

# Clinical Performance and Wear Resistance of Highly Translucent Nano Zirconia Reinforced Glass Ionomer Filling Versus Conventional Resin Composite Restorations in Patients with Proximal Carious Teeth: Randomized Clinical Trial

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## ABSTRACT

**Aim:** This study aimed to evaluate the clinical performance and occlusal wear resistance of nano- zirconia reinforced glass ionomer restorations in comparison to nano-hybrid resin composite restorations in proximal cavities.

**Material and Method:** This randomized clinical trial was conducted on thirty-two patients who had proximal carious lesions in posterior teeth. Participants were randomly allocated into two groups (n=16 for each group) in which they received either; Nano zirconia reinforced glass ionomer restorations (Zirconomer Improved, Shofu, Japan) or Conventional nano hybrid resin composite (Filtek Z250 XT, 3M ESPE, USA), all materials were applied according to manufacturers' instructions. Restorations were evaluated at baseline (immediately), after six months, and after 12 months by two blinded assessors using modified USPHS criteria measuring (postoperative hypersensitivity, secondary caries, gross fracture, color match, cavo-surface marginal discoloration, marginal integrity, proximal contact and wear resistance). Data was analyzed using Medcalc software, intergroup comparisons between interventions was performed using the Chi-Squared test with statistical significance level set at ( $P \leq 0.05$ ) while intragroup at ( $P \leq 0.016$ ) after Bonferroni correction, relative risk was used to assess the clinical significance.

**Results:** Intergroup comparison between both materials regarding USPHS criteria and wear resistance have shown no statistically significant difference within different follow up periods; baseline, 6 and 12 months respectively except for the color match shown significant difference with highly translucent nano zirconia reinforced GI. Intragroup comparison within highly translucent nano zirconia reinforced glass ionomer and within conventional resin composite regarding USPHS criteria have shown no statistically significant difference between different follow-up periods except for the wear resistance shown significant difference within highly translucent nano zirconia reinforced GI.

**Conclusion:** Nano zirconia reinforced glass ionomer and Nano hybrid resin composite have a similar clinical performance and wear resistance after one year follow up.

**Keywords:** Nano Zirconia Reinforced Glass Ionomer, Nano Hybrid Resin Composite, Zirconomer Improved, Z250XT, Proximal Carious Lesions, Class II and Randomized Clinical Trial

## Introduction

Any restorative material's purpose is to replace the lost biological, functional, and aesthetic properties of the tooth structure. To obtain best treatment delivery, a great advancements and improvement have been occurred in restorative materials technology to improve these properties Bahgat et al., [1]. Conventional resin composite restorations are the most widely used materials in dental practice and considered due to its enhanced mechanical and esthetic properties compared to the other materials. On the other hand, resin composite restorations

have limited usage with patients that are not easily to maintain strict isolation during operative procedures. Additionally, since resin composite is not a cariostatic material due to absence of fluoride release property, it is not indicated in patients with high caries index, Mohamed et al., [2].

The most important advantage of glass ionomer restorations (GICs) its ability to survive properly in patients with high caries index due to its prolonged anti-cariogenic effect owing to fluoride release and recharge abilities. Without the need for an adhesive application, these GICs adhere chemically to enamel and dentin via an ion exchange layer. Also, they could offer acceptable mechanical and aesthetic properties making them the restoration of choice in many cases like cervical and occlusal

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cavities in geriatric and high caries risk patients Wafaie et al., [3]. Despite all these benefits, glass ionomer restorations cannot maintain the proximal contact which make proximal restoration is a challenge, due to its inherent lower wear and fracture resistance and most varieties of glass ionomer restorations currently on the dentistry market do not provide a higher fracture resistance restoration that need in this area. Safy et al., [4].

