


## RESEARCH ARTICLE

WILEY

# Five-year randomized clinical trial to evaluate the clinical performance of high-viscosity glass ionomer restorative systems in small class II restorations

Ramy Ahmed Wafaie BDS, MDS, PhD<sup>1</sup>  | Ashraf Ibrahim Ali BDS, MDS, PhD<sup>2</sup> |  
Salwa Abd El-Raof El-Negoly BDS, MDS, PhD<sup>3</sup> | Salah Hasab Mahmoud BDS, MDS, PhD<sup>2</sup>

<sup>1</sup>Operative Dentistry Department, Faculty of Oral and Dental Medicine, Delta University for Science and Technology, Gamasa, Egypt

<sup>2</sup>Operative Dentistry Department, Faculty of Dentistry, Mansoura University, Mansoura, Egypt

<sup>3</sup>Dental Biomaterials Department, Faculty of Dentistry, Mansoura University, Mansoura, Egypt

**Correspondence**

Salah Hasab Mahmoud, Operative Dentistry Department, Faculty of Dentistry, Mansoura University, Mansoura, Egypt.  
Email: [salahmahmoud2010@mans.edu.eg](mailto:salahmahmoud2010@mans.edu.eg)

**Abstract**

**Objective:** Evaluate and compare the 5-year clinical performance of three high-viscosity glass ionomer restorative materials in small class II restorations.

**Materials and Methods:** Forty patients, each with four class II restorations, were enrolled in this trial. A total of 160 restorations were placed, 25% for each material, as follows: three high-viscosity conventional glass ionomer restorative systems (Ketac Universal Aplicap, EQUIA Forte and Riva Self Cure HV) and a microhybrid resin composite system (Filtek Z250). Clinical evaluation was performed at baseline and after 1, 3, and 5 years by two independent examiners using FDI criteria. Epoxy resin replicas were observed under scanning electron microscope (SEM) to examine surface characteristics. Data were analyzed with Kruskal-Wallis, Mann-Whitney *U*, Friedman, and Wilcoxon signed-rank tests ( $p < 0.05$ ).

**Results:** The success rates were 100% for resin composite, 97.4% for Ketac Universal, and 94.9% for both EQUIA Forte and Riva HV restorations. Statistically significant differences were observed between all groups in terms of surface luster and color match criteria ( $p < 0.05$ ). Statistically significant changes were found over time for all criteria except for fracture of material, postoperative hypersensitivity, recurrence of caries, tooth integrity, periodontal response, adjacent mucosa, and oral health criteria ( $p > 0.05$ ). SEM evaluations were in accordance with the clinical findings.

**Conclusions:** Although drawbacks in surface luster and color match appeared over the 5-year evaluation period, the three high-viscosity glass ionomer restorative materials provided successful clinical performance in small to medium sized class II cavities compared to microhybrid resin composite.

**Clinical Significance:** Glass ionomer restorations exhibited clinical performance similar to that of microhybrid resin composite restorations in small class II cavities subsequent to 5-year evaluation.

**KEYWORDS**

class II restorations, clinical performance, clinical trial, glass ionomer, resin composite

## 1 | INTRODUCTION

The growing interest from researchers and clinicians in the development of ideal materials to replace the lost tooth structure leads to a major advancement in restorative dentistry.<sup>1</sup> Amalgam has been used routinely for many decades because of its superior mechanical properties resulting in high survival rates.<sup>2</sup> The concerns about possible toxicity through mercury content in amalgam restorations in addition to patients' esthetic demands and adoption of minimally invasive technique have a great influence on the treatment plan of decayed posterior teeth.<sup>3</sup> In 2013, a global agreement was signed at the Minamata Convention aiming to diminish the use of mercury containing products globally. This Convention also advocated a gradual phase-down of dental amalgam.<sup>4</sup>

Recently, direct resin composite restorations have become a successful routine procedure for class I and II cavities. However, polymerization shrinkage and associated stresses are still a major problem which produce cracks and defects at the adhesive interface resulting in some possible consequences such as bond failure, microleakage or tooth structure deformation.<sup>5,6</sup> Previous systematic reviews<sup>7,8</sup> reported that the annual failure rates for posterior resin composite restorations were 1%–3% and the main reason for replacement was secondary caries.

Conventional glass ionomer cements (GICs) are clinically attractive restorative materials that have therapeutic action on demineralized dentin and anticariogenic effect extended for a period of time due to fluoride release and recharge abilities. They have coefficient of thermal expansion similar to tooth structure and superior biocompatibility.<sup>9,10</sup> These GICs bond chemically to enamel and dentin through an ion exchange layer without the need for any adhesive system. Clinically, this is considered invaluable as no other restorative material shows any sign of such a chemical union which prevents microleakage.<sup>11,12</sup> Despite all these advantages, some unfavorable characteristics may limit their clinical usage as permanent restorations in stress bearing areas such as low fracture toughness and high occlusal wear rate in comparison to other restorative materials.<sup>13,14</sup>

Many enhancements and modifications have been made to overcome the drawbacks and to improve the overall properties of GICs. High-viscosity glass ionomer cements (HVGICs) were released to dental market with high cross-linkage in GIC matrix. They have superior mechanical and physical properties in particular wear resistance with a faster setting time so that restorations can be placed and finished at one visit. Compared to their conventional predecessors, they have more translucent appearance due to incorporation of small glass particles.<sup>15,16</sup>

By the end of 2011, SDI released high-viscosity glass ionomer (Riva Self Cure HV) with higher compressive strength for wide range of restorative options in posterior teeth.<sup>17</sup> Based on novel glass hybrid technology, GC introduced in 2015 a new reinforced restorative system called EQUIA Forte to be used in restoring stress bearing class I and II cavities. This system includes a nano-filled resin coating material that has an important role in protecting and strengthening the restoration with an obvious enhancement in esthetic appearance.<sup>18,19</sup> In 2015, 3M Oral Care released a new generation of conventional GICs (Ketac Universal Aplicap) with modified chemical composition as an

ideal solution for posterior restorations. This material does not require cavity preconditioning or coating agent, so the restoration placement steps are diminished without compromising surface hardness and compressive strength.<sup>20</sup>

Previously conducted systematic reviews<sup>4,21,22</sup> reported that there is no enough solid evidence to support the superiority claims of the success rates of direct resin composite over GICs that have shown promising results in restoring posterior teeth. However, to date and according to the authors' knowledge, a paucity of information is available regarding the long-term clinical performance of high-viscosity glass ionomer in class II restorations. No randomized controlled clinical trials evaluating class II glass ionomer restorations using all the FDI criteria were found. Debate also exists around using these restorative materials as a capable counterpart of resin composites in class II cavities. Therefore, more data from clinical trials are required for the evaluation of potential benefits or possible failure problems in comparison to resin composite as these materials deserve further surveillance in class II cavities.

The aim of this prospective randomized controlled clinical trial was to evaluate and compare the 5-year clinical performance of three high-viscosity glass ionomer restorative materials in small class II restorations using the FDI evaluation criteria. The primary clinical outcome was fracture of material and retention, but the following secondary outcomes were also evaluated: surface luster, surface and marginal staining, color match, esthetic anatomical form, marginal adaptation, occlusal wear, approximal anatomical form, radiographic examination, patient's view, postoperative sensitivity, recurrence of caries, tooth integrity, periodontal response, adjacent mucosa, and oral and general health. The research hypothesis tested was that there would be no difference between the clinical performance of high-viscosity glass ionomer and resin composite in small class II restorations after 5 years for the criteria assessed.

## 2 | MATERIALS AND METHODS

### 2.1 | Ethics approval and protocol registration

This clinical trial was approved by the Dental Research Ethics Committee of Faculty of Dentistry, Mansoura University, Mansoura, Egypt (approval no. A12071020). The volunteers were consulted to obtain authorization for their participation by signing a free and informed consent prior to the trial explaining all aspects included in the study. Participants were also informed about their rights to withdraw at any time of the trial. This trial was also registered at <https://www.thaiclinicaltrials.org/> under the registration number TCTR20220920003.

### 2.2 | Trial design, settings, and location of data collection

This was a prospective randomized controlled clinical trial (RCT) with a single-blinded (participants) and a split-mouth design. It followed the

guidelines and recommendations published by World Dental Federation (FDI)<sup>23,24</sup> and Consolidated Standards of Reporting Trials (CONSORT).<sup>25</sup> The clinical trial was conducted from April 2017 to May 2022. All the procedures were carried out in Operative Department Clinic at the Faculty of Dentistry, Mansoura University, Egypt. Patient data including detailed medical and dental history were recorded in case record. No protocol deviations emerged during the trial.

### 2.3 | Recruitment and eligibility criteria

Patients were selected from a pool of candidates seeking routine dental treatment at the Operative Department Clinic in order to attend the screening session, forming a convenience sample. No advertisement was made for participant recruitment. The average age of patients was 25 years (range, 20–40 years).

Inclusion criteria were as follows: a patient presenting with (1) a need for at least four posterior tooth-colored restorations in permanent premolars and molars, (2) small to medium sized mesio-occlusal or disto-occlusal primary carious lesions, (3) the presence of teeth to be restored in contact with the adjacent teeth and in normal occlusion with the natural antagonist teeth, (4) symptomless and vital teeth with no signs for pulpal inflammation or pathological lesions, (5) a normal periodontal status and good oral hygiene, and (6) good likelihood of recall availability with high motivation. Exclusion criteria were as follows: (1) adverse medical history, allergies or systemic diseases, (2) pregnant or lactating females, (3) heavy bruxism habits, fractured or visibly cracked teeth, and (4) potential behavioral problems. Oral hygiene instructions were given to all selected patients including mouthwash and fluoride-based tooth paste.<sup>9,11,16</sup>

### 2.4 | Sample size calculation

The primary outcome used for sample size calculation was fracture of material and retention. Therefore, the sample size was calculated on the basis of the retention rate (91% in 6 years) of posterior high-viscosity glass ionomer restorations observed in a previous study<sup>11</sup> using statistical software program (G\*Power, Ver.3.1.9.1, Dusseldorf, Germany) at 95% confidence level with a statistical power of 80% and a significance level (alpha value = 5%). In agreement with Hickel et al.<sup>23</sup> who advised not to use more than one restoration per group per patient, a representative sample composed of 160 restorations in 40 patients was determined taking into consideration the possible patient dropout during the trial period.

### 2.5 | Random sequence generation and allocation concealment

A split-mouth study design was performed using the dental midline as a reference. Each patient received four class II restorations (1:1:1:1). A staff member who was not involved in any of the phases of the clinical

trial prepared sequentially numbered, opaque, and well-sealed envelopes containing identification cards for the different groups. Prior to the operative procedures, the randomization process started from the right side of the mouth followed by the left side, thus allowed each side of the mouth to receive two of the four tested materials. The four allocated carious teeth (premolars or molars) in each patient and the four restorative materials used in the study were then sorted by numbers from 1 to 4 using computer generated random numbers via a specific website (<https://www.randomizer.org>) resulting in simple randomization procedure. The number of sets was two (set 1; teeth to be restored and set 2; restorative materials) and the number range per set was from 1 to 4. Any particular number remained unique by appearing only once in each set. The first number in set #1 representing the tooth corresponded to the first number in set #2 representing the restorative material and the tooth with the next number in sequence received the material mentioned second, and so forth. The allocation assignment was revealed only on the day of the restorative procedure guaranteed the concealment of the random sequence in order to prevent selection bias.

