

The 24 months clinical evaluation of class II bulk fill composite restorations

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Abstract

Background: Resin Composite materials are widely used in daily clinical dentistry because of their moderate cost compared with ceramics, easy placement, adequate esthetics, ability to bond with enamel and dentine, and physico-chemical properties. Bulk-fill composite materials were introduced to reduce chairside time. These materials have properties such as optimal bond strength, decreased polymerization shrinkage, and reduced cuspal deflection. This in-vivo study compared the clinical performance of three different class II resin composite restorations.

Methods: Seventy-one patients (41 females and 30 males) aged 20–43 years with at least three approximal caries were included in the present study. Two hundred twenty-three teeth with approximal caries were restored with two bulk-fill composites (Tetric-N Ceram Bulk fill [TEC], Filtek Bulk Fill [FB]) and a posterior resin composite (Gradia Direct Posterior [GDP]). Two experienced dentists clinically evaluated the restorations with a 5x magnification loupe using the modified United States Public Health Service (USPHS) criteria at baseline and at 24 months.

Results: The chi-square test was performed for statistical analysis. The cumulative retention rate for all restorations at 24 months was 90.5%. Retention loss was observed for three TEC (6.1%), four FB (8.2), and seven GDP (14%) restorations. There was no statistically significant difference among the three resin composite restoration groups in color match, marginal adaptation, surface roughness, marginal discoloration, anatomical form, and secondary caries criteria ($P>0.05$).

Conclusion: Bulk-fill composite restorations in class II slot cavities have the same clinical results as traditional posterior composite restorations.

Keywords: Bulk-fill resin composite, Class II restoration, Clinical follow-up

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Introduction

Resin composites have long been used in clinical dentistry. They consist of monomers, inorganic filler particles, silane for better adhesion, and an initiator-accelerator system to aid the polymerization reaction. They can be used for sealing, luting, and restorative procedures.¹ Materials science and technology advances have led to the continuous improvement and expanded clinical applications of dental composites.²

Resin composites have a significant disadvantage in that they undergo polymerization shrinkage, resulting in shrinkage stresses that can cause delamination from the cavity walls, interfacial voids, and microleakage. This can lead to discoloration of the restoration margins, recurrent caries, and adverse effects on the pulp and enamel fractures. These limitations can be overcome by applying resin composites in layers, which can extend the treatment time.^{3,4}

Excellent restorations can be achieved, and the negative impact of shrinkage stress can be reduced using the incremental technique. However, especially in large cavities, this can be difficult and time-consuming. As a result, most dental professionals seek simpler ways of restoring the posterior tooth region. Recent research has focused on developing materials to overcome these problems and allow faster restoration. The polymerization shrinkage stress and the depth of cure of universal composites are the two main reasons for using the incremental technique. The first reason requires using oblique layers to eliminate stress on the bond interface and residuary tooth structure. The second requires layers no thicker than 2 mm to achieve good bottom curing. Manufacturers have developed various strategies to modify these two main characteristics, producing bulk-fill composites, which can be used in thicker horizontal layers.⁵



Bulk-fill composites were introduced to reduce chairside time. They have properties such as optimal bond strength, decreased polymerization shrinkage, and reduced cuspal deflection.⁶ Although there are many in vitro studies on the mechanical and optic properties of bulk-fill composites,⁷⁻¹⁰ there is not enough in-vivo research on bulk-fill resin composite materials to support their use.

There are several types of studies that require the assessment of dental restorations. Clinical trials of new materials are essential, and they typically require a comprehensive assessment of restorations after restoration, during follow-up, and at final recall. For direct and indirect restorations, at least three and five years of follow-up are recommended.¹¹ Dental professionals must consider the potential advantages and disadvantages of bulk composite restorations for each clinical scenario.¹²

This in-vivo study compared the clinical performance of three Class II resin composite restorations. The null hypothesis was that the bulk-filled composite restorations would not differ from the conventional posterior composite restorations regarding clinical performance.

Methods

Patient selection

The University of Ordu Ethics Committee approved this clinical study (2018/14). In the study, premolars and molars with approximal carious lesions were restored with two bulk-fill composites (Tetric N Ceram Bulk Fill [TEC], Ivoclar, Schaan, Liechtenstein; Filtek Bulk Fill [FB], 3M ESPE, Saint Paul, MN, USA) and a posterior composite (Gradia Direct Posterior [GDP], GC Corporation, Tokyo, Japan). The composition and manufacturers of the composites used in this study are shown in Table 1. Restorations were carried out for six months by a research assistant with experience in restorative dentistry.

