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Thirty-Six-Month Clinical Comparison of Bulk Fill and Nanofill Composite Restorations

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Clinical Relevance

Bulk fill restorative resin might be a good alternative to conventional resin composites in terms of marginal adaptation and discoloration under clinical conditions.

SUMMARY

Objectives: The aim of this study was to evaluate the clinical performance of a nanofill and a bulk fill resin composite in class II restorations.

Methods and Materials: In accordance with a split-mouth design, 50 patients received at least one pair of restorations, restored with a nanofill resin composite (Filtek Ultimate [FU]) and with a bulk fill resin composite (Tetric EvoCeram Bulk Fill [TB]). Each restorative resin was used with its respective adhesive system according to the manufacturers' instructions. A total of 104 class II restorations were placed by two operators. The restorations were blindly evaluated by two examiners at baseline and at six, 12, 18, 24, and 36 months using modified US Public Health Service Ryge criteria. The comparison of the two restorative materials for each category was performed with the chi-square test (α=0.05). The baseline scores were compared with those at the recall visits using the Cochran Q-test.

Results: At six, 12, 18, and 24 months, the recall rate was 100%, 98%, 94%, and 82%, respectively, with a retention rate of 100%. At 36 months, 81 restorations were evaluated in 39 patients with a recall rate of 78%. For marginal adaptation, four restorations from the TB group and 10 from the FU group rated as Bravo. Two restorations from the TB and eight restorations from the FU group showed marginal discoloration. There were statistically significant differences between the two restorative resins in terms of marginal adaptation and marginal discoloration ($p<0.05$). No differences were observed between the restorative resins in terms of retention ($p>0.05$). One restored tooth from the FU group was crowned. The retention rates for the TB and the FU groups were 100%. In the FU group, two

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restorations showed slightly rough surfaces, and two showed a slight mismatch in color. None of the restorations showed postoperative sensitivity, secondary caries, or loss of anatomic form.

Conclusions: The tested bulk fill restorative resin demonstrated better clinical performance in terms of marginal discoloration and marginal adaptation.

INTRODUCTION

The use of resin composites has become a routine procedure for the restoration of posterior teeth.[1,2] Several factors have contributed to their acceptance, including esthetics, improved mechanical properties to match amalgam's performance, and mercury concerns.[2,3] Additionally, their preparation design is more conservative. Although resin composites are being continually developed in order to improve their mechanical and physical properties, polymerization shrinkage still remains a main challenge.[4,5] Polymerization shrinkage stress that is concentrated at the adhesive interface can lead to marginal breakdown, gap formation, marginal leakage, and even cuspal deflection, secondary caries, and restoration loss.[6,7]

The incremental placement technique is the common procedure adopted in clinical practice to avoid depth-of-cure limitations and to overcome polymerization shrinkage stress.[8-10] However, there are various disadvantages of the incremental placement technique, such as voids that can be entrapped between these layers, contamination risk between layers, difficulty in the placement of layers in small cavities that are difficult to access, and increased chair time.[11]

One of the major changes in resin-based composite technology is the introduction of bulk fill resin composites. This category has been launched to simplify and shorten application time, making the clinical procedure more user friendly.[12] Bulk fill resin composites can be placed up to 4-mm in thickness with proper polymerization and low polymerization shrinkage.[13-16] Various strategies are implemented by different manufacturers to accomplish increased depth of cure and lower shrinkage. The addition of stress-relieving monomers, more reactive photoinitiators, and prepolymerized particles result in lower polymerization shrinkage.[17,18] Moreover, the increased translucency of these resins allows greater light transmission and adequate depth of cure.[19] For resin composites, not only adequate polymerization but also proper marginal adaptation are important to ensure optimum clinical behavior. In most of the studies, the performance of bulk fill restorative resins was found to be similar to incrementally placed conventional resins in terms of marginal integrity.[20-23] Although the mechanical and physical properties of bulk fill restorative resins have been evaluated under *in vitro* conditions,[24-29] the ultimate test for a dental restorative material is its clinical durability and effectiveness. This test is needed to validate results from the *in vitro* studies. Therefore, the aim of this clinical study was to compare the clinical performance of a bulk fill resin composite with a conventional resin composite for three years. The null hypothesis tested was that there would be no difference between bulk fill and conventional resin composites.

