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EFFICACY OF BIOACTIVE RESTORATIVE MATERIALS IN THE TREATMENT OF DEEP CARIOUS LESIONS: A COMPARATIVE CLINICAL STUDY

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ABSTRACT

Background: Deep carious lesions represent a significant clinical challenge in restorative dentistry, requiring materials that not only seal the cavity but also promote pulp protection and dentin remineralization. Bioactive restorative materials have emerged as promising alternatives to conventional resins due to their ion-releasing and antimicrobial properties.

Objective: This study aimed to compare the clinical performance of three bioactive restorative materials — resin-modified glass ionomer cement (RMGIC), calcium silicate-based cement (CSC), and conventional composite resin — in the treatment of deep carious lesions over a 12-month follow-up period.

Methods: A total of 90 patients (mean age 28.4 ± 6.7 years) with deep carious lesions (radiographic depth ≥ 2/3 of dentin) were randomly allocated into three treatment groups (n=30 each). Clinical outcomes were assessed at baseline, 3, 6, and 12 months using the USPHS/Ryge criteria. Outcomes included postoperative sensitivity, marginal adaptation, secondary caries, and pulp vitality.

Results: At 12 months, calcium silicate-based cement demonstrated superior pulp protection (93.3% success) and significantly lower rates of postoperative sensitivity compared to RMGIC (86.7%) and composite resin (76.7%). Marginal adaptation was highest in the composite group initially but declined over time. No secondary caries were detected in the CSC group. Statistical significance was established at $p < 0.05$.

Conclusion: Calcium silicate-based bioactive cements show superior biological compatibility and remineralizing capacity in deep carious lesion management and may be considered the material of choice in such clinical scenarios.

Keywords: bioactive restorative materials, deep caries, calcium silicate cement, glass ionomer cement, pulp protection, remineralization, dentin

1. INTRODUCTION

Dental caries remains one of the most prevalent chronic diseases worldwide, affecting an estimated 2.5 billion individuals globally. Among the spectrum of carious presentations, deep carious lesions — defined as those extending to the inner third of dentin — pose a unique diagnostic and therapeutic dilemma. The proximity of the carious process to the dental pulp necessitates materials that fulfil both mechanical and biological functions, specifically those capable of stimulating tertiary dentinogenesis while providing an adequate seal against microbial ingress.

Conventional composite resins, despite their superior aesthetic properties and mechanical strength, are inherently biologically inert and demonstrate limited capacity to interact with residual carious dentin. In contrast, bioactive restorative materials — a category encompassing glass ionomer cements (GICs), resin-modified glass ionomer cements (RMGICs), and more recently, calcium silicate-based cements (CSCs) — release ions such as calcium, phosphate, and fluoride that actively promote remineralization of adjacent dentin and suppress residual bacterial activity.

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Calcium silicate-based cements, including Biodentine (Septodont, France) and mineral trioxide aggregate (MTA), have demonstrated remarkable biocompatibility and the ability to induce reparative dentin bridge formation. These materials stimulate the differentiation of odontoblast-like cells and upregulate the expression of dentinogenic proteins such as dentin sialoprotein (DSP) and dentin matrix protein-1 (DMP-1). Clinical evidence supporting their use as dentine substitutes in deep carious lesions is accumulating, yet direct comparative trials with other bioactive materials under standardized clinical conditions remain limited.

This study was designed to evaluate and compare the 12-month clinical performance of RMGIC, CSC, and conventional nanohybrid composite resin in patients presenting with deep carious lesions, using internationally validated clinical criteria. The findings are intended to provide evidence-based guidance for the selection of restorative materials in complex carious scenarios encountered in routine therapeutic dentistry practice.

2. MATERIALS AND METHODS

2.1. Study Design and Ethical Approval. This prospective, single-blind randomized controlled trial was conducted at the Department of Therapeutic Dentistry, Tashkent State Dental Institute, between January 2023 and January 2024. The study protocol was reviewed and approved by the institutional ethics committee (Protocol No. 14/2023). All participants provided written informed consent prior to enrollment. The trial was conducted in accordance with the Declaration of Helsinki (revised 2013).

2.2. Patient Selection. Inclusion criteria comprised adult patients (18–45 years) with at least one mandibular or maxillary molar presenting a deep carious lesion (radiographic depth ≥ 2/3 of dentin without pulp involvement), confirmed by periapical radiography and cold sensitivity testing. Exclusion criteria included patients with systemic diseases, those undergoing antibiotic therapy, pregnant or lactating women, teeth with signs of irreversible pulpitis or periapical pathology, and patients with known allergies to dental materials.

