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An eighteen-month clinical evaluation of posterior restorations with fluoride releasing adhesive and composite systems

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This study evaluated the clinical performance of a fluoride releasing restorative system (FL-Bond II & Beautifil II) in posterior restorations after 18-month placement. IRB forms were submitted with each patient approving by signing their acceptance. Seven Class I and 46 Class II restorations were placed by three clinicians in 38-patients. Each FL-Bond II & Beautifil II restoration was placed under rubber dam isolation according to manufacture's instruction. Clinical evaluation was assessed at baseline, 6 and 18-months using modified USPHS criteria. No post-operative sensitivity was reported in any restored tooth at each patient assessment. Only slight color change with some surface staining was noted. Slight marginal changes were observed in 12 of 53-restorations —seen as step irregularities when a sharp explorer was drawn across the tooth from the enamel toward the restoration interface. Utilizing USPHS evaluation criteria, the clinical performance of each (FL-Bond II & Beautifil II) posterior fluoride releasing system was clinically acceptable at 18-month.

Keywords: Clinical study, Posterior restoration, S-PRG filler, Fluoride release

INTRODUCTION

In 2000, Shofu Inc. (Kyoto, Japan) developed an innovative filler technology of resin composite that created a stable Glass-ionomer phase on a glass core in which they induced an acid-base reaction between acid-reactive fluoride containing glass and polycarboxylic acid in the presence of water —developed as a Pre-Reacted Glass-ionomer (PRG) filler[1-3]. This PRG technology was applied to the filler component of resin composite materials to provide a bioactive result that released and was recharged with fluoride —like a traditional glass-ionomer cement— all the while maintaining the original physical properties of the resin composite system[4,5]. This resin composite material with PRG filler technology is totally different from other compomers or resin modified glass-ionomer cements —consequently these new PRG filler containing products are categorized as a giomer[1,4,6]. This concept is based on hybridized technology between PRG filler and resin composite material[3]. When the PRG technology was first developed, two PRG filler types were available: a fully pre-reacted glass-ionomer (F-PRG) filler and a surface pre-reacted glass-ionomer (S-PRG) filler. Each F-PRG and S-PRG filler technology has been applied to the self-etch adhesive system and resin composite materials[3,7,8]. The clinically accepted long-term performances of GIOMER products with S-PRG filler, "Beautifil", an aesthetic direct restorative material for anterior and posterior teeth and "FL-Bond", a two-step bonding system, consists of a self etching primer and fluoride releasing bonding agent as previously reported[6].

Recently, improvement on the PRG technology has been developed that resulting in the development of modified "S-PRG filler" which consists of a three-layered structure with an original glass core of multifunctional fluoro-boro-alminosilicate glass and two-surface layers that form a pre-reacted glass-ionomer phase on the surface of a glass core and a reinforced modified layer that covers the surface of pre-reacted glass-ionomer phase —it is important to recognize the modified S-PRG filler is reinforced. With this enhanced S-PRG filler, a new clinical restorative system is offered for both the "Beautifil II" and "FL-Bond II" restoratives.

The purpose of this study was to evaluate the intermediate and extended clinical safety and effects of fluoride releasing restorative system with modified S-PRG filler (FL-Bond II & Beautifil II), in Class I & Class II restorations using modified USPHS criteria[9,10].

MATERIALS AND METHODS

Experimental protocol

The Institutional Review Board of Tsurumi University received and approved the forms prior to permission to commence the study. Patients were selected from individuals who were seeking clinical treatment at the Department of Operative Dentistry Dental Clinic at Tsurumi University Dental Hospital in Yokohama, Japan. Study procedures were explained to each patient and annotated that each patient would be provided a written consent for their signature, prior to their registration and participation in this clinical evaluation. The clinical requirements for inclusion in this study were as follows:

1) Patients with molar-supported permanent dentitions, free of any edentulous spaces or occlusal interferences of clinical significance.

2) Patients with no history of allergic reactions to methacrylate compounds and in good general health.

3) Patients required at least one premolar or molar Class I or Class II restoration or for replacement of

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restoration.

In addition, the following items were applied in tooth selection for this clinical study: vital teeth, normal appearance and morphology, no defects and lesions for other operative intervention, occlusal and proximal contacts with adjacent teeth. Exclusion criteria are seen in Table 1.

