OPEN SCIENCE REVIEW21
ISSN 3086-4089

v.1, n.2, 2026

PUMP-VALVE DEVICES: A PROMISING ALTERNATIVE FOR SAFE TOOTHPASTE DOSING

DISPOSITIVOS COM VÁLVULA DOSADORA (VÁLVULA PUMP): UMA ALTERNATIVA PROMISSORA PARA A DOSAGEM SEGURA DE CREME DENTAL

DISPOSITIVOS CON VÁLVULA DOSIFICADORA: UNA ALTERNATIVA PROMETEDORA PARA LA DOSIFICACIÓN SEGURA DE DENTÍFRICO

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e1212
https://doi.org/10.66649/bx6vff24

PUBLISHED: 08/2026

ABSTRACT

Standardizing the amount of toothpaste used by children may reduce dose variability and unintentional ingestion of fluoride, which is important considering dental fluorosis risk. This study aimed to evaluate the amount of toothpaste dispensed by two different pump valves (SMALL and LARGE), according to toothpaste brand and storage period. An in vitro study with a factorial design was conducted using four toothpastes brands (COL, EVEN-P, EVEN-G and TAN) and three storage periods (baseline, 14 days and 21 days) with two metered pump valves of 0.1 (SMALL) and 1.5 mL (LARGE). Ten samples were measured for each experimental combination, totaling 240 observations. Data were expressed as means and standard deviations. For each pump valve, the effects of toothpaste brand and storage period were assessed using two-way analysis of variance followed by Tukey's test, with the significance level set at $p<0.05$. The SMALL valve dispensed between 0.084 and 0.177 g of toothpaste, with all mean values remaining below the reference amount of 0.3 g. Significant differences were observed among brands and storage periods. TAN presented mean values equal to or lower than 0.1 g and showed no significant temporal difference, although its variability increased on Day 21. The LARGE pump valve dispensed between 0.573 and 1.614 g of toothpaste. COL produced significantly lower values than the other brands, whereas TAN showed a progressive increase during storage. It may be concluded that the 0.1-mL valve (SMALL) showed potential for controlling the amount of toothpaste dispensed in the toothbrush for children. However, the influence of formulation and storage indicates that the nominal valve capacity alone does not ensure standardization of the dispensed amount.

KEYWORDS: Fluorosis, Dental; Toothpaste; Dental Caries; Fluorides; Toothbrushing; Pediatric Dentistry.

RESUMO

A padronização da quantidade de creme dental utilizada por crianças pode reduzir a variabilidade da dose e a ingestão involuntária de fluoreto, o que é importante quando se considera o risco de fluorose dentária. O objetivo do estudo foi avaliar a massa de creme dental dispensada por dois tamanhos de válvulas dosadoras: PEQUENA (0,1 mL) e GRANDE (1,5 mL), considerando diferentes marcas e períodos de armazenamento. Realizou-se um estudo in vitro com delineamento fatorial: quatro marcas de creme dental (COL, EVEN-P, EVEN-G e TAN), e três períodos de armazenamento (inicial, 14 e 21 dias), em duas válvulas dosadoras (PEQUENA: 0,1 mL e GRANDE: 1,5 mL). Foram mensuradas dez amostras por combinação, totalizando 240 observações. Os dados foram expressos como média e desvio-padrão do peso de creme dental (g). Para cada válvula, os efeitos da marca e do armazenamento foram avaliados por análise de variância (ANOVA 2 fatores) + teste de Tukey,

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adotando-se p < 0,05 como limite de significância. A válvula PEQUENA dispensou entre 0,084 e 0,177 g de creme dental, mantendo as médias abaixo da quantidade de referência de 0,3 g. Foram encontradas diferenças significativas entre marcas e períodos. TAN apresentou médias iguais ou inferiores a 0,1 g e não demonstrou diferença temporal significativa, embora sua variabilidade tenha aumentado no dia 21. A válvula GRANDE dispensou entre 0,573 e 1,614 g de creme dental. COL apresentou valores significativamente inferiores aos das demais marcas, enquanto TAN demonstrou aumento progressivo durante o armazenamento. Pode-se concluir que a válvula pump de 0,1 mL (PEQUENA) apresentou potencial para controlar a quantidade de dentifrício dispensada na escova de dentes para crianças. Entretanto, a influência da formulação e do armazenamento demonstra que a capacidade nominal da válvula, isoladamente, não garante padronização da quantidade dispensada.
***PALAVRAS-CHAVE**: Fluorose Dentária; Dentifrícios; Cárie Dentária; Fluoretos; Escovação Dentária; Odontopediatria.*

RESUMEN
Estandarizar la cantidad de pasta dental utilizada por los niños puede reducir la variabilidad de la dosis y la ingestión involuntaria de flúor, lo cual es importante al considerar el riesgo de fluorosis dental. El objetivo de este estudio fue evaluar la masa de pasta dental dispensada por válvulas dispensadoras de 0,1 mL (PEQUEÑA) y 1,5 mº~L (GRANDE), considerando la marca y el período de almacenamiento. Se realizó un estudio factorial in vitro que incluyó cuatro pastas dentales (COL, EVEN-P, EVEN-G y TAN) y tres períodos de evaluación (inicial, 14 días y 21 días), utilizando dos válvulas dispensadoras (0,1 mL y 1,5 mL). Se midieron diez réplicas para cada combinación experimental, totalizando 240 observaciones. Los datos se expresaron como medias y desviaciones estándar en gramos de pasta dental. Para cada válvula, los efectos de la marca y el período de almacenamiento se evaluaron utilizando un análisis de varianza de dos vías seguido de la prueba de Tukey, con un nivel de significancia de 0,05. La válvula de 0,1 mL (PEQUEÑA) dispensó entre 0,084 y 0,177 g de pasta dental, con todos los promedios por debajo de la cantidad de referencia de 0,3 g. Se observaron diferencias significativas entre marcas y periodos de almacenamiento. La pasta dental TAN mostró valores promedio iguales o inferiores a 0,1 g y no presentó diferencias significativas a lo largo del tiempo, aunque su variabilidad aumentó el día 21. La válvula de 1,5 mL (GRANDE) dispensó entre 0,573 y 1,614 g de pasta dental. La válvula COL mostró valores significativamente inferiores a los de las otras marcas, mientras que la válvula TAN mostró un aumento progresivo durante el almacenamiento. Se concluye que la válvula de 0,1 mL (PEQUEÑA) demostró potencial para controlar la cantidad de pasta dental dispensada a los niños. Sin embargo, la influencia de la formulación y el almacenamiento indica que la capacidad nominal de la válvula, por sí sola, no garantiza la estandarización de la cantidad dispensada.
***PALABRAS-CLAVE**: Fluorosis Dental; Dentífricos; Caries Dental; Fluoruros; Cepillado de los Dientes; Odontopediatría.*

1- INTRODUCTION

Fluoridated toothpastes are globally recognized as the most effective vehicle for daily fluoride (F) delivery, playing a pivotal role in the significant decline of dental caries over recent decades (Cury and Tenuta 2014, Lima and Cury 2001). In Brazil, the universal fluoridation of toothpastes in 1989 is considered a major milestone in public health (Cury et al. 2004, Fluoretos 2009). However, children in the early stages of life represent a vulnerable cohort due to the incomplete mastery of the swallowing reflex, which leads to the involuntary ingestion of significant portions of the applied dentifrice during toothbrushing (Lima and Cury 2001, Lima-Arsati et al. 2018).

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Research indicates that children in the critical age for fluorosis can ingest approximately 70% of the toothpaste placed on the brush, which often results in a total fluoride intake that exceeds the safety threshold of 0.05 to 0.07 mg F/kg/day (Burt, 1992, Lima-Arsati et al. 2018, Omena et al. 2006).

Dental fluorosis is a developmental defect of enamel resulting from chronic and cumulative exposure to excessive fluoride during amelogenesis (DenBesten 1999, Saldarriaga et al. 2021). The biological mechanism involves a subsurface hypomineralization caused by a delay in the removal of enamel proteins during the maturation stage, which leads to increased porosity (DenBesten 1999, Fluoretos 2009). In Brazil, epidemiological data from the SB Brasil 2010 revealed a fluorosis prevalence of 8.5% among 12-year-olds, with only 0.7% presenting moderate or severe forms (Fluoretos 2009). By the 2010 national survey, while 16.7% of 12-year-olds showed some sign of fluorosis, the majority were classified as questionable or very mild, and moderate cases remained low at 1.5% (SB Brasil, 2010, Cury and Tenuta 2014). Despite these low national averages, regional disparities are stark; in tropical areas such as Penedo, Alagoas, approximately 96% of children have been found to exceed the daily safe fluoride limit, largely due to inappropriate toothpaste use (Lima-Arsati et al., 2018, Omena et al. 2006).

