

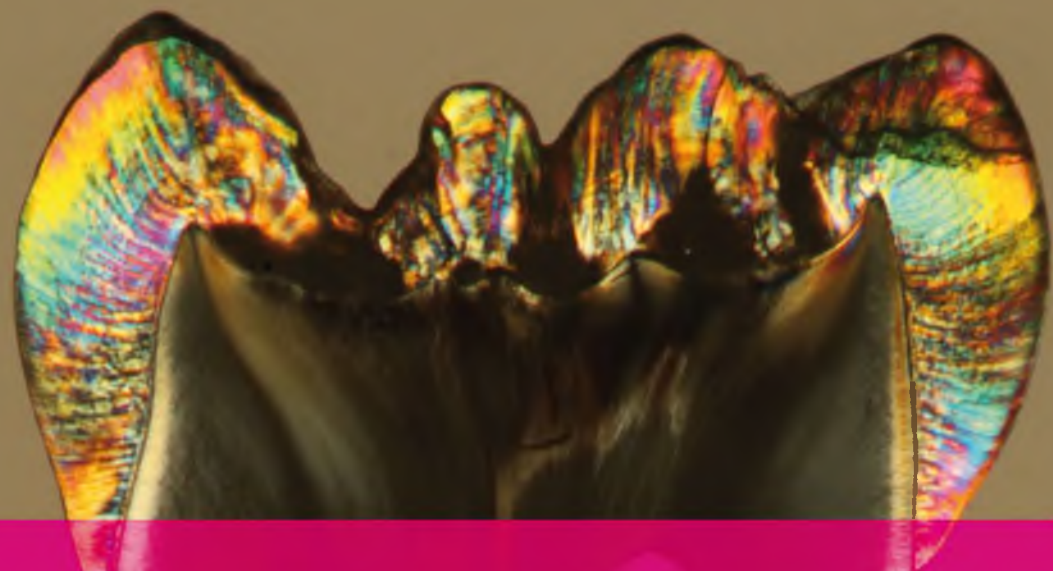
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Management of occlusal caries

Miluska Hevinga

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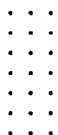
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NMT

Nederlandse Maatschappij
tot bevordering
der Tandheelkunde

Management of occlusal caries

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Medische Wetenschappen

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(Roosbeef)

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1

General Introduction

One of the risk factors for caries lesion development in the pits and fissures of occlusal surfaces is the morphological configuration of pit and fissure systems. Especially in narrow and deep fissures, plaque can easily accumulate and become cariogenic, due to the fact that it is shielded from the cleaning action of the bristles of the toothbrush, and from the protective influence of saliva. In such an environment, demineralisation of the enamel may proceed unchecked, resulting over time in dentine lesions and cavities. The demineralisation process follows the enamel rods until it reaches the enamel-dentinal junction, where it continues in the dentine in the direction of the pulp. With progressing enamel destruction, a proper cavity is formed¹ (see Figure 1). Although caries lesion development in pits and fissures is often seen in recently erupted teeth, it may occur at any age.

Figure 1 Cross-section of a molar with an occlusal caries lesion extending into the dentine, undermining the enamel.



Prevention of caries in occlusal surfaces has a long history. One of the first methods used was the prophylactic odontotomy.² Superficial cavity preparations were made in the pit and fissure systems and restored with amalgam. Bödecker³ introduced the 'eradication' of enamel fissures, a technique in which the slopes of the cusps were reduced in order to increase the accessibility of pits and fissures to plaque removal. Both methods resulted in the sacrifice of sound tooth tissue, while their effectiveness has never been proven.^{4,5} Nowadays, non-invasive methods, like tooth brushing with fluoridated toothpaste, or the application of fluoride varnishes or pit and fissure sealants are preferred. Adhesive fissure sealing was introduced by Cueto and Buonocore.^{6,7} Caries susceptible pits and fissures were cleaned with brushes and pumice, etched with 50% phosphoric acid and covered with a chemically cured resin. This technique marked the beginning of the era of adhesive dentistry. Since that time, new materials, methods and treatment protocols have been developed and investigated. A more conservative approach could be realized in managing dental caries, called Minimally Invasive Dentistry.

Sealing of sound pits and fissures

Sealants are usually applied in pits and fissures clinically free of caries lesions (preventive sealant application), or when first signs of enamel demineralisation are visible (therapeutic sealant application). Preventive as well as therapeutic sealants are often applied soon after eruption of (pre-)molars. However, sealing fissures so early, particularly first permanent molars, may compromise sealant retention due to reduced cooperation of the younger patient and anatomical factors leading to problems in the application procedure, such as lack of proper isolation from saliva.

Different sealant materials have been researched, but this thesis will concentrate on the most commonly used resin based sealant materials. The clinical effectiveness of resin based pit and fissure sealants has been reported in systematic reviews.⁸⁻¹¹ However, these systematic reviews vary somewhat in their conclusions and recommendations, which may in part be due to the use of different search strategies and inclusion criteria. In general, resin based sealants were more effective in preventing caries lesion development in pits and fissures than no sealant application. Their effectiveness depended on the caries risk of the population or individual,¹¹⁻¹³ and on the type of tooth that was sealed. A crucial factor, compromising the value of the evidence for contemporary populations, is the fact that most of the included studies in the systematic reviews were performed in the 1970s, when caries prevalence was high. Furthermore, most included studies evaluated sealant treatment carried out in university clinics by well-trained dental operators, had only a short follow-up and

used sealant materials that are no longer available. Actual information on the effectiveness of currently used resin based sealant materials is scarce, as well as its long-term effect in private practice. These aspects are addressed in this PhD thesis.

Sealing enamel/dentine lesions

Sealants are increasingly used as a therapeutic measure by sealing over incipient caries lesions to prevent lesion progression.¹⁴⁻¹⁶ In these cases, the concern has been voiced that micro-organisms are left behind that could induce further progression of the caries lesion. Taking into account current knowledge of cariology, progression of a caries lesion under a resin based sealant is a concern only if the sealant material used adhered insufficiently to the enamel surface. Under those circumstances, cariogenic plaque may continue the demineralisation process in the absence of proper plaque control, saliva fluids and fluorides. Another reason might be the degradation behaviour of the resin based sealant material over time. Resin based sealants tend to fracture, creating a plaque retention place which, in a caries active oral environment, may lead to a reactivation of the caries lesion.

Research showed that the application of sealants on fissures with questionably cavitated caries lesions, so called sticky fissures on probing, resulted in a reduction of the viable bacteria under the placed sealants compared to unsealed teeth.¹⁷⁻²⁰ The use of acid etching alone, killed up to 75% of the viable micro-organisms in pits and fissures.²⁰ Cutting away an enamel caries lesion in order to kill or remove micro-organisms appears, therefore, to be unnecessary and is not advocated in the concept of Minimally Invasive Dentistry. Radiographic evaluation of the sealed fissures in the above-mentioned studies showed either no progression of the caries lesion or even a slight improvement.²¹ Only one study²² reported in some cases the presence of cariogenic micro-organisms under the sealed surface. This study was a retrospective one and no comparison of the numbers of viable bacteria before and after placement of the sealants was possible. Thus, the total number of viable bacteria might have decreased in time.

The sealing of incipient lesions is supported by the results of a meta-analysis that showed that application of resin based sealants over non-cavitated caries lesions in pits and fissures of permanent teeth in children, adolescents and young adults was effective.²³ The median annual progression rates for sealed and non-sealed caries lesions were reported to be 5.0% and 16.1%, respectively. However, others only found little evidence that application of sealant material over an arrested or enamel caries lesion reduced the risk of caries progression.¹⁰

Effectiveness of pit and fissure sealants in clinical studies is often expressed in full retention rates of the applied sealant material. Therefore it is important to improve the retention of resin based sealants and thus increase the likelihood that caries lesions beneath the sealant remain arrested. For contemporary resin based materials there is a need to establish the effects of technique factors, such as use of an additional adhesive system (cured or uncured), on outcome variables related to retention such as level of marginal leakage and fissure penetration depth. In the previous section, the uncooperative behaviour of young children and the need to seal erupting molars, were mentioned as possible reasons for failures of resin based sealants. It is not uncommon that etched and dried pits and fissures are contaminated with saliva or moisture. The scientific literature is inconclusive about the effect of bonding sealant material to caries lesions in such contaminated circumstances.²⁴⁻²⁷ In this PhD thesis the above mentioned effects are being addressed.

Only few studies report on the sealing of unambiguously cavitated fissures. Mertz-Fairhurst et al.^{28, 29} compared in 14 patients contra laterally sealed and unsealed occlusally cavitated teeth. Radiographs of sealed and unsealed teeth were made at regular intervals during the observation period. Radiographic measurements after 12 months observation time showed that lesion depth decreased in sealed teeth, while in the unsealed teeth lesion depth increased. No viable bacteria in the sealed teeth could be counted, however, in the control group viable bacteria were found, ranging from only a few to too numerous to count. After reopening the sealed teeth, a thin layer of powdery, dry and whitish dentine was observed with hard and glassy-smooth dentine underneath. After opening the unsealed teeth, a layer of moist, soft and yellow-amber dentine was observed. We conclude that it is still uncommon and considered experimental to seal cavitated occlusal lesions with a resin based sealant material. Therefore, the sealing of cavitated occlusal lesions with resin based sealants is addressed in this PhD thesis.

Restoring cavitated caries lesions

Resin based restorative materials are commonly used to restore advanced caries lesions. In cavitated pits and fissures the dentine is always involved in the caries process.^{31, 32} As the cariogenic plaque within the cavity cannot be removed by preventive measures, a cavitated caries lesion often cannot be stopped without further opening of the cavity to improve access. Excavation of infected dentine and restoring the cavity is then usually considered necessary. Different options play a role in the treatment of occlusal caries, especially when the caries process reaches the deeper parts of the dentine. Once the lesion has approached or reached the

pulpo-dentinal junction, complete excavation of the carious tissue might lead to exposure of the pulp and/or loss of pulp vitality. Endodontic treatment or extraction of the tooth is then necessary. To prevent this, treatment concepts like stepwise excavation and indirect pulp capping have been proposed.

In stepwise excavation,³³ decalcified enamel is removed and only the superficial part of the soft, infected dentine is removed, reducing the bacterial load in the cavity before temporary restoration. In a second visit, after weeks or months, the cavity is reopened, the remaining infected dentine removed and the cavity is permanently restored. The purpose of this treatment method is to arrest the caries process, and allow for remineralisation of the affected dentine and the formation of tertiary dentine, thus reducing the risk of pulp exposure. Research has shown that stepwise excavation results in increased preservation of pulp vitality³⁴⁻³⁸ and reduction of viable bacteria over time.³⁹⁻⁴² In most cases, at re-entrance the dentine is dryer, harder and darker than immediately after the first excavation step.^{37, 38, 42} Studies comparing the effectiveness of stepwise excavation with one step complete excavation, showed about 15-17.5% pulp exposures in the first group, compared to 40-53% in the second group.^{35, 36}

Indirect pulp capping is a treatment in which the cavity is excavated as much as possible, except for a portion of the carious tissue close to the pulp. This portion is usually covered by a calcium hydroxide containing paste and restored with a dental restorative material. This treatment is applied in teeth with deep caries lesions, in which there is no clinical evidence of pulpal degeneration or periapical pathology.⁴³ The second step as used in the stepwise excavation studies is omitted. In a Cochrane systematic review, Ricketts et al.⁴⁴ have stated that there is insufficient evidence, whether or not the second step of the stepwise excavation technique can be omitted. Some studies have shown that incomplete excavation of the infected tissues arrested the caries process.^{42, 45, 46} Kidd⁴⁷ suggested that the need for complete excavation of infected dentine should be discussed, since incomplete excavation of these tissues did not lead to caries progression, pulpitis or pulp death.

Currently, most cariologists advise not to remove all the carious tooth tissue, based upon the biology of the caries process and the remineralisation of arrested dentine. However, in clinical studies we should also include the long-term mechanical behaviour of restorations placed over soft, carious tissue. In one of the above-mentioned studies,⁴⁵ some clinical failures were observed in the group with bonded and sealed composite restoration applied over dentine caries. In another study, one third of the included teeth with indirectly pulp capped lesions, fractured after 36-45 months.⁴⁶ This thesis, therefore, investigates the influence of a soft layer of either

simulated or real carious dentine left underneath a composite restoration, on the fracture strength of the tooth-restoration complex.

Aim of the PhD research

The indication for the use of pit and fissure sealants has been extended from sealing sound pits and fissures to the sealing of incipient caries lesions. However, little is known about the effectiveness of sealing cavitated caries lesions. Is it possible to obtain a good adhesion of resin based sealant materials to such lesions, or is there a need to carry out enameloplasty and restore the created cavity? From a biological point of view, there is no need for removal of all infected dentine in order to prevent caries progression, pulpitis or pulp death, prior to application of a restoration. However, the restorative material must provide an adequate seal of the infected dentine from the oral environment and so far, the mechanical aspects of this treatment approach have not been sufficiently studied.

The following main research objectives will be addressed in this thesis:

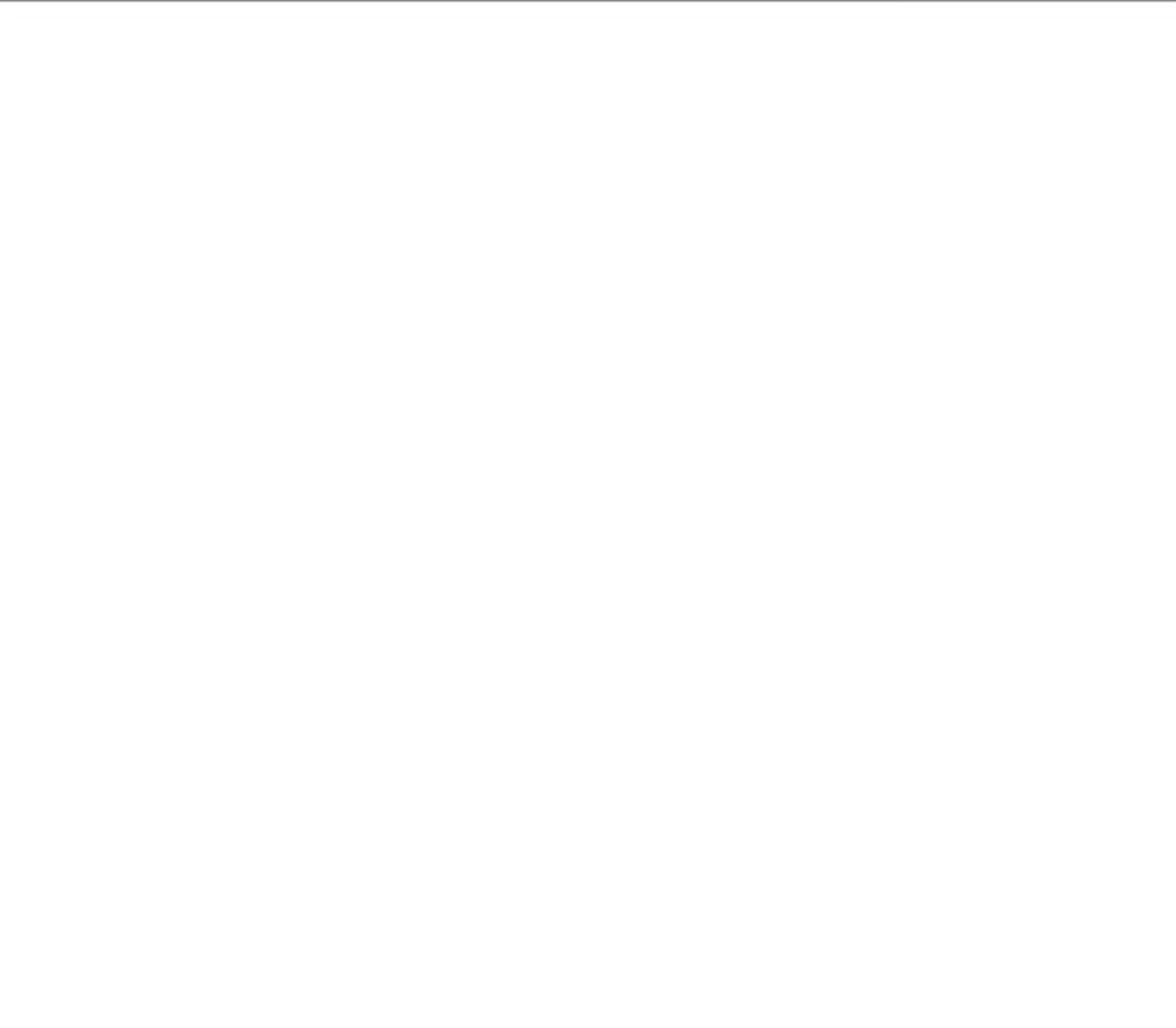
- To investigate the long-term performance of routinely placed resin based pit and fissure sealants placed in a general dental practice.
- To investigate the ability of resin based sealant material to seal cavitated caries lesions in pits and fissures and the effect on this of contamination by saliva or moisture.
- To investigate the influence of residual carious dentine under an occlusal resin composite restoration on the fracture strength of the tooth-restoration complex.

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2

Long-term performance of resin based fissure sealants placed in a general dental practice

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Abstract

Objectives: The aim of the present retrospective study was to evaluate the long-term performance of resin based fissure sealants applied in a general dental practice.

Methods: Regularly attending patients visiting the practice between July 2006 until November 2007 and who had received sealants before 1st of January 2000 were included in the study. Date of placement of a sealant in posterior non-discoloured permanent teeth and replacement by a restoration was recorded. In a clinical examination occlusal surfaces were scored for (partial) sealant loss and fissure discolouration. The restoration profile of the patient was assessed as low or high, based on the number of restorations placed per year since the first sealant. Sealants had been applied by four dentists and a dental hygienist.

Results: 1204 sealants were placed in 148 patients. After a mean follow-up time of 11.6 years, 41.3% of placed sealants were still fully retained and 11.4% were replaced by a restoration. Failure rates were significantly higher in high than in low restoration profile patients and in molars compared to premolars. In those fissures with lost or partially lost sealants, discolouration frequently occurred (40% of all surfaces) irrespective of restoration profile of the patient.

Conclusions: In this retrospective practice based study, long-term performance of sealants depended on restoration profile of the individual patient and the tooth type (molar versus premolar).

Introduction

Systematic reviews have investigated the clinical effectiveness of pit and fissure sealants. In general, these reviews show that fissure sealants prevent dental caries.¹⁻⁴ However, the reported results in these reviews regarding the level of caries reduction vary greatly, probably due to different search strategies and the use of different inclusion criteria. Reported caries reduction for fissure sealants ranges from 86% at 12 months to 57% at 48 to 54 months^{1,2} and depends on the type of sealant materials used.^{4,5} With a single sealant application, the relative caries risk reduction varied from 4% to 54%, whereas with repeated sealant application, the relative caries risk reduction varied from 69% to 93%.³ As a consequence, in the reviews different recommendations for the use of resin based fissure sealants are made.

While systematic reviews are ambiguous on the effectiveness of sealing premolars and molars as a preventive treatment, some other factors even increase the confusion. Firstly, most studies that were included in the reviews were performed in the 1970s, when caries prevalence in Western countries was high. Nowadays, caries prevalence is lower and lesion progression seems to have altered, especially in populations with low caries risk.⁶⁻⁸ As a result, a population that is preventively sealed nowadays will contain many low risk patients. It has been shown that use of resin based fissure sealants is more effective in preventing dental caries in high caries risk populations² and individuals.⁹ Secondly, many studies have been carried out in university clinics by well-trained dental staff and have limited observation intervals. Not much is known about the performance of resin based sealants and their caries preventive effect on the long-term when placed routinely in a general dental practice.

