ORIGINAL RESEARCH

Clinical Assessment of Injectable Flowable Composite with Giomer-based Technology vs Smart Bioactive Restoration in Carious Class V Cavities: An 18-month Randomized Clinical Trial

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Abstract

Purpose: The purpose of this study was to evaluate the clinical performance of two different bioactive injectable composite materials in restoring class V cavities over 18 months.

Materials and methods: Thirty-four participants with class V dental carious lesions were randomly enrolled in this study. The participants were allocated into two groups (n = 17): Group I (the intervention group): Giomer-based composite (Beautifil Flow Plus X) and group II (the comparator group): ACTIVA bioactive restorative. The modified United States Public Health Service (USPHS) criteria were used to evaluate the restorations at baseline, after 6, 12, and 18 months. Categorical data were described as frequency and percentage. Chi-squared test was applied for intergroup comparisons between intervention and comparator, while Cochran's Q test was used for intragroup comparison in each group, followed by multiple comparisons.

Results: There was no statistically significant difference in the intergroup comparisons in marginal integrity, postoperative hypersensitivity, marginal discoloration, secondary caries, fracture, and retention criteria, with $p = 1.000$, while $p > 0.05$ in anatomical form and surface texture criteria. Intragroup comparison within a giomer-based composite (Beautifil Flow Plus X) has shown a significant difference in anatomical form between different follow-up periods ($p = 0.029$). While intragroup comparison within ACTIVA bioactive and giomer-based composite (Beautifil Flow Plus X) has shown significant difference in surface texture between different follow-up periods $p = 0.007$ and $p = 0.001$, respectively. In survival analysis, ACTIVA group has shown 76.5% alpha score, while Beautifil group has shown 58.8% alpha score after 18 months, with no difference between them ($p = 0.2771$).

Conclusions: Both giomer-based composite (Beautifil Flow Plus X) and ACTIVA bioactive have acceptable clinical performance in restoring class V cavities after 18 months. This suggests that giomer-based composite (Beautifil Flow Plus X) may be a promising bioactive material in restoring class V carious lesions.

Keywords: ACTIVA bioactive, Beautifil, Clinical performance, Injectable composite, Smart restoration, Surface prereacted glass-ionomer.

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Introduction

Dental caries was thought to be a progressive condition that needed to be completely removed to prepare a cavity. Since dental caries is now recognized as a disease that may be prevented and reversed, efforts have focused on reducing its occurrence and reversing early lesions through ion precipitation remineralization.[1] Furthermore, the selective caries removal approach was made feasible by the potential to remineralize dentin collagen that has been partially demineralized by dental caries.[2] Nowadays, fully demineralized dentin matrix has been successfully remineralized using recent biomimetic remineralization techniques.[3]

Several materials have been successively used to restore class V cavities, including glass-ionomer cement (GIC), resin-modified GIC, and composite resin. Although composite resin is the most popular restoration because of its esthetic and strength, polymerization shrinkage remains the main drawback of composite, which eventually causes failure and caries recurrence via marginal leakage.[4]

The term "smart materials" refers to the relatively new concept of bioactive restorative materials, which are stated to have more fluoride release than glass ionomers. They react to pH changes in the oral cavity by releasing calcium, phosphate, and fluoride ions, thus helps to maintain the chemical integrity of the tooth structure.[5] These materials can be influenced by a variety of stimuli, including pH, moisture, temperature, and stress. These bioactive materials can

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release and recharge depending on the environmental conditions.[6] One such material is ACTIVA Bioactive restorative (Pulpdent, United States), which is made up of a patented bioactive shock-absorbing rubberized ionic-resin (Embrace resin) matrix with a small amount of water. It has no Bisphenol A, Bis-GMA (bisphenol A-glycidyl methacrylate), or Bisphenol A (BPA) monomer.[7]

