A clinical evaluation of a self-etching primer and a giomer restorative material

Results at eight years

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During the last decade, resin-based composite materials have been used widely to restore posterior teeth.[1-4] However, the long-term clinical results remain controversial as studies report inconsistencies.[5,6] Occlusal and proximal wear have been identified as possible limitations of resin-based composite materials in posterior restorations. Other areas of concern include marginal leakage, discoloration, polymerization shrinkage and postoperative sensitivity.[7] Some of these clinical characteristics have improved over time as the adhesive technology has advanced and additional features, such as fluorides, have been added to the materials.[8-10]

One feature that has enhanced resin-based restorative materials is fluoride release; several fluoride-containing materials have been developed, such as resin-modified glass ionomer,[11] compomer,[12] giomer[13] and fluoride-containing resin-based composite.[14] Marginal discoloration and marginal integrity remain a problem for some of the

DISCLOSURE: Shofu, Kyoto, Japan, the manufacturer of Beautifil restorative material and FL-Bond bonding system, provided financial support for this research.

ABSTRACT

Background. The authors evaluated the performance of a giomer restorative material (Beautifil, Shofu, Kyoto, Japan) with a self-etching primer (FL-Bond, Shofu) for posterior restorations.

Materials and Methods. Two clinicians placed 26 Class I restorations and 35 Class II restorations in 31 patients ranging in age from 21 to 62 years (mean age, 34 years). Inclusion criteria required patients to have molar-supported permanent dentition free of any edentulous spaces and no clinically significant occlusal interference, as well as one or more permanent molars or premolars requiring new or replacement Class I or II restorations. Two of the authors examined the restorations using modified U.S. Public Health Service/Ryge criteria for color match, marginal adaptation, anatomy, surface roughness, marginal staining, interfacial staining, proximal and occlusal contacts, secondary caries, postoperative sensitivity and luster.

Results. The two authors examined all restorations at the one-year recall visit, 58 at the two-year visit, 47 at the three-year visit, 39 at the four-year visit and 41 at the eight-year visit (16 Class I and 25 Class II restorations). During the eight-year period, they detected no changes with respect to surface roughness, postoperative sensitivity or secondary caries. The majority of changes recorded were for marginal adaptation at occlusal (29 percent) and proximal (16 percent) surfaces and marginal staining at occlusal (15 percent) and proximal (32 percent) surfaces. The McNemar test showed significant changes between baseline and the eight-year evaluation only for marginal adaptation at occlusal surfaces ($P = .0047$) and marginal staining at proximal surfaces ($P = .04$). None of the restorations failed.

Conclusion. Most of the restorations maintained good quality during the observation period.

Clinical Implications. Beautifil restorative material and FL-Bond bonding system, when placed in Class I and II preparations, achieved clinically acceptable results after eight years of service.

Key Words. Class I and II restorations; giomer; self-etching adhesive; pre-reacted glass filler; universal restorative; acidic primer.

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TABLE 1

Composition of FL-Bond* bonding system and Beautifil* giomer restorative material.

MATERIAL	COMPOSITION
FL Primer A	Distilled water, acetone, initiators
FL Primer B	2-hydroxyethyl methacrylate (2-HEMA), 4-acryloxyethyltrimellitic acid, 4-acryloxyethyl trimellitate anhydride, urethane-triacrylate, triethyleneglycol dimethacrylate, acetone, initiators, stabilizers, pigment
FL-Bond	Distilled water, 2-HEMA, 4-acryloxyethyltrimellitic acid, 4-acryloxyethyltrimellitate anhydride, triethylene glycol dimethacrylate (TEGDMA), urethane dimethacrylate, pre-reacted glass ionomer filler, DL-camphorquinone, initiators
Beautifil	Bisphenol A glycidyl dimethacrylate, TEGDMA, inorganic glass filler, aluminuoxide, silica, pre-reacted glass ionomer filler, DL-camphorquinone

* FL-Bond bonding system and Beautifil giomer restorative material are manufactured by Shofu, Kyoto, Japan.

TABLE 2

Clinical exclusion criteria.

