Clinical trial on glass ionomer ART sealant and fluoride-releasing resin sealant in fissure caries prevention

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Abstract - Clinical trial on glass ionomer ART sealant and fluoride-releasing resin sealant in fissure caries prevention

Objective: To report on the relative effectiveness of ART sealant and fluoride-releasing resin sealant in preventing fissure caries in permanent molars.

Methods: After obtaining ethical approval, a split-mouth designed randomized controlled trial was conducted in southern China. Healthy schoolchildren who had sound permanent first molars with occlusal fissures which were deep or presented with early enamel caries were recruited for the study. Included molars on one side (right/left) of an individual mouth were randomly allocated into one of four study groups receiving the intervention of fluoride application or sealant placement. In the two groups receiving sealant, single placement of ART sealant or fluoride-releasing resin sealant was provided. The methods of sealant placement could combine with each other or either of the fluoride-using methods in the same mouth in this study. Fissure status of the molars in each group was evaluated every 6 months. Development of dentine caries and sealant retention over 24 months in the molars in the two sealant-using groups was compared in this report.

Results: At baseline, totally 280 children (383 molars) with mean age 7.8 years were involved for the two sealant groups. After 24 months, 261 children (357 molars) were followed. Proportions of molars with caries into dentin were 7.3% and 3.9% in the ART sealant and fluoride-releasing resin sealant groups, respectively (chi-square test, p=0.171). Life-table survival analysis showed that sealant retention (full and partial) rate over 24 months for the resin sealant (73%) was significantly higher than that (50%) for the ART sealant (p<0.001). Molar survival (no dentine caries developed) rates over 24 months in the ART sealant (93%) and fluoride-releasing resin sealant (96%) groups were not significantly different (p=0.169). Multilevel logistic regression (GEE modeling) accounting for the effects of data clustering and confounding factors confirmed this finding.

Conclusion: Though the retention of fluoride releasing resin sealant was better than that of the ART sealant, their effectiveness in preventing fissure caries in permanent molars was not significantly different. However, further studies are needed to determine the long-term effectiveness and potential long-term toxicity of these materials.
molars was similar over 24 months. ART sealant could be a good alternative when and
where the use of resin sealant is problematic.

**Key Words:**
Fissure Sealants, Glass-Ionomer Cement, Child, Dental Caries, Dental Fissures,
Preventive Dentistry
**Introduction**

Pits and fissures in the first molars are the most susceptible sites for dental caries in the permanent dentition [1, 2] and contemporary studies show specifically that 85% or more of the caries is nested in the above-mentioned sites [3, 4]. Thus, prevention of caries in these tooth sites is of crucial importance in keeping a sound permanent dentition.

Sealing the pits and fissures of molars and premolars for prevention of dental caries was first introduced in the 1960s [5]. It is now accepted as a highly effective method in preventing dental caries [6]. The two predominant types of dental sealant nowadays are resin-based and glass ionomer cement (GIC) sealants. Inconsistent findings have been found regarding the comparative effectiveness of GIC to resin sealant in preventing fissure caries [6, 7] and there is no clear evidence to support the superiority of either of the two types of sealants [8, 9]. The effectiveness of resin sealant in preventing fissure caries depends primarily on its retention after placement [6, 10]. For high-quality resin sealant placement, electrically powered dental equipment and good clinical conditions are required. However, this may be difficult to achieve in places where access to a modern dental clinic is limited. This problem may be overcome by using GIC sealant because it can be placed without the use of electrically powered dental equipment.

