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PERFORMANCE OF SELF-ADHESIVE BULK-FILL HYBRID VERSUS INCREMENTAL RESIN COMPOSITE IN COMPOUND CLASS II RESTORATIONS: A ONE-YEAR RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Aim: The aim of this randomized clinical trial was to assess the performance of a self-adhesive, bulk-fill hybrid (Surefil One™, Dentsply Sirona, Konstanz, Germany) versus incremental, nanohybrid resin composite (Ceram.x® SphereTEC™ one Universal Nano-Ceramic Restorative, Dentsply Sirona, Konstanz, Germany) in restoring compound class II lesions over one-year follow up period.

Materials and Methods: Sixty-two participants were randomly assigned to each group. All materials were placed upon manufacturer's instructions. Restorations were assessed after 6- and 12-months intervals using the modified USPHS clinical criteria. Categorical data were analyzed using Fisher's exact and McNemar's tests for inter and intragroup comparisons respectively. Ordinal data were analyzed using Mann-Whitney U and Friedman's test followed by Nemenyi post hoc test for inter and intragroup comparisons respectively. Survival analysis was done using Kaplan-Meier estimate and log-rank test.

Results: Except for retention at 6 months, for all parameters and at both time intervals, there was a significant difference between the two groups with the control group having significantly higher percentage of cases with alpha score ($p<0.05$). For retention, surface roughness, recurrent caries, color match, anatomic form and proximal contact, there was a significant reduction in the percentage of cases with alpha score for the intervention group only after 12 months ($p<0.05$).

Conclusion: Incremental, nanohybrid resin composite showed superior clinical performance than the self-adhesive, bulk-fill resin hybrid over one-year follow up.

KEYWORDS: Self-adhesive bulk-fill resin hybrid restorations, incremental packing, nanohybrid resin composite, randomized clinical trial.

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INTRODUCTION

Resin composite has become widely popular and has taken the lead as the material of choice for the direct restoration of posterior teeth, demonstrating high clinical performance with a 2% long-term annual failure rate [1]. In addition to having superior mechanical and physical properties, resin composite restorative materials have extended to include a range of new potentials, such as antibacterial and therapeutic effects [2].

Over the years, resin composite advances have primarily focused on simplification by decreasing the number or time of clinical application steps. One simplification is high-viscosity bulk-fill resin composites. This has greatly eased placement of resin composite, avoiding the time-consuming and technique-sensitive incremental layering technique, thus minimizing its undesired effects [3].

Another simplification is the rise of self-adhesive resin composites which do not need the application of a separate adhesive system [4]. Self-adhesive resin composites were introduced into the market by different manufacturers claiming they exhibit properties that can meet the demands of the oral environment, including stress-bearing class II restorations [1].

Promoting self-adhesion to the tooth is obtained by modifying the structural monomers with acidic groups. This is attained in polyacids of glass ionomer cements. Yet, polyacids are unable to interconnect to the polymerized chains due to the absence of polymerizable groups [5,6].

An added method of simplification introduced, a self-adhesive, dual cured, bulk-fill resin-based material (Surefil One™, Dentsply Sirona, Konstanz, Germany). It is based on a modified polyacid system (MOPOS) that self-adheres to the tooth and acts as a copolymerizing crosslinker within the structural network [6,7]. This restorative material categorized as self-adhesive composite hybrid, combines the self-adhesive nature of glass ionomer polyacids and the crosslinking potential of resin composite monomers [8,9]. Accordingly, it is claimed to become a favorable esthetic substitute for amalgam and a desired substitute for conventional resin composite [1].

To date, only a few in vitro studies have been conducted while there are no enough clinical studies addressing the performance of this material. Due to the limited available literature and absence of adequate long-term clinical evidence, this randomized clinical trial was conducted to assess the clinical performance of the self-adhesive, dual cured, bulk-fill resin-based hybrid restorative material versus conventional incremental resin composite restorative material placed in posterior teeth over a period of one year. The null hypothesis was that both adhesive would behave similarly as evaluated via Modified USPHS clinical criteria.

MATERIALS AND METHODS

Study Design and Registration

This is a one-year, two parallel arms, double-blind, randomized controlled trial that was carried out in the Conservative Dentistry outpatient clinic, Faculty of Dentistry, Cairo University, starting in February 2021 till April 2023. Approval from the Research Ethics Committee (REC), Faculty of Dentistry, Cairo University was obtained January 2021 (ID: 28121). The study was registered on clinicaltrials.gov database (ID: NCT04790383). Participants were randomly assigned to the groups based upon the restoration placed in carious posterior teeth (class II cavities) where group 1: self-adhesive bulk-fill resin composite hybrid, group 2: conventional, incremental nanohybrid resin composite. Tested materials' description and composition as specified by the manufacturer are shown in table (1).

TABLE (1) Materials' description, manufacturer and composition.

