Caries Research 1994;28:64–67

*L. Seppä*[a]
*L. Pöllänen*[b]
*H. Hausen*[a]

[a] Faculty of Dentistry, University of Kuopio,
[b] Public Dental Service, Kuopio, Finland

# Caries-Preventive Effect of Fluoride Varnish with Different Fluoride Concentrations

**Key Words**
Fluoride, concentration
Fluoride varnish

**Abstract**
Based on the current concept of the caries-preventive mechanism of fluoride, the fluoride concentration of some professionally applied fluoride preparations appears unnecessarily high. The aim of this trial was to study whether reducing the fluoride concentration of the sodium fluoride varnish Duraphat® from the present 2.3% to 1.1% affects its clinical efficacy. A total of 274 children aged 12–14 years and having high past caries experience were randomly divided into two groups. The participants received 3 annual applications of either 2.3% or 1.1% varnish for 3 years. Clinical and radiographical examinations were performed at baseline and at the end of the follow-up. The mean total DMFS increments of the 2.3% and 1.1% varnish groups were 5.5 (SD 5.7) and 5.7 (5.3), respectively, when initial caries was excluded, and 14.3 (12.0) and 14.9 (12.9) when initial caries was included. The differences were statistically non-significant. There were no significant differences in the surface-specific DMFS increments between the groups either. The 95% confidence interval for the difference between the groups in total mean DMFS increment (initial caries excluded) was calculated at –1.21 to +1.54, i.e. at this level of confidence at most 0.5 surfaces per year would have been saved using the more concentrated varnish. Consequently, it can be stated at a reasonable level of certainty that if a difference in the efficacy of the two varnishes exists, it probably is minute. Lowering the fluoride concentration of Duraphat is worth considering at least when used for children.

Concentrated topical fluorides were originally developed with a view of increasing the amount of firmly bound fluoride in the surface enamel, which requires relatively high fluoride concentrations in the preparations. According to the current concept, however, the caries-preventive effect of concentrated topical fluorides is mainly based on the slow release of calcium fluoride-like material formed during the application [Rølla, 1988]. Although the amount of calcium fluoride on the enamel can be increased by increasing the concentration of a fluoride solution from 0.1 to 0.9% [Saxegaard and Rølla, 1988], there is little evidence of a dose-response relationship using more concentrated fluoride preparations. In an early study of Galagan and Knutson [1948] no significant difference in the clinical efficacy between a 1% and a 2% NaF solution was observed. In vivo and in situ model experiment with severe caries challenges showed no dose-response relationship for concentrated fluoride solutions [Øgaard and

Received:
February 3, 1993
Accepted after revision:
July 20, 1993

Liisa Seppä
Faculty of Dentistry
University of Kuopio
POB 1627
FIN-70211 Kuopio (Finland)


0008–6568/94/0281–0064
$5.00/0

Rølla, 1992]. Whether fluoride was applied as neutral 0.05, 0.2 or 2% NaF solutions daily, weekly or as one single application, the cariostatic effects were not significantly different. However, in a clinical study [Hagan and Bawden, 1985], there was a tendency for 0.6% acidulated phosphate fluoride to be somewhat less effective than 1.23% acidulated phosphate fluoride, although the difference was not statistically significant.

In children, high plasma fluoride values after application of 1.1% fluoride gel have been found [Ekstrand et al., 1981]. Consequently, the safety of concentrated topical fluorides in children has aroused some concern in recent years. The sodium fluoride varnish Duraphat®, commonly used in Europe, has a fluoride concentration as high as 2.3%. Application of Duraphat can be considered safer than treatment with fluoride gels [Ekstrand et al., 1980], probably mainly due to the slow release of the varnish material from the teeth. No adverse effects of the high fluoride concentration of the varnish have been reported so far. However, in the light of the current concept of the cariostatic mechanism of fluoride, the fluoride content of Duraphat appears to be unneccessarily high especially when used for children. The dose of fluoride received from the varnish is dependent on several factors, among which the fluoride concentration is only one. However, the lower the fluoride concentration, the smaller the likelihood of harmful effects even in case of excessive use of material. Therefore, it would seem reasonable to lower the fluoride concentration if the clinical efficacy were the same. In a previous in vitro study, no significant difference in remineralization of enamel was found with Duraphat containing 2.3 or 1.1% fluoride [Seppä, 1988]. Furthermore, in a study in rats, reducing the fluoride content of Duraphat by half did not significantly reduce its efficacy, but the progress of caries seemed somewhat slower with the 2.3% varnish [Seppä et al., 1989]. In a clinical study by Haugejorden and Nord [1991], 2.3% Duraphat was not more effective than 1.8% experimental sodium fluoride varnish. The aim of this randomized trial was to study whether reducing the fluoride content of Duraphat by half affects its clinical efficacy.

