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## Review Article

# Over-the-counter Dental Products: Need for Regulation

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### ABSTRACT

Over-the-counter, (OTC) dental products are oral care products sold directly to a consumer without a prescription from a healthcare professional. In the recent years, there is an increase in a number of the OTC products which make false claims and without sound scientific evidence. In many developed countries, OTC products are regulated by federal regulatory agencies such as the Food and Drug Administration and also by the countries professional dental organizations such as the American Dental Association (ADA). ADA provides a seal of approval to those products, however, in many developing countries; the OTC dental products are not regulated due to lax rules. Vendors use this opportunity and are marketing OTC products without sound scientific evidence. While in the some developed countries of Northern America professional bodies provide with their seal of approval for many OTC products. This will help individuals to make their choice. This review paper presents an overview of OTC dental products with questionable scientific evidence and their effects on the oral health. The main purpose of the review is to highlight the need for regulation in the sale of these OTC dental products.

**Key words:** Dental products, oral health, over-the-counter, regulations

### INTRODUCTION

Over-the-counter, (OTC) drugs are medicines sold directly to a consumer without a prescription from a healthcare professional.<sup>[1]</sup> These drugs are also known as nonprescription drugs, as they can be purchased by the consumer without a valid prescription from the doctor. OTC drugs such as aspirin are drugs and combinations that do not require a doctor's prescription. Drugs/products for oral health care can be delivered professionally by the dentist or in some circumstances personally by the patient himself. In the past decade, there has been a significant increase in the number of OTC products for oral health. The advantages of OTC products are it can be purchased easily without visiting a doctor/dentist, so it is inexpensive. Patients who are anxious to visit the dentist, patients with busy schedules could find OTC products as easier alternatives to their oral health problems.<sup>[2]</sup>

In many countries, OTC drugs are selected by a regulatory agency to ensure that they are ingredients that are safe and effective when used without a physician's care. In United

States, the Food and Drug Administration (FDA) is a federal agency of the United States Department of Health and Human Services, is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and OTC, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices, cosmetics, animal foods and feeds, and veterinary products.<sup>[3]</sup>

Many other developed countries have their own regulatory agencies to ensure that only approved products reach the market as nonprescription drugs. The FDA has a list of approximately 800 approved ingredients that are combined in various ways to create more than 100,000 OTC drug products.<sup>[3]</sup> Many OTC drug ingredients had been previously approved prescription drugs now deemed safe enough for use without a medical practitioner's supervision such as ibuprofen. Apart from the regulatory agencies, the professional bodies have also established rigorous guidelines for testing and advertising of dental products. American Dental Association (ADA) has established rigorous guidelines for testing and approving dental products.<sup>[4]</sup> The first ADA seal of acceptance was awarded in 1931. Today, about 350 manufacturers participate in the voluntary program and more than 1300 products have received the seal of acceptance.<sup>[4]</sup>

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In some developing countries, the regulatory agencies which are approving/disapproving these OTC products are not strong. In other circumstances, the implementation of the rules of the regulatory agencies is weaker. In these countries, markets are flooded with OTC dental products without approval from the concerned regulatory agencies. This review focuses on the some of the OTC dental products which are not backed by sound scientific evidence and also highlights the need for regulations among OTC products for oral health care. In the following section, authors highlight the few of the OTC dental products which are short of sound scientific evidence.

## OVER-THE-COUNTER DENTAL PRODUCTS WITH QUESTIONABLE SCIENTIFIC EVIDENCE

### Mouth fresheners

Halitosis can be a result of both intra- and extra-oral causes.<sup>[5]</sup> Evidence-based treatment of halitosis is always etiology-based. Many advanced diagnostic tests are available to diagnose halitosis.<sup>[5]</sup> One of the commonly used treatment methods for halitosis is the mouth freshener. These mouth fresheners are available in the form of sprays, chewing gums, and candies. A commonly available mouth freshener in the spray form is shown Figure 1. However, these mouth fresheners provide symptomatic relief to the patient and mask the actual problem of halitosis. This temporary relief from halitosis may actually worsen the severity of halitosis. Patients may not comprehend that the real cause of halitosis was never diagnosed. ADA in 2003 documented acceptance guidelines for the management of oral malodor.<sup>[6]</sup> All of the mouth fresheners do not meet the guidelines for the management of oral malodor. Patients need to make aware of the mouth fresheners capacity for only symptomatic relief from halitosis.

### Abrasive stain removers

Pigmented deposits seen on the tooth surface are called dental stains. It is a common knowledge that the use of

tobacco products, coffee, tea, mouthrinses (chlorhexidine), and pigments in the food result in extrinsic stain formation. Stains do not result in gingival inflammation. On the contrary presence of black extrinsic stains has been associated with reduced caries rates in some populations.<sup>[7]</sup> However, for aesthetic reasons many patients seek treatment for dental stains. Dental stain removers are marketed in Malaysia and South East Asian nations which have abrasive properties [Figure 2]. These tiny hand held aids are advised to be rubbed on stained areas of teeth. These stain removers also claim to remove plaque, tartar, and tobacco stains. The efficacy of these abrasive stain removers is highly questionable and actually could be counterproductive due to their abrasive properties. Lee *et al.*, studied human extracted teeth to evaluate the presence of any particular component in milk which has the ability to reduce the stain causing property of tea.<sup>[8]</sup> Lee *et al.*, reported that addition of milk to tea significantly reduces the tea's ability to stain teeth. Casein was determined to be the component of milk that is responsible for preventing the tea-induced staining of teeth to a similar order of magnitude that can be obtained by vital bleaching treatments.<sup>[8]</sup> In an era, wherein clinical dentistry is moving ahead with treatments based on scientific evidence, use of materials which could result in irreversible damage to the tooth structure should be discouraged. The patients should be advised of the possible damage due to the abrasive nature of these "dental stain removers." As rightly pointed out by van Loveren and Duckworth there has been a shