3M ESPE

Clinpro™ White Varnish

technical product profile

Clinpro™ White Varnish

3M ESPE

Dental Products

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Introduction

Background

Cavity varnishes are used for the treatment of dentinal hypersensitivity which has been estimated to affect 10% to 20% of the population[1].

Dentine contains naturally-occurring channels called tubules that are in direct contact with the nerve endings in the tooth pulp chamber. In a healthy tooth, these tubules and the nerve endings are protected from the oral environment. Tubules in the coronal portion of the dentine are protected from the oral environment by the enamel crown. Tubules in the root portion of the dentine do not come into contact with the oral environment because the tooth root is covered with a thin layer of organic and mineral debris called cementum and healthy gingiva.

As patients age, the gingiva may recede and expose the cementum (also known as the smear layer) to the oral environment. The smear layer may then be removed by poor toothbrushing habits and/or by repeated exposure to acidic foods. When the smear layer is removed, the tubules will no longer be protected from the oral environment (Figure 1).

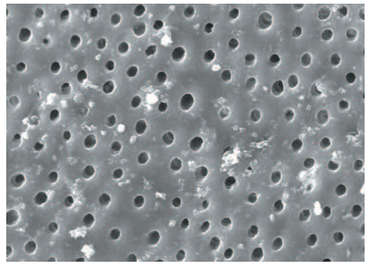


Figure 1: Exposed dentine tubules

These open tubules are filled with fluid through which tactile, thermal, chemical and osmotic changes are easily transmitted. Because these tubules are in direct contact with nerves, exogenous stimuli are quickly transmitted and nerve polarization occurs which leads to the sensation of pain. This phenomenon is often referred to as hydrodynamic conductance or the hydrodynamic theory. The theory was first reported by Gysi in 1900[2], studied heavily and corroborated in the 1950s and 1960s[3,4] and remains the most widely accepted theory to date[5].

The two most common methods of treating tooth hypersensitivity are: 1) topical application of drugs such as potassium nitrate[6] that serves to decrease the perception of pain and 2) topical application of products that serves to replace the smear layer and physically block the tubules, thus curing the condition rather than masking the pain.

When varnish is applied to the surface of exposed root dentine, it serves to replace the naturally occurring smear layer. This application provides immediate relief of pain. As the varnish is applied, the solvents (alcohol and water) rapidly evaporate leaving behind a hard lacquer film that contains insoluble sodium fluoride. This seals or occludes the exposed tubules and blocks the nerve endings from being in direct contact with the oral environment[7].

Fluoride varnishes are also used as a cavity liner under amalgam restorations. When applied to the dentine surface in a cavity preparation, fluoride varnish provides a barrier that prevents the penetration of the amalgam into the dentinal tissue.

Composition

Varnishes typically contain few ingredients (see Table 1). Each of the ingredients has an important function and serves to ensure a high quality, stable formulation. Ingredients widely used in varnishes include:

Table 1: Typical Ingredients

Ingredient	Function
Alcohol	Solvent
Resin	Sealant
Sodium Fluoride	Fluoride release
Water	Solvent
Flavors	Flavor

Resin
The ingredient that helps to maintain oral health in patients with tooth sensitivity is resin. Resin is a viscous liquid secreted by plants. When purified, the resin solidifies and is called rosin. Rosin is insoluble in water, but soluble in alcohol. When the alcohol solvent is removed, the rosin returns to a solid state. Rosin is typically amber in color. The rosin in Clinpro™ White Varnish has been modified, which makes it different than most fluoride varnishes. This modification process reduces the yellow color associated with the colophony found in most other fluoride varnish brands.

Alcohol
Alcohol is added to the formulation to solubilize the rosin and therefore makes a flowable resin. The flowable resin can be easily painted onto tooth surfaces, either in a cavity preparation or in an exposed root surface. When the product is applied to the tooth surface and is then wetted with saliva, the alcohol quickly evaporates and the solubilized rosin returns to its more solid state to form a thin lacquer film.

