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Original Article

# Esthetic and Mechanical Evaluation of Calcium and Phosphate Releasing Hybrid Restorative Material and Fluoride Releasing Hybrid Restorative Material versus the Conventional Resin Composite in Proximal Carious Lesions over a Period of One Year Follow-up Using USPHS criteria: A Randomized Controlled Trial.

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## Abstract

**Objectives:** The aim of the current study was esthetic and mechanical evaluation of calcium and phosphate releasing and fluoride releasing hybrid restorative materials versus nanohybrid resin composite in posterior proximal carious lesions.

**Materials and methods:** 45 participants with class II carious lesions were enrolled in three groups: ACTIVA Presto, GIOMER, and Neo Spectra ST. Cavities were prepared, restorative materials applied, and restorations evaluated using USPHS criteria at baseline, after 1, 3, 6 and 12 months by two calibrated assessors.

**Results:** There was no statistically significant difference among the tested materials regarding the mechanical and esthetic criteria except color match.

**Conclusions:** Compared to Giomer and Neo Spectra ST, ACTIVA Presto showed comparable mechanical properties but inferior esthetic properties.

**Clinical Relevance***:* The three categories of restorative materials have similar clinical performance in posterior teeth.

**Keywords:** Calcium and phosphate releasing hybrid composite; fluoride releasing hybrid composite; nanohybrid composite; class II restorations; esthetic and mechanical evaluation; USPHS criteria.

## *I. INTRODUCTION*

Dental caries, or teeth decay, is the most prevalent oral health issue globally, affecting 60-90% of children and 100% of adults, according to the World Health Organization [1]. Secondary caries due to microleakage is the primary cause of composite restoration failure, necessitating restoration retention, restoration, and prevention to prevent recurrence [2].

Methacrylate-based resin composites experience high polymerization shrinkage, while nanoceramic resin composites, incorporating ceramic nanofillers and nanoparticles, show reduced monomer release and improved esthetics [3].

Nanofilled resin composite materials are popular for posterior tooth restorations due to their wear resistance, strength, and

low polymerization shrinkage. However, long-term therapeutic outcomes remain debated due to wear, leakage, discoloration, and postoperative sensitivity [3].

Adhesive technology has improved clinical properties by incorporating fluorides. A smart material combining resin composites' mechanical properties with glass ionomers' biocompatibility, fluoride release, and adaptability is needed. Fluoride-containing materials like giomers, compomers, and resin-based composites have improved these properties. Giomers offer higher fluoride release, rechargability, wear resistance, and fluorescence. They use pre-reacted glass filler technology, like Beautifil II, to integrate aesthetic and mechanical properties with caries protection [4].

S-PRG technology prevents caries by using glass ionomer qualities, fluoride release, and recharging characteristics. It offers superior aesthetics, biocompatibility, and surface finish. Saliva creates a coating layer, reducing plaque adhesion and preventing bacterial colonization [5].

Advancements in material sciences have led to the development of bioactive materials, such as Activa™ BioActive, which initiates tissue regeneration and reacts with the oral environment, including teeth. This bioactive restorative material consists of a bioactive ionic resin matrix that releases calcium, phosphate, and fluoride ions rapidly [6]. It has been claimed that they release fluoride ions more than glass ionomers [7]**.**

This trial examines Pulpdent's ACTIVA Presto, a wear-resistant, aesthetically appealing universal stackable composite. It releases calcium, phosphate, and fluoride, absorbs stress, and resists chipping and fracture. It's recommended for restorative procedures and may be suitable for carious lesions treatment. ACTIVA Presto builds on ACTIVA BioACTIVE-RESTORATIVE's success [8].

The study aimed to help clinicians choose the best restorative substance from limited literature. It compared bioactive calcium, phosphate, and fluoride-releasing composites ACTIVA Presto, Giomer, and conventional resin composite Neo Spectra ST clinically, with a null hypothesis.

## *II. MATERIALS AND METHODS*

### A. Materials

The materials' names, descriptions, compositions, lot numbers and manufacturer were presented in **Table (1)**.

| | Material | Description | Composition | Lot number | Manufacturer |
|---|---|---|---|---|---|
| **Esthetic Restorative Materials** | **ACTIVA Presto restorative material** | Bioactive composite | - Calcium, phosphate, and fluoride ions (0.1 µm) in a hydrophilic resin marix (blend of diurethane and other methacrylate resins)<br>- Contains No BIS-GMA, No Bisphenol A, No BPA derivatives. | 210105 | Pulpdent, USA |
| | **Giomer restorative material** | Fluoride releasing hybrid restorative material | Fillers: 0.01-4.0 µm with an average of 0.8 µm S-PRG filler, multifunctional glass filler, discrete nano fillers<br>- Monomers (Bis-GMA, TEGDMA,UDA) | 032114 | Shofu, Japan |

| | | | | | |
|---|---|---|---|---|---|
| | **Neo Spectra ST restorative material** | Nano-ceramic composite | - Spherical, prepolymerized fillers (d3,50≈15 µm), non-agglomerated barium glass (d3,50≈0.6 µm) and ytterbium fluoride (d3,50≈0.6 µm) with methacrylic polysiloxane nano-particles. ( - 77-79% wt.<br>- 59-61% vol.)<br>- Monomers (poly-urethane-methacrylate, bis-EMA, and TEGDMA). | 21050000413 | Dentsply Sirona, Detrey, Germany |
| | **Acid etchant** | Phosphoric acid etchant | Phosphoric acid, H2O and Xanthan gum. | MET2207111 | META BIOMED, Korea |
| **Bonding Systems** | **Prime & Bond universal adhesive** | Universal adhesive (mild pH>2.5) | Bi- and multi-functional acrylates, phosphoric acid esters (PENTA, 10-MDP), isopropanol and water. | 2102000710 | Dentsply Sirona, Detrey, Germany |
| | **BeautiBond Universal** | HEMA-Free "All-in-One" 7th Generation bonding agent | Acetone, Distilled water, BIS-GMA, carboxylic acid monomer, TEGDMA, phosphonic acid monomer and others. | 062142 | Shofu, Japan |

HEMA: 2 hydroxyethyl methacrylates, MDP: Methacryloxydecyl dihydrogen phosphate, PENTA: dipentaerythritol pentacrylate phosphate, BIS-GMA: Bisphenol A-glycidyl methacrylate, UDA: Urethane diacrylate, BIS-EMA: Bisphenol A Ethoxylated Dimethacrylate, PEGDMA: Polyethylene Glycol Dimethacrylate, TEGDMA: Triethylene Glycol Dimethacrylate.

