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ORIGINAL ARTICLE

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# A 2-year clinical evaluation of sealed noncavitated approximal posterior carious lesions in adolescents

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**Abstract** The objective was to evaluate the clinical performance of a therapeutic sealant to arrest the progression of noncavitated approximal posterior carious lesions. The study population comprised 50 adolescents in whom bitewing radiographs had been taken for diagnosis of caries. Approximal noncavitated lesions in premolars and molars (4d–7m) were selected. One group ($n$=17) had a sealant placed after tooth separation on all enamel lesions. A second group ($n$=7) received sealant and fluoride varnish in a split-mouth design. A control group ($n$=26) received a standard fluoride varnish treatment without tooth separation. Follow-up radiographs were taken after 2 years and were analyzed together with the baseline radiographs in a blind study setting. About 93% of the sealed initial carious lesions showed no progression. The corresponding value for the fluoride varnish control group was 88%. In the split-mouth study, 92 and 88% of the surfaces with enamel caries showed no progression after sealant or fluoride varnish treatment, respectively. The difference between the two treatment procedures was not statistically significant. The incidence rate for the transition from enamel caries to dentin caries or fillings was 3.5–3.9 surfaces/100 years in the sealant groups and 5.9–6.1 surfaces/100 years in the fluoride varnish groups. The results show the potential of sealants to act as a noninvasive treatment of early approximal enamel lesions.

**Keywords** Approximal initial caries · Prevention · Sealant · Fluoride · Adolescents

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## Introduction

Despite significant improvements in dental health in most industrial countries [14], the majority of children and adolescents have manifest caries when they reach adulthood [15, 25]. In many countries, initial lesions constitute the majority of approximal caries [15]. The presence of initial caries and its significance for further caries development underline the need for exploring new strategies for prevention and therapy [6].

Different modes of fluoride treatment have been used for the remineralization of initial carious lesions on approximal tooth surfaces to decrease the potential risk that they will develop into manifest lesions requiring restorations [3, 11, 22]. Fluoride exposure has, however, not been completely successful in the long-term perspective [16]. Some studies have suggested the possibility of sealing noncavitated enamel carious lesions on premolar and molar surfaces with adhesive resin-based materials [2, 4, 19]. This mode of treatment seems interesting, since long-term studies of occlusal tooth surfaces have shown that, as long as the sealants remained intact, caries left underneath were arrested for up to 10 years [7, 17, 23, 24].

In spite of the usefulness of this method for occlusal surfaces, few long-term clinical evaluations of the method for managing approximal tooth surfaces with initial caries have been reported [4]. Therefore, the purpose of this study was to evaluate the clinical performance of sealants to arrest the progression of noncavitated approximal carious lesions over a time period of 2 years.

## Materials and methods

### Subjects

Fifty patients (14 males and 36 females)—most of them adolescents with a mean age of 14.7 years (range 10–20 years, SD 2.1 years)—from the Navy Dental Clinics (Vina del Mar, Chile) participated. The patients belonged to the same population and came from an area with the same

socioeconomic status and where fluoride content in drinking water was about 0.6 ppm. The criterion for inclusion was the existence on posterior bitewing radiographs of one or more surfaces with incipient approximal carious lesions on molars and premolars. All the children and their parents gave informed consent to participate in the study, which was approved by the ethics committee of the Valparaiso University. Three groups were formed. One group ($n$=17) had dental sealants placed on all interproximal surfaces with noncavitated lesions. The second group ($n$=7) used a split-mouth design and had sealants or fluoride varnish applied on approximal enamel lesions. Since tooth separation, as performed in these two groups, was not considered standard care, the third group ($n$=26) was a control group that received fluoride varnish treatment without tooth separation.

## Diagnostic methods and criteria

Two posterior bitewing radiographs were taken on each side of the dentition. Approximal surfaces (4d–7m) were assessed for caries using a scoring system defined as: 0=no visible radiolucency; 1=radiolucency in the enamel; 2=radiolucency in the outer half of the dentin; 3=radiolucency in the inner half of the dentin; and 4=restoration. Caries in the enamel was not subdivided into two states (caries in the outer half or inner half) to avoid problems with depth assessment mainly of superficial lesions [10]. Surfaces showing enamel caries were selected, 1 to 16 per subject.