There are wide ranges of GIC materials available in the market with different formulations, properties, and performance for use in dentistry. Strengthened highly viscous (type II restorative) GIC has the property of rapid setting, considerably reduced moisture sensitivity in the early setting stage and low solubility in oral fluids [11] which make it an improved GIC material for the atraumatic restorative treatment (ART) technique [12]. The latest granulation formula of such kind of GIC material improved its wettability leading to an easier and faster mixing for practical use. Placement of ART sealant uses such kind of GIC material to seal pits and fissures with the aid of a similar “finger-press” technique as used in the ART restoration
procedure. It was found that retention rate of ART sealants was higher than that of the earlier developed lower viscosity ones [13, 14]. It was also shown recently that an as high as 85% success rate over 6 years can be achieved by using ART sealant [15]. Individual study even showed that ART sealant can outperform resin sealant in fissure caries prevention [16]. It seems promising for ART sealant to be used as an alternative to resin sealant. However, well conducted clinical/field trials demonstrating the relative effectiveness of ART sealant and that of resin sealant are still limited, yielding insufficient evidence to draw a conclusion on the comparison between the two [17]. More studies are therefore needed to document the possible differences between resin and ART sealants in their effectiveness in fissure caries prevention.

A randomized controlled trial aimed at comparing the effectiveness of four different methods in preventing pit and fissure caries in permanent molars was conducted in southern China. The aim of this article was to report on the 24-month results of this trial, targeting specifically on the relative effectiveness of a self-cured ART sealant and that of a light-cured fluoride releasing resin sealant in fissure caries prevention in permanent first molars of schoolchildren. The null hypothesis was that there was no difference between the effectiveness of the two types of fissure sealants.

**Materials and Methods**

This study was a split-mouth designed randomized controlled trial with four parallel groups. Besides the two sealant-adopting groups compared here, the other two groups used the method of fluoride application. Ethical approval of the study was obtained from the Institutional Review Board of the University of Hong Kong. It was carried out in Shenzhen, China where the water supply was not fluoridated but fluoride toothpaste was common in the market. The dental caries prevalence of the 12-year-old children in Shenzhen was 29.8% (mean DMFT score: 0.54) and 66.7% of the dental caries was nested in the permanent 1st molar [18].

Children aged 7 to 9 years attending two of the largest primary schools in Shenzhen
were invited to participate in the study. Children with written parental consent were clinically examined by trained and calibrated dentists in their school. Children who did not have any major general health problems and had permanent first molars with occlusal fissures which were deep (base of fissure cannot be seen) or presented with signs of early caries (opacity and discoloration seen when viewed wet), similar to ICDAS code 2 [19] were included. Children who were uncooperative or refused dental treatments were excluded. Molars fulfilling the above requirements in the recruited children were visually assessed by using an intra-oral LED light and disposable mouth mirrors to record their baseline status (1-no caries, deep fissures; 2-fissures with signs of early caries). CPI probes were used to remove plaque obscuring visual assessment when necessary. The molars were also assessed by DIAGNOdent 2095 (KaVo Dental, Biberach, Germany), a laser-induced fluorescence based caries detection device [20]. DIAGNOdent measurement was repeated three times for each molar and the highest reading was recorded. In this study, DIAGNOdent readings ≥40 were taken to indicate that the screened molars potentially had dentin caries [21]. Molars presented with DIAGNOdent reading ≥40, carious cavities, dental sealant, fillings, and/or hypoplasia were excluded. Calibration of the examiner with an experienced epidemiologist was performed on a group of selected child patients before the start of this study.

Included molars on one side (right/left) of an individual mouth were randomly allocated into the study groups. The randomization was accomplished by drawing grouped numbers blindly from an envelope by an assistant. Molars allocated in the two sealant groups received single placement of the fluoride-releasing resin sealant (Clinpro, 3M ESPE, Seefield / Oberbay, Germany) or ART sealant (Ketac-Molar Easymix, 3M ESPE, Seefield, Germany). Sealants were provided in the schools by two trained dentists with help from chair-side assistants. Oral hygiene instructions were provided to all children in the study at baseline.

In sealant placement, the molar was isolated with cotton rolls. Occlusal surfaces of
molars in resin sealant group were etched with 37% phosphoric acid for 15-20 seconds, washed with water which was removed by suction connected to a portable dental unit, and then dried with air blow using the 3-in-1 syringe attached to the dental unit. Resin sealant was then applied and light-cured. Occlusal surfaces of molars in ART sealant group were conditioned with polyacrylic acid for 10-15 seconds, cleaned by cotton pellets soaked with water, and then dried with cotton pellets. GIC material was hand mixed according to the manufacture’s instruction and placed using the finger-press technique [22]. Complete setting and retention of sealants and occlusion were checked before the children left.

Development of dentine caries (ICDAS Code 4-6) and sealant retention (completely retained, partially retained, and no sealant) in the molars was assessed blindly every 6 months by one calibrated dentists. Intra-oral LED light, disposable plane front-surface mouth mirrors were used in the examinations. CPI probes or sharp sickle-shaped dental explorers were used to aid the diagnosis of dental caries and sealant retention respectively when necessary. Fissures with sealant fully retained were regarded as sound. A 10% random sample was re-examined during every examination (baseline and follow-up) to monitor inter- and intra-examiner reproducibility. The primary outcome was development of dentine caries in the study molars.

In sample size calculation, it was anticipated that around 90% of molars receiving resin sealant would not have dentin caries after 24 months [23]. To detect a clinically significant 10% absolute difference between two groups by using chi-square test based on $\alpha=0.05$ and 80% power, a total of 288 molars for two groups was required. With estimation of intraclass correlation (ICC) among the molars to be 0.1 and on average two molars were expected to be included in each child (i.e., $m = 2$), the calculated number was raised to 318 [24]. To allow for an overall 15% drop-out rate, a sample size of 376 molars in total for two groups was required at baseline.

**Data analysis**
Data was input into computer and analysis was performed using SPSS 20.0 (SPSS Inc., Chicago, IL, USA). Chi-square test was used to compare the caries incidence rates. Life-table survival analysis was used to compare the cumulative molar survival (no dentine caries developed) rates and sealant retention (full and partial) rates over 24 months of the two groups. A multi-level logistic regression analysis using generalized estimating equation (GEE) modeling was also performed. Outcome was reported at the tooth level, and a two-level structure (level 1 - tooth; level 2 - child) was adopted. The dependent variable was presence of dentin caries at the 24-month examination. Independent variables included those at the child level: gender (boy/girl), age, snacking (≥2 times daily or not), toothbrushing (≥2 times daily or not); as well as variables at the tooth level: treatment (RS, GIS), status at baseline (sound or present with signs of early caries), molar location (upper/lower), baseline DIAGNODent reading (≤15/16-39) of the molar, and period of sealant retention (0-4 times 6 months). Interaction effects between and among the independent variables were considered. Exchangeable and independent correlation structure of the clustering of molars in each child was also assessed, and the model yielding the lowest adjusted QIC value was selected as the final model.

**Results**

At baseline, a total number of 280 children (44% boys) with 383 permanent first molars were included into the two sealant groups in the study (Fig. 1). Mean age of these children was 7.8 years. No statistically significant differences were found between the involved children for the two groups regarding their background and oral health behaviors as well as the distribution of included molars, except that a higher proportion of molars in the ART sealant group than in the resin sealant group had signs of early caries (19.6% vs. 12.2%, p=0.047) (Table 1). The Kappa values of inter- and intra-examiner agreement in the dental examinations were all greater than 0.85.

A total of 261 (93.2%) children with 357 (93.2%) molars were followed at 24 months for the two sealant groups. There was no statistically significant difference between
the two groups in the proportion of children and molars lost to follow-up. No complaints from the children and no adverse effect of the treatments were found during this study.

The proportions of study molars with dentin caries at the 24-month examination in the resin and ART sealant groups were 3.9% (7 out of 178) and 7.3% (13 out of 179) respectively (p=0.171). Results of the Life-table survival analysis showed that the cumulative sealant retention (full and partial) rate over 24 months was 75% for the resin sealant and 52% for the ART sealant (p<0.001). The mean number of survival periods (in units of 6 months) were 3.4 (SD=1.2) and 2.7 (SD=1.5) for the resin and ART sealants, respectively (p<0.001). The cumulative molar survival (no dentine caries developed) rates over 24 months in the resin sealant and ART sealant groups were 96% and 93% respectively (p=0.169). Sealant retention and molar survival (no development of dentin caries) in the two groups over the 24-month period of this study is shown in Figure 2. GEE modeling confirmed that the risk to develop fissure caries of molars receiving ART sealant did not significantly differ from that of molars receiving resin sealant in this study (Table 2). It was also found that the longer the retention time of the sealant on the molar, the lower the risk of developing dentin caries in the occlusal surfaces of the molar (OR=0.453, p<0.001), and that presence of early caries in the fissures before the placement of sealant would increase the risk of dentine caries development (OR=4.662, p=0.008).

