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Clinical Research

Clinical Performance of a Glass Hybrid Restorative in Extended Size Class II Cavities

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Clinical Relevance

The clinical effectiveness of a glass hybrid restorative system was as acceptable as composite resin in large size Class II cavities subsequent to 24-month evaluation.

SUMMARY

Objective: To evaluate the clinical performance of a glass hybrid restorative compared with a resin composite in the restoration of large and deep Class II cavities after 24 months.

Methods and Materials: A total of 108 extended size, with the width of the proximal box not interfering with the peak of the cusps and the proximal box in occlusion, Class II lesions in 37 patients were either restored with a glass hybrid restorative or with a micro-hybrid composite resin in combination with selective etching by two experienced operators according to the manufacturer's instructions. Two independent examiners evaluated the restorations at baseline and at the six-, 12-, 18-, and 24-month recalls according to the modified US Public Health Service criteria. Negative replicas at each recall were observed under scanning electron microscopy (SEM) to examine surface characteristics. Data were analyzed statistically.

Results: After 24 months, 90 restorations were evaluated in 32 patients (recall rate: 86.5%). Four glass hybrid restorations were missing; three were due to bulk and one was due to proximal fracture at 12 months. Only six restorations were scored as bravo at baseline and at the six-, 12-, 18-, and 24-month recalls for color ($p<0.05$). No significant differences were observed between the two restorative materials for the other criteria evaluated ($p>0.05$). SEM observations exhibited acceptable surface and marginal adaptation characteristics for both restorative materials at 24 months.

Conclusions: Although glass hybrid restorations showed significant mismatch in color, both restorative materials exhibited successful performance for the restoration of large Class II cavities after 24 months.

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INTRODUCTION

Dental amalgam has been considered the most commonly used restorative material in posterior teeth for over 150 years, but its use has declined over the past years[1–3] because of the environmental concerns from its mercury content and increased demand for esthetic alternatives. Today's modern restorative dentistry focuses on minimal removal of tooth tissues and on application of adhesive restorative materials that may have a therapeutic effect on demineralized tissues.[3]

Resin-based composites were introduced in dentistry more than 50 years ago[4,5] and have been successfully used for the restoration of Class I and Class II lesions.[6] However, their polymerization shrinkage and associated stresses could affect the resin composite and tooth tissue bond, resulting in bonding failure and microleakage or in deformation of the tooth structure predisposing it to fracture.[7,8]

Glass ionomers (GIs) have been recommended to be used as restorative cements, cavity liners/bases, and luting cements since their introduction in dentistry in the early 1970s.[9] Compared with resin composites, they have certain unique properties that make them favorable. This includes chemical bonding to enamel and dentin, thermal expansion similar to that of tooth structure, biocompatibility, uptake and release of fluoride, and decreased moisture sensitivity.[10]

The survival rates of high-viscosity GIs that were placed in stress-bearing surfaces of both deciduous and permanent teeth as permanent restorative materials were reported as the same as or superior to amalgam restorations.[11] On the other hand, other studies that have evaluated the clinical performance of high-viscosity GIs in multiple-surface permanent restorations showed that the use of these materials did not exhibit successful results.[12,13]

During the past years, GIs have undergone major changes. Advancements in their formulations led to better properties, such as improvement in handling characteristics, wear resistance and strength and decreased setting time, which have widened the indication spectrum of GIs.[14,15]

Recently, a high-viscosity GI processed with a light-cured, nano-filled resin coating has been introduced and marketed as a restorative material in load-bearing Class I and in limited size Class II cavities. Application of this resin coating to the GI restoration after the GI sets is supposed to improve its wear resistance and esthetic appearance.[3]

Clinical studies are of great importance in predicting the longevity of restorations and providing evidence of the safety and efficacy of new techniques. Until now, only a few clinical trials of these GI restoratives have been done,[16–18] and satisfactory clinical performances were reported in Class I and in small Class II cavities.[19,20] However, this material still has not typically been considered as permanent restoration material for the restoration of extended-size Class II cavities.

One very recent development with GIs was the introduction of glass hybrids (GHs). The manufacturer of GH material stated that it is reinforced with smaller and more reactive silicate particles and acrylic acid molecules with higher molecular weights, which increase the matrix cross-linking of the material. This reinforcement is thought to improve the flexural strength of the material, and the manufacturer claims it may be used in larger Class II cavities.[21]

As it remains unclear if GHs may truly be used to restore extended cavities, the present study aimed to evaluate the clinical performance of this GH restorative compared with a micro-hybrid resin composite in the restoration of large and deep Class II cavities after 24 months. The null hypothesis was that the clinical performance of the GH restorative system would be as successful as resin composite in the restoration of extended Class II cavities.

