

**Clinical Performance of Zirconia-Reinforced Glass Ionomer Versus Injectable
Giomer in Class V Restorations of Diabetic and Non Diabetic Patients:
18 Months Controlled Clinical Trial**

Protocol

Submitted to Faculty of Dentistry, Cairo University
For partial fulfillment of the requirements for the PhD Degree in
Restorative and Esthetic Dentistry

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I. Administrative information:

1. Title:

Clinical Performance of Zirconia-Reinforced Glass Ionomer Versus Injectable Giomer in Class V Restorations of Diabetic and Non-Diabetic Patients: 18 Months Controlled Clinical Trial

2. Protocol Registration: This study is registered in clinicaltrials.gov
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3. Protocol Version: First Version

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- **Scientific Committee, Conservative Dentistry Department, Faculty of Dentistry, Cairo University:** Reviewing protocol and assuring that it is following the scientific writing guidelines. Faculty of Dentistry, Cairo University.
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- **Research Ethics Committee (REC):** Reviewing the protocol of this clinical trial to protect the rights, safety, dignity, and wellbeing of the participants in the trial. Faculty of Dentistry, Cairo University.
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II. Introduction:

A. Background and Rational:

6. a. Research Question:

Does restoration with Zirconia-reinforced Glass Ionomer show any difference in clinical performance when compared to injectable Giomer in controlled Type II diabetic and non-diabetic healthy patients with Class V carious lesions in permanent teeth over 18 months?

Statement of the Problem:

Restoring Class V carious lesions in diabetic patients is particularly challenging due to systemic alterations in dentin and a high-risk oral environment that subjects the patient to recurrent caries and mechanical debonding. Numerous bioactive materials are available, including zirconia-reinforced glass ionomer cements and giomer-based composites, not all have been sufficiently assessed with significant follow-up periods in medically compromised populations to clinically determine their comparative success or failure.

This research will be conducted to allow clinical assessment of Zirconomer, which utilizes zirconia-reinforced glass ionomer technology for high mechanical strength and fluoride release, in comparison to a Giomer (Beautifil Flow Plus X, SHOFU). The injectable giomer boasts unique Surface-Pre-Reacted Glass ionomer (S-PRG) technology that offers anti-cariogenic benefits while providing excellent handling and adaptation without the need for high-viscosity packing. Their clinical performance in the specific environment of diabetic patients will be assessed throughout the duration of the trial.

Rational for conducting the research:

Bioactive restorative materials have proven themselves as a breakthrough that has simplified the cervical restoration protocol through the enhancement of remineralization and the inhibition of acidogenic bacteria. It has been found that clinical factors as marginal adaptation, recurrence of caries, mechanical failure of restoration and retention have shown clinical success when using materials that offer both chemical adhesion and ion-release potential. (Abozaid et al., 2025)

Zirconomer is a zirconia-reinforced glass ionomer that can provide high mechanical strength and durability while maintaining the bioactive benefits of a glass ionomer. The reinforcement with zirconia is intended to improve the material's resistance to the significant tensile stresses that lead

to the failure of Class V restorations, particularly in patients with altered dentin substrates and high-risk oral environments found in diabetic patients.

Furthermore, giomers are characterized by its unique Surface Pre-Reacted Glass ionomer (S PRG) technology that is capable of functioning as a fluoride reservoir for release and recharge. The injectable nature of this material facilitates the restoration placement in of Class V cavities with favorable adaptation to the tooth structure.

To date, no clinical trials have been conducted to assess and compare the clinical performance of Zirconomer against injectable giomer in Class V restorations in diabetic patients using a standardized structured randomized clinical trial. Accordingly, this clinical trial aims to bridge that gap.

Review of Literature

The etiology of Class V lesions is multifactorial that may be related to impaired oral hygiene, salivary flow alterations, and systemic predisposing conditions. The cervical region is subject to unique mechanical stresses from tooth flexure under occlusal loading. However, carious cervical lesions specifically arise as a consequence of plaque accumulation and acid dissolution at the gingival margin, where biofilm is typically difficult to disrupt (**Grippo et al., 2012**). The clinical challenge of restoring these lesions is related to unfavorable substrate where the cervical margin frequently terminates in cementum or dentin rather than enamel, reducing the available surface for reliable adhesive bonding and increasing susceptibility to microleakage and secondary caries (**Peumans et al., 2014**).

