



Fluoride varnish as a caries remineralization and preventive agent

Lieutenant Commander Jonathan Stahl, DC, USN, Captain Kim E. Diefenderfer, DC, USN,
and Captain N. Blaine Cook, DC, USN

Rationale for remineralization

Dental caries is a dynamic disease process involving the cyclic demineralization and remineralization of tooth structure. A state of health exists when net mineral loss (demineralization) and net mineral gain (remineralization) remain in equilibrium.¹ Fluoride plays a key role in the remineralization of both enamel and dentin caries lesions. Remineralization occurs when calcium and phosphate from saliva, together with fluoride, enter the subsurface region of the lesion and form a new veneer on the existing crystalline remnants in the lesion.² The remineralized surface is more stable and more resistant to further acidic attack. Subsequent acid challenges must be quite strong and prolonged to dissolve the remineralized enamel.

Because initial demineralization occurs below the enamel surface, the outer layer of enamel generally remains intact during the early stages of caries development. In fact, a substantial amount of subsurface demineralization can occur without destroying the outer enamel structural integrity. Using both radiographic and direct visual examination, Pitts and Rimmer³ assessed the caries status of 1468 permanent posterior approximal surfaces in 211 children. For caries lesions located radiographically in the outer half of enamel, none of the enamel surfaces exhibited cavitation; for lesions in the inner half of enamel, only 10.5% were cavitated; for lesions in the outer half of dentin, 40.9% were cavitated. Only when caries extended radiographically to the inner half of dentin was cavitation evident in all affected enamel surfaces. Similarly, other studies have reported that only an approximate 50% of caries lesions in the outer half of dentin exhibited clinical enamel cavitation.^{4,5}

It is crucial to remember that, prior to cavitation of the outer enamel surface, caries remineralization is possible. Therefore, all caries lesions that do not exhibit frank cavitation of the enamel surface (i.e., all lesions in enamel, as well as most lesions in the outer 1/3 to 1/2 of dentin) are potential candidates for remineralization therapy.⁶ By arresting a lesion prior to cavitation, restoration of the tooth can often be avoided. The primary goal of the modern restorative dentist should be to reduce disease activity and place restorations only when all other therapeutic options have been exhausted.

Remineralization therapy

Remineralization therapy is accomplished primarily via application of topical fluoride. Accepted agents include sodium fluoride (NaF), stannous fluoride (SnF₂), and acidulated phosphate fluoride (APF). They may be applied professionally (in-office gels, foams, rinses, and varnishes) or at home (pastes, gels, and rinses). Concentrations range from 230 to 22,600 ppm F. Efficacy depends on the concentration of fluoride used, the frequency and duration of application, and, to a lesser extent, the specific compound utilized.⁷ Clinicians must also consider other factors, including ease of use, cost, and

patient compliance when determining specific treatment regimens.

Fluoride varnish

Over the past few decades in Europe, fluoride varnishes have replaced topical gels and foams as the standard of practice for professionally applied fluoride treatments. Among the reasons cited for their popularity are that the application procedure is safe, easy, convenient, and well accepted by patients, and that varnish actually requires less chair time than gels and foams to apply.^{8,9} In addition, fluoride varnish sets in contact with moisture, which eliminates the need for constant suction during application. Finally, since no tray is required, varnishes are advantageous for patients with a strong gag reflex.

In the United States, fluoride varnishes are approved by the Food and Drug Administration (FDA) as cavity liners and for the treatment of hypersensitive teeth. Employing them in caries prevention and remineralization is considered "off-label" use.¹⁰ Off-label use is very common, entirely legal, and accepted by FDA, providing that the off-label use is generally recognized as acceptable in the scientific community and does not constitute "experimentation."¹¹ In fact, FDA "recognizes that off-label use... is often appropriate and may represent the standard of practice."¹²

TABLE 1. Fluoride varnishes available in the US.¹³

Product	Agent/Concentration	Packaging
Duraphat™ (Colgate Oral Pharmaceuticals)	5% NaF (22,600 ppm F)	Tube (10 ml)
Duraflor™ (Pharmascience Inc.)	5% NaF (22,600 ppm F)	Tube (10 ml); Unit Dose
CavityShield™ (Omnii Oral Pharmaceuticals)	5% NaF (22,600 ppm F)	Unit Dose
ALLSolutions™ (Dentsply)	5% NaF (22,600 ppm F)	Unit Dose
Fluor Protector™ (Ivoclar Vivadent)	1% difluorosilane (1000 ppm F)	Unit Dose

