Evaluating the Retention of Resin-Based Sealant and a Glass Ionomer Sealant among 7-10 Year-Old Children: A Randomized Controlled Trial

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Introduction

Over the past three decades, there has been a substantial improvement in the oral health of children as evidenced by declines in the prevalence and severity of dental decay because of the outstanding scientific advances in restorative materials and techniques as well as in the understanding of its principles. The fissures of permanent molars are usually the first tooth surfaces to be affected by caries in younger age groups as young permanent teeth have specific occlusal morphology with deep and narrow pits and fissures that cannot be adequately cleaned, and therefore present particularly vulnerable places for the development of initial caries [1,2]. Although the occlusal surface presents only 12.5% of the complete tooth surface, 85% of dental caries in children occur on the occlusal surface [2].

The term pit and fissure sealants are used to describe a material that is introduced into the occlusal pits and fissures of caries-susceptible teeth, thus forming a micromechanically-bonded, protective layer cutting the access of caries-producing bacteria from their source of nutrients [3]. Although the results of previous clinical trials have provided evidence of sealants demonstrating caries-preventive effects, a clinical question remains concerning the choice of sealant type. Various materials and techniques to be used as pit and fissure sealants...
are available in the market. Materials such as polyurethane, cyanoacrylate resins, glass ionomer sealants, Bis-GMA resins, polyacid-modified composite resins (compomers), and ormocers have been used as fissure sealant. Among them, resin-based sealants and glass ionomer (GI) sealants predominantly used.

Resin-based materials have been studied since the 1960s as fissure sealants and have shown high retention rates after different evaluation periods [4]. They are hydrophobic materials and require an isolated environment for a proper seal. GI sealants are moisture friendly and can tolerate a moist environment. It also releases fluoride for caries stabilization and protection of susceptible tooth surfaces [5]. So, the choice of a better fissure sealant is still problematic.

Therefore, the aim of the present study was to evaluate the retention rate and the caries-preventive efficacy of a Glass Ionomer sealant compared with a conventionally light-cure, resin-based sealant among 7-10 years-old children over a 1-year period.

Materials and Methods

A randomized controlled trial using split-mouth design was carried out to compare the retention and caries preventive effects of two types of sealants on a group of school children aged 7-10 years in a private school of Bangalore City. This study was carried out from July 2016 to June 2017. The study protocol was reviewed by the Ethical Committee of the Institutional Review Board and was granted ethical clearance. The trial is registered under the Clinical trial registry- India (Ref no: REF/2015/10/009895). Informed consent was taken from the parents of the children.

The inclusion criteria included fully erupted, caries-free, and untreated (sealant application) first permanent mandibular molars. The post-eruptive period should not be greater than 2-3 years and there should be an absence of bruxism with the presence of deep pits and fissures.

One hundred and fifty children of age between 7-10 years, studying in 2nd, 3rd, 4th, and 5th standards were examined using mouth mirror and dental explorer (Figure 1). The children who fulfilled the inclusion criteria and whose parents gave written informed consent were taken into the study (50 students). Among them, 35 children (70 first mandibular teeth of right and left side) with a mean age of 8.91 ± 1.15 years were chosen randomly using the lottery method for the sealant application procedure. Among 35 children, 20 were boys and 15 were girls. A split or half mouth design was followed to apply the sealants.

The sample size was determined using the following formula,

\[
n = \frac{(r+1)\left(z_\alpha + z_{1-\beta}\right)^2}{r d^2},
\]

where \( r \) is the ratio of the sample size required for 2 groups (1), \( Z_\alpha \) is the normal deviate at a level of significance (1.96), \( Z_{1-\beta} \) is the normal deviate at 1-\( \beta \)% power with \( \beta \)% of type II error (1.28), \( \sigma \) is the pooled standard deviation (4) and \( d \) is the difference of means of 2 groups (2.2). A final sample size of 70 was obtained. Hence, 70 teeth (35 children) were included as the tooth was taken as the unit of the study.

The children were brought to the Department of Public Health Dentistry of a dental college, Bangalore, and a scaling procedure was carried out for all the children. After successfully carrying out the scaling procedure, the contralateral first permanent mandibular molar teeth were sealed with two different types of sealants. On one side of the mouth, GI sealant (Fuji VII manufactured by GC Corporation, Tokyo, Japan) and on another side, resin sealant (Delton FS+ manufactured by DENTSPLY professional, DENTSPLY International, York) was applied according to the manufacturer’s instructions. Occlusal high points were checked using articulating paper and if present, were reduced with a composite finishing bur.
showed complete retention, more than half of the teeth i.e 20 teeth (57%) showed partial retention and only one tooth (3%) showed complete loss of sealant. In the 9th month, complete retention was found in 14 teeth (40%) of the glass ionomer sealant group, partial retention of the sealant in 19 teeth (54%), and complete loss of sealant in 7 teeth (20%). Final evaluation of the retention of sealant showed that sealant in the resin group was completely retained in 16 teeth (46%), partially retained in 18 (51%) and no ‘complete loss’ of the sealant. Glass ionomer sealant showed that in only 1 tooth (3%) complete retention was present, partial retention of the sealant in 18 teeth (51%) and more than half of the teeth, i.e, 18 teeth (51%) showed complete loss of the sealant. The association between the types of sealant (Resin or glass ionomer sealant) and the retention type (Complete retention, partial retention, or complete loss) was found to be statistically significant at 3rd, 6th, 9th, and 12th month (Table 1).