Diabetes mellitus (DM) is a common chronic disease characterized by hyperglycemia resulting from an absolute or relative insulin deficiency. The biological environment in diabetic patients is marked by hyposalivation and a higher plaque index that elevates the risk of marginal microleakage and secondary caries at the cervical margin. Type II DM, the predominant form approximately 90–95% of all diagnosed cases, is of particular relevance to restorative dentistry due to its systemic effects on the oral microenvironment and dental substrate (**Antar et al., 2023**). The oral manifestations of DM are well-documented and include xerostomia, increased susceptibility to periodontal disease, impaired wound healing, and an altered microbiome that predisposes to cariogenic bacterial colonization (**Preshaw et al., 2012**). Reductions in salivary flow volume and altered salivary composition in diabetic patients have been shown to increase

cariogenic challenge, elevate plaque accumulation, and impair the natural self-cleansing of cervical surfaces (**Botelho et al., 2026**).

Beyond the oral microenvironment, hyperglycemia has direct effects on dentin structure and composition that are relevant to restorative outcomes. **Hwang et al. 2025** conducted a systematic review examining the effect of diabetes and hyperglycemia on the physical and mechanical properties of dentine, concluding that chronic hyperglycemia induces advanced glycation end-product (AGE) accumulation within the collagen matrix of dentine, reducing its elastic modulus and fracture toughness. These AGE-mediated structural alterations impair the ability of adhesive systems to form a stable hybrid layer by compromising collagen fibril integrity at the bonding interface. The consequence is a demonstrably reduced bond strength of conventional resin-based adhesives to diabetic dentin compared to healthy controls, with implications for the retention and marginal integrity of Class V restorations in this population

The increased prevalence of cervical caries in diabetic patients compared to non-diabetic patients may be related to higher caries indices in poorly controlled DM, with cervical surfaces affected due to the combined effects of xerostomia, gingival inflammation, and plaque accumulation (**Zhang et al., 2021**).

Restoring cervical lesions may be challenging due to difficulties in accessibility, visibility, moisture control and bonding to different tooth hard tissues. In addition, cervical regions are subjected to recurrent caries especially in bad oral hygiene and plaque accumulation. Several restorative materials are available to restore those lesions including glass-ionomer cement (GIC), resin modified GIC, and resin composite. Conventional glass ionmer restorative materials as a permanent restorative material is not advocated due to their inferior mechanical properties and susceptibility to fractures compared to other restorative materials. Therefore, modifications in GI restorations were introduced to achieve a good long-term performance. Zirconia filler particles were added to the composition of glass ionmer to enhance mechanical properties with enhanced esthetic appearance (**Abdou et al., 2024**).

The incorporation of zirconia (ZrO_2) filler particles into the glass ionomer matrix serves to reinforce the inorganic filler phase, increasing compressive strength, flexural strength, and resistance to surface wear while preserving the essential bioactive properties of fluoride, calcium, and phosphate ion release inherent to the GIC chemistry (**Abdou et al., 2024**). The enhanced mechanical profile of zirconia-reinforced GICs positions them as potentially viable restorative

options for Class V cavities, particularly in patients requiring sustained bioactivity as a priority alongside acceptable durability.

Abdou et al., 2024 conducted a one-year randomized controlled clinical trial comparing zirconia-reinforced GIC with conventional viscous GIC in Class I cavities of geriatric patients. The study demonstrated that Zirconomer exhibited statistically superior marginal adaptation and retention rates compared to conventional viscous GIC at the 12-month follow-up, attributed to the enhanced mechanical properties conferred by zirconia reinforcement

Abozaid et al. 2025 defined bioactive restorative materials as those capable of releasing biologically active ions—including fluoride, calcium, phosphate, and strontium—that stimulate remineralization of demineralized tooth structure, inhibit acidogenic bacteria, and potentially modulate the response of pulpal and periodontal tissues. The clinical appeal of bioactive materials is particularly pronounced in high-caries-risk populations, where conventional restorative approaches offer limited protection against recurrent caries at restoration margins.

