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Fluoride content of toothpastes available in South Africa

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A high dental caries burden coupled with a lack of water or salt fluoridation make it imperative that toothpastes available to the South African consumer demonstrate adequate potential for caries control and contain between 1000ppm and 1500ppm total fluoride (TF), with at least 1000ppm F in free available/soluble form. ***Methods:*** The objective was to determine TF, total soluble fluoride (TSF) and insoluble fluoride (IF) concentrations in 22 fluoride toothpastes commercially available in South Africa. Samples were purchased from a major pharmaceutical and food retailer located in the two metropolitan areas in South Africa. TF and TSF concentrations were determined potentiometrically, in quadruplicate, following acid hydrolysis of the samples using a calibrated Combination Fluoride Ion Selective Electrode. IF was calculated by subtracting TSF from TF. ***Results:*** Although TF content was found to be statistically significantly lower than manufacturer declaration ($3.2x10^{-7}$; $p \leq 0.05$), 77.3% of the samples still contained adequate free, available/soluble F levels. Relative mean TSF content for toothpastes formulated with a calcium-based abrasive was 85% (sd ±14.5; n=6) as opposed to 98.6% (sd ±2.6; n=16) for those containing silica. ***Conclusions:*** The total fluoride concentration of all the toothpastes was lower than that declared by the manufacturers, with one in four having TSF concentrations of less than 1000ppm F. The relative TSF concentrations for the calcium-containing toothpastes were lower than for the silica-based products, reducing their preventive and protective potential. The results call for strengthened regulation and quality control of fluoride toothpastes in South Africa, as well as international efforts to improve related norms.

Key words: *Fluoride toothpaste, dental caries prevention, toothbrushing, oral health, public dental health*

Background

The global caries pandemic is a major neglected international public health issue, despite extensive knowledge about its aetiology, prevention and treatment (FDI World Dental Federation, 2015; Benzian *et al*., 2011). Of the 291 conditions analysed in the Global Burden of Disease Study, untreated caries of the permanent and deciduous dentition ranked first and tenth, making tooth decay the most common disease affecting about 2.9 billion people (Marcenes *et al*., 2013). The decline in caries prevalence in high-income countries over the past 20 years is largely attributable to widespread exposure to fluoride toothpastes. Still, the highest burden of tooth decay is found in middle-income countries (van Palenstein Helderman *et al*., 2015). Untreated tooth decay is the second leading cause of disability adjusted life years (DALYs) in seven of the world's regions, including southern Sub-Saharan Africa (Marcenes *et al*., 2013).

Two expert consultations organized by the World Health Organization (WHO), FDI World Dental Federation (FDI) and the International Association for Dental Research (IADR), convened in 2006/2007, concluded that exposure to appropriate amounts of fluoride provides the most effective and realistic population-based caries-preventive measure (Benzian *et al*., 2012). Fluoride toothpaste was considered the most widespread and significant form of fluoride used globally and the most rigorously evaluated vehicle for fluoride use (WHO, FDI, IADR, Chinese Stomatological Association, 2007). The evidence for the protective effect and efficacy of fluoride toothpastes is overwhelmingly strong (Walsh *et al*., 2010; Public Health England, PHE, 2017). Ensuring the quality, accessibility and affordability of fluoride toothpastes is thus a major pillar of population-wide approaches to address the global caries burden.

The most recent Cochrane review on fluoride toothpaste found a positive relationship between caries-reducing effects and fluoride concentrations above 1000ppm F (Walsh *et al*., 2010). According to van Loveren and colleagues (2005), however, a minimum concentration of 1000ppm free ionic (F^-) or ionizable (PO_3F^{2-}) fluoride, also termed soluble fluoride, needs to dissociate during brushing and before expectoration to allow for enamel remineralization. Unfortunately, the soluble fluoride content (i.e. the active caries-inhibitory component) is unstable in toothpastes formulated with monofluorophosphate and calcium containing abrasives. Further reductions in total soluble fluoride (TSF) may occur in response to chemical incompatibility between these constituents (Cury *et al.*, 2010), ageing and storage at high ambient temperatures (Conde *et al.,* 2003; Hashizume *et al.,* 2003).

