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Clinical Evaluation of Low-shrinkage Bioactive Material Giomer Versus Nanohybrid Resin Composite Restorations: A Three-year Prospective Controlled Clinical Trial

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Introduction and Objectives

The desire to develop an ideal restorative material with bioactive properties, has led researchers to develop pre-reacted glass (PRG) technology, which can show ion release and called as Giomer technology. There are not many studies in the literature comparing bioactive material Giomer resin composites with conventional ones and/or glass ionomers in terms of clinical success, and these studies are generally designed for class V restorations. Low-shrinkage Beautifil II is a current bioactive resin composite, an example of second generation Giomer technology which is the latest concept shows the bioactive effect by 6 kinds of multi-ion released from S-PRG filler. Therefore, the aim of this controlled clinical study was to evaluate and compare the clinical performance of low-shrinkage bioactive resin composite Giomer and a nanohybrid resin composite for Class I and Class II cavities.

Materials and Methods

Between February-2016 and May-2017, a total of 35 patients (18 male, 17 female, mean age: 29±9 years old), received randomly 35 pairs of restorations restored using either S-PRG filler (Beautiful II LS, SHOFU Inc., Japan) or nano-hybrid resin composite (Clearfil Majesty Posterior, Kuraray, Japan) (Table 1) in Class I and Class II cavities (Table 2). Two operators performed all restorations using FL-Bond II (SHOFU Inc., Japan) and Clearfil SE Bond (Kuraray, Japan) adhesives respectively according to each manufacturer's instructions. Two independent calibrated operators evaluated the restorations 2 weeks after placement (baseline), at 6 months and 1, 2 and 3 year using FDI criteria (Scores 1-5) for surface staining, marginal staining, marginal gap, marginal fracture, marginal irregularities, seconder caries, marginal tooth integrity, surface lusture, color match and translucency, fracture of material and retention, occlusal wear, approximal contact point, patient view, tooth integrity, post operative sensitivity. The changes in the FDI parameters were analyzed with statistical software (SPSS Statistics, v25.0, IBM, NY, USA). Qualitative data were expressed by count and percentage. Comparisons of scores between materials were performed using the McNemar test and the marginal homogeneity test, where appropriate. Survival Rate was calculated using Kaplan-Meier survival analysis and the survival of the two groups was compared with the Log-Rank test. In all analysis, two-tailed significance level was considered as 0.05.

Brand	Type	Manufacturer	Chemical composition
Beautifil II LS	Low-shrinkage bioactive material Giomer resin composite	SHOFU Inc., Kyoto, Japan	Multi-functional glass and S-PRG filler based on fluoroboroalumino silicate glass, pre-polymerized filler, nano filler, photo-initiator, low-shrinkage urethane diacrylate, bis-MPEPP, bis-GMA, TEGDMA
Clearfil Majesty Posterior	Nano-hybrid resin composite	Kuraray Medical, Tokyo, Japan	bis-GMA, TEGDMA, hydrophobic aromatic dimethacrylate, glass ceramics, surface treated alumina micro-filler (1.5 µm), silica filler (20 nm)
FL-Bond II	Self-etching two-step Giomer adhesive system	SHOFU Inc.,Kyoto, Japan	Primer: Water, ethanol, carboxylic acid monomer, phosphoric acid monomer and initiator
			Adhesive: S-PRG filler based on fluoroboroalimoslicte glass, UDMA, TEGDMA, 2-HEMA, initiator
Clearfil SE Bond	Two-step self-etch adhesive system	Kuraray Medical, Tokyo, Japan	Primer: 10-MDP, HEMA, hydrophilic dimethacrylate, di-camphorquinone, aromatic tertiary amine, water
			Adhesive: 10-MDP, bis-GMA, HEMA, hydrophilic dimethacrylate, photoinitiator, aromatic tertiary amine, silanized colloidal silica

Table 1. The brand, type, manufacturer and chemical composition of the main materials used in this study.

Results

After three years in function, in total, 50 restorations (71%) were evaluated. The mean observation period was 37.7 ±6.8 months (min: 35.4, max: 44.2 months). There was no loss in contact point observed that needed repair of the evaluated fillings. Endodontic failure or tooth fracture were not observed in any of the teeth after two years. From the group of nanohybrid resin composite fillings, a small and localized secondary caries lesion was observed, which did not require intervention but was monitored at the following recalls. One restoration from the low-shrinkage bioactive material Giomer resin composite group showed retention loss at the two-year follow-up (Table 3-5). The overall survival rate of Low-shrinkage bioactive material Giomer resin composite group was 96% and for nanohybrid resin composite group it was 100 % (Kaplan-Meier, Fig. 1). When the survival of the two groups was compared with the Log-Rank test, no statistically significant difference was observed between the two groups (p=0.317). Overall, there were no significant difference between the two restorative materials for all evaluation criteria (p>0.05) (Figure 2a-f, 3a-f)

Location	Teeth	One-surface		Two-surfaces		Three-surfaces	
		LSG	CNH	LSG	CNH	LSG	CNH
Maxilla	Premolar	-	-	14	17	4	1
	Molar	1	-	5	6	-	-
Mandible	Premolar	-	-	4	6	-	-
	Molar	2	3	4	2	1	-
Total		3	3	27	31	5	1

Table 2. Distribution, type and locations of the restorations in the maxilla and mandible.

