BIOAVAILABILITY OF FLUORIDE FROM 3 DIFFERENT TOOTHPASTES IN VIVO

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Abstract

The aim of the present 3-leg crossover study was to assess the oral bioavailability of fluoride delivered with two NaF toothpastes (one longer marketed 1350 ppm and one recently introduced 1450ppm F), and a MFP toothpaste (1450 ppm F). Ten adult volunteers brushed their teeth for 1 min, followed by rinsing with 10 ml de-ionised purified water for 10 s. Samples of about 2mL of whole mixed unstimulated saliva were collected 1, 5, 10, 20, 30, 60, 180 min after brushing. Individual salivary fluoride-time plots were established and the area under the curve (AUC) calculated. Cmax and AUC of MFP were significantly ($p<0.05$) lower than that of the NaF formulations, but not difference was shown between both NaF formulations ($p>0.05$). The newly introduced NaF toothpaste had a sufficient bioavailability of fluoride comparable to that of standard NaF toothpaste. The MFP toothpaste showed a lower availability of ionisable fluoride.

Key words: sodium fluoride, sodium monofluorophosphate, toothpaste, saliva

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Introduction

Fluoride-containing toothpastes are thought to be the reason of decline of caries in many countries [Bowen, 1995]. However, erosion poses a new threat to dental hard tissues [Truin et al., 2005]. There is debate whether fluoride is able to prevent erosion [Larsen and Richards, 2004; Lussi et al., 2008] and whether toothpastes present a suitable vehicle to deliver fluoride in this context. Recently, toothpastes have been marketed with the claim of protecting enamel against erosion. One of these is claimed to contain an adapted abrasive system and show a high bioavailability of fluoride. The aim of the present study was to evaluate fluoride bioavailability in human volunteers and compare it to a conventional sodium fluoride (NaF) and sodium monofluorophosphate (MFP) toothpaste.

Materials and Methods

The study design was a simplified version of that described by Issa and Toumba [2004]. Ten healthy adult volunteers participated in this 3-leg crossover study. Inclusion criteria were: absence of oral health problems, presence of at least 24 natural teeth (including fixed prosthesis), no removable prosthesis or orthodontic appliances. The permission of the medical ethics committee of the medical school and academic hospital of the VUB was obtained. Volunteers gave written informed consent prior to the study.

The toothpastes used were:

Pronamel (Pronamel, GSK, Genval, Belgium, batch number 037A L2) containing 1450 ppm of fluoride as NaF, potassium nitrate and silica as abrasive.

Previon (Sensodyne Previon Fluor, GSK, Genval, Belgium, batch number BN 4170 T2), containing 1350 ppm of fluoride as NaF, potassium chloride and triclosan in a base of silica.

MFP (Signal Protection Caries-Blancheur, Unilver, Brussels, Belgium, batch number 718561WA) containing 1450 ppm of fluoride as sodium monofluorophosphate, sodium bicarbonate in a base of calcium carbonate and silica.

The volunteers were given a fluoride-free toothpaste (Sensodyne Previon Classic, GSK, Genval, Belgium, batch number 377 A T2) to be used 1 week prior to the experiment and in the 1-week washout periods between experiments. The morning of the experiment, no tea and sea-food was permitted to exclude their influence on the baseline salivary fluoride concentration.

In the morning, a baseline saliva sample was obtained by drooling during 5 minutes in a graduated 50 mL centrifuge tube (Falcon, Becton-Dickinson, Franklin Lakes, USA). Thereafter, volunteers brushed during 1 minute with 1 gram of toothpaste applied on a new toothbrush. The excess toothpaste/saliva slurry was expectorated in another graduated centrifuge tube, followed by a short rinse with 10 mL of purified water, which was also collected. Further salivary samples were obtained after 2, 5, 10, 20, 30, 60 and 180 minutes after the brushing stopped.

Fluoride in saliva was assessed after addition of 100 mL TISAB III to 900mL saliva. The solution was stirred after addition of TISAB. The toothpaste slurry and rinsing solutions were analyzed after 2-fold dilution and addition of TISAB. Fluoride was then analyzed electrochemically. The electrode

was calibrated before each series of measurements against a standard series of NaF (Merck, Darmstadt, Germany) in ultrapurified water with 10% TISAB III added. Millivolt readings were obtained after 5 minutes equilibration under constant stirring. The fluoride concentration was determined using the "standard curve" option of the computer software Prism (Graph Pad, USA) and corrected for dilution. The same program was used to calculate the area under the fluoride-time curve (AUC) after subtracting the baseline values. The maximum concentration (Cmax) was derived from the curves.

