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A Prospective Six-Year Clinical Study Evaluating Reinforced Glass Ionomer Cements with Resin Coating on Posterior Teeth: Quo Vadis?

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Clinical Relevance

Despite minor reparable defects, the overall clinical performance of EquiaFil was found to be excellent even in large posterior class II restorations after a period of six years compared to Riva SC.

SUMMARY

Objective: The aim of this study was to evaluate the long-term clinical performance of two encapsulated glass ionomer cements (GICs) (EquiaFil and Riva SC) covered with two different coatings (Equia Coat and Fuji Varnish) over six years using modified US Public Health Service (USPHS) criteria.

Methods: Fifty-four patients having class I and II restorations/caries were included in the study. A total of 256 restorations were made with EquiaFil and Riva SC. Equia Coat or Fuji Varnish was used randomly on the surface of the restorations. After cavity preparations, the teeth were randomly restored with one GIC and coated with Equia Coat or Fuji Varnish. The restorations were evaluated at baseline; six, 12, and 18 months; and six years after placement using modified USPHS criteria. Two evaluators checked color match, marginal discoloration, marginal adaptation, caries formation, anatomical form, postoperative sensitivity, and retention rate, and photographs were taken at each recall. The results were evaluated with Pearson chi-square and Mann-Whitney U-test ($p<0.05$).

Results: Thirty-seven patients were evaluated. There was a significant difference between EquiaFil and Riva SC regarding retention rate and color match after six years ($p=0.033$ and 0.046). When comparing baseline to six years, the overall success of EquiaFil was better than Riva SC, having significant problems regarding retention rate and anatomical form ($p=0.016$ and 0.031). Class II cavities were

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significantly worse in marginal adaptation, anatomical form, and retention rate in the Riva SC groups (p=0.033, 0.015, and 0.007) but not in the EquiaFil groups. The combination of the coatings had no effect on the overall success of the materials.

Conclusions: The EquiaFil system was more successful than Riva SC regarding color match, marginal adaptation, anatomic form, and retention rate after a six-year clinical evaluation period.

INTRODUCTION

For a few decades, a broad range of restorative dental materials has been emerging onto the market. Some of them needed special cavity designs, whereas others were intended to be used with adhesive dentistry. More recently, another treatment approach, minimal invasive dentistry, has gained popularity, especially in the field of operative dentistry. Today, restoring a tooth is not the only objective; it is also important to protect the existing tooth structures for a long period of time from any invasive treatment procedures. For that purpose, besides being esthetically pleasing, the new restorative materials of choice need to have good physical and mechanical properties and at the same time induce the remineralization of the tooth. One of the most popular and effective dental materials belonging to this group is glass ionomer cement (GIC).[1-3]

GICs, introduced by Wilson and Kent[4] in 1972, are a special group of dental materials having some very unique properties. They adhere to slightly moist enamel and dentin without the need for any adhesive system, they release fluoride and thus have anticariogenic effects for an extended period of time, they can absorb and release fluoride from topical fluoride solutions, they have thermal expansion similar to enamel, and they are biocompatible with a low toxicity. This group of materials is also considered to be "bioactive" due to these unique features. However, traditional GICs have some drawbacks, such as low fracture toughness, higher occlusal wear, and the need to be protected from initial dehydration and moisture uptake at the early maturation stage compared to other restorative materials, such as amalgam and modern resin composite restorative materials.[1-3,5] To avoid problems in the first 24 hours, copal varnish, light-cured bonding resins, petroleum jelly, cocoa butter, and even nail varnish have been used over the years.[6,7] It is presumed that this layer will prevent the restoration from dehydrating and maintain the all-important water balance in the system.[8] The longer this protective material is in contact with the restoration, the smaller the chance that its mechanical properties will decrease.[9]

In the late 1990s, many improvements and modifications have been made in GICs to overcome their disadvantages and to develop a material that may replace amalgam and that can be used in field conditions with atraumatic restorative treatment (ART) techniques.[10] However, these GICs exhibited a wear rate five times higher than amalgam and three times higher than resin composite materials[11] and were not found very successful in early clinical studies.[12,13] Consequently, their reputation did not change much, and they were still considered a semipermanent restorative material for small to moderate-size class I and II fillings in permanent teeth.[14] A few years later, due to the need for a cheap, tooth-colored material with easy handling properties, the development of high-viscosity, encapsulated, and packable GICs occurred. These were introduced to the market claiming superior physical and mechanical properties and a more translucent appearance than their predecessors due to the incorporation of glass particles.[1]

Early reviews published in 2004 and 2005 on the clinical performance of highly viscous GICs in posterior teeth indicated that their annual failure rate was estimated to be around 8%.[15,16] Scholtanus and Huysmans[17] published a six-year study in 2007 performed by two dentists in private practice with 116 class II restorations. According to their results, until 18 months, there were no problems; at the 3.5-year recall, the survival was 93%; and at six years, the survival dropped to 60% for the GIC tested. On the other hand, clinical trials performed with ART techniques and highly viscous GICs were very promising. Frencken and others[18] performed an ART study with Fuji IX and Ketec Molar, reporting a cumulative survival rate of 66.1% for GIC and 57% for amalgam after 6.3 years. Ersin and others[19] conducted a two-year clinical study with Fuji IX GP and a packable resin composite on primary molars restored again with ART and found a survival rate of 96.7% in class I and 76.1% in class II GIC restorations with no significant difference with the resin composite tested. A few years later, in 2011, Burke and others[20] evaluated 169 Fuji IX restorations in class I and II cavities placed by three dentists and found a survival rate of 98% after two years of follow-up, the main reason for replacement being fracture.

