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 participants had at least two Class II cavities included the study. Class II cavities restored with either a Tetric EvoCeram bulk-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 Alpha 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

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

H Çolak¹², U Tokay³⁴, R Uzgur⁵⁶, MM Hamidi⁷, E Ercan’

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]

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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 lengthy 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

**Table 1**

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Gender</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>23-26</td>
<td>Male</td>
<td>12</td>
</tr>
<tr>
<td>27-30</td>
<td>Female</td>
<td>12</td>
</tr>
<tr>
<td>31-34</td>
<td>Male</td>
<td>8</td>
</tr>
<tr>
<td>35-56</td>
<td>Female</td>
<td>2</td>
</tr>
</tbody>
</table>

**Table 2**

<table>
<thead>
<tr>
<th>Material</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetric EvoCeram</td>
<td>34</td>
</tr>
<tr>
<td>Tetric EvoCeram bulk-fill</td>
<td>34</td>
</tr>
</tbody>
</table>

**Table 3**

<table>
<thead>
<tr>
<th>Material</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetric EvoCeram</td>
<td>34</td>
</tr>
<tr>
<td>Tetric EvoCeram bulk-fill</td>
<td>34</td>
</tr>
</tbody>
</table>

**Figure 1**

A poster showing 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.
Randomization determined which of the materials was assigned to the teeth to be restored for each patient. The materials included Easymix, 3M-ESPE, Seefeld, Germany) and/or glass ionomer cement (KetacMolar, Ivoclar Vivadent, Schaan, Liechtenstein), a high-viscosity bulk-fill composite.

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) on a high-speed air turbine. Caries were removed) using a spherical diamond bur (Meisinger Dental Burs, Hager and Meisinger GmbH, Neuss, Germany) on a high-speed air turbine. Caries were removed. The most caries were in the premolar teeth, and 67.6% were in the maxilla, 58.5% were in the mandible, and 32.4% were in the premolar teeth. All restorations (37 for each restorative material) were performed to replace existing restorations with clinical or surgical procedures. The antagonist and adjacent tooth in contact; the molar teeth.

Restorative procedures all restorations that were performed to treat primary caries lesions.

Bitewing radiographs of the teeth to be restored were taken preoperatively unless the patient had already had radiographs taken within the previous year. There were at least two Class II restorations randomly – one with the universal nano-hybrid composite (Tetric EvoCeram) and the other with Tetric EvoCeram (Ivoclar Vivadent, Schaan, Liechtenstein), a conventional viscosity composite, and the other with Tetric EvoCeram (Ivoclar Vivadent, Schaan, Liechtenstein), a high-viscosity bulk-fill resin composite (RC). The materials were used under the same clinical conditions to ensure comparisons between their performances were objective.
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[69] 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 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 charlie 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>
<thead>
<tr>
<th>Age group</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-29</td>
<td>2</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>30-39</td>
<td>16</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>40-49</td>
<td>5</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>50-59</td>
<td>1</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>24</td>
<td>10</td>
<td>34</td>
</tr>
</tbody>
</table>

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

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

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

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

<table>
<thead>
<tr>
<th>Restorative material</th>
<th>Premolar</th>
<th>Molar</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Two surface</td>
<td>Three surface</td>
<td>Two surface</td>
</tr>
<tr>
<td>Tetric EvoCeram</td>
<td>9</td>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>Tetric EvoCeram Bulk-Fill</td>
<td>10</td>
<td>2</td>
<td>25</td>
</tr>
</tbody>
</table>

Table 4: Modified United States Public Health Service evaluation criteria

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

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

<table>
<thead>
<tr>
<th>USPHS criteria</th>
<th>6-months</th>
<th>12-months</th>
<th>6-months</th>
<th>12-months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anatomic form, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alfa</td>
<td>35 (100)</td>
<td>35 (100)</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Bravo</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Contd...
**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.\(^\text{[41,42]}\) 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.\(^\text{[41,42]}\)

After 12 months of clinical service, all restorations evaluated for both materials were classified as ideal, receiving predominantly Alfa scores for all parameters 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\(^\text{[38]}\) compared conventional (Ceram-X mono\(^{\text{+}}\)) 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 that evaluated the efficacy of a flowable RC (SDR) bulk-fill technique in posterior restorations and compared the results intrindividually 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 and that its performance is clinically acceptable.

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. 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. 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 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, and the differences between the two materials have been attributed to improvements in their initiator system and increased translucency. In addition, Benetti, Havndrup–Pedersen 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. 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. 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. 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 influence on shrinkage stress because of its inherent connection with the development of polymerization contraction and elastic modulus. 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. Achieving a high degree of polymerization is key to obtaining superior physical and mechanical properties. Inadequate polymerization might lead to marginal microleakage, discoloration, and decreased bonding strength in RC restorations. During the early phase of the polymerization reaction, shrinkage stress increases gradually in an almost linear manner to the conversion. The degree of conversion may be influenced by material composition (matrix and filler) and translucency. 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 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-dentine 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.

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**Conflicts of interest**

There are no conflicts of interest.

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