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CLINICAL PERFORMANCE OF SELF- ADHERING FLOWABLE COMPOSITE IN CLASS V RESTORATIONS WITH EDTA SURFACE PRETREATMENT: THREE YEARS EVALUATION

Abeer ElEmbaby* and Maha El Tantawi**

ABSTRACT

Aim: This randomized clinical study evaluated and compared the three years clinical performance of self-adhering flowable composite with or without EDTA surface treatment in Class V restorations. Materials and Methods: Thirty patients, each with three moderate cervical carious lesions, were enrolled in the present single - center study. Total 90 restorations were randomly assigned by one operator not involved in the restoration or the evaluation procedures, in each patient, one lesion was allocated to be restored using self-adhering flowable composite (Fusio liquid Dentin (FL)) without surface treatment, the second using self-adhering flowable composite (Fusio liquid Dentin after EDTA(EFL)) surface treatment, the third to be restored using conventional flowable composite (Tetric Flow (FF)). The allocation sequence of restorations was concealed from the operator in sealed and stapled envelopes. A single operator restored all the preparations according to the manufacturer's instructions. The restorations were finished and polished immediately after placement. Clinical evaluation was performed at one week, six, 12,18,24,30, and 36 months, by independent examiner according to United States Public Health Services (USPHS), modified Ryge criteria. Statistical analysis was performed by IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. Results: Two cases could not be reassessed at 18 and 30 months follow up. Time significantly affects the clinical performance within the tested groups except the marginal integrity criterion with the EFL group. However there was significant different between the three groups at 36 months interval in marginal discoloration, marginal integrity criteria. No significant differences were observed between the tested materials from baseline to those of three years in the other USPHScriteria. Conclusions: Self-adhering light cured resin composite achieved clinical acceptable performance at three years follow up interval. The combination of EDTA/ selfadhering light cured resin composite reveals enhancement of the clinical stability and durability of the restorations over time.

^{*} Assistant Professor, Department of Restorative Dental Sciences, College of Dentistry, Mansoura University, Mansoura, Egypt, Department of Restorative Dental Sciences, College of Dentistry, Imam Abdulrahman bin Faisal University, Dammam, Kingdom of Saudi Arabia

^{**} Professor, Department of Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Alexandria University, Alexandria, Egypt; Department of Preventive Dental Sciences, College of Dentistry, Imam Abdulrahman bin Faisal University, Dammam, Kingdom of Saudi Arabia

INTRODUCTION

Recently, composite restorations have become a routine procedure in dental offices, concurrently with the improvements of their performance. Despite this improvement, polymerization contraction and associated stresses remain a challenge. Many factors possibly influencing stress development are the cavity configuration (C-factor), composite application technique as well as the elastic behavior of restorative materials. 3,4

There is a recognized concept that high modulus restorative materials are unable to flex in the cervical region under load. To overcome this, materials with low elastic modulus, for example microfilled composites, flowable composites and glass ionomer cements have been indicated to restore cervical lesions, with the aiming of absorbing the stresses induced with polymerization contraction of the composites and the mechanical loading during function. ⁵⁻⁷

Nowadays, efforts are being made to simplify and reduce the number of steps during bonding procedure whereas retain the efficacy of dentin adhesives. Self-etching adhesive systems were produced to eradicate personal variables and diminish clinical working time. ^{8,9}

Flowable composite resins do not include adhesive properties per se, therefore the application of dental adhesive system is obligatory. Lately, selfadhering flowable composite was introduced to eliminate the issue of time-consumption associated with conventional materials. Self-adhering flowable composite unites the virtues of adhesive and restorative material technologies in one product, providing novel prospect to restorative techniques, as it is a direct composite resin restorative material that has a self-etch adhesive resin with a flowable composite resin. 10-12 It is rely on the adhesive technology includes glycerophosphate that dimethacrylate (GPDM) to etch enamel and dentin, and hydroxyethyl methacrylate (HEMA) to improve

wetting and penetration by resin into dentin. This resin bonds chemically between the phosphate groups of a GPDM monomer and the hydroxyapatite of tooth structure and, also, micromechanically between the polymerized monomers of the self-adhering flowable composite resin and the collagen fibers and smear layer of dentin.¹³⁻¹⁵

In vitro researches are essential for an early evaluation of a dental restorative material, however only a clinical study can consider all the potential variables influencing the overall performance of restorations. ¹⁶⁻¹⁹ Although many in vitro studies were investigated self-adhering flowable composite, only few studies have evaluated their clinical behavior at 6 months as Class I restorations, two years as pit and fissure sealant and 18 months as Class V restorations. ^{20,21} Therefore, the current study compared the three years clinical performance of a self-adhering flowable resin composite with or without EDTA surface treatment with a conventional flowable composite applied in ClassV cavities.