## Materials and Methods

The participants were selected so that of all the 12- to 14-year-old residents of Kuopio about 20% (n = 326) with the highest DMFS and initial caries (grade 1) scores were asked to participate in the study. The piped water of Kuopio was fluoridated (1.0 ppm) during the study. Positive consent was received from the parents of 274 children. These children were randomly divided into two groups. The first group received applications of a sodium fluoride varnish Duraphat (Woelm, FRG) containing 2.26% fluoride, and the second group received applications of Duraphat in which the fluoride content had been reduced to 1.13% (the experimental varnish was provided by the manufacturer). Applications of both varnishes were performed 3 times a year at 4-month intervals. The varnish was applied according to the manufacturer's instructions using brushes or cartridges. The children were told not to eat for 2 h and not to brush their teeth on the day of application. During the study period of 3 years the children received ordinary dental care provided by the Public Dental Clinics. In principle, for adolescents with high caries risk this includes annual dental check-ups, restorative care when needed, fluoride applications, fissure sealants in second molars and intensified dental health education. For the participants of this study, applications of the varnishes comprised the only mode of professional fluoride treatment.

Clinical recordings were performed by L.P. and the examination of bite-wing radiographs by L.S. at the beginning of the study and after 3 years. The dentists performing the clinical and radiographic examinations did not know to which group the children belonged. Caries was registered according to Möller and Poulsen [1973]. In addition, the number of sealants present at the end of the follow-up was recorded.

Student's t tests for independent samples were applied for analysing the differences between the two groups. Confidence intervals were calculated for both the mean increment values and their absolute differences [Altman and Gardner, 1989], and the percentage differences between the groups [Wallenstein et al., 1982]. The possible effect of the slight imbalance between the groups in baseline DMFS values was evaluated using analyses of covariance.

**Table 1.** Mean values (±SD) for DMFS and sealants

| | 2.3% varnish | 1.1% varnish |
|---|---|---|
| Baseline DMFS | 8.9±7.0 | 8.5±6.0 |
| Final DMFS | 13.1±11.0 | 12.7±9.4 |
| Sealants | 5.8±3.2 | 5.5±3.2 |

## Results

A total of 247 children, 122 in the 2.3% varnish group and 127 in the 1.1% varnish group, completed the study. The mean baseline DMFS values were not significantly different for the two treatment groups. The same was true for the number of sealants at the end of the study (table 1). The surface-specific and total mean 3-year DMFS increments and the differences between the groups are shown in figure 1 with their 95% confidence intervals. In this figure, initial caries (grade 1) has been omitted. When initial caries was included, the total DMFS increments for 2.3% and 1.1% varnish groups were 14.3 (SD 12.0) and 14.9 (12.9), respectively. None of the observed differences was statistically significant. For the total DMFS, the mean

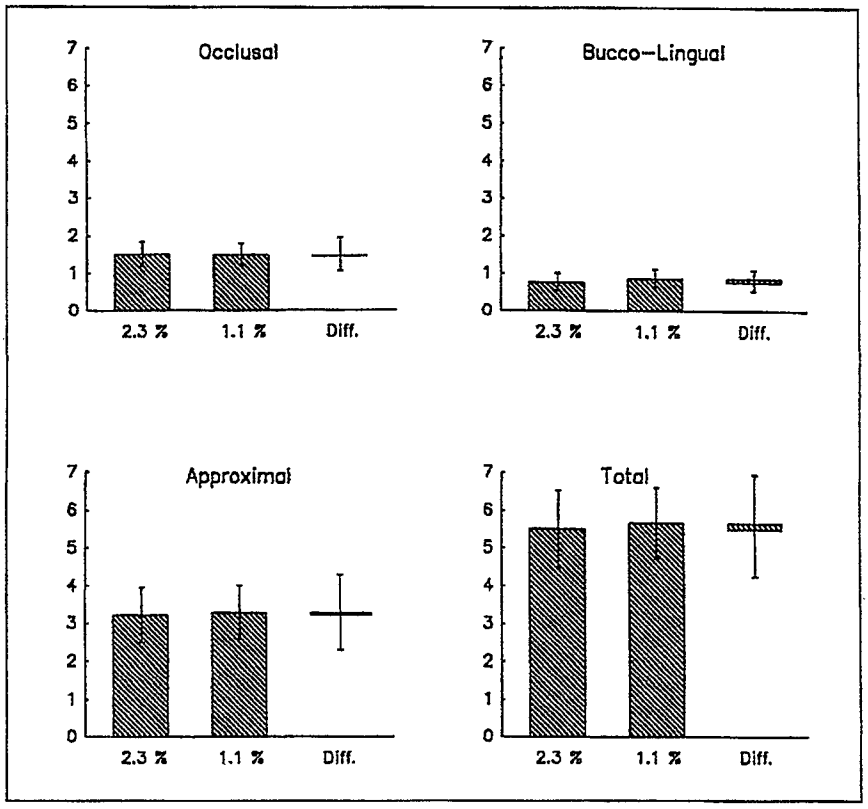


**Fig. 1.** Mean 3-year DMFS increments (initial caries excluded) with their 95% confidence intervals in the two varnish groups. The difference (Diff.) between the groups and its confidence interval are also given.

difference was 0.2 when initial caries was excluded (fig. 1). The 95% confidence interval for the mean difference was from –1.2 (1.2 surfaces in favour of the 1.1% varnish) to 1.5 (1.5 surfaces in favour of the 2.3% varnish). The 90% confidence interval for the percentage difference (1.1% vs. 2.3% varnish) was from –16 to 27%. The covariance adjustment increased the difference in the total DMFS increment without initial caries by 0.1 surfaces. Even the covariance-adjusted difference was statistically non-significant (p=0.716).

## Discussion

Ninety percent of the original participants completed the study. The number of drop-outs can be considered small for a 3-year study. For ethical reasons, no placebo control group could be included in the study. Thus this study does not reveal information about the actual caries-preventive efficacy of the varnishes. However, there is enough evidence on the efficacy of the 2.3% varnish to allow its use as a reference material. The fact that the drinking water in Kuopio was fluoridated during the study is unlikely to have affected the difference between the two groups, since both groups used this water.

Three annual applications per year instead of the more common regimen of semi-annual applications were chosen for the present study because at that time we anticipated that an increased frequency of applications would allow the possible difference between the varnishes to show better. However, we later found that fluoride varnish applications performed 4 times a year were not more effective than semi-annual applications [Seppä and Tolonen, 1990]. At present, the varnish is seldom applied more than twice a year in Finland.

An expert committee commissioned by the ADA Council of Dental Therapeutics [1988] has developed guidelines for superiority and equivalence submissions of fluoride dentifrices. Recently these guidelines have been amended to include the 'at least as good' (LAG) claim for demonstrating efficacy [Kingman, 1992]. Using this approach it is sufficient for a LAG claim to show that the upper limit of the 90% confidence interval for the ratio (R) of the true average caries increments for the test and control products, respectively, is less than 1.1 or 110%. In our study this upper limit would correspond to a 10%

difference in favour of the 2.3% varnish. The observed upper limit was 27%, which is too wide for a formal LAG claim according to the above decision rule. For conclusive evidence on the equivalence of the two varnishes, larger studies are needed.

