1 CE CONTINUING EDUCATION

NEW YORK UNIVERSITY
College of Dentistry
Center for Continuing Dental Education
New York City, NY

The Use of Fluoride Varnishes as Topical Preventive Agents

Ardean Nickerson, RDH, MEd
Gayle Orton, RDH, MEd
LeeAnn Hoaglin-Cooper, RDH

A new form of professionally applied fluoride has been introduced as a topical caries-preventive agent for young children—fluoride varnishes. Although the United States Food and Drug Administration (FDA) has not approved the use of fluoride varnishes as caries preventive agents, a trend has emerged in the United States to apply them to prevent decay in high risk groups. As the "off-label" use of fluoride varnishes increases, the dental hygienist needs to become knowledgeable in the effectiveness, advantages, application, and safety of fluoride varnishes.

Introduction

There is a growing trend in the United States to develop preventive programs that address the oral health needs of young children. These comprehensive programs, which target high risk children from 1-5 years of age, are encouraging parents to seek dental care for their children early in their development. Along with patient education and nutritional counseling, a major component of these programs is a fluoride varnish application.[1-4] The goal of these innovative fluoride varnish preventive programs is to increase the parents' knowledge concerning proper dental health and to introduce the children to very early, basic dental care.

Ardean Nickerson, RDH, MEd, is an associate professor at Eastern Washington University, Spokane, WA. She specializes in community dental programs and restorative dental hygiene.

Gayle Orton, RDH, MEd, is Professor and Chairperson of the Dental Hygiene Department at Eastern Washington University, Spokane, WA. She specializes in preventive dentistry and periodontology.

LeeAnn Hoaglin-Cooper, RDH, BS, is a public health hygienist for Snohomish Health District, Everett, WA. She specializes in community dentistry and dental sealant programs.

Use and Effectiveness of Fluoride Varnishes

Three fluoride varnish products are available in the United States: Fluor Protector C (Ivoclar North America, Amherst, NY) which is a polyurethane liquid varnish containing 0.1% difluorosilane, and Durafluor (Pharmascience Laboratories, Tenafly, NJ) and Duraphat (Colgate Oral Pharmaceuticals, Canton, MA), which are viscous gels containing 5% sodium fluoride (2.26% F) suspension of natural resins. The viscous gel varnish is being used as a topical fluoride agent.

Fluoride varnishes have been used as topical fluoride agents extensively in Europe for the last 30 years and in Canada for approximately 15 years.[5-8] Only recently, however, have dental professionals in the United States advocated the use of fluoride varnishes as an alternative to traditional fluoride applications.[1-4] The reasons for the slow acceptance of fluoride varnishes in the United States include:

- Absence of the Food and Drug Administration (FDA) and American Dental Association (ADA) approval for the use of fluoride varnishes as a preventive agent.
- Lack of aggressive marketing.
- Perceived economic disadvantage, when compared to professionally applied gels, foams, and solutions.
- Minimal research conducted in the United States.

Figure 1. Parent assisting with varnish application. (Photograph courtesy of Robert Shaw, DDS.)

As a result, fluoride varnishes have not been emphasized by oral health educators in America as effective topical fluoride agents. The FDA has only approved their use as cavity liners or for the treatment of dentinal hypersensitivity. To date, manufacturers have not pursued the ADA seal of acceptance or sought FDA approval for the use of varnishes as anticaries agents.

Clinical studies in Europe have established the effectiveness of fluoride varnishes as caries-preventive agents for children (over age 3) and adults. The first controlled clinical trials were conducted in Europe in 1968.[5] Since then, the results of numerous *in vitro* and *in vivo* studies have demonstrated the effectiveness of varnishes in caries prevention.[6-10] Caries reduction percentages from a variety of clinical studies range from 18% to 75%.[7] These results are comparable to the clinical trials of caries reduction for more traditional stannous, sodium, and acidulated phosphate fluorides.[6] Some studies have tested the effectiveness of fluoride varnish in caries prevention in *primary* teeth.[11-13] A 44% caries reduction was demonstrated in a two-year clinical study conducted in Sweden, where Duraphat was applied semiannually to 225 three-year-olds.[12] In this and other studies,[10,11,14,15] fluoride varnish applications demonstrated a pronounced reduction in the number of occlusal caries, where the effect of topically applied fluorides is normally expected to be low. Sealants, however, remain the most effective means of preventing pit and fissure caries.[15] Other researchers found varnishes produce a cariostatic effect on proximal caries[9,13]; after 2 years, the varnish group showed a 66% caries progression, compared to a 91% progression of proximal caries for the untreated group.