MATERIALS AND METHODS

Patient selection: Thirty patients, with healthy gingiva and normal occlusion were selected in random basis from the pool of patients attending the Dental Hospital at Imam Abdulrahman Bin Faisal University. Ethical clearance was obtained by institutional review board. Written consents were obtained from all patients before being enrolled in the study, the form and protocol were approved by the university ethical committee (IRB-2014-02-290); each patient had at least three anterior cervical unexposed carious lesions (1-2mm axial depth) with the gingival margin of the cavity in enamel. Presence of functional teeth opposing each restoration was mandatory.

The exclusion criteria were; patient with known pregnancy, disabilities, systemic disease, sever medical condition, rampant caries, xerostomia. In addition, teeth with potential prosthodontics

restoration, non-vital or endodontically treated teeth were excluded.

Enrolled patients underwent oral prophylaxis within two weeks before the beginning of the treatment procedure. Lesions per tooth location were recorded in the patient's file.

Clinical procedures: The flowable composite restorative systems in the current study were a self-adhering flowable resin composite with or without 17% EDTA was applied before selfadhering light cured resin composite application and conventional flowable composite. They were used in following the manufacturers' instructions. Table 1 shows the information of material compositions.

All 90 Class V restorations were prepared, restored, finished and polished by one operator. Each of the 30 patients had two Fusio liquid Dentin restorations one without EDTA application (FL), the second with EDTA (EFL) and the third restoration filled with Tetric Flow (FF). The allocation sequence of restorations was concealed from the operator in numbered, sealed and stapled envelopes. Restorations were evaluated by independent examiner at one week, six, 12, 18, 24, 30 and 36 months intervals.

For each procedure, local anesthesia was

administered, and rubber dam isolation was performed former to start the restorative procedure. Conventional design Class V cavity was prepared on the buccal surface of each tooth. The preparations were restored with one of the flowable composite resins included in this study in accordance to the manufacturer's instructions. Prior to evaluation all restorations were finished and polished. The patients were instructed to use a soft brush with non-bleaching toothpaste postoperatively.

Evaluation procedures:

The cervical restorations were examined at one week, six, 12, 18, 24, 30 and 36 months intervals after restoration. Restorations were evaluated by independent examiner immediately after polishing the restorations without knowing which material was used. A magnifying aid (HR2.5X-HEINE-Germany) was used for examination of restorations. Examiner was not involved in the restoration procedures.

Restorations were evaluated on the reference to the United States Public Health Services (USPHS), modified Ryge criteria for retention, color match, cavosurface marginal discoloration, recurrentcaries, surface texture and marginal integrity (Table 2). All observations were categorized and recorded.

TABLE ((1):	Composi	tion of th	e studied	materials
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Materials	Fusio liquid Dentin(FL) Self-adhering light cured flowable resin composite;	Tetric Flow (FF) light cured flowable resin composite;	Excite adhesive system Bonding agent	EDTA
Composition	4-metha-cryloxy ethyl trimellitic acid with nano-sized amorphous silica and glass fillers	BisGMA, TEGDMA and UDMA Barium glass, ytterbium trifluoride; microhybrid 64.6/39.7	Etchant: 37% phosphoric acid with colloidal silica Adhesive: HEMA, DMA, phosphoric acid acrylate silicon dioxide, initiator, stabilizers in an alcohol solution	17% EDTA Solution
Manufacturer	Pentron Clinical	IvoclarVivadent, Schaan,Liechtenstein)	IvoclarVivadent, Schaan, Liechtenstein	PulpDent

