Original Article

A Prospective, Randomized, Double-blind Clinical Trial of One Nano-hybrid and One High-viscosity Bulk-fill Composite Restorative Systems in Class II Cavities: 12 Months Results

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Abstract

Background: Recently, manufacturers have introduced bulk-fill composite resins that reportedly can be placed in increments of 4 mm or greater. **Objective:** The purpose of this article was to report the results of 12 months prospective randomized clinical trial that evaluated the clinical performance of one high-viscosity bulk-fill composite resin in Class II cavities of posterior teeth. **Materials and Methods:** Thirty-four participantshad at least two Class II cavities included the study. Class II cavities restored with either a Tetric EvoCeram bulk-fi fill or universal nano-hybrid resin composite (Tetric EvoCeram). A total of 74 restorations (37 with each material) on 34 patients were placed according to the manufacturers' instructions by one calibrated operator. **Results:** Seventy restorations were evaluated after 12 months evaluation period. No postoperative sensitivity, anatomic form, retention, and secondary caries were observed after 6 and 12 months. Regarding the items color match, marginal discoloration, and marginal adaptation, the statistical analysis did not detect any statistical significance between two materials ($P > 0.05$). **Conclusion:** After 12 months of clinical service, all restorations evaluated for both materials were classified as ideal, receiving predominantly Alfa scores for all parameters analyzed. **Clinical Relevance:** This study presents that high-viscosity bulk-fill resin composites (RCs) perform just as well as nano-hybrid RCs with the 2 mm RC layering technique, therefore could be alternative to conventional nano-hybrid RCs.

Keywords: *Bulk-fill composite, Class II restorations, clinical trial*

Date of Acceptance:
16-Dec-2015

Introduction

Resin-based composite (RBC) is the most widely used modern dental restorative material. It offers advantages such as excellent esthetics and ease of handling. However, it is also characterized by the risk of complications due to insufficient polymerization of the material and the occurrence of polymerization shrinkage.[1] Since photo-polymerized resin composites (RCs) were introduced, the degree of conversion was acknowledged as vital to the clinical success of these materials.[2] Photo-cured RCs polymerize only to a certain depth. This depends on the penetration of visible light through the bulk of the material.[3] It has been shown that the insufficient polymerization may lead to a decrease in the physical/mechanical[4] and biological[5] properties of RCs. Even so, complications related to polymerization shrinkage stress and curing depth still cause significant reluctance to use them. This polymerization shrinkage stress not only will trap within the material itself but also will exert forces on the adhesive interfaces of the dentin.[6]

Access this article online

Quick Response Code:

Website: www.njcponline.com

DOI: 10.4103/1119-3077.212449

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How to cite this article: Çolak H, Tokay U, Uzgur R, Hamidi MM, Ercan E. A prospective, randomized, double-blind clinical trial of one nano-hybrid and one high-viscosity bulk-fill composite restorative systems in class II cavities: 12 months results. Niger J Clin Pract 2017;20:822-31.

For sufficient polymerization, three vital characteristics are essential for the light-curing unit: Adequate light output, appropriate wavelength range of the light, and exposure time.[7] Other factors affect the depth of cure, including RC type, shade and translucency, increment thickness, distance from the tip of the light-curing unit, postirradiation period,[8] and size and distribution of filler particles.[9]

A number of approaches can be employed to place composite resins into a cavity. Some researchers recommend the use of an incremental technique, through which the material is gradually placed in layers of 2 mm or less.[10-13] This approach to restoring teeth has a number of advantages; for example, it results in better light penetration and better polymerization of the composite resin,[10,14-16] reduces the cavity configuration factor,[11,17] reduces cuspal deflection,[11,18,19] reduces polymerization shrinkage stresses, and ensures that the resin adheres better to cavity walls.[17,20] However, in addition to these advantages, there are a number of disadvantages associated with the use of an incremental approach to placing resin; for example, voids can be trapped between the increments,[17,21] bonding failures may occur between the increments, it can be difficult to place composite material after conservative cavity preparation, and the time taken to complete the procedure is more lengthily due to the time required to place and polymerize each increment.[22]

In an effort to overcome many of the downsides associated with an incremental approach to placing resin, a number of new restorative materials have emerged that are marketed as "bulk-fill" composites. However, clinicians who have become accustomed to the incremental cure philosophy when placing light-cured composites, quite rightly question what specifically has changed to make these "bulk-fill" light-cured composites a viable alternative.[23] While bulk-fill composites represent an attempt to speed up the restoration process by allowing dentists to place composite material in increments of 4 or 5 mm thickness,[24] the basic concept behind this approach is by no means new, and similar approaches to restorations have been evaluated numerous times in existing literature.[25-27]