Discussion
Regarding the design of the study, cross-over effect of fluoride on the effectiveness of sealant placement in fissure caries prevention might exist, the amount of which cannot be estimated in this study. Despite this, similar proportions of molars in the two sealant groups were exposed to a fluoride-using method in the same mouth. In addition, both the sealants used in this study are fluoride-releasing materials. Thus, the above mentioned factor was considered to be balanced between the two sealant groups which would not affect the relative comparison between them much in this
Resin sealant placement in this study is regarded as the positive control because its effectiveness in fissure caries prevention has been well established [6]. Over the 24-month study period, incidence of dentine caries in the molars receiving resin sealant was only 3.9%, corresponding to a cumulative molar survival rate of 96% (SE=0.01). This finding is comparable to that in a similar study conducted in southern China [25] as well as those of other studies [23, 26, 27]. Noting the background that the prevalence of dental caries in 12-year-old children in the study site was 29.8%, with 66.7% of which nested in the permanent 1st molar [18], such a low incidence of dentine caries may be taken to reflect the effectiveness of the resin sealant in preventing fissure caries in this study.

There was no statistically significant difference regarding the 24-month dentine caries incidence rates as well as the molar survival rates between the two sealant groups in this study. Multivariate two-level logistic regression analysis (GEE modeling) which can account for the effects of confounding factors and data clustering was adopted [28]. Results of the GEE modeling confirm that the risks to develop dentine caries in the fissures of the molars in the two sealant groups did not significantly different from each other. Therefore, the null hypothesis of this study cannot be rejected.

There is currently no systematic review specially targeted on the comparison between ART sealant and light-cured resin sealant in fissure caries prevention. A literature search yielded three comparable original studies [16, 29, 30]. Oba et al. found 3-year caries incidence rates of around 10% in both groups of molars receiving ART sealant and resin sealant respectively [30]. Low 2-year caries incidence rates (<2%) in both the ART sealant and resin sealant groups were found by Chen et al., again, no significant difference in their effectiveness in fissure caries prevention was found [29]. In the third study, no caries was observed in molars receiving ART sealant over 2 years and this was significantly better than that in the resin sealant group which
showed a 4% caries incidence rate over the same period [16].

The 24-month retention rate of the resin sealant in this study is lower than those commonly reported in other studies which are around 80% [6, 32]. The lower retention rate of resin sealants in this study may be related to the less-than-optimal operation condition for its placement which was the compromised school setting instead of a well-equipped clinical environment. Under a field condition, ample illumination, good moisture control, and thorough cleaning of the pits and fissures cannot be guaranteed. Similar problem was encountered in another study where sealants were also provided under simple school settings which found a 93.8% complete loss of resin sealant 3 years after placement [30]. Improvement of the operation conditions would probably lead to a better retention of resin sealants. Despite this, retention of the resin sealants in this study was still significantly higher than that of the ART sealants. This is in line with what has been reported [6].

The 24-month retention rate of ART sealant in this study (52% full + partial retention) is generally lower than those reported in previous comparable studies conducted under similar field settings which ranged 50-72% over a longer 3-year period [30,33-35]. It was found in previous studies that retention of ART sealant was influenced by the experience of different operators with experienced ones performed better than the inexperienced ones [15, 33, 34]. Probably operators in those studies received better training and being more experienced in ART sealant placement.