Another example of smart hybrid materials is giomer, which was introduced in 2000. It includes a stable glass ionomer phase on a glass core, which initiates an acid–base reaction between fluoride-containing glass and polycarboxylic acid in the presence of water, forming prereacted glass-ionomer (PRG) filler.[8] There are two types of PRG filler. Full reaction type [fully prereacted glass-ionomer (F-PRG)], where the entire glass filler reacted with polycarboxylic acid, and surface reaction type [surface prereacted glass-ionomer (S-PRG)], in which the surface of the glass filler reacted with polyacids.[9,10]

Surface prereacted glass-ionomers are inorganic bioactive fillers with the added capability of ion release. Because S-PRG filler may release a variety of ions, including aluminum, borate, fluoride, sodium, silicate, and strontium (Al, B, F, Na, Si, and Sr), it is regarded as a multifunctional bioactive glass.[11] Numerous bioactive behaviors, such as inhibiting bacterial and fungal adherence, antibacterial activity, neutralizing acids, preventing demineralization, and promoting remineralization, can be displayed by the discharged ions.[12]

To the best of authors' knowledge, no study was carried out to compare between giomer-based composite (Beautifil Flow Plus X) and ACTIVA bioactive. So, this study was conducted to evaluate the clinical performance of both materials in patients with carious class V cavities using modified United States Public Health Service (USPHS) criteria. The primary outcome was the marginal discoloration as an indication of caries recurrency. The null hypothesis proposed that there would be a similarity in the clinical performance of giomer-based composite (Beautifil Flow Plus X) and ACTIVA bioactive composite restorations in patients with carious class V moderately deep cavities.

Materials and Methods

Ethical Approval and Trial Registration

All procedures in this randomized controlled trial followed the ethical principles of the 1975 Helsinki Declaration[13] after receiving approval of the Research Ethics Committee of Cairo University (CREC) (approval number: 5-5-22). The trial was reported in line with the 2010 Consolidated Standards of Reporting Trials (CONSORT) guidelines[14] (Fig. 1) and was registered retrospectively on July 15, 2022, at https://clinicaltrials.gov with the ID NCT05466461.

Sample Size Calculation

A power analysis was designed to have adequate power to apply statistical test (statistical test used: Chi-square test) of the research hypothesis to evaluate giomer-based restorative material compared to smart bioactive restorative material for class V restoration of carious teeth in terms of marginal discoloration after 18 months. According to the results of Nassar et al.,[15] in which the probability of score A for marginal discoloration of smart bioactive material (comparator) was (0.867), probability of score C was (0.133) with effect size $w = 0.734$ ($n = 15$). The estimated probability of marginal discoloration for giomer-based restorative material (intervention) was (0.9) for score A, (0.1) for score C with effect size $w = 0.8$ ($n = 13$).