Material	Composition
Self-adhesive bulk-fill resin composite hybrid (Surefil One™, Dentsply Sirona, Konstanz, Germany)	Crosslinking dimethacrylate (DMA), triethylene glycol dimethacrylate (TEGDMA), Phosphoric acid functionalized methacrylate. Camphorquinone photointiator, oxidizing and reducing agents. Filler loading: 74% (w/w) strontium-fluoro-alumino-silicate filler, zirconia-silica filler
Conventional, nanohybrid resin composite (Ceram.X® SphereTEC™ one Universal Nano-Ceramic Restorative, Dentsply Sirona, Konstanz, Germany)	methacrylate-, acid-modified methacrylate-, inorganic polycondensate- or epoxide based) modified version of the polysiloxane. Poly-urethanemethacrylate, bis-EMA and TEGDMA. Filler loading: 77-79 weight Prepolymerized spherical fillers, Barium-aluminum borosilicate glass, ytterbium fluoride, functionalized silicon dioxide (Nano filler), 10 nm
Vococid® Etchant (VOCO GmbH, Cuxhaven, Germany)	35% orthophosphoric acid gel
Prime&Bond® Universal Adhesive, (Dentsply Sirona, Konstanz, Germany)	Bi- and multifunctional acrylate, 10-MDP, PENTA, phosphoric acid modified acrylate resin stabilizer, isopropanol, camphorquinone /tertiary amine.

Sample Size Calculation

Based on a former study (10), with the power of test set at 80% and 5% significance level, the predicted sample size was a total of 53 restorations. This number was increased to 62 restorations (n= 31) for any losses at follow-up intervals.

Eligibility Criteria

The inclusion criteria were male or female cooperative participants with good oral hygiene and approved to take part in the study aged from 20 to 50 years with asymptomatic vital proximal carious posterior teeth (compound class II lesions) of ICDAS score 4 or 5. Included teeth should also be with healthy periodontium and no radiographic findings indicating any pulp affection. In addition to presence of contacting with adjacent teeth that should be with intact sound marginal ridge and in functioning occlusion with the opposing teeth,.

The exclusion criteria were carious symptomatic posterior teeth with irreversible pulpitis; subgingival cavities that can't be restored; teeth suffering from periodontitis (probing pocket depth ≥5 mm). Also, participants with any parafunctional habits and/or temporomandibular joint disorders; or severe medical problems, under medications that may alter oral health; with history of allergic reaction concerning methacrylate; pregnancy; alcohol drinkers; heavy smokers; or with any conditions that may affect patient retention to the trial.

Randomization, Sequence Generation, and Allocation Concealment

62 eligible participants (39 females, 23 males) were randomly assigned via online randomization (https://www.random.org). The generated random numbers were filed in enclosed envelopes arranged by a contributor who wasn't engaged in any part of the trial. The allocation sequence was obscured from the operator. Only 55 participants completed the study follow up (Figure 1, CONSORT 2010 Flow Diagram).

