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 Durão[1] Ana Karina Maciel de Andrade[2] Maria do Carmo Moreira da Silva Santos[1] Marcos Antônio Japiassú Resende Montes[1] Gabriela Queiroz de Melo Monteiro[1]

[1]School of Dentistry, University of Pernambuco, Avenida Agamenon Magalhães, S/N - Santo Amaro - Recife - PE, Brazil
[2]Department 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).

Eur J Dent 2021;15:179–192

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.

Keywords
- dental restoration failure
- permanent dental restoration
- direct restoration
- posterior teeth
- resin composite
- bulk-fill resin composite
- randomized controlled trial

published online
November 26, 2020

DOI https://doi.org/10.1055/s-0040-1718639
ISSN 1305-7456.

Thieme Medical and Scientific Publishers Pvt. Ltd., A-12, 2nd Floor, Sector 2, Noida-201301 UP, India

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.[2,4,5] 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,[9-11] 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 phosphine 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.

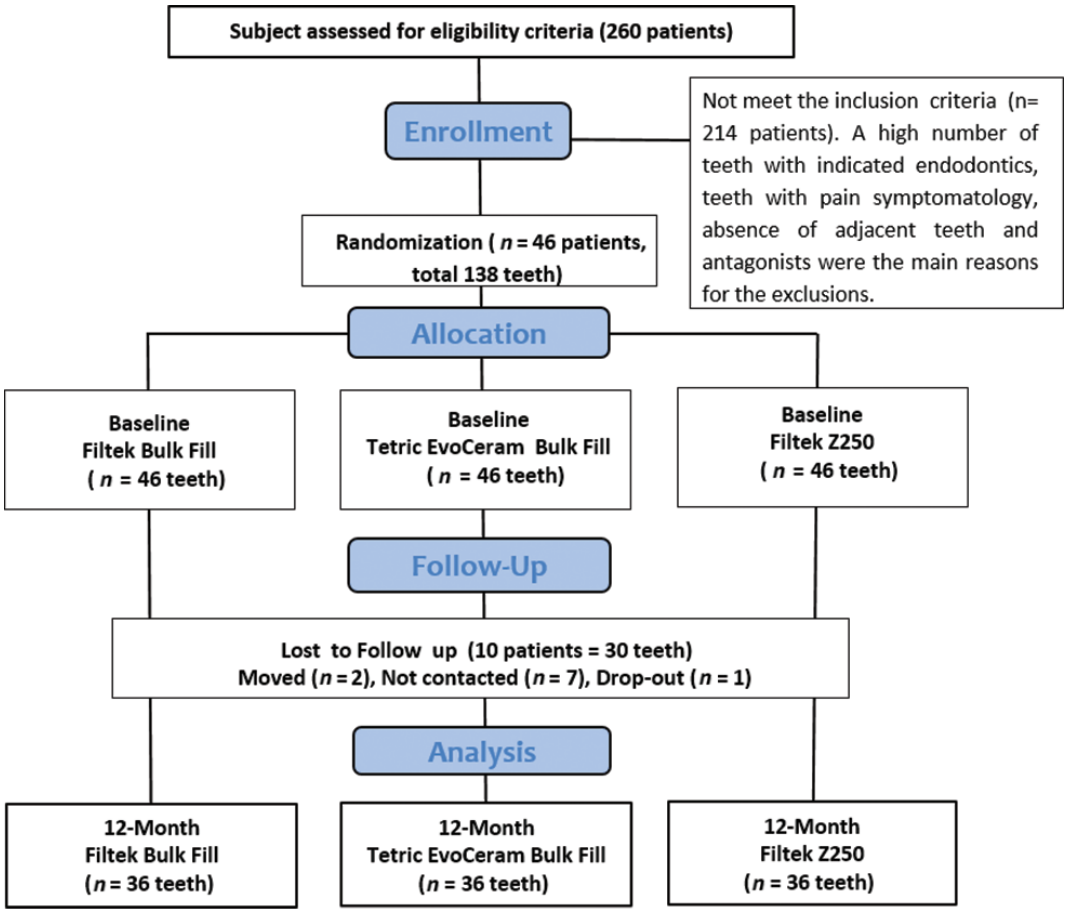

Fig. 1 Flow diagram of the study (Consolidated Standards of Reporting Trials [CONSORT] 2010).

