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Randomized 36-month follow-up of posterior bulk-filled resin composite restorations

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ABSTRACT

Objective: The aim of this double blind, randomized controlled trial was to evaluate the 36-month clinical performance of the layering technique (incremental [IF] vs. bulk-fill [BF]) in posterior composite resin restorations bonded with self-etch (SE) and etch-and-rinse (ER) strategies.

Methods: Posterior dental cavities of 72 participants (n = 236), with a cavity depth of at least 3 mm, were randomly divided into four groups. The restorations were bonded using either the Tetric N-Bond ER or Tetric N-Bond SE. The composite resin Tetric N-Ceram Bulk-Fill was placed either IF or using BF. Two experienced and calibrated examiners evaluated the restorations using FDI criteria in the baseline and after 12, 24 and 36-month. The statistical analyses were performed using the Wilcoxon Signed rank test ($\alpha = 0.05$)

Results: After 36-month, 14, 21 and 33 restorations showed minor fractures, marginal desadaptation and color mismatch, respectively ($p > 0.05$). Thirty-three restorations showed some marginal discoloration after 36-month with significant difference between ER (3 for ER-IF; 3 for ER-BF) and SE (14 for SE-IF; 12 for SE-BF; $p < 0.05$).

Conclusion: The BF technique showed excellent clinical performance, which was comparable during the 36-month of clinical evaluation with the 2-mm IF and it was not affected by the adhesive strategy. However, using the ER strategy reduces the risk of some marginal discoloration, irrespectively of the filling technique.

Clinical relevance: The bulk-fill material showed excellent clinical behavior when compared to its use in an incremental filling technique, mainly when associated to etch-and-rinse adhesive material after 3 years of clinical evaluation.

1. Introduction

It is estimated that more than 290 million restorations are placed each year worldwide [1], and among the restorative materials used for this purpose direct resin composite is frequently used. In posterior teeth, direct resin composite restorations have surpassed the placement of amalgam over the last 15 years in most countries [2], due to the increased durability of the direct composite resin restorations [3,4] and to restrictions on the use of mercury-based compounds, such as amalgam, in more than 140 signatory countries of the Minamata Convention on Mercury [5].

Direct resin composite restorations are usually built-up in increments, which are cured separately, in the so-called incremental filling. This protocol has long been accepted as a standard technique mainly to guarantee adequate depth of cure and reduced polymerization shrinkage stress [6–10]. However, this filling protocol is time-consuming and, therefore, increases the costs associated with the placement of a posterior restoration [11].

Keeping this drawback in mind, manufacturers have launched onto the market bulk-fill resin composites to be placed in increments up to 4–5 mm. This class of material can be delivered in a flowable viscosity, and, as such, requires an occlusal increment of composite resin with regular viscosity or a regular viscosity without the need for a final cover layer of other material [12,13]. Bulk-fill materials have the advantage of reducing chair-time, which is in line with the clinician's desire for simplified and fast procedures [14,15], and the number of steps for

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cavity restorations, which makes this procedure less prone to technical errors, such as void incorporation and contamination between composite resin increments [13].

In vitro studies showed promising findings when bulk-fill materials were compared to conventional resin composites [12,13,16], but we still need to rely on randomized controlled trials (RCTs) to ensure the equivalence or even superiority of bulk-fill materials to traditional incremental composites. Published RCTs conducted with flowable bulk-fill materials have already demonstrated adequate clinical performance in 2–6 years of follow-up [17–24], but little information about the performance of regular viscosity bulk-fill composites in follow-ups longer than 2 years is available, as well as pointed by a recent published review of bulk-fill materials in posterior restorations [25].

For bonding, studies either employ etch-and-rinse [17–19] or self-etch strategies [20–24]. While etch-and-rinse adhesives use phosphoric acid for substrate conditioning before adhesive application, self-etch adhesives, in theory, demineralize and infiltrate the substrate simultaneously during the application of acidic monomers [26,27]. To the extent of the author's knowledge, only Costa et al. [28] evaluated both adhesive strategies for incremental and bulk-filling composite resins, but they focused mainly on the immediate postoperative sensitivity.

Therefore, the objective of this double–blind RCT was to compare some clinical parameters of posterior restorations placed in bulk or with incremental fillings and bonded either with a self-etch or etch-and-rinse bonding system. The null hypotheses tested were that the layering technique and the adhesive strategy do not influence any clinical parameter of the performance of posterior composite resin restorations.

2. Materials and methods

2.1. Ethics approval and protocol registration

The Ethics Committee of the State University of Ponta Grossa (UEPG; Paraná, Brazil) reviewed and approved this study under protocol number 109.846. This study is reported according to the CONSORT statement [29]. This clinical trial was registered in the REBEC (www.ensaiosclinicos.gov.br) clinical registry under protocol number RBR-5kb5kz. All participants were informed about the nature and objectives of the study.

2.2. Trial design, settings and location of data collection

This was a double–blind (evaluator and patient), split–mouth randomized controlled trial with four study groups with an equal allocation ratio. The study was conducted in a university setting at the clinics of the School of Dentistry from the State University of Ponta Grossa, Paraná, Brazil. Restorations were placed in May 2014 through May 2015 by previous calibrated residents.

2.2.1. Participant's recruitment

We recruited eligible patients in the order they appeared for the screening session in the dental clinics of the local university. The recruitment was performed by two calibrated dental residents.

2.2.2. Eligibility criteria

Participants were at least 18 years old, with at least 12 posterior teeth in occlusion and were not receiving orthodontic treatment. Each patient had at least two or four posterior teeth in need of restorative treatment, due to carious lesions, defective restorations with secondary caries, fractures, or the patient's request for amalgam replacement for esthetic reasons. Pregnant or breastfeeding women; participants with known allergies to resin-based materials or any other material used in this study; and those taking anti-inflammatory, analgesic, or psychotropic drugs were not included in this study.

2.3. Characteristics of the teeth/cavities to be included

Each tooth to be restored was in occlusion with its natural antagonist and adjacent teeth. Teeth were periodontally healthy and vital, responding positively with a short and transient pain response to a sensitivity test with cold [Roeko-Endo-Frost, Coltène/Whaledent, Langenau, Germany] applied for a maximum of 10 s.

The dental cavities were at least 3-mm deep. A bitewing radiograph of each tooth was taken using an X-ray device (Timex 70 E, Gnatus, Ribeirão Preto, SP, Brazil). The operators measured the height and depth of the proximal and occlusal cavity boxes with a periodontal probe (#6 Satin Steel Handle; mm, Hu-Friedy, Chicago, IL, USA).

2.4. Sample size calculation

In the preliminary report of the present study, we considered the risk of postoperative sensitivity for the sample size calculation [28]. However, for this study report we also used the annual failure rate (fracture) of the direct posterior restorations as a parameter for the sample size calculation. Earlier literature review reported that the annual failure rate (fracture) in posterior teeth was approximately 3.2–3.5% [3,30,31]. Considering that this decline follows a linear trend, the annual failure rate in posterior teeth will be approximately 20% after 6 years of clinical service. With an α of 0.05, a power of 80%, and a two-sided test, the minimal sample size was 59 restorations in each group in order to detect a difference of 15% among the test groups [32]. The sample size calculation was performed using the website www.sealedenvelope.com, freely available online.

2.5. Randomization and allocation concealment mechanism

We performed two different randomization schemes: one for the subjects with four teeth and another scheme for the subjects with two available teeth for restoration. For the subjects with four teeth, the randomization was done on an intra-individual basis so that each subject ended up with four restorations, each one resulting from one of all possible combinations of the filling techniques (incremental filling [IF] or bulk-filling [BF]) and adhesive strategies (etch-and-rinse [ER] or self-etch [SE]).

In the patients with two teeth, two different randomization lists were performed with block sizes of two and four to guarantee an equal number of restorations in the groups and prevent disclosure of the allocation concealment. The first randomization list defined the type of adhesive strategy used in that patient. The second randomization list defined the order of the composite resin placement.

These randomization schemes were also performed using the website www.sealedenvelope.com. A researcher not involved in any of the experimental phases performed this procedure. The randomization lists were numbered consecutively and individually placed in opaque and sealed envelopes. These envelopes were opened the day of the restorative intervention to prevent disclosure of the randomization scheme.

In all cases, the tooth with the highest tooth number received the treatment described first, while the tooth with the next number in sequence received the treatment mentioned second, with placement continuing in a similar manner until the fourth tooth (for the patients with four teeth). All restorations in the same subject (2 or 4) were always placed in different arches.

2.6. Interventions: restorative treatment

For each restoration, the tooth type (molar/premolar) and cavity type (number of restored surfaces) were recorded. Four operators with five or more years of clinical experience conducted all restorative procedures. The operators were previously calibrated by one experienced professor, who was a specialist in restorative dentistry and had

Table 1
Application mode of each material used in the study.

Material (manufacturer) batch number	Composition	Application mode
Total N-Etch (Ivoclar Vivadent) N05612	Phosphoric acid (37%), thickness agent and color pigments	Apply phosphoric acid on the prepared enamel and then flow the etchant onto the prepared dentin. The etchant was left to react on the enamel for 15 to 30 seconds, and on the dentin for 10 to 15 seconds. After that, the phosphoric acid was removed with a vigorous water spray for at least 5 seconds. Excess moisture was removed with air gun leaving the dentin surface with a slightly glossy wet appearance (wet- bonding).
Tetric N-Bond (Ivoclar Vivadent) N40889	Bis-GMA, urethane dimethacrylate, dimethacrylate, hydroxyethyl methacrylate, phosphonic acid acrylate, nanofillers (SiO_2), ethanol, initiators and stabilizers	After acid-etching, apply a thick layer of adhesive on the enamel and dentin surfaces, using a microbrush. Brush the material gently into the dentin for 10 seconds. Remove excess material and the solvent by a gentle stream of air so that the adhesive completely covers the enamel and dentin without pooling. Light-cure adhesive for 10 s (light intensity 1200 mW/cm^2). A shiny tooth surface prior to the application of the composite shows that all surfaces are completely covered.
Tetric N-Bond Self-Etch (Ivoclar Vivadent) R59913	Bis-acrylamide derivatives, Bis- methacrylamide dihydrogenphosphate, amino acid acrylamide, hydroxyalkyl methacrylamide, water, nanofillers (SiO_2), initiators and stabilizers	No applied acid etching. Apply a thick layer of adhesive on the enamel and dentin surfaces, using a microbrush. Brush the material gently into the dentin for 30 seconds. Remove excess material and the solvent by a gentle stream of air so that the adhesive completely covers the enamel and dentin without pooling. Light-cure adhesive for 10 s (light intensity 1200 mW/cm^2). A shiny tooth surface prior to the application of the composite shows that all surfaces are completely covered.
Tetric N-Ceram Bulk Fill (Ivoclar Vivadent) R52450	- Dimethacrylates, Prepolymer, Barium glass filler, Ytterbium trifluoride, Mixed oxide, Additive, Initiators, Stabilisers, Pigments	Apply resin composite in layers of max. 2 mm (incremental technique) or 4 mm (bulk technique) and contour/adapt the material to the cavity walls using a suitable instrument. Light-cure each increment for 20 s (light intensity 1200 mW/cm^2).

more than 20 years of clinical and research experience.

All patients received oral hygiene instructions and a professional tooth cleaning before initiating the restorative intervention. The operators anesthetized the teeth (Mepisv 3%, NovaDFL, Rio de Janeiro, RJ, Brazil) and performed rubber dam isolation. The cavity design was restricted to the elimination of carious tissue or defective restorations using a spherical diamond bur (# 1015–1017; KG Sorensen, Barueri, SP, Brazil) mounted in a high-speed hand-piece with an air-water spray. No liner or base was used. For restoration of class II cavities, a sectional or circumferential matrix system was used in according with the clinical case.

Two adhesive systems were used: Tetric N-Bond (two-step, etch-and–rinse [ER], Ivoclar Vivadent, Schaan, Liechtenstein) and Tetric N-Bond SE (one-step, self-etch [SE], Ivoclar Vivadent). The adhesives were applied following the manufacturer´s instructions (Table 1). The composite resin, Tetric N-Ceram Bulk Fill (also known as Tetric Evo-Ceram Bulk-Fill in other countries, Ivoclar-Vivadent) was placed either according to the incremental [IF] or the bulk-filling [BF] technique (Table 1).

In the groups assigned for increment filling, we restored the dental cavity with 2-mm thick horizontal layers. In the incremental filling technique, a small increment of resin composite was removed from the syringe, shaped into a ball using the right thumb and index finger, and finally placed in the cavity with a resin spatula. During this step, the operators wore clean gloves to avoid contamination between composite resin layers. In the bulk-filling groups, one 4-mm thick horizontal layer was placed at the bottom of the cavity, as previously described for the incremental filling technique. If the cavity had a depth greater than 4 mm, additional material was added to fill the whole cavity. We also recorded the number of layers required for the restoration of each dental cavity.

The operators adapted the composite resin using a flat-faced or elliptical condenser and light-cured each increment for 20 s using a Bluephase light-curing unit (Ivoclar-Vivadent) at 1200 mW/cm^2. The curing tip was placed as close as possible to the occlusal surface of the teeth, as some light attenuation was anticipated due to the cavity depth. The light curing output was checked daily.

Finishing and polishing was also performed immediately after the final light-curing step using fine-grit diamond burs (KG Sorensen), OptraPol NG (one-step silicon polishing set with diamond particles, Ivoclar Vivadent) and Astrobrush (Ivoclar Vivadent) under constant water-cooling. We used abrasive strips (3 M ESPE, St. Paul, MN, USA) on the proximal surfaces, when necessary. We performed occlusal adjustments using fine-grit diamond burs (KG Sorensen) and checked the quality of the interproximal contact and the cervical adaptation by means of dental flossing and bitewing radiographs.

2.7. Blinding

The operator, who implemented the interventions, was not blinded to the procedure. However, participants and the evaluators were kept blind to the group allocation during examinations.

2.8. Clinical evaluation

Two experienced and calibrated examiners, who were not involved in the placement of the restorations, performed the evaluation of the restorations using the World Dental Federation (FDI) criteria [33,34] after one week and after 12, 24, and 36 months of clinical service. The following items were evaluated: fracture, marginal adaptation/discoloration, wear, contact point/food impact, radiographic examination, and patient view. Color stability, translucency, postoperative sensitivity, and recurrence of caries were also evaluated. These variables were ranked according to FDI criteria into the following scores: clinically very good; clinically good; clinically sufficient/satisfactory; clinically unsatisfactory but can be repaired, and clinically poor and needing replacement [33,34].

