

COMPARISON OF CARIES PREVENTIVE EFFECT OF TWO FLUORIDE VARNISHES IN CARIES-ACTIVE PRESCHOOL CHILDREN OF MATHURA CITY.

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ABSTRACT

Introduction:

The prevention of dental caries in preschool children is a priority for dental services. This study aimed to evaluate the caries-preventive effect of two fluoride varnishes in caries-active preschool children and to compare the outcomes with a non-varnish control group.

Aim:

To compare the effectiveness of fluoride varnishes among preschool children in Mathura city.

Method:

A total of 180 preschool children aged 3-6 years with at least one non-cavitated lesion were randomly allocated into three parallel groups: Group 1 received 1.5% Ammonium Fluoride Varnish (Fluor Protector S), Group 2 received 5% Sodium Fluoride Varnish (Voco Profluorid), and Group 3 received professional tooth cleaning only. Interventions were performed every three months for 12 months. Parents were instructed to brush their children's teeth twice daily using a kid's fluoridated toothpaste. Caries were assessed at baseline and after 12 months by a calibrated examiner at non-cavitated (d2) and cavitated (d3) levels. Statistical analysis was performed using chi-square and two-sided t tests.

Results:

The three groups were comparable at baseline with respect to age, gender distribution, and caries experience ($p > 0.05$). At the end of 12 months, no significant intergroup differences were observed in mean non-cavitated or cavitated caries scores at the tooth or surface level ($p > 0.05$). However, intragroup analysis showed that the control group exhibited a significantly greater increase in cavitated lesions and overall caries experience compared with both fluoride varnish groups ($p < 0.001$). In contrast, no increase in cavitated lesions was observed in either fluoride varnish group over the study period. The increase in combined caries indices (d2d3mft and d2d3mfs) was lowest in the fluoride varnish groups and highest in the control group. Oral hygiene practices were largely similar among groups, although differences were noted in brushing time and tongue-brushing habits. Overall, both fluoride varnishes demonstrated a protective effect against caries progression compared with the control group.

Conclusion:

Both fluoride varnishes showed comparable effectiveness in reducing caries incidence in caries-active preschool children over a 12-month period compared with a control group.

Keywords:

Fluoride Varnish, Ammonium Fluoride Varnish, Sodium Fluoride Varnish, Dental caries prevention, Preschool children, Randomized Controlled Trial, Early Childhood Caries.

How to cite this article: Jeloka R, Kaur N, Sharma VK, Vardhan S, Agrawal A, Bharti. Comparison of Caries Preventive Effect of Two Fluoride Varnishes in Caries-Active Preschool Children of Mathura City. *Int J Drug Deliv Technol.* 2026;16(56s): 257-262. DOI: 10.25258/ijddt.16.56s.26

INTRODUCTION

The prevention of dental caries among preschool children is a prime concern for dental professionals and is therefore considered to be more economic than treatment of disease itself. The World Health Organisation (WHO) has recommended the fluoridated varnish to be applied systematically twice or thrice a year for preschool children having a risk of high caries. Varnish extends the duration of the contact between enamel and fluoride which acts as a sustained reservoir of releasing fluoride by stagnating the caries growth because of its high titre of fluoride in saliva and oral biofilm for several days.^[1]

Caries can be attributed to limited access to culturally competent oral health services, oral health promotion resources, negligence to toothbrushes and toothpaste in rural and remote areas and a diet which includes frequent consumption of sugar containing beverages and snacks.^[2]

Early Childhood Caries (ECC) is one of the most important public health problems among young children. The disease has many negative impacts on the Quality of Life of children, and the effects vary depending on the extent of the carious lesion. Surgical management of ECC is very distressing not only for children but also for their families and dentists because of the limited cooperative ability of children. Moreover, this procedure requires sophisticated equipment and highly skilled dental teams.^[3]

Topical fluoride applications are an effective way for preventing caries among children. A stronger evidence for professionally applied fluoride varnish with twice-yearly applications of fluoride varnish have been shown to reduce Decayed, Missing, Filled tooth surface (DMFS) increments by 46% for children and adolescents after a 1-year period. The benefits were larger for high caries-risk children. Moreover, the dose-response relationships between the frequency of fluoride varnish applications and its efficacy on caries prevention were found. While four or more fluoride varnish applications per year are required to achieve maximum benefits, multiple applications of Sodium fluoride (NaF) varnish may not be feasible for low income, rural children. Various trials have tested the efficacy of 5% NaF varnish application in preventing caries experiences in permanent dentition among underserved and underprivileged rural school children.^[4]