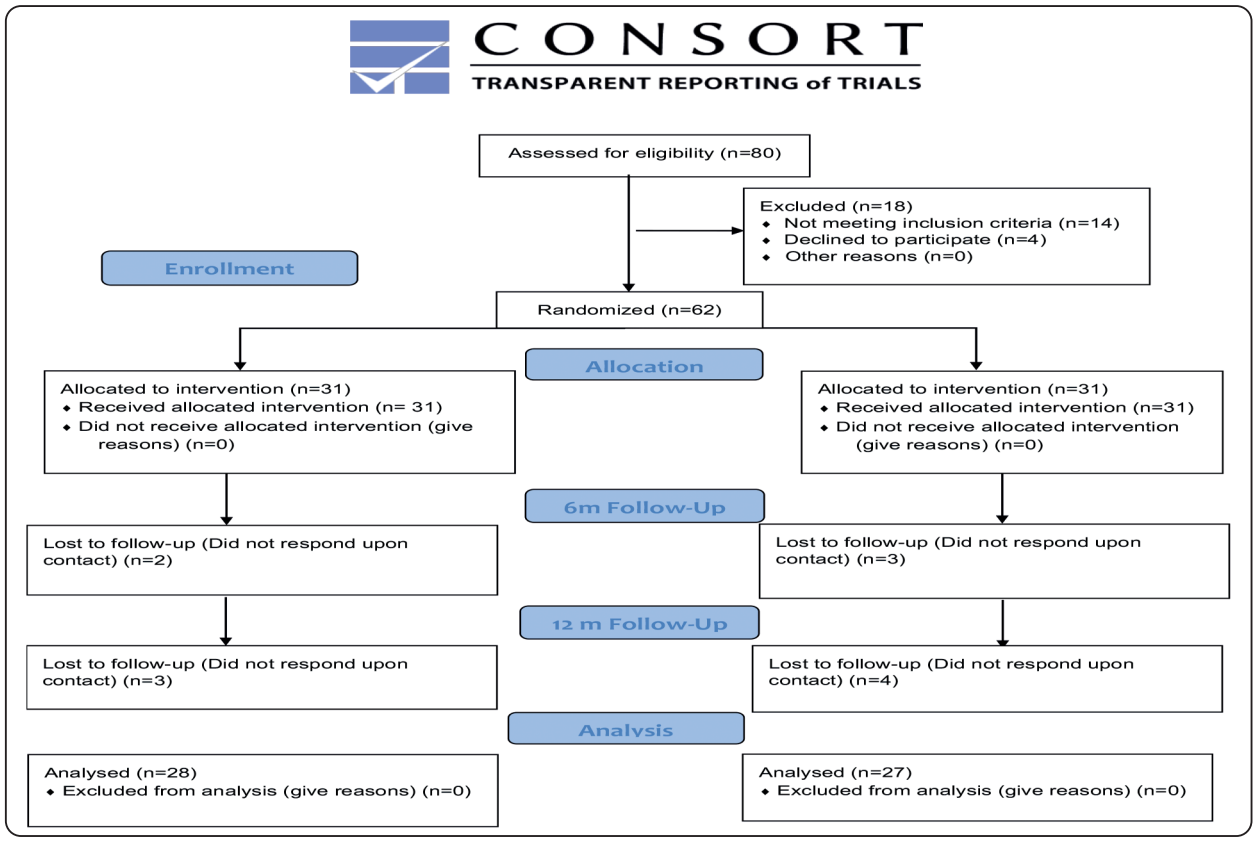

Fig. (1) CONSORT 2010 Flow Diagram

Study Participants

Detailed history-taking was done for all participants and recorded in dental charts. Participants were informed regarding the trial's aim, benefits, safety measures and anticipated study period. Afterwards, an informed consent was obtained. Oral hygiene instructions were given, prophylactic scaling was performed, and any complaints were resolved before commencing the trial. Participants were instructed to brush their teeth daily. During follow-up visits, the primary operator confirmed participants followed regular oral hygiene.

Clinical Examination

Two trained examiners blinded to the group allocation performed clinical examination. A random 15% of the participants were reexamined to ensure the examiners' calibration and repeatability. If disagreements arose, a discussion and consensus was obtained between the examiners. Carious lesions were given scores based on the International Caries Detection and Assessment System "ICDAS"(11). Radiographs were taken when additional investigation was required. Excising carious lesions and placing restorations after baseline examination was performed. Any caries lesions detected through the follow up period received the needed dental treatment.

Clinical Operative Procedures

Clinical steps were performed by the same dentist who was not blinded due to the different manipulation and application techniques of the restorative materials.

Cavity Preparation

Prior to any procedure, the teeth were cleaned with rubber cups and prophylactic polishing paste. After local anesthesia administration (Artinibsa 4% with 1:100.000 epinephrine; Inibsa S.L.U,

Barcelona, Spain), field isolation was done using heavy rubber dam (Sanctuary™ Powder Free Latex Dental Dam, Sanctuary Health Sdn Bhd, Perak, Malaysia). Cavities were prepared following the fundamentals of conservative cavity designs for adhesive resin composite restorations, using pear shaped carbide burs (H245 bur, Komet, South Carolina, USA) and a high-speed handpiece with copious water coolant and high-volume suction. Any remaining carious dentin was removed using an excavator (51/52 double ended excavator, Dentsply Maillefer, Ballaigues, Switzerland), following the contemporary caries removal clinical guidelines (12). Finishing of the cavity walls was performed using yellow coded tapered with round end stone (TC Yellow, Mani, Japan) . Afterwards, prepared cavities were properly rinsed and blot-dried with cotton pellet.

Restorative Procedures

Materials were applied upon manufacturer's instructions. For compound class II prepared cavities, a thin, pre-contoured and proper-sized sectional matrix band with its corresponding ring (Sectional Contoured Metal Matrices Kit № 1.398, TOR VM, Moscow, Russia) and suitable wooden wedge were placed before the restorative procedure to restore the missing proximal wall.

A) Intervention group (Surefil One™, Dentsply Sirona, Konstanz, Germany)

The capsule was activated by pressing the plunger to its limit. The activated capsule was instantly administered into a capsule mixer (4200-5000 oscillations/minute) for 10 seconds. The capsule was loaded into a capsule extruder, and the extruder trigger was pressed till the material was ejected from the nozzle. Beginning at the deepest part of the cavity while maintaining the nozzle tip at the bottom of the cavity floor and avoiding lifting the tip out, the material was dispensed. The tip was moved to all cavity areas while gradually withdrawing until the cavity was overfilled. Removal of the excess and contouring with a gold-plated composite applicator was performed immediately after placement and before the end of the working time (1 minute and 30 seconds after activation). The occlusal surface was cured for 20 seconds using an LED light-curing unit of 1600~1800 mW/cm2 light intensity (LED.F Curing Light, Guilin Woodpecker Instruments Co., Guangxi, China). The light intensity was verified for every five patients by a radiometer built in the light cure device. Upon manufacturer recommendation, the placed material was left undisturbed, and the matrix band was kept in place for at least 6 minutes after activation. After removal of the matrix system, the buccal and lingual surfaces were light cured for 20 seconds.