GENERAL HISTORY	▬ Adverse reaction to dental materials ▬ Involvement in investigation of other restorative material or system
ORAL HISTORY	▬ Defective restorations opposing or adjacent to the study tooth ▬ Evidence of parafunctional or pathological tooth wear ▬ Rampant caries ▬ Atypical extrinsic staining of the teeth or staining of any existing tooth-colored restorations ▬ Poor oral hygiene

polyacid-modified resin-based composite materials.[15-17] The addition of pre-reacted glass (PRG) filler to the resin matrix has been the latest trend for the giomer materials.[13] The PRG filler allows the material to release fluoride and be recharged with fluoride,[13] which is an excellent characteristic for long-term fluoride release.

Beautifil (Shofu, Kyoto, Japan) is a tooth-colored giomer restorative material that uses a resin base and PRG technology. An in vitro study of the long-term release and uptake of fluoride by the restorative material found that a small amount of fluoride was released during the first few days; however, after 21 days, the amount of fluoride released increased significantly.[18]

The PRG filler is made by reacting the acid-reactive glass containing the fluoride with polyalkenoic acid in water before being incorporated into the resin materials. This technology is different from that used in compomers, in which dehydrated polyalkenoic acid is part of the resin matrix, and the reaction between the glass and the acid does not occur until water is taken up by the restorative material. Two types of PRG filler are available: surface-reacted PRG filler (S-PRG filler) technology and fully reacted PRG filler (F-PRG filler) technology. The restorative material used in this study is composed of the S-PRG filler.

The bonding technology has received significant attention, and it has been one of the most important components of resin-based restorations. One step in the advancement of this technology has been the development of a self-etching primer, which combines the etching and priming steps.[19,20] This development has simplified the bonding procedure and has resulted in a reduction in postoperative sensitivity.[21,22] The enhanced features of the bonding material also are designed to increase the longevity of the restorations.

The aim of this clinical study was to evaluate whether combining the self-etching adhesive system with a giomer restorative material would yield satisfactory long-term clinical results for Class I and II restorations placed in permanent posterior teeth, according to modified U.S. Public Health Service (USPHS)/Ryge[23] criteria.

MATERIALS AND METHODS

Two clinicians placed 61 restorations in 31 patients (13 Class I and 11 Class II restorations in 24 premolars and 13 Class I and 24 Class II restorations in 37 molars) using the giomer restorative material and the self-etching adhesive system (FL-Bond, Shofu) (Table 1). The patients' ages ranged from 21 to 62 years (mean age,

ABBREVIATION KEY: F-PRG: Fully reacted pre-reacted glass. **PRG:** Pre-reacted glass. **S-PRG:** Surface-reacted pre-reacted glass. **USPHS:** U.S. Public Health Service.

34 years). Two of us (V.V.G., E.M.) informed patients about the study and they signed a consent form, which was approved by the University of Florida's Institutional Review Board.

The clinical requirements for inclusion in this study were as follows:

- patients had a molar-supported permanent dentition that was free of any edentulous spaces and any clinically significant occlusal interference;
- patients required new or replacement Class I or II restorations in one, two or three first and/or second permanent molars or premolars.

Specific inclusion criteria were vital teeth, normal appearance and morphology of teeth, and sound occlusal and interproximal contacts with adjacent teeth. Table 2 lists the exclusion criteria.

After preparing the cavities with carbide burs (Brasseler USA, Savannah, Ga.), the dentists placed the restorations according to the manufacturer's instructions under rubber dam isolation. They did not use any base or cavity liners. The restorations were finished under water cooling with fine and superfine diamond points (Hybrid Points Kit, Shofu) and polished with diamond-impregnated rubber points (CompoSite Fine, Shofu).

The dentists restored the occlusion and proximal contact points to normal anatomy. They took preoperative and postoperative clinical photographs from an occlusal view at ×1.5 magnification and took impressions using a polyvinyl siloxane material (Extrude Kerr Manufacturing, Orange, Calif.).

Two calibrated clinicians (R.E.W., I.A.M.) (different clinicians from those who placed the restorations) evaluated the restorations using modified USPHS/Ryge[23] clinical criteria throughout the study. Applying these criteria involves visual inspections and use of a dental explorer, dental floss and articulating paper to check various clinical properties. Each restoration is categorized into one of the following four ratings:

- Alfa (A): the restoration falls within a range of excellence (that is, the restoration is expected to last for a long time);
- Bravo (B): the restoration falls within a range of acceptability (that is, the restoration has one or more features that deviate from the range of excellence, but with no need for replacement);
- Charlie (C): the restoration needs to be replaced or corrected to prevent damage (that is, damage to the tooth structure is likely to occur);
- Delta (D): the restoration needs to be replaced immediately (that is, damage to the tooth structure is occurring).

