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### Assessment of Health Risk of Daily Fluoride Intake of Some Selected Dentifrices used in Port Harcourt, Nigeria

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### Authors' contributions

This work was carried out in collaboration among all authors. Author KPT, performed the first literature search, statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors BE-AS and BH designed the study, managed the analyses of the study and the final draft. All authors read and approved the final manuscript.

### Article Information

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### ABSTRACT

**Background:** Several dentifrices are marketed and used by individuals for the purposes of cleaning and maintaining the aesthetic and health of the teeth, promote oral hygiene and aid in removal of dental plaque and food materials from the teeth. This study was thus designed to assess the pH and fluoride concentrations in selected dentifrices and the possible health risks associated with daily fluoride intake of these selected dentifrices used in Port Harcourt, Nigeria.

**Materials and Methods:** This study estimated the pH and fluoride concentration of the different dentifrices by the pH meter and Ion Selective Electrode method. In addition, the Daily fluoride intake (DFI), Chronic daily intake (CDI) and Hazard quotient (HQ) for the different dentifrices to assess the risk of fluoride intake was calculated.

**Results:** From the result of this study, it was noticed that only one dentifrice, chewing stick (*Massularia acuminate*) has a pH (6.8) that conform to the recommended pH range (6.0-7.5) by NAFDAC while the other dentifrices have a pH value (7.6-10.1) that was higher than the pH range recommended by NAFDAC. For the fluoride concentration, it was observed that some of the



dentifrices like Dr. Agnes Nwanmma dental powder (440 ppm), Dr. White dental powder (480 ppm) and Eradental powder (760 ppm) have low fluoride concentration when compared with the fluoride standard concentration stipulated by SON/ NAFDAC (825-1250 ppm) while the other dentifrices showed fluoride concentration within the range stipulated by stipulated by SON/ NAFDAC but they were below the fluoride concentrations stated on their different labels. The DFI of the dentifrices was within the range (53.86-131.58 mg/day), CDI (0.744-1.8275 mg/kg/day and the HQ (12.27-30.46).

**Conclusion:** Although the fluoride concentrations of the dentifrices were within the normal range as stipulated by NAFDAC and SON, the observation of HQ > 1 in all the dentifrices implied that dentifrices commonly used in Nigeria may pose health risk to the consumers.

Keywords: Dentifrice; toothpaste; fluoride; fluorosis; dental.

### **1. INTRODUCTION**

Dentifrice or toothpaste is a substance that is used with toothbrush or other oral hygiene device to clean the teeth, tongue and gingival. It delivers cosmetic and therapeutic agent to the teeth and the oral environment [1]. The term dentifrice is derived from two words; dens (tooth) and fricare (to rub). They are marketed as tooth powders, tooth-pastes and gels. Individuals brush their teeth for multiple reasons; to avoid bad breath, to refresh themselves, to prevent dental diseases and to have an attractive smile. Most often, people consult oral healthcare professionals in order to seek for the most appropriate and effective toothpaste for their oral health. Several toothpastes are available in the market, however, there is difference in them and some are designed for a specific purpose such as caries control, dentinal hypersensitivity reduction and tooth whitening [2].

Toothpastes are classified as drugs and not cosmetics because drugs are known to contain an ingredient that helps the consumer to achieve the effect that is desired [3]. The main purpose of toothpaste is to help reduce oral bacterial flora and to deliver fluoride to the teeth. This is because fluoride has been proven to protect teeth against attack from bacteria and can be found naturally in food and drinking water.

The active ingredient sodium fluoride is also known to have antibacterial properties [4]. Natural toothpastes are those without triclosan or fluoride. They usually contain natural ingredients such as special mineral salts like sodium fluoride and sodium chloride, and plant extracts like lemon, eucalyptus, rosemary, chamomile, sage and myrrh [5]. Dentifrices are considered as agents with antibacterial potential which could have a beneficial effect on plaque control and disease prevention [6] and some attributes may affect their cosmetic or therapeutic effect such as their physical form, chemical composition, pH, and solubility [7]. According to Dean [8], it was reported that most tooth pastes contain trace amounts of chemicals that may be toxic when ingested and the bacteria in the mouth are mainly present in the saliva and at the tooth surface.

Dentifrices (toothpastes) are known to be composed of active and inactive ingredients that must be compatible with each other in order for it to be effective and acceptable. The active ingredients are those that have therapeutic benefits and help to improve the oral hygiene status such as abrasives and therapeutic agents while the inactive ingredients help in making the formulation thick, binds the components together and also have a specific color or flavor for appealing such as humectants, binders, water, detergents, flavoring agents, preservatives, sweeteners and dyes or coloring agents [9].

Fluoride is an inorganic, mono-atomic anion whose salts are typically white or colorless and is naturally present in the food and drink consumed and it is considered a normal constituent of the human body. About 99% of the body's fluoride is strongly bound to calcified tissues and fluoride in bone tends appear in both rapidly and slowly exchangeable pools. Fluoride can be ingested from several sources such as foods, fluoridated and unfluoridated water, fluoridated toothpastes and some dietary supplements. Fluoride intake from most food is low but inadequate or excessive intakes of fluoride can affect dental health. Inadequate intake of fluoride is associated with increased tooth decay (dental caries) while excessive intakes of fluoride results in damage to the tooth enamel (dental fluorosis).

Fluoride occurs in small amounts in plants, animals, and some natural water sources. Fluoride appears in various forms and it is the most popular active ingredient in toothpaste that helps in preventing cavities. The addition of fluoride in toothpaste has beneficial effects on the formation of dental enamel and bones and also in the prevention and treatment of microbial infection, inflammation, cancer, occurrence of renal stone [10] while chronic fluoride intoxication can cause damage to osseous tissue (teeth and bone) and soft tissues like liver, kidney and brain [11]. Sodium fluoride (NaF) is the most common source of fluoride, but stannous fluoride (SnF<sub>2</sub>), olaflur (an organic salt of fluoride), and sodium monofluorophosphate (Na<sub>2</sub>PO<sub>3</sub>F) are also used. Stannous fluoride has been shown to be more effective than sodium fluoride in reducing the incidence of dental caries and controlling gingivitis [12], but causes surface stains [13].

According to Walsh et al. [14], clinical trials support the use of high fluoride dentifrices as it was found to reduce the amount of plaque accumulation, decrease the number of mutans streptococci and lactobacilli and possibly promote calcium fluoride deposits to a higher degree than after the use of traditional fluoride containing dentifrices [15]. However, these effects must be balanced with the increased risk of harm at higher concentrations [14]. Fluoride available systemically during tooth development is incorporated into teeth as fluorapatite. Fluorapatite in tooth enamel alters the enamel crystalline structure, reduces the solubility of enamel to acid dissolution, or demineralization. When fluoride intake is high, the crystalline structure may be disrupted during the period of tooth development thereby forming porosities which is the basis of dental fluorosis that is a change in the cosmetic appearance of teeth [16-18]. Prolonged exposure to very high fluoride intake can also lead to situations like skeletal fluorosis and bone fractures [19]. Fluoride at the surface of the enamel can also form calcium fluoride which is a more rapid exchangeable pool of fluoride which alters the demineralization and re-mineralization balance, a dynamic process behind dental decay [16-18].

Dental decay has been a severe problem throughout the world [20-22]. Streptococci (bacteria) metabolizes the fermentable carbohydrates from the diet and release acids [23-25] and these acids that are released starts the demineralization of tooth enamel which is made of hydroxyapatite calcium phosphate and is soluble in the acidic environment [26]. The presence of fluoride helps in demineralization of dental enamel by being adsorbed at the tooth enamel surface, thereby decreasing its solubility in acids. According to the Scientific Committee on Cosmetic Products and Non-Food Products (SCCNFP), if toothpaste is the only source of fluoride exposure, fluoride levels of 1,000-1,500 ppm are the permitted range to be effective and void of dental fluorosis as well, especially for children under 6 years of age. Also, pea sized (quarter of a brush size) amount of toothpastes are recommended for children under 6 years of age [27].

In Nigeria, various brands of toothpaste, dental powders and chewing sticks are marketed in various stores and supermarkets. It is suspected that most of these dentifrices may contain fluoride at amounts which are inimical to health of the consumers. Therefore, this study was designed to assess the pH and fluoride concentrations in selected dentifrices and the possible health risks associated with daily fluoride intake of these selected dentifrices used in Port Harcourt, Nigeria.

### 2. MATERIALS AND METHODS

### 2.1 Sample Collection

The different dentifrice brands and chewing sticks were randomly selected and purchased in various stores and supermarkets in Port Harcourt, Nigeria.

### 2.2 Determination of the Colour

The colour determination was done by visual examination method.

## 2.3 Determination of the pH of the Dentifrices

The determination of pH of the dentifrices were done based on method developed by [28], and pH meter manufactured by Mettler Toledo was used to determine the pH of the dentifrices.

### 2.4 Determination of Fluoride Concentration

The fluoride concentration in the dentifrices and chewing sticks was determined using lon-Selective Electrode (ISE) Method according to the method reported by [28]

# 2.4.1 Estimation of daily fluoride consumption and risk assessment of fluoride intake

Estimated daily fluoride intake (DFI) and fluoride intake risk due to the consumption of preference

dentifrice were calculated from the following formulas (1) and (2) according to the method of USEPA [29].

 $CDI = C \times DI / BW \dots (1)$ 

Where CDI = Chronic daily intake (mg/kg/day).

C = Fluoride concentration from preference dentifrices (mg/kg).

DI = Average daily intake rate of preference dentifrice (mg/day).

BW = Body weight (kg).

Based on report from the Norwegian Scientific Committee for Food and Environment [30], the DI for toothpaste was set at 0.1224mg/day. According to USEPA [29], the default weight for adult was set at 70kg.

The multiplication of C and DI gives the estimated daily fluoride intake (DFI, mg/kg). Hazard Quotient (HQ) was calculated using the following formulas (2) (USEPA, [31].

HQ=CDI/RfD.....(2)

Where HQ = Hazard Quotient. RfD = Reference dose.

Reference dose (RfD) is an estimate of daily exposure that is not expected to be a significant risk of adverse effects throughout life. The RfD of fluoride is 0.06 mg/kg/day [32]. When the HQ is greater than 1, the estimated potential fluoride exposure exceeds the RfD and a risk of fluorosis may be posed.

### 3. RESULTS

The colours of the dentifrices and chewing sticks as observed visually is shown in Table 1. The table shows that the colours of the dentifrices examined white, blue, sea green, lemon, red and cream. The comparison of the results of the pH and fluoride concentration of the dentifrices with stipulated reference standards by National Agency for Food and Drug Administration and Control (NAFDAC) and Standard Organization of Nigeria (SON) is shown in Table 2. The table shows that the pH of most of the dentifrices marketed in Nigeria are higher than the NAFDAC recommended pH except the native chewing stick *Massularia acuminate* with a pH of 6.8.

It was also observed that the fluoride concentration of most determined from the dental powders are lower than SON/NAFDAC approved value as seen Dr Agnes Nwanmma, Dr White powders and Eradental with fluoride concentrations of 440 ppm, 480 ppm and 760 ppm respectively. However, the fluoride concentration of the other dentifrices such as Oral B (Extra Fresh gel), Pepsodent (cavity fighter), Colgate (Herbal), Macleans (Herbal), Close uo-- up (Deep action), Sensodyne (Daily care) and chewing stick (Massularia acuminate) were within the NAFDAC/SON range although the fluoride concentrations provided on the labels and packets of these dentifrices were generally higher than the evaluated concentrations.

The estimated fluoride daily intake and hazard quotient for the dentifrices and *Massularia acuminate* is shown in Table 3. The hazard quotients calculated with RfD of 0.06 [32] for the dentifrices were generally higher than 1.0 indicating estimated potential fluoride exposure that has exceeded the RfD.