The aim of the present study was to evaluate the long-term performance of resin based fissure sealants applied in a general dental practice. Two parameters were evaluated: 1). sealant retention and 2). sealant failure due to placement of an occlusal restoration.

Materials and Methods

This retrospective study was conducted in a general dental practice in the Netherlands. The study was approved by the ethics committee of the Radboud University of Nijmegen (CEOM: 2008/336). The study group consisted of regularly attending patients who visited the dental practice for routine oral examination in the period of July 2006 until November 2007. All patients who had one or more sealants on their

permanent dentition before 1st of January 2000 were selected, and the sealed occlusal surfaces included in the study.

In the period of July 1988 through December 1999, the sealant strategy in the dental practice for all operators was to seal sound, non-discoloured fissures as early as possible during the stage of eruption to prevent lesion development. No reapplication was performed where a sealant was lost over time. Resin based opaque white sealant material combined with phosphoric acid as an etching agent was used. The sealants were placed by four different dentists and one oral hygienist.

All data were recorded by a single operator (NO), who was an experienced dentist well trained in making clinical observations. From the patient records, the date of application of the sealant for each included surface and the operator type (dentist or oral hygienist) was recorded, and also the date of placement of a restoration in the sealed occlusal surface, where applicable. During the routine clinical examination performed in the period of July 2006 until November 2007, the operator (NO) recorded one time if a sealant was present in all fissures (fully retained), if sealant material was present in parts of fissures (partially absent) or completely absent. Independent of the status of the sealant, dark-brown or black discolouration of the fissure, presence of an occlusal restoration or a cavitated caries lesion was assessed (see Figure 1). Sealant failure was defined as the moment of placement of an occlusal restoration or the presence of a cavitated caries lesion at examination. Sealant absence was not considered as failure of the sealant.

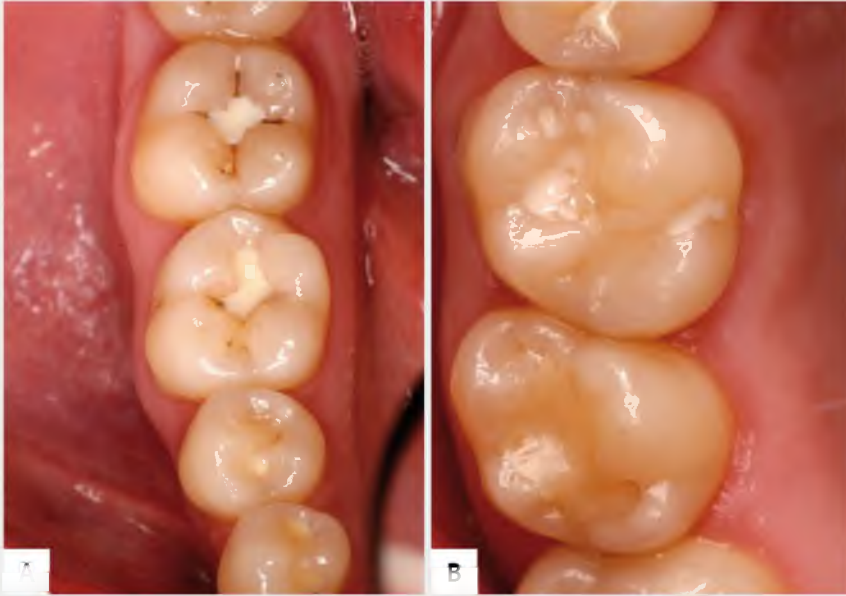
In order to categorize the patients by restoration profile the number of restorations per patient placed in the primary and permanent dentition since the first sealant application was counted. The median overall number of restorations placed per year was calculated to be 0.33. The patient group was then divided into equal groups of high (> 0.33 restorations per year) and low (≤ 0.33 restorations per year) restoration profile.

In 10 out of the 148 patients data were recorded for a second time (on average 6 months later, at the next routine oral examination) to calculate intra-observer kappa.

Statistical analysis

Statistical analyses were performed with SPSS 16 (SPSS Inc., Chicago, IL, USA) and R (v. 2.8.0: R. Foundation for Statistical Computing, Vienna, Austria). Life tables were used to calculate survival rates and Kaplan-Meier analysis was used to create survival curves. Since most patients contributed multiple sealants to this study, the observations were not independent but clustered. Therefore, standard Kaplan-Meier analysis would underestimate variances and the log-rank test could not be applied. To solve this, the

Figure 1 **A.** Example of first and second molar with dark-brown discoloured fissures and partial absence of sealant material. **B.** Example of first and second molar with partial absence of sealant material and placement of an occlusal restoration.



method described by Ying and Wei ¹⁰ (applied in ¹¹) was used to produce statistically valid standard errors for the estimates of survival. Using these estimates for a given point in time, testing for statistical significant differences between two survival curves reduces to a straightforward T-test. In this study, all comparisons are made at 5, 10 and 15 years.

Results

In this study 1204 sealants placed in 148 patients (48% male, 52% female with a mean age of 21.4 (SD 4.97) years during data recording) were investigated. The mean follow-up time of the sealants was 11.6 (SD 3.74) years. From the 1204 sealants, 477 were placed in premolars, 501 in first permanent molars and 226 in second permanent molars. The intra-observer reliability for scoring the presence of sealant material showed a κ -value of 0.98, and for presence or absence of discolouration in the fissures, a κ -value of 0.89 was found.

Figure 2 shows the distribution of sealant retention for the non-failed (no occlusal restoration was made) sealants at the moment of oral examination. Per group of three consecutive years the mean percentages of sealant retention were counted. On average 40-50% of the sealant material was fully retained, independent of the evaluation period.

Figure 2 Sealant presence of the non-failed sealants (no restoration placed) at the time of oral examination.

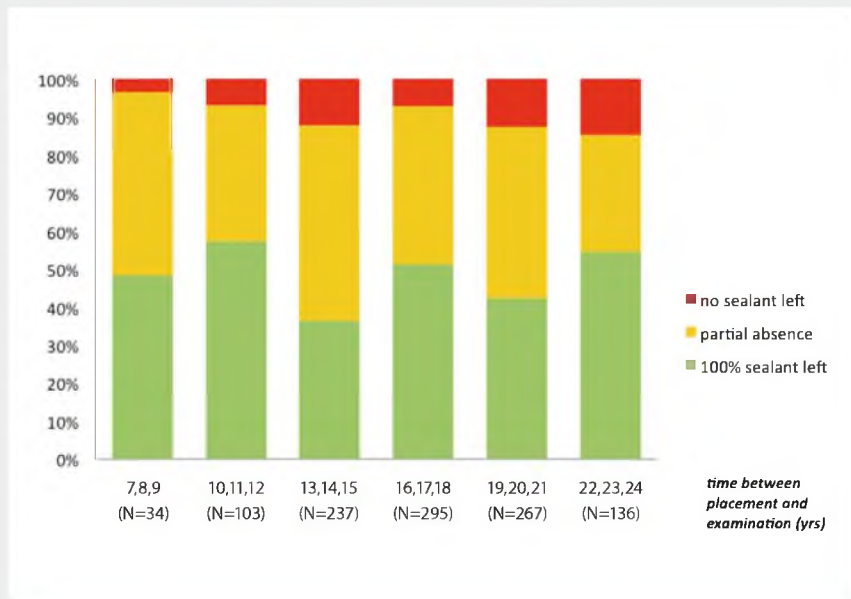


Table 1 shows the relation between restoration profile of the patient and sealant loss and/or failure. In 41.3% of the cases, the sealant was fully retained whereas in 11.4% it was replaced by a (composite resin) restoration. The group with a high restoration profile received more than three times as many occlusal restorations compared to the low restoration profile group (17.0% versus 5.1%). Further analysis of the retention rates for sealants revealed that in premolars 73.6% were fully retained and partially absent in 18%, compared to 20.1% and 51.2% for molars.

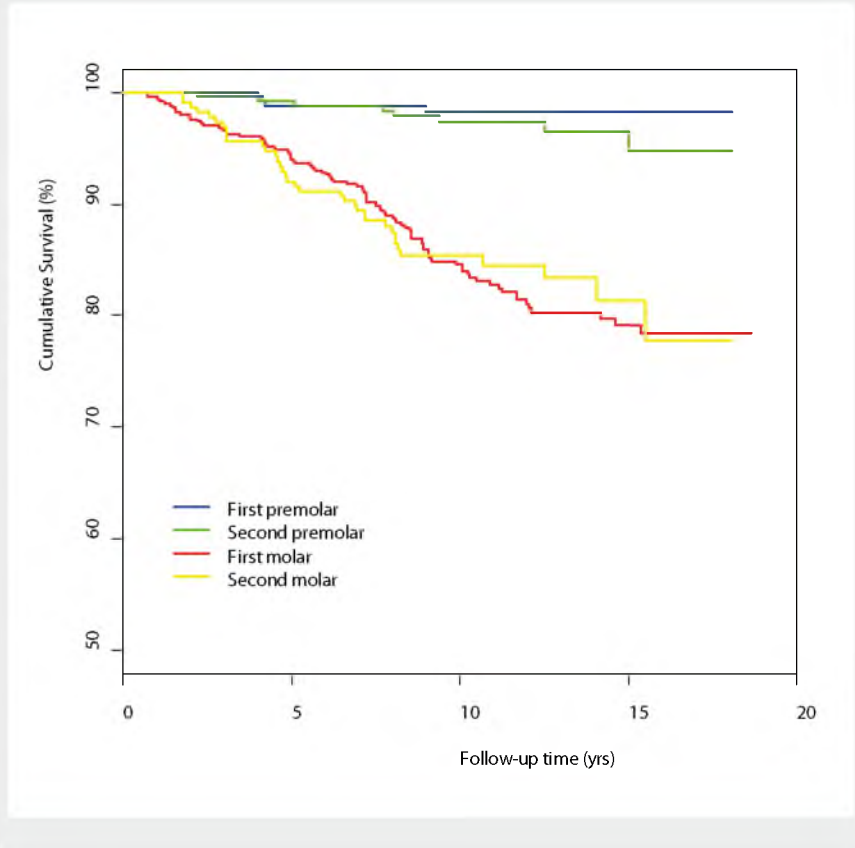
Table 1 Relation between restoration profile of the patient and presence of sealant material.

	Low restoration profile (n)	High restoration profile (n)	Total
no sealant left	62 (10.9%)	50 (7.9%)	112 (9.3%)
partial absence	252 (44.3%)	206 (32.4%)	458 (38.0%)
100% sealant left	226 (39.7%)	271 (42.7%)	497 (41.3%)
restoration	29 (5.1%)	108 (17.0%)	137 (11.4%)

During the examination three teeth showed a cavitated caries lesion in the occlusal surface and received a restoration at that time. In total, 12 (out of 477) sealants in premolars were replaced by an occlusal restoration. These numbers were 89 (out of 501) for first molars and 36 (out of 226) for second molars. The 12 occlusal restorations in the premolars were all placed in the high restoration profile group, while 3 times more restorations in the molars were applied in the high compared to the low restoration profile group. Kaplan-Meier analysis revealed a significant higher failure rate of sealants placed in the permanent molars as compared to sealants placed in premolars (at 5, 10 years and 15 years: $P < 0.001$). Figure 3 shows the Kaplan-Meier curve representing the failure of sealants in molars and premolars.

Due to the low sealant failure in premolars, the further statistical analysis to calculate the influence of jaw, operator involvement and restoration profile of the patient was restricted to sealed molars ($n = 727$). Failure rates on the long-term were lower in low than in high restoration profile patients (at 5 years: $P = 0.06$; 10 and 15 years: $P < 0.001$) (see Figure 4).

Figure 3 Kaplan-Meier curves representing the survival of sealants (n = 1204) placed in different tooth types.



No statistically significant difference between the dentists and oral hygienist could be shown (at 5, 10 and 15 years $P > 0.30$). Also no statistical significant differences between the maxilla and mandible were observed (at 5, 10 and 15 years $P > 0.61$).

Table 2 shows the relation between discoloured fissures, presence of a restoration and restoration profile of the patient. It can be seen that 45.3% (467 out of 1030) of the formerly sealed fissures had become discoloured without receiving a restoration. The percentages were comparable in the low and high restoration profile group (46.4% versus 44.3%).

Figure 4 Kaplan-Meier curves representing the survival of sealants (n=727) in molars for high and low restoration profile patients.

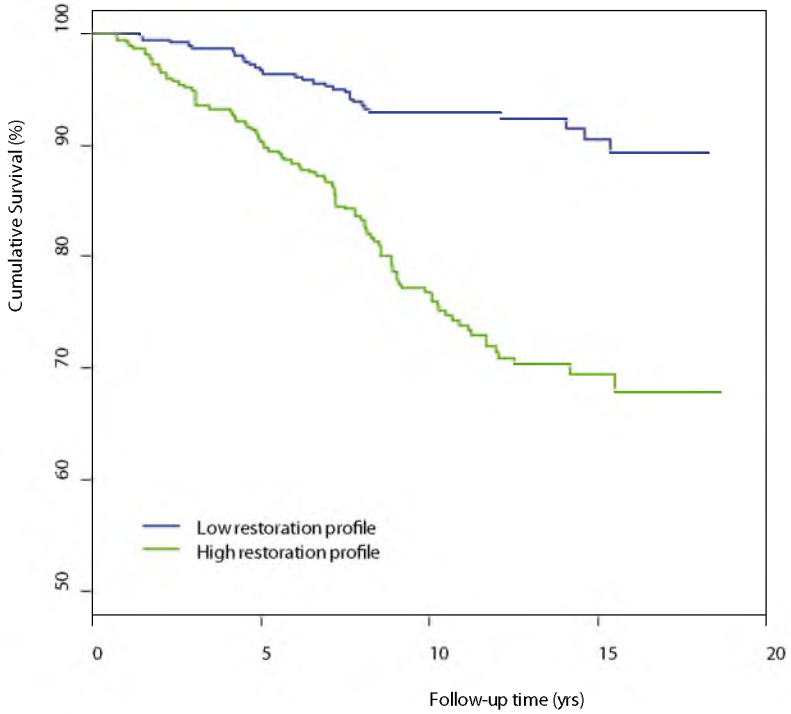


Table 2 Presence of discolouration in the formerly sealed fissures in relationship to restoration profile and presence of an occlusal restoration.

		Presence of discolouration (in %)		
		No	Yes	Total
Low restoration profile	No restoration present	280 (50.8%)	242 (43.9%)	522 (94.7%)
	Restoration present	22 (4.0%)	7 (1.3%)	29 (5.3%)
High restoration profile	No restoration present	283 (45.9%)	225 (36.5%)	508 (82.5%)
	Restoration present	82 (13.3%)	26 (4.2%)	108 (17.5%)
Total	No restoration present	563 (48.3%)	467 (40.0%)	1030 (88.3%)
	Restoration present	104 (8.9%)	33 (2.8%)	137 (11.7%)

*37 missing data

Discussion

In the present retrospective study the long-term performance of sealants in a general dental practice were evaluated. Survival curves were created for the sealed teeth that had received an occlusal restoration, representing the ultimate failure of the sealant to prevent occlusal caries. Sealant loss could not be used as a relative failure criterion because the time of loss of the sealant material could not be retrieved from the patient records.

All data were collected by one observer (NO) at one point in time, namely during the routine oral examination performed in the period of July 2006 until November 2007. All patients included in the study have only been patients in the general dental practice mentioned in this study in the period between sealant application and data collecting. In this study diagnostic thresholds might have changed through the years. However, since the beginning of the 1990s a conservative approach concerning the treatment of dental caries was carried out and no reapplication of sealant material

was performed. This conservative approach is supported by the large amount of discoloured fissures found among the patients, in both the low and high restoration profile group.

There was a logistic reason for evaluating the reproducibility of the observer in this study after 6 months. The patients included in this study were regularly attending patients, who visit the dental practice on average every 6 months. There might have been actual changes, but kappa scores that are shown are high, so this is negligible.

Retention rates in the present study showed full retention of the sealants in 41.3% of the cases after an average follow-up time of 11.6 years. Data from other studies on long-term performance of resin based sealants showed full retention rates of 56.7% after 10 years¹² and 80 % after 8 years,¹³ 85% after 8 to 10 years¹⁴ and up to 65% after 20 years.¹⁵ The present study was a practice based study without patient selection and the sealants were not placed as part of a clinical study. Besides, no reapplication of the sealant material was performed as in some other studies.^{14, 15} This might be an explanation for the lower retention rates found in the present study.

Sealants were placed in premolars and molars. Assuming that all occlusal restorations were placed because of caries, more failures in caries prevention were observed in molars than in premolars. This might be due either to a lower incidence of occlusal caries in premolars or to the better retention rate of sealants in premolars (complete retention: 73.6% versus 20.1% for molars) in the present study. Therefore, the results of this observational study should be carefully interpreted, as it is not clear whether the higher sealant retention in premolars contributed to the lower incidence of occlusal caries. For that purpose, a control group in which no sealants have been applied would have been necessary. A systematic review by Mejàre et al.³ showed a limited evidence for the caries preventive effect in sealing first permanent molars and the evidence was estimated as incomplete for sealing premolars.

Sealants were shown to be more effective and providing cost savings if placed in patients with a high rather than a low caries risk.^{2, 9, 16, 17} In general, to predict the caries risk of an individual patient before sealant placement is difficult.⁶ A frequently used criterion for the screening of young individuals for caries increment is past caries, preferably in the primary dentition.¹⁸ In the present study the patients were divided retrospectively into a low or high restoration profile, eliminating the inaccuracies of prediction and reflecting the cumulative caries risk over the follow-up period.

More failed sealants were found in the high restoration profile group. One might assume that this would be inevitable, as the restorations made to replace sealants contribute to the restoration profile. However, analysis of the restoration data showed that in total 1243 restorations were placed in the primary and permanent dentition of

the 148 patients. The percentage of restorations in sealed surfaces is 137/1243, only 11%. Thus, the sealant failures only marginally influenced the restoration profile.

In the general dental practice involved in this study, during the study period four different dentists and one dental hygienist placed the sealants. No statistical significant differences were present in survival rates of the sealants between the dentists and the dental hygienist. Previous studies showed that the long-term performance of sealants applied by auxiliary staff was good,¹⁹ and compared favourably with sealants applied by dentists.^{20,21} However, proper education in application of sealants is a prerequisite and the success rate showed a great variation among different dental assistants.²²

At the examination, the presence of a discolouration in the fissures was recorded. Although it is unclear whether this discolouration would have been different if no sealant had been placed, there are few indications that it would be. Many of the fissures where sealant material had been lost became discoloured without receiving a restoration during the follow-up time, irrespective of the restoration profile of the patients. Discoloured fissures may represent sound surfaces (where the discolouration descends from organic material trapped in the fissure) or non-cavitated caries lesions (where the demineralised enamel has been stained). The question arises whether and when a discoloured fissure will become cavitated. A cross-sectional study showed that dark-brown or black discoloured fissures had a probability of 42 to 54% to become cavitated or get restored within 4 years.²³ Other researchers showed that 72% of brown or black discoloured fissures remained sound after 2.5 years.²⁴ Therefore, it should be questioned whether a discoloured fissure is a proper indication for placing a sealant.

