

ORIGINAL RESEARCH



Performance of Self-adhering Flowable Composite in Class V Restorations: 18 Months Clinical Study

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ABSTRACT

Aim: The present randomized clinical study compared the 18 months performance of self-adhering flowable composite with a conventional flowable composite in anterior Class V restorations.

Materials and methods: Totally, 20 patients, each with two moderate cervical carious lesions, participated in this single-center study. Forty restorations were allocated on a random basis by one examiner 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)] and the other to be restored using conventional flowable composite [Tetric Flow (FF)]. The allocation sequence of the restorations was concealed from the operator in sequentially numbered, opaque, sealed, and stapled envelopes. An operator restored all the preparations in accordance to the manufacturer's instructions. Finishing and polishing of the restorations were done immediately after placement. Evaluation of the restorations was done in accordance to the United States Public Health Services (USPHS), modified Ryge criteria. Statistical analysis was completed with Statistical Package for the Social Sciences (SPSS) version 20.0 (IBM Product, Chicago, USA).

Results: One case could not be reassessed at 18 months follow-up in both groups. No significant differences were detected between the tested materials from baseline to those of 18 months using the modified USPHS criteria.

Conclusion: Self-adhering flowable composite exhibited acceptable clinical performance comparable with the conventional flowable composite in anterior Class V restorations over an 18-month period. Nevertheless, the findings of this study must be validated by a longer clinical study.

Clinical significance: Self-adhering flowable composite exhibited clinical performance comparable with the conventional flowable composite in Class V restoration.

Keywords: Class V, Clinical performance, Flowable composite, Self-adhering composite.

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INTRODUCTION

Recently, composite restorations have become widely used restorative materials in dental offices, alongside with the improvements in their performance.¹ Despite this enhancement, polymerization contraction and associated stresses remain a challenge.² 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 common concept that high modulus restorative materials are incapable of flexing in the cervical region under load. To overcome this, materials with low elastic modulus have been designated to restore cervical lesions, with the aim of absorbing the stresses induced during polymerization contraction of the composites and the mechanical forces during function.⁵⁻⁷

Nowadays, efforts are being made to simplify and reduce the number of steps during bonding procedure, while keeping the efficiency of dentin adhesives. Self-etching adhesive systems were established to decrease operator variables and reduce working time.^{8,9}

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Flowable composite resins do not have adhesive properties per se; therefore, usage of dental adhesive system is mandatory. Lately, the self-adhering flowable composite was launched to resolve the issue of time consumption associated with conventional materials. Self-adhering flowable composite combines the advantages of both adhesive and restorative material properties in one product, thus providing beneficial prospects to restorative systems. This is due to the fact that it is a direct flowable composite resin restorative material that includes a self-etch adhesive resin in its composition.¹⁰⁻¹² It is built on the adhesive's technology that uses glycerophosphate dimethacrylate (GPDM) to etch enamel and dentin, and hydroxyethyl methacrylate (HEMA) to improve penetration into dentin. This resin bonds chemically and micromechanically to the tooth structures; the chemical bond is between the phosphate groups of a GPDM monomer and the hydroxyapatite of tooth structure, and micromechanically, it is between the polymerized monomers of the self-adhering flowable composite resin and the collagen fibers and smear layer.¹³⁻¹⁵

Laboratory research is vital for the primary evaluation of the restorative material, but a clinical study may consider all the variables affecting the performance of restorations.¹⁶⁻¹⁹ Although a number of *in vitro* investigations were conducted on self-adhering flowable composites, only two studies have evaluated their clinical behavior at 6 months as Class I restorations and 2 years as pit and fissure sealant.²⁰ Therefore, the current clinical study compared the 18 months performance of a self-adhering flowable resin composite with a conventional flowable composite in Class V restorations.

MATERIALS AND METHODS

Patient Selection

Twenty patients, with healthy gingiva and normal occlusion, were randomly selected from the pool of patients attending the Dental Hospital at University of Dammam. Written consents were obtained from all patients before being enrolled in the study; the form and protocol were

approved by the University of Dammam's ethical committee (IRB-2014-02-290); each patient had at least two anterior cervical unexposed carious lesions (1–2 mm 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 less than 18 years with known pregnancy, disabilities, systemic disease, severe medical conditions, rampant caries, and xerostomia. In addition, teeth with potential prosthodontics restoration and nonvital or endodontically treated teeth were excluded.

Enrolled patients had oral prophylaxis 2 weeks before the beginning of the treatment procedure. Caries per tooth location were recorded in the patient's file.

Clinical Procedures

The flowable composite restorative systems in this study were a self-adhering flowable resin composite and a conventional flowable composite. They were used following the manufacturers' instructions. Table 1 shows the information of material compositions.

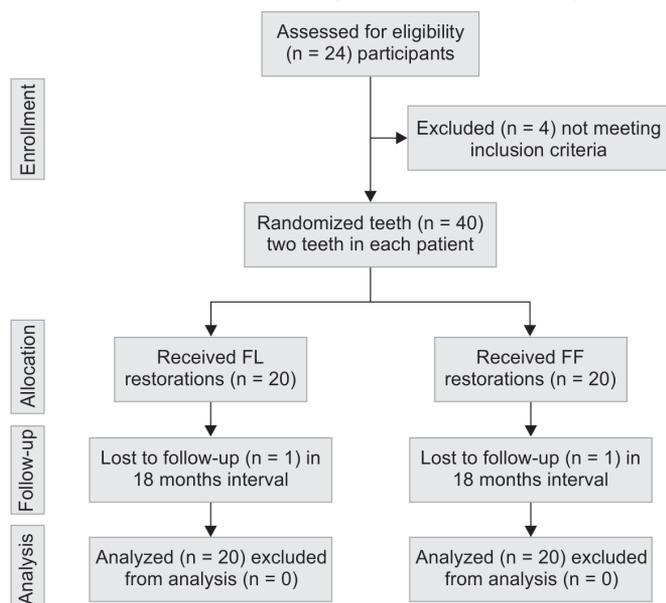
All 40 Class V restorations were prepared, restored, finished, and polished by one operator. Each of the 20 patients had one FL restoration and the other restoration was filled with FF. The allocation sequence of restorations was concealed from the operator using sequentially numbered, opaque, sealed, and stapled envelopes. Restorations were evaluated by two independent evaluators at baseline, 1 week and 6, 12, and 18 month intervals (Flow Chart 1).

For each procedure, local anesthesia was administered and the operative field was isolated with rubber dam before starting the restorative procedure. Conventional design Class V cavity was prepared on the buccal surface of tooth. The preparations were restored with one of the flowable composite resins included in the study accordance to the manufacturer's instructions. Before baseline evaluation, all restorations were finished and polished. The patients were instructed to use a soft brush with nonbleaching toothpaste postoperatively.

Table 1: Composition of the studied materials

Materials	FL self-adhering light-cured flowable resin composite	FF light-cured flowable resin composite	Excite adhesive system bonding agent
Composition	4-metha-cryloxy ethyl trimellitic acid with nano-sized amorphous silica and glass fillers	Bis-GMA, 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
Manufacturer	Pentron Clinical	Ivoclar Vivadent, Schaan, Liechtenstein	Ivoclar Vivadent, Schaan, Liechtenstein

Bis-GMA: Bisphenol A glycidyl methacrylate; TEGDMA: Triethylene glycol dimethacrylate; UDMA: Urethane dimethacrylate

Flow Chart 1: Flow diagram of the clinical study**Table 2:** Evaluation criteria

The USPHS modified Ryge direct evaluation criteria rating system category and rating criteria

Retention

Alpha (A): Restoration is present.

Delta (D): Restoration is partially or totally missing.

Color match

Alpha (A): The restoration matches the adjacent tooth tissue in color, shade, or translucency.

Bravo (B): There is a slight mismatch in color, shade, or translucency, but within the normal range of adjacent tooth structure.

Charlie (C): There is a slight mismatch in color, shade, or translucency, but outside of the normal range of adjacent tooth structure.

Marginal discoloration

Alpha (A): There is discoloration anywhere along the margin between the restoration and the adjacent tooth structure.

Bravo (B): Discoloration is present, but has not penetrated along the margin in a pulpal direction.

Charlie (C): Discoloration has penetrated along the margin in a pulpal direction.

Recurrent caries

Alpha (A): No caries are present at the margin of the restoration, as evidenced by softness, opacity, or etching at the margin.

Bravo (B): There is evidence of caries at the margin of the restoration.

Surface roughness

Alpha (A): The restoration surface is as smooth as surrounding enamel.

Bravo (B): The restoration surface is rougher than the surrounding enamel.

Charlie (C): Surface pitting is sufficiently coarse to inhibit the continuous movement of an explorer across the surface.

Marginal integrity

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 (C): 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 sensitivity

Alpha (A): Normal reaction to cold spray compared with that of nonrestored teeth.

Bravo (B): Increased cold sensitivity.

Charlie (C): Spontaneous pain.

Delta (D): Nonvital.

Evaluation Procedures

The cervical restorations were examined at baseline and 1 week, and 6, 12, and 18 months after restoration. Restorations were examined by two independent evaluators immediately after polishing the restorations, without knowing which material was used. A magnifying aid (HR2.5X-HEINE, Germany) was used for examination of restorations. Interexaminer agreement was measured with the Cohen Kappa index. Examiners were not involved in the restoration procedures. When disagreement occurred, the restorations were reevaluated by both examiners and an agreement was gained.

Restorations were examined according to the USPHS, modified Ryge criteria for retention, color match, cavo-surface marginal discoloration, recurrent caries, surface texture, and marginal integrity (Table 2). All observations were categorized and recorded.

Statistical analysis was completed with SPSS version 20.0 (IBM Product, Chicago, USA). The results of subjective scores, i.e., Alpha, Bravo, Charlie, and Delta, are presented as frequencies and percentages. The frequencies and percentages of cases with scores for different criteria per group were calculated. Comparisons between groups at each follow-up period and between baseline and 18 months values were done using Wilcoxon signed rank test or McNemar test (when the cases were distributed over two scores only). A case was lost to follow-up at the 18th month follow-up, and the values of these scores were imputed using the last observation carried forward principle in an intention to treat analysis. Statistical analysis was performed with SPSS version 20.0. Significance was set at the 5% level.

RESULTS

The ranking of the tested criteria was Alpha, Bravo, and Charlie; the results of this study are presented in Table 3 and Graph 1.

All evaluated restorations were given an Alpha score for all the criteria evaluated at the baseline and after one week. All restorations were rated Alpha (100%) for retention criterion after 18 months evaluation. In both groups, three restorations were scored as Bravo (15%) for color

Table 3: Differences between FL and FF in color match, marginal discoloration, surface roughness, and marginal integrity at 6, 12, and 18 months

