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Three-year Randomized Prospective Clinical Trial of Class II Restorations Using Flowable Bulk-fill Resin Composites

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Clinical Relevance

Initial marginal discoloration was observed more frequently in class II restorations performed using flowable bulk-fill resin composites. All restorative systems had decreased proximal contact strength over time.

SUMMARY

Objectives: This randomized, prospective, and split-mouth study aimed to evaluate flowable bulk-fill resin composites in class II restorations and to compare with a conventional layering technique after a 3-year follow-up.

Methods and Materials: Fifty-three subjects received three class II restorations according to the restorative systems: conventional microhybrid resin composite (PA, Peak Universal + Amelogen Plus, Ultradent), flowable bulk-fill and nanoparticulate resin composites (ABF, Adper Single Bond 2 + Filtek Bulk Fill Flow + Filtek Z350XT, 3M Oral Care), and flowable bulk-fill and microhybrid resin composites (XST, XP Bond + SDR + TPH3, Dentsply). The clinical performance and interproximal contacts were evaluated. Statistical

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analyses were performed using the equality test of two proportions, Logistic regression analysis, Friedman, Wilcoxon, Kruskal-Wallis, and Mann-Whitney tests (a=0.05).

Results: Forty-seven patients were evaluated at 3 years. XST bulk-fill restorative system presented higher marginal discoloration than PA, and the opposite occurred for surface staining. All restorative systems resulted in decreased interproximal contacts, occurring early for XST.

Conclusions: Although the restorative system using incremental technique presented better performance for marginal discoloration, one of the restorative systems that used flowable bulk-fill resin composite (XST) showed the lowest surface staining. All restorative systems had decreased proximal contact over time.

INTRODUCTION

Resin composites became the most employed material for restoration of dental elements and has also been used for replacement of unsatisfactory amalgam restorations or for esthetic reasons. The improvement of restorative adhesive systems has avoided the incidence of secondary caries and fracture.[1] To improve the success of these restorations, factors related to the patient and operator are fundamental.[1]

However, the main challenge for the professional is the correct technique required by this material. Another difficulty in direct resin composite restorations is the reconstruction of posterior large cavities, such as those involving the posterior proximal wall, to achieve adequate proximal contacts.[2] The literature recommends inserting the resin composite on the inner proximal surface of the matrix band, from gingival to occlusal, to minimize the c-factor, polymerization shrinkage, and formation of marginal gaps.[3,4] Another important factor is the amount of energy that must be supplied at the correct wavelengths to achieve a satisfactory degree of conversion of the resin material.[4] Furthermore, to achieve success of conventional resin composite, it is fundamental to use the 2-mm layering technique. However, the insertion of 2-mm increments and their correct light curing require more clinical time and patient discomfort. In this context, newer bulk-fill restorative resins allow the insertion of increments up to 4 mm, optimizing the clinical time and reducing the technique sensitivity by the professional.[5]

The bulk-fill composites have monomers with a high molecular weight to reduce the shrinkage stress.[6] The first generation of bulk-fill materials had flowable consistency, requiring a final increment with conventional composites.[7] Some clinical studies and meta-analysis demonstrated that bulk-fill composites have shown similar results to conventional resin composites until 6-year follow-up.[6,8-13] However, more randomized clinical trials (RCT) with longer periods are still necessary, as well as studies evaluating the maintenance of interproximal contact over time.

Thus, the main outcome of this RCT was to compare the clinical performance and interproximal contact of incremental resin composite and two flowable bulk-fill restorative systems. The null hypotheses tested were that there would be no difference between the three restorative systems for the clinical parameters and that there would be no differences for the same restorative strategy over time.

METHODS AND MATERIALS

Study Design

This clinical trial was a prospective, randomized, double-blind (volunteers and examiners), and split-mouth model. It was registered and conducted according to CONSORT guidelines (Figure 1). Three restorative systems were used: microhybrid conventional resin composite, considered the control group (PA, Peak Universal + Amelogen Plus, Ultradent, South Jordan, UT, USA); flowable bulk-fill and nanoparticulate resin composites (ABF, Adper Single Bond 2 + Filtek Bulk Fill Flow + Filtek Z350XT, 3M Oral Care, St Paul, MN, USA); and flowable bulk-fill and microhybrid resin composites, (XST, XP Bond + SDR + TPH3, Dentsply, Caulk Milford, DE, USA); the two latter restorative systems were considered as test groups.