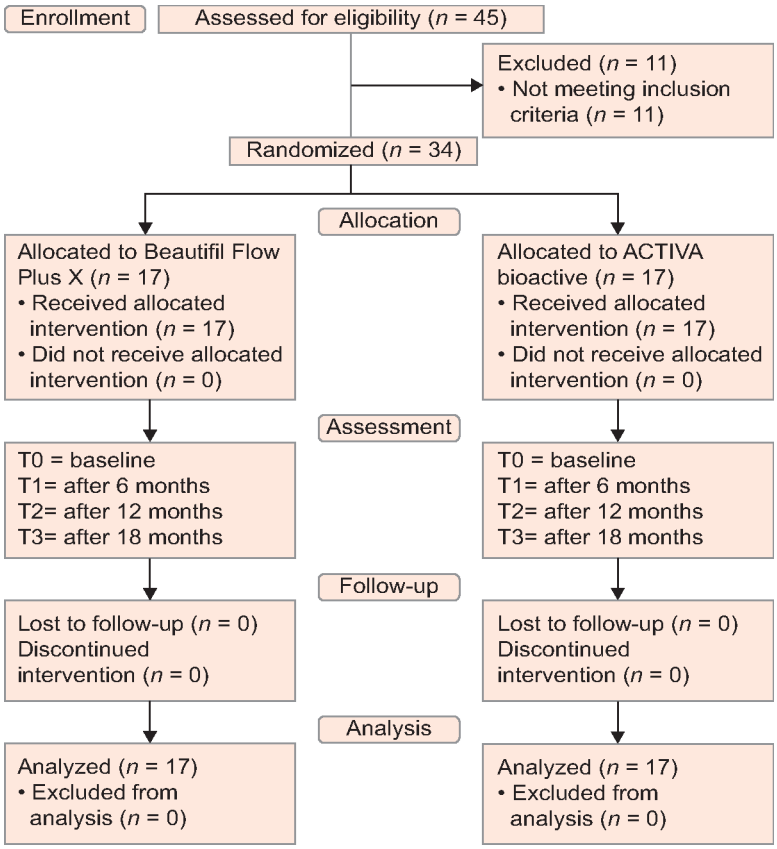


Fig. 1: Participants CONSORT flow diagram

By adopting an alpha (α) level of 0.05 (5%), power = 80%. The predicted sample size (n) was a total of 28. Sample size was increased by (20%) to account for anticipated missing data to be total of 34 cases, that is, 17 for each group. Sample size calculation was performed using G*Power 3.1.9.2.

Study Design and Study Setting

This study was an 18-month follow-up evaluation of a prospective controlled randomized clinical parallel blinded study design. The allocation ratio was 1:1. The study was carried out from June 2023 to January 2025 in the Clinic of the Conservative Dentistry department, Faculty of Dentistry, Cairo University, from where the patients were recruited. The researcher (BR) was incharge of participant selection, explanation, and performance of restorative procedures in this study. The procedure and purpose of the study were described to the participants, and each one signed an informed consent. A total of 34 patients with class V cavities were enrolled randomly into two groups (n = 17 teeth for each group). Group I (the intervention group): Giomer-based composite (Beautifil Flow Plus X) was used, while in group II (the comparator group): ACTIVA Bioactive was used. USPH criteria were evaluated immediately after application and finishing (T0), after 6 months (T1), after 12 months (T2), and after 18 months (T3).

Eligibility Criteria

The inclusion criteria were male or female patients with good general health and recall availability, aged 18–55 years, with class V cavity categorized according to the International Caries Detection and Assessment System as ICDAS 4 or 5,[16] vital upper or lower anteriors or premolars with no signs of pulpal involvement. While the exclusion criteria were pregnant and lactating females, patients included in other studies, parafunctional habits, noncarious lesions, nonvital teeth, and any advanced periodontal diseases.

Randomization, Allocation, and Blinding

After applying the inclusion and exclusion criteria, the patients were randomly enrolled to two groups [giomer-based composite (Beautifil Flow Plus X) or ACTIVA bioactive] based on randomized sequences created by the computer using random integer generator (www.randomization.com). The allocation ratio was set to be equal, and the randomization was occurred at the patient level rather than the tooth level to avoid amplifying confounding factors such as oral hygiene, salivary flow, or diet. During treatment, the type of material was concealed from the patient, and the patient had no idea which material would be used. The type of restoration was not mentioned in the patient's file. Instead, it was replaced by a combination that is unfamiliar to the evaluators. Both the patients and the examiners (ON and SK) were blinded to the material allocation. While the operator (BR) was not blinded because of the differences in packaging and manipulation of both tested materials.

