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Original Article

One-Year Clinical Evaluation of a Fluoride, Calcium and Phosphate-Releasing New Bioactive Material versus a Fluoride-Releasing Hybrid Restorative Material in Cervical Lesions: A Randomized Clinical Trial

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Abstract

Aim: This study aimed to clinically evaluate the functional, esthetic, and biological properties of a fluoride, calcium, and phosphate-releasing new bioactive material compared to a fluoride-releasing hybrid restorative material in cervical carious lesions.

Subjects and methods: In a parallel study design, a fluoride, calcium, and phosphate-releasing bioactive material (Activa™ Presto, Pulpdent®, USA) or a fluoride-releasing hybrid restorative material (Beautifil II, Shofu, Japan) was randomly applied to fifteen cervical cavities each, using a universal adhesive system (Beautibond, Shofu, Japan). All materials were applied according to the manufacturers' instructions. Restorations were evaluated at baseline and after 3, 6, 9, and 12 months by two blinded assessors using modified USPHS criteria to measure marginal adaptation, retention, surface texture, marginal discoloration, recurrent caries, and postoperative sensitivity.

Results: This study found no statistically significant differences between the two materials regarding all measured outcomes at any interval of the follow-up period up to the end of 12 months ($P > 0.05$), with both showing a 100% survival rate.

Conclusion: Compared to Beautifil II, Activa™ Presto showed comparable functional, esthetic, and biological properties. After 12 months, both materials exhibited satisfactory clinical performance in restoring cervical carious lesions.

Keywords: Bioactive material, Giomer, Hybrid restoration, Cervical carious lesions, USPHS criteria.

Introduction

Dental caries develop due to a complex interaction of acid-producing bacteria, fermentable carbohydrates, and host factors such as teeth and saliva. The enamel's integrity is maintained through a balance between demineralization and remineralization. However, frequent consumption of fermentable sugars leads to an increase in acidogenic bacteria, disrupting this balance and accelerating demineralization. When mineral loss surpasses remineralization over

time, a visible lesion forms, signaling the onset of caries (Chen et al., 2020).

The challenge persists even after restorative treatment, as secondary carious lesions often develop. This occurs because the initial treatment addresses the symptoms but not the underlying causes, such as the presence of bacteria or improper oral hygiene. Secondary lesions typically form near the gingival margins of restorations, where biofilm tends to accumulate (Nedeljkovic et al., 2015).

Fluoride-releasing materials have garnered attention due to their ability to reduce caries activity and promote remineralization. Fluoride acts by incorporating into the enamel and dentin, forming a more resistant structure called fluoroapatite (Tokarczuk et al., 2024). This process helps prevent the progression of secondary caries, especially near restoration sites. Among the materials available, glass ionomers stand out because of their ability to release fluoride and maintain a "reservoir effect," allowing recharging of fluoride over time. However, conventional glass ionomers face challenges like poor marginal adaptation and solubility, leading to the development of hybrid materials like resin-modified glass ionomers and giomers (Elshweekh et al., 2019).

Giomers are hybrid restorative materials that consist of a resin base combined with a pre-reacted glass ionomer based on S-PRG technology, offering fluoride release and recharge with better mechanical properties, aesthetics, and polishability. These materials also exhibit antiplaque properties, reducing bacterial colonization and plaque formation, helping prevent recurrent caries (Rusnac et al., 2019).

Recently, bioactive restorative materials have emerged, combining properties from glass ionomers and resins to promote remineralization while preventing demineralization. These materials release and recharge fluoride, calcium, and phosphate, providing long-term stability and durability.

ACTIVA™ PRESTO™ is a recent innovation in bioactive restorative materials, designed to mimic natural processes and resist wear. It releases fluoride, calcium, and phosphate ions and incorporates a rubberized resin for increased strength and resilience. It does not contain BIS-GMA, Bisphenol A, or any BPA by-products. As bioactive materials evolve, they offer promising alternatives for clinicians, especially in treating cervical carious lesions (Bhadra et al., 2019). With continuous advancements in dental materials, choosing the optimal one can be challenging. To address the limited research comparing giomer and bioactive restorations for cervical carious lesions, this study aimed to evaluate whether bioactive restorations offer similar clinical performance to giomers. A randomized controlled trial tested the null hypothesis using a modified USPHS system.

Materials and Methods

A. Materials

The materials with their composition, lot number, and manufacturer, are summarized in Table 1.

