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Four-year Randomized Clinical Trial to Evaluate the Clinical Performance of a Glass Ionomer Restorative System

S Gurgan • ZB Kutuk • E Ergin
SS Oztas • FY Cakir

Clinical Relevance

The clinical effectiveness of Equia and Gradia Direct Posterior was acceptable in Class 1 and Class 2 cavities subsequent to four-year evaluation.

SUMMARY

Objective: The aim of this study was to evaluate the clinical performance of a glass ionomer restorative system compared with a microfilled hybrid posterior composite in a four-year randomized clinical trial.

Methods: A total of 140 (80 Class 1 and 60 Class 2) lesions in 59 patients were either restored with a glass ionomer restorative system (Equia, GC, Tokyo, Japan), which was a combination of a packable glass ionomer (Equia Fil, GC) and a self-adhesive nanofilled coating (Equia Coat, GC), or with a microfilled hybrid composite (Gradia Direct Posterior, GC) in combination with a self-etch adhesive (G-Bond, GC) by two experienced operators according to the manufacturer's instructions. Two independent examiners evaluated the restorations at baseline and at one, two, three, and four years postrestoration according to the modified US Public Health Service criteria. Polyvinyl siloxane impression negative replicas at each recall were observed under scanning electron microscopy (SEM) to evaluate surface characteristics. The statistical analyses were carried out with McNemar, Pearson Chi-square, and Cochran *Q*- tests ($p<0.05$).

Results: After four years, 126 (76 Class 1 and 50 Class 2) restorations were evaluated in 52 patients, with a recall rate of 88.1%. None of the restorations showed trends to downgrade in anatomical form, secondary caries, surface texture, postoperative sensitivity, and color

Sevil Gurgan, DDS, PhD, professor, Hacettepe University, Restorative Dentistry, Ankara, Turkey

Zeynep Bilge Kutuk, DDS, Hacettepe University, Restorative Dentistry, Ankara, Turkey

Esra Ergin, DDS, PhD, associate professor, Hacettepe University, School of Dentistry, Department of Restorative Dentistry, Ankara, Turkey

Sema Seval Oztas, DDS, Hacettepe University, School of Dentistry, Department of Restorative Dentistry, Ankara, Turkey

*Filiz Yalcin Cakir, DDS, PhD, professor, Hacettepe University, Restorative Dentistry, Ankara, Turkey

*Corresponding author: Sihhiye, Ankara, 06100, Turkey; e-mail: fyalcin@hacettepe.edu.tr

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match ($p>0.05$). Significant differences in marginal adaptation and discoloration were found at four years compared to baseline for both restorative materials for Class 1 and Class 2 restorations ($p<0.05$). Only one Class 2 Equia restoration was missing at three years (3.9%), and another one was missing at four years (7.7%) ($p>0.05$). SEM evaluations were in accordance with the clinical findings.

Conclusions: The use of both materials for the restoration of posterior teeth exhibited a similar and clinically successful performance after four years.

INTRODUCTION

Over the course of the last several decades, an increasing variability of dental restorative materials has conquered the market. The concepts in restorative dentistry are also changing, and adhesive dentistry has steadily gained in importance. Today, the modern operative dentistry focus is on minimal removal of tooth tissue and on application of adhesive restorative materials that possibly perform therapeutic action on demineralized dentin. Those requirements are perfectly matched by glass ionomer cements (GICs).[1-3]

GICs are clinically attractive dental materials and have certain unique properties that make them useful as restorative and adhesive materials. Since the introduction of GICs by Wilson and Kent,[4] many modifications of these materials have been performed over the years. Despite having advantages such as adhesion to moist tooth structure and base metals, anticariogenic properties due to the release of fluoride, thermal compatibility with tooth enamel, and biocompatibility and low toxicity, GICs suffer from low fracture toughness and a higher rate of occlusal wear compared to other restorative materials, such as amalgam and modern composite restorative materials.[1-3,5]

Today, highly viscous GICs achieve superior physical properties compared to traditional GICs by optimizing polyacid and particle size distribution, resulting in a high cross-linkage in the GIC matrix.[1] Recently, a new restorative concept has been marketed (Equia, GC, Tokyo, Japan): a system consisting of a highly viscous conventional GIC (Equia Fil, formerly known as Fuji IX GP Extra) combined with a novel nanofilled coating material (Equia Coat, formerly known as G-Coat Plus).[6] This self-adhesive, nanofilled resin coating, which provides a high hydrophilicity combined with an extremely low viscosity, accounts for the perfect seal of a GIC surface. Compounded nanofillers are thereby intended to protect the system against abrasive wear. This is of importance in the first months until the GIC is completely matured and able to withstand the intraoral stresses. The coating acts as a glaze, further increasing the esthetic properties.[1,6,7]

Reviews have indicated that to date no study regarding the long-term clinical success of this new restorative system has been reported. Therefore, the purpose of this study was to evaluate the clinical performance of this highly viscous conventional GIC restorative system (Equia System/GC) and a microfilled hybrid resin composite (Gradia Direct Posterior/GC) as a comparison material using modified US Public Health Service (USPHS) criteria. The null hypothesis was that under the conditions of this study there would be no difference in the clinical performance of the two restorative materials for the criteria assessed.