The incidence of a carious lesion was evaluated after one year using radiographs. It was seen that no new caries lesion was observed in either group (resin sealant or glass ionomer sealant) (Figure 3). At the end of the procedure, oral hygiene instructions were given to every student.

Retention of both the sealants was evaluated and compared by the same examiner at 3rd, 6th, 9th and 12th month using a mouth mirror and probe, based on the following criteria: 1) Complete or total retention: Total retention of the fissure sealant on the occlusal surface; 2) Partial loss: The sealant is present, but as a result of either wear or fracture or loss of material, part of a previously sealed pit or fissure, or both, has been exposed and 3) Complete loss: A complete absence of fissure sealant on the occlusal surface of the tooth. Caries lesion incidence was evaluated by the absence or presence of a lesion after one year using radiograph (Figure 3).

Statistical analysis

The Statistical software Statistical Package for Social Science (SPSS) (IBM Company, Chicago, USA) version 15.0 was used for the analysis of the data and Microsoft Excel (Microsoft Company, USA) has been used to generate graphs, tables, etc. Descriptive statistics with frequency and percentage were obtained. Both Chi-square test and Fisher’s exact test were used to find the association between retention and types of sealant at 3rd, 6th, 9th, and 12th months. The p-value was taken as significant when less than 0.05.

Results

A total of 35 (100%) children with a mean age of 8.91 ± 1.15 years were included in the study. Among them, 06 (17.1%) students belonged to 7 years of age, 07 (20%) were in the age of 08 years, 06 (17.1%) belonged to the age of 09 years and 16 (45.8%) were in the age of 10 years. Twenty students (57.1%) were boys and 15 (42.9%) were girls.

In the third month, complete retention of resin sealant was found in 33 teeth (94%) and only 02 teeth (6%) showed partial retention whereas in glass ionomer sealant, 23 teeth (66%) showed complete and 12 teeth (34%) showed partial retention. In the 6th month, complete retention was found in 31 teeth (89%), partial retention in 04 teeth (11%), and no “complete loss” was seen in the resin sealant group. In the glass ionomer sealant group, 14 teeth (40%) showed complete retention, more than half of the teeth i.e 20 teeth (57%) showed partial retention and only one tooth (3%) showed complete loss of sealant. In the 9th month, complete retention was observed in 28 teeth (80%), partial retention in 07 teeth (20%), and no ‘complete loss’ was seen in the resin sealant group. In contrast, 09 teeth (26%) of the glass ionomer sealant group showed complete retention, partial retention of the sealant in 19 teeth (54%), and complete loss of sealant in 07 teeth (20%). Final evaluation of the retention of sealant showed that sealant in the resin group was completely retained in 24 teeth (69%), partially retained in 11 teeth (31%) and no ‘complete loss’ was seen in the resin sealant group. Glass ionomer sealant showed that in only 01 teeth (3%) complete retention was present, partial retention of the sealant in 16 teeth (46%) and more than half of the teeth, i.e, 18 teeth (51%) showed complete loss of the sealant. The association between the types of sealant (Resin or glass ionomer sealant) and the retention type (Complete retention, partial retention, or total loss) was found to be statistically significant at 3rd, 6th, 9th, and 12th month (Table 1).

The incidence of a carious lesion was evaluated after one year using radiographs. It was seen that no new caries lesion was observed in either group (resin sealant or glass ionomer sealant) (Table 2).

| Retention | Resin sealant (n = 35) | Glass ionomer sealant (n = 35) | χ² (p-value) | Fisher’s exact test (p-value) |
|-----------|------------------------|-----------------------------|-------------|-----------------------------|
|           | Complete retention     | Partial retention           | Complete loss| Complete retention           | Partial retention | Complete loss |          |                |              |
| 3rd month | 33 (94%)               | 2 (6%)                      | 0            | 12 (34%)                    | 0               | 8.929 (0.003) | 169.6 (0.001) |
| 6th month | 31 (89%)               | 4 (11%)                     | 0            | 14 (40%)                    | 20 (57%)        | 1 (3%)        | 18.089 (< 0.001) | 173.5 (0.001) |
| 9th month | 28 (80%)               | 7 (20%)                     | 0            | 9 (26%)                     | 19 (54%)        | 7 (20%)       | 22.295 (< 0.001) | 175.8 (0.000) |
| 12th month| 24 (69%)               | 11 (31%)                    | 0            | 1 (3%)                      | 16 (46%)        | 18 (51%)      | 8.929 (< 0.003) | 173.6 (0.000) |

