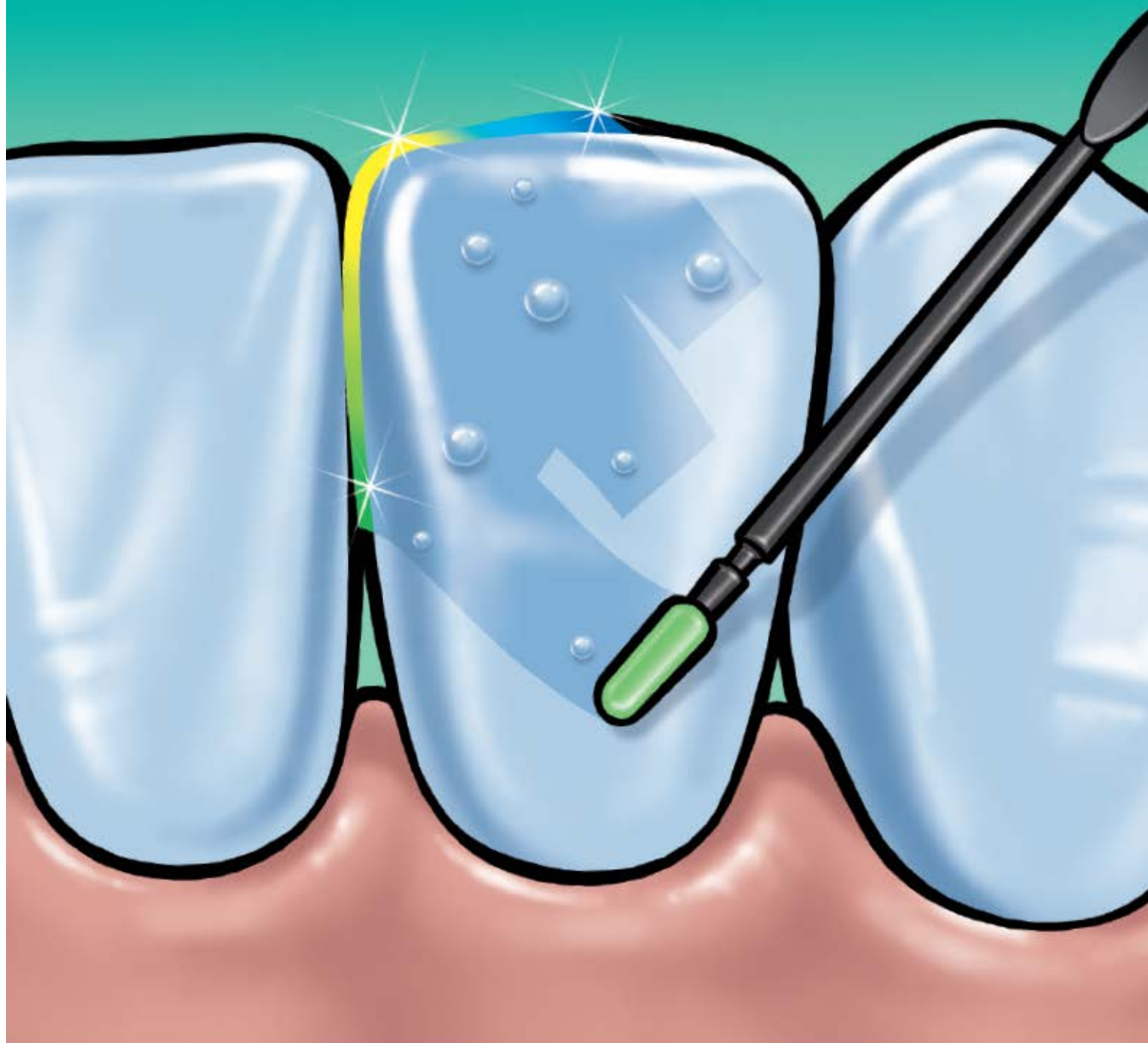


Fluor Protector



**Scientific
Documentation**

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1. Introduction

1.1 Fluoride varnishes

Oral health is crucial for overall health. Poor oral health can cause esthetic and functional impairments, pain and finally result in partial or total tooth loss. The importance of avoiding gingivitis, tooth decay and periodontal disease is therefore clear; and one of the most important long-term weapons in this fight has proven to be fluoride.

Fluoride varnishes were first developed around the late 1960s and early 70s. The idea was that by lengthening the time in which the fluoride is in contact with the teeth the fluoride uptake should be increased and improved^{1,2}. In support, Zero *et al.* state that the primary anti-caries activity of fluoride occurs topically³. Moreover, Zimmer *et al.* note that fluoride uptake, reaction and release in enamel are strongly dependent on the duration of contact⁴. By the 1980s, fluoride varnishes were widely used throughout Europe.

The WHO notes that there is no doubt that fluoride varnishes have a significant caries reducing potential⁵. A recent Cochrane review of randomised/quasi-randomised controlled trials, comparing fluoride varnishes with placebo or no treatment, concluded that fluoride varnishes exhibited a substantial caries-inhibiting effect in both permanent and deciduous dentitions⁶.

In-vitro and *in-vivo* studies have also shown that varnishes supply fluoride more efficiently than other topical agents with reductions in caries ranging from 50-70%^{7,8}. Furthermore, from a toxicological safety point of view, varnishes are preferable, as the bioavailability of fluoride in varnish is relatively low. In contrast, gels may have a bioavailability of almost 100% and hence, plasma peaks of around 1500 ng/ml have been measured. Cousins and Mazze suggested that a plasma level of 850 ng/ml is nephrotoxic⁹.

Thus, the primary reason for the wide acceptance of fluoride varnishes is the easy, safe, convenient and well accepted application procedure¹⁰. According to the recommendations of the American Dental Association, the application of fluoride varnishes is particularly beneficial in subjects with a moderate or high caries risk; for children below the age of 6 years, fluoride varnish is the only recommended fluoridation product due to the low risk of ingestion and thus of fluoride intoxication (see Table 1)¹¹.

Table 1: Evidence-based clinical recommendations for professionally applied topical fluoride. (Adapted from American Dental Association Council on Scientific Affairs¹¹).

Risk category	Age category for recall patients		
	< 6 years	6-18 years	> 18 years
Low	May not receive additional benefit from professional topical fluoride application (fluoridated water and toothpastes may be sufficient)		
Moderate	Varnish application at 6-month intervals	Varnish application at 6-month intervals OR Fluoride gel application at 6-month intervals	
High	Varnish application at 6-month intervals OR Varnish application at 3-month intervals	Varnish application at 6-month intervals OR Varnish application at 3-month intervals OR Fluoride gel application at 6-month intervals OR Fluoride gel application at 3-months intervals	

1.2 Fluor Protector

Fluor Protector is a fluoride varnish. Originally developed in 1975 by Arends and Schuthof with a fluoride concentration of 0.7%, the concentration was changed to 0.1% in 1987. A study by De Bruyn *et al.*¹² investigated the efficacy of Fluor Protector with different fluoride concentrations (0.7%, 0.1%, 0.05%) in the prevention of demineralisation. An unfluoridated varnish was used as a control. The participants carried varnished human enamel slabs in prostheses. Mineral loss, lesion depth and mineral distribution of the demineralised enamel were measured at different time points (2, 4 or 6 months). All concentrations of Fluor Protector protected equally well from demineralization after 4 or 6 months. Thus, the reduced concentration of Fluor Protector (0.1%) is as efficacious as the formerly used 0.7%, but reduces the risk of excessive fluoride ingestion, especially in young children.

Fluor Protector contains 0.9% difluorsilane in a polyurethane varnish base with ethyl acetate and isoamylpropionate solvents. The fluoride content is equivalent to 0.1%, or 1000 parts per million (ppm) in solution. As the solvents evaporate, the fluoride concentration at the tooth surface will increase to much higher values (nearly 10 times higher). Another advantage of the formulation of Fluor Protector is the ease of application. Due to its low viscosity, it gains access even to proximal surfaces. Finally, the varnish hardens to a clear transparent film on the tooth surface, providing a highly esthetical result.

Fluor Protector is suitable for patients of all age groups and is professionally applied by dentists or skilled personnel. Unless otherwise indicated, a twice yearly application is sufficient.



Fig. 1: The Fluor Protector VivAmpoule. As of 2010, Fluor Protector is available in the VivAmpoule, providing safe and easy breakage. Application is particularly comfortable using the Vivabrush G applicator.

1.3 Indications

Indications for fluoride varnishes can be divided into the following groups, though they are not entirely separate from one another:

- Treatment of hypersensitive teeth
- Remineralisation of initial caries lesions / inhibition of demineralisation
- Long-term caries prophylaxis
- Protection from erosion

Countless *in-vitro* and *in-vivo*-studies and over thirty years of successful clinical experience with Fluor Protector attest to its efficacy for these indications.

1.4 Working principles of fluoride

1.4.1 Fluorapatite and calcium fluoride layer formation

The benefits of fluoride in preventing enamel demineralisation, promoting remineralisation, reducing plaque growth and consequently helping to prevent dental caries are well documented¹³.

In the past the inhibition of caries by fluorides was ascribed to the reduced solubility of enamel due to the incorporation of fluoride ions into the crystal lattice of enamel in the form of fluorapatite (see Figure 2).

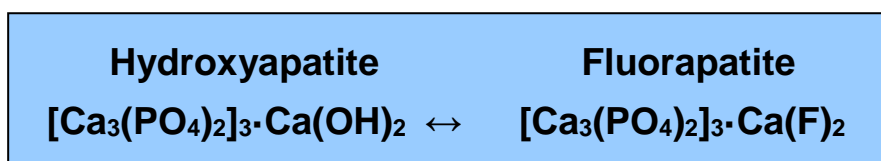


Fig. 2: Conversion of hydroxyapatite to fluorapatite. In the presence of fluoride ions, the hydroxyl ion (OH⁻) of the hydroxyapatite can be exchanged by fluoride (F⁻), yielding fluorapatite.

Though important, this is now known to have a more limited effect, with general acceptance that the primary anti-caries activity of fluoride occurs topically, via the formation of a calcium fluoride layer over the teeth^{3,14}.

Depicted in Fig. 3a, demineralisation refers to the loss of minerals (largely calcium and phosphate ions) from the tooth structure that occurs during acid attack/cariogenic challenge. Fluoride can help prevent this mineral loss.

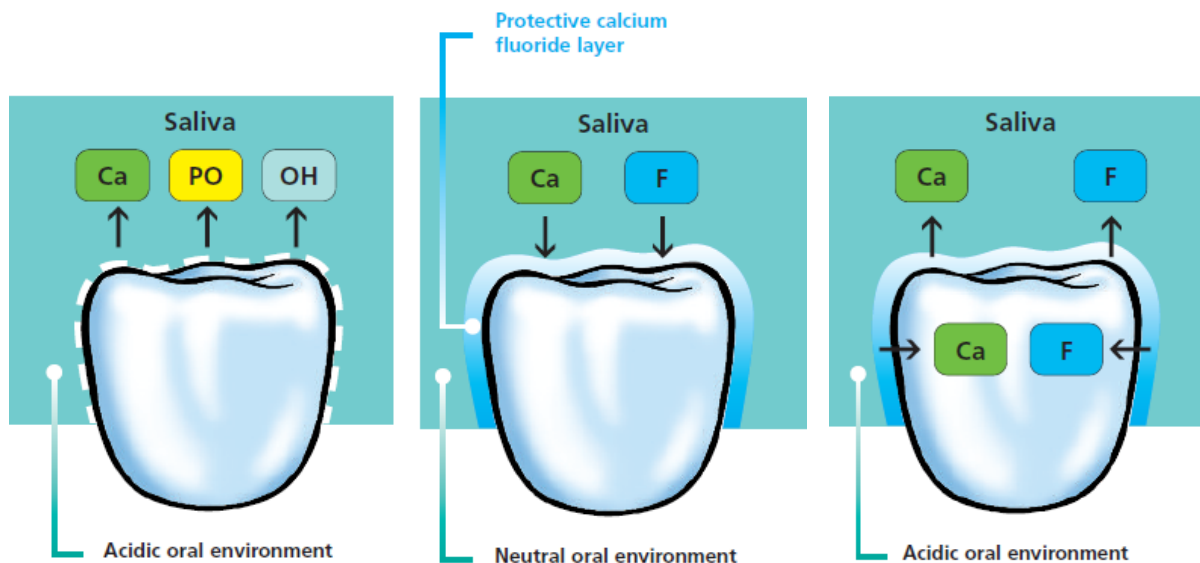


Fig. 3a: Demineralisation without fluoride protection.

At acidic pH, enamel is demineralised via the release of calcium (Ca²⁺) and phosphate ions (HPO₄²⁻) into the saliva.

Fig. 3b: Protective calcium fluoride layer.

After application of fluoride, a protective calcium fluoride layer (CaF₂) forms.

Fig. 3c: Bioavailability of fluoride.

At low pH, calcium (Ca²⁺) and fluoride (F⁻) ions are released. The tooth structure is no longer attacked directly. The calcium fluoride layer forms a depot releasing fluoride over time to the saliva.

Human saliva is usually saturated with calcium, such that following a topical application of fluoride, hardly soluble calcium fluoride (CaF₂) forms and a calcium fluoride-like layer precipitates over the treated tooth surfaces (Fig. 3b and 4).

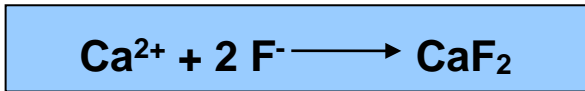


Fig. 4: Formation of calcium fluoride. After the application of fluoride varnish, fluoride ions and calcium ions (Ca²⁺) contained in the saliva precipitate to form calcium fluoride (CaF₂).

It has been shown that CaF₂ particles adhere especially well to porous surfaces such as fissures and demineralised surfaces¹⁵. The adsorption of hydrogenphosphate ions additionally stabilizes the CaF₂ layer^{14,16}. At neutral pH, the CaF₂ layer is practically insoluble and may remain on the teeth for months¹⁷.

Under acidic conditions, e.g. after carbohydrate intake and bacterial metabolism, the CaF₂ layer releases fluoride and calcium ions (Fig. 3c). The fluoride ions may remain in the saliva or settle in free spaces on the crystal lattice of the tooth structure - producing fluorapatite or fluor hydroxyapatite which is more acid stable than hydroxyapatite. Fluoride ions dissolved in saliva prevent fluoride attached to the enamel from being dissolved by acids¹⁸. The CaF₂ layer functions therefore as a pH-controlled fluoride reservoir and is the most important supplier of free fluoride ions during the cariogenic challenge¹⁴.

Studies show that fluoride uptake, reaction and release in the enamel are strongly dependent on the duration of contact with the fluoride agent^{19,20}. There is no distinct difference in the caries-preventive effects of concentrate fluoride solutions, gels or varnishes¹⁰. However, as fluoride varnishes adhere to tooth surfaces and thereby prevent immediate loss after application they may be optimal in this respect.

In conclusion, fluoride provides protective action through the control of the demineralisation and remineralisation processes. Via the deposition of a calcium fluoride layer at the tooth surface, fluoride hampers acidic demineralisation of the tooth structure and promotes remineralisation.

1.4.2 *Anti-plaque activity*

Bacterial biofilms or dental plaques are a prerequisite for the development of caries and periodontal disease. In addition to their effect on the enamel strength, fluorides can help reducing plaque growth and activity. The formation of the CaF₂ layer has been suggested to impair plaque development²¹. Moreover, fluoride also reduces the cariogenic (lactic) acid formation in plaque bacteria, such as *Streptococcus mutans*, by impairing bacterial glucose uptake and glycolysis^{22,23}. However, chlorhexidine exerts a much higher anti-microbial effect than fluoride²⁴.

2. Composition

Composition of the sales article:

Function	Component	Weight %
Solvent	Ethyl acetate, isoamylpropionate	84.0
Varnish base	Polyurethane	15.0
Active ingredient	Difluorosilane	1.0

Fluoride content:

Fluoride content	Weight %
In solution	0.1
In dry residue	0.81

3. *In-vitro* investigations and clinical experience

3.1 *Treatment of hypersensitive cervicals*

Hypersensitive cervicals are a common occurrence. Not just painful, hypersensitive teeth may lead to the neglect of oral hygiene. Hypersensitivity can usually be traced back to exposed dentine tubules. The circumstances leading to exposed tubules are manifold and include gingival recession, periodontitis, bruxism, erosion, professional tooth cleaning, scaling and root planing and even bleaching treatments that may lead to a temporary loss of the smear layer.

The hydrodynamic theory of tooth sensitivity as described by Brännstrom is widely accepted as the explanation²⁵. The theory concludes that certain stimuli such as temperature changes, sweet foods or osmotic activity elicit pressure changes within the dentine. This causes bi-directional fluid flow within the tubules which activates the dental nerves. *In-vivo* studies have revealed that the pulp-nerve response is related to the pressure exerted and thus to the rate of fluid movement²⁶.

Consequently, there are two main approaches to treating hypersensitivity: blocking the dentine tubules to prevent fluid movement, or inhibiting the neuronal transmission of the stimuli. The first mechanism – blocking of the dentine tubules - is employed by the large majority of products available.

Fluor Protector also operates via sealing open dentine tubules. The low viscosity varnish is able to penetrate well into the tubules and block the entrances mechanically²⁷⁻²⁹.

3.1.1 *In-vitro* studies with Fluor Protector

Arends J, Duschner H, Ruben JL. (1997): *Penetration of varnishes into demineralised root dentine in vitro*.

An *in-vitro* investigation by Arends *et al.*²⁹ used a confocal laser scanning microscope (CLSM) to study dentine permeability of fluoride varnishes. They showed that penetration is influenced by dentinal tubule direction. Moreover, Fluor Protector was able to penetrate the dentine tubules more efficiently than the resinous varnish Duraphat (see Table 2).

Varnish	Penetration in μm		
	wet	1-min air drying	3 min air drying
Duraphat	-	< 5	< 5
Fluor Protector	10 \pm 4	8 \pm 5	9 \pm 6

Table 2: Varnish penetration

3.1.2 Clinical experience with Fluor Protector

Collaert B, Söderholm G, Bratthall G, De Bruyn H. (1990): *Evaluation of a fluoride varnish for the treatment of dentine hypersensitivity.*

Collaert *et al.* examined the effect of Fluor Protector on the level of sensitivity to temperature changes (“hot-cold stimuli”). Fluor Protector was applied twice: at baseline 1 and one week later. Fig. 5 shows the decrease in hypersensitivity: Already after the first application, the pain sensation was significantly reduced. Four weeks after the first application, a clear reduction of the hypersensitivity was observed²⁸.

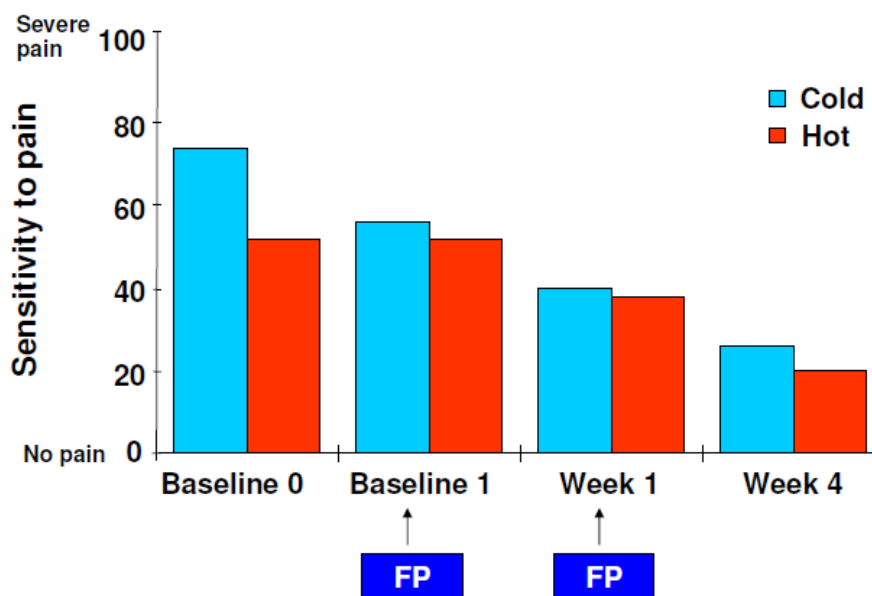


Fig. 5: Reduction of hypersensitivity after application of Fluor Protector. The pain sensation in patients with hypersensitive cervicals was examined before and after application of Fluor Protector (FP). A marked decrease in the hypersensitivity to cold/hot stimuli after Fluor Protector treatment is obvious.

(Modified after Collaert, 1990²⁸).

Rudhart B, Rompola E, Hopfenmüller W, Bernimoulin JP. (1998): *Effectiveness of Cervitec and Fluor Protector in patients with dentin hypersensitivity.*

Rudhart *et al.* performed a clinical study with both Cervitec and Fluor Protector to compare their effect on the reduction of hypersensitivity. No significant difference between the two varnishes was found. Both significantly reduced the sensitivity of all 20 patients over the study period of one month²⁷.

3.2 Inhibition of demineralisation and promotion of remineralisation

Demineralisation refers to the loss of minerals (mainly calcium and phosphate ions) from the dental hydroxyapatite due to exposure to acidic compounds. Application of fluoride varnishes leads to the formation of a calcium fluoride (CaF₂) layer covering the natural enamel. This calcium fluoride layer protects the tooth structure from demineralisation and promotes remineralisation, as under acidic conditions, the CaF₂ layer releases calcium and fluoride ions. These ions either remain in the saliva as an ion reservoir or contribute to the formation of fluorapatite or fluor hydroxyapatite which have a higher resistance to acid attacks than hydroxyapatite^{14,15}.

3.2.1 In-vitro studies with Fluor Protector

Liu X, Zhou X, Guo B, Jin S, Zhang P. (2002): Observation on the inhibiting effect of Fluor Protector on the demineralization of bovine enamel after exposure to some beverages.

This comparative study investigated the role of Fluor Protector in the demineralisation of bovine enamel after exposure to some beverages. Twenty-four bovine teeth were divided into experimental and control groups. The enamel specimens of the experimental group were pre-treated with Fluor Protector and then exposed to beverages; the specimens of the control group were exposed to the drinks directly. All specimens were exposed 10 times a day for 5 minutes each time. After 7 days of exposure, all specimens were observed by scanning electron microscope (SEM). Varying degrees of enamel prism solubilisation were seen in the control group. Solubilisation/demineralisation was however much reduced in the Fluor Protector group. The authors conclude that Fluor Protector is able to inhibit the demineralisation of enamel caused by sweet drinks³⁰.

3.2.2 Clinical experience with Fluor Protector

Binus E, Grube M, Stiefel A. (1982): Remineralisation of initial caries lesions by fluor silane.

Binus *et al.* showed an improvement in the surface quality of enamel lesions treated with fluor silane (the fluoride releasing compound in Fluor Protector). Some appeared fully remineralised after repeated Fluor Protector applications in 7-13 year olds over 12 months³¹.

De Bruyn H, Van Rijn LJ, Purdell-Lewis DJ, Arends J. (1988): Influence of various fluoride varnishes on mineral loss under plaque.

De Bruyn *et al.* investigated the mean lesion depth of enamel under accumulating plaque which represents a demineralising challenge. Fluor Protector or Duraphat were applied once in the test group, the control group received an unfluoridated varnish. After four months, the mean lesion depth was measured by microradiography. Fig. 6 illustrates the results: In subjects treated with Fluor Protector, the lesions were significantly shallower than those of the control group or the Duraphat-treated group¹².

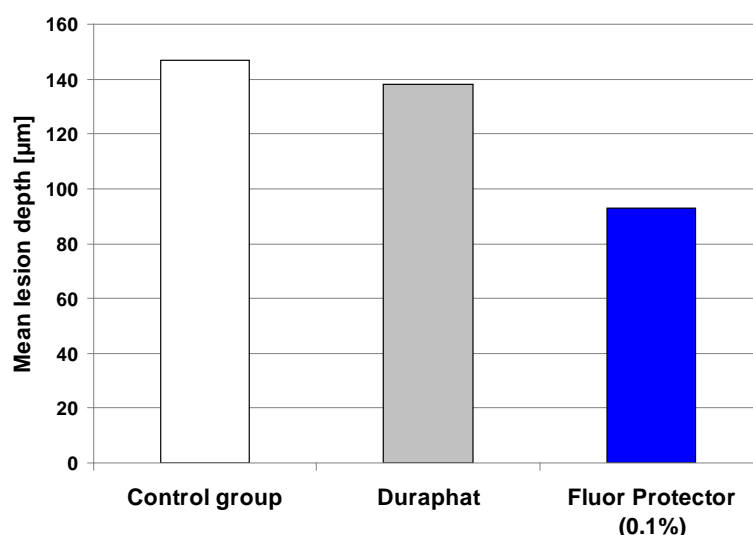


Fig. 6: Mean lesion depth under plaque after treatment with fluoride varnishes. Enamel was treated once with an unfluoridated varnish (control), Fluor Protector or Duraphat. The mean lesion depth under accumulated plaque was determined by microradiography. After treatment with Fluor Protector, the lesion depth was significantly shallower.

