10.21608/adjc.2023.169905.1179 Advanced Dental Journal
Volume 6 (2024) | Issue 2| Pages 320-330

Original Article

CLINICAL EVALUATION OF NEW BIOACTIVE RESTORATIVE MATERIAL VERSUS HIGH VISCOSITY GLASS HYBRID REINFORCED GLASS IONOMER IN RESTORATION OF PROXIMAL LESIONS: A RANDOMIZED CLINICAL TRIAL

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Submitted: 26-10-2022
Accepted: 07-05-2023

Abstract

Objective: The present clinical trial was conducted in order to compare Bioactive composite (ACTIVA Presto) to high viscosity glass hybrid reinforced Glass Ionomer (EQUIA Forte) in class II cavity restorations. **Materials and Methods:** A total of 22 participants randomly received 22 proximal restorations using either; ACTIVA™ Presto™ by Pulpdent Corp. (Watertown, MA, USA) or EQUIA® Forte Fil HT GC Corporation (Tokyo, Japan.). Cavity preparation was done followed by restorative material application according to manufacturers' instructions. Restorations were assessed using modified USPHS criteria by two blinded assessors at baseline, 6 and 12 months regarding retention, marginal discoloration, marginal adaptation, post-operative hypersensitivity, anatomical form and survival rate. **Results:** Regarding the primary outcome proximal contact, there was a statistically significant difference between both materials at 6 and 12 months (P= 0.136 and P= 0.0246) respectively. As for surface texture there was a statistically significant difference at 6 and 12 months between both materials respectively (P = 0.0184, and P = 0.0128). Nonetheless, there was no statistically significant difference between both restorative materials regarding survival rate after 12 months (P = 0.057). **Conclusion:** ACTIVA Presto is highly recommended as a reliable permanent restoration especially for proximal cavities. EQUIA Forte is not advised to be used as a permanent restoration in proximal cavities.

Keywords: Bioactive restoration, ACTIVA Presto, High Viscosity, Glass Hybrid, EQUIA Forte Fil, Class II

I. INTRODUCTION

The most prevalent problem with oral health to date is dental caries. According to the World Health Organization (WHO), caries affects 60-90 percent of children and about 100 percent of adults worldwide [1]. Clinicians constantly struggle with the technique sensitivity associated with direct class II composite restorations, which includes poor marginal adaptation, marginal discoloration, marginal fractures, micro-leakage, secondary caries, and postoperative sensitivity typically based on polymerization shrinkage stress [2]

In order to overcome these drawbacks, glass ionomer cements have been considered as an alternative restorative material. These cements have benefits such as similar coefficient of thermal expansion to natural tooth tissue, physicochemical adhesion to tooth, biocompatibility, as well as anti-caries properties and increased remineralization, particularly helpful in high risk caries patients [2] Not only does it chemically attach to dentin via an ionic link with hydroxyapatite but it is also able to release and recharge fluoride, both of which are crucial for the prevention of caries and provide effective cavity sealing[3] However, it was demonstrated that glass ionomer exhibited wear five times greater than amalgam and three times worse than resin composites[4]

Subsequently high viscosity glass ionomers were employed as a solution in stress bearing class II cavities due to their high flexural strength and high acid and wear resistance. EQUIA Forte Fil [GC America] is a material with improved high viscosity and highly reactive micron-sized fluoroalumino-silicate (FAS) fillers of high molecular weight that release more metal ions to promote cross-linking in polyacrylic acidic matrix, which enhances both physical qualities and fluoride release[5] [6].

The clinical benefits of HVGIC for direct posterior tooth restorations in permanent teeth are claimed to be comparable to those of dental amalgam restorations [7]. Nevertheless, there are concerns regarding the mechanical and physical characteristics as well as the handling properties of this material where it is still deemed by many a runner up for resin composite restorative materials[8] [9]. Therefore, there is a need for a smart material that combined the superior mechanical properties of resin composites, while preserving the biocompatibility, fluoride release and versatility of glass ionomers.

