Seal&Protect®

Protective Sealant for Exposed Dentine

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For Individual Attention Only

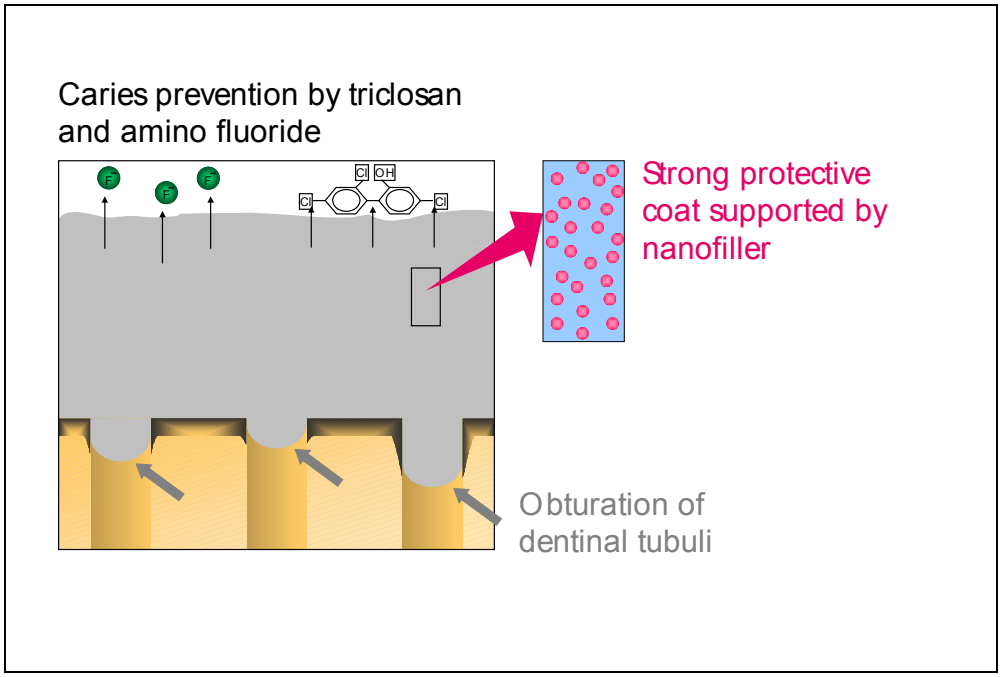
Table of contents

1 Introduction

Gingival retraction caused by long-standing periodontitis results in exposed cervical surfaces. Up to now, no specific preventive measure had been available to protect these sensitive areas from mechanical, bacterial and chemical trauma.

Seal&Protect, a self-adhesive, light-curing, translucent sealing material was developed with the objective to close this gap: To prevent or reduce cervical abrasion, to prevent root caries and to treat cervical hypersensitivity.

The functions of the key components of Seal&Protect (nanofiller and triclosan) are explained by the illustration below:



Results of in-vitro and clinical research prove the safety and efficacy of Seal&Protect as a cervical sealant:

- cervical abrasion is prevented for at least 3 months
- the number of caries-associated micro-organisms on sealed surfaces is drastically reduced when compared to untreated surfaces
- cervical hypersensitivity is cured or alleviated for up to 1 year

With Seal&Protect a new era of dental prevention has started comparable to the introduction of fissure sealants for the prevention of occlusal caries.

2 Seal&Protect- the first dentine sealant

2.1 Preventive care for a changing population

In prospering industrial societies, life expectancy steadily increases. At the same time, a drop in birth rate is observed. Both factors result in a change in age distribution characterised by a high proportion of elderly people.

In the field of dentistry, the increased average age of patients along with achievements regarding caries prophylaxis and treatment result in an increased average age of teeth which have to be cared for.

The prevention of caries and periodontitis can therefore not be limited to children and adolescents as the lifelong conservation of teeth demands a preventive approach also for middle-aged and elderly patients. Otherwise there is the risk that the positive results of early preventive measures will be lost within a few years ending up with tooth loss at old age.

2.2 Preventive care for exposed root surfaces

Older teeth exhibit additional vulnerable areas, exposed root surfaces being one of them.
As average annual attachment loss is at least 0.1mm (Löe et al 1978), retraction of the gingiva will in the end lead to exposed cervical surfaces.
This condition is in many ways a locus minoris resistentiae, a biophysical problem zone:

Cervical root cement with only 45% anorganic components (by volume) is relatively soft, has a high permeability and a thickness of only 10 to 100µm (Klimm, Graehn 1993).
Once it has lost its protection by the marginal gingiva, cervical root cement is easily destroyed by mechano-abrasive forces or by penetration of cariogenic micro-organisms.
After destruction of the cement layer, the underlaying dentine is exposed. Open, permeable

dentinal tubules allow the progression of stimuli towards the pulp causing cervical hypersensitivity commonly associated with exposed root surfaces.

The therapeutic concept of Seal&Protect is to close the openings of dentinal tubules, thus curing or alleviating hypersensitivity.

Cervical dentine with approximately 70% anorganic components (by volume) is harder than cementum. Due to its microstructure, the outer 1/3 is, however, more affected by abrasion than the deeper layers.
Exposed cervical dentine leads to cervical abrasion which in the long run turns into V-shaped defects.

The preventive concept observed with Seal&Protect is to cover the sensitive root dentine with a strong and hard surface coat, thus preventing abrasion.

Pathogenesis and prevention of V-shaped defects
Toothbrush abrasion is still considered the main factor responsible for the development of V-shaped defects.

Other factors causing or contributing to V-shaped defects are:

- superficial carious destruction (the softened layer of which is removed during the next toothbrushing)
- occlusal forces submitted to the weak crystal structure of cervical enamel
- erosive factors (e. g. fruit juice or gastric acid)

Seal&Protect prevents the forming and progression of wedge-shaped lesions by producing a hard coat increasing the resistance of cervical areas against abrasive forces, bacteria, and acids.

Cervical plaque and root caries
Cementum and exposed root dentine offer ideal conditions for the adherence and growth of cariogenic micro-organisms. The root surface offers only a very limited resistance towards carious attacks. The composition of supragingival cervical plaque on dentine surfaces is similar to that of plaque adherent to enamel. Soft cervical carious lesions, however, exhibit higher concentrations of S. mutans and Lactobacilli than plaque on unaffected surfaces.

The preventive concept of Seal&Protect is to reduce the number of colony-forming units of S. mutans and Lactobacilli by long-term release of triclosan on the surface of the sealant. In addition, Seal&Protect contains cetylamine hydrofluoride, which has a well documented caries preventive action.

2.3 Seal&Protect- a new concept

Pit and fissure sealing as a way of protecting enamel is an established concept in preventive dentistry. It is routinely used to establish good dental health of younger patients.
However, a similar protective procedure for dentine is not routinely employed even though the idea has been discussed (Johnston AD et al, 1991).

Seal&Protect is a product specifically designed to protect exposed dentine, similar to the way pit and fissure sealants protect enamel. Seal&Protect thus truly is the first dentine sealant as it helps to overcome the problems associated with exposed dentine.

Seal&Protect is a light curing material that is applied as a thin solution, capable of thoroughly penetrating the dentine. It is light cured in situ and afterwards forms a strong protective coat. The main functions of the material are

- to improve wear and reduce abrasion
- to reduce sensitivity of the tooth
- to have an antimicrobial effect, thus reducing the caries risk.

Seal&Protect is part of the wide range of preventive care products available from DENTSPLY. It has been designed to be applied regularly, preferably biannually, by the dentist or skilled personnel.

2.4 Seal&Protect- components and functions

Seal&Protect contains a variety of components, the nature and ratio of which has been optimised to achieve maximum protection of the exposed dentine. A detailed list of the components and their individual functions is shown in 2.4.3. However, two components of Seal&Protect are particularly important both with regard to their part in achieving dentine protection and in the novelty of their use in a dental material. These two components, the

nanofiller and the antimicrobial agent triclosan, therefore will be dealt with separately in chapters 2.4.1 and 2.4.2.

2.4.1 **Nanofiller**

Restorative materials such as composites and compomers generally contain fine fillers as it is known that filler incorporation increases the wear resistance of these materials.
The properties above are also desirable for Seal&Protect, the first dentine sealant. However, a low viscosity is necessary for Seal&Protect to be capable of infiltrating the porous dentine. In contrast, filled materials usually display a high viscosity or are unstable towards phase separation.

Therefore nanotechnology is employed for Seal&Protect. Nanotechnology is an important area of modern chemistry that allows formulation of a material displaying both low viscosity (and thus, high dentine penetration and dentine adhesion) and the mechanical strength of filled materials. Nanotechnology is already used in similar applications, e.g. to create scratch-resistant surfaces of optical glasses.

Basically, the idea behind the use of nanotechnology in Seal&Protect is to combine the flexibility and toughness of an organic matrix with the strength of inorganic substances. To achieve this, an ultrafine filler (= nanofiller) of a primary particle size of 7 nm is incorporated into the formulation of the Seal&Protect.

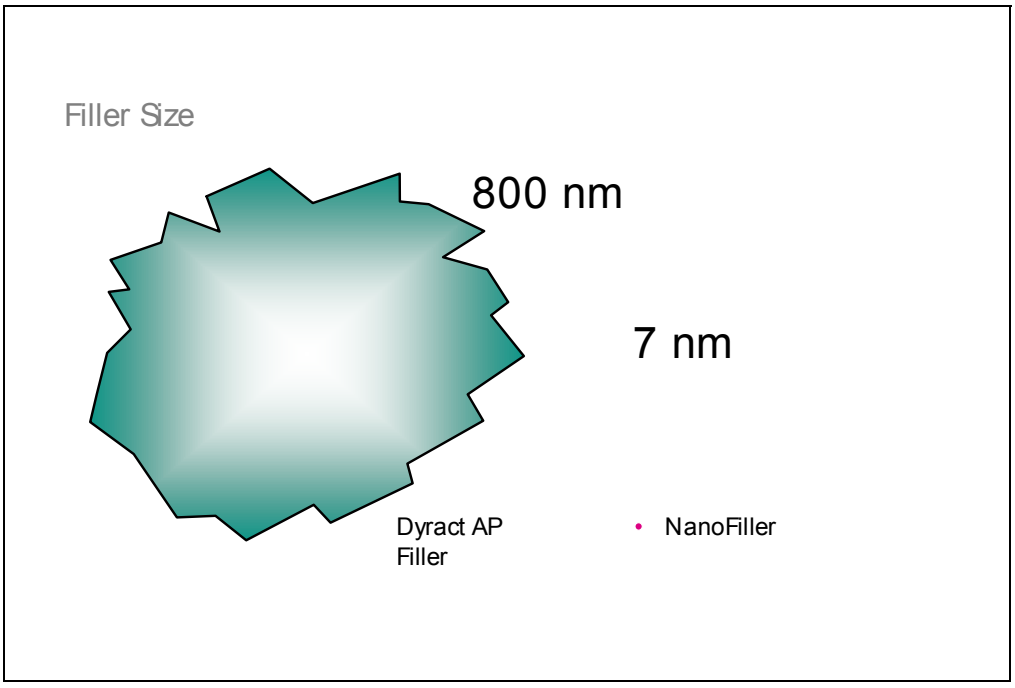


Figure 1: Particle size of nanofiller compared to conventional filler of Dyract AP

The nanofiller in the Seal&Protect formulation improves a number of properties. The most important aspects are:

- scratch resistance,
- surface hardness, and
- abrasion resistance.

