INTRODUCTION

Pit caries accounts for about 90% of the total incidence of caries in children and adolescents and there are signs that the severity of caries in the first molar is increasing in young children, especially in those at high risk (HR) of caries. Use of pit and fissure sealants plays an important role in preventing the development of occlusal caries by isolating the covered tooth surfaces from microorganisms and food particles. There are two predominant types of sealant: resin-based sealant and glass-ionomer cement (GIC). Light-cured resin sealant is effective in caries control due to forming a physical barrier, but is technique sensitive.

As a sealant material, GIC has the advantage of being moisture tolerant. More importantly, GIC can provide continuous fluoride release and thus its preventive effect can persist even with visible loss of the material. However, the effect on caries reduction of GIC is equivocal due to its unsatisfactory retention rate. The low viscosity, pink colored, high fluoride releasing Fuji VII glass ionomer cement (GC Fuji VII, GC Corporation, Tokyo, Japan) has been in use for several years. Several investigators have reported that the amount of fluoride released by Fuji VII is statistically significantly higher than that released by previous GICs, but questions remain regarding its clinical performance compared with resin sealants.

The results of studies assessing the effectiveness of fissure sealant according to patients’ caries risk status have been contradictory. Some studies have shown that fissure sealants are more effective if used in HR rather than low risk (LR) children; others have found that the higher the dft, the higher the risk of fissure sealant failure, though such sealants are effective in individuals with low or moderate carious activity. There has been no study discussing the preventive effect of Fuji VII in children of different caries risk status.

The purpose of this study was to evaluate and compare the retention and the cariostatic effect of Fuji VII and a resin-based sealant in children susceptible or insusceptible to caries.

MATERIALS AND METHODS

Study population
Children aged 6–8 years attending the pediatric department of First Dental Center, Peking University School and Hospital of Stomatology for pit and fissure sealing were included. On the first and each recall visit, the teeth present in the mouth along with all carious, filled and missing teeth were recorded in standard dental records. Individual caries risk was based on the baseline dmft index of each patient. Two categories of caries risk severity were considered: a) children with no or one carious tooth (dmft<2) were included in the LR group; and b) children with dmft>5 were placed in the HR group. Children with dmft 2–5 were not included in the present study. The guardians of the participants signed individual informed consent forms containing information about the aim of the study and the treatment procedures.

Some of the investigators contributed to the work equally and should be regarded as co-first authors.

Color figures can be viewed in the online issue, which is available at J-STAGE.

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Inclusion criteria
Inclusion criteria for the study were as follows:
1. Clinical crown completely erupted and not covered by gum;
2. Two or four symmetrical permanent molars present;
3. No caries found in first molars by visual inspection and probing;
4. Patient cooperation with and acceptance of the treatment;
5. Proper isolation possible with cotton rolls;
6. No fluoride mouth rinse program practiced in the participant’s school.

Exclusion criteria
Exclusion criteria were:
1. Stain on grooves, suspected caries, enamel hypoplasia or dental fluorosis;
2. Pits and fissures sealed previously;
3. Highly uncooperative child.

Sealant
A split mouth design was used in this study. Random numbers determined the material used to seal the teeth. Bacterial plaques were removed from all surfaces and grooves of the molars using a rotary brush. Fuji VII sealant was placed to seal the pits and fissures on the teeth of one side of the mouth; a resin-based sealant (3M Concise; 3M Dental Products, St. Paul, USA) was placed on the other side. The procedure was performed exactly according to the manufacturers’ instructions and under cotton roll isolation. All patients were advised to follow a preventive program that included education in oral hygiene, diet counseling, use of fluoridated toothpaste (600 ppm) and topical fluoridated foam treatment (6,000 ppm) at every clinic recall.

Clinical evaluation
Retention of sealants and presence of caries were evaluated 6 months, 1 year and 2 years after the procedure, three times in total, by two calibrated independent evaluators. In cases of disagreement, consensus was reached after consultation with a third researcher.