## B. Method

### Study Setting

The current study's protocol was registered in (www.clinicaltrials.gov) database, with specific identification number NCT04854655. The ethical guidelines for all procedures taken during this investigation involving human participants were set by the Research Ethics

Committee (REC), Faculty of Dentistry, Cairo University, with identification number: 11721. The current study was carried out in Conservative Dentistry Department, Faculty of Dentistry, Cairo University. The researcher was ultimately in charge of all aspects of a study project's execution, including patient recruiting and the explanation and execution of the operations on them.

### Trial design:

The current study was a randomized clinical trial (RCT) with three parallel arms, superiority framework and 1:1:1 allocation ratio.

### Recruitment strategy:

The primary investigator recruited participants from the outpatient clinic of Conservative Dentistry department in Faculty of Dentistry, Cairo University, who met the participant timeline's eligibility requirements and signed an informed consent. Patients were recruited by convenient consecutive sampling method until the desired population was reached. Using dental charts, the patients underwent a thorough examination and diagnosis. The principle investigator phoned the patients who would have been eligible for this study after identifying them, explaining the details of the investigation and confirming the patients' interest.

### Sample size calculation:

Sample size was 0.9 and score B was 0.1 with effect size w 0.8 (n=13) and the estimated probability of score A of anatomic form for giomer was 0.9 and score B was 0.1 a with effect size w 0.8 (n=13), thus a total of 36 restorations was needed to be able to reject the null hypothesis that the success rates for case and controls were equal with probability (power) 0.8. This was increased to 45 subjects, 15 in each group to compensate for losses during follow-up. The type I error probability associated with this test of this null hypothesis was 0.05. Sample size was calculated using G*Power version 3.1.9.2 for windows using chi-square test.

**Eligibility Criteria**

**Inclusion criteria of Participants:**

- Study Participants: 25-40 Years
- Medically free to attend multiple appointments.
- Tolerance for necessary restorative procedures.
- Cooperative patients following instructions.
- Informed consent provided for participant's wellbeing.
- High compliance with one-year follow-up period.

**Exclusion criteria of Participants:**

- Pregnant women; as radiographs were indicated to check the proximal contacts.
- Patients with allergies to anaesthetics or any of the restorative materials.

**Inclusion Critertia of teeth:**

• Posterior primary proximal carious lesions without pulpal encroachment.
• Moderate class II lesions due to no cavity liner or base.
• Teeth in contact with adjacent teeth.
• Vital according to pulp-sensitivity tests.
• Free from active gingival or periodontal diseases.

**Exclusion Critertia of teeth:**

• Retained deciduous teeth for permanent teeth only.
• Mesial cavities in first premolars due to proximal contacts with canine not posteriors.
• Old restorations adding additional variables.
• Irreversible pulpitis pain resulting from sensitivity testing.
• Pulp necrosis indicated by sensitivity to axial or lateral percussion, periapical radiolucencies, and negative sensitivity tests.
• Potential internal or external resorption with negative pulpal reactions.
• Cervical caries not evaluated by periapical radiographs.

- **Allocation of participants:**

**Sequence generation and Allocation concealment:**

Random Sequence generation: Simple randomization was done by generating numbers from 1:45 using Random Sequence Generator, Randomness and Integrity Services Ltd (https://www.random.org/) either interventions or comparator group. Each generated random number from 1:15 represents intervention 1, 16-30 is intervention 2 and 31-45 is for the comparator. The operator chose between numbers by a contributor who was arranged by a contributor who was not involved in any of the phases of the clinical trial.

- **Blinding**

This study was a Double Blinded in which the patients were blinded to the technique utilized. Moreover, the outcome assessor was blinded to the restorative material utilized. However, the principle investigator was not blinded due to difference in the application protocol of each material.

- **Recruitment**

Patients selected by the principal investigator from the outpatient clinic of Conservative Dentistry department in Faculty of Dentistry, Cairo University; from which suitable patients were

selected to meet the eligibility requirements in accordance with the participant timeline. **(Figure 1)**