Restorative Procedures

Scaling and polishing were done one week before the study for all patients. After anesthesia and rubber dam application with multiple isolation sequences to ensure a lack of contamination of the operative field. Cavities were prepared using high-speed carbide round bur (MANI, INC., Tokyo, Japan) under water coolant. Finishing stone was used to round the internal line angles of the cavity. A 45° bevel 0.5 mm wide was prepared at the cavosurface occlusal enamel margins in all cavities using tapered yellow finishing stone (Komet USA, Fort Mill, South Carolina, United States) to improve esthetic with blending effect and to increase the adhesive area in enamel for better bonding. Spoon excavator (Dentsply Maillefer, Ballaigues, Switzerland; size 51/52) was used to remove soft caries in case of deep cavities. The cavities are restored with the respective restorative materials.[15]

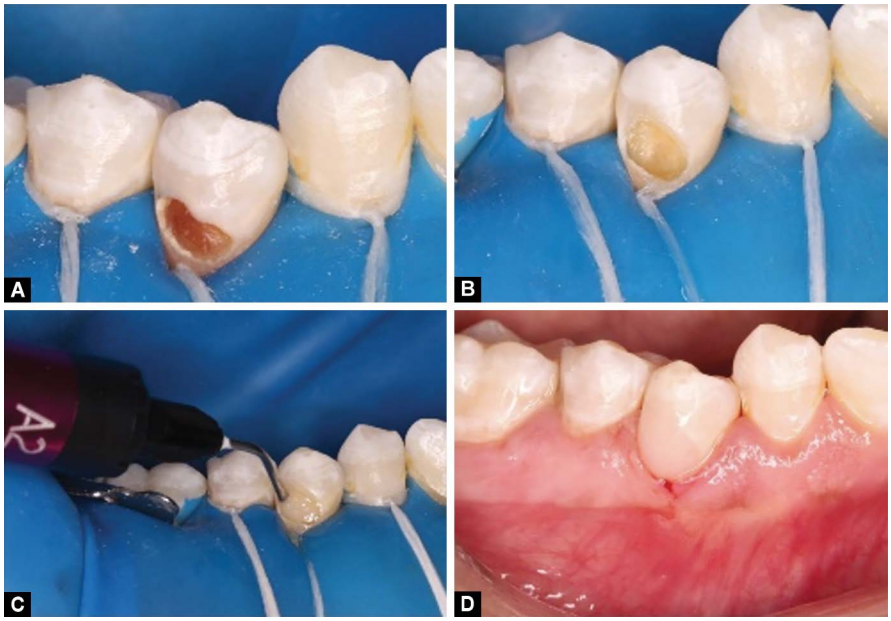
Selective etching technique using phosphoric acid etching gel for 15 seconds was done, then air/water spray was used for 20 seconds, followed by gentle drying to keep dentin wet. Single Bond TM Universal (Single Bond TM, 3M Deutschland GmbH, Neuss, Germany) was applied to all the walls of the cavity using a disposable microbrush with agitation for 20 seconds, followed by 5 seconds of air dispersion. Light curing was done for 20 seconds (Woodpecker i-LED, Woodpecker Co., Ltd., Guangxi, China; light intensity of up to 2300 mW/cm^2). The light output of the curing unit was monitored with a curing light intensity meter (Dent America, California, United States).

For group I: Giomer-based composite (Beautifil Flow Plus X) (Shofu Dental Corporation, Kyoto, Japan) composite was placed according to manufacturer's instructions. It was applied to the cavity in increments of 2 mm with polymerization of each increment for 10 seconds. The last increment was placed and carved to the required shape using gold plated composite applicator (Zeffiro, Lascod, Italy) (Fig. 2).[17] For group II: ACTIVA bioactive (Pulpdent Corporation, Watertown, Massachusetts, United States) was manipulated following the manufacturer's instructions. To prevent air bubbles, the dispenser tip was placed on the cavity floor, keeping it submerged in the composite material. ACTIVA bioactive was applied in one bulk layer, gold plated composite applicator was used to adapt the material in the cavity then it was light cured using LED light curing device for 20 seconds (Fig. 3).[18,19] Rounded end yellow finishing stone (Komet USA, Fort Mill, South Carolina, United States) was used with water cooling to contour and remove the excess of material followed by polishing using polishing discs (TOR VM Dental Manufacturing Company, Moscow, Russia).[19]

