Fluoride Varnish: an Evidence-Based Approach  
Research Brief  
Association of State and Territorial Dental Directors  
Fluorides Committee  
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Is Fluoride Varnish Safe?

Fluoride varnishes are generally considered safe and well accepted. (Beltran-Aguilar, Goldstein, Lockwood, 2000; Seppa L, 1999; Bawden, 1998) However, published data on possible adverse effects is scarce. (Marinho, Higgins, Sheiham, Logan, 2004a, Marinho, Higgins, Logan, 2004)

Although fluoride varnish preparations contain up to 50,000 ppm sodium fluoride, only a very small amount is applied (2.3 to 5.0 mg) (Ekstrand, Koch, Petersson, 1980) Since the resin-based varnish sticks to the teeth, fluoride is ingested over a period of time as the varnish slowly breaks away from the tooth surface. The Beltran-Aguilar, Goldstein and Lockwood review (2000) found the risk of acute toxic reactions with varnishes to be minimal due to the rapid setting time and small dosages even with ingestion of some product during application and following application.

A few articles on fluoride varnish for the prevention, management, and treatment of dental caries reported no acute toxic effects in children or adolescents as a result of the therapeutic application of fluoride varnish. (Seppa, 1999; Moberg, Petersson, Lith, Birkhed, 2005)

Two studies looked at differences in plasma fluoride levels after fluoride varnish application in preschool children specifically. Ekstrand and colleagues (1980) reported a low plasma fluoride level following placement of a 5% fluoride varnish on two preschool children, which was comparable to plasma fluoride levels experienced after toothbrushing with a fluoridated dentifrice or after ingesting a 1 mg fluoride tablet. (Roberts, Longhurst, 1987; Ekstrand J, Koch G, Petersson, 1983)

The level was also significantly lower than plasma fluoride levels seen after a professionally applied 1.23 percent APF gel. (Ekstrand J, Koch G, Lindgren LE, Petersson, 1981)
Infants and toddlers

The two Cochrane reviews by Marinho and colleagues (2004, 2004a) recommended that future fluoride varnish studies include reports of adverse events or safety concerns. The UCSF study was the first one to intentionally collect data on adverse effects and report the lack of such effects for infants and toddlers. (Weintraub, Ramos-Gomez, June, 2006) No adverse effects were reported from 250 children following application of fluoride varnishes. Infants and toddlers absorb fluoride differently from older children, due to the substantial growth rate between birth and age two. (Whitford, 1999) Hence, care must be exercised by applying fluoride sparingly and preventing children from swallowing the excess product during applications.

Allergy

According to the ADA (2006), there are no confirmed allergic reactions to fluoride. Though uncommon, allergic reactions can occur in individuals with a known sensitivity to colophony/rosin. (Sharma, 2006)

Colophony is a contact sensitizer present in fluoride varnish and in many household products such as cosmetics, nail varnish, sticking plasters and chewing gum, as well as in some dental materials. Direct skin/mucosa exposure to colophony from varnish in a hypersensitive person may initiate an allergic contact dermatitis/stomatitis. Two cases of contact allergy to Duraphat varnish have been reported in the literature: one is a case of dermatitis on a dental assistant’s hand, and the other is a case of stomatitis in a patient. (Isaksson, Bruze, Bjorkner, Kiklasson, 1993) These allergies were likely related to the colophony component of the varnish. A thorough health history to determine known allergies, similar to that obtained prior to the administration of any therapeutic agent, is recommended prior to fluoride varnish use. Fluoride varnish is contraindicated when ulcerative gingivitis and stomatitis is present and should not be applied on large open lesions.

Does Fluoride Varnish Contribute To Fluorosis?

Fluoride varnish (with peak plasma fluoride levels less than a daily fluoride tablet or brushing with fluoride toothpaste) applied infrequently (two to four times a year at three-to-six-month intervals) is unlikely to contribute to fluorosis in children under age six. (Ekstrand, Koch, Petersson, 1980) Any risk for very young children following multiple applications (three or more times in one week or greater than four times a year) has not been determined.

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