10.21608/adjc.2023.177122.1203 Advanced Dental Journal
Volume 6 (2024) | Issue 2| Pages 339-349

Original Article

CLINICAL EVALUATION OF NEW BIOACTIVE RESTORATIVE MATERIAL VERSUS RESIN MODIFIED GLASS IONOMER IN RESTORATION OF CERVICAL CARIOUS LESIONS: RANDOMIZED CLINICAL TRIAL

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Submitted: 28-11-2022
Accepted: 19-05-2023

Abstract

Aim: The aim of the current study was to evaluate the clinical performance of bioactive composite (ACTIVA Presto) versus resin modified glass ionomer (Fuji II) in restoration of cervical carious lesions. **Subjects and methods:** 34 participants received 34 cervical restorations randomly using either; ACTIVATM PrestoTM (Pulpdent Corp) or Fuji II LC capsule (GC Corporation). After cavity preparation, restorative materials were applied according to manufacturers' instructions. Restorations were evaluated using modified USPHS criteria by two blinded assessors at baseline, 6 and 12 months. **Results:** After 12 months there was no statistically significant difference between both materials for surface texture, marginal adaptation, marginal discoloration, retention and gingival inflammation (P = 0.8616, P = 0.5050, P = 0.8618, P = 0.5050 and P = 0.6241) respectively. There was 30% more risk for slight gingival inflammation for ACTIVA presto when compared to Fuji II LC after 12 months (P = 0.6206). Regarding color match, there was no statistically significant difference at baseline and 6 months (P = 0.2786 and P = 0.2506) respectively, while at 12 months there was statistically significant difference (P = 0.0003). There was 4.6 times more risk for slight color mismatch for ACTIVA presto when compared to Fuji II LC after 12 months (P = 0.0045). **Conclusion:** Both ACTIVA Presto and Fuji II showed accepted clinical performance in restoration of cervical carious lesions after 12 months.

Keywords: Bioactive restoration, ACTIVA Presto, Fuji II LC, Class V, USPHS criteria

I. INTRODUCTION

Restoration of class V cavities is difficult in clinical practice since the cervical margin is usually found in dentin or cementum. As a result of this trait, the cervical margin is more vulnerable to microleakage, resulting in cavo-surface stains, postoperative sensitivity, and an increased risk of recurrent caries (Francois et al., 2020).

Conventional glass ionomer fillings have been recommended as the best material for treating cervical carious lesions in high caries risk individuals because this material offers chemical bonding, fluoride release, and caries inhibitory abilities. However, due to their poor aesthetics, low tensile strength, brittleness, and low resistance to wear, clinical acceptability of these materials has been limited (Somani et al., 2016).

The development of a new type of bioactive restoratives (ACTIVA BioACTIVE, Pulpdent, Watertown, MA, USA) in 2013 marked a paradigm shift in restorative dentistry. Pulpdent's newest product, ACTIVA Presto, is a light-cured material that offers biomimicry as ACTIVA Bioactive dual-cured material. The manufacturer claimed that ACTIVA Presto built on the success of ACTIVA BioACTIVE-RESTORATIVE while offering improved esthetics with wider range of shades and easier dispensing and placement (ACTIVA Presto – Pulpdent) (Lardani et al., 2022).

The data concerning the use of ACTIVA™ Presto as a tooth restoration in permanent teeth are not available in the literature. Therefore, it was found beneficial to evaluate the clinical performance of the newly introduced bioactive restorative material (ACTIVA Presto) versus resin modified glass ionomer (Fuji II) in restoration of cervical carious lesions. The null hypothesis tested that there will be no difference in the clinical performance of both restorative materials after 12 months for restoration of cervical carious lesions.

II. SUBJECTS AND METHODS

- **Study Design and Trial Registration**

The study is a randomized controlled clinical trial, with two parallel groups design with 1:1 allocation ratio and equivalence framework. The participants were randomly assigned into two groups (n=17) according to the tested groups. The protocol of this study was registered on clinical trials (www.clinicaltrials.gov) with I.D.: NCT04363996. Ethical approval was obtained prior to the start of the study. This clinical trial is reported in accordance with 2010 CONSORT guidelines.

- **Sample Size Calculation**

A power analysis was designed to have adequate power to apply a 2-sided statistical test of the research hypothesis (null hypothesis) that bioactive restorative material will have the same clinical performance as resin modified glass ionomer restorations in carious cervical carious lesions in high caries risk patients. According to the results of (Nassar et al., 2014) in 2014 in which the probability of score A for resin modified glass ionomer restorations was 0.9615, probability of score B was 0.0385 with effect size w=0.923 (n=10). If the estimated probability of score A for bioactive restorative material was 0.85, probability of score B was 0.15 with effect size w=0.7 (n=17). By adopting an alpha (α) level of 0.05 (5%), power=80%. The predicted sample size (n) was a total of 27. Sample size was increased by (20%) to account for possible dropouts during follow-up intervals to be total of (34) cases i.e. (17) for each group. Sample size calculation was performed using G*Power 3.1.9.2.

- **Eligibility criteria**

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 anterior teeth and premolar with no signs of irreversible pulpitis, small to moderate class V lesions (Si/Sta 3.2) 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, smokers and xerostomic patients, patients with parafunctional habits or temporomandibular joint disorders.

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

- **Study Setting**

This study was conducted in the Conservative Dentistry Department's clinic, Faculty of Dentistry, Cairo University. The trial commenced in July 2021 and was completed in July 2022. The modified USPHS criteria was used to evaluate the tested materials at baseline, 6 months, and 12 months.

- **Allocation of participants**

Simple randomization was done by generating numbers from 1:34 using Random Sequence Generator, Randomness and Integrity Services Ltd (https://www.random.org/). Each generated random number from 1-17 represents the intervention and from 18-34 is the comparator. Patient chose between random numbers placed in an opaque sealed envelope. Whether the intervention or the comparator treatment group was chosen, it was

recorded on a computer. The operator could not be blinded because of the difference in the application procedures of each restorative material. However, the participants, both assessors and statistician were blinded to the material used.

- **Caries risk assessment**

Participants who had two or more cavitated carious lesions with at least one risk factor from the risk factors declared by CAMBRA (Caries Management By Risk Assessment) were considered patients with high caries risk (Cambra, 2011) (Jenson et al., 2007).

- **Clinical Procedures**

The materials utilized in the current clinical trial are summarized in table (1). The restorative procedure was done by a single operator (A.N.). Patients were given local anesthesia (Mepecaine – L Cartridges, Alexandria Co. for pharmaceuticals & chemical industries, Egypt) as required. The proper shade was selected using a custom shade guide which was created using plastic cutlery as handles and PVS impressions of VITA shade tabs as molds. The cavity to be restored with ACTIVA Presto was isolated using rubber dam (Nic Tone, Expertech Solutions, Bucharest, Romania) and Sub-gingival clamps (KSK, DENTECH Corporation, Japan). While for Fuji II restoration group, the field was isolated using cotton rolls and a saliva ejector to allow normal moisture of dentin substrate (El-Bialy et al., 2020).

Cavities were prepared with width not extending across the labio-proximal line angles mesially and distally and 1 mm above the gingival margin with an axial depth of 1.5-2 mm. The soft carious dentin was removed using a sharp excavator (DENTSPLY Maillefer, USA) from the cavity floor, walls and margins in a direction from the periphery to the center. The walls of the cavities were cleared from any carious structure till reaching hard dentin, and undermined enamel was removed using a No. #330 bur (0.8 mm in diameter and 1.6 mm in length) (MANI, INC, Japan) operated by high-speed hand piece with air /water coolant (W&H high speed handpiece, Bürmoos, Austria), burs were discarded after three preparations to maintain cutting efficiency. This was followed by finishing the cavity walls with a fine grit diamond stone.

For the intervention (ACTIVA Presto):

Areas of exposed dentin were covered with Teflon tape before selective etching enamel with 36% Phosphoric acid-etching gel (DeTrey® Conditioner 36, Denstply, USA) for 15 seconds (Sattar et al., 2017). The surfaces were rinsed with vigorous water spray for 15 seconds and dried by blowing gently with oil free compressed air for 5 seconds, till chalky white appearance of the enamel margin was shown. Prime&Bond Universal™ (Dentsply Sirona) was applied to cavity walls with bond brush (TPC Advanced technology, Inc.) and was agitated for 20 seconds followed by air thinning for 5 seconds until a glossy and uniform layer resulted then photo cured for 10 seconds using light emitting diode (LED) light curing unit with a light intensity of 1000-2500 mW/cm2 (Woodpecker i-LED, Woodpecker Co., Ltd, Guilin, Guangxi, China). ACTIVA restorative was applied in 2 mm increments inside the cavity then light polymerized for 20 seconds using LED light curing unit between each layer. In order to remove excess filling and contouring, superfine yellow ringed finishing diamond stones (MANI, INC, Japan) were used under copious water coolant then diamond discs were used for polishing (DIACOMP® PLUS TWIST, EVE, Germany).

For the comparator (GC Fuji II LC®):

The prepared cavities were conditioned using Dentin conditioner (KetacTM Conditioner, 3M ESPE AG, Saint Paul, MN, USA) 20-30% polyacrylic acid for 10 seconds then rinsed with copious amount of water for 15 seconds and dried with oil free compressed air for 5 seconds till the surface had a matte shiny appearance. The Fuji II capsule was inserted into a high-speed amalgamator (Mix 2000, Carlo De Giorgi, Milano, Italy) and triturated for 10 seconds. The mixture was extruded directly out of the capsule into the prepared cavity with a capsule gun ensuring that no air bubbles were included. Excess material was removed then light cured for 20 seconds for every 2mm increment. Then EQUIATM Coat (GC America Inc.) was applied immediately to the restoration surface before finishing using the disposable micro-tip applicator. Immediate light curing of all coated surfaces was done using LED light curing unit (1000mW/cm²) for 20 seconds. Finishing of restorations was done with superfine

yellow ringed finishing diamond stones (MANI, INC, Japan) then polishing using rubber cup (Elephant, China). Spraying of the finishing debris away with water was done followed by drying by gentle blowing with oil free air without desiccation (chalky appearance). Then final EQUIATM Coat (GC America Inc.) was applied immediately to the restoration surface using the disposable micro-tip applicator then light cured for 20 seconds.

- **Outcomes**

Modified USPHS criteria for dental restorations was evaluated by two blinded assessors at baseline, three, six months and after one year. In some cases, as both assessors scored differently, they discussed to reach for a consensus, in cases they did not agree a third assessor resolved the conflict. (Nassar et al., 2014) Modified USPHS criteria for assessment of dental restorations is described in table (2). Assessment was done using visuo-tactile examination using dentals mirrors and explorers under standardized examination conditions, operating light source, pre-set position of the dental chair and proper moisture control. Flow of the participants in the current study is described in the CONSORT flow diagram. (Figure 1).

- **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 at each follow-up was performed using the Chi-Squared test, with statistical significance set at ($P \leq 0.05$), while intragroup comparison within each intervention between different follow-up periods was performed using the Cochran's-Q test followed by multiple pairwise comparisons, with statistical significance adjusted with Bonferroni correction set at ($P \leq 0.017$). 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.

III. Results

A total of 34 restorations were placed. 33 restorations were assessed after a 12 month follow up period. Data was recorded and statistically analyzed for each participant including demographic data and modified USPHS criteria, which were: surface texture, marginal adaptation, marginal discoloration, retention, gingival inflammation, and color match.

- **Demographic Data**

The study was conducted on (34) high caries risk participants with carious cervical lesions that were randomly allocated to the intervention and the comparator arms (n=17). After 12 months 33 participants completed the follow-up with 97 % retention rate. Regarding gender, all participants in the current study were females, there was no statistically significant difference between both groups regarding gender (P=1.0000). Mean age of the participants in the current trial was 32.15±5.8 years; mean age within intervention group was 33.5±4.6 years, while within the comparator group mean age was 30.8±6.6 years, there was no statistically significant difference between both groups regarding age (P=0.145). According to teeth distribution in the dental arches, there were 5 maxillary incisors, 6 mandibular incisors, 4 maxillary canines, 8 mandibular canines, 2 maxillary premolars and 9 mandibular premolars in the current study, there was no statistically significant difference between both groups regarding teeth distribution (P=0.2101). (Table 3)

- **Modified USPHS criteria**

After 12 months, surface texture, marginal adaptation, marginal discolouration, retention, and gingival inflammation were not statistically different between the two materials (P = 0.8616, P = 0.5050, P = 0.8618, P = 0.5050, and P = 0.6241), respectively. Furthermore, ACTIVA presto had a 30% higher incidence of mild gingival inflammation compared to Fuji II LC (RR= 1.3281 (95% CI 0.4318 to 4.0855; P = 0.6206). In terms of colour match, there was no statistically significant change at the baseline or the six-month mark (P = 0.2786 and P = 0.2506, respectively), but there was at the 12-month mark (P = 0.0003). ACTIVA presto was 4.6 times more likely than Fuji II LC to experience a minor colour mismatch (RR= 4.6042 (95% 1.6055 to 13.2039; P= 0.0045). (Table 4)

Table (1). Materials' specifications, composition, lot number and manufacturer

Materials	Composition	Lot number	Manufacturer
Fuji II LC® capsules	**Distilled water: 20-30%, Polyacrylic acid: 20-30%, HEMA: 30-35%, UDMA < 10, Camphorquinone < 1, Fluroaluminosilicate glass**	**N21SB**	**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 AG, Saint Paul, Minnesota, USA. https://www.3m.com
EQUIA™ Coat	Methyl methacrylate 40%-50%, Colloidal silica 10%-15%, Camphor-quinone 0.09%, Urethane methacrylate 30%-40%, Phosphoric ester monomer 1%-5%	190122B	GC Corporation, 3-2-14 Hongo, Bunkyo-ku, Tokyo, 113-0033, Japan, https://www.gcamerica.com
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, NC 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, NC 28277, USA, https://www.dentsplysirona.com

HEMA: 2 hydroxyethyl methacrylates, MDP: Methacryloxydecyl dihydrogen phosphate, PENTA: dipentaerythritol pentacrylate phosphate

Table (2) Modified USPHS criteria for assessment of dental restorations

Outcome	Criterion	Score	Characteristic
Primary	Surface Texture	A	No surface defect
		B	Minimal surface defect
		C	Severe surface defect
Secondary	Marginal Adaptation	A	Closely adapted, no detectable margin
		B	Detectable marginal discrepancy clinically acceptable
		C	Marginal crevice, clinically unacceptable
	Marginal Discoloration	A	No discoloration between tooth structure and restoration
		B	Non penetrating marginal discoloration which can be polished away
		C	Discoloration has penetrated margin in pulpal direction
	Retention	A	No loss of restoration
		C	Loss of restoration
	Gingival Inflammation	A	No inflammation
		B	Slight gingival inflammation
		C	Moderate to severe inflammation
	Color Match	A	Restoration color matches color of tooth
		B	Acceptable mismatch
		C	Un-acceptable mismatch

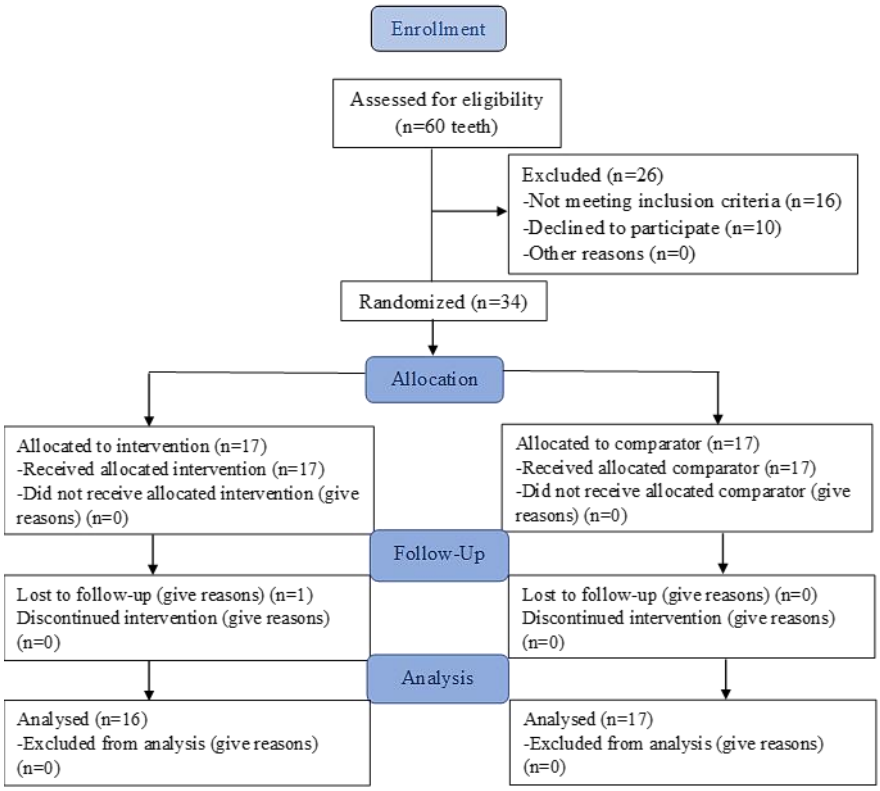
Table (3): Teeth distribution among interventions

Teeth distribution	(ACTIVA Presto)	(Fuji II LC)	Total
Maxillary incisors	3 (60 %)	2 (40 %)	5 (14.7 %)
Mandibular incisors	5 (83.3 %)	1 (16.7 %)	6 (17.6 %)
Maxillary canines	1 (25 %)	3 (75 %)	4 (11.8 %)
Mandibular canines	5 (62.5 %)	3 (37.5 %)	8 (23.5 %)
Maxillary premolars	1 (50 %)	1 (50 %)	2 (5.9 %)
Mandibular premolars	2 (22.2 %)	7 (77.8 %)	9 (26.5 %)
Total	17 (50 %)	17 (50 %)	34

Table (4): Frequency and percentage of Modified USPHS criteria scores of both interventions at each follow-up period