All the observed differences in caries increment between the two groups were statistically non-significant. The point estimate for the difference in mean total DMFS increment (0.2 surfaces in favour of the 2.3% varnish in 3 years) clearly was also clinically insignificant. At 95% confidence, the mean DMFS increment was at most 1.5 surfaces lower in the group treated with the 2.3% varnish than in the 1.1% varnish group, i.e. at most 0.5 surfaces per year would have been saved using the more concentrated varnish. Even this size of difference can be considered being of little clinical significance. On the other hand, at the same level of confidence the difference could have been up to 1.2 surfaces in 3 years in favour of the less concentrated varnish. The confidence intervals for the surface-specific differences were in line with those of the total DMFS increment. Consequently it can be stated at a reasonable level of certainty that if a difference in the efficacy of the two varnishes exists, it most probably is minute.

The results are in line with our previous in vitro and animal studies of Duraphat with 2.3% and 1.1% varnishes [Seppä, 1988; Seppä et al., 1989]. Bearing in mind the current concept of the caries-preventive mechanism of concentrated fluorides it is also theoretically feasible that a fluoride concentration of 1.1% is high enough for maximal protection of the enamel. Although no adverse effects of the high fluoride concentration of Duraphat have been reported so far, further studies on a less concentrated varnish are indicated especially considering the use of Duraphat in children.


## Acknowledgements

The authors gratefully acknowledge the assistance provided by the personnel of the Public Dental Clinics. The Woelm Company is acknowledged for supplying the 1.1% varnish.


## References


ADA Council on Dental Therapeutics: Report of workshop aimed at defining guidelines for caries clinical trials: Superiority and equivalency claims for anticaries dentifrices. J Am Dent Assoc 1988;117:663–665.

Altman DG, Gardner MJ: Calculating confidence intervals for means and their differences; in Gardner MJ, Altman DG (eds): Statistics with Confidence: Confidence Intervals and Statistical Guidelines. London, British Medical Journal, 1989, pp 20–27.

Ekstrand J, Koch G, Lindgren LE, Petersson LG: Pharmacokinetics of fluoride gels in children and adults. Caries Res 1981;15:213–220.

Ekstrand J, Koch G, Petersson LG: Plasma fluoride concentration and urinary fluoride excretion in children following application of the fluoride containing varnish Duraphat®. Caries Res 1980;14:185–189.

Galagan DJ, Knutson HW: Effect of topically applied fluoride on dental caries experience. VI. Experiments with sodium fluoride and calcium chloride: Widely spaced applications; use of different solution concentrations. Public Health Rep 1948;63:1215–1221.

Hagan PP, Bawden JW: The caries-preventive effects of full- and half-strength topical acidulated phosphate fluoride. Pediatr Dent 1985;7: 185–191.

Haugejorden O, Nord A: Caries incidence after topical application of varnishes containing different concentrations of sodium fluoride: 3-year results. Scand J Dent Res 1991;99:295–300.

Kingman A: Statistical vs clinical significance in product testing: Can they be designed to satisfy equivalence? J Public Health Dent 1992; (special issue)52:353–360.

Möller I, Poulsen S: A standardized system for diagnosing, recording and analyzing dental caries data. Scand J Dent Res 1973;81:1–13.

Øgaard B, Rølla G: The in vivo orthodontic banding model for vital teeth and the in situ orthodontic banding model for hard tissue slabs. J Dent Res 1992;71(special issue):832–835.

Rølla G: On the role of calcium fluoride in the cariostatic mechanism of fluoride. Acta Odontol Scand 1988;46:341–345.

Saxegaard E, Rølla G: Fluoride acquisition on and in human enamel during topical application in vitro. Scand J Dent Res 1988;96:523–535.

Seppä L: Effects of sodium fluoride solution and varnish with different fluoride concentrations on enamel remineralization in vitro. Scand J Dent Res 1988;96:304–309.

Seppä L, Forss H, Sormunen P: Prevention of rat fissure caries by sodium fluoride varnish (Duraphat®) with different fluoride concentrations. Caries Res 1989;23:365–367.

Seppä L, Tolonen T: Caries preventive effect of fluoride varnish applications performed two or four times a year. Scand J Dent Res 1990;98: 102–105.

Wallenstein S, Fleiss JL, Chilton NW: Confidence intervals for percentage reduction in caries increment. J Dent Res 1982;61:828–830.