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Clinical evaluation of bioactive resin based pits & fissures sealants versus conventional resin based pits & fissures sealants in caries susceptible fissures in permanent molars: A randomized controlled

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Short title: Clinical Evaluation of Bioactive Resin Fissures Sealants versus Conventional Resin Fissures Sealants in Susceptible Fissures in Permanent Molars

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Abstract---Objectives: This study was carried out to evaluate the clinical performance of bioactive versus fluoride releasing resin-based pits and fissure sealants in molars in high caries risk patients

regarding retention and caries incidence. Material and methods: A total of 38 participants received 38 pits and fissure sealants randomly using either; BioCoat™ by Premier® (Plymouth Meeting, Pennsylvania, USA) or Clinpro™ by 3M™ ESPE (St. Paul, Minnesota, USA), all materials were utilized obeying manufacturers' instructions. Sealants were evaluated using Simonsen's criteria for retention and using VistaProof fluorescent camera for caries detection around sealants or in presealed fissures by two blinded assessors after 6- and 12- months. Chi square test was used to associate between the type of sealants and their clinical performance. Relative risk was used to assess the clinical significance. Survival rate was analysed using Kaplan-meier and Log-rank test Results: For retention, comparison between both sealants have shown no statistically significant difference throughout different follow up periods; baseline, 6 and 12 months ($P = 1.0000$, $P = 0.9277$ and $P = 0.3185$) respectively. There was 16% less risk for failure in retention for Biocoat sealant when compared to Clinpro sealant after 12 months ($RR = 0.8366$ (95% CI 0.4306 to 1.6252; $P = 0.5985$). Regarding caries incidence, there was no statistically significant difference between two groups within follow up periods; baseline and 6 months ($P = 1.0000$ and $P = 0.1396$) respectively, while after 12 months there was statistically significant difference ($P = 0.0303$). There was 89.5% less risk for caries incidence for Biocoat sealant when compared to Clinpro sealant after 12 months ($RR = 0.1049$ (95% CI 0.006097 to 1.8062; $P = 0.1205$) Conclusions: Both Clinpro™ and BioCoat™ showed similar successful clinical performance after 6-months-time interval while BioCoat™ had superior caries inhibition after 12 months.

Keywords---Bioactive, Caries, Fluoride, Retention, Sealant.

Introduction

Dental caries is considered one of the most prevalent diseases characterized by localized destruction of dental hard tissues by bacterial acids from biofilm bacteria due to fermentation of dietary carbohydrates over time.¹ The paradigm shift in understanding the reversible nature of caries process mandates prevention and earliest detection.² It is now well-known that caries occurs when cariogenic species has an ecological advantage leading to disease initiation. An entire range of bacteria, not just mutans streptococci or lactobacilli, can contribute to the caries process at different stages.³ Many strategies are validated to prevent caries, as community water fluoridation, professional fluoride application, mechanical and chemotherapeutic management of biofilm and dietary intake modification.⁴

Pits and fissures are defective fossae and grooves that act as a niche for bacteria and debris resulting in stagnation and caries initiation.⁵ Morphological complexity of pits and fissures makes enamel less prone to receive the same level of caries protection from fluoride as smooth surface enamel.⁶ Pits and fissure sealants are inserted to deep retentive pits and fissures of teeth in children and adults as a

modality to prevent dental caries in patients at risk of developing caries. They act as a barrier that deprives fissure microorganisms from metabolic exchange with oral environment.⁷

According to the ADA and AAPD guidelines for pits and fissure sealants use, when it is evident that the tooth, or the patient, is at risk of caries, sealants should be applied to seal pits and fissures of primary teeth in children and permanent teeth in adolescents and adults.⁸ Molars, particularly second molars, were shown to be the most vulnerable teeth to occlusal caries among college students in a study by Stahl and Katz⁹. In this study, they found a 9.9% occlusal caries incidence rate in years 11–14 after first molars erupted, assuming first molars erupted in the sixth year of life. If the second molars emerged in the twelfth year of life, the same group showed a 14% occlusal caries incidence rate in the years 5–8 after tooth eruption. Hence, it has been proposed that after erupting into the mouth, posterior teeth may be vulnerable to caries for many years, while the use of fissure sealants in adults was widely neglected.¹⁰