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 dimeth-acrylate, 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 polyethyleneglycoldiether-dimethacrylate; Bis–GMA, bisphenol A-diglycidylether dimethacrylate; DDDMA, 1,12-dodecanediol dimethacrylate; HEMA, 2-hydroxyethyl methacrylate; UDMA, urethanedimethacrylate.
[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/cm^2 (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 $K = 0.84$).[34] The restorations were clinically assessed according to the modified USPHS criteria (►**Table 2**) and FDI criteria (►**Table 3**) considering esthetic, functional, and biological features.[35]

Table 2 Modified United States Public Health Service Evaluation (USPHS) criteria

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

Table 3 FDI criteria used to assess the esthetic, functional and biological properties of restorations

Score	Esthetic properties				Functional properties					Biological properties			
	1	2	3	4	5	6	7	8	10	11	12	13	15
	Surface gloss/ luster and roughness	Staining: (a) surface and (b) margin	Color match and translucency	Anatomic form	Fracture of restorative material and retention	Marginal adaptation	Occlusal contour and wear	Approximal anatomical form: (a) contact point and (b) contour	Patient's view	Postoperative sensitivity and tooth vitality	Recurrent caries	Tooth integrity	Adjacent mucosa
1. Clinically excellent	1.1 Comparable to enamel	2.1 No marginal or surface staining	3.1. Color and translucency of the restoration have a clinically excellent match with the surrounding enamel	4.1 Form is ideal	5.1. No fractures/cracks	6.1. Harmonious outline, no gaps, no white or discolored lines	7.1 Physiological wear equivalent to enamel. Wear corresponding to 80–120% of enamel	8.1. Normal contact point (floss or 25 µm metal blade can pass)	10.1 Entirely satisfied with esthetics and function	11.1. No hypersensitivity, normal vitality	12.1 No secondary or primary caries	13.1. Complete integrity	15.1. Healthy mucosa adjacent to restoration
2. Clinically good	1.2 Slightly dull, not noticeable from speaking distance	2.2. Minor surface or marginal staining, easily removable by polishing	3.2. Minor deviations in shade and translucency between tooth and restoration are apparent	4.2. Form deviates only slightly from norm	5.2. Small hairline crack	6.2. Marginal gap (<150 µm), white lines. Small marginal fracture removable by polishing	7.2 Normal wear only slightly different from that of enamel. 50–80% or 120–150% of wear compared with enamel	8.2. Contact slightly too strong but acceptable (floss or 25 µm metal blade can only pass with pressure)	10.2 Satisfied: (a) esthetic and (b) function	11.2. Minor hypersensitivity for a limited period of time, normal vitality	12.2. Small and localized. Demineralization area	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.)
3. Clinically satisfactory	1.3 Dull surface but acceptable if covered with a film of saliva	2.3. Moderate staining not noticeable from a speaking distance, also present on other teeth. Not esthetically unacceptable	3.3. Distinct deviation but acceptable. Does not affect esthetics	4.3. Form deviates from the norm but is esthetically acceptable	5.3. Two or more or larger hairline cracks and/or chipping (not affecting the marginal integrity or approximal contact)	6.3. Gap <250 µm not removable. Several small marginal fractures. Major irregularities, ditching or flashes, steps	7.3 Different wear rate than enamel but within the biological variation. Corresponding < 50% or 150–300% of enamel	8.3. Somewhat weak contact, no indication of damage to tooth, gingival or periodontal structures; 50-µm metal blade can pass. Visibly deficient contour	10.3 Minor criticism but no adverse clinical effects. Esthetic short comings	11.3. Moderate hypersensitivity. delayed/mild sensitivity; no subjective complaints, no treatment needed	12.3. Larger areas of demineralization. Only preventive measures necessary	13.3. Marginal enamel defect and crack <250 µm. Enamel chipping. Multiple cracks	15.3. Mucosal alteration but no suspicion of causal relationship with filling material

(*Continued*)

Table 3 (*Continued*)