Patient Selection

During the period from March to June 2015, all patients attending the undergraduate clinic who needed three class II restorations were asked to participate in the study.

The sample power for two proportions, 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 with minimum depth of 3 mm in permanent premolar or molar with an adjacent tooth, patients with good periodontal health, and patients with no clinical history of allergies to dental products. The exclusion criteria were pregnant or lactating women, patients receiving orthodontic treatment, a tooth without an antagonist, and endodontically treated teeth.

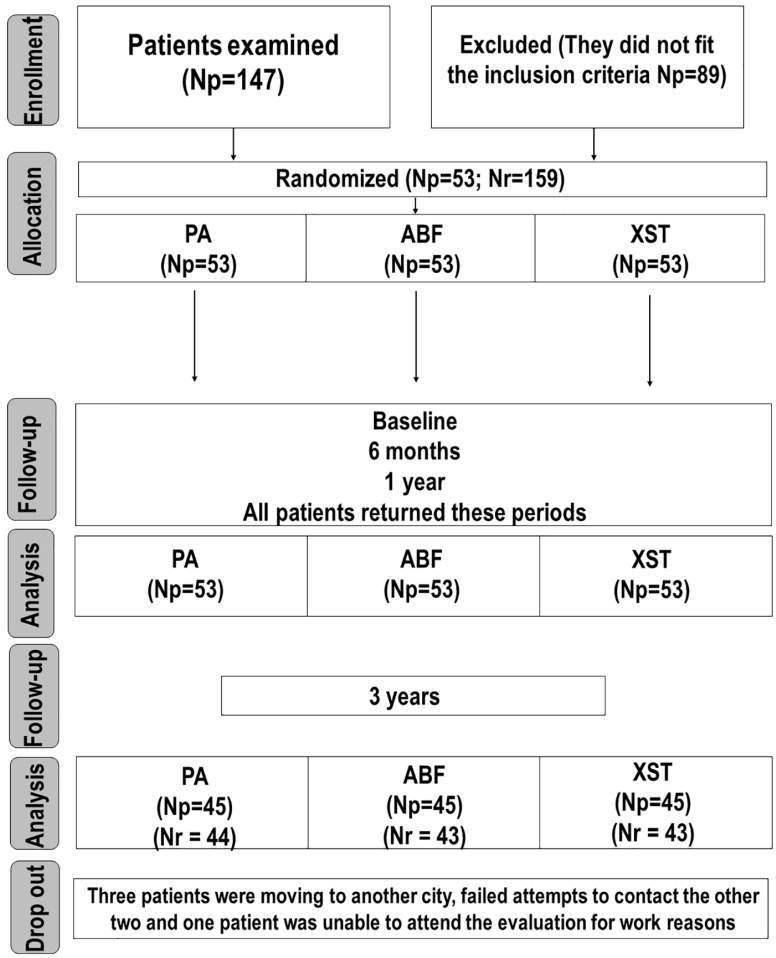

Figure 1. *Flowchart of patients. Abbreviations: ABF, Adper Single Bond 2 + Filtek Bulk Fill Flow + Filtek Z350XT; Np, number of patients; Nr, number of restorations; PA, Peak Universal + Amelogen Plus; XST, XP Bond + SDR + TPH3.*

Fifty-three subjects were selected from the local undergraduate clinic, and patients were submitted to clinical and radiographic examination after signing the informed consent.

Calibration and Randomization

Two calibrated operators (residents), with clinical experience 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 in patients not selected for the research. The operators were identified on the procedure sheets. Visible plaque index; gingival bleeding index; and decayed, missing and filled teeth index were assessed at baseline. The subjects then received oral hygiene instructions, and initial photographs were taken.

All subjects received local anesthesia prior to restorative procedures. 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 in the same clinical appointment.

Restorative Procedures

The complete restorative procedures have been described in our previous study.[14] The cavity preparations were performed using round diamond burs (#1015-1017; KG Sorensen, Barueri, SP Brazil). When there was carious tissue, smooth round carbide burs (#1/2-4, Dentsply-Maillefer, Ballaigues, Switzerland) were also used in slow-speed handpiece. Isolation of the operative field was performed with a rubber dam. A probe with one side being a periodontal tip was used to measure the deeper region of the cavity.

Then, 35% phosphoric acid gel (Ultra-etch, Ultradent Products Inc) was used for 30 seconds on enamel and 15 seconds on dentin for all groups. Subsequently, adhesive systems and restorative materials were applied,

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	Dental surfaces were rinsed thoroughly for 5 seconds and lightly dried using the air/water syringe. The adhesive was applied with a microbrush by rubbing on the cavity for 10s. Adhesive was air dried for 10s and photoactivated for 10s.[a]
	Amelogen Plus		Organic matrix: Bis-GMA, TEGDMA. Filler: silica dioxide and silicate particles (76% wt)	Oblique 2-mm increments were inserted and photoactivated for 20s. The last increment was photoactivated for 40s.[b]
Test ABF	Adper Single Bond 2	3M Oral Care Dental Products TM (St Paul, MN, USA)	Water, ethanol, Bis-GMA, HEMA, UDMA, bisphenol A glycerolate, sílica nanofillers treated with acid copolimer, dimetacrylate	Dentin was left slightly moist. The adhesive was applied with a microbrush and air dried for 5s. A second layer of the adhesive was applied and air dried for 5s. Photoactivation was performed for 20s.[c]
	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 40s. Material was kept 2 mm below the occlusal margin.[d]
	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 20s and the last increment for 40s.[e]

Abbreviations: ABF, Adper Single Bond 2 + Filtek Bulk Fill Flow + Filtek Z350XT; Bis-EMA, bisphenol A ethoxylate methacrylate; Bis-GMA, bisphenol A glycidyl methacrylate; CQ, camphorquinone; EBPADMA, bisphenol A ethoxylated dimethacrylate; EDAB, ethyl-4-dimethylamino benzoate; PA, Peak Universal + Amelogen Plus; TEGDMA, triethylene-glycol dimethacrylate; UDMA, urethane dimethacrylate; XST, XP Bond + SDR + TPH3.

[a] *https://downloads.ctfassets.net/wfptrcrbtkd0/720cc075-a5d8-4113-8f12-8c58a6c9c80b/212e0f1d907a848f628f3b5e8b361593/Peak_Universal_BondBottle_-Peak_SE.pdf*

[b] *https://assets.ctfassets.net/wfptrcrbtkd0/7d495004-256c-4100-9c4d-bedb272215f4/434abf25dddd417d033c0c3a14da67e6/Amelogen_Plus_Singles.pdf*

[c] *https://multimedia.3m.com/mws/media/276868O/adper-single-bond-2-technical-profile.pdf*

[d] *https://multimedia.3m.com/mws/media/792321O/filtek-bulk-fill-flowable-restorative-technical-product-profile.pdf*

[e] *https://multimedia.3m.com/mws/media/631547O/filtek-z350-xt-technical-product-profile.pdf*

Table 1: *Products (Material, Manufacturer, Composition and Mode of Application) Used in this Study (cont.)*				
Test XST	XP Bond2	DENTSPLY (Caulk Milford, DE, USA)	PENTA, UDMA, dimethacrylate modified by carboxilic acid (TCB resin), triethileneglycol dimethacrylate, hydroxyethylmethacrylate, canphoroquinone, ethyldimethylaminebenzoato, 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 20s, air dried for 5s, and photoactivated for 20s.[f]
	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 40s.[g]
	TPH3		Organic matrix: Bis-GMA, 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 20s. The last increment was photoactivated for 40s.[h]

[f] *https://media.dentalcompare.com/m/25/Downloads/XP%20Bond%20Universal%20Total%20Etch%20Adhesive%20Directions%20for%20Use.pdf*

[g] *https://assets.dentsplysirona.com/flagship/en/explore/restorative/sdr_flow_plus_eu-version/SM%20SDR%20FlowPlus%20V01%202017-12-08.pdf*

[h] *https://www.dentsply.de/directions-for-use?ifufile=SpectrumTPH3_IFU.pdf*

following the recommendations of the respective manufacturers. Table 1 presents the specifications for each group.

To restore the shape of proximal walls, wooden wedges, preformed metal matrices, and rings (Unimatrix sectional matrix system, TDV Dental Ltda, Pomerode, SC, Brazil) were used. Adhesive and resin composites were light-cured with a curing light (Valo, Ultradent Products Inc), in the standard application mode and an output of 1000 mW/cm^2. In the experimental groups, the top layer was standardized with a 2-mm capping layer with a conventional composite resin. When the height of the proximal cavity was greater than 4 mm, the bulk-fill resin was inserted in two layers. Fine and ultrafine diamond burs (#1190F, 3118F, 1190FF, 3118FF; KG Sorensen, Cotia, SP, Brazil) were used to finish the restorative procedures. All restorations were polished with polishing points (Jiffy, Ultradent Products Inc).

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 one side with explorer tip.

After 3-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

Table 2: *Modified USPHS Criteria Rating System for Clinical Evaluation of the Restorations*
Retention
Alpha (A): Presence of the restoration Bravo (B): Partial absent of the retention, less than one-third of the restoration Charlie (C): More than one-third or total absent of the retention
Marginal Integrity
Alpha (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
Alpha (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
Alpha (A): Smooth and shiny, similar to enamel Bravo (B): Slightly rough Charlie (C): High roughness, not reflective
Wear
Alpha (A): No wear, continuous interface Bravo (B): Discontinuous interface, no exposed dentin Charlie (C): Discontinuous interface, exposed dentin
Secondary Caries
Alpha (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
Alpha (A): The restoration presents continuity with the anatomical form of the existing tooth. Bravo (B): The restoration has a slight overcontour or undercontour. Charlie (C): There is loss of restorative material leading to exposure of dentin and/or base.
Surface Staining
Alpha (A): Absent Bravo (B): Present
Color
Alpha (A): Nonapparent interface with the tooth Bravo (B): Subtle visualization between tooth and restoration Charlie (C): Clear visualization between tooth and restoration
Gingival Tissue
Alpha (A): No inflammation Bravo (B): Mild inflammation Charlie (C): Severe inflammation
Abbreviations: USPHS, United States Public Health Service.

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.[15] 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 evaluators. 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.

The Hosmer-Lemeshow test was applied to evaluate the efficacy of the logistic regression model. Logistic regression analysis was performed to predict the probability of total success (alpha score) of the clinical performance results at 3 years, using the characteristics cited in Table 3. All tests were performed at a significance level of 0.05%.

RESULTS

The mean age of the 53 subjects was 48.3 (±10.0) years. A total of 65 molars and 94 premolars were restored (159 restorations). The characteristics of preparations and restorative procedures are described in Table 3. Forty-seven (88.6%) subjects and 130 restorations were evaluated at 3-year follow-up.

Table 3: *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
Depth of the cavity	3 mm	29	12	9	8
	≥4 mm	61	17	19	25
	≥5 mm	69	24	25	20
Previous dentin before restoration	Normal	34	10	15	9
	Sclerotic	125	43	38	44
Anesthesia	Yes	156	52	52	52
	No	3	1	1	1
Restorative time	≤10 min	133	43	45	45
	≤20 min	26	10	8	8
Operator perception	Easy	113	39	38	36
	Medium	38	13	12	13
	Difficult	8	1	3	4

Abbreviations: ABF, Adper Single Bond 2 + Filtek Bulk Fill Flow + Filtek Z350XT; PA, Peak Universal + Amelogen Plus; XST, XP Bond + SDR + TPH3.

There was statistically significant agreement among evaluators at the periods analyzed ($p<0.001$), showing an excellent Kappa agreement (baseline=0.79, 6 months=0.91, 1 year=0.89, 3 years=0.92).

Data from the USPHS criteria are presented in Table 4. All failure data were accumulated even if the patient did not return at the evaluation. Also, in the first evaluation in which the restoration failed, all other criteria were evaluated if possible; however, only the criterion that failed was considered at following evaluations.

Concerning the analysis between groups, statistically greater marginal discoloration was observed for XST compared to PA; the opposite occurred for surface staining. The ABF group was similar to other restorative systems for those two criteria. No differences were found between groups for other criteria.

When comparing the evaluation periods for each group, no statistically significant difference was found for secondary caries, anatomical form, and gingival tissue for all groups. Other criteria had decreased alpha score at 3 years, except for retention (XST) and color (ABF and XST). Representative images from each group can be seen in Figure 2.

Data on interproximal contacts are shown in Table 5. There was no significant difference between groups. However, all restorative systems resulted in decreased interproximal contacts, occurring from 1 year for XST.

The probability of success was influenced by the number of tooth surfaces involved in the restoration and the presence of sclerotic dentin for marginal integrity. The same was observed for cavity depth and operator for marginal discoloration.

