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Received: 27 November, 2017; Accepted: 13 December, 2017; Published: 14 December, 2017

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Keywords: Flowable composite; Clinical performance; Primary molars

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Research Article

Clinical efficacy of novel self-adhesive flowable composite resin restoration: *in vivo* study

Abstract

Objective: This study was carried out to evaluate the clinical performance of the conventional flowable composite resin restoration, using one- step adhesive system versus the novel self-adhesive flowable composite restoration.

Method: Twenty patients received forty class I restorations in primary carious molars using split-mouth design. Clinical performance was evaluated using US Public Health Service modified Ryge criteria. Restorations of both materials were evaluated for: anatomic form, marginal integrity, marginal discoloration, surface texture and recurrent caries after 1 week, 3, 6, 9 months and after 12 months.

Results: Concerning the anatomic form, the marginal integrity and marginal discoloration, there was no statistical difference between both materials till 9 ms but at 12 ms, there was a significant difference in favor of the self-adhering flowable composite. As for the secondary caries till 6 ms, both materials scored 100% score 1, while, at 9 and 12 ms, there was no significant difference between both materials. The surface texture of both restorative materials scored (score1). Tracing both materials by time, there was a statistically significant difference in both materials in the anatomic form, marginal integrity and marginal discoloration.

Conclusion: self-adhesive flowable composite showed improved clinical performance at 12 months than to conventional flowable composite.

Introduction

In recent years, the popularity of the aesthetic restorations has increased, such as the composite resin, which is the most aesthetic restorative material currently available for restoring anterior teeth. It offers an acceptable aesthetics and has good handling properties. Nevertheless, problems still exist, in terms of polymerization shrinkage and subsequent inadequate adhesion to cavity walls, which lead to micro-leakage [1]. Accordingly, the adhesive dentistry which is an area of clinical practice, where the technology of the adhesives and the techniques are being developed to be used with them, is continuously changing [2]. The purpose of adhesive techniques, regardless if total acid etching or self-etching system is used, is to obtain a well-bonded structure, with minimal microleakage and absent post-operative sensibility. Restoration must be able to maintain stability under temperature variation and mechanical stress, which are elements present in the oral activity [3-5]. Despite the constant improvement of composite resins, polymerization contraction stress remains a challenge. For this reason, composite resins with a reduced filler load

and a lower modulus of elasticity marketed as “flowable” composites have been used [6- 11]. Since flowable composite resins did not have adhesive properties, the combined use of a dental bonding system was mandatory. Although the two-step procedures worked well in the majority of cases, there are some situations where a one-step composite restoration would be advantageous, especially when working with pediatric patient, in order to reduce the number of clinical steps and the chair-side time for small or uncooperative children [12,13].

Therefore the aim of this study was to compare the clinical performances of self-adhesive flowable restorative resin composite and a conventional flowable restorative resin composite with its corresponding self-etch adhesive system over one year evaluation period.

Materials and Methods

Two restorative materials were used in this study, A self-adhesive flowable restorative resin composite (Fusio Liquid Dentin) and a conventional (non-self-adhesive) flowable restorative resin composite (Flow-It[®] ALC[™]) with

its corresponding self-etch adhesive system (Bond 1[®]SF). Approval to the clinical study was given by the scientific and ethical committee of Pediatric Dentistry Department, Faculty of Dentistry, Suez Canal University.

Sample selection

A consecutive sample of 20 patients was selected from the outpatient's clinic of the Department of Pediatric Dentistry, Faculty of Dentistry, Suez Canal University according to the following inclusion and exclusion criteria.

Inclusion criteria

- 1-Healthy cooperative children of both sexes
- 2-Aged between (4-6 years old)
- 3-Children had at least two bilateral carious primary molars which were in need for class I cavity preparations.

Exclusion criteria

Any child was having one of these criteria was excluded:

- 1- Systemic disease or severe medical complications.
- 2- Known allergy to any component of the materials used
- 3- History of spontaneous pain (pulpitis), or periapical pathosis.
- 4- Deep carious defects.
- 5- Heavy occlusal contacts or history of bruxism.
- 6- Rampant caries.

Personal data, medical and dental histories were recorded, and clinical dental examination was done and recorded. The parents of the participants were informed by the nature of the study before commencement of the treatment and a written consent were signed by the parents. In this study, following anesthesia, all carious structures, in the selected teeth, were excavated.

Operative and restorative procedures

Forty cavity preparations were performed, using conventional carbide burs #330 in a high speed hand piece with water coolant. A new bur was used every six preparations [14]. The preparation design was dedicated by the extent of the decay. Cavity preparations were rinsed for 20 seconds with air-water spray and gently air-dried before the placement of the restorations. All the cavity preparations were restored according to the split-mouth design. Cavity preparations that were assigned to be the experimental group (Group I) were restored with Fusio Liquid Dentin). On the other hand, all the cavity preparations that were assigned to be the control group (Group II) were restored with flowable restorative resin composite (Flow-It[®] ALC[™]) using its corresponding self-etch adhesive system (Bond 1[®]SF).The teeth were restored following the manufacturer's instructions of both materials.

Clinical evaluation of the restored teeth

Direct evaluation of the restorations was undertaken by one investigator. During the follow-up evaluations, the clinical success of the restorations was based on modified US Public Health Service Criteria (Anatomic form- Marginal integrity- Marginal discoloration- Surface texture- Recurrent caries) [15,16]. Evaluations were carried out after 1 week, 3 months, 6 months, 9 months and 1 year under normal clinical conditions using a dental operating light, a dental mirror and a dental explorer.

The scoring system will be as follows

Score 1: Indicates clinically ideal situation

Score 2: indicates a clinically acceptable situation

Score 3: indicates a clinically unacceptable situation, which usually requires replacement of the restoration

Score 4: indicates a clinically unacceptable situation because of fracture, mobility or loss of the restoration, which makes it necessary to replace it.

Statistical analysis

The results were recorded, tabulated, and statistically analyzed. Assessment criteria scores were presented as frequencies (n) and percentages (%). Wilcoxon signed-rank test was used to compare between the two materials. Friedman's test was used to study the changes by time within each material. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM¹³® SPSS¹⁴® Statistics Version 20 for Windows.

Results

Anatomic form

In Fusio Liquid Dentin group, Score 1 decreased gradually from 3 to 12 months evaluations from 95% to 60% of evaluated molars, while in the same time, score 2 increased from 5% to 20%. Score 3 was not recorded in all evaluation time. In Flow-It[®] ALC[™] group, Score 1 decreased gradually from 1 week to 12 months evaluations from 95% to 25% of evaluated molars, while in the same time, score 2 increased from 5% to 55%. Score 3 was not recorded in all evaluation time for both materials. Statistical analysis showed no statistically significant difference between both materials at 1 week, 3, 6, 9 months but at 12 months evaluation, there was missing 4 restorations with a percentage of 20%. Statistical analysis showed statistically significant difference between both materials in favor with Fusio Liquid Dentin with a P-value 0.020. Tracing the changes occurring in each material by time showed that there is a statistically significant difference in both materials recording a P-value of 0.029 and 0.001 for Fusio Liquid Dentin and Flow-It[®] ALC[™] respectively (Table 1, Figure 1).

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Marginal integrity

In Fusio Liquid Dentin group, Score 1 decreased gradually from 3 to 12 months evaluations from 95% to 60% of evaluated molars, while in the same time, score 2 increased from 5% to 20%. Score 3 was not recorded in all evaluation time. In Flow-It® ALC™ group, Score 1 decreased gradually from 1 week to 12 months evaluations from 95% to 30% of evaluated molars, while in the same time, score 2 increased from 5% to 50%. Score 3 was not recorded in all evaluation time for both materials. Statistical analysis showed no statistically significant difference between both materials at 1 week, 3, 6, 9 months but at 12 months evaluation, there was missing 4 restorations with a percentage of 20%. Statistical analysis showed statistically significant difference between both materials with a P-value 0.034. Tracing the changes, occurring in each material, by time showed that there is a statistically significant difference in both materials recording a P-value of 0.029 and 0.001 for Fusio Liquid Dentin and Flow-It® ALC™ (Table 2, Figure 2).

Marginal discoloration

In Fusio Liquid Dentin group, Score 1 decreased gradually from 1 week to 12 months evaluations from 95% to 50% of evaluated molars, while in the same time, score 2 increased

Table 2: Comparisons between percentages of marginal integrity scores of the two materials and changes by time within each material.

