

# CLINICAL EVALUATION OF CONTEMPORARY HIGHLY FILLED FLOWABLE COMPOSITE RESIN RESTORATIONS

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## Abstract

**Aim of the study:** This study aimed to evaluate the clinical performance of 2 highly filled flowable resin composites in class I cavities over a period of 18 month follow -up. **Materials and Methods:** a total of 48 moderate-sized class I carious lesions were selected in 24 patients aged between 20-45 years. Class I cavities were divided comprising 2 equal groups (n = 24). Group I: Prime & bond universal adhesive was applied to the cavity walls, followed by bulk fill application of SDR flow+, while in Group II: G-Premio Bond universal adhesive was applied, followed by incremental application of G-aenial universal injectable composite. All restorations were clinically evaluated at baseline (24 h), 6, 12, and 18 months using modified (USPHS) criteria. Marginal adaptation was further objectively examined during all the evaluation periods by the inverse replica technique which were observed under (ESEM). **Results:** st the 18-month follow-up, 48 restorations were evaluated in 24 patients. After 18 months, the difference between both highly filled flowable composite restorations was not statistically significant with respect to all evaluation parameters ( $p < 0.05$ ). No secondary caries was observed. **Conclusions:** both tested materials with their application techniques showed acceptable comparable clinical effectiveness over 18 months follow up.

**Keywords:** Flowable Bulk Fill, Highly Filled Flowable Composites, Inverse Replica, Modified USPHS Criteria, Scanning Electron Microscope.

## INTRODUCTION

With the advancement of dental materials and clinical techniques, composites have become the most widely used direct restorative materials <sup>(1)</sup>. However, they exhibit volumetric shrinkage ranging from less than 1 % up to 6 % depending on its formulation and curing conditions <sup>(2)</sup>. Consequently, shrinkage stresses could lead to abundant clinical problems such as microleakage, which is a matter of concern because it leads to marginal staining, recurrent caries, hypersensitivity, and pulp pathology <sup>(3)</sup>. Several restorative techniques have been proposed in literature to reduce polymerization shrinkage stresses and achieve a better marginal adaptation such as using low modulus liner or low viscosity resinous materials <sup>(4)</sup>. Flowable composites, with their low elastic modulus compete with stress development, potentially helping to maintain the marginal seal of the restoration <sup>(5)</sup>. However, they have reduced percentage of inorganic filler particles and higher amount of resinous components <sup>(6)</sup>. The need for long lasting restorations is one of the driving forces for the development of improved materials. Reinforcing the resin with ceramic fillers and optimization of filler levels are among the

methods that have been studied to improve the wear resistance as well as reduce the polymerization shrinkage of composite restorative materials <sup>(7)</sup>. In an effort to overcome many of the downsides associated with an incremental approach to placing resins, new restorative materials have emerged that are marketed as “bulk-fill” composites. In this regard, manufacturers have produced new generation “bulk-fill” nanohybrid composites that can be placed and cured as one increment up to 4 mm thick, aiming to simplify and speed-up the placement of posterior restorations. In addition, flowable bulk fill resins with improved mechanical and chemical characteristics have been introduced <sup>(8)</sup>. They are more translucent, which allow the light to get to much deeper layers. It was also reported to possess a lower modulus of elasticity, as well as lower levels of polymerization stress without compromising on depth of cure <sup>(9)</sup>.

Dentsply Sirona launched the first bulk fill flowable composite, SDR®, to the global market with the incorporation of Stress Decreasing Resin (SDR™) technology and high depth of cure. This technology is a patented urethane dimethacrylate structure that is responsible for the reduction in polymerization shrinkage and stress claiming to provide an exceptional clinical performance <sup>(10)</sup>, however it was recommended to be capped with a regular composite resin. SDR® flow+ Bulk Fill Flowable with a higher filler content was then developed to meet additional clinical needs such as improved mechanical strength, wear resistance and radiopacity which can greatly improve the efficiency and productivity of clinician's ever-increasing composite restorations <sup>(11)</sup>. It was recommended to be suitable for conservative Class I, Class III, and V restorations without a capping layer <sup>(12)</sup>.

Furthermore, GC launched G-ænial Universal Flo, the first injectable composite eligible for an incrementally built whole restoration. Despite its injectable viscosity, it has a high filler rate. Its formulation is based on ultra-fine barium particles, which are strongly bonded into the resin matrix thanks to GC's Full-coverage Silane Coating technology. This provides enhanced thixotropic properties that provides the most beautiful & durable restorations in all indications with a minimum of manipulation <sup>(13)</sup>. Previous in vitro studies have been carried out with different flowable highly filled composite resins reporting considerably various results <sup>(14, 15)</sup>. However in vivo studies are still recommended to verify their expected improved clinical performance. So, this study was conducted to clinically evaluate two contemporaries highly filled flowable composite resins with different application techniques [Bulk fill (SDR® flow+) and incremental fill (G-ænial Universal Injectable)] in class I cavities over a period of 18 month.

## **MATERIALS AND METHODS**

This study was conducted as a randomized clinical trial. The study was carried out at Restorative Dentistry Department, Faculty of Dentistry, Tanta University. The purpose of the study was explained to the patients and informed consents (appendix) were obtained according to the guidelines on human research adopted by the Research Ethics Committee, Faculty of Dentistry, Tanta University.