The clinical effectiveness of a sealant depends upon its ability to be retained to the tooth occlusal surface for the longest time interval.¹¹ If a sealant is partially or completely lost, a stagnation area may be present favoring caries initiation and progression. Thus, the need for a material with caries inhibition and remineralizing potential was raised.¹² Recently, experimental formulations of bioactive pits and fissure sealants are evolving, yet there are very few commercial products available for clinical practice. The caries-preventive effect of bioactive sealants is based on antimicrobial activity and remineralization of dental hard tissues in response to pH fluctuations.¹³ A new attempt is SmartCap™ Technology by Premier® which is utilized in a bioactive resinous sealant. The sealant matrix contains rechargeable semi-porous resin microcapsules filled with ionic fluoride, calcium, and phosphate solutions.¹⁴

This study was intended to evaluate the clinical performance of recently introduced bioactive pits and fissure sealant compared to fluoride releasing resin pits and fissure sealant in susceptible fissures in patient with high risk of developing caries in terms of sealant retention and caries inhibition potential. The null hypothesis is that both pits and fissure sealants will have the same retention rates and caries inhibition effect after one year.

Materials and Methods:

Study settings and study design:

This randomized controlled clinical study was conducted in the Faculty of Dentistry, Cairo University, Egypt. The protocol of this study was registered in www.clinicaltrials.gov database, with unique identification number NCT03779893. All the procedures in the current trial involving human participants were conducted following the Helsinki Declaration of 1975, as revised in 2013, in accordance with the ethical standards of the Research Ethics Committee (CREC) of Faculty of Dentistry, Cairo University with approval number 19-1-16 and reported according to consort guidelines. The study design of the

present trial is double blinded, parallel, two armed with superiority framework and 1:1 allocation ratio.

Sample size calculation:

According to the results of Ratnadya *et al*¹⁵ in which the probability of complete sealant retention for fluoride releasing resin-based fissure sealant was (0.594), probability of partial sealant retention was (0.151) and the probability of complete sealant loss was (0.226). The estimated probability of bioactive fissure sealant was (0.85) for complete sealant retention, (0.047) for partial sealant retention and (0.103) for complete sealant loss. By adopting an alpha (α) level of 0.05 (5%), power=80%. The predicted sample size (n) was a total of 35. Sample size was increased by (10%) to account for possible dropouts during follow-up intervals to be total of (38) cases i.e. (19) for each group. Sample size calculation was performed using G*Power 3.1.9.2 (Universität Kiel, Germany).

Eligibility criteria:

Patients aged between 18- 30 years old with caries susceptible fissures in second and third molars and good oral hygiene were included. They should not show any signs of caries by visual tactile examination method and VistaProof fluorescent camera. Teeth should have intact contact with opposing teeth, no previous restorations in other surfaces, no previous sealing procedures and scoring 0.9 or less when tested with VistaProof. Patients with poor oral hygiene, lack of compliance, parafunctional habits, temporomandibular joint disorders, periodontal disease, disabilities, systemic disease, severe medical conditions, allergic history concerning methacrylates, rampant caries, heavy smoking and xerostomia were excluded. Teeth with frank carious pits and fissures, developmental anomalies, periapical pathology or signs of pulpal pathology, hypersensitivity, possible prosthodontic restoration, heavy occlusion and occlusal contacts, history of bruxism, severe periodontal affection and scoring > 0.9 when tested with VistaProof were excluded.