Seal&Protect looks as transparent as an unfilled material. Essentially this means the filler is too small to be visible. More importantly, the filler is small enough and chemically modified at its surface so that it forms a stable sol with the liquid components of Seal&Protect. Due to its optimal degree of dispersion, the nanofiller does not settle. Also, the nanofiller does not change the viscosity of the dentine sealant.
In the cured coat of the Seal&Protect, the nanofiller is evenly distributed in the resin matrix. The nanofiller serves as an additional crosslinker and provides strength due to its intrinsical hardness. It therefore strengthens the sealant coat and increases its abrasion resistance. With a primary particle size of about 7 nm, the nanofiller also easily penetrates into any open dentine tubules as part of the Seal&Protect formulation.
The nanofiller provides the Seal&Protect with a strengthening, inorganic element comparable to the apatite filler crystallites in the dentine. Furthermore, the intrinsic hardness of the nanofiller also strengthens the resin matrix. For example, the Barcol hardness of cured filler containing Seal&Protect resin is higher than without filler.

2.4.2 Triclosan

Triclosan is a highly effective antimicrobial agent with a broad spectrum of activity against both Gram-positive and Gram-negative bacteria as well as fungi, yeasts and viruses. As a component of Seal&Protect, its antimicrobial properties towards Streptococcus mutans and lactobacilli are of particular importance. The minimum inhibitory concentrations (MIC) of triclosan against both S. mutans and lactobacillus is 10 ppm (Marsh, 1991).
The specific antimicrobial properties of the dentine sealant were tested in a number of experiments; the results are described in 3.5, Antimicrobial Properties.

Chemically, triclosan is 2,4,4´,-trichloro-2'-hydroxy diphenyl ether, an organic diphenyl ether with a molecular weight of 289.5. It is sparingly soluble in water, leading to a very low leaching rate from the sealant coat, as proven by our experiments. In contrast, it is readily soluble in acetone, the solvent in Seal&Protect, leading to a homogenous distribution of the triclosan in the sealant coat.

Triclosan is considered to be safe for humans and the environment in the recommended concentrations (Ciba-Geigy, 1989). It is registered or pending registration in all industrialised

countries where registration is required. The low allergenic potential of triclosan is described by Lachapelle et al. (1979).

The primary site of antimicrobial action of triclosan is the bacterial cytoplasmic membrane. Triclosan prevents essential amino acid uptake at bacteriostatic concentrations.
At bacteriocidal concentrations, it causes cytoplasmic disorganisation of the bacterial cytoplasmic membrane, and leakage of cellular contents (Regos et al, 1974).
Mustafa et al (1998) found that triclosan reduces the production of the inflammatory mediator interleukin-1β in gingival fibroblasts, which supports the view that triclosan exhibits an anti-inflammatory effect.

Though initially mostly used in surgical soaps and deodorants, the combination of the favourable toxicity data and the high antimicrobial activity of triclosan towards relevant oral bacteria make it an ideal antimicrobial agent for use in oral care products. In fact, triclosan is presently used in a number of mouthrinses and toothpastes.

A wealth of scientific literature supports the efficacy of triclosan in oral care products. Gaffar et al (1997), in an overview on chemical agents for the control of plaque, conclude that unlike the first generation of agents, a triclosan/ copolymer/ sodium fluoride system in toothpastes is effective in long-term clinicals in reducing plaque, gingivitis and dental caries, and does not cause staining of the teeth, increase in calculus, or disturbances in the oral microbial ecology.

A large number of clinical studies supporting the beneficial effects of triclosan in toothpastes are listed in Volpe et al (1993). In fact, in the light of these findings the Colgate-Palmolive company received FDA approval to label a triclosan-containing toothpaste as able to prevent gingivitis in 1997.

2.4.3 List of components and functions

Figure 2 gives an overview of the various components employed in Seal&Protect. As Seal&Protect combines various properties to optimally protect the dentine, a well-selected combination of substances had to be selected to guarantee optimum performance of the product.

PENTA	Adhesion promoter, wetting aid and crosslinker.
MA resins	Di- and trimethacrylate resins forming strong protective coat.
Nanofiller	Ultrafine functionalized filler for increased abrasion resistance of the cured coat.
Initiators	Initiate the light- curing reaction.
Stabilizer	Stabilizes material during storage.
CAHF	Fluoride source (organic amine fluoride).
Acetone	Solvent and carrier for the resins; water displacer.
Triclosan	Antimicrobial agent.

Figure 2: Composition of Seal&Protect, and function of the components

3 Seal&Protect- Properties of the first dentine sealant

A large number of in-vitro investigations were run both at the DENTSPLY laboratories in Konstanz and at universities worldwide. This chapter lists the more important results of these tests.

3.1 Adhesion

To guarantee sufficient retention of the sealant coat of the dentine, adhesion of Seal&Protect to dentine was tested in a shear bond strength test.
Clean, prepared dentine surfaces of human molars were treated with Seal&Protect. After 20 seconds, the solvent was evaporated with an air syringe. The bonding agent was light-cured for 20 seconds. Spectrum TPH restorative material was applied and light-cured for 40 seconds. After 24 h at 37°C and thermocycling (500 cycles, 20 seconds each at 5°C and at 55°C), the specimens were debonded with a Zwick testing machine.

An adhesion value of 14.5 ± 2.8 MPa was obtained. This is a value similar to adhesion values obtained with competitive dental adhesives, but lower than that of Prime&Bond NT in the identical test (19.5 ± 4.3 MPa).

The adhesion value of Seal&Protect guarantees sufficient adhesion to the dentine. However, significantly higher adhesion can be achieved with Prime&Bond NT, a material specifically designed as a dental adhesive. Seal&Protect was optimised to give high abrasion resistance and to have an antimicrobial effect, not to give the highest possible adhesion and marginal integrity. Therefore we recommend not to use Seal&Protect as an adhesive but to use Prime&Bond NT instead.

3.2 Fluoride release

Numerous clinical studies have established the effectiveness of the fluoride ion in lowering the incidence of dental caries (Craig et al., 1992). Therefore a large number of dental materials are designed to release fluoride.
The figure below compares the incremental fluoride release of both Prime&Bond 2.1 and Seal&Protect. Fluoride release was determined by preparing disks from the resin matrix of the adhesive. These disks of a diameter of 20 mm and a thickness of 1 mm were prepared and light-cured from both sides (2 x 4 min curing time with a Triad 2000 dental curing lamp), minimising the oxygen inhibited layer by covering the material with plastic foil during curing. These disks were stored in 25 ml demineralised, fluoride-free water at 37°C. The fluoride content of the water was measured at regular intervals with a fluoride selective electrode. Each measurement was followed by replacement of the water with fresh fluoride-free water. Measurements were done weekly up to week 6 and then every 4 weeks. The values given are the incremental fluoride releases at the end of the week given on the x-axis.

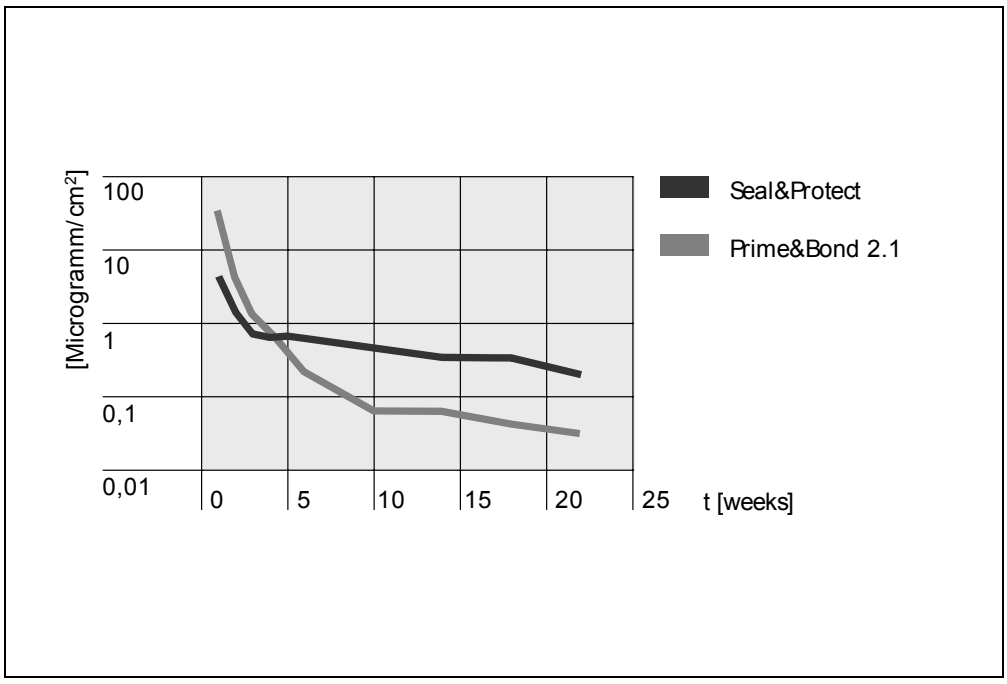


Figure 3: Incremental fluoride release of Seal&Protect compared to Prime&Bond 2.1

The figure clearly shows that while Prime&Bond 2.1 displays an initial burst in fluoride release, this phenomenon is distinctly more gradual with Seal&Protect. The beneficial effects of the fluoride therefore are expected to last over a long period of time. In fact, even after one year a significant fluoride release of 0.13 $\mu g/cm^2$ per week could still be measured.

3.3 Abrasion resistance

3.3.1 Pre-tests with Taber abraser

To optimise Seal&Protect for maximum abrasion resistance, a number of prototype formulations were tested with a Taber abraser, an abrasion resistance testing machine. This type of machine is used in other industries to test the wear resistance of car varnishes, carpets, and other materials that are subjected to strong abrasive forces.

The weight losses of cured varnish coats applied to steel plates were measured after 400 cycles on a Taber abraser 5130. Rubber rolls CS-0 in combination with abrasive paper S-33 were used; weight on rolls was 1 kg. Figure 4 illustrates the principle behind the Taber abraser test.