Score	Esthetic properties				Functional properties					Biological properties			
	1	2	3	4	5	6	7	8	10	11	12	13	15
	Surface gloss/ luster and roughness	Staining: (a) surface and (b) margin	Color match and translucency	Anatomic form	Fracture of restora-tive material and retention	Marginal adaptation	Occlusal contour and wear	Approximal anatomical form: (a) contact point and (b) contour	Patient's view	Postoperative sensitivity and tooth vitality	Recurrent caries	Tooth integrity	Adjacent mucosa
4. clinically unsatisfac-tory (but repairable)	1.4 Rough sur-face, cannot be masked by saliva film, simple pol-ishing is not sufficient	2.4. Unacceptable surface stain-ing 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 unaccept-able	5.4. Material Chip fractures which damage marginal quality and/ or approximal contacts. Bulk fractures with partial loss of (less than half of the resto-ration)	6.4. Gap > 250 µm, may result in exposure of dentine or base. Severe ditching or marginal fractures. Larger irreg-ularities or steps (repair necessary)	7.4 Wear considera-bly exceeds normal enamel wear; or occlusal contact points are lost. >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 improve-ment: (a) esthetic and (b) function	11.4. Intense delayed with minor subjective symptoms. No clinical detect-able sensitivity intervention necessary, but not replace-ment	12.4. Caries with cavitation and suspected under-mining 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 (replace-ment necessary)	1.5 Very rough, unacceptable plaque reten-tive surface	2.5. Severe surface staining and/ or subsurface staining, generalized or localized, not accessible for interven-tion. Deep marginal staining, not accessible for intervention	3.5. Color match and/or translucency are clinically unsatis-factory, replacement necessary	4.5. Anatomic form is unsatis-factory and/or lost	5.5. (Partial or complete) loss of the restoration or multiple fractures	6.5. Restoration (total or par-tial) 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/or clear damage due to food impaction and/or pain gingivitis. Requires replacement	10.5 Completely dissatisfied and/or adverse effects, including pain	11.5. Intense, acute pulpitis or nonvital tooth. Endodontic treatment is necessary and restoration has to be replaced	12.5. Deep secondary caries or exposed dentine that is not acces-sible 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, reexamining 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).[26]

The Eq. $(\text{-year})^z = (1\text{-}x)$ 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[a]	
	Z250		TBF		FBF					
	Baseline	12 mo	Baseline	12 mo	Baseline	12 mo	Baseline	12 mo	Baseline	12 mo
Tooth										
Upper premolar	11	10	9	7	12	9	32	26	$p^1 = 0.987$	$p^{(1)} = 0.600$
Lower premolar	4	3	5	5	5	5	14	13		
Upper molar	23	17	22	16	21	17	66	50		
Lower molar	8	6	10	8	8	5	26	19		
Cavity classification										
Class I	36	29	34	27	31	25	101	81	$p^2 = 0.736$	$p^{(2)} = 0.553$
Class II	10	7	12	9	15	11	37	27		
Cavity width										
<1/3	24	13	19	8	21	11	64	32	$p^2 = 0.575$	$p^{(2)} = 0.430$
>1/3	22	23	27	28	25	25	74	76		
Cavity depth										
Medium	23	17	13	7	12	9	48	33	$p^2 = 0.029$	$p^{(2)} = 0.028$
Deep	23	19	33	29	34	26	90	74		
Pulp protection										
Bonding agent	30	22	23	17	27	22	80	62	$p^2 = 0.333$	$p^{(2)} = 0.309$
Glass ionomer cement	16	14	23	19	19	14	58	46		

Abbreviations: FBF, Filtek bulk fill; TBF, Tetric EvoCeram bulk fill.
[a](1)Fischer's exact test; (2)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		TBF		FBF		Z250		TBF		FBF	
		n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Marginal adaptation	A	39[a]	84.8	41[a]	89.1	39[a]	84.8	9[b]	25	16[c]	44.4	16[c]	44.4
	B	7[a]	15.2	5[a]	10.9	7[a]	15.2	27[b]	75	19[c]	52.8	20[c]	55.6
	C	–	–	–	–	–	–	–	–	1	2.8	–	–
Color match	A	46	100	46	100	46	100	36	100	36	100	36	100
	B	–	–	–	–	–	–	–	–	–	–	–	–
	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[A,a]	63	44[B]	95.7	32[A,a]	69.6	7[A,b]	19.4	33[B]	91.7	11[Ab]	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
	C	2	4.3	–	–	–	–	–	–	–	–	–	–
Recurrent caries	A	46	100	46	100	46	100	36	100	36	100	36	100
	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).

