Fluoride varnishes: should we be using them?

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Abstract

Fluoride varnishes are fast becoming the standard of care as topical fluoride treatments. Fluoride varnishes still await approval from the FDA for use as caries preventive agents. In the meantime, their use for such purposes is considered "off-label." This article highlights the efficacy of fluoride varnishes as caries preventive agents and introduces some of the commercially available fluoride varnishes to the reader. As more clinical trials in the US unravel the efficacy of these agents, there is little doubt that fluoride varnishes will become an integral part of our preventive armamentarium in the battle against dental caries. (Pediatr Dent 22:513-516, 2000)

There is no doubt that topical fluoride agents provide effective control and protection against dental caries.[1] In recent years researchers have questioned the efficacy of frequency of topical fluoride applications. Concerns regarding fluorosis, ingestion, and toxicity have spurred recent research in reevaluating the clinical efficacy of topical fluoride agents. From the plethora of published research, two factors appear as key players in caries control: recognition and prevention. Recognition and identification of children at risk of developing dental caries is critical. Several factors need to be considered in caries risk assessment and categorization of children into risk groups such as "high," "moderate," and "low" caries risk.[2,3,4] Once an individual's susceptibility to caries is determined, an appropriate prevention regimen tailored to suit the needs of the individual patient must be instituted.

The growing emphasis on prevention-based dentistry has led to rapid development of newer and more innovative treatment modalities aimed at early disease prevention. In this context, fluoride varnishes are fast becoming an integral component of prevention based programs along with patient and parent education. In Europe and Canada, the use of fluoride varnishes has become the standard of care. Despite vast evidence that early intervention with fluoride varnishes is effective, its use in the United States is still in its infancy. In 1994, the US Food and Drug Administration (FDA) approved the use of fluoride varnishes for use as cavity liners and desensitizing agents. In the face of a lack of adequate clinical trials it will be a while before these agents are approved as prevention agents. Promising work by Weinstein et al., and Domoto et al., provide encouraging results.[5,6] At the University of North Carolina Pediatric Dentistry Department, fluoride varnishes have replaced other topical fluoride treatments. Encouraged by these early results, fluoride varnishes are now a Medicaid covered service in the states of Washington and North Carolina. With more clinical trials being done at various centers around the country, it is only a matter of time before professionally applied fluoride varnishes emerge as a valuable tool in our fight against dental caries.

Efficacy in caries reduction

Several excellent studies testify to the potential of fluoride varnishes as effective anti-caries agents. When used appropriately, varnishes offer a 40-56% reduction in caries incidence.[7] Bravo et al., contend that varnishes afford a 36% reduction in fissure caries and a 66% reduction for non-fissured surfaces.[8] Weinstein et al., showed a 51% reversal of decalcified tooth structure and a 35-21% reduction in enamel demineralization.[9] A recent report confirms that fluoride varnish application is effective in reversing and arresting active enamel lesions and therefore reduces the need for restorative intervention.[10] Holm's study on primary teeth showed a 44% reduction in caries with the use of fluoride varnishes in preschool children.[11] Recently, Peyron et al., concluded that fluoride varnish application has a definite cariostatic effect on approximal caries.[12] In comparison with other topical applied fluoride agents, Seppa et al., concluded that fluoride varnishes are as effective as APF gels in controlling approximal caries.[13] Tewari et al., claim significantly high, 70-75% caries reduction with Duraphat fluoride varnish compared to APF or NaF application.[14]

Types of fluoride varnish

Several fluoride varnishes are available commercially

I) Duraphat® [Woelm and Pharma, Eschwege, Germany] (Fig 1) is a 5% sodium fluoride formulation in a viscous colophonium base. One milliliter of the varnish contains 50 mg of NaF(22.6 mg fluoride/ml). Duraphat is marketed in the US by Colgate Oral Pharmaceuticals, Canton, MA. It is available as a 10 ml tube and costs approximately

Fig 1. Duraphat® Fluoride Varnish (Woelm and Pharma, Eschwege, Germany)

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Fig 2. Fluor Protector™ (Ivoclar/Vivadent, Schaan, Lichtenstein)

Fig 3. Duraflor® Varnish (Medicom, Montreal, Canada)

$25.00/tube(estimated at $1.25-2.50/application). Its current FDA status restricts its use as a desensitizing agent for hypersensitive teeth. The resinous base is an alchoholic suspension which, when applied to the tooth surface, evaporates, leaving a layer of fluoride rich varnish attached to the tooth surface.