Tetric EvoCeram bulk-fill (TBF) contains in its composition an inhibitor of sensitivity to light and thus provides prolonged time for modeling of filling, an inhibitor of shrinkage stress to achieve optimal marginal seal and Ivocerin, polymerization photoinitiator allowing curing of 4 mm layers of material. According to the manufacturer's information, this new composite will achieve full-depth bulk-fill up to 4 mm without a superficial capping layer, unlike the bulk-fill flowable. The manufacturer states that TBF contains a shrinkage stress reliever to minimize polymerization shrinkage; this is a modified unique filler partially functionalized with silanes.

While numerous laboratory studies have explored the depth of cure,[16,28,29] marginal adaptation,[21,27] shear-bond strength,[30] internal adaptation,[31] microhardness, degree of conversion,[24,32] cuspal deflection,[16] polymerization contraction,[29,33-35] and light irradiation potential[36] of bulk-fill materials, clinical data are hard to find. To date, just two studies[37,38] are in existence that assess the clinical performance of flowable bulk-fill composites. In addition, these studies did not provide any clinical data pertaining to the performance of high-viscosity composites. As such, the aim of this clinical study was to evaluate the clinical performance of one high-viscosity bulk-fill composite resin (Tetric EvoCeram bulk-fill) in Class II cavities over the course of 1 year. A conventional posterior hybrid composite resin (Tetric EvoCeram) was used as the control group. The null hypothesis was that bulk-fill composite resins exhibit the same clinical performance as conventional composite resins that have been applied using the incremental technique.

Materials and Methods

Study design and patient selection

The prospective clinical trial involved a randomized, double-blinded design that was in compliance with the requirements outlined by the Ishik University Research Center Committee of Ethics in Research (#2013–004). During December 2013–March 2014, all adult patients attending the Ishik University School of Dentistry Conservative Dentistry Clinics, who needed at least two pair similar Class II restorations, were asked to participate the study. A total of 34 volunteers aged between 23 and 56 years (mean age: 33.74 ± 6.824) were participated in the study. Before commencing the research, they each were provided with detailed information about the conditions and objectives of the study before asked to sign informed consent forms that confirmed their agreement to participate in the research. The participants were informed that they were free to withdraw from the trial without justification at any stage of the research. The age and gender distributions of the participants are presented in Table 1. The inclusion criteria were as follows: Patient in need of restoration of caries lesion or replacement of existing failing restoration (diagnosed with bitewing radiograph and clinical examination); teeth in need of restoration to be first or second molars or permanent premolars; at least two Class II restorations required in each patient and the number of restorations of each material to be equal in

each patient; the antagonist and adjacent tooth in contact; pulp vitalized and absence of painful symptoms; teeth involved not to have undergone direct pulp capping; no history of hypersensitivity in the teeth to be restored; permanent dentition; good oral health and absence of periodontal disease; patients not to have suffered from systemic diseases or allergies; and absence of deleterious habits and bruxism. Specific exclusion criteria were as follows: Fewer than 20 teeth; history of existing tooth sensitivity; known allergy to resin-based materials or any of the other materials used in this study; pregnancy or breastfeeding; chronic use of anti-inflammatory drugs, analgesic, and/or psychotropic drugs, nonvital teeth; abutment teeth for fixed or removable prostheses. Bitewing radiographs of the teeth to be restored were taken preoperatively unless the patient had already had radiographs taken within the previous year. There was an even distribution of the restorations that were performed to replace existing restorations with clinical or radiographic signs of recurrent caries or esthetic failures and those that were performed to treat primary caries lesions.

Restorative procedures

All restorations (37 for each restorative material) were performed by the same operator to ensure consistency. Thirty-one patients received two restorations and three patients received four restorations. As such, each patient received at least two Class II restorations randomly – one with Tetric EvoCeram (Ivoclar Vivadent, Schaan, Liechtenstein), a conventional viscosity composite, and the other with Tetric EvoCeram bulk-fill (Ivoclar Vivadent, Schaan, Liechtenstein), a high-viscosity bulk-fill composite. The materials were used under the same clinical conditions to ensure comparisons between their performances were objective.