To gain access to the approximal space to confirm the presence of enamel lesions and their clinical status in the test groups, a temporary tooth separation was performed [19]. An orthodontic elastic separator (Dentalastic; Set-O-Loops, Michigan, USA) was placed around the approximal contact area involving the affected tooth. A pliers was used to stretch the separator and to snap it in between the two teeth. The patient was seen about 1–2 days later when the separator was removed. In most cases, the space obtained after tooth separation was between 0.8 and 1 mm. The surface was gently cleaned with pumice, dental floss without wax (Oral-B Laboratories, Iowa City, USA), and a sharp, soft handbrush (Interprox-micro; Dentaid, Barcelona, Spain). After washing and drying with contaminant-free compressed air, a cotton roll or a rubber dam was applied. Visual examination of the approximal surface was done for color, stain, and verification of a noncavitated carious lesion state.

## Intervention

In the teeth selected for sealant treatment, the carious tooth area and the 1-mm enamel surrounding the lesion were etched for 20 s with a 35% phosphoric acid gel (3M ESPE, St. Paul, USA) using a fine marten hairbrush (no. 00; Ocean, Berlin, Germany) bent to 45°. The adjacent surface was protected with a nylon adhesive strip (Dispens-O-Mat; Polydent, Mezzovico, Switzerland). When both adjacent approximal surfaces were to be treated with the sealant, the etching procedure was done simultaneously. The etchant was thoroughly washed away with water then air-dried. When the approximal surface was completely dried, a light-cured, low-viscosity pit and fissure sealant (Concise Sealant; 3M ESPE) was slowly applied in a very thin layer onto the etched area with a marten hairbrush. After waiting for 30 s, the sealant was cured with a light-curing unit (Curing Light XL 3000; 3M ESPE). During the procedure, a dental floss without wax was placed in the interdental sulcus space to avoid sealant flow to the cervical zone. After polymerization, the sealant was inspected for complete coverage. Excess sealant from nonetching areas was carefully removed with an explorer, and the margins were slightly polished with a fine polish strip.

In each subject of the split-mouth design group, random numbers were used to decide which surfaces with enamel caries should be treated with sealant or fluoride varnish material. On the surfaces chosen for fluoride treatment, a 5% sodium fluoride varnish (Duraphat; Colgate Oral Pharmaceuticals, Canton, MA, USA) was used twice a year. The approximal surfaces were cleaned with dental floss. After a thorough rinse with water, the teeth were dried with compressed air. The fluoride varnish was applied with a fine brush in the interproximal spaces using both buccal and lingual approaches. A temporary tooth separation was performed only before the first varnish treatment. The patients receiving varnish application were told not to brush their teeth on the day of application. The control group received the fluoride varnish twice a year as described for the split-mouth group but without tooth separation.

One of the authors (C.P.B.) treated all the children in the sealant and split-mouth groups, whereas the control group was treated by the dentist in charge of the Preventive Dental Program.

## Evaluation

The patients were clinically examined 6 months later and then once a year. Posterior bitewing radiographs were taken of each patient to control the lesions. The radiographs from the baseline and the 2-year examination were coded and then analyzed blindly in a random order by one observer. The evaluation was carried out under optimal conditions using a light desk and a special viewer with ×2 magnification. The approximal surfaces were classified according to the scoring index. To assess intraexaminer reliability, the radiographs of 76 tooth surfaces (29%) with caries lesions from both the baseline and the 2-year examination ($n$=152) were read twice, with an interval of 6 weeks.