A total of 53-clinical restorations were placed by three of the authors in the teeth of 38-patient (11-male and 27-female). Following the research protocol, each restoration was restored with the fluoride releasing restorative system (Table 2) according to manufacture's instruction. After conservative removal of enamel to open the cavity, Caries Detector (Kuraray Medical, Tokyo, Japan) was applied to each cavity to visually identify and differentiate the outer carious dentin (infected carious dentin) and the inner affected carious dentin (transparent dentin). Removal of the outer carious infected dentin was achieved using either an ultra-low speed round steel bur or a sharp spoon excavator. Rubber dam isolation was routinely placed and each cavity was restored using FL-Bond II & Beautifil II according to the manufacturer's instruction. The FL-Bond II primer was applied to the cavity and left undisturbed for 10-second and then gently air dispersed. A uniform layer of the FL-Bond II Bond was then applied to the entire primed surface of the cavity, and light-cured for 10-second using an Oprilux 501 (Kerr Co. Demetron, Danbury, CT, USA) light curing unit. The proper aesthetic shade of Beautifil II was selected and incrementally placed into the cavity —a flowable composite resin, Beautifil Flow F2 or F10 was also used if considered necessary. Each Beautifil II increment was light-cured for 20-seconds. After the final light curing of the resin composite, the rubber dam was removed and an occlusal adjustment, contouring, finishing and polishing was immediately completed with superfine diamond points or carbide bur under water-cooling and then final polished with Super-snap (Shofu) and Occlubrush (Kerr Co. Orange, CA, USA) or Compomaster (Shofu).

Clinical evaluation

A clinical evaluation of each restoration was assessed by two investigators at baseline placement, all clinical data were collected on each restorations at 6 and 18-month following the modified USPHS criteria and Silness & Löe

Table 1 Clinical exclusion criteria

Patients will be excluded from participation, if :
(1) They are included in the evaluation of other restorative materials and systems involving the anterior and/or posterior teeth.
(2) There is a history of any adverse reaction to clinical materials of the types to be used in the evaluation.
(3) There is evidence of active caries, occlusal parafunctions and/or atypical tooth wear.
(4) There is a history of atypical intrinsic staining of the teeth and any existing tooth-colored restorations.
(5) Pregnant and lactating females and any patients with medical and/or dental histories which could possibly complicate the provision of the proposed restoration and/or influence the behavior and performance of the restorations in clinical service.
(6) Patients who maintain an unacceptable standard of oral hygiene.

Table 2 Composition of GIOMER restorative system (FL-Bond II and Beautifil II, Shofu, Kyoto, Japan)

Material	Composition
FL-Bond II (Two step self-etching system)	
FL-Bond Primer	Carboxylic acid monomer, Phosphonic acid monomer, Water, Solvent, Initiator
FL-Bond Bond	S-PRG filler, UDMA, TEGDMA, 2-HEMA, Initiator
Beautifil II	
Filler	S-PRG filler, MF (Multi-functional) glass filler, Nano filler
Monomer	Bis-GMA, TEGDMA, UDA, Initiator

Abbreviation:
S-PRG filler: Surface reaction type Pre-reacted glass-ionomer filler, UDMA: Urethane dimethacrylate, TEGDMA: Triethyleneglycol dimethacrylate, 2-HEMA: 2-Hydroxyethyl methacrylate, MF(Multi-functional)glass filler: special surface-treated fluoroboroaluminosilicate glass filler, Bis-GMA: Bisphenol A-glycidyl methacrylate, UDA: Urethane diacrylate
pH of Primer: 2.4
Filler Contents of Beautifil II: 83.3wt% Mean particle size: 0.8 μm

Gingival Status Index (Table 3). When differing evaluator decisions were noted for any restoration, a consensus decision was discussed and agreed upon during that recall period. Additionally, each restoration was recorded by an intra-oral color photographs and impressions then taken with addition-cured silicon impression material (ExaFine, GC, Tokyo, Japan) to fabricate an individual replica for SEM observations at each evaluation period.