Bioactive restorative materials have been developed as a result of the gradual advancement of material sciences. These smart substances can trigger the body's natural tissue regeneration process and cause the surroundings, including the teeth, to react[10]. According to claims, ACTIVA BioACTIVE products are the first dental resins to feature a bioactive ionic resin matrix, a rubberized resin ingredient that absorbs shock, and reactive ionomer glass fillers that match the physical and chemical characteristics of teeth[11] actively taking part in the ionic exchange cycles that control the chemistry of teeth and saliva and help to preserve tooth structure, thus potentially combine the greatest qualities of both materials as strength, esthetics and bioactivity.

Pulpdent's ACTIVA Presto is its most recent product which was investigated in this trial. It improves upon the success of ACTIVA BioACTIVE-RESTORATIVE (prior generation) while also providing improved aesthetics with a larger spectrum of shades and easier dispensing[12].

With the development of such new materials and scarcity of immediate evidence, it is often difficult for the clinician to decide on the material that would provide optimum results. Hence the conduction of this research which aims to contribute in providing evidence-based literature concerning comparative clinical evaluation between the bioactive restorative material ACTIVA Presto and high viscosity glass hybrid reinforced glass ionomer EQUIA Forte.

The null hypothesis stated that there would be no significant difference in clinical performance between ACTIVA Presto (bioactive restoration) and EQUIA Forte (high viscosity glass hybrid reinforced glass ionomer) in restoring proximal carious lesions at baseline, 6 and 12 months.

II. SUBJECTS AND METHODS

- **Study Design and Trial Registration**

This study is a controlled clinical trial, a two parallel group design, with a 1:1 allocation ratio as well as equivalence framework. The subjects were randomly split into two groups (n=11). All procedures done were clarified to subjects and before trial commencement, written informed consents were signed. The proposal of this study is registered in (clinicaltrials.gov), with trial registration number: NCT04365283. Ethical approval was obtained prior to the start of the study. This clinical trial is reported in accordance with the CONSORT guidelines of 2010, figure 1.

- **Sample Size Calculation**

Sample size was calculated based on a previous study by Frankenberger in 2009[13]. Prior data indicate that the probability of score A of proximal contact for HVGIC is 0.8, score B is 0.1 and score C is 0.1 with effect size w 0.98. If the estimated probability of score A of anatomic form for ACTIVA Presto is 0.85, score B is 0.1 and score C is 0.05 with effect size w 1.09. A total of 18 subjects would be required to be able to reject the null hypothesis that the success rates for case and controls are equal with probability (power) 0.8. This was increased to 22 subjects, 11 in each group to compensate for losses during follow up. Type I error probability associated with this test of this null hypothesis is 0.05. Sample size was calculated using G*Power version 3.1.9.2 for windows using chi-square test.

- **Material and Methodology**

The materials utilized in this trial can be found summarized in table (1). The material name, Lot number, composition and manufacturer.

- **Eligibility criteria for participants**

Inclusion criteria:

Patient-related criteria: ages between 20–40 years, male or female co-operative subjects that agree to participate in the trial.

Tooth-related criteria: Vital upper and lower teeth with no signs of irreversible pulpitis, small to moderate class II lesions confirmed by bitewing radiographs and teeth with favorable occlusion and in normal contact with the adjacent teeth.

Exclusion criteria:

Patient-related criteria: patients with systemic diseases or severe medical complications in addition to pregnant females, patients with heavy bruxism which was assessed using the patient dental history and a clinical evaluation of wear patterns on the posterior teeth.

Tooth-related criteria: teeth needing prosthodontic restoration, or with severe periodontal affection or with periapical pathology or signs of pulpal affection confirmed by periapical radiographs.

- **Study Setting**

This study took place in the clinics of the Faculty of Dentistry Cairo University. The trial commenced in July 2021 and was completed in July 2022.The modified USPHS criteria was adopted to evaluate the tested materials at baseline, 6 months, and 12 months.

- **Allocation**

Simple randomization was made by generating random numbers using Random Sequence Generator, Randomness and Integrity Services Ltd (https://www.random.org/) by a partaker, not associated with the clinical trial and was independent of the recruitment steps. The allocation sequence was held with that partaker and obscured from the prime investigator. Each generated random number from 1-11 represents the intervention and from 12-22 is the comparator. Random numbers that the patient selected from were arranged and placed in an opaque sealed envelope, regardless of whether the comparator treatment group or the intervention is selected, and they were recorded on a computer. Because each restorative substance has a different application process, it is not possible to keep the operator blinded. The participants, assessors and statistician, however, were not aware of the materials utilized.