B) Control group (Ceram.x® SphereTEC™ one Universal Nano-Ceramic Restorative, Dentsply Sirona, Konstanz, Germany)

Selective enamel etching protocol was performed using 35% phosphoric acid gel (Vococid®, VOCO GmbH, Cuxhaven, Germany) for 20 seconds. Rinsing was performed under vigorous water spray and high-volume suction for at least 15 seconds. Afterwards, excess water was removed by blot drying with a cotton pellet. A single coat of the universal adhesive (Prime&Bond® Universal Adhesive, Dentsply Sirona, Konstanz, Germany) was applied using a disposable micro brush on all cavity surfaces and slightly agitated for 20 seconds. Air thinning was performed for solvent evaporation using clean, dry air from an air-water syringe with gentle air flow for 5 seconds until a glossy and uniform layer was achieved. The adhesive was cured for 10 seconds with the LED light-curing unit of 1600~1800 mW/cm^2 light intensity (LED.F Curing Light, Guilin Woodpecker Instruments Co., Guangxi, China) as recommended by the manufacturer. An incremental, nanohybrid resin composite restorative material was placed in increments of 2 mm thickness following a centripetal technique. Each increment was light cured for 20 seconds.

Finishing and Polishing

Finishing was done with cups and points (Enhance® Finishing System, Dentsply Sirona, Konstanz, Germany) using low-speed handpiece with sufficient water spray. Polishing for a lustrous

surface was achieved using diamond and aluminum oxide polishing paste with felt wheel and goat hairbrushes (ENA shiny polishing kit, Micerium S.p.A., Genoa, Italy).

Outcomes

Restorations were assessed at baseline (after 1 week), 6- and 12-months using the modified USPHS clinical criteria by two blinded examiners, Figure (2) and Figure (3). The assessment was conducted under adequate light with mirrors and dental explorers giving scores for each criterion as listed in Figure (4). Alpha (A) and Bravo (B) are considered "clinically acceptable" while Charlie (C) is considered "clinically unacceptable".

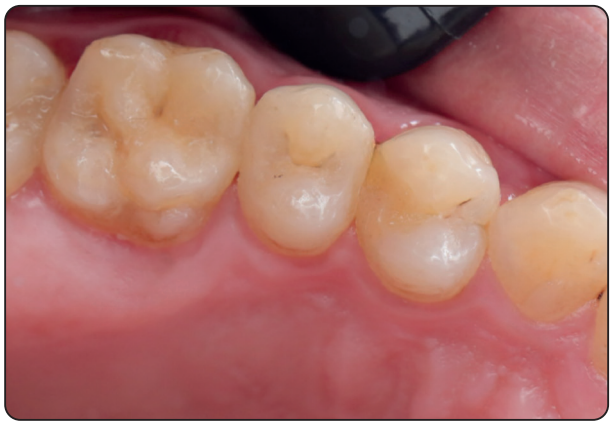

Fig. (2) A representative photograph of the Intervention Group; self-adhesive bulk-fill hybrid resin composite (Surefil OneTM, Dentsply Sirona, Konstanz, Germany) restoration in the distal of the upper second premolar.

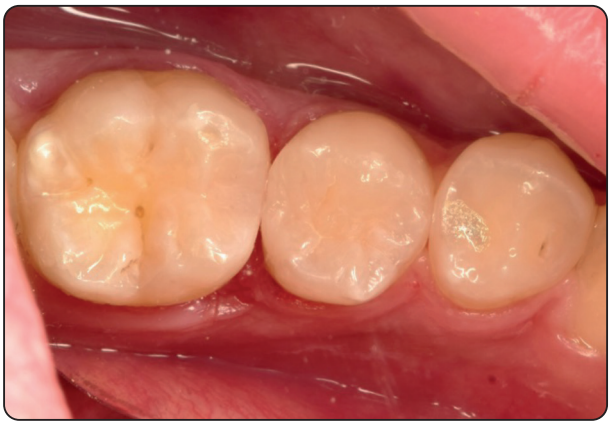

Fig. (3) A representative photograph of the Control group; conventional, incremental resin composite restoration (Ceram.x® SphereTEC™ one Universal Nano-Ceramic Restorative, Dentsply Sirona, Konstanz, Germany) in the distal of lower second premolar.