Sodium Fluoride
Insoluble sodium fluoride is slowly released as the hard lacquer film slowly dissolves over time. This occurs as the calcium-rich saliva and biofilm come into contact with the hardened varnish. When this occurs, the sodium fluoride slowly dissolves and releases fluoride ions. Fluoride ions are rapidly sequestered by free calcium, which is in saliva, plaque and on tooth surfaces. This results in the formation of insoluble calcium fluoride. These insoluble globules of calcium fluoride are capable of providing additional blockage of exposed dentine tubules for sustained relief of tooth hypersensitivity. Additionally fluoride's ability to inhibit demineralization of teeth and reverse the initiation and progression of tooth decay is well documented. When present at low concentrations in the solution surrounding enamel crystals, fluoride is absorbed onto the surface of enamel mineral (carbonated apatite) and acts as a potent protection mechanism against acid dissolution during the inevitable caries challenge. When present in high concentrations, fluoride acts as a catalyst to speed the body's natural remineralization process by absorbing onto the surface of tooth mineral and attracts calcium and phosphate from saliva. When fluoride is incorporated into the tooth mineral in this manner, a new mineral, fluorapatite, is formed. Fluorapatite is much less soluble in acid than fluoride-free carbonated apatite.

Water
Water is incorporated into the cavity varnishes as a co-solvent to alcohol, assisting alcohol in the solubilization of certain ingredients.

Flavor
Flavors are added to the varnish to enhance the patient's experience and to provide fresh breath after the varnish is applied.

Product Description

Clinpro white varnish is a white, viscous fluid that contains 5% sodium fluoride. When applied to the tooth surface in a thin layer, the solvent system (alcohol and water) evaporates rapidly, leaving behind a hard lacquer-like film. This film adheres well to the surface of the teeth and slowly releases fluoride ion.

The rosin used in most cavity varnishes is typically yellow in color. Although the yellow color does not have a negative effect on the performance of a cavity varnish, many patients prefer a white or invisible film, rather than yellow on their teeth, especially as they leave the dental office and return to their daily activities. Clinpro white varnish contains a specially designed rosin that is white or tooth colored. After Clinpro white varnish is applied to the teeth, the product is virtually invisible (Figure 2).

Figure 2: Fluoride varnish appearance on the teeth after application


Clinpro varnish


Conventional resin varnish

Clinpro white varnish is packaged in single unit-doses to eliminate the problems of phase separation and inter-patient contamination. Fluoride varnishes packaged in bulk tubes have been shown to separate during shipment and storage, introducing problems of sodium fluoride and resin uniformity[8]. Unit-dose formulations, however, contain the correct amount of resin and fluoride in the individual package. Although some phase separation may occur during shipment and storage, the unit-dose is easily mixed just prior to application to ensure proper amounts of both resin and sodium fluoride.

Clinpro white varnish is available with a pleasant tasting mint flavor.

Evaluations

Fluoride Release

Aim: The aim of this experiment was to determine the amount of fluoride released from three fluoride varnishes over a 24 hour period.

Approach: A thin, uniform coating of varnish was applied to one end of six (n=6) 6mm diameter acrylic rods. Rods were individually suspended in 2ml of distilled water. Specimens were stored in a 37°C oven with constant stirring. The water was collected and replaced with fresh water after 1, 3 and 24 hours. The water collected was diluted with an equal volume of TISAB II buffer and analyzed for fluoride ion concentration using a calibrated ion selective electrode in the usual manner. Concentrations of fluoride in the water were used to calculate the mass of fluoride released from the 28mm2 surface of varnish.

Results: Cumulative mean micrograms of fluoride released (± standard deviation) for the three varnishes tested were: Duraflor® [2.35 ± 0.15], Duraphat® [4.90 ± 0.45] and Clinpro™ White Varnish [6.02 ± 0.57]. These results are shown in Figure 3 below.

Conclusions: The white fluoride varnish released more fluoride than the conventional yellow-colored fluoride varnishes.

Note: These results have recently been confirmed using a similar experiment (ref 9)

Figure 3: Fluoride released from Clinpro™ White Varnish and a conventional varnish

