Clinical Performance of Bulk-Fill Resin Composite Restorations Using the United States Public Health Service and Federation Dentaire Internationale Criteria: A 12-Month Randomized Clinical Trial

Márcia de Almeida Durão1, Ana Karina Maciel de Andrade2, Maria do Carmo Moreira da Silva Santos1, Marcos Antônio Japiassú Resende Montes1, Gabriela Queiroz de Melo Monteiro1

1School of Dentistry, University of Pernambuco, Avenida Agamenon Magalhães, S/N - Santo Amaro - Recife - PE, Brazil
2Department of Restorative Dentistry, Dental School, Universidade Federal da Paraíba, Cidade Universitária, Brazil

Address for correspondence Márcia de A. Durão, PhD, School of Dentistry, University of Pernambuco, Avenida Agamenon Magalhães, S/N - Santo Amaro, Recife, PE 50100-010, Brazil (e-mail: marciadurao.fop@gmail.com).

Abstract

Objective This study was aimed to compare the 12-month clinical performance of two full-body bulk-fill resin composites Filtek bulk fill/3M ESPE (FBF) and Tetric EvoCeram bulk fill/Ivoclar Vivadent (TBF) and a conventional microhybrid resin composite Filtek Z250/3M ESPE (Z250) using the modified the United States Public Health Service (USPHS) and Federation Dentaire Internationale (FDI) criteria. Also, the agreement between the two evaluation criteria was evaluated at baseline and after 12 months of follow-up.

Materials and Methods A total of 138 class I and II restorations were placed in posterior teeth (split-mouth design) of 46 volunteers following manufacturer’s instructions and bonded with a self-etching bonding agent (Clear fill SE Bond/Kuraray). The restorations were evaluated at baseline and after 12 months of follow-up by three previously calibrated dentists (Cohen’s K = 0.84).

Statistical Analysis Fisher’s exact test and Pearson’s Chi-squared test were used to evaluating the homogeneity of distribution of the clinical characteristics. Friedman’s test was applied to evaluate differences among the resin composites. The results obtained for the USPHS and FDI criteria at the different observation times were compared using the Wilcoxon test. A level of significance of 0.05 was adopted for all tests.

Results After 12 months (recall rate, 78.3%, n = 36 patients), the overall success rate was 99.07% for both criteria. Only one failed restoration (0.93%) was detected for each system during follow-up in the TBF group.

Conclusion The bulk-fill resin composites showed satisfactory clinical performance compared with conventional resin composite after 12 months. The percentage of the acceptable scores was significantly higher for the USPHS criteria, due to discrepancies in the score description for each criterion.
Introduction

Bulk-fill resin composites have been introduced into the market for restorations in posterior teeth. The main characteristic of these materials is their insertion in single-increment applications of 4 to 5 mm.1-3 Low-viscosity bulk-fill resin composites were the first materials developed. These flowable materials are indicated as a restorative base and require a 2-mm thick covering layer with a regular/conventional resin composite.4-6 Subsequently, paste-like “full-body” bulk-fill restorative resin composites were introduced. These materials contain a higher percentage of inorganic filler, which allows their use in high-masticatory load-bearing areas without the need of coverage.2,5,8 Bulk-fill resin composites consist of conventional methacrylate monomers. Low-polymerization shrinkage stress and improved physical and mechanical properties can be achieved by incorporating prepolymerized particles and modified monomers. These particles act as chemical modulators of the polymerization reaction, such as aromatic urethane dimethacrylate (AUDMA)12 and addition fragmentation monomers (AFM), incorporated into Filtek bulk fill.13 In general, this class of materials has a high translucency to ensure a greater depth of cure.9,11,14,15 Other manufacturers added alternative photoinitiators other than camphorquinone. The Tetric EvoCeram bulk-fill resin composite contains the Ivocerin (dibenzoyl germanium derivative) and TPO (mono-alkyl phosphate oxide) photoinitiators to increase the light-curing capacity of the resin.12,16,17

Laboratory studies reported satisfactory results in terms of the physical properties of bulk-fill resin composites similar to those of conventional composites inserted by the incremental technique.8,10,18-21 However, due to the short time on the market, only a few clinical studies regarding the long-term behavior of these materials are available. The systematic review by Veloso et al pointed to dental and material fractures as the leading causes of failures, considering the majority due to bruxism.22 One-year clinical evaluations of different types of bulk-fill resin composites, related failures in marginal adaptation with the incidence of secondary caries, and contamination with saliva during the restorative procedure were studied.23

Different clinical criteria are used for the evaluation of dental restorations. The United States Public Health Service (USPHS) criteria, also known as the Ryge criteria,24 is the most widely used.25 In 2007, a new system for evaluating the clinical performance of dental restorations was introduced, known as the criteria of the Federation Dentaire Internationale (FDI).26,27 This criterion is divided into three main categories that evaluate esthetic, functional, and biological properties by attributing a score that ranges from 1 to 5.28,30

Within this context, the objective of this study was to evaluate and compare the effectiveness of restorations performed with two full-body bulk-fill resin composites and a conventional resin composite. The materials were inserted into class I and II cavities and observed for 12 months using the modified USPHS and FDI criteria. The agreement between the two criteria was also assessed. Two null hypotheses were tested as follows: (1) the clinical effectiveness of the materials does not differ over the studied period, and (2) the evaluation criteria do not provide divergent results for the common categories.

Materials and Methods

Study Design

A controlled, double-blind (evaluator and patient), randomized clinical trial with three study groups with an equal allocation ratio (split-mouth design) was conducted. The study was approved by the Ethics Committee on Research Involving Humans of the University of Pernambuco, Brazil (protocol no. 944.518). The study was registered with the Brazilian Registry of Clinical Trials (ReBEC, RBR-5v6dsj) and was conducted following the Consolidated Standards of Reporting Trials (CONSORT).

Population and Sample Size

Adolescents aged 12 to 18 years (mean age of 14.82) regularly enrolled in three public schools of Camaragibe and Recife, Pernambuco, Brazil, who required dental treatment were recruited. Most of these adolescents live in poor, low-income communities without guidance and access to healthy food and oral hygiene or dental services. This population was chosen since it represents the social reality of this region, and the study may make a social contribution.

The sample size was 46 restorations per group to detect differences in the outcomes assuming a significance level of 5% and power of the study of 80%. The sample size was calculated using previous studies that evaluated restorations in posterior teeth.31-33 Study designs that enable the evaluation of groups of materials with similar intraindividual comparisons have found significant differences for this sample size.34

Eligibility Criteria

The following inclusion criteria were adopted: (1) the presence of three vital posterior teeth with primary caries or that require the replacement of class I and II restorations, (2) absence of parafunctional habits, (3) absence of noncarious cervical lesions in the evaluated teeth, (4) the presence of occlusal and proximal contacts, (5) good general health, (6) absence of any contraindication for dental treatment, and (7) good recall availability.

Criteria for exclusion were as follows: (1) advanced periodontal disease, (2) posterior teeth with pulp alterations or endodontically treated, (3) posterior teeth with carious lesions on surfaces other than the cavity used for this study, (4) teeth with any symptomatology, (5) smoking, and (6) lack of adjacent and antagonist teeth. All patients participated voluntarily, and the adolescents and their legal representatives signed the free, informed consent form.

Randomization, Allocation, and Blinding

A total of 138 restorations from 46 volunteers were performed by the same operator (►Fig. 1). Each patient received three restorations, each performed with one of the three materials tested (►Table 1). In each patient, the restorations were started in the most posterior tooth with the largest cavity. After cavity preparation and rubber dam isolation, opaque sealed envelopes were used to randomize the resin composite to be inserted in each tooth. The patients were unaware of the type of material used in each tooth.
Fig. 1 Flow diagram of the study (Consolidated Standards of Reporting Trials [CONSORT] 2010).

Table 1 Composition, application, manufacturer, and batch number of each material used

| Material                        | Composition                                                                 | Application step                                                                 | Manufacturer/batch number                  |
|---------------------------------|-----------------------------------------------------------------------------|----------------------------------------------------------------------------------|--------------------------------------------|
| Clearfil SE bond (SEB)          | Primer: HEMA, 10-MDP, 10-Methacryloyloxydecyl dihydrogen phosphate, hydrophilic aliphatic dimethacrylate, colloidal silica, dl-camphorquinone, water, accelerators, dyes, (pH±idyl methacrylate, HEMA, 10 MDP-methacryloyloxydecyl dihydrogen phosphate, hydrophobic aliphatic dimethacrylate, colloidal silica, camphorquinone | Primer: Active application for 20 seconds air dried for 5 seconds for solvent evaporation. Bond: active application, air dried for solvent evaporation, and light cured for 10 second | Kuraray Medical, Inc.; Tokyo, Japan (01245A) (01882A) |
| Tetric EvoCeram Bulk Fill (TBF) | Organic matrix: dimethacrylates (Bis-GMA, Bis-EMA, UDMA). Fillers: barium glass, ytterbium trifluoride, mixed oxide, silica Nanohybrid, 79–81% weight and 60–61% volume (17% prepolymers) | Increment up to 4 mm and light cured for 10 seconds each side\(^a\) | Ivoclar Vivadent; Schaan, Liechtenstein, GE (T23727) |
| Filtek bulk fill (FBF)          | Organic matrix: UDMA, AFM, AUDMA, DDDMA 1,12-dodecanediol dimethacrylate Fillers: zirconia–silica, ytterbium trifluoride. Nanoparticle, 76.5% weight and 58.4% volume | Increment up to 5 mm, light cured for 10 seconds each side: occlusal, buccal and lingual\(^a\) | 3M ESPE; St. Paul, Minnesota, United States (N633573) |
| Filtek Z250 XT (Z250) (control group) | Organic matrix: Bis-GMA, UDMA and Bis-EMA. Fillers: zirconia–silica. Microhybrid, 82% weight and 60% volume | Incremental technique. A 2-mm increment was applied and light cured for 20 seconds | 3M ESPE; St. Paul, Minnesota, United States (228214) |

Abbreviations: 10-MDP, 10-methacryloyloxydecyldihydrogenphosphate; AFM, addition fragmentation monomers; AUDMA, aromatic urethane dimethacrylate; Bis-EMA, bisphenol A polyethylene glycol diether-dimethacrylate; Bis–GMA, bisphenol A-diglycidylether dimethacrylate; DDDMA, 1,12-dodecanediol dimethacrylate; HEMA, 2-hydroxymethyl methacrylate; UDMA, urethane dimethacrylate.

\(^a\)Class-II bulk fill restorations: after removal of the matrix band, the proximal regions were polymerized additionally on the buccal and lingual surfaces for 10 seconds.
Adherence and Recall Process
To ensure adherence of the participants to the study, all volunteers underwent complete dental treatment and periodic follow-up. For the assessments, the volunteers were contacted by telephone, WhatsApp message, Facebook, and e-mail. Four attempts, including visits to the schools, were made to contact a volunteer before he/she was considered a “loss.”

Clinical Procedure
Conservative cavity preparation was performed with a high-speed spherical diamond bur (no.: 1015–1017, KG Sorensen, Barueri, Brazil) under constant refrigeration. Intermittent rotary instrument contact with tooth limited to the removal of compromised enamel. The cavity outline was restricted to the removal of carious tissue with a manual instrument and spherical carbide bur at low speed. In the removal of defective restorations, the friable enamel and remnant carious tissue were removed in the same way. Anesthesia was applied if necessary to improve patient comfort.

All teeth were restored using a rubber dam. The self-etch bonding agent (Clearfil SE Bond, SEB, Kuraray, Tokyo, Japan) was applied with previous selective enamel etching with 37% phosphoric acid for 30 seconds. In deep cavities (≥4 mm), dentine hardness was considered to define the need for lining with a modified glass ionomer cement (Vitrebond, 3M ESPE, St. Paul, Minnesota, United States). In the presence of harder reparative dentin, no lining was used. These materials were inserted following the manufacturer’s instructions (► Table 1). All photoactivation procedures were performed with a LED unit in the continuous mode at a light intensity of 1200 mW/cm² (Radii-cal, SDI, Victoria, Australia). A precontoured sectional matrix system (Unimatrix, TDV, Pomerode, Santa Catarina, Brazil) and wooden wedges (TDV, Pomerode, Santa Catarina, Brazil) were used to restore class-II cavities. The resin composites were applied and light-cured following the manufacturer’s instructions (► Table 1).

At the end of each restoration, occlusal contacts were checked (AccuFilm, Parkell, New York, United States), and fine-grit dental burs were used for occlusal adjustments. The proximal contact and cervical adaptation were checked with dental floss and adjusted with aluminum oxide-impregnated strips (Sof-Lex Finishing and Polishing System, 3M ESPE, St. Paul, Minnesota, United States). After 24 hours, the restorations were finished with fine and extra-fine-grit diamond burs (KG Sorensen). Silicon polishers with diamond particles (Astropol, Ivoclar Vivadent, Schaan, Liechtenstein) in a decreasing sequence of abrasiveness and silicon carbide brush (Astrobrush, Ivoclar Vivadent) were also used at low speed under constant water-cooling using intermittent movements.

Calibration and Data Collection
After 1 week (baseline), the restorations were evaluated after 12 months by three dentists who did not participate in the restorative procedure and were blind regarding treatment allocation. The evaluators were calibrated before the study by a joint examination of 20 direct resin composite restorations from other volunteers who did not participate in the clinical trial (Cohen’s $K = 0.84$). The restorations were clinically assessed according to the modified USPHS criteria (► Table 2) and FDI criteria (► Table 3) considering esthetic, functional, and biological features.

| Category              | Score | Definition                                                                 |
|-----------------------|-------|-----------------------------------------------------------------------------|
| Anatomic form         | Alpha | Restoration continuous with existing anatomic form                          |
|                       | Bravo | Restoration discontinuous with existing anatomic form, but loss of material is not sufficient to expose the dentin or base |
|                       | Charlie | Loss of material sufficient to expose the dentin or base                     |
| Marginal adaptation   | Alpha | Restoration completely adapted to the tooth. No visible gap. No explorer catch at the margins or in any direction |
|                       | Bravo | Explorer catch. There is no visible evidence of a gap into which the explorer could penetrate |
|                       | Charlie | Explorer penetrates into a deep gap that exposes dentin or base              |
| Marginal discoloration | Alpha | No discoloration along the cavosuperficial margin                           |
|                       | Bravo | <50% of the cavosuperficial margin affected by stain                        |
|                       | Charlie | >50% of the cavosuperficial margin affected by stain                        |
| Color match           | Alpha | Restoration with color and translucency similar to those of the adjacent dental structure |
|                       | Bravo | Change in color and translucency within an acceptable standard              |
|                       | Charlie | Change in color outside the acceptable standard                             |
| Surface roughness     | Alpha | Restoration surface is smooth                                               |
|                       | Bravo | Restoration surface is slightly rough or has scratches, but can be refinished |
|                       | Charlie | Surface deeply rough, with irregular scratches; cannot be refinished         |
| Recurrent caries       | Alpha | Absent                                                                       |
|                       | Charlie | Present                                                                     |
| Postoperative sensitivity | Alpha | Absent                                                                       |
|                       | Charlie | Present                                                                     |
| Score | Esthetic properties | Functional properties | Biological properties |
|-------|--------------------|-----------------------|-----------------------|
| 1.1   | Comparable to enamel | 1.1 No marginal or surface staining | 1.1 No hyper-sensitivity, normal vitality |
| 2.1   | No marginal or surface staining | 3.1. Color and translucency of the restoration have an ideal match with the surrounding enamel | 12.1 No secondary or primary caries |
| 3.1   | Color and translucency of the restoration have a clinically excellent match with the surrounding enamel | 4.1 Form is ideal | 13.1. No hyper-sensitivity, normal vitality |
| 4.1   | 5.1. No fractures/cracks | 6.1. Harmonious outline, no gaps, no white or discolored lines | 12.1 No secondary or primary caries |
| 5.1   | 6.1. No fractures/cracks | 7.1 Physiological wear equivalent to enamel. Wear corresponding to 80–120% of enamel | 13.1. Complete integrity |
| 6.1   | 7.1 Physiological wear equivalent to enamel. Wear corresponding to 80–120% of enamel | 8.1. Normal contact point (floss or 2.5 μm metal blade can pass) | 15.1. Healthy mucosa adjacent to restoration |
| 7.1   | 8.1. Normal contact point (floss or 2.5 μm metal blade can pass) | 9.1. Entirely satisfied with esthetics and function | Adjacent mucosa |
| 8.1   | 9.1. Entirely satisfied with esthetics and function | 10.1. Patient’s view | 15.1. Healthy mucosa adjacent to restoration |
| 9.1   | 10.1. Patient’s view | 11.1. No hyper-sensitivity, normal vitality | 15.1. Healthy mucosa adjacent to restoration |
| 10.1  | 11.1. No hyper-sensitivity, normal vitality | 12.1. No secondary or primary caries | 13.1. Complete integrity |
| 11.1  | 12.1. No secondary or primary caries | 13.2. Small marginal enamel fracture (<150 μm). Hairline crack in enamel (>150 μm) | 15.2. Healthy after minor removal of mechanical irritations (plaque, sharp edges, etc.) |
| 12.1  | 13.2. Small marginal enamel fracture (<150 μm). Hairline crack in enamel (>150 μm) | 14.2. Small and localized. Demineralization area | 15.2. Healthy after minor removal of mechanical irritations (plaque, sharp edges, etc.) |
| 13.2  | 14.2. Small and localized. Demineralization area | 15.1. Healthy after minor removal of mechanical irritations (plaque, sharp edges, etc.) | 15.2. Healthy after minor removal of mechanical irritations (plaque, sharp edges, etc.) |
| 14.2  | 15.1. Healthy after minor removal of mechanical irritations (plaque, sharp edges, etc.) | | 15.2. Healthy after minor removal of mechanical irritations (plaque, sharp edges, etc.) |

(Continued)
Table 3 (Continued)

| Score | Esthetic properties | Functional properties | Biological properties |
|-------|---------------------|-----------------------|-----------------------|
| 4.     | Clinically unsatisfactory (but repairable) |                         |                        |
| 1.4    | Rough surface, cannot be masked by saliva film, simple polishing is not sufficient |                         |                        |
| 2.4    | Unacceptable surface staining on the restoration and major intervention necessary. Pronounced marginal staining major intervention necessary |                         |                        |
| 3.4    | Localized clinical deviation that can be corrected by repair |                         |                        |
| 4.4    | Anatomic form is altered, the esthetic result is unacceptable |                         |                        |
| 5.4    | Material Chip fractures which damage marginal quality and/or approximal contacts. Bulk fractures with partial loss of less than half of the restoration |                         |                        |
| 6.4    | Gap > 250 μm, may result in exposure of dentine or base. Severe ditching of marginal fractures. Larger irregularities or steps (repair necessary) |                         |                        |
| 7.4    | Wear considerably exceeds normal enamel wear; or occlusal contact points are lost. Greater than 300% of enamel wear or antagonist >300% |                         |                        |
| 8.4    | Too weak and possible damage due to food impaction. 100 μm metal blade can pass. Inadequate contour. Repair possible |                         |                        |
| 10.4   | Desire for improvement: (a) esthetic and (b) function |                         |                        |
| 11.4   | Intense delayed with minor subjective symptoms. No clinical detectable sensitivity intervention necessary, but not replacement |                         |                        |
| 12.4   | Caries with cavitation and suspected undermining caries. Localized and accessible can be repaired |                         |                        |
| 13.4   | Major marginal enamel defects; gap >250 μm or dentin or base exposed. Larger cracks >250 μm, probe penetrates. Larger enamel chipping or wall fracture |                         |                        |
| 15.4   | Suspected mild allergic, lichenoid or toxic reaction |                         |                        |

| 5.     | Clinically poor (replacement necessary) |                         |                        |
| 1.5    | Very rough, unacceptable plaque retentive surface |                         |                        |
| 2.5    | Severe surface staining and/or subsurface staining, generalized or localized, not accessible for intervention. Deep marginal staining, not accessible for intervention |                         |                        |
| 3.5    | Color match and/or translucency are clinically unsatisfactory, replacement necessary |                         |                        |
| 4.5    | Anatomic form is unsatisfactory and/or lost |                         |                        |
| 5.5    | (Partial or complete) loss of the restoration or multiple fractures |                         |                        |
| 6.5    | Restoration (total or partial) is loose but in situ. Generalized major gaps or irregularities |                         |                        |
| 7.5    | Wear is excessive. Restoration or antagonist >500% of corresponding enamel |                         |                        |
| 8.5    | Too weak and clear damage due to food impaction and/or pain. gingivitis. Requires replacement |                         |                        |
| 10.5   | Completely unsatisfied and or adverse effects, including pain |                         |                        |
| 11.5   | Intense, acute pulpitis or mononital tooth. Endodontic treatment is necessary and restoration has to be replaced |                         |                        |
| 12.5   | Deep secondary caries or exposed dentine that is not accessible for repair of restoration |                         |                        |
| 13.5   | Cusp or tooth fracture |                         |                        |
| 15.5   | Suspected severe allergic, lichenoid or toxic reaction |                         |                        |

Abbreviation: FDI, Federation Dentaire Internationale.
For each volunteer, one tooth was evaluated at a time by all three evaluators. In the case of score disagreement, a consensus decision was obtained, reexaming the patient when necessary.36

For the modified USPHS criteria, failure was only considered when a Charlie score was attributed. For the FDI criteria, scores 1, 2, and 3 are clinically excellent, good, and satisfactory. Score 4 was clinically unsatisfactory but repairable, while in the case of score 5, the restoration was considered clinically poor/failure and should be replaced.

The modified USPHS and FDI criteria were compared in each group at the different observation times considering the common categories: marginal adaptation, color match/color match and translucency, marginal discoloration/staining (margin), anatomic form, surface roughness, and surface gloss/luster and roughness, postoperative sensitivity, and recurrent caries. The restorations were categorized by relating the USPHS and FDI criteria, where alpha corresponds to scores 1 and 2 (success); bravo corresponds to score 3 (clinically acceptable), and; charlie corresponds to scores 4 (clinically unsatisfactory but repairable) and 5 (clinically poor/failure).36

The Eq. \((1-x)^z\) was used to calculate the annual failure rate (AFR) of the restorations. The mean AFR is expressed by “y” and “x” the total failure rate at “z” years.37

Data Analysis

The Statistical Package for the Social Sciences (SPSS, version 23) was used for statistical analysis. Statistical measures were calculated to describe the distribution of the data. Fisher's exact test and Pearson's Chi-squared test were used to evaluating the homogeneity of distribution of the clinical characteristics of the samples. Friedman's test was applied to evaluate the resin composites' difference at each time point and differences between time points for each resin composite. The results obtained for the USPHS and FDI criteria at the different observation times were compared using the Wilcoxon test. A level of significance of 0.05 was adopted for all tests.

Results

Twenty-two (47.8%) of the 46 adolescents were boys, and 24 (52.2%) were girls. The initial decayed, missing and filled teeth (DMF) index of the 46 volunteers was 9.12. However, the caries component made the most substantial contribution to this value (87%), followed by the missing (11%) and filled (2%) components.

The clinical characteristics of the restored cavities are shown in Table 4. The distribution of the variables was homogenous in the three groups for the type of tooth restored, cavity classification, cavity width (buccal-lingual

### Table 4 Clinical characteristics of the different groups studied

| Characteristic | Group | Total | \(p\)-Value* |
|----------------|-------|-------|-------------|
|                |       | Baseline | 12 mo | Baseline | 12 mo | Baseline | 12 mo | Baseline | 12 mo | Baseline | 12 mo |
| Tooth          |       | Z250    | TBF   | FBF      |       | Z250    | TBF   | FBF      |       | Z250    | TBF   | FBF      |       |
| Upper premolar| 11    | 10      | 9     | 7        | 12    | 9       | 32    | 26       | 0.987 | 0.600   |
| Upper molar    | 4     | 3       | 5     | 5        | 5     | 5       | 14    | 13       | 0.736 | 0.553   |
| Lower premolar | 23    | 17      | 22    | 16       | 21    | 17      | 66    | 50       | 0.029 | 0.028   |
| Lower molar    | 8     | 6       | 10    | 8        | 8     | 5       | 26    | 19       | 0.333 | 0.309   |
| Cavity classification | |       |       |         |       |       |       |         |       |         |       |         |
| Class I        | 36    | 29      | 34    | 27       | 31    | 25      | 101   | 81       | 0.736 | 0.553   |
| Class II       | 10    | 7       | 12    | 9        | 15    | 11      | 37    | 27       | 0.575 | 0.430   |
| Cavity width   |       |         |       |         |       |         |       |         |       |         |       |         |
| <1/3           | 24    | 13      | 19    | 8        | 21    | 11      | 64    | 32       | 0.029 | 0.028   |
| >1/3           | 23    | 23      | 27    | 28       | 25    | 25      | 74    | 76       | 0.333 | 0.309   |
| Cavity depth   |       |         |       |         |       |         |       |         |       |         |       |         |
| Medium         | 23    | 17      | 13    | 7        | 9     | 8       | 48    | 33       | 0.333 | 0.309   |
| Deep           | 23    | 19      | 33    | 29       | 34    | 26      | 90    | 74       |       |         |
| Pulp protection|       |         |       |         |       |         |       |         |       |         |       |         |
| Bonding agent  | 30    | 22      | 23    | 17       | 27    | 22      | 80    | 62       | 0.033 | 0.309   |
| Glass ionomer cement | 16 | 14 | 23 | 19 | 19 | 14 | 58 | 46 | 0.033 | 0.309 |

Abbreviations: FBF, Filtek bulk fill; TBF, Tetric EvoCeram bulk fill.