### Sample size calculation:

The sample size was 23 restorations for each group with 90% power and 5% type I error rate based on a previous study<sup>(16)</sup>. An oversizing was done to compensate the potential loss during follow up, so it was increased to 24 restorations per group. It was calculated using a computer program G power version 3.

### Materials:

Two highly filled flowable composite resins and their corresponding bonding agents were used in the study and their compositions & manufacturers are listed in **Table (1)**.

**Table 1: The materials used in the study:**

Materials	Composition	Manufacturer	Website
SDR Flow+ composite Bulk-filled based on Stress-Decreasing Resin Technology	<b>Resin matrix:</b> modified urethane dimethacrylate resin; TEGDMA; polymerizable dimethacrylate resin; polymerizable trimethacrylate resin; camphorquinone (CQ) photoinitiator; ethyl 4(dimethylamino)benzoate photoaccelerator; butylated hydroxy toluene (BHT); fluorescent agent, and UV stabilizer. <b>Filler:</b> 70.5 wt% / 47.4 vol%.silanated barium-alumino-fluoro-borosilicate glass; silanated strontium alumino-fluoro-silicate glass; surface treated fume silicas; ytterbium fluoride; synthetic inorganic iron oxide pigments, and titanium dioxide.	Dentsply DeTrey Konstanz, Germany	<a href="http://www.dentsplysirona.com">www.dentsplysirona.com</a>
Prime &Bond universal Adhesive	MDP, PENTA, Bi- and multifunctional acrylate, Phosphoric acid modified acrylate resin Dentsply Sirona Active-Gaurd™, Initiator, Stabilizer, Isopropanol, Water. pH > 2.5.	Dentsply DeTrey Konstanz, Germany	<a href="http://www.dentsplysirona.com">www.dentsplysirona.com</a>
G-aenial Universal Injectable composite	<b>Matrix:</b> methacrylate monomer (31 wt%). <b>Filler:</b> silica, barium glass (69 wt%, 50 vol%). Pigments, photo initiator: trace. Particle size (150nm).	GC Australasia	<a href="http://www.gcaustralasia.com">www.gcaustralasia.com</a>
G-Premio BOND™ Universal adhesive	MDP, 4-MET, MEPS, BHT, acetone, dimethacrylate resins, initiators, water. . pH=1.5.	GC Australasia	<a href="http://www.gcaustralasia.com">www.gcaustralasia.com</a>

TEGDMA, triethylene glycol dimethacrylate; 4-MET, 4-methacryloxyethyl trimellitate; MDP, 10-methacryloyloxydecyl dihydrogen phosphate; MEPS, methacryloyloxyalkyl thiophosphate methyl-methacrylate; BHT, butylated hydroxytoluene.

### **Patient selection:**

Twenty-four patients (16 female and 8 male) aged between (20-45) years were selected. They all required to restore at least two moderate class I carious lesions, scored as code 3 or 4 based on ICDAS<sup>(17, 18)</sup> patients' selection was according to the following inclusion and exclusion criteria<sup>(19)</sup>. Inclusion criteria involved patients with good general health without relevant disease; good oral hygiene, with healthy periodontium and absence of parafunctional habits; presence of at least 2 posterior vital teeth with class I primary carious lesions; normal occlusion; no orthodontic treatment; absence of teeth mobility; Possibility to get proper isolation with rubber dam and good recall availability. While Exclusion criteria involved patients with pathologic pulpal involvement; history of allergic reactions against composite resin materials; fractured or evidently cracked teeth; teeth with secondary caries or in need of replacement of existing restoration and pregnant or lactating women.

### **Clinical procedures:**

The selected teeth were visually diagnosed for moderate class 1 carious lesion representing (code 3 or 4) according to ICDAS system. Examination was aided by a plane dental mirror, a periodontal probe and gentle air jets under a light source. The Restorative steps were performed under local anaesthesia if necessary. The teeth were completely isolated using rubber dam<sup>1</sup>. Class I cavities were prepared according to the principles of minimally invasive dentistry with no.245 carbide burs<sup>2</sup> held in high speed contrangled hand piece<sup>3</sup> with water cooling system. The burs were replaced with new ones after every five preparations. The cavity design was limited to eradicating carious tissue. Adhesive cavity design was performed where the inner angles of the cavities were rounded, and the margins were not beveled<sup>(20)</sup>. A total of 48 posterior teeth were used in the study. The participants were not aware of which type of composite material was used in which cavity. Teeth in each patient were randomly selected by tossing a coin<sup>(19)</sup> to be restored with either of the restorative materials under investigation comprising 2 equal groups (n = 24), where the materials were applied according to the manufacturer's instructions as follows:

**Group I:** the prepared cavities were checked for any debris, rinsed by water then dried with an intermittent stream of air for 5 seconds. Selective etching of enamel margins was done using 37% phosphoric acid to ensure good marginal bonding. Uniform thin layer of Prime & bond universal adhesive was applied with a disposable micro brush to the prepared cavity walls and margins, slightly agitated for 20 seconds, then dispersed with a stream of air for at least 5 seconds to evaporate the solvent and light cured<sup>4</sup> for 10 seconds. The flowable Bulk-Fill restorative material SDR Flow<sup>+</sup> (shade A3) was dispensed directly into the cavity from the dispensing syringe tip using slow, steady pressure, beginning at the deepest portion of the cavity, and keeping the tip close to the cavity floor. The tip was gradually withdrawn as the cavity was completely filled then the material was cured for 20 seconds.