TABLE (2): Evaluation Criteria

Us Public Heal Category and R	th Service (USPHS) Modified Ryge Direct Evaluation Criteria Rating System Rating Criteria
Retention	
Alpha (A)	Restoration is present.
Delta (D)	Restoration is partially or totally missing.
Color match	Restoration is partially of totally missing.
	restoration matches the adjacent tooth tissue in color, shade, or translucency.
	re is a slight mismatch in color, shade, or translucency, but within the normal range of adjacent toothstructure. The is a slight mismatch in color, shade, or translucency, but outside of the normal range of adjacent tooth
Marginal disco	loration
Alpha (A)There	e is discoloration anywhere along the margin between the restoration and the adjacent tooth structure.
Bravo(B)Disco	loration is present but has not penetrated along the margin in a pulpal direction.
Charlie (C)Disc	coloration has penetrated along the margin in a pulpal direction.
Recurrent carie	es .
Alpha(A) No c	aries are present at the margin of the restoration, as evidenced by softness, opacity, or etching at themargin.
Bravo (B) Then	re is evidence of caries at the margin of the restoration
Surface roughn	iess
Alpha (A)The 1	restoration surface is as smooth as surrounding enamel.
Bravo (B) The	restoration surface is rougher than the surrounding enamel.
Charlie(C)Surf	ace pitting is sufficiently coarse to inhibit the continuous movement of an explorer across the surface
Marginal integr	rity
Alpha (A)	There is no visible evidence of a crevice along the margin into which the explorer penetrates.
Bravo (B)	There is visible evidence of a crevice along the margin into which the explorer penetrates or catches.
Charlie	The explorer penetrates the crevice, and dentin or base is exposed.
Delta (D)	The restoration is mobile, or missing, either in part or total.
Postoperative s	ensitivity
Alpha(A)	Normal reaction to cold spray compared to that of non-restored teeth
Bravo(B)	Increased cold sensitivity
Charlie(C)	Spontaneous pain
Delta(D)	Nonvital

Statistical analysis

Qualitative data were presented as frequencies and percentages. Friedman's test was used to compare between the three groups as well as to study the changes by time within each group.

The significance level was set at $P \le 0.05$. Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.

RESULTS

Demographic data

Thirty patients were selected in random basis from the pool of patients, Age of patients were between 20 to 50 years old; 60% male and 40% female patients.

Evaluation criteria

Retention

After 1 week, 6, 12, 18 as well as 24 months; all restorations in the three groups showed (Alpha) score. After 30 months, 96.7% of restorations in FL group showed (Alpha) score and 3.3% showed (Delta) score. In FF as well as EFL groups, 100% of the restorations showed (Alpha) score. However, there was no statistically significant difference between the three groups (*P*-value = 0.368, Effect size = 0.033). After 36 months, 93.3% of restorations in FL group showed (Alpha) score, 3.3% showed (Bravo) score and 3.3% showed (Delta) score. In FF as well as EFL groups, 100% of the restorations showed (Alpha) score. However, there was no statistically significant difference between the three groups (*P*-value = 0.135, Effect size = 0.067).

TABLE (3) Descriptive statistics and results of Friedman's test for comparison between retention in the three groups as well as the changes within each group

		FL (n = 30)		FF (n = 30)		FL = 30)		Effect size
Time	n	- <u>30)</u> %	N N	- 30) %	n	- <u>50)</u> %	_ I-value	(w)
1 week								
Alpha	30	100	30	100	30	100	N	IC [†]
6 months								IO÷
Alpha	30	100	30	100	30	100	ľ	IC [†]
12 months								IC†
Alpha	30	100	30	100	30	100	NC^{\dagger}	
18 months							NC [†]	
Alpha	30	100	30	100	30	100		
24 months								IC†
Alpha	30	100	30	100	30	100	ľ	√C [†]
30 months								
Alpha	29	96.7	30	100	30	100	0.368	0.033
Delta	1	3.3	0	0	0	0		
36 months								
Alpha	28	93.3	30	100	30	100	0.125	0.067
Bravo	1	3.3	0	0	0	0	0.135	0.067
Delta	1	3.3	0	0	0	0		
P-value	0.	136	N.T.	·C†	NIC†			
Effect size (w)	0.0	054	IN	NC^{\dagger}		$ m NC^\dagger$		

^{*:} Significant at $P \le 0.05$, NC^{\dagger} : Not Computed because the variable is constant

As regards the changes by time within each group; in FL group, there was no statistically significant change in retention scores by time (P-value = 0.136, Effect size = 0.054). Both FF and EFL groups showed (Alpha) score through all follow up periods.