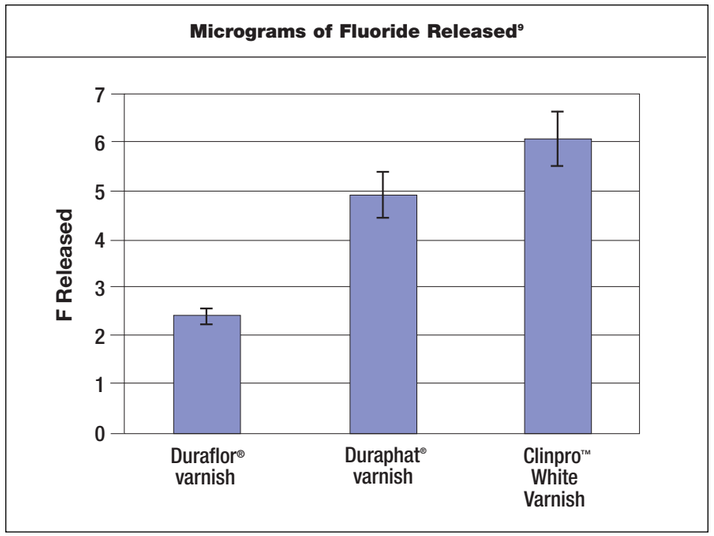
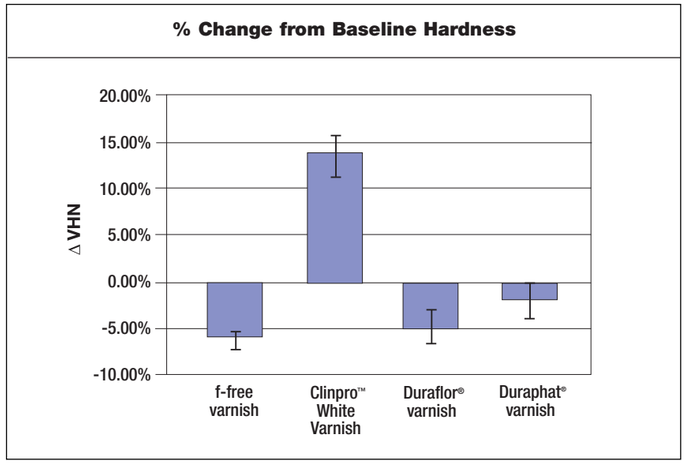


Figure 4: Change in surface microhardness after application of varnish and 40 hours of soaking in artificial saliva at 22°C[9]



Duraphat is a registered trademark of Colgate Oral Pharmaceuticals. Duraflor is a registered trademark of Medicom.

Repair of Tooth Surfaces Damaged by Citric Acid[10]

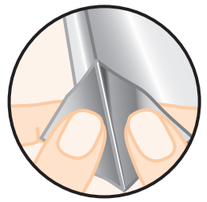
Aim: This study examined the ability of three commercially available and popular 5% sodium fluoride varnishes to repair acid eroded tooth surfaces. It should be noted that tooth erosion differs from caries in that tooth erosion is caused by diet-borne acids while caries (tooth decay) is caused by plaque-borne acids and poor oral hygiene.

Approach: The experiment consisted of four groups: Placebo varnish, Duraflor®, Duraphat®, and Clinpro™ White Varnish with ten bovine enamel specimens in each group. The specimens were ground and polished according to standard procedures. The specimens were then demineralized for 10 minutes in 1% citric acid (pH = 3) to produce enamel lesions. Prior to varnish application, four baseline Vickers microhardness (ΔVHN) indentations were measured and recorded for each specimen. The varnishes were then applied to the enamel specimens and immersed in an artificial saliva solution [ten Cate et al.: Caries Res 1988; 22:20-26]. The specimens remained in solution for 40 hours at 22°C, after which the varnishes were removed with acetone and post-Vickers microhardness measurements were made.

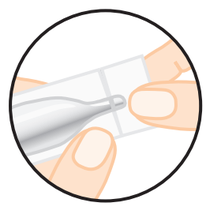
Results: In this study, the measure of varnish efficacy was determined by considering the difference between post and baseline microhardness measurements (ΔVHN). The ΔVHN mean and standard deviations for the four groups are shown in the above chart and are as follows: -16.7 ± 9.2 (Placebo), 32.7 ± 17.5 (Clinpro white varnish), -13.1 ± 15.8 (Duraflor), and -4.5 ± 14.0 (Duraphat). Statistical differences were found based on the Kruskal-Wallis One Way Analysis of Variance using SigmaStat 3.11 software. The Student-Newman-Keuls (SNK) method was used to determine where the differences were ($p < 0.05$). All groups were found to be significantly different from each other except for the comparison between Duraflor and the Placebo which were found to be statistically equivalent. These results are shown in Figure 4 above.