The interval between 20 and 30 months of age is identified as the critical period for the permanent maxillary central incisors, which are of paramount aesthetic importance (Evans and Darvell 1995, DenBesten 1999). During this window, the enamel is highly susceptible to F challenges (Evans and Darvell 1995, Lima-Arsati et al. 2018). To balance the high caries-preventive efficacy of F with systemic safety, clinical guidelines have recommended the use of small, controlled amounts of toothpaste (at least 1,000 ppm F) since the eruption of the first tooth (Cury and Tenuta 2014, Toumba et al. 2019, Lima-Arsati et al. 2018).

Despite these clear clinical guidelines, the visual standardization of these portions—using terminology such as a "grain of rice" (0.1 g) or "pea-sized" (0.25 g)—remains exceptionally difficult for parents and caregivers to replicate (Sudradjat et al. 2024, Lima-Arsati et al. 2018). Studies have shown that parents frequently superdose the toothpaste, applying amounts 5.9 to 7.2 times higher than the recommended rice-sized portion (Sudradjat et al. 2024, Chedid et al. 2020). This lack of precision is further exacerbated by the design of conventional toothpaste tubes, whose large, round orifices (typically 7.4–8.0 mm) are not engineered for accurate volumetric dispensing of such minute quantities (Olmez et al. 2004, Chedid et al. 2020). Even caregivers familiar with the guidelines often apply excessive amounts, suggesting that verbal or written instructions alone are insufficient to ensure safety (Chen et al. 2018, Sudradjat et al. 2024).

In this context, the implementation of mechanical dispensing systems has emerged as a promising technological alternative to remove the subjective interpretation of visual cues and ensure a more consistent and safer dose (Chedid et al., 2020). Some manufacturers of packaging incorporating a pump-valve mechanism indicate a fixed flow volume for certain models, confirming that these packages can deliver a standardized dose per actuation (Cernic et al. 2018). Pump-valve packages of various sizes are commonly used for cosmetics such as liquid soaps, creams, lotions, and alcohol gels,

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owing to their practicality, safety, and capacity to conserve products through controlled dispensing (Cernic et al. 2018). In this context, the implementation of mechanical dispensing systems has emerged as a promising technological alternative to remove the subjective interpretation of visual cues and ensure a more consistent and safer dose (Chedid et al. 2020; Sudradjat et al., 2024).

Therefore, the objective of the present study was to evaluate the adaptation of metered pump-valve devices for dispensing appropriate and safe amounts of dentifrice for children within the critical age range for dental fluorosis.

2- METHODS

Experimental Design

This in vitro experimental study evaluated the precision and consistency of toothpaste delivery using a factorial design. The independent variables consisted of: (1) pump-valve flow capacity at two levels (Small = 0.1 mL and Large = 1.5 mL); (2) storage duration at three intervals (Baseline, 14 days, and 21 days); and (3) dentifrice in four distinct formulations. To ensure statistical robustness, 10 independent replicates were performed for every experimental combination of storage duration and toothpaste.

Procedures and Materials

The metered pump-valve devices utilized in this study consist of a cap-shaped body integrated with a bottle-clamping mechanism. The dispensing system is triggered by a push-button actuation that extends into the reservoir, propelling a controlled volumetric discharge with each stroke. This mechanical approach aims to overcome the variability inherent in traditional visual dosing methods, such as the "pea-size" or "rice-grain" recommendations.

The following commercial toothpastes, widely used in the Brazilian market, were evaluated:

- **COL**: Colgate Máxima Proteção Anticáries® (1,450 ppm F; NaF/Silica; Colgate-Palmolive, São Bernardo do Campo, Brazil; batch 8010BR121J);
- **EVEN-P**: Creme Dental Even® Fluoride and Calcium (1,100 ppm F; Grupo Raymundo da Fonte, Paulista, Brazil; batch 116);
- **EVEN-G**: Gel Dental Even® 2-in-1 (1,100 ppm F; Grupo Raymundo da Fonte, Paulista, Brazil);
- **TAN**: Colgate Tandy® (1,100 ppm F; NaF/Silica; Colgate-Palmolive, São Bernardo do Campo, Brazil; batch 7353BR123K).