- **Procedures**

The restorative procedure was done by a single operator (R.A). Firstly, local anesthesia was administered to the patients (ARTINIBSA 40 mg/ml + 0,01mg/ml solution for injection). Shade selection was done under appropriate conditions. Cavities to be restored were isolated with rubber dam (Nic Tone, Expertech Solutions, Bucharest, Romania) to ensure moisture control of the operative field and lack of contamination of the cavities [14].Molar and /or premolar clamps were used for stabilization and impervious isolation of the teeth (TOR VM Dental Manufacturing Company, Russia).

The bulk of soft caries was removed using a sharp excavator (LASCOD Zeffiro Excavator, Italy) very conservatively leaving only smooth, hard dentinal bridge pulpally. The walls of the cavities were cleared from any carious structure, and undermined enamel was removed using a No. #330 bur (0.8 mm in diameter and 1.6 mm in length) (MANI, INC, Japan) ,and high-speed hand piece

with water coolant and air (NSK high speed hand-piece Pana Air FX PAF-SU-M4, Japan) followed by finishing of the cavity walls with a fine grit diamond stone.

Sectional matricing was done in order to obtain positive contact in cases of proximal wall restoration. Sectional matrices (TOR VM Dental Manufacturing Company, Russia) were used, and stabilized using sectional ring (Composi-Tight® 3D Fusion™ Matrix Rings America, Garrison® Dental Solution). Sectional Rings ensure tight contacts an provide separation to compensate for thickness of the matrix band[15]. Composi-Tight® 3D Fusion™ Ultra-Adaptive wedges (Garrison® Dental Solution) were inserted between the teeth to avoid overhangs.

For the intervention (ACTIVA Presto):

Only enamel was etched for 10 seconds with 37% phosphoric acid gel (DeTrey® Conditioner 36, Denstply, USA) (selective etching technique) , then rinsed for 20 seconds and air dried carefully so as not to desiccate the dentinal structure.

The Dentsply Sirona Prime & Bond Universal™ bonding agent was applied and rubbed into the cavity, then air thinned and light cured for 10 seconds using LED light curing unit with a light intensity of up to 2300 mW/cm2 (Woodpecker i-LED, Woodpecker Co., Ltd, Guilin, Guangxi, China). The intervention ACTIVA Presto restorative material was injected in bulk inside the cavity and light cured for 20 seconds using LED light curing system.

The occlusion was checked using 40 nm articulating paper AccuFilm® II (Parkell®, Edgewood, NY,USA). High spots were removed with yellow coded stones.

Excess remaining flashes of the restorative material were removed using superfine yellow then white coded tapered diamond stone (MANI, INC, Japan). Polishing was done using composite polishing kit (KENDA®, Vaduz, Liechtenstein).

For the Comparator (EQUIA Forte Fil):

Prepared cavities were conditioned for 20 seconds using Dentin conditioner (KetacTM Conditioner, 3M ESPE AG, Saint Paul, MN, USA) 10% polyacrylic acid for 10 seconds followed by rinsing, and excess water blotted away using gauze, leaving the prepared surface hydrated.

The EQUIA Forte capsule was then set into an amalgamator for 10 seconds, immediately loaded into the cavity. Primary contour was created then after at least 2 minutes 30 seconds after start of mixing, the restoration was finished using superfine diamond burs with water coolant. EQUIA Forte coat was then applied to the surfaces to be coated using a micro-tip applicator, and floss was used to apply the coat on proximal surface. It was then cured for 20 seconds by visible LED light. The coating's application boosts the glass ionomer's tensile strength and abrasion resistance. It is thought that resin has the ability to penetrate the glass ionomer surface, filling pores and fissures[4].

- **Outcomes**

Modified USPHS criteria was the criteria selected to assess the clinical performance for functional and biological aspects (Table 2). USPHS criteria was evaluated by two blinded assessors at baseline, six months and after a year. In a few cases, when both assessors disagreed, they held discussions to reach a final consensus, and if that was to no avail, a third assessor intervened to resolve the conflict.