Table (1): Materials' composition, lot number and manufacturer

Materials	Composition	Lot Number	Manufacturer
ACTIVA™ Presto™ restorative material	Composed of calcium, phosphate, and fluoride ions within a hydrophilic resin matrix, which includes a blend of diurethane and other methacrylate resins. - Free from Bis-GMA, Bisphenol A, and BPA derivatives.	210105	Pulpdent, USA
N-Etch	37% phosphoric acid, polyethylene glycol, synthetic amorphous silica, pigments, and H2O.		Ivoclar Vivadent, Schaan, Liechtenstein
BeautiBond Universal	Ingredients include acetone, distilled water, Bis-GMA, carboxylic acid monomer, TEGDMA, and phosphoric acid monomer, among other components.	062142	Shofu, Japan
Beautifil II restorative material	Consisting of Bis-GMA, TEGDMA, and UDMA monomers with fillers ranging from 0.01 to 4.0 µm, averaging 0.8 µm, including S-PRG fillers, multifunctional glass fillers, and discrete nanofillers.	032114	Shofu, Japan

Bis-GMA = Bisphenol A-glycidyl methacrylate, BPA= Bisphenol A, H2O= Water, HEMA = Hydroxyethyl methacrylate, S-PRG = Surface pre-reacted glass-ionomer, TEGDMA= Triethylene glycol dimethacrylate, UDMA = Urethane dimethacrylate.

B. Methods

- **Trial Registration and Ethical Approval**

The protocol for this study was registered in the ClinicalTrials.gov database under the identifier NCT05149209. All procedures involving human participants adhered to ethical guidelines established by the Research Ethics Committee (CREC) at the Faculty of Dentistry, Cairo University, with identification number 13122.

- **Study Setting and Design**

A randomized, double-blind clinical trial, with two parallel arms, was conducted at the outpatient clinic of the Conservative Dentistry Department, Faculty of Dentistry, Cairo University. The study took place from March 2022 to March 2023, with patient recruitment occurring between February and March 2022. The study followed a 1:1 allocation ratio within a superiority framework. The modified USPHS criteria were used to assess the materials at baseline, 3, 6, 9, and 12 months.

- **Sample Size Calculation**

The study aimed to use independent case and control groups, with the sample size determined based on previous findings by Nassar et al. (2020). Their data showed a 0.9375 probability for score A and 0.0625 for score B in giomer restorations, with an effect size of 0.875 and a sample size of 11. Assuming a 0.9 probability for restorations, with an effect size of 0.8, the necessary sample size was 24 restorations (12 per group) to achieve a statistical power of 0.8. To accommodate potential dropouts, the sample size was

increased to 30 participants (15 per group). The study used G*Power 3.1.9.2 for Windows and employed a chi-square test, with a Type I error probability set at 0.05.

- **Eligibility Criteria**

Inclusion and exclusion criteria are summarized in Table 2, 3.

Table (2): Inclusion and exclusion criteria of participants

Inclusion Criteria	Exclusion Criteria
- Male or female gender. - Only cooperative patients are approved to participate in the trial. - Medically free adult patients. - The age range of the patients is 18 - 40 years.	- Allergic history concerning methacrylates. - Pregnancy. - Heavy smoking; xerostomia. - Lack of compliance. - Patients with disabilities. - Patients having systemic diseases or severe medical compromised. - Patients with severe bruxism, clenching, or temporomandibular joint disorders.

Table (3): Inclusion and exclusion criteria of teeth

Inclusion Criteria	Exclusion Criteria
- Cervical carious lesions (ICDAS 3, 4, or 5). - Vital upper or lower teeth with no signs of irreversible pulpitis. - Caries extension shouldn't exceed mesiodistal width and inciso (occluso) gingival length not exceed incisal (occlusal) one-third.	- Deep defects (close to pulp, less than 1 mm distance). - Periapical pathology or signs of pulpal pathology. - Possible prosthodontic restoration of teeth. - Heavy occlusion or history of bruxism. - Pulpitis, non-vital or endodontically treated teeth. - Sever periodontal affection.

- **Recruitment**

Patients were recruited from the outpatient clinic at Cairo University's Conservative Dentistry Department **(Figure 1)**. Caries risk assessments were conducted using the ADA tool, followed by thoroughly documenting personal, medical, and dental histories. Patients were fully informed about the study's objectives, procedures, benefits, precautions, and duration before signing an informed consent form, provided in Arabic by the Research Ethics Committee at Cairo University. Preventive care, including scaling and polishing, was provided, and patients were trained in proper oral hygiene practices.

