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CLINICAL EVALUATION OF FLOWABLE VERSUS PACKABLE BULK-FILL GIOMER RESTORATIVE MATERIALS: A TWO-YEAR RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Aim: To compare the clinical performance of flowable versus packable bulk-fill Giomer restorative materials in compound class II restorations.

Materials and methods: 188 compound class II cavities were prepared and equally divided according to the type of restorative material (n=94): Group 1 (BFP): BEAUTIFIL Flow Plus X (SHOFU INC., Kyoto, Japan) and Group 2 (BBR): BEAUTIFL-Bulk Restorative (SHOFU INC., Kyoto, Japan). The restorations were assessed at baseline, after 6, 12, 18 and 24 months using the modified USPHS criteria for the following parameters: retention, marginal adaptation, marginal discoloration, surface texture, postoperative hypersensitivity, and recurrence of caries. Statistical analysis was performed using Mann-Whitney U, Friedman's test and Nemenyi post hoc test.

Results: 172 restorations were evaluated at 24-month follow-up. For all parameters and intervals, no significant differences were observed between both groups ($p<0.05$). For marginal discoloration measured in both groups, there was a significant increase in the percentage of cases with bravo score after 18 and 24 months ($p<0.05$). For postoperative hypersensitivity measured in both groups, there was a significant increase in the percentage of cases with alpha score at 6 months ($p<0.05$).

Conclusion: The clinical performance of flowable and packable bulk-fill Giomers was accepted after two years of evaluation.

KEYWORDS: Giomer, Flowable, Bulk-fill, Modified USPHS criteria

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INTRODUCTION

The application of resin composite for direct restorations has surpassed dental amalgam due to the improved properties of new formulations, together with the increasing demands of patients for durable tooth-colored restorations [1]. Despite the increased durability of direct resin composite restorations, they are replaced at relatively higher rates than those of other restorative materials, mainly due to recurrence of caries and discoloration [2].

Glass ionomer cements have been proposed as an alternative to resin composites in posterior teeth due to their fluoride-releasing and anticariogenic properties, which could prevent the recurrence of caries in addition to their biocompatibility and chemical adhesion to tooth tissues [3,4]. However, concerns have been raised about the survival of conventional glass ionomer restorations due to their low wear and fracture resistance, especially in restorations subjected to extensive masticatory forces and inadequate esthetic properties [5,6].

Several attempts have been made to introduce a restorative material combining the fluoride-releasing property of conventional glass ionomers with the durability of resin composites such as compomers and resin modified glass ionomer cements. In 2000, a new category of fluoride-releasing resin-based restorative materials known as "Giomer" was introduced by SHOFU INC. (Kyoto, Japan) [7]. Giomer differs from other fluoride-releasing restorative materials because it is based on hybridized technology between resin composite material and prereacted glass-ionomer (PRG) filler, providing a new bioactive material with fluoride-releasing and recharging capability like conventional glass ionomer cements and maintaining the properties of resin composites [8].

Resin-based restorative materials are usually applied and polymerized in increments. This "incremental packing technique" was adopted to ensure sufficient curing depth and to reduce polymerization shrinkage stresses. On the other hand, this technique is consumes more time [9]. To overcome this drawback, bulk-fill restorative materials were launched onto the market, allowing the application and polymerization of the restorative materials in increments up to 4 or 5 mm. These materials reduce the number of steps and chair-time required for the restorative procedures, leading to less possibility of manipulation errors such as contamination between successive resin composite increments or void incorporation [10]. Bulk-fill materials have sufficient curing depth and degree of conversion with less polymerization shrinkage compared to their conventional resin composite counterparts, thus the adaptation to the walls of the prepared cavities is not affected [11,12]. Bulk-fill restorative materials are available in two viscosities. Low-viscosity (flowable) requires a final cover increment of other conventional resin composite, while high-viscosity (packable) does not require an occlusal cover layer [13].