ZIGI is commercialized as a white amalgam. The first generation was (Zirconomer, Shofu, Japan), the zirconia fillers have been added to the glass component to contribute to the structural integrity and increase its strength. Then, a newer version of nano zirconia GI was introduced to the market (Zirconomer Improved, Shofu, Japan) with unique fillers made of nano sized zirconia for enhancing translucency, aesthetic properties mainly and improving the mechanical and handling characteristics compared to its previous version Shetty et al., [5].

Due to lack of enough knowledge about the clinical performance of ZIGI it was found beneficial to make this clinical study to evaluate the clinical performance and occlusal wear resistance of nano zirconia reinforced glass ionomer restorations in comparison to nano hybrid resin composite in proximal cavities. The null hypothesis proposed that there would be no difference in the clinical performance and wear resistance of nano zirconia reinforced glass ionomer restorations versus nano hybrid resin composite restorations in patients with proximal caries cavities.

#### Materials and Methods

In this randomized controlled clinical trial the variables were two restorative materials as **Conventional nano hybrid resin composite (Filtek Z250 XT, 3M, USA)** as a control Figure (1) and **Highly translucent nano zirconia reinforced glass ionomer restorations (Zirconomer Improved, Shofu, Japan)** as an intervention Figure (4). 32 teeth were selected and assigned in two groups after randomization and each group has 16 teeth with proximal caries lesion according to sample size calculation. Each generated random number represented assigning either intervention or comparator to each patient in a random manner. To ensure the allocation concealment, opaque sealed envelopes were made containing the grouping generated previously and titled by numbers. Patients who met the inclusion criteria were enrolled into the study by the assessors. The operator chose between numbers in an opaque sealed envelope as the randomization codes were not released until the participants had been recruited into the trial. All procedures performed in this study, involving human participants, this study was registered in ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)) with I.D: **NCT05403008**. The study was approved by the Research Ethics Committee (CREC), Cairo university with approval number **15/3/22**. This randomized controlled clinical study was held in Faculty of Dentistry, Cairo University, Egypt. The assessors and statistician were blinded to the material assignment while the operator and the patient were not due to the difference in material presentation and its application protocol.

#### Comparator

**Resin Composite:** Conventional nano hybrid resin composite (Filtek Z250 XT, 3M, USA) Figure (1).

**Adhesive System:** Selective enamel etching protocol was used with these materials:

- **Light cured adhesive (Single Bond Universal Adhesive, 3M ESPE, USA) Figure (2).**
- **37 % phosphoric acid etching gel (Meta Etchant, MetaBiomed, Korea) Figure (3).**



**Figure 1:** Conventional nano hybrid resin composite (Filtek Z250 XT, 3M ESPE, USA)



**Figure 2:** Light cured adhesive (Single Bond Universal Adhesive, 3M ESPE, USA)



**Figure 3:** 37 % phosphoric acid etching gel Etchant



**Figure 4:** Zirconomer Improved, Shofu, Japan (Meta Meta Biomed Korea)

All Material's specifications, chemical composition, lot number and manufacturers used in this study are presented in Table (1).

Material	Composition	Lot number	Manufacturer
Zirconomer Improved	zirconium oxide, glass powder, tartaric acid (1- 10%), polyacrylic acid (20-50%), and deionized water as its liquid. Zirconium oxide, the main powder component of Zirconomer, results from Baddeleyite (ZrO <sub>2</sub> ) that contains high levels of zirconia ranging from 96.5 to 98.5%.	11201380 Exp 13/10/2023	Shofu Inc., Japan <a href="https://www.shofu.com/global/">https://www.shofu.com/global/</a>
Conventional nano hybrid resin composite Z250 XT	visible-light activated, radiopaque, restorative composite. The filler is zirconia/silica. The inorganic filler loading is 60% by volume (without silane treatment) with a particle size range of 0.01 to 3.5 µm. Filtek Z250 restorative contains BIS- GMA, UDMA, and BIS- EMA resins.	Z017 JN	3M ESPE, USA <a href="https://www.3m.com/3M/en_US/dental-us/">https://www.3m.com/3M/en_US/dental-us/</a>
Single bond Universal	Single component light cured universal adhesive MDP phosphate monomer, Dimethacrylate reins, HEMA, Vitrebond TM Copolymer, Filler, Ethanol, water, Initiators, silane. mild self-etch adhesive pH 2.7.	95635c	3M ESPE, USA <a href="https://www.3m.com/3M/en_US/dental-us/">https://www.3m.com/3M/en_US/dental-us/</a>
Meta Etchant	Etching Gel Containing 37% Phosphoric acid, H <sub>2</sub> O, xanthan gum	Z011RJ	Meta Biomed, Korea <a href="https://www.meta-biomed.com/">https://www.meta-biomed.com/</a>