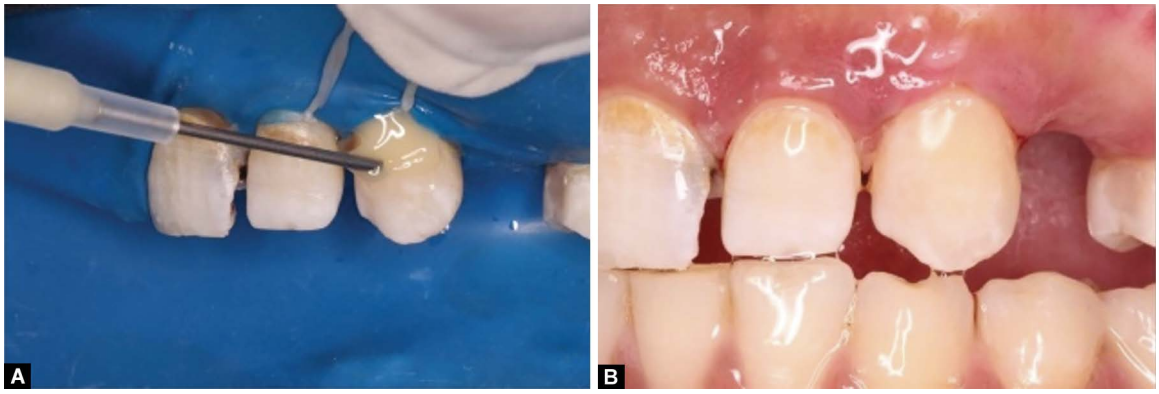
All participants were instructed to follow oral hygiene measures (brush the teeth, modified bass technique twice a day, floss once a day, and consider a mouthwash) to avoid plaque and bacterial accumulation, which might negatively affect the clinical performance of restoration.

Outcome Assessment

Restorations were evaluated during the three periods of follow-up (at baseline, after 6, 12, and 18 months). During this time, two examiners (ON and SK) who were not involved in the restorative procedures were trained to assess the restorations using the modified USPHS criteria.[16] The primary outcome was marginal discoloration. The secondary outcomes were retention, marginal adaptation, postoperative sensitivity, secondary caries, anatomical form, and surface texture. The restorations were scored as Alfa (A): The ideal clinical situation, Bravo (B): Clinically acceptable, or Charlie (C): Clinically unacceptable. Calibration of the assessors was done to enhance the inter and intraexaminer reliability by reviewing 20 photographs representing different scores for all the evaluated criteria to achieve a kappa (κ) value of at least 90% for both inter- and intraexaminer agreement on each criterion. Evaluation was conducted with direct vision under a dental operating light, using a mouth mirror and dental probe. Additionally, intraoral digital photos were taken for documentation. The agreement between examiners should not be less than 85% to be considered as significant. To facilitate the uniformity among examiners, when there was any uncertainty between the scores A and B rated by the



Figs 2A to D: (A) Class V carious lesion; (B) After cavity preparation; (C) Giomer-based composite (Beautifil Flow Plus X) application; (D) Postoperative



Figs 3A and B: (A) ACTIVA bioactive application; (B) Postoperative

two examiners, a third examiner (HH, who did not participate in any other aspects of the study) was ready to decide the final score.[15]

Statistical Analysis

The data were analyzed using MedCalc software, version 22 for Windows (MedCalc Software Ltd, Ostend, Belgium). Categorical data were presented as frequencies and percentages. Chi-squared test was used for intergroup comparisons between the intervention group and the comparator group, while Cochran's *Q* test was used for intragroup comparison in each group followed by multiple comparisons. The clinical significance was assessed using relative risk. The Kaplan–Meier and logrank tests were used to analyze the survival rate. The confidence limit was set at 95%, 80% power, with statistical significance level set at ($p \leq 0.05$). All statistical tests conducted were two-tailed.