Conclusions: In this study, the Clinpro white varnish formulation provided significantly better repair of acid eroded tooth surfaces relative to Duraflor and Duraphat fluoride varnishes.[10]

Technical Guide

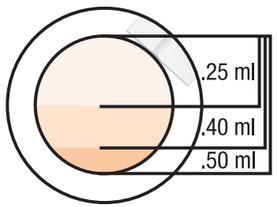


Peel the foil pouch open to expose the Clinpro™ White Varnish unit-dose package and applicator brush.



Open unit-dose package and dispense contents onto dispensing guide sticker or back of foil pouch.

IMPORTANT: Use the applicator brush to thoroughly mix Clinpro varnish. Components of all sodium fluoride varnishes can separate during storage. While mixing, keep the material evenly distributed inside the inner circle of the dosing guide.



Dispense entire contents onto the shaded inner circle. Use Dosage Guidelines to determine amount of Clinpro varnish

Apply Clinpro varnish evenly over treatment area(s).

For best results, excessive saliva should be removed by blotting the tooth. Clinpro varnish will, however, uniformly set to dentition in the presence of saliva. Avoid passing applicator brush through pooled saliva to prevent premature setting on bristles.

Application Tip: Clinpro varnish is designed for rapid application. It is not necessary to apply excessive amounts of varnish, only a thin coating is needed. Clinpro varnish will flow across tooth surfaces after application.

Instructions for Use

General:

Clinpro white varnish is a fluoride-containing varnish for application to enamel and dentine for the treatment of hypersensitive teeth and for use as a cavity liner under amalgam restorations. Clinpro varnish is moisture and saliva tolerant. It will spread on and adhere to moist teeth. 1ml of Clinpro varnish contains 50mg sodium fluoride, equivalent to 22.6mg fluorine, in an alcohol-based solution of modified rosins. The product is sweetened with xylitol.

Indications: Dentinal hypersensitivity, cavity varnish under amalgam restorations.

Contraindications: Ulcerative gingivitis and stomatitis.

Precautions: To limit ingestion, determine the proper dosage amount for the patient. Discontinue patient's use of other prescriptive fluoride preparations (i.e. gels, rinses) for 24 hours following Clinpro varnish application. Children taking fluoride supplements should discontinue use of supplements for 2-3 days following treatment.

Warnings: Edematous swelling has been reported only in rare instances, especially following application to extensive surfaces with fluoride varnish. Dyspnea, although extremely rare, has occurred in asthmatic people. Nausea can occur in patients with known sensitive digestive systems, especially following extensive applications.

Instructions for Use:

Treatment: Follow steps described below.

1. Treatment area(s) should minimally be "toothbrush" clean. A prophylaxis is not required.
2. Open unit-dose package and dispense entire content onto the round dosing guide on the back of the foil pouch, or onto one of the dosing guide stickers provided in the box.
3. IMPORTANT: Use the applicator brush to thoroughly mix Clinpro varnish, since components of all sodium fluoride varnishes can separate during storage. While mixing, keep the material evenly distributed inside the inner circle of the dosing guide.
4. Use the dosing guide to determine the amount of Clinpro varnish required for dosages referenced below.

Dosage Determination:

0.25ml dosage	• To be used to treat patients with primary dentition only. • To be used to treat any patient requiring limited tooth surface or cavity area coverage.
0.40ml dosage	• To be used to treat patients with mixed dentition who require extensive tooth surface or cavity area coverage. • DO NOT use this amount to treat patients with primary dentition only. Follow guidelines above.
0.50ml dosage	• To be used to treat only patients with permanent dentition who require extensive coverage. • DO NOT use this amount to treat patients with primary dentition only. Follow guidelines above. NOTE: If the full amount (0.50ml) is being used, the Clinpro varnish does not need to be dispensed on the dosing guide. A mixing pad or other surface may be used.

5. For best results, excessive saliva should be removed by blotting the tooth surfaces. Clinpro™ White Varnish will, however, uniformly set to dentition in the presence of saliva. Avoid passing applicator brush through pooled saliva to prevent premature setting on bristles.

6. Apply Clinpro varnish evenly over treatment area(s).

7. Saliva quickly and uniformly sets Clinpro varnish onto tooth surfaces. After application, instruct the patient to close their mouth to set Clinpro varnish. Rinsing or suctioning immediately after application is not recommended. You may see a thin coating on the teeth. The patient may feel the thin coating when rubbing with their tongue.