(Modified after De Bruyn *et al.*, 1988¹²).

De Bruyn H, Buskes H. (1988): Die kariespräventive Wirkung von Fluor Protector und Duraphat unter stark kariogenen Bedingungen.

In a similar study, De Bruyn *et al.* compared the clinical performance of Duraphat and Fluor Protector (0.7%) under highly cariogenic conditions. Eight patients carried 3 enamel specimens treated with either Fluor Protector, Duraphat or a control varnish intra-orally over 4 months. Plaque was allowed to accumulate on the specimens and fluoride administration from other sources was avoided. The enamel was analysed via microradiography after 4 months and the degree of caries protection obtained from each varnish was calculated according to the following equation:

$$\text{Caries protection} = \frac{\text{Mineral loss of test teeth} - \text{Mineral loss of control teeth}}{\text{Mineral loss of control teeth.}} \times 100\%$$

The results showed that the enamel treated with Fluor Protector was significantly better protected from caries (65%) than enamel treated with Duraphat (3%)³².

Tranaeus S, Al-Khateeb S, Björkman S, Twetman S, Angmar-Månsson B. (2001): Application of quantitative light induced fluorescence to monitor incipient lesions in caries active children. A comparative study of remineralisation by fluoride varnish and professional cleaning.

Tranaeus *et al.* performed a randomised controlled study which compared the treatment of white spot lesions in caries-active adolescents. One group (n=13) received Fluor Protector (FP) plus professional tooth cleaning (PTC), the other group (n=18) only professional tooth cleaning. In the FP group, the varnish was applied at baseline, after 1 week and then every 6 weeks for 6 months. In the control group, PTC was carried out once every 6 weeks for 6 months. Enamel fluorescence was measured at baseline and at each visit using quantitative light fluorescence (QLF) techniques. A significant time-dependent change was observed in the FP group for both lesion area and average change in fluorescence (see Fig. 7a and 7b). These changes were not seen in the control group. The difference in the average change in fluorescence between control and test group was statistically significant. Hence, the repeated application of fluoride can have a favourable effect on the remineralisation of white spot lesions³³.

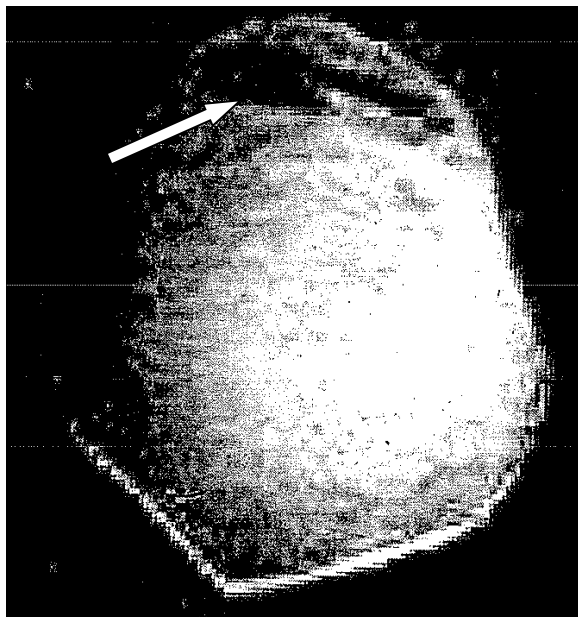


Fig. 7a: Fluorescence image of a white spot lesion at baseline. The white spot region (arrow) appears dark. Mineralised healthy enamel exhibits a high fluorescence, demineralised areas emit less fluorescence.

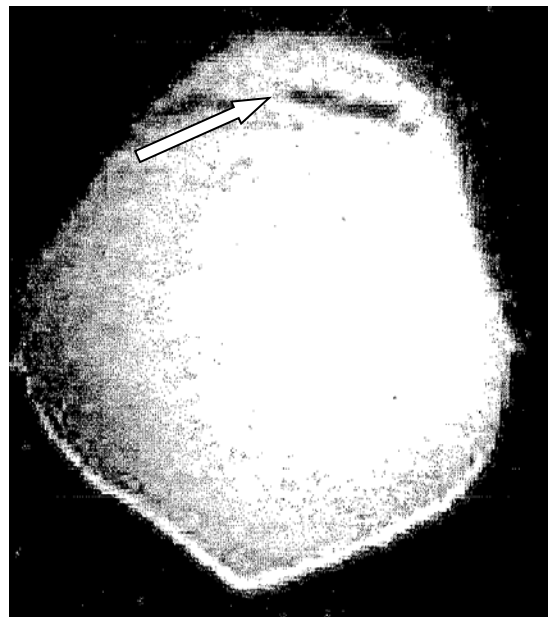


Fig. 7b: Fluorescence image of a white spot lesion after treatment with Fluor Protector for 6 months. The size of white spot (arrow) is markedly reduced and fluorescence is increased.

(Modified after Tranaeus *et al.*, 2001³³).

3.3 Long-term caries prophylaxis

A major part of the fluoride retained on tooth surfaces after topical application is calcium fluoride or calcium fluoride-like material. Calcium fluoride particles have been shown to adhere particularly well to porous surfaces, such as demineralised areas. They also remain on such areas for comparatively long periods¹⁵. This net retention by the enamel facilitates the long-term protective effects of fluoride.

3.3.1 In-vitro studies with Fluor Protector

Dijkman AG, Tak J, Arends J. (1982): Fluoride deposited by topical applications in enamel.

The fluoridation of human enamel by three different topical fluorides (Fluor Protector, Duraphat and APF gel) was compared by Dijkman *et al.* After a single application for 24 hours (Fluor Protector and Duraphat) and 5 min for APF gel respectively, the content of superficial, alkali-soluble calcium fluoride formation (fluoride “on”) as well as the amount of structurally bound fluoride (fluoride “in”, i.e. the fluoride that is incorporated into the hydroxyapatite crystals) was measured. Fluor Protector induced a substantial fluoridation, depositing more fluoride on and in the enamel as the APF gel or the resinous sodium fluoride varnish Duraphat (see Fig. 8). Moreover, the authors note that the contact time plays a dominant role in the fluoridating effect in deeper layers (5-30 μm) in the enamel as well as for the amount of CaF_2 deposited on the enamel surfaces for agents at the same pH value³⁴.

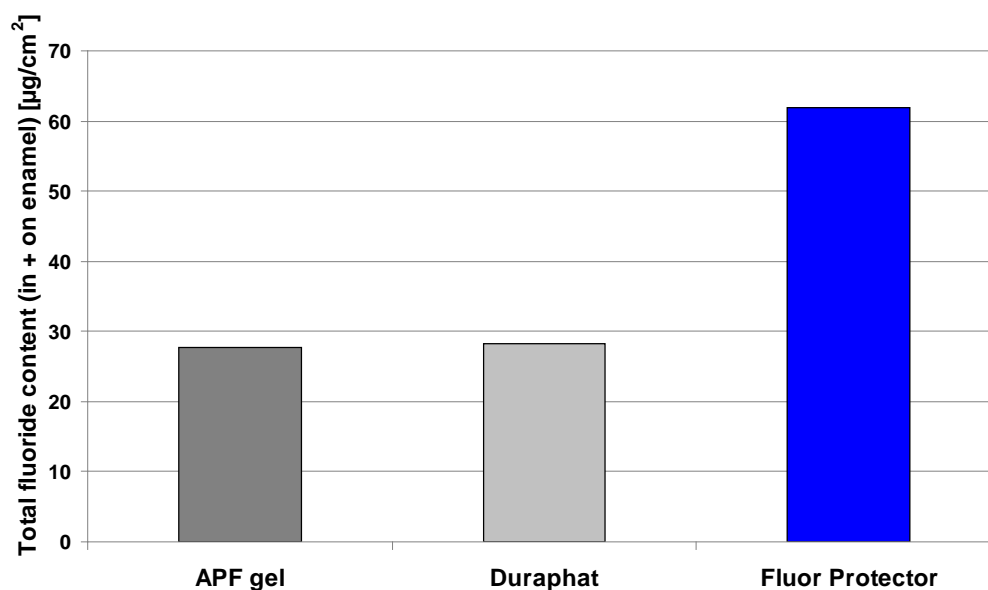


Fig. 8: Total fluoride content on and in the enamel after application of topical fluorides. Human enamel was treated *in vitro* with APF gel (5 min), Duraphat or Fluor Protector (24 hours). The fluoride was solubilised by KOH (fluoride on the enamel) or etching with HClO₄ (fluoride in the enamel) and measured via fluoride electrodes. The use of Fluor Protector provided the highest fluoride contents.

(Modified after Dijkman *et al.*, 1982³⁴).

Retief DH, Sorvas PG, Bradley EL, Taylor RE, Walker AR. (1980): *In vitro* fluoride uptake, distribution and retention by human enamel after 1- and 24-hour application of various topical fluoride agents.

Similar results were also found by Retief *et al.* The *in-vitro* acquisition of fluoride by human enamel after a 1-hour and 24-hour application of APF, Duraphat and Fluor Protector was evaluated. Fluoride acquisition was greatest in teeth treated with Fluor Protector and least in the APF group. Fluoride uptake and distribution were increased by prolonging the contact time³⁵.

3.3.2 Clinical experience with Fluor Protector

Dijkman AG, Arends J. (1988): *The role of “CaF₂-like” material in topical fluoridation of enamel in situ.*

A later study by Dijkman and Arends with the same products confirms these results *in vivo*. The authors investigated the uptake and binding of fluoride ions into the enamel after application of Fluor Protector, APF gel and Duraphat. Enamel slabs were treated for one hour with the fluoride varnishes or 5 min with APF gel and worn in the mouths of 12 test persons in dentures for 5 days. The results revealed an increased amount of alkali-soluble and permanently bound fluoride only after treatment with Fluor Protector (see Fig. 9). Moreover, the fluoride availability was calculated – i.e. the ratio of the applied fluoride concentration to the totally acquired fluoride. It is about 5%, 1% and 44% for APF gel, Duraphat and Fluor Protector respectively – this means, the uptake of fluoride from Fluor Protector was particularly effective; even if the nominal fluoride concentration is the lowest of the three compared products (Fluor Protector: 0.7%, APF gel: 1.23%, Duraphat: 2.26%)³⁶.

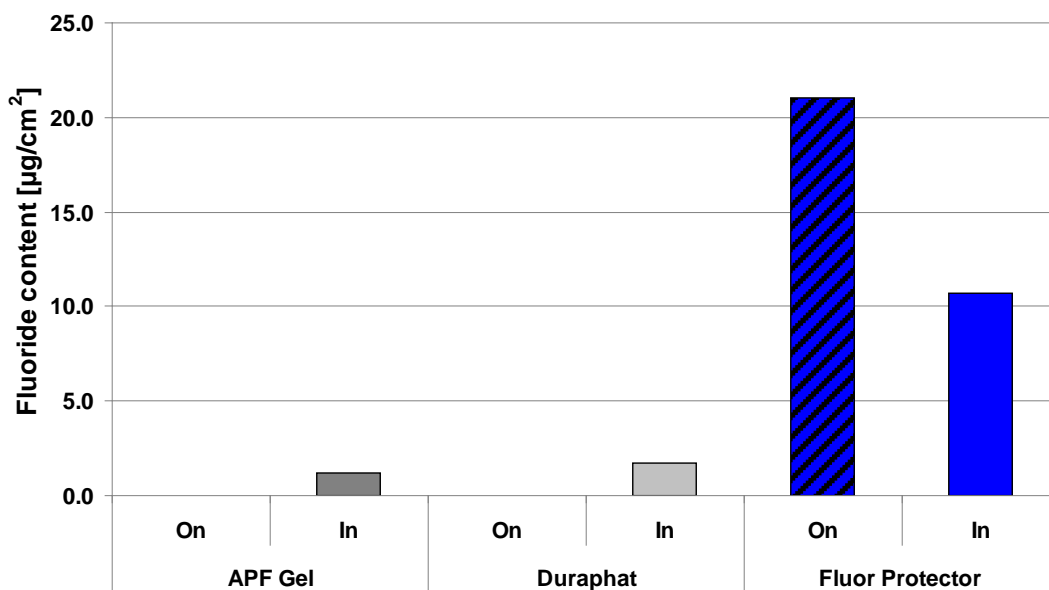


Fig. 9: Fluoride content *on* and *in* the enamel after application of topical fluorides *in situ*. Human enamel slabs were treated with APF gel (5 min), Duraphat or Fluor Protector (24 hours) and worn in dentures for 5 days. The fluoride was solubilised by KOH (fluoride *on* the enamel) or etching with HClO₄ (fluoride *in* the enamel) and measured via fluoride electrodes. Fluor Protector achieved the highest fluoride content *in* and *on* the enamel.