Although a significantly lower retention rate and shorter retention time than those of the fluoride releasing resin sealant were found for the ART sealant in this study, the effectiveness of ART sealant in fissure caries prevention did not differ significantly from that of the resin sealant used in this study. This might be explained by the findings of Beiruti et al. that high-viscosity GIC sealants had a four times higher chance of preventing caries development in re-exposed pits and fissures of occlusal surfaces in first molars than resin sealant over a 1- to 3-year period [16]. It is also in
agreement with a long-term follow-up study on ART sealant that the drop of the effectiveness of ART sealant in fissure caries prevention lagged the fall of its retention [15]. In that study, it was found that dentine caries cavitation in molars with complete loss of ART sealant was relatively infrequent. Probably there were some clinically undetectable glass-ionomer particles retained in the deeper parts of the fissure as observed by Frencken and Wolke [36] and these offered continuing protection against caries. It is reiterated that due to the difference in the materials used, the success of a fissure sealing method should finally be assessed by the outcome of dentine caries prevention rather than material retention [8].

In the final GEE modeling in this study, it was also found that presence of early caries in the occlusal surfaces of the molars before sealant placement and shorter retention of sealant on the molars significantly increased the risk of developing dentine caries in the pits and fissures. These findings are consistent with those of other studies [1, 6, 25, 31].

Comparing the placement of the two types of sealants, it is noted that the number and training of dental personal required as well as the time used are similar. However, the set-up and running of an ART sealant program for children in schools will be easier than those of a resin sealant program. It is because the equipment required for ART sealant placement is rather simple (only a few hand instruments) whereas that for resin sealant placement includes electricity-powered dental unit. Given that the two methods yield similar effectiveness in fissure caries prevention, their relative affordability, availability, and simplicity should be considered when making choice between the two. ART sealant might be more appropriate than resin sealant for use in less developed areas or in outreach dental service programs.

**Conclusion**

ART sealant and fluoride releasing resin sealant have similar effectiveness in preventing fissure caries in permanent molars in schoolchildren over 24 months.
although ART sealant is less retentive than the resin sealant.

List of abbreviations
ART- atraumatic restorative treatment; GIC- glass ionomer cement

Competing interests
The authors declare that they have no competing interests.

Authors' contributions
YX participated in the study’s design, performed the study as well as assisted the preparation of the manuscript. BL helped the carrying out of the study and prepared the manuscript. EL and CC participated in the study’s design, supervised the carrying out of this study, and read and approved the final manuscript.

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Reference


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Legend

Figure 1 Subjects flow until 24 months in the two sealant groups in the study (n-number of subject, N-number of molar).

Figure 2 Cumulated proportions of sealant retention and molar survival over 24 months in the two sealant groups, resin sealant (RS) and ART sealant (GIS) (error bars show the 95% confidence intervals of the estimated mean).
Table 1 Comparison of the baseline factors between the two groups

<table>
<thead>
<tr>
<th>Factors</th>
<th>Resin sealant</th>
<th>GIC sealant</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Age (SD)</td>
<td>7.8 (0.66)</td>
<td>7.8 (0.66)</td>
<td>0.695</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td>0.881</td>
</tr>
<tr>
<td>-Boy</td>
<td>70 (44.6%)</td>
<td>70 (43.8%)</td>
<td></td>
</tr>
<tr>
<td>-Girl</td>
<td>87 (55.4%)</td>
<td>90 (56.2%)</td>
<td></td>
</tr>
<tr>
<td>Snacking habit</td>
<td></td>
<td></td>
<td>0.152</td>
</tr>
<tr>
<td>-Once a day or less</td>
<td>116 (73.9%)</td>
<td>129 (80.6%)</td>
<td></td>
</tr>
<tr>
<td>-Twice or more a day</td>
<td>41 (26.1%)</td>
<td>31 (19.4%)</td>
<td></td>
</tr>
<tr>
<td>Tooth brushing habit</td>
<td></td>
<td></td>
<td>0.901</td>
</tr>
<tr>
<td>-Once a day or less</td>
<td>56 (35.7%)</td>
<td>56 (35.0%)</td>
<td></td>
</tr>
<tr>
<td>-Twice or more a day</td>
<td>101 (64.3%)</td>
<td>104 (65.0%)</td>
<td></td>
</tr>
<tr>
<td><strong>Molar</strong></td>
<td></td>
<td></td>
<td>0.047</td>
</tr>
<tr>
<td>Baseline molar status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Sound with deep fissure</td>
<td>166 (87.8%)</td>
<td>156 (80.4%)</td>
<td></td>
</tr>
<tr>
<td>- Present with incipient caries</td>
<td>23 (12.2%)</td>
<td>38 (19.6%)</td>
<td></td>
</tr>
<tr>
<td>Location</td>
<td></td>
<td></td>
<td>0.964</td>
</tr>
<tr>
<td>-Upper molar</td>
<td>53 (28.0%)</td>
<td>54 (27.8%)</td>
<td></td>
</tr>
<tr>
<td>-Lower molar</td>
<td>136 (72.0%)</td>
<td>140 (72.2%)</td>
<td></td>
</tr>
<tr>
<td>DIAGNOdent reading</td>
<td></td>
<td></td>
<td>0.543</td>
</tr>
<tr>
<td>-0–15</td>
<td>77 (40.7%)</td>
<td>85 (43.8%)</td>
<td></td>
</tr>
<tr>
<td>-16–39</td>
<td>112 (59.3%)</td>
<td>109 (56.2%)</td>
<td></td>
</tr>
</tbody>
</table>