METHODS AND MATERIALS

In this four-year randomized controlled clinical study, the GIC restorative material (Equia System, GC, Tokyo, Japan) and a microfilled hybrid composite resin (Gradia Direct Posterior, GC, Tokyo, Japan) were compared. These materials are described in Table 1.

Study Population and Sample Size

Following the approval of the study by the Ethical Committee of Hacettepe University, Ankara, Turkey (protocol HEK 09/112-10), a group of patients seeking routine dental care and recruited by the Hacettepe University, School of Dentistry, Department of Restorative Dentistry were screened, and a total of 59 patients satisfying the inclusion and exclusion criteria were selected. Inclusion criteria were as follows: a patient presenting with 1) a need for at least two but not more than four posterior tooth-colored restorations; 2) the presence of teeth to be restored in occlusion; 3) teeth that were symptomless and vital; 4) a normal periodontal status; and 5) a good likelihood of recall availability. Exclusion criteria were as follows: 1) partly erupted teeth; 2) absence of adjacent and antagonist teeth; 3) poor periodontal status; 4) adverse medical history; and 5) potential behavioral problems. The average age of patients was 24 years (range, 15-37 years). All patients participated voluntarily and were required to provide written informed consent.

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

Material	Type	Manufacturer	Composition
Equia Fil	Conventional glass ionomer cement	GC, Tokyo, Japan	Powder: 95% strontium fluoroalumino-silicate glass, 5% polyacrylic acid
			Liquid: 40% aqueous polyacrylic acid
Equia Coat	Low-viscosity nanofilled surface coating resin	GC, Tokyo, Japan	50% Methyl methacrylate, 0.09% camphorquinone
Gradia Direct Posterior	Microfilled hybrid composite	GC, Tokyo, Japan	Urethane dimethacrylate co-monomer matrix, silica, pre-polymerized fillers, fluoroalumino-silicate glass
G-Bond	All-in-one dentin/enamel bonding agent	GC, Tokyo, Japan	40% Acetone, 20% distilled water, 15% 4-methacryloxy-ethyltrimellitate anhydride, 10-20% urethane dimethacrylate, 10% triethyleneglycoldimethacrylate

Restoration Placement

Two experienced dentists placed 80 Class 1 and 60 Class 2 restorations, totaling 140 restorations in 59 patients (Table 2). The filling materials Equia or Gradia Direct Posterior were randomized over these two cavity groups using a table of random numbers.[8] Before treatment, initial periapical radiographs of the teeth to be treated were taken and vitality test scores were recorded. Cavities were prepared using diamond fissure burs (MS Rounded Edged Cylinder Bur [835R-012-4], Diatech, Heerbrugg, Switzerland) at high speed with water-cooling. Hand instruments and slow-speed tungsten carbide burs were used to remove the caries. Local anesthesia was applied to patients complaining about pain or sensitivity to prevent discomfort during restorative procedures.[9] Conservative cavity design was used according to the principals of minimal invasive dentistry. None of the cavity preparations involved one or more cusps. All of the gingival margins included sound enamel. No beveling was applied to the cavity walls. $CaOH_2$ cavity liner (Life Regular Set, Kerr Corporation, Romulus, MI, USA) was applied where needed as base material. An ivory type matrix system (Hahnenkratt, Königsbach-Stein, Germany) was used for Class 2 cavities. All of the cavities were either restored with glass ionomer restorative system (Equia, GC), which is a combination of a packable glass ionomer (Equia Fil, GC) and a self-adhesive nanofilled coating (Equia Coat, GC) or microfilled hybrid composite (Gradia Direct Posterior, GC) in combination with a self-etch adhesive (G-Bond, GC), according to the manufacturer's instructions.

Glass Ionomer Restorations

The dentin and enamel of cavities were conditioned with 20% polyacrylic acid for 20 seconds (Cavity Conditioner, GC), washed, and briefly dried. Equia Fil was injected into the cavity. Isolation was maintained using cotton rolls and a saliva ejector. After the passage of the manufacturer's recommended setting time of 2.5 minutes, the restoration was trimmed and polished wet using high-speed fine diamonds (Diatech, Swiss Dental, Heerbrugg, Switzerland). After the restoration was briefly dried, Equia Coat was applied and photocured for 20 seconds using a photo-curing light (Radii Plus, SDI, Bayswater, Australia).

Composite Resin Restorations

After the enamel and dentin were conditioned with G-Bond (GC) using a microtip applicator, left undisturbed for five to 10 seconds, and then dried thoroughly for five seconds with oil-free air under air pressure, Gradia Direct Posterior resin was applied with the incremental technique (2-mm thick layers) and light-cured for 20 seconds. Finally, the restoration was shaped with finishing diamonds and silicon instruments (Hi Luster Plus Polishing System, KerrHave, Bioggio, Switzerland).