Giomers are hybrid materials that incorporate Surface Pre-Reacted Glass-ionomer (S-PRG) filler within a resin composite matrix. S-PRG fillers are produced by reacting glass ionomer powder with polyacrylic acid to a pre-reacted state before incorporation into the composite matrix. This pre-reaction creates a stable glass-ionomer phase within each filler particle that is capable of releasing and recharging multiple ions including fluoride, boron, sodium, silicon, aluminum, and strontium ions upon exposure to the oral environment. Unlike conventional GICs, where ion release is dependent on the acid-base setting reaction and may diminish over time, S-PRG-containing giomers theoretically maintain a sustained ion-release capacity owing to the stable pre-reacted filler particles, which can be recharged by fluoride from toothpastes and fluoride treatments (**Neto et al., 2022**).

Injectable giomers represent a further evolution of this material category, specifically designed to optimize adaptation and marginal seal in cavities with complex geometry, such as the cervical region. Beautifil Flow Plus X (SHOFU) is an injectable giomer incorporating S-PRG filler technology within a low-viscosity resin matrix, designed to allow flowable injection into Class V preparations without the packing difficulties associated with high-viscosity composite materials. The flowable nature of this material facilitates intimate adaptation to the cavity walls and gingival margin, theoretically reducing marginal gap formation and the associated risks of microleakage and secondary caries (**Hendam et al., 2025**).

Hendam et al. evaluated the clinical performance of injectable giomer versus resin-modified GIC in Class V carious lesions over an 18-month follow-up period, demonstrating comparable retention rates but superior marginal discoloration scores in favor of the giomer at the final assessment, suggesting enhanced marginal sealing capacity and colour stability for the giomer formulation compared to resin-modified glass ionmer.

b. Explanation for choice of comparators

Beautifil Flow Plus X is an injectable Giomer that has been advocated as a bioactive restorative material of reliable bond strength and excellent adaptation to cervical tooth structure. However, it is still to be decided whether there'll be a significant difference in clinical performance in direct comparison with the zirconia-reinforced glass ionomer Zirconomer in the challenging oral environment of diabetic patients.

c. External Validity

Bioactive restorative materials have produced a paradigm shift in clinicians' perspective to the restoration of cervical carious lesions. The simplification of the restorative protocol allows for easier, quicker, and more reliable bonding through chemical adhesion and bioactive ion release. In turn, this leads to improved clinical performance of the Class V restorations, which minimize the recurrent caries and mechanical failure cycle often seen in high-risk populations such as diabetic patients.

B) Objectives

7. Aim of the study

The study aims to compare the clinical performance of Class V restorations using Zirconia-reinforced Glass Ionomer versus injectable Giomer over 18 Months follow-up period using modified USPHS criteria in diabetic and non-diabetic patients.

PICOTS

P (Problem/Population): Patients with Class V carious lesions in Posterior Region categorized into: non-diabetic healthy patients and controlled Type II diabetic patients.

I (Intervention) 1: Restoration using Zirconia-reinforced Glass Ionomer (Zirconomer, SHOFU) in controlled type II diabetic patients.

I (Intervention) 2: Restoration using Injectable Giomer (Beautifil Flow Plus X, SHOFU) in controlled type II diabetic patients.

I (Intervention) 3: Restoration using Zirconia-reinforced Glass Ionomer (Zirconomer, SHOFU) in non-diabetic patients.

C (Comparator) s: Restoration using Injectable Giomer (Beautifil Flow Plus X, SHOFU) in non-diabetic patients.

