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Evaluating the Clinical Performance of Highly Filled Injectable Composite and Condensable Universal Composite Restorations: A One-Year Randomized Clinical Trial

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ABSTRACT

Objective: Composite materials are constantly renewed and developed. Recently, injectable composite materials with filler ratios similar to condensable composites have been made available to clinicians. The purpose of this randomized controlled clinical trial was to evaluate the one-year clinical performance of Class II restorations performed with injectable and condensable universal composite resins.

Methods: The study involved 71 patients (45 female, 26 male) and 140 restorations. It used G-aenial Universal Injectable (GCI; GC, Tokyo, Japan), G-aenial A'CHORD (GCA; GC, Tokyo, Japan), Tetric Prime (TP; İvoclar Vivadent, Lichtenstein), Filtek Ultimate (FU; 3M ESPE, St. Paul, MN, USA) universal composites, and the Clearfil SE Bond (Kuraray Noritake Dental, Japan) self-etch adhesive system. Restorations were evaluated and scored according to modified USPHS criteria at baseline, six months, and one year. Cochran Q and Fisher-Freeman-Halton tests were used for statistical analysis ($p < .05$).

Results: At the end of the first year, no significant differences over time were observed in any parameter within any material group ($p > .05$). The study's materials were compared, showing statistically similar results ($p > .05$).

Conclusion: This study found that all materials, including the injectable universal composite, demonstrated similar and successful clinical performance at the end of the first year.

Keywords: Class II restoration, clinical evaluation, high-fill injectable, universal composite resin

1. INTRODUCTION

Composite resins' high aesthetic properties, ability to allow minimally-invasive cavity design, and improved mechanical and physical properties have increased their popularity today (1). Due to aesthetic and possible toxic concerns, amalgam has been abandoned in many countries, and composite resins have become the primary materials for restoring posterior teeth (2–4).

Composite resins have made remarkable advances in recent years and are available in various forms (5–8). Universal composites offer clinicians a wide range of applications thanks to their functional durability in the posterior region, and the high degree of polishability and aesthetic properties required to imitate natural tooth tissue in the anterior region (9,10).

Choosing the appropriate composite material for restoring posterior teeth requires balancing many requirements. Mechanical and physical properties affect the restorations' life, such as fracture resistance, optimized elastic modulus, low solubility, and low polymerization shrinkage. At the same time, it must fulfill aesthetic properties such as color stability, optimum polishability, and long-term preserved anatomical form (11). In addition, technical precision is also critical in the use of composite materials. While the clinical survival of restorations not made under appropriate conditions decreases, secondary caries may also occur (12,13). These disadvantages have shown the need to produce materials that are easy to apply and mechanically and physically resistant (14).

In recent years, second-generation flowable composites with a high filler ratio entitled "high filler flowable composite" (HFFC) or "high filler injectable composite" (HFIC), have been introduced to the market. These materials have been reported to have reduced polymerization shrinkage/stress and improved mechanical properties. The aim is to simplify the application and shorten the time spent on the restoration

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step with these composites (14,15). In addition, due to their increased physical and mechanical properties, manufacturers recommend using HFICs as permanent restoration materials even in areas that will receive chewing loads (16).

Filtek Ultimate conventional universal composite (CUC), preferred in our study, has been widely used in dentistry for many years (17–19). However, G-aenial A'CHORD, Tetric Prime and G-aenial Universal Injectable composite materials considered in the study are relatively new, and studies on them are limited (9,20–23). We have yet to find a study in the literature comparing the clinical performance of HFIC and CUCs in posterior restorations. Clinical follow-up studies are neededin which these materials, that provide ease of application and are thought to reduce technical sensitivity, are investigated together with CUCs.

This study evaluated the clinical performance of Class II restorations performed with one HFIC and three CUCs at baseline, 6 months, and 1st year according to modified USPHS criteria (United States Public Health Service criteria) (24). The study's null hypothesis was that there is no difference in the clinical performance of Class II restorations performed with HFIC and CUCs.