Criterion	Score	Characteristics
Postoperative hypersensitivity	A	No postoperative sensitivity
	C	Sensitivity present
Retention analysis	A	No loss of restoration
	C	Loss of restoration
Color match	A	Matches tooth
	B	Acceptable mismatch
	C	Unacceptable mismatch
Marginal discoloration	A	No discoloration between tooth structure and restorative material
	B	Nonpenetrating marginal discoloration which can be polished away
	C	Discoloration has penetrated margin in pulpal direction
Marginal adaptation	A	Closely adapted, no detectable margin
	B	Detectable marginal discrepancy clinically acceptable
	C	Marginal crevice, clinically unacceptable
Anatomic form	A	Continuous, well contoured
	B	Slight discontinuity or slight undercontoured, clinically acceptable
	C	Discontinuous, sever undercontoured, clinically unacceptable
Surface texture	A	Smooth surface
	B	Surface rougher than enamel with no pores or craters, clinically acceptable
	C	Surface unacceptably rough with pores or craters
Secondary caries	A	No caries present
	C	Caries present

Fig. (4) Modified USPHS criteria for dental restorations

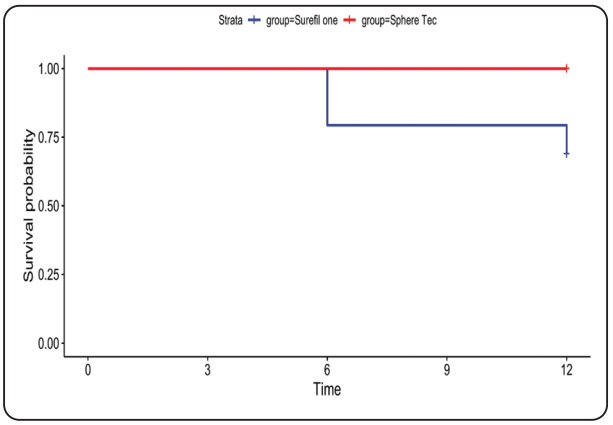

Fig. (5) Survival plot analysis of both groups

TABLE (2) Intergroup comparison of demographic data

Parameter		Intervention Group (self-adhesive bulk-fill hybrid)	Control group (conventional, incremental resin composite)	Statistic	p-value
Sex [n (%)]	**Male**	12 (38.7%)	11 (35.5%)	**0.07**	**0.793**
	Female	19 (61.3%)	20 (64.5%)		
Age (mean±SD) (years)		32.19±9.81	33.06±10.27	**0.34**	**0.734**
Tooth [n (%)]	**Premolar**	12 (38.7%)	14 (45.2%)	**0.26**	**0.607**
	Molar	19 (61.3%)	17 (54.8%)		

TABLE (3) Inter and intragroup comparisons of different clinical parameters.

Parameter	Time	Score	*n (%)*		*u-value*	*p-value*
			Intervention Group (self-adhesive bulk-fill hybrid)	**Control group (conventional, incremental resin composite)**		
Retention	**Baseline**	***Alpha***	31 (100%)[A]	31 (100%)	**NA**	**NA**
		Charlie	0 (0.00%)	0 (0.00%)		
	6 months	***Alpha***	26 (89.66%)[B]	28 (100.00%)	**448.00**	**0.087**
		Charlie	3 (10.34%)	0 (0.00%)		
	12 months	***Alpha***	23 (82.14%)[B]	27 (100.00%)	**445.50**	**0.024***
		Charlie	5 (17.86%)	0 (0.00%)		
	q-value		**6.33**	**NA**		
	p-value		**0.042***	**NA**		
Marginal discoloration	**Baseline**	***Alpha***	31 (100%)[A]	31 (100%)	**NA**	**NA**
		Bravo	0 (0.00%)	0 (0.00%)		
		Charlie	0 (0.00%)	0 (0.00%)		
	6 months	***Alpha***	24 (82.76%)[A]	28 (100.00%)	**476.00**	**0.024***
		Bravo	2 (6.90%)	0 (0.00%)		
		Charlie	3 (10.34%)	0 (0.00%)		
	12 months	***Alpha***	15 (53.57%)[B]	25 (92.59%)	**530.50**	**0.001***
		Bravo	8 (28.57%)	2 (7.41%)		
		Charlie	5 (17.86%)	0 (0.00%)		
	q-value		**17.35**	**4.00**		
	p-value		**<0.001***	**0.135**		
Marginal adaptation	**Baseline**	***Alpha***	31 (100%)[A]	31 (100%)	**NA**	**NA**
		Bravo	0 (0.00%)	0 (0.00%)		
		Charlie	0 (0.00%)	0 (0.00%)		
	6 months	***Alpha***	22 (75.86%)[A]	27 (96.43%)	**491.00**	**0.025***
		Bravo	4 (13.79%)	1 (3.57%)		
		Charlie	3 (10.34%)	0 (0.00%)		
	12 months	***Alpha***	14 (50.00%)[B]	24 (88.89%)	**532.50**	**0.001***
		Bravo	9 (32.14%)	3 (11.11%)		
		Charlie	5 (17.86%)	0 (0.00%)		
	q-value		**17.76**	**4.67**		
	p-value		**<0.001***	**0.097**		