## Statistical analysis

A change from score 1 to scores 2 and 3 or to a filling was defined as a progressed caries lesion. Differences between the sealant and fluoride treatment groups were determined using a two-factor analysis of variance and with the subject

**Table 1** Distribution of approximal scores at baseline and after 2 years, percentage of enamel caries with no progression, length of time-at-risk, and incidence rates for the transition from enamel to dentine caries

| Group | Number of score 1 surfaces at baseline | Score on year 2[a] | | | | Percent of score 1 surfaces with no progression | Time-at-risk (years) | Incidence rate per 100 years |
|---|---|---|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | | | |
| Sealant | 115 | 107 | 7 | 0 | 1 | 93.0 | 230 | 3.5 |
| Control Fluoride varnish | 76 | 67 | 3 | 1 | 5 | 88.2 | 152 | 5.9 |
| Split-mouth | | | | | | | | |
| Sealant | 38 | 35 | 2 | 0 | 1 | 92.1 | 76 | 3.9 |
| Fluoride varnish | 33 | 29 | 2 | 0 | 2 | 87.9 | 66 | 6.1 |

[a]Score 1=enamel caries; scores 2 and 3=dentin caries; score 4=restoration

and treatment as independent variables. The significance level was set at $p<0.05$. The incidence rate was used for the expression of the rate of lesion progression [10] and was calculated as the number of events divided by time-at-risk. Events were defined as the number of lesions that progressed from carious state 1 to 2 or higher, whereas time-at-risk was the amount of risk time during the period of all treated lesions expressed in surface years. The unit for the incidence rate was surfaces per 100 years.

## Results

The lesions on the approximal tooth surfaces were characterized by a whitish/brownish discoloration of the enamel. A total of 153 posterior tooth surfaces with this appearance were treated with sealant and 109 were treated with fluoride varnish. They comprised 22% of all available tooth surfaces in the three approximal spaces between the first premolars and second molars. After 2 years, all patients were available for reexamination.

The assessment of intraexaminer reliability showed a $\kappa$ value of 0.86 when the calculations included carious surfaces (scores 1–4). For surfaces with score 1, the $\kappa$ value was 0.84.

The progression of the approximal caries lesions during the experimental period in relation to status at baseline is presented in Table 1. In the sealant group, 107 of 115 surfaces (93%) did not progress to dentin lesions or fillings. For the fluoride-varnish-treated surfaces, 88% showed no progression. The difference between the two treatment groups was not statistically significant. The incidence rate of the sealed surfaces for the transition from state 1 to states 2–4 was 3.5 surfaces/100 years, indicating that of 100 enamel lesions present at baseline, caries progressed into the dentin or became filled in 3.5 surfaces/year. The corresponding value in the fluoride varnish group was 5.9 surfaces/year. In the split-mouth study, the incidence rates were 3.9 and 6.1 in the sealant and fluoride varnish groups, respectively. Of all enamel lesions at baseline, 1.3% of sealed surfaces and 6.4% of fluoride-varnish-treated surfaces were restored on the 2-year radiographs.

Table 2 shows that most of the sealed approximal surfaces were located between the second premolars and first molars (54%). For sites between the first and second molars, more surfaces were sealed in the lower jaw than in the upper jaw, whereas the opposite situation was noted in the other two locations of approximal sites. Of the 11 sealed lesions, which progressed during the 2 years, seven were found between second premolars and first molars. There was no difference in progression for sealed surfaces between the upper and lower jaws.

## Discussion

The present clinical study has demonstrated that the progression of early noncavitated approximal caries lesions under a bonded resin sealant can be arrested. After 2 years, 92–93% of the sealed surfaces showed no progression. It is thus obvious that a resin sealant bonded to the surface enamel after acid etching is able to retard the progression of an already established incipient lesion on approximal posterior surfaces. The application of sealants on occlusal tooth surfaces has been demonstrated in several clinical trials to be a safe and effective method of preventing pit and fissure caries [23]. A systematic review revealed that the proportion of prevented occlusal decay among children receiving a fissure sealant was 71% compared to controls [12]. In addition to preventing caries, sealants have also been shown to arrest incipient decay in fissures over a 10-year period [17].