- **Sequence Generation and Allocation Concealment**

Randomization can be simply done by generating random numbers from 1 to 30 using the Random Sequence Generator (https://www.random.org/). The number will correspond to a certain assignment whereby numbers 1 through 15 correspond to the control group and numbers 16 through 30 correspond to the intervention group. The operator selected from the series of numbers in the row of opaque sealed envelopes, which themselves had been prepared by an assistant who had no input whatever into the clinical trial. The side for the restorative material was then recorded.

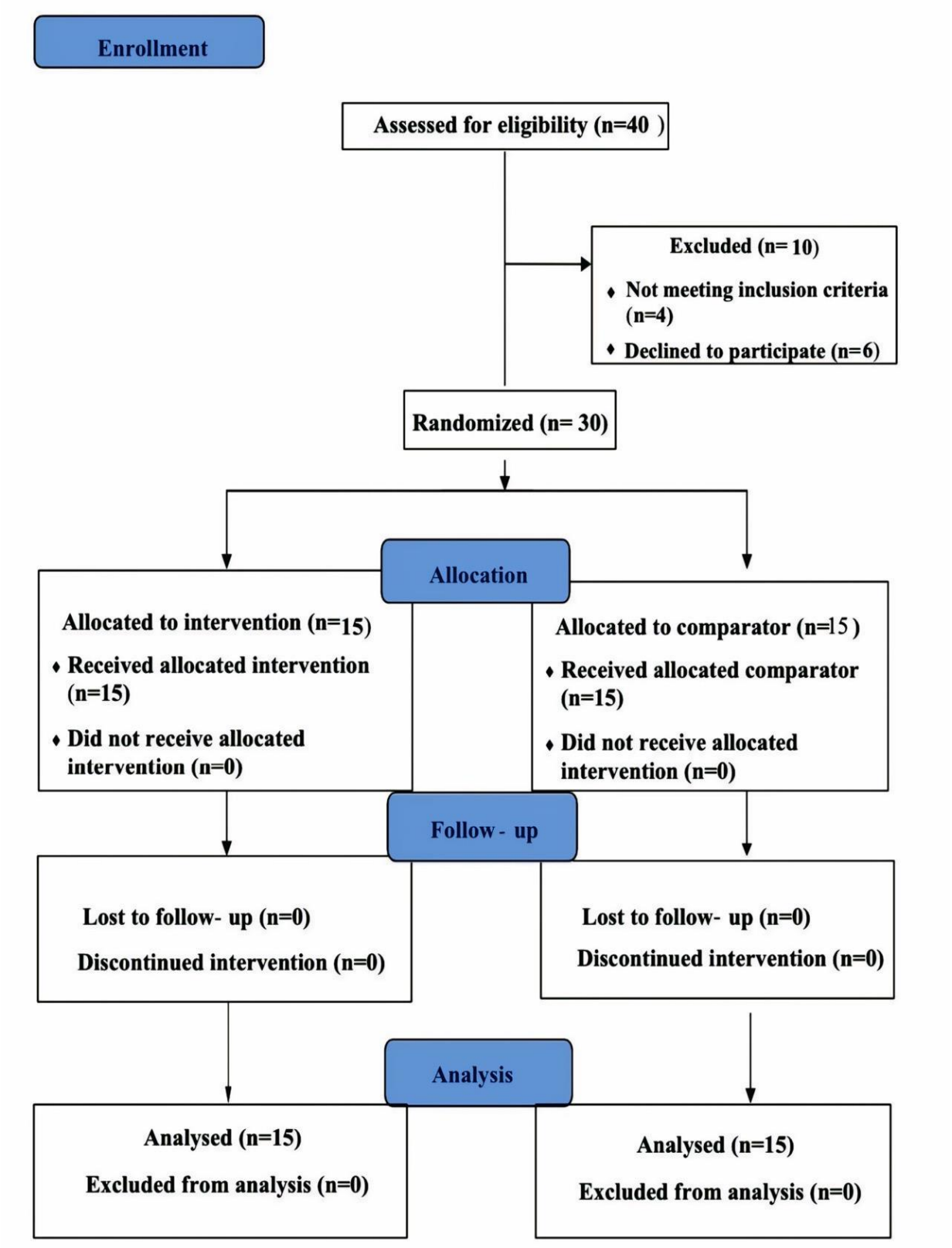

Figure (1): CONSORT flow diagram

- **Masking/blinding**

Blinding of the operator was impossible since there are different application protocols for each restorative material. However, patients and assessors were blinded to the assignment of materials.

