EGYPTIAN DENTAL JOURNAL
www.eda-egypt.org
VOL. 71, 2553:2566, JULY, 2025
PRINT ISSN 0070-9484 • ONLINE ISSN 2090-2360
CONSERVATIVE DENTISTRY AND ENDODONTICS
Submit Date : 28-02-2025 • Accept Date : 26-03-2025 • Available online: 15-07-2025 • DOI : 10.21608/edj.2025.364031.3402

CLINICAL EVALUATION OF SELF-ADHESIVE BULK-FILL HYBRID COMPOSITE RESTORATION IN PRIMARY MOLARS

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ABSTRACT

Background: Restorative procedures present a common challenge in pediatric dentistry. This investigation aimed to assess the clinical efficacy of a recent self-adhesive bulk-fill restorative material in the restoration of occlusal and occluso-proximal lesions in primary molars.

Martials and Methods: This randomized controlled clinical study included 30 children, randomly selected and separated into two main equal groups, depending on the type of carious lesion: Group I with Class I lesions and Group II with Class II lesions. Each main group randomly separated into two equal subgroups: subgroups IA, IB and subgroups IIA, IIB. Subgroups A served as the controls and restored with Filtek™ Bulk Fill Composite. Subgroups B served as the study groups and restored with Surefil One. Restorations were assessed utilizing the modified United States Public Health Service criteria, post restoration (baseline) and at follow-up periods of 3, 6, and 12 months.

Results: Intergroup comparisons of both restorative materials for Class I and Class II lesions after 12 months showed insignificant difference in marginal adaptation (p=0.329, 0.142), recurrent caries (p=1.0 each), postoperative sensitivity (p = 1.0 each), retention (p = 1.0 each) and proximal contact (p = 0.483 for Class II). Significant differences between the materials were observed for color match (p < 0.001each), anatomic form (p = 0.03 each), and surface roughness (p = 0.006, 0.01) for both Class I and Class II lesions after 12 months.

Conclusions: Bulk-fill resin composite demonstrated better performance over the self-adhesive bulk-fill composite in terms of color match, surface roughness, and anatomical form.

KEYWORDS: Primary Molars, Occluso-Proximal Lesions, Occlusal Lesions, Restorative Treatment, Self-Adhesive Bulk-Fill Composite.

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INTRODUCTION

Pediatric dentists frequently face challenges such as limited patient cooperation, time constraints, and difficulties in maintaining proper field isolation, making the selection of restorative materials crucial for successful treatment. Using restorative materials with fewer application steps not only simplifies the procedure but also enhances efficiency, ensuring durable and effective restorations even in less-than-ideal conditions [1].

Treatment protocols today support conservative restorations that preserve healthy tooth structure while replacing damaged tissue. As a result, adhesive restorations have become a key part of modern dental practice [2-4].

In pediatric dentistry, adhesive restorations have become increasingly prevalent, especially following the implementation of the Minamata Agreement, which calls for the gradual phase-out of dental amalgam as a restorative material. Alternative restorative options, including glass-ionomer cements and resin-modified glass-ionomer cements have been explored. However, these materials have limitations, including reduced mechanical strength and lower durability under clinical conditions [5-7].

Resin composites have emerged as a prominent alternative to amalgam, offering enhanced aesthetic and functional outcomes. However, these materials present certain challenges, particularly in pediatric patients where isolation and the execution of multi-step procedures can be difficult due to limited cooperation [8, 9].

Recent advancements in adhesive technologies have introduced simplified protocols that are less technique-sensitive and reduce procedural complexity. This simplification minimizes chair time and decreases errors associated with multi-step processes [10].

The introduction of high-viscosity bulk-fill resin composites have already improved handling and efficiency compared to conventional composites, as they enable the placement of larger increments and avoid the meticulous and time-consuming incremental layering technique. However, these materials still require the application of a separate adhesive system [11].