METHODS AND MATERIALS

This was a two-year, double-blind, randomized, and controlled clinical study. The restorative materials tested are shown in Table 1.

Study Population and Sample Size

After recruiting and screening a group of patients seeking routine dental care by the Hacettepe University School of Dentistry's Department of Restorative Dentistry, a total of 37 patients satisfying the inclusion and exclusion criteria were selected. Inclusion criteria were that patients should 1) have two but not more than four extended-size proximal carious lesions in the posterior teeth, 2) have a healthy periodontal status (patients with a gingival index range of 0.28-0.35, plaque index range of 0.08-0.16,[22] and zero bleeding on probing were included[23]), 3) present a good likelihood of recall availability, 4) have teeth in which the restoration must be in occlusion, and 5) be symptomless and vital. Exclusion criteria were 1) partially erupted teeth, 2) potential behavioral problems, 3) unhealthy

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

Brand	Type	Manufacturer (Batch No.)	Composition
EQUIA Forte Fil	Bulk fill, glass hybrid restorative	GC Corp, Tokyo, Japan (1502091)	Fluoroaluminosilicate glass, polyacrylic acid powder, surface-treated glass
EQUIA Forte Coat	Nanofilled resin	GC Corp, Tokyo, Japan (2684031)	Methylmethacrylate, colloidal silica, camphorquinone, urethane methacrylate, phosphoric ester monomer
Cavity Conditioner	Cavity cleaning agent	GC Corp, Tokyo, Japan (1609061)	Polyacrylic acid 20%, aluminum chloride 3%, distilled water
G-ænial Posterior	Micro-filled resin hybrid composite	GC Corp, Tokyo, Japan (140922B)	UDMA, DMA co-monomer, inorganic filler >100 nm; fluoroaluminosilicate, inorganic filler <100 nm; fumed silica, pre-polymerized fillers (16–17 μm); strontium and lanthanoid fluoride filler (wt/vol %): 77/65
G-ænial Bond	one-step self-etch bonding agent	GC Corp, Tokyo, Japan (1411201)	4-MET, UDMA, TEGDMA, phosphoric acid, monomer, acetone, water, silanated colloidal, silica, initiator

Abbreviations: UDMA; urethanedimethacrylate, DMA; di-methacrylate co-monomer, TEGDMA; triethylene glycol dimethacrylate, 4-MET: 4 methacryloxyethyltrimellitate anhydride.

periodontal status, 4) systemic diseases, and 5) absence of adjacent and antagonist teeth. The average age of patients was 24 years (range, 15-37 years). To ensure statistical power, the minimal representative sample size was based on the required number of fillings to evaluate both materials (n=108). All patients participated voluntarily and were required to provide written informed consent.

Restorative Procedures

Two experienced clinicians placed 108 Class II restorations in 37 patients (Table 2). Before treatment, periapical and bitewing radiographs were taken, and electric pulp testing was performed using a pulp sensitivity tester (Parkell Electronics Division, Farmingdale, NY, USA). Cavity preparation was done using a diamond fissure bur (MS Rounded Edged Cylinder Bur [835R-012-4], Diatech, Heerbrugg, Switzerland) at high speed. Carious tissue was removed with hand instruments and slow-speed tungsten carbide bur (C31L-314-012-6.0, DIATECH, Coltène/Whaledent AG, Altstätten, Switzerland). Local anesthesia was applied where needed. The manufacturer of the GH restorative material limited the cavity size with the width of proximal box not interfering with the peak of cusps (Figure 1). So, before restorative treatment, after the caries was removed completely, the depth and width of the cavities were measured with a periodontal probe. If the cavity depth was <3 mm or a carious pulpal exposure was found, the tooth was excluded from the study. Cavities with multiple surfaces (>two surfac-

Table 2: *Distribution of Materials According to Tooth Type, Preparation and Arch*

	EQUIA Forte		G-ænial Posterior		Total
	MO/DO	MOD	MO/DO	MOD	
Maxillary arch					
Premolar	18	2	14	4	38
Molar	9	1	9	2	21
Mandibular arch					
Premolar	12	2	10	2	26
Molar	10	1	7	5	23
Total	49	6	40	13	108

