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Original

Three-year clinical evaluation of posterior composite restorations placed with a single-step self-etch adhesive

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Abstract: In this clinical study, we evaluated the 3-year clinical performance of a resin composite containing a surface-prereacted glass ionomer (S-PRG) filler (Beautifil II; Shofu Inc., Kyoto, Japan) placed with a single-step self-etch adhesive (Beauti-Bond; Shofu Inc.) in posterior restorations. Using modified US Public Health Service criteria, two experienced investigators performed clinical evaluations at the baseline, 6 months, 18 months, and 3 years. Color match, marginal adaptation, anatomical form, surface roughness, marginal discoloration, postoperative sensitivity, and secondary caries were evaluated. After 3 years, 26 patients attended the recall and 31 restorations were evaluated. No postoperative sensitivity or secondary caries was observed at any time point, and no restorations failed during the follow-up period. However, surface roughness, marginal adaptation, and marginal discoloration showed deterioration after 3 years. In conclusion, although some clinical changes were observed, resin composite containing S-PRG filler placed with self-etch adhesive exhibited acceptable clinical behavior in posterior restorations. (J Oral Sci 57, 101-108, 2015)

Keywords: single-step self-etch adhesive; posterior composite restoration; S-PRG filler.

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Introduction

Reliable bonding of resin composites to the tooth substrate has long been desired in restorative dentistry, because it reduces postoperative sensitivity and increases the longevity of restorations (1). Advances in adhesive technology have facilitated restoration of tooth defects by direct resin composite placement (2). Recently, single-step self-etch adhesives, which combine the functions of the conditioner, primer, and bonding resin, have been developed to simplify and shorten this clinical procedure (3). Single-step self-etch adhesive is applied to the tooth surface and improves adhesion by enhancing monomer penetration of the tooth substrate. Although self-etch adhesives are user-friendly adhesive systems, careful management of each product is required in order to achieve optimal results (4,5). Most single-step self-etch adhesives have a moderately acidic pH: they dissolve the smear layer but do not demineralize the deeper portion of the dentin (6). Self-etch adhesives do not etch enamel as deeply as phosphoric acid; thus, bond strength with the enamel is lower. The moderate pH results in lower enamel bond strength as compared with adhesives utilizing phosphoric acid for pretreatment. The clinical performance of composite restorations is likely to be affected by carious dentin, lesion location, size, and shape, operator variability, and occlusal forces (7,8).

Multi ion-releasing resin composite containing surface-prereacted glass ionomer (S-PRG) filler has been developed for dental applications (9-12). This S-PRG filler has a layered structure consisting of a fluoro-boroaluminosilicate glass core, reacted layers forming

Table 1 Restorative systems used in this clinical study

	Main components
Adhesive system	
BeautiBond (Shofu Inc., Kyoto, Japan)	Phosphoric acid monomer, carboxylic acid monomer, bis-GMA, TEGDMA, water, solvent, acetone, initiator
Restorative	
Beautifil II (Shofu Inc., Kyoto, Japan)	bis-GMA, TEGDMA, aluminofluoro-borosilicate glass, S-PRG filler, *dl*-camphorquinone

bis-GMA: 2,2bis[4-(2-hydroxy-3-methacryloyloxy propoxy) phenyl] propane, S-PRG: surface-prereacted glass ionomer, TEGDMA: triethylene glycol dimethacrylate.

a glass ionomer phase on the surface of the core, and a reinforced layer covering the surface of the prereacted phase (13,14). Resin composites containing S-PRG fillers are used in combination with self-etch adhesives, which partially dissolve the smear layer without demineralizing the dentin as deeply as etch-and-rinse systems. However, their performance and longevity in clinical situations have not been adequately studied (15).

We investigated the clinical performance of posterior teeth restored with resin composites containing S-PRG fillers, which were placed with a single-step self-etch adhesive.

Material and Methods

The Ethics Committee of the Nihon University School of Dentistry, Tokyo, Japan, reviewed and approved the protocol and consent form for this study (#2008-18). Written informed consent was obtained from all patients before their participation in the clinical evaluation.

Patients eligible for inclusion had molar-supported permanent dentition free of any edentulous spaces or clinically significant occlusal interferences. Patients required at least one Class I or II premolar or molar restoration or replacement of an existing restoration. In addition, the teeth for restoration had to be vital, of normal appearance and morphology, and lacking in defects or lesions requiring other operative interventions. Patients were also excluded if they had a history of tooth sensitivity; bruxism; visible wear facets in posterior teeth; existing periodontal disease; or a history of severe medical complications such as xerostomia or chronic periodontitis.

