Clinical efficacy between conventional pit and fissure sealant and self -etching self- adhering flowable composite as a pit and fissure sealant using split -mouth design- A Randomized Control Trial

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KEYWORDS

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ABSTRACT

Clinical efficacy between conventional pit and fissure sealant and self-etching self-adhering flowable composite as a pit and fissure sealant using split-mouth design–A Randomized Control Trial.

Aim: To Compare the clinical efficacy of conventional pit and fissure sealant and self-etching self-bonding flowable composite at 3, 6, and 12-month intervals.

Materials & Methodology: A total of 104 bilateral mandibular first permanent molars from 52 children between 6 12 years of age were included and randomly allocated into 2 groups using a split-mouth design. Group A- conventional pit and fissure sealant.
Group B – self-etch self-adhering flowable composite as pit fissure sealant
All the sealed teeth were evaluated for clinical parameters like marginal discoloration, marginal adaptation, caries formation, retention, and surface roughness of the sealant at regular intervals of 3, 6, and 12 months using Ryge criteria. The difference in clinical parameters in both groups was analyzed using the Chi-square test.

Result: After 12 months, the clinically acceptable marginal discoloration, marginal adaptation, caries formation, retention, and surface roughness for Group A were 63.8%, 74.4%, 89.36%, 63.8%, 74.46%, and for Group B were 85.1%, 89.36%, 97.87%, 95.74%, and 93.61%, respectively. There was a statistically significant difference ($p < 0.05$) in clinical parameters such as surface roughness, retention, and marginal adaptation.

Conclusion: Self-etch self-adhering flowable composites can be used as a sealant since their improved flowability, greater retention rates, and shorter chair-side duration are beneficial in both cooperative and noncooperative children.

1. Introduction

The most prevalent dental condition is dental caries. Occlusal surfaces account for almost 50% of caries in school children, making pits and fissures extremely vulnerable.[1] Enamel allows dentin to demineralize more quickly in pits and fissures because the enamel is thinner there. It has been demonstrated that applying sealants is an efficient and dependable way to shield a child's teeth from fissure caries.[2] Recent developments in restorative dentistry have produced self-adhering flowable composites. The self-etching system does not need an "etch and rinse" phase which not only lessens clinical application time but also reduces technique sensitivity. [3] So, the objective of this study was clinical evaluation and compare the conventional pit and fissure sealant with a flowable composite with self-etching and self-adhering properties used as a pit and fissure sealant.

2. Materials and Methods

This prospective randomized clinical trial was conducted at the Department of Pedodontics and Preventive Dentistry. It was approved by the institutional ethical committee with reference number (ETHICSCOMMITEE/PEDO-02/2022).

Clinical Trials Registry - India (CTRI) registration: The protocol for this study has been registered in the CTRI, which is maintained by the National Institute of Medical Statistics of the ICMR (http://nims-icmr.in). [Identification number for the trial: [CTRI/2022/09/045179; REF/2022/07/056890].

Sample-

Before the start of the study informed consent was obtained from parents. One hundred and four bilateral mandibular permanent first molars from 52 children between the ages of 6 to 12 years were chosen for sealant application based on the following criteria for inclusion and exclusion.

The criteria for inclusion:

Children age group of 6 to 12 years who have bilateral permanent mandibular first molars that have partially or fully erupted, which have either intact, sound retentive fissures, and that are discolored or calcified but not carious. Children who are generally healthy and ready to accept treatment.

The criteria for exclusion:

Children on long-term medication that affects salivary flow; Special child, a child with systemically compromised health, Children who signed up for fluoridation or other studies; and uncooperative kids were dropped from the research.

Sample size determination

Total sample size (Split mouth study design) = 52
considering the probable attrition/ dropout rate in the study follow-up period and being a split-mouth study (52 teeth –Group A, 52 teeth –Group B), would provide 80% power at the significance level of 0.05 and an effect size of 0.65 to detect significant differences.

Treatment group allocation

The sample of 52 children was divided into 2 groups by randomization using the coin toss method of bilateral mandibular molars for group A and group B each.
Group A- with conventional sealant for pits and fissures (Helioseal –F): (52 teeth)
Group B –with (DME Constic) self-etching, self-adhering flowable composite as a sealant for pit and fissures:(52 teeth).

