were as shown in Table 2.

Treatment Protocol

Each patient received four Class I restorations, which included a HEMA-containing (Clearfil S3 Bond, Kuraray Medical Inc, Tokyo, Japan) or HEMA-free (G-aenial Bond, GC Corp, Tokyo, Japan) one-step self-etch adhesive system, a HEMA-containing adhesive

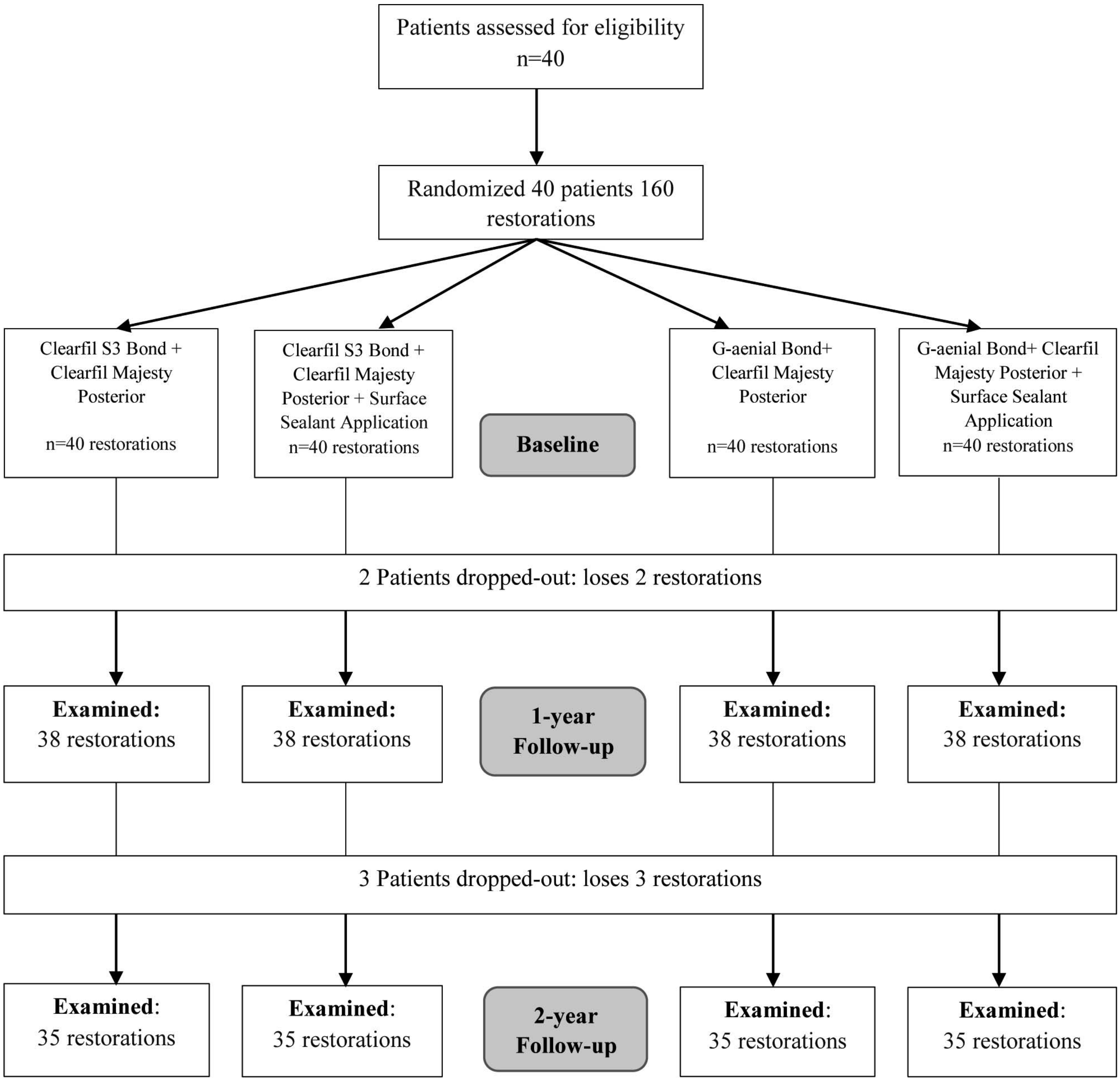

Figure 1. *Flow diagram for history of restorations.*

(Clearfil S3 Bond) with a surface sealant, or a HEMA-free adhesive (G-aenial Bond) with surface sealant. All restorations were performed with the same super-filled nanohybrid composite (Clearfil Majesty Posterior, Kuraray Medical Inc). Randomization was performed by selecting the HEMA-containing dentin adhesive and tooth number by flipping a coin, followed by the selection of restoration type, also determined by the flip of a coin.