METHODS AND MATERIALS

Approval for the clinical trial was obtained from the Human Ethics Committee of the Hacettepe University School of Dentistry, and all patients signed a written informed consent form. The inclusion criteria for patients were as follows: good oral hygiene, minimal periodontal disease, absence of deleterious habits (eg, mouth breathing, nail biting, bruxism, and tooth clenching or grinding), and the presence of at least two similar-sized approximal primary caries lesions in premolar and molar teeth. Teeth with secondary caries or in need of replacement of existing restorations were not included in the study. Subjects were excluded from participating in the study if they had a history of adverse reaction to the test materials, were pregnant or lactating, had poor oral hygiene, or had systemic disease and severe periodontal disease and were potentially unable to attend recall visits.

A total of 50 patients—24 males and 26 females—ages 24 to 55 years participated in the study. Bitewing radiographs of the teeth to be restored were taken preoperatively. The teeth to be restored had a normal class I occlusal relationship with natural dentition and had adjacent teeth in contact. The minimal sample size of each group was found to be 40 restorations according to power analysis.

The teeth to be restored were first cleaned with a nonfluoridated prophylaxis paste on a rubber cup and then rinsed with water. Class II slot preparations were completed with a diamond straight (flat end) and round burs (Diatech, Heerbrugg, Switzerland) at high speed with water coolant. The dimension of the preparation was determined by

Table 1: *Composition of the Materials Used in the Study*

Materials	Composition	Mode of Application
Filtek Ultimate (3M ESPE, St Paul, MN, USA) (N214468)	Bis-GMA, UDMA, TEGDMA, bis-EMA, PEGDMA, silica filler, zirconia filler	Insert incrementally in 2-mm increments. Light cure for 40 s.
Adper Single Bond 2 (3M ESPE) (9XN)	Bis-GMA, HEMA, copolymer of acrylic/ itaconic acids, diurethane dimethacrylate, glyceroldimethacrylate, water and ethanol	Apply two consecutive coats of Adper Single Bond adhesive to etched enamel and dentin. Dry gently for 2 to 5 s. Light cure for 10 s.
Tetric EvoCeram Bulk Fill (Ivoclar Vivadent, Schaan, Liechtenstein) (P84129)	Bis-GMA, UDMA, bis-EMA, barium alumina silicate glass filler, ytterbium fluoride, spherical mixed oxide	Insert up to 4 mm thick. Light cure for 20 s.
Excite F (Ivoclar Vivadent) (R06148)	HEMA, methacrylate, phosphonic acid acrylate, highly dispersed silicone dioxide, initiators, stabilizers and potassium fluoride	Apply adhesive to etched enamel and dentin and agitate the adhesive for at least 10 s. Dry gently for 2 to 5 s. Light cure for 10 s.

Abbreviations: bis-GMA, bisphenol-A diglycidyl dimethacrylate; UDMA, urethane dimethacrylate; TEGDMA, triethylene glycol dimethacrylate; bis-EMA, ethoxylated bisphenol A dimethacrylate; PEGDMA, polyethylene glycol dimethacrylate; HEMA, hydroxyethyl methacrylate.

the extent of the caries. The caries removal was completed using a round steel bur in a slow-speed hand piece. The tissue removal was terminated when the dentin was hard on probing. Isolation was accomplished using a rubber dam.

Two different restorative resins were placed in each patient, resulting in a total of 104 restorations. Half of the preparations were restored using the bulk fill resin composite Tetric EvoCeram Bulk Fill (TB, Ivoclar Vivadent, Schaan, Liechtenstein) (n=52), and half of them were restored with Filtek Ultimate (FU, 3M ESPE, St Paul, MN, USA) (n=52) with their respective etch-and-rinse adhesives according to the manufacturers' instructions. The materials used in the study are shown in Table 1.

An Ivory #1 retainer and matrix band with wooden wedges were utilized for placement of the resin composite. The restorative material Filtek Ultimate was applied using an incremental filling technique beginning at the gingival wall. The increments, not exceeding 2-mm in thickness, were added to complete the proper anatomical form. Each increment was polymerized for 20 seconds with an LED light-curing unit (440-465nm) (Starlight s Mectron s.p.a., Carasco, Italy) with an irradiance of >1400 mW/cm^2. The output of the curing unit was checked after each patient with a curing radiometer (Demetron, Danbury, CT, USA). The restorative material Tetric EvoCeram Bulk Fill was placed in bulk up to 4-mm thickness and cured for 20 seconds with the same curing unit. The randomization of restorative material was done using a table of random numbers. Occlusal adjustments were made using articulating paper. Finishing was completed with finishing diamond burs (Diatech), and polishing was accomplished with aluminum oxide disks of decreasing abrasiveness (Sof-Lex, 3M ESPE) and rubber points (Kerr Corp, Orange, CA, USA). The clinical procedure of tooth preparation and placement of restorations was performed by the same operator.