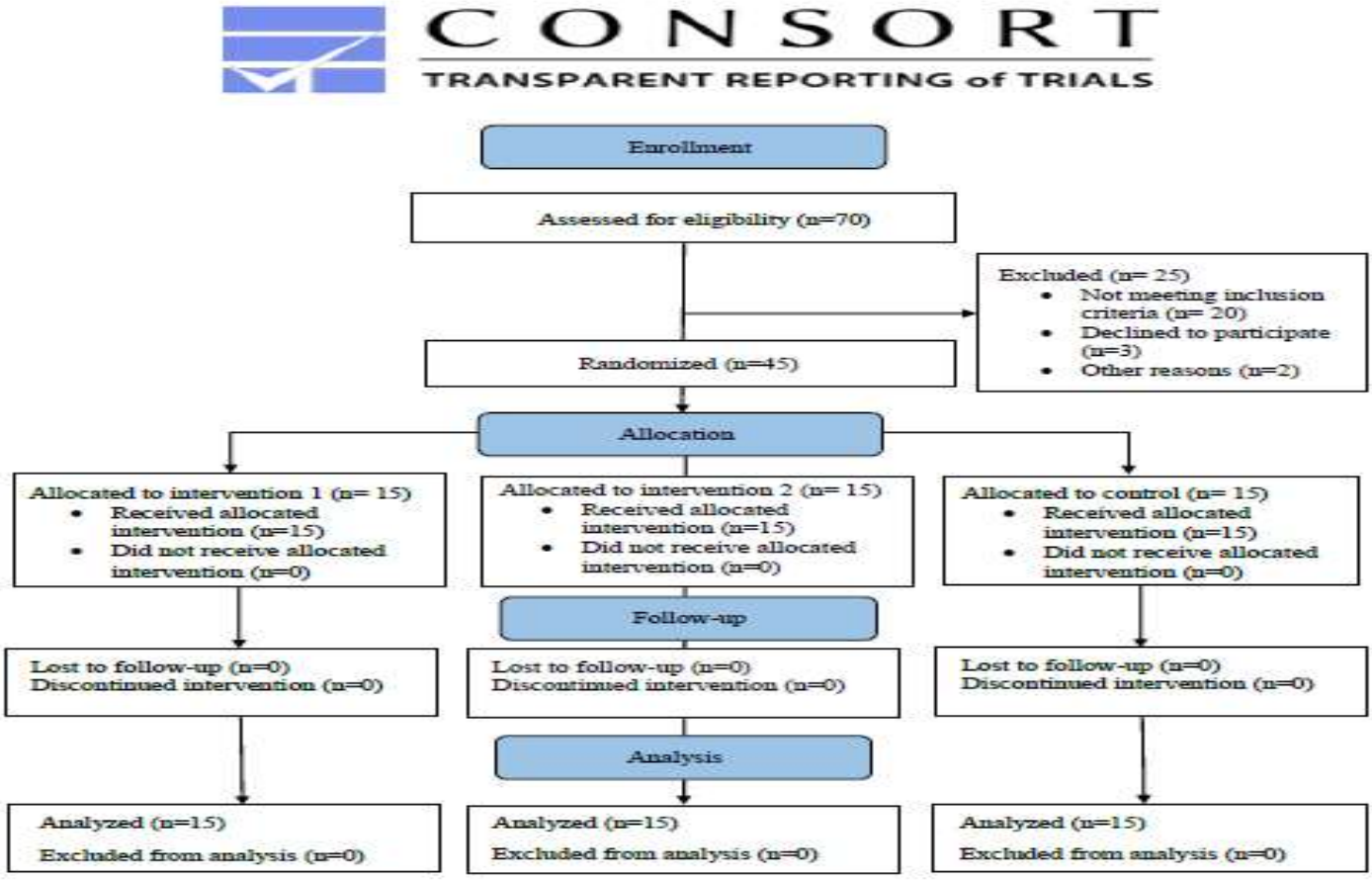


**Figure (1):** CONSORT flow diagram

- **Clinical restorative procedures:**

**Shade Selection:**

Shade selection on a clean teeth surface was done during natural daylight, based on tooth value, using composite increments. A black and white filter was used to eliminate hue and chroma, allowing for precise selection of the desired value.

**Isolation and Cavity Preparation:**

The study involved multiple isolation using rubber-dam of medium thickness (Sanctuary, Malaysia) and clamps (KSK, DENTECH, Japan) , cavity preparation using round bursize 014 1/10 mm (Komet Medical Gebr, Brasseler GmbH & Co.KG, Lemgo Deutschland), and intermittent cutting technique with coolant copious irrigation. Soft caries was removed using a discoid excavator (LASCOD ZEFFIRO, Italy) , and only moderate cavities were restored. The walls and margins were finished using yellow-coded finishing tapered stones size 014 1/10 (Intensiv SA, Montagnola, Switzerland).

**Matrix and Wedge Application:**

The study utilized sectional matrix and wooden wedge (TOR-VM, Russia) to restore optimal proximal contact in teeth. Medium or large size matrix bands were selected and stabilized using sectional

rings. Sectional matrix band systems were superior to circumferential ones [10]. A strong correlation was found between sectional matrix system and ideal proximal contact points. The circumferential matrix system was the primary cause of both tight and open interactions, independent of operator expertise [11].

**Adhesive Application and Curing:**

The tooth is cleaned and selective enamel etching is performed using phosphoric acid 37% (META BIOMED, Korea) for 15 seconds to create micropores and remove smear layer. The etchant gel is refrigerated, rinsed, and dried until a chalky white enamel appearance is achieved. Prime&Bond Universal adhesive (Dentsply Sirona, Detrey, Germany) is applied for ACTIVA Presto and nano-ceramic restorations, agitated and air thinned. Following the same steps, Beautibond (HEMA-Free "All-in-One" 7th Generation bonding system, Shofu, Japan) was used for Giomer restorations, with curing time of 10 seconds for Prime&Bond Universal and 5 seconds for Beautibond using 3M Elipar DeepCure-S LED Curing Light (3M, Saint Paul, MN, USA). Light intensity was checked and curing was done at 0mm distance.

**Cavity Restoration and Finishing:**

Composite was applied using a centrripetal technique, transforming class II into Class I, creating a marginal ridge, and restoring the occlusal cavity. Light cured for 20 seconds **(Figure 2).** 2 mm Increments were applied obliquely to reduce postoperative sensitivity and polymerization shrinkage. The restoration was finished with water coolant and tapered stoneswith rounded end of size 014 1/10, Intensiv (Intensiv SA, Montagnola, Switzerland). Occlusal contact was adjusted using Accufilm (PARKELL, USA), and proximal contact was checked using waxed dental floss (Essentialfloss, Oral-B, Ireland). Final finishing and polishing were done using a Microdont composite polishing kit (MICRODONT MU, Brazil). Margins and gingival margins were inspected using digital radiographs. (**Figure 3), (Figure 4).**

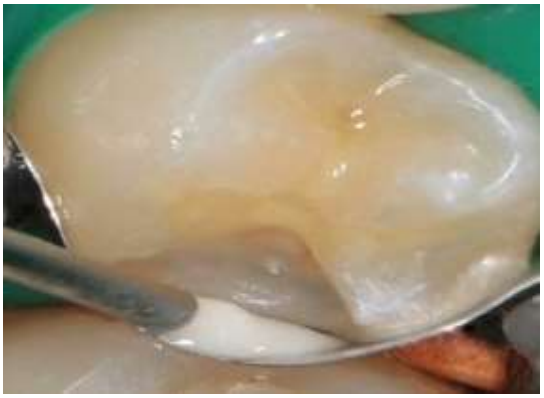

**Figure (2):** Application of Activa Presto proximally.

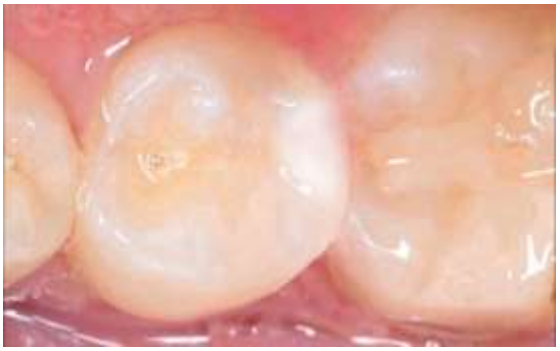

**Figure (3):** Final ACTIVA Presto restoration "Baseline".

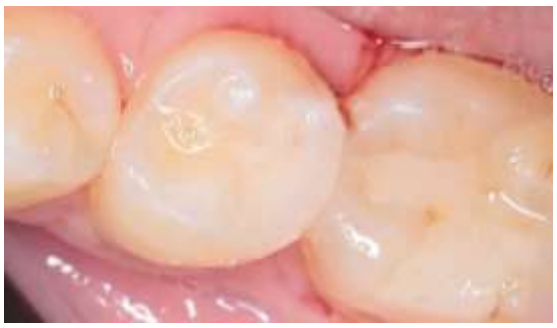

**Figure (4):** Follow up after 12 months of L5 restored with ACTIVA Presto.

**Restoration Assessment:**

The esthetic and mechanical properties of the three groups were evaluated visually using modified USPHS criteria **Table (2)**.