**Group II:** the prepared cavities were checked for any debris, rinsed, and dried as before. Selective etching of enamel margins was also done using 37% phosphoric acid to ensure good marginal bonding. G-Premio Bond universal adhesive was applied to all the prepared cavity walls and margins, left for 10 seconds, air dried for 5 seconds, and light cured for 10 seconds. G-aenial universal injectable composite (shade A3) was then applied in increments not more than 2mm from the base of the cavity and moving the material with the dispensing tip. After composite placement, the potential for ‘stringing’ was decreased by removing the tip perpendicular to the surface of the material then the material was cured for 20 seconds. A second layer was then applied to completely fill the cavity. For both groups, the curing light was in the range of 440-480 nm and its intensity was verified after each case using a dental radiometer<sup>5</sup>. Occlusal adjustments for all restorations were made using articulating paper<sup>6</sup>. Sequential finishing was accomplished by using water-cooled high speed football finishing stone starting with red coded stone followed by yellow coded one<sup>7</sup>, followed by polishing using low speed rubber points<sup>8</sup>.

### Evaluation procedure:

All restorations were clinically evaluated at baseline (24 h), 6, 12, and 18 months for retention, surface texture, marginal adaptation, marginal discoloration, secondary caries, and postoperative sensitivity using modified (USPHS) criteria <sup>(21)</sup> presented in **Table (2)**. Examination was performed under a dental operating light, using flat surfaced mouth mirrors<sup>9</sup> and dental explorers<sup>10 (22)</sup> with the aid of an intraoral camera<sup>11</sup>. An evaluation sheet (appendix) was used to record the patient rating scores at each follow up visit <sup>(23)</sup>. In addition, intraoral color digital photographs were taken at each evaluation visit as a permanent record for subsequent evaluation and later reference.

**Table 2: Modified USPHS criteria:**

Category	Score	Criteria
Retention	Alpha	Complete retention of the restoration
	Charlie	Loss of the restoration
Surface texture	Alpha	Enamel like surface.
	Bravo	Surface rougher than enamel, clinically acceptable.
	Charlie	Surface unacceptably rough.
Marginal adaptation	Alpha	Closely adapted, no detectable margin.
	Bravo	Visible evidence of crevice along the margins, dentine not exposed; clinically acceptable.
	Charlie	Explorer penetrates into crevice, dentine is exposed; clinically unacceptable
Marginal discoloration	Alpha	Absence of marginal discoloration
	Bravo	Presence of marginal discoloration without axial penetration
	Charlie	Evident marginal discoloration with axial penetration; clinically unacceptable.
Secondary caries	Alpha	No evidence of caries
	Charlie	Caries is evident
Postoperative sensitivity	Alpha	Absence hypersensitivity
	Bravo	Sensitive but diminishing in intensity
	Charlie	Constant sensitivity, not diminishing in intensity
	Delta	Immediate replacement necessary

To evaluate any possible postoperative sensitivity, the patients were verbally questioned regarding the following aspects: sensitivity to cold and/or hot, spontaneous pain either prolonged or not and pain during mastication and sensitivity from other stimuli <sup>(24)</sup>. In addition, blowing a stream of air for a period of 3 seconds at a distance of 2 to 3 cm from the isolated restoration and by moving the probe above the restored tooth surface toward the cavity margins were applied during testing the sensitivity <sup>(25)</sup>. Marginal adaptation was further objectively evaluated during all the evaluation periods by the inverse replica technique that were examined under Environmental Scanning Electron Microscope (ESEM) <sup>12(26)</sup>. Replicas were prepared using silicone impression material<sup>13</sup>. Replicas were analyzed directly under (ESEM), initially at magnification (10x) for the detection of whole restoration margins, followed by a higher magnification (1000x) to detect marginal gaps of the restoration <sup>(27)</sup>. The marginal integrity was measured as percentages of continuous margins to the full marginal length <sup>(25)</sup>.

### Statistical analysis

All data were collected, tabulated, and statistically analyzed using software Statistical Package for Social Sciences (SPSS) version 26.

## RESULTS

The collected data of modified USPHS criteria expressed in the form of frequency & percentage regarding each tested criterion was statistically analyzed using Chi-square test. Comparison between both tested groups regarding the % of perfect marginal seal evaluated by SEM was performed by t-test. While ANOVA test detected difference among the evaluation periods in each group. The recall rate of patients was 100% at all evaluation periods. For all criteria there is no clinical significance difference between both groups denoting their nearly comparable performance. While ANOVA test revealed no statistically significant difference between the different evaluation periods for both groups denoting the non-significant effect of the study time on all evaluated criteria for both tested restorations.

Concerning the retention rate and recurrence of caries, 100% of restorations recorded Alpha scores denoting their retention and absence of secondary caries at both groups till the period of 18 months follow up. Regarding the surface texture of the tested restorations in both groups, after 12 months follow up only 1 case (4.2%) in both groups recorded Bravo score (surface rougher than enamel), this was increased at the end of the study period (18 months) to be 3 cases (12.5%) in group I restored with SDR Flow+ and 2 cases (8.3%) in group II restored with G-aenial Universal Injectable.

The data collected for marginal adaptation scoring, revealed that, Bravo score (visible evidence of crevice along the margins, with no exposed dentin was first detected in 2 cases (8.3%) in group I, at the 18<sup>th</sup> month, while in group II, this score was recorded in 1 case (4.2%) & 3 cases (12.5%) at the 12<sup>th</sup> & 18<sup>th</sup> months respectively. Tracing of the SEM micrographs revealed a high mean % values of the perfect marginal seal were recorded and were nearly comparable in both groups throughout the study time. ANOVA

test revealed no statistically significant difference between the different evaluation periods ( $p= 0.533$  &  $0.620$ ) for both groups respectively denoting the non-significant effect of the study time on the marginal seal of the tested restorations. Comparing both tested groups at each follow up period, independent t-test recorded no significant difference between them at all the evaluation periods ( $p =0.205, 0.888, 0.835$  &  $0.471$ ) at base line, 6, 12 & 18 months respectively **Table (3)**.

**Table 3: Statistical analysis of the mean % values of the perfect marginal seal of restoration replicas of both groups at the different evaluation periods**

Evaluation periods \ Groups	Perfect marginal seal %			Comparison between groups(T-test )	
		Group I (SDR Flow+)	Group II (G-ænial Universal Injectable)	T	P-value
Baseline	Range	98.87 —100	98.06 —100	1.286	<b>0.205</b>
	Mean $\pm$ SD	99.83 $\pm$ 0.37	99.64 $\pm$ 0.62		
6 Months	Range	98.03 —99.99	98.03—99.93	0.142	<b>0.888</b>
	Mean $\pm$ SD	99.56 $\pm$ 0.65	99.53 $\pm$ 0.67		
12 Months	Range	98.01—99.99	98.01—99.83	0.209	<b>0.835</b>
	Mean $\pm$ SD	99.39 $\pm$ 0.79	99.35 $\pm$ 0.66		
18 Months	Range	98 —99.93	98—99.79	0.726	<b>0.471</b>
	Mean $\pm$ SD	99.31 $\pm$ 0.79	99.16 $\pm$ 0.64		
ANOVA test Comparison between periods	F P-value	1.660 <b>(0.533)</b>	1.531 <b>(0.620)</b>		

Regarding the marginal discoloration of the tested restorations, Bravo score was first recorded in the 18<sup>th</sup> month in 4.2% in group I & 8.3% in group II.

Concerning the postoperative sensitivity criterion, at the base line, Bravo scoring (presence of sensitivity that was diminishing in intensity and completely disappeared in the next follow up at 6<sup>th</sup> month) in 4.2% of case in group I & 12.5% in group II. At the 12<sup>th</sup> month evaluation period no sensitivity was recorded in group I, while 4.2% of case in group II scored Bravo (representing mild pain with a stream of air, hot or cold drinks or when moving a probe above the restored tooth surface toward the cavity margins and disappears immediately after removing the stimulus). At the end of the study period 8.3% & 12.5% scored Bravo in groups I & II respectively. Data of clinical evaluation (percentage) of all criteria in all tested groups at each follow-up period was illustrated in **Table (4)**.

Spearman correlation test was performed between the related tested criteria in each group to study their statistical relationship. Regarding the relationship between marginal adaptation and marginal discoloration, **Table (5)**: showed a highly significant positive relation between both tested criteria after 18 months at both groups ( $p=0.000$ ). There was also a significant positive relation between marginal adaptation and postoperative sensitivity after 18 months at both groups ( $p=0.000$ ) as shown in **Table (6)**.

