Fluoride Toothpastes and Mouthwashes: A Review of Formulations, Efficacy, and Usage Patterns in Caries Management

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Abstract

Background: Dental caries has consequently emerged as one of the most prevalent chronic disorders affecting individuals across all age groups. Topical fluoride, administered via toothpaste and mouthwash, is a crucial component of caries prevention. Understanding the evolving composition, clinical efficacy, safety concerns, and usage trends of fluoride solutions is essential for optimising individual and population-level oral health activities. **Objective:** This review examined the chemical compositions, mechanisms of action, comparative efficacy, public health implications, and recent advancements in fluoride toothpaste and mouthwashes. It addresses global practices and risk-based recommendations as well. **Methods:** A comprehensive literature analysis was conducted utilising the PubMed, Scopus, and Web of Science databases for publications published from 2000 to 2024. Keywords included fluoride toothpaste, fluoride mouthrinse, caries prevention, formulation, and fluorosis. Relevant articles pertaining to the review issue, including randomised controlled trials, systematic reviews, public health data, and regulatory guidelines, were analysed. **Results:** Sodium fluoride, stannous fluoride, and sodium monofluorophosphate are recognised fluoride compounds. Fluoride concentrations of 1000 to 1500 ppm in toothpaste reduce caries incidence by 24 to 35 percent, while mouthwashes provide an additional 20 to 30 percent efficacy in individuals at risk. The extent of usage is contingent upon age, geographic location, and socioeconomic status. Dental fluorosis in young children can be managed with appropriate safety measures, provided that dosing and supervision are conducted properly. Emerging technologies, including nano-hydroxyapatite, bioactive glass, and pH-sensitive delivery methods, are enhancing the efficacy of fluoride treatments and their acceptability among patients. **Conclusion:** Fluoride toothpastes and mouthwashes are accessible, convenient, and versatile means of managing caries. It should be utilised personally concerning risk and integrated into community health assistance strategies. Future research need a similar focus on improving delivery systems, minimising adverse effects, and expanding access for marginalised populations.

Keywords: Fluoride Toothpaste, Mouthwash, Dental Caries, Fluorosis, Public Health, Remineralization, Formulation.

Introduction

Dental caries is a significant chronic condition that impacts individuals across various age groups and socioeconomic statuses. Despite advancements in preventative and restorative dentistry, dental caries remains a significant public health issue because to its multifactorial pathogenesis, which encompasses factors such as nutrition, oral microbiota, host susceptibility, and time. Untreated dental caries in permanent teeth are predicted to harm about 2.5 billion individuals worldwide, according to the Global Burden of Disease Study 2019. Caries of primary teeth is prevalent among children and is defined by discomfort, difficulties in eating, diminished

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quality of life, and absenteeism from school. Fluoride has been shown as one of the most effective agents for the prevention and management of caries. Since its introduction into public health dentistry in the early 20th century, fluoride has been pivotal in reducing the incidence and severity of caries. The primary mode of action is the inhibition of enamel demineralisation and the enhancement of remineralisation through the production of fluorapatite crystals, which exhibit resistance to acidic dissolution. Fluoride, while exhibiting antibacterial properties, modifies the metabolism of bacteria, particularly Streptococcus mutans, a key cariogenic microorganism. Topical fluoride delivery systems, including toothpastes (dentifrices) and mouthwashes (rinses), represent some of the most accessible and cost-effective preventative strategies worldwide. They facilitate constant contact with the surfaces of our teeth through fluoride, making them indispensable for our daily oral hygiene. Fluoride-containing toothpaste is considered the most straightforward universal health intervention against caries, following water fluoridation. Over the years, many formulations of fluoride have been shown to enhance stability, bioavailability, and therapeutic efficacy. Numerous prominent instances of fluoride compounds utilised in toothpaste include sodium fluoride (NaF), stannous fluoride (SnF2), and sodium monofluorophosphates (MFP), each exhibiting distinct chemical properties and efficacy. Fluoride mouth rinses are routinely utilised as an adjunct, particularly for individuals at heightened risk of caries, such as orthodontic patients, those with xerostomia, and individuals with inadequate oral hygiene practices. These rinses consist of low-concentration formulations suitable for everyday usage and high-concentration formulations necessitating monitoring for weekly or regular use. The use of fluoride mouthrinse alongside daily brushing with fluoride toothpaste has consistently demonstrated a significant reduction in caries incidence, as evidenced by clinical trials and systematic reviews.

Despite the efficacy of fluoride products, their utilisation is not uniformly distributed across the population. Factors influencing usage patterns include age, education level, economic level, accessibility to dental care, awareness of oral health maintenance, and municipal or national hygiene mandates. Excessive fluoride exposure poses a possible risk in specific regions due to the likelihood of dental fluorosis, particularly in young children. Therefore, age-specific fluoride administration that adheres to dosage recommendations and focusses on risk assessment is crucial for optimising benefits while minimising drawbacks. Another area of increasing interest is the development of a novel fluoride formulation that exhibits enhanced bioavailability and prolonged retention in the oral cavity. The application of remineralising agents such as calcium phosphates, casein phosphopeptide-amorphous calcium phosphate (CPP-ACP), and nano-hydroxyapatite, with efforts to enhance patient compliance through flavouring and the use of multifunctional products (e.g., products with desensitising qualities).

