Clinical performance of class I cavities restored with bulk fill composite at a 1-year follow-up using the FDI criteria: a randomized clinical trial

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ABSTRACT

Objectives: The present study aimed to evaluate the survival rate and clinical performance of class 1 composite restorations restored with the Filtek Bulk Fill composite material using either the bulk fill technique or the incremental technique at baseline (1 week) and at 3, 6 and 12 months of follow-up.

Materials and Methods: Forty-two patients with at least 2 carious teeth were selected. Following randomization, one tooth was restored with the Filtek Bulk Fill composite using the incremental fill technique, and the other tooth was restored with the same material using the bulk fill technique. Patients were recalled for follow-up at baseline (1 week) and 3, 6, and 12 months and evaluated using the FDI criteria.

Results: The data were analyzed using the McNemar χ² test. No statistically significant differences were found between the scores of teeth restored with either technique. At baseline and at 3, 6, and 12 months of follow-up; there were no significant difference in the clinical status of both groups of restorations.

Conclusions: Within the limitations of this study, using the bulk fill technique for restorations with the Filtek Bulk Fill material seems to be equally efficient to using the incremental fill technique.

Trial Registration: Clinical Trials Registry-India Identifier: CTRI/2017/07/008961

Keywords: Bulk fill; FDI criteria; Incremental layering; Resin composite

INTRODUCTION

With increasing demands from patients for esthetic restorations, the popularity of composites has extended to use as posterior restorative materials. However, the drawbacks of composites, such as polymerization shrinkage, can lead to microleakage at the cavosurface margin, postoperative sensitivity, secondary caries, and stresses causing cuspal deflection.
The incremental layering technique was advocated to overcome these effects. Incremental layering allows the placement of composite resin at up to 2-mm increments, thereby ensuring proper curing of the composite. This technique has disadvantages such as void formation between increments, bonding failure at the interface, a long operating time, and difficulty of placement in conservative cavity preparations [1].

Currently, bulk fill composites are gaining popularity due to their ease of application. With advancements in the material sciences, changes have been made in the composition of the material, including reducing the filler content, increasing the filler particle size (thereby reducing scattering at the filler and resin interface and increasing light absorption), and using additional photo-initiators (ivocerin along with camphorquinone and lucririne). These modifications reduce the translucency and allow better light penetration. Thus, bulk fill composites can be cured in large increments (up to 4–5 mm), which is their primary advantage.

There are 4 types of bulk fill resin-based composites (RBCs): bulk fill RBCs (packable), bulk fill-based RBCs (flowable), sonic-activated bulk fill RBCs, and dual-cure bulk fill RBCs. Bulk fill-based RBCs have a flowable consistency. They are injected in deep cavities and a conventional composite is used over the deep cavity site. Bulk fill packable RBCs can be used alone; thus, they are more time-saving and simpler than flowable materials [2].

Ambiguity persists regarding the long-term survival rate of bulk fill composites in vivo, and few randomized clinical trials have been reported regarding this issues. Some authors have compared the survival rate of bulk fill composites restored using the bulk fill technique to that of conventional composites restored with the incremental layering technique. Some of these randomized clinical trials are described in Table 1 [3-5]. However, no studies have yet compared the long-term survival of bulk fill composites restored with the bulk fill technique versus the incremental layering technique in vivo.

The present clinical trial aimed to evaluate the clinical performance of Filtek Bulk Fill composite restorations using the incremental layering technique or the bulk fill technique at baseline and at 3, 6, and 12 months of follow-up using the Fédération Dentaire Internationale (FDI) criteria. The null hypothesis was that there would be no difference in the clinical performance of the Filtek Bulk Fill composite, whether restored with the incremental technique or the bulk fill technique, for 1 year.