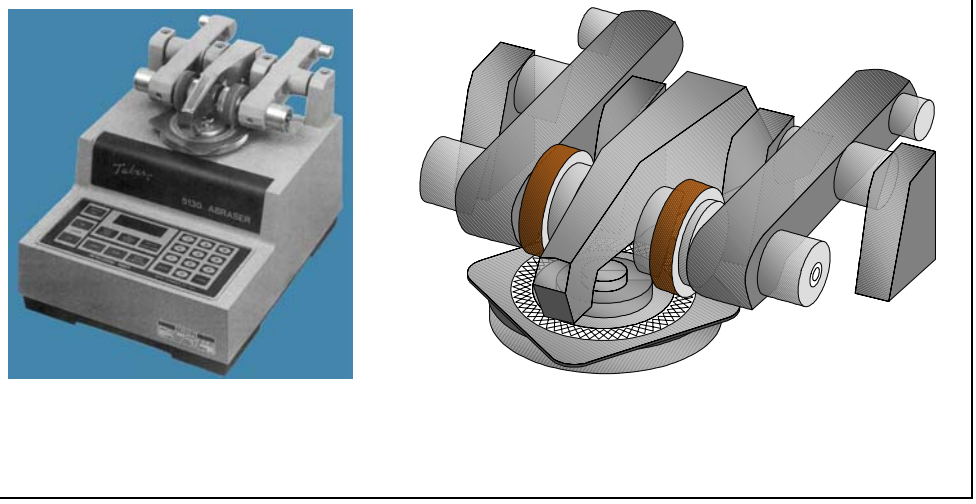


Figure 4: **Taber abraser. Photo of testing machine (left) and schematic enlargement of the parts relevant for the abrasion test (right). Weight loss of different varnish coats on plate is compared to judge abrasion resistance.**

The Taber abraser allows comparison of the abrasion resistance of different formulations. The table below compares the weight loss of several formulations after 400 cycles.

Formulation	Crosslinked Resin	Nanofiller	Weight loss
Seal&Protect	yes	yes	0.69 g
Prototype I	yes	no	1.13 g
Prototype II	no	yes	0.95 g
Prototype III	no	no	1.45 g

Table 1: **Weight loss of Seal&Protect and prototypes depending on composition**

This table clearly shows that the abrasion resistance of the sealant material depends on its composition. One way to achieve a higher resistance is to incorporate more resins that lead

to a higher degree of crosslinking (e.g. trimethacrylate resins replacing dimethacrylate resins). Another way also employed in Seal&Protect is the incorporation of the nanofiller. The comparison of prototype I and Seal&Protect indicates that the nanofiller reduces abrasion by 39%.

3.3.2 In-vitro tests at University of Zurich (Krejci)

These tests were done with early prototypes of Seal&Protect. However, these tests were instrumental in demonstrating the feasibility of the concept of a dentine sealant.

9 different prototypes were applied to root dentine in a one-coat technique, and light-cured. After 3 weeks in artificial saliva at 37°C, the samples were subjected to a three-bodied tooth brush abrasion test. After 5, 10, 15, 20, 50 and 110 minutes (5 minutes equalling 1 month in vivo according to the researcher), the surfaces of the samples were examined by etching with phosphoric acid and applying methylene blue. Only exposed dentine takes up the blue colour, indicating that in those coloured blue areas the protective sealant has gone.

In his conclusion, Krejci states that in none of the samples the sealant was abraded completely after 110 minutes of abrasion (equalling almost 2 years in vivo). After 10 minutes (i.e. 2 months in vivo), all samples were judged good in the visual evaluation. Only at longer brushing times, some retentive failures starting from the corners of the coats were observed. This phenomenon was one of the criteria judged to evaluate the different prototypes, and to decide which prototypes to pursue further.

3.3.3 In-vitro tests at University of Indiana (Schemehorn)

The procedure used in this test was a modification of the ADA recommended procedure for determination of dentifrice abrasivity. The dentine specimens (4 for each test group) were placed in a neutron flux under the controlled conditions outlined by the ADA (see also Figure 5). The specimens were then mounted in methylmethacrylate so they fit in a V-8 cross brushing machine. The brushes used were those specified by the ADA, and brush tension was 150 g.

One test group was left untreated as a reference. The other groups were coated with either one or two coats of Seal&Protect, following the instructions for use.

The specimens were then brushed for a defined number of strokes at 150 g tension using a 25 g/ 40 ml toothpaste / water slurry. The slurries were then sampled for radioactivity. All

data are given as net counts per minute (CPM). The number of days was calculated by dividing the number of brushstrokes by 60 (assuming two brushings with 30 strokes per surface and brushing).

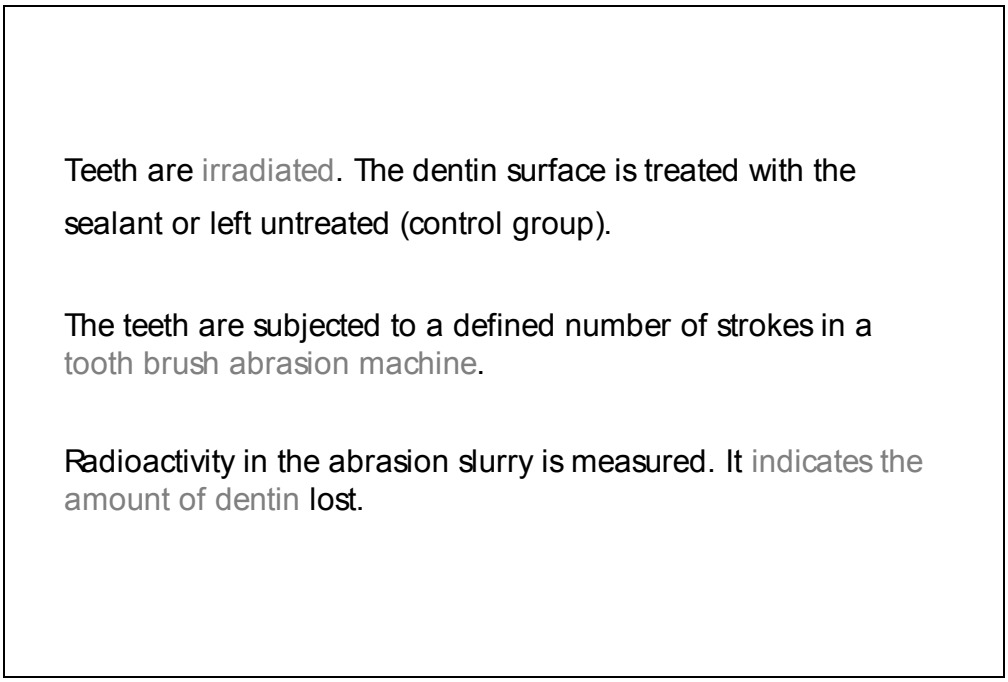


Figure 5: Principles of tooth brush abrasion test (Schemehorn)

In this test, the amount of dentine abraded is proportional to the amount of radioactivity measured in the abrasion slurry. Therefore if the test groups coated with the Seal&Protect display a lower radioactivity in the slurry as the untreated reference group, this indicates that the Seal&Protect has a protective effect on the dentine, reducing its abrasion. In the short term study, a competitive antimicrobial varnish (Cervitec, VIVADENT) was included.

The figures below show the results of two tests, one conducted over a relatively short period of time, one run for the equivalent of 2 years in vivo.

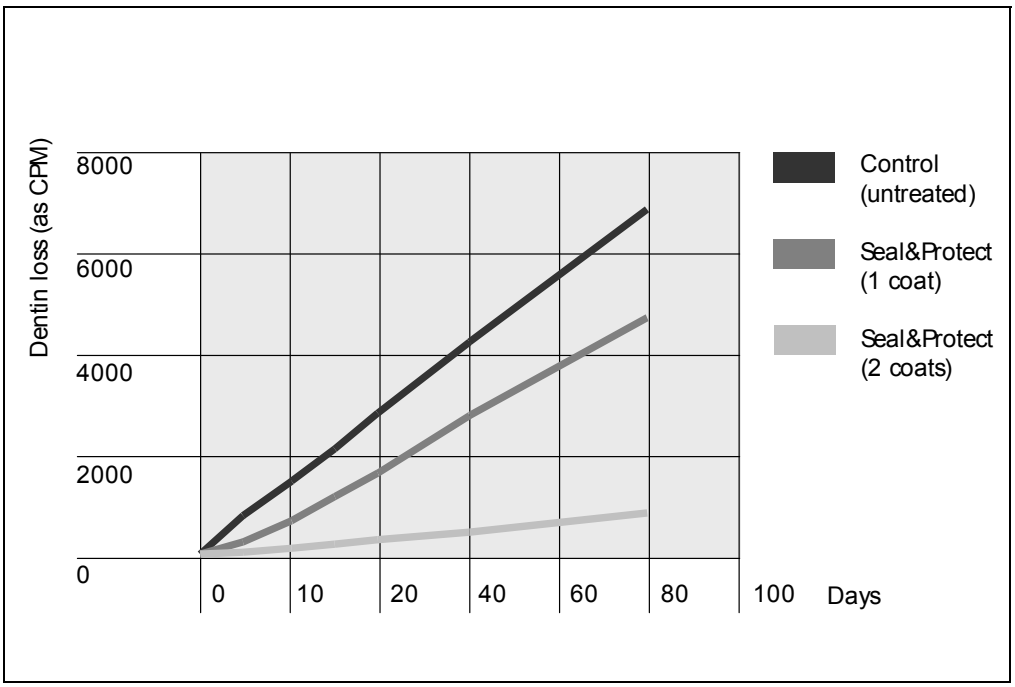


Figure 6: Results of short-term tooth brush abrasion test (Schemehorn); S&P is Seal&Protect

A reduction of dentine abrasion by approximately 38% (one coat) or 88% (two coats) was observed after approximately 2.5 months in this short-term study. In contrast, the competitive product Cervitec does not offer any significant mechanical protection.