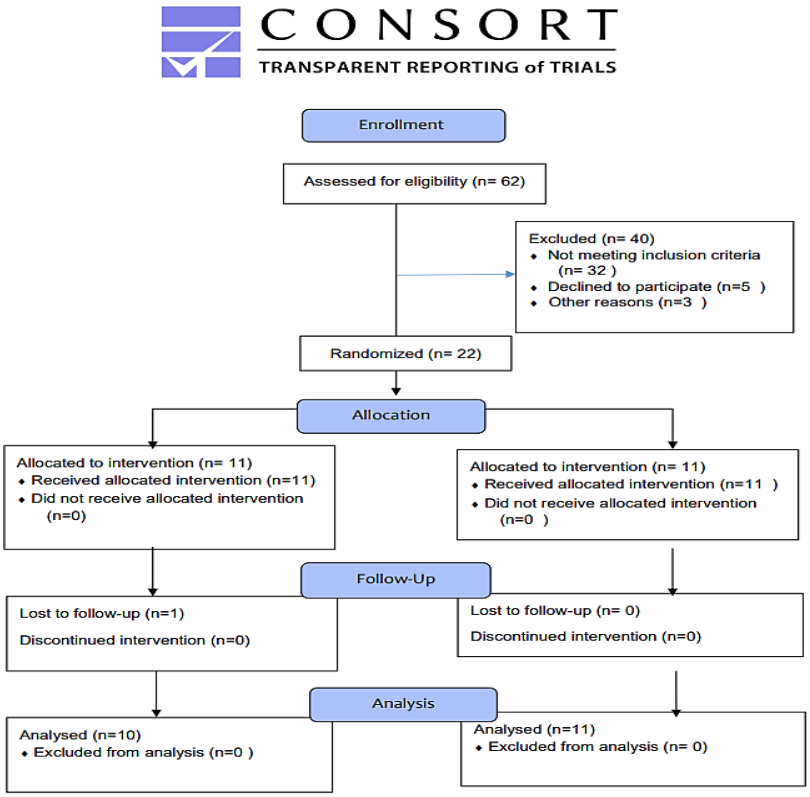
- **Statistical Methods**

Data was analyzed using Medcalc software, version 19 for windows (MedCalc Software Ltd, Ostend, Belgium). Categorical data was described as frequency and percentage, intergroup comparison between interventions was performed using the Chi-Squared test, while intragroup comparison within each intervention was performed using the Cochran's-Q test followed by multiple pairwise comparisons, with statistical significance level set at ($P \leq 0.05$). Relative risk was used to assess the clinical significance. Survival rate was analyzed using Kaplan-meier and Log-rank test. The confidence limit was set at 95% with 80% power and all tests were two tailed.

Table 1: Material name, composition, Lot number and manufacturer

Materials	Composition	Lot number	Manufacturer
ACTIVA Presto™	Matrix: Blend of diurethane and other methacrylate resins (35%) Filler: Silica, amorphous (4.8%)	191107	PULPDENT Corporation 80 Oakland Street, Watertown, MA 02472, USA https://www.pulpdent.com
DeTrey Conditioner 36	36% Phosphoric acid, Water, Synthetic amorphous silica, Polyethylene glycol		Dentsply Sirona, 13320-B, Ballantyne Corporate Pl Charlotte, 28277, USA https://www.dentsplysirona.com
Prime&Bond Universal™	Mono-, di-, and trimethacrylate resins;10-MDP, PENTA diketone; organic phosphine oxide; stabilizers; cetylamine hydrofluoride;	181000081	Dentsply Sirona, 13320-B, Ballantyne Corporate Pl Charlotte, 28277, USA https://www.dentsplysirona.com
EQUIA® Forte Fil HT	Powder: Fluoro-alumino-silicate glass, Polyacrylic acid powder, Pigment Liquid: Polyacrylic acid, Distilled water, Polybasic carboxylic acid	2002151	GC Corporation, 3-2-14 Hongo, Bunkyo-ku,, Tokyo, 113-0033, Japan. https://www.gcamerica.com
Ketac Conditioner™	20-30% Polyacrylic acid, 70-80% Distilled water (by weight)	7229316	3M ESPE, Saint Paul, Minnesota, USA. https://www.3m.com
EQUIA® Forte Coat	40%-50% methyl methacrylate, 10%-15% colloidal silica, 0.09% camphorquinone, 30% 40% urethane methacrylate, 1%-5% phosphoric ester monomer	1904191	GC Corporation, 3-2-14 Hongo, Bunkyo-ku, Tokyo, 113-0033, Japan https://www.gcamerica.com
HEMA: 2 hydroxyethyl methacrylates, MDP: Methacryloxydecyl dihydrogen phosphate, PENTA: dipentaerythritol pentacrylate phosphate			

