



Fluoride in dentifrices: Safe or unsafe?

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GSC Biological and Pharmaceutical Sciences, 2026, 36(01), 197–202

Publication history: Received on 08 June 2026; revised on 15 July 2026; accepted on 17 July 2026

Article DOI: <https://doi.org/10.30574/gscbps.2026.36.1.0264>

Abstract

Fluoride-based dentifrices/Toothpaste emerged at the forefront of preventive dentistry in the eighteenth century and have remained relevant over the years. However, as knowledge continuously evolves and expands, the safety of the continued consumption and prophylactic use of fluorides in different formulations has come under deep scrutiny in recent years. Following reports of dental malformations of fluorosis and the potential of skeletal deformations from its toxicity, the net benefit of fluoride in dentifrices used over time deserves an assessment. The review of published scientific literature in this article revealed that the use of toothpaste containing fluoride is beneficial on topical application, provided it is used in strict compliance with evidence-based regulations and recommendations of global health agencies and associations. The review acknowledges the possibility of a negative impact from the excessive consumption of fluoride; however, it highlights the fact that the benefit of using fluoride-containing dentifrices in the prevention of dental caries, particularly in the right volume and the right environment, is more beneficial in preventing dental caries and it substantially outweighs the potential risks.

Keywords: Fluoride; Dentifrices; Toothpaste; Dental caries; Fluorosis

1. Introduction

Fluoride-based dentifrices are regarded as the pillar of preventive dentistry, because it remains the most globally accepted consumer-friendly method of delivering caries prophylaxis agents [1,2]. Brushing twice daily with fluoride-based dentifrice (Toothpaste) is an established global standard for maintaining optimum oral hygiene and for keeping dental caries at bay. However, in recent times, there have been a lot of concerns over the overall safety of the long-term use of dentifrices containing fluoride, particularly among children and their dental development [3]. The focus of this paper, therefore, is to weigh the balance between the historically well-established benefit of “effective remineralization of enamel, against the long-standing reported potential risk of systemic toxicity and developmental enamel defects [4,5].

2. Historical Context and Development

The origin of oral hygiene products began with the production of abrasive non-fluoride formulations designed primarily for the mechanical removal of plaque. Then came the discovery of the clinical anticariogenic properties of fluoride, which transformed the industry completely [3]. The transition from simple abrasive powders to fluoride-enriched pastes signified a paradigm shift in public health, and resulted in the long-term decline in global caries prevalence [6]. In the mid-20th century, different regulatory frameworks evolved through organizations such as the American Dental Association (ADA), which established, by rigorous testing criteria, a standard for the safety and efficacy profiles for

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fluoride inclusion in commercial products [7]. Subsequently, fluoride concentrations in consumer dentifrices were restricted internationally to a range of 1000–1450 ppm as the optimum balance for the caries prevention benefit and the lowest point for systemic ingestion risks [7]. Several studies in the 1940s and 1950s reported that fluoridated products resulted in a significant reduction in caries occurrence; hence, dentifrices were no longer regarded as just cosmetic cleaners but as therapeutic medical formulations [8].

2.1. Evolution of Fluoride Toothpaste

Historically, fluoride-containing toothpaste transitioned from the traditional stannous fluoride formulations to the more stable sodium fluoride and monofluorophosphate variations, enhancing bioavailability and clinical efficacy [9,10]. Then further progress was in the stratification of products that were age-specific, with low-concentration formulations specifically designed for the younger population in order to prevent the risk of fluorosis [11]. However, manufacturers still had challenges with the stability and bioavailability of the ionic fluoride in the products, due to chemical degradation that could occur during storage before reaching the consumer [12].

2.2. Mechanisms of Fluoride Action

The biochemical efficacy of fluoride is based on its ability to promote the remineralization of dental enamel while simultaneously inhibiting the metabolic activity of cariogenic bacteria, thus reducing the rate of demineralization [13]. Specifically, fluoride ions substitute into the hydroxyapatite lattice to form fluorapatite, which is a more stable and acid-resistant crystalline structure that resists dissolution in low-pH oral environments compared with the natural hydroxyapatite structure of enamel [13]. Furthermore, fluoride ions inhibit the metabolic activity of cariogenic bacteria by slowing down the production of organic acids that weaken tooth integrity [14]. Also, at the tooth-biofilm interface, fluoride ions accelerate the reintegration of calcium and phosphate into demineralized lesions, thereby restoring the mineral density of the enamel surface [15].

