

Clinical Evaluation of FUJI VII Sealant Material:

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200 children of the age groups of 3-5 years and 6-7 years were selected for sealant application, each consisting of 100 children. The clinical retention of Fuji VII was tested in both primary and permanent molar teeth at time intervals of 6 months, 12 months and 24 months follow-up and compared with a resin based sealant, Concise. Results demonstrated that there was no difference in the performance of the materials in primary and permanent teeth.

Key words: sealant, pits & fissure, retention.

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INTRODUCTION

In this era of preventive dentistry galore of dental materials for prevention of dental diseases are available. Since last decade efforts are being directed towards prevention of dental caries which is the major dental disease. The main avenues available are plaque control, use of systemic and topical fluorides and fissure sealants. Though use of fluorides has been shown to be very effective, their relative effect is seen to be least for pits and fissures. Keeping in mind the proneness of the occlusal surfaces towards caries, maintenance of oral hygiene in conjunction with fluoride therapy and prudent use of pit and fissure sealant seems to be the best preventive strategy.

The anatomical pits and fissures of the teeth have long been recognized as susceptible areas for initiation of dental caries. Fissures or narrow isolated crevices and grooves that harbor food and microorganisms have been described as "the single most important anatomical feature leading to the development of occlusal caries". The extreme vulnerability to decay of these areas on the occlusal surfaces has prompted dental scientists to seek methods of caries prevention, mainly for the pits and fissures.

Keeping in mind the proneness of the occlusal surfaces towards caries maintenance of oral hygiene in conjunction with fluoride therapy and prudent use of pit and fissure sealant seems to be the best preventive strategy.

Taking into consideration a developing country like India, the low dentist to patient population ratio makes the preventive measures towards oral health imperative. Even if the initial cost of preventive measures like sealants may be higher than the cost of restorative

materials like dental amalgam, at long term basis sealant or any other preventive measure would be more cost effective as the tooth is being maintained in the state of health.

For variety of reasons fissure sealant have not been widely accepted by the dental profession, despite overwhelming evidence in support of their caries preventive potential. The main problems usually encountered are towards retention of the sealant or microleakage leading to deterioration of the materials and increased possibility of development of caries. Several studies have been done to compare resin and glass ionomer sealant. Recently, Fuji VII has been launched in Indian market which has been claimed to have all the properties of an ideal sealant material. Not many scientific studies have been conducted on this material until. Also with the introduction of a new material it is pertinent to re-examine its properties today. Motivated by the role of sealant in caries prevention, a study was undertaken to compare the efficacy of Fuji VII and Concise (resin based sealant) as sealant material.

MATERIALS AND METHODS

A total of 200 children with informed consent from the parents were included from seven different schools in Udupi district of Karnataka state, India. These children were divided into two groups of 100 each. Group I comprised children in the 3-5 years age group for sealant application on second primary molars and Group II with children of 6-7 years age group for sealant placement on the first permanent molars. A randomized bilateral study design was followed in which both sealant materials were applied in the same mouth on contra-lateral teeth for direct comparison of the material performance under similar environmental conditions. For each of these patients, Fuji VII (glass ionomer pink sealant, GC Corporation - Tokyo, Japan) was placed on one side while Concise (unfilled white resin sealant, 3M ESPE Dental Products, St.Paul, Minn) was used on the contra-lateral tooth.

Selection criteria:

- The children should have the teeth present in the arch for which sealant application was intended.
- The teeth in question should have erupted less than 4 years ago.
- The teeth selected should be free of any caries.

