

A randomized controlled trial of the effectiveness of a one-step conditioning agent in sealant placement: 6-month results

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Summary. *Aim.* The objectives of this study were: to compare the retention of fissure sealants (sealants) placed on occlusal surfaces following the use of a self-etching priming agent and traditional acid etch; to compare the caries incidence of occlusal surfaces sealed using the two techniques; and to compare the ease of placement of sealant following the use of the two techniques, as assessed by subjects and operators.

Design. The study took the form of a randomized controlled trial conducted in UK National Health Service community dental service and dental hospital clinics. Sixty subjects were recruited to this study by seven dental professionals who placed sealants on lower permanent molar pairs. The technique used for enamel preparation prior to sealant placement on the right and left side of the lower arch was randomized. On one side of the lower arch, Xeno® III was used to prepare the occlusal enamel, and on the other, phosphoric acid etch together with Prime & Bond® was used. Opaque Delton® was used to seal all surfaces. Subjects were blinded to the techniques used. The subjects and operators recorded their impressions of the techniques used on individual questionnaires.

Results. Forty-six (77%) of the 60 subjects were reviewed by the principal researcher after 6 months. The retention of the acid-etch group was significantly superior ($P < 0.01$), as was the caries preventive effect ($P < 0.01$). Subjects tended to report that placement of sealants was easier following enamel preparation with Xeno® III ($P = 0.085$), and in the opinion of the operators, sealants were significantly easier to place when using Xeno® III ($P = 0.016$).

Conclusions. In view of the findings of this investigation, best practice for the placement of sealants remains enamel preparation with acid etch and the use of an intermediate bonding layer.

Introduction

Following work by Takeuchi [1], and Cueto and Buonocore [2], fissure sealants (sealants) were introduced into dentistry over 30 years ago to protect susceptible occlusal surfaces from dental caries. A recent Cochrane Review [3] has confirmed the effectiveness of resin-based sealants on the occlusal surfaces of permanent molars. Most children accept this procedure with no difficulty [4]. However, there are a number of children who find the procedure difficult, and it is often the taste, rinsing and suction associated with the phosphoric acid etching stage that patients find unpleasant [5].

Sealants are traditionally placed after the fissure enamel is cleansed and etched with phosphoric acid.

Phosphoric acid etching removes contaminants and creates an irregular microporous enamel surface that is infiltrated by the resin-based sealant material. The technique of including a bonding primer between etched enamel and fissure sealant resin has gained popularity since the early 1990s. Hitt and Feigal [6] described the technique as a means of overcoming the negative effects of salivary contamination of etched enamel surfaces by using hydrophilic materials which contain water, applied under sealants, in order to improve sealant retention rates.

New nonrinse conditioning systems are now becoming available which enable composite-to-enamel bonding without previous phosphoric acid etching of the enamel surface. These new materials have been hailed clinically as the most promising approach in terms of both user-friendliness and technique sensitivity [7]. The etch-and-rinse phase is no longer required, which reduces clinical application time, and also reduces the risk of making errors

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during application and manipulation. It is also possible that this technique is more forgiving of mild salivary contamination.

Salivary contamination of the tooth surface after acid etching compromises the ultimate bond between resin and enamel, and has been implicated in sealant failure [8,9].

The volume of literature which exists at present on the subject of sealants only includes limited documentation comparing conventional acid-etch systems with nonrinse conditioning acid-etch systems *in vivo*. Feigal and Quelhas [5] reported on a clinical trial of a self-etching adhesive for sealant application over 24 months. They showed equivalent sealant retention on occlusal and buccal/lingual surfaces of permanent molars using a self-etching primer/adhesive system (Prompt L-Pop®, 3M ESPE, St Paul, MN, USA) compared to conventional etch and seal methods on contralateral teeth over this time period. It is likely that the above study was underpowered, and therefore, the conclusions drawn are questionable and its clinical relevance is limited because of the small number of sealants placed and reported upon.

Venker *et al.* [10] retrospectively compared a self-etching primer (Prompt L-Pop®) and phosphoric acid etch in a school-based sealant programme over a one-year period. They found that sealant retention with the use of the self-etching primer was poorer than with phosphoric acid etch.

