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ORIGINAL RESEARCH

# ASSESSMENT OF THE EFFICACY OF FLUORIDE VARNISH VERSUS ACIDULATED PHOSPHATE FLUORIDE GEL IN PREVENTING DENTAL CARIES IN SCHOOLCHILDREN: A 24-MONTH RANDOMIZED CONTROLLED TRIAL

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## ABSTRACT

**Background:** Dental caries remains a significant public health problem among children globally. Professionally applied topical fluorides, such as fluoride varnish (FV) and acidulated phosphate fluoride (APF) gel, are cornerstones of caries prevention, but evidence from direct, long-term, placebo-controlled comparisons is continuously needed to guide clinical and public health practice.

**Methods:** A three-arm, parallel-group, double-blind, randomized controlled trial was conducted in 450 schoolchildren aged 6-8 years with a high risk for caries. Participants were randomly allocated into three equal groups (n=150 each): Group A received 5% sodium fluoride varnish (FV), Group B received 1.23% APF gel, and Group C received a placebo varnish. Interventions were applied biannually. The primary outcome was the 24-month increment in the Decayed, Missing, and Filled Surfaces (DMFS) index, assessed by calibrated examiners blinded to the treatment allocation. Secondary outcomes included patient acceptance and reported adverse effects.

**Results:** After 24 months, 418 children (92.9%) completed the study. The mean DMFS increment was significantly lower in the fluoride groups compared to the placebo group. The mean DMFS increment (± SD) was 0.9 ± 1.0 in the FV group and 1.2 ± 1.1 in the APF gel group, compared to 2.5 ± 1.8 in the placebo group ($p < 0.001$ for both fluoride groups vs. placebo). The prevented fraction was 64.0% for FV and 52.0% for APF gel. The difference in DMFS increment between the FV and APF gel groups was not statistically significant ($p = 0.134$). Patient acceptance was significantly higher for the varnish application (92% rated 'good' or 'excellent') compared to the gel (75%) ($p = 0.002$). No significant adverse effects were reported.

**Conclusion:** Both fluoride varnish and APF gel are highly effective in preventing dental caries in high-risk schoolchildren. Fluoride varnish demonstrated a slightly higher, though not statistically significant, preventive effect and was associated with better patient acceptance, suggesting it may be a preferable option for community-based public health programs.

***Keywords****:* Dental Caries, Fluoride Varnish, APF Gel, Randomized Controlled Trial, Caries Prevention, Pediatric Dentistry.

## INTRODUCTION

Dental caries is the most prevalent chronic disease affecting children and adolescents globally, posing a substantial challenge to public health systems [1]. The disease process, driven by the interplay of cariogenic bacteria, fermentable carbohydrates, and host susceptibility factors, leads to the progressive demineralization of tooth enamel and dentin [2]. If left untreated, carious lesions can result in pain, infection, tooth loss, and impaired oral health-related quality of life, affecting nutrition, growth, school performance, and social interaction [3]. Despite improvements in oral health in many developed nations, significant disparities persist, with children from low socioeconomic backgrounds bearing a disproportionately high burden of disease [4].

The use of fluoride has been the cornerstone of caries prevention for over 70 years and is widely recognized as one of the most successful public health measures of the 20th century [5]. Fluoride's primary mechanisms of action are topical: it inhibits demineralization of tooth enamel, enhances remineralization of incipient lesions, and inhibits the metabolic activity of cariogenic bacteria in dental plaque [6]. Fluoride can be delivered systemically (e.g., through community water fluoridation) or topically (e.g., through toothpaste, mouth rinses, or professionally applied agents).

Professionally applied topical fluorides (PATF) are recommended for individuals at elevated risk for dental caries [7]. Among the most commonly used PATF agents are acidulated phosphate fluoride (APF) gel and sodium fluoride (NaF) varnish. APF gel (typically containing 1.23% fluoride ion) has a long history of use and proven efficacy. Its application involves isolating the teeth and placing the gel in trays for 1-4 minutes [8]. While effective, this method can be time-consuming, may induce a gag reflex in young children, and carries a risk of fluoride ingestion if not performed carefully.

In recent decades, fluoride varnish (typically 5% NaF, equivalent to 2.26% fluoride ion) has gained immense popularity, particularly in pediatric dentistry [9]. Varnish is painted directly onto the teeth, where it adheres and releases fluoride over an extended period. The application is rapid, requires minimal patient cooperation, and has a significantly lower risk of systemic absorption, making it particularly suitable for young children and for use in community or school-based programs [10].