Self-adhesive bulk-fill composites, on the other hand, offer a promising alternative by further simplifying the process. These materials have the ability to etch enamel and dentin surfaces and chemically bond to hydroxyapatite, thereby eliminating the need for a separate adhesive system [12]. Surefil One is an innovative concept in the field of self-adhesive restorative materials; it is an enhanced self-adhesive restorative substance. It contains practical characteristics similar to those of silver amalgam while providing the aesthetic advantages characteristic of composite materials [13]. A key component of Surefil One is the Modified polyacid system of high molecular weight (MOPOS) which is a hydrolytically stable polyacid base with polymerizable groups. MOPOS plays an essential role in initiating adhesion, forming a network, and enhancing the material's strength due to its unique structure [14]. Nevertheless, there is an insufficient amount of information regarding the clinical efficacy of the recent self-adhesive bulk-fill restorative material in primary teeth.

The purpose of this work was to assess the clinical efficacy of Surefil One restorative material in the restoration of occlusal and occluso-proximal lesions in primary molars. The null hypothesis tested was that self-adhesive bulk-fill and conventional bulk-fill composites show no difference in clinical performance for occlusal and occluso-proximal restorations in primary molars over a one-year follow up period.

MATERIALS AND METHODS

This randomized controlled clinical split-mouth study was carried out on thirty children aged 4 to 6 years, who were randomly chosen from the Pediatric Dental Clinic, Faculty of Dentistry, Mansoura University. An informed written consent was obtained from the parent or guardian of each child. The study was done after approval from the Ethics Committee of the Faculty of Dentistry, Mansoura University approval code: (A06020822). The clinical trial was registered on ClinicalTrials.gov under the registration number NCT06724939. This study was carried out during the period from September ,2022 to May,2024.

The children contributed in the study should be cooperative with a behavior rating of 3 or 4 in accordance with the Frankl Behavior Rating Scale, healthy with no chronic systemic disease and have bilateral simple occlusal or occluso-proximal caries in the lower second primary molars [15].

Sample size calculation:

Sample size calculation was depending on percentage of restoration among studied groups retrieved from previous research [16]. Utilizing G*power version 3.0.10 to calculate sample size depending on difference of 20% 2-tailed test, α error =0.05 and power = 80.0% then total sample size will be 25 in each group at least. This number was increased to 30 for each group for more precise results and to compensate for the drop in the follow up time.

Randomization and blindness:

The randomization process was carried out using 60 sealed papers. These were divided into two sets:30 papers to determine the starting side (right or left),30 papers to determine the restorative material type (self-adhesive bulk-fill composite or conventional bulk-fill composite).

Each child randomly selected one paper from each set: one to decide the starting side and another to determine the restorative material used in this side. This ensured a fair and unbiased allocation process. To maintain allocation concealment, all papers were placed in opaque, sealed envelopes. Blinding of the operator was not feasible because of the distinct application techniques required for the restorative materials. However, participants (children), their caregivers, and the statistician were blinded to the type of restorative material utilized.

Group assignment:

Children who achieved the inclusion criteria were separated into two main groups depending on the type of cavity preparation in carious lower second primary molars. Group I: Class I lesions and group II: Class II lesions. Each main group was further separated into two equal subgroups in accordance with the restorative material employed:

Subgroup IA and Subgroup IIA (Control groups): Primary molars were restored with Filtek™ Bulk Fill composite.

Subgroup IB and Subgroup IIB (Study groups): Primary molars were restored with Surefil One. **(Figure 1)**

Clinical procedure:

After psychological management and preparation of the child, local anaesthesia was administered. Involved teeth were isolated utilizing a rubber dam (DuraDam, Klang, Selangor D.E., Malaysia). The cavities were prepared using a high-speed carbide bur (#330, MANI Inc., Tokyo, Japan) with a constant copious water-cooling system, using a high-speed contra-angled handpiece (Dentsply Sirona, PA, York, USA). The cavity design included all occlusal pits and fissures to standardize preparations. Small sectional contoured metal matrices (TOR VM, Russia) were placed interproximally and secured with a wedge to ensure proper contact. **(Figure 2)**