Recruitment:

Patients were recruited from Clinic of Conservative Dentistry Department at Faculty of Dentistry, Cairo University, one month before intervention. Baseline caries detection was confirmed by Vista Proof. Teeth were assessed three times, and the average values were recorded in the examination charts in addition to saving images produced by the software. Out of 80 patients examined, 38 patients fulfilled the eligibility criteria and informed consent was signed by the eligible patients before enrolment in the current study. Figure 1 shows the flow of participants in the current trial.

Randomization, Sequence generation and blinding:

Simple randomization was done by generating numbers from 1:38 into 2 columns using Random Sequence Generator, Randomness and Integrity Services Ltd (www.randomization.com). Operator chose between numbers from opaque sealed envelopes, the patients and assessors were blinded to the material assignment

while the operator was not blinded due to the difference in fissure sealants translucencies and colour.

Interventions:

Caries susceptible fissures were sealed either using BioCoat®, bioactive resin pit & fissure sealant (Premier®, Plymouth Meeting, Pennsylvania, USA) or Clinpro™ pit & fissure Sealant (3M™ ESPE, St. Paul, Minnesota, USA). BioCoat is a light cured, filled, bioactive resin pit and fissure sealant introducing SmartCap® Technology. The sealant matrix contains semi-porous rechargeable resin microcapsules filled with ionic fluoride, calcium, and phosphate solutions with high diffusivity in and out of the sealant. It was used in conjunction with Premier® Etch. Clinpro™ is a light-cured, unfilled, resin-based pit and fissure sealant that releases fluoride. It was used in conjunction with Scotchbond™ Universal Etchant. Materials' description and manufacturers are described in table 1.