*Fisher’s exact test; Pearson’s Chi-square test.
isthmus), and type of pulp protection (p > 0.05). However, regarding cavity depth, the number of deep cavities was higher for the bulk-fill resin composites.

The results of the restorations, clinical evaluation according to the modified USPHS and FDI criteria are shown in Tables 5 and 6. Among the 138 restorations performed in 46 patients, 108 were evaluated after 12 months in 36 patients (recall rate of 78.3%). However, the absence of 10 patients (21.7%) did not characterize the loss of individual groups due to the split-mouth design.

Significant differences between observation times were observed for “marginal adaptation” and “surface roughness” (Table 5). For marginal adaptation, differences were observed between time points (p < 0.001) for all resin composites tested, with a reduction in the number of alpha ratings. No significant differences were observed between groups. However, at 12 months, one failure (Charlie) was observed for the Tetric EvoCeram bulk fill (TBF) group.

Surface roughness differed significantly between the TBF group and the other groups studied. A significant increase in roughness was observed in the Z250 and Filtek bulk fill (FBF) groups after 12 months (p < 0.001 and 0.003, respectively). A higher percentage of alpha scores was obtained for the TBF resin at baseline (95.7%) and after 12 months (91.7%), with no significant difference between time points (p = 0.383).

Evaluation of anatomic form revealed no significant differences between groups or times (p = 1.0). However, one restoration of the TBF group was scored bravo at baseline and after 12 months.

Two volunteers in the Z250 group reported postoperative sensitivity at baseline. Clinical follow-up showed that sensitivity was transient. After 12 months, these restorations received an alpha score after clinical examination, vitality testing, and radiographic examination.

Among the esthetic properties evaluated by the FDI criteria (Table 6), significant differences between groups at baseline and after 12 months were observed for the surface gloss/luster and roughness category (p < 0.001), with score 3 being attributed at baseline (2.2%) and score 2 after 12 months (5.6%) in the Z250 group. A similar trend was found for the other resin composites at baseline and 12 months, with more than 90% of the restorations receiving scores 1 and 2 (excellent/good) at the different time points. For the anatomic form category, significant differences were observed between the TBF group and the other resins at baseline (p < 0.001), with 15.2% of the restorations receiving score 2 and 6.5% receiving score 3. At 12 months, 50% of the TBF restorations received score 2.

None of the functional properties differed significantly among groups. When observation times were compared, significant differences were observed for all three groups.

### Table 5 Results of clinical evaluation of the restorations according to the modified USPHS criteria

| Category                  | Score | Baseline (n = 46) | 12 months (n = 36) |
|---------------------------|-------|-------------------|--------------------|
|                           |       | Z250 n % | TBF n % | FBF n % | Z250 n % | TBF n % | FBF n % |
| Marginal adaptation       |       |           |         |         |           |         |         |
| A                         |       | 39 84.8   | 41 89.1  | 39 84.8 | 9 25      | 16 44.4 | 16 44.4 |
| B                         |       | 7 15.2    | 5 10.9   | 7 15.2  | 27 75     | 19 52.8 | 20 55.6 |
| C                         |       | –         | –        | –        | –         | 1 2.8   | –        |
| Color match               |       |           |         |         |           |         |         |
| A                         |       | 46 100    | 46 100  | 46 100  | 36 100    | 36 100  | 36 100  |
| B                         |       | –         | –        | –        | –         | 2 5.6   | 1 2.8   |
| C                         |       | –         | –        | –        | –         | –       | –       |
| Marginal discoloration    |       |           |         |         |           |         |         |
| A                         |       | 46 100    | 46 100  | 46 100  | 34 94.4   | 35 97.2 | 33 91.7 |
| B                         |       | –         | –        | –        | 2 5.6     | 1 2.8   | 3 8.3   |
| C                         |       | –         | –        | –        | –         | –       | –       |
| Anatomic form             |       |           |         |         |           |         |         |
| A                         |       | 46 100    | 45 97.8  | 46 100  | 36 100    | 35 97.2 | 36 100  |
| B                         |       | –         | 1 2.2    | –        | –         | 1 2.8   | –       |
| C                         |       | –         | –        | –        | –         | –       | –       |
| Surface roughness         |       |           |         |         |           |         |         |
| A                         |       | 29 63     | 44 95.7  | 32 69.6  | 7 19.4    | 9 33.3  | 11 30.6 |
| B                         |       | 17 37     | 2 4.3    | 14 30.4  | 29 80.6   | 3 8.3   | 25 69.4 |
| C                         |       | –         | –        | –        | –         | –       | –       |
| Postoperative sensitivity |       |           |         |         |           |         |         |
| A                         |       | 44 95.7   | 46 100  | 46 100  | 36 100    | 36 100  | 36 100  |
| B                         |       | 2 4.3     | –        | –        | –         | –       | –       |
| C                         |       | –         | –        | –        | –         | –       | –       |
| Recurrent caries          |       |           |         |         |           |         |         |
| A                         |       | 46 100    | 46 100  | 46 100  | 36 100    | 36 100  | 36 100  |
| B                         |       | –         | –        | –        | –         | –       | –       |
| C                         |       | –         | –        | –        | –         | –       | –       |

Abbreviations: FBF, Filtek bulk fill; TBF, Tetric EvoCeram bulk fill; USPHS, the United States Public Health Service.

Note: Different superscript letters indicate significant differences between groups by the Friedman’s test (lower case letters [footnotes]: differences between times of observation; upper case letters [footnotes]: differences between groups).
| Category                       | Score | Baseline (n = 46) | 12 months (n = 36) |
|-------------------------------|-------|------------------|------------------|
|                               |       | Z250 TBF FBF     | Z250 TBF FBF     |
|                               |       | n % n % n % n % | n % n % n % n % |
| Esthetic properties           |       |                 |                 |
| Surface gloss/luster and roughness | 1   | 35 76.1 a | 46 100 a | 43 93.5 a | 16 (44.4) a | 34 94.4 a | 26 72.2 a |
|                               | 2   | 10 21.7   | – –       | 3 6.5     | 18 (50.0) | 2 5.6     | 10 27.8   |
|                               | 3   | 1 2.2     | – –       | – –       | 2 5.6     | – –       | – –       |
|                               | 4   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 5   | – – – – – | – –       | – –       | – –       | – –       | – –       |
| Staining: (a) surface        | 1   | 46 100    | 46 100    | 46 100    | 34 94.4   | 35 100    | 35 100    |
|                               | 2   | – – – – – | – –       | – –       | 2 5.6     | 1 2.8     | 1 2.8     |
|                               | 3   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 4   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 5   | – – – – – | – –       | – –       | – –       | – –       | – –       |
| Staining: (b) margin         | 1   | 46 100    | 46 100    | 46 100    | 34 94.4   | 35 100    | 34 94.4   |
|                               | 2   | – – – – – | – –       | – –       | 2 5.6     | 1 2.8     | 2 5.6     |
|                               | 3   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 4   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 5   | – – – – – | – –       | – –       | – –       | – –       | – –       |
| Color match and translucency | 1   | 46 100    | 46 100    | 46 100    | 36 100    | 36 100    | 36 100    |
|                               | 2   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 3   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 4   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 5   | – – – – – | – –       | – –       | – –       | – –       | – –       |
| Anatomic form                 | 1   | 45 97.8 a | 36 78.3 a | 46 100 a  | 36 (100) a| 17 47.2 a | 36 100 a  |
|                               | 2   | – – 7 15.2 | – –       | – –       | 18 50.0   | – –       | – –       |
|                               | 3   | – – 3 6.5  | – –       | – –       | 1 2.2     | – –       | – –       |
|                               | 4   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 5   | – – – – – | – –       | – –       | – –       | – –       | – –       |
| Functional properties         | Fracture and retention | 1 | 46 100 | 45 97.8 | 36 100 | 36 100 | 35 97.2 | 36 100 |
|                               | 2   | – – 1 2.2  | – –       | – –       | 1 2.8     | – –       | – –       |
|                               | 3   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 4   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 5   | – – – – – | – –       | – –       | – –       | – –       | – –       |
| Marginal adaptation           | 1   | 38 82.6 a | 40 87 a  | 39 84.8 a | 10 27.8 a | 17 47.2 a | 14 38.9 a |
|                               | 2   | 8 17.4   | 6 13 7 15.2 | 26 72.2 | 17 47.2 a | 20 55.6 |
|                               | 3   | – – – – – | – –       | – –       | 1 2.8     | 2 5.6     |
|                               | 4   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 5   | – – – – – | – –       | – –       | – –       | – –       | – –       |
| Occlusal contour and wear     | 1   | 46 100    | 46 100    | 46 100    | 36 100    | 36 (100)  | 36 (100)  |
|                               | 2   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 3   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 4   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 5   | – – – – – | – –       | – –       | – –       | – –       | – –       |
| Approximal anatomic form      | contact point | 1 | 10 100   | 12 100    | 15 100    | 8 1,000   | 10 100    | 12 100    |
|                               | 2   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 3   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 4   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 5   | – – – – – | – –       | – –       | – –       | – –       | – –       |
| Approximal anatomic form      contour | 1 | 10 100   | 12 100    | 15 100    | 8 1,000   | 10 100    | 12 100    |
|                               | 2   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 3   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 4   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 5   | – – – – – | – –       | – –       | – –       | – –       | – –       |
| Patient’s view                | 1   | 46 100 a | 46 100 a  | 45 97.8 a | 17 47.2 a | 18 50 a  | 16 44.4 a |
|                               | 2   | – – – – – | – –       | – –       | – –       | – –       | 2 5.6     |
|                               | 3   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 4   | – – – – – | – –       | – –       | – –       | – –       | – –       |
|                               | 5   | – – – – – | – –       | – –       | – –       | – –       | – –       |

(Continued)
Table 6 (Continued)

| Category                      | Score | Baseline (n = 46) | 12 months (n = 36) |
|-------------------------------|-------|-------------------|------------------|
|                               |       | Z250 n % | TBF n % | FBF n % | Z250 n % | TBF n % | FBF n % |
| **Biological properties**     |       |           |         |         |           |         |         |
| Postoperative (hyper) sensitivity and tooth vitality | 1     | 44 | 95.7 | 46 | 100 | 46 | 100 | 36 | 100 | 36 | 100 | 36 | 100 |
|                              | 2     | 2 | 4.3 | – | – | – | – | – | – | – | – | – | – | – |
|                              | 3     | – | – | – | – | – | – | – | – | – | – | – | – | – |
|                              | 4     | – | – | – | – | – | – | – | – | – | – | – | – | – |
|                              | 5     | – | – | – | – | – | – | – | – | – | – | – | – | – |
| **Recurrent caries**          |       |           |         |         |           |         |         |
|                              | 1     | 46 | 100 | 46 | 100 | 46 | 100 | 36 | 100 | 36 | 100 | 36 | 100 |
|                              | 2     | – | – | – | – | – | – | – | – | – | – | – | – | – |
|                              | 3     | – | – | – | – | – | – | – | – | – | – | – | – | – |
|                              | 4     | – | – | – | – | – | – | – | – | – | – | – | – | – |
|                              | 5     | – | – | – | – | – | – | – | – | – | – | – | – | – |
| **Tooth integrity**           |       |           |         |         |           |         |         |
|                              | 1     | 46 | 100 | 46 | 100 | 46 | 100 | 36 | 100 | 36 | 100 | 36 | 100 |
|                              | 2     | – | – | – | – | – | – | – | – | – | – | – | – | – |
|                              | 3     | – | – | – | – | – | – | – | – | – | – | – | – | – |
|                              | 4     | – | – | – | – | – | – | – | – | – | – | – | – | – |
|                              | 5     | – | – | – | – | – | – | – | – | – | – | – | – | – |
| **Adjacent mucosa**           |       |           |         |         |           |         |         |
|                              | 1     | 46 | 100 | 46 | 100 | 46 | 100 | 36 | 100 | 36 | 100 | 36 | 100 |
|                              | 2     | – | – | – | – | – | – | – | – | – | – | – | – | – |
|                              | 3     | – | – | – | – | – | – | – | – | – | – | – | – | – |
|                              | 4     | – | – | – | – | – | – | – | – | – | – | – | – | – |
|                              | 5     | – | – | – | – | – | – | – | – | – | – | – | – | – |

Abbreviations: FBF, Filtek bulk fill; FDI, Federation Dentaire Internationale; TBF, Tetric EvoCeram bulk fill.
Note: Different superscript letters indicate significant differences between groups by the Friedman test (lower case letters [footnotes]: differences between times of observation; upper case letters [footnotes]: differences between groups).

