

# Comparative Evaluation of Self-Adhesive Bulk Filled Composite and Conventional Bulk Filled Composite for Class 1 Restorations in Primary Molars: A Randomized Clinical Split Mouth Study: *In vivo*

Shreeja Anand<sup>1</sup>, Subash Singh<sup>2</sup>

<sup>1</sup>Resident, Department of Pediatric and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences, Lucknow, Uttar Pradesh, India,  
<sup>2</sup>Reader, Department of Pediatric and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences, Lucknow, Uttar Pradesh, India

## Abstract

**Objectives:** This randomized clinical split-mouth study aimed to compare the clinical performance of a self-adhesive bulk-filled composite and a conventional bulk-filled (CBF) composite for Class I restorations in primary molars over a period of 6 months, using FDI World Dental Federation clinical criteria.

**Materials and Methods:** Twenty-one pediatric patients requiring restorative treatment of bilateral Class I cavities in primary molars were recruited. Each patient received one restoration with a self-adhesive bulk-filled composite and one with a CBF composite, randomly assigned. Rubber dam isolation was used wherever feasible; otherwise, cotton rolls were employed. Restorations were evaluated by two blinded examiners at baseline (1 week post-restoration) 1 month, 3 months, and after 6 months according to selected FDI criteria including esthetic, functional, and biological properties. Statistical analysis was performed using Chi-square tests at a significance level of  $\alpha = 0.05$ .

**Results:** A total of 42 restorations were evaluated. At 6 months, the clinical success rate was 100% for conventional composites and 95.2% for self-adhesive composites. Functional properties like marginal adaptation showed slight deterioration in both groups but remained clinically acceptable, with no significant differences in retention, fracture, or occlusal wear. Esthetically, conventional composites performed significantly better in surface luster and marginal staining ( $P < 0.05$ ), while both groups showed good color match and translucency. Biologically, no significant issues were observed – no post-operative sensitivity, secondary caries.

**Conclusion:** Both self-adhesive and CBF composites exhibited clinically acceptable results over 6 months in primary molars. However, CBF composites demonstrated superior esthetic performance. Both materials can be recommended for clinical use in pediatric restorative dentistry.

**Key words:** Bulk-fill composite, Class I cavities, FDI criteria, Pediatric dentistry, Primary molars, Self-adhesive composite

## INTRODUCTION

Resin-based composites have become the material of choice for restoring posterior teeth in children due to

their esthetics, biocompatibility, and improved mechanical properties. Bulk-fill composites have simplified the restorative process by allowing placement of thicker increments without compromising curing depth or mechanical strength.<sup>[1,2]</sup> However, conventional bulk-filled (CBF) composites require separate adhesive application, which can be technique-sensitive and time-consuming in pediatric patients.<sup>[1-6]</sup>

Self-adhesive bulk-fill composites, recently introduced, claim to eliminate the need for separate etching and bonding, thereby simplifying the procedure and reducing

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**Corresponding Author:** Shreeja Anand, Resident, Department of Pediatric and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences, Lucknow, Uttar Pradesh, India;

chair time. However, evidence regarding their clinical performance, especially in primary teeth, remains limited. Given the differences in enamel and dentin structure between primary and permanent teeth, it is crucial to assess the efficacy of these materials in a pediatric population.

The aim of this randomized clinical split-mouth study was to evaluate and compare the clinical performance of a self-adhesive bulk-filled composite with a CBF composite for Class I restorations in primary molars over 6 months using the FDI clinical criteria. The null hypothesis was that both materials would perform equally well regarding clinical success.

## MATERIALS AND METHODS

### Study Design

The present study is a 6 months follow-up examination of a prospective controlled randomized clinical split-mouth study investigating the clinical performance of two restorative materials for restoration of Class I cavities in primary molars, one being a novel self-adhesive dual-curing bulk-fill material self-adhesive bulk-fill (SABF), and other is conventional light-curing bulk-fill resin bases bulk filled composite (BF, DENSPLY) which is applied in combination with a universal adhesive in self-etch mode. Sample size calculation was performed on the basis of previous studies done on resin-based composite. Assuming a type I error of 0.05, a power of 80%, and a relative risk of 0.33544, the minimum sample size for this split-mouth study was calculated to be 21 patients with two restorations each. Based on that, it was decided to recruit 25 patients for each group to compensate for later drop-outs during the course of the study.<sup>[7]</sup>

The study design followed the requirements outlined in the CONSORT 2010 statement and was approved by the internal review board of the University. Written informed consent was obtained from all individual participants included in the study after receiving a detailed description of the proposed treatments.<sup>[7]</sup>

### Patient Selection

Patients were recruited from the outpatient pool of the Department of Pediatric and Preventive Dentistry. For inclusion, patients had to be between 4 and 8 years of age and in need of restorative treatment in at least two primary molars with Class I cavities due to caries add without interproximal involvement. Patients were excluded if they had any systemic illness or medical condition classified as ASA score >2, if they exhibited signs of bruxism or traumatic occlusion, or if they had any known allergy or

intolerance to the restorative materials used in the study. Teeth with signs or symptoms of pulpal involvement, spontaneous pain, or pathological mobility were excluded also under exclusion criteria. The selected teeth did not need to be contralateral and could include both maxillary and mandibular molars.

### Clinical Restorative Procedures

The restorative procedures were standardized and carried out by single operator in the Department of Pediatric and Preventive Dentistry. Randomization of the restorations to either the group CBF or the test group SABF was done by drawing envelope, assigning one material (CBF or SABF) to the tooth with the lower tooth FDI number and the other to the contralateral or adjacent tooth with the higher number. Wherever possible, restorations were placed under rubber dam isolation. In cases where rubber dam placement was not feasible, moisture control was achieved using cotton rolls, cheek retractors, and a high-volume saliva ejector to maintain a dry operating field. Before isolating the teeth, appropriate composite shades were selected for CBF and SABF materials using the VITAPAN® classical shade guide.