- **Clinical Procedures**

Shade selection

Tooth shade selection was done on a clean surface before isolation to avoid dehydration and opacity changes. It was performed under natural light between morning and noon to prevent hue overestimation. The "button-try technique" applied restorative material in increments, light-cured without etching or adhesive. A black-and-white filter was used to select the value first, followed by hue and chroma.

Isolation and cavity preparation procedure

Patients were given local anesthesia as needed, and their teeth were isolated using a rubber dam and subgingival clamps. A high-speed handpiece with a #330 bur was used to prepare the cervical cavity, and sharp excavators removed soft carious tissue. Cavity walls and margins were finished with tapered finishing stones. Teeth with pulpal exposure were excluded. Patients were randomly assigned to control or intervention groups using random numbers generated by an uninvolved facilitator.

Adhesive application and curing

Enamel selective etching was performed using 37% phosphoric acid (N-Etch ®, Ivoclar vivadent, Liechtenstein) for 15 seconds to enhance bond strength and remove the smear layer **(Figure 2a)**. The etchant was rinsed, and the enamel was dried until it appeared chalky white. BeautiBond was then applied following the manufacturer's instructions **(Figure 2b)** and light-cured for 5 seconds using an LED curing unit at close range, with the curing tip disinfected after each use.

Intervention: fluoride, calcium, and phosphate-releasing new bioactive material

Activa™ Presto was applied in 2mm layers using a 19-gauge applicator **(Figure 2c)** and light-cured for 20 seconds per layer.

Comparator: fluoride-releasing hybrid restorative material

Beautifil II was applied with a gold-plated applicator and light-cured for 10 seconds, followed by 20 additional seconds for each 2mm increment.

Contouring, finishing, and polishing

Excess material was removed, and the restoration was contoured, finished, and polished using superfine yellow diamond stones, discs, and silicone polishers under water coolant.

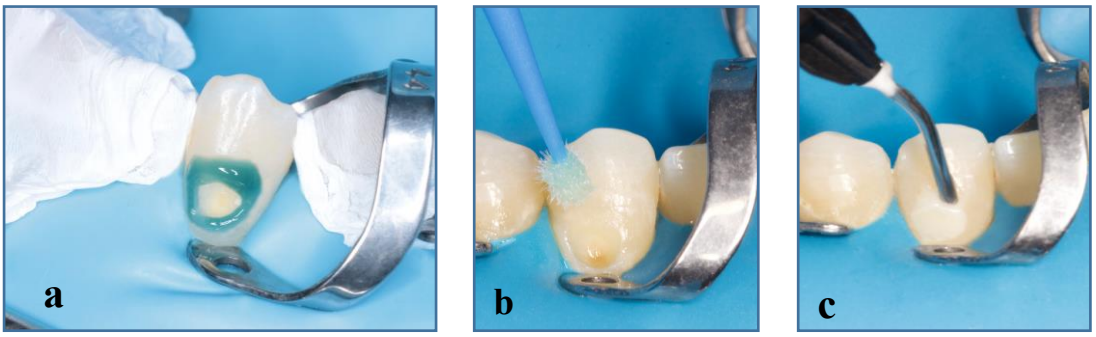

Figure (2):a. Selective enamel etching, **b.** adhesive application, and **c.** Activa™ Presto application

- **Outcomes**

The mechanical, esthetic, and biological properties of both groups were evaluated using modified USPHS criteria, summarized in Table 4. Two blinded assessors assigned alpha, bravo, or charlie scores, with calibration conducted before and early in the trial to ensure consistent assessments.

Table (4): Modified USPHS criteria for outcome measurement

Outcome	Criterion	Score	Characteristic
Primary	Marginal adaptation	A	Closely adapted, no detectable margin
		B	Detectable marginal discrepancy clinically acceptable
		C	Marginal crevice, clinically unacceptable
Secondary	Retention	A	No loss of restoration
		C	Loss of restoration
	Surface texture	A	No surface defect
		B	Minimal surface defect
		C	Severe surface defect
	Marginal discoloration	A	No discoloration between tooth structure and restoration
		B	Non penetrating marginal discoloration which can be polished away
		C	Discoloration has penetrated margin in pulpal direction
	Secondary caries	A	No recurrent caries detected
		C	Recurrent caries detected
	Postoperative sensitivity	A	Not present
		B	Sensitive but diminishing in intensity
		C	Constant sensitivity not diminishing

- **Statistical Analysis**

Data were analyzed using MedCalc software. Categorical data were presented as frequencies and percentages, with chi-square tests comparing interventions at a significance level of $P \leq 0.05$. Cochran's Q test, with Bonferroni correction ($P \leq 0.005$), was used for within-group comparisons. Relative risk was calculated for clinical significance, and survival rates were assessed using Kaplan-Meier and Log-rank tests. The study maintained 95% confidence and 80% power, with all tests being two-tailed.