Color match

After one week as well as 6 months; all restorations in the three groups showed (Alpha) score. At 12 months, 96.7%, 93.3% and 100% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. However, there was no significant difference between the three groups (P-value = 0.368, Effect size = 0.033). After 18 months, 90%, 86.7% and 93.3% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. However, there was no significant difference between the three groups (P-value = 0.549, Effect size = 0.020). In 24 months interval, 83.3%, 83.3% and 90% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. However, no statistically significant difference between the three groups was observed (P-value = 0.444, Effect size = 0.027). After 30 months, 69%, 73.3% and 80% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. However, there was no statistically significant difference between the three groups (P-value = 0.309, Effect size = 0.039). After 36 months, 34.5%, 56.7% and 40% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. However, there was no statistically significant difference between the three groups (P-value = 0.343, Effect size = 0.036).

As regards the changes by time within each group; there was a statistically significant change in color match scores by time in each group (*P*-value <0.001, Effect size = 0.432), (*P*-value <0.001, Effect size = 0.291) and (*P*-value <0.001, Effect size = 0.428), respectively. There was a decrease in prevalence of (Alpha) score and an increase in prevalence of (Bravo) and (Charlie) scores.

Marginal discoloration

After 1 week as well as 6 months; all restorations in the three groups showed (Alpha) score. After 12 months, 100%, 90% and 100% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. There was a statistically significant difference between the three groups (P-value = 0.050, Effect size = 0.100). After 18 months, 96.7%, 86.7% and 100% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. Statistically significant difference between the three groups was recorded (P-value = 0.039, Effect size = 0.108). After 24 months, 96.7%, 86.7% and 100% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. There was a statistically significant difference between the three groups (P-value = 0.039, Effect size = 0.108). After 30 months, 89.7%, 86.7% and 100% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. However, there was no statistically significant difference between the three groups (P-value = 0.115, Effect size = 0.072). After 36 months, 65.5%, 80%and 86.7% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. There was a statistically significant difference between the three groups (P-value = 0.006, Effect size = 0.173).

As regards the changes by time within each group; there was a statistically significant change in marginal discoloration scores by time in each group (P-value <0.001, Effect size = 0.272), (P-value = 0.001, Effect size = 0.130) and (P-value =0.001, Effect size = 0.133), respectively. There was a decrease in prevalence of (Alpha) score and an increase in prevalence of (Bravo) and (Charlie) scores.

Recurrent caries

Through all follow up periods; none of the restorations in the three groups showed recurrent caries.

TABLE (4) Descriptive statistics and results of Friedman's test for comparison between color match in the three groups as well as the changes within each group

Time	FL (n = 30)			FF (n = 30)		EFL (n = 30)		Effect size
	n	%	N	%	n	%	<i>P</i> -value	(w)
1week								· ICI÷
Alpha	30	100	30	100	30	100	Γ	NC [†]
6 months								AIC†
Alpha	30	100	30	100	30	100	ľ	NC [†]
12 months								
Alpha	29	96.7	28	93.3	30	100	0.368	0.033
Bravo	1	3.3	2	6.7	0	0		
18 months								
Alpha	27	90	26	86.7	28	93.3	0.549	0.020
Bravo	3	10	2	6.7	2	6.7	0.549	0.020
Charlie	0	0	2	6.7	0	0		
24 months								
Alpha	25	83.3	25	83.3	27	90	0.444	0.027
Bravo	5	16.7	3	10	3	10	0.444	
Charlie	0	0	2	6.7	0	0		
30 months	(n =	= 29)						
Alpha	20	69	22	73.3	24	80	0.200	0.020
Bravo	9	31	6	20	6	20	0.309	0.039
Charlie	0	0	2	6.7	0	0		
36 months	(n =	= 29)						
Alpha	10	34.5	17	56.7	12	40	0.242	
Bravo	17	58.6	10	33.3	18	60	0.343	0.036
Charlie	2	6.9	3	10	0	0		
P-value	<0.	001*	<0.	001*	<0.001*			
Effect size (w)	0.	432	0.	291	0.	428	_	