Flowable resin composites were introduced by reducing the filler loading to minimize the consequences of polymerization shrinkage of conventional resin composites. However, due to mechanical shortcomings, their use was restricted to minimally invasive Class II restorations [14,15]. A new flowable Giomer restorative material (BEAUTIFIL Flow Plus X, SHOFU INC., Kyoto, Japan) was launched onto the market. The manufacturer claims that this new flowable Giomer restorative material does not require capping with other restorative materials. The manufacturer recommends the use of this new material for restoration of all classes of prepared cavities (I, II, III, IV, V) [16]. *Abdelwahed et al.* reported that the curing depth and marginal adaptation of bulk-fill Giomer restorative materials were acceptable when compared to other bulk-fill resin composites [17]. However, there is a scarcity of clinical trials evaluating the performance of these materials. The current study aimed to evaluate the clinical performance of flowable versus packable

bulk-fill Giomer restorative materials in compound class II restorations. The two null hypotheses of the study were that there would be no differences between the two restorative materials and that both restorative materials would exhibit good clinical performance.

MATERIALS AND METHODS

Trial registration

This study was conducted following the guidelines of the CONSORT 2010 statement [18]. The local Institutional Review Board at the Faculty of Dentistry, October 6 University, reviewed the proposal for this clinical trial on April 5, 2021 (RECO6U/4-2021). This study was registered in the Pan African Clinical Trials Registry under protocol number PACTR202109664816731.

Trial design and settings

This study was designed as a split-mouth, double-blinded (participants and outcomes assessors), two-arm randomized clinical trial with a 1:1 allocation ratio between May 9, 2021, and September 26, 2023. Only the two assessors were blinded in this study because the operator and participants could not be blinded due to the different application of the restorative materials.

Sample size calculation

Based on the findings of *Abdel-karim et al.* [19], A power analysis was designed by adopting an alpha level of (0.05) a beta of (0.2) i.e. power=80% and an effect size (W) of (0.229). The predicted sample size was 150 cases which was increased to 188 participants (n=94) to overcome the possible loss of participants during follow-ups. Sample size calculation was performed using PASS 15 (NCSS, LLC. Kaysville, Utah, USA).

Participants recruitment and randomization

Patients seeking restoration of proximal posterior cavities were examined clinically and radiographically using bitewing radiography to determine their eligibility for participation in the study. Each participant must have at least two or four compound proximal cavities indicated for restoration with at least 12 permanent posterior teeth in occlusion. The exclusion criteria were as follows: patients with parafunctional habits, wearing orthodontic appliances, or pregnant or breastfeeding females. 305 patients were examined, and 117 patients were excluded. Figure 1. shows the participants' flow diagram during the study. Written informed consent was obtained from the participants. Each participant received at least one pair of restorations. Block randomization was implemented. In this method, both the "tooth" and the "restorative material" were randomly allocated, creating a pair of matched data to determine which tooth would receive which type of restorative material.

Restorative procedures

All restorations were performed by an experienced operator (S.E.F.). Local anesthesia (Artapharmdent 4%, Artpharma Egypt Pharmaceuticals, 6th of October city, Egypt) was administrated to all patients. Quadrant isolation was implemented for isolation. All cavities were prepared using diamond fissure and inverted cone burs (ökoDENT, ökoDENT GmbH & Co KG, Lindenweg, Germany) at a high-speed handpiece (T3 Racer, Dentsply Sirona, NA, USA). The outline of the prepared cavities was restricted to removing the carious lesion, with no additional retentive features or beveling. The depth of the cavities was approximately 4-5 mm.