Comparisons were performed by using Chi-square test otherwise specified while respective percentage was reported in the parenthesis.

* Independent samples t-test was performed for the comparison while standard deviation (SD) of the respective data was reported in the parenthesis.
**Table 2.** Full model of the 2-level GEE logistic regression ($n_{\text{subject}}=261$, $N_{\text{molar}}=357$)

<table>
<thead>
<tr>
<th>Factors</th>
<th>Estimation (S.E.)</th>
<th>p-value</th>
<th>Odds Ratio (OR)</th>
<th>95% C.I for OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sealant (resin vs. ART sealant)</td>
<td>0.120 (0.583)</td>
<td>0.837</td>
<td>1.128</td>
<td>0.359 3.539</td>
</tr>
<tr>
<td>Age</td>
<td>-0.187 (0.472)</td>
<td>0.692</td>
<td>0.830</td>
<td>0.329 2.090</td>
</tr>
<tr>
<td>Gender (boy vs. girl)</td>
<td>-0.829 (0.648)</td>
<td>0.201</td>
<td>0.436</td>
<td>0.123 1.554</td>
</tr>
<tr>
<td>Candy snacking habit (&lt;2 vs. ≥2 daily)</td>
<td>-0.095 (0.610)</td>
<td>0.877</td>
<td>0.910</td>
<td>0.275 3.004</td>
</tr>
<tr>
<td>Tooth brushing habit (&lt;2 vs. ≥2 daily)</td>
<td>1.147 (0.744)</td>
<td>0.123</td>
<td>3.149</td>
<td>0.733 13.532</td>
</tr>
<tr>
<td>Incipient caries at baseline (yes vs. no)</td>
<td>1.539 (0.582)</td>
<td>0.008</td>
<td>4.662</td>
<td>1.491 14.582</td>
</tr>
<tr>
<td>Molar location (lower vs. upper)</td>
<td>0.270 (0.758)</td>
<td>0.722</td>
<td>1.310</td>
<td>0.297 5.787</td>
</tr>
<tr>
<td>DIAGNOdent reading (16-39 vs. ≤15)</td>
<td>1.987 (1.027)</td>
<td>0.053</td>
<td>7.293</td>
<td>0.974 54.618</td>
</tr>
<tr>
<td>Sealant retention (0-4 half-year periods)</td>
<td>-0.792 (0.175)</td>
<td>&lt;0.001</td>
<td>0.453</td>
<td>0.321 0.639</td>
</tr>
<tr>
<td>Intercept</td>
<td>-2.255 (4.178)</td>
<td>0.589</td>
<td>0.105</td>
<td>0.000 376.812</td>
</tr>
</tbody>
</table>

Odds Ratio (OR) is the ratio of the odds to develop dentine caries under two compared conditions.
Figure 1- Subjects flow until 24 months in the two sealant groups in the study (n- number of subject, N-number of molar)
Figure 2 - Cumulated proportions of sealant retention and molar survival over 24 months in the two sealant groups, resin sealant (RS) and ART sealant (GIS) (error bars show the 95% confidence intervals of the estimated mean).