Caries incidence after topical application of varnishes containing different concentrations of sodium fluoride: 3-year results

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Abstract – Previous studies have shown that topical application of the fluoride varnish Duraphat reduces caries incidence. The aim of the present study was to compare the caries inhibiting effect of a new fluoride varnish (Carex) containing 1.8% fluoride (F) with that of Duraphat (2.26%F). Informed consent was obtained from the guardians of 495 children 10–12 yr old in Voss Dental Health District (low F area). The children were randomly allocated to two groups. One group of subjects received 6-monthly application of Duraphat ($n=185$), the other Carex ($n=165$). Ethical considerations precluded the use of a placebo varnish. All participants received dental examinations including one pair of posterior bitewing radiographs and necessary dental care annually. One trained examiner interpreted bitewing radiographs blindly. Total 3-yr net DFS increment for 24 posterior approximal surfaces was 2.63 (SD = 3.81) in the Duraphat group and 2.12 (SD = 3.50) in the Carex group. DMFS increments based on 40 posterior occlusal and approximal surfaces were 5.21 (SD = 5.79) and 4.04 (SD = 4.92), respectively. Thus the results indicate a comparable efficacy for Carex and Duraphat at the caries activity level exhibited by these study participants.

Key words: dental caries; fluoride varnish; fluorides; prevention.

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Clinical trials lasting 1–3 yr have shown that professional biannual topical applications of Duraphat (2.26% F) to the permanent teeth of children 5–13 yr of age at baseline may give caries reductions ranging from 18% to 77% (1, 2). Biannual applications of Fluor Protector (0.7% F) have given caries reductions in permanent teeth of children initially 6–13 yr of age from 1% to 17% in studies lasting up to 3 yr (3–5). Comparative studies of the two fluoride-containing varnishes have favored Duraphat (4–6).

Studies of the absorption of F after full-mouth operator-applied topical F agents have shown that the amounts absorbed may be considerable (7, 8) and reach levels which

may contribute to the risk of developing dental fluorosis in small children who also take F tablets and use a F-containing dentifrice (2, 7–11). Exposure to a combination of these F-containing agents is common among Norwegian preschool-children. Furthermore, clinical trials have shown that there is little clinical difference between the more standard topical fluoride compounds when they are employed in technically appropriate and well-manufactured products (2, 8, 12). Consequently, it was decided to test a varnish with a lower concentration of F than Duraphat. It was hoped that there would be no loss of caries-preventive efficacy and that the new varnish would be less costly than Duraphat.

The aim of the present study was to compare the caries inhibiting effect of biannual topical applications of a test F-containing varnish (Carex) with that of Duraphat.

Material

The guardians of 495 children 10–12 yr old (born 1973 75) living in Voss (<0.05 mg/l F in the drinking water) gave written informed consent for their dependents to participate in the trial. These children were allocated randomly to two study groups.

One hundred and six subjects were excluded because they wore a fixed orthodontic appliance at one or more examinations. Another 39 subjects moved from the district or were absent from one or more scheduled examinations. This left 350 subjects who had been present at all four annual examinations of the trial; 185 (85 girls) in the Duraphat group and 165 (83 girls) in the Carex group. Exclusions and loss of subjects accounted for 84 subjects (31.1%) in the Duraphat group and 61 subjects (27.0%) in the Carex group.

Methods

All participants received annual clinical and radiographic examinations and necessary dental treatment from the Public Dental Services. In addition, they received a thorough dental prophylaxis using a rubber cup, a pumice slurry, and dental floss for interdental cleaning. This was followed by professional topical application of one or the other F varnish. One group of children received Duraphat (Woelm Pharma, Eschwege, FRG), which contains 5% sodium fluoride (2.26% F) in an alcohol suspension of natural resins. Duraphat was used as a positive control treatment instead of a F-free placebo varnish for ethical reasons because the caries inhibiting effect of Duraphat is well established and it is in routine use in the Norwegian Public Dental Services for children (13). The children in the other group received topical applications of a F-containing test varnish (Carex). Carex was developed by A. Nord and produced by a local chemist. It consisted of colophonium, shellac, ethanol, vanilla, and sodium fluoride (1.80% F). From 0.3 to 0.5 ml of varnish was used per application and the children were instructed not to eat for 1 h and to refrain from toothbrushing till the following morning. The members of both groups received on average 5.8 topical applications of F varnish in the course of the 3-yr-trial.