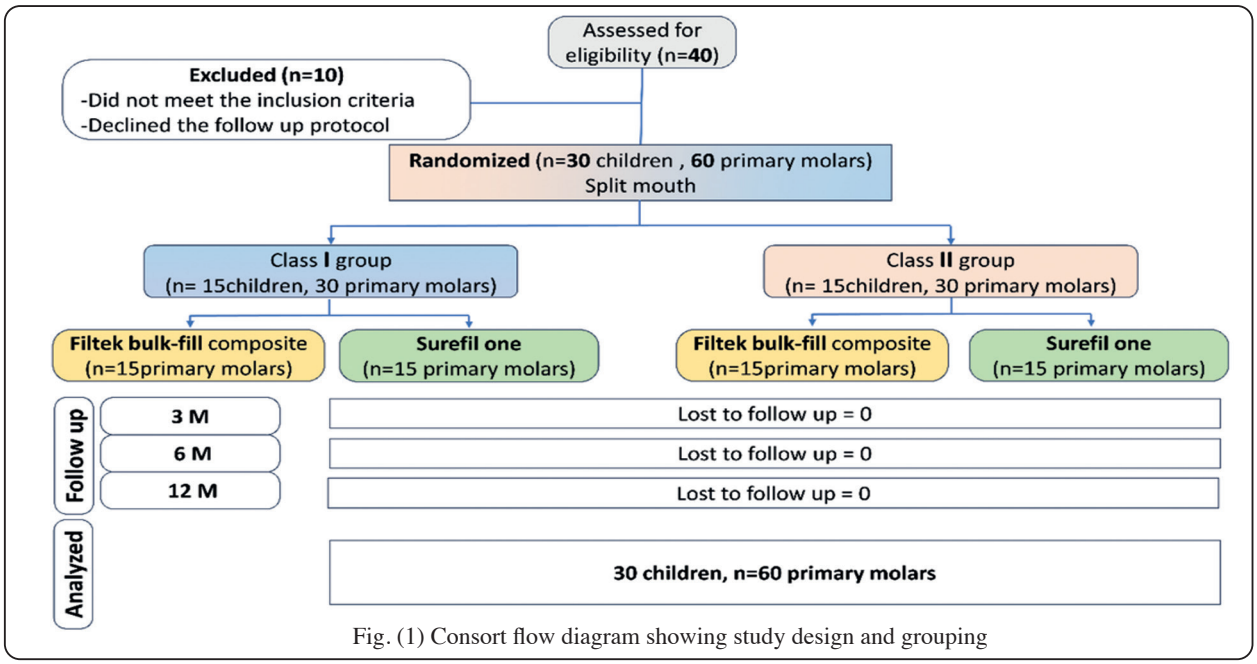

Fig. (1) Consort flow diagram showing study design and grouping

Fig, (2) Cavity preparation for class II in tooth no 75

The cavities in each subgroup were restored using the specified restorative materials in alignment with the manufacturer's guidelines as follow:

In subgroup IA and IIA (control groups):

A 37% phosphoric acid etchant (Scotchbond Universal Etchant, 3M, ESP) was implemented for 15 seconds on the dentine and 30 seconds on the enamel. After rinsing for 40 seconds with water and air-drying gently, the adhesive system (Scotchbond Universal Adhesive, ESPE, 3M, MN, St. Paul, USA) was applied actively to the entire surface utilizing a disposable bond brush for 20 seconds. The adhesive was then dispersed into a thin layer with a gentle stream of air for 5 seconds, followed by light curing for 10 seconds utilizing an LED light-curing unit (BluePhase N, Ivoclar Vivadent AG) with an intensity of 1200 mW/cm^2. Filtek™ Bulk Fill (St. Paul, USA, MN) was then utilized to fill the cavities in one increment, light-cured for 40 seconds [17].

