

Clinical comparison of Fuji VII and a resin sealant in children at high and low risk of caries

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The purpose was to compare the retention and caries preventive effect of Fuji VII and a resin-based sealant in children at high risk (HR) and low risk (LR) of caries. Fifty-seven schoolchildren (150 teeth) with completely erupted bilateral permanent first molars were included. The study was a split-mouth, randomized trial. Sealant retention and caries were evaluated after 6 months, 1 year and 2 years. After 2 years, there was no statistically significant difference in the incidence of caries between Fuji VII and Concise in the HR and LR groups. With Concise, LR children were less likely to have dental caries than HR. With Fuji VII, there was no difference in caries incidence between LR and HR. Retention of Concise was superior to that of Fuji VII. Our results suggest that Fuji VII and Concise sealants had similar caries preventive effects in children at high and low risk of caries.

Keywords: Pit and fissure sealant, Fuji VII, Glass ionomer, Caries risk

INTRODUCTION

Pit caries accounts for about 90% of the total incidence of caries in children and adolescents¹ 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 caries². 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^{3,4}. 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^{5,6}, 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^{7,8}. However, the effect on caries reduction of GIC is equivocal due to its unsatisfactory retention rate^{9,10}. 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 GICs¹¹⁻¹³, but questions remain regarding its clinical performance compared with resin sealants¹⁴⁻¹⁶.

The results of studies assessing the effectiveness of fissure sealant according to patients' caries risk status

have been contradictory^{17,18}. Some studies have shown that fissure sealants are more effective if used in HR rather than low risk (LR) children^{18,19}; others have found that the higher the dft, the higher the risk of fissure sealant failure²⁰, though such sealants are effective in individuals with low or moderate carious activity²¹. 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 according to Ditmyer *et al.*²² and Kneist *et al.*²³: 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.

These two authors 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 1 Numbers of children and sealants lost over 2 years

	Fuji VII		Concise	
	HR group	LR group	HR group	LR group
Baseline	Children: <i>n</i> =21 tooth: <i>n</i> =29	Children: <i>n</i> =40 tooth: <i>n</i> =50	Children: <i>n</i> =21 tooth: <i>n</i> =29	Children: <i>n</i> =40 tooth: <i>n</i> =50
2 years later	Children: <i>n</i> =19 tooth: <i>n</i> =27	Children: <i>n</i> =38 tooth: <i>n</i> =48	Children: <i>n</i> =19 tooth: <i>n</i> =27	Children: <i>n</i> =38 tooth: <i>n</i> =48

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

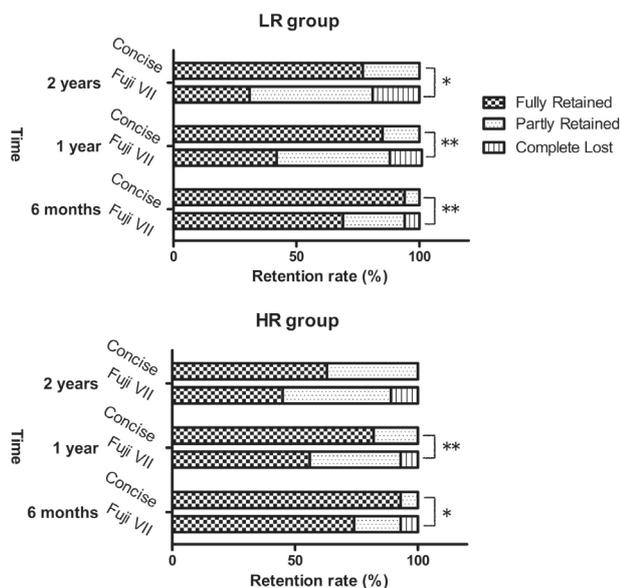


Fig. 1 Retention of Fuji VII and Concise sealants in HR and LR groups after 6 months, 1 year and 2 years (* $p < 0.05$; ** $p < 0.01$).

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.

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

Detected caries		Tooth pairs	
Fuji VII	Concise	<i>n</i>	%
No	No	44	92.7
No	Yes	1	2.1
Yes	No	3	6.2
Yes	Yes	0	0
Total		48	100

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

Detected caries		Tooth pairs	
Fuji VII	Concise	<i>n</i>	%
No	No	21	77.8
No	Yes	3	11.1
Yes	No	1	3.7
Yes	Yes	2	7.4
Total		27	100

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

		Fuji VII		Concise	
		LR	HR	LR	HR
6 months	Completely retained	33 (68.8%)	20 (74.1%)	45 (93.8%)	25 (92.6%)
	Partly retained	12 (25%)	5 (18.5%)	3 (6.2%)	2 (7.4%)
	Completely lost	3 (6.2%)	2 (7.4%)	0 (0)	0 (0)
1 year	Completely retained	20 (41.7%)	15 (55.6%)	41 (85.4%)	22 (81.5%)
	Partly retained	22 (45.8%)	10 (37%)	7 (14.6%)	5 (18.5%)
	Completely lost	6 (12.5%)	2 (7.4%)	0 (0)	0 (0)
2 years	Completely retained	15 (31.2%)	12 (44.5%)	37 (77.1%)	17 (63%)
	Partly retained	24 (50%)	12 (44.4%)	11 (22.9%)	10 (37%)
	Completely lost	9 (18.8%)	3 (11.1%)	0 (0)	0 (0)