In the present study, only 11.4% of the sealants failed in the way that a caries lesion was not prevented and a restoration had to be placed. Considering the large number of partially (38%) or totally (9.3%) lost sealants, the applied protocol in the practice of sealing all occlusal surfaces preventively, has clearly led to many unnecessarily placed fissure sealants. As it has never been shown that a sealant provides negative health effects for the patient and it can be defined as a strictly preventive measurement it can be debated if this sealant protocol, which is also recommended by Azarpazhooh and Main,¹ should be viewed as overtreatment. In any case, the sealing of fissures in patients with a high caries risk will lead to a more favourable cost management.²⁵

Nowadays, it is also advised to use sealants not only as a preventive measurement, but to apply sealants when a fissure becomes discoloured and to seal over the discolouration without preparation. However, the results from the present study show that many fissures became discoloured without developing lesions that had to be restored in both low and high restoration profile patients. Therefore, it is unclear if this

approach would lead to a more effective sealant practice, as probably still many fissures would be sealed that would not become cavitated in the future.

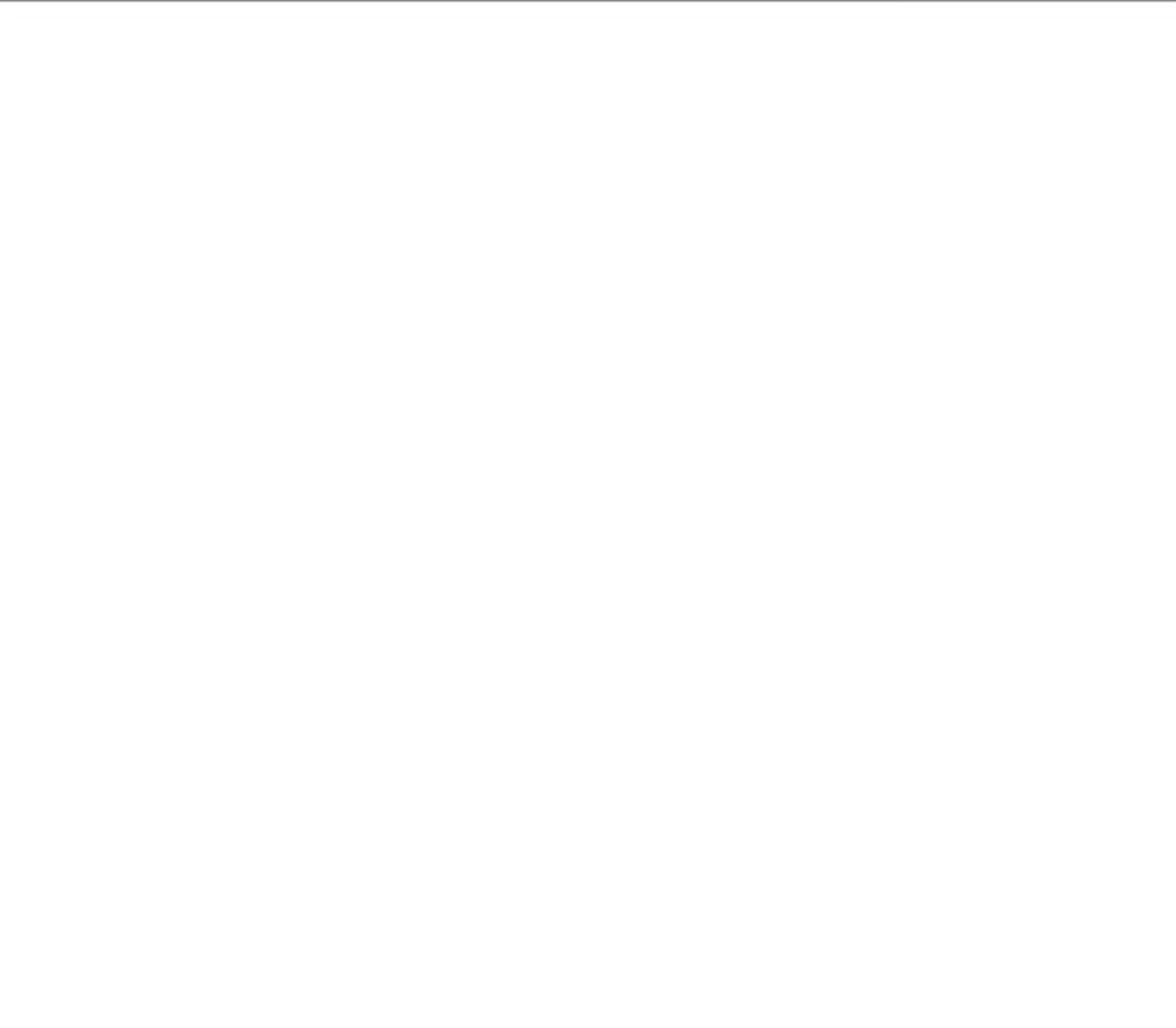
Conclusions

In conclusion, the present practice based study showed that after 11.6 years, 41.3% of placed resin based sealants were still fully retained and 11.4% were replaced by a restoration. Differences in the long-term performance of sealants depended on tooth type (premolar versus molar) and restoration profile of the individual patient.

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Can caries fissures be sealed as adequately as sound fissures?

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Abstract

Sealing caries fissures is considered an appropriate treatment option for arresting the caries process. However, little information is available regarding the sealing of occlusal cavitated dentin lesions. The hypothesis tested in this *in vitro* study was that no difference in microleakage and sealant penetration depth exists between cavitated and sound sealed fissures when a resin is used. Eighty molars, each with an occlusal cavitated dentin lesion were treated according to five experimental protocols and compared with a control group of sealed sound molars. In the experimental groups, fissure sealants were placed with and without an adhesive, and in various ways. All teeth were sectioned and microleakage and sealant penetration into the fissure were evaluated. Sealed carious fissures showed significantly more microleakage and insufficient sealant penetration depth than sound fissures. Neither the use of an adhesive, nor its intermediate curing influenced the microleakage score and the penetration ability of sealants.

Introduction

The prevalence of dental caries in Western societies is still dominated by the occurrence of caries lesions at occlusal surfaces of, predominantly, permanent molars.^{1, 2} Fissure sealants can be applied to prevent occlusal caries.^{3, 4} Several factors influence adequate placement of fissure sealants, such as operator skill, sealant material, fissure type, quality of enamel and phase of eruption.⁵ The application of an adhesive can improve sealant quality when sound fissures are sealed^{6, 7} but other researchers have raised doubts about this.^{8, 9} Contemporary protocols for treatment of dental caries support the use of sealants, not only as a preventive treatment for sound fissures, but also to arrest progression of dental caries by sealing over active occlusal caries lesions.^{10, 11} Whether caries fissures can be sealed as effectively as sound fissures has not been sufficiently investigated. Some clinical studies have shown that a fissure sealant applied in a carious fissure has resulted in reduction of viable micro-organisms and eventually leading to lesion arrest.^{12, 13} However, the observation time in these studies was limited and the caries status of the sealed teeth was not documented precisely. Caries fissures are often surrounded by demineralized enamel and dentin with reduced adhesive properties.^{14, 15} Moreover, cavitated fissures may contain biofilm¹⁶ which is impossible to remove because of difficult access, thus preventing a sealant from adapting properly in the fissure. No *in vitro* studies are available on the sealing of cavitated occlusal dentin lesions and it is not known whether an adhesive can enhance sealant penetration ability in cavitated caries fissures. The objective of this *in vitro* study was to compare microleakage and penetration depth of sealants applied in caries and sound fissures, using different adhesives and curing methods. The hypothesis tested was that there is no difference in microleakage scores and sealant penetration depths of sealants placed in caries and sound fissures, by different adhesives and curing methods.

Materials & Methods

Tooth selection and sealant application

From a batch of third molars stored in tap water immediately after extraction, eighty were selected on the basis of the presence of a small occlusal cavitated dentin lesion. These molars were collected with the donors' informed consent. Institutional Review Board approval was secured for the use of human teeth.

Cavitated lesions to which a dental probe had access (1 mm) were included in the study. Bitewing radiographs were taken to exclude molars without occlusal radiolucency (D1 and D2 lesions) or with a radiolucency indicating a D4 lesion close to the pulp.¹⁶ Sixteen molars with sound non-discolored fissures were also selected. The carious molars were randomly divided into 5 experimental groups, and the sound molars formed the control group. Teeth were cleansed with pumice and treated by one operator according to 6 different protocols (Table 1).

Table 1 Treatment groups and treatment procedures.

	Caries status	Number of teeth	Primer and bonding adhesive	Intermediate curing
Group 1	carious	n=16	none	no
Group 2	carious	n=16	OptiBond FL	yes
Group 3	carious	n=16	OptiBond FL	no
Group 4	carious	n=16	SA primer + Photo Bond	yes
Group 5	carious	n=16	SA primer + Photo Bond	no
Group 6	sound	n=16	none	no

All occlusal surfaces were etched for 15 sec with 37% phosphoric acid, rinsed thoroughly with water for 10 sec, and gently air-dried until the surface appeared 'frosted'. In groups 1 and 6 (control), a fissure sealant (Teethmate F-1, Kuraray, Japan) was applied. A dental probe was used to remove entrapped air from the sealant. The sealant was cured for 20 sec, by means of an LE-Demetron I curing device (Kerr, USA) with an output of 800 mW/mm². In groups 2-5, 2 three-step adhesives were applied to the etched surface before sealant placement, according to 1 of 4 protocols. In groups 2 and 3, OptiBond FL (Kerr, USA) was used. The primer was scrubbed vigorously for 15 sec over the occlusal surface and gently air-dried for a few sec, care being taken to avoid desiccating dentin. The adhesive was then applied and cured for 30 sec (group 2), or left uncured (group 3). In groups 4 and 5, Clearfil SA primer/Photo Bond (Kuraray) was applied and gently air-dried. In group 4, the adhesive was spread by a gentle stream of air and cured for 10 sec, whereas in group 5 the adhesive was left uncured

before sealant application. The sealant (Teethmate F-1, Kuraray) was subsequently applied in groups 2-5 as in groups 1 and 6.

Teeth were thermocycled (500 cycles; 5-55 °C; dwell time 30 sec), covered with nail varnish (except on the occlusal surfaces), and immersed in 1% methylene-blue for 24 hrs. Thereafter, teeth were embedded in acrylic resin (Struers, Copenhagen, Denmark) and sectioned in a bucco-lingual direction through the mesial, central and distal areas of the fissure by means of sawing apparatus (Leica, Heidelberg, Germany: 300 µm thick blade). This resulted in 4 molar fragments and 6 section sides *per* molar.

Evaluation

Using a microscope with a 20x magnification (Forty: American Optical, New York, NY, USA) two independent observers scored microleakage *per* section side on a three-point rating scale (Score 0, no microleakage visible; Score 1, microleakage in up to half of the fissure; Score 2, microleakage in more than half of the fissure). In case of disagreement, a third independent observer was consulted, who made the final decision. Each molar received 1 microleakage score calculated from the 6 sections according to a worst-case scenario, so the highest microleakage score of all section sides of the same tooth determined the final score. To determine intra-examination reliability, we randomly selected and re-examined 10 molars (10%) after 1 wk.

Furthermore, section sides were digitally photographed, by means of a microscope with a 40x magnification (Leica). The presence of an unfilled area below the sealant material (incomplete sealant penetration) was determined on the basis of the digitized photographs of the section sides. Moreover, each section side was evaluated on the presence of a caries lesion in dentin, leading to the score "caries present" or "caries absent". Since both section sides adjacent to 1 sawing line were closely related to each other, a final score for the presence or absence of an unfilled area below the sealant material was formulated for those combined sections. Accordingly, when 1 section side was diagnosed as carious, it was decided that the final score for the combined sections would be considered "caries present". Finally, the micro-morphological fissure type was scored either as wide (including U or V fissure type) or as narrow (including Y1 or Y2 fissure type), because several studies have shown an influence of fissure type on sealant penetration.¹⁷ To determine intra-examiner agreement, we randomly selected and re-examined 46 section sides (7%).

Statistical analysis

Data were analysed with SPSS 12 (SPSS Inc., Chicago, IL, USA). Chi-square tests with Fisher's Exact tests were conducted, and risk ratios (RR) and 95% confidence intervals

were calculated, to test whether the independent variables (caries status, use and type of adhesive, intermediate light curing of adhesive) influenced the performance of sealant application. Microleakage scores *per* molar and sealant penetration *per* combined section were analyzed. The influence of adhesive application and intermediate curing was calculated from the 'cariou combined' sections only. We used the chi-square test to see whether the division of micro-morphological fissure type (wide vs. narrow) among the experimental groups was balanced.

For microleakage, sealant penetration measurements, and presence of a dentin lesion, Kappa scores were calculated from those molars that had been evaluated twice.

Results

Examples of incomplete sealant penetration and microleakage are shown in the Fig. Statistical analysis revealed that the molars in control group 6 showed significantly less microleakage than did carious molars (group 1) (Chi-square test: $p = 0.004$). No significant differences could be observed ($p = 0.80$) among the different experimental groups (groups 1-5) (Table 2).

Results after comparison of the combined sections in groups 1 and 6, where no adhesive was used, showed that significantly better sealant penetration was achieved when a sound fissure was present (chi-square test: $p < 0.0001$) (RR = 2.70). Thus, the chances of having incomplete sealant penetration when the fissure is carious are 2.7 times (170%) higher than when the fissure is sound (Table 3). The use and type of adhesive had no significant influence on sealant penetration in caries fissures (chi-square test: $p = 0.92$). Moreover, separate curing of the adhesive before sealant placement did not influence sealant penetration in caries fissures (chi-square test: $p = 1.00$) (Table 3).

Analysis of the distribution of micro-morphological fissure types revealed an independent distribution of fissure types among the 5 experimental groups (chi-square test: $p = 0.53$).

For microleakage measurements, Kappa statistics showed a perfect intra-examination reliability ($\kappa = 1$). The intra-examiner reliability for sealant penetration ability scores showed a κ -value of 0.83, and for the presence of a dentin lesion, a κ -value of 0.79 was calculated.

Figure Examples of incomplete sealant penetration and microleakage score. **(A)** The black area indicated by the white arrows is the zone of incomplete sealant penetration. The dye penetration is indicated by black arrows **(B, score 2)**.

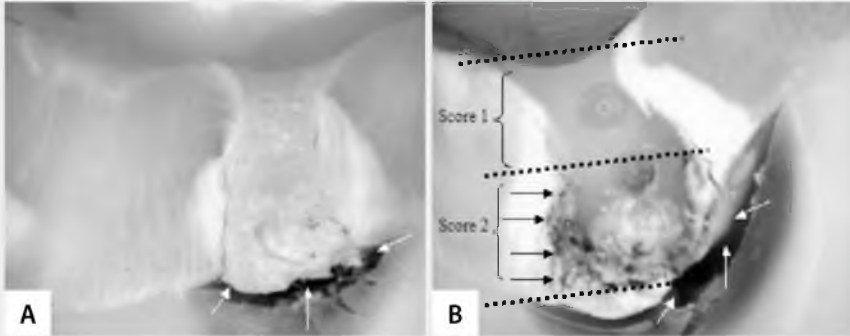


Table 2 Microleakage scores *per* molar for each group.

	Treatment groups (sealed caries fissures)					Control group (sealed sound fissures)
	No adhesive	OptiBond FL		SA primer + Photo Bond		No adhesive
		With intermediate curing	Without intermediate curing	With intermediate curing	Without intermediate curing	
Score 0	9	6	8	9	8	14
Score 1	4	8	6	6	4	0
Score 2	3	2	2	1	4	2

Table 3 Results for sealant penetration *per* combined section related to caries status, application of adhesive, and curing technique. RRs indicate risk on incomplete sealant penetration. Last column is used as reference.

	Sections from group 1 + 6*		Use of adhesive in carious sections*			Intermediate curing of adhesive in carious sections*	
	Carious sections	Sound sections	OptiBond	SA primer + Photo Bond	No adhesive	Intermediate curing	No intermediate curing
Full sealant penetration	2	53	4	6	2	4	8
Incomplete sealant penetration	13	25	19	23	13	17	38
p-value (χ^2)	<0.0001		0.92			1.00	
RR	2.70		0.95 ^a	0.92 ^b	0.96 ^c	0.98	
95% CI	1.83-3.95		0.73-1.25 ^a	0.70-1.20 ^b	0.74-1.25 ^c	0.77-1.25	

*Only the combined sections with a caries lesion in the dentin were included in the analysis

^a Risk for *OptiBond* with *no adhesive* as reference

^b Risk for *SA primer/Photo Bond* with *no adhesive* as reference

^c Risk for *SA primer/Photo Bond* with *OptiBond* as reference

Discussion

In contemporary cariology, there is a paradigm shift from the concept that carious tissues should be removed before a tooth with a caries lesion is restored, toward the view that a caries lesion can be sealed and thus, be arrested.¹⁶ Consequently, excavation of carious tissues can be limited, or even omitted, as long as the seal is properly placed.¹⁸ The present study deals with the question as to whether a cavitated occlusal caries lesion can be sealed adequately. The hypothesis tested in this *in vitro* study was that no difference would be found in microleakage scores and sealant penetration depths of sealants placed in caries and sound fissures if different bonding systems and curing methods were used. This hypothesis was rejected, because analysis of the

data revealed that, in caries fissures, significantly more microleakage was present, and penetration of the sealant in the caries fissure was often incomplete, with unfilled space left under the sealant.

Clinical studies have shown that sealants placed in caries fissures can arrest the carious process, but either their evaluation periods were short or the carious status of the fissures was unclear.^{12, 13} However, in a retrospective study,¹⁹ cariogenic microorganisms were found in 50% of the sealed teeth, and the dentin was soft and moist, which indicated the presence of active caries. In the present study, molars with occlusal cavitated dentin lesions surrounded by demineralized enamel were used. Therefore, inadequate adhesion to demineralized enamel could be one reason why microleakage scores were higher in the 'caries combined' sections than in the 'sound combined' sections. Several *in vitro* studies have been carried out to investigate the influence of resin penetration into white-spot enamel lesions on smooth enamel surfaces, some showing good infiltration of resin into these lesions.^{20, 21} A recent study, however, showed that infiltration depended on the type of adhesive being used.²² In the current study, demineralized enamel was not visible on smooth surfaces, but was located in the fissures, which could explain the different outcome. This argument is supported by recently published research²³ reporting higher microleakage scores in sealants placed over natural enamel caries lesions, especially when the outline was situated on carious enamel. In any event, application of an adhesive did not improve microleakage and sealant penetration depth. It is probably more likely that the irregular shapes of cavitated fissures might have hampered sealant penetration into the caries fissure, as found in this study, even when a probe was used to prevent porosities inside the sealant material. The suboptimal sealant adaptation found in the caries fissures might also have been caused by the presence of biofilm, left in the deeper parts, which are difficult to access.¹⁶ These findings indicate that cavitated caries fissures cannot be sealed as adequately as sound fissures. However, the clinical implication of these findings is unclear, owing to the *in vitro* design of the study.

Molars in the experimental groups were selected if a small occlusal cavitated dentin lesion was present. In the current study, the sealed molars were cut 3 times with a saw, resulting in 4 fragments and 6 section sides for scoring. Some sections showed no sealant material in the fissures. These sections were excluded from the analysis, which explained the lower number of combined section sides than expected. To establish a relationship between the presence of an unfilled area below the sealant and the presence of a dentin lesion, we divided the molars into combined carious and sound section sides. The score *per* combined section side was used in the analysis, on the assumption that no statistical dependence existed between combined section

sides within one molar. This assumption was justified by the presence of differences in morphological fissure type and caries status within one molar, and by the fact that the combined sides of the fragments were located at a distance from each other.

