

The clinical effectiveness of a colored pit and fissure sealant at 24 months

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Abstract

In 1100 permanent and deciduous teeth examined two years after application of a colored sealant, 31 surfaces showed partial loss of the sealant. No teeth lost all of the sealant. Three of the 31 surfaces that lost sealant became carious prior to sealant reapplication. No difference in retention was found when the etch time for deciduous molars was varied (60 sec. or 120 sec.). Loss of sealant is attributed almost exclusively to a breakdown in the application technique. The sealant used in this study was found to be an effective material for protecting occlusal, buccal, and lingual pits and fissures against caries. The unique white color gives this sealant several advantages over the more common clear resin sealants.

Introduction

Since the first report of a clinical trial using a pit and fissure sealant by Cueto and Buonocore,¹ many published studies have documented the caries preventing aspect of sealants.²⁻²² Buonocore found 100% caries reduction at 12 and 18 months and 96% caries reduction after two years on 200 sealed pits and fissures of deciduous and permanent teeth.²³ More recent results, including Horowitz, Heifetz and Poulsen,¹⁵ report total sealant retention of 42% five years after treatment. This investigation together with Rock's work¹⁸⁻¹⁹ prove beyond question that if the sealant is retained, pit and fissure caries will be prevented. The goal now must be to study and improve, either by technique or materials, the retentive quality of pit and fissure sealants, and to study their overall place in dentistry today from a preventive viewpoint.

The objective of this study was to test the clinical effectiveness of a sealant containing titanium dioxide

added as a white coloring agent.* The addition of color to a sealant greatly improves operator visual perception at application and recall examination. A secondary objective was to observe the retention of the sealant when variables such as etch time, wash time after etching, fluoride content of the resin, and filler content of the resin were introduced.

The study population resides in suburban Minneapolis which is a fluoridated area (1.2 ppm).

Materials and Methods

The sealant under study is a diluted bis-GMA type resin.* Polymerization occurs chemically and the sealant is opaque white in color thus allowing total visualization during application and clarity on recall. The white color comes from the addition of 1% titanium dioxide. As can be seen from Figures 1-3, the color also simplifies the maintenance of retention records by utilization of clinical photographs.

Patients were selected at random from the Preventive Dental Health Program at Group Health Medical Center, Bloomington, Minnesota, and they ranged in age from three to 15 years. Most of the children were seven to 11 years of age with 27% of the children aged seven and eight at application time. Initially 472 children were sealed, over a period of 18 months. This report covers the first 164 patients who reported for recall two years after sealant application. Since, at each recall, the sealant retention was observed to improve as more patients were examined (Table 8), reaching a plateau retention rate after approximately 100 patients had been sealed, it was decided to use a smaller sample for the one and two year reports. A larger sample size would be expected to slightly improve the results.

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* CONCISE Brand White Sealant System, 3M Co., St. Paul, Minnesota.



Figure 1. At the six-month recall, all the sealant was still present, including all the lingual grooves. These lingual grooves and the buccal grooves of mandibular molars will retain sealant almost as well as occlusal grooves, if proper application techniques are adhered to.

Since unsealed homologous paired teeth can not, for ethical reasons, be utilized as controls, a control group of patients was selected. Unfortunately, this group decreased to a non-valid sample size, as many parents of control group children requested sealant application for their children. Such requests were honored.

All available non-carious, non-restored posterior permanent and deciduous teeth were sealed for the purpose of studying retention in all conditions. Thus, teeth were included where retention could be expected to be poor, such as in areas of difficult access or poor moisture control, and where tooth anatomy (rounded grooves) or early eruptive stage reduced the retention prognosis.

After clinical (sharp Starlite No. 5 explorer) and roentgenographic (bitewings) diagnosis to eliminate carious or questionable teeth, parental approval was obtained prior to scheduling for sealant application. In order to keep the technique as uniform as possible, all sealants were placed by one operator with the same assistant in the same operatory. The unit was complete with vacuum suction and compressed air/water for cleaning and drying etched teeth.

On seating the patient, the time was noted and the procedure timed to completion. Cotton rolls were chosen as the most reliable method of isolation. The teeth were cleaned in the areas to be sealed using a pointed bristle brush (dry), water and air. An explorer tine was used to remove as much residual plaque from the grooves as possible. Thirty-seven percent orthophosphoric acid was used as the etchant. This strength of acid falls within the range (30 to 40%) regarded as ideal by Silverstone.²⁴ Small cylin-

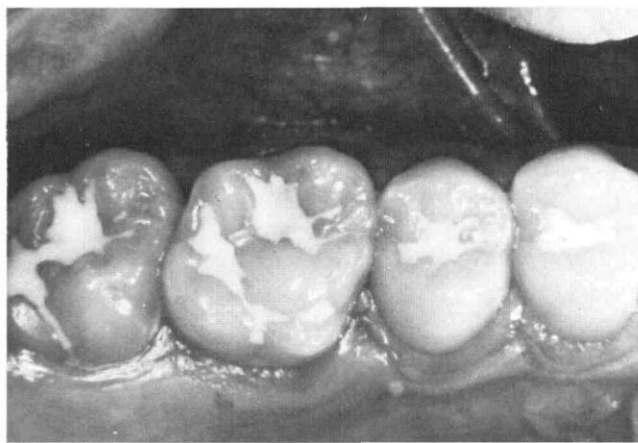


Figure 2. Two years after application, the shadow from the covered amalgam in the first molar becomes more apparent. No further loss of the material has occurred, however, and the patient has remained caries-free since sealant application was carried out on all four quadrants. The white color in the sealant allows, by comparison with previous photographs, confirmation of suspected loss areas and elimination of any doubt as to where the sealant was applied. Recall examinations are also much more rapid when the sealant is so clearly seen.

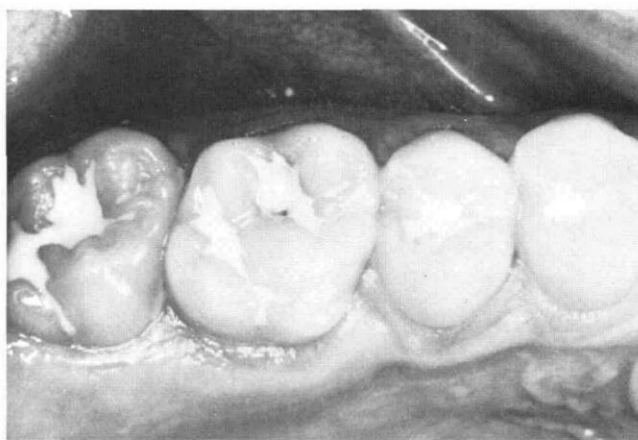


Figure 3. Three years after sealant treatment, it can be seen that the amalgam that was covered by the sealant is now uncovered. By comparing this photograph with Figures 1 and 2, one can see that very little significant wear of the sealant has taken place since the six-month photograph.

drical-shaped sponges were used in a lockable cotton pliers and found to be very useful for applying the etchant, but not satisfactory for applying sealant. The sponges are in fact contraindicated for sealant application, since they become quickly saturated with resin. Pressure on the tooth is then necessary to extract the resin from the sponge. This can damage the delicate enamel latticework created by etching and can also

Table 1. Retention of white sealant system 24 months after application

Teeth	No. of Teeth Sealant Applied	No. and Completely Retained %	No. and Partially Missing %	Totally Missing %
Permanent	778	747 (96.0%)	31 (4.0%)	0
Deciduous	322	318 (98.8%)	4 (1.2%)	0
Total	1100	1065 (96.8%)	35 (3.2%)	0

Total number of patients: 164

The 31 permanent surfaces showing partial loss include 12 surfaces with sealant present after having been reapplied at an earlier recall. Three of the 31 surfaces showing partial sealant loss became carious prior to sealant reapplication.

