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. 181:189

ASSESSMENT OF FUNCTIONAL 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

FDI criteria,
glass hybrid technology,
Zirconia reinforced glass ionomer

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ABSTRACT

Introduction: Glass-ionomer cements (GICs) may be the restoration of choice in patients with a high caries risk, owing to their anticariogenic and remineralizing capabilities. Regrettably, as compared to other restorative materials, it has lower flexural and tensile strength, fracture resistance, and a higher rate of wear, all of which have an implication on its survival rates when used in load bearing areas. **Materials and methods:** Sixty patients with high caries risk were selected. Class II occlusal slot cavities were prepared in the first permanent molar and restored randomly by two restorations, either; EQUIA®Forte Fil or Zirconomer® Improved. Restorations were evaluated according to FDI criteria in terms of functional 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 for the tested properties at 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 40% 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 than zirconia-reinforced glass ionomer in class II slot cavities after six months and one year with high success rate in the purpose of restoring posterior permanent teeth.

INTRODUCTION

Resin composites have been used for decades as all-purpose direct restorative materials for both anterior and posterior teeth with a high esthetic quality. However, owing to technique-sensitivity throughout manipulation as well as necessity of specialized equipment, the durability of resin composites is critically relevant to the operator, who must have impeccable skills. Consequently, resin composite may not always be a good alternative to amalgam in some care situations, such as rural community hospitals and areas with restricted access to reticulated water and electricity [(1)]. It is also worth noting that one of the most challenging tasks for clinicians in class II composite restorations is obtaining perfect proximal contacts and preventing overhangs at the cavosurface margins. Besides which, food impaction, chronic caries,

and periodontal issues have all been linked to the formation of overhangs[2]. Furthermore, in Class II restorations, the cervical proximal margins are often regarded as a point of weakness, where dentin bonding is less predictable[3]. Owing to their anticariogenic and remineralizing capabilities, glass-ionomer cements (GICs) may be the restoration of choice in patients with a high caries risk[4]. Regrettably, it has lower flexural and tensile strength, fracture resistance, and a higher rate of wear, all of which have an implication on its survival rates when used in load bearing areas[5]. As a result, many modifications have been introduced to overcome these deficiencies. Among these modifications was the introduction of Zirconomer® Improved (Shofu, Kyoto, Japan), a high-strength restorative material that is reinforced with zirconia fillers and was launched in the dental market as a substitute for dental amalgam [6]. Another trial for GIC reinforcement is EQUIA ® Forte Fil (GC, Tokyo, Japan) which was marketed, with an innovative glass hybrid technology. Apart from its fluoride release, this category of materials is characterized by high strength properties that enable it to be used in stress bearing areas [7]. Even though several in-vitro studies have been carried out to evaluate the mechanical properties of Zirconomer® Improved and EQUIA® Forte Fil, just few in-vivo investigations have been performed to evaluate them in stress-bearing areas. Therefore it was found that, it would be purposive to evaluate and compare the clinical performance of these currently available restorative using a randomized controlled clinical trial to test the null hypothesis that glass ionomer with glass hybrid technology will have the same clinical performance in terms of functional 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 double-blinded, randomized controlled clinical trial. Apparently healthy patients with one proximal carious lesion in the upper or lower first permanent molar were selected and signed an informed written consent to participate. This study was approved by the committee of Ethics of 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 [9]. 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.

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 were excluded immediately from the current study; disabilities, systemic diseases or severe medically compromised, bruxism, clenching or temporomandibular joint disorders.

Inclusion and exclusion criteria of teeth:

Proximal carious lesions in either upper or lower first molars located approximately 1 mm above the cementoenamel junction (CEJ) and its width not exceeding half the inter-cuspal distance buccolingually were selected in the present study.

