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Clinical Evaluation of a Nanofilled Fissure Sealant Placed with Different Adhesive Systems: 24-month Results

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Clinical Relevance

The use of an etch-and-rinse adhesive prior to the placement of sealants yielded better retention than did the use of a self-etch adhesive.

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SUMMARY

Objective: This clinical study compared the retention rates of a nanofilled occlusal fissure sealant placed with the use of an etch-and-rinse or a self-etch adhesive over 24 months.

Methods: Two-hundred and forty-four sealants were placed on the permanent premolars and molars of 16 subjects who had no restorations or sealants present on the fissures and no detectable caries. The sealants were placed with either SoloBond M two-step etch-and-rinse adhesive or FuturaBond NR one-step self-etch adhesive by four previously calibrated dentists, using a table of random numbers. After completion of the adhesive application, a nanofilled sealant, Grandio Seal, was applied and light-cured. Clinical evaluations were done at baseline and at 1-, 3-, 6-, 12-, 18- and 24-month recalls. Two other calibrated examiners, who were unaware of which adhesive had been used, independently

evaluated the sealants. Evaluation of the sealants on every follow-up visit involved visual examination with the aid of a dental explorer and an intra-oral mirror. Each sealant was evaluated with the following criteria: 1= completely retained; 2= partial loss; 3= total loss. The Pearson Chi-square test was used to evaluate differences in the retention rates among the sealants used with different adhesives for each evaluation period.

Results: For the 12-month recalls, complete retention rates of 89.3% for the SoloBond M group and 20.5% for the FuturaBond NR group were observed. Sixteen of the 244 restorations were unavailable after 12 months. At 24 months, a total loss of 9 sealants in the SoloBond M group and 84 in the FuturaBond NR group were observed, resulting in retention rates of 81.6% and 15.8%, respectively. There were statistically significant differences in retention rates between the SoloBond M and FuturaBond NR groups in all periods of evaluation ($p<0.05$). No statistically significant difference between the retention rates for premolars and molars was found at each evaluation period ($p>0.05$). There was no new caries formation throughout the 24-month recall period.

Conclusion: Fissure sealants placed with etch-and-rinse adhesive showed better retention rates than those placed with self-etch adhesive.

INTRODUCTION

The configuration of pits and fissures is a significant factor for occlusal caries. As these areas are very susceptible to caries formation, the application of fissure sealants plays a key role in the field of occlusal caries prevention.[1-2] The caries-preventive property of sealants is based on a reduction of available retention sites by forming a smooth surface layer and providing the inhibition of bacterial survival by preventing nutrients from reaching microflora in the fissures. Dental sealants have proven to be highly effective in the prevention of pit and fissure caries. It is generally accepted that the effectiveness of sealants for caries prevention depends on long-term retention.[3-4] Retention rates differ according to proper isolation of the working field, preparation of enamel surfaces, viscosity of sealant material and the use of adhesive systems. Many studies have confirmed the benefits of adhesive systems used under sealants. The use of a bonding agent under sealants has been demonstrated to increase bond strength, decrease microleakage and even increase the clinical success rate.[5-11] Feigal and others[12] reported that these agents protect sealant survival, yielding half the usual risk of failure for occlusal sealants and one-third the risk for buccal/lingual sealants.

Etch-and-rinse adhesives have been widely used for the application of sealants; however, these systems cause an extended treatment time, which is important when treating young children. Currently, one-step self-etch adhesives that combine etching, priming and bonding into a single step have great acceptance among dentists. The elimination of separate etching and rinsing steps simplifies and shortens the bonding procedures. These systems not only reduce chair time, but they also reduce technique sensitivity.[13-14] Therefore, it might be thought that the self-etch approach could be a good choice for placing sealants. On the other hand, despite the popularity of self-etch adhesives, their bonding ability to enamel, especially to unground enamel, presents a challenge.[15-17] Adhesive systems are mostly tested *in vitro*, but the value of that method is quite limited, therefore, clinical studies are required to test these materials in the oral cavity.

The current clinical study evaluated the performance of a nanofilled fissure sealant, Grandio Seal, using two different adhesive systems: an etch-and-rinse adhesive, SoloBond M (Voco, Cuxhaven, Germany), and a self-etch adhesive, FuturaBond NR (Voco).

METHODS AND MATERIALS

The protocol and consent form for the current study were reviewed and approved by the Hacettepe University Human Ethics Committee and written informed consent was obtained from all patients. Sixteen patients with a mean age of 20 (range 18-21) were drawn from the Conservative Dentistry Clinics at Hacettepe University, Faculty of Dentistry. Inclusion criteria included: good general health and hygiene and the absence of caries, previously placed restorations, bruxism, malocclusion and an allergy to resins.