Results

1. Demographic Data

This study involved 30 patients with cervical carious lesions, randomly assigned to intervention and comparator groups (n=15 each). All participants completed the 12-month follow-up with a 100% retention rate. There were no significant differences between groups in gender ($P = 0.6713$), age (mean age 33.33±4.49 years, $P = 0.812$), or teeth distribution ($P = 0.9518$).

2. Clinical Evaluation

The study found no statistically significant differences between Activa Presto and Beautifil II in all measured outcomes across baseline and 12-month follow-up periods, as summarized in Table 5. Activa Presto showed a 1.5 times higher risk of marginal adaptation issues, a 25% higher risk of surface texture problems, and a 7 times higher risk of marginal discoloration compared to Beautifil II after 12 months, though none of these risks were statistically significant. Both materials demonstrated no risk differences in fracture, retention, secondary caries, or postoperative sensitivity.

Table (5): Modified USPHS criteria scores of both groups at each follow-up period

Outcome	Follow-up	Bioactive Restorative Material (ACTIVA Presto)			Giomer (Beautifil II)			P value
		A	B	C	A	B	C	
Marginal adaptation	Baseline	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	3 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	6 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	9 months	13 (86.7%)	2 (13.3%)	0 (0%)	14 (93.3%)	1 (6.7%)	0 (0%)	P = 0.5496
	12 months	12 (80%)	3 (20%)	0 (0%)	13 (86.7%)	2 (13.3%)	0 (0%)	P = 0.6300
	P value		P = 0.040			P = 0.171		
Retention	Baseline	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	3 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	6 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	9 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	12 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	P value		P = 1.0000			P = 1.0000		
Surface texture	Baseline	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	3 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	6 months	12 (80%)	3 (20%)	0 (0%)	14 (93.3%)	1 (6.7%)	0 (0%)	P = 0.2909
	9 months	10 (66.7%)	5 (33.3%)	0 (0%)	12 (80%)	3 (20%)	0 (0%)	P = 0.4169
	12 months	10 (66.7%)	5 (33.3%)	0 (0%)	11 (73.3%)	4 (26.7%)	0 (0%)	P = 0.6953
	P value		P = 0.002*			P = 0.017		
Marginal discoloration	Baseline	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	3 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	6 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	9 months	13 (86.7%)	2 (13.3%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 0.1501
	12 months	12 (80%)	3 (20%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 0.0726
	P value		P = 0.040			P = 1.0000		
Recurrent caries	Baseline	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	3 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	6 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	9 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	12 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	P value		P = 1.0000			P = 1.0000		
Postoperative sensitivity	Baseline	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	3 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	6 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	9 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	12 months	15 (100%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 1.0000
	P value		P = 1.0000			P = 1.0000		

3. Survival analysis

The 12-month survival of Activa Presto and Beautifil II for cervical restorations showed no significant difference between the materials (P = 0.2131). Activa Presto had a 40% alpha score, while Beautifil II had a 60% alpha score. Both materials demonstrated similar performance in marginal adaptation, discoloration, and surface texture (**Figure 3**).

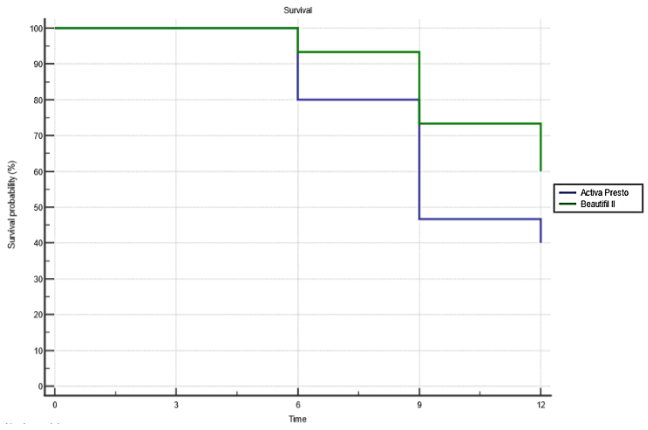

Figure (3): Survival analysis after 12 months

Discussion

Dental caries is a widespread, multifactorial disease caused by the interaction of cariogenic bacteria, dietary sugars, and host factors, leading to tooth demineralization.

