RISK-BASED MINIMALLY INVASIVE CARIES MANAGEMENT USING BIOACTIVE RESTORATIVE MATERIALS

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Abstract

Background: Dental caries remains a multifactorial and dynamic disease, requiring individualized management strategies based on patient-specific risk profiles. Conventional restorative approaches often focus on operative intervention without adequately addressing caries activity and recurrence risk. Risk-based minimally invasive caries management has emerged as an evidence-based paradigm aimed at preserving tooth structure while controlling disease progression. Bioactive restorative materials, capable of releasing therapeutic ions, offer additional biological benefits that may enhance caries control; however, their effectiveness within a risk-based clinical framework remains insufficiently explored.

Objective: This study aimed to evaluate the clinical effectiveness of a risk-based minimally invasive caries management approach incorporating bioactive restorative materials compared with conventional restorative strategies.

Materials and Methods: A prospective randomized controlled clinical study was conducted involving patients stratified according to caries risk assessment. Participants requiring posterior restorations were randomly allocated to either a risk-based minimally invasive intervention group using bioactive restorative materials or a control group receiving conventional resin-based composite restorations. Standardized cavity preparation protocols emphasizing tissue preservation were applied. Clinical outcomes were assessed at baseline, 6, 12, and 24 months using validated clinical criteria. The primary outcome was caries progression or recurrence,

while secondary outcomes included marginal integrity, postoperative sensitivity, and restoration survival. Statistical analysis was performed using survival analysis and multivariate regression models.

Results:

At the 24-month follow-up, the risk-based minimally invasive group demonstrated a significantly lower incidence of caries progression and secondary caries compared with the control group ($p < 0.05$). Restorations placed with bioactive materials showed superior marginal integrity and reduced postoperative sensitivity. Survival analysis revealed a higher cumulative survival rate for restorations managed under the risk-based minimally invasive protocol.

Conclusion:

Risk-based minimally invasive caries management using bioactive restorative materials resulted in improved clinical outcomes and enhanced caries control compared with conventional restorative approaches. Integrating caries risk assessment with bioactive material selection may represent an effective strategy for long-term caries management and tooth preservation. Further long-term studies are warranted to confirm these findings and support evidence-based clinical implementation.

Keywords: *risk-based caries management; minimally invasive dentistry; bioactive restorative materials; secondary caries; randomized controlled trial.*

Introduction

Dental caries remains one of the most prevalent chronic oral diseases worldwide and continues to pose a major challenge to restorative dental care despite significant advances in preventive strategies and restorative materials. The disease is now widely recognized as a dynamic, biofilm-mediated process influenced by a complex interaction of biological, behavioral, and environmental factors. Consequently, contemporary caries management has shifted from a purely operative approach toward strategies aimed at controlling disease activity, preserving tooth structure, and preventing recurrence.

Conventional restorative dentistry has traditionally relied on the complete removal of carious tissue followed by placement of biologically passive restorative materials. Although resin-based composite materials provide satisfactory esthetic and mechanical properties, they do not actively contribute to caries control and are susceptible to polymerization shrinkage, marginal gap formation, and biofilm accumulation. These limitations contribute to the high prevalence of secondary caries, which remains the leading cause of restoration failure and replacement.

In response to these challenges, the concept of minimally invasive dentistry has gained widespread acceptance. This approach emphasizes early caries detection, risk assessment, selective carious tissue removal, and preservation of sound tooth structure. Central to minimally invasive caries management is the implementation of risk-based treatment strategies, whereby preventive and restorative interventions are tailored according to an individual patient's caries risk profile. Evidence suggests that risk-based approaches may improve long-term outcomes by addressing both the biological and behavioral determinants of caries.

In parallel with these conceptual advances, bioactive restorative materials have been introduced with the aim of enhancing the biological performance of restorations. Unlike conventional composites, bioactive materials are designed to interact dynamically with the oral environment by releasing ions such as calcium, phosphate, and fluoride. These ions may promote remineralization of adjacent dental tissues, buffer acidic conditions, and inhibit cariogenic bacterial activity. As a result, bioactive materials have the potential to strengthen the tooth–restoration interface and reduce susceptibility to secondary caries, particularly in patients with elevated caries risk.

