Dispensing Device to Deliver Small and Standardized Amount of Fluoride Dentifrice on the Toothbrush

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Abstract
Objective: To evaluate the efficacy of a dispensing device specially developed to standardize the amount of fluoride dentifrice to be delivered on the toothbrush. The amount and variability of dentifrice applied using this device were compared with recommendations to apply dentifrice amounts equivalent to "rice size" or "pea-size".

Material and Methods: Two dentifrices, one used by children (NaF/Silica-based) and one used by the entire family (MFP/CaCO3-based), and five methods to apply them on the toothbrush (pea and rice sizes, and three different amounts using the developed device) were tested by 12 volunteers. The amount of dentifrice placed on the toothbrush was weighed, and the experiment was repeated three times. Data were analyzed by two-way ANOVA and Tukey test.

Results: No differences were observed between the dentifrices used (p>0.05), but the method of application significantly affected the amount of dentifrice applied (p<0.05). Smaller amounts (p<0.05) and less variability were observed when the volunteers used the dispenser device than when they were asked to apply a pea or rice size.

Conclusion: The device can help parents and caregivers to safely use fluoride dentifrice on children.

Keywords: Preventive Dentistry; Toothbrushing; Toothpastes; Dental Caries; Fluorosis, Dental.
Introduction

The importance of fluoride dentifrice to control caries in children is based on evidence [1]. In addition, data show that there is a dose-response effect between fluoride concentration in dentifrices and caries reduction, either for permanent [2] or deciduous dentition [3]. Considering the relevance of fluoride concentration for the anti-caries benefit of dentifrice and the fact that it is a risk factor for developing dental fluorosis [4], a small amount of fluoride dentifrice could balance the benefit/risk of brushing the teeth of young children [5].

However, there is no consensus on the proper amount to be used, which ranges from smear to rice, bean or pea-size amounts [6]. Recently, the International Association of Paediatric Dentistry highlighted as one of four actions to reduce early childhood caries to "perform twice-daily toothbrushing with fluoridated toothpaste (at least 1000 ppm) in all children, using an age-appropriate amount of paste" [7]. The American Academy of Pediatric Dentistry [8] and the American Academy of Pediatrics [9], among other professional organizations, have endorsed the amount of a smear (in the size of a rice grain) of fluoride dentifrice for all children starting at tooth eruption regardless of caries risk; and after the age of three years, a pea-size amount of fluoride dentifrice may be used [9]. Different approaches have been recommended to deliver reduced amounts of dentifrice, such as the transversal technique [10]. However, although ~0.25 g is the amount expected to be applied when using the transversal technique [10], or a "pea-size" [9], American, British, and German parents apply more, from 0.41 to 0.61 g when instructed to apply the amount of a pea grain [11].

In other populations, even higher amounts (from 0.52 to 0.67 g) have been used [12-16]. Regarding the recommendation of using the amount of a smear of dentifrice (0.125 g) on the toothbrush, both British [17,18] and North American parents [19] use amounts greater than these recommendations (on average, 0.22 and 0.40 g, respectively). These studies also concluded that verbal instructions were not effective to guide the proper dentifrice amounts to be used [17-19].

Considering that the global recommendation is to start brushing teeth since the eruption of the first tooth, a safe amount of dentifrice placed on the toothbrush is desirable to prevent dental caries. In this regard, a dispensing device was designed, considering the benefit/risks for very young children according to their weight, age, and number of teeth. The amounts of dentifrice were calculated considering the anti-caries benefit of tooth brushing twice a day with a dentifrice containing 1,100 μg F/g [20], and 20% of the upper limit dose for fluorosis risk (0.07 mg F/kg/day) [21]. Accordingly, for children aged 4-8 months, weighing 6.5-8 kg and presenting one to four erupted teeth, around 0.025 g of dentifrice should be used for tooth brushing; for children aged 9-12 months, 8-9.5 kg, 8 to 12 teeth, around 0.06 g of dentifrice should be used; and around 0.1 g of dentifrice for children aged 13-18 months, weighing 9-11 kg, with 13-16 teeth [22,23].