A total of 53 posterior carious or secondary carious lesions (11 Class I and 42 Class II cavities) in 35 patients (15 men, 20 women; mean age, 46 years; age range, 21-72 years) were restored. No patient had more than two restorations. The criteria used to select patients included the presence of posterior lesions.

Shade selection was performed in accordance with the manufacturer's guidelines under natural light. The single-step self-etch adhesive (BeautiBond; Shofu Inc., Kyoto, Japan) was used in combination with the restorative resin (Beautifil II; Shofu Inc.), as described in Table 1. A visible-light curing unit (Optilux 501; Kerr/Demetron, Danbury, CT, USA) was used at a power density of 800 mW/cm^2, which was confirmed by radiometer (Model 100; Kerr/Demetron).

Operative procedures were performed under local anesthesia. Using caries detector dyes, we removed existing restorations and/or caries under water-cooling with a high-speed dental air turbine and ultralow-speed round steel bur or sharp spoon excavator. No bevels were prepared, and the final preparation was performed with a superfine diamond point. For Class II cavities, a sectional matrix system (V-Ring System; Triodent Ltd., Katikati, New Zealand) was used. After application of rubber dam isolation, the self-etch adhesive was applied to the cavity and left undisturbed for 10 s, after which it was gently air-dried and light-cured for 10 s. A thin-bladed instrument (MM Resin Creator; Seto Dental Instrument, Tsukuba, Japan) was used to manipulate the resin composite into the cavity. After shade selection, resin paste was incrementally placed into the cavity, and a flowable resin composite (Beautifil Flow F10; Shofu Inc.) was also used if the cavity was deep (depth >2 mm). Each increment of resin paste was light-cured for 20 s. After light-curing the resin paste, occlusal adjustment, contouring, and finishing were accomplished with superfine diamond points (BluWhite Composite Finishing Diamonds; Kerr Corp., Orange, CA, USA) used at high speed with a water spray. Then, final polishing was performed with diamond particle-impregnated silicone points (CompoMaster CA ISO#030; Shofu Inc.) and polishing strips (Super-Snap Polystrips; Shofu Inc.).

We used a modified version of the US Public Health Service criteria (Alpha, Bravo, Charlie; 16) to evaluate color match, marginal adaptation, anatomical form, surface roughness, marginal discoloration, postoperative

Table 2 Modified US Public Health Service criteria used in this study

Color match	
Alpha	The restoration matches the adjacent tooth structure in color and translucency
Bravo	The mismatch in color and translucency is within the acceptable range
Charlie	The mismatch in color and translucency is outside the acceptable range
Anatomical form	
Alpha	The general contour of the restoration follows the overall contour of the tooth
Bravo	The general contour of the restoration does not follow the overall contour of the tooth
Surface roughness	
Alpha	The surface of the restoration does not have any defects
Bravo	The surface of the restoration has minimal defects
Charlie	The surface of the restoration has severe defects
Marginal adaptation	
Alpha	Explorer does not catch or has a one-way catch when drawn across the restoration/tooth interface
Bravo	Explorer falls into a crevice when drawn across the restoration/tooth interface
Marginal discoloration	
Alpha	There is no discoloration between the restoration and tooth
Bravo	There is discoloration on less than half of the circumferential margin
Charlie	There is discoloration on more than half of the circumferential margin
Postoperative sensitivity	
Alpha	No sensitivity when air syringe is activated for 2 s at a distance of 1.25 cm from the restoration/unrestored lesion with the facial surface of the proximal tooth covered with gauze
Bravo	Sensitivity is present when the air syringe is activated for 2 s at a distance of 1.25 cm from the restoration/unrestored lesion with the facial surface of the proximal tooth covered with gauze, and ceases when the stimulus is removed.
Charlie	Sensitivity is present when the air syringe is activated for 2 s at a distance of 1.25 cm from the restoration/unrestored lesion with the facial surface of the proximal tooth covered with gauze, and does not cease when the stimulus is removed.
Secondary caries	
Alpha	No clinical diagnosis of caries
Bravo	Clinical diagnosis of caries

sensitivity, and secondary caries (Table 2). The restorations were assessed at baseline, and after 6 months, 18 months, and 3 years. Baseline was defined as 1 week after completion of the polishing procedure. Two clinicians who were uninvolved with the restoration placement process conducted independent clinical evaluations using standardized evaluation criteria. In the event of a disagreement, consensus was reached by discussion and re-examination. Intraoral photographs were obtained to help with the evaluation at baseline and at each recall appointment.