### 2.6 | Clinical procedures

The restorative materials (Table 1) were three high-viscosity conventional glass ionomer restorative systems; Ketac Universal Aplicap (3M Oral Care, St. Paul, MN, USA), EQUIA Forte (GC, Tokyo, Japan), Riva Self Cure HV (SDI, Bayswater, Victoria, Australia) and a resin composite system; Filtek Z250 Universal Restorative (3M Oral Care). They were used in accordance with the manufacturers' instructions. A well-controlled light emitting diode (LED) curing unit Elipar S10 (3M Oral Care) was used for light polymerization with a wave length between 430–480 nm and a light intensity 1200 mW/cm<sup>2</sup> as measured by the built-in light meter. One experienced dentist placed a total of 160 class II restorations in 40 patients (26 male and 14 female) fulfilling the inclusion and exclusion criteria.

Preoperative digital photographs and periapical digital radiographs of the teeth to be treated were taken. Pulp vitality test scores were recorded by application of cold dry ice.<sup>10,11</sup> The teeth were then cleaned in order to remove dental plaque using pumice-water slurry with a rubber cup.<sup>16</sup> Local anesthesia was applied to prevent patient pain and discomfort during the restorative procedures. Cavities were prepared using diamond round and straight fissure instruments (801.314.012 & 835KR. 314.014, Komet, Brasseler, Lemgo, Germany) at high-speed handpiece (Sirona T3, Bensheim, Germany) under copious air-water cooling. Caries removal was carried out using hand excavator (Maillefer, Dentsply DeTrey, Konstanz, Germany) and slow-speed tungsten carbide bur (H1SM.204.018, Komet). The cavity depth was assessed using Prepometer (Hager & Werken, Duisburg, Germany). All cavity preparations were finished using extra-fine diamond instruments (835KREF.314.012, Komet) in order to round all line angles. Conservative cavity design was performed according to the principles of minimally invasive dentistry as following: (1) The cavity preparations did not involve any cusps, (2) all of the gingival

**TABLE 1** Restorative systems used in the study

Restorative systems	Type	Manufacture	Composition	Batch no.
Filtek Z250 Universal Restorative	Microhybrid resin composite	3M Oral Care	Organic matrix: bisphenol A-glycidyl methacrylate, urethane dimethacrylate, bisphenol A polyethylene glycol diether dimethacrylate, triethylene glycol dimethacrylate Inorganic filler: zirconia/silica, Aluminum oxide	N730958
Adper Single Bond 2	Two-step etch-and-rinse primer/adhesive	3M Oral Care	2-hydroxyethyl methacrylate, bisphenol A-glycidyl methacrylate, dimethacrylate, ethanol, water, photoinitiator system, methacrylate functional copolymer of polyacrylic and polyitaconic acids, 10% colloidal silica	N800163
Scotchbond Universal Etchant	Etching gel	3M Oral Care	Phosphoric acid 35%, water, synthetic amorphous silica	603087
Ketac Universal Aplicap	Bulk-fill, radiopaque glass ionomer restorative material	3M Oral Care	Powder/Liquid ratio (g/g) 0.339/0.106 Powder: oxide glass chemicals >95% by wt. Liquid: water 40%–60%, copolymer of acrylic acid–maleic acid 30%–50%, tartaric acid 1%–10%, benzoic acid <0.2% by wt.	663540
EQUIA Forte Fil	Bulk-fill, glass hybrid restorative material	GC	Powder/Liquid ratio (g/g) 0.40/0.13 Powder: surface-treated fluoro aluminosilicate glass, ultrafine-highly reactive glass, higher-molecular weight polyacrylic acid, iron (III) oxide. Liquid: polybasic carboxylic acid (tartaric acid) 5%–10% by wt.	170216A
EQUIA Forte Coat	Light-cured, nano-filled, self-adhesive wear resistant resin coating	GC	Low viscosity methyl methacrylate 25%–50%, silicon dioxide 5%–10%, diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide 1%–5%, phosphoric acid ester monomer (methacryloyloxydecyl dihydrogen phosphate) 0.5%–1%, 2,6-di-tert-butyl-p-cresol 0.5%–1%, camphorquinone 0.09% by wt.	1512051
Riva Self Cure HV	Bulk-fill, radiopaque, high viscosity glass ionomer restorative material	SDI	Powder/Liquid ratio (g/g) 0.50/0.13 Powder: fluoro aluminosilicate glass 90%–95%, acrylic acid homopolymer 5%–10% by wt. Liquid: acrylic acid homopolymer 20%–30%, tartaric acid 10%–15% by wt.	C1512031F
Riva Coat	Light-cured coating material	SDI	Acrylic monomer 100% by wt.	160603
Riva Conditioner	Polyacrylic acid conditioner	SDI	Polyacrylic acid 25%–30% by wt.	160613

margins were placed supragingivally and included sound enamel, and (3) beveling was not applied for cavity walls and margins. The isthmus width of the cavities was not more than 1/3 of the intercuspal distance.<sup>5,9</sup> The operative field was isolated with cotton rolls together with high-volume saliva ejector.<sup>26–29</sup> A sectional coated metal matrix band fixed with a ring and plastic wedge (Palodent, Dentsply DeTrey, Konstanz, Germany) was used for restoring all cavities.<sup>5,11</sup>

For resin composite restorations, a thin layer of calcium hydroxide-based material (Dycal, Dentsply Caulk, Milford DE, USA) was applied directly over the deepest portion of the cavity and then covered with resin modified glass ionomer cement (Vitrebond, 3M Oral Care), while adhesive protocol (two-step etch-and-rinse) was applied directly to shallow and moderate depth cavities. The

preparation was etched with 35% phosphoric acid gel (Scotchbond Universal Etchant, 3M Oral Care) for 15 s, then rinsed thoroughly with air-water syringe for 10 s, and gently dried with oil-free air. The bonding agent (Adper Single Bond 2, 3M Oral Care) was applied to the etched enamel and dentin in two consecutive coats. The adhesive was then gently dried for 2–5 s and cured for 10 s. Filtek Z250 resin composite was placed incrementally in oblique layers (less than 2.5 mm thick) and cured for 20 s. The proximal surface of the restoration was additionally cured buccally and lingually/palatally for 20 s after removing the matrix band and wedge. The occlusion was checked using articulating paper (Bausch, Dr. Jean Bausch GmbH & Co.KG, Koln, Germany), then the occlusal surface of the restoration was finished using high-speed diamond finishing instruments (4092.314, Komet)

under copious air-water cooling. Flexible points and cups impregnated with aluminum oxide (Enhance, Dentsply Caulk) were used in order to obtain smooth and glossy occlusal surface. The proximal surface was finished and polished with flexible discs (Sof-Lex XT Pop On, 3M Oral Care) and aluminum oxide finishing strips (Sof-Lex finishing strips, 3M Oral Care).<sup>6,9</sup>

For cavities restored with glass ionomer restorations, a calcium hydroxide-based material was placed as a lining material where needed.<sup>10,16</sup> The capsules were mixed according to the manufacturers' instructions in a capsule mixing device (CapMix, 3M Oral Care). The injection of material into cavity was started from the bottom of cavity until the material was extended over the marginal ridge in bulk-fill technique. A gloved index finger was used with pressure "press-finger technique" followed by compaction with a manual plugger to allow maximum adaptation of the material to cavity floor and walls.<sup>12,28</sup> After completion of the recommended setting time, the restoration was shaped and finished using high-speed extra-fine diamond finishing instruments under copious air-water cooling. The proximal surface was finished with flexible discs. For Ketac Universal Aplicap restorations, there was no need for cavity preconditioning or surface coating according to the manufacturer's instructions. Dentin conditioner was not also used for cavities restored with EQUIA Forte Fil, while Equia Forte coat was applied to the briefly dried restoration surface in one coat with microbrush and cured for 20 s. For Riva HV restorations, enamel and dentin were conditioned with Polyacrylic acid (Riva Conditioner, SDI) for 10 s in order to partially remove the smear layer, then rinsed thoroughly with water and gently dried with oil-free air without desiccating the surface. After placing and finishing the Riva HV restoration, Riva coat was applied to all the exposed surfaces of the restoration and cured for 20 s.

## 2.7 | Evaluation of the restorations

All restorations were clinically evaluated at baseline (1 week after the placement of restorations) and after 1, 3, and 5 years according to FDI criteria as described by Hickel et al.<sup>23,24</sup> The standardized case report for each patient was applied to record the FDI parameters during the evaluation procedures. The primary and secondary clinical outcomes were assessed according to the criteria in the following scores: (clinically very good, clinically good, clinically sufficient/satisfactory, clinically unsatisfactory, and clinically poor).

Two independent calibrated examiners who were not involved in the restorative procedures performed the evaluations. For maximum validity, both examiners were calibrated before starting the evaluation process by assessing photographs for posterior restorations that were representative of each score for each criterion.<sup>16,29-31</sup> The Cohen's Kappa coefficient was used to measure the inter-examiner agreement. When disagreement occurred during evaluations, the restorations were reevaluated by both examiners and a consensus was obtained before the patients left.<sup>5,9,32</sup> Before starting the assessment, each patient was requested to brush his/her teeth for 3 min in order to remove the plaque and food debris. The occlusal surface of the

restoration was then dried with gentle air stream. The examination was performed using dental mirror and periodontal probe. Two special probes with different blunt tips of 150  $\mu\text{m}$  and 250  $\mu\text{m}$  (Deppeler, Rolle, Switzerland) were used as assistant tools to assess some criteria. All the evaluation methods are illustrated in Table 2.

## 2.8 | Micromorphological analysis using scanning electron microscope (SEM)

Impressions of air-dried restored teeth were taken from randomly selected patients with one-step putty-wash impression technique using polyvinyl siloxane impression material (Elite HD+ putty and light body, Zhermack, Badia Polesine, Italy) at each evaluation period. The impressions were then poured with epoxy resin (SwissChem, 6th of October City, Giza, Egypt). All epoxy replicas were uniformly trimmed and mounted on aluminum stubs to be easier in handling and repositioning. The replicas were then sputter-coated with gold (SPI-Module Sputter Carbon/Gold Coater Systems, EDEN instruments, Alixan, France) and examined under scanning electron microscope (JSM-6510LV SEM, JEOL, Tokyo, Japan) at 200 $\times$  magnification.<sup>10,16,28,33</sup>

## 2.9 | Statistical analysis

The extracted data were analyzed using the Statistical Package for the Social Sciences (IBM-SPSS, version 24, Armonk, NY, USA). At first, the normality of data was tested with Kolmogorov-Smirnov test. Descriptive statistics were used to illustrate the frequency distributions of the evaluated criteria and then expressed in the form of median, minimum, and maximum. Since the evaluation of restorations yielded clearly ordinal structural data, only nonparametric statistical procedures were used to test the significance of difference for every criterion at a significance level of  $p < 0.05$ . Kruskal-Wallis test was used to compare the differences in performance between the four restorative materials for every criterion in each follow-up period followed by Mann-Whitney  $U$  test for pairwise comparisons. Whilst, Friedman test was used to compare the differences in performance of each material for every criterion throughout the follow-up periods followed by Wilcoxon signed-rank test for pairwise comparisons. Kaplan-Meier estimator was used for survival analysis of the restorations over time with a Log-rank test to detect any statistically significant differences in survival between the tested restorative materials.