Secondary caries, typically occurs at restoration margins and is a leading cause of restoration failure, responsible for 50-60% of cases (Bernardo et al. 2007; Demarco et al. 2015). Factors like the quality of restorative materials, marginal adaptation, and oral hygiene influence its development. Studies highlighted the importance of selecting appropriate materials and clinical techniques to reduce failures. Fluoride-releasing materials are particularly effective in preventing secondary caries by promoting remineralization and inhibiting demineralization, making them ideal for high-risk patients.

Cervical carious lesions, occurring near the cementoenamel junction, pose unique challenges such as proximity to the gingiva, multifactorial etiology, and involvement of both enamel and dentin substrates, making them ideal for evaluating restorative materials. Successful management requires materials with strong adhesion, mechanical strength, and esthetic properties.

Glass ionomer cements (GICs) are frequently chosen for cervical lesions due to their chemical adhesion, biocompatibility, and fluoride release, which aids in caries prevention. However, they have drawbacks such as lower strength and moisture sensitivity (Nicholson et al., 2020). Resin-modified GICs (RMGICs) address some of these issues by offering better strength and esthetics while maintaining fluoride release, though they still face challenges like wear resistance and suboptimal esthetics (Taha et al., 2015).

Giomers have emerged as a strong alternative to traditional materials, combining the fluoride release and chemical bonding benefits of glass ionomer cements with the superior esthetics and mechanical properties of resin composites. Made with pre-reacted glass ionomer particles (S-PRG fillers), giomers can release and recharge fluoride, helping buffer the acidic oral environment and prevent plaque build-up. They offer good wear resistance, making them ideal for cervical lesions (Rusnac et al., 2019). Clinical studies show giomers, like Shofu's Beautifil® II, provide high retention rates, excellent marginal adaptation, and resistance to marginal discoloration (Bheda et al., 2020).

Bioactive composites have advanced restorative dentistry by promoting remineralization and providing antimicrobial benefits. These materials release ions like calcium and phosphate, supporting natural tooth repair and preventing microleakage by sealing margins with apatite-like material. Bioactive composites offer strong mechanical properties and esthetic versatility, making them a promising alternative to RMGIs and traditional composites (Balhaddad et al., 2019).

ACTIVA Presto, a new bioactive material, combines resin composite and glass ionomer features, releasing calcium, phosphate, and fluoride to support tooth regeneration and reduce secondary caries (Bhadra et al., 2019). However, long-term clinical trials are needed to fully assess its performance. This study compared ACTIVA Presto with Beautifil II in a randomized clinical trial for cervical carious lesions.

Parallel randomized clinical trials (RCTs) are the gold standard for assessing restorative materials, minimizing bias, and providing reliable evidence (Schulz et al., 2010). In this study, 30 cervical cavities were randomly assigned to Beautifil II or Activa™ Presto, ensuring comparability and internal validity. Standardized protocols ensured results were directly related to the materials used.

Strict adherence to manufacturer instructions is essential for the success of restorative materials. Deviations, such as not using bonding agents with ACTIVA Bioactive

Restorative, have led to higher failure rates (Benetti et al. 2019; Van Dijken et al. 2019). Both Beautifil II and ACTIVA™ PRESTO™ require precise handling, including proper surface preparation, adhesive use, and curing times, to ensure optimal performance, which contributed to the positive outcomes in this study.

According to the manufacturer of Beautifil II, the use of BeautiBond is recommended for optimal results. Therefore, in this study, BeautiBond was used as the universal adhesive for both Beautifil II and Activa™ Presto, standardizing the application process and ensuring that any outcome differences were due to the materials themselves. BeautiBond enhances bond strength, retention, and marginal adaptation, providing strong evidence of the clinical performance of these restorative materials (Giannini et al., 2022).

The modified USPHS criteria were used in this study. This widely accepted system allows for standardized comparisons between studies, enhancing the reliability and generalizability of findings. The use of two blinded assessors further ensured objective and reliable data on the performance of Beautifil II and Activa™ Presto (Hickel et al., 2007).

Although the 12-month follow-up provided useful insights into early performance, longer-term studies are needed to assess durability and long-term benefits. Despite the short duration, this study contributes valuable evidence supporting the clinical use of giomer and Activa™ Presto.

To prevent bias, the study employed randomization to assign cavities to two treatment groups and implemented a double-blinded design, where both patients and assessors were unaware of the materials used. Blinded assessors independently evaluated the restorations, minimizing subjective bias (Renjith, 2017). Standardized application protocols ensured that any outcome differences were due to the materials.

