Fluoride Varnish

Full Summary

Description:

Fluoride varnish is a concentrated topical fluoride containing 5% sodium fluoride (NaF) in a resin or synthetic base[1]. Bifluoride differs significantly in fluoride concentration at 6%. [2] Depending on the manufacturer, the preparations of varnish vary. It was first introduced in 1964 in Europe (Duraphat) and has been used widely in Europe since then[3, 4]. In 1994 the U.S. Food and Drug Administration (FDA) approved its use as a cavity liner and for treating hypersensitive teeth. However, fluoride varnish is not officially approved in the U.S. for use as a caries-preventive agent. [4] Therefore varnish is used for caries prevention among children and adults as an off-label use in the U.S.[5]. Varnish, when brushed onto the teeth, provides a highly concentrated dose of fluoride and maintains prolonged contact with enamel to inhibit caries. Fluoride varnish must be applied professionally and has been used for over 30 years since its introduction in the 60s. Two concentrations are available in the U.S. Products that contain 5 percent weight sodium fluoride (NaF) at a fluoride (Fl) concentration of 22,600 ppm include Duraphat®, Colgate Oral Pharmaceuticals; Duraflor®, Pharmascience, Inc.; and CavityShield, Omni Oral Pharmaceuticals. One product containing difluorosilane at a lower FI concentration of 1,000 ppm (0.1%) is available: Fluor Protector®, Ivoclar-Vivadent. Varnish products that are available globally include Nupro (Dentsply), ClearShield (Zenith Dental), Bifluoride (Voco, Germany) and Vella (Preventech). Duraphat and Fluor protector are also available globally.

Use and application:

Systematic reviews provide evidence for a caries-preventive effect in the young permanent dentition when applied at least two times per year. In fact, 2-4 applications per year are considered as the most cost-effective mode. [3-6] Fluoride varnish is applied directly on the tooth surfaces and remains on the tooth surface for several hours. Thorough drying of the tooth surfaces is not required because fluoride varnish sets on contact with intra-oral moisture. Prior application of varnish professional prophylaxis of teeth is not required; it is sufficient to brush the teeth. Among children, a small amount is required for application, which is no more than a small drop for each arch.
The varnish should be applied in a thin layer (0.3-0.5 mL) to clean teeth using a disposable brush or applicator. Once the varnish is applied, contamination with saliva is not a concern because the varnish sets quickly. An application takes about one minute in the usual child patient and can increase to up to 4 minutes if doing both arches. Patients (and parents) are instructed to maintain a soft (nonabrasive) diet for the remainder of the day and not to brush or floss the teeth until the following morning. Under these conditions, the varnish remains on the teeth for a number of hours, especially in the pits and fissures, the interproximal and the cervical areas, where it is most needed. Parents should be told that the varnish coating will prevent the teeth from looking bright and shiny, as is seen typically following a prophylaxis and conventional fluoride treatment.

**Effectiveness and Efficacy:**

Numerous clinical trials have been conducted on fluoride varnish, and all have been among children. In a Cochrane Database Review[7] on effectiveness of fluoride varnish, randomized trials comparing varnish to placebo treatment were reviewed. A total of 9 studies were included in the data analysis with a sample of 2,709 children. The authors reported that fluoride varnish has substantial caries-inhibiting effects (pooled prevention fractions were 46% for D(M)FS and 33% for d(e/m)fs). This was based largely on trials that compared varnish to placebo control groups. The authors also reported that there was little or no information on adverse effects of fluoride varnish. The efficacy of fluoride varnish in the prevention of Early Childhood Caries (ECC) was evaluated in a 2-year randomized controlled clinical trial. [4] This study included 376 caries-free children from low-income Chinese and Hispanic families located in the San Francisco area. The authors found that the caries incidence was lower for “counseling + fluoride varnish assigned once/year” (OR = 2.20, 95% CI 1.19–4.08) and “twice/year” (OR = 3.77, 95% CI 1.88–7.58) versus counseling only. In a systematic review for the NIH Consensus Conference, seven studies of fluoride varnish were compared[8]. The analysis showed mixed effectiveness on primary teeth. However, some of the studies that were included were not randomized clinical trials. In a systematic review of clinical trials on fluoride varnish treatment for caries control 302 papers between 1966 and 2003 were included,[9] of these 24 were randomized controlled trials. The trials that met
the inclusion criteria were reviewed, and the main outcome was preventive fraction expressed as a percentage. The results showed evidence for caries-preventive effect of fluoride varnish for permanent teeth in children. The average preventive fraction was 30% (0-69%) when compared with untreated controls. There was inconclusive evidence for primary teeth and adults. In a review of seven studies on effectiveness of varnish in primary teeth, the preventive fraction ranged from 5% to 44%[7]. Of the seven studies reviewed in this study only 2 were randomized trials. Poulsen et al. [10] conducted a systematic review evaluating the data available for the effectiveness of fluoride varnish between 2000-2008. Six papers were included in the review, with preventive fraction ranging between 34% to 57%. Furthermore, a review of reviews has confirmed that a clear and similar effectiveness of topical fluoride toothpastes, mouth rinses, gels and varnishes for preventing caries, and shows that approximately an additional 10% reduction in caries can be expected when another topical fluoride is combined with fluoride toothpaste.[11, 12]

In a large, systemic review of caries diagnostic and management methods 39 diagnostic studies and 27 management studies were included. [13] In this review, the strength of evidence for the efficacy of fluoride varnish for prevention of dental caries in high-risk subjects was fair, and the evidence for all other methods was incomplete. While most studies have been in favor of fluoride varnish, not all have shown effectiveness in public health trials,[14] as there is a potential risk of publication bias.