Restorative Procedure

First, the teeth were cleaned using pumice water and a rubber cup to remove the surface stains and any residual dental plaque. The lesions were diagnosed macroscopically with a probe; they involved fissures that had reached the dentin, but in which lateral spread was limited and localized to the dentin. Cavity preparation only involved removal of enamel and dentin carious tissues. The average

Table 2: *Distribution of Class I Restorations with Sealing and Without Sealing According to Dentin Adhesives, Composite Material Types, and Teeth Number*

Materials	n	Tooth No.															
		14	15	16	17	24	25	26	27	34	35	36	37	44	45	46	47
Clearfil S3 Bond + Clearfil Majesty Posterior	40	—	—	5	6	—	1	4	4	—	—	6	3	1	—	6	4
Clearfil S3 Bond + Clearfil Majesty Posterior + surface sealant application	40	—	—	5	4	1	—	—	7	—	1	2	13	—	—	—	7
G-aenial Bond + Clearfil Majesty Posterior	40	—	—	4	7	1	—	3	3	—	—	3	7	—	—	8	4
G-aenial Bond + Clearfil Majesty Posterior + surface sealant application	40	—	—	6	4	—	—	5	3	—	1	4	—	—	—	8	9
		—	—	20	21	2	1	12	17	—	2	15	23	1	—	22	24

facio-lingual width of the cavities was approximately one-third of the intercuspal width. The cavity margins were not left in occlusal contact. Isolation of cavities was provided with cotton rolls and saliva ejectors.[25] After isolating the cavities, the same experienced practitioner (NT), who was familiar with the materials used in the present study, performed the tooth preparation and applied the materials per the manufacturers' instructions (Table 1). Polymerization was performed using an Elipar S10 (3M ESPE, St Paul, MN, USA) at no less than 1200 mW/cm^2. The composite shade was selected using the corresponding composite guide or custom composite samples. If the restorations had a depth greater than 2 mm, the composite was applied incrementally. First, a super-filled nanohybrid composite (Clearfil Majesty Posterior) was applied in layers no greater than 2 mm with an oblique incremental placement technique. Then the composite increment was light-cured for 20 seconds, in accordance with the manufacturer's instructions. Occlusion and articulation were checked after the restorations were completed. Then the removal of excess material and finishing were performed using microfine finishing diamonds (8368.204.023 Komet, Gebr Brasseler, Lemgo, Germany). Finally, the restorations were polished using Sof-Lex abrasive disks (3M ESPE). For restorations that required surface sealant, the surface sealant (Fortify Plus, Bisco, Schaumburg, IL, USA) was applied in line with the manufacturer's instructions (Table 1). This step was repeated at the end of one year to enhance the clinical effectiveness of marginal sealing. The patients were informed about the evaluation periods and their cooperation was requested.

Evaluation

Two experienced calibrated examiners from the Department of Restorative Dentistry at Kocaeli University evaluated the restorations using a dental explorer and mirror, according to the modified US Public Health Service (USPHS) criteria (Table 3).[25-27] The examiners were not involved in the operation or insertion of the restorations and were fully blind to the experimental protocol. For training purposes, the examiners were given a set of photographs as a reference to illustrate each score for each criterion. Then they clinically evaluated 20 Class I restorations with two days' separation between examinations. These restorations were not included in the present study. The evaluation phase of the study was performed only when at least 85% intraexaminer and interexaminer agreement was achieved in the calibration phase.[28] At baseline and one- and two-year recalls, color match, wear and loss of anatomic form, marginal discoloration, caries, marginal adaptation, and surface texture were evaluated and scored as Alfa (A) = ideal clinical findings, Bravo (B) = clinically acceptable, Charlie (C) = clinically unacceptable and requiring restoration replacement, and Delta (D) = fractured restoration, mobile, or missing and requiring immediate replacement. Also, in restorations with surface sealant, after clinical evaluation of surface sealant application at the end of one year, surface sealant was again reapplied. This surface sealant reapplication was evaluated at the end of two years (another one year). Thus, surface sealant reapplication was evaluated annually. Conflicts in scoring were resolved through consensus.

