Clinical Evaluation of Low-shrinkage Giomer Resin Composite versus Resin-Modified Glass ionomer in Treatment of Cervical Caries Lesions: A Randomized Clinical Trial

التقييم السريرى لمركب الراتنج ذى الانكماش المنخفض مقابل الايونمر الزجاجى المعدل بالراتنج فى علاج آفات التسوس العنقية: تجربة سريرية عشوائية

Protocol

Submitted to the Faculty of Oral and Dental Medicine, Cairo University for partial fulfilment of the requirements of PhD degree in Conservative Dentistry

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Faculty of Dentistry
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Evidence based committee (Reviewers)		
Name	**Signature**	**Date**
1.		
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Research plan committee		
Name	**Signature**	**Date**
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2.		

I. Administrative information:

1. **Title:**

   Clinical Evaluation of Low-shrinkage Giomer Resin Composite versus Resin-Modified Glass ionomer in Treatment of Cervical Caries Lesions: A Randomized Clinical Trial

2. **Protocol Registration:**

   The study is registered on www.clinicaltrials.gov under ID NCT05930548.

3. **Protocol version:**

   This is the second version of the protocol (July - 2023).

4. **Funding:**

   This study is self-funded research by the main researcher.

5. **Roles and responsibilities:**

a) Principal Investigator

- Assistant Lecturer of Conservative Dentistry, School of Dentistry, New Giza University.
- Main Researcher and principal investigator responsible for patients' recruitment, screening, and clinical work. Also, responsible for writing the protocol, the research and the final manuscript retrieved from the research, baseline data collection, application of intervention.

b) Main supervisor

- Professor of Conservative Dentistry, Faculty of Dentistry, Cairo University.
- The main supervisor and responsible for randomization, auditing, and data monitoring.
- Supervising clinical work and contributing in writing and revising of the research work.

c) co-supervisor:

- Lecturer of Conservative Dentistry, Faculty of Dentistry, Cairo University.
- The co-supervisor and responsible for outcome assessment.
- Supervising clinical work and contributing in writing and revising of the research work.

d) Name, Contact information and trial sponsor.

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- Mail: dentmail@dentistry.cu.edu.eg
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e) Role of study sponsor and funders

The principal investigator will fund the trial and all the materials required for the research. Funding will be sought and attempted upon approval of protocol.

f) Role of steering committee

Scientific committee of the Department of Conservative Dentistry

- Ensuring that the research idea follows the research plan of the department.
- Approve the protocol and the research after being reviewed by the evidence-based dentistry committee and ethical committees.
- Picots revision.
- Protocol revision.
- Approving the methodology.
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Medical Biostatistics Unit (MBU), Faculty of Dentistry, Cairo University:

- Sample size revision.
- E-mail: mbu@dentistry.cu.edu.eg

Ethical Committee, Faculty of Dentistry, Cairo University

- Responsible for ensuring that the trial does not violate participant's privacy.
- Undertake review free from bias and influence.
- Provide advice to the researchers on all aspects of welfare and safety of research participants.
- Protect dignity, rights, and well-being of the potential research participants.
- Approval of informed consent form.
- E-mail: rec@dentistry.cu.edu.eg

g) Faculty and University board:

Protocol approval following departmental approval.

II. Introduction

A) Background and Rationale:

6.a)

Research Question:

In patients with cervical caries lesions, will low-shrinkage giomer resin composite have similar clinical performance as resin-modified glass ionomer?

Statement of the problem:

Management of cervical lesions presents serious problems with any restorative material. The two most common reasons for restoration failure are secondary caries at the tooth-restoration interface and loss of retention ***(AlQranei et al, 2021)***. Class V lesions often exhibit a low retentive cavity configuration (C-factor); which is responsible for marginal gaps around the restorations ***(AL-Gailani et al, 2019)***. Cervical margins -lying in either dentin or cementum- show unfavorable bonding performance ***(Kim et al, 2017)***, besides being usually subgingival where moisture control is difficult ***(Zhang et al, 2021)***. The subgingival margin is not clinically desirable due to difficulty in cleaning and increased biofilm accumulation ***(AlQranei et al, 2021)***. Therefore, the selection of the restorative material can be challenging.

