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SCIENTIFIC articles

A clinical comparison of sealant and amalgam in the treatment of pits and fissures

*Part 1: Clinical performance after 18 months**

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Abstract

A comparative study was made of two alternative methods for the clinical treatment of occlusal pits and fissures in the early post-eruption state. Contralateral pairs of permanent first and second molars were carefully selected so that one molar could be given a preventive treatment with pit and fissure sealant, while the paired molar surfaces were restored with amalgam. Dental Health Center criteria for color change, margin discoloration, margin adaptation, anatomic form and the presence of caries were modified to increase sensitivity to the early signs of treatment failure. Both treatments were evaluated independently by two examiners at periods of zero, six, 12, and 18 months after placement, and at the earliest sign of sealant deterioration, the involved areas were retreated and a resume of the maintenance required to gain clinical efficacy in caries control is cited. Statistical analysis was used to compare the breakdown within each treatment group at various time intervals and between treatment groups. The retreatment rate for sealant was highest after 6 months (17.3 percent) and declined to 7.8 percent after 18 months. There was evidence of a generalized margin deterioration in more than 50 percent of amalgam restorations whereas 55 percent of the sealant margins remained not detectable clinically.

Introduction

The treatment of occlusal pits and fissures with a resin sealant coating to prevent dental caries has been proven effective in a number of clinical investigations.[1-8] In most clinical studies, a half-mouth design is utilized to compare a treated tooth or surface with its contralateral untreated tooth or surface as an internal reference for caries activity in the study population. One application of sealant is usually made at baseline and the efficacy of a single treatment for caries reduction is monitored at specified time intervals. Retention rates were found to vary in different studies and with various sealant materials. The clinical loss of material due to bond failure of the resin to enamel was a common problem in most studies. Typical results show a loss of sealant on permanent molars after one year of 28.6 percent in Kalispel, MT,[9] 20.1 percent in Chelsea, MI,[10] 32.9 percent in Alachua, FL,[11] and 29.4 percent in Birmingham, England.[12] The loss of sealant continued to increase with time for each study, thus indicating the need for continual observation and periodic maintenance once sealant treatment is instituted.

The clinical criteria and the protocol utilized during evaluation also vary somewhat among studies and, therefore, data are very difficult to compare. More recent studies have utilized clinical criteria developed by Cvar and Ryge[13] in coordination with those used previously for the evaluation of anterior or posterior restorations.[14-16] Although validity has been established as a clinical testing instrument, further attempts have been made to modify the criteria to improve sensitivity.[17,18]

It is the objective of this clinical investigation to compare, over a five-year period, two dissimilar methods for the management of defects on the pit and fissure surfaces of molar teeth. This study will address several major questions of primary importance to the dental practitioner. (1) Can a properly maintained sealant program result in 100 percent efficacy in the prevention of pit and fissure caries? (2) What are the maintenance factors and retreatment needs associated with a successful fissure sealant program? (3) How do these factors relate to the clinical performance of similar amalgam restorations? A summary is presented of the clinical evaluations performed during the first 18 months.

Methods and Materials

A group of children undergoing dental treatment in the Pedodontic Clinic at the University of Michigan School of Dentistry were screened by clinical and radiographic examination, and a population of 26 children selected for treatment. Each patient had at least one pair of contralateral permanent first or second molars with the diagnosis of caries on one pit or fissure surface, the contralateral surface being caries free. Of the 110 paired occlusal surfaces treated in the study, 55 received a standard one surface amalgam[a] restoration while the matched surfaces were treated with a low viscosity filled resin pit and fissure sealant.[b]

At the treatment appointment, the tooth to be sealed was polished with a non-fluoride abrasive slurry[c] on a rubber cup rotating at conventional speed. Isolation for the sealant treatment was obtained utilizing cotton rolls, absorbent wafers and high volume evacuation. The exposed fissure surface was conditioned for 60 seconds using the manufacturer's etchant solution and recommended procedures, rinsed for 15 seconds and then dried thoroughly with warm air. Isolation was renewed and the freshly mixed sealant was applied immediately by drawing small increments across the fissures with a ball-tipped applicator,[d] pushing air ahead of the sealant flow. Isolation was maintained for three minutes from the start of mixing. The air-inhibited layer of resin was removed from the surface with a dampened cotton roll and the coating evaluated carefully for surface defects.