(Modified after Dijkman et al., 1988³⁶).

Hellwig E, Klimek J, Albert G. (1989): *In-vivo Retention angelagerten und festgebundenen Fluorids in demineralisiertem Zahnschmelz.*

Another *in-vivo* study utilising cylindrical enamel blocks with initial caries lesions showed that after the application of Fluor Protector the uptake of KOH-soluble and permanently bound fluoride clearly increased compared to cases in which Fluor Protector was not applied. Blocks were treated for one hour with Fluor Protector or Duraphat. After removal of the fluoride varnishes the enamel blocks were kept in the mouths of 3 subjects for 5 days. Plaque was allowed to accumulate on half of the blocks while the other half was kept clean. The fluoride content of three consecutive enamel layers was examined. Treatment with Fluor Protector induced a significantly higher fluoride content in all three layers compared to Duraphat treatment (see Fig. 10). The slow dissolution of CaF₂-like precipitates on the enamel surface and the concomitant fluoride uptake in the underlying demineralised enamel is suggested as a mechanism for a durable cariostatic effect of fluoride varnishes³⁷.

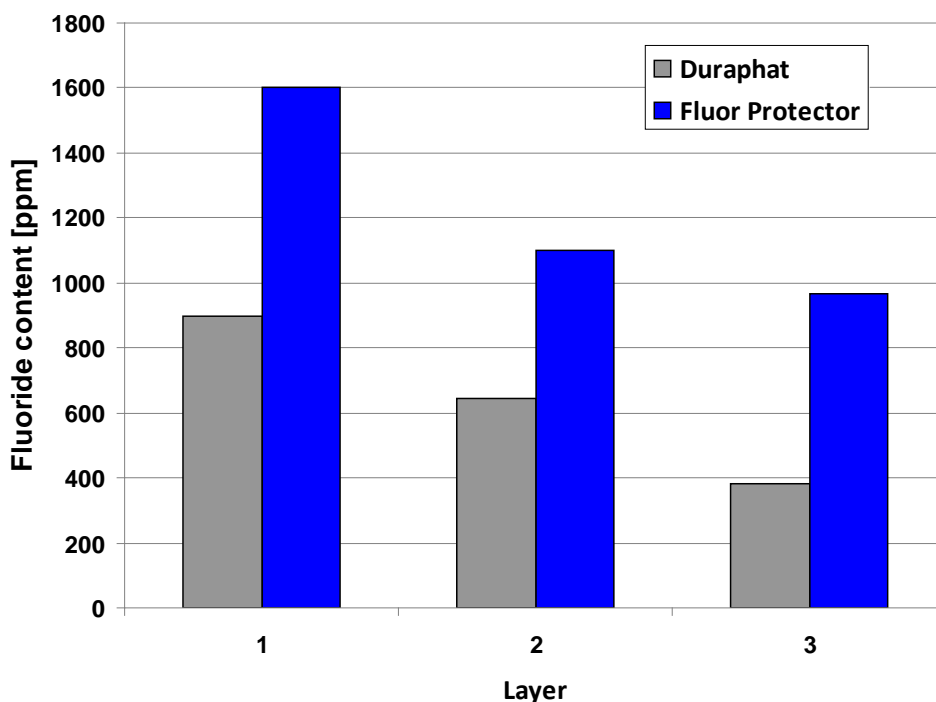


Fig. 10: Mean fluoride content in three consecutive enamel layers after application of topical fluorides. Cylindrical bovine enamel blocks with artificial initial carious lesions were treated for one hour with Duraphat or Fluor Protector and kept in the mouths of 3 subjects for 5 days. Afterwards, three enamel layers per sample were removed consecutively (20 μm , 30 μm , 30 μm). The layers were solubilised by HClO_4 and the fluoride content measured via fluoride electrodes. The amount of acquired fluoride was higher in all layers for Fluor Protector than for Duraphat.

(Modified after Hellwig et al., 1989³⁷).

3.4 Anti-plaque activity

Plaque is a prerequisite for dental caries. Fluoride is able to impede plaque development by disturbing the metabolic activity of certain species of plaque bacteria.

3.4.1 In-vitro studies with Fluor Protector

Balzar Ekenbäck S, Linder EL., Sund ML, Lönnies H. (2001): *Effect of fluoride on glucose incorporations and metabolism in biofilm cells of Streptococcus mutans.*

In order to evaluate the effect of fluoride on lactic acid formation *in vitro*, hydroxyapatite discs were either left untreated or pre-treated with a placebo varnish, Fluor Protector, 0.2% NaF or 0.05% NaF. A biofilm of *Streptococcus mutans* was then allowed to grow on the disks. Discs were incubated in growth medium at pH 7.0 with 1% glucose for 3 hours. As can be seen in Fig. 11, fluoride (both NaF and Fluor Protector) significantly reduced the lactate production compared to untreated controls or placebo discs²².

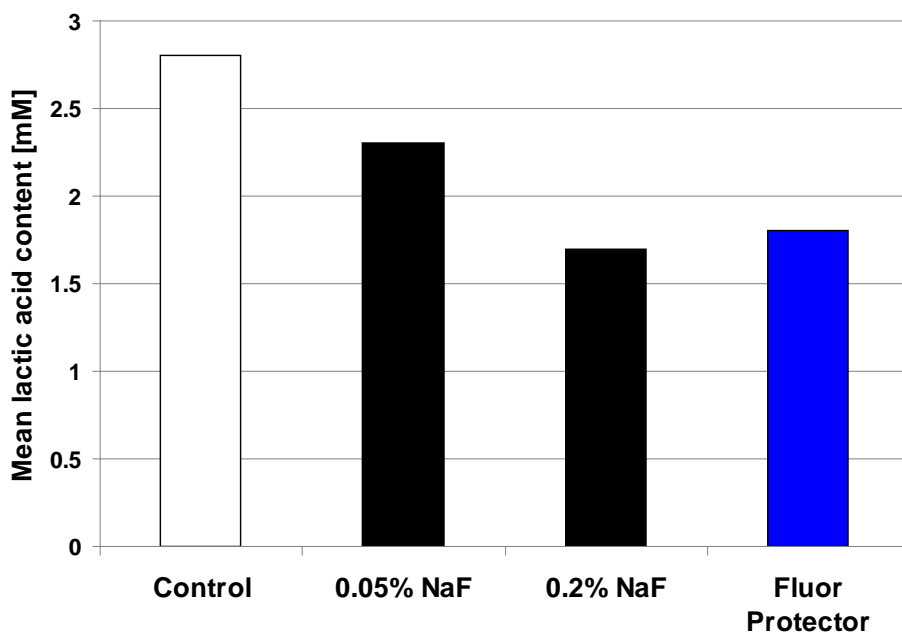


Fig. 11: Impairment of lactic acid production in biofilm after fluoride treatment. Hydroxyapatite disks were pretreated with 0.05% NaF, 0.2% NaF (incubation time 10 min), Fluor Protector or a placebo varnish without fluoride (varnishes were peeled off after 3 hours). The discs were then coated with a *Streptococcus mutans* biofilm and incubated for 3 hours at 37°C in a growth medium containing 1% glucose. The amount of lactic acid formation was determined by gas-liquid chromatography. Fluoride treatment significantly reduced lactic acid production.

(Modified after Balzar Ekenbäck et al., 2001²²).

3.4.2 Clinical experience with Fluor Protector

Twetman S, Petersson LG, Pakhomov GN. (1996): *Caries incidence in relation to salivary mutans streptococci and fluoride varnish applications in pre-school children from low- and optimal-fluoride areas.*

Twetman et al. performed a study with 1044 Swedish children (4-5 years old) on fluoride exposure/treatment and its effect on caries incidence and the levels of salivary *mutans streptococci*. Three different study groups were established: Group A (448 children) and B (389 children) from an area with 0.1 ppm fluoride in drinking water. In group C (207 children) the drinking water fluoride level was 1.2 ppm. Every six months, groups A and C were treated with Fluor Protector. Group B received no fluoride varnish treatment. The authors reported an elevated number of streptococci in children from areas with low levels of fluoride in drinking water at baseline and after 2 years. The caries incidence was statistically significantly higher in the control group (without Fluor Protector) compared to the groups treated with fluoride varnish (see Fig. 12). Moreover, a positive correlation was found between salivary *mutans streptococci* scores at baseline and caries incidence in all 3 groups. Thus, a close association between *mutans streptococci* and caries incidence could be confirmed and a caries protective effect after the application of fluoride varnish was suggested³⁸.

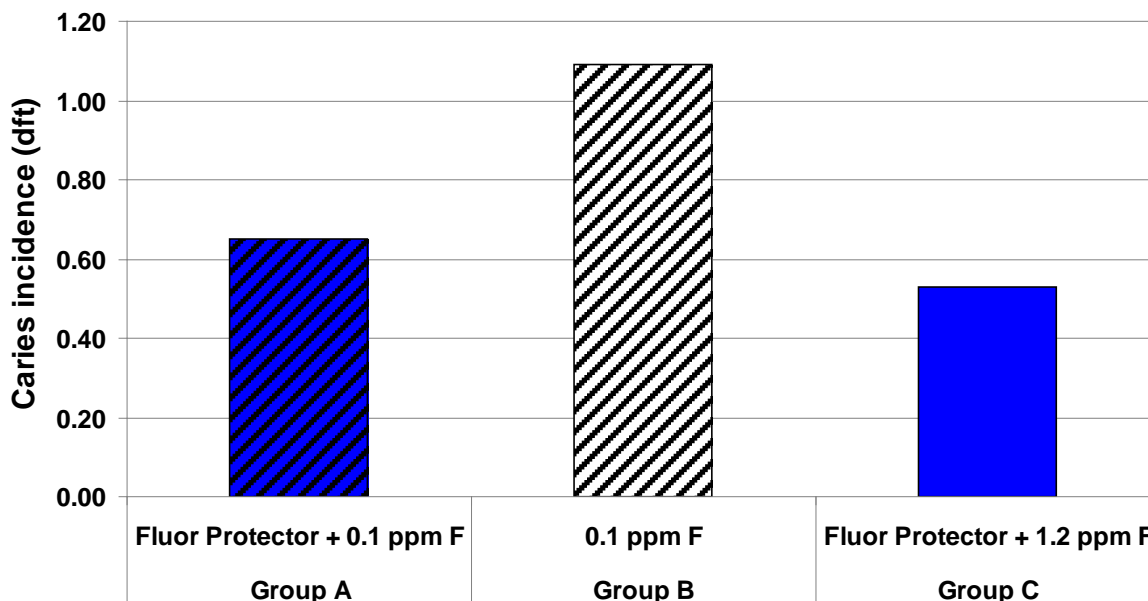


Fig. 12: Caries incidence in pre-school children after treatment with Fluor Protector. 1044 Swedish children, aged 4-5 years, either from areas with low (0.1 ppm, Group A and B) or optimal (1.2 ppm, Group C) levels of fluoride in the drinking water were treated semi-annually with Fluor Protector (Group A and C) or received no special treatment (Group B). The caries incidence after 2 years was evaluated (dft: index of decayed and filled teeth) and found to be significantly reduced in groups treated with Fluor Protector.

(Modified after Twetman et al., 1996³⁸).

