Clin Oral Invest (2011) 15:879–884
DOI 10.1007/s00784-010-0457-z

ORIGINAL ARTICLE

Sealing proximal surfaces with polyurethane tape: three-year evaluation

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Received: 17 March 2010 / Accepted: 29 July 2010 / Published online: 10 August 2010

Abstract The purpose of this investigation was to test the safety and clinical effect of a new material for the treatment of proximal caries. In 50 patients with two proximal initial lesions, one of the lesions was randomly chosen and sealed with a thin polyurethane-dimethacrylate foil using bonding. The other lesion received oral home care and was left as the control. In clinical follow-ups after 6 and 12 months and X-ray evaluation after 2 and 3 years, the sealants showed good retention, marginal adaptation, and color. No relevant significant differences in plaque accumulation or gingival status were found between sealed and control teeth. On the radiographs, almost all sealed and control lesions appeared stable, indicating an arrest of the lesion. In conclusion, sealing initial proximal lesions showed no clinical problems and mostly arrest of caries on bitewing radiographs.

Keywords Proximal sealant · Proximal caries · Initial caries

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Introduction

The strategies of caries prevention such as fluorides, plaque control, and less frequent sugar intake inhibit caries formation or progression, but with active patient behavior being involved, compliance remains a problem. The approach of establishing a permanent barrier between the tooth and dental biofilm has been a tremendous success as a preventive measure for pit-and-fissure caries using the adhesive technique to seal the at-risk surfaces [1]. The sealing of initial enamel lesions in occlusal surfaces is widely recommended [2].

Extending this approach to other tooth surfaces, the idea of sealing proximal surfaces arose early [3, 4]. These early trials showed the feasibility of applying sealing material on proximal surfaces, but also problems such as imperfect etching, incomplete sealant layer, and difficulties in clinical application. Advances in adhesive dentistry encourage continuing these efforts to achieve an effective and practical sealing of proximal caries.

Up to now, few clinical studies have evaluated proximal sealants, reporting that sealing of proximal initial lesions reduced the progression rate [5] or arrested the sealed lesions [6, 7].

A critical question in proximal sealing is the smooth surface sealant per se which offers less retention than fissures. Therefore, a pre-cured adhesive monomer patch could offer ideal physico-mechanical properties for smooth surface sealing, including the proximal area. After a series of in vitro studies, the adhesive patch showed complete protection of the underlying enamel from demineralization and provided an excellent protection against caries [8, 9], but there is still a need for in vivo testing. Thus, the aim of this investigation was to test the safety and clinical effect of proximal sealing using a pre-cured adhesive monomer patch in initial non-cavitated carious lesions.

The null hypothesis (H_0) to test the safety and the clinical effect of proximal sealants was: there are no differences between sealed and control surfaces in plaque accumulation, gingival bleeding, and caries development.

Materials and methods

Sample

After the approval of the ethics committee, 50 patients (27 male; 23 female; mean age, 21.3±5.6 years) with two proximal carious lesions (D1–D3) in vital teeth were included in this split mouth study. The exclusion criteria were relevant general disease, allergies—especially to composite materials—pregnancy, and presence of cavitation on tested or control proximal surfaces.

Radiographic classification for caries [10] was used:

- D0: no radiolucency
- D1: radiolucency in the outer half of the enamel
- D2: radiolucency in the inner half of the enamel including lesions extending up to but not beyond the enamel–dentin junction
- D3: radiolucency with spread into the outer half of the dentin
- D4: radiolucency with spread into the inner half of the dentin

All patients participating in the investigation had to give written informed consent and were offered dental care during the study period.

Materials and study design

The baseline examination consisted of the medical history, dental status (DMFT/S), plaque, gingival status, and vitality of test and control teeth.

The bitewing X-rays were taken with conventional film (Kodak® INSIGHT-F E-Speed) with holders (KKD RWT Filmhaltersysteme) at a standardized exposure (60 KV, 0.25 mAs). The X-ray diagnosis was performed under 2.5× magnification on a light box (Dentaurum, Ispringen, Germany).

At the end of the first visit, an orthodontic separating rubber ring (standard size, Ø 3 mm, Dentaurum, Ispringen, Germany) was inserted into the proximal contact area of the two lesions with the help of rubber-dam pliers.

After 3–5 days, a 0.8- to 1-mm interproximal space was gained for a final assessment of the status of the carious lesions under direct vision with gentle probing, excluding cavitation. One of the two lesions was randomly assigned—by throwing a coin—to be sealed; the other lesion was left as a control. There were no restrictions on the sites of test or control teeth; they could be contra-lateral, ipsilateral or adjacent, in any part of the dentition from the canine to the second molar.