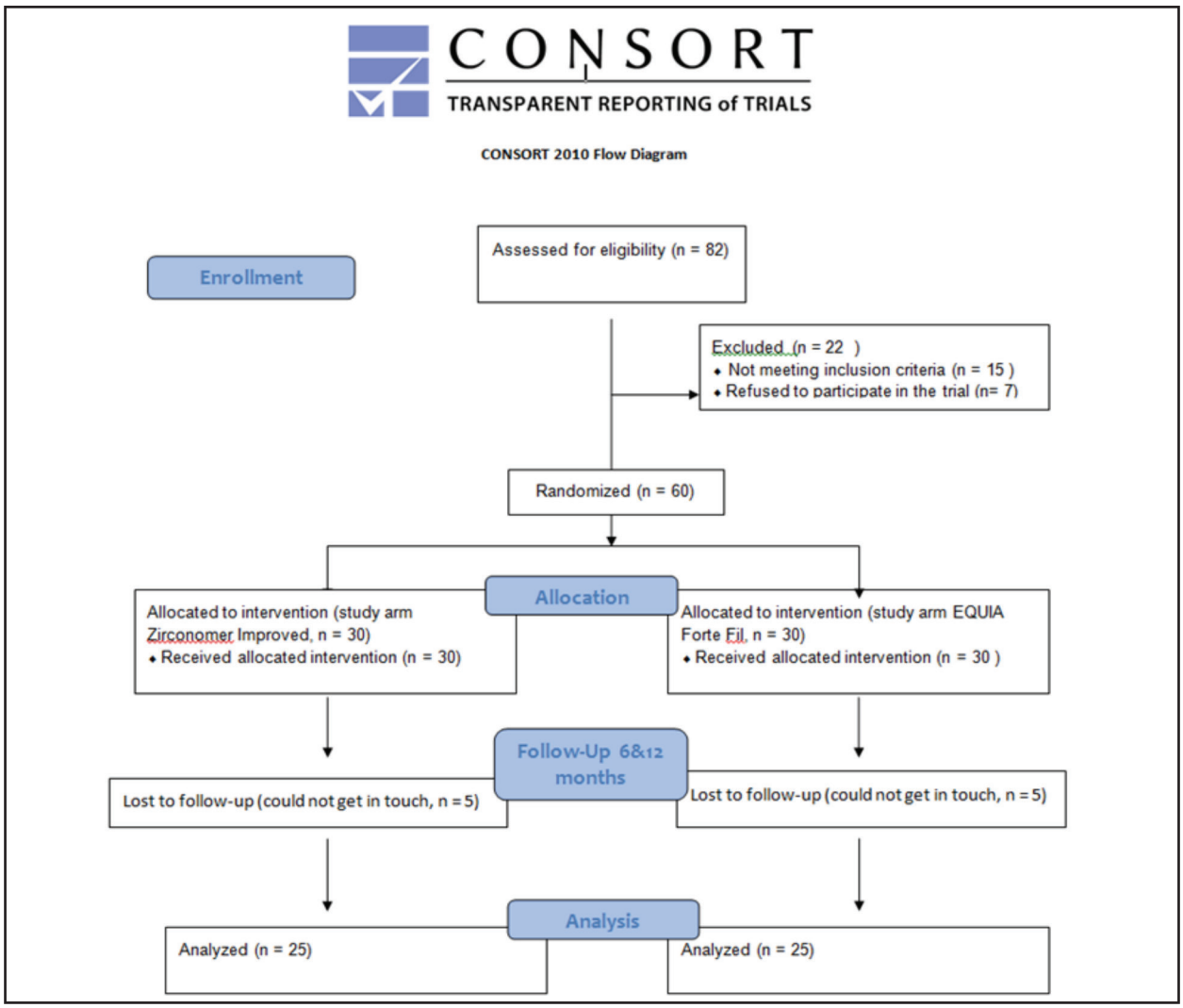

Fig. (1) CONSORT chart

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 were excluded from the study; teeth with severe attrition, deep carious lesions approximating the pulp and lesions extended subgingivally.