Period	Score	Fusio		Flow-it		P-value (Between materials)
		n	%	n	%	
1 week	1	20	100.0	19	95.0	0.317
	2	0	0.0	1	5.0	
	3	0	0.0	0	0.0	
3 months	1	19	95.0	19	95.0	1.000
	2	1	5.0	1	5.0	
	3	0	0.0	0	0.0	
6 months	1	18	90.0	14	70.0	0.157
	2	2	10.0	6	30.0	
	3	0	0.0	0	0.0	
9 months	1	15	75.0	9	45.0	0.083
	2	5	25.0	11	55.0	
	3	0	0.0	0	0.0	
12 months	1	12	60.0	6	30.0	0.034*
	2	4	20.0	10	50.0	
	3	0	0.0	0	0.0	
	Missing	4	20.0	4	20.0	
P-value (Changes by time)		0.029*		<0.001*		

*: Significant at P ≤ 0.05

Table 1: Comparisons between percentages of anatomic form scores of the two materials and changes by time within each material.

Period	Score	Fusio		Flow-it		P-value (Between materials)
		n	%	n	%	
1 week	1	20	100	19	95.0	0.317
	2	0	0.0	1	5.0	
	3	0	0.0	0	0.0	
3 months	1	19	95.0	18	90.0	0.564
	2	1	5.0	2	10.0	
	3	0	0.0	0	0.0	
6 months	1	18	90.0	13	65.0	0.096
	2	2	10.0	7	35.0	
	3	0	0.0	0	0.0	
9 months	1	15	75.0	8	40.0	0.052
	2	5	25.0	12	60.0	
	3	0	0.0	0	0.0	
12 months	1	12	60.0	5	25.0	0.020*
	2	4	20.0	11	55.0	
	3	0	0.0	0	0.0	
	Missing	4	20.0	4	20.0	
P-value (Changes by time)		0.029*		<0.001*		

*: Significant at P ≤ 0.05

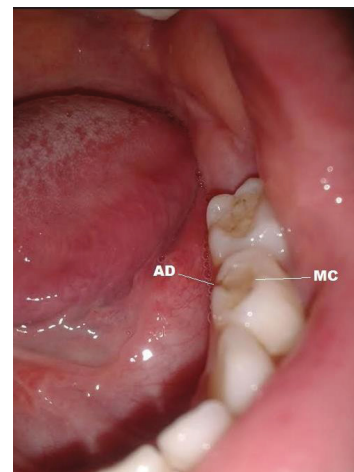


Figure 2: Shows Flow-It® ALC™ (FL) restoration at 9 months with marginal crevice (MC) and anatomic defect (AD).

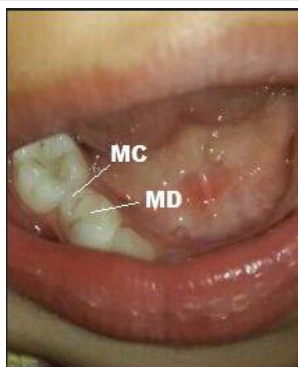


Figure 1: Shows Fusio Liquid Dentin (FLD) restoration at 12 months with marginal crevice (MC) and anatomic defect (AD).

from 5% to 30%. In Flow-It® ALC™ group, Score 1 decreased gradually from 1 week to 12 months evaluations from 95% to 5% of evaluated molars, while in the same time, score 2 increased from 5% to 75%. Score 3 was not recorded in all evaluation time for both materials. Statistical analysis showed no statistically significant difference between both materials at 1 week, 3, 6, 9 months but at 12 months evaluation, there was missing 4 restorations with a percentage of 20%. Statistical analysis showed that Fusio Liquid Dentin showed statistically higher prevalence of score 1 and lower prevalence of score 2 than Flow-It® ALC™, with a P-value of 0.007. Tracing the changes occurring in each material by time showed that there is a statistically significant difference in both materials recording a P-value of 0.002 and 0.001 for Fusio Liquid Dentin and Flow-It® ALC™ respectively (Table 3).

Surface texture

After 1 week, 3, 6, 9 as well as 12 months, all cases of Fusio Liquid Dentin and Flow-It® ALC™ showed score 1.

Recurrent caries

In Fusio Liquid Dentin group, Score 1 decreased gradually from 9 to 12 months evaluations from 95% to 70% of evaluated molars, while in the same time, score 2 increased from 5% to 10%. In Flow-It® group, Score 1 decreased gradually from 9 to 12 months evaluations from 90% to 60% of evaluated molars, while in the same time, score 2 increased from 10% to 20%. Score 3 was not recorded in all evaluation time for both materials. Statistical analysis showed no statistically significant difference between both materials at 1 week, 3, 6, 9 months but at 12 months evaluation, there was missing 4 restorations with a percentage of 20%. Statistical analysis showed statistically insignificant difference between both materials with a P-value 0.317. Tracing the changes occurring in each material by time showed that there is a statistically insignificant difference for Fusio Liquid Dentin recording a P-value of 0.171, while for Flow-It® ALC™, there was a statistically significant change by time in recurrent caries with a P-value of 0.010 (Table 4).

