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Caries-Preventive Effects of Self-Applied Subacidic 0.5% NaF-HF Gel via Toothbrushing in 7–8-Year-Old Schoolchildren: A Randomized Controlled Clinical Trial

Ki-Ho Rim[1], Chol-Jun Hwang[2,*], So Yon Kim[3], Chol Ho Kim[4], Byong-So Ri[5], Sun-Yong Choe[6], Jin-Hyok Kim[7]

Abstract

To assess the caries-preventive effectiveness of self-applied subacidic 0.5% sodium fluoride–hydrofluoric acid (NaF-HF) gel used during toothbrushing in children aged 7–8 years ***Objective:*** *To assess the caries-preventive effectiveness of self-applied subacidic 0.5% sodium fluoride–hydrofluoric acid (NaF-HF) gel used during toothbrushing in children aged 7–8 years.* ***Methods:*** *This 1-year, multi-arm, double-blind, placebo-controlled, parallel-group randomized study evaluated the caries-preventive efficacy of self-applied 0.5% NaF-HF gel among primary schoolchildren. A total of 1200 children from nine primary schools were randomized into four groups: Group 1 (once-yearly application), Group 2 (twice-yearly application), Group 3 (four times yearly application), and Group 4 (placebo control). Dental examinations were conducted by calibrated examiners using a mouth mirror and sickle probe under natural light in the school environment. The primary outcome was the increment in decayed, missing, and filled teeth (DMFT) index (including D1MFT and D2MFT) for maxillary and mandibular first permanent molars at baseline and 1-year follow-up. Data were analyzed using SPSS 23.0.* ***Results:*** *Statistically significant differences were observed in the mean increments of D1MFT and D2MFT across the study groups ($P<0.001$). Compared to the control group, the prevented fractions for D1MFT were 33% (Group 1), 67% (Group 2), and 81% (Group 3), while those for D2MFT were 30% (Group 1), 46% (Group 2), and 78% (Group 3). No significant differences in D3MFT increments were detected ($P=0.057$), and no adverse effects were reported.* ***Conclusion:*** *Subacidic 0.5% NaF-HF gel is highly effective for caries prevention in 7–8-year-old children when self-applied. The caries-preventive effect is dose-dependent, with four yearly applications yielding the highest efficacy (≥78%).*

Keywords: Caries prevention, Dental caries, Randomized controlled trial, Self-application, Subacidic 0.5% NaF-HF gel

INTRODUCTION

High-fluoride agents have truly long been used for caries prevention, including professional application in school-based programs and self-application for children at high caries risk. The American Dental Association (ADA) recommends professional use of 2.26% fluoride varnish and 1.23% acidulated phosphate fluoride (APF) gel, as well as home use of 0.5% APF gel and fluoride toothpaste. In contrast, self-applied 0.1% fluoride varnish and fluoride-containing pastes have shown no caries-preventive effects, while 1.23% APF foam and 0.09% fluoride mouthwash lack sufficient evidence for efficacy [1]. A previous study investigating self-applied high-fluoride gel (Elmex, 12,500 ppm) in 12–13-year-olds (once or twice weekly for 2 years, totaling ≥60 applications) reported relatively low preventive effects [2].

***Author for Correspondence**
Chol-Jun Hwang
E-mail: edu25hcj@163.com

[1–7]Researcher, Department of Orthodontics, Pyongyang University of Medical Sciences, Pyongyang, DPR Korea.

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Meanwhile, fluoride toothpaste is widely recognized as an effective preventive measure to reduce caries prevalence. In Sweden, 5000 ppm fluoride toothpaste has been utilized for caries prevention in high-risk children since 2003. Fluoride concentrations in toothpaste typically range from 500 ppm to 5000 ppm, and multiple studies have confirmed that its efficacy increases with higher fluoride concentrations across several key mechanisms. Collectively, the effectiveness of fluoride toothpaste can be attributed to [1]: reduced plaque accumulation [2]; decreased counts of cariogenic bacteria, specifically *Streptococcus mutans* and Lactobacillus species [3]; elevated fluoride levels in saliva and dental plaque; and [4] the formation of fluorapatite within the dental mineral matrix [3–6].

However, the presence of inorganic and organic additives in toothpaste limits fluoride's chemical reactivity, which also varies by fluoride type.

Recently, we developed a novel subacidic 1% NaF-HF gel (pH 5.67) containing sodium fluoride, hydrofluoric acid, and carboxymethyl cellulose (CMC) as a base (without phosphoric acid), with clinically confirmed caries-preventive efficacy [7]. Experimental data also demonstrated that 1.23% NaF-HF solution exhibits superior chemical reactivity compared to APF solution at the same fluoride concentration [8]. However, the 1% NaF-HF gel is a high-concentration agent requiring professional application. To enable home self-application, we reduced the fluoride concentration to 0.5% (5000 ppm). Its subacidity and high chemical reactivity (due to hydrofluoric acid) ensure clinical safety.