Figure 1.: CONSORT flowchart of the study



III. RESULTS

A total of 22 restorations were placed. 21 restorations were assessed after a 12 month follow up. Data was recorded and statistically analyzed for each participant including demographic data and modified USPHS criteria, which were: retention, marginal discoloration, marginal adaptation, surface texture, post-operative hypersensitivity,

anatomical form and survival rate. The primary and secondary outcomes of the study were summarized and demonstrated in tables 3, 4 and 5).

- **Demographic Data**

After 12 months 21 participants completed the follow-up with 95.4 % retention rate. Regarding gender, there were 4 males and 18 females in the current study, in the ACTIVA group there was 1 male and 10 females, while in the EQUIA forte group there were 3 males and 8 females, there was no statistically significant difference between both groups regarding gender (P=0.2801). Mean age of the participants in the current trial was 30.4±6.7 years; mean age within intervention group was 29.2±7 years, while within the comparator group mean age was 31.7±6.4 years, there was no statistically significant difference between both groups regarding age (P=0.388). According to teeth distribution in the dental arches, there were 7 maxillary premolars, 7 maxillary molars, 5 mandibular premolars and 3 mandibular molars in the current study, there was no statistically significant difference between both groups regarding teeth distribution (P=0.4070).

- **Modified USPHS Criteria**

After 12 months, there was no statistically significant difference between both materials regarding retention, marginal discoloration, marginal adaptation , postoperative hypersensitivity ,anatomical form and survival rate (P= 0.8273, P=0.1665, P=0.9449, P=0.9449, P=0.0796, P=0.057) respectively. Relative risk was used to assess the clinical significance. Regarding the primary outcome proximal contact, there was a statistically significant difference between both materials at 6 and 12 months (P= 0.136 and P= 0.0246) respectively, where there was 59% less risk for score B and C proximal contact of ACTIVA presto when compared to EQUIA forte after 12 months. With regards to color match there was a statistically significant difference at baseline (P = 0.0488), while at 6 and 12 months there was no statistically significant difference (P = 0.3842 and P = 0.0601) respectively .As for surface texture there was a statistically significant difference at 6 and 12 months between both materials respectively (P = 0.0184, and P = 0.0128).

Table 2: Modified USPHS criteria, score, characteristics for assessment of dental restorations

Outcomes	Criterion	Score	Characteristic
Primary	Proximal Contact	A	Normal Contact
		B	Light Contact
		C	None
Secondary	Retention	A	No loss of restoration
		C	Loss of restoration
	Marginal Discoloration	A	No discoloration between tooth structure and restoration
		B	Non penetrating marginal discoloration that can be polished away
		C	Discoloration has penetrated margin in pulpal direction
	Color Match	A	Restoration matches the color of the tooth
		B	Acceptable mismatch
		C	Un-acceptable mismatch
	Marginal Adaptation	A	Closely adapted, no detectable margin
		B	Detectable marginal discrepancy clinically acceptable
		C	Marginal crevice, clinically un-acceptable
	Anatomical Form	A	Correct Contour
		B	Slightly under-contoured
		C	Slightly over or under-contoured
		D	Restoration fractured or mobile
	Surface Texture	A	No surface defect
		B	Minimal surface defect
		C	Severe surface defect
	Post-operative hypersensitivity	A	No post-operative hypersensitivity
		C	Sensitivity present

Table 3 Gender distribution among intervention and comparator groups:

Gender	(Intervention)	(Comparator)	Total
Males	1 (9.1%)	3 (27.3%)	4
Females	10 (90.9%)	8 (72.7%)	18
Total	11	11	22