Abbreviations: MO; Mesioocclusal, DO; Distoocclusal, MOD; Mesioocclusodistal

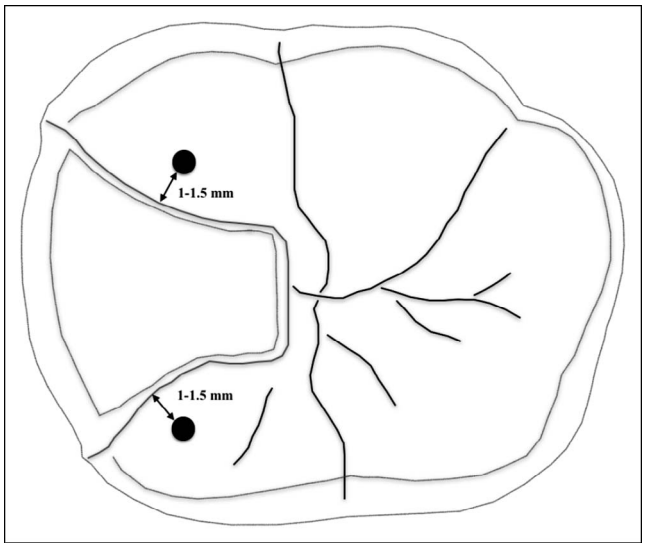

Figure 1. *Recommended Class II cavity size from the manufacturer of EQUIA Forte.*

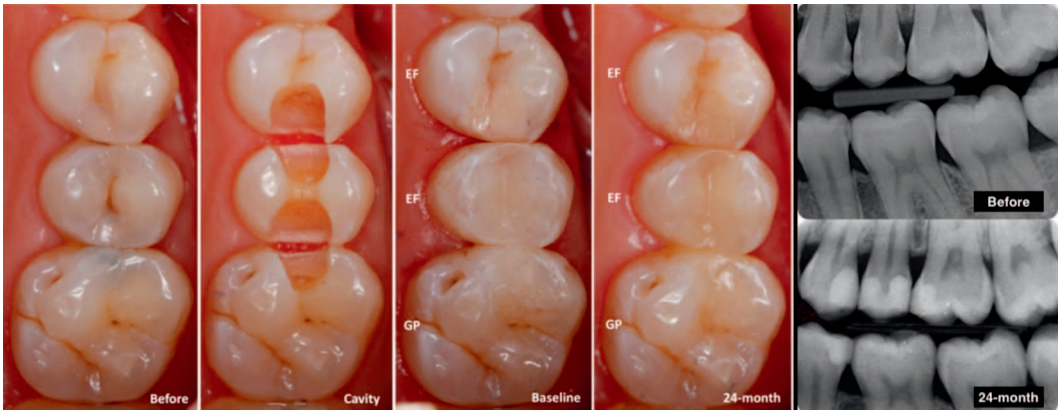

Figure 2. *Clinical and radiologic representatives of EQUIA Forte and G-ænial Posterior. Before restorations (a), cavity preparations (b), restorations at baseline (c), restorations after 24 months (d), bitewing radiograph before treatment (e), bitewing radiograph 24 months after treatment.*

es) were not included, unless unexpected cavity extension to a multiple-surface restoration during treatment occurred. Resin-modified calcium silicate pulp protectant/liner (Theracal LC, BISCO, Inc. Schaumburg, IL, USA) was applied as base material where needed. A sectional matrix system (Palodent, Dentsply, Konstanz, Germany) was used. Cavities were restored with GH restorative (EQUIA Forte, GC Corp, Tokyo, Japan) or micro-hybrid composite resin (G-ænial Posterior, GC Corp) according to the manufacturer's instructions. The restorative materials; EQUIA Forte and G-ænial Posterior, were randomized over two cavity groups using a table of random numbers.

GH Restorations

The cavity was conditioned with 20% polyacrylic acid for 20 seconds (Cavity Conditioner, GC Corp), washed, and briefly dried. Then, EQUIA Forte was mixed automatically for 10 seconds and immediately injected into the cavity. Cotton rolls and saliva ejector were used for isolation. The restoration was finished and polished wet using high-speed fine diamonds (Diatech, Swiss Dental, Heerbrugg, Switzerland) and silicones (HiLusterPLUS, Kerr Corp, Orange, CA, USA) after a setting time of 2.5 minutes. The restoration was briefly dried; then, EQUIA Forte Coat was applied to the surface and light polymerized for 20 seconds using a photo-curing light (Starlight s, Mectron spa, Carasco, Italy) with an irradiance of >1400 mW/cm^2. The output of the light unit was checked after each patient with a radiometer (Demetron, Danbury, CT, USA).

Resin Composite Restorations

G-ænial Bond (GC Corp) was used with a selective etching technique according to the manufacturer's instructions. Enamel was etched with 35% phosphoric acid gel for 10 seconds, rinsed for 5 seconds, and gently dried. Then, G-ænial Bond was applied to the enamel and dentin using a disposable applicator, left undisturbed for 10 seconds, and dried thoroughly for 5 seconds with oil-free air under air pressure. After achieving a frosted glass appearance, G-ænial Posterior was applied with the incremental technique (layers 2 mm thick). Each layer was light-cured for 20 seconds. The restoration was finished and polished with ultrafine diamonds and silicone instruments.