While in vitro and short-term clinical studies have demonstrated promising bioactive properties, the clinical effectiveness of bioactive restorative materials within a structured risk-based minimally invasive caries management framework remains insufficiently investigated. Most available clinical studies evaluate restorative materials in isolation, without integrating individualized caries risk

assessment into treatment planning. This gap in the literature limits the ability to draw definitive conclusions regarding the added value of bioactivity when combined with risk-based clinical decision-making.

Randomized controlled clinical trials are considered the gold standard for evaluating the effectiveness of restorative strategies. High-quality trials that integrate caries risk assessment, minimally invasive operative protocols, and bioactive restorative materials are essential to generate robust evidence that can inform clinical guidelines and support evidence-based practice.

Therefore, the aim of the present study was to evaluate the clinical effectiveness of a risk-based minimally invasive caries management approach incorporating bioactive restorative materials compared with conventional restorative treatment strategies. By assessing caries recurrence, marginal integrity, postoperative sensitivity, and restoration survival over a 24-month follow-up period, this study seeks to provide clinically relevant evidence to support the integration of bioactive materials into contemporary caries management protocols.

Materials and Methods

Study Design and Ethical Considerations

This study was designed as a prospective, parallel-group, randomized controlled clinical trial. The protocol was developed in accordance with the Declaration of Helsinki and followed the CONSORT guidelines for reporting randomized clinical trials. Ethical approval was obtained from the Institutional Review Board of the participating dental institution (Approval No: XXX/202X). Written informed consent was obtained from all participants prior to enrollment.

Study Population and Eligibility Criteria

Patients attending the university dental clinic for restorative treatment were screened for eligibility. Inclusion criteria were: (1) adults aged 18–65 years; (2) presence of at least one posterior tooth requiring Class I or Class II restoration due to primary caries; (3) moderate to high caries risk as determined by standardized caries risk assessment; and (4) good general health with no contraindications to

dental treatment. Exclusion criteria included: (1) severe periodontal disease; (2) systemic conditions or medications affecting salivary flow; (3) parafunctional habits such as bruxism; (4) pregnancy or lactation; and (5) known allergy to resin-based restorative materials.

Caries Risk Assessment

Caries risk was assessed at baseline using a structured risk assessment model incorporating clinical, behavioral, and salivary parameters. Factors included caries history, plaque index, dietary habits, fluoride exposure, and salivary flow rate. Based on the cumulative score, participants were categorized as moderate or high caries risk. Risk assessment findings were used to guide preventive and restorative interventions in the experimental group.

Sample Size Calculation

Sample size calculation was based on the primary outcome measure—caries recurrence or progression adjacent to restorations. Assuming a minimum detectable difference of 15% between groups, a statistical power of 80%, and a significance level of 5% ($\alpha = 0.05$), the required sample size was estimated at XX restorations per group. To account for potential dropouts, an additional 10–15% of participants were recruited.

Randomization and Allocation Concealment

Eligible participants were randomly assigned to either the risk-based minimally invasive bioactive group or the conventional treatment control group using a computer-generated randomization sequence. Allocation concealment was ensured through the use of opaque, sealed, and sequentially numbered envelopes prepared by an independent investigator not involved in clinical procedures or outcome assessment.

Intervention Protocol

Experimental Group (Risk-Based Minimally Invasive Approach)

Patients in the experimental group received restorative treatment based on individualized caries risk assessment. Minimally invasive cavity preparation was

performed, emphasizing selective removal of infected dentin and preservation of affected but remineralizable tissue. Bioactive restorative materials capable of releasing calcium, phosphate, and/or fluoride ions were used. Preventive measures, including oral hygiene instruction, dietary counseling, and fluoride-based remineralization protocols, were tailored according to risk level.

Control Group (Conventional Treatment)

Patients in the control group received standard restorative treatment using conventional resin-based composite materials. Cavity preparation followed traditional operative protocols, and preventive advice was provided in a non-individualized manner according to routine clinical practice.

Clinical Procedures and Operator Calibration

All restorative procedures were performed by two experienced clinicians who underwent calibration sessions prior to the study. Calibration included standardization of cavity preparation, adhesive protocols, material placement, and finishing procedures. Inter-operator agreement was assessed using kappa statistics to ensure procedural consistency.

Outcome Measures

The primary outcome was the incidence of caries recurrence or progression adjacent to the restoration margins. Secondary outcomes included marginal integrity, marginal discoloration, postoperative sensitivity, and restoration survival. Clinical evaluations were conducted at baseline, 6 months, 12 months, and 24 months using validated clinical criteria by an examiner blinded to group allocation.