Table 1: *Description of Materials Used in This Study*

Material	Type	Manufacturer	Composition
EquiaFil	Conventional glass ionomer cement	GC (Tokyo, Japan)	Powder: 95% strontium fluoro alumino-silicate glass, 5% polyacrylic acid Liquid: 40% aqueous polyacrylic acid
Riva SC	Conventional glass ionomer cement	SDI (Bayswater, VIC, Australia)	Powder: Strontium fluoro alumino-silicate glass, polyacrylic acid copolymer powders, pigments Liquid: polyacrylic acid copolymers
Equia Coat	Low-viscosity nanofilled surface coating resin	GC	40%-50% methyl methacrylate, 10%-15% colloidal silica, 0.09% camphorquinone, 30%-40% urethane methacrylate, 1%-5% phosphoric ester monomer
Fuji Varnish	Classical varnish	GC	Isopropyl acetate, acetone, vinyl acetate, vinyl chloride copolymer, glycerol, resin acid esters

In 2007, a new glass ionomer concept consisting of a highly viscous encapsulated GIC, Fuji IX GP Extra (GC, Tokyo, Japan), and a nanofilled light-cured coating material, G-Coat Plus (GC), named Equia, was developed.[6] The changes in the formulation over the traditional GICs included a reduction in the size of the glass particles in the matrix, offering improved physical properties and stiffer syringeable materials that allow some packability to the material. The G-Coat Plus, with its low viscosity, can be used as a glaze on the top of the GICs and resin composites and can adhere to enamel and dentin as well. Furthermore, the nanofillers protect the GIC against abrasive wear that may occur during the early stage of a few months until the material becomes fully mature and resistant to intraoral situations.[1,8,21,22] A few years later, in 2009, this system was renamed EquiaFil and the coating Equia Coat.

To date, few prospective clinical studies have compared the long-term clinical performance of this new restorative system to other dental materials, these usually being resin composites. The available published studies derive mainly from data obtained from retrospective studies, including many operators of private practices,[8,23] or are performed with ART techniques in field conditions on primary teeth. The authors of this study could not find any other long-term clinical study comparing the clinical performance of encapsulated GICs between themselves. Furthermore, there are also no clinical studies comparing the effect of light-cured coatings to classical varnishes on GIC restorations.

Therefore, the aim of this study was to evaluate the long-term clinical performance of two encapsulated GICs (EquiaFil and Riva SC) covered with two different coatings (Equia Coat and Fuji Varnish) over six years using modified US Public Health Service (USPHS) criteria. The null hypothesis of the study was that after six years, there would be no difference in the clinical performance of the two GICs tested for the assessed criteria.

METHODS AND MATERIALS

In this six-year randomized prospective controlled clinical trial, two encapsulated GIC restorative materials—EquiaFil and Riva SC (SDI, Bayswater, VIC, Australia) in combination with two different coatings (Equia Coat and Fuji Varnish)—were evaluated. The materials used are described in Table 1.

Patient Recruitment

Patients applying for routine dental care at Ege University, School of Dentistry, were screened by the Department of Restorative Dentistry. The inclusion criteria for the selection of the patients for the study were as follows: 1) the patient should have good oral hygiene, 2) the patient has a need for at least two or more posterior restorations in contact with the neighbouring tooth and in occlusion with the antagonist teeth, 3) teeth planned to be restored should be vital and symptomless, and 4) the cavity isthmus size should be more than one-third the intercuspal distance. The exclusion criteria were as follows: 1) absence of adjacent and antagonist teeth, 2) teeth with periodontal problems, 3) teeth with preoperative pain or pulpal inflammation, 4) teeth formerly subjected to direct pulp capping, and 5) patients having severe systemic diseases, allergies, or adverse medical histories.

A total of 54 patients satisfying the inclusion criteria were selected to participate in this clinical trial. The average age of the patients was 34.6 years (range 17-55 years). All included patients were voluntary and signed a written informed consent.

Table 2: *Distribution of the Restorative Material Groups Among Dental Arches and Cavity Classes at the Beginning of the Study*

Restorative Materials	Maxillar		Mandibular		Class I	Class II	Total
	Premolar	Molar	Premolar	Molar			
EquiaFil + Equia Coat	10	19	10	37	28	44	**72**
EquiaFil + Fuji Varnish	9	14	11	20	33	21	**54**
Riva SC + Equia Coat	15	22	7	21	28	40	**68**
Riva SC + Fuji Varnish	11	29	9	16	35	27	**62**
Total	45	84	37	94	124	132	**256**

Restorative Procedures

One experienced dentist placed 124 class I and 132 class II restorations (256 restorations in total). The distribution of the materials, cavity classes, and tooth groups are depicted in Table 2. The filling materials EquiaFil or Riva SC were randomized over these two cavity groups using a randomization list.