### Table 1. Published randomized clinical trials using bulk fill composite materials

| Author          | Year | Study                                                                 | Materials used                                      | Criteria used                      | Conclusion                                                                 |
|-----------------|------|----------------------------------------------------------------------|-----------------------------------------------------|------------------------------------|---------------------------------------------------------------------------|
| Bayraktar et al. [3] | 2015 | One-year clinical evaluation of different types of bulk-fill composites | Clearfil Photo posterior, Filtek Bulk-Fill Flowable Restorative Posterior Filtek P60, Tetric EvoCeram Bulk Fill, SonicFill | The modified USPHS criteria       | The bulk-fill composite resin materials showed similar clinical performance when compared with a conventional posterior composite resin. |
| Colak et al. [4]    | 2017 | A prospective, randomized, double-blind clinical trial of 1 nano-hybrid and 1 high-viscosity bulk-fill composite restorative system in class II cavities | Tetric EvoCeram Bulk-Fill, Tetric EvoCeram universal nano-hybrid resin composite | The modified USPHS criteria       | High-viscosity bulk-fill RCs performed just as well as nano-hybrid RCs with the 2-mm RC layering technique, and therefore could be alternative to conventional nano-hybrid RCs. |
| van Dijkenand Pallesen [5] | 2014 | A randomized controlled 3-year evaluation of “bulk-filled” posterior resin restorations based on stress decreasing resin technology. | SDR flowable resin composite and nano-hybrid resin composite (Ceram X mono), Ceram X (resin composite) | The modified USPHS criteria       | The 4-mm bulk-fill technique with the flowable resin composite SDR showed high clinical effectiveness, which was comparable during the 3-year follow-up with the 2-mm resin composite layering technique. |

USPHS, United States Public Health Service; RC, resin composite.
MATERIALS AND METHODS

Selection of subjects
Approval of the study protocol and ethical clearance were obtained from the Institutional Review Board (registration No. NDC/PG-2015-2016/EC/2015). The study was also registered in the Clinical Trials Registry-India (registration No. CTRI/2017/07/008961).

In total, 42 outpatients attending the Department of Conservative Dentistry and Endodontics from May 1, 2016 to May 31, 2016 who volunteered to participate were included in the study. All patients were informed about the background of the study. Written informed consent was obtained from the participants.

Sample size and design
The study design was a parallel, randomized, single-center clinical trial with an allocation ratio of 1:1. The ideal sample size was set to 40 restorations per group to determine a significant difference in outcomes at the 95% confidence level, with an alpha value of ≤ 0.05 and 80% power ($\alpha$). This sample size was found to be sufficient to observe significant differences between material groups in similar intra-individual comparison designs [6,7].

Inclusion and exclusion criteria
The included patients were in the age group of 18 to 50 years, with 2 carious lesions scored based on the International Caries Detection and Assessment System (ICDAS) as code 4 or 5 and a prepared cavity depth of minimum 3 mm. The ICDAS scoring system is presented in Table 2.

Patients with abnormal occlusion, fewer than 20 teeth, hypersensitivity, or non-vital teeth; medically compromised patients; and pregnant women were excluded from the study.

Subject allocation and randomization method
One hundred patients were screened using central allocation randomization by another investigator. Out of the 100 patients screened, 42 patients who met the inclusion criteria were selected. For each of the 42 patients included in the study, one tooth was restored using the bulk fill method, and the other tooth was restored using the incremental layering technique. Both teeth received the same restorative material (i.e., Filtek Bulk Fill posterior composite material; Filtek Bulk Fill Restorative Composite, 3M ESPE, St. Paul, MN, USA).

The randomization and grouping of the subjects are presented in Figure 1. Randomization was done by choosing a block of 4 numbers from a random table. If the number was an odd number, the first tooth was restored using the bulk fill technique, and if the number was even, the first tooth was restored using the incremental layering technique. The first tooth was determined based on the order of appearance of the tooth in the FDI notation.

Table 2. International Caries Detection and Assessment System (ICDAS) scoring

| Code | Description |
|------|-------------|
| 0    | Sound tooth surface: No evidence of caries after 5 seconds of air-drying |
| 1    | First visual change in enamel: Opacity or discoloration (white or brown) is visible at the entrance to the pit or fissure seen after prolonged air drying |
| 2    | Distinct visual change in enamel visible when wet, lesion must be visible when dry |
| 3    | Localized enamel breakdown (without clinical visual signs of dentinal involvement) seen when wet and after prolonged drying |
| 4    | Underlying dark shadow from dentin |
| 5    | Distinct cavity with visible dentin |
| 6    | Extensive (more than half the surface) distinct cavity with visible dentin |
In total, 84 restorations were included in the study: 42 in the incremental fill group and 42 in the bulk fill group.