2. METHODS

2.1. Ethical approval and protocol registration

The T.R.Ministry of Health, Turkish Pharmaceuticals, and Medical Devices Ethical Committee approved this prospective clinical trial (2022/152). Participants were informed of the objectives and content of the study, and voluntary consent forms were signed. This clinical trial was registered at ClinicalTrials.gov under the registration number NCT06346756.

2.2. Trial design, settings, and location of data collection

The study was a single-blind (patient) randomized controlled clinical study. It was conducted in the Restorative Dentistry Department Clinic of Selçuk University.

2.3. Participant recruitment and randomization

Participants were selected from patients who applied to the Restorative Dentistry Clinic of the Faculty of Dentistry of Selçuk University and met the inclusion criteria for the study. Table 1 presents the inclusion and exclusion criteria for patients to be included in the study. A total of 71 patients (45 female, 26 male) aged between 18 and 50 years, and involving 140 restorations were included in the study.

The patients included in the study had at least two and a maximum of four posterior approximal caries. At least two different restorative materials were used in each patient. The study used well-sealed envelopes containing material information to determine which restoration material would be applied to the teeth.

Table 1. *Inclusion and exclusion criteria.*

Inclusion Criteria	Exclusion Criteria
A patient presenting with; 1) over 18 years of age 2) a normal periodontal status and good general health 3) proximal caries that similar size on premolar and molar teeth 4) cavity width not exceeding ½ of the intercuspal distance 5) teeth that were vital 6) teeth in contact with the opposing tooth and subjected to normal occlusal forces 7) attend follow-up appointments	1) poor oral hygiene status 2) those with severe or chronic periodontitis 3) absence of adjacent and antagonist teeth 4) potential behavioural problems (e.g. bruxism) 5) allergy to any product used in the study 6) exposure of the pulp during cavity preparation 7) systemically unhealthy 8) pregnant and lactating women

2.4. Sample size calculation

The study calculated the sample size based on the difference between the groups' initial, 6-, and 12-month clinical success rates. The minimum sample size for determining the statistical difference with a significance level of 5%, a statistical power of 80%, and an effect size of 0.30 (moderate) was 31 restorations in each group. Considering the potential for patients to discontinue follow-up, the number of restorations in each group was determined to be 35.

2.5. Restoration Procedures

A single practitioner (M.G.) performed all cavity preparations and restorations. A rubber dam (heavy – 0.25 mm, Sanctuary Dental, Malaysia) was used for isolation purposes. Operative procedures and restoration processes were performed under local anesthesia if necessary (Ultracain, Sanofi aventis, Germany). In cavity preparation enamel tissue was removed in cavity preparation with a high-speed aerator and green band diamond round burs under water cooling (Green band, NO:12C, SWS-MDT, Turkey). Class II cavities were prepared according to the boundaries of the carious tissue. Necrotic and infected dentin were removed using a low-speed micromotor with tungsten carbide burs (ISO size 014-016, Meisinger, Neuss, Germany). All cavity margins were finished in sound enamel tissue. After cavity preparation was completed, the cavities were washed and dried. Proximal contacts were achieved using a metallic matrix (Tofflemire Contoured Matrices, Kerr/USA) and wooden wedges (SycamoreInterdental Wood Wedge, Kerr/USA).

In the study, G-aenial A'CHORD (GCA), Tetric Prime (TP), Filtek Ultimate Universal (FU), and G-aenial Universal Injectable (GCI) composite resins, and a Clearfil SE Bond adhesive system were used. Adhesive systems and composite resins were applied according to the manufacturer's instructions. The types, contents, and manufacturer's instructions for the materials used in the study are shown in Table 2. The adhesive system and composite resins were polymerized with a Valo LED light device (1000 mW/cm2, Ultradent, South Jordan, UT, USA). After removing the matrix band from the tooth, the light was applied for 20 seconds on the buccal and palatal/lingual surfaces. The power of the light device was checked with a radiometer (Hilux Curing Light Meter, Benlioğlu Dental, Turkey) every ten applications.