Sköld-Larsson K, Modeer T, Twetman S. (2000): Fluoride concentration in plaque in adolescents after topical application of different fluoride varnishes.

This study examined the fluoride concentration in plaque after a single topical application of different fluoride varnishes with different fluoride contents. Thirty adolescents (12-17 years) with fixed orthodontic appliances were randomly assigned to one of three groups: Bifluoride (6% F), Duraphat (2.23% F) or Fluor Protector (0.1% F). The varnishes were applied after professional cleaning in one upper quadrant, leaving the opposite quadrant untreated according to the split-mouth technique. Pooled plaque samples from each quadrant were collected at baseline and 3 days, 7 days and 30 days after the varnish treatment, and the fluoride content was determined by microdiffusion and measurement with fluoride electrode. All fluoride varnishes increased the fluoride concentration in plaque compared with the baseline. The results for Fluor Protector are shown in Fig. 13.

Moreover, this study also determined the amount of varnish required per treatment and the fluoride dose that is applied via this amount to the teeth. Table 3 illustrates that, in comparison to the highly viscous Duraphat varnish, only half the volume of Fluor Protector is needed to treat one quadrant (0.15 ml versus 0.3 ml). Furthermore, the fluoride dose applied in one treatment is the least for Fluor Protector, thus minimizing the risk of fluoride intoxication. However, as numerous studies presented in this documentation and elsewhere prove, the efficacy of Fluor Protector is excellent, despite its comparatively low fluoride content³⁹.

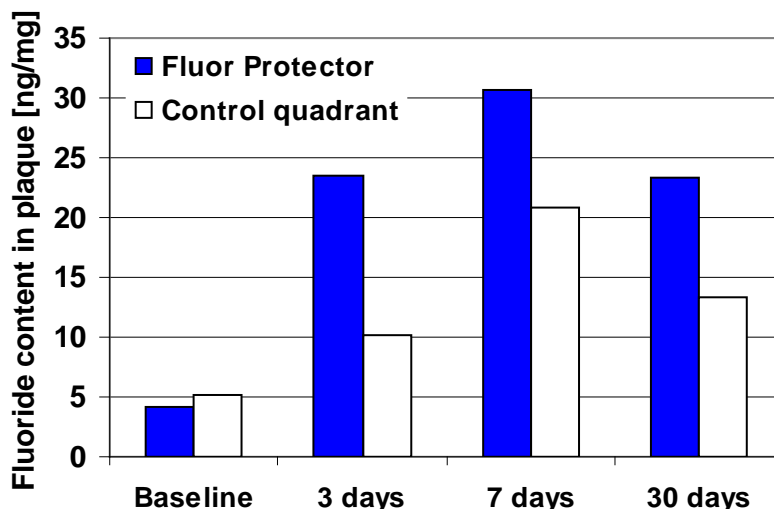


Fig. 13: Fluoride content in plaque after treatment with Fluor Protector. 30 adolescent orthodontic patients were treated with Fluor Protector, Bifluorid or Duraphat in a split-mouth approach. At baseline and after 3, 7 and 30 days, plaque was collected from the patients and the fluoride content in the plaque was determined. The fluoride concentration in the quadrants treated with Fluor Protector were higher than in the untreated control quadrant for all time points after treatment.

(Modified after Sköld-Larsson *et al.*, 2000³⁹).

Table 3: Fluoride content, required volume and applied dose per treatment for three different fluoride varnishes. (Modified after Sköld-Larsson, 2000³⁹).

Product	Fluoride content [%]	Volume per treatment / quadrant [ml]	Dose [mg fluoride]
Fluor Protector	0.1	0.15	0.3
Bifluorid	6.0	0.15	9.0
Duraphat	2.26	0.30	6.8

3.5 Protection from erosion



Fig. 14: Erosion of teeth. The frequent ingestion of highly acidic food or beverages (citrus fruits, soft drinks) as well as specific pathological conditions involving frequent vomiting may lead to the erosion of teeth. The exposure of the dentine (yellow) may cause hypersensitivity and discoloration of the teeth.

Courtesy of Prof. Dr. Lussi

There is some evidence that the presence of erosion is increasing in developed societies. Enamel erosion (see Fig. 14) affects all ages, with a somewhat more pronounced rate of erosion in younger age groups⁴⁰. A case control study by Jarvinen *et al.* including 106 cases

with erosion and 100 controls found the most important risk factors to be ingestion of citrus fruits more than twice daily, vomiting daily, consumption of soft drinks, apple vinegar ingestion, use of sport drinks, gastric symptoms and xerostomia⁴¹.

3.5.1 In-vitro studies with Fluor Protector

Via their capacity to enhance enamel resistance, fluoride varnishes can also help to prevent erosion. Fig. 15 illustrates the surface changes of enamel exposed to erosive conditions. The rather smooth topography that is present before erosion (upper left) becomes rough and uneven (lower left) after exposure to erosive acids. In contrast, treatment with Fluor Protector (right) protects the surface effectively from erosion.

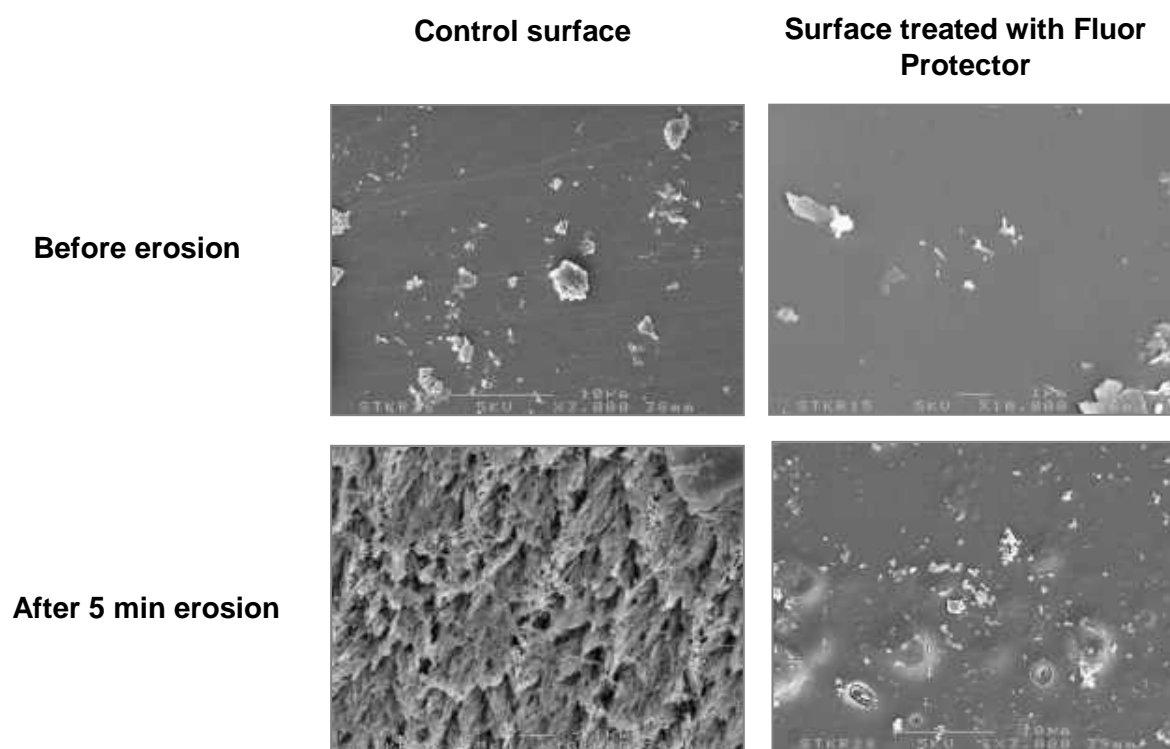


Fig. 15: Surface erosion with and without Fluor Protector. Bovine enamel surfaces were either treated with Fluor Protector (right) or left untreated (left) and then exposed for 5 minutes to erosive conditions (citric acid solution, pH 3). Scanning electron microscopy was performed to analyse the surface topography. Fluor Protector treatment efficiently protected the surface from erosion.

(Courtesy of Ana Vieira).

Vieira A, Ruben JL, Huysmans MC. (2005): Effect of titanium tetrafluoride amine fluoride and fluoride varnish on enamel erosion in vitro.

This study evaluated the effect of different fluoride products on the erosion of bovine enamel. A titanium tetrafluoride gel (TiF₄; 1% and 4%), two amine fluoride (AmF) products (Elmex medical: 0.25% AmF and Elmex fluid: 1% AmF) and Fluor Protector (0.1% F) were compared. Two groups served as controls, one receiving pre-treatment with a fluoride-free varnish (placebo) and the other no treatment at all (control). Dental erosion was modeled by alternate cycles of acid exposure in citric acid and remineralisation in artificial saliva. Erosion depth was analyzed by white light confocal microscopy scanning. As Fig. 16 demonstrates, a statistically significant protective effect on the prevention of dental erosion was only established for treatment with Fluor Protector⁴².

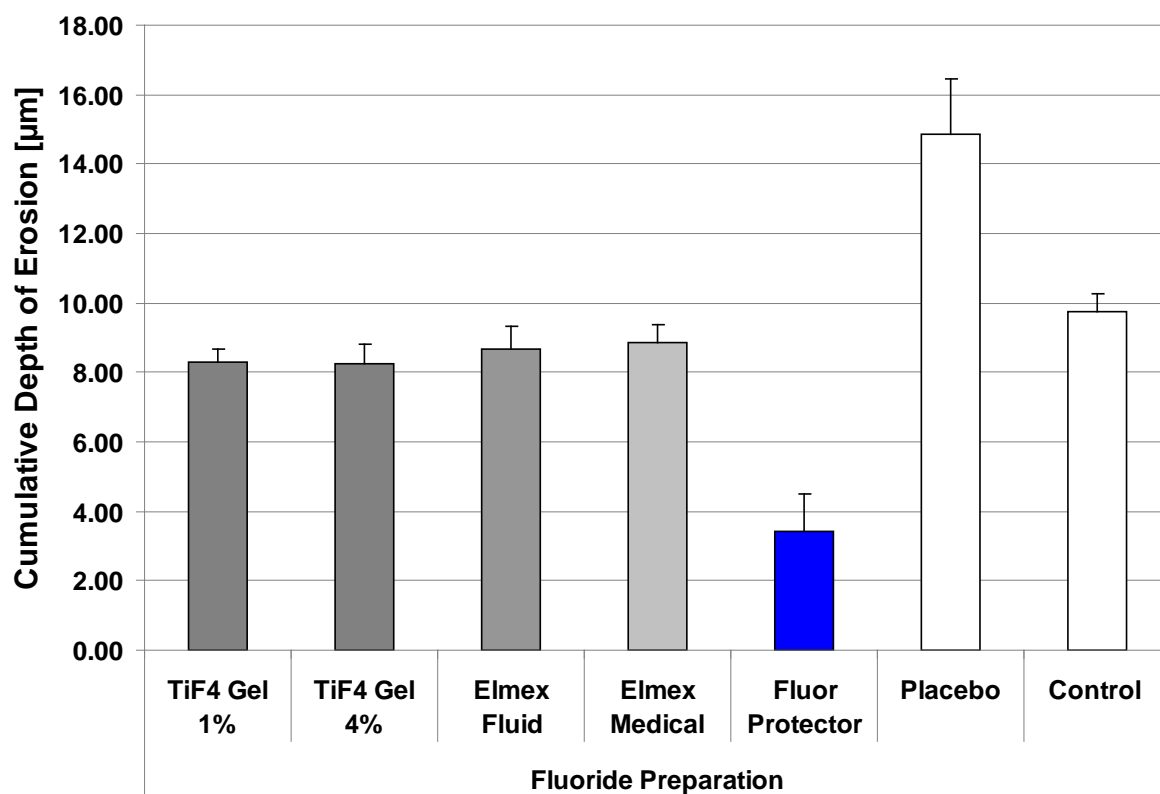


Fig. 16: Prevention of erosion by Fluor Protector. Bovine enamel samples were treated with different fluoride preparations (gels: 4 minutes, varnish was not removed after application) and exposed to 6 alternate cycles of acid exposure and remineralisation in artificial saliva (in total 72 minutes). Erosion depth was analyzed by white light confocal microscopy scanning. Fluor Protector provided the best protection from erosion.