Table 4: Jaw distribution among intervention and comparator groups

Jaw distribution	(Intervention)	(Comparator)	Total
Maxillary premolars	5 (71.4 %)	2 (28.6 %)	7 (31.8 %)
Mandibular premolars	1 (20 %)	4 (80 %)	5 (22.7 %)
Maxillary molars	3 (42.9 %)	4 (57.1 %)	7 (31.8 %)
Mandibular molars	2 (66.7 %)	1 (33.3 %)	3 (13.6 %)
Total	**11 (50 %)**	**11 (50 %)**	**22**

Table 5: Outcome, follow up, frequency, percentage and P value for all the USPHS criteria

Outcome	Follow-up	Bioactive Restorative Material (ACTIVA Presto)			High Viscosity Glass Hybrid reinforced Glass Ionomer (EQUIA Forte)			P value
		A	B	C	A	B	C	
Proximal Contact	Baseline	10 (90.9%)	1 (9.1%)	0 (0%)	11 (100%)	0 (0%)	0 (0%)	P = 0.3173
	6 months	9 (90%)	1 (10%)	0 (0%)	4 (36.4%)	7 (63.6%)	0 (0%)	P = 0.0136
	12 months	7 (70%)	3 (30%)	0 (0%)	16 (27.3%)	5 (45.4%)	3 (27.3%)	P = 0.0246
	P value		P = 0.097			P = 0.003		
Retention	Baseline	11 (100%)	0 (0%)	0 (0%)	11 (100%)	0 (0%)	0 (0%)	P = 1.0000
	6 months	10 (100%)	0 (0%)	0 (0%)	11 (100%)	0 (0%)	0 (0%)	P = 0.8273
	12 months	10 (100%)	0 (0%)	0 (0%)	11 (100%)	0 (0%)	0 (0%)	P = 0.8273
	P value		P = 0.368			P = 1.0000		
Marginal Discoloration	Baseline	11 (100%)	0 (0%)	0 (0%)	11 (100%)	0 (0%)	0 (0%)	P = 1.0000
	6 months	10 (100%)	0 (0%)	0 (0%)	10 (90.9%)	1 (9.1%)	0 (0%)	P = 0.3404
	12 months	10 (100%)	0 (0%)	0 (0%)	9 (81.8%)	2 (18.2%)	0 (0%)	P = 0.1665
	P value		P = 0.368			P = 0.223		
Color Match	Baseline	6 (54.4%)	4 (36.4%)	1 (9.1%)	1 (9.1%)	8 (72.7%)	2 (18.2%)	P = 0.0488
	6 months	3 (30%)	6 (60%)	1 (10%)	1 (9.1%)	9 (81.8%)	1 (9.1%)	P = 0.3842
	12 months	3 (30%)	6 (60%)	1 (10%)	0 (0%)	8 (72.7%)	3 (27.3%)	P = 0.0601
	P value		P = 0.050			P = 0.607azx		
Marginal Adaptation	Baseline	11 (100%)	0 (0%)	0 (0%)	11 (100%)	0 (0%)	0 (0%)	P = 1.0000
	6 months	9 (90%)	1 (10%)	0 (0%)	10 (90.9%)	1 (9.1%)	0 (0%)	P = 0.9449
	12 months	9 (90%)	1 (10%)	0 (0%)	10 (90.9%)	1 (9.1%)	0 (0%)	P = 0.9449
	P value		P = 0.135			P = 0.368		
Anatomical Form	Baseline	11 (100%)	0 (0%)	0 (0%)	10 (90.9%)	1 (9.1%)	0 (0%)	P = 0.3173
	6 months	9 (90%)	1 (10%)	0 (0%)	10 (90.9%)	1 (9.1%)	0 (0%)	P = 0.9449
	12 months	9 (90%)	1 (10%)	0 (0%)	6 (54.5%)	5 (45.5%)	0 (0%)	P = 0.0796
	P value		P = 0.264			P = 0.018		
Surface Texture	Baseline	8 (72.7%)	3 (27.3%)	0 (0%)	6 (54.4%)	5 (45.5%)	0 (0%)	P = 0.3865
	6 months	8 (80%)	2 (20%)	0 (0%)	3 (27.4%)	8 (72.6%)	0 (0%)	P = 0.0184
	12 months	7 (70%)	3 (30%)	0 (0%)	3 (27.3%)	3 (27.3%)	5 (45.4%)	P = 0.0128
	P value		P = 0.368			P = 0.050		
Postoperative Sensitivity	Baseline	9 (81.8%)	0 (0%)	2 (18.2%)	11 (100%)	0 (0%)	0 (0%)	P = 0.1473
	6 months	9 (90%)	0 (0%)	1 (10%)	9 (81.8%)	0 (0%)	2 (18.2%)	P = 0.6015
	12 months	9 (90%)	0 (0%)	1 (10%)	10 (90.9%)	0 (0%)	1 (9.1%)	P = 0.9449
	P value		P = 1.0000			P = 0.223		