O (Primary Outcome):

Outcome (s)	Evaluation Criteria	Measuring Unit
Primary Outcome	Restoration Retention using modified USPHS criteria	Modified USPHS criteria measured of restoration using Alpha, Bravo, and Charlie scales. (Hendam et al., 2025)
Secondary Outcome (s)	Marginal Adaptation Secondary Caries Marginal Discoloration Post operative Sensitivity	

Criteria	Alpha	Bravo	Charlie
Retention	No Loss of restorative material	————	Fracture and/or loss of restorative material
Marginal Adaptation	There is no viable evidence of a cervic along the margin into which the explorer will penetrate	There is visible evidence of a cervic along margin into which the explorer will penetrate or catch	The explorer penetrates the cervic, and dentin or base is exposed.
Marginal discoloration	There is no discoloration anywhere on the margin between the restoration and tooth structure	Discoloration is present but has not penetrated along the margin in a pulpal direction	Discoloration has penetrated along the margin in a pulpal direction
Secondary Caries	No evidence secondary caries	————	Evidence secondary caries
Postoperative Sensitivity	No postoperative sensitivity, after the restorative procedure and during the study	Slight sensitivity at any stage of the study	Severe Sensitivity at any stage of the study

T (Time Frame): (Hendam et al., 2025)

- **T0, T1, T2, T3:** Periodic follow up and assessment according to modified USPHS criteria

S (Study Design): This study will be conducted in the form of a stratified randomized controlled, unicenter, clustered four-arm superiority trial with a 1:1:1:1 allocation ratio.

7. Hypothesis:

There is no difference in clinical performance between Zirconia-reinforced Glass Ionomer and Injectable Giomer (Beautifil Flow Plus X, SHOFU) in Controlled Type II diabetic and non-diabetic healthy patients with Class V carious lesions in permanent teeth.

III. Methods

A. Participants, Interventions & Outcomes

9. Study Settings

This is a randomized controlled trial assessing the clinical performance of Zirconomer which is zirconia-reinforced glass ionmer in Class V carious lesions among diabetic and non-diabetic patients attending the Cairo University Dental Hospital. The Faculty of Dentistry, Cairo University is an open public facility, a tertiary healthcare and a referral center.

10. Eligibility Criteria (Hendam et al., 2025)

The inclusion criteria:

Inclusion criteria for patients

- Male or Female participants from 22 to 55 years
- Controlled diabetic and non-diabetic patients consulting the outpatient clinic
- Patients categorized as moderate or high caries risk
- Patients willing to provide informed consent
- Co-operative patients agreeing to participate in the trial

Inclusion Criteria for teeth

- Teeth with class V carious lesion classified according to the International Caries Detection and Assessment System (ICDAS II) as ICDAS code (4) or ICDAS code (5)
- Teeth with normal pulp vitality testing; no signs of inflammation or spontaneous pain before treatment

The exclusion criteria

Exclusion criteria for patients

- Patients with spontaneous or elicited pain from caries.
- Systemic illnesses other than diabetes.
- Severe bruxism/clenching.
- Temporomandibular joint disorders.
- Inability to return for recall visits/ Refusal to participate in the study.
- Pregnancy.
- heavy smoking.
- Lack of compliance.

Exclusion criteria for teeth

- Teeth presenting with spontaneous or elicited pain
- A lack of normal pulp vitality testing
- Visible or clinical signs of pulpal/periapical inflammation before treatment.
- Class V carious lesions that are not classified as ICDAS code (4) or ICDAS code (5).

11. Intervention

Dental patients will be recruited in a consecutive manner from the Outpatient Diagnostic Center, Faculty of Dentistry, Cairo University. Before any clinical examination, the aim of the study will be explained to the patient and the patient's acceptance to participate in the study will be received. Non-respondent patients or patients refusing to participate will be reported with the cause of their refusal. Conventional oral examination will be conducted on a dental unit using the light of the unit, mirror and probe. Clinical examinations will be performed using a dental mirror and aided by the tactile detection of a dental explorer under LED illumination to confirm class V carious lesion in labial surface of posterior permanent teeth, classified as ICDAS-4 and ICDAS-5.