Patient inclusion/exclusion criteria

Inclusion Criteria: 1. Having good oral health (the patients have to brush their teeth twice a day with fluoride toothpaste, their gums should not bleed when brushing or flossing, and they should not smoke or use tobacco); 2. Having at least three class II carious lesions, including approximal surfaces in premolars and molars; 3. Being

older than 18 years.

Criteria for exclusion: 1. Missing the adjacent teeth and the antagonist teeth; 2. Having severe bruxism; 3. Having severe periodontal diseases and poor oral hygiene; 4. Showing symptoms of pulpitis, including intense pain, sensitivity to cold that lasts more than 30 seconds, pain when the tooth is tapped, and swelling around the tooth and gums; 5. Having endodontically treated teeth.

Considerations for the sample size

Based on previous sample size calculations, the sample size was calculated using the G*Power software version 3.1.9.2 (Universität Düsseldorf, Germany). With a 95% confidence interval and 0.05 significance level, 84 restorations in 3 groups were required.

Finally, the present study included 71 patients (41 female and 30 male) aged 20–43 years with 223 class 2 restorations. All patients were informed about the study and asked to sign the informed consent form before starting the study.

Restorative procedures

The composites and adhesive system application procedures used in restorations were as follows. The teeth were brushed with polishing pastes (Clinpro Prophy Pasteto, 3M Espe, USA) to remove the dental plaque and pellicle. The color of the composite resin was selected using the button shade technique. After the shade selection, the cavities were opened under local anesthesia. Class II slot cavity design was used. The cavities were prepared with diamond burs (Green/Black bands, SWS Dental, Turkey). The infected dentine was removed using tungsten carbide burs at a slow speed (SS White, USA). The pulp tissue was protected with a pulp liner (Theracal LC, Bisco Inc, Schaumburg, IL) when the remaining sound dentin was close to the pulp. A matrix system (Palodent V3, Dentsply, Germany) was placed in the cavities and fixed with anatomic plastic wedges. The teeth were isolated with a rubber dam and retraction chords. Clearfil S3 Bond universal adhesive was applied with selective etch. Enamel surfaces of the class II cavities were conditioned for 15 seconds with orthophosphoric acid, then rinsed thoroughly for 30 seconds to remove the acidic agents and dried gently to ensure optimal adhesive bonding. The adhesive was applied to all cavity surfaces

Table 1. Composition and manufacturers of composite resins used in this study

Composite resins	Organic matrix	Inorganic particle size	Inorganic matrix	Inorganic matrix (% by weight)	Color	Manufacturer
Tetric N Ceram Bulk-fill	Bis EMA, Bis GMA, UDMA,	Nano-hybrid	Ba cam, prepolymer, YbF3, oksit	75–77	IVB	Ivoclar Schaan, Liechtenstein
Filtek™ Bulk-fill Posterior	UDMA, 1,12-dodecane-AUDMA, DMA, AFM		YbF ₃ , Silika, Zirkonyum ve Zirkonyum/silika	76.5	A2	3M, St Paul, MN, USA
Gradia Direct Posterior	UDMA, co-monomer matrix	Micro-hybrid	Filler type: silica, pre-polymerized fillers, fluoroaluminio-silicate glass Particle size 0.85 m	80	A2	GC Corporation, Tokyo, Japan

(enamel and dentin) with rubbing action for 10 seconds, dried by blowing mild air, and then cured for 10 seconds (Elipar S10, 3M, USA) according to the manufacturer's instructions. Then, 1 mm G-aenial Universal Flo flowable composite was positioned to the gingival seat, pulpal floor, and axial wall and cured for 20 seconds.

The Bulk-fill composites (Tetric N Ceram Bulk-fill and Filtek Bulk-fill) were applied in bulk at about 4 mm thickness, and Gradia Direct Posterior was applied in increments not exceeding 2 mm using the oblique incremental technique. The restorations were shaped with composite handling instruments (Carl Martin, Germany), light-cured for 20 seconds, contoured with finishing burs, and polished with wet abrasive rubber points and cups.

Clinical evaluation

After restoration, at baseline, the restorations were clinically assessed by two experienced physicians using a 5x magnification loupe and modified United States Public Health Service (USPHS) criteria (Table 2). Any inconsistency between the evaluating dentists was reevaluated, and a joint decision was reached. The patients could not be recalled six months and 12 months after the restoration placement, due to the COVID-19 pandemic. The final evaluation of the restorations was done at 24 months.

