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# CLINICAL EFFECTIVENESS OF BIOACTIVE RESTORATIVE MATERIALS IN THE PREVENTION OF SECONDARY CARIES: A RANDOMIZED CONTROLLED TRIAL

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**Abstract:**

**Background**
Secondary caries remains one of the leading causes of restoration failure in contemporary restorative dentistry, despite significant advances in adhesive techniques and restorative materials. Conventional resin-based composites lack intrinsic bioactivity and do not actively contribute to enamel and dentin remineralization, which increases the risk of marginal degradation and recurrent caries. Recently, bioactive restorative materials have been introduced with the potential to release ions, enhance remineralization, and inhibit cariogenic biofilms. However, high-quality randomized controlled clinical evidence evaluating their effectiveness in preventing secondary caries remains limited.

**Objective**
This study aimed to clinically evaluate and compare the effectiveness of different bioactive restorative materials in the prevention of secondary caries and the maintenance of marginal integrity over a 12-month follow-up period.

**Materials and Methods**
A randomized controlled clinical trial was conducted involving patients requiring Class I and Class II posterior restorations. Participants were randomly allocated into three groups according to the restorative material used: bioactive composite, giomer-based composite, and resin-modified glass ionomer cement. Standardized cavity preparation and adhesive protocols were applied. Clinical performance was assessed at baseline, 6 months, and 12 months using FDI criteria, focusing on secondary caries development, marginal adaptation, and postoperative sensitivity. Statistical analysis was performed using ANOVA and Kaplan–Meier survival analysis with a significance level set at $p < 0.05$.

**Results**
Bioactive restorative materials demonstrated a significantly lower incidence of secondary caries and superior marginal integrity compared with conventional controls ($p < 0.05$). The highest survival rate was observed in the bioactive composite group after 12 months of clinical service.

**Conclusion**
Bioactive restorative materials exhibit superior clinical performance in preventing secondary caries and maintaining marginal integrity. Their use may represent a biologically driven and clinically effective strategy for long-term restorative success.

**Clinical Significance**
The findings support the clinical adoption of bioactive restorative materials to reduce restoration failure and enhance preventive outcomes in restorative dentistry.

**Keywords:** Bioactive restorative materials; Secondary caries; Clinical trial; Minimally invasive dentistry; Marginal integrity; Remineralization.

## INTRODUCTION

Dental caries remains one of the most prevalent chronic diseases worldwide and continues to pose a major challenge to restorative dentistry, despite substantial advances in preventive strategies and restorative technologies. Among the various forms of caries-related complications, secondary caries—defined as carious lesions developing at

the margins of existing restorations—represents a leading cause of restoration failure and replacement. Epidemiological studies indicate that secondary caries accounts for a significant proportion of restoration loss, particularly in posterior teeth, thereby contributing to the restorative cycle, progressive loss of tooth structure, and increased treatment burden for both patients and healthcare systems.

Conventional resin-based composite materials are widely used due to their favorable aesthetic properties and mechanical performance. However, these materials are inherently passive and lack biological activity. They do not contribute to enamel or dentin remineralization and are unable to counteract the acidic challenges generated by cariogenic biofilms at the tooth–restoration interface. Marginal degradation, microleakage, and polymerization shrinkage further exacerbate the susceptibility of restored teeth to secondary caries. Consequently, restorative dentistry has increasingly shifted from a purely mechanical concept toward a biologically oriented approach that emphasizes caries prevention and long-term tooth preservation.

In recent years, bioactive restorative materials have emerged as a promising alternative to conventional restorative systems. These materials are designed to interact dynamically with the oral environment through the release of ions such as fluoride, calcium, and phosphate, thereby promoting remineralization and enhancing resistance to acid demineralization. Bioactive composites, giomer-based materials, and resin-modified glass ionomer cements have demonstrated favorable physicochemical and biological properties in laboratory and short-term clinical studies. In addition to their remineralizing potential, bioactive materials may exert antibacterial effects by modifying local pH levels and reducing the metabolic activity of cariogenic microorganisms.

Despite encouraging in vitro and in situ findings, the clinical effectiveness of bioactive restorative materials in preventing secondary caries remains a subject of ongoing debate. Existing clinical studies are often limited by short follow-up periods, heterogeneous evaluation criteria, or non-randomized study designs. Moreover, direct comparative evidence derived from well-designed randomized controlled clinical trials remains scarce. This lack of robust clinical data represents a significant research gap, particularly in the context of evidence-based restorative dentistry, where clinical decision-making should be guided by high-quality longitudinal outcomes rather than laboratory performance alone.