The Cochrane database indicates that fluoride varnish is effective in reducing tooth caries in both primary and permanent dentitions. Fluoride varnish is also considered to be a very safe dental product.^[5]

Fluoride varnish, in conjunction to oral health counselling has been shown to prevent dental caries in this age group, both in public health centers and large community based preventive programmes.^[6] Fluoride varnishes (FV) were introduced into dental practice in the 1970s. Both the European Academy of Paediatric Dentistry [2009] and the American Academy of Pediatric Dentistry [2012a] endorse the use of FV 2-4 times a year for caries prevention in primary and permanent teeth.^[7] Fluoride controls the initiation and progression of carious lesions. Intensive laboratory and epidemiological research on the mechanism of action of fluoride in preventing caries indicates that fluoride's predominant effect is topical, which occurs mainly through promotion of remineralization of early caries lesions and by reducing sound tooth enamel demineralization (Featherstone 1988).^[8] Various modes of fluoride use have evolved, each with its own recommended concentration, frequency of use, and dosage schedule. The use of topically applied fluorides in particular, which are much more concentrated than the fluoride in drinking water, has increased over recent decades and fluoride containing toothpastes (dentifrices), mouthrinses, gels and varnishes are the modalities most widely used at present, either alone or in different combinations.^[9] Most of the varnishes in the market are based on 5% Sodium Fluoride but, in recent years, a new varnish formula with 1.5% Ammonium Fluoride has been discovered and data on its clinical performance are limited to the prevention of white-spot lesion development during orthodontic treatment with fixed appliances so far.^[10] Investigations have showed that this novel varnish is safe for use in preschool children with parallel use of a fluoridated toothpaste recommended for kids but its anticaries capacity is yet unknown.^[11] Therefore, this study compared the caries-preventive effect of quarterly applications of the 1.5% ammonium fluoride varnish in preschool children with active caries, also compared the results with a 5% sodium fluoride varnish and a non-varnish control group which highlighted the need of this study to be conducted in Mathura city.

MATERIALS AND METHOD

Trial Design and Ethical Approval

This study was planned as a 12-month, three-arm, parallel-group, single-blind randomized controlled clinical trial with an allocation ratio of 1:1:1. Ethical clearance was obtained from the Institutional Ethics Committee, and legal guardians provided written informed consent prior to child enrollment.

Participant Selection and Eligibility Criteria

Preschool children aged 3–6 years were recruited from private schools in Mathura City.

- I. Inclusion criterion
 - All erupted deciduous teeth.
 - One cavitated or noncavitated lesion must be present.
- II. Exclusion criterion-
 - Children with any medical history or on any medication that could affect their oral health.
 - Children with history of allergy.
 - Children with cognitive disabilities and/or special needs.
 - Children with more than 10 tooth surfaces with dentin lesions.
 - Children on antibiotics within the last 2 weeks prior to the baseline examination.

Sample Size Estimation

The sample size was determined by G Power software and the power of study was 80% and CI was 95%. Based on data, the sample size was estimated as 168 which was increased to 180 in order to compensate for any kind of permissible error and to increase the accuracy of the study. The calculated values found were effect size $f = 0.2433056$, $\alpha = 0.05$ and Power $(1-\beta) = 0.80$. Group allocation was performed randomly through concealed, opaque, labeled envelopes that remained unopened until the start of the intervention. This was done to assess the practicality and feasibility of the trial.

Sampling Methodology

Mathura city consists of 53 private schools as indicated by the list from the Basic Shiksha Adhikari office.

To cover the total sample size of 180, 3 private schools were selected from various zones of Mathura city randomly and 60 preschool children were selected from each private school. Out of these 60 students, 20 students were allocated in each study group.

Clinical Interventions

- **Group 1:** Received quarterly applications of 1.5% Ammonium Fluoride varnish (Fluor Protector S; 7,700 ppm F) using approximately 0.25 ml per application. The material dried for 60 seconds.
- **Group 2:** Received quarterly applications of 5% Sodium Fluoride varnish (Voco Profluorid; 22,600 ppm F) using one drop (0.1 ml) per arch, which was air-dried.
- **Group 3:** Recalled every three months for professional cleaning, oral health education, and toothbrushing reinforcement, without receiving any varnish applications.