Measurements were recorded at three experimental time points: immediately after filling the devices (baseline), and following 14 and 21 days of storage under ambient conditions. The mass of the dispensed toothpaste (g) was determined using a high-precision scale, following established protocols for volumetric dispensing accuracy.

Statistical Analysis

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Statistical processing was conducted using Biostat 5.0 software. Data were initially summarized using measures of central tendency and dispersion. The influence of the factors "storage time" and "toothpaste brand" on the dispensed amount was assessed using two-way analysis of variance (ANOVA) for each size of pump-valve. For subsequent comparisons within each independent factor, one-way ANOVA followed by the Tukey post-hoc test was employed. The threshold for statistical significance was established at $p < 0.05$.

3- RESULTS

Significant differences in the mass of toothpaste dispensed were observed according to toothpaste brand and storage duration ($p<0.05$), although the direction and magnitude of these differences depended on valve size and toothpaste brand.

The small pump-valve device consistently dispensed less than 0.3 g under all experimental conditions, with mean values ranging from 0.084 to 0.177 g. At baseline, the dispensed mass ranged from 0.090±0.012 g for TAN to 0.160±0.013 g for EVEN-P. COL produced a significantly higher mass at Day 21 (0.131±0.018 g) than at Days 0 and 14, whereas EVEN-P increased from 0.160±0.013 g at baseline to 0.177±0.006 g at Day 21, with Day 14 showing an intermediate value. EVEN-G exhibited a transient reduction at Day 14, followed by recovery at Day 21. TAN was the only brand without significant temporal differences and maintained mean values ≤0.1 g throughout the study. Nevertheless, its relative variability increased at Day 21. Although all values remained below 0.3 g, the difference among toothpastes indicates that pump-valve did not necessarily ensure complete dose standardization.

Table 1. Mean ± standard deviation of the weight of toothpaste (g) dispensed by the small pump-valve (0.1 mL) device according to toothpaste brand and storage time.

Small	COL	EVEN-P	EVEN-G	TAN
Day 0	0.101 Aa ± 0.014	0.160 Ca ± 0.013	0.141 Bb ± 0.019	0.090 Aa ± 0.012
Day 14	0.086 Aa ± 0.026	0.165 Bab ± 0.015	0.094 Aa ± 0.013	0.084 Aa ± 0.007
Day 21	0.131 Bb ± 0.018	0.177 Cb ± 0.006	0.125 Bb ± 0.011	0.096 Aa ± 0.029

Values followed by different uppercase letters indicate statistically significant differences ($p < 0.05$) among toothpaste brands (ANOVA + Tukey). Values followed by different lowercase letters indicate statistically significant differences ($p < 0.05$) among storage times (ANOVA + Tukey).

The large pump-valve device dispensed more than 0.3 g under all tested conditions, with mean values ranging from 0.573 to 1.614 g. EVEN-P, EVEN-G, and TAN produced statistically similar masses within each storage period and dispensed amounts closer to the nominal valve capacity, ranging from 1.342±0.186 to 1.614±0.191 g. In contrast, COL consistently dispensed significantly lower masses than the other brands, with a transient increase from 0.573±0.107 g at baseline to 0.882±0.234 g at Day 14, followed by a return to 0.593±0.162 g at Day 21. EVEN-P showed a significant reduction at Day 14 and subsequently recovered, whereas EVEN-G remained statistically stable throughout storage. TAN

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exhibited a significant and progressive increase from 1.514±0.025 g at baseline to 1.558±0.036 g at Day 14 and 1.606±0.046 g at Day 21.

Table 2. Mean ± standard deviation of the weight of toothpaste (g) dispensed by the large pump-valve (1.5 mL) device according to toothpaste brand and storage time.

Large	COL	EVEN-P	EVEN-G	TAN
Day 0	0.573Aa ± 0.107	1.590Bb ± 0.025	1.532Ba ± 0.167	1.514Ba ± 0.025
Day 14	0.882Ab ± 0.234	1.342Ba ± 0.186	1.431Ba ± 0.243	1.558Bb ± 0.036
Day 21	0.593Aa ± 0.162	1.565Bb ± 0.175	1.614Ba ± 0.191	1.606Bc ± 0.046

Values followed by different uppercase letters indicate statistically significant differences ($p < 0.05$) among toothpaste brands (ANOVA + Tukey). Values followed by different lowercase letters indicate statistically significant differences ($p < 0.05$) among storage times (ANOVA + Tukey).