First permanent molars erupt around 6 years of age and are highly susceptible to caries, making this period critical for fluoride intervention to maximize preventive efficacy [9, 10]. Thus, this study aimed to evaluate the caries-preventive effect of self-applied (or parent-supervised) subacidic 0.5% NaF-HF gel via toothbrushing in 7–8-year-olds. Three application regimens were tested: once yearly (for 5 consecutive days), twice yearly (6-month intervals), and four times yearly (3-month intervals).

Null Hypotheses

- No difference in 1-year mean D1MFT increment exists between the placebo control group and the 0.5% NaF-HF gel groups.
- No difference in 1-year mean D1MFT increment exists among the three gel application regimens.

MATERIALS AND METHODS

Study Design and Ethics

This trial was specifically a 1-year, multi-arm, placebo-controlled, double-blind, parallel-group randomized trial evaluating the caries-preventive effect of self-applied subacidic 0.5% NaF-HF gel via toothbrushing in 7–8-year-old primary schoolchildren. The study was reviewed and approved in March 2023 by the Ethics Board of the Health Office of the Pyongyang People's Committee (Approval No.: 19/2023). Written informed consent was obtained from all parents/guardians.

Study Setting, Participants, and Sample Size

The study was conducted between 2023 and 2024 in nine primary schools in Pyongchon District, Pyongyang, Democratic People's Republic of Korea, where drinking water fluoride concentration was <0.1 ppm.

Sample Size Calculation

Based on a preliminary study, the mean annual D1MFT increment in 7–8-year-olds was 0.5 with a standard deviation of 0.58. A sample size of 270 per group was required to detect a clinically significant absolute difference of 0.15 in D1MFT increment (α=0.05, β=0.20). Accounting for a 20% dropout rate, the final sample size was set to 300 per group (total 1200 children).

Inclusion and Exclusion Criteria

- *Inclusion:* Second-year primary school students aged 7–8 years (born January 2015–December 2016) with high caries risk and parental consent.

- *Exclusion:* Dental hypoplasia, fluorosis, orthodontic appliances, regular use of fluoride toothpaste, or concurrent systemic diseases.

Recruitment

A total of 1515 eligible children were identified in April 2023. After excluding 34 children using fluoride toothpaste and 5 with systemic diseases, 1200 children were enrolled. Baseline examinations were conducted in July 2023, and follow-up in July 2024. Children completing both examinations were included in the intention-to-treat (ITT) analysis.

Randomization and Blinding

Block randomization (individual level) was used to allocate 1200 children to four groups (300 per group) by the principal investigator, with allocation concealment until data analysis. All participants, parents, dentists, school doctors, and teachers were blinded to group assignments.

Groups:

- *Group 1:* 0.5% NaF-HF gel (5 consecutive days/day, once yearly)
- *Group 2:* 0.5% NaF-HF gel (5 consecutive days/day, twice yearly, 6-month interval)
- *Group 3:* 0.5% NaF-HF gel (5 consecutive days/day, four times yearly, 3-month interval)
- *Group 4:* Placebo (fluoride-free CMC gel, identical appearance, 5 consecutive days/day, four times yearly)

Intervention and Clinical Examinations

- *Gel Preparation:* Subacidic 0.5% NaF-HF gel (pH 5.67) and placebo gel were manufactured by Pyongyang Pharmaceutical Factory. Parents/children received training on proper application (toothbrushing under supervision, focusing on first/second molars, rinsing with water after 1 minute, and avoiding swallowing).
- *Examinations:* Calibrated dental examiners used a mouth mirror and sickle probe under natural light. Caries was diagnosed using the Pitts and Fyffes criteria [9]. Inter- and intra-examiner reliability was assessed (κ>0.90 for both, via re-examination of 10% of participants). Adverse effects (tooth staining, mucosal changes, abnormal taste, systemic symptoms) were recorded.

Outcome Measures

- *Primary Outcome:* 1-year increment in DMFT (D1MFT: enamel caries; D2MFT: dentin caries; D3MFT: deep dentin caries) for maxillary and mandibular first permanent molars (calculated as follow-up DMFT minus baseline DMFT).
- *Prevented Fraction (PF):* Calculated as [(Control group increment – Intervention group increment) / Control group increment] × 100%.

Statistical Analysis

Data were analyzed using SPSS 23.0 (IBM Corp., Armonk, NY, USA) with an ITT approach. Baseline characteristics were compared using one-way ANOVA (age), Pearson's chi-square test (sex, brushing habits, socioeconomic status), and Kruskal-Wallis test (baseline DMFT). Caries increments were compared using Kruskal-Wallis test (intergroup) and Mann-Whitney U test (pairwise comparisons). Statistical significance was set at $P<0.05$.