Statistical Analysis

Statistical analysis was performed using SPSSWIN 20.0 (SPSS, Chicago, IL, USA). The data obtained were statistically analyzed using the Friedman test to examine changes that occurred throughout the two-year evaluation period (Table 4). Comparisons of data between the two dentin adhesives with or without a surface sealing were performed using the Mann-Whitney *U*-test, Kruskal-Wallis one-way

Table 3: *Direct Clinical Evaluation Criteria (Modified USPHS Criteria)*

Rating	Aspect	Method
Color match		
Alfa (A)	There is no mismatch in color, shade, and/or translucency between the restoration and the adjacent tooth structure.	Visual inspection
Bravo (B)	There is a mismatch in color, shade, and/or translucency between the restoration and the adjacent tooth structure, but the mismatch is within the normal range of tooth color, shade, and/or translucency.	Visual inspection
Charlie (C)	The mismatch is between restoration and adjacent tooth structure outside the normal range of tooth color, shade, and/or translucency.	Visual inspection
Cavosurface marginal discoloration		
Alfa (A)	There is no discoloration anywhere on the margin between the restoration and the tooth structure.	Visual inspection
Bravo (B)	There is discoloration anywhere on the margin between the restoration and the tooth structure, but the discoloration has not penetrated along the margin of the restorative material in an enamel direction and can be polished away.	Visual inspection
Charlie (C)	The discoloration has penetrated along the margin of the restorative material in an enamel direction.	Visual inspection
Wear/anatomic form		
Alfa (A)	The restoration is not undercontoured: that is, the restorative material is not discontinuous with existing anatomic form.	Visual inspection and explorer
Bravo (B)	The restoration is undercontoured: that is, the restorative material is discontinuous with existing anatomic form, but sufficient restorative material is not missing so as to expose the enamel or base.	Visual inspection and explorer
Charlie (C)	Sufficient restorative material is missing so as to expose the enamel or base.	Visual inspection
Caries		
Alfa (A)	There is no evidence of caries contiguous with the margin of the restoration.	Visual inspection
Bravo (B)	There is evidence of caries contiguous with the margin of the restoration.	Visual inspection
Marginal adaptation		
Alfa (A)	There is no visible evidence of a crevice along the margin into which the explorer will penetrate.	Visual inspection and explorer
Bravo (B)	There is visible evidence of a crevice along the margin into which the explorer will penetrate. The enamel or base is not exposed.	Visual inspection and explorer
Charlie (C)	There is visible evidence of a crevice along the margin into which the explorer will penetrate. The enamel or base is exposed.	Visual inspection and explorer
Delta (D)	The restoration is fractured or missing in part or *in toto*.	Visual inspection and explorer
Surface texture		
Alfa (A)	Surface of restoration is smooth.	Explorer
Bravo (B)	Surface of restoration is slightly rough or pitted, can be refinished.	Explorer
Charlie (C)	Surface deeply pitted, irregular grooves (not related to anatomy), cannot be refinished.	Explorer
Delta (D)	Surface is fractured or flaking.	Explorer

analysis of variance, and the Dunn post hoc test. When a statistically significant difference was identified for any assessed criterion, the Dunn post hoc test was used for multiple comparisons between each recall time interval (Tables 5-7). Kaplan-Meier survival analysis was used to determine the probability of the clinical survivability of the two dentin adhesives with or without the surface sealing for a given time period (Table 4). P-values of <0.05 were considered statistically significant. Interexaminer and intraexaminer agreement was tested using Cohen kappa coefficient.

RESULTS

After one year, two patients with eight restorations left the study. At the end of two years, three patients with 12 restorations did not return (Figure 1). After one and two years, the cumulative recall rates for patients were 95% and 87.5%, respectively.

The Cohen kappa coefficient (0.87) revealed strong agreement between the examiners, with no statistical difference between them ($p>0.05$). The Kaplan-Meier survival analyses are given in Table 4. After one and two years, no restorations failed, giving a 100% success rate for each evaluation period.