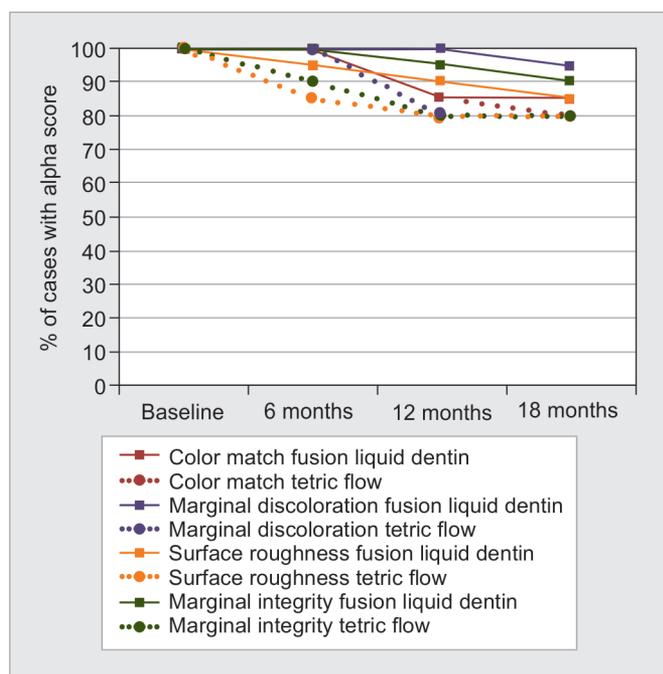
Criteria at follow-up periods			FL	FF	p-value
Color match	6 months	A	20 (100)	20 (100)	–
		B	0	0	
		C	0	0	
	12 months	A	17 (85)	17 (85)	–
		B	3 (15)	3 (15)	
		C	0	0	
	18 months [¶]	A	17 (85)	16 (80)	0.33
		B	3 (15)	2 (10)	
		C	0	2 (10)	
	p-value		0.25	0.06	
Marginal discoloration	6 months	A	20 (100)	20 (100)	–
		B	0	0	
		C	0	0	
	12 months	A	20 (100)	16 (80)	0.06
		B	0	3 (15)	
		C	0	1 (5)	
	18 months [¶]	A	19 (95)	16 (80)	0.10
		B	1 (5)	3 (15)	
		C	0	1 (5)	
	p-value		1.00	0.06	
Surface roughness	6 months	A	19 (95)	17 (85)	0.50
		B	1 (5)	3 (15)	
		C	0	0	
	12 months	A	18 (90)	16 (80)	0.08
		B	2 (10)	3 (15)	
		C	0	1 (5)	
	18 months [¶]	A	17 (85)	16 (80)	0.32
		B	3 (15)	3 (15)	
		C	0	1 (5)	
	p-value		0.25	0.06	
Marginal integrity	6 months	A	20 (100)	18 (90)	0.50
		B	0	2 (10)	
		C	0	0	
		D	0	0	
	12 months	A	19 (95)	16 (80)	0.13
		B	1 (5)	2 (10)	
		C	0	2 (10)	
		D	0	0	
	18 months [¶]	A	18 (90)	16 (80)	0.13
		B	2 (10)	1 (5)	
		C	0	3 (15)	
		D	0	0	
	p-value		0.50	0.06	

[¶]One case missing at 18 months follow-up in both groups and its values were imputed using the last observation carried forward

match in a 12 months recall. As in 18 months interval, three FL restorations were rated Bravo (15%), two FF restorations were rated Bravo, and two restorations were rated Charlie.

Regarding the marginal discoloration, three restorations were scored Bravo (15%) and one was scored as Charlie (5%) in FF restorations in 12 months interval. In an 18 month interval, one FL (5%) and three FF (15) restorations were scored as Bravo, while the Charlie score

was recorded for one FF restoration (5%). Recurrent caries was not recorded in all restorations during the observing intervals. For surface roughness, one FL restoration was rated as Bravo (5%), two were rated Bravo (10%) and three were rated Bravo (15%) in 6, 12, and 18 recall visits respectively. In the FF restorations, three were rated as Bravo (15%) in the same mentioned intervals and one was rated as Charlie (5%) in 12 and 18 months intervals.



Graph 1: The results of the clinical evaluation in different intervals

According to the marginal integrity criterion, one FL restoration was scored Bravo (5%) after 12 months and two restorations were rated as Bravo after 18 months. However, in FF restorations, two were scored as Bravo (10%) after 6 months, two restorations were scored as Bravo (10%), and other two restorations were scored Charlie (10%) after 1-year interval. While in 18 months interval, one FF restoration (5%) was scored as bravo and three (15%) were scored as Charlie.