Table 2. *Materials used in the study.*

Product Name	Composition	Mode of Application
Clearfil SE Bond Kuraray Noritake Dental, Japan *(self-etch adhesive system)*	Primer: 10-Methacryloyloxidodecyl dihydrogen phosphate (10-MDP), 2-Hydroxyethyl methacrylate (HEMA), hydrophilic aliphatic dimethacrylate, dl-camphorquinone, N,N-diethanol-p-tolidine, water. Bond: 10-Methacryloyloxidodecyl dihydrogen phosphate (MDP), Bisphenol A diglycidyl methacrylate (Bis-GMA), 2-hydroxyethyl methacrylate (HEMA), hydrophobic aliphatic dimethacrylate, dl-camphorquinone, N,N-diethanol-p-tolidine, colloidal silica.	The primer is applied to the cavity for 20 seconds, dried with air for 5 seconds, and light-cured for 10 seconds after applying the bonding agent.
G-aenial A'CHORD GC/ Tokyo, Japan *(high viscous classic)*	Monomers: UDMA, TEGDMA, BisMEPP Filler (wt%): Glass-filler (barium glass) and fumed silica organic filler (fumed silica) (82 wt%).	2 mm layers are placed in the cavity, each layer is light-cured for 20 seconds.
Tetric Prime İvoclar Vivadent/Lichtenstein *(high viscous classic)*	Monomers: Bis GMA, UDMA, Bis-EMA Filler (wt%): Ba-Al-Silicate glass, copolymer, mixed oxide, ytterbium trifluoride (79–80%).	2 mm layers are placed in the cavity, each layer is light-cured for 20 seconds.
Filtek Ultimate Universal 3M ESPE, St. Paul, MN, USA *(high viscous classic)*	Monomers: Bis-GMA, UDMA, TEGDMA, bis-EMA, PEGDMA Filler (%wt): Silica filler and zirconia filler (76.5%).	2 mm layers are placed in the cavity, each layer is light-cured for 20 seconds.
G-aenial Universal Injectable GC/ Tokyo, Japan *(high filler injectable)*	Monomers: UDMA, bis-EMA, methacrylate monomers Filler (wt%): Silica and barium glass (69%).	2 mm layers are placed in the cavity, each layer is light-cured for 20 seconds.

Contacts in occlusion and articulation were controlled with double-sided articulating paper and adjusted where necessary. Yellow-band diamond burs (Meisinger Dental Burs, Hager & Meisinger GmbH, Germany) were used to remove premature contacts, make occlusal adjustments, and shape interproximal areas. Finishing and polishing procedures were performed using rubbers (Dentsply/Canada) and discs (Sof-LexTM 3M ESPE, USA) with micromotor under water cooling. The rubber dam was removed. After the procedures were completed, patients were given oral hygiene motivation.

2.6. Clinical Evaluation of Restorations

In this study, calibration training was given to two dentists who participated as evaluators before the study was conducted. After the restorations were placed, patients were called for follow-up at one week (baseline), six months, and one year. Dental mirrors, probes, floss, bitewing radiographs, and intraoral photographs were used to clinically evaluate the restorations. The restorations were evaluated for retention, color match, marginal discoloration, marginal adaptation, surface texture, secondary caries, anatomical form, and postoperative sensitivity by double-blind and calibrated by two experienced dentists according to modified USPHS criteria. Cohen's Kappa coefficient was used for interobserver reliability. If there were discrepancies between the observers' evaluations, both observers re-evaluated the restorations, and consensus was reached before the patients were left (25,26). Restorations were scored as Alpha, Bravo, and Charlie. Clinical examination was performed using a dental mirror, probe, and floss.