^{*:} Significant at $P \le 0.05$, NC^{\dagger} : Not Computed because the variable is constant

TABLE (5) Descriptive statistics and results of Friedman's test for comparison between marginal discoloration in the three groups as well as the changes within each group

	(1	FL $(n = 30)$		FF (n = 30)		L 30)	<i>P</i> -value	Effect size
Time	n	%	N	%	n	%	1 -value	(w)
1week							NG	
Alpha	30	100	30	100	30	100	NC [†]	
6 months							NC	
Alpha	30	100	30	100	30	100	NC†	
12 months								
Alpha	30	100	27	90	30	100	0.050*	0.100
Bravo	0	0	3	10	0	0		
18 months								
Alpha	29	96.7	26	86.7	30	100	0.039*	0.108
Bravo	1	3.3	3	10	0	0		
Charlie	0	0	1	3.3	0	0		
24 months								
Alpha	29	96.7	26	86.7	30	100	0.039*	0.108
Bravo	1	3.3	3	10	0	0		
Charlie	0	0	1	3.3	0	0		
30 months	(1	n = 29)						
Alpha	26	89.7	26	86.7	30	100	0.115	0.072
Bravo	3	10.3	3	10	0	0	0.115	0.072
Charlie	0	0	1	3.3	0	0		
36 months	(1	n = 29)						
Alpha	19	65.5	24	80	26	86.7	0.006*	0.173
Bravo	7	24.1	5	16.7	4	13.3	0.006*	0.173
Charlie	3	10.3	1	3.3	0	0		
P-value	<	0.001*	0.0	01*	0.00	0.001*		
Effect size (w)		0.272	0.	130	0.13	33		

^{*:} Significant at $P \le 0.05$, NC^{\dagger} : Not Computed because the variable is constant

Surface roughness

After 1 week; all restorations in the three groups showed (Alpha) score. After 6 months, 96.7%, 90% and 100% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. However, there was no statistically significant difference between the three groups (P-value = 0.097, Effect size = 0.078). After 12 months, 93.3%, 86.7% and 93.3% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. There was a statistically significant difference between the three groups (Pvalue = 0.050, Effect size = 0.100). After 18 months, 90%, 86.7% and 90% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. However, there was no statistically significant difference between the three groups (P-value = 0.368, Effect size = 0.033). After 24 months, 90%, 86.7% and 90% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. However, there was no statistically significant difference between the three groups (P-value = 0.368, Effect size = 0.033). After 30 months, 89.7%, 86.7% and 90% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. However, there was no statistically significant difference between the three groups (P-value = 0.368, Effect size = 0.033). After 36 months, 79.3%, 80% and 76.7% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. There was no statistically significant difference between the three groups (P-value = 0.424, Effect size = 0.029).

As regards the changes by time within each group; there was a statistically significant change in surface roughness scores by time in each group (*P*-value = 0.001, Effect size = 0.120), (*P*-value <0.001, Effect size = 0.136) and (*P*-value <0.001, Effect size = 0.140), respectively. There was a decrease in prevalence of (Alpha) score and an increase in prevalence of (Bravo) and (Charlie) scores.

Marginal integrity

After 1 week; all restorations in the three groups showed (Alpha) score. After 6 months, 100%,

96.7% and 100% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. However, there was no statistically significant difference between the three groups (P-value = 0.368, Effect size = 0.033). After 12 months, 96.7%, 86.7% and 100% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. There was no statistically significant difference between the three groups (P-value = 0.074, Effect size = 0.087). After 18 months, 90%, 86.7% and 100% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. However, there was no statistically significant difference between the three groups (P-value = 0.056, Effect size = 0.096). After 24 months, 90%, 86.7% and 100% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. However, there was no statistically significant difference between the three groups (P-value = 0.056, Effect size = 0.096). After 30 months, 75.9%, 86.7%and 96.7% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. There was a statistically significant difference between the three groups (P-value = 0.037, Effect size = 0.110). After 36 months, 41.4%, 83.3% and 93.3% of restorations in FL, FF and EFL groups respectively showed (Alpha) score. There was a statistically significant difference between the three groups (P-value < 0.001, Effect size = 0.379).