Moreover, contemporary perspectives on public health policies have increasingly emphasised behavioural interventions and the targeted administration of fluoride to at-risk individuals. For instance, both supervised toothbrushing initiatives in educational settings and fluoride mouthrinse programs in communities have demonstrated significant efficacy in decreasing the incidence of caries in children and adolescents. Dental experts play a crucial role in recommending appropriate fluoride agents, providing individualised instructions, and doing follow-ups to enhance the preventative efficacy of these agents. Fluoride is integral to contemporary caries care, which adopts a medical perspective for disease treatment and caries control, as opposed to a solely surgical methodology. A crucial element of minimally invasive dentistry is the early detection, risk assessment, and non-invasive preventive therapy, with fluoride application being the paramount preventative measure. The American Dental Association (ADA), the European Federation of Conservative Dentistry (EFCD), and the World Health Organisation (WHO), among other dental organisations, provide robust evidence-based recommendations advocating the use of fluoride toothpaste and mouthwash as primary measures for caries prevention. In general, fluoride toothpaste Platform. The robust scientific foundation and past clinical application render them effective. However, they function effectively only when properly manufactured, utilised correctly, and their application in a particular context is endorsed by a healthcare professional. This research offers a comprehensive analysis of the formulations, mechanisms of action, clinical efficacy, and usage trends of fluoride toothpaste and mouth rinses. It emphasises the necessity for public education, professional supervision, and regulatory measures to optimise the benefits of fluoride while mitigating the risks of misuse or overexposure.

Mechanisms of Action of Fluoride

Fluoride is a crucial component in caries prevention due to its multifaceted impact on tooth surfaces and dental microbiota. It is effective in facilitating enamel remineralisation, preventing demineralisation, and interrupting the metabolic processes of cariogenic bacteria. These activities occur at the tooth-biofilm-saliva interface and depend on the bioavailable fluoride present in the oral cavity. Understanding these pathways is essential for comprehending how various fluoride delivery systems, including as toothpaste and mouthwash, exert their preventative effects.

Enamel Demineralization Inhibition

Hydroxyapatite (Ca10(PO4)6(OH)2), a crystalline mineral structure, constitutes the majority of dental enamel and is soluble in acidic environments. The cariogenic process entails acid production due to bacterial fermentation of dietary carbohydrates, leading to a localised decrease in pH

on the tooth surface. At low pH levels (below the crucial threshold of around 5.5 for enamel), the demineralisation of hydroxyapatite commences when calcium and phosphate ions are liberated into the surrounding medium. Fluorides from plaque fluid and saliva are incorporated into the crystal lattice of enamel during demineralisation events. The substitution of hydroxide ions (OH-) with fluoride ions (F-) results in the formation of fluorapatite (Ca10 (PO4)6F2), which exhibits significantly lower solubility in acid compared to hydroxyapatite. Consequently, the enamel becomes increasingly resilient to future acid attacks. The alteration in enamel structure is one of the primary mechanisms by which fluoride enhances the durability of the tooth surface.

Remineralization Prepromotion

The natural remineralisation process entails the deposition of dissolved mineral ions, primarily calcium and phosphate, into the enamel matrix. The presence of fluoride significantly enhances this process. Fluoride acts as a catalyst, facilitating the recrystallisation of minerals into the enamel crystal structure, resulting in the formation of a more stable and less soluble fluoride apatite structure. Fluoride is also present at the demineralization-remineralization interface, contributing to the shift in equilibrium towards net mineral gain in subsurface lesions.[1] Research indicates that low, sustained concentrations of fluoride (about 0.01 to 0.05 ppm in saliva) are sufficient to promote remineralisation. Frequent exposure to modest doses of fluoride is essential, as evidenced by daily brushing with fluoride toothpaste and occasional use of fluoride rinses.

Inhibition of Bacterial Metabolism

The influence of fluoride extends beyond the mineral composition of enamel; it also possesses significant antibacterial properties. It can disrupt bacterial enzymes, particularly those of acidogenic and aciduric species such as Streptococcus mutans, which are significantly associated with the initiation and progression of dental caries. In an acidic environment, fluoride transforms into hydrogen fluoride (HF) at low pH levels, exhibiting hydrophobic properties that enable it to penetrate bacterial membranes. Upon entering the cytoplasm, HF dissociates into F- and H+, resulting in the acidification of the intracellular environment. This disrupts proton gradients, enzymatic activity (including enolase and proton-translocating ATPases), and inhibits bacterial glycolysis and acid generation. Furthermore, fluoride impedes bacterial adhesion to tooth surfaces and restricts the synthesis of extracellular polysaccharides, which are essential for biofilm formation and pathogenicity. All these effects diminish the ability of the plaque biofilm to induce sustained acidic conditions, hence reducing the likelihood of enamel demineralisation.

Fluoride Reservoir Effect

Another facet of fluoride action is its formation of reservoirs within the oral cavity, particularly in dental plaque, saliva, and the pellicle. In acidic conditions, such reservoirs can extracellularly release fluoride ions, resulting in rapid local synthesis during cariogenic occurrences. Fluoride utilised in brushing or rinsing can be retained in the plaque fluid and absorbed by the enamel pellicle on teeth, thereafter releasing gradually over time. The mechanism serves as a protective barrier against demineralisation during acid assaults. Furthermore, topical fluoride, when applied to enamel and soft tissues, functions as an ionic reservoir, particularly effective overnight in combating caries development.

