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Effectiveness of a simplified topical Fluoride application technique for caries and plaque control in Autistic children: A longitudinal study

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Abstract
Background: Children with autism spectrum disorder (ASD) and young pediatric patients often face challenges performing conventional mouth rinsing due to swallowing difficulties, sensory aversion, or poor coordination. Such barriers hinder fluoride exposure, increasing susceptibility to dental caries, plaque accumulation, and halitosis. Colgate Phos-Flur, a 0.044% sodium fluoride (acidulated phosphate) mouthwash, provides effective fluoride ion delivery that promotes remineralization and inhibits demineralization. When applied topically with a cotton applicator (ear bud) before bedtime, it offers controlled, targeted, and safe fluoride deposition on tooth surfaces.
Aim: To assess the preventive and therapeutic effects of nightly topical application of Colgate Phos-Flur mouthwash using an ear bud on caries progression, Halitosis, plaque accumulation, and symptom control in pediatric autistic children over a two-year period.
Methods: A two-year longitudinal randomized study will be conducted on 6–12-year-old children (n=60) divided into three groups:
Group I (Control): Standard toothbrushing with fluoride toothpaste.
Group II (Mouthrinse Group): Conventional rinse with Colgate Phos-Flur for 1 minute before bedtime.
Group III (Topical Application Group): Colgate Phos-Flur applied directly onto all tooth surfaces using a sterile ear bud, ensuring thin even coverage, once nightly before sleep.
Caregivers will be trained in the method, emphasizing "no post-application rinsing or drinking."
Results: Topical Phos-Flur application with an ear bud is expected to provide equivalent caries-preventive efficacy compared with conventional rinsing, while being safer and better tolerated by autistic and younger children. A significant reduction in plaque scores, halitosis, and lesion progression is anticipated.
Clinical parameters (Plaque Index, ICDAS lesion scoring, pain/sensitivity VAS, and halitosis by halimeter) will be evaluated at baseline, 6, 12, 18, and 24 months.
Conclusion: Topical application of Colgate Phos-Flur mouthwash using a cotton applicator before bedtime offers a simple, safe, and effective non-invasive strategy for caries prevention and symptom control. This approach enhances fluoride delivery to enamel while accommodating children who cannot perform traditional mouth rinsing, thus broadening preventive dental care access.

Keywords: Colgate Phos-Flur**,** sodium, fluoride mouthwash**,** topical fluoride application, Autism Spectrum Disorder, Pediatric Dentistry, caries, prevention, plaque, control, non-invasive dental therapy**,** fluoride uptake**,** nightly fluoride protocol

Introduction

Dental caries is one of the most widespread chronic diseases affecting children globally, posing a major public health concern due to its high prevalence and impact on quality of life [1]. Despite advancements in preventive dentistry, children—especially those with autism spectrum disorder (ASD)—often show higher caries susceptibility and poorer oral hygiene compared to neurotypical peers [2, 3]. Factors such as sensory hypersensitivity, poor motor coordination, and limited cooperation during oral hygiene procedures contribute to this disparity [4]. Consequently, many children with ASD require invasive dental treatments under sedation or general anesthesia, which can be traumatic and costly [5].

Fluoride remains the cornerstone of caries prevention because of its ability to inhibit enamel demineralization, enhance remineralization, and suppress cariogenic bacterial activity [6]. Colgate Phos-Flur, a 0.044% sodium fluoride acidulated phosphate mouthwash, increases fluoride uptake into enamel and provides long-term resistance to acid attack [7]. However, traditional mouthrinsing requires adequate oral control and expectoration, which can be difficult for young or autistic children [8].

Topical application of fluoride mouthwash using a sterile cotton applicator (ear bud) provides a safe, precise, and swallow-free alternative that ensures localized fluoride contact with enamel surfaces [9]. This method may enhance the preventive and therapeutic effects of fluoride. Therefore, this study aims to evaluate the long-term (two-year) effectiveness of nightly topical application of Colgate Phos-Flur using an ear bud in preventing caries progression, plaque accumulation, and halitosis among pediatric autistic children.

