

Clinical performance of a glass ionomer restorative system: a 6-year evaluation

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Abstract

Objectives The aim of this study is to evaluate the long-term clinical performance of a glass ionomer (GI) restorative system in the restoration of posterior teeth compared with a micro-filled hybrid posterior composite.

Materials and methods A total of 140 (80 C11 and 60 C12) lesions in 59 patients were restored with a GI system (Equia) or a micro hybrid composite (Gradia Direct). Restorations were evaluated at baseline and yearly during 6 years according to the modified-USPHS criteria. Negative replicas at each recall were observed under SEM to evaluate surface characteristics. Data were analyzed with Cochran's Q and McNemar's tests ($p < 0.05$).

Results One hundred fifteen (70 C11 and 45 C12) restorations were evaluated in 47 patients with a recall rate of 79.6% at 6 years. Significant differences were found in marginal adaptation and marginal discoloration for both restorative materials for C11 and C12 restorations ($p < 0.05$). However, none of the materials were superior to the other ($p > 0.05$). A significant decrease in color match was observed in Equia restorations

($p < 0.05$). Only one C12 Equia restoration was missing at 3 years and another one at 4 years. No failures were observed at 5 and 6 years. Both materials exhibited clinically successful performance after 6 years. SEM evaluations were in accordance with the clinical findings.

Conclusions Both materials showed a good clinical performance for the restoration of posterior teeth during the 6-year evaluation.

Clinical relevance The clinical effectiveness of Equia and Gradia Direct Posterior was acceptable in C11 and C12 cavities subsequent to 6-year evaluation.

Keywords Glass ionomer cement · Composite resin · Posterior teeth · Clinical performance

Introduction

Direct restorations have been largely employed to restore posterior teeth due to their low cost and less need for removal of sound tooth substance when compared to indirect restorations, as well as to their acceptable clinical properties [1–5]. Amalgam and composite resin are considered suitable materials for restoring class 1 (C11) and class 2 (C12) cavities but some advantages can be related to composite restorations such as better esthetics, their adhesive properties, resulting in reduced preparation time, and reinforcement of the remaining dental structure [6, 7].

Since the introduction of glass ionomer cements (GICs) by Wilson and Kent [8], many modifications of these materials have been performed over the years. Their physical properties, in particular; wear resistance, reduced sensitivity to early water uptake so that restorations could be placed and finished at the same visit and translucency were improved by increasing their viscosity and reducing filler size in order to achieve certain packability. Compared to other permanent filling

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materials like resin-based composites, GICs show several advantages, such as the ability to adhere to moist enamel and dentin and anti-cariogenic properties such as the long-term fluoride release [9, 10]. Other clinical advantages like biocompatibility and low coefficient of thermal expansion support their valuable position in the daily dental practice [11–15]. However, despite having these significant advantages, they suffer from a poor surface polish, a high porosity, and rather weak mechanical properties such as brittleness, surface wear, or fracture toughness [16–19]. So, it was doubtful that GICs represent a capable counterpart of amalgam or resin-based composites in posterior teeth [9, 20].

In 2007, a concept called Equia was introduced which tries to combine the main advantages of the highly viscous GIC with a nano-filled, light curing varnish to provide protection in the early setting phase and to occlude any surface cracks and porosity thus increasing the wear resistance and toughness [21–24].

So far, very few studies have investigated the clinical performance of this material [22–24]. Long-term clinical trials are certainly needed, because they remain the ultimate way to collect scientific evidence on the clinical effectiveness of restorative treatments. Thus, the aim of this study was to assess the 6-year clinical performance of this glass ionomer (GI) restorative system in comparison with a micro hybrid composite in the treatment of posterior teeth. The null hypothesis to be tested was that there would be no difference in the clinical performance between the restorative systems used after 6 years.

Materials and methods

Human Ethics in Clinical Research Committees of the University of Hacettepe, Ankara, Turkey approved this study (protocol HEK 09/112-10). Fifty-nine patients satisfying the inclusion and exclusion criteria were selected among a group of patients seeking routine dental care and recruited by the Hacettepe University, School of Dentistry, Department of Restorative Dentistry. 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 (1) partly erupted teeth, (2) the 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.