RESULTS

Of the 53-original restorations placed at baseline, two-restorations were unavailable for clinical evaluation at the 18-months recall. Tables 4 and 5 shows the clinical evaluation results from each recall period. No post-operative sensitivity was reported by any patient in any of the restored teeth at any recall period. In addition, there was no loss of any resin composite restoration (retention) and no secondary caries observed during any clinical follow-up. No clinical changes with regard to

Table 3 Evaluation criteria of the restorations

1. Retention

Category	Call	Criteria
A	Alpha	Full retention is present.
B	Bravo	Part of the restoration is fractured and the retention is partially lost.
C	Charlie	Retention is absent.

2. Color Match

Category	Call	Criteria
A	Alpha	Restoration matches adjacent tooth structure in shade and/or translucency.
B	Bravo	Mismatch in shade and/or translucency is within normal range of tooth shade.
C	Charlie	Mismatch in shade and/or translucency is outside normal range of tooth shade.

3. Marginal Adaptation Occlusal

Category	Call	Criteria
A	Alpha	Explorer does not catch crevice when drawn across the restoration/tooth interface. No crevice an explorer can be drawn is visible on the restoration margin.
B	Bravo	Explorer catches and crevice is visible but no exposure of dentin.
C	Charlie	Explorer penetrates crevice defect with exposure of dentin but restoration is not mobile in the cavity.

4. Marginal Adaptation Proximal

Category	Call	Criteria
A	Alpha	Explorer does not catch crevice when drawn across the restoration/tooth interface. No crevice an explorer can be drawn is visible on the restoration margin.
B	Bravo	Explorer catches and crevice is visible but no exposure of dentin.
C	Charlie	Explorer penetrates crevice defect with exposure of dentin but restoration is not mobile in the cavity.

5. Marginal Discoloration Occlusal

Category	Call	Criteria
A	Alpha	No discoloration is visible along restoration/tooth interface.
B	Bravo	Partial discoloration is visible along restoration/tooth interface but has not penetrated in pulpal direction.
C	Charlie	Marginal discoloration has penetrated in pulpal direction.

Table 3 (continued)

6. Marginal Discoloration Proximal

Category	Call	Criteria
A	Alpha	No discoloration is visible along restoration/tooth interface.
B	Bravo	Partial discoloration is visible along restoration/tooth interface but has not penetrated in pulpal direction.
C	Charlie	Marginal discoloration has penetrated in pulpal direction.

7. Anatomical Form Occlusal

Category	Call	Criteria
A	Alpha	Restoration is visually continuous with existing anatomical form. Restoration is not under contoured compared to the surrounding teeth.
B	Bravo	Restoration is under contoured compared to the surrounding teeth with no exposure of dentin (partial anatomical form is lost).
C	Charlie	Restoration is sufficiently lost to expose dentin.

8. Anatomical Form Proximal

Category	Call	Criteria
A	Alpha	Restoration is visually continuous with existing anatomical form. Restoration is not under contoured compared to the surrounding teeth.
B	Bravo	Restoration is under contoured compared to the surrounding teeth with no exposure of dentin (partial anatomical form is lost).
C	Charlie	Restoration is sufficiently lost to expose dentin.

9. Surface Roughness Occlusal

Category	Call	Criteria
A	Alpha	Restoration has smoothness and luster equal to the surrounding teeth when dried by air blow.
B	Bravo	Restoration is smooth but has no luster.
C	Charlie	Restoration is rough and has severe surface defects.

10. Surface Roughness Proximal

Category	Call	Criteria
A	Alpha	Restoration has smoothness and luster equal to the surrounding teeth when dried by air blow.
B	Bravo	Restoration is smooth but has no luster.
C	Charlie	Restoration is rough and has severe surface defects.

11. Surface Staining Occlusal

Category	Call	Criteria
A	Alpha	Stain is absent on the restoration surface.
B	Bravo	Stain is present on the restoration surface.

12. Surface Staining Proximal

Category	Call	Criteria
A	Alpha	Stain is absent on the restoration surface.
B	Bravo	Stain is present on the restoration surface.

Table 3 (continued)

13. Secondary Caries

Category	Call	Criteria
A	Alpha	Secondary caries is absent.
B	Bravo	Secondary caries is present.