RESULTS

Participant Flow and Baseline Characteristics

A CONSORT flow diagram is now shown in Figure 1. Of 1515 invited children, 1239 provided parental consent. After exclusions, 1200 children were randomized (Group 1: 271, Group 2: 267, Group 3: 270, Group 4: 269; mean age 7.5 years). Baseline characteristics (age, sex, brushing frequency, family income, and DMFT indices) were balanced across groups ($P>0.05$; Table 1).

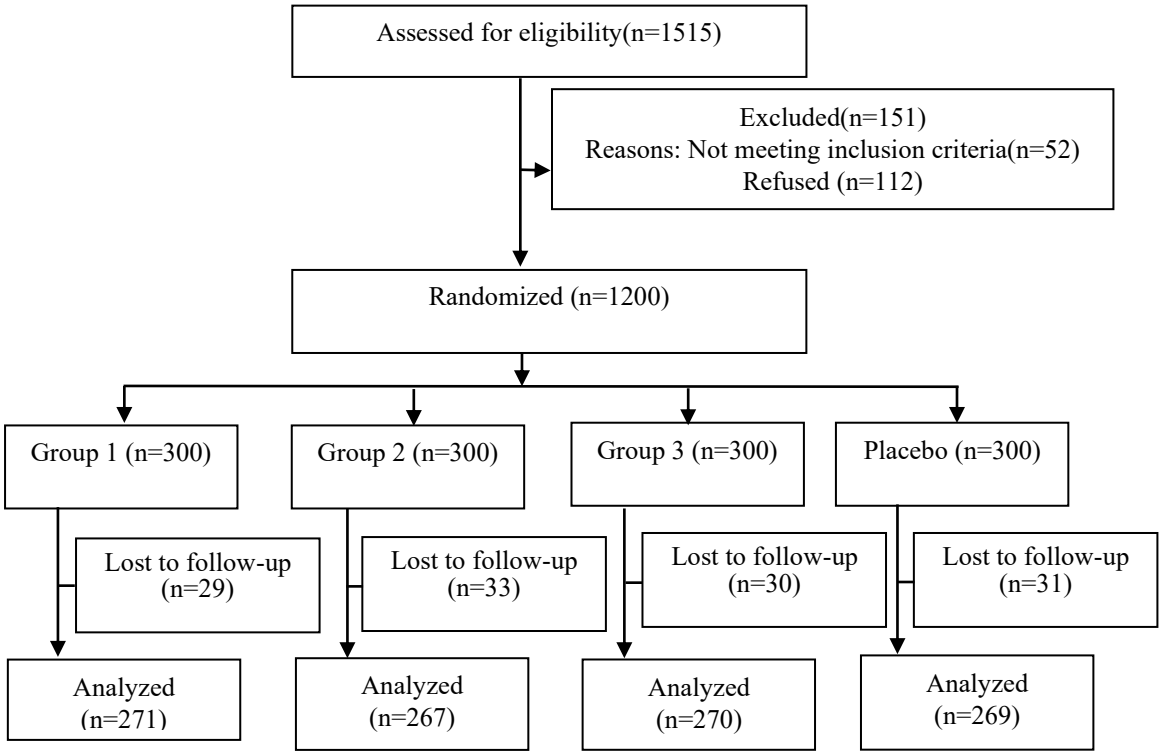

Figure 1. A CONSORT flow diagram of participants.

Table 1. Baseline characteristics of participants.

characteristics	Group1	Group2	Group3	Placebo	P value
Number of Children, n	271	267	270	269	
Age, years (SD)	7.5(0.5)	7.5(0.5)	7.5(0.5)	7.5(0.5)	0.856
Sex, n (%)					
Boy	136(50.2)	133(49.8)	134(49.6)	134(49.8)	0.999
Girl	135(49.8)	134(50.2)	136(50.4)	135(50.2)	
Toothbrushing frequency, n (%)					
Less than once per day	55(20.3)	52(19.5)	54(20.0)	53(19.7)	0.991
Once per day	206(76.0)	201(75.3)	204(75.6)	203(75.5)	
More than twice per day	10(3.7)	14(5.2)	12(4.4)	13(4.8)	
Household income, n (%)					
High	87(31.1)	94(35.2)	100(37.0)	99(36.8)	
Medium	88(32.5)	78(29.2)	92(34.1)	91(33.8)	0.443
Low	96(35.4)	95(35.6)	78(28.9)	79(29.4)	
D_1MFT, Mean (SD)	0.81(1.07)	0.79(1.00)	0.82(0.95)	0.80(0.99)	0.847
D_2MFT, Mean (SD)	0.39(0.87)	0.45(0.87)	0.43(0.84)	0.40(0.87)	0.549
D_3FT, Mean (SD)	0.09(0.36)	0.10(0.37)	0.08(0.36)	0.10(0.37)	0.601

Follow-Up: A total of 1077 children (89.75%) completed follow-up, with a dropout rate of 10.25% (lower than the expected 20%). Dropout reasons included school transfer (41.7%), relocation (30.1%), hospitalization (15.4%), and other causes (13.8%). No significant differences in baseline characteristics were observed between completers and dropouts.