Table 4: *Clinical Evaluation of Resin Composite Restorations (USPHS)*[a]

Category	**Groups**	**Baseline**[b]	**6 Months**[b]
Retention	PA	100% (53-A/0-B/0-C) Aa	98.1% (52-A/1-B/0C) Aab
	ABF	100% (53-A/0-B/0-C) Aa	100% (53-A/0-B/0-C) Aa
	XST	100% (53-A/0-B/0-C) Aa	100% (53-A/0-B/0-C) Aa
Marginal integrity	PA	100% (53-A/0-B/0-C) Aa	92.5% (49-A/4-B/0-C) Ab
	ABF	100% (53-A/0-B/0-C) Aa	94.3% (50-A/3-B/0-C) Aa
	XST	100% (53-A/0-B/0-C) Aa	94.3% (50-A/3-B/0-C) Aa
Marginal discoloration	PA	98.1% (52-A/1-B/0-C) Aa	98.1% (52-A/1-B/0-C) Aa
	ABF	98.1% (52-A/1-B/0-C) Aa	83.0% (44-A/9-B/0-C)Bb
	XST	100% (53-A/0-B/0-C) Aa	96.2% (51-A/2-B/0-C) Aa
Surface texture	PA	100% (53-A/0-B/0-C) Aa	100% (53-A/0-B/0-C) Aa
	ABF	100% (53-A/0-B/0-C) Aa	98.1% (52-A/1-B/0-C) Aa
	XST	100% (53-A/0-B/0-C) Aa	98.1% (52-A/1-B/0-C) Aa
Wear	PA	100% (53-A/0-B/0-C) Aa	100% (53-A/0-B/0-C) Aa
	ABF	100% (53-A/0-B/0-C) Aa	100% (53-A/0-B/0-C) Aa
	XST	100% (53-A/0-B/0-C) Aa	98.1% (52-A/1-B/0-C) Aab
Secondary caries	PA	100% (53-A/0-C) Aa	100% (53-A/0-C) Aa
	ABF	100% (53-A/0-C) Aa	100% (53-A/0-C) Aa
	XST	100% (53-A/0-C) Aa	100% (53-A/0-C) Aa
Anatomical form	PA	98.1% (52-A/1-B/0-C) Aa	98.1% (52-A/1-B/0-C) Aa
	ABF	100% (53-A/0-B/0-C) Aa	100% (53-A/0-B/0-C) Aa
	XST	100% (53-A/0-B/0-C) Aa	100% (53-A/0-B/0-C) Aa
Surface staining	PA	100% (53-A/0-B) Aa	96.2% (51-A/2-B) Ba
	ABF	100% (53-A/0-B) Aa	86.8% (46-A/7-B) Bb
	XST	100% (53-A/0-B) Aa	100% (53-A/0-B) Aa
Color	PA	71.7% (38-A/13-B/2-C) Ba	75.5% (40-A/12-B/1-C) Ba
	ABF	92.5% (49-A/3-B/1-C) Aa	90.6% (48-A/4-B/1-C) Aa
	XST	92.5% (49-A/4-B/0-C) Aa	94.3% (50-A/3-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
	ABF	96.2% (51-A/2-B/0-C) Aa	98.1% (52-A/1-B/0-C) Aa
	XST	100% (53-A/0-B/0-C) Aa	98.1% (52-A/0-B/1-C) Aa

Table 4: *Clinical Evaluation of Resin Composite Restorations (USPHS) (cont.)*[a]