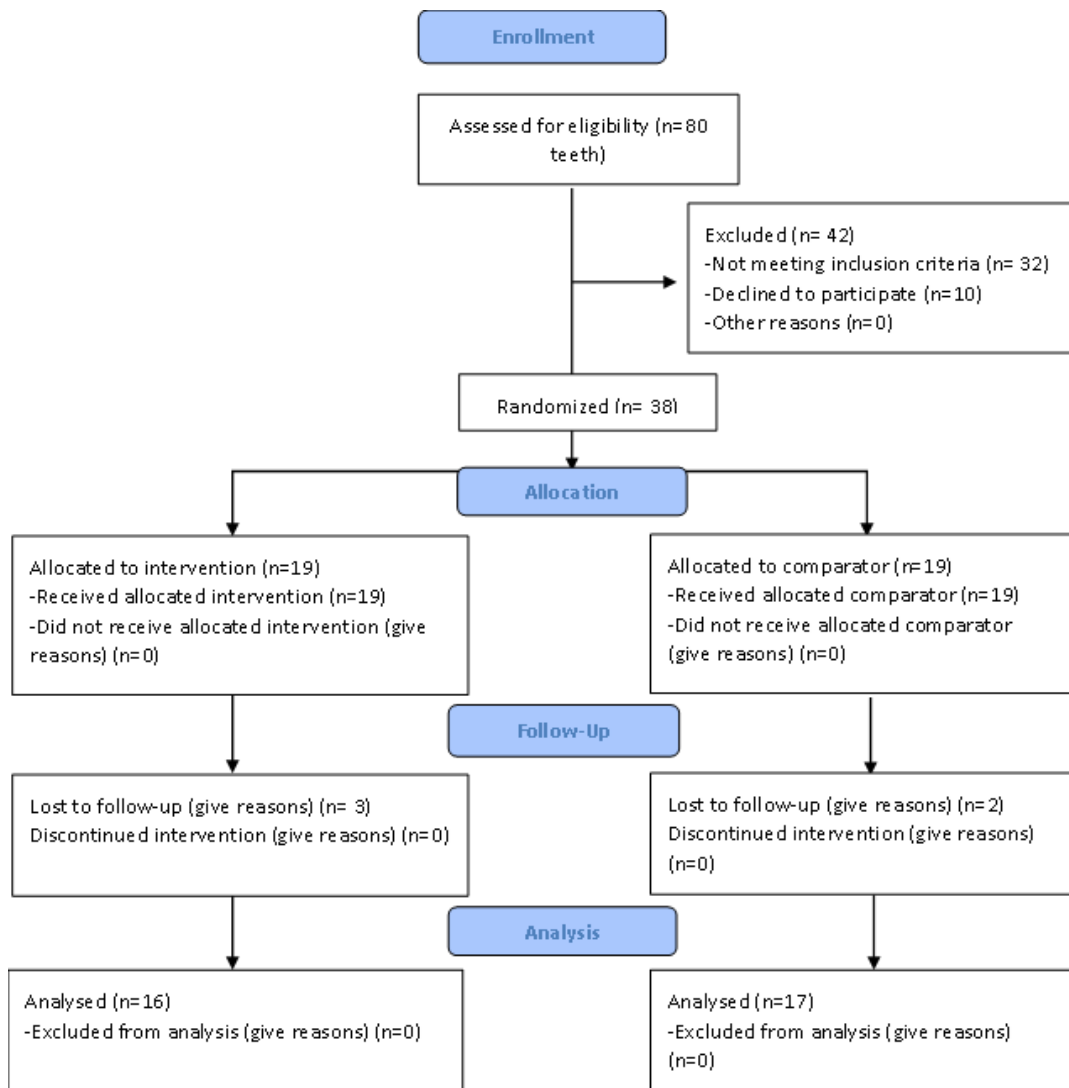


Figure (1): CONSORT Flow Diagram

| Material | Description | Manufacturer |
|--------------------------------------|--|---|
| BioCoat® | Bioactive resin-based pit & fissure sealant | Premier® , Plymouth Meeting, Pennsylvania, USA |
| Premier® Etch | 37% phosphoric acid | |
| Clinpro™ | Fluoride releasing resin-based pit & fissure sealant | 3M™ ESPE , St. Paul, Minnesota, USA |
| Scotchbond™ Universal Etchant | 32 % phosphoric acid. | |

Table (1): Materials' description and manufacturers

Clinical procedures:

Pre-sealing preparation procedure:

Scaling was performed for each patient, followed by prophylaxis with fluoride free medium polishing paste (Proxylt®, Ivoclar Vivadent, Schaan, Liechtenstein) and a rotating brush to remove any plaque or food particles from the fissures.¹⁶ The occlusal surfaces of all teeth were then carefully flushed with water, to eliminate any traces of pumice. Teeth to be sealed were isolated using rubber dam after suitable selection of size of clamps (KSK dentech, Tokoyo, Japan) and rubber dam sheets (Sanctuary Dental Dam, Perak, Malaysia)

Enamel etching

A generous amount of etchant was applied to pits and fissures using dispensing syringe tip, extending beyond fissures to be sealed. Etching was done for 20 seconds in accordance with manufacturers' instruction for both pits and fissure sealants. Rinsing of etchant was done thoroughly with oil free air/water spray for 20 seconds. Drying of etched enamel was done with oil and water free air from triple-way syringe of the dental unit. Dry etched surfaces were inspected and should appear as a matte, chalky white, if not, enamel surfaces were re-etched for another 20 seconds.¹⁷

Sealant application

Both sealants were applied according to manufacturers' instructions. Sealants were placed into pre-etched pits and fissures using the dispensing tip, with no

sealant flowing beyond the etched surfaces. After insertion, the sealant was mixed with the dispensing tip to minimize any voids and improve the sealant's wetting to the enamel surface, followed by light curing for 20 seconds using Elipar™ LED Curing Light (3M ESPE, St Paul, MN, USA), with the light's tip as near as possible to the sealant, without touching the sealant according to manufacturer's instructions. Afterwards, the sealant was inspected for the presence of deficient areas or air inclusions. If present, and the surface was not yet contaminated, addition of sealant to defective areas was done and light cured for another 20 seconds. Sealants were then rubbed with a cotton pellet to remove oxygen inhibited layer. Finishing was done using yellow coded diamond finishing stones (MANI, Tochigi, Japan). Checking of occlusion was done using 40 nm articulating paper AccuFilm® II (Parkell®, Edgewood, NY, USA) and then premature contacts were eliminated. Polishing of the sealant was then carried out using composite polishing kit (KENDA®, Vaduz, Liechtenstein).