In placing the amalgam restoration, topical anesthetic[e] was applied over the injection site for 30 seconds prior to the administration of local anesthetic,[f] and a two minute waiting period was used. Rubber dam isolation was applied and a Class I cavity was prepared and restored according to the principles taught within the Department of Pedodontics. After seven days, the patient returned to the clinic for polishing of the amalgam restoration utilizing only steel finishing burs.

All operating procedures were performed by two experienced faculty members with the aid of trained auxiliary personnel. Stopwatches were used to record the exact time utilized to perform every aspect of both treatments and these data will be presented in a subsequent report. At the second appointment, baseline clinical evaluations, including color photographs and stone models for reference, were made for both treat-

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[a]Tytin, S.S. White Division of Pennwalt Corp., King of Prussia, PA.
[b]Kerr Sealant, Kerr Manufacturing Company, Romulus, MI. (No longer commercially available.)
[c]xxx Silex, J. Bird Moyer Company, MOYCO, Philadelphia, PA.
[d]Kerr Cavitec Applicator, Kerr Manufacturing Company, Romulus, MI.
[e]Hurricane, Beutlich, Inc. Chicago, Ill.
[f]Xylocaine, 2%, Astra Pharmaceutical Co., Worcester, Mass.

ments. Similar evaluations were made at each six-month recall period, and both preventive and restorative treatment were rendered according to the patients needs.

For clinical evaluation, the criteria developed at the Dental Health Center[13] in San Francisco were modified as presented in Tables 1 through 5. The criteria for color change (Table 1) in the sealant were identical to those previously established. For margin discoloration (Table 2), the "Bravo" category for noticeable discoloration is divided into two ratings, dependent upon whether the length of discoloration was less than 50 percent of the exposed margin ("Bravo-1") or greater than 50 percent ("Bravo-2"). The category for penetrating discoloration is similarly divided into a "Charlie-1" rating for less than 50 percent involvement and a "Charlie-2" rating for greater than 50 percent. The criteria for margin adaptation (Table 3) were modified to detect a one-way catch of the explorer, resulting in "Alfa-1", "Alfa-2", or "Alfa-3" ratings according to the length of detectable margin. Crevice formation was also rated as "Bravo-1" or "Bravo-2" according to the extent of crevicing. The criteria for anatomic form (Table 4) were reworded to distinguish the peripheral loss of material ("Bravo-1" or "Bravo-2") from a severe loss of material exposing a fissure ("Charlie-1") or total loss of material ("Charlie-2"). A "Charlie" rating was added to the criteria for caries (Table 5) to include retreatment necessitated by unrelated caries. In modifying the criteria, an attempt was made to increase the discrimination of

Table 1. Criteria for quality evaluation

Color Change*	Health Center Criteria
Amalgam Restoration	Hotel
Visually Undetectable	Oscar
Visually Detectable - No mismatch in color	Alfa
Mismatch in Color - Within acceptable range	Bravo
Mismatch in Color - Outside acceptable range	Charlie

* Examined wet at 18 inches

Table 2. Criteria for quality evaluation

Margin Discoloration (Dry)	Modified Rating	Health Center Criteria
Amalgam Restoration	Hotel	Hotel
No discoloration anywhere on the margin between the sealant and tooth structure	Alfa	Alfa
Discoloration noted along margin - less than 50% of exposed margin area	Bravo-1	Bravo
Discoloration along margin - more than 50% of exposed margin area	Bravo-2	Bravo
Discoloration penetrating along the margin at the tooth-sealant interface - less than 50% of exposed margin area	Charlie-1	Charlie
Discoloration penetrating along the margin at the tooth-sealant interface - more than 50% of exposed margin area	Charlie-2	Charlie

Table 3. Criteria for quality evaluation

Margin Adaptation (Examined Dry)	Modified Rating	Health Center Criteria
Restorative material is continuous with adjacent tooth structure - not detectable with a sharp explorer passed in either direction	Alfa-1	Alfa
Margin detectable by explorer examination - less than 50% of exposed margin area	Alfa-2	Alfa
Margin detectable by explorer examination - more than 50% of exposed margin area	Alfa-3	Alfa
Visible evidence of crevice formation into which the explorer will penetrate - less than 50% of exposed margin area	Bravo-1	Bravo
Visible evidence of crevice formation into which the explorer will penetrate - more than 50% of exposed margin area	Bravo-2	Bravo
Crevice formation with exposure of underlying dentin or base (amalgam only)	Charlie	Charlie

the evaluation scale using the standard conditions that potentiate treatment failure.