Table 2: *Distribution of the Restorative Materials Among Dental Arches*

Restorative Materials	Maxillary				Mandibular				Total
	Premolar		Molar		Premolar		Molar		
	Class 1	Class 2	Class 1	Class 2	Class 1	Class 2	Class 1	Class 2	
Equia	8	8	10	8	4	8	18	6	70
Gradia Direct Posterior	9	7	9	9	5	5	17	9	70
Total	17	15	19	17	9	13	35	15	140

Table 3: *Recall Rates of Patients*

Restorative Materials	Baseline		1 Year		2 Years		3 Years		4 Years	
	Class 1	Class 2	Class 1	Class 2	Class 1	Class 2	Class 1	Class 2	Class 1	Class 2
Equia	33	26	32	25	33	22	33	21	32	20
Gradia Direct Posterior	33	26	32	25	33	22	33	20	32	20
Total	59		57		55		53		52	
(%)	100		96.6		93.2		89.8		88.1	

One week after restoration placement (baseline), patients were recalled and restorations were examined clinically. Direct clinical evaluation of restorations was performed using the modified USPHS criteria[10] by two independent investigators using mirrors, probes, bitewing radiographs, and intraoral photographs. Patients were recalled at one, two, three, and four years for assessments of the restorations using the same criteria as at baseline. At each recall, the same two calibrated evaluators, who were blinded to the restoratives used for cavities and patients, examined the restorations. When disagreement occurred during the evaluation, the final decision was made by consensus of both examiners.

Scanning Electron Microscopy (SEM) Analysis

At each recall, impressions of each air-dried, cotton-roll–isolated tooth were taken from one patient selected randomly from each group with polyvinyl siloxane impression material and used as negative replicas for morphological observation with SEM. The replicas were gold sputter-coated and observed under SEM (JSM-6400 SEM, JEOL, Tokyo, Japan) at 50× and 200× magnifications for surface morphology and marginal integrity.

Statistical Analysis

Statistical analysis was performed with SPSS 15.0 software. To compare the performance of restorative materials according to USPHS criteria over the study period, the McNemar test was used. Within each material group, further analysis was done using the Pearson Chi-square test to distinguish the differences between different cavity types for marginal adaptation and marginal discoloration. The Cochran *Q*-test was then used to compare the marginal adaptation and marginal discoloration scores of each material with baseline scores for each cavity type to evaluate the changes of each dependent group by the time. The level of significance was set at $p<0.05$ for all tests.

RESULTS

After four years, 126 (76 Class 1 and 50 Class 2) restorations in 52 patients were evaluated and scored according to the USPHS criteria. The recall rate of the patients was 88.1% at four years (Table 3). The overall clinical recall rate of restorations at the four-year recall was 90%. Fourteen (four Class 1 and 10 Class 2) original restorations could not be evaluated at four years because seven patients (11.9%) had moved away. Table 3 also shows the number of recalls at one, two, three, and four years.

After four years, success rates for Class 1 Equia, Class 1 Gradia Direct Posterior, and Class 2 Gradia Direct Posterior were 100%, whereas the failure rate was 7.7% for only Class 2 Equia restorations. Only one Class 2 restoration had to be replaced as a result of marginal fracture at three years and one at four years. 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 ($p>0.05$).

Clinically acceptable (Bravo) moderate marginal discolorations were noted for both materials at one year (three [7.7%] Class 1 and two [6.9%] Class 2 Equia restorations and three [7.7%] Class 1 and two [6.9%] Class 2 Gradia Direct Posterior restorations), two years (three [7.7%] Class 1 and two [7.7%] Class 2 Equia restorations and five [12.9%] Class 1 and five [18.6%] Class 2 Gradia Direct Posterior restorations), three years (three [7.7%] Class 1 and two [8%] Class 2 Equia restorations and five [12.9%] Class 1 and five [18.6%] Class 2 Gradia Direct Posterior restorations), and four years (two [5.3%] Class 1 and two [8.4%] Class 2 Equia restorations and five [13.2%] Class 1 and five [19.3%] Class 2 Gradia Direct Posterior restorations) (Table 4a,b). Equia Class 1 restorations exhibited a significant difference starting at two years, whereas Class 2 restorations showed significant differences starting at three years ($p<0.05$) for marginal discolorations. Both Class 1 and Class 2 Gradia Direct Posterior restorations exhibited significant changes starting

Table 4a: *Clinical Evaluation Scores of the Equia Restorations at Baseline and at One, Two, Three, and Four Years*