AUC and Cmax values were compared statistically using the Friedman test for related samples followed by comparisons with the Wilcoxon test with Bonferroni correction for multiple comparisons. The individual fluoride concentrations were compared to baseline with a paired Wilcoxon test. Statistical significance was accepted at a p-value of < 0.05. Calculations were performed using the SPSS software package, version 16. Post-hoc power was determined using g*power 3.1.9.2.

Results and Discussion

All volunteers completed the study without adverse effects and all samples could be processed as planned. Figure 1 shows the fluoride-time graphs of the different toothpaste experiments. Pronamel had a slightly higher AUC and Cmax value than Previon, but not to a significant extent ($p>0.05$), due to a somewhat higher fluoride concentration. MFP showed significantly ($p<0.05$) lower AUC and Cmax values than both NaF toothpastes (table 1). All toothpastes achieved a significant elevation of salivary fluoride levels compared to baseline (Wilcoxon test, $p<0.05$) at all measuring points.

At an effect size (Hedges' G) above 3.0 between both NaF toothpastes and MFP, power was 1.0 at the given sample size. For a comparison between both NaF toothpastes (effect size 0.55), a theoretical sample size of 45 volunteers was calculated in order to achieve a power of 0.8.

Table 1. Synopsis of the parameters derived from the fluoride-time curves. AUC: area under the curve, Cmax: maximum concentration. Superscript letters designate groups not significantly ($p>0.05$) different from each other.

Toothpaste	AUC (ppm*min)		C_{max} (ppm)	
	median	range	median	range
Pronamel	277[a]	257-471	235[a]	167-377
Previon	251[a]	145-398	213[a]	111-270
Signal	61[b]	38-75	31[b]	13-46

In this study we could show that a newly introduced NaF-containing toothpaste had a comparable bioavailability of inonisable fluoride to a product already introduced on the market but higher than a MFP toothpaste. Bioavailability is known to be influenced by formulation of a toothpaste [Hattab, 1989] and should be assessed regularly. When we compare the present data to a previous study with comparable experimental conditions [Issa and Toumba, 2004], we obtained comparable results. A difference could be found in the post-rinse fluoride concentration since in the present study rinsing was preceded by expectoration of toothpaste slurry. This could be seen as a "worst-case" situation, since it is reported to eliminate about 50% of the administered fluoride [Sjögren et al., 1994]. Expectoration of toothpaste slurry after brushing was reported in about 40% of the subjects in a Brazilian study on fluoride retention [Oliveira et al., 2006].

In the past there was much discussion about the equivalence of sodium fluoride and sodium monofluorophosphate in terms of bioavailability and caries preventive potential [Stookey et al., 1993; Saporito et al., 2000]. It was shown that the amount of ionisable fluoride was lower in MFP toothpastes [Issa and Toumba, 2004]. Bruun et al. [1984] showed that the total salivary fluoride, measured with gas chromatography was equivalent between NaF and MFP toothpastes but inonizable fluoride availability was lower in MFP, although some MFP hydrolysis occurred after 20-30 minutes in saliva. Klimek et al [1997] showed that in volunteers with higher plaque levels or open cavities hydrolysis of MFP occurred faster and on a higher level.

Whereas the caries protective effect of both NaF or MFP toothpastes is widely accepted, their efficacy to prevent erosion is subject to debate. Spectroscopic studies showed no protective effect of fluoride against erosion in vitro [Wang et al., 2008]. Larsen and Richards [2004] came to the conclusion that acidic beverages even when supplemented with high amounts of fluoride could not prevent the dissolution of enamel and CaF2. Studies involving toothpastes [Lussi et al., 2008; Rees et al., 2007] demonstrated a certain protective effect of toothpaste slurry, especially if administered before the acidic challenge. Not only NaF but also MFP seemed to provide some, but not complete protection against acid [Bartlett et al., 1994]. Next to the fluoride compound, properties of the toothbrush itself [Lippert et al., 2017] and other constituents of the toothpaste, such as abrasives and cleaning agents [Ganss et al., 2016; Danelon et al, 2017] have an influence on post-erosive tissue loss. Attin et al. [2001] recommended not to brush immediately after acidic challenge to prevent the removal of softened minerals from the enamel surface. Since the present study only demonstrated a sufficient level of fluoride in saliva after use of a toothpaste of which an erosion protection is claimed, this claim could neither be confirmed nor rejected.

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Введение

Эстетика зубов во все времена волновала человечество, а в современном мире красивая и здоровая улыбка стала неотъемлемой частью успешного человека, его своеобразной «визитной карточкой». В настоящее время в клинической практике встречаются различные дефекты коронковой части фронтальной группы зубов. Кариозные и некариозные поражения (патологическая стираемость), травматический отлом являются частыми причинами повреждения режущего края фронтальной группы зубов [1,5,6].