The author clinicians made independent evaluations about each characteristic observed. If they disagreed about a rating, the clinicians re-examined the restoration together and arrived at a final joint decision. The disagreement percentage between the two clinicians was less than 3 percent. Most of the disagreements were in the assessment of marginal discrepancies.

The author clinicians examined the restorations one week after they were placed (baseline) and at the six-month, one-year, two-year , three-year, four-year and eight-year recall examinations. The two-year[24] and four-year results[25] have been reported elsewhere. In this report, we compare the clinical status of the restorations at baseline with that at the end of eight years of clinical service. We used the McNemar test for statistical analysis ($\alpha = .05$).

RESULTS

Table 3 shows the ratings for the restorations at baseline and at the eight-year recall examination for each clinical characteristic. Of the 61 restorations placed at baseline, 41 (four Class I and 15 Class II premolars and nine Class I and 13 Class II molars) were examined at the eight-year recall examination (the remaining 13 patients with 20 restorations were lost to follow-up).

Table 4 summarizes the frequency with which the ratings at the eight-year recall examination changed from those at baseline. Marginal adaptation, marginal staining and interfacial staining constitute the majority of the recorded changes. In general, the frequency of downgrades from Alfa to Bravo was higher than the frequency of upgrades from Bravo to Alfa (Table 4). The clinicians did not record any Charlie ratings (that is, none of the restorations failed) at the eight-year examination (Figures 1 and 2, page 626).

The McNemar test of the frequency of clinical ratings for each characteristic revealed no statistically significant differences between findings at the eight-year recall examination and those at baseline ($P > .05$), with the exception of marginal adaptation at occlusal surfaces ($P = .0047$) and marginal staining at proximal surfaces ($P = .04$).

The clinicians observed minimal changes with regard to color match, anatomical form and luster of the restorations. They observed no changes with regard to roughness at occlusal and proximal

TABLE 3

Clinical evaluation of FL-Bond bonding system* with Beautifil* giomer restorative material at baseline and eight-year recall examination.†

EXAMINATION	NO. OF RESTORATIONS‡	COLOR MATCH		MARGINAL ADAPTATION				ANATOMICAL FORM				SURFACE ROUGHNESS				MARGINAL STAINING			
				O§		P¶		O		P		O		P		O		P	
		A#	B**	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B
Baseline	61	95	5	79	21	83	17	100	0	98	2	97	3	100	0	100	0	86	14
Eight-Year Recall	41	93	7	71	29	84	16	95	5	92	8	100	0	100	0	85	15	68	32

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surfaces, interfacial staining at proximal surfaces, occlusal contact, postoperative sensitivity or secondary caries after eight years of clinical service.

DISCUSSION

Favorable results for resin-based composite materials frequently are based on short-term results.[26] Part of the problem in achieving long-term clinical results is patients' attrition rate. In this study, the response rate with respect to the recall examination was 100 percent for the first year, 95 percent for the second year, 77 percent for the third year, 64 percent for the fourth year and 67 percent for the eighth year, which is considered a good response rate[27] when compared with similar studies in restorative dentistry.[3,6,7,15,17,28] Notwithstanding this fact, the results of our study must be interpreted with caution.

USPHS/Ryge criteria. The modified USPHS/Ryge criteria[23] (Table 3) have been used widely for the clinical evaluation of restorations. Although these criteria do not consider critical issues such as the oral hygiene index and number of decayed, missing and filled teeth, they are the only criteria available for long-term evaluation of restorations. They are considered valid criteria for comparison purposes among studies at different observation periods.

Hayashi and Wilson[29] reported an overlap from Alfa to Bravo ratings for certain characteristics, including marginal adaptation. This overlap might explain the variations that occurred for some characteristics at various recall examinations in our study. Fukushima and colleagues[30] emphasized the importance of calibration among examiners. In our study, the interexaminer agreement ratio was kept close to 0.97.

