Effect of a Nonrinse Conditioner on the Durability of a Polyacid-modified Resin Composite Fissure Sealant

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ABSTRACT

Purpose: The aim of this study was to evaluate the effect of the simplified conditioning on durability of polyacid-modified resin composite (PMRC; Dyract Seal) fissure sealants. The effectiveness of a nonrinsing conditioner (NRC) on retention of PMRC sealants (92) was studied in a split-mouth design.
Methods: The enamel of 1 molar was pretreated with NRC and coated with Prime & Bond NT (Dentsply DeTrey, Konstanz, Germany)/PMRC. The contralateral molar was conditioned with 36% phosphoric acid and sealed with Delton. The sealant retention was evaluated during 2 years. In addition 49 pairs were sealed with Prime & Bond NT/PMRC after conditioning with 36% phosphoric acid and evaluated after 1 year.
Results: Significantly higher loss rates at 1 and 2 years were observed for the NRC/Prime & Bond NT/PMRC sealants. At 2 years, partial and total loss rates for Delton were 23% and 11%, and for NRC/Prime & Bond NT/PMRC sealants were 44% and 40%, respectively. At 1 year, phosphoric acid-conditioned Prime & Bond NT/PMRC sealants showed significantly better retention than the NRC-conditioned PMRC sealants and the phosphoric acid-conditioned Delton sealants.
Conclusions: Conditioning with NRC prior to sealant application cannot be recommended. (*J Dent Child.* 2004;71:152-157)

KEYWORDS: BONDING, CARIES, CONDITIONING, SEALANTS

Cueto and Buonocore and Roydhouse reported the first studies of pit and fissure sealing with low-viscous restoratives as cariostatic agents.[1,2] Longitudinal studies showed pit and fissure sealants applied during childhood had a long-term retention and caries-preventive effect.[3-6] The effectiveness of the resin sealant was directly related to the resin impregnation in the acid-etched enamel. Evaluation of fissure sealing efficacy has been presented in a large number of studies with a wide variation in retention rates.[6] Wendt and Koch explained this mainly via differences in technical performance e.g. with or without chairside assistance, different categories of dental personal, optimal conditions vs field conditions.[7]

Sealant placement is technique sensitive, and effective cleaning, etching, rinsing, and drying is influenced by operator performance and patient cooperation. Excluding one of these steps will decrease the sensitivity factor. Recently, a simplified conditioning method excluding the phosphoric acid conditioning has been suggested to reduce technique sensitivity. A nonrinse conditioner (NRC), composed of a combination of organic acids, is used to condition the enamel tissue. No water rinsing is performed, but it requires the subsequent application of a separate adhesive. The simplified conditioning step replaces several conventional steps (eg, phosphoric acid etching, rinsing with water, change of cotton rolls) and reduces the risk of inadvertent contamination of the tooth tissue.

According to the manufacturer, the NRC is not just a replacement of phosphoric acid—it also contains priming components. It is recommended the NRC be combined with a new light-cured polyacid-modified resin composite (PMRC; compomer) fissure sealant material. Introduced in

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1993, PMRC was developed as a direct esthetic restorative material with desirable properties of resin composites and those of fluoride-releasing glass ionomer cements. PMRC is a single-component, hydrophobic resin filled with the acid-leachable glass particles of a glass ionomer cement.[8] Advantages of the PMRC sealants compared to traditional resin fissure sealants include its low stress developed during polymerization, lower E-modulus, and fluoride release from the material. No clinical studies have been performed with the PMRC sealant and the self-priming conditioner.

The aim of this study was to evaluate the effect of the simplified conditioning on durability of PMRC sealants.

METHODS

Patients attending for routine care at the Public Dental Health Clinic in Kiruna, Sweden, were included in the clinical trial. Fissure sealants were placed in permanent first and second molars according to a split-mouth design. For each subject, 2 or 4 fully erupted teeth, with no previous filling or clinical evidence of caries, were sealed. All sealants were placed because of deep fissures and/or caries risk. Each patient and one of his/her parents provided informed consent to participate in the university approved study.