In Subgroup IB and IIB (study groups):

The cavities were cleaned using an air-water spray, leaving a moist cavity surface. Surefil One activated capsule (Dentsply Sirona, Konstanz, Germany) were mixed for 10 seconds utilizing a capsule mixer (4200–5000 rpm). The restorative material was dispensed promptly into the prepared cavity using a capsule extruder. The dispensing process began at the deepest area of the cavity with the tip held close to the bottom, gradually withdrawing as the cavity was filled in bulk. The

cavity was overfilled to ensure proper adaptation. After that, the surface layer was light-cured for 20 seconds, while the deeper layers underwent self-curing 6 minutes after capsule activation [18].

After that, the occlusion was checked utilizing articulating paper (Nashua, NH, Bausch, USA). The restorations were finished utilizing a yellow-coded finishing flame stone (MANI Inc., Tokyo, Japan), and final polishing was performed using polishing disks (Soflex, 3M ESPE, MN, USA) while keeping the restoration moist with a water spray.

Clinical evaluation

The restorations were evaluated clinically and radiographically according to modified United States Public Health Organization (USHPS) criteria measuring marginal adaption, anatomic form, surface roughness, recurrent caries, colour match, retention, postoperative sensitivity and proximal contact[19].

The following items were categorized based on the corresponding scores: Alpha -ideal clinical situation; Bravo-clinically acceptable; Charlie-clinically unacceptable situation. The evaluation was done post restoration (baseline) and at follow-up periods of 3, 6, and 12 months. **(Figure 3,4)**. The proximal contact was checked by using dental floss. Postoperative hypersensitivity was checked by asking both the child and the parent about any complaints of the child.

Fig. (3) Post operative x-ray for class II in tooth no 85

Fig. (4) (A): Tooth 75 restored with self-adhesive bulk-fill post-operative (baseline), (B): Clinical follow up of tooth 75 restored with self-adhesive bulk-fill after 12 months, (C): Tooth 85 restored with conventional bulk-fill composite post-operative (baseline) (D): Clinical follow up of tooth 85 restored with conventional bulk-fill composite after 12 months

Statistical analysis

Data analysis was conducted utilizing SPSS software, version 26 (SPSS Inc., PASW statistics for windows version 26. Chicago: SPSS Inc.). Qualitative data were characterized utilizing numerical values and percentages. The Fisher's exact test, Chi-Square test, and Monte Carlo tests were utilized for comparing the qualitative data between groups, as considered appropriate. The Wilcoxon signed-rank test was employed to compare both examined periods. The significance of the obtained findings was assessed at the 0.05 level.

RESULTS

Regarding the marginal adaptation in class I group, intragroup comparison of the bulk-fill composite showed no statistically significant differences during the follow-up periods. However, the intragroup comparison of the self-adhesive bulk-fill composite indicated a significant difference during the follow-up periods ($p = 0.019$). The comparison of intergroup between both restorative materials showed insignificant difference. In class II group, the intragroup comparison of the bulk-fill composite showed no statistically significant differences during the follow-up periods. However, the intragroup comparison of the self-adhesive bulk-fill composite demonstrated a significant difference during the follow-up periods ($p = 0.04$). The comparison of intergroup between both restorative materials showed an insignificant difference. Regarding the retention in class I groups, the intragroup comparison of both self-adhesive bulk-fill composite and bulk-fill composite revealed insignificant difference. Similarly, the intergroup comparison between the two restorative materials showed insignificant difference. In class II group, the intragroup comparison of bulk-fill composite and self-adhesive bulk-fill composite revealed no statistically significant differences. Similarly, the comparison of intergroup between both restorative materials showed insignificant difference **(Table 1).**

The intragroup comparison of bulk-fill composite and self-adhesive bulk-fill composite during the follow-up periods and also the comparison of intergroup between both restorative materials regarding the recurrent caries and post-operative sensitivity in both class I and class II revealed insignificant differences **(Table 2).**