Failure rates for posterior restorations com-

TABLE 4

Changes in ratings from baseline to eight-year recall examination, according to modified U.S. Public Health Service/Ryge criteria.*

NO. OF RESTORATIONS (n = 41)	COLOR MATCH		MARGINAL ADAPTATION				ANATOMICAL FORM				SURFACE ROUGHNESS				MARGINAL STAINING		
			O†		P‡		O		P		O		P		O		P
	+1§	−1¶	+1	−1	+1	−1	+1	−1	+1	−1	+1	−1	+1	−1	+1	−1	+1
	1	3	2	12	4	4	0	2	1	2	0	0	0	0	0	6	1

(continued on next page)

TABLE 3 (CONTINUED)

INTERFACIAL STAINING				CONTACTS				POSTOPERATIVE SENSITIVITY		SECONDARY CARIES		LUSTER	
O		P		O		P							
A	B	A	B	A	B	A	B	A	B	A	B	A	B
100	0	100	0	100	0	97	3	100	0	100	0	100	0
88	12	100	0	100	0	88	12	100	0	100	0	95	5

* FL-Bond and Beautifil are manufactured by Shofu, Kyoto, Japan.
† Data are percentage of restorations.
‡ There were 26 Class I restorations at baseline and 16 at the eight-year recall examination.
§ O: Occlusal.
¶ P: Proximal.
# A: Alfa rating using modified U.S. Public Health Service/Ryge criteria. Source: Cvar and Ryge.[23]
** B: Bravo rating using modified U.S. Public Health Service/Ryge criteria. Source: Cvar and Ryge.[23]

posed of resin-based materials have varied from 5 percent during a four- to five-year observation period[30,31] to 16 percent during a 10-year period.[32] The most common reasons for failure of resin-based composite restorations are marginal defects and secondary caries (that is, caries adjacent to the margin of the restoration).[2,7,8,33,34] Marginal breakdown has been reported to be one feature of resin-based composite restorations that can lead to secondary caries.[35] Several studies,[36-38] however, have challenged the notion that marginal breakdown leads to secondary caries. No relationship exists between the development of secondary caries and the size of the crevice at the tooth-restoration interface,[36-38] except in cases of macroleakage in which the crevice exceeds 250 nanometers[36] or 400 nm.[37] Similarly, in our study, none of the restorations failed as a result of secondary caries, even though the examiners noted significant changes with regard to marginal adaptation and marginal staining at the four- and eight-year recall examinations.

Marginal deterioration and cavosurface discoloration. Hayashi and colleagues[39] suggested that marginal deterioration and cavosurface discoloration are predictors of failure for posterior resin-based composite restorations, because their analysis revealed that restorations with marginal deterioration at three years were 5.3 times more likely to have failed by five years than were restorations with Alfa-rated marginal adaptation at three years. Similarly, these authors[39] found that restorations with cavosurface marginal discoloration at three years were 3.8 times more likely to have failed at five years than were restorations with no cavosurface marginal discoloration at three years.

Moreover, restorations with both marginal deterioration and cavosurface marginal discoloration at three years failed 8.7 times more frequently than did restorations with sound margins at three years.[39] Although the changes in marginal staining and marginal adaptation were of significance in our study, none of the restorations failed at the eight-year recall examination on the basis of the clinical criteria used. These results are consistent with those of other clinical studies in which marginal adaptation and marginal staining were noted.[40,41] Matis and colleagues[42] conducted a clinical study of cervical restorations that compared Beautifil giomer restorative material with a conventional resin-based composite material and reported no significant difference between the two materials with regard to any of the clinical

TABLE 4 (CONTINUED)

INTERFACIAL STAINING				CONTACTS				POSTOPERATIVE SENSITIVITY		SECONDARY CARIES		LUSTER	
O		P		O		P							
+1	−1	+1	−1	+1	−1	+1	−1	+1	−1	+1	−1	+1	−1
0	5	0	0	0	0	0	3	0	0	0	0	0	2

* Source: Cvar and Ryge.[23]
† O: Occlusal.
‡ P: Proximal.
§ +1: The examiner upgraded the rating from Bravo to Alfa.
¶ -1: The examiner downgraded the rating from Alfa to Bravo.

