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Fluoride Concentration in Orthodontic Tooth pastes

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ABSTRACT

Purpose: No information on the fluoride concentration in orthodontic tooth pastes sold in Iraq is presently available. The goal of this investigation was to establish and compare the fluoride content of five orthodontic tooth pastes offered in Iraqi drugstores, as well as testing the null hypothesis that entails the consistency of fluoride concentration measured over time may not deviate from the labelled amounts.

Methods: Laboratory investigation on five brands of orthodontic tooth pastes namely Wisdom, Ortho Kin, Kemphor Ortho, VITIS Orthodontic and G.U.M. Ortho to determine the fluoride concentration in triplicate using a fluoride ion-selective electrode at two time points. A paired sample t-test and a one-sample t-test were used to determine the difference between the fluoride concentration reported on the tube and the observed value in both time intervals.

Results: Initially all brands exhibited levels exceeding 1000 ppm with mean concentrations as follows; Wisdom Orthoclean (1355 ppm) Ortho Kin (1349 ppm) Kemphor Ortho (1361 ppm) VITIS Orthodontic (1348 ppm) and G.U.M. Ortho (1494 ppm) which were significantly lower than stated on the tube. After one month, a significant drop was noticed in the levels of fluoride in all tooth pastes (p-value ≤ 0.05).

Conclusions: The fluoride concentration in orthodontic tooth pastes decreases over time and does not reach the levels stated on the packaging. It is advisable to recommend tooth pastes that retain their effectiveness even after being opened for some time.

Key-words: *Tooth pastes, fluoride concentration, ion-selective electrode, oral hygiene, quality control.*

INTRODUCTION

Orthodontic patients, in particular, face unique challenges in maintaining optimal oral hygiene levels due to the existence of additional surfaces for plaque to accumulate. This is due to the brackets and wires in orthodontic appliances shielding the plaque from the mechanical action of tooth brushing, chewing, and the natural cleansing effect of saliva [1].

Enamel decalcification is an adverse effect of orthodontic therapy that is amplified by inadequate hygiene. Subsurface demineralization occurs beneath an intact surface layer because of early enamel caries. The demineralized surfaces reflect light in a different way than adjacent healthy enamel, giving a chalky-white appearance known as white spot lesions (WSLs) [2,3].

An instantaneous shift in the plaque-bacterial environment occurs following the placement of orthodontic fixed appliances inside the oral cavity. Acidogenic bacteria, including Lactobacilli and Streptococcus mutans, are more common one. Orthodontic patients suffer a more significant decrease in plaque pH due to high levels of bacteria compared to non-orthodontic patients. Hence the advancement of tooth decay is accelerated in individuals using full orthodontic appliances [4].

According to studies, the prevalence of WSLs after fixed-appliance orthodontic therapy ranges from 73% to 95% [5,6]. Proper oral hygiene is the keystone of preventive procedures in fixed-appliance orthodontic patients. Brushing the tooth surfaces two times per day with fluoridated tooth paste is a highly recommended method of mechanically controlling and removing plaque, particularly in places where biofilm is intact [3].

Fluoridated tooth paste is the most important form of fluoride used globally and the most scrupulously evaluated medium for fluoride use. The fluoride ion found in tooth pastes prevents tooth decay by altering the metabolism of bacteria in dental plaque. It does this by inhibiting certain enzymatic processes and reducing the acid produced, which changes the composition of the bacterial population and their metabolic activity. Furthermore, fluoride decreases the demineralization of teeth and encourages the remineralization of early-stage cavities, particularly when present in low concentrations [7]. Fluoridated tooth paste may boost fluoride levels on the surface of the tooth as well as in the mouth for up to ten hours after brushing [8,9].

Evidence emphasized the importance of regular monitoring and quality control of fluoride levels in dental products to ensure meeting the declared specifications as the efficacy of fluoride in preventing dental caries is significantly influenced by its concentration and availability in the tooth paste's formulation. Therefore, it is crucial for orthodontic patients to use tooth pastes that not only meet the minimum fluoride concentration but also maintain this level over time to effectively prevent enamel demineralization and dental caries. Many studies measured fluoride levels in various toothpaste brands and found that fluoride concentrations decreased significantly after a period of storage, emphasizing the need for monitoring the stability of fluoride in dental products [9,10].