Before treatment, preoperative digital photographs and periapical radiographs were taken, and the vitality of the tooth was recorded. Old restorations were removed and the enamel was prepared using diamond round and fissure burs (Komet, Gebr. Brasseler GmbH & Co KG, Lemgo, Germany) at high speed with water cooling. To remove caries, hand instruments and slow-speed steel burs were used. Local anesthesia was used only in patients complaining about pain or sensitivity. The isolation of the cavities was performed with cotton rolls and high-speed evacuation. For initial caries excavations, a minimal invasive cavity design was used. The two surface class II cavities were mostly medium size to large, but none of them involved any cusps. No beveling was performed in any of the cavities. A $Ca(OH)_2$ cavity liner (Dycal, Dentsply DeTrey, Konstanz, Germany) was applied where needed as a limited base material. A sectional matrix system (Palodent, Dentsply) was used to restore the class II cavities.

The cavities were restored using a bulk fill method with one of the encapsulated GICs (EquiaFil or Riva SC) and covered with a light-cured coating (Equia Coat) or a classical varnish (Fuji Varnish) according to the manufacturer's instructions. The P/L ratios of the glass ionomers were similar, being 0.40/0.12 for EquiaFil and 0.45/0.14 for Riva SC.

EquiaFil and Riva SC Restorative Procedures

After the cavity preparations, the dentin and enamel were conditioned with 20% polyacrylic acid for 10 seconds (Cavity Conditioner, GC) to remove the smear layer, rinsed thoroughly, and briefly air-dried without desiccating the surface. Both EquiaFil and Riva SC capsules were mixed for 10 seconds in a capsule mixer (Silvermix90, GC) and packed into the cavities with their respective gun injectors. The major grooves and fissures were modeled and the restorations left undisturbed for two minutes for initial setting according to the manufacturer's recommendations. Then the occlusion was checked with two layers of articulation paper and adjusted with water-cooled high-speed fine diamond burs (Komet).

As a last step, the restorations were quickly dried and covered randomly with one of the coating materials to be tested. Equia Coat was applied in one coat with its microbrush and light cured for 20 seconds using a light-curing unit (Bluephase C5, Ivoclar Vivadent, Liechtenstein), while Fuji Varnish was applied in two coats and left undisturbed until setting.

Evaluations and Recall Periods

One week after the restorations were placed, the patients were recalled, and two independent blinded clinicians making the baseline evaluations scored the restorations according to modified USPHS criteria.[10] The criteria evaluated were color match, marginal discoloration, marginal adaptation, anatomic form, caries development, postoperative sensitivity, and retention loss. The clinicians used mirrors and probes and took bitewing radiographs and intraoral digital photographs at baseline, six, 12, 18, and 72 months. If disagreement occurred during the evaluation stages, the final score decision was made by consensus of both examiners.

We anticipated that some marginal ridges of class II restorations might show some chipping during the course of the study that might not require the replacement of the entire restoration, only its repair. Thus, in agreement with the study of Peumans and others,[24] we thought that these restorations should be scored differently because they were not proper failures and could be maintained and monitored throughout the trial. For that purpose, we divided

Table 3: *Modified US Public Health Service (Ryge) Direct Evaluation Criteria*

Criteria	Inspection Method	Rating Scale
Color match	Visual inspection with a mirror at 18 inches	Alpha: The restoration matches the adjacent tooth structure in color and translucency. Bravo: Light mismatch in color, shade, or translucency between the restoration and the adjacent tooth. Charlie: The mismatch in color and translucency is outside the acceptable range of tooth color and translucency.
Marginal discoloration	Visual inspection with a mirror at 18 inches	Alpha: No discoloration anywhere along the margin between the restoration and the adjacent tooth. Bravo: Slight discoloration along the margin between the restoration and the adjacent tooth. Charlie: The discoloration penetrated along the margin of the restorative material in a pulpal direction.
Marginal adaptation	Visual inspection with a mirror at 18 inches	Alpha 1: Harmonious outline. Alpha 2: Marginal gap (max 100 μ) with discoloration (removable). Bravo: Marginal gap (>100 μ) with discoloration (unremovable). Charlie: The restoration is fractured or missing.
Anatomical form	Visual inspection with a mirror at 18 inches	Alpha 1: Continuous with existing anatomical form. Alpha 2: Slightly discontinuous due to some chipping on the proximal ridge. Bravo: Discontinuous with existing anatomical form due to material loss, but proximal contact still present. Charlie: Proximal contact is lost with ridge fracture.
Caries formation	Visual inspection with a mirror at 18 inches	Alpha: No evidence of caries. Bravo: Evidence of caries along the margin of the restoration.
Postoperative sensitivity	Visual inspection with a mirror at 18 inches	Alpha: No evidence of postoperative sensitivity. Bravo: Sensitivity present.
Retention rate	Visual inspection with a mirror at 18 inches	Alpha 1: Clinically excellent. Alpha 2: Clinically good with slight deviations from ideal performance; correction possible without damage of tooth or restoration. Bravo: Clinically sufficient with few defects; corrections or repair of the restoration possible. Charlie: Restoration is partially missing. Delta: Restoration is totally missing.

score Alpha into two groups, A1 and A2, for marginal adaptation, anatomic form, and retention rate criteria, as shown in Table 3.