Outcome assessment:

Pit-and-fissure sealants were evaluated for retention and presence of new carious lesions after six- and 12-months by two calibrated blinded assessors. If assessors differ in score, they discussed, if did not agree a third assessor was counselled. Evaluation of retention was performed according to Simonsen's criteria¹⁸, teeth were air-dried and observed under standardized illumination and chair position

Regarding caries occurrence, teeth were examined using VistaProof light fluorescent camera (Dürr Dental, Bietigheim-Bissingen, Germany). For each tooth a spacer was used in order to standardize the distance between the camera tip and the tooth. Outcome assessment criteria were described in table 2.

| Criterion | Score | Characteristics |
|--------------------|-------|---|
| Retention analysis | A | Completely retained: If some fissures were uncovered at periphery due to wear, but no ledges were visible. |
| | B | Partially retained: following either wear or material loss, part of pit/fissure was exposed |
| | C | Missing: No trace of sealant is detectable. |
| Caries incidence | A | No Caries around pits and fissure sealant (<0.9) |
| | C | Caries around pits and fissures sealant (>0.9) |

Table (2): Outcome assessment

Statistical analysis:

Data was analyzed using Medcalc software, version 19 for windows (MedCalc Software Ltd, Ostend, Belgium). Categorical data was described as frequency and percentage, comparisons between categorical variables was performed using the

chi square test. Relative risk was used to assess the clinical significance. Survival rate was analysed using Kaplan-meier and Log-rank test. A P value less than or equal to 0.05 was considered statistically significant and all tests were two tailed.

Results:

Demographic data:

This study was conducted on 38 participants that were randomly allocated to the intervention and the comparator arms. After 12 months 33 participants completed the follow-up with 86.8% retention rate. 16 males (42.1%) and 22 females (57.9%) participated in the current clinical trial, there was no statistically significant difference between both groups regarding gender ($P=1.0000$). Mean age of the participants in the current trial was 26.3 ± 5.9 years, there was no statistically significant difference between both groups regarding age ($P=0.770$). According to teeth distribution in the dental arches, there were 19 maxillary molars and 19 mandibular molars, there was no statistically significant difference between both groups regarding teeth distribution ($P=0.3368$)

Retention:

Intergroup comparison between both materials have shown no statistically significant difference within different follow up periods; baseline, 6 and 12 months ($P = 1.0000$, $P = 0.9277$ and $P = 0.3185$) respectively. Intragroup comparison within Biocoat sealant have shown statistically significant difference between different follow-up periods ($P = 0.0032$). Intragroup comparison within Clinpro sealant have shown statistically significant difference between different follow-up periods ($P = 0.0029$). (Table 3) There was 16% less risk for failure of Biocoat sealant when compared to Clinpro sealant regarding retention after 12 months ($RR= 0.8366(95\% \text{ CI } 0.4306 \text{ to } 1.6252; P = 0.5985)$).

Caries incidence around sealants:

Intergroup comparison between both materials have shown no statistically significant difference within different follow up periods; baseline and 6 months ($P = 1.0000$ and $P = 0.1396$) respectively, while after 12 months there was statistically significant difference ($P = 0.0303$). Intragroup comparison within Biocoat sealant have shown no statistically significant difference between different follow-up periods ($P = 0.9460$). Intragroup comparison within Clinpro sealant have shown statistically significant difference between different follow-up periods ($P = 0.0212$). (Table 3) There was 89.5% less risk for failure of Biocoat sealant when compared to Clinpro sealant regarding caries incidence around sealants after 12 months ($RR= 0.1049(95\% \text{ CI } 0.006097 \text{ to } 1.8062; P = 0.1205)$).