The tooth surface was cleaned using a slurry of pumice and water to remove any residual plaque or biofilm. Carious lesions were then removed, and Class I cavities were prepared according to the extent of the lesion, using a high-speed handpiece with diamond burs under adequate water cooling.

For the CBF group, an etch-and-rinse adhesive protocol was followed. 37% phosphoric acid gel was applied to the cavity for 20 s, rinsed thoroughly, and gently air-dried. A universal adhesive was then applied actively with a microbrush, gently air-thinned, and light-cured for 10 s using an LED curing light (Bluephase® N, Ivoclar Vivadent; intensity  $\geq 1,200$  mW/cm<sup>2</sup>). The CBF composite was placed in a single increment up to 2 mm and light-cured for 30 s.

For the SABF group, the material was placed directly into the cavity in a single increment up to 4 mm without the use of a separate adhesive, following the manufacturer's instructions, and light-cured for 20 s. If the depth of the cavity exceeded 4 mm, an additional increment was added and cured separately.

In the SABF group, the material was applied directly into the unconditioned cavity and light-cured for 20 s. The placement procedure was similar to that of conventional glass ionomer cements. The capsule tip was inserted at the base of the cavity, and the material was extruded slowly while moving the tip coronally, allowing it to flow and adapt adequately to the cavity floor and walls.<sup>[8-10]</sup>

The conventional bulk filled material provided sufficient working time to sculpt the occlusal morphology before initiating light polymerization. This enabled precise anatomical contouring in its unpolymerized state. The cavity was slightly overfilled to ensure full adaptation, and the final occlusal morphology was achieved by shaping and finishing the restoration through subtractive techniques after the material had set. Finishing and polishing of the restorations of both materials was performed using fine (46  $\mu\text{m}$ ) and ultra-fine (25  $\mu\text{m}$ ) diamond burs.

### Clinical Examination

Clinical examinations were performed by two blinded examiners, who had all been calibrated in advance and who were not involved in the treatments and neither aware of the restorative material used in the individual teeth nor of earlier examination scores. The restorations were evaluated at baseline (BL; 1 weeks after restorative procedures) as well as after 1 months (1-mo), 3 months (3-mo), and 6 months (6-mo). The FDI clinical criteria and scoring system were employed for evaluation of the restorations.<sup>[11]</sup>

The following were selected here for evaluating the clinical performance of the restorations over the course of study:

#### *Esthetic properties*

- Surface luster (A1)
- Surface staining (A2a)
- Marginal staining (A2b)
- Color match and translucency (A3).

#### *Functional properties*

- Fracture of material and retention (B5)
- Marginal adaptation (B6)
- Occlusal contour and wear (B7).

#### *Biological properties*

- Post-operative (hyper-)sensitivity and tooth vitality (C11)
- Tooth integrity (enamel cracks, tooth fractures) (C13)
- Periodontal response (C14).

The clinical assessment of the investigation criteria was done by means of a five-score scale. Tooth vitality was investigated using the ice-spray test and post-operative hypersensitivities were determined by interview of the patients. Each restoration was examined independently by both examiners. In case of any disagreement between the examiners, consensus between both examiners was reached by immediate joint re-examination and discussion with the patient still being present.

### Data Analysis

For the evaluation of clinical performance over time and comparison of both restorative materials based on the FDI

World Dental Federation criteria, clinical data from all the include study patients with both restorations *in situ* were available at baseline (BL- 1 week), 3-month, and 6-month follow-up appointments. To assess statistically significant differences between the two materials at each time point, as well as within the same material across different time intervals, pairwise  $\chi^2$  (Chi-square) tests were conducted for each individual FDI criterion. A significance level of  $\alpha = 0.05$  was applied for all comparisons. Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) for Windows, version 25.0 (SPSS Inc., Chicago, IL, USA).

## RESULTS

### Recall Rate

At baseline, a total of 25 patients (100%) were included in the study out of which four patients into report till the end of the study, remaining patients receiving both a SABF and a CBF composite restoration. At the 6-month recall, 21 patients returned for clinical evaluation, resulting in a recall rate of 70%. Among these patients, all corresponding restorations ( $n = 42$ ) were available for evaluation, and no restorations were lost to follow-up. The reduced recall rate at 6 months was primarily attributed to missed appointments due to personal scheduling conflicts and patient non-compliance with the follow-up protocol.<sup>[9]</sup> Despite this, the available data allowed for a reliable comparative assessment of both materials under clinical conditions.

### Clinical Success Rate (Primary Outcome)

At the 6-month evaluation, all 42 restorations available for assessment (21 SABF and 21 CBF) satisfied the predetermined FDI criteria for clinical acceptability (scores 1–3) across esthetic, functional, and biological domains. None of the restorations showed loss of retention, bulk fracture, secondary caries, unacceptable marginal adaptation, or post-operative hypersensitivity. Accordingly, the clinical success rate – defined as the proportion of restorations scoring within the acceptable range for every criterion – was 100 % for both SABF and CBF, resulting in an overall 100 % restoration survival at the 6month recall. These findings indicate that, under the conditions of this splitmouth study, both restorative systems demonstrated equivalent and excellent shortterm clinical performance.<sup>[10]</sup>