Statistical Analysis

Statistical analysis was performed with SPSS version 13.0 software. To test the performance of the restorative materials according to USPHS criteria over the study period and to compare the acceptable versus unacceptable scores, the Pearson chi-square test was used. The Mann-Whitney U-test evaluated the comparison of the different coatings on the performance of the GIC tested. The level of significance was set at $\alpha=0.05$ for all tests.

RESULTS

Through 18 months, 52 patients with 248 restorations were evaluated. However, after six years, 37 patients and 88 restorations per glass ionomer group (total of 176 restorations, recall rate 68.75%) were available for recall. The scores obtained during the recalls and the distribution of the materials/coating combinations over the study period are detailed in Table 4.

In the modified USPHS evaluation criteria, scores A and A1 meant the highest degree of clinical acceptability, while A2 meant a clinically acceptable restoration having minor reparable problems. Score B stood for a clinically acceptable restoration that did not need replacement but could survive with some repairs, and scores C/D stood for unacceptable restorations that needed to be replaced.

None of the patients at any time interval of the study experienced pain or postoperative sensitivity from the restored teeth, and no incidence of caries formation was observed.

Table 4: *US Public Health Service Scores Obtained During the Recall Periods*

Criteria	Baseline			Six Months			12 Months			18 Months			Six Years			
	A1/A2	B	C	A1/A2	B	C	A1/A2	B	C	A1/A2	B	C	A1/A2	B	C	D
Color match																
EG	19	36	7	19	36	7	19	36	7	19	36	19	43	2	0	—
EV	16	36	10	16	36	10	16	36	10	16	36	16	43	0	0	—
RG	0	8	54	0	8	54	0	8	54	0	8	0	30	5	12	—
RV	1	6	55	1	6	55	1	6	55	1	6	1	28	5	8	—
Marginal adaptation																
EG	62	0	0	59/1	2	0	55/4	2	1	53/4	1	53/4	35/0	4	1	—
EV	62	0	0	60/0	1	1	59/1	1	1	58/1	1	58/1	43/2	3	0	—
RG	62	0	0	62/0	0	0	59/3	0	0	56/4	1	56/4	39/4	3	3	—
RV	62	0	0	59/3	0	0	56/6	0	0	55/6	1	55/6	30/3	4	2	—
Anatomic form																
EG	62	0	0	59/1	2	0	56/3	2	1	53/3	1	53/3	40/1	4	1	—
EV	62	0	0	60/0	1	1	59/1	1	1	58/1	1	58/1	37/1	3	1	—
RG	62	0	0	62/0	0	0	60/2	0	0	57/3	1	57/3	43/2	4	4	—
RV	62	0	0	59/3	0	0	56/6	0	0	55/6	1	55/6	28/4	1	2	—
Retention rate																
EG	62	0	0	59	3	0	55	6	1	52	5	52	40	3	1	0
EV	62	0	0	60	1	1	59	2	1	58	2	58	41	3	0	0
RG	62	0	0	62	0	0	58	4	0	55	6	55	37	2	3	1
RV	62	0	0	59	3	0	58	4	0	57	4	57	40	2	2	1
Marginal discoloration																
EG	62	0	0	62	0	0	62	0	0	62	0	62	43	0	0	—
EV	62	0	0	61	1	0	61	1	0	61	1	61	43	2	0	—
RG	62	0	0	61	1	0	60	2	0	60	2	60	43	0	0	—
RV	62	0	0	62	0	0	62	0	0	62	0	62	43	2	0	—
Caries formation																
EG	62	0	—	62	0	—	62	0	—	62	0	62	44	0	—	—
EV	62	0	—	62	0	—	62	0	—	62	0	62	44	0	—	—
RG	62	0	—	62	0	—	62	0	—	62	0	62	44	0	—	—
RV	62	0	—	62	0	—	62	0	—	62	0	62	44	0	—	—
Postoperative sensitivity																
EG	62	0	—	62	0	—	62	0	—	62	0	62	44	0	—	—
EV	61	1	—	62	0	—	62	0	—	62	0	62	44	0	—	—
RG	61	1	—	62	0	—	62	0	—	62	0	62	44	0	—	—
RV	62	0	—	62	0	—	62	0	—	62	0	62	44	0	—	—

Abbreviations: EG, EquiaFil + Equia Coat; EV, EquiaFil + Fuji Varnish; RG, Riva SC + Equia Coat; RV, Riva SC + Fuji Varnish.