2.9. Statistical analysis

The statistician was blinded to the type of study groups, and the analyses followed the intention-to-treat protocol [29]. Descriptive statistics were used to describe the distributions of the evaluated criteria. For the primary outcome fractures, we also calculated the risk ratio and

Table 2
World Dental Federation (FDI) criteria used for clinical evaluation [33,34].

	Functional Properties					Esthetic Property		Biological Properties	
	1. Fracture	2. Marginal adaptation	3. Contact point/ food impact	4. Radiographic exam	5. Patient view	6. Marginal staining	7. Colour stability and translucency	8. Postoperative (hyper-) sensitivity	9. Recurrence of caries
1. Clinically very good	Restoration retained, no fractures / cracks	Harmonious outline, no gaps, no discoloration	Normal contact point (floss or 25 μm)	No pathology, harmonious transition between restoration/ tooth	Entirely satisfied	Good color match No difference in shade and translucency	No marginal staining	No hypersensitivity	No secondary or primary caries
2. Clinically good (after correction very good	Small hairline crack	Marginal gap (50 μm) or small marginal fracture removable by polishing	Slightly too strong but no disadvantage	Acceptable cement excess present or positive/negative step present at margin < 150 μm	Satisfied	Minor deviations	Minor marginal staining (under dry conditions) is present	Low hypersensitivity for a limited period of time	Very small and localized demineralization. No operative treatment required
3.Clinically sufficient / satisfactory (minor shortcomings with no adverse effects but not adjustable without damage to the tooth)	Two or + larger hairline cracks and/or chipping (not affecting the marginal integrity)	Gap < 150 μm not removable or several small enamel or dentin fractures	Slightly too weak, no indication of damage to tooth, gingivae or periodontal structures	Marginal gap < 200 μm; negative steps visible with no adverse effects. Noticed or poor radiopacity of filling material	Minor criticism due to aesthetic shortcomings; some lack of chewing comfort or; Time consuming procedure and/or similar; No adverse clinical effects	Clear deviation but acceptable. Does not affect aesthetics: (more opaque; translucent; dark or bright)	Moderate marginal or surface staining not noticeable from a speaking distance	Premature/slightly more intense or delayed/weak sensitivity; no subjective complaints, no treatment needed	Larger areas of demineralization, but only preventive measures necessary (dentine not exposed)
4. Clinically unsatisfactory (repair for prophylactic reasons)	Chipping fractures which damage marginal quality; bulk fractures with or without partial loss (- than ½ of the restoration)	Gap > 250 μm or dentine/base exposed; chip fracture damaging margins or notable enamel or dentine wall fracture	Too weak (100 μm metal blade can pass) and possible damage (food impaction). Repair possible	Marginal gap > 250 μm; cement excess accessible but not removable or; negative steps > 250 μm and repairable	Desire for improvement (reshaping of anatomic form or refurbishing etc.)	Localised – clinically unsatisfactory but can be corrected by repair (too opaque; translucent; dark or bright)	Localized marginal staining is present and not removable by polishing. The aesthetic properties of the dentition are affected.	Premature/ very intense; extremely delayed/weak with subjective complaint or negative Sensitivity Intervention necessary but not replacement	Caries with cavitation (localized and accessible and can be repaired
5. Clinically poor (replacement necessary)	Partial or complete loss of restoration	Filling is loose but in situ	Too weak and/or clear damage (food impaction) and/or pain/ gingivitis)	Secondary caries, large gaps; apical pathology or; Fracture/loss of restoration or tooth	Completely dissatisfied and / oral adverse effects including pain	Unacceptable, replacement necessary	Generalized/ profound marginal discoloration is present. Replacement is necessary	Very intense, acute pulpitis or non vital. Endodontic treatment is necessary	Deep secondary caries or exposed dentine
Acceptable or not acceptable (n, % and reasons	Functional criteria					Aesthetic criteria		Biological criteria	