Resin composites are known for their high mechanical properties, excellent esthetic properties, and ease of clinical application. However, when compared with glass ionomers, resin composite has no cariostatic effect on tooth structure ***(Tonprasong et al, 2021)***. In addition, microleakage caused by polymerization shrinkage of resin composite leads to plaque accumulation and secondary caries ***(Huang et al, 2021)***. On the other hand, resin-modified glass ionomer has many advantages, yet still it has lower weakness and esthetic properties compared to resin composite ***(AlQranei et al, 2021)***.

Rationale for carrying out the trial:

Many factors may impede the ability to achieve optimum cervical restorations with perfect marginal seal and long-term success ***(AlQranei et al, 2021)***. In high caries-risk patients, restoring class V caries lesions requires a material with high mechanical, esthetic, and biological properties.

Resin-modified glass ionomer bonds chemically to tooth structure, and releases fluoride, but has poor esthetic and wear resistance properties. Resin composite has enhanced esthetic properties, but show high failure rates due to marginal discoloration, secondary

caries because of polymerization shrinkage ***(Toz-Akalin et al, 2023)***. Low-shrinkage giomer resin composite has been developed to deal with such defects. However more investigations are needed to compare between resin-modified glass ionomer and giomer low-shrinkage resin composite regarding microleakage and secondary caries in cervical carious lesions ***(AL-Gailani et al, 2019)***.

Surface reaction PRG (S-PRG, known as giomer resin composite) is formed using fluoro-boro-aluminaosilicate glass. The surface layer of the glass filler is coated with a porous inorganic silica glass layer "surface-modified layer" through the sol-gel method. Then, polyacrylic acid is sprayed on the fillers leading to formation of glass ionomer phase. This glass ionomer phase is located between the surface modified layer and the surface of fluoro-boro-aluminaosilicate glass core, giving a tri-laminar structure. Such unique structure gives giomer resin composites the capability to release six key ions which are fluoride, aluminum, borate, silicate, strontium, and sodium ions. These ions exhibit acid neutralizing ability and help to prevent demineralization of enamel and dentin, reducing the possibility of secondary caries ***(Toz-Akalin et al, 2023)***.

Giomers have other advantages such as low volumetric shrinkage and hence low polymerization shrinkage stresses. Thus, they can be used in areas where bonding to dentin is poor as the gingival margin in cervical lesions ***(AL-Gailani et al, 2019)***. The most remarkable feature of the low-shrinkage giomer resin composite is its unique shrinkage of 0.85 percent by volume. Such remarkable feature is due to the novel SRS (Steric Repulsion Structured) molecule which is designed to decrease polymerization shrinkage through molecular steric repulsion resulting in a stable restoration microstructure ***(AlQranei et al, 2021)***. Thus, it is claimed to help prevent marginal leakage, secondary caries, marginal discoloration, and postoperative sensitivity. Its main benefits are low volumetric shrinkage, chameleon effect, easy to handle, and sustained fluoride release and can be recharged due to the integrated S-PRG filler technology ***(Toz-Akalin et al, 2023)***.

However more investigations are needed to compare between resin-modified glass ionomer and low-shrinkage giomer resin composite regarding microleakage and secondary caries in cervical carious lesions ***(AL-Gailani et al, 2019)***.

Review of literature:

The development of cervical lesions in permanent dentition may be related to carious or non- carious origin. Class V caries lesions may occur due to different factors

such as poor oral hygiene, dietary habits, or xerostomia ***(Akarsu et al, 2021)***.

Management of cervical lesions presents serious problems with any restorative material. The two most common reasons for restoration failure are secondary caries at the tooth-restoration interface and loss of retention ***(AlQranei et al, 2021)***. Class V lesions often exhibit a low retentive cavity configuration (C-factor); which is responsible for marginal gaps around the restorations ***(AL-Gailani et al, 2019)***. Cervical margins -lying in either dentin or cementum- show unfavorable bonding performance ***(Kim et al, 2017)***, besides being usually subgingival where moisture control is difficult ***(Zhang et al, 2021)***. The subgingival margin is not clinically desirable due to difficulty in cleaning and increased biofilm accumulation ***(AlQranei et al, 2021)***. Therefore, the selection of the restorative material can be challenging.

In this context, fluoride containing adhesive materials are considered ideal in restoring class V carious lesions. Resin modified glass ionomers (RMGI) are highly recommended in the restoration of cervical lesions. The most important advantages of glass ionomer are its chemical adhesion to the tooth structure, and its fluoride release ***(Toz-Akalin et al, 2023)***. However, RMGI has lower weakness and esthetic properties compared to resin composite ***(AlQranei et al, 2021)***.