The resin coating and the varnish applied on all restorations were worn away in nearly all of the restorations after six months. However, this was not seen as a problem, and during the other study recalls, we could not find any significant difference or influence of the different coatings on the success rate of either glass ionomer ($p \geq 0.05$) (Figure 1).

Regarding the color-match criteria, there was a significant difference between EquiaFil and Riva SC in all of the recall periods ($p \leq 0.05$). After 18 months, there was a pronounced color mismatch (score C) in Riva SC coated with Equia Coat (87.1%) and Riva SC coated with Fuji Varnish (88.7%) compared to both EquiaFil groups. The color match of both EquiaFil groups was eight times better than all the Riva SC groups. The match of these groups was found to be better after six years, but the significant difference was maintained ($p \leq 0.05$).

Compared to baseline, the difference in the marginal discoloration scores of EquiaFil and Riva SC groups was not significantly different in any of the recalls during the six years ($p \geq 0.05$) (Figure 2).

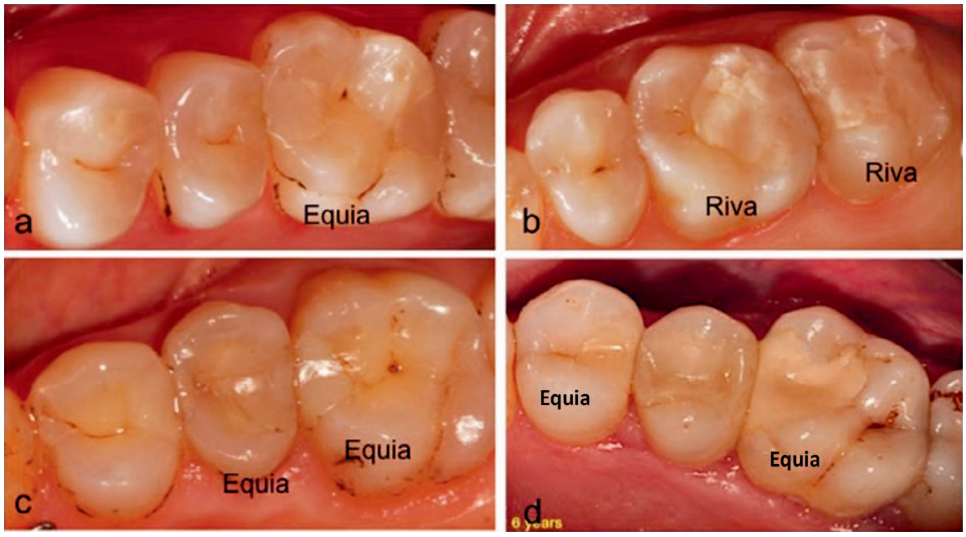

Figure 1. *(a-d): EquiaFil and Riva SC class II restorations scored as 'A' after six-year recall.*

Until the 18-month recall, for marginal adaptation, anatomic form, and retention rate, due to the low number of restorations that had problems in all the groups, Pearson chi-square could not be performed. All the class I restorations were found to be perfect, while a total of nine class II restorations had to be replaced: five cases of EquiaFil + G Coat (8.1%), two cases of EquiaFil + Fuji Varnish (3.2%), one case of Riva SC + G Coat (1.6%), and one case of Riva SC + Fuji Varnish (1.6%). However, at the six-year recall, the difference was significant for all three criteria mentioned above for class II restorations between the two main GIC groups regardless of the coating used ($p \leq 0.05$) (Figure 3). Regarding the marginal adaptation criteria, in the EquiaFil group, one restoration had to be replaced (1.1%), while in the Riva SC group, five cases (5.6%) were scored as unacceptable ($p=0.033$). For the anatomic form criteria, in the EquiaFil group, two restorations had to be replaced (2.27%), while in the Riva SC group, six cases (6.81%) were scored as unacceptable ($p=0.015$) (Figure 4).

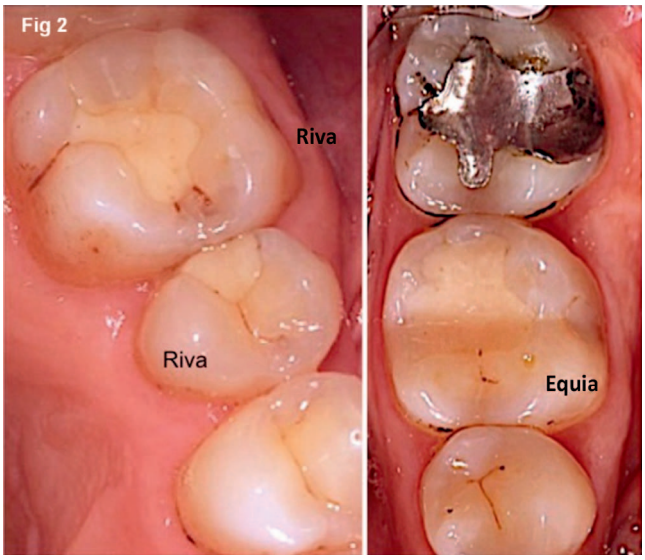

Figure 2. *(Left): Two Riva SC restorations having a color mismatch and some marginal discolorations after six years. (Right): One EquiaFil occlusal restoration having an 'A' score in all the criteria after six years.*

In the retention rate criteria, both partial loss (score C) and total loss of the restorations (score D) were considered as failure. In the EquiaFil group, one restoration had to be replaced (1.13%), while six had to be repaired. In the Riva SC group, five cases (5.68%) were scored as partial loss, while two restorations (2.27%) had to be replaced and were scored as unacceptable ($p=0.007$) (Figure 5). The total failure rate for Riva SC was found to be 7.95% after six years of clinical service.

DISCUSSION

Clinical evaluations of restorative materials are essential in order to obtain data on their clinical performance and *in vivo* longevity. Clinical trials with GICs as permanent restorative materials were conducted mostly on class I cavities,[10,25,26] and there are limited data showing their performance in class II cavities. Moreover, in the past, clinical studies on GICs were performed usually in primary molars and with ART techniques.[19,27,28] The results were mostly positive; however, the materials were powder/liquid, and the coatings were usually classical varnishes. In the past decade, long-term clinical studies on GICs have been performed on adult patients' posterior teeth having small to moderate-size cavities[18] with

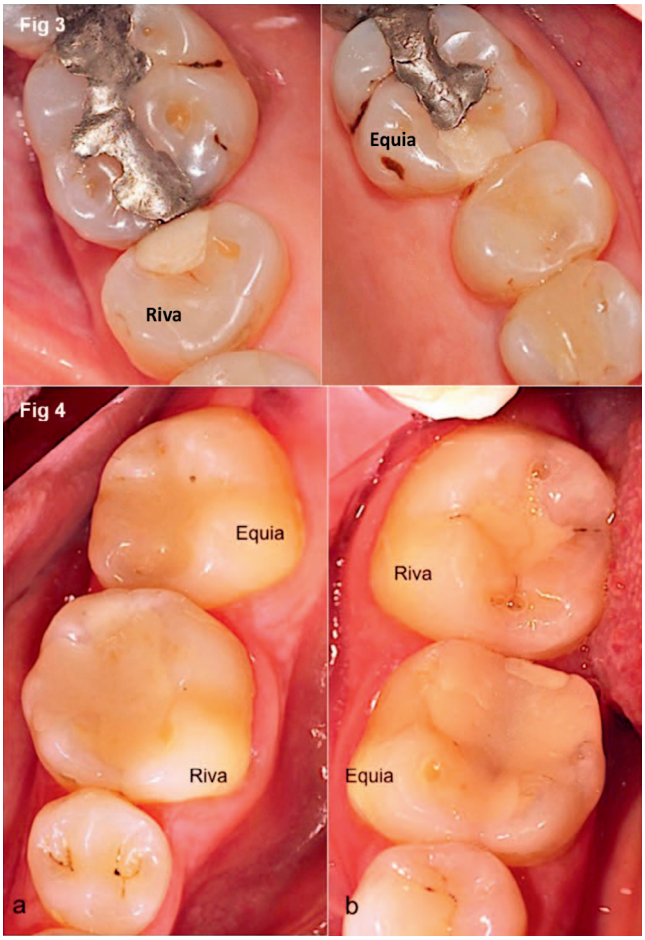

Figure 3. *(Left): One class II Riva SC restoration receiving an 'A2' score for marginal adaptation and anatomic form and a 'C' score for color match after six years. (Right): One class II EquiaFil restoration receiving an 'A' score for all the criteria after six years.*
Figure 4. *(a): Six-year recall of perfect EquiaFil restoration and a 'B' score for Riva SC restoration. (b): Six-year recall of an occlusal Riva SC restoration having a slight color mismatch and a large class II EquiaFil restoration being repaired at 18 months and still functioning at the six-year recall.*

better results with reinforced GICs and in small restorations.[14,17,23] The present study was performed on adult patients with an average age of 34.6 years and having moderate-size to large class I and II cavities. Many of the class II cavities had very large proximal boxes that were beyond the indicated application of both glass ionomers. This procedure was an especially great challenge for Riva SC, which was more clearly indicated for non–stress-bearing class II cavities.

According to the American Dental Association, a material intended to be used in posterior teeth needs to have a retention rate of at least 90% after 18 months of clinical service to become fully accepted as a definitive restorative material.[29] In our study, after 18 months, only a few changes were noted in the evaluated GICs, making both materials suitable for permanent posterior teeth restorations. However, at the six-year recall, the difference between the materials was more pronounced.

Color match was a great problem in conventional GICs due to the lack of translucency of the material. However, some reinforced and modern GICs exhibit a better match with adjacent tooth structures, partially due to the small glass particles and filled resin-based coating materials. In our study, both GICs were reinforced; however, EquiaFil's color match was found to be eight times better than Riva SC after 18 months. The difference was less visible after six years due to the improvement in translucency over time of the materials as the cements mature.[7] To overcome these shade problems, in 2014, the manufacturer of Riva SC launched more translucent and esthetic shades (T-A2, T-A3, and T-A3.5).