The correlation and regression plots of the pH and Fluoride values of the various toothpastes are shown in Fig. 1. There was no significant negative correlation between pH and fluoride at p<0.05

R=-0.4294, P=0.2155

Product Name	Dentifrices Colour		
Dr. Agnes Nwanmma	White		
Dr. White Dental Powder	White		
Eradental Powder	White		
Oral B (Extra Fresh gel)	Blue		
Pepsodent (Cavity Fighter)	Blue		
Colgate (Herbal)	White and Sea green		
Maclean (Herbal)	White, Red and Lemon green		
Close Up (Deep Action)	Red		
Sensodyne (Daily Care)	White		
Chewing Stick (Massularia acuminate)	Cream		

Table 1. Colour description of the dentifrices

Product Name	pH measured	pH by NAFDAC (6.0-7.5)	Fluoride concentration measured (ppm)	Fluoride concentration as stated on dentifrices label (ppm)	Fluoride Standard by SON/NAFDAC (ppm)
Dr. Agnes Nwanmma (Powder)	10.1	6.0-7.5	440	Not specified	825-1250
Dr. White Dental (Powder)	10.1	6.0-7.5	480	Not specified	825-1250
Eradental (Powder)	10.1	6.0-7.5	760	Not specified	825-1250
Oral B (Extra Fresh gel)	7.8	6.0-7.5	850	1100	825-1250
Pepsodent (Cavity Fighter)	7.9	6.0-7.5	950	1450	825-1250
Colgate (Herbal)	10.1	6.0-7.5	1075	1450	825-1250
Macleans (Herbal)	7.6	6.0-7.5	825	1450	825-1250
Close Up (Deep Action)	8.0	6.0-7.5	950	1450	825-1250
Sensodyne (Daily Care)	7.6	6.0-7.5	850	1450	825-1250
Chewing Stick ( <i>Massularia</i> acuminate)	6.8	6.0-7.5	825		825-1250

### Table 2. Fluoride and pH value for the dentifrice and chewing stick

### Tabe 3. Estimated fluoride daily intake and hazard quotient of dentifrices

Species	Average daily intake (mg/day)	Daily Fluoride intake (mg/day)	CDI (mg/kg/day)	RfD (mg/kg/day)	Hazard Quotient (HQ)	
Oral B (Extra Fresh Gel)	0.1224	104.04	1.445	0.06	24.08	
Colgate (Herbal)	0.1224	131.58	1.8275	0.06	30.46	
Macleans (Herbal)	0.1224	100.98	1.4025	0.06	23.38	
Close Up (Deep Action)	0.1224	116.28	1.615	0.06	26.92	
Sensodyne (Daily Care)	0.1224	104.04	1.445	0.06	24.08	
Pepsodent (Cavity Fighter)	0.1224	116.28	1.615	0.06	26.92	
Dr. Agnes Nwanmma Dental Powder	0.1224	53.86	0.748	0.06	12.47	
Chewing Stick (Massularia acuminate)	0.1224	100.98	1.4025	0.06	23.38	
Eradental Powder	0.1224	93.02	1.292	0.06	21.53	
Dr. White Dental Powder	0.1224	58.75	0.816	0.06	13.60	

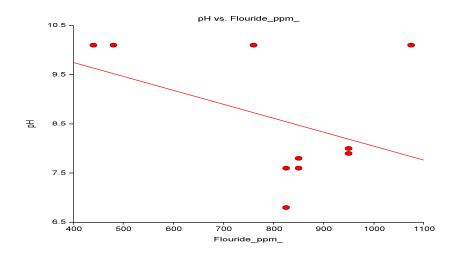


Fig. 1. Correlation and regression plots of pH and fluoride values of toothpastes

### 4. DISCUSSION

After visual examination of the different dentifrices, it was noticed that the dentifrices differ in their colour. For example, Dr. Agnes Nwanmma, Dr. White Dental Powder, Eradental Powder and Sensodyne (Daily Care) has a 'White' colour, Oral B (Extra fresh gel) and Pepsodent (Cavity fighter) has a 'Blue' colour, Colgate (Herbal) has a 'White and Sea green' colour, Maclean (Herbal) has a 'White, Red and Lemon green' colour, Close Up (Deep action) has a 'Red' colour and Chewing Stick (Massularia acuminate) has a 'Cream' colour. These colors were chosen by the manufacturers in order to make the dentifrices attractive and acceptable to the consumers. The dentifrices (toothpastes, tooth powder and chewing stick), it was observed have different unique and specific colours which differentiates and also makes them appealing and attractive according to [9].