### Eligibility Criteria

The patients in this study were selected following different exclusion and inclusion criteria:

### Criteria of the participants: Inclusion criteria of the participants

- Age group 18-55.
- Good oral hygiene.
- Patient with normal occlusion

### Exclusion criteria of the participants

- Poor periodontal status.
- Adverse medical history.
- Potential behavioral problems.
- Presence of any parafunctional habits

### Criteria of the teeth: Inclusion criteria of the teeth

- Vital teeth free from any developmental or formative pathosis.
- Class II cavity in permanent teeth without active periodontal or irreversible pulpal diseases.
- Upper or lower posterior teeth with present adjacent tooth.
- The opposing occlusion should be natural teeth

### Exclusion criteria of the teeth

- Participants presenting mobile teeth.
- The absence of adjacent and antagonist teeth
- Teeth with signs and symptoms of irreversible pulpitis or pulp necrosis.
- Maligned teeth.
- Cracked teeth.

### Sample Size Calculation

Sample size was determined by the Center of Evidence Based at the Faculty of Dentistry, Cairo University. Convenient sampling method was applied to recruit all eligible candidates in the hospitals in a period of 12 months. The predicted sample size (n) was a total of (26). Sample size was increased by (20%) to account for possible dropouts during follow-up intervals to be total of (32) cases i.e. (16) for each group. Sample size calculation was performed using G\*Power 3.1.9.2.

### Procedures

Clinical examination of proximal carious lesion was performed after scaling and polishing with the aid of dental mirror and sharp explorer. According to manufacturer instructions of (Zirconomer Improved, Shofu, Japan) the operative field was isolated with rubber dam before starting the restorative procedure to avoid moisture contamination that leads to retardation of the material setting. The cavity was formed using minimally invasive dentistry with # 245 or # 330 carbide burs at high-speed Figure (5).

For restoring the proximal contact and the marginal ridge, evaluation of the remaining tooth structure and interdental space was done properly to select the proper sectional matrix system either Ring system or Saddle matrix system (Tor VM, Russia) and a wooden wedge.



Figure 5: Rubber dam isolation and cavity preparation

### Intervention Material

Two level scoops of powder were dispensed onto a mixing pad followed by one drop of liquid, followed by mixing for 30 seconds until thick putty-like consistency was achieved. Then, the cavity was filled with the restoration using a suitable size condenser (Helmut Zepf, Germany) to establish proper contact and contour Figure 6. According

to the manufacturer instructions after the recommended setting time that is 7 minutes, finishing and polishing of the restoration were performed using abrasive discs and stones (Dura-White stones, Shofu, Japan) with water spray lubrication. Finally, petroleum jelly was applied to the surface of the final restoration in accordance with the manufacturer's recommendations to prevent moisture contamination during the early hardening phase.



**Figure 6:** Zirconomer Improved restoration

#### Control Material

the enamel was etched with 37% phosphoric acid for 15 s, washed with air/water spray for 20 s. Afterward, Light cured adhesive (Single Bond Universal Adhesive, 3M ESPE, USA) was actively applied for 20 s with a micro- brush, gently air sprayed for 5 s and light- cured for 10 s using bluephase light curing unit (Ivoclar Vivadent, Schaan, lichtenstein). Oblique increments (up to 2 mm in thickness) of Conventional nano hybrid resin composite (Filtek Z250 XT, 3M ESPE, USA) was inserted in the proximal box, followed by the occlusal box. Each increment was light-cured for 20 s in the same manner as the adhesive Figure (7). Polishing was done with KENDA (C.G.I COMPOSITE & COMPOMER, Australia) polishing system.