Table 4: *Results of Clinical Evaluation of a HEMA-containing and a HEMA-free One-step (All-in-one) Self-etch Adhesive with and Without Surface Sealing Process in Class I Restorations Using Modified USPHS Criteria. Observations Are Shown in Percent (Cumulative Number of Restorations)*

Time	Groups	Recall Rate	Retention		Color Match			Marginal Discoloration		
			A	C	A	B	C	A	B	C
Baseline	Clearfil S3 Bond	100 (40)	100 (40)	—	100 (40)	—	—	100 (40)	—	—
	G-aenial Bond	100 (40)	100 (40)	—	100 (40)	—	—	100 (40)	—	—
	Clearfil S3 Bond + surface sealant application	100 (40)	100 (40)	—	100 (40)	—	—	100 (40)	—	—
	G-aenial Bond + surface sealant application	100 (40)	100 (40)	—	100 (40)	—	—	100 (40)	—	—
1 year	Clearfil S3 Bond	95.0 (38)	100 (38)	—	94.7 (36)	5.3 (2)	—	86.8 (33)	13.2 (5)	—
	G-aenial Bond	95.0 (38)	100 (38)	—	94.7 (36)	5.3 (2)	—	86.8 (33)	13.2 (5)	—
	Clearfil S3 Bond + surface sealant application	95.0 (38)	100 (38)	—	97.4 (37)	2.6 (1)	—	84.2 (32)	15.8 (6)	—
	G-aenial Bond + surface sealant application	95.0 (38)	100 (38)	—	89.5 (34)	10.5 (4)	—	89.5(34)	10.5 (4)	—
2 Year	Clearfil S3 Bond	87.5 (35)	100 (35)	—	94.3 (33)	5.7 (2)	—	82.9 (29)	17.1 (6)	—
	G-aenial Bond	87.5 (35)	100 (35)	—	91.4 (32)	8.6 (3)	—	77.1 (27)	22.9 (8)	—
	Clearfil S3 Bond + surface sealant application	87.5 (35)	100 (35)	—	91.4 (32)	8.6 (3)	—	82.9 (29)	17.1 (6)	—
	G-aenial Bond + surface sealant application	87.5 (35)	100 (35)	—	85.7 (30)	14.3 (5)	—	85.7 (30)	14.3 (5)	—

Abbreviations: A, Alfa; B, Bravo; C, Charlie; D, Delta; HEMA, 2-hydroxyethyl methacrylate.

Statistical analyses revealed no significant differences ($p>0.05$) between Clearfil S3 Bond and G-aenial Bond dentin adhesives with or without surface sealants within each evaluation period with regard to the defined parameters.

Only the G-aenial Bond with the surface sealant showed statistically significant differences ($p=0.015$) between baseline and one-year rates and between baseline and two-year rates with respect to color matching (Tables 5 and 7). After two years, 94.3% of Clearfil S3 Bond, 91.4% of G-aenial Bond, 91.4% of Clearfil S3 Bond with sealant and 85.7% of G-aenial Bond with sealant restorations were scored as clinically ideal (Alfa) with respect to color match. For Clearfil S3 Bond and G-aenial Bond dentin adhesive with or without a surface sealant, statistically significant differences ($p<0.05$) were determined between baseline and one-year rates and baseline and two-year rates with respect to marginal discoloration and surface texture (Tables 5 and 7). After two years, 17.1% of Clearfil S3 Bond and Clearfil S3 Bond restorations with sealant showed marginal discoloration, and 22.9% of G-aenial Bond and 14.3% of G-aenial Bond restorations with sealant showed marginal discoloration. This marginal discoloration was a result of the adhesive system. However, this discoloration was superficial, located on a nonspecific part of the enamel, did not penetrate toward the pulp along the margin of the restorative material, and could be polished away. Regarding surface texture, 82.9% of Clearfil S3 Bond restorations, 77.1% of G-aenial Bond restorations, 80% of Clearfil S3 Bond restorations with sealant, and 74.3% of G-aenial Bond restorations with sealant were clinically ideal after two years. Regarding the marginal adaptation rate, there were statistically significant differences ($p=0.014$) between baseline and two-year rates of Clearfil S3 Bond without the surface sealant (Table 7). Statistically significant differences were determined between baseline and two-year rates ($p=0.008$) and between the one-year and two-year rates ($p=0.046$) of G-aenial Bond without the

Table 5: p-*values (statistical difference) Between Baseline and One Year*

Groups	Retention	Color Match	Marginal Discoloration	Wear/Anatomic Form	Caries	Marginal Adaptation	Surface Texture
Clearfil S3 Bond	1.0 (NS)	0.135 (NS)	0.025 (S)	0.368 (NS)	1.0 (NS)	0.083 (NS)	0.025 (S)
G-aenial Bond	1.0 (NS)	0.097 (NS)	0.025 (S)	0.097 (NS)	1.0 (NS)	0.083 (NS)	0.046 (S)
Clearfil S3 Bond + surface sealant application	1.0 (NS)	0.097 (NS)	0.014 (S)	1.0 (NS)	1.0 (NS)	0.046 (S)	0.046 (S)
G-aenial Bond + surface sealant application	1.0 (NS)	0.046 (S)	0.046 (S)	0.317 (NS)	1.0 (NS)	0.025 (S)	0.008 (S)

Abbreviations: NS, not significant; S, significant ($p<0.05$*).*

Table 4: Extended.