Discussion

Recent research advancements have mainly aimed at reducing technique sensitivity and chair time, especially with children. From this perspective, the elimination of a bonding step can be considered as a breakthrough. Therefore, it seemed reasonable to consider, in this study, the one-step self-etch adhesive system (Bond 1®SF, Pentron Clinical) followed by the application of a flowable resin (Flow-It® ALC™, Pentron Clinical) as the comparative product group for this recently formulated self-adhering flowable composite (Fusio Liquid Dentin, Pentron Clinical, Orange, CA, USA).

In this current study, 20 healthy, cooperative children aged between 4-6 years old, were included in this study. Each selected child was having at least two primary molars in need for class I cavity preparations. This age range was chosen since this was our target group, for the cooperation ability of the patients and for a predicted survival of these teeth, for at least

Table 4: Comparisons between percentages of recurrent caries scores of the two materials and changes by time within each material.

Period	Score	Fusio		Flow-it		P-value (Between materials)
		n	%	n	%	
1 week	1	20	100.0	20	100.0	1.000
	2	0	0.0	0	0.0	
	3	0	0.0	0	0.0	
3 months	1	20	100.0	20	100.0	1.000
	2	0	0.0	0	0.0	
	3	0	0.0	0	0.0	
6 months	1	20	100.0	20	100.0	1.000
	2	0	0.0	0	0.0	
	3	0	0.0	0	0.0	
9 months	1	19	95.0	18	90.0	0.564
	2	1	5.0	2	10.0	
	3	0	0.0	0	0.0	
12 months	1	14	70.0	12	60.0	0.317
	2	2	10.0	4	20.0	
	3	0	0.0	0	0.0	
	Missing	4	20.0	4	20.0	
P-value (Changes by time)		0.171		0.010*		

*: Significant at P ≤ 0.05

2 years until normal shedding. The forty cavity preparations were performed, using conventional carbide burs #330, in a high speed hand piece with water coolant. Same bur was also used by Pascon et al. [17]. This pear-shaped bur might be the most suitable bur for adhesive restorations due to its dimension, as well as, the production of a cavity with rounded edge. The cavity preparations were restored in a split-mouth design to limit the patient-effect. During the follow-up evaluations, the clinical success of the restorations was based on modified US Public Health Service Criteria [15]. Maintenance of inter-proximal contact criteria was excluded because of the nature of study since they were class I restorations with no inter-proximal contact. Also, the evaluation of postoperative sensitivity was excluded due to the risk of obtaining false results from the young age group selected in this study.

The results of this present investigation, concerning the anatomic form, showed that, there was no significant difference between the two restorative materials till 9 months evaluation period. This finding could imply that as the life-time of the restorations increase so does the wear, for both materials, equally. This result is in accordance with Çelik et al. [18]. On the other hand, at 12 months, there was a statistically significant difference in favor of Fusio Liquid Dentin. This might be due to the increase of monomers 1,6-bis(methacryloxy-2-ethoxycarbonylamino) 2,4,4-trimethylhexane (UDMA) and triethylene glycol dimethacrylate (TEGDMA) in the composition of Fusio Liquid Dentin which promoted more resistance to abrasion. This is in agreement with Soherholm et al [19]. Tracing the changes occurring in each material by time showed that there was a statistically significant difference in both materials. This result may be due to the effect of the time factor over the wear resistance of both materials.

The results of the evaluation of the marginal integrity showed that, there were no significant differences between the two restorative materials till 9 months evaluation period. This result is in accordance with the results of Çelik et al. [18]. While et al., 12 months, the marginal integrity of Fusio Liquid Dentin was significantly better than Flow-It® ALC™. This finding

Table 3: Comparisons between percentages of marginal discoloration scores of the two materials and changes by time within each material.

