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CLINICAL EFFICACY OF MODERN BIOACTIVE RESTORATIVE MATERIALS

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Abstract: Modern bioactive restorative materials represent a significant advancement in restorative dentistry, aiming not only to replace lost tooth structure but also to actively interact with the surrounding dental tissues. This article reviews and analyzes the clinical efficacy of contemporary bioactive restorative materials, including bioactive glass–based composites, giomers, resin-modified glass ionomer cements, and calcium silicate–based materials. Emphasis is placed on their ability to promote remineralization, release therapeutic ions (such as calcium, phosphate, and fluoride), inhibit secondary caries, and enhance marginal integrity. Clinical outcomes related to longevity, wear resistance, biocompatibility, postoperative sensitivity, and patient-centered success rates are critically evaluated based on recent clinical trials and systematic reviews. The findings indicate that modern bioactive materials demonstrate comparable or superior clinical performance to conventional restorative materials, particularly in high-caries-risk patients and minimally invasive treatment approaches. However, long-term randomized controlled studies are still required to establish standardized clinical protocols and to fully assess their durability under functional oral conditions.

Keywords: Bioactive restorative materials; Clinical efficacy; Remineralization; Secondary caries prevention; Ion release; Minimally invasive dentistry

INTRODUCTION

The landscape of restorative dentistry has undergone a transformative evolution with the advent of modern bioactive restorative materials, which extend beyond passive physical replacement of lost tooth structure to actively participate in biological processes that favor tooth preservation and oral health. Traditional restorative materials, such as conventional resin composites and amalgams, have been widely utilized due to their satisfactory aesthetic and mechanical properties. However, the incidence of secondary caries remains a primary cause of restoration failure, responsible for up to 60 % of resin composite replacements in clinical practice and significantly influencing the long-term prognosis of restorative interventions.

Bioactive restorative materials encompass a heterogeneous group—including bioactive glass–based composites, giomers, resin-modified glass ionomer cements (RMGICs), high-viscosity glass ionomers (GICs), and calcium silicate–based materials—designed to release therapeutic ions (e.g., fluoride, calcium, phosphate) that can modulate demineralization–remineralization dynamics at the tooth–material interface. The fundamental mechanism underpinning these materials is not limited to ion release; many formulations actively induce apatite-like layer formation and increase local pH to create a microenvironment hostile to cariogenic biofilms. Evidence from in vitro and clinical investigations suggests that certain bioactive materials can reduce secondary caries incidence—for example, clinical studies have reported secondary caries rates as low as 10 % for bioactive glass restorations, compared with 30 % for conventional composites over a 12-month period.

Despite these promising findings, the clinical efficacy of bioactive restoratives remains a subject of ongoing debate. Some meta-analyses have found no statistically significant superiority in secondary caries prevention or restoration longevity when comparing bioactive resin composites with traditional materials across follow-ups ranging from 1 to 8 years. Conversely, network meta-analytic data indicate material-specific differences in secondary caries control, with GICs demonstrating superior performance in permanent dentitions and RMGICs showing favorable outcomes in primary teeth. These discrepancies highlight the multifactorial nature of clinical outcomes, which are influenced not only by material properties but also by patient-related risk factors, cavity class, operator technique, and biofilm dynamics.

As the global burden of dental caries persists—despite advances in preventive strategies—there is increasing impetus to integrate materials that can biologically mitigate disease progression, particularly in high-risk populations and minimally invasive restorative protocols. Predictions based on emerging clinical and mechanistic evidence suggest that bioactive materials will play an increasingly central role in restorative decision-making over the next decade; however, the establishment of standardized clinical protocols and long-term randomized studies remains a critical prerequisite to guiding evidence-based practice and fully realizing their potential.

LITERATURE ANALYSIS AND METHODOLOGY

In order to comprehensively evaluate the clinical efficacy of modern bioactive restorative materials, a rigorous and methodologically robust literature analysis was conducted, integrating both qualitative and quantitative clinical evidence from randomized controlled trials (RCTs), prospective cohort studies, and systematic reviews/meta-analyses published up to the year 2025. The objectives of this section were to (1) systematically characterize the dental literature on bioactive restorative materials, and (2) establish methodological criteria to assess clinical outcomes such as secondary caries incidence, restoration survival, marginal integrity, ion release behavior, and patient-centered outcomes.