This study therefore aims to assess and compare the fluoride content in different brands and formulations of orthodontic tooth pastes that are available in Iraqi drugstores as these variations may impact the efficacy of these products in preventing enamel demineralization and dental caries.

MATERIAL AND METHODS

Materials

Five different brands of tooth paste (Table 1) specifically designed for orthodontic patients were used in this study. The selection of these brands was based on their wide utilization, accessibility, and packaging that explicitly states the fluoride concentration.

In total 30 samples were tested and divided into 15 samples for initial time and 15 samples after 30 days of opening the tooth pastes. The 15 samples comprised of three samples from each of the five brands of the tooth pastes.

Methods

Assessment of fluoride concentration is important since there can be differences between the fluoride concentrations claimed by manufacturers to be present and the actual value. The fluoride ion concentration in orthodontic tooth paste samples was determined using an ion-selective electrode analysis. The samples were processed prior to their expiration dates to ensure the accuracy of results [10].

Ion-selective electrodes provide rapid, precise, and efficient measurements of fluoride ion concentration in orthodontic toothpaste. They eliminate complex sample preparation, making them practical for dental product development and quality assurance, and demonstrate excellent selectivity for fluoride ions. The presence of fluoride can be detected directly in the liquid medium under investigation without the need for arduous and time-consuming sample preparation procedures such as analytical enrichment [11].

Sample Preparation

A sample of 0.5 g of each tooth paste was thoroughly dissolved with 0.5 ml of distilled water and 0.5 ml of 2 M HCl. The suspension was heated at 90°C for one minute to catalyze the conversion of sodium fluoride (NaF) ions to fluoride ions and dissolve the insoluble fluoride particles linked to the abrasive. The resulting suspension was left to cool to room temperature (25°C) then transferred into a plastic beaker and dilute it with 100 ml of deionized water.

Measurement of Fluoride Concentration

A reaction mixture was prepared by combining 5 ml of the suspension sample with 20 ml of a buffer solution called total ionic strength adjuster buffer (TISAB IV), which contains ammonium acetate, ammonium chloride, and CDTA (1,2-cyclohexylenedinitrilo tetraacetic acid). The fluoride-selective electrode (Crison Instruments, Barcelona, Spain) was calibrated using fluoride standards. After that, the electrode in TISAB IV was conditioned for five minutes between standard additions. The reaction mixture was gently swirl and the clean, dry indicator and reference electrodes were introduced to record the results once the measurement becomes stable three times, then the electrodes were removed, cleaned with a soft tissue, dried and left exposed to air for next testing. The data were expressed in molar units that will be converted to parts per million (ppm) using the formula: ppm = mol/L × MW × 1000, where MW is the molecular weight of fluoride.

The measurements were conducted immediately after opening the tubes and after one month of storage to assess the stability of the fluoride concentration over time.

Statistical analysis

The data were statistically analyzed using SPSS software (version 28.0; SPSS Inc., Chicago, IL, USA). The normality of data distribution was tested by Shapiro-Wilk test. A one sample t-test was used to compare the declared concentration of fluoride on the tube with that measured. This concentration was assessed again after one month using paired sample t-test. The statistical analysis was carried out with a predetermined significance level of p-value ≤ 0.05.

Table 1: Information of orthodontic tooth pastes being analysed

Commercial brands (Manufacturers)	Fluoride compound	Declared Fluoride (ppm)	Abrasive
Wisdom (Ortho Clean)- Haver hill-wisdom tooth brushes LTD, England	NaF	1450	Hydrated silica
Ortho Kin- Barcelona-Laboratories KIN S.A, Spain	NaF	1450	Hydrated silica
Kemphor ®- Ortho Pinseque-VERKOS laboratories, Spain	NaF	1450	Hydrated silica
VITIS ® Orthodontic toothpaste-DENTAID S.L., Spain	NaF	1450	Silica
G.U.M Ortho- Sunstar Europe, Spain	NaF	1490	Hydrated silica

RESULTS

First the normality of distribution for the collected data was assessed using Shapiro Wilk test and the results showed normally distributed data (p-value > 0.05). Table 2 shows the mean and standard deviation of fluoride concentration at the time of opening the tooth paste and one month later. In general, the concentration of the fluoride decreased significantly after one month (lower than 1450 ppm for Wisdom, Ortho Kin, Kemphore Ortho and VITIS ortho) except for G.U.M. which showed significantly higher mean value than stated one (1494 ppm) at the time of tube opening.