USPHS Criteria	USPHS Scores	Equia, No. (%)									
		Class 1 (N=40)					Class 2 (N=30)				
		Baseline	1 Year	2 Years	3 Years	4 Years	Baseline	1 Year	2 Years	3 Years	4 Years
Anatomical form	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	30 (100)	29 (100)	26 (100)	25 (100)	24 (100)
	Bravo	0	0	0	0	0	0	0	0	0	0
	Charlie	0	0	0	0	0	0	0	0	0	0
Color match	Alfa	40 (100)	39 (100)	38 (97.4)	38 (97.4)	37 (97.3)	30 (100)	29 (100)	26 (100)	25 (100)	24 (100)
	Bravo	0	0	1 (2.6)	1 (2.6)	1 (2.7)	0	0	0	0	0
	Charlie	0	0	0	0	0	0	0	0	0	0
Marginal discoloration	Alfa	40 (100)	36 (92.3)	36* (92.3)	36* (92.3)	36* (94.7)	30 (100)	27 (93.1)	24 (92.3)	23* (92)	22* (91.6)
	Bravo	0	3 (7.7)	3 (7.7)	3 (7.7)	2 (5.3)	0	2 (6.9)	2 (7.7)	2 (8)	2 (8.4)
	Charlie	0	0	0	0	0	0	0	0	0	0
Marginal adaptation	Alfa	40 (100)	33 (84.6)	31* (79.5)	31* (79.5)	31* (81.5)	30 (100)	25 (86.2)	22 (84.6)	19* (76)	18* (75)
	Bravo	0	6 (15.4)	8 (20.5)	8 (20.5)	7 (18.5)	0	4 (13.8)	4 (15.4)	6 (24)	6 (25)
	Charlie	0	0	0	0	0	0	0	0	0	0
Secondary caries	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	30 (100)	29 (100)	26 (100)	25 (100)	24 (100)
	Charlie	0	0	0	0	0	0	0	0	0	0
Postoperative sensitivity	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	30 (100)	29 (100)	26 (100)	25 (100)	24 (100)
	Bravo	0	0	0	0	0	0	0	0	0	0
	Charlie	0	0	0	0	0	0	0	0	0	0
Surface texture	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	30 (100)	29 (100)	26 (100)	25 (100)	24 (100)
	Bravo	0	0	0	0	0	0	0	0	0	0
	Charlie	0	0	0	0	0	0	0	0	0	0
Retention	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	30 (100)	29 (100)	26 (100)	25 (96.1)	24 (96)
	Charlie	0	0	0	0	0	0	0	0	1 (3.9)	1 (4)

Abbreviation: USPHS, US Public Health Service.
** Indicates significant difference in comparison with baseline according to Cochrane Q-test ($p<0.05$).*

at two years ($p<0.05$) (Table 4b). However, the McNemar test indicated no significant difference between the two restorative materials in terms of marginal discoloration at any recall period ($p>0.05$) (Table 5). In addition, there were no significant differences between the marginal discoloration scores of Class 1 and Class 2 cavities for either restorative material at one, two, three, and four years ($p>0.05$) (Table 6).

Moderate marginal adaptation was also noted for both materials at one year (six [15.4%] Class 1 and four [13.8%] Class 2 Equia restorations and seven [18%] Class 1 and five [17.3%] Class 2 Gradia Direct Posterior restorations), two years (eight [20.5%] Class 1 and four [15.4%] Class 2 Equia restorations and 10 [25.7%] Class 1 and eight [29.7%] Class 2 Gradia Direct Posterior restorations), three years (eight [20.5%] Class 1 and six [24%] Class 2 Equia restorations and 10 [25.7%] Class 1 and eight [29.7%] Class 2 Gradia Direct Posterior restorations), and four years (seven [18.5%] Class 1 and six [25%] Class 2 Equia restorations and 10 [26.4%] Class 1 and eight [30.8%] Class 2 Gradia Direct Posterior restorations) (Table 4a,b). Equia Class 1 restorations showed moderate changes starting at two years, whereas Class 2 restorations showed changes starting at three years ($p<0.05$). Gradia Direct Class 1 restorations exhibited significant changes starting at one year, whereas Class 2 restorations did at two years ($p<0.05$) (Table 4b). The differences between two restorative materials were not statistically significant at any recall period in terms of marginal adaptation ($p>0.05$) (Table 5). Additionally, no significant difference was observed between Class 1 and Class 2 cavities within each restorative material at one, two, three, and four years ($p>0.05$) (Table 6).

No patient at any time interval experienced pain or sensitivity from the restored teeth, and no incidence of secondary caries was observed.

The SEM observations of one representative GIC restoration and one composite resin are shown in Figures 1 and 2, respectively. The SEM evaluation of the replicas of the restorations demonstrated the occlusal surface characteristics. Both materials

Table 4b: *Clinical Evaluation Scores of the Gradia Direct Posterior Restorations at Baseline and at One, Two, Three, and Four Years*

USPHS Criteria	USPHS Scores	Gradia Direct Posterior, No. (%)									
		Class 1 (N=40)					Class 2 (N=30)				
		Baseline	1 Year	2 Years	3 Years	4 Years	Baseline	1 Year	2 Years	3 Years	4 Years
Anatomical form	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	30 (100)	29 (100)	27 (100)	27 (100)	26 (100)
	Bravo	0	0	0	0	0	0	0	0	0	0
	Charlie	0	0	0	0	0	0	0	0	0	0
Color match	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	30 (100)	29 (100)	27 (100)	27 (100)	26 (100)
	Bravo	0	0	0	0	0	0	0	0	0	0
	Charlie	0	0	0	0	0	0	0	0	0	0
Marginal discoloration	Alfa	40 (100)	36 (92.3)	34* (87.1)	34* (87.1)	33* (86.8)	30 (100)	27 (93.1)	22* (81.4)	22* (81.4)	21* (80.7)
	Bravo	0	3 (7.7)	5 (12.9)	5 (12.9)	5 (13.2)	0	2 (6.9)	5 (18.6)	5 (18.6)	2 (19.3)
	Charlie	0	0	0	0	0	0	0	0	0	0
Marginal adaptation	Alfa	40 (100)	32* (82)	29* (74.3)	29* (74.3)	28* (73.6)	30 (100)	24 (82.7)	19* (70.3)	19* (70.3)	18* (69.2)
	Bravo	0	7 (18)	10 (25.7)	10 (25.7)	10 (26.4)	0	5 (17.3)	8 (29.7)	8 (29.7)	8 (30.8)
	Charlie	0	0	0	0	0	0	0	0	0	0
Secondary caries	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	30 (100)	29 (100)	27 (100)	27 (100)	26 (100)
	Charlie	0	0	0	0	0	0	0	0	0	0
Postoperative sensitivity	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	30 (100)	29 (100)	27 (100)	27 (100)	26 (100)
	Bravo	0	0	0	0	0	0	0	0	0	0
	Charlie	0	0	0	0	0	0	0	0	0	0
Surface texture	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	30 (100)	29 (100)	27 (100)	27 (100)	26 (100)
	Bravo	0	0	0	0	0	0	0	0	0	0
	Charlie	0	0	0	0	0	0	0	0	0	0
Retention	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	30 (100)	29 (100)	27 (100)	27 (100)	26 (96)
	Charlie	0	0	0	0	0	0	0	0	0	0

