Efficacy of Fluoride Toothpaste Over Time

Ref.: Comments on paper "Fluoride concentration in the top-selling Brazilian toothpastes purchased at different regions" by Ricomini Filho et al., published in Braz Dent J 2012;23:45-48.

By Benzian H¹, Holmgren C², van Palenstein Helderman W³

¹The Health Bureau Ltd, Haversham, UK ²Aide Odontologique Internationale, Puychevier, France ³Dental Health International Nederland, Linschoten, Netherlands

Corresponding author:

Habib Benzian, habib.benzian@health-bureau.com

This paper reports on an assessment of the total fluoride and the total soluble fluoride in different top-selling brands of toothpastes in Brazil. The authors rightly state that the concentration of soluble fluoride in toothpaste determines its anti-caries efficacy and that at least 1000 ppm of soluble fluoride are necessary for a toothpaste to have an anti-caries effect (1).

According to the paper, four of the five toothpastes analyzed were NaMFP toothpastes and one was a NaF toothpaste. The results of the analysis, undertaken within the product's expiry dates, revealed that the NaF toothpaste contained similar amounts of soluble fluoride as compared to the total fluoride content. In contrast, the four NaMFP toothpastes contained notably less soluble fluoride than the total fluoride content; the soluble fluoride fraction being on average about 80% that of the total fluoride (but still above the 1000 ppm of soluble fluoride required for anti-caries efficacy). Based on the samples analyzed, the authors rightly conclude that "the top-selling Brazilian toothpastes presented available (soluble) fluoride concentration to control caries".

Another recent study by Carrera et al. (2) on total and soluble fluoride content in toothpastes purchased in a chain of drugstores in Chile and analyzed within the product's expiry date, came to similar conclusions regarding the anti-caries efficacy of the toothpastes analyzed. Of the 18 toothpastes analyzed only one contained less than 1000 ppm total soluble fluoride. However, only four of the toothpastes analyzed in Chile were NaMFP, while the others were NaF with silica. Two of the four NaMFP toothpastes had a reduced soluble fluoride fraction of about 70% and only one contained less than the required 1000 ppm of soluble fluoride. All NaF toothpastes contained soluble fluoride similar to the total amount of fluoride.

While the analyses of fluoride toothpaste in the two papers were undertaken within the expiry date, no information was provided as to the age of the toothpastes at the time of analysis. This differs from the paper from de Oliveira Conde et al. (3), where the initial analysis of toothpastes was undertaken more than two years before the expiry date (defined by ISO to be three years after the date of production). The age of toothpastes is a point of serious concern since a recent paper on soluble fluoride in toothpastes purchased in different countries shows that toothpastes using a NaMFP formulation have considerably reduced fractions of soluble fluoride, in many cases far below the required 1000 ppm of soluble fluoride (4). Most of these toothpastes analyzed had no information on the package regarding production date or expiry date, the latter being a requirement of the ISO (5). Previous studies on the soluble fluoride content of toothpastes revealed a considerably reduced concentration of soluble fluoride for NaMFP toothpastes as well as a gradual decrease over time (3,4).

We are concerned that the data presented on total soluble fluoride in toothpastes in Brazil (1) and Chile (2) might not be totally representative of the true situation in these countries since the toothpastes were purchased in supermarkets or in a chain of drugstores where the turnover time is most likely to be short. De Oliveira Conde et al. (3), analyzing fluoride toothpaste in Manaus, Brazil, estimated the time that toothpastes stay in a supermarket to be approximately three months. Toothpastes sold by smaller shops, drugstores or on markets, as well as those sold in more remote regions of these countries are more likely to have much longer turnover time. If this is the case then it is quite possible

that by the time the consumer uses the toothpaste, NaMFP toothpastes with calcium-containing abrasives will be compromised in their anti-caries efficacy. This is because the MFP ion is less stable than anticipated in the past since the MFP ion is hydrolyzed during storing and releases F ions that react with the Ca⁺⁺ from the abrasive to form insoluble F salts that have no anti-caries efficacy.

There is a clear need for more research in this area, particularly with respect to the amount of total soluble fluoride of toothpastes over time while they are approaching their expiry date under different climatic and storage conditions. However, based on the growing recognition that this is a crucial aspect of the desired caries-protective effect, manufacturers of fluoride dentifrices should seriously reconsider the use of calcium-containing abrasives in NaMFP toothpaste.

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Author's Reply

Ref.: Comments by Dr Benzian et al. (2012) on the paper "Fluoride concentration in the top-selling Brazilian toothpastes purchased at different regions" by Ricomini Filho et al., published in the Braz Dent J 2012;23:45-48.

By Antonio Pedro Ricomini Filho Livia Maria Andaló Tenuta Jaime Aparecido Cury

Piracicaba Dental School, UNICAMP - University of Campinas, Piracicaba, SP, Brazil

Corresponding author:

Livia Maria Andaló Tenuta, litenuta@fop.unicamp.br

We would like to thank Dr. Benzian and colleagues for the comments on our publication because they gave us the opportunity to clarify some points on this important discussion about fluoride stability in toothpastes.