**Table 4: Data of clinical evaluation (percentage) of all criteria in all tested groups at each follow-up period**

Evaluation criteria materials	Scores	Baseline		After 6 months		After 12 months		After 18 months		Comparison between periods Chi-Square Test	
		GI	GII	GI	GII	GI	GII	GI	GII	GI	GII
Retention rate	A	24 (100%)	24 (100%)	24 (100%)	24 (100%)	24 (100%)	24 (100%)	24 (100%)	24 (100%)		
	B	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)		
Surface texture	A	24 (100%)	24 (100%)	24 (100%)	24 (100%)	23 (95.8%)	23 (95.8%)	21 (87.5%)	22 (91.7%)	6.261 <b>(0.100)</b>	3.785 <b>(0.286)</b>
	B	0(0%)	0(0%)	0(0%)	0(0%)	1 (4.2%)	1 (4.2%)	3 (12.5%)	2 (8.3%)		
	C	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)		
<b>Chi-Square Test Comparison between groups</b>	<b><math>\chi^2</math> (P-value)</b>	-----		-----		-----		0.223 <b>(0.637)</b>		-----	
Marginal adaptation	A	24 (100%)	24 (100%)	24 (100%)	24 (100%)	24 (100%)	23 (95.8%)	22 (91.7%)	21 (87.5%)	6.129 <b>(0.106)</b>	6.261 <b>(0.100)</b>
	B	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	1 (4.2%)	2 (8.3%)	3 (12.5%)		
	C	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)		
<b>Chi-Square Test Comparison between groups</b>	<b><math>\chi^2</math> (P-value)</b>	-----		-----		1.021 <b>(0.312)</b>		0.223 <b>(0.637)</b>		-----	
Marginal discoloration	A	24 (100%)	24 (100%)	24 (100%)	24 (100%)	24 (100%)	24 (100%)	23 (95.8%)	22 (91.7%)	3.032 <b>(0.387)</b>	6.128 <b>(0.106)</b>
	B	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	1(4.2%)	2 (8.3%)		
	C	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)		
<b>Chi-Square Test Comparison between groups</b>	<b><math>\chi^2</math> (P-value)</b>	-----		-----		-----		0.356 <b>(0.551)</b>		-----	
Secondary caries	A	24 (100%)	24 (100%)	24 (100%)	24 (100%)	24 (100%)	24 (100%)	24 (100%)	24 (100%)		
	B	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)		
Postoperative sensitivity	A	23 (95.8%)	21 (87.5%)	24 (100%)	24 (100%)	24 (100%)	23 (95.8%)	22 (91.7%)	21 (87.5%)	3.785 <b>(0.286)</b>	4.161 <b>(0.245)</b>
	B	1 (4.2%)	3 (12.5%)	0(0%)	0(0%)	0(0%)	1 (4.2%)	2 (8.3%)	3 (12.5%)		
	C	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)		
<b>Chi-Square Test Comparison between groups</b>	<b><math>\chi^2</math> (P-value)</b>	1.091 <b>(0.296)</b>		-----		1.021 <b>(0.312)</b>		0.223 <b>(0.637)</b>		-----	



**A: Alpha, B: Bravo, C: Charlie, GPI: (SDR Flow+), GPII: (G-ænial Universal Injectable)**

**Table 5: Statistical correlation between marginal adaptation versus marginal discoloration of the three groups at different follow up periods.**

Correlation between marginal adaptation and marginal discoloration								
Groups	Baseline		6 months		12 months		18 months	
	<i>r</i>	<b>P</b>	<i>r</i>	<b>p</b>	<i>r</i>	<b>P</b>	<i>r</i>	<b>p</b>
Group I (SDR Flow+)	-----	-----	-----	-----	-----	-----	0.692	<b>0.000**</b>
Group II (Gaenial Universal Injectable)	-----	-----	-----	-----	-----	-----	0.798	<b>0.000**</b>

**Table 6: Statistical correlation between marginal adaptation versus postoperative sensitivity of the three groups at different follow up periods.**

Correlation between marginal adaptation and postoperative sensitivity								
Groups	Baseline		6 months		12 months		18 months	
	<i>r</i>	<b>P</b>	<i>r</i>	<b>p</b>	<i>r</i>	<b>p</b>	<i>r</i>	<b>p</b>
Group I (SDR Flow+)	-----	-----	-----	-----	-----	-----	0.455	<b>0.026*</b>
Group II (Gaenial Universal Injectable)	-----	-----	-----	-----	-----	-----	0.619	<b>0.001*</b>

## DISCUSSION

Composite resins occupy a paramount position among tooth colored restorative materials for they offer exemplary esthetic potential, acceptable longevity, and cost. Among these resins, regular viscosity bulk-filling is highly desired in routine restorative practice, but their relatively high shrinkage stress has caused certain reluctance in its application. However flowable types with higher filler content result in lower shrinkage stress, simple handling characteristics and save in chairside time as claimed by the manufacturer <sup>(28)</sup>. Thus, a flowable bulk-fill restorative material (SDR flow+) was chosen to be tested currently.

On the other hand, it was reported that, flowable bulk fill resins with lower flexural modulus may not provide an effective buffer to occlusal stress when they are capped with regular RBCs <sup>(29)</sup>. Thus, its performance was currently evaluated without a capping layer in moderately carious class 1 cavities in permanent teeth, and it was lately recommended to be suitable as a stand-alone restorative material in conservative Class I, Class III and V restorations without a separate capping being applied on top. This was represented in a case report and one-year clinical study in primary molars reporting quite satisfactory results <sup>(30)</sup>.

In addition, it is widely accepted that incremental filling decreases shrinkage stress as a result of reduced polymerization material volume <sup>(31)</sup>. Newer launched products of flowable highly filled composites are suitable for full-depth cavity filling without a need for a capping layer. One of these new materials is G-ænial Universal Injectable, which is designed to be applied incrementally to provide a true universal restorative material that

can be used for a variety of indications including Class I restorations. Thus, currently it was interesting to evaluate its clinical performance.

Regarding the recorded results of retention rate, a 100% of the tested restorations was retained by the end of the study. These results may be attributed to the type of the adhesive used; universal adhesives (Prime& Bond universal and G-Premio Bond) due to the presence of the functional monomer 10-MDP, which bonds chemically with hydroxyapatite through its phosphate groups, providing a more effective bond and more stability in water than other monomers, good adaptability to the cavity walls and the high filler content of the tested flowable materials which was found to have less shrinkage than conventional composite.