Abbreviation: USPHS, US Public Health Service.
** Indicates significant difference in comparison with baseline according to Cochrane Q-test ($p<0.05$).*

exhibited successful surface characteristics, with the absence of significant wear, surface porosities, cracks, and marginal gap formation during the four-year evaluation.

DISCUSSION

The advantages of GICs as restorative materials are clearly reflected by the literature.[11] The most significant advantages of these materials include their chemical adhesion to dentin and enamel, release of fluoride, the high tolerance of tissues, and biocompatibility. However, the lack of resistance to abrasion and their poor esthetics are two of the reasons why they are not used frequently by most professionals. In the late 1990s, the conventional GIC was overtaken by the highly viscous GIC, which has a faster setting time and notably higher strengths.[11] A new generation of highly dispersed nanofilled resin coating that has been recently introduced claims to increase the resistance of the GIC and improve marginal sealing and the esthetics

Table 5: *McNemar Test Results: Comparisons of Equia and Gradia Direct Posterior Restorations Are Presented for Marginal Discoloration and Marginal Adaptation*[a]

Criteria Assessed	Material	Evaluation Periods, *p*-Value			
		1 Year	2 Years	3 Years	4 Years
Marginal discoloration	Equia	1.00	1.00	1.00	0.637
	Gradia Direct Posterior	1.00	0.775	0.775	0.759
Marginal adaptation	Equia	1.00	0.845	0.985	0.764
	Gradia Direct Posterior	1.00	1.00	1.00	0.637

[a] *The level of significance was set at* $p < 0.05$.

Table 6: *Pearson Chi-square Test Results Present the Differences Between Cl1 and Cl2 Cavities Within Each Material Group for Marginal Discoloration and Marginal Adaptation*[a]

Criteria Assessed	Cavity Type	Evaluation Periods, *p*-Value			
		1 Year	2 Years	3 Years	4 Years
Marginal discoloration	Class 1	1.00	0.5	0.5	0.5
	Class 2	1.00	0.25	0.25	0.25
Marginal adaptation	Class 1	1.00	0.5	0.5	0.5
	Class 2	1.00	0.125	0.5	0.5

[a] *The level of significance was set at* $p < 0.05$.

of the restoration.[7] Several *in vitro* tests had proved the positive influence of this coating on the fracture strength and the early wear on GIC.[12-14]

Although a variety of clinical trials with different types of GICs as permanent restorative materials were carried out in primary molars only,[15-17] very few prospective studies or long-term trials are published about GICs in permanent premolars and molars.[18] Retrospective studies primarily reported disappointing results when GICs were applied in average cavities and slightly better results when minimum intervention cavities were restored with conventional GIC.[18]

This clinical trial was conducted on permanent posterior teeth both in Class 1 and Class 2 caries lesions of young patients with the average age of 24 years. The clinical efficacy of the systems tested was determined by evaluating the anatomical form, color match, marginal discoloration, marginal adaptation, secondary caries occurrence, and retention at one year and annually for four years. In most of the restorations evaluated, only a few changes were noted from baseline to the four-year evaluation visit.

The American Dental Association requires a retention rate of at least 90% of the restorations placed after 18 months to obtain full acceptance.[19] In this study, at the end of two years, the success rates for both of the restorative materials were 100%. Because of the retention loss of two Equia Class 2 restorations, the overall clinical success rate was 97.1% (100% for Class 1 and 92.3% for Class 2 restorations) for the Equia System after four years. Therefore, both restorative materials evaluated in the present study demonstrated good clinical performance and full acceptance. The results of this study disagreed with those reported by Hickel and others,[20] who reviewed annual failure rates of stress-bearing cavities in posterior primary teeth and determined median annual failure rates of 0-25.8% for GIC. They reported fractures to represent the main reason for failure in Class 2 restorations, with a higher load situation compared to Class 1 restorations. Although a variety of clinical trials with GICs as permanent restorative materials were carried out in Class 1 cavities,[11-13] there are limited data showing the performance of GIC in Class 2 cavities. As the Equia restorative system was introduced with the claim that it could be used both in moderate Class 1 and Class 2 cavities, in this study, the intent was to evaluate the performance of this restorative system separately for the restoration of Class 1 and Class 2 cavities.

The clinical assessment of the loss of anatomical form of restorations is essentially an indication of the

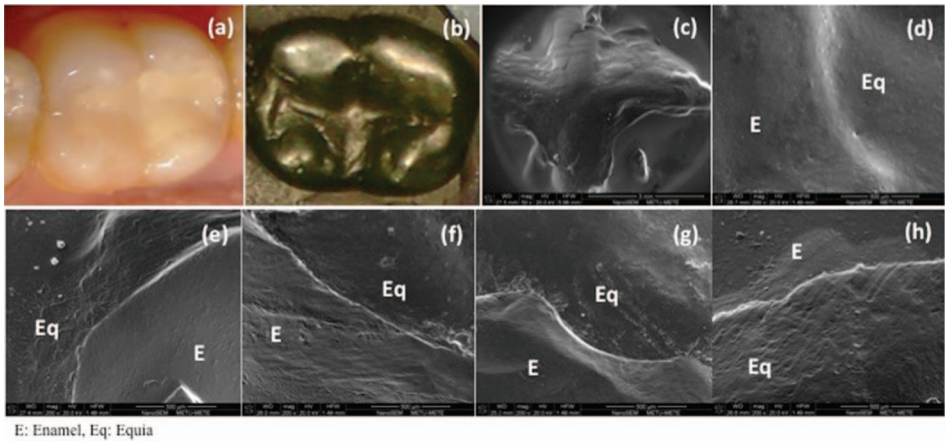

Figure 1. *A representative Equia Cl1 restoration. This figure includes a representative clinical picture (a), a negative replica (b); a SEM photomicrograph of the occlusal view of the restoration, 50× (c); and the occlusal contact area shared by enamel and restoration at baseline, 200× (d), 12 months 200× (e), 24 months 200× (f), 36 months 200× (g), and 48 months 200× (h). E = enamel; Eq = Equia.*

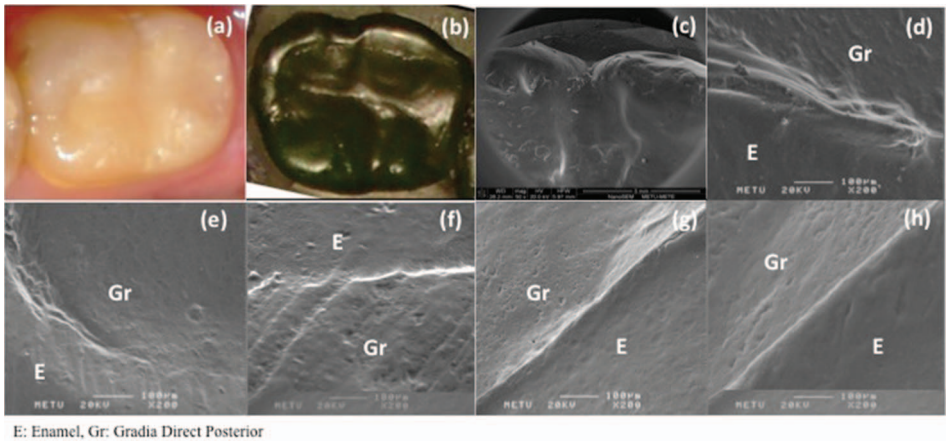

Figure 2. *A representative Gradia Direct Posterior CI1 restoration. This figure includes a representative clinical picture (a); a negative replica (b); a SEM photomicrograph of the occlusal view of the restoration 50× (c); and the occlusal contact area shared by enamel and restoration at baseline 200× (d), 12 months 200× (e), 24 months 200× (f), 36 months 200× (g), and 48 months 200× (h). E = enamel; Gr = Gradia Direct Posterior.*

restored surface exhibiting morphological alterations due to wear. The alpha scores of the criteria anatomical form and retention in almost all restorations throughout the study period showed that the wear on the restoration morphology and retention was barely visible to the naked eye. Therefore, both of the materials have smooth surface textures, successful anatomic form, and retention. SEM examinations also supported the clinical observations.

The absence of failures due to secondary caries after four years could be due to good oral hygiene status of the patients. The time and attention devoted to the restoration placement techniques and the clinically acceptable properties of the restorative materials that minimize the hydrostatic dentin fluid movement might explain the lack of postoperative sensitivity after four years. Postoperative sensitivity has been attributed to several factors, such as operative trauma, desiccation, leakage, and other sources.[21-23] The ability of the coating in Equia restorations and the adhesive in the Gradia Direct Posterior restorations played roles in reducing sensitivity.

In contrast to the previous reports,[18] in the present study, Class 2 restorations recorded as not having lost the interproximal contact could be explained by the special attention given to the appropriate use of the matrix in building up the proximal part of the restorations. Only two retention losses in Class 2 Equia restorations may be related to cyclic stress resulting in occlusal-proximal marginal fracture, weakening the proximal points in the evolving periods of three and four years.

In the present study, marginal discoloration was moderate and was observed in few restorations. The staining appeared only as superficial discoloration (Bravo score), and although it was not significantly different, it mainly occurred in Gradia Direct Posterior restorations rather than in the Equia restorations. This might be due to the adhesive system used. The application of the self-etch adhesive system might have led to a compromise concerning adhesion to the cavosurface margins. Studies have shown that self-etch adhesive systems and the all-in-one adhesives were less effective than total etch systems in terms of dentin and enamel bond strength.[24-26] The discolorations could also be due to food consumption or related to pigment absorption from dietary habits and antagonist teeth during mastication.

Color match was within the alpha range and the color stability of both restorative materials was good, indicating no mismatch in color, shade, or translucency between the restorations and adjacent teeth during the four years of clinical service.

There are only a few clinical studies describing the clinical performance of the Equia System. These clinical reports are mainly abstracts from research meetings. Friedly and others[27] examined retrospectively the performance of Fuji IX GP Extra in posterior restorations over 24 months and reported that volume loss was proportional to the cavity size. However, all restorations were assessed as satisfactory. Gurgan and others[28-30] showed that the 12-, 24-, and 36-month performance of the Equia System was similar to that of the resin composite. Turkun and Kanic[31] compared the Equia System to Riva-conventional GIC and found no difference in performance. Basso[32] used Fuji IX GP Extra in a four-center study, and after a mean follow-up of 18 months, 100% of the Class 1 restorations were successful. In a six-center study, Khandelwal and others[33] also evaluated the Equia System after an evaluation time of 24 months. They reported 88.8%

success in Class 1 cavities and a visible and perceptible roughness in 11.5% of restorations with less than 1% of marginal disintegration.

The only published data were reported by Diem and others.[7] They used Fuji IX Extra (Equia Fil) with and without coating (G-Coat Plus/Equia Coat) and also compared the Equia System with a microfine hybrid resin composite in first premolars of 11-12-year-old children with the ART technique. The study was carried out under field conditions. At the end of three years, the color match of all of the restorations was assessed as 'good,' with no significant differences among materials. Moderate marginal staining was noted, and marginal adaptation loss was minimal for all restorations. They concluded that Fuji IX GP Extra either with or without the coating showed acceptable clinical performance but that the application of G-Coat Plus to Fuji IX GP Extra was beneficial in reducing wear in occlusal cavities.

In the present study, Equia System either in Class 1 or Class 2 cavities exhibited significantly good clinical outcome over the observation period of four years. Therefore, the null hypothesis was accepted, because there was not a distinct difference between Equia Fil-GIC and Gradia Direct Posterior microfilled hybrid composite resin. However, further long-term clinical studies are required to confirm the results of the present clinical trial.

This clinical trial furthermore included SEM analyses to demonstrate the micromorphologic features of the restoration surface. The presented observations on the microscopic level have supported the clinical observations of the occlusal surface on marginal adaptation and surface texture.

The introduction of GIC was connected with the hope of being able to replace amalgam. Especially in Europe, this was an interesting aspect because amalgam was more and more disregarded during the 1990s, with many amalgam restorations having been replaced by GICs. Therefore, GICs might turn out to be the more reliable restorative material in minimally invasive dentistry based on adhesive techniques. However, these materials still offer opportunities for improvement. Several attempts to improve their mechanical parameters are still underway, and some forecast a promising future for GIC as a dental filling material with extended indications.

CONCLUSION

The highly viscous GIC restorative system, Equia, and microfilled hybrid resin composite, Gradia Direct Posterior, showed acceptable clinical performance according to modified USPHS criteria assessed in Class 1 and Class 2 cavities over the course of four years.

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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REFERENCES

1. Davidson CL (2009) Advances in glass-ionomer cements *Journal of Minimum Intervention in Dentistry* **2(1)** 3-12.
2. Lohbauer U (2010) Dental glass ionomer cements as permanent filling materials?—Properties, limitations and future trends. *Materials* **3(1)** 76-96.
3. McLean J, & Wilson A (1977) The clinical development of the glass ionomer cement: II. Some clinical applications *Australian Dental Journal* **22(2)** 120-127.
4. Wilson AD, & Kent BE (1971) The glass-ionomer cement: A new translucent cement for dentistry *Journal of Applied Chemistry and Biotechnology* **21(11)** 313.
5. Ilıe N, Hickel R, Valceaune AS, & Huth KC (2012) Fracture toughness of dental restorative materials *Clinical Oral Investigations* **16(2)** 489-498.
6. Bonifacio CC, Werner A, & Kleverlaan CJ (2012) Coating glass-ionomer cements with a nanofilled resin *Acta Odontologica Scandinavica* **70(6)** 471-477.
7. Diem VTK, Tyas MJ, Hien CN, Phuong LH, & Khanh ND (2013) The effect of a nano-filled resin coating on the 3-year clinical performance of a conventional high-viscosity glass-ionomer cement *Clinical Oral Investigations* doi:10.1007/s00784-013-1026-z
8. Karaman E, Yazici AR, Tuncer D, Firat E, Unluer S, & Baseren M (2013) A 48-month clinical evaluation of fissure sealants placed with different adhesive systems *Operative Dentistry* **38(4)** 369-375.
9. Mahmoud SH, El-Embaby AE, & AbdAllah AM (2014) Clinical performance of ormocer, nanofilled, and nanoceramic resin composites in Class I and Class II restorations: A three-year evaluation *Operative Dentistry* **39(1)** 32-42.
10. Van Dijken JW, & Pallesen U (2011) Four–year clinical evaluation of Class II nano-hybrid resin composite restorations bonded with a one-step self-etch and two-step etch-and-rinse adhesive *Journal of Dentistry* **39(1)** 16-25.
11. Tyas MJ (2006) Clinical evaluation of glass-ionomer cement restorations *Journal of Applied Oral Science* **14** 10-13.
12. Lohbauer U, Kramer N, Siedschlag G, Schubert EW, Lauerer B, Muller FA, Petschelt A, & Ebert J (2011) Strength and wear resistance of a dental glass-ionomer cement with a novel nanofilled resin coating *American Journal of Dentistry* **24(2)** 124-128.