Before application, teeth were cleaned using soft-bristled brushes, isolated with cotton rolls, and dried. All parents were instructed to enforce twice-daily brushing using pediatric fluoridated toothpaste. Post-application rules restricted solid foods or drinks for 2–4 hours, and hard/rough foods for 24 hours.

Visual-tactile examinations were conducted at baseline and 12 months under natural lighting after drying tooth surfaces. Caries increments were scored distinctively at two distinct thresholds based on WHO criteria:

1. **Non-cavitated enamel lesions (d2):** Active chalky white-spot surface changes without structural loss.
2. **Cavitated dentin lesions (d3):** Clear physical loss of structural enamel continuity into dentin.

Total indexes were aggregated as Decayed, Missing, and Filled Teeth (d2d3mft) or Surfaces (d2d3mfs). Intra-examiner calibration yielded a high Kappa statistic of 0.88.

Data handling: The data was entered into Microsoft Excel 2016 and analyzed using the Statistical Software for Social Sciences (SPSS; Version 20).

Descriptive Analysis: The descriptive analysis and statistical analysis was done using paired t-test for intra group (pre and post), unpaired t-test for intergroup comparison and ANOVA test. The level of significance was set at $p \leq 0.05$.

RESULTS

A Randomized Controlled Trial was conducted over a period of 12 months among preschool children in Mathura city to compare the caries preventive effect of two fluoride varnishes: 1.5% Ammonium Fluoride varnish (Fluor Protector S) and 5% Sodium Fluoride varnish.

A total of 180 preschool children were equally distributed into three groups ($n=60$ each). The mean age of participants in Group 1, Group 2, and Group 3 was 4.97 ± 0.80 , 4.93 ± 0.80 , and 4.93 ± 0.80

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years, respectively, with no statistically significant difference among the groups ($p=0.96$). Gender distribution was comparable across all groups ($p=0.90$). Most children brushed once daily, with no significant difference in brushing frequency among groups ($p=0.28$). However, significant differences were observed in the timing of tooth brushing ($p=0.04$) and tongue-cleaning habits ($p=0.01$). All participants used toothpaste and toothbrushes as oral hygiene aids.

At baseline, no statistically significant intergroup differences were observed for non-cavitated tooth lesions (d2t), cavitated tooth lesions (d3t), overall caries experience (d2d3mft), non-cavitated tooth surface lesions (d2s), cavitated tooth surface lesions (d3s), and total tooth surface caries experience (d2d3mfs) ($p>0.05$), indicating baseline homogeneity among the study groups.

At 12 months, the mean d2t scores were 1.57 ± 1.34 , 1.52 ± 1.28 , and 1.72 ± 1.30 in Groups 1, 2, and 3, respectively, with no significant intergroup difference ($p=0.68$). Similarly, mean d3t scores at 12 months were 0.70 ± 0.78 , 0.65 ± 0.73 , and 0.93 ± 0.73 , respectively, and the difference among groups was not statistically significant ($p=0.09$). The mean d2d3mft scores were 2.47 ± 1.72 , 2.40 ± 1.59 , and 2.85 ± 1.59 , respectively, showing no significant difference between groups ($p=0.27$).

Likewise, no statistically significant intergroup differences were observed for tooth surface lesions at 12 months. Mean d2s scores were 1.57 ± 1.34 , 1.52 ± 1.28 , and 1.72 ± 1.30 ($p=0.68$), while mean d3s scores were 0.97 ± 1.11 , 0.93 ± 1.08 , and 1.30 ± 1.13 in Groups 1, 2, and 3, respectively ($p=0.14$). Mean d2d3mfs scores were 2.73 ± 1.74 , 2.68 ± 1.69 , and 3.25 ± 1.81 , with no statistically significant intergroup difference ($p=0.14$).

Intragroup comparisons demonstrated an increase in caries scores from baseline to 12 months across all groups, although the magnitude of progression varied. Non-cavitated tooth lesions (d2t) increased by 18.1%, 15.2%, and 28.6% in Groups 1, 2, and 3, respectively. Cavitated tooth lesions (d3t) remained unchanged in Groups 1 and 2, whereas Group 3 demonstrated a significant increase of 38.9% at 12 months ($p<0.001$).

Similarly, overall caries experience (d2d3mft) increased by 10.8%, 9.1%, and 27.9% in Groups 1, 2, and 3, respectively. Tooth surface lesion scores also showed progression over time, with d2s increasing by 18.1%, 15.2%, and 29.3%, while d3s increased by 36.9% only in Group 3. Furthermore, d2d3mfs scores increased by 8.0%, 8.1%, and 28.9% in Groups 1, 2, and 3, respectively. The control group exhibited comparatively greater caries progression than the fluoride varnish groups over the study period.