2.7. Statistical Analysis

Statistical analyses were performed using R version 4.1.2 (The R Foundation for Statistical Computing, Vienna, Austria) statistical software. The change rates of GCA, TP, FU, and GIC restorations were examined over time with the Cochran Q test according to the modified USPHS criteria. Alpha score rates for the study's materials at the same measurement time were compared with the Fisher-Freeman-Halton test. The significance value was determined as $p<.05$.

3. RESULTS

Our study evaluated 140 restorations in 71 patients (45 female, 26 male). The distribution of restorations according to composite materials and teeth is shown in Table 3. Follow-up appointments were carried out on the 7th day, 6th month, and 1st year after the restorations were performed. All patients attended their control appointments. The clinical evaluation of Class II restorations according to the Modified USPHS criteria is shown in Table 4.

Table 3. *Distribution of composite materials according to teeth.*

MATERIAL	Premolar	Molar	TOTAL
G-aenial A'CHORD	18	17	35
Tetric Prime	18	17	35
Filtek Ultimate Universal	19	16	35
G-aenial Universal Injectable	20	15	35

Table 4. *Baseline, six-months and one-year clinical evaluation of restorations.*

USPHS Criterion	Baseline			Six months			One year		
	A	B	C	A	B	C	A	B	C
Retention									
GCA	35	0	0	35	0	0	35	0	0
TP	35	0	0	35	0	0	35	0	0
FU	35	0	0	35	0	0	35	0	0
GCI	35	0	0	35	0	0	35	0	0
Color match									
GCA	35	0	0	35	0	0	35	0	0
TP	35	0	0	35	0	0	35	0	0
FU	35	0	0	35	0	0	35	0	0
GCI	35	0	0	35	0	0	35	0	0
Marginal discoloration									
GCA	35	0	0	35	0	0	35	0	0
TP	35	0	0	35	0	0	35	0	0
FU	35	0	0	35	0	0	35	0	0
GCI	35	0	0	35	0	0	35	0	0
Marginal adaptation									
GCA	35	0	0	35	0	0	34	1	0
TP	35	0	0	35	0	0	35	0	0
FU	35	0	0	35	0	0	34	1	0
GCI	35	0	0	35	0	0	32	3	0
Secondary caries									
GCA	35	–	0	35	–	0	35	–	0
TP	35	–	0	35	–	0	34	–	1
FU	35	–	0	35	–	0	35	–	0
GCI	35	–	0	35	–	0	35	–	0
Surface texture									
GCA	35	0	0	35	0	0	35	0	0
TP	35	0	0	34	1	0	34	1	0
FU	35	0	0	35	0	0	35	0	0
GCI	35	0	0	35	0	0	35	0	0
Anatomical form									
GCA	35	0	0	35	0	0	35	0	0
TP	35	0	0	35	0	0	35	0	0
FU	35	0	0	35	0	0	35	0	0
GCI	35	0	0	35	0	0	35	0	0
Postoperative sensitivity									
GCA	35	0	0	33	2	0	35	0	0
TP	35	0	0	35	0	0	35	0	0
FU	35	0	0	35	0	0	35	0	0
GCI	35	0	0	35	0	0	35	0	0

Abbreviation: USPHS, US Public Health Service; A, Alpha; B, Bravo; C, Charlie; GCA, G-aenial A'CHORD; TP, Tetric Prime; FU, Filtek Ultimate Universal; GCI, G-aenial Universal Injectable.

3.1. Evaluation of Restorations

At the end of the first year, no significant differences over time were observed in any parameter within any material group (Figure 1) (p> .05). In the GCA group, postoperative sensitivity was observed in two teeth at six months. However, these complaints disappeared in patients at the one-year evaluation. In one GCA, one FU, and three GCI restorations scored as Bravo in the marginal adaptation parameter at one year, and excess composite resin at the finishing margins was corrected with yellow-band diamond burs and polished. In the TP group, at one year, secondary caries was diagnosed in one restoration. Although there was no loss in the overall form of the restoration, decay was detected on a bite-wing radiograph. The restoration was renewed with GCA. In the 6th month and 1st year, one TP restoration scored as Bravo in the surface texture parameter. The study's materials were compared, and statistically similar results were observed (p> .05).

