ORIGINAL RESEARCH

Clinical Performance of a Bioactive Restorative Material vs a Glass Hybrid Restorative in Posterior Restorations in High-risk Caries Patients

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Abstract

Aim and objective: This randomized clinical trial aimed to evaluate the clinical performance of a bioactive restorative material vs a glass hybrid restorative material in posterior restorations in high caries risk patients.

Materials and methods: High-risk caries patients with multiple posterior cavitated caries lesions were enrolled in this split-mouth clinical trial. Fifty randomly selected teeth received either a resin-modified glass ionomer bioactive resin-based composite [ACTIVA™ BioACTIVE-RESTORATIVE (Activa)] ($n = 25$) or a bulk-fill glass hybrid restorative [EQUIA Forte Fil (Equia)] ($n = 25$). Materials were applied according to the manufacturer's instructions. Two well-trained experienced blinded assessors evaluated the restorations at baseline, 6, and 12 months using FDI criteria for direct and indirect restorations.

Results: The survival percentages for the intervention and comparator groups were 98% after 6 and 12 months. Regarding the primary outcome, no statistically significant difference was observed between the two groups. While for the secondary outcome, the color match parameter showed a significantly better score for Activa at baseline, 6, and 12 months. With respect to the anatomic form, Activa scored significantly better compared to Equia At 6 and 12 months ($p < 0.001$). Regarding functional properties, at baseline, no difference between the tested groups was observed for all functional parameters ($p > 0.05$). Furthermore, at 6 and 12 months, Activa scored significantly better for occlusal contour and wear compared to Equia ($p < 0.001$).

Conclusion: Both ACTIVA™ BioACTIVE-RESTORATIVE™ and EQUIA Forte Fil showed similar successful clinical performance while restoring permanent posterior teeth in high-risk caries patients. The use of EQUIA Forte Fil may be more appropriate as a semi-permanent restorative material in stress-bearing restorations. With respect to the esthetics of upper premolars, ACTIVA™ BioACTIVE RESTORATIVE™ exhibited superior esthetics.

Clinical significance: ACTIVA™ BioACTIVE-RESTORATIVE™ may be used to restore permanent posterior teeth in high-risk caries patients offering enhanced esthetics and wear resistance.

Keywords: ACTIVA bioactive restorative, Bioactive restorative material, EQUIA forte, FDI criteria, Glass hybrid restorative, Glass ionomer, High-risk caries, Posterior restorations, Randomized clinical trial, Split mouth.

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Introduction

As one of the most commonly used restorative materials, resin composites have been widely used for about 50 years. Resin composites are now considered the first choice as restorative material due to their esthetics and direct-filling properties.[1] About 200 million resin composite dental restorations are placed per year in the United States, of which half failed within 10 years.[2] Obviously, there is a need for improvement to decrease the failure rates and enhance longevity. The long-term durability of resin composites faces challenges due to failures caused by secondary caries and bulk fractures. More strategies in the development of self-repairing, antibacterial, and bioactive materials enhancing tissue regeneration, will provide new approaches to improve composite restorations.[1]

While glass ionomers are not superior in esthetics, there are certain clinical situations where they are the material of choice for restoring teeth. The unique chemistry of glass ionomer allows for the release of fluoride at the margins of restorations and can have fluoride inside its chemical matrix recharged by exposure to other fluoride-releasing materials, thus offering important clinical advantages for patients at risk of caries or with caries lesions.[3]

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However, conventional glass ionomer cement is more liable to wear than resin composite and has low physical-mechanical properties, while in addition, they are slow self-setting. Furthermore, they have poorer esthetics compared to resin composites.[4] Resin-modified glass ionomers (RMGI) have improved physical-mechanical properties, such as being moisture contamination resistant at the

early stages, decreased microleakage, and enhanced adhesion to the tooth structure, in addition to significant enhancement in esthetic properties when compared to conventional GICs.[4] While in recent years, RMGI as a direct restorative material has become more user-friendly, most are not recommended for definitive restorations in permanent teeth in stress-bearing areas because they do not have the physical and mechanical properties of amalgam or resin composite.[5]

ACTIVA BioACTIVE RESTORATIVE (Pulpdent Corporation, Watertown, MA, USA) has recently been introduced with claims to be the first bioactive dental material with an ionic resin matrix, a shock-absorbing resin component, and bioactive fillers that mimic the chemical and physical properties of natural teeth. It is durable, wear and fracture-resistant, and chemically bonds to teeth, seals against bacterial microleakage, and releases and recharges with calcium, phosphate, and more fluoride ions than glass ionomers.[4]

EQUIA Forte Fil (GC Corporation, Tokyo, Japan) is a bulk-fill fluoride-releasing restorative system that unites EQUIA Forte Fil, which is a high strength glass hybrid restorative with EQUIA Forte Coat, a wear-resistant, self-adhesive, light-cured resin coating. Due to its new glass hybrid technology, improved acid and wear resistance, and flexural strength, the manufacturer claims that Equia extends the recommended indications to include stress-bearing Class II restorations.[6]

The clinical performance of these materials regarding functional, esthetic, and biological properties is yet to be evaluated. Controlled randomized clinical trials based on widely adopted evaluation systems are crucial for effective evidence-based dental knowledge and restorative practice.[7] The FDI clinical criteria introduced in 2007 and further modified in 2008 provide detailed evaluation criteria and better differentiation between different types of failure and incorporate objective assessment tools and a clear scoring system.[8]

Thus, this randomized clinical trial aimed to evaluate the clinical performance of a bioactive restorative material ACTIVA BioACTIVE RESTORATIVE vs a glass hybrid restorative material EQUIA Forte Fil in posterior restorations of high-risk caries patients over a period of one year. The null hypothesis was that there will be no difference in the clinical performance of Activa and Equia in high-risk caries patients after one year.

Materials and Methods

Materials used in the current study are listed in Table 1.

The protocol of the current study was registered on *www.clinicaltrials.gov*/database with unique identification number NCT03608306. All procedures done involving human candidates were in fulfillment of the ethical standards of the Research Ethics Committee of Faculty of Dentistry, Cairo University (CREC), (Ref. 18/09/24).

Sample size calculation was done using PS: Power and Sample Size Calculation Software Version 3.1.2 (Vanderbilt University, Nashville, Tennessee, USA). Based on an overall clinical performance score of 56%, 21 restorations were needed in each group to test the null hypothesis with a power of 0.8. By increasing this to 25

Table 1: Material specification, composition, manufacturer, and lot numbers

Material	*Specification*	*Composition*	*Lot number*	*Manufacturer*
ACTIVA™ BioACTIVE RESTORATIVE™	Enhanced RMGIC (Bioactive ionic resin-based composite)	• Aliphatic urethane/polyurethane methacrylate: 24–26% • Aliphatic multi-methacrylate resins: 8–10% • Acid functional methacrylate • Monomers/oligomers: 8–10% • Ionomer glass: 25–27% • Barium glass: 26–28% • Submicron silica: 4.0–5.0% • Initiators, stabilizers, and colorants: 1.0–1.5%	180914	Pulpdent Corporation, Watertown, MA, USA
Single Bond™ Universal	Universal multi-mode adhesive	MDP phosphate monomer, dimethacrylate resins, HEMA, Vitrebond™ Copolymer, nanofiller, ethanol, water, initiators, silane	00131A	3M Deutschland GmbH, Germany
Scotchbond™ Universal Etchant	Phosphoric acid etching gel	35% by weight phosphoric acid, 60% water, and 5% synthetic amorphous silica as thickening agent	4319005	3M Deutschland GmbH, Germany
EQUIA® Forte Fil	Glass ionomer with glass hybrid technology, bulk fill, fluoride releasing, glass hybrid restorative in capsule	Powder: 95% strontium fluoro alumino-silicate glass, 5% polyacrylic acid; liquid: 40% aqueous polyacrylic acid	1803261	GC Corporation, Tokyo, Japan
EQUIA® Forte Coat	Light-cure coating	40–50% methyl methacrylate, 10–15% colloidal silica, 0.09% camphorquinone, 30–40% urethane methacrylate, 1–5% phosphoric ester monomer	1503061	
Dentin Conditioner	Liquid, mild polyacrylic solution	10% Polyacrylic acid, 90% distilled water (by weight)	1711101	

HEMA, hydroxyethyl methacrylate; MDP, methacryloxydecyl dihydrogen phosphate

per group to compensate for attrition, a statistical significance of $p < 0.05$ can be attained.

Recruitment and Eligibility Criteria

Patients were recruited from the outpatient clinic of the Conservative Dentistry Department, Faculty of Dentistry, Cairo University. The following inclusion criteria were established. High caries risk patients, 16–55 years of age, male or female, with multiple posterior cavitated caries lesions. The teeth had to be vital and asymptomatic and had to be in contact with adjacent teeth and in occlusion. The participant (parents of minors) had to be willing to sign an informed consent form. Exclusion criteria were the following: systemic disease or severe medical conditions, pregnant women, heavy smoking, disabilities, bruxism, clenching, or TMJ disorders. In addition, teeth with deep extensive caries lesions that may lead to fracture or teeth with pulpal involvement with signs and/or symptoms of pulp necrosis or irreversible pulpitis were excluded. Flowchart 1 shows a flow diagram of recruitment, allocation and number of restorations available for analysis.

This trial had a split-mouth design with a randomization process on site.[9] In this clinical double-blind trial, the participants and both assessors were blinded as to the type of material used.[10] Participating patients had to have at least two cavitated caries lesions in the posterior teeth. To record preoperative conditions digital photographs were taken (Canon Inc., Taichung, Taiwan). After local anesthesia (Mepecaine–L) (Alexandria Co. for pharmaceuticals & chemical industries Alexandria, Egypt) the teeth were isolated with rubber dam. Cavity preparation was performed with a #245 carbide bur in a high-speed handpiece under copious air/water coolant. A sharp spoon #52 excavator (Dentsply Maillefer, Ballaigues, Switzerland) was used for caries excavation. A new bur was used for every six preparations. Once completed the cavity was thoroughly rinsed with a copious air/water spray.

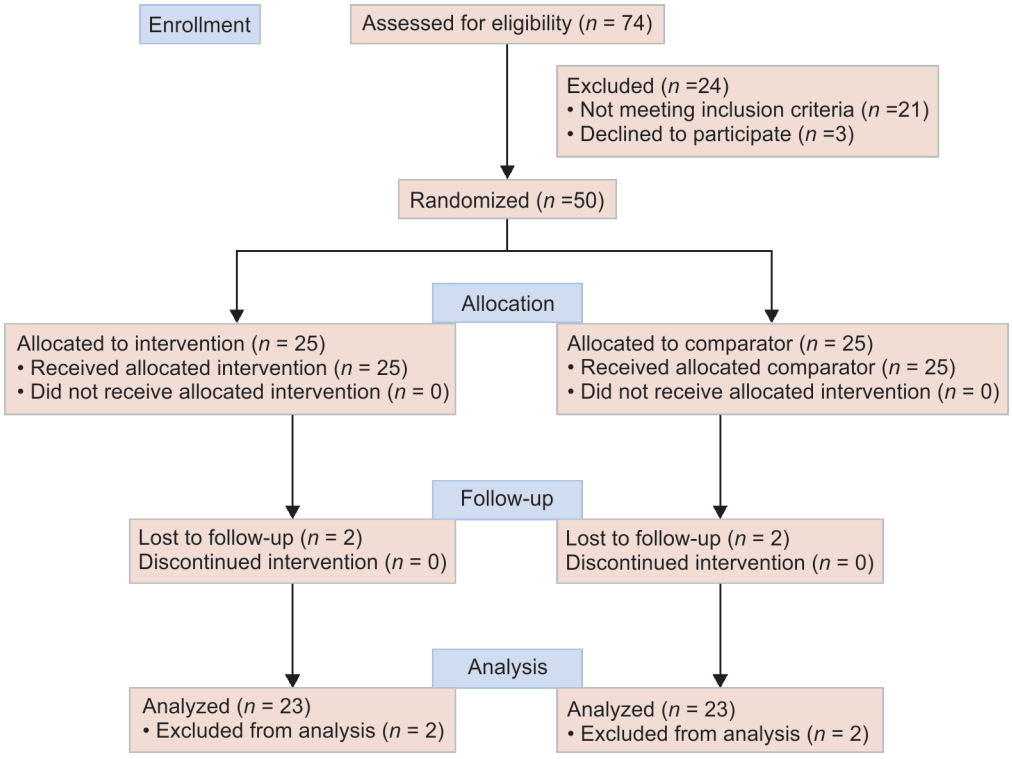
Restorative Procedures for ACTIVA™ BioACTIVE-RESTORATIVE™

Selective etching of enamel margins was carried out with 35% phosphoric acid etching gel (Scotchbond™ Universal Etchant, 3M Deutschland GmbH, Neuss, Germany) for 15 seconds followed by a 20 second air/water spray and drying, leaving the dentin moist. Single Bond™ Universal (Single Bond TM 3M Deutschland GmbH, Neuss, Germany) was applied to cavity walls and margins with agitation for 20 seconds using a disposable micro-brush followed by air dispersion for 5 seconds. The adhesive was light-cured at 1200 mW/cm^2 for 20 seconds (Woodpecker, Guangxi, China). Activa was applied according to the manufacturer's instructions. The dispenser needle tip was placed on the floor of the cavity and kept submerged in the material at all times to avoid air bubbles. A thin insulating layer of Activa was applied and massaged into the dentin for 20 seconds, light-cured and followed by increments of 4 mm, each light-cured for 20 seconds. Light irradiance was checked using the built-in radiometer. Following occlusal adjustment, the restorations were finished, and polished (ENA HRi; SYNCA, New York, USA).

Restorative procedures EQUIA® Forte Fil

The material was applied according to the manufacturer's instructions. After activation of the capsule, the materials were mixed for 10 seconds in low-speed mode (3600 rpm) in a triturator (Mix 2000, Carlo De Giorgi, Milano, Italy). Immediately upon removal the capsule was loaded in the applicator, primed and the material injected into the preparation. Contour was established with a ball burnisher. After setting (2.30 minutes) and rubber dam removal the occlusion was adjusted, the preparation cleansed with an air/

Flowchart 1: Consort flow diagram showing the process of case selection



water spray, and lightly dried. EQUIA® Forte Coat was applied with a microbrush, while dental floss was used for the interproximal surfaces. All surfaces were light-cured for 20 seconds. Detailed oral and written instructions and postoperative recall appointments were provided before the dismissal of the patient. Reminder phone calls were made every 2 months to ensure patient compliance.[11]

The clinical performance of dental restorations was evaluated using FDI Criteria. Two calibrated independent blinded assessors were responsible for the assessment of the restorations at baseline, 6, and 12 months according to the FDI Criteria for direct and indirect restorations.[8] The following parameters were evaluated: esthetics, marginal integrity, occlusal contour, wear, and proximal anatomical form. In case of disagreement, a third party made the final decision.

Statistical Analysis

Data were recorded as frequency (*n*) and percentage (%). A Chi-square test was used to compare the two groups for each parameter evaluated. The Kaplan–Meier survival analysis was performed for restorations after 6 and 12 months at a significance level of $\alpha = 0.05$. Statistical analysis was performed using IBM SPSS (version 26, Armonk, USA).

Results

Assessment of 25 restorations in each group was to be done at the baseline, 6, and 12 months. After 6 months, each group had 2 participants drop out, representing 8%. Complete loss of one restoration occurred in one patient of the Activa group at the 6 months evaluation period. After 12 months, 22 ($n = 22$) restorations in the Activa group and 23 ($n = 23$) restorations in the Equia group could be evaluated.

The survival percentage for both groups was 98% (86–100 95% CI) after 6 and 12 months. There was no statistically significant difference between the two groups $p < 0.05$ (Table 2). While for the secondary outcome, at baseline no difference between the tested groups was observed for all esthetic parameters except in color match, which was significantly better for the Activa group ($p < 0.05$). The same was observed after 6 and 12 months. Activa also scored better in esthetic anatomic form at the 6 and 12 months observation periods ($p < 0.05$) (Table 3). Regarding functional properties, at baseline, there was no difference between the tested groups with respect to all functional parameters ($p > 0.05$); however, after 6 and 12 months, Activa scored significantly better for occlusal contour and wear $p < 0.001$ (Table 4). Regarding, overall primary and secondary outcome result scores, at baseline, no difference between the tested groups was found for all parameters ($p > 0.05$), except in overall esthetics, which showed a significantly better score for Activa ($p < 0.001$). At 6 and 12 months, insignificant difference between the tested groups was found for overall biological parameters ($p > 0.05$). While overall esthetic and functional parameters showed significantly better scores for Activa compared to Equia group.

Discussion

For treatment of cavities in stress-bearing areas, resin composite may be considered the gold standard for treatment in general. However, plaque studies evaluating the level of cariogenic bacteria showed significant lower levels of caries-associated microorganisms related to glass ionomers compared to both resin composite and amalgam restorations.[12]

Glass ionomers are indicated in high-risk caries patients as they inhibit cariogenic bacteria that cause demineralization at the tooth-restoration interface. They also provide good sealing to cavity walls, while in addition providing continuous fluoride ion release and uptake by enamel.[13] However, glass ionomers are susceptible to dissolution during setting, have reduced wear resistance and poor fracture strengths, long setting times, and undesirable esthetics.[14]

Hybrid materials uniting the advantages of glass-ionomer and composites were evolved to overcome these problems, resulting in resin-modified glass ionomer cements (RMGIs), compomers (polyacid-modified composites), Giomers, and recently bioactive resin composites.[15]

Recently, in 2013, ACTIVA BioACTIVE RESTORATIVE was launched. Referred to by some[16] as a bioactive composite and considered by others an RMGI.[3,17] It is composed of an ionic resin matrix and a shock-absorbing resin component. Bioactive fillers mimic the physical and chemical properties of teeth. It releases and recharges with Ca, phosphates, and F ions and is esthetically pleasing. Another advantage is a lack of Bis-GMA and BPA derivatives.

Thus, according to Pameijer et al.,3 Activa has the strength, esthetics and physical properties of composites and offers the best of RMGIs. It responds to pH cycles and by releasing Ca, phosphates, and F-ions the formation of mineralized hard tissue is stimulated resulting in a phosphate apatite layer that seals the interface. It has been reported that the biomineralization is at the same level as MTA, Biodentine, and TheraCal LC.[18]

For comparison, EQUIA Forte Fil was selected based on properties such as the release of fluoride ions, antimicrobial effect, and the ability to chemically bond to the tooth, thus minimizing microleakage and recurrent caries according to Croll et al.[19] Activa and Equia are both injectable materials with excellent handling characteristics.

The American Dental Association Caries Risk Assessment >6 model was used in this study for the purpose of caries risk assessment and to guide treatment planning. In contrast to a study by Van Dijken et al.,[17] selective enamel etching was performed, and a dentin-bonding agent used prior to restoring the tooth with Activa according to the manufacturer's instructions.

The Activa restorations were finished with EQUIA Forte Coat to enhance the mechanical properties of the restorations.[18] The coating increases the strength of the glass ionomer and increases its abrasion resistance.[20]

Assessment of the restorations was performed at baseline, 6 months, and after 1 year. Although long-term follow-up is essential to evaluate the clinical performance of restorative materials, short-term clinical data can give important pieces of information.[21]

The clinical success of restorations depends on many elements, such as caries risk, quality of the restorative material, the size and site of the restoration, parafunctional habits, and operator skills.[22] ABR and EFF demonstrated similar successful clinical performance when posterior permanent teeth in high caries risk patients were restored with a 98% survival after 1 year. This is in agreement with Bhadra et al.[23] The success was attributed to the ionic resin component of Activa that has phosphate acid groups with antimicrobial action, which enhances the interactivity between the resin and the reactive glass fillers, thus enhancing the interaction with tooth structure. The hydrogen ions separate from the phosphate groups due to an ionization process in the presence of water and are replaced by calcium in the tooth. This ionic interaction unites the restoration

Table 2: Primary outcome (biological properties) result scores

		Baseline					*6 months*					*12 months*				
		A (I)		*E (C)*			*A (I)*		*E (C)*			*A (I)*		*E (C)*		
		n	*%*	*n*	*%*	*p value*	*n*	*%*	*n*	*%*	*p value*	*n*	*%*	*n*	*%*	*p value*
Postoperative hypersensitivity and tooth vitality	Excellent	25	100.0	25	100.0	1.00 ns	22	95.7	22	95.7	0.368 ns	22	100.0	22	95.7	1.00 ns
	Good	0	0.0	0	0.0		0	0.0	1	4.3		0	0.0	1	4.3	
	Sufficient	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Unsatisfactory	0	0.0	0	0.0		1	4.3	0	0.0		0	0.0	0	0.0	
	Poor	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
Recurrence of caries, erosion, and abfraction	Excellent	25	100.0	25	100.0	1.00 ns	23	100.0	23	100.0	1.00 ns	22	100.0	23	100.0	1.00 ns
	Good	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Sufficient	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Unsatisfactory	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Poor	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
Tooth integrity (enamel cracks or tooth fractures)	Excellent	25	100.0	25	100.0	1.00 ns	23	100.0	23	100.0	1.00 ns	22	100.0	23	100.0	1.00 ns
	Good	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Sufficient	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Unsatisfactory	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Poor	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
Periodontal response (compared to a reference tooth)	Excellent	25	100.0	25	100.0	1.00 ns	23	100.0	22	95.7	0.312 ns	22	100.0	22	95.7	0.323 ns
	Good	0	0.0	0	0.0		0	0.0	1	4.3		0	0.0	1	4.3	
	Sufficient	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Unsatisfactory	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Poor	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
Adjacent mucosa	Excellent	25	100.0	25	100.0	1.00 ns	22	95.7	22	95.7	1.00 ns	22	100.0	22	95.7	0.323 ns
	Good	0	0.0	0	0.0		1	4.3	1	4.3		0	0.0	1	4.3	
	Sufficient	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Unsatisfactory	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Poor	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
Oral and general health	Excellent	25	100.0	25	100.0	1.00 ns	22	95.7	22	95.7	0.368 ns	22	100.0	22	95.7	0.323 ns
	Good	0	0.0	0	0.0		0	0.0	1	4.3		0	0.0	1	4.3	
	Sufficient	0	0.0	0	0.0		1	4.3	0	0.0		0	0.0	0	0.0	
	Unsatisfactory	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Poor	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	

A(I) = Activa BioACTIVE RESTORATIVE, E(C) = Equia Forte Fil

Table 3: Secondary outcome (esthetic properties) result scores

		Baseline					*6 months*					*12 months*				
		A (I)		*E (C)*			*A (I)*		*E (C)*			*A (I)*		*E (C)*		
		n	*%*	*n*	*%*	*p value*	*n*	*%*	*n*	*%*	*p value*	*n*	*%*	*n*	*%*	*p value*
Surface luster	Excellent	25	100.0	25	100.0	1.00 ns	22	100.0	23	100.0	1.00 ns	21	95.5	22	95.7	0.974 ns
	Good	0	0.0	0	0.0		0	0.0	0	0.0		1	4.5	1	4.3	
	Sufficient	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Unsatisfactory	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Poor	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
Staining (surface and margin)	Excellent	25	100.0	25	100.0	1.00 ns	22	100.0	23	100.0	1.00 ns	21	95.5	22	95.7	0.975 ns
	Good	0	0.0	0	0.0		0	0.0	0	0.0		1	4.5	1	4.3	
	Sufficient	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Unsatisfactory	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Poor	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
Color match and translu-cency	Excellent	25	100.0	0	0.0	**<0.001***	22	100.0	0	0.0	**<0.001***	22	100.0	0	0.0	**<0.001***
	Good	0	0.0	0	0.0		0	0.0	23	100.0		0	0.0	23	100.0	
	Sufficient	0	0.0	25	100.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Unsatisfactory	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Poor	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
Esthetic anatomical form	Excellent	25	100.0	25	100.0	1.00 ns	20	90.9	15	65.2	**0.041***	20	90.9	14	60.9	**0.021***
	Good	0	0.0	0	0.0		2	9.1	8	34.8		2	9.1	9	39.1	
	Sufficient	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Unsatisfactory	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Poor	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	

A(I) = Activa BioACTIVE RESTORATIVE, E(C) = Equia Forte Fil

Table 4: Secondary outcome (functional properties) result scores

		Baseline					*6 months*					*12 months*				
		A (I)		*E (C)*			*A (I)*		*E (C)*			*A (I)*		*E (C)*		
		n	*%*	*n*	*%*	*p value*	*n*	*%*	*n*	*%*	*p value*	*n*	*%*	*n*	*%*	*p- value*
Fracture or material retention	Excellent	25	100.0	25	100.0	1.00 ns	22	95.7	22	95.7	0.3679 ns	22	100.0	21	91.4	0.3675 ns
	Good	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Sufficient	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	1	4.3	
	Unsatisfactory	0	0.0	0	0.0		0	0.0	1	4.3		0	0.0	1	4.3	
	Poor	0	0.0	0	0.0		1	4.3	0	0.0		0	0.0	0	0.0	
Marginal integrity	Excellent	25	100.0	25	100.0	1.00 ns	22	95.7	23	100.0	0.312 ns	21	95.5	22	95.7	0.368 ns
	Good	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	1	4.3	
	Sufficient	0	0.0	0	0.0		1	4.3	0	0.0		1	4.5	0	0.0	
	Unsatisfactory	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Poor	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
Occlusal contour and wear	Excellent	25	100.0	25	100.0	1.00 ns	21	91.3	15	65.2	**0.032***	20	90.9	15	65.2	**0.038***
	Good	0	0.0	0	0.0		2	8.7	8	34.8		2	9.1	8	34.8	
	Sufficient	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Unsatisfactory	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Poor	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
Proximal anatomical form (contact point and contour)	Excellent	4	100.0	3	100.0	1.00 ns	3	75.0	2	66.7	0.349 ns	3	100.0	1	33.3	0.223 ns
	Good	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Sufficient	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	1	33.3	
	Unsatisfactory	0	0.0	0	0.0		0	0.0	1	33.3		0	0.0	1	33.3	
	Poor	0	0.0	0	0.0		1	25.0	0	0.0		0	0.0	0	0.0	
Patient's view	Excellent	25	100.0	25	100.0	1.00 ns	22	95.7	22	95.7	0.368 ns	22	100.0	22	95.7	0.323 ns
	Good	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Sufficient	0	0.0	0	0.0		0	0.0	0	0.0		0	0.0	0	0.0	
	Unsatisfactory	0	0.0	0	0.0		0	0.0	1	4.3		0	0.0	1	4.3	
	Poor	0	0.0	0	0.0		1	4.3	0	0.0		0	0.0	0	0.0	

A(I) = Activa BioACTIVE RESTORATIVE, E(C) = Equia Forte Fil

and the tooth, fills microgaps, minimizes sensitivity, and protects against secondary caries forming a strong resin apatite complex.

The clinical success of Equia has been reported by several authors[12,22,24,25] and our data are in agreement with these findings. Only Balkaya et al.[21] reported a high failure rate for Activa in Cl II restorations and recommended its use to be carefully considered.

The biological properties as primary outcome and recurrence of decay scored 100% success with a score of 1 for both restorative materials after 1 year. This could be due to cavity design, with no weak cusps or undermined enamel,[26,27] biocompatibility of the materials,[28] and the superior sealing of Activa.[29] This contradicts reports that the weak antibacterial properties of Activa are not effective in preventing caries.[30,31]

Regarding postoperative hypersensitivity and tooth vitality, periodontal response, adjacent mucosa and oral and general health, 95.7% of the restorations had excellent scores after 1 year with no statistically significant difference between both materials $p > 0.05$. In each group one restoration failed, Activa due to lack of retention and Equia due to fracture.

With respect to functional properties, Activa after 6 months had statistically significantly better scores for occlusal contour and wear ($p < 0.005$). This is in agreement with Garcia-Godoy and Morrow,[32] and Bansal et al.[4] Loss of anatomic form of Equia restorations may occur following abrasion of the coating.[24]

According to the American Dental Association, a restorative material intended for use in posterior teeth needs to have a retention rate of at least 90% after 18 months of clinical service to be accepted as a definitive restorative material.[8] The current study lasted 12 months with both groups scoring a retention rate >90%. This suggests that both materials performed well up to 12 months. Each group had a failure, ABR with the loss of one restoration and EFF with 2 chipped restorations. These failures may be attributed to excessive occlusal loads or less than ideal cavity preparations.[33]

The Equia Forte restoration with an unsatisfactory score was a compound class II restoration. Due to the difficulty applying the protective resin coating interproximal this surface may be prone to early moisture exposure resulting in loss of material. Glass ionomers can chemically adhere to metals, and microcracks may be induced by the force applied during removing the matrix in the glass ionomer cement. These microcracks make the restoration more prone to chemical attacks.[21]

With respect to esthetic properties, our results are in agreement with Balkaya et al.[21] At baseline, 6, and 12 months, Activa had a significantly better score (100% clinically excellent) compared to Equia. Of interest is to note that after 6 months, the color match of Equia improved from score 3 (sufficient) to score 2 (good). These findings are in agreement with Diem et al.[34] who also observed an improvement over a 3-year period (25% good at baseline, increasing to 80% good at 3 years), as well as better translucency over time with the cement maturation. However, improvement of color is not universally shared as other authors[21] reported no improvement of Equia.

Our findings agree with Bhadra et al.[23] who stated that Activa imitates the physical and chemical properties of natural teeth by uniting the good mechanical properties and esthetics of composites with all the advantages of glass ionomers.

The null hypothesis was accepted. There was no difference in the clinical performance of ACTIVA™ BioACTIVE-RESTORATIVE and EQUIA Forte in high caries risk patients at the end of 1 year. However, ACTIVA™ BioACTIVE RESTORATIVE™ exhibited better clinical performance than EQUIA Forte in particular for occlusal contour and wear, color match, and esthetic anatomic form.

The main limitation of our study was being a short-term clinical study; however, patients will continue to be evaluated in the future. To encourage compliance, participants received comprehensive dental treatment and are scheduled for periodic follow-ups.

Conclusion

At the end of 1 year, both ACTIVA™ BioACTIVE-RESTORATIVE™ and EQUIA Forte showed similar and successful clinical performance while restoring posterior permanent teeth in high-risk caries patients. The use of EQUIA Forte as a semi-permanent restorative material in stress bearing cavities rather than a permanent material might be more appropriate. Regarding restoring posterior teeth in the esthetic zone (upper premolars), ACTIVA™ BioACTIVE RESTORATIVE™ exhibited superior esthetics.

Disclosure Statement

Drs. Essa, Akah, Yousry, Hassanein and Hamza declared no conflict of interest. Dr Pameijer is a consultant for Pulpdent Corporation. Dr Mai Mahmoud Yousry passed away during the preparation of this manuscript.

References

1. Zhou X, Huang X, Li M, et al. Development and status of resin composite as dental restorative materials. J Appl Poly Sci 2019;136(44):48180. DOI: 10.1002/app.48180.
2. Drummond JL. Degradation, fatigue, and failure of resin dental composite materials. J Dent Res 2008;87(8):710–719. DOI: 10.1177/154405910808700802.
3. Pameijer CH, Garcia-Godoy F, Morrow BR, et al. Flexural strength and flexural fatigue properties of resin-modified glass ionomers. J Clin Dent 2015;26(1):23–27.
4. Bansal R, Burgess J, Lawson NC. Wear of an enhanced resin-modified glass-ionomer restorative material. Am J Dentis 2016;29(3):171–174.
5. Strassler HE, Fadm F. Glass ionomers for direct-placement restorations. Dent Econom 2011. 14.
6. Fuhrmann D, Murchison D, Whipple S, et al. Properties of new glass-ionomer restorative systems marketed for stress-bearing areas. Operat Dentis 2020;45(1):104–110. DOI: 10.2341/18-176-L.
7. Hickel R, Roulet JF, Bayne S, et al. Recommendations for conducting controlled clinical studies of dental restorative materials. Clinical Oral Investigat 2007;11(1):5–33. DOI: 10.1007/s00784-006-0095-7.
8. Hickel R, Peschke A, Tyas M, et al. FDI World dental federation: clinical criteria for the evaluation of direct and indirect restorations—update and clinical examples. Clin Oral Investigat 2010;14(4):349–366. DOI: 10.1007/s00784-010-0432-8.
9. Alqadasi B, Aldhorae K, Halboub E, et al. The effectiveness of micro-osteoperforations during canine retraction: a three-dimensional randomized clinical trial. J Int Soc Prevent Commun Dentis 2019;9(6):637. DOI: 10.4103/jispcd.JISPCD_233_19.
10. Karanicolas PJ, Farrokhyar F, Bhandari M. Blinding: Who, what, when, why, how? Canadian J Surg 2010;53(5):345.
11. Atreja A, Bellam N, Levy SR. Strategies to enhance patient adherence: making it simple. Medscape General Med 2005;7(1):4.
12. El-Bialy MR, Shaalan OO, El-Zohairy AA, et al. 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. J Int Oral Health 2020;12(3):203. DOI: 10.4103/JIOH.JIOH_297_19.
13. Nassar HM, Platt JA. Effect of brushing with two different abrasives on fluoride release by high-viscosity glass ionomer cement. J Oral Sci 2015;57(4):379–384. DOI: 10.2334/josnusd.57.379.

14. El-Bahrawy EM, Attia RM. Fluoride releasing potential and recharging capacity of different bioactive restorative materials (a comparative In-Vitro study). Egypt Dent J 2020;66(2-April (Fixed Prosthodontics, Dental Materials, Conservative Dentistry & Endodontics):1295–1309.
15. Francois P, Fouquet V, Attal JP, et al. Commercially available fluoride-releasing restorative materials: a review and a proposal for classification. Materials 2020;13(10):2313. DOI: 10.3390/ma13102313.
16. Garoushi S, Vallittu PK, Lassila L. Characterization of fluoride releasing restorative dental materials. Dent Mater J 2018(2):2017–2161. DOI: 10.4012/dmj.2017-161.
17. van Dijken JW, Pallesen U, Benetti A. A randomized controlled evaluation of posterior resin restorations of an altered resin modified glass-ionomer cement with claimed bioactivity. Dent Mater 2019;35(2):335–343. DOI: 10.1016/j.dental.2018.11.027.
18. Kunert M, Lukomska-Szymanska M. Bio-inductive materials in direct and indirect pulp capping—a review article. Materials 2020;13(5):1204. DOI: 10.3390/ma13051204.
19. Croll TP, Berg JH, Donly KJ. Dental repair material: a resin-modified glass-ionomer bioactive ionic resin-based composite. Compend Contin Educ Dent 2015;36(1):60–65.
20. Lohbauer U, Krämer N, Siedschlag G, et al. Strength and wear resistance of a dental glass-ionomer cement with a novel nanofilled resin coating. Am J Dentis 2011;24(2):124–128.
21. Balkaya H, Arslan S, Pala K. A randomized, prospective clinical study evaluating effectiveness of a bulk-fill composite resin, a conventional composite resin and a reinforced glass ionomer in Class II cavities: one-year results. J Appl Oral Sci 2019. 27. DOI: 10.1590/1678-7757-2018-0678.
22. Miletić I, Baraba A, Basso M, et al. Clinical performance of a glass-hybrid system compared with a resin composite in the posterior region: results of a 2-year multicenter study. J Adhes Dentis 2020;22(3):235–247. DOI: 10.3290/j.jad.a44547.
23. Bhadra D, Shah NC, Rao AS, et al. A 1-year comparative evaluation of clinical performance of nanohybrid composite with Activa™ bioactive composite in Class II carious lesion: a randomized control study. J Conservat Dentis: JCD 2019;22(1):92.
24. Gurgan S, Kutuk ZB, Ozturk C, et al. Clinical performance of a glass hybrid restorative in extended size class II cavities. Operat Dentis 2020;45(3):243–254. DOI: 10.2341/18-282-C.
25. Vural UK, Meral E, Ergin E, et al. Twenty-four-month clinical performance of a glass hybrid restorative in non-carious cervical lesions of patients with bruxism: a split-mouth, randomized clinical trial. Clin Oral Investigat 2020;24(3):1229–1238. DOI: 10.1007/s00784-019-02986-x.
26. Ruengrungsom C, Palamara JE, Burrow MF. Comparison of ART and conventional techniques on clinical performance of glass-ionomer cement restorations in load bearing areas of permanent and primary dentitions: a systematic review. J Dentis 2018;78:1–21. DOI: 10.1016/j.jdent.2018.07.008.
27. Sidhu SK, Nicholson JW. A review of glass-ionomer cements for clinical dentistry. J Funct Biomater 2016;7(3):16. DOI: 10.3390/jfb7030016.
28. Sidhu SK, ed. Glass-ionomers in dentistry. Switzerland: Springer International Publishing; 2015. p. 60.
29. Bishnoi N, de Ataide ID, Fernandes M, et al. Evaluating the marginal seal of a bioactive restorative material activa bioactive and two bulk fill composites in class II restorations: an in vitro study. Int J Appl Dent Sci 2020;6(3):98–102.
30. Zaghlool RS, El-Baky A, Mahmoud R, et al. In Vitro evaluation of antibacterial effect of a new bioactive restorative material (activa). Indian J Pub Health Res Develop 2020;11(2):1820–1826.
31. Abou ElReash A, Hamama H, Eldars W, et al. Antimicrobial activity and pH measurement of calcium silicate cements versus new bioactive resin composite restorative material. BMC Oral Health 2019;19(1):235. DOI: 10.1186/s12903-019-0887-1.
32. Garcia-Godoy F, Morrow BR. Wear resistance of new ACTIVA compared to other restorative materials. J Dent Res 2015;94:3522.
33. Hayashi M, Sugeta A, Takahashi Y, et al. Static and fatigue fracture resistances of pulpless teeth restored with post–cores. Dent Mat 2008;24(9):1178–1186. DOI: 10.1016/j.dental.2008.01.009.
34. Diem VT, Tyas MJ, Ngo HC, et al. The effect of a nano-filled resin coating on the 3-year clinical performance of a conventional high-viscosity glass-ionomer cement. Clin Oral Investigat 2014;18(3):753–759. DOI: 10.1007/s00784-013-1026-z.