PH-Activated Factors of Fluoride Action

The pH of the oral environment significantly influences the efficacy of fluoride. At a neutral pH, fluoride promotes the reinforcement of crystals in enamel. However, at acid challenges below pH 5.5, fluoride plays a crucial role in preventing additional mineral loss and facilitating the repair of early lesions.[2] The efficacy of fluoride as a bactericide increases in acidic environments, where it transforms into HF and penetrates bacterial membranes more readily. The capacity to remineralise at neutral pH and eliminate microorganisms at low pH characterises fluoride's function as a reflective agent of the changing oral environment.

Synergistic Effects with Calcium and Phosphate Ions

Contemporary formulations of fluoride toothpastes and rinses frequently use supplementary ingredients such as calcium phosphates (e.g., amorphous calcium phosphate [ACP], casein phosphopeptide-amorphous calcium phosphate [CPP-ACP], or calcium sodium phosphosilicate [NovaMin]) to improve remineralisation. These compounds function synergistically with fluoride by enhancing the availability of calcium and phosphate ions essential for mineral deposition. When fluoride, calcium, and phosphate are concurrently present in appropriate concentrations, remineralisation is enhanced, and enamel integrity is more thoroughly restored. The creation of these synergistic formulations signifies progress in preventive tactics designed to enhance fluoride's therapeutic efficacy.

Formulations of Fluoride Products

Fluoride-based oral care solutions exist in multiple forms to address diverse clinical needs, age demographics, risk levels, and user preferences. The efficacy of fluoride in halting dental caries is contingent not only upon its mere presence but also on the specific form of fluoride utilised in prevention, its concentration, bioavailability, and mode of administration. This section outlines the primary fluoride compounds utilised in toothpaste and mouthwash, along with their unique features and therapeutic applications.

Fluoride Toothpastes

Toothpaste is the most prevalent medium for fluoride delivery, utilised daily to provide a low yet consistent dose of fluoride to the tooth surface (Table 1). The most

common kinds of fluoride in dentifrices are:

a. Sodium Fluoride (NaF): Sodium fluoride is an inorganic salt with high solubility in water that releases free fluoride ions immediately upon contact with saliva. It is non-corrosive and utilised at concentrations ranging from 1000 to 1500 parts per million (ppm) fluoride. Sodium fluoride (NaF) has demonstrated efficacy in combating dental cavities and is a regular ingredient in toothpaste for both adults and children.

b. MFP Sodium Monofluorophosphate: MFP is an organofluoride molecule that releases free fluoride ions by hydrolysis in the mouth due to enzymatic activity. It is marginally less reactive than NaF and has greater stability in abrasive solutions containing calcium carbonate. MFP is commonly utilised in children's toothpastes or those with mild abrasiveness.

c. Stannous Fluoride (SnF 2): Stannous fluoride offers dual advantages by providing protective fluoride ions to the enamel and exhibiting significant antibacterial properties due to its tin content. It has been shown to reduce gingivitis, plaque accumulation, and dentin hypersensitivity. SnF2 is less stable in aqueous solutions and cannot stain teeth; hence, more stable forms of SnF2, such as stabilised SnF2 combinations, have emerged in contemporary products.

d. High-Fluoride Toothpastes : Toothpaste available by prescription, including elevated fluoride levels (e.g., 2800 ppm or 5000 ppm), may be administered to individuals at high risk for caries (e.g., patients with xerostomia, those with orthodontic devices, or individuals experiencing radiation-induced salivary dysfunction). These products provide enhanced fluoride availability and subsequent reinforcement of initial carious lesions.

e. Combined and New Formulations: Contemporary fluoride toothpaste typically incorporates other active components with synergistic effects, such as potassium nitrate for desensitisation, triclosan or essential oils for antibacterial properties, and calcium phosphate technologies like CPP-ACP or nano-hydroxyapatite for remineralisation. These multifunctional formulations tackle various oral health concerns within a single product.

Table 1: Common Fluoride Compounds.

Fluoride Compound	Application	Features	Typical Concentration (ppm)
Stannous Fluoride (SnF2)	Toothpaste	Antibacterial and anti-gingivitis; may stain teeth if unstabilized	1000
Sodium Monofluorophosphate (MFP)	Toothpaste	Requires enzymatic activation; stable with abrasives	1000
Acidulated Phosphate Fluoride (APF)	Mouthwash	Low pH formulation to enhance enamel fluoride uptake	-675

Fluoride Mouthwashes

Fluoride mouth rinses are suggested as an adjuvant therapy to tooth brushing for patients at high risk of caries or with inadequate manual dexterity. They help maintain elevated fluoride levels in the oral cavity between toothbrushing sessions.

a. Washed Real- Use every day Rinses: The typical concentration of NaF (225 ppm fluoride) in daily rinses is 0.05 percent. These products are intended for daily use at home and are suitable for children over six years of age, as well as adults requiring consistent fluoride supplementation.

b. Weekly or Fortnightly high dose rinses: Higher concentration rinses (0.2% NaF or 900 ppm fluoride) are recommended for regular use (weekly or biweekly), particularly in school-based programs or under physician supervision. They are beneficial for patients with braces or active caries.

c. Alcohol Free Formulations: To enhance tolerability and minimize the amount of side effects, especially among young children and mouth sore patients (dry mouth), alcohol-free fluoride mouthwashes are now available. These formulations retain the ability to work but minimize such risk of irritation.[3]

d. Acidulated Phosphate Fluoride (APF): Some mouth rinses contain APF, a blend of fluoride and phosphoric acid, which facilitates the absorption of fluoride by enamel. Professional gels and foams utilise APF rather than over-the-counter mouthwashes due to their acidic pH, which renders them inappropriate for daily use.