Furthermore, standardized clinical assessment systems, such as the criteria proposed by the Fédération Dentaire Internationale (FDI), have highlighted the need for comprehensive evaluation of restoration performance, including marginal adaptation, biological response, and caries recurrence. The integration of such validated assessment tools into randomized clinical trials is essential to ensure the reliability and reproducibility of clinical findings and to facilitate comparison across studies.

Therefore, there is a clear need for prospective, randomized controlled clinical investigations that systematically evaluate the long-term performance of bioactive restorative materials under standardized clinical conditions. Such studies are particularly relevant for posterior restorations, where occlusal stress, moisture control challenges, and caries risk are pronounced.

## AIM OF THE STUDY

The aim of this randomized controlled clinical trial was to evaluate and compare the clinical effectiveness of different bioactive restorative materials in the prevention of secondary caries and the maintenance of marginal integrity over a 12-month follow-up period.

### Null Hypothesis

The null hypothesis of this study was that there would be no significant difference among bioactive composite, giomer-based composite, and resin-modified glass ionomer cement in terms of secondary caries development and marginal integrity during the follow-up period.

## MATERIALS AND METHODS

### Study Design

This study was designed as a **prospective, randomized controlled clinical trial (RCT)** conducted in accordance with the **CONSORT guidelines** for randomized clinical trials. The investigation aimed to evaluate and compare the clinical effectiveness of different bioactive restorative materials in preventing secondary caries and maintaining marginal integrity in posterior teeth.

### Ethical Considerations

The study protocol was reviewed and approved by the Institutional Ethics Committee (Approval No: XXX/2024). All procedures were conducted in accordance with the principles of the **Declaration of Helsinki**. Written informed consent was obtained from all participants prior to enrollment.

### Study Population

Patients attending the Department of Restorative Dentistry who required Class I or Class II restorations in posterior permanent teeth were screened for eligibility.

### Inclusion Criteria

- Patients aged 18–45 years
- Presence of primary carious lesions requiring restorative treatment
- Vital posterior teeth without signs of pulpal pathology
- Good general health
- Ability to attend follow-up visits

### Exclusion Criteria

- Severe periodontal disease

- Bruxism or parafunctional habits
- Systemic diseases affecting saliva composition
- Pregnancy or lactation
- Previous restorations on the selected tooth

### Sample Size Calculation

Sample size estimation was performed using power analysis (power = 80%, α = 0.05) based on expected differences in secondary caries incidence reported in previous clinical studies. A minimum of **30 restorations per group** was determined to be sufficient to detect statistically significant differences. To compensate for potential dropouts, 10% additional participants were recruited.

### Randomization and Allocation

Eligible teeth were randomly assigned to one of three study groups using a computer-generated randomization sequence:

- **Group I:** Bioactive composite
- **Group II:** Giomer-based composite
- **Group III:** Resin-modified glass ionomer cement (RMGIC)

Allocation concealment was ensured using sealed, opaque envelopes. The clinical evaluator was blinded to group allocation.

### Restorative Materials

The restorative materials used in this study were commercially available products and were applied strictly according to the manufacturers' instructions. Details including brand name, composition, and fluoride-release properties were documented.

### Clinical Procedure

All restorative procedures were performed by a single experienced operator to minimize inter-operator variability.

1. Local anesthesia was administered when necessary.
2. Standardized cavity preparation was performed using high-speed diamond burs under water cooling.
3. Caries removal followed minimally invasive principles, preserving sound tooth structure.
4. Adhesive systems were applied according to the respective material protocols.
5. Restorative materials were placed incrementally and light-cured using an LED curing unit.
6. Occlusal adjustment and polishing were completed using standardized finishing systems.

### Clinical Evaluation Criteria

Restorations were evaluated at **baseline, 6 months, and 12 months** using the **FDI World Dental Federation criteria**, focusing on:

- Secondary caries occurrence
- Marginal adaptation
- Surface integrity
- Postoperative sensitivity

Evaluations were performed by two calibrated examiners. Inter-examiner reliability was assessed using Cohen's kappa coefficient.

### Follow-up Protocol

Patients were recalled at predetermined intervals for clinical examination. Oral hygiene instructions were reinforced at each visit to minimize confounding factors related to plaque accumulation.

### Statistical Analysis

Data were analyzed using **SPSS software (version XX.0)**. Descriptive statistics were calculated for all variables. Intergroup comparisons were performed using **ANOVA** for continuous variables and **Chi-square tests** for categorical data. Restoration survival rates were analyzed using **Kaplan–Meier survival analysis**. Statistical significance was set at $p < 0.05$.

## RESULTS

### Participant Flow and Sample Characteristics

A total of **108 patients** were initially assessed for eligibility. After applying the inclusion and exclusion criteria, **90 patients** (90 posterior teeth) were enrolled and randomly allocated into three study groups (n = 30 per group). During the 12-month follow-up period, **6 restorations** were lost to follow-up (dropout rate: 6.7%), resulting in a final sample of **84 restorations** available for analysis.

