Fluoride Varnish in a Pediatric Practice
Created by
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OMNII Oral Pharmaceuticals
The Preventive Care Consultants

OMNII “Firsts In Dentistry”
OMNII Gel™ PerioMed™ white & brite® FlossRx™
Another OMNII “First”!
CavityShield®
5% Neutral Sodium Fluoride Varnish

May 2000 - Cover Story

“Off Label” Efficacy

Tewart & Associates reported that after 2.5 years, the fluoride varnish resulted in a higher percentage of caries reduction than did the 2% sodium fluoride solution and the 1.23% acidulated phosphate fluoride gel.

Source: JADA, MAY, 2000
“Off Label” Efficacy

- Numerous randomized clinical trials conducted outside the United States point to the efficacy and safety of fluoride varnishes as a caries-preventive agent.

Source: JADA, MAY, 2000

Other Feature Articles

RDH
April 2001

Journal of Clinical Orthodontics
June 2000

Pediatric Dentistry
November/December 2000

March 2001, Washington, D.C.

“The overall preventive effect of professional fluoride gel treatments on caries increments between children treated and children not treated was between 18 and 25 percent; Clinical investigation of the application of fluoride varnish to permanent teeth of children provided preventive effects of between 25 and 50 percent.”

R. Gary Rozier, D.D.S.
Worldwide Usage

- Developed in late 1960s and early 1970's
- Numerous studies show efficacy
- Used extensively in Europe and Canada as a primary preventive agent
- 92% of Denmark's municipal preventive programs use Fluoride Varnish exclusively
- As much as 75% reduction in decay*

* Boran Esh et al. 1975

Fluoride Varnishes Available In The U.S.

- Duraphat® (Colgate Oral Pharmaceuticals) 5% NaF - 10 ml tube
- Duraflo® (Johnson & Johnson) 5% NaF - 10 ml tube
- Fluor Protector® (Dentron International) 1% Difluorosilane (unit-dose)
- CavityShield® (OMNII) 5% NaF (unit-dose)

Advantages of Fluoride Varnish

- Neutral taste
- Apply in less than one minute
  - Does not require special equipment or the need for prophylaxis prior to application
- Safety
- Application in Orthodontics
  - As much as 50% reduction in demineralization
- Special applications for handicapped, mentally and medically compromised patients
- Delay caries progression

I. N. Todd et al., "Effect of fluoride varnish on demineralization adjacent to orthodontic brackets," American Journal of Orthodontics and Dentofacial Orthopedics (August 1999) 139-142
Neutral Taste

- CavityShield® sets on contact with saliva
- CavityShield® is sweetened with Xylitol

Application

- No need for prophy prior to application
- Yellow tint for application control
- “Tooth brush cleaning”
- Applicator brush provided for convenience and cost savings
- Unit-dosed for asepsis control

Color
Inherently Inconsistent Dosage Delivery

Product Safety

- CavityShield®
  - 1 ml = 50 mg sodium fluoride = 22.6 mg F
  - 22,600 ppm F
- Dosage Applied
  - 0.25 ml for primary dentition
  - 0.40 ml for mixed dentition
  - 0.65 ml for permanent dentition

Following application of varnish on four children, age 4, 5, 12, and 14: "Peak plasma fluoride concentrations of 3.2 to 9.3 mmol/L were found within two hours of treatment… These levels were comparable with those found after brushing with a fluoridated toothpaste (7.63 ± 0.40 mmol/L) or after ingesting a 1 mg F tablet (4.47 ± 0.37 mmol/L) and were considerably lower than those reported for APF gels (16 to 76 µmol/h)… If 0.50 ml of varnish is consumed this is 11.3 mg F and is 1/9 the potential toxic dose for a 44 lb (20 kg) child. Clark et al."
Orthodontic Application


50% Reduction Demineralized Enamel

Conservative Treatment of White Spot Lesions
White Lesions Not Visible on X-ray

White Spot Treatment

Other Current Treatment Modalities

• Severe Early Childhood Caries
  (Arrest progression to time when child will tolerate needed treatment)
• Placement under the flap of partially erupted six or twelve year old molars
Glass Ionomer

Recharge Fluoride Content

Fluoride Treatments for the Future

"Nine out of ten patients prefer fluoride varnish."(1)


**Care After Treatment**

**Directions For Care After Treatment With CavityShield® Fluoride Varnish.**

- After the application of CavityShield® you will feel a coating and may notice a difference in color while the varnish remains on your teeth. To obtain the maximum benefit during the 4 - 6 hour treatment period, we ask that you take the following care after you leave our office:

  - Do not remove CavityShield® by brushing or flossing for at least 4 - 6 hours.
  - If possible, wait until tomorrow morning to resume normal oral hygiene.
  - Eat a soft food diet during the treatment period.
  - Avoid hot drinks and products containing alcohol (i.e.: beverages, oral rinses, etc.) during the treatment period.
  - A thorough brushing and flossing will easily remove any remaining CavityShield®. Your teeth will return to the same shine and brightness as before the treatment.

**Cost Per Application**

- CavityShield® Unit-Dose (0.25 ml - 32 packages)  $0.91
- Duraphat (10 ml tube)  $1.48
- Duraflor (10 ml tube)  $1.54

Average cost per application for gel or foam in disposable tray is between $0.55 and $1.18.

* Includes cost of brush, if not provided. Retail price comparison (Cylomes and Schein) as of 5/2001.

**OMNII Oral Pharmaceuticals®**

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