## 3 | RESULTS

A consort flow diagram with the number of participants, restorations, and dropouts at the different recall periods is shown in Figure 1. The recall rate of patients was 100% at baseline and 1-year evaluations, while at the 3- and 5-year clinical evaluations the recall rate was 97.5% because one patient (including one restoration from each group) could not be followed up. The dropout reason was traveling

**TABLE 2** Different evaluation methods

Criteria	Evaluation method
<b>1. Primary outcome</b>	
Fracture of material and retention	A magnifying aid (loupe 4.5×) was used for evaluation.
<b>2. Secondary outcomes</b>	
Surface luster	The operator light was switched off and the evaluation was performed at a distance of 60 to 100 cm (speaking distance).
Surface and marginal staining	Clinical examination using dental mirror and operating light.
Color match and translucency	The operator light was switched off and the evaluation was performed at a distance of 60 to 100 cm.
Esthetic anatomical form	The operator light was switched off and the evaluation was performed at a distance of 60 to 100 cm.
Marginal adaptation	A magnifying aid (loupe 4.5×) was used for evaluation with the help of two special probes (150 and 250 μm).
Occlusal contour and wear (qualitative)	Photodocumentation (baseline and follow-up images) for the occlusal surface of each restored tooth.
Approximal anatomical form (contact point and contour)	The same type of waxed dental floss was used for evaluation at baseline and all recalls.
Radiographic examination	Periapical radiographs.
Patient's view	A structured interview with the patient on his/her satisfaction/dissatisfaction with the restoration using visual analogue scale (VAS).
Postoperative (hyper-)sensitivity and tooth vitality	Intensity was assessed with VAS. Postoperative sensitivity was evaluated by blowing a stream of compressed air for 3 s at a distance of 2–3 cm from the restoration. Vitality was tested with application of cold (dry ice) and the reaction was compared to that of the adjacent vital teeth.
Recurrence of caries (CAR), erosion, abfraction	Diagnosis of caries was carried out according to ICDAS-II using loupe, dental mirror, and the two special blunt probes.
Tooth integrity (enamel cracks, tooth fractures)	Evaluation was performed using loupe with the help of the two special blunt probes.
Periodontal response	Periodontal probe was used to compare the reaction of gingival tissues of the restored tooth to an unrestored tooth in the same patient based on the Papillary Bleeding Index (PBI).
Adjacent mucosa	Broad clinical inspection of the mucosa in the oral cavity.
Oral and general health	Broad clinical inspection of the whole oral cavity. Recording medical status and history of the patient regarding systemic diseases, allergies or medications.

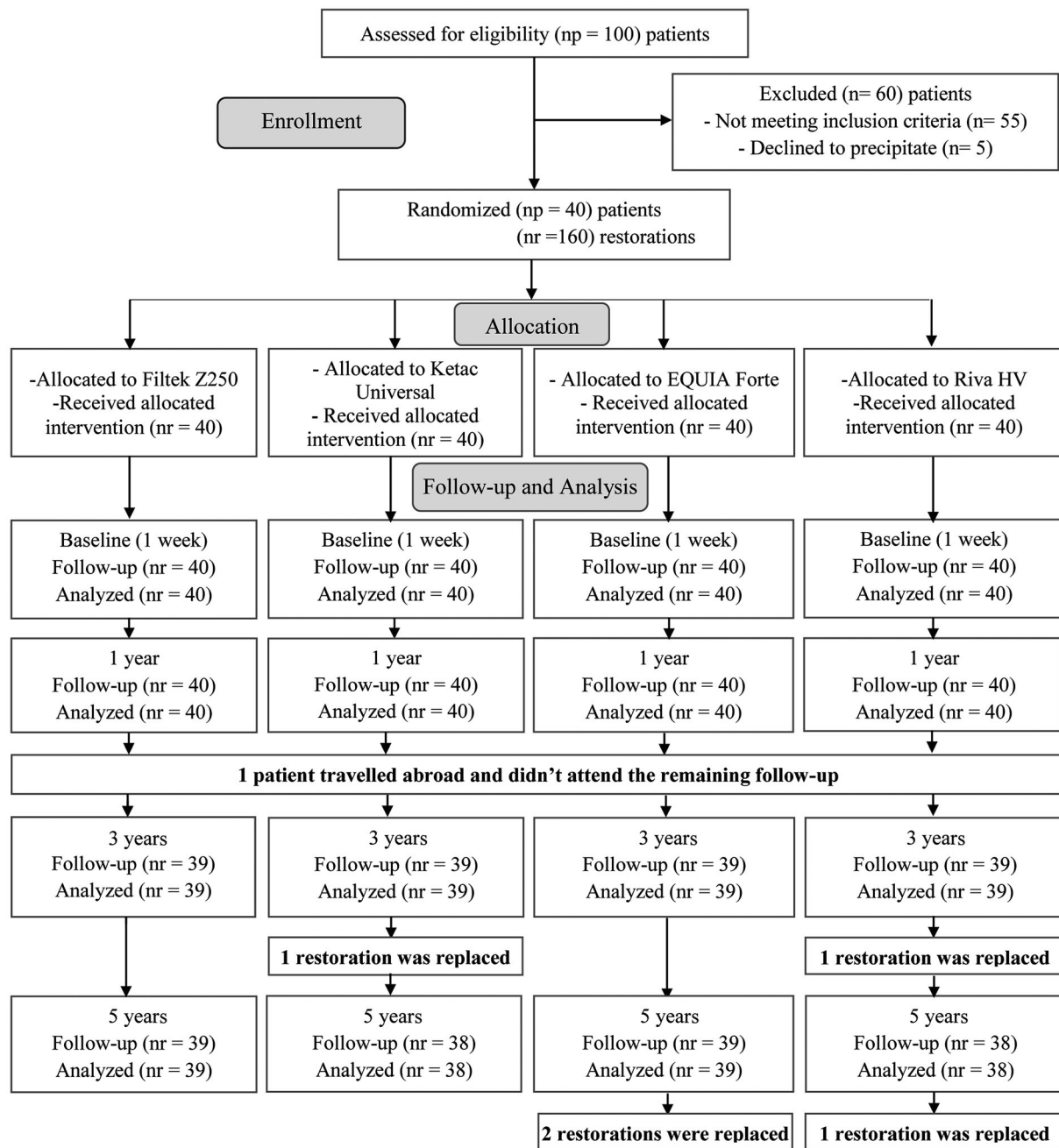
abroad during the trial. The demographic data and clinical characteristics of each group are shown in Table 3. The Cohen's Kappa statistics showed strong inter-examiner agreement (Kappa = 0.89). Also, no statistically significant difference was observed in patients' answers ( $p > 0.05$ ). The results of the current clinical trial are summarized in Table 4.

After 5 years, the success rate for class II Filtek Z250 microhybrid resin composite restorations was 100%, while five failed class II glass ionomer restorations were observed during the evaluation periods; one Ketac Universal (2.6%), two EQUIA Forte (5.1%), and two Riva HV (5.1%). This resulted in annual failure rate (AFR) of 0.5% for Ketac Universal group and 1% for both EQUIA Forte and Riva HV groups. The main reason for failure was the fracture of class II glass ionomer restorations, while one Riva HV restoration failed because of partial looseness in situ. Failures occurred at both premolars and molars. Kaplan–Meier estimator was used for survival analysis of the restorations over time (Figure 2). Log-rank test indicated no statistically

significant difference between the survival rates of all restorations over the 5 years ( $p = 0.514$ ).

Regarding surface luster, Ketac Universal group showed a significantly inferior clinical performance among the other groups at baseline ( $p \leq 0.001$ ), while no statistically significant differences were detected between Filtek Z250, EQUIA Forte, and Riva HV groups ( $p > 0.05$ ). After 1-, 3-, and 5-year recall, Filtek Z250 group exhibited significantly higher surface luster in comparison to the different glass ionomer groups ( $p \leq 0.001$ ). At 3- and 5-year recall, no nonsignificant differences were observed between all glass ionomer groups ( $p > 0.05$ ). A significant reduction in the surface gloss scores was found between baseline and 5-year recall for all groups ( $p < 0.05$ ).

Clinical evaluation for surface and marginal staining showed no statistically significant differences between the different restorations at baseline and after 1-, 3-, and 5-year recall ( $p > 0.05$ ). Moreover, there were no statistically significant differences between baseline



**FIGURE 1** A CONSORT flow diagram showing the number of enrolled patients and the evaluated restorations during this study

and different recalls for Filtek Z250 and EQUIA Forte groups ( $p > 0.05$ ). No statistically significant differences were found also between baseline and 1-year recall for Ketac Universal and Riva HV groups ( $p > 0.05$ ), while signs of marginal discoloration were detected for some Ketac Universal and Riva HV restorations after 3- and 5-year recall ( $p < 0.05$ ).

By comparing all groups at baseline and after 1-, 3-, and 5-year recalls in terms of color match and translucency, Filtek Z250 group exhibited a significantly superior clinical performance over the different glass ionomer groups ( $p \leq 0.001$ ). EQUIA Forte restorations showed color match comparable to that of the surrounding tooth

tissue when compared with both Ketac Universal and Riva HV restorations at the baseline evaluation ( $p \leq 0.05$ ), while no statistically significant difference was detected between Ketac Universal and Riva HV groups ( $p > 0.05$ ). At 1- and 3-year recall, no statistically significant difference was detected between all glass ionomer groups ( $p > 0.05$ ). After 5 years, EQUIA Forte restorations showed significantly better color match in comparison to Ketac Universal and Riva HV restorations ( $p \leq 0.05$ ), while no statistically significant difference was observed between Riva HV and Ketac Universal groups ( $p > 0.05$ ). Statistically significant differences were found between baseline and different evaluations for Ketac Universal, EQUIA Forte,

**TABLE 3** The demographic data and clinical characteristics of the research subjects and class II lesions per group

Clinical characteristics	Number of lesions			
	Filtek Z250	Ketac Universal	EQUIA Forte	Riva HV
Age	20–40	20–40	20–40	20–40
Gender				
Male	26	26	26	26
Female	14	14	14	14
Tooth preparation				
Mesio-occlusal (MO)	25	21	18	16
Disto-occlusal (DO)	15	19	22	24
Tooth distribution				
Premolars	22	23	26	16
Molars				24
Dental arch distribution				
Maxillary	18	22	19	25
Mandibular	22	18	21	15
Cavity depth				
Shallow	32	30	28	30
Medium	3	8	8	5
Deep	5	2	4	5
Pulp protection				
Yes	5	2	4	5
No	35	38	36	35
Reason for treatment				
Caries	34	37	37	35
Fracture	4	1	1	3
Esthetic	2	2	2	2
Total	40	40	40	40

and Riva HV groups ( $p < 0.05$ ). Conversely, no statistically significant differences were detected between baseline and different recalls for Filtek Z250 group ( $p > 0.05$ ).