Two experienced dentists placed 140 restorations (80 C11 and 60 C12). The filling materials (Table 1), glass ionomer

restorative system (Equia, GC Co., Tokyo, Japan) or micro hybrid composite (Gradia Direct Posterior, GC Co., Tokyo, Japan), were used according to the manufacturer's instructions and were randomized over these two cavity groups using a table of random numbers. 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. 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. CaOH₂ cavity liner (Life Regular Set, Kerr Corporation, Romulus, MI, USA) was applied where needed as base material. An ivory type matrix system (Hahnenkratt, Konigsbach-Stein, Germany) was used for C12 cavities.

When placing glass ionomer restorations, the dentin and enamel of cavities were conditioned with 20% polyacrylic acid for 20 s (Cavity Conditioner, GC co., Tokyo, Japan), 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 min, the restoration was trimmed and polished wet using high-speed fine diamonds (Diatech, Swiss Dental, Heerbrugg, Switzerland). When the restoration was briefly dried, Equia Coat was applied and photocured for 20 s using a photo-curing light (Radii Plus, SDI, Bayswater, Australia).

For composite resin restorations, after the enamel and dentin were conditioned with G-Bond (GC) using a microtip applicator, left undisturbed for 5 to 10 s, and then dried thoroughly for 5 s 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 s. Finally, the restoration was shaped with finishing diamonds and silicon instruments (Hi Luster Plus Polishing System, KerrHave, Bioggio, Switzerland).

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 [25] by two independent investigators using mirrors, probes, bitewing radiographs, and intraoral photographs. Patients were recalled at 1, 2, 3, 4, 5, and 6 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.

Table 1 Description of materials used in this study

Material	Type	Manufacturer (batch no)	Composition
EquiaFil	Conventional glass-ionomer cement	GC Co, Tokyo, Japan (1008061)	Powder: 95% strontium fluoro-alumino-silicate glass, 5% polyacrylic acid liquid: 40% aqueous polyacrylic acid
Equia Coat	Low-viscosity nano-filled surface coating resin	GC Co, Tokyo, Japan (0908061)	50% methyl methacrylate, 0.09% camphorquinone
Gradia Direct Posterior	Micro hybrid composite	GC Co, Tokyo, Japan (0810231)	Urethane dimethacrylate co-monomer matrix, silica, pre-polymerized fillers, fluoro-alumino-silicate glass
G-Bond	All-in-one dentine/enamel bonding agent	GC Co, Tokyo, Japan (080691)	40% acetone, 20% distilled water, 15% 4-methacryloxy-ethyltrimellitate anhydride, 10–20% urethane dimethacrylate, 10% triethyleneglycoldimethacrylate

Impressions of each air-dried, cotton-roll isolated tooth were taken from one patient selected randomly from each group with polyvinyl siloxane impression material at each recall. Negative replicas were gold sputtered and investigated with scanning electron microscope (JSM-6400 SEM, JEOL, Tokyo, Japan) at $\times 50$ and $\times 200$ [26].

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 Cochran’s *Q* test was used. The McNemar’s 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. Within each material group and cavity type, further analysis was done using the McNemar’s test to distinguish the differences between different cavity types for marginal adaptation, marginal discoloration, and color match. The level of significance was set at $p < 0.05$ for all tests.

Results

The present study covers the recall periods of baseline, 1, 2, 3, 4, 5, and 6 years. One hundred fifteen (70 C11 and 45 C12) restorations were evaluated and scored according to USPHS criteria in 47 patients after 6 years. The overall clinical success rate of recalls at 6 years was 79.6% (47 of 59 patients) (Table 2).

Twenty-five restorations (10 C11 and 15 C12) could not be evaluated at 6 years because 12 patients (20.4%) had moved

away. Only one C12 restoration had to be replaced as a result of marginal fracture at 3 years and one at 4 years. Although success rate of C12 Equia restorations were 92.3% at 4-year recall, success rate of C12 Equia restorations was calculated as 100% at 6-year recall as two patients with failed restorations could not be evaluated at 6-year recall.

No significant change over time was found for the anatomical form, secondary caries, postoperative sensitivity, surface texture, and retention for either restorative material ($p > 0.05$).