Advantages of Fluoride Varnishes

When selecting a fluoride agent for professional use, the dental clinician should consider various characteristics, including patient acceptance, ease of use, and safety. There are some practical advantages of varnishes over traditional fluorides. Fluoride varnishes have an acceptable taste, they set rapidly, and can be applied to a complete dentition in less than 1 minute. These are important advantages for very young children and physically or medically compromised patients who may have difficulty tolerating a fluoride tray for the required 4 minutes. In addition, the application of fluoride varnish does not require special dental equipment, including high- or low-volume suction. This allows the varnish to be applied in an alternative setting for those patients who find the dental operatory a threatening environment. In this setting, the parent can play an important role in treatment by increasing the cooperation of the child during the short application procedure (Figure 1).

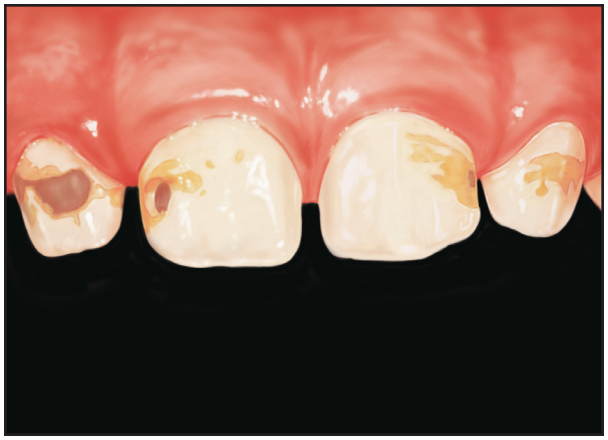

Figure 2. Early decay or decalcification.

Figure 3. Varnish used to remineralize white spot lesions. (Photograph courtesy of Peter Domoto, DDS.)

Providing dental care to a young child can be challenging, especially when early and extensive decay has occurred (Figure 2). Restorative treatment for young children can be traumatic and may result in lasting negative impressions that can adversely affect future dental visits. An advantage of preventive varnish treatments is that they enable the clinician to provide a noninvasive and nonthreatening technique for early intervention and remineralization of early white spot lesions (Figure 3).[1-3] Varnish treatments may also delay caries progression, allowing the postponement of treatment to a later date when the child may be more cooperative.

The frequency of reapplication will vary according to the caries activity level in each child.[16] Any caries preventive strategy and treatment depends on the child's caries risk level. Risk factors include present and past carious lesions, evidence of decalcification, history of fluoride utilization, diet, age, socioeconomic factors, access to care, medical and/or physical compromises, and oral hygiene. High-risk

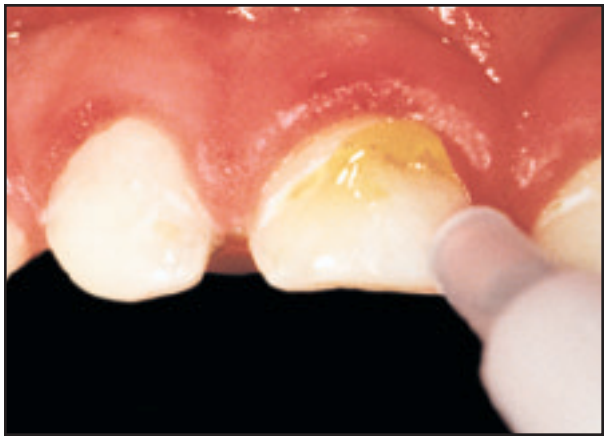

Figure 4. Application of varnish. (Photograph courtesy of Peter Domoto, DDS.)

Table

Safety Comparison of 5% Sodium Fluoride Varnishes and 1.23% Acidulated Phosphate Fluoride

Product	Concentration	Fluoride/ml	Safety level for 22 lb. child (PDT)
Durafluor or Duraphat	2.26% wt.	22.6 mg F	2.2 ml F
APF Fluoride	1.23% wt.	12.3 mg F	4.06 ml F

children should receive more frequent recall appointments to ensure that the patient and/or parent complies with preventive measures. The choice and combination of preventive agents selected will depend on the number and type of risk factors and specific clinical situations. For instance, sealants are more effective preventive agents for pits and fissures, and require the ability to completely isolate the tooth, while topical fluoride treatments are more effective on smooth or demineralized surfaces and can be applied with limited isolation and cleaning.