NRC/PRIME & BOND NT/PMRC

One maxillary or 1 mandible molar was randomly assigned to receive a PMRC sealant, while the opposite molar in the arch received a resin sealant. A total of 92 molars were sealed—42 in the maxilla and 50 in the mandible. Of the 92 teeth treated, 68 were first molars and 24 were second molars. The sealants were placed by 2 experienced dentists assisted by dental auxiliaries. After thoroughly cleaning occlusal surfaces with an oil-free paste and water spray, the teeth were isolated with cotton rolls, dry tips, and a saliva suction device. The occlusal surface of the PMRC fissure sealant tooth was pretreated with the nonrinse conditioner of the system containing maleic acid, itaconic acid, and water (NRC, Dentsply/DeTrey, Konstanz, Germany; batch=lot KP3-105-2). Maleic acid conditions the tissue and has some priming properties. Itaconic acid contains carboxylic groups, which will prime the tooth tissue.

The surface to be sealed was wetted with sufficient conditioner amounts using a disposable brush or applicator tip. It was left undisturbed for 20 seconds and not rinsed. Evaporation of solvent was performed by gentle air drying. One coat of the primer Prime & Bond NT (Dentsply/DeTrey; batch=KP3-124-1) was then applied to the conditioned enamel surfaces. This self-etching primer is acetone-based and contained elastomeric monomers, PENTA (dipentaerythrietol pentacrylate phosphoric acid ester), and initiators. The conditioned enamel surface was wet thoroughly and left undisturbed for 20 seconds, followed by gentle air blowing.

The PMRC sealant (Dyract Seal, Dentsply/DeTrey; batch=MG 1-89-1) was then applied to the surface and spread into the fissures with a working time of about 45 seconds. The sealant contains phosphoric acid-modified polymerisable monomers, carboxylic acid- modified macromonomers, reactive diluent, polymerization inhibitor, stabilizer, and strontium-aluminum natriumfluoro-silicate glass. The sealant surface was light cured for at least 20 seconds and then checked for complete coverage, retention, and occlusal contacts.

The contralateral tooth was conditioned with 36% phosphoric acid (DeTrey conditioner 36) for 60 seconds, rinsed with water for 20 seconds, and then thoroughly dried. The resin sealant (Delton DDS [Direct Delivery System] Opaque, Dentsply/DeTrey) was applied according to the manufacturer's instructions. The Delton DDS contains aromatic and aliphatic dimethacrylate monomers, ethyl-p-dimethyl-aminobenzoate, light activators, colloidal silica, and titanium dioxide. After setting, coverage and occlusion were carefully checked.

PHOSPHORIC ACID/PRIME & BOND NT/PMRC

During the first year of the evaluation, a high loss was observed in the Prime & Bond NT/PMRC sealant group with enamel conditioning with NRC. Therefore, the authors decided to investigate if the NRC conditioning was the cause of the high loss of retention of the PMRC. The 36% phosphoric acid conditioning was performed as a positive control in another group of Prime & Bond NT/PMRC sealants by one of the operators (EL).

EVALUATION

The sealants in the split-mouth study were evaluated at baseline after 3, 6, 12, and 24 months, and the PMRC sealants were placed in teeth conditioned with phosphoric acid at baseline, 6, and 12 months after their placement. At each evaluation, retention, presence of caries, marginal adaptation, and marginal discoloration were registered. Radiographs of all molars were exposed before application and during the evaluation dependent on the individual participant's caries risk. Slightly modified USPHS criteria were used (van Dijken, 1986).[9] Sealant retention was registered as:

1. sealant intact (score=0);
2. sealant partly lost, fracture of the material (score=1);
3. sealant totally lost (score=2).

Marginal adaptation was registered as:

1. sealant is continuous with existing anatomical form; explorer does not catch (score=0);
2. explorer catches, no crevice is visible into which explorer will penetrate (score=1);
3. crevice at margin, enamel exposed (score=2);
4. obvious crevice at margin, dentin or base exposed (score=3);
5. sealant mobile, fractured, or missing (score=4).

Caries was registered as:

1. no evidence of caries (score=0);
2. superficial secondary caries of the enamel (score=1);
3. secondary caries of the dentine (score=2).

STATISTICAL ANALYSIS

The SPSS 10.0 (Statistical package for the social sciences, SPSS, Chicago, Ill) was used to process the data. Differences in evaluated variables scores between Prime & Bond NT/PMRC and Delton—at the different recalls and for each of the sealants between the different recalls and effect of conditioning on retention of the Prime & Bond NT/PMRC

sealants—were tested with Wilcoxon-signed ranks test or the McNemar test. Differences between operators were tested with the Kruskal-Wallis test. Variances in age distribution between the groups were tested with Levene's test for variance equality. The significance level used was $P<.05$.

