

Availability of non- and low- fluoride paediatric toothpastes in Nigeria: a need for indigenous affordable formulations

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Abstract

Objective: Some studies in Nigeria have shown a high prevalence of fluorosis. This study looks at toothpastes manufactured locally to determine the availability and affordability of low- fluoride paediatric toothpastes in Nigeria.

Method: Toothpastes manufactured locally in Nigeria which bear the Nigerian Agency for Food and Drug Administration (NAFDAC) approval number were purchased from open markets, reputable supermarkets and pharmacies. The cost price and fluoride content were recorded for each of the toothpastes.

Result: Twenty-one toothpastes manufactured locally in Nigeria were identified. Thirteen toothpastes had sodium fluoride as the active fluoride compound while five had sodium monofluorophosphate. Seventeen toothpastes had optimum fluoride content (1100 - 1450 ppm fluoride or 0.306 - 0.32% w/w sodium fluoride or 0.76 - 0.85% w/w sodium monofluorophosphate), one had low-fluoride content (500ppm or 0.1106% w/w sodium fluoride) while three were non-fluoride toothpastes. The low-fluoride toothpaste was designated as paediatric while the non-fluoride toothpastes were herbal formulations. A cost analysis of the toothpastes showed that the lone paediatric low-fluoride toothpaste was sold at more than three times the cost of the optimum-fluoride toothpastes.

Conclusion: The majority of toothpastes manufactured locally in Nigeria have optimum fluoride content, the non-fluoride toothpastes are herbal formulations while only one toothpaste is a low-fluoride paediatric toothpaste. The present cost of the paediatric toothpaste makes it unaffordable and unavailable to the average child in Nigeria. Companies which manufacture toothpastes locally are encouraged to produce more brands of paediatric low-fluoride toothpastes for the Nigerian market at affordable prices.

Key words: Fluoride, toothpastes, Nigerian, availability, paediatric

Introduction

Fluoride has been well documented to have both beneficial and detrimental effects on the dentition⁽¹⁻⁵⁾. Reduction in caries lesions are beneficial effects attributable to fluoride⁽⁵⁾. Fluoride achieves its caries preventive effects in several ways. It makes teeth more resistant to acid attacks by making the tooth structure stronger. Fluoride also acts to remineralize areas in which acid attack has already begun on teeth. The remineralization effect of fluoride not only reverses the early caries process but also creates a tooth surface that is more resistant to decay^(1,4).

Fluoride is available in two forms to the human dentition: topical and systemic. A proper mix of both topical and systemic forms of fluoride should be made available to individuals for effective prevention of dental caries. Topical sources of fluoride include toothpastes, mouth rinses and professionally applied fluoride therapies such as gels, foams and varnishes. Topical fluoride strengthens teeth that are already in the mouth, making them more caries-resistant^(1,4). Systemic fluorides are those that are ingested into the body and become incorporated into developing tooth

structures. Systemic fluoride sources include water fluoridation from natural sources or community water fluoridation, dietary fluoride supplements such as tablets, drops or lozenges, fluoridated milk and fluoride salt^(1,4). Systemic fluoride may give topical protection since fluoride is excreted into saliva which continually bathes the teeth⁽⁶⁾.

Individuals may be exposed to higher than optimum levels of fluoride especially if multiple sources of fluoride are being used or consumed by such persons⁽⁷⁾. The detrimental effects of fluoride are due to its systemic absorption during tooth development resulting in fluorosis. Enamel opacities and fluorosis may be caused by excessive fluoride ingestion during the pre-eruptive development of teeth. At the fluoride levels used to prevent dental caries, opacities and fluorosis only occur in a relatively small proportion of the population and the changes are very mild and primarily of aesthetic interest^(1,7). High levels of fluoride may result in more severe forms of fluorosis which may manifest as stained and pitted enamel as well as enamel hypoplasia, the term "mottling" has been used to describe such severe forms of fluorosis^(8,9). Water fluoridation has been advocated as an extremely

effective and inexpensive means of delivering fluoride for dental caries prevention and an optimum level of fluoridation has been set at one part per million fluoride (1ppm) or 1mg/litre^(9,10). It is an accepted fact that not everyone lives in a community that has a centralized public or private water source that can be fluoridated. Toothpaste has long been recognized as a viable alternative for the delivery of fluoride with the optimum fluoride level set at 1450 - 1550 parts per million fluoride^(1,3,4).