Analytic studies conducted on toothpastes purchased in non-established market economies using the reliable,

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inexpensive and time-efficient fluoride ion selective electrode (F ISE) method have repeatedly demonstrated discrepancies between manufacturers' declaration of fluoride content and concentrations found on analysis, highlighting the need for more quality assurance studies to ensure the effectiveness of fluoride toothpaste in preventing tooth decay (Benzian *et al.*, 2012; van Loveren *et al.*, 2005; Kikwilu *et al.*, 2008; Adejumo *et al.*, 2009).

In South Africa, fluoride toothpaste is the only available population-wide caries control measure as no water or salt fluoridation schemes exist. These latter approaches face multiple challenges due to human rights concerns, inadequate infrastructure, as well as restricted financial and technological resources (Goldman *et al.*, 2008). Given the high burden of tooth decay in South Africa (van Wyk and van Wyk, 2004) it is imperative that the fluoride toothpastes marketed in the country are effective for caries control. The aim of this study was therefore to determine total (TF), TSF and insoluble fluoride (IF) concentrations in 22 fluoride toothpastes commercially available in South Africa.

Methods

This study analysed toothpastes for, TF, TSF and IF contents. Table 1 details the chemical definitions of these three types of fluoride.

Sampling

A convenience sample of 22 toothpastes was purchased between December 2014 and January 2015 from a major pharmaceutical and food retailer located in Johannesburg and Cape Town. All samples were analysed within six months of purchase and before the declared expiry date (Table 2 a, b, c). Toothpaste samples were coded and the analysis sequence was randomised to allow masked assessment.

Fluoride content analysis

The TF and TSF were determined potentiometrically using a Jenway Fluoride Combination Ion Selective Electrode (924-305) coupled to a PHM80 portable pH/mV meter (Orion EA-740). The electrode was calibrated daily using eight standards from 0.0625ppm F to 6.25ppm F freshly prepared from a 1000ppm NaF standard solution by serial dilution. Test samples were prepared according to a protocol modified from Cury and colleagues (2010) (Figure 1). Only plastic lab-ware, reagent grade chemicals and double distilled water (DDW) were used. All analyses were performed in quadruplicate.

Before opening, the toothpaste tube was repeatedly squeezed from top to bottom to distribute the contents homogeneously. The first few grams extruded from the tube orifice were then discarded, as contents are often not adequately homogenized in this region. Thereafter, approximately 100mg (0,10g) to 135mg (0.135g) of each sample was homogenized in 10ml (10g) DDW by shaking vigorously by hand for 30 seconds. This dilution range was set on data obtained from pilot trials that demonstrated similar fluoride concentration results, using an ion selective electrode, for both NaF/silica and Na_2PO_3F/calcium-containing toothpastes when initially diluted 101 times (i.e. 100mg in 10ml DDW) and 70 times (i.e. 145mg in 10ml DDW). Following homogenization the assay tubes were examined to ensure that no toothpaste remnants adhered to the sides. Variations in weight between trials were controlled by calculation of a dilution factor specific to each toothpaste weighing. Four 0.25ml aliquots of the homogenized toothpaste-water slurry were then taken for estimation of TF content and processed according to the procedure in Figure 1. Thereafter, the residual toothpaste-water slurry was centrifuged at 2800rpm for 45 minutes to remove any IF bound to toothpaste constituents. The supernatant obtained contained only the TSF. As fluoride ion concentration (FI) provides a measure of the TSF for the NaF, NH_4F and SnF_2-containing toothpastes, these samples were processed for TSF analysis according to the same procedure applied to preparation of Na_2PO_3F-containing samples for FI determination (right hand column, Figure 1). In order to assess TSF for the Na_2PO_3F-containing samples it was necessary to release F^- from PO_3F^{2-}. Therefore 0.25ml 2M HCI was added to 0.25ml aliquot of the supernatant and incubated at 45°C for one hour prior to completion of sample processing (left hand column, Figure 1). IF was calculated through subtraction of TSF from TF obtained on analysis.

All test samples had a final volume of 2ml and a pH between 5 and 5.5. Sample temperature was monitored and millivolt (mV) potentials recorded only when the samples had equilibrated to room temperature and were within 1°C of the temperature recorded for the standards.

