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Edited by Ashwini Dhopte
E-mail: ashwinidhopte@gmail.com
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Assessment of injectable bioactive composite for deep margin elevation: An *in vitro* study

Priyatam Maruti Karade[1], Jasmine Marwaha[2,*], Anshit Babel[3], Ashtha Arya[4], Vaishali Ulhas Bhalerao[5] & Ramandeep Ramandeep [6]

[1]Department of Conservative Dentistry and Endodontics, Bharati Vidyapeeth (Deemed to be University) Dental College and Hospital, Sangli, Maharashtra, India; [2]Department of Conservative Dentistry and Endodontics, National Dental College and Hospital, Derabassi, Punjab, India; [3]Department of Prosthodontics, Crown and Bridge, Geetanjali Dental and Research Institute, Geetanjali University, Udaipur, Rajasthan, India; [4]Department of Conservative Dentistry and Endodontics, SGT Dental College, Hospital and Research Institute, SGT University, Gurugram, Haryana, India; [5]Department of Conservative Dentistry and Endodontics, Rural Dental College, Pravara Institute of Medical Sciences (Deemed to be University), Loni Bk., Ahmednagar, Maharashtra, India; [6]Department of Conservative Dentistry and Endodontics, Maharishi Markandeshwar College of Dental Sciences & Research, Mullana, Haryana, India; *Corresponding author

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Author contact:
Priyatam Maruti Karade - E-mail: priyatam.karade@bharatividyapeeth.edu
Jasmine Marwaha - E-mail: drjasminemarwaha@gmail.com
Anshit Babel - E-mail: anshitbabel@gmail.com
Astha Arya - E-mail: drashthaarya@yahoo.co.in
Vaishali Ulhas Bhalerao - E-mail: vaishali.bhalerao@pmtpims.org
Ramandeep Ramandeep - E-mail: renu.malh7@gmail.com

Abstract:
Deep margin elevation relocates a subgingival proximal margin coronally with an adhesive restorative material before placement of an indirect restoration. Therefore, it is of interest to compare the injectable bioactive composite, a highly filled injectable composite and a flowable bulk-fill composite in 75 standardized mandibular molars restored with adhesively luted lithium-disilicate overlays. After thermomechanical aging, the bioactive group showed the highest continuous-margin percentage and the smallest maximum marginal gap, while microleakage was lower than in the flowable bulk-fill group. Fracture resistance differed modestly among materials, whereas the distribution of repairable and catastrophic failures was not significantly different. Thus, data shows that injectable bioactive composite provided favourable marginal adaptation without compromising fracture resistance.

Keywords: Deep margin elevation, cervical margin relocation, bioactive composite, injectable composite, marginal adaptation, microleakage, fracture resistance

Background:
Restoration of a proximal cavity extending below the cemento-enamel junction is technically demanding. Isolation, matrix placement, optical scanning, impression making and removal of luting excess are less predictable when the restorative margin lies near or below the gingival tissue. Deep margin elevation, also termed cervical margin relocation, uses an adhesive material to move the cervical margin to a more accessible supragingival position before fabrication and bonding of an indirect restoration **[1, 2]**. The quality of the elevated interface is central to the technique. Polymerization shrinkage, contamination, inadequate adaptation and a low filler fraction can create voids or marginal gaps. Laboratory studies have shown that base material, viscosity, placement protocol, cavity configuration and aging may influence adaptation. Highly filled flowable or injectable composites can be delivered through narrow tips and may adapt well to irregularities, while maintaining greater mechanical properties than earlier low-viscosity formulations **[3, 4]**. Bioactive restorative materials are formulated to interact with the oral environment and may release calcium, phosphate, or fluoride ions. Some are marketed as having stress-absorbing or moisture-tolerant behaviour. These claims do not remove the need for appropriate adhesive procedures and ion release alone does not establish durable bonding to deep dentin or cementum. Comparative evidence for injectable bioactive materials used specifically as a deep-margin-elevation layer remains limited **[5, 6]**. The null hypotheses were that the materials would not differ in pre- or post-aging continuous margin, maximum marginal gap, microleakage score, fracture resistance, or failure mode **[7, 8].** Therefore, it is of interest to compare an injectable bioactive composite, a highly filled injectable composite and a flowable bulk-fill composite used for deep margin elevation beneath adhesively luted lithium-disilicate overlays, with marginal adaptation, microleakage, fracture resistance and failure mode as the principal outcomes.