We used a three-point rating scale to score microleakage, instead of the more sophisticated methods, such as measuring the length of dye penetration, as used in other *in vitro* studies.^{17,23} This was because the sealed cavitated dentin lesions in the present study had many irregular borders, making the current technology standard unusable. Second, in most sections, microleakage was seen in small amounts, either at the bottom of the fissures or at their edges. To underline the impact of differences in microleakage at these two sides, we chose a three-point rating scale.

The use of an adhesive system before sealant placement was not shown to reduce microleakage or enhance sealant penetration for the carious treatment groups. Also, no differences among groups could be observed regarding intermediate curing of the adhesive. Application of an adhesive and intermediate curing of the adhesive had been expected to result in better adaptation of the sealant. That no better results were achieved may have been due to the caries status of the fissures and to cavitation with irregular borders that might have prevented proper application of an adhesive.

Within the restrictions of this *in vitro* study, it can be concluded that sound fissures can be sealed with resin more adequately than cavitated caries fissures. Neither the use of an adhesive nor intermediate curing of the adhesive improved adaptation of the sealant material.

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Microleakage and sealant penetration in contaminated carious fissures

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Abstract

Objectives: The aim of the present in vitro study was to evaluate the effect of an adhesive system on microleakage and sealant penetration depth in carious fissures after different surface contamination circumstances.

Methods: Extracted third molars (n=128) with small occlusal cavitated carious lesions were randomly divided into eight experimental groups and sealed under four different surface conditions. 1. Dry conditions; 2. water contamination; 3. saliva contamination; 4. saliva contamination and air-drying. Two sealant protocols were applied, one using a fissure sealant (Teethmate F) and one using an additional adhesive system (SA primer and Photo Bond). The control group consisted of sound third molars (n=16), that were sealed under dry conditions. After thermocycling (n=500 cycles), teeth were immersed in 1% methylene blue for 24 h, sectioned and digitally photographed. Microleakage was evaluated on a three-point rating scale and analysed using a chi-square test. Additionally, the presence of caries and incomplete sealant penetration was scored from photographs and analysed using logistic regression.

Results: A statistical significant difference regarding microleakage scores was present between sealed carious and sealed sound fissures. The use of an adhesive system in case of water contamination significantly reduced microleakage ($p < 0.05$). With regard to sealant penetration depth, there were significant differences present for carious sealed fissures, use of an adhesive system prior to sealing, and water and saliva contamination.

Conclusions: Use of an adhesive system improved the effectiveness of sealants placed after water contamination in carious fissures. However, sound fissures showed less microleakage and better penetration abilities than carious fissures.

Introduction

Fissure sealants are placed on occlusal surfaces of permanent molars and premolars to prevent the development of dental caries.^{1,2} Nowadays, sealants can also be used to arrest progression of occlusal carious lesions.^{3,4} This means that not only sound but also carious pits and fissures can be sealed. Clinical studies have shown that, a fissure sealant applied in a carious fissure results, in the short term, in a reduction of viable micro-organisms and eventually may lead to the arrest of the lesion.^{5,6} On the other hand, an in-vitro study by Celiberti and Lussi⁷ demonstrated that carious fissures cannot be sealed as adequately as sound fissures, calling into question the long-term success of sealants placed over occlusal carious lesions.

Particularly when molar teeth in younger patients and teeth, which are not fully erupted are sealed, the occlusal surface may get contaminated by moisture and saliva, jeopardising the effectiveness of the sealant. In such a situation, the use of an adhesive system has shown to result in less microleakage.^{8,9} However, in the absence of such a contamination, the advantage of applying an adhesive system is unclear. Whereas, in some studies, its use has been reported to be beneficial,^{10,11} other studies reported the opposite effect.^{12,13}

No information is available on the effect of bonding in contaminated carious cavitated fissures. Due to the fact that sealant strategies are changing into a non-invasive treatment of discoloured pits and fissures, there is a higher risk of sealing in dentine caries which demands for an effective seal of the caries lesion to prevent caries progression. Secondly, sealing of pits and fissures always brings the risk of contamination which influences an effective seal. In such a situation an ethanol-based adhesive system should be used, as the adhesive may lead to evaporation of water on the occlusal surfaces, which may result in a better sealant adaptation. In case of saliva contamination, the drying effect of an ethanol-based adhesive may be present, but may not be sufficient as peptides from the saliva may hinder a proper sealant adaptation to the etched enamel.

The aim of this in vitro study was to evaluate the effect of an adhesive system on microleakage and sealant penetration depth in contaminated and uncontaminated carious and non-carious pits and fissures. The null hypothesis tested was that the use of an adhesive system does not affect microleakage scores and sealant penetration depth in carious and non-carious contaminated fissures.

Materials and Methods

Tooth selection and sealant treatment

One hundred and twenty-eight extracted third molars with a 1 mm wide occlusal cavitated dentine lesion opening and 16 extracted sound third molars were selected from a batch of recently extracted teeth which were stored in tap water. Bitewing radiographs were taken to exclude molars without occlusal radiolucency (D1 and D2 lesions: enamel lesions with 'intact' surfaces or 'cavities' limited to enamel) or with a radiolucency indicating a D4 lesion (lesions into pulp).^{14, 15} The carious third molars were randomly divided into eight experimental groups and the sound third molars served as the control group. The experimental groups were defined by the use of an adhesive and four different surface conditions (Table 1). In half of the experimental groups a three-step adhesive system was applied prior to sealing. This adhesive system consisted of a dentine primer (SA primer, Kuraray, Japan), containing water and ethanol as solvent. The bonding agent was a dual cure adhesive system (Photo Bond, Kuraray, Japan), containing ethanol as solvent. The adhesive was applied according to the manufacturer's instructions before the sealant material was placed. No adhesive system was applied in the remaining four experimental groups, nor in the control group. All teeth in the experimental and control groups were treated by the same operator according to the following protocol and stored in tap water until the dye penetration procedure was performed:

1. The fissures were cleaned with pumice and rinsed thoroughly with water.
2. The fissures were acid etched with 37% phosphoric acid for 15 s, rinsed thoroughly with water for 10 s and gently air dried until a frosted appearance of the occlusal surface appeared.
3. Variable surface conditions were created on the occlusal surface. Table 1 presents the various conditions in each experimental group:
 - a. no contamination. A dry surface was available for bonding.
 - b. 0.1 ml water was applied and left undisturbed for 10 s.
 - c. 0.1 ml fresh human saliva was applied and left undisturbed for 10 s.
 - d. 0.1 ml fresh human saliva was applied and left undisturbed for 10 s.
Subsequently, the surface was air dried until the frosted appearance reappeared.
4. In groups 5-8, SA primer was applied on the occlusal surfaces and gently air dried. Thereafter, the two components (universal and catalyst) of the bonding adhesive were mixed and applied on the surface with a small brush and gently air-dried for 2-3 s. The adhesive system was not light cured before sealant application.

5. Sealant application: Teethmate F-1 (Kuraray, Japan) was applied into 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 s with an LE-Demetron I curing device (Kerr, USA) with an output of 800 mW/mm².
6. Finally, the uncured oxygen-inhibited layer was removed with a brush and pumice.

Table 1 Use of primer and bonding agent and variable surface conditions per experimental and control group (n = 16).

	Caries status	Primer and bonding adhesive	Surface condition
Group 1	carious	none	dry
Group 2	carious	none	water contamination
Group 3	carious	none	saliva contamination
Group 4	carious	none	saliva contamination + air-drying
Group 5	carious	SA primer + Photo Bond	dry
Group 6	carious	SA primer + Photo Bond	water contamination
Group 7	carious	SA primer + Photo Bond	saliva contamination
Group 8	carious	SA primer + Photo Bond	saliva contamination + air-drying
Group 9	sound	none	dry

Thermocycling and dye penetration

The sealed molars were thermocycled in water for 500 cycles between 5 and 55 °C with a dwell time of 30 s. After thermocycling, the molars including the apices of the teeth, were covered with nail varnish, except for their occlusal surfaces, and immersed in 1% methylene-blue for 24 h.

Evaluation

After thermocycling and dye penetration, the molars were rinsed thoroughly with water and the roots were removed using a diamond bur. Secondly, the nail varnish

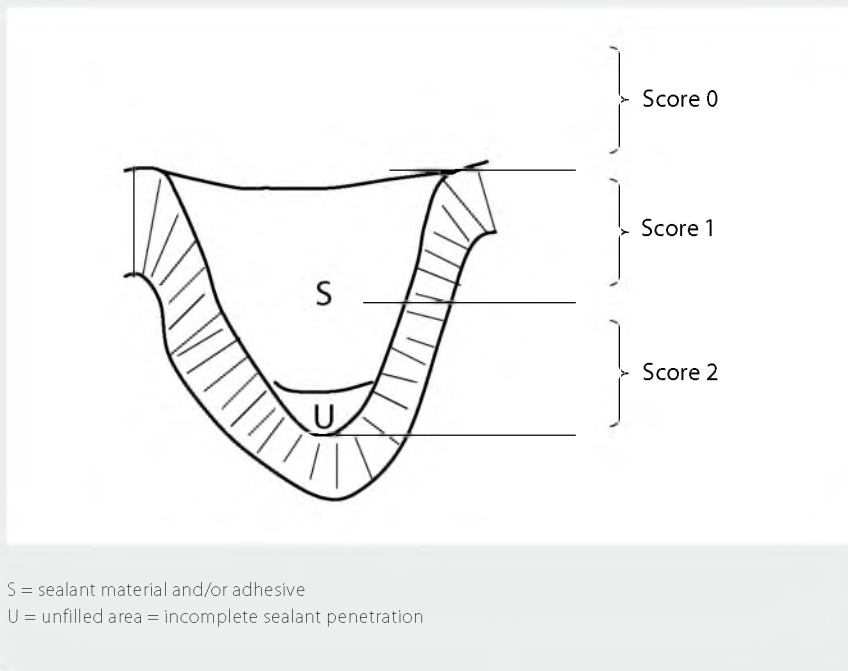
was removed from the crown part of the teeth. The sealed crowns were embedded in self-curing acrylic (Struers, Copenhagen, Denmark) and sectioned in four parts with three parallel cuts in bucco-lingual direction through the mesial, central and distal fissure using a Leica sawing machine (Leica, Germany) with a 300 µm thick blade, resulting in four molar fragments with six section sides available for inspection. Subsequently, microleakage was scored by two independent observers using a microscope with a magnification of x20 (Forty: American Optical, New York, USA). Microleakage per section side was scored on a 3-point rating scale (Score 0: no microleakage visible, Score 1: microleakage up to half of the fissure, Score 2: microleakage more than half of the fissure – Figure 1). In case of disagreement between the two observers, a third independent observer was consulted, who then took the final decision. Using a worst case scenario, each molar was given the highest microleakage score, which was calculated from the six section sides. Subsequently, sections were digitally photographed using a microscope with a magnification of x40 (Leica, Germany). To assess sealant penetration depth, the presence or absence of an unfilled area below the sealant material (incomplete sealant penetration) was determined on the basis of the digitised photographs of the section sides (Fig. 1). Finally, each section side was evaluated on the presence of a carious lesion into the dentine leading to the score 'caries present' or 'caries absent'. As both section sides adjacent to one sawing line were considered dependent, a final score for sealant penetration was formulated for those two combined sections. Accordingly, when one of the two section sides was diagnosed as carious, it was decided that the final score for the combined sections was considered 'caries present'. In the remainder of this paper each combined section will be referred to as 'section'.

To determine intra-examination reliability, the observers re-examined fifteen randomly selected molars for microleakage (10.4%) and 81 section sides (9.4%) for sealant penetration after one week.

Statistical analysis

Data were analysed using SPSS 12 (SPSS Inc., Chicago, IL, USA). Microleakage scores were analysed per molar. Kappa scores were calculated to assess intra-examination agreement for microleakage, sealant penetration depth measurements and presence or absence of a dentine lesion. The Chi-square test with Fisher's exact test was conducted to test whether there were significant differences in microleakage scores between the experimental and control groups. Logistic regression was applied to analyse the relation between sealant penetration and the experimental variables 'caries status', 'use of an adhesive' and 'variable surface conditions'. To allow for the

Figure 1 Graph of image analysis measurements per fissure per section side for scoring microleakage and sealant penetration depth.



possibility that the effect of the adhesive varied with the variable surface conditions, an interaction between those two variables was added to the logistic regression model.

Results

For microleakage measurements, Kappa statistics showed a perfect intra-examination reliability ($\kappa = 1$). With regard to 17 out of the 144 molar teeth (11.8%), the third observer had to make a final decision for microleakage scoring. The intra-examiner reliability for scoring sealant penetration depth scores per section side showed a κ -value of 0.78, and for presence or absence of a dentine lesion, a κ -value of 0.49 was calculated.

Table 2 shows the microleakage scores per molar for the experimental and control groups. The sound molars in the control group (group 9) showed statistically significantly less microleakage than the carious molars in group 1 ($p = 0.011$). The use of an adhesive system in sealing carious molars (groups 5-8) showed statistically significantly less microleakage ($p = 0.005$) compared to the groups in which no adhesive was used (groups 1-4). The use of an adhesive system in sealing carious molars under dry circumstances (group 1 vs. group 5) showed no statistically significant differences in microleakage scores ($p = 0.70$). For water contamination (group 2 vs. group 6), microleakage was statistically significantly lower ($p < 0.0001$), whereas saliva contamination and air-drying after saliva contamination showed no significant differences (group 3 vs. group 7; $p = 0.054$ and group 4 vs. group 8; $p = 1.00$).

Comparing sound and carious sections with regard to sealant penetration depth, a marked difference was found. In the group of carious sections, 115 out of 117 combined sections showed incomplete sealant penetration (Table 3), whereas in the sound sections, 179 complete and 137 incomplete sealant penetrations were found. Therefore, the logistic regression aiming at analysing the effect of the use of the adhesive system on the variable surface conditions was restricted to the sound combined sections. Although cavitated carious molars were evaluated in this study, most of the sections evaluated for sealant penetration were caries free, due to the fact that more sections per molar were made and the dentine lesion was restricted to one part of the fissure complex.

Table 4 contains the effect estimates and p-values. To find the effect estimate of a specific situation, the odds ratios in the corresponding lines have to be multiplied. For example, if an adhesive system is applied and the surface condition is 'saliva contamination and air drying', three lines of the table refer to this situation: adhesive, 'saliva contamination and air drying' and interaction adhesive with saliva contamination and air drying. In this example resulting in an odds ratio of 0.474 ($0.812 \times 2.473 \times 0.236$).

Table 2 Microleakage scores per molar, per experimental and control group.

	Experimental groups (sealed carious fissures)								Control group (sealed sound fissures)
	No adhesive				SA primer + Photo Bond				No adhesive
	Group 1 ^a	Group 2 ^b	Group 3 ^c	Group 4 ^d	Group 5 ^a	Group 6 ^b	Group 7 ^c	Group 8 ^d	Group 9 ^a
Score 0	6	2	2	9	8	12	8	9	14
Score 1	3	0	1	1	1	1	0	1	1
Score 2	7	14	13	6	7	3	8	6	1

^a = dry circumstances; ^b = water contamination; ^c = saliva contamination; ^d = saliva contamination and air-drying

4

Table 3 Sealant penetration scores per combined sections, per experimental and control group.

	Sealant penetration	Experimental groups								Control group
		No adhesive				SA primer + Photo Bond				No adhesive
		Group 1 ^a	Group 2 ^b	Group 3 ^c	Group 4 ^d	Group 5 ^a	Group 6 ^b	Group 7 ^c	Group 8 ^d	Group 9 ^a
CCS	Full	0	0	0	0	2	0	0	0	0
CCS	Incomplete	14	18	13	8	20	10	18	14	0
SCS	Full	15	6	10	17	18	24	24	27	38
SCS	Incomplete	19	24	27	23	8	14	5	7	10

^a = dry circumstances; ^b = water contamination; ^c = saliva contamination; ^d = saliva contamination and air-drying; CCS=carious combined sections; SCS=sound combined sections

Table 4 Results of logistic regression for dichotomised sealant penetration scores (full sealant penetration vs. incomplete sealant penetration) per combined section related to use of adhesive and variable surface conditions.

	p-value	Odds Ratio	95% CI
Constant	0.009	0.547	-
Application of adhesive	0.667	0.812	0.315-2.096
Application circumstances	dry	reference	reference
	water	<0.0001	7.310
	saliva	<0.0001	4.934
	saliva/dry	0.022	2.473
Interaction: adhesive and water contamination	0.021	0.180	0.042-0.774
Interaction: adhesive and saliva contamination	0.003	0.095	0.020-0.440
Interaction: adhesive and saliva contamination/air drying	0.044	0.236	0.058-0.964

Discussion

In the present in vitro study, we tested the effect of an adhesive system in water and saliva contaminated cavitated carious fissures. The null hypothesis was rejected. The additional use of an adhesive system in contaminated carious fissures significantly influenced microleakage and sealant penetration depth.

Several other studies have shown that the use of an adhesive prior to sealing after saliva contamination significantly reduced microleakage.^{8,16} The primer and bonding used in this study contained ethanol, which can help to evaporate water from the fissures. Its use resulted in a statistically significantly lower microleakage after water contamination, whereas saliva contamination ($p = 0.054$) and air-drying after saliva contamination ($p = 1.00$) showed no significant differences. The differences in effects compared to the aforementioned studies might be explained by the fact that, in the present study, cavitated carious fissures were sealed, instead of sound fissures. The irregular shape of the cavitated fissures might have hampered the adhesive system to evaporate sufficient water from the saliva, resulting in higher microleakage scores. Secondly, saliva contains peptides which may have remained on the surface prohibiting a proper bonding of the sealant to the etched fissures. Another difference

between the present in-vitro study and the studies mentioned before is the etching time. In the present study teeth were acid etched for 15 s, whereas an etching time of 30 s was used in the reference studies. Several studies investigating the influence of etching time on the quality of sealants in sound fissures showed no significant differences between etching times of 15, 30, 45 or 60 s.^{17,18,19} Celiberti and Lussi⁷ used an etching time of 40 or 60 s in the natural enamel caries group, and the results showed the same trend in microleakage scores as in the present study. Thus, we think that the difference in etching time is not an explanatory factor.

As almost all the carious combined sections showed statistically incomplete penetration of the sealant material into the fissures, only the sound combined sections were analysed to assess sealant penetration depth. The combination of the adhesive system with either water contamination, saliva contamination or a combination of saliva contamination and air-drying resulted in an increased sealant penetration depth compared to sealant material that had not been treated with an adhesive system.

Several clinical studies have shown that sealants placed in carious fissures are able to arrest the carious process, resulting in a decrease in micro-organisms with carious dentine becoming dry, dark and leathery if the sealant remains intact.^{5,6,20} Several in vitro studies have been carried out studying the influence of resin penetration into white-spot enamel lesions on smooth enamel surfaces. The results showed a good infiltration of resin into the white-spot lesion^{21,22} which appears to be dependent on the type of adhesive used.²³ In their recent in vitro study, Celiberti and Lussi⁷ compared the penetration depth and level of microleakage of fissure sealants applied in sound fissures with those of fissure sealant applied in fissures with artificial and natural enamel carious lesions. The results revealed that sealant microleakage was significantly influenced by the condition of the enamel (sound, artificial or natural enamel carious lesion) and the location of the carious lesion in the fissures. The microleakage scores were higher in the natural enamel carious lesion group compared to the sound or artificially carious lesion groups. It was concluded that the location of a carious lesion in the fissure rather than its depth is a determining factor when applying a fissure sealant. When the outline of the fissure sealant was situated on carious enamel, we observed a significantly higher microleakage. The same factor could explain the significantly higher microleakage scores found in the sealed cavitated fissures compared to the sealed sound fissures in the present in vitro study.