Caries Increments and Prevented Fractions

Statistically significant differences in D1MFT and D2MFT increments were observed across groups ($P < 0.001$; Table 2). Pairwise comparisons showed that all intervention groups had significantly lower

increments than the control group ($P < 0.05$). The PF for D1MFT was 33% (Group 1), 67% (Group 2), and 81% (Group 3), while for D2MFT it was 30% (Group 1), 46% (Group 2), and 78% (Group 3). Group 1 differed significantly from Groups 2 and 3 ($P < 0.001$), and Group 2 differed from Group 3 ($P = 0.012$). No significant differences in D3MFT increments were detected ($P = 0.057$). No adverse effects were reported.

Table 2. Mean DMFT increment in each group at the final follow-up.

Group	n	Mean increment (SD)		
		D_1MFT	D_2MFT	D_3MFT
Placebo	269	0.58(0.52)	0.54(0.68)	0.17(0.44)
Group 1	271	0.39(0.49)	0.38(0.54)	0.13(0.37)
Group 2	267	0.18(0.39)	0.29(0.50)	0.15(0.36)
Group 3	270	0.11(0.31)	0.12(0.33)	0.10(0.30)
P value		<0.001	=0.002	=0.197

DISCUSSION

Despite the very widespread use of fluoride toothpaste and water fluoridation, topical high-fluoride agents remain important for high-risk populations. This study evaluated a novel self-applied subacidic 0.5% NaF-HF gel (5000 ppm) in 7–8-year-olds, a critical age for first permanent molar protection. These teeth have the highest caries incidence in the permanent dentition, particularly in children with developing oral hygiene habits [10, 11]; by 12 years, 92% of mandibular first molars may be carious [10]). Focusing on occlusal surfaces (e.g., first permanent molars) reduced diagnostic error compared to proximal caries, enhancing result accuracy [12].

This trial's strengths include its double-blind, placebo-controlled design, balanced baseline characteristics, high follow-up rate (89.75%), and excellent examiner reliability ($\kappa>0.90$). The subacidic 0.5% NaF-HF gel's superior chemical reactivity (compared to APF gel) and safety (subacidity) likely contributed to its efficacy [8, 13]. We defined a "treatment cycle" as 5 consecutive days of application (1 minute/day) to balance efficacy and feasibility for non-professional use (vs. 4 minutes for professional APF gel application).

Consistent with previous studies [7, 14], our results showed a dose-dependent caries-preventive effect: four yearly applications yielded the highest PF (78–81%), followed by twice-yearly (46–67%) and once-yearly (30–33%) regimens. The lower PF for D2MFT compared to D1MFT suggests that early fluoride intervention (before enamel breakdown) is more effective, emphasizing the importance of timely application in high-risk children. The lack of significant D3MFT differences is consistent with fluoride's role in preventing early caries rather than treating established dentin lesions.

A previous study using 12,500 ppm fluoride gel (self-applied once/twice weekly for 2 years) reported limited efficacy [2]. This may be due to the older study population (12–13-year-olds) with established caries, whereas our 7–8-year-old cohort targeted primary prevention. Additionally, NaF-HF gel's higher chemical reactivity (vs. conventional fluoride agents) may explain its superior efficacy despite fewer total applications (5 days/cycle vs. ≥60 applications in the previous study).

LIMITATIONS

- No direct comparison with 5000 ppm fluoride toothpaste or 0.5% APF gel. However, based on prior data [7, 13], NaF-HF gel's higher reactivity suggests it may outperform these agents, warranting future head-to-head trials.
- Incomplete blinding due to differing application intervals. However, since the impact of interval frequency was unknown to participants and staff, bias is unlikely to have significantly affected results.
- Short follow-up (1 year). Long-term studies are needed to assess sustained efficacy.

FUTURE DIRECTIONS

Further research should compare NaF-HF gel with validated fluoride products, evaluate long-term effects, and investigate its efficacy in areas with fluoridated drinking water or habitual fluoride toothpaste use.

CONCLUSIONS

Subacidic 0.5% NaF-HF gel can be a truly safe and highly effective self-applied caries-preventive agent for 7–8-year-old children. Four yearly applications (3-month intervals) yield the highest efficacy (≥78% prevented fraction), making it a promising addition to school-based and home caries prevention programs for high-risk populations.

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