Outcome	Follow-up	Bioactive Restorative Material (ACTIVA Presto)			Resin Modified Glass Ionomer (Fuji II LC)			P value
		A	B	C	A	B	C	
Surface Texture	Baseline	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 1.0000
	6 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 1.0000
	12 months	16 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 0.8618
	P value		P = 0.368			P = 1.0000		
Marginal Adaptation	Baseline	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 1.0000
	6 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 1.0000
	12 months	16 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 0.8618
	P value		P = 0.368			P = 1.0000		
Marginal Discoloration	Baseline	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 1.0000
	6 months	17 (100%)	0 (0%)	0 (0%)	16 (94.1%)	1 (5.9%)	0 (0%)	P = 0.3173
	12 months	16 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 0.8618
	P value		P = 0.368			P = 0.368		
Retention	Baseline	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 1.0000
	6 months	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 1.0000
	12 months	16 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 0.8618
	P value		P = 0.368			P = 1.0000		
Gingival Inflammation	Baseline	17 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 1.0000
	6 months	12 (70.6%)	5 (29.4%)	0 (0%)	14 (82.4%)	3 (17.6%)	0 (0%)	P = 0.4257
	12 months	11 (68.7%)	5 (31.3%)	0 (0%)	13 (76.5%)	4 (23.5%)	0 (0%)	P = 0.6241
	P value		P = 0.012*			P = 0.039		
Color Match	Baseline	7 (41.2%)	10(58.8%)	0 (0%)	4 (23.5%)	13 (76.5%)	0 (0%)	P = 0.2786
	6 months	3 (17.6%)	14 (82.4%)	0 (0%)	6 (35.3%)	11 (64.7%)	0 (0%)	P = 0.2506
	12 months	3 (18.8%)	13 (81.2%)	0 (0%)	14 (82.4%)	3 (17.6%)	0 (0%)	P = 0.0003*
	P value		P = 0.018			P < 0.001*		

Figure (1): CONSORT flow diagram of the study



IV. DISCUSSION

Glass ionomers were introduced as a restorative material by Wilson and Kent in the United Kingdom in 1969, then developed by Mclean and Wilson and brought to market in the 1970s. It has many advantages, including biocompatibility, long-term fluoride release and recharge, coefficient of thermal expansion close to tooth structure, inhibition of bacterial acid metabolism and activity, chemical bonding to tooth structure, and ease of application (Berg and Croll, 2015)**.** However, these materials were not accepted as permanent restorations by the dentists due to their high solubility, low wear resistance and low strength, long setting time and unacceptable esthetics (Najeeb et al., 2016)**.**

To overcome the shortcomings of glass ionomer cements, hybrid materials combining glass-ionomer and composite technologies were developed. These hybrid materials primarily include resin modified glass ionomer cements (RMGICs), compomers (polyacid-modified composites), Giomers, and, more recently, bioactive resin composites. These hybrid materials were developed to overcome the drawbacks of conventional glass ionomers and composite resions while retaining their advantages (Tiwari and Nandlal, 2013)**.**

Recently, a new class of materials known as "bioactive" materials has emerged. A biomaterial's ability to form apatite-like material that fills micro-gaps and seals margins against microleakage when immersed in simulated body fluid (SBF) for a period of time is defined as "the property of a biomaterial to form apatite-like material that blocks the micro-spaces preventing microleakage, and thus aiding in tooth repair".

ACTIVA Presto supposedly possesses these attributes. The manufacturer also 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 (Pameijer et al., 2015)**.** 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 (Bhadra et al., 2019)**.**

The present study aimed to compare the clinical performance of bioactive composite (ACTIVA Presto) with that of resin modified glass ionomer (Fuji II) in restoration of cervical carious lesions.

Cervical lesions restorations were selected for the present study because they pose a challenge to the dental profession (Kaushik and Yadav, 2017)**.** Failure of class V adhesive restorations is frequently related to moisture contamination, bonding to different structures (enamel and dentin), dentin composition, and high flexural stresses acting on the restoration, which can lead to early loss or fracture (Bollu et al., 2016)**.**

Patients with high caries risk were selected in this study in order to test material in challenges such as pH fluctuation, high sugar intake, increased bacterial load, or lower salivary secretion in such cases (De Moor et al., 2011).

Follow-up period was selected to be baseline, six months and 12 months. This was not regarded as a reliable indicator of the tested materials' long-term suitability. However, the one-year testing period is acceptable providing information about the performance of the tested materials (Celik et al., 2010)**.**

The current study was conducted on (34) high caries risk participants with carious cervical lesions that were randomly allocated to the intervention and the comparator arms (n=17). After 12 months 33 participants completed the follow-up with 97 % retention rate. One patient dropped out due to pregnancy. Neither age or teeth distribution affected the outcomes significantly.

All participants in the current study were females. Previous trial revealed that the gender was not a prognostic confounder that influences the longevity of the cervical restorations (Namgung et al., 2013).

In terms of surface texture, marginal adaptation, marginal discoloration and retention, comparison between both materials have shown no statistically significant difference within different follow up periods baseline, 6 and 12 months.

Regarding surface texture, there was no significant difference between both materials

regardless of the time. Both materials can retain the surface smoothness for 12 months. This could be related to the small particles size of the two materials that grant the smooth polished surface. These results were in accordance with (Ismail et al., 2020), they compared Fuji II LC and ACTIVA to conventional glass-ionomer. They found that both materials have lower surface roughness than conventional glass ionomer, this was attributed to materials' smaller particle sizes in comparison to typical glass ionomer. Furthermore, the presence of resin in the Fuji II LC and ACTIVA compositions may aid in the removal of fine chips from the material's surface during polishing, resulting in a smooth surface.