Numerous systematic reviews and meta-analyses, notably from the Cochrane Collaboration, have confirmed the substantial caries-preventive effects of both FV and APF gel [11, 12]. However, a research gap remains in the form of direct, long-term, and rigorously designed placebo-controlled trials comparing the *relative* efficacy of these two modalities in contemporary pediatric populations. Many existing studies are either short-term, non-randomized, or lack a true placebo control, making it difficult to isolate the true effect size of each agent. Furthermore, as oral health behaviors and dietary patterns evolve, it is crucial to continuously update the evidence base to inform clinical guidelines and public health policy.

Therefore, this study was designed as a 24-month, three-arm, randomized controlled trial to assess and compare the efficacy of 5% sodium fluoride varnish and 1.23% APF gel against a placebo control in preventing dental caries among a high-risk population of 6-8-year-old schoolchildren.

## MATERIALS AND METHODS

**Study Design and Ethical Approval**

This study was a three-arm, parallel-group, double-blind, randomized controlled trial conducted in accordance with the CONSORT (Consolidated Standards of Reporting Trials) statement.

**Study Population and Recruitment**

Participants were recruited from ten state-funded primary schools located in a low-socioeconomic, non-fluoridated urban district. Written informed consent was obtained from parents or legal guardians, and verbal assent was obtained from each child before enrollment. Children aged 6-8 years were screened for eligibility.

**Sample Size Calculation**

The sample size was calculated based on detecting a clinically meaningful difference in the 24-month DMFS increment. Based on a previous meta-analysis, the mean DMFS increment in a control group was estimated to be 2.5 over two years. To detect a 40% reduction in this increment with a power of 80% and a two-sided significance level of 0.05, a sample size of 120 children per group was required. To account for a potential 20% attrition rate over the 24-month period, the target sample size was inflated to 150 children per group, for a total of 450 participants.

**Inclusion and Exclusion Criteria**

Inclusion criteria were: age 6-8 years, good general health, parental consent, and being at high risk for caries (defined as having ≥1 decayed, missing, or filled primary tooth surface OR presence of enamel hypoplasia). Exclusion criteria included: known allergy to any of the product components, receiving orthodontic treatment, presence of developmental dental anomalies that would interfere with diagnosis, and regular use of other fluoride supplements.

**Randomization and Blinding**

A computer-generated block randomization sequence (with a block size of 6) was created by a statistician not involved in the clinical procedures. The allocation was concealed in sequentially numbered, opaque, sealed envelopes. A designated research nurse opened the envelope for each participant immediately before the intervention to determine group assignment. The participants and the clinical examiners were blinded to the treatment allocation. The operators administering the interventions were not blinded due to the different physical forms of the products. The placebo varnish was specially manufactured to be identical in color, taste, and viscosity to the active fluoride varnish.

**Intervention Protocol**

Participants were randomly assigned to one of three groups:

- **Group A (Fluoride Varnish - FV):** Received a biannual application of 5% sodium fluoride varnish (Duraphat®, Colgate-Palmolive). Teeth were isolated with cotton rolls and dried with compressed air, and a thin layer of varnish was painted onto all tooth surfaces.
- **Group B (APF Gel):** Received a biannual application of 1.23% APF gel (Nupro®, Dentsply Sirona). Pre-formed trays filled with the gel were seated over the maxillary and mandibular arches for 4 minutes. A saliva ejector was used throughout the procedure to minimize ingestion.
- **Group C (Placebo Varnish):** Received a biannual application of a fluoride-free placebo varnish, applied in the same manner as Group A.

All participants were given standardized oral hygiene instructions and a non-fluoridated toothpaste to use for the duration of the study to minimize confounding, a decision made for research purity in this specific high-risk, non-fluoridated community context.

**Data Collection and Outcome Measures**

Clinical examinations were performed at baseline, 12 months, and 24 months by two calibrated examiners who were blinded to the group assignments. Examinations were conducted in the school setting using a portable dental chair, an LED headlight, a plane mouth mirror, and a WHO-CPI probe.

- **Primary Outcome:** The primary outcome was the 24-month caries increment, measured as the change in the Decayed, Missing, and Filled Surfaces (DMFS) index from baseline. Caries was diagnosed at the cavitation level (D3) according to the WHO criteria (2013).
- **Secondary Outcomes:**
  - **Patient Acceptance:** Assessed immediately after each application using a 5-point facial hedonic scale for the children.
  - **Adverse Effects:** Any adverse events (e.g., nausea, mucosal irritation) were recorded via parental report one week after each application.