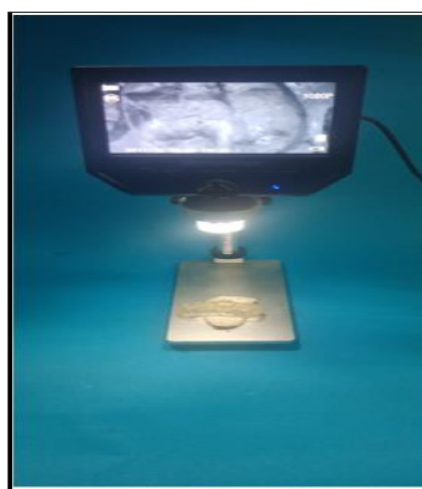


**Figure 7:** Resin composite restoration

#### Outcome Assessment

All restorations were evaluated immediately, then followed up for 6 and 12 months. Assessors were blinded to the material assignment. Each restoration was photographed and scored using the modified USPHS criteria Ryge criteria: (postoperative hypersensitivity, secondary caries, gross fracture, color match, cavo-surface marginal discoloration, marginal integrity, proximal contact) for primary outcome: evaluation of direct restorations. Secondary outcome wear resistance evaluation: a partial impression was taken for the tooth restored and the neighboring teeth using vinylpolysiloxane (Elite HD +, Zhermack, Italy) addition silicon in partial stock trays at baseline (immediately), after 6 months and after one year, and replicas were manufactured

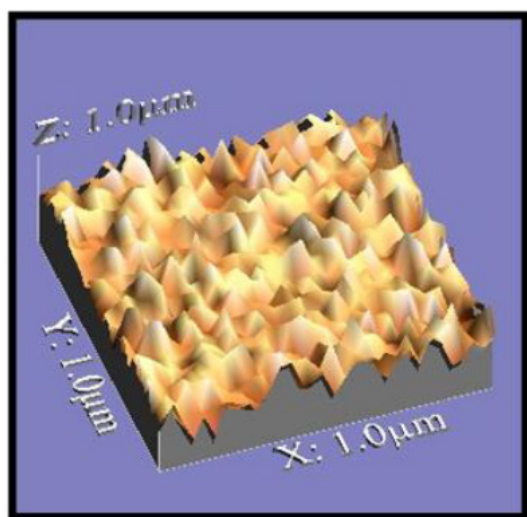
from the epoxy resin. Epoxy resin casts were shot using a USB Digital microscope with a built-in camera attached to an IBM compatible personal computer at a fixed magnification of 120x and a resolution of 1280 1024 pixels per image for wear evaluation Figure (8). To standardize the region of measurement, digital microscope photos were cropped to 350 x 400 pixels in Microsoft Office Picture Manager. WSxM software was used to evaluate the cropped photos. All limitations, sizes, frames, and measured parameters in this software were expressed in pixels. All limitations, sizes, frames, and measured parameters in this software were expressed in pixels. As a result, system calibration was performed in order to transform the pixels into absolute real-world units. Calibration was performed by comparing a known size object (a ruler in this investigation) to a scale created by the software. Following that, a 3D picture of the tooth's surface profile was developed Figure (9). Five 3D images were collected for each tooth in the central area and in the sides at the area of 10  $\mu\text{m}$  x 10  $\mu\text{m}$  Figure (10). These period images were superimposed against one another using tripodization by identifying three points on the occlusal anatomy which were expected to remain stable (i.e., marginal ridges). The cropped images were analyzed using WSxM software to calculate the average of heights expressed in  $\mu\text{m}$  "Wear measurements" Figures (11). After the achievement of proper matching between different periods of follow-up, the maximum wear of teeth at these time periods was compared and recorded. After that, topographic changes were determined by an optical profilometer.