Recruitment and allocation:

Patients were recruited from the outpatient clinic of Conservative Dentistry Department at the Faculty of Dentistry, Suez Canal University. Bite-wing radiography was used to examine eligible patients in addition to clinical examination. 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 using Random Integer Set Generator, Randomness and Integrity Service Ltd (http://www.random.org/). Participants with odd numbers were restored with EQUIA®Forte Fil (GC); meanwhile participants with even numbers were restored with Zirconomer®Improved (Shofu), the allocation ratio was set to be equal [10].

Cavity preparation:

Class II (occlusal slot) cavity was prepared using fissure carbide bur No. #245 (Mani INC, Utsunomiya, Japan), the occlusal outline was performed as approximately half of the intercuspal distance buccolingually with buccal and lingual proximal walls straight or slightly converge occlusally and the cavosurface angles were 90°. The gingival floor width was about 1.5-1.75 mm mesiodistally and both of axial wall and gingival floor were flat. A sharp excavator and low-speed round bur were used to remove carious lesions in dentin. The gingival margins of all the cavities were located supragingivally (≥1mm above CEJ) and included sound enamel. Each case had been isolated through application of rubber dam (GDC/ Hu Friedy, Chicago, USA) for effective moisture control. For establishment of proper proximal contour and anatomically correct contact with the adjacent tooth, 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 to enhance the bond between the glass ionomer and the tooth. It was applied for 20 seconds, washed and blot dryness of the cavity was done using a small cotton pellet, where the prepared surfaces appeared moist (glistening). Cavities 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 (shofu, Kyoto, Japan). EQUIA® Forte Fil was used to restore M1 group, its manipulation was done according to the instructions of manufacturer where each capsule was shaked 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. 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 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 microtip applicator was achieved; the coat was applied to the contact area using dental floss. 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 (Shofu), 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 mixed with the liquid 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, 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 assessed by two trained examiners, who were blinded to the type of material. In some cases, where both examiners scored differently, the final decision was made by consensus of both examiners. Each case was evaluated according to FDI criteria, based on functional properties (Fracture of material and retention, Marginal adaptation, Occlusal contour and wear, Proximal contact point and food impaction, and Radiographic examination) [11]. 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 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 [11] (150x and 250x, Deppeler, Switzerland). Bitewing radiographs were also used for assessment of all restorations. 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 [12]. 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 functional 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 10 cases (40%) of M2 groups were clinically successful with significant difference between them. Repeated measures ANOVA revealed that there is highly significant difference in overall functional properties results induced by the tested materials, follow up times and interaction between them.

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

Follow up time (T)	Collective Functional 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%)	10 (40%)	15 (60%)	<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

Evaluation of the fracture of material and retention as well as occlusal contour and wear results revealed that at baseline all cases (100%) of both groups showed clinically excellent behavior, with no significant difference between them. Meanwhile after six months and one year the success rate of EQUIA® Forte Fil restorations was significantly higher than Zirconomer® Improved restorations. This might be explained by the fact that EQUIA® Forte Fil is a reinforced GIC through the introduction of highly reactive glass particles, interspersed throughout the conventional glass ionomer structure. Also it is characterized by the addition of a polyacrylic acid with high molecular weight which supposedly increases the matrix cross-linking and overall physical properties and resulting in high strength properties [13]. This material coupled with a nano-filled resin coat (EQUIA® Forte Coat) that increases its abrasion resistance and improves the marginal integrity by including a novel multi-functional monomer that provides a tougher resin matrix. This nano coat may infiltrate the GIC surface and seal any defect, slowing crack propagation [14]. According to some research, it can greatly enhance the flexural strength of EQUIA® Forte Fil while also minimizing occlusal wear [15]. Moreover, another beneficial effect might be attained from curing of the resin coat, as external heat derived from light curing of resin coat during the setting of glass ionomer could improve the mechanical properties of the material through acceleration of its setting. Application of external heat that is often known as thermo-curing is a command set method and technique for increasing the mechanical properties and adhesion of glass ionomer[16]. All of the above advances combine to provide a glass hybrid bulk fill restorative system with outstanding physical and mechanical properties. Also, it worth noting that encapsulation and automatic mixing of the EQUIA® Forte Fil plays an important role in improving its mechanical properties in comparison to manipulation of Zirconomer® Improved which is