Period	Score	Fusio		Flow-it		P-value (Between materials)
		n	%	n	%	
1 week	1	19	95.0	19	95.0	1.000
	2	1	5.0	1	5.0	
	3	0	0.0	0	0.0	
3 months	1	17	85.0	11	55.0	0.083
	2	3	15.0	9	45.0	
	3	0	0.0	0	0.0	
6 months	1	15	75.0	8	40.0	0.090
	2	5	25.0	12	60.0	
	3	0	0.0	0	0.0	
9 months	1	12	60.0	5	25.0	0.071
	2	8	40.0	15	75.0	
	3	0	0.0	0	0.0	
12 months	1	10	50.0	1	5.0	0.007*
	2	6	30.0	15	75.0	
	3	0	0.0	0	0.0	
	Missing	4	20.0	4	20.0	
P-value (Changes by time)		0.002*		<0.001*		

*: Significant at P ≤ 0.05

coincides with Wei et al. [20]. Several explanations can justify the improved performance of Fusio Liquid Dentin over Flow-It® ALC™ after 12 months: first; the reported bond strength of Fusio Liquid Dentin to enamel and dentin was 27.7 MPa and 26.9 MPa respectively, while, that of Flow-It® to enamel and dentin was 25.5 MPa and 14.6 MPa respectively. This is in accordance with Dental Tribune [21]. Second; since the composition of Fusio Liquid Dentin includes 4-Methacryloxyethyl trimellitic acid (4-META), thus, Fusio Liquid Dentin has a higher flowability and also a good chemical bonding potential to hydroxyl apatite and subsequent better adaptability than other resin restorative materials. This is in agreement with Miyasaki and Okamura [22]; Fu et al. [23] and Poitevin et al. [24]. Third; the fact that the self-adhering flowable composite undergoes hygroscopic expansion, this might be contributing to the improved marginal integrity by time according to Wei et al. [20].

The results of this current study, regarding marginal discoloration, showed no statistically significant difference between both materials till 9 months evaluation period. This result is in agreement with the results of The Dental Advisor [25]; Çelik et al. [18], and Malavasi et al. [26]. However, at 12 months, statistical analysis showed that Fusio Liquid Dentin showed statistically higher prevalence of score 1 and lower prevalence of score 2 than Flow-It®. A direct strong correlation existed between both marginal integrity and marginal discoloration as they followed the same pattern. This can be easily inferred as marginal discoloration is sequelae of marginal deterioration. Therefore, any factor that affects marginal sealing would directly be reflected as marginal discoloration. Tracing the changes of marginal discoloration occurring in each material by time showed that there is a statistically significant difference in both materials. This is may be attributed to the aging of both materials and the change of their marginal integrity with time leading to increased marginal discoloration.

Meanwhile, the results of this current study, concerning surface texture, showed that; After 12 months evaluation period, all cases of Fusio Liquid Dentin and Flow-It® showed score 1 due to the absence of roughness and graininess in both materials. This behavior might be justified by the smaller volume of fillers found in these resins.

The result of this current study, regarding the secondary caries, showed scored 100% score 1 till 6 months evaluation period for both materials scored 1. At 9 months, score 1, of both materials, started to slightly decrease with the increase of score 2 but also there was no statistically significant difference between them. This might be due to the normal sequela of the time factor over the increasing marginal discrepancy between the tooth and the restoration. At 12 months, as well, there was statistically insignificant difference between both materials. Tracing the changes occurring in each material by time showed that there is a statistically insignificant difference for Fusio Liquid Dentin. This may be due to that the self-adhesive flowable composite undergoes hygroscopic expansion; this might have contributed to improved marginal adaptation by offsetting resin polymerization shrinkage. The ability of an adhesive to keep the tooth-restoration sealed is considered

predictive of the clinical outcome, especially as concerns the occurrence of post-operative sensitivity and secondary caries. This is in agreement with Van Meebreek et al. [27], and Wei et al. [20]. On the other hand, tracing the changes occurring in each material by time showed that there is a statistically significant difference for Flow-It®. The improved performance of Fusio Liquid Dentin compared to Flow-It® further emphasizes the importance of a durable interfacial bond to maintain efficiently sealed margins resisting subsequent recurrent caries.

Conclusion

Fusio Liquid Dentin showed improved clinical performance regarding the anatomic form, marginal integrity and marginal discoloration at 12 months than to Flow-It®. Flow-It® showed significant deterioration with time considering recurrent caries.

Clinical relevance

Scientific rationale for the study

There are some situations where a one-step composite restoration would be advantageous, especially when working with pediatric patient, therefore this comparative study is designed to compare between one-step adhesive systems versus the self-adhesive flowable composite restoration in primary molars.

Principal findings

Significantly improved clinical performance was observed with Fusio Liquid Dentin restoration in primary molars after 1 year follow up period.

Practical implications

Clinically speaking, for pediatric patients, with their short-attention span, restoring the teeth with the self-adhering flowable composite would be more convenient, with less effort and time-consumption than the traditional flowable composite resin.

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