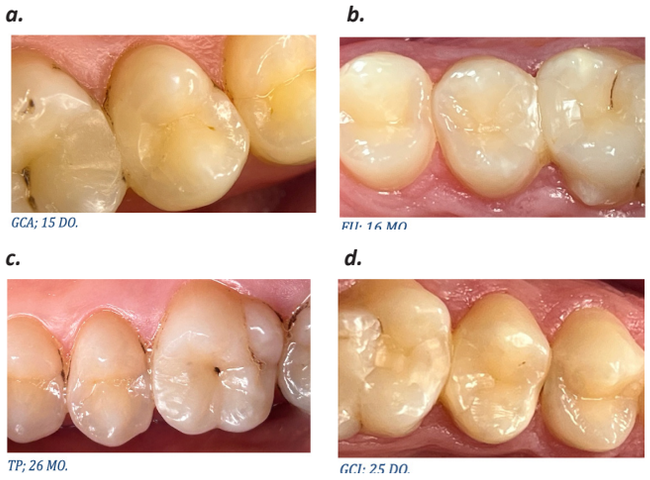

Figure 1. *Restorations that scored as Alpha from all parameters at one year: a. 15 DO restorations performed with GCA, b. 16 MO restorations performed with FU, c. 26 MO restorations performed with TP, and d. 25 DO restorations performed with GCI.*

4. DISCUSSION

This study presents a one-year clinical follow-up of Class II restorations restored with one HFIC (GCI) and three CUCs (GCA, FU, TP). The study's results led to an acceptance of the null hypothesis. At the end of the first year, HFIC and CUCs' clinical performances were comparable and successful.

FU has been a preferred material in clinical routine for many years. The literature includes both in vitro and clinical studies of this material (18,27–29). The study presenting the clinical follow-up of FU and a bulk-fill composite in Class II restorations reported that both materials showed successful clinical performance at 12 months (17). These results are compatible with those of our study. However, in the sixth year of the same study, the marginal adaptation and marginal coloration rate of FU showed a significant increase compared to the initial situation (18). Based on these data, it seems that long-term clinical follow-ups are necessary to determine the effects of a dynamic environment such as that found in the mouth on materials.

The literature lacks long-term clinical follow-up studies of GCA, TP, and GCI composites, which are relatively new materials. In vitro studies examining materials' physical and mechanical properties are also limited (9,20,21,30).

In an in vitro study, Class II cavities prepared in extracted primary and permanent molars were restored with TP, an HFFC, and a bulk-fill composite. The marginal integrity of the restorations was examined before and after mechanical

loading. No significant difference was observed in the marginal compliance of the TP after mechanical loading (30). It is not possible to directly compare the results of our study with those of this study. However, in our study, all TP restorations were scored as Alpha in the marginal adaptation parameter in the first year.

In another study, the surface roughness and microhardness values of GCI and four different HFFC (Filtek Supreme Flowable, 3M; Estelite Universal Flow, Tokuyama; Omnichroma Flow, Tokuyama; Filtek Universal Restorative, 3M) materials were investigated after brushing. It has been reported that the surface roughness values of all materials increased, and the microhardness values decreased after brushing. The lowest microhardness values were observed in GIC (31). Properties such as surface roughness, microhardness, and the wear behavior of thin occlusal veneers made with GIC and two different HFICs (Beautifil Injectable, Shofu; Sonicfill-2, Kerr) were compared in vitro with resin-based CAD/CAM material (Ceresmart, GC). The materials were subjected to thermomechanical loading in a chewing simulator. The study reported that GIC showed the least wear and was more durable than Ceresmart. In addition, other HFICs were reported to undergo degradation after thermomechanical loading (20). While GIC showed the lowest microhardness values in one study (31), it was reported as the material with the highest wear resistance in another study (20). The fact that the materials compared with GIC in the studies are entirely different may affect the results. During the restoration phase of our work, notes were taken and recorded for each material. It has been noted that in restorations made with GIC, more restorative material is removed from the surface during the polishing stage than other materials. This situation is parallel to the low microhardness data in Canyurt's study (31). In the first year, the results of our research showed that GCI showed very successful clinical performance. The marginal adaptation of only three restorations was scored as Bravo. Excess composite material that exceeded the restoration-tooth boundary was corrected in these restorations at the control appointment. The high fluidity of the material may be a factor in exceeding the tooth-restoration limit.