Data analysis

Two linear regressions, based on TF and FI of the standards, were constructed by plotting electrode response on the linear (y-axis) against analyte concentration on the logarithmic (x-axis) using Microsoft Excel software. These calibration curves were then used to quantify the concentration of an unknown sample directly from the electrode response. The slope, intercept and correlation coefficient for the standards were calculated via linear regression analysis in Excel. A slope between -54mV to -60mV per decade of F^- confirmed that the electrode was functioning correctly.

The electrode response values (millivolt potentials) for all samples were recorded and converted to concentration values using the following formula:

Conc. (ppm) = 10^(electrode response(mV) – intercept/slope), where Intercept: y=mx + b; and Slope = $\Delta y/\Delta x$

The mean and standard deviation for TF, FI and TSF were calculated using Microsoft Excel. An initial calibration verification using a 1.25ppm F and continuing calibration verification after every fourth measurement were used to validate the accuracy analysis results. A coefficient of variation, based on standard deviation, equal to or less than 5% was considered acceptable.

Ethical considerations and declaration of interest

Ethical approval was obtained from the Senate Research Ethics Committee of the University of the Western Cape (registration number: 15/1/7).

Table 1. Key to Definitions and Abbreviations for Fluoride Concentrations Analysed

	Fluoride Type	Acronyms	Chemical Forms of F in Dentifrices	Definition
1	Total Fluoride Concentration	TF	NaF/SnF_2/Amine Fluoride Na_2PO_3F	$TF = F^- + IF$ $TF = TSF + IF$
2	Total Soluble (Free Available) Fluoride Concentration	TSF	NaF/SnF_2/Amine Fluoride Na_2PO_3F	$TSF = F^-$ $TSF = F^- + PO_3F^{2-}$
3	Insoluble Fluoride	IF	NaF/SnF_2/Amine Fluoride Na_2PO_3F	$IF = TF - F^-$ $IF = TF - (F^- + PO_3F^{2-})$

*Typically 4 chemical forms of F are found in toothpastes: NaF=Sodium Fluoride, SnF_2=Stannous Fluoride, Amine Fluoride and Na_2PO_3F=Sodium Monofluorophosphate.
F^-=chemical symbol Fluoride ion.

Table 2a. Total, total soluble and insoluble fluoride concentrations for toothpastes containing only a silica-based abrasive

Toothpaste type		*Aquafresh All-in-one Protection*	*Aquafresh Extreme Clean*	*Colgate Total 12*	*Elgydium Sensitive*	*GUM Caries Protect*	*Mentadent P Protection*	*Oral B Pro-Expert*	*Sensodyne Cool Gel*
Expiry		09/16	07/16	04/17	09/15	07/17	04/17	04/16	07/16
Abrasive agent		Silica	Silica	Silica	Silica	Silica	Silica	Silica	Silica
Chemical form of F		NaF	NaF	NaF	NH*	Na_2PO_3F NaF	NaF	SnF_2 NaF	NaF
[TF] declared (ppm)		-	1450	1450	1250	1490	1450	1450	1400
Mean [TF] in analysis (ppm)		1371.2	1223.5	1343.9	1125.3	1470.0	1239.5	1223.0	1349.8
SD		± 70.2	± 64.4	± 45.4	± 26.6	± 42.3	± 40.3	± 40.8	± 69.6
[TSF] in analysis (ppm)	[FI]	1358.7	1175.2	1359.7	1100.4	1248.5	1184.0	1251.2	1368.7
	SD	± 70.5	± 59.6	± 26.2	± 27.2	± 37.8	± 38.1	± 29.7	± 47.3
	$[PO_3F^2]$	0	0	0	0	140.3	0	0	0
	Total	1358.7	1175.2	1359.7	1100.4	1388.8	1184.0	1251.2	1368.7
	SD	± 70.5	± 59.6	± 26.2	± 27.2	± 32.3	± 38.1	± 29.7	± 47.3
[TSF] as % [TF]		99.1	96.1	101.2	97.8	94.5	95.5	102.3	101.4
Mean [IF] in analysis (ppm)		12.5	48.3	-15.8	24.9	81.3	55.5	-28.2	-18.9
% Diff. [TF] declared vs. analysis			15.6	7.3	10.0	1.3	14.5	15.7	3.6
% Diff [TF] vs. [TSF] in analysis		0.9	3.9	-1.2	2.2	5.5	4.5	-2.3	-1.4