Four specially trained and experienced research assistants performed the operative procedures. After taking bitewing radiographs, the fissures of the premolars and molars were cleaned with slurry of pumice applied with a bristle brush in a slow-speed handpiece to remove salivary pellicle and any remaining plaque. The teeth were assigned for restoration with either an etch-and-rinse adhesive (SoloBond M) or a one-step self-etch adhesive (FuturaBond NR) using a table of random numbers. All the adhesives were placed according to the manufacturers' instructions and are summarized in Table 1. Careful moisture control was maintained by way of adapted cotton-roll-isolation procedures and a chairside assistant. A nanofilled fissure sealant, Grandio Seal, was applied to the fissures with a needle tip syringe and carefully spread with a dental probe to prevent air entrapment. The sealant material was light-cured for 20 seconds with a quartz-tungsten-halogen light (Hilux, Benlioglu, Ankara, Turkey). Light output of the curing unit was found to exceed 550mw/cm^2 prior to and after the study, as verified with a radio-

meter. The occlusion was checked with articulating paper. Finishing and polishing were performed using fine-grit diamond burs (Diatech, Swiss Dental, Switzerland) and rubber cups (Edenta AG, AU SG, Switzerland).

A total of 244 sealants, distributed in 128 molars and 116 premolars, were placed in 16 patients. One patient was lost after the 12-month recall. After 12 months, 15 patients with 228 sealants were available for evaluation. Each restoration was evaluated at baseline and at 1, 3, 6, 12, 18 and 24 months. Two calibrated investigators who were unaware of which adhesive system had been used and who were not involved with the treatment procedures evaluated the restorations with a mirror, blunt explorer and air stream. The sealants were evaluated in terms of caries formation as present or absent and retention as:

1= Completely retained

2= Partial loss

3= Total loss

The Pearson Chi-square test was used to evaluate the differences in retention rates between the two adhesive systems at a 5% level of significance. Future recalls at 36 months and 60 months are also planned.

RESULTS

All the patients returned for the 12-month evaluation. After 12 months, one patient with 16 sealants could not be evaluated due to moving to another city. At the end of the 24-month follow-up, 15 patients with 228 sealants were evaluated. Table 2 shows that there were statistically significant differences in retention rates between the SoloBond M and FuturaBond NR groups for all periods of evaluation ($p<0.05$). There were 9 total losses with SoloBond M, while there were 84 total losses with FuturaBond NR after 24 months, representing 7.9% and 73.7% of the total sealants, respectively. Of the 84 lost sealants in the FuturaBond NR group, 34 were lost prior to the one-month recall. A total of 49 sealants were lost at the end of three months, another 11 sealants were lost at the six-month recall and 21 more were lost at the 12-month recall. Three more sealants were lost between the 12- and 24-month intervals. The retention rate was higher for the SoloBond M group, with 93 completely retained sealants at the end of 24 months ($p<0.05$).

Distribution of the retention rates of the premolars and molars is shown in Tables 3 and 4. No statistically significant differences were found between the retention rates of the premolars and molars at each evaluation period ($p>0.05$). No carious lesions were observed in the sealed teeth throughout the 24-month recall period.

DISCUSSION

This study examined the clinical effectiveness of fissure sealants placed with different adhesive systems. In the current study, a significant difference was observed between the tested adhesive systems. SoloBond M presented better retention rates than the self-etch adhesive, FuturaBond NR, at each period of evaluation. While the retention rate of FuturaBond NR showed a definite downward trend as the recall time increased, the retention rates for SoloBond M fell within the expected retention rates. It has been

Table 1: Adhesive Systems Used in This Study

Adhesive Systems	Composition	Applicaton Mode
SoloBond M (etch-and-rinse) (Voco, Cuxhaven, Germany) Batch #550440	Bis-GMA, HEMA, BHT, acetone, organic acids	Acid etch 34.5% phosphoric acid (30 seconds), rinse (30 seconds), air dry (15 seconds), adhesive application, light-cure (20 seconds)
FuturaBond NR (self-etch) (Voco, Cuxhaven, Germany) Batch #641657	Bis-GMA, HEMA, BHT, ethanol, organic acids, fluorides	Air dry (5 seconds), adhesive application, light-cure (10 seconds)