Resin composites have been widely used in dental practice; because of their high mechanical properties, excellent esthetic properties, and ease of clinical application. However, when compared with glass ionomers, resin composite has no cariostatic effect on tooth structure ***(Tonprasong et al, 2021)***. In addition, polymerization shrinkage of resin composite is of major concern; where mechanical stresses are developed due to contraction leading to break the marginal seal between resin composite and tooth structure. Polymerization shrinkage can cause clinical issues such as restoration or tooth fracture, bond degradation and solubility, and microleakage ***(Algailani et al, 2022)***. The microleakage caused by polymerization shrinkage of resin composite leads to plaque accumulation and secondary caries ***(Huang et al, 2021)***. Thus, choosing a fluoride-releasing and low-shrinkage resin composite may play a critical role in success of cervical restorations ***(AL-Gailani et al, 2019)***.

The continued development of resin composites has led to the introduction of Giomer technology. By combining the characteristics of resin composite and glass ionomer, hybrid products called giomers have been obtained. Giomer resin composite

offers protection against caries, along with improved functional and esthetic properties; through incorporating particles of pre-reacted glass fillers (PRG) into the matrix of resin composite ***(Rusnac et al, 2019)***. The PRG-ionomer phase has the capability to release six key ions which are fluoride, aluminum, borate, silicate, strontium, and sodium ions. These ions exhibit acid neutralizing ability and help prevent demineralization of enamel and dentin, leading to decrease the possible incidence of secondary caries ***(Toz-Akalin et al, 2023)***. This PRG technology provides giomer with both fluoride release and recharge, similar to glass ionomer while still maintaining the original physical properties of resin composite ***(Bheda et al, 2020)***.

Beautifil™ II LS (Low shrinkage) giomer resin composite (Shofu Inc, Kyoto, Japan) shows both sustained fluoride release and recharge, and low volumetric shrinkage of less than 1% with low resultant polymerization shrinkage stress. Such remarkable feature is due to the novel SRS (Steric Repulsion Structured) molecule which is designed to decrease polymerization shrinkage through molecular steric repulsion resulting in a stable restoration microstructure ***(AlQranei et al, 2021)***. Thus, low shrinkage giomers are best indicated in class V cavities where the dentin bonding agent does not have high strength ***(Algailani et al, 2022)***.

A recent clinical trial compared the clinical performance of giomers versus resin modified glass ionomer in proximal lesions. Marginal adaptation was higher in giomers than resin-modified glass ionomers after 12 months ***(Inthihas et al, 2019)***. Also, a systematic review investigated in vivo longevity of giomers compared to other adhesive restorative materials (hybrid resin composite, compomer, and RMGIC), and concluded that RMGIC was the most successful material in terms of biological properties while giomers had the longest survival rate ***(Bheda et al, 2020)***. An in-vitro study evaluated the surface roughness and fluoride release of Beautifil II and Fuji II LC (resin-modified glass ionomer). Resin-modified glass ionomer showed the highest fluoride release, while the giomer showed an intact, smooth surface with no irregularities as those found in glass ionomer. Thus, the smooth surface of giomers inhibit biofilm formation, decreasing the risk of dental caries and periodontal diseases ***(Komalsingsakul et al, 2022)***. Regarding the mechanical properties of giomers, it has exhibited a higher flexural strength value when compared to glass ionomer cements. The hardness values were twice as high for the giomer when compared to self-curing and light-curing glass ionomer cements ***(da Silva et al, 2021)***.

6.b) Choice of comparators:

In our study, the comparator material will be light cured resin modified glass ionomer restorative. RMGI is recommended to restore carious cervical lesions; especially with its ability to inhibit secondary caries due to its fluoride releasing ability. The main advantage of RMGI is its capability to chemically bond to tooth structure, even in the presence of moist dentin. RMGI reaction can be achieved by both acid-base reaction (induced by glass ionomer component) and polymerization reaction (induced by resin component). Thus, RMGI has better mechanical properties, wear resistance, and improved esthetics compared with conventional glass ionomer ***(AlQranei et al, 2021)***. In addition, the coefficient of thermal expansion of glass ionomer which is similar to that of tooth structure, allows for proper marginal adaptation without marginal leakage ***(Bollu et al, 2016)***.