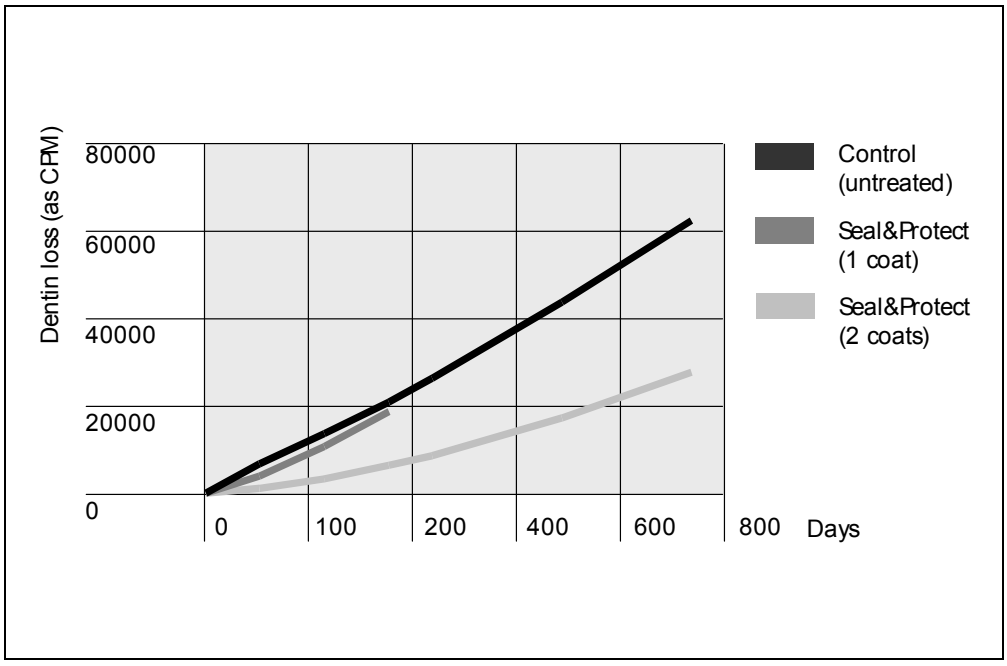


Figure 7: Results of long-term tooth brush abrasion test (Schemehorn)

The short-term data of this study is quite similar to the data of the first study, proving the good reproducibility of the test method. The data for longer periods (e.g. 0.5 years) shows that one coat of Seal&Protect tends to lose its efficacy; dentine abrasion after half a year is

almost as high as in the untreated reference. However, two coats of Seal&Protect have a very long-lasting effect, with an overall abrasion reduction of more than 50% during the two years after application. Even during the last 4000 strokes of this study (equalling the time period from approximately 1.8 years to 2 years after application), still a reduction in abrasion by 42% was detected, clearly demonstrating that the Seal&Protect in this two-coat technique provides a long-lasting abrasion reduction.

3.4 Protection from erosion

This test was run at the University of Freiburg, Germany by Attin T and Buchalla W. The aim was to examine whether Seal&Protect would offer any protection from erosion and tooth brush abrasion, i.e. the demineralisation of tooth surfaces by acidic liquids.
Teeth coated with a Seal&Protect prototype were subjected to an acid attack (Sprite light) before each brushing cycle in a tooth brush abrasion machine. In the test, the two Seal&Protect prototypes performed best, followed by PB 2.1 and Cervitec which does not offer any significant protection. Attin/ Buchachalla conclude that prototype I is a very promising material for dentine protection.

Brushing in combination with acid attack (Attin/ Buchalla)

Percentage of unprotected dentin with time (1 day equals two brushings of 100 strokes):

	1d	5d	10d	20d
S&P Prototype I	0	0	0	0
S&P Prototype II	0	20	30	-
PB 2.1	0	30	50	-
Cervitec	20	100	100	-

Figure 8: Acid erosion/ tooth brush abrasion test of coated dentine; S&P is Seal&Protect

3.5 Antimicrobial Properties

A number of microbiological tests was run to examine the antimicrobial efficacy of Seal&Protect. In these tests thin layers of Seal&Protect were cured under nitrogen to avoid oxygen inhibition. Then a suspension carrying relevant oral microorganisms was brought into contact with the sealant coat. After 6 h, the inhibition of microorganism growth was determined by transferring the microorganisms to a different vessel, cultivating them and assaying their number.
The tests were run with streptococcus mutans and lactobacillus rhamnosus, bacteria known to be involved in caries development.

In a first series of experiments, the effects of the potentially antimicrobial Seal&Protect components cetylamine hydrofluoride and triclosan was examined to establish whether there is any antimicrobial effect towards S. mutans, and to determine which of the two components might be responsible for it. The results are shown below. The data clearly demonstrates that triclosan is the active antimicrobial ingredient in Seal&Protect (see section 2.4.2 for details on triclosan).

Effect of experimental Seal&Protect on S. mutans:
growth inhibition after 6 h as function of formulation.

F: Cetylamine hydrofluoride; T: Triclosan

Formulation	F-, T-	F+ , T-	F-, T+	F+ , T+
Inhibition*	0%	0%	72%	63%

* after 1 week water storage

Figure 9: Microbiological tests with Seal&Protect: Determination of antimicrobially active ingredient

In a second series of tests, the long-term antimicrobial efficacy of Seal&Protect (final formulation) was tested. For these experiments, Seal&Protect test specimens were subjected to water which was changed weekly. At certain intervals, antimicrobial activity of the specimen was tested by incubating with test medium containing S. mutans and L. rhamnosus. After 6 h contact time, the growth inhibition of the microorganisms (compared to

uncoated test wells as reference) was determined. The specimens were sterilised, again subjected to water and stored until the next antimicrobial test was run. See Figure 10 for the test results.

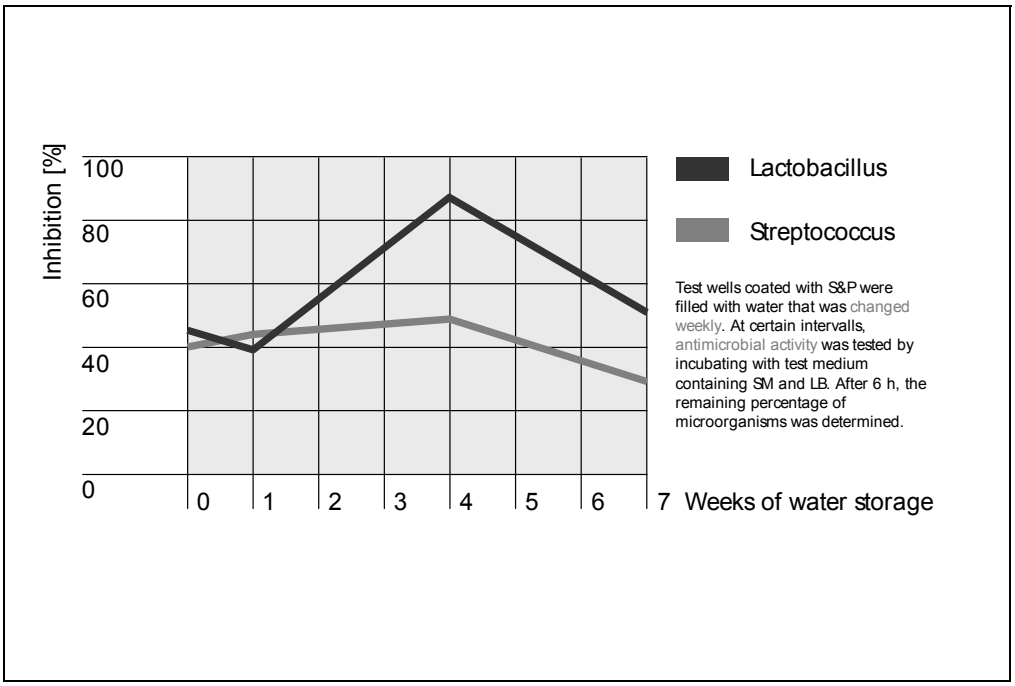


Figure 10: Microbiological tests with Seal&Protect (S&P): long-term antimicrobial activity

These long-term tests clearly demonstrate that Seal&Protect displays a significant antimicrobial effect for at least 7 weeks. In fact, the clinical investigations (see section 4) show this antimicrobial effect even more clearly.

3.6 Interaction with dentine

The interaction of Seal&Protect with dentine was examined in several studies at various universities. T Pioch at the university of Heidelberg employed Confocal Laser Scanning Microscopy (CLSM) to look at the distribution of the Seal&Protect on the dentine. In this technique, the Seal&Protect was marked with a fluorescent dye. On the CLSM images, the areas reached by the dentine sealant are those visible, with a lighter colour indication a higher concentration of adhesive. Below a typical CLSM image is shown.

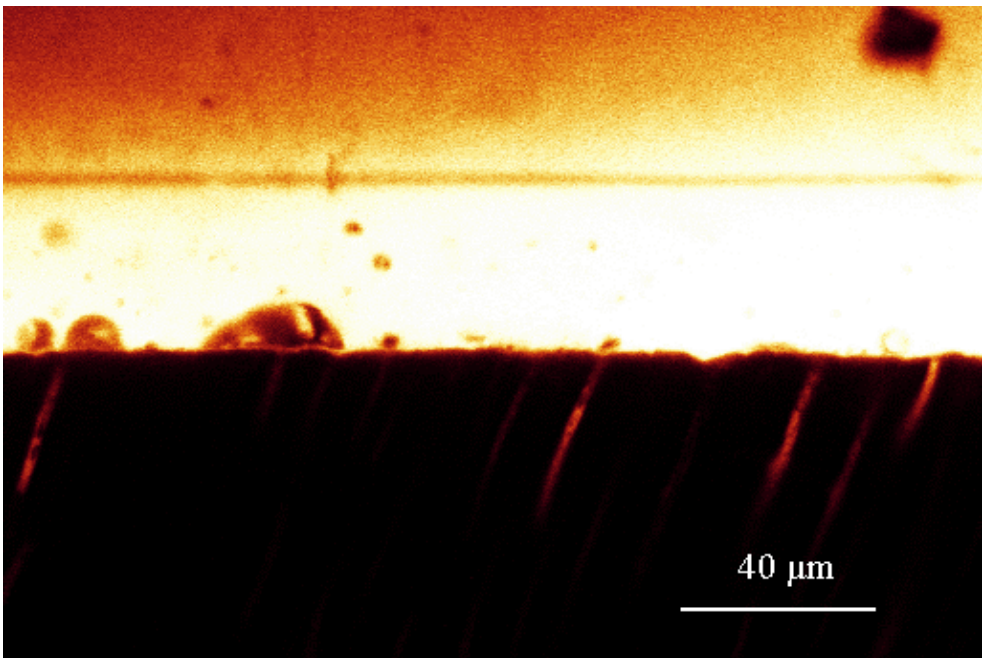


Figure 11: CLSM photo of interface between dentine and Seal&Protect (photo by T Pioch)

The sealant forms a continuous protective coat on top of the dentine, also covering some debris on top of the tooth surface. As the Seal&Protect is used without prior surface conditioning, it is not surprising that only minor penetration of dentine tubules can be observed.

Photos taken by Schemehorn under a regular light microscope show the difference between a nonprotective varnish such as Cervitec and the Seal&Protect. These photos were taken after the equivalent of one year (20,000 strokes) in a tooth brush abrasion machine, and the remaining sealant was coloured before taking the photo.