Two experienced double-blinded dentists not involved with the placement of the restorations performed the evaluation. The dentists were calibrated to a predetermined level of inter- and intra-examiner agreement of at least a Kappa value of 95% for each criteria. The restorations were evaluated at baseline, at 6, 12, 18, 24, and 36 months using modified US Public Health Service Ryge criteria[30] and scored as Alpha, Bravo, or Charlie. Alpha corresponds to excellent, Bravo to clinically acceptable, and Charlie to clinically unacceptable results. Postoperative sensitivity was assessed by blowing a stream of compressed air for three seconds at a distance of 2 to 3 cm from the restoration under isolation from the adjacent teeth with gauze and by moving the probe over the restored tooth surface. Subjects were also questioned regarding sensitivity to cold/hot or stimuli. Color photographs at 1:1 magnification were taken at baseline and each recall. In case of disagreement, a consensus was reached based on assessment of the photographs. Bitewing radiographs were also taken at the end of a three-year recall.

The statistical analyses were carried out with the IBM SPSS version 22.0 software package (SPSS, Chicago, IL, USA). The restoration groups for each category were compared using the Pearson chi-square test, and the Cochran Q-test was used to compare the changes across different time points within each restorative material (α=0.05).

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

	Maxillary Arch		Mandibular Arch		Total
	Premolar	Molar	Premolar	Molar	
Tetric EvoCeram Bulk Fill	21	13	6	12	52
Filtek Ultimate	21	15	6	10	52
Total	42	28	12	22	104
	70		34		

RESULTS

A total of 104 restorations were placed in 50 patients. The distribution of the restorations is displayed in Table 2. Fifty restorations (48%) were placed in molars, whereas 54 (52%) were placed in premolars. Table 3 presents the results of the clinical evaluation of the restorations.

Retention and Recall Rates

At six, 12, 18, and 24 months, the recall rates were 100%, 98%, 94%, and 82%, respectively, with a retention rate of 100%. One restoration from the FU group received a crown at the 24-month recall. At the end of 36 months, 81 restorations were evaluated in 39 patients with a recall rate of 78% and a retention rate of 100%.

Marginal Adaptation

All restorations from Tetric Bulkfill EvoCeram group showed perfect adaptation until the 24-month evaluation. At 24 months, one restoration from the TB group and eight from the FU group were rated as Bravo.

At 36 months, there was a crevice along the margin of four restorations from the TB group and 10 restorations from the FU group that were detectable with an explorer. In terms of marginal adaptation, significantly better adaptation was observed in the TB group at the 24-month (p=0.015) and 36-month recalls (p=0.048).

Marginal Discoloration

None of the restorations showed marginal discoloration until the 18-month evaluation. At 18 months, two restorations from the FU group showed slight discoloration. At 24 months, while none of the restorations showed discoloration from the TB group, seven from the FU group showed discoloration. At the end of 36 months, two restorations from the TB and eight from the FU group rated as Bravo. Significant differences were observed between the two groups at the 24-month (p=0.005) and 36-month recalls (p=0.048).

Color Match

From the FU group, two restorations at 12 and 18 months, one restoration at 24 months and two restorations at 36 months showed a slight mismatch in color within the normal range of the adjacent tooth structure.

Surface Texture

At 24 and 36 months, only the surface of two restorations from the FU group was rougher than the surrounding enamel.