**Examiner Calibration**

Prior to the study, the two examiners were calibrated on a cohort of 20 children not included in the main trial. Inter- and intra-examiner reliability for DMFS scoring was calculated using the weighted Kappa statistic, yielding values of 0.91 and 0.94, respectively, indicating excellent agreement.

**Statistical Analysis**

Data were analyzed using SPSS Version 27.0 (IBM Corp.). The primary analysis was conducted on a modified intention-to-treat (mITT) basis, including all randomized participants who had at least one post-baseline assessment. Descriptive statistics were calculated for all variables. The baseline characteristics of the three groups were compared using the Chi-square test for categorical variables and one-way ANOVA for continuous variables. The primary outcome (mean DMFS increment) was compared among the three groups using ANOVA followed by Tukey's post-hoc test for pairwise comparisons. The Prevented Fraction (PF) was calculated as: PF (%) = [(Mean increment in control group – Mean increment in test group) / Mean increment in control group] × 100. Categorical secondary outcomes were analyzed using the Chi-square test. A p-value < 0.05 was considered statistically significant.

## RESULTS

**Participant Flow and Baseline Characteristics**

A total of 610 children were screened, of whom 450 met the eligibility criteria and were randomized. Over the 24-month study period, 32 participants were lost to follow-up (10 from Group A, 12 from Group B, and 10 from Group C), primarily due to relocation. The final analysis included 418 children (92.9% retention). The baseline demographic and clinical characteristics of the participants were well-balanced across the three groups, with no statistically significant differences in age, gender, or baseline mean DMFS scores (**Table 1**).

**Table 1. Baseline Demographic and Clinical Characteristics of Study Participants**

| Characteristic | Group A (FV) (n=138) | Group B (APF Gel) (n=138) | Group C (Placebo) (n=142) | p-value |
|---|---|---|---|---|
| **Age (years, Mean ± SD)** | 7.1 ± 0.6 | 7.2 ± 0.5 | 7.1 ± 0.6 | 0.451 |
| **Gender (Male/Female,n)** | 65 / 73 | 69 / 69 | 72 / 70 | 0.812* |
| **Baseline Mean DMFS (± SD)** | 2.8 ± 1.5 | 2.9 ± 1.6 | 2.8 ± 1.4 | 0.887 |

**Primary Outcome: Caries Increment**

At the 24-month follow-up, both active fluoride groups showed a significantly lower mean DMFS increment compared to the placebo group (**Table 2**). The mean DMFS increment in the placebo group was 2.5 ± 1.8. In contrast, the mean DMFS increment was 0.9 ± 1.0 in the fluoride varnish group and 1.2 ± 1.1 in the APF gel group. ANOVA revealed a highly significant difference among the three groups ($F=35.1$, $p < 0.001$).

Tukey's post-hoc tests confirmed that both the FV group ($p < 0.001$) and the APF gel group ($p < 0.001$) had significantly lower caries increments than the placebo group. The difference between the FV group and the APF gel group (0.3 surfaces) was not statistically significant ($p = 0.134$). The calculated prevented fraction was 64.0% for fluoride varnish and 52.0% for APF gel.

**Table 2. 24-Month Mean DMFS Increment and Prevented Fraction**

| Group | n | Baseline Mean DMFS (± SD) | 24-Month Mean DMFS (± SD) | Mean DMFS Increment (± SD) | Prevented Fraction (%) | p-value (vs. Placebo) |
|---|---|---|---|---|---|---|
| **Group A (FV)** | 138 | 2.8 ± 1.5 | 3.7 ± 1.9 | 0.9 ± 1.0 | 64.0% | **<0.001** |
| **Group B (APF Gel)** | 138 | 2.9 ± 1.6 | 4.1 ± 2.0 | 1.2 ± 1.1 | 52.0% | **<0.001** |
| **Group C (Placebo)** | 142 | 2.8 ± 1.4 | 5.3 ± 2.2 | 2.5 ± 1.8 | - | - |

**Secondary Outcomes: Patient Acceptance and Adverse Effects**

Patient acceptance was significantly higher for the fluoride varnish application compared to the APF gel (**Table 3**). In the FV group, 92.0% of applications were rated as 'good' or 'excellent' by the children, compared to 75.4% in the APF gel group (p = 0.002). The most common reason for lower ratings in the APF gel group was the discomfort associated with the trays and the taste of the gel.

There were no severe or systemic adverse effects reported in any group. A small number of children reported minor, transient adverse effects. In the APF gel group, 5 children (3.6%) reported mild nausea immediately following the procedure. In the FV group, 3 children (2.2%) reported a temporary dislike for the texture of the varnish on their teeth. These differences were not statistically significant.