The aim of the present study was to test the proposed device and to compare the amount delivered on the toothbrush by volunteers using the device or instructed to apply the global recommendations of rice size or pea size amount of dentifrice.

Material and Methods

Sampling

Twelve volunteers, 6 females and 6 males (aged 25-56 years) were selected among employees of Piracicaba Dental School, State University of Campinas, Piracicaba, SP, Brazil. Adult volunteers were used because the recommendation is that children under 3 years of age should have their teeth brushed by a responsible caregiver. All volunteers were literate, and six had a higher education degree.
Experimental Design

Factors being evaluated were fluoride dentifrice at two levels (children and family use) and application mode of dentifrice on the toothbrush at five levels (pea and rice sizes, and three different dentifrice lengths using a dispensing device), with 10 treatment groups. The study was crossover according to the type of dentifrice tested; however, the sequence of application of toothpastes on the brush was constant: pea size, followed by rice size, and the 3 amounts of red, blue and green dosage marks.

Commercial dentifrices Tandy® (NaF/silica-based, 1,100 ppm F, Colgate-Palmolive Comercial Ltda., São Paulo, SP, Brazil) and Sorriso® (MFP/CaCO3-based, 1,450 ppm F, Colgate-Palmolive Comercial Ltda., São Paulo, SP, Brazil) were used. They are the most consumed by Brazilian children [24], but Tandy® is used only by children of higher socioeconomic status (children market dentifrice). Sorriso® is used by both children and the rest of the family with lower socioeconomic conditions [24]. The intake of total soluble fluoride by children is the same for both dentifrices used in the study (family or child) [24,25]. Children’s toothbrush (Cocoricó Primeiro Dentinho, Bitufo/Coty Brasil Comércio Ltda., Campinas, SP, Brazil) was used.

Volunteers received individual verbal instructions to apply pea size or rice size amounts of dentifrice directly from the tube, or to apply an amount according to the three lengths of dispenser marks (Figure 1). All tests were individually performed by each volunteer.

Toothbrushes were weighed (± 0.01 g) using an analytical scale (AS 2000C, Marte Cientifica & Instrumentacao Industrial Ltda., São Paulo, SP Brazil) by the same operator before and after the five types of application of both dentifrices, and the applied amount (mg) was calculated by difference. Volunteers repeated each procedure three times. New toothbrushes were used for the three repetitions, and the mean amount of dentifrice applied was calculated for each volunteer and treatment group.

Dispensing Device and Mode of Use

The dispenser (Figure 1) was developed to deliver amounts around 20 (green), 30 (blue), and 50 (red) mg of dentifrice on the toothbrush as described and justified in the introduction section of this manuscript. The dispenser was attached to the dentifrice tube, and the lowest amount represents the length of fluoride dentifrice from the tip of the device to the green mark, whereas the largest is up to the red mark and the intermediate is up to the blue mark. Volunteers were instructed to squeeze a length of dentifrice on the toothbrush corresponding to the assigned test group.

Figure 1. Illustration of the dispensing device attached to the dentifrice tube and the desired amounts of dentifrice that should be placed on the toothbrush: smallest (A), intermediate (B) or greatest (C) amount.
Statistical Analysis

Data were analyzed through analysis of variance (ANOVA), considering volunteer as an experimental unit, and dentifrice type and fluoride dentifrice application method as factors. Tukey test was used for post-ANOVA comparisons. SAS system (version 8.01) was applied for statistical calculations, with p level set at 5%.

Ethical Considerations

The research was previously approved by the Ethics Research Committee of Piracicaba Dental School (Protocol No. 054/2008). All participants signed a written informed consent form.