Table 6 Results of clinical evaluation according to the FDI criteria

Category		Score	Baseline (*n* = 46)						12 months (*n* = 36)					
			Z250		TBF		FBF		Z250		TBF		FBF	
			n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Esthetic properties	Surface gloss/ luster and roughness	1	35	76.1^{Aa}	46	100^{B}	43	93.5^{B}	16	(44.4)^{Ab}	34	94.4^{B}	26	72.2^{C}
		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^{B}	46	100^{A}	36	(100)^{A}	17	47.2^{B}	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^{b}	17	47.2^{b}	14	38.9^{b}
		2	8	17.4	6	13	7	15.2	26	72.2	17	47.2	20	55.6
		3	–	–	–	–	–	–	–	–	1	2.8	2	5.6
		4	–	–	–	–	–	–	–	–	1	2.8	–	–
		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^{b}	18	50^{b}	16	44.4^{b}
		2	–	–	–	–	1	2.2	19	52.8	18	50	18	50
		3	–	–	–	–	–	–	–	–	–	–	2	5.6
		4	–	–	–	–	–	–	–	–	–	–	–	–
		5	–	–	–	–	–	–	–	–	–	–	–	–

(*Continued*)

Table 6 (*Continued*)

Category		Score	Baseline (n = 46)						12 months (n = 36)					
			Z250		TBF		FBF		Z250		TBF		FBF	
			n	%	*n*	%	*n*	%	*n*	%	*n*	%	*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.[23,38,39] However, the studied populations' DMF index was not mentioned, and poor oral hygiene was considered an exclusion criterion.[23,38] Bayraktar et al. (2017)[23] 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

Table 7 Comparison of the results for surface roughness (modified USPHS) and surface gloss/luster and roughness (FDI)

Evaluation	Group	Score[a]	Criteria				*p*-Value
			FDI		USPHS		
			n	%	*n*	%	
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.
[a]Success: 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

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

Evaluation	Group	Score[a]	Criteria				*p*-Value
			FDI		USPHS		
			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.
Note: The Wilcoxon test was used for comparison at the different observation times.
[a]Success: alpha (USPHS), 1 and 2 (FDI); acceptable: bravo (USPHS), 3 (FDI); failure: charlie (USPHS), 4 and 5 (FDI).

materials, [38]pairs of class-II, and 15 pairs of class-I restorations were performed in 38 adults.[34,43] The authors observed six failed class-II molar restorations, three in each group, and an AFR of 1.0% for both groups. It should be highlighted that the evaluation of the flowable bulk-fill resin composites is made through an indirect analysis, by analyzing the conventional resin composite that covers the flowable layer. Direct evaluation is only performed when a full-body bulk-fill resin is used.

The randomized clinical trials that evaluated full-body bulk-fill resin composites have used the USPHS criteria.[22] According to Göstemeyer et al,[44] the USPHS criteria have shown limited sensitivity, and their categories may not fully reflect the clinical success of restorations. Using other criteria in addition to the USPHS system, clinical trials tend to detect significantly higher failure rates, more than four times those obtained with the USPHS criteria. The FDI criteria is an alternative that could be further simplified by joining scores 1 to 3, corresponding to clinically good/satisfactory/acceptable.

In the present study, the clinical assessments used the USPHS and FDI criteria independently for evaluation. The FDI criteria were used considering the trend toward its use for evaluating restorations, while the USPHS allowed further comparison with previous studies. When comparing the corresponding categories within the USPHS and FDI criteria, significant differences were observed for roughness (USPHS)/surface gloss/luster and roughness (FDI) and marginal 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.[2] 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

require a scientific background to guide them in decision making on the adoption or rejection of new materials and techniques.[45]

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.

Conflict of Interest
None declared.