Application of Varnish

The recommended technique for applying the viscous gel type of fluoride varnish is as follows:

1. Prepare armamentarium, consisting of fluoride varnish, applicator dish or pad, disposable bent-angle brush, child's toothbrush, and 2" × 2" gauze.
2. Wipe off excess plaque from the teeth with toothbrush or gauze.
3. Dry the teeth with cotton roll or gauze. (Note: compressed air can be used if available.) Even though varnishes will adhere to moist teeth, the fluoride application is more effective when the teeth are relatively dry.
4. Dispense a small amount of varnish (0.3 ml to 0.5 ml, or 2 drops, for the *entire primary dentition*) to the applicator dish or pad. Utilizing the disposable brush, apply a thin layer of varnish to the prescribed teeth (Figure 4). Since varnishes set rapidly when they come in contact with saliva, no drying is necessary.
5. Instruct the patient not to eat hard foods, drink, rinse, or brush for several hours, allowing the varnish as much contact time as possible.
6. Inform the parents or caregivers that the varnish will leave a temporary light-yellow stain on the teeth until it dissolves or is brushed off several hours later.

Safety of Fluoride Varnishes

Some controversy exists over the "off-label" use of fluoride varnishes since there are limited studies on the risks of topical fluoride for use on infants or toddlers. Careful application of varnishes is particularly important since all the varnish applied to the teeth is eventually swallowed. This occurs because the film of varnish is allowed to set on the teeth. The fluoride is eventually dissolved from the teeth and is swallowed over an extended period of time. Fluorosis, intrinsic staining, and toxicity are related to the amount ingested, the fluoride concentration within the product, and the weight of the child. Therefore, total fluoride exposure should be monitored.

Toxicity

When applying professional fluorides of any type (ie, gel, solution, or varnish), care should be taken to ensure that any ingested fluoride will be within a safe dose. The "probable toxic dose" (PTD) for fluoride is estimated to be 5 mg F/kg body weight.[17] The PTD is the minimum dose that could cause toxic signs and symptoms requiring emergency treatment, including hospitalization. For a typical two-year-old, weighing 22 pounds, this would equate to 50 milligrams of fluoride ingested at one time.

Comparisons of different topical fluoride treatments relative to safety and ingestion have been reported.[8,11,17-19] Although some fluoride varnishes deliver a higher concentration of fluoride, the application itself is given in *smaller* amounts, therefore there is less chance of a toxic overdose occurring. Clark et al calculated for a typical varnish treatment, an average

of no more than 0.5 ml of varnish was used per application.[11] Using this amount, the patient would receive approximately 11 mg of fluoride (approximately one fourth the PTD for a 22 lb. child). He calculated that the actual amount ingested would be less since a certain amount would remain on the brush and application dish. Studies of plasma and urinary fluoride concentrations following varnish application indicate that a child actually ingests approximately 5.0 mg to 5.2 mg of fluoride when 0.5 ml (11 mg) of varnish is used.[19] This amount is well within the safety range.

In contrast, the amount of fluoride ingested using the typical dose of 3 ml to 8 ml of an acidulated phosphate gel (APF) in a tray ranges from 6.5 mg to 36 mg.[11] Therefore, during a typical APF treatment, the child would ingest *more* fluoride than during a fluoride varnish treatment. Additionally, investigators concluded that the overall potential toxic dose is greatly reduced for varnish since it is gradually ingested over a period of hours, while the APF gel is ingested immediately during and after treatment.[11,20]

Clinicians should be aware that some fluoride varnishes may contain a higher concentration of fluoride than traditionally applied fluoride gels. For example, Durafluor and Duraphat contain 2.26% wt. fluoride (22.6 mg/ml fluoride) compared to 1.23% wt. (12.3 mg/ml fluoride) for acidulated phosphate gels (Table). A two-year-old child weighing 22 lbs would reach the PTD by ingesting 50 mg F which is equivalent to 4.06 ml of APF gel or 2.2 ml of varnish (Table). A toxic dose of fluoride varnish would then be approximately 1/5 to 1/4 of a 10 ml tube.