Results

Of the 53 original restorations placed at baseline, 31 were available for clinical evaluation at the 3-year recall (recall rate: 45% for Class I cavities and 62% for Class II cavities). During the 3-year follow-up period, restorations were evaluated at the time intervals described in Table 3. Representative photographs of restorations scored Alpha and Bravo for all criteria after 3 years are shown in Figs. 1 and 2.

No secondary caries were found at any of the follow-up evaluations, and none of the patients reported postoperative sensitivity. Surface roughness, marginal adaptation, and marginal discoloration were the most frequent changes observed at 3 years (Bravo ratio: 23.1%-41.9%). Regarding marginal adaptation, more than 40% of restorations showed evidence of slight crevices along the marginal interface of the occlusal surfaces. As compared with baseline observations, a significant increase was evident in Bravo ratings for surface roughness.

Discussion

We performed a clinical evaluation of posterior lesions to determine whether resin composite containing S-PRG filler bonded with self-etch adhesive is suitable for use in complex clinical situations. The clinical success and acceptability of restorative materials can be tested using several approaches, including cross-sectional or longitudinal studies and controlled clinical experiments (17). Cross-sectional studies have been widely used for clinical evaluations because they are relatively simple to perform and yield rapid results (18). However, with respect to the reliability of clinical studies, long-term longitudinal studies under controlled, standardized conditions are optimal: they allow the same individuals to be followed

Table 3 Clinical evaluation of a single-step self-etch adhesive

USPHS criteria	Recall period Baseline	6 months	18 months	3 years
Color match				
Alpha	60.4 (32/53)	58.5 (31/53)	45.7 (21/46)	45.2 (14/31)
Bravo	39.6	41.5	54.3	54.8
Anatomical form				
Occlusal cavities				
Alpha	100 (53/53)	100 (53/53)	100 (46/46)	90.3 (28/31)
Bravo				9.7
Approximal cavities				
Alpha	100 (42/42)	100 (42/42)	100 (37/37)	100 (26/26)
Surface roughness				
Occlusal cavities				
Alpha	100 (53/53)	100 (53/53)	69.6 (32/46)	58.1 (18/31)
Bravo			30.4	41.9
Approximal cavities				
Alpha	100 (42/42)	90.5 (38/42)	81.1 (30/37)	76.9 (18/27)
Bravo		9.5	18.9	23.1
Marginal adaptation				
Occlusal cavities				
Alpha	100 (53/53)	100 (53/53)	71.7 (33/46)	58.1 (18/31)
Bravo			28.3	41.9
Approximal cavities				
Alpha	100 (42/42)	100 (42/42)	100 (37/37)	76.9 (20/26)
Bravo				23.1
Marginal discoloration				
Occlusal cavities				
Alpha	100 (53/53)	100 (53/53)	100 (46/46)	83.9 (26/31)
Bravo				16.1
Approximal cavities				
Alpha	100 (42/42)	100 (42/42)	100 (37/37)	76.9 (20/26)
Bravo				23.1
Post-operative sensitivity				
Alpha	100 (53/53)	100 (53/53)	100 (46/46)	100 (31/31)
Secondary caries				
Alpha	100 (53/53)	100 (53/53)	100 (46/46)	100 (31/31)

Numbers in parentheses indicate scored teeth/evaluated teeth
USPHS, US Public Health Service

and offer the best opportunities for understanding changes (19). For this reason, we selected a 3-year observation period with 1- and 2-year intermediate examinations in this study.

One challenge in long-term clinical trials is achieving high recall rates. In this study, the recall rate was 100% at 6 months and 87% at 18 months, which are comparable to rates reported in similar clinical trials. However, the 3-year recall rate was 59%. Therefore, to obtain sufficient clinical validity, additional guidelines will be needed in order to implement a correction factor for these low recall rates.