This study, involving 30 participants over 12 months, found no significant differences between Activa™ Presto and Beautifil II, supporting the null hypothesis and confirming that both materials are effective for treating cervical carious lesions.

Marginal adaptation is vital for the durability of restorative materials, preventing microleakage and secondary caries. In this study, Activa Presto and Beautifil II showed comparable marginal adaptation over 12 months, likely due to their strong adhesive properties. Studies by El-Gaaly et al. (2024) and Kamal et al. (2024) agree, finding no significant differences in marginal adaptation for Activa Presto and hybrid materials after 12 months, attributing it to Activa's bioactive properties and shock-absorbing resin. However, a slight, non-significant increase in marginal adaptation issues was noted for Activa Presto in this study, warranting further research.

Intragroup analysis of Activa Presto revealed consistent performance, supported by studies like Kaushik et al. (2017) and Bhadra et al. (2019), which emphasize its fluoride-releasing and fluoroapatite-forming abilities. The use of BeautiBond adhesive further enhanced its performance, as confirmed by Van Dijken et al. (2019). However, Gebril et al. (2023) observed microleakage in ACTIVA™ Presto during in vitro testing, suggesting possible issues when used without an adhesive system.

Beautifil II showed stable marginal adaptation, attributed to its S-PRG fillers and bioactive properties, aligning with findings from Gordan et al. **(**2002) to Toz-Akalin et al. (2023). Though Bacelar et al. **(**2017) reported BeautiBond reduced microleakage, Ozer et al. (2021) noted decreased marginal integrity at 36 months, highlighting the need for longer-term studies to confirm durability.

Both Activa Presto and Beautifil II showed excellent retention over 12 months, consistent

with study by McCabe et al. (2011), which reported high retention rates for fluoride-releasing materials. Activa's performance is supported by studies such as Kaushik and Yadav (2017), Prathima et al. (2023), and El-Gaaly et al. (2024), all reporting 100% retention rates. Activa's resilience is attributed to its resin monomers and bioactive ionomer component, which enhance fracture toughness and prevent bacterial leakage, as noted by Alrahlah (2018) and Bhadra et al. (2019). This bioactivity promotes remineralization through continuous ion exchange and improves marginal adaptation by sealing micro-gaps.

However, Eissa et al. (2021) observed a complete loss of one restoration in the ACTIVA group over six months, and Nassar et al. (2020) reported a 6.3% loss of ACTIVA BioACTIVE restorations after 12 months. These losses may be due to the absence of an adhesive system, as highlighted by Kaushik & Yadav (2017); Benetti et al. (2019); Van Dijken et al. (2019), and Tohidkhah et al. (2022), suggesting that an adhesive system's use is crucial for maximizing retention.

Manufacturer guidelines recommend using a bonding agent with bioactive restorations like ACTIVA Presto to improve retention and bonding, particularly in cervical areas. The use of selective enamel etching followed by Beautibond, a universal adhesive containing 4-MET and MDP, enhances bonding and durability by forming stable ionic bonds, as noted by de Paris Matos et al. (2020). Beautibond's HEMA-free formulation avoids issues with water sorption, improving adhesive interface stability (Cardoso et al., 2011).

Giomer restorations generally show high retention, with Nassar et al. (2020) reporting up to 100%, though Gordan et al. (2014) observed only 66% after 13 years due to the extended follow-up. Jyothi et al. (2011) noted a slightly lower alpha rating after one year, while Priyadarshini et al. (2017) reported the loss of eight giomer restorations in non-carious cervical lesions (NCCLs), possibly due to sclerotic dentin and the material's higher elastic modulus. Despite these variations, studies like Nakamura et al. (2009) and Bacelar et al. (2017) show that giomers and resin-modified glass ionomers have similar bond strengths, making them suitable for Class V lesions. These findings suggest that both giomer and ACTIVA Presto are effective, though retention rates may vary with follow-up duration and specific material properties.

This study found no significant differences in marginal discoloration between Activa Presto and Beautifil II, consistent with Tuncer et al. (2018). Although Activa Presto had a seven times higher risk of discoloration after 12 months compared to Beautifil II, this difference was not statistically significant. The bioactive properties of Activa, which promote remineralization, may make it more susceptible to staining due to interactions with oral fluids and external agents (Nassar et al., 2020; Sajini et al., 2022). Despite slight discoloration, clinical performance remained unaffected, as noted by Hafez et al. (2022). However, studies like Kaushik & Yadav (2017), Bhadra et al. (2019), and Prathima et al. (2023) reported no discoloration in Activa restorations, while Slimani et al. (2021) suggested that Activa's ion-releasing properties offer therapeutic benefits despite aesthetic changes.