The clinical relevance of the results of the present study is not clear yet. It is obvious that cavitated occlusal carious lesions are more difficult to penetrate with sealant material, show more microleakage than sealed sound fissures and that the use of an

adhesive does not add much in improving the situation. In circumstances in which carious fissures are contaminated, the use of an adhesive showed improved sealant penetration depth and reduced microleakage. So, because the risk of contamination is always present during a clinical procedure, the use of an adhesive may improve the effectiveness of sealants in carious fissures. Practitioners should therefore be advised to use such an adhesive.

The long-term clinical effect of incompletely sealed carious and non-carious fissures with microleakage is not known yet. As stated with regard to secondary caries development around restoration, microleakage seems not to be the cause^{24, 25, 26} and accordingly, sealed fissures that show some microleakage could still be functioning well provided the surfaces are kept plaque-free. Clinical studies have also shown a short-term reduction in micro organisms and caries arrest when carious fissures were sealed.^{5, 6} However, in the long term, there is always the risk of incompletely sealed fissures becoming prone to 'macroleakage'^{26, 27, 28} due to further wear and fatigue of the sealant material. In such a case, it is possible that the caries arrest is only temporary, with an increased risk of the carious lesion becoming active again. Much depends on the patient's ability to manage plaque removal. Further clinical studies with a longer observation period will be required to answer this clinically relevant issue.

Conclusions

The present in vitro study showed that application of an adhesive system prior to sealing carious fissures after contamination with water significantly reduced microleakage and increased sealant penetration depth. Application of an adhesive system after saliva contamination or a combination of saliva contamination and air-drying revealed no significant differences in microleakage, but enhanced sealant penetration depth significantly. Compared to sealing carious fissures, sealing sound fissures proved to be more effective in terms of obtaining an adequate seal and better penetration depth of the sealant material.

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5

A soft, elastic layer reduces fracture strength of composite restored molar teeth *in vitro*

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Abstract

The need for complete removal of caries infected and affected dentine before restoration in order to stop the caries process is increasingly being challenged. However, little information is available about whether the presence of a soft, elastic layer of carious dentine beneath an occlusal composite restoration affects the fracture strength of the restored tooth (complex). This *in vitro* study evaluated the effect of a standardised soft, elastic layer underneath an occlusal composite restoration, on fracture strength. One hundred and five extracted third molars were selected and randomly divided over 7 groups. They received no restoration (sound control), or an occlusal composite restoration of moderate ($\varnothing = 2.3$ mm) or large size ($\varnothing = 2.9$ mm), with either no, a thin or a thick soft, elastic layer underneath ($n = 15$ for all groups). The soft layer was composed of a zinc-oxide eugenol cement. All teeth were placed in a testing machine and a static occlusal load was applied, until fracture occurred. Failure load and fracture mode were recorded. Teeth with a soft, elastic layer showed more fractures above the CEJ whereas the groups with no soft, elastic layer showed more failures below the CEJ. Results showed that restorations placed over a soft, elastic layer resulted in a significant ($p < 0.001$) reduced fracture strength of restored teeth, while fracture strength of restored teeth without a soft layer and sound teeth differed not significantly.

Introduction

The need for complete removal of caries infected and affected dentine before restoration in order to stop the caries process is increasingly challenged. Clinical studies indicate that leaving carious tissue on the axial wall in case of a deep lesion should be preferred to vigorous excavation.¹ A recent systematic review concluded that there was less pulpal damage in incomplete vs. complete caries removal, and that no difference in caries process arrestment or restoration longevity could be confirmed.²

Most data is available on results for partial excavation, where infected dentine is largely removed, but caries affected dentine is retained. One-session ART excavation approach revealed a substantial decrease in numbers of micro-organisms and increased mineral density in the remaining dentine over time.^{3,4} No caries progression was observed radiographically in a clinical evaluation of indirect pulp capping using composite restorations, after 36 to 54 months.⁵ Clinical studies on the 'stepwise excavation' technique, in which final excavation is postponed and carious tissue is covered with a temporary restoration, revealed at re-entry that both infected and affected dentine were darker, harder and dryer and contained substantially fewer viable micro-organisms⁶⁻⁸ indicating arrestment of the caries process. There is some evidence that simple sealing, without removal of any infected dentine, is sufficient for the arrestment of the caries process.⁹ Mertz-Fairhurst *et al.*¹⁰ showed that when occlusal cavitated carious lesions reaching well into the dentine were only sealed off with a small bonded restoration, carious lesion progression was arrested over a 10-year period.

Although these results indicate that caries lesion progression is effectively arrested, there is insufficient information about the longevity of such restorations. Bonded restorations with no excavation showed a higher prevalence of clinical failures than did restorations in which carious dentine was removed completely before a sealed amalgam restoration was placed.¹⁰ In the study of indirect pulp capping mentioned above, three restorations (out of 32 restorations in 27 patients) placed over a residual layer of partially removed carious tissues fractured after 36-45 months.⁵ The reason for the higher number of failures is unclear in both studies, and no other long-term clinical studies on that subject are available. We hypothesize that the presence of a soft, elastic layer of considerable size has contributed to an increased failure of these restorations.

Such a layer may affect restoration strength in two ways. Several *in-vitro* studies have revealed that higher bond strength is achieved when a restoration material is

bonded to sound dentine instead of carious dentine.¹¹⁻¹³ Also, carious dentine is softer and has a lower elastic modulus than sound dentine.^{14, 15} Both factors may result in larger deformation of the tooth-restoration complex, leading to higher marginal stresses with risk of marginal deterioration, and increased susceptibility to fatigue failure. Thus, when a soft layer of carious tissue is left in the cavity before the restoration is placed, the fracture strength of the tooth-restoration complex may be reduced, resulting in a higher fracture rate.

Some clinical support for this theory can be found in the literature. Composite restorations showed an increased failure rate when the restoration was placed on top of a lining or base of glass-ionomer cement¹⁶ compared to restorations that had been bonded using a total etch technique. In another study¹⁷ ceramic restorations placed on a glass-ionomer base, showed decreased marginal adaptation, tooth and inlay integrity.

The aim of the present *in vitro* study was to investigate whether a soft, elastic layer beneath an adhesive occlusal composite restoration affects the fracture strength of restored teeth.

Materials & Methods

Cavity preparation and restoration

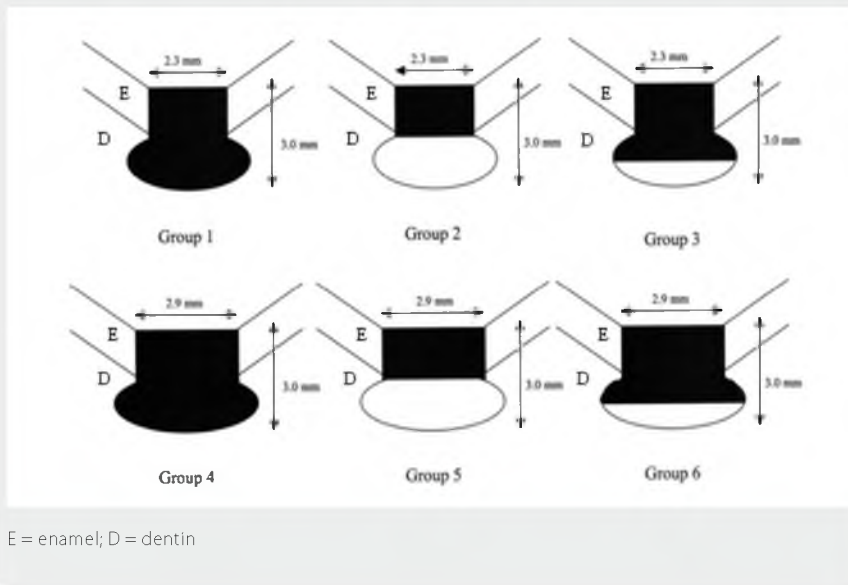
One hundred and five upper third molars were selected from a large batch stored in 1% chlorine-amine after extraction. These molars were collected with patients' informed consent. Molars had to be caries-, restoration- and sealant free. Size of the crown had to be 9 x 11 mm (\pm 0.1 mm). Teeth were randomly divided into 6 experimental groups (n=15) and a control group of sound molars (group 7: n=15). All molars were embedded in a standardized metal holder with the occlusal surface of the tooth placed horizontally, using self-curing acrylic (Auto Plast polymer, Candulor AG, Wangen, Switzerland) up to 1 mm below the cemento-enamel junction. In groups 1 to 6 standardized Class I preparations (see Figure 1) were ground with a mechanical cutting duplicator in the central fossa, using either a round diamond bur No. 023 (groups 1-3) or No. 029 (Komet, Lemgo, Germany) (groups 4-6). For all groups, a specially modified round diamond bur, No. 023 (Komet), whose cutting end was flattened by one-third of its length, was used to ground the undermining part below the occlusal enamel. Preparations were restored as follows (see Figure 1): A. restoration with composite (group 1+4: complete composite restoration); B. application of a soft layer (Tempbond NE Unidose; Kerr, Romulus MI, USA) in the entire preparation, except

in the access opening, before placement of a composite restoration (group 2+5: thick soft layer); C. application of a soft layer (Tempbond) at the bottom, halfway of the preparation, before placement of a composite restoration (group 3+6: thin soft layer).

Tempbond is a zinc-oxide eugenol cement used for temporary cementation. Vickers hardness of Tempbond was measured by placing small amounts of the material in a plastic mould (radius = 3 mm, height = 3 mm), showing a VHN of 0.1 GPa ($SD \pm 0.1$). The Young's Modulus (YM) of zinc-oxide eugenol cement has been reported as 0.3 GPa.¹⁸

Each specimen was acid etched with 37% phosphoric acid for 15 sec, rinsed thoroughly with water for 10 sec and gently air-dried until the enamel appeared 'frosted'. SA Primer (Kuraray, Osaka, Japan) was applied in the cavity and gently air-dried. Then Photo Bond (Kuraray) was mixed and applied, gently air-dried and light cured for 10 sec with an LE-Demetron I curing device (Kerr, Danbury, CT, USA) with an output of 800 mW/mm². A hybrid composite (Clearfil AP-X, Kuraray) was applied using a syringe technique into the preparation in one layer (groups 2+5) or two layers (groups 1+3+4+6). Each layer was light cured for 20 sec, from the occlusal surface. The composite restorations were finished, using a fine-grit diamond bur.

Figure 1 Schematic depiction of the experimental groups (black surface = composite material; white surface = soft layer).



Evaluation

Specimens were placed in the same metal holder as used during preparation and placed in a 858 Mini Bionix II testing machine (MTS, Eden Prairie MN, USA). Samples were loaded vertically with a cylindrical ball-ended stylus of stainless steel with a diameter of 2.3 mm (and a curve radius of 3.0 mm) until fracture occurred. In groups 1 to 6, load was applied on the restoration and in group 7 (control group), in the central fossa of the sound molars, at a crosshead speed of 0.25 mm/minute.

For each tested specimen failure load (in N) and fracture mode was recorded. For the fracture mode a distinction was made between fractures above or below the cemento-enamel junction (CEJ). Classification in fracture mode was based on a two-examiner agreement.

Statistical analysis

Multiple regression analysis was used to compare failure loads statistically. For this analysis, group 2 (small preparation size with a thick soft layer) from Figure 1 was defined as reference group. The main independent variables were preparation size and soft layer status. As it was deemed possible that the preparation size would influence the effect of the amount of soft layer on the dependent variable 'failure load', an interaction between preparation size and soft layer status was added to the model. Chi-square test analysis was used in analyzing fracture modes. For all crosstabs Fisher's Exact test was used to calculate p-values. The analyses were performed with SPSS 16 (SPSS Inc., Chicago IL, USA).

Results

Table 1 shows the mean failure load and fracture modes for each group. In the control group for three out of fifteen sound molars the stylus slid off from the central fossa to the marginal ridge during loading, resulting in a non-comparable loading configuration. These teeth were excluded. In some molars the fracture mode could not be defined, because no visible separation of tooth fragments occurred after fracture. In most of these cases the composite restoration was pushed into the soft layer.

Chi-square analysis revealed that preparation size did not influence the fracture mode significantly (for all experimental groups: $p > 0.5$). Therefore, groups with different preparation sizes for the same restoration treatment were combined for further fracture mode analysis. The fracture modes of the restored groups without a soft,

elastic layer differed significantly from those of the groups with a soft, elastic layer (thick soft layer: $p < 0.001$ and thin soft layer: $p = 0.047$). Teeth with a soft layer showed more fractures above the CEJ whereas the other groups showed more failures below the CEJ. Fracture modes were not significantly different between groups with different thickness of soft layer ($p = 0.14$). No differences in fracture mode were found between the different treatment groups and the sound control group (complete composite group: $p = 0.28$; thick soft layer: $p = 0.15$; thin soft layer: $p = 1.00$).

Regression analysis of the mean failure loads (Table 2) revealed that fracture resistance increased significantly with decreased thickness of the soft, elastic layer. A larger preparation size resulted in a decreased fracture resistance. Additionally, a statistically significant interaction existed for the case in which the complete composite restoration group is combined with a large preparation size ($p = 0.007$). No statistically significant interaction existed for the case in which the thin soft, elastic layer group is combined with a large preparation size ($p = 0.52$).

Table 1 Mean failure load (in N) and fracture modes per experimental group.

Group	Failure load				Fracture mode		
	n	Mean failure load (N)	SEM	95% CI	No. of fractures below CEJ	No. of fractures above CEJ	Fracture mode not defined
Complete composite restoration Ø2.3 mm	15	2461	74.5	2311 - 2630	10	4	1
Thick soft layer Ø2.3 mm	15	1058	63.9	921 - 1194	2	9	4
Thin soft layer Ø2.3 mm	15	1946	84.0	1765 - 2126	6	6	3
Complete composite restoration Ø2.9 mm	15	2768	125	2500 - 3036	11	4	0
Thick soft layer Ø2.9 mm	15	900	40.1	814 - 986	4	10	1
Thin soft layer Ø2.9 mm	15	1682	80.9	1509 - 1856	6	8	1
Sound (control)	12	2707	130	2422 - 2993	6	6	0

Table 2 Results of regression analysis of mean failure loads.

Variable		p-value	Effect	95% CI for effect
Constant (thick soft layer, Ø 2.3 mm)		<0.001	1058	[894...1221]
Preparation size (0=2.3mm; 1=2.9mm)		0.18	-158	[-389...73]
Variable: soft layer status	Thin soft layer (0=no; 1=yes)	<0.001	888	[657...1119]
	Complete composite restoration (0=no; 1=yes)	<0.001	1413	[1182...1644]
Interaction: size x thin soft layer (1=thin soft layer and large preparation; 0=all other conditions)		0.52	-105	[-432...222]
Interaction: size x complete composite restoration (1=complete composite restoration and large preparation; 0=all other conditions)		0.007	456	[129...782]

Discussion

In this *in vitro* study the fracture strength of composite restored teeth with an underlying soft, elastic layer of different thickness was tested. Fracture strength was significantly higher in groups restored with a thin soft, elastic layer and in groups without a soft, elastic layer, compared to groups restored with a thick soft, elastic layer.

In this study, a zinc-oxide eugenol cement was used to make the soft, elastic layer, resulting in a layer with uniform hardness and young's modulus (YM). The hardness of the layer is comparable with that of soft infected carious tissue.^{15, 19} The YM is about 10 times lower than that reported for carious dentine. The present model can therefore be regarded as a worst case scenario. Extrapolation to a clinical situation can only be limited, as more factors interact clinically in the fracture strength of composite restored teeth placed on a residual layer of partially removed carious tissues. Natural carious dentine is composed of different layers, with a gradient of hardness and YM.²⁰ Moreover, carious dentine that is adequately sealed with an adhesive restoration may remineralize, becoming harder, darker and dryer,⁶⁻⁸ thus resulting in dentine with a higher VHN and a lower YM¹⁵ over time.

In this study we could not distinguish between the possible explanatory factors of lack of adhesion to the underlying layer and the lack of support for the restoration by the soft and elastic layer, as both factors were present. However, as both factors may also play a role when restoring over carious dentine, this distinction seems to be of little relevance. The clinical studies reporting on the effect of glass-ionomer bases on the failure rate of composite or ceramic restorations,^{16,17} suggest that the mechanical properties of the base are more important, as composite can be bonded to glass-ionomer cement. Considering that glass-ionomer cement has a much higher hardness and YM compared to the cement model used in the present study, the implication is that the effect of natural carious dentine is also likely to be significant.

Restored teeth without a soft, elastic layer more frequently showed fractures below the CEJ. The teeth were loaded with a spherical contact on the restoration. In the groups with a soft layer, this loading drives the restorative material axially into the tooth and, especially in case of the thick soft layer groups this would test the bond of the restoration to the enamel and in a lesser extent to the dentine. When debonding occurs, particularly if it starts at one wall and propagates around the restoration outline, the restoration will also move laterally. This movement may contribute to the development of fractures above the CEJ. In case the preparation is restored completely with a composite restoration, debonding may be less likely and loading drives the restoration toward the pulp chamber, resulting in a fracture below the CEJ. The less favourable failure mode of restored teeth without a soft layer may be related to a compromised clinical prognosis. However, as restored teeth without a soft layer showed fracture strength and fracture modes comparable to those of sound teeth, the relevance of this issue is questionable.

The applied load in this *in vitro* study was static, resulting in very high fracture strength. Clinical loading of teeth is a dynamic process in which loading force, frequency and direction vary greatly. It is suggested that future studies are performed using cyclic loading, to evaluate a more clinically relevant mechanical performance.