Each evaluation was conducted independently by the same two trained examiners and a consensus agreement was reached by consultation when necessary. The consensus ratings were analyzed statistically for variations between the two treatments at each recall period and for variations within each treatment at various time intervals.

Results

The interexaminer agreement (Table 6) was greater than the suggested 85 percent[13] for all criteria except color match of the sealant at both 12 and 18 months and for margin adaptation of both materials at six, 12, and 18 months. The poorest agreement was 68.8 percent for color match at 12 months.

The retreatment requirement for a sealant program was assessed by noting the number of surfaces requiring retreatment at each recall period (Table 7). Of the 55 surfaces treated with sealant initially, two required reapplication of sealant at the baseline evaluation one week after initial treatment. After six months, nine teeth required reapplication; after twelve months, five teeth were retreated; and after eighteen months, four teeth were resealed. The rate of retreatment seems to decrease consistently with time through the 18-month period.

The consensus ratings for criteria used to evaluate the sealant were tested statistically using the sign test for a significant change between each time interval. Color became more noticeable (Table 8) between 6 and 12 months (18 detectable and 3 mismatch, $p = 0.002$), but showed little additional change between 12 and 18 months ($p = 0.607$). There was approximately a ten percent incidence in margin discoloration at each time interval, but this change was not statistically significant ($p > 0.13$). In at least 55 percent of the surfaces sealed (Table 9), the margin between sealant and

Table 4. Criteria for quality evaluation

Anatomic Form*	Modified Rating	Health Center Criteria
Harmonious and continuous with occlusal morphology - no change from original anatomic form	Alfa	Alfa
Evidence of loss of material from original anatomic form in one local area - sealant still present on all treated surfaces	Bravo-1	Bravo
Evidence of loss of material from original anatomic form in multiple areas - sealant still present on all treated surfaces	Bravo-2	Bravo
Loss of material with exposure of underlying dentin or base - total loss of sealant from a treated surface (designate surface number)	Charlie-1	Charlie
Total loss of all material from all surfaces treated	Charlie-2	Charlie

* Examined dry with model reference

tooth structure was not detectable by explorer examination at any recall. The extent of crevice formation did not appear to increase with time. A loss of sealant (Table 10) was noted between baseline and six months (5 with partial loss and 2 totally lost, $p = 0.007$), but sealant was fully retained on all surfaces from six to 18 months. The amalgam restorations showed evidence of margin deterioration (Table 9) after 12 months ($p < 0.01$) with an increase in the number of restorations exhibiting crevice formation. There was no change in anatomic form (Table 10) for amalgam restorations, and there was no incidence of caries associated with either treatment.

A chi-square test for association was used to compare the two treatments at each recall period. There was a greater change in margin adaptation for the amalgam restorations than for the sealant coating after six months ($p = 0.006$); the changes occurring after 12 months ($p = 0.07$) and after 18 months ($p = 0.41$) were not significantly different. There was a greater change ($p < 0.05$) in anatomic form for the sealant treatment than there was for amalgam at each recall period.

Table 5. Criteria for quality evaluation

Caries	Modified Rating	Health Center Criteria
No caries associated with the treated surfaces	Alfa	Alfa
Secondary caries related to the treated surfaces	Bravo	Bravo
Replacement of material due to non-related caries	Charlie	---

Discussion

The basic objective of this study was to compare a preventive treatment, sealant coating, to a restorative approach in handling the pit and fissure surfaces of permanent molars. By utilizing contralateral pairs,

both treatments were subject to similar influences from the oral environment and a more effective time-utilization analysis could be made. After eighteen months, the sealing of occlusal fissures was 100 percent effective in preventing dental caries on treated tooth surfaces and the need for retreatment was approximately 10 percent after each six-month period.

The color of a filled resin sealant coating was difficult to assess, as evidenced by the low interexaminer agreement for mismatch with tooth structure (Table 6). The reflection of light from stained fissures through varying thicknesses of sealant material did create a color mismatch similar to that resulting from material degradation. The sealant was relatively color stable since only one tooth showed a severe discoloration outside the normal range for tooth shade.

