ORIGINAL RESEARCH

# Comparison and Clinical Evaluation of Two Pit and Fissure Sealants on Permanent Mandibular First Molars: An *In Vivo* Study

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## Abstract

**Aim:** The aim of the study was to compare and evaluate the clinical efficacy of a microfilled pit and fissure sealant and a nanofilled pit and fissure sealant at 3, 6, and 12 months of interval.

**Materials and methods:** Samples consisting of 55 healthy 8- to 12-year-old children with deep pits and fissures in mandibular first permanent molars were selected for the study. It was a split mouth design and randomized clinical trial. A total of 110 mandibular first molars were divided into two groups of 55 each: group I Fissurit FX sealant and group II Grandioseal nanofilled fissure sealant. The sealed teeth were clinically evaluated at 3, 6, and 12 months of interval to assess marginal adaptation, sealant retention, fissure caries development, roughness of sealant surface, and change of color around the sealant.

**Results:** The results showed that both Fissurit FX and Grandioseal pit and fissure sealants were effective in preventing dental caries. Marginal adaptation was significantly better with Fissurit FX when compared to Grandioseal pit and fissure sealant. There was no difference in sealant retention between the two groups. The surface roughness of Fissurit FX was high when compared to that of Grandioseal. Statistical analysis was done using the Chi-squared test for intra-group comparison and Fisher's exact test for inter-group comparison. Results were considered statistically significant if $p \leq 0.05$.

**Conclusion:** Fissurit FX and Grandioseal pit and fissure sealants provided similar caries preventive effects and there was no difference in retention of sealants over a period of 1 year. However, surface roughness was better with Grandioseal fissure sealants.

**Clinical significance:** This study is significant because there is limited evidence about the efficacy of nanofilled pit and fissure sealants *in vivo*. It will also provide dental practitioners an insight into the clinical efficacy of nanofilled pits and fissure sealant when compared to micro-filled sealant enabling them to make the right choice for the betterment of their dental practice.

**Keywords:** Microfilled, Nanofilled, Pit and fissure sealant, Retention.

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## Introduction

Dental caries is the most common dental disease. In the past decades the decline in the prevalence of dental caries in most of the industrialized countries were noted. Caries as a widespread disease with multifactorial nature majorly affects the population of the world.[1,2] In Canada during the late 1990s, the cost of treating dental disorders was more than treating cancer, digestive disorders, respiratory diseases, and mental disorders.[3] The cost involved in treating the disease in terms of manpower and the hours spend is enormous.[4]

Dental disorders are an expensive burden to the population, especially with regard to the patient's poor oral health and systemic illness. In dealing with disease, "prevention is better than cure." There is a changing trend toward prevention as compared to the treatment-oriented dentistry in the past. Over the years, caries prevention has made several advancements. In preventing caries on smooth surfaces of the teeth, systemic and topical fluoride has been found to be extremely effective, but least on the occlusal surfaces.[5]

For many years it has been recognized that the occlusal pit and fissures of posterior teeth are highly susceptible to caries.[6] Due to the occlusal morphology of young permanent teeth with deep narrow pits and fissures, there is inadequate cleaning in these vulnerable areas leading to development of initial caries.[7] In a complete tooth surface, the occlusal aspect present only 12.5% and 85% of dental caries is seen on the occlusal surface itself.[8] Even in countries with well-organized preventive programs, occlusal and buccolingual aspects constitute 90% of caries lesions.[9,10] Numerous techniques and methods have been advocated for prevention of pit and fissure caries of occlusal surface.[6]

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**Conflict of interest:** None

Sealant placement is considered an effective treatment modality for prevention of caries in the occlusal pits and fissures.[11] Fissure sealants are materials that are placed in the occlusal surfaces of caries prone teeth that bond micromechanically with the tooth surface thus forming a protective layer and limiting the availability of nutrients for caries causing bacteria.[12]

The efficiency of these pit and fissure sealants mainly depends on the penetration depth of the sealants and microleakage at the sealant tooth interface. The application of nanomaterials and functional fillers in dentistry has evolved due to the development of nanotechnology. There is a wide range of microfilled pit and fissure sealants and recently introduced nanofilled pit and fissure sealants available in the market, but there are very few *in vivo* studies pertaining to clinical success of nanofilled pit and fissure sealants especially in parameters like marginal adaptation and surface roughness which mainly determines the clinical efficiency of a pit and fissure sealant. As there is inadequate evidence about the efficiency of nanofilled pit and fissure sealants *in vivo*, the aim of the present study is to evaluate and compare the clinical efficiency of microfilled pit and fissure sealant (Fissurit FX) with nanofilled pit and fissure sealant (Grandioseal) on permanent mandibular first molars at 3, 6, and 12 months of interval using the Cvar and Ryge criteria (Table 1).

## Materials and Methods

Materials used in the study (Fig. 1)

- Voco acid etchant—37% phosphoric acid liquid (Voco, Germany)
- Voco Fissurit FX™ pit and fissure sealant (Voco, Germany): it is a microfilled pit and fissure sealant with 55% by weight filler particles and it is considered a highly filled composite sealant. The filler comprises 92% by weight glass-ceramics and 8% by weight glass ionomer with a maximum particle size of 10 µm. Fissurit FX contains 1.0% fluoride, which is equivalent to adding 2% by weight sodium fluoride. The high filler content guarantees excellent abrasion resistance. The high marginal integrity due to the low polymerization shrinkage and excellent bond strength of Fissurit FX on tooth structure ensure that the tooth surfaces are sealed long term. Fissurit FX is a single-component material, and its low viscosity ensures that the material flows deep into the fissure, filling and sealing it to ensure marginal integrity.
- Voco Grandioseal™ pit and fissure sealant (Voco, Germany): it is the 1st nano-fissure sealant that enables long-term sealing. Grandioseal is a highly flowable, light curing fissure sealant material with filler content of more than 70% w/w, which makes it the most abrasion resistant fissure sealant. The viscosity of Grandioseal guarantees that the material penetrates deep fissures without forming bubbles. Grandioseal's pronounced thixotropic property permits sealing material to become more flowable when agitated with cannula, probe, or fine brush, and thus it reaches the depth of fissures providing long-lasting and marginally tight fissure sealing.

## Methodology

A total of 500 children were screened and assessed for eligibility to be included in the study. Patients who are medically compromised, children with developmental defects/hypoplastic molars or caries affected teeth, teeth with restorations or partially retained sealant restorations, and partially erupted teeth were excluded.

Written informed consent was obtained from parents of all children participating in the study. Ethical clearance to conduct the study was obtained from the Institutional Review Board of Sri Rajiv Gandhi College of Dental Sciences and Hospital, Bengaluru. A total

**Table 1:** Criteria for clinical evaluation of sealant

| | *Rating* | *Description* | *3 months* | *6 months* | *12 months* |
|---|---|---|---|---|---|
| Marginal | | | | | |
| A | Alpha | No visible evidence of a crevice along the margin of the sealant that the explorer could penetrate | | | |
| B | Bravo | Visible evidence of a crevice along the margin of the sealant that the explorer could penetrate | | | |
| Sealant retention | | | | | |
| A | Alpha | Complete retention | | | |
| B | Bravo | Partial retention | | | |
| C | Charlie | No retention | | | |
| Fissure caries | | | | | |
| A | Alpha | Sound fissures | | | |
| B | Bravo | Fissures with caries | | | |
| Surface roughness | | | | | |
| A | Alpha | The sealant is similar to polished enamel | | | |
| B | Bravo | The sealant surface is similar to composite material surface contained submicron filler | | | |
| C | Charlie | The surface is so rough that prevents the explorer movement along the surface | | | |
| Change of color around the sealants | | | | | |
| A | Alpha | No discoloration anywhere on the margin around the sealant | | | |
| B | Bravo | Visible partial discoloration on the margin around sealant | | | |
| C | Charlie | Visible discoloration on the margin around all sealant | | | |


**Fig. 1:** Pit and fissure sealants

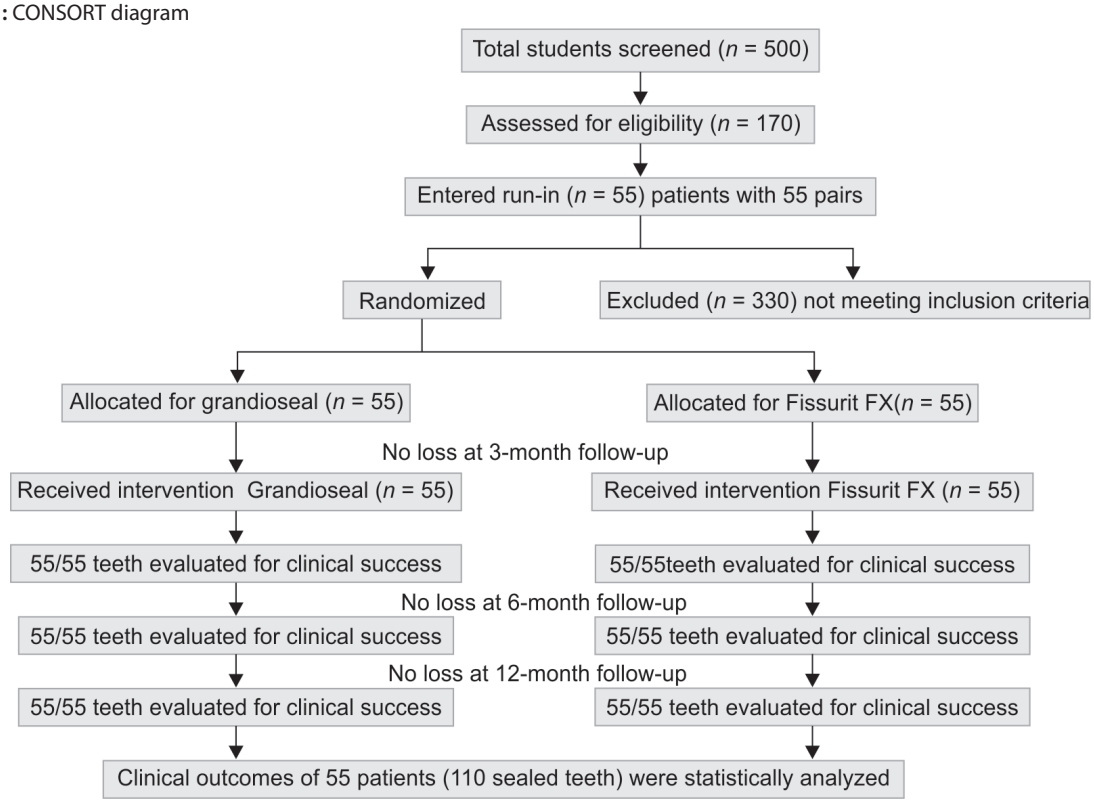
of 110 bilateral mandibular first permanent molars (Fig. 2A) which are fully erupted, with deep pits and fissures, were selected in the split mouth designed study after examination (CONSORT diagram). They were chosen from 55 healthy, 8–12-year-old children with a mean age of 9.84 (SD ± 1.34) years, who attended the Department of Paedodontics and Preventive Dentistry, Sri Rajiv Gandhi College of Dental Sciences and Hospital, Bengaluru (Flowchart 1).

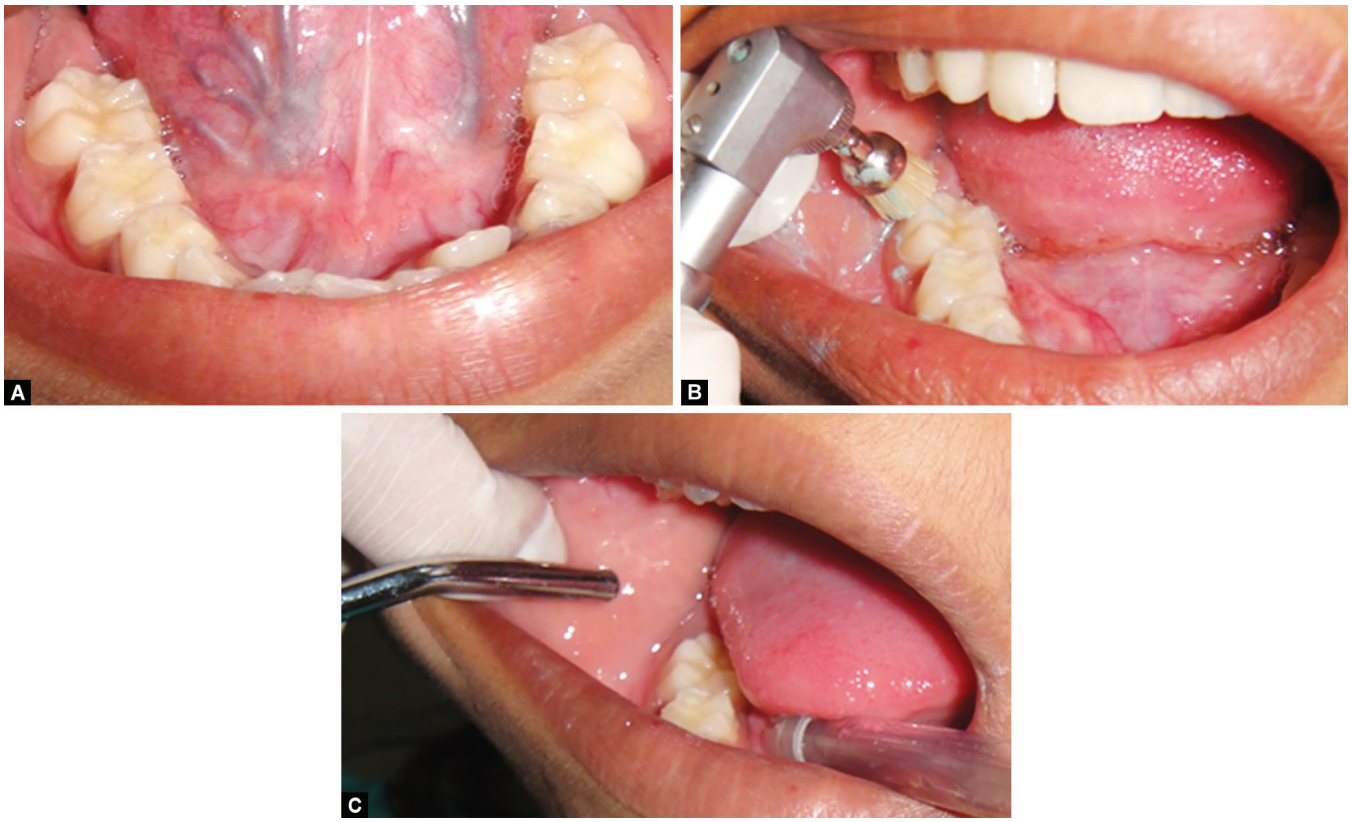
Using a coin toss method, each side was randomly assigned to either group I: GrandioSeal Nanofilled fissure sealant (Voco, Germany) or group II: Fissurit FX fissure sealant (Voco, Germany). All the sealants were placed in a dental clinic setting by a single operator working with proper illumination. Isolation was carried out using a rubber dam with adequate suctioning to remove saliva from the operating field. A slurry of pumice and a rotating pointed bristle brush at slow speed were used to clean the teeth (Fig. 2B) and then rinsed thoroughly to make sure the removal of prophylactic paste and debris from the fissures of mandibular permanent first molars. The occlusal aspects of these bilateral permanent mandibular 1st molars were completely rinsed with water spray and air syringe was used for drying (Fig. 2C). Etchant containing 37% phosphoric acid was applied to the pits and fissures extending 1/3rd of the cuspal inclines (Fig. 3A). Each tooth was etched for 30 seconds, washed thoroughly, and dried using an oil-free air water syringe as per the manufacturer's instructions. Dull frosty white appearance of the enamel confirmed etching (Fig. 3B). The occlusal surface was again cleaned, re-etched, and dried in case of any surface contamination.

Fissure sealant was gradually applied along the fissures (Fig. 4A). For removal of air bubbles and proper sealant penetration into the pits and fissure a probe was used. The sealant was immediately light cured after their placement by a 20 second exposure using light curing unit as per the manufacturer's instructions (Fig. 4B). The sealed teeth were checked for high points with articulating paper. Excess material was removed using a small round finishing bur at a low speed. Figure 4C shows the final appearance of sealed tooth after pit and fissure sealant application. Patients were informed not to eat or consume any fluids or eat for 30 minutes after the sealant placement. The entire procedure was cross-checked by another examiner to avoid any procedural errors and to ensure adequate sealing of teeth. The second examiner was also unaware of the different groups to avoid any bias. The sealants were applied only once at the beginning of the study. Repair or replacement of insufficient sealants were not attempted during the follow-up period.

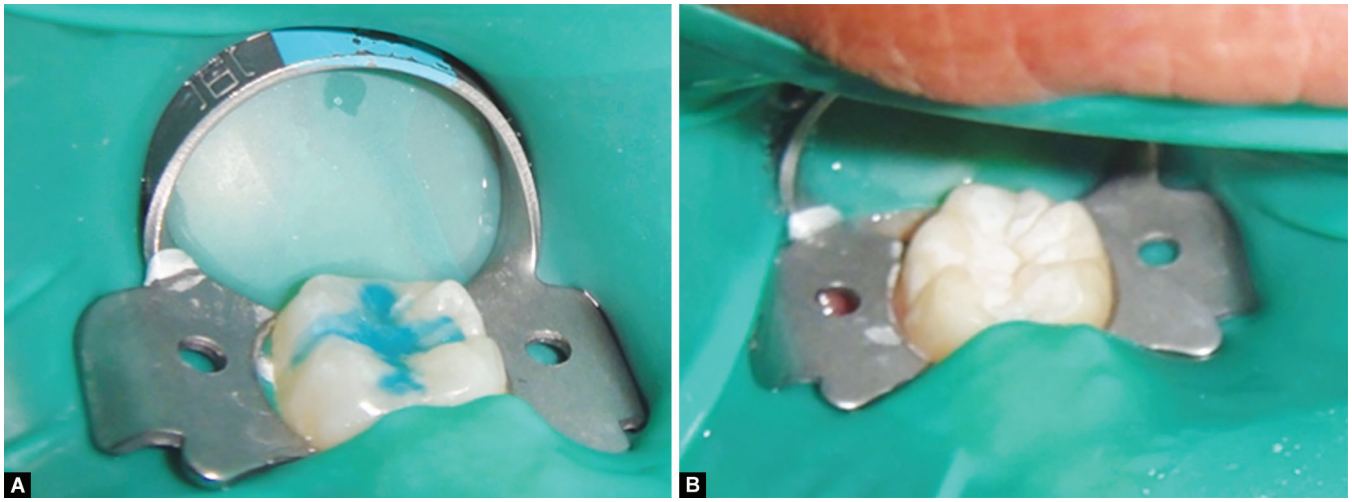
Using Cvar and Ryge criteria as recommended by the American Dental Association (ADA) (Table 1) the sealed teeth were evaluated clinically by two examiners at 3, 6, and 12 months of interval. The clinical

**Flowchart 1:** CONSORT diagram






**Figs 2A to C:** (A) Bilaterally fully erupted permanent mandibular first molar; (B) Oral prophylaxis; (C) Washing and rinsing



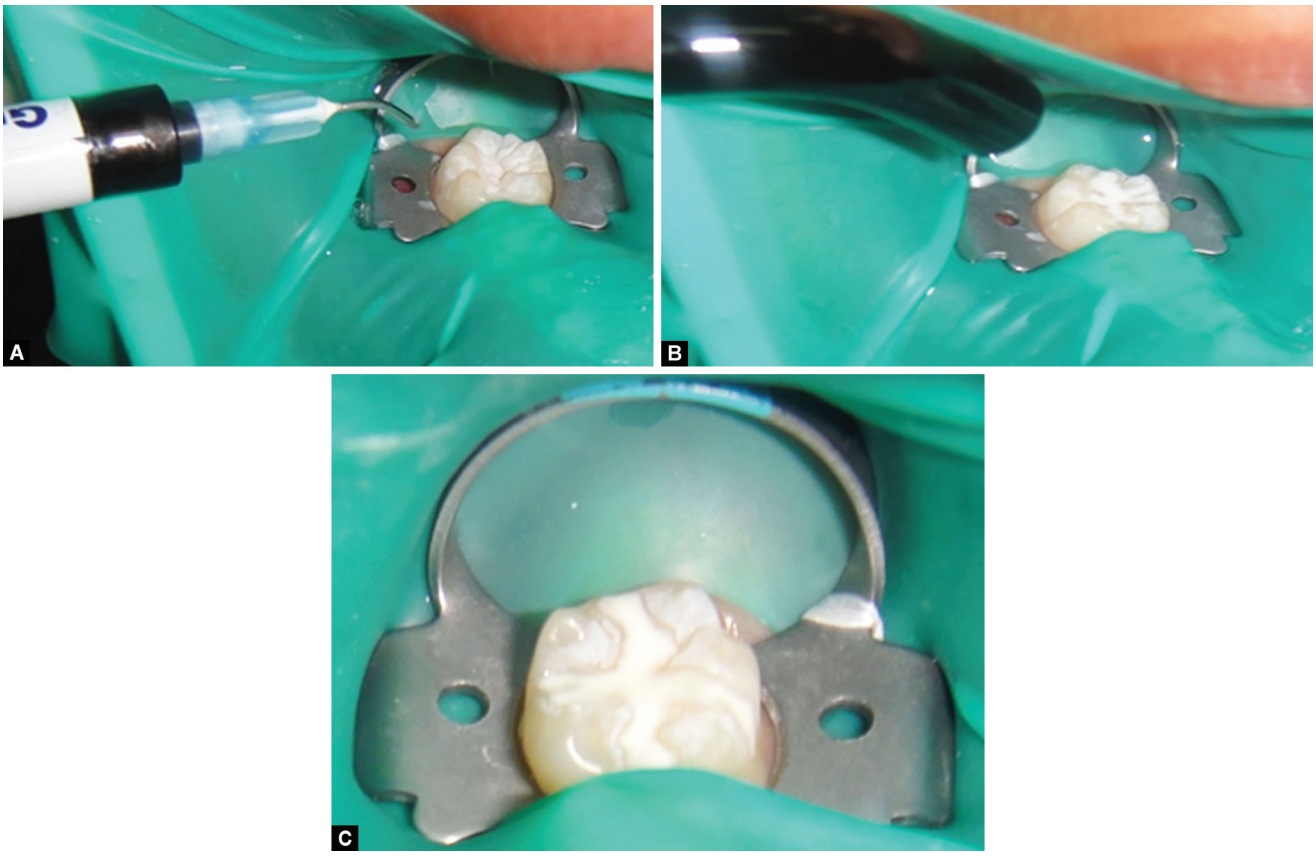

**Figs 3A and B:** (A) Acid etching; (B) Frosty white appearance after etching

parameters evaluated were change of color around the sealant, sealant retention, marginal adaptation, roughness of sealant surface, and fissure caries development. Marginal adaptation and fissure caries were clinically evaluated under the rating as Alpha (A) and Bravo (B). Sealant retention, surface roughness, and change of color around the sealant were evaluated with the ratings Alpha (A), Bravo (B), and Charlie (C) (Table 1). During each recall visit clinical examinations were done without referring to the previous records. The intra- and interexaminer reliabilities were calculated using Cohen's Kappa statistic.

Collected data were tabulated and imported into Statistical Package for Social Sciences version 10.0.5 software (SPSS Inc, Chicago, IL, USA) for statistical analysis using the Chi-squared test for intragroup comparison and Fisher's exact test for intergroup comparison. Results were considered statistically significant if $p \leq 0.05$.