Cavity Preparation

Class V cavities will be prepared by the same operator. After local anesthesia administration, field isolation will be performed using rubber dam sheets (Nic Tone rubber dam latex, MDC Dental, Jalisco, Mexico), dental floss ligatures, retraction cord (Gingi-Pak Soft-Twist Cords, California, USA), and subgingival clamps (B4 Brinker clamp, TOR VM, Moscow, Russia), (KSK Clamp no. 44, Dentech Corporation, Tokyo, Japan). A conservative cavity design will be prepared using round-shaped carbide burs (HM1, Hager and Meisinger GmbH, Neuss, Germany) with sharp dental excavators (Zeffiro excavator, Lascod spA, Florence, Italy) to remove soft carious dentin. The prepared cavity will be finished using yellow-coded, extra-fine diamond finishing stones 52 (Mani Inc., Utsunomiya, Japan). A short incisal bevel will be performed for prepared cavities.

Restorative procedures

Zirconomer Placement

Following cavity preparation, the rubber dam will be removed for the Zirconomer group. Field isolation during restoration placement will be maintained using cotton rolls, a saliva ejector to ensure adequate moisture control. Dentine conditioner (10% Polyacrylic acid, shofu, Japan) was

used and applied according to the manufacturer's instructions to enhance the bond between the glass ionomer and the tooth.. The material will be prepared according to the manufacturer's instruction by dispensing two separate full scoops of powder and one drop of liquid. The first portion of the dispensed powder will be mixed with the liquid for 5–10 s. Then, the remaining powder portion will be added and mixed until reached a thick putty-like consistency. Mixing will be completed within a total of 30 s. Cavities will then be filled by the bulk placement of the GI and restored according to the tooth anatomy form, while the excess material will be removed completely using a flat plastic instrument (Hu-Friedy Mfg. Co., Chicago, Ill, USA).

Giomer-based resin composite Placement

Selective enamel etching will be performed for 15 sec (FineEtch 37, Spident Co., South Korea), followed by copious rinsing and gentle air drying. A universal adhesive (BeautiBond Xtreme, Shofu Dental Corporation, Japan) will be applied, rubbed for 20 sec, gently air-thinned for 3 sec, followed by a strong air-blow until the surface appeared glossy with no visible movement of the adhesive. The adhesive will be photo-polymerized for 10 sec using an LED light-curing device (DTE O-Light II, Woodpecker, China). Low shrinkage Giomer resin composite (Beautifil II LS, Shofu Dental Corporation, Kyoto, Japan) will be incrementally placed and shaped with gold plated applicators, with each increment not exceeding 2 mm in thickness and photo-polymerized for 20 sec, in accordance with the manufacturer's instructions.

Finishing and polishing

Restoration contouring will be performed using yellow-coded diamond burs, followed by finishing and polishing with cups and points (OneGloss, Shofu Dental Corporation, Japan) until an even, glossy surface will be achieved.

Intervention Modification

No modification to the planned intervention will be permitted during the study period. All Class V cavities will be restored according to the manufacturer's instructions. The restorative protocol, including cavity preparation, restorative materials placement and finishing and polishing procedures, will be standardized and performed identically for both controlled diabetic and non-diabetic participants to ensure procedural consistency.

Intervention adherence:

Intervention adherence will be ensured by having all restorative procedures performed by the same operator under standardized clinical conditions. A strict operative protocol will be followed for cavity preparation, isolation, adhesive application, restorative materials placement. Participants will be scheduled for follow-up visits according to the study timeline to monitor restoration performance and ensure adherence to recall appointments.

Intervention concomitant care:

All participants will receive standardized oral hygiene instructions and routine dental care throughout the study period. No additional preventive or restorative procedures will be performed on the restored teeth during the follow-up period. Participants will be instructed to avoid the use of desensitizing agents, topical fluoride applications, or any materials that may interfere with the performance of the restorative material on the study teeth. Any dental treatment unrelated to the study restorations will be documented.

12. Outcomes

The restorations will be assessed by O.H & A.A at baseline, and after 6, 12, and 18 months using the modified USPHS criteria. The criteria included restoration retention, marginal Adaptation, secondary caries, marginal discoloration and post-Operative Sensitivity. The restorations will be scored as either Alfa (A), indicating an ideal clinical condition; Bravo (B), indicating clinically acceptable; or Charlie (C), indicating a clinically unacceptable condition.