2.3. Topical vs Systemic Action

Topically, fluoride promotes anticariogenic activity through the formation of fluorapatite crystals and by catalyzing the precipitation of calcium and phosphate in the oral fluid. While simultaneously exerting antimicrobial effects on cariogenic bacteria [16]. Furthermore, the therapeutic success of topical applications is strengthened by the formation of calcium fluoride reservoirs, which provide a sustained release of ions at the enamel-plaque interface during acidic challenges [17]. On the contrary, systemic exposure to fluoride as it occurs in water fluoridation or dietary intake, particularly during the pre-eruptive development of enamel, directly influences the mineral maturation of teeth in children [18]. While this systemic incorporation occurs during amelogenesis, it is distinct from the topical contact provided by dentifrices, which primarily targets existing enamel surfaces to arrest decay [19]. Dental fluorosis occurs only during tooth development (from birth to approximately 8 years of age). The underlying mechanisms include: cellular stress from fluoride, which triggers apoptosis (programmed cell death), Protein retention from high levels of fluoride, which delays the hydrolysis and removal of amelogenin, and hypomineralization, which occurs due to the retained proteins disrupting proper crystal formation, hence creating a subsurface porous structure. Staining and Pitting: Abnormally porous enamel is susceptible to absorbing exogenous ions (iron and copper), which causes the characteristic yellow-to-brown staining.

Skeletal fluorosis develops following chronic, long-term exposure to high levels of fluoride (typically ≥ 4 mg/L in drinking water) over 10 to 20 years. This occurs when there is a crystal lattice alteration: Fluoride ions readily substitute for hydroxyl ions in the bone's hydroxyapatite structure, creating a more stable but less flexible crystal lattice (fluorapatite). This incorporation alters normal bone turnover rates, and it inhibits mineralization, leading to brittle, hardened, and less resilient bones. In extreme cases, it causes joint stiffness, ligament calcification, and bone deformation [20].

3. Evidence for Safety and Efficacy

There are clinical and epidemiological data that validates that the regular use of fluoridated toothpaste is associated with a 24% reduction in caries formation in permanent teeth [21]. Supported by over 800 controlled trials, the topical application of fluoride appears to be the most effective prophylactic measure against dental decay [22]. Furthermore, there are longitudinal studies that confirm that fluoride-induced reservoirs, such as calcium fluoride, ensure a sustained release of ions that stabilize the tooth surface against acidic challenges.

3.1. Clinical Trial Evidence

In a randomized controlled trial, fluoride dentifrice significantly reduced caries incidence compared to a placebo, with a dose-response relationship and the best therapeutic efficacy at concentrations of 1000 ppm and above [23]. Some Meta-analyses indicate that daily use of these formulations consistently achieves a 24–44% reduction in caries incidence across diverse populations [24]. These protective benefits are particularly pronounced in children and adolescents, where consistent application supports enamel remineralization and inhibits the activity of cariogenic bacteria [25].

3.2. Population-Level Outcomes

The use of fluoride dentifrice over the last 70 years is widely recognized as the primary factor driving the dramatic decline in dental caries prevalence [26]. Epidemiological studies consistently demonstrate that using fluoride dentrifices is protective to enamel [27]. Similarly, a cohort study has highlighted the additional benefit, particularly for pit and fissure surfaces on permanent first molars [28].

3.3. Potential Risks and Adverse Effects

In spite of the highly appraised therapeutic benefits of fluoride to enamel, there are valid concerns regarding fluoride ingestion, particularly the risk of dental fluorosis caused by chronic overexposure during the critical stages of tooth development [29]. This condition is characterized by insufficient mineralization of the enamel, hypomineralization. The condition manifests as visible opacities or pitting on the tooth surfaces of either deciduous or permanent teeth, especially in early childhood [30]. This creates an unpleasant dental aesthetic that could be psychologically disturbing, depending on the severity [31]. Other concerns include the potential to cause systemic challenges such as skeletal fluorosis and neurological defects, particularly from chronic high-level fluoride ingestion in developing populations [32]. This is more likely in young children because they often struggle with controlling the swallowing reflex; hence, they inadvertently ingest dentifrice during the first six years of life when brushing. They therefore would require careful parental supervision to maintain an appropriate risk-benefit balance [33].