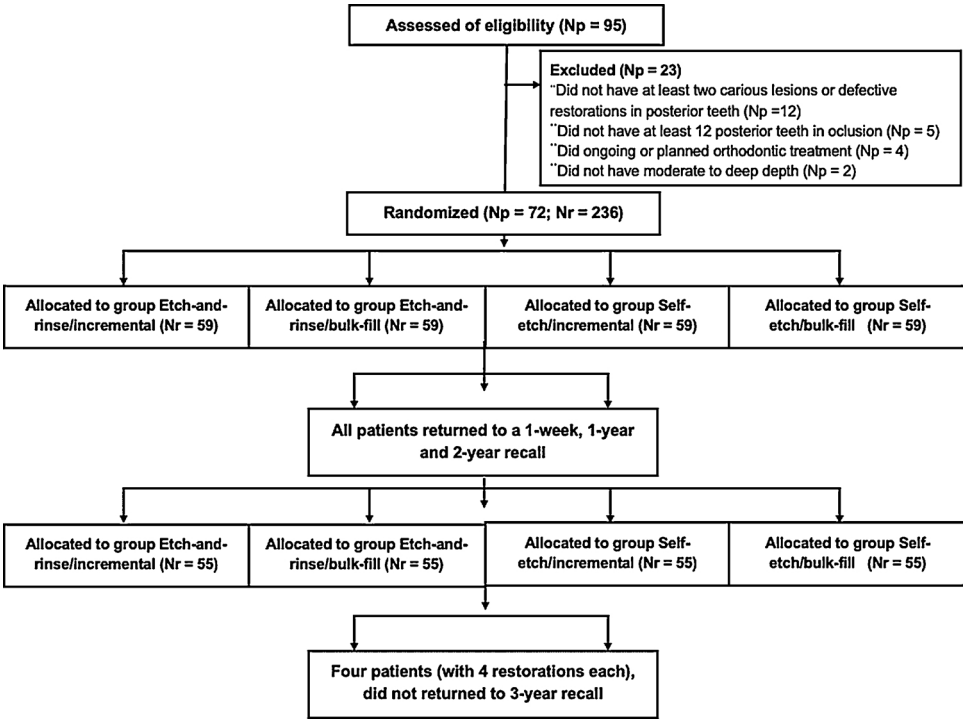

Fig. 1. Participant flow diagram in the different phases of the study design. Abbreviations: Np – number of participants; Nr – number of restorations.

the relative risk of all approaches relative to the most traditional approach (etch-and-rinse incremental filling). The 95% confidence interval was also reported.

Statistical analysis for each individual item was performed for each of the evaluation criteria. Differences in the ratings of groups at each assessment period were compared using the Wilcoxon Signed rank test ($\alpha = 0.05$). Cohen's kappa statistics was used to test the inter-examiner agreement. In all statistical tests, we pre-set the level of significance at 5% (Statistica for Windows 7.0, StatSoft Inc., Tulsa, OK, USA) (Table 2).

3. Results

3.1. Characteristics of the participants and cavities

The experimental protocols were implemented exactly as planned, and no modifications were performed. Fig. 1 depicts the participant flow diagram at the different phases of the study design. The majority of the participants of the study were women (72%). The mean age of the participants was 34 ± 10 years. Two hundred thirty-six restorations were placed, fifty-nine for each group. Baseline features of the cavities were similar among the study groups (Table 3). The distribution of the restorations was similar between Class I (126) and Class II (110) cavities (Table 3). All participants attended the one-week recall, and 12- and 24-month recalls. Four patients did not attend the 36-month recall because they moved to another city.

Table 3
Characteristics of the dental arches and cavities.

Characteristic	Number of restorations			
	ER – IF*	ER – BF	SE – IF	SE – BF
Tooth distribution				
Premolar	19	18	23	18
Molar	40	41	36	41
Spontaneous pre-operative sensitivity				
Yes	9	5	9	9
No	50	54	50	50
Cavity depth				
3 mm	43	42	43	36
4 mm	8	9	9	11
> 4 mm	8	8	7	12
Black Classification				
I	33	32	32	29
II	26	27	37	30
Number of restored surfaces				
1	26	22	21	23
2	27	30	30	30
3	5	4	6	5
4	1	3	2	1
Reasons for replacement				
Marginal fracture	6	5	7	5
Esthetic reasons	33	32	25	32
Marginal Discoloration	4	5	3	5
Bulk fracture	7	4	5	5
Primary of secondary caries lesion	9	13	19	12

(*) ER-IF (Etch-and-Rinse, incremental filling), ER-BF (Etch-and-Rinse, bulk filling), SE-IF (Self-etch, incremental filling); SE-BF (Self-etch, bulk filling).

3.2. Fractures

After 36 months, fourteen restorations showed fractures classified as "clinically good" or "clinically sufficient/satisfactory" (3 for ER−IF; 4 for ER−BF; 3 for SE−IF and 4 for SE−BF; Table 4). No significant difference was detected between any pair of groups at the 12-, 24-, and 36-month recalls ($p > 0.67$). Table 5 shows the absolute risk of fracture for all groups, as well as the risk ratio to the group etch-and-rinse incremental filling. Overall, all groups showed a low absolute risk of fractures in the 36-month recall. The fact that the 95% CI interval of the risk ratio crosses the null value of 1 means that none of the groups were different from the most traditional approach of placing composites (etch-and-rinse incremental filling).