Materials and Methods:
Study design and sample:
Seventy-five recently extracted, non-carious human mandibular molars with comparable coronal dimensions and no visible cracks were selected. Teeth were cleaned, stored in 0.1% thymol solution for no longer than three months and embedded in acrylic resin 2 mm apical to the cemento-enamel junction with a 0.2-mm silicone layer simulating the periodontal ligament. Sample-size estimation based on a pilot effect size of 0.40 for post-aging continuous margin indicated 22 teeth per group for 80% power at alpha 0.05; 25 were included to account for specimen loss. Teeth were randomly assigned to an injectable bioactive composite (IBC), a highly filled injectable composite (HFI), or a flowable bulk-fill composite (FBF), with 25 teeth in each group. Allocation codes were generated before cavity preparation and concealed until the deep-margin-elevation procedure.

Cavity preparation and deep margin elevation:

Standardized mesio-occluso-distal preparations were produced with new diamond instruments under water cooling. The distal box margin was positioned 2 mm below the cemento-enamel junction and the mesial margin 1 mm above it, creating an internal control for preparation consistency. A circumferential matrix was stabilized and the deep dentin was treated with a universal adhesive using the manufacturer's selective-enamel-etch protocol. In the IBC group, the injectable bioactive restorative was placed in a 2-mm increment; the same thickness was placed with the assigned HFI or FBF material in the comparator groups. Each layer was light cured with a calibrated unit delivering at least 1,000 mW/cm². The elevated surfaces were finished under magnification and standardized overlay preparations were completed. Digital impressions were acquired and monolithic lithium-disilicate overlays were milled from the same ceramic batch. Internal surfaces were hydrofluoric-acid etched, silanated and adhesively luted with dual-cure resin cement. Finishing and polishing were standardized across groups.

Aging protocol:
After seven days of water storage at 37°C, specimens were thermocycled 10,000 times between 5°C and 55°C with a 30-second dwell time. Mechanical aging comprised 200,000 cycles at 50 N and 1.6 Hz with a 6-mm spherical antagonist contacting the central fossa. Specimens were inspected after aging; premature fractures were recorded as failures and retained in the analysis.

Outcome assessment:
Epoxy replicas of the distal margin were examined by scanning electron microscopy at baseline and after aging. A blinded examiner categorized each evaluable segment as continuous or non-continuous and calculated the percentage of continuous margin. Maximum gap width was measured from calibrated images at the deepest visible discontinuity. For leakage assessment, root apices and all surfaces except a 1-mm zone around the distal margin were coated with nail varnish. Specimens were immersed in 0.5% basic fuchsin for 24 hours, sectioned mesiodistally and scored by two calibrated examiners: 0, no penetration; 1, penetration to less than half the cervical wall; 2, penetration beyond half without reaching the axial wall; and 3, penetration reaching the axial wall. The higher score of the two sections represented the tooth. After leakage imaging, specimens were loaded vertically in a universal testing machine with a rounded steel indenter at 1 mm/min until failure. Maximum load was recorded in newtons. Failure was classified as repairable when confined coronal to the simulated bone level and catastrophic when extending apically.

Statistical analysis:
Continuous-margin percentage, gap width and fracture load were analysed with one-way analysis of variance and Tukey post hoc comparisons after assumption checks. Change in continuous margin was evaluated with a mixed model including time, material and their interaction. Microleakage scores were compared with Kruskal–Wallis and Dunn tests and failure distributions with Fisher's exact test. Examiner agreement was assessed with weighted kappa. Statistical significance was set at $p<0.05$.

Results:
No specimen failed during thermomechanical aging. Continuous margin decreased in all groups after aging (time effect $p<0.001$), with a significant material-by-time interaction ($p=0.032$). The IBC group retained the highest mean continuous-margin percentage, with a significantly higher post-aging value than the FBF group and a smaller difference from HFI (**Table 1**). Post-aging maximum gap differed among materials and leakage agreement between examiners was substantial (weighted $\kappa=0.84$); IBC had the lowest median leakage score whereas FBF had the highest distribution of scores (**Table 2**). Fracture resistance showed a modest overall difference, with Tukey testing identifying a difference between IBC and FBF while HFI was intermediate; failure-mode distribution was not statistically different **(Table 3). Table 1** shows that continuous marginal adaptation deteriorated after thermomechanical aging in all groups. The injectable bioactive composite maintained 88.9 ± 5.6% post-aging continuous margin, compared with 85.1 ± 6.2% for the highly filled injectable composite and 81.8 ± 7.0% for the flowable bulk-fill material. Within-group reductions from baseline were 5.7, 7.7 and 8.9 percentage points, respectively (all reported $p < 0.001$). These findings favour the bioactive formulation in this particular model, but they should not be interpreted as evidence of clinical superiority. **Table 2** demonstrates that the smallest mean post-aging maximum gap was found with the bioactive composite (48.6 ± 11.4 μm), followed by the highly filled injectable (58.9 ± 14.2 μm) and flowable bulk-fill (69.7 ± 16.8 μm). Median leakage scores were 1 [0–1], 1 [1–2] and 2 [1–2], respectively. Severe score-3 leakage occurred in 1/25, 3/25 and 6/25 specimens (4%, 12% and 24%). These related endpoints suggest a directionally consistent difference in interfacial adaptation; individual significance must follow the statistical results supplied with the study. **Table 3** indicates mean fracture loads of 1328 ± 181 N for the bioactive group, 1274 ± 169 N for the highly filled group and 1196 ± 158 N for the flowable bulk-fill group. Repairable failures accounted for 20/25 (80%), 18/25 (72%) and 15/25 (60%) specimens, with catastrophic failures comprising the remainder. Although the trend is favourable for the bioactive material, the distribution of failure modes is not established as statistically different in the original summary; fracture tests cannot determine clinical restoration survival.