In the SEM study, simulated gastric acid was applied to GCA, and four different composite materials (Omnichroma, Tokuyama; Vittra Unique, FGM; Charisma Diomand One, Kulzer; Neo Spectra ST, Dentsply; Nova Compo C, Imicryl) and their surface roughness and microhardness changes were examined. On the 7th day of acid application, the roughness values of all materials were found to be acceptable. On the 14th day, a significant difference was observed in all materials' roughness and microhardness values. However, on the 14th day, the surface roughness values of GCA were reported to be clinically acceptable (21). Gürgan et al.'s study (9) compared the physical properties of GCA, FU, and three universal composites (Estelite Asteria, Tokuyama; Charisma Dimond, Kulzer; Neo Spectra ST HV, Dentsply). The results indicated that GCA showed the lowest surface roughness and microhardness values. While FU shows the highest microhardness values, it is just below those of Charisma Dimond, which shows the highest values in surface roughness. GCA and FU showed similar values in terms of color change and translucency examination. In addition, in the SEM images of the study, the smoothest surface was observed in GCA (9). In our study, all GCA restorations scored as Alpha for parameters such as color change, marginal discoloration, marginal adaptation, and surface texture that can be affected by surface roughness.

The study detected secondary caries in only one TP restoration in the first year mark in the case of one patient whose oral hygiene was found to be inadequate. The patient was given oral hygiene motivation, and the restoration was renewed. Postoperative sensitivity was observed in two GCA restorations at six months. However, no symptoms or pathology were found in these restorations at the 1-year follow-up. Short-term and spontaneously-resolving postoperative sensitivity may be associated with periodically increasing bruxist forces in patients.

In line with these data, although in vitro studies have an important place in determining materials' physical and mechanical properties, they should be supported by clinical findings. Since the literature does not appear to exist for clinical follow-up of GCA, TP, and GCI materials, we could not compare our study's results clinically. Therefore, we think our study's results are valuable.

There are several limitations in our study. First of all, more than one year is needed to determine the clinical behaviour of the materials. Long-term clinical follow-up of this study is planned in the future. Additionally, split-mouth randomization was not applied in our study. It is quite challenging to include patients in whom four restorative materials can be applied split-mouth. Since materials without clinical follow-up were used in the study, it was planned for individuals with good oral hygiene and have small approximal caries. Studies evaluating the clinical performance of these materials in individuals with high caries risk patients and cavities with high material loss are also required.

5. CONCLUSION

G-aenial Universal Injectable, G-aenial A'CHORD, Tetric Prime, and Filtek Ultimate universal composites showed similar and successful clinical performance. In addition, G-aenial Universal Injectable, a high filler injectable composite, can be considered an alternative to conventional universal composites in the restorations of Class II posterior cavities.

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Author Contributions:

Research idea: N.Ü., M.G.
Design of the study: N.Ü., M.G.
Acquisition of data for the study: M.G., N.Ü.
Analysis of data for the study: M.G., N.Ü.
Interpretation of data for the study: M.G., N.Ü.
Drafting the manuscript: M.G., N.Ü.
Revising it critically for important intellectual content: M.G., N.Ü.
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