References

1 Li X, Pongprueksa P, Van Meerbeek B, De Munck J. Curing profile of bulk-fill resin-based composites. J Dent 2015;43(6):664–672
2 Van Ende A, De Munck J, Lise DP, Van Meerbeek B. Bulk-fill composites: a review of the current literature. J Adhes Dent 2017;19(2):95–109
3 Chesterman J, Jowett A, Gallacher A, Nixon P. Bulk-fill resin-based composite restorative materials: a review. Br Dent J 2017;222(5):337–344
4 Ilie N, Bucuta S, Draenert M. Bulk-fill resin-based composites: an in vitro assessment of their mechanical performance. Oper Dent 2013;38(6):618–625
5 Van Ende A, De Munck J, Van Landuyt KL, Poitevin A, Peumans M, Van Meerbeek B. Bulk-filling of high C-factor posterior cavities: effect on adhesion to cavity-bottom dentin. Dent Mater 2013;29(3):269–277
6 Alshali RZ, Silikas N, Satterthwaite JD. Degree of conversion of bulk-fill compared to conventional resin-composites at two time intervals. Dent Mater 2013;29(9):e213–e217
7 Didem A, Gözde Y, Nurhan Ö. Comparative mechanical properties of bulk-fill resins. Open J Comp Mat 2014;4: 117–121
8 Miletic V, Pongprueksa P, De Munck J, Brooks NR, Van Meerbeek B. Curing characteristics of flowable and sculptable bulk-fill composites. Clin Oral Investig 2017;21(4): 1201–1212
9 Jang JH, Park SH, Hwang IN. Polymerization shrinkage and depth of cure of bulk-fill resin composites and highly filled flowable resin. Oper Dent 2015;40(2):172–180
10 Fronza BM, Rueggeberg FA, Braga RR, et al. Monomer conversion, microhardness, internal marginal adaptation, and shrinkage stress of bulk-fill resin composites. Dent Mater 2015;31(12):1542–1551
11 Rocha MG, de Oliveira D, Correa IC, et al. Light-emitting diode beam profile and spectral output influence on the degree of conversion of bulk fill composites. Oper Dent 2017;42(4): 418–427
12 Moszner N, Fischer UK, Ganster B, Liska R, Rheinberger V. Benzoyl germanium derivatives as novel visible light photoinitiators for dental materials. Dent Mater 2008;24(7): 901–907
13 3M ESPE. Filtek Bulk Fill, Technical product profile. Available at: https://multimedia.3m.com/mws/media/792321O/filtek-bulk-fill-flowable-restorative-technical-product-.profile.pdf. Accessed October 16, 2018
14 Flury S, Peutzfeldt A, Lussi A. Influence of increment thickness on microhardness and dentin bond strength of bulk fill resin composites. Dent Mater 2014;30(10):1104–1112
15 Bucuta S, Ilie N. Light transmittance and micro-mechanical properties of bulk fill vs. conventional resin based composites. Clin Oral Investig 2014;18(8):1991–2000
16 Ivoclar Vivadent. Scientific Documentation. Available at: http://www.ivoclarvivadent.com/en/download-center/scientific-documentations/#T. Accessed May 21, 2016
17 Benetti AR, Havndrup-Pedersen C, Honoré D, Pedersen MK, Pallesen U. Bulk-fill resin composites: polymerization contraction, depth of cure, and gap formation. Oper Dent 2015;40(2):190–200
18 Czasch P, Ilie N. In vitro comparison of mechanical properties and degree of cure of bulk fill composites. Clin Oral Investig 2013;17(1):227–235
19 Al-Harbi F, Kaisarly D, Bader D. El Gezawi M. Marginal integrity of bulk versus incremental fill class II composite restorations. Oper Dent 2016;41(2):146–156
20 Algamaiah H, Sampaio CS, Rigo LC, et al. Microcomputed tomography evaluation of volumetric shrinkage of bulk-fill composites in class II cavities. J Esthet Restor Dent 2017;29(2):118–127
21 Fonseca ASQS, Labruna Moreira AD, de Albuquerque PP, de Menezes LR, Pfeifer CS, Schneider LFJ. Effect of monomer type on the CC degree of conversion, water sorption and solubility, and color stability of model dental composites. Dent Mater 2017;33(4):394–401
22 Veloso SRM, Lemos CAA, de Moraes SLD, do Egito Vasconcelos BC, Pellizzer EP, de Melo Monteiro GQ. Clinical performance of bulk-fill and conventional resin composite restorations in posterior teeth: a systematic review and meta-analysis. Clin Oral Investig 2019;23(1):221–233
23 Bayraktar Y, Ercan E, Hamidi MM, Çolak H. One-year clinical evaluation of different types of bulk-fill composites. J Investig Clin Dent 2017;8(2):1–9
24 Ryge G. Clinical criteria. Int Dent J 1980;30(4):347–358
25 Turgut MD, Tekçiçek M, Olmez S. Clinical evaluation of a polyacid-modified resin composite under different conditioning methods in primary teeth. Oper Dent 2004;29(5): 515–523
26 Hickel R, Roulet JF, Bayne S, et al. Recommendations for conducting controlled clinical studies of dental restorative materials. Clin Oral Investig 2007;11(1):5–33
27 Hickel R, Peschke A, Tyas M, et al. FDI World Dental Federation - clinical criteria for the evaluation of direct and indirect restorations. Update and clinical examples. J Adhes Dent 2010;12(4):259–272
28 Da Rosa Rodolpho PA, Donassollo TA, Cenci MS, et al. 22-Year clinical evaluation of the performance of two posterior composites with different filler characteristics. Dent Mater 2011;27(10):955–963
29 Häfer M, Jentsch H, Haak R, Schneider H. A three-year clinical evaluation of a one-step self-etch and a two-step etch-and-rinse adhesive in non-carious cervical lesions. J Dent 2015;43(3):350–361
30 Coelho-De-Souza FH, Camargo JC, Beskow T, Balestrin MD, Klein-Júnior CA, Demarco FF. A randomized double-blind clinical trial of posterior composite restorations with or without bevel: 1-year follow-up. J Appl Oral Sci 2012;20(2): 174–179
31 Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c332
32 de Andrade AK, Duarte RM, Medeiros e Silva FD, et al. 30-Month randomised clinical trial to evaluate the clinical performance of a nanofill and a nanohybrid composite. J Dent 2011;39(1): 8–15