**Clinical procedure**

Class 1 cavity preparations were done for both teeth using high-speed air rotor 245 burs (Midwest, operative carbide bur; FGSS, Dentsply Sirona, York, PA, USA) under rubber dam isolation. The cavity outline was established to eliminate the carious lesion, and the depth of the cavities were at least 3 mm, as evaluated using a periodontal probe. A single bonding system (Single Bond Universal Adhesive, 3M ESPE) was used to etch and bond the tooth surface and cured for 20 seconds in continuous mode with the intensity of 1,000 mW/cm² (poly-wave LED curing light; Ivoclar-Vivadent AG, Schaan, Liechtenstein). The patients were blinded, as they did not know which technique was used for which tooth.

For teeth restored using an incremental layering technique, the oblique incremental technique was used. The first increment was placed in a wedge shape along the internal line angle, making a 45° angle with the pulpal floor. The thickness of each increment was not greater than 2 mm. The first increment was light-cured for 20 seconds, followed by placement of the next increment. To complete the restoration, 3 to 4 increments were required.

For the teeth restored using the bulk fill technique, the composite was placed into the cavity and condensed using a parallelogram-shaped Teflon-coated condenser, and anatomic carving was done followed by light curing for 40 seconds.
Evaluation

The restorations were evaluated using the FDI criteria at baseline (1 week) and at 3, 6, and 12 months by 2 blinded, calibrated clinicians not involved with the treatment procedures. The investigators did not know which tooth was restored using which technique. The baseline rating was carried out 1 week after restoration. Thus, as neither the investigators nor the patients knew which technique was used in which tooth, this was a double-blinded study. For training purposes, the clinicians were required to evaluate 20 class I restorations according to the FDI criteria before examining the restored teeth included in the study. When disagreements arose between the investigators during the evaluation, the investigators were required to reach a consensus. The inter-examiner agreement was assessed using kappa statistics.

Out of a total of 16 FDI properties, 7 properties that were relevant to this study were selected. The properties selected were fracture of material and retention, marginal adaptation, radiographic examination, the patient’s view, postoperative sensitivity and tooth vitality, recurrence of caries, erosion and abfraction, and tooth integrity. These 7 factors comprised the primary outcome of the study (Table 3) [8].

Table 3. FDI evaluation criteria of functional and biological properties used in this study