Shade selection was performed before the restorative procedure was performed and while the teeth were moist. If necessary, local anesthesia was administered. The cavity was opened (or the existing restoration was removed) using a spherical diamond bur (Meisinger Dental Burs, Hager and Meisinger GmbH, Neuss, Germany) on a high-speed air turbine. Caries were removed using slow-speed metal burs (Meisinger Dental Burs, Hager and Meisinger GmbH, Neuss, Germany) and hand instruments. Discolored, but hard, dentine was left in place at the cavity floor. The cavities were designed according to the principles of minimal invasive dentistry. The dentin in deeper cavities was covered with calcium hydroxide (Dycal, Dentsply Detrey, Konstanz, Germany) and/or glass ionomer cement (KetacMolar Easymix, 3M-ESPE, Seefeld, Germany). The minimum amount of glass ionomer needed was used to cover the calcium hydroxide so that most of the dentin surface was left exposed to ensure the adhesive system achieved a better bond between the tooth and the composite. The outline shape of the preparations was limited to the removal of caries/defective restoration; as such, no additional retention and bevel were prepared. All cavities were restored using a precurved metallic sectional matrix (Unimatrix System, TDV, Pomerode, SC, Brazil) fixed with a ring and wooden wedges. To remove water, the lesions were rinsed for 10 s and air-dried for 5 s. A two-step self-etching adhesive system, AdheSE Bond (Ivoclar Vivadent, Schaan, Liechtenstein), was utilized on the teeth in all test groups to reduce variability in the results of the investigation. The adhesive was dried with a gentle stream of air for at least 5 s and polymerized for 10 s with a light emitting diode (LED)-curing unit (Elipar S10, 3M-ESPE, Seefeld, Germany). The light was directed perpendicular to the occlusal surface. All light-curing procedures were performed with the same LED-curing unit operating in a continuous mode while emitting a light-intensity of 1000 mW/cm^2. Randomization determined which of the teeth to be restored were assigned restoration with either the universal nano-hybrid composite (Tetric EvoCeram) or the bulk-fill composite (Tetric EvoCeram bulk-fill). The randomization process was performed with a flipping a coin. The side of the coin determines the assignment of each subject. Operator assigned heads for control (conventional RC) and tails for test (high-viscosity bulk-fill RC). The tooth with higher number was assigned to the first treatment according the universal numbering system (teeth #1–32). From that point, second higher number tooth assigned other teeth to be restored for the same participant (two-four restorations allowed per participant) with another material.

The materials used in the study (including the compositions, application steps, batch numbers, and information about the manufacturers) are listed in Table 2. Of the restorations that were placed, 41.5% were in the maxilla, 58.5% were in the mandible, 32.4% were in the premolar teeth, and 67.6% were in the molar teeth. Table 3 presents an overview of the distribution of the restorations according to the type of tooth and arch. After removal of the matrix system, the restorations on the teeth in both groups were light-cured for further 20 s from the buccal, lingual, and occlusal aspects. The cotton rolls were then removed, and occlusion and articulation were checked and adjusted. The surface of the teeth were finished with fine-grit diamond instruments (Diatech, Coltene, Switzerland),

polishing disks (Sof-Lex, 3M-ESPE, MN, USA), and rubber polishing instruments (One Gloss, Shofu, Kyoto, Japan). Water-cooling was used through the finishing procedures.

Periods and evaluation criteria

The Modified United States Public Health Service (USPHS) criteria[39] were used to evaluate retention, marginal integrity, marginal discoloration, anatomic form, and secondary caries [Table 4] at baseline (1 week), 6 and 12 months by two blinded, calibrated clinicians not involved with the treatment procedures. The baseline rating was carried out 1 week after restoration, immediately after the finishing and polishing procedures were completed. Each examiner evaluated the restoration once. To ensure a double-blind study, the evaluators were not informed as to which filling material had been used on which teeth. For training purposes, the clinicians were required to evaluate 20 Class II restorations according to the USPHS criteria before examining the teeth restored in the current study. In the event that disagreements arose during the evaluations, the examiners were required to reach a consensus evaluation. Inter-examiner agreement was assessed using Kappa. Clinical scoring was performed using a mirror, a Hu-Friedy CH3 (Hu-Friedy, Chicago, USA) probe for marginal scoring and anatomy and dental floss to check the contact points. Vitality testing was performed at baseline and each recall. The restorations were scored as follows:

- Alfa: The ideal clinical situation
- Bravo: Clinically acceptable
- Charlie: Clinically unacceptable.

Statistical analysis

The data were entered into a spreadsheet (Excel 2013, Microsoft, Seattle, WA, USA) to calculate the descriptive statistics. Data were analyzed using statistical computer software (SPSS version 22, Chicago, IL, USA). The Mann–Whitney U test was used to compare the differences between the results taken at 6 months and 12 months. In addition, the Friedman test was also used to evaluate the changes of intragroup results between baseline and 12 months. The confidence level was set to 95% ($P < 0.05$).

Results

The Cohen's Kappa statistics (0.95) showed strong agreement between the examiners and no statistical difference was observed in their answers.

After 1 year, 70 restorations (Tetric EvoCeram $n = 35$; Tetric EvoCeram bulk-fill = 35) in 32 patients were available for evaluation. Two female patients with 4 molar Class II restorations could not be observed at the baseline 1 week recalls and excluded from the study.

Table 1: Distribution of patients according to the age and gender

Age group	Gender		Total
	Male	Female	
20-29	2	5	7
30-39	16	4	20
40-49	5	1	6
50-59	1	-	1
Total	24	10	34

Table 5 summarizes the evaluation data for each criterion per group at each evaluation time. No postoperative sensitivity, anatomic form, retention, and secondary caries were observed after 6 and 12 months. Regarding the items color match, marginal discoloration, and marginal adaptation, the statistical analysis did not detect any statistical significance between two materials [Table 5]. Lack of marginal discoloration was observed in only one restoration (Tetric EvoCeram) after 6 and 12 months period.

The percentages of alpha scores for color match were 97.1% ($n = 34$) for Tetric EvoCeram restorations and 100% ($n = 35$) for Tetric EvoCeram bulk-fill restorations. Only one Tetric EvoCeram restorations (2.9%) received Bravo score ($P = 0.368$) at 12 months recall. However, no significant differences were observed between two materials in 6 and 12 months ($P = 0.317$).

Three Tetric EvoCeram restorations (8.6%) received bravo ratings and one restoration (2.9%) received Charlie ratings while only one Tetric EvoCeram bulk-fill restoration received Bravo score for marginal discoloration after 12 months. The statistical comparison between the results at baseline and after 1 year of clinical service showed a significant increase in marginal discoloration ($P = 0.05$) for Tetric EvoCeram restorations. However, no significant differences were observed between two materials (For 6 and 12 months $P = 0.547$ and 0.163, respectively).

All restorations received Alfa ratings for 6 months while only one restoration in Tetric EvoCeram bulk-fill received Bravo ratings (2.9%) for marginal adaptation. This difference was not found to be statistically significant ($P = 0.368$) between baseline (1 week) and the 1-year follow-up in terms of marginal adaptation for Tetric EvoCeram bulk-fill.

Table 2: The composition, application steps, batch number, and manufacturer of materials

Material	Composition	Application steps	Batch number	Manufacturer
Tetric EvoCeram	Bis-GMA, Bis-EMA, UDMA, Ba-Glas, YbF3, mixed oxide, prepolymers; additives, catalysts, stabilizers, and pigments (Filler weight/volume: 76/54)	2 mm layers, light cured 20 s		Ivoclar Vivadent, Schaan, Liechtenstein
Tetric EvoCeram Bulk Fill	Bis-GMA, Bis-EMA, UDMA, Ba-Glas, YbF3, mixed oxide, prepolymers; additives, catalysts, stabilizers, and pigments (Filler weight/volume: 80/60)	4 mm layers, light cured 20 s	P87656	Ivoclar Vivadent, Schaan, Liechtenstein
AdheSE Bond	Primer: Acrylic ether phosphonic acid, bisacrylamide, water, CQ, and stabilizers Bonding: Bis-GMA, GDMA, HEMA, fumed silica, CQ, tertiary amine, and stabilizers	Apply primer 30 s, careful air drying for 5 s, apply adhesive, light-cured 10 s	R06822	Ivoclar Vivadent, Schaan, Liechtenstein

Bis-EMA=Ethoxylated bisphenol A dimethacrylate; Bis-GMA=Bisphenol A diglycidyl dimethacrylate; CQ=Camphorquinone; GDMA=Glycerol dimethacrylate; UDMA=Urethane dimethacrylate; Basic composition based on manufacturers' technical profiles; HEMA=Hydroxyethyl methacrylate

Table 3: Distribution of restorative material according to the tooth type, cavity type, and restorative material placed

Restorative material	Distribution of restorations				Total
	Premolar		Molar		
	Two surface	Three surface	Two surface	Three surface	
Tetric EvoCeram	9	3	24	1	37
Tetric EvoCeram Bulk-Fill	10	2	25	0	37

Table 4: Modified United States Public Health Service evaluation criteria

Category	Scores	Criteria
Anatomic form	Alpha	Continuous
	Bravo	Slight discontinuity, clinically acceptable
	Charlie	Discontinuous, failure
Color match	Alpha	Restoration matches adjacent tooth structure in color and translucency
	Bravo	Mismatch is within an acceptable range of tooth color and translucency
	Charlie	Mismatch is outside the acceptable range
Marginal discoloration	Alpha	Absence of marginal discoloration
	Bravo	Presence of marginal discoloration limited and not extended
	Charlie	Evident marginal discoloration penetrated toward the pulp chamber
Marginal adaptation	Alpha	Closely adapted, no visible crevice
	Bravo	Visible crevice, explorer will penetrate
	Charlie	Crevice in which dentin is exposed
Secondary caries	Alpha	No evidence of caries
	Charlie	Caries is evident
Postoperative sensitivity	Alpha	Absence of the dentinal hypersensitivity
	Bravo	Presence of mild and transient hypersensitivity
	Charlie	Presence of strong and intolerable hypersensitivity
Retention	Alpha	Complete retention of the restoration
	Charlie	Loss of the restoration

Table 5: Number of restorations evaluated by each score for each material, period, and criterion

USPHS criteria	6-months			12-months		
	Tetric EvoCeram	Tetric EvoCeram Bulk-Fill	*P**	Tetric EvoCeram	Tetric EvoCeram Bulk-Fill	*P**
Anatomic form, *n* (%)						
Alfa	35 (100)	35 (100)	1.00	35 (100)	35 (100)	1.00
Bravo	-	-		-	-	

Contd...

Table 5: Contd...

USPHS criteria	6-months			12-months		
	Tetric EvoCeram	Tetric EvoCeram Bulk-Fill	*P**	Tetric EvoCeram	Tetric EvoCeram Bulk-Fill	*P**
Charlie	-	-		-	-	
Color match, *n* (%)						
Alfa	34 (97.1)	35 (100)	0.317	34 (97.1)	35 (100)	0.317
Bravo	1 (2.9)	-		1 (2.9)	-	
Charlie	-	-		-	-	
Marginal discoloration, *n* (%)						
Alfa	33 (94.3)	34 (97.1)	0.547	31 (88.6)	34 (97.1)	0.163
Bravo	1 (2.9)	1 (2.9)		3 (8.6)	1 (2.9)	
Charlie	1 (2.9)	-		1 (2.9)	-	
Marginal adaptation, *n* (%)						
Alfa	35 (100)	35 (100)	1.00	34 (97.1)	35 (100)	0.317
Bravo	-	-		1 (2.9)	-	
Charlie	-	-		-	-	
Secondary caries, *n* (%)						
Alfa	35 (100)	35 (100)	1.00	35 (100)	35 (100)	1.00
Bravo	-	-		-	-	
Charlie	-	-		-	-	
Postoperative sensitivity, *n* (%)						
Alfa	35 (100)	35 (100)	1.00	35 (100)	35 (100)	1.00
Bravo	-	-		-	-	
Charlie	-	-		-	-	
Retention, *n* (%)						
Alfa	35 (100)	35 (100)	1.00	35 (100)	35 (100)	1.00
Bravo	-	-		-	-	
Charlie	-	-		-	-	

*P** Mann–Whitney U test. USPHS=United States Public Health Service

Discussion

In clinical studies, the success of a material is indicated by its longevity in the oral cavity; as such, retention rates represent the most important evaluation criteria. The American Dental Association guidelines for submitted dentin and enamel adhesive materials specify provisional acceptance, means that no more than 5% of the restorations should have been lost at the 6 months recall and, to obtain full acceptance, the cumulative incidence of clinical failures in each of the two independent clinical studies needs to be <5% of the restorations lost by the 6 months recall visit and <10% by the 18 months recall.[40] In this study, 100% of the restorations in both groups were retained at the 12 months recall.

The number of patients who attend recalls is of significance to the reliability of the data obtained during the clinical trials. A total of 94% of the patients involved in this study attended the 12 months recall. The patient population was selected from reliable, easily accessible individuals (individuals who exhibited a high standard of oral hygiene and a motivation to maintain good oral hygiene). No statistically significant differences between the two selected RC materials (nano-hybrid and bulk-fill) were observed during the 12 months recall period. As previously described, to ensure consistency, one operator placed all the restorations in this study to ensure consistency and eliminate the risk that the use of different techniques would influence the reliability of the results. Previous studies involving more than one technician have revealed that some of the variables evaluated were more dependent on the operator than they were on the material tested.[41,42]

After 12 months of clinical service, all restorations evaluated for both materials were classified as ideal, receiving predominantly Alfa scores for all parameters analyzed [Table 5]. No significant differences between the conventional and high-viscosity bulk-fill materials were observed for all parameters after the testing periods, accepting the null hypothesis tested. To our best knowledge, no previous clinical study has attempted to evaluate the clinical performance of high-viscosity bulk-fill composite resins. However, Van Dijken and Pallesen[38] compared conventional (Ceram-X mono^{+}) and flowable bulk-fill RCs (SDR) in Class I and II,

and also reported no significant differences between the materials in terms of the criteria assessed (retention, marginal staining, recurrent caries, marginal adaptation, gingival recession, color change, and wear) up to 3 years postrestoration. Similar findings were also reported in another randomized controlled prospective clinical trial[37] that evaluated the efficacy of a flowable RC (SDR) bulk-fill technique in posterior restorations and compared the results intraindividually with a conventional 2 mm RC curing technique after a 3-year follow-up period. In the present study, there is the possibility that the adhesive system employed contributed to the effective performance of the restorations tested. It is widely accepted that the adhesive used in a restoration plays an important role in resisting the forces of polymerization shrinkage. Previous research on the adhesive employed in this study (AdheSE) revealed that it offers an excellent bond strength between composite and dental tissues[43-46] and that its performance is clinically acceptable.[47]

A recent innovation in posterior resin restoratives is the development of high-viscosity bulk-fill restorative resins. Many *in vitro* studies have been published that evaluate the performance of these bulk-fill materials. In the present study, the Tetric EvoCeram and Tetric EvoCeram bulk-fill systems exhibited statistically similar clinical performance. This may be because they have very similar mechanical properties and exhibit consistent behavior.[48,49] As confirmed in different *in vitro* studies, bulk-fill RCs can be cured in larger increments than more traditional systems because the degree of cure and the micromechanical properties can be maintained within 4 mm layers at an irradiation time of up to 20 s.[50] Thus, layering two consecutive 2 mm increments with Tetric EvoCeram or one 4 mm increment with Tetric EvoCeram bulk-fill could produce similar mechanical properties to conventional filling techniques. In a study by Benetti, Havndrup–Pedersen[33] Tetric EvoCeram bulk-fill exhibited a higher depth of cure than a conventional RC. Furthermore, a higher depth of cure has been previously reported for bulk-fill RCs,[51,52] and the differences between the two materials have been attributed to improvements in their initiator system[51] and increased translucency.[51,53] In addition, Benetti, Havndrup–Pedersen[33] reported that the use of high-viscosity bulk-fill RCs with reduced polymerization contraction (SonicFill and Tetric EvoCeram bulk-fill) produced a similar gap formation to the conventional RCs. This finding is partially in agreement with the results of the current study. According to the Tetric EvoCeram bulk-fill approach, the increased depth of cure was realized by adding a new initiator, Ivocerin, in addition to the camphorquinone (CQ)/amine initiator systems as opposed to reducing the filler amount and increasing the filler size as per the process that is typically employed with the majority of bulk-fill materials.[48] Ivocerin is a germanium-based initiator system that demonstrates a higher photo-curing activity than CQ because it can achieve higher absorption in the wavelength region between 400 and 450 nm. Moreover, it is possible to use the initiator without the addition of an amine as a co-initiator, and this forms at least two radicals that can initiate the radical polymerization. Ivocerin is, therefore, considered to be more efficient than the CQ/amine systems because the use of this system results in the production of radicals that can initiate polymerization.[54] The efficiency of the initiator is further confirmed by the fact that Tetric EvoCeram bulk-fill offered an increased depth of cure in comparison to the regular nano-hybrid RBC pendant Tetric EvoCeram even though the chemical composition and the filler systems in both materials are comparable.

