## Official Title of the Study:

Comparative Clinical Evaluation of Partial Coverage CAD/CAM Restoration Versus Nanohybrid Composite of Carious Hypomineralized Permanent Molars: A Randomized Controlled Trial

**NCT Number:** Not yet assigned

**Date of the Document:** December 2023

# Comparative Clinical Evaluation of Partial Coverage CAD/CAM Restoration Versus Nanohybrid Composite of Carious Hypomineralized Permanent Molars: A Randomized Controlled Trial.

# التقييم السريري المقارن للتغطية الجزئية لترميم CAD/CAM مقابل مركب Nanohybrid من الأضراس الدائمة ناقصة المعادن: تجربة عشوائية محكومة.

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**Administrative information:**

**1. Title:**

**Comparative Clinical Evaluation of Partial Coverage CAD/CAM Restoration Versus Nanohybrid Composite of Carious Hypomineralized Permanent Molars: A Randomized Controlled Trial.**

**2. Protocol Registration:**

**3. Protocol version:**

**4. Funding:** Self-funded

**University Responsibilities:** All contribute in initiated the study design, will generate random sequence, contribute in clinical work, provide statistical expertise in clinical trial design and make the final edited of the article.

## II. Introduction:

### 5. Background and rationale:

Hypomineralization of carious permanent molars is defined as qualitative defects caused by disruptions in either the calcification or maturation phases of amelogenesis. (1)

**Statement of the problem**:

Conventionally, stainless steel crowns were used for those molars. However, due to the need for esthetics and the young age of patients, it was necessary to look for a cosmetic and conservative restoration alternative. (2) Partial coverage restorations were recommended as a substitute for crowns to maintain teeth healthy. It is considered a minimally invasive approach. (3)

**The rationale for conducting the research:**

Conventional restoration for such hypomineralized molars necessitates massive removal of the tooth structure to receive full coverage crowns that cause more biologically harmful consequences like pulp exposure especially in young permanent teeth and aggressive tooth structure loss (4). To fulfill the biological criteria for tooth preparation, conservatism is the major notion and goal that dental practitioners strive to achieve. Nowadays, minimally invasive techniques are frequently employed to

support this idea. To meet the growing need for conservative and esthetics tooth restorations, partial coverage ceramic restorations are becoming more necessary. These CAD/CAM restorations show satisfactory mechanics, restoring function, and esthetic with preserving tooth structure (5)

Since all materials used to treat such cases have distinct chemical compositions, they have different properties that affect their clinical outcome. Therefore, it is essential to compare them clinically because any restoration's clinical outcome affects its long-term success. According to the null hypothesis, different materials would not significantly affect the clinical result of ceramic overlay restorations.

Patients in all groups will receive a minimally invasive restoration with high esthetic advantages (Protection of the weak cusps and elimination of carious lesions with an esthetic way out) and long-term success of their affected carious hypomineralized permanent molars (IPS e.max CAD or Direct nanohybrid flowable composite) that require minimal preparation depends on the type of restoration will receive.

**Aim of the study:**
This randomized controlled trial study will evaluate the clinical success of direct nanohybrid flowable composite versus IPS e.max CAD Partial Coverage.

**Research question:**
Are the direct nanohybrid flowable composite and IPS e.max CAD Partial Coverage clinically successful materials in restoring the carious Hypomineralized Permanent Molars?

## PICOS:

**P:** Patients suffer from hhypomineralized permanent molars

**I**: Direct nanohybrid flowable composite

**C:** IPS e.max CAD

**O:** Clinical Success (aesthetics, functional and biological criteria))

## II. Methods

**Study Design:**

| | |
|---|---|
| Study design: | Randomized Controlled Trial |
| Estimated Enrolment: | 48 Carious Hypomineralized Permanent Molars |
| Allocation: | Randomized |

Intervention Model: Parallel Assignment

Primary Purpose: Restorations Hypomineralized Permanent Molars

Official Title: Comparative Clinical Evaluation of Partial Coverage CAD/CAM Restoration Versus Nanohybrid Composite of Carious Hypomineralized Permanent Molars: A Randomized Controlled Trial.

Estimated Study Start Date: December 2023 [Time frame: 12 months] Estimated Primary

Completion Date: January 2025

**Trial design:**

The study is a randomized controlled trial (RCT) where 2 arm parallel groups with a 1:1 allocation ratio were compared. The child participants and the legal guardian of each participating child and the statistician were blinded.

## Outcome Measures:

1. **Primary outcome:** Clinical success [Time Frame: 12 months].

    - According to FDI World Dental Federation criteria **[Appendix A]**
    - There were three assessment categories (aesthetics, function, and biological), each with five subcategories. From best to worst, the subcategories were:
      (1) clinically excellent, (2) clinically good, (3) clinically sufficient, (4) clinically not sufficient but repairable, and (5) clinically unacceptable. Assessment with category (5) was rated as a clinical failure.
    - At the follow-up visits over one year at (baseline "1 day ", 6 and 12 months) after cementation., will take standardized photographs and the restorations will clinically evaluate by an independent and calibrated clinician.