First of all, we do not share the authors' concern that in Brazil "it is quite possible that by the time the consumer uses the toothpaste, NaMFP toothpastes with calcium-containing abrasives will be compromised in their anti-caries efficacy", based on the following:

Regarding the study by Ricomini Filho et al., 2012 (1), all toothpastes were analyzed in March and April of 2010, 4 to 15 months after manufacturing (calculated from the expiration date and considering 3 years for expiration). By plotting the total soluble fluoride concentration (as MFP plus fluoride ions) as a function of time of manufacturing (Figure 1), it is possible to observe that, irrespective of the age, all toothpastes presented soluble fluoride concentration higher than 1000 ppm, the minimum necessary for a toothpaste to have anticaries effect (2). Although Figure 1 shows that there is a trend for reduction of soluble fluoride with time, we sincerely do not believe that they are stored for times longer than 15 months before being used. With these new analyses of soluble fluoride as a function of time, we strengthen our conclusion that "the top-selling Brazilian toothpastes presented available (soluble) fluoride concentration to control caries", with which Dr. Benzian et al. agreed in their letter.

The widespread availability of fluoride toothpastes

in Brazil may be considered a public health measure due to its wide dissemination in the country, being co-responsible for the continuous caries decline observed in Brazil since the 1990's (3). Due to their lower cost of production, MFP/CaCO₃ formulations have always dominated the Brazilian market share of fluoride toothpastes; their anticaries effectiveness, therefore, cannot be overruled. Based on recent national epidemiological surveys (4), Brazil is now classified among countries with low caries prevalence (DMFT of 2.1 at 12 years of age), and fluoride toothpastes, mostly MFP/CaCO₃ formulations, have played an important role for this scenario.

The *per* capita consumption of toothpaste in Brazil is 1.5 g/day/person, one of highest of the world. Therefore, the short turnover time of toothpastes in supermarkets or drugstores described in our previous publications (around 3 months) (5) can be considered representative of the toothpaste consumption by the majority of the Brazilian population. Although it is possible that "Toothpastes sold by smaller shops, drugstores or on markets, as well as those sold in more remote regions of these countries are more likely to have much longer turnover time", this situation is more likely to be an exception than a rule. Supermarkets are the main sellers of toothpastes in Brazil because, due

to the great sell volume, prices are often lower than in drugstores. Furthermore, the possibility that large amounts of toothpastes are purchased and stored at home for longer periods of time is remote because inflation is under control and 90 g of a of MFP/CaCO₃ toothpaste costs in Brazil less 1.0 US\$.

On the other hand, we agree with the authors of the referenced letter that "There is a clear need for more research in this area, particularly with respect to the amount of total soluble fluoride of toothpastes over time while they are approaching their expiry date under different climatic and storage conditions". Nevertheless, instead of "seriously reconsider the use of calcium-containing abrasives in NaMFP toothpaste", in our opinion manufacturers and independent researchers should be encouraged to develop more stable MFP/ CaCO₃-based toothpastes because they are considered affordable choices to NaF/Silica formulations (6), what could help other developing countries, like Brazil, to control caries. Moreover, there is science behind the technology of MFP/CaCO₃-based toothpaste, not followed by all manufacturers, as we have shown along years of toothpaste analyses (7,10) and reported in some publications (8) or newsletters.

Fluoride availability and stability in Brazilian toothpastes have been our concern since 1980 (9). In our

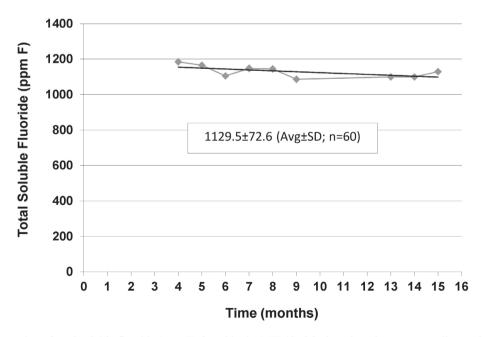


Figure 1. Concentration of total soluble fluoride (ppm F) found in the MFP/CaCO₃-based toothpastes according to the time (months) from manufacturing to analysis (secondary analysis of data from Ricomini Filho et al., 2012).

opinion, guidelines about how much soluble fluoride a toothpaste should maintain before its expiration period should be established in each country. Unfortunately, the expiration date found in toothpastes' label is not related to the soluble fluoride concentration that toothpastes should maintain but to the physical properties required during their shelf-life. Discussions like this might help shedding light on the importance of availability and stability of soluble fluoride in toothpastes (10), and sensitizing policy-makers regarding the guidelines on quality of fluoride toothpastes considering their pivotal role in caries control.

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