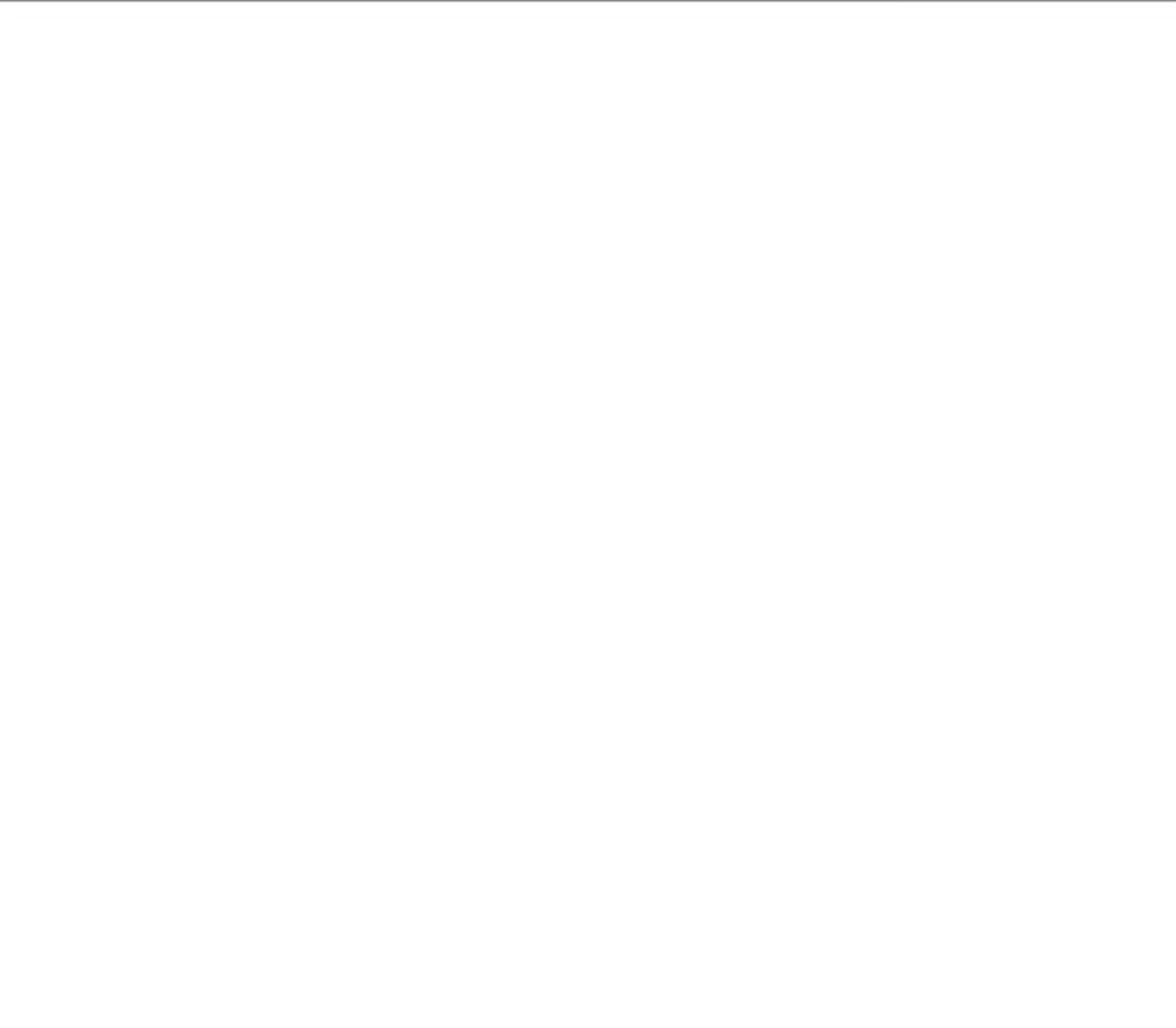
The present study illustrates the need to expand the current discussion on minimally invasive operative dentistry. Although unnecessary for stopping the caries process, partial removal of carious dentine may contribute negatively to the longevity of the tooth-restoration-complex. On the other hand, when complete carious lesion removal leads to pulp exposure during excavation, tooth life prognosis is seriously reduced. Future research should be aimed at finding the optimal method and/or level of excavation to obtain a strong and durably restored tooth while at the same time avoiding pulp exposure and necrosis.

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Does incomplete caries removal reduce strength of restored teeth?

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Abstract

Little information is available about whether the presence of residual caries beneath an occlusal restoration affects fracture strength of the tooth. This *in vitro* study tested the hypothesis that restored teeth after incomplete excavation have lower fracture strengths than restored teeth after complete excavation. Fourteen pairs of molars were randomly assigned to an experimental (incomplete excavation) or to a control group (complete excavation) and loaded vertically (after cyclic loading). Failure load and fracture mode were recorded. Restored teeth in the incomplete excavation group resulted in reduced fracture strength ($p < 0.001$) of the tooth-restoration complex ($1276 \text{ N} \pm 626 \text{ N}$) compared with the control group ($2768 \text{ N} \pm 710 \text{ N}$). Teeth in the complete excavation group all fractured vertically, while in the experimental group, cracks in the restoration were observed, characterized as 'ice-cracks'. The fracture strength of teeth restored over incomplete caries excavation was significantly reduced, possibly resulting in long-term clinical failure.

Introduction

The role of operative intervention in the treatment of caries is changing. Caries progression can be stopped when carious tissue is sealed with a restoration.¹⁻³ Clinical studies on the 'stepwise excavation' technique, in which final excavation is postponed and carious dentin is covered with a temporary restoration, revealed that at re-entry, both infected and affected dentin were darker, harder and dryer and contained substantially less viable micro-organisms.⁴⁻⁶ Even the one-session ART excavation approach revealed a substantial decrease in micro-organisms and increased mineral density in the remaining dentin over time.^{7,8}

Leaving carious tissue on the axial floor in case of a deep lesion should be preferred over vigorous excavation, since incomplete caries removal leads to less pulpal damage, caries arrest, and acceptable short-term restoration longevity.^{3,9,10} As a result of caries arrest, tubular sclerosis and reactionary dentin are produced, reducing the permeability of remaining dentin.¹¹ Therefore, the suitability of traditional operative techniques of removing all infected/affected dentin is questioned.^{11,12} Instead, the recommendation is to remove only carious tissues that cannot be remineralized.^{11,12}

However, there is insufficient information about the long-term survival of restorations placed after incomplete caries removal. Composite restorations placed on top of soft carious tissue (infected dentin) showed a higher prevalence of clinical failures than sealed amalgam restorations with complete excavation.² Some fractures of restorations placed over a residual layer of soft dentin occurred after 36-45 mos.³ Leaving a layer of carious dentin may influence restoration strength in two ways. As we know, higher bond strengths are achieved when a restoration material is bonded to sound instead of carious dentin.¹³⁻¹⁵ Second, carious dentin is softer and has a lower Young's Modulus than sound dentin.^{16,17} Both factors may result in larger deformation of the tooth-restoration complex, leading to higher marginal stresses and increased susceptibility to fatigue failure. Thus, when soft carious tissue is left in the cavity before the tooth is restored, the fracture strength of the tooth-restoration complex may be reduced.

The aim of the present *in vitro* study was to investigate whether residual soft carious dentin beneath an adhesive occlusal composite restoration affects the fracture strength of restored teeth. We hypothesized that the presence of a soft, elastic layer of considerable size may contribute to an increased failure of these restorations.

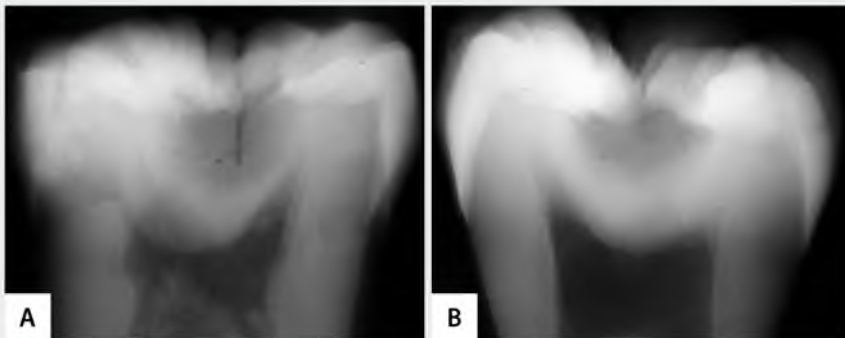
Materials & Methods

Selection of molar teeth

From a large batch of extracted molars (first, second and third molars from different patients) stored in 1% chlorine-amine and collected with patients' informed consent (in accordance with the rules of the regional ethics committee, The Netherlands), molar teeth were selected according to the following criteria: (1) visual presence of an occlusal cavitated caries lesion (ICDAS code 5 or 6);¹⁸ (2) radiographs of the extracted teeth showed a lesion more than halfway into the dentin, with no obvious pulpal involvement; and (3) absence of restorations, sealants, cavities, or decalcifications on other surfaces. After more than 500 molars were screened, the inclusion procedure resulted in 46 molar teeth with deep occlusal caries lesions. From these 46 teeth, 23 pairs were formed based on similar sizes of the teeth (measured with a caliper rule in mesio-distal and bucco-lingual directions), as well as similarly sized and localized caries lesions. The selection of molars and pair formation was performed by two researchers on a consensus basis (MH/NO).

All molars were embedded in a standardized metal holder with the occlusal surface of the tooth placed, horizontally, with self-curing acrylic (Auto Plast polymer, Candulor AG, Wangen, Switzerland) up to 1 mm below the cemento-enamel junction. After the molars were embedded, new baseline standardized microradiographs were taken using Transversal Wavelength Independent Microradiography¹⁹ with optimal setting conditions of 60 kV, 30 mA, and an exposure time of 30 sec (Fig. 1).

Figure 1 Example of baseline standardized radiographs of a paired molar teeth.

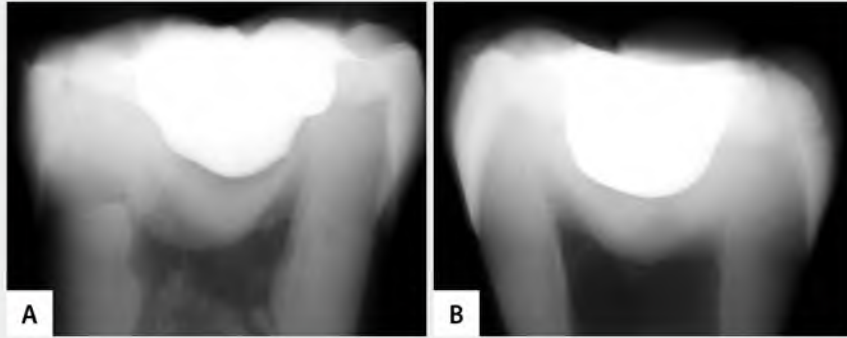


Preparation and restoration of teeth

From each pair of molar teeth, 1 tooth was randomly assigned at the start of the study to the experimental (incomplete caries excavation) and 1 to the control (complete caries excavation) treatment group by a blinded dentist, who did not participate in this study. This dentist randomly assigned a label "A" or "B" to both molars, using only an object code on a list to identify the molars, without knowing the meaning of "A" and "B". In both groups, decalcified enamel was removed with a diamond bur up to the dentino-enamel junction. Subsequently, 1 mm below the dentino-enamel junction, all soft dentin was excavated by means of a hand excavator (no 1020/153-154; Carl Martin, Solingen, Germany), until the surface felt hard to the touch of a sharp probe. Soft carious dentin was left behind on the preparation floor in both treatment groups. Then the paired molars were visually compared for preparation outline, and the smallest preparation was adjusted to a size equivalent to the largest preparation. Minor adjustments (< 0.5 mm) were needed in 4 molars. Adjustments were performed in both treatment groups. As a result, both preparation outlines of the paired molars were comparable. Subsequently, for the control group, all the carious dentin was excavated with a large hand excavator (no 1020/129-130; Carl Martin), until the surface felt hard. For the experimental group, no further caries removal was performed, leaving behind soft carious tissue on the preparation floor. When a preparation in the control group resulted in a macro-exposure of the pulp (> 0.5 mm), the molar pair was excluded from the study. When, complete excavation resulted in a micro-exposure (< 0.5 mm), the molar pair was not excluded from the study.

Preparations were acid etched with 37% phosphoric acid for 15 sec, rinsed thoroughly with water, and gently air-dried. SA primer (Kuraray, Osaka, Japan) was applied in the preparation and gently air-dried. Next, Photo Bond (Kuraray) was mixed and applied, gently air-dried, and light cured for 10 sec with an LE-Demetron I curing device (Kerr, Danbury, CT, USA) with an output of 800 mW/mm². A hybrid composite (Clearfil AP-X, Kuraray) was syringed from a compule into the preparation in layers of 2 mm height, shaped with a hand instrument and cured for 20 sec each. The restorations were finished, by means of a fine-grit diamond bur and mini-points (Shofu, Kyoto, Japan). Preparation/restoration interfaces were checked for irregularities with a microscope (2.5x magnification), polished if necessary, and new standardized microradiographs were taken (Fig. 2).

Figure 2 Example of the paired molar teeth from Fig. 1, randomly divided into the 2 experimental treatment groups: **(A)** incomplete excavation group and **(B)** complete excavation group.



Fatigue test and fracture strength

Specimens were placed in a 858 Mini Bionix II testing machine (MTS, Eden Prairie MN, USA). Cyclic load was applied vertically to the restored molars with a stainless steel cylindrical ball stylus (\varnothing 2.3 mm, radius 3 mm) placed centrally on the restoration. A cyclic load of 350 N was applied at a frequency of 5 Hz during 400,000 cycles, in tap water.

Following the cyclic loading, fracture strength of the restored molars was tested. Load was applied vertically on each restoration at a crosshead speed of 0.25 mm/minute until fracture occurred, and expressed as the failure load (N). A static load was applied until fracture occurred of either the restoration, tooth or tooth-restoration complex. After fracture, 4 randomly chosen teeth from the experimental group were dehydrated in ethanol, embedded in PMMA and sectioned with a saw (300 μ m thick blade). The teeth were sectioned in bucco-lingual direction in 7 sections, and the sections were photographed.

Statistical analysis

The analyses were performed with SPSS 16 (SPSS Inc., Chicago, IL, USA). We used a paired *t* test to analyze failure loads for the paired molar teeth. Second, we performed regression analysis to check for any influence of size of the molars on the failure loads. To analyze the possible influence of micro-exposure on the failure load, we used a *t* test. All *t* tests were performed two-sided. The investigators performing the fatigue

and fracture tests were masked to the treatment allocation, because, on the outside of the restored teeth, they could not see whether residual caries was left. Besides, prior to the statistical analysis, our statistician was unaware of which data belonged to which group.

Results

During the study, 9 pairs of molars had to be excluded due to large pulp-exposures. Additionally, 5 teeth which were fully excavated showed micro-exposure of the pulp (< 0.5 mm). Additionally, one molar pair was excluded from the statistical analysis because the stylus slid off the surface during loading. No difference in fracture strength between the teeth in the complete excavation group with (marked with an asterisk in Fig. 3) and those without a micro-exposure was found ($p = 0.12$; difference = 608 N; 95% CI [-181 N...1396 N]).

Figure 3 Failure loads (N) for the paired molars in the complete and incomplete excavation group. Teeth with a micro-exposure in the complete excavation group are marked with an asterisk.

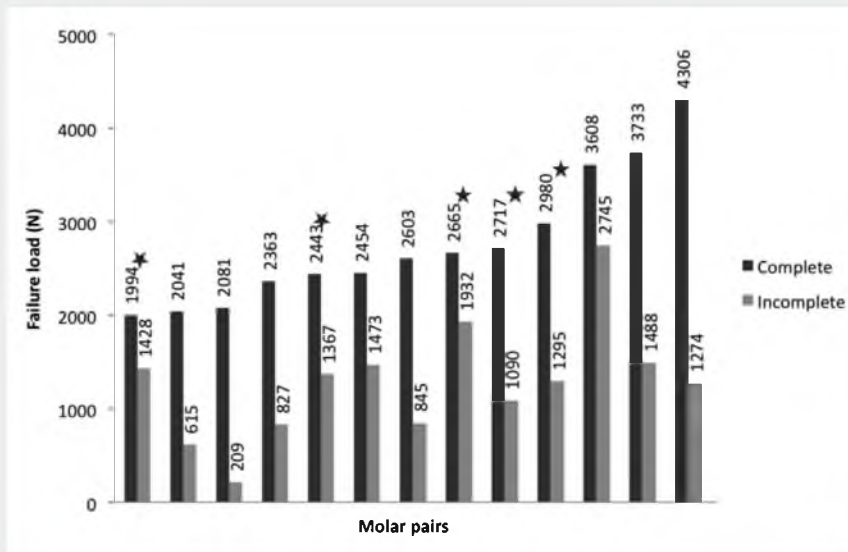


Figure 4 Example of molar from the incomplete excavation group after final failure load test, showing 'ice-cracks' on the occlusal surface (black arrows in **A**) and after sectioning the molar (black arrows in **B, C**).



The results for the failure loads *per* molar pair are shown in Fig.3 (n = 13). Pearson's correlation coefficient between the teeth in the experimental and the control groups was 0.50, illustrating an acceptable matching of the paired teeth. Statistical analysis revealed a significant difference in failure strength between the teeth in both groups ($p < 0.001$; 95% CI [1084 N...1901 N]). For the complete caries excavation group the mean failure load was 2768 N (SD = 710 N), while for the experimental group teeth failed at a mean of 1276 N (SD = 626 N).

Regression analysis showed no statistically significant effect of the size of the molar on the fracture strength ($p = 0.25$; effect = 17N/mm²; 95% CI [-13 N/mm²...47 N/mm²]).

The restored molars in the control group all showed vertical root fractures, below the cemento-enamel junction. The molars in the experimental group showed cracks in the restoration, called 'ice-cracks' due to their appearance (Fig. 4). The 4 embedded and sectioned teeth from the experimental group showed cracks radiating from the point of loading.

Discussion

In this *in vitro* study, the hypothesis addressed the question of whether incomplete excavation compromises the fracture strength of composite restored molar teeth. Results showed that the fracture strength for the restored teeth after complete excavation was significantly higher than for comparable teeth after incomplete excavation. This issue is currently very relevant, since incomplete excavation has been recommended for deep caries lesions to avoid pulp exposure.¹⁰

Studies of natural teeth and natural caries lesions are characterized by a large source of variation, due to the variation in tooth size and lesion size and distribution. To reduce this variation, we chose the current paired set-up. To improve the pairing, we adjusted preparation outlines within each pair. This design thus optimized standardization, while still using natural caries lesions, thus compensating for the limited sample size.

The clinical problem addressed in this study, namely, how to restore teeth with very deep caries lesions, is reflected in the frequency of pulp-exposures found (9 large exposures and 5 micro-exposures in 23 molar pairs). It illustrates the enhanced risk of pulp-exposure after complete excavation, as shown in several clinical studies on indirect pulp-capping and stepwise excavation.⁴⁻⁶ Inclusion of the teeth with micro-exposures in the present study did not seem to influence the fracture strength.

To introduce a factor of fatigue, we subjected the restored teeth to cyclic loading, followed by static loading until failure. The cyclic load used (350 N) was the outcome of a pilot study on 4 test specimens, showing only minor occlusal damage to the composite surface. Clinical loading of teeth is a dynamic process, in which force, frequency and direction vary greatly. Although the rate of mastication is normally about 2 Hz,²⁰ we used cyclic loading with a 5 Hz interval, a frequency also used in other cyclic loading studies,^{21,22} to accelerate the aging process. Studies measuring chewing forces in natural dentitions varied greatly among individuals, from 360N²³ to 1550N.²⁴

No damage could be observed on the molars after the cyclic loading, except for a small indentation on the point of loading. After the final load, molars in the complete excavation group all showed fatal vertical fractures. The molars in the incomplete excavation group showed 'ice-cracks' in the restoration, indicating that the restoration had collapsed into the underlying soft layer of carious dentin. The 4 sectioned specimens, all showed fractures radiating from the point of loading. In a clinical situation, such fractures may or may not be observed by the patient. When remaining unnoticed, such teeth would continue to be loaded, and it can be assumed that at the interface of the restoration and underlying carious dentin, the tension will spread laterally. This may lead to clinical fracture of the cusps of the tooth. It is also possible that due to the formation of large cracks and gaps, the carious process will become active again.

Extrapolation to a clinical situation of this study must be done with caution. Several clinical variables may influence the long-term behavior of restorations over incomplete caries excavation. Carious dentin that is adequately sealed with an adhesive restoration will remineralize, becoming darker, harder and dryer,⁴⁻⁶ resulting in a greater hardness and stiffness and a higher fracture strength over time.