B) Study Objectives:

7. Aim of the study:

This study is conducted to evaluate the clinical performance of low-shrinkage giomer resin composite versus resin-modified glass ionomer in restoration of cervical caries lesions, using both Modified USPHS and Revised FDI criteria.

Hypothesis:

This study will be designed to test the null hypothesis that the low-shrinkage giomer resin composite will have the same clinical performance as resin-modified glass ionomer in cervical restorations, using both Modified USPHS and Revised FDI criteria.

Primary Objectives:

Measure the functional, biological, and aesthetic properties of both restorations (using Revised FDI criteria for direct restorations) at baseline, after 6, and 12 months.

Secondary Objectives:

Measure Cost-Effectiveness Analysis: Cost-effectiveness will be assessed by calculating the Incremental Cost-Effectiveness Ratio (ICER) and the Cost per Success Ratio (CPSR).

C) Trial Design

- Study design: Randomized clinical trial (parallel group, two arm study).
- Triple-blinded (participants, outcome assessors and statisticians).
- Allocation ratio; 1:1
- Framework: Superiority frame.

PICOTS Elements:

P (Population): Adult patients with cervical carious lesions in maxillary anterior teeth (ICDAS II score 4).

I (Intervention): Low Shrinkage, giomer paste-like resin composite (Beautifil™ II LS, Shofu Inc, Kyoto, Japan).

C (Comparison): Light cured resin reinforced glass ionomer restorative Fuji II LC® (GC Corporation, Tokyo, Japan).

Outcomes:

a) Primary Objectives:

Measure the functional, biological, and aesthetic properties of both restorations (using Revised FDI criteria for direct restorations) at baseline, after 6, and 12 months.

b) Secondary Objectives:

Measure Cost-Effectiveness Analysis: Cost-effectiveness will be assessed by calculating the Incremental Cost-Effectiveness Ratio (ICER) and the Cost per Success Ratio (CPSR).

T (Time): 12 months; with follow up at baseline, 6, and 12 months.

S (Study design): Randomized clinical trial.

III. Methods

A) Participants, interventions, and outcomes

9. Study setting:

This clinical trial will be held in the Conservative Dentistry Department, Faculty of Dentistry, Cairo University, Egypt.

10. Eligibility Criteria of study population:

Inclusion Criteria of participants:

- Moderate to high caries-risk patients with carious cervical lesions (ICDAS score 4) in maxillary anterior teeth.
- Patients with at least 20 teeth under occlusion.
- Age: 25-50 years.
- Asymptomatic vital teeth.
- Co-operative patients approving to participate in the trial.

Exclusion Criteria of participants:

- Patients younger than 25 years old or older than 50 years old.
- Extensive cervical lesions extending beyond proximal line angles.
- Teeth with signs and symptoms of irreversible pulpitis or pulp necrosis.
- Teeth supporting removable prostheses, or orthodontic appliances.
- Candidates with parafunction or bruxism.
- Candidates with systemic diseases or disabilities that may affect participation.
- Drug-induced xerostomia.
- Known allergy to resin-based composites or RMGIs.
- Heavy smoking.
- Pregnancy.
- Lack of compliance.

11. Proposed Intervention:

Clinical examination:

- For every patient, medical and dental history, caries risk assessment profile, and salivary flow test will be obtained. If bleeding on probing of the gingiva is positive, scaling will be performed at least 1 week before restoration.
- Clinical examination will be done by mouth mirror, explorer, dentin hypersensitivity test using compressed air through triple syringe, and standardized photographs.

Restorative procedures:

- Cavity preparation procedures for both the intervention and control groups:

After giving local anesthesia, the operative field will be isolated using rubberdam by performing multiple teeth isolation with at least two teeth before and after tooth to be treated. Using a water-cooled high-speed handpiece (380.000-480.000 rpm), class V cavity will be prepared on the facial surface of the tooth using a pear-shaped diamond bur (MANI Ltd., Utsunomiya, Japan), and then a bevel is prepared 45^{O} on the incisal wall of the cavity using a diamond finishing tapered bur (MANI Ltd., Utsunomiya, Japan). The bur will not be used for more than 3 cavity preparations. Any remaining soft carious dentin will be excavated by a small, sharp excavator (Dentsply® Maillefer, Switzerland).

Intervention:

Low Shrinkage, giomer paste-like resin composite (Beautifil™ II LS, Shofu Inc, Kyoto, Japan).