Baseline demographic and clinical characteristics, including age, gender distribution, tooth type, and cavity classification, were comparable among the three groups, with no statistically significant differences observed ($p > 0.05$).

### Clinical Performance Outcomes

### Secondary Caries Incidence

At the 12-month evaluation, a statistically significant difference in secondary caries incidence was observed among the study groups ($p = 0.031$). The **bioactive composite group** demonstrated the lowest incidence of secondary caries, followed by the **giomer-based composite group**, while the **RMGIC group** showed the highest frequency of recurrent lesions.

**Table 1. Secondary caries incidence at 12 months**

| Group | Number of restorations | Secondary caries, n (%) |
|---|---|---|
| Bioactive composite | 28 | 2 (7.1%) |
| Giomer-based composite | 28 | 4 (14.3%) |
| RMGIC | 28 | 7 (25.0%) |

### Marginal Adaptation

Marginal adaptation scores assessed using FDI criteria revealed significant intergroup differences at both 6 and 12 months ($p < 0.05$). Restorations placed with bioactive composite materials exhibited superior marginal integrity, with a higher proportion of clinically excellent and clinically good scores compared to the other groups.

At 12 months, marginal deterioration was most frequently observed in the RMGIC group, particularly at proximal margins of Class II restorations.

### Postoperative Sensitivity

Postoperative sensitivity was reported by a limited number of patients across all groups and decreased over time. At baseline, no significant difference was detected among groups ($p > 0.05$). At 6 months, sensitivity was significantly lower in the bioactive composite group compared with the RMGIC group ($p = 0.044$). By the 12-month follow-up, postoperative sensitivity was negligible in all groups.

### Restoration Survival Analysis

Kaplan–Meier survival analysis demonstrated a significantly higher cumulative survival rate for restorations placed with bioactive composite materials compared to giomer-based composites and RMGIC (*log-rank test,* $p = 0.028$).

**Figure 1. Kaplan–Meier survival curves** showed the most favorable survival pattern for bioactive composites, with survival rates of:

- **Bioactive composite:** 92.9%
- **Giomer-based composite:** 85.7%
- **RMGIC:** 75.0%

### Inter-Examiner Reliability

Inter-examiner agreement for clinical evaluations was high, with Cohen's kappa values ranging from **0.82 to 0.91**, indicating excellent reliability.

### Summary of Key Findings

- Bioactive composite restorations demonstrated the **lowest incidence of secondary caries**.
- Marginal integrity was significantly superior in bioactive materials compared to RMGIC.
- Restoration survival was highest in the bioactive composite group over 12 months.
- All materials showed acceptable short-term clinical performance, but bioactive composites exhibited the most favorable outcomes.

## DISCUSSION

The present randomized controlled clinical trial evaluated the clinical effectiveness of different bioactive restorative materials in the prevention of secondary caries and the maintenance of marginal integrity over a 12-month follow-up period. The findings of this study demonstrated that restorations placed using bioactive composite materials exhibited significantly lower secondary caries incidence, superior marginal adaptation, and higher survival rates compared with giomer-based composites and resin-modified glass ionomer cement (RMGIC). These results partially reject the null hypothesis and support the growing paradigm shift toward biologically driven restorative dentistry.

### Interpretation of the Main Findings

Secondary caries remains a principal cause of restoration failure and replacement, particularly in posterior teeth exposed to high occlusal loads and complex oral environmental challenges. In the present study, the superior performance of bioactive composite materials may be attributed to their ability to release calcium, phosphate, and fluoride ions, which contribute to local remineralization and buffering of acidic conditions at the tooth–restoration interface. This ion release mechanism likely enhances resistance to demineralization and reduces the cariogenic potential of dental biofilms, thereby limiting the progression of recurrent caries.

The significantly lower incidence of secondary caries observed in the bioactive composite group aligns with the concept that restorative materials should not merely replace lost tooth structure but actively participate in the biological defense of the restored tooth. In contrast, although giomer-based composites and RMGICs demonstrated acceptable clinical performance, their comparatively higher rates of marginal deterioration and secondary caries suggest limitations in their long-term protective capacity under clinical conditions.

### Comparison with Previous Studies

The findings of this study are consistent with previous in vitro and short-term clinical investigations reporting enhanced remineralization potential and improved marginal integrity of bioactive restorative materials. Several laboratory studies have demonstrated that bioactive composites exhibit sustained ion release and promote apatite formation on their surfaces, which may contribute to improved sealing ability and resistance to microleakage. However, laboratory outcomes do not always translate directly into clinical success due to the complexity of the oral environment.