Results

After 18 months, all of the 34 patients completed the evaluation period with no dropouts. Mean age of the patients in the present study was 30.1 ± 7.7 years [active group 30.8 ± 7.4 years; Giomer-based composite (Beautifil Flow Plus X) group 29.3 ± 8.2 years]. There was no statistically significant difference in age between the two tested groups ($p = 0.588$). The teeth distribution analysis in the upper and lower arches revealed 20 maxillary anterior, four maxillary premolars, four mandibular anterior, and six mandibular premolars in the current study ($p = 1.0000$).

Marginal Integrity, Postoperative Hypersensitivity, Marginal Discoloration, Secondary Caries, Fracture, and Retention

There was no statistically significant difference in the intergroup comparisons between the two tested materials within different periods of evaluation. Intragroup comparison in ACTIVA bioactive and giomer-based composite (Beautifil Flow Plus X) showed no statistically significant difference within different periods of evaluation ($p = 1.0000$).

Surface Texture

Intergroup comparisons showed no statistically significant difference between the two tested materials within different periods of evaluation; baseline and after 6 months ($p > 0.05$), while there was difference after 12 months ($p = 0.0359$). There was statistically significant difference in intragroup comparison in

ACTIVA bioactive group within the periods of evaluation ($p = 0.007$). Intragroup comparison within giomer-based composite (Beautifil Flow Plus X) has shown statistically significant difference between different periods of evaluation ($p = 0.001$). There was 43% more risk of surface texture (score B) of ACTIVA bioactive when compared to giomer-based composite (Beautifil Flow Plus X) after 18 months.

Anatomic Form

Intergroup comparisons between the two tested materials showed no statistically significant difference between different periods of evaluation: Baseline, after 6, 12, and 18 months ($p > 0.05$). Intragroup comparison in ACTIVA bioactive group showed no statistically significant difference within different periods of evaluation ($p = 0.112$). Intragroup comparison in giomer-based composite (Beautifil Flow Plus X) group showed statistically significant difference within different periods of evaluation ($p = 0.029$). There was 33% more risk of anatomic form (score B) of ACTIVA bioactive when compared to giomer-based composite (Beautifil Flow Plus X) after 18 months.

Survival Analysis

Survival curves were obtained using Kaplan–Meier analysis, while logrank test was used for survival curves comparison (Fig. 4). The curve showed no statistically significant difference between the two tested materials ($p = 0.1920$). ACTIVA bioactive group has shown 76.5% alpha score, while giomer-based composite (Beautifil Flow Plus X) group has shown 58.8% alpha score after 18 months with no difference between them ($p = 0.2771$), yet all restorations were considered successful.

Discussion

The main concern with cervical composite restorations is the microleakage because of the polymerization shrinkage, particularly at the cervical wall. This phenomenon is characterized by the infiltration of bacteria, fluids, or molecules into the interface between cavity walls and restoration, leading to marginal discoloration, sensitivity, and recurrent caries.[20] As that, the main cause for restoration replacement due to failure was recurrent caries; remineralization was enhanced in recent bioactive restorative materials.[3] These materials can release and exchange different ions like, fluoride, calcium, and phosphorus in oral environment.

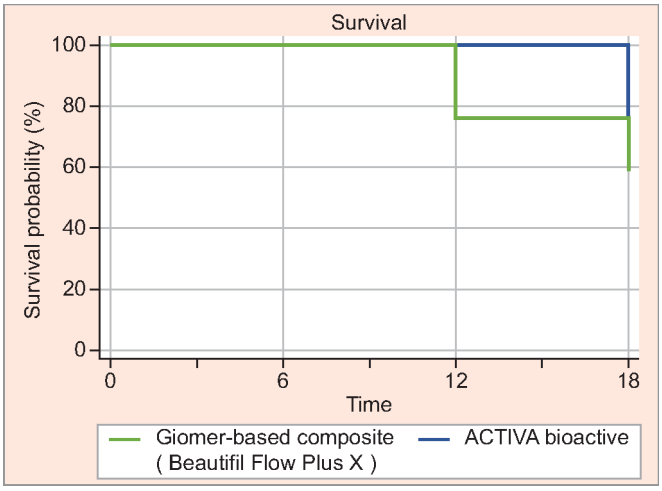


Fig. 4: Survival analysis of ACTIVA bioactive and giomer-based composite (Beautifil Flow Plus X) for cervical restorations after 18 months