Sealants were categorized as completely retained, partly retained or completely lost. No resealing was performed after the follow-up examinations. The diagnostic criteria for caries were consistent with those of the World Health Organization Oral Health Survey and assessed using a probe and by drying with compressed air. All carious lesions were restored after the visit, when there was definite softness or demineralization of the pit or fissure with a visually apparent defect or loss of enamel.

Statistical analysis
Statistical analysis of data was performed using SPSS 16 software. Retention rates were compared by the Mann-Whitney U test between HR and LR and between the two sealants. The incidence of caries was compared between the 2 sealants by the McNemar test for paired data, the relative risk of the caries was reported, as well as the 95% confidence interval and between HR and LR groups using Fisher chi-square test.

RESULTS
One-hundred and fifty teeth in 57 children with an average age of 7.2 years (range 6.1–8.9 years) were studied. The numbers of children and sealants that were lost over the 2 years are presented in Table 1. Patients who were lost to follow-up were not included in the statistical analysis.

The Kappa coefficient was 0.91 for intra-evaluator consistency, 0.78 for the inter-evaluator examination of sealant retention and 0.75 for the inter-evaluator diagnosis of caries. Retention rates at 6 months, 1 year and 2 years are shown in Fig. 1. The number of intact Fuji VII sealants after 2 years was 31.2% in the LR group and 44.5% in the HR group; 77.1% of Concise sealants remained intact in LR and 63% in HR. There was no statistically significant difference in survival between Fuji VII and Concise in the HR group at 2 years. Except at that time point, the retention rate of Fuji VII was significantly inferior to that of Concise. There was no statistically significant difference in retention of the same material and same observation period between LR and HR group (Table 2).

Comparison of caries rates of sealed tooth pairs between children at high and low risk of caries is shown

<table>
<thead>
<tr>
<th>Table 1 Numbers of children and sealants lost over 2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Baseline</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>2 years later</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Overall dropout rate: 6.60%. Reason of dropout: School transfer out of Peking; Immigrant abroad
in Table 3 and Table 4. After 2 years, there was no statistically significant difference in the incidence of caries between the 2 sealants in either HR or the LR group. The relative risk for Fuji VII-sealed tooth vs. Concise-sealed tooth of having detectable caries was 0.55 (95% CL: 0.117; 2.575) in LR group and 3.133 (95% CL: 0.314; 31.246) in HR group. Confidence limits included an invalid value (RR=1), the difference was not significant. Fuji VII sealant and Concise exhibited similar caries preventive effects in children at high and low risk of caries.

Comparison of caries rates between children at high and low risk of caries is shown in Table 5. For molars sealed with Fuji VII, the difference in caries incidence

![Fig. 1 Retention of Fuji VII and Concise sealants in HR and LR groups after 6 months, 1 year and 2 years (* p<0.05; ** p<0.01). The retention rate of Fuji VII was significantly inferior to that of Concise at 6 months, 1 year in both HR and LR group and at 2 years only in LR group. There was no statistically significant difference in retention between Fuji VII and Concise in the HR group at 2 years. There was no statistically significant difference in retention of the same kind sealant between LR and HR group.](image)

### Table 3 The cumulative caries rate of sealed tooth pairs after 2 years in the LR group from 57 children

<table>
<thead>
<tr>
<th>Detected caries</th>
<th>Tooth pairs</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>No</td>
<td>44</td>
<td>92.7</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td>1</td>
<td>2.1</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>3</td>
<td>6.2</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>48</td>
<td>100</td>
</tr>
</tbody>
</table>

### Table 4 The cumulative caries rate of sealed tooth pairs after 2 years in the HR group from 57 children

<table>
<thead>
<tr>
<th>Detected caries</th>
<th>Tooth pairs</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>No</td>
<td>21</td>
<td>77.8</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td>3</td>
<td>11.1</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>1</td>
<td>3.7</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>2</td>
<td>7.4</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>27</td>
<td>100</td>
</tr>
</tbody>
</table>