Table 2. Patient age at application of sealant for subjects examined at 24 month recall

Subject Age:	3	4	5	6	7	8	9	10	11	12	13+	Years
% of total:	3	3	5	6	13	14	12	13	15	7	9	%

Table 3. Distribution of sealed permanent teeth at 24 months

	No.	%
First bicuspid:	136	17.5%
Second bicuspid:	128	16.4%
First molars:	456	58.6%
Second molars:	58	7.5%
Total	778	100.0%

cause bubbles to be introduced into the sealant. In this study a disposable nylon brush was used for sealant application.

Permanent teeth were etched for 60 seconds and deciduous teeth for 120 seconds (or 60 seconds, as described later). After etching, the teeth were washed thoroughly with copious amounts of water under pressure. (Differential wash time experiment is described later). A water/air spray was used towards the end of the washing procedure before non-contaminated air was applied to thoroughly dry the teeth to be sealed. Air hoses were periodically checked for oil and/or water contamination; none was ever found.

In order that the study be consistent with the most common method of isolation used in general practice, cotton rolls were used rather than rubber dam. The cotton rolls were changed after washing and drying, with great care being taken not to allow salivary contamination of the etched surfaces. In order to avoid

Table 4. Deciduous molar retention with variable etch time (24 month results)

	Teeth etched 1 minute	Teeth etched 2 minutes	Total
No. of Teeth	210	112	322
Complete Retention	208	110	318
Complete Retention %	99.0%	98.2%	98.8%

Total patient number examined: 51

Table 5. The retention of white sealant system with variable wash time (24 month results)

	Wash Time			
	5 sec	10 sec	15 sec	30 sec
No. of teeth	8	7	3	12
Complete Retention	8	7	3	12

All teeth except three in five seconds group and three in 30 seconds group are permanent teeth.

contamination, particularly during the change of cotton rolls phase, it was found to be easier to manually hold the cotton rolls in place, rather than use cotton roll holders. After washing and initial drying, new

Table 6. The retention of white sealant system compared to white sealant containing 5% sodium fluoride (24 month results)

	<i>Permanent Teeth</i>		<i>Deciduous Teeth</i>	
	<i>White Sealant</i>	<i>5% NaF + White Sealant</i>	<i>White Sealant</i>	<i>5% NaF + White Sealant</i>
No. of teeth	70	68	37	36
Complete Retention	70	68	37	36

Table 7. The retention of white sealant system compared to partially filled white sealant (24 month results)

	<i>Permanent Teeth</i>		<i>Deciduous Teeth</i>	
	<i>White Sealant</i>	<i>White Sealant + Filled Resin</i>	<i>White Sealant</i>	<i>White Sealant + Filled Resin</i>
No. of Teeth	42	45	24	24
Complete Retention	42	45	24	24

Table 8. Retention of white sealant system at 3, 6, 12, 24, and 36 months

	<i>Permanent Teeth</i>	<i>Deciduous Teeth</i>
1. Complete Retention (53 patients @ 3 months)	98.8%	96.3%
2. Complete Retention (265 patients @ 6 months)	98.4%	99.4%
3. Complete Retention (153 patients @ 12 months)	96.1%	98.9%
4. Complete Retention (72 patients @ 24 months)	94.1%	98.8%
5. Complete Retention (164 patients @ 24 months)	96.0%	98.8%
6. Complete Retention (95 patients @ 36 months)	93.5%	94.9%

cotton rolls were placed on top of the saturated ones by the operator. The assistant then quickly removed the saturated cotton rolls with a cotton pliers. Thus the oral tissues were never allowed to touch and contaminate the freshly etched enamel surfaces.

In the upper quadrants, one buccal cotton roll was utilized and the operator used either his index or second finger to restrain the patient's tongue from contaminating the lingual surfaces to be sealed. In the lower quadrants, two cotton rolls were used, one buccally and one lingually, held by the operator's thumb and index finger.

While the sealant was being mixed with care being taken not to incorporate bubbles into the mix, air was again played over the etched surfaces to reduce possible moisture contamination from breath humidity.