RESULTS

Fourteen girls and 17 boys, with a mean age of 8 years (range=6-13) received sealants. Thirty-one patients received at least 2 fissure sealants—1 of each of the 2 investigated materials according to the split-mouth technique. Prime & Bond NT/PMRC sealants applied after conditioning with the phosphoric acid (49 pairs) were placed in 25 patients (12 girls, 13 boys) under the same circumstances as the first part of the study, with a mean age of 10 years (range=6-16). Of the 98 teeth treated, 58 were first molars and 40 were second molars.

In the split-mouth design, all sealant pairs were evaluated at all recalls, except for 2 pairs at the 2-year recall. Both dropouts moved from the city. The cumulative relative frequencies of the evaluated scores are shown in Table 1. During the first 3 months, low partial and no total loss rates for the sealants were observed. The loss rates increased significantly for both sealants at each recall, especially for the NRC/Prime & Bond NT/Dyract Seal sealant.

Highly significant differences were found between the baseline and 3-month frequencies, compared to the 1- and 2-year frequencies for retention and marginal adaptation ($P<.0001$). Significant higher loss rates were observed for the NRC/Prime & Bond NT/PMRC sealants compared to Delton at 1 and 2 years ($P<.001$). Partial and total loss rates at 2 years for Delton were 23% and 11%, and for NRC/Prime & Bond NT/Dyract Seal were 44% and 40%, respectively. Marginal adaptation differed significantly between the sealants at 1- and 2-years ($P<.001$).

Three moderate caries lesions were detected contiguous to Delton sealants: 1 in a high caries-active child at 3 months, 1 at 1 year, and 1 at 2 years. Two superficial lesions were observed contiguous: 1 Delton and 1 PMRC sealant. No differences were observed between the 2 operators. No marginal discoloration was observed for the materials, except for the NRC/Prime & Bond NT/Dyract Seal margins at 2 years (6%).

Two of the patients with phosphoric acid-conditioned teeth sealed with Prime & Bond NT/Dyract Seal were not evaluated at the 6- and 12-month evaluations. All other sealants were evaluated at the recalls. The scores of the Prime & Bond NT/PMRC sealants placed after conditioning with phosphoric acid are shown in Table 2. No differences in age distribution were found between groups of patients treated by one of the operators (EL) with Delton, NRC/Prime & Bond NT/PMRC sealants, or phosphoric acid/ Prime & Bond NT/PMRC sealants. Therefore, these groups could be tested against each other.

At 6-months ($P<.05$) and at 1-year, retention rate and marginal adaptation ($P<.01$) were significantly better for the phosphoric acid/Prime & Bond NT/PMRC sealants, compared to the NRC/Prime & Bond NT/PMRC sealants. The phosphoric acid-conditioned PMRC sealants also showed a significantly better retention than the phosphoric acid-conditioned Delton sealants ($P<.05$). No secondary caries was observed.

Table 1. Cumulative Relative Retention, Marginal Adaptation, and Secondary Caries Frequencies for Dyract Seal and Delton Fissure Sealants at Baseline, 3, 6, 12, and 24 Months

		NRC/Prime & Bond NT/Dyract Seal					Phosphoric acid/Delton				
		Scores (%)					Scores (%)				
		0	**1**	**2**	**3**	**4**	**0**	**1**	**2**	**3**	**4**
Retention	Baseline	100					100				
	3 mos	89	11				96	4			
	6 mos	70	22	9			78	20	2		
	12 mos	41	44	15			67	28	4		
	24 mos	16	44	40			66	23	11		
Marginal adaptation	Baseline	100					100				
	3 mos	80	9	11			85	9	2	4	
	6 mos	46	22	2	22	9	70	7	2	20	2
	12 mos	4	35	4	41	15	46	15	7	28	4
	24 mos	0	14	2	44	40	43	11	11	23	11
Caries	Baseline	100					100				
	3 mos	100					98	2			
	6 mos	100					96	2	2		
	12 mos	100					94	2	4		
	24 mos	98	2				91	2	7		

Table 2. Cumulative Relative Retention, Marginal Adaptation, and Secondary Caries Frequencies for Dyract Seal Placed After Phosphoric Acid Conditioning at Baseline, 6, and 12 Months

		Phosphoric acid/ Prime & Bond NT/Dyract Seal			
		Scores (%)			
	0	1	2	3	4
Retention	Baseline	100			
	6 mos	94	6		
	12 mos	89	11		
Marginal adaptation	Baseline	100			
	6 mos	49	40	4	
	12 mos	34	53	2	11
Caries	Baseline	100			
	6 mos	100			
	12 mos	100			

DISCUSSION

Retention rates for the Delton resin in this study were lower than expected. The yearly failure rate was comparable with average yearly failure rates of 15% to 29%, recently reported by Feigal et al, but lower than the 1- to 2-year failure rates reported by other studies for the same material.[10-12] One reason for the differences in retention frequencies can be the use of a larger part of "difficult-to-seal" teeth, such as including second molars in some studies. A second reason for the high observed failure rates is the stringent criteria used for judging sealant failure. In the present study, the criteria were applied to all sealants and the relative effects of various factors in sealant's behavior are, therefore, probably accurately estimated.