However, an important source of systemic fluoride which is often overlooked is from the swallowing of large quantities of topical fluorides in toothpastes by young children below the age of six years during tooth brushing^(1,6). It has been advocated that paediatric toothpaste formulations which contain low fluoride level of 500 parts per million fluoride be made available to children under the age of six years, while only a smear of such toothpastes should be used for children below the age of two years, to minimise the amount of fluoride being consumed or ingested by these children⁽¹⁰⁻¹²⁾.

This study was carried out to determine the availability of low-fluoride paediatric toothpastes being manufactured locally in Nigeria and compare their affordability relative to the optimum-fluoride family toothpastes.

Materials and method

This study is a cross-sectional descriptive study. A market survey was carried out and toothpastes manufactured locally in Nigeria which bear the National Agency for Food and Drugs Administration (NAFDAC) approved logo and a NAFDAC number were purchased from the open market, reputable retail supermarkets and pharmacies in Lagos, South-west Nigeria. NAFDAC is the Federal Government Agency under the Federal Ministry of Health which is vested with the responsibility of ensuring that such goods made in or brought into Nigeria are fit for human use. The toothpastes which bear NAFDAC approval but which were not manufactured in Nigeria were excluded from the study. The fluoride content of each locally manufactured toothpaste as advertised on the tubes and packaging was recorded. The toothpastes were then categorized as optimum (1100 - 1450 ppm F), low-fluoride (500 ppm) and non-fluoride content toothpastes. The cost price of each toothpaste was also recorded.

Result

A total of twenty-one locally manufactured toothpastes were identified during the study (**Table 1**). The toothpastes were manufactured by eight different companies, some companies had multiple products. Different fluoride compounds were present in the toothpastes. Thirteen toothpastes had sodium fluoride while five toothpastes had sodium monofluorophosphate as the active fluoride compound. Seventeen of the toothpastes had optimum fluoride content ranging from 1100ppm -

1450ppm fluoride (0.306 - 0.32% w/w sodium fluoride or 0.76 - 0.85% w/w sodium monofluorophosphate). One of the toothpastes had low-fluoride content of 500ppm fluoride (0.1106% w/w sodium fluoride) while three toothpastes had zero fluoride content. The three non-fluoride toothpastes were classified as herbal while two of the optimum fluoride toothpastes were also classified as herbal. A cost analysis of some of the toothpastes, excluding the herbal formulations, from the different manufacturers based on volume and fluoride content is presented (**Table 2**). The available paediatric low-fluoride toothpaste had a volume of 50ml and cost 205 to 380 naira depending on the store visited. The optimum-fluoride toothpastes had different size presentations ranging from small sachets to family sizes of 125ml to 175 ml. The family size toothpastes cost between 100 to 200 naira, depending on the brand. The cost analysis showed that the optimum-fluoride toothpastes had a per ml price of 0.80 - 1.60 naira/ml giving an average cost of 1.18 naira/ml. The low-fluoride paediatric toothpastes cost an average of 4.10 naira/ml. The low-fluoride paediatric toothpaste cost about 3.5 times the cost of the optimum-fluoride family toothpaste.

