

Fluoride Varnish in the Prevention of Dental Caries in Children and Adolescents: A Systematic Review

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SOMMAIRE

Objectif : Élaborer un protocole fondé sur des données scientifiques probantes et à jour sur l'utilisation des vernis fluorurés pour prévenir la carie dentaire chez les enfants et les adolescents à risque élevé.

Méthodologie : Les précédentes revues systématiques de la littérature sur le sujet ont servi de base à la présente étude. Ovid MEDLINE, CINAHL et plusieurs autres bases de données bibliographiques pertinentes ont été consultées, à la recherche d'articles publiés en anglais, avec des sujets humains, entre 2000 et 2007.

Résultats : La recherche documentaire a permis de recenser 105 articles, dont la pertinence a été évaluée à partir du titre, du sommaire et du corps de l'article. Sept recherches originales satisfaisaient aux critères d'inclusion. Ces articles ont été lus et notés par 2 examinateurs indépendants, et les données probantes en ont été extraites aux fins de la revue systématique.

Recommandations : Les recommandations qui suivent ont été formulées sur la base des données compilées :

1. Dans le cas des populations à haut risque (p. ex., personnes de faible statut socioéconomique, nouveaux immigrants et réfugiés, enfants et adolescents des Premières Nations et des Inuits), l'application de vernis fluorurés devrait se faire 2 fois par année à moins que la personne ne présente pas de risque de carie, d'après ses antécédents et son état actuel à l'égard des caries. Cette fréquence d'application permettrait de faire vérifier les scellants 2 fois par année pour s'assurer de leur bonne rétention.
2. Des flacons à dose unique devraient être utilisés pour les enfants; le cas échéant, il faut agiter vigoureusement le vernis avant de l'appliquer pour assurer la remise en solution de tout fluorure précipité.
3. Il existe de bonnes données attestant de l'efficacité complémentaire des stratégies préventives comme les scellants et les vernis, ainsi que le brossage des dents et le counseling nutritionnel. Les programmes de santé buccodentaire devraient donc inclure le plus de stratégies préventives complémentaires possibles.

Pour les citations, la version définitive de cet article est la version électronique : www.cda-adc.ca/jcda/vol-74/issue-1/73.html

First developed and marketed in the 1960s in the form of sodium fluoride (Duraphat, Colgate, New York, N.Y.) and in the 1970s in the form of silane fluoride (Fluor Protector, Ivoclar Vivadent, Lichtenstein, Germany), fluoride varnishes prolong contact between

fluoride and enamel. The effectiveness, ease of application and relative safety of these products offer significant advantages over other topical fluoride treatments, such as gels and rinses.¹⁻³ The general method of application is shown in Fig. 1.

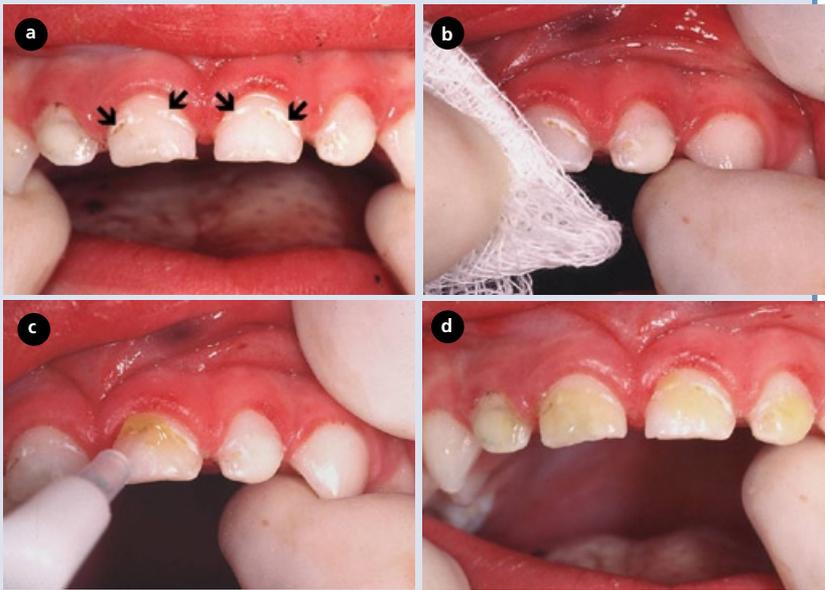


Figure 1: Demonstration of fluoride varnish technique. **(a)** Areas of demineralized enamel on the primary incisors. **(b)** Teeth are dried with gauze square. **(c)** Varnish is applied to the tooth surface with a small brush. **(d)** After application, a yellow film remains on the teeth. (Source: Courtesy of the University of Iowa—Center for Leadership Training in Pediatric Dentistry. Available from: www.uiowa.edu/~c090247/fluoride_varnish.htm)

Several reviews of the use of fluoride therapies in preventing dental caries have been published since the year 2000,⁴⁻¹⁷ including 2 evidence-based reports.^{18,19} The Cochrane reviews of this topic¹⁹⁻²² concluded that “Fluoride varnishes applied professionally two to four times a year would substantially reduce tooth decay in children. ... The review of trials found that fluoride varnish can substantially reduce tooth decay in both milk teeth and permanent teeth. However, more rigorous research is needed to be sure of how big a difference the treatment makes, and to study acceptability and adverse effects.”¹⁹

The Community Dental Health Services Research Unit of the University of Toronto¹⁸ concluded that “Both APF [acidulated phosphate fluoride] gel and fluoride varnish are efficacious and can be recommended. Fluoride varnish, while efficacious, has not been found to be superior to or ‘at least as good as’ APF gel. However, there may be a significant cost advantage in favour of fluoride varnish but it is poorly documented. Thus, APF gel remains the first choice for PATF [professionally applied topical fluoride].”

In addition, an expert panel of the American Dental Association recently concluded that “Fluoride varnish applied every six months is effective in preventing caries in the primary and permanent dentition of children and adolescents. Two or more applications of fluoride varnish per year are effective in reducing the caries prevalence in high-risk populations. Fluoride varnish applications take less time, create

less patient discomfort and achieve greater patient acceptability than fluoride gels, especially in preschool-aged children.”⁸

In addition to these reports, guidelines have been established by several dental organizations, including the American Academy of Pediatric Dentistry,²³⁻²⁵ the British Society of Paediatric Dentistry²⁶ and the European Academy of Paediatric Dentistry.⁵

As an update to the previously published reviews on this topic, the present systematic review was undertaken with the aim of developing a scientifically current and evidence-based protocol. More specifically, the authors of the report attempted to answer the following questions:

1. How effective is fluoride varnish in preventing dental caries in a predominantly high-risk population? In particular, how effective is fluoride varnish for young children?
2. Does the efficacy of fluoride varnish improve with multiple applications within a short time frame?
3. What is the recommended frequency for the use of fluoride varnish?
4. Are there any concerns related to concentration and method of application?
5. Are fluoride varnishes cost-effective?

For the purposes of this study, it was assumed that any benefit in terms of improved health outcomes had to be both clinically significant (i.e., the smallest difference identified by clinicians and patients as improving oral health or wellness) and statistically significant ($p < 0.05$); if there was no benefit at the clinical and statistical threshold of health improvement, then the procedure should not be used for that purpose.

Methods

Database Search

The following data sources were searched, for the period from 2000 to 2007, for articles about fluoride varnish and concerns about its concentration and application: Ovid MEDLINE (In-Process and Other Non-Indexed Citations, Daily Update), CINAHL (Cumulative Index to Nursing and Allied Health Literature), the Evidence Based Medicine section of the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, EMBASE, Health and Psychosocial Instruments, HealthSTAR, International Pharmaceutical Abstracts, Journals@Ovid and *ACP Journal Club*.

Table 1 Search strategy for systematic review of fluoride varnish in the prevention of dental caries in children and adolescents

Step	Search terms	No. of articles returned
1	(fluoride\$ or fluor\$ or AMF or Amine F or amine fluor\$ or SNF2 or stannous F or stannous fluor\$ or NAF\$ or sodium F or sodium fluor\$ or APF\$ or MFP or SMFP or monofluor\$ or duraphat or SNF\$ or acidulated\$ phosphate\$ fluorid\$ or acidulated\$ fluorid\$ or phosphate\$ fluorid\$ or varnish\$ or gel\$).mp. [mp=ti, ot, ab, nm, hw, sh, tn, dm, mf, it, rw, ac, de, tx, kw, ct, bt]	1,605,774
2	(topical\$ FLUORIDE\$ or professiona\$ applied\$ fluoride\$).mp. [mp=ti, ot, ab, nm, hw, sh, tn, dm, mf, it, rw, ac, de, tx, kw, ct, bt]	1,503
3	(CARIOSTATIC AGENT\$ or ANTICARI\$ or ANTI\$ CARI\$ or DENTAL CARIE\$ or tooth carie\$ or dental decay or tooth decay or DMF\$ or tooth or teeth or DENT\$).mp. [mp=ti, ot, ab, nm, hw, sh, tn, dm, mf, it, rw, ac, de, tx, kw, ct, bt]	578,381
4	1 and 2 and 3	1,407
5	limit 4 to English	1,317
6	limit 5 to humans	1,241
7	limit 6 to yr="2000 - 2007"	529
8	remove duplicates from 7	386
9	8 and varnish.mp. [mp=ti, ot, ab, nm, hw, sh, tn, dm, mf, it, rw, ac, de, tx, kw, ct, bt]	94
10	Included on basis of screening title and abstract	42
11	Included on basis of reading complete article	8
12	Included after application of checklist score cut-off (>11/16)	7

Inclusion Criteria

The searches were limited to articles in English and those concerning humans. Other inclusion criteria were age 0–18 years (which resulted in no change in citations identified) and year of publication from 2000 to 2007 (the Cochrane reviews^{19–22} and the University of Toronto’s Community Dental Health Services Research Unit review,¹⁸ which were used as a base for the current review, covered the literature up to 2000). Original research articles addressing the efficacy of varnish, protocols for its use or its toxic effects, as well as review articles providing background information, were included.

Search Strategy

Table 1 lists the key words and combinations of key words used in the searches. Articles were retrieved using the appropriate search strategy for each database. Additional articles were identified by reviewing the reference lists and bibliographies of the articles obtained by database searching. The identified articles and their abstracts were reviewed independently by the 2 authors. Articles that did not concern the efficacy of varnish, protocols for the use of varnish or the toxic effects of varnish or that did not provide background information (review articles or guidelines) were excluded. Review articles^{4,6,7,9–11,14,15,27–29} and all known guidelines^{5,8,10,23–26} were retrieved and reviewed for their conclusions and to identify additional citations. The total number of articles

retrieved, after removal of duplicates, was 42 (**Table 1**). All 42 articles were retrieved and read, and 8 were scored using the University of Toronto faculty of dentistry “Checklist to Assess Evidence of Efficacy of Therapy or Prevention.”³⁰ This checklist consists of questions addressing ethics, study design, methodology and appropriateness of the results to the population of interest. Only studies with a score of at least 11 (out of a maximum score of 16) were included as the evidence for this review ($n = 7$). The evidence from these 7 studies, which was deemed to represent the best available evidence, was summarized according to the inclusion criteria, and the strength and quality of each study were determined according to the evidence classification system developed by the Canadian Task Force on Preventive Health Care.³¹ This system includes a hierarchy of evidence, from the highest (level I; properly randomized controlled trials) to the lowest (level III; opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees). The system also includes a bidirectional classification of recommendations for specific clinical preventive actions (grades A to E and grade I, with grade A representing good evidence to recommend *for* the clinical preventive action, grade E representing good evidence to recommend *against* the clinical preventive action, and grade I representing insufficient evidence, in quantity and/or quality, to make a recommendation). Recommendations for the use of varnish

for caries prevention were made on the basis of the information in these 7 articles.