Two blinded and calibrated assessors gave the restoration alpha, bravo or Charlie scores according to the modified USPHS criteria. The intra and inter-examiner calibration was performed before the trial and repeated early to ensure the examiners' agreement [12]. The intra and inter-calibration was achieved by evaluating 10 restorations and agreement was obtained in 90% of the restorations. The assessors evaluated the restorations by visual examination using mirror and FDI probe. They checked the proximal contact by waxed dental floss (Essentialfloss, Oral-B, Ireland) and checked the presence of overhangs by radiographic films.

**Table (2)** showing the Modified USPHS criteria

| Outcome | Criterion | Score | Characteristics | Method of Diagnosis |
|---|---|---|---|---|
| **Primary Outcome (mechanical evaluation)** | **1.Proximal contact** | A | Normal contact. | Dental floss. |
| | | B | Light contact. | |
| | | C | None. | |
| | **2. Retention** | A | No loss of restorative material. | Visual inspection with mirror. |
| | | C | Missing restoration. | |
| | **3.Marginal Adaptation** | A | Closely adapted, no detectable margin. | Digital Radiographs were taken at baseline, after 6 months and after 12 months to evaluate the gingival margins and Visual inspection with mirror And tactile using an explorer (occlusal margins). |
| | | B | Detectable marginal discrepancy clinically acceptable. | |
| | | C | Marginal crevice, clinically un-acceptable. | |
| | **4.Anatomic Form** | A | Correct Contour. | Visual inspection with mirror. |
| | | B | Slightly under-contoured. | |
| | | C | Slightly over or under-contoured. | |
| | | D | Restoration fractured or mobile. | |
| | **5.Surface Texture** | A | No surface defect. | Visual inspection with mirror. |
| | | B | Minimal surface defect. | |
| | | C | Severe surface defect. | |
| **Secondary Outcome (esthetic evaluation)** | **1. Color Match** | A | Restoration matches the color of the tooth. | Visual inspection with mirror. |
| | | B | Acceptable mismatch. | |
| | | C | Unacceptable mismatch. | |
| | **2.Marginal Discoloration** | A | No discoloration between tooth structure and restoration. | Visual inspection with mirror. |
| | | B | Non penetrating marginal discoloration which can be polished away. | |
| | | C | Discoloration has penetrated margin in pulpal direction. | |

**Statistical Analysis:**

Data was analyzed using Medcalc software, version 19 for windows (MedCalc Software Ltd, Ostend, Belgium). Categorical data was described as frequency and percentage, intergroup comparisons between interventions was performed using the Chi-

Squared test with statistical significance level set at ($P \leq 0.016$) after Bonferroni correction, intragroup comparison within each intervention was accomplished using the Chi-Squared test with statistical significance level set at ($P \leq 0.005$) after Bonferroni correction. Relative risk was used to weigh the clinical significance.

## III. Results

### 1. Demographic data

A study involving 45 participants with proximal carious lesions was conducted. After 12 months, all participants completed the follow-up with 100% retention. The study found no significant differences in gender, age, or teeth distribution between the intervention and comparator groups. The mean age was 32.4±5.2 years, with no significant differences between the groups. The study also found no significant difference in teeth distribution between the intervention and comparator groups. Distribution of teeth is shown in **Table (3).**

### 2. Clinical evaluation:

The study found no significant differences in fracture & retention, marginal integrity, marginal discoloration, anatomic form, proximal contact, and surface texture between restorative materials over different follow-up periods. However, there were significant differences in color match. Intragroup comparisons within ACTIVA Presto, Giomer, and conventional resin composite showed no significant differences in these areas. Anatomic form, proximal contact, and surface texture showed significant differences. Overall, there were no significant differences in these aspects between restorative materials. **Table (4).**

**Table (3):** Teeth distribution among groups.

| Teeth distribution | ACTIVA Presto | Giomer | Conventional resin composite | Total |
|---|---|---|---|---|
| **Maxillary premolars** | 7(46.7%) | 7(46.7%) | 6(40%) | **20(44.4%)** |
| **Maxillary molars** | 3(20%) | 3(20%) | 2(13.3%) | **8(17.8%)** |
| **Mandibular premolars** | 3(20%) | 3(20%) | 5(33.3%) | **11(24.4%)** |
| **Mandibular molars** | 2(13.3%) | 2(13.3%) | 2(13.3%) | **6(13.3%)** |
| **Total** | **15 (33.33 %)** | **15 (33.33 %)** | **15 (33.33 %)** | **45** |

**Table (4):** Frequency and percentage for fracture and retention, marginal integrity, anatomic form, proximal contact, surface texture, marginal discoloration, and color match scores between different materials within each follow-up period:

| | Follow-up | ACTIVA Presto | | | Giomer | | | Conventional resin composite | | | P value |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A | B | C | A | B | C | A | B | C | |
| **Fracture and retention** | Baseline | 15(100%) | 0(0%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | 1 month | 15(100%) | 0(0%) | 0(0%) | 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%) | 15(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | 6 months | 15(100%) | 0(0%) | 0(0%) | 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%) | 15(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | P value | P = 1.0000 | | | P = 1.0000 | | | P = 1.0000 | | | |
| **Marginal integrity** | Baseline | 15(100%) | 0(0%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | 1 month | 15(100%) | 0(0%) | 0(0%) | 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%) | 15(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | 6 months | 12(80%) | 3(20%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | P = 0.0402 |
| | 12 months | 12(80%) | 3(20%) | 0(0%) | 13(86.7%) | 2(13.3%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | P = 0.2070 |
| | P value | P = 0.0443 | | | | | | P = 1.0000 | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | P = 0.0839 | | | | | | |
| **Anatomic Form** | Baseline | 15(100%) | 0(0%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | 1 month | 15(100%) | 0(0%) | 0(0%) | 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%) | 15(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | 6 months | 11(73.3%) | 4(26.7%) | 0(0%) | 14(93.3%) | 1(6.7%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | P = 0.0537 |
| | 12 months | 11(73.3%) | 4(26.7%) | 0(0%) | 12(80%) | 3(20%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | P = 0.1109 |
| | P value | P = 0.0015* | | | P = 0.0110 | | | P = 1.0000 | | | |
| **Proximal Contact** | Baseline | 15(100%) | 0(0%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | 1 month | 15(100%) | 0(0%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | 3 months | 13(86.7%) | 2(13.3%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | P = 0.1233 |
| | 6 months | 11(73.3%) | 4(26.7%) | 0(0%) | 14(93.3%) | 1(6.7%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | P = 0.0537 |
| | 12 months | 11(73.3%) | 4(26.7%) | 0(0%) | 11(73.3%) | 4(26.7%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | P = 0.0878 |
| | P value | P = 0.0039* | | | P = 0.0032* | | | P = 1.0000 | | | |
| **Surface Texture** | Baseline | 15(100%) | 0(0%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | 1 month | 15(100%) | 0(0%) | 0(0%) | 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%) | 15(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | 6 months | 11(73.3%) | 4(26.7%) | 0(0%) | 14(93.3%) | 1(6.7%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | P = 0.0537 |
| | 12 months | 10(66.7%) | 5(33.3%) | 0(0%) | 11(73.3%) | 4(26.7%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | P = 0.0541 |
| | P value | P = 0.0004* | | | P = 0.0032* | | | P = 1.0000 | | | |
| **Marginal Discoloration** | Baseline | 15(100%) | 0(0%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | 15(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | 1 month | 15(100%) | 0(0%) | 0(0%) | 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%) | 15(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | 6 months | 15(100%) | 0(0%) | 0(0%) | 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%) | 15(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | P value | P = 1.0000 | | | P = 1.0000 | | | P = 1.0000 | | | |
| **Color Match** | Baseline | 8(53.3%) | 7(46.7%) | 0(0%) | 12(80%) | 3(20%) | 0(0%) | 14(93.3%) | 1(6.7%) | 0(0%) | P = 0.0108* |
| | 1 month | 8(53.3%) | 7(46.7%) | 0(0%) | 12(80%) | 3(20%) | 0(0%) | 14(93.3%) | 1(6.7%) | 0(0%) | P = 0.0108* |
| | 3 months | 6(40%) | 9(60%) | 0(0%) | 12(80%) | 3(20%) | 0(0%) | 14(93.3%) | 1(6.7%) | 0(0%) | P = 0.0013* |
| | 6 months | 3(20%) | 10(66.7%) | 2(13.3%) | 12(80%) | 3(20%) | 0(0%) | 13(86.7%) | 2(13.3%) | 0(0%) | P = 0.0012* |
| | 12 months | 2(13.3%) | 10(66.7%) | 3(20%) | 10(66.7%) | 5(33.3%) | 0(0%) | 13(86.7%) | 2(13.3%) | 0(0%) | P = 0.0006* |
| | P value | P = 0.0622 | | | P = 0.8753 | | | P = 0.9180 | | | |

## IV. DISCUSSION

The study found no significant differences in retention, proximal contact, marginal discoloration, adaptation, anatomical form, surface texture, or color match among 45 patients with proximal carious lesions. The intervention and control arms were randomly assigned to patients with proximal carious lesions.

ACTIVA creates apatite-like crystals at tooth-restoration interface, filling micro-spaces, preventing secondary caries, and promoting interaction with glass fillers and tooth structure [13]. It features an ionic resin matrix, allowing fluoride, calcium, and phosphate release while maintaining restorative properties [14]. ActivaTM Bioactive Restorative, delivered using a dual-barrel automix syringe [7], can be applied with or without an adhesive agent, using the "Adhesion-Decalcification" concept [14]. Manufacturer suggests adhesive for class V lesions, but marginal integrity challenges, leading to microleakage and potential clinical issues [7]. ACTIVA BioACTIVE

Restorative fails without tooth surface treatment [15].

ACTIVA Bioactive Restorative's primary failures include restoration loss, postoperative sensitivity, and secondary caries due to inadequate bonding, as demonstrated by dye penetration tests and clinical trials [7], [16]. In 2019, ACTIVA Bioactive Restorative's modified polyacrylic acid was suggested for micromechanical bonding [15] , but its weak PAA necessitates a universal bonding agent for strong bonding [18]. Therefore, it was decided to apply a universal bonding agent in addition to the ACTIVA Presto in this study.

The study explores Beautifil II®, a bioactive fluoride-releasing hybrid restorative material. It combines bioactive glass fillers and a bis-GMA matrix for aesthetics, handling, and anti-plaque effects. Beautifil II is certified for class I–V restorations and uses giomers to buffer acidic environments and create fluoroapatite crystals [5]. Beautibond, a light-cure HEMA-Free 7th Generation bonding system, is used for Beautifil II, extending restorations' lifetime and treating Class V lesions due to similar shear bond strength. [19].

ACTIVA restorations achieved 100% retention rate in clinical trial due to bioactive ionomer component, preventing bacterial leakage and forming chemical bonds with teeth [9]. Also, the dental advisor indicated that ACTIVA BioACTIVE had a (100%) retention rate [13]. However, another study stated that one patient in the ACTIVA group experienced complete loss of one restoration throughout the six-month evaluation period [20]. Furthermore, it was reported that at the conclusion of the 12-month follow-up period, 6.3% of the ACTIVA BioACTIVE restorations were lost [21]. Manufacturer suggests using adhesive agents for enhanced retention rates [7], [15]. Similarly, Giomer group have shown 100% retention rate which in agreement with Abuelniel [22]. A 13-year follow-up study found a retention rate of 66% for giomer-based restorative material, possibly due to the long follow-up period [5].

Conventional nanohybrid resin composite presented Alpha retention scores regarding retention, which is in agreement with other study [61]. The chemomechanical interlocking caused by resin diffusion around demineralized enamel and partially demineralized dentin is what causes the adhesion in nanohybrid composites [9]. The American Dental Association mandates a restorative material for posterior teeth to have a retention rate of at least 90% after 18 months of clinical service [17]. Hence, the three restorative materials performed very well for 12 months regarding retention.