33 de Andrade AK, Duarte RM, Guedes Lima SJ, Passos TA, Lima KC, Montes MA. Nanohybrid versus nanofill composite in class I cavities: margin analysis after 12 months. Microsc Res Tech 2011;74(1):23–27
34 van Dijken JW, Pallesen U. A randomized 10-year prospective follow-up of Class II nanohybrid and conventional hybrid resin composite restorations. J Adhes Dent 2014;16(6):585–592
35 Cvar JF, Ryge G. Reprint of criteria for the clinical evaluation of dental restorative materials. 1971. Clin Oral Investig 2005;9(4):215–232
36 Opdam NJ, van de Sande FH, Bronkhorst E, et al. Longevity of posterior composite restorations: a systematic review and meta-analysis. J Dent Res 2014;93(10):943–949
37 Alkurdi RM, Abboud SA. Clinical evaluation of class II composite: Resin restorations placed by two different bulk-fill techniques. J Oral Fac Sci 2016;8:34–39
38 Çolak H, Tokay U, Uzgur R, Hamidi MM, Ercan E. A prospective, randomized, double-blind clinical trial of one nano-hybrid and one high-viscosity bulk-fill composite restorative systems in class II cavities: 12 months results. Niger J Clin Pract 2017;20(7):822–831
39 Yazici AR, Antonson SA, Kutuk ZB, Ergin E. Thirty-six-month clinical comparison of bulk fill and nanofill composite restorations. Oper Dent 2017;42(5):478–485
40 Opdam NJ, Bronkhorst EM, Cenci MS, Huysmans MC, Wilson NH. Age of failed restorations: a deceptive longevity parameter. J Dent 2011;39(3):225–230
41 van Dijken JWV, Pallesen U. Clinical performance of a hybrid resin composite with and without an intermediate layer of flowable resin composite: a 7-year evaluation. Dent Mater 2011;27(2):150–156
42 van Dijken JWV, Pallesen U. Posterior bulk-filled resin composite restorations: a 5-year randomized controlled clinical study. J Dent 2016;51:29–35
43 van Dijken JWV, Pallesen U. Bulk-filled posterior resin restorations based on stress-decreasing resin technology: a randomized, controlled 6-year evaluation. Eur J Oral Sci 2017;125(4):303–309
44 Göstemeyer G, Blunck U, Paris S, Schwendicke F. Design and validity of randomized controlled dental restorative trials. Materials (Basel) 2016;9(5):372
45 Opdam NJM, Collares K, Hickel R, et al. Clinical studies in restorative dentistry: New directions and new demands. Dent Mater 2018;34(1):1–12