Patients were evaluated for baseline one week after restoration placement. Two independent dentists who were blinded to the restorative materials and patients performed clinical evaluations according to the modified US Public Health Service (USPHS) criteria using mirrors, probes, and bitewing radiographs.[24] The two dentists, with more than 20 years' experience in USPHS criteria evaluation, were calibrated to a predetermined level of inter- and intraexaminer agreement of at least a Kappa value of 95% for each criterion.

Patients were recalled at six, 12, 18, and 24 months for assessments of the restorations using the same criteria as at baseline and using the same two calibrated dentists who examined the restorations at baseline. Final decisions were made by consensus of both examiners if disagreement occurred during the evaluations. Photographs and bitewing radiographs of each restoration were also taken at each recall (Canon macro 100 mm lens, Canon Inc, Tokyo, Japan) (Figure 2).

SEM Analysis

Impressions were taken from one patient selected randomly from each group with polyvinylsiloxane

Table 3: *Recall Rates of Patients*

	Recalls				
	Baseline	**6 Months**	**12 Months**	**18 Months**	**24 Months**
Number of patients (%)	37 (100)	37 (100)	32 (86.5)	32 (86.5)	32 (86.5)

impression material at each recall. The replicas were gold sputter-coated and the surface morphology and marginal integrity of the restorations were examined under SEM (JSM-6400 SEM, JEOL, Tokyo, Japan) at ×10, ×50, and ×200 magnifications.

Statistical Analysis

The statistical analyses were carried out with the IBM SPSS version 22.0 software package (SPSS, Chicago, IL, USA). The Cochran Q test was used to compare the changes according to USPHS criteria across different time points within each restorative material. The changes in each category within the restorative groups were compared using the Fisher exact test (α=0.05).

RESULTS

The distribution of the restorations is shown in Table 2. Forty-four restorations (41%) were placed in molars and 64 restorations (59%) were placed in premolars where as 59 (55%) restorations were placed in the maxillary arch and 49 (45%) restorations were placed in mandibular arch.

The recall rate was 100% at six months and 86.5% at 12, 18, and 24 months (Table 3). At the end of 24 months, 90 restorations were evaluated in 32 patients. Eighteen restorations could not be evaluated because five patients (13.5%) had moved away. The success rate of G-ænial Posterior was 100%. Although the success rate of EQUIA Forte restorations was 93.7% at the 12-month recall, success rate was calculated as 100% at the 24-month recall as three patients with failed restorations at the 12-month recall could not be evaluated at the 24-month recall.

The results of the clinical evaluation of the restorations are presented at Table 4. According to Cochran Q test results, no significant differences were seen between baseline and other evaluation periods for both restoratives ($p>0.05$).

All restorations from the G-ænial Posterior group showed perfect anatomical form at all evaluation periods. None of the restorations from the EQUIA Forte group showed anatomical form deformation until the 12-month evaluation. Two restorations (4.4%) showed slight form deformation at 12 months. These restorations were in need of simple maintenance treatment, and their scores were upgraded to alpha (A).

Six EQUIA Forte restorations (10.9%) showed slight mismatches in color at baseline as well as six (10.9%) at six months, six (13.3%) at 12 months, six (13.3%) at 18 months, and six (13.3%) at 24 months. So, a significant difference was seen between the EQUIA Forte and G-ænial Posterior groups (p=0.011) for color change.

Three (6.3%) EQUIA Forte restorations were lost at 12 months due to bulk fracture (p=0.092). One (2.2%) EQUIA Forte restoration exhibited partial fracture at the proximal contact point of the restoration and was recorded as a failure of the restoration (p=0.429) at the end of 24 months. One EQUIA Forte restoration showed minimal discoloration at the restoration-enamel interface (p=0.429) at 12 months. No differences were observed for the rest of the evaluated criteria (secondary caries, polishability, surface staining, sensitivity, and soft tissue health) ($p>0.05$).

SEM observations of one EQUIA Forte and G-ænial Posterior restoration are shown in Figures 3 and 4. Both materials exhibited acceptable marginal adaptation and surface characteristics during the 24-month evaluation. A slight surface roughness was observed in both restorative materials after 24 months.