* NH = Nicomethanol hydrofluoride

Table 2b. Total, total soluble and insoluble fluoride concentrations for toothpastes containing only a silica-based abrasive

Toothpaste type		*Sensodyne Repair & Protect*	*Aquafresh Ultimate*	*Colgate MaxFresh*	*Colgate Sensitive MultiPro-tection*	*Close Up Deep Action*	*Mentadent P Gel Protection*	*Sensodyne Multi Care*	*Sensodyne Rapid Action*
Expiry		05/16	08/16	04/17	09/16	12/16	07/17	07/16	04/16
Abrasive agent		Silica	Silica	Silica	Silica	Silica	Silica	Silica	Silica
Chemical form of F		Na_2PO_3F	NaF	NaF	Na_2PO_3F	NaF	NaF	NaF	NaF
[TF] declared (ppm)		1450	1450	1000	1000	1450	1450	1400	1040
Mean [TF] in analysis (ppm)		1279.2	1258.5	897.3	908.0	1108.9	1238.7	1343.9	981.5
SD		± 45.2	± 18.6	± 36	± 24	± 35.7	± 42.3	± 27.1	± 25.2
[TSF] in analysis (ppm)	[FI]	47.9	1217.3	866.9	73.3	1074.7	1223.2	1328.2	954.7
	SD	± 3.4	± 20.5	± 25.6	± 3	± 52.2	± 33.7	± 28.4	± 21.5
	$[PO_3F^2]$	1270	0	0	844.3	0	0	0	0
	Total	1318.0	1217.3	866.9	917.6	1074.7	1223.2	1328.2	954.7
	SD	± 39.4	± 20.5	± 25.6	± 35.6	± 52.2	± 33.7	± 28.4	± 21.5
[TSF] as % [TF]		103.0	96.7	96.6	101.1	96.9	98.7	98.8	97.3
Mean [IF] in analysis (ppm)		-38.8	41.2	30.4	-9.6	34.2	15.5	15.7	26.8
% Diff. [TF] declared vs. analysis		11.8	13.2	10.3	9.2	23.5	14.6	4.0	5.6
% Diff [TF] vs. [TSF] in analysis		-3.0	3.3	3.4	-1.1	3.1	1.3	1.2	2.7

Table 2c. Total, total soluble and insoluble fluoride concentrations for toothpastes containing calcium based abrasives

Toothpaste type		*Colgate Active Salt*	*Colgate Gel*	*Colgate Max. Cavity Protection*	*Colgate Pro-Relief Sensitive*	*Enamel Care*	*Pepsodent*
Expiry		05/16	09/16	07/16	04/17	08/16	03/16
Abrasive agent		$CaCO_3$ Silica	DCPD* Silica	$CaCO_3$	$CaCO_3$	$CaSO_4$ $NaHCO_3$ Silica	$CaCO_3$ Silica DCPD*
Chemical form of F		Na_2PO_3F	Na_2PO_3F NaF	Na_2PO_3F	Na_2PO_3F	NaF	Na_2PO_3F
[TF] declared (ppm)		1000	1450	1450	1450	1100	1450
Mean [TF] in analysis (ppm)		959.5	1305.9	1244.4	1366.6	1036.8	1356.1
SD		± 27.3	± 59.1	± 32.9	± 57.4	± 63.6	± 38.3
[TSF] in analysis (ppm)	[FI]	152.7	418.3	102.1	192.4	676.6	357.6
	SD	± 6.3	± 19.5	± 5.7	± 8.8	± 22.4	± 11.6
	$[PO_3F^{2}]$	545.3	890.2	1045	896.8	0	992.1
	Total	698.0	1308.5	1147.1	1089.2	676.6	1349.6
	SD	± 17.5	± 40	± 38.1	± 39.2	± 22.4	± 50.8
[TSF] as % [TF]		72.7	100.2	92.2	79.7	65.3	99.5
Mean [IF] in analysis (ppm)		261.5	-2.6	97.3	277.4	360.2	6.4
% Diff. [TF] declared vs. analysis		4.1	9.9	14.2	5.8	5.7	6.5
% Diff [TF] vs. [TSF] in analysis		27.3	-0.2	7.8	20.3	34.7	0.5