Note: The high erosion depth observed in the placebo group (fluoride varnish) is, according to the authors of this study, possibly due to the following effect: The varnish may become porous after some erosion cycles and thus provide reservoirs for erosive medium underneath, resulting in longer erosive periods. The calcium loss is consequently higher under these conditions than in untreated control samples where the erosive medium can easily be washed away.

(Modified after Vieira et al., 2005⁴²).

Vieira A, Lugtenborg M, Ruben JL, Huysmans MC. (2006): Brushing abrasion of eroded bovine enamel pretreated with topical fluorides.

A later study by Vieira *et al.* evaluated the *in-vitro* effect of a single professional application of 4% titanium tetrafluoride (TiF₄), 1% amine fluoride (AmF) i.e. Elmex fluid and 0.1% difluorosilane varnish i.e. Fluor Protector in preventing wear caused by erosion and brushing abrasion. A total of 108 bovine enamel samples were used. Controls were divided into 3 groups: no pre-treatment (control), pre-treatment with a fluoride-free varnish (placebo), fluoridated varnish or fluoride varnish application followed by varnish removal. Wear was modeled by submitting the samples to 3 cycles of various regimens: erosion/remineralisation, abrasion/remineralisation or erosion/abrasion/remineralisation. Erosion was simulated by immersion in citric acid. Abrasion was carried out in a wear device and remineralisation took place in artificial saliva between cycles. Significant interaction between the wear regimens and fluoride treatments could be shown. Under erosion/remineralisation a significant wear

protective effect was found for the varnish groups, regardless of the fact whether they were fluoridated or not and removed or not. Under erosion/abrasion/remineralisation all products showed a significant protective effect except for TiF_4 . Abrasion/remineralisation conditions resulted in no significant effect. In conclusion, Fluor Protector and Elmex fluid protected bovine enamel against erosion followed by abrasion *in vitro*⁴³.

Vieira A, Jager DH, Ruben JL, Huysmans MC. (2007): Inhibition of erosive wear by fluoride varnish.

In a third study, Vieira *et al.* probed the anti-erosive effect of Fluor Protector with 11 volunteers wearing for 3 weeks, during working hours, appliances containing 2 control and 2 FP-treated human enamel samples. Erosion was simulated extraorally by immersing the appliances 3 times a day for 5 min in the soft-drink Sprite. At the end of each experimental day one control and one FP-sample were brushed for 5 seconds with a fluoridated dentifrice. The remaining samples were left unbrushed. Enamel volume loss was quantified by optical profilometry at day 5, 10 and 15. A statistically significant progression in enamel loss was found for the control groups and in the FP-group with brushing, but not in the FP-group without brushing. Moreover, the groups treated with Fluor Protector showed a significant lower volume loss than the control groups (see Fig. 17). The results indicate that Fluor Protector is effective in the reduction of erosive wear⁴⁴.

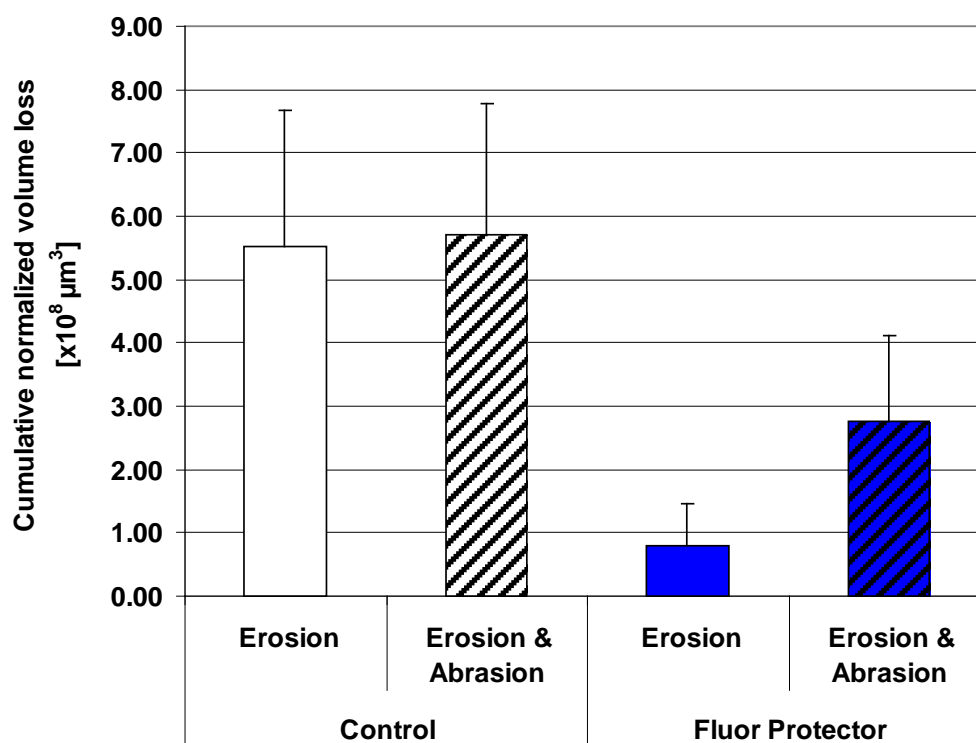


Fig. 17: Prevention of erosion and abrasion by Fluor Protector. Human enamel samples were worn by volunteers (each two controls and two treated with Fluor Protector). Erosion was simulated extraorally 3 times a day in the soft-drink Sprite. One control and one treated sample were brushed once daily, the other samples left unbrushed. Enamel volume loss was quantified by optical profilometry. The results on day 15 demonstrated a considerable protective effect of Fluor Protector treatment against erosion in comparison with the untreated control.

(Modified after Vieira *et al.*, 2007⁴⁴).

3.6 Use of Fluor Protector in particular cohorts of patients

3.6.1 Orthodontic patients

Excellent oral hygiene is a prerequisite for the optimal outcome of orthodontic work. As they create an unavoidable increase in the number of bacterial retention sites, fixed brace appliances pose a particular challenge to patients, dentists and orthodontists (see Fig. 18). Moreover, standard oral hygiene measures are hindered by the presence of wires and brackets and the natural flow of saliva and movement of the mucous membranes over the teeth is adversely affected. With inadequate oral hygiene, enamel lesions, caries and inflammation of the gums is likely to result.



Fig. 18: Application of Fluor Protector in orthodontic patients. Orthodontic patients have an increased caries risk as oral hygiene is hampered by the presence of fixed braces. Thus, the use of Fluor Protector is particularly beneficial in the prevention of caries and white spot lesions in these subjects. Due to its low viscosity, Fluor Protector is easy to apply and reaches even surfaces that are otherwise hard to access.

Both the caries-preventive effect of Fluor Protector and any effects on bonding within the framework of orthodontic therapy have been investigated.

3.6.1.1 *In-vitro* studies with Fluor Protector

It has been suggested that etching with phosphoric acid prior to bonding may predispose the uncovered etched enamel to caries - hence fluoride is usually applied at some stage in the bonding process⁴⁵. However, it needed to be assessed if fluoride affected the stability of the bonding.

Bryant S, Retief DH, Bradley E L, Denys FR. (1985): The effect of topical fluoride treatment on enamel fluoride uptake and the tensile bond strength of an orthodontic bonding resin.

Bryant *et al.* investigated in an *in-vitro* study the effect of fluoride uptake of different topical fluoride treatments on the tensile bond strength of an orthodontic bonding system. Fluor Protector, APF, SnF₂ and Duraphat were applied prior to acid etching and bonding. The facial surfaces of 10 maxillary incisors served as controls, and 10 each for each test product (total n=50). Analysis showed that the enamel surface treated with Fluor Protector acquired significantly more fluoride than the enamel surfaces treated with the other products. No significant adverse effects on the bond strengths of orthodontic attachments were demonstrated for any of the fluoride treatments⁴⁶.

3.6.1.2 Clinical experience with Fluor Protector

Stecksén-Blicks C, Renfors G, Oscarson ND, Bergstrand F, Twetman S. (2007): Caries-preventive effectiveness of a fluoride varnish: a randomized controlled trial in adolescents with fixed orthodontic appliances.

This double blind, randomized, placebo-controlled study aimed at evaluating the efficacy of topical fluoride varnish applications on white spot lesion formation in adolescents undergoing orthodontic treatment with fixed braces. The children were 12 to 15 years old; test and control groups included 137 and 136 children respectively. The test group received six

weekly applications of Fluor Protector and the control group a placebo varnish. At debonding, the incidence and progression of white spot lesions (WSL) as scored from digital photographs was evaluated by 2 independent examiners. The prevalence of WSL at baseline was comparable for both groups (4.3% in the Fluor Protector group, 4.0% in the control group). At debonding, the prevalence of WSL was 11.7% in the Fluor Protector group versus 29.7% in the control group, thus, the WSL incidence between the test group (7.4%) and the control group (25.3%) differed significantly (see Fig. 19). The mean progression score was also significantly lower in the fluoride varnish group (0.8 ± 2.0) than in the placebo group (2.6 ± 2.8). Moreover, in the analysis of the score distribution (see Fig. 20), it becomes evident that treatment with Fluor Protector decreased the frequency of WSL at all three levels as compared to the control. In conclusion, the authors strongly advocate use of fluoride varnish to prevent WSL formation adjacent to brackets in orthodontic patients⁴⁷.

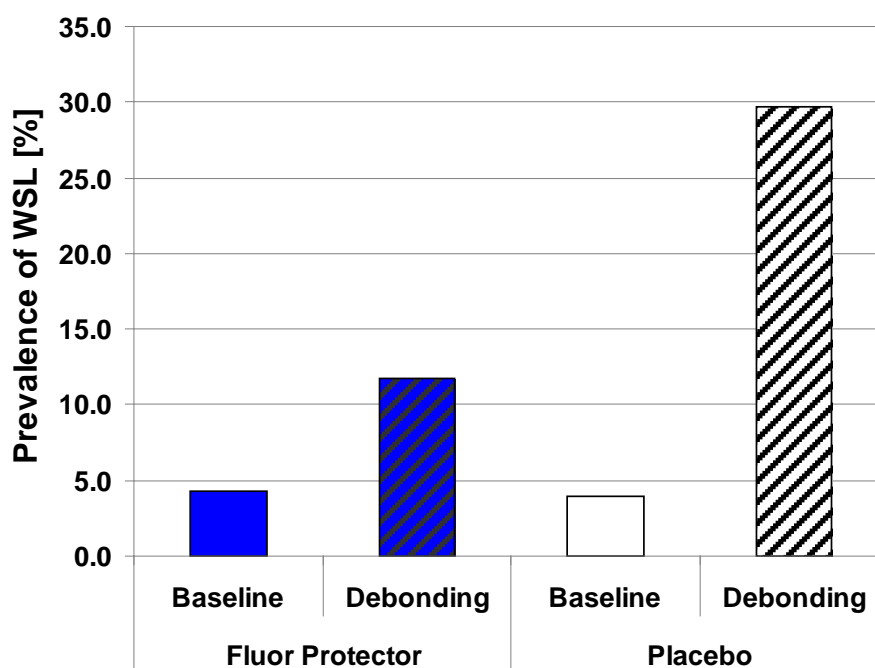


Fig. 19: Prevalence of white spot lesions (WSL) in orthodontic patients after treatment with Fluor Protector or a placebo varnish. 273 adolescents with fixed orthodontic braces were either treated once a week for six weeks with Fluor Protector ($n=137$) or a placebo varnish ($n=136$). The prevalence of white spot lesions was evaluated at baseline and after debonding. Treatment with Fluor Protector considerably decreased the frequency of WSL.

(Modified after Stecksén- Blicks et al., 2007⁴⁷).