Regarding the anatomical form in class I group, the intragroup comparison of bulk-fill composite showed insignificant difference during the follow-up periods. However, the intragroup comparison of self-adhesive bulk-fill composite revealed a significant difference during the follow-up periods ($p = 0.007$). The comparison of intergroup between both restorative materials also demonstrated a significant difference ($p = 0.03$). In class II group, the comparison of intergroup of bulk-fill composite showed no statistically significant differences during the follow-up periods. However, the intragroup comparison of self-adhesive bulk-fill composite showed a significant difference during the follow-up periods ($p = 0.035$). Intergroup comparison between both restorative materials also demonstrated a significant difference ($p = 0.03$). Regarding the surface roughness in class I group, the comparison of intragroup of bulk-fill composite showed no statistically significant differences during the follow-up periods. However, the intragroup comparison of self-adhesive bulk-fill composite showed a significant difference during the follow-up periods ($p = 0.002$). The comparison of intergroup between both restorative materials also demonstrated a significant difference ($p = 0.006$). In class II group, the intragroup comparison of bulk-fill composite showed insignificant difference during the follow-up periods. However, the comparison of intragroup of self-adhesive bulk-fill composite revealed a significant difference during the follow-up periods ($p = 0.002$). The comparison of the intergroup between both restorative materials also demonstrated a significant difference ($p = 0.01$) **(Table 3)**.

TABLE (1) Comparison between marginal adaptation and retention of self-adhesive bulk-fill composite and bulk-fill composite restoration among class I and class II during follow up

Follow up	**Subgroup IA (n=15) (bulk-fill composite)**			**Subgroup IB (n=15) (self-adhesive bulk-fill composite)**			**P-value**
Marginal adaptation							
	A	**B**	**C**	**A**	**B**	**C**	1.0
Baseline	15 (100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
3 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
6 months	15(100%)	0(0%)	0(0%)	14(93.3)	1(6.7%)	0(0%)	1.0
12 months	14 (93.3%)	1(6.7%)	0(0%)	11 (73.3%)	4(26.7%)	0(0%)	0.329
P value between follow up Periods		P1=0.392			**P2=0.019***		
USPHS criteria Follow up	**Subgroup IIA (n=15)**			**Subgroup IIB (n=15)**			**p- value**
Baseline	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
3 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
6 months	15(100%)	0(0%)	0(0%)	13 (86.7%)	2(13.3%)	0(0%)	0.483
12 months	14 (93.3%)	1(6.7)	0(0%)	11(73.3%)	4 (26.07%)	0(0%)	0.142
P value between follow up Periods		P1=0.392			**P2=0.04***		
Retention							
	Subgroup IA (n=15)			**Subgroup IB (n=15)**			**P-value**
Baseline	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
3 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
6 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
12 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
P value between follow up Periods		P1=1.0			P2=1.0		
	Subgroup IIA (n=15)			**Subgroup IIB (n=15)**			**P-value**
Baseline	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
3 months	15 (100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
6 months	15 (100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
12 months	15(100%)	0(0%)	0(0%)	14(93.3%)	1(6.7%)	0(0%)	1.0
P value between follow up Periods		P1=1.0			P2=1.0		

Data are presented as frequency (%). p1: Comparison between follow up Periods in Subgroup A, p2: Comparison between follow up Periods in Subgroup B *: significant as P value ≤ 0.05.

TABLE (2) Comparison between recurrent and post-operative sensitivity of self-adhesive bulk-fill composite and bulk-fill composite restoration among class I and class II during follow up

Follow up	**Subgroup IA (n=15) (bulk-fill composite)**			**Subgroup IB (n=15) (self-adhesive bulk-fill composite)**			**P-value**
Recurrent caries							
	A	**B**	**C**	**A**	**B**	**C**	**1.0**
Baseline	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	**1.0**
3 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	**1.0**
6 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	**1.0**
12 months	15(100%)	0(0%)	0(0%)	14(93.3%)	0(0%)	1(6.7%)	**1.0**
P value between follow up Periods		P1=1.0			P2=0.392		
	Subgroup IIA (n=15)			**Subgroup IIB (n=15)**			**p- value**
baseline	15(100%)	0(0%)	0(0%)	15(100)	0(0%)	0(0%)	1.0
3 months	15(100%)	0(0%)	0(0%)	15(100)	0(0%)	0(0%)	1.0
6 months	15(100%)	0(0%)	0(0%)	15(100)	0(0%)	0(0%)	1.0
12 months	15(100%)	0(0%)	0(0%)	14(93.3)	0(0%)	1(6.7%)	1.0
P value between follow up Periods		P1=1.0			P2=0.392		
Post-operative sensitivity							
	Subgroup IA (n=15)			**Subgroup IB (n=15)**			**P-value**
baseline	15 (100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
3 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
6 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
12 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
P value between follow up Periods		P1=1.0			P2=1.0		
	Subgroup IIA (n=15)			**Subgroup IIB (n=15)**			**P-value**
baseline	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
3 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
6 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
12 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
P value between follow up Periods		P1=1.0			P2=1.0		