The applied coatings sealed the restorations in a thickness of 35-40 μ,[30] protected the margins, and created a regular and glossy surface. However, they disappeared in nearly all cases at the six-month recall, leaving a slightly rougher surface than the adjacent enamel. With time, these coatings were lost by oral mastication wear, but during this time, the cements are expected to become more resistant to variation in water balance and fully mature with maximum mechanical strength.[31] The same findings were obtained in a study by Miletic and others.[32] Lohbauer and others[25] conducted an *in vitro* study to compare the three-point fracture strength (FS) and three-body wear of G-Coat Plus–coated and –non-coated Fuji IX GP Extra samples. According to their findings, the GIC surface must be resin coated to improve its mechanical strength and wear resistance. Similarly, Bonifacio and others[21] measured the FS and wear of coated versus uncoated Fuji IX GP Extra specimens and concluded that the resin coating improved the FS and wear resistance of the GIC tested. In contrast to these studies, Bagheri and others[33] compared the fracture toughness (FT) by a four-point bending test of Fuji IX GP Extra and a resin-modified GIC and found that the FT of the GIC was not affected by the resin coating.

The absence of failures due to secondary caries after six years is most likely due to the anticariogenic effect and fluoride release of the GICs.

Marginal discoloration was moderate and was seen only in a few cases during the six-year period

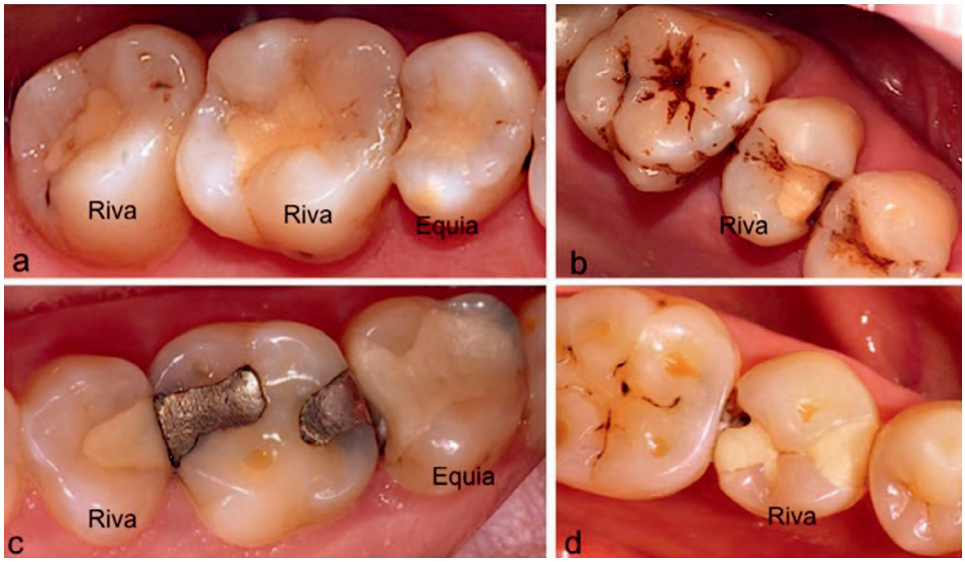

Figure 5. *(a): EquiaFil OD restoration receiving a 'B' score for anatomic form and retention rate after six years. (b): Riva SC restoration being scored as 'C' for marginal adaptation, anatomic form, and retention rate after six years. (c): Perfect Riva SC restoration and EquiaFil restoration scored as 'B' for anatomic form and 'A2' for retention rate after six years. (d): Riva restoration scored as 'C' for anatomic form and retention rate after six years.*

of evaluation. This is probably due to the self-adhesion of the glass ionomers to tooth structures without the need of adhesive systems.

Anatomic form, marginal adaptation, and retention loss are more or less related USPHS criteria for posterior restorative materials. The loss of anatomical form of restorations is an indication of wear and morphological changes, especially in class II restorations. In the present study, as in the study of Peumans and others,[24] all of the three criteria were modified for the Alpha score because of the nature of the GIC. In the original USPHS criteria, an Alpha score meant that the monitored restoration was in perfect condition, while a Bravo score meant that it had some minor problems that did not affect the performance of the material. In our study, an Alpha 2 score was added for marginal adaptation and meant that a marginal gap less than 100 μ was present with a slight discoloration that could be removed by polishing. Regarding anatomical form, an Alpha 2 score meant that the restoration was slightly discontinuous due to some chipping on the proximal ridge of the class II restorations. For the retention loss criteria, an Alpha 2 score was set mainly for class II restorations that deviated slightly from ideal performance and that had minimal material loss that may be corrected without inducing any damage to the adjacent tooth structures or the restoration itself.

