Official Dental Journal of Suez Canal University
DENTAL SCIENCE Updates
Print ISSN 2636-3836
Online ISSN 2636-3844
www.dsujournals.ekb.eg
DSU — Vol. 3, No. 2, September (2022) — PP. 191:198

ASSESSMENT OF BIOLOGICAL PROPERTIES OF ZIRCONIA REINFORCED GLASS IONOMER VERSUS GLASS IONOMER WITH GLASS HYBRID TECHNOLOGY IN CLASS II CAVITIES: RANDOMIZED CONTROLLED CLINICAL TRIAL

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DOI: 10.21608/dsu.2022.113472.1095
Manuscript ID: DSU-2112-1095

KEYWORDS

Biological properties, FDI criteria, Glass hybrid technology, Glass ionomer, Zirconia reinforced.

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ABSTRACT

Introduction: Glass ionomer cement (GIC) has numerous advantages over other restorative materials. In particular, self-adhesion to tooth structure in addition to its fluoride release that makes it suitable for treatment of majority of high caries risk cases. However, clinical usage of GIC is still limited due to their sensitivity to initial desiccation, low resistance to abrasion and low esthetic properties explaining why these materials are not widely used for permanent fillings. **Materials and Methods:** Class II occlusal slot cavities were prepared in the first permanent molar of sixty patients and restored randomly by two restorations, either; EQUIA® Forte Fil (Glass ionomer with glass hybrid technology) or Zirconomer® Improved (Zirconia-reinforced glass ionomer). Restorations were evaluated according to FDI criteria in terms of biological properties at baseline, after six months and one year. **Results:** Chi-square and Mann-Whitney tests revealed that there was no statistically significant difference between both materials with 100% success in all restorations in both groups at the base line. At six months follow up time, 92% of the EQUIA®Forte Fil group and 68% of the Zirconomer® Improved group were clinically successful. Meanwhile, at 12 months follow up time, 88% of the EQUIA®Forte Fil group and 48% of the Zirconomer® Improved group were clinically successful with significant difference between them at both six and 12 months. **Conclusions:** Glass ionomer with glass hybrid technology exhibited better clinical performance in terms of biological properties than zirconia-reinforced glass ionomer in class II slot cavities after six months and one year.

INTRODUCTION

Popularity of resin-based composite restoration has increased recently because of its excellent aesthetic and other favorable characteristics. However, failure is seen in composite restoration especially in posterior teeth as polymerization shrinkage that results in stress induced on the bonded surfaces and gaps formation with postoperative sensitivity and recurrent caries, which affects the restoration's longevity [(1)]. The clinical use of resin composite is considered to be technique-sensitive where filling's layer should not exceed 2 mm in isolated operating field. This is difficult to achieve in non-cooperative patients with high caries risk or when the rubber dam is impossible to install. Furthermore, resin composite is not cariostatic material, and bonding to dentin can be unpredictable with a significant variation in the bonding efficiency[(2)].

To overcome these shortcomings, glass ionomer has been widely researched because of the numerous advantages it offers. In particular, self-adhesion to tooth structure, ease of manipulation, biocompatibility, low technique sensitivity, low coefficient of thermal expansion and contraction. Additionally its superior anticariogenic efficiency owing to fluoride release and recharge making it suitable for treatment of majority of high caries risk cases[3]. However, clinical usage of GICs is still limited due to their sensitivity to moisture, low abrasion resistance and low esthetic properties explaining why these materials are not widely used as permanent fillings. The poor mechanical properties of conventional GIC make them unsuitable to be used in stress bearing areas[4]. Which is why attempts have been made to enhance the mechanical and handling properties of the material without compromising their adhesive and fluoride release properties which in turn, would make them a desirable choice for posterior restorations. Recently, there have been many modifications in the formulations of the acidic and basic parts of the GICs. Glass ionomer with glass hybrid technology (EQUIA® Forte Fill) is considered the first glass ionomer restorative material recommended by the manufacturer to be used in stress bearing occlusal cavities even in cavities with proximal surfaces involvement. Its manufacturers claimed increased mechanical properties and fluoride release compared to conventional glass ionomer materials[5]. Zirconia reinforced GIC is another recent modification which has been introduced to address all the issues that have limited the use of conventional GICs in stress bearing areas. Zirconomer®Improved material is composed of ceramic and zirconia reinforced glass ionomer cements that could overcome the drawbacks of amalgam as well as tooth-colored restorative materials. Its manufacturers claimed that it exhibits the strength of amalgam and at the same time maintain the fluoride releasing capacity of GIC[6]. Unfortunately, most of recent studies of GIC in the posterior areas have been conducted in vitro which is placed at the lowest level of the evidence based pyramid, meanwhile Randomized Controlled Trials (RCTs) are placed at the pyramid's top, representing the highest level of available evidence with characteristic freedom from bias and high validity [7]. So, a randomized controlled trial was adopted for the current study to test the null hypothesis that glass ionomer with glass hybrid technology will have the same clinical performance in terms of biological properties as zirconia-reinforced glass ionomer in proximal cavities of high caries risk patients using FDI criteria for assessment of dental restorations.