This property results in acid neutralization, caries inhibition, and development of a protective layer on the surface of tooth.[21]

The American Dental Association (ADA) guideline panel suggested the use of either conventional GIC, hybrid resin composite (RC), or resin-modified GIC for restoring moderate and advanced carious class V lesions in permanent teeth.[22] So, there is no universal "gold standard" for restoring class V cavities, as material choice depends on clinical context, patient factors, and lesion etiology.[23] ACTIVA bioactive is a bioactive restorative material that combines the bioactivity characteristic through responding to changes in oral environment and bonds chemically to the tooth structure that decreases marginal leakage.[24] Giomers are a novel type of hybrid material that has been demonstrated to have an antiplaque action through reducing bacterial adherence on tooth surface.[25] S-PRG filler contains resinous materials, which can release different ions in neutral and acidic environment that can help in controlling caries progression.[26] 3M single bond universal adhesive was employed, as it contains 10-methacryloyloxydecyl dihydrogen phosphate (10-MDP) monomer, which is a functional monomer that forms chemical interaction with residual hydroxyapatite and provides a stable nanolayer, resulting in a stronger adhesive interface.[20]

Modified USPHS criteria were used in our study due to their widespread and simple use in the evaluation of the important restoration criteria.[27] All restorations were evaluated at baseline and at 6, 12, and 18-month intervals (Table 1). This follow-up period can provide significant information about the clinical performance, such as success or failure, functional, and biological.[28] Giomer-based composite (Beautifil Flow Plus X) has shown similar clinical performance to ACTIVA bioactive in restoring class V carious cavities after 18 months of clinical service. Age and gender have no significant impact on clinical performance of both materials. Therefore, the null hypothesis was accepted in the present study. Both tested materials showed accepted performance without any failure over the evaluation period of the study.

Concerning the marginal adaptation, leakage, discoloration, postoperative hypersensitivity, and secondary caries, there were no significant differences between the two evaluated restorative materials through different follow-up periods. The superior adaptation, accurate application, and void-free restoration of the two tested injectable materials [giomer-based composite (Beautifil Flow Plus X) and ACTIVA bioactive] could explain this result. This can be supported by the anticariogenic effect of bioactive restorations through continuous release and absorbance of fluoride, phosphate, and calcium ions in response to the pH changes in oral cavity.[29] This process fills the gaps that can enhance the marginal adaptation and prevent secondary caries formation.[30] Also, the low modulus of elasticity of the injectable restorative materials, which act as an elastic buffer that can relieve stresses at the interface, resists the polymerization shrinkage of composite restoration. This property can prevent marginal gap formation that may cause marginal discoloration.[31]

For retention, both tested materials showed no statistically significant difference over the different periods of evaluation in both inter and intragroup comparisons. The 100% retention rate of ACTIVA bioactive restoration recorded in our study over the period of evaluation was in agreement with a study done by Kaushik and Yadav.[7] These results can be linked to the manufacturer`s recommendations for using bonding agent with ACTIVA bioactive restorations that enhanced the retention and bonding performance.[32] These findings were in accordance with