No significant differences were recorded between the tested materials following the different criterion evaluated from baseline to 18 months at $p \leq 0.05$ (Table 3).

DISCUSSION

This randomized clinical study compared the recently launched self-adhering flowable composite with the conventional flowable composite. The performance of the restorations was assessed by the modified USPHS criteria.²¹

Clinical retention efficacy of restorations is better examined in Class V because cervical lesions do not have any macromechanical retention; so, the efficiency of the bonding will be clearly assessed.²² Based on the results of this study, retention criterion was scored as 100% for the tested restorative materials after 18 months.

The success of the restoration is designated by its longevity, which confirms retention as the most important criteria. The American Dental Association (ADA)²³ guidelines require conditional approval if less than 5% of the restorations have been lost at 6 months and, to achieve full approval, the failures rate must be less than 10% of

lost restorations at 18 months. Similarly, the restorative materials in this study are acceptable with a retention rate of 100%, as they meet the ADA guidelines.

In the 18 months recall, color changes were scored Bravo for three FL and two FF restorations, while two FF restorations were rated Charlie. Built on that, the FL restorative materials clinically demonstrated good color stability; all FL restorations were scored Alpha or Bravo. In this study, it is probable that the discoloration was fortified by the presence of the large filler particles in the FF restorative material.

Flowable resin composite has lower modulus of elasticity due to its low filler content accordingly decreasing curing stress and enhancing its adaptation to tooth structure for cavities that suffer from tooth flexure. On the contrary, the higher matrix content increases the water solubility and it undergoes greater polymerization shrinkage affecting the restoration's long-term performance. Improper marginal sealing relates to other clinical criteria, such as marginal discoloration and marginal integrity.²⁴⁻²⁶

Although there was no significant difference, FL restoration might show superior performance with regards to marginal discoloration (95%) and marginal integrity (90%) criteria. This finding may relate to the chemical composition of the self-adhering flowable composite resin restorative material with GPDM to etch enamel and dentin, HEMA bonding agent, and featuring nano-sized amorphous silica and glass fillers. Its sole formula is both hydrophilic and of low pH value. On contact with the tooth surface, the negatively charged carboxylic acid groups of the methacrylate monomers bond to the mineral ions in the tooth structure. As the carboxylic acid groups are neutralized and the monomers polymerized, they become incorporated into the dentin surface, enhancing both dentin bonding and sealing ability.²⁷

Our findings reach agreement with other laboratory studies that revealed that the self-adhesive flowable composite revealed superior sealing ability under aging condition.²⁸

The different compositions and filler sizes create various surface textures after polishing; and greater surface roughness results in a simultaneous greater plaque accumulation.²⁹ Surface roughness varies generally in accordance with filler composition and size. Self-adhering light-cured resin composite provides a better finish after polishing than conventional flowable composite. In the present study, the nano-sized amorphous silica and glass filler in the FL material may have made the surface smoother.

Recurrent caries was not reported in the current study despite the 18 months follow-up being a short duration

to develop recurrent caries, which was mainly recorded after 4 to 5 years as mentioned in previous studies.³⁰

In the present study, no significant differences were recorded between the two tested materials following the different criteria evaluated from baseline to 18 months. This was in accordance with the clinical study that assessed clinical outcomes of Class I restored with self-etch flowable composite after a 6-month follow-up period.¹⁵

CONCLUSION

Within the limitations of this study, and even with the small sample size and short period of evaluation, it seems reasonable to conclude that self-adhering flowable composites showed acceptable clinical performance comparable with the conventional flowable composite in anterior Class V restorations over 18 months. However, the results of this study must be validated by a longer time clinical evaluation.

CLINICAL CONSIDERATION

Self-adhering flowable composite exhibited clinical performance similar to the conventional flowable composite in Class V restorations.

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