* DCPD, Dicalcium phosphate dihydrate

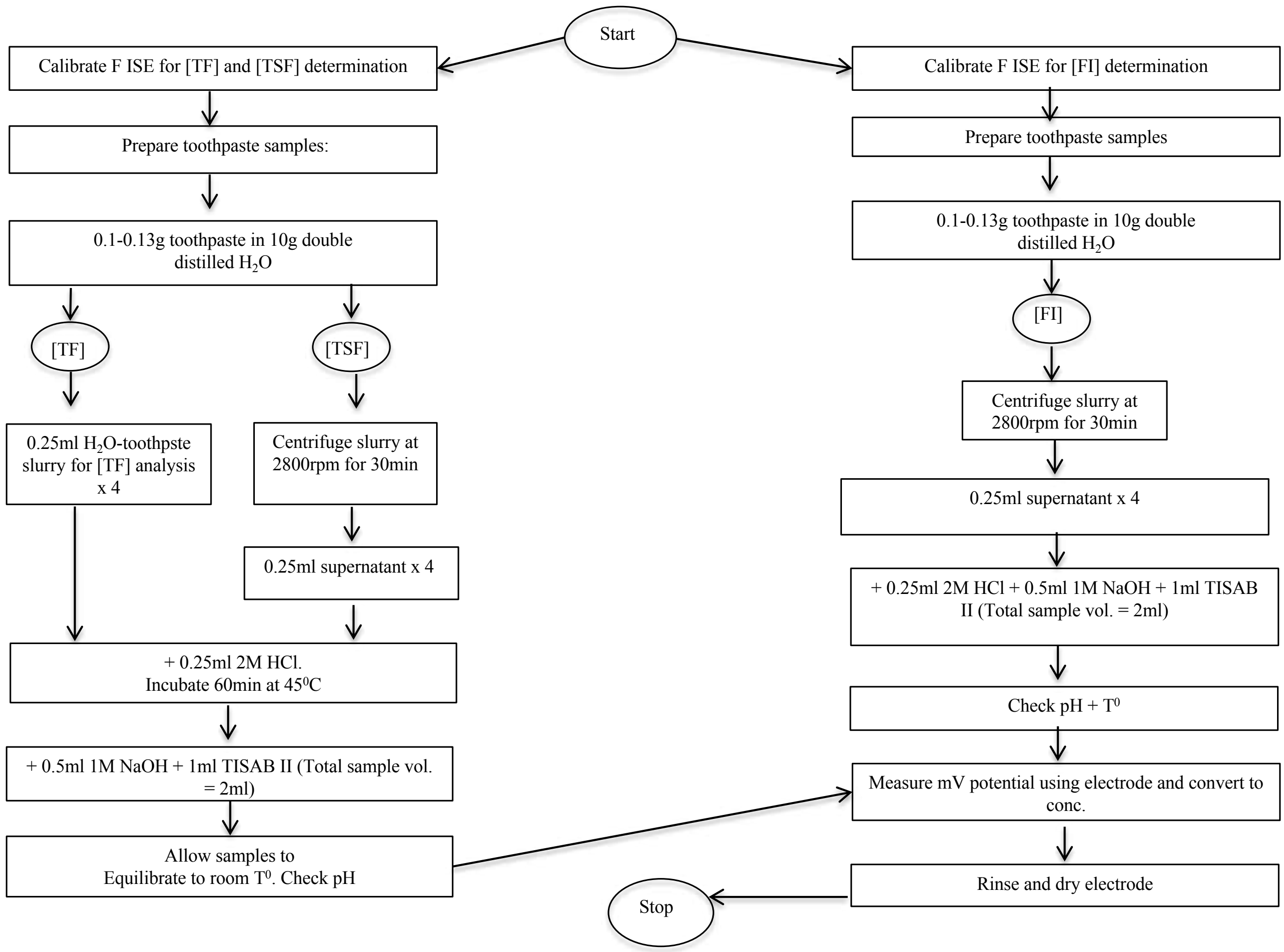

Figure 1. Sample preparation using acid hydrolysis for potentiometric determination of fluoride in aqueous solutions of fluoride toothpastes.