### Clinical Performance According to Selected FDI Criteria

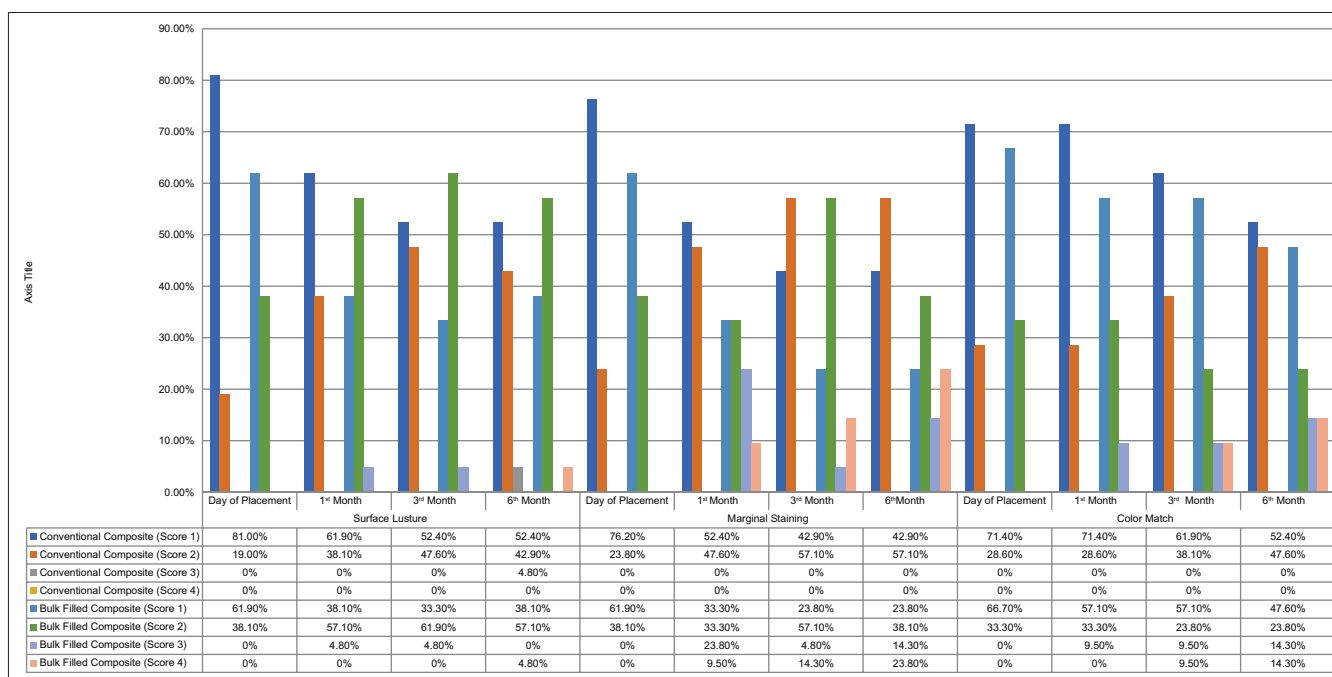
#### *Esthetic properties*

Table 1 and Graph 1 show the clinical data of all restoration at all examination time point (BL, 1 month, 3 months, and 6 months) for selected criteria from the FDI esthetic properties panel. At the 6-month evaluation, all

**Table 1: Intergroup comparison of esthetic properties between the groups at different time intervals**

Time interval	Group 1 (conventional composite)				Group 2 (bulk-filled composite)				P-value
	Score 1 (%)	Score 2 (%)	Score 3 (%)	Score 4 (%)	Score 1 (%)	Score 2 (%)	Score 3 (%)	Score 4 (%)	
<b>Surface luster</b>									
Day of placement	17 (81.0)	4 (19.0)	0 (0)	0 (0)	13 (61.9)	8 (38.1)	0 (0)	0 (0)	$P \geq 0.05$ (NS)
1 <sup>st</sup> month	13 (61.9)	8 (38.1)	0 (0)	0 (0)	8 (38.1)	12 (57.1)	1 (4.8)	0 (0)	$P \geq 0.05$ (NS)
3 <sup>rd</sup> month	11 (52.4)	10 (47.6)	0 (0)	0 (0)	7 (33.3)	13 (61.9)	1 (4.8)	0 (0)	$P \geq 0.05$ (NS)
6 <sup>th</sup> month	11 (52.4)	9 (42.9)	1 (4.8)	0 (0)	8 (38.1)	12 (57.1)	0 (0)	1 (4.8)	$P \geq 0.05$ (NS)
<b>Marginal staining</b>									
Day of placement	16 (76.2)	5 (23.8)	0 (0)	0 (0)	13 (61.9)	8 (38.1)	0 (0)	0 (0)	$P \geq 0.05$ (NS)
1 <sup>st</sup> month	11 (52.4)	10 (47.6)	0 (0)	0 (0)	7 (33.3)	7 (33.3)	5 (23.8)	2 (9.5)	$P \leq 0.05$ (Sig)
3 <sup>rd</sup> month	9 (42.9)	12 (57.1)	0 (0)	0 (0)	5 (23.8)	12 (57.1)	1 (4.8)	3 (14.3)	$P \leq 0.05$ (Sig)
6 <sup>th</sup> month	9 (42.9)	12 (57.1)	0 (0)	0 (0)	5 (23.8)	8 (38.1)	3 (14.3)	5 (23.8)	$P \leq 0.05$ (Sig)
<b>Color match</b>									
Day of placement	15 (71.4)	6 (28.6)	0 (0)	0 (0)	14 (66.7)	7 (33.3)	0 (0)	0 (0)	$P \geq 0.05$ (NS)
1 <sup>st</sup> month	15 (71.4)	6 (28.6)	0 (0)	0 (0)	12 (57.1)	7 (33.3)	2 (9.5)	0 (0)	$P \leq 0.05$ (Sig)
3 <sup>rd</sup> month	13 (61.9)	8 (38.1)	0 (0)	0 (0)	12 (57.1)	5 (23.8)	2 (9.5)	2 (9.5)	$P \leq 0.05$ (Sig)
6 <sup>th</sup> month	11 (52.4)	10 (47.6)	0 (0)	0 (0)	10 (47.6)	5 (23.8)	3 (14.3)	3 (14.3)	$P \leq 0.05$ (Sig)

Score - 1 Clinically excellent, Score - 2 Clinically good, Score - 3 Clinically satisfactory, Score - 4 Clinically unsatisfactory, Score - 5 Clinically poor



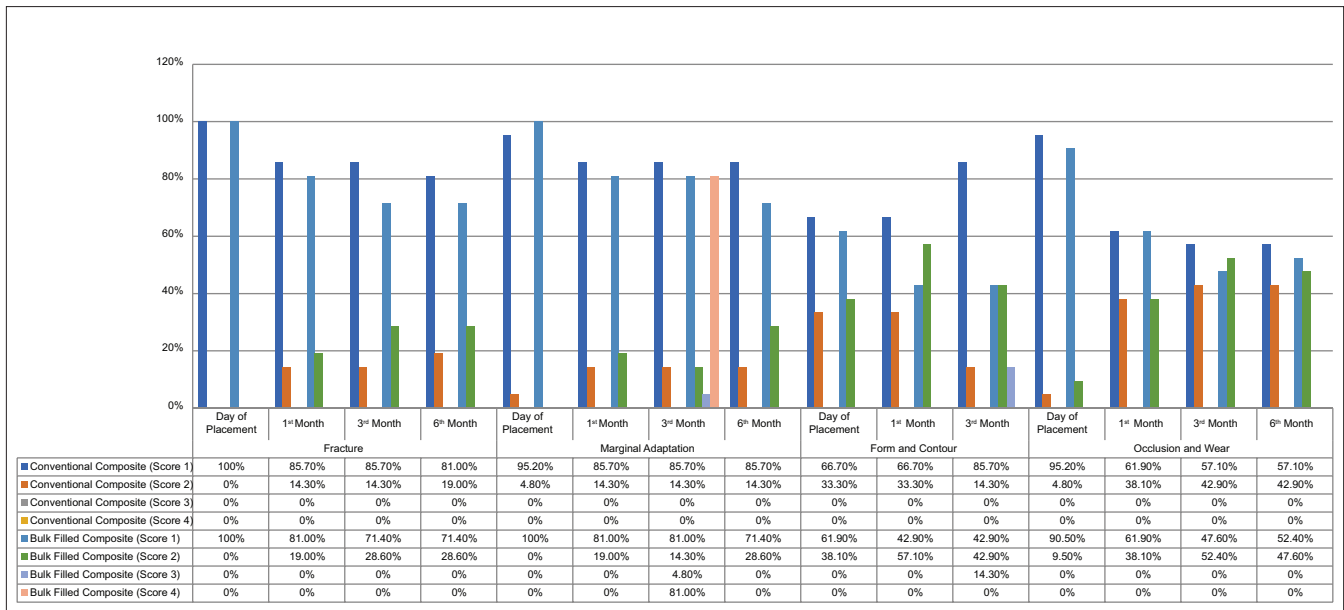
**Graph 1: Intergroup comparison of aesthetic properties between the groups at different time intervals**

restorations in both the SABF and CBF groups exhibited clinically acceptable FDI scores (1–3) for all assessed esthetic parameters, including surface luster (A1), surface staining (A2a), marginal staining (A2b), color match and translucency (A3), and esthetic anatomical form (A4) ( $P < 0.001$  each).<sup>[11]</sup> In the SABF group, a higher frequency of restorations displayed a slightly dull surface (score 2) compared to CBF, which more often maintained a lustrous finish (score 1). Minor surface staining (score 2) was noted in a limited number of restorations in both groups but were considered easily removable and non-critical. Marginal staining was more evident in SABF restorations, although still within acceptable limits. Color match and

translucency remained within the acceptable range in both groups; however, SABF restorations showed slightly more deviation from the natural tooth shade compared to CBF. Esthetic anatomical form was preserved in nearly all restorations, with the majority scoring 1. Overall, both materials demonstrated favorable esthetic performance at 6 months, although CBF presented slightly superior outcomes in terms of surface luster and color match.<sup>[12]</sup>

**Functional properties**

Table 2 and graph 2 show the clinical data of all restoration at all examination time point (Bl, 1 month, 3 months, 6 months) for selected criteria from the FDI functional



Graph 2: Intergroup comparison of functional properties between the groups at different time intervals

Table 2 . Intergroup Comparison Of Functional Properties Between The Groups At Different Time Intervals

N=21	Time Interval	Group 1 (Conventional Composite)				Group 2 (Bulk Filled Composite)				P Value
		Score 1	Score 2	Score 3	Score 4	Score 1	Score 2	Score 3	Score 4	
Fracture resistance	Base line	21 (100%)	0 (0%)	0 (0%)	0 (0%)	21 (100%)	0 (0%)	0 (0%)	0 (0%)	p≥0.05(NS)
	1 <sup>st</sup> Month	18 (85.7%)	3 (14.3%)	0 (0%)	0 (0%)	17 (81.0%)	4 (19.0%)	0 (0%)	0 (0%)	p≥0.05(NS)
	3 <sup>rd</sup> Month	18 (85.7%)	3 (14.3%)	0 (0%)	0 (0%)	15 (71.4%)	6 (28.6%)	0 (0%)	0 (0%)	p≥0.05(NS)
	6 <sup>th</sup> Month	17 (81.0%)	4 (19.0%)	0 (0%)	0 (0%)	15 (71.4%)	6 (28.6%)	0 (0%)	0 (0%)	p≥0.05(NS)
Marginal Adaptation	Base line	20 (95.2%)	1 (4.8%)	0 (0%)	0 (0%)	21 (100%)	0 (0%)	0 (0%)	0 (0%)	p≥0.05(NS)
	1 <sup>st</sup> Month	18 (85.7%)	3 (14.3%)	0 (0%)	0 (0%)	17 (81.0%)	4 (19.0%)	0 (0%)	0 (0%)	p≥0.05(NS)
	3 <sup>rd</sup> Month	18 (85.7%)	3 (14.3%)	0 (0%)	0 (0%)	17 (81.0%)	3 (14.3%)	1 (4.8%)	0 (0%)	p≥0.05(NS)
	6 <sup>th</sup> Month	18 (85.7%)	3 (14.3%)	0 (0%)	0 (0%)	15 (71.4%)	5 (22.6%)	1 (3%)	0 (0%)	p≥0.05(NS)
Form and Contour	Base line	14 (66.7%)	7 (33.3%)	0 (0%)	0 (0%)	13 (61.9%)	8 (38.1%)	0 (0%)	0 (0%)	p≥0.05(NS)
	1 <sup>st</sup> Month	14 (66.7%)	7 (33.3%)	0 (0%)	0 (0%)	9 (42.9%)	12 (57.1%)	0 (0%)	0 (0%)	p≥0.05(NS)
	3 <sup>rd</sup> Month	13 (54.7%)	5 (22.3%)	3 (9%)	0 (0%)	9 (42.9%)	11 (52.38%)	1 (4.8%)	0 (0%)	p≤0.05(Sig)
	6 <sup>th</sup> Month	13 (85.7%)	4 (14.3%)	4 (11%)	0 (0%)	9 (42.9%)	9 (42.9%)	3 (14.3%)	0 (0%)	p≤0.05(Sig)
Occlusion and Wear	Base line	20 (95.2%)	1 (4.8%)	0 (0%)	0 (0%)	19 (90.5%)	2 (9.5%)	0 (0%)	0 (0%)	p≥0.05(NS)
	1 <sup>st</sup> Month	13 (61.9%)	8 (38.1%)	0 (0%)	0 (0%)	13 (61.9%)	8 (38.1%)	0 (0%)	0 (0%)	p≥0.05(NS)
	3 <sup>rd</sup> Month	12 (57.1%)	9 (42.9%)	0 (0%)	0 (0%)	10 (47.6%)	11 (52.4%)	0 (0%)	0 (0%)	p≥0.05(NS)
	6 <sup>th</sup> Month	12 (57.1%)	9 (42.9%)	0 (0%)	0 (0%)	10 (52.4%)	11 (47.6%)	10 (0%)	0 (0%)	p≥0.05(NS)

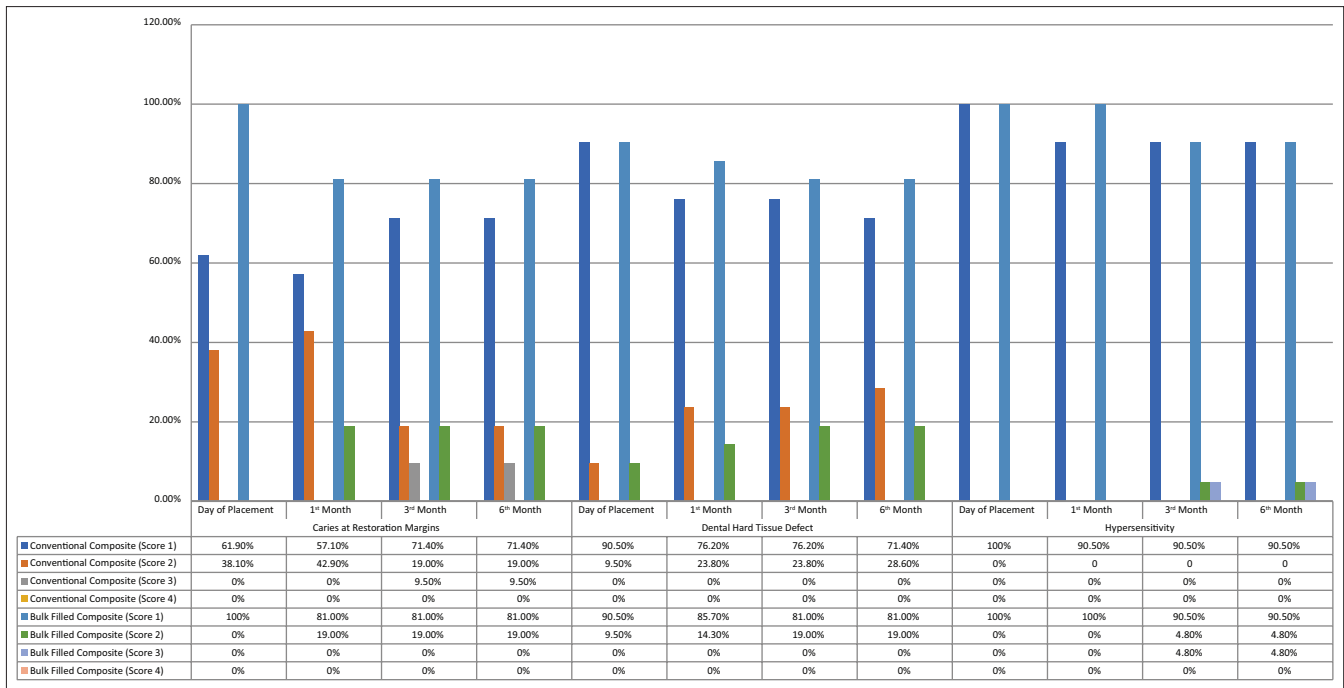
Score -1: Clinically Excellent, Score -2: Clinically Good, Score -3: Clinically Satisfactory, Score -4: Clinically Unsatisfactory, Score -5: Clinically poor

properties panel. At the 6-month follow-up, all evaluated restorations in both the SABF and CBF groups achieved clinically acceptable scores (1–3) for all selected functional criteria, including fracture of material and retention (B5), marginal adaptation (B6), and occlusal contour and wear (B7). No restoration in either group exhibited any signs of material fracture, loss of retention, with all restorations scoring 1 for the B5 criterion. Marginal adaptation (B6) was also maintained within acceptable parameters in both groups; however, SABF restorations demonstrated a slightly higher incidence of minor marginal irregularities (score 2) compared to CBF, which predominantly showed well-adapted margins (score 1) p≥0.05(NS). In terms of occlusal contour and wear (B7), both groups preserved

proper anatomical form and occlusal harmony without any signs of excessive wear or flattening. These findings support that both restorative materials provided satisfactory functional performance at 6 months, with no significant differences observed between SABF and CBF in terms of clinical functionality.<sup>[13]</sup>

**Biological properties**

Table 3 and Graph 3 show the clinical data of all restoration at all examination time point (Bl, 1 month, 3 months, 6 months) for selected criteria from the FDI biological properties panel. At the 6-month evaluation, all restorations in both the SABF and CBF groups demonstrated clinically acceptable outcomes (FDI scores 1–3) for the selected