Bravo scores were observed in three (8.6%) C11 and eight (36.4%) C12 Equia restorations, whereas, in seven (20%) C11 and in nine (39.2%) C12 Gradia Direct Posterior restorations for marginal discoloration (Tables 3 and 4). No significant difference was seen between two restorative materials in terms of marginal discoloration ($p > 0.05$) (Table 5). There were no significant differences between the marginal discoloration scores of C11 and C12 cavities for either restorative material at 1, 2, 3, 4, and 5 years ($p > 0.05$) but significant difference was seen at 6 years for Equia restorative materials ($p = 0.025$) (Table 6).

Moderate marginal adaptation scores (bravo) were also noted in 9 (25.8%) C11 and 7 (31.9%) C12 Equia restorations, whereas, in 12 (34.3%) C11 and in 10 (43.5%) C12 Gradia Direct Posterior restorations (Table 3 and 4). According to McNemar test, no significant difference was observed between restorative materials in terms of marginal adaptation ($p > 0.05$) (Table 5). There were also no significant differences in the marginal adaptation scores of C11 and C12 cavities for both materials during 6 years ($p > 0.05$) (Table 5).

Table 2 Recall rates of patients

Restorative materials	Baseline		1st year		2nd year		3rd year		4th year		5th year		6th year	
	C11	C12	C11	C12	C11	C12	C11	C12	C11	C12	C11	C12	C11	C12
Equia	33	26	32	25	33	22	33	21	32	20	32	20	28	19
Gradia Direct Posterior	33	26	32	25	33	22	33	20	32	20	32	20	28	19
Total (%)	59 (100)		57 (96.6)		55 (93.2)		53 (89.8)		52 (88.1)		52 (88.1)		47 (79.6)	

Table 3 Clinical evaluation scores of the Equia restorations at baseline (BL), 1, 2, 3, 4, 5, and 6 years

USPHS criteria	USPHS scores													
	Equia, no. (%)													
	Class 1 (N=40)					Class 2 (N=30)								
	BL	1 Y	2 Y	3 Y	4 Y	5 Y	6 Y	BL	1 Y	2 Y	3 Y	4 Y	5 Y	6 Y
Anatomical form	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	35 (100)	30 (100)	29 (100)	26 (100)	25 (100)	24 (100)	24 (100)	22 (100)
	Bravo	0	0	0	0	0	0	0	0	0	0	0	0	0
	Charlie	0	0	0	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)	37 (97.3)	30 (85.7)	30 (100)	29 (100)	26 (100)	25 (100)	24 (100)	19 (86.3)
	Bravo	0	1 (2.6)	1 (2.6)	1 (2.6)	1 (2.7)	1 (2.7)	5 (14.3)	0	0	0	0	0	3 (13.7)
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0
Marginal discoloration	Alfa	40 (100)	36 (92.3)	36 ^a (92.3)	36 ^a (92.3)	36 ^a (94.7)	36 ^a (94.7)	32 ^a (91.4)	30 (100)	27 (93.1)	24 (92.3)	23 ^a (92)	22 ^a (91.6)	14 ^a (63.6)
	Bravo	0	3 (7.7)	3 (7.7)	3 (7.7)	2 (5.3)	2 (5.3)	3 (8.6)	0	2 (6.9)	2 (7.7)	2 (8)	2 (8.4)	8 (36.4)
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0
Marginal adaptation	Alfa	40 (100)	33 (84.6)	31 ^a (79.4)	31 ^a (79.4)	31 ^a (81.5)	31 ^a (81.5)	26 ^b (74.2)	30 (100)	25 (86.2)	22 (84.6)	19 ^a (76)	18 ^a (75)	15 ^a (68.1)
	Bravo	0	6 (15.4)	8 (20.6)	8 (20.6)	7 (18.5)	7 (18.5)	9 (25.8)	0	4 (13.8)	4 (15.4)	6 (24)	6 (25)	7 (31.9)
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0
Secondary caries	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	35 (100)	30 (100)	29 (100)	26 (100)	25 (100)	24 (100)	24 (100)	22 (100)
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0
	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	35 (100)	30 (100)	29 (100)	26 (100)	25 (100)	24 (100)	24 (100)	22 (100)
Postoperative sensitivity	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	35 (100)	30 (100)	29 (100)	26 (100)	25 (100)	24 (100)	24 (100)	22 (100)
	Bravo	0	0	0	0	0	0	0	0	0	0	0	0	0
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0
Surface texture	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	35 (100)	30 (100)	29 (100)	26 (100)	25 (100)	24 (100)	24 (100)	22 (100)
	Bravo	0	0	0	0	0	0	0	0	0	0	0	0	0
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0
Retention	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	35 (100)	30 (100)	29 (100)	26 (100)	25 (96.1)	24 (96)	24 (100)	22 (100)
	Charlie	0	0	0	0	0	0	0	0	0	1 (3.9)	1 (4)	0	0