Group 1: With conventional pit and fissure sealant (Helioseal –F)

The water spray was used to completely rinse the mandibular first permanent molars. To dry things out, an air syringe was used. On the pits and fissures spanning one-third of the cuspal inclines, an etchant was applied, for the best outcome each tooth was thoroughly cleaned, allowed to etch for 30 seconds, and then dried using an air syringe. Using disposable micro applicator tips, the bonding agent was applied and allowed to cure for 15 seconds, then the fissures were gradually filled in with Helioseal, a fissure sealant. Following the manufacturer's recommendations, a light-curing unit was used to light-cure the sealant for 20 seconds after placement. To make sure that all teeth were adequately sealed and to prevent procedural errors, a second examiner double-checked the entire process. In order to prevent bias, the second examiner was blinded.

Group 2: With self-etch self-adhering flowable composite was used as a pit and fissure sealant (DMG Constic)

Mandibular first permanent molars were thoroughly cleaned using a water spray. An air syringe was used

for drying same as in group A and then a self-etch, self-adhering flowable composite (DMG Constic) was used as a pit and fissure sealant placed by an operator working with proper illumination and isolation. Then the material immediately light-cured for 20 seconds, following the guidelines provided by the manufacturer. The cross-checking was the same as Group A. At the start of the investigation, the sealants were only applied once. There was no attempt to replace or repair insufficient sealants during the follow-up time.

Scoring

In both groups, after three, six, and twelve months, sealed teeth were clinically assessed by another examiner. Marginal discoloration, marginal adaptation, caries formation, retention, and surface roughness were the clinical parameters that were assessed, using the Ryge Criteria as recommended by USPHS (Modified United States Public Health Science) [4] [Figure 1]. Clinical evaluations of these parameters were conducted at 3, 6, and 12-month intervals and rated as (A) alpha, (B) bravo, and (C) charlie. Clinical examinations were conducted during each recall visit without consulting the prior records.

Data statistical analysis –

The statistical analysis was conducted using SPSS Version 21 for Windows, which is a program developed by SPSS Inc. located in Chicago, IL. Descriptive quantitative data, represented, respectively, by mean and standard deviation. The Shapiro-Wilk test was used to verify the normality of the data. The level of significance, or probability of alpha error, was set at 5%, and the confidence interval was set at 95%. The study's power was set at 80%. Using the Chi-square test or Fischer exact test, Intergroup and intragroup comparisons were made concerning the study parameters.

Result-

A total of 146 teeth from 73 children were assessed for eligibility, out of which 104 mandibular first permanent molars from 52 children irrespective of gender were incorporated into the study. The total number of teeth assessed for eligibility, recruitment, randomization, allocation, and evaluation was represented in the CONSORT flow diagram [Figure 2].

Out of the 52 children, 46.2% were males and females being 53.8%, with the majority of them around 8 years old (21.2 %). The results of clinically acceptable marginal discoloration rates of conventional pit and fissure sealant (Group A) at 3 months, 6 months, and 12 months were 86.5%, 70 %, and 63.82% respectively. whereas self-etching self-adhering flowable composite (Group B), at 3 months, 6 months, and 12 months clinically acceptable marginal discoloration rates were 96.2%, 90%, and 85.1%, respectively [Table 1].

The rates for clinically acceptable marginal adaptation of conventional sealant (Group A), at 3, 6, and 12 months were 88.5%, 76%, and 74.46% respectively. For self-etching self-adhering flowable composite (Group B), the clinically acceptable marginal adaptation, the rates were 96.2%, 94%, and 89.36% respectively [Table 1].

The rates for clinically no evidence of caries formation of conventional sealant (Group A), at 3, 6, and 12 months were 98.1%, 94%, and 89.36% respectively. For self-etching self-adhering flowable composite (Group B), the clinically no evidence of caries formation, the rates were 100 %, 100%, and 97.87% respectively [Table 1].