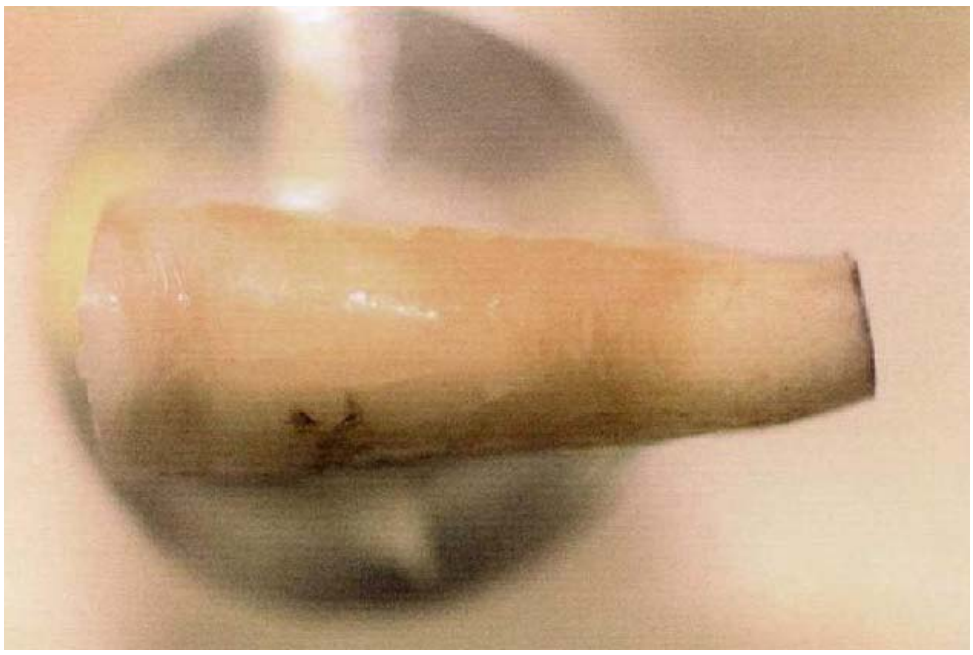


Figure 12: **Dentine surface treated with Cervitec after 20,000 strokes (equals 1 year) in a tooth brush abrasion test. No varnish is left. Photo: B Schemehorn.**

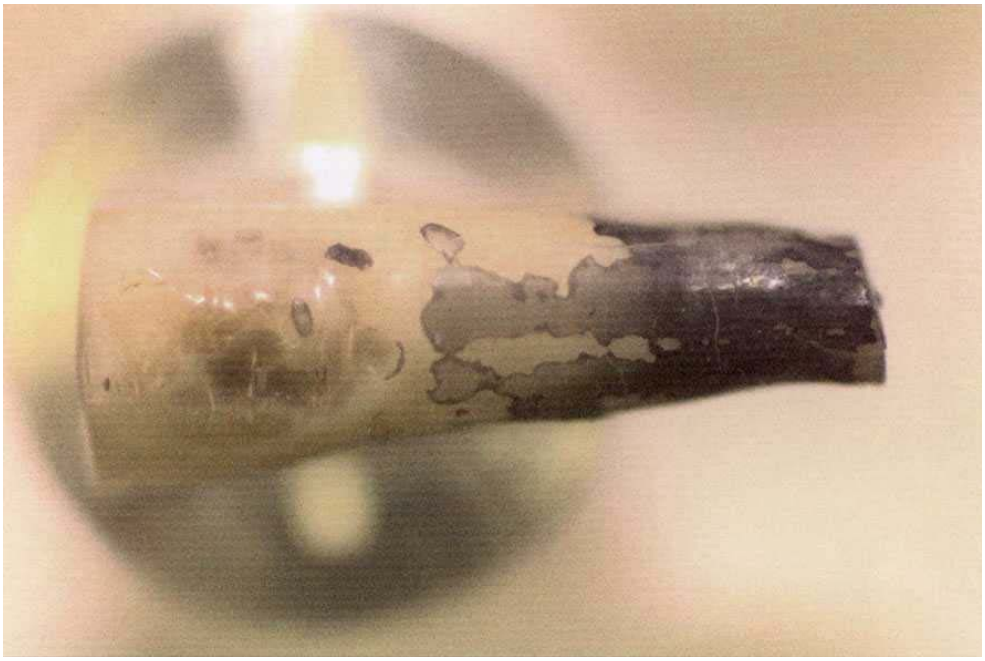


Figure 13: **Dentine surface treated with Seal&Protect (one coat) after 20,000 strokes (equals 1 year) in a tooth brush abrasion test. Some sealant coat is still visible (dark areas). Photo: B Schemehorn.**

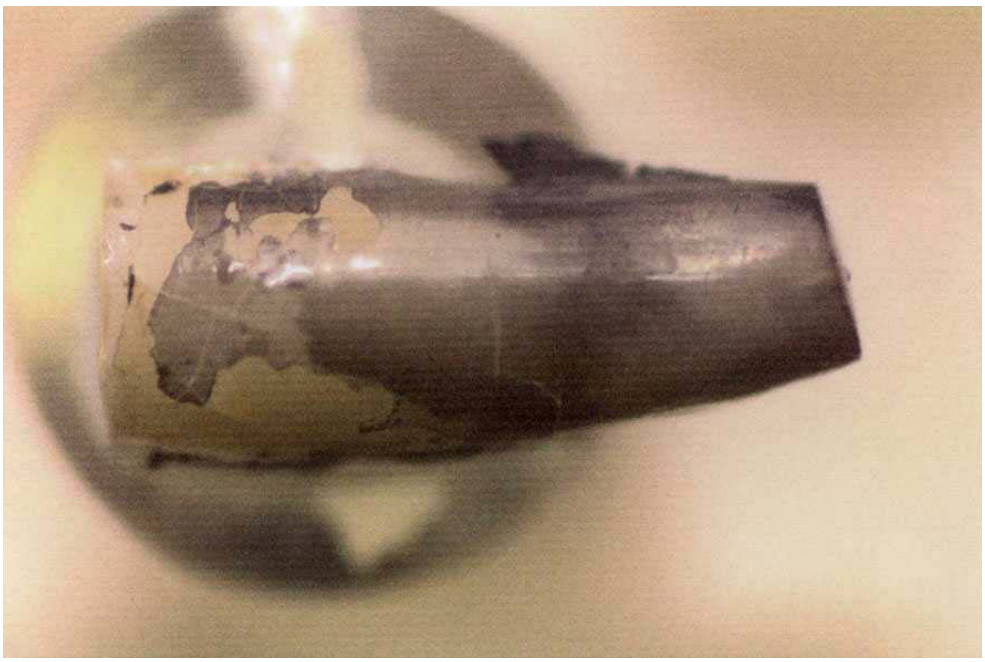


Figure 14: Dentine surface treated with Seal&Protect (two coats) after 20,000 strokes (equals 1 year) in a tooth brush abrasion test. Most areas are still covered with sealant coat (dark areas). Photo: B Schemehorn.

Another study was run by Perdigao. He used both scanning electron microscopy and transmission electron microscopy to examine the interface between the Seal&Protect and dentine. These photos give valuable information on the layer thickness of the Seal&Protect (SEM photo). Furthermore, the even nanofiller distribution is clearly visible in the TEM photo shown below (Figure 16).

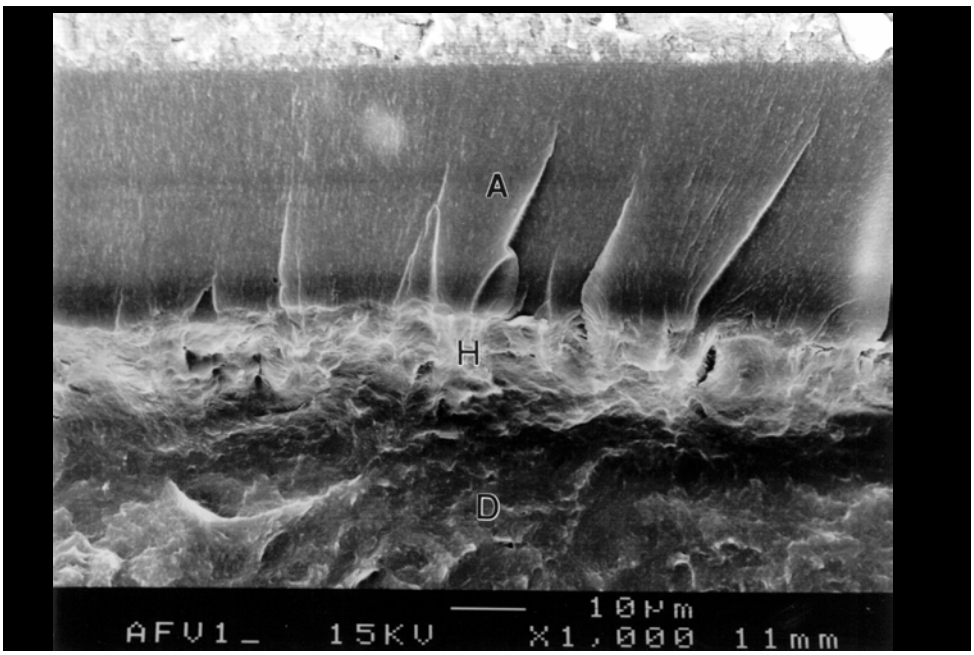


Figure 15: SEM photo (Perdigao) of dentine (D) treated with Seal&Protect (A). The interdiffusion layer (H) is composed of sealant and dentine.

From Figure 15 (and similar photos), a coat thickness of 35-40 μm on the dentine surface was determined. Furthermore, it was found that a 7-10 μm thick interdiffusion zone (H) is formed that is resistant to decalcification and deproteinisation.

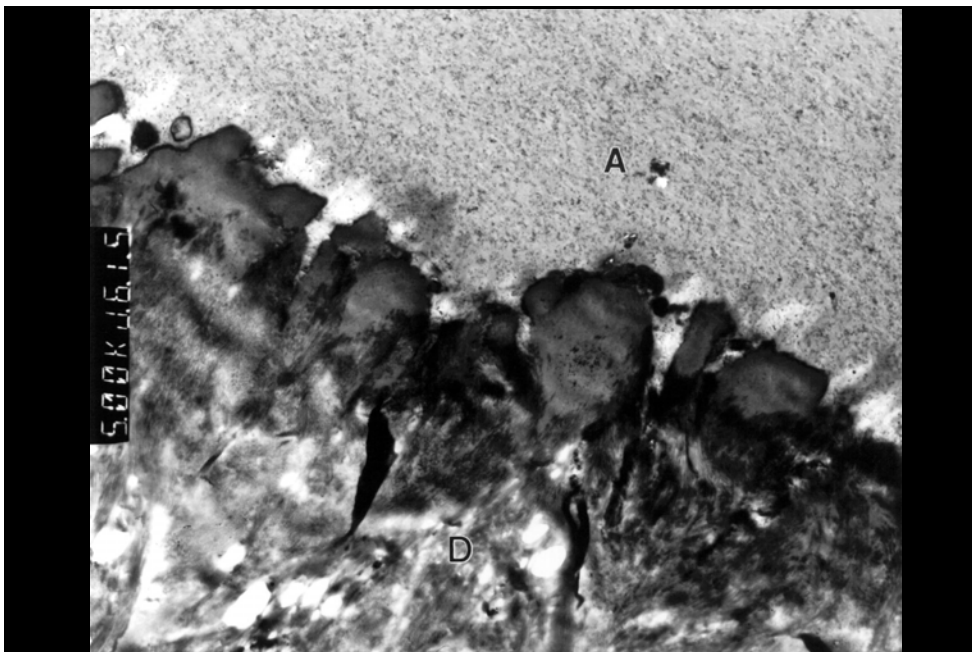


Figure 16: TEM photo (Perdigao) of dentine (D) protected by Seal&Protect (A). The evenly distributed nanofiller in the Seal&Protect is clearly visible.