Table 1: Fluoride content of toothpastes produced in Nigeria

Toothpaste	Manufacturer	Type	Fluoride Content Dose
1. Close-up Red Hot	H	SF	1450ppm
2. Close-up Menthol Chill	H	SF	1450ppm
3. Close-up Fire-Freeze	H	SF	1450ppm
4. Close-up Herbal	H	SF	1450ppm
5. Close-up White Now	H	SF	1450ppm
6. Close-up Complete 8	H	SF	1450ppm
7. Daily Need	C	SMFP	0.85% w/w
8. Dentoclean	E	SMFP	0.85% w/w
9. Holdent Red Gel	G	SF	0.32% w/w
10. Macleans Complete Care	F	SF	0.306% w/w
11. Macleans Freshmint	F	SF	0.306% w/w
12. Macleans Herbal	F	SF	0.306% w/w
13. Macleans Milk Teeth	F	SF	0.1106% w/w (500ppm)
14. My My Blue Gel	D	SF	0.32% w/w
15. My My Denta Fresh Red Gel	D	SMFP	0.76% w/w
16. My My Herbal	D	SMFP	0.76% w/w
17. Olive Red gel	A	SF	0.32% w/w
18. Pepsodent Cavity Fighter	H	SMFP	1450ppm
19. Dabur Herbal Toothpaste with Basil	B	SMFP	Listed as other ingredient
20. Dabur Herbal Gel with Mint and Lemon	B		0.0
21. Dabur Medicated Natural Toothpaste	B		0.0

Key to Table 1:

Fluoride Content:

SF = Sodium fluoride

SMFP = Sodium monofluorophosphate

Optimum fluoride = 1100ppm - 1450ppm fluoride, 0.306 - 0.32% w/w sodium fluoride or 0.76

- 0.85% w/w sodium monofluorophosphate.

Low Fluoride = 500ppm fluoride or 0.1106% w/w sodium fluoride

**List of toothpaste manufacturers:**

- A = Classic Soap Industries (Nig) Limited, Nigeria
 B = Dabur International Limited, Nigeria
 C = Daily Need Industries Limited, Nigeria
 D = Daraju Industries Limited, Nigeria
 E = Doyin Industries Limited, Nigeria
 F = Glaxo Smith Kline Consumer (Nigeria) PLC, Nigeria
 G = Holdent International Ltd, Nigeria
 H = Unilever Nigeria Limited, Nigeria

Table 2: Cost Analysis of Toothpastes by volume and fluoride content

Toothpaste	Volume	Fluoride Content	Unit	Cost
			(Naira)	Naira/ml
1. Close-up Complete 8	125ml	1450ppm (SF)	200	1.60
2. Close-up Menthol Chill	125ml	1450ppm (SF)	180	1.44
3. Daily Need	125ml	0.85% (SMFP)	120	0.96
4. Holdent Red Gel	175ml	0.32% (SF)	150	0.86
5. Macleans Complete Care	125ml	0.306% (SF)	200	1.60
6. Macleans Freshmint	125ml	0.306% (SF)	170	1.36
7. My My Blue Gel	125ml	0.32% (SF)	100	0.80
8. Olive Red Gel	125ml	0.32% (SF)	100	0.80
9. Macleans Milk Teeth	50ml	0.1106% (SF)	205	4.10

Key:**SF = Sodium fluoride****SMFP = Sodium monofluorophosphate****Discussion**

The use of fluorides for the prevention and control of caries has been documented to be safe and highly effective^(3,4,12-14). Optimizing fluoride levels in water supplies is ideal as a public health measure because it is an effective and inexpensive method of fluoride delivery and it does not require conscious daily cooperation from individuals⁽¹⁴⁾. The optimum level of fluoridation having been set at 0.7 - 1.2 parts per million fluoride⁽¹⁰⁾. However, it is a fact that not everyone lives in a community that has a centralized public or private water source which can be fluoridated.

Toothpaste, as it is known today, first emerged in the 1800s with ingredients that included soap and chalk. It was not until 1956 that the company Procter and Gamble introduced toothpaste with fluoride⁽¹⁵⁾. It has been established that fluoride toothpaste is the most widespread and significant form of fluoride delivery and hence of prevention of and protection against dental caries worldwide^(1,3,7). The use of fluoride-containing toothpaste is, therefore, recommended as a primary caries preventive procedure after 6

months of age when the teeth have started to erupt into the mouth^(10,12,14). However, the use of fluoridated toothpaste in children who cannot expectorate predictably carries an increased risk of dental fluorosis^(7,11,15-19).