Parameter	Time	Score	*n (%)* Intervention Group (self-adhesive bulk-fill hybrid)	*n (%)* Control group (conventional, incremental resin composite)	*u-value*	*p-value*
Surface texture	Baseline	*Alpha*	31 (100%)[A]	31 (100%)	NA	NA
		Bravo	0 (0.00%)	0 (0.00%)		
		Charlie	0 (0.00%)	0 (0.00%)		
	6 months	*Alpha*	23 (79.31%)[A]	28 (100.00%)	490.00	0.012*
		Bravo	3 (10.34%)	0 (0.00%)		
		Charlie	3 (10.34%)	0 (0.00%)		
	12 months	*Alpha*	11 (39.29%)[B]	27 (100.00%)	607.50	<0.001*
		Bravo	12 (42.86%)	0 (0.00%)		
		Charlie	5 (17.86%)	0 (0.00%)		
	q-value		25.08	NA		
	p-value		<0.001*	NA		
Recurrent caries	Baseline	*Alpha*	31 (100%)[A]	31 (100%)	NA	NA
		Charlie	0 (0.00%)	0 (0.00%)		
	6 months	*Alpha*	25 (86.21%)[B]	28 (100.00%)	462.00	0.045*
		Charlie	4 (13.80%)	0 (0.00%)		
	12 months	*Alpha*	23 (82.14%)[B]	27 (100.00%)	445.50	0.024*
		Charlie	5 (17.86%)	0 (0.00%)		
	u-value		6.33	NA		
	p-value		0.042*	NA		
Anatomic form	Baseline	*Alpha*	31 (100%)[A]	31 (100%)	NA	NA
		Bravo	0 (0.00%)	0 (0.00%)		
		Charlie	0 (0.00%)	0 (0.00%)		
	6 months	*Alpha*	23 (79.31%)[A]	28 (100.00%)	490.00	0.012*
		Bravo	3 (10.34%)	0 (0.00%)		
		Charlie	3 (10.34%)	0 (0.00%)		
	12 months	*Alpha*	15 (53.57%)[B]	27 (100.00%)	553.50	<0.001*
		Bravo	8 (28.57%)	0 (0.00%)		
		Charlie	5 (17.86%)	0 (0.00%)		
	q-value		18.88	NA		
	p-value		<0.001*	NA		
Color match	Baseline	*Alpha*	31 (100%)[A]	31 (100%)	NA	NA
		Bravo	0 (0.00%)	0 (0.00%)		
		Charlie	0 (0.00%)	0 (0.00%)		
	6 months	*Alpha*	21 (72.41%)[B]	28 (100.00%)	518.00	0.003*
		Bravo	5 (17.24%)	0 (0.00%)		
		Charlie	3 (10.34%)	0 (0.00%)		
	12 months	*Alpha*	19 (67.86%)[B]	27 (100.00%)	499.50	0.002*
		Bravo	4 (14.29%)	0 (0.00%)		
		Charlie	5 (17.86%)	0 (0.00%)		
	q-value		13.87	NA		
	p-value		<0.001*	NA		
Proximal contact	Baseline	*Alpha*	31 (100%)[A]	31 (100%)	NA	NA
		Bravo	0 (0.00%)	0 (0.00%)		
		Charlie	0 (0.00%)	0 (0.00%)		
	6 months	*Alpha*	20 (68.97%)[B]	28 (100.00%)	532.00	0.002*
		Bravo	3 (10.34%)	0 (0.00%)		
		Charlie	6 (20.69%)	0 (0.00%)		
	12 months	*Alpha*	14 (50.00%)[B]	27 (100.00%)	567.00	<0.001*
		Bravo	5 (17.86%)	0 (0.00%)		
		Charlie	9 (32.14%)	0 (0.00%)		
	q-value		20.18	NA		
	p-value		<0.001*	NA		
Post-operative hypersensitivity	Baseline	*Alpha*	31 (100%)	31 (100%)	NA	NA
		Charlie	0 (0.00%)	0 (0.00%)		
	6 months	*Alpha*	23 (79.31%)	28 (100.00%)	490.00	0.012*
		Charlie	5 (17.24%)	0 (0.00%)		
	12 months	*Alpha*	23 (82.14%)	27 (100.00%)	490.00	0.012*
		Charlie	5 (17.86%)	0 (0.00%)		
	q-value		NA	NA		
	p-value		NA	NA		

Statistical Analysis

Categorical and ordinal data are presented as frequency and percentage values. Categorical data were analyzed using Fisher's exact and McNemar's tests for inter and intragroup comparisons respectively. Ordinal data were analyzed using Mann-Whitney U and Friedman's test followed by Nemenyi post hoc test for inter and intragroup comparisons respectively. Numerical data are represented as mean, standard deviation (SD), and standard error (SE) values. Age data were tested for normality using Shapiro-Wilk's test, were found to be normally distributed, and were analyzed using independent t-test. Univariate survival analysis was done using Kaplan-Meier estimate and log-rank test. Significance level was set at $p<0.05$. Intention to treat (ITT) analysis was adopted for the lost patients during follow up. Statistical analysis was done using R statistical analysis software version 4.3.1 for Windows (R Core Team (2023).