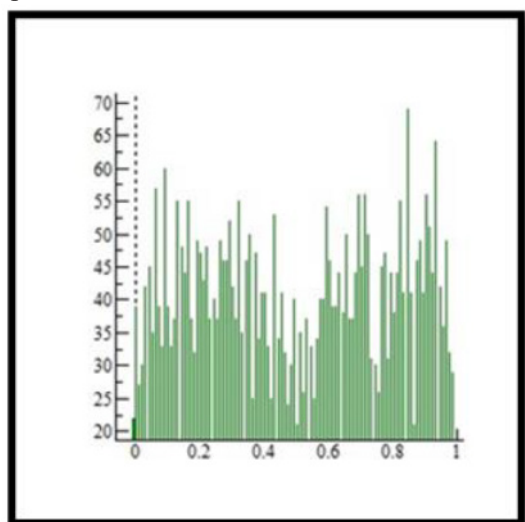
**Figure 8:** USB Digital microscope with a built-in camera



**Figure 9:** A 3D image of the surface profile of the tooth



**Figure 10:** Three-dimensional digital image showing topographic features



**Figure 11:** Histogram showing different average of elevations

## Results

### Demographic Data

This study included 32 people with proximal carious lesions who were assigned at random to either the intervention or comparison arms (n=16). With a 93.75% retention rate, 30 individuals finished the follow-up after 12 months. There were 21 maxillary molars and 11 mandibular molars in the dental arches, however there was no statistically significant difference in tooth distribution between the two groups ( $P = 0.2718$ ).

### Statistical Analysis

Medcalc software, version 19 for Windows (MedCalc Software Ltd, Ostend, Belgium), was used to analyze the data. Intergroup comparisons between interventions were performed using the Chi-Squared test with a statistical significance level of ( $P \leq 0.05$ ), and categorical data were described as frequency and percentage. Intragroup comparison within each intervention was performed using the Chi-Squared test with statistical significance level set at ( $P \leq 0.016$ ) after Bonferroni correction. The clinical relevance was determined using relative risk. Continuous data was described using mean and standard deviation, intergroup comparisons between interventions was performed using the

independent test with statistical significance level set at ( $P \leq 0.05$ ), intragroup comparison within each intervention was performed using repeated measures ANOVA followed by tukey post-hoc test with statistical significance level set at ( $P \leq 0.016$ ) after Bonferroni correction.

### Clinical Significance

Intergroup comparison between both materials regarding USPHS criteria and wear resistance have shown no statistically significant difference within different follow up periods; baseline, 6 and 12 months respectively except for the color match intergroup comparisons of both materials have revealed statistically significant variations over three monitoring time frames: the starting point, six, and twelve months ( $P < 0.0001$ ). There was 31 times more risk for color match (score C) of ZIGI when compared to RC after one year (RR= 31.0000 (95% 2.0226 to 475.1406;  $P = 0.0137$ )).

### Discussion

**Regarding marginal integrity, marginal discoloration, secondary caries, and postoperative sensitivity** Intergroup comparison between both materials and Intragroup comparison within highly translucent nano zirconia reinforced glass ionomer have revealed no statistically significant variations over three monitoring time frames: the starting point, six, and twelve months.