Modified USPHS criteria:

Outcome name		Score	Criteria	M.unit	Methods of diagnosis
Primary	Retention	Alpha (A)	No loss of restorative material	Ordinal	Visual inspection using magnifying loupes
		Charlie (C)	Any loss of restorative material		

Secondary	Marginal adaptation	Alpha (A)	Smooth margins	Ordinal	Visual inspection using magnifying loupes and tactile sensation using sharp explorer
		Bravo (B)	Visible evidence of a crevice along the margin, no dentin exposed		
		Charlie (C)	Explorer penetrates into a crevice, dentin exposed		
	Secondary caries	Alpha (A)	No caries present	Binary	Visual inspection using magnifying loupes
		Charlie (C)	Caries present		
	Marginal Discoloration	Alpha (A)	No loss of restorative material	Ordinal	Visual inspection using magnifying loupes
		Bravo (B)	Shallow discoloration which can be polished away		
		Charlie (C)	Any loss of restorative material		
	Post-operative sensitivity	Alpha (A)	No post- operative sensitivity	Binary	Taking history from patients
		Charlie (C)	Presence of post-operative sensitivity		

13. Participant timeline:

		T0	T1	T2	T3
Activity	Staff member	Baseline	Follow up 6 months	Follow up 12 months	Follow up 18 months
Recruitment	MA	√			
Diagnosis	MA	√			
Consent	MA	√			
Cavity Preparation	MA	√			
Application of intervention	MA	√			
Outcome assessment	OH – AA	√	√	√	√

14. Sample Size Calculation

The sample size was calculated based on a previous study by **Hendam et al in 2025**, in which retention success rate in injectable giomer restorations was 100% in carious cervical lesions after 18 months. 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 22 per group in order to detect a difference of 30%. Sample size was increased by 15% to compensate for possible dropouts to reach 25 restorations per group. Sample size was performed using G*Power version 3.1.9.2 for windows.

15. Recruitment

Patients will be recruited by the principal investigator (M.A) from Outpatient Clinic of Conservative Dentistry Department in Faculty of Dentistry, Cairo University; from which eligible patients will be recruited to fulfill the eligibility criteria according to participant timeline.

B) Assignment of interventions:

16. Allocation

a. Randomization

The randomization unit will be the tooth. Sequence generation will be performed using Microsoft Excel (Microsoft, Washington, USA) by an independent contributor. Simple

randomization will be performed with 1:1:1:1 allocation ratio. The interventional variables being the diabetic and non-diabetic patients and restorative material type (Injectable Giomer (Beautifil Flow Plus X, SHOFU) and Zirconia-reinforced Glass Ionomer (Zirconomer, SHOFU) will be allocated during the ongoing process of the clinical trial and will be concealed from the primary investigator up to the time of actual operatory work.

b. Allocation concealment mechanism and implementation

Allocation sequence will be entrusted to an external participant who will have a generated sequence allocating patient order into their allotted blocks and will be contacted via telephone to inform principal operator of the intervention to be done.

c. Implementation

Participants will be enrolled by the principal investigator, and they will be assigned to the respective interventions through the Microsoft Excel software.

17. Masking/blinding

The trial participants and statisticians will be strictly blinded to the assigned interventions. Due to the inherent differences in optical properties, surface texture, and color variation between the zirconia-reinforced glass ionomer (Zirconomer) and the injectable giomer (Beautifil Flow Plus X), complete blinding of the outcome assessors to the restorative materials is not clinically feasible. However, to minimize detection bias, the outcome assessors will be completely blinded to the patients' systemic health status (whether they belong to the controlled Type II diabetic group or the healthy, non-diabetic control group). The assessors will not be involved in the preliminary medical screening or preclinical enrollment of the participants. The principal investigator will be blinded up to the step of restorative material application where they will be informed by the external participant responsible for the allocation concealment.