DISCUSSION

Adequate strength to resist masticatory and occlusal forces is mainly expected from restorative materials used in the posterior area. Resin composites have been the restorative material of choice for posterior teeth because they offer an extended manipulation time, direct-curing options, reduced number of steps required, and decreased chairside time with the introduction of bulk-fill restoratives partially in deep cavities.[25,26]

Although the merits of GIs, as restorative materials, are clearly shown in the literature,[13] the major drawbacks of conventional GIs have been the relatively low fracture toughness and higher rate of occlusal wear compared with that of other restorative materials, such as amalgam and resin compos-

Table 4: *Clinical Evaluation Scores of the Restorations at Baseline (BL) and at 6, 12, 18, and 24 Months* [a]

Modified USPHS Criteria/Scores	EQUIA Forte					
	Baseline	Six Month	12 Month	18 Month	24 Month	*p*
Anatomic form						
A: Restoration contour is continuous with existing anatomic form and margins.	55 (100)	55 (100)	43 (95.6)	45 (100)	45 (100)	0.406
B: Restoration is slightly overcontoured or undercontoured.	0	0	2 (4.4)	0	0	
C: Marginal overhang or tooth structure (dentin or enamel) is exposed.	0	0	0	0	0	
D: Restoration is missing; traumatic occlusion or restoration causes pain in tooth or adjacent tissue.	0	0	0	0	0	
Secondary caries						
A: No visible caries.	55 (100)	55 (100)	45 (100)	45 (100)	45 (100)	1.000
C: Caries contiguous with the margin of the restoration.	0	0	0	0	0	
Color match						
A: No mismatch in color, shade, or translucency between restoration and adjacent tooth structure.	49 (89.1)*	49 (89.1)*	39 (86.7)*	39 (86.7)*	39 (86.7)*	1.000
B: Mismatch between restoration and tooth structure within the normal range of tooth.	6 (10.9)	6 (10.9)	6 (13.3)	6 (13.3)	6 (13.3)	
C: Mismatch between restoration and tooth structure outside the normal range of tooth.	0	0	0	0	0	
D: Esthetically displeasing color, shade, and translucency.	0	0	0	0	0	
Retention						
A: Present.	55 (100)	55 (100)	45 (93.7)	45 (100)	45 (100)	0.406
B: Partial loss.	0	0	0	0	0	
C: Absent.	0	0	3 (6.3)	0	0	
Marginal adaptation						
A: Excellent continuity at resin–enamel interface; no ledge formation, no discoloration.	55 (100)	55 (100)	45 (100)	45 (100)	44 (97.8)	0.406
B: Slight discoloration at resin–enamel interface; ledge at interface.	0	0	0	0	1 (2.2)	
C: Moderate discoloration at resin–enamel interface measuring 1 mm or greater.	0	0	0	0	0	
D: Recurrent decay at margin.	0	0	0	0	0	
Polishability						
A: Smooth and highly shiny, similar to enamel.	55 (100)	55 (100)	45 (100)	45 (100)	45 (100)	1.000
B: Smooth and satin, highly reflective.	0	0	0	0	0	
C: Rough and shiny, satin, somewhat reflective.	0	0	0	0	0	
D: Rough and dull or satin, not reflective.	0	0	0	0	0	
Surface staining						
A: Absent.	55 (100)	55 (100)	45 (100)	45 (100)	45 (100)	1.000
C: Present.	0	0	0	0	0	
Sensitivity						
Preoperative						
Yes	0	0	0	0	0	1.000
No	55 (100)	55 (100)	45 (100)	45 (100)	45 (100)	
Postoperative						
Yes	0	0	0	0	0	1.000
No	55 (100)	55 (100)	45 (100)	45 (100)	45 (100)	
Soft tissue health						
A: Excellent response-no inflammation.	55 (100)	55 (100)	45 (100)	45 (100)	45 (100)	1.000
B: Slight inflammation of gingival tissue.	0	0	0	0	0	
C: Moderate to severe gingival inflammation.	0	0	0	0	0	
Proximal contact points						
A: Present.	55 (100)	55 (100)	45 (97.8)	45 (100)	45 (100)	1.000
C: Absent.	0	0	1 (2.2)	0	0	

Abbreviation: USPHS, US Public Health Service.

[a] Asterisks indicate that the *p* values in the columns show the difference of restorations in comparison with baseline according to Cochrane Q test for all criteria.