Xeno® III (Dentsply, Konstanz, Germany) is a single-step, self-etching dental adhesive designed to bond light-cured restoratives to enamel and dentine. The single-step bonding system treats enamel and dentine simultaneously with acid-conditioning, priming and bonding functions. The aim of this study was to compare the clinical effectiveness of a nonrinse conditioner with conventional acid-etch bonding for enamel preparation prior to sealant placement. The specific research questions were:

- 1 Is there a difference between the two techniques with regard to retention of fissure sealant following its placement on the occlusal surfaces of permanent molar teeth?
- 2 Is there a difference between the two techniques with regard to caries incidence following fissure sealant placement on the occlusal surfaces of permanent molar teeth?
- 3 Is either technique more acceptable to subjects?
- 4 Is either technique more acceptable to operators?

Subjects and methods

Ethical approval for this study was granted by the Lothian Research Ethics Committee, Edinburgh, UK. Written informed consent for the involvement in the trial was obtained from an adult with parental responsibilities and rights, the consent of each subject having also been gained.

Subjects were recruited from regular patients attending dental hospital and community dental service clinics in the Lothian area, and were eligible for inclusion in the trial if fissure sealant placement on contralateral lower permanent molar teeth was indicated according to British Society of Paediatric Dentistry recommendations [11] and Scottish Intercollegiate Guideline Network guidelines [12], i.e. those at high risk of caries. Paired lower permanent molars were assessed by individual operators, who required them to be erupted enough to isolate teeth sufficiently for the placement of fissure sealant and caries free. Children who were felt not to be sufficiently cooperative to allow sealant placement were excluded.

Sealants were placed on upper molars as part of the trial, if clinically indicated; however, the paired lower molar teeth were the principal unit of analysis because of the effect of clustering.

In a review of sealant clinical trials, Feigal [13] reported a sealant failure rate (sealants needing repair, replacement or restoration) of between 5% and 10% each year. A power calculation based on these figures indicated that a sample of 80 would give a 90% power of detecting a difference in effectiveness between the two systems, assuming a significance level of 5%. To allow for dropout of subjects over the duration of the study, the aim at the outset was to recruit 50% more subjects in the first instance, giving a total of 120 subjects.

A total of nine operators were recruited to place sealants for this clinical trial. All operators routinely worked with an assistant. Dentists and therapists were involved from the hospital dental service as well as dentists and hygienists from the community dental service. All operators were fully qualified clinicians.

The operators received written and verbal direction in the two fissure sealant techniques to be used from the principal researcher (L.B.). These were identical to those issued by the manufacturer for each product.

Operators were instructed to always place sealant on the lower right molar tooth first. Randomization

of the sealant technique to be used on the lower right molar tooth was achieved by computer generation of a random number sequence.

Light-curing unit efficacy was measured in all clinics where sealants were placed using an Optilux® radiometer (Demetron Research Corporation, Danburg, CT, USA). Readings between 300 and 800 mW nm⁻² were considered acceptable.

Before placement of the sealant, prophylaxis of each molar tooth was undertaken using only a dry prophylaxis brush. Individual teeth were isolated using cotton-wool rolls and/or narrow bore suction (saliva ejector), and surfaces were washed and dried with a 3-in-1 tip.

Control group

Phosphoric acid 37% was applied to molar occlusal surfaces in the usual manner and left for 20 s for etching to occur. Teeth were rinsed with water for 20 s and then air-dried using a 3-in-1 tip. Prime & Bond® (Dentsply, Konstanz, Germany) was applied, left for 20 s, air-dried and light-cured for 10 s. Delton® (Dentsply, Tulsa, OK, USA) opaque light-curing fissure sealant was applied to fissures and cured for 20 s.

Test group

Equal quantities of Xeno® III liquids were mixed together in a dappens pot for 5 s. This liquid was then applied to the occlusal surface of the molar tooth, left for 20 s, air-dried using a 3-in-1 tip and light-cured for 10 s. Delton® opaque light-curing fissure sealant was applied to fissures and cured for 20 s.

The outcome measures used were retention of sealant, presence of caries and ease of use, as recorded by subjects and operators. Questionnaires were used by operators and subjects immediately following placement of fissure sealants to score ease of placement of the systems used, using a visual analogue scale (VAS) and a face scale, respectively. In addition, baseline DMFT/dmft was recorded for all subjects, along with age and sex, level of co-operation, and degree of salivary contamination.

Sealants were assessed according to a modified version of the Colour, Coverage, Caries (CCC) Sealant Evaluation System described by Deery *et al.* [14], as summarized in Table 1.

The integrity of fissure sealants was reviewed and recorded at between 6 and 11 months following

Table 1. Summary of Colour, Coverage, Caries (CCC) Sealant Evaluation System criteria.

Variable	Clinical appearance
<i>Sealant coverage</i>	
A	Sealant covering all of fissure system
B	Sealant present on > 50% of fissure system
C	Sealant present on < 50% of fissure system
D	No sealant present
<i>Caries score</i>	
0	Surface sound, no caries
1W	Initial enamel caries – white spot lesion
1B	Initial enamel caries – brown spot lesion
2	Enamel caries
3P	Caries into dentine – cavity < 0.5 mm
3L	Caries into dentine – cavity > 0.5 mm
4	Caries with probable pulpal involvement

placement by an independent clinician (L.B.), who was blind to the techniques used for tooth preparation prior to sealant placement in all cases. This clinician received training and calibration in assessment of the integrity of fissure sealants and caries diagnosis at the D₁ and D₃ diagnostic thresholds [14,15] from an experienced epidemiologist (C.D.).

Intraexaminer reproducibility was calculated by re-examination of eight subjects (17%) by the principal researcher (L.B.) at a subsequent appointment. Interexaminer reproducibility was calculated by examination of 15 subjects (33%) by both the principal researcher (L.B.) and another independent clinician (C.D.).

Sealants which were observed to be failing or lost at review visits were replaced using control materials and techniques, and these teeth were censored at this stage.

Data collected in this investigation were analysed using the SPSS statistical computer program.

Results

Of the nine dental professionals who had agreed to participate as operators in this study, seven succeeded in placement of fissure sealants for the purposes of the research. Of those who placed fissure sealants, three operators were dental surgeons, three were dental hygienists and one was a dental therapist.

Baseline data

A total of 60 subjects were recruited to this study by the seven operators. Eighty-one pairs of fissure

sealants were placed on permanent molar teeth, of which 60 pairs were on lower permanent molars and 21 pairs on upper permanent molars.

Of the 60 subjects recruited to this study, 28 were male and 32 female. The mean age of subjects was 9.15 years (range = 5–13 years). Mean baseline DMFT/dmft was 3.27 (range = 0–18).

The score for behaviour recorded on a 100-mm VAS by operators for individual subjects ranged from 0 mm (very cooperative) to 100 mm (very uncooperative). The mean VAS score for all subjects was 19.6 mm.

Of the 120 fissure sealants placed on lower permanent molar teeth for this study, 26 teeth (22%) were reported by operators to have suffered a degree of salivary contamination during placement. Of these, 13 teeth had been prepared with etch and Prime & Bond®, and the remaining 13 with Xeno® III. Of the 26 teeth which had suffered salivary contamination, this happened to both teeth in eight subjects. The remaining 10 were in individual patients; five of these had been treated with etch and Prime & Bond®, and the other five with Xeno® III. Because of the small numbers and the balance between groups, no further analysis was undertaken.

Light-curing unit efficacy

The light-curing efficacy range was between 300 and 700 mW cm⁻² for all clinics involved in the placement of fissure sealants for this study.

Baseline review data

The mean time between placement and review was 7 months and 27 days, and ranged from 5 months and 9 days to 10 months and 26 days.

During the review period, 46 patients (77%) were seen. These subjects had a total of 60 pairs of fissure sealants placed as part of the trial: 46 pairs on lower permanent molar teeth and 14 pairs on upper permanent molar teeth. Of these 46 subjects, 28 had sealants placed on paired first permanent molars and the remaining 18 subjects had sealants placed on pairs of second permanent molar teeth.

Sealant coverage scores

Sealant coverage scores were recorded blind at review by the principal researcher (L.B.). The results for the lower permanent molars ($n = 92$ teeth)

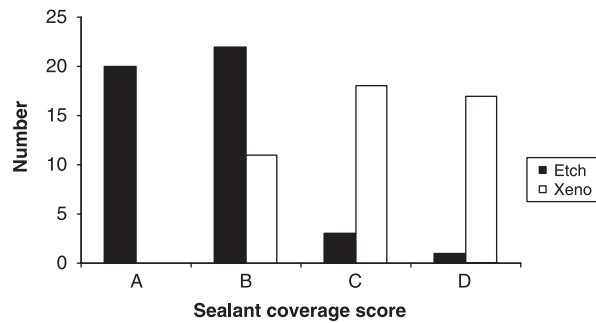


Fig. 1. Lower permanent molar sealant coverage scores at review ($n = 92$ teeth).

Table 2. Frequency of upper arch sealant coverage scores by group ($n = 28$ teeth).

Sealant coverage score	Etch group	Xeno® III group
A	2	0
B	12	2
C	0	1
D	0	11

are shown in Fig. 1. Scores for the upper permanent molars ($n = 28$ teeth) are shown in Table 2.