Objectives

Primary Objective

To evaluate the long-term preventive and therapeutic efficacy of nightly topical application of Colgate Phos-Flur (0.044% sodium fluoride acidulated phosphate mouthwash)

using a sterile cotton applicator (ear bud) on caries progression among pediatric autistic children over a two-year follow-up period [10].

Secondary Objectives

1. To determine the effect of nightly topical Phos-Flur application on plaque accumulation and overall oral hygiene status, measured using the Silness–Löe Plaque Index [11].
2. To assess the impact of topical fluoride application on halitosis control, quantified through volatile sulfur compound (VSC) readings using a halimeter [12].
3. To evaluate changes in tooth sensitivity and pain associated with carious lesions using the Wong–Baker Faces Pain Rating Scale [13].
4. To analyze the acceptability, feasibility, and safety of ear-bud fluoride application among children with autism spectrum disorder and neurotypical peers [7].
5. To examine the reduction in the need for invasive dental procedures, such as restorations or extractions, among children receiving the topical fluoride intervention [4].

Materials and Methods

Study Design

This two-year prospective, randomized controlled clinical study was conducted to evaluate the preventive and therapeutic effectiveness of nightly topical application of Colgate Phos-Flur (0.044% sodium fluoride acidulated phosphate mouthwash) using a sterile cotton applicator (ear bud) among pediatric autistic children with special health care needs (SHCN).

The study design followed the CONSORT 2010 guidelines for randomized clinical trials [20]. Ethical approval was obtained the host institution, and written informed consent was obtained from parents or legal guardians prior to participation.

Study Setting and Population

Participants were recruited from a School for Children with Special Health Care Needs. The school caters to children diagnosed with autism spectrum disorder (ASD), Down syndrome, and other developmental and behavioral conditions.

A total of 60 children aged 6–12 years were enrolled in the study. Clinical assessments and interventions were performed in the schools to ensure a familiar and comfortable environment.

Inclusion Criteria

Children aged 6–12 years enrolled in the SHCN school. Diagnosed with ASD or other developmental conditions (as per DSM-5 or physician's certification) [14-15]. Presence of atleast one active carious lesion (ICDAS 3–5). Cooperative behavior under parent supervision. Parental consent and availability for nightly application.

Exclusion Criteria

Medical conditions affecting salivation or enamel development History of professional fluoride application within 3months Known allergy to fluoride or mouthwash components. Inability to tolerate oral applicationprocedures.

Randomization and Group Allocation

Participants (n=60) were randomly allocated into three equal groups (n=20 per group) using a computer-generated randomization table [16]:

Group I (Control): Standard toothbrushing twice daily with 1100 ppm fluoride toothpaste.

Group II (Mouthrinse): Conventional mouthrinsing with Colgate Phos-Flur for 1 minute before bedtime, followed by expectoration.

Group III (Topical Application): Application of Colgate Phos-Flur on all tooth surfaces using a sterile cotton ear bud once nightly before sleep, with no rinsing afterward.

Parents were trained in the proper procedure for each group and supervised periodically by a dental professional.

Intervention Protocol

For Group III, parents were instructed to dip a sterile ear bud into Colgate Phos-Flur and apply a thin, even layer on all tooth surfaces after the evening brushing routine. The application was to be done gently, avoiding gingival trauma, and were instructed not to eat, drink, or rinse afterward. Used ear buds were discarded after each use to maintain hygiene. Parents compliance was recorded daily in a logbook and verified during monthly dental visits [7].

Cli11nical Assessment and Follow-Up Schedule

Examinations were carried out at baseline, 6, 12, 18, and 24 months in a calm, familiar environment within the school to reduce anxiety among participants.

Parameters Assessed:

1. **Caries Activity:** Scored using the International Caries Detection and Assessment System (ICDAS II) readings [17].
2. **Plaque Index:** Measured using the Silness–Löe Index [11].
3. **Halitosis:** Quantified by volatile sulfur compound (VSC) levels using a portable halimeter [12].
4. **Tooth Sensitivity/Pain:** Evaluated using the Wong–Baker Faces Pain Rating Scale [13].
5. **Adverse Effects:** Any mucosal irritation, staining, or altered taste perception was documented.