(\(p < 0.001\)). Concerning proximal anatomic form (contact point and contour), 37 restorations were evaluated at baseline and 30 restorations after 12 months, and no differences were observed between groups or time points.

Regarding biological properties, no differences were observed between groups or observation times. Two of the 46 patients evaluated at baseline reported postoperative sensitivity in the restored teeth, attributing score 2 to the Filtek Z250 resin composite, which did not persist at 12 months, changing to score 1.

The overall success rate in 12 months was 97.2%. Failure was detected in one restoration (1%) during the follow-up of the TBF group for the marginal adaptation category using either the USPHS or FDI criteria.

The Wilcoxon test for paired data compared the USPHS and FDI criteria. Among all comparisons, differences were only found for the surface roughness and surface gloss/luster and roughness and the marginal adaptation categories. Table 7 shows statistically significant differences for the evaluation of surface roughness (modified USPHS) and surface gloss/luster and roughness (FDI) in the Z250 and FBF group at baseline and after 12 months. In general, for these groups, a higher percentage of acceptable scores was obtained by the USPHS criteria. For marginal adaptation, significant differences between the criteria were observed in all groups at 12 months of observation (Table 8). The percentage of the acceptable scores was significantly higher for the USPHS criteria.

Discussion

The first null hypothesis of this study was not rejected since no significant differences were found in the clinical performance of the materials tested. The overall success rate of the restorations after 12 months was 97.22% for both criteria. The resin composites inserted into 92 molars (73 class I and 19 class II) and 46 premolars (28 class I and 18 class II) that exhibited a similar clinical performance over the 12-month observation period. According to both the modified USPHS and FDI criteria, failure was only found for the TBF resin composite in the marginal adaptation category. A class-I restoration in an upper premolar (tooth 25) restored due to a primary carious lesion using only the bonding agent as the pulp protection. No failures were observed in the Z250 and FBF groups. Therefore, the AFR of the TBF group was 1.0% for the two criteria used.

These findings are in agreement with those reported by other 1-year clinical evaluation using the USPHS criteria. However, the studied populations' DMF index was not mentioned, and poor oral hygiene was considered an exclusion criterion. Bayraktar et al. (2017) analyzed 172 class-II restorations (recall rate of 86%, 43 patients) and compared three bulk-fill resin composites (Tetric EvoCeram Bulk Fill, Sonic Fill, Filtek Bulk Fill Flow + Filtek P60) with a conventional resin composite (Clearfil photo posterior). The prepared cavities were isolated with cotton rolls, and
Full-body Bulk-fill Resin Composite 12-Month Follow-up

Durão et al.

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of 104 class-II restoration over 36 months using the USPHS criteria showed better clinical performance for Tetric EvoCeram Bulk Fill in the marginal adaptation and marginal discoloration categories compared with conventional resin composite Filtek Ultimate, due to the higher number of Bravo ratings. 39

Clinical studies with a longer observation period of resin composite restorations are essential to better understand the material’s performance in the oral cavity and during the function. In a retrospective 22-year follow-up study, Da Rosa Rodolpho et al 28 observed an average AFR of 1.85% for composite resin restorations and good clinical performance of the material in posterior teeth. 39- 41  Van Dijken and Pallesen conducted clinical studies with more extended evaluation periods. 42, 43  Restorations prepared with flowable bulk-fill Surefil Smart Dentin Replacement (SDR) covered with conventional resin composite Ceram X mono were compared with restorations prepared only with Ceram X mono resin composite. In their 5-year follow-up, 43 acceptable clinical results were obtained for the Surefil SDR restorations according to the modified USPHS criteria, with a success rate of 100% for 38 class-I restorations. Sixty-two pairs of class-II restorations received an AFR of 1.4% for Surefil SDR and 2.1% for those restored only with the conventional resin composite (Ceram X mono). In another study with 6 years of follow-up with these restorative

| Evaluation | Group | Score* | Criteria | p-Value |
|------------|-------|--------|----------|---------|
| Baseline (n = 46) | Z250 | Success | 45 | 97.8 | 29 | 63.0 | <0.001 |
| | | Acceptable | 1 | 2.2 | 17 | 37.0 |
| | | Poor/failure | – | – | – | – |
| | TBF | Success | 46 | 100 | 44 | 95.7 | 0.500 |
| | | Acceptable | – | – | 2 | 4.3 |
| | | Poor/failure | – | – | – | – |
| | FBF | Success | 46 | 100 | 32 | 69.6 | <0.001 |
| | | Acceptable | – | – | 14 | 30.0 |
| | | Poor/failure | – | – | – | – |
| 12 months (n = 36) | Z250 | Success | 36 | 100 | 7 | 19.4 | <0.001 |
| | | Acceptable | – | – | 29 | 80.6 |
| | | Poor/failure | – | – | – | – |
| | TBF | Success | 36 | 100 | 33 | 91.7 | 0.250 |
| | | Acceptable | – | – | 3 | 8.3 |
| | | Poor/failure | – | – | – | – |
| | FBF | Success | 34 | 94.4 | 11 | 30.6 |
| | | Acceptable | 2 | 5.6 | 25 | 69.4 |
| | | Poor/failure | – | – | – | – |

Abbreviations: FBF, Filtek bulk fill; FDI, Federation Dentaire Internationale; TBF, Tetric EvoCeram bulk fill; USPHS, the United States Public Health Service.

Note: The Wilcoxon test was used for comparison at the different observation times.