Overall the caries-preventive fraction for fluoride varnish ranges from 20-50%. However, treatment effect may be overestimated due to the relative lack of placebo-controlled publications. Extensive laboratory research and clinical trials conducted in Europe have reported that that fluoride varnishes are as efficacious as other caries-preventive agents. [15] Fluoride varnishes are widely used in European caries-preventive programs.

Safety:

Studies evaluating safety and toxicity of fluoride varnish have been based on amount ingested by children of different ages. [2] The ingestion occurs over several
hours and days following application of the varnish. The peak plasma concentration is lower for varnish when compared to gel or mouth rinse. On average the amount of varnish applied to treat one child is only 0.5 ml, which delivers 3-11 mg of fluoride ion. [12] In a Cochrane review by Marinho et al. the authors reported that this dose is far below the probable toxic dose (PTD) of 5 mg/kg body weight. [12] In fluoride varnish studies conducted so far, no negative side effects have been reported. [16] In Europe, Duraphat has been the most commonly used fluoride varnish among children for over two decades, and it has not shown any adverse effects. [3]

Currently fluoride varnishes are used widely in Europe and Canada. Fluoride varnish is increasingly being used in the U.S., and more clinical trials are being conducted to evaluate fluoride varnish for use among children and adults.

Cost:

Bawden (1998) reported that fluoride varnish applications cost about 65 cents, including the cost of the brush. [2] The cost of trays is eliminated. Taken together, the total cost of a varnish application may be slightly higher than a gel application, but the advantages are considerable. In a study by Vaikuntam et al the authors reported the estimated cost for varnish to be $1-$4 per application, depending on the brand. The major expense is the personnel needed to apply the varnish. [17] Furthermore, fluoride varnish takes less time, creates less patient discomfort and achieves greater patient acceptability, especially in pre-school children, compared with fluoride gel.[18]

In a cost analysis of school-based fluoride varnish and fluoride rinsing programs reported in Sweden the outcome and costs of fluoride varnish treatment (FVT) and fluoride mouth rinse programs (FMR) were modeled. [9] The FVT program had a better outcome in reducing caries than FMR, and costs were lower. The FVT was expected to result in cost containment compared to controls 3 years after the end of the preventive FVT program. The ratios of benefits to costs were 1.8: 1 for FVT and 0.9: 1 for FMR. Therefore, prevention by FVT may result in cost containment at a benefit-cost ratio of 1.8: 1, given that the program for children can be administered at school.
Recommendations for community-based protocol:

1. The scientific evidence for community-based use of fluoride varnish is based on studies conducted in children. [2] There is a lack of evidence documenting its effectiveness for high-risk adults. The current recommendations suggest that 5% NaF varnish should be used every six months or 2-4 times per year. If only 1 topical fluoride agent is being used (in addition to fluoride dentifrice), and professional personnel are available, varnish is preferred to APF gel and may be preferable to 0.2% NaF mouth rinse. [19] Fluoride varnish is even more effective if the community water is optimally fluoridated.

2. The Centers for Disease Control and Prevention (CDC) reported that based on the evidence from studies, fluoride varnish is effective with biannual applications, i.e., 2 applications, 6 months apart. [4] The CDC recommends that the target population for this recommendation be those at “high-risk”. This is based on evidence from randomized clinical trials. Some studies suggest 4 applications per year. Whether this improves the benefits when compared to 2 applications is not evident. The strength of recommendation by CDC for fluoride varnish was rated as “A” which means “good evidence.”

3. The National Institutes of Health (NIH) Consensus Statement (2001) regarding fluoride varnish reported that the evidence for benefit from applying fluoride varnish to permanent teeth is positive. [20] However, the evidence for primary teeth is incomplete.

4. The World Health Organization (WHO) provided separate recommendations for high-caries and low-caries communities. [21] For high-caries communities WHO recommends varnish application for all children 2-4 times in a year. [22] This will decrease caries by 30-40%. For low-caries communities, varnish can be used for children based on their history of caries.
5. In a systemic review by Azarpazhooh and Main (2008), the authors summarized the recommendations for use of fluoride varnish for the prevention of caries among high-risk children and adolescents. [23] These recommendations were based on 105 scientific studies and reviews. The recommendations are:

a. Fluoride varnish should be applied twice a year unless there is no risk of caries based on past and current caries history.

b. Single-dose packages of varnish should be used for children, and these packages should be stirred vigorously to ensure any precipitated fluoride is dissolved.

c. There is good evidence that varnish complements other preventive strategies such as sealants, tooth brushing and counseling.
References:


