Dental Varnish Systems in Focus
Preventive and minimally invasive treatment strategies have become more and more important in dentistry. Varnish systems containing active ingredients play an increasingly significant role in this development. Ivoclar Vivadent AG is a worldwide leader in the development and production of dental varnishes. These innovative dental solutions are based on decades of expertise from Ivoclar Vivadent AG in this field. Fluor Protector, the protective fluoride varnish, for example, has been successful on the market for over 40 years. Newer varnish systems, such as Cervitec® Plus containing chlorhexidine, Fluor Protector S with fluoride and VivaStyle® Paint On Plus for whitening the teeth, are the result of this vast experience plus close cooperation with dentists and their teams. Ivoclar Vivadent AG will continue to develop new, needs-oriented varnish systems in the future and further extend its know-how in this area.

All the formulations on the market were subject to numerous in vitro and clinical investigations, both within the company as well as in cooperation with international study partners. Varnish systems demonstrate a wide range of applications and allow for the gentle and effective care of both natural teeth and high-quality restorations.

The present Report focuses on various varnish systems with regard to their different compositions, properties and quality attributes – as well as clinical use. A selection of study results completes the overview.
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Dental Varnishes: Types and Applications

Introduction

Technical and medical applications of varnishes

Varnishes can be defined as coating materials that are applied to surfaces in a thin layer. They form a continuous and solid film after undergoing chemical or physical changes. This solid end state differentiates varnishes from medical/cosmetic lotions and creams, which may also be applied in layers, but do not form a solid film.

Varnishes are ubiquitous in daily life and for technical, cosmetic or medical purposes, their versatile application makes them indispensable. Depending on their composition and additives, varnishes are mainly intended for the protection or decoration of surfaces. However, they can also demonstrate special properties as functional coatings. Some examples of the latter are listed in Table 1.

Varnishes are employed in liquid or powder form, depending on their intended use or necessary processing conditions. Emulsion paints, which are aqueous dispersions of polymer particles, are an everyday example. Somewhat more specialized, but no less common, are solvent-borne varnishes, based on dissolved polymer film formers or reactive varnishes made of monomer or prepolymer raw materials (alkyd resin varnishes). For economic and ecological reasons, solvent-free varnishes in liquid or powder formulations are preferred for large-scale applications, such as spray-painting car parts or furniture. Table 2 provides a short overview of common varnish systems.

<table>
<thead>
<tr>
<th>Usage</th>
<th>Purpose</th>
<th>Protection</th>
<th>Decoration</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical</td>
<td></td>
<td>Corrosion</td>
<td>Colouring</td>
<td>Electrostatic discharge</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Water absorption</td>
<td>Surface gloss</td>
<td>Self-cleaning</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pest infestation</td>
<td></td>
<td>Photocatalytic properties</td>
</tr>
<tr>
<td>Cosmetic</td>
<td></td>
<td>UV protection (Hairspray)</td>
<td>Nail polish</td>
<td>Styling (Hairspray)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hairsprays</td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td></td>
<td>Wear protection for glass ionomer cements</td>
<td>Fluoride varnishes</td>
<td>Antimicrobial properties</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cervical desensitization</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1 Function of varnishes used for technical, cosmetic and medical purposes
Irrespective of the varnish type, appearance or intended use, all varnishes contain film formers, which impart the desired measure of solidity and persistence on the surface after curing [1].

These film formers, their curing and interaction with the surface, surrounding conditions, as well as the remaining varnish components, determine the properties of a varnish.

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Composition</th>
<th>Curing</th>
<th>Technical examples</th>
<th>Dental examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid</td>
<td>Dispersion of polymer particles in a liquid medium</td>
<td>Physical</td>
<td>Emulsion paints / Wall paints</td>
<td>Fluoride varnishes</td>
</tr>
<tr>
<td></td>
<td>Solution of polymers in a solvent</td>
<td>Physical</td>
<td>Wood varnishes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reactive pre-stages in solvents</td>
<td>Chemical</td>
<td>Wood varnishes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1-component and 2-component isocyanate- or epoxy-based systems</td>
<td></td>
<td>Protective steel coatings</td>
<td></td>
</tr>
<tr>
<td></td>
<td>UV-/light-curing monomer mixtures or solutions</td>
<td>Chemical</td>
<td>Wood varnishes</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Protective steel coatings</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Car paints</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fluoride varnishes</td>
<td></td>
</tr>
<tr>
<td>Solid</td>
<td>Powder coatings</td>
<td>Physical and chemical</td>
<td>Car paints, Coil coatings</td>
<td>None known</td>
</tr>
</tbody>
</table>

Table 2  Common varnish systems for technical and dental applications
<table>
<thead>
<tr>
<th>Components</th>
<th>Function</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Film formers</td>
<td>Film formation on surfaces</td>
<td>Polymers (cellulose derivatives, polyvinyl compounds, styrol-butadiene-acrylate copolymers, polyacrylates, polyurethane, polyamides ...)</td>
</tr>
<tr>
<td></td>
<td>Mechanical stability</td>
<td>Reactive monomers (epoxy resins, isocyanates, acrylates, linseed oils ...)</td>
</tr>
<tr>
<td></td>
<td>Inclusion/delayed release of functional additives</td>
<td>Non-reactive low-molecular compounds (various coniferous resins)</td>
</tr>
<tr>
<td>Solvents</td>
<td>Surface wettability</td>
<td>Water</td>
</tr>
<tr>
<td></td>
<td>Homogeneity</td>
<td>Organic solvents (ethanol, butanol, acetone, methyl-ethyl ketone, butyl acetate, methoxypropyl acetate, xylene ...)</td>
</tr>
<tr>
<td></td>
<td>Handling</td>
<td>Low-viscosity monomers (styrol, 2-ethylhexyl glycidyl ether, HEMA ...)</td>
</tr>
<tr>
<td>Reactive diluents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pigments/Colourants</td>
<td>Colouring</td>
<td>Pigments (titanium dioxide, iron oxide ...)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Colourants</td>
</tr>
<tr>
<td>Functional additives</td>
<td>Rheology modifiers, surfactants</td>
<td>Rheology modifiers, surfactants (mostly high-boiling solvents or reactive diluents)</td>
</tr>
<tr>
<td></td>
<td>Electrostatic discharge</td>
<td>UV protection (triazines, benzophenone derivatives)</td>
</tr>
<tr>
<td></td>
<td>Fluoride source</td>
<td>Fluoride sources (metal fluorides, ammonium fluorides, fluor silanes, fluoride glass)</td>
</tr>
<tr>
<td></td>
<td>Bacterial control</td>
<td>Bacterial control (chlorhexidine, thymol, benzalkonium chloride, octenidine)</td>
</tr>
<tr>
<td>Odorants/Flavourings</td>
<td>Improvement of odour and flavour</td>
<td>Miscellaneous</td>
</tr>
</tbody>
</table>

Table 3  Varnish components and function

In addition to film formers and depending on the requirements and intended use, varnishes contain solvents, reactive diluents, pigments, colourants, odorants/flavouring substances and functional additives. Table 3 provides an inevitably incomplete overview of possible varnish components – given the multitude of potential application areas.

The liquid varnishes preferred for medical and cosmetic purposes can be divided into “physically cured” and “chemically cured” systems. Depending on the base composition of the varnish, additional subdivisions present themselves, such as one- or multi-component, light-, auto- or oxidatively-cured, isocyanate- epoxy- or acrylate-based etc. More extensive lists can be found in the corresponding technical literature [1].
**Varnish systems in dentistry**

In dentistry, only water- or solvent-based liquid systems are used, as they enable simple, quick and reliable application on the surfaces to be treated. Disregarding niche applications for the moment (e.g. white pigmented varnishes for short-term tooth whitening [2]), varnishes are used in dentistry for topical application and delayed release of active compounds (e.g. fluoride compounds, chlorhexidine, bleaching agents) and as mechanically effective protective varnishes. In this context, the varnish layer assumes the role of a matrix, which enables the slow release of active substances, such as fluoride compounds, antimicrobial compounds or oxidative bleaching agents, on the tooth surface.

There are certain basic requirements placed on dental varnishes, which are intended to ensure safe application and treatment success. A homogeneous quality without phase separation or insoluble components, quick and technique-tolerant application using standard equipment, biocompatibility and good storage stability, are all important aspects for users.

The adhesion of a varnish to the tooth surface is determined by the physical and chemical properties of the interface. The main determining factors are the wettability of the surface and adhesion-promoting interactions between the tooth and the varnish, for example, by polar groups or bonding groups on the film former. On microstructural surfaces, such as demineralized enamel [3], the chemical adhesion can be enhanced by the mechanical retention of the varnish. Figure 1 shows a schematic representation of the chemical and mechanical adhesion mechanisms of varnishes on the tooth structure.

The wettability of the substrate by the liquid varnish is a mandatory requirement for a coating, and is determined by the relative surface tension of the varnish and the substrate. The surface tension of the tooth is determined by its surface quality (intact, demineralized, polished) and any pellicle or plaque that may be present [4]. In the varnish, the surface tension is produced by the strong, usually polar interactions of the varnish components with each other. A varnish with a high

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**Fig. 1** Chemical (left) and mechanical (right) adhesion mechanisms of varnishes to the tooth structure.
surface tension flows less favourably over e.g. very rough surfaces. If the surface tension of the varnish is much higher than that of the substrate, wetting will not occur, as the attractive interactions of the varnish particles amongst themselves cannot be overcome.

The attraction of the interfaces of solid phases is called adhesion and is defined as force per unit area. Adhesion or “bond strength” is usually measured as the force per unit area necessary to induce de-bonding. The chemical aspects of adhesion are determined by those groups in the film former, which demonstrate surface affinity, such as acid groups and other polar or chelating groups (Figure 1). Due to the polarity of tooth structure, the affinity of polymer-based polar film formers, such as cellulose derivatives, polycarbamides and polyacrylates, is generally good. However, low-molecular conifer resins also contain polar groups, which permit sufficient compatibility between the tooth and the varnish.

The micromechanical retention of varnishes on tooth surfaces becomes evident on demineralized i.e. porous or rough surfaces. It is determined, as can be seen in Figure 1, by the degree of infiltration of the retentive structural elements and thus by the wettability of the tooth structure. Naturally low-viscosity varnishes with a lower surface tension have an advantage in this respect and can better benefit from this bonding mechanism.

The extent to which adhesion is either chemical or mechanical, is in practice impossible to separate. This is because film formers with a high chemical affinity to the substrate usually also enhance wettability and therefore mechanical retention. In general, hard or at least tough-elastic varnishes lead to better mechanical stability and adhesion than very soft layers. The curing/setting of a varnish is therefore an important step in the formation of an adequately adhesive layer.

Mechanisms of varnish curing

Physically curing liquid varnishes

Most of the varnishes used in dentistry contain biocompatible solvents, such as water, ethanol, acetone or esters. In these solvents, film formers based on high-molecular polymers (e.g. polyamides, cellulose derivatives) or low-molecular resins (e.g. colophony) are dissolved. Once applied to the tooth, the solvent starts to evaporate, meaning the film former and active ingredients are available in ever increasing concentrations (Figure 2). That is, the concentration of the active substance in the hardened varnish is increased. As evaporation is a purely physical process which happens without any chemical reaction, such varnishes are referred to as physically-cured.

The increasing concentration of the solid and dissolved components of the varnish during evaporation of the solvent leads to a closer proximity of the film forming molecules to each other. This induces an increase in van der Waals forces and/or the purely mechanical interactions of the molecules amongst each other. These interactions eventually lead to the immobility of the molecules and thus the formation of a layer on the tooth surface. The strength and consistency of the formed layer can be controlled by way of the physical and chemical properties of the film formers.

In high-molecular film formers, solidification is based on the entanglement of the polymer chains that occurs with the rise in concentration. This severely restricts their mobility. In contrast, low-molecular film formers, which usually consist of water-insoluble coniferous resins in ethanol, are deposited on the surfaces as a tough-elastic layer due to attracting van der Waals forces (Figure 2).
The mechanical stability of the varnish layer is determined by the mobility of the film former molecules at usage temperature, which in turn is affected by the molecules' flexibility and water absorption. The mechanical strength of the varnish layer increases with the molecular weight of the film formers such that polymeric varnish raw materials lead to more solid varnishes than low-molecular film formers, such as colophony.

In order to produce sufficiently stable films that adhere to the tooth surface in the warm and humid oral environment, special film formers that feature good biocompatibility are required. The film-forming polymers must be soluble in the solvent used, must be able to soundly wet the tooth surface as a solution and demonstrate sufficient interaction with the substrate in order for the varnish film to maintain the adhesion to the tooth. As the tooth structure constitutes a polar surface, polar polymers serve well as film formers for dental varnishes. In the case of high-molecular polymers – these are often cellulose derivatives which feature high biocompatibility (e.g. hydroxyethyl cellulose or cellulose nitrate) or synthetic polymers, such as polyacrylates or polyamides. Polysiloxanes are rarely used. Due to their chemical inertness they are only used in tooth whitening varnishes.
Of the low-molecular film formers, coniferous resins such as colophony, rosin resins or their chemically-modified derivatives are usually employed. These viscous and sticky substances are dissolved in ethanol and mixed with the desired active ingredient to achieve a manageable consistency. The film-forming properties of the low-molecular resins and their adhesion to a polar substrate can primarily be attributed to van der Waals interactions [5]. Combinations of high- and low-molecular film formers are also used on occasion in order to supplement the mechanical film properties of the low-molecular resins with film-fortifying polymers and to enhance the mechanical properties of the film.

In general, the film formers used in physically cured varnishes demonstrate good storage stability due to the absence of reactive groups. They also feature good handling and sufficient adhesion to the tooth surface for most applications. Therefore, they represent the largest group among dental varnishes, covering a wide range of applications - as shown in Table 4.

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Film formers</th>
<th>Solvents</th>
<th>Active ingredients</th>
<th>Product examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoride varnish</td>
<td>Polyamides + colophony</td>
<td>Ethanol</td>
<td>Sodium fluoride</td>
<td>Cavity Shield/3M ESPE</td>
</tr>
<tr>
<td></td>
<td>Colophony</td>
<td>Ethanol</td>
<td>Sodium fluoride</td>
<td>Duraphat/Colgate-Palmolive</td>
</tr>
<tr>
<td></td>
<td>Rosin (resin acids)</td>
<td>Ethanol</td>
<td>Sodium fluoride</td>
<td>Enamelast/Ultradent/PreviDent Varnish/Colgate-Palmolive</td>
</tr>
<tr>
<td></td>
<td>Nitro-cellulose</td>
<td>Ethanol, Ethyl acetate, i-Pentyl propionate</td>
<td>Sodium fluoride</td>
<td>Polylfluorid L/VOCO</td>
</tr>
<tr>
<td>Desensitization</td>
<td>Acrylate-copolymers Polyacrylates</td>
<td>Ethanol, water</td>
<td>Ammonium fluoride</td>
<td>Fluor Protector S/Ivoclar Vivadent AG</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ethanol, water</td>
<td>Potassium fluoride, Phosphonic acids</td>
<td>VivaSens/Ivoclar Vivadent</td>
</tr>
<tr>
<td>Bacterial control</td>
<td></td>
<td>Ethanol, water</td>
<td>Chlorhexidine diacetate, thymol</td>
<td>Cervitec Plus/Ivoclar Vivadent AG</td>
</tr>
<tr>
<td></td>
<td>Sandarak</td>
<td>Ethanol</td>
<td>Chlorhexidine diacetate</td>
<td>Bio C CHX/Biodent</td>
</tr>
<tr>
<td>Bleaching</td>
<td>Ethylcellulose</td>
<td>Ethanol</td>
<td>Hydrogen peroxide</td>
<td>VivaStyle Paint On Plus/Ivoclar Vivadent AG</td>
</tr>
<tr>
<td></td>
<td>Silikonpolymere</td>
<td>Unknown</td>
<td>Hydrogen peroxide</td>
<td>Crest Night Effects/Procter &amp; Gamble</td>
</tr>
</tbody>
</table>

Table 4  Examples and applications of commercially available physically-cured dental varnishes
In contrast to technical varnishes, dental varnishes are not expected to remain on the substrate permanently. Quite the opposite: patients usually prefer that varnish residue can be removed via tooth brushing after a reasonable wear period. Suitable film formers should therefore neither adhere too strongly to the tooth nor be too hard or too tough in order to prevent any unpleasant chipping or the formation of a smear layer.

**Chemically curing liquid varnishes**

Unlike physically curing liquid varnishes, the film formation of chemically curing systems involves changes in the molecular structure of the raw materials of the varnish. These chemical reactions can be due to contact between reactive groups, for example isocyanates with water or alcohol, or brought forth by the photopolymerization of methacrylates induced by light.

In the broadest sense, fissure sealants and dentin adhesives fall into this category, as they are also polymerized in thin layers. However, fissure sealants are intended to fill occlusal recesses rather than form wide-spread layers; thus they are not really considered dental varnishes. Even though adhesives are required to form wider-spread layers, their function as a bonding agent between the tooth structure and composite material is an entirely different one, therefore they are also not dealt with here.

**Chemical curing:** Multi-component reactive varnishes based on molecules that react with each other, usually exhibit rapid curing upon mixing of the components. To ensure appropriate storage stability, reactive varnishes are therefore offered as multi-component systems in which the ingredients that react with each other are separately stored. They are combined just before application, initiating the curing reaction. A similar and well-known approach in dentistry is employed with two-component, self-curing luting cements. Separate packing/storage helps to limit secondary reactions that impair the function of the material during the storage period. The disadvantages of this approach however, include the time-consuming, labour-intensive and non-economic mixing procedure, as well as defined processing times. These constraints are inconsistent with the requirements for dental varnishes, which are applied in small, individual doses, often under certain cost and time pressure. Two-component systems have not therefore established themselves for varnish applications – as they have for adhesive cementation.

Based on the principle of 2-component systems with separate reaction partners - Fluor Protector, the only 1-component reactive varnish in dentistry was developed. The second reaction partner in the case of Fluor Protector, is the water present in the oral cavity. This eliminates any mixing step prior to application, whilst still achieving a rapid film layer, due to water contact. Several examples of commercially available chemically curing varnishes are shown in Table 5.

**Photo-chemical curing:** Liquid varnishes based on photo-chemically polymerizing monomer solutions or mixtures also belong to the category of chemically curing materials. They are based on established dental methacrylates (e.g. HEMA, bisGMA), which are diluted to an easy-flowing consistency with solvents or reactive diluents (e.g. methylmethacrylates, dipenta-erythrol pentaacrylates). The addition of photoinitiators that are sensitive to blue light, enables the quick formation of a film by radical polymerization after illumination with a dental curing light. Carbonyl compounds, such as diketones or other acrylic components, have established themselves as the most prevalent group of photoinitiators in dentistry. The initiator molecule, which is energetically stimulated by light absorption, can either decompose under radical formation (Norrish Type 1) or abstract a hydrogen atom from a co-initiator and lead to radical formation there (Norrish Type 2). The radicals formed by the photoinitiator react with the methacrylate monomers in a chain reaction that results in the formation of a polymer network that encapsulates the active ingredients and thus permits their slow release. As the polymers formed in this reaction are usually mechanically resilient films with a longer retention period on the tooth, they are predominantly used in protective varnishes. These mechanically resilient protective layers are applied to desensitize exposed tooth necks and seal glass.
ionomer cement surfaces. These restoration-sealants are additive-free monomer mixtures that permit at least temporary surface gloss and wear resistance after light curing. There are however also light cured varnishes which release fluoride in addition to providing a mechanical protective effect. Table 5 provides some examples of commercially available photo-chemically curing varnishes.

As can be seen in Table 5, mechanical protection is the main purpose of photo-chemically curing dental varnishes, whilst other functions, such as fluoride release, play a more subordinate role. Photo-chemically curing dental varnishes are, therefore, not examined in more detail in this chapter.

Chemistry of the polyisocyanate varnish “Fluor Protector”

Varnishes applied in the oral cavity using dental brushes, are required to exhibit rapid film formation, in order to prevent any uncured varnish from being rinsed off by saliva and to ensure good patient “compliance”. Successful clinical application also calls for a material that is easy to spread, achieves even surface wetting and shows good adherence to the polar tooth structure. The film formers used in such varnishes thus need to impart the material with rapid curing capabilities, low viscosity and compatible varnish/tooth surface properties. These prerequisites are met by certain isocyanates, which, when diluted in organic solvents, show good wettability on polar substances and quickly form a sound adhesive film.

To benefit from the good film forming properties of isocyanates without involving a complex 2-component application form consisting of the isocyanate and the curing agent, Fluor Protector was designed as a 1-component varnish without a curing agent. Besides poly-functional isocyanates (polyisocyanates), the intended second reactive component, is the water present in the patient’s breath and saliva. Its rapid reaction with polyisocyanates allows for a user-friendly, clinically effective varnish.

In addition to polyisocyanate film formers and the active ingredient fluor silane, Fluor Protector also contains bio-compatible, ester-based solvents. These slightly polar, somewhat water-soluble liquids lead to good adaptation behaviour on the tooth as well as to quick blending of varnish former and water. Such low-viscosity polyisocyanate formulations quickly absorb water through diffusion, such that moisture in the

<table>
<thead>
<tr>
<th>Type</th>
<th>Varnish raw materials</th>
<th>Solvents</th>
<th>Active ingredients</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Light-curing</td>
<td>bisGMA, HEMA, adhesive monomer, ormocer, HEMA, UDMA</td>
<td>Acetone</td>
<td>Mechanical effect only</td>
<td>Admira Protect/ VCO</td>
</tr>
<tr>
<td></td>
<td>Dipentaerythrolpent-aacrylat, methylmethacrylat</td>
<td>–</td>
<td>Mechanical effect only</td>
<td>Easy Glaze/ VCO</td>
</tr>
<tr>
<td></td>
<td>HEMA, adhesive polymer</td>
<td>–</td>
<td>Mechanical effect Fluoride glass</td>
<td>Vanish XT/ 3M ESPE</td>
</tr>
<tr>
<td>Self-curing</td>
<td>Polyisocyanates</td>
<td>Ethylacetate, i-Amylpropionate</td>
<td>Fluor silane</td>
<td>Fluor Protector/ Ivoclar Vivadent AG</td>
</tr>
</tbody>
</table>

Table 5 Examples of commercially available, chemically cured dental varnishes
breath triggers the curing reaction when the solvent evaporates. In the first reaction step, carbamic acids are formed by the reaction of polyisocyanate with water. They are then quickly converted into primary amines under CO₂ separation. Being strong nucleophiles, amines immediately react with the remaining isocyanate groups to form cross-linked polycarbamides, which constitute the hardened varnish on the tooth. Figure 3 shows the reaction diagram of the formation of polycarbamides from isocyanates.

As shown in Figure 3, the polyisocyanates used in Fluor Protector are converted into a tight polymer network on the tooth when they come into contact with moisture. The active ingredient is embedded within this network. The mechanical strength of the polycarbamide film, allows for the application of a thin, inconspicuous layer that is both esthetic and feels pleasant in the mouth. The good adhesion of the polar polycarbamides to the tooth surface prolongs the retention period of the active fluor silane and enables delayed (clinically proven) fluoride release.
**Fluor Protector packaging requirements:** Even though polyisocyanates are chemically very stable if they are stored correctly, the use of a water-vapour-proof packaging is required because of the high reactivity of the material to compounds that contain OH groups.

During the development of Fluor Protector, it was found that plastic bottles commonly used in dentistry were not sufficiently airtight regarding the diffusion of atmospheric humidity and did not allow for adequate storage stability. Not only the wall of the container, but also the lid constitutes a critical area regarding moisture diffusion. Consequently, glass or metal containers with screw-type caps or crimp seals are also unsuitable. Pharmaceutical glass-ampoules, which are sealed immediately after filling, have proven to be the optimum packaging for Fluor Protector. Such ampoules are the only packaging type that is absolutely water-tight, guaranteeing long term storage stability with consistent product quality.

To ensure the quick and safe opening of these glass ampoules, Ivoclar Vivadent developed the VivAmpoule, whereby the glass ampoule is encased in a plastic sheath. This plastic sheath removes the need to directly handle the glass neck or body of the ampoule.

Based on years of storage stability tests, positive handling reports and high customer satisfaction, the VivAmpoule can be considered the optimum type of packaging for polyisocyanate-based 1-component reactive varnishes.
Summary

Dental varnishes for topical application and the delayed release of active ingredients, such as fluoride ions or chlorhexidine, are characterized by their easy, safe application. Physically and chemically cured technical varnishes were the basis for the development of these dental varnishes.

Literature


[2] Chopra S, Prencipe M, Invention comprising a siloxane pressure sensitive adhesive and a whitening particulate (hydroxyapatite); enhanced whitening efficacy and aesthetics, improved adherence of the whitening composition to the tooth surface in the presence of saliva.: Google Patents; 2005.


Development of Dental Varnishes

Introduction

A dental varnish is a coating liquid for teeth, which is applied in thin layers and converted to a consistent, solid film by chemical or physical processes. Most dental varnishes consist of binding agents (resins, monomers, polymers), solvents and additives (active and auxiliary ingredients).

Physically cured varnishes consist of volatile solvents and non-volatile components. After the application of the varnish, the solvent evaporates during drying, while the non-volatile components remain on the coated object in the form of a film.

Chemically cured varnishes may be low-viscosity mixtures of reactive substances, which are brought to react by water absorption, the mixing of several components or via stimulation with light. This reaction then causes curing.

The important basic components of a dental varnish are the binding agent and the solvent, as well as orally active substances, such as fluoride. The varnish forms a solid layer on the substrate, which should remain stable for a certain amount of time without separating from the substrate. During this time, the varnish acts as a physical barrier on the tooth surface or releases orally active substances. If the surface is contaminated, e.g. by saliva, the bond between the substrate and the varnish may be compromised.

The main tasks of dental varnishes are:

- **Protection of the teeth from caries**
  To protect the teeth from caries through the release of active substances – fluoride or antimicrobial substances are used. Fluoride reduces the demineralization of dental enamel and antimicrobial substances combat cariogenic bacteria.

- **Desensitization of sensitive tooth necks**
  Desensitizing sensitive tooth necks can be achieved via the creation of a mechanical block, i.e. a physical layer covering exposed dentin tubuli. This prevents or minimizes any conduction of pain stimuli into the tubuli via effectively sealing them. A sustainable seal below the tooth surface is therefore ideal.

- **Enhancing the esthetics of the tooth shade**
  Varnishes that contain bleaching agents are applied to remove discolorations or to whiten the teeth.

Consequently, the following types of varnish are used in dentistry today:

- Fluoride varnishes
- Antimicrobial varnishes
- Desensitizing varnishes
- Tooth whitening varnishes
General requirements for dental varnishes

In terms of clinical application, the previously mentioned types of varnish have various functions and requirements. Aspects regarding handling, adhesion to the tooth, comfort of wear and safety are comparable for all varnishes. This chapter discusses these general requirements. These plus other requirements, such as the release of active substances, are based on the interaction of various parameters, which are depicted in Figure 1.

As shown, the interplay of a multitude of parameters affects the final effect of the dental varnish on the tooth.

**Fig. 1** Influence of the properties of the varnish on its effect
Handling properties during application

A sufficient quantity of varnish should be able to be applied simply, with a standard applicator and reliably transferred to the teeth, to enable the treatment of the entire dentition in as few steps as possible. The varnish should be tolerant of residual moisture on the tooth, must show good wettability of the surface and should be easy to distribute evenly.

The final varnish layer does not contain any solvents. They are used to adjust the properties of the varnish to ensure easy application and subsequent film formation. Solvents enhance the wetting behaviour by reducing the surface tension and viscosity of the varnish.

The most common solvents used in dental varnishes are organic solvents, like alcohols (e.g. ethanol, isopropanol) or esters (e.g. ethyl acetate, isoamyl propionate). Varnishes that contain solvents and have a low binding agent content usually demonstrate low viscosity and can be applied in thin, quick-drying layers. With thickening binding agents and a high solvent content, thicker layers of a liquid varnish can be applied, which may still dry relatively quickly and form comparably thin varnish layers. A high binding agent content and low solvent concentration usually results in a high-viscosity varnish, which forms rather thick, slow-drying layers.

The good wettability of the substrate surface and the adaptation of the varnish film to this surface, affects the adhesion and thus the retention time. As the oral cavity is a perpetually moist environment, the varnish layer that is formed needs to be insoluble or at least difficult to dissolve. To simplify the handling of dental varnishes on the tooth surface, a certain tolerance of the composition to water is an advantage. A water-tolerant solvent can mix with the saliva/water film on the tooth surface, thus ensuring the best possible wettability of the surface with the binding agent. If the latter also demonstrates a certain water tolerance, the premature precipitation of the resin or the polymer on moist surfaces can be avoided and an even film can be formed. The use of components which react with water and also embed small quantities of it within the network/varnish film, as reaction products, is also possible (e.g. polyisocyanates).

After application, the varnish should quickly form a well-adhering film, preferably without forced drying so that patients are able to close their mouths shortly after – particularly helpful when treating children. The varnish layer should adhere to the tooth until the active substances have been transferred to the surface. In this way, the varnish acts as a “release device” to bring the active substance to the tooth.

Adhesion to the tooth

As shown in Figure 1, the adhesion of varnishes to teeth is one of many factors that influence the effect of the varnish. Chewing results in minute, but continuous wear of the teeth, restorative materials and also, of course, of varnishes. Longer adhesion to the enamel is achieved mainly in areas that are less stress-bearing, such as interdental spaces or fissures. Adhesion can usually be enhanced by application on a clean, dry surface and, naturally, also depends on the composition of the varnish. The retention time of a dental varnish depends, among other factors, on the adhesion to the surface and the wear resistance. It is geared towards the intended effect and can last between a few minutes to several weeks. Long term adhesion is not always desired or useful. A tooth whitening varnish, for example, should release the active substance quickly and the coating should be easy to remove once the release is complete – which should only take a few minutes.
Release of active substances

Dental varnishes can protect teeth in a purely mechanical way e.g. the protection of sensitive teeth from external stimuli, via the formation of a barrier. Many varnishes, however, act principally as a carrier of active ingredients, such as fluoride, chlorhexidine or peroxides. They ensure the presence and retention of these substances on the oral substrate. The quantity of the varnish or the concentration of an active substance may influence the success of the therapy. More important however, are properties that are often determined by several components. Solutions exhibiting maximum homogeneity, ensure the most even distribution of ingredients and the evaporation of the solvent leads to an increase in concentration of the active ingredients in the varnish layer.

The effect on the coated tissues depends on the period of effect and the concentration of the active substance in the solution or the film layer, which in turn correlates with the release rate of the active substances. The release rate additionally depends on the hydrophilic properties and solubility of the system or individual components, as well as the ratio or the interaction between the active substance and the binding agent or even the layer thickness formed on the tooth (Figure 1).

Patient comfort

During the retention period in the mouth, the varnish film should not feel uncomfortable or be visibly noticeable. The esthetic appearance after application to the teeth is determined by the colour, transparency and layer thickness of the applied varnish. Best results can therefore be achieved with thin, transparent, colourless films, which to all intents and purposes are “invisible”. The inherent colour of thin layers of varnish is not as noticeable as in thick layers. Thus even varnish layers with a whitish-cloudy tone or a slightly yellow colour can be applied such that they are barely noticeable and are rated as esthetic. Thin layers of varnish are therefore preferable in terms of esthetics and any potential discomfort. Thicker layers of varnish, particularly of coloured varnishes, can clearly be distinguished from the natural tooth colour and fall short of today’s esthetic demands.

Safety

The varnish should not negatively affect the tooth surface, i.e. it must not soften or erode tooth structure.

General test methods in the development of varnishes

Determination of viscosity

Viscosity can also be described as “fluidity”. It strongly depends on the temperature, but can also be influenced by other factors. Fluid materials can be distinguished as either high viscosity (thick) or low viscosity (runny). In physically cured varnishes, a pronounced increase in viscosity occurs during and after application due to solvent evaporation. This may affect the dispersion and flowability of the varnish. A relatively simple method to determine viscosity uses a flow cup. The test measures the time required for a defined volume to flow through a hole with a defined diameter. For application-related tests, experiments using a tooth model (Figures 2 and 3) are adequate to determine whether a varnish can be easily picked up and dispersed with an applicator and whether it flows suitably into interdental spaces. Quantitative rheological methods with automated analysis equipment are employed for stability and quality investigations.
Applying the product in a patient’s mouth is the best way to gain information about handling properties. The following pictures show the adaptation and flow into interdental spaces of Fluor Protector S which has been dyed blue.