Results

How effective is fluoride varnish in preventing dental caries in a predominantly high-risk population? In particular, how effective is fluoride varnish for young children?

The level of evidence and the recommendations for each of the 7 acceptable articles^{28,32-37} are listed in **Appendix 1** (see www.cda-adc.ca/jcda/vol-74/issue-1/73.html), where they are presented in descending order, from highest level of effectiveness and highest score on the checklist for efficacy.³⁰ For example, in the strongest article in this series (level of evidence I, grade of recommendation A), Moberg Sköld and others³³ found that monthly application of fluoride varnish (for 8 months per year) was the most effective preventive regime (compared with 3 times a year within 1 week or semiannual applications) for a group of 13- to 16-year-olds from 3 different communities (with high, medium and low socioeconomic status, respectively). However, over the 3-year follow-up period, application of fluoride varnish every 6 months was the most cost-effective method for those from the high- and medium-risk areas (**Appendix 1**).

The second strongest study in this series (level of evidence I, grade of recommendation A) was a 2-year randomized study of 1,275 children from 20 Canadian First Nations communities, ranging in age from 6 months to 5 years (13.7% < 1 year old, 24.7% 1 year old, 25.9% 2 years old, 21.6% 3 years old and 14.0% 4–5 years old).³⁴ The study protocol required a minimum of 2 applications of fluoride varnish per year. Caries reduction was greater with at least the twice-yearly application of fluoride varnish (decayed, missing, filled surfaces [dmfs] 11.00 ± 0.50 vs. 13.47 ± 0.90 for the First Nations control group, $p = 0.061$), yielding a reduction of 18.3% in the dmfs increment (**Appendix 1**).

Does the efficacy of fluoride varnish improve with multiple applications within a short time frame?

Research to date has shown no difference in efficacy with multiple applications of varnish within a short period (e.g., 3 applications within 2 weeks). Moberg Sköld and others³³ studied a total of 4 different protocols in children with different caries risk: (1) twice a year, at 6-month intervals, for 3 years, for a total of 6 applications over 3 years; (2) 3 times within a 1-week period, repeated over 3 years, for a total of 9 times in 3 years; (3) 8 times per year for 3 years, at 1-month intervals during school semesters, for a total of 24 times in 3 years; and (4) no treatment (control). Caries prevalence rates were as follows:

- Approximal dental lesions: The only significant differences were between group 1 and the control group in the high-risk area (0.23 ± 0.74 vs. 0.85 ± 1.35 ,

$p = 0.031$) and for all 3 locations combined (0.16 ± 0.56 vs. 0.43 ± 1.05 , $p = 0.012$).

- Filled approximal surfaces and approximal enamel lesions: No significant differences between groups.

The authors concluded that school-based application of fluoride varnish every 6 months is an excellent way of preventing approximal caries in 13- to 16-year-olds living in areas with medium and high caries risk.

What is the recommended frequency for the use of fluoride varnish?

According to the risk assessment literature,^{1,38-43} the best predictor of future caries development is past history or current evidence of caries. Therefore, it is important to determine the level of caries risk and treat accordingly. The appropriate frequency of use of fluoride varnish depends on the level of risk. As such, we recommend that a well-stirred single-dose package of fluoride varnish be applied once a year for patients at low risk and twice a year for those at high risk. In an earlier evidence-based report,⁴⁴ we suggested the following criteria for caries risk: low to moderate risk defined as 0–3 caries, fillings or extractions in the past 3 years (i.e., decayed, extracted or filled primary teeth [deft]/DMFT of 0, 1, 2 or 3), cariogenic diet, active orthodontic treatment, physical disability, restoration with overhangs or open margins, and presence of exposed root surfaces (in older populations); high risk defined as deft/DMFT ≥ 4 , with prominent medical history causing dry mouth (e.g., disease, radiation or medication).

Are there any concerns related to concentration and method of application?

Several articles have addressed the potential for fluoride gradients to occur within multidose varnish vials.⁴⁵⁻⁴⁷ These gradients have been identified most often with Durafluor (Pharmascience, Montreal, Que.) and Duraphat, such that samples from the same vial may contain different amounts of fluoride. The authors of these articles suggested that the gradients are caused by separation of the fluoride out of the varnish. As a result of these observations, it is recommended that single-dose preparations be used. In addition, the same studies demonstrated the slow release of fluoride, for periods of up to 6 months, with Durafluor and Duraphat,⁴⁵⁻⁴⁷ the greatest release occurring in the first 3 weeks and more gradual release thereafter. This observation supports the recommendation for twice-yearly application of single-dose preparations, with vigorous stirring before application to minimize any separation.

Are fluoride varnishes cost-effective?

In a Canadian setting, Hawkins and others⁴⁸ compared the costs and patient acceptance of 2 methods of professional application of topical fluorides (varnish vs. foam) and found that application of varnish took significantly less time and resulted in significantly fewer signs of gagging discom-

fort than application of foam. For children 3–6 years of age, the cost per varnish application, including labour, was substantially less (Can\$3.43 for varnish vs. Can\$4.43).