Table 4: *Extended.*

Modified USPHS Criteria/Scores	G-ænial Posterior					
	Baseline	**Six Month**	**12 Month**	**18 Month**	**24 Month**	***p***
Anatomic form						
A: Restoration contour is continuous with existing anatomic form and margins.	53 (100)	53 (100)	45 (100)	45 (100)	45 (100)	1.000
B: Restoration is slightly overcontoured or undercontoured.	0	0	0	0	0	
C: Marginal overhang or tooth structure (dentin or enamel) is exposed.	0	0	0	0	0	
D: Restoration is missing; traumatic occlusion or restoration causes pain in tooth or adjacent tissue.	0	0	0	0	0	
Secondary caries						
A: No visible caries.	53 (100)	53 (100)	45 (100)	45 (100)	45 (100)	1.000
C: Caries contiguous with the margin of the restoration.	0	0	0	0	0	
Color match						
A: No mismatch in color, shade, or translucency between restoration and adjacent tooth structure.	53 (100)*	53 (100)*	45 (100)*	45 (100)*	45 (100)*	1.000
B: Mismatch between restoration and tooth structure within the normal range of tooth.	0	0	0	0	0	
C: Mismatch between restoration and tooth structure outside the normal range of tooth.	0	0	0	0	0	
D: Esthetically displeasing color, shade, and translucency.	0	0	0	0	0	
Retention						
A: Present.	53 (100)	53 (100)	45 (100)	45 (100)	45 (100)	1.000
B: Partial loss.	0	0	0	0	0	
C: Absent.	0	0	0	0	0	
Marginal adaptation						
A: Excellent continuity at resin–enamel interface; no ledge formation, no discoloration.	53 (100)	53 (100)	45 (100)	45 (100)	45 (100)	1.000
B: Slight discoloration at resin–enamel interface; ledge at interface.	0	0	0	0	0	
C: Moderate discoloration at resin–enamel interface measuring 1 mm or greater.	0	0	0	0	0	
D: Recurrent decay at margin.	0	0	0	0	0	
Polishability						
A: Smooth and highly shiny, similar to enamel.	53 (100)	53 (100)	45 (100)	45 (100)	45 (100)	1.000
B: Smooth and satin, highly reflective.	0	0	0	0	0	
C: Rough and shiny, satin, somewhat reflective.	0	0	0	0	0	
D: Rough and dull or satin, not reflective.	0	0	0	0	0	
Surface staining						
A: Absent.	53 (100)	53 (100)	45 (100)	45 (100)	45 (100)	1.000
C: Present.	0	0	0	0	0	
Sensitivity						
Preoperative						
Yes	0	0	0	0	0	1.000
No	53 (100)	53 (100)	45 (100)	45 (100)	45 (100)	
Postoperative						
Yes	0	0	0	0	0	1.000
No	53 (100)	53 (100)	45 (100)	45 (100)	45 (100)	
Soft tissue health						
A: Excellent response-no inflammation.	55 (100)	55 (100)	45 (100)	45 (100)	45 (100)	1.000
B: Slight inflammation of gingival tissue.	0	0	0	0	0	
C: Moderate to severe gingival inflammation.	0	0	0	0	0	
Proximal contact points						
A: Present.	55 (100)	55 (100)	45 (100)	45 (100)	45 (100)	1.000
C: Absent.	0	0	0	0	0	