Comparing the measured and stated concentrations on the package in both time intervals revealed significant lower measured concentrations (below 1450) for all the brands of tooth paste except G.U.M. Ortho where at the time of tooth paste opening there was a higher non-significant difference (Tables 3 and 4).

Table 2: Descriptive and comparative statistics of the fluoride concentration (ppm) in different time intervals

Tooth pastes	Descriptive statistics				Comparison		
	0 day		30 days				
	Mean	S.D.	Mean	S.D.	Mean difference	t-test	p-value
Wisdom orthoclean	1355.000	3.000	1328.667	4.041	26.333	11.286	0.008
Ortho KIN	1349.333	4.509	1331.333	3.215	18.000	11.784	0.007
Kemphor Ortho	1361.333	4.163	1331.667	4.163	29.667	6.171	0.025
VITIS Ortho	1348.000	5.568	1311.667	3.055	36.333	21.800	0.002
G.U.M. Ortho	1494.333	3.512	1433.000	4.000	61.333	26.286	0.001

Table 3: Comparison of the fluoride concentration (ppm) between the stated and measured one at the time of tooth paste opening

Tooth pastes	Stated Conc.	Measured Conc.	Comparison		
			Mean difference	t-test	p-value
Wisdom orthoclean	1450	1355.000	-95.000	-54.848	≤0.000
Ortho KIN	1450	1349.333	-100.667	-38.667	≤0.001
Kemphor Ortho	1450	1361.333	-88.667	-36.888	0.001
VITIS Ortho	1450	1348.000	-102.000	-31.731	0.001
G.U.M. Ortho	1490	1494.333	4.333	2.137	0.166

Table 4: Comparison of the fluoride concentration (ppm) between the stated and measured one after one month of tooth paste opening

Tooth pastes	Stated Conc.	Measured Conc.	Comparison		
			Mean difference	t-test	p-value
Wisdom orthoclean	1450	1328.667	-121.333	-52.000	≤0.000
Ortho KIN	1450	1331.333	-118.667	-63.939	≤0.000
Kemphor Ortho	1450	1331.667	-118.333	-49.230	≤0.000
VITIS Ortho	1450	1311.667	-138.333	-78.428	≤0.000
G.U.M. Ortho	1490	1433.000	-57.000	-24.682	0.002

DISCUSSION

One of the damaging effects of fixed orthodontic appliance is the development of white spot lesions and caries if the oral hygiene was not controlled using the mechanical tooth brushing with daily use of fluoridated tooth paste. Nanoparticles and bioactive composite could have a valuable and promising effect in reducing the white spot lesions associated with the fixed orthodontic therapy and even the erosive lesion due to acidic beverages [12-14].

Assessment of fluoride concentration is important since there can be differences between the fluoride concentrations claimed by manufacturers to be present and the actual value [10]. Ion-selective electrodes provide rapid, precise, and efficient measurements of fluoride ion concentration in orthodontic tooth pastes. They eliminate complex sample preparation, making them practical for dental product development and quality assurance, and demonstrate excellent selectivity for fluoride ions. The presence of fluoride can be detected directly in the liquid medium under investigation without the need for arduous and time-consuming sample preparation procedures such as analytical enrichment [11].

Fluoride concentrations are likely to change if stringent quality control measures are not followed. Since the information provided is inaccurate and may violate consumers' rights, this disparity in value is extremely harmful to consumers. Therefore, these items need to be routinely monitored and controlled.

This study is the first in the world to investigate the level of fluoride content found in orthodontic tooth pastes by using fluoride ion-selective electrodes. Prior research conducted in Iraq [15,16] assessed the fluoride content of several adult and pediatric tooth paste brands and found that the fluoride content was apparently lower than what was stated on the packaging.