4. Efficacy of Fluoride Toothpastes and Mouthwashes

The clinical efficacy of fluoride-containing toothpastes and mouthwashes in the prevention and management of dental caries is established. Numerous randomised controlled trials (RCTs), cohort studies, and systematic reviews have consistently demonstrated the efficacy of these products in preventing caries and halting early carious lesions.[4-7] The protective benefits are significantly dependent on fluoride concentrations, patient compliance, caries prevalence, and frequency of administration. This section presents evidence concerning the efficacy of fluoride toothpastes and mouthwashes, as well as their impact on oral health outcomes at both individual and population levels.

Evidence-Based Caries Reduction-Fluoride Tooth Pastes

Toothpastes remain the primary medium for administering fluoride globally. The analysis of meta-analyses indicated that consistent use of fluoride toothpaste significantly reduces dental caries in both adults and children. A Cochrane review of over 70 randomised controlled trials concluded that fluoride toothpaste is, on average, 24 percent more effective in decreasing caries compared to non-fluoride toothpaste when used twice daily. Ingredients of Toothpaste*Fluoride is present in toothpaste and significantly enhances its efficacy (Fig 1). The fluoride concentrations in dentifrices range from 1000 to 1500 ppm, and these levels have demonstrated efficacy in enamel remineralisation and the prevention

of demineralisation. Toothpastes with higher fluoride concentrations (e.g., 2800 ppm or 5000 ppm) are designated for patients at elevated caries risk and have demonstrated superior efficacy in preventing coronal and root cavities. A dose-response relationship has been firmly established: increased fluoride levels correlate with a greater reduction in caries, albeit up to a certain threshold. This must be considered in relation to safety concerns, particularly in children, since excessive consumption may increase the risk of dental fluorosis. The American Dental Association (ADA) recommends that children aged 3 to 6 years use a pea-sized amount of fluoride toothpaste under adult supervision, while those under 3 years should use a smear or a quantity equivalent to a grain of rice.

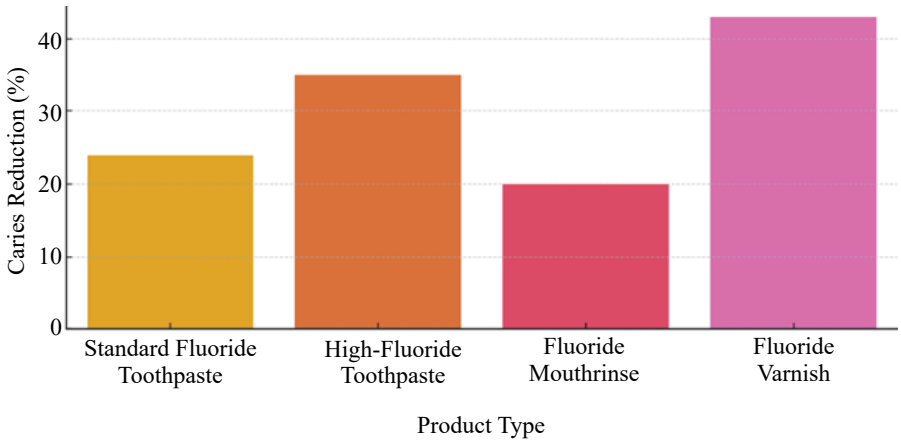

Figure 1: Caries Reduction by Fluoride Product Type.

Fluoride Mouthwashes: Adjunctive Benefits

Fluoride mouth rinses are advantageous and effectively complement toothpaste, especially for individuals at intermediate and high risk of caries. Their action is to increase the frequency and duration of fluoride exposure in the oral cavity while maintaining protective fluoride levels in plaque and saliva (Table 2). The daily application of low-concentration rinses (0.05% NaF or 225 ppm) and the weekly application of high-concentration rinses (0.2% NaF or 900 ppm) have been shown to reduce caries incidence by 20 to 30 percent in most populations. A prior study conducted a systematic review and found that the supervised use of fluoride mouthrinses diminished the decayed, missing, and filled tooth surfaces (DMFS) score in children and adolescents, with a notable reduction compared to supervised tooth brushing with fluoride toothpaste.

Fluoride mouth wash is especially helpful in:

- Orthodontic patients likely to demineralization and white spot lesions
- Persons who have poor salivary secretion or xerostomia
- Patients being treated with head and neck radiotherapy
- Users with impaired needs or lack of manual dexterity

The use of mouthwash should not be regarded as a substitute for brushing, but rather as a supplement. Brush without rinsing Brushing occurs prior to rinsing to maximise the retention of fluoride from the toothpaste on the tooth surface. The retention of fluoride can be compromised if one immediately rinses the mouth with water after brushing teeth, a fact corroborated by the advice from various oral health organisations to avoid rinsing post-brushing.

Table 2: Comparative Efficacy of Fluoride Products.

