RESEARCH ARTICLE

Clinical Evaluation of the Retention of Self-adhering Flowable Composite as Fissure Sealant in 6–9-year-old Children: A Randomized Controlled Trial

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Abstract

Aim: To evaluate the retention rate of self-adhering flowable composite as fissure sealant in comparison with the unfilled resin sealant on first permanent molars of 6–9-year-old children.

Materials and methods: A 2-arm, split-mouth randomized controlled trial included 100 children of age 6–9 years with completely erupted mandibular first permanent molars. A total of 200 teeth were randomly divided into two groups, group I: self-adhering flowable composite; group II: unfilled resin sealant. Sealants were placed on the mandibular first permanent molars and the children were recalled at 6, 12, and 18 months intervals to evaluate the retention rate. Chi-square test was used to analyze the data.

Results: Self-adhering flowable composite has shown a complete retention rate of 67%, 47%, and 46% at 6, 12, and 18-month intervals, respectively, whereas unfilled resin sealant has shown 41%, 8%, and 5% retention rate at 6, 12, and 18-month intervals, respectively. The difference in the complete sealant retention rates between the groups is found to be statistically highly significant at all the follow-up intervals ($p = 0.0004$, 0.0001, and 0.0001 at 6, 12, and 18-month intervals, respectively). In both groups, maximum sealant loss occurred between 6 and 12-month intervals. Retention rates were higher at 6 months intervals which were significantly reduced over 18 months intervals.

Conclusion: Self-adhering flowable composite has shown a higher retention rate compared to unfilled resin sealant at all the time intervals. The retention rate of both materials decreased with time. However, the loss of sealant was more with unfilled resin sealant.

Clinical significance: In pediatric dental practice, the elimination of a step in restorative dentistry protocol makes a big difference as time is a critical factor in obtaining children's cooperation. The use of self-adhering materials eliminates the step of bonding agent application, which simplifies the restorative protocol and makes the clinical practice effective. Therefore, these self-adhering flowable composite resin materials can be considered fissure sealants in routine clinical practice.

Keywords: Pit and fissure sealant, Randomized controlled trial, Sealant retention, Self-adhering flowable composite, Unfilled resin sealant.

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Introduction

Dental caries in children can occur soon after the eruption and continue to progress as the age increases. Preventive measures like good oral hygiene and the use of fluoride are proven to be effective in reducing smooth surface and proximal caries, but less effective on occlusal surfaces. Pits and fissures are favorable areas for bacterial colonization and since the floor of the fissure is close to the dentinoenamel junction, and underlying enamel thickness is less, caries can quickly progress into dentin.[1]

Fissure sealants were proven to be effective in preventing occlusal caries, by making the occlusal surface less retentive and more easily cleanable.[2] Conventional pit and fissure sealants are mostly low viscous unfilled resins having poor wear resistance resulting in the early loss. In order to overcome the early loss, flowable composites with fillers are frequently being used as sealants to improve the retention rate.

A novel type of resin restorative composite called self-adhering flowable composite has been introduced with the advantage of bonding to tooth structure by both chemical and micromechanical means. This resin composite consists of glycerol phosphate dimethacrylate (GPDM) adhesive monomer, prepolymerized fillers such as 1-µm barium glass filler, nano-sized colloidal silica, and nano-sized ytterbium fluoride. These prepolymerized filler particles give better polishability, mechanical properties, ease of handling, and flow, thus allowing deeper penetration into the fissures.[3] These materials are also indicated for fissure sealing.

There is a paucity of evidence regarding the clinical performance of self-adhering flowable composite as a fissure sealant. Hence, the present clinical trial was carried out with an aim to evaluate the retention rate of self-adhering flowable composite as fissure sealant in comparison with the conventional unfilled resin sealant. The research hypothesis is that there will be a difference in the retention rate of unfilled resin sealant and self-adhering flowable composite as fissure sealant.

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Materials and Methods

A 2-arm, split-mouth randomized controlled trial was approved by the Institutional review board (VDC/IEC/2017/14), and the trial was registered with the Clinical Trials Registry of India (CTRI/2018/05/014,214). The protocol is in compliance with the ethical standards of the human experimentation, Declaration of Helsinki. After obtaining the written informed consent from both the parents and school authorities, a total of 100 children aged 6–9 years were brought to the department of pediatric dentistry for the application of sealants.

Children with completely erupted caries-free right and left mandibular 1st permanent molars having deep retentive pits and fissures were included in the study. Children with a history of any systemic disease, abnormal parafunctional activity, early childhood caries, and developmental anomalies of teeth were excluded from the study.

Sample Size Calculation and Allocation

The sample size was calculated using G*Power 3.1 software based on the data from the previous study.[4] At a level of significance set at 5%, the power of the study at 98%, and for an expected critical Z-value of 1.95, it was calculated that 89 samples per group are required to perform the study. Finally, a sample size of 100 teeth was taken in each group assuming a 12% of the loss to follow-up.

A total of 400 children were screened, out of which 190 children were excluded because of not meeting the inclusion criteria. In the remaining 210 children, 100 children were randomly selected by computer-generated random number tables. A total of 200 teeth and two teeth in each child were randomly allocated into two groups, the test group (self-adhering flowable composite, n = 100 teeth) and the control group (Unfilled resin sealant, n = 100 teeth) using block randomization of block size 4.

A split mouth design was followed, wherein self-adhering flowable composite was applied on one side and unfilled resin sealant was applied on the other side. Allocation details were noted on the cards and sealed in envelopes which were then numbered. The data analyst was kept blinded to the allocation. The operator and outcome assessor could not be blinded because of the difference in the color of the materials used.

Clinical Procedure

The selected teeth were cleaned using nonfluoridated pumice powder, rinsed thoroughly with water, and air-dried for 5 seconds. The teeth were isolated with cotton rolls and a saliva ejector. Then 37% phosphoric acid gel was applied to the occlusal pits and fissures and left for 15 seconds. Teeth were then rinsed with water for 20 seconds and air-dried for 5 seconds. Then the occlusal pits and fissures were sealed with the respective sealant.

Group I: Self-adhering Flowable Composite

A thin layer (<0.5 mm) of self-adhering flowable composite (Dyad flow, Kerr, USA) was applied with moderate pressure for 15–20 seconds using a micro applicator tip and light-cured for 20 seconds with LED curing light of wavelength 420–480 nm as per the manufacturer instructions.

Group II: Unfilled Resin Sealant

Unfilled resin sealant (Clinpro, 3M ESPE, USA) was applied onto the etched pits and fissures of the occlusal surface using a micro applicator tip and light-cured for 20 seconds with LED curing light of wavelength 420–480 nm according to manufacturer instructions.

Occlusion evaluation was done for both the groups using articulating paper and the premature occlusal contacts if present were relieved using finishing bur. Evaluation of sealant retention was done at 6, 12, and 18-month intervals using Tonn and Ryge criteria[5] under a dental operating microscope at 0.6x magnification.

Statistical Analysis

The collected data were statistically analyzed using a nonparametric chi-square test in IBM SPSS Statistics for Windows, version 21 (IBM Corp., Armonk, New York, USA). For all the tests, a "p" value ≤ 0.05 was considered significant and $p \leq 0.001$ highly significant.

Results

Participation of subjects in the study is depicted in the CONSORT flow diagram (Flowchart 1). The mean age of the participants was 7.59 ± 0.98 years. The study sample consisted of 48 males and 52 females. Participants were recruited in February 2018 and followed up by August 2019. All the children were available for the follow-up without any dropouts.

On intragroup comparison, self-adhering flowable composite (group I) has shown a complete retention rate (score 0) of 67%, 47%, and 46% at 6, 12, and 18 months intervals, respectively. A score of 1 representing partial sealant loss was noticed with 29%, 44%, and 44% of the teeth at 6, 12, and 18-month intervals, respectively. Whereas a score of 2 representing complete sealant loss was noticed with 4%, 9%, and 10% of the teeth at 6, 12, and 18 months intervals, respectively (Table 1).

On pairwise comparison of the retention rate of a self-adhering flowable composite at different time intervals, the difference in the number of teeth scored 0 at 6 and 12 months, and at 6 and 18 months was found to be statistically significant (p = 0.007 and 0.004, respectively). Whereas, the difference between 12 and 18 months was not statistically significant. A similar trend was observed with score 1, but with score 2 no statistically significant difference was observed between any of the follow-up intervals (Table 2).

On intragroup comparison of unfilled resin sealant (group II), a complete retention rate (score 0) of 41%, 8%, and 5% were found at 6, 12, and 18 months intervals, respectively. A score of 1 representing partial sealant loss was noticed with 59%, 86%, and 83% of teeth at 6, 12, and 18 months, respectively. Whereas a score of 2 representing complete sealant loss was noticed with 0%, 6%, and 12% of teeth at 6, 12, and 18 months, respectively (Table 3).

On pairwise comparison of the retention rate of the unfilled resin sealant group at different time intervals, the difference in the number of teeth scored 0 at 6 and 12 months, and at 6 and 18 months was found to be statistically significant (p = 0.0001). Whereas, the difference between 12 and 18 months was not statistically significant. A similar trend was observed with scores 1 and 2 (Table 4).

On intergroup comparison of the self-adhering flowable composite and unfilled resin sealant, the differences in the complete sealant retention (score 0), as well as the partial sealant retention (score 1) between both the groups, were found to be statistically highly significant at all the follow-up intervals. Whereas the difference in the complete sealant loss (score 2) was not statistically significant (Table 5).

Flowchart 1: CONSORT flow diagram

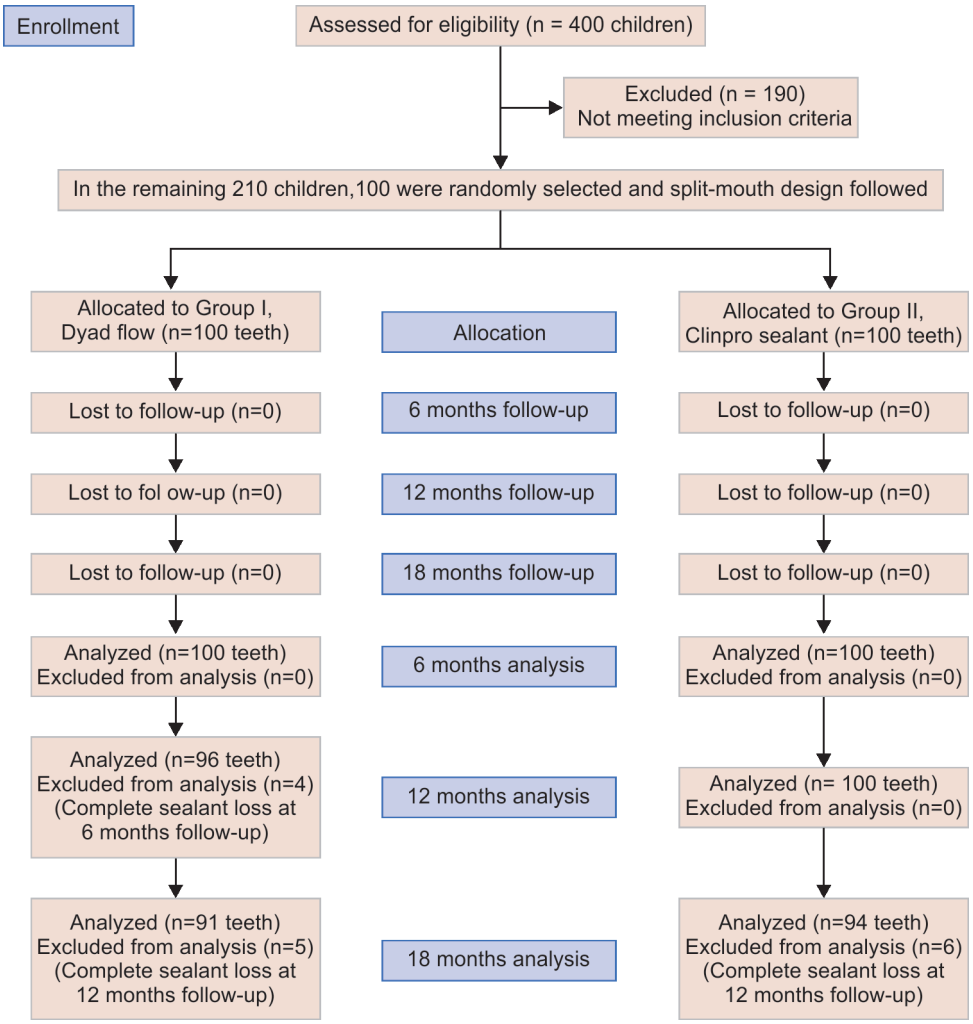


Table 1: Retention rate of self-adhering flowable composite at different time intervals

Retention scores	*6 months*	*12 months*	*18 months*	*p-value*
Score 0	67%	47%	46%	0.001, HS
Score 1	29%	44%	44%	
Score 2	4%	9%	10%	

Chi-square test; HS, highly significant

The self-adhering flowable composite showed a higher retention rate at all intervals compared to unfilled resin sealant. Retention rates were higher at 6 months intervals which were significantly reduced through 18 months intervals. Finally, at 18 months interval, only 5% of teeth with unfilled resin sealant and 46% with self-adhering flowable composite have shown complete retention. In both the groups, maximum sealant loss occurred between 6 and 12-month intervals (Table 5).

Discussion

Pit and fissure caries account for approximately 90% of all caries in the permanent posterior teeth and 44% in the primary teeth.[6] Children lack fine dexterity, which makes it difficult to clean the retentive pits and fissures. Strategies for the prevention of occlusal caries remain to be critical for the preservation of the tooth structure. Young permanent molars are at an increased risk of decay due to the complicated morphology with many grooves and fissures on the occlusal, buccal, and palatal surfaces. They also lack protection from the flushing effect of saliva, leading to more plaque accumulation.

The application of resin sealants is an effective method of preventing caries in susceptible pits and fissures on occlusal surfaces. Bravo et al. reported a lower caries incidence rate of 27% on sealed surfaces when compared to 77% in the unsealed control group.[7] Unsealed teeth require restorations approximately 50% more frequently than sealed counterparts.[8]

Flowable composites are being used for sealing fissures and in preventive resin restoration protocol because of their low viscosity. They contain a higher percentage of fillers which provides lesser porosity and better wear resistance than conventional resin-based sealants. Corona et al. have reported a complete retention rate of 100% with flowable composite

Table 2: Pairwise comparison of the retention rate of self-adhering flowable composite at different time intervals

Retention scores	*Time interval*		*% difference in the retention rate at different time intervals*	*p-value*
Score 0	6 months vs	12 months	29.8%	0.007, S
		18 months	31.3%	0.004, S
	12 months vs	18 months	2.1%	1.00, NS
Score 1	6 months vs	12 months	21.1%	0.04, S
		18 months	21.1%	0.04, S
	12 months vs	18 months	0%	0.887, NS
Score 2	6 months vs	12 months	5.2%	0.251, NS
		18 months	6.25%	0.164, NS
	12 months vs	18 months	1.09%	1.00, NS

Chi-square test; S, significant; NS, non-significant

Table 3: Retention rate of unfilled resin sealant at different time intervals

Retention scores	*6 months*	*12 months*	*18 months*	*p-value*
Score 0	41%	8%	5%	0.001, HS
Score 1	59%	86%	83%	
Score 2	0%	6%	12%	

Chi-square test; HS, highly significant

Table 4: Pairwise comparison of the retention rate of unfilled resin sealant at different time intervals

Retention scores	*Time interval*		*% difference in the retention rate at different time intervals*	*p-value*
Score 0	6 months vs	12 months	80.4%	0.0001, HS
		18 months	87.8%	0.0001, HS
	12 months vs	18 months	37.5%	0.566, NS
Score 1	6 months vs	12 months	65.8%	0.0001, HS
		18 months	58.5%	0.0003, HS
	12 months vs	18 months	21.4%	0.696, NS
Score 2	6 months vs	12 months	6%	0.029, S
		18 months	12%	0.0003, HS
	12 months vs	18 months	6.3%	0.217, NS

Chi-square test; HS, highly significant; S, significant; NS, non-significant

Table 5: Intergroup comparison of the retention rates at different time intervals

Follow-up interval	*Retention scores*	*Group I (Self-adhering flowable composite)*	*Group II (Unfilled resin sealant)*	*p-value*
6 months	Score 0	67%	41%	0.0004, HS
	Score 1	29%	59%	0.0001, HS
	Score 2	4%	0%	0.121, NS
12 months	Score 0	47%	8%	0.0001, HS
	Score 1	44%	86%	0.0001, HS
	Score 2	9%	6%	0.591, NS
18 months	Score 0	46%	5%	0.0001, HS
	Score 1	44%	83%	0.0001, HS
	Score 2	10%	12%	0.821, NS

Chi-square test; HS, highly significant; NS, non-significant

and 95% with conventional pit and fissure sealant over a 1 year follow-up period.[9] This shows that the clinical performance of flowable composite for sealing fissures was comparable to the conventional filled sealant.

A novel material, self-adhering flowable composite, claims to have both micro-mechanical as well as chemical bonds with the tooth structure. A chemical bond occurs by phosphate functional groups of GPDM binding to calcium ions of the tooth. Whereas

micromechanical bonding is by an interpenetrating network formed between the polymerized monomers and collagen fibers of dentin, thus providing better retention. Experiments have shown that they have better bond strength as well as flexural strength.[3]

Manufacturers of the self-adhering flowable composite used in the current study claim that it does not require a bonding agent. It has an adhesive monomer GPDM which acts as a coupling agent and provides tenacious bond to both enamel and dentin. It is also having an acidic phosphate group to etch the tooth structure [Technical bulletin Kerr/ 35104 (2010)]. However, the manufacturer recommends etching when it is used as a fissure sealant.

In the current study, etching was performed before the application of self-adhering flowable composite to improve the retention rate of sealant. Eliades et al. reported that the low flow of self-adhesive composites affects their fissure penetration capacity. They stated that selective enamel etching or surface preparation with air abrasion could facilitate better adaptation and less microleakage whenever used on uncut surfaces.[10]

Schuldt et al. reported that the shear bond strength of the self-adhesive fissure sealant without prior acid etching was significantly lower (4.3 MPa) compared to prior acid etching (17.1 MPa).[11] Prior etching results in the formation of a micro-retentive etching pattern on the enamel. Lower microleakage scores were recorded when self-adhering flowable composite was used with etching compared to unfilled resin sealant.[12] This might be attributed to the higher hygroscopic expansion and low polymerization shrinkage of self-adhering flowable composites.[13]

A split-mouth design was followed to address the confounding factors such as masticatory forces, oral hygiene practices, and dietary habits to ensure a similar oral environment for both control and test materials. The retention rate was evaluated based on the criteria proposed by Tonn and Ryge.[5] It is commonly used due to its simplicity, ease to record the data in a presentable form, and better communication. Sealants were evaluated under the dental operating microscope using 0.6x magnification to avoid any bias in identification.

Self-adhering flowable composite has shown a higher rate of complete retention at all the time intervals compared to unfilled resin sealant in the current study. Wadhwa et al. also reported that self-adhering flowable composite has shown a higher retention rate and good marginal integrity compared to resin-based fissure sealant.[14] The higher retention rate of self-adhering flowable composite might be facilitated by the GPDM and the high filler content.

The complete retention of unfilled resin sealant has been decreased from 6–18 months. The reason for this might be, that over a period of time unfilled resin sealants undergo abrasive wear to masticatory forces. In the present study, maximum sealant loss was observed between 6 and 12-month intervals in both groups. However, this frequency of loss was more with unfilled resin sealant due to the absence of fillers. The limitation of the study is, that it has been carried out only for a period of 18 months. Much more solid conclusions can be drawn if the study has been carried out further.

In summary, self-adhering flowable composite as fissure sealant has shown a higher retention rate compared to unfilled resin sealant. With this evidence, self-adhering flowable composites can be used for sealing fissures effectively. In pediatric dental practice, the elimination of a step in restorative dentistry protocol makes a big difference as time is a critical factor in obtaining children's co-operation. The use of self-adhering materials eliminates the step of bonding agent application, which simplifies the restorative protocol and makes the clinical practice effective. Therefore, these self-adhering flowable composite resin materials can be considered fissure sealants in routine clinical practice.

Conclusion

Self-adhering flowable composite has shown a higher percentage of complete retention compared to unfilled resin sealant at all the time intervals. Retention rates of both materials decreased with time. However, the loss of sealant was more with unfilled resin sealant. Maximum sealant loss was noticed between 6 and 12-month intervals with both the materials. At 18 months interval, only 5% of teeth with unfilled resin sealant and over 50% of teeth with self-adhering flowable composite have shown complete retention.

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