**Application of varnishes (in vitro)**

**Fig. 2** Enamel Pro Varnish/Premier Dental: Application of a high-viscosity varnish on an enamel cylinder (R&D Biotechnology, Ivoclar Vivadent AG, March 2013)

**Fig. 3** Fluor Protector S: Application of a low-viscosity varnish on an enamel cylinder using a Vivabrush G (R&D Biotechnology, Ivoclar Vivadent AG, March 2013)

**Adaptation in interdental spaces (in vivo)**

**Fig. 4** Buccal application of blue coloured Fluor Protector S (R&D Clinic, Ivoclar Vivadent AG, May 2012)

**Fig. 5** Adaptation of blue coloured Fluor Protector S in proximal spaces and wetting along the gingival margin (R&D Clinic, Ivoclar Vivadent AG, May 2012)
Determination of water tolerance

A simple method for low-viscosity varnishes is the step-by-step addition of water to the varnish liquid until the first component, which is usually the binding agent, becomes insoluble and in turn visible as cloudiness. Compositions which tolerate a high proportion of water before the first cloudiness appears should take longer before any insoluble precipitation occurs when applied in vivo to moist surfaces. They should therefore achieve a more even coating.

Five to ten percent polymer was dissolved in pure ethanol. Then water was added until the first permanent cloudiness appeared. Table 1 shows that the various varnish solutions tolerated different proportions of water in the mixture before the polymer precipitated. A higher value means fewer problems when applying a varnish to moist surfaces. However, good water solubility can also mean that a varnish film is less resistant to saliva.

Results: Water tolerance of various polymer solutions

<table>
<thead>
<tr>
<th>Polymer</th>
<th>Concentration in Ethanol [%]</th>
<th>Water content of solutions at first cloudiness [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poly(ethylacrylate-co-methylmethacrylate-co-trimethylammonium-ethylmethacrylate chloride)</td>
<td>10</td>
<td>36</td>
</tr>
<tr>
<td>Poly(methacrylic acid-co-methyl methacrylate)</td>
<td>10</td>
<td>52</td>
</tr>
<tr>
<td>Poly(vinylacetate-co-crotonic acid)</td>
<td>10</td>
<td>&gt; 50</td>
</tr>
<tr>
<td>Poly(octyl acrylamide-co-butyl amino ethyl methacrylate-co-acrylate)</td>
<td>10</td>
<td>33</td>
</tr>
<tr>
<td>Poly(octyl acrylamide-co-acrylate)</td>
<td>10</td>
<td>23</td>
</tr>
<tr>
<td>Polyvinyl caprolactam</td>
<td>10</td>
<td>&gt; 67</td>
</tr>
<tr>
<td>Poly(vinyl acetate-co-crotonic acid-co-vinyl neodecanoate)</td>
<td>10</td>
<td>41</td>
</tr>
<tr>
<td>Polyvinyl butyral (high degree of acetalisation)</td>
<td>5</td>
<td>19</td>
</tr>
<tr>
<td>Polyvinyl butyral (low degree of acetalisation)</td>
<td>5</td>
<td>31</td>
</tr>
<tr>
<td>Cellulose acetate butyrate</td>
<td>5</td>
<td>22</td>
</tr>
</tbody>
</table>

Table 1 Water tolerance of various polymers in ethanol (R&D Ivoclar Vivadent AG, August 2015)
**Measuring adhesion to substrate**

Bovine enamel is ground with sandpaper under water cooling and then polished. The tooth is then rinsed thoroughly under running tap water. The varnish is applied to the enamel using a suitable application aid according to the Instructions for Use. The varnish can be dyed in order to increase visibility of the varnish layer. The prepared test specimen is stored in water at 37°C for 24 hours and quickly dried with compressed air after removal. A piece of transparent adhesive tape is pressed against the dried varnish layer. The adhesive tape is pulled off slowly at an acute angle as possible, parallel to the treated tooth surface. The evaluation is then carried out visually after the adhesive tape has been removed. The amount of varnish remaining on the tooth is examined plus how well it can be removed by mechanical means. The results are classified using a roughly graduated scale (1 – 6: with 6 being the best value):

1: No varnish left after water storage.
2: Entire varnish layer removed in one piece after water storage.
3: Almost the entire varnish layer removed in one piece after the adhesive tape test.
4: Partially removed, the remainder can be removed with a fingernail.
5: Matt layer, nothing removed. Can be scratched off with a fingernail.
6: Smooth layer, nothing removed. Difficult to scratch off with a fingernail.

The different amounts of residue left on the enamel or pulled off via the tape are clearly visible in Figure 6. After the application of Cervitec Plus on dry dentin for instance, only very little of the varnish layer was removed with the adhesive tape, while far more was pulled off when applied to very moist dentin. The predecessor product Cervitec was almost entirely removed by the adhesive tape even when applied to dry dentin.

![Figure 6](image-url)
Adhesion to enamel (in vitro)

<table>
<thead>
<tr>
<th>Varnish base</th>
<th>Polymer concentration [%]</th>
<th>Solvent [%]</th>
<th>Scale 1 – 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poly(ethylacrylate-co-methylmethacrylate-co-trimethylammonium-ethylmethacrylate chloride)</td>
<td>10</td>
<td>80</td>
<td>3</td>
</tr>
<tr>
<td>Poly(vinylacetate-co-crotonic acid)</td>
<td>10</td>
<td>94</td>
<td>5</td>
</tr>
<tr>
<td>Poly(octyl acrylamide-co-butyl amino ethyl methacrylate-co-acrylate)</td>
<td>10</td>
<td>80</td>
<td>5.5</td>
</tr>
<tr>
<td>Polyvinyl caprolactam</td>
<td>10</td>
<td>80</td>
<td>1</td>
</tr>
<tr>
<td>Poly(vinyl acetate-co-crotonic acid-co-vinyl neodecanoate)</td>
<td>10</td>
<td>90</td>
<td>5</td>
</tr>
<tr>
<td>Poly(vinyl acetate-co-butyl maleate-co-isobornyl acrylate)</td>
<td>10</td>
<td>80</td>
<td>4</td>
</tr>
<tr>
<td>Polyvinyl acetate</td>
<td>10</td>
<td>94</td>
<td>2</td>
</tr>
<tr>
<td>Poly(vinyl pyrrolidone-co-vinyl acetate)</td>
<td>10</td>
<td>80</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 2  Adhesion of various polymers on polished bovine enamel (R&D Ivoclar Vivadent AG, August 2015)

After application and drying of the polymer solutions, the adhesion to dry enamel was roughly determined by means of the pull-off test using adhesive tape. 80% to 94% ethanol was used as the solvent. The above table clearly shows the considerable differences in adhesion of the various varnishes to enamel. For instance, a layer of polyvinyl caprolactam completely dissolved in the water, while other polymers, like polyvinyl acetate, peeled off the tooth entirely. Varnishes with good adhesion still completely covered the tooth after water storage and could only be removed from the tooth surface by means of mechanical intervention.
Adhesion to enamel (in vivo)

For better visibility, Fluor Protector S varnish was stained blue and applied to air-dried teeth using a Vivabrush G. The teeth of the maxilla in the visible region were treated with stained and unstained varnish. After a picture of the initial situation was taken, the lip/cheek retractor was removed after 1 – 2 minutes and the mouth was closed. The retention of the varnish layer was controlled at various intervals (Figures 7 – 10).

Fig. 7 Fluoride varnish immediately after application
Fig. 8 Fluoride varnish 2.5 hours after application
Fig. 9 Fluoride varnish 3.5 hours after application and after eating lunch
Fig. 10 Fluoride varnish 5.5 hours after application and after eating lunch
Determination of esthetics after application

Esthetics can only be realistically judged via in-vivo application; as in vitro tests outside the oral cavity cannot simulate the effects of temperature, moisture, drying and subsequent wetting of teeth surfaces with saliva adequately.

Results: Esthetics after application

Fig. 11 Visibility after application: Comparison of Fluor Protector S (left) with Duraphat/Colgate (right), a colophony-based varnish with 5% NaF, shortly after application (R&D Clinic, Ivoclar Vivadent AG, May 2012)
Fluoride varnishes

Requirements for fluoride varnishes

A fluoride varnish should provide protection from demineralization or erosion via the creation of a layer with a high fluoride content, made from calcium fluoride-like precipitates. A strongly fluoridated layer can be achieved either by establishing a lengthy exposure time with a low fluoride concentration, or a shorter exposure time with a higher fluoride concentration. Alternatively quick, targeted release of fluorides to the enamel is also possible. It should be kept in mind that varnishes which contain pre-dissolved fluoride are effective as soon as they are applied, whereas varnishes containing suspended fluoride first need to dissolve the fluorides in saliva before transporting them to the tooth surfaces.

Measuring fluoride release

200 – 300 µl of varnish were dispensed into a plastic petri dish with a pipette and evenly distributed with a brush. The varnish was briefly allowed to dry at room temperature. After that, artificial saliva was added and the petri dish was slightly agitated with horizontal movements. The artificial saliva was replaced by fresh saliva at various points in time. All the saliva samples were mixed with a buffer and the fluoride concentration measured with an electrode.

Results: Fluoride release

Five varnishes with 5% NaF (22,600 ppm fluoride) and Fluor Protector S with 1.5% NH₄F (7,700 ppm fluoride) show very different fluoride release profiles. No relation between the fluoride concentration in the varnish and the fluoride release was identified.

![Fig. 12 Fluoride release of various fluoride varnishes](image-url)
Measuring fluoride deposition in enamel

**Alkali-soluble fluoride:**
Alkali-soluble fluoride refers to surface-precipitated fluoride, mainly calcium fluoride [3, 4]. Cylindrical test specimens with a diameter of approximately 4 mm were drilled out of polished bovine teeth using a diamond hollow drill and demineralized with diluted lactic acid (adjusted to a pH of 4.4). Subsequently, the test specimens were sealed with a fluoride-free adhesive with the exception of the enamel surface. Test-varnishes were then applied to the exposed enamel surface, briefly allowed to dry at room temperature and then stored in artificial saliva at 37°C for a defined period of time. The medium was replaced after 1 hour. The saliva solution was rinsed off and the varnish completely removed with a suitable solvent. The test specimen was then stored in a potassium hydroxide solution at room temperature for 24 hours to dissolve the alkali-soluble superficial fluoride. The alkaline solution was neutralized with diluted nitric acid. Then a buffer was added to adjust the pH value and the ionic strength before the solution was measured with an ion-selective fluoride electrode.

**Structurally-bound fluoride:**
Structurally-bound fluoride mainly stems from fluorapatite and is thus integrated in the crystal lattice of the enamel. For the determination of the structurally-bound fluoride, the test specimens to determine the alkali-soluble fluoride were dried and freshly sealed, if required. After that, they were covered with perchloric acid (0.1 mol/l) for 15 minutes to etch away the top layer of enamel (approx. 100 µm). After the addition of a buffer, the solution was again measured with the ion-selective fluoride electrode.