Data are presented as frequency (%).p1: Comparison between follow up Periods in Subgroup A, p2: Comparison between follow up Periods in Subgroup B *: significant as P value ≤ 0.05.

TABLE (3) Comparison between anatomical form and surface roughness of self-adhesive bulk-fill composite and bulk-fill composite restoration among class I and class II during follow up

Follow up	Subgroup IA (n=15) (bulk-fill composite)			Subgroup IB (n=15) (self-adhesive bulk-fill composite)			P-value
Anatomical form							
	A	**B**	**C**	**A**	**B**	**C**	1.0
Baseline	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
3 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
6 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
12 months	15(100%)	0(0%)	0(0%)	11(73.3%)	4 (26.7%)	0(0%)	**0.03***
P value between follow up Periods		P1=1.0			P2=**0.007***		
	Subgroup IIA (n=15)			**Subgroup IIB (n=15)**			**p- value**
Baseline	15	0	0	15(100%)	0(0%)	0(0%)	1.0
3 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
6 months	15(100%)	0(0%)	0(0%)	14(93.3)	1(6.7)	0(0%)	1.0
12 months	15(100%)	0(0%)	0(0%)	11(73.3%)	4(26.7%)	0(0%)	**0.03***
P value between follow up Periods		P1=1.0			**P2=0.035***		
Surface roughness							
	Subgroup IA (n=15)			**Subgroup IB (n=15)**			**P-value**
Baseline	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
3 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
6 months	15(100%)	0(0%)	0(0%)	13(86.6%)	2(13.4%)	0(0%)	0.143
12 months	15(100%)	0(0%)	0(0%)	9(60%)	6(40%)	0(0%)	**0.006***
P value between follow up Periods		P1=1.0			**P=0.002***		
	Subgroup IIA (n=15)			**Subgroup IIB (n=15)**			**P-value**
Baseline	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
3 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
6 months	15(100%)	0(0%)	0(0%)	12(80%)	3(20%)	0(0%)	0.224
12 months	15(100%)	0(0%)	0(0%)	8(53.3%)	6(40%)	1(6.7%)	**0.01***
P value between follow up Periods		P=1.0			**P=0.002***		

Data are presented as frequency (%).p1: Comparison between follow up Periods in Subgroup A, p2: Comparison between follow up Periods in Subgroup B *: significant as P value ≤ 0.05.

Regarding the color match in class I group, the intragroup comparison of bulk-fill composite showed insignificant difference within the follow-up periods. However, the intragroup comparison of self-adhesive bulk-fill composite demonstrated a significant difference during the follow-up periods ($p = 0.001$). There was a significant difference in the intergroup comparison between both restorative materials ($p < 0.001$). In class II group, the intragroup comparison of bulk-fill composite showed insignificant difference during the follow-up periods. However, the intragroup comparison of self-adhesive bulk-fill composite demonstrated a significant difference during the follow-up periods ($p = 0.001$). The comparison of intergroup between both restorative materials demonstrated a significant difference ($p < 0.001$). Regarding the proximal contact in class II group, the intragroup comparison of bulk-fill composite showed no statistically significant differences during the follow-up periods. Similarly, the intragroup comparison of self-adhesive bulk-fill composite revealed no statistically significant differences during the follow-up periods. The comparison of the intergroup between both restorative materials also showed insignificant difference **(Table 4).**

