

Original Article

Sealants revisited: An efficacy battle between the two major types of sealants – A randomized controlled clinical trial

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ABSTRACT

Background: The aim of this study is comparing the retention and caries preventive effect of the glass-ionomer fissure sealant and resin-based fissure sealant.

Materials and Methods: A randomized-controlled split-mouth study was conducted to compare the retention and the caries preventive effect of light-cured resin-based sealant (3M ESPE) and glass ionomer sealant (Fuji VII). The sealants were applied to either the right or the left lower mandibular molars (7-9 yrs of age) in 120 school children, based on the randomization process. They were recalled for assessment of clinical retention at intervals of 3, 6, and 12 months. The caries-preventive effect between the two materials was tested statistically by the McNemar's test for matched pairs, and the differences observed with regard to the retention of the materials was tested by Chi-square tests. The level of significance was set to be at $P < 0.05$.

Results: At the end of 12th month, sealant retention is found to be higher in the resin-based sealant group compared to the glass ionomer group. In the glass ionomer sealants placed, 101 (91%) were caries-free and 10 (9%) had caries. In the resin-based sealant, 105 (94.60%) had sound teeth and 6 (5.4%) had dental caries ($P = 0.34$).

Conclusion: The glass ionomer sealant was less retentive when compared to resin sealants. The caries incidence between the glass ionomer and resin-based sealants was not statistically significant.

Key Words: Dental caries, fissure sealant, glass ionomer, incidence, sealants

Received: August 2017
Accepted: April 2018

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INTRODUCTION

Pit and fissure sealants are now considered as a comprehensive tool for caries prevention, both for an individual and for community.^[1] These fissure sealants are placed on the occlusal surfaces of sound teeth, noncavitated carious lesions, and incipient carious lesions to arrest caries progression by creating a physical barrier between the microorganisms and the deep pit and fissure system.^[2,3]

There are two types of sealant materials that are in use today, namely the resin-based sealants and the glass ionomer-based sealants. The resin-based sealants were traditionally considered to be effective as a caries preventive tool, due to higher retention rates and a proven cariostatic effect.^[2,4-7]

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How to cite this article: Prathibha B, Reddy PP, Anjum MS, Monica M, Praveen BH. Sealants revisited: An efficacy battle between the two major types of sealants – A randomized controlled clinical trial. Dent Res J 2019;16:36-41.

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Having said this, the resin-based sealants do have a cumbersome placement technique as they demand a near-perfect moisture control during application. Glass ionomer sealants negate the drawbacks of resin based sealants because of their hydrophilic properties. These sealants also do release fluoride over a period of time, thus configuring an anticariogenic property.^[8-14]

Studies in the past have stated that the resin-based sealants have been more effective in caries reduction in comparison to the glass ionomer sealants over a period of 24–44 months in the permanent teeth of children.^[6,9,10,15]

Recent reviews have evaluated the effectiveness of resin-based sealants and glass ionomer sealants with regard to caries prevention and have found an inconsistent effect with the quality of the evidence being graded as very low.^[16-19]

The caries preventive effects of Fuji type III glass ionomer sealants have been studied in several clinical trials, whereas there has not been sufficient data regarding Fuji type VII sealants. Therefore, this study was conceived to further substantiate the data regarding the retention and caries preventive effects of Fuji Type VII versus the light-cured resin-based sealant among a section of schoolgoing children at a district in southern part of India.

MATERIALS AND METHODS

This clinical trial was conducted in the municipality jurisdiction of Vikarabad, a small town located in the newly formed Indian state of Telangana, India and ethical clearance had been obtained by Sri Sai College of Dental surgery and is registered with the United States National Library of Medicine (NLM registration number: NCT02795728). The sealant applications were done during the months of January to February 2011, and the evaluations were concluded by March 2012.

A written consent was obtained from all the parents/guardians of the children who were involved in the study, after explaining the benefits and risks involved. The fluoride content of the drinking water supply was 0.09 ppm F⁻, and all the children commonly used fluoridated toothpastes as part of their routine oral self-care practice.

The materials used in this split-mouth randomized-controlled clinical trial were the Fuji VII, a glass ionomer sealant (GC dental industrial Corp,

Tokyo, Japan) and Clinpro, a light-cured BisGMA resin-based sealant (Clinpro, 3M ESPE Dental product, USA).

Based on the minimum expected difference of 20% between the two materials, assuming 95% confidence interval and 80% power, the sample size was calculated to be 96 individuals. Expecting a 20% dropout rate, the final sample size was rounded off to 120 teeth in each group.

Before the enrollment and start of the study, several training sessions were carried out for the graduate student who was responsible for the sealant applications. Many aspects of the study such as criteria for caries diagnosis, sealant retention, and indications for sealant placement were discussed.

The study population comprised of government school children in the age group between 7 and 9 years of age, attending the dental clinics of the district hospital. Children with fully erupted carious-free, nonsealed contralateral permanent mandibular first molars with a well-defined pit and fissure system and from a lower socioeconomic status were included in the study.

Children with teeth affected with developmental anomalies or with hypoplastic teeth, presence of a cavitated carious lesions on the occlusal surface of the mandibular first molars, or on the other surfaces of the same tooth were promptly excluded from the study. Informed consent was obtained from their parents after explaining the details of the clinical trial.

For an individual born in an even numbered month, the resin sealant was applied on the right permanent mandibular first molar, and the contralateral tooth received a glass ionomer sealant. Similarly, for a child born in an odd numbered month, a resin sealant was placed on the lower right segment and a glass ionomer sealant was placed on the lower left segment. Sealant applications were done in the preventive dental clinics of the dental school located in the district of Vikarabad.

The teeth which received resin sealants were cleaned with water/pumice slurry. Etching was done for 20 s, with 37% phosphoric acid (Clinpro, 3M ESPE Dental Product, USA) supplied with the material, washed and air-dried for 5 s. The resin sealant was then applied according to the manufacturer's instructions.

The teeth which received glass ionomer sealants was initially cleaned in the same way and conditioned with 10% polyacrylic acid for 10 s, rinsed, and dried.

The examiner applied the glass ionomer sealant as per the manufacturer's instructions (GC Dental Industrial Corp, Tokyo, Japan). The children were instructed not to eat or drink anything for the next 30 min. After each application, the sealants were tested for lack of air bubbles, marginal adaptation, and complete polymerization. If a sealant was found inadequate based on the above parameters, it was immediately retreated.

The study individuals were recalled for assessing sealant retention at intervals of 3rd, 6th, and 12th month, respectively, and for caries preventive effects at the end of the 12th month. These follow-up examinations were carried out by an investigator who had no knowledge about the specifics of the study. The investigator was well trained on sealant retention criteria and also to clinically examine for the presence or absence of secondary caries. These examinations were carried out within the preventive dental clinics of the department by recalling the study individuals in an orderly manner. Resealing was not carried out at the scheduled follow-up examinations.

Sealant retention was classified as completely retained, sealant partially lost, and sealant completely lost according to the Simensen's criteria,^[4] and the presence or absence of caries was scored without the usage of radiographs.

Statistical analysis

Data were analyzed using the statistical package IBM SPSS (version 20.1 for Mac, IBM, Chicago, IL, USA). A difference at the 5% level of probability was considered statistically significant. The caries-preventive effect between the two materials was tested statistically by the McNemar's test for matched pairs, and the differences observed with regard to the retention of the materials were tested by the Chi-square tests.

RESULTS

The screening of the study individuals was performed at the dental clinics of the district hospital. A total of 242 children in the age group between 7 and 9 years were scrutinized by the trained examiner, and 178 children satisfied the inclusion criteria. The sealant applications were done among 120 children by randomly picking them up from the list. Three children were lost during the followup phase at the 3rd month, 7 lost at the end of the 6th month and 9 children lost to follow up by the end of the study. These children

were not traceable as they shifted their place of residence. Thus, they were excluded from the study [Flow Chart 1].

The mean age group of the study individuals was 7.88 ± 0.80 years and included 71 males and 49 females, respectively. From the data collected, the resin-based sealants had a higher retention than the glass ionomer sealants at 3, 6, and 12 months, respectively, and was statistically significant [Table 1].

In the glass ionomer sealants placed, 101 surfaces (91%) were caries-free and 10 surfaces (9%) were decayed. With respect to the light cured resin based sealants, 105 surfaces (94.6%) were sound and 6 surfaces were decayed (5.4%). The difference was not statistically significant ($P > 0.05$) [Table 2].

DISCUSSION

The investigators assessed the retention and the caries-preventive features of the glass ionomer sealant (Fuji Type VII) which has been sparsely used in the studies carried out earlier. The study individuals belong to a low socioeconomic status as these individuals were enrolled in government schools in the district.

The results suggest that there was a gradual loss of sealants which was observed in both glass ionomer and resin sealants. However, the loss was more prominent in glass ionomer when compared to resin group. The considerably lower retention seen with the glass ionomer sealant when compared with the resin-based sealant was highly significant and is in agreement with studies by Subramaniam *et al.*,^[20] Forss *et al.*,^[21] Sari Kervanto-Seppälä *et al.*,^[22] Williams *et al.*,^[23] Karlzén-Reuterving and van Dijken *et al.*,^[24] Raadal *et al.*,^[25] Chen and Liu^[26] Ulusu *et al.*,^[27] and Kumaran.^[28]

In a recent study carried by Subramaniam *et al.*^[20] which used the Fuji type VII sealant, very low retention rates of the glass ionomer sealant were observed and are much lower in comparison to the present study.

Interestingly, a 24-month follow study carried out by Antonson *et al.*^[29] found no significant difference between glass ionomer and resin-based sealants with respect to the retention.

The lower retention rate is attributed to the brittle nature of glass ionomer cements.^[30] The insufficient

Table 1: Comparison of the retention of the sealant materials at three different intervals

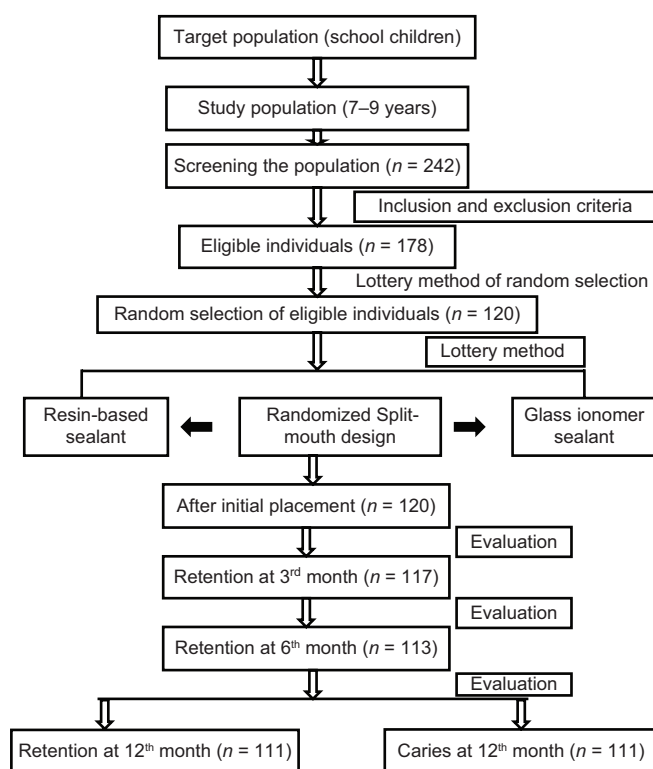
Retention	3 rd month		6 th month		12 th month	
	GIC sealant (%)	Resin sealant (%)	GIC sealant (%)	Resin sealant (%)	GIC sealant (%)	Resin sealant (%)
Completely present	89 (76.1)	102 (87.2)	78 (69.0)	91 (80.5)	57 (51.4)	84 (75.7)
Partially lost	22 (18.8)	15 (12.8)	21 (18.6)	20 (17.7)	17 (15.3)	16 (14.4)
Missing	6 (5.1)	0	14 (12.4)	2 (1.8)	37 (33.3)	11 (9.9)
Total	117 (100.0)	117 (100.0)	113 (100.0)	113 (100.0)	111 (100.0)	111 (100.0)
<i>P</i>	0.01* [#]		0.007* [#]		<0.001* [#]	

*Chi-square test, **P*<0.05 statistically significant. GIC: Glass ionomer cement

Table 2: Comparison of the caries incidence between the glass ionomer and resin-based sealants at the 12th month

Status of tooth	Glass ionomer sealant, <i>n</i> (%)	Light-cured resin-based sealant, <i>n</i> (%)	OR	Power (1-β)	<i>P</i>
Sound tooth	101 (91.0)	105 (94.6)	2.33	0.15	0.34
Cariou	10 (9.0)	6 (5.4)			
Total	111 (100.0)	111 (100.0)			

Pearson test, *P*=0.34 (NS). OR: Odds ratio, NS: Nonsignificant

**Flow Chart 1:** Schematic representation of the methodology.

physical properties of the material, especially in stress-bearing areas, might have resulted in high failure rate.