Prior to sealant application, the teeth to be sealed were examined for the normal frosty white appearance of etched enamel. Sealant was applied within the margins of the etched enamel so that no sealant was applied over unetched areas of enamel. Polymerization time of the sealant was approximately 60 seconds, which time was found sufficient for quadrant application. Only one quadrant was sealed at a time.

Variations in technique

1) *Etch time for deciduous teeth.* *In vitro* studies, such as Silverstone,²⁵ show a superior etching pattern with a 120-second etch as opposed to a 60-second etch. Whether the so-called prismless enamel layer is responsible for this is still a matter of conjecture. Silverstone reported, however, that "with deciduous

enamel, a 60 second etch with phosphoric acid in the concentration range 20-50% did not produce etch patterns comparable to those seen in permanent enamel . . . although areas of so-called prismless enamel could conceivably have been identified with a 60 second etch, such regions were not seen with etching periods of 120 seconds . . . it was only with the increased etching times that a characteristic etching pattern was obtained with deciduous enamel." Decreasing the etch time to 60 seconds for deciduous teeth could reduce the operating time for four quadrants by about 25% and make a considerable improvement in acceptance of the application technique by the very young children (under five years of age). This, in turn, should have a significant effect on the cost-effectiveness of sealant placement on deciduous teeth. It was therefore decided as part of this study to compare the retention of sealant on deciduous enamel etched for 60 seconds, to that of sealant on deciduous enamel etched for 120 seconds.

Some subjects (27 examined) had all their deciduous molars etched for 60 seconds, others (17 examined) had all deciduous molars etched for 120 seconds and a third group (seven examined) had contralateral (and upper/lower quadrants on the same side), etched for different times (60 seconds or 120 seconds). Previous publications have documented the results at six months and 12 months.²⁶⁻²⁷

2) *Wash time after etching.* It has been assumed that "thorough washing" is desirable to remove the phosphoric acid and reaction precipitates. However no data is available as to what constitutes "thorough washing" in a clinical situation.

Therefore, for some subjects (four examined), the water-air spray wash time for single teeth and/or quadrants was varied from a minimum of five seconds, to a maximum of 30 seconds in different quadrants on the same subject.

3) *Fluoride content of resin.* A special experimental White Sealant containing 5% sodium fluoride was formulated to see if the addition of fluoride would have any deleterious effect on the clinical performance of the resin.

The White Sealant containing fluoride was applied to different quadrants in the same subjects with the regular White Sealant acting as a control (32 patients examined). Application technique for both sealants was identical.

4) *Filler content of resin.* To assess the long-term wear characteristics of an unfilled resin (White Sealant) against a partially-filled resin (White Sealant with the addition of CONCISE), alternate quadrants in the same subjects (22 examined) were sealed with each resin. Application technique for both resins was identical except for the steps noted below.

The partially-filled resin was made by mixing two drops of the colored resin portion (A) of the White Sealant with an equal portion of paste B from the CONCISE-filled composite resin system. A thin layer of pure unfilled resin (Enamel Bond) was applied prior to application of the partially-filled sealant.

Results

The clinical effectiveness of 3M CONCISE Brand White Sealant System was investigated three years after application. The complete retention of the sealant (Table 1) for 778 permanent teeth was 96.0% and for 322 deciduous teeth was 98.8%. Only three teeth out of 1,100 teeth examined had developed caries as a result of sealant loss. No teeth lost all the sealant, and loss in all but one case was very minimal (less than 5% of sealant area). One case lost approximately 20% of applied sealant area. The total retention for 1,100 permanent and deciduous teeth at 24 months was found to be 96.8%.

Varying the etch time for deciduous teeth (60 seconds or 120 seconds) produced no significant difference in retention rates at 24 months. Similarly, no difference in retention was detected by varying the wash time after etching from five seconds to 30 seconds or by adding filler to the sealant. Adding 5% sodium fluoride to the White Sealant produced no difference in retention rates at 24 months.