## Results

The efficiency of nanofilled and microfilled pit and fissure sealants were clinically evaluated and compared in 55 school children of 8–12 years age group. Periodic evaluations were done at 3, 6, and 12 months to evaluate change of color around the sealant, sealant




**Figs 4A to C:** (A) Application of fissure sealant along the pits and fissures; (B) Light curing of pit and fissure sealant; (C) Pit and fissure sealant after light curing

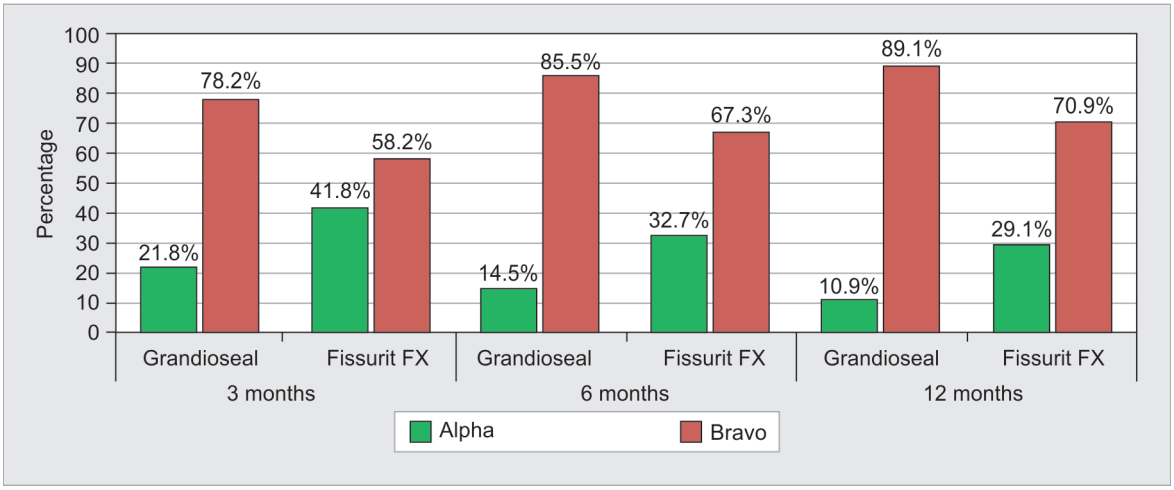



**Fig. 5:** Distribution of marginal adaptation at different time intervals in two different groups of sealants

retention, marginal adaptation, roughness of sealant surface, and fissure caries development. On comparison of the marginal adaptation between the different groups it was observed that the microfilled (Fissurit FX) group was better with less evidence of crevice along the margin when compared to nanofilled (Grandioseal) group (Fig. 5) and the differences observed among the two groups at 3, 6, and 12 months were statistically significant with $p$ value $< 0.05$ (Table 2). On evaluating the retention of sealant, it was observed that complete retention reduced from 3 months to 12 months in both the groups. At 12 months, total loss of sealant was observed to be higher in microfilled group (12.7%) when compared to nanofilled group (7.3%) (Fig. 6). The difference was not statistically significant.

Evaluation of fissures at 3 months revealed that one tooth from the microfilled Fissurit FX group showed sign of fissure caries. There were no other changes in the other groups and hence no significant difference. On comparison of the surface roughness, it was observed that at 3 months, 6 months, and 12 months the surface of the sealant was more similar to polished enamel in the nanofilled Grandioseal group than the microfilled Fissurit FX group and the difference was statistically significant (Table 3). It was observed that there was no

**Table 2:** Comparison of marginal adaptation at different time intervals between the two different groups of pit and fissure sealants

| | | *Marginal adaptation* | | | | |
|---|---|---|---|---|---|---|
| *Visit* | *Material* | *Alpha* | *Bravo* | *Total* | $\chi^2$ *value* | *p value* |
| 3 months | Grandioseal | 12 | 43 | 55 | 5.070 | 0.024 |
| | | 21.8% | 78.2% | 100.0% | | |
| | Fissurit FX | 23 | 32 | 55 | | |
| | | 41.8% | 58.2% | 100.0% | | |
| 6 months | Grandioseal | 8 | 47 | 55 | 5.037 | 0.025 |
| | | 14.5% | 85.5% | 100.0% | | |
| | Fissurit FX | 18 | 37 | 55 | | |
| | | 32.7% | 67.3% | 100.0% | | |
| 12 months | Grandioseal | 6 | 49 | 55 | 5.682 | 0.017 |
| | | 10.9% | 89.1% | 100.0% | | |
| | Fissurit FX | 16 | 39 | 55 | | |
| | | 29.1% | 70.9% | 100.0% | | |