**Table 2** Distribution of scores for total sealed approximal surfaces among premolars (P) and molars (M) at baseline and after 2 years, and the incidence rate

| Approximal site | Number of score 1 surfaces at baseline | Score on year 2 | | | | Time-at-risk (years) | Incidence rate per 100 years |
|---|---|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | | |
| First P/second P | 38 (26+12)[a] | 35 | 2 | 0 | 1 | 76 | 3.9 |
| Second P/first M | 83 (48+35) | 76 | 6 | 0 | 1 | 152 | 4.6 |
| First M/second M | 32 (4+28) | 31 | 1 | 0 | 0 | 64 | 1.6 |

[a]Number of surfaces in the upper and lower jaws

The initial carious lesions treated in the present study were mostly so-called "white spot" lesions, which implies that there is a subsurface area with microporosities within the enamel tissue. In vitro studies have shown that the surface zone of artificial lesions of enamel can be occluded following infiltration with a polymer material [21]. The application of a pit and fissure sealant on extracted human teeth with proximal noncavitated enamel lesions showed the presence of resin tags of up to 6 μm in length [8]. This physical barrier may act as protection against exposure of acids produced by bacteria in the overlying plaque biofilm, but may also decrease the number of viable microorganisms in the lesion under the sealant [7].

Overall, about 7–8% of the sealed initial enamel lesions showed progression. One explanation can be that the sealant material was only applied once. It has been shown that the effectiveness of a sealant decreases over time after a single application [12]. This implies that if the retention of the sealant was not complete during the experimental period or it became deficient, this could lead to progression of the lesion. In clinical situations, it is more difficult to examine the retention of the sealant on the approximal posterior surfaces without tooth separation than in the case with occlusal surfaces. The very thin layer of sealant is hard to see, even by using magnification, in spite of the extension of the sealant to the buccal and lingual areas. It is possible that the use of a colored sealant might offer an advantage in these situations. The fact that the majority of the enamel lesions remained unchanged during the following 2 years in spite of one sealant application is therefore of clinical interest.

There was no control group included in the study, as all surfaces with incipient lesions were treated for ethical reasons. Thus, the study did not provide information on the actual effects of the applied sealant. Moreover, no caries risk assessment was done in the approximal sites; it is therefore possible that some of the "white spot" lesions could have been inactive and remained unchanged without treatment, or could have been repaired naturally [1]. In order to compare the progression rate, reference groups with fluoride varnish were included, as different studies have shown that frequent topical application of Duraphat has resulted in a significant reduction in the incidence and progression of proximal caries lesions [13, 18]. The fluoride varnish treatment in this study was highly protective, and no significant differences in effect were found between the sealed and fluoride-treated groups. Furthermore, no difference in caries development was noted when varnish treatment was compared with or without an initial tooth separation. In the split-mouth study, the carryover effect of fluoride from the varnish was probably very small, as fluoride had a limited ability to move to other sites due to fact that the rate of fluoride clearance was highly site-specific [20].

The incidence rate for the transition from enamel caries to dentin caries and fillings was 5.9–6.1 surfaces/100 years in the two fluoride groups. For the sealed surfaces, the incidence rate was 3.5–3.9 surfaces/100 years. A recent Danish study of caries progression in late teenagers showed that the incidence rate for progression from the enamel to the outer half of the dentin was 9.2 surfaces/100 years [10]. Furthermore, the proportion of surviving enamel lesions on the posterior surfaces of premolars and molars in teenagers has been shown to decrease to 78% during the 2-year period [9]. For the sealant group in the present study, 92–93% showed no progression after 2 years. The beneficial effect of sealant application was further supported by a recent clinical study on the sealing of noncavitated approximal lesions [4]. After 1.5 years, 77% of the test lesions remained stable compared with 28% for control lesions receiving only flossing. Placing orthodontic separators and having the patient return are time-consuming and therefore relatively costly in public health settings. However, although interpreted with caution, the results of the present study suggest that sealants can serve as a promising approach for arresting approximal incipient carious lesions.

In conclusion, the results of the present study show the potential of sealants to act as a noninvasive treatment for early approximal enamel lesions. This is also in line with strategies aimed at a more tissue-preserving approach when restoring teeth. The concept of minimally invasive dentistry has focused on the maximum conservation of demineralized noncavitated enamel and dentin [5]. The therapeutic approach of using a sealant on noncavitated demineralized approximal surfaces is in accordance with this new concept.

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