The scores of performance criteria for esthetic anatomic form revealed no statistically significant differences between all groups during all the follow-up periods ( $p > 0.05$ ). No statistically significant differences were found also between baseline and different recalls for Filtek Z250 and EQUIA Forte groups ( $p > 0.05$ ), whilst after 5 years, Ketac Universal and Riva HV restorations showed a significant change in the anatomic form when compared to the baseline ( $p < 0.05$ ).

Regarding fracture of material and retention criterion, there were no statistically significant differences between the different groups at baseline and during all evaluations ( $p > 0.05$ ). Moreover, no statistically significant differences were noted between baseline and different recalls for Filtek Z250 group ( $p > 0.05$ ). EQUIA Forte group exhibited a significant change in the fracture scores at 5 years when compared to the baseline ( $p < 0.05$ ). Ketac Universal and Riva HV groups showed also inferior clinical performance at 1-, 3-, and 5-year recall when compared to the baseline ( $p < 0.05$ ).

By clinical examination of marginal adaptation, no statistically significant differences were found between all groups at baseline and after 1-, 3-, and 5-year recall ( $p > 0.05$ ). No statistically significant

differences were detected also between baseline and different evaluation periods for Filtek Z250 group ( $p > 0.05$ ), while some signs of marginal discrepancies in all glass ionomer groups were noted after 5 years in comparison to the baseline ( $p < 0.05$ ).

The clinical evaluation for occlusal contour and wear indicated no statistically significant differences between the different groups at baseline and over the 5 years ( $p > 0.05$ ). Filtek Z20 restorations showed a significant change in the wear rate after 5 years ( $p < 0.05$ ). When the baseline and 1-, 3-, and 5-year recall for all glass ionomer groups were compared, a significant decrease in the wear resistance was detected ( $p < 0.05$ ).

Clinical evaluation for approximal anatomical form revealed no statistically significant differences between all groups at baseline and during all evaluations ( $p > 0.05$ ). Also, nonsignificant differences were found between baseline and different recalls for all groups ( $p > 0.05$ ).

Radiographic examination showed no statistically significant differences between all groups at baseline and through the different evaluations ( $p > 0.05$ ), while a statistically significant change was detected only for EQUIA Forte group between the baseline and 5-year recall ( $p < 0.05$ ).

The results of comparing patient's view among all groups at different times indicated no statistically significant differences ( $p > 0.05$ ).

TABLE 4 Results of FDI criteria scores for the tested groups during the recall periods

	Score	Filtek Z250			Ketac Universal			EQUIA Forte			Riva HV						
		Baseline	1 Year	3 Years	5 Years	Baseline	1 Year	3 Years	5 Years	Baseline	1 Year	3 Years	5 Years				
<b>A. Esthetic properties</b>																	
1. Surface luster	1	40 (100%)	35 (87.5%)	32 (82.1%)	30 (76.9%)	0	0	0	0	40 (100%)	6 (15%)	0	0	40 (100%)	0	0	0
	2	0	5 (12.5%)	7 (17.9%)	8 (20.5%)	40 (100%)	36 (90%)	34 (89.5%)	33 (86.8%)	0	34 (85%)	38 (97.4%)	36 (97.3%)	0	38 (95%)	35 (92.1%)	33 (86.8%)
	3	0	0	0	1 (2.6%)	0	4 (10%)	4 (10.5%)	5 (13.2%)	0	0	1 (2.6%)	1 (2.7%)	0	2 (5%)	3 (7.9%)	5 (13.2%)
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2. surface and marginal staining	1	40 (100%)	40 (100%)	38 (97.4%)	37 (94.9%)	40 (100%)	39 (97.5%)	35 (92.1%)	35 (92.1%)	40 (100%)	40 (100%)	36 (92.3%)	35 (94.6%)	40 (100%)	40 (100%)	36 (94.7%)	34 (89.5%)
	2	0	0	1 (2.6%)	2 (5.1%)	0	1 (2.5%)	3 (7.9%)	3 (7.9%)	0	0	3 (7.7%)	2 (5.4%)	0	0	2 (5.3%)	3 (7.9%)
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (2.6%)
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3. Color match and translucency	1	37 (92.5%)	36 (90%)	35 (89.7%)	33 (84.6%)	0	0	0	0	0	0	0	0	0	0	0	0
	2	3 (7.5%)	4 (10%)	4 (10.3%)	6 (15.4%)	25 (62.5%)	25 (62.5%)	28 (73.7%)	30 (78.9%)	40 (100%)	34 (85%)	33 (84.6%)	37 (100%)	29 (72.5%)	28 (70%)	31 (81.6%)	32 (84.2%)
	3	0	0	0	0	15 (37.5%)	15 (37.5%)	10 (26.3%)	8 (21.1%)	0	6 (15%)	6 (15.4%)	0	11 (27.5%)	12 (30%)	7 (18.4%)	6 (15.8%)
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4. Esthetic anatomical form	1	39 (97.5%)	38 (95%)	37 (94.9%)	37 (94.9%)	36 (90%)	34 (85%)	31 (81.6%)	30 (78.9%)	37 (92.5%)	36 (90%)	34 (87.2%)	32 (86.5%)	36 (90%)	35 (87.5%)	32 (84.2%)	29 (76.3%)
	2	1 (2.5%)	2 (5%)	2 (5.1%)	2 (5.1%)	4 (10%)	4 (10%)	4 (10.5%)	5 (13.2%)	3 (7.5%)	4 (10%)	2 (5.1%)	3 (8.1%)	4 (10%)	3 (7.5%)	2 (5.3%)	5 (13.2%)
	3	0	0	0	0	0	2 (5%)	3 (7.9%)	3 (7.9%)	0	0	3 (7.7%)	2 (5.4%)	0	2 (5%)	4 (10.5%)	3 (7.9%)
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>B. Functional Properties</b>																	
5. Fracture of material and retention	1	40 (100%)	38 (95%)	36 (92.3%)	36 (92.3%)	40 (100%)	36 (90%)	35 (89.7%)	33 (86.8%)	40 (100%)	37 (92.5%)	35 (89.7%)	35 (89.7%)	40 (100%)	35 (87.5%)	34 (87.2%)	34 (89.5%)
	2	0	2 (5%)	3 (7.7%)	3 (7.7%)	0	1 (2.5%)	1 (2.6%)	3 (7.9%)	0	3 (7.5%)	1 (2.6%)	1 (2.6%)	0	2 (5%)	2 (5.1%)	1 (2.6%)
	3	0	0	0	0	0	3 (7.5%)	2 (5.1%)	2 (5.3%)	0	0	3 (7.7%)	1 (2.6%)	0	3 (7.5%)	2 (5.1%)	3 (7.9%)
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	1 (2.6%)	0	0	0	0	2 (5.1%)	0	1 (2.6%)	0	0
6. Marginal adaptation	1	40 (100%)	37 (92.5%)	37 (94.9%)	36 (92.3%)	40 (100%)	36 (90%)	35 (92.1%)	34 (89.5%)	40 (100%)	37 (92.5%)	36 (92.3%)	34 (91.9%)	40 (100%)	36 (90%)	35 (92.1%)	33 (86.8%)
	2	0	3 (7.5%)	2 (5.1%)	2 (5.1%)	0	2 (5%)	2 (5.3%)	3 (7.9%)	0	2 (5%)	1 (2.6%)	1 (2.7%)	0	3 (7.5%)	1 (2.6%)	2 (5.3%)
	3	0	0	0	1 (2.6%)	0	2 (5%)	1 (2.6%)	1 (2.6%)	0	1 (2.5%)	2 (5.1%)	2 (5.4%)	0	1 (2.5%)	2 (5.3%)	2 (5.3%)

TABLE 4 (Continued)

	Filtek Z250			Ketac Universal			EQUIA Forte			Riva HV							
	Score	Baseline	1 Year	3 Years	5 Years	Baseline	1 Year	3 Years	5 Years	Baseline	1 Year	3 Years	5 Years				
	4	0	0	0	0	0	0	0	0	0	0	0	0				
	5	0	0	0	0	0	0	0	0	0	0	0	1 (2.6%)				
7. Occlusal contour and wear (qualitative)	1	40 (100%)	39 (97.5%)	36 (92.3%)	35 (89.7%)	40 (100%)	32 (80%)	30 (78.9%)	28 (73.7%)	40 (100%)	35 (87.5%)	33 (84.6%)	30 (81.1%)	40 (100%)	33 (82.5%)	29 (76.3%)	26 (68.4%)
	2	0	1 (2.5%)	3 (7.7%)	4 (10.3%)	0	8 (20%)	5 (13.2%)	6 (15.8%)	0	5 (12.5%)	4 (10.3%)	4 (10.8%)	0	6 (15%)	5 (13.2%)	7 (18.4%)
	3	0	0	0	0	0	0	3 (7.9%)	4 (10.5%)	0	0	2 (5.1%)	3 (8.1%)	0	1 (2.5%)	4 (10.5%)	5 (13.2%)
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8. Approximal anatomical form (contact point and contour)	1	39 (97.5%)	39 (97.5%)	38 (97.4%)	38 (97.4%)	40 (100%)	39 (97.5%)	38 (97.4%)	37 (97.3%)	40 (100%)	38 (95%)	37 (94.9%)	37 (94.4%)	40 (100%)	39 (97.5%)	38 (97.4%)	37 (97.3%)
	2	1 (2.5%)	1 (2.5%)	1 (2.6%)	1 (2.6%)	0	1 (2.5%)	0	1 (2.7%)	0	2 (5%)	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	2 (5.1%)	0	0	1 (2.5%)	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	1 (2.6%)	0	0	0	0	2 (5.1%)	0	0	1 (2.6%)	1 (2.7%)
9. Radiographic examination	1	39 (97.5%)	37 (92.5%)	36 (92.3%)	36 (90%)	36 (90%)	36 (90%)	35 (89.7%)	35 (92.1%)	38 (95%)	36 (90%)	36 (92.3%)	34 (87.2%)	37 (92.5%)	35 (87.5%)	35 (89.7%)	34 (89.5%)
	2	1 (2.5%)	3 (7.5%)	3 (7.7%)	2 (5.1%)	4 (10%)	3 (7.5%)	2 (5.1%)	2 (5.3%)	2 (5%)	3 (7.5%)	1 (2.6%)	1 (2.6%)	3 (7.5%)	4 (10%)	2 (5.1%)	2 (5.3%)
	3	0	0	0	1 (2.6%)	0	1 (2.5%)	1 (2.6%)	1 (2.6%)	0	1 (2.5%)	2 (5.1%)	2 (5.1%)	0	1 (2.5%)	1 (2.6%)	1 (2.6%)
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	1 (2.6%)	0	0	0	0	2 (5.1%)	0	0	1 (2.6%)	1 (2.6%)
10. Patient's view	1	38 (95%)	38 (95%)	37 (94.9%)	37 (94.9%)	40 (100%)	37 (92.5%)	36 (92.3%)	36 (94.7%)	40 (100%)	38 (95%)	37 (94.9%)	35 (89.7%)	40 (100%)	36 (90%)	35 (89.7%)	34 (89.5%)
	2	0	2 (5%)	2 (5.1%)	2 (5.1%)	0	2 (5%)	2 (5.1%)	0	0	2 (5%)	0	1 (2.6%)	0	3 (7.5%)	3 (7.7%)	1 (2.6%)
	3	2 (5%)	0	0	0	0	1 (2.5%)	0	2 (5.3%)	0	0	2 (5.1%)	1 (2.6%)	0	1 (2.5%)	0	2 (5.3%)
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	1 (2.6%)	0	0	0	0	2 (5.1%)	0	0	1 (2.6%)	1 (2.6%)