3.3. Marginal adaptation

Thirty-two restorations at the 36-month follow-up were considered to have minor discrepancies in marginal adaptation (3 for ER−IF, 3 for ER−BF, 14 for SE−IF, and 12 for SE−BF; Table 4). No significant

Table 4
Number of evaluated restorations for each experimental group (*) classified according to the World Dental Federation (FDI) criteria for functional properties [33,34].

FDI Criteria	Score	Baseline				12 months				24 months				36 months			
		ER – IF	ER – BF	SE – IF	SE – BF	ER – IF	ER – BF	SE – IF	SE – BF	ER – IF	ER – BF	SE – IF	SE – BF	ER – IF	ER – BF	SE – IF	SE – BF
Fractures	VG	59	59	59	59	58	58	57	57	57	57	57	56	52	51	52	51
	GO	–	–	–	–	01	01	02	01	01	02	–	01	02	04	–	01
	SS	–	–	–	–	–	–	–	01	01	–	02	02	01	–	03	03
	UN/PO	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Marginal adaptation	VG	59	59	59	59	59	59	57	55	57	59	48	48	51	50	37	41
	GO	–	–	–	–	–	–	02	04	01	–	03	04	01	01	02	02
	SS	–	–	–	–	–	–	–	–	01	01	08	07	02	02	12	10
	UN/PO	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Contact point/food impact	VG	59	59	59	59	59	59	59	59	59	59	59	59	54	55	53	53
	GO	–	–	–	–	–	–	–	–	–	–	–	–	01	–	02	02
	SS	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	UN/PO	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Radiographic exam	VG	59	59	59	59	59	59	59	59	59	59	59	59	55	55	55	55
	GO	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	SS	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	UN/PO	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–

(*) ER-IF (Etch-and-Rinse, incremental filling), ER-BF (Etch-and-Rinse, bulk filling), SE-IF (Self-etch, incremental filling); SE-BF (Self-etch, bulk filling); (**) VG for clinically very good; GO for clinically good; SS for clinically sufficient/satisfactory; UN for clinically unsatisfactory and; PO for clinically poor.

Table 5
Absolute risk (95% CI) and relative risk (95% CI) for outcome fracture for different groups after 3 years of clinical evaluation.

	Absolute risk (95% CI)	Relative risk (95% CI)*
Etch-and-rinse – Incremental filling	5.4 (1.8-14.8)	1.33 (0.31-5.68)
Etch-and-rinse – Bulk filling	7.2 (2.8-17.3)	
Self-etch – Incremental filling	5.4 (1.8-14.8)	1.00 (0.21-4.70)
Self-etch – Bulk filling	7.2 (2.8-17.3)	1.33 (0.31-5.68)

Related to group Etch-and-rinse – Incremental filling.

difference was detected between any pair of groups at the 12-month follow-up ($p > 0.05$; Table 4). However, a significant worsening of marginal adaptation was observed for the SE−IF and SE−BF groups at the 24- and 36-month follow-ups ($p < 0.05$; Table 4).

3.4. Contact point/food impact and radiographic exam

Only five restorations at the 36-month follow-up were considered to have minor problems related to contact point/food impact (1 for ER−IF, 2 for SE−IF, and 2 for SE−BF; Table 4). No significant difference was detected between any pair of groups at the 12-, 24-, and 36-month follow-ups ($p > 0.05$; Table 4).

3.5. Color stability and translucency

Thirty-eight restorations at the 36-month follow-up were considered to have some minor discrepancies in color match (9 for ER−IF, 12 for ER−BF, 7 for SE−IF, and 10 for SE−BF; Table 6). No significant difference was detected between any pair of groups at the 12-, 24-, and 36-month recalls ($p > 0.05$; Table 6).

3.6. Marginal staining

Thirty-four restorations at the 36-month follow-up were considered to have some staining in the margins (9 for ER−IF, 12 for ER−BF, 7 for SE−IF, and 10 for SE−BF; Table 6). No significant difference was detected between any pair of groups at the 12-month recall ($p > 0.05$; Table 6). However, SE−IF and SE−BF groups were significantly different to ER−IF and ER−BF in the 24- and 36-month recalls ($p < 0.05$).

3.7. Postoperative sensitivity

Although forty-eight restorations showed immediate post-operative sensitivity (13 for ER-IF, 10 for ER-BF, 14 for SE-IF, and 11 for SE-BF; $p > 0.05$; Table 6), none of them showed post-operative sensitivity after 12, 24, and 36 months of clinical evaluation (Table 6).

3.8. Recurrence of caries

No restoration showed recurrence of caries after 12, 24, and 36 months of clinical evaluation (Table 6).

3.9. Patient view

Seven patients (two with four restorations, four with two restorations, and one with one restoration) were not entirely satisfied with their restorations. This means that 89.7% of patients (61 out of 68) were satisfied with the restorations after 36 months of clinical evaluation. No significant difference was detected between any pair of groups at the 12-, 24-, and 36-month recall ($p < 0.05$; Table 6).