Table 3: *Results of the Clinical Evaluation of the Restorations*

Evaluation Criteria	Score	Six-Month n (%)		12-Month n (%)		18-Month n (%)		24-Month n (%)		36-Month n (%)	
		TB (n=52)	FU (n=52)	TB (n=51)	FU (n=51)	TB (n=49)	FU (n=49)	TB (n=43)	FU (n=42)	TB (n=41)	FU (n=40)
Marginal adaptation	Alpha	52 (100)	52 (100)	51 (100)	51 (100)	49 (100)	48 (98)	42 (97.7)	34 (80.9)	37 (90.3)	30 (75)
	Bravo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	1 (2.3)	8 (19.1)	4 (9.7)	10 (25)
Marginal discoloration	Alpha	52 (100)	52 (100)	51 (100)	51 (100)	49 (100)	47 (95.9)	43 (100)	35 (83.3)	39 (95)	32 (80)
	Bravo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4.1)	0 (0)	7 (1.7)	2 (5)	8 (20)
Color match	Alpha	52 (100)	52 (100)	51 (100)	49 (96)	49 (100)	47 (96)	43 (100)	41 (97.6)	41 (100)	38 (95)
	Bravo	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	2 (4)	0 (0)	1 (2.4)	0 (0)	2 (5)
Surface texture	Alpha	52 (100)	52 (100)	51 (100)	51 (100)	49 (100)	49 (100)	43 (100)	40 (95)	41 (100)	38 (95)
	Bravo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	2 (5)

Abbreviations: TB, Tetric EvoCeram Bulk Fill; FU, Filtek Ultimate.

Postoperative Sensitivity

One patient from the TB group reported postoperative sensitivity that disappeared at the 12-month recall. No differences were detected for the rest of the evaluated criteria ($p>0.05$).

For the TB group, significant differences were observed between baseline and 36 months only for marginal adaptation ($p=0.010$). For the FU group, differences were found between baseline and 24 months and baseline and 36 months for marginal discoloration ($p<0.05$) and adaptation ($p<0.05$).

DISCUSSION

To the extent of the authors' knowledge, there are only limited studies that compare the clinical effectiveness of bulk fill resin composites. Two of them were conducted by van Dijken and Pallesen.[31,32] In one of their studies, five-year clinical durability of the flowable bulk fill resin composite SDR capped with CeramX Mono was compared with CeramX Mono that had been placed incrementally. No difference was observed between restorations with and without SDR in any of the evaluated criteria. None of the restorations showed postoperative sensitivity. Tooth and restoration fracture was also observed.[31] In their other clinical study, they also found that the bulk fill flowable SDR showed highly acceptable clinical results comparable to the conventional 2-mm incremental technique in the three-year follow-up. None of the restorations showed marginal discoloration. Although not statistically different, poor marginal adaptation was seen in incrementally placed restorations.[32]

The results of our study do not correlate with these previous studies mentioned above. This might be related to the bulk fill resin used in our study. In the mentioned studies, bulk fill flowable resin composites were compared. However, in our study, bulk fill resin without the need of capping was investigated, and significant differences were found between bulk fill and conventional resin composite that was placed incrementally in terms of marginal discoloration and marginal adaptation at the end of 36 months. The tested resin composites performed differently in these criteria over the 36-month evaluation period, leading to rejection of the tested hypothesis. In another short-term clinical study, bulk fill restorations demonstrated comparable performance to conventional posterior composite resin.[33] However, these results were obtained at the end of 12 months. Even in our study, there were no differences between tested restoratives at any evaluated criteria until 18 months of recall. The important issue is to evaluate the performances and survival of restoratives for a long time period to reach better conclusions. The results might vary according to the recall time. As seen in our clinical study, clinical outcomes had changed after long-term recalls.

The integrity of the adhesive bond at the tooth/resin interface plays an important role in the clinical success and survival of restorations. The reason for better marginal adaptation observed in bulk fill resin composite might be related to its lower polymerization stress. Moreover, the manufacturer states that TB contains a shrinkage stress reliever, which is a special filler functionalized with silane to minimize polymerization shrinkage (scientific documentation).[34] It is known that stresses are affected by the composition and filler content of resin composite, its elastic modulus.[4,35]

