Evaluation of Total pH and Soluble and Ionic Fluoride Concentrations in Dentifrices Commercially Available in Brazil

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Purpose: To verify the total (TF), soluble (SF) and ionic (IF) fluoride concentrations in the main Brazilian dentifrices for comparison and quality control according to the current Brazilian Ministry of Health Regulations, 2000.

Materials and Methods: Nineteen brands, from 2 batches, fresh or aged at $45^{\circ}C/48$ h, had their F concentrations and pH analyzed with a specific electrode and pHmeter. To analyze the TF, 0.25 ml of 2M HCL was added to 0.25 ml of the suspension of each dentifrice. This was kept at $45^{\circ}C/1$ h and 0.50 ml of M NaOH and 1.0 ml of TISAB II was added. To assay SF and IF, after centrifugation, the supernatant was used and the same steps described above were followed for SF. The analysis of IF was made by adding 0.25 ml of the supernatant to 1.0 ml of TISAB II, 0.5 ml of M NaOH and 0.25 ml of 2M HCL. Paired *t* tests were used for statistical analysis.

Results: The concentration of TF, SF and IF ranged from 555.7 – 1835.1; 449.3 – 1619.3 and 96.9 – 1534.6 ppm respectively. After aging, a significant reduction in the SF concentration (p = 0.00002) was observed, which did not occur for TF and IF (p > 0.05). Only the brand Colgate BabyTM presented pH 6.8. The other dentifrices had an alkaline pH, ranging from 7.1 – 9.9.

Conclusion: Although the term 'soluble' was suppressed by the new regulation, the dentifrices analyzed were in accordance to the Brazilian Ministry of Health Regulations, 1989.

Key words: dentifrices, fluoride, pH, quality control, stability

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T he decline in the prevalence and incidence of dental caries in the past two decades is considered to be largely the result of the use of fluoride. Much of the decline in caries levels experienced in westernized societies during the past decade has been attributed to the widespread use of fluoride dentifrices (Glass, 1981; O'Mullane, 1982; Jenkins, 1985; Thylstrup and Fejerskov, 1986; Stookey, 1990).

The ability of fluoride-containing dentifrices to contribute to caries control has been more extensively documented than any other topical fluoride Table 1

oduct sar uru-SP, B	nples of dentifrices purchased in razil				
Code	Brand name				
1	Colgate com Cálcio				
2	Colgate Bicarbonato de sódio				
3	Colgate Herbal Branqueador				
4	Colgate Total				
5	Colgate Controle de Tártaro				
6	Colgate Júnior				
7	Colgate Baby				
8	Close-up Liqui Fresh				
9	Close-up Eucaliptus Mint Max				
10	Close up Triple Hortelã				
11	Sorriso Dentes Brancos com Cálcio				
12	Sorriso Fresh Cristal Mint				
13	Sorriso Herbal com Cálcio				
14	Tandy				
15	Signal Tripla Ação				
16	Sensodyne Proteção Total				
17	Gessy Cristal Menta Fresca Juá				
18	Ice Fresh				
19	Ki Pasta				

Orden and trade no

measure, and their cariostatic benefits are widely acknowledged and utilized. It has been estimated that over 90% of the dentifrices sold in the USA and several other countries contain fluoride (Stookey, 1990). In 1998, Cury claimed that the presence of fluoride in more than 95% of dentifrices sold in industrialized countries is mainly responsible for the decline of dental caries. ABIHPEC/SIPATESP (2001) data showed that in Brazil a mean consumption of 567 grams of dentifrice per person/year was one of the largest of the world.

The effect of fluoride dentifrices on caries decline and remineralization of initial caries lesions has also been analyzed and demonstrated (Melberg et al, 1986; Melberg et al, 1988; Melberg et al, 1990; Ten Cate, 1990; Wefel, 1990). Most of the studies have evaluated the efficacy of the products manufactured by well-known companies such as Colgate-Palmolive, Procter and Gamble, and Unilever. However, the composition and effectiveness of locally manufactured dentifrices in many developing countries is not well documented. Thus, in order to be caries control effective, the dentifrice must present available fluoride in its formulation (soluble fluoride) in ionic (NaF) or ionizable (Na_2PO_3F) forms (Cury, 2002).