C. Data collection, management, and analysis

18. Data collection methods

Data will be collected Baseline data records, medical and dental history sheets. The assistant supervisor will have the role of monitoring the process of data collection and check if there is any incomplete data.

Outcome Data Collection

The restorations will be evaluated using modified USPHS criteria and given a score of alpha, bravo and Charlie. Evaluation will be done at baseline, 3 months, 6 months, 12 months and 18 months. Patients will be given the appropriate post-operative instructions Meticulous oral hygiene measures will be instructed as well.

19. Data management

Data sources will include readings from the clinical examinations which will be performed on the participants. All data will be entered and saved electronically by the main researcher. Patient files will be stored in numerical order and stored in a secured file. Data will be encrypted using a password. All data will be maintained after completion of the study.

20. Statistical methods

Data will be analyzed using Medcalc software, version 22 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. Statistical power of the study will be set at 80 % with 95 % confidence level.

D) Data monitoring

21. Monitoring

The main supervisor will monitor this study (M.A). The role is to monitor any risk of bias that could arise from participants, operator, or assessors, and to monitor blinding of the assessors and patient safety, outstanding benefits, or harms.

22. Harms

The principal investigator will inform participants about the possible harms (pain, loss of restoration, leakage, and fracture of restorations) if present. Participants are allowed to contact the operator at any moment through telephone. For assessment inspection, percussion, and sensitivity tests will be performed. The data will be reported to the co-supervisor and managed.

23. Audit

In the present trial, auditing will be done by the main supervisors and co-supervisors to assure quality of the research methods, technique and intervention.

IV. Ethics and Dissemination

24. Research ethics approval

This protocol and the template informed consent form will be reviewed by the Ethics Committee of Scientific Research – Faculty of Dentistry – Cairo University.

25. Protocol amendments

Any modifications to the protocol which may have an impact on the conduct of the study, potential benefit to the patient, or may affect patient safety, including changes to study objectives, study design, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendment will be agreed upon by the Council of Restorative Department.

26. Informed consent

The researcher will introduce the trial to patients and provide a full explanation of its aim and benefits in plain language. Patients will then be able to have an informed discussion with the researcher. The researcher will obtain written consent from patients willing to participate in the trial. All consent forms will be translated into Arabic.

27. Confidentiality

All study-related information will be stored securely. All participant information will be stored in locked file cabinets in areas with limited access. All reports, data collection, and administrative forms will be identified by a coded ID [identification] number only to maintain participant confidentiality. All records that contain names or other personal identifiers will be stored separately from study records identified by code number. All local databases will be secured with password-protected access systems.

28. Declaration of interest

This study has not been conducted before in the Faculty of Dentistry, Cairo University, as a master's or PhD degree program study.

29. Access to data

The principal investigator and the supervisors will be given access to the datasets. All data sets will be password protected. To ensure confidentiality, data will be blinded to any identifying participant information.

30. Post-trial care

Patients will be followed up to ensure oral hygiene measures.

31. Dissemination policy

Study results will be published as partial fulfillment of the requirements for a PhD degree. Topics suggested for presentation or publication will be circulated to the authors.

V. Appendices

32). Informed consent materials:

Informed Consent Model of (REC) faculty of Dentistry, Cairo University will be used this

Appendix II: Diagnostic chart



Cairo University
Faculty of Dentistry
Department of Conservative Dentistry

Examined by Dr. _____

Date: ____/____/20

• Personal Information

Patient name: _____ Date of birth: ____/____/____ Sex: ____ Age: ____ Marital: ____
Address: _____ Occupation: _____ Contact Phone no.: _____
Referred to us by: _____ Department: _____ Other Phone no.: _____

• Medical History

Do you have any of the following:

- ☐ **Active Tuberculosis** [Persistent cough more than 3 weeks—Cough that produce blood] notes: _____]
☐ **Diabetes** [Controlled — Uncontrolled] notes: _____]
☐ **High blood pressure** [Taking medication — Not taking medication] notes: _____]
☐ **Heart Condition** [Angina — Heart attack — Artificial valves — Arteriosclerosis] Other: _____]
☐ **Hepatitis** [or Other infectious disease: _____]

Are you undergoing any medical treatment? (Yes - No) notes: _____]
Or had any serious operation or hospitalization? (Yes - No) notes: _____]
Are you taking any medication? (Yes - No) notes: _____]

Are you a Smoker? (Yes - No) — if yes, How Many /day? _____

For Females Only: Are you pregnant? (Yes - No - Not Sure) -- if Yes, Weeks? _____ -- Nursing? (Yes - No)

Allergic or Unusual Reaction to Any of the Following: (Yes - No), if yes, what triggers the reaction?