Results: Enamel fluoridation with fluoride varnishes

![Graph](image)

Fig. 13 Total fluoride of various commercially available fluoride varnishes (Duraphat/Colgate, Clinpro White Varnish/3M ESPE, MI Varnish/GC Corp., Profluorid Varnish/VOCO GmbH, Enamel Pro Varnish/Premier Dental): Enamel fluoridation after 1 hour of storage in artificial saliva after application on polished, demineralized bovine enamel. [2]

Five varnishes with 5% NaF and Fluor Protector S with 1.5% NH4F showed different levels of enamel fluoridation. Even though Fluor Protector S contains less fluoride than the other varnishes, it deposited more fluoride on and in the enamel after 1 hour [2].
Enamel fluoridation by exposure time shows that Fluor Protector S achieves rapid and good fluoride deposition of mainly alkali-soluble fluoride on the surface even after brief exposure. Similar amounts of fluoride deposition both on and in the enamel were seen with Duraphat, however the same level of enamel fluoridation as achieved with Fluor Protector S was only possible after lengthy exposure.

Antimicrobial varnishes

Requirements for antimicrobial varnishes

Certain biofilm bacteria produce acids that jeopardize the tooth structure. An antimicrobial protective varnish can reduce these bacteria and help shift the bacterial balance to a healthier level.
Measuring the antimicrobial effect

An inhibition zone assay was employed to examine whether or not a sample material contained antimicrobial properties. If a substance has an antimicrobial effect, the growth of the microorganisms is inhibited, rendered visible by a zone of inhibition.

Inhibition zone assay with solid test specimens:
This method is used if the test material is solid or if the material to be tested is applied on a carrier material. For example, varnishes, gels or pastes can be applied to a carrier material such as Teflon. In this version of the test, the microorganisms are spread on the surface of the agar plate and are thus in direct contact with the material to be tested.

Results: Antimicrobial effect

![Graph showing diameter of inhibition zones for different bacteria](image)

**Fig. 15** Inhibition zone against S. mutans: Zone of inhibition around a composite test specimen coated with an experimental chlorhexidine varnish. No cloudy bacterial growth can be identified within this zone. (R&D Biotechnology, Ivoclar Vivadent AG, February 2006)

**Fig. 16** Inhibition zone of Cervitec Plus against various bacteria. The varnish was applied on a resin test specimen and placed on an inoculated culture medium after drying. Measurement includes the diameter of the test specimen: i.e. 10mm involves inhibition below the test specimen. [1]
Tooth whitening varnishes

Requirements for tooth whitening varnishes

A tooth whitening varnish contains an oxidant, usually a peroxide, which diffuses into the tooth after the application of the varnish. Peroxides are unstable in the conditions prevalent in the oral cavity. Their decomposition produces oxygen, which converts stains and discoloration into colourless compounds. A lengthy retention period is therefore not necessary or desirable because the main effect of the peroxide occurs within minutes and then diminishes rapidly along with the concentration. Subsequently, the varnish contains no or very little of the active substance, thus there is no added benefit to the varnish remaining on the tooth, and it should be easily removed. Given the short application time, the varnish does not have to meet the highest requirements in terms of adhesion and esthetics. More important, is the selection of a formulation that permits easy handling and safe storage (preferably at room temperature), both in the dental office and at home.

Measuring peroxide release

To measure the peroxide release from the varnish, the product was spread out in a petri dish and covered with water. Samples were taken at various time intervals and the concentration of the peroxide measured by means of an enzymatic test. The test uses peroxidase as the catalyst and 2,2’-Azino-bis-(3-ethylbenzthiazoline-6-sulphonic acid) (ABTS) as the chromogen. In the photometric test, hydrogen peroxide oxidizes the chromogen ABTS to an intense blue-green colour – via a peroxidase-catalyzed indicator-reaction. This reaction can be photometrically tracked at a wavelength of 420 nm [5, 6].

Results: Peroxide release from a tooth whitening varnish

Fig. 17 Hydrogen peroxide release from VivaStyle Paint On Plus. The hydrogen peroxide in the material is released rapidly from the ethyl cellulose-based varnish. [8]
At first, a standard curve is recorded by fabricating solutions with various concentrations of hydrogen peroxide. 960 µl ABTS solution and 20 µl peroxidase solution are poured into a cuvette. Then the absorption at 420 nm is measured in a photometer. After the addition of 20 µl of the peroxide solution followed by shaking for mixing purposes, another measurement is taken. The peroxide concentration in the sample can be calculated in the linear range with the help of the calibration curve.  

**Measuring changes in surface hardness (ISO 28399)**

Cylindrical test specimens made of polished bovine enamel were cleaned and dried, and the microhardness of the surface was determined (Knoop hardness; 0.49N, 15 s). The test specimens were treated with VivaStyle Paint On Plus and immersed in artificial saliva for 10 minutes at 37°C. After that, the varnish was removed with a soft toothbrush, the surface rinsed with water and the test specimen stored in artificial saliva at 37°C without agitation. The treatment was repeated twice daily for 7 days (application according to the recommendation in the Instructions for Use). After the last whitening treatment, the test specimens were stored in artificial saliva for another 24 hours before the microhardness measurement was taken.

### Results: Changes in surface hardness

![Graph showing changes in surface hardness](image-url)

**Fig. 18** Changes in the hardness of the enamel surface after application of VivaStyle Paint On Plus. Measurement according to ISO 28399:2011 after 14 (10 minute) applications and storage in artificial saliva at 37°C. The initial hardness measured corresponds to 100%. (R&D Ivoclar Vivadent AG)
Determining enamel and dentin erosion

Bovine teeth embedded in resin were ground down to the enamel or dentin. The edges of the tooth surfaces were covered with adhesive tape, such that a strip of approximately 2–3 mm remained free. The enamel or dentin was treated with VivaStyle Paint On Plus in a twice daily 10-minute application for one week and stored in artificial saliva at 37°C between treatments. For the negative control, the teeth were attached to the bottom of a beaker glass with adhesive tape, covered with deionized water and stirred for 60 Minutes at 35°C. For the positive control, a 1% citric acid solution (pH 3.9) was used instead of water. After every treatment, the adhesive tape was removed from the enamel, the adhesive residue wiped off with acetone and the height difference in the surface profile of the tooth measured with a profilometer.

Example: Erosion

As Figures 19 and 20 show, treatment with VivaStyle Paint On Plus tooth whitening varnish, does not erode the enamel: over a length of more than 4 mm, only fluctuations caused by surface roughness were identified. In contrast, citric acid solution as a positive control, creates a step in the enamel with a depth of more than 20 μm.
Determining the tooth whitening effect

Discoloured teeth can be whitened very quickly at the dental practice using a varnish. VivaStyle Paint On Plus, proved successful after two practice-visits, each involving successive 6x 10 minute applications. Treatment proceeded as follows:

The treatment area was isolated with a lip/cheek retractor, such as OptraGate, and the gingiva was covered with Vaseline. A thin layer of the tooth whitening varnish was applied (from canine to canine) and the dried varnish film was removed with a scaler after 10 minutes. The application was repeated 5 times, which resulted in a total application time of 60 minutes. After one week, the treatment was repeated as described and the shade change was evaluated.

Results: In-vivo tooth whitening with VivaStyle Paint On Plus

Fig. 21 Baseline situation before treatment: Before the application of VivaStyle Paint On Plus, the tooth shade was in the range of A3 / B4 (VITA Shade Guide).[7]

Fig. 22 Situation after completion of treatment: After repeated application of VivaStyle Paint On Plus, the tooth shade was brightened by approximately 8 shades to A2 / B1 (VITA Shade Guide). [7]

Conclusion

A multitude of parameters, need to be considered when developing a dental varnish – all of which can influence the efficacy of the product. The practical usability, fast and easy application must also be kept in mind to ensure users are happy to integrate the material into their daily routine.

Even the best varnish will not work in the bottle – only when it is applied to the tooth!

To develop a varnish efficiently and in a target-oriented fashion, numerous test methods are required, to evaluate the performance of the various required properties. Sometimes, suitable measuring/evaluation methods can be found in the scientific literature. Oftentimes, however, they have to be specifically developed or adjusted.

Even the best laboratory methods only hint at the subsequent behaviour of a product and its effect in the oral cavity, thus only clinical tests carried out in vivo allow for any definitive judgement to be made.

Literature

Clinical Studies: Highlights

Over the next few pages, we will present a selection of clinical studies on the varnishes of Ivoclar Vivadent, which impressively confirm their effectiveness for their various indications. Depending on the product, the broad range of possible applications includes desensitization, caries prevention and tooth whitening.

For most of the products there are many more scientific publications than the ones outlined here, which further prove their clinical performance and effectiveness. The corresponding Scientific Documentation reports, which you can download free from our website (www.ivoclarvivadent.com), provide a more comprehensive overview of our products.
Fluor Protector

Treatmen of hypersensitive tooth necks

Title: Evaluation of a fluoride varnish for the treatment of dentine hypersensitivity

Location: Lund University, Sweden

Time: 1990

Authors: B. Collaert, G. Söderholm, G. Bratthall, H. de Bruyn

Method: The study included 15 patients, who had suffered from dentin hypersensitivity for an average of more than 6.5 years. Sensitivity to blown air or scratching on the tooth surface was determined at the beginning of the study (baseline 0 and baseline 1) as well as after 1 and 4 weeks. Furthermore, the patients reported and rated their sensitivity to temperature and tooth brushing. A placebo solution was applied at baseline 0; at baseline 1 and after one week, Fluor Protector was administered.

Results: In week 4, the sensitivity to all stimuli (blown air, scratching, temperature) was significantly reduced (see Figure 1 for the example temperature). Eleven patients felt a clear reduction in symptoms after treatment with Fluor Protector, such that they were no longer affected by their hypersensitive teeth during eating/drinking or tooth brushing. The remaining 4 patients still considered their hypersensitivity to be too severe. These four patients all suffered from hypersensitivity of all teeth.

Conclusion: Fluor Protector reduces dentin hypersensitivity, even if it has persisted for years.

Reference: Collaert et al. 1990 [1]
Fluor Protector

Increasing the resistance of enamel

**Title:** Influence of various fluoride varnishes on mineral loss under plaque

**Location:** Dental School, University of Groningen, The Netherlands

**Time:** 1988

**Authors:** H. de Bruyn, L.J. Van Rijn, D.J. Purdell-Lewis, J. Arends

**Method:** In this study, the protective effect of several fluoride varnishes under demineralizing conditions was examined. For this purpose, 15 patients wore enamel discs of human anterior teeth in their mouths for 2, 4 or 6 months. Before the discs were inserted, varnishes were applied to the discs for 24 hours and then removed. Plaque was allowed to accumulate on the discs in vivo. The patients used a fluoride-free toothpaste. The following varnishes were investigated: A placebo varnish without fluoride, Duraphat (Colgate) and Fluor Protector with various fluoride concentrations (0.7%, 0.1% and 0.05%). The lesion depth as well as the mineral loss and mineral distribution were examined by means of microradiography at the end of every experimental phase.

**Results:** After 4 months, all Fluor Protector versions achieved a significantly higher protective effect than Duraphat, which did not show any difference to the fluoride-free control group (see Figure 2). The various fluoride concentrations of Fluor Protector did not exhibit any significant differences – they protected the disc from demineralization below the plaque in equal measure. After 6 months, the lesion depths of all fluoride varnishes were comparable – it became apparent that the protective effect was no longer present after this period of time.

**Conclusion:** Fluor Protector provides effective protection against demineralization, even under highly caries-producing conditions.