Kallestal and others⁴⁹ performed a systematic review of economic evaluations of different forms of caries prevention published from 1966 to 2003. They identified only 2 original case-control studies that included an economic evaluation with 4-year follow-up: 1 from Sweden,⁵⁰ which showed similar cost-effectiveness between the cases and the control group, and 1 from Finland,⁵¹ which showed a cost-effectiveness ratio of 1.8 over 4 years in favour of fluoride varnish. The authors stated that the evidence for the economic value of fluoride varnish application was inconclusive.

Recently, Quinonez and others⁵² compared the cost-effectiveness of universal application of fluoride varnish at 9, 18, 24 and 36 months with no intervention by medical providers. The fluoride treatment, if given, was implemented within a well-child periodic health examination schedule for children aged 9 to 42 months who were receiving health care through Medicaid. The authors found that application of fluoride varnish improved clinical outcomes by 1.52 cavity-free months at a cost of US\$7.18 for each cavity-free month gained per child and US\$203 for each treatment averted. They concluded that the use of fluoride varnish in the medical setting is effective in reducing early childhood caries in low-income populations but does not save any expense in the first 42 months of life.

Conclusions and Recommendations

The review that has been reported here leads to the following conclusions:

1. Any protocol on the application of fluoride varnish should be based on risk assessment. The best indicator of risk for caries is previous or current caries experience.^{1,38–44}
2. There is clear evidence of the efficacy of fluoride varnish in preventing dental caries in children and adolescents (level of evidence I, grade of recommendation A).
3. There is clear evidence of efficacy with 2 applications in a year (level of evidence I, grade of recommendation grade A).³⁴
4. There is insufficient evidence to support 3 applications within a short interval such as 1 or 2 weeks (level of evidence I, grade of recommendation E).³³
5. Logistical considerations may also drive the choice to apply varnish twice yearly; in this situation, varnish application should be combined with a review of any sealants to ensure retention (level of evidence I, grade of recommendation A).³³
6. There is good evidence of the complementary efficacy of preventive strategies such as sealants and varnish, as well as toothbrushing and nutritional counselling.³⁶
7. Consistent availability of fluoride in the varnish preparation is very important to efficacy and cannot be assured with multidose packages.^{45–47}

8. The enhanced slow release of fluoride from Durafluor and Duraphat³² makes them the materials of choice at this time.^{45–47}
9. The most recent Cochrane reviews^{53,54} state that contemporary information is insufficient to determine whether fissure sealants or fluoride varnishes are the most effective measures for preventing caries, although there is some evidence that pit and fissure sealants are superior to fluoride varnishes for the prevention of occlusal caries.

On the basis of these conclusions, the following strategies are recommended:

1. For predominantly high-risk populations (e.g., people with low socioeconomic status, new immigrants and refugees, all First Nations and Inuit children and adolescents), fluoride varnish should be applied twice a year, unless the individual has no risk of caries, as indicated by past and current caries history.
2. Single-dose packages of fluoride varnish should be used for children; the varnish from such packages should be stirred vigorously before application, to ensure that any precipitated fluoride is redissolved.
3. Given that there is good evidence of the complementary effectiveness of sealants and varnish, as well as toothbrushing and nutritional counselling, oral health care programs should include as many complementary preventive strategies as possible. ♦

THE AUTHORS

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Appendix 1 Efficacy of fluoride varnish in preventing caries of primary and permanent teeth: critical appraisal of studies included in the systematic review

Citation: Möberg Skold U, Petersson LG, Lith A, Birkhed D. Effect of school-based fluoride varnish programmes on approximal caries in adolescents from different caries risk areas. *Caries Res* 2005; 39(4):273–9.

Population: 758 subjects (13 to 16 years old; 48% females) from 9 secondary schools in 3 areas with different socio-economic status (SES), followed for 3 years

Study Setting:

Characteristic	Kungsbacka (low caries risk)	Möndal (medium caries risk)	Göteborg (high caries risk)
1998 income (Swedish krona)	190,000	169,000	71,300
1998 mean DFT for 12-year-old children	0.60	0.85	2.65
Fluoride level in tap water (ppm)	1.0-1.2	0.1	0.1

Population Represented: Adolescents from different SES backgrounds who received free yearly preventive treatments

Intervention or Test Treatment: In each school class within each area, fluoride (F) varnish (Duraphat, Colgate, Piscataway, N.J.) was applied to approximal surfaces from the distal surface of the canines to the mesial surface of second molars, as follows:

- Group 1: $n = 190$, twice per year at 6-month intervals (6 times in 3 years)
- Group 2: $n = 186$, 3 times per year within a 1-week period each year (9 times in 3 years)
- Group 3: $n = 201$, 8 times per year during school semesters with 1-month intervals between applications (24 times in 3 years)

Control (group 4): $n = 181$, no treatment

Outcome: Results assessed after 3 years (with 11% loss to follow-up); no adverse effects; 95% of adolescents in all areas received another F application each year as part of standard procedure during regular dental check-ups in Sweden

Prevalence of Caries:

- Approximal dental lesions: The only significant difference was between group 1 and the control group in the high-risk area (0.23 ± 0.74 vs. 0.85 ± 1.35 , $p = 0.031$) and for all areas combined (0.16 ± 0.56 vs. 0.43 ± 1.05 , $p = 0.012$) (mean \pm standard deviation [SD])
- Filled approximal surfaces and approximal enamel lesions: No significant differences

Total Incidence of Approximal Caries

Occurrence of approximal caries was defined as an enamel or dentin lesion or a filling on an initially caries-free surface.

- Greater incidence of caries in control groups than in F varnish groups in all areas (significant difference for medium-risk and high-risk areas and for all areas combined)
- Largest difference in the high-risk area: 3.05 ± 3.37 new approximal caries lesions in control group compared to 0.54 ± 1.26 for group 3, 0.95 ± 1.67 for group 1 and 1.40 ± 1.89 for group 2 ($p < 0.001$)
- More than 90% of new approximal lesions in all treatment groups and in all geographic areas were enamel lesions.