Although margin adaptation was detectable in a large number of teeth for both treatments (Table 9), the extent of the catch to the explorer was much greater for the amalgam restorations. In a few cases, the margin between sealant and enamel did show crevicing with time as thin featheredged sections fractured during function.

There was a need to reapply sealant on two treated pit or fissure surfaces before the baseline examination (Table 7) could be made and an even greater degree of bond failure after six months, the period at which retreatment rate was the highest (17.3 percent). This is an indication that the first six months are critical to long term sealant success. The failure of bonding between sealant and conditioned enamel will occur soon after placement if it is related to either contamination of the acid etched surface or an increase in sealant viscosity.

The retreatment requirements for this type of sealant in a controlled program have been defined to a greater degree than in previous clinical studies. The decreasing rate of retreatment with time (Table 7) in-

Table 6. Interexaminer agreement (percent)

Criteria	Baseline (55)	6 Months (52)	12 Months (52)	18 Months (51)
Sealant				
Color Change	94.6	88.0	68.6	74.5
Margin Discoloration	100.0	98.0	94.2	96.0
Margin Adaptation	91.1	82.0	84.4	84.3
Anatomic Form	100.0	96.1	88.5	94.1
Caries	100.0	100.0	100.0	100.0
Amalgam				
Margin Adaptation	100.0	80.7	78.7	80.4
Anatomic Form	98.2	100.0	100.0	100.0
Caries	100.0	100.0	100.0	98.0

Table 7. Retreatment required to maintain sealant

	Baseline	6 Months	12 Months	18 Months
Surfaces evaluated	55	52	52	51
Surfaces retreated	2	9	5	4
Retreatment rate	3.6%	17.3%	9.6%	7.8%

Table 8. Color evaluation of sealant

Criteria	Ratings		
Color Match	Not visible	Visible	Shade Mismatch
Baseline	53	2	0
6 months	43	6	1
12 months	31	18	3
18 months	30	20	1
Margin Discoloration	None	Along Margin	Penetrating
Baseline	55	0	0
6 months	48	3	1
12 months	45	5	2
18 months	45	4	2

dicates that a sealant program requires its greatest time and financial outlay for maintenance early in the program, and patients must be educated to this clinical requirement if the treatment is to be completely successful in eliminating pit and fissure caries. Since there was a need for one or more teeth to be retreated at each six-month recall period, there is strong indication that sealant should only be utilized as part of a controlled preventive program where there is reasonable assurance that patients will return regularly for recall observations.

Conclusion

In a controlled pilot project, sealant treatment of occlusal fissures was compared to amalgam restoration on contralateral paired permanent molars. The clinical course was accurately documented for both treatments, with maintenance and retreatment procedures provided at each six-month recall. When observed critically after 18 months, the retreatment of sealed fissures was necessary one week after placement and at each six-month recall examination. The greatest degree of retreatment (17.3 percent) took place at six months. The sealant coatings showed evidence of a color change from nonvisible to visible, but there was no indication of polymer degradation.

Table 9. Evaluation of margins for both sealant and amalgam

Treatment time	Not detectable	Detectable (local)	Detectable (general)	Crevice formation
Sealant				
Baseline	30	25	0	0
6 months	27	21	0	2
12 months	27	20	0	5
18 months	22	25	0	4
Amalgam				
Baseline	2	52	1	0
6 months	4	45	2	1
12 months	3	35	10	4
18 months	2	20	24	5

Results of this study support those of previous studies by demonstrating that sealant failure was related to material loss whereas amalgam failure was associated with a loss of margin integrity. There was no incidence of dental caries associated with either treatment during the first 18 months.

Sealant treatment provided complete protection against the development of dental caries for 18 months, but the importance of recall visits and retreatment procedures is documented. Modified criteria were shown to improve sensitivity of the evaluation scale with only a minimal loss of reliability.

Table 10. Evaluation of material loss for both sealant and amalgam

Treatment time	No loss	Peripheral loss	Pit or fissure-exposed	All material lost
Sealant				
Baseline	54	1	0	0
6 months	42	3	5	2
12 months	43	8	1	0
18 months	44	7	0	0
Amalgam			Enamel wall exposed	Dentin or Base exposed
Baseline	56	0	0	0
6 months	52	0	0	0
12 months	52	0	0	0
18 months	50	0	1	0

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