Fluorosis

Increased prevalence of dental fluorosis and intrinsic staining due to the ingestion of fluoride from a *variety* of accumulative daily sources, invoked the American Dental Association's Council on Scientific Affairs and the American Academy of Pediatric Dentistry to recommend a reduction in the dietary fluoride supplementation in 1994.[21] This recommendation is based on evidence of the overall consumption of daily fluoride from dentifrices, water, and food. To avoid dental fluorosis, a child's *daily* consumption should not exceed more than 0.1 mg F/kg body weight.[18] While it has not been determined that semiannual applications of professionally applied fluorides influence fluorosis risk, precautions should still be taken to minimize the ingestion of fluoride since the amount ingested can be substantial.[18] All sources of fluorides should be considered by the dental professional, (eg, daily fluoride supplements, water fluoridation, fluoridated food products, fluoridated toothpaste) to ensure that the ingestion is not above the recommended level.

Conclusion

Fluoride varnishes are being used experimentally as viable alternatives to the traditional topical fluoride treatment. While their use as topical fluoride agents has been studied in Europe and Canada, more research needs to be conducted before fluoride varnishes will be approved for caries reduction in the United States. Additionally, more research needs to be performed regarding the use of varnishes on children under the age of five.

Fluoride varnishes have some obvious advantages over other traditional fluoride treatments, including reduced application time and alternative application settings. Varnishes serve as important treatment alternatives for the delivery of topical fluoride to young children and/or medically compromised patients. Since fluoride varnishes have a high fluoride concentration, the minimum dosage should be used.

References

1. Nowak AJ, Casamassimo PS. Using anticipatory guidance to provide early dental intervention. J Am Dent Assoc 1995;126(8):1156-1163.
2. Weinstein P, Domoto P, Koday M, Leroux B. Results of a promising open trial to prevent baby bottle tooth decay: A fluoride varnish study. J Dent Child 1994;61(5-6):338-341.
3. Domoto P, Weinstein P, Leroux B, et al. White spots caries in Mexican-American toddlers and parental preference for various strategies. J Dent Child 1994;61(5-6):342-346.
4. Milgrom P, Hujoel P, Grembowski D, Ward JM. Making Medicaid child dental services work: A partnership in Washington State. J Am Dent Assoc 1997;128(10):1440-1446.
5. Sepp(L. Studies of fluoride varnishes in Finland. Proc Finn Dent Soc 1991; 87(4):541-547.
6. De Bruyn H, Arends J. Fluoride varnishes—A review. J Biol Buccale 1987;15(2):71-82.
7. Clark DC. A review on fluoride varnishes: An alternative topical fluoride treatment. Community Dent Oral Epidemiol 1982;10(3):117-123.
8. Yanover L. Fluoride varnishes as cariostatic agents: A review. J Canad Dent Assoc 1982;48(6):401-404.
9. Modéer T, Twetmans, Bergstrand F. Three-year study of the effect of fluoride varnish (Duraphat) on proximal caries progression in teenagers. Scand J Dent Res 1984;92(5):400-407.
10. Haugejorden O, Nord A. Caries incidence after topical application of varnishes containing different concentrations of sodium fluoride: 3-year results. Scand J Dent Res 1991; 99(4):295-300.
11. Clark DC, Stamm JW, Robert G, Tessier C. Results of a 32-month fluoride varnish study in Sherbrooke and Lac-Megantic, Canada. J Am Dent Assoc 1985;111(6):949-953.
12. Holm AK. Effect of a fluoride varnish (Duraphat) in preschool children. Dent Oral Epidemiol 1979;7(5):241-245.
13. Peyron M, Matsson PL, Birkhed D. Progression of approximal caries in primary molars and the effect of Duraphat treatment. Scand J Dent Res 1992;100(6):314-318.
14. Tewari A, Chawla HS, Utreja A. Comparative evaluation of the role of NaF, APF and Duraphat topical fluoride applications in the prevention of dental caries—a 2 l/2 years study. J Indian Soc Pedo Prev Dent 1991;8(1):28-36.
15. Bravo M, Baca P, Llodra JC, Osorio E. A 24-month study comparing sealant and fluoride varnish in caries reduction on different permanent first molar surfaces. J Public Health Dent 1997;57(3):184-187.
16. Petersson LG, Arthursson L, Ostberg C, et al. Caries-inhibiting effects of different modes of Duraphat varnish reapplication: A 3-year radiographic study. Caries Res l991; 25(1):70-73.
17. Whitford GM. The physiological and toxicological characteristics of fluoride. J Dent Res 1990;69(Spec Iss):539-549.
18. Levy SM, Kiritsy MC, Warren JJ. Sources of fluoride intake in children. J Public Health Dent 1995;55(1):39-52.
19. Ekstrand J, Koch G, Petersson LG. Plasma fluoride concentration and urinary fluoride excretion in children following application of the fluoride-containing varnish Duraphat. Caries Res 1980;14:185-189.
20. Ripa LW. An evaluation of the use of professional(operator-applied) topical fluorides. J Dent Res 1990;69(Spec Iss):786-796.
21. Levy SM, Kohout FJ, Kiritsy MC. Infants' fluoride ingestion from water, supplements and dentifrice. J Am Dent Assoc 1995;126:(12)1625-1632.