Clinical research showed 10% failures of indirect pulp capped restorations due to fracture after 40 mos,³ indicating that the fracture strength of such restorations may be compromised. The thickness of the carious layer left behind may be important. In our study, large caries lesions were involved, and a considerable amount of carious tissue was left under the restoration. What remains to be investigated is the amount of carious tissue that can be left behind without impairing the strength of the tooth. For now, it may be advisable to choose the stepwise excavation technique when treating deep caries lesions. On the one hand, this method prevents pulpal damage, while on the other hand, the second step of complete excavation will increase the strength of the final tooth-restoration complex.

Within the limits of this *in vitro* study, we concluded that the fracture strength of teeth restored over incomplete caries excavation was significantly reduced, possibly resulting in long-term clinical failure.

Acknowledgements

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ADDENDUM

Response letter: 'Does incomplete caries removal reduce strength of restored teeth?'

Journal of Dental Research (2011): Accepted for publication

Comments by dr M.Maltz:

Hevinga *et al.*¹ published, in the November's issue, a study on the strength of teeth restored over carious tissue. Some aspects of this article deserve to be enlightened: Based on a paper by Mertz-Fairhurst *et al.*², the authors stated that "composite restorations placed on top of soft carious tissue showed a higher prevalence of clinical failures than sealed amalgam restorations with complete excavation". This statement ignored the third experimental group (conventional unsealed amalgam restorations) which presented a failure rate similar to that found in the group treated with "restorations over caries". These findings show that the failures cannot be attributed to the carious tissue under the restoration.

A fracture rate of 6.5% was found by Maltz *et al.*³ These fractures occurred in large restorations (≥ 2 surfaces) dissimilar to the occlusal cavities performed by Hevinga *et al.* The absence of a "complete caries removal group" conflicts with the statement that "the fracture strength of such (incomplete caries removal) restorations may be compromised" as published by Hevinga *et al.*¹ Additionally, studies on extensive restorations longevity report fractures as the main reason for restoration failure.⁴

Hevinga's *et al.*¹ recommendation that "it may be advisable to choose the stepwise excavation technique when treating deep caries lesions" disregards changes occurring in the sealed carious dentine, such as increment of hardness. This characterizes a typical case of "absence of evidence". The clinical recommendation inferred from a *vitro* study with restricted sample size is clearly a step beyond the data.

Acknowledgment

The author declares no proprietary, financial, or professional conflicts in any product, service, and/or company that could be construed as influencing the position presented in this Letter to the Editor.

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Dear Editor,

We would like to respond to the comments made by dr Maltz to our paper.¹

Firstly, regarding the study by Mertz-Fairhurst et al.², it was pointed out that we had ignored the failure rate of conventional amalgam restorations being just as high as that of "composite restorations over caries". However, in that study, caries was the only reason that conventional amalgams failed whereas the 'restorations over caries' failed due to various reasons including restoration loss and fracture, suggesting that fatigue may have played a role in failure behavior. Dr. Maltz' statement that similar failure rates show that the failures cannot be attributed to the carious tissue, ignores this considerable difference in failure behavior.

Secondly, regarding the clinical study by van Nieuwenhuysen³, where fracture was the main failure reason of composite restorations, it must be noted that a glass-ionomer lining cement was used. Surprisingly, composite restorations with a GIC lining showed significantly more fracture than those placed with only an adhesive.⁴ With carious tissue being an even softer base than GIC, it may well be that restorations over caries also show increased fracture.

Dr. Maltz considers our carefully worded recommendation a step beyond the data. However, we feel that in the absence of evidence it is better to err on the side of caution. If more evidence emerges that substantial volumes of carious tissue can be retained without compromising tooth/restoration prognosis, we will be most happy to change our recommendation.

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7

General discussion

The main objective of this thesis was to investigate the role of adhesive dentistry in the management of occlusal caries lesions in pits and fissures. In this chapter research methodology, the main results and suggestions for future research will be discussed.

Research methodology

This thesis consists of one retrospective clinical and four *in vitro* studies. In terms of quality of evidence, these types of study design are not at the top of the pyramid of evidence. Therefore, it is not possible to use the results directly for decisions in clinical care. However, the topics that have been investigated in the *in vitro* studies play a fundamental role in caries prevention through sealant application. Besides, the studies in this thesis have been carried out according to high scientific standards. The reliability of the measurements was high and whenever possible, evaluation was carried out blindly, so as to minimise bias.

Some critical comments could be made on the research methodology. The optical techniques used to measure microleakage and fissure penetration depth of sealants (Chapter 3 and 4), through slicing the teeth in sections, will increasingly become obsolete by the availability of micro-CT. This technique is non-destructive, and permits the measurement of the deepest point of microleakage and fissure penetration depth on a continuous scale, instead of a categorical scale as used in the present studies. However, this technique also poses some problems, particularly, if sealant materials of low density, such as resin based ones, are used.¹

A point that needs attention for future *in vitro* studies on restorations placed over residual carious dentine, is the development of artificial materials that may mimic the gradient of mechanical characteristics of carious dentine. In this thesis, Tempbond® was used, but this material is not a perfect match in hardness and elastic modulus to carious dentine (Chapter 5). Carrying out experiments to develop a carious dentine substitute is important, as modern cariology and minimally invasive restorative dentistry consider preserving remineralizable tooth tissue more important than removing demineralised tooth tissues.

The retrospective clinical study showed the possibility to retain newer resin based sealants for a long time, allowing them to exercise their caries preventive effect in adolescents and young adults effectively. The reported restriction of using resin based materials in erupting teeth and in uncooperative children was not investigated. Future studies researching these factors should include other sealant materials, for example high viscosity glass-ionomers.

Sealing of pits and fissures

Systematic reviews that have been published, recommend the application of sealants in high-caries risk individuals and in teeth at risk.²⁻⁴ This recommendation is indirectly supported by the retrospective clinical study (Chapter 2), although the (retrospective) term restoration profile was used instead of the (prospective) caries risk of the patient. The study showed that resin based sealants placed in permanent molars and those in high restoration profile patients, showed significantly higher failure rates as compared to sealants placed in premolars and low restoration profile patients. Secondly, many fissures became discoloured over time, irrespective of the restoration profile of the patient. Discoloured fissures may represent sound surfaces (where the discolouration originates from organic material trapped in the fissure) but may also be enamel/dentine caries lesions (where the demineralised enamel has been stained and possibly arrested). The question arises if and for how long these discoloured pits and fissures will remain arrested. Will they progress and become cavitated, needing operative treatment, and if so, when will this occur? Scientific literature reports varying rates of dark-brown or black discoloured fissures becoming decayed.^{5,6} The findings in Chapter 2 suggest that many fissures become discoloured without presence of an active carious process that will lead to the need for operative treatment. Therefore, it is doubtful if a discoloured fissure expresses generally a viable indication for placing a fissure sealant, or even an operative intervention.

Diagnosing occlusal caries lesions, especially non-cavitated lesions, with a high level of accuracy often remains a problem. To improve the diagnosis of occlusal caries lesions newly developed and existing diagnostic techniques have been investigated in the past decades. Recently, new detailed visual detection systems were described, resulting in improved correlation with lesion depth⁷ and lesion activity.⁸ These detailed visual detection systems are still being adapted, to improve accuracy and validity (ICDAS II and UniViSS).^{9,10} Formulation of the presence, size and colour of the discoloration and presence or absence of microcavitation during the routine oral examination, may help to decide whether to monitor the discoloured fissure or to place a sealant over the discoloration.

Placement of sealants over non-cavitated caries lesions is effective in preventing lesion progression.¹¹ Most of the non-cavitated lesions are limited to the enamel or extend to just beyond the dentino-enamel junction. Where the occlusal surface is cavitated, the caries process has extended into the dentine. Due to the morphological configuration of the pits and fissures, this cavity is often insufficiently accessible to regular plaque removal, so restorative intervention is then needed. In the past, occlusal cavitation was often determined by the presence of sticky fissures, that would catch

and hold an explorer tine or could be penetrated by probing. However, it was shown that probing may actually induce cavitation in a previously non-cavitated demineralised surface.¹² Nowadays, cavitation is determined by visual evidence of loss of tooth structure at the entrance to or within the pit or fissure within an area of demineralization (opaque white, brown or dark brown discoloured), where, to the examiners judgment, dentine is exposed.¹³ This change in definition makes it hard to integrate existing scientific literature on sealant use in cavitated fissures. To our opinion, only the visual evidence of loss of tooth structure at the occlusal surface should be called cavitation. Searching the literature resulted in only a few studies concerning the sealing of truly cavitated fissures.¹⁴⁻¹⁶ Lesion depth measurements after 12 months observation time showed that lesion depth decreased in sealed teeth, while in the unsealed teeth lesion depth increased. The sealed teeth showed very little or no radiographic change in radiolucency.

The sealed cavitated fissures in the two *in vitro* studies performed for this thesis (Chapter 3 and 4) showed significantly more microleakage than sealed sound fissures. The use of an adhesive system nor its intermediate curing improved the effectiveness of sealing. One may question the clinical relevance of microleakage. For instance, research on secondary caries formation has shown that it is predominantly observed with large restoration gaps (>50 µm).^{17, 18} Some researchers even stated that secondary caries formation is only possible when gaps are as wide as 250-400 µm.^{19, 20} These researchers speak about macroleakage instead of microleakage. The sections of the teeth evaluated in the two studies showed minor gaps, which were often clinically invisible. Due to these small gaps little influence of microleakage on functional behaviour is expected. However, a sealed fissure is different from a tooth-restoration interface. It may be that sealants placed on top of cavitated fissures that show microleakage in almost all cases, are not able to prevent caries progression on the long-term. Microleakage may lead to (partial) sealant loss, and this is likely to be more detrimental in cavitated fissures than the loss of sealants on sound teeth. Loss of the sealant material or improper adhesion to the tooth surface might create a plaque retention site, which in a caries active environment may lead to a reactivation of the caries lesions. Routine examination of the sealed cavitated teeth is a must to check proper adhesion of the sealant material.

Only randomized controlled trials can provide a proper answer to the question whether cavitated fissures can be sealed to prevent caries lesion progression. In such a trial, sealing of cavitated pits and fissures should be compared with a traditional treatment approach (complete excavation and placement of a composite or preventive resin restoration). Placement of sealants on cavitated fissures makes it necessary to

follow-up a proper adhesion of the sealant material with digital photographic documentation and visual clinical examination using standardized criteria. Additionally, standardized bitewing radiographs to evaluate caries lesion progression is needed.

Restoring cavitated caries lesions

One of the main objectives of this thesis was to investigate the treatment options concerning the treatment of cavitated occlusal caries lesions (Chapter 5 and 6). There exists an area of tension between cariologists and restorative dentists. Cariologists have shown that the caries process is stopped when an adequate restoration or sealant is placed over carious dentine. Stepwise excavation studies have shown that the previously soft, moist, yellow-brownish dentine becomes harder, dryer and darker in colour. Besides, the number of viable cultivable bacteria goes down and preservation of pulp vitality is increased. However, restorative dentists remain sceptical about this treatment option. In their minds, leaving affected and certainly infected carious dentine behind and placement of a restoration over these carious tissues, may lead to problems on the long-term. They feel one is building on quicksand. Bonding to carious dentine results in decreased bond strength and adequate quality and durability of the tooth-restoration complex is compromised.²¹⁻²³ On the long-term this may lead to lesion progression of the residual carious tissue. The two *in vitro* studies highlighted possible mechanical problems, as they showed that restorations placed over either a soft, elastic layer or after incomplete excavation of the carious tissues, resulted in reduced fracture strength of the restored teeth, compared to teeth restored after complete excavation. Again, extrapolation of the study results to the clinical situation must be done with caution. However, it seems that even if complete caries excavation is not essential for arresting the caries process, the fracture strength of the restored teeth might be compromised if carious tissues is left behind.

This work has shown that for future randomised controlled trials it is essential that failure outcomes are reformulated and validated. Not only the outcome caries arrest, but also preservation of the tooth-restoration complex on the long-term should be evaluated. Not only caries lesion progression, but also fracture of either the restoration, tooth or tooth-restoration complex must be regarded as a failure of the treatment. Practice based retrospective clinical trials may be a first step in this direction. Adequate recording of treatment procedures and clinical findings on colour, structure and size of the lesion are necessary. Also, parafunctions like clenching and bruxing may have to be recorded and evaluated, as these factors may have an influence on the fracture of the tooth-restoration complex. One has to accept that not all factors influencing the strength of the tooth-restoration complex may be quantified. Assessment of the

exact amount of the carious tissue that is left under the restoration, and a differentiation into infected and/or affected dentine in clinical circumstances is impossible.

Finding an answer to the question how much carious tissue can be left behind to stop the caries lesion progression while still ensuring a long-term performance of the tooth-restoration complex is a challenge. Detailed recording of dental treatment and an open mind in research might bring us pretty far.

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8

Summary

The main objective of this thesis was to investigate the role of the adhesive dentistry in the management of occlusal caries. The research area of interest was restricted to the application of resin based sealants and composite materials. A retrospective clinical study (Chapter 2) and two *in vitro* studies (Chapter 3 and 4) were performed to evaluate the effect of sealing sound and carious fissures with a resin based material. Furthermore, two *in vitro* studies (Chapter 5 and 6) focused on the influence of leaving behind soft, carious tissues under an occlusal composite restoration on the strength of the tooth-restoration complex.

Chapter 1 describes the background of the study and reviews the literature on sealing sound and carious pits and fissures. In case the caries process has extended leading to cavitation of the occlusal surface, various treatment options are available. In addition, the main research objectives of the thesis are described.

In **Chapter 2** a retrospective clinical study is described. The aim was to evaluate the long-term performance of resin based fissure sealants applied preventively in a general dental practice in the Netherlands. Regularly attending patients who had received sealants were included in the study. Sealants were applied to sound, non-discoloured permanent teeth and replacement by a restoration was recorded and regarded as a failure. Sealants were placed on sound pits and fissures by either a dentist or an oral hygienist, without reapplication in case of loss of retention. Complete retention rates of 41.3% after an average follow-up time of 11.6 years were found. Patients were categorized by restoration profile by counting the number of restorations placed in the primary and permanent dentition since the first sealant was applied. The patient group was divided into two equal groups representing a high and low restoration profile. The group with a high restoration profile received more than three times as many occlusal restorations than the low restoration profile group (17.0% versus 5.1%). More sealants failed in the high restoration profile group. The present study demonstrated that, irrespective of the restoration profile of the patient, many fissures became discoloured on the long term. It could be seen that 45.4% of the sealed fissures had become discoloured without needing a restoration. Percentages of 46.4% versus 44.3% for the low and high restoration profile group were comparable.

In **Chapter 3** and in **Chapter 4** two *in vitro* studies are described that tested whether carious fissures could be sealed as adequately as sound fissures. In **Chapter 3** eighty molars with an occlusal cavitated dentine lesion were treated according to five

experimental protocols and compared with a control group of sealed sound molars. In the experimental groups, resin based fissure sealants were applied with and without an adhesive system, and cured with or without intermediate curing. After immersion in a colouring dye, teeth were sectioned and microleakage and sealant penetration depth into the fissure was scored. Sealed cavitated fissures exhibited significantly more microleakage and diminished sealant penetration depth than sound fissures. Neither the use of an adhesive, nor its intermediate curing affected the microleakage score and the penetration ability of resin based sealants. In **Chapter 4** 128 molar teeth with cavitated caries lesions in the occlusal surface were sealed under four different surface conditions (dry, water-, saliva contamination or saliva contamination followed by air-drying) and compared with a control group of sealed sound teeth. In the experimental groups two sealant protocols were tested, namely application of a resin based sealant only and one adding an adhesive system prior to the application of the sealant. Teeth were immersed in a colouring dye before they were sectioned to score microleakage and sealant penetration depth. According to the results the addition of an adhesive system improved the effectiveness of sealants placed after water contamination. Sound fissures were sealed more effectively than cavitated caries fissures.

In **Chapter 5** and **Chapter 6** two *in vitro* studies are described that tested whether residual soft carious dentine beneath an adhesive occlusal composite restoration affects the fracture strength of restored teeth. In **Chapter 5** the effect of a standardised soft, elastic layer underneath an occlusal composite restoration, on its fracture strength was tested. One hundred and five similar sized extracted third molars were selected and randomly assigned to 7 groups. They received no restoration (sound control), or an occlusal composite restoration of moderate ($\varnothing = 2.3$ mm) or large size ($\varnothing = 2.9$ mm), with either no, a thin or a thick soft, elastic layer underneath ($n = 15$ for all groups). The soft layer was composed of a zinc-oxide eugenol cement. Afterwards, all teeth were subjected to a static occlusal load until fracture occurred. Failure load as well as fracture mode were recorded. Teeth with a soft, elastic layer demonstrated predominantly fractures above the cemento enamel junction (CEJ), whereas in the groups with no soft, elastic layer most failures extended below the CEJ. According to the results, restorations placed over a soft, elastic layer exhibited a significant ($p < 0.001$) reduced fracture strength, while fracture strength of restored teeth without a soft layer and sound teeth was the same. **Chapter 6** tested the hypothesis that teeth restored after incomplete excavation have lower fracture strengths than teeth restored after complete excavation. Molar teeth with visual presence of an occlusal cavitated

caries lesion were selected. Radiographs of the teeth showed a lesion more than half-way into the dentine with no obvious pulpal involvement. Then the molars were paired based on their size. Fourteen pairs of molars could be randomly assigned to the experimental (incomplete excavation) or to the control group (complete excavation) and were loaded vertically after being subjected to cyclic loading. The failure load and fracture mode were recorded. In the incomplete excavation group a lower fracture strength of the tooth-restoration complex was found ($1276 \text{ N} \pm 626 \text{ N}$) ($p < 0.001$) compared to the control group ($2768 \text{ N} \pm 710 \text{ N}$). All the teeth in the complete excavation group fractured vertically, while in the experimental group visible cracks in the restoration were observed, characterized as 'ice-cracks'.

Finally in **Chapter 7** the most important findings of the previous chapters are discussed and suggestions for future research are highlighted. Based on this thesis one may conclude that sealing of sound pits and fissures should be restricted to patients and teeth at risk. Preferably one should wait with sealant application until pits and fissures become discoloured. However, once pits and fissures become cavitated, adhesion of the resin based sealant material to the tooth is less effective. Occasionally, preparation of the enamel and/or dentine becomes necessary to provide good adhesion. In such a case, one could doubt about the extensiveness of the excavation to achieve a good long-term performance of the restored tooth. Though incomplete caries removal may not be essential for arresting the caries process, the fracture strength of the restored teeth might be compromised on the long-term.





9

Samenvatting

Het hoofddoel van dit proefschrift was om inzicht te krijgen in de rol die adhesieve technieken kunnen betekenen bij het voorkomen en behandelen van occlusale cariës. Het onderzoeksgebied heeft zich beperkt tot het gebruik van op kunststof gebaseerde fissuurlakken en composieten. Een retrospectieve klinische studie (Hoofdstuk 2) en twee *in vitro* studies (Hoofdstuk 3 en 4) zijn uitgevoerd om te bekijken of er een verschil is tussen het verzegelen van gave fissuren en carieuze fissuren met een fissuurlak. Daarnaast zijn twee andere *in vitro* studies uitgevoerd (Hoofdstuk 5 en 6) om te kijken of er een invloed is op de sterkte van het gerestaureerde element wanneer zacht, carieus weefsel wordt achtergelaten onder een Klasse-I restauratie.