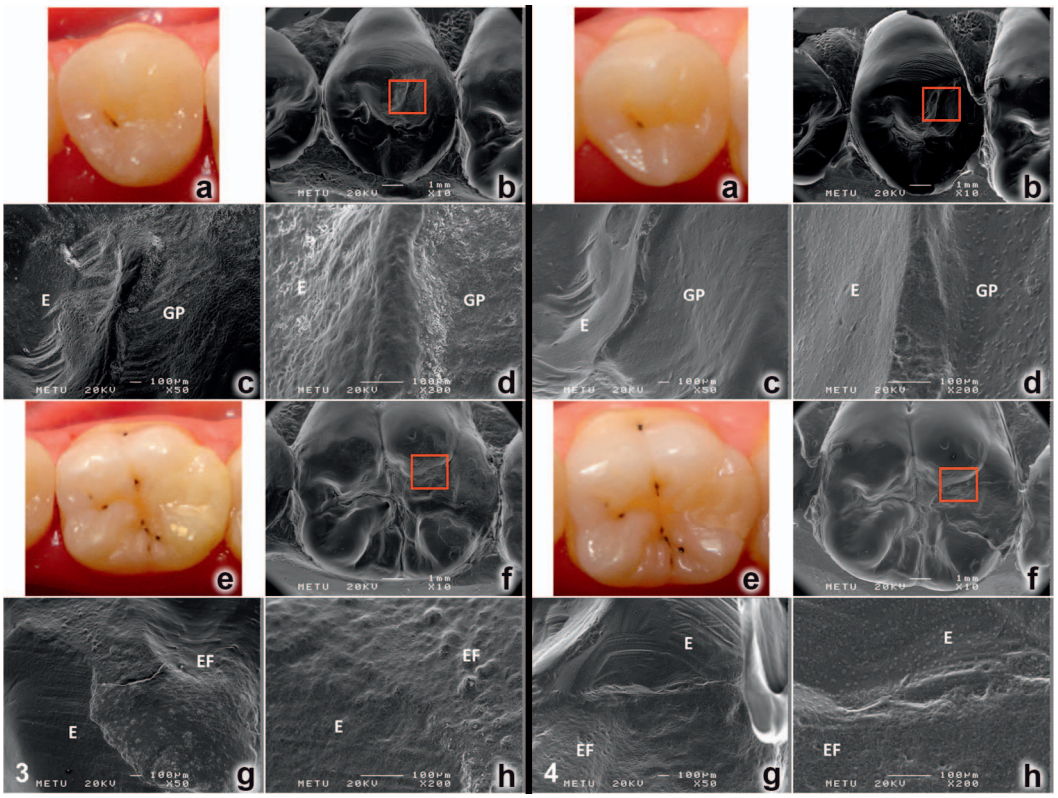

Figure 3. *Representatives of G-ænial Posterior and EQUIA Forte restorations at baseline. Clinical picture of G-ænial Posterior restoration (a), SEM photomicrograph of the G-ænial Posterior restoration ×10 (b), ×50 (c), and ×200 (d). Clinical picture of EQUIA Forte restoration (e), SEM photomicrograph of the G-ænial Posterior restoration ×10 (f), ×50 (g), and ×200 (h). E: enamel; EF: EQUIA Forte; GP: G-ænial Posterior.*

Figure 4. *Representatives of G-ænial Posterior and EQUIA Forte restorations after 24 months. Clinical picture of G-ænial Posterior restoration (a), SEM photomicrograph of the G-ænial Posterior restoration ×10 (b), ×50 (c), and ×200 (d). Clinical picture of EQUIA Forte restoration (e), SEM photomicrograph of the G-ænial Posterior restoration ×10 (f), ×50 (g), and ×200 (h). E: enamel; EF: EQUIA Forte; GP: G-ænial Posterior.*

ites.[27] For this reason, conventional modified GIs were previously not considered materials of choice in Class II restorations, neither in primary nor permanent molars.[12,13] In recent years, further improvements in the composition of GIs have been made to enhance their clinical handling and physical or mechanical properties. Laboratory studies showed that highly viscous GIs could compete with resin composites.[21,28,29]

Although the overall data density on amalgam or composite resin is very high,[30–32] to date, only few studies regarding clinical success of GI-based restorative systems have been reported. These studies were mostly performed on Class I cavities.[17,33] There have been limited data showing their performance in Class II cavities, and clinical trials on Class II cavities were carried out on patients with small to moderate size cavities.[20,34] Although a few clinical studies with different restorative GIs have been carried out,[16,20,34] as far as we could determine, this is the first clinical trial that compared the use of the newly developed GH system in the restoration of extended size Class II cavities. Since no data are available on the clinical success of this new reinforced GH in the restoration of large Class II restorations, the comparison with those of other studies could not be done.

Previously, Scholtanus and Huysmans [12] examined the performance of a high-viscosity GI (Fuji IX, GP Corp) in Class II restorations over six years in a retrospective study. One hundred and sixteen Class II restorations (70 two-surface and 46 three-surface) in 72 patients were made in 1996 and 1997 in general dental practice by two experienced dentists. The authors observed no failures until 18 months; but the survival rate was 93% at 42 months. Failure rate increased after 42 months, and at 72 months the survival rate was reported as 60%. Fracture of the GI in the proximal areas was reported as the reason for replacing restorations. No restorations failed due to the occlusal wear or isthmus fracture. Later, in a prospective clinical study, Frankenberger and oth-

ers[13] examined the clinical performance of a viscous GI (Ketac Molar) in posterior cavities over 2 years and reported that the recall rates were 24% and failure rates were 40% for Class II cavities after 2 years. Bulk fracture at occlusally loaded areas was the main reason for failures.

In 2011, Friedl and others[16] evaluated the clinical behavior of a new GI restorative system, EQUIA in posterior teeth. In this retrospective study, 26 Class I and 125 Class II restorations were placed in permanent molars and premolars of 43 patients in six dental offices. After 24 months, they observed no failures but marginal disintegrities were seen in 1.2% of two-surface Class II cavities and 7.3% of Class II cavities with three or four surfaces. A visible roughness was observed in 14% of two-surface Class II restorations and in 24% of Class II restorations with three or four surfaces. The authors concluded that this system could be used as a permanent restoration material for any size Class I and smaller Class II cavities.

Klinke and others[18] also carried out a multicentered prospective clinical field study with the EQUIA restorative system (EQUIA Fil + EQUIA coat) and examined the clinical performance of this system according to the World Dental Federation criteria. The study was conducted in 144 different private dental clinics in 29 cities. A total of 232 Class II restorations were placed out of 1001 restorations in adult patients aged 20-80 years. However, after four years, they could evaluate only 32 Class II restorations. Eight restorations lost proximal contact or fractured and were found to be clinically poor and needed to be replaced after four years.