Proximal sealing

All sealants were performed by one trained dentist. After removal of the rubber ring and cleaning the initial lesion with fluoride-free paste and dental floss, a rubber dam was placed and proximal sealing was performed under the following guidelines:

- Isolation of the neighboring tooth with a metal matrix band (Demedis GmbH, Langen, Germany)
- Etching of the proximal surface of the test tooth (60 s) and occlusal surfaces of test and control teeth (30 s) with 37% phosphoric acid (Email Preparator, Ivoclar-Vivadent, Schaan, Liechtenstein)
- Application of bonding agent (Heliobond, Ivoclar-Vivadent, Schaan, Liechtenstein) on the proximal surface of the test tooth with an extra fine brush (Ø= 1 mm)
- Application and adaptation of the adhesive patch (thin polyurethane-dimethacrylate foil, Ivoclar-Vivadent, Schaan, Liechtenstein) (Fig. 1)
- Light curing for 20 s lingually and 20 s buccally (wave length, 400–500 nm; 0,7A, ELIPAR II, ESPE, Seefeld, Germany)
- Occlusal sealing of test and control teeth (Helioseal, Ivoclar-Vivadent, Schaan, Liechtenstein).
- Removal of rubber dam, then finishing of the contour of the proximal sealant with finishing disks and polishing strips (Sof-Lex, 3M ESPE, MN, USA).

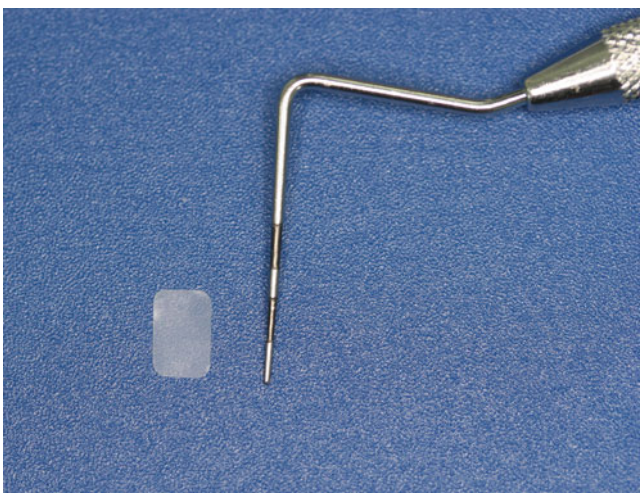

Fig. 1 Polyurethane-dimethacrylate tape for proximal sealant (Ivoclar-Vivadent, Schaan, Liechtenstein)

The other proximal lesion on a different tooth was left as a control and the patient was instructed in oral home care with dental floss and fluoridated toothpaste.

Recall and clinical evaluation

Recall appointments were scheduled 2 weeks, 6, 12, 24, and 36 months after sealant application. The examiners were different from the dentist who applied the sealants.

During recall visits, the following parameters were included:

- Medical and dental history
- Examination of test and control teeth (thermal sensitivity test, recording of visible plaque and gingival bleeding)

The quality of sealants was assessed and graded in accord with the modified Ryge criteria [11] for surface roughness of the patch, retention, discoloration, and marginal adaptation of both the adhesive patch and underlying bonding.

The recall ended with professional tooth cleaning and fluoride application (Elmex Fluid, GABA, Münchenstein, Switzerland).

At the 24- and 36-month recalls, bitewing radiographs were taken including the sealed and the control lesions.

Radiographic examination

The radiographic evaluation was performed with the same criteria as the baseline examination.

Two dentists with high intra- and inter-examiner reliability values, blindly and randomly assessed the radiographs separately and then compared their readings. If a conflict existed, they discussed it on the basis of the evaluation criteria to reach a unanimous decision.

Statistical analysis

All data of baseline and recall examinations were entered into Microsoft Office Excel 2003 and transferred into SPSS11.5 for further statistical analysis.

The H_0 was tested using the two-sided Fisher's exact test for the clinical safety. The Wilcoxon test was used to analyze the clinical effect of the proximal sealants. The level of significance for both tests was $p=0.05$.

Results

At the end of the study, 14 patients could not be contacted by telephone or mail. Three patients told the examiner that they would move away. One non-cavitated D3-lesion was filled by another dentist almost immediately after the placement of the sealant. One patient received an orthodontic band on a sealed tooth, which made the clinical and radiographic examination impossible. One patient was pregnant at the last recall so only a clinical examination could be performed. Thus, the reasons for dropout were not associated with the study.