The glass ionomer sealant was formulated to have a short setting time, to avoid water contamination during the early setting stage and decrease the amount of time a child should keep his or her mouth open.^[31] As the setting reaction of the glass ionomer sealant is rapid, the ability of the sealant to penetrate into

fissures is questionable, and its adhesive strength may be compromised if the application is not done at the earliest. The retention rate may be related to these properties associated with the sealant setting time.

The higher retention of the resin sealants when compared to the glass ionomer sealants can be credited to the etching process which helps the resin to form a chemomechanical bond. The material used in the present study was a light-cured resin sealant, which provides the operator with a better control over polymerization. There is no necessity of mixing which can vary the flow, as it is available in preformed single tube/bottle form.

At the end of 12 months, 9% of the evaluated surfaces had carious lesions in glass ionomer group and 5.4% of the surfaces had developed carious lesions in the resin-based group.

The findings of the present study are in contrast with Kamala *et al.*,^[32] where no caries was observed on the occlusal surfaces of teeth sealed with glass ionomer sealants. The incidence of caries in the glass ionomer group was higher than that of Komatsu *et al.*^[33] (3.2%), Forss *et al.*^[21] (2.9%), Weerheijm *et al.*^[34] (5%), Williams *et al.*^[23] (7%), and Boksman *et al.*^[35] (0%) at the end of 1 year. A higher caries incidence of 14.6% was found in the study by Shimokobe.^[30]

In the resin sealant group, caries incidence in our study (5.4%) had contrasting results compared to the studies by Mihailovici and Dănilă^[36] (9.4%) and Tianviwat *et al.*^[37] (14.3%). Studies by Forss *et al.*^[21] (2.6%) and Williams *et al.*^[23] (2%) had lower incidence of caries.

The difference in caries incidence between the two materials in this particular study was not statistically significant and is in tune with studies carried out by Liu *et al.*,^[38] Chen and Liu,^[26] and Ulusu *et al.*^[27]

The follow-up period of this study has been for a period of 12 months and is considered as inadequate, considering the fact that dental caries is a chronic insidious disease and it takes several months to detect cavitation at the clinical level. Regardless of the early loss of the glass ionomer sealants, there was no major difference in-between the materials with regard to the caries incidence although a few more surfaces were decayed in the glass ionomer group. This is expected, considering the fact that glass ionomer sealants do act as fluoride depots which help to maintain the salivary fluoride levels in the saliva, thus rendering an anticariogenic property.^[39,40] It is also been demonstrated that there are microscopic remnants of the glass ionomer sealants intact within the deep fissures even when the sealant was lost completely on examination.^[41]

Another important aspect to consider is the fact that the use of glass ionomer sealants generally elevates the fluoride levels in whole saliva, and thus, there may be a masking effect on the possible differences between these two groups in a spilt-mouth technique.^[23,42]

Caries is a progressively slow disease, and the follow-up period should have been longer to assess the caries incidence. This is one of the inherent drawbacks of the study. The opaque nature of the material also posed some difficulty in detecting the presence of dental caries below the sealant.

Tooth selection for sealant application was performed through a visual/tactile method and not through a radiographic examination.^[43] Diagnosing fissure caries, especially under a defective sealant, is often difficult without microscopes. These children were not exposed to any radiographic investigations for ethical reasons.

In an ideal scenario, it would have made more sense to differentiate these individuals based on the baseline caries experience or the caries activity. This was not recorded before the start of the study and will be considered as a drawback of this clinical trial.

Assessing the effectiveness of sealants from a bird's eye, it is recommended that resin-based sealants are used as the first choice for preventing tooth decay and glass ionomers being an alternative choice as stated by the American Dental Association council on scientific

affairs.^[44] However, it is suggested that sealant studies in the future should be carried out among high-risk groups as such a scenario would provide us with a much more realistic answer to the effectiveness of the sealants.

CONCLUSION

The results obtained from this current study reiterate the fact that resinbased sealants are superior to glass ionomers in terms of retention although significant results were not obtained with regard to caries prevention.

Acknowledgment

We would like to thank the Para medical staff, students, and parents for their active cooperation toward the making of this manuscript.

Financial support and sponsorship

Nil.

Conflicts of interest

The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or nonfinancial in this article.

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