Hoofdstuk 1 beschrijft de achtergrond van de studie en presenteert de beschikbare literatuur betreffende het verzegelen van gave en carieuze pitten en fissuren. In het geval dat het carieuze proces zich uitbreidt en aanleiding geeft tot cavitatie, spelen verschillende behandelmogelijkheden een rol bij de behandeling. Daarnaast worden de belangrijkste doelen van dit proefschrift toegelicht.

In **Hoofdstuk 2** wordt een retrospectieve klinische studie beschreven. Doel van deze studie was het lange termijn gedrag van preventief verzegelde fissuren met behulp van een kunststof fissuurlak vast te leggen. Het onderzoek werd uitgevoerd in een algemene tandartspraktijk in Nederland. Patiënten die periodiek de praktijk bezochten en in het bezit waren van een of meerdere fissuurlakken, deden mee aan deze studie. De fissuurlakken werden preventief aangebracht in gezonde blijvende elementen in de zijdelingse delen door een tandarts of mondhygiënist. De fissuurlak werd eenmalig geapliceerd en niet naderhand aangevuld of vervangen. Het aanbrengen van een occlusale restauratie bij deze verzegelde elementen werd gescoord en beschouwd als een mislukking. Na een periode van gemiddeld 11,6 jaar was bij 41,3% van de behandelde elementen sprake van een volledige retentie. Patiënten werden ingedeeld naar hun restauratie profiel, door het aantal restauraties te tellen dat in hun melkgebit en blijvend gebit zijn aangebracht vanaf het moment van de eerste fissuurverzegeling. De groep patiënten werd in gelijke groepen met het label hoog en laag restauratie profiel ingedeeld. Analyse van de resultaten laat zien dat bij de hoog restauratie profiel groep meer dan drie keer zoveel occlusale restauraties zijn gelegd in vergelijking met de groep met een laag restauratie profiel (17,0% versus 5,1%). In de groep met een hoog restauratie profiel waren meer fissuurlakken verloren gegaan. Deze studie toonde aan dat op de lange termijn veel fissuren verkleurden ongeacht het restauratie profiel van de patiënt. Namelijk 45,4% van de oorspronkelijk, verzegelde fissuren waren verkleurd zonder dat er een occlusale restauratie werd vervaardigd.

Het percentage verkleurde fissuren in de hoog restauratie profiel groep en de laag restauratie profiel groep waren vergelijkbaar, namelijk 46,4% versus 44,3%.

In **Hoofdstuk 3** en in **Hoofdstuk 4** worden twee *in vitro* studies beschreven waarin gekeken werd of carieuze fissuren net zo effectief te verzegelen zijn als gave fissuren. In **Hoofdstuk 3** werden tachtig blijvende molaren met een occlusale caviteit tot in het dentine behandeld volgens een van de vijf experimentele behandelprotocollen. De controle groep bestond uit verzegelde gave molaren. In de experimentele groepen werd een kunststof fissuurlak aangebracht al dan niet in combinatie met een adhesiefsysteem inclusief hechtlak. De hechtlak werd initieel of na plaatsing van de fissuurlak gepolymeriseerd. Na verzegeling werden de elementen aan kleuring blootgesteld en vervolgens in plakken geslepen, waarna microlekkage en de penetratiediepte van de fissuurlak kon worden vastgesteld. Verzegelde occlusale fissuren met caviteiten vertoonden significant meer microlekkage en verminderde penetratiediepte van de fissuurlak dan gezonde fissuren. Noch het gebruik van een hechtlak, noch het belichtingsprotocol hadden effect op de microlekkage en penetratiediepte van de fissuurlak. In **Hoofdstuk 4** werden honderachtentwintig blijvende molaren met occlusale caviteiten verzegeld onder verschillende condities zoals droog, met water of speeksel bevochtigd, of contaminatie met speeksel gevolgd door droogblazen. De controle groep bestond uit blijvende molaren met verzegelde gave fissuren. In de experimentele groepen werden twee verschillende fissuurlak protocollen vergeleken. Het ene protocol bestond uit alleen een fissuurlak, het andere uit applicatie van een adhesiefsysteem voorafgaande aan de fissuurlak. Na kleuring en het zagen van de elementen in secties werden de microlekkage en penetratiediepte van de fissuurlak geëvalueerd. Uit de resultaten blijkt dat in geval van een contaminatie met water het toevoegen van een adhesiefsysteem de effectiviteit van de fissuurlak verbeterd. Gezonde fissuren van blijvende molaren waren beter te verzegelen dan gecaviteerde fissuren.

In **Hoofdstuk 5** en **Hoofdstuk 6** worden twee *in vitro* studies beschreven die hebben onderzocht of achtergebleven zacht, carieus dentine onder een adhesief bevestigd occlusale composiet restauratie de breukweerstand van de gerestaureerde elementen beïnvloedt. **Hoofdstuk 5** behandelt het effect van een op gestandaardiseerde wijze aangebrachte zachte, elastische laag op de breukweerstand na restauratie. Er werden honderdenvijf vergelijkbare blijvende molaren geselecteerd die vervolgens over zeven experimentele groepen werden verdeeld. Bij deze molaren werden standaard preparaties vervaardigd met een doorsnede van 2,3 mm of 2,9 mm, waarbij geen, een

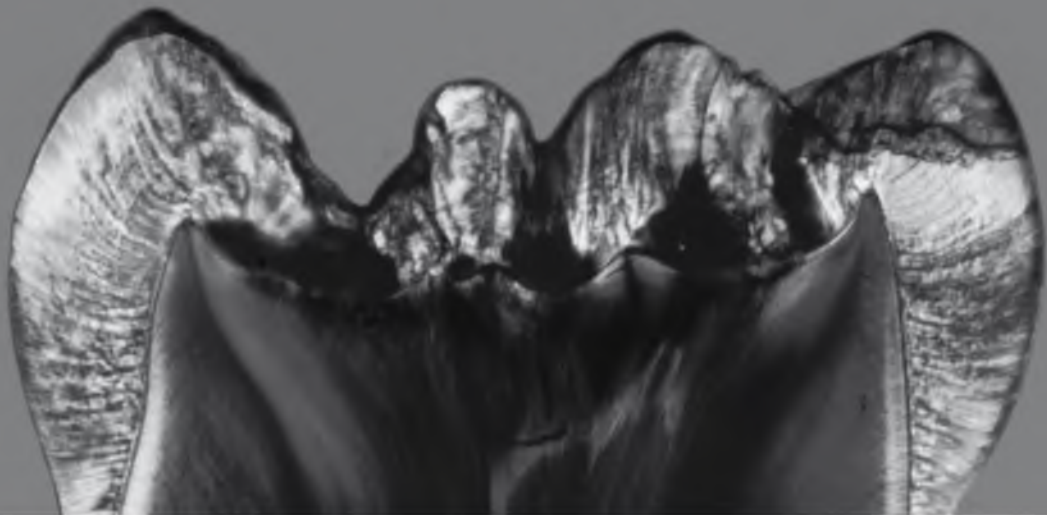
dunne of dikke zachte, elastische onderlaag werd aangebracht voordat een composiet restauratie werd geapliceerd. Bij vijftien molaren werd geen standaard preparatie in het occlusale vlak vervaardigd (controle groep). De eventueel aangebrachte zachte, elastische laag bestond uit een zink-oxide eugenol cement. Alle elementen werden aan een statische occlusale belasting blootgesteld totdat er breuk optrad. De maximale faalbelasting en wijze van breuk werden geregistreerd. Elementen met een zachte elastische onderlaag vertoonden meer breuk boven de glazuurcement grens. Groepen zonder een dergelijke laag fractureerden vaker onder de glazuurcement grens. Uit de resultaten bleek dat aanwezigheid van een zachte elastische laag onder de composiet restauratie een significant lagere breuksterkte ($p < 0.001$) opleverde. Het verschil tussen de breukweerstand van een gezond element of een element gerestaureerd nadat al het zachte weefsel verwijderd was, was niet significant.

Hoofdstuk 6 beschrijft een onderzoek waarin de hypothese wordt getoetst dat gerestaureerde elementen na onvolledige verwijdering van het carieuze weefsel een lagere breuksterkte vertonen dan gerestaureerde molaren na volledige excavatie. Molaren met een grote gecaviteerde, occlusale dentine laesie werden verzameld. Bitewing röntgenfoto's werden vervaardigd, en elementen werden geïnccludeerd in de studie als er een occlusale radiolucentie aanwezig was groter dan halverwege het dentine, zonder betrokkenheid van de pulpa. De molaren werden gepaard op basis van een gelijke grootte van de elementen en aan de hand van de grootte en locatie van de carieuze laesie. Veertien paren molaren werden willekeurig toegewezen aan een experimentele groep (onvolledige excavatie) of aan de controle groep (volledige excavatie). De gerestaureerde elementen werden na een cyclische vermoeiingsbelasting verticaal belast en de breuksterkte en het faalgedrag werd vastgesteld. Elementen in de experimentele groep lieten een lagere breuksterkte zien ($1276 \text{ N} \pm 626 \text{ N}$, $p < 0.001$) in vergelijking met de controle groep ($2768 \text{ N} \pm 710 \text{ N}$). Elementen uit de controle groep fractureerden verticaal terwijl de gerestaureerde elementen na onvolledige excavatie barsten in de restauratie vertoonden, gelijkend op barsten in ijs. De gereduceerde breukweerstand kan mogelijk op termijn klinische implicaties opleveren.

In **Hoofdstuk 7** worden de resultaten uit de voorgaande hoofdstukken besproken en suggesties aangedragen voor een mogelijk vervolgonderzoek. Op basis van dit proefschrift blijkt dat verzegelen van gezonde pitten en fissuren moet worden beperkt tot patiënten en gebitselementen met een verhoogd cariërisico. Het is beter om te wachten met het appliceren van een fissuurlak totdat pitten en fissuren tekenen van verkleuring vertonen. Echter, indien fissuren gaan caviteren gaat dit ten koste van

de adhesieve verzegeling. Om toch een goed adhesie te krijgen is het prepareren van glazuur en/of dentine niet te vermijden. In dergelijke gevallen kan men twijfels hebben over de mate van excavatie die nodig is om de restauratie ook op de lange termijn goed te laten functioneren. Het schijnt dat onvolledige cariës verwijdering niet noodzakelijk is om het cariësproces te stoppen, maar de breukweerstand van het geresatureerde element kan gecompromitteerd worden.





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Zoals op de titelpagina van dit proefschrift staat geschreven, is het uitvoeren van een promotieproject een wetenschappelijke proeve. Het omvat het vergaren van wetenschappelijke kennis, het opzetten en uitvoeren van experimenten, het analyseren van de data en het leren bekritisieren van het eigen werk. Zoals wel vaker bij promoties, kreeg ik het gevoel dat er meer mis ging dan goed. Maar uiteindelijk hebben de successen gewonnen van de teleurstellingen, anders had ik dit dankwoord nu niet kunnen schrijven.

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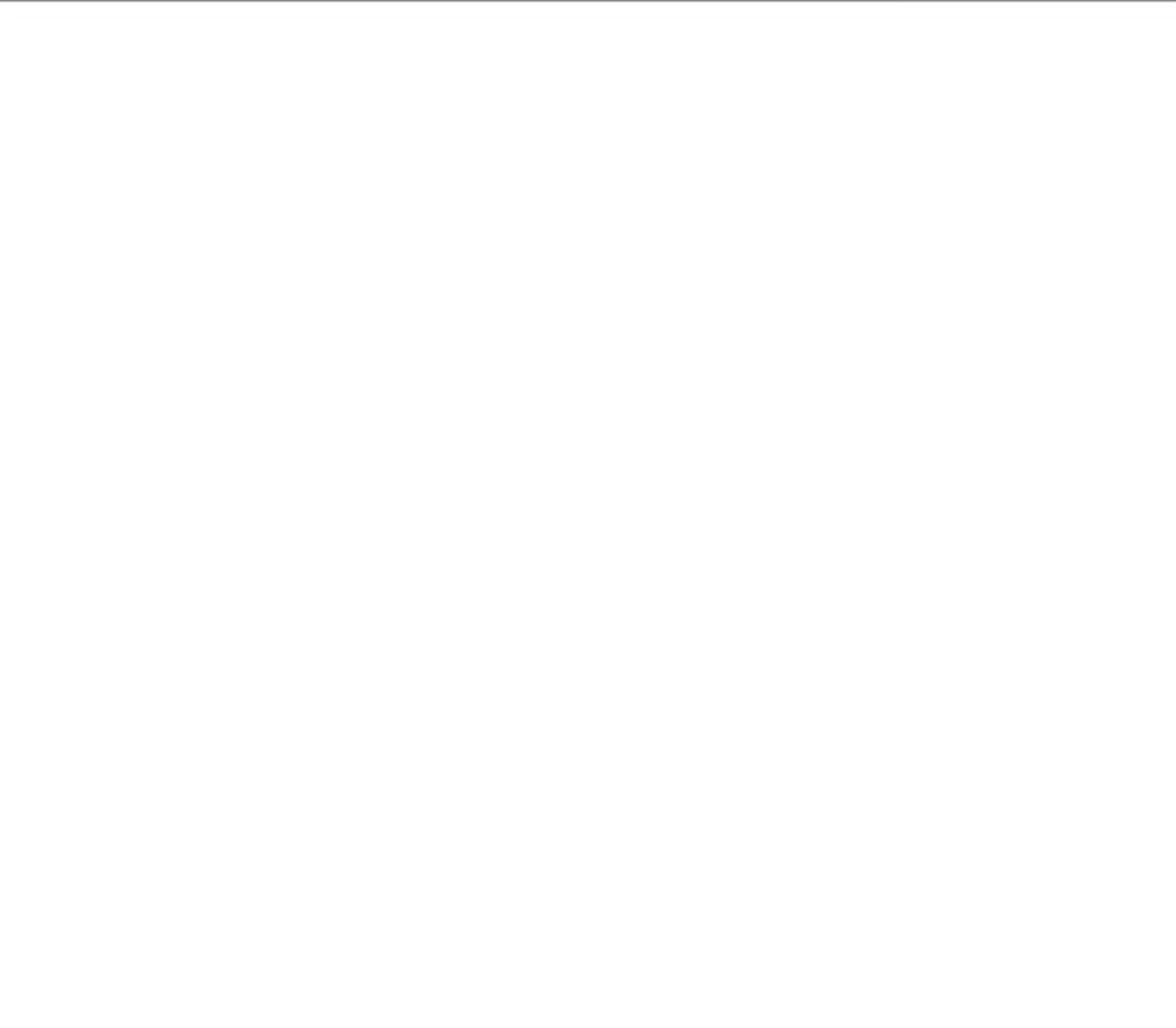
studenten. In het bijzonder dank ik diegenen die een luisterend oor hebben geboden als zaken wel eens niet zo liepen als dat ze moesten gaan.

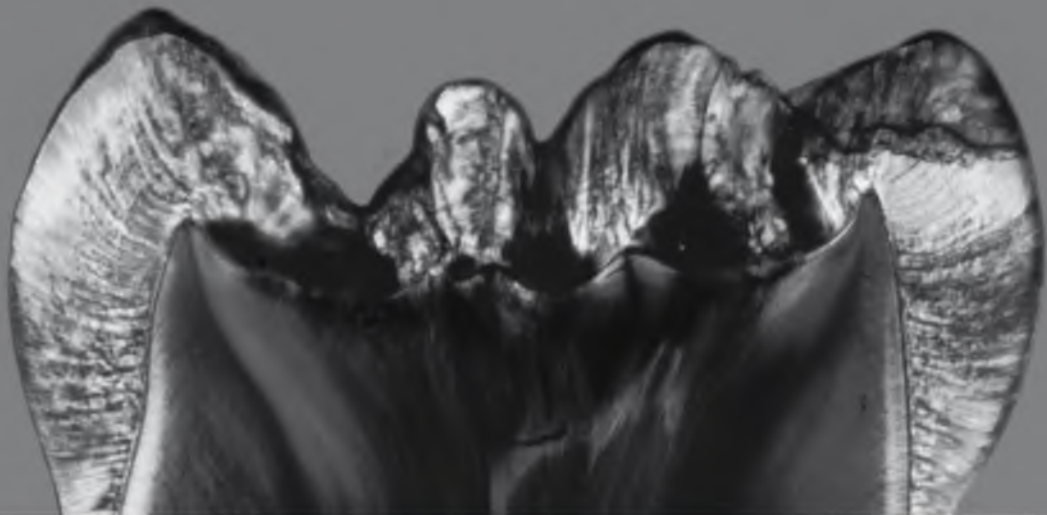
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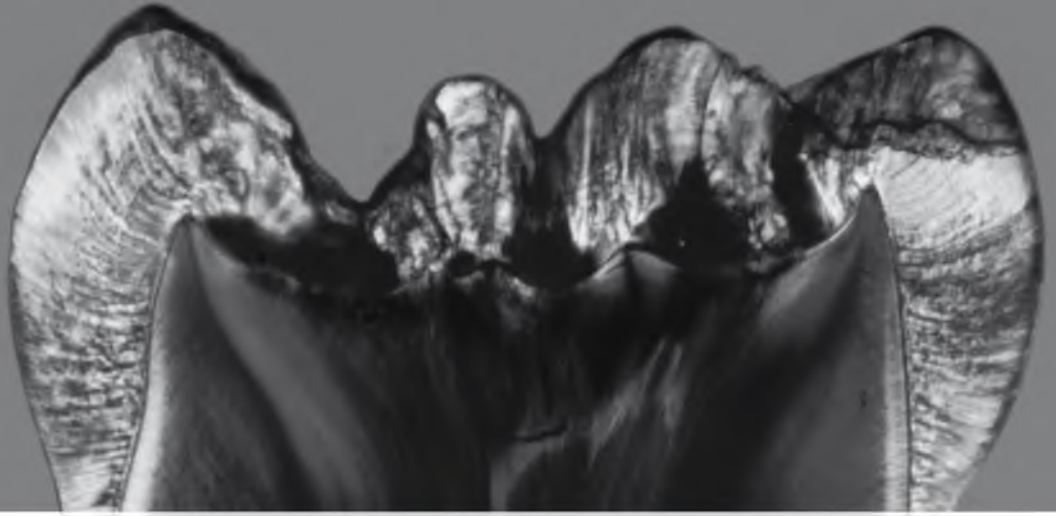


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Curriculum Vitae



Miluska Hevinga is op 8 mei 1974 geboren te Veendam. Na het behalen van het VWO diploma aan de R.S.G. Winkler Prins in Veendam, begon zij in 1992 met de studie Tandheelkunde aan de Katholieke Universiteit Nijmegen (heden: Radboud Universiteit Nijmegen), waar zij in 1997 het Tandartsexamen behaalde. Na haar afstuderen nam zij gedurende een aantal jaren waar in diverse algemene tandheelkundige praktijken, alvorens voor langere tijd in een groepspraktijk in Cuijk te gaan werken. In januari 2002 startte zij als junior-onderzoeker bij de vakgroep Preventieve en Curatieve Tandheelkunde van het UMC St Radboud te Nijmegen. Sinds januari 2008 is zij daarnaast als universitair docent betrokken bij het onderwijs aan studenten en in nascholingsverband.

Sinds 2010 omvatten haar werkzaamheden patiëntenbehandeling in een groepspraktijk te Arnhem, in de Expertisekliniek voor Gebitsherstel aan de Radboud Universiteit en diverse taken binnen het studentenonderwijs.