MATERIAL AND METHODS

Study design and sample size calculation:

The current study was a randomized controlled double-blinded (where both of patients and examiners were blinded to the group assignment) clinical trial, comparing the biological properties of glass ionomer with glass hybrid technology **(EQUIA® Forte Fil)** with zirconia reinforced glass ionomer **(Zirconomer® Improved)** in proximal cavities using FDI criteria for assessment of dental restorations. This study was approved by the Ethical committee of the Faculty of Dentistry, Suez Canal University with approval no. **#196/2019**. Also it was reported according to the protocol established by CONSORT (Consolidated Standards of Reporting Trials) guidelines to ensure transparent and complete reporting (figure 1)[8]. According to sample size calculations (according to G*Power software version 3.1.9.3) the required sample number was determined as at least 25 samples per group. Due to problems that could arise during the study and follow up periods, the sample size was increased by 20% to compensate dropouts, resulting in 30 restorations for each group [9].

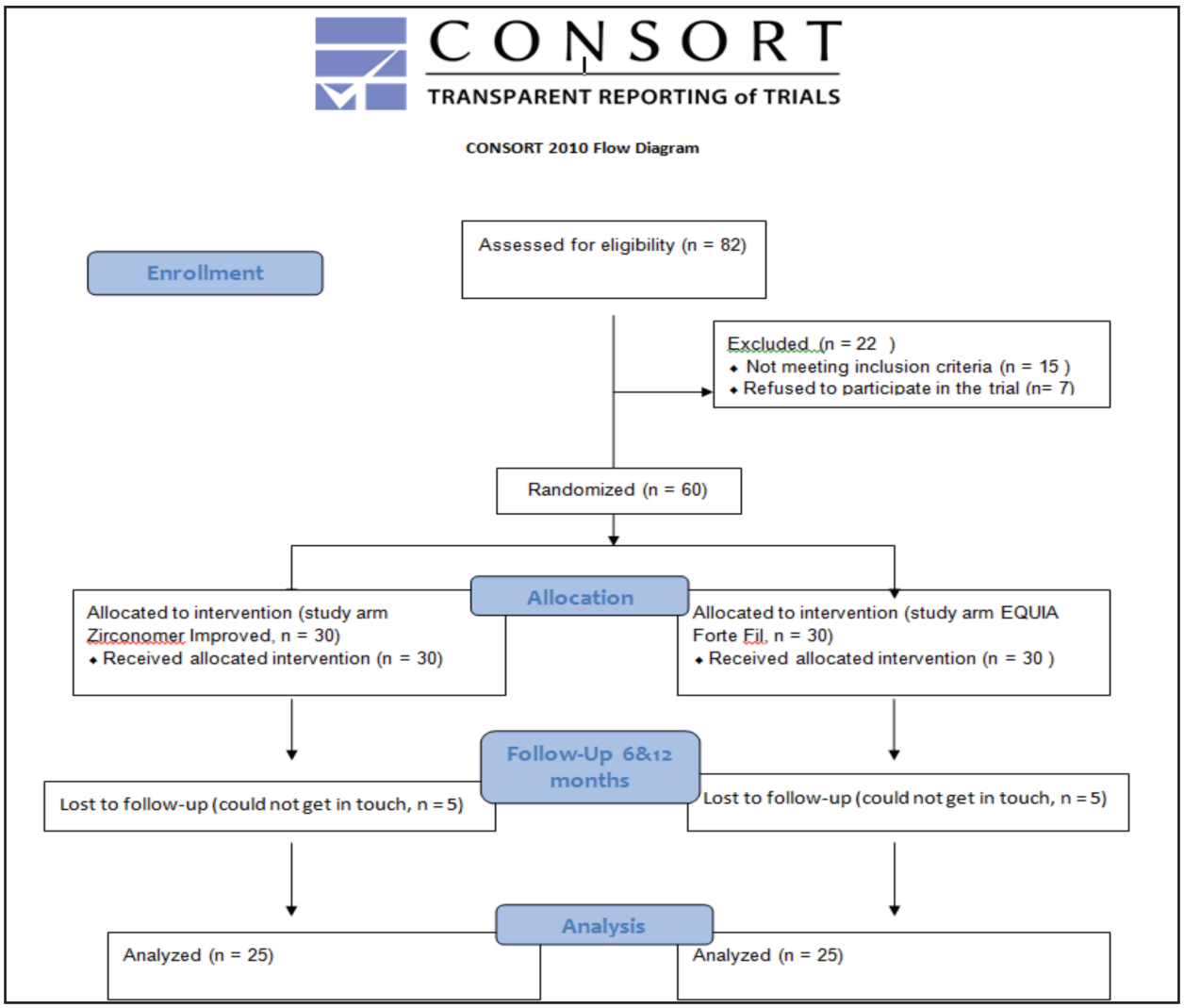

Fig. (2) CONSORT chart

Inclusion and exclusion criteria of participants:

Co-operative patients with high caries risk who were approving to participate in the trial of age range 20-45 years were selected for the current study. Patients complaining from any of the following criteria; disabilities, systemic diseases or severe medically compromised, bruxism, clenching or temporomandibular joint disorders were excluded immediately from the study.

Inclusion and exclusion criteria of teeth:

Proximal carious lesions in upper or lower first molars located approximately 1 mm above the cement enamel junction (CEJ) and its width not exceeding half the inter-cuspal distance buccolingually were selected in the present study. All selected teeth were vital without any signs or symptoms of irreversible pulpitis or periapical pathosis. All selected teeth had proximal contacts