Time	Wear/Anatomic Form			Caries		Marginal Adaptation				Surface Texture			
	A	B	C	A	B	A	B	C	D	A	B	C	D
Baseline	100 (40)	—	—	100 (40)	—	100 (40)	—	—	—	100 (40)	—	—	—
	100 (40)	—	—	100 (40)	—	100 (40)	—	—	—	100 (40)	—	—	—
	100 (40)	—	—	100 (40)	—	100 (40)	—	—	—	100 (40)	—	—	—
	100 (40)	—	—	100 (40)	—	100 (40)	—	—	—	100 (40)	—	—	—
1 year	97.4 (37)	2.6 (1)	—	100 (38)	—	92.1 (35)	7.9 (3)	—	—	86.8 (33)	13.2 (5)	—	—
	97.4 (37)	2.6 (1)	—	100 (38)	—	92.1 (35)	7.9 (3)	—	—	89.5 (34)	10.5 (4)	—	—
	100 (38)	—	—	100 (38)	—	89.5 (34)	10.5 (4)	—	—	89.5 (34)	10.5 (4)	—	—
	97.4 (37)	2.6 (1)	—	100 (38)	—	86.8 (33)	13.2 (5)	—	—	81.6 (31)	18.4 (7)	—	—
2 Year	97.1 (34)	2.9 (1)	—	100 (35)	—	82.9 (29)	17.1 (6)	—	—	82.9 (29)	17.1 (6)	—	—
	91.4 (32)	8.6 (3)	—	100 (35)	—	80 (28)	20 (7)	—	—	77.1 (27)	22.9 (8)	—	—
	100 (35)	—	—	100 (35)	—	85.7 (30)	14.3 (5)	—	—	80.0 (28)	20.0 (7)	—	—
	88.6 (31)	11.4 (4)	—	100 (35)	—	82.9 (29)	17.1 (6)	—	—	74.3 (26)	25.7 (9)	—	—

surface sealant (Tables 6 and 7). Also, for the Clearfil S3 Bond and G-aenial Bond with the surface sealant, there were statistically significant differences between baseline and one-year rates (p=0.046 and p=0.025, respectively) (Table 5) and baseline and two-year rates (p=0.025 and p=0.014, respectively) (Table 7). In addition, 82.9% of Clearfil S3 Bond restorations, 80% of G-aenial Bond restorations, 100% of Clearfil S3 Bond restorations with sealant, and 82.9% of G-aenial Bond restorations with sealant were clinically ideal (Alfa) with respect to marginal adaptation after two years. Only the G-aenial Bond with the surface sealant showed statistically significant differences (p=0.046) between the baseline and two-year rates with regard to wear or loss of anatomic form (Table 7). After two years, 97.1% of Clearfil S3 Bond, 91.4% of G-aenial Bond, 100% of Clearfil S3 Bond restorations with sealant, and 88.6% of G-aenial Bond restorations with sealant were clinically ideal with regard to wear and anatomic form. After two years, none of the restorations demonstrated caries.

DISCUSSION

After two years, there were no significant differences between the clinical performance of HEMA-containing and HEMA-free one-step self-etch adhesives with regard to color match, marginal discoloration, wear and loss of anatomic form, caries, marginal adaptation, and surface texture. Therefore, the first null hypothesis must be accepted. With the exception of caries, there was a decline in restoration performance from clinically ideal to clinically acceptable with respect to all criteria evaluated in the study. In our study, the two-year survival rates for Clearfil S3 Bond and G-aenial Bond restorations were 100%. In agreement with our results, other studies[29,30] reported 100% success rates after two and three years for Class I cavities. In accordance with our findings, it was reported[31] that the restorations performed well overall and were successful at the two-year recall for Class I/II restorations, regardless of which bonding agent was used. Moreover, 100% success rates were obtained for a nanohybrid composite material (Grandio) with a self-etch adhesive (Futur-