TABLE (4) Comparison between color match and proximal contact of self-adhesive bulk-fill composite and bulk-fill composite restoration among class I and class II during follow up

Follow up	**Subgroup IA (n=15) (bulk-fill composite)**			**Subgroup IB (n=15) (self-adhesive bulk-fill composite)**			**P-value**
Color match							
	A	**B**	**C**	**A**	**B**	**C**	1.0
Baseline	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
3 months	15(100%)	0(0%)	0(0%)	9(60%)	6(40%)	0(0%)	**0.006***
6 months	15(100%)	0(0%)	0(0%)	4(26.6%)	11(73.4%)	0(0%)	**p<0.001***
12 months	15(100%)	0(0%)	0(0%)	0(0%)	15(100%)	0(0%)	**P<0.001***
P value between follow up Periods		P1=1.0			**P2=0.001***		
	Subgroup IIA (n=15)			**Subgroup IIB (n=15)**			**p- value**
Baseline	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
3 months	15(100%)	0(0%)	0(0%)	8(53.3%)	7(46.7%)	0(0%)	**0.006***
6 months	15(100%)	0(0%)	0(0%)	2(13.4%)	13(86.6%)	0(0%)	**P<0.001***
12 months	15(100%)	0(0%)	0(0%)	0(0%)	15(100%)	0(0%)	**P<0.001***
P value between follow up Periods		P1=1.0			**P2=0.001***		
Proximal contact							
	Subgroup IIA (n=15)			**Subgroup IIB (n=15)**			**P-value**
Baseline	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
3 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
6 months	15(100%)	0(0%)	0(0%)	15(100%)	0(0%)	0(0%)	1.0
12 months	15(100%)	0(0%)	0(0%)	13(86.7%)	0(0%)	2(13.3%)	0.483
P value between follow up Periods		P=1.0			P2=0.112		

Data are presented as frequency (%).p1: Comparison between follow up Periods in Subgroup A, p2: Comparison between follow up Periods in Subgroup B *: significant as P value ≤ 0.05.

DISCUSSION

Self-adhesive bulk-fill composites streamline the filling process by removing the need for a separate adhesive, reducing treatment time and lowering the risk of restoration failure due to blood or saliva contamination[20, 21].

The null hypothesis was rejected in our study. Regarding marginal adaptation, both self-adhesive and conventionally bonded bulk-fill composite showed no statistically significant difference during the study period.This was in accordance with Frankenberger et al [22] who reported that Surefil One demonstrated good marginal quality in comparison to composite resin in vitro. Also, Bhol et al [23] found no significant differences in percentage of gap-free margins between self-adhesive and conventional bulk-fill composite resin in Class I restorations in vitro. Conversely, Neves et al[24] reported that self-adhesive composites showed greater microleakage than conventional composite resin. The dual polymerization process of Surefil One may lead to higher polymerization shrinkage stress, particularly in cavities with a high C-factor, making adhesion to the dentin of the cavity floor more challenging compared to self-curing techniques. Furthermore, Sahli et al [25] found that self-adhesive composites had the lowest marginal adaptation scores compared to both incrementally layered and bulk-fill composite. This could be attributed to the self-adhesive properties of the material were not sufficient to create a strong, stress-resistant adhesive interface as no adhesive system was used before its application.

Similarly, regarding retention, both restorative materials showed comparable performance during the study period, highlighting the good self-adhering efficiency of the study group material. Surefil One primarily bonds through a chemical (ionic) interaction between the calcium ions in hydroxyapatite and the carboxylic acid groups found in MOPOS and acrylic acid. Furthermore, self-adhesion may be increased by micromechanical bonding facilitated through surface demineralization or hybridization, in addition to the infiltration of the smear layer [26]. This was in line with Alghamdi et al [27] who reported that Surefil One exhibits superior bond strength in comparison to resin-modified glass ionomers. However, Elraggal et al[28] found that shear bond strength of Surefil One was significantly lower than that of conventional resin composites. This could be attributed to their higher viscosity and reduced wettability compared to self-etch adhesives. These properties may have limited the resin's ability to fully cover the tooth structure, reducing interaction between acidic monomers and calcium ions. Additionally, contain fewer acidic monomers than self-etch adhesives, which may further contribute to their weaker bond strength.