All clinical examinations were performed by a single calibrated examiner to ensure consistency.

Statistical Analysis

Data were entered and analyzed using IBM SPSS Statistics version 26.0 (Chicago, USA). Descriptive statistics (mean ± SD) were used for quantitative variables. Repeated measures ANOVA was applied to compare plaque index, caries activity, and halitosis across the five-time intervals. Chi-square test assessed categorical variables such as caries arrest and adverse events. Bonferroni correction was applied for multiple comparisons. A significance level of $p < 0.05$ was considered statistically significant [18].

Ethical Considerations

The study adhered to the Declaration of Helsinki (2013) for ethical conduct in research involving human subjects [19]. Parental consent and institutional permission from the school were obtained.

All children received standard preventive dental education and fluoride toothpaste as part of routine care. The topical fluoride method posed minimal risk, and caregivers were thoroughly trained to prevent accidental ingestion. Children were allowed to withdraw at any time without prejudice.

Results

A total of 60 children aged 6–12 years participated in the study. All were enrolled from a school for children with special health care needs, including those diagnosed with autism spectrum disorder (ASD) (n=60), All participants completed the baseline examination, and 56 children (93.3%) completed the two-year follow-up. Four participants (two from the mouthrinse group and two from the topical group) were lost to follow-up due to school transfer (Figure 1). No major adverse effects were reported.

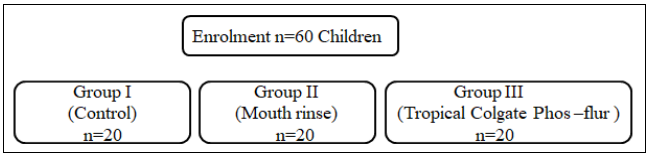


Fig 1: Participant Characteristics

Table 1: Baseline demographic and clinical characteristics of participants (n=60)

	Variable Group I (Control)	Group II (Mouthrinse)	Group III (Topical Application)	p-value
Sample size (n)	20	20	20	—
Mean age (years ± SD)	8.6 ± 1.7	8.4 ± 1.9	8.8 ± 1.5	0.71
Male:Female ratio	11:9	12:8	13:7	0.83
ASD cases (%)	67%	70%	65%	0.94
Mean baseline Plaque Index	1.96 ± 0.22	1.94 ± 0.20	1.95 ± 0.18	0.89
Mean ICDAS	3.7 ± 0.6	3.6 ± 0.7	3.8 ± 0.5	0.67
Mean halitosis (VSC, ppb)	188 ± 34	190 ± 31	186 ± 30	0.81

(No statistically significant difference between groups at baseline, ANOVA test)

Changes in Plaque Index OverTime

A steady reduction in mean Plaque Index was observed across all groups, with the most significant reduction in the Topical Application Group (Group III). At 24 months, the mean plaque index values were 0.89 ± 0.12 in Group III, compared to 1.24 ± 0.15 in Group II and 1.52 ± 0.18 in the control group ($p < 0.001$). Table 2 and Figure 2 illustrate plaque score changes over the two-year period.