This study's findings are supported by Jyothi et al. (2011) and Gordan et al. (2014), who reported that hybrid materials, like Beautifil II, are less prone to discoloration. Beautifil II's resistance is attributed to its resin-based composition and S-PRG fillers, which mimic the optical properties of natural teeth (Rusnac et al., 2021). However, Ozer et al. (2021) observed significant discoloration over 36 months, indicating the need for longer-term studies to fully assess color stability.

Surface texture plays a key role in the wear resistance and longevity of restorative materials. This study found no significant intergroup differences in surface texture, consistent with Prathima et al. (2023) and

Kamal et al. (2024), who observed only minor differences between bioactive and hybrid materials. Garoushi et al. (2018) also found no significant difference in surface texture between Activa and Beautifil II, despite variations in fracture toughness. Bhadra et al. (2019) and El Gaaly et al. (2024) similarly reported that both materials maintained surface smoothness over 12 months, attributed to the small particle size of the materials ensuring a smooth polished surface. However, Bansal et al. (2016) noted significant differences, suggesting material properties can influence clinical outcomes.

Intragroup analysis revealed surface degradation in Activa Presto over time, in line with Hafez et al. (2022), who attributed this to ionic exchange and interactions with the oral environment. This dynamic process can alter surface texture and impact aesthetics. Activa's resin matrix and bioactive glass particles contribute to these changes, and factors like pH and mechanical forces may affect bioactive materials more than hybrids. Eissa et al. (2021) found Activa had better surface texture compared to bulk-fill glass hybrids, linking smoother surfaces to better wear resistance.

Beautifil II showed no significant surface changes, likely due to its strong resin matrix and pre-reacted glass ionomer (PRG) fillers, which improve wear resistance and maintain smoothness. This aligns with findings from Gordan et al. (2002), Jyothi et al. (2011), and Toz-Akalin et al. (2023), all of whom highlighted the resilience of hybrid materials like giomer restorations in preserving surface integrity. However, Bagheri et al. (2005) noted increased surface roughness in Beautifil II, possibly due to weak bonding between the resin matrix and S-PRG fillers, as matrix degradation exposes more filler particles, contributing to rougher surfaces.

Throughout the study, no recurrent caries were observed, indicating that both materials effectively sealed cavities and prevented bacterial infiltration. This aligns with studies by Eissa et al. (2021), Hafez et al. (2022), and others, which demonstrate that fluoride-releasing and bioactive materials provide significant caries protection. However, longer-term studies are needed to assess the materials' sustained anti-cariogenic effects

This study found no postoperative sensitivity in both Activa™ Presto and Beautifil II groups. This aligns with studies like Eissa et al. (2021) and Prathima et al. (2023), which highlighted the ability of both materials to control sensitivity effectively. The bioactivity of Activa Presto, which promotes remineralization and seals dentinal tubules, and the S-PRG fillers in Beautifil II, which inhibit bacterial activity and release fluoride, both contribute to reducing sensitivity. The use of universal adhesives, as supported by Rouse et al. (2020), further enhances these outcomes.

This study's limitations include a 12-month follow-up and a small sample size, which may not fully assess long-term performance. Longer studies, as suggested by Hickel et al. (2007), are needed to confirm the durability of Activa™ Presto and Beautifil II. Despite this, the study provides useful preliminary insights into their comparative performance.

Conclusion

This study demonstrated that Activa™ Presto and Beautifil II are effective in treating cervical carious lesions over 12 months. Despite the limitations, the findings support the use of bioactive, fluoride-releasing materials in clinical practice for improved oral health.

Recommendations

Longer-term, multi-center trials with larger sample sizes are needed to better assess the durability and effectiveness of bioactive materials across diverse clinical settings.

Conflict of Interest:

The authors report no conflicts of interest.

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Ethics:

The study protocol was approved by the Ethical Committee of the Faculty of Dentistry, Cairo University, with approval number 13122 on 25/01/2022.

Data availability statement:

The data supporting this study are available from the corresponding author upon reasonable request.

CRediT statement:

Author 1: Conceptualization, Data curation, Formal analysis, Investigation, Resources, Writing - original draft preparation.

Author 2,3: Conceptualization, Data curation, Formal analysis, Methodology, Supervision, Writing - review and editing.

Author 4: Conceptualization, Data curation, Formal analysis, Project administration, Writing - review and editing.

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