Progression of Enamel Lesions to Dentin Lesions or Filling:

- Significantly less mean caries progression (\pm SD) in F varnish groups in high-risk area (0.18 ± 0.45 for group 1, 0.30 ± 0.96 for group 2 and 0.37 ± 0.93 for group 3) and all areas combined (0.10 ± 0.35 for group 1, 0.21 ± 0.79 for group 2 and 0.22 ± 0.95 for group 3) than for control group (0.90 ± 1.24 in high-risk areas [$p = 0.003$] and 0.40 ± 0.92 in all areas combined [$p = 0.009$])

Prevented Fraction:

Prevented fraction was defined as the difference in treatment effect between the F varnish and control groups, with approximal lesions as diagnostic threshold

- All areas combined: group 3 (76%) > group 1 (57%) > group 2 (47%)
- High-risk area: group 3 (82%) > group 1 (69%) > group 2 (54%)
- Medium-risk area: group 3 (83%) > group 1 (66%) > group 2 (31%)
- Low-risk area: group 2 (68%) > group 3 (50%) > group 1 (20%)

Authors' Conclusion: School-based application of F varnish every 6 months in 13- to 16-year-olds is an excellent means of preventing approximal caries in geographic areas with medium and high caries risk.

Critical Appraisal: No adjustment for difference between sexes, no logarithmic regression models.

Level of Evidence, Grade of Recommendation and Score on “Checklist to Assess Evidence of Efficacy of Therapy or Prevention”: Level I; grade A for application of F varnish twice a year to prevent approximal caries in geographic areas with medium and high caries risk; score 15.5/16.

Citation: Lawrence H, Binguis D, Douglas J, Switzer B, McKeown, L, Figueiredo R, Laporte A. A 2-year community trial of fluoride varnish for the prevention of early childhood caries in aboriginal children. Annual Canadian Association of Public Health Dentistry Conference; 2006 Aug 24–26; St John's, Newfoundland.

Population: 1,275 children 6 months to 5 years of age (13.7% < 1 year old, 24.7% 1 year old, 25.9% 2 years old, 21.6% 3 years old, 14.0% 4–5 years old; 50% male [$n = 637$] and 50% female [$n = 638$]) from 20 Canadian First Nations communities, randomly assigned to treatment groups between September 2003 and March 2004; 1,749 non-Aboriginal children in the same geographic area

Study Setting: First Nations communities in the Sioux Lookout Zone (SLZ) of northwestern Ontario, Canada. The SLZ is a large geographic area (about the size of France) reaching north to Hudson Bay; it comprises 28 isolated First Nations communities. Control subjects were recruited in nearby Thunder Bay.

Population Represented: Young First Nations children living on reserves in northwestern Ontario, Canada

Intervention or Test Treatment: 5% sodium fluoride varnish (Duraflor, Pharmascience) applied 2 or 3 times per year for 2 years (total of 4 treatments required for inclusion in analysis), caregiver counselling and standard restorative care

- Group 1: $n = 915$ children from 12 First Nations communities in the SLZ
- Group 2: $n = 102$ non-Aboriginal children of the same age from childcare organizations in the neighbouring city of Thunder Bay

Control: Caregiver counselling and standard restorative care

- Group 3: $n = 360$ children from 8 First Nations communities in SLZ
- Group 4: $n = 416$ children 3 to 5 years old attending junior kindergarten in Thunder Bay in 2003
- Group 5: $n = 687$ children 3 to 5 years old attending junior kindergarten in Thunder Bay in 2004
- Group 6: $n = 544$ children 3 to 5 years old attending junior kindergarten in Thunder Bay in 2005

Comparative cross-sectional oral health data for children who did not receive fluoride (F) treatments were collected by dental hygienists and recorders working for the Thunder Bay District Health Unit.

Lost to Follow-up in SLZ Intervention Group:

- $n = 97$ (38 had relocated, 10 could not be contacted, 35 did not show up for appointments [34 with no reason provided, 1 because parent could not bring child to appointments], 8 were in foster care and unavailable for appointments, 3 had died, 2 discontinued intervention [1 parent reported that child might be allergic to lanolin, 1 had lost all remaining teeth], 1 could not be examined)
- Number analyzed = 818

Lost to Follow-up in SLZ Control Group:

- $n = 32$ (7 had relocated, 14 could not be contacted, 9 did not show up for appointments [7 with no reason provided, 2 because parent could not bring child to appointments], 1 was sick, 1 discontinued intervention [child had lost all remaining teeth])
- Number analyzed = 328

Outcomes: Data were analyzed for a total of 1,146 (818 + 328) children with a 12- or 24-month follow-up visit

Net Decayed, Missing, Filled Surfaces (dmfs) Increment for F Varnish Group vs. Control:

- First Nations children: 11.00 ± 0.50 vs. 13.47 ± 0.90 , $p = 0.061$
- First Nations and non-First Nations children combined: 10.17 ± 0.46 vs. 13.47 ± 0.90 , $p = 0.047$
- Per protocol, excluding those who did not receive at least 2 F applications per year (or a total of 4 F treatments): 10.08 ± 0.50 vs. 13.47 ± 0.90 , $p = 0.048$

Percentage Reduction in Early Childhood Caries:

- Intention to treat:
 - First Nations children: 18.3%

- First Nations and non-First Nations children combined: 24.5%
- Per protocol, First Nations and non-First Nations children combined, excluding the 119 (out of 920) children who did not receive at least 2 F applications per year (or a total of 4 F treatments): 25.2%

Multivariate Analysis:

Controlled for baseline decayed and filled surface (dfs), age, caregiver's high school education and number of children in the home:

- Relative risk (RR) for caries incidence over 2 years: 1.96 times higher for control group than F varnish group (95% confidence interval [CI] = 1.08–3.56, $p = 0.027$)

Poisson Regression:

Controlled for age and previous caries experience:

- RR for caries incidence over 2 years: about 1.4 times higher for control group than F varnish group (95% CI = 1.01–1.94, $p = 0.049$)

Need for Dental Treatment under General Anesthesia:

Data from SLZ hospital:

- About 25% of all participants had general anesthesia for dental purposes during study period
- Rate of general anesthesia 25% lower in F varnish group than in control group
- Number needed to treat (NNT) with F varnish to prevent one child from undergoing treatment requiring general anesthesia: about 14

Oral-Health-Related Quality-of-Life Score:

- The prevalence of oral impacts reported “often or almost every day” in the year preceding the final assessments was significantly greater in the control group than in the F varnish group (38.9% vs. 20.6%, $p < 0.001$).
- Parents or caregivers of children in the F varnish group were also more likely to rate their children's oral health as being “good” or “very good” than those whose children were in the control group.

Authors' Conclusion: F varnish applied 2 or 3 times per year (preferably 3) in First Nations preschool children with high caries risk was effective in preventing and reducing early childhood caries, thereby reducing the rates of dental care under general anesthesia and improving oral-health-related quality of life.

Critical Appraisal:

- No blinding
- 25% loss to follow-up after 24 months
- Several of the results presented are based on follow-up after just 1 year
- No evidence to support 3 applications of F varnish (as stated in the conclusion of the paper)

Level of Evidence, Grade of Recommendation and Score on “Checklist to Assess Evidence of Efficacy of Therapy or Prevention”: Level I; grade A for application of F varnish in reduction of early childhood caries among high-risk First Nations children; score 14.5/16.

Citation: Chu CH, Lo EC, Lin HC. Effectiveness of silver diamine fluoride and sodium fluoride varnish in arresting dentin caries in Chinese pre-school children. *J Dent Res* 2002; 81(11):767–70.

Population: 375 Chinese children with carious upper anterior teeth (mean age 4.0 years [standard deviation 0.8]; 56% boys) from 8 kindergartens

Study Setting: Guangzhou, southern China; fluoride (F) concentration in the drinking water < 0.2 ppm; greater usage of nonfluoridated toothpaste than fluoridated toothpaste (because of cost); no F supplements; professional application of topical F rare

Population Represented: Preschool Chinese children

Intervention or Test Treatment:

- Group 1: $n = 76$, removal of soft carious tissues and annual applications of 38% silver diamine fluoride solution (SDF; Saforide, Toyo Seiyaku Kasei Co. Ltd., Osaka, Japan) (F concentration 44,800 ppm)
- Group 2: $n = 77$, annual applications of SDF, but no removal of soft carious tissue
- Group 3: $n = 76$, removal of soft carious tissues and application of 5% sodium fluoride (NaF) varnish (Duraphat, Inpharma GmbH, Cologne, Germany) (F concentration 22,600 ppm) every 3 months
- Group 4: $n = 73$, application of NaF every 3 months, but no removal of soft carious tissue

Control (Group 5): $n = 73$, no treatment

Outcomes:

- 18% loss to follow-up at 30 months (20%, 19%, 18%, 16% and 15%, for groups 1 through 5, respectively)
- Statistically significant differences in mean number of arrested carious tooth surfaces among the 5 treatment groups (2.5, 2.8, 1.5, 1.5 and 1.3 for groups 1 through 5, respectively; $p < 0.001$)
- Highest number of arrested caries in group receiving annual application of SDF, which had a higher proportion of arrested caries appearing black
- More new caries in control group than in groups that received SDF or NaF varnish
- No differences in increment of nonvital teeth among the 5 groups
- No difference in arrested dentin caries related to removal of carious tissues before application of F agents
- No adverse effects (e.g., discolouration or damage to the gingival tissues)

Analysis of covariance (ANCOVA), with adjustment for age, decayed, missing, filled surfaces (dmfs) scores, number of decayed tooth surfaces of the upper anterior teeth and number of nonvital teeth at baseline examination:

- Children with higher baseline caries experience in the upper anterior teeth, those who underwent application of SDF and those who brushed their teeth more often had significantly more arrested carious tooth surfaces at the 30-month examination

Authors' Conclusion: SDF was effective in arresting dentin caries in the primary anterior teeth of preschool children.

Critical Appraisal: No control over F exposure and care outside the study.

Level of Evidence, Grade of Recommendation and Score on “Checklist to Assess Evidence of Efficacy of Therapy or Prevention”: Level I; grade A for application of NaF or SDF varnishes in hardening or arresting dentin caries; score 14/16.

Citation: Källestål C. The effect of five years' implementation of caries-preventive methods in Swedish high-risk adolescents. *Caries Res* 2005; 39(1):20–6.

Population: 903 children (12 years old at baseline; sex ratio not mentioned) from 26 public dental health clinics throughout Sweden, identified as being at high risk on the basis of having more than 1 decayed proximal surface, enamel or dentin caries, a filled proximal surface, or a missing tooth because of caries, or because of physical or mental disability or chronic disease, or on the basis of count of colony-forming units $> 10^5$ (for lactobacilli in saliva), and examined annually from 1995 to 2000. All subjects received sealant for second molars with deep fissures.