Table 2: *Distribution of Sealant Retention Rates*

Evaluation	1-Month		3-Months		6-Months		12-Months		18-Months		24-Months	
	Solo-Bond M	Futura-Bond NR	Solo-Bond M	Futura-Bond NR	Solo-Bond M	Futura-Bond NR	Solo-Bond M	Futura-Bond NR	Solo-Bond M	Futura-Bond NR	Solo-Bond M	Futura-Bond NR
1 N (%)	119 (97.5%)	75 (61.5%)	113 (92.6%)	46 (37.7%)	111 (91%)	37 (30.3%)	109 (89.3%)	25 (20.5%)	97 85.1%)	19 (16.7%)	93 (81.6%)	18 (15.8%)
2 N (%)	2 (1.6%)	13 (10.7%)	7 (5.7%)	27 (22.1%)	7 (5.7%)	25 (20.5%)	8 (6.6%)	16 (13.1%)	10 (8.8%)	12 (10.5%)	12 (10.5%)	12 (10.5%)
3 N (%)	1 (8%)	34 (27.9%)	2 (1.6%)	49 (40.2%)	4 (3.3%)	60 (49.2%)	5 (4.1%)	81 (66.4%)	7 (6.1%)	83 (72.8%)	9 (7.9%)	84 (73.7%)
Total No	122	122	122	122	122	122	122	122	114	114	114	114
p value	**<0.001**		**<0.001**		**<0.001**		**<0.001**		**<0.001**		**<0.001**	

1= Completely Retained; 2= Partial Loss; 3= Total Loss.

Table 3: *Distribution of Sealant Retention Rates of SoloBond M Group for Premolars and Molars*

Evaluation	SOLOBOND M											
	1-Month		3-Months		6-Months		12-Months		18-Months		24-Months	
	Premolar	Molar	Premolar	Molar	Premolar	Molar	Premolar	Molar	Premolar	Molar	Premolar	Molar
1 N (%)	56 (47.1%)	63 (52.9%)	55 (48.7%)	58 (51.3%)	55 (49.5%)	56 (50.5%)	54 (49%)	56 (51%)	48 (49.4%)	49 (50.6%)	47 (50.3%)	46 (49.7%)
2 N (%)	1 (50%)	1 (50%)	2 (28.6%)	5 (71.4%)	0 (0%)	7 (100%)	1 (12.5%)	7 (87.5%)	2 (20%)	8 (80%)	2 (16.7%)	10 (83.3%)
3 N (%)	1 (100%)	0 (0%)	1 (50%)	1 (50%)	3 (75%)	1 (25%)	3 (75%)	1 (25%)	4 (57.1%)	3 (42.9%)	5 (55.5%)	4 (44.5%)
Total No	58	64	58	64	58	64	58	64	54	60	54	60
p value	<0.05		<0.05		<0.05		<0.05		<0.05		<0.05	

1= Completely Retained; 2= Partial Loss; 3= Total Loss.

Table 4: *Distribution of Sealant Retention Rates of FuturaBond NR Group for Premolars and Molars*

Evaluation	FUTURABOND NR											
	1-Month		3-Months		6-Months		12-Months		18-Months		24-Months	
	Premolar	Molar	Premolar	Molar	Premolar	Molar	Premolar	Molar	Premolar	Molar	Premolar	Molar
1 N (%)	36 (46.8%)	41 (53.2%)	25 (51%)	24 (49%)	18 (48.6%)	19 (51.4%)	14 (56%)	11 (44%)	11 (57.8%)	8 (42.2%)	10 (55.5%)	8 (44.5%)
2 N (%)	5 (31.3%)	11 (68.8%)	9 (32.1%)	19 (67.9%)	7 (28%)	18 (72%)	5 (31.2%)	11 (68.7%)	3 (25%)	9 (75%)	4 (33.3%)	8 (66.7%)
3 N (%)	17 (58.6%)	12 (41.4%)	24 (53.3%)	21 (46.7%)	33 (55%)	27 (45%)	39 (48.1%)	42 (51.9%)	40 (48.1%)	43 (51.9%)	40 (47.7%)	44 (52.3%)
Total No	58	64	58	64	58	64	58	64	54	60	54	60
p value	<0.05		<0.05		<0.05		<0.05		<0.05		<0.05	

1= Completely Retained; 2= Partial Loss; 3= Total Loss.

