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Short-term effect of adhesive system on clinical performance of bulk fill composite: randomized clinical trial

Vanessa Cristiane Araújo Oliveira[1], Fernanda Piana Santos Lima de Oliveira[2], Claudia Silami Magalhães[3], Fabíola Belkiss Santos de Oliveira[4], Isabella Pereira Marques[4], Mayara dos Santos Noronha[5], João Gabriel Silva Souza[5,6*], Daniela Araújo Veloso Popoff[1,2]

[1] State University of Montes Claros, Montes Claros, Brazil.

[2] Dental School, Pitágoras Integrated Colleges, Montes Claros, MG, Brazil.

[3] School of Dentistry, Federal University of Minas Gerais, Belo Horizonte, Brazil.

[4] Dental School, United Colleges of Northern Minas (FUNORTE), Brazil.

[5] Dental Science School (FCO), Montes Claros, Brazil.

[6] Dental Research Division, Guarulhos University, Guarulhos, Brazil.

Corresponding author:
João G. S. Souza, Dental Research Division, Guarulhos University. Praça Tereza Cristina, 88 - Centro – Guarulhos, São Paulo, Brazil. 07023-070
E-mail: jgabriel.ssouza@yahoo.com.br

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Aim: Although bulk fill composites have been widely used as restorative material, there is no consensus regarding the best clinical protocol in terms of composite technique and adhesive system. Therefore, this clinical trial evaluated the clinical performance of bulk fill composites for class I restorations under different protocols. **Methods:** A randomized clinical trial including 155 class I restorations was conducted using different adhesive systems: conventional technique (phosphoric acid + conventional three-step adhesive system) (Group 1, 2 and 3); or self-etching adhesive system (Groups 4, 5 and 6). Control groups 1 and 4 were restored with conventional composite; groups 2 and 5 with low viscosity bulk fill and conventional composite as occlusal coverage; groups 3 and 6 with high viscosity bulk fill. The FDI criteria was used for clinical evaluation at baseline and after 6 months. **Results:** All groups showed good clinical performance. At baseline, the adhesive system did not affect postoperative hypersensitivity. After 6 months, group 5 showed a significant reduction in color and translucency; group 6 a reduction in terms of anatomical form and for postoperative sensitivity and an improvement in patient satisfaction ($p<0.05$). Considering the same restorative technique, the use of the self-etching adhesive system showed a significant decrease in color and translucency ($p<0.05$). **Conclusion:** All groups showed favorable clinical performance, and promising results were found for the conventional adhesive system and high viscosity bulk fill protocol.

Keywords: Composite resins. Phosphoric acids. Adhesives. Dental restoration, permanent. Esthetics, dental. Clinical studies as topic.

Introduction

The improvement of dental materials, as well the increased demand for esthetic treatments by patients, have improved the development of less invasive restoration techniques and the use of composites with enhanced biomechanical and esthetic properties[1-3], even for posterior teeth[4]. However, the polymerization shrinkage and the development of stress in the tooth-restoration interface, still being an important clinical problem that can degrade the adhesive layer, create cracks, and, consequently lead to treatment failure[5]. In this sense, different incremental techniques have been developed to reduce the material shrinkage[6,7]. Although an increment thickness of 2 mm of composite has been suggested for tooth restoration to reduce this effect[4], this approach can increase the clinical time[8]. Therefore, to reduce the polymerization shrinkage effect different materials and techniques have been suggested, among them, bulk fill composites[4].

Bulk fill composites have been widely used for tooth restoration and shown enhanced translucence and polymerization properties compared to conventional composites, allowing the use of a single increment (4–5 mm). These properties reduce clinical time and the polymerization shrinkage stress[9,10]. Modifications in the organic matrix of bulk fill composites, such as monomers with higher molecular weight and the size of particles, explain these advantages[9,11].

These composites are available in two forms: low (flow) and high viscosity, in terms of organic matrix composition[12]. Overall, clinical trials have compared the use of bulk fill and conventional composites showing similar clinical performance for both materials[13], but with a better marginal adaptation for bulk fill material[4]. However, different clinical protocols have been tested by these studies, and differences in the experimental designs make it hard to compare between the materials and techniques used. Although bulk fill composites have been evaluated by long-term clinical studies[14-16], there is no consensus regarding the optimal clinical protocol, as well as the effect of the adhesive system in the clinical performance of this material[16]. Previous studies evaluated the use of high viscosity bulk fill restorations under different adhesive systems[16-18]. However, to the best of our knowledge, no study compared the short-term effect of different adhesive systems under different clinical protocols, considering the bulk fill form (low and high viscosity) and conventional composites under the same technique. Therefore, the present randomized clinical trial evaluated the clinical performance of low and high viscosity bulk fill composites for class I restorations, compared to conventional composites, and under different adhesive systems. The hypothesis is that the adhesive does not affect the clinical performance.