Denotes significant difference (p < 0.001 is highly significant).
Discussion

Dental caries is a chronic infectious disease that produces lesions experienced by more than two-thirds of all children and more than 90% of all dentate adults [6]. Despite various routine prevention methods, the disease displays a wide range of severity both in children and adults in terms of the number of tooth surfaces that are decayed and/or filled.

One of the most effective ways to prevent caries in pits and fissures is to place sealants as they are an important part of caries-preventive strategies because of their non-invasive and convenient method of preventing or arresting occlusal caries. The first clinical study on sealant retention was done by Cueto and Buonocore in 1967. They found an 86.3% reduction in caries one year after the application of sealant [7].

In the present study, the split-mouth design was used to expose both the sealants to a similar environment in the oral cavity and hence avoids variation among individuals, because it uses individuals as their own controls.

In our study, school children aged between 7-10 years were selected. This was in accordance with the study by Winkler M, et al. [8], Kumaran P, et al. [9], and Haznedaroglu, et al. [10]. Children and adults can benefit from sealants, but the earlier we get them, the better is the effect of sealants as the highest risk of occlusal caries is believed to exist during the eruption of teeth as well as after the first few years, not only because of mineral immaturity as post-eruptive maturation has not taken place but also due to the more intense dental plaque accrual because of infra-occlusion [11].

Various authors have used different criteria to assess sealant retention. For evaluating the retention of sealants, the scoring criteria used in the present study were: 1) Total Retention; 2) Partial Loss, and 3) Total Loss. The same criteria were used in several other studies [9,10,12-16]. To evaluate the occurrence of a new carious lesion, the following criteria were used in the present study: 1) Present and 2) Absent. This was in accordance with several other studies [9,10,17,18].

In the present study, the difference in the retention between the two sealants was statistically significant at 3rd, 6th, 9th, and 12th month (p < 0.05). The results of our study were comparable with a study done by Sub-ramaniam, et al. [19]. They found a statistical difference in the retention between the two sealants (p < 0.001). Haznedaroglu E, et al. [10] compared resin sealant and GI sealant over a period of 4 years with recall interval at 6th, 12th, 24th, 36th, and 48th month and a statistical difference was found between the resin and GI sealant (p = 0.005). In a study conducted by Chavez M, et al. [16], the clinical condition of the materials (resin sealant and GI sealant) used were evaluated after three and six months. After six months, 53.12% of the resin-based sealants, as well as the same percentage of GI sealants, were completely present and no statistically significant difference was found between the two sealants. Baseggio W, et al. [12] compared the resin-modified GI sealant and resin-based sealant over the period of 36 months with recall interval at 6th, 12th, 18th, 24th, 30th, and 36th month. A complete loss was observed in none of the teeth in the resin sealant group and in 27.50% of GI sealants. With regard to the retention rate, a statistically significant difference (p < 0.01) was observed between the two sealants. Antonson S, et al. [15] compared two types of sealants for a period of two years. The complete loss was observed in 5.5% of resin sealants and 2.8% of GI sealants. No statistically significant difference was observed in retention rates between the two groups. Gorseta K, et al. [20] compared resin sealant and GI sealant over one year period and no statistically significant difference was found between the two sealants. One main reason for the loss of the glass ionomer sealants in the present study as well as in the previous studies could be due to an inadequate adhesion of the cement to the enamel surface. In addition, lack of cooperation, which is required for isolation in the younger children, which would predispose to surface degradation and early loss of sealant.

The Cochrane Review estimated that the caries-preventive effect of sealants ranges from 87% at 12 months to 60% at 48-54 months; however, this effect relies on adequate retention of the sealant [21]. In the present study, there was no occurrence of new carious lesions in both groups. The same results were found in various studies [8,16,18]. An absence of caries could be due to the short time period of twelve months, which was insufficient to assess and compare the caries preventive effect of the sealants.

Some limitations were present in our study that should be recognizable. The short time period of twelve months or one year was insufficient to assess and compare the caries prevention effectiveness of the sealants. Although none of the participants developed caries in the sealed teeth, the caries history of each child was not recorded regarding their dietary habits and other factors, so it could not be correlated to the sealant retention status for each child.

Conclusion

In the present study, retention of resin sealant was
found to be statistically better than the GI sealant as observed over the one year period and there was no difference between the sealants in terms of their caries preventive effects.

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Conflict of Interest

The authors declared no conflict of interest.

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