RESULTS

Demographic data are presented in table (2) showing no significant difference between the two groups in terms of sex (p=0.793), age (p=0.734) and treated tooth (p=0.607). Results of inter and intragroup comparisons for clinical scores are presented in table (3). Except for retention at 6 months, in all parameters and at both time intervals, there was a statistically significant difference between the two groups with the control group having higher percentage of cases with alpha score ($p<0.05$). For retention, surface roughness, recurrent caries, anatomic form, color match, and proximal contact; there was a significant reduction in the percentage of cases with alpha score after 12 months for the intervention group only ($p<0.05$). The intervention group showed reduction in alpha score in marginal discoloration, marginal adaptation, surface roughness, and anatomic form with no significant difference between baseline and 6 months ($p>0.05$) yet with significant difference between baseline and 12 months values ($p>0.05$). The intervention group showed no significant difference between baseline, 6 months, and 12 months values in postoperative hypersensitivity.

Results of inter and intragroup comparisons for clinical outcome are presented in table (4). After 6 months, there were six failed cases in the intervention group. After 12 months, the number of failed cases in the intervention group increased to nine cases. The difference between both groups was statistically significant ($p<0.05$), with odds ratio being (15.77) and (26.79) after 6 and 12 months respectively.

TABLE (4) Inter and intragroup comparison of clinical outcome

Time	Outcome	*n (%)*		*χ2*	*p-value*	*Odds ratio (95% CI)*
		Intervention Group (self-adhesive bulk-fill hybrid)	**Control group (conventional, incremental resin composite)**			
6 months	**Success**	23 (79.31%)	28 (100.00%)	**6.47**	**0.023***	**15.77 (0.84:294.63)**
	Failure	6 (20.69%)	0 (0.00%)			
12 months	**Success**	19 (67.86%)	27 (100.00%)	**10.38**	**0.002***	**26.79 (1.47:488.17)**
	Failure	9 (32.14%)	0 (0.00%)			
χ2		**1.33**	**NA**			
p-value		**0.248**	**NA**			

NA: Not Applicable, *significant (p<0.05)

Results of univariate survival analysis are presented in table (5) and figure (5). The mean survival time in the control group was significantly higher than the intervention group (p=0.001).

NA: Not Applicable, Values with different superscripts within the same vertical column and parameter are significantly different, *significant (p<0.05)

TABLE (5) Univariate survival analysis

Survival time (Mean±SE)			
Intervention Group (self-adhesive bulk-fill hybrid)	Control group (conventional, incremental resin composite)	$\chi 2$	p-value
10.75±0.45	12.00±00	10.15	0.001*

Significant (p<0.05)

DISCUSSION

This randomized trial assessed class II self-adhesive bulk-fill resin hybrid restorations in comparison to conventional, incremental nanohybrid resin composite restorations over a one-year follow up using the modified USPHS criteria.

According to this study results in terms of marginal adaptation and discoloration, a statistically significant difference was found between the two groups after 12 months follow up with higher risk of marginal discoloration and loss of marginal integrity for the intervention group (Surefil One™, Dentsply Sirona, Konstanz, Germany). It is assumed that volumetric polymerization shrinkage might induce stresses on the adhesive interface and accordingly have a negative effect on the marginal integrity [13]. According to Neves et al. [9], Jassé et al., [14] and Garcia et al., [15], the self-adhesive bulk-fill hybrid resin composite showed greater percentage of volumetric polymerization shrinkage compared to the traditional incremental composite which might have led to defects between the restoration and cavity margins resulting in marginal discoloration and reduced marginal adaptation. Cieplik et al., [1] as well stated that self-adhesive bulk-fill hybrid resin restorations showed inferior enamel etching patterns with a lower interaction zone at the adhesive interface which might contribute to imperfect restoration margins.

Regarding recurrent caries, significant difference was found between the two groups within different follow up periods where only the intervention group exhibited higher risk of recurrent caries. This might be attributed to the previously mentioned higher polymerization shrinkage tendency of self-adhesive bulk-fill hybrid resin material creating defects or flawed cavity-restoration margins that accelerates the accumulation of saliva, debris and bacteria initiating recurrent caries [1,13].

Regarding surface roughness, a statistically significant difference was found with higher risk of surface roughness shown for the intervention group only. This is in an accordance with a trial conducted by Gjorgievska et al., [16] as they concluded that the self-adhesive, bulk-fill hybrid material exhibited highest surface roughness. They recommended this material to be used only as a dentin substitute in large cavities followed by a final capping layer of enamel composite. This might be due to the complex formulation of the material containing urethane dimethacrylate resin, dimethacrylate resin, di-functional diluents, barium- and strontium-alumino-fluoro-silicate glasses, photo-initiating components and colorant. Also, this could be due to the reduced filler loading, the larger particle size and the chemically embedded modulators in the centre of the polymerizable resin which would also result in lower wear resistance [16]. Another study by Ibrahim et al., [17] found that the non-agglomerate fillers in the self-adhesive bulk-fill hybrid material degraded after invitro aging simulating conditions. They hypothesized this is due to the increased space between the matrix and the fillers, promoting higher water sorption, weakening the interaction between the matrix and fillers, and thus affecting the material performance regarding marginal adaptation and wear resistance. Cieplik et al., (1) also reported higher surface roughness clinically with self-adhesive,

bulk-fill resin composite compared to conventional bulk-fill resin composite after 12 months service and attributed this to the material's composition as well as minor porosities and voids that might be resulted from the mixing process of this two-component material. All these explanations might be considered contributing factors and support the results of this study regarding the proximal contact and anatomic form where only the intervention group showed a statistically significant higher risk of loss of the proximal contact and anatomic form within different follow up periods.