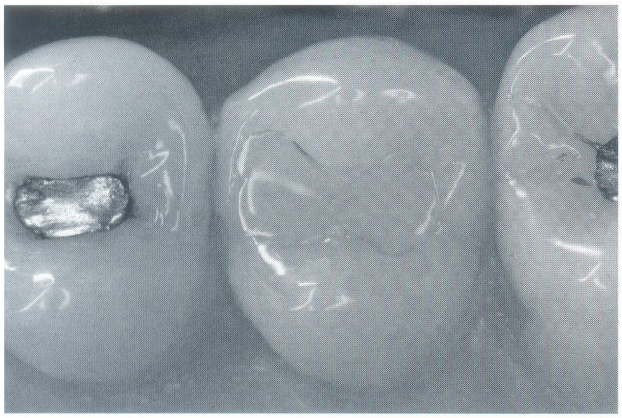

Figure 1. Class I restoration at the occlusal surface of an upper right premolar. This restoration received a Bravo rating for occlusal marginal staining.

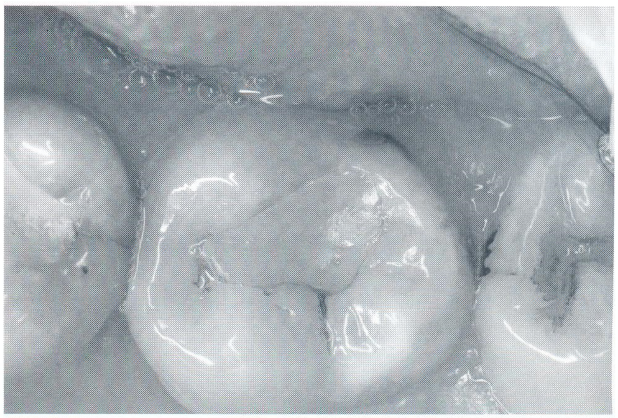

Figure 2. Class I restoration in a lower right molar. The examiners noted the greatest number of changes in this restoration, which received Bravo ratings for color match, marginal adaptation, anatomy and marginal staining.

criteria evaluated.

Fluoride release. Fluoride release may be an important property of the restorative material, and it might assist in the prevention of secondary caries. Even though studies have reported an insignificant initial "burst" effect,[18] the cumulative fluoride release during the first week has been shown to be higher for compomers than for other materials.[43,44] Despite the fact that previous studies have not been consistent in demonstrating long-term fluoride release from giomer restorative materials, none of the restorations in our study failed as a result of secondary caries.

The examiners in our study rated some of the restorations as Bravo for marginal adaptation at baseline and then rated them as Alfa at a recall examination. In some locations on the restoration, it is possible that the examiner recorded the restoration as Bravo because a small excess amount of material was left at the cavosurface margin at the baseline examination. After occlusal loading and clinical use of the restorations, the excess restorative material at the cavosurface margin may have been fractured and worn off, resulting in minor irregularities at the margin, which were recorded as Alfa on follow-up examinations. This observation might explain the results found at the six-month, one-year and two-year examinations for marginal adaptation, surface roughness and marginal staining.

Regarding proximal contact changes during the course of the study, it is possible that the tooth drifted after a few months of clinical service and that interproximal wear may have developed. However, the results of our study showed no significant variations in proximal contact between the baseline examination and the eight-year recall examination.

One in vitro study[45] reported that a significant degree of restoration swelling occurred when the material was restrained within a cavity, suggesting that water absorption and dimensional change may be a concern for giomer restorations. As mentioned above, two kinds of filler are used in PRG technology. Although restorations composed of the F-PRG filler have a tendency to absorb water and expand, these problems rarely are seen with the S-PRG filler that is included in the restorative material used in our study. Therefore, we were not concerned with water absorption and dimensional changes in this study.

Initial postoperative sensitivity seems to be a problem with resin-based materials.[9] Studies generally have found that postoperative sensitivity diminishes during the first few weeks after the restoration is placed, but it may persist for a longer period.[33,46-49] None of the restorations in our study exhibited sensitivity at the eight-year observation. In vitro studies have reported different responses in dentin permeability with and without removal of the smear layer.[21,50,51] Self-etching primers dissolve the smear layer, incorporating it into the mixture of collagen fibers and resin monomers that make up the hybrid layer.[52,53] The low sensitivity response found during the course of our study might be explained by this integration of the smear layer with the hybrid layer.[52] In addition, the initial postoperative sensitivity experienced by subjects in our study was insignificant. The self-etching bonding system might have contributed to these results.

CONCLUSION

This study showed that FL-Bond self-etching primer and Beautifil giomer restorative material, when used in Class I and Class II preparations, exhibited good clinical characteristics after eight years of clinical service. ■

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