### Table 2 Comparison of retention of the same material and same observation period between LR and HR group

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>LR</th>
<th>HR</th>
<th>LR</th>
<th>HR</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
<td>Completely retained</td>
<td>33 (68.8%)</td>
<td>20 (74.1%)</td>
<td>45 (93.8%)</td>
<td>25 (92.6%)</td>
</tr>
<tr>
<td></td>
<td>Partly retained</td>
<td>12 (25%)</td>
<td>5 (18.5%)</td>
<td>3 (6.2%)</td>
<td>2 (7.4%)</td>
</tr>
<tr>
<td></td>
<td>Completely lost</td>
<td>3 (6.2%)</td>
<td>2 (7.4%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>1 year</td>
<td>Completely retained</td>
<td>20 (41.7%)</td>
<td>15 (55.6%)</td>
<td>41 (85.4%)</td>
<td>22 (81.5%)</td>
</tr>
<tr>
<td></td>
<td>Partly retained</td>
<td>22 (45.8%)</td>
<td>10 (37%)</td>
<td>7 (14.6%)</td>
<td>5 (18.5%)</td>
</tr>
<tr>
<td></td>
<td>Completely lost</td>
<td>6 (12.5%)</td>
<td>2 (7.4%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>2 years</td>
<td>Completely retained</td>
<td>15 (31.2%)</td>
<td>12 (44.5%)</td>
<td>37 (77.1%)</td>
<td>17 (63%)</td>
</tr>
<tr>
<td></td>
<td>Partly retained</td>
<td>24 (50%)</td>
<td>12 (44.4%)</td>
<td>11 (22.9%)</td>
<td>10 (37%)</td>
</tr>
<tr>
<td></td>
<td>Completely lost</td>
<td>9 (18.8%)</td>
<td>3 (11.1%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
Table 5  Comparison of caries incidence of teeth sealed with the same sealant material in HR and LR groups after 2 years

<table>
<thead>
<tr>
<th>Caries status</th>
<th>Fuji VII LR</th>
<th>Fuji VII HR</th>
<th>Concise LR</th>
<th>Concise HR</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caries present</td>
<td>3 (6.3%)</td>
<td>3 (11.1%)</td>
<td>1 (2.1%)</td>
<td>5 (18.5%)</td>
<td>12</td>
</tr>
<tr>
<td>Caries absent</td>
<td>45 (93.7%)</td>
<td>24 (88.9%)</td>
<td>47 (97.9%)</td>
<td>22 (81.5%)</td>
<td>138</td>
</tr>
<tr>
<td>Total</td>
<td>48</td>
<td>27</td>
<td>48</td>
<td>27</td>
<td>150</td>
</tr>
</tbody>
</table>

that in the HR group (p=0.038). In the Concise group, caries occurred in fissures from which sealant had been lost. Data sealant retention at 6 months and 1 year was not analyzed statistically because the numbers of caries were too low.

Figure 2 shows a representative sample of teeth 2 years after sealing.

DISCUSSION

GIC sealant has lower technique sensitivity than resin-based sealant. An advantage of Fuji VII is that visible light accelerates the curing process, minimizing the risk of salivary contamination. Another major advantage of GIC materials is fluoride release by the sealant. The fluoride released by Fuji VII 2 weeks after application was nine times greater than that released by fluoride-containing resin sealant, and it had a more pronounced effect in promoting remineralization of early artificial caries. Clinical evaluation of Fuji VII has shown this GIC sealant to have good fluidity and better fluoride-releasing properties as well as a higher fluoride recharge capacity than other sealants.

Cavitated caries in primary molars and past experience of caries have been suggested as caries predictors and enabled the selection of true caries-negative children and a high caries risk group from a 6–7-year-old Chinese child population. In the present study, individual caries experience in the primary dentition (dmft<2 or dmft>5) was the criterion used to divide patients into groups at high or low risk of caries. These same categories have been used as benchmarks in other studies.