Of the fissure sealants placed in the etch (control) group in both the upper and lower arches ($n = 60$ teeth), score A (complete sealant coverage) was recorded for 37% teeth at review. In the same group, 93% teeth were given an A or B sealant coverage score.

When comparing all permanent molar pairs seen at review, the sign test showed that the sealant coverage was significantly worse ($P < 0.001$) for the Xeno® III group than for the control group.

For sealant coverage score A, a significant overall difference ($P < 0.001$) was found between the etch and Prime & Bond® group, and the Xeno® III group using the sign test. This test shows that use of etch and Prime & Bond® is significantly more likely to result in placement of a fissure sealant that remains covering the entire pit-and-fissure system over a 6-month period than use of Xeno® III for enamel preparation.

For sealant coverage score D, a significant overall difference ($P < 0.001$) was found between the control group and the Xeno® III group using the sign test. This shows that Xeno® III sealants were more likely to completely fail.

Using the sign test, with data for both upper and lower permanent molar pairs combined, there was no significant difference ($P = 0.58$) in sealant coverage between left and right.

Table 3. Frequency of lower arch caries scores by group ($n = 92$ teeth).

Caries score	Etch group	Xeno® III group
0	45	32
1W	1	8
1B	0	6

Table 4. Frequency of upper arch caries scores by group ($n = 28$ teeth).

Caries score	Etch group	Xeno® III group
0	14	13
1W	0	0
1B	0	0
2	0	0
3P	0	1

Caries scores

The results for the lower permanent molar teeth ($n = 92$ teeth) are shown in Table 3. Caries scores for the upper permanent molars ($n = 28$ teeth) are shown in Table 4.

When comparing caries scores in the lower permanent molar pairs using the sign test, the teeth prepared with Xeno® III were significantly more likely to show 1B or 1W scores ($P = 0.001$) than those in the etch and Prime & Bond® group. There was only one upper molar tooth with a positive caries score, and therefore, no statistics were practical for this data. As a result, when upper and lower permanent molar pairs are considered together, the results are the same as for the lower jaw.

Ease of placement (subjects)

For all 60 subjects, a Wilcoxon signed-rank test showed that the face scores are lower for those teeth where Xeno® III was used than those where etch and Prime & Bond® was used, but the difference was not significant ($P = 0.085$). This suggests that subjects tended to find that placement of fissure sealants was easier following enamel preparation with Xeno® III.

The Wilcoxon signed-rank test showed no significant difference in the face scores ($P = 0.258$) between left and right for all 60 subjects.

Ease of placement (operators)

For all 60 subjects, a paired t -test showed that operator VAS scores were significantly higher for

the etch group than the Xeno® III group ($P = 0.016$). This shows that, in the opinion of the operators, sealants were significantly easier to place when using Xeno® III.

Reproducibility

Both intraexaminer and interexaminer reproducibility were analysed, and kappa (κ) values were determined for both. The kappa values were interpreted using Landis and Koch's [16] six-point scale.

Intraexaminer reproducibility

For the lower permanent molar pairs, there was complete intraexaminer agreement ($\kappa = 1.00$) between the sealant coverage scores at visit 1 and visit 2.

For the lower permanent molar pairs, the intra-examiner kappa value for caries scores at visit 1 and visit 2 was 0.85 (almost perfect agreement).

Interexaminer reproducibility

For lower permanent molar pairs, interexaminer agreement had a kappa value of 0.96 (almost perfect agreement) for sealant coverage scores.

For lower and upper permanent molar pairs together, interexaminer agreement had a kappa value of 0.90 (almost perfect agreement) for sealant coverage scores. Because of the small number of carious teeth reviewed by both examiners, it was not possible to calculate a kappa value for caries scores.

Discussion

Operator recruitment for this clinical investigation was demanding. It was difficult to monitor operator commitment throughout the duration of the subject recruitment and sealant placement phase of the study. The operators who demonstrated an increased level of commitment to the investigation tended to be those who recruited more subjects to the trial.

As in most clinical trials, it was anticipated at the outset that a percentage of subjects recruited to the investigation would be lost to follow-up. In this study, 14 of 60 patients (23%) recruited did not attend for examination by the principal researcher (L.B.) at review. Given the significant difference between the two interventions, the power of the study was adequate, even with the reduced sample size. It is possible that the relatively high dropout

rate may have influenced the results. However, there is no reason to think that either product would have performed differently in the patients who failed to re-attend.