It has been well shown that using fluoride tooth paste on a regular basis can lower the incidence and development of new dental caries [17,18]. Additionally, it has been discovered that there are statistically significant advantages to preventing dental cavities at a minimum concentration of 1000 ppm [19].

Numerous systematic evaluations have examined the use of fluoride tooth paste in children [20,21]. While the World Dental Federation (FDI) promotes the use of tooth paste with a fluoride concentration between 1000 and 1500 ppm (with a minimum of 800 ppm fluoride ion bioavailability), the European Academy of Paediatric Dentistry suggested that children's tooth paste should have 1000 ppm of fluoride as a minimum concentration [22]. The fluoride content of the studied dental pastes in the current study were more than 1000 ppm and less than 1450 ppm, which means that children under six years old should use them under supervision, while older children can use them safely.

It is common knowledge that many brands do not provide clear information regarding the types and levels of fluoride they contain [23]. The fluoride content in the brands examined in this study was found to be more than 1000 ppm, which has the advantage of preventing the development of dental cavities, but lower than what was indicated on the labels [19]. After one month of opening the tube, the results likewise revealed a notable and significant drop in the fluoride concentration, while it was still over 1000 ppm.

Matias et al. [24] attributed the reduction in fluoride concentration over time to first, the reaction that happened between the fluoride (monofluorophosphate) and the abrasive agent (calcium carbonate) leading to the formation of high concentrations of insoluble fluoride and second, the increasing temperature accelerating the hydrolysis. In the present study, silica was the abrasive material, and the storage was at a temperature ranged between 20–30°C.

Since NaF is highly ionizable in tooth pastes containing silica, the fluoride is activated once it reaches the oral cavity and decreases the demineralization of enamel, indicating the presence of soluble fluoride concentration [25]. In this investigation, silica served as the abrasive agent and NaF as the primary active component in all tooth pastes. It has been shown that tooth pastes based on NaF/Si have much higher fluoride content than other tooth pastes. For optimal efficacy, the additional fluoride must not form chemical bonds with other substances, particularly calcium, which can act as an abrasive. However, because calcium carbonate is cheaper than silica, it is included in most tooth pastes in impoverished nations [14,23]. So, to guarantee the stability of fluoride in the tooth paste, it is not advisable to use NaF in conjunction with calcium-based abrasives [26].

The analytical technique used in this study has limitations since it only measures the total fluoride concentration, although the quantity of dissolved fluoride ions in the mouth is the only factor that can be used to establish a tooth paste's anti-cavity efficacy [27,28]. Other restrictions on detecting the fluoride concentration include heterogeneous distribution brought on by the presence of abrasives, interference from ingredients, sample preparation, storage, and stability, production variability, and regulatory compliance. Thus, it is essential to carefully choose analytical techniques, prepare samples with care, and strictly follow to established protocols. Furthermore, manufacturers should ensure consistency in their production processes and conduct regular quality control inspections in order to maintain accurate fluoride concentrations in orthodontic tooth paste compositions.

CONCLUSIONS

As a conclusion, this research reveals that the fluoride level in tooth pastes decrease significantly (p-value ≤0.05) over time with brands showing lower fluoride level than advertised except for G.U.M. Ortho. While the initial concentrations were generally beneficial for preventing cavities at over 1000 ppm, the decrease poses a risk for patients relying on these products for hygiene during orthodontic treatment.

The study emphasizes the importance of quality control in producing tooth pastes to ensure consistent fluoride levels as claimed by manufacturers. Given the incidence of WSLs in orthodontic patients, it is suggested to use tooth pastes that maintain maximum fluoride effectiveness even after being opened for some time.

Further studies are required to measure the fluoride concentration in the different forms of fluoride and assess the total fluoride, total soluble fluoride and fluoride ions present over a long period of time (more than 30 days). The variation in fluoride level based on the frequency of opening of tooth paste tubes may astonishingly govern the results to aware consumers.

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Not applicable.

CONFLICT OF INTERESTS

None.

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