USPHS US Public Health Service

^aIndicates significant difference in comparison with baseline according to Cochran's Q test followed by McNemar's test ($p < 0.05$)

Table 4 Clinical evaluation scores of the Gradia Direct Posterior restorations at baseline (BL), 1, 2, 3, 4, 5, and 6 years

USPHS criteria	USPHS scores	Class 2 (N = 30)													
		Gradia Direct Posterior, no. (%)										BL			
		1 Y	2 Y	3 Y	4 Y	5 Y	6 Y	1 Y	2 Y	3 Y	4 Y		5 Y	6 Y	
Anatomical form	Alfa	40 (100)	39 (100)	39 (100)	39 (100)	38 (100)	38 (100)	35 (100)	30 (100)	29 (100)	27 (100)	27 (100)	26 (100)	26 (100)	23 (100)
	Bravo	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Color match	Alfa	40 (100)	39 (100)	39 (100)	38 (100)	38 (100)	34 (97.1)	30 (100)	29 (100)	27 (100)	27 (100)	26 (100)	26 (100)	26 (100)	22 (95.6)
	Bravo	0	0	0	0	0	1 (2.9)	0	0	0	0	0	0	0	1 (4.4)
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Marginal discoloration	Alfa	40 (100)	36 (92.3)	34 ^a (87.1)	34 ^a (87.1)	33 ^a (86.8)	28 ^a (80)	30 (100)	27 (93.1)	22 ^a (81.4)	22 ^a (81.4)	21 ^a (80.7)	21 ^a (80.7)	21 ^a (80.7)	14 ^a (60.8)
	Bravo	0	3 (7.7)	5 (12.9)	5 (12.9)	5 (13.2)	7 (20)	0	2 (6.9)	5 (18.6)	5 (18.6)	5 (19.3)	5 (19.3)	9 (39.2)	
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0	
Marginal adaptation	Alfa	40 (100)	32 ^a (82)	29 ^a (74.3)	29 ^a (74.3)	28 ^a (73.6)	23 ^a (65.7)	30 (100)	24 (82.7)	19 ^a (70.3)	19 ^a (70.3)	18 ^a (69.2)	18 ^a (69.2)	13 ^a (56.5)	
	Bravo	0	7 (18)	10 (25.7)	10 (25.7)	10 (26.4)	12 (34.3)	0	5 (17.3)	8 (29.7)	8 (29.7)	8 (30.8)	8 (30.8)	10 (43.5)	
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0	
Secondary caries	Alfa	40 (100)	39 (100)	39 (100)	38 (100)	38 (100)	35 (100)	30 (100)	29 (100)	27 (100)	27 (100)	26 (100)	26 (100)	23 (100)	
	Bravo	0	0	0	0	0	0	0	0	0	0	0	0	0	
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0	
Postoperative sensitivity	Alfa	40 (100)	39 (100)	39 (100)	38 (100)	38 (100)	35 (100)	30 (100)	29 (100)	27 (100)	27 (100)	26 (100)	26 (100)	23 (100)	
	Bravo	0	0	0	0	0	0	0	0	0	0	0	0	0	
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0	
Surface texture	Alfa	40 (100)	39 (100)	39 (100)	38 (100)	38 (100)	35 (100)	30 (100)	29 (100)	27 (100)	27 (100)	26 (100)	26 (100)	23 (100)	
	Bravo	0	0	0	0	0	0	0	0	0	0	0	0	0	
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0	
Retention	Alfa	40 (100)	39 (100)	39 (100)	38 (100)	38 (100)	35 (100)	30 (100)	29 (100)	27 (100)	27 (100)	26 (100)	26 (100)	23 (100)	
	Bravo	0	0	0	0	0	0	0	0	0	0	0	0	0	
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0	