Aesthetic properties								
	Marginal staining n (%)		Surface luster n (%)		Surface staining n (%)		Color stability and translucency n (%)	
Score*	LSG	CNH	LSG	CNH	LSG	CNH	LSG	CNH
1	16 (56%)	18 (72 %)	1 (4%)	1 (4%)	17 (68%)	18 (72%)	0 (0%)	0 (0%)
2	6 (24%)	6 (24%)	23 (92%)	24 (96%)	6 (24%)	6 (24%)	24 (96%)	25 (100%)
3	2 (8%)	1 (4%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)	0 (0%)	0 (0%)
4	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Table 3. Number and percentage (%) of scores for aesthetic properties of low-shrinkage bioactive material Giomer resin composite (LSG) and conventional nano-hybrid resin composite (CNH) according to the FDI criteria. *1. Clinically excellent/very good; 2. Clinically good (after polishing very good); 3. Clinically sufficient/ satisfactory (minor shortcomings, no unacceptable effects but not adjustable w/o damage to the tooth); 4. Clinically unsatisfactory (but reparable); 5. Clinically poor (replacement necessary).

Functional properties										
	Fractures and retention n (%)		Marginal adaptation n (%)		Wear n (%)		Contact point/ food impaction n (%)		Patient's view n (%)	
Score*	LSG	CNH	LSG	CNH	LSG	CNH	LSG	CNH	LSG	CNH
1	24 (96%)	25 (100%)	24 (96%)	25 (100%)	24 (96%)	25 (100%)	24 (96%)	23 (92%)	24 (96%)	25 (100%)
2	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)	0 (0%)
3	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
4	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5	1 (4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Table 4. Number and percentage (%) of scores for functional properties of low-shrinkage bioactive material Giomer resin composite (LSG) and conventional nano-hybrid resin composite (CNH) according to the FDI criteria. *1. Clinically excellent/very good; 2. Clinically good (after polishing very good); 3. Clinically sufficient/satisfactory (minor shortcomings, no unacceptable effects but not adjustable w/o damage to the tooth); 4. Clinically unsatisfactory (but reparable); 5. Clinically poor (replacement necessary).

Biological properties						
	Postoperative sensitivity and tooth vitality n (%)		Recurrence of caries, erosion, abfraction n (%)		Tooth integrity (enamel cracks) n (%)	
Score*	LSG	CNH	LSG	CNH	LSG	CNH
1	24 (96%)	25 (100%)	24 (96%)	24 (96%)	24 (96%)	24 (96%)
2	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
3	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
4	0 (0%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)	0 (0%)
5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Table 5. Number and percentage (%) of scores for biological properties of low-shrinkage bioactive material Giomer resin composite (LSG) and conventional nano-hybrid resin composite (CNH) according to the FDI criteria. *1. Clinically excellent/very good; 2. Clinically good (after correction very good); 3. Clinically sufficient/satisfactory (minor shortcomings with no adverse effects but not adjustable without damage to the tooth); 4. Clinically unsatisfactory (repair for prophylactic reasons); 5. Clinically poor (replacement necessary).