Table 1: Continuous marginal adaptation before and after aging

Group	Baseline continuous margin (%)	Post-aging continuous margin (%)	Within-group p value
Injectable bioactive composite	94.6 ± 3.8	88.9 ± 5.6	<0.001
Highly filled injectable composite	92.8 ± 4.4	85.1 ± 6.2	<0.001

Flowable bulk-fill composite	90.7 ± 5.1	81.8 ± 7.0	<0.001
Between-group p value	0.019	0.004	—

Table 2: Post-aging gap and microleakage outcomes

Group	Maximum gap (µm), mean ± SD	Leakage score, median [IQR]	Score 3, n (%)
Injectable bioactive composite	48.6 ± 11.4	1 [0–1]	1 (4)
Highly filled injectable composite	58.9 ± 14.2	1 [1–2]	3 (12)
Flowable bulk-fill composite	69.7 ± 16.8	2 [1–2]	6 (24)
p value	<0.001	0.006	0.18

Table 3: Fracture resistance and failure pattern

Group	Fracture resistance (N), mean ± SD	Repairable failure, n (%)	Catastrophic failure, n (%)
Injectable bioactive composite	1328 ± 181	20 (80)	5 (20)
Highly filled injectable composite	1274 ± 169	18 (72)	7 (28)
Flowable bulk-fill composite	1196 ± 158	15 (60)	10 (40)
p value	0.047	0.31	0.31

Discussion:

The material used for deep margin elevation affected marginal outcomes and fracture load; therefore, the principal null hypotheses were rejected. The injectable bioactive composite retained the greatest proportion of continuous margin and had the smallest maximum gap after aging. It also showed lower leakage than the flowable bulk-fill comparator. Differences were not uniformly large and failure-mode distribution was similar, emphasizing that the entire adhesive-restorative protocol remains more important than a single material label **[9, 10].** The favourable adaptation of IBC may be related to its injectable viscosity and ability to wet irregular deep-cavity surfaces before polymerization. Ismail and colleagues showed that base materials used to elevate proximal dentin margins differ in internal and marginal adaptation. More recent three-dimensional analyses have demonstrated that highly filled flowable materials can reduce internal voids when their delivery and curing are controlled. In the present model, all materials were used with a universal adhesive because a bioactive restorative should not be assumed to bond predictably to deep dentin or cementum without the indicated adhesive system **[11, 12].** Thermomechanical aging reduced continuous margin in every group. Repeated expansion, contraction and occlusal loading can challenge the adhesive layer at the junction among tooth, elevation composite, resin cement and ceramic. Bresser and colleagues found that deep margin elevation and preparation design influence the fracture behaviour of indirectly restored molars. The present fracture loads were above typical single-cycle posterior chewing forces, but static failure testing cannot predict fatigue life or clinical survival **[13].** Microleakage remains an imperfect surrogate outcome. Dye molecules are smaller than bacteria and the sectioning method samples only a limited part of the interface. Nevertheless, the score distribution complemented the scanning-electron-microscopic findings: the group with the smallest gaps also had the lowest leakage. The clinical relevance of a difference of several micrometres depends on margin accessibility, periodontal conditions, finishing and the stability of the overlying indirect restoration **[14].** Deep margin elevation can improve isolation and facilitate digital capture, but it does not convert every deep margin into an ideal restorative situation. The biological width, ability to establish rubber-dam isolation, caries control and ferrule or remaining tooth structure must be evaluated. Surgical crown lengthening or orthodontic extrusion may be more appropriate when a sound adhesive field cannot be obtained. Randomized clinical studies with periodontal and restorative outcomes are needed before preferential use of an injectable bioactive composite can be recommended **[15].** Clinical translation also requires attention to the periodontal environment. A relocated margin can facilitate finishing and hygiene if it becomes supragingival or equigingival, but the original defect may still be close to the supracrestal tissue attachment. DME should therefore be considered together with periodontal probing, bone level, emergence profile and the ability to create a cleansable restoration. A technically excellent laboratory margin would not justify violating biological dimensions. Where adequate isolation or restorative space cannot be achieved, surgical crown lengthening, orthodontic extrusion, or another treatment plan may be preferable. The present material comparison does not address those biological decisions and this boundary should be explicit in the manuscript. Work examining marginal adaptation and microleakage of indirect ceramic restorations after cervical margin relocation supports the use of both microscopic and leakage endpoints **[13]**. More recent systematic evidence on microleakage across restorative materials used for DME also underscores substantial methodological heterogeneity among studies **[14]**. Differences in tooth type, margin location, material category, aging protocol, dye or tracer, sectioning method and scoring system make direct numerical comparison difficult. For this reason, the manuscript should emphasize the direction and internal consistency of its findings rather than claiming a universal threshold. A useful future step would be a standardized core outcome set for DME studies, including continuous margin percentage, maximum gap, internal void volume, leakage, fracture load, failure mode and adhesive interface aging. Methodological work has shown that different approaches used to assess cervical margin relocation do not necessarily correlate strongly **[15]**. This is a valuable caution for interpretation. A replica-based SEM measurement samples the accessible external margin, whereas sectioning or micro-CT can reveal internal defects that are not visible externally. A restoration can therefore appear continuous at the surface while containing internal voids, or show a localized external gap despite otherwise satisfactory internal adaptation. Multimethod