| Property                                | Criteria                                                                 |
|-----------------------------------------|--------------------------------------------------------------------------|
| Fracture of material and retention      | No fractures/cracks                                                      |
|                                         | Small hairline crack                                                     |
|                                         | Two or more or larger hairline cracks and/or material chip fracture       |
|                                         | (not affecting the marginal integrity or approximal contact)              |
|                                         | Material chip fractures which damage marginal quality or approximal       |
|                                         | contacts/bulk fractures with partial loss (less than half of the         |
|                                         | restoration)                                                             |
|                                         | (Partial or complete) loss of restoration or multiple fractures          |
| Marginal adaptation                     | Harmonious outline, no gaps, no white or discolored lines                |
|                                         | Marginal gap (< 150 μm), white lines/small marginal fracture              |
|                                         | removable by polishing/slight ditching, slight step/flashes, minor       |
|                                         | irregularities                                                           |
|                                         | Gap < 250 μm not removable/several small marginal fractures/major         |
|                                         | irregularities, ditching or flash, steps                                |
|                                         | Gap > 250 μm or dentin/base exposed/Severe ditching or marginal           |
|                                         | fractures/larger irregularities or steps (repair necessary)              |
|                                         | Restoration (complete or partial) is loose but in situ/generalized major |
|                                         | gaps or irregularities                                                   |
| Radiographic examination                | No pathology, harmonious transition between restoration and tooth        |
|                                         | Acceptable material excess present/positive/negative step present at     |
|                                         | margin < 150 μm                                                          |
|                                         | Marginal gap < 250 μm/negative steps visible < 250 μm. No adverse        |
|                                         | effects noticed/poor radiopacity of filling material                     |
|                                         | Marginal gap > 250 μm/Material excess accessible but not removable/      |
|                                         | negative steps > 250 μm and repair necessary                            |
|                                         | Secondary caries, large gaps, large overhangs/apical pathology/fracture/|
|                                         | loss of restoration or tooth                                             |
| Patient’s view                          | Entirely satisfied with esthetics and function                            |
|                                         | Satisfied esthetics/function, e.g., minor roughness                      |
|                                         | Minor criticism but no adverse clinical effects/esthetic shortcomings/   |
|                                         | some lack of chewing comfort/unpleasant treatment procedure              |
|                                         | Desire for improvement in esthetics/function, e.g., tongue irritation;    |
|                                         | reshaping of anatomic form or refurbishing is possible                   |
|                                         | No hypersensitivity, normal vitality                                     |
|                                         | Minor hypersensitivity for a limited period of time, normal vitality     |
|                                         | Moderate hypersensitivity/delayed/mild sensitivity; No subjective         |
|                                         | complaints, no treatment needed                                          |
|                                         | Intense hypersensitivity/delayed with minor subjective symptoms/no       |
|                                         | clinical detectable sensitivity. Intervention necessary, but not         |
|                                         | replacement                                                              |
|                                         | Intense, acute pulpitis or non-vital tooth. Endodontic treatment is       |
|                                         | necessary and restoration has to be replaced                             |
| Postoperative (hyper-) sensitivity and  | No secondary or primary caries                                           |
| tooth vitality                          | Small and localized (1) demineralization (2) erosion or (3) abfraction   |
|                                         | Larger areas of (1) demineralization (2) erosion or (3) abrasion/abfraction, dentin not exposed; only preventive measures necessary |
|                                         | Caries with cavitation and suspected undermining caries/erosion in dentin/abrasion/abfraction in dentin. Localized and accessible, can be repaired |
|                                         | Deep caries or exposed dentin that is not accessible for repair of       |
|                                         | restoration                                                              |
| Recurrence of caries (CAR), erosion,    | Complete integrity                                                      |
| abfraction                              | Small marginal enamel fracture (< 150 μm)/hairline crack in enamel       |
|                                         | (< 150 μm).                                                              |
|                                         | Marginal enamel defect < 250 μm/crack < 250 μm; Enamel chipping/multiple  |
|                                         | cracks                                                                  |
|                                         | Major marginal enamel defects; gap > 250 μm or dentin or base exposed/large |
|                                         | cracks > 250 μm, probe penetrates/large enamel chipping or wall fracture  |
|                                         | Cusp or tooth fracture                                                   |
All these properties were clinically evaluated by examiners and scored as clinically excellent, good, satisfactory, unsatisfactory (needing to be repaired), or poor (needing to be replaced).

**Statistical analysis**
The data collected at baseline (1 week) and 3, 6, and 12 months of follow-up were scored and tabulated, and statistically analyzed using the $\chi^2$ test in SPSS version 22 (IBM Corp., Armonk, NY, USA). The intragroup evaluation between time periods was carried out using the McNemar $\chi^2$ test.

**RESULTS**
The scores obtained at baseline (1 week) and 3, 6, and 12 months are shown in Table 4. All restorations, regardless of technique, were scored as clinically excellent or clinically good. All 42 patients attended follow-up at 3 and 6 months, while 2 patients were lost to follow-up at 12 months.

At baseline (1 week), all restorations were scored as clinically excellent with respect to all parameters. With respect to fracture of material and retention, out of all the restorations restored with the incremental layering technique, 42 (100%), 40 (95%), and 37 (92%) restorations were scored as clinically excellent at 3, 6, and 12 months of follow-up, respectively. The remaining restorations were scored as clinically good. In the teeth restored with the bulk fill technique, 42 (100%), 39 (93%), 36 (90%) restorations were scored as clinically excellent at 3, 6, and 12 months of follow-up, respectively. The remaining teeth were scored as clinically good.

Regarding marginal adaptation, in the teeth restored with the incremental layering technique 40 (95%), 35 (83%), and 33 (82%) restorations were scored as clinically excellent at 3, 6, and 12 months of follow-up, respectively. In the teeth restored with the bulk fill technique 41 (98%), 35 (83%), and 32 (80%) restorations were scored as clinically excellent at 3, 6, and 12 months of follow-up, respectively. The remaining teeth were scored as clinically good.

All the restorations restored with incremental layering technique were scored as clinically excellent at all the follow-up periods with respect to properties such as the patient’s view, postoperative sensitivity, and recurrence of caries. Out of all the restorations restored with the bulk fill technique, 1 restoration was scored as clinically good at the 6- and 12-month follow-up periods. The remaining 41 restorations (97%) were scored as clinically excellent. In terms of the radiographic examination and tooth integrity properties, all restorations (restored with either technique) were scored as clinically excellent at each follow-up point.