The rates for clinically acceptable retention of conventional sealant (Group A), at 3, 6, and 12 months were 75 %, 64%, and 63.82 % respectively. For self-etching self-adhering flowable composite (Group B), the clinically acceptable retention, rates were 92.3%, 96%, and 95.74% respectively [Table 2].

The rates for clinically acceptable surface roughness of conventional sealant (Group A), at 3, 6, and 12 months were 94.2%, 76%, and 74.46% respectively. For self-etching self-adhering flowable composite

(Group B), the clinically acceptable surface roughness, the rates were 96.2%, 96%, and 93.6% respectively [Table 2].

Among the sealants, there was no statistically significant difference in Group A and B evaluated with marginal discoloration (P = 0.114) and caries formation (P = 0.241) after 12 months but there was a statistically significant difference among the sealants in Group A and B in relation with marginal adaptation, retention, and surface roughness with P value of (P = 0.045), (P<0.001), (P = 0.007) respectively.

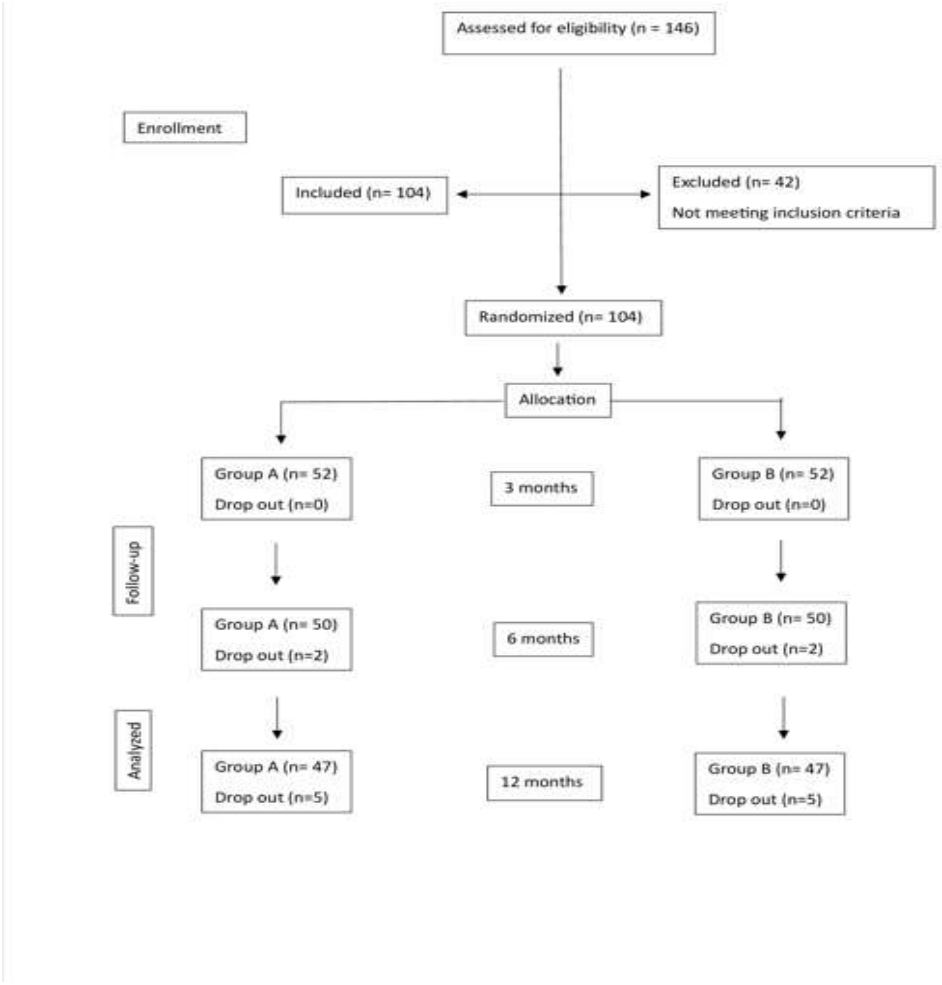
		Marginal Discoloration		Marginal Adaptation		Caries Formation	
		Group A	Group B	Group A	Group B	Group A	Group B
3 Month	alpha	86.5%	96.2%	88.5%	96.2%	98.1%	100.0%
	bravo	13.5%	3.9%	11.5%	3.9%	1.9%	0.0%
	charlie	0%	0%	0%	0%	0%	0%
6 Month	alpha	70%	90%	76%	94%	94%	100%
	bravo	30%	10%	24%	6%	6%	0%
	charlie	0%	0%	0%	0%	0%	0%
12 Month	alpha	63.8%	85.1%	74.5%	89%	89.4%	98%
	bravo	34.0%	14.9%	23.4%	11%	10.6%	2%
	charlie	1.8%	0%	2.1%	0%	0.0%	0%