Graph 3: Intergroup comparison of biological properties between the groups at different time intervals

Table 3. Intergroup Comparison Of Biological Properties Between The Groups At Different Time Intervals

	Time Interval	Group 1 (Conventional Composite)				Group 2 (Bulk Filled Composite)				P Value
		Score 1	Score 2	Score 3	Score 4	Score 1	Score 2	Score 3	Score 4	
Caries at Restoration Margins	Base line	19(87.9%)	2(9.5.1%)	0 (0%)	0 (0%)	21 (100%)	0 (0%)	0 (0%)	0 (0%)	p≤0.05(Sig)
	1 <sup>st</sup> Month	18(87.1%)	3(4.9%)	0 (0%)	0 (0%)	17 (81.0%)	4 (19.0%)	0 (0%)	0 (0%)	p≥0.05(NS)
	3 <sup>rd</sup> Month	15 (71.4%)	4 (19.0%)	2 (9.5%)	0 (0%)	17 (81.0%)	4 (19.0%)	0 (0%)	0 (0%)	p≥0.05(NS)
	6 <sup>th</sup> Month	15 (71.4%)	4 (19.0%)	2 (9.5%)	0 (0%)	17 (81.0%)	4 (19.0%)	0 (0%)	0 (0%)	p≥0.05(NS)
Dental Hard Tissue Defect	Base line	19 (90.5%)	2 (9.5%)	0 (0%)	0 (0%)	19 (90.5%)	2 (9.5%)	0 (0%)	0 (0%)	p≥0.05(NS)
	1 <sup>st</sup> Month	16 (76.2%)	5 (23.8%)	0 (0%)	0 (0%)	18 (85.7%)	3 (14.3%)	0 (0%)	0 (0%)	p≥0.05(NS)
	3 <sup>rd</sup> Month	16 (76.2%)	5 (23.8%)	0 (0%)	0 (0%)	17 (81.0%)	4 (19.0%)	0 (0%)	0 (0%)	p≥0.05(NS)
	6 <sup>th</sup> Month	15 (71.4%)	5(28.6%)	1(4%)	0 (0%)	17 (81.0%)	4 (19.0%)	0 (0%)	0 (0%)	p≥0.05(NS)
Hypersensitivity	Base line	21 (100.0%)	0 (0%)	0 (0%)	0 (0%)	21 (100.0%)	0 (0%)	0 (0%)	0 (0%)	p≥0.05(NS)
	1 <sup>st</sup> Month	19 (90.5%)	1 (4.8%)	1 (4.8%)	0 (0%)	21 (100.0%)	0 (0%)	0 (0%)	0 (0%)	p≥0.05(NS)
	3 <sup>rd</sup> Month	19 (90.5%)	1 (4.8%)	1 (4.8%)	0 (0%)	19 (90.5%)	1 (4.8%)	1 (4.8%)	0 (0%)	p≥0.05(NS)
	6 <sup>th</sup> Month	19 (90.5%)	1 (4.8%)	1 (4.8%)	0 (0%)	19 (90.5%)	1 (4.8%)	1 (4.8%)	0 (0%)	p≥0.05(NS)

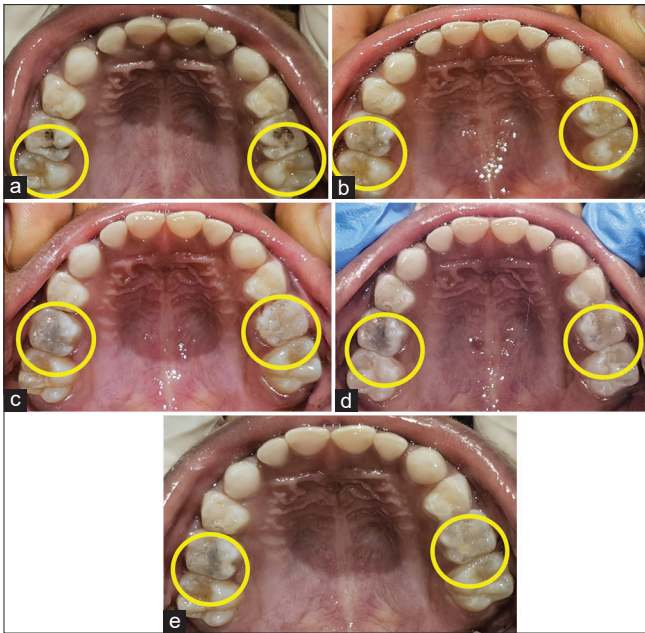
Score -1: Clinically Excellent, score -2: Clinically Good, score -3: Clinically Satisfactory, Score -4: Clinically Unsatisfactory, Score -5: Clinically poor

biological criteria, which included post-operative (hyper) sensitivity and tooth vitality (C11), tooth integrity (C13), and periodontal response (C14). No cases of persistent post-operative sensitivity were reported in either group, and all restored teeth responded positively to vitality testing, yielding a score of 1 or 2 for C11. Regarding tooth integrity (C13), hairline enamel cracks were observed in a few cases in both groups but remained within the clinically acceptable range and did not compromise restoration performance or tooth structure. For the periodontal response (C14), mild gingival inflammation without pocket formation (score 2) was noted in a limited number of restorations, particularly in the SABF group, while most CBF restorations scored 1, indicating healthy periodontal conditions. No intervention was required in any case. Overall, both materials exhibited

satisfactory biological behavior at the 6-month recall, with no adverse tissue reactions and preservation of tooth vitality and structural integrity  $P \geq 0.05$  (NS) [Figure 1].