2.3. Treatment Protocol. Following rubber dam isolation and local anaesthesia, standardized caries excavation was performed using slow-speed steel burs and hand excavators to remove infected dentin while preserving affected dentin over the pulp. Patients were randomly assigned to one of three groups: Group I received RMGIC (Fuji II LC, GC Corporation, Japan); Group II received calcium silicate-based cement (Biodentine, Septodont, France); and Group III received nanohybrid composite resin (Filtek Z250 XT, 3M ESPE, USA) with selective dentin bonding (Scotchbond Universal Adhesive). All restorations were placed by a single calibrated operator to minimize inter-operator variability.

2.4. Clinical Evaluation. Restorations were assessed at 3, 6, and 12 months using the modified USPHS/Ryge criteria by a blinded examiner. Parameters evaluated included postoperative sensitivity (none/mild/severe), marginal adaptation (Alpha/Bravo/Charlie), marginal discoloration, secondary caries, and pulp vitality (electric pulp test and periapical radiography). Statistical analysis was performed using SPSS v.26.0; chi-square and Kruskal-Wallis tests were applied. Significance level was set at $p < 0.05$.

3. RESULTS

3.1. Postoperative Sensitivity. At 12 months, the CSC group recorded the lowest incidence of postoperative sensitivity (6.7%), compared to RMGIC (13.3%) and composite resin (23.3%). The difference between CSC and composite groups was statistically significant ($p = 0.031$). Sensitivity in the composite group was predominantly reported as mild and transient in the early follow-up periods, with two cases of severe persistent sensitivity at 6 months requiring endodontic intervention.

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3.2. Marginal Adaptation and Discoloration. Composite resin restorations demonstrated superior marginal adaptation scores (Alpha rating: 93.3%) at 3-month recall; however, a progressive decline was observed at 12 months (Alpha: 76.7%). RMGIC maintained stable marginal adaptation throughout (Alpha: 80.0% at 12 months). CSC restorations showed comparatively lower initial adaptation scores but stable long-term performance. Marginal discoloration was highest in the RMGIC group (16.7% at 12 months).

3.3. Secondary Caries and Pulp Vitality. No secondary caries were detected in any group during the 12-month observation period. Pulp vitality was maintained in 93.3% of CSC cases, 86.7% of RMGIC cases, and 76.7% of composite cases. Three cases in the composite group and two in the RMGIC group required endodontic treatment due to irreversible pulpitis. The superiority of CSC in pulp vitality preservation was statistically significant ($p = 0.042$).

4. DISCUSSION

The results of this study corroborate the growing body of evidence supporting calcium silicate-based cements as biologically superior restorative materials for deep carious lesion management. The significantly higher pulp vitality preservation rate observed in the CSC group is consistent with the established mechanism of action of calcium silicate hydrates, which create an alkaline microenvironment conducive to reparative dentin formation and inhibitory to residual bacterial activity.

The bioactivity of Biodentine is mediated through the release of calcium ions that stimulate the TGF-β1 signalling pathway, promoting odontoblast differentiation and tertiary dentinogenesis. This mechanism, documented by Laurent et al. (2012) and Zanini et al. (2012), distinguishes CSCs from both RMGIC and composite resin, neither of which exerts a direct cellular effect on the pulp-dentin complex.

RMGIC, while demonstrating adequate clinical performance, exhibited higher rates of postoperative sensitivity and marginal discoloration compared to CSC. These findings are attributable to the hygroscopic expansion characteristic of glass ionomer matrices, which may cause internal stresses within the restoration-dentin interface over time. Nevertheless, the fluoride-releasing properties of RMGIC remain clinically relevant in caries-active patients, a factor not accounted for in the present study.

The higher incidence of pulpal complications in the composite resin group highlights the limitations of inert restorative materials in deep cavities where the smear layer and adhesive interface represent the sole biological barrier between the restoration and the pulp. Despite superior initial marginal adaptation, the biological inertness of composite resin renders it less suitable as a standalone restorative solution in high-risk deep cavities without additional pulp-protective liners.

Limitations of the present study include the relatively short follow-up period of 12 months, the exclusion of micro-CT analysis for three-dimensional assessment of marginal gap formation, and the single-centre design. Future multi-centre randomized controlled trials with extended follow-up periods and biomarker analysis of pulpal inflammatory response are warranted.

5. CONCLUSION

This comparative clinical study demonstrates that calcium silicate-based cement (Biodentine) provides superior pulp protection, lower postoperative sensitivity, and stable long-term marginal adaptation in the management of deep carious lesions compared to RMGIC and conventional composite resin over a 12-month follow-up. Bioactive restorative materials, particularly CSCs, should be considered as the primary restorative option in clinical situations involving deep carious lesions with confirmed pulp vitality. Further long-term evidence from multi-centre trials is necessary to consolidate these findings.

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