Clinical results throughout the study

No changes in the medical history could be detected and no local or systemic effects such as allergic or toxic reactions were observed with respect to the proximal sealants.

The overall caries experience of the study sample increased marginally throughout the study time [baseline, 4.96 DMFT± 4.73, 8.67; decayed, missing, filled surface (DMFS)±9.86; at 3-year recall, 5.96 DMFT±4.84, 10.31 DMFS±10.44].

Plaque and gingival bleeding did not differ significantly between proximal spaces with sealants and control teeth (Table 1), and all teeth remained vital.

Most of the sealants could only be detected when the examiner was informed about their location (Fig. 2). Discoloration was negligible. A few sealant patches were lost completely or partially, but the underlying bond was still detectable. Table 2 details the retention and marginal adaptation of the sealing tape during the study.

Radiographic evaluation

Five dentists were asked for testing the reliability of reading bitewing radiographs. Each dentist had to evaluate ten

Table 1 Plaque accumulation and gingival bleeding in sealed and control surfaces during the study, in percent (Fisher's exact test, two-way)

		Baseline	6-month recall	12-month recall	2-year recall	3-year recall
Plaque	Sealed surfaces (%)	56	55	60	53	64
		$p=1.00$	$p=0.66$	$p=0.65$	$p=0.81$	$p=1.00$
	Control surfaces (%)	54	48	55	47	60
Gingival bleeding	Sealed surfaces (%)	28	26	36	25	28
		$p=0.65$	$p=0.28$	$p=1.00$	$p=0.78$	$p=1.00$
	Control surfaces (%)	22	14	26	19	24

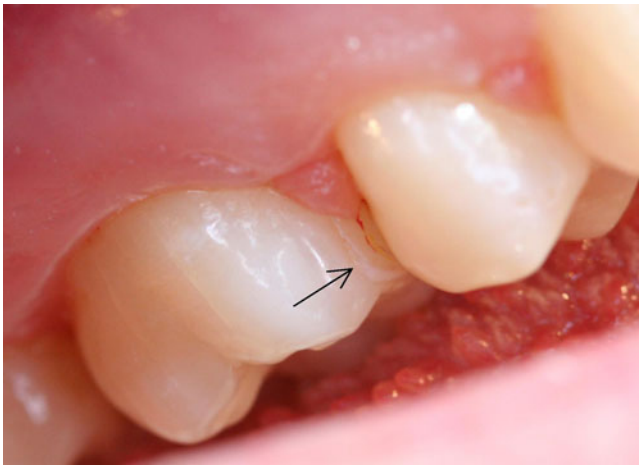

Fig. 2 Proximal sealant at 3-year follow-up on mesial surface of first maxillary permanent molar (vestibular view)

radiographs twice at different points of time, and intra-examiner reliability was assessed for each dentist. The gold standard was defined after a discussion and assessing the most frequent readings of these five dentists. Then, inter-examiner reliabilities were calculated. The two dentists, who had the best intra- and inter-examiner reliability values, were chosen for the radiographic examination in this study. They assessed the radiographs separately then compared their readings and in case of a conflict, they discussed it on the basis of the evaluation criteria to find a unanimous vote. Intra-examiner reproducibilities of radiographic assessments of the two examiners were 92% and 82%, and the agreements of each examiner with the gold standard were 92% and 80%. Inter-examiner agreement was 90%.

At the 3-year follow-up, ten sealed lesions presented with regression (33%) while two had progressed in comparison to baseline (7%). Eight control lesions regressed (27%) and two progressed (7%). All other sealed and control lesions were stable, indicating an arrest of the lesions (60% and 66%, respectively).

The Wilcoxon test (two-way) showed no significant difference in the development of lesions on radiographs between sealed and control surfaces (p=0.78).

Discussion

The aim of this study was to assess the feasibility and the clinical effect of proximal sealants using polyurethane-dimethacrylate tape in initial carious lesions. The clinical procedure of the proximal sealant was in line with the well-established techniques in adhesive dentistry. The cleaning, etching (60 s, 35–38% phosphoric acid), and application of the sealant followed the current guidelines on sealants [12]. The bonding agent (Heliobond/Ivoclar Vivadent), which has been used for many years in adhesive dentistry, has shown excellent clinical success [13]. The adhesive patch used in this study is a methacrylic, urethane-based, polymer material of approximately 100-μm thickness. The uncured material is insoluble, but swells in organic solvents. Upon light curing by blue light, full polymerization of the methacrylic groups occurs, rendering the patch hard and solid. Thus, it can copolymerize with other resin-based dental materials such as bonding agents. A series of in vitro studies has proven that the modification of adding an adhesive patch offers good chemo-mechanical properties [8, 9].

