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Randomized prospective clinical trial of class II restorations using flowable bulk-fill resin composites: 4-year follow-up

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Abstract

Objectives This randomized, prospective, and split-mouth study aimed to evaluate flowable bulk-fill resin composites in class II restorations, comparing it with a conventional layering technique after 4-year follow-up.

Materials and methods Fifty-three subjects received three class II restorations according to the restorative systems: conventional microhybrid composite resin (PA – Peak Universal + Amelogen Plus, Ultradent); flowable bulk-fill and nanoparticulate composite resins (ABF – Adper Single Bond 2 + Filtek Bulk Fill Flow + Filtek Z350XT, 3M/Espe); and flowable bulk-fill and microhybrid composite resins, (XST – XP Bond + SDR + TPH3, Dentsply). The clinical performance and interproximal contacts were evaluated. Statistical analyses were performed using the Kaplan-Meier, equality test of two proportions, Friedman, Wilcoxon, Kruskal-Wallis, Mann-Whitney, and Logistic regression analysis tests (alpha = 0.05).

Results In total, 106 restorations were evaluated at 4 years. Both systems with bulk-fill composites presented higher marginal discoloration than PA. About surface texture, ABF restorative system showed superior bravo scores being statistically similar to XST. Better performance for wear and surface staining was found for XST restorative system. All restorative systems resulted in the decreased interproximal contacts, occurring early for XST.

Conclusions The restorative systems that used flowable bulk-fill resin composites showed satisfactory clinical performance compared with conventional resin composite after 4 years. All restorative systems had decreased proximal contact after 4 years.

Clinical relevance Initial marginal discoloration was observed in more than 50% of class II restorations performed with restorative systems that used flowable bulk-fill resin composite. All restorative systems had decreased proximal contact strength over time.

Keywords Adhesive systems · Class II · Clinical trials · Resin composite

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Introduction

Composite resins became the most employed material for restoration of dental elements. The improvements in resin composite formulations and the increasing demand for esthetics have made composite resin restoration the optimal choice for restoring posterior. To improve the success of these restorations, factors related to the patient and operator are of primary importance [1].

However, the main challenge for the professional is the correct technique required by these materials. Another difficulty in direct composite resin restorations is the reconstruction of posterior large cavities, such as involving posterior proximal wall, to achieve the adequate proximal contacts [2]. The literature recommends inserting the composite resin on the inner proximal surface of the matrix band from gingival to occlusal to minimize the C-factor, the polymerization shrinkage, and the formation of marginal gaps [3, 4]. Another important factor is the amount of energy that must be supplied in the correct wavelengths to achieve a satisfactory degree of conversion of the resin material [4]. Besides, the use of 2-mm layering technique to achieve the success of conventional composite resin is also indispensable. However, the insertion of 2-mm increments and its correct light curing requires more clinical time and patient discomfort.

In this context, bulk-fill restorative resins required significantly less chair time to apply than the layering one, optimizing the clinical time and reducing the sensitivity to the technique by the professional [5, 6]. The bulk-fill composites have monomers with a high molecular weight to reduce the shrinkage stress [7]. The early bulk-fill resin-based composite (RBC) was composed with flowable consistency, being necessary a final increment with conventional composites [8, 9]. Currently, there are more three types of bulk fill RBC: bulk fill RBC (packable), sonic-activated bulk fill RBC, and dual-cure bulk fill RBC [9]. Bulk-fill packable RBC can be used alone; thus, they are more time-saving and simpler than flowable materials [9].

Some clinical studies and meta-analysis have demonstrated that bulk-fill composites have shown similar results to conventional resin composites mainly after short-term follow-up [7, 10–19]. Few randomized clinical trials (RCT) were conducted evaluating bulk-fill materials after long-term follow-up [20–22]. However, no randomized clinical trials (RCT) have yet compared two bulk fill restorative systems versus the incremental layering technique after 4 years. Additionally, more RCT with longer periods are necessary to evaluate the maintenance of interproximal contact of bulk fill restorative systems.

Thus, this RCT aimed to evaluate the clinical performance and interproximal contact after the placement of direct composite resin restorations in class II cavities, comparing restorative systems: one conventional 2-mm incremental resin composite with two using flowable bulk-fill covered with conventional composites. The null hypotheses tested were that there would be no difference among the three restorative systems for the clinical parameters, and that there would be no differences for the same restorative strategy over time.

Materials and methods

Study design

This clinical trial was a prospective, randomized, double-blind (volunteers and examiners), and split mouth model. It was executed after gaining approval from the local Ethics Committee (approval code: 1.235,100). This RCT was registered (#RBR-3gg3mg) and conducted according to CONSORT guidelines (Fig. 1). Three restorative systems were used: microhybrid conventional composite resin-considered control group (PA - Peak Universal + Amelogen Plus, Ultradent); flowable bulk-fill and nanoparticulate composite resins (ABF – Adper Single Bond 2 + Filtek Bulk Fill Flow + Filtek Z350XT, 3M/ESPE); and flowable bulk-fill and microhybrid composite resins, (XST – XP Bond + SDR + TPH3, Dentsply), and the two last restorative systems were considered test groups.

Patient selection

During March to June 2015, all patients attending the undergraduate clinic, at local faculty of dentistry who needed three class II restorations, were asked to participate in the study. The sample power for two proportions, when considering 95% success achieved for the control group and 80% for the test group, indicated that an experimental sample with 159 restorations had a high power of 98.3%.

The following inclusion criteria were used: patients presenting at least three unsatisfactory class II restorations that were at least 3 mm deep in a vital permanent premolar or molar of the maxilla or mandible with an adjacent tooth, patients with good periodontal health, and patients with no clinical history of allergies to dental products. The exclusion criteria were the following: pregnant or lactating women, patients receiving orthodontic treatment, tooth without an antagonist, and endodontically treated teeth.

In total, 53 subjects were selected and subjected to clinical and radiographic examination after signing the informed consent form.

Fig. 1 Flow chart of patients. Np, number of patients; Nr, number of restorations
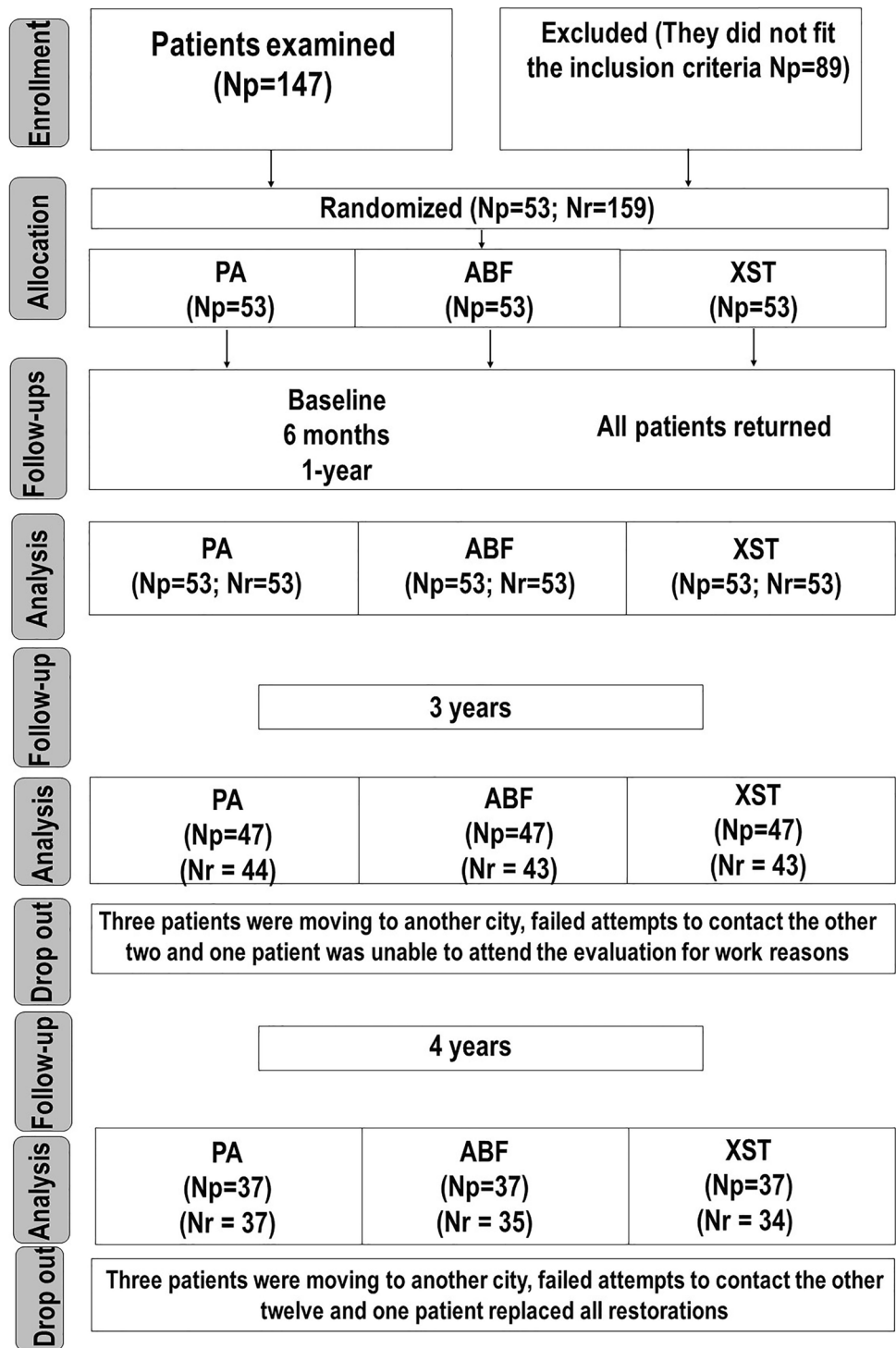
Calibration and randomization

Two calibrated operators (residents), with clinical experiences of 19 years and 1 year, were trained by a faculty member specialized in restorative dentistry to perform the restorative procedures. For calibration, each operator performed two restorations for each group of patients that were not selected for the research. The operators were identified on the procedure sheets. The subjects then received oral hygiene instructions and initial photographs were taken.

All subjects received local anesthesia prior to restorative procedures. The randomization was performed by putting numbers in a sealed envelope and drawing which restorative procedure would be performed on each of the

selected teeth. Each subject received three restorations, one from each group.

Restorative procedures

The complete restorative procedures have been described in our previous studies [23, 24]. The cavity preparations were performed using spherical diamond burs (#1015–1017; KG Sorensen, Barueri, SP Brazil), which were replaced after every three procedures. When carious tissue was found, smooth spherical carbide burs (#1/2–4, Dentsply-Maillefer, Ballaigues, Vaud, Switzerland) were also used in a slow speed handpiece. The operative field was isolated with a rubber dam.

Then, 35% phosphoric acid gel (Ultra-etch, Ultradent Products Inc., South Jordan, UT, USA) was used for 30 s on enamel and 15 s on dentin for all groups. Subsequently, adhesive systems and restorative materials were applied, following the recommendations of the respective manufacturers. Table 1 presents the specifications for each group.

To restore the shape of the proximal walls, wooden wedges, preformed metal matrices, and rings (Unimatrix sectional matrix system, TDV Dental Ltda. Pomerode, SC, Brazil) were used. Adhesives and composite resins were light-cured with a LED curing light (Valo, Ultradent Products Inc., South Jordan, UT, USA), in the standard application mode and an output of 1000 mW/cm^2.

Finally, ultra-fine diamond burs (#1190F, 3118F, 1190FF, 3118FF; KG Sorensen, Cotia, SP, Brasil), and polishing points (Jiffy, Ultradent Products Inc., South Jordan, UT, USA) were used to finish all restorations.

Evaluation

Two independent and calibrated examiners, neither of which placed the restorations, were responsible for the clinical evaluations. The examiners were kept blind in the assessments. The clinical performance of restorations was assessed by visual and tactile inspection, using a flat dental mirror and a probe with both periodontal/explorer tips.

After 4-year follow-up, the restorations were evaluated using the modified US Public Health Service (USPHS) criteria, as described in Table 2. The tightness of the proximal contact was determined based on the resistance to dental floss (Sanifill, São Paulo, SP, Brazil) between the restored surface and the adjacent tooth. The following scores were used: 0 – no contact, 1 – minimum contact, 2 – ideal contact, 3 – tight contact, 4 – very tight contact [25]. In cases where more than

one proximal surface was involved, the worst score of the two contacts was recorded.

Statistical methods

The Kappa index was used to measure the degree of agreement between the two evaluators. The annual failure rates were calculated. The Kaplan-Meier test was used to demonstrate the survival curve. The equality test of two proportions was used to evaluate clinical performance. The Friedman and Wilcoxon tests were used to evaluate interproximal contacts within each group, and the Kruskal-Wallis and Mann-Whitney tests were used within the same evaluation period. Dropout patients' data were evaluated per protocol strategy used. No intention to be treated was used.

Logistic regression analysis was performed to predict the probability of total success (alpha score) of the clinical performance results at 4 years. Afterwards, the Hosmer-Lemeshow test was performed to evaluate the efficacy of the logistic regression model. All tests were performed at a 0.05% significance level. Statistical procedures were performed in the SPSS version 13.

Results

The mean age of the 53 subjects was 48.3 years (± 10.0). A total of 65 molars and 94 premolars were restored (159 restorations). The characteristics of the preparations and the restorative procedures are described in Table 3. In total, 38 subjects (71.7%) and 106 restorations were evaluated at 4-year follow-up.

There was an excellent concordance of Kappa (Baseline = 0.79, 6 months = 0.91, 1 year = 0.89, 3 years = 0.92, 4 years = 0.94). The Kaplan-Meier test showed no differences among groups regarding the survival curves when considering only charlie score or both bravo and charlie scores as failure (Fig. 2).

Table 4 shows data from the USPHS criteria. All failure data were accumulated even if the patient did not return at the evaluation, for example: PA group had 37 restorations evaluated for retention being 5 charlie scored at 4 years; however, 33 restorations were considered for marginal integrity because 1 had failed for this criterion at 3 years. Furthermore, in the first evaluation in which the restoration failed, all other criteria were evaluated if possible; however, only the criterion that failed was considered for next evaluations. Considering charlie scores, the annual failure rates at 4 years are 3.6%, 3.0%, and 2.3% for PA, ABF, and XST, respectively.

When the analysis among groups was executed, a statistically significant difference was observed for the

Table 1 Products (material, manufacturer, composition, and mode of application) used in this study

Group	Material	Manufacturer	Composition	Application
Control PA	Peak Universal	Ultradent, South Jordan, UT, USA	Ethyl alcohol and 2-hydroxyethyl methacrylate	Dentin was dried and the adhesive was applied with a microbrush by rubbing on the cavity for 10s. Adhesive was air dried for 10s and photoactivated for 10 s
	Amelogen Plus		Organic matrix: BisGMA, TEGDMA. Filler: silica dioxide and silicate particles (76% wt)	Oblique 2-mm increments were inserted and photoactivated for 20 s. The last increment was photoactivated for 40s
Test ABF	Adper Single Bond 2	3M ESPE Dental Products TM, St. Paul, MN, USA	Water, ethanol, Bis-GMA, HEMA, UDMA, bisphenol A glycerolate, silica nanofillers treated with acid copolimer, dimetacrylate	Dentin was left slightly moist. The adhesive was applied with a microbrush and air dried for 5 s. A second layer of the adhesive was applied and air dried for 5 s. Photo-activation was performed for 20 s
	Filtek Bulk Fill Flow		Organic matrix: Bis-GMA, Bis-EMA, UDMA, Procrylat. Filler: ytterbium trifluoride filler with a range of particle sizes from 0.1 to 5.0 microns and zirconia/silica with a particle size range of 0.01 to 3.5 μm (64.5% wt)	A single increment was inserted in the cavity without submerging the tip of the syringe in the material already dispensed and photoactivated for 40 s. Material was kept 2 mm below the occlusal margin
	Filtek Z350XT		Organic matrix: Bis-GMA, Bis-EMA, UDMA and TEGDMA. Filler: agglomerated silica nanofillers and nanoagglomerated zirconia/silica (78.5% wt)	Oblique increments of up to 2 mm were inserted, finishing the restorations. Each increment was photoactivated for 20 s and the last increment for 40 s
Test XST	XP Bond2	DENTSPLY Caulk Milford, DE, USA	PENTA, UDMA, dimethacrylate modified by carboxilic acid (TCB Resin), Triethileneglycol dimethacrylate, Hydroxyethylmethacrylate, Canphoroquinone, Ethyl-dimethylaminebenzoato, Tert-butylhydroquinon,silica, Tert-Butanol (T-butanol)	Dentin was left slightly moist. One drop of XP Bond was applied with a microbrush, allowed to sit for 20 s, air dried for 5 s, and photoactivated for 20 s
	SureFil SDR		Organic matrix: SDR-UDMA, EBPADMA, TEGDMA, CQ, butyl hydroxy toluene; stabilizers UV; titanium dioxide; iron oxide pigments. Filler: barium glass fluoride aluminum silicate, strontium glass, with average particle size of 4.2 μm (68% wt)	A single increment was inserted using a constant and slow pressure in the deepest part of the cavity, keeping the tip inside the material until an increment of not more than 4 mm was obtained. The material was kept 2 mm below the cavosurface angle for posterior insertion of the universal resin and photoactivated for 40 s
	TPH3		Organic matrix: BisGMA, Silica Dimethacrylate; EDAB and others. Filler: Silanized barium glass aluminum borosilicate; Silanized barium glass, fluoride, aluminum borosilicate (75% wt)	Resin was placed using the incremental technique, and each increment was photoactivated for 20 s. The last increment was photoactivated for 40 s

Bis-GMA bisphenol A glycidil methacrylate, *Bis-EMA* bisphenol A ethoxylate methacrylate, *UDMA* urethane dimethacrylate, *TEGDMA* triethylene-glycol dimethacrylate, *EBPADMA* bisphenol A ethoxylated dimethacrylate, *EDAB* ethyl-4-dimethylamino benzoate, *CQ* canphoroquinone

Table 2 Modified USPHS Criteria rating system for clinical evaluation of the restorations

Retention

  Alfa (A): Presence of the restoration

  Bravo (B): Partial absent of the retention, less than a third of the restoration

  Charlie (C): More than a third or total absent of the retention

Marginal integrity

  Alfa (A): There is no visual evidence of marginal fracture and the tip of the dental probe is not trapped in the tooth/restoration interface

  Bravo (B): There is visible and tactile evidence of a cleft, but the dentin and/or base is not exposed nor does the restoration present mobility

  Charlie (C): The dental probe penetrates the tooth/restoration interface, presenting exposed dentin and/or base, but the restoration is not mobile, fractured, or lost

Marginal discoloration

  Alfa (A): There is no visual evidence of marginal discoloration at the tooth/restoration interface

  Bravo (B): There is visual evidence of marginal discoloration at the tooth/restoration interface, which can be removed with polishing

  Charlie (C): There is visual evidence of deep marginal discoloration at the tooth/restoration interface, which cannot be removed with polishing

Surface texture

  Alfa (A): Smooth and shiny, similar to enamel

  Bravo (B): Slightly rough

  Charlie (C): High roughness, not reflective

Wear

  Alfa (A): No wear, continuous interface

  Bravo (B): Discontinuous interface, no exposed dentin

  Charlie (C): Discontinuous interface, exposed dentin

Secondary caries

  Alfa (A): There is no visual evidence of tooth decay at the tooth/restoration interface

  Charlie (C): There is visual evidence of tooth decay at the tooth/restoration interface

Anatomical form

  Alfa (A): The restoration presents continuity with the anatomical form of the existing tooth

  Bravo (B): The restoration has a slight over-contour or under-contour

  Charlie (C): There is loss of restorative material leading to exposure of dentin and/or base

Surface staining

  Alfa (A): Absent

  Bravo (B): Present

Color

  Alfa (A): Non-apparent interface with the tooth

  Bravo (B): Subtle visualization between tooth and restoration

  Charlie (C): Clear visualization between tooth and restoration

Gingival tissue

  Alfa (A): No inflammation

  Bravo (B): Mild inflammation

  Charlie (C): Severe inflammation

following criteria: marginal discoloration, surface texture, wear, and superficial staining. Both systems with flowable bulk-fill composites presented higher initial marginal discoloration than PA. About surface texture, ABF restorative system showed superior bravo scores being statistically similar to XST. Better performance for wear and surface staining was found for XST when compared to other restorative systems.

When comparing the evaluation periods for each of the groups, no statistically significant difference was found for secondary caries, anatomical form, and gingival tissue for all groups. Considering retention, surface texture, and wear

statistical differences were more evident from 3 years for all groups. However, the three groups presented statistical differences for marginal integrity, marginal discoloration, and surface staining from 1 year. Figure 3 represents some images of restored teeth from each group.

Table 5 shows the interproximal contacts data. No significant difference among the groups was found. However, all restorative systems resulted in the decreased interproximal contacts, occurring from 1 year for XST.

The probability of success was influenced by the number of tooth faces involved in the restoration, previous condition, and time spent during the restorative procedures (Table 6).

Table 3 The characteristics of the cavities and the restorative procedures

Variables	Characteristics	n	Groups		
			PA	ABF	XST
Operator	1 (experience of 19 years)	81	27	27	27
	2 (experience of 1 year)	78	26	26	26
Teeth	Maxillary premolar	67	22	23	22
	Maxillary molar	34	11	13	10
	Mandibular premolar	27	7	9	11
	Mandibular molar	31	13	8	10
Restored faces	2	87	30	30	27
	3	67	20	23	24
	4	5	3	0	2
Previous condition	Unsatisfactory amalgam	106	39	35	32
	Unsatisfactory resin composite	52	14	18	20
	Primary caries lesions	1	0	0	1
Deep	3 mm	29	12	9	8
	$\geq$ 4 mm	61	17	19	25
	$\geq$ 5 mm	69	24	25	20
Previous dentin	Normal	34	10	15	9
	Sclerotic	125	43	38	44
Anesthesia	Yes	156	52	52	52
	No	3	1	1	1
Restorative time	$\leq$ 10 min	133	43	45	45
	$\leq$ 20 min	26	10	8	8
Operator perception	Easy	113	39	38	36
	Medium	38	13	12	13
	Dificult	8	1	3	4
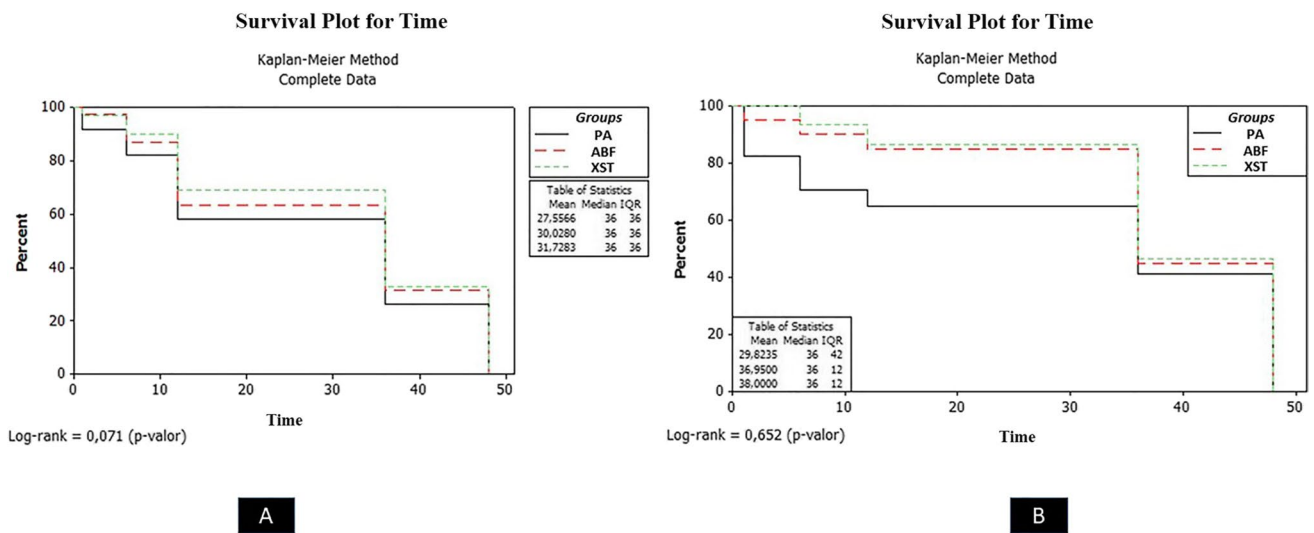
Fig. 2 Curves from survival analysis. **A** Considering both bravo and charlie scores as failure; **B** considering only charlie score as failure

Table 4 Clinical evaluation of resin composite restorations (USPHS). Percentage values of "A" score and numbers of "A," "B," and "C" scores in parentheses, respectively

Category	Groups	Baseline	6 months	1 year	3 years	4 years
Retention	PA	100% (53-A/0-B/0-C)^Aa	98.1% (52-A/1-B/0C)^Aab	94.3% (50-A/2-B/1-C)^Aab	91.5% (43-A/1-B/3-C)^Abc	86.5% (32-A/0-B/5-C)^Ac
	ABF	100% (53-A/0-B/0-C)^Aa	100% (53-A/0-B/0-C)^Aa	98.1% (52-A/0-B/1-C)^Aa	87.0% (40-A/3-B/3-C)^Ab	88.6% (31-A/0-B/4-C)^Ab
	XST	100% (53-A/0-B/0-C)^Aa	100% (53-A/0-B/0-C)^Aa	96.2% (51-A/0-B/2-C)^Aa	95.6% (43-A/0-B/2-C)^Aab	91.2% (31-A/0-B/3-C)^Ab
Marginal integrity	PA	100% (53-A/0-B/0-C)^Aa	92.5% (49-A/4-B/0-C)^Ab	71.7% (38-A/15-B/0-C)^Ac	56.8% (25-A/18-B/1-C)^Ac	60.6% (20-A/12-B/1-C)^Ac
	ABF	100% (53-A/0-B/0-C)^Aa	94.3% (50-A/3-B/0-C)^Aa	73.6% (39-A/14-B/0-C)^Ab	58.1% (25-A/16-B/2-C)^Abc	51.5% (17-A/14-B/2-C)^Ac
	XST	100% (53-A/0-B/0-C)^Aa	94.3% (50-A/3-B/0-C)^Aa	83.0% (44-A/9-B/0-C)^Ab	67.4% (29-A/13-B/1-C)^Abc	50.0% (16-A/15-B/1-C)^Ac
Marginal discoloration	PA	98.1% (52-A/1-B/0-C)^Aa	98.1% (52-A/1-B/0-C)^Aa	73.6% (39-A/14-B/0-C)^Ab	68.2% (30-A/14-B/0-C)^Ab	68.8% (22-A/10-B/0-C)^Ab
	ABF	98.1% (52-A/1-B/0-C)^Aa	83.0% (44-A/9-B/0-C)^Bb	73.6% (39-A/14-B/0-C)^Ac	55.8% (24-A/17-B/2-C)^ABcd	42.4% (14-A/17-B/2-C)^Bd
	XST	100% (53-A/0-B/0-C)^Aa	96.2% (51-A/2-B/0-C)^Aa	77.4% (41-A/12-B/0-C)^Ab	44.2% (19-A/23-B/1-C)^Bc	37.5% (12-A/19-B/1-C)^Bc
Surface texture	PA	100% (53-A/0-B/0-C)^Aa	100% (53-A/0-B/0-C)^Aa	96.2% (51-A/2-B/0-C)^Aab	90.9% (40-A/4-B/0-C)^Ab	84.4% (27-A/5-B/0-C)^Ab
	ABF	100% (53-A/0-B/0-C)^Aa	98.1% (52-A/1-B/0-C)^Aa	94.3% (50-A/3-B/0-C)^Aa	79.1% (34-A/9-B/0-C)^Ab	61.3% (19-A/12-B/0-C)^Bb
	XST	100% (53-A/0-B/0-C)^Aa	98.1% (52-A/1-B/0-C)^Aab	92.5% (49-A/4-B/0-C)^Aab	81.4% (35-A/8-B/0-C)^Abc	77.4% (24-A/7-B/0-C)^ABc
Wear	PA	100% (53-A/0-B/0-C)^Aa	100% (53-A/0-B/0-C)^Aa	98.1% (52-A/1-B/0-C)^Aa	75% (33-A/11-B/0-C)^Ab	68.8% (22-A/10-B/0-C)^Bb
	ABF	100% (53-A/0-B/0-C)^Aa	100% (53-A/0-B/0-C)^Aa	98.1% (52-A/1-B/0-C)^Aa	76.7% (33-A/10-B/0-C)^Ab	71.0% (22-A/9-B/0-C)^Bb
	XST	100% (53-A/0-B/0-C)^Aa	98.1% (52-A/1-B/0-C)^Aab	98.1% (52-A/1-B/0-C)^Aab	90.7% (39-A/4-B/0-C)^Ab	90.3% (28-A/3-B/0-C)^Ab
Secondary caries	PA	100% (53-A/0-C)^Aa	100% (53-A/0-C)^Aa	100% (53-A/0-C)^Aa	100% (44-A/0-C)^Aa	97.0% (32-A/1-C)^Aa
	ABF	100% (53-A/0-C)^Aa	100% (53-A/0-C)^Aa	98.1% (52-A/1-C)^Aa	97.7% (43-A/1-C)^Aa	96.9% (31-A/1-C)^Aa
	XST	100% (53-A/0-C)^Aa	100% (53-A/0-C)^Aa	98.1% (52-A/1-C)^Aa	95.6% (43-A/2-C)^Aa	93.9% (31-A/2-C)^Aa
Anatomical form	PA	98.1% (52-A/1-B/0-C)^Aa	98.1% (52-A/1-B/0-C)^Aa	98.1% (52-A/1-B/0-C)^Aa	97.7% (43-A/1-B/0-C)^Aa	96.9% (31-A/1-B/0-C)^Aa
	ABF	100% (53-A/0-B/0-C)^Aa	100% (53-A/0-B/0-C)^Aa	98.1% (52-A/1-B/0-C)^Aa	97.6% (42-A/1-B/0-C)^Aa	96.8% (30-A/1-B/0-C)^Aa
	XST	100% (53-A/0-B/0-C)^Aa	100% (53-A/0-B/0-C)^Aa	100% (53-A/0-B/0-C)^Aa	100% (43-A/0-B/0-C)^Aa	96.8% (30-A/1-B/0-C)^Aa
Surface staining	PA	100% (53-A/0-B)^Aa	96.2% (51-A/2-B)^Ba	84.9% (45-A/8-B)^Ab	63.6% (28-A/16-B)^Bc	62.5% (20-A/12-B)^Bc
	ABF	100% (53-A/0-B)^Aa	86.8% (46-A/7-B)^Bb	66.0% (35-A/18-B)^Bc	67.4% (29-A/14-B)^ABc	48.4% (15-A/16-B)^Bc
	XST	100% (53-A/0-B)^Aa	100% (53-A/0-B)^Aa	94.3% (50-A/3-B)^Aab	83.7% (36-A/7-B)^Ab	87.1% (27-A/4-B)^Ab
Color	PA	71.7% (38-A/13-B/2-C)^Ba	75.5% (40-A/12-B/1-C)^Ba	84.9% (45-A/8-B/0-C)^Ba	95.5% (42-A/2-B/0-C)^Ab	95.5% (42-A/2-B/0-C)^Ab
	ABF	92.5% (49-A/3-B/1-C)^Aa	90.6% (48-A/4-B/1-C)^Aa	92.5% (49-A/4-B/0-C)^Ba	95.3% (41-A/2-B/0-C)^Aa	95.3% (41-A/2-B/0-C)^Aa
	XST	92.5% (49-A/4-B/0-C)^Aa	94.3% (50-A/3-B/0-C)^Aa	96.2% (51-A/2-B/0-C)^Aa	97.7% (42-A/1-B/0-C)^Aa	97.7% (42-A/1-B/0-C)^Aa
Gingival Tissue	PA	98.1% (52-A/0-B/1-C)^Aa	98.1% (52-A/0-B/1-C)^Aa	96.2% (51-A/1-B/1-C)^Aa	100% (44-A/0-B/0-C)^Aa	100% (32-A/0-B/0-C)^Aa
	ABF	96.2% (51-A/2-B/0-C)^Aa	98.1% (52-A/1-B/0-C)^Aa	96.2% (51-A/2-B/0-C)^Aa	100% (43-A/0-B/0-C)^Aa	96.8% (30-A/1-B/0-C)^Aa
	XST	100% (53-A/0-B/0-C)^Aa	98.1% (52-A/0-B/1-C)^Aa	98.1% (52-A/1-B/0-C)^Aa	100% (43-A/0-B/0-C)^Aa	100% (31-A/0-B/0-C)^Aa

Capital letters compare groups within the same evaluation period (columns), lower case compares the periods of each group individually (lines); therefore, the different capital letters compare alpha and beta scores, when the item does not have a bravo score; the comparison is between alpha and charlie score. Numbers in parenthesis: number of scores present in Table 2

Fig. 3 Evaluation of clinical performance according to USPHS criteria. **A** Second premolar of PA group, bravo score for the marginal integrity, and wear criteria and alpha for other criteria; **B** first molar representative of ABF group, charlie score for the retention criterion because a repair was performed in the buccal surface; **C** second premolar of XST group, alpha scores for all criteria; **D** second molar of the PA group, bravo scores for marginal integrity and surface staining, alpha scores for other criteria; **E** First molar of ABF group, bravo score for marginal integrity, marginal discoloration, wear and surface staining; alpha scores for other criteria; **F** second premolar of XST group, bravo scores for marginal discoloration and surface staining criteria, alpha score for other criteria; **G** second molar of PA group, bravo scores for marginal discoloration and wear criteria; alpha scores for other criteria; **H** First molar of ABF group, bravo scores for marginal integrity, marginal discoloration and surface staining, alpha scores for other criteria; **I** first molar of ABF group, marginal discoloration and surface staining, alpha scores for other criteria; **J** second premolar of PA group, charlie score for retention, bravo score for wear, and alpha scores for other criteria; (**K**) first molar of ABF group, charlie score for retention criterion and marginal integrity, bravo score for marginal discoloration alpha scores for other criteria; (**L**) second molar of XST group, bravo scores for marginal integrity and marginal discoloration, alpha scores for other criteria

Table 5 Median (1st quartile–3rd quartile) of the interproximal contacts for groups and evaluation periods

Groups	Evaluation periods				
	Baseline	6 months	1 year	3 years	4 years
PA	2 (2–2)[Aa]	2 (2–2)[Aa]	2 (2–2)[Aa]	1.5 (1–2)[Ab]	2 (1–2)[Ab]
ABF	2 (2–2)[Aa]	2 (2–2)[Aa]	2 (2–2)[Aa]	2 (1–2)[Ab]	2 (1–2)[Ab]
XST	2 (2–2)[Aa]	2 (2–2)[Aa]	2 (1–2)[Ab]	2 (1–2)[Ac]	2 (1–2)[Ac]

Capital letters compare groups within a same evaluation period (columns), lower case compares the periods of each group individually (lines)

Discussion

This study represents a prospective, randomized, double-blind, and split-mouth clinical trial, making possible to analyze the test and control groups under the same conditions, increasing the statistical efficiency and decreasing the number of patients required for the study [26]. Furthermore, the distribution of restorations (maximum of 3 pairs in the same patient) is in accordance to the American Dental Association guidelines when testing a new material [27]. According to van Dijken et al. [21], the theoretical sample size of 120 restorations is adequate to determine significant differences between groups treated with different materials in similar evaluations of intra-individual comparison design. The number of 53 restorations per group performed in this study was superior to that estimated by these authors [21]. Thereby, 159 restorations were considered a power of 98.3%. Also, 106 restorations were evaluated at 4-year follow-up, making the detection of statistical differences possible among the groups.

The method used for the performance of the restorations was USPHS, used in several clinical trials [11, 12, 21, 28, 29], although other criteria for the clinical evaluation of restorations can be found, such as those used by the World Dental Federation (FDI criteria) [13]. The FDI criteria better presented the restorations' clinical success. However, in the case of failure, both criteria provided the same result [14]. The Kappa test revealed an increased and excellent agreement among the evaluators over time.

In this study, the annual failure rates were 3.6% for PA, 3.0% for ABF, and 2.3% for XST. In other study, the annual failure rate was 2.2% for flowable bulk-fill and 1.6% for conventional composite resin place in class II restorations, both over a 3-year period of comparison [29]. The causes of failure were mentioned dental fracture followed by fracture of the restorative material [29]. In a 5-year follow-up, flowable bulk-fill showed a satisfactory success rate, with an annual failure rate of 1.4% when observing only class II cavities [30]. Among the main causes of failure, a cusp fracture with 40% frequency was found, and the authors conclude that over the 5-year evaluation period; these materials present adequate results that support the indication in clinical practice [30]. In a systemic review, bulk-fill and conventional composites of class II restorations based on RCTs found annual failure rates of 1.1 ($\pm$ 0.9) and 1.4 ($\pm$ 1.4), respectively [31]. Although the curves from survival analysis showed no statistical differences among groups, possible changes may be detected in future evaluations considering both bravo and charlie scores.

Retention, marginal integrity and marginal discoloration are the main criteria that determine the longevity of restorations [32]. These parameters are directly related to the stress produced at the tooth/restoration interface, which may be influenced by the geometry of the cavity, adhesive systems, viscosity of the restorative materials, and placement technique [32].

When considering retention, no statistical difference of conventional composite resin, if compared to the bulk-fill resin composites, was found. However, XST group presented 2 charlie score after 1-year follow-up, and ABF group presented 3 bravo and 3 charlie scores at 3-year follow-up. In the case of bulk-fill resin composites, although

Table 6 Coefficients of the logistic regression model for success at 4 years

4 years	Retention		Marginal integrity		Marginal discoloration		Surface texture		Wear		Surface staining	
	Coef.	P-value	Coef.	P-value	Coef.	P-value	Coef.	P-value	Coef.	P-value	Coef.	P-value
Constant	4.26	0.217	3.79	0.055	4.06	0.041	4.47	0.067	−2.71	0.237	5.90	0.015
Operator	0.73	0.373	−0.18	0.713	−0.63	0.189	−1.14	0.061	−0.22	0.702	−0.11	0.847
Number of restored faces	−1.55	0.025	−1.13	0.018	−0.32	0.517	0.07	0.897	0.45	0.463	−1.06	0.053
Previous condition	1.38	0.124	0.35	0.516	−0.81	0.142	−0.39	0.592	−1.40	0.045	−0.35	0.606
Deep	−0.27	0.637	0.03	0.941	−0.54	0.112	0.16	0.689	0.13	0.734	−0.68	0.097
Previous dentin	0.45	0.617	−1.27	0.060	0.18	0.766	−1.00	0.213	0.14	0.848	0.83	0.245
Restorative time	0.15	0.904	0.13	0.854	0.37	0.587	−1.06	0.165	0.61	0.478	−2.59	0.002
Operator perception	−0.18	0.776	−0.32	0.509	0.29	0.555	0.60	0.373	1.30	0.116	0.51	0.384

they present similar percentage of filler particles (64.5% for ABF and 68% for XST), the monomers of Filtek Bulk Fill Flow present similar structure to conventional resins, while Surefil SDR has a patented monomer (SDR-UDMA) [33, 34]. A study comparing conventional resins to flowable and full-body bulk-fill composite resins, using tomography analysis, concluded that the flowable bulk-fill resins can promote an increased void in class II restorations, and it seems to be more related to voids present inside the syringe of the material than to the use of incremental or bulk-fill restorative techniques [35]. A clinical trial that evaluated the SDR bulk resin found one fractured restoration only after 5 years [21]. Furthermore, when partial retention occurs, both low and high-viscosity resin composites are amenable to successful repair using adhesives with functional monomers [36].