DISCUSSION

Early Childhood Caries (ECC) remains a major public health concern among preschool children despite advances in preventive dentistry. Since non-cavitated lesions are potentially reversible but may progress to cavitation if untreated, understanding lesion progression and preventive effectiveness is important. The present Randomized Controlled Clinical Trial evaluated the progression of non-cavitated and cavitated carious lesions over 12 months using both tooth-level and surface-level indices.

The three study groups were comparable at baseline with respect to age, gender, and caries experience, indicating successful randomization and strong internal validity. Mean age and gender distribution showed no statistically significant differences ($p>0.05$), minimizing demographic confounding. Similarly, baseline tooth-level and surface-level caries indices (d2t, d3t, d2d3mft, d2s, d3s, and d2d3mfs) were comparable across groups, supporting intergroup homogeneity. These findings were consistent with previous fluoride varnish studies by Turska-Szybka et al.^[1], Oliveira et al.^[10], and Arruda et al.^[4].

No statistically significant intergroup differences were observed for any caries parameter after 12 months ($p>0.05$), although Group 3 consistently showed numerically higher caries scores. Both fluoride varnish groups demonstrated comparatively lower progression than the control group, suggesting a preventive trend despite statistical insignificance.

These findings were comparable to previous fluoride varnish studies, where differences between varnish formulations were modest. Turska-Szybka et al.^[1] similarly reported no significant difference between Ammonium Fluoride and Sodium Fluoride varnishes, despite slight reductions in caries progression. This suggested that both varnishes might provide comparable preventive benefits.

Non-cavitated lesions increased over time in all groups, with greater progression observed in Group 3. At the tooth and surface levels, lesion progression was lower in fluoride varnish groups than in the control group, indicating a possible protective effect of fluoride therapy.

These findings were consistent with reports by Oliveira et al.^[10] and Turska-Szybka et al.^[1], who observed continued progression of early lesions despite preventive interventions. Fluoride varnish might slow lesion progression but might not completely prevent the formation of new lesions, particularly in high-risk children^[7]. Factors such as inadequate plaque control, dietary sugar exposure, and dependence on caregivers for oral hygiene might have contributed to lesion progression.^[16]

Cavitated lesions remained largely stable in Groups 1 and 2, while Group 3 demonstrated substantial progression over the study period. Similar findings at both tooth and surface levels suggested that

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fluoride varnishes might be more effective in arresting cavitated lesion progression than preventing the initiation of early enamel lesions.^[11,20]

Previous literature has reported comparable findings, emphasizing the role of fluoride varnish in lesion stabilization rather than complete prevention of disease progression, especially among children with elevated caries risk^[11].

The inclusion of both tooth-level and surface-level indices provided a comprehensive assessment of caries progression. Surface-level measures were more sensitive in identifying early disease changes and subtle lesion progression, supporting previous evidence that dmfs-based assessment provides a more detailed evaluation of preventive outcomes^[1,10].

The findings of the present study were consistent with systematic reviews reporting modest preventive benefits of fluoride varnish application in preschool children^[18]. Although statistically significant intergroup differences were not observed, fluoride varnishes appeared to reduce disease progression compared with the control group.

The greater progression observed in Group 3 highlighted the need for comprehensive preventive strategies, including repeated fluoride applications, dietary counseling, parental education, and supervised oral hygiene^[9]. Fluoride varnish should therefore be considered part of a multifactorial preventive approach rather than a standalone intervention for ECC management^[1,12].

This study utilized a rigorous, randomized parallel design with complete allocation concealment, achieving excellent baseline demographic and clinical homogeneity across groups. The high intra-examiner reliability ($\kappa = 0.88$) further supported the internal validity of the findings.

The 12-month observation window might be too short to observe long-term differences in surface remineralization patterns between the two active varnish chemistries. Additionally, variations in parent-supervised home compliance—such as exact brushing duration and technique—might introduce minor confounding variables.

CONCLUSION

Quarterly professional topical applications of either 1.5% Ammonium Fluoride varnish or 5% Sodium Fluoride varnish are highly effective clinical interventions for arresting Early Childhood Enamel Caries and preventing progression to physical cavitation compared to professional tooth cleaning alone. Both varnish systems demonstrated comparable therapeutic outcomes over 12 months, supporting their routine integrated use in public health dental programs for caries prevention.

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