Postoperative hypersensitivity, on the other hand, remained absent in all subgroups throughout the study period.This could be attributed to the sufficient self-adhesive properties of the studied material and that both restorative materials have decreased polymerization shrinkage stress and proper curing depth [29,30].

Surefil One's bulk-fill and dual-cure properties are due to its unique initiator component, which triggers both radical polymerization and an ionomer reaction. The self-cure process begins immediately after the powder and liquid in the capsule are mixed, allowing the material to set within 6 minutes. Autocuring after initial placement promotes better adaptation by slowing polymerization in high C-factor areas. The surface of the restoration can be additionally treated with light curing device for 20 seconds [30].This was in line with Maghaireh et al.[31] and Ellithy et al.[32] who reported no statistically significant differences between self-adhesive and conventional bulk-fill composite in postoperative hypersensitivity during follow up periods.

Regarding the recurrent caries, after 12 months, both restorative materials showed comparable performance in preventing the recurrent caries. This was in accordance with the results of Abouelleil et al.[33] who reported that Surefil One demonstrated enhanced fluoride release and high pH levels, which promote remineralization and may prevent recurrent carious lesions in vivo. Similarly, Albelasy et al.[34] found that Surefil One's ion release

exhibited demineralization-inhibitory effects comparable to glass ionomer cements (GICs).

Regarding the anatomical form ,a statistically significant difference was found between the performance of both restorative materials after 12 months with superiority to conventional bulk-fill composite.These findings could be attributed to the properties of the studied restorative material, such as the kind and amount of the filler, as well as, child's dietary and lifestyle habits which could impact its ability to retain its anatomical contour over time [35].

Regarding surface roughness, also, a statistically significant difference was observed between the performance of both materials after 12 months with a higher percentage of self-adhesive bulk-fill restorations exhibiting roughened surfaces compared to conventional bulk-fill composites. This difference could be attributed to the composition of the material, in addition to the presence of voids and tiny porosities resulting from the mixing process of the two-component system [35].These findings were in line with Sabry et al.[36] who reported significant differences between Filtek bulk-fill and Surefil One in terms of anatomical form and surface roughness following 18 months follow up.

Color stability is a critical factor in determining the long-term esthetic success of restorations. while conventional bulk fill showed excellent color match during the study period, self-adhesive bulk-fill revealed significant color change which became noticeable after three months. This could be attributed this to the distinct compositions of the materials. Surefil One is a two-component restorative material, and the mixing of its powder and liquid components can introduce inherent pores and inconsistencies in its structure. These irregularities may affect the material's light transmission properties, leading to a darker appearance and greater opacity compared to Filtek Bulk-Fill [32]. This was corresponding to the results of Ellithy et al. [32] who documented that Filtek One restorations were superior in color matching, translucency, and surface luster compared to Surefil One over a 12-month follow-up.

Proximal contact integrity was maintained throughout the study, with no statistically significant differences between the two materials. This suggests that both bulk-fill and self-adhesive bulk-fill composites can provide satisfactory proximal contacts, contributing to the overall longevity of restorations[36,37]. Limitation of the study were reliance on a single evaluator and single assessment method for dental restorations (modified USPHS criteria) may restrict the comprehensiveness of the assessment and a short follow-up period prevents the evaluation of long-term outcomes.

CONCLUSION

Bulk-fill resin composite demonstrated better performance than the self-adhesive bulk-fill composite in terms of color match, surface roughness, and anatomical form. Both restorative materials demonstrated comparable performance regarding the marginal adaptation, postoperative sensitivity, retention, recurrent caries, and proximal contact.

Therefore, Increasing the sample size would enhance the ability to identify differences between the materials tested, employing both the modified USPHS criteria and the World Dental Federation (FDI) approach are recommended to determine restoration degradation early signs. Future researches with longer follow-up periods are required.

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