Study Setting: 26 public dental health clinics throughout Sweden

Population Represented: 12-year-old children in Sweden

Intervention or Test Treatment:

- Group C: $n = 228$, semiannual applications of fluoride (F) varnish (Duraphat); each semiannual treatment consisted of 3 applications over a 1-week period
- Group D: $n = 231$, quarterly appointments at which participants were given individualized information on oral hygiene and diet, along with application of F varnish

Control:

- Group A: $n = 231$, information on tooth-brushing techniques
- Group B: $n = 213$, prescription for F lozenges (three 0.25-mg lozenges daily up to 16 years of age; 4 to 6 lozenges daily after 16 years of age)

Loss to Follow-up:

- 18% after 5 years

Compliance:

Group A: 31%

Group B: 62%

Group C: 76%

Group D: 65%

Mean 5-Year Caries Increment: No significant differences

Regression Analysis:

Factors significantly associated with lower risk of caries increment:

- At least one sealant
- F varnish (group C)

Factors significantly associated with higher risk of caries increment:

- Working-class homes
- Frequent consumption of sweets
- Not brushing the teeth twice a day (for all examinations during the whole study period)

Author's Conclusion: The preventive programs tested were equivalent in having low efficiency for adolescents with high caries risk.

Critical Appraisal: No power calculation

Level of Evidence, Grade of Recommendation and Score on "Checklist to Assess Evidence of Efficacy of Therapy or Prevention": Level I; grade E for the application of F varnish; score 13/16.

Citation: Weintraub JA, Ramos-Gomez F, Jue B, Shain S, Hoover CI, Featherstone JD, and other. Fluoride varnish efficacy in preventing early childhood caries. *J Dent Res* 2006; 85(2):172–6.

Population: Initial sample of 376 caries-free children (mean age 1.8 years [standard deviation 0.6]; 53% girls) from low-income Chinese or Hispanic San Francisco families who were planning to reside in San Francisco for at least 2 years (final sample size = 280).

Study Setting: 2 public health centres in San Francisco (where optimal fluoridation of water supply at 1.0 ppm has been in place since 1952)

Population Represented: High-risk Chinese and Hispanic children living in the United States

Intervention or Test Treatment:

- 4 fluoride (F) varnish applications: $n = 87$, parental counselling plus F varnish (5% sodium fluoride, Duraphat, Colgate Oral Pharmaceuticals, New York, N.Y.) twice yearly (at baseline and 6, 12 and 18 months)
- 2 F varnish applications: $n = 93$, parental counselling plus F varnish once yearly (at baseline and 12 months)

Control: $n = 100$, counselling only, no F varnish applications

Loss to Follow-up:

- $n = 115$ (31%) at 12 months (261 remaining)
- $n = 59$ additional at 24 months (202 remaining)

Percentage of Caries-Free Children:

- Dose–response effect was observed for reduction in the percentage of children with caries and increasing numbers of intended or actual active applications (both $p < 0.001$).

Caries Incidence:

- Statistically significantly higher for “counselling only” vs. “counselling + F varnish once per year” (odds ratio [OR] = 2.20, 95% confidence interval [CI] 1.19–4.08) and “counselling + F varnish twice per year” (OR = 3.77, 95% CI 1.88–7.58)

Authors’ Conclusion: F varnish combined with caregiver counselling was efficacious in reducing the incidence of early childhood caries.

Critical Appraisal:

- Loss to follow-up > 20%
- No data on similarities between the groups at baseline
- Over one 10-month period during the study, some children unintentionally received placebo varnish instead of active product
- No control over care provided outside the study

Level of Evidence, Grade of Recommendation and Score on “Checklist to Assess Evidence of Efficacy of Therapy or Prevention”: Level I; grade A for the application of F varnish + caregiver counselling in reducing incidence of early childhood caries; score 12/16.

Citation: Pienihäkkinen K, Jokela J. Clinical outcomes of risk-based caries prevention in preschool-aged children. *Community Dent Oral Epidemiol* 2002; 30(2):143–50.

Population: 2-year-old children ($n = 299$; about 51% boys in both groups) from 2 municipal health centres (comparable in terms of socioeconomic status, soil fluoride [F] level) in Vanha Korpilahti central Finland. These children were born in 1987 or 1988 and were followed for 3 years. The parents of all children received oral health education on the following topics: visible plaque and gingivitis, controlling for F exposure (F tablets or very small amount of F-containing toothpaste) and dietary counselling (sugar restriction and a recommendation to use xylitol).

Study Setting: Municipal health centres in Vanha Korpilahti and Saarijärvi, central Finland

Population Represented: 2-year-old children with relatively few caries subject to care through a health organization providing systematic dental care for young children. (In central Finland, prevention-oriented dental health care had been in place for more than 15 years before the study.)

Intervention or Test Treatment:

Risk-based prevention groups (screening criteria were presence of *Streptococcus mutans* in plaque and incipient caries lesions):

- Intermediate-risk group (caries-free children who were positive for *S. mutans*, $n = 59$): twice-yearly health education and twice-yearly application of F varnish (Duraphat, Woelm Pharma GmbH & Co., Eschwege, Germany)
- High-risk group (children with any caries, $n = 31$): twice-yearly clinical examination and determination of presence of *S. mutans*, along with the following intensive preventive measures:
 - if positive result on test for *S. mutans*, application of chlorhexidine varnish (EC40, Certichem, Nijmegen, Netherlands) and F varnish every 3 months
 - if negative result on test for *S. mutans*, application of F varnish alone every 3 months

Control:

- Low-risk group (caries-free children who were negative for *S. mutans*) $n = 209$
- Routine prevention group: 226 children from Saarijärvi who received regular annual oral health care, i.e., preventive (health education or F varnish treatments) and restorative treatments as deemed necessary by the examining dentist

Loss to Follow-up (after 3 Years):

- 13% in risk-based group
- 16% in routine prevention group

Caries and/or Fillings:

Tooth decay, fillings and sealants were recorded at surface level. Degree 0: sound surface with no sign of demineralization; degree 1: incipient lesions in enamel (opaque or discoloured surface which was slightly rough or covered by dental plaque; degree 2: early dentinal lesions with no cavity present clinically; degree 3: defect on the surface that needs restoration