USPHS US Public Health Service

^aIndicates significant difference in comparison with baseline according to Cochran's Q test followed by McNemar's test ($p < 0.05$)

Table 5 McNemar's test results: comparisons of Equia and Gradia Direct Posterior restorations are presented for marginal discoloration and marginal adaptation

Criteria assessed	Material	Evaluation periods, <i>p</i> values					
		1st year	2nd year	3rd year	4th year	5th year	6th year
Marginal discoloration	Class 1	1.000	0.500	0.500	0.250	0.250	0.125
	Class 2	1.000	0.500	1.000	1.000	1.000	1.000
	Total	1.000	0.125	0.250	0.125	0.125	0.125
Marginal adaptation	Class 1	1.000	0.500	0.500	0.250	0.250	0.250
	Class 2	1.000	0.250	1.000	1.000	1.000	0.500
	Total	0.500	0.063	0.500	0.250	0.250	0.063

The level of significance was set at $p < 0.05$

McNemar's test showed a significant change in color match in Equia restorations at 6 years ($p = 0.016$). Five (14.3%) C11 and three (13.7%) C12 Equia restorations exhibited bravo scores. Besides, only one (2.9%) C11 and one (4.4%) C12 Gradia Posterior restorations were scored as bravo for color match ($p > 0.05$).

The SEM observations of one representative of Equia and Gradia Direct Posterior restorations are shown in Figs. 1 and 2. Both materials exhibited successful marginal adaptation characteristics during the 6-year evaluation.

Discussion

Resin-based composites have been used extensively over the past decade to restore posterior teeth. Many clinicians have used this class of materials in posterior stress-bearing areas quite successfully for the last 5 to 10 years [20, 27].

GICs were previously not considered as material of choice in the restoration of permanent posterior teeth. Although the highly viscous GI materials, which were introduced in the market late in 90s, achieved superior physical properties compared to traditional GICs, the reputation of GICs did not change and continued to be considered as a semi-permanent restoration material for C11 and C12 lesions in permanent teeth.

A new glass ionomer restorative system called Equia was introduced in 2007 with the claimed purpose from the manufacturer to be used in the restoration of posterior teeth as a permanent restorative material. However, there have been lacks of long-term evaluations of this material in the treatment of posterior teeth as permanent restorative material [19, 23].

This study investigated the long-term clinical performance of Equia restorative system on permanent posterior teeth both in C11 and C12 caries lesions and compared it with a micro hybrid resin composite (Gradia Direct Posterior) that is used for the treatment of posterior teeth.

The longevity and functional characteristics of a dental restoration are the most important factors in determining the long-term effectiveness of invasive caries treatment [28]. Clinical evaluations on performance and longevity of restorations have been done for more than 100 years, but a large number of clinical trials are short-term evaluations and in general, in up to 3 years of follow-up, most restorations have good performance [22].

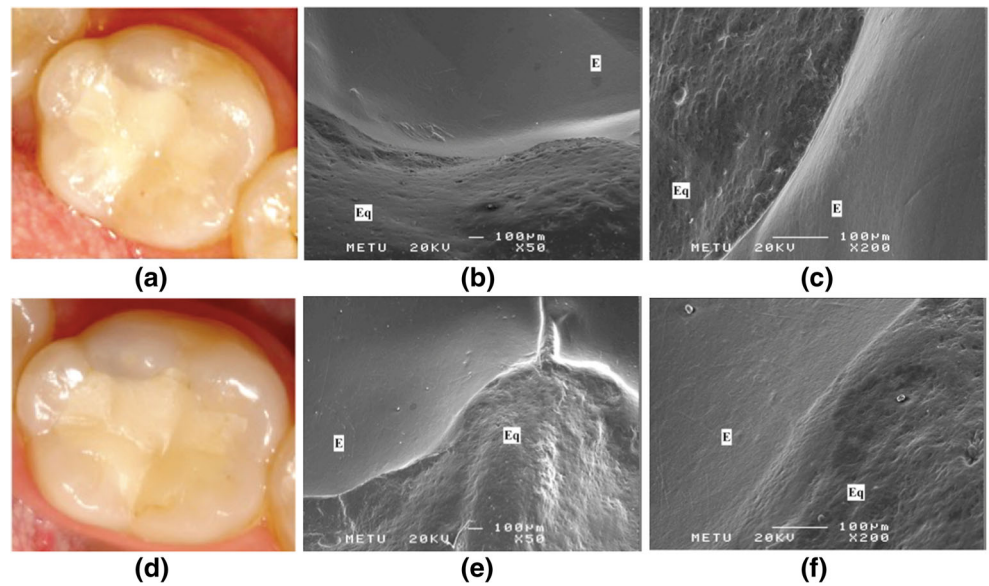
Until now, clinical research on Equia System has been limited to 3–4-year periods and some are related to application in the ART technique [22–24]. Friedl et al. [22] examined the suitability of Equia as a restorative permanent restoration in posterior teeth. In their retrospective cohort study, 26 C11 and 125 C12 restorations were placed in 94 molars and 57 premolars in 43 patients in 6 different dental clinics by experienced 6 dentists. After 2 years, no