Results

Calibration of the fluoride electrode

The coefficient of determination R^2 obtained for the calibration curves had a mean of 0.9982 and 0.9978 for total and ionic fluoride content respectively demonstrating an almost perfect straight-line relationship.

Sample characteristics

Toothpastes were grouped on the basis of their abrasive components; and other characteristics were recorded (see Table 2 a, b, c for details).

Total and total soluble fluoride concentrations

The mean TF was 10.4% lower than that declared by the manufacturer ($p < 0.0001$, paired t-test). In general, the toothpastes were formulated with either a 1450ppm F or 1000ppm F content. A mean TF ranging from 1108.9ppm F (sd ±35.7) to 1366.6ppm F (sd ±57.4) was recorded for samples declaring a 1450ppm, while TF for samples declaring a 1000ppm F content ranged between 897.3ppm F (sd ±36) and 959.5ppm F (sd ±27.3).

The mean TSF relative to mean TF obtained for all 22 toothpastes was 94.9% (sd ±9.7). Most samples (72.7%, n=16) contained a silica-based abrasive. For the remaining 27.3% (n=6) formulated with a calcium-based abrasive, two were manufactured locally and three contained a combination of $Na_2PO_3F/CaCO_3$. The relative mean TSF for toothpastes formulated with a calcium-based abrasive was 84.9% (sd ±14.6; n=6) compared to 98.6% (sd ±2.6; n=16) for those containing a silica-based abrasive (Table 2 a, b).

Five toothpastes (12.7%) had mean TSF below the critical 1000ppm F concentration considered necessary for anti-caries activity.

Insoluble fluoride concentrations

Calcium-containing toothpastes showed TSF <1000ppm F with IF fractions of 261.5ppm F, and 360.2ppm F respectively, larger than for the three silica-containing toothpastes with TSF <1000ppm F with insoluble fractions of 30.4ppm F, 9.6ppm F and 26.8ppm F respectively. All the toothpastes with TSF <1000ppm F were only, as per manufacturer declaration, formulated with TF ranging between 1000ppm F and 1100ppm F (Tables 2 a, b, c). Although one toothpaste had an IF fraction of 277.4ppm F, the mean TSF, recorded at 1089.2ppm F (sd ±39.2) was marginally in excess of 1000ppm F.

One toothpaste was classed as a calcium-containing product as it contained calcium sulphate ($CaSO_4$). This toothpaste presented with a mean IF concentration of 360.2ppm (sd ±43.7) in contrast to the other calcium-containing toothpastes (n=5) having a mean 128ppm (sd ±135) IF concentration.

Discussion

Studies on toothpastes from non-established market economy countries have often shown that the analysed levels of TF and TSF were inconsistent with manufacturers' declarations of fluoride concentration.

In this analysis all toothpaste samples tested conformed to South African toothpaste standards with respect to the TF concentration. Of concern however, was that their analysed TF concentration was generally lower than that declared by the manufacturers; and TSF was lower than TF. Three silica-based toothpastes, showed TSF concentrations marginally lower than 1000ppm F, even though stability studies have demonstrated that the TSF of silica-containing toothpastes tends to remain constant (Conde *et al*., 2003; Hashizume *et al*., 2003). Of the calcium-based products, one third had very low TSF levels, even though they were analysed before their expiry date.

There is international consensus that exposure to optimum fluoride levels is fundamental in caries prevention (Benzian *et al*., 2012; van Loveren *et al*., 2005; Cury *et al*., 2010; Marinho *et al*., 2003). Various authorities regulate fluoride concentrations in toothpaste to ensure they are safe and effective (Benzian *et al*., 2012). In alignment with the ISO11609:2017 norm (ISO, 2017), the South African *Medicines and Related Substances Act 101* of 1965 (R510) only specifies the maximum total fluoride concentration of toothpaste to be not more than a mass fraction of 0.15% (1500ppm) (University of Pretoria, South African Legal Information Institute, SAFLII, 2014). Moreover, similar to ISO11609:2017, minimum concentrations of TSF for effective caries prevention are not specified (van Loveren *et al*., 2005; Cury *et al*., 2010).