manual mixed. It was observed that encapsulated glass-ionomers had significantly higher mechanical properties than the commonly used hand- mixed one [17]. As a result, variability of the liquid / powder ratio of Zirconomer® Improved as well as any human error may have an impact on its mechanical and physical properties. As evidenced by the literature, capsulated GIC outperforms hand mixing due to decreased operator variability and simplicity of application during cavity preparation, therefore availability of EQUIA® Forte Fil as capsules may provide an increased compressive fracture strength and modulus of elasticity and more wear-resistance compared to hand mixed Zirconomer® Improved[18]. These results were in agreement with the results of **Al-Taee *et al*** [19], who have concluded that EQUIA®Forte Fil showed significantly better fracture and wear resistance comparing to other hand mixed materials. On the other hand, the inferior results of Zirconomer ® Improved material in both criteria may be attributed to its manual mixing which is responsible for the presence of air bubbles in the matrix that causes surface hydrolytic instability and softening [20].

Regarding the marginal adaptation results, EQUIA® Forte Fil group showed significantly more successful marginal adaptation results than Zirconomer® Improved group at six months and 12 months follow up. The satisfactory marginal adaptation results of EQUIA® Forte Fil group might be attributed to the presence of a resin layer (EQUIA® Forte Coat) that secures a protective barrier, which protects the restoration from all external contamination and improves the marginal adaptation[21]. This result was in agreement with Silva R, et al[22], who noticed that the resin coating ensures that the restoration is sealed and protected against porosities and cracks. On the contrary, Zirconomer® Improved restorative material lacks chemical bonding between the zirconia fillers and the polysalt matrix, resulted in areas of stress concentrations with subsequent loss of the material. Also, Zirconomer® Improved has lower elastic modulus and higher elastic deformation than EQUIA®Forte Fil. So, Zirconomer® Improved will deform when loaded with functional stresses, disrupting the bond between the restoration–tooth interface that is associated with reduced marginal adaptation, postoperative sensitivity, and caries recurrence [7]. This result is consistent with findings of Asafarlal S [23], who found that the sealing ability of EQUIA was better than Zirconomer and the values of microleakage of Zirconomer was higher. This finding could be attributed to the large size of zirconia filler particles, which causes poor adaptation at the tooth-restoration interface. The results of proximal contact point and food impaction property showed that after six months and after one year, EQUIA®Forte Fil group was clinically more successful than Zirconomer ® Improved group with significant difference between them. This could be due to the superior mechanical properties and enhanced wear resistance of EQUIA®Forte Fil. Also, the contact areas of EQUIA®Forte Fil restorations were protected by EQUIA®Forte Coat. This coating may protect the material during the early setting process by occluding surface cracks and porosity, hence improving wear resistance and toughness[24]. In contrast, after the initial hardening phase, the contact area of Zirconomer® Improved restorations was not well protected against water uptake. Another reason for the loss of the proximal area with Zirconomer® Improved is its decreased wear resistance and inferior mechanical properties as previously mentioned. The findings of the radiographic examination matched those of the clinical evaluation, where at baseline both materials showed normal radiographic image with

no significant difference between them. Meanwhile after six months and after one year, there was a significant difference between the two materials, where some cases of Zirconomer® Improved group showed marginal changes in comparison to EQUIA® Forte Fil group. The improved marginal integrity of EQUIA® Forte Fil reflects its improved performance as mentioned in discussing the marginal adaptation criterion. Based on 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 functional properties than zirconia-reinforced glass ionomer in class II slot cavities after six months and one year with high success rate in the purpose of restoring posterior permanent teeth.

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. Clinical trials testing performance of glass hybrid glass ionomer in other clinical indications are encouraged, to recommend utilizing this material in various clinical applications.
3. 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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