The two devices showed differences in their dispensing ranges, the maximum mass delivered by the small valve was 0.177g, whereas the minimum delivered by the large valve was 0.573g. However, the large-to-small ratio varied markedly among brands, TAN produced the lowest mean value with the small valve but the highest mean with the large valve.

4- DISCUSSION

Controlling the amount of fluoridated toothpaste used during early childhood is conceptually simple but technically difficult to achieve (Lima and Cury, 2001; Lima-Arsati et al., 2018). Although caregivers are commonly instructed to apply a “smear,” “rice-grain-sized,” or “pea-sized” amount, these visual descriptors are subjective and may result in substantial variation in the mass placed on the toothbrush (Ellwood and Cury, 2009; Sudradjat et al., 2024). Parents have been shown to dispense amounts 5.9–7.2 times greater than a reference rice-grain-sized portion (Sudradjat et al., 2024), while other studies have demonstrated wide variation in caregivers’ interpretation of a pea-sized dose (Creeth et al., 2013; Huebner et al., 2013). This gap between clinical guidance and its practical implementation provides the rationale for mechanically controlled dispensing systems (Chedid et al., 2020).

The present study investigated whether pump-valve devices could provide a more objective alternative to visually guided toothpaste application. Its principal contribution lies in evaluating the combined effects of valve capacity, toothpaste formulation, and storage duration. The findings demonstrated complete separation between the two devices: the 0.1-mL valve dispensed 0.084–0.177 g, whereas the 1.5-mL valve dispensed 0.573–1.614 g. Thus, all mean values produced by the small valve remained below the predefined 0.3-g reference threshold (Paiva et al., 2003), while every value obtained with the large valve exceeded it. Nevertheless, the effects of brand and storage indicate that nominal valve volume alone does not guarantee a uniform mass per actuation.

The performance of the 0.1-mL pump-valve device is particularly relevant to pediatric toothpaste dosing. All tested brands remained below 0.3 g throughout the 21-day period, suggesting that a

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mechanically restricted chamber can prevent the high-output dispensing commonly associated with conventional toothpaste tubes. This finding is consistent with previous evidence showing that purpose-built dispensers, reduced tube-orifice dimensions, and controlled application techniques can produce smaller quantities of toothpaste (Olmez et al., 2004; Vilhena et al., 2008; Chedid et al., 2020).

However, the small valve did not produce an identical dose across formulations. EVEN-P yielded the highest mean values, whereas TAN produced the lowest. COL increased significantly at Day 21, EVEN-G showed a transient reduction at Day 14, and EVEN-P increased between baseline and the final measurement. TAN was the only brand without statistically significant temporal differences, maintaining mean values between 0.084 and 0.096 g and therefore approximating the 0.1-g reference used in this study for a rice-grain-sized application (Lima-Arsati et al., 2018; Cury and Tenuta, 2014). Nevertheless, the comparatively high standard deviation observed for TAN at Day 21 indicates that temporal stability of the mean should not be interpreted as complete repeatability between actuations.

More broadly, the approximately twofold difference between the lowest and highest means obtained with the small valve, together with coefficients of variation approaching 30% in some conditions, demonstrates that compliance with an upper threshold is not equivalent to dose standardization. A dispensing system should ideally be evaluated in terms of both accuracies, defined as proximity to a prespecified target, and precision, defined as reproducibility between actuations. The small valve successfully limited excessive output, but the results indicate that brand-specific calibration may still be required if a narrowly defined dose is intended, especially considering the influence of toothpaste rheology on flow (Ahuja et al., 2018; Teoman et al., 2025).

In contrast, the 1.5-mL pump-valve device was unsuitable for delivering a single pediatric portion according to the criterion adopted in this study. Even its lowest mean output—0.573 g for COL at baseline—was approximately 1.9 times the 0.3-g threshold. EVEN-P, EVEN-G, and TAN produced values between 1.342 and 1.614 g, approaching the nominal volumetric capacity of the valve but substantially exceeding the intended pediatric quantity. These findings illustrate that technical conformity with the nominal chamber volume does not represent clinical suitability when that volume is itself inconsistent with the target dose.

The large valve also revealed pronounced formulation-dependent behavior. COL consistently dispensed significantly lower masses than EVEN-P, EVEN-G, and TAN and showed comparatively high relative variability. In contrast, TAN produced high but highly repeatable outputs. The mass dispensed by TAN increased progressively from 1.514 g at baseline to 1.606 g at Day 21, while its coefficient of variation remained below approximately 3%. This pattern is more consistent with systematic temporal drift than with random dispensing error. COL showed the opposite behavior: lower mean output combined with greater variability, suggesting less predictable filling or expulsion of the valve chamber, potentially due to higher formulation viscosity (Teoman, 2025).

Comparison of the two devices further indicates that the large valve did not act as a simple proportional enlargement of the small valve. Although their nominal capacities differed by a factor of 15, the overall mean mass differed by approximately 10.9-fold. Moreover, the ratio between the large- and

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small-valve means ranged from approximately 6.4 for COL to 17.3 for TAN. TAN produced the lowest output with the small valve but the highest numerical mean with the large valve, whereas COL remained particularly low in the large device. These findings suggest a device–formulation relationship in which valve geometry and toothpaste properties jointly determine the mass delivered (Teoman et al., 2025).

A rheological framework provides a plausible explanation for the brand-dependent findings (Teoman et al., 2025). Toothpastes are complex, non-Newtonian materials whose flow may be influenced by viscosity, yield stress, thixotropy, density, air incorporation, and shear history (Teoman et al., 2025). These properties could affect product movement through the intake tube, filling of the valve chamber, and expulsion during actuation (Teoman et al., 2025). The lower output of COL with the large valve, for example, is consistent with incomplete chamber filling caused by greater resistance to flow associated with its rheological behavior (Ahuja et al., 2018). However, viscosity and yield stress were not measured in the present study; therefore, COL cannot be definitively classified as the most viscous formulation, and the proposed mechanism should be considered hypothesis-generating rather than demonstrative.

Storage-related changes should be interpreted with similar caution. Values at Day 21 were numerically higher than baseline in six of the eight device–brand combinations, but the trajectories were neither uniform nor consistently monotonic. With the large valve, COL increased at Day 14 and subsequently returned toward baseline, EVEN-P decreased at Day 14 and recovered by Day 21, EVEN-G remained statistically stable, and TAN increased progressively. Potential explanations include redistribution of entrapped air, settling, phase rearrangement, changes in chamber priming, and thixotropic restructuring (Teoman et al., 2025). Some of these processes may facilitate chamber filling, whereas increased structural recovery could also increase resistance to flow. Direct rheological and density measurements are therefore required before attributing the temporal patterns to a specific physicochemical mechanism (Teoman et al., 2025).

The clinical relevance of limiting toothpaste mass is greatest in children who cannot reliably expectorate (Lima and Cury, 2001; Cochran et al., 2004; Adé et al., 2024). Multicenter studies have reported that children approximately 1.5–3.5 years old may ingest a substantial proportion of the toothpaste placed on the toothbrush, although the percentage varies with age and population (Cochran et al., 2004; Adé et al., 2024; EFSA Scientific Committee 2025). Brazilian studies have likewise shown that toothpaste can make a major contribution to total systemic fluoride exposure. In children aged 20–30 months, Lima and Cury found that toothpaste accounted for approximately 55% of total fluoride intake and concluded that reducing the amount applied was an appropriate risk–benefit strategy (Lima and Cury, 2001).

The potential exposure associated with the large valve illustrates this concern. If 1.6 g of a toothpaste containing 1,100 ppm fluoride were completely swallowed, approximately 1.76 mg of fluoride would be ingested. For a child weighing 10 kg, this corresponds to approximately 0.176 mg F/kg in a single brushing, exceeding twice the historically proposed daily reference of 0.07 mg F/kg from all sources (Burt, 1992; Omena et al., 2006; Lima-Arsati et al., 2018). This calculation represents a

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conservative worst-case exposure scenario and should not be interpreted as evidence of acute toxicity. It nevertheless demonstrates why a high-volume valve is inappropriate for unrestricted pediatric use.

Regional exposure patterns also reinforce the importance of considering all fluoride sources. In Penedo, Alagoas, 96% of the evaluated children exceeded 0.07 mg F/kg/day, and toothpaste accounted for most of the measured exposure (Omena et al., 2006; Lima-Arsati et al., 2018; Oliveira et al., 2017). Conversely, a later study conducted in a Brazilian semiarid region concluded that the evaluated children were not exposed to a risk dose, despite the potential influence of climate on water consumption (Lima-Arsati et al., 2018). These apparently contrasting findings indicate that climate alone does not determine exposure; local water fluoride concentration, toothpaste use, diet, body weight, and ingestion behavior must be considered together.