II) Fluor Protector [Ivoclar/Vivadent, Schaan, Lichtenstein] (Fig 2) contains 1% difluorosilane in a polyurethane base. Each milliliter of varnish contains 1 mg of fluoride ion (1,000 ppm). Fluor Protector has a lower pH than Duraphat and is supplied in a box containing 20 vials. Each vial contains 0.4 ml (0.4 mg F) of the varnish solution. Fluor Protector is less viscous than Duraphat or Duraflor (discussed below). It is distributed in the USA by Ivoclar, North America, Amherst, NY. The cost of a box of 20 vials, which includes a supply of applicator brushes and handles, runs approximately $81.58. (estimated at $4.00/application)

III) Duraflor® [Medicom, Montreal, Canada] (Fig 3) is similar to Duraphat in formulation and contains 5% sodium fluoride varnish in an alcoholic suspension of natural resins. The one additional ingredient in Duraflor (22.6 mg fl/ml) is the artificial sweetening agent xylitol which, as per manufacturer, improves taste and patient acceptability. The varnish is less viscous in nature than Duraphat and is supplied in a 10 ml tube. Each tube costs approximately $24-$28 (estimated at $1.00-$2.00/application). Duraflor is distributed in the USA by Medicom, Buffalo, NY.

IV) CavityShield™ (Omnii Products, West Palm Beach, FL) (Fig 4) is the most recent entrant into the fluoride varnish market. It is a 5% sodium fluoride varnish in a resinous base. Each milliliter contains 50mg NaF. The difference between CavityShield and the other varnishes is that it is a unit-dosed fluoride varnish. Each individual package contains either 0.25 ml(12.5 mg NaF) or 0.40 ml(20 mg NaF) depending on the number of teeth to be treated. This offers several advantages: a) It avoids waste and therefore improves cost effectiveness; b) Each patient gets a controlled amount of fluoride and this prevents over-application; c) It reduces the chance of over-ingestion and prevents fluoride toxicity. Additionally, there is a tendency for the sodium fluoride in the varnishes to settle down due to the particulate nature of NaF (Fig 5). This may be significant because in the tubes (Duraflor, Duraphat) there is no way to assess the amount of fluoride each child is getting. The CavityShield varnish are supplied in individual pouches that are light resistant to avoid congealing of the varnish. The cost of a box of varnish is $24.50 for the 0.25 ml dose, $29.50 for the 0.40 ml dose and $34.50 for a combination package. (estimated at $3.00-$3.75/application)

Varnish application and technique

The frequency of varnish application is best determined based on individual caries risk. Several studies have evaluated the op-

Fig 4. CavityShield™ Fluoride Varnish (Omnii Products, West Palm Beach, Florida)

timum frequency of application as it relates to disease control. The most often used regimen seems to be a semi-annual application.[8] In his review, Clark discussed the various application protocols along with percentage caries reduction seen with each application.[15] Three trends in application frequencies seem to appear:

1. One application every six months;[8]
2. One application four times a year;[16]
3. Three application over a one week period;[17]

It is important to stress that for fluoride varnishes to be effective, reapplication is necessary. How often this is done depends on the child's caries risk. A semi-annual application frequency, however, is the optimum frequency if any benefit is to be expected.