Table 6: p-*values (statistical difference) Between One and Two Years*

Groups	Retention	Color Match	Marginal Discoloration	Wear/Anatomic Form	Caries	Marginal Adaptation	Surface Texture
Clearfil S3 Bond	1.0 (NS)	0.135 (NS)	0.317 (NS)	0.368 (NS)	1.0 (NS)	0.083 (NS)	0.317 (NS)
G-aenial Bond	1.0 (NS)	0.097 (NS)	0.083 (NS)	0.097 (NS)	1.0 (NS)	0.046 (S)	0.046 (S)
Clearfil S3 Bond + surface sealant application	1.0 (NS)	0.097 (NS)	1.0 (NS)	1.0 (NS)	1.0 (NS)	0.317 (NS)	0.083 (NS)
G-aenial Bond + surface sealant application	1.0 (NS)	0.317 (NS)	0.317 (NS)	0.083 (NS)	1.0 (NS)	0.317 (NS)	0.157 (NS)

Abbreviations: NS, not significant; S, significant ($p<0.05$).

Table 7: p-values (statistical difference) Between Baseline and Two Years

Groups	Retention	Color Match	Marginal Discoloration	Wear/Anatomic Form	Caries	Marginal Adaptation	Surface Texture
Clearfil S3 Bond	1.0 (NS)	0.135 (NS)	0.014 (S)	0.368 (NS)	1.0 (NS)	0.014 (S)	0.014 (S)
G-aenial Bond	1.0 (NS)	0.097 (NS)	0.005 (S)	0.097 (NS)	1.0 (NS)	0.008 (S)	0.005 (S)
Clearfil S3 Bond + surface sealant application	1.0 (NS)	0.097 (NS)	0.014 (S)	1.0 (NS)	1.0 (NS)	0.025 (S)	0.008 (S)
G-aenial Bond + surface sealant application	1.0 (NS)	0.025 (S)	0.025 (S)	0.046 (S)	1.0 (NS)	0.014 (S)	0.003 (S)

Abbreviations: NS, not significant; S, significant ($p<0.05$).

abond NR) after two years.[32] However, the adhesive system used in that study was different from the adhesive used in our study. Another study[33] that clinically evaluated self-etch adhesives in posterior restorations reported 96% and 95.2% retention rates for Adper Prompt L-Pop and iBond, respectively, and a 100% retention rate for Clearfil S3 Bond and One-Step Plus in Class I/II restorations after two years; compared with our study, slightly lower or the same percentage success rates were obtained in these studies. Unlike the present study, Class I and II restorations in these studies were evaluated together. In addition, with the exception of Clearfil S3 Bond, different adhesives and composite materials were used in those studies. Therefore, cavity location and size and composite material and adhesive variability may account for the different failure rates between our study and those in the literature. However, a meta-analysis on prospective studies[34] concerning survival of direct resin restorations in posterior teeth showed a 1.46% mean annual failure rate in short-term studies that included Class I/II restorations. When both short- and long-term studies were considered, recall rate, ratio of Class I fillings to Class II fillings, observation period, and study size (number of restorations and patients) each significantly influenced the overall failure rate.

The data obtained after two years shows the performance of this surface sealant reapplication after another one year because the surface sealant was reapplied again in the first-year recall. Thus, data for restoration with surface sealant related to all criteria evaluated in the study were obtained annually. The annual reapplication of the surface sealing did not significantly affect the clinical performance of a HEMA-containing and a HEMA-free one-step self-etch adhesive in regard to the evaluation criteria used at the end of two years. Thus, the second null hypothesis must be accepted. With the exception of caries, there was a decline in the performance of the restorations from clinically ideal (Alfa) to clinically acceptable (Bravo) with respect to the evaluation criteria. The two-year survival rates for Clearfil S3 Bond and G-aenial Bond restorations with sealant were 100%. None of the restorations failed, resulting in a 100% success rate. In agreement with our findings, a study[6] that evaluated sealed composite after 10 years in Class I and II cavities reported no failures in Class I restorations. However, the survival rate of Class II restorations was 85%.