The pH of the dentifrices after analysis showed that the chewing stick (*Massularia acuminate*) have pH of 6.8 which is within the pH range (6.0-7.5) for dentifrices stipulated by NAFDAC while the other dentifrices have pH values that were higher than the stipulated pH range by NAFDAC (6.0-7.5). According to [7], pH of the dentifrices can affect their cosmetic and therapeutic property and encourage the growth of mouth bacteria that cause dental caries [32].

The fluoride concentration of the powdered dentifrices such as Dr. Agnes Nwanmma, Dr. White Dental and Eradental powder showed fluoride concentrations in the range of 480 ppm

to 760 ppm which is lower than the fluoride reference standard by SON/NAFDAC (825-1250 ppm). The labels/package of these dentifrices did indicate the manufacturer's concentration of fluoride. The fluoride concentrations of the toothpastes were within the reference standard of SON/NAFDAC (825-1250 ppm). In the chewing stick (Massularia acuminate), the fluoride concentration was analyzed to be 825 ppm which is within the fluoride standard by SON/NAFDAC. According to [14] and SON/NAFDAC, the expected level of fluoride concentration to prevent tooth decay (dental caries) and dental fluorosis ranges from700-1500 ppm and 825-1250 ppm respectively. Thus, the toothpastes and Massularia acuminate has the expected fluoride concentration constituted in them. The implication of this finding is that dental powders studied which are popular dental powders marketed in the South Eastern and South-South regions of Nigeria may not provide beneficial effects with respect to the formation of dental enamel and bone, prevention of dental decay (caries), treatment of microbial infection and inflammation [10].

The comparison of the fluoride concentration measured and that stated on the dentifrice labels showed that the fluoride concentration measured in the different dentifrices were below that stated on the dentifrice labels. This is a common practice in Nigeria as most manufacturers of products tend to present their products to the unsuspecting public in a form that can make them easily accepted without recourse to the negative impact of such strategy on the lives of the consumers. The Chronic daily intake (CDI) calculated according to the method [29] was highest for Colgate (herbal) (1.8275 mg/kg/day) and lowest for Dr. Agnes Nwannma Dental powder (0.748 mg/kg/day). Close-up (Deep action) and Pepsodent (Cavity Fighter) showed 1.615 mg/kg/day, Oral B (Extra fresh gel) and Sensodyne (Daily care) showed 1.445 mg/kg/day, chewing stick (Massularia acuminate) (herbal) showed 1.4025 and Macleans mg/kg/day, Eradenal Powder showed 1.292 mg/kg/day while Dr. White dental powder showed 0.816mg/kg/day. In all the species of the dentifrices, RfD exceeded 0.06 mg/kg/day. When the HQ is greater than 1, the estimated potential fluoride exposure exceeds the RfD and a risk of fluorosis may be posed [32,33,34]. From the calculation, all varieties of the dentifrices had Hazard Quotient (HQ) greater than 1 (i.e. HQ>1), which indicate that they can pose a risk of fluorosis.

### 5. CONCLUSION

Oral hygiene is important for the well-being of the whole body and so the use of dentifrice is of great importance for oral and dental hygiene. Although the fluoride concentrations of the toothpastes were within the normal range as stipulated by NAFDAC and SON, the observation of HQ > 1 in all the dentifrices implied health risk may be associated use of the dentifrices commonly used by Nigerians. Further stringent scientific research on dentifrices is therefore recommended to fully unravel the health risk associated with use of these dentifrices.

### CONSENT

These dentifrices are already in use and their consent was sort for and was freely given.

### ETHICAL APPROVAL

It is not applicable.

### **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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