Product Type	Caries Reduction (%)	Recommended Frequency	Target Group
Standard Fluoride Toothpaste	24	Twice daily	General population
High-Fluoride Toothpaste	35	Twice daily	High-risk individuals
Fluoride Mouthrinse	20	Daily or weekly	Orthodontic/xerostomic patients
Fluoride Varnish	43	Every 3–6 months	Children/high-risk patients

Comparative Effectiveness and Combined Use

Certain studies have addressed the cumulative effects of utilising both fluoride toothpaste and mouthwash. The combination of the two is expected to enhance the bioavailability of fluoride and facilitate remineralisation more effectively than each product used independently. This is particularly true for high-risk people, where enhancing fluoride exposure can significantly influence disease progression. A randomised trial shown that the combination of 1450 ppm fluoride toothpaste and 225 ppm NaF mouthrinse had a more pronounced effect on the remineralisation of early carious lesions than the use of toothpaste alone.[8] The nocturnal administration of fluoride mouthrinse facilitates prolonged fluoride retention in the oral cavity, hence aiding in caries prevention. However, the enhancement in outcomes from fluoride

mouthrinse compared to fluoride toothpaste, particularly in low-risk individuals, may be minimal, and clinician recommendations should be tailored to risk levels to prevent excessive exposure.

Guidelines and Recommendations of Professionals

- According to such leading dental associations as the ADA, the European Academy of Paediatric Dentistry (EAPD), and the World Health Organization (WHO), there are quite specific recommendations on the use of fluoride products:[9-12]
- Children aged less than 6 years: Take fluoride of 1000 ppm toothpaste, supervised and rinsed minimally.
- Children older than 6 and adults: Apply toothpaste having 1350 1500 ppm fluoride two times a day.
- Individuals with increased risk: Mouthwash (0.05% NaF daily or 0.2% weekly), professional application of fluoride varnish and high-fluoride toothpaste (e.g. 5000 ppm).
- Public health schemes: Fluoride rinses and supervised brushing schemes in schools are to be suggested in regions of low caries prevalence.

Usage Patterns and Public Health Recommendations

The effectiveness of fluoride toothpastes and mouthwash in preventing dental cavities is significantly influenced by the degree of proper and consistent usage among various groups. The utilisation pattern varies according on age groups, social status, cultural habits, availability to healthcare facilities, and the quality of public health infrastructure. Understanding these usage trends and aligning with evidence-based practices are essential for optimising outcomes in the public health impact of fluoride-based dental care initiatives.

Age and Risk Group Patters of Usage

Fluoride toothpaste is widely utilised globally as an integral component of regular oral hygiene routines (Table 3 and Fig 2). However, there exists a variety in frequency, dose, and supervision according on age and caries risk.

- Children: Consumption in children is usually dictated by parental control, taste and knowledge on appropriate brushing skills. Children who are younger are more prone to swallowing toothpaste that causes fluorosis of the teeth. Thus, regimens consider taking low-fluoride formulations and regulated quantities (e.g. a smear or pea sized) under monitoring.[13]
- Adolescents and Adults: In majority of adolescents and adults, standard concentrations of fluoride toothpaste (1000 1500 ppm) is used, however, during adolescence, compliance can also decrease because of changes in living lifestyle. Among adults, the overall use is usually high, and the technique, duration of brushing, and frequency may differ.[14]
- High-risk people: People who wear orthodontic devices and others with xerostomia, diminished dexterity, special needs, or systemic conditions (e.g. diabetes) are at high risk, where high-fluoride toothpaste and mouthrinses are recommended as a particular fluoride intervention. Adjunctive dental rinses and professional fluoride are usually prescribed by the dental professionals in such groups.

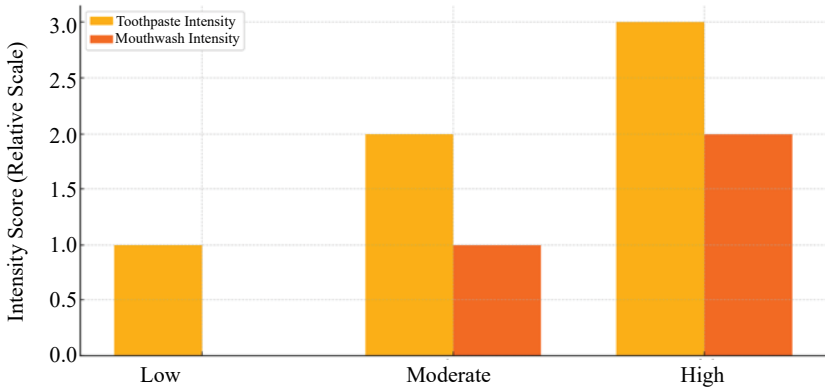

Figure 2: Fluoride Use Recommendations by Risk Category (Grouped Bar Chart).

Table 3: Risk-Based Fluoride Recommendations.

Risk Category	Toothpaste Recommendation	Mouthwash Use	Professional Applications
Low	1000–1500 ppm fluoride twice daily	Not necessary	Annually if needed
Moderate	Same as low + daily fluoride rinse (0.05%)	0.05% NaF daily	Bi-annually
High	5000 ppm fluoride toothpaste + varnish	0.2% NaF weekly or daily + supervised use	Every 3–6 months

Socioeconomic and Geographic Variability Socioeconomic Factors also Influence the use of Fluoride Containing Products

High-income countries typically exhibit elevated availability to toothpaste containing fluorides, with fluoride mouth rinses readily available in pharmacies and supermarkets. In established situations, access to oral health care and goods for underprivileged or minority

groups can be considered a barrier. Inconsistency in the supply of fluoride products is typically observed in low and middle-income countries (LMICs), alongside a diminished level of public knowledge. The expense of toothpaste, particularly fluoridated varieties, remains an issue. In some low- and middle-income countries, fluoride toothpaste may be exchanged for traditional cleaning alternatives or herbal pastes, which typically lack adequate fluoride levels. Organisations like the WHO and FDI World Dental Federation have endeavoured to integrate fluoride toothpaste into national oral health strategies, especially in regions where community water fluoridation is impractical.