**Reference:** De Bruyn et al. 1988 [2]
Fluor Protector

Increasing the resistance of enamel

**Title:** 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

**Location:** Institute of Odontology, Karolinska Institutet, Stockholm, Sweden

**Time:** 2001

**Authors:** S. Tranaeus, S. Al-Khateeb, S. Björkman, S. Twetman, B. Angmar-Månsson

**Method:** This randomized, controlled study compared the enamel demineralization (white spot lesions) in caries-active adolescents after different treatments. One group (n=13) was treated with Fluor Protector (FP) and received professional tooth cleaning, while the other group (n=18) received only professional tooth cleaning. For the FP group, the varnish was applied at baseline, one week later and then every 6 weeks over 6 months. In the control group, professional tooth cleaning was conducted once every six weeks for 6 months. The fluorescence of the enamel was determined by means of quantitative light-induced fluorescence measurement at the beginning of the study and at every appointment.

**Results:** The demineralized lesions treated with Fluor Protector changed with time (see Figure 3). Fluorescence, a measure of mineral content, increased. Such changes were not found in the control group. The difference in the mean change of fluorescence between the control and the test group was statistically significant.

**Conclusion:** The repeated application of fluoride in the form of Fluor Protector causes the remineralization of demineralized enamel areas.

**Reference:** Tranaeus et al. 2001 [3]
Fluor Protector

Caries prophylaxis

Title: Caries-preventive effectiveness of a fluoride varnish: a randomized controlled trial in adolescents with fixed orthodontic appliances

Location: Public Orthodontic Clinic Skellefteå and Lycksele, Sweden

Time: 2007

Authors: C. Stecksén-Blicks, G. Renfors, N.D. Oscarson, F. Bergstrand, S. Twetman

Method: This randomized, placebo-controlled double blind study investigated the effectiveness of topical fluoride varnish application against caries lesions (white spot lesions, WSLs) in adolescents with fixed orthodontic appliances. The patients were 12 to 15 years old and the test and control groups consisted of 137 and 136 participants, respectively. For the test group, Fluor Protector was applied once a week over a period of 6 weeks, while a placebo varnish was administered to the control group. Upon removal of the brackets, the incidence and progression of white spot lesions were examined by two independent examiners, with the help of digital images.

Results: The prevalence of enamel demineralization was comparable in both groups at the beginning of the study (4.3% in the Fluor Protector group and 4.0% in the control group). Upon removal of the brackets, the prevalence of initial caries lesions was 11.7% in the Fluor Protector group and 29.7% in the control group. Ergo, there was a significant difference between the test group and the control group (see Figure 4). The average progression was also significantly lower in the fluoride varnish group (0.8 ± 2.0) than in the placebo group (2.6 ± 2.8). Moreover, the analysis of the results showed that Fluor Protector treatment reduced the incidence of enamel demineralization compared to the control group.

Conclusion: Fluor Protector reduces the development of initial caries lesions during orthodontic treatment.

Fluor Protector

Caries prophylaxis

Title: Preventive oral health care programme for Filipino children

Location: Primary schools in Misamis Oriental, Northern Mindanao, Philippines


Authors: B. Monse-Schneider, R. Heinrich-Weltzien

Method: In 1998, a caries prevention program was started in 19 primary schools in the Philippines. It included non-traumatic restorative treatment of carious teeth, daily supervised tooth brushing with fluoridated tooth paste and the application of Fluor Protector by trained parents every 4 months, as well as various educational activities with children, parents and teachers. At the beginning of the study, 1600 7-year olds were examined. These children showed an average caries prevalence of 7.2 dmft (decayed, missing and filled teeth) in deciduous teeth and 1.2 DMFT in permanent dentition. Only 8.8% were entirely free of caries.

Results: Three years later, 16.2% of the 1162 children re-examined, were free of caries (see Figure 5). The other children showed an average caries incidence of 1.6 DMFT. The minor increase of 0.4 DMFT in caries incidence was considered proof of the effectiveness of this comprehensive prevention program - an annual increase of at least 1.0 of the DMFT index would be expected without any intervention, i.e. an increase of approximately 3.0 over a period of 3 years.

<table>
<thead>
<tr>
<th>Share of caries-free children [%]</th>
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</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>8</td>
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<td>10</td>
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<td>12</td>
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<td>14</td>
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<tr>
<td>16</td>
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<tr>
<td>18</td>
</tr>
</tbody>
</table>

Fig. 5 Increase in caries-free children in a caries prevention program in the Philippines, in which Fluor Protector was one of the materials used. 1600 children aged 7 were subject to a comprehensive oral health and prevention program, which included supervised tooth brushing and the application of Fluor Protector every 4 months, amongst other measures. The percentage of caries-free children almost doubled after 3 years from 8.8% to 16.2%.

Conclusion: Fluor Protector proved effective under field conditions for the prevention of caries in children.

Fluor Protector

Caries prevention in tumour patients

Title: Strategies for prevention and treatment of head and neck radiotherapy complications – oral health improvement using fluoride containing products

Location: University of Zagreb, Croatia

Time: 2010–2012

Authors: I. Alajbeg, A. Andabak Rogulj, I. Bakale Hodak, K. Gršić, M. Pastorčić Grgić, B. Stubljar

Method: Eleven cancer patients participated in this prospective pilot study. They had to undergo radiation treatment due to tumours in the throat, head or mouth. As the oral mucous membranes and salivary glands are often located in the irradiated area, radiation treatment causes various undesired side effects, such as mucositis, xerostomia, caries and osteoporosis. The objective of the study was to examine if intensive caries prevention results in an improvement in oral health in these patients. For this purpose, Fluor Protector varnish was applied 2 times a week for the first 3 months and subsequently once a month for the next 3 months. In addition, patients used Cervitec Gel (2 or 4 times a day) and Cervitec Liquid (1 or 2 times a day) at home. The caries risk status was determined by means of CRT bacteria at the beginning and after 3 and 6 months. The buffer capacity of the saliva was also determined using CRT buffer. Initial lesions were recorded clinically and with DIAGNOdent (KaVo). Furthermore, the patients were questioned regarding their quality of life with a questionnaire.

Results: The mutans streptococci count was reduced with this preventive care program. After the treatment, fewer patients were included in the high caries risk group. Demineralized lesions were diminished (see figure). The condition of the teeth and mucous membranes was improved, as was the quality of life of the patients.

Conclusion: Patients with a tumour in the head, throat or mouth profit from a caries prevention program, which includes the regular application of Fluor Protector, Cervitec Gel and Cervitec Liquid.

Fluor Protector and Cervitec*

Caries prevention for exposed roots

Title: The effects of the combination of chlorhexidine/thymol- and fluoride-containing varnishes on the severity of root caries lesions in frail institutionalized elderly people

Location: Dental Caries Research Group, GKT Dental Institute, London, United Kingdom

Time: 2002

Authors: S.R. Brailsford, J. Fiske, S. Gilbert, D. Clark, D. Beighton

Method: The authors of this randomized double blind longitudinal study compared the clinical effectiveness of a combination of Fluor Protector and Cervitec on existing root caries lesions in a group of 102 fragile, elderly test subjects aged 78-87. The test subjects were randomly assigned to a test or placebo group. All test subjects received Fluor Protector on their leathery and soft root caries lesions. The test group also received Cervitec in addition to Fluor Protector, while the placebo group was treated with a placebo varnish in addition to Fluor Protector. The treatment was repeated five times in the course of a year.

Results: The test group (Cervitec + Fluor Protector) showed no significant change in the clinical severity of the lesions. In the placebo group (placebo varnish + Fluor Protector) however, the mean lesion width as well as the height and length of the exposed roots, plus the distance to the gingival seam significantly increased (see Figure 7).

Conclusion: The combination of Cervitec and Fluor Protector represents a useful, quick, easy and non-invasive method for monitoring and treating existing root canal lesions in elderly people.


* Cervitec is the predecessor of Cervitec Plus varnish. The two varnishes contain the same active substances in the same concentration. Cervitec Plus features an optimized varnish base.
Cervitec Plus

Reduction of bacterial activity on the tooth surface

**Title:** Microbiological changes in plaque and saliva after using chlorhexidine varnish in orthodontic patients treated with fixed appliances

**Location:** Semmelweis University Budapest, Hungary

**Time:** 2014

**Authors:** M. Madléna, G. Nagy

**Method:** At the beginning of the study, the colonization of mutans streptococci and lactobacilli in saliva and plaque was determined in 29 patients (average age 16.5 +/- 2.75 years) using the CRT bacteria test. The number of initial lesions (white spot lesions) was also determined. After patients had received a fixed orthodontic appliance, either Cervitec Plus or a placebo varnish was randomly applied to the left or right quadrant of the same dental arch. The application of the varnish was repeated once a month over a period of 6 months. The bacterial status was always determined before the application. The number of initial lesions was again determined after 6 months.

**Results:** The bacterial count continuously decreased over the course of the study. The reduction on the teeth that were treated with Cervitec Plus was statistically significantly higher than on the “placebo” teeth (see Figure 8). The number of new initial caries lesions was also smaller in the quadrant treated with Cervitec Plus than in the quadrant that received the placebo varnish (see Figure 9).

![Fig. 8 Decrease of S.mutans counts (sum of the mean values of 4 teeth per patient) after treatment with Cervitec Plus (green) or a placebo varnish (grey) in patients with fixed orthodontic appliances over a period of 6 months [9].](image1)

![Fig. 9 Number of new initial caries lesions (white spot lesions) in the control (placebo) group and the test group (Cervitec Plus) after 6 months [8].](image2)

**Conclusion:** Cervitec Plus reduces the cariogenic bacterial count. This is particularly important for patients with fixed orthodontic appliances, since the treatment minimizes the occurrence of initial caries lesions, which can be an undesirable side effect in this patient group.

**Reference:** Lipták et al. 2015 und Madléna et al. 2013 [8; 9]
VivaSens und VivaStyle Paint On Plus

Treatment of sensitivity after tooth whitening

Title: Influence of a desensitizing agent on efficacy of a paint-on bleaching agent

Location: University of Göttingen, Germany
Time: 2008
Authors: D. Ziebolz, C. Hannig, T. Attin

Method: The objective of this study was to assess the clinical effectiveness and safety of VivaSens in conjunction with a tooth whitening procedure with VivaStyle Paint On Plus (6% hydrogen peroxide). A total of 80 patients were randomly classified into two groups (n=40 per group). Group A was treated without any prior application of VivaSens; Group B used the tooth whitening agent after one application of VivaSens. The tooth shade was determined at the beginning of the study (baseline) and after 10 days using a VITA shade guide. The sensitivity reaction was triggered using cold blown air and was rated on a scale from 1 (no sensitivity) to 10 (high sensitivity). Sensitivity was determined at the beginning of the study, after seven days (end of the tooth whitening procedure) and again ten days after the end of the tooth whitening treatment. Patients (n=23) who exhibited hypersensitivity after the tooth whitening treatment were treated with VivaSens or a placebo. The abatement of hypersensitivity caused by the tooth whitening procedure was then examined.