Effectiveness of fluoride varnish

Many studies have evaluated the efficacy of fluoride varnishes. Meta-analyses of 15 clinical studies have reported that Duraphat™ reduced caries development in permanent teeth by 38%¹⁴ to 46%.¹⁵ One recent study determined that fluoride varnish is effective in arresting and reversing active enamel lesions in the primary dentition.¹⁶

Seppa et al.¹⁷ found semi-annual applications of Duraphat™ and 1.23% APF gel to be equally effective in preventing caries among 254 children over three years. In contrast, Tewari et al.¹⁸ reported that, among 1251 children receiving semi-annual in-office fluoride treatments over 2.5 years, Duraphat™ reduced caries experience by 74%, compared to 28% for 2% NaF and 37% for 1.23% APF. Seppa et al.¹⁹ reported that semi-annual applications of Duraphat™ reduced two-year caries increments by 21%, while neither a similar regimen of Fluor Protector™ nor bi-weekly 0.2% NaF rinses reduced caries increment. Similarly, Koch et al.²⁰ reported that children receiving semi-annual Duraphat™ applica-

tions developed 30% fewer caries lesions over two years than children receiving weekly 0.2% NaF rinses.

Application technique

A dental prophylaxis is not required prior to varnish application.²¹ Isolate the teeth with cotton rolls; drying is not critical. Apply the varnish using a bonding agent brush, cotton tip applicator, or syringe type applicator. Usually 0.5-1.0 ml will be enough to coat the entire dentition; therefore, a 10-ml tube of varnish should deliver 10-20 applications; the cost is approximately \$1.00 to \$2.00 per application, with unit dose application costing slightly more. Unit dose systems offer convenience, as well as an assurance of measured dosage, minimizing the risk of acute fluoride toxicity. Fluoride exposure should be limited to less than 1 mg fluoride ion per kilogram of body weight. Currently available unit dose products typically contain 0.50 ml NaF. Based on molecular weight, one ml of 5% NaF contains 22.6 mg fluoride ion, a safely tolerated dose for adults and most children over age 6.

Varnish should be applied to the entire tooth surface. Floss has been suggested as an aid to ensure that the varnish is placed in contact with the interproximal surfaces. This may be beneficial when attempting to remineralize interproximal lesions; however, there is no evidence demonstrating the efficacy of such an approach. Application time ranges from 1-4 minutes, depending on the number of teeth to receive treatment. The varnish will set within a few seconds after placement. Advise the patient to avoid eating for two hours and avoid brushing for the remainder of the day so as not to remove the varnish prior to normal salivary dilution.

Application frequency

To be effective in the treatment of non-cavitated lesions, reapplication of varnish is required. Seppa and Tolonen found no significant differences in two-year caries increment among 300 at-risk children receiving varnish applications either two or four times per year.²² Two studies compared an intensive application regimen (fluoride applied every other day for a total of three applications in one week once per year) to either annual (three-year study) or semi-annual applications (four-year study).^{23,24} The intensive treatment group had significantly greater caries reduction in both studies.

There is no single protocol that can be applied to all patients. Clinical recommendations should be based on a thorough assessment of individual caries risk. The American Dental Association recommends two to four topical fluoride applications annually, depending on caries risk status.²⁵ The US Navy Oral Disease Risk Management Guidelines recommend four applications over 2-4 weeks for all moderate- and high-caries risk patients.²⁶

Summary

The purpose of caries remineralization therapy is to retard, arrest, or reverse the caries process. Periodic topical application of high-concentration fluoride varnish, combined with daily low-dose fluoride exposure (via dentifrice and fluoridated water), is effective in significantly reducing caries experience and should be utilized as a preventive agent for caries-active and high caries-risk patients.

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Dr. Stahl is a resident in Operative and Preventive dentistry at Indiana University. Dr. Diefenderfer is BUMED Specialty Leader for Preventive Dentistry, and a member of the Operative Dentistry staff, Fisher Healthcare Clinic, Naval Hospital, Great Lakes, IL. Dr. Cook is chairman of the NPDS Operative Dentistry Department and BUMED Specialty Leader for Operative Dentistry.

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