3.7 Layer thickness of Seal&Protect

Layer thickness of the Seal&Protect was determined both by Confocal Laser Scanning Microscopy (Pioch T, 1998) and by SEM (Perdigao J, 1999). Some exemplary photographs are shown in section 3.6, Interaction with dentine.

For one coat, a layer thickness of 15.1 μm ± 2.6 μm was observed by CLSM. This is in line with the layer thickness of 35 - 40 μm as observed by SEM for two coats of the Seal&Protect.

In vivo, therefore a layer thickness of about 35 - 40 μm is obtained if the application technique described in the instructions for use is employed.

4 Clinical investigations

Data on two independent clinical investigations are on file and have been published:

Clinical investigation on the Protective Sealant K-0106 for cervical surfaces of teeth, London, by Dr. A. Baysan and Dr. E. Lynch

Therapy of root caries lesions with antimicrobial varnishes and sealants, Cologne, by Dr. M. J. Wicht, Dr. D. Lummert, Dr. R. Haak, Prof. Dr. M. J. Noack

Both studies follow a similar investigation plan and make use of metrological analysis for monitoring the wear of untreated and Seal&Protect-treated exposed root surfaces.

4.1 Summary of the London study

Design of the investigation

24 patients are included in the trial with the target to have data on 20 patients available at recalls at 3 months, 6 months, and 12 months. Based on previous clinical experience, it could be expected that these patient numbers will still give statistically significant data, when it comes to the measurement of cervical wear. A limitation of the patient numbers was found necessary because of the highly time-consuming and cost-intensive method (Jovanovski et al 1996) for measuring wear with the employment of the Co-ordinate measuring machine (CMM), Laser Scanning and Superposition Software of the Department of Conservative Dentistry.

Objectives of the investigation

To monitor wear of the cervical surface, to assess influence of application of the material of existing hypersensitivity and to assess the influence of the coating on caries-associated bacteria in the overlaying plaque.

Method of monitoring wear

- Replicas representing pre-operative, baseline, 3-, 6- and 12-month situations
- Laser scanning of replicas
- Replicas digitised at a pitch of 100µm (xyz)

- Superposition of datasets of pre-operative and postoperative replicas
- Calculation of abrasion with standard deviation of around 10µm

Results from wear measurement

After 3 months, wear of 22 cervical surfaces of 22 patients was determined. For comparison, wear of untreated cervical surfaces of 22 other subjects was measured.
For the group treated with Seal&Protect, mean wear excluding 3 lost sealants was 22µm (± SD: ± 31). As in a 2-layer technique, a layer thickness of 35 to 40µm is obtained (see Chapter 3.7), this means that wear was still within the protective layer and that, over 3 months, wear of root dentine could be prevented.

For the control group, with comparable cervical surfaces, wear of 48µm (± SD: ± 21) was determined.

Seal & Protect: Clinical investigation, London: Results of wear measurement at 3 months		
	Seal&Protect	**Control**
Wear of sealant	22 ± 31	n/a
Wear of tooth substance	**0** ± 0	**48** ± 21

Table 2: **Seal & Protect: Clinical investigation, London: Results of wear measurement at 3 months**

Method of assessing influence on hypersensitivity

A patient questionnaire was filled in asking to score from zero to nine whether any sensitivity was associated with any of the surfaces.
Each side was isolated from adjacent teeth and exposed to a standardised air stimulus.

Hypersensitivity results

Symptoms of discomfort for the patients 3, 6 and 12 months following application of the sealant had significantly disappeared compared to pre-application (baseline).

Seal&Protect™: Clinical investigation London

Hypersensitivity results

Mean of sensitivity scores (on a scale from zero to 9) at baseline and following 3, 6, and 12 mths

Follow-up	Sensitivity scores
Baseline	6.91
3-mth	0.36
6-mth	0.94
12-mth	2.08

Method of assessing influence on caries-associated bacteria

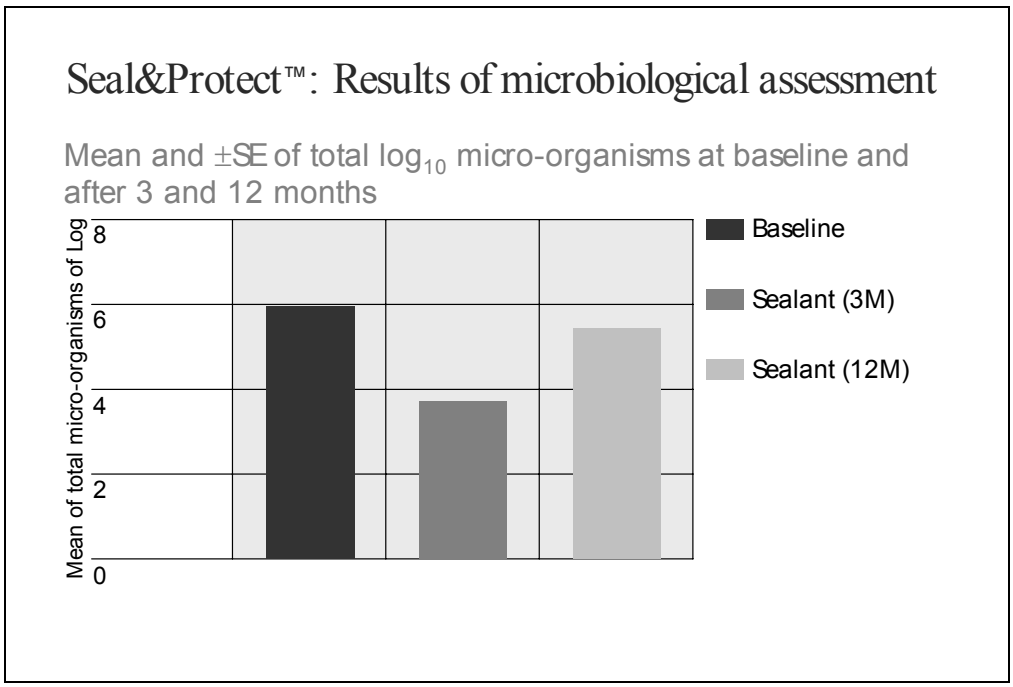
- Plaque was recorded from untreated surfaces and surfaces treated with Seal & Protect at baseline, 3, and 12 months
- Transport in anaerobe broth to microbiological laboratory was done within 30 minutes
- Assessment for Streptococcus mutans (MS), Lactobacilli, yeasts, GPPRs (Gram-positive plemorphic rods), and not caries-associated Streptococci (SM) was carried out.

Microbiology results

The effect of the sealant on micro-organisms was evaluated at baseline and at 3 and 12 months after sealant application.

It is evident that 3 months after sealing, the total number of micro-organisms is reduced when compared to the situation prior to treatment (baseline).

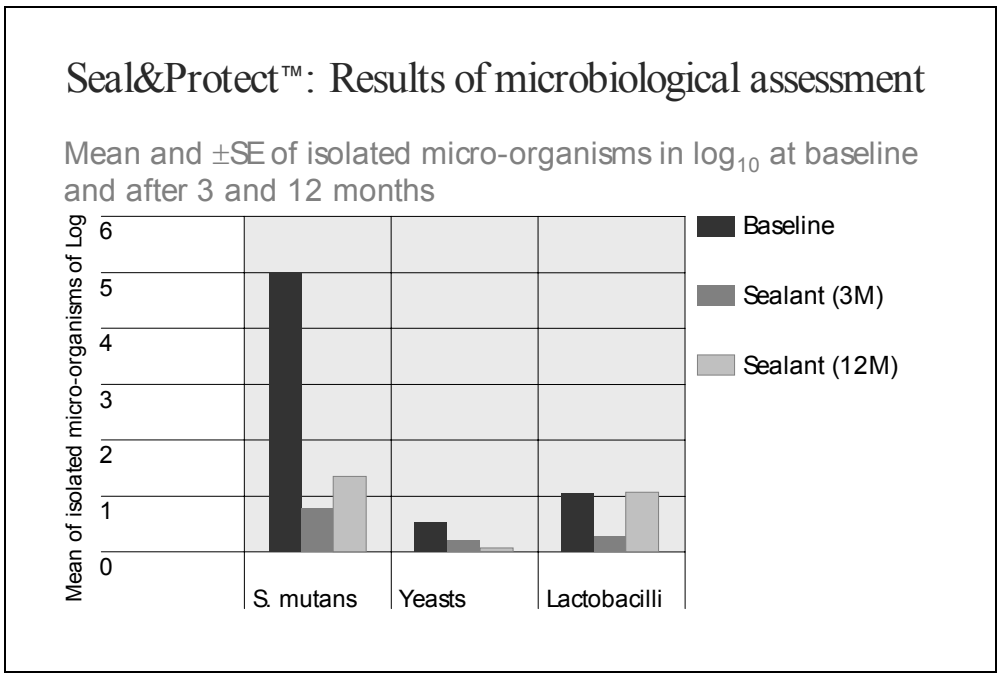
At 12 months, the total number of micro-organisms is only slightly and not statistically significantly reduced.



The effect of the sealing procedure on the number of isolated S. mutans, yeasts, and Lactobacilli is illustrated by the next Figure.

At 3 months, the number of all three micro-organisms is reduced.

At 12 months, S. mutans and yeast counts are still lower than prior to treatment, but Lactobacilli have reached their original level.



Conclusions from the London investigation

- Treatment with Seal & Protect prevented cervical abrasion for over 3 months.
- Seal & Protect reduces hypersensitivity for up to 1 year.

- Seal & Protect reduces the amount of caries-associated bacteria of cervical plaque over a time period of at least 3 months.

4.2 Summary of the Cologne study

Objectives

Purpose of this clinical study was to investigate the effects of root caries therapy with antimicrobial varnishes or dentine bonding agents.

Materials and methods

60 primary root caries lesions were identified in 22 adult patients.
Prior to and after treatment, each lesion was evaluated regarding colour, tactile judgement and laser fluorescence diagnosis (Diagnodent, KaVo). Furthermore, mutans streptococci (MS counts) associated with each lesion were noted. Soft dentine was removed with curettes and lesions were polished until laser fluorescence values below 15 were obtained. Surfaces were randomly treated with Cervitec (Vivadent), EC 40 (Explore), Prime&Bond (DENTSPLY DeTrey), and the triclosan-containing Seal&Protect (DENTSPLY DeTrey). Re-examination was performed after one month.

Results after one month

Surface texture and colour of the lesions did not change in all groups. Application of EC 40 reduced MS counts on the lesions' surfaces after one month whereas Cervitec, Prime&Bond, and Seal&Protect did not. Diagnodent values increased in the Cervitec and EC 40 groups, but remained stable in the Prime&Bond and Seal&Protect groups.