Results: No difference in the whitening result was noticed between the groups with and without VivaSens. The tooth shades brightened by 2.7 ± 1 or 2.8 ± 0.9 shade levels. It should be noted that a tooth shade of A2 was required for inclusion in the study. This is relatively light for tooth whitening studies, which ordinarily require the shade A3. If only the group with a tooth shade of A3 and darker is analyzed, a mean whitening of 3.2 shade levels is observed.

![Fig. 10 Change of tooth shade before and after tooth whitening with VivaStyle Paint On Plus.](image)

Distribution of the tooth shades in VITA shade levels before and after the tooth whitening procedure. Group A: Without pre-treatment with VivaSens, Group B: Pre-treatment with VivaSens. The tooth shade was brightened by more than 2 levels for both groups. Pre-treatment with VivaSens did not affect the whitening effect.
The application of VivaSens did not affect the tooth shade achieved by the tooth whitening procedure. However, tooth whitening resulted in a significant increase in hypersensitivity compared to the initial value. In Group A, who used the tooth whitening agent without prior application of a desensitizer, 5 test subjects reported increased sensitivity to pain, while only one test subject from Group B (tooth whitening following an application of VivaSens) reported increased hypersensitivity. Even though the hypersensitivity of the VivaSens group was lower than that of the control group, the differences were not statistically significant. The high number of drop-outs may be responsible here (n=13). The application of VivaSens in patients with hypersensitivity after tooth whitening resulted in a significant reduction in pain within the first 24 hours (p=0.0012), whilst sensitivity only abated on the third day after tooth whitening in the control group (see Figure 11).

Fig. 11 Decrease in hypersensitivity after tooth whitening. Patients who underwent tooth whitening treatment and then suffered from increased sensitivity of the tooth necks were treated with VivaSens or a placebo. At the beginning of the investigation (day zero), there were no statistically significant differences between the VivaSens and placebo groups. Pain sensations were recorded in a pain diary by patients. The group treated with VivaSens noticed a statistically significant abatement in hypersensitivity within the first 24 hours. Consequently, VivaSens led to an immediate reduction in hypersensitivity caused by tooth whitening, whilst hypersensitivity in the placebo group only decreased significantly after three days.

Conclusion: The application of VivaSens before tooth whitening does not affect the bleaching results and can have a positive effect on hypersensitivity. Certainly, the application of VivaSens after treatment results in the immediate abatement of hypersensitivity caused by the tooth whitening treatment.

Reference: Ziebolz et al. 2008 [10]
VivaStyle Paint On Plus

Tooth whitening

**Title:** A Novel Technique for In-Office Bleaching with a 6% Hydrogen Peroxide Paint-On Varnish

**Location:** Instituto Superior de Ciencia da Saude Egas Moniz, Monte Caparica, Portugal

**Time:** 2006

**Authors:** A. Duarte Sola Pereira da Mata, D. Nuno da Silva Marques

**Method:** Six test subjects participated in the study. VivaStyle Paint On Plus was applied at the dental practice 6 times in a row for 10 minutes each at 2 separate appointments within 2 weeks. Both at the beginning and at the end of the treatment, digital images were taken of the upper central incisors and the tooth shade was determined using a VITA shade guide. In addition, patient satisfaction and the occurrence of hypersensitivity was evaluated.

**Results:** Tooth whitening was successful in all test subjects. Shade changes of 7 to 13 levels on the VITA scale were achieved (see Figure 12). None of the test subjects reported any sensitivity of the teeth. Overall, the tooth whitening varnish was very well accepted by the users.

![Fig. 12 Individual shade change after whitening with VivaStyle Paint On Plus](image)

**Conclusion:** VivaStyle Paint On Plus whitens the teeth effectively and gently.

Ivoclar Vivadent varnishes: Clinically tested ...

Ivoclar Vivadent offers a wide range of dental varnishes for various indications. Whether for caries prevention, antimicrobial effect, desensitization or tooth whitening - the effectiveness and safety of these products has been examined and confirmed in numerous studies throughout the world.

The following table contains an overview of the number of scientific publications in the Medline database, which investigated Ivoclar Vivadent varnishes*.

<table>
<thead>
<tr>
<th>Product</th>
<th>Publication date period</th>
<th>In-vitro investigations</th>
<th>In-vivo investigations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluor Protector</td>
<td>1977 – 2015</td>
<td>29</td>
<td>40</td>
</tr>
<tr>
<td>VivaStyle Paint On Plus / VivaStyle Paint On</td>
<td>2006 – 2015</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>


For the two newest members of the Ivoclar Vivadent family of varnishes, i.e. the fluoride varnish Fluor Protector S (market launch 2013) and the 2-in-1 varnish Cervitec F (with fluoride and chlorhexidine, market launch 2016), there are not yet any publications in Pubmed. However, these varnishes have been and will be the subject of extensive scientific investigation. In this context, there are currently various studies or as of yet unpublished results by several universities, which are listed in the following table.

<table>
<thead>
<tr>
<th>Product</th>
<th>In-vitro investigations</th>
<th>In-vivo investigations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluor Protector S</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Cervitec F</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

* The Medline database Pubmed was searched for the respective product and the number of publications presenting results from laboratory investigations or clinical studies was recorded. As older studies in particular, were not always entirely accessible and it was not always clear what products were tested, it can be assumed that there are even more studies overall. Review articles and duplicates, which reported on the same study, were not included.
As every study is conducted under defined conditions (special patient collective, different reference products, treatment methods etc.), the general significance of an individual study is naturally limited. Therefore often in medicine/science the data of many studies on an active substance or a product/product family is compiled in order for a sound and reliable conclusion regarding effectiveness to be drawn. Such a synopsis of many study results is called a review; if a quantitative evaluation is conducted on top of that, it is referred to as a meta-analysis. On the basis of such overviews, renowned scientists or medical organizations give recommendations as to which preventive or curative treatment methods are suitable for which patients or medical conditions. Doctors and patients can use these recommendations to get their bearings in the “jungle” of treatment options and products to find the most suitable and effective solutions in a timely fashion.

Numerous reviews and recommendations have been published regarding dental varnishes over the past few years.

**Fluoride varnishes for caries prevention**

**Reviews by the Cochrane Collaboration**

The Cochrane Collaboration is a network of independent scientists and health experts who regularly publish comprehensive reviews on medical (including dental) products.

For example, the effectiveness of topical (i.e. applied in the oral cavity) fluoride preparations for the prevention of caries in children and adolescents was repeatedly investigated. The focus was placed on fluoridated toothpastes, mouth rinses, gels and varnishes. Randomized or quasi-randomized controlled clinical studies with blinded evaluation, which compared the various fluoride products with a placebo or no treatment at all, were analysed. Children and adolescents up to the age of 16 were considered relevant study populations and the studies had to have an observation period of at least 1 year. The main target parameter was the caries increment or the prevented fraction as measured by the change in decayed, missing or filled tooth surfaces (D(M)FS).

In an extensive review from 2003, a prevented fraction of 26% was determined from 133 studies regarding topical fluoride products. A clear reduction of the caries increment was achieved by the fluoride in the groups treated. According to the conclusion of the authors, fluoride varnishes were superior to other fluoride products [12].

The results of the above review were confirmed in updates in 2009 and 2013 [13, 14]. The prevented fraction for fluoride varnishes was estimated at 43% compared to placebo or no treatment at all, in the review of 2013.

- Fluoride varnishes like Fluor Protector and Fluor Protector S represent a very effective measure for protecting children and adolescents from caries.
Recommendations of the American Dental Association (ADA) and the U.S. Preventive Services Task Force

**Fluoride varnishes**

Based on reviews by the Cochrane Library and the MEDLINE Database, experts from the American Dental Association developed recommendations regarding the use of topically applied fluoride for caries prevention. They are shown in the following table:

<table>
<thead>
<tr>
<th>Caries Risk</th>
<th>Age group of recall patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 6 years</td>
</tr>
<tr>
<td>Low</td>
<td>Most likely no added benefit of topically applied fluorides (fluoridated water and toothpastes are probably sufficient)</td>
</tr>
<tr>
<td>Moderate</td>
<td>Varnish application every 6 months</td>
</tr>
<tr>
<td>High</td>
<td>Varnish application every 6 or 3 months</td>
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</tbody>
</table>

Fluoride varnish is recommended for patients of all age groups with a moderate to high caries risk. For children below the age of 6, fluoride varnishes are recommended exclusively, as their method of application reduces any risk of swallowing and therefore systemic over-exposure to fluoride. In this way, undesirable side effects, such as fluorosis, can be prevented [15]. This recommendation was confirmed in an update of the report from 2014 [16].

The U.S. Preventive Services Task Force is an organization independent of the American Government. It issues recommendations about the effectiveness of special prevention measures. The recommendations are based on an analysis and careful balancing of the risks and benefits of the measures. A publication from the year 2014 examines measures to prevent caries in children up to the age of 5. It recommends protecting all newly erupted teeth with fluoride varnish in this patient group [17, 18].

**Chlorhexidine thymol varnish / Cervitec Plus**

In patients with exceptionally high bacterial counts and saliva with a notably low pH, the protective effect of fluoride can reach its limits. In such cases, caries prevention can be performed and/or supported with additional products. The experts of the ADA also compiled and evaluated data regarding this issue. A total of 50 randomized and 15 non-randomized studies were considered. The general conclusion was that certain products may be beneficial when used as supplementary therapy for children and adults with a high caries risk.
The detailed recommendation by the American Dental Association for root caries reads as follows:

“Apply a 1:1 mixture of chlorhexidine-thymol varnish every 3 months to reduce the incidence of root caries.”

In contrast to all other measures that were examined and/or assessed, a reliable data basis for a recommendation was found only for a measure regarding a chlorhexidine-thymol varnish. That is, sufficient positive scientific data support the recommendation [19].

Only one varnish on the market contains this recommended mixture of chlorhexidine and thymol – Cervitec Plus.

Literature

Clinical Application

Protective varnishes in the dental office

Lifelong, beautiful, healthy teeth and gums are the prime concern of dentists and their patients. Healthy teeth should remain healthy and restored teeth and dentures should be given the care that they need.

Teeth and gums are however subject to various influences that can jeopardize their health. Bacterial biofilms promote the development of caries as well as periodontal and peri-implant diseases. Acid from foodstuffs attacks the structure of the tooth and can lead to erosion. Exposed cervicals are sensitive to thermal, mechanical and chemical stimuli and this can lead patients to neglect dental hygiene, as tooth brushing is painful. The consequence is plaque accumulation. The gums become inflamed. The risk of root caries increases.