TB contains a mixture of bisphenol-A diglycidyl dimethacrylate, urethane dimethacrylate, and ethoxylated bisphenol A dimethacrylate, all of which are high-molecular-weight monomers with high viscosity and low polymerization shrinkage. On the other hand, FU beside these monomers has a diluent monomer, triethylene glycol dimethacrylate that reduces its viscosity. Because of its smaller molecules, it might have a negative effect on polymerization shrinkage.[36] Due to its low molecular weight, it increases water sorption.[37] The use of prepolymerized filler particles as in TB also contributes to a lower elastic modulus.[38] In a recent study comparing other bulk fill resins, the elastic modulus of TB was found to be moderate.[39] A direct relationship between marginal integrity and polymerization contraction/stress has been reported in some *in vitro* studies.[22,40,41] Although better performance of bulk fill resin composite was found in terms of marginal adaptation in the present study, comparable results with traditional incrementally placed resin composites were reported in most of the *in vitro* studies.[21,42,43] In a recent *in vitro* study,[21] Tetric EvoCeram Bulk Fill demonstrated similar gap formation to conventional resin composite. Al-Harbi and others[23] also analyzed the cervical marginal integrity of class II preparations restored with bulk fill vs incrementally placed resin composites. They found similar marginal integrity compared to conventional incremental fill composites. Concurring with these results, Fronza and others[22] also found that TB was not different in percentage of internal gap formation from incrementally placed resin composite. However, in clinical conditions, restorations are subjected to temperature changes and, more important, masticatory stresses. These factors cause a strain accumula-

tion that leads to chemical and mechanical degradation.[42] Therefore, it might not be accurate to directly compare our findings with the results obtained from *in vitro* studies.

The perfect seal between restoration and tooth has great importance in preventing microleakage and its clinical consequences, such as marginal discoloration, recurrent caries, and pain. There are only few *in vitro* studies evaluating the microleakage of bulk fill resin composites. In one of them, flowable bulk fill resin showed less leakage in comparison with nanohybrid resin composite at dentinal margins. However, they showed similar microleakage values at enamel margins.[43] In another study, no difference was observed in cervical microleakage when an incrementally filled conventional resin composite was compared with a bulk fill flowable resin composite base in class II preparations.[44] However in both studies, flowable bulk fill composites were used. In the present study, bulk fill restorations led to significantly better clinical outcomes regarding marginal discoloration. This can be explained by the lower elastic modulus of TB (10 GPa) than FU (12 GPa). Taking into account that the same six restorations rated as Bravo for both marginal discoloration and adaptation, the higher marginal discoloration observed in the FU group may have been related to the poor marginal adaptation. The contraction stress might have caused a dislodgment of resin composite from the tooth margin, thereby inducing gap formation. These defects along the margin might have facilitated susceptibility to staining.

Although not statistically different, two restorations from the FU group showed slightly rougher surfaces. This might be related to void entrapment during the increment filling technique. Surface texture is important since rougher surfaces would cause surface staining and increase plaque retention and bacterial adhesion. The intrinsic filler particle size of resin composites also determines the smoothness of restoration.

It might have been expected that subjects with bulk fill restorative might have suffered from postoperative sensitivity more than incrementally placed restoratives. However, at the end of the study, none of the patients complained of sensitivity. Adequate depth of cure of the bulk fill resin used in the present study might have contributed to this result. The bulk fill resin TetricEvoCeram Bulk used in the present study contains a new photoinitiator system, Ivocerin, a dibenzoyl germanium compound that has a higher photocuring activity than camphorquinone, as it absorbs visible light over a wider range of wavelengths from 370 to 460 nm.[17,34]

In the present study, two tested restorative resins were used with their respective adhesive systems. The authors decided to compare two different restorative resins as they are optimized by their manufacturer. Marginal adaptation and discoloration might be affected by the adhesive type. However, it might not be accurate to think that the adhesives were the sole responsible factor for the observed difference between the two restorative materials in terms of adaptation and discoloration since both of the adhesive systems used were etch-and-rinse adhesives. On the other hand, their pH values were quite different (Adper Single Bond 2 = 4.1; Excite F = 2.5). The lower acidity of Excite F might contribute to a deeper etching pattern and improved marginal adaptation.

Bravo-scored restorations are considered to be clinically acceptable. A slight lack of marginal adaptation or superficial discoloration does not require further treatment and might be considered negligible. However, degradation between restoration and the tooth interface might continue and cause restoration loss over time. Therefore, clinical research studies with long-term follow-up are needed to confirm the efficacy of bulk fill resin composites.

Moreover, further investigations should be conducted in patients with deleterious/parafunctional habits as well as in other type of cavities that are larger than a slot preparation to support these findings.

CONCLUSIONS

Within the limitations of this study, the 36-month evaluation of a bulk fill restorative resin compared to a nanofill showed better clinical performance with reference to marginal discoloration and marginal adaptation.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the Department of Restorative Dentistry, Hacettepe University School of Dentistry. The approval code for this study is 04(KA-15004).

Conflict of Interest

The authors of this article 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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