8. The treatment period for Clinpro varnish is minimally 4 hours, preferably overnight.

9. During the treatment period, instruct the patient to avoid hard and sticky foods, products containing alcohol (beverages, oral rinses, etc.), tooth brushing, and flossing. A thorough brushing and flossing will remove Clinpro varnish from tooth surfaces following the treatment period.

Storage and Use: Store at controlled room temperature. Keep away from open flame.

Questions and Answers

Why is Clinpro white varnish a white color and not yellow like conventional varnsihes?
Clinpro white varnish contains a modified-colophony rosin, which makes it different than most products in this class. This modification reduces the yellow color associated with the colophony found in most other fluoride varnish brands

I've heard some patients may have allergic reactions for fluoride varnish. Is there a potential for allergic reaction to Clinpro white varnish?
The modification process used to make Clinpro white varnish white also reduces allergenic potential following exposure.

How long will the sensitivity benefit last?
Research shows that when applied topically, the fluoride varnish will continue to release fluoride ions into the mouth for about 24 hours (Ref 11). After that the resin may remain and continue to block transmission through the dentin tubules for quite some time. This, of course will depend on the patient's habits. For example, aggressive brushing habits may prematurely remove the lacquer film.

What about use for tooth decay?
Because fluoride varnishes contain a high concentration of fluoride in a small amount of material, they are sometimes used as an in-office fluoride treatment. They have practical advantages over other in-office fluoride treatments such as ease of application, nonoffensive taste and small amounts of fluoride than required for gel applications (Ref 12), however Clinpro white varnish is only indicated for dentinal hypersensitivity and as a cavity varnish.

Comparison of Varnishes

The following is a table that compares and contrasts different fluoride varnishes.

Product Name	Distributor	Fluoride	Vehicle/Base	Delivery
Flor-Opal®	Ultradent Products, Inc. South Jordan, UT 800-552-5512	5% NaF	Natural colophonium resin	Unit dose syringe
DuraShield®	Sultan Healthcare Englewood, NJ 800-637-8582	5% NaF	Natural colophonium resin	Unit dose
Fluor Protector	Ivoclar Vivadent, Inc. Amherst, NY 800-533-6825	0.1% difluorosilane	Polyurethane base	Unit dose package/brush
AllSolutions®	Dentsply Professional York, PA 800-877-0020	5% NaF	Natural colophonium resin	Unit dose package/brush
Duraphat®	Colgate Oral Pharmaceuticals New York, NY 800-226-5483	5% NaF	Natural colophonium resin	Tube
Duraflor®	Medicom Tonawanda, NY 800-308-6589	5% NaF	Natural colophonium resin	Unit dose package/brush
Fluorilaq™	Pascal Co., Inc. Bellevue, WA 800-426-8051	5% NaF	Natural colophonium resin	Tube
CavityShield™ 5% Sodium Fluoride Varnish	OMNI Preventive Care, A 3M ESPE Company West Palm Beach, FL 800-445-3386	5% NaF	Natural colophonium resin	Unit-dose package/brush
Clinpro™ White Varnish	OMNI Preventive Care, A 3M ESPE Company West Palm Beach, FL 800-445-3386	5% NaF	Natural white resin	Unit-dose package/brush

Flor-Opal is a registered trademark of UltraDent Products Inc. DuraShield is a registered trademark of Sultan Healthcare. AllSolutions is a registered trademark of Dentsply International. Duraphat is a registered trademark of Colgate Oral Pharmaceuticals. Duraflor is a registered trademark of Medicom. Fluoridex is a trademark of Discus Dental. Fluorilaq is a trademark of Pascal Co., Inc.

Summary

The following is a summary of the features of Clinpro™ White Varnish:

- Contains a patented resin that is uniquely white in color
- Helps maintain oral health in patients with tooth decay
- Helps maintain oral health in patients needing immediate and sustained relief of dentinal hypersensitivity
- Available in convenient unit-dose packaging that eliminates phase separation issues and cross-contaminations
- Specially designed to adhere to the teeth rapidly and remain for extended periods of time
- Releases more of its fluoride than conventional varnishes
- Strengthens tooth mineral softened by acidic foods
- Easy instructions
- Dosing instructions for primary dentition, mixed dentition or permanent dentition

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Warranty

3M ESPE warrants this product will be free from defects in material and manufacture. 3M ESPE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

Limitation of Liability

Except where prohibited by law, 3M ESPE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

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