Normal dental hygiene with a fluoridated toothpaste is often insufficient and additional fluoride treatment becomes necessary. The application of a fluoride varnish [1, 2], for example Fluor Protector or Fluor Protector S (Figure 1), is a measure that is explicitly recommended by dental organizations, and is an option for providing professional protection against:

- Hypersensitive teeth
- Caries
- Erosion

For patients with increased levels of certain bacteria, personal oral hygiene measures, professional tooth cleaning and topical fluoride application alone are not enough. The health of teeth
and gums is at risk. Implants, prosthetic reconstructions and restorations are also at risk. Bacterial growth needs to be reduced in a targeted manner. Only then can fluoride fully realise its protective effect. In such cases, the use of Cervitec Plus with chorhexidine and thymol is advisable. The protective varnish is used:

- to protect exposed root surfaces,
- to treat hypersensitive tooth necks
- to reduce bacterial activity on the tooth surface

Varnishes from other manufacturers, are often available as suspensions, containing undissolved solid substances, which have to be mixed thoroughly before use. An even distribution of the solid ingredients cannot therefore be ensured i.e. fluctuations in concentration cannot be ruled out.

The excellent flow and wetting properties of all the Fluor Protector and Cervitec liquid varnishes, also ensure the adequate treatment of areas that are difficult to access. In contrast to high-viscosity products, these varnish systems are quick and easy to distribute and they adapt well to complex surface profiles. High risk areas, such as abutment teeth for removable dentures, exposed cervicals and root surfaces, fissures, proximal surfaces, restoration and crown margins, implant-retained restorations, brackets and bands or initially porous tooth structure are provided with the necessary protection. In patients with exposed cervicals, the preparations tightly seal open dentin tubuli and block unpleasant thermal, chemical and mechanical stimuli. Painful hypersensitivity can be eliminated or at least considerably alleviated.

Varnish preparations are clear solutions, in which the ingredients are completely dissolved. Thus, they are ready for direct use and a controlled-dose is easily applied (Figure 3). The low viscosity facilitates the application of a thin layer, which enhances adhesion. As patients usually do not perceive the varnish layer as foreign matter, manipulation with the tongue, which can lead to premature loss, is also less likely. There is no interference regarding the accuracy of fit when it is applied to the retention elements of removable dentures.

Varnish systems – quality characteristics promote clinical use

All the varnish systems from Ivoclar Vivadent are characterized by special quality features, which positively affect their clinical application. The concentration of an ingredient is not the only aspect that determines effectiveness. Rather, the interplay of various properties is key.

Fig. 3 A homogeneous varnish system like Fluor Protector S is ready for direct application. The dosing tube permits precise dispensing.
All Cervitec and Fluor Protector varnishes meet the highest requirements with regard to esthetics, as they are transparent after curing. The mild flavour of all varnish systems also promotes patient acceptance.

Clinical use of the varnishes

Given the concentration of their ingredients and the targeted local nature of their application, the varnish systems are very reliable. As they are applied professionally, application is independent of any need for patient compliance. Varnish systems cure quickly and act directly on the spot where they are applied. Therefore, they are also suitable for small children, who in accordance with their stage of development, have not yet mastered the swallowing reflex. The use of protective varnishes has also been proven under field conditions. Due to their quick and easy application and the limited need of instruments, they can be applied hygienically without sophisticated dental equipment or offices.

Application – step-by-step

In principle, the application of all the varnishes is carried out in the same way (Figure 4). If professional tooth cleaning e.g. with a Proxyl prophy paste is not possible, thorough tooth brushing is sufficient before the application of the varnish. Relative isolation is required for the tooth surfaces to be cleaned. This is a “must” for all varnishes, irrespective of the manufacturer, to ensure adhesion. Varnishes with an aqueous solvent, such as Cervitec Plus or Fluor Protector S, show a higher tolerance to moisture, which facilitates the application in children or under field conditions. If the teeth are too wet with saliva, the varnishes turn whitish and stringy. In these cases, isolation should be repeated. The varnishes thus contain an internal quality control mechanism which benefits treatment success. Other varnish systems do not have this control mechanism, meaning varnishes may be applied to overly moist teeth without the problem being recognized.

A one-time application of a thin layer of the Ivoclar Vivadent varnishes is entirely sufficient to provide optimum protection. A thicker layer or several layers applied on top of each other provide no advantage.

Fig. 4 Step-by-step application of the varnish systems from Ivoclar Vivadent
The varnish coats the tooth evenly and matches its colour very well. After a short drying period, the patient should avoid rinsing and wait for 1 hour before eating and drinking so that the varnish system can fully develop its effect. For Fluor Protector, 45 minutes are sufficient. For other, viscous varnish systems, which cure in thicker layers, solid foodstuffs should only be consumed after 4 hours.

**Risk-oriented application**

Normally, fluoride is applied every 6 months, with shorter intervals recommended if there is a very high risk of caries or erosion. Treatment every six weeks has proven useful in such cases, during very critical phases [3, 4].

The protective chlorhexidine varnish Cervitec Plus is usually applied every three months. Here, too, the treatment interval can be shortened if indicated.

If an examination reveals a very high load of cariogenic bacteria, this count should be reduced in order for fluoride to develop its full effect [5 - 7]. Combined treatment with a protective chlorhexidine varnish, such as Cervitec Plus from Ivoclar Vivadent, lends itself for this purpose. It is important however that Cervitec Plus and Fluor Protector S are applied at separate appointments. Both varnishes consist of a similar varnish matrix and solvent. If the two preparations are applied on top of each other, the second varnish partly dissolves the first, which affects its effectiveness. The combination of Cervitec Plus and Fluor Protector is a different matter however. The two varnishes can be applied consecutively in the same appointment. First Cervitec Plus, short drying, then a thin coat of Fluor Protector.

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**Zielgruppen und Einsatzgebiete**

- Small children
- Orthodontic patients
- Removable dentures
- Senior patients
- Initial root caries
- Motor impairment
- Limited oral hygiene ability
- After fissure sealing
- Under field conditions
- Implants
- Quality assurance of crowns, bridges, restorations
- Exposed tooth necks
- After professional tooth cleaning
- During tooth eruption
- After restorative therapy
- After tooth whitening

Table 1 Target groups and areas of application of Fluor Protector S and Cervitec Plus
Various clinical situations

**Fluoride varnishes**

Fig. 5 Small children

Fig. 6 Under field conditions (Picture: Dr. B. Monse)

Fig. 7 Fluor Protector under field conditions (Picture: Courtesy of Special Olympics. Special Olympics World Summer Games Athens 2011)

Fig. 8 Orthodontic patients

Figs 9a, b After restorative therapy. a) Polishing the composite restoration. b) Followed by fluoride varnish application. (Pictures: Dr E. Mahn)
Protective varnish with chlorhexidine

**Fig. 10** Exposed cervicals (Picture: Dr A. Peschke)

**Fig. 11** During tooth eruption, before fissure sealing is possible (Picture: Dr T. Repetto-Bauchhage)

**Figs 12a, b** Initial caries next to an implant (Pictures: Dr L. Enggist)

**Figs 13a, b** Implant-retained restorations (Pictures: Dr R. Watzke)

**Figs 14a, b** Prosthetic treatment (Pictures: Dr F. Zimmerling)
Combination treatment in high risk cases

Figs 15a, b  a) Bacterial reduction with Cervitec Plus. b) Topical fluoridation with Fluor Protector in one appointment

Figs 16a, b  a) Initial situation after orthodontic treatment. b) Situation one month later. After application of a chlorhexidine varnish and a fluoride varnish (Pictures: Prof. Dr S. Twetman)

Figs 17a, b  a) Application of Cervitec Plus on the ball attachments along the gingival seam. b) Protection of the natural residual dentition with Fluor Protector S (Pictures: Dr F. Zimmerling)
Whitening teeth without a tray

Naturally white teeth – a desire frequently voiced. The varnish system VivaStyle Paint On Plus permits effective tooth whitening without a tray (Figure 18). The tooth whitening agent with 6% hydrogen peroxide and provitamin D-panthenol is applied directly to the teeth with a brush. A coat, insoluble by saliva is formed, which adheres to the teeth and is able to withstand the mechanical friction of the lips and cheeks. The hydrogen peroxide is quick-acting and develops its effect directly where it is applied. The varnish can therefore be removed after just 10 minutes.

In contrast, the application of tooth whitening gels with brushes/pens only achieves limited whitening effects. Unlike varnishes, gels are dissolved in saliva, and there is no tray, which operates as a barrier to saliva and the mechanical effects of the lips and cheeks. The product therefore does not remain on the teeth for long enough.

The examination and diagnosis provide important information for the consultation and the results likely possible. It should be pointed out that tooth whitening treatments can only whiten the teeth as light as the individual natural shade. If even whiter teeth are desired, veneers are possible.

The possibility of targeted application facilitates the whitening of the entire smile line, crooked or crowded teeth, as well as the proximal areas. Individual discoloured teeth can be treated in a targeted manner.

Intensive treatment at the dental office

At the dental office, VivaStyle Paint On Plus can be applied several times during one appointment. The flexible lip/cheek retractor OptraGate from Ivoclar Vivadent facilitates access to the tooth surfaces (Figure 19).

Procedure:
- Pour the varnish into a dispensing cup. This amount is usually enough for treating both the upper and lower jaw.
- After cleaning and drying the teeth, apply a thin layer of the varnish using a brush. A thick layer or several varnish layers on top of each other do not provide better results. Contact with the gums should be avoided as far as possible.

Different treatment procedures

VivaStyle Paint On Plus is suitable for various treatment concepts:
- intensive treatment exclusively in the dental office
- at home use after dental examination and consultation
Contact with the gums can cause a slight burning sensation, but this disappears quickly. After a 10-minute reaction time, the varnish is removed, e.g. with a probe. Then another layer is applied on the dried surfaces. This procedure is repeated a further five times [8].

The effectiveness of this method is substantiated by various studies. Operators rate the intensive therapy with the varnish system as gentler and more pleasant compared to the in-office application of products with a high concentration of hydrogen peroxide [8–10].

Tooth whitening at home

During the consultation regarding the home application of the varnish, the suitable OptraGate can be chosen and the patient also instructed in its use. Without OptraGate, a broad smile also enables access to the tooth surfaces.

Procedure

- Thoroughly brush the teeth, floss the proximal spaces and rinse off toothpaste residue.
- Blot dry first the front and then the back teeth of the upper jaw with a soft absorbent towel. To facilitate the application, lips must be pulled back.
- Apply VivaStyle Paint On Plus directly to the teeth in a thin layer using a brush. Keep the lips pulled up and away for another 30 seconds. The dry varnish layer appears matt-white. The lower jaw is treated in the same way.
- The mouth is then closed. The varnish is barely noticeable and does not interfere with speaking.
- After 10 minutes, remove the varnish layer using either a soft toothbrush without toothpaste or a paper towel.

VivaStyle Paint On Plus can be used once a day for 14 days or twice daily for 7 days. The varnish should be applied every day without interruption. To prevent the risk of new discolouration, patients should abstain from smoking and avoid or reduce the consumption of coffee, black tea, red wine and Cola-type drinks.

Procedure

1. Brush teeth
2. Floss teeth
3. Dry teeth
4. Dispense varnish
5. Apply VivaStyle Paint On Plus
6. Let varnish dry
7. Wait
8. Remove varnish

Fig. 20 Application of VivaStyle Paint On Plus.
Once the varnish system has been removed, Fluor Protector Gel from Ivoclar Vivadent, for example, is recommended for gentle and effective dental care. The mild gel with a neutral pH value contains calcium, fluoride and phosphate. D-panthenol cares for the gingiva.

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