## DISCUSSION

For the present study, only those FDI criteria were reported which were considered to have clinical relevance for the evaluation of Class I restorations in primary molars after 6 months of clinical service. These included parameters assessing esthetic properties (criteria A1, A2a, A2b, and A3), functional properties (criteria B5, B6, and B7), and biological properties (criteria C11, C13, and C14). All other FDI criteria not specifically mentioned here did not demonstrate any noticeable clinical discrepancies



**Figure 1: (a) Pre-operative, (b) post-operative (1 week), (c) post-operative (1 month follow-up), (d) post-operative (3-month follow-up), and (e) post-operative (6-month follow-up)**

or statistically significant differences between the two restorative materials across the evaluation period.<sup>[14,15]</sup>

Both the SABF composite and the CBF composite restorations exhibited clinically acceptable scores (scores 1–3) in all assessed FDI parameters. This reflects a clinical success rate of 100% for both materials at the end of the 6-month follow-up. None of the restorations presented with signs of failure such as secondary caries, marginal gap formation, post-operative sensitivity, or unacceptable surface degradation.

As outlined above, the scope of the present study was to clinically evaluate the novel restorative material – SABF composite – and compare it with CBF composite in Class I restorations of primary molars.<sup>[16]</sup> This study aimed to determine the clinical performance and feasibility of SABF as a potential alternative to conventional composites in pediatric patients, particularly in terms of simplifying the clinical procedure without compromising on restoration quality. The focus was not to reduce cost alone, but to assess whether the reduction in working steps provided by SABF composites could be clinically justified through comparable performance.

The clinical evaluation of restorations was based on the FDI World Dental Federation (FDI) clinical criteria and scoring system, which is widely recognized for its greater sensitivity and discriminatory capacity compared to the traditional United States Public Health Service criteria. This is especially true for detecting early signs of deterioration

in parameters such as marginal adaptation and surface staining. All FDI criteria were assessed at each follow-up interval for both types of restorations; however, in alignment with the aims and scope of this study, only those criteria deemed most relevant for evaluating Class I restorations in primary teeth after 6 months of clinical service were included in the final analysis.<sup>[17]</sup>

These included selected esthetic properties (criteria A1 - surface luster, A2a - color match, A2b - translucency and opacity, and A3 - anatomical form), functional properties (criteria B5 - marginal adaptation, B6 - fracture and retention, and B7 - wear), and biological properties (criteria C11 – post-operative sensitivity and tooth vitality, C13 - recurrence of caries, and C14 - erosion and abfraction). The selective inclusion of FDI parameters is consistent with existing literature, as most clinical studies report specific criteria tailored to the objective and design of the trial. This methodological approach aligns with the recommendations proposed by Hickel *et al.*, and is supported by findings in systematic reviews evaluating the clinical use of FDI criteria in trials involving direct restorative materials.

### Clinical Performance According to Selected FDI Criteria

#### *Esthetic properties*

In the present study, surface luster was observed to be significantly inferior in restorations placed using the SABF composite as compared to the CBF composite at all evaluation intervals. The diminished polishability of the SABF material may be partially attributed to its intrinsic composition and the mixing protocol, which can introduce small porosities and internal voids due to its two-component nature. These micro-defects were often associated with a dull surface appearance and inconsistent surface texture, leading to lower surface luster scores.<sup>[18]</sup> Despite these surface irregularities observed with SABF restorations, no significant difference in surface staining was recorded between the two materials throughout the 6-month observation period.

Both restorative materials demonstrated a progressive increase in marginal staining over time (from baseline to 6 months), although the difference was not statistically significant between groups. The increased staining may be related to limitations in the adhesive interface, particularly at enamel margins. SABF composites incorporate a mild self-adhesive mechanism, which may not achieve the same depth or quality of etching as conventional phosphoric acid. Similarly, the universal adhesive (Scotchbond Universal, SBU) used with the CBF material, having a pH of approximately 2.7, may result in less defined etching patterns, thus affecting enamel bonding and promoting marginal discoloration during intraoral aging.<sup>[18]</sup>

Nonetheless, mild marginal staining, especially in pediatric Class I restorations, can typically be managed with routine re-polishing during recall visits. This approach has been consistently recommended in the literature to enhance the longevity and appearance of restorations. While more detailed assessment of marginal integrity at both enamel and dentin interfaces could provide valuable clinical insights – particularly with self-adhesive materials – such separation of evaluation is often challenging in primary molars. In Class I restorations, the cavity margins predominantly involve enamel, making it difficult to distinctly evaluate the adaptation and staining at enamel versus dentin margins as suggested in studies focused on non-cariou cervical lesions. Nevertheless, the current findings emphasize the importance of careful surface finishing and periodic maintenance, especially when using newer self-adhesive materials in pediatric dental restorations.<sup>[19]</sup>

**Color Match, Translucency** – In the present study, color match and translucency were consistently rated as significantly less suitable for the SABF restorations compared to the CBF restorations at all examination time points. However, both materials remained within the clinically acceptable range, with FDI scores ranging between 1 and 3. While the CBF group frequently exhibited ideal optical properties closely matching the surrounding primary tooth structure, SABF restorations often displayed minor esthetic deviations, primarily in the form of reduced translucency. These differences may be attributed to material-specific characteristics, including variations in filler composition and particle size. Furthermore, the presence of intrinsic voids or micro-porosities in the SABF material, possibly introduced during the mixing process, may have altered light transmission and resulted in a more opaque or slightly darker appearance.<sup>[19]</sup>

With regard to anatomical form, both materials allowed for acceptable esthetic contouring, although the techniques required to achieve the final morphology differed between the two. The CBF composite permitted precise sculpting in the pre-cured state, allowing the operator to shape the material directly before polymerization. This facilitated the reproduction of natural tooth morphology with minimal finishing. In contrast, the handling properties of the SABF material did not permit detailed sculpting before curing. Instead, restorations were intentionally overfilled and subsequently refined through subtractive finishing and polishing procedures after polymerization. This difference in approach, dictated by the material's viscosity and setting behavior, reflects inherent limitations in manipulation with self-adhesive bulk fill materials.<sup>[20]</sup>

Despite these procedural differences, both materials met the esthetic demands for restorations in primary molars within

the scope of this study. However, the slightly inferior visual outcomes and lack of sculptability observed with SABF may be relevant in cases where higher esthetic precision is desired, particularly in anterior regions or permanent dentition. In posterior primary teeth, where function and efficiency are often prioritized, such differences may be clinically acceptable when weighed against the potential benefits of reduced technique sensitivity and simplified application.

#### ***Functional properties***

Regarding fracture resistance and material retention, both SABF and CBF composites demonstrated comparable clinical performance throughout the 6-month follow-up period. No bulk fractures, cohesive failures, or complete loss of restorations were observed in either group, indicating satisfactory mechanical durability and retention even in moderately extensive Class I cavities in primary molars. These results reflect the good wear resistance of both materials under functional occlusal loads typically encountered in pediatric patients.

However, a significant decline in marginal adaptation was observed over time in the SABF group, with minor defects such as slight ditching, marginal steps, and irregularities detected between baseline and the 6-month recall. In contrast, the CBF restorations maintained stable marginal adaptation throughout the study duration.<sup>[21]</sup> The deterioration noted in SABF restorations is consistent with the higher levels of marginal staining observed in the same group, likely pointing to adhesive interface degradation. This may be attributed to limited etching effectiveness and reduced micro-mechanical interlocking at enamel margins, which can lead to early wear and the formation of small marginal gaps.<sup>[22]</sup>

It is well-documented that marginal deterioration often coincides with marginal discoloration and may serve as an early clinical sign of interface fatigue or material wear at the adhesive margin. Nonetheless, despite the statistically significant decline in marginal adaptation for SABF restorations, all restorations in both groups were scored within the FDI range of 1 (clinically very good) to 2 (clinically good) at the 6-month evaluation. This indicates that, although minor marginal changes were noted in SABF restorations, they did not reach a threshold of clinical concern or failure.

From a clinical perspective, the observed change in marginal integrity from a very good to good rating in the SABF group, while statistically significant, does not appear to compromise the overall clinical acceptability of the restorations within the study's observation period.

**Biological properties**

In the present study, post-operative hypersensitivity was observed in a limited number of restorations at baseline, with two cases reported in the CBF group and three in the SABF group. These episodes of sensitivity were mild, fell within clinically acceptable FDI scores (scores 2 and 3), and resolved spontaneously before the 6-month follow-up.<sup>[23]</sup> The transient nature of these symptoms aligns with findings from previous clinical studies, where post-operative hypersensitivity has been commonly reported in the early days or weeks following restorative treatment and generally attributed to procedural factors such as caries excavation, use of rubber dam isolation, or over-drying of dentin rather than to the restorative material itself.<sup>[24]</sup>

The absence of persistent hypersensitivity beyond the early post-treatment phase may indicate favorable pulpal responses and biocompatibility of both materials. In particular, the SABF material, despite being self-adhesive and applied in bulk increments, did not exhibit any long-term negative pulpal effects, suggesting adequate sealing ability and depth of cure even in deeper cavity areas. This may be a reflection of its appropriate polymerization behavior and the self-etching, self-adhering capacity of the material.<sup>[25]</sup>

In addition to hypersensitivity, the structural integrity of restored teeth was monitored to assess for potential enamel cracks or tooth fractures over time. This is especially relevant for materials like SABF, which incorporate acid-reactive glass fillers. Such components can be associated with hygroscopic expansion due to water uptake, a phenomenon that has previously raised concerns regarding internal stresses and subsequent enamel fractures.<sup>[26]</sup> However, throughout the 6-month observation period, no such adverse effects were noted in any of the restorations, suggesting that SABF demonstrated a stable behavior within the clinical conditions of this study.

The biological outcomes observed, therefore, reinforce the suitability of both SABF and CBF materials for Class I restorations in primary molars from a pulp and tooth integrity standpoint, at least within the short-term clinical timeframe of this investigation.

With regard to periodontal response, a statistically significant decline was noted for both restorative materials from baseline to the 6-month evaluation. However, all findings remained well within clinically acceptable FDI scores, indicating no need for intervention. It is important to note that the periodontal response criterion (C14) in the FDI evaluation system records only a brief and localized plaque bleeding index (PBI) snapshot in comparison to baseline and a control tooth.<sup>[27]</sup> Interestingly, the full-mouth

median PBI values of the patient cohort actually showed a slight improvement, decreasing from 8.5% at baseline to 7.5% at the 6-month recall, which reflects a generally good level of oral hygiene among the participants.<sup>[28]</sup>

During the course of this study, some limitations in the original instructions for scoring the FDI periodontal response criterion became evident. According to the standard guidance, a localized increase of one PBI grade is to be scored as 3 (clinically acceptable), while increases beyond one grade that require clinical intervention are to be scored as 4 (not acceptable). However, these instructions do not clearly address how to interpret transient or minor fluctuations in local PBI scores that do not warrant treatment – for instance, a temporary two-grade increase without signs of inflammation or overhanging margins. To address this gap, the interpretation of criterion C14 was adapted in this study: Scores 3 and 4 were differentiated based on whether there was a genuine clinical need for intervention, such as recontouring the cervical margin of the restoration due to plaque-retentive overhangs.<sup>[29]</sup>

**CONCLUSION**

The null hypothesis of this clinical investigation could not be rejected. Both the SABF and the CBF/FOBF restorative materials demonstrated only clinically acceptable outcomes across all examined FDI criteria over the 6-month follow-up period. Functional and biological performance – including retention, fracture resistance, post-operative sensitivity, and periodontal health – was comparable between the two groups. However, statistically significant differences were observed in esthetic properties. The CBF (FOBF) material showed superior performance in surface luster color match, and translucency across all time points, as well as in marginal staining at 6 months and it was statically significant. These esthetic differences were already evident at baseline and did not worsen over time, suggesting that they are inherent to the material properties rather than a result of clinical degradation.

Therefore, while SABF may present as a slightly less esthetic alternative to CBF, it remains a clinically acceptable option, especially when ease of use, reduced technique sensitivity, and shorter chair time are prioritized – key factors in pediatric dentistry. Within the limitations of this short-term study, both materials showed promising results for Class I restorations in primary molars. However, extended clinical follow-up is essential to assess the long-term durability, esthetic stability, and marginal integrity of the SABF material under intraoral conditions.

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