After two years, color change was observed for Clearfil S3 Bond and G-aenial Bond restorations without sealant from clinically ideal (Alfa) to clinically acceptable (Bravo) (Table 4), and these changes were not statistically significant ($p>0.05$). It was reported[29,30] that ideal restorations with regard to color match were 100% and 96% in Class I restorations that did not include sealant application protocols after two and three years, respectively. However, 86.5% of restorations that included nanofill and nanohybrid composite materials exhibited ideal color match after 30 months in Class I restorations.[23] These results partially agree with our findings, in which similar or lower ideal restoration rates were observed. In our study, we used the same brand of composite material for all adhesives to exclude potential intervening variables.[33] After two years, color changes were observed for Clearfil S3 Bond and G-aenial Bond restorations with sealant from clinically ideal to clinically acceptable (Table 4); these changes were not statistically significant ($p>0.05$), with the exception of G-aenial Bond restorations with sealant (Tables 5-7). The color change was only statistically significant for G-aenial Bond restorations with sealant between baseline and one year ($p=0.046$) (Table 5) and between baseline and two years ($p=0.025$) (Table 7). In addition, Clearfil S3 Bond and G-aenial Bond restorations with sealant showed a greater color change than was seen without sealant restorations of Clearfil S3 Bond and G-aenial Bond between one and two years. On the other hand, it was reported[35] that 75% of sealed and only 33% of unsealed restorations were rated Alfa with regard to color match in Class I and II restorations at a five-year recall. This difference may be associated with the difference in evaluation times between that study and our study. In contrast to our findings, it was shown[36] that the surface sealant did not alter the color stability of the tested materials after artificial aging using ultraviolet radiation and staining solutions. We used a different surface sealant material including amorphous silica filler; therefore, this may have affected the color change. In addition, *in vivo* conditions may cause different results compared to *in vitro* conditions. Fortify Plus contains ethoxylated bisphenol A dimethacrylate resin (Bis-EMA). The Bis-EMA component, which is present in many restorative resin composites, was considered to contribute increased staining of composite resin coated with Fortify Plus surface sealant.[37]

After two years, Clearfil S3 Bond and G-aenial Bond restorations without surface sealant exhibited significant marginal discoloration and the deterioration of marginal adaptation. However, these changes were clinically acceptable. In partial agreement with the present study, a clinically acceptable marginal discoloration rate, which was 14.3%-22.9% in our study, was reported[23,29,30] as 0%-27% in Class I restorations after three and two years and after 30 months. In addition, with regard to marginal adaptation, the ideal restoration rates in these studies were found to be 56%-92%. The differences in results between trials are accounted for by differences in the adhesives used, chemical and physical properties of the materials, compositions of brands, and duration of the clinical studies.[23] However, in another study[33] that used the same adhesive (Clearfil S3 Bond), ideal restorations rates were, respectively, 54.5% and 50% with regard to marginal discoloration and marginal adaptation in Class I/II restorations after two years. The comparatively lower ideal restoration rates may have been caused by cavity size differences because they included both Class II and Class I cavities.

In our study, although there were no statistical differences, Clearfil S3 Bond restorations without sealant showed lower marginal discoloration and deterioration of marginal adaptation than did G-aenial Bond restorations without sealant. Clearfil S3 Bond had 10-MDP (10-methacryloyloxydecyl dihydrogen phosphate) in its chemical structure. The "Adhesion-decalcification" idea reports that this specific functional monomer can interact ionically with hydroxyapatite, forming self-assembled "nanolayers." Combined with nano-layering, stable MDP-calcium salt deposition will contribute to clinical longevity of the hybrid layer and thus the bond to dentin.[38] However, HEMA-free one-step adhesives are prone to phase separation; therefore, they are complex blends of solvents, water, and hydrophilic and hydrophobic ingredients. This may explain their lower bonding effectiveness[16] and may account for differences between Clearfil S3 Bond and G-aenial Bond restorations.

After two years, Clearfil S3 Bond and G-aenial Bond restorations with surface sealant exhibited significant marginal discoloration and the deterioration of marginal adaptation. However, these changes were clinically acceptable. In addition, in the present study, G-aenial Bond restorations with surface sealant exhibited lower marginal discoloration than did G-aenial Bond restorations without surface sealant. Moreover, Clearfil S3 Bond and G-aenial Bond restorations with surface sealant both showed higher clinically ideal (Alfa) restoration rates than did restorations without sealant with regard to marginal adaptation. It may be said that the surface sealant improved the quality of the marginal seal, especially for G-aenial Bond restorations with surface sealant. In agreement with this finding, Femiano and others[39] observed that the use of a hydrophobic bonding agent for resealing direct restorations showed the small deteriorations of marginal seal, such as overhang resin or brown line at finish lines in enamel in the short term. On the other hand, after 24 months, restorations without the additional marginal seal showed a greater prevalence of gaps that retained the probe or included probe penetration of more than 1 mm. On this basis, the authors[39] concluded that the quality of marginal seal could be improved by applying an enamel adhesive on the margins of finished direct resin restorations, thereby increasing their longevity. Dickinson and Leinfelder[35] found that over five years, sealed restorations showed a higher rate of ideal restorations than did unsealed restorations with respect to marginal discoloration and marginal integrity. They reported that surface-penetrating sealant had the potential to penetrate and fill microstructural defects, including defects both on the occlusal surface of the restoration and at the restoration-preparation interface. Thus, their surface-penetrating sealant was effective at enhancing marginal integrity.[35] In addition, it was reported[6] that sealing the defective margins of restorations improved marginal staining and marginal adaptation parameters, although the findings of this study were similar to those associated with the group without sealing by the 10th year.