Dental fluorosis has been found to be of public health and individual health importance in Nigeria. A study of 12 year-old Nigerian children in South-west Nigeria using the Dean index for fluorosis showed that 36.5% had dental fluorosis of different degrees⁽¹¹⁾. In another study of 12 - 15 year-old Nigerians in Northern Nigeria using the Thylstrup and Fejerskov index for fluorosis, dental fluorosis was present in 12.9% of the subjects, high levels of fluoride was also found in drinking water in this study⁽²⁰⁾. Studies on dental caries experience of Nigerian children reveals a low prevalence of caries in the population (21-28). The combination of low caries prevalence and presence of dental fluorosis in a population is a pointer that the children in that population are receiving higher than optimum levels of fluoride due possibly to multiple sources of fluoride or the ingestion of excessive amount of fluoride from one source^(7,16).

Four general sources of fluoride have been identified namely diet, water, toothpaste and dietary supplements when estimating the total fluoride intake of individuals or their risk of developing fluorosis^(7,29-31). Individual dietary exposure to fluoride through food and beverages has been adjudged to be complex to determine and to control, the focus is therefore on the adjustment of recommended dietary fluoride supplements regimen and limiting excessive ingestion of toothpaste by young children^(7,32).

Since ingestion of fluoridated toothpaste carries a risk of fluorosis, this risk must be weighed against the benefit of caries prevention in determining the use of fluoridated toothpaste by a child. In order to harness the protective effect of fluoride while limiting the occurrence of fluorosis, dental researchers have recommended that the fluoride children are exposed to should be reduced by the use of a smear of low-fluoride toothpastes in children below the age of two years and a pea-size of low-fluoride toothpastes containing 500 - 550ppm fluoride in children between the ages of two years to six years^(12,29,31). Children above the age of seven years may use optimum-fluoride toothpaste containing up to 1450ppm fluoride. A pea-sized amount of toothpaste is recognized as the proper measure for dispensing the recommended toothpastes⁽¹²⁾. The use of liquid dentifrice has been found to reduce and standardize the amount of dentifrice applied to the toothbrush by children⁽³³⁾. It is therefore recommended that companies manufacturing toothpastes locally should introduce liquid paediatric dentifrices into the Nigerian market as an additional measure to reduce the amount of fluoride children are ingesting during toothbrushing. This study on availability of low-fluoride toothpastes reveals that there is presently just one low-fluoride paediatric toothpaste that is locally manufactured in Nigeria. The non-fluoride toothpastes recorded in this study are herbal formulations. Herbal toothpastes cannot be recommended for use in very young

children who do not expectorate during brushing as the possible adverse or side effects of swallowing such herbal formulations have not been characterized by local studies. Moreover, the use of non-fluoride toothpaste is no longer recommended in children.

The cost analysis of purchasing the family size optimum-fluoride toothpastes versus purchasing the available low-fluoride paediatric toothpaste shows that the latter cost more than three times the former. This price differential means that the low-fluoride paediatric toothpastes are not really available to the poor and average families in Nigeria who typically have more than one child at a time within the paediatric age group of interest. There is, therefore, a need for the companies which manufacture toothpastes locally to introduce more low-fluoride paediatric toothpaste brands into the Nigerian market and these should be made more affordable to Nigerian families.

Conclusion

The present study on the availability and affordability of non- and low-fluoride paediatric toothpaste shows that of the twenty-one locally produced toothpastes available in the Nigerian market only one of them is a paediatric low-fluoride formulation. The average cost of the available low-fluoride toothpaste is over three times the cost of the optimum-fluoride family-size toothpastes making it unaffordable and thus non-available to the average Nigerian child below the age of six years. Companies manufacturing toothpastes locally are encouraged to produce affordable low-fluoride paediatric toothpastes and liquid dentifrices for the children in Nigeria.

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