The study found no significant difference in proximal contacts between groups at baseline, but significant differences at 6 and 12 months, with ACTIVA Presto and Giomer restorations showing significant differences which was consistent with Abuelniel [22] who stated that after a year, Giomer revealed a statistically significant rise in the prevalence of Bravo scores. Gordan et al. [5] found tooth drift and interproximal wear after Giomer restorations, but no significant difference in proximal contact was found between baseline and eight-year follow-ups. Conventional nanohybrid resin composite have also exhibited no statistically significant difference over the range of follow-up times and this was in accordance with Schmidt et al. [23].

Regarding Marginal integrity, ACTIVA group has revealed insignificant difference between baseline and other follow-up intervals. This was in agreement with other clinical trials [9], [21]. The ionization process in tooth restorations replaces hydrogen ions with calcium, creating a strong resin-apatite complex that fuses restoration to tooth, reduces sensitivity, and prevents recurrent caries [56]. Additionally, the shock-absorbing resin components that are claimed to reduce minor chipping and fracture [24]. According to an in vitro study revealed significant micro-leakage near cervical margins due to tooth surface morphology changes [25]. These in vitro results, however, may not necessarily translate to in vivo outcomes [21].

Giomer group has revealed insignificant difference between baseline and other follow-up intervals as well. This can be justified by the use of the HEMA free universal adhesive (BeautiBond) showed no micropermeability [19]. However

Abdel-Karim et al. [26] found conflicting results on Giomer restorations, attributed to contraction stresses during polymerization and pre-reacted glass-polyacid zones. These factors resulted in reduced adaptation and marginal deterioration, resembling resin composites. The material's marginal deterioration is attributed to pre-reacted glass-polyacid zones, which create an osmotic effect, causing swelling and pressure [27].

Conventional nanohybrid resin composite has shown no significant difference among different follow-up intervals. The nanohybrid resin composite's adhesion process relies on functional monomers like PENTA and 10-MDP due to their mild acidity and pH [28]. However, Kandil & Sherief [29] noted that due to the increased filler loading in Ceram X, the material was more rigid than ACTIVA BioACTIVE, which may have caused wider marginal gaps and higher polymerization shrinkage stresses.

Concerning marginal discoloration, none of the three groups has shown significant differences during different time intervals. Absence of marginal discoloration in ACTIVA group supported the findings of [7], [9]**.** These outcomes were in disagreement with a study that stated that ACTIVA group showed significant differences after 12 months [30].

According to Gordan et al. [5], no Giomer restorations showed marginal discoloration after a year of clinical follow-up. However, Ozer et al stated that there were significant differences between the baseline and 36-month follow-up scores [31]. Gordan et al noticed after thirteen years, some of the intact restorations did experience some alterations in terms of marginal discoloration but these findings weren't significant [5].

The nanohybrid resin composite showed no significant difference in marginal discoloration, but a positive correlation was found between marginal adaptation and discoloration, suggesting stain buildup and adhesive agent involvement [32].

With regards to surface texture, ACTIVA group have shown significant differences after 6 months. Hafez et al. [30] found that ACTIVA maintains a smooth surface for six months, with a wear rate comparable to resin composites. The material's hardness performance is influenced by filler type, morphology, and size. On the contrary to our results, Eissa et al. [20] no significant difference between ACTIVA BioActive and nanohybrid resin composite groups, with only one restoration scoring Charlie. ACTIVA BioActive consists of glass particles and polyacid components, with ionic resin containing antibacterial phosphate acid groups.

The Giomer group discovered significant surface roughness variations in Beautifil II material, possibly due to the resin matrix not bonding with the S-PRG filler and increased filler loading [22]**.** On the contrary to our results, Gordan et al. [5] found that Giomer restoration showed no significant differences throughout the two-year follow-up period. On the other hand, conventional nanohybrid resin composite presented no surface texture throughout the year. Lai et al. [33] stated that surface roughness (Ra < 0.2 μm) is crucial for appropriate surface gloss and low plaque adhesion risk in resin composites, even with nanohybrid Ceram X restorations showing increased roughness.

It was found a significant difference in anatomical form between ACTIVA and other restorations after 12 months, indicating that bioactive resin composites prevent biofilm formation and secondary caries [35]. The literature on bioactive resin composites is limited, necessitating an overview of previous studies. On the other side, our results were in disagreement with Bansal et al. [24] and Bhadra et al. [9].

On the contrary, Giomer restoration have shown no significant difference after 12 months. These results aligned with Garcia et al. [36] who stated that despite the fact that Giomer and ACTIVA restorative materials contain dimethacrylates and inorganic filler, Giomer exhibits superior wear resistance due to improved filler size selection and distribution over the resin matrix promotes homogeneity and the

preservation of surface qualities. However, Abuelniel [22] reported that after a year, the Giomer restorations revealed a statistically significant rise in the prevalence of Bravo scores.

Conventional nanohybrid resin composite also revealed no significant difference in terms of anatomic contour. This was supported by the fact that for posterior restorations, nanofilled resin composite materials are highly filled to give wear resistance, strength and comparatively low polymerization shrinkage [3].

The color match within ACTIVA Presto, Giomer, and conventional nanohybrid resin composite showed no significant difference in color over follow-up periods, consistent with other studies [9], [21]. ACTIVA Presto showed a 7-fold higher risk for color match compared to conventional resin composite after 12 months, possibly due to its glass-ionomer constituent [9]. Due to the manufacturer's provision of several hues and the minimal surface roughness measured, ACTIVA color's match was better initially. Water sorption and mineral exchange are to blame for the hue match changing over time [30]. Beltrami et al. [37] discovered that surface roughness due to dental plaque accumulation can decrease restoration luster and color match, influenced by restorative material, staining agent, and polishing surface smoothness.

Throughout the follow-up intervals. Giomer group also showed significant difference in comparison to conventional nanohybrid resin composite group. Gonulol et al. [38] found that Giomers, a fluoride-releasing material, may have pores and roughness in their matrix, potentially affecting the color stability and aesthetic performance. Ceram X showed the best color match among restorative materials, with decreased discoloration compared to nanofilled materials. Its highly disseminated methacrylic polysiloxane nanoparticles contribute to its superior performance [39]. On the contrary to our results, Sulaiman et al. [40] found Activa Bioactive superior in color stability, while Sajini et al. [41] found it superior to conventional resin composite (Filtek Z350) due to its absence of Bis-GMA.

The study found no significant difference in survival rates among three ACTIVA Presto restorations at 12 months, highlighting the need for further research with longer follow-up times and larger sample sizes.