All materials will be applied according to the manufacturer's instructions. The prepared tooth surfaces will be rinsed and dried by gently blowing with an air syringe. Selective enamel etching will be done; where the enamel margins will only be etched with 35-40% phosphoric acid gel for 10-15 seconds, rinsed for 5 seconds and gently dried. The unfilled universal adhesive (Shofu Inc, Kyoto, Japan) will be applied onto the entire cavity surface and left undisturbed for 10 seconds. Then the adhesive will be air dried with gentle air for 3 seconds and then, dried with stronger air to dry the surface. It will be light-cured using LED light-curing unit (Light output: 1200 mW/cm^2) for 20 seconds. Beautifil™ II LS will be applied according to manufacturer's instructions as follows: shade selection will be done before rubberdam isolation. The material will be applied into the cavity using a gold-plated instrument, where incremental filling and light-curing of the material in layers, does not exceed 2 mm each. Each increment will be light-cured using LED light-curing unit (Light output: 1200 mW/cm^2) for 20 seconds. The restorations will be finished using water-cooled microfine diamond finishing burs for contouring and removal of excess restorative material and will be polished with aluminum oxide polisher immediately after filling.

Comparator:

Light-cured glass ionomer restorative, available in premeasured unit dose capsules (Fuji II LC®, GC Corporation, Tokyo, Japan).

All materials will be applied according to the manufacturer's instructions. The prepared tooth surfaces will be rinsed and dried by gently blowing with an air syringe. Cavity conditioner (GC Corporation, Tokyo, Japan) will be applied for 10 seconds, rinsed, and gently dried without dessication. GC Fuji II LC™ will be dispensed according to manufacturer's instructions, followed by LED light curing (Light output: 1200 mW/cm^2) for 20 seconds. The restorations will be finished using water-cooled

microfine diamond finishing burs for contouring and removal of excess restorative material and will be polished. Then, G-COAT PLUS™ (GC Corporation, Tokyo, Japan) will be applied to finished restorations following manufacturer`s instructions.

12. Outcomes

Outcomes will be assessed by mouth mirror, dental explorer, standardized photographs and FDI probe according to modified USPHS criteria and Revised FDI criteria for direct and indirect restorations:

- **Primary outcomes:** All restorations will be assessed for functional, biological, and aesthetic properties using Revised FDI criteria for direct and indirect restorations. They will be given a score (clinically excellent/very good, clinically good, clinically satisfactory, clinically unsatisfactory, clinically poor).

- **Secondary outcomes:** Cost-Effectiveness Analysis

Cost-effectiveness will be assessed by calculating the Incremental Cost-Effectiveness Ratio (ICER) and the Cost per Success Ratio (CPSR). These metrics will be used to compare the cost and clinical outcomes of LS-GRC and RMGI in treating class V cavities.

Incremental Cost-Effectiveness Ratio (ICER)

The ICER will be used to compare the cost-effectiveness of LS-GRC versus RMGI by evaluating the additional cost for each successful outcome provided by LS-GRC compared to RMGI. The ICER will be calculated using the following formula:

$$ICER = \frac{(C_2 - C_1)}{(E_2 - E_1)}$$

Where:

- C_2 and C_1 are the total costs of LS-GRC and RMGI, respectively,
- E_2 and E_1 are the respective effective outcomes (i.e., clinically excellent rates after 12 months).

The cost calculation methodology will account for several key factors, including the material cost per restoration, clinical application costs, and replacement or repair costs over time. Additionally, indirect costs, such as patient time, transportation, and the number of follow-up visits, will also be considered.

Cost per Success Ratio (CPSR)

The CPSR will be calculated to evaluate the cost per clinically successful restoration, determining the cost-effectiveness of each material in achieving successful outcomes, defined as restorations that will show no failure after 12 months. The CPSR will be calculated using the following formula:

$$CPSR = \frac{Total\ Cost}{Number\ of\ Successes}$$

Where:

- Total Cost refers to the overall cost per patient for each material,

- Number of Successes refers to the number of restorations that met the pre-defined criteria for clinical success (i.e., clinically excellent rate after 12 months).