## Eligibility Criteria

| | |
|---|---|
| Ages Eligible for Study: | Above 6 Years |
| Sexes Eligible for Study: | All |
| Accepts Healthy Volunteers: | Yes |

## Criteria

## Inclusion Criteria:

1. Above 6 years old
2. Cooperative children with large carious First Permanent Molars (FPM) lesions associated with weak cusps and defected hypo-mineralized enamel.
3. Apparently healthy patients.
4. Patients will be available to be clinically reviewed up to 1 year

## Exclusion Criteria:

1. Patients with Symptoms of pulpitis.
2. Patients with uncontrolled active tooth decay or periodontal disease (i.e. 4+ mm probing depth and bleeding on probing).
3. Poor oral hygiene and motivation.
4. Patients with parafunctional habits (e.g., bruxism, biting on hard objects).
5. Patients with debilitating illnesses or complicating medical conditions

**Explanation regarding the choice of comparators:**

**IPS e.max CAD**: Till now, glass–ceramic-based restorations still offer the best translucency and esthetic qualities. The novel generation of lithium disilicate-based materials as IPS e.max CAD provides standard thickness and quick fabrication. Moreover, the adhesive technique used with this restoration type significantly raises its mechanical properties. (6)

**Beautifil Flow Plus X** (Shofu)is a bioactive flowable nano-hybrid restorative with a newly developed patented nanofiller. It is indicated for all classes including occlusal and cusp. It has all the Giomer Technology attributes, anti-bacterial, acid neutralization, and fluoride release and recharge, with improved handling and effortless polishing, and maintains a long-lasting shine. Beautifil Flow Plus X has the strength, durability, and aesthetics of a hybrid composite. (7)

## Sample size (Power analysis):

Sample size calculated depending on a previous study (Alaa M. Eldehna a et al., 2023) as reference. (8) According to this study, the probability of surface gloss as an aesthetics criterion in group 1 is 0.96. If the estimated probability of group 2 is 0.6, we will need to study 20 cases in each group with probability (power) 0.8. The Type I error probability. We used the chi-squared test to evaluate that was performed by using P.S.Power 3.1.6. Total sample size increased to 24 subjects per group to compensate for a 15 % drop out. Sample size calculation was achieved using chi-squared test to evaluate that was performed by using P.S. Power3.1.6, software Version 3.1.2 (Vanderbilt University, Nashville, Tennessee, USA).

## Statistical Methods

**Statistical analysis:**

Data was collected, tabulated, and statistically analyzed using Microsoft Excel ® 2016, Statistical Package for Social Science (SPSS)® Ver. 24. And Minitab ® statistical software Ver. 16.

**Handling of numerical / quantitative variables:**

Numerical data will be explored for normality by checking the data distribution using Kolmogorov-Smirnov and Shapiro-Wilk tests. Data will be presented as mean & amp, standard deviation. If data will

be normally distributed comparison between 2 different groups will be performed by using independent t-test, comparison between 2 related groups will be performed by using Paired t-test, while comparison between more than 2 groups will be performed by using One Way ANOVA test followed by Tukey`s Post Hoc test for multiple comparisons. If data will be non-parametric data comparison between 2 different groups will be performed by using Mann-Whitney test, comparison between 2 related groups will be performed by using Wilcoxon Signed Rank test, while comparison between more than 2 groups will be performed by using Kruskal-Walli's test.

**Handling of categorial / qualitative variables:**

Data will be presented as frequency and percentages. All comparisons will be performed

by using Chi square test.

## Recruitment:

The study will be conducted at the pediatric dentistry department of MSA University pediatric outpatients. All subjects will be monitored and reviewed at day 1 after 6 months and 12 months.

## Post-trial care

- Oral hygiene instructions and serving brush and toothpaste
- Dietary recommendations

**Patients Guardians Consent and Ethical Approval**

An informed Consent will be read in detail, explained and signed by the patients' guardians and will make sure that all risk expectations are well understood along with benefits and expected outcomes of this clinical research trial to the patient's well-being. The consent will authorize a treatment plan aimed at a mutually acknowledged treatment goal.

**[Appendix B]**

**Ethical Approval Number:**

## III. References


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2. De Leon, F.M., Garza, N., Coronado, J., Ancona, M., 2022. Indirect ceramic overlay restorations as a minimally invasive alternative for posterior rehabilitation. Inter. J. App. Dent. Sci. 8, 79–83.
3. Schiffenhaus, S., 2021. The Nonretentive Ceramic Overlay. A biomimetic alternative to the full coverage crown. Ins. Dent. J. 17, 24–31.
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7. Pinto NS, Jorge GR, Vasconcelos J, Probst LF, De-Carli AD, Freire A. Clinical efficacy of bioactive restorative materials in controlling secondary caries: a systematic review and network meta-analysis. BMC Oral Health. 2023 Dec;23(1):1-20.

8. Eldehna AM, Montaser AG, ALrafee SA, Abdelgawad A. Clinical outcome of CAD/CAM overlays of MIH affected young permanent molars. The Saudi Dental Journal. 2023 Sep 1;35(6):699-706.