Category	Groups	1 Year[b]	3 Years[b]
Retention	PA	94.3% (50-A/2-B/1-C) Aab	91.5% (43-A/1-B/3-C) Ab
	ABF	98.1% (52-A/0-B/1-C) Aa	87.0% (40-A/3-B/3-C) Ab
	XST	96.2% (51-A/0-B/2-C) Aa	95.6% (43-A/0-B/2-C) Aa
Marginal integrity	PA	71.7% (38-A/15-B/0-C) Ac	56.8% (25-A/18-B/1-C) Ac
	ABF	73.6% (39-A/14-B/0-C) Ab	58.1% (25-A/16-B/2-C) Ab
	XST	83.0% (44-A/9-B/0-C) Ab	67.4% (29-A/13-B/1-C) Ab
Marginal discoloration	PA	73.6% (39-A/14-B/0-C) Ab	68.2% (30-A/14-B/0-C) Ab
	ABF	73.6% (39-A/14-B/0-C) Ac	55.8% (24-A/17-B/2-C) ABc
	XST	77.4% (41-A/12-B/0-C) Ab	44.2% (19-A/23-B/1-C)Bc
Surface texture	PA	96.2% (51-A/2-B/0-C) Aab	90.9% (40-A/4-B/0-C) Ab
	ABF	94.3% (50-A/3-B/0-C) Aa	79.1% (34-A/9-B/0-C) Ab
	XST	92.5% (49-A/4-B/0-C) Aab	81.4% (35-A/8-B/0-C) Ab
Wear	PA	98.1% (52-A/1-B/0-C) Aa	75% (33-A/11-B/0-C) Ab
	ABF	98.1% (52-A/1-B/0-C) Aa	76.7% (33-A/10-B/0-C) Ab
	XST	98.1% (52-A/1-B/0-C) Aab	90.7% (22-A/9-B/0-C) Ab
Secondary caries	PA	100% (53-A/0-C) Aa	100% (44-A/0-C) Aa
	ABF	98.1% (52-A/1-C) Aa	97.7% (43-A/1-C) Aa
	XST	98.1% (52-A/1-C) Aa	95.6% (43-A/2-C) Aa
Anatomical form	PA	98.1% (52-A/1-B/0-C) Aa	97.7% (43-A/1-B/0-C) Aa
	ABF	98.1% (52-A/1-B/0-C) Aa	97.6% (42-A/1-B/0-C) Aa
	XST	100% (53-A/0-B/0-C) Aa	100% (43-A/0-B/0-C) Aa
Surface staining	PA	84.9% (45-A/8-B) Ab	63.6% (28-A/16-B) Bc
	ABF	66.0% (35-A/18-B) Bc	67.4% (29-A/14-B) ABc
	XST	94.3% (50-A/3-B) Aab	83.7% (36-A/7-B) Ab
Color	PA	84.9% (45-A/8-B/0-C) Ba	95.5% (42-A/2-B/0-C) Ab
	ABF	92.5% (49-A/4-B/0-C) Ba	95.3% (41-A/2-B/0-C) Aa
	XST	96.2% (51-A/2-B/0-C) Aa	97.7% (42-A/1-B/0-C) Aa
Gingival tissue	PA	96.2% (51-A/1-B/1-C) Aa	100% (44-A/0-B/0-C) Aa
	ABF	96.2% (51-A/2-B/0-C) Aa	100% (43-A/0-B/0-C) Aa
	XST	98.1% (52-A/1-B/0-C) Aa	100% (43-A/0-B/0-C) Aa

Abbreviations: ABF, Adper Single Bond 2 + Filtek Bulk Fill Flow + Filtek Z350XT; PA, Peak Universal + Amelogen Plus; USPHS, US Public Health Service; XST, XP Bond + SDR + TPH3.
[a]*Percentage values of A score and numbers of A, B, and C scores in parentheses, respectively.*
[b]*Different letters represent statistical differences (*p<*0.05). Uppercase letters compare different restorative systems, and lowercase letters compare evaluation periods.*

DISCUSSION

The present study represents a prospective, randomized, double-blind, and split-mouth clinical trial, allowing analysis of the test and control groups under the same conditions, increasing the statistical efficiency and decreasing the number of patients required for the study.[16] Furthermore, the distribution of restorations (maximum of three pairs in the same patient) is in accordance to the American Dental Association guidelines when testing a new material.[17] The number of 159 restorations in the present study was superior to that estimated by van Dijken and others,[9] allowing to determine significant differences between groups treated with distinct materials in similar evaluations of intra-individual comparison design with a power of 98.3%. In addition, 138 restorations were evaluated at the 3-year follow-up, maintaining the possibility of detection of statistical differences between groups.

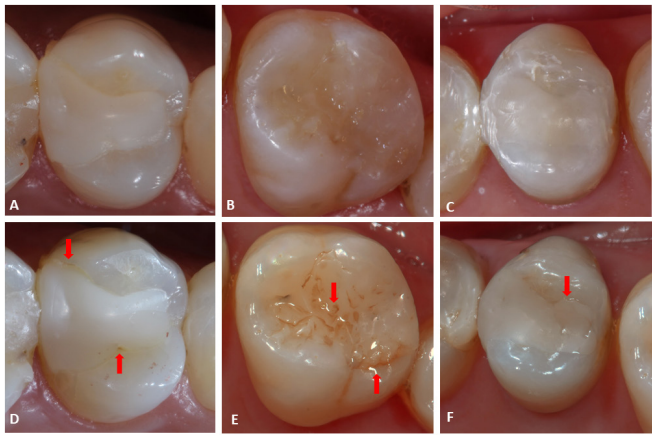

Figure 2. *Representative clinical images from all groups. (A): First premolar of the PA group with alpha scores for all criteria at baseline. (B): First molar of the ABF group with alpha scores for all criteria at baseline. (C): Second premolar of the XST group with alpha scores for all criteria at baseline. (D): First premolar representative of the PA group with bravo scores for only marginal integrity and marginal discoloration as pointed with arrows, at 3-year follow-up. (E): First molar of the ABF group with bravo scores for only marginal discoloration and surface staining as pointed with arrows, at 3-year follow-up. (F): Second premolar of the XST group with bravo scores for only marginal integrity as pointed with arrows, at 3-year follow-up.*

The method used for the performance of restorations was USPHS, commonly used in several clinical trials,[9,11,12,18,19] although there are other criteria for the clinical evaluation of restorations, such as those used by the World Dental Federation (FDI criteria).[13] It is worth mentioning that the kappa test revealed increased and excellent agreement between the evaluators over time.

These resin composites were selected to compare the clinical behavior of conventional resin using incremental technique and flowable bulk-fill resin composites. Retention, marginal integrity, and marginal discoloration are directly related to the stress produced at the tooth/restoration interface, which may be influenced by the cavity geometry, adhesive systems, viscosity of restorative materials, and placement technique.[19]

Concerning retention, no statistical difference between conventional resin composite and bulk-fill resin composites was found; however, the XST group presented two charlie scores after 1-year follow-up, and three bravo and three charlie scores were found for the ABF group at 3-year follow-up. A clinical trial that evaluated the SDR bulk resin found one fractured restoration only after 5 years.[9] In the case of bulk-fill resin composites, although 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).[20,21] A study comparing conventional resins to flowable and full-body bulk-fill resin composites, by tomography analysis, concluded that flowable bulk-fill resins can promote increased voids in class II restorations, and this appears to be more related to voids present inside the material syringe than to the use of incremental or bulk-fill restorative techniques.[22]

Regarding marginal integrity, there were no differences between groups in all evaluations. Corroborating with this study, similarity in marginal adaptation among incremental and bulk-fill techniques after thermomechanical cycling was found using FDI criteria.[23] This fact can probably be explained by the presence of enamel margins and the low modulus of elasticity of bulk materials, reducing the stresses generated by the polymerization shrinkage and thus maintaining the marginal integrity.[23,24] Another study comparing the same flowable bulk-fill resin composites used in this study showed similar polymerization shrinkage between them using microtomography in class II cavities.[25] It was evident that the higher number of bravo scores began at 6-month follow-up, and statistical increase occurred at 1 and 3 years for the PA group, or ABF and XST groups began at 1 year and remained statistically similar between 1 and 3 years. In another study comparing 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 an increased number of bravo scores after 2 years, but one of the flowable bulk-fill composite (everX Posterior + G-aenial Posterior) had twice as much slight marginal misfits than the other restorative system (SureFil SDR flow + Ceram.X mono).[12]

In relation to marginal discoloration, the differences between performances of the resin composite systems became more evident after 3 years, where XST presented greater marginal discoloration than the conventional. When the percentage of restorations with marginal gaps for the same three resin composites after artificial ageing was studied, the conventional resin composite may be superior regarding marginal gap formation in enamel than flowable bulk-fill resin composites.[26] Flowable bulk-fill composites also had more imperfect margins than the full-body bulk-fill[25,27] and conventional microhybrid composites in class II restorations performed in an *in vitro* study.[27] The viscosity of the bulk-fill restorative material also influenced the proportion of gap-free marginal interface in dentin.[28] One meta-analysis demonstrated that only marginal adaptation after 12 months showed

Table 5: *Means (SD) of the Interproximal Contacts for Groups and Evaluation Periods*[a]

Groups	Evaluation Periods			
	Baseline	6 Months	1 Year	3 Years
PA	*1.92 (0.51) Aa*	*1.87 (0.48) Aa*	*1.79 (0.49) Aa*	*1.48 (0.59) Ab*
ABF	*1.85 (0.45) Aa*	*1.79 (0.41) Aa*	*1.79 (0.41) Aa*	*1.55 (0.69) Ab*
XST	*1.94 (0.41) Aa*	*1.83 (0.38) Aa*	*1.73 (0.44) Ab*	*1.54 (0.64) Ac*

Abbreviations: ABF, Adper Single Bond 2 + Filtek Bulk Fill Flow + Filtek Z350XT; PA, Peak Universal + Amelogen Plus; XST, XP Bond + SDR + TPH3.

