Official Title of the Study:

Graphene-Reinforced CAD/CAM Restorations for MIH-Affected Molars in Adolescents: A Prospective Clinical Study

NCT Number:

NCT: Not yet assigned

Document Type:

Study Protocol

Document Date:

December 11th, 2025

Version:

3.0

Sponsor:

Universitat Internacional de Catalunya (UIC)

Study Sites:

Universitat Internacional de Catalunya — Department of Restorative Dentistry

University of Barcelona

1. BACKGROUND AND SCIENTIFIC RATIONALE

Molar–Incisor Hypomineralization (MIH) is a qualitative enamel defect affecting 10–20% of European children. MIH molars show porosity, post-eruptive breakdown, and hypersensitivity, reducing the predictability of conventional restorative treatments. Current therapy options—composites, resin-modified glass ionomers, stainless-steel crowns—face limitations such as polymerization shrinkage, marginal degradation, and short service life.

Advances in nanotechnology have introduced graphene-based biomaterials featuring high flexural strength (>180 MPa), biocompatibility, and favorable esthetics. Graphene-reinforced CAD/CAM polymers (e.g., G-CAM®) permit minimally invasive adhesive restorations that may improve outcomes in MIH-affected posterior teeth.

This study prospectively evaluates the 12-month clinical performance of graphene-reinforced CAD/CAM indirect restorations in adolescent MIH patients.

2. STUDY OBJECTIVES AND HYPOTHESIS

Primary Hypothesis

Graphene-reinforced CAD/CAM indirect restorations provide high clinical acceptability at 12 months, according to predefined FDI criteria, while reducing postoperative hypersensitivity relative to baseline and preserving structural tooth integrity.

Primary Objective

Evaluate the overall clinical performance of graphene-reinforced CAD/CAM inlays/onlays/overlays in MIH-affected molars at 12 months.

Secondary Objectives

• Assess FDI domain scores: marginal integrity, surface roughness, color stability, fractures, proximal contacts, occlusion/function, and soft-tissue response.
• Measure postoperative sensitivity using VAS.
• Assess patient-reported satisfaction.
• Evaluate structural preservation via pre/post 3D scans.
• Measure restoration survival (Kaplan–Meier).
• Assess workflow efficiency (chair time, need for adjustments).

3. STUDY DESIGN

A **prospective, single-arm, monocentric, interventional clinical study** with 12-month follow-up.
Number of participants: 30 adolescents (10–16 years old).
Study duration: 18 months.

Follow-up: Baseline, 48 h, 1 m, 3 m, 6 m, 12 m.

4. STUDY POPULATION

Inclusion Criteria

• Adolescents aged 10–16.

• Permanent molars with moderate/severe MIH (EAPD).

• Vital, restorable teeth.

• Ability to attend follow-ups.• Informed consent + minor assent.

Exclusion Criteria

• Fluorosis, amelogenesis imperfecta, other enamel anomalies.

• Severe bruxism.

• Extensive active caries or irreversible pulpitis.

• Systemic diseases affecting enamel/healing.

• Allergy to dental materials.

• Analgesics/AINE <24 h before baseline sensitivity assessment.

5. STUDY INTERVENTION

All participants undergo:

1. Baseline diagnostics and imaging
2. Minimally invasive cavity preparation
3. Composite base build-up if required
4. CAD/CAM fabrication of graphene-reinforced polymer inlay/onlay/overlay
5. Adhesive cementation under rubber dam
6. Finishing and occlusal evaluation

Material used: **Graphene-reinforced CAD/CAM polymer block (G-CAM®)**

6. OUTCOME MEASURES

Primary Outcomes

1. FDI Global Acceptability (Success = all domains ≤3) at 12 months

2. Postoperative sensitivity (VAS 0–10) at baseline, 48 h, 1, 3, 6, 12 months

Secondary Outcomes

• Patient satisfaction (Likert 1–5)

• Structural preservation (volumetric analysis of 3D scans)

• Vitality retention

• Restoration survival (Kaplan–Meier)
• Workflow efficiency (chair time, adjustments)

7. SAFETY AND ADVERSE EVENTS

Adverse events include:
• Persistent pain >72 h
• Severe hypersensitivity (VAS ≥7)
• Soft-tissue inflammation
• Partial or total restoration failure
• Complications requiring reintervention

8. DATA COLLECTION AND MANAGEMENT

• Standardized photos and 3D scans at baseline and follow-up.
• Pseudonymized data stored on encrypted servers at Dental Esthetic BCN, GDPR compliant.
• Data preserved 15 years, then securely destroyed.• Investigator and promoter maintain separate encrypted linkage file.

9. STATISTICAL ANALYSIS PLAN (SAP)

Sample Size

30 participants (27 required for detecting a ≥2-point VAS reduction; β=0.80, α=0.05).

Analysis Methods

Descriptive Statistics

Mean ± SD, median [IQR], and proportions.

Primary Analyses

• FDI scores (ordinal):
Friedman repeated-measures test + Holm correction
or ordinal mixed-effects model (time = fixed, participant = random)
• VAS sensitivity (continuous):
Linear mixed-effects model
or repeated-measures ANOVA (Greenhouse-Geisser correction)

Survival Analysis

• Kaplan–Meier survival curve
• Failure = debonding or fracture requiring replacement

Performance Threshold Tests

• FDI success proportion at 12 months with 95% CI
• One-sample binomial test vs threshold ≥80%
• Mean VAS reduction ≥2 points with CI>0

Missing Data

• Missing-at-random assumption
• Mixed models inherently robust; no imputation planned

Interim Analysis

None planned.

10. ETHICAL CONSIDERATIONS

• Conducted under the Declaration of Helsinki and GDPR.
• CEIm HOUB approval granted (protocol version 3.0).
• Informed consent from guardian + patient assent.
• No biological samples collected.
• Minimal risk: all materials CE-marked and used in routine care.

11. ADMINISTRATIVE INFORMATION

Study Site:
Dental Esthetic BCN
Funding:
Self-funded (material costs detailed in protocol).