Table 1: Frequency (*n*), percentage (%) for all the USPHS criteria

	Follow-up	*ACTIVA bioactive*			*Beautifil Flow Plus X*			*p-value*
		A	*B*	*C*	*A*	*B*	*C*	
Marginal integrity	Baseline	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	6 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	12 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	18 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	p-value		1.0000 (NS)			1.0000 (NS)		
Postoperative hypersensitivity	Baseline	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	6 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	12 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	18 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	p-value		1.0000 (NS)			1.0000 (NS)		
Marginal discoloration	Baseline	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	6 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	12 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	18 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	p-value		1.0000 (NS)			1.0000 (NS)		
Surface texture	Baseline	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	6 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	12 months	17 (100%)	0 (0%)	0 (0%)	13 (76.5%)	4 (23.5%)	0 (0%)	0.0359 (NS)
	18 months	13 (76.5%)	4 (23.5%)	0 (0%)	10 (58.8%)	7 (41.2%)	0 (0%)	0.2786 (NS)
	p-value		0.007 (NS)			0.001 (NS)		
Secondary caries	Baseline	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	6 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	12 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	18 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	p-value		1.0000 (NS)			1.0000 (NS)		
Fracture and retention	Baseline	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	6 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	12 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	18 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	p-value		1.0000 (NS)			1.0000 (NS)		
Anatomic form	Baseline	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	6 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	12 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	1.0000 (NS)
	18 months	15 (88.2%)	2 (11.8%)	0 (0%)	14 (82.4%)	3 (17.6%)	0 (0%)	0.6333 (NS)
	p-value		0.112 (NS)			0.029*		

*Statistically significant; NS, Nonsignificant

another study that stated the reason for good retention of ACTIVA bioactive was due to its bioactivity, which creates chemical bonding at tooth-restoration interface.[33,34] However, the present findings were not in accordance with those obtained from a study done by Bhadra et al.[35] that revealed (6.6%) loss of retention in ACTIVA bioactive group after 1 year. This confliction is attributed to the absence of adhesive bonding agent application in that study, while it was applied in our study.

Regarding anatomical form, there was no significant difference between the groups at different follow-up periods. While intragroup comparison in giomer-based composite (Beautifil Flow Plus X) group showed statistically significant difference between different periods of evaluation, with 33% more risk of anatomic form loss. These current results could be supported by another study, which reported that S-PRG filler can release various types of ions, resulting in weight loss of the restoration. The weight loss of resin composite is directly related to solubility characteristics, which has a bad impact on maintaining the anatomical form of the restoration.[36]

Regarding surface texture, the two tested materials showed no significant difference between different periods of evaluation in intergroup comparisons. The low risk of rough surface texture of ACTIVA bioactive is due to the absence of Bis-GMA monomers in its composition. This monomer, which has high tendency to water sorption and more hydrolytic degradation than other types of composites, may affect the surface texture of restoration.[37] While there was significant difference between different periods of evaluation in intragroup comparison in giomer-based composite (Beautifil Flow Plus X) group, with 43% more risk of surface texture roughness. In accordance with another study done by Radwanski et al., who stated that materials contained S-PRG fillers might

cause microcrack formation and matrix-filler separation because of continuous releasing of ions that results in surface roughness.[38]

Despite the limitations of this clinical trial, such as its relatively small sample due to strict eligibility criteria and challenges in patient recruitment over the evaluation period (18 months), larger sample size might be valuable in identifying any difference between the two tested materials accurately. Moreover, the evaluation period of 18 months may not be fully accurate to evaluate the long-term survival of restorative material.

Conclusions

Under the limitations of this study, it can be concluded that although giomer-based composite (Beautifil Flow Plus X) showed minor deviation in surface texture and anatomical form, both giomer-based composite (Beautifil Flow Plus X) and ACTIVA bioactive have an acceptable clinical performance in restoring class V cavities after an 18-month follow-up period. This suggests that giomer-based composite (Beautifil Flow Plus X) may be a promising bioactive material in restoring moderate to deep carious class V lesions.

Disclaimer

This manuscript has been published as a preprint on Research Square (https://www.researchsquare.com/article/rs-6237005/v1) prior to its formal publication in the International Journal of Prosthodontics and Restorative Dentistry.

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