Our study demonstrates that Fuji VII is useful as a pit and fissure sealant for children and effectively prevents caries. We found no statistically significant difference in the incidence of caries between Fuji VII and Concise sealants whatever in LR group or in HR group, which was consistent with studies on related materials. There might be several interpretations. First, the fluoride release from Fuji VII enhanced its caries-resistance ability. Fuji VII had significantly higher fluoride release than the other sealant materials at all times tested during 42 days. The pattern of fluoride release from Fuji VII was consistent, with an initial high release followed by low prolonged leakage before a return to the baseline value after 1 year.

Release of fluoride over the long term could enhance
the cariostatic ability of the surrounding enamel, and increase the acid resistance of the demineralized enamel in the fissures.\(^{33}\) Second, children were treated with 6,000 ppm fluoridated foam at every clinic recall and used 600 ppm fluoridated toothpaste twice every day during the experimental period. These sources of fluoride could be recharged by Fuji VII and release again, which favored the caries-preventive effect of Fuji VII. Thirdly, using scanning electron microscopy, a study has indicated that remnants of GIC sealant material are retained and block the deeper parts of pits and fissures, thereby continuing to have caries preventive effect even after the sealant appears to have disappeared clinically.\(^{7}\) Aranda & Garcia-Godoy also reported microscopic retention of GIC in the depths of fissures that was invisible to the naked eye.\(^{8}\)

In the present study, for molars sealed with Concise, the rates of development of caries were 2.1% and 18.9% in LR and HR subjects after 2 years respectively and there was significant difference. This result was in agreement with the failure rates of 8.1% and 17.8% found in the study of Simecek et al.\(^{39}\). The likelihood of caries development was thus high in HR subjects compared with LR subjects when tooth sealed with Concise. This agrees with Oulis, who discovered that children of a high baseline caries risk status showed higher occlusal caries prevalence following sealant loss compared with those of moderate and low risk status.\(^{35}\) Researchers pointed out that sealants block a susceptible surface without reducing etiologic factors of the caries activity of an individual.\(^{36,37}\) Another explanation was that more questionable or incipient fissure caries might have been sealed in those HR children and higher microleakage happened. The structure of enamel in pit and fissure have undergone changed before sealant application because of plaque accumulation during eruption.\(^{38,39}\) But this does not mean that sealing strategies are unnecessary in HR children. Recently published systematic reviews recommend fissure sealing in children at high risk of caries, and sealants have been shown to be more cost effective if used in patients with a high rather than low caries risk.\(^{18,19}\) These results indicate a need for comprehensive health promotion work to reduce overall caries activity in HR adolescents, including shorter recall intervals, professional tooth cleaning, changing children’s carbohydrate intake and oral hygiene habits, resealing in cases of sealant loss and combined use of topical fluoride.\(^{20,34}\)

For molars sealed with Fuji VII, the rates of development of caries LR and HR subjects were 6.3% and 11.1% respectively and there was no significant difference. Fluoride released from Fuji VII had specific caries-preventive effect and restrained caries from occurring, and this mechanism of Fuji VII reflected in the present study could be recharged by Fuji VII and release again, which reinforce the caries-preventive effect of Fuji VII.\(^{27}\)

In the present study, there was significant difference for sealant retention between materials for 2 years in LR group, although there was no significant difference for caries rate. The Concise performed better in terms of sealing ability than did the Fuji VII glass ionomer sealant and GIC suffered greater abrasion than resin sealant under similar conditions contributed to the lower retention of Fuji VII. But in LR children, the caries rate was low both in Concise sealed tooth and Fuji VII sealed tooth because microleakage leaded by microorganism erosion occurred infrequently and there was no difference in microleakage between the two materials under the stereomicroscope.\(^{42}\) But Fuji VII was more fluid than resin-based sealant, it could enter most of the fissures. Even after the sealant appears to have disappeared clinically, the remnants of GIC sealant material in the deeper parts of pits and fissures could release fluoride to protect the fissure from caries. Mahesh showed that fluoride released by the glass ionomer cements is able to produce an inhibitory effect against Streptococcus Mutans.\(^{44}\) Given these findings, the nature of GICs and modifications of the material may help explain why, in the present study, Fuji VII had a lower survival rate than Concise but a comparable cariostatic effect in whatever HR group or in LR group. Longer trials will be needed to confirm any differences in the caries preventive effects of GIC and resin-based materials.