The mean baseline DMFT/dmft in this study was 3.27. This figure is higher than results published in Scottish Health Board Dental Examination Programme reports for both 1999–2000 and 1998–1999 in both Scotland and the Lothian region [17]. This reflects the high caries risk groups seen by these services.

The teeth in the etch group were significantly more likely to have a sealant coverage score that reflected that a greater percentage of the fissure system remained covered by fissure sealant at review.

In addition, a significant difference was found in the number of sealant A-scores recorded between groups; those teeth where etch and Prime & Bond® were used to prepare enamel were significantly more likely to retain a sealant covering all of the fissure system. When looking at the converse, i.e. sealant score D, those in the Xeno® III group were significantly more likely to record this score, reflecting that sealants were more likely to have been lost when this enamel preparation system had been used.

A significant difference between the caries scores recorded in the lower arch between the etch group and the Xeno® III group was identified. Members of the Xeno® III group were more likely to show early enamel caries than those in the etch group. This result can be explained by the sealants being significantly more likely to be lost in the Xeno® III group, and the pit-and-fissure system no longer being protected by the sealant.

In both the groups of subjects reviewed and in all subjects recruited to the study, no significant difference was found in the ease of placement scores reported by the subjects following sealant placement between the control and Xeno® III group, or between left and right.

Patients tended to score low for both techniques used in this study, which suggests that, in general, this group of subjects found the placement of sealants a relatively acceptable procedure.

In all subjects, and in those subjects reviewed, operators reported that Xeno® III was statistically significantly easier to use than the control technique. The operators scoring the ease of placement were not blind to the technique used, and therefore, may have had preconceptions. Since conditioning with Xeno® III involves fewer steps, this result was predictable.

Both intraexaminer and interexaminer kappa agreement were high in this study. The high kappa agreement scores in this investigation reflect the prestudy training of the examiner and may reflect the ease of use of the CCC system, which has previously been reported to be both valid and reliable [14].

The result in this investigation for sealant retention of 93% (when combining sealant scores A and B) in the control group at review compares favourably with previously published figures for sealant retention in clinical trials. In a review of clinical trials [13], an average failure rate of between 5% and 10% per year was reported.

This study produced results opposing those of Fiegall and Quelhas [5], who had concluded that the use of Prompt L-Pop® was as effective as use of etch alone for sealant placement in their 24-month clinical study. The pH of Prompt L-Pop® is approximately 1 and that of Xeno® III is less than 1. The principles of activation of the two products are similar, involving mixing two liquids prior to application.

However, the results of this investigation support the results of the *in vitro* study undertaken by Hannig *et al.* [18] and the retrospective analysis of sealant application techniques carried out by Venker *et al.* [10]. The conclusions of these studies were that the use of self-etching adhesives could not be recommended for enamel preparation prior to sealant placement and that further work on this subject was required.

An *in vitro* study by Atash and Van den Abbeele [19] investigated the bond strengths of a number of adhesives to bovine enamel and dentine, including Xeno® III. In this study, Xeno® III performed better than some self-etch adhesives on the dental market, but did not perform as well as the products which used separate etching and bonding steps. The results of this *in vivo* study would appear to support the results that this group of workers achieved *in vitro*.

Celiberti and Lussi [20] have reported on an *in vitro* study in which sealants were placed following phosphoric acid etching both with and without the subsequent use of Xeno® III. They concluded that the additional use of Xeno® III did not improve fissure sealing under the conditions of their study.

In a recent *in vitro* investigation [21], it was found that, when using some self-etching adhesives, higher bond strengths to sealant materials were achieved with the application of two layers of the adhesive product. It is possible that the use of two layers of

Xeno® III could have produced different results in this clinical investigation.

What this paper adds

- This paper adds to the literature results of a randomised controlled clinical trial using a one-step conditioning agent in the placement of fissure sealants.

Why this paper is important to paediatric dentists

- This paper shows that fissure sealing using the traditional etch and bond method remains the best clinical technique in terms of retention and caries prevention.

Conclusions

This randomised controlled clinical trial has demonstrated that enamel preparation with etch and Prime & Bond® is a superior method over 6 months when compared using clinical effectiveness with the use of Xeno® III when placing sealants. Thus, the null hypothesis was disproved.

This appears to be the first clinical trial to investigate the use of Xeno® III for this application. In view of the findings of this investigation, best practice for the placement of pit-and-fissure sealants remains enamel preparation with acid etch and the use of an intermediate bonding layer such as Prime & Bond®.

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