While for the retention, the findings of this trial showed the intervention group had statistically significant reduction in retention compared to the control group after 12 months. As discussed before, the higher polymerization shrinkage in the intervention group, initiating small imperfections or gaps within critical areas as cavity-restoration margins might result in the degradation of the adhesive interface with the loss of retention over time [9,14]. It is postulated that dual polymerization may itself initiate higher polymerization shrinkage stresses within a high C factor cavity and pose an obstacle for adhesion [9,18]. Thus, conventional, incremental resin composites might promote lower polymerization shrinkage tendency, decreasing associated gaps and stresses and thus attaining restorations with greater longevity [18]. The liquid of the self-adhesive bulk-fill hybrid material mainly consists of high molecular weight polyacrylic acid functionalized with polymerizable groups (MOPOS). After mixing, an acid-base reaction is initiated, and the silanated fluoro-alumino-silicate (FAS) fillers are partially attacked. The calcium and aluminium ions released will create ionic bonds with the ionized carboxylic groups. This is followed by resin polymerization reaction, where the monomers copolymerize with FAS fillers, unreacted fillers, and other monomers. Eventually, two interconnected networks are attained due to the modified polyacrylic acid system (7). The adhesion depends on these high molecular weight polyacrylic acids, promoting smear layer hybridization and ionic interactions between the ionized carboxylic groups of the Modified Polyacid System (MOPOS) and the hydroxyapatite calcium[9,19]. This self-adhesive, bulk-fill hybrid resin necessitates moisture to release the functional acids. Therefore, dentin must be moist and not completely dehydrated. Controlling the moisture level might make it a challenge to obtain the ideal moistened dentin [7,18]. Studies claimed that over-wet surfaces would dilute acids, causing reduced permeation into the smear layer [6,20]. The fact that this material also performs shallow hybridization, it was found that its interaction with the dentin smear layer is greatly affected by the thickness of the smear layer which might influence its self-adhesion capability. Another study revealed that the dentin bond strength was superior for the self-adhesive material when used with a universal adhesive [20]. All these mentioned factors may justify the lower retention values of the intervention group.

Concerning the color match, the results of this trial showed only the intervention group had statistically significant reduction in color match compared to the control group. This agrees with a study conducted Cieplik et al., [21] where the self-adhesive bulk-fill resin hybrid exhibited significantly inferior results in color match. They claimed this may be attributed to powder and liquid mixing, resulting in intrinsic pores and inhomogeneities, leading to different light transmission giving the opaque and dark appearance of the material [21]. Another tiral conducted by Rathke et al., [6] revealed that self-adhesive bulk-fill restorative material yielded significant difference in color match scores with a 12% clinically unacceptable Charlie scores after 12 months clinical service. The previously mentioned factors such as high surface roughness and water sorption tendency of this material might lead to the uptake of pigments resulting in surface staining and change in color of the restorations over time.

Regarding postoperative hypersensitivity, there was no statistically significant reduction in alpha score for both groups. Our results are similar to a study conducted by Maghaireh et al [22] where they also found that self-adhesive bulk-fill resin hybrid

in posterior restorations showed no difference in the postoperative hypersensitivity compared to conventional bulk-fill resin composite. This might be attributed to the mild acidity and the less technique sensitive nature of self-adhesive, bulk-fill resin composites.

Regarding the overall survival rate of the two materials placed in class II restorations and assessed after one-year follow up period, a total of nine restorations failed in the self-adhesive, bulk-fill resin composite hybrid group indicating statistically significant lower clinical performance compared to the conventional, incremental nanohybrid resin composite group. Accordingly, the null hypothesis tested has to be rejected. Results of this trial indicate conventional, incremental resin composite performs significantly better than the self-adhesive, bulk-fill resin composite hybrid in the tested clinical parameters. More clinical trials are needed to confirm the findings of this study. Limitations of the study included the reduced sample size and short follow up period.

CONCLUSION

Under this study limitations, it can be concluded that conventional, incremental nanohybrid resin composite demonstrated better clinical performance and an overall higher survival rate compared to the self-adhesive, bulk-fill hybrid resin composite.

RECOMMENDATIONS

Trials with different methodologies might be useful in determining self-adhesive bulk-fill restorative materials performance by implementing various strategies such as selective enamel etching or application of an adhesive prior to its placement which might improve their clinical performance and longevity.

CONFLICT OF INTEREST

Authors declare no conflicts of interest in respect to authorship and/or publication of this article.

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