13. Participant timeline:

		-1	T	F2	F3
Activity	**Staff member**	**1 month before intervention**	**Intervention (Zero point)**	**Follow up (6 months)**	**Follow up (12 months)**
Recruitment	**M.G. E.M.**	**X**			
Diagnosis	**M.G.**	**X**			
Consent	**M.G.**	**X**			
Baseline data collection	**M.G.**	**X**			
Cavity preparation	**M.G.**		**X**		
Randomization	**H.H**		**X**		
Application of interventions	**M.G.**		**X**		
Outcome assessment	**E.M.**			**X**	**X**

14. Sample size calculation:

The sample size was calculated based on a previous study by ***Vural et al in 2021***, in which percentage of successful class V restorations (Score A and B) using resin modified glass ionomer regarding marginal discoloration was 68.7%. By implementing a two tailed Z test for difference between two independent proportions with an alpha level of 5% and a power of 80%. The minimum sample size needed was 23 per group in order to detect a difference of 30%. Sample size was increased by 20% to compensate for possible dropouts to reach 28 teeth per group. Sample size was performed using G*Power version 3.1.9.2 for windows.

15. Patient Recruitment:

Patients will be recruited by M.G. using stratified sampling method until reaching to the target sample size. They will be recruited from clinic of conservative dentistry department in Faculty of Dentistry, Cairo University, where there is a continuous and high patient flow from which eligible patients will be recruited to fulfill the eligibility criteria 1 month before intervention.

B) Assignment of interventions:

16. Allocation:

16. a) Random sequence generation (Randomization):

H.H. will perform simple randomization according to a check list, including the number of participants by generating numbers from 1 to 56, divided into two groups denoting with letter A and B. Randomization will be generated using (www.randomization.com).

16. b) Allocation concealment mechanism:

The allocation sequence will be kept with the contributor (E.M.) in sealed tight envelopes concealed from the primary investigator. The principal investigator (M.G.) will know the allocation of the consented participant just before starting the restorative procedures.

16. c) Implementation

All participants who fulfill eligibility criteria and who give consent for participation will be randomized by E.M. into two groups.

17. Blinding (masking):

Participants will be blinded to the intervention they were assigned too. Outcome assessors will be blinded as well as statisticians. The principal investigator cannot be blinded due to the difference in manipulation and application of restorative materials

C) Data collection, management, and analysis:

18. Data Collection methods:

For every patient, medical and dental history and caries risk assessment profile will be obtained. The examination chart will be filled in by (M.G). M.G. will record telephone numbers and address of all subjects in the study as a part of the signed consent. M.G. will receive a phone call at the time of the pre-determined follow-up date.

Patient retention:

The patient's phone number will be recorded in their charts and before every visit the patient will receive a reminder call by (M.G. and E.M.). If the patient did not answer, another appointment will be scheduled within a week.

19. Data management:

All paper sheets that are concerned with the personal or outcome data will be stored in locked cabinet and in the computer at the Conservative department. The excel sheets of the patient's data will be stored in the computer of the Conservative Department- Faculty of Oral and Dental Medicine. The computer will have a password only known to M.G. and D.K. to prevent unauthorized access to data and double data entry.

20. Statistical analysis plan:

a) Statistical Methods:

Data will be analyzed using Medcalc software, version 19 for windows (MedCalc Software Ltd, Ostend, Belgium). Categorical data will be described as frequency and percentage. Intergroup comparisons between categorical variables will be performed using the chi square test, while intragroup comparisons within each intervention will be performed using Cochran's Q test followed by pairwise multiple comparisons. A p-value less than or equal to 0.05 will be considered statistically significant and all tests will be two tailed. The statistical power of the study will be set at 80 % with 95 % confidence level.

b) Primary and Secondary Outcomes:

All outcomes will be assessed after 12 months; with follow up at baseline, 6, and 12 months.

Prioritization of outcomes	Outcome	Measuring device	Measuring unit
Primary Outcome	Functional, biological, and aesthetic properties.	Revised FDI criteria for direct and indirect restorations ***(Hickel R, 2022)***	Ordinal data (Scores)
Secondary Outcomes	Cost-Effectiveness Analysis	Incremental Cost-Effectiveness Ratio (ICER) and the Cost per Success Ratio (CPSR)	Currency

c) Handing of missing data:

All randomized participants will be included in the primary analysis according to the intention per protocol analysis. Participants who discontinue or are lost to follow-up will be analyzed in the groups to which they were originally assigned, regardless of adherence to the intervention. No imputation will be performed for missing outcome data unless otherwise specified.

d) Interim analyses and stopping rules:

The study will be designed to continue until the planned sample size was reached and all follow-up completed, with no provision for early stopping. The trial will be completed according to this original protocol without any interim evaluations or modifications.