Results

ANOVA showed that the effect of factor dentifrice type on the amount of dentifrice used by volunteers was not statistically significant (p>0.05), but the effect of the application method was significant (p<0.05). All application methods differed from each other (Tukey, p<0.05). The amount of applied fluoride dentifrice was significantly higher for pea size application, followed by rice size, and then by the three marks of the dispenser (Table 1). Table 1 also shows that the variability among volunteers to apply the dentifrice was lower when the dispenser was used (27 to 34%) than the suggestion to use pea (49%) or rice-size dentifrice applications (65%).

Table 1. Amount of dentifrice applied (mg) on the toothbrush according to fluoride dentifrice type and verbal instructions to place the dentifrice on the tooth brush (pea or rice sizes, or using the dispensing device instruction (red, blue and green marks). Mean and standard deviation (coefficient of variation in %).

<table>
<thead>
<tr>
<th>Fluoride Dentifrice</th>
<th>Pea Size Mean (SD)</th>
<th>Rice Size Mean (SD)</th>
<th>Red Mark Mean (SD)</th>
<th>Blue Mark Mean (SD)</th>
<th>Green Mark Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NaF/Silica</td>
<td>326.5 ± 161.1A,a</td>
<td>115.2 ± 74.5A,b</td>
<td>45.3 ± 15.2A,c</td>
<td>34.8 ± 9.4A,d</td>
<td>20.7 ± 5.7A,e</td>
</tr>
<tr>
<td></td>
<td>(49.3%)</td>
<td>(64.7%)</td>
<td>(33.6%)</td>
<td>(26.9%)</td>
<td>(27.6%)</td>
</tr>
<tr>
<td>MFP/CaCO₃</td>
<td>307.1 ± 198.5A,a</td>
<td>93.3 ± 60.2A,b</td>
<td>42.9 ± 7.7A,c</td>
<td>31.2 ± 6.3A,d</td>
<td>23.2 ± 5.6A,e</td>
</tr>
<tr>
<td></td>
<td>(64.6%)</td>
<td>(64.5%)</td>
<td>(17.9%)</td>
<td>(20.1)</td>
<td>(24.3%)</td>
</tr>
</tbody>
</table>

Distinct capital letters show statistically significant differences (p<0.05) between dentifrice types (within columns), and distinct lower cases for ways to apply the dentifrice (within lines).

Discussion

The use of fluoride, particularly in young children, is a balance between maximizing caries protection efficacy and minimizing the risk of fluorosis. This can be achieved by using “small amounts” of fluoridated dentifrice (1,100 ppm F) and under close parental supervision [5]. However, “small amounts” is a relative value, and according to published data [6,11,16-18], amounts of dentifrice greater than recommendations are being used for children by parents or caregivers.

Our findings (Table 1) showed that the developed dentifrice dispensing device allowed volunteers to place not only smaller but also more precise amounts of dentifrice on toothbrushes when compared with the amounts equivalent to “rice-size” or “pea-size”. The relevance of these data may be discussed considering the balance of fluorosis risk to permanent dentition during the first three years of life and the anticaries benefit of fluoride dentifrice for the primary teeth [2].

Regarding the risk of dental fluorosis and considering the upper limit dose of 0.07 mg F/day/kg body weight, the device was developed to help parents and health professionals to safely reduce and standardize the
amount of fluoride intake. Thus, considering an 8-month-old child weighing 8 kg, if parents or caregivers applied the rice size amount (Table 1) of a dentifrice containing 1,000 ppm (1.0 mg F/g) of total soluble fluoride \(^{25}\) and all the dentifrice was swallowed, the child would be exposed to a dose of 0.0144 (0.1152 g x 1.0 mg F/g/8 kg) mg F/kg/brush. If teeth were brushed twice a day, the fluoride dose from a rice-size amount of dentifrice would be around 0.029 mg F/day/kg body weight; and if the child lived in a fluoridated city, the total dose of fluoride intake would be around 0.06 mg F/day/kg \(^{15}\). Although it is safe (it is below the limit of 0.07 mg F/day/kg that causes aesthetically objectionable dental fluorosis \(^{21}\), if the amount referring to the green mark of the dispenser is used to apply the dentifrice, the fluoride dose will be 5.5 times lower (0.0057 mg F/day/kg of body weight, instead of 0.029 mg F/day/kg of body weight).