Survival analysis:

Overall survival of fissure sealants was assessed after 12 months, 8 restorations in Bioacoat sealant group and 9 restorations in Clinpro sealant group failed after 12 months either due to loss of retention or caries incidence around sealants. Kaplan-meier analysis was used to obtain survival curves, comparison of survival

curves was performed using Logrank test, there was no statistically significant difference between both sealants ($P = 0.7084$). (Figure 2)

Table (3): Frequency and percentage for retention and caries around sealants scores for the intergroup comparison between materials within each follow-up periods

* denotes statistically significant difference, NS denotes no statistically significant difference

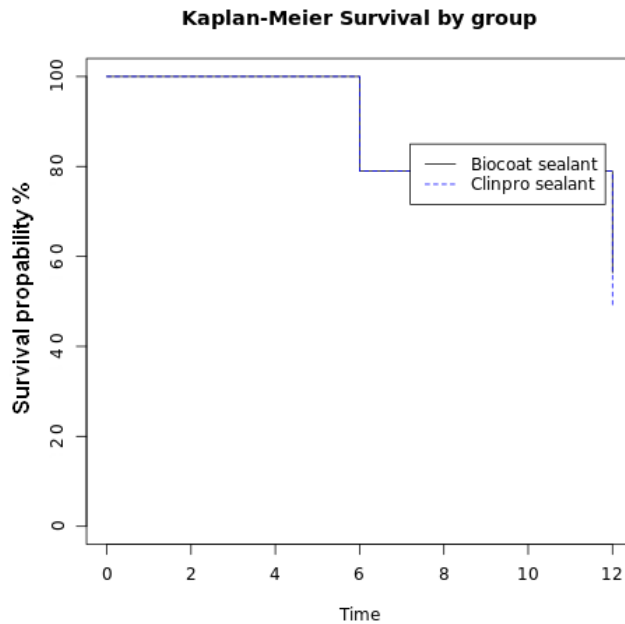


Figure 2: Survival analysis of both sealants after 12 months

Discussion

The aim of the current study was to evaluate the clinical performance bioactive resin-based pits and fissure sealant compared to resin-based fluoride releasing pits and fissure sealant when placed in caries free susceptible fissures in adults.

Regarding retention; comparison between both sealants have shown no statistically significant difference within different follow up periods baseline, 6 and 12 months. Thus, the null hypothesis cannot be rejected. Despite the different composition and filler presence in Biocoat, both sealants performed equally in terms of retention; this could be because both of them are resin based and due to adopting the same application protocol. Putting into consideration that Clinpro is an unfilled resin sealant while Biocoat is a filled resin sealant, these results were in accordance with Reddy *et al.* and Baheti *et al.* were they compared the retention rates of filled versus unfilled RBPFS sealants; and found no statistically significant differences after 12 months follow up.^{19, 20} Bagheri *et al.*, in a systematic study with meta-analysis, found no significant difference in

retention rate or caries incidence between filled and unfilled sealants. This highlights that the final decision should be made individually for each patient based on the type of fissure, patient's age, and habits.²¹ It was also found that, intragroup comparison within Biocoat sealant and within Clinpro sealant have shown statistically significant difference between different follow-up periods. This emphasizes the importance of follow-ups and maintenance for applied sealants as recommended by ADA. It is advised to reapply sealants every 6 months when needed.²²

Prior to sealant application, acid etchant was done without any mechanical preparations. Acid etching of occlusal surfaces is a prerequisite before resin-based sealant placement.²³ The time of etching has insignificant effect on sealant retention. A Meta-analysis was carried to evaluate the effect of different acid etching time on retention of fissure sealant to permanent and deciduous molars. There was no significant difference in fissure sealants' retention with different etching times.²⁴