Table 1: Clinical evaluation of marginal discoloration, marginal adaptation and caries formation in both groups.

Sr. no.	Criterion	Inspection method	Score rating
1.	Marginal Discoloration	Visual inspection with mirror at 45 cm	**A:** No discoloration anywhere along the margin **B:** Superficial staining (removable, usually localized) **C:** Deep staining
2.	Marginal Adaptation	Visual inspection with mirror at 45 cm	**A:** Undetectable crevice along the margin. **B:** Detectable V-shaped defect in enamel only **C:** Detectable V-shaped defect in DEJ.
3.	Caries Formation	Visual inspection with explorer, mirror	**A**: No evidence of caries **B:** Evidence of caries along the margin of the restoration
4.	Retention	Visual inspection with mirror at 45 cm	**A:** Retained **B:** Partially retained **C:** Missing
5.	Surface roughness	Visual inspected with explorer and mirror	A: Sealant is similar to polished enamel. B: Sealant surface is similar to composite material surface that contained submicron filler. C: The surface is so rough that prevent the explorer movement along surface.

		Retention		Surface Roughness	
		Group A	Group B	Group A	Group B
3 Month	alpha	75%	92.3%	94.2%	96.2%
	bravo	25%	7.7%	5.8%	3.8%
	charlie	0%	0%	0%	0%
6 Month	alpha	64%	96%	76%	96%
	bravo	36%	4%	24%	4%
	charlie	0%	0%	0%	0%
12 Month	alpha	63.8%	95.7%	74.5%	93.6%
	bravo	27.7%	4.3%	19.2%	6.4%
	charlie	8.5%	0%	6.4%	0%

Table 2: Clinical evaluation of retention and surface roughness in both groups.



3. Discussion

This study employed a split-mouth study design since it is one of the extremely uncommon dental study designs that is self-controlled in dentistry. This study design allows for the comparison of two treatment modalities in the same patient over the same length of time in a comparable oral environment.[5]

Conventional sealants require a high level of technical sensitivity, and patient cooperation, area contamination, and operator skill and knowledge are all necessary for them to be clinically effective.

Moisture contamination during sealant placement reduces adhesion quality at the sealant enamel interface, affecting the microorganism's ability to continue resisting microleakage.[6]

Not only does the self-etching system save time during clinical application, but it also lessens technique sensitivity by eliminating the need for an "etch and rinse" phase. Self-adhering flowable composites have advantages when restoring a child's tooth, as the outcome of the most recent developments in restorative dentistry. These composites have greater retention rates, shorter chair-side times, and improved flowability.[7]

When a restoration exhibits marginal discoloration, it may be a sign that the adjacent tooth structure is losing its marginal integrity. When there is a marginal breakdown, a restoration's margins become discolored and the surface becomes uneven and rough, which happens due to poor marginal adaptation. The marginal adaptation plays an important role in sealant success because bacteria under the sealant may be able to initiate and/or progress caries. To prevent microleakage the ability of the sealant to adequately seal the pits and fissures is very important. Sealant fracture and marginal fissure formation eventually contribute to microleakage, which ultimately leads to marginal discoloration, secondary caries formation, and failure of the restoration. [8]

By the end of 12th month, in our study conventional pit and fissure sealant showed poor marginal adaptation that is unacceptable (23.40%) when compared to the self-etch, self-adhering flowable composite used as sealant which showed (10.64 %), which leads to marginal discoloration at the end of one-year, conventional pit and fissure sealant revealed more marginal discoloration (34.04%) when compared to the self-etching self-adhesive flowable composite used as sealant (14.90%). Microleakage in operative dentistry not only leads to pulpal injuries, secondary caries, and postoperative tooth hypersensitivity but also causes poor marginal adaptation and eventually marginal discoloration.