Daily toothbrushing with fluoridated dentifrices reduces the prevalence of caries by about 25%. This small success percentage may be related to the soluble fluoride concentration and its stability (Cury, 1986). In Brazil, Cury et al (1981) demonstrated that the fluoride content in commercially available dentifrices was heterogeneous.

In terms of its chemical form, the fluoride of the dentifrices may oxidize (Manly 1961), bind to the abrasive agent (Ericsson, 1961; Forsman and Ericsson, 1973; Drummond and Curzon, 1985) or decompose (Hill and Audrieth, 1950).

Although Forward (1980) stated that the fluoride stability in dentifrices can be maintained for more than three years, Bushee et al (1971); Pearce (1974); and Freitas (1984) demonstrated that this does not occur in commercially available products in USA, New Zealand and Australia, respectively.

Thus, this study aimed to evaluate some parameters related to the effectiveness of fluoride dentifrices commercially available in Brazil. Hence, the pH and fluoride content (total, soluble and ionic fluoride) of 19 brands of dentifrices, fresh or aged, were analyzed.

MATERIALS AND METHODS

Sampling

Nineteen product samples of dentifrices were purchased in Bauru-SP, Brazil (Table 1). The dentifrices were coded and blind analyses were performed for the fresh and aged products. Aging (equivalent to 8 months) was done at 45°C for 48 h. Two distinct batches were analyzed to verify TF, SF and IF (in triplicate) and pH (in duplicate).

Preparation of Samples

- 1. 100.0 mg of dentifrice was homogenized with 10 ml of deionized water.
- For TF analysis: 0.25 ml 2M HCl was added to 0.25 ml of the suspension mentioned above. The solution was kept at 45°C for 1 h in a double boiler. Then, 0.5 ml M NaOH was added followed by 1.0 ml TISAB II (Total ionic strength adjustment buffer). The sample was centrifuged (5,000 rpm, 3 min) and the supernatant was used.

- 3. For SF analysis: 0.25 ml 2M HCl was added to 0.25 ml of the supernatant described in 2 above, and the solution was kept at 45°C for 1 h in a double boiler. Then, 0.5 ml M NaOH was added followed by 1.0 ml TISAB II.
- 4. For IF analysis: 1.0 ml TISAB II was added to 0.25 ml of the supernatant described in 2 above. Then, 0.5 ml M NaOH and 0.25 ml 2 M HCl was added.

Fluoride Analysis

After preparation of the sample, F was analyzed with an ion specific electrode (Orion 96-09). A set of standards (ranging between 0.5 - 4.0 ppm F) was prepared in triplicate, using serial dilution from a 100 ppm NaF stock solution (Orion#940907). The millivoltage potentials were converted to μ g F using a standard curve with a coefficient correlation of *r* ≥ 0.99 . Based on the triplicate samples, the mean repeatability of the fluoride readings was 94.87%.

pH Analysis

For pH analysis, 1.0 g of dentifrice was homogenized in 10 ml of deionized water. The Micronal B371 pHmeter was used having been previously calibrated with a set of standards of pH 4, 7 and 9. All the dentifrices were analyzed in duplicate. The pHmeter was recalibrated after every 5 readings. Based on the duplicate samples, the mean repeatability of the readings was 99.50%.

Statistical Analysis

Paired *t* tests were used for comparison between the SF of the fresh and aged dentifrices, using the GraphPad InStat. Regression analysis was also applied.