The part of Education and Health Promotion

Education with the masses is critical in enhancing the usage patterns. The most important strategies are:

- Programs carried out in schools: They are usually characterized by classroom supervised brtwshing, dispensing of fluoride mouthrinse and oral hygiene instruction. These programs have shown potential in enhancing better oral hygiene measures and decreasing the occurrence of caries in schoolchildren.[15]
- Community outreach: Parents, care givers and teachers can be influenced through educational campaigns to adopt good oral hygiene practices in children.
- Professional health care advice: Dentists, community health workers, and pediatricians should reiterate the right techniques to use fluoride products during a normal checkup. This is done by prescribing appropriate toothpaste materials, educating on modalities of tooth brushing and on how frequently and at what intervals mouthwash should be used.

Fluoride Delivery Strategies and Public Health Guidelines

Standardized recommendations have been provided in the national and international guidelines to inform the use of fluoride at population levels (Table 4 and Fig 3):

- World Health Organization (WHO): The fluoride toothpaste, with levels varying between 1000 and 1500 ppm should be used twice a day in individuals of age 6 years and above. It also encourages the community-based fluoride intervention in non-fluoridated communities.[14-17]
- American Dental Association (ADA): Recommends brushing with fluoride toothpaste, starting in infancy, and age-specific amounts as well as fluoride adjunctive oral care products like mouthrinses or varnishes on the basis of risk.
- EAPD: European Academy of Paediatric Dentistry: Offers age and category specific fluoride advice based on caries risk according to the need to start oral health education early and supervised brushing.

Table 4: Public Health Fluoride Programs.

Program Type	Population Reach	Caries Reduction (%)	Implementation Challenges
Water Fluoridation	Large urban/rural	-15	Political resistance, infrastructure
Salt Fluoridation	Regional	-10	Cultural dietary habits
Milk Fluoridation	Selected countries	-10	Logistical distribution
School Rinse Program	Children (school-aged)	-10	School participation, supervision

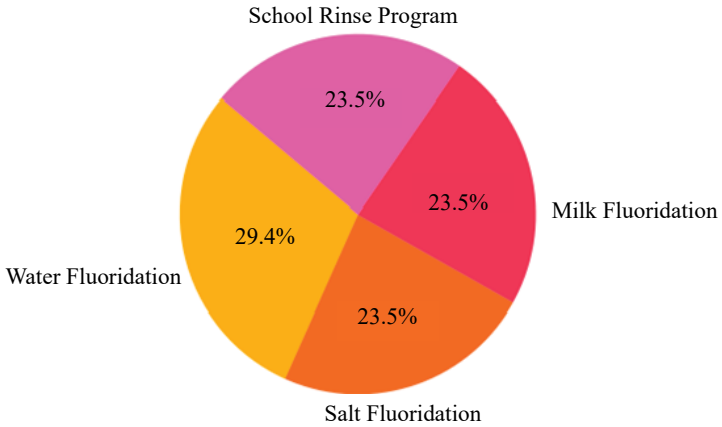

Figure 3: Population Reach by Fluoride Public Health Programs.

Safety and Adverse effects

While fluoride is recognised as a highly efficient preventive agent against caries, its safety profile, particularly regarding dosage and the age of the user, warrants careful consideration. When used appropriately, fluoride in toothpaste and mouthwash is not hazardous. However, the issue may result in adverse repercussions such as dental fluorosis in the event of an overdose, especially during early developmental years. This study examines the primary safety concerns, risk management strategies,

and regulatory ramifications associated with fluoride products.

Dental Fluorosis

The most commonly reported harmful impact of fluoride excess during tooth development, typically occurring at birth or between ages 6 to 8, is dental fluorosis. It results in diminished enamel mineralisation and is linked to white opacities or, in severe instances, brown discolouration and pitted surfaces. The primary source of fluoride-induced fluorosis in children is the ingestion of toothpaste during dental hygiene practices. Young infants often ingest excessive amounts of toothpaste due to immature spitting reflexes or when let to brush independently (Table 5 and Fig 4). It is imperative to underscore:

- Applying a small amount (as small as a grain of rice) of fluoride toothpaste to children below the age of 3 years.
- Application of a pea-sized dose in children of 3 years to 6 years.
- Adult supervision during the brushing should be maintained to avoid excessive use and the swallowing.

The need to tackle fluorosis risk is by proper parental guidance, education and labeling of products specific to children.

Table 5: Adverse Effects and Mitigation.

Adverse Effect	Cause	Mitigation Strategies
Dental Fluorosis	Excessive fluoride ingestion during tooth development	Supervised brushing, correct dosage for age
Tooth Staining	Unstabilized stannous fluoride	Stabilized SnF2 formulations
Mucosal Irritation	Alcohol-based rinses or allergies	Use alcohol-free mouthwash
Fluoride Toxicity	Acute ingestion of high doses (rare)	Child-proof packaging, education

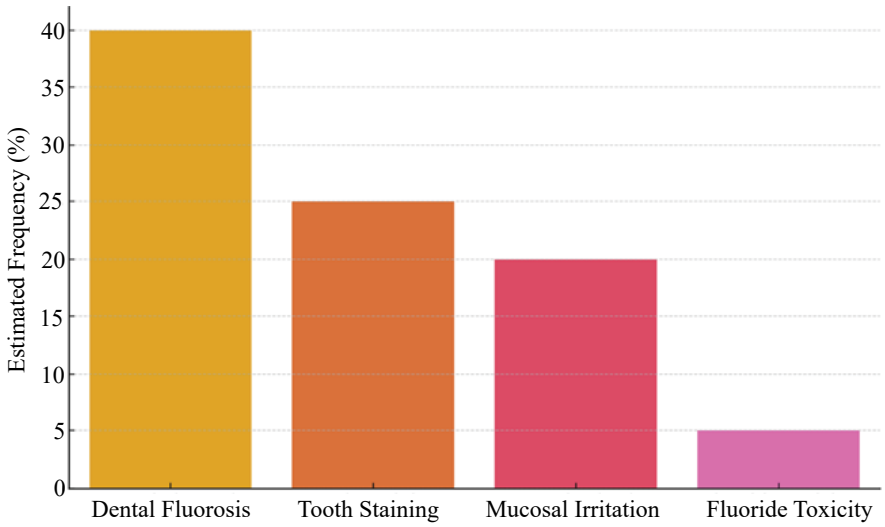

Figure 4: Relative Frequency of Adverse Effects.

Systemic Fluoride Exposure

Topical fluoride products are designed for local application; nonetheless, there is a minor degree of systemic absorption when these products are ingested, especially in children. Nonetheless, the quantity absorbed by appropriately utilised toothpaste or mouthwash typically remains beneath the tolerated upper intake level (UL) set by the U.S. Institute of Medicine, which is:

- 0.7 mg/day for children aged 1–3 years
- 1.0 mg/day for children aged 4–8 years

Prolonged excessive fluoride exposure, especially in regions with naturally elevated fluoride concentrations in drinking water, may result in skeletal fluorosis—a uncommon yet severe disorder impacting bones and joints. This is not linked to the utilisation of toothpaste or mouthwash.

Mucosal and Soft Tissue Effects

Certain users, especially individuals with oral sensitivity or xerostomia, may encounter moderate mucosal irritation or burning sensations from fluoride mouthwashes, particularly those containing alcohol. To address this, alcohol-free mouth rinses are now readily accessible and are advised for youngsters, elderly patients, and persons receiving radiotherapy or suffering from mucosal illnesses.

Regulatory Oversight and Product Labeling

Regulatory bodies, including the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and national health authorities, rigorously regulate the allowable quantities of fluoride in over-the-counter oral care products.

- Toothpastes: typically 1000–1500 ppm fluoride for general use; up to 5000 ppm for prescription-only products.

- Mouthwashes: typically 225 ppm (0.05% NaF) for daily use and 900 ppm (0.2% NaF) for weekly use.

Mandatory labeling requirements include dosage instructions, fluoride concentration, age-appropriate warnings, and recommendations to seek professional advice for children under 6 years.[18]

Innovations and Trends in Fluoride Product Development

The evolving landscape of oral care and preventive dentistry has resulted in modifications to the formulation of fluoride products. While conventional fluoride toothpaste and mouth rinses remain fundamental in caries prevention, recent experimental and market trends have prompted the creation of new products designed to replace, supplement, or enhance them, aiming for improved efficacy, patient compliance, and safety (Table 6 and Fig 5). These improvements are designed not just to enhance the delivery and absorption of fluoride but also to incorporate additional features that address other oral health needs. This section examines the rising trends and novel methodologies in the creation of fluoride-infused oral care products.

Fluoride Stabilized Fluoride and Multifunctional Fluoride: Traditional fluorides such as sodium fluoride (NaF) and sodium monofluorophosphate (MFP) are highly effective but may pose stability issues, particularly in the presence of calcium-based abrasives. The incorporation of stabilised stannous fluoride (SnF2) in contemporary formulations enhances anti-caries properties, along with exhibiting antimicrobial and anti-inflammatory effects. The stabilisation methods enable resistance to tin oxidation, prolong longevity, and reduce the likelihood of tooth staining, addressing limitations of previous SnF2 products. Multifunctional toothpastes incorporate fluoride alongside agents that mitigate dentinal hypersensitivity (e.g., potassium nitrate, arginine), combat gingivitis (e.g., chlorhexidine, triclosan, essential oils), or regulate calculus (e.g., pyrophosphates, zinc citrate). These combinations confer a significant health benefit for dental health and maintain caries prevention efficacy.

High-Strength and Prescribable Formulations: Prescription-strength fluoride toothpastes, containing 2800 or 5000 ppm fluoride, have become standard for patients at elevated risk of cavities, including those with xerostomia, orthodontic equipment, and systemic diseases. These provide increased fluoride availability to promote remineralisation and inhibit the progression of existing lesions. Dental practice fluoride gels and varnishes offer high concentrations (e.g., 22,600 ppm in varnishes) and prolonged exposure times, hence enhancing protection for high-risk populations.

Bioactive Additives and Nano-Technology: The application of nanotechnology in fluoride products is a cutting-edge trend. Biomimetic nano hydroxyapatite (nHAp) immobilised on porous calcite (nHAp/PC) is frequently utilised as a nano enamel, wherein fluoride is employed to enhance remineralisation and address microscopic imperfections in enamel. These formulations are advantageous for individuals allergic or sensitive to fluoride or fluoride-free goods. Another instance of innovation is the application of bioactive glass (e.g., NovaMin(r)), which has demonstrated the ability to release calcium, phosphate, and fluoride ions in reaction to saliva, hence facilitating remineralisation and alleviating hypersensitivity. The synergistic action of these ion-releasing compounds with fluoride fortifies the restorative enamel during its earliest phases.