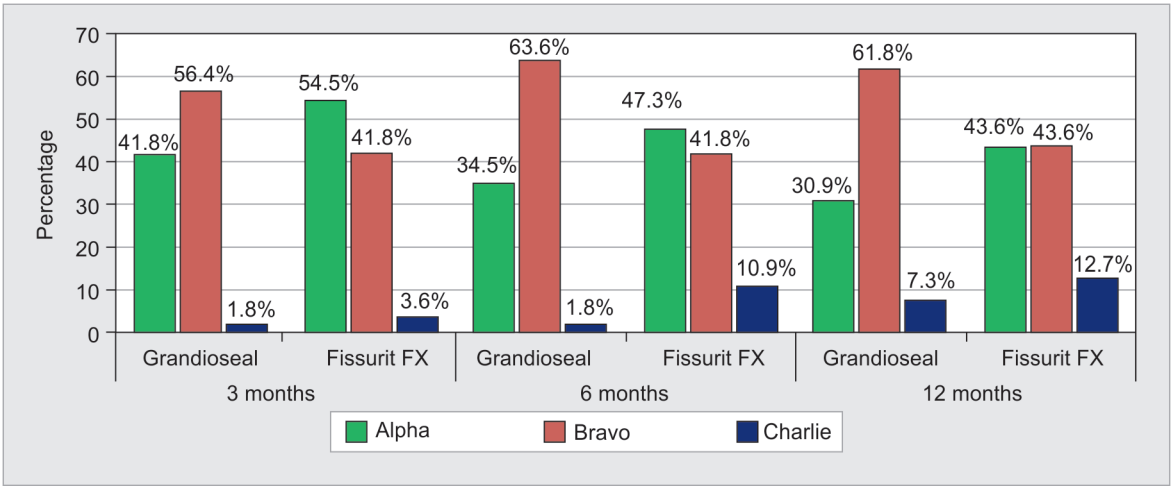



**Fig. 6:** Distribution of sealant retention at different time intervals between the two different groups of pit and fissure sealants

change in color at different time intervals between two different groups of pit and fissure sealants.

## Discussion

Among children of developed countries in Europe and USA, there was a decline in the prevalence of dental caries. As per the data on dental caries, there was a significant increase (84%) in pit and fissure caries lesions of the total new caries experience.[13] The choices for the management of deep pit and fissures are confined to the application of fluoride containing varnishes/a fissure sealant. Fissure sealants have played a vital role in preventing and controlling dental caries in the past few decades. Besides fluorides, sealant materials contain no active ingredient for the prevention of dental caries. Their preventive role is provided by adhering to the enamel and by physically sealing the pit and fissures thereby isolating them from the oral environment.[14] Nanotechnology has improved the size of filler particles used in pit and fissure sealants.

Due to the inadequate evidence about the efficiency of nanofilled pit and fissure sealants *in vivo*, the present study compared and evaluated the clinical efficacy of nanofilled pit and fissure sealant (Grandioseal) with microfilled pit and fissure sealant (Fissurit FX) on permanent mandibular first molars. Grandioseal, a nanofilled pit and fissure sealant, was evaluated in few clinical studies in comparison to other sealant materials.[15–17] In the present study, clinical evaluation of the sealant was done using the Cvar and Ryge criteria similar to the study conducted by Mladenovic et al.[18] The parameters evaluated were sealant retention, marginal adaptation, fissure caries, surface roughness and change of color around the sealants.

Evaluation of marginal adaptation at 3 months, 6 months, and 12 months revealed the presence of crevice along the margin of the sealant through which an explorer was able to penetrate in both Grandioseal and Fissurit FX group. There was an increase in the visible evidence of crevice from 3 months to 12 months and it was more in the Grandioseal group. Studies conducted by Futatsuki et al.,[19] Gungor et al.[20] and Yilmaz et al.[21] also evaluated marginal integrity with various sealant materials and concluded that loss of marginal adaptation was seen with various sealant and flowable composite materials. This high rate of marginal disintegration can be due to the presence of unetched areas after cleaning and acid etching. In our study, the performance of Grandioseal group was less than the Fissurit FX group ($p$ value $< 0.05$), which could be due to the increased viscosity and increased amount of filler

**Table 3:** Comparison of surface roughness at different time intervals between the two different groups of pit and fissure sealants

| | | *Surface roughness* | | | | |
|---|---|---|---|---|---|---|
| *Visit* | *Material* | *Alpha* | *Bravo* | *Total* | $\chi^2$ *value* | *p value* |
| 3 months | Grandioseal | 45 | 8 | 53 | 14.806 | <0.001 |
| | | 84.9% | 15.1 % | 100.0% | | |
| | Fissurit FX | 27 | 27 | 54 | | |
| | | 50.0% | 50.0% | 100.0% | | |
| 6 months | Grandioseal | 42 | 7 | 49 | 17.557 | <0.001 |
| | | 85.7% | 14.3% | 100.0% | | |
| | Fissurit FX | 25 | 29 | 54 | | |
| | | 46.3% | 53.7% | 100.0% | | |
| 12 months | Grandioseal | 40 | 8 | 48 | 15.622 | <0.001 |
| | | 83.3% | 16.7% | 100.0% | | |
| | Fissurit FX | 23 | 28 | 51 | | |
| | | 45.1% | 54.9% | 100.0% | | |

particles. The findings were similar to the study conducted by Gungor et al.[20] and Irinoda et al.[22] which concluded that sealants that had high viscosity did not penetrate sufficiently to ensure good marginal seal.