RESULTS

Table 2 shows the mean of TF, IF and SF concentrations (ppm) and the pH of the 19 brands of fresh (F), and aged (A) dentifrices from the two different batches. The concentration of TF, SF and IF ranged from 555.7 - 1835.1; 449.3 - 1619.3 and 96.9 - 1534.6 ppm respectively. After aging, a significant reduction in the SF concentration (p = 0.00002) was observed, which did not occur for TF and IF (p > 0.05). A very strong positive correlation was found between the SF obtained for fresh and aged products (r = 0.9316, p < 0.0001). Only the commercial brand Colgate BabyTM presented a slightly acidic pH (6.8). The other dentifrices had an alkaline pH ranging from 7.1 – 9.9. Table 3 shows a comparison between the two batches (B) with respect to TF, IF and soluble SF fluoride concentrations (ppm) in 19 brands of fresh (F) and aged (A) dentifrices. The values obtained for each product were similar for the two different batches.

Table 4 shows the chemical forms (MFP or NaF), fluoride concentrations, abrasive agents, manufacturing date, expiry date expressed on the container label and TF and SF concentrations found in fresh dentifrices in this study.

DISCUSSION

The laboratory evaluation of fluoridated dentifrices is important for preliminary and equivalence tests for new products and quality control of the products already established in the market.

When Considering the Brazilian dentifrices, Cury (1989) reported that only four out of ten dentifrices analyzed met the stability, availability and reactivity criteria specified by the Council of Dental Therapeutics of the American Dental Association (1985). Although the Brazilian market has about 30 commercially available brands of dentifrice only 5 of them account for 90% of the sales. On the other hand, these 5 dentifrices are manufactured in the São Paulo region. Considering the size of the country, there is concern as to whether transportation of these products would alter their fluoride content (Cury, 2002). However, variations of 100 - 200 ppm in the fluoride concentrations do not influence the caries reduction potential (Featherstone et al, 1990).

The use of sodium monofluorphosphate (MFP) is of particular importance in Brazil, because the most-consumed dentifrices contain calcium in their formulations. This inactivates most of the fluoride contained in the dentifrices in circumstances where these preparations are based on sodium fluoride (NaF) (Richards and Banting, 1996).

In the above study, 68.42% of the dentifrices contained MFP. In spite of this, all the analyzed dentifrices had adequate levels of soluble fluoride.

	TF		IF		SF		pН
	F	А	F	А	F	А	
1	1476.3	1332.2	155.7	182.1	1242.7	1116.1	9.7
2	1542.4	1484.2	346.2	361.5	1404.8	1155.4	9.3
3	1584.0	1449.7	253.2	271.3	1152.9	1093.4	9.6
4	1529.3	1441.0	1409.1	1477.4	1580.2	1401.7	7.6
5	1192.9	1094.2	1216.7	1150.6	1194.6	1155.6	8.6
6	1167.2	1175.9	1139.9	1061.8	1115.3	1084.7	7.2
7	555.9	565.2	520.0	520.6	550.7	483.5	6.8
8	1021.9	1187.8	99.2	107.7	993.5	998.7	7.6
9	1315.4	1392.7	620.7	796.0	1196.9	1270.2	7.2
10	1622.5	1705.0	176.7	207.9	1255.3	1257.6	9.9
11	1498.9	1564.1	169.1	190.2	1325.3	1229.1	9.5
12	1213.6	1173.3	1078.9	1037.4	1125.9	1051.1	7.6
13	1586.1	1360.3	236.9	247.7	1090.4	1040.5	9.8
14	1203.0	1162.7	1117.9	1021.8	1234.0	1005.4	7.5
15	1611.7	1449.8	244.0	261.7	1280.5	1122.9	9.4
16	1453.0	1392.0	1387.7	1309.6	1550.0	1386.6	8.6
17	1603.4	1626.0	213.5	253.5	1373.1	1299.7	9.7
18	1712.3	1608.5	179.6	203.2	1385.5	1284.2	9.5
19	1571.3	1655.3	206.2	203.2	1284.1	1204.2	

Table 2Total (TF), ionic (IF) and soluble (SF) fluoride concentrations (ppm) and pH in 19 brands of fresh(F) and aged (A) dentifrices

In 1989, the Brazilian Ministry of Health Sanitary Vigilance Cabinet regulated the incorporation of fluoride in dentifrices (Regulation n° 22, 20 de dezembro de 1989). This regulation established that if fluoride was incorporated in the dentifrice, the minimum concentration of soluble fluoride at the time of manufacture should be 1,000 ppm and the maximum, 1,500 ppm. One year after manufacture, the dentifrice should have at least 600 ppm of soluble fluoride; a minimum of 450 ppm soluble fluoride should be present at the expiry date. All the dentifrices analyzed in this study met these criteria, even when aged. The aging process applied in this study corresponds to eight months (Motta et al, 2002).