CONTINUING EDUCATION (CE) EXERCISE NO. 1

NEW YORK UNIVERSITY
College of Dentistry
Center for Continuing Dental Education
New York City, NY

To submit your CE Exercise answers, please use the answer sheet found within the CE Editorial Section of this issue and complete it as follows: 1) Identify the Article; 2) Place an X in the appropriate box for each question; 3) Clip the answer sheet from the page and mail it to the CE Department at Montage Media Corporation. For further instructions, please refer to the CE Editorial Section.

Answers to the 10 multiple-choice questions for this CE exercise are based on the article "The Use of Fluoride Varnishes as Topical Preventive Agents" by Ardean Nickerson, RDH, MEd; Gayle Orton, RDH, MEd; and LeeAnn Hoaglin-Cooper, RDH, BS. Answers will be mailed to all subscribers on a per test basis within one month of the exam deadline.

WARNING: *The Journal of Practical Hygiene* encourages its readers to pursue further education when necessary before implementing any new procedures expressed in this article. Reading an article in *The Journal of Practical Hygiene* does not fully qualify you to incorporate these new techniques or procedures into your practice.

Learning Outcomes:

- Develop an understanding of the effectiveness of fluoride varnishes.
- Become familiar with the advantages and disadvantages of fluoride varnishes when compared to traditional fluoride.
- Gain sufficient information for the proper application of fluoride varnishes.

1. The Food and Drug Administration has approved fluoride varnishes as anticaries agents.
   A. True.
   B. False.

2. Which statement(s) is a reason for the slow acceptance of fluoride varnish use in the United States?
   A. ADA has not approved the use of fluoride varnishes.
   B. Lack of aggressive marketing by the manufacturers.
   C. Lack of research in the United States.
   D. All of the above.

3. Clinical studies in Europe have established that fluoride varnish can be an effective alternative to typical fluoride agents.
   A. True.
   B. False.

4. Which statement indicates an advantage for the use of fluoride varnish over other traditional topical fluoride agents?
   A. Varnishes have a lower fluoride and can be tolerated better by the patient.
   B. Varnish will remineralize white spot lesions more effectively.
   C. Varnish does not need to be applied as frequently.
   D. Varnish takes less time to apply.

5. Which of the following factors determines whether caries-prevention programs and treatment strategies should be implemented on high-risk children?
   A. Diet.
   B. Past caries lesions.
   C. Socioeconomic factors.
   D. All of the above.

6. Which statement(s) accurately describe(s) the application of fluoride varnish?
   A. Apply the same amount of fluoride varnish as fluoride used for acidulated phosphate treatments.
   B. Brush a thin layer of fluoride varnish on the teeth.
   C. It is essential to thoroughly clean the teeth before applying fluoride varnish.
   D. Meticulously dry the teeth since varnish will only adhere to a completely dry surface.

7. The estimated "probable toxic dose" for fluoride is:
   A. 5 mg F/kg body weight.
   B. 10 mg F/kg body weight.
   C. 22 mg F/kg body weight.
   D. 50 mg F/kg body weight.

8. The "probable toxic dose" for fluoride is defined as the:
   A. Minimum amount that can be used to ensure that the fluoride ingestion is not above the recommended level.
   B. Minimum dose that can cause an acute lethal reaction.
   C. Minimum dose that can cause toxic signs and symptoms.
   D. Amount of fluoride used on a two-year-old patient.

9. Which of the following statements is true when comparing the fluoride concentration of varnishes to traditional fluorides?
   A. The chemistry of traditional fluoride and fluoride varnishes is completely different, therefore the concentrations cannot be accurately compared.
   B. Traditional fluorides have the same comparable concentration of fluoride as varnishes.
   C. Traditional fluorides normally have a higher concentration than varnishes.
   D. Varnishes normally have a higher concentration than traditional fluorides.

10. Beyond question, research has proven that semiannual application of topical fluoride causes fluorosis.
    A. True.
    B. False.