A sectional metal matrix (Composi-Tight 3D Fusion™, Garrison Dental Solutions, Michigan, USA) was used. A calcium hydroxide liner (Dycal®, Dentsply Sirona, NA, USA) was applied where needed in very deep cavities. A self-etching one component dental adhesive (BeautiBond, SHOFU INC., Kyoto, Japan) was applied according to the

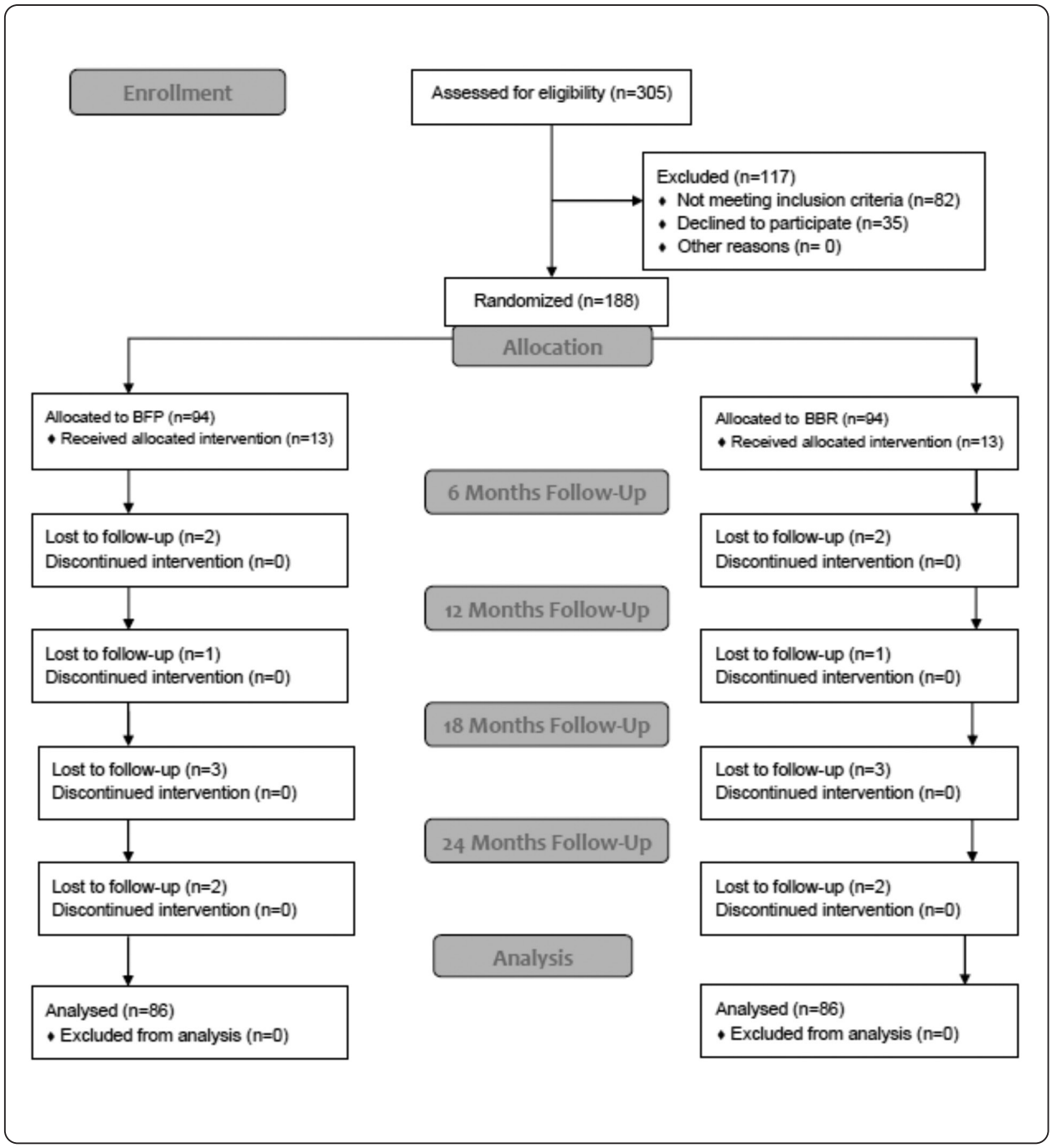

Fig. (1) Participants flow diagram during the study

manufacturer instructions, and light cured using Premium Plus™ LED light curing unit (Premium Plus Dental Supplies Inc., NY, USA) for 5 seconds at a light intensity of 1200 mW/cm^2. The prepared cavities were restored using one of the two restorative materials:

Group 1 (BFP): A flowable Giomer restorative material (BEAUTIFIL Flow Plus X, SHOFU INC., Kyoto, Japan) was applied in increments not exceeding 2 mm each. Each increment was light cured for 10 seconds at a light intensity of 1200 mW/cm^2.