with adjacent teeth, in occlusion with antagonist teeth and having healthy periodontium. Teeth with the following criteria; severe attrition, deep carious lesions approximating the pulp and lesions extended subgingivally were excluded from the study.

Recruitment:

Patients were recruited from the outpatient clinic of Operative Dentistry Department at the Faculty of Dentistry, Suez Canal University. Eligible patients were examined clinically and radiographically using bite-wing radiography. All participants signed written informed consents after being completely aware of the aim, settings, benefits and potential side effects of the study. Simple randomization was assigned for participants by generating numbers from 1:60 using Random Integer Set Generator, Randomness and Integrity Service Ltd (http://www.random.org/). Participants with odd numbers were restored with EQUIA®Forte Fil; meanwhile participants with even numbers were restored with Zirconomer®Improved.

Cavity preparation:

Class II (occlusal slot) cavity was prepared using fissure carbide bur No. #245 (Mani INC, Utsunomiya, Japan), with the occlusal outline was performed as approximately half of the intercuspal distance buccolingually with buccal and lingual proximal walls straight or slightly converge occlusally. The gingival floor width was about 1.5-1.75 mm mesiodistally and both of axial wall and gingival floor were flat, the gingival margins of all the cavities were located supragingivally (≥1mm above CEJ) and included sound enamel. A sharp excavator (N.51-52 excavator, Dentsply Maillefer international INC, Ballaigues, Switzerland) and slow-speed tungsten round carbide burs (Frank Denta GmbH , Tölzer, Gmund, Germany) were used to remove carious lesions in dentin. The depth and width of the cavities was estimated using a graded periodontal probe (Medesy Probe Double Goldman-Fox/Williams, Maniago, Italy). Each tooth had been isolated using rubber dam (GDC/ Hu Friedy, Chicago, USA) for effective moisture control, in addition to saliva ejector. For establishment of anatomically correct contact with the adjacent tooth and proper proximal contour, a sectional matrix system (TOR VM Sectional Matrix Kit, Moscow, Russia) was used.