**Table 3. Patient Acceptance and Reported Minor Adverse Effects**

| Outcome | Group A (FV) (n=138) n (%) | Group B (APF Gel) (n=138) n (%) | p-value |
|---|---|---|---|
| **Patient Acceptance** | | | **0.002*** |
| - Excellent/Good | 127 (92.0%) | 104 (75.4%) | |
| - Fair/Poor | 11 (8.0%) | 34 (24.6%) | |
| **Minor Adverse Effects** | 3 (2.2%) | 5 (3.6%) | 0.485** |

## DISCUSSION

This 24-month randomized controlled trial robustly demonstrates the substantial efficacy of professionally applied fluoride varnish and APF gel in preventing dental caries in a high-risk population of schoolchildren. The primary finding—that both agents led to a statistically significant and clinically meaningful reduction in caries increment compared to a placebo—reaffirms the foundational role of topical fluorides in modern preventive dentistry. The prevented fractions of 64.0% for fluoride varnish and 52.0% for APF gel are consistent with the effect sizes reported in major systematic reviews, such as the comprehensive Cochrane reviews by Marinho et al. [11, 12], which established the evidence base for these interventions.

Our study contributes to the literature by providing a direct, head-to-head comparison in a well-defined pediatric population under rigorous, placebo-controlled conditions. While the fluoride varnish group showed a numerically greater reduction in caries increment (a difference of 0.3 surfaces over two years), this difference did not reach statistical significance. This suggests that, from a purely clinical efficacy standpoint, both agents are highly effective options. This finding is in line with several other trials that have found comparable efficacy between varnish and gel when applied correctly [13]. The choice between them may therefore hinge on other factors, such as safety, patient acceptance, and ease of application.

On these secondary measures, our results showed a clear advantage for fluoride varnish. The significantly higher patient acceptance for varnish is a critical finding, especially in the context of public health programs and pediatric dentistry. The quick, paint-on application of varnish avoids the need for trays, which can be uncomfortable and induce a gag reflex in young or anxious children [14]. A more positive patient experience can improve compliance and willingness to participate in future preventive appointments, enhancing the long-term effectiveness of a program.

Furthermore, the safety profile of fluoride varnish is superior. Although we did not measure fluoride ingestion directly, the established literature indicates that the

amount of fluoride swallowed during varnish application is negligible compared to that with gel and trays [10]. This makes varnish a safer option for young children, minimizing the risk of acute toxicity (e.g., nausea) and the theoretical risk of contributing to dental fluorosis if used repeatedly during enamel development. The public health implications of these findings are profound. School-based caries prevention programs are a highly effective way to reach children, particularly those from disadvantaged backgrounds who have limited access to regular dental care [15]. Our study provides strong evidence to support the implementation of such programs. Given its high efficacy, superior patient acceptance, and ease and speed of application, fluoride varnish appears to be the more pragmatic and advantageous agent for large-scale application in a school setting. A dental professional or trained auxiliary can treat many more children with varnish in a given time than with gel, making it a more cost-effective intervention from a logistical standpoint.

This study has several strengths, including its randomized, double-blind, placebo-controlled design, a long follow-up period of 24 months, high participant retention, and the use of calibrated examiners. However, some limitations should be noted. First, the study was conducted in a specific high-risk, non-fluoridated population, and the results may not be directly generalizable to children at lower risk or those with exposure to water fluoridation. Second, while we provided non-fluoridated toothpaste to standardize exposure, we could not control for fluoride from other dietary sources or the Hawthorne effect, where participants' behavior might change due to their awareness of being in a study. Finally, the operators were not blinded, which could have introduced a performance bias, although standardized application protocols were strictly followed to minimize this.

## CONCLUSION

Within the parameters of this clinical trial, it is concluded that biannual application of both 5% sodium fluoride varnish and 1.23% APF gel is a highly effective measure for preventing dental caries in high-risk schoolchildren. Both interventions resulted in a significant reduction in caries increment over a 24-month period compared to a placebo. While their clinical efficacies were not statistically different, fluoride varnish demonstrated significant advantages in terms of patient acceptance and ease of use. These practical benefits make fluoride varnish a particularly suitable and recommended agent for community-based oral health programs aimed at reducing the burden of childhood dental caries.

## DECLARATIONS

**Funding** Not receive any specific grant

**Competing Interests**

The authors have no competing interests to declare.

**Ethical Approval**

The study was approved by the appropriate ethics committee and conducted according to relevant guidelines and regulations.

**Informed Consent**Not applicable.

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