In this study, all restorations remained intact, without any postoperative sensitivity or secondary caries, after 3 years of service. After the use of self-etch adhesives, incorporation of the smear layer, resin monomer, collagen, and minerals into the superficial portion of the tooth surface may prevent postoperative sensitivity, which is common after using etch-and-rinse adhesive systems. The most obvious deterioration among the present restorations was marginal adaptation, which was observed in 58.1% (Alpha score) of restorations after 3 years. Marginal gaps develop over time with exposure to the oral environment, because of differences in the coefficient of thermal expansion and surface wear (20). An incremental filling technique, combined with a low configuration factor, may reduce damaging polymerization shrinkage stresses and maintain satisfactory adaptation of a restoration (21). The size and location of restorations affect the wear of resin composites (22). Increases in the surface area and length of cavosurface margins increases wear of resin composites. To optimize the physical and mechanical

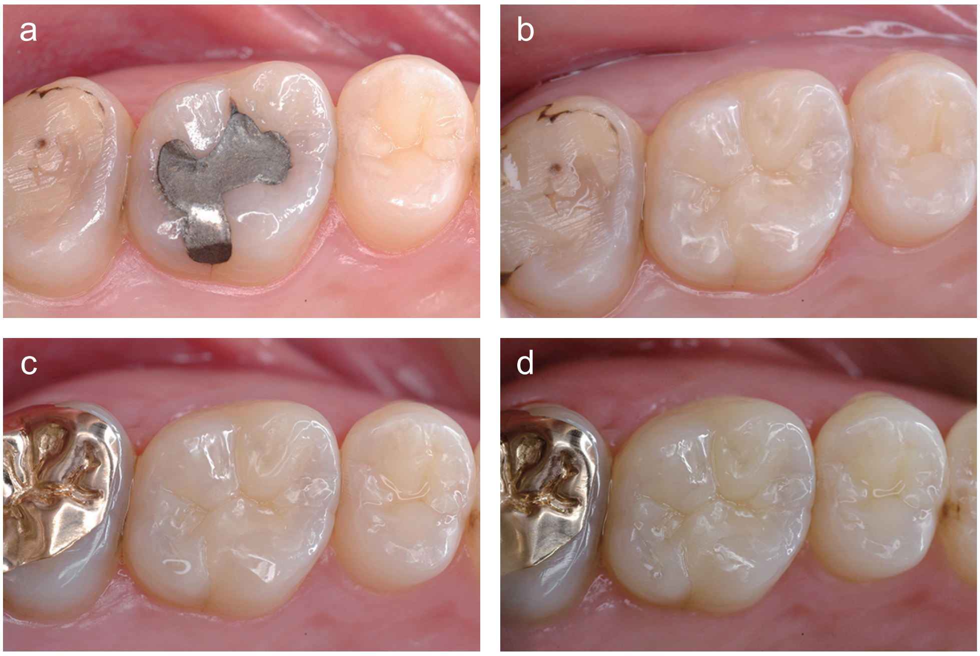

Fig. 1 Restorations scored “Alpha” for all scores after 3 years (a: before, b: baseline, c: 18 months, d: 3 years).

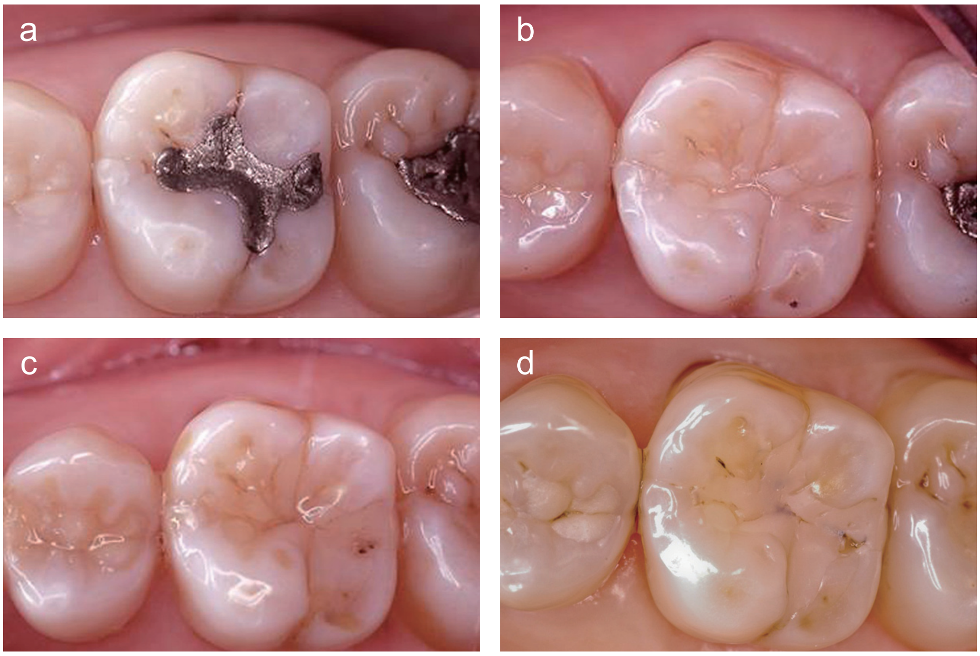

Fig. 2 Restorations scored “Bravo” for marginal adaptation after 3 years (a: before, b: baseline, c: 18 months, d: 3 years).

properties of resin composites, manufacturers modify their composition by increasing the filler volume and by hybridization of filler particles. These modifications decrease polymerization shrinkage and enhance mechanical properties, as compared with older resin composites (23).