Statistical evaluation

Statistical analyses were conducted using the NCSS software package. The normality assumption was tested using the Shapiro-Wilk test and the chi-square test. The results were evaluated with a significance level of $P < 0.05$ and a 95% confidence interval.

Results

In this study, 223 restorations were evaluated in 71 patients. Of the restorations, 75 (33.6%) were premolars, and 148 (66.4%) were molars. In the evaluation made using the modified USPHS criteria at baseline, all restorations had an alpha score for anatomic form, discoloration, color match, marginal adaptation, roughness of surface,

and postoperative sensitivity. The restorations could not be evaluated due to the restrictions of the COVID-19 pandemic at 6 and 12 months. In the 24-month follow-up, 23 patients did not come, and 75 restorations (23 TEC, 27 FB, and 25 GDP) could not be evaluated, so only 48 patients out of 71 could be followed. The evaluation results at 24 months are shown in Table 3.

The cumulative retention rate for all restorations at 24 months was 90.5%. Retention loss was observed for 3 TEC (6.1%), 4 FB (8.2%), and 7 GDP (14%) restorations (two teeth were extracted, and root canal treatment was performed on four teeth). Although retention rates at 24 months varied among groups (93.9% Group TEC, 91.8% Group FB, and 86% Group GDP), they did not differ significantly ($P > 0.05$).

Regarding marginal integrity, crevices in which dentine was not exposed (code Bravo) were observed in 6 TEC (13%), 4 FB (8.9%), and 6 GDP (14%) restorations. Superficial staining without axial penetration (code Bravo) was observed in 6 TEC (13%), 6 FB (13.3%), and 2 GDP (7%) restorations. Similar to the results in the marginal adaptation, clinically acceptable mismatch was observed in 6 TEC (13%), 6 FB (13.3%), and 3 GDP (4.7%) restorations. Minimal surface defects (code Bravo) were observed on 8 TEC (17.4%), 4 FB (8.9%), and 4 GDP (9.3%) restoration surfaces.

The evaluation at 24 months showed that the general contours of 3 TEC (6.5%), 6 FB (13.3%), and 3 GDP (7%) restorations did not follow the contour of the tooth. None of the restorations were found to have secondary caries. For marginal adaptation, discoloration, color match, roughness of surface, anatomical shape, and secondary caries criteria, the differences between the three groups of resin composite restorations were not statistically significant ($P > 0.05$).

Although some restorations were rated Bravo according to the modified USPHS criteria at 24 months, all restorations that had not lost retention were clinically acceptable.

Discussion

This clinical study evaluated the 2-year clinical success

Table 2. Modified USPHS rating criteria

	Alfa (A)	Bravo (B)	Charlie (C)
Retention	Retained		Partially or totally lost
Marginal discoloration	No staining	Superficial discoloration	Deep discoloration
Marginal adaptation	Closely adapted, no visible crevice	A visible crack can be penetrated by the explorer.	Crack in dentin is exposed
Color match	No mismatch	Clinically acceptable mismatch	Clinically unacceptable mismatch
Seconder caries	No caries present		Caries present
Surface roughness	The restoration surface is free from defects.	The restoration surface includes minimal defects.	The restoration surface includes starched defects
Anatomic form	The restoration's general contours follow the contours of the tooth.	The restoration's general contours do not follow the contours of the tooth.	The restoration includes an overhang

Table 3. Evaluation of restorations according to modified USPHS criteria

	Retention		Marginal adaptation		Marginal discoloration		Color match		Surface roughness		Anatomic form		Secondary caries
	A	C	A	B	A	B	A	B	A	B	A	B	A
Group TEC	46 93.9%	3 6.1%	40 87%	6 13%	40 87%	6 13%	40 87%	6 13%	38 82.6%	8 17.4%	43 93.5%	3 6.5%	46 100%
Group FB	45 91.8%	4 8.2%	41 91.1%	4 8.9%	39 86.7%	6 13.3%	39 86.7%	6 13.3%	41 91.1%	4 8.9%	39 86.7%	6 13.3%	45 100%
Group GDP	43 86%	7 14%	37 86%	6 14%	41 93%	2 7%	40 85.3%	3 4.7%	39 80.7%	4 9.3%	40 93%	3 7%	43 100%

of three class II posterior composite restorations made with two bulk-fill composite resins and one traditional posterior resin composite. At 24 months, the class II composites were not statistically significantly different. The null hypothesis of this study, that the clinical results of class II composite restorations made with bulk-fill composite resins were not different from conventional posterior composite restorations, was accepted.