Restorative treatment:

Dentin conditioner (10% Polyacrylic acid, GC, Tokyo, Japan) was used and applied according to the manufacturer's instructions to enhance the bond between the glass ionomer and the tooth. Cavities then were classified into two groups according to the tested material used (M) where M1: cavities were restored using EQUIA® Forte Fil (GC, Tokyo, Japan), meanwhile M2: cavities were restored using Zirconomer® Improved (GC, Kyoto, Japan). EQUIA® Forte Fil was used to restore M1 group, its manipulation was done according to the manufacturer's instructions where each capsule was shacked to loosen the powder, followed by pushing the plunger of the capsule until it was flush with the main body. Then, the capsule was placed into a metal applicator (Ketac applicator, 3M ESPE, California, USA) and the lever was clicked once to activate the capsule, the capsule was then set into a mixer (Mix 2000, Milano, Italy) and mixed for 10 seconds in low speed mode (3600 rpm). The mixed capsule was immediately removed from the mixer and loaded into the applicator. Two clicks were made to prime the capsule then syringed to extrude the mixture directly and slowly into the preparation as a single bulk within ten seconds. The preliminary

contour was done using ball burnisher (112-495-25, Towne Brothers Pvt. Ltd, Sialkot, Pakistan). After the manufacturer's recommended setting time of 2.5 minutes, the matrix system was removed carefully followed by finishing and polishing. The rubber dam was then removed and any occlusal prematurity was checked and any premature interference was removed. Then, immediate application of the EQUIA®Forte Coat (GC, Tokyo, Japan) to each restoration surface using the disposable micro-tip applicator was achieved; the coat was applied to the contact area using dental floss (Oral.B, Lowa, USA). Light curing of all coated surfaces for 20 seconds according to the manufacturer's instructions was done. For M2 group that was restored with Zirconomer®Improved, two scoops of the powder were dispensed using the provided measuring scoop and one drop of the liquid was dispensed separately on the mixing pad. The powder was divided into 2 equal portions, the first portion was mixed with the liquid for 5-10 sec with the provided plastic spatula, followed by mixing of the remaining portion till thick putty-like consistency reached. This procedure was completed within a total of 30 sec in accordance with the manufacturer's instructions, then; the mixture was packed toward the cavity walls and the matrix band using a suitable size condenser (Helmut Zepf, Seitingen-Oberflacht, Germany) to establish proper contact. After the manufacturer's recommended setting time of 7 minutes, the matrix system was removed carefully, followed by finishing and polishing, removal of rubber dam and checking of occlusal prematurities as mentioned before for M1 group. Finally the surface of the final restoration was coated with petroleum jelly according to the manufacturer's instructions for protection against moisture contamination during the initial hardening phase.

Assessment of clinical performance and follow up:

All restorations were evaluated by two trained examiners, who were not involved in the placement of restorations and were also blinded to the type of material. Each case was evaluated according to FDI criteria [10], based on biological properties (Postoperative sensitivity, Recurrence of caries and Tooth integrity). Each restoration was evaluated three times (T); immediately after restoration i.e. Base line (T0), after 6 months (T1) and after one year (T2). Assessment of restorations was performed radiographically using bitewing radiographs and clinically by visual inspection using magnification loupes (4.5x; Carl Zeiss GmbH, Jena, Germany), dental mirrors, a light source and FDI recommended probes with different tip diameters of 150 and 250 micrometer diameter (10) (150x and 250x, Deppeler, Switzerland). Restorations were scored using a scale of 1 to 5, where score 1: clinically excellent/very good, 2: clinically good, 3: clinically satisfactory, 4: clinically unsatisfactory but repairable and 5: clinically poor/irrepairable that needs replacement. So the scores 1, 2 and 3 considered clinically successful while scores 4 and 5 considered clinically not successful.

Statistical analysis:

Data were collected, tabulated and statistically analyzed. Differences in evaluations between materials (M1 and M2) were carried out by Chi-squared and Mann-Whitney U test at 0.05 level. However, differences between follow-up times (T0, T1 and T2) were carried out by Friedman's test for related samples for nonparametric data. Variations caused by both materials and follow up times in addition to interaction between them were assessed by repeated measures ANOVA for ranked data at significance levels of 0.05.

RESULTS

The overall biological properties results of both tested materials (M1 & M2) at different follow up times (T0, T1 & T2) are listed in table 1. The results showed that at baseline (T0), all cases (100%) of both groups were clinically successful, with no significant difference between them. At six months follow up time (T1), 23 cases (92%) of M1 and 17 cases (68%) of M2 groups were clinically successful with significant difference between them. Meanwhile, at 12 months follow up time (T2), 22 cases (88%) of M1 and 12 cases (48%) of M2 groups were clinically successful with significant difference between them. Repeated measures ANOVA revealed that there is highly significant difference in overall biological properties results induced by the tested materials, follow up times and interaction between them.