The use of self-etching primers not requiring rinsing and which simultaneously serve as conditioner and primer for dentin and enamel is a recent approach to simplify bonding techniques in operative dentistry. A similar approach has been suggested to minimize sealant technique sensitivity and reduce the number of operating steps. Kunzelman et al evaluated fissure sealing with self-etching primers in vitro and concluded there are possibilities to simplify the procedure of fissure sealing, but this should be proved in a clinical study.[13] No clinical sealant evaluation of the NRC, with or without the following treatment with Prime & Bond NT, has been reported to the authors' knowledge.

The NRC method evaluated in this study simplified the treatment procedure considerably. The technique eliminated the:

1. phosphoric acid-etching and water-rinsing steps;
2. contamination risk of presence of oil and/or water vapor in the compressed air used to dry the etched tooth surface;
3. reisolation of the operative field after rinsing.

Maleic acid has been used as conditioning agent for some dentin-enamel bonding systems during the nineties. A 10% solution did not affect the intact enamel surface after 15 seconds.[14] The nonrinse conditioner contains the organic maleic acid dissolved in water as conditioning agent and has a pH of 1.2.[15,16] Pashley and Tay treated unground buccal enamel with the moderately aggressive NRC, which exhibited a "coral-like" aprismatic etching pattern. In fractured specimens, the overall etching depth was shallow.[16] A nonuniform hybrid layer of only 100-nm thick was observed. Çehreli and Altay reported, after a 20-second treatment, similar findings with only superficial demineralization of the enamel.[17] No loss of enamel prisms was evident, although a homogeneous enamel porosity associated with a pattern of generalized pitting suggested a potentially retentive surface.

One of the simplest means to evaluate adhesive techniques is testing the bond strength to enamel and/or dentin. This is done by either applying a tensile or a shear stress to a bonded specimen and measuring the load per unit area at the time of rupture of the bond. These techniques, however, show very large variations among samples. The mean microtensile bond strength of NRC-treated enamel specimens was significantly lower (10.3 MPa) than that of the phosphoric acid-conditioned control specimens (27 MPa).[16]

NRC conditioning was recommended to be combined with the one-bottle adhesive Prime & Bond NT. This adhesive is, in fact, a self-etching primer containing PENTA (dipentaerythrol penta-acrylate monophosphate), a molecule of mild acidity (pH=2.4).[18] According to the manufacturer, the adhesive could be used in different ways: (1) without conditioning; or (2) combined with phosphoric acid or NRC. No acid etching was required, except in stress-bearing Class I, Class II, and Class IV cases.[19] Unlike bonding to sound dentin, application of self-etching systems on enamel has been a controversial issue.[15,16] Application in vitro of Prime & Bond NT on enamel surfaces showed neither characteristic etch pattern of enamel nor detectable resin tags.[20] Etching with phosphoric acid prior to the application of the self-etching primer and PMRC restorative produced stronger micromechanical interlocking and higher bond strength to enamel and dentin.[21,22]

The combination of NRC and Prime & Bond NT, as recommended by the manufacturer, combines 2 self-etching or self-conditioning methods of the enamel. Besides maleic acid, the NRC contains itaconic acid, containing carboxylic groups, which is suggested to behave as a priming agent with the ability to copolymerize with Prime & Bond NT.[15] All in vitro investigations of the NRC have been performed not on the conditioner itself, but on the combination NRC/Prime & Bond NT. The NRC is more acidic than Prime & Bond NT, and an increased etching pattern of the tooth tissue may be expected. Enamel treated with NRC combined with Prime & Bond NT, however, showed an enamel etch pattern shallower and less uniform with shorter resin tags than those with phosphoric acid.[20] The shallow depth of demineralization and minimal etching pattern in enamel may explain the reported decreased bond strength for PMRC.[20-22]

Luo et al investigated the effect of 36% phosphoric acid and NRC on marginal adaptation of Dyract AP in Class I cavities. They showed the marginal quality at the enamel/PMRC interface was not affected by the conditioning method.[23] Çehreli and