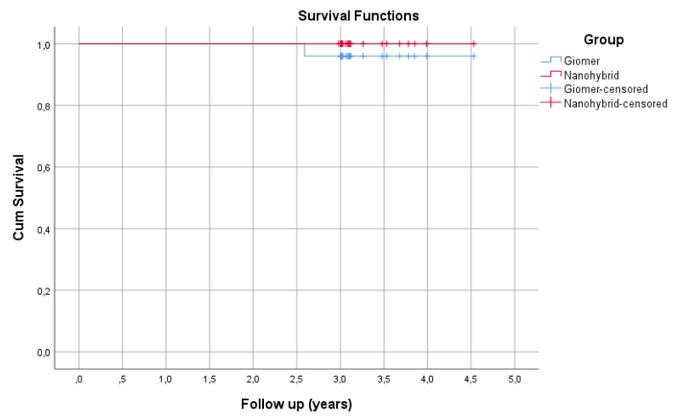
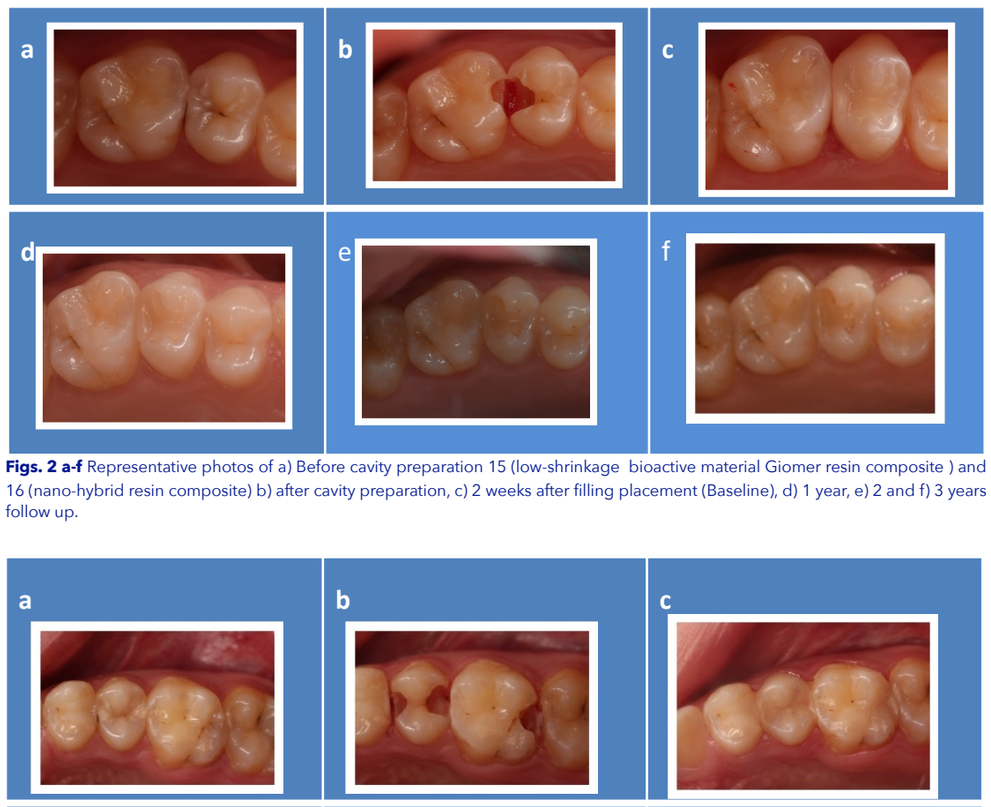
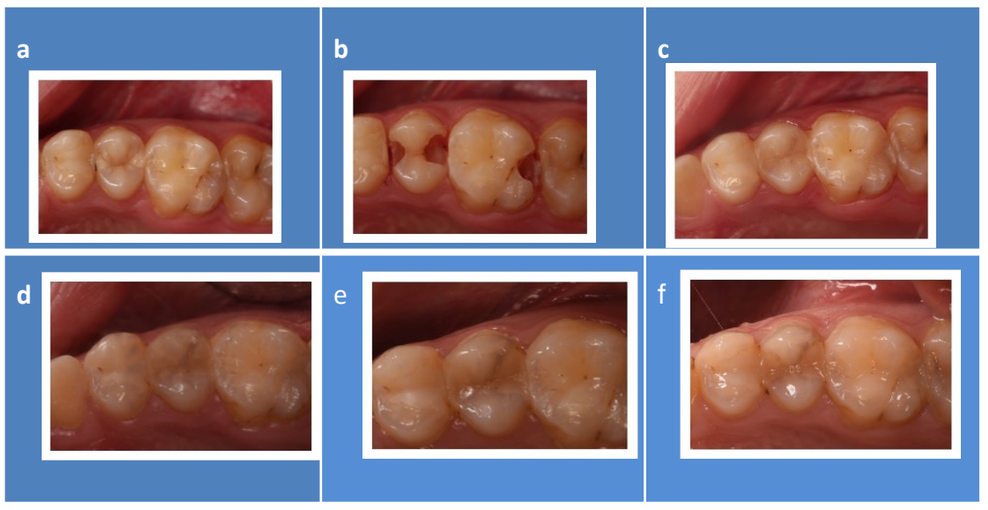


Fig. 1 Event-free survival rates of resin composite restorations for class I and class II cavities (n=25). Mean survival time of Giomer group was 54.17±0.93 months (95% C.I. = 52.36±55.98).



Figs. 2 a-f Representative photos of a) Before cavity preparation 15 (low-shrinkage bioactive material Giomer resin composite) and 16 (nano-hybrid resin composite) b) after cavity preparation, c) 2 weeks after filling placement (Baseline), d) 1 year, e) 2 and f) 3 years follow up.



Figs. 3 a-f Representative photos of a) Before cavity preparation 25 (low-shrinkage bioactive material Giomer resin composite) and 26 (nano-hybrid resin composite) b) after cavity preparation, c) 2 weeks after filling placement (Baseline), d) 6 months, e) 2 and f) 3 years follow up. Marginal staining observed in Giomer Group after the two-year follow-up (tooth no: 25, scored as 3)

Conclusion

After a three-year evaluation period, low-shrinkage bioactive material Giomer resin composite showed similar clinical behavior to the conventional nanohybrid resin composite, with both materials showing minor surface deteriorations at the final follow-up.

References

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