Regarding marginal integrity, no differences among the groups in all evaluations were found. Corroborating with this study, similarity in marginal adaptation among incremental and bulk-fill techniques after thermomechanical cycling was found using FDI criteria [37]. This fact maybe can be explained by the presence of enamel margins and the low modulus of elasticity of bulk materials, reducing the stresses generated by the polymerization contraction and, thereby, maintaining the marginal integrity [37, 38]. Another study comparing the same flowable bulk-fill composite resins used in our work showed similar polymerization shrinkage between them when performed analysis of microtomography in class II cavities [39]. Furthermore, a systematic review and meta-analysis of in vitro studies were observed that bulk fill composites had marginal integrity comparable to conventional resin composites with incremental techniques, corroborating with our study [40]. Clearly, the higher number of bravo scores begun at 1-year follow-up, since they kept statistically similar from 1 year until 4 years for PA and a statistical increase occurred for ABF and XST between 1 and 3 years, keeping similar to 4 years. In other study that compared conventional and bulk-fill composites in class II cavities, increased bravo scores were found only for conventional microhybrid composite at 2-years; however, the full-body Filtek Bulk Fill was used instead of the flowable version [11]. All restorative flowable bulk-fill systems also presented increased number of bravo scores after 2 years, but one of the flowable bulk-fill composite (ever X Posterior + G -aenial Posterior) had the double number of slight marginal unfitness than the other restorative system (SureFil SDR flow + Ceram.X mono) [12]. Durão et al. [14] indicated significant differences between all observation times for marginal adaptation (baseline, 12, and 36 months) when incremental and bulk-fill restorative systems were evaluated. One meta-analysis demonstrated that only marginal adaptation after 12 months showed statistically significant outcomes, in which conventional composites presented

significantly better results than resin composites containing modified monomers [7].

In relation to marginal discoloration, the differences among the performances of the resin composites became more evident after 4-year follow-up, where bulk restorative systems presented greater marginal discoloration than conventional one. When the percentage of restorations with marginal gaps for same three resin composites after artificial aging was studied, the conventional composite resin was superior regarding marginal gap formation in enamel than flowable bulk-fill resin composites [41]. Flowable bulk-fill composites also had a higher imperfect margins than full-body bulk-fill [39, 42] and conventional microhybrid composites in class II restorations performed in an in vitro study [42]. The viscosity of the bulk-fill restorative material also influenced the proportion of gap-free marginal interface in dentin [42].

However, in other clinical trials evaluating posterior restorations, no marginal discoloration was found in 100% and 89.2% restorations with flowable bulk-fill resin composite (Surefil SDR) at 3- and 6-year follow-up, respectively [21]. Furthermore, superior discoloration and marginal adaptation were found for conventional nanofill (Filtek Ultimate) compared to full-body bulk-fill composite (Tetric EvoCeram Bulk Fill) at 3 and 6 years [22, 28]. A superiority of the etch-and-rise adhesive technique was seen compared to self-etch approach for marginal discoloration in vivo and adaptation in vitro, irrespective of the composite used [13, 43]. Although adhesive systems present different compositions, in our study, phosphoric acid gel was applied for all groups. Furthermore, two operators performed the restorations with different time of clinical experience, reflecting the actual clinical practice, in those clinical trials [21, 28]. Only an operator performed all restorations may improve the results [1]. Decreased alpha scores for marginal discoloration occurred over time for all groups, corroborating with other studies which evaluated bulk resins [11–13, 21, 28].

The next three criteria that will be discussed involve the resins used as top layer. With regard to surface texture, ABF showed the lowest number of alpha scores at 4-year follow-up, probably due to the presence of the TEGDMA monomer, which has an aliphatic chain, being more susceptible to the constant challenges of the oral cavity, such as water absorption and when exposed to acid environment [44, 45]. Furthermore, PA and ABF presented a high number of bravo scores for wear and surface staining, since only TPH resin has no TEGDMA monomer in its composition [46]. All restorative systems studied had statistical differences for surface texture and wear over time; however, the resins used as top layer, which contain TEGDMA, had initial surface staining from 6-month.

Clinical literature evaluating the intensity of the proximal contacts of posterior flowable bulk resin composite

restorations in vivo is scarce. A recent study assessed the proximal contact of a full-body bulk-fill resin composite in class II restorations where all teeth restored with conventional and bulk resin had alpha score for this criterion after 2 years [11]. The current study also found no difference among the groups; however, all restorative system showed a decreased proximal contact over time, occurring early for XST. Manufacturers of both flowable bulk-fill composites studied recommend a 2-mm capping layer with a conventional composite resin; nonetheless, the bulk-fill composite may extend to reestablish the proximal contacts in a clinical situation. Algamaiah et al. [39] report that volumetric changes of flowable bulk-fill composites may compromise the precision of proximal contacts, leaving a space between adjacent teeth for food impaction. Van Ende et al. [47], in a review of the literature, suggested that a thicker consistency of bulk-fill composite might also help in obtaining a good contact point. Our findings showed that a mean of 1.9 was detected for all proximal contacts at baseline because the operators carefully observe if the contact was established after final curing.

According to the logistic regression analysis, some factors influenced the results, but the number of restored faces was the main factor because influenced three criteria: retention, marginal integrity and surface staining. Probably, higher volume of composite resins may promote an increase in the shrinkage stress, promoting greater chance of failure. This factor influenced the retention, marginal integrity, and surface staining. Polymerization shrinkage stress of resin-based materials has been related to several unwanted clinical consequences, such as marginal and internal gaps, and decreased bond strength [48].

Gingival floor of the proximal box and pulpal floor of the cavity had higher imperfect margin percentage than buccal and lingual walls of the proximal box [38]. In this study, radiographies were taken at all evaluation period to help in diagnosis when with only visual exam was not sufficient to define the scores. However, only standardized radiographies will be used in a future study, as well as clinical analysis with longer evaluation will be performed. New versions of a direct bulk fill resin composites should also be studied, such as short-fiber-reinforced resin composite which is indicated in large complex cavities [49] The limitations of this study included the inability to introduce blind operators and patient dropouts.

Conclusion

The restorative systems that used flowable bulk-fill resin composites showed satisfactory clinical performance compared with conventional resin composite after 4 years. However, the restorative systems with flowable bulk-fill resin composites presented initial marginal discoloration more

evident than conventional one. All restorative systems had decreased proximal contact until 4-year of clinical service.

Declarations

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