Table (1) *Statistical analysis of collective biological properties results*

Follow up time	Collective biological properties				Mann-Whitney sign.
	EQUIA Forte Fill (M1)		Zirconomer Improved (M2)		
	S	F	S	F	
Baseline (T0)	25 (100%)	0 (0%)	25 (100%)	0 (0%)	>0.05
6 months (T1)	23 (92%)	2 (8%)	17 (68%)	8 (32%)	0.036*
12 months (T2)	22 (88%)	3 (12%)	12 (48%)	13 (52%)	<0.001***
Freidman's test	<0.001***		<0.001***		
ANOVA -repeated measures					
Materials (M)	0.001***				
Follow up time (T)	<0.001***				
Materials x Time	<0.001***				

S means successful cases, F means failed cases

DISCUSSION

Regarding the biological properties, the results showed that EQUIA® Forte Fil group was more clinically successful than Zirconomer ® Improved group after six months and one year. Where the results of post-operative sensitivity and tooth vitality showed that there was no significant difference between both materials at base line, where both were clinically successful with no post-operative sensitivity and normal tooth vitality. However, after six months and one year, EQUIA®Forte Fil group was clinically more successful than Zirconomer ® Improved group with significant difference between them. The good results of post-operative sensitivity of EQUIA®Forte Fil is due to its superior marginal adaptation which may be attributed to the presence of a resin layer (EQUIA® Forte coat) that secures a protective barrier, isolates the restoration from all external contamination and improves the marginal adaptation [(11)]. On the other hand, the inferior results

of post-operative sensitivity and tooth vitality of Zirconomer® Improved may be due to lack of marginal adaptation of Zirconomer® Improved that is associated with marginal leakage, post-operative sensitivity and recurrence of caries, as the higher rate of microleakage, the greater postoperative sensitivity would be [12]. This result is in agreement with **Asafarlal** [13] who investigated the microleakage of three different GICs; Zirconomer, EQUIA and Ketac Molar quantitatively and found that the sealing ability of EQUIA was better than Zirconomer and the microleakage value of Zirconomer was higher compared to the other GICs. This finding could be attributed to the large size of the filler particles of zirconia leading to poor adaptation at the tooth-restoration interface. The results of the present study revealed a statistically significant difference between the glass hybrid GIC (EQUIA® Forte Fil) and zirconia-reinforced GIC (Zirconomer® Improved) in caries recurrence property after six months and after one year, where EQUIA® Forte Fil was clinically more successful than Zirconomer® Improved. This may be due to the superior adaptation of EQUIA® Forte Fil in camparison to Zirconomer® Improved as mentioned before. Also, this result could be explained on the basis of that EQUIA® Forte Fil released significantly higher fluoride ions which is six times more than the conventional GIC as reported by the manufacturer[5]. Where the composition of this cement type (95% strontium fluoroaluminosilicate glass), as the substitution of Ca2+ with Sr2+ ions improved the fluoride release rate due to faster dissociation of strontium fluoride complex (SrF2) than calcium fluoride complex (CaF2). This was in agreement with the findings of **Habib** [14]. This result also is in agreement with a study by **Schwendicke**[15], which reported that Equia was not susceptible for secondary caries in restored premolars in vitro. On the other hand, Zirconomer®Improved showed non-successful results regarding recurrence of caries, this might be related to a decrease in fluoride release, which could be owing to an increase in zirconia fillers (96.5% - 98%) and a decrease in fluoroaluminosilicate glass in the powder [16]. Also, results of tooth integrity property revealed a significant difference between both materials with EQUIA®Forte Fil being more clinically acceptable than Zirconomer ® Improved which could be related to its effective mechanical properties. In addition to the nature of chemical bonding obtained in the tooth-glass hybrid interface that shows a reliable support for tooth structure which is in agreement with **Sidhu and Nicholson** [17]. From all previously mentioned results, the null hypothesis could be rejected, as there was a significant difference between the clinical performance of glass ionomer with glass hybrid technology and zirconia-reinforced glass ionomer in class II occlusal slot cavities.

CONCLUSION

Glass ionomer with glass hybrid technology exhibited better clinical performance in terms of biological properties than zirconia-reinforced glass ionomer in class II slot cavities after six months and one year.

RECOMMENDATIONS FOR FURTHER STUDIES

1. As a result of committing to a specific follow-up period because it is a PhD thesis, clinical trials with longer follow-up periods are advised to confirm the current results.
2. Due to availability of Zirconomer® Improved material in the form of powder and liquid, it is recommended to supply it with more advanced manipulation method than the manual mix.

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