There was no statistically significant difference between the scores of teeth restored with either technique. The McNemar $\chi^2$ test was also performed in order to compare the differences in each group between baseline (1 week) and 3, 6, and 12 months. No statistically significant differences were found.
DISCUSSION

The most important criterion to evaluate the success of a material is its retention rate. For a material to be provisionally accepted as a restorative material, the ADA specifies that the cumulative incidence of failure should be < 5% at the 6-month recall and < 10% by the 18-month recall [9].

In this study, 100% of the restorations were retained until the 12-month recall in both groups. Further, all the restorations evaluated in both groups were scored as clinically excellent or clinically good. At 6 months, all patients presented for follow-up, while 2 patients were...
lost to follow-up at 12 months. There were no statistically significant differences in the performance of the restorations evaluated in terms of any of the parameters. Hence, the null hypothesis was accepted.

As restorations were placed using the 2 different techniques in the teeth of the same patients, both groups were subjected to similar environmental, mechanical, and oral hygiene conditions and similar caries susceptibility. The longevity of dental restorations depends on the material and technique used, the patient's compliance with oral hygiene, and the patient's susceptibility to caries [3]. The majority of patients in this study had good oral hygiene and no periodontal problems, so a low rate of failure was anticipated.

Since the variables that impact the clinical result are more dependent on the operator than on the material tested, only 1 experienced operator placed all the restorations in the present study [10,11]. This ensured that the restorations were consistent and performed under the same conditions. This minimized the risk of bias, so that the results would only be influenced by the different restorative techniques, rather than any other variables.

A clinical assessment of the performance of restorations requires criteria that are objective, reliable, and relevant to the outcome. Many published studies have used the modified United States Public Health Service (USPHS) criteria for evaluating outcomes [3,5,12], but the recently-introduced FDI criteria have more validity than the USPHS criteria. The FDI criteria are categorized into 3 groups: esthetic parameters (4 criteria), functional parameters (6 criteria), and biological parameters (6 criteria). Thus, a total of 16 parameters can be evaluated. These clinical criteria and their scoring system are well structured and flexible, and can be selected and adjusted according to the needs of the investigation. Even minor changes in restorations can be detected, which helps to ensure accurate scoring [8]. In the present study, as class I restorations were evaluated, only 7 criteria relevant to the study were selected (fracture of the material and retention, marginal adaptation, radiographic examination, patient's view, postoperative sensitivity, recurrent caries, and tooth integrity).

Polymerization shrinkage of composites results in shrinkage stress when the contraction is obstructed, and the material is rigid and resists the plastic flow that is required to compensate for the original volume. These stresses are then transferred to the margins of the restoration, possibly affecting the quality of the restoration. The incremental layering approach due to its advantages, such as better light penetration and polymerization; reduction of the cavity C-factor, polymerization shrinkage stresses, and cuspal deflection; and better resin adaptation to walls. However, the drawbacks of this technique include void entrapment between increments, which results in bond failure between increments, and the tedious and time-consuming nature of the procedure [13-15].

The currently available bulk fill composites use different mechanisms to achieve an increased depth of cure. They have less shrinkage stress due to the stress-relieving rheology of the material and allow adaptation of the material to walls. Recent studies have shown that bulk fill composites can be cured in larger increments than conventional systems because the degree of cure and the micromechanical properties can be maintained within 4-mm layers at a curing time of up to 20 seconds [16-18]. A previous study found that the polymerization stresses and mean cuspal deflections of cavities restored with bulk fill composites were significantly lower than when the incremental technique was used with a conventional composite [19].

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No stand-alone clinical study has yet been conducted to evaluate the clinical performance of the Filtek Bulk Fill posterior composite in posterior cavities with a high C-factor. van Dijken and Pallesen [5] compared conventional (Ceram X mono, Dentsply/DeTrey, Konstanz, Germany) and flowable bulk fill RBC (SDR, Dentsply/DeTrey) in class I and class II restorations and concluded that there was no significant difference between the materials in terms of the selected modified USPHS criteria up to 3 years after the restoration. However, they used flowable bulk fill and did not report results for class I cavities separately. This study attempted a clinical validation of in vitro studies to observe the long-term performance of bulk fill composites in class I cavities with 2 different restorative techniques using the same material.

