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Evaluation of Fluoride Concentration in Some Mouthwashes Available on the Iranian Market

Firoozeh Nilchian[1], **Bahareh Tahani**[2], **Saba Teimuri**[3*]

1. Associate Professor, Oral Public Health Department, Dental Material Research Center, Dental Research Institute, School of Dentistry, Isfahan University of Medical Sciences, Isfahan, Iran.
2. Associate Professor, Oral Public Health Department, Dental Research Center, Dental Research Institute, School of Dentistry, Isfahan University of Medical Sciences, Isfahan, Iran.
3. Dental Student, School of Dentistry, Isfahan University of Medical Sciences, Isfahan, Iran

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ABSTRACT

Introduction: The use of mouthwashes is an effective method of combating tooth decay. The anti-caries effect of mouthwashes depends on the amount of fluoride they contain. Knowing the ingredients of mouthwashes can help users to choose the right products. The aim of this study was to determine the fluoride concentration in the mouthwashes.

Materials & Methods: In this in vitro study, the mouthwashes available on the market were investigated. 18 bottles of mouthwashes from six brands (Misswake, Zenon, Bencer, Dent-a-xyl, Vi-One, and Plastrin) were analyzed using ion-selective electrodes (ISEs) according to the standard addition method (direct potentiometry) to examine. A one-sample T-test was used to analyze the data. A value of $p< 0.05$ was considered statistically significant.

Results: The results showed a significant difference between the measured values and the information on the label of the bottles. The mean fluoride concentration of 6 mouthwashes was measured (Misswake: 74.08±27.89 ppm , Zenon: 89.12±4.48 ppm, Bencer: 774.31±19.37 ppm, Dent-a-xyle: 861.44±31.54 ppm, Plastrin: 122.01±2.24 ppm and Vi-One: 151.02±101.47 ppm). The amount of fluoride in the Bencer and Dent-a-xyl mouthwashes was sufficient to prevent tooth decay, despite the different amounts indicated on the bottle.

Conclusion: The amount of fluoride released in the mouthwashes did not match the amount of fluoride claimed by the manufacturer. There is a need to monitor and improve the methods used to evaluate fluoride. In addition, adequate and accurate information should be provided on the bottles of mouthwashes and further research is needed on the amount of fluoride in mouthwashes.

Keywords: Mouthwashes, Sodium fluoride, Ion-selective electrodes (ISE), Dental caries.

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* **Corresponding Author:** Saba Teimuri, Dental Student, School of Dentistry, Isfahan University of Medical Sciences, Isfahan, Iran.
Tel: +983137925594
E-mail: sabateimuri@gmail.com

Introduction

Dental caries is a common bacterial disease that can cause a variety of discomforts and health problems. [1] Dental caries is a significant problem, especially in countries with middle and lower class population. [2] It is also increasing in certain developing countries due to high sugar consumption. [3] The increased caries rate in Iran is an indication of inadequate preventive measures. [4] Fluoride-containing products such as toothpaste, mouthwash, fluoridated drinking water and varnishes are the first line of defense against dental caries.[5] By forming calcium fluoride and inhibiting the cariogenic activity of bacteria in dental plaque, the application of fluoride in various forms contributes to the reduction of enamel demineralization. [6, 7]

There are therapeutic mouthwashes on the market that can be used to treat periodontal disease and halitosis, reduce dental plaque and prevent dental caries. [8-11] Mouthwashes can also be used as an antiseptic in dental offices before dental procedures. [12] Aluminum fluoride, stannous fluoride, sodium monofluorophosphate, and sodium fluoride are among the ingredients of fluoride-containing mouthwashes. [13] The fluoride concentration in mouthwashes is usually between 200 ppm (0.05%) and 1000 ppm (0.2%). Mouthwashes with 230 ppm should only be used once a week. [14]

Fluoride-containing mouthwashes have been shown to improve oral health due to their remineralizing effect. [15] Anti-caries effects of mouthwashes depend on the bioavailability of their fluoride content. [16] A study by P. Rirattanapong on mouthwashes for children in Thailand suggested that the fluoride concentration in most products was below the recommended limits. [17] A study by van Swaj et al. on 54 mouthwashes from 20 brands in the Netherlands showed that the fluoride concentration of the mouthwashes was at least as high as the amount of fluoride on the labels. [18] E Pizzatto analyzed the amount of fluoride in mouthwashes prepared in Brazilian pharmacies and found that all solutions had a higher fluoride concentration than the prescribed amount, which increased the risk of fluoride toxicity. [19]

Few studies have measured the fluoride content of mouthwashes in Iran. Considering the importance of fluoride in the prevention of dental and oral problems, the aim of this study was to measure the fluoride concentration of 6 mouthwashes available on the Iranian market.