Standardization of evaluation criteria in clinical studies is essential. In 2007, FDI published the FDI criteria, consisting of three sections (functional, aesthetic, and biological) to guide researchers in standardizing clinical evaluation criteria.¹³ However, the number of clinical studies using FDI criteria with which we can compare the results of our study is low. For this reason, the modified USPHS criteria, which are common and simple to use, were preferred in the clinical evaluation of restorations.

Based on ADA guidelines, the expected rate of restoration loss is <5% in the first six months and <10% at 18 months.¹⁴ In this study, a recall could not be made in the 6th and 12th months due to coronavirus restrictions in Turkey. At 24 months, the rate of retention loss in restorations was 6.1% for TEC, 8.2% for FB, and 14% for GDP. Although no statistically significant difference was found, composite restorations using GDP showed a higher retention loss than bulk-fill composite restorations. Previous studies have supported the similarity in retention rates between bulk-fill and traditional posterior composite restorations.¹⁵⁻²³ The durability of restorations can be affected by patient, clinician, material, and tooth-related factors.²⁴ To ensure maximum standardization in our study, individuals with good oral health and no parafunctional behavior were included. In addition, restorations were completed by the same physician using the same adhesive system. In patients with GDP restoration losses, oral hygiene status generally regressed, and some became ill with coronavirus.

Marginal gap and poor adaptation negatively affect composite restorations' longevity and clinical performance by causing marginal discoloration, secondary caries, and postoperative sensitivity.²⁵ Many factors can affect marginal adaptation in composite restorations, including cavity size, angle of enamel prisms and dentinal tubules, placement method, polymerization technique, and adhesive system.²⁶ Although we aimed to

prepare class II slot cavities of similar sizes in this study, there were differences in cavity dimensions depending on the width of the caries. Although no statistically significant difference was found among the three groups, there were differences in marginal adaptation and discoloration rates. The difference in composite resin types and polymerization shrinkage stresses, which depend on the cavity dimensions at the restoration tooth interface, may account for this difference.

In previous studies, more microleakage was observed at the restoration margins under the enamel-cementum junction, leading to an increase in secondary caries.^{27,28} There was no evidence of any secondary caries in any of the restorations in the present study. This is consistent with studies showing that secondary caries formation in posterior composite restorations occurs after three or more years.²⁹

Surface roughness and anatomical form are essential to clinical success in posterior composite restorations. The amount of occlusal wear may vary depending on the resin composite content and parafunctional habits such as bruxism.^{30,31} Additionally, the content of composites, the degree of conversion, and the finishing and polishing processes are other factors that affect surface roughness.³² The Super-Snap SuperBuff Set polishing system was employed in this study to standardize the polishing material. Although minimal surface defects were observed on the restoration surfaces, none had a severe surface defect that would require replacement or restoration.

The compatibility of composite restorations with the natural tooth is critical to their aesthetic success. Intrinsic and extrinsic factors can affect the color stability of composite restorations. Resin composites can experience intrinsic discoloration due to chemical changes within the material. This can be caused by the leaching of unreacted monomers through hydrolysis reactions and photoinitiator components not consumed during the polymerization process. In contrast, extrinsic discoloration is caused by contact and absorption of pigments from beverages, smoke, and food.^{33,34} All restorations showed clinically acceptable color match at 24 months.

Strengths and Limitations

Comparing the results of this study was challenging due

to the numerous variables involved in the in-vivo studies reviewed, including different etching and bonding techniques for various restorative materials, as well as differences in patient demographics (age, sex, and parafunctional activities), operator, cavity, evaluation time, and oral hygiene status. Restorations could not be evaluated at 6 and 12 months due to the COVID-19 pandemic. Some patients' oral health status and parafunctional habits had changed due to coronavirus treatment during the COVID-19 pandemic. Evaluation criteria methods could not be standardized.

Conclusion

At 24 months, the clinical results for bulk-fill composite restorations in class II cavities were comparable to those of traditional posterior composite restorations.

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Authors' Contribution

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Competing Interests

The authors declare that they have no known competing financial interests or personal relationships that could have influenced the work reported in this paper.

Data Availability Statement

All data can be made available on request.

Ethical Approval

This clinical study was approved by the Ethics Committee of Ordu University (2018/14).

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