In terms of caries incidence, comparison between both materials have shown no statistically significant difference at baseline and after 6 months, while after 12 months there was statistically significant difference. Biocoat showed 89.5% less risk for caries initiation around sealed fissures or at presealed fissures after 12 months when compared to Clinpro sealant. This may be attributed to the novel technology utilized by Premier® named SmartCap™ technology. SmartCap™ semi-porous resin microcapsules possess polyurethane-based shell acting as a semi-permeable membrane. The microcapsules are filled with ionic solutions of fluoride, calcium and phosphate, which are claimed to diffuse in and out of the sealant, from high concentration gradient to lower concentration gradient, ensuring greater ion uptake by the adjacent tooth structure. The ions supersaturation state inhibits demineralization during acid attacks, strengthens enamel and seals margins against microleakage.¹⁴ The microcapsule's shell offers two-way permeability, hence, permits the influx of aqueous solution containing calcium, phosphate and fluoride solutions, to enter the microcapsules to replenish the amount present within them.²⁵

In fluoride resin-based materials, the source of fluoride would come from the glass filler particles, resulting in a slow diffusive release. The pattern of fluoride release from Clinpro sealant tends to be high initially and declines afterwards till reaching a plateau.^{26,27} Moreover, the remineralizing potential of fluoride needed to arrest initial lesions is dependent on the availability of Ca and Ph ions in the saliva or biofilm.²⁸

VistaProof was used to detect caries incidence around sealant or in presealed fissures, if the sealant was partially or completely lost. VistaProof offers an intraoral fluorescence camera (Dürr Dental, Bietigheim-Bissingen, Germany), it emits blue light with a wavelength of 405 nm. In case of presence of cariogenic bacteria, this wavelength causes porphyrins to alter the spectrum of incident light to red light, in contrast to sound enamel, which emits green light. The camera records the fluorescence, which is processed using DBSWIN software (Dürr Dental, Bietigheim-Bissingen, Germany). Numerical information and color

mapping of the lesion are generated according to its depth.²⁹ Pits and fissures showing score more than 0.9 were considered carious.³⁰

In the current study neither gender, age or teeth distribution affected the retention rates or caries incidence significantly. This is in accordance with a study conducted by Papageorgiou *et al.*³¹, in which they concluded that the performance of pit and fissure sealants does not seem to be negatively affected by mouth side, jaw or tooth type. The success rate of Clinpro and Biocoat regarding retention after 12 months were 43.75%, 52.94 respectively. Concerning anticariogenic effect, the success rate to inhibit caries incidence was 75% and 100% for Clinpro and Biocoat respectively. This is in accordance with a study by Al-Jobair *et al.*³² where the retention rates of Clinpro was 42.9% and caries inhibition rate was 88.6% after 12 months.

To our knowledge, this current study was pioneer in evaluating bioactive resin sealant as an ion-releasing pits and fissure sealant clinically. Limitations were relatively small sample size and considerably short follow-up period. More well-designed RCTs with larger sample size and longer follow up intervals are recommended to confirm the current results

Conclusion

Under the conditions and the limitations of this study, the following conclusions were evident:

1. Retention rate of bioactive resin-based fissure sealant was similar to fluoride releasing resin-based fissure sealant when used to seal retentive, caries-free fissures in high caries risk patients after 12 months.
2. After 12 months, bioactive resin-based fissure sealant had superior caries inhibition potential when compared to fluoride releasing resin-based fissure sealant.

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Ethical policy and Institutional Review board statement: The Research Ethics Committee (CREC) of Faculty of Dentistry, Cairo University with approval number 19-1-16.

Patient declaration of consent statement:

We have obtained all appropriate patient consent forms. The patients understand that their names and initials will not be published, and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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