Table 6
Number of evaluated restorations for each experimental group (*) classified according to the World Dental Federation (FDI) criteria for esthetic and biological properties, as well as, patient satisfaction [33,34].

FDI Criteria	Score	Baseline				12 months				24 months				36 months			
		ER – IF	ER – BF	ER – IF	ER – BF	SE – IF	SE – BF	SE – IF	SE – BF	ER – IF	ER – BF	SE – IF	SE – BF	ER – IF	ER – BF	SE – IF	SE – BF
Color stability and translucency	VG	52	49	53	51	52	49	53	51	51	47	53	50	46	43	48	45
	GO	07	10	06	08	07	10	06	08	08	12	06	09	09	12	07	10
	SS	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	UN/PO	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Marginal staining	VG	59	59	59	59	59	59	57	55	57	59	48	48	51	50	37	41
	GO	–	–	–	–	–	–	02	04	01	–	03	04	01	02	04	02
	SS	–	–	–	–	–	–	–	–	01	01	08	07	03	03	14	12
	UN/PO	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Post-operative (hyper-) sensitivity	VG	46	49	45	48	59	59	59	59	59	59	59	59	55	55	55	55
	GO	13	10	14	11	–	–	–	–	–	–	–	–	–	–	–	–
	SS	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	UN/PO	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Recurrence of caries	VG	59	59	59	59	59	59	59	59	59	59	59	59	55	55	55	55
	GO	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	SS	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	UN/PO	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Patient satisfaction	VG	49	50	51	49	54	55	57	57	54	55	57	57	49	50	52	50
	GO	09	09	07	10	05	04	02	02	05	04	02	02	06	05	03	05
	SS	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	UN/PO	01	–	01	–	–	–	–	–	–	–	–	–	–	–	–	–

(*) ER-IF (Etch-and-Rinse, incremental filling), ER-BF (Etch-and-Rinse, bulk filling), SE-IF (Self-etch, incremental filling); SE-BF (Self-etch, bulk filling)(**) VG for clinically very good; GO for clinically good; SS for clinically sufficient/satisfactory; UN for clinically unsatisfactory and; PO for clinically poor.

Table 7
Restorations acceptable or not acceptable according to the Federation Dental International (FDI) criteria after 18 months [33,34].

	Fractures				Marginal adaptation				Contact point/food impact				Radiographic exam			
	ER – IF	ER – BF	ER – IF	ER – BF	ER – IF	ER – BF	ER – IF	ER – BF	ER – IF	ER – BF	ER – IF	ER – BF	ER – IF	ER – BF	ER – IF	ER – BF
Acceptable	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55
Not acceptable	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
General	All restorations were acceptable regarding functional properties															

	Color stability and translucency				Marginal staining				Postoperative (hyper-) sensitivity				Recurrence of caries			
	ER – IF	ER – BF	ER – IF	ER – BF	ER – IF	ER – BF	ER – IF	ER – BF	ER – IF	ER – BF	ER – IF	ER – BF	ER – IF	ER – BF	ER – IF	ER – BF
Acceptable	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55
Not acceptable	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
General	All restorations were acceptable regarding aesthetic property								All restorations were acceptable regarding biological properties							

3.10. General overview

When the criteria for 'acceptable' vs. 'not acceptable' restorations were applied, all restorations evaluated after 36 months were ranked as 'acceptable' (Table 7), regardless of their study group.

4. Discussion

In the present RCT, restorations placed using the bulk-fill technique showed similar performances to those placed with the traditional 2-mm incremental technique after 36 months of clinical evaluation. Therefore, we cannot reject the null hypothesis of equality between layering protocols, making bulk-fill restoratives attractive for use in posterior teeth cavities when large and deep cavities are to be restored [35–37].

The key parameter for the clinical success of the bulk-fill resin composites placed in deep cavities is the improved depth of cure. To produce these materials, several strategies were employed by manufacturers [13]. In the case of Tetric N-Ceram Bulk Fill, the material still contains the traditional camphorquinone-tertiary amine initiation system but a new photo-initiator system (called 'Ivocerin', a germanium-based initiator system) was added to the material. This Ivocerin initiator is considered to be more effective than camphorquinone [38] alone, as it allows for a higher and constant depth of cure (4–5 mm) [16,35,39–41] and higher mechanical properties in the whole thickness (4–5 mm) of the restoration [12,16,29]

The good mechanical behavior of this material, mainly used in the bulk-fill technique, was observed for the lower percentage of the restorations with fractures or failures in the contact points or in the restoration margins after 36 months of clinical evaluation. The absolute risk of fractures varied from 5.4–7.2%, making these differences not clinically important. Additionally, the presence of large pre-polymerized filler particles of up to 50 μm, consisting of inorganic fillers (barium glass and silica) embedded in an already polymerized organic matrix, allowed for the inclusion of a high filler load in this material [16].