Sealant retention was evaluated and compared at 3, 6, and 12 months as complete retention, partial retention, and no retention. In the Grandioseal group, the sealant retention was less than the Fissurit FX group at 3 months. However, there were no significant statistical data. The result was similar to the study reported by Autio Gold which reported that unfilled sealant material performed better than medium filled flowable restorative material.[23] In our study Grandioseal, which was used, had 70% filler content whereas Fissurit FX had only 55% filler content. It was observed that at 6 months 63.6% had partial sealant retention in Grandioseal group whereas only 41.8% had sealant retention in Fissurit FX group. The difference was statistically significant ($p$ value $< 0.05$). Yildiz et al. also reported a significant reduction in the retention rate for a conventional fissure sealant in comparison to fluoride containing fissure sealant.[24]

Similarly, at 12 months Grandioseal group 30.9% had complete retention, 61.8% had partial retention, and 7.3% had total loss of sealants. In Fissurit FX group, 43.6% had complete retention, 43.6% had partial retention, and 12.7% had total loss of sealants. The difference was not statistically significant. Dhar and Chen also reported that 80% of teeth sealed with resin based sealants showed total loss of sealants.[25] However, in a similar study conducted by Beresescu and Pacurar,[15] results showed that the retention was 91.52% at 1 year and 83.2% at 2 years for Fissurit FX material whereas for Grandioseal material the retention was 90.36% at 1 year and 82.32% at 2 years. The sealant retention rate reported was much higher compared to the present study. The difference could be due to the presence of unetched areas after routine cleaning and acid etching which could be a major cause of early sealant loss.[19] Similarly Yilmaz et al.[21] also evaluated fissure sealants and concluded that there was difference in retention among different resin matrices. Sealant retention may be affected by the organic structure of the material and surface conditioning.

Teeth sealed with fissure sealants in both the groups were evaluated at 3, 6, and 12 months for evidence of caries in the pits and fissures. It was observed that at 3 months, one tooth showed evidence of fissure caries in the Fissurit FX group and no further changes at 6 and 12 months. There was no evidence of caries in the Grandioseal group at 3, 6, and 12 months. Studies done by various investigators like Sardana et al.,[4] Yazici et al.,[17] Yilmaz et al.,[21] Irinoda et al.[22] have assessed the caries preventive effect of flowable composite materials and resin sealants. All of them have highlighted the caries preventive effect of pit and fissure sealants. Yildiz et al.[24] reported a caries incidence of 5.7% in fissure sealant treated group. In comparison, the present study had 1.9% incidence of fissure caries, which was not statistically significant.

Surface roughness is another parameter, which was assessed in the present study as rough surfaces lead of food lodgment and biofilm formation. In Grandioseal group the sealant surface was similar to polished enamel in 84.9%, 85.7%, and 83.3% at 3, 6, and 12 months whereas it was 50%, 46.3%, and 45.1%, respectively, in Fissurit FX group. Grandioseal sealant was better than the Fissurit FX and the difference was statistically significant. This can be explained by the difference in composition between the two different sealant materials.[15] Grandioseal is a nanohybrid composite with 70% filler particles whereas Fissurit FX is a microhybrid composite with 55% filler particles. So the surface of sealant in Grandioseal group was similar to polished enamel.

On evaluation of the color, there was no change in the color of sealants in both the groups at 3, 6, and 12 months. Even though there was crevice formation along the margin of the sealant that is visibly evident in both the groups, there were no changes in color over a period of 12 months.

## Conclusion

In the present clinical study, the data determined that multiple factors (marginal adaptation, retention, caries, surface roughness, and color) affect the success of sealant material. From the present study we can reach the following inferences:

- Both Grandioseal (nanofilled) and Fissurit FX (microfilled) pit and fissure sealants were efficacious in dental caries prevention in permanent first molars.
- Marginal adaptation was significantly better with Fissurit FX pit and fissure sealant when compared to Grandioseal as the filler content was less with Fissurit FX sealant.
- Sealant retention showed no difference between the two groups of sealant material studied.

- Surface roughness of Fissurit FX sealant was more when compared to Grandioseal, which leads to retention of micro-organisms.

The present study suggests that Grandioseal (nanofilled) and Fissurit FX (microfilled) sealant provide similar caries preventive effects and there was no difference in retention of the sealants over a period of 1 year.

## Clinical Significance

In this study we highlight how the application of nanomaterials and functional fillers in dentistry has evolved due to the development of nanotechnology. This study is significant because there is inadequate evidence about the efficiency of nanofilled pit and fissure sealants *in vivo*. It will also provide dental practitioners an insight into the clinical efficiency of nanofilled pit and fissure sealant when compared to microfilled sealant enabling them to make the right choice for the betterment of their dental practice.

## Acknowledgment

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