Table 5 Comparison of caries incidence of teeth sealed with the same sealant material in HR and LR groups after 2 years

	FujiVII		Concise		Total
	LR	HR	LR	HR	
Caries present	3 (6.3%)	3 (11.1%)	1 (2.1%)	5 (18.5%)	12
Caries absent	45 (93.7%)	24 (88.9%)	47 (97.9%)	22 (81.5%)	138
Total	48	27	48	27	150

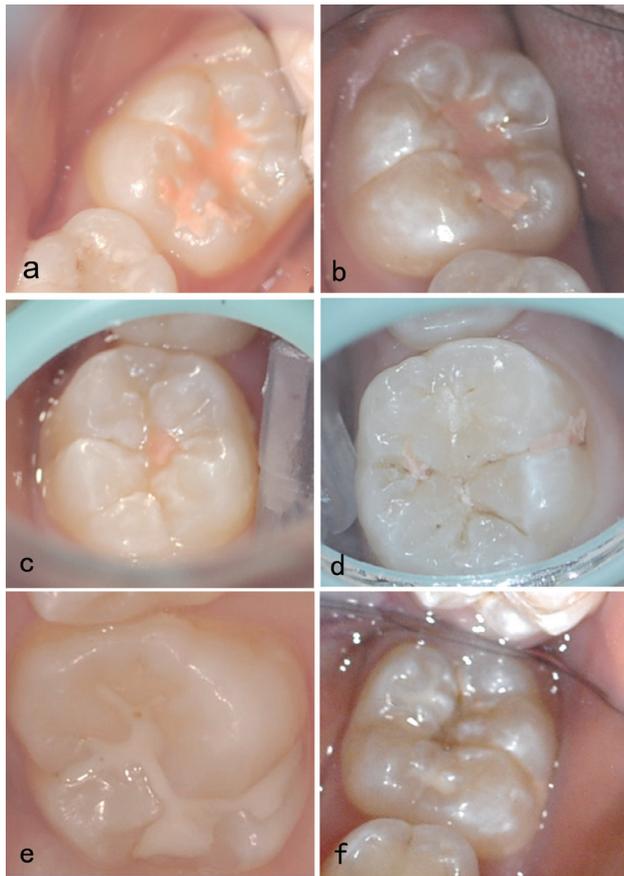


Fig. 2 Representative sample of teeth 2 years after sealing. (a) Fuji VII sealant completely retained after 2 years. The pink appearance aids observation. (b) Fuji VII partly retained after 2 years. Fissure was clean and caries free. (c) Another Fuji VII sealant partly retained after 2 years. (d) Fuji VII was almost completely lost after 2 years. Fissure was stained but hard. (e) Concise sealant completely retained after 2 years. (f) Concise sealant partly retained after 2 years. Where the sealant had been lost, caries had developed.

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^{24,25}. 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^{26,27}. Clinical evaluation of Fuji VII has shown this GIC sealant to have good fluidity and better fluoride-releasing properties^{11,15,27} as well as a higher fluoride recharge capacity than other sealants²⁷.

Cavitated caries in primary molars and past experience of caries have been suggested as caries predictors^{28,29} and enabled the selection of true caries-negative children and a high caries risk group from a 6–7-year-old Chinese child population³⁰. 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^{22,31}.

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^{15,32}. 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 days²⁷. 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 year¹¹. Release of fluoride over the long term could enhance

between LR and HR was not significant ($p=0.76$), whereas for molars sealed with Concise, the caries incidence in the LR group was significantly lower than

the cariostatic ability of the surrounding enamel, and increase the acid resistance of the demineralized enamel in the fissures³³). 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 clinically⁷. Aranda & Garcia-Godoy also reported microscopic retention of GIC in the depths of fissures that was invisible to the naked eye⁹).

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.*³⁴). 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 status³⁵). 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^{35,38}). 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 caries³⁹), 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 both HR and LR group. Considering that fluoride release by Fuji VII is supposed to be six-times the release of fluoride than any other Glass ionomer, Mousavinasab measured the amounts of fluoride released from fluoride-containing materials, recovered that the maximum cumulative fluoride release was related to Fuji VII,

followed by Fuji IX Extra, Fuji II LC, Fuji IX, Dyract Extra and Beautifil in descending order and this order remained the same until the end of the experimental period¹²). As glass ionomers have the ability to reload fluoride from outside sources, the application of fluoride in the present study could be recharged by Fuji VII and release again, which reinforce the caries-preventive effect of Fuji VII²⁷).

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 sealant⁴⁰) and GIC suffered greater abrasion than resin sealant under similar conditions⁴¹) 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 led by microorganism erosion occurred infrequently and there was no difference in microleakage between the two materials under the stereomicroscope⁴²). But Fuji VII was more fluid than resin-based sealant⁴³), 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 (80.21% complete retention) reported in study of Poulsen¹⁰). 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 years³⁵), 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 placement⁴⁵). 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 years⁹). Baseggio reported Resin-modified glass ionomer cement (Vitremmer) 8.75% fully retention, 11.87% partial retention, 79.37% complete loss at 24 months⁴⁶). A meta-analysis revealed the low retention rates of glass-ionomer-cement-based sealants:

12.3% after 2 years, in which Fuji VII not included⁴⁷. 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 years⁴⁸. 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^{14,16}. 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 conditions⁴¹. Unsurprisingly, most failures of resin-based sealant are due to debonding, 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 led 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 recharges fluoride but Concise does not²⁷ 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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