A mechanically limited dispenser could therefore reduce the “dose available for ingestion” by restricting the initial amount placed on the toothbrush (Chedid et al., 2020). This does not ensure that total fluoride exposure will remain below a particular threshold, because water, diet, brushing frequency, fluoride concentration, total soluble fluoride, and the swallowed fraction remain relevant (Lima-Arsati et al., 2018; Lima and Cury, 2001; Ellwood and Cury, 2019. However, unlike visual instructions, a calibrated device could reduce one important and modifiable source of variation (Chedid et al., 2020). This interpretation is consistent with evidence that conventional tube-orifice dimensions and ambiguous visual descriptors contribute to over dispensing (Olmez et al., 2004; Creeth et al., 2013; Huebner et al., 2013; Sudradjat et al., 2024).

Dose control is particularly relevant during enamel formation (DenBesten, 1999; Evans and Darvell, 1995). Epidemiological estimates have placed the period of greatest susceptibility of permanent maxillary central incisors approximately between 15 and 30 months, with some variation according to sex and dental region (Evans and Darvell, 1995). Nevertheless, susceptibility is not restricted to a single narrow window, and a meta-analysis found insufficient evidence to identify one universally critical period (Bårdsen, 1999). Excessive systemic fluoride exposure during enamel development may interfere with matrix protein removal and mineralization, resulting in subsurface porosity and the opacities characteristic of dental fluorosis (DenBesten, 1999; Fluoretos.pdf). Accordingly, the small valve should be regarded as a potentially useful exposure-control technology rather than a device already proven to prevent fluorosis.

Statistical significance must also be distinguished from clinical relevance (Cury and Tenuta, 2014). Some differences among brands and storage periods within the small-valve groups may have limited practical importance because all means remained below the predefined 0.3-g threshold (Paiva et al., 2003). However, these differences remain technologically relevant because they reveal imperfect calibration and formulation dependence (Teoman et al., 2025). Conversely, the absence of a significant temporal difference for TAN does not establish equivalence; an equivalence analysis would require a prespecified tolerance margin and adequate statistical power (Munro, 1997).

The principal strengths of this study include objective gravimetric measurement, evaluation of commercially relevant formulations, comparison of two distinct valve capacities, and assessment at

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multiple storage times. The findings provide practical evidence for the development of age-calibrated packaging (Cernic et al., 2018; Chedid et al., 2020). Several limitations should nevertheless be acknowledged. The 21-day period was shorter than the likely household use and shelf life of the packaging (Valadas et al., 2023); rheological properties, density, total soluble fluoride, and valve-chamber filling were not directly measured (Teoman et al., 2025; Oliveira et al., 2013; Valadas et al., 2023); and the study did not evaluate different product lots or performance throughout package depletion. As an in vitro investigation, it also did not incorporate variations in actuation force, incomplete button depression, dispensing angle, ambient temperature, repeated actuations, caregiver behavior, or accidental child use (Teoman et al., 2025; Sudradjat et al., 2024).

Further studies should therefore characterize viscosity, yield stress, thixotropy and density; measure total soluble fluoride in the dispensed mass; evaluate repeatability from the first actuation until package depletion; and test longer storage periods and different temperatures (Teoman et al., 2025; Oliveira et al., 2013; Valadas et al., 2023). Factorial or mixed models should be used to examine interactions among formulation, valve capacity, storage, product lot, and fill level. Human-factors studies should compare pump-valve devices with conventional tubes under domestic conditions and assess acceptability, hygiene, repeated actuation, supervision, cost and accessibility. Age-calibrated valves targeting approximately 0.1 or 0.25 g should be developed and tested against prespecified accuracy and precision criteria.

5- CONCLUSIONS

In conclusion, the adaptation of a 0.1 mL pump-valve device constitutes a highly promising approach for the safe delivery of fluoridated toothpaste in children, considering dental fluorosis risk. By limiting the dispensed mass to a range between 0.08g and 0.17g, the device successfully keeps the fluoride dose below the 0.3 g safety threshold for dental fluorosis. The Tandy brand showed the most consistent compatibility with the 0.1 mL system, making it an ideal candidate for further clinical testing. Ultimately, these mechanical systems represent a critical step toward reconciling the high anti-caries efficacy of fluoride with the systemic safety required for pediatric populations.

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