As regards the changes by time within each group; there was a statistically significant change in marginal integrity scores by time in FL and FF groups (P-value <0.001, Effect size = 0.367) and (P-value =0.001, Effect size = 0.127), respectively. There was a decrease in prevalence of (Alpha) score and an increase in prevalence of (Bravo) and (Charlie) scores. In EFL group, there was no statistically significant change in marginal integrity scores by time (P-value =0.193, Effect size = 0.048).

Post-operative sensitivity

Through all follow up periods; none of the restorations in the three groups showed post-operative sensitivity.

TABLE (6) Descriptive statistics and results of Friedman's test for comparison between surface roughness in the three groups as well as the changes within each group

Time	FL (n = 30)		FF (n = 30)			EFL = 30)	P-value	Effect size
Time	n	%	N	%	n	%	P-value	(w)
1week								
Alpha	30	100	30	100	30	100	N	IC [†]
6 months								
Alpha	29	96.7	27	90	30	100	0.097	0.078
Bravo	1	3.3	3	10	0	0		
12 months								
Alpha	28	93.3	26	86.7	28	93.3	0.050*	0.100
Bravo	2	6.7	3	10	2	6.7		0.100
Charlie	0	0	1	3.3	0	0		
18 months								
Alpha	27	90	26	86.7	27	90	0.368	0.033
Bravo	3	10	3	10	3	10		
Charlie	0	0	1	3.3	0	0		
24 months								
Alpha	27	90	26	86.7	27	90	0.368	0.033
Bravo	3	10	3	10	3	10		
Charlie	0	0	1	3.3	0	0		
30 months	(n :	= 29)						
Alpha	26	89.7	26	86.7	27	90	0.260	0.000
Bravo	3	10.3	3	10	3	10	0.368	0.033
Charlie	0	0	1	3.3	0	0		
36 months	(n = 29)							
Alpha	23	79.3	24	80	23	76.7	0.424	0.020
Bravo	5	17.2	3	10	7	23.3		0.029
Charlie	1	3.4	3	10	0	0		
P-value	0.0	001*	<0.0>	001*	<0.001*			•
Effect size (w)	0.	120	0.3	136	0.	140		

^{*:} Significant at $P \le 0.05$, NC^{\dagger} : Not Computed because the variable is constant

TABLE (7) Descriptive statistics and results of Friedman's test for comparison between marginal integrity in the three groups as well as the changes within each group

Time	FL (n = 30)		FF (n = 30)		EFL (n = 30)		<i>P</i> -value	Effect size (w)
	N	%	N	%	n	%		
1 week								r Ct
Alpha	30	100	30	100	30	100	N	IC [†]
6 months								
Alpha	30	100	29	96.7	30	100	0.368	0.033
Bravo	0	0	1	3.3	0	0		
12 months								
Alpha	29	96.7	26	86.7	30	100	0.054	
Bravo	1	3.3	3	10	0	0	0.074	0.087
Charlie	0	0	1	3.3	0	0		
18 months							0.056	
Alpha	27	90	26	86.7	30	100		
Bravo	3	10	1	3.3	0	0		0.096
Charlie	0	0	3	10	0	0		
24 months								
Alpha	26	86.7	26	86.7	29	96.7		0.096
Bravo	4	13.3	1	3.3	1	3.3	0.056	
Charlie	0	0	3	10	0	0		
30 months	(n =	: 29)						
Alpha	22	75.9	26	86.7	29	96.7		
Bravo	7	24.1	1	3.3	1	3.3	0.037*	0.110
Charlie	0	0	3	10	0	0		
36 months	(n =	: 29)						
Alpha	12	41.4	25	83.3	28	93.3	<0.001*	0.370
Bravo	15	51.7	2	6.7	2	6.7		0.379
Charlie	2	6.9	3	10	0	0		
P-value	<0.0>	001*	0.0	01*	0.1	193		1
Effect size (w)	0.3	367	0.1	127	0.0)48		