This was proved by Sagsoz et al, <sup>(32)</sup> reporting that other highly filled flowable composites (GrandioSO Flow and GrandioSO Heavy Flow) containing (80 & 83 w%, filler) respectively had lower polymerization shrinkage which could ensure less debonding of the material and higher bond strength, thus better retention rates in restored cavities. They also mentioned that the bond strength values of these highly filled flowable composites were not superior to Surefill SDR flow containing fillers (68 w%) which was lower than that of the currently tested materials SDR Flow+ (70.5 w%) which approximates that of G-aenial Universal flow (69 w%). This could support the current findings of 100% retention rate utilizing both materials regardless the different application techniques (bulk fill and incremental). Furthermore, Sarapultseva et al, <sup>(33)</sup> reported good and identical clinical performance of flowable bulk-fill SDR when used to restore Class I cavities of primary molars without occlusal capping in comparison to CeramX mono over a period of 24 months.

On the other hand, the findings of Karaman et al, <sup>(34)</sup> revealed that the retention rates were very low (54.0% after 24 months), for a different highly filled flowable composite resin. Considering the difference between both studies, their study was conducted in non-carious cervical lesions in old patients (48 to 70 years) where they contain hypermineralized dentin and denatured collagen that is not ideal for a bonding substrate.

Concerning the results of the surface texture in both tested groups, Bravo score was recorded at the 12<sup>th</sup> month in only (4.2%) in each group that was increased at the end of the study period to 3 cases (12.5 %) in group I that was higher than that recorded in group II (8.3%). This could be explained by wear during function and routine teeth brushing causing roughness of the restoration surface, it may also be due to diet containing acidic beverages, with inefficient buffering action of the salivary PH in individual cases. The results of group I could be explained according to Gjorgievska et al, <sup>(35)</sup> they found that the surface roughness of the SureFil SDR™ flow was higher than that of the Tetric EvoFlow Bulk Fill. They attributed this to be due to the nature of fillers being nanohybrid that contain a mixture of both nanoparticles and larger irregular shaped particles resulting in low wear resistance, as well as to the difference of filler loading. The difference between their findings and the currently reported for SDR flow+, should be considered where they evaluated the surface roughness in-vitro by AFM, while the current clinical evaluation of surface texture was subjective. On the other hand, in the transition from SDR-to-SDR

flow+, the composition of both the resin matrix as well as the fillers has been modified. In order to strengthen the material, improve its radiopacity and reduce its wear the filler load has been increased by 2.5% and the previous glass filler of SDR has been partially replaced by an alternative filler which provides higher strength.

This was supported by Khazaal et al, <sup>(36)</sup> reporting satisfying surface texture of SDR Flow+ that was similar to Ceram x Universal Sphere TEC™, an ORMOCER-based composite, that already proved itself in clinical practice.

The results of Sarapultseva et al, <sup>(33)</sup> comparing the clinical performance of flowable bulk-fill SDR in Class I cavities of primary molars without occlusal capping could also support the current study. They reported almost identical results with a nanoceramic composite CeramX mono over a period of 24 months regarding all tested criteria including the surface texture. The favorable occlusal loading of primary teeth might coincide with their tested material while currently used SDR Flow + with its modified fillers as well as the careful consideration of the patient's occlusion before treatment as recommended for resin composites in posterior teeth accounts for its promising results.

Regarding Genial universal injectable, its silane-coated ultra-fine particles (150 nm) that are extremely well bonded to the matrix thanks to GC's FSC technology, form a homogenous, uniformly dispersed layer that provide a reduced risk of filler drop out during occlusal loading. The high filler load (69%) also enables the material to achieve high strength and wear resistance thus providing excellent polishability and gloss retention. The currently recorded surface texture of Genial universal injectable was in agreement with Kitasako et al, <sup>(37)</sup> & Badr et al, <sup>(38)</sup> who found that, G-ænial Universal Flo presented excellent surface properties, their explanation was also attributed to its filler technology being round-shaped with a new silane treatment method that enhances the adhesion between filler particles and resin matrix. This gives superior thixotropic qualities that result in the most aesthetically pleasing and lasting restorations with minimal modification. While nanoclusters are intended to wear at the same rate as the surrounding resin matrix, as each nanolayer or nanocluster is abraded away, a similar nanolayered surface is revealed below. Thus, the surface of a purely nanofilled RBCs remains smooth during function, and the abrasion process is slower in the purely nanofilled RBCs than for hybrid RBCs. However, this was not always the case in the in-vivo studies which involve many other factors affecting the quality of surface texture.

Regarding the marginal adaptation, it is well known that this criterion is of optimal importance since it plays an important role in the prevention of microleakage at the tooth-restoration interface. The defects at the bonding interface are due to the polymerization shrinkage during restoration and subsequent thermal, functional, and mechanical stresses. This was found to be influenced by the composition of the restorative material and adhesive system. In the present study a universal adhesive system was used in both groups and resulted in the positive results. Although the phosphoric acid is not applied in universal adhesive systems, the acidic monomers in their composition make the bond strength of restoration to the tooth surface reliable <sup>(39)</sup>.