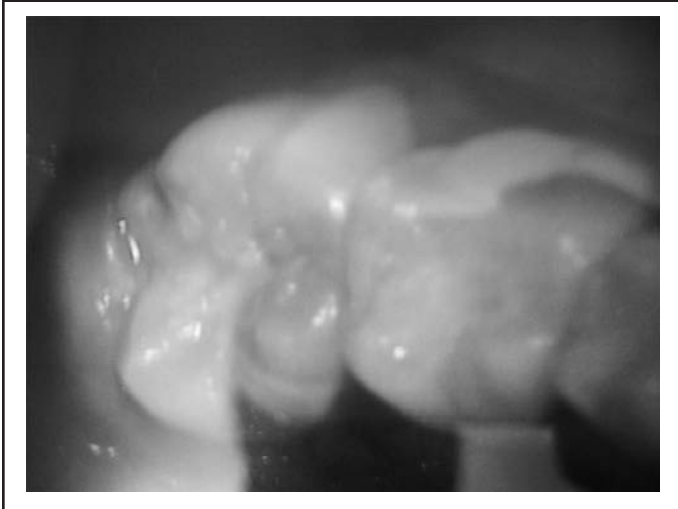
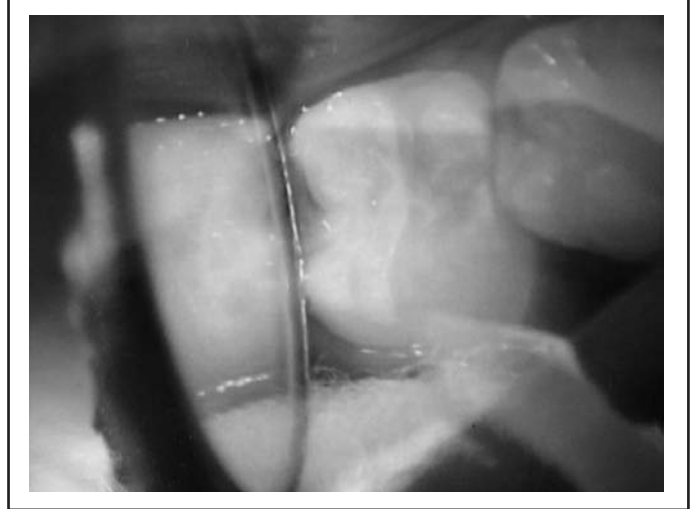
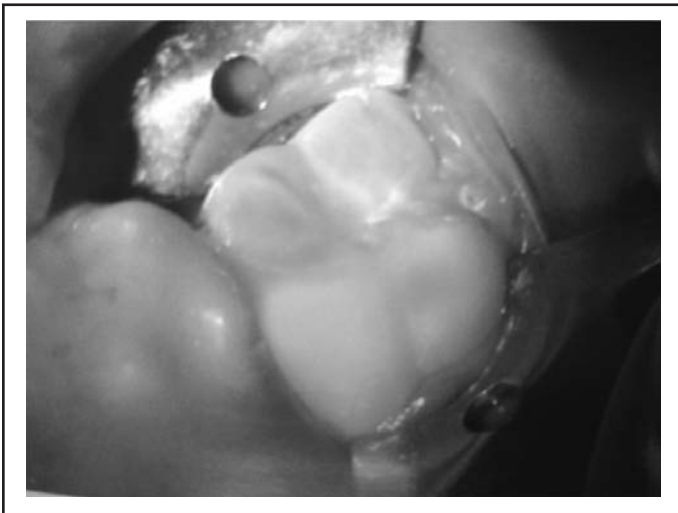
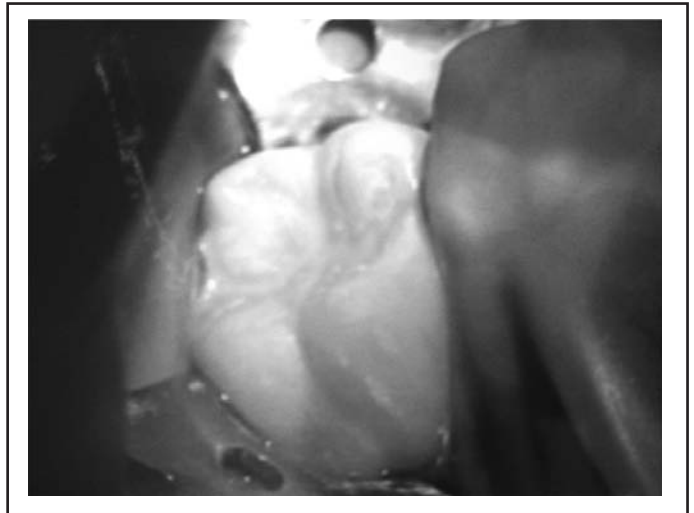
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Figure 1: Partial sealant retention in Fuji VII group**Figure 2:** Partial retention in Concise group**Figure 3:** Complete retention in Fuji VII**Figure 4:** Complete retention in Concise group

- The teeth selected should be healthy, non-hypoplastic with complete tooth structure intact.

Procedure for sealant placement:

1. The teeth selected for sealant application were isolated either using cotton roll and suction or with the help of rubber dam wherever placement was feasible.
2. Sealant placement was then carried out following the manufacturer's instructions.

For Concise group, the steps in the placement were as follows:

1. Cleaning of tooth surfaces: It was done using a polishing brush cone in a slow speed hand piece, while applying a constant stream of water.
2. Cleaning the pits and fissures: Pits and fissures were thoroughly cleaned using an explorer probe.
3. Acid-etching: Etchant Gel (35% phosphoric acid) was dispensed onto the mixing plate and a small disposable brush was used for application. The etchant was allowed to remain in place for about 15 seconds; tooth was flushed with water for another 15 seconds to wash off the etchant and the surface was dried in oil free compressed air thoroughly to get a frosty white appearance.

4. Resin placement: Applicator cap was removed and the applicator nozzle was attached. The tip was bent for easy access and convenient handling. Then the applicator nozzle was placed against the tooth pits and fissures and the barrel of the applicator was gently squeezed for precise resin placement.
5. Light curing: The emitting tip of the curing light was held vertical to the resin surface and about 1 mm away; light cured for 20 seconds.

For Fuji VII, steps in the placement were as follows:

1. Cleaning the tooth surfaces: Plaque was removed from the pits and fissures and the area was carefully cleaned with a brush cone under running water.
2. Rinsing with water and drying: Area was rinsed with water and the tooth surface was gently dried using an air syringe as instructed by the manufacturer making sure not to desiccate the surface.
3. Mixing:
 - a) Powder/Liquid ratio: For standard consistency, the powder-to-liquid ratio was taken as 1.8 grams of powder to 1 gram of liquid. This was approximated by mixing one drop of liquid with level spoonful of powder using the measuring spoon provided.
 - b) Procedure: The correct amounts of powder and liquid were

placed on one of the mixing pads provided. Powder and liquid were mixed with a plastic spatula. As a standard mixing practice powder was divided in half. The liquid was added to one half and mixed for 7 to 10 seconds (Until it reached a uniform milky state). This was then added to the remaining powder and mixed for 15 to 20 seconds using mixing pad widely to achieve a uniform mix.

4. Application: An accessory applicator was used to apply the mixed cement into the pits and fissures.
5. Light curing: The emitting tip of the curing light was held vertical to the sealant surface and about 1 mm away; then it was light cured for 20 seconds.
6. Application of Fuji Varnish: When the cement lost its gloss, Fuji Varnish was applied to its surface also to the adjacent areas using the accessory sponge soaked in the varnish. Then it was gently dried with an air syringe. This varnish consisted of copal resin or synthetic resins in aqueous solution of chloroform or acetone. This was done for surface protection of the sealant material as it is moisture sensitive during initial stages of setting.

Follow-up:

Following a single application of the sealants, the patients were followed up at time intervals of 6 months, 12 months and 24 months to evaluate the retention of the materials.

Criteria for evaluation :(Simonsen) 1

- Score 0: no loss of sealant and no evidence of caries
- Score 1: partial loss of sealant and no evidence of caries
- Score 2: partial loss of sealant and evidence of caries
- Score 3: complete loss of sealant and no evidence of caries
- Score 4: complete loss of sealant and evidence of caries

Thus, following this criteria the lower score attained by any material indicates its better performance in terms of retention as compared to one obtaining a higher score.