Materials and Methods

Ethical Aspects

This study was approved by the local Ethics Committee (CAAE 96708418.5.0000.5109) and registered and approved by the Brazilian Clinical Trials Registry (ReBec) (Protocol RBR-2h9qkd), being conducted according to CONSORT guidelines.

Trial Design

This is a prospective, double-blind, controlled, and randomized clinical trial.

Participants

The restoration was the experimental unit. For sample calculation, a 50% difference between the groups was considered, a power (1 - β) = 0.90 and a type I error (α) = 0.05, totaling 155 experimental units (more than 22 units per group was considered), resulting in a minimum increase of 15% in the pre-defined n for each group.

Patients (35) were chosen from a dental clinic school and met the inclusion criteria described by Marques et al.[19] (2018), exhibiting the need for class I restorations and/or restoration replacement considering the assessment in score 5 (Clinically poor: Fédération Dentaire Internationale - FDI) in at least one of the FDI criteria[20]. The same patients received more than one treatment according to clinical necessity.

Patients with physiological limitations that contraindicated dental treatment were excluded from the study[19]. Eligible patients were checked for visible plaque index (IPV) and submitted to oral hygiene instructions (IHO) and diet. All the included teeth received a professional cleaning before the restoration protocol.

Randomization and Intervention

A sequence of random numbers was generated by MS Excel software (Microsoft Corp, Redmond, Wash., USA) to assign each experimental unit to treatment groups according to the randomization list generated. The experimental units were randomized and submitted to the restorative procedures listed below:

Group 1 (control 1): 37% phosphoric acid etching + Conventional adhesive system (Adper Scotchbond Multipurpose Adhesive) + Restoration with conventional nanoparticulated composite resin by incremental technique (Filtek Z350 XT).

Group 2: 37% phosphoric acid etching (Maquira®) + Conventional adhesive system (Adper Scotchbond Multipurpose Adhesive – 3M) + Restoration with low viscosity bulk fill composite resin (Filtek Bulk fill Flow – 3M) as a single increment base + conventional nanoparticulate composite resin (Filtek Z350 XT – 3M) by incremental technique for occlusal coverage.

Group 3: 37% phosphoric acid etching (Maquira®) + Conventional adhesive system (Adper Scotchbond Multipurpose Adhesive – 3M) + Restoration of high viscosity bulk fill composite resin by a single increment (Filtek One Bulk fill – 3M).

Group 4 (control 2): Self-etching adhesive system (Single Bond Universal – 3M; multi-mode) + Restoration with conventional nanoparticulated composite resin by incremental technique (Filtek Z350 XT – 3M).

Group 5: Self-etching adhesive system (Single Bond Universal - 3M) + Restoration with low viscosity bulk fill composite resin (Filtek Bulk fill Flow – 3M) as a single increment base + conventional nanoparticulate composite resin (Filtek Z350 XT – 3M) by incremental technique for occlusal coverage.

Group 6: Self-etching adhesive system (Single Bond Universal – 3M) + Restoration of high viscosity bulk fill composite resin by a single increment (Filtek One Bulk fill – 3M).

The cavity depth (≈3–5 mm) was measured using a millimeter probe. All restorations protocols were conducted according to the manufacturer's recommendations for each restorative material and performed by three calibrated blinded dentists[19]. The dentists were calibrated by an expert in this field with more than 20 years of experience in Operative Dentistry and conducting clinical trials. For the clinical protocol, the composite increments were inserted in an oblique direction; the conventional technique used 2 mm increments; bulk fill composites only one increment. Furthermore, a photoactivation (EC 450 ECEL® - ≥900 mW/cm^2 or VALO® Fotopolimerizador Curing Light Shield – Ultradent - 1000 mW/cm^2) also followed each composite and adhesive manufacturer's recommendation regarding the application and photoactivation time (in a range of 10–20 seconds). Immediately after performing the restorations, occlusal adjustment was conducted and the finishing and polishing were performed with a 9714FF® carbide burr (KG Sorensen) and Enhance® system (Dentsply) 7 days after the restorative procedure[19].

Clinical evaluation

Clinical evaluations at baseline (after polishing) and after 6 months were performed by two calibrated dentists using items from the FDI criteria[20]. Divergences between examiners about the assessments were reviewed and a consensus was reached through discussion among them.