Table 6 McNemar's test results present the differences between class 1 and class 2 cavities within each material group for marginal discoloration and marginal adaptation

Criteria assessed	Material	Evaluation periods, <i>p</i> values					
		1st year	2nd year	3rd year	4th year	5th year	6th year
Marginal discoloration	Equia	1.000	1.000	1.000	0.637	0.637	0.025*
	Gradia Direct Posterior	1.000	0.775	0.775	0.759	0.759	0.196
Marginal adaptation	Equia	1.000	0.845	0.985	0.764	0.764	0.844
	Gradia Direct Posterior	1.000	0.939	0.939	0.915	0.915	0.668

The level of significance was set at $p < 0.05$

Fig. 1 A representative Equia CII restoration. This figure includes a representative clinical picture at baseline (a) and 6 year (d). SEM photomicrographs of the occlusal view of the restoration and the occlusal contact area shared by enamel and restoration at baseline $\times 50$ (b), $\times 200$ (c) and at 6 year $\times 50$ (e), $\times 200$ (f). *E* enamel, *Eq* Equia

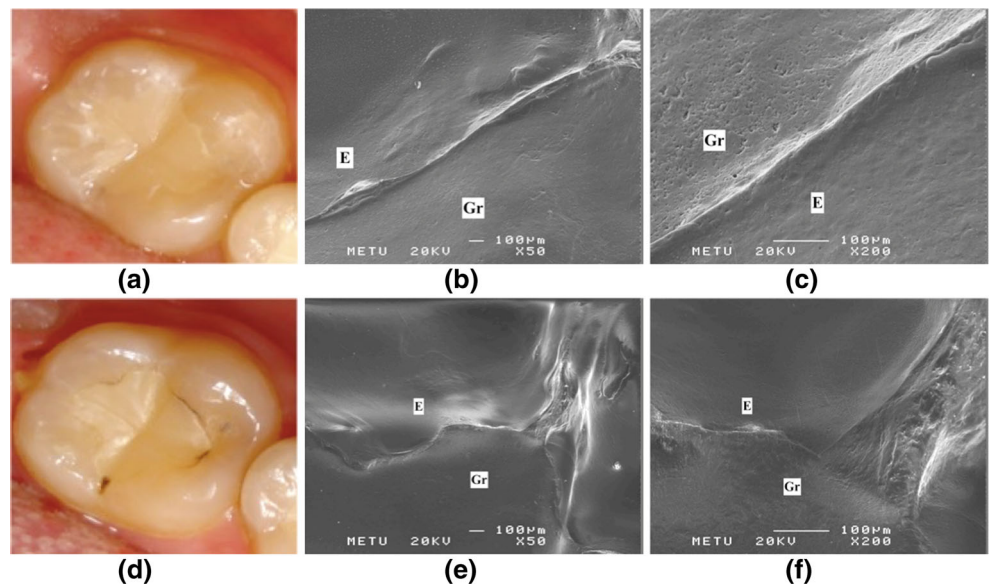


failures were observed, and marginal discoloration was found less than 1%.

Diem et al. [23] compared the clinical performance of Equia system (formerly, Fuji IX GP Extra) with a resin composite. The study was carried out under field conditions.