Concerning the marginal adaptation of ACTIVA Presto, 100% alpha scores were recorded throughout the study. These results were in accordance with the results of (Bhadra et al., 2019), they found that ACTIVA bioactive restorations had no statistically significant difference in marginal adaptation compared to nanohybrid composite. The shock absorbing resin components of ACTIVA improved fracture, and marginal chipping (Bansal et al., 2016). Furthermore, the dynamic ionic exchange between saliva and tooth structure, which promotes remineralization of the tooth structure by continuous releasing and absorbing calcium, phosphate, and fluoride ions in response to reacting to pH changes in the oral cavity. This procedure fills micro-gaps improving the marginal adaptation (Alrahlah, 2018).

In addition, using selective enamel etching using phosphoric acid, followed by universal adhesive containing the acidic monomers; phosphoric acid modified acrylate resins PENTA (dipentaerythritol pentacrylate phosphate) and MDP (10-methacryloyloxydecyl dihydrogen phosphate) enhanced the marginal quality and the bonding performance of ACTIVA presto especially in the cervical area which is subjected to complex stresses and harsh conditions. Both monomers reliably etch the dental substrate releasing calcium ions. These ions were instantly retained in the hybrid layer by forming stable ionic bonding to calcium through a nanolayered structure of Ca salts at the interface. Such hydrophobic nano-layering improves the long-term durability of enamel and dentin bonding (de Paris Matos et al., 2020). Furthermore, the absence of HEMA as a co-solvent, which is responsible for increasing the water sorption of adhesives, has a negative impact on the mechanical properties and stability of the adhesive interface. Instead, isopropanol is used, which is less hydrophilic and more viscous than ethanol, and improves stability during storage (Cardoso et al., 2011).

The current study findings of marginal adaptation of Fuji II are in accordance with (Ebaya et al., 2019), they stated that the micro-gaps at the tooth-material interface have been blocked by the coat applied over RMGI, as well as the strong chemical and micromechanical bonding between Fuji II and tooth structure. Furthermore, the flowability of the restorations improves wetting of the cavity walls, enhancing dental restoration adaptation to the cavity walls (Aggarwal et al., 2011). On the other hand, the results of (Sampaio et al., 2011) were in disagreement with the current study, which could be explained by RMGI's high tendency for absorbing water, resulting in swelling and hydrolysis. This emphasizes the importance of final coat after application of glass ionomer restorations.

ACTIVA Presto did not show marginal discoloration after 12 months, this was confirmed by (Kaushik and Yadav, 2017) reporting that none of ACTIVA restorations in combination with a bonding agent showed marginal discoloration in cervical restorations after 12 months clinical follow-up period. This is an indication of good bonding with the tooth structure without microleakage. As previously mentioned, universal adhesive containing PENTA and MDP improved the marginal quality and minimized microleakage of ACTIVA presto restorations.

Moreover, no marginal discoloration was found in Fuji II restorations. This was in agreement with (Jyothi et al., 2011), they found no marginal discoloration in cervical lesions restored using Fuji II LC after 12 months, attributing this to the chemical bonding between Fuji II and tooth structure in conjunction with micro-mechanical interlocking, depending on the extra use of a conditioner.

The 100% retention rate of ACTIVA restoration reported in the present study throughout

the whole evaluation period was supported by (Kaushik and Yadav, 2017)**.** The resin monomers in ACTIVA presto formulation improved the material's resiliency, fracture toughness, and marginal chipping. Moreover, the manufacturer`s recommendations for using bonding agent with ACTIVA restorations enhanced retention and bonding performance.

The retention of Fuji II LC throughout the study might be explained by resiliency of the material and the chemical interaction between Fuji II and tooth structure, based on ionic interaction of the numerous carboxylic groups of polyalkenoic acid with calcium in hard tooth tissue. The exact bonding mechanism of glass-ionomer involves micro-mechanical interlocking in addition to chemical interaction discussed previously, depending on the extra use of a conditioner. The organic glass-ionomer components are infiltrated into a partially demineralized dentin surface to produce this micro-mechanical retention. As a result, a sub-micron hybrid layer is generated, which is essentially identical to that produced by mild self-etch adhesives (Cardoso et al., 2011)**.**

In the current study, regarding gingival inflammation; 5 restorations in ACTIVA presto group and 4 restorations in Fuji II LC group showed slight gingival inflammation. (Ismail et al., 2020) evaluated the effect of resin-modified glass ionomer (RMGIC), high viscosity GIC (HV-GIC), flowable bulk fill resin composite and bioactive ionic resin (ACTIVA) on the viability of gingival epithelial cells when placed sub-gingivally. It was found that Bulk Flow and ACTIVA showed the highest cell viability values while HV-GIC and RMGI had the lowest values relating this to the composition of the restorative material. Moreover, HEMA and resinous components in RMGIC might be the cause of the slight gingival inflammation. ACTIVA Bioactive Restorative was found to elute 4-dimethylaminobenzoic acid ethyl ester photoinitiator (DMABEE) significantly. DMABEE has been found to exhibit cytotoxic effects on pulp and gingival fibroblasts (Roussou et al., 2021)**.**

ACTIVA color's match was better at baseline and 6 months thanks to different shades provided by the manufacturer and surface smoothness recorded in both groups but there was a change in color over time. This could be attributed to the water sorption and hydrophilicity of matrix resin. Moreover, mineral exchange between the material and the saliva could lead to lower color stability. The color stability is also attributed to the size of filler particles, depth of polymerization, and staining compounds (Lassila et al., 2020)**.** Color improvement of Fuji II was recorded throughout the study. This could be explained by the maturation process that results in opacity declining and translucency improvement after 24 hours (Nicholson, 2018).

To our knowledge, the current study was pioneer in evaluating ACTIVA Presto restorative material clinically. Limitations were the small sample size and considerably short follow-up period. More well-designed RCTs with larger sample size and longer follow up intervals are recommended to confirm the current results.

V. CONCLUSIONS

After 12 months of clinical evaluation, despite Bioactive composite (ACTIVA Presto) had inferior gingival response and color match than resin modified glass ionomer (Fuji II), both materials did not show score C in any of the evaluated criteria. Therefore, the null hypothesis could not be rejected.

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:
This study protocol was approved by the ethical committee of the faculty of dentistry- Cairo university on: 24-11-2020, approval number: 51120.

VI. REFERENCES

AGGARWAL, V., SINGLA, M. & MIGLANI, S. 2011. Effect of thermal and mechanical loading on marginal adaptation and microtensile bond strength of a self-etching adhesive with caries-affected dentin. *Journal of Conservative Dentistry: JCD,* 14**,** 52.

ALRAHLAH, A. 2018. Diametral tensile strength, flexural strength, and surface microhardness of bioactive bulk fill restorative. *J contemp dent pract,* 19**,** 13-9.

BANSAL, R., BURGESS, J. & LAWSON, N. C. 2016. Wear of an enhanced resin-modified glass-ionomer restorative material. *American journal of dentistry,* 29**,** 171-174.

BERG, J. H. & CROLL, T. P. 2015. Glass ionomer restorative cement systems: an update. *Pediatric Dentistry,* 37**,** 116-124.

BHADRA, D., SHAH, N. C., RAO, A. S., DEDANIA, M. S. & BAJPAI, N. 2019. A 1-year comparative evaluation of clinical performance of nanohybrid composite with Activa™ bioactive composite in Class II carious lesion: A randomized control study. *Journal of Conservative Dentistry: JCD,* 22**,** 92.

BOLLU, I. P., HARI, A., THUMU, J., VELAGULA, L. D., BOLLA, N., VARRI, S., KASARANENI, S. & NALLI, S. V. M. 2016. Comparative evaluation of microleakage between nano-ionomer, giomer and resin modified glass ionomer cement in class V cavities-CLSM study. *Journal of clinical and diagnostic research: JCDR,* 10**,** ZC66.

CAMBRA, H. M. 2011. Best practices in dental caries management. *Ada Cerp,* 96.

CARDOSO, M., DE ALMEIDA NEVES, A., MINE, A., COUTINHO, E., VAN LANDUYT, K., DE MUNCK, J. & VAN MEERBEEK, B. 2011. Current aspects on bonding effectiveness and stability in adhesive dentistry. *Australian dental journal,* 56**,** 31-44.

CELIK, C., ARHUN, N. & YAMANEL, K. 2010. Clinical evaluation of resin-based composites in posterior restorations: 12-month results. *European Journal of Dentistry,* 4**,** 057-065.

DE MOOR, R. J., STASSEN, I. G., VAN'T VELDT, Y., TORBEYNS, D. & HOMMEZ, G. M. 2011. Two-year clinical performance of glass ionomer and resin composite restorations in xerostomic head-and neck-irradiated cancer patients. *Clinical oral investigations,* 15**,** 31-38.

DE PARIS MATOS, T., PERDIGÃO, J., DE PAULA, E., COPPLA, F., HASS, V., SCHEFFER, R. F., REIS, A. & LOGUERCIO, A. D. 2020. Five-year clinical evaluation of a universal adhesive: a randomized double-blind trial. *Dental Materials,* 36**,** 1474-1485.

EBAYA, M. M., ALI, A. I. & MAHMOUD, S. H. 2019. Evaluation of marginal adaptation and microleakage of three glass ionomer-based class V restorations: in vitro study. *European Journal of Dentistry,* 13**,** 599-606.

EL-BIALY, M. R., SHAALAN, O. O., EL-ZOHAIRY, A. A. & EL-ZOGHBY, A. F. 2020. Clinical evaluation of glass ionomer with glass hybrid technology versus conventional high viscosity glass ionomer in class I cavities in patients with high caries risk: Randomized controlled trial. *Journal of International Oral Health,* 12**,** 203.

FRANCOIS, P., FOUQUET, V., ATTAL, J.-P. & DURSUN, E. 2020. Commercially available fluoride-releasing restorative materials: a review and a proposal for classification. *Materials,* 13**,** 2313.

ISMAIL, H. S., ALI, A. I., EL-ELLA, M. A. A. & MAHMOUD, S. H. 2020. Effect of different polishing techniques on surface roughness and bacterial adhesion of three glass ionomer-based restorative materials: In vitro study. *Journal of Clinical and Experimental Dentistry,* 12**,** e620.

JENSON, L., BUDENZ, A. W., FEATHERSTONE, J., RAMOS-GOMEZ, F. J., SPOLSKY, V. W. & YOUNG, D. A. 2007. Clinical protocols for caries management by risk assessment. *Journal of the California Dental Association,* 35**,** 714-723.

JYOTHI, K., ANNAPURNA, S., KUMAR, A. S., VENUGOPAL, P. & JAYASHANKARA, C. 2011. Clinical evaluation of giomer-and resin-modified glass ionomer cement in class V noncarious cervical lesions: An in vivo study. *Journal of conservative dentistry: JCD,* 14**,** 409.

KAUSHIK, M. & YADAV, M. 2017. Marginal microleakage properties of activa bioactive restorative and nanohybrid composite resin using two different adhesives in non carious cervical lesions-an in vitro study. *Journal of the west african college of surgeons,* 7**,** 1.

LARDANI, L., DERCHI, G., MARCHIO, V. & CARLI, E. 2022. One-year clinical performance of Activa™ bioactive-restorative composite in primary molars. *Children,* 9**,** 433.

LASSILA, L., SÄILYNOJA, E., PRINSSI, R., VALLITTU, P. K. & GAROUSHI, S. 2020. The

effect of polishing protocol on surface gloss of different restorative resin composites. *Biomaterial investigations in dentistry,* 7**,** 1-8.

NAJEEB, S., KHURSHID, Z., ZAFAR, M. S., KHAN, A. S., ZOHAIB, S., MARTÍ, J. M. N., SAURO, S., MATINLINNA, J. P. & REHMAN, I. U. 2016. Modifications in glass ionomer cements: nano-sized fillers and bioactive nanoceramics. *International journal of molecular sciences,* 17**,** 1134.

NAMGUNG, C., RHO, Y., JIN, B., LIM, B. & CHO, B. 2013. A retrospective clinical study of cervical restorations: longevity and failure-prognostic variables. *Operative dentistry,* 38**,** 376-385.

NASSAR, A., ABDALLA, A. & SHALABY, M. 2014. One year clinical follow up of nano filled glass ionomer and composite resin restorations. *Tanta Dental Journal,* 11**,** 21-35.

NICHOLSON, J. W. 2018. Maturation processes in glass-ionomer dental cements. *Acta biomaterialia odontologica Scandinavica,* 4**,** 63-71.

PAMEIJER, C. H., GARCIA-GODOY, F., MORROW, B. R. & JEFFERIES, S. R. 2015. Flexural strength and flexural fatigue properties of resin-modified glass ionomers. *J Clin Dent,* 26**,** 23-7.

ROUSSOU, K., NIKOLAIDIS, A. K., ZIOUTI, F., ARHAKIS, A., ARAPOSTATHIS, K. & KOULAOUZIDOU, E. A. 2021. Cytotoxic evaluation and determination of organic and inorganic eluates from restorative materials. *Molecules,* 26**,** 4912.

SAMPAIO, P., DE ALMEIDA JÚNIOR, A., FRANCISCONI, L., CASAS-APAYCO, L., PEREIRA, J. C., WANG, L. & ATTA, M. T. 2011. Effect of conventional and resin-modified glass-ionomer liner on dentin adhesive interface of Class I cavity walls after thermocycling. *Operative Dentistry,* 36**,** 403-413.

SATTAR, M., PATEL, M. & ALANI, A. 2017. Clinical applications of polytetrafluoroethylene (PTFE) tape in restorative dentistry. *British Dental Journal,* 222**,** 151-158.

SOMANI, R., JAIDKA, S., SINGH, D. J. & SIBAL, G. K. 2016. Comparative evaluation of shear bond strength of various glass ionomer cements to dentin of primary teeth: An in vitro study. *International journal of clinical pediatric dentistry,* 9**,** 192.

TIWARI, S. & NANDLAL, B. 2013. Effect of nano-filled surface coating agent on fluoride release from conventional glass ionomer cement: An: in vitro: trial. *Journal of Indian Society of Pedodontics and Preventive Dentistry,* 31**,** 91-95.