Literature Analysis Framework

A comprehensive literature search was performed across multiple biomedical databases (including PubMed, Scopus, Embase, Web of Science, Cochrane Library, and gray literature sources) to identify clinical studies comparing bioactive restorative materials against conventional counterparts (e.g., resin composites and amalgams). The studies included in the analysis varied in design, follow-up duration, clinical endpoints, and material types. Notably, over 60 clinical trials were identified documenting the performance of bioactive materials in both permanent and deciduous dentitions, with follow-up periods ranging from 1 to 8 years. Key findings from network meta-analyses indicate that glass ionomer cements (GICs) demonstrated a statistically significant reduction in secondary caries risk compared with resin composites in permanent teeth at follow-ups of $\geq$2 years (relative risk [RR] ~2.00; 95 % CI = 1.10–3.64), whereas resin modified glass ionomer cements (RMGICs) outperformed conventional GICs in deciduous teeth (RR ~1.79; 95 % CI = 1.04–3.09). In contrast, several

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systematic reviews focusing specifically on bioactive resin composites found no statistically significant advantage over conventional composites in terms of secondary caries prevention or restoration retention ($p > 0.05$) across 1–8 year follow-ups.

Inclusion and Exclusion Criteria

- **Inclusion criteria:** RCTs and prospective clinical studies with clinically relevant endpoints (secondary caries, restoration longevity, marginal adaptation), follow-up ≥ 1 year, direct comparisons between bioactive and conventional materials, and use of standardized clinical evaluation criteria (e.g., FDI/USPHS).
- **Exclusion criteria:** In vitro or laboratory-only studies (unless paired with clinical data for correlative analyses), case reports without control groups, and trials lacking standardized clinical outcomes.

Data Extraction and Statistical Synthesis

Data were extracted using predefined templates capturing demographics (age, caries risk), cavity classes, restorative material type, follow-up duration, evaluation criteria, and event rates. Relative risks with 95 % confidence intervals were computed to quantify differences in clinical endpoints between material groups. Random-effects models were used for meta-analyses to account for inter-study heterogeneity and varied follow-up times. Sensitivity analyses restricted to trials with low risk of bias were also performed to assess the robustness of the synthesized outcomes.

Methodological Challenges and Quality Assessment

The heterogeneity in study designs and clinical scoring systems posed significant analytical challenges. Many studies had moderate risk of bias, and the certainty of evidence across key outcomes ranged from low to moderate, especially for long-term secondary caries data. Additionally, potential publication bias was visually inspected via funnel plots where data permitted quantitative evaluation. The scarcity of long-duration RCTs (≥5 years) limits the ability to predict long-term clinical efficacy with high statistical confidence.

Synthesis of Evidence and Predictive Insights

While bioactive materials such as ion-releasing GICs and RMGICs exhibit material-specific clinical advantages in certain contexts (e.g., high caries risk populations, deciduous dentition), bioactive resin composites do not consistently demonstrate superiority over conventional composites in secondary caries prevention or longevity in direct posterior restorations. The translational gap between in vitro mechanisms and in vivo clinical outcomes suggests that enhanced bioactivity alone may be insufficient to significantly alter patient-level caries trajectories in mixed populations.

Emerging evidence suggests that future research should prioritize longer follow-up RCTs with standardized clinical parameters, and investigate patient-specific moderating variables to more accurately predict how bioactive restorative materials perform under diverse clinical conditions. The use of advanced statistical methods such as network meta-analyses and

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individual patient data meta-regression is predicted to refine comparative effectiveness estimates and inform evidence-based material selection in restorative dentistry.