However, a new regulation was established in Brazil in 1996 (Regulation n° 71, 29 de maio de 1996). In fact, the only modification was that this new regulation did not insert the term 'soluble'. In Brazil, the benefit of this fluoride application method is threatened as a consequence of the modification of regulation n. 72 of May 29 1996. The only real modification was that it did not specify that the fluoride in the dentifrices should be in soluble form. This fact is relevant because in this way there is no guarantee of quality covering the commercial dentifrices that are available. Furthermore, this regulation allows for several salts to be used in the fluoridation of the dentifrices. Lower solubility salts, like CaF_2 (1.5 mg %) can be theoretically used, resulting in a formulation with no more than 8 ppm soluble fluoride. In 2000 a new regulation was made (n° 29) but the presence of soluble fluoride was not emphasized.

If Tables 3 and 4 are analyzed together, it is noticeable that the fluoride concentrations displayed in the product labels are correct. This shows that the manufacturers appear to have good control over the amount of fluoride added to the products.

The responsibility for enhancing the safe use of topical fluoride products belongs to dental organizations and the allied health professionals, the dental and dental hygienist schools and their graduates, as well as the manufacturers of the topical fluoride products. It will be to everyone's benefit if these groups and individuals periodically evaluate the formulations, efficacies and recommendations

Table ŝ (F) anc	3 Compar 1 aged (A) (ison of two b dentifrices	atches (B)	with respect	t to total (TF), ionic (IF)	and soluble	(SF) fluorid	e concentra	tions (ppm) i	n 19 brands	of fresh
Brand		TF				1				SF		
	В	1	B	2	B	1	B	5	В	1	B	
	ш	A	ш	A	ш	A	LL.	А	ш	A	ш	A
Ч	1433.5	1422.5	1519.0	1241.9	163.2	179.4	148.16	184.7	1173.9	1055.4	1311.4	1176.8
7	1488.9	1418.4	1595.9	1550.0	318.9	323.1	373.55	399.9	1425.1	1121.1	1384.4	1189.8
ю	1507.9	1369.5	1660.0	1529.9	197.4	211.4	309.15	331.3	1251.7	1152.6	1054.2	1034.3
4	1591.9	1353.8	1466.7	1528.2	1534.6	1439.9	1283.6	1514.8	1596.1	1381.4	1564.4	1422.1
വ	1192.9	1094.2	I	I	1216.7	1150.6	I	I	1194.6	1155.6	I	I
9	1153.2	1182.8	1181.2	1168.9	1166.4	1041.7	1113.4	1081.9	1142.2	1057.0	1088.5	1112.5
7	555.7	600.2	556.0	530.2	520.0	494.6	520.1	546.6	559.6	517.7	541.8	449.3
∞	1158.5	1329.6	885.3	1046.0	101.4	108.5	96.9	106.8	1097.7	992.5	889.3	1004.8
ი	1095.9	1288.3	1534.9	1497.1	99.5	99.2	1142.0	1492.9	1108.5	1114.3	1285.4	1426.2
10	1548.8	1835.1	1696.3	1575.0	183.4	201.8	170.1	214.0	1345.1	1220.0	1165.5	1295.2
11	1553.3	1575.9	1444.4	1552.4	217.6	240.8	120.7	139.6	1229.2	1114.2	1421.4	1344.0
12	1141.8	1095.0	1285.3	1251.6	1094.4	1057.2	1063.3	1017.6	1148.2	1029.0	1103.5	1073.2
13	1450.7	1395.7	1721.5	1324.8	200.57	205.0	273.3	290.5	1130.6	1063.4	1050.1	1017.5
14	1186.5	1037.3	1219.6	1288.1	1148.2	980.9	1087.5	1062.6	1178.5	1002.7	1289.4	1008.1
15	1595.6	1328.9	1627.8	1570.6	346.9	367.5	141.0	155.9	960.6	994.2	1600.3	1251.6
16	1403.3	1391.0	1502.6	1393.0	1425.4	1234.5	1350.0	1384.8	1480.6	1340.6	1619.3	1432.6
17	1695.5	1587.9	1511.2	1664.0	155.3	185.3	271.8	321.8	1516.6	1372.3	1229.6	1227.0
18	1712.3	1608.5	I	I	179.6	203.2	I	I	1385.5	1284.2	I	I
19	1736.7	1632.2	1405.9	1678.5	240.3	244.3	172.2	197.0	1415.1	1265.9	1153.1	1140.7