Polymerization shrinkage can cause gap formation between the tooth and restorative, leading to microleakage, marginal discoloration, secondary caries, and postoperative sensitivity. Incorporation of inorganic filler particles reduces resin monomer concentration, thereby decreasing the rate of polymerization shrinkage. Although the resin composite used in this study had a high inorganic particle content, a degree of marginal discoloration occurred after 3 years of service (Alpha score, 83.9%). Similar results were reported in a previous clinical study (24), in which marginal discoloration was observed in some restorations but scores were not worse for posterior resin composite restorations after 5 years. However, long-term service in the oral environment increases the surface roughness of resin composites. In clinical situations, resin composites must be able to withstand toothbrush abrasion, which causes wear. Retention of the surface smoothness of resin composites is an indicator of wear resistance (25).

The ability to release fluoride may be one of the most important properties of restorative materials, as such release may prevent secondary caries. In this study, a resin composite containing S-PRG filler was used to restore posterior lesions. This resin composite was developed to exhibit structural strength and release ions (26). The use of S-PRG fillers promotes rapid fluoride release through ligand exchanges between fluoride ions and counter cations within the prereacted hydrogel (13). In addition to F^-, S-PRG fillers release Al^{3+}, BO_3^{3-}, Na^+, SiO_3^{2-}, and Sr^{2+} ions (27). Silicate and fluoride are strong inducers of remineralization of the tooth substrate (28). Strontium and fluoride also increase the acid resistance of teeth by converting hydroxyapatite to strontium apatite and fluorapatite (29). S-PRG fillers exert a modulation effect that neutralizes the pH of the surrounding environment after contact with acidic solutions (30). The present study was adequately randomized and patients who did not maintain an acceptable standard of oral hygiene were not excluded from the study. These factors may explain why no secondary caries were observed at any of the follow-up evaluations.

Self-etch adhesives do not etch enamel to the same depth as phosphoric acid and thus result in slightly lower bond strength with enamel as compared with etch-and-rinse adhesive systems. However, the enamel and dentin bond strengths of single-step adhesives are similar (31). This is advantageous because polymerized composites are likely to be pulled toward strongly bonded sites inside the cavity. If bond strength had been insufficient, more restorations would have exhibited staining along the margins. However, in teeth with marginal discoloration, this was not considered to be of clinical significance. In this study, none of the restorations failed as a result of secondary caries at any recall examination, even when an increase in marginal interfacial discoloration around the restoration margins was detected. This increased marginal discoloration may be due to the weaker etching effect on enamel of self-etch adhesives as compared with phosphoric acid.

A previous study noted that the surface preparation method used significantly affects the nature of the smear layer and its interaction with mild self-etch adhesives: a silicon carbide paper-prepared surface is more uniform and dense than a diamond bur-cut surface (32). The smear layer is regarded as a barrier to resin infiltration during bonding. This zone of debris is a mixture of partly denatured collagen fibrils, other organic materials, and several minerals, in accordance with the underlying tooth surface (33). Therefore, in the present clinical study, cavity preparation was finished with superfine diamond points, to avoid creating a thick smear layer. A previous study (34) found no significant difference in bond strength between diamond point-cut enamel and laser-cut enamel when using a two-step self-etching primer adhesive and single-step self-etch adhesives. In the final preparation of the restored cavity, superfine diamond points should be used with self-etch adhesives to create a uniform, thin smear layer.

In restorative dentistry, indications for use of resin composites have recently expanded (35). Adhesively bonded, extensive direct resin restorations have the advantage of conserving the remaining tooth structure and the potential for tooth reinforcement. These restorations are an alternative to indirect restorations. The present results indicate that the evaluated restorative system had excellent performance characteristics during 3 years of clinical service and performed within acceptable ranges. At the 3-year examination, no secondary caries or retention were found, and none of the patients reported postoperative sensitivity during follow-up. Thus, the 3-year findings demonstrate that BeautiBond/Beautifil II can be used for restoring Class I and Class II cavities in the posterior teeth of carefully selected patients.

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Conflict of interest

The authors declare no conflicts of interest and are solely responsible for the content and writing of this report.

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