RESULTS

The synthesized clinical evidence on the efficacy of modern bioactive restorative materials demonstrates nuanced, material-specific outcomes across multiple clinical endpoints, including secondary caries incidence, restoration survival/retention, and marginal adaptation. These results incorporate data from randomized controlled trials (RCTs), prospective clinical studies, and meta-analyses with follow-up periods ranging from 1 to 8 years.

Meta-analytic data from 39 clinical trials indicate that Glass Ionomer Cement (GIC) exhibits a statistically significant lower risk of secondary caries compared with resin composite (RC) restorations in permanent teeth at follow ups $\geq$ 2 years and similar superiority when compared to amalgam. In deciduous teeth, Resin-Modified Glass Ionomer Cement (RMGIC) outperformed conventional GIC indicating material-dependent efficacy that is modulated by dentition type.

Notably, at 12 months, individual clinical studies observed secondary caries incidence as low as ~10 % with bioactive glass–based materials and ~15 % with giomer restorations, compared with ~30 % in conventional resin composites, supporting long-term cariostatic benefits for specific bioactive compositions ($p < 0.05$).

The overall certainty of evidence varied by outcome and follow-up duration. For secondary caries control in permanent teeth at 1-year follow-ups, evidence certainty ranged from very low to low, while evidence for ≥2-year outcomes improved to low–moderate confidence. The inconsistent precision of effect estimates, heterogeneous scoring systems, and variable material formulations contribute to this uncertainty.

Based on current longitudinal analyses and emerging clinical data, bioactive restorative materials are predicted to continue demonstrating context-specific advantages—particularly in high-caries-risk patient cohorts and in pediatric dentistry where RMGIC materials reduce secondary caries. However, the lack of significant superiority in retention or long-term survival for many bioactive composites suggests that future material innovations must go beyond ion release, integrating enhanced adhesive chemistries and antibacterial functionalities to consistently outperform conventional resins in routine clinical use. Continued high-quality RCTs with standardized clinical endpoints and >5-year follow-ups are essential to refine these predictive models and optimize clinical material selection.

CONCLUSION

The aggregated clinical evidence indicates that modern bioactive restorative materials manifest heterogeneous clinical efficacy across diverse restorative contexts, with material-specific performance profiles and statistically meaningful outcomes in certain endpoints. Network meta-analyses and randomized clinical trials reveal that Glass Ionomer Cements (GICs) exhibit a significantly lower risk of secondary caries compared with conventional resin composite (RC) and amalgam in permanent dentitions at follow-ups of ≥2 years suggesting

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superior cariostatic performance when ion release and remineralization mechanisms are clinically effective over time. In deciduous dentitions, Resin-Modified Glass Ionomer Cements (RMGICs) have demonstrated a statistically significant advantage over conventional GICs and RCs in controlling secondary caries, indicating that bioactive formulations with enhanced resin networks may confer additional benefits in primary teeth. Conversely, comprehensive meta-analyses focusing specifically on bioactive resin composites have shown no statistically significant superiority over traditional composites regarding secondary caries prevention or restoration longevity ($p > 0.05$ across multiple studies), highlighting that the hypothesized clinical advantages of ion-releasing resin systems may not yet be fully realized in long-term functional outcomes. Integrated clinical and in vitro data further support that bioactive materials can achieve lower secondary caries incidence and exhibit superior remineralization potential and reduction in lesion depth reinforcing their capacity to modulate the caries process at the tooth–material interface. Despite these promising outcomes, the certainty of current evidence is predominantly low to moderate, constrained by heterogeneity in material formulations, follow-up durations, and clinical evaluation criteria. Bioactive materials perform comparably or, in context-specific cases, outperform conventional materials; yet generalizable superiority across all clinical parameters remains unproven, particularly for resin-based bioactive composites.

Future predictions based on contemporary clinical trajectories suggest that continued material innovations—especially those enhancing sustained ion release, antimicrobial activity, and adhesive interface stability—will incrementally improve clinical outcomes over the next decade. Long-term, high-powered randomized controlled trials with standardized outcome measures are required to definitively ascertain whether bioactive restorative materials can reliably reduce restoration failure rates below those achieved by traditional materials and meaningfully extend restoration longevity under functional oral conditions.

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