With the observation time, the number of completely retained sealants showed a trend towards a decrease from 6 months, to 2 years. The retention situation of two sealants at the same point between HR and LR was not significantly different. The complete retention of Concise at the end of the 2 years was 77.1% in LR group and 63% in HR group. This result does not differ significantly from the data (80.2% complete retention) reported in study of Poulsen\(^{10}\). Oulis reported that 79.4% teeth in dmft=0 group and 69.1% in dmft>4 group need to be resealed or filled at 3 years, which was very close to our study. In the present study, Fuji VII sealant had a completely retention rate of 44.5% in the HR group and 31.2% in the LR group 2 years after application. In a study of resin-modified Fuji III LC, no seals were completely retained and 62% were partially retained 2 years after placement.\(^{45}\) Raadal reported that a resin-reinforced glass-ionomer cement (Vitrebond) was increasingly lost and could be observed in only 9% of the sealed sites after 3 years.\(^{9}\) Baseggio reported Resin-modified glass ionomer cement (Vitremer) 8.75% fully retention, 11.87% partial retention, 79.37% complete loss at 24 months. A meta-analysis revealed the low retention rates of glass-ionomer-cement-based sealants:
12.3% after 2 years, in which Fuji VII not included. Therefore, the survival rate of Fuji VII sealant is better than that of other low-viscous GICs. Another meta-analysis showed a full retention rate of 72% of high-viscosity GIC fissure sealants, as compared to 50% of low-viscous GIC material after 3 years. Further high-quality randomized control trials are needed in order to confirm such initial findings.

Our finding that Concise sealant was superior to Fuji VII with respect to retention agrees with most previous studies. This was significant at the 6 months and 1 year evaluation. This can be attributed to the low wear strength of GIC to occlusal force. Under functional state, Fuji VII became disintegrated and thinner, eventually fracturing it off from the tooth surface. A study has confirmed that GIC suffers greater abrasion than resin sealant under similar conditions. Unsurprisingly, most failures of resin-based sealant are due to de-bonding, formation of caries as a result of sealant leakage, and difficulty in application because of limited access or contamination.

The reason of retention difference between Fuji VII and Concise in HR group at 2 years was not statistically significant was difficult to confirm. Larger sample size might allow a more accurate judgment. But it was sure that bad oral microenvironment in HR children would lead more microleakage or caries happening in teeth sealed by Concise at 2 years than at 6 month or 1 year, which perhaps leaded additional sealant failed, so the retention difference between 2 sealants were not statistically significant any more.

The subjects in the present study included high caries risk children, so it was considered unethical in China not to use fluoride in the caries risk group. We applied topical fluoride treatment (6,000 ppm fluoridated foam) to children at every clinic recall and all subjects use 600 ppm toothpaste twice every day according to the WHO guideline. The fact that Fuji VII contains and releases fluoride but Concise does not could possibly interfere with the results as is always the situation in split-mouth studies. The caries-preventive effect with Fuji VII was equal with Concise in the present study, so this action theoretically did more favorable condition to Fuji VII. But this phenomenon showed the benefit of Fuji VII. It was difficult to calculate the effect of the use of fluoride, which is a weakness in this study.

CONCLUSIONS

Fuji VII sealant and Concise exhibited similar caries preventive effects in children at high and low risk of caries, though the retention of Fuji VII was poorer than that of Concise within two years.

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