Altay showed via scanning electron microscopy that 20 seconds of NRC application on primary unground enamel resulted in almost clear prism structures.[24] No comparison with phosphoric acid was performed. Tay and Pashley reported the NRC/Prime & Bond NT was moderately aggressive, dissolving partly smear layer and smear plugs.[15]

Rosa and Perdigão confirmed the NRC/Prime & Bond NT pretreatment was not as effective as phosphoric acid.[25] Enamel bond strength values of 18.7 and 18.9 MPa were observed, combining the NRC/Prime & Bond NT pretreatment with a PMRC and a resin composite, respectively. Conditioning with phosphoric acid combined with Prime & Bond NT priming resulted in values of 23 and 23.4 MPa, respectively. When the self-etching primer NT was applied without a separate acid-etching step, they resulted in the lowest bond strengths values of 8.5 and 8 MPa, respectively. Sunico et al, on the other hand, reported similar bond strengths of Prime & Bond NT with both types of etchants (17 MPa).[19] They stated NRC was comparable to 36% phosphoric acid as an enamel conditioner.

After 6 months, the authors observed a high loss of retention for the PMRC sealants in teeth conditioned with NRC. A significant increasing loss rate was seen during the 2-year follow-up, compared with the Delton control sealants. To evaluate if the high loss rate was due to the noneffective etching of the NRC, the authors placed Prime & Bond NT/PMRC sealants in phosphoric acid-conditioned teeth in the second part of the study. A significantly better clinical 1-year retention rate was seen for the sealant teeth conditioned with phosphoric acid compared to the NRC-treated teeth.

Peters et al studied the efficacy of NRC and phosphoric acid on the retention of Class V Prime & Bond NT/Dyract AP restorations in abfraction lesions.[26] In these Class V abrasion/erosion lesion, the largest surface area consisted of dentin tissue. After 18 months, the phosphoric acid treated lesions showed a significantly higher retention rate (92%). No difference was seen between the NRC/Prime & Bond NT and Prime & Bond NT-conditioned lesions (71% and 72% retention rate, respectively), which failed to approve the American Dental Association full acceptance level of 90% retention rate after 18 months.

Use of an intermediate bonding layer between enamel and sealant has been suggested to minimize sealant sensitivity to moisture contamination. Increased bond strength to enamel and reduced microleakage have been reported for sealants placed with bonding compared to control sealants only.[27]

Recent studies support the hypothesis that amphiphilic monomers are excellent for bonding to enamel, and that they can overcome much of the negative aspects of saliva contamination.[28] Hebling and Feigal showed Prime & Bond reduced microleakage of sealants placed on saliva-contaminated enamel to the same level as in the control group, where no contamination was performed.[28] Few studies reported the effectiveness of the use of bonding agents.

Recently a 5-year clinical study showed that use of fifth-generation, single-bottle bonding systems halved the risk of sealant loss at any observation time.[10] No difference in retention, however, was found after 2 years, when a bonding agent was used prior to sealant application on noncontaminated teeth.[29]

An interesting finding in the present study was the significantly better retention rate for the Prime & Bond NT/PMRC sealants placed in teeth conditioned with phosphoric acid compared to the Delton resin sealants also placed in teeth conditioned with phosphoric acid. No other clinical studies have reported the effectiveness of PMRC as sealant material. A possible explanation of the better retention rates may be the amphiphilic character of the primer used, which can increase the bond strength against moisture or contamination. Another reason may be found in the viscoelastic properties of the PMRC, which, because of its lower modulus of elasticity, may counteract occlusal stressors better than the more rigid sealant resins and, consequently, reduce the fracture rate.[30,31]

Luo et al investigated Dyract AP placed in combination with NRC/Prime & Bond NT in Class I and II cavities.[32] After 1 year, they reported no failures for the Class I cavities and an 8% failure rate—caused by secondary caries and fracture of the PMRC—for the Class II restorations, which was considered a satisfactory clinical result by the authors.

CONCLUSIONS

This study showed that, during the short follow-up, the combination Prime & Bond NT/Dyract Seal was as effective as the Delton resin at sealing phosphoric acid-conditioned fissures. The sealant retention loss frequencies of the NRC-conditioned teeth were significantly higher than the phosphoric acid-conditioned ones. Conditioning with NRC prior to sealant application cannot be recommended. Use of an intermediate resin layer and a PMRC sealant after phosphoric acid etching resulted in significantly higher retention rates, compared to the conventional resin sealants.

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