Other clinical studies on proximal sealants used a bonding agent or conventional sealant materials only [5, 6, 14]. The elastic polyurethane foil allows an even layer of bonding/sealant under the patch, more controllable application, and the removal of excess cervical bonding prior to light curing. It solves the problem of thin sealant layers and oxygen inhibition, and the thickness of 80–100 μm is tolerable when not all proximal surfaces are sealed in one quadrant.

In addition, the new adhesive patch approach seems to be statistically more resistant to lactic acid exposure than two layers of enamel bonding, at least in vitro [8]. The continuous patch also provides excellent protection in a cariogenic environment [9].

The use of a rubber dam was very important to isolate the operating field from moisture and blood contamination, and to hinder excess bonding agent from entering the proximal gingival sulcus. It also helped to retract the gingiva and provide a good overall view during this

Table 2 Retention and marginal adaptation of the sealing tape during the study

		Baseline	6months	12months	2years	3years
Retention of patch	No loss	48	39	37	27	20
	Partial loss	1	1	2	2	3
	Total loss	1	2	3	7	7
Marginal adaptation	Perfect	42	30	30	26	16
	Edged margin	8	12	12	9	12
	Step-like loss of retention	0	0	0	1	2
	Open margin	0	0	0	0	0

technique-sensitive procedure. The time required to place proximal sealants was comparable to the time required for a two-surface composite filling, but the patients needed no local anesthesia or tooth preparation.

The sample size of 50 was chosen in accordance with other feasibility studies on proximal sealants and new restorative techniques [6, 15]. The dropout throughout the study after 6, 12, 24, and 36 months were 8, 8, 14, and 20, respectively. The reasons for dropping out were independent and the risk for selection bias was excluded.

In general, the sealants were hard to detect and hardly distinguishable from normal enamel, indicating good marginal adaptation. Anatomical form, surface roughness, and color were far superior to composite restorations assessed with the similar Ryge criteria [11] and remained stable throughout the study. Marginal adaptation with mostly perfect margins and 20–30% minor steps was equivalent to composite fillings [15].

Retention of the patches decreased slightly throughout the study, perhaps due to the mechanical stress of proximal flossing. In total, seven patches were completely and three were partially lost within 3 years, but caries was not associated with loss of the patch. The partial loss of the patch might be worse than a complete loss as it may enhance plaque accumulation.

As the use of proximal sealants is a completely new technique, the safety of the method was an important variable. No adverse effect on general or dental health could be recorded. One problematic factor in dental restorations is an increased plaque accumulation and gingivitis [16], but plaque accumulation and gingivitis on the sealed and neighboring teeth did not differ significantly from the control teeth ($1.00 \geq p \geq 0.28$).

In contrast to a previous studies [5, 17], where about 10% and 26% in the sealed and control group progressed, the radiographic evaluation after 3 years showed very little caries progression. Only two (7%) of the control teeth with oral home care and two (7%) of the sealed teeth progressed and were subsequently filled. Most of the lesions showed stabilization; both proximal sealants in the test teeth and oral home care in the controls arrested initial non-cavitated lesions for 3 years. In ten sealed and eight control lesions, a regression was diagnosed on the bitewing radiographs. The changes in cases with caries development were in mostly one degree on the radiographic caries classification. The overall development of sealed and control lesions did not differ significantly (Wilcoxon test, $p=0.78$). The reason for this could be a very high level of prevention and the low caries risk of the participants as they all received semi-annual professional tooth cleaning, fluoride applications, and additional motivation for dental home care.

In the recruitment of the participants, the criteria were constructed to reduce the risk of a selection bias. Mostly young adults were enrolled in the study as they often exhibit initial carious lesions which commonly progress and are filled in older adults. About five DMFT at the mean age of 21 can be considered low caries prevalence and is a common value for young adults after the caries decline [18, 19]. Still, regular dental attendance, the decision to take part in a preventive study, and compliance with recall exams tends to select participants with higher dental awareness. This resulted in very few teeth with caries progression, even in control teeth with only home-care flossing and fluoride. Normally, patients tend to comply little with flossing, which results in a higher progression rate of proximal caries, especially at the D3-level. Thus, in a more caries-active population, the difference in caries progression between proximal sealants and flossing only could be more pronounced.

In conclusion, sealing initial proximal lesions with a new adhesive patch and bonding agent offers a novel technique in preventive dentistry which shows no clinical problems and general stabilization of the lesions after 3 years as oral hygiene with flossing and fluorides did.

Conflict of Interest This study was supported by Ivoclar-Vivadent (Schaan, Liechtenstein).

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