Evidence of caries was evaluated by the use of visual and tactile method for caries detection using mirror and explorer probe.

The results obtained were analyzed for statistical significance using SPSS-PC package using the statistical tests required.

RESULTS

The retention of the materials was evaluated at time intervals of 6 months, 12 months and 24 months follow-up. Results were analyzed using SPSS-PC package.

During the 6th month follow up, the mean values of different groups showed that least mean value was in Fuji VII (permanent) group with 0.745 + 0.54, giving the best performance in terms of retention. During the 12th month follow-up, the performance of the materials in ascending order is like: Fuji VII (permanent), Concise (primary), FujiVII (primary) followed by Concise (permanent). At 24th month, the best retention score was shown by FujiVII (permanent) group (TABLE 1). Intra-group comparison of sealant retention in Fuji VII group showed a significant reduction in retention in both permanent and primary teeth during all the follow-up periods (TABLE 3). Inter-group comparison between permanent and primary molar for Fuji VII and Concise (TABLE 4) showed significant difference in retention with a “p” value of 0.01 in permanent as well as deciduous molars at 12th and 24th month follow-ups respectively.

DISCUSSION

In this era of preventive dentistry galore of dental materials for prevention of dental diseases are available. Since the last decade efforts are being directed towards prevention of dental caries. The main avenues available are plaque control, use of systemic and topical fluorides and use of fissure sealants. Though use of fluorides has been shown to be very effective, their relative effect is seen to be least for pits and fissures. The rationale of using fissure sealant is, when applied on caries prone fissures, it penetrates these pits and fissures and seals them from the oral environment. Also the microorganisms present in these fissures lose their viability. The latest generation sealants have the added advantage of having fluoride incorporated into them. Anti-caries effect of fluorides is a well proven fact. There are many factors that contribute towards a successful sealant restoration such as properties of enamel, duration of etching, acid used in etching and other manipulative variables. However, the prime factors governing the efficacy and life expectancy of a sealant are marginal adaptability, which is reflected by the retention of the material.

In the age group of 3-5 years, the primary second molar were chosen for sealant application² while in the 6-7 years age group, the first permanent molar was chosen for sealant application.³ Since Fuji VII is a new material ,this study was designed to evaluate its efficacy as a sealant material and its performance was compared with a resin based sealant material (Concise).⁵ The sealant application was done using proper isolation using rubber dam wherever possible or thorough cotton roll isolation was undertaken. Their authors found that there exists no difference in efficacy of the sealant using any method of isolation.⁶ Manufacturer’s instructions were meticulously followed for sealant application and single operator applied the sealants in all the children, in order to avoid operator variability.⁷ As both the sealants were tinted, were easily visible and less chair-side time was needed during follow-up.³ Same operator carried out the follow-ups.

Mean sealant retention scores at different time intervals in each subgroup:

The best performance in terms of retention was obtained by Fuji VII (permanent) group as the lowest mean values were seen in this subgroup.

Intragroup comparison of sealant retention in Concise group used in permanent molars:

From the obtained values it could be found that there was a statistically significant difference in retention for Concise between 6th month and 12th month but subsequently there was no much change. Similar results were seen by Powell *et al*⁸ where there was initial loss of the sealant material, but later it remained stable. This could be attributed to the fact, some sealant remains in excess on the pits and fissures which may not be apparent clinically. This excess material gets split off under the influence of occlusal forces, instead of the bulk of the sealant which persists for a considerable time period undergoing wear at a very slow rate.

Intragroup comparison of sealant retention in Concise group used in primary molars:

Statistical evaluation gave similar results as seen for Concise in permanent teeth. These results were also seen by Simonsen⁹ who also tested the retention of the sealants in primary molars and found

RESULTS

TABLE 1: Mean sealant retention scores at different time intervals in each sub groups

	6 th MONTH	12 th MONTH	24 th MONTH
CONCISE (PER)	1.15+1.03	1.954+1.077	1.977+1.14
CONCISE (DEC)	0.846+0.847	1.564+0.944	1.692+1.01
FUJI VII (PER)	0.745+0.544	1.203+0.846	1.58+0.97
FUJIVII (DEC)	1.10+0.944	1.75+1.085	1.96+1.146

Total sample size in each subgroup: 100

TABLE 2: Intragroup comparison of sealant retention in concise group used in permanent & primary molars

Follow-ups (months)	N	Mean		Standard deviation		Z		P value	
		P	D	P	D	P	D	P	D
6 vs 12	100	0.77	0.71	1.02	1.02	3.90	3.58	0.015 S	0.01 S
12 vs 24	100	2.22	0.12	0.15	0.47	1.00	1.63	0.317	0.10
6 vs 24	100	0.80	0.84	1.01	1.03	3.99	3.88	0.01 S	0.02 S

Wilcoxon signed rank , S -“p” value <0.05

TABLE 3: Intragroup comparison of sealant retention in FUJI VII group used in permanent & primary molars

Follow-ups (months)	N	Mean		Standard deviation		Z		P value	
		P	D	P	D	P	D	P	D
6 vs 12	100	0.46	0.64	0.76	0.43	3.83	4.98	0.01S	0.04 S
12 vs 24	100	0.36	0.21	0.76	1.01	3.14	2.87	0.01S	0.013 S
6 vs 24	100	0.83	0.86	0.93	0.63	4.82	5.65	0.02S	0.016S

Wilcoxon signed rank, S -“p” value <0.05

TABLE 4: intergroup comparison between permanent & primary molar for FUJI VII and concise

Follow-up (months)	6 th MONTH		12 th MONTH		24 th MONTH	
	P	D	P	D	P	D
MEAN	0.745	0.8462	1.2034	1.564	1.582	1.692
STANDARD DEVIATION	0.544	0.8747	0.8863	0.9946	0.9739	1.0
Z	1.735	1.479	2.087	1.708	1.973	1.0263
P VALUE	0.083	0.143	0.01 S	0.366	0.054	0.017S

Mann Whitney S-“p” value <0.05

TABLE 5: Sealant retention in percentage for concise & FUJI VII at different time intervals

SAMPLE: 100	PERMANENT						DECIDUOUS					
	6 th		12 th		24 th		6 th		12 th		24 th	
	C	F	C	F	C	F	C	F	C	F	C	F
COMPLETE RETENTION	(32)%	(30%)	(4%)	(2%)	(4%)	(2%)	(40%)	(60%)	(8%)	(4%)	(4%)	(4%)
PARTIAL RETENTION	(66%)	(68%)	(66%)	(70%)	(66%)	(68%)	(56%)	(24%)	(66%)	(56%)	(66%)	(28%)
COMPLETE LOSS	(2%)	(2%)	(30%)	(28%)	(30%)	(30%)	(4%)	(4%)	(26%)	(50%)	(30%)	(68%)

that the greatest loss of the sealants occurred during early follow-up and later on the rate of loss gets stabilized and is slower.

Intragroup comparison of sealant retention in Fuji VII group used in permanent molars:

In this experimental group when the follow-up scores were compared, there existed a statistically significant difference in the retention rates of Fuji VII between 6th month and 12th month, 12th month and 24th month and hence 6th month and 24th month scores also showed the same results. This indicates that there is a gradual loss in the retention of the material during all the follow-up periods. Although there are no published studies on Fuji VII, but studies on retention of other glass ionomers have shown that retention of the material is poorer. Apparently, the reasons for choosing glass ionomers as sealant material are due to other qualities than good retention. In a population with low caries risk as in the present study, where these children were regularly seen and followed-up under the school health program, a satisfactory goal might be to seal the pits and fissures of the teeth for first few years after eruption when the risk of caries is highest. Long-term retention might be less important; even more if the sealant material contains fluoride, which is taken up by the adjacent teeth.

Intragroup comparison of sealant retention in Fuji VII group used in primary molars:

The retention rates of Fuji VII on primary teeth gave similar results to one obtained for the permanent teeth where there is a significant difference in the retention rate when 6th month, 12th month and 24th month scores were compared.