- ☐ Penicillins
☐ Aspirin
☐ Local anesthesia
☐ Latex
☐ Other drugs:
List: 1. _____ 2. _____ 3. _____
☐ Other Substances (food, metals, etc.)
List: 1. _____ 2. _____ 3. _____

• Dental History

Darken the circle beside items that describe past dental problem and dental care:

Dental Care: ☐ Regular dental care ☐ Irregular ☐ More than twice a year ☐ Emergencies ☐ First visit

Past Treatment:

- ☐ Wisdom tooth extractions ☐ Orthodontics
☐ Gum disease (gingivitis or periodontal disease)
☐ Treatment for jaw trauma/fracture notes: _____]
☐ Have an adverse reaction to dental treatment (please describe) notes: _____]
☐ Dental fears or anxiety notes: _____]

State of ORAL HEALTH in general: ☐ Excellent ☐ Very Good ☐ Good ☐ Fair ☐ Poor

• Extra-Oral and Intra-Oral Examination

General appearance: patient's gait: _____ mobility: _____ lesions or scars: _____
Other notes: _____

Head and Neck exam.: Lymph node: (tenderness - enlargements) in _____ Other notes: _____
TMJ: (clicking - tenderness - swelling) Other notes: _____
Asymmetries: _____

Intraoral Soft Tissue exam.: (detect any abnormal variations)

- Lips and Labial mucosa: _____
Buccal and Vestibular mucosa: _____
Hard and Soft palate: _____
Tongue: _____
Floor of mouth: _____

Further Examinations needed:



Appendix III: MBU Acceptance



Medical Biostatistics Unit review report for sample size

Individual Details

First Name: Mohamad

Surname: Ayman

Email address: mohamed.ayman@dentistry.cu.edu.eg

Your Status *

PhD Degree Candidate

Department *

Conservative Dentistry

Main Supervisor Details (if applicable)

Prof. Dr. Olfat Hassanin

Email address: olfat.hassanein@dentistry.cu.edu.eg

Research Information

Research title: Clinical Performance of Zirconia-Reinforced Glass Ionomer Versus Injectable Giomer in Class V Restorations of Diabetic and NonDiabetic Patients: 18 months Controlled Clinical Trial

Research question: Does restoration with Zirconia-reinforced Glass Ionomer show any difference in clinical performance when compared to injectable Giomer in controlled Type II diabetic and non-diabetic healthy patients with Class V carious lesions in permanent teeth over 18 months?

Complete items used in sample size calculated *

- The outcome used: Retention (Success)
- Values used for outcome: Proportions
- Entry 1: estimated intervention 0.7
- Entry 2: Comparator 1
- Alpha level of significance: 0.05 (5%)
- Effect size: a difference of 30%
- Power of the study: 80%

- Statistical test used: Z test
- The calculated sample size: 22 per group
- Increased number for anticipated missing data (15%): **25 teeth per group**

Decision of MBU:

- Accepted*

☒

- Needs modifications

☐

What to be modified:

- A meeting is needed

☐

Date of meeting: / /

Time of meeting:

Place of meeting:

N.B. If you couldn't attend the meeting, show up to apologize or contact your reviewer by e-mail to set up another convenient time.

MBU member/Dr Yehia Hafez

MBU Director/ Prof.Dr.Noha Ghallab

* Date of submission: 6 / 7 / 2026

Date of approval: 7 / 7 /2026

Vice Dean for Postgraduate affairs and research

Appendix IV: Clinical Trial Registration

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