14. Occlusal Contact

Category	Call	Criteria
A	Alpha	Excellent occlusal contact is present.
B	Bravo	Occlusal contact is within clinically acceptable range.
C	Charlie	Occlusal contact is absent.

15. Proximal Contact

Category	Call	Criteria
A	Alpha	Excellent proximal contact is present.
B	Bravo	Proximal contact is within clinically acceptable range.
C	Charlie	Proximal contact is absent.

16. Marginal Fracture

Category	Call	Criteria
A	Alpha	Marginal fracture is absent.
B	Bravo	Marginal fracture is present.

17. Body Fracture

Category	Call	Criteria
A	Alpha	Body fracture is absent.
B	Bravo	Body fracture is present.

Gingival status: based on the Modified Silness & Löe Gingival Index

Category	Call	Criteria
A	Alpha	Healthy gingivae
B	Bravo	Mild inflammation, slight change of color, slight oedema, but no bleeding on sulcus probing.
C	Charlie	Moderate inflammation with marked redness, oedema and glazing. Bleeding on probing.
D	Delta	Severe inflammation with marked redness, oedema and ulceration. Bleeding on probing and tendency to spontaneous bleeding.

Sensitivity: determined by interviewing the patient and by clinical examination of the treated tooth (including direct stimulus)

Category	Call	Criteria
A	Alpha	No sensitivity
B	Bravo	Mild sensitivity with no pain
C	Charlie	Sensitivity is present when the stimulus is given.
D	Delta	Sensitivity with strong pain does not cease when the stimulus is removed.

patient service regarding anatomical form, surface roughness, occlusal and proximal contact and gingival inflammation were observed by the clinicians after 18-months. The operators evaluated some slight color change (Figure 1), marginal change (Figure 2) and surface staining, respectively at 18-months. These slight changes that were noted for any clinical case was recorded as Bravo —the normal USPHS range of clinical status— no clinical cases were rated as Charlie.

DISCUSSION

Numerous research papers have reported and published data demonstrating that fluoride-releasing restorative materials do provide many benefits to the oral environment, such as inhibition of secondary caries around the restoration interface as well as to promote remineralization of the subjacent tooth substrates[11-13]. It is well known that fluoride release of glass-ionomer

Table 4 Results of clinical evaluations

		Base line			6 months			18 months		
		A	B	C	A	B	C	A	B	C
Retention		53	0	0	53	0	0	51	0	0
Color Match		49	4	0	47	6	0	46	5	0
Marginal Adaptation	Occlusal	53	0	0	41	12	0	39	12	0
	Proximal	46	0	0	38	8	0	33	11	0
Marginal Discoloration	Occlusal	53	0	0	53	0	0	51	0	0
	Proximal	46	0	0	46	0	0	38	6	0
Anatomical Form	Occlusal	53	0	0	51	0	0	51	0	0
	Proximal	46	0	0	46	0	0	44	0	0
Surface Roughness	Occlusal	53	0	0	53	0	0	51	0	0
	Proximal	46	0	0	46	0	0	44	0	0
Surface Staining	Occlusal	53	0	–	52	1	–	49	2	–
	Proximal	46	0	–	46	0	–	43	1	–
Secondary Caries		53	0	–	53	0	–	51	0	–
Occlusal Contact		53	0	0	53	0	0	51	0	0
Proximal Contact		46	0	0	46	0	0	44	0	0
Marginal Fracture		53	0	–	53	0	–	50	1	–
Body Fracture		53	0	–	53	0	–	51	0	–

Table 5 Results of Gingival status and Sensitivity

	Base line				6 months				18 months			
	A	B	C	D	A	B	C	D	A	B	C	D
Gingival status	53	0	0	0	53	0	0	0	51	0	0	0
Sensitivity	53	0	0	0	53	0	0	0	51	0	0	0

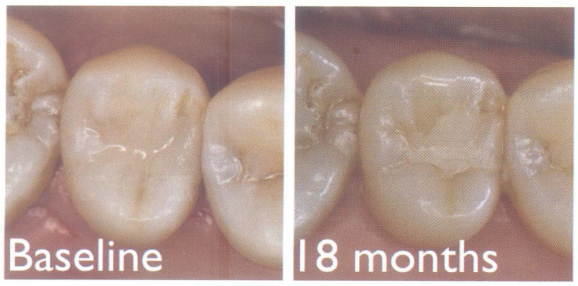

Fig. 1 This Class II restoration received Bravo rating for Color Match at 18 months recall.