^{*:} Significant at $P \le 0.05$, NC^{\dagger} : Not Computed because the variable is constant

DISCUSSION

This randomized clinical study compared the recently launched self-adhering flowable composite with or without EDTA surface treatment with the conventional flowable composite. The performance of the restorations was evaluated according to the Modified USPHS Criteria. ²²

Clinical retention efficacy of restorations is more relevant to be evaluated in Class-V studies because cervical lesions have not any macro-mechanical retention, in order that ineffective bonding will result in early loss of the restorations.²³ Rely on the results of this study, retention criterion was scored 100% Alpha for FF and EFL restorative materials after three years and 93.3, 3.3, 3.3 % for FL restoration was scored Alpha, bravo and Charlie respectively.

As regards the results of the current study there was no statistical difference however the least retention 93.3% scored for FL restorations. EDTA application enhanced the retention of self-adhering flowable resin composite.

These findings were probably due to ability of carboxylic acid groups within EDTA to remove hydroxy apatite selectively, most of intrafibrillar minerals remain and the structural support by the minerals is conserved and these facilitate the resin infiltration.²⁴ Partially removal of the smear layer by EDTA permitting direct contact of self-adhering light cured resin composite with the dentin achieve more intimate chemical interaction on the molecular levelleading to increase the durability of the bond after 36 months interval.²⁵

However, no statistically significant difference between the three groups was observed; regard to color match and surface roughness at 36 months interval FF restoration (56.7%, 80%) might show superior performance.

Flowable resin composite due to its lower filler content and higher matrix content leads to increases the affinity of discoloration. The different compositions generate various surface conditions after polishing; and greater surface roughness synchronized with greater plaque accumulation and discoloration by time.²⁶

Flowable composite has a lower modulus of elasticity thus reducing curing stress and enhancing its adaptation to tooth structure. On the other hand, the higher matrix content increases water solubility undergoes greater polymerization shrinkage affecting the restoration long term performance. Improper marginal sealing relate to other clinical criteria; marginal discoloration and marginal integrity.^{27, 28}

There was significant difference; EFL restoration might show superior performance with regards to marginal discoloration (96.7%) and marginal integrity (93.3%) criteria at 36 months interval. This finding may relate to the chemical composition of the self-adhering flowable composite resin restorative material with GPDM to etch enamel and dentin, hydroxyethyl methacrylate (HEMA) bonding agent and nano-sized amorphous silica and glass fillers. Its exclusive formula is both acidic (low pH value) and hydrophilic. With contact with the tooth structure, the negatively charged carboxylic acid groups of the methacrylate monomers bond to the mineral ions in the tooth structure. While neutralization of the carboxylic acid groups and the monomers polymerization they integrated into the dentin surface improving both dentin bonding and sealing ability.²⁹

Pretreatment of dentin with phosphoric acid has favorable effect on immediate dentin bond strength. However remarkable reduction has been demonstrated after 36 months. Etching of dentin with phosphoric acid leads to dissolving both the intra and extra-fibrillar minerals resulting in collapse and recession of the collagen matrix.³⁰ Many researches reported that when the depth of dentin demineralization by phosphoric acid etching exceeds the depth of resin impregnation and diffusion, hydroxy-apatite depleted collagen fibers is

left unsupported and exposed. This layer is not resin infiltrated or hybridized contributing to a great extent in bonding failure by time.³¹ Structurally unstable collagen fiber contributes to poor resin infiltration, or loss of this protection within the hybrid layer in the course of time compromising the longevity of the restoration.Our findings reach agreement with other laboratory studies that revealed that the self-adhesive flowable composite revealed superior sealing ability under aging condition.³²

Recurrent caries was not reported in the current study after three years follow up.In previous study recurrent caries which mainly recorded after four to five years as mentioned in previous studies.^{19, 21}

CONCLUSIONS

Based on the obtained results, it may be concluded that Self-adhering light cured resin composite achieved clinical acceptable performance at three years follow up interval.

The combination of EDTA/ self-adhering light cured resin composite reveals enhancement of the clinical stability and durability of the restorations over time.

CONFLICT OF INTEREST

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

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