The above-mentioned results were in contrast with the study by Mohamed et al., which indicated that nano zirconia reinforced glass ionomer restoration had inferior results regarding the post-operative sensitivity and tooth vitality which was attributed to the lack of marginal adaptation that is associated with marginal leakage, post-operative sensitivity and recurrence of caries [2]. The large size of zirconia filler particles that results in poor adaptation at the tooth-restoration interface may be responsible for this finding. The deficiency of chemical interaction between the zirconia fillers and the polysalt matrix led to areas of concentrated stress and ultimate material loss. Additionally, nano zirconia reinforced glass ionomer had greater elastic deformation and a lower elastic modulus so, it will deform when subjected to functional loads this lead to prevent diminished marginal adaptation, postoperative sensitivity, and caries recurrence. Regarding the proximal contact, Intergroup comparison between both materials and Intragroup comparison within highly translucent nano zirconia reinforced glass ionomer have revealed no statistically significant variations over three monitoring time frames: the starting point, six, and twelve months. Which was in match with the investigation achieved by Raina et al. revealed that the proximal contact of the (ZI) and urethane dimethacrylate (CN) when used in class II restorations, offer clinically acceptable proximal contact tightness with score 2 for (ZI) while with score 1 for (CN), this a statistically significant difference between them due to the different viscosities of the two materials [6]. On the other hand, this result is against with Mohamed et al. which indicated that hand mixed (ZI) had inferior results regarding proximal contact after 6 months and a one year because he did not apply a layer of jelly petroleum that protect (ZIGI) restorations material against water uptake (ZI) and during the early hardening phase by occluding surface cracks and

porosity [2]. Also, the manual mixing that increases operator variability and difficulty of application that led to influence on its mechanical properties.

The most significant drawbacks of GIC restorative materials are connected to the decreased wear resistance and fracture of the dental material. Clinical researches are crucial for a good understanding of the wear resistance of dental materials when subjected to the complex masticatory process that takes place in the oral environment. A number of studies have been conducted to stimulate the wear of dental materials in the lab Hesse et al. [7]. Regarding the wear resistance, intergroup comparison between both materials have revealed no statistically significant variations over three monitoring time frames: the starting point, six, and twelve months. This finding may be due to the layer of jelly petroleum that applied protected the (ZI) restorations material during the early hardening phase by occluding surface cracks and porosity and protected against water uptake, hence improving wear resistance and toughness. The above-mentioned results were in contrast with the study by Mohamed et al. which indicated that hand mixed (ZI) had inferior results regarding the wear resistance resulted from variance in liquid/ powder ratio due to human error and the air bubbles in the matrix caused by manual mixing are that cause to surface hydrolytic instability softening and decreased its mechanical properties [2].

**In relation to the color match**, intergroup comparisons of both materials have revealed statistically significant variations over three monitoring time frames: the starting point, six, and twelve months Which was in match with the examination managed by Balkaya et al., that reported that the color and translucency qualities of HVGIC restorations were still insufficient, and their color match was not exactly the same as composite resin restorations [8-15].

**Regarding the gross fracture**, Intergroup comparison between both materials and Intragroup comparison within highly translucent nano zirconia reinforced glass ionomer have revealed no statistically significant variations over three monitoring time frames: the starting point, six, and twelve months. This result is in agreement with Safy et al., who reported that applying (ZI) in the Zr and RC/Zr groups had the greatest outcomes in terms of fracture mode, with 80% and 70% of fractures being repairable, respectively [4]. This outcome could be explained by using a special glass particle ZrO<sub>2</sub> as filler fine controlled micronization which creates particle size homogeneity, provide high strength and permits the material to withstand occlusal load. This consequently reduces the occurrence gross fracture [16-31].

## Conclusion

Under the limitation of the clinical trial, it was found that:

1. Zirconomer Improved GI restorations have similar clinical performance compared to Nano hybrid resin composite material in class II carious cavities after 1 year follow-up.
2. No differences in the occlusal wear resistance compared to Nano hybrid resin composite material in class II carious cavities after 1 year follow-up.

## Recommendations

1. Clinical trials with longer follow-up periods and larger sample sizes are needed to confirm the current results.
2. Clinical trials testing performance of Zirconomer Improved GI restorations in other clinical indications are encouraged, to recommend utilizing the new material in various clinical applications.
3. Further development of the material application forms to be supplied as capsules to reduce the drawbacks of that in hand mixing that may affect its clinical performance.

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