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Original Article

Evaluation of Clinical Performance of Self-Adhering Flowable Composite Vs Conventional Flowable Composite In Cervical Carious Lesions: A Randomized Clinical Trial

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Abstract

Aim: This study was conducted to compare between Clinical Performance of Self adhering Flowable Composite versus Conventional Flowable Composite in Cervical Carious Lesions.

Material and Method: A randomized clinical trial was conducted on twenty patients who had cervical carious lesions in anterior teeth and premolars. Participants were randomly allocated into two groups (n=10 for each group) in which they received randomly two pairs of restorations, either; Fusio Liquid Dentin (self-adhering flowable composite), or Tetric Evo Flow (conventional flowable composite) with using ExciTE F (Light-curing total-etch adhesive) all materials were applied according to manufacturers' instructions. Restorations were evaluated at baseline (one week), after three, six months, and after 12 months by two blinded assessors using modified USPHS criteria measuring (marginal adaptation, hypersensitivity, marginal discoloration, surface roughness, color match, surface luster, and secondary caries). **Results**: Intergroup comparison between both materials have shown no statistically significant difference within different follow up periods; baseline, 3, 6 and 12 months respectively. The overall clinical performance of Fusio liquid dentin compared to Tetric Evo Flow have shown a relative risk of 1.0000 (95% CI 0.1732 to 5.7723; P = 1.0000). There was no difference between both materials in restoration of cervical carious lesions after 12 months. **Conclusion**: The null hypothesis tested in this current study was there is no significant difference between conventional flowable composite versus self-adhering flowable composite in clinical performance of cervical carious lesions.

Keywords: Self-adhering Flowable Composite, Conventional Flowable Composite, vi Fusio liquid dentin and Tetric evo flow

I. INTRODUCTION:

Cervical lesions are located along the gingival margins of the clinical teeth crowns, they are mainly associated with high caries risk individuals and are aggravated with improper brushing teeth techniques. 1

Patients seek treatment of such defects driven by the discomfort arising from teeth hypersensitivity, teeth decay, and the subsequent poor esthetics when such lesions occur in the esthetic zone. From the restorative point of view; restoration of cervical caries prevents the progression of caries which is likely to invade the pulp space if left untreated and prevent adverse periodontal effects. Furthermore, restored cervical caries gives the natural desired esthetics of teeth occurring in the esthetic zone .2

Since the first introduction of tooth-colored restorations; there is a continuous quest for more durable and esthetically pleasing restorations with predictable clinical performance- Among aesthetic restorations, resin composite (RC) is the first choice to treat anterior and posterior teeth, due to its ability to bond to the teeth substrates and the superior aesthetic appearance, which made it popular among the dental clinicians .3 However; polymerization contraction and associated stresses remain the main limitation of RC. Numerous factors possibly affecting stress development are the cavity configuration (C-factor), composite insertion technique together with the elastic behavior of restorative materials .4

Low viscosity flowable resin composites have become more feasible and accepted for clinicians to be used in the restoration of cervical lesions as an alternative to the conventional higher viscosity resin composite. These materials are superior in esthetic properties and have low viscosity, which makes them easier to place and more self-adaptable than conventional resin composites. Moreover, flowable consistency resin composite materials are extensively placed as a base material in proximal restorations involving the gingival margins, due to their stress-reducing effect. Unfortunately, these materials have a higher rate of polymerization shrinkage, a higher coefficient of thermal expansion, and poor mechanical properties, which is due to their lower filler content .5

Nowadays, efforts are being made to simplify and reduce the number of steps during bonding procedure, while keeping the efficiency of dentin adhesives .6

Self-adhering flowable composite offers even less steps with subsequent less technique sensitivity while providing a final restoration with comparable clinical performance; combining the advantages of both adhesive and restorative material properties in one product, which offers beneficial prospects to the overall restorative systems .7

Therefore, it was found beneficial to assess the clinical effectiveness of conventional flowable composite versus self-adhering flowable composite in cervical carious lesions. The null hypothesis tested in this current study was there is no significant difference between conventional flowable composite versus self-adhering flowable composite in clinical effectiveness of cervical carious lesions.

II. MATERIALS AND METHODS

Sample size calculation:

Sample size was determined by the Center of Evidence Based at the Faculty of Dentistry, Cairo University. Convenient sampling method was applied to recruit all eligible candidates in the hospitals in a period of 12 months.

In this randomized controlled clinical trial the variables were two restorative materials as Tetric Evo Flow (FF): (Ivoclar vivadent /schaan,liechtenstein) as a control and Fusio liquid dentin(FL)flowable composite (Pentron clinical Technologies LLC, Wallingford, CT, USA) as an intervention. 20 teeth were selected and assigned in two groups after randomization and each group has 10 teeth with cervical lesion according to sample size calculation. Each generated random number represented assigning either intervention or comparator to each patient in a random manner. To ensure the allocation concealment, opaque sealed envelopes were made containing the grouping generated previously and titled by numbers. Patients who met the inclusion criteria were enrolled into the study by the assessors. The operator chose between numbers in an opaque sealed envelope as the randomization codes were not released until the participants had been recruited into the trial. All procedures performed in this study, involving human participants, were in accordance with the ethical standards of Research Ethics Committee of Faculty of Dentistry, Cairo University (CREC), and approval no. 3- 9-20. This randomized controlled clinical study was held in Faculty of Dentistry, Cairo University, Egypt. The assessors and statistician were blinded to the material assignment while the operator and the patient were not due to the difference in material presentation and its application protocol.

1. Eligibility criteria:

In order to obtain homogenous participants within the sample size in this trial and to avoid any heterogeneity or limitation, the following inclusion and exclusion criteria were selected.

- **Inclusion criteria of the participants:**
  - Cervical Class V carious lesions in anterior teeth.
  - Age of (30 -50) years.
  - Males and females.
- **Exclusion criteria of the participants:**
  - Patient less than 18 years was excluded.
  - Pregnant female.
  - Patients with disabilities, or systemic disease.
  - Severe medical conditions.
  - Patients had rampant caries.
  - Patients suffered from xerostomia.

- **Eligibility Criteria of teeth:**
- Inclusion criteria of the teeth:
  - Small to moderate class V carious lesion.
  - Vital upper or lower teeth with no signs of irreversible pulpitis.
  - Cervical margins above CEJ.
  - Caries extension shouldn't exceed mesio-distal width and inciso (occluso) gingival length not exceed to incisal (occlusal) one third.

- **Exclusion criteria of the teeth:**
  - Deep carious defects (close to pulp, less than 1 mm distance).
  - Periapical pathology or signs of pulpal pathology.
  - Tooth hypersensitivity.
  - Possible prosthodontic restoration of teeth.
  - Heavy occlusion and occlusal contacts or history of bruxism.
  - Pulpitis, non-vital or endodontically treated teeth.
  - Sever periodontal affection.

2. Interventions:

Clinical examination of active cervical carious lesion was performed after scaling and polishing to assess the size and extension of cervical caries by visual tactile examination with the aid of dental mirror and sharp explorer, Enrolled patients had oral prophylaxis two weeks before the beginning of the treatment procedure. Caries per tooth location were recorded in the patient's file. 7

All patients were selected according to inclusion and exclusion criteria to have active cervical carious lesions in anterior teeth. Patients were given local anesthesia as required, and the operative field was isolated with rubber dam before starting the restorative procedure. .

3. Comparator:

Cavity preparation procedure:

Conventional design class V cavity was prepared on the buccal surface of tooth. A No. #330 bur (0.8 mm in diameter and 1.6 mm in length) in a high speed hand piece with air /water coolant was used to prepare class V cavity and the tooth surfaces were kept moist to protect them against dehydration. One new bur was used for every five cavities and no bevels were placed at cavity margins. 7

Restorative phase:

After the cavity preparation as mentioned before, for compartor material: the total etch (etch and rinse) technique was used on enamel and dentin for 20 seconds using N-Etch (Ivoclar Vivadent, Schaan, lichtenstein) followed by air-water spray washing for 30 seconds as recommended by the manufacturer instructions. Then the cavity was air dried with oil-free air spray till there was no visible moisture in the prepared cavity. Then the adhesive agent ExiTE F (Ivoclar Vivadent, Schaan, lichtenstein) was applied followed by air thinning till no adhesive movement could be visible, then repeated for a second coat of the adhesive according to the manufacturer's instructions. Then the adhesive was photopolymerized for 20 seconds using bluephase light curing unit (Ivoclar Vivadent, Schaan, lichtenstein). Then Tetric Evoflow (Ivoclar Vivadent, Schaan, lichtenstein) was incrementally placed in 1mm layers each one was photopolymerized in the same manner as the adhesive. After the cavity was satisfactory filled; the desired contour of the restoration was achieved using course contouring discs (Soflex, 3M, CA, USA) followed by gross finishing using the medium discs, then the excess restorative material was carefully removed using a number 12 bard-parker blade (Aspen Surgical, Caledonia, MI, USA).Then the final restoration polishing was done using fine, super fine discs, pre-polish and polish rubbers (Diacomp Plus Twist, EVE, Keltern , Germany).After cavity preparation as mentioned before, regarding the self-adhering flowable composite (Fusio, Pentron, USA) was incrementally placed in 1mm layers each one was spread into the cavity using a metal ball burnisher for 20 seconds to allow complete

adaptation to the cavity preparation and to ensure eliminating any air bubbles, then photo polymerized in the same manner as the comparator. After the cavity was satisfactory filled; the restoration was contoured, finished and polished as previously explained with the comparator

Outcome assessment:
The cervical restorations were evaluated at baseline, 3, 6 and 12 months. Evaluation was done by two assessors. In this study, a modified USPHS guidelines was used, including color match, marginal adaptation, anatomic form, marginal staining, surface roughness and caries. Primary outcome assessment (marginal integrity of restorations) and secondary outcomes evaluated by using Modified USPHS criteria for dental restorations 8

III. RESULTS

Statistical analysis:

Data was analyzed using Medcalc software, version 19 for windows (MedCalc Software Ltd, Ostend, Belgium). Categorical data was described as frequency and percentage, comparisons between categorical variables was performed using the chi square test. Relative risk was used to assess the clinical significance. A P value less than or equal to 0.05 was considered statistically significant and all tests were two tailed.

Demographic data:

This study was conducted on 20 participants with 10 restorations per group that were randomly allocated to the intervention and the control arms (n=10). There were 10 males (50%) and 10 females (50%) in the current study. The results of the current study have revealed no statistically significant difference between both materials for all tested outcomes at baseline, 3,6 and after 12 months.

All patients returned for 12 months follow-up visit; thus, the recall rate was 100%. Restorations were randomly placed in two maxillary canines, one maxillary premolar, five mandibular canines and 12 mandibular premolars in the current trial, for each restorative material. Performance of materials for marginal integrity and post-operative hypersensitivity (binary data), marginal discoloration and color match (ordinal data) was compared for each criterion separately. The results of the current study have revealed no statistically significant difference between both materials for all tested outcomes at baseline, 3,6 and after 12 months (tables 1-5).

IV. DISCUSSION:

Regarding marginal integrity results, there was no significant difference between both materials within different follow up periods; baseline, 3, 6 and 12 months respectively.

Although there was no significant difference, FL restoration might show superior performance with regards to 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. This may have attributed to GPDM revealed hydrophilicity and greater demineralization of dentin than bonding to calcium of hydroxyapatite, producing un-stable complex of di-calcium phosphate dehydrate deposited on hydroxyapatite surface; that will dissolve easily in a gradual manner in aqueous environment thus deteriorating the interfacial integrity.This result is in agreement with AlHumaid et al. (2018) 7 who reported that Fusio Liquid Dentin showed marginal integrity (90%) criteria, also Bektas et al. (2013) 9, Rengo et al. (2012) 10 reported a similar sealing ability of self-adhering composites to the etch-and-rinse adhesives in enamel and dentin and Celik et al. (2015) 11, Vichi et al. (2010) 12 who reported acceptable marginal adaptation and superficial marginal discolorations.

Regarding hypersensitivity, there was no significant difference between both materials regardless of the time. within different follow up periods; baseline, 3, 6 and 12 months respectively. In tetric evo flow flowable group, all restorations scored alpha at baseline, 3

months follow up, 6 months, so no sensitivity was recorded, but at 12 month follow up there was one restoration scored (Charlie) demonstrated sensitivity. This sensitivity may be attributed to depth of the cavity, etching with phosphoric acid which removed the smear layer thus, opening up the dentinal tubules or pain threshold of the patients.