Initial three-year results are presented, as a comparison to earlier months, in Table 8. These results are comparable to initial two-year results (column 4) since the sample sizes are similar. It was noted at 12 and 24 months that overall retention improved as more patients were examined. If this trend continues, the retention percentage may be slightly higher after approximately 150 patients have been seen at three years.

Discussion

It is unfortunate that a matched control group could not be maintained in order to get a figure for the caries protection offered by a highly-retained pit and fissure sealant. It can be stated, however, that the sealant used in this study is protective inasmuch as no surfaces where sealant was completely retained became carious, while three of 31 surfaces showing partial sealant loss became carious after sealant loss and prior to sealant reapplication at the next recall. Furthermore, it is highly unlikely that in children of this age group only three pit and fissure surfaces would become carious in 1,100 posterior teeth followed for two years. It is hoped for the more significant later reports (at three years and five years or

longer) to include a carefully matched retrospectively chosen control group in order to get an accurate assessment of caries prevention and cost effectiveness.

Although many more patients were actually sealed than were included in this report, this study is not a select group out of the total population treated. Since the study population was sealed over a period of 18 months, in order to avoid tedious repetition for the single operator and a potential breakdown in the technique which would be critical to this particular treatment, and since it was clearly seen in an analysis of the first group of patients sealed, compared to subsequent groups, that familiarization with the technique led to slightly increased retention rates, it was decided to report one and two year results based on approximately half the total population. This enables results to be more quickly analyzed, and it is doubtful if a significant difference in retention would be found with a larger sample size. Originally, the sample size was made in excess of 400 patients in order to have at least 300 patients available for the 5-year retention rates to be analyzed, allowing for the normal attrition of study populations.

Comparing in Table 8 the retention figures for the various recall times, it can be seen that there has been very little drop in the retention rate between 12 and 24 months for the larger sample sizes. Columns 3 and 5 show a 0.1% drop for both permanent and deciduous teeth. A greater proportion of sealant loss occurred prior to one year. In comparing the clinical photographs of many cases, it can also be seen that any significant amount of wear takes place within the first six months. After six months, there is very little clinically detectable wear in a comparison of the margins of sealant seen on successive photographs. The technique of covering an occlusal amalgam enables an estimate of wear to be made from the darkening shadow that becomes visible under the sealant (Figure 2) until such a time as the sealant wears through to the amalgam (Figure 3). The time it takes for the amalgam to show through the sealant will, of course, depend on whether the amalgam was in occlusal contact at the time of sealant placement, or not.

This study found a slightly greater sealant retention rate for deciduous compared to permanent teeth, which is similar to a finding by Gourley.¹⁰

Conclusion

At the initiation of the study, there was some concern whether parents and their children would accept the clearly visible sealant from an esthetic point of view. It was found, however, that with proper explanation and demonstration, the colored sealant was very well accepted by both parents and their children.

In fact, it was found to be of great benefit to be able to visually demonstrate to parents what had been done clinically. Also, since the sealant is clearly visible to the child, it was found to be of benefit to involve the child in looking periodically for any sealant loss. This constant reminder of a preventive agent being present has helped the motivational aspects of the overall preventive program, since it is emphasized to patients that pit and fissure sealants are just one part of the total preventive program.

An additional significant benefit to the white color in the sealant was the markedly decreased examination time at recall examination, as compared to some subjects who had clear resin sealants placed for comparison. Some subjects also had clear and white sealant placed on contralateral quadrants. The clearly visible margins of the white sealant led to a rapid diagnosis of sealant presence or absence. A painstaking, time-consuming and, in this author's opinion, less accurate examination was necessary where clear resin sealants were placed.

The author believes that the white color addition to the sealant, which allows sealant presence to be visually confirmed at application and easily checked on recall, along with strict adherence to accepted techniques of sealant application, are the main factors in the high retention rate reported. The white color also allows for more accurate assessment of sealant presence, particularly when clinical photographs are utilized, than was previously possible with the earlier clear resin sealants.

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