Conclusions from the Cologne investigation

Progressing demineralisation of root surfaces represented by laser fluorescence values can be prevented by sealing with Prime&Bond and Seal&Protect. It can be concluded that sealing excavated root caries lesions may provide better protection against demineralisation than the exclusive reduction of mutans streptococci.

5 Indications

Indications of Seal&Protect are:

- Reduction of abrasion, erosion and abfraction of exposed cervical dentine
- Reduction of plaque accumulation
- Treatment of hypersensitive cervical areas
- Presently under investigation: Non-restorative treatment of cervical caries

Contraindications

Seal & Protect should not be used for patients with a known hypersensitivity to any of the components of the sealant.

Side effects

In very rare cases, reversible inflammatory changes of the oral mucosa have been reported after accidental contact with acetone solutions and acrylate monomers. Therefore, avoid contact of Seal & Protect with mucous membranes.

Warnings

1. Seal&Protect contains acetone. Acetone is highly flammable. Keep away from sources of ignition- no smoking. Do not breathe vapour. Take precautionary measures against static discharges.
2. Seal&Protect is harmful to the eyes when in direct contact. In case of contact, rinse immediately with plenty of water and seek medical advice.
3. Seal&Protect contains methacrylates and triclosan which may be irritating to oral tissues and skin and which may cause sensitisation in susceptible persons.
   Minimise contact with oral mucosa. After contact, rinse with water or water/air spray by using suction.
   After contact with skin, wash immediately with plenty of soap and water.

Adverse reactions

The following adverse reaction has been associated with the use of acetone solutions and acrylate monomers:

- Reversible inflammatory changes of the oral mucosa after accidental contact.

6 Presentation form

Seal&Protect is available in two presentation forms:

6.1 Specially designed solvent-proof laminated container

The 4.5ml bottle (Figure 17) offers the most popular and economical delivery form for Seal&Protect and has unique properties:

- The middle layer integrated in the laminated plastic out of which the bottle is manufactured prevents evaporation of solvent.
- The outer and inner layers are heavily pigmented and protect the light-curing content from ambient light.
- The bottle has an ideal elasticity to allow a controlled dosage of the sealant.
- The opening of the dropper is of such a small diameter (0.13mm) that evaporation of solvent is minimised when the bottle is open during treatment.

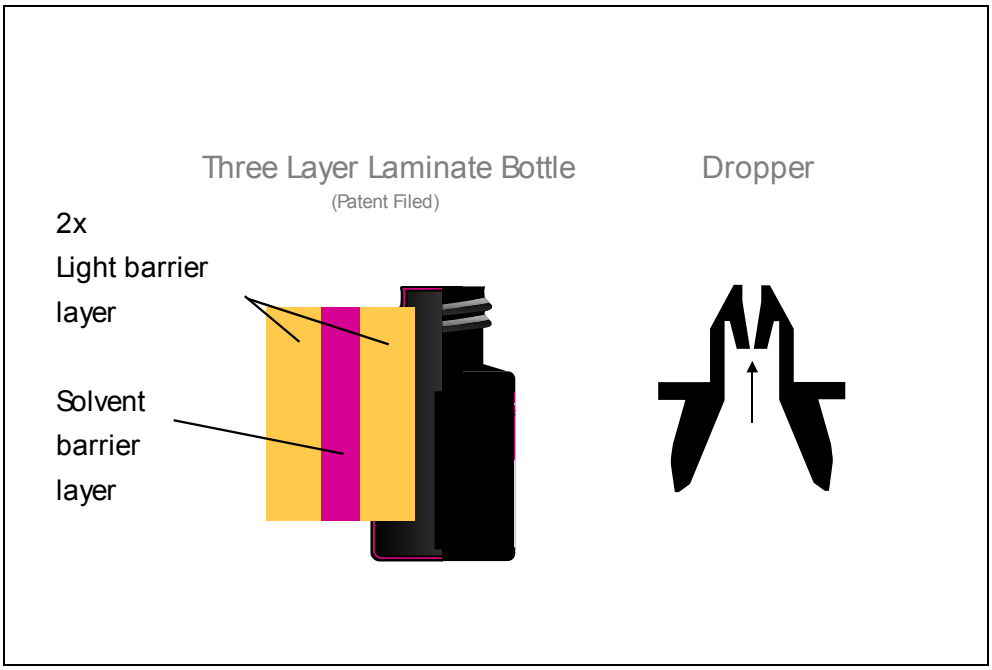


Figure 17 3-layer laminated bottle for Seal&Protect

The best technique to dispense sealant from the bottle is to apply the sealant in a non-touch technique directly onto an applicator tip (Figure 18).

This technique offers two major advantages:

- Less material is used than by dispensing the sealant into a dappen dish.
- The sealant has the optimum resin: solvent ratio when freshly dispensed.

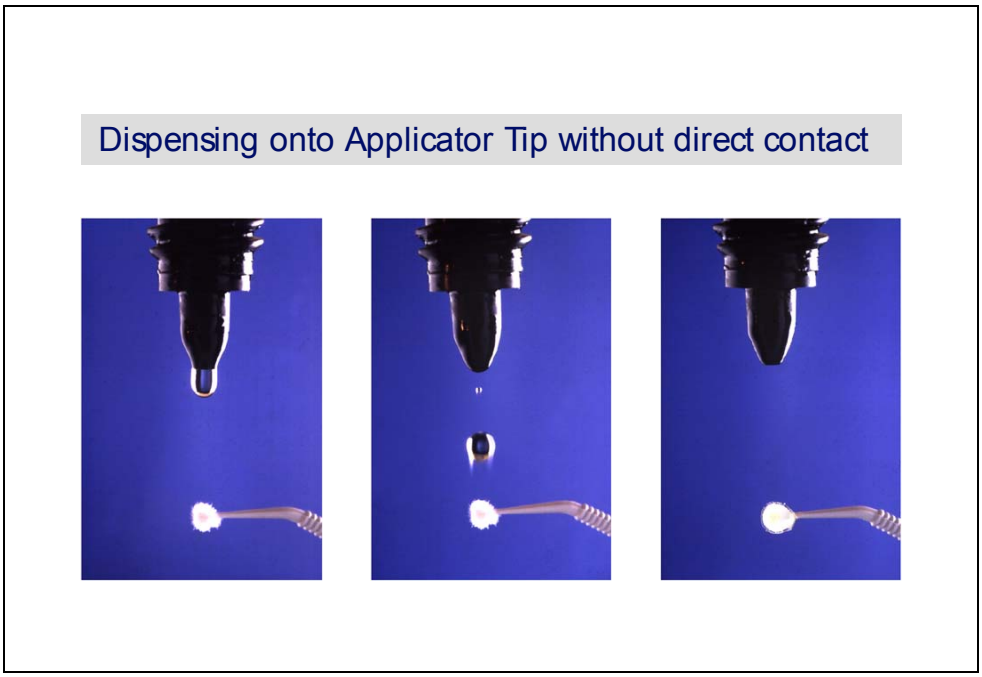


Figure 18 Recommended dispensing and application techniques for Seal&Protect

6.2 Single patient dosage packaging

In the last few years, the demand for dental materials in single patient dosage packages has been growing. As single patient dose packages are convenient to use and help to avoid cross-contamination between patients, it is to be expected that this type of packaging will become even more popular in the future.

Quix patient dose packages are made of Topas®[1], the latest member of the family of cycloolefin copolymers. The Topas resin achieves high vapour and solvent resistance and biocompatibility and can be autoclaved; all of these features make it supreme for medicinal packaging. With regard to environmental considerations, the material is also ideal, as during recycling or incineration, no toxic by-products are formed.

The design of quix - patient dose is illustrated by Figure 19.

[1] Ticona

6.2.1 Advantages of quix - patient dose

The quix - patient dose delivery for single patient use offers the following advantages:

- Best possible delivery form regarding treatment ergonomics
- best possible delivery form with regard to hygiene and infection control
- convenient, quick opening of container with only one hand
- opening large enough to insert applicator tip for uptake of the adhesive (no adhesive is squeezed off), but still small enough to prevent evaporation of solvent during the time necessary for application (working time up to 5 minutes)
- Ideal for multiple application
  (Treatment of several lesions of one patient during 1 session)
- secure storage and opening of container by means of the provided autoclavable holder
- takes very little storage place
- High stability (Topas®)
- No environmental issues (Topas®)
- rated best by German dental practitioners in a market survey on comparable single patient dose containers

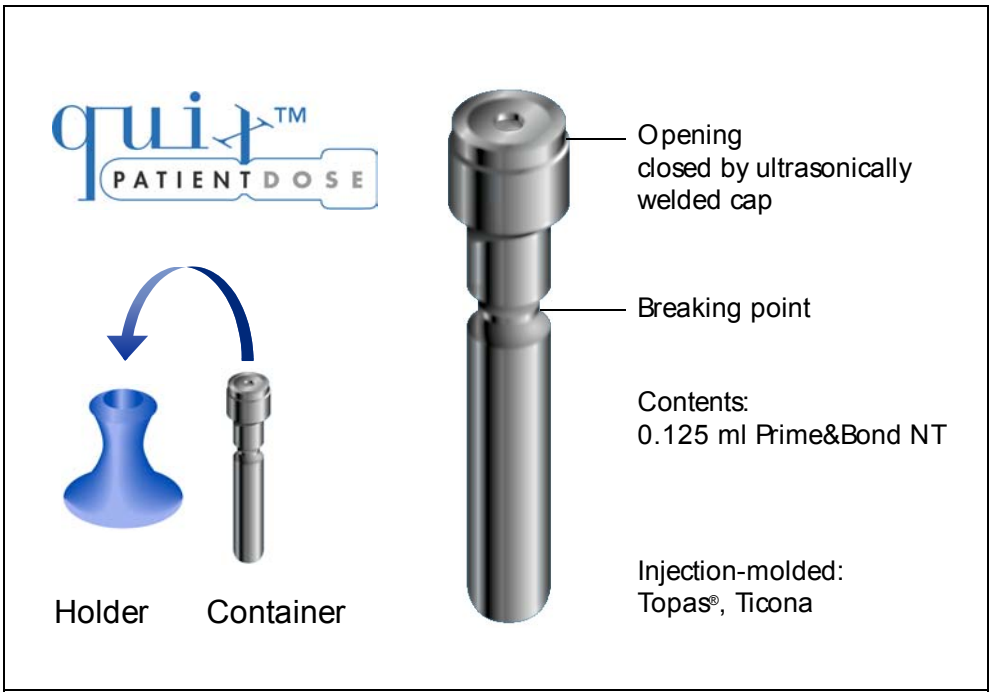


Figure 19 Design of quix - patient dose. The opening through which the sealant was filled into the container is permanently sealed by ultrasonic welding. Container is opened by removing top at breaking point.

7 Instructions for use

Seal&Protect is a light-curing, self-adhesive sealant which is applied in a 2-coat-2-cure technique to exposed cervical root surfaces.