## CONCLUSIONS

- Calcium and phosphate releasing hybrid restorative material has comparable mechanical properties to Giomer and conventional nanohybrid resin composite.
- Giomer and conventional nanohybrid resin composite show better esthetic properties.
- Calcium and phosphate releasing hybrid restorative material is recommended for permanent restoration, especially for posterior proximal cavities.

### Clinical Relevance

The three categories of the restorative materials have similar clinical performance in posterior teeth.

## V. RECOMMENDATIONS

- Conduct multi-centric research with larger sample size and longer follow-up periods.
- Conduct more clinical trials to evaluate effectiveness of calcium and phosphate releasing hybrid restorative material.

### Conflict of interest

No conflict of interest.

### Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors

### Compliance with Ethical Standards

The protocol of the current study was registered on clinical trials with a unique identification number (I.D. NCT04854655.). Ethical approval was obtained before the start of the study. The study was approved by the Research Ethics Committee

(CREC), Faculty of Oral and Dental Medicine with ethical approval number (11721). This was in accordance to the ethical standards of Helinski.

**Informed consent**

An informed consent with an easy Arabic language was signed by the recruited participants.

## VI. REFERENCES


1. **Martins, M.T., Sardenberg, F., Bendo, C.B., Abreu, M.H., Vale, M.P., Paiva, S.M. and Pordeus, I.A., 2017.** Dental caries remains as the main oral condition with the greatest impact on children's quality of life. PloS one, 12(10), p.e0185365.
2. **Sampaio, C.S., Garcés, G.A., Kolakarnprasert, N., Atria, P.J., Giannini, M. and Hirata, R., 2020.** External marginal gap evaluation of different resin-filling techniques for class II Restorations—A micro-CT and SEM Analysis. Operative dentistry, 45(4), pp.E167-E175.
3. **Bogra, P., Gupta, S. and Kumar, S., 2012.** Comparative evaluation of microleakage in class II cavities restored with Ceram X and Filtek P-90: An: in vitro: study. Contemporary clinical dentistry, 3(1), pp.9-14.
4. **Rusnac, M.E., Gasparik, C., Irimie, A.I., Grecu, A.G., Mesaroş, A.Ş. and Dudea, D., 2019.** Giomers in dentistry–at the boundary between dental composites and glass-ionomers. Medicine and pharmacy reports, 92(2), p.123.
5. **Gordan, V.V., Blaser, P.K., Watson, R.E., Mjör, I.A., McEdward, D.L., Sensi, L.G. and Riley III, J.L., 2014.** A clinical evaluation of a giomer restorative system containing surface prereacted glass ionomer filler: results from a 13-year recall examination. The Journal of the American Dental Association, 145(10), pp.1036-1043.
6. **Lardani, L., Derchi, G., Marchio, V. and Carli, E., 2022.** One-year clinical performance of Activa™ bioactive-restorative composite in primary molars. Children, 9(3), p.433.
7. **Kaushik, M. and Yadav, M., 2017.** Marginal microleakage properties of activa bioactive restorative and nanohybrid composite resin using two different adhesives in non carious cervical lesions-an in vitro study. Journal of the west african college of surgeons, 7(2), p.1.
8. **ACTIVA Presto - Pulpdent.** (n.d.-a). Retrieved April 5, **2020.**
9. **Bhadra, D., Shah, N.C., Rao, A.S., Dedania, M.S. and Bajpai, N., 2019.** A 1-year comparative evaluation of clinical performance of nanohybrid composite with Activa™ bioactive composite in Class II carious lesion: A randomized control study. Journal of Conservative Dentistry and Endodontics, 22(1), pp.92-96.
10. **Ahmad, M.Z., Gaikwad, R.N. and Arjumand, B., 2018.** Comparison of two different matrix band systems in restoring two surface cavities in posterior teeth done by senior undergraduate students at Qassim University, Saudi Arabia: A randomized controlled clinical trial. Indian Journal of Dental Research, 29(4), pp.459-464.
11. **Shaalan, O.O. and Ibrahim, S.H., 2021.** Clinical evaluation of sectional matrix versus circumferential matrix for reproduction of proximal contact by undergraduate students and postgraduate dentists: A randomized controlled trial. Journal of International Oral Health, 13(1), pp.10-16.
12. **Olegário, I.C., Moro, B.L., Tedesco, T.K., Freitas, R.D., Pássaro, A.L., Garbim, J.R., Oliveira, R., Mendes, F.M. and Raggio, D.P., 2022.** Use of rubber dam versus cotton roll isolation on composite resin restorations' survival in primary molars: 2-year results from a non-