manufacturing date, expiry date and TF and SF concentrations found in fresh dentifrices in this study								
		Content found in fresh dentifrices						
Brand	Chemical form	[TF] (ppm)	Abrasive agent	Manufacturing date	Expiry date	[TF](ppm)	[SF] (ppm)	
1	MFP	1500	CaCO3	10/2002 01/2003	10/2005 01/2006	1476.3	1242.7	
2	MFP	1500	CaCO3	11/2002 09/2002	11/2005 09/2005	1542.4	1404.8	
3	MFP	1500	CaCO3	01/2003 06/2002	01/2006 06/2005	1584.0	1152.9	
4	NaF	1500	silicon dioxide	02/2003 01/2003	02/2006 01/2006	1529.3	1580.2	
5	NaF	1100	silica	07/2002	07/2005	1192.9	1194.6	
6	NaF	1100	silica	09/2002 07/2002	09/2005 07/2005	1167.2	1115.3	
7	NaF	500	silica	03/2002 12/2001	03/2005 12/2004	555.9	550.7	
8	MFP	1000	silica	Not displayed on label	01/2006 02/2006	1021.9	993.5	
9	MFP	1100	silica	12/2002 01/2003	12/2005 01/2006	1315.4	1196.9	
10	MFP	1500	CaCO3	09/2002 01/2003	09/2005 01/2006	1622.5	1255.3	
11	MFP	1500	CaCO3	08/2002 02/2003	08/2006 02/2006	1498.9	1325.3	
12	NaF	1100	silicon dioxide	02/2003 05/2002	02/2006 05/2005	1213.6	1125.9	
13	MFP	1500	CaCO3	01/2003 09/2002	01/2006 09/2005	1586.1	1090.4	
14	NaF	1100	silica	08/2002 02/2003	08/2005 02/2006	1203.0	1234.0	
15	MFP	1455	silica	10/2002 02/2003	10/2005 02/2006	1611.7	1280.5	
16	NaF	1400	silica	12/2002 05/2002	12/2004 05/2004	1453.0	1550.0	
17	MFP	1500	CaCO3	01/2003 04/2002	01/2006 04/2005	1603.4	1373.1	
18	MFP	1500	CaCO3	11/2002	11/2005	1712.3	1385.5	
19	MFP	1500	CaCO3	01/2003 12/2002	01/2006 12/2005	1571.3	1284.1	

Table 4 Chemical forms (MFP or NaF), fluoride concentrations expressed on the container, abrasive agents,

for the use of these important health products (Whitford, Allmann and Shahed, 1987).

CONCLUSION

In conclusion, despite the fact that the term 'soluble' was removed in the 1996 regulation, the dentifrices analyzed were in accordance with the Brazilian Ministry of Health Regulations, 1989. However, if dentifrices are to continue contributing to the control and prevention of dental caries, it is necessary to revise the current regulations so as to guarantee a greater standardization, thereby ensuring that the marketed dentifrices are adequately fluoridated.

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