C. Biological Properties

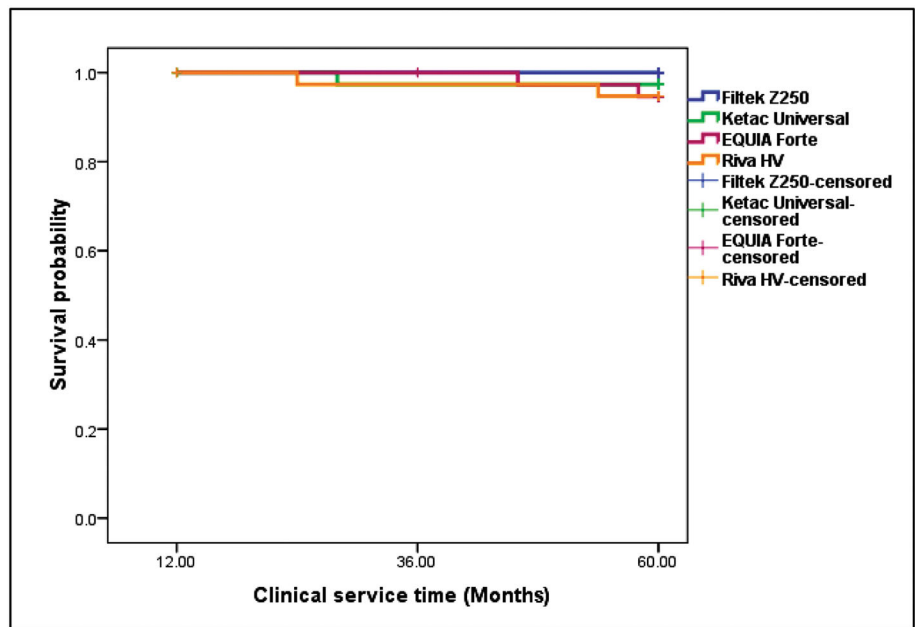
11. Post-operative (hyper-) sensitivity and tooth vitality	1	38 (95%)	40 (100%)	39 (100%)	39 (100%)	40 (100%)	40 (100%)	38 (97.4%)	38 (100%)	40 (100%)	40 (100%)	39 (100%)	37 (94.9%)	40 (100%)	40 (100%)	38 (97.4%)	37 (97.4%)
	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	2 (5%)	0	0	0	0	0	1 (2.6%)	0	0	0	0	2 (5.1%)	0	0	1 (2.6%)	1 (2.6%)
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1	40 (100%)	40 (100%)	39 (100%)	39 (100%)	40 (100%)	40 (100%)	40 (100%)	39 (100%)	38 (100%)	40 (100%)	40 (100%)	39 (100%)	39 (100%)	40 (100%)	40 (100%)	39 (100%)	38 (100%)

(Continues)

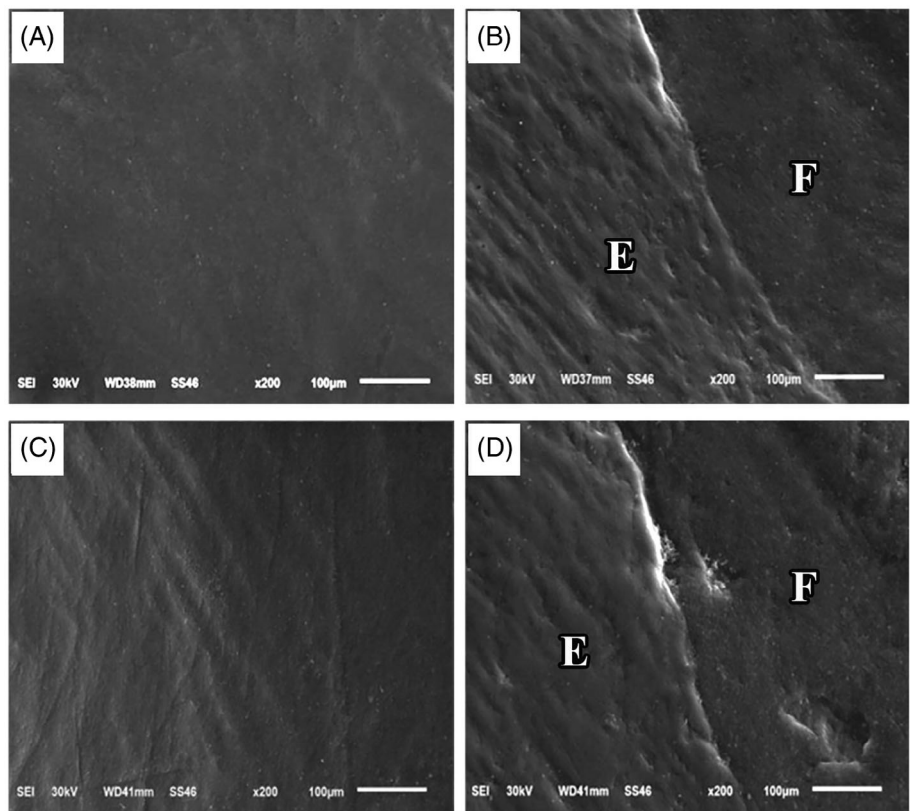
TABLE 4 (Continued)

	Filtek Z250				Ketac Universal				EQUIA Forte				Riva HV				
	Score	Baseline	1 Year	3 Years	5 Years	Baseline	1 Year	3 Years	5 Years	Baseline	1 Year	3 Years	5 Years	Baseline	1 Year	3 Years	5 Years
12. Recurrence of caries (CAR), erosion, abfraction	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13. Tooth integrity (enamel cracks, tooth fractures)	1	40 (100%)	40 (100%)	39 (100%)	38 (100%)	40 (100%)	40 (100%)	39 (100%)	38 (100%)	40 (100%)	40 (100%)	39 (100%)	39 (100%)	40 (100%)	40 (100%)	39 (100%)	38 (100%)
	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14. Periodontal response (always compared to a reference tooth)	1	40 (100%)	39 (97.5%)	38 (97.4%)	37 (94.9%)	40 (100%)	39 (97.5%)	38 (97.4%)	37 (97.3%)	40 (100%)	39 (97.5%)	37 (94.9%)	37 (94.9%)	40 (100%)	38 (95%)	37 (94.9%)	37 (97.4%)
	2	0	1 (2.5%)	1 (2.6)	2 (5.1%)	0	1 (2.5%)	0	1 (2.7%)	0	1 (2.5%)	2 (5.1%)	0	2 (5%)	2 (5.1%)	0	0
	3	0	0	0	0	0	0	1 (2.6)	0	0	0	0	2 (5.1%)	0	0	0	1 (2.6%)
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15. Adjacent mucosa	1	40 (100%)	39 (97.5%)	38 (97.4%)	37 (94.9%)	40 (100%)	39 (97.5%)	38 (97.4%)	37 (97.3%)	40 (100%)	39 (97.5%)	37 (94.9%)	37 (94.9%)	40 (100%)	38 (95%)	37 (94.9%)	37 (97.4%)
	2	0	1 (2.5%)	1 (2.6)	2 (5.1%)	0	1 (2.5%)	1 (2.6)	1 (2.7%)	0	1 (2.5%)	2 (5.1%)	2 (5.1%)	0	2 (5%)	2 (5.1%)	1 (2.6%)
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16. Oral and general health	1	40 (100%)	40 (100%)	39 (100%)	38 (100%)	40 (100%)	40 (100%)	39 (100%)	38 (100%)	40 (100%)	40 (100%)	39 (100%)	39 (100%)	40 (100%)	40 (100%)	39 (100%)	38 (100%)
	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

**FIGURE 2** Kaplan–Meier survival curves for tested groups (Log-rank,  $p = 0.514$ )



**FIGURE 3** A representative of Filtek Z250 restoration showing: SEM photomicrograph of the occlusal contact area  $200\times$  at baseline (A) and after 5 years (C), SEM photomicrograph of the marginal adaptation  $200\times$  at baseline (B) and after 5 years (D). E, enamel; F, Filtek Z250

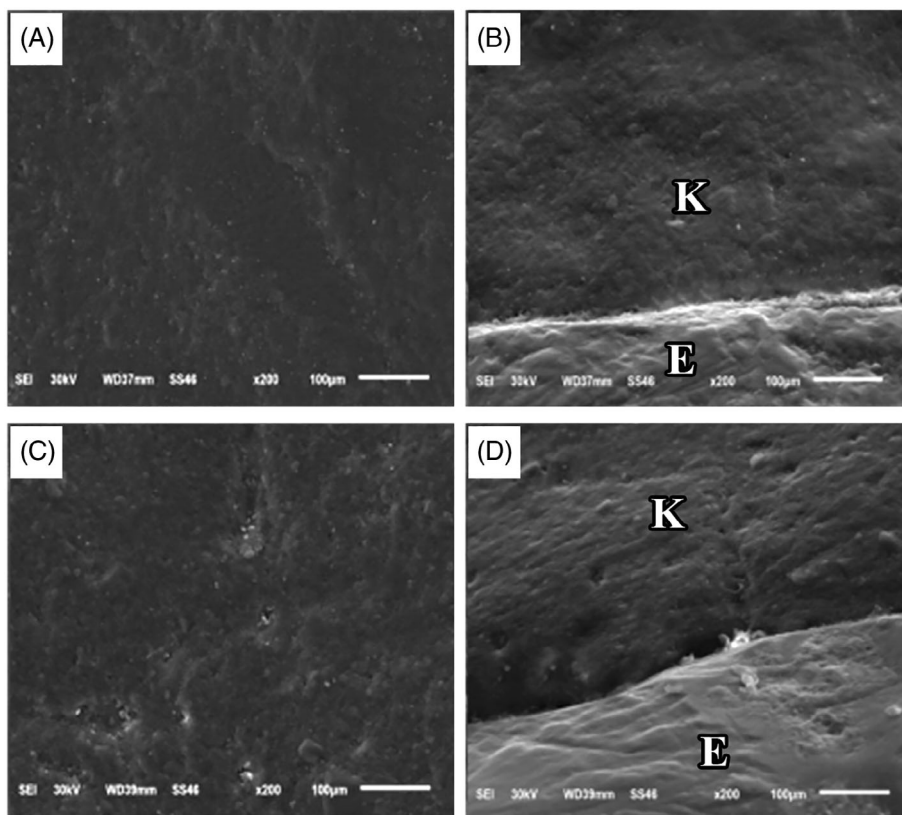


No statistically significant differences were noted also between baseline and different recalls for Filtek Z250 and Ketac Universal groups ( $p > 0.05$ ), while a significant decrease in the patient satisfaction was detected for EQUIA Forte and Riva HV restorations when compared the baseline to 5-year recall ( $p < 0.05$ ).