Turkun and Kanik[34] reported the clinical performance of EQUIA System over six years. In their long-term clinical trial, 44 Class II cavities out of 256 restorations were restored with the EQUIA system (EQUIA Fil + G Coat). They defined Class II cavities as mostly medium to large in size but not involving any cusps. After 18 months, five Class II restorations (EQUIA Fil + G Coat) had to be replaced, but at the end of six years, they only observed one more restoration that was partially missing and had to be replaced, while six restorations had to be repaired.

In these clinical studies, cavity size in relation to the remaining tooth structure was less considered. However, the manufacturer of the EQUIA Fil restorative system indicated that if used in small to moderate sized Class II cavities; the isthmus width must be less than the half of the intercuspal distance.[18]

Gurgan and others[20] reported another long-term clinical study. Sixty Class II lesions were restored with EQUIA or a micro-hybrid resin composite (Gradia Direct Posterior). In this study, a conservative cavity design was used with the principles of minimally invasive dentistry. None of the cavity preparations involved one or more cusps. Restorations were evaluated yearly according to the modified USPHS criteria. At the end of six years, 45 Class II restorations could be evaluated. Only four Class II EQUIA restorations were lost at three years and another one at four years. No failures were observed at five and six years. However; none of the materials were found to be superior to the other.

The present study was performed on patients with at least two extended size Class II lesions. A new GH restorative system was compared with a resin composite used in the restoration of posterior teeth. In contrast to the previous GI restorative material (EQUIA Fil), the manufacturer of this new GH restorative material (EQUIA Forte) recommended using this material reinforced with ultrafine and highly reactive glass particles for larger and deeper Class II cavities.[35]

As pointed out by American Dental Association, a restorative 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.[36] In this study, after 24 months, the retention rate of EQUIA Forte Class II restorations was 93.7%. This suggests that the new reinforced GH performs well. So, the null hypothesis is accepted.

None of the restorations showed secondary caries or postoperative sensitivity. Their polishability was successful, and none of the restorations showed surface staining. This may be attributed to the resin coating applied to the surface of restorations. Only a few EQUIA Forte restorations showed slight changes in anatomic form (4.4%) and proximal contact points (2.2%), and three (6.3%) restorations failed during the 12-month follow-up. At the end of 24 months, only one (2.2%) EQUIA Forte restoration had slight discoloration at the restorative material-enamel interface. Much more important were the contact points on lateral ridges, which showed special risk of bulk fractures. Chipping of proximal marginal ridges was reported in earlier studies with conventional reinforced GIs.[12,37] The anatomic form loss seen in the present study in 4.4% of the GH restorations may have been caused by the intrinsic material parameters after abrasion of the surface

coating; the single proximal contact point loss and three failures may be due to the masticatory forces or stresses.

Besides physical properties, the esthetic properties of this material were enhanced by the small glass particles added to the material in different sizes and the application of the coating layer.[35,38] In the present study, color match was seen as the major problem. Six restorations, starting from baseline, showed mismatches in color during all evaluation periods. Controversially, Diem and others[17] reported that 25% of the GI restorations were evaluated as good at baseline but steadily increased to 80% as good at three years. Turkun and Kanik[34] also reported that difference in color was less visible after six years due to the improvement in translucency over time.

This clinical trial also included SEM analyses, as did a previous study, to examine the marginal adaptation and surface characteristics.[20] Twenty-four-month SEM evaluations supported the clinical observations. Both restorations showed acceptable occlusal and marginal characteristics.

On the other hand, the resin composite (G-ænial Posterior) used with a one-step self-etch adhesive (G-ænial Bond) showed clinically successful performance. All G-ænial Posterior restorations performed perfectly in all criteria at all evaluation periods. However, clinical data on resin composites used with self-etch adhesives in selective etch technique for the restoration of Class II cavities are limited, and there have been no long-term results yet. The evaluation period of the present study may not be long enough and further reports of long-term studies are needed to confirm the results of the present study. It should not be ignored that the clinical performance of these materials can also be affected by factors like operator skill.

CONCLUSIONS

The following conclusions may be drawn within the limitations of the present study:

1. Micro-hybrid resin composite showed clinically successful performance in the restoration of large Class II cavities after 24 months;
2. The GH restorative system showed significant mismatches in color and negligible failures, with no significant differences in retention, anatomic form, and proximal contact points;
3. The GH restorative system used could also be a viable option for restoring large Class II lesions.

Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the Hacettepe University, Ankara, Turkey. The approval code for this study is 2015/KA-15053. This clinical trial was also registered in a clinical trial registry system under ClinicalTrials.gov ID: NCT02991664.

Conflict of Interest

The authors of this manuscript certify that they 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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