*sSuccess: alpha (USPHS), 1 and 2 (FDI); acceptable: bravo (USPHS), 3 (FDI); failure: charlie (USPHS), 4 and 5 (FDI).

suctioning was used to maintain the area dry. Calcium hydroxide–based material was used in deep cavities. After 1 year, four restorations of the TBF group received unacceptable scores for anatomic form and marginal adaptation and two restoration due to secondary caries. The conventional resin composite inserted by an incremental technique exhibited a single failure due to secondary caries. Nevertheless, the resins tested showed similar clinical performance according to the modified USPHS criteria.

Alkurdi and Abboud 37 observed full-body bulk-fill resin composites (Tetric N-Ceram Bulk Fill and Sonic Fill) for 12 months. A total-etch bonding procedure was used without lining or base materials. The overall success rate was 91.3%. Of the five restoration failures, four were restored with Tetric N-Ceram Bulk Fill (two in the marginal discoloration category and two others with persistent hypersensitivity). The success rate was 78.9% for this resin composite. The authors concluded that the single-increment technique provided acceptable clinical results similar to that of conventional resin composite. Çolak et al 38 compared conventional Tetric EvoCeram resin composite with Tetric EvoCeram Bulk Fill in 74 restorations after 12 months. Deep cavities were capped with calcium hydroxide and glass ionomer cement. One restoration performed with the conventional resin failed in the marginal discoloration category. In contrast, the evaluation of 104 class-II restoration over 36 months using the USPHS criteria showed better clinical performance for Tetric EvoCeram Bulk Fill in the marginal adaptation and marginal discoloration categories compared with conventional resin composite Filtek Ultimate, due to the higher number of Bravo ratings. 39

Clinical studies with a longer observation period of resin composite restorations are essential to better understand the material’s performance in the oral cavity and during the function. In a retrospective 22-year follow-up study, Da Rosa Rodolpho et al 28 observed an average AFR of 1.85% for composite resin restorations and good clinical performance of the material in posterior teeth. 39- 41  Van Dijken and Pallesen conducted clinical studies with more extended evaluation periods. 42, 43  Restorations prepared with flowable bulk-fill Surefil Smart Dentin Replacement (SDR) covered with conventional resin composite Ceram X mono were compared with restorations prepared only with Ceram X mono resin composite. In their 5-year follow-up, 43 acceptable clinical results were obtained for the Surefil SDR restorations according to the modified USPHS criteria, with a success rate of 100% for 38 class-I restorations. Sixty-two pairs of class-II restorations received an AFR of 1.4% for Surefil SDR and 2.1% for those restored only with the conventional resin composite (Ceram X mono). In another study with 6 years of follow-up with these restorative
adaptation. In both categories, the percentage of the “acceptable” score was significantly higher for the USPHS criteria. The two systems were equivalent to the other corresponding categories. Thus, the second null hypothesis was rejected, since there was no agreement between all the common categories between both criteria. Differences in the evaluation score parameters could explain these discrepancies. For FDI gloss/luster/roughness and USPHS roughness, the detection of a slightly dull surface (score 2/success—FDI) could also be considered to have a slightly rough surface or to a surface with scratches, but that could be refinished (bravo/acceptable—USPHS). For marginal adaptation, the FDI criteria admit as success (score 2) small gaps (<150 μm) and small marginal fractures removable by polishing. For USPHS, any explorer catch was considered acceptable (bravo), even if there is no visible evidence of a gap that the explorer could penetrate.

The restorations’ clinical success depends on factors such as caries risk of the patient, quality of the material, extent, and location of the restoration. Other variables, such as parafunctional habits (bruxism), socioeconomic situation, and operator experience, also interfere directly with the restorations’ longevity against the challenges to which they are exposed in the oral cavity. Many clinical trials exclude high-risk patients from the study population, especially patients with high caries and bruxism. However, these challenges are encountered by dentists in daily practice and

Table 8 Comparison of the results for marginal adaptation obtained with the modified USPHS and FDI criteria

| Evaluation | Group | Score* | Criteria | p-Value |
|------------|-------|--------|----------|---------|
|            |       |        | USPHS | FDI |      |      |
|            |       |        | n | % | n | % |       |
| Baseline (n = 46) | Z250 | Success | 38 | 82.6 | 39 | 84.8 | 0.317 |
|            |       | Acceptable | 8 | 17.4 | 7 | 15.2 |       |
|            |       | Poor/failure | – | – | – | – |       |
|            | TBF  | Success | 40 | 87.0 | 41 | 89.1 | 0.317 |
|            |       | Acceptable | 6 | 13.0 | 5 | 10.9 |       |
|            |       | Poor/failure | – | – | – | – |       |
|            | FBF  | Success | 39 | 84.8 | 39 | 84.8 | 1.0 |
|            |       | Acceptable | 7 | 15.2 | 7 | 15.2 |       |
|            |       | Poor/failure | – | – | – | – |       |
| 12 months (n = 36) | Z250 | Success | 36 | 100 | 9 | 25.0 | <0.001 |
|            |       | Acceptable | – | – | 27 | 75.0 |       |
|            |       | Poor/failure | – | – | – | – |       |
|            | TBF  | Success | 34 | 94.4 | 16 | 44.4 | <0.001 |
|            |       | Acceptable | 1 | 2.8 | 19 | 52.8 |       |
|            |       | Poor/failure | 1 | 2.8 | 1 | 2.8 |       |
|            | FBF  | Success | 36 | 100 | 16 | 44.4 | <0.001 |
|            |       | Acceptable | – | – | 20 | 55.6 |       |
|            |       | Poor/failure | – | – | – | – |       |

Abbreviations: FBF, Filtek bulk fill; FDI, Federation Dentaire Internationale; TBF, Tetric EvoCeram bulk fill; USPHS, the United States Public Health Service.

*Success: alpha (USPHS), 1 and 2 (FDI); acceptable: bravo (USPHS), 3 (FDI); failure: charlie (USPHS), 4 and 5 (FDI).
require a scientific background to guide them in decision making on the adoption or rejection of new materials and techniques.\textsuperscript{35}

\textbf{Conclusion}

The bulk-fill resin composites showed satisfactory clinical performance compared with conventional resin composite after 12 months. The percentage of the acceptable scores was significantly higher for the USPHS criteria, due to discrepancies in the score description for each criterion. Despite the positive results, further clinical studies are necessary to analyze the long-term performance of these resin composites, with longer than 12 months of follow-up time.

\textbf{Conflict of Interest}

None declared.

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