D) Data monitoring:

21. Monitoring

H.H. and D.K. will monitor this study, who will have full access to the results and will take the final decision to terminate the trial.

22. Harms

Operator M.G. should inform participants about the possible harms (pain, loss of restorations, leakage, and fracture of restoration). If present, participants should contact the operator at the moment through telephone. For assessment radiograph, inspection, percussion, and vitality tests are performed; the data should be reported to the main supervisor (H.H.) and managed through removal of the restorations and alleviation of pain.

23. Audit

In this trial auditing will be done by the main and co-supervisors (H.H. & D.K.) to assure quality of the research methods, restorative techniques, and interventions.

IV. Ethics and dissemination

24. Research ethics approval

Application forms for accomplishing clinical trial, checklist and informed consent of Research Ethics Committee (REC) Faculty of Oral and Dental Medicine, Cairo University will be retrieved and filled, then will be delivered for REC committee for approval, this is done to prevent any ethical problems during the study or any harms for any of the participants.

25. Protocol amendments

If a new protocol is used a protocol amendment will be submitted, containing a copy of the new protocol and a brief explanation about the differences between it and the previous protocols. If there is a change in the existing protocol that affects safety of subjects, investigation scope, or scientific quality of the trial an amendment containing a brief explanation about the change must be submitted. If a new author is added to accomplish the study an amendment including the investigator's data and qualifications to conduct the investigation will be submitted to prevent ghost authorship.

26. Informed consent

M.G. is responsible for admitting and signing the informed consents during enrollment day.

27. Confidentiality

The name and the personal data of the participants will not appear on the protocol form and should be maintained secured for 10 years after the trial. This is done for protection of participants' privacy and civil rights.

28. Declaration of interest

There is no conflict of interest, no funding or material supply from any parties.

29. Access to data

Access to final data will be allowed to M.G. and the main and co-supervisors (H.H. & D.K.) of the study who are not involved in assessment of the outcome.

30. Post-trial care

Patients will be followed up after restoration to ensure oral hygiene measures. When there is any evidence of restoration failure, patients will be treated by immediate restoration removal and glass ionomer restoration will be placed.

31. Dissemination policy

Trial results will be available in the database department and a copy of the thesis will be available at the department library and at the official site of the Egyptian Universities Libraries Consortium. Final report of the trial will be also published in international journals. The trial will be further publicized via conferences, seminars and expert meetings in Egypt and abroad.

V. Appendices
32. Informed consent

الموافقه المستنيرة للمتطوعين

عنوان البحث البحث باللغة العربية:

التقييم السريرى لمركب الراتنج ذات الانكماش المنخفض مقابل اسمنت الايونمر الزجاجى المعدل بالراتنج فى علاج آفات التسوس العنقية: تجربة سريرية عشوائية

الهدف من إجراء البحث:

معرفة الأداء السريري لحشوات الراتنج االمهجنة ذات الانكماش المنخفض مقارنة بالأداء السريري لحشوات اسمنت الايونمر الزجاجى المعدل بالراتنج فى علاج آفات التسوس.

مقدمة عن وما سيتم اجراؤه على المريض بالتفصيل (خطة العمل)

1. **الكشف على المرضى و تشخيصهم.**
2. **شرح خطة العمل و الهدف من البحث و اخذ الموافقة المستنيرة من المرضى المناسبين للتجربة و الموافقين على الخوض في التجربة.**
3. **التوزيع العشوائي للمرضى على مجموعتي التجربة (حشوات الراتنج االمهجنة ذاتية اللصق) و (*الحشوات للراتنج المعتاد*)**
4. **علاج المرضى بالحشوات المستخدمة في التجربة بخطوات مطابقة لترشيحات و خطوات المصنع.**
5. **تقييم الحشوات سريريا بإستخدام معايير الولايات المتحدة للصحة العامة المعدلة.**
6. **متابعة المرضى لتقييم أداء الحشوات عند ست شهور و بعد مرور عام و عام و نصف ثم عامين.**

الفائدة المباشرة للشخص المتطوع

علاج ضرسه المسوس بحشوة تطابق المعايير التكنولوجية الحديثة و التي من المتوقع ان تعطي أداءا سريريا جيدا وذلك خلال زيارة واحدة فقط.