[a]*Uppercase letters compare groups within a same evaluation period (columns), and lowercase letters compare the periods of each group individually (lines).*

statistically significant outcomes in which conventional composites presented significantly better results than resin composites containing modified monomers.[6]

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;[9] 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 years.[18] A superiority of the etch-and-rinse adhesive technique was seen compared to self-etch approach for marginal discoloration *in vivo* and adaptation *in vitro*, irrespective of the composite used.[13,29] It is important to emphasize that in our study, phosphoric acid gel was applied for all groups. Furthermore, the two operators performing the restorations had different times of clinical experience, reflecting the actual clinical practice; however, in those clinical trials,[9,18] only one operator performed all restorations, improving the results.[1] Decreased alpha scores for marginal discoloration occurred over time for all groups, corroborating other studies in which bulk resins were evaluated.[9,11-13,18]

The next criteria that will be discussed involve the resins used as the top layer. PA and ABF presented a high number of bravo scores for surface staining, since only TPH resin does not include tryethylene glycol dimethacrylate (TEGDMA) monomer in its composition.[30,31,32] The presence of the TEGDMA monomer, which has an aliphatic chain, increases the susceptibility to the constant challenges of the oral cavity, such as water absorption and acid environment.[30,31] Furthermore, all restorative systems studied had statistical differences for surface texture and wear over time; however, one of the resins used as the top layer, which contains TEGDMA, had initial surface staining from 6 months.

The literature is scarce in clinical work evaluating the intensity of proximal contacts of posterior flowable bulk resin composite restorations. Only one 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 between groups; however, all restoratives showed 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; however, the bulk-fill composite may extend to reestablish the proximal contacts in a clinical situation. Therefore, it is difficult to state which type of resin the proximal contact was established clinically. Algamaiah and others[25] 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. Our findings showed that a mean of 1.9 was detected for all proximal contacts at baseline because the operators carefully observed if the contact was established after final curing. It is important to highlight that, if the patient complained about food impaction, the restoration was classified as 0 score and was repaired.

According to the logistic regression analysis, some factors influenced the results. The number of restored surfaces influenced the marginal integrity, and the depth of cavities influenced the marginal discoloration. It is known that the greater the volume of material, the greater the shrinkage, contributing to increasing the chance of failures in the margins.[33] Presence of sclerotic dentin also affected the marginal integrity, since it can reduce the bond strength,[34] interfering with marginal integrity. The operator with 1 year of experience had 40 restorations classified with alpha score, while the operator with 19 years of experience had 33 restorations with the same score. It is speculated that the younger operator would be more updated than the other, mainly about the care during evaporation of the adhesive solvent. Technique-related aspects of a posterior restoration rely on the knowledge and sufficient skills of the operator.[1]

A limitation of the present study is the greater extension of cavities with very thin remaining cusps for many teeth. Additionally, the proximal contact strength is not a constant value and can be affected by a variety of factors, such as patient position and time of day.[35] Then, future studies are necessary to evaluate the accuracy of clinician evaluation of interproximal contacts after bulk restorations using different methods, such as with the use of a shim stock.[36] It is also important to highlight that the gingival floor of the proximal box and pulpal floor of the cavity had higher imperfect margin percentage than the buccal and lingual walls of the proximal box.[27] In the current study, radiographs were taken at all evaluation periods to help the diagnosis when visual examination only was not sufficient to define the scores. However, only standardized radiographs will be used in a future study, and clinical analysis with a longer evaluation period will be performed.

CONCLUSION

Although the restorative system using incremental technique presented better performance for marginal discoloration, one of the restorative systems that used flowable bulk-fill resin composite (XST) showed the lowest surface staining. All restorative systems had decreased proximal contact after 3 years.

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Regulatory Statement

This study was conducted in accordance with all provisions of the human subjects oversight committee guidelines and local institutional review boards. The approval code for this study is 1.235.100.

Conflicts of Interest

The authors of this article certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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