Table 6: Innovations in Fluoride Formulations.

Innovation Type	Benefit	Current Use
Nano-hydroxyapatite	Enamel-like structure, supports remineralization	High-end toothpastes
Bioactive Glass	Releases calcium, phosphate, and fluoride	Sensitive teeth products
Controlled-Release Gels	Extended fluoride release over time	Clinic-applied gels
Smart Delivery Systems	pH-responsive fluoride release	Research/prototype

Caries Reduction by Fluoride Product Type.

Caries Reduction by Fluoride Product Type

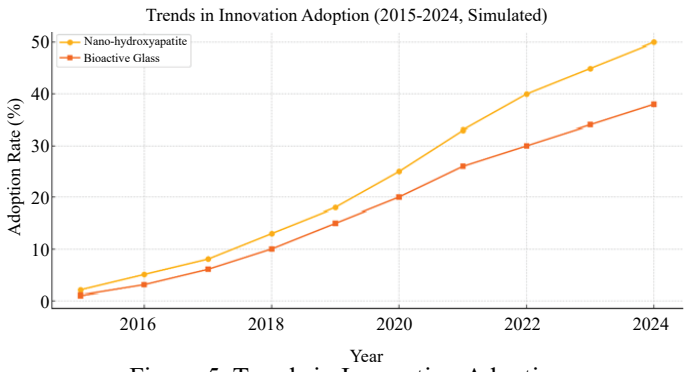

Figure 5: Trends in Innovation Adoption.

Controlled-Release and Smart Delivery Systems

New delivery platforms aim to improve fluoride retention and substantivity in the oral cavity. Controlled-release formulations, including mucoadhesive gels, lozenges, and chewing gums, enable prolonged exposure of the teeth to therapeutic fluoride concentrations. Some use encapsulated fluoride particles that release ions slowly over time, providing sustained protection against demineralization. Emerging "smart" delivery systems integrate pH-responsive materials that release fluoride during acid attacks—precisely when demineralization risk is highest. This approach mimics the natural dynamics of the oral environment and targets fluoride action more efficiently.

Conclusion

Fluoride is the most extensively researched and endorsed universal agent for the prevention and control of dental cavities. Decades of scientific research and practical application in public health have established the significance of fluoride as an agent employed in toothpaste, mouthwashes, and professional applications, effectively reducing the incidence of caries in adult populations across varying risk levels. Its functions in inhibiting demineralisation, promoting remineralisation, and regulating cariogenic bacterial activity establish it as a highly effective and adaptable agent in both individual and population health initiatives. This review has highlighted the multifaceted efficacy of fluoride from both chemical and microbiological perspectives. Fluoride products significantly diminish the incidence of caries, as sodium fluoride, stannous fluoride, and monofluorophosphate act as efficacious agents against caries when routinely and correctly applied. Moreover, when integrated with additional active ingredients and cutting-edge delivery techniques, such as nano-hydroxyapatite and controlled-release mechanisms, they have expanded the potential for therapeutic applications, even within conventional preventive medicine.

Fluoride toothpastes are utilised worldwide, with particularly notable utilisation in high-income settings. Nonetheless, disparities in the accessibility and usage patterns of fluoride persist, especially in developing countries, rural populations, and economically disadvantaged areas. Factors including as cost, parental awareness, and access of child-friendly or culturally acceptable formulations continue to impact the utilisation of fluoride in numerous regions. Such differences necessitate a sustained initiative to educate the community, implement regulatory measures, and contextualise fluoride-based remedies within broader health systems. The adaptability of fluoride is among its most significant advantages. It may be tailored to the specific risks, age, oral condition, and compliance capacity of an individual patient, making it fundamental to risk-based caries management models such as CAMBRA and MID. Specialised products, like high-fluoride toothpaste, fluoride mouth rinses, and varnishes, are advantageous for individuals at elevated risk, while standard-fluoride toothpaste remain effective for the broader population's maintenance. The most effective strategies for reducing caries prevalence at the public health level include the ongoing implementation of fluoride through water fluoridation, salt and milk fluoridation initiatives, and school-based rinse and brushing programs. Evidence supporting fluoride as a scalable and cost-effective intervention is derived from programs enabled by longitudinal and community-based study outcomes.

Documented safety problems, especially related to dental fluorosis in children, can be effectively managed through explicit labelling, carer education, supervised brushing, and compliance with age-specific dosing guidelines. Regulatory supervision and ongoing product innovation have enhanced safety profiles while increasing user acceptance and compliance. In conclusion, fluoride toothpastes and mouthwashes are essential instruments in the arsenal against dental cavities. Their success is rooted in robust scientific principles, adaptability to changing dental care paradigms, and shown cost-effectiveness. Future integration of fluoride with advanced delivery technologies, customised oral care, and comprehensive public health systems presents exciting avenues for research and clinical implementation. To effectively leverage fluoride's preventative capabilities, a comprehensive strategy encompassing doctors, educators, legislators, manufacturers, and communities is imperative—ensuring that access to effective fluoride-based interventions becomes a universal standard rather than a localised privilege.

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