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

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Study Protocol – Informed Consent Form

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Universitat Internacional de Catalunya (UIC)

Study Sites:

Universitat Internacional de Catalunya — Department of Restorative Dentistry

University of Barcelona

1. Introduction

You are being invited to participate in a clinical research study because you (or your child/ward) have been diagnosed with molar–incisor hypomineralization (MIH) affecting permanent molars. Before you decide whether to participate, it is important that you understand why the research is being conducted and what it will involve. Please take time to read the following information carefully.

If anything is unclear or if you would like more information, please ask the investigator or the dental team.

2. Purpose of the Study

The purpose of this study is to evaluate the clinical performance of a graphene-reinforced CAD/CAM polymer material (G-CAM®) used for indirect restorations (inlays, onlays, or overlays) in permanent molars affected by MIH. The study aims to assess the restoration's durability, clinical behavior, and patient comfort over time.

3. Study Procedures

If you agree to participate, the following procedures will be performed:

- Clinical and radiographic examination of the affected tooth/teeth.
- Digital intraoral scanning of the tooth.
- Fabrication of an indirect restoration using CAD/CAM technology.
- Adhesive cementation of the restoration under rubber dam isolation.
- Follow-up visits for clinical evaluation according to the study protocol.

All procedures included in this study are part of standard restorative dental care.

4. Duration of Participation

Participation in the study will involve the restorative treatment appointment and scheduled follow-up visits over the observation period defined in the protocol. The total duration of participation will be explained by the investigator.

5. Potential Benefits

Possible benefits of participating in this study include:

- Restoration of the affected tooth with a modern CAD/CAM material.

- Improvement in tooth function, comfort, and aesthetics.
- Close clinical monitoring during the follow-up period.

However, no guarantee can be made that participation will provide direct benefit.

6. Potential Risks and Discomforts

The risks associated with this study are minimal and similar to those of routine restorative dental treatment. These may include:

- Temporary tooth sensitivity
- Discomfort during or after the procedure
- Risk of restoration failure or need for replacement

No additional risks beyond standard dental care are anticipated.

7. Alternatives to Participation

Participation in this study is voluntary. Alternative treatment options include conventional restorative materials and procedures, which will be explained by your dentist.

8. Voluntary Participation and Right to Withdraw

Participation in this study is entirely voluntary. You may refuse to participate or withdraw from the study at any time without any penalty or loss of benefits to which you are otherwise entitled.

9. Confidentiality

All information collected during the study will be kept confidential in accordance with applicable data protection laws. Participants will be identified by a study code, and no personally identifiable information will be disclosed in publications or presentations.

10. Compensation and Costs

Participation in the study will not involve additional costs beyond standard dental treatment. No financial compensation is provided for participation.

11. Ethics Approval

This study has been reviewed and approved by the appropriate Ethics Committee. The study will be conducted in accordance with the Declaration of Helsinki and applicable regulations.

12. Contact Information

If you have any questions about the study or your rights as a participant, please contact:

Principal Investigator: _____
Institution: Universitat Internacional de Catalunya (UIC)
Email: _____
Phone: _____

13. Consent Statement

I have read and understood the information provided above. I have had the opportunity to ask questions and have received satisfactory answers. I voluntarily agree to participate in this study.

If the participant is a minor, consent is provided by a parent or legal guardian.

Participant Name: _____

Signature: _____

Date: _____

Parent/Legal Guardian Name (if applicable): _____

Signature: _____

Date: _____

Investigator Name: _____

Signature: _____

Date: _____