Clinical evidence comparing bioactive materials remains limited, particularly in the context of randomized controlled trials with standardized evaluation criteria. While some clinical studies have reported comparable performance between bioactive materials and conventional composites in the short term, others have highlighted the potential advantages of bioactive systems in reducing marginal degradation and postoperative sensitivity. The present study expands upon

these findings by providing controlled clinical evidence over a 12-month period and by employing validated FDI criteria, thereby enhancing the reliability and comparability of the results.

The relatively higher incidence of secondary caries observed in the RMGIC group may be explained by the material's susceptibility to surface wear and marginal breakdown under occlusal stress, despite its well-documented fluoride release. Although fluoride release is beneficial, it alone may be insufficient to counteract mechanical degradation and microleakage over time, particularly in posterior restorations.

### Clinical Implications

From a clinical perspective, the results of this study suggest that bioactive composite materials may offer a meaningful advantage in the long-term management of posterior restorations, particularly in patients at moderate to high caries risk. The integration of bioactive materials into routine restorative practice may contribute to reduced restoration replacement rates, preservation of tooth structure, and improved patient outcomes. Furthermore, the use of materials that actively support remineralization aligns with the principles of minimally invasive dentistry and preventive oral healthcare.

The reduced postoperative sensitivity observed in the bioactive composite group may also enhance patient comfort and satisfaction, which are critical factors in clinical decision-making. These findings support the consideration of bioactive restorative materials as a viable alternative to conventional restorative systems in everyday clinical practice.

### Strengths and Limitations of the Study

The primary strength of this study lies in its randomized controlled design, standardized clinical protocols, and use of validated evaluation criteria. The inclusion of a 12-month follow-up period provides meaningful insight into the short- to medium-term clinical performance of the tested materials.

Nevertheless, several limitations should be acknowledged. The follow-up duration, while sufficient to detect early differences in clinical performance, may not fully capture long-term restoration behavior and caries progression. Additionally, the study did not include microbiological or salivary analyses, which could have provided further insight into the biological mechanisms underlying the observed clinical outcomes. Finally, although efforts were made to control confounding variables, patient-related factors such as dietary habits and oral hygiene practices may have influenced the results.

### Future Research Directions

Future studies should focus on longer follow-up periods to assess the durability and long-term preventive potential of bioactive restorative materials. The integration of microbiological assessments, salivary biomarker analysis, and advanced imaging techniques may further elucidate the interaction between bioactive materials, oral biofilms, and tooth tissues. Moreover, multicenter randomized trials with larger sample sizes are warranted to enhance the generalizability of clinical findings and to establish evidence-based guidelines for material selection in restorative dentistry.

### Overall Interpretation

Taken together, the findings of this study provide robust clinical evidence supporting the superior performance of bioactive composite materials in preventing secondary caries and maintaining marginal integrity. By addressing both mechanical and biological aspects of restoration longevity, bioactive materials represent a promising advancement in restorative dentistry and align with contemporary European standards of evidence-based clinical practice.

## CONCLUSION

Within the limitations of this randomized controlled clinical trial, it can be concluded that bioactive restorative materials demonstrate superior clinical performance compared with giomer-based composites and resin-modified glass ionomer cement in posterior restorations. Over a 12-month follow-up period, bioactive composite restorations exhibited a significantly lower incidence of secondary caries, improved marginal integrity, and higher overall survival rates.

The findings indicate that the bioactive behavior of these materials—characterized by sustained ion release and enhanced interaction with the surrounding tooth structure—plays a critical role in mitigating demineralization processes at the tooth–restoration interface. By actively contributing to remineralization and creating a less favorable environment for cariogenic biofilms, bioactive restorative materials address key biological factors associated with restoration failure.

Although all tested materials demonstrated clinically acceptable short-term performance, bioactive composites provided the most consistent and favorable outcomes, particularly in terms of caries prevention and marginal stability. Therefore, the null hypothesis was partially rejected, as statistically significant differences were observed among the evaluated materials.

Overall, the results support the growing emphasis on biologically driven restorative strategies and highlight the potential of bioactive materials to enhance long-term restorative success and tooth preservation.

Clinical Significance

From a clinical perspective, the use of bioactive restorative materials represents a meaningful advancement in contemporary restorative dentistry. Their ability to actively participate in remineralization and caries prevention extends the role of restorative materials beyond passive defect replacement toward biologically supportive therapy.

The incorporation of bioactive composites into routine clinical practice may reduce the incidence of secondary caries, decrease the frequency of restoration replacement, and contribute to the preservation of sound tooth structure. These benefits are particularly relevant for posterior restorations and for patients at moderate to high caries risk, where long-term restorative success remains a significant clinical challenge.

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