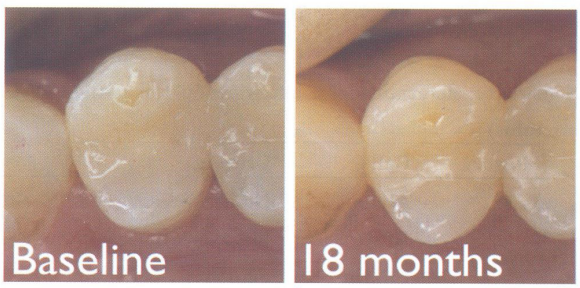

Fig. 2 This Class II restoration received Bravo rating for marginal adaptation of occlusal at 18 months recall.

cement is greater than the other polymeric restorative materials such as resin compomer and resin composite[14]. However certain traditional restorative glass-ionomer cements have a few disadvantages such as a slow setting reaction, low physical properties, water sensitivity and poor esthetics.

The PRG technology that has successfully demonstrated the release the several ions from S-PRG filler has enabled the development of the new fluoride releasing resin composite materials, all the while maintaining optimal mechanical and clinical properties. The clinical evaluations of the restorations with S-PRG filler have been reported with excellent clinical characteristics[15-18]. Recently, the newly improved restorative materials, such as evaluated in this study were modified and developed with S-PRG filler. It has been demonstrated that the new fluoride releasing restorative system with modified S-PRG filler also releases the F-ion as well as other ions such as Al, B, Na, Si, and Sr[19]. It has also been reported that the affected dentin portion of the *in vitro* carious lesion will remineralize as a sclerotic zone following the placement of the new restorative materials with bio-active effect of S-PRG filler due to its ion release[20]. This filler technology is applied to not only resin composite technology, but also to resin adhesive systems. Both the FL-Bond II two-step self-etching adhesive and Beautifil II resin composite material used in this study are called a GIOMER restorative system.

The new restorative system assessed in this clinical study has fulfilled the 18-month ADA full acceptance criteria[21] for retention with a 100% retention rate. All restorations in this study rated a Bravo measure of marginal adaptation demonstrating only minor step irregularities when a sharp explorer was drawn across the tooth from the enamel toward the restoration interface —in addition, these restorations did not show any crevice formation. These marginal interfacial irregular steps supposedly developed from chip fractures of the resin composite or adhesives along the cavo-surface margin due to overfilling the composite resin onto the uncut enamel surfaces. Occasional slight fracture of class II restoration in premolar were observed, which the operators rated as Bravo. The operators discovered that a patient's strong clenching habit was not confirmed before restoration at 18-months evaluation and so it is now reported that confirmation of any patient's habit such as jaw clenching is necessary before and during the clinical trial.

The FL-Bond II two-step self-etching adhesive as used in this clinical study demonstrated clinically acceptable performance, with no lost restorations nor patient postoperative sensitivity after 18-months. The single-step self-etching adhesive system was introduced to operative clinicians in the early 2000's, and this clinically effortless adhesive system has been widely accepted by general practitioners. While this adhesive system has simplified the clinical steps due to the combined self-etching primer and bond functions, several problems adhesion concerns have been considered[22-24]. On the other hand, it has been reported that the original self-etch system (two-step self-etching adhesive system) have easily demonstrated the benefits of long-term clinical performance in the oral environments[25-27]. The modified GIOMER restorative system in this study has demonstrated acceptable clinical results in the same manner as previous reported with two-step adhesive resin composite restoratives.

Although some slight change of restorative color, marginal adaptation, discoloration, and surface staining was observed, there was no restoration loss, no secondary caries and no postoperative sensitivity after 18-months, which was recorded as excellent. These results indicated that the posterior restorations by FL-Bond II and Beautifil II are clinically acceptable in human teeth after 18-months.

CONCLUSIONS

The data from this 18-months clinical study demonstrate that the fluoride releasing restorative system is acceptable for clinical restoration in Class I and Class II posterior restoration in human teeth.

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