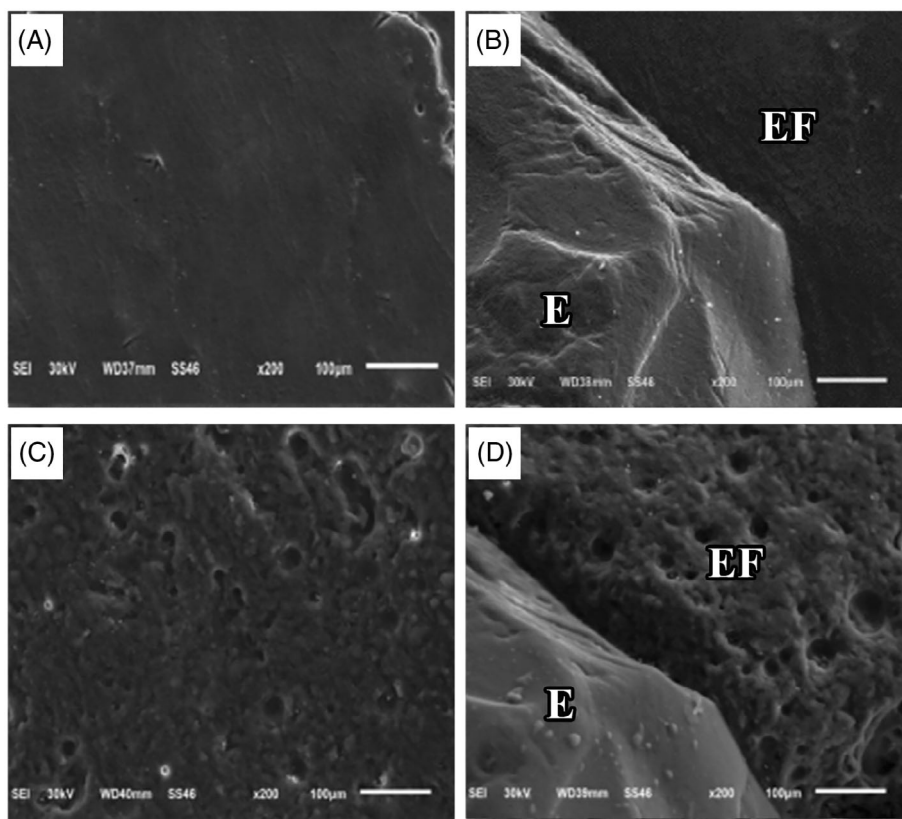
No statistically significant differences were found between the different groups at baseline and after 1-, 3-, and 5-year recall for the

scores of postoperative sensitivity/tooth vitality, recurrence of caries, tooth integrity, periodontal response, adjacent mucosa, and oral health criteria ( $p > .05$ ). Also, no significant changes over time were detected for all groups ( $p > .05$ ).

The representative replica for each restoration was evaluated at baseline under SEM and compared to that of the 5-year recall (Figures 3, 4, 5, and 6). All restorations exhibited adequate



**FIGURE 4** A representative of Ketac Universal restoration showing; SEM photomicrograph of the occlusal contact area 200× at baseline (A) and after 5 years (C), SEM photomicrograph of the marginal adaptation 200× at baseline (B) and after 5 years (D). E, enamel; K, Ketac Universal

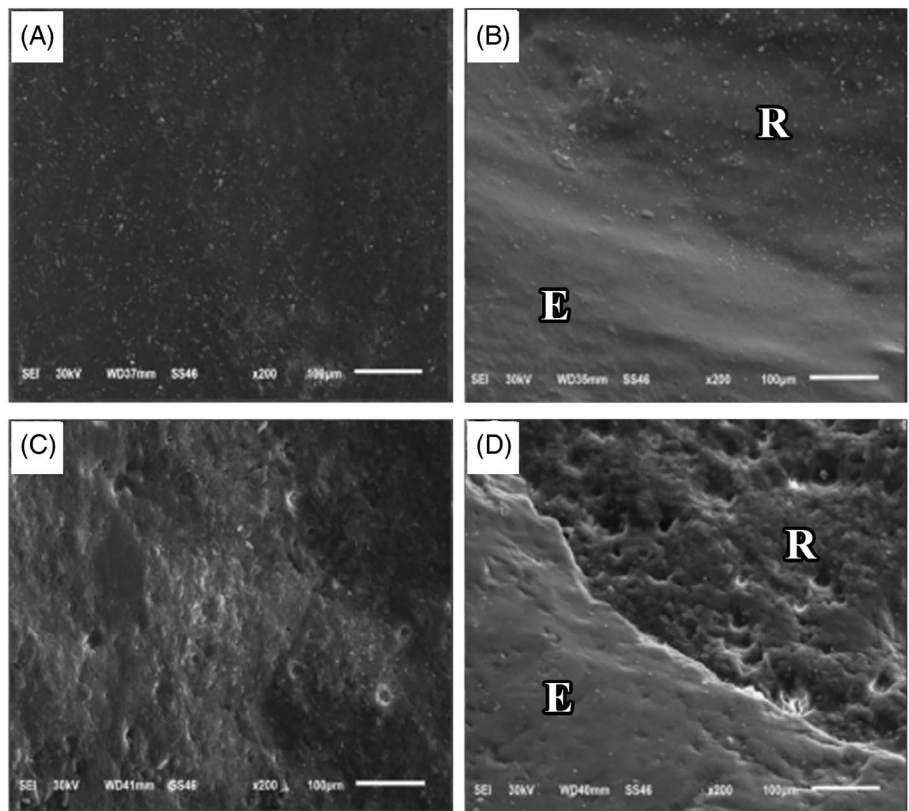


**FIGURE 5** A representative of EQUIA Forte restoration showing; SEM photomicrograph of the occlusal contact area 200× at baseline (A) and after 5 years (C), SEM photomicrograph of the marginal adaptation 200× at baseline (B) and after 5 years (D). E, enamel; EF, EQUIA Forte

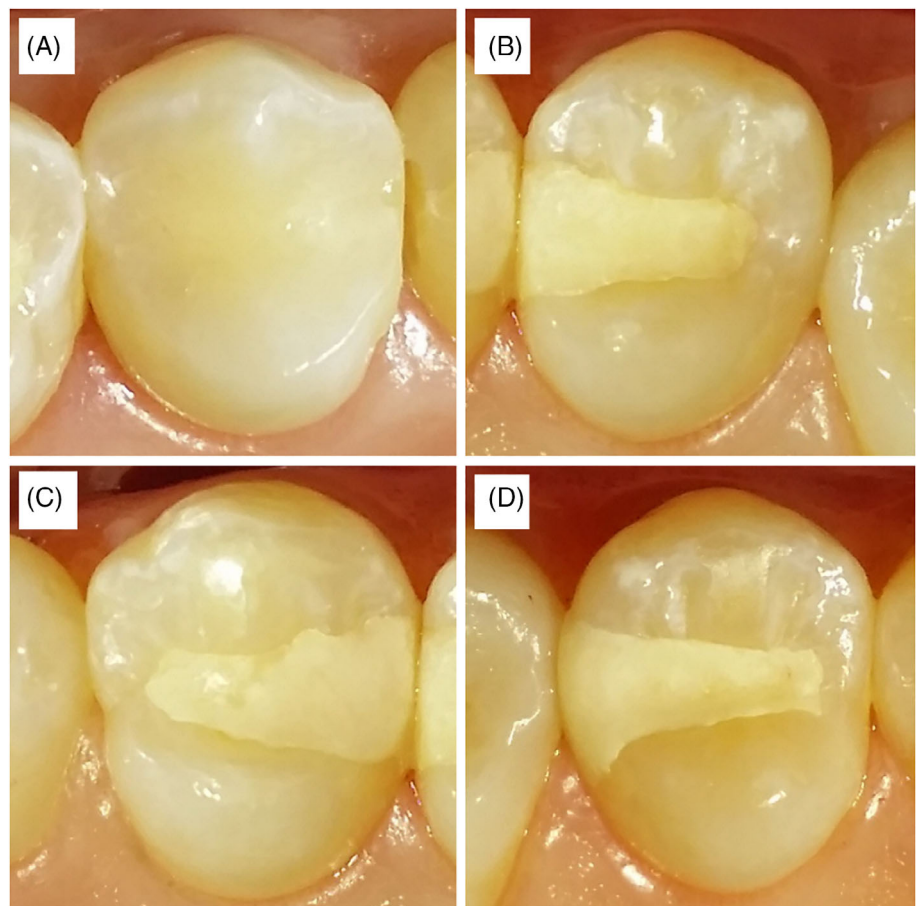
marginal adaptation in addition to the absence of fractures or wear at baseline evaluation. After 5 years of clinical service, the occlusal surface of the restorations showed successful

marginal adaptation and surface characteristics. However, some micromorphological changes regarding material chip fracture, small marginal gaps or normal wear were observed (Figure 7).

**FIGURE 6** A representative of Riva HV restoration showing; SEM photomicrograph of the occlusal contact area 200 $\times$  at baseline (A) and after 5 years (C), SEM photomicrograph of the marginal adaptation 200 $\times$  at baseline (B) and after 5 years (D). E, enamel; R, Riva HV



**FIGURE 7** A representative of all tested restorative materials after 5 years showing; Filtek Z250 restoration (A), Ketac Universal restoration (B), EQUIA Forte restoration (C), Riva HV restoration (D)



The SEM analyses of the epoxy replicas reinforced the previously described results by FDI.

## 4 | DISCUSSION

This prospective randomized controlled clinical study evaluated and compared the 5-year clinical performance of three high-viscosity conventional glass ionomer restorative materials with that of a direct microhybrid resin composite in small class II restorations using the FDI evaluation criteria. Although the survival rate of all restorations did not make a statistically significant difference between the groups by the end of 5-year follow-up and the overall successful clinical performance of class II glass ionomer restorations, some clinical drawbacks were found for high-viscosity glass ionomer restorations regarding surface luster and color match. Therefore, the research hypothesis formulated at the beginning of the trial was partially accepted. The highly recall rates (97.5%) during all the evaluation periods were attributed to the selection of highly-motivated participants in this study.