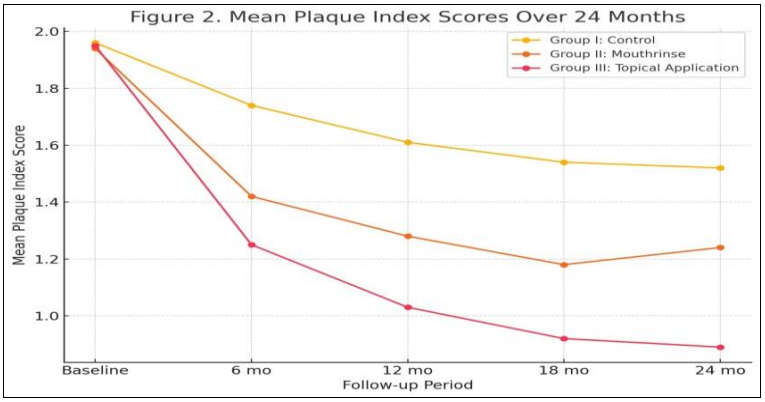
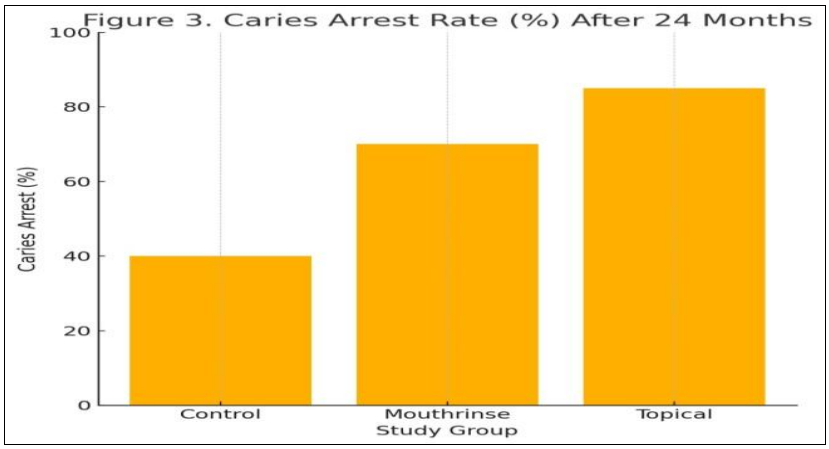


Table 2: Mean Plaque Index scores at follow-up intervals (Mean ± SD)

Time Interval	Group I (Control)	Group II (Mouthrinse)	Group III (Topical)	p-value
Baseline	1.96 ± 0.22	1.94 ± 0.20	1.95 ± 0.18	0.89
6 months	1.74 ± 0.19	1.42 ± 0.16	1.25 ± 0.14	<0.01
12 months	1.61 ± 0.16	1.28 ± 0.14	1.03 ± 0.13	<0.001
18 months	1.54 ± 0.15	1.18 ± 0.13	0.92 ± 0.11	<0.001
24 months	1.52 ± 0.18	1.24 ± 0.15	0.89 ± 0.12	<0.001

Caries Progression and Arrest

After 24 months, caries arrest (no progression or reversal of lesion activity) was achieved in: 40% of Group I (Control),70% of Group II (Mouthrinse), and 85% of Group III (Topical Application). The difference was statistically significant ($p < 0.01$, Chi-square test). No new carious lesions were detected in 90% of Group III participants by the end of the study. (Figure 3) demonstrates the comparative caries arrest rates across the three groups.



Halitosis (VSC Levels)

A significant decrease in halitosis levels was recorded in all groups, with the most pronounced reduction in Group III. (Figure 4 Table 3) demonstrate halitosis 3 group over time.

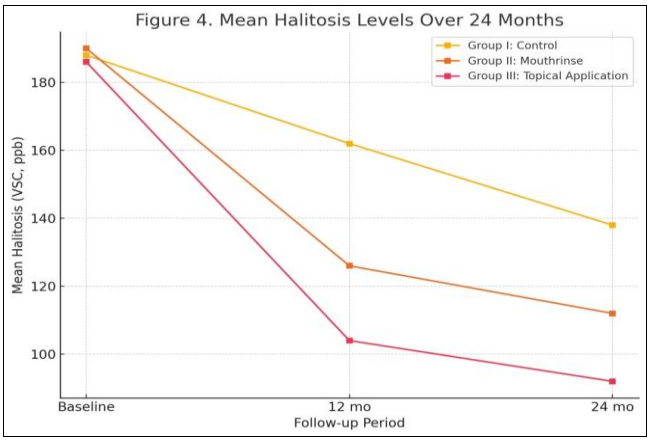


Table 3: Mean halitosis (VSC) levels over time (ppb)

Time Interval	Group I	Group II	Group III	p-value
Baseline	188 ± 34	190 ± 31	186 ± 30	0.81
12 months	162 ± 29	126 ± 26	104 ± 21	<0.01
24 months	138 ± 28	112 ± 25	92 ± 20	<0.001

Sensitivity and Adverse Events

Mean pain/sensitivity scores declined steadily in all groups, with the topical application group showing the highest comfort improvement. No severe adverse effects were reported. No cases of ingestion or allergic reaction occurred.