IV. DISCUSSION

Despite the many favorable properties of glass ionomer cements, owing to their questionable strength , high solubility and unacceptable esthetic results rendered them unsuitable as permanent restorative materials [4] [11].To overcome these shortcoming newer modifications of the material have been developed. High viscosity resin modified glass ionomers have been employed in stress bearing class II cavities due to their high flexural strength and high acid and wear resistance[10]

Bioactive materials, which compose a new era of restorative materials are capable of sealing margins by filling micro-gaps when submerged in simulated body fluid (SBF) , defined as "the property of a biomaterial to form apatite-like material that blocks the micro-spaces preventing micro-leakage, and thus aiding in tooth repair[16].

Our intervention, the bioactive material ACTIVA Presto supposedly possesses these attributes. The manufacturer stated that the resin monomers added to ACTIVA improve the material's resiliency and resistance to wear, fracture, and marginal chipping. ACTIVA features a patented bioactive shock-absorbing rubberized ionic-resin matrix that contains a small quantity of water[17]. The reactive glass fillers and the contact with tooth structure are both improved by the antibacterial phosphate acid groups that are present in the ionic resin component[18].

In this study we also examined new high viscosity glass hybrid reinforced glass ionomer **EQUIA® Forte Fil HT** (GC, Tokyo, Japan). EQUIA Forte is a bulk-fill, rapid restorative system based on glass ionomers. Additionally, the GIC is supplemented with additional, smaller, and more reactive silicate particles and molecules of higher molecular weight acrylic acid, which are believed to boost matrix cross-linking[6] In other words the reactivity is increased which reportedly has a considerable impact on the material's mechanical properties and qualifies it for long-lasting fillings in the posterior teeth [7] [11].

Proximal cavities were selected for this study due to the technique sensitivity associated with direct class II composite restorations, which includes poor marginal adaptation, marginal discoloration, micro-leakage, secondary caries, and post-operative hypersensitivity typically based on polymerization shrinkage stress [2].

The chosen follow-up intervals were baseline, six months, and twelve months. This is not considered to be an accurate predictor of the long-term compatibility of the tested materials. However, if information on the effectiveness of the tested products is provided, the one-year testing time is appropriate[19]. This study was conducted on (22) participants with carious proximal lesions and after 12 months 21 participants completed the follow-up. One patient dropped out due to personal reasons.

In terms of, marginal discoloration, marginal adaptation, anatomic form, post-operative hypersensitivity and overall survival there were no statistically significant differences when comparing the two groups at baseline, 6 months and 12 months.

Regarding proximal contacts, there was no statistically significant difference between both groups at baseline. This could be attributed to the reliable matricing technique that was used[12]. After 12 months, in the ACTIVA Presto group 7 teeth scored Alfa and 7 and 3 scored Bravo, while in the EQUIA Forte group 3 teeth score Alfa, 5 scored Bravo and 3 scored Charlie. this was in accordance with **Scholtanus & Huysmans (2007)[21]** who reported material loss on the proximal surfaces of the restorations as observed on the radiographs, usually below the contact sites, while in absence of neighboring teeth, there was no material loss at the proximal surfaces of the GIC, and also in agreement with **Klinke et al., (2016)[22], Tal et al., (2017)[23], Balkaya (2019)[2] and Eissa et al., (2021)[24]** .**Tal et al., (2017) and Balkaya and Arslan (2020)[8]** who attributed interproximal material loss to difficulty of glazing this surface with resin coat which causes this surface to be vulnerable to early moisture exposure. **Eissa et al., (2021)** explained that glass ionomers can chemically bond to metals, and the force used to remove the matrix from glass ionomer cement may cause micro cracks that may lead to the restoration being more vulnerable in an event of acid attacks.