13. inferiority clinical trial. BMC Oral Health, 22(1), p.440.
14. **ACTIVA™ BioACTIVE-RESTORATIVE™ Archives** - Pulpdent. (n.d.). Retrieved February 24, 2020.
15. **Pires, P.M., Neves, A.D.A., Makeeva, I.M., Schwendicke, F., Faus-Matoses, V., Yoshihara, K., Banerjee, A. and Sauro, S., 2020.** Contemporary restorative ion-releasing materials: Current status, interfacial properties and operative approaches. British Dental Journal, 229(7), pp.450-458.
16. **Benetti, A.R., Michou, S., Larsen, L., Peutzfeldt, A., Pallesen, U. and Van Dijken, J.W.V., 2019.** Adhesion and marginal adaptation of a claimed bioactive, restorative material. Biomaterial investigations in dentistry, 6(1), pp.90-98.
17. **Van Dijken, J.W., Pallesen, U. and Benetti, A., 2019.** A randomized controlled evaluation of posterior resin restorations of an altered resin modified glass-ionomer cement with claimed bioactivity. Dental Materials, 35(2), pp.335-343.
18. **Hickel, R., Mesinger, S., Opdam, N., Loomans, B., Frankenberger, R., Cadenaro, M., Burgess, J., Peschke, A., Heintze, S.D. and Kühnisch, J., 2023.** Revised FDI criteria for evaluating direct and indirect dental restorations—recommendations for its clinical use, interpretation, and reporting. Clinical oral investigations, 27(6), pp.2573-2592.
19. **Sultan, M., ElKorashy, M. and Fawzy, A., 2020.** Bonding effectiveness of bioactive self-adhesive restorative material to enamel and dentin using different bonding protocols. Egyptian Dental Journal, 66(3-July (Conservative Dentistry and Endodontics)), pp.1883-1892.
20. **Bacelar-Sa, R., Sauro, S., Abuna, G., Vitti, R.P., Nikaido, T., Tagami, J., Bovi Ambrosano, G.M. and Giannini, M., 2017.** Adhesion Evaluation of Dentin Sealing, Micropermeability, and Bond Strength of Current HEMA-free Adhesives to Dentin. Journal of Adhesive Dentistry, 19(4).
21. **Eissa, M.M., Akah, M., Yousry, M.M., Hamza, H., Hassanein, H. and Pameijer, C.H., 2021.** Clinical performance of a bioactive restorative material vs a glass hybrid restorative in posterior restorations in high-risk caries patients. World Journal of Dentistry, 12(4), pp.292-300.
22. **Hegazi, R.I., Jamil, W.E. and Fawzy, A., 2023.** Comparative Evaluation of Clinical Performance of Three Different Glass Hybrid Restorations in High Caries Risk Patients: A Randomized Control Trial. Dental Science Updates, 4(1), pp.171-183.
23. **Abuelniel, G.M., 2018.** Clinical Assessment and Microleakage Evaluation of Three Esthetic Restorative Materials in Class II in Primary Molars. Egyptian Dental Journal, 64(4-October (Orthodontics, Pediatric & Preventive Dentistry)), pp.3013-3030.
24. **Schmidt, M., Dige, I., Kirkevang, L.L., Vaeth, M. and Hørsted-Bindslev, P., 2015.** Five-year evaluation of a low-shrinkage Silorane resin composite material: a randomized clinical trial. Clinical oral investigations, 19, pp.245-251.
25. **Bansal, R., Burgess, J. and Lawson, N.C., 2016.** Wear of an enhanced resin-modified glass-ionomer restorative material. American journal of dentistry, 29(3), pp.171-174.
26. **Owens, B.M., Phebus, J.G. and Johnson, W.W., 2018.** Evaluation of the marginal integrity of a bioactive restorative material. Gen Dent, 66(3), pp.32-36.
27. **Abdel-Karim, U.M., El-Eraky, M. and Etman, W.M., 2014.** Three-year clinical evaluation of two nano-hybrid giomer restorative composites. Tanta Dental Journal, 11(3), pp.213-22

28. **Sokolowski, K., Szczesio-Wlodarczyk, A., Bociong, K., Krasowski, M., Fronczek-Wojciechowska, M., Domarecka, M., Sokolowski, J. and Lukomska-Szymanska, M., 2018.** Contraction and hydroscopic expansion stress of dental ion-releasing polymeric materials. Polymers, 10(10), p.1093.
29. **Ikemura, K., Kadoma, Y. and Endo, T., 2011.** A review of the developments of self-etching primers and adhesives—Effects of acidic adhesive monomers and polymerization initiators on bonding to ground, smear layer-covered teeth. Dental materials journal, 30(6), pp.769-789.
30. **Kandil, M. and Sherief, D., 2021.** Marginal adaptation, compressive strength, water sorption, solubility and ion release of a claimed bioactive restorative material. Egyptian Dental Journal, 67(1-January (Fixed Prosthodontics, Removable Prosthodontics and Dental Materials)), pp.547-561.
31. **Yehia, Y.H., Ibrahim, A.H., Abou-auf, E. and Elzogbhi, A.F., 2022.** Clinical Evaluation of Bioactive Restorative Material versus Resin Modified Glass Ionomer in Cervical Restorations: A Randomized Controlled Clinical Trial. Open Access Macedonian Journal of Medical Sciences (OAMJMS), 10(D), pp.33-40.
32. **Ozer, F., Irmak, O., Yakymiv, O., Mohammed, A., Pande, R., Saleh, N. and Blatz, M., 2021.** Three-year clinical performance of two giomer restorative materials in restorations. Operative Dentistry, 46(1), pp.E60-E67.
33. **Tuncer, D., Çelik, Ç., Yamanel, K. and Arhun, N., 2017.** Clinical evaluation of microhybrid composites in noncarious cervical lesions: 24-month results. Nigerian journal of clinical practice, 20(2), pp.176-181.
34. **Lai, G., Zhao, L., Wang, J. and Kunzelmann, K.H., 2018.** Surface properties and color stability of dental flowable composites influenced by simulated toothbrushing. Dental Materials Journal, 37(5), pp.717-724.
35. **Khazaal, G., Daou, M., Mahdi, S.S., Ahmed, Z., Maalouf, E., Batteni, G., Qasim, S.S.B., Kassis, C., Agha, D., Haddad, H. and el Hajj Assaf, R., 2023.** In vitro evaluation of the color stability and surface roughness of a new composite flow. Journal of clinical and experimental dentistry, 15(1), p.e43.
36. **Balhaddad, A.A., Kansara, A.A., Hidan, D., Weir, M.D., Xu, H.H. and Melo, M.A.S., 2019.** Toward dental caries: Exploring nanoparticle-based platforms and calcium phosphate compounds for dental restorative materials. Bioactive materials, 4, pp.43-55.
37. **Garcia, I.M., Balhaddad, A.A., Aljuboori, N., Ibrahim, M.S., Mokeem, L., Ogubunka, A., Collares, F.M. and Melo, M.A.S.D., 2021.** Wear behavior and surface quality of dental bioactive ions-releasing resins under simulated chewing conditions. Frontiers in Oral Health, 2, p.628026.
38. **Beltrami, R., Ceci, M., De Pani, G., Vialba, L., Federico, R., Poggio, C. and Colombo, M., 2018.** Effect of different surface finishing/polishing procedures on color stability of esthetic restorative materials: A spectrophotometric evaluation. European journal of dentistry, 12(01), pp.049-056.
39. **Gonulol, N., Ozer, S. and Sen Tunc, E., 2015.** Water sorption, solubility, and color stability of giomer restoratives. Journal of esthetic and restorative dentistry, 27(5), pp.300-306.
40. **Ren, Y.F., Feng, L., Serban, D. and Malmstrom, H.S., 2012.** Effects of common beverage colorants on color stability of dental composite resins: the utility of a thermocycling stain challenge model in vitro. Journal of dentistry, 40, pp.e48-e56.

41. **Sulaiman, T.A., Rodgers, B., Suliman, A.A. and Johnston, W.M., 2021.** Color and translucency stability of contemporary resin-based restorative materials. Journal of Esthetic and Restorative Dentistry, 33(6), pp.899-905.
42. **Sajini SI, Mushayt AB, Almutairi TA, Abuljadayel R., 2022.** Color stability of bioactive restorative materials after immersion in various media. Journal of International Society of Preventive and Community Dentistry, 1;12(4):418-25.