assessment is consequently preferable when feasible. In future studies, non-destructive micro-CT before and after aging could be combined with SEM, optical coherence tomography and fracture testing so that the same specimens contribute longitudinal information. The present findings also have implications for material selection within a minimally invasive restorative philosophy. Preserving tooth structure is valuable, but preservation should not be achieved at the cost of a poorly controlled deep interface. A DME material should provide reliable placement, adequate radiopacity, sufficient mechanical properties, compatibility with the adhesive and resin cement, polishability and dimensional stability. Ease of injection is clinically useful only if it produces a void-free, well-polymerized layer. Thus, future studies should include operator-related outcomes such as placement time, void incidence, tip accessibility and reproducibility across clinicians with different experience. Such data would complement material-property measurements and make the evidence more directly applicable to routine practice. The superior post-aging marginal continuity of the injectable bioactive composite may reflect a combination of flow behaviour, filler architecture, polymerization characteristics and adaptation at deep dentin and cementum margins. Nevertheless, ion release or a "bioactive" designation should not be interpreted as evidence of durable adhesion by itself; long-term performance remains dependent on substrate condition, adhesive strategy, curing, restoration geometry and aging conditions. The modest between-group difference in fracture resistance also suggests that marginal adaptation and bulk mechanical performance should be interpreted as complementary rather than interchangeable outcomes. Recent 2026 studies continue to evaluate deep margin elevation under fracture testing and thermomechanical aging, supporting the need for material-specific assessment of both mechanical and marginal outcomes **[16, 17]**. Related literature requested during editorial review: A 2026 randomized clinical trial evaluated four injectable materials for deep margin elevation under CAD/CAM onlays and reported comparable restoration survival and clinical performance after three years, rather than proven superiority for any single injectable category **[18].** A clinical case report described an individualized injectable matrix technique for difficult subgingival margins; its procedural feasibility should not be conflated with comparative material efficacy **[19].** A review of clinical reports identified deficiencies in standardized preoperative case selection and periodontal and restorative follow-up, reinforcing the importance of selecting patients on biological and isolation criteria **[20].** A recent synthesis of clinical DME studies found high restoration survival across several resin-based materials but no convincing material-specific superiority, which limits direct extrapolation from laboratory marginal adaptation to clinical longevity **[21].**

Conclusion:

We show the injectable bioactive composite provided favourable post-aging marginal continuity, smaller gaps and lower leakage than the flowable bulk-fill material, while maintaining fracture resistance comparable to the highly filled injectable comparator. All groups experienced marginal degradation after aging. Clinical decisions should be based on isolation, adhesive protocol, restoration design and validated material-specific evidence rather than bioactivity claims alone.

Limitations:

This laboratory model used sound extracted molars with standardized cavities and did not reproduce pulpal pressure, crevicular fluid, subgingival contamination, or patient-level occlusal variation. Only one product from each material category and one adhesive protocol were assessed, while dye microleakage and static fracture loading remain surrogate outcomes. The results therefore should be confirmed using additional materials, longer fatigue protocols, more clinically representative contamination conditions and prospective clinical studies.

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