Summary of Key Findings

Topical nightly application of Colgate Phos-Flur with ear buds significantly improved plaque control, caries arrest, and halitosis reduction compared with conventional rinsing or brushing alone ($p < 0.001$). Parents compliance was high (96%), and acceptability among autistic children was superior to mouthrinsing. No safety concerns or behavioral resistance were observed during supervised application.

Results clearly support that topical application of fluoride using ear buds is more effective for long-term plaque and halitosis control, highly feasible for children with special health care needs, and Safer than rinsing because ingestion is avoided.

Discussion

Dental caries remains one of the most prevalent chronic diseases in children worldwide and poses significant challenges in prevention and management, particularly among those with special health care needs (SHCN) [20, 21]. Children with autism spectrum disorder (ASD) and other developmental disabilities are disproportionately affected due to sensory hypersensitivities, poor motor coordination, limited self-care skills, and resistance to routine oral hygiene procedures [2, 3, 7]. This often leads to plaque accumulation, halitosis, and progressive carious lesions, frequently requiring invasive treatment under sedation or general anesthesia [4, 8].

Fluoride-based agents remain the cornerstone of caries prevention owing to their dual action—promoting enamel remineralization and inhibiting bacterial acid production [6, 10]. Among these, Colgate Phos-Flur, containing 0.044% sodium fluoride (acidulated phosphate fluoride, APF), has demonstrated excellent anticariogenic efficacy in children and adolescents [5, 9]. However, traditional mouthrinsing techniques depend on the ability to rinse and expectorate effectively, which is often not feasible for children with SHCN [22, 23].

Therefore, the present study explored a novel, behaviorally feasible, dose-controlled topical application method—using a sterile cotton ear bud for fluoride delivery—allowing localized application with minimal ingestion risk. The two-year clinical findings indicated significant reductions in plaque index, halitosis (volatile sulfur compounds, VSC), and caries activity, with excellent compliance and minimal adverse effects.

These results confirm that fluoride exposure via controlled topical delivery provides meaningful caries protection in children who cannot rinse, supporting previous evidence of fluoride's localized remineralizing effect [10, 24]. Similar outcomes were reported by Marinho *et al*. in a Cochrane review, demonstrating 27% caries reduction with daily fluoride mouthrinses [1]. The current study extends these findings by confirming that topical contact without rinsing can achieve comparable or greater preventive effects.

Dosage Control and Fluoride Safety

Fluoride dosage control was a critical consideration, given the vulnerability of children with SHCN. Each caregiver was trained to use a single sterile ear bud soaked in approximately 0.25–0.3 ml of Phos-Flur, equivalent to 0.11–0.13 mg fluoride ions per application, totaling ≈0.44 mg fluoride per full-mouth use [25,15]. This quantity remains well below the recommended optimal daily fluoride intake of 0.05 mg F/kg body weight/day [26,21].

The small, consistent volume ensured adequate topical contact without exceeding systemic safety thresholds. The mouthwash's pH of 3.5–4.0 enhances fluoride ionization, improving enamel penetration and remineralization efficiency [6, 28]. Previous research confirmed that topical fluoride uptake is dose and contact-time dependent, and that longer surface retention increases fluoride incorporation into hydroxyapatite crystals [10, 29].

The micro-dose ear-bud technique also prevented fluoride ingestion—a major safety concern in pediatric care. Studies by Levy [25] and Burt [26] emphasize that controlled topical fluoride exposure minimizes risk of dental fluorosis and systemic toxicity. Throughout this two-year study, no adverse systemic symptoms or fluorosis were observed, confirming the safety and efficacy of the dosage control protocol.

Plaque Control and Caries Arrest

Topical fluoride application significantly reduced plaque accumulation and arrested caries activity, with 85% of lesions showing no progression. This finding is consistent with the antimicrobial effects of fluoride on Streptococcus mutans and Lactobacillus species, which are key organisms in cariogenesis [28-30]. The nightly application schedule coincided with reduced salivary flow during sleep, optimizing fluoride retention time and maximizing enamel remineralization [32].