Materials & Methods

This study was approved by the Ethics Committee of Isfahan University of Medical Sciences (ethical number IR.MUI.RESEARCH.REC.1402.007). Fluoride-containing mouthwashes approved by the Islamic Republic of Iran Food and Drug Organization (I.R.I.FDO) were selected as the sample. The bottles whose labels did not indicate the fluoride content of the mouthwash were excluded from the sample. The convenience sampling method was used to collect the samples. In February 2023, 18 mouthwash bottles of 6 different brands (three from each brand) were purchased in a local market in Isfahan, and all products were within the expiration date; based on this formula:

$$n=\frac{(z_{1-\alpha/2})^2\ \sigma^2}{d^2}=\frac{(1.96)^2\ 331.4^2}{(0.48\times 331.4)^2}=16.67$$

n= sample size, z= the value from the standard normal distribution, α=0.05, σ=SD from Pakdaman et al study [20], d = error

At least 18 bottles were required, including 10% drops. To avoid bias and reduce test error, an equal number of each brand of mouthwash on the market was included in the study. Besides, each bottle was evaluated 3 times. A total of 6 mouthwash brands and 3 containers of each brand were measured, with each container being measured 3 times. The mouthwash samples were provided from Misswake Mouthwash Total Care (Sylaneh Sabz Co., Alborz, Iran), Zenon Sensitive Mouthwash (Sylaneh Sabz Co., Alborz, Iran), Bencer Fluoride Mouthwash (Pakalmas Derakhshan Pardis Co., Tehran, Iran), Plastrin Sensitive Mouthwash (Behsaman Darmain Parsian Co., Tehran, Iran), Fuchs dent-a-xyl Mundwasser (Interbros GmbH, Eiterfeld, Germany) and Vi-One General Total Care Mouthwash (Rojin Co., Tabriz, Iran). Table 1 shows the information about the bottles that were examined by a qualified laboratory technician from the Department of Chemistry, Faculty of Basic Science, Tarbiat Modares University.

All bottles were coded from 1 to 18 to allow blind analysis. The fluoride content of the samples was measured using the standard addition method. It is applied by direct potentiometry and is used for the determination of fluoride in foods and liquids. [21, 22] To do so, 1 mL of each sample, 10 mL of Total Ionic Strength Adjustment Buffer (TISAB) IV and 10 mL of deionized H2O were pipetted into a measuring vessel. The standard addition was carried out using the fluoride standard solution (1 g/L) and the fluoride-specific ion electrodes (ISE). Different and precise volumes of the fluoride standard solution were pipetted into a measuring vessel. Then, the ISE was used to measure the potential difference after each addition. Ultimately, the fluoride concentration of the primary solution was measured.

Table 1. Manufacturer's information on the mouthwash labels

Brand	Fluoride on the label	Other components	Volume of mouthwash
Plastrin Sensitive Mouthwash	(0.3%)1400 ppm NaF	Sodium saccharin, glycerin, sorbitol, potassium nitrate, methylparaben, deionized water	300 mL
Zenon Sensitive Mouthwash	500 ppm NaF	Sodium saccharin sorbitol, potassium citrate, cetylpyridinium chloride	400 mL
MisswakeTotal care	1000 ppm NaF	Sodium saccharin, glycerin, benzoic acid, deionized water	400 mL
Fuchs Dent-a-xyl mundwasser	1200 ppm Na2PO3F2	Xylitol, Sodium saccharin, glycerin	500 mL
Bencer Fluoride Mouthwash	900 ppm NaF	cetylpyridinium chloride, phosphoric acid, deionized water	400 mL
Vi-One General Total Care Mouthwash	230 ppm NaF	Sodium saccharin, glycerin, sorbitol, ethanol, deionized water	330 mL

This procedure was repeated three times for each code and the mean fluoride concentration was reported. The electrode was conditioned in TISAB IV/deionized.H2O (1/1) for 5 minutes between additions. The difference between the tested fluoride concentration and the labeled amounts was determined using a one-sample t-test.

Results

All mouthwash samples contained sodium fluoride (NaF), except the mouthwash produced by Dent-a-xyl, which was formulated with sodium monofluorophosphate (Na2PO3F). Table 2 shows that the fluoride content of the Bencer, Dent-a-xyl and Vi-One mouthwash samples was close to label claims. However, the fluoride concentration of the mouthwash samples of the other three brands was much lower than the value printed on the bottles. Table 3 illustrates the significant difference between the collected data and label.

Table 2. Fluoride measurements and pH of the mouthwashes

Name	code	type	F- (free) measurement(ppm) Mean (n=3)	SD	Label (ppm)
Misswake	1	NaF	77.63	1.90	1000
	2		104.36	0.85	
	3		47.33	0.67	
Zenon	4	NaF	94.85	1.62	500
	5		86.43	0.71	
	6		86..09	1.92	
Bencer	7	NaF	782.25	11.63	900
	8		780.20	29.12	
	9		760.04	7.90	
Dent-a-xyl	10	Na2PO3F2	823.77	22.75	1200
	11		870.10	1.92	
	12		890.26	1.96	
Plastrin	13	NaF	123.71	1.96	1400
	14		120.20	1.52	
	15		122.10	2.16	
Vi- one	16	NaF	235.65	1.75	230
	17		200.44	1.60	
	18		17.08	0.41	

Table 1. T-test comparison between the mean value of the fluoride concentration and amounts on the label

Brand	Mean & SD(N=9)	Test value(label)	Sig.(2-tailed)	95% confidence interval of the Difference
Misswake	74.08±27.89	1000	0.0001	-947.35, -904.47
Zenon	89.12±4.48	700	0.0001	-614.32, -607.42
Bencer	774.31±19.37	900	0.0001	-140.58, -110.79
Dent-a-xyle	861.44±31.54	1200	0.0001	-362.80, -1276.26
Plastrin	122.01±2.24	1400	0.0001	-1279.71, -1276.26
Vi-One	151.02±101.47	230	0.048	-156.79, -0.79

Discussion

The results of the study indicated that the measured values for all samples deviated from the information on the label. This descriptive study demonstrated that the fluoride concentration of the mouthwash samples from two brands (Plastrin and Zenon) was 7 to 10 times lower than the value printed on the label. The fluoride concentration of the Misswake mouthwash samples was 12 to 21 times lower than the value printed on the label. Possible reasons for this discrepancy include poor quality ingredients, improper storage conditions, and faulty manufacturing processes. [18] Since the actual fluoride concentration in these samples was not between 230 and 1000 ppm, the term "caries prevention" printed on the label is misleading. [14]

Although some studies have measured the fluoride concentration of toothpaste brands marketed in Iran, there are few studies that have measured fluoride in mouthwashes. Yaghini et al. conducted a study on four different brands of toothpaste and found that the total fluoride concentration in one of the brands exceeded the maximum permissible level. [23] According to a study by Movahhed et al. on 13 fluoride-containing toothpastes for children, the fluoride concentration in none of the toothpastes corresponded to the information on the labels. [24] Pakdaman et al. also reported that the fluoride concentration of Iranian brand toothpaste was similar to that of imported brands. [20]

Due to the drug sanctions imposed on Iran, it was impossible to obtain internationally known mouthwash brands such as Colgate and Oral B, which are being investigated in similar studies in other countries. [25] However, fluoride ISEs were used in the current study, similar to previous studies. The fluoride-containing mouthwashes available on the Russian market are usually formulated with NaF, AlF3, Na2PO3F and AmF. Reshetnyak et al. measured the total and free fluoride concentration in Moscow mouthwashes and demonstrated that the ratio of free fluoride to total fluoride was more than 80% in six samples and less than 60% in three samples. Their study suggests that the methods used for fluoride measurement should be improved to reflect in vivo conditions. [26]

A study on mouthwashes in Brazil and Chili showed that the fluoride concentration of some products in both countries was low but almost in line with label claims. [27] A study in Saudi Arabia

showed that the fluoride concentration of mouthwashes was lower than the label claims but higher than the recommended concentration (0.05%). [28] Another study in Brazil revealed that the fluoride concentration of mouthwashes from 5 out of 6 pharmacies was close to the expected value and underlined the need for a quality control program for pharmacies to improve the quality of fluoride-containing mouthwashes. [29]

Despite the wide range of mouthwash brands in the Iranian market, the high cost of laboratory testing limited sampling. Future studies are recommended to investigate fluoride-containing mouthwashes of other brands.

Conclusion

The present study suggests that there are differences between the fluoride concentration and amounts on the labels of brands and that some manufacturers of fluoride-containing mouthwashes need to improve their quality control standards. In addition, the labels of their products should contain correct information so that consumers can make better choices.

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Conflict of interest:

All authors declare no conflict of interest.

Author's Contribution:

Firozeh Nilchian: developed the original idea and the protocol and revised the manuscript. Bahareh Tahani: summarized and analyzed the data and supervised the manuscript. Saba Teimuri: contributed to the development of the protocol and wrote the manuscript.

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