To assess postoperative hypersensitivity, a pain scale numbered from 0 to 10 was applied to the participants, using 0 for the absence of pain and 10 for unbearable pain. Then, the vitality of the restored tooth was evaluated using the Endo-ice cold vitality test (Maquira). Patient satisfaction with the treatment was also determined by a scale from 0 to 10, where 0 was totally dissatisfied and 10 was totally satisfied.

Statistical analysis

The IBM SPSS 22.0 for Windows software was used. Treatment groups were described by the percentage of the best clinical condition for each criterion (clinically adequate - excellent / good). The Kruskal–Wallis test was used to compare treatment groups within each clinical criterion and assessment time (baseline and 6 months). Then, pair comparisons among the groups were performed using the Mann–Whitney test. Wilcoxon's test was used to assess changes in assessments over time. A significance level of 5% ($p<0.05$) was adopted.

Results

155 teeth were submitted to the restoration procedure at baseline according to the treatment groups. The loss to follow-up rate was approximately 23.5% (Fig. 1). On average, each patient received 4.42 restorations. At baseline, all groups showed clinically satisfactory results with a positive assessment (excellent or good) greater than 70% for all criteria (Table 1). However, a significant difference was identified between the groups for surface staining ($p=0.012$) and anatomical contour ($p<0.001$). At baseline, the results suggest no clinical effect of the adhesive system.

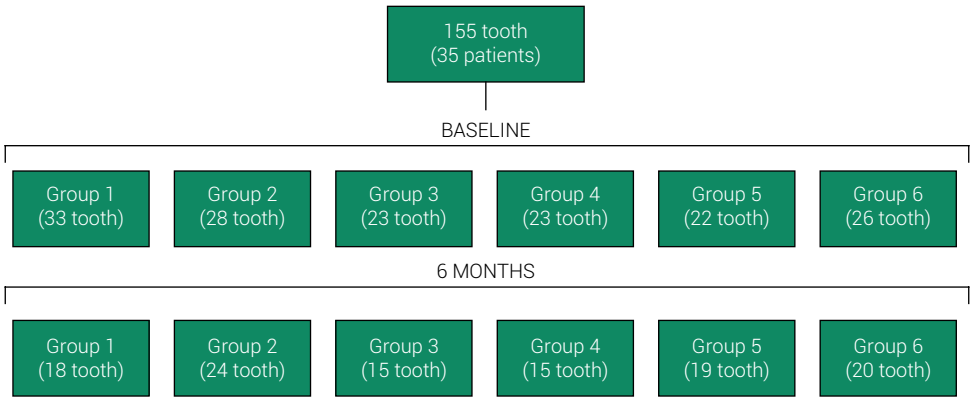

Figure 1. Flowchart clinical trial (CONSORT)

Table 1. Comparison among the treatment groups for each clinical criterion at baseline and after 6 months according to clinical condition evaluated. The percentage of best clinical outcome was reported (clinically adequate - excellent / good). The average rating scale was used for patient satisfaction and postoperative sensitivity. Comparison among all the groups at each time (baseline and 6 months) and clinical criterion was conducted by Kruskal–Wallis test (p (all groups)). Comparison in the same group at different times (baseline x 6 months) by Wilcoxon test (p (time)). Mann–Whitney test was used for paired comparisons at 6 months and different upper letters mean statistical difference ($p<0.05$).

Criterion		Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	*p (all groups)*
Surface brightness	*Baseline*	84.8	89.3	90.0	91.3	90.9	96.2	*0.822*
	6 months	100.0	100.0	100.0	100.0	100.0	100.0	*1.000*
	p (time)	0.317	0.157	1.000	1.000	0.180	1.000	
Surface staining	*Baseline*	87.9	100.0	100.0	100.0	100.0	100.0	0.012
	6 months	100.0	100.0	100.0	100.0	100.0	100.0	*1.000*
	p (time)	0.317	1.000	1.000	1.000	1.000	1.000	
Marginal staining	*Baseline*	90.9	96.4	90.0	100.0	95.5	100.0	*0.388*
	6 months	100.0	100.0	100.0	100.0	100.0	100.0	*1.000*
	p (time)	1.000	0.317	0.157	1.000	1.000	1.000	
Color and translucence	*Baseline*	97.0	96.4	100.0	100.0	100.0	100.0	*0.693*
	6 months	72.7^{A}	100.0^{B}	100.0^{B}	60.0^{A}	73.7^{A}	100.0^{B}	<0.001
	p (time)	0.102	0.317	1.000	**0.014**	**0.025**	1.000	
Anatomical contour	*Baseline*	72.7	96.4	95.0	100.0	100.0	96.2	<0.001
	6 months	94.4^{AB}	91.7^{AB}	100.0^{B}	73.3^{A}	94.7^{AB}	75.0^{A}	*0.069*
	p (time)	0.285	1.000	1.000	**0.046**	0.317	**0.025**	
Fracture	*Baseline*	100.0	100.0	100.0	95.7	100.0	100.0	*0.351*
	6 months	100.0	100.0	100.0	100.0	100.0	100.0	*1.000*
	p (time)	1.000	1.000	1.000	1.000	1.000	1.000	
Marginal adaptation	*Baseline*	90.6	82.1	95.0	91.3	77.3	84.6	*0.507*
	6 months	100.0	100.0	100.0	100.0	100.0	100.0	*1.000*
	p (time)	0.083	0.066	0.317	0.317	**0.025**	0.157	