With respect to wear and anatomic form, 97.1% of Clearfil S3 Bond and 91.4% of G-aenial Bond restorations without sealants were ideal (Alfa). In partial agreement with our findings, the ideal restoration rates were reportedly 85.7%-93% after two years, 88%-100% after three years, and 94.6% after 30 months.[23,29-31,33] The difference in rates between our study and others may have been caused by the use of different composite materials. In addition, only G-aenial Bond restorations with surface sealant exhibited significantly lower rates of ideal restoration with regard to wear and anatomic form after two years. However, there was no statistically significant difference between Clearfil S3 Bond and G-aenial Bond restorations with and without sealant. On the other hand, the G-aenial Bond restorations with the surface sealant exhibited statistically significant differences ($p=0.046$) between the baseline and two-year rates (Table 7). Thus, the surface sealant was effective at reducing the wear rate of Clearfil S3 Bond restorations, but ineffective at reducing the wear rate of G-aenial Bond restorations. In partial support of our finding, Dickinson and Leinfelder[35] found that after two years, the values for the loss of material was 33.8 μm for unsealed restorations and 26.2 μm for sealed samples, and they stated that the unfilled surface sealant was effective at reducing the wear rates of the composite resin.

No restorations exhibited caries that were contiguous with their margin. In accordance with our findings, no caries were found in Class I restorations after either two or three years.[29,30] However, after 30 months, the caries rates were respectively reported[23] as 0% and 2.7% for nanohybrid and nanofill composite restorations in Class I restorations.

Regarding surface texture, 82.9% of Clearfil S3 Bond and 77.1% of G-aenial Bond restorations were ideal. In partial agreement with our finding, the ideal restoration rates were reported as 59.9%-100% in Class I restorations after two years, three years, and 30 months.[23,29,30] In addition, in Class I/II restorations, the achieved clinically ideal (Alfa) restorations rates were 71.4%-100% after two years.[33,40] The differences in results between our study and those of others may be explained by the differences in the compositions of brands and the physical and chemical properties of the materials used.[23] However, although there were no significant differences in the present study, surface-sealed Clearfil S3 Bond and G-aenial Bond restorations exhibited lower ideal restoration rates than did non–surface-sealed restorations with respect to surface texture. In agreement with our findings, a previous study[35] found no significant differences between sealed and unsealed restorations over five years; however, unsealed restorations had a higher percentage of Alfa ratings until the fifth-year evaluation. Furthermore, surface-penetrating sealants did not improve the roughness of the nanofiller composite resin, which supports our findings.[41] Nevertheless, the surface roughness values of G-aenial Posterior and Filtek Ultimate Universal Restorative increased significantly after the application of surface sealant, and sealant application had no significant effect on the microhardness of Clearfil Majesty Posterior, which was used in the present study.[42] Our study found that surface roughness values increased following the application of surface sealant, compared with unsealed teeth after two years, which may be explained by the relatively high filler content (17.3% vol) and particle size of Fortify Plus.[42] This is supported by the finding that sealant performance worsened compared with that of controls after six months of tooth brushing when filler was added, as in Fortify Plus. The wear in the organic matrix of this sealant potentially allowed the filler to protrude or become lost, which caused a rougher surface.[41]

CONCLUSIONS

None of the restorations failed after two years, and there were no significant differences between the clinical performance of HEMA-containing and HEMA-free all-in-one self-etch adhesives with and without surface sealing in Class I restorations over the same time period. Regarding marginal discoloration, marginal adaptation, and surface texture, each dentin adhesive, no matter whether with or without seal, showed significant changes from clinically ideal to clinically acceptable. Sealed restorations exhibited greater changes in color matching and surface texture than did unsealed restorations. However, the sealing process improved the marginal adaptation of restorations compared with unsealed restorations, and the sealing process reduced the marginal discolorations of the HEMA-free self-etch adhesive restorations.

Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the Kocaeli University, Basiskele, Kocaeli, Turkey. The approval code for this study is KOU KAEK 2014/239.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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