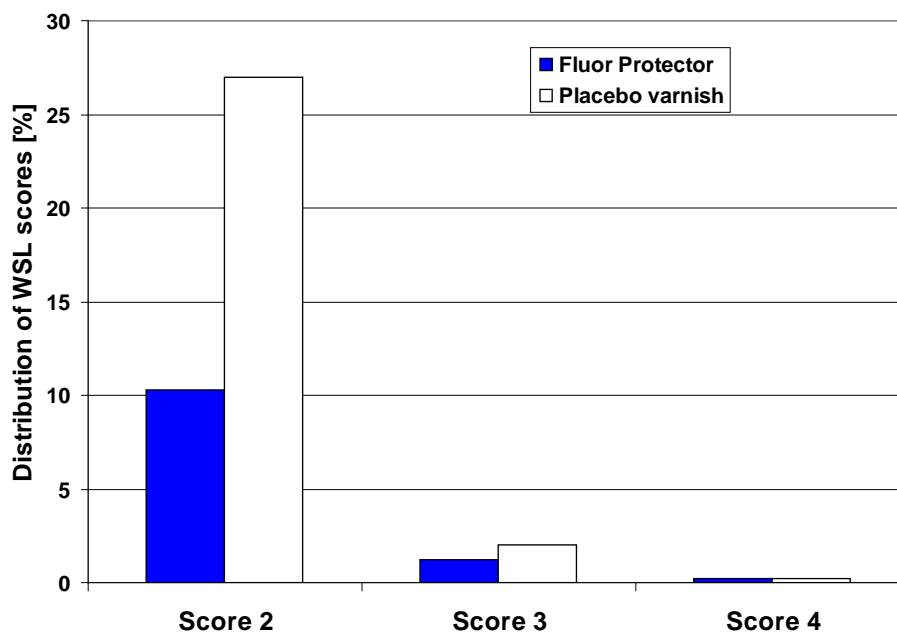


Fig. 20: Percentage distribution of WSL scores at the time of debonding. Score 2: slight white spot formation (thin rim); score 3: excessive white spot formation (thicker rim); score 4: WSL with cavitation.

(Modified after Stecksén-Blicks *et al.*, 2007⁴⁷).

Adriaens ML, Dermaut LR, Verbeeck RMH. (1990): The use of "Fluor Protector", a fluoride varnish, as a caries prevention method under orthodontic molar bands.

Adriaens *et al.* analysed the effectiveness of Fluor Protector (0.7% fluoride content) for caries prevention under orthodontic bands. 104 molars in 28 patients with orthodontic bands were included in a 'split-mouth design' study. The study showed that Fluor Protector can significantly prevent the formation of initial carious lesions under orthodontic bands⁴⁸.

Kronenberg O, Lussi A. (2009): Preventive effect of ozone on the development of white spot lesions during multibracket appliance therapy.

Kronenberg *et al.* focused on the prevention of white spot lesions by various treatments in orthodontic patients. 20 patients requiring fixed braces and with poor oral hygiene were included in this split-mouth study. The four quadrants of each patient were either treated with ozone (which is suggested to be toxic to bacteria), a combination of Cervitec and Fluor Protector or served as controls. The visible plaque index (VPI) and white spot formation were analysed clinically. The average VPI in all four quadrants was 55.6%. Considering the development of new, clinically visible white spots, treatment with Cervitec/Fluor Protector resulted in formation of WSLs in only 0.7% of the areas. This was significantly less than the quadrants treated with ozone (3.2%). Thus, the caries protective effect of the Cervitec/Fluor Protector treatment was superior to ozone or no treatment at all⁴⁹.

3.6.2 Patients with esthetic restorations

The need for long term caries prophylaxis clearly includes many patients who have undergone restorative work. A frequently voiced concern is that fluoride varnishes may cause discolouration of esthetic restorations due to staining by absorption. Unacceptable colour matches or staining are major reasons for unsatisfying anterior restorations⁵⁰. Fig. 21 illustrates the esthetic qualities of Fluor Protector: In contrast to Duraphat, it is invisible after application on teeth.

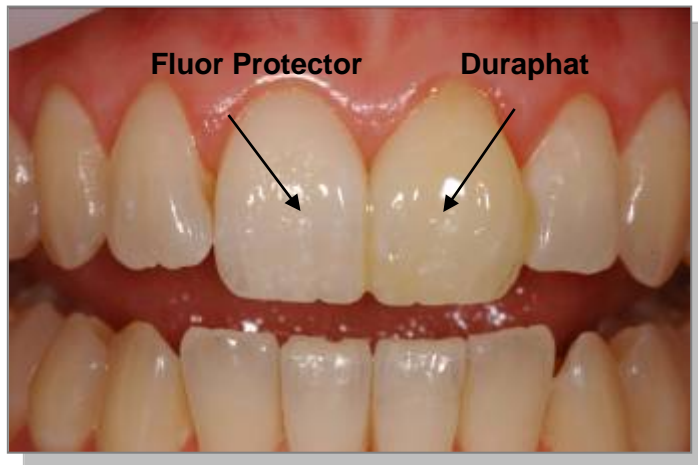


Fig. 21: Outstanding esthetic properties of Fluor Protector. Fluor Protector was applied on tooth 11, Duraphat on tooth 21. The application of Fluor Protector is invisible and thus highly aesthetical, whereas Duraphat provokes a yellowish discolouration.

(R&D Ivoclar Vivadent, Schaan, Liechtenstein)

Moreover, as Fig. 22 shows, Fluor Protector was the only out of 4 different fluoride varnishes which retained a smooth surface after a 4-day immersion in physiological buffer, thus providing a highly esthetical, homogenous appearance after the application on the teeth.

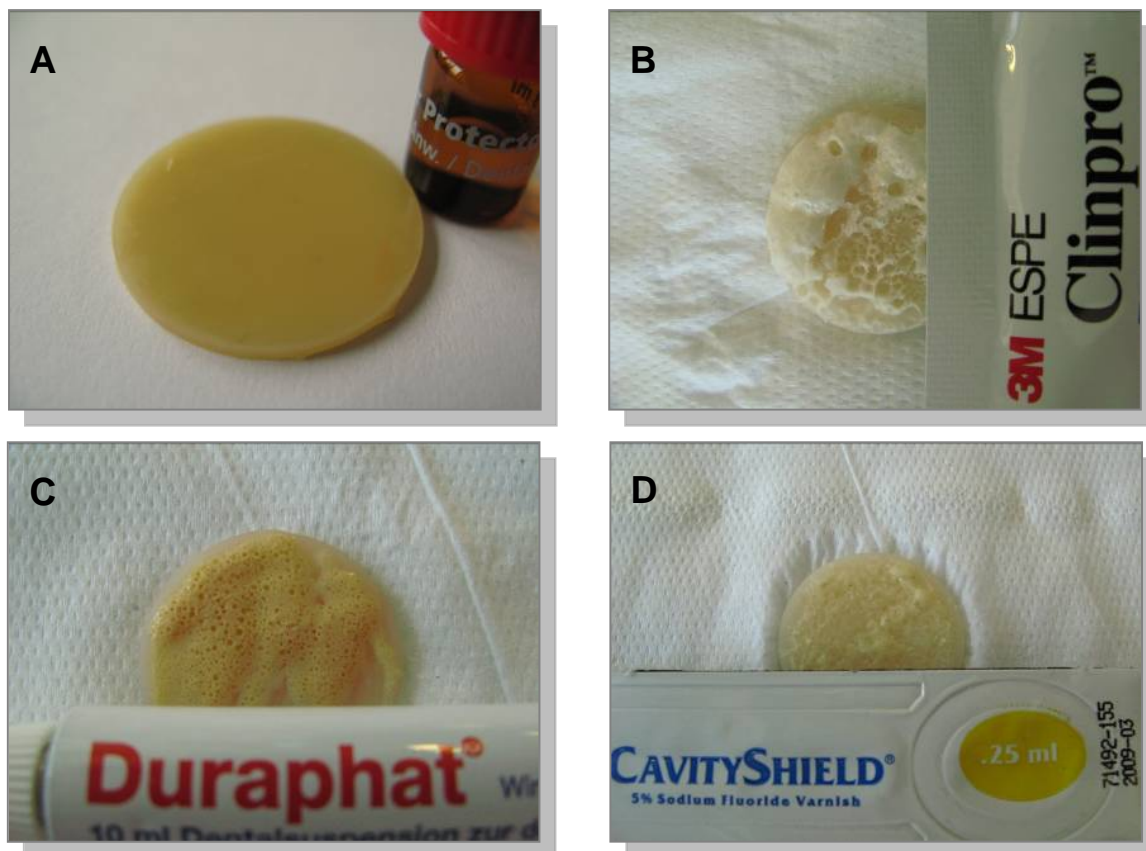


Fig. 22: Surface of different fluoride varnishes after immersion in buffer. Specimens of Fluor Protector (A), Clinpro (B), Duraphat (C) and Cavity Shield (D) were prepared and immersed for 4 days in buffer at a physiological pH. Only Fluor Protector retained a smooth surface.

(Ivoclar Vivadent, R&D, Schaan, Liechtenstein, 2008).

Autio-Gold JT, Barrett AA. (2004): Effect of fluoride varnishes on color stability of esthetic restorative materials.

Autio-Gold *et al.* evaluated the colour change of various restorative materials after the treatment with different fluoride varnishes: Duraphat (Colgate), Cavity Shield (OMNII), Duraflor (Pharmascience Inc.) and Fluor Protector (Ivoclar Vivadent). Baseline colour measurements were taken of all materials and specimens were suspended in artificial saliva. Fluoride varnishes were applied twice and finally specimens were brushed with an electric toothbrush. They found significant colour changes in all restorative materials tested with Duraphat. Cavity Shield produced significant changes on the composite Esthet-X (Dentsply) shade A1 (see Fig. 23). The changes were considered visually perceptible though all were within the clinically acceptable range. No significant colour changes were noted for Duraflor or Fluor Protector⁵¹. *Note: The formulations of Duraphat and Duraflor used in this study are no longer available. The recent Duraphat formulation would provoke less discoloration.*

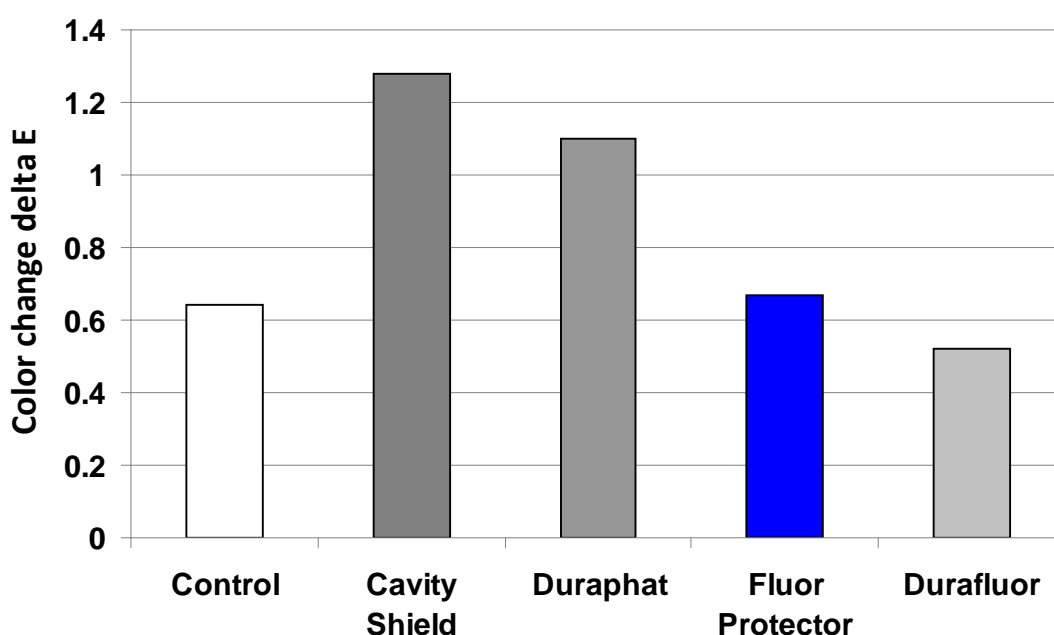


Fig. 23: Mean colour change delta E of Esthet-X (Dentsply) after treatment with fluoride varnishes. Experimental specimens of the composite material Esthet-X, shade A1, were produced, immersed in artificial saliva and treated twice with various fluoride varnishes with brushing in between and afterwards. Colour measurements were performed with a tristimulus colorimeter. Fluor Protector and Duraflor did not induce significant colour changes, whereas Cavity Shield and Duraphat changed the colour of the material considerably.

Note: The formulations of Duraphat and Duraflor used in this study are no longer available. The recent Duraphat formulation would provoke less discoloration.

(Modified after Autio-Gold et al., 2004⁵¹).

Debner T, Warren DP, Powers JM. (2000): Effects of fluoride varnish on color of esthetic restorative material.