3.4. Dental Fluorosis

This is a condition that results from excessive fluoride ingestion during the pre-eruptive mineralization phase of the enamel. It occurs as a result of the disruption in enamel matrix formation and manifests clinically as visible opacities or structural pitting [34]. The severity of hypomineralization is often dose-dependent; hence, utilizing higher fluoride concentrations for children under six must be carefully weighed against the balance of the potential risk to aesthetic and structural integrity [35].

3.5. Systemic Toxicity Concerns

Acute toxicity typically occurs from accidental ingestion of high-dose fluoride and usually presents with nausea or abdominal pain. However, the major clinical concern, particularly in our contemporary times, is the possibility of a resulting systemic harm from chronic ingestion of fluoride from multiple sources, such as toothpaste, water, etc. [36]. However, during the literature search of this article, no scientific literature was found reporting systemic challenges from chronic use of fluoride-containing dentifrice. It is therefore critical to distinguish between clinical challenges of acute accidental high-dose fluoride ingestion and the subsurface hypomineralization in dental fluorosis, which occurs from chronic fluoride ingestion at early stages of life. Dental fluorosis remains the only scientifically established risk linked to chronic fluoride ingestion [37].

4. Risk-Benefit Analysis

The crux of the issue, then, is attaining the healthy balance between accessing the therapeutic benefit of fluoride in enamel while mitigating against the potential hazard of fluoride toxicity. challenge in clinical dentistry remains achieving a therapeutic balance where the potent anticariogenic efficacy of fluoride is maximized while minimizing the risk of developmental dental fluorosis [38].

4.1. Dose-Response Considerations

Optimal clinical management requires calibrating fluoride exposure to match developmental stages, such as acknowledging that children under five years of age may have a limited ability to expectorate, and may result in ingesting a significant quantity [39]. To mitigate these risks, it is recommended that the quantity of dentifrices used should be limited to a smear or pea-sized amount for young children, and that total fluoride intake remains below the threshold for systemic toxicity [40]. It is therefore important that careful considerations be given to procedures

requiring a combined fluoride regimen, particularly for children [41]. Consequently, in managing pediatric dental cases, a personalized approach is recommended, such that the fluoride concentration recommended is adjusted to the child's individual caries risk to minimize potential ingestion [42].

4.2. Vulnerable Populations

Besides children below age three, Pregnant mothers and those with swallowing difficulties require similar monitoring to prevent excessive systemic absorption, to prevent both fluorosis and potential toxicity. Vigilant monitoring of total daily fluoride intake from all sources—including fluoridated water, food, and oral hygiene products—is essential for populations at elevated risk, as these cumulative exposures can influence the development of both dental and skeletal fluorosis [43]. Although clinicians must balance these prophylactic advantages against the potential for undesirable outcomes, it remains clear from documentation that serious adverse events are largely associated with acute, high-dose ingestion rather than standard topical regimens [44].

It is therefore paramount that the right knowledge regarding key issues of public health matters be disseminated among stakeholders, such as dental healthcare workers. This brings to the fore the role of continuous medical education (CME'S), as emphasized in a study among dental healthcare workers [45]. Fluoride in dentifrices is currently reported to be one of the most effective, cost-efficient interventions for preventing dental caries, despite the potential possibility of risk from acute toxicity. These risks are largely preventable through appropriate use, particularly among young children. Thus, fluoride toothpaste should be regarded as a highly beneficial preventive agent whose safety depends on proper usage and adherence to recommended guidelines [46].

5. Conclusions

Based on the reviewed scientific literature in this article, the use of fluoride-containing dentifrices\toothpaste is beneficial and safe, provided it's used within the limits of the recommended age-related concentration and the right population.

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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