Marginal adaptation is influenced mainly by the polymerization shrinkage of the RC and the adhesive type, so both factors might have influenced the clinical results exhibited in the case of these restorations.[55] Ideally, marginal adaptation should be examined at baseline before assessing the consequence of polymerization shrinkage and resulting stress because both occur during the placement of the restoration. Clinical consequences, such as wear and integrity of the adhesive interface, may also modify marginal adaptation during the 1 year period of clinical use. However, in the present study, all of the restorations exhibited almost flawless performance after the 1 year study period.

When it comes to direct composite restorations, both marginal adaptation and adequacy of the polymerization are important considerations when assessing clinical behavior. The degree of conversion has a fundamental infiuence on shrinkage stress because of its inherent connection with the development of polymerization contraction and elastic modulus.[56-58] As such, the degree of conversion is an important tool that can be employed to estimate the physical, mechanical, and biological properties of composite resin restorations.[59,60] Achieving a high degree of polymerization is key to obtaining superior physical and mechanical properties. Inadequate polymerization might lead to marginal microleakage,[61] discoloration,[62] and decreased bonding strength[63] in RCs restorations. During the early phase of the polymerization reaction, shrinkage stress increases gradually in an almost linear manner to the conversion.[56] The degree of conversion may be influenced by material composition (matrix and filler) and translucency.[64] The main concern that many technicians have with the

use of the bulk-filling technique is that the composite may not cure sufficiently in the deeper portions of the restoration.[16] However, to date, very few studies have evaluated the degree of conversion[32] and polymerization kinetics of bulk-fill composites. One recent study[65] evaluated the polymerization properties of bulk-fill RCs using two different light-curing protocols. The results revealed that in terms of degree of conversion, all investigated bulk-fills exhibited sufficient polymerization properties at 4 mm increment thickness. Li and Pongprueksa[66] evaluated the curing profile of bulk-fill RBC using micro-Raman spectroscopy, and four bulk-fill RBCs were compared to a conventional RBC. The researchers concluded that the bulk-fill RBCs tested can be cured "effectively" to at least 4 mm depth (the middle of the specimen).

None of the patients involved in the study reported postoperative sensitivity at the 12 months evaluation point. The lack of sensitivity may be the result of the use of the calcium hydroxide liner and/or resin-modified glass ionomer liner in deep and very deep cavities. The use of liners protects the pulpal-dentin complex, avoiding or decreasing the possibility of thermal/electric stimuli, minimizing hydrodynamic fluid movements, and promoting the formation of respiratory dentin in very deep cavities.[67]

The changes in the color of RCs are a multifactorial phenomenon; it is associated with the intrinsic discoloration and extrinsic staining that can occur during use. Intrinsic factors involve alterations in the chemical stability of the resin matrix and the matrix-particle interface. Extrinsic factors are related to pigment absorption from exogenous sources in oral fluids, poor oral hygiene, dietary intake, and smoking. At the end of the 1 year period, 100% of the Tetric EvoCeram bulk-fill and 97.1% of the Tetric EvoCeram composites were awarded an alpha rating in terms of color match.

Marginal discoloration is one of the first clinical signs of the failure of an RC restoration.[68] In the current study, the majority of the scores allocated for the marginal discoloration criteria was Alfa. However, the relatively low incidence of Bravo scores for both restorative materials may be attributed to the fact that phosphoric acid etching was not employed.[69]

The external validity of this study was influenced by the fact that it was conducted at a dental school and that the same dentist placed all restorations. One could argue that neither the patients nor the dentist was representative of a true population. The outcome of this study was dependent not just on the patients and materials used, it may also have been affected by other factors, such as the skills of the operator, the isolation method employed, the type of light source used, and the finishing instruments utilized. It is, therefore, not possible to state with confidence that the results of the present study would be replicated in everyday dental practice. It is recognized that the duration of this study is insufficient to confirm the long-term suitability of the materials tested; nevertheless, these findings provide an indication of how they can be expected to perform in clinical use. The results observed after the 1 year period could provide some useful information about the clinical performance of resin materials; however, the period tested was too short to identify the development of any secondary caries. At the end of the 2 years study period, no caries was found adjacent to the restorations. These findings are in line with several other clinical studies.[37,70,71]

Conclusion

Tetric EvoCeram bulk-fill performs just as well as Tetric EvoCeram in the clinical setting at 12 months evaluation period.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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