No sensitivity was recorded for fusio liquid dentin restorations at baseline ,3, 6 months follow up, this may be attributed to absence of phosphoric acid etching before application of fusio liquid dentin, therefore smear layer was not removed and dentinal tubules were kept sealed, also, the manufacturers of self-adhering composites claim that eliminating the need for separate etching and conditioning of the tooth substrate offers good marginal sealing, reduces the risk of over-etching and over-wetting, and that it may avoid over-drying which leads to the collapse of the collagen fiber network, but after 12 months follow up only one case complained from sensitivity.This result is in agreement with another study 7 who reported that Fusio Liquid Dentin showed no post-operative sensitivity. Also according to another study 5 , it was found that the sealability of Fusio Liquid Dentin was better than self-adhesives. Another studies 12, 13 reported that Vertise Flow showed no post-operative sensitivity. Another study 14 conducted that the Vertise Flow layer covered the exposed surface of dentine leading to tubular sealing and reduction of sensitivity. This result is disagreed with another study 15 showed that tetric evo flow flowable composite exhibited the least postoperative sensitivity after 1 year and fusio liquid dentin showed the lowest results.

Regarding color match, there was no significant difference between both materials regardless of the time within different follow up periods; baseline, 3, 6 and 12 months respectively.

This result is in agreement with another study 11 showed that a significantly higher number of restorations performed with Fusio liquid dentin exhibited a score of 2 or 3 at the baseline color and translucency results showed. The reason for the differences between the SAFC and E&Ra/flow at baseline may be explained by the limited number of shade alternatives (only 4 shades) for the SAFC. Besides the limited shade alternatives for fusio liquid dentin, the differences in the results reported in the present study may partly be ascribed to variations in the composition of the tested materials, including differences in filler size, type, and load that may result in differences in solubility. In a previous study, an SAFC was reported to have a higher solubility than conventional composite resins, which could affect the color stability. 16 This result is in agreement with another study 7 concluded that fusio liquid dentin showed good color stability after 18 months follow up.

This result is against with another study 11 reported that the SAFC yielded a worse color match than did the control group E &Ra / nano C after 6 months follow up.

Regarding secondary caries, there was no significant difference between both materials within different follow up periods; baseline, 3, 6 and 12 months respectively secondary caries was appeared in one restoration only scored (Charlie), secondary caries may be attributed to the bacterial infection coming from either infected dentin tissues that was not completely removed during the cavity preparation, or from bacterial microleakage occurring at the tooth-restoration interface. One other reason for secondary caries may be the result of the inevitable polymerization shrinkage occurring during the setting of all resin-based materials, which should be counteracted by all means possible. 17 This result is in agreement with another study 7 concluded that fusio liquid dentin showed no secondary caries after 18 months follow up.

Regarding marginal discoloration; there was no significant difference between both materials within different follow up periods; baseline, 3, 6 and 12 months respectively. This result was attributed to difficulty in bonding in class V cavities due to high flexural stresses on the restorations that causes debonding .18 Also the aging of both materials leading to increased marginal discoloration. This result is in agreement with another study 7 concluded that Fusio Liquid Dentin showed marginal discolorations after 18 months follow up.

Regarding the surface roughness, surface luster results, both flowable materials have shown (Alpha score) for all restorations at baseline, 3 months, 6 months and after 12 months with no statistically significant difference between both materials over time the different compositions and filler sizes create various surface textures

after polishing and greater surface roughness results in a simultaneous greater plaque accumulation . 19

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. This result is in agreement with another study 7 who reported that Fusio Liquid Dentin showed no surface roughness in restorations.

Finally, the tested null hypothesis was confirmed according to the results of the current study and self-adhering flowable composite could be considered as a promising restorative material, with minimal technique sensitivity.

Conclusions

Under the limitation of the following trial the following conclusion can be mentioned:

- Self-adhering composite and conventional flowable composite have the same clinical performance after one year follow up.

Recommendations

Under the limitation of the current study, further clinical trials with increased sample size are recommended also, Clinical trials testing performance of self-adhering flowable composites in other clinical indications are encouraged, to recommend utilizing the new material in various clinical applications.

Table 1 Frequency, percentage and P value for hypersensitivity scores for the intergroup comparison between materials within each follow-up and intragroup comparison within each material between different follow-up periods.

Follow-up	Fusio Liquid Dentin			Tetric Evo Flow			P value
	A	B	C	A	B	C	
Baseline	7 (70%)	3 (30%)	0 (0%)	9 (90%)	1 (10%)	0 (0%)	P = 0.2758 NS
3 months	6 (60%)	4 (40%)	0 (0%)	6 (60%)	4 (40%)	0 (0%)	P = 1.0000 NS
6 months	0 (0%)	10 (100%)	0 (0%)	2 (20%)	8 (80%)	0 (0%)	P = 0.1462 NS
12 months	0 (0%)	8 (80%)	2 (20%)	1 (10%)	8 (80%)	1 (10%)	P = 0.5134 NS
P value	P = 0.0004*			P = 0.0046*			

Table 2 : Frequency, percentage and P value for color match scores for the intergroup comparison between materials within each follow-up and intragroup comparison within each material between different follow-up periods.

Follow-up	Fusio Liquid Dentin			Tetric Evo Flow			P value
	A	B	C	A	B	C	
Baseline	10 (100%)	0 (0%)	0 (0%)	10 (100%)	0 (0%)	0 (0%)	P = 1.0000 NS
3 months	10 (100%)	0 (0%)	0 (0%)	10 (100%)	0 (0%)	0 (0%)	P = 1.0000 NS
6 months	9 (90%)	1 (10%)	0 (0%)	8 (80%)	2 (20%)	0 (0%)	P = 0.5416 NS
12 months	9 (90%)	0 (0%)	1 (10%)	7 (70%)	2 (20%)	1 (10%)	P = 0.3247 NS
P value	P = 0.4115 NS			P = 0.2553 NS			

Table 3: Frequency, percentage and P value for recurrent caries scores for the intergroup comparison between materials within each follow-up and intragroup comparison within each material between different follow-up periods.

Follow-up	**Fusio Liquid Dentin**		**Tetric Evo Flow**		**P value**
	A	C	A	C	
Baseline	10 (100%)	0 (0%)	10 (100%)	0 (0%)	P = 1.0000 NS
3 months	10 (100%)	0 (0%)	10 (100%)	0 (0%)	P = 1.0000 NS
6 months	10 (100%)	0 (0%)	10 (100%)	0 (0%)	P = 1.0000 NS
12 months	9 (90%)	1 (10%)	9 (90%)	1 (10%)	P = 1.0000 NS
P value	P = 0.3799		P = 0.3799		

Table 4 : Frequency, percentage and P value for recurrent caries scores for the intergroup comparison between materials within each follow-up and intragroup comparison within each material between different follow-up periods.

Follow-up	**Fusio Liquid Dentin**		**Tetric Evo Flow**		**P value**
	A	C	A	C	
Baseline	10 (100%)	0 (0%)	10 (100%)	0 (0%)	P = 1.0000 NS
3 months	10 (100%)	0 (0%)	10 (100%)	0 (0%)	P = 1.0000 NS
6 months	10 (100%)	0 (0%)	10 (100%)	0 (0%)	P = 1.0000 NS
12 months	9 (90%)	1 (10%)	9 (90%)	1 (10%)	P = 1.0000 NS
P value	P = 0.3799		P = 0.3799		

Table 5 : Frequency, percentage and P value for marginal discoloration scores for the intergroup comparison between materials within each follow-up and intragroup comparison within each material between different follow-up periods.

Follow-up	**Fusio Liquid Dentin**			**Tetric Evo Flow**			**P value**
	A	B	C	A	B	C	
Baseline	10 (100%)	0 (0%)	0 (0%)	10 (100%)	0 (0%)	0 (0%)	P = 1.0000 NS
3 months	9 (90%)	1 (10%)	0 (0%)	10 (100%)	0 (0%)	0 (0%)	P = 0.3173 NS
6 months	4 (40%)	6 (60%)	0 (0%)	6 (60%)	4 (40%)	0 (0%)	P = 0.3833 NS
12 months	4 (40%)	6 (60%)	0 (0%)	2 (20%)	8 (80%)	0 (0%)	P = 0.3415 NS
P value	P = 0.0029*			P = 0.0001*			

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