Technique for application

One of the primary advantages of fluoride varnishes is their ease of application. There is considerable confusion as to whether a thorough prophylaxis is essential prior to varnish application. Seppa's study shows that plaque removal is not critical prior to varnish application. The author suggests that a time consuming professional prophylaxis is not necessary and can be replaced with a toothbrush prophylaxis performed by the patients themselves.[18] This may be advantageous from a behavioral standpoint in young patients who are afraid of the handpiece. Most manufacturers however, recommend a prophylaxis prior to varnish application, despite evidence to the contrary. The following sequence of steps can be followed to ensure proper varnish application:

a) Prophylaxis (tooth brush or professional).
b) Isolate quadrant that is ready to receive the varnish using cotton rolls. Most commercially available varnishes set in the presence of moisture, so meticulous drying of the teeth is not critical.
c) Dispense fluoride varnish as per manufacturer's instruction. Usually 0.5-1 ml is more than adequate for the entire dentition.
d) Apply varnish on tooth surfaces using a disposable brush or cotton applicator (Fig 6). The entire surface of the tooth must be treated. Avoid getting varnish on the soft tissue. The varnish sets in a few seconds leaving a fluoride rich layer adjacent to the tooth surface.
e) The entire process takes 3-4 minutes. Duraflor and Duraphat set to a yellowish-brown layer causing a temporary change in tooth color. Parents and patients should be instructed that this discoloration is temporary and will vanish once toothbrushing is commenced. Patients should avoid brushing their teeth for the rest of the day and to avoid eating for the next two hours. It is advisable to put the patients on a soft diet for the rest of the day.

A tube of varnish of Duraflor or Duraphat should last for about 10-20 applications at an average cost of $0.80-$1.00 per application. In comparison to APF gel treatments, the cost of fluoride varnishes is only slightly more expensive.[19] Fluor Protector and CavityShield are meant for single one time use only. Fluoride varnishes are charged out in the Pediatric Dental Clinic in San Antonio as topical fluoride applications. As stated earlier, several states are now reimbursing fluoride varnish in the Medicaid programs.

Fig 5. Sedimentation of NaF in test tube. (Reproduced with kind permission of Omnii Products®).

Ingestion and toxicity concerns

Fluoride varnishes are highly concentrated in their fluoride content. Three of the four commercially available fluoride varnishes have a fluoride content of 22.6 mg/ml (22,600 ppm of fluoride ion). So the potential for ingestion and toxicity does exist. In addition, overapplication is a common occurrence and one must be careful to apply just the required amount on the tooth surface. Varnish application must be carefully monitored until further data proves otherwise. In the state of Texas, its application is still limited to use by dental professionals only. However, in some states, pediatricians and nurse practitioners are prescribing it and advocating its use. Since patients are instructed not to brush their teeth for 24 hours, most of the varnish applied to the tooth surface is ingested and not expectorated. The probable toxic dose for a child weighing 20 kg is approximately 100 mg (potential toxic dose for fluoride – 5 mg/kg). If 0.5 ml is used in one fluoride application, the

Fig 6. Application of fluoride varnish. Note yellow discoloration of teeth. This discoloration is temporary and is removed when normal tooth-brushing resumes. Care must be taken not to place excessive varnish on gingival tissue.

amount of fluoride ingested could amount to 11.30 mg, well below the toxic dose.

Ekstrand et al., evaluated the plasma fluoride concentration and urinary fluoride excretion following application of Duraphat varnish. Their studies revealed that urinary fluoride concentration 12 hours after application was between 500-1,100 μg F ion. These levels are well below the toxic dose.[20] Roberts and Longhurst evaluated 128 patients treated by 39 operators and found that the amount of varnish used was consistent between the providers and that none of the patients received a toxic fluoride dose.[21]

Conclusion

Fluoride varnishes are a safe and efficacious way of delivering and retaining fluoride on tooth structure. In addition, they are effective in controlling caries progression by enhancing remineralization at the tooth surface and inhibiting demineralization. In this regard it is important to note that fluoride varnishes are most effective when used on early white spot lesions which have an intact surface layer. Once obvious cavitation has occurred, it is more appropriate to place a restoration. Varnishes provide a useful alternative for caries control in special needs patients such as those with developmental disabilities, children receiving head and neck radiation, and children on chronic oral medications. Children and adolescents undergoing orthodontic treatment tend to have poor plaque control and can benefit greatly from periodic fluoride varnish application. Its ease of application and relative safety make it a perfect candidate for prevention in community based dental programs. As more data becomes available, use of fluoride varnishes will continue to gain support as an effective tool in disease prevention.

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