الفائده العلميه والفائدة العامة المرجوة من البحث

متابعة و تقييم *الأداء السريري لحشوات الراتنج االمهجنة ذات الانكماش المنخفض في حشو الأسنان الأمامية خلال 12 شهر.*

الأعراض الجانبية و درجة المخاطرو المتوقع حدوثها وكيفية التعامل معها

متوقع انها تكون قليلة الحدوث و هي حدوث كسر في الحشوة او تسوس ثانوي و سيتم التعامل معها بإعادة العلاج مرةاخرى بإستخدام حشوة كمبوزيت من نوع آخرذات جودة عالية و مطابقة لمعايير العلاج الحديثة.

المعرفه الكامله للمريض بخطوات البحث: قراءة [ ] شرح شفهي [√] أخرى [ ]

1. **لقد اطلعت بعناية وفهمت الغرض من إجراء البحث وطبيعة هذه الدراسة ، وأنا أفهم ما هو ضروري لإنجاز هذه الإجراءات.**
2. **قد أعلمنى الطبيب الباحث بالبدائل العلاجية الممكنة لهذا البحث.**
3. **لقد أبلغنى الطبيب الباحث بجميع المخاطر المحتملة لهذا البحث و كيفية التعامل معها.**

4. **أوافق على التصوير والتسجيل ، وجميع أنواع الأشعة والتي يتعين القيام بها فى هذا الدراسة ، بشرط عدم الكشف عن هويتي.**
5. **-لقد قدمت تقريرا دقيقا عن تاريخ حالتى الصحية. وأبلغت الطبيب بجميع أنواع ردود الأفعال الصحية أو الحساسية غير العادية من الأدوية أوالأغذية أولدغ الحشرات أومواد التخدير أوالغبار أو أى ردود أفعال حدثت لى من أى مواد أخرى ، أونزيف غير طبيعي أو أي ظروف أخرى ذات صلة على صحتي**

6. **أقر بأننى غير مشترك فى أى بحث أخر منذ بداية هذا البحث و حتى إنتهائه و أننى سأعلم الطبيب الباحث لو دخلت أى بحث أخر طوال فترة هذا البحث.**
7. **أتعهد باعادة الأجهزة (الأدوات) الطبية المستخدمه في البحث في حالة التوقف أو عند انتهاء البحث.**

بعد معرفة المعلومات المتاحة الخاصة بالبحث يتفضل الشخص المتطوع أو المسئول عنه بالاختيار بحرية ما بين الاشتراك من عدمه. في حال الموافقة يتفضل بملء البيانات الموضحة . من حق المتطوع الإنسحاب من البحث بدون إبداء الأسباب مع مراعاة حق إسترجاع الباحث لأى أجهزة أو أدوات طبية مستعملة بغرض البحث بحوزة المتطوع (تسمى من قبل الباحث)

تعهد الطبيب المسئول عن البحث بالحفاظ على سرية المعلومات الخاصة بالشخص المتطوع بالمشاركة في البحث مع ذكر الطرق المستخدمه لذلك مثل استبدال الاسماء بارقام كوديه أو اخفاء معالم الوجه عند التصوير الفوتوغرافي ان امكن (الخ..)

من حق المتطوع الاحتفاظ بنسخه مصورة من الموافقه المستنيرة للبحث الذي تطوع فيه

اسم المتطوع: تاريخ الميلاد:
الرقم القومي (ان وجد)
اسم ولي الأمر أو المرافق(عند اللزوم): الرقم القومي:
العنوان: الهاتف:
التاريخ:

توقيع الباحث: التاريخ

د. منة عمر الغمراوى

د. دينا محمد كمال الدين

د. هبة صلاح الدين حمزة

توقيع المشرف على البحث (في حالة الرسائل): التاريخ:

بيانات تملأ بمعرفة اللجنة

هذا البحث تمت موافقة اللجنه عليه برقم

VI. Statement of originality

33. Statement of originality

The impact of cervical caries is bidirectional on both the tooth surface and periodontal tissues, increasing the impact of both diseases on a patient's oral health status. The ability to obtain a completely isolated field, gain proper access to the lesion, restore it while fulfilling the biological, esthetic, and mechanical properties should be considered. Thus, it will eliminate the financial burden for the community in return, through long standing restorations without the need for repair or replacement ***(AlQranei MS et al, 2021)***.

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