Table 1

Scoring codes and criteria for diagnosis of approximal radiographic caries (14)*

Scoring code	Description
0–	Caries free surfaces (sound)
1–	Caries in the enamel not penetrating more than halfway into enamel
2–	Caries penetrating more than halfway into enamel but not involving the amelodentinal junction
3–	Caries of enamel and dentin regardless of depth of penetration
4–	Secondary caries regardless of depth
5–	Filled surfaces without evidence of secondary caries
6–	Extracted surfaces because of caries
7–	Missing for other reasons
8–	Surfaces missing from the film or overlapping and unreadable
9–	Unerupted surfaces

*If in doubt regarding the existence or degree of caries according to these criteria, then "sound" or the lesser degree of caries was recorded.

The results to be presented here are based on the radiographs taken at annual examinations over a period of 38 months. One pair of posterior bitewing radiographs were taken using Kodak DF57 or DF53 ultra-speed films and a Kwik-bite filmholder. Exposure time and processing were according to the manufacturer's recommendations. The radiographs were assessed under standardized conditions in a darkened room using a radiographic viewer with a ×2 magnification. A trained examiner who was unaware of the subjects' group identity employed the criteria shown in Table 1 (14). The examination comprised 24 approximal surfaces of molars and premolars. In addition radiographic occlusal fillings and gross caries were recorded as it was expected that occlusal surfaces would contribute a sizable proportion of total caries experience and incidence.

Caries diagnostic reproducibility was assessed by independent re-examination of about 10% of the bitewing radiographs. Reproducibility was acceptable with Cohen's kappa always greater than 0.80 (15). No evidence of systematic error was detected using Student's *t*-test for paired observations ($P > 0.10$).

Data were analyzed using StatView program packages (16) on a MacIntosh PC. The frequency distributions of subjects according to annual and 3-yr DFS increments were positively skewed. For this reason the results given by Student's *t*-test for independent samples were checked using chi-square analysis. Unless otherwise stated the *P* values based on the former test are presented as both tests led to the same conclusions. ANOVA and multiple regression analysis were employed in the statistical analysis of the results to check for confounding in the comparison between groups. The significance level was set at 5%.

Results

Baseline data - The baseline characteristics of the study groups are shown in Table 2. It will be observed that there were no statistically significant differences between groups in mean age, the number of erupted surfaces, caries prevalence and surfaces at risk ($P > 0.30$). It will also be seen that occlusal fillings and carious lesions contributed 60–64% of baseline DMFS scores when considering 40 occlusal and approximal surfaces (Table 2).

Caries increments - Fig. 1 shows net radiographic DFS increments for 24 approximal molar and premolar surfaces according to year of study and group, as well as for the whole 3-yr study period. The M component of the DMF index has been ignored because only 12 surfaces were lost due to caries during the 38 months of the trial, all in the Duraphat group.

Mean DFS increment per year, including all lesions varied from 0.80 to 1.02 in the Duraphat group, between 0.62 and 0.82 in

Table 2

Baseline characteristics of subjects who completed the trial according to group

	Duraphat ($n=185$)		Carex ($n=165$)		
Characteristics	Mean	SD	Mean	SD	*P*
Age (yr)	11.74	0.84	11.80	0.89	>0.40
24 approximal surfaces					
Erupted	16.86	5.81	16.90	6.07	>0.90
At risk	15.31	5.57	15.56	5.74	>0.60
DS	0.91	1.73	1.02	1.64	>0.50
DFS	1.36	2.16	1.59	2.21	>0.30
DMFS	1.38	2.19	1.61	2.21	>0.30
16 occlusal surfaces					
DMFS	2.38	1.85	2.44	1.87	>0.70
40 occlusal and approximal surfaces					
DMFS	3.82	3.46	4.02	3.52	>0.50

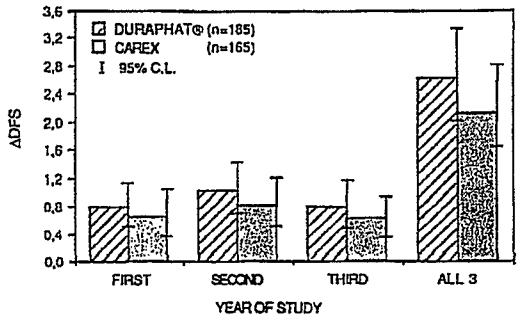

Fig. 1. Mean net radiographic DFS increments on 24 approximal surfaces of molars and premolars according to group and year of study.

the Carex group. The 3-yr mean net DFS increments at the D_1-level were 2.63 and 2.12, respectively. The corresponding estimates at the D_2-level (halfway through enamel) were 0.52 to 0.81; 0.41 to 0.62; 1.99 and 1.52 DF surfaces. None of these differences between groups were statistically significant ($P>0.15$). Fig. 1 shows a consistent but non-significant difference in mean DFS increment in favor of the Carex group. Inclusion of the 12 surfaces lost due to caries by subjects belonging to the Duraphat group accentuated, but did not increase this systematic difference between groups to statistical significance.