In the present study, the evaluated clinical performance of GIC until 18 months was found to be excellent without any difference between the materials or coating applications.[34] However, between 18 months and six years, the clinical performance of Riva SC GIC in moderate-size to large class II restorations was significantly worse that EquiaFil for marginal adaptation, anatomic form, and retention loss. Similar to our results, Scholtanus and others[17] found no failure at 18 months in their long-term clinical study evaluating the previous version of EquiaFil: Fuji IX GP. However, at six years, the survival rate dropped to 60%. Our results might be due to the composition and amount of the strontium fluoro alumino-silicate glass present in the Riva SC material, probably being more close to conventional glass ionomers than to reinforced materials. In addition, Riva SC was developed for the restoration of only small and non–stress-bearing class II restorations, and this could have made it less successful in moderate-size to large restorations. It is our opinion that to be able to have long-term successful results with this material, the cavity size should be small to moderate, and the width of the proximal box should not exceed the half of the intercuspal distance.

In a review performed in 2005 by Hickel and others[15] on primary molar teeth and with conventional GICs, the main reason of failure in class II restorations was reported to be fracture. Again, in the study by Frankenberger and others,[14] Ketac Molar covered with Ketac Glaze in class I and II restorations was evaluated for two years, and they reported having lost the interproximal contacts in 40% of the class II restorations due to bulk

fracture, meaning an annual failure of 20%. However, the dropoff rate was 76%, and this may have influenced the low performance of the material. According to Basso and others,[30] the possibility of achieving durable class II restorations with GICs is related to the width of the mesial or distal box of the cavity. Much chipping and some failures of their 48-month clinical study performed with Equia were located in the marginal proximal crest of wider restorations. Similarly, in our study, marginal chipping and fractures were seen mainly in large proximal ridges of the class II restorations. Some of them could be repaired and maintained, while some had to be replaced. For repairing the chipping, we performed a retentive slot cavity in the proximal box of the class II restoration, placed a sectional matrix, and filled the new cavity with a fresh glass ionomer capsule to restore the proximal contact. When the fracture is large and the dentin is exposed or the proximal contact is totally lost, the replacement of the filling would be more appropriate than a repair.

Reinforced restorative GICs are a relatively new group of material; thus, published long-term clinical studies with these materials are few. To the authors' knowledge, there are no long-term clinical studies comparing the performance of two glass ionomers and two coating materials. Of the few published studies, many compared GICs to resin composites and were mainly retrospective and performed with more than one operator in general dental practices. However, carefully designed prospective studies performed in ideal conditions by a single operator and evaluated by two independent calibrated clinicians are superior to retrospective studies that provide data that were recorded for other reasons than research and evaluated by the operator him- or herself.

In a clinical study comparing EquiaFil and a resin composite, Gradia Direct Posterior, performed by Gürgan and others,[35] it was found that after four years, the success rates for class I and class II Gradia Direct Posterior restorations were 100%, whereas the failure rate was 7.7% for class II EquiaFil restorations. No significant change over time was found for the anatomical form, color match, secondary caries, postoperative sensitivity, surface texture, and retention for either restorative material. There was also no significant difference between the two restorative materials in terms of marginal discoloration at any recall period.

Diem and others[8] reported one of the few published studies comparing Fuji IX Extra (EquiaFil) with and without coating (Equia Coat) and also a microfine hybrid resin composite in the restoration of the first premolars of young children with the ART technique in field conditions. After three years, the color match of all the restorations improved, with no differences between the materials. Moderate marginal staining was depicted, and marginal adaptation loss was minimal for all restorations. They concluded that Fuji IX GP Extra with or without the coating showed acceptable clinical performance compared to the tested resin composite. Moreover, according to casts obtained from these restorations, the application of Equia Coat was found beneficial in reducing the wear of this GIC in class I restorations. Similar to our results, they found a rate of 3% of surface chipping or cracks in the GIC and of 2% in the resin composite. They concluded that notable marginal fractures did not become apparent until the third year in the Fuji IX Extra group.

Friedly and others[23] evaluated the performance of 151 Equia restorations in single- and multisurface posterior restorations for 24 months and found that large cavities had more volume loss, but all the restorations were scored as satisfactory at the end of the study. Khandelwal and others[36] evaluated the EquiaFil system for a period of two years. They reported 88.8% success in class I restorations and a perceptible roughness in 11.5% of the restorations with very few marginal disintegrations. Miletic and others[32] evaluated 45 Equia system restorations in a one-year pilot study and found that all the restorations were clinically acceptable.

In the present study, the EquiaFil system in both cavity types exhibited significantly better clinical outcomes over the observation period of six years than Riva SC. Therefore, the null hypothesis formulated at the beginning of the study was rejected.

Reinforced GICs may be considered as the material of the future in restorative dentistry and minimally invasive dentistry. Their long-term clinical success is making them promising as a permanent restorative material, even in moderate-size class II restorations. Further developments are needed to improve their mechanical properties and extend their indications.

CONCLUSION

The highly viscous reinforced GIC restorative system EquiaFil showed acceptable clinical performance according to modified USPHS criteria in

class I and moderate-size to large class II restorations over a period of six years.

Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subject's oversight committee guidelines and policies of Ege University. The approval code for this study is 08-10.1/6, 29.12.2007.

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Conflict of Interest

The authors have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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