However, some studies reported reduction in microleakage was noted when using self-adhering flowable composite compared to conventional pit and fissure sealant material. [8,9,10] as self-adhesives or self-etching sealants, which do not need rinsing and thus, decrease the risk of contamination which leads to microleakage. Ganesh and Shobha believe that the primary factor affecting the performance and durability of a sealant is its marginal adaptation to the enamel, which provides a good seal and minimizes microleakage, and marginal discoloration.[11]

A pit and fissure sealant's ability to prevent caries primarily determines its success.
The sealant remains for a longer time helps to reduce the incidence of caries beneath it. The ability of fissure sealants to prevent caries has been demonstrated by several studies and is related to sealant retention. [12,13,14] The retention rate of a pit and fissure sealant is directly related to the micromechanical bond between the sealant and enamel.[15] This study evaluated retention was better in self-etching self-adhering flowable composite (95.74%) used as a pit and fissure sealant than conventional pit and fissure sealant (63.82%) at the end of one year. The possible reason for this, fillers increase the viscosity and the viscosity of the sealant materials affected the penetration into the microporosities created by acid etching which is a prerequisite for sealant placement, that was the reason for less retention in conventional pit and fissure sealant, while flowable composite is nanofilled that contain filler size so small to adhere tooth structure perfectly. [13,14]

Although in our study, there was poor retention in conventional sealant which is the source of microleakage and caries formation both groups show unnoticeable caries formation at the end of 12 months. Conventional pit and fissure sealant shows less caries formation (10.64%) and self-etch self-adhering flowable composite shows very little caries formation (2.13%) at the end of 12th month.

Subramaniam P and co-workers reported caries formation was very low in sealed teeth based on Simonsen's criteria, at regular intervals for 12 months. The possible reason can be even where the material appears

clinically to have been partially lost, there may remain small particles of material attached to the enamel of the occlusal fissures, even in case of loss of sealant, the rest of the sealant often remains in the grooves and served in a protective role.[16]

Surface roughness of sealant leads to more plaque accumulation and failure of sealant.
At the end of 12 th month, the conventional pit and fissure sealant showed more surface roughness (19.14%) when compared to self-etching self-adherable flowable composite as a pit and fissure sealants (6.39%). The possible reason for this, self-adhering flowable composite contains pre-polymerized filler particles that have better polishability, mechanical properties, ease of handling and flow, thus allowing deeper penetration into the fissures and more retention which leads to less surface roughness. [17] Another possible reason for surface roughness is the viscosity of the sealant which influences the penetration of sealants, higher viscosity of the sealant also lessens the penetration of sealants and may cause poorer adaptation and incomplete penetration to the bottom of the pit and fissures resulting in decreased retention and surface roughness, with low viscosity flowable composite, there is a greater potential of the sealant to flow, spread more rapidly over the surface and penetrate.[18]

Galo R and co-workers reported that surface roughness was more in conventional pit and fissure sealant (Helioseal) than flowable composite (Tetric N). The reason for this, that the conventional sealant showed, a smaller bond between the inorganic filler particles and the organic matrix and has larger filler particles size when compared to resin composite (flowable composite) in which filler particles contain smaller sized particles and bond more effectively with the organic phase susceptible to higher wear volume and surface roughness. [19]

4. Conclusion

Self-etching, self-adhesive flowable composites are useful for sealing pits and fissures, particularly in children who have a high caries risk, excessive salivation, special needs, young children, and uncooperative behavior. These materials' adherence to teeth, ease of application, and shortened operating time all support their placement. The advantages of this self-etching self-adhesive flowable composite as a pit and fissure sealant make it suitable for clinical settings and outreach programs.

Declaration of patient consent-
The authors confirm that they have all necessary patient consent forms in their control. The patient(s) has(have) provided consent in the form for the clinical information about them to be published in the journal. The patients are aware that although every attempt will be made to cover up their identity and that their names and initials will not be published, anonymity cannot be ensured.

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Conflicts of interest -There are no conflicts of interest.

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