A 2-factor ANOVA revealed that caries incidence had been significantly ($P<0.01$) lower among girls than among boys during the 3-yr study, i.e. 2.01 and 3.27 DMFS in the Duraphat group; 1.13 and 2.93 in the Carex group, respectively.

Table 3 shows results of an analysis pertaining to occlusal and approximal surfaces

Table 3

Mean net radiographic DMFS increment on 16 occlusal and 24 posterior approximal surfaces according to group for the subjects who completed the 3-yr trial

Group	*n*	Mean	SD	*t*	*P*
Duraphat	185	5.21	5.79	2.05	<0.05
Carex	165	4.04	4.92		

of molars and premolars combined (40 surfaces). There was a statistically significant difference of 1.17 DMF surfaces in favor of the Carex group ($P<0.05$). A multiple linear regression analysis with group, age, gender, total number of topical applications and baseline DMFS (40 surfaces) as independent variables; DMFS increment (40 surfaces) as dependent variable confirmed a statistically significant effect of group ($P<0.02$), gender ($P<0.01$) and baseline DMFS score ($P<0.01$; adjusted $R^2=16.2\%$).

No side effects ascribable to the topical application of F varnishes were observed or reported during the trial.

Discussion

Partial recording based on posterior bitewing radiographs will have underestimated both baseline caries prevalence and caries incidence during the trial. There is, however, no evidence to suggest that this has biased the results in favor of either of the two study groups.

Lowering the F content of a varnish from 2.26% (Duraphat) to 1.80% (Carex) does not appear to have affected caries incidence adversely in the present double-blind clinical trial (Fig. 1, Table 3). In a study of rat fissure caries, SEPPÄ *et al.* (17) found that reducing the F concentration of Duraphat by half did not significantly reduce the caries-preventive effect of three 15 s applications on consecutive days. Furthermore, reviews of the literature show that, among the currently most used operator-applied topical agents, there are few clear data supporting the clinical superiority of one formulation over another (2, 8, 12, 18).

It is difficult to explain a caries inhibiting effect in favor of Carex when occlusal surfaces were included in the assessment ($P<0.02$). Inclusion of the missing (M) component of the DMF index when considering 40 approximal and occlusal surfaces contributed 0.06 MS of the observed 1.17 DMFS

difference in Table 3. The involvement of caries free occlusal surfaces when restoring approximal surfaces may have accounted for another 0.35 surfaces, leaving 0.25 surfaces of the increased DMFS difference due to caries activity in occlusal surfaces. Other possible explanations for the observed difference may be availability of F in the local environment for a longer period of time (7, 8) when using Carex than when using Duraphat. Alternatively, it may be ascribable to a prolonged sealant effect of Carex. The latter possibility is unlikely as Carex and Duraphat have similar composition and physical properties, and because SEPPÄ *et al.* (17) found no sealant effect of Duraphat when studying rat fissure caries. Since dental treatment may have contributed to the statistically significant difference in the 3-yr caries increment reported in Table 3, further evidence is needed before deciding whether the observed difference in favor of Carex is real or not.

Boys exhibited higher caries incidence than girls in this study ($P<0.01$). The finding that Norwegian 11–13-yr-old girls brush their teeth using a fluoride toothpaste more often than boys of the same age, and report less frequent intake of sugar-containing sweets and soft drinks may explain the observed difference in caries increment between genders (19). However, the multiple regression analysis shows that neither gender nor other potential confounding variables have invalidated the comparisons of caries incidence between groups.

That ethical considerations precluded the inclusion of a placebo or negative control group makes it impossible to decide on the efficacy of Carex in terms of reduction in caries incidence. Provided it is accepted that biannual professional applications of Duraphat have reduced caries incidence in the permanent teeth of children by 18–77% in previous clinical trials (1, 2), then the present results indicate a comparable efficacy for Carex at the caries activity level of these study participants.

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