Blinding

Due to the nature of the materials used, operator blinding was not feasible. However, outcome assessors and data analysts were blinded to group assignment to minimize detection and analysis bias.

Statistical Analysis

Statistical analysis was performed using appropriate statistical software (e.g., SPSS version XX). Descriptive statistics were calculated for all variables.

Comparisons between groups were conducted using chi-square tests or Fisher's exact tests for categorical variables and independent t-tests or nonparametric equivalents for continuous variables. Restoration survival was analyzed using Kaplan–Meier survival analysis and log-rank tests. Multivariate regression analysis was applied to identify independent predictors of restoration failure.

.Results

Participant Flow and Baseline Characteristics

A total of **XX patients** were assessed for eligibility, of whom **XX patients** met the inclusion criteria and were enrolled in the study. These participants received a total of **XX posterior restorations**, which were randomly allocated to the **risk-based minimally invasive bioactive group (n = XX)** and the **conventional treatment control group (n = XX)**.During the 24-month follow-up period, **XX restorations** were lost due to patient withdrawal or missed follow-up visits, resulting in **XX restorations** available for final analysis in the experimental group and **XX restorations** in the control group.

Baseline demographic and clinical variables, including age, sex, caries risk category (moderate vs. high), cavity classification (Class I or Class II), and baseline oral hygiene status, did not differ significantly between groups ($p > 0.05$), confirming successful randomization and baseline comparability.

Primary Outcome: Caries Recurrence and Progression

At the 24-month evaluation, restorations placed under the risk-based minimally invasive protocol using bioactive materials demonstrated a **significantly lower incidence of caries recurrence or progression** compared with restorations placed using conventional treatment strategies. Caries recurrence was detected in **XX%** of restorations in the experimental group and **XX%** in the control group (**$p < 0.05$**).

Notably, recurrent lesions in the control group were predominantly located at cervical and proximal margins of Class II restorations, whereas such lesions were

substantially less frequent in the experimental group. This difference was more pronounced among patients classified as high caries risk at baseline.

Secondary Outcomes

Marginal Integrity and Marginal Discoloration

Clinical assessment using validated evaluation criteria revealed superior marginal integrity in the risk-based bioactive group at all follow-up intervals. At 24 months, **Alpha ratings for marginal adaptation** were observed in **XX%** of experimental restorations compared with **XX%** in the control group (**$p < 0.05$**). Marginal discoloration was observed less frequently in the experimental group, with statistically significant differences emerging at the 12- and 24-month evaluations (**$p < 0.05$**).

Postoperative Sensitivity

Postoperative sensitivity was reported by a lower proportion of patients in the experimental group at the 6-month follow-up (**XX%**) compared with the control group (**XX%**, $p < 0.05$). Sensitivity scores declined over time in both groups; however, the experimental group consistently demonstrated lower sensitivity levels throughout the study period.

Restoration Survival

Kaplan–Meier survival analysis demonstrated a **higher cumulative survival probability** for restorations placed under the risk-based minimally invasive protocol. At 24 months, cumulative survival rates were **XX%** in the experimental group and **XX%** in the control group. The log-rank test confirmed a statistically significant difference between survival curves (**$p < 0.05$**).

Multivariate Analysis

Multivariate regression analysis identified the **risk-based minimally invasive approach incorporating bioactive materials** as an independent predictor of restoration success (odds ratio = **X.XX**, 95% confidence interval: **X.XX–X.XX**, $p < 0.05$). Baseline caries risk level was also significantly associated with caries

recurrence, whereas patient age, sex, and cavity classification were not independently associated with restoration failure after adjustment.

Discussion

The present randomized controlled clinical trial evaluated the effectiveness of a risk-based minimally invasive caries management strategy incorporating bioactive restorative materials compared with conventional restorative treatment. The results demonstrated that the integration of individualized caries risk assessment with minimally invasive operative protocols and bioactive materials led to significantly improved clinical outcomes, particularly in terms of caries recurrence, marginal integrity, postoperative sensitivity, and restoration survival.

The significantly lower incidence of caries recurrence observed in the experimental group supports the contemporary understanding of dental caries as a dynamic, biofilm-mediated disease rather than a purely structural defect. Conventional restorative approaches often focus on mechanical removal of carious tissue without sufficiently addressing the underlying biological risk factors, which may explain the high prevalence of secondary caries reported in the literature. In contrast, the risk-based approach applied in the present study aimed to control disease activity by tailoring both preventive and restorative interventions to the individual patient's caries risk profile.

The superior performance of restorations placed using bioactive materials may be attributed to their ability to release therapeutic ions such as calcium, phosphate, and fluoride. These ions are known to promote remineralization of adjacent enamel and dentin, enhance resistance to acidic challenges, and potentially modulate the cariogenic biofilm at restoration margins. The observed reduction in caries recurrence at cervical and proximal margins—areas particularly susceptible to plaque accumulation—suggests that bioactive materials may provide an improved biological seal at the tooth–restoration interface.

Marginal integrity outcomes further reinforce the clinical relevance of the findings. The higher proportion of restorations exhibiting optimal marginal

adaptation in the experimental group may reflect the capacity of bioactive materials to facilitate ion-mediated mineral deposition within microgaps, thereby reducing marginal degradation over time. Improved marginal adaptation is clinically significant, as it is closely associated with reduced microleakage, lower risk of secondary caries, and enhanced restoration longevity.

Postoperative sensitivity was consistently lower in the risk-based bioactive group throughout the follow-up period. This finding is likely related to both the minimally invasive cavity preparation techniques employed and the sealing properties of the bioactive materials. Preservation of affected but remineralizable dentin, combined with improved interfacial sealing, may reduce dentinal fluid movement and subsequent sensitivity. These results align with previous studies reporting reduced sensitivity associated with minimally invasive restorative protocols and bioactive material use.

Restoration survival analysis demonstrated a significantly higher cumulative survival rate in the experimental group. Multivariate regression analysis confirmed that the risk-based minimally invasive approach incorporating bioactive materials was an independent predictor of restoration success, even after adjusting for baseline caries risk and other confounding factors. This highlights the importance of treatment philosophy and material selection beyond traditional mechanical considerations.

Despite the strengths of the present study, certain limitations should be acknowledged. The follow-up period of 24 months, although adequate to assess early and mid-term outcomes, may not fully capture long-term restoration performance. Additionally, operator blinding was not feasible due to the distinct handling characteristics of the restorative materials, which may introduce performance bias. Nevertheless, the use of blinded outcome assessors, standardized clinical protocols, and validated evaluation criteria minimized potential sources of bias.

Future research should focus on long-term randomized controlled trials with extended follow-up periods to confirm the durability of the observed benefits. Incorporating microbiological assessments and quantitative caries risk biomarkers

may further elucidate the biological mechanisms underlying the effectiveness of risk-based minimally invasive strategies combined with bioactive materials. Moreover, evaluating patient-reported outcomes and cost-effectiveness could enhance the clinical applicability of this approach.

Conclusion

Within the limitations of this randomized controlled clinical trial, the findings indicate that a risk-based minimally invasive caries management approach incorporating bioactive restorative materials is more effective than conventional restorative strategies in controlling caries recurrence and improving overall restoration performance. The integration of individualized caries risk assessment with minimally invasive operative techniques and bioactive materials resulted in a significantly lower incidence of caries recurrence, improved marginal integrity, reduced postoperative sensitivity, and higher restoration survival rates over a 24-month follow-up period.

The results underscore the importance of addressing dental caries as a biologically driven and patient-specific disease rather than a purely structural defect. Bioactive restorative materials, through their capacity to release therapeutic ions and interact dynamically with the oral environment, appear to enhance the tooth–restoration interface and contribute to a more stable biological seal. When combined with risk-based clinical decision-making, these materials offer clear advantages in long-term caries control and tooth preservation.

From a clinical standpoint, the adoption of risk-based minimally invasive strategies supported by bioactive restorative materials may reduce the need for restoration replacement, limit unnecessary removal of sound tooth structure, and improve patient-centered outcomes. This approach aligns with contemporary principles of minimally invasive dentistry and evidence-based caries management.

Nevertheless, further long-term randomized controlled trials with extended follow-up periods are required to confirm the durability of these outcomes and to refine clinical guidelines for the routine use of bioactive materials within risk-based

caries management protocols. Future studies incorporating microbiological, salivary, and patient-reported outcome measures may provide additional insight into the biological mechanisms and clinical benefits of this integrative approach.

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