Moderate-depth occlusal cavities in the first molars of 91 11–12-year-old children were restored with either Equia or a micro hybrid resin composite. Four clinicians placed 84 Fuji XP GP Extra with coating, 87 without coating, and 83 micro hybrid composite resin. Of the original 254 restorations, 198

Fig. 2 A representative Gradia Direct Posterior CII restoration. This figure includes a representative clinical picture at baseline (a) and 6 year (d). SEM photomicrographs of the occlusal view of the restoration and the occlusal contact area shared by enamel and restoration at baseline $\times 50$ (b), $\times 200$ (c) and at 6 year $\times 50$ (e), $\times 200$ (f). *E* enamel, *Gr* Gradia Direct Posterior



were available for 3-year evaluation. Fifty-six restorations could not be evaluated at 3 years. None of the restorations were assessed as having failed and marginal staining and marginal adaptation were minimal for all restorations (7%). Three restorations exhibited secondary caries at 3 years.

The authors of the present study had also reported the clinical performance of Equia system comparing with a micro hybrid resin composite after 4 years [24]. None of the restorations showed to downgrade in anatomical form, secondary caries, surface texture, postoperative sensitivity, and color match. Moderate marginal discoloration was observed in few restorations and only two restorations were failed at 3 and 4 years.

The durability of a restoration is multifactorial, and other factors such as the handling of the material by the operator, the bonding capability of the restorative system, the application and curing technique used, and several patient-dependent factors such as temperature and pH cycles in the month during aging may all play a role. Additionally, the shape and size of restoration, operator variability, and occlusal factors could account for the retention of restorations [5].

In this clinical trial, at 6-year recall, the success rates were 100% both for C11 and C12 Gradia Direct Posterior and Equia restorations. As there have been no data concerning long-term clinical use of Equia system, it is not possible to compare the results with other studies.

Few clinical trials suggested a limited longevity for GI restorations compared with resin composite restorations [29–31]. So, the result of this study is not in agreement with those studies.

In the present study, no significant change over time was found for the anatomical form, secondary caries, and postoperative sensitivity. Results from an earlier cross-sectional study [32], which included 2137 GI restorations, have indicated that secondary caries is the reason for failure of 17–40% of GI restorations. None of the restorations in this clinical trial showed secondary caries during the 6-year evaluation period.

Clinically acceptable (bravo) moderate marginal discoloration and adaptation were noted for both materials at 6 years. However, these changes from Alpha to Bravo ratings maintained the restorations as clinically acceptable. Marginal discoloration usually results from defects present between the restoration and the cavity margins. These defects may be caused by unsatisfactory bonding and by subsequent stress fatigue. Bravo scores also for marginal adaptation may have been caused by intrinsic material parameters.

Color match with the surrounding tooth structure had been assessed clinically good for both materials until 5-year period, but 6-year evaluations showed significant differences between Equia and Gradia Direct restorations. Five (14.3%) C11 and three (13.6%) C12 Equia restorations exhibited bravo scores. In contrast, Diem et al. [23] reported steadily increase in color match of the Equia restorations over time (about 25% ‘good’

as baseline to about 80% ‘good’ at 3 years). They attributed this positive change to the improvement in translucency over-time as the cement matures [33].

Only two Equia restorations were missed at 3 and 4 years. The reason for failures was fracture of the fillings. In general, early failures, which are encountered after weeks or months, must be distinguished from late failures that occur after several years of clinical service. Late failures are predominantly caused by fractures, secondary caries, and wear or deterioration of materials. This result is not worrisome, because all other restorations were classified as clinically acceptable and the overall better behavior of Equia restorations is in accordance with the previous report [24].

SEM evaluations at 6 years still supported the clinical observations. Micrographs of Equia and Gradia Direct restorations showed acceptable occlusal and marginal characteristics.

Equia system in either C11 or C12 cavities exhibited significantly good outcome over the 6 years. Therefore, the null hypothesis was accepted. However, other further long-term clinical studies are required to confirm the results of this study.

Conclusion

The GIC restorative system and micro hybrid resin composite exhibited similar and clinically successful performance after 6 years. It can be concluded that both restoratives evaluated in this long-term evaluation showed good longevity.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Fundings There is no funding information available.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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