Prime& Bond universal adhesive contains a newly developed hydrolysis stable crosslinker, phosphoric acid esters, isopropanol, and water. Its acidic monomer with a clear advantage, good penetration behavior that is comparable to the clinically proven phosphoric acid modified acrylate resins PENTA and MDP were considered and included into the mixture design, both monomers reliably etch the dental substrate releasing solvated ions of calcium. In particular, MDP forms self-assembled nanolayer structures which further strengthen the hybrid layer of the adhesive. The PENTA molecule exhibits intrinsic advantages that are not covered by MDP which contains a hydrophilic core and five double-bonds per molecule. Thus, it is not only a highly effective crosslinker but also a powerful wetting aid and renders Prime&Bond universal™ as a unique universal adhesive <sup>(40)</sup>. While G-Premio Bond universal adhesive has three functional monomers; the first one is 4-methacryloyloxyethyl trimellitate anhydride which is responsible for bond strength of restoration to dentin and enamel surface. The second functional monomer is MDP which can improve the long-term bond strength of restoration to the tooth surface, thus good marginal adaptation. The third functional monomer is methacryloyloxydecyl dihydrogen thiophosphate, which enables acceptable bond strength to precious metals. High penetration and wettability of this adhesive results in favorable infiltration into dentinal tubules <sup>(41)</sup>.

Regarding the acceptable results of the current study, where only 8.3% & 12.5 % scored Bravo after 18 months in group I & II respectively, being flowable composites, it was previously reported that the degree of fluidity of composite provides better adhesion to the cavity walls and margins. The non-significant difference between both groups throughout all evaluation periods could be related to the advancements, low viscosity, and high fluidity of both tested materials. This was supported by Ilie and Hickel, <sup>(42)</sup> who revealed that the flowable composite materials based on SDR technology show a lower polymerization shrinkage compared with other flowable materials such as Filtek Supreme Flow and Esthet X Flow. Owing to SDR technology, a proprietary urethane dimethacrylate structure that claims to give outstanding clinical performance by reducing polymerization shrinkage and stress. This highly stress-relieving internal monomer might delay the gel point, which could allow more time to compensate for the shrinkage; consequently, polymerization shrinkage would be reduced. In addition to a lower modulus of elasticity, SDR might act as a stress buffer. Compared to conventional resin systems, the SDR® Bulk Fill Flowable composite has a self-leveling feature that allows intimate adaptation to the prepared cavity walls. These results of group I came also in agreement with many other clinical studies <sup>(33, 35)</sup>.

Concerning G-aenial Universal Injectable, the result is expected where it exhibits an improvement in polymerization shrinkage due to the inclusion of nanosized fillers in a resin system that is claimed to control polymerization kinetics. This result was in agreement with Kitasako et al, <sup>(37)</sup> where G-aenial Universal Flo posterior restorations showed superior marginal adaptation showing only 0.05 % unacceptable margins according to FDI criteria despite their longer evaluation time (36 months). On the other hand, the results were in disagreement with Oz et al, <sup>(43)</sup> reporting that, occlusal cavities

restored with G-aenial Universal Flo showed a significant marginal change after 24-month compared to baseline, which could be attributed to their longer study period.

The inverse replica examined under SEM was utilized in this study to confirm the clinical scores of marginal adaptations. Non-continuous gap formation & minute marginal defects were detected in very low % (1.7-2%) with no significant difference between both groups. These could be explained by infrequent debonding points which might be caused by minute polymerization shrinkage stresses explained as accumulated stresses causing fatigue due to occlusal load by time, which might increase if the evaluation period was elongated.

Currently it was found that time was also an ineffective factor related to the percentage of marginal adaptation, which was in agreement with Kitasako et al, <sup>(37)</sup> in their 36-month clinical evaluation of G-aenial Universal Flo compared to a conventional paste-type composite in posterior restorations, reporting non statistically significant in the recorded acceptable high percentage of marginal adaptation scores. They attributed the marginal defect of the heavy filled flowable composite to its expected flowing over the margins, resulting in thin flashes that will fracture with function and result in marginal defects even if they are appeared to be smooth, continuous, and clinically acceptable at the time of placement. However, these defects could be easily polished or repaired with a flowable resin composite. This was not the present case since the cavosurface margins of class I cavities were performed without beveling.

Concerning the recorded results of marginal discoloration, Bravo score was recorded at the 18<sup>th</sup> month in 4.2% in group I & 8.3% in group II, with no significant difference between both tested groups denoting their nearly comparable performance. These results may be attributed to the good marginal adaptation of both tested materials and controlled oral hygiene care followed by the selected patients. Sarapultseva et al, <sup>(33)</sup> agreed the current result reporting a non-significant difference between the marginal discoloration of flowable bulk-fill SDR in class I restorations compared to nano-ceramic composite (CeramX mono). While Badr et al, <sup>(38)</sup> proved that Genial Universal Flo exhibited acceptable marginal staining in Class I and II restorations compared to a nanohybrid universal composite resin (Tetric EvoCeram). They attributed the results of G-aenial Universal Flo to its previously mentioned resin system that is claimed to control polymerization kinetics having incorporated nanosized fillers which allows improvement in mechanical properties, good marginal adaptation thus reduced marginal staining. On the other hand, Torres et al, <sup>(44)</sup> disagreed the current results reporting higher % of Bravo score (39.5%). They attributed this to longer evaluation time and different cavities evaluated in their studies.