Children aged eight months usually have two to four erupted teeth, which could be easily brushed with 0.025 g of dentifrice intended to be delivered by the green mark of the device.

In terms of dental fluorosis risk, such discussion is also valid for older children, regarding the use of other marks of the dentifrice dispenser. Thus, a 12-month-old child weighing 9.5 kg would be submitted to a dose of 0.0073 (0.0348 x 1/9.5 x 2) mg F/day/kg using the amount of dentifrice equivalent to the blue mark of the dispenser. When comparing with the rice-size amount, this dose would be 3.3 times lower. Performing the same calculation for an 18-month-old child weighing 11 kg, the amount of dentifrice using the red mark of the dispenser would subject this child to dose of 0.0082 (0.0453 x 1/11.0 x 2) mg F/day/kg, which is 2.6 lower than by using the rice-size amount of dentifrice.

Fluoride dentifrice is recommended since the eruption of the first tooth \(^{8,9}\) because dental caries affects the quality of life of children more than fluorosis \(^{26,27}\). There is no biological marker to predict if a child will have or not caries in the future. Therefore, using small amounts of fluoride dentifrice to brush the teeth of very young children reduces caries. The amount of dentifrice used is considered important \(^{12,28-30}\) to fluoride dilution by saliva when brushing the teeth, but this has only been tested in full dentition patients. For example, when the two to four teeth present in the mouth of an 8-month-old child are brushed, the dentifrice is applied directly on the teeth surface without saliva dilution. Thus, the fluoride concentration in the dentifrice is more important than its amount \(^{5,30}\). Nevertheless, further studies should be carried out to assess if the small amount of a 1,000-1,100 ppm F dentifrice placed on the toothbrush using the device would be able to increase fluoride concentration in dental biofilm and saliva of very young children, considering the anti-caries benefit of fluoride.

Finally, the dentifrice dispensing device was designed to be used for helping the tooth brushing of very young children until they develop the reflex to spit, when they are recommended to use an amount of dentifrice equivalent to a rice grain. The dispenser use allows applying safer amounts of dentifrice than the reference rice size, with lower variability (Table 1). After the age of 3 years, the child is recommended to apply a pea-size amount of dentifrice. Table 1 shows that, in agreement with the literature \(^{17-19}\), amounts applied on the toothbrush by volunteers were greater than the recommended 0.25 g. However, in terms of fluorosis risk, a 3-year-old 14-kg \(^{22,23}\) child ingesting all the applied dentifrice would be subjected to dose of 0.046 (0.326 x 1/14 x 2) mg F/day/kg, which is 1.5 times lower than the upper limit dose of aesthetically objectionable dental fluorosis, but high variability was found (65%).

In terms of study limitations, all volunteers were literate, and results should be tested with a broader range of individuals with different socioeconomic conditions. In addition, other factors related to instructing parents on how to apply the dentifrice to the toothbrush, such as the recommendation of pushing the dentifrice within the toothbrush bristles, should be assessed in future studies.
Conclusion

The developed dispenser device was effective to standardize and reduce the variability of fluoride dentifrice amount placed on the toothbrush. The use of the device allows using safer amounts of fluoride dentifrice compared to the conventional recommendation of rice or pea sizes.

Authors’ Contributions

SJC 0000-0001-6478-8555 Conceptualization, Validation and Investigation.
LMAT 0000-0003-4626-4477 Methodology, Formal Analysis and Writing – Original Draft Preparation.
JAC 0000-0003-1046-5605 Methodology, Formal Analysis and Writing – Original Draft Preparation.

All authors declare that they contributed to critical review of intellectual content and approval of the final version to be published.

Financial Support

None.

Conflict of Interest

The first author declares that the device tested in this study is regularly patented under register number (MU–8801868–7).

References