Handling of quix – patient dose is illustrated on the disinfectable user guide which accompanies the material (Figure 26):

1. quix – patient dose is placed in holder and kept ready for use chairside.
2. Immediately prior to use, quix - patient dose is opened by breaking off the top at the notch.
3. A little twist may be necessary to completely remove the top.
4. quix – patient dose is now ready for uptake of the sealant by the applicator tip.
5. After use, the quix – patient dose container is directly disposed into the waste container by turning the holder and pushing the container out.
6. The empty container as well as its top are disposed with the other disposable products which were used during the treatment procedure.

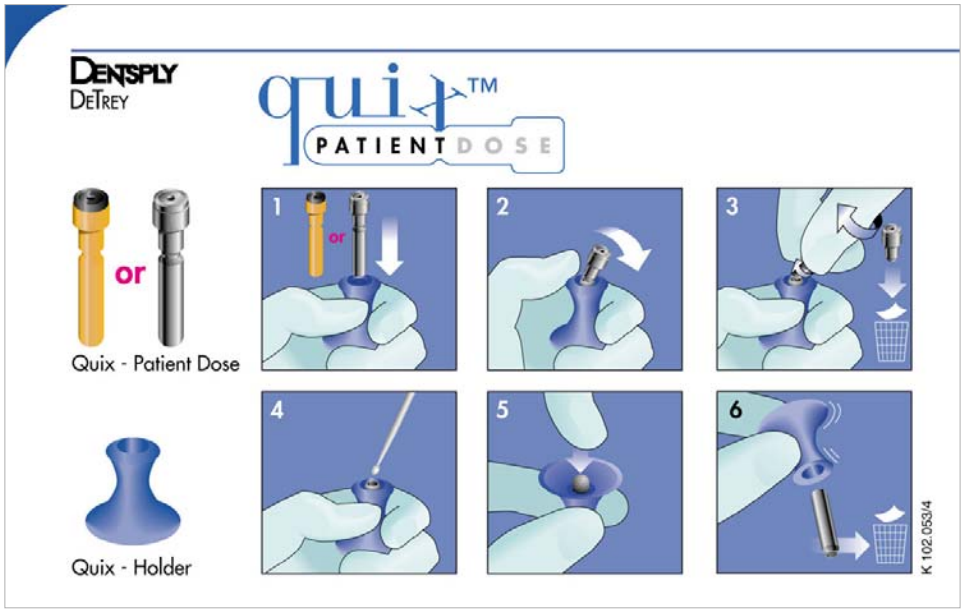
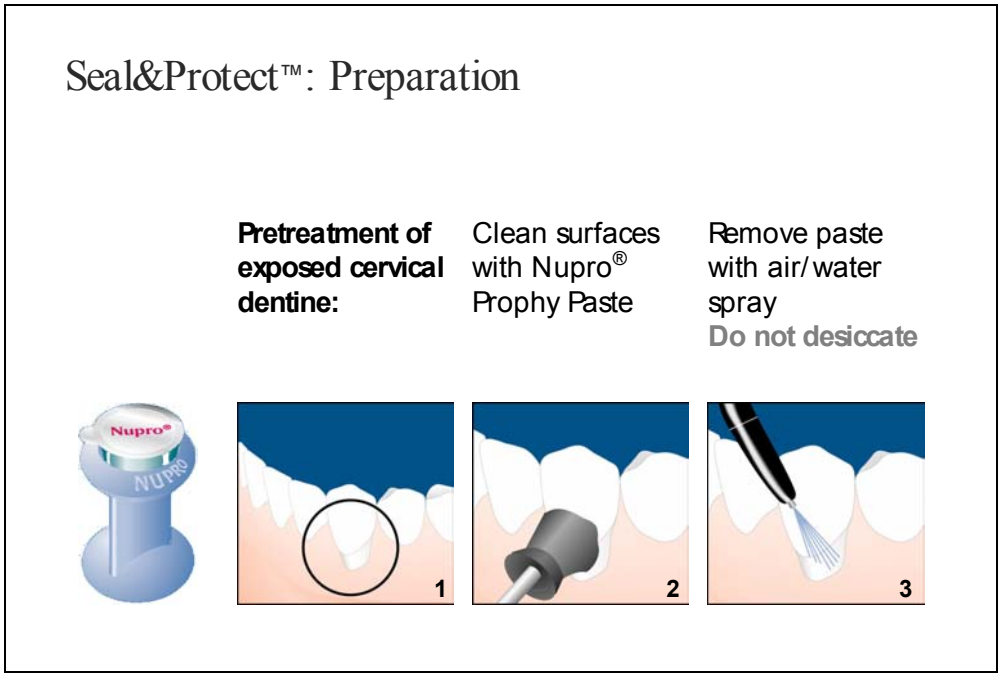


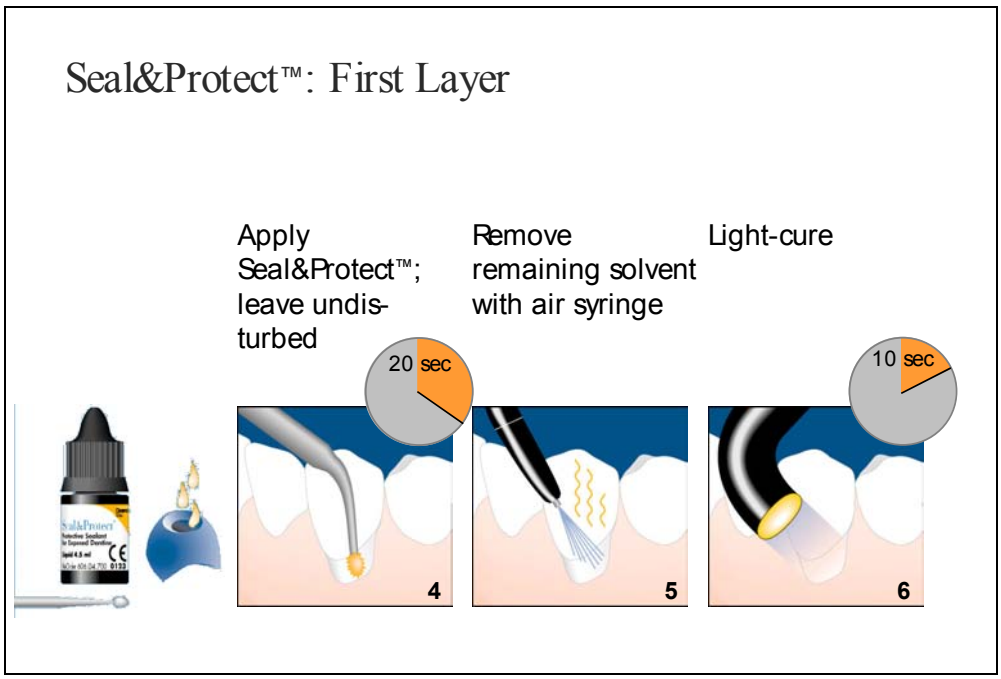
Figure 20 Use of quix - patient dose

1. Cleanliness is paramount for the development of a protective layer of Seal & Protect. Clean the dentine surface with a rubber cup and pumice or a prophy-paste (Nupro®).
2. Remove prophylaxis paste with air/water spray. Isolate area to be treated with cotton rolls. In the case of mandibular teeth, place saliva ejector. Dry cleaned area with a 2-second blow of air free of oil or water contamination. Avoid desiccating the dentine, - leave a moist, but not wet glistening surface. Do not desiccate.

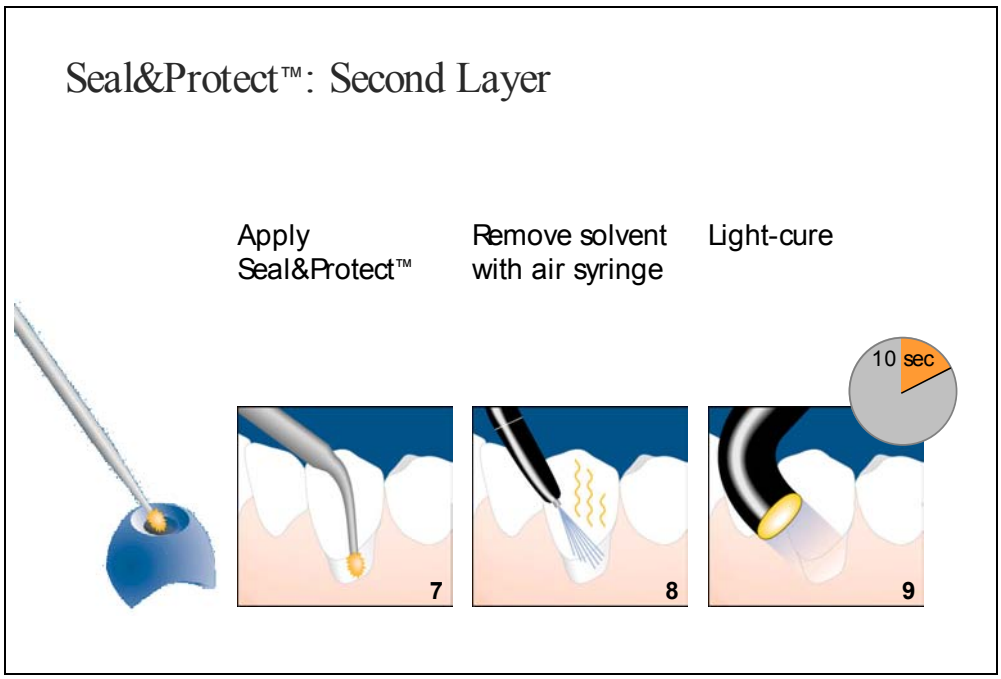


3. Dispense Seal & Protect into a fresh DENTSPLY Applicator Dish[2] or standard dappen dish. For handling of quix – patient dose, please see illustrated instructions. Per surface to be treated, two to three drops are required. It is recommended to treat no more than three adjacent surfaces per application procedure.
4. Immediately after dispensing apply ample amounts of Seal & Protect to the dentine surface with a DENTSPLY Applicator Tip[1]. Thoroughly saturate the exposed dentine.
5. Leave the dentine surface undisturbed for 20 seconds.
6. Remove excess solvent by blowing gently with air for a few seconds from a dental syringe.
7. Cure Seal & Protect for 10 seconds using a curing light.

[2] DENTSPLY Applicator Dish and Applicator Tips are available from your dental dealer.



8. Apply a second layer of Seal & Protect .
9. Remove excess solvent from the second layer by blowing gently with air from a dental syringe.
10. Cure Seal & Protect for 10 seconds using a curing light.



11. Remove oxygen-inhibited (soft surface) layer with a cotton pellet or cotton roll. Check for excess material in the gingival sulcus, and remove if any, with a periodontal probe.
12. Discharge used DENTSPLY Applicator Tip and DENTSPLY Applicator Dish.

Patient Recalls

It is recommended that all treated surfaces be checked for partial or total loss of the sealant during a second appointment. Depending on individual oral hygiene, wear of the sealant will require re-application in a one or two layer technique every three to six months.

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