These results are comparative to that obtained by Williams and Winter¹⁰ who found there was a loss of the material during follow-ups thus a decrease in retention scores. This has been thought to depend on the unfavorable fissures morphology of the teeth.

Intergroup comparison for Concise in primary and permanent teeth:

No significant difference could be found in the retention rates of Concise in primary and permanent teeth during the follow-up periods. Other authors² have shown that comparable rates of retention can be accomplished for primary and permanent teeth. No special treatment such as increasing the etching time from 60 seconds to 120 seconds was necessary when applying sealants for primary teeth.

Intragroup comparison for Fuji VII in primary and permanent teeth:

No significant difference could be found in the retention rates of Fuji VII in primary and permanent teeth during the follow-up periods.

Comparison between Fuji VII and Concise in permanent molar:

There existed a statistically significant difference in the retention rate between the two materials at 24th month. It was seen from the performance of Fuji VII that there is a gradual loss in the retention of the material during all the follow-up periods in contrast to that shown by Concise. Concise though it showed an initial loss of retention during the 6th month follow-up but later on during subsequent follow-ups, it got stabilized with not much appreciable change in the

retention rate of the material. Studies by Forss et al¹¹ found similar results where the performance of resin sealants was better than GIC sealants.

Comparison between Fuji VII and Concise in primary molar:

When the retention of both the materials compares at differently time intervals, a statistically significant difference was seen in the retention between the materials at 12th month follow-up. From the results obtained from the intergroup comparisons it could be derived that the Concise material performed better than Fuji VII in terms of retention. Concise sealant comes in a fluid form, which maintains a constant viscosity until cured with visible light. Fuji VII on the other hand comes as a powder /liquid system. Though a correct powder-liquid ratio was followed, but minor variations might have caused some change in the viscosity of the materials during its application to the pits and fissures system. Brooks *et al*¹² found that the ability of the sealants to penetrate the micropores of the pits and fissures could be greatly influenced by the viscosity of the material. This could be a factor, which might have contributed to the lower retention performance seen by Fuji VII as compared to Concise.

Percentage of sealant retention at different time intervals in each subgroup:

When we look at the retention of the sealants in terms of percentage almost 67-70% of the samples i.e. almost 32-35 samples out of 50 in each sub-groups at various follow-up periods showed partial retention. These results are lower than values found by studies conducted by Hardison² in primary teeth and by Simonsen⁹ in permanent where a high percentage of complete retention had been seen. This could be due to the fact that in these studies they have used a different method for recording the retention of the material. They have divided the occlusal surface of the teeth into different surfaces like mesial, distal, palatal etc. Therefore, if a sealant is partially retained on one surface, yet completely retained on the other two, two surfaces would be added to the completely retained surfaces category and only one surface to the partially retained group. If the complete tooth is used as in the present study for as the means for assessing retention, it would mean that the whole teeth would be regarded as partially retained. In none of the patients in any groups initiation of caries could be elicited. This could be due to the fact that

- There remained some amount of sealant into the depths of the pits and fissures even when the bulk is clinically lost.¹³
- It could be due to the fluoride release of glass ionomer sealant like Fuji VII.¹⁴
- An extended follow-up of more than 2 years might give a clearer picture in this regard.

SUMMARY AND CONCLUSIONS

The retention of the materials was evaluated at time intervals of 6 months, 12 months and 24 months follow-up. The results obtained were subjected to statistical analysis and the following conclusions could be drawn:

1. When the performance of the materials was seen in terms of retention during the follow-up periods of 6th month, 12th month and 24th month, Fuji VII sealant showed the lowest mean retention score among all the sub-groups at different follow-ups.
2. But, when a direct comparison between Fuji VII and Concise was done in both primary and permanent teeth there existed a statis-

tically significant difference in performance of the materials. This difference could be seen at the 12th month follow-up in the permanent molar and during the 24th month follow-up in primary molars.

3. There was no difference in the performance of the materials in primary and permanent teeth.

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