Continue

Continuation

Patient satisfaction	*Baseline*	9.5	9.5	9.7	9.6	9.6	9.3	*0.351*
	6 months	9.8	9.4	9.6	9.6	9.6	9.9	*0.238*
	p (time)	0.317	0.713	0.317	0.655	0.655	**0.034**	
Postoperative hypersensitivity	*Baseline*	1.0	0.8	0.3	0.3	0.8	1.4	*0.328*
	6 months	0.3	0.6	0.4	0.4	0.2	0.3	*0.794*
	p (time)	0.067	0.573	0.655	1.000	0.102	**0.010**	

Group 1 – Conventional Adhesive + Conventional Composite Resin, Group 2 – Conventional Adhesive + low viscosity *bulk fill* + Conventional Composite Resin, Group 3 – Conventional Adhesive + high viscosity *bulk fill* Composite Resin, Group 4 – Self-etching Adhesive + Conventional Composite Resin, Group 5– Self-etching Adhesive + low viscosity *bulk fill* + Conventional Composite Resin, Group 6 – Self-etching Adhesive + high viscosity *bulk fill* Composite Resin.

After 6 months, all groups remained with a proper clinical performance (Table 1). However, the groups were statistically different regarding color and translucency ($p<0.001$), with lower values of clinical performance for groups 1, 4 and 5.

Regarding the individual comparisons of the clinical performance of the treatment groups over time (baseline x after 6 months) in each criterion, there was a significant decrease for restorations using the self-etching adhesive system (Table 1). Moreover, there was a significant reduction ($p<0.05$) in the evaluation of color and translucency for groups 4 and 5; and anatomical contour for groups 4 and 6 (Table 1). However, a significant improvement ($p<0.05$) in the satisfactory assessment was identified for marginal adaptation for group 5; and in postoperative sensitivity and patient satisfaction in group 6 (Table 1).

The use of the self-etching adhesive system led to a significant decrease of clinical performance after 6 months in terms of color/translucency for restorations using low viscosity bulk fill + conventional composite, and the anatomical contour for high viscosity bulk fill restorations (Table 2). Moreover, comparing the restorative tech-

Table 2. Pair comparison of the adhesive systems tested of treatment groups using the same restorative technique (same composite) after 6 months. Mann–Whitney test ($p<0.05$). p values.

Criterion	Group 1 x 4	Group 2 x 5	Group 3 x 6
Surface brightness	1.000	1.000	1.000
Surface staining	1.000	1.000	1.000
Marginal staining	1.000	1.000	1.000
Color and translucence	0.465	**0.008**	1.000
Anatomical contour	0.097	0.698	**0.039**
Fracture	1.000	1.000	1.000
Marginal adaptation	1.000	1.000	1.000
Patient satisfaction	0.417	0.313	0.804
Postoperative hypersensitivity	0.717	0.272	0.836

Group 1 – Conventional Adhesive + Conventional Composite Resin, Group 2 – Conventional Adhesive + low viscosity *bulk fill* + Conventional Composite Resin, Group 3 – Conventional Adhesive + high viscosity *bulk fill* Composite Resin, Group 4 – Self-etching Adhesive + Conventional Composite Resin, Group 5– Self-etching Adhesive + low viscosity *bulk fill* + Conventional Composite Resin, Group 6 – Self-etching Adhesive + high viscosity *bulk fill* Composite Resin.

nique (high viscosity bulk fill only or low viscosity bulk fill + conventional composite), a better performance was identified for group 6 in terms of color and translucency (p=0.015) compared to group 5.