reported that 5% to 10% of all sealants can be expected to fail annually[2] and the percentage of the total loss of sealants was 7.9 % for SoloBond M at the end of 24 months. The low retention rates observed in the FuturaBond NR group were not surprising. Even though the use of self-etch adhesives has gained considerable popularity in recent years, their etching capability and bonding ability to unground enamel presents a challenge. The result that was obtained in the current study could be explained by the insufficient etching capacity of the self-etch adhesive used in the current study. It is known that enamel bonding is accomplished by the formation of resin tags in etched enamel to create micromechanical interlocking. Most of the one-step self-etch adhesives are not as acidic as phosphoric acid, which is used with etch-and-rinse adhesives.[18] In a SEM study evaluating the etching pattern of self-etch and phosphoric acid etchants, it was found that the self-etch adhesives did not etch ground and unground enamel as well as phosphoric acid.[19] In another SEM study, none of the tested self-etch adhesives could reach the same level of demineralization as phosphoric acid, which was used as the control.[20] dos Santos and others[21] investigated the penetration (tags) of adhesive materials into enamel etched with phosphoric acid or treated with a self-etch adhesive before the application of a pit and fissure sealant. Those authors found that the teeth etched with phosphoric acid exhibited significantly greater penetration than the specimens treated with a self-etch adhesive.

The hypermineralized aprismatic layer and more fluoride content of unground enamel might prevent penetration of self-etch adhesives. Most of the studies, and even some manufacturers, recommend the adjunctive use of phosphoric acid with self-etch adhesives when bonding to enamel, especially in the case of unground enamel.[22-23] However, in a study that evaluated the effects of a self-etch adhesive applied to pre-etched fissures on microleakage and the penetration ability of a fissure sealant, it was found that the traditional etching process was still the most effective method for etching intact fissures and the additional use of a self-etch adhesive did not improve the sealing ability of sealants.[24] Hannig and others[25] evaluated the microleakage and internal seal of fissure sealants placed with self-etching priming agents in comparison with the phosphoric acid etching of enamel. They found that the sealing ability of self-etch systems was less effective as compared to the conventional acid-etch technique.

Another concern regarding insufficient penetration could be related to prophylaxis. Although prophylaxis with pumice has been performed before sealant placement, the remaining debris, comprising pellicle and pumice, can still remain in the depths of fissures. The etching capacity of FuturaBond NR might be low

enough to allow for the presence of organic remnants,[26-27] while phosphoric acid could remove them. Contrary to the current results, Feigal and Quelhas[28] evaluated the two-year clinical sealant success when using Prompt-L-Pop adhesive prior to the sealant application and found no difference with the conventional phosphoric acid etching method without the use of any bonding agent. The adhesive used in that study was one of the highest acidic self-etch adhesives, with a pH of 1. Moreover, it was demonstrated that the aggressiveness of Prompt-L-Pop was almost equivalent to that of conventional phosphoric acid treatment.[29] An *in vitro* study compared the shear bond strength of Prompt-L-Pop to regular acid etching when bonded to fissure sealants. That study found that the use of this adhesive significantly increased enamel bond strength when compared to fissure sealants bonded with phosphoric acid etching.[30] Therefore, in such cases, it could be a good idea to use a more aggressive self-etch adhesive prior to the placement of fissure sealants to offer a more favorable alternative. However, it should be taken into account that no adhesive system was used in conjunction with phosphoric acid in both studies mentioned above; therefore, the results cannot be compared directly with the data obtained in the current study. It should be kept in mind that it is not always possible to compare the retention rates of different studies due to many variables that can influence the retention rates of fissure sealants *in vivo*. These variables include patient age, isolation method, location and the use and type of adhesive systems.

In another clinical study, two sealant application techniques involving a self-etching primer system and traditional acid etching in a school-based program were compared retrospectively.[31] Sealant placement with self-etch adhesives was found to have poor retention when compared to those sealants placed with phosphoric acid etching. Similar to the current study, Burbridge and others[32] compared the retention of fissure sealants placed on occlusal surfaces following the use of a self-etching priming agent and traditional acid etch. While Xeno III (Dentsply International, York, PA, USA) was used to prepare the occlusal enamel on one side of the lower arch, phosphoric acid, together with Prime & Bond (Dentply Caulk, Milford, DE, USA), was used on the other side. Retention of the acid-etch group was significantly superior. Those authors concluded that the best practice for the placement of sealants remains enamel preparation with acid etching and the use of an intermediate bonding layer.

In the current study, the differences in retention rates between molars and premolars showed no statistically significant differences at each period of evaluation. However, in most of the studies, the premolar retention rates were found to be higher than the molar retention rates.[33-34]

Long-term recalls are planned to determine if the obtained data will get worse or remain the same. Further clinical studies are needed to confirm the reproducibility of the current findings.

CONCLUSIONS

Within the limitations of the current study, it can be concluded that fissure sealants placed with an etch-and-rinse adhesive showed better retention rates than sealants placed with a self-etch adhesive.

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