A study by Debner *et al.* also evaluated the colour stability of a compomer, hybrid ionomer and a composite restorative material after exposure to the fluoride varnishes Duraphat, Duraflor and Fluor Protector. Varnishes were applied just once and cleaning was performed

with a toothbrush and toothpaste. Directly after application, only Fluor Protector did not affect the colour of the materials⁵².

3.6.3 Children

Fluoridation is important for oral health already in children. However, in young children, special attention has to be taken considering excessive fluoride intake by accidental ingestion of fluoridated toothpaste, mouthwash etc. Hence, the use of a fluoride varnish is particularly suitable for children as it minimizes the risk of fluoride ingestion but simultaneously provides a very effective topical fluoridation⁵³. Treatment with Fluor Protector is safe and can be used already for children of preschool age. Moreover, with an average application time of only 3-5 minutes per patient, the acceptance even by very young children is very positive^{5,54}.

Petersson, LG. Twetman S, Pakhomov GN. (1998): The efficiency of semi-annual silane fluoride varnish applications: a two year clinical study in pre-school children.

In a large Swedish study, 5137 preschool children aged 4-5 years were treated with Fluor Protector or a placebo varnish. Treatment took place once every six months with all children/parents receiving counseling with regard to tooth brushing and diet. Caries prevalence data was collected at baseline and after 1 and 2 years. No statistically significant difference in the caries incidence could be observed in the total number of carious/decayed and filled surfaces (dfs) between the control and the test group. However, the incidence of proximal lesions (dfsa) was significantly lower in the fluoride group than in the placebo group. In children with clinical caries at the outset i.e. dfsa scores of 1-4 or ≥ 5 proximal caries was reduced by 19% and 25% respectively compared to the placebo group (see Fig. 24)⁵⁵.

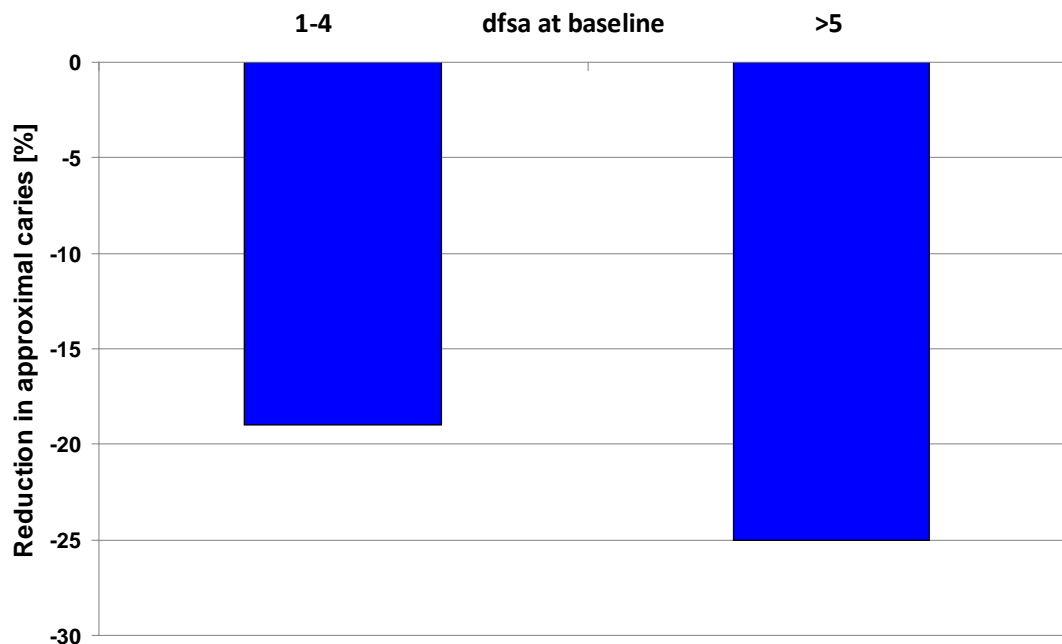


Fig. 24: Reduction in proximal caries after 2 years treatment with Fluor Protector in children with clinical caries at baseline. 5137 Swedish children, aged 4-5 years were treated semi-annually with Fluor Protector (n=2535) or a placebo varnish (n=2602). The caries incidence after 2 years was evaluated by clinical examinations. For both intermediate (1-4) and high (>5) dfsa values at baseline (dfsa: index of decayed and filled proximal surfaces), the incidence of proximal caries decreased by 19% and 25%, respectively, in the Fluor Protector group compared to the placebo group.

(Modified after Petersson et al., 1998⁵⁵).

Petersson LG, Magnusson K, Andersson H, Almquist B, Twetman S. (2000): Effect of quarterly treatments with a chlorhexidine and a fluoride varnish on approximal caries in caries-susceptible teenagers: A 3-year clinical study.

This 3-year study compared the effect of two different dental varnishes (Fluor Protector and the chlorhexidine/thymol varnish Cervitec) on the incidence of proximal caries in teenagers with proven caries susceptibility. 180 subjects with at least 2 proximal enamel caries lesions were included. Varnish treatment occurred every 3rd month in both groups. Proximal caries were recorded from bitewing radiographs. In both groups, the differences of the caries incidence at baseline and after 3 years were not statistically significant (*Note: The study comprised no real control group which did not receive any treatment. The comparison of two groups receiving different anti-caries treatments does not necessarily give different results*). Hence, the authors concluded that treatments every 3rd month with either a fluoride- or a chlorhexidine/thymol-containing varnish was promising with respect to reducing proximal caries incidence and progression in teenagers with proven caries susceptibility⁵⁶.

Caries is not only a problem in children of developed countries. In developing countries, oral hygiene is often poor and consequently, the caries incidence in children is often elevated. Thus, the possibility to use fluoride varnishes like Fluor Protector even under field conditions, e.g. in schools, may be particularly beneficial for the promotion of oral health in the population of developing countries.

Monse-Schneider B, Heinrich-Weltzien R. (2002): Preventive oral health care programme for Filipino children.

In 1998, a preventive oral health care programme was initiated in 19 elementary schools in the Philippines. It comprised atraumatic restorative treatment for decayed teeth, daily supervised tooth brushing with fluoridated toothpaste and the application of Fluor Protector by trained parents every 4th month as well as diverse educational activities involving children, parents and teachers. At baseline, 1600 7-year old children were examined. These children had a mean caries prevalence of 7.2 dmft (decayed, missing and filled teeth) for the primary dentition and of 1.2 DMFT for the permanent dentition. Only 8.8% were entirely caries free. Three years later, of the 1162 children who were re-examined, 16.2% were caries-free (see Fig. 25); the remaining children showed a mean caries prevalence of 1.6 DMFT. The small increase of 0.4 DMFT in the caries incidence was recognized as prove for the effectiveness of the comprehensive preventive programme – without intervention, the annual increase in DMFT was expected to be at least 1.0, thus approximately 3.0 for the 3-year period⁵⁷.

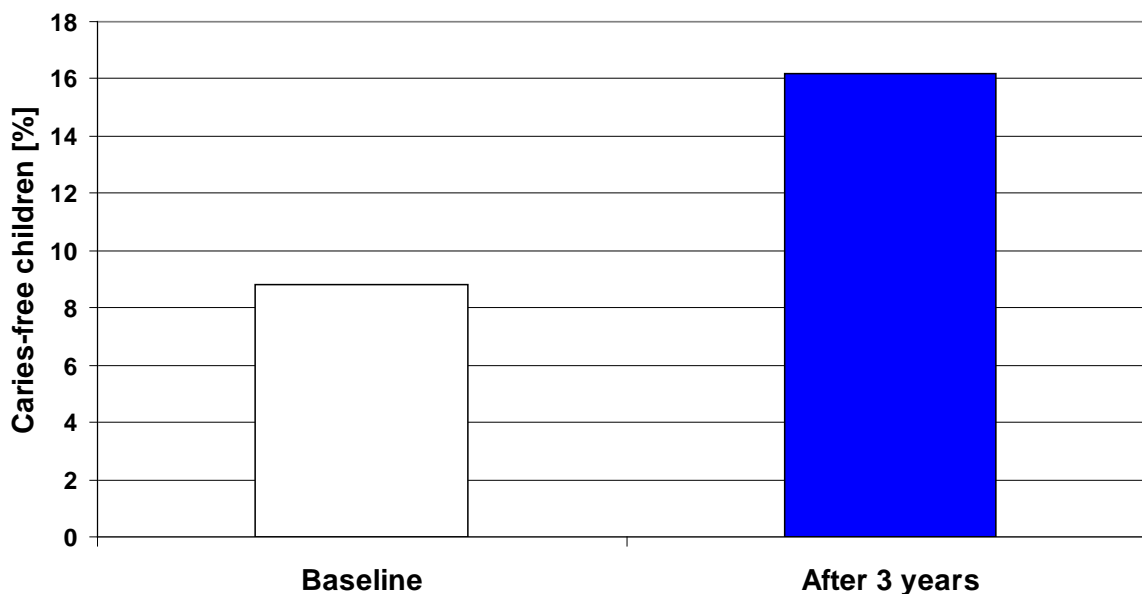


Fig. 25: Increase in the frequency of caries-free children participating in a preventive oral health programme in the Philippines including Fluor Protector application. 1600 children at the age of 7 were subjected to a preventive oral health programme including among other activities including supervised tooth brushing and the application of Fluor Protector every 4th month. The percentage of caries-free children after 3 years nearly doubled (16.2% versus 8.8%).

(Modified after Monse-Schneider *et al.*, 2002⁵⁷).

3.6.4 Elderly patients

Aging populations and an increase in those that are able to retain some or most of their natural teeth into old age means that root caries also poses an increasing problem. Furthermore, manual dexterity and therefore adequate cleaning are often a challenge for elderly patients, in particular, if they suffer from diseases like Alzheimer's or Parkinson's. Just as children can be treated with fluoride varnishes in school-based programmes, the elderly can also be efficiently treated in nursing homes. Varnishes are quick and easy in their application⁵³ and are able to set in contact with intra-oral moisture¹ providing thus a convenient means to prevent caries in elderly patients.

Brailsford SR, Fiske J, Gilbert S, Clark D, Beighton D. (2002): The effects of the combination of chlorhexidine/thymol- and fluoride-containing varnishes on the severity of root caries lesions in frail institutionalized elderly people.

Brailsford *et al.* compared the clinical effects of a combination of Fluor Protector and Cervitec on existing root caries lesions in a group of 102 frail elderly subjects aged 78-87. In this randomized double blind longitudinal study subjects were randomly allocated to a test or placebo group. All subjects received Fluor Protector applied to all leathery and soft root caries lesions. The test group comprised those receiving Cervitec in addition to Fluor Protector and the placebo group received a placebo varnish in addition to FP. Treatment was repeated 5 times over a year. In the test group the clinical severity of the lesions did not change significantly. In the placebo group the mean lesion width, the height and the length of the exposed root increased significantly. The authors conclude that the combination of Cervitec and Fluor Protector is a useful, simple, quick and non-invasive method for the control and management of existing root caries lesions in elderly people⁵⁸.

4. Biocompatibility

4.1 Toxicity of Fluor Protector: Acute toxicity, cytotoxicity, mutagenicity

For Fluor Protector, acute oral toxicity was determined in rats. The concentration which killed 50% of the animals (lethal dose 50; LD₅₀) was found to be 6.1 g per kg bodyweight (1).

The cytotoxicity of extracts of Fluor Protector was examined in the Agar Diffusion Test using the mouse cell line L929. No cytotoxic potential was observed at all concentrations tested (2).

Mutagenicity, i.e. the potential to induce DNA alterations, of Fluor Protector extracts was tested in the widely used bacterial mutagenicity test (AMES). Concentrations of up to 100 µl 100% extract per plate did not induce DNA mutations in any of the 5 test strains (*Salmonella typhimurium*) with or without metabolic activation (3).

4.2 Sensitisation and irritation

Neither a sensitising nor an irritating potential is known for any of the constituents of Fluor Protector.

4.3 Conclusion

For Fluor Protector, no adverse toxic, sensitising or irritating effects could be observed.

Regarding fluoride, the toxic dose for children is estimated to be 5 mg fluoride per kg bodyweight. The total amount of fluoride administered at the recommended dose approximates 0.5 mg per treatment. Thus, toxic fluoride concentrations in the serum will never occur following regular application.

On the basis of the current knowledge, it can be concluded that Fluor Protector is safe when administered at the recommended doses.

4.4 References biocompatibility

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