In this trial, split-mouth design was used to expose all tested restorative materials to the same oral environmental condition. Inclusion and exclusion criteria were defined before starting the trial to preserve the methodological quality and to control the confounding variables that may affect the clinical outcome and results validity. All the restorative procedures were performed by one experienced operator to avoid any variations between operators. Eliminating the influence of the operator on the clinical performance of the restorations allowed a more controlled comparison between restorative materials.

In present-day restorative dentistry, the main goal is treatment of dental caries using minimal invasive technique in combination with adhesive restorative materials. Preventing the recurrence of caries, restoring the function, preserving and supporting the remaining tooth structure are considered the main concerns for researchers when developing a new restorative material. The selection of high-viscosity conventional glass ionomer restorative systems; Ketac Universal, EQUIA Forte and Riva HV in the current trial was related to their improved mechanical properties and enhanced wear resistance.

The surface luster, which is the ability of the surface to reflect light, is essential for the proper esthetic appearance of a restoration, being inversely proportional to the surface roughness. The present study revealed that Filtek Z250, EQUIA Forte, and Riva HV restorations had surface luster comparable to the surrounding enamel at baseline evaluation, while Ketac Universal restorations showed slightly dull surface. This could be attributed to the adequate finishing and polishing protocol used for composite restorations leading to smooth and glossy occlusal surface. The application of coating agent on the surface of EQUIA Forte and Riva HV restorations had a great influence on their luster appearance, while Ketac universal restorations were not covered with coating material making them less shiny than enamel at baseline evaluation. This outcome is supported by the results of previous studies<sup>10,11</sup> which revealed that the application of resin coating could transform the surface of the restoration into a

glossy layer without further polishing. However, significant changes were observed in the scores of surface luster for EQUIA Forte and Riva HV restorations after 5 years due to the wear of the coating agent by chewing cycles resulting in dull appearance of the restorations as observed by previous studies.<sup>15,29</sup> The deterioration in surface texture for glass ionomer restorations might be also attributed to the positive correlation between wear and surface roughness.<sup>13</sup> The quality of the occlusal surface for Filtek Z250 restorations was changed also over the course of 5 years due to the large-sized filler particles of microhybrid resin composite that were exposed relatively fast by the wear of the organic matrix and the friction with food and antagonist teeth during mastication.<sup>33</sup>

In relation to surface staining, all glass ionomer groups did not show any significant variations from microhybrid resin composite group at any evaluation period. This could be related to the self-adhesion properties of glass ionomer to enamel and dentin without the need for any bonding agents. Only two Filtek Z250 restorations suffered a slight change after 5 years with no significant differences when compared with other materials. This could be attributed to the polymerization shrinkage which is considered one of the main factors causing this problem. Two EQUIA Forte, three ketac Universal and four Riva HV restorations showed marginal discoloration after the 5-year recall. This marginal staining occurring in the crevice between the restoration and the cavity wall could be related to pigment absorption from dietary habits in addition to the presence of fractures, defects or gaps at the margins. This also supported with previous study<sup>11</sup> who reported that marginal discoloration is seen only in few cases during the 6-year examinations.

Glass ionomer groups exhibited inferior color match in comparison to microhybrid resin composite group over all the different recalls. This could be attributed to the optical properties of glass ionomer which is still not at the same performance as resin composite due to the lack of translucency of the material which coincides with similar outcomes.<sup>3,26</sup> This finding is contradictory to the results of previous study<sup>9</sup> which showed that both of glass ionomer and resin composite restorations showed no mismatch in color with the surrounding tooth structure. EQUIA Forte group exhibit better color match with adjacent tooth structures due to the incorporation of small highly reactive glass particles in the chemical composition of the material in addition to the application of nano-filled resin coating agent on the restoration surface.<sup>18</sup> The enhancement in color match for glass ionomer groups after 5 years could be related to the maturation of glass ionomer over time. This finding is in agreement with another study<sup>28</sup> which reported that the color match of high-viscosity glass ionomer restorations was improved over the 3-year examination. On the contrary, a clinical study<sup>16</sup> reported that 24.6% of glass ionomer restorations showed a significant decrease in color match at 6 and 10 years. Six Filtek Z250 restorations showed minor color deviations due to the susceptibility of monomers to absorb water and chemicals from the oral environment.<sup>32</sup> Since the restorations were in the posterior region, and the patients were not disturbed by the appearance of the restorations, the replacing of the restoration was not considered in order to remedy the color mismatch.

The 5-year clinical evaluation did not show any differences in the esthetic anatomic form between the different groups. However, the significant changes in Ketac Universal and Riva HV groups after 5 years could be related to the higher wear rate or material chip fracture. A previous study<sup>9</sup> reported that the alpha scores for glass ionomer restorations were related to that the wear on the occlusal surface of the restorations was barely visible to the naked eye.

Only one Ketac Universal, two EQUIA Forte, and one Riva HV restorations were fractured throughout the 5-year follow-up with no significant differences when compared with Filtek Z250 group. The higher success rate could be related to that all restorations were placed in small to medium sized cavities that resulted in decreasing their fracture possibilities. Moreover, all cavity preparations were made according to the principles of minimally invasive dentistry without any cuspal involvement, bevels or subgingival class II margins in order to decrease the risk of failure. The special filler composition and the presence of benzoic acid in the co-polymeric acids of Ketac Universal produced a mechanical interlocking effect upon hardening. The application of resin coating on the surface of EQUIA Forte and Riva HV restorations allowed lasting protection and increased the strength of the restorations. Also, the compressive strength of the GIC increases with time. This outcome is supported by the results of previous studies<sup>10,27</sup> which showed that the modern reinforced glass ionomer restorative materials performed well in class II cavities. Quite interestingly, this result is in accordance with previous studies<sup>28,30</sup> which showed that fracture was the main reason for failure of glass ionomer restorations. However, some glass ionomer restorations exhibited material chipping, cracks and small fractures that did not interfere with their function. This could be related to the lower fracture toughness of glass ionomer in addition to the fatigue fractures after 5 years of clinical service.

Regarding marginal adaptation, the chemical adhesion of glass ionomer to the tooth structure forms acid-base resistant layer resulting in long-lasting marginal seal. Also, the similar coefficient of thermal expansion of glass ionomer to that of tooth structure reduces the micro-gap between the tooth and restoration. Consistent with this outcome, another finding<sup>31</sup> stated that the use of coat minimized the formation of marginal gaps. However, four ketac Universal, three EQUIA Forte, and five Riva HV restorations exhibited changes after 5 years with no significant differences when compared with Filtek Z250 group. Only one Riva HV restoration showed unacceptable partial looseness in situ. Marginal gaps, steps or irregularities that were detected during examinations could be related to the fracture of slightly overlapping marginal excess or thin flashes extended on non-prepared enamel surfaces adjacent to the cavity margins. Three Filtek Z250 restorations showed also a slight change in marginal adaptation over time, which could be resulted from the degradation of the resin/bond interface as a result of slow water hydrolysis. All marginal disintegrations were detected by the two special probes (150 and 250  $\mu\text{m}$ ) during the follow-up periods.

Clinical evaluation of wear was conducted to help in understanding the behavior of dental restorative materials when submitted to the complex oral masticatory changes. Based on the results of this study,

all the restorations were clinically acceptable in terms of wear resistance. The three glass ionomer groups exhibited similar wear resistance to microhybrid resin composite after 5 years. This could be attributed to the higher flexural strength and wear resistance of modern GICs as reported in previous study.<sup>28</sup> Also, the coating agent penetrates the porosities and reduces the propagation of cracks in the restorations. Only patients with normal occlusion were included in the trial to avoid the excessive wear rates resulting from clenching or bruxism habits. Other finding<sup>16</sup> reported also that none of glass ionomer or microhybrid resin composite restorations require replacement because of clinically non-acceptable wear. However, there are significant changes in the scores for all groups when comparing baseline to the 5-year recall. This could be explained as the pitting micro-wear areas were present along the food escape pathways of the occlusal surface of restorations. This reflected the impact of coarse particles in dietary constituents in addition to the heavy occlusal forces in posterior region.<sup>33</sup>

The tightness and strength of the proximal contact points of restorations were clinically evaluated by passing waxed dental floss through the interdental spaces as the lack of adequate contact leads to food impaction and discomfort during chewing.<sup>23,24</sup> The current study results indicated no differences in approximal anatomical form between the different groups during all follow-up periods, which might be attributed to the usage of sectional matrix system that resulted in strong contact points and appropriate contours. The non-sticky coated matrices were used also to overcome the adherence of the glass ionomer to the traditional metal matrices in order to avoid microcracks formation during matrix removal.<sup>30</sup> Conversely, this is in contrast with another finding<sup>3</sup> which stated that the use of high-viscosity glass ionomer in class II cavities showed high failure rates compared to resin composite after 1 year. After 5 years, only one Filtek Z250 restoration exhibited a slightly too strong contact. All the failed glass restorations had too weak contacts and insufficient contours that required replacement. The loss of glass ionomer in proximal contact areas might be explained by acidogenicity of dental plaque accumulated in these areas. It might be related also to the inability of the protective resin to be applied effectively to the proximal wall of glass ionomer restoration leaving the proximal area unprotected from moisture contamination during the initial hardening phase.<sup>3</sup> A previous study<sup>9</sup> revealed that cyclic stresses resulted in occlusal-proximal marginal fractures and weakened the proximal points.

The scores of the current study indicated that three Filtek Z250 restorations suffered a slight difference in radiographic findings after 5 years with no significant differences when compared with other groups. No periapical changes related to any restoration were found. Moreover, all the tested restorative materials have adequate level of radiopacity. One Ketac Universal, two EQUIA Forte, and one Riva HV restorations exhibited fracture in the proximal areas just below the contact points as observed radiographically. Only one failed Riva HV restoration showed large gaps. A previous study<sup>14</sup> reported that the radiographic performances of class II restorations involving high-viscosity glass ionomer indicated a concavity on the proximal wall of the restorations at the 18-month recall.

Patient's view was scored by means of a Visual Analogue Scale (VAS). Each patient was asked about his/her point of view regarding esthetics, chewing comfort, pain, hypersensitivity, ease of ability to clean the restoration with toothbrush or dental floss, gingival bleeding and any other problems such as detection of the restoration with the tongue. Most of the patients were satisfied with esthetics and functions of the restorations with no significant differences between the different tested groups during the different evaluation periods. Only two patients reported minor criticism about microhybrid resin composite restorations at baseline examination due to the postoperative hypersensitivity, while the patients having the failed restorations were completely dissatisfied. A significant regression occurred in patients' satisfaction with some EQUIA Forte and Riva HV restorations over time. This could be attributed to the changes in the texture of the restorations. In contrast, a previous study<sup>29</sup> revealed no significant changes in patient's view for conventional glass ionomer restorations during the 3-year recall periods.