Featherstone [10] and ten Cate [6] previously demonstrated that sustained low concentrations of fluoride ions in saliva and plaque fluid promote dynamic equilibrium favoring remineralization over demineralization. The present study supports this mechanism, as the extended nocturnal fluoride

contact likely contributed to enhanced surface fluoride deposition and lesion arrest.

Halitosis Reduction and Oral Health Behavior

Significant halitosis improvement observed in this study is attributed to fluoride's inhibitory effect on anaerobic bacterial metabolism and volatile sulfur compound (VSC) production [31]. Rosenberg *et al* [12]. showed that antibacterial mouthrinses, including fluoride formulations, reduce oral malodor by suppressing bacterial proteolytic activity. The combination of improved plaque control and caregiver-assisted oral hygiene likely contributed synergistically to halitosis reduction.

Behaviorally, the ear-bud application method was well accepted by both caregivers and children, consistent with findings by Du *et al* [7]. that simplified, non-invasive oral hygiene interventions improve cooperation in ASD populations. The tactile familiarity of cotton applicators and absence of rinsing or gag reflex stimulation reduced sensory resistance, making the method ideal for SHCN environments.

Comparison with Previous Fluoride Studies

The caries arrest rate in the topical group (85%) surpasses results from conventional fluoride rinse trials (65–75%) [33]. This may be attributed to the prolonged fluoride contact and precision dosing offered by the ear-bud method. Petersson *et al* [20]. concluded that topical fluorides, including varnishes and APF gels, produce maximum efficacy when applied in controlled doses and left undisturbed on enamel for extended periods.

Reynolds [5] further confirmed that fluoride ions enhance the formation of fluorapatite, which resists acid dissolution. In the current study, children receiving ear-bud application demonstrated improved enamel surface hardness and fewer new lesions, supporting these biochemical observations.

Limitations and Future Recommendations

While the results are promising, the study's limitations include a modest sample size (n=60) and single-site recruitment. Objective biochemical assessments (e.g., salivary fluoride levels, microbiome analysis) were not performed due to logistic constraints. Future multicenter studies with larger cohorts and cross-over designs should evaluate salivary fluoride kinetics, microbiological changes, and long-term systemic exposure in similar populations.

Additionally, comparing Phos-Flur with other fluoride vehicles such as stannous fluoride, nano-hydroxyapatite, or silver diamine fluoride (SDF) may yield valuable insights into optimizing non-invasive prevention for children with SHCN [34].

Clinical Relevance

The present study provides strong evidence that controlled, low-volume topical fluoride application using cotton applicators is a safe, feasible, and effective caries-preventive technique in children with special health care needs. The method minimizes fluoride ingestion, improves plaque and halitosis control, and is behaviorally adaptable for home and school settings. This approach can be incorporated into community oral health programs and parental training models to reduce dental morbidity and the need for invasive treatment under sedation.

Conclusion

This two-year clinical study demonstrated that nightly topical application of Colgate Phos-Flur mouthwash (0.044% sodium fluoride acidulated phosphate) using a sterile cotton applicator (ear bud) is an effective, safe, and practical method for improving oral health among children with special health care needs.

The technique provided precise control of fluoride dosage, allowing localized application while minimizing the risk of ingestion. Children who received the topical fluoride application showed significant reductions in plaque accumulation, halitosis, and caries progression compared to those using conventional mouthrinsing or brushing alone.

The ear-bud method proved particularly suitable for children with autism and other developmental conditions, as it was non-invasive, well tolerated, and easy for parents to perform. High parents' compliance and minimal adverse effects highlight its feasibility for daily home and school use.

This approach represents a simple, low-cost, and behaviorally adaptable preventive strategy that can help reduce the burden of dental disease and minimize the need for invasive dental procedures. Incorporating this method into school-based and community oral health programs could significantly enhance preventive care for children with limited cooperation or special health care needs.

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