Group 2 (BBR): A packable bulk-fill Giomer restorative material (BEAUTIFL-Bulk Restorative, SHOFU INC., Kyoto, Japan) was applied in one increment and light cured for 10 seconds at a light intensity of 1200 mW/cm^2.

The specification and components of the restorative materials are described in Table 1.

All restorations were finished using fine-grit diamond burs (ökoDENT, ökoDENT GmbH & Co KG, Lindenweg, Germany) and polished by polishing discs (Sof-Lex, 3 M, MN, US).

Clinical evaluation

Two calibrated and experienced evaluators (A.G.A. & M.M.A.), assessed the restorations following the modified USPHS criteria for the following items: retention, marginal adaptation, marginal discoloration, surface texture, postoperative hypersensitivity, and recurrence of caries (Table 2) [20,21]. The restorations were examined at baseline (seven days after restoration placement), after 6, 12, 18 and 24 months. The two evaluators assessed the restorations independently. When any disagreement occurred, both evaluators re-evaluated the restoration to reach a consensus.

Statistical analysis

Ordinal data were presented as frequency and percentage values and were analyzed using Mann-Whitney U and Friedman's test followed by Nemenyi post hoc test for inter and intragroup comparisons respectively. The significance level was set at $p<0.05$ within all tests. Statistical analysis was performed with R statistical analysis software version 4.3.1 for Windows (R Core Team (2023). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria.

TABLE (1) Materials used in the study and their specification, composition, and manufacturers.

Product	Abbreviation	Specification	Composition		Fillers Wt% (Vol%)	Manufacturer
			Resin matrix	Fillers		
BEAUTIFIL Flow Plus X	BFP	Flowable Giomer restorative material	Bis-GMA* TEGDMA** Bis-MPEP^{P***}*	S-PRG	72.5 (51%)	SHOFU INC., Kyoto, Japan
BEAUTIFL-Bulk Restorative	BBR	Packable bulk-fill Giomer restorative material	Bis-GMA* UDMA**** TEGDMA** Bis-MPEPP***	S-PRG	87% (74.5%)	SHOFU INC., Kyoto, Japan

**BIS-GMA, Bisphenol A Dimethacrylate*

***TEGDMA, Triethylene Glycol Dimethacrylate*

****Bis-MPEPP, Bisphenol A polyethoxy methacrylate*

*****UDMA, Urethane Dimethacrylate*

TABLE (2) Modified USPHS criteria

	Alpha (A)	**Bravo (B)**	**Charlie (C)**
Retention	Retained	---	Mobility or loss of restoration
Marginal adaptation	No visible crack along the margin for the explorer to penetrate	Visible evidence of a crack along the margin with non- exposed dentin	Explorer penetrates fissure, exposed dentine
Marginal discoloration	No discoloration along the margin	Marginal discoloration which can be polished away	Discoloration in interface restorative material and tooth, no able to polish
Surface texture	Surface is as smooth as the surrounding enamel	Surface is rougher than surrounding enamel	Surface is very rough avoiding continuous movement of the explorer
Postoperative hypersensitivity	No postoperative hypersensitivity	---	Presence of postoperative hypersensitivity
Recurrence of caries	No secondary caries	---	Presence of secondary caries

RESULTS

188 class II restorations (58 premolars and 130 molars) were placed in 87 participants (36 males and 51 females) ranging from 18-49 years of age (Table 3).

Results of inter and intragroup comparisons for clinical scores are presented in Table 4 and in Figure 2. For all parameters and intervals, there was no significant difference between both groups ($p<0.05$). For marginal discoloration measured in both groups, there was a significant increase in the percentage of cases with bravo score after 18 and 24 months ($p<0.05$). For postoperative hypersensitivity measured in both groups, there was a significant increase in the percentage of cases with alpha score at 6 months ($p<0.05$).]

TABLE (3) Number of restorations at base line according to the teeth and the type of restorative material

Group	Premolars	Molars
BFP	26	68
BBR	32	62
Total	58	130

TABLE (4) Inter and intragroup comparisons of different clinical parameters

Parameter	*Time*	*Score*	*n (%)*		*Test statistic*	*p-value*
			BFP	*BBR*		
– Retention	**Baseline (n=94)**	**Alpha**	94 (100.00%)	94 (100.00%)	**NA**	**NA**
		Bravo	0 (0.00%)	0 (0.00%)		
		Charlie	0 (0.00%)	0 (0.00%)		
– Marginal adaptation	**6 months (n=92)**	**Alpha**	92 (100.00%)	92 (100.00%)	**NA**	**NA**
		Bravo	0 (0.00%)	0 (0.00%)		
		Charlie	0 (0.00%)	0 (0.00%)		
– Recurrence of caries	**12 months (n=91)**	**Alpha**	91 (100.00%)	91 (100.00%)	**NA**	**NA**
		Bravo	0 (0.00%)	0 (0.00%)		
		Charlie	0 (0.00%)	0 (0.00%)		
– Surface texture	**18 months (n=88)**	**Alpha**	88 (100.00%)	88 (100.00%)	**NA**	**NA**
		Bravo	0 (0.00%)	0 (0.00%)		
		Charlie	0 (0.00%)	0 (0.00%)		
	24 months (n=86)	**Alpha**	86 (100.00%)	86 (100.00%)	**NA**	**NA**
		Bravo	0 (0.00%)	0 (0.00%)		
		Charlie	0 (0.00%)	0 (0.00%)		
	Test statistic		**NA**	**NA**		
	p-value		**NA**	**NA**		

Parameter	**Time**	**Score**	**n (%)**		*Test statistic*	*p-value*
			BFP	**BBR**		
Marginal discoloration	**Baseline (n=94)**	**Alpha**	94 (100.00%)^{A}	94 (100.00%)^{A}	**NA**	**NA**
		Bravo	0 (0.00%)	0 (0.00%)		
		Charlie	0 (0.00%)	0 (0.00%)		
	6 months (n=92)	**Alpha**	92 (100.00%)^{A}	92 (100.00%)^{A}	**NA**	**NA**
		Bravo	0 (0.00%)	0 (0.00%)		
		Charlie	0 (0.00%)	0 (0.00%)		
	12 months (n=91)	**Alpha**	91 (100.00%)^{A}	91 (100.00%)^{A}	**NA**	**NA**
		Bravo	0 (0.00%)	0 (0.00%)		
		Charlie	0 (0.00%)	0 (0.00%)		
	18 months (n=88)	**Alpha**	85 (96.59%)^{B}	84 (95.45%)^{B}	**3916.00**	**0.704**
		Bravo	3 (3.41%)	4 (4.55%)		
		Charlie	0 (0.00%)	0 (0.00%)		
	24 months (n=86)	**Alpha**	81 (94.19%)^{B}	81 (94.19%)^{B}	**3698.00**	**1**
		Bravo	5 (5.81%)	5 (5.81%)		
		Charlie	0 (0.00%)	0 (0.00%)		
	Test statistic		**17.09**	**13.78**		
	p-value		**0.002***	**0.008***		

Parameter	**Time**	**Score**	**n (%)**		*Test statistic*	*p-value*
			BFP	**BBR**		
Postoperative hypersensitivity	**Baseline (n=94)**	**Alpha**	83 (88.30%)^{A}	87 (92.55%)^{A}	**4606.00**	**0.342**
		Charlie	11 (11.70%)	7 (7.45%)		
	6 months (n=92)	**Alpha**	92 (100.00%)^{B}	92 (100.00%)^{B}	**NA**	**NA**
		Charlie	0 (0.00%)	0 (0.00%)		
	12 months (n=91)	**Alpha**	91 (100.00%)^{B}	91 (100.00%)^{B}	**NA**	**NA**
		Charlie	0 (0.00%)	0 (0.00%)		
	18 months (n=88)	**Alpha**	88 (100.00%)^{B}	88 (100.00%)^{B}	**NA**	**NA**
		Charlie	0 (0.00%)	0 (0.00%)		
	24 months (n=86)	**Alpha**	86 (100.00%)^{B}	86 (100.00%)^{B}	**NA**	**NA**
		Charlie	0 (0.00%)	0 (0.00%)		
	Test statistic		**12.00**	**28.00**		
	p-value		**0.017***	**<0.001***		

NA: Not Applicable, Values with different superscript letters within the same vertical column and clinical parameter are significantly different *significant (p<0.05)

Fig. (2) Stacked bar chart showing clinical scores

DISCUSSION

Remarkable improvements in the formulations of resin-based restorative materials have been made. However, bulk fractures and secondary caries remain the main reasons for failure. Previous in vitro studies have reported that Giomers with surface prereacted glass (S-PRG) have improved mechanical and physical properties, besides better fluoride release and recharging [22]. Although in vitro studies offer an initial comparison of the performance of new restorative materials, randomized controlled trials are the best method to evaluate restorative materials. Well-conducted randomized clinical trials assess clinical factors affecting the longevity of restorations, such as saliva, microorganisms, fluctuations in temperature, and masticatory stress[20,23].

It has been reported that the mean follow-up period in clinical studies assessing the restorative material was a mere 2 years which, was adopted in this study [24]. The number of participants attending follow-ups is related to acquiring trustworthy data about the clinical performance of the restorative materials [20]. In the present study, 91.5% of participants attended the 24-month follow-up.

In most clinical trials, modified USPHS criteria are used for evaluation of restorations; therefore, they were used for evaluation by two different well-experienced evaluators [25]. The parameters assessed in this clinical trial include objective and subjective, i.e., retention and marginal adaptation, surface texture, recurrence of caries, marginal discoloration, and postoperative hypersensitivity, respectively.

The results of the clinical evaluation showed no significant differences between flowable and packable bulk-fill restorative materials, and both restorative materials showed accepted clinical performance; therefore, the two null hypotheses were accepted. Flowable resin composites have less filler loading (37%-53%) by volume compared to (50%-70%) for conventional resin composites. This reduced filler loading modifies their viscosity and lowers their modulus of elasticity, allowing them to have the ability to relieve polymerization shrinkage stresses as well as thermal and occlusal stresses. Clinical studies comparing flowable and conventional resin composites using the USPHS showed that there were probably no differences in performance between the two materials [15,26].

Bulk-fill resin composites were developed by enhancing their translucency to improve the depth of cure. *Kunz et al*. affirmed that posterior resin-based restorations placed with bulk-filling technique presented acceptable clinical performance resembling those restorations placed with the standard incremental technique [27].

Retention of restorations is often used to assess their longevity. Loss of retention is the most evident and reliable sign of failure of restorations because it is the least sign of being biased unlike the other evaluated parameters of the modified USPHS criteria, which may be evaluated differently among the examiners. According to the American Dental Association (ADA) guidelines, the retention rate should be at least 90% after 18 months to be considered clinically successful [28]. In this study, both restorative materials showed an excellent retention rate with 100% Alpha ratings for the 24-month evaluation period. This excellent retention rate could be attributed to the quality of tested restorative materials in addition to proper isolation of the operative field by the application of rubber dam and the effectiveness of the self-etching adhesive agent, which was reported to have the same longevity as the etch-and-rinse adhesive system [29].