Regarding the recorded results of recurrence of caries, it is considered an association with a defective restoration mainly via gaps between the restoration and the tooth allowing acidic fluids or biofilm to enter the interface <sup>(45)</sup>. Currently no cases of caries recurrence are detected, which informs that, the observed gaps depth was an important factor which was not measured. The recorded observed gaps might be shallow in depth limited to the enamel surface thus not involving the dentin walls, where enamel is known to have more resistance to caries compared to dentin. In addition, it was reported that the impact of the

restorative material on secondary caries risk seems to be limited. Notably, though, the follow-up period of clinical trials was short, and most were performed in low-risk patients under controlled settings. Hence, the overall number of lesions which developed was low. Since the selected patients in the current study were at a young age range who didn't have any limitations for oral hygiene, their inclusion criteria didn't include any health problem that cause dry mouth or mobility limitations which may affect oral hygiene measures and increase the risk of secondary caries.

This was in agreement with Kitasako et al, <sup>(37)</sup> and Badr et al, <sup>(38)</sup> they attributed this to the good marginal adaptation and the maintenance of a good oral hygiene by all patients. On the other hand, Sarapultseva et al, <sup>(33)</sup> disagreed the current results recording (3.7%) of secondary caries in bulk-fill SDR class I restorations after 24 months. The difference to the current study could be attributed to their longer evaluation period.

Regarding the collected data it was concluded that, Postoperative hypersensitivity is related to many factors as the procedure of cavity preparation, adhesive approach, and type of resin composite used as well as the placement technique of the resin composite. It is not only influenced by the marginal adaptation and integrity but also affected by crucial reduction in the degree of conversion, since an increase in the release of free monomers might damage the material's physical qualities. Which may lead to postoperative hypersensitivity. In addition, Sancakli et al, <sup>(46)</sup> attributed the outcome of postoperative hypersensitivity to the operator skill and experience during the restorative procedures. While Ashgar et al, <sup>(47)</sup> attributed the low postoperative hypersensitivity to the lower post-gel shrinkage of bulk-fill composites. However, utilization of an incremental technique and polymerization methods can increase the gel phase, thus improving the flowability of the material and, consequently, the marginal adaptation and minimizing the occurrence of possible damage to the adhesive interface, finally minimum postoperative hypersensitivity.

However, it was reported that it is a patient-related factor, such as pain experience and amount of discomfort that can vary between patients. Most patients complain of postoperative hypersensitivity informed their observations about the complete disappearance of sensitivity within 2 to 4 days after receiving their restorations. This observation was explained by postoperative hypersensitivity being a temporary symptom that resolves as the degree of conversion is increased by time bearing in mind that all the restorative steps were properly performed.

Our findings indicate that the initial sensitivity recorded at the baseline completely disappeared within days while at the 18<sup>th</sup> month 8.3 & 12.5 % recorded pain in groups I & II respectively that were concomitant with those of the previously mentioned marginal adaptation results.

Sarapultseva et al, <sup>(33)</sup> disagreed the current results reporting a 100% absence of postoperative sensitivity in flowable bulk-fill SDR class I restorations after 24 months follow up. Also Kitasako et al, <sup>(37)</sup> disagreed the current results where no sensitivity was recorded in G-aenial Universal Flo posterior restorations throughout the study period of

36 months despite the recorded minute marginal defects reporting that it seems that such defects had apparently resulted from the fracture of these thin flashes of composite that extended onto enamel surfaces adjacent to the cavity margins assuming that these defects could be easily polished or repaired. While Badr et al, <sup>(38)</sup> reported slight reversible sensitivity which disappeared at 12<sup>th</sup> & 24<sup>th</sup> month in Class I and II restorations of Genial Universal Flo and attributed their results to using of the layering technique and the soft start polymerization mode which may have reduced this shrinkage and thus the postoperative sensitivity.

## CONCLUSIONS

Under the limitations of the current study, it could be concluded that:

Both tested highly filled flowable composites with their different application techniques presented acceptable nearly comparable results in moderate sized class I restorations over 18 months follow up.

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### Conflict of interest:

There is not any conflict of interest.

### Footnotes

- 1) Dental Dam, Sanctuary Latex Powder Free, Malaysia
- 2) no. 245 (Midwest, operative carbide bur; FGSS, Dentsply Sirona, York, PA, USA)
- 3) (Sirona, Gemany)
- 4) I LED curing unit.WOODPECKER. China.
- 5) Hand-held radiometer (Curing Radiometer Model 100; Demetron Corp, USA).
- 6) HDA, blue, red straight articulating paper, Turkey.
- 7) G&Z Instrumente GmbH, Austria.
- 8) Kenda dental polishers, Liechtenstein.
- 9) Dental Cap Dental Photographic Mirror – Strigh, Egypt.
- 10) Lascod Zeffiro Explorer Probe, Italy.
- 11) Canon 6D mark I with sigma 105 macro lens, USA.
- 12) Environmental Scanning Electron Microscope: Quanta FEG-250 SEM ESEM, Spain.
- 13) Aquasil Ultra XLV.Dentsply

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- 13) G-ænial® Universal Injectable from GC TECHNICAL MANUAL.  
[https://cdn.gceurope.com/v1/PID/gaenialuniversalinjectable/manual/MAN\\_G-aenial\\_Universal\\_Injectable\\_Technical\\_Manual\\_en.pdf](https://cdn.gceurope.com/v1/PID/gaenialuniversalinjectable/manual/MAN_G-aenial_Universal_Injectable_Technical_Manual_en.pdf).
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