# Appendices

**Appendix A:** FDI World Dental Federation criteria

| Properties | Parameters | Excellent Score1 | Good Score 2 | Satisfactory Score 3 | Mediocre Score 4 | Poor Score 5 |
|---|---|---|---|---|---|---|
| Esthetic | Surface lustre | Luster comparable to enamel | Slightly dull; some isolated pores | Dull surface; multiple pores (>1/3 of the surface) | Rough surface; presence of voids | Very rough surface |
| | Marginal and Surface staining | No staining | Minor staining | Moderate staining | Pronounced staining | Severe staining |
| | Anatomical form | Ideal form | Form slightly deviated | Moderate changes of form | Pronounced changes of form | Lost of form |
| Functional | Fracture of material and retention | No fractures or cracks | Small hairline cracks | Two or more larger hairline cracks and/or chipping (not affect marginal integrity) | Chipping fractures, bulk fractures with or without partial loss (less than half of the restoration) | Partial or compete loss of restoration |
| | Marginal adaptation | Harmonious outline, no gaps | Marginal gaps (<150 µm); small marginal fractures | Marginal gaps (>150 µm and <250 µm); several marginal fractures | Marginal gaps >250 µm or dentin/ base exposed; severe marginal fractures | Restoration lost but *in situ*; generalized major gaps |
| | Radiographic examination* | No pathology | Adhesive pooling and/or slightly internal maladjustment of the restoration | | Evidence of secondary caries; apical pathology; fracture or loss of restoration or tooth | |
| Biological | Postoperative (hyper) sensitivity and tooth vitality | No hypersensitivity; normal vitality | Minor hypersensitivity for a limited period of time (<1 week); normal vitality | Moderate hypersensitivity for a limited period of time (>1 week and <6 months); mild sensitivity, no complains | Intense hypersensitivity; cold sensitivity with minor subjective symptoms | Acute pulpitis or non vital tooth; endodontic treatment is mandatory |
| | Recurrence of caries | No secondary or primary caries | Small and localized demineralization area | Larger areas of demineralization with no dentin exposure | Localized and accessible caries with cavitation | Deep secondary caries with exposed dentin |
| | Tooth integrity | Complete integrity | Small marginal enamel fracture (<150 µm); hairline crack in enamel | Marginal enamel fractures (<250 µm); multiple cracks | Major marginal enamel fractures (>250 µm) with exposed dentin; large enamel chipping or wall fracture | Cusp or tooth fracture |
| | Adjacent mucosa | Healthy mucosa adjacent to restoration | Healthy mucosa after minor removal of mechanical irritation | Alteration of mucosa but not suspicion of causal relationship with restorative material | Suspected mild allergic lichenoid or toxic reaction | Suspected severe allergic lichenoid or toxic reaction |

## [Appendix B]: Informed consent

**Scientific Research Ethics Committee**

Informed Consent for Volunteers

**Research Title:**

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**Objective of the Research:**

This randomized controlled trial study will evaluate the clinical success of direct nanohybrid flowable composite versus IPS e.max CAD Partial Coverage.

**Introduction and Details of What Will Be Performed on the Patient**

(Work plan)

- Direct benefit to the volunteer

- Scientific benefits and general expected benefits from the research

- Side effects, risk level, expected occurrences, and how to handle them

- Patient duties regarding oral and dental health care during the research/study

[ ] Full understanding of the patient regarding the research steps:

[ ] Reading

[ ] Verbal explanation

I have carefully reviewed and understood the purpose of the research and the nature of this study. I understand what is required to complete these procedures.

1. The research doctor has informed me of possible alternative treatments to this research.

2. The research doctor has informed me of all potential risks of this research and how to handle them.

3. I agree to photography, recording, and all types of radiographs required in this study, provided that my identity will not be disclosed.

4. I have provided an accurate report about my health history. I have informed the doctor of all types of health reactions or unusual allergies to medications, foods, insect stings, anesthetics, dust, or any other materials, or abnormal bleeding, or any other conditions related to my health.

5. I declare that I am not participating in any other research from the start of this study until its end, and I will inform the research doctor if I participate in any other research during this study.

6. I pledge to return any medical equipment (tools) used in the research if I stop or upon completion of the research.

After being informed of the available information regarding the research, the volunteer or their guardian is free to choose whether or not to participate. If they agree, they are requested to fill in the data below, knowing that they have the right to withdraw from the research at any time without giving reasons, with due regard for the researcher's right to retrieve any medical devices or tools used for research purposes that are in the volunteer's possession (as required by the researcher).

**Volunteer's Name:**

**Date of Birth:**

**National ID (if available):**

**Guardians or companion's name (if applicable):**

**National ID:**

**Address:**

**Phone:**

**Date:**

The physician responsible undertakes to maintain the confidentiality of the volunteer's information in the research, mentioning the methods used for this, such as replacing names with coded numbers or hiding facial features in photographs where possible, etc.

**Researcher's signature:**