Polymerization shrinkage stresses can result in the presence of gaps, which lead to microleakage, marginal discoloration, and recurrence of caries. Recurrence of caries was cited as the main reason for failure of direct resin composite restorations (30). All the restorations in the current study showed Alpha ratings regarding their marginal adaptation and recurrence of caries, indicating good marginal sealing and adaptation along the tooth-restoration

interface. It was widely believed that the application of resin composite incrementally decreases polymerization shrinkage. However, several in vitro studies proved that the incremental filling technique did not cause less polymerization shrinkage when compared with the bulk-fill technique. [31–33].

All the restorations (100%) showed Alpha ratings regarding the surface texture. Surface smoothness is essential for the success of resin-based restorative materials. Satisfactory smoothness of the restorations enhances esthetics and decreases dental plaque accumulation and initial bacterial adhesion, thus reducing the risk of recurrence of caries along the margins of the restoration [34]. Usually, surface smoothness of the restoration is determined by the restorative materials and finishing and polishing procedures[35]. BFP and BBR are categorized as nanohybrid restorative materials because they contain nanoparticles (<100 nm) and sub-micron particles (≤1 μm). These nanosized fillers produced smoother surfaces after finishing and polishing. Finishing of the restoration achieves the proper contour of the restoration, but it introduces surface roughness. Polishing is then done to decrease this roughness [36].

At 12-month, all restorations (100%) showed Alpha ratings regarding marginal discoloration. Unfortunately, at 18 months, 3.41% and 4.55% of the restorations showed Bravo ratings in the BFP and BBR groups, respectively. At 24 months, 5.81% of the restorations in both groups showed Bravo ratings. Despite the improvements in resin-based restorative materials, tooth-colored restorations are still susceptible to staining. Several extrinsic and intrinsic factors can induce color changes in resin-based restoration during clinical service [37]. The methacrylate copolymers in the matrix of resin composites are hydrophilic in nature, which causes water sorption, either from saliva or dentinal tubules. Surface roughness and irregularities also contribute in increasing plaque adherence and staining [38]. All these factors cause marginal discoloration and jeopardize marginal adaptation. However, in this study, neither marginal adaptation nor recurrence of caries was observed. Minor marginal discoloration has been reported to appear over time, but it can be managed by repolishing the stained margins [39].

At baseline, 11.7% and 7.45% of the restorations showed Charlie ratings regarding postoperative hypersensitivity in the BFP and BBR groups, respectively. Clinical trials assessing the performance of resin-based restorative materials reported some discomfort or pain after the placement of restorations in up to 30% of participants[40]. This immediate postoperative hypersensitivity could be attributed to the consequences of the polymerization shrinkage of the restorative materials, as well as incomplete infiltration of the bonding agent leading to inadequate sealing of the dentinal tubules [41]. Postoperative hypersensitivity subsided thereafter, and all restorations (100%) showed Alpha ratings at the following follow-ups. Previous clinical trials have found that postoperative hypersensitivity decreases gradually over time [42,43].

The limitations of this study should be noticed. First, the study was conducted in a university setting where only patients with good oral condition were involved. All the restorations were placed under ideal conditions by a well-trained operator. As a result, the obtained results cannot be extended to all clinical settings. Second, the restorations were followed up for only two years. Short-term evaluation data yields limited failures. A recent systematic review found that recurrence of caries occurs mostly after several years of clinical service[44]. Finally, this clinical trial was designed as a split-mouth study which can reduce most inter-patient variables such as brushing and oral hygiene habits, occlusion, and dietary habits. On the other hand, possible participant loss is a major disadvantage of this study design because more than one restoration would be lost when a participant failed to attend the follow-ups [6].

CONCLUSIONS

Flowable and packable bulk-fill Giomer restorative materials showed satisfactory performance over two years of observation with no significant differences between the two restorative materials. However, longer-term follow-up practice-based clinical trials are required to confirm these findings.

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