- No differences between the groups at diagnostic level of $d1-3mfs > 0$ (level of incipient lesions, i.e., all carious lesions of enamel and dentin and fillings)
- Significantly fewer caries and/or fillings in the risk-based group than in the routine prevention group:
 - For diagnostic level $d23mfs > 0$ (level of dentinal lesions, i.e., all lesions reaching the dentin + fillings), relative risk (RR) = 1.7, 95% confidence interval [CI] = 1.2–2.4
 - For diagnostic level $d3mfs > 0$ (cavitated carious lesions + fillings), RR = 2.1, 95% CI = 1.3–3.2
- No sex-related differences in relation to caries

Treatment Effect:

Number needed to treat (NNT) with intensive care for 3 years to avoid restorative treatment of dental caries by the age of 5 years in one subject:

- Overall NNT = 8.3 (95% CI 5.3–20.0)

- Intermediate-risk group NNT = 4.9 (95% CI 2.8–20.4)
- High-risk group NNT = 2.0 (95% CI 1.4–3.8)

Prevalence of Cavitated Caries and Fillings: Strongest treatment effect in high-risk group (NNT = 2, 95% CI 1.4–3.8)

Outcomes for *S. mutans*: Higher proportion of positive findings for *S. mutans* in the routine prevention group than in the risk-based prevention group (RR = 1.4, 95% CI 1.1–1.7)

Screening Accuracy (i.e., validation of screening tests for predicting the presence of cavitated carious lesions or fillings [d3mfs > 0] by the age of 5 years according to 2 cut-off points within the routine prevention group [n = 226]):

- Low risk/intermediate risk + high-risk, whereby the low-risk group was considered “negative” and the intermediate- and high-risk groups combined were considered “positive” (proportion of positive = 35%):
 - Sensitivity (proportion of diseased subjects correctly identified) = 72%
 - Specificity (proportion of healthy subjects correctly identified) = 77%
 - Predictive value of a positive test (proportion of diseased subjects among positive test results) = 49%
 - Predictive value of a negative test (proportion of healthy subjects among negative test results) = 90%
 - Accuracy (proportion of correct predictions) = 76%
- Low risk + intermediate risk/high risk, whereby the low- and intermediate-risk groups combined were considered “negative” and the high-risk group was considered “positive” (proportion of positive = 9%):
 - Sensitivity = 32%
 - Specificity = 98%
 - Predictive value of a positive test = 85%
 - Predictive value of a negative test = 83%
 - Accuracy = 83%

Authors’ Conclusion: In young children, risk-based management of caries seems practical, and prevention of caries can be targeted efficiently to individuals at risk.

Critical Appraisal:

- At baseline and during final examination, each child was examined by 1 of 5 calibrated dentists; calibrated dentists were blinded to the results of earlier examinations and information about *S. mutans*
- Dental assistants who had received special training in observing incipient caries lesions and in preventive care provided the care in the risk-based prevention group
- Recommending even a very small amount of F toothpaste for children in this age range is not a good strategy
- Study design was not ideal to evaluate efficacy of treatment
- No power calculation
- Good use of logistic regression
- No randomization

Level of Evidence, Grade of Recommendation and Score on “Checklist to Assess Evidence of Efficacy of Therapy or Prevention”: Level II-2; grade A for the use of extensive F varnish/chlorhexidine varnish for preventing caries for high risk children; score 13/16.

Citation: Schuller AA, Kalsbeek H. Effect of the routine professional application of topical fluoride on caries and treatment experience in adolescents of low socio-economic status in the Netherlands. *Caries Res* 2003; 37(3):172–7.

Population: 745 adolescents (15–17 years old; 42.9% male) who had each been registered with the same high-fluoride (F) or low-F dental clinic for 5 years or longer (where high F and low F refer to the frequency of fluoride application in the clinics)

Study Setting: Friesland, north Netherlands

Population Represented: Adolescents with insurance coverage

Intervention or Test Treatment: $n = 396$ adolescents attending dental clinics with professional F application as a routine procedure (high-F clinics, with ≥ 70 F applications for every 100 routine dental examinations, as determined by claims to the insurance company for patients 6 to 18 years old); of these, 395 underwent a clinical examination and 201 underwent radiographic examination

Control: $n = 351$ adolescents from other clinics (low-F clinics, with ≤ 5 F applications for every 100 routine dental examinations, as determined by claims to the insurance company for patients 6 to 18 years old); of these, 350 underwent a clinical examination and 188 underwent radiographic examination

Outcomes:

Clinical observations for low-F group ($n = 350$) vs. high-F group ($n = 395$):

- No statistically significant differences in number of filled surfaces (FS) (3.9 ± 5.4 vs. 4.3 ± 6.1) or number of decayed and filled surfaces (DFS) (5.4 ± 6.9 vs. 5.0 ± 5.0)
- Statistically significantly greater number of decayed surfaces (DS) in low-F group (1.5 ± 3.3 vs. 1.0 ± 2.5 , $p = 0.018$)

Radiographic observations in low-F group ($n = 188$) vs. high-F group ($n = 201$):

- No statistically significant differences in the number of DS, FS or DFS

Authors' Conclusions: Professionally applied F had no effect on caries and treatment experience in this population.

Critical Appraisal:

- Study design not ideal for evaluating efficacy of F varnish
- No randomization
- No control over the type of F varnish used
- Not a reliable method for measuring the intervention (insurance claims over a 13-year period)
- No calibration
- No power calculation

Level of Evidence, Grade of Recommendation and Score on “Checklist to Assess Evidence of Efficacy of Therapy or Prevention”: Level II-3; grade C for the application of F varnish; score 10.5/16.