Discussion

Bulk fill composites are a promising clinical approach for tooth restoration due to the enhanced polymerization process and reduced clinical time. Thus, the clinical evaluation of this restorative material under different techniques allows the standardization of appropriate protocols[4]. The results of the present study showed similar clinical performance of restorations made under different adhesive systems, with slight differences that were not clinically relevant. Moreover, we also showed a good clinical performance of bulk fill composites after 6 months, associated or not with conventional composite. However, a slight negative effect on the clinical performance was observed in terms of color, translucency and anatomical form in the groups treated with bulk fill composite. This result was found only for groups treated with the self-etching adhesive system, which, in general, showed worse performance after 6 months.

Restorations using only high viscosity bulk fill composite with the self-etching adhesive system showed less postoperative sensitivity and a higher level of patient satisfaction after 6 months. Moreover, the use of this material associated with the conventional adhesive system showed a similar pattern of results, but without statistical differences. Since patient satisfaction and lower postoperative sensitivity are important results to be achieved in esthetic restorative procedures, mainly at a short-term parameter, high viscosity bulk fill composites seem to be a promising strategy. The postoperative sensitivity for bulk fill and conventional composites using the Single Bond Universal adhesive showed a similar response, as also demonstrated by a previous study[5]. In fact, the adhesive strategy may not play an important role in the intensity of postoperative sensitivity[16], but the depth of cavity can affect this parameter directly. These results can also be explained by the composite composition, mainly in terms of monomers, which allow additional fragmentation and structural rearrangement of their bonds favoring the tension relief of the polymer chain. Then, these properties may reduce the polymerization contraction process and, consequently, lower the postoperative sensitivity. Six-year follow-up clinical studies[10] showed similar performances between combined or incremental techniques. It should be noted that there is a promising result from the use of only high viscosity bulk fill without coverage with conventional resin using conventional adhesive, with higher percentages of good/excellent evaluation in all criteria.

After 6 months some restorations showed a decrease in terms of color/translucency when using the bulk fill resin associated with the conventional resin and universal adhesive system. In fact, bulk fill resins have greater translucency, which allows a greater depth of polymerization[21]. Thus, the use of the Universal adhesive system, also known as Single Bond Universal, can affect color properties when associated with conventional composite[22]. This result for bulk fill composites is expected, since it was identified by a previous clinical study[18]. However, this effect was not considered

to be clinically important. It suggests that the translucency present in low viscosity bulk fill composites, a property that allows a greater depth of polymerization of these materials, may have influenced the clinical evaluation.

The comparison between the adhesive strategies showed a decrease in the clinical performance for restorations using self-etching adhesive. The universal adhesive tested resulted in greater color changes, a condition that appears to be associated with the oxidation of camphorquinone in this material[22]. Additionally, there is no consensus on the influence of the adhesive system on the clinical performance of this restorative material. Although some adhesive failures are to be expected in conventional and bulk fill restorations using the conventional three-step adhesive system, there is no clinical consensus on whether variations in adhesive techniques can interfere with the restorative clinical performance. Clinical studies compared the high viscosity bulk fill composite using different adhesive systems[16,18] but did not compare clinically with conventional composites. Moreover, bulk fill and conventional composites restorations using different adhesive systems have been evaluated using limited clinical criteria[17]. Therefore, clinical studies that also consider adhesive systems in the clinical performance of restorative techniques and materials are of great importance.

Clinical deficiency in anatomical form was identified after 6 months for the groups using conventional resin or bulk fill. A previous study showed that restorations with the low viscosity bulk fill composite provided clinically unacceptable scores after 1 year for anatomical form, showing a significant increase in this type of failure when compared to the other evaluation periods (one week and 6 months)[23]. However, it is noteworthy that studies whose restorative procedures involved more than one professional, as in the present study, revealed that some of the variables evaluated were more dependent on the operator than the tested material[24]. Therefore, it is expected that the anatomical form is not affected by material properties.

In conclusion, the clinical protocols evaluated showed a similar pattern of results and good clinical performance. Although the results presented here are preliminary, they highlight important comparisons to determine restorative protocols using bulk fill material. At baseline, the adhesive systems and composite did not significantly affect the clinical performance of restorations. The use of high viscosity bulk fill resin with a conventional adhesive system seems to be a promising restorative strategy for class I restorations. Longitudinal evaluation is necessary to assess the clinical performance of these restorations considering all the evaluated clinical parameters.

Data availability

Datasets related to this article will be available upon request to the corresponding author.

Conflicts of interest: none

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