Our findings are consistent with studies from different countries showing that TSF is markedly lower than TF in toothpastes formulated with calcium-containing abrasives (Benzian *et al*., 2012; Cury *et al*., 2010; Kikwilu *et al*., 2008; Thakkar *et al*., 2012); a finding primarily ascribed to chemical incompatibility between the abrasive and the fluoride component.

A growing body of evidence highlights problems of stability of soluble fluoride and hence anti-caries efficacy of $Na_2PO_3F/CaCO_3$ formulated toothpastes, which raises the question why such formulations are still produced and marketed, despite the risk of lower health benefits? Calcium-based are cheaper to produce than silica-based abrasives, which is one reason for the World Health Organization to recommend that precipitated $CaCO_3$ be the abrasive of choice (Jones *et al*., 2005). A critical review of this recommendation should be reconsidered in the light of emerging science.

The ISO11609:2017 norm and the South African *Medicines and Related Substances Act 101* (University of Pretoria, SAFLII, 2014) only specify maximum TF concentration of toothpastes in order to protect consumers from overexposure. However, in the absence of defining minimal concentrations of TSF these standards leave consumers unprotected with regard to the anti-caries efficacy of some toothpastes, mainly those formulated with calcium-based abrasives. These results strengthen the call on standards organisations to re-examine the norms for fluoride toothpastes. There is strong evidence that new legislation should ensure a minimum of 1000ppm TSF concentration in toothpaste formulations for the duration of their shelf life.

Limitations of this analysis relate to the sample and analysis methods. There is no internationally accepted method to analyse TSF in toothpaste. Fluoride analysis of silica-based toothpaste is generally easier since fluoride is available in its ionic form, which can be measured with a Fluoride Ion Selective Electrode. For Na_2PO_3F/$CaCO_3$-containing toothpastes, F^- is covalently bonded to phosphate within PO_3F^2. This necessitates the hydrolysis of PO_3F^{2-} to release of F^-. The most common method is to use HCI for this purpose, although other investigators have used acid phosphatase (Benzian *et al*., 2012; van Loveren *et al*., 2005). This study followed Cury's (2010) protocol, with only minor modifications so the results should be relatively comparable.

The study used a small, non-systematic convenience sample of fluoride toothpastes, using only one sample of each brand. The results should therefore not be seen as representative of all fluoride toothpastes in South Africa (even though they corroborate findings from other countries). Since samples were purchased from a major pharmaceutical and food retailer located in the two biggest cities of the country, they might not reflect the range and quality of products available in other settings where lower turnover leads to longer storage times under less than optimal conditions (i.e. higher temperatures). In the absence of market share and usage data from South Africa, it is not possible to assess the negative public health effect that toothpastes with sub-therapeutic levels of fluoride may have on the burden of tooth decay.

Conclusions

In this convenience sample of fluoride toothpastes available in South Africa, the analysed total fluoride concentration of all the toothpastes was lower than that declared by the manufacturers. One in four had TSF levels of less than 1000ppm F. The relative TSF concentration and therefore the expected preventive and therapeutic value for the calcium-containing toothpastes were also markedly lower than for the silica-based products. The findings corroborate those from studies elsewhere.

Exposure to appropriate amounts of fluoride is among the most effective and realistic population-based caries-preventive measures available. In order to maximise the impact of fluoride toothpaste as a key public health tool to prevent tooth decay, it is recommended to strengthen quality control and regulations for labelling practices. There is an urgent need for international and national standards organisations to re-examine the norms and to promote better quality control mechanisms for fluoride toothpastes.

Declarations

Consent for publication

All authors have approved the final version and its publication.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

L. Vorster contributed to conception, design, data analysis and interpretation, and drafted the manuscript; S. Naidoo contributed to conception and design and critically revised the manuscript; C. Holmgren contributed to interpretation of data and critically revised the manuscript. H. Benzian contributed to conception and design and critically revised the manuscript; N. Stauf contributed to interpretation and critically revised the manuscript. All authors read and approved the final manuscript and agree to be accountable for all aspects of the work.

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