13. Aljamhan A (2012) Resin-coated glass ionomer cement abrasion and wear resistance. *Journal of Dental Research* **91(Special Issue A)** Abstract #1045.
14. Bagheri R (2012) Effect of G-Coat Plus on the properties of aesthetic restorations *Journal of Dental Research* **91(Special Issue B)** Abstract #753.
15. Ersin NK, Candan U, Aykut A, Önçag Ö, Eronat C, & Kose A (2006) Clinical evaluation of resin-based composite and glass ionomer cement restorations placed in primary teeth using the ART approach: Results at 24 months *Journal of the American Dental Association* **137(11)** 1529-1536.
16. Hübel S, & Mejare I (2003) Conventional versus resin-modified glass-ionomer cement for Cl II restorations in primary molars. A 3-year clinical study *International Journal of Paediatric Dentistry* **13(1)** 2-8.
17. Rutar J, McAllan L, & Tyas MJ (2000) Clinical evaluation of a glass ionomer cement in primary molars *Pediatric Dentistry* **22(6)** 486-488.
18. Frankenberger R, Garcia-Godoy F, & Kramer N (2009) Clinical performance of viscous glass ionomer cement in posterior cavities over two years *International Journal of Dentistry* Article ID781462.1-7, doi:101155/2009/781462
19. Loguercio AD, & Reis A (2008) Application of a dental adhesive using the self-etch and etch-and-rinse approaches: An 18-month clinical evaluation *Journal of the American Dental Association* **139(1)** 53-61.
20. Hickel R, Kaaden C, Paschos E, Buerkle V, Garcia-Godoy F, & Manhart J (2005) Longevity of occlusually-stressed restorations in posterior primary teeth *American Journal of Dentistry* **18(3)** 198-211.
21. Prati C, Cervellati F, Sanasi V, & Montebugnoli L (2001) Treatment of cervical dentin hypersensitivity with resin adhesives: 4-week evaluation *American Journal of Dentistry* **14(6)** 378-382.
22. Swift EJ Jr, May KN Jr, & Mitchell S (2001) Clinical evaluation of Prime & Bond 2.1 for treating cervical dentin hypersensitivity *American Journal of Dentistry* **14(1)** 13-16.
23. Ianzano JA, Gwinnett AJ, & Westbay G (1993) Polymeric sealing of dentinal tubules to control sensitivity: Preliminary observations *Periodontal Clinical Investigations* **15(1)** 13-16.
24. Moosavi H, Kimyai S, Forghani M, & Khodadadi R (2013) The clinical effectiveness of various adhesive systems: An 18-month evaluation *Operative Dentistry* **38(2)** 134-141.
25. Awe TC, Lepe X, Johnson GH, & Mancl LA (2005) A three-year clinical evaluation of two-bottle versus one-bottle dentin adhesives *Journal of the American Dental Association* **136(3)** 311-322.
26. Van Dijken JW, & Pallesen U (2008) Long-term dentin retention of etch-and-rinse and self-etch adhesives and a resin-modified glass ionomer cement in non-carious cervical lesions *Dental Materials* **24(7)** 915-922.
27. Friedly K, Hiller KA, & Friedl KH (2011) Clinical performance of a new glass ionomer based restoration system: A retrospective cohort study *Dental Materials* **27(10)** 1031-1037.
28. Gurgan S, Cakir FY, Firat E, Kutuk ZB, Ak SS, & Korkmaz Y (2011) 12-month clinical performance of a glass-ionomer restorative system *Journal of Dental Research* **90(Special Issue A)** Abstract #3246.
29. Gurgan S, Cakir FY, Firat E, Kutuk ZB, Ak Oztas SS, & Ceylan YK (2012) 24-month clinical performance of a glass-ionomer restorative system *Journal of Dental Research* **91(Special Issue B)** Abstract #107.
30. Gurgan S, Cakir FY, Firat E, Kutuk ZB, & Oztas SS (2013) 36-month clinical performance of a glass-ionomer restorative system *Journal of Dental Research* **92(Special Issue A)** Abstract #2933.
31. Turkun LS, & Kanic O (2010) Clinical evaluation of new glass ionomer coating combinated systems for 18-months *Journal of Dental Research* **89(Special Issue B)** Abstract #402.
32. Basso M (2010) Long-term dental restorations using high-viscosity coated glass ionomer cements *Journal of Dental Research* **89(Special Issue B)** Abstract #2494.
33. Khandelwal P, Hiller K-A, Friedl K, & Friedl K-H (2010) Clinical performance of a glass ionomer based restorative system *Journal of Dental Research* **89(Special Issue B)** Abstract #3240.