According to Leprince et al. [42] and Bucuta e Ilie [16], the main advancement in the depth of cure for the most recent generation of bulk-fill materials results from their higher translucency. For instance, the material used in this study (Tetric N-Ceram Bulk Fill) has an increased translucency [16,38] that leads to a higher passage of light into the depth [35,39–41] by reducing light and scattering and improving the deeper blue light penetration [12,43]. Bucuta e ilie [16] described that in the case of Tetric N-Ceram Bulk Fill the round-shape of the filler particles also positively increases the translucency [44].

The increased translucency jeopardized some esthetic properties of restorations. Around 15% were rated as clinically good, meaning that minor deviations of translucency and color match were already observed in the baseline evaluation. However, previous clinical studies that evaluated the same material reported an absence of esthetic problems in the baseline evaluation [17,19,20,22].

Differences in the clinical evaluation criteria used could be responsible for these controversial results in terms of color match. While previous authors used a modified USPHS criteria [17,19,20,22], in the present study, the FDI criteria was used. Although both criteria were not compared in this study, previous studies that evaluated restorations in non-carious cervical lesions showed that the former is less sensitive to small variations in the clinical outcomes than the FDI criteria [45–47]. Considering that an increase in the number of restorations with some translucency or color mismatch was observed after 36 months of clinical evaluation, as well as observed in earlier trials [17,19,20,22], it seems that this is not of clinical importance for the bulk-fill material used.

In terms of marginal discrepancies, no significant difference was observed, when incremental vs. bulk-fill techniques were compared after 36 months of clinical evaluation. There is a widespread belief

among clinicians that the use of the incremental technique reduces polymerization shrinkage of the resin composite by reducing the volume of resin composite placed in each increment, as well as the consequences related to the polymerization shrinkage [6–10]. Although there is some physical plausibility behind this belief [6–10], in vitro studies do not show that the incremental filling technique causes less polymerization shrinkage than the bulk-fill technique; therefore, this belief seems to be more anecdotal than an evidence-based finding [48,49].

Several in vitro studies showed that Tetric N-Ceram Bulk-Fill polymerized in 4-mm increments has polymerization shrinkage [39–41,50,51] and shrinkage stress values [41,50,51] similar to the composite resins cured in several increments. No significant differences in the marginal gap formation and marginal integrity failures were observed when bulk-fill composite resins were compared with incremental composite resins, confirming the similar performance of both layering techniques in this clinical study [39,52,53].

Actually, the results of the present study do not correlate with the study published by Yazici et al. [19]. The authors showed lower marginal discrepancies when a bulk-fill resin composite technique was used in comparison with conventional resin composites placed incrementally. However, in the previously study [19], two different resin composites were used, one for each layering technique. This prevents the authors from considering the layering technique itself as responsible for the marginal discrepancies observed, as not only the layering technique but also the resin-based material were sources of variation [19].

When adhesive strategy was evaluated, the results of the present study showed that restorations with better marginal adaptation and with less marginal discoloration were those bonded with the etch-and-rinse adhesive. This is in agreement with recent published systematic reviews that compared adhesive strategies in anterior and posterior permanent restorations [54–57].

According to Heintze et al. [54], the tendency towards a higher risk of marginal discrepancies of restorations bonded with self-etch adhesives rather than etch-and-rinse adhesives is due to the inferior enamel etching pattern of self-etch systems. Marginal defects of esthetic restorations are usually associated with deposits of food stains or bacterial biofilm into the marginal irregularities, such as gaps and microfractures causing marginal staining [54]. Despite these small differences among bonding techniques, all restorations were considered 'clinically acceptable' because this slight lack of marginal adaptation or superficial discoloration did not require further treatment but only a new polishing procedure [58,59].

Finally, we should mention the limitations of the present study. The whole study was performed in a university setting, in which restorations are placed under ideal conditions with very calibrated operators to produce restorations as near perfect as possible. In this scenario, only motivated patients with good oral health and, consequently, low caries risk were included. It was shown that restorations in a high-caries risk group had a failure rate more than twice as high compared to low-risk patients [4]. Also, it is worth mentioning that more than 50% of the restorations in the present study were performed in Class I (single-surface restorations). Due to the fact that Class II placements in multiple-faced restorations have a higher relative risk of failure when compared to Class I restorations [60,61], future clinical studies should be conducted evaluating bulk-fill materials placed in more complex cavities and in patients with high-caries risk.

It seems that the university setting is the most appropriate to determine the material's optimal performance, but it is only in a practice-based setting that one can gather the material's typical performance. Therefore, further clinical studies mainly in a practice-based setting should be conducted to highlight whether or not the current results observed under optimal conditions can be generalized to all clinical settings.

5. Conclusion

The bulk-fill resin composite evaluated in this study showed similar clinical performance when used in bulk or in increments, as all restorations were scored as 'clinically acceptable'. Regarding the adhesive strategy, the etch-and-rinse strategy showed lower marginal discoloration and better marginal adaptation than the self-etch approach.

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