In the present study, when the incremental technique was used, the fracture resistance of the restoration was 100% at baseline, whereas it decreased to 92.5% at 12 months. Similarly, when the bulk fill technique was used, the fracture resistance decreased from 100% to 90% at 12 months. Parameters such as the patient’s view, radiographic examination, postoperative sensitivity, recurrent caries, and tooth integrity remained the same from baseline to 12 months when the incremental technique was used. For the bulk fill technique, the radiographic examination and tooth integrity remained the same from baseline to 12 months, whereas the patient’s view, postoperative sensitivity, and recurrent caries showed a slight decrease from baseline to 12 months (i.e., from 100% to 97.5%).

Fracture of material and retention depend on both the mechanical properties and polymerization stress. There was no significant difference in these parameters between the 2 groups restored with either of the techniques. The marginal adaptation of the material depends on degree of conversion and polymerization shrinkage of the material. Both restorative techniques in this study performed equally with respect to marginal adaptation, thus proving that the bulk fill technique did not compromise the polymerization of the material.

An improper degree of cure leads to marginal gap and leakage leading to postoperative sensitivity, secondary caries, and discomfort to the patient. Hence, factors such as postoperative sensitivity, caries recurrence, radiographic examination, and the patient’s view are inter-related. All the restorations except 1 were scored as excellent with respect to these factors. One restoration restored using the bulk fill technique developed a small demineralized area adjacent to the restoration, it was scored as good. This lesion may have caused discomfort in the patient, who reported occasional mild sensitivity. As the lesion was a demineralization lesion, it was not radiographically evident. All the teeth were scored as clinically excellent with respect to the radiographic examination.

The findings of our study are similar to those of Bayraktar et al. [3], who compared the 1-year clinical performance of 3 different bulk fill composites, namely Filtek Bulk Fill Flowable (3M ESPE) and Filtek P60 (3M ESPE), Tetric EvoCeram Bulk Fill (Ivoclar Vivadent, Schaan, Liechtenstein), and Sonic Fill (Kawo Sonic Fill System; Kerr, Orange, CA, USA) composites with a Clearfil Photo Posterior (Kuraray, Okayama, Japan) nanohybrid resin composite in class II cavities. Their study concluded that bulk fill composite resin materials showed similar clinical performance when compared with a conventional posterior composite resin. Colak et al. [4] conducted a prospective randomized clinical trial comparing a high-viscosity bulk fill composite (Tetric EvoCeram Bulk Fill) with a nano-hybrid composite (Tetric EvoCeram Universal) in class II cavities over a year. They reported that all restorations evaluated for both materials were classified as ideal for all parameters analyzed. An in vitro study showed that the marginal adaptation of bulk fill composites was adequate and similar to standard composites.
when observed under scanning electron microscopy [13]. Both these studies reported that bulk fill composites showed high clinical effectiveness and therefore could be an alternative to conventional nano-hybrid RBCs.

In a study that compared the depth of cure of 2 bulk-filling composites using a stainless steel mold, the depth of cure of Tetric EvoCeram Bulk Fill was found to be greater than that of Filtek Bulk Fill (4.03 ± 0.14 vs. 3.56 ± 0.38 mm). However, the authors used a rectangular hole instead of a circular hole for the comparison, and this might have influenced the results. The Filtek Bulk Fill still had a similar depth of cure to the Tetric EvoCeram Bulk Fill with the use of a tooth mold [20].

The observation period of the clinical evaluation of the bulk fill composite was 12 months, which sufficed to observe any failures that could have been caused by an inadequate depth of cure or polymerization shrinkage stresses in the restoration. An ideal bulk fill composite would be one that can be placed into a high C-factor preparation design and exhibits very little polymerization shrinkage stress while maintaining a high degree of cure throughout [21]. Future studies should be conducted to observe the clinical performance of bulk fill composite materials over a longer time period.

CONCLUSIONS

The Filtek Bulk Fill Posterior Composite material, when cured using the bulk fill technique, performed just as well as the material cured with the incremental layering technique within a 1-year follow-up period. Thus, the bulk fill composite material can be considered as an alternative to the conventional composite, as it is an equally effective, less sensitive, and more time-saving technique.

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