With regards to color match, between both materials there was statistically significant difference at baseline, while at 6 and 12 months there was no statistically significant difference

between them. Intragroup comparison within ACTIVA presto have shown statistically significant difference between different follow-up periods, while EQUIA Forte have shown no statistically significant difference between different follow-up periods. These findings were in line with **Balkaya et al., (2019) and Balkaya and Arslan (2020).**

ACTIVA Presto's color match was better initially at baseline where 6 teeth scored Alfa and 4 scored Bravo, due to the variety of shades provided by the manufacturer and the smoothness achieved after finishing and polishing. However, discoloration occurred over time and this maybe a product exchange of minerals between the saliva and the material. This may be accounted for by the surface of the material becoming opaque due to changes in light reflection as a result of increases in surface roughness, where the restorations may become unaesthetic due to staining and colour changes brought on by a decrease in reflectivity[25].

With regards to surface texture, this study found no statistically significant difference between both materials at different follow up periods. ACTIVA Presto showed no statistically significant difference regarding surface texture which was in accordance with**, Bansal et al. [25]** and **Bhadra et al.**[18]. This could be attributed to the shock absorbing rubberized resin matrix that accounts for the minimal surface changes that might take place as well as the bioactive ionic resin matrix, and reactive ionomer glass fillers[11].

As for EQUIA Forte we found statistically significant differences in surface texture over time within the group. After 12 months 3 teeth scored Alfa, 3 scored Bravo and 5 scored Charlie. This was also confirmed by **Friedl et al**.[27] and more recently **Eissa et al. [24]** who found a statistically significant difference in surface texture between ACTIVA and EQUIA Forte after 6 months. **Balkaya et al. [2]** reported slight surface roughness in EQUIA Forte after 12 months and after 2 years as well **Balkaya and Arslan[8]** This was attributed to the possible wearing away of the protective surface coating during mastication[28] [29].

On the contrary to our results, **Turkun and Kanik[30]** found no statistically significant change in surface texture for EQUIA Forte restorations over six-years. This may be attributed to differences in curing parameters for the protective coat.

As for anatomical form, the results showed no statistically significant difference when comparing both materials after 12 months. Intragroup comparison within ACTIVA presto have shown no statistically significant difference between different follow-up periods while for EQUIA forte there was statistically significant difference .Our results aligned with **Bansal et al [26] , Bhadra et al [18], Balkaya and Arslan[8] and Eissa et al [24].**

However, **Miletec et al[31]** observed no statistically significant difference on comparing EQUIA Forte and Tetric EvoCeram regarding anatomical form. **Gurgan et al[29] ,** who found only 2 EQUIA Forte restorations (4.4%) that were slightly anatomically deformed.

El Bialy et al[32] reported no statistically significant difference among groups (high viscosity glass ionomer and GHGIC EQUIA Forte), however they observed 4 restorations which scored 2 for occlusal contour and wear after 12 months, and this was attributed to the stickiness and difficulty in handling and contouring of the glass ionomer cements compared to resin composites[33].

It is established that this study is a pioneer in terms of evaluating the clinical efficacy of ACTIVA Presto as a bioactive restorative material in a clinical setting. Limitations that were encountered were mainly the small sample size and short follow-up time.

V. CONCLUSIONS

ACTIVA Presto bioactive restorative material showed a satisfactory clinical performance, thus it is highly recommended as a reliable permanent restoration especially for proximal cavities. EQUIA Forte is not advised to be used as a permanent restoration in proximal high stress bearing areas. ACTIVA Presto ought to be assessed in more clinical trials regarding its performance in various clinical scenarios. It is recommended that further multicentric research is conducted with extended follow-up periods of a minimum of 3 years with larger sample sizes.

Conflict of Interest:

The authors declare no conflict of interest.

Funding:
This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Ethics:
The study was approved by Research Ethics Committee (REC), Faculty of Dentistry, Cairo University in November 2020 with identification number: 61120.

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