None of the cases showed any problems related to tooth vitality. The depth of cavities was shallow or moderate in most cases and the lining material was applied in deeper cavities in order to protect pulp vitality. This result is in agreement with previous one<sup>9</sup> which reported that the time and attention devoted to the restoration placement techniques minimized the hydrostatic dentinal fluid movement and consequently the postoperative sensitivity. The reported postoperative hypersensitivity for two Filtek Z250 restorations could be related to polymerization shrinkage stresses or the etching of dentin in the used etch-and-rinse adhesive protocol.<sup>5</sup> However, this disappeared by the 1-year examination. All the failed glass ionomer restorations exhibited moderate sensitivity because of the exposed dentin with no significant differences in comparison to Filtek Z250 group after 5 years.

Secondary caries is reported to be the most usual reason for failure in clinical evaluations.<sup>7,8</sup> However, no secondary caries was observed on any of the restorations in this study during the different recalls. The absence of recurrent or secondary caries in all cases could be related to the selection of well-motivated participants with good oral hygiene status in addition to the instructions given to all of them after the placement of the restorations. Also, the adequate marginal seal of the restorations prevented the interfacial bacterial penetration. The anticariogenic effect and fluoride release of glass ionomer played a crucial role in preventing caries.<sup>11,27</sup> No enamel cracks or tooth fracture were detected during the different recalls for all groups. This could be related to the minimal invasive cavity preparations where it was more important to keep the tooth unaffected even if a fracture occurred for any restoration. Also, the exclusion of teeth with large carious lesions had a significant effect on the study results.

The majority of cases did not show any periodontal problems. However, only two restorations from each group showed little plaque accumulation or a difference up to one grade in severity of Papillary Bleeding Index (PBI) with no significant changes for all groups when compared baseline to the different recall periods. This could be related to the deficiencies in some proximal areas or anatomical forms.

This is consistent with a previous study<sup>3</sup> which revealed that marginal fracture or material loss in the proximal region resulted in food impaction and gingival inflammation. All cases showed healthy mucosa adjacent to the restorations without any allergic reactions due to the biocompatibility of the tested restorative materials with oral tissues. Only two restorations from each group showed mild redness and swelling as a result of mechanical irritations such as plaque and sharp edges. This is in accordance with a previous study<sup>27</sup> which revealed that there was no observed difference for the soft tissue health of conventional glass ionomer and microhybrid resin composite restorations after 24 months. The current trial results indicated that all groups did not show any oral or general symptoms during the 5-year clinical examination due to the exclusion of participants with adverse medical history, allergies or systemic diseases.

The outcomes of the current clinical trial are limited by the small sample size and the limited number of treated teeth. The results could not prove a statistically significant influence of the tooth type on the failure of restorations, which could be probably attributed also to the low sample size. Sample size was calculated for the primary outcome (fracture/retention) of glass ionomer restorations in 6 years of previous relevant study because no available data regarding the retention rate of class II glass ionomer restorations after 5 years were found. High-viscosity glass ionomer restorative materials have certainly progressed remarkably from their inception to their present-day use as the permanent restorative material choice for a variety of clinical situations. It would be advisable to conduct future long-term randomized clinical trials evaluating HVGICs in wide class II cavities in large number of patients with high recall rates to test these materials for further clinical applications.

## 5 | CONCLUSIONS

Within the limitations of this current study, it was concluded that the three high-viscosity conventional glass ionomer restorative materials exhibited successful clinical performance in small to medium sized class II cavities compared to microhybrid resin composite after 5 years of clinical evaluation. The major drawbacks of glass ionomer restorations were related to their surface luster in addition to the mismatch in color and translucency with the surrounding tooth structure.

### ACKNOWLEDGEMENTS AND DISCLOSURE

The authors would like to thank 3M Deutschland, Seefeld, Germany for supplying the trial with Ketac Universal Aplicap, applicator, and activator. We are grateful also for our patients who participated in the study. The authors declare that they do not have any financial interest in the companies whose materials are included in this article.

### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

## ORCID

Ramy Ahmed Wafaie  <https://orcid.org/0000-0002-2291-2110>

## REFERENCES

- Fuhrmann D, Murchison D, Whipple S, Vandewalle K. Properties of new glass-ionomer restorative systems marketed for stress-bearing areas. *Oper Dent*. 2020;45(1):104-110.
- Bernardo M, Luis H, Martin MD, et al. Survival and reasons for failure of amalgam versus composite posterior restorations placed in a randomized clinical trial. *J Am Dent Assoc*. 2007;138(6):775-783.
- 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:e20180678.
- Kielbassa AM, Glockner G, Wolgin M, Glockner K. Systematic review on highly viscous glass-ionomer cement/resin coating restorations (part I): do they merge Minamata convention and minimum intervention dentistry? *Quintessence Int*. 2016;47(10):813-823.
- Mahmoud SH, El-Embaby AE, AbdAllah AM. Clinical performance of ormocer, nanofilled, and nanoceramic resin composites in class I and class II restorations: a three-year evaluation. *Oper Dent*. 2014;39(1):32-42.
- Mahmoud SH, Ali AK, Hegazi HA. A three-year prospective randomized study of silorane- and methacrylate-based composite restorative systems in class II restorations. *J Adhes Dent*. 2014;16(3):285-292.
- Astvaldsdottir A, Dagerhamn J, van Dijken JWV, et al. Longevity of posterior resin composite restorations in adults – a systematic review. *J Dent*. 2015;43(8):934-954.
- Opdam NJ, van de Sande FH, Bronkhorst E, et al. Longevity of posterior composite restorations: a systematic review and meta-analysis. *J Dent Res*. 2014;93(10):943-949.
- Gurgan S, Kutuk ZB, Ergin E, Oztas SS, Cakir FY. Four-year randomized clinical trial to evaluate the clinical performance of a glass ionomer restorative system. *Oper Dent*. 2015;40(2):134-143.
- Gurgan S, Kutuk ZB, Ergin E, Oztas SS, Cakir FY. Clinical performance of a glass ionomer restorative system: a 6-year evaluation. *Clin Oral Investig*. 2017;21(17):2335-2343.
- Türkün LS, Kanik Ö. A prospective six-year clinical study evaluating reinforced glass ionomer cements with resin coating on posterior teeth: quo Vadis? *Oper Dent*. 2016;41(6):587-598.
- Mickenautsch S, Mount G, Yengopal V. Therapeutic effect of glass-ionomers: an overview of evidence. *Aust Dent J*. 2011;56(1):10-15.
- Bonifácio CC, Werner A, Kleverlaan CJ. Coating glass-ionomer cements with a nanofilled resin. *Acta Odontol Scand*. 2012;70(6):471-477.
- Scholtanus JD, Huysmans MC. Clinical failure of class-II restorations of a highly viscous glass-ionomer material over a 6-year period: a retrospective study. *J Dent*. 2007;35(2):156-162.
- Friedl K, Hiller KA, Friedl KH. Clinical performance of a new glass ionomer based restoration system: a retrospective cohort study. *Dent Mater*. 2011;27(10):1031-1037.
- Gurgan S, Kutuk ZB, Yalcin Cakir F, et al. A randomized controlled 10 years follow up of a glass ionomer restorative material in class I and class II cavities. *J Dent*. 2020;94:103175.
- Riva Self Cure HV. *High Viscosity Glass Ionomer Restorative Material*. SDI; 2011. Accessed June 2, 2017. [https://www.sdi.com.au/pdfs/brochures/au/riva%20self%20cure\\_sdi\\_brochures\\_au.pdf](https://www.sdi.com.au/pdfs/brochures/au/riva%20self%20cure_sdi_brochures_au.pdf)
- Pitel ML. An improved glass ionomer restorative system: stress-bearing class I and II indications. *Dent Today*. 2017;36(2):130-134.
- Equia Forte Bulk Fill. *Fluoride Releasing Glass Hybrid Restorative System*. GC; 2015. Accessed June 2, 2017. [https://cdn.gceurope.com/v1/PID/equiaforte/leaflet/LFL\\_EQUIA\\_Forte\\_en.pdf](https://cdn.gceurope.com/v1/PID/equiaforte/leaflet/LFL_EQUIA_Forte_en.pdf)
- Ketac Universal Aplicap. *Glass Ionomer Restorative*. 3M Oral Care; 2015. Accessed June 2, 2017. <https://multimedia.3m.com/mws/media/12204710/3m-ketac-universal-aplicap-glass-ionomer-restorative-fewer-steps-to-keep.pdf>
- Mickenautsch S, Yengopal V. Failure rate of direct high-viscosity glass-ionomer versus hybrid resin composite restorations in posterior permanent teeth – a systematic review. *Open Dent J*. 2015;9:438-448.
- Mickenautsch S. Research gaps identified during systematic reviews of clinical trials: glass-ionomer cements. *BMC Oral Health*. 2012;12:18.
- Hickel R, Roulet JF, Bayne S, et al. Recommendations for conducting controlled clinical studies of dental restorative materials. *Clin Oral Investig*. 2007;11(1):5-33.
- 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 Investig*. 2010;14(4):349-366.
- Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340:c869.
- Balkaya H, Arslan S. A two-year clinical comparison of three different restorative materials in class II cavities. *Oper Dent*. 2020;45:e32-e42.
- Gurgan S, Kutuk ZB, Ozturk C, Soleimani R, Cakir FY. Clinical performance of a glass hybrid restorative in extended size class II cavities. *Oper Dent*. 2020;45(3):243-254.
- 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 Investig*. 2014;18(3):753-759.
- Fotiadou C, Frasher I, Reymus M, et al. Corrigendum: a 3-year controlled randomized clinical study on the performance of two glass-ionomer cements in class II cavities of permanent teeth. *Quintessence Int*. 2019;51(1):e1-e11.
- Heck K, Frasher I, Diegritz C, Manhart J, Hickel R, Fotiadou C. Six-year results of a randomized controlled clinical trial of two glass ionomer cements in class II cavities. *J Dent*. 2020;97:103333.
- Klinke T, Daboul A, Turek A, Frankenberger R, Hickel R, Biffar R. Clinical performance during 48 months of two current glass ionomer restorative systems with coatings: a randomized clinical trial in the field. *Trials*. 2016;17(1):239.
- De Andrade AKM, Duarte RM, Medeiros e Silva FD, et al. 30-month randomized clinical trial to evaluate the clinical performance of a nanofill and a nanohybrid composite. *J Dent*. 2011;39(1):8-15.
- Palaniappan S, Elsen L, Lijnen I, Peumans M, van Meerbeek B, Lambrechts P. Three-year randomised clinical trial to evaluate the clinical performance, quantitative and qualitative wear patterns of hybrid composite restorations. *Clin Oral Investig*. 2010;14(4):441-458.

**How to cite this article:** Wafaie RA, Ibrahim Ali A, El-Negoly S-R, Mahmoud SH. Five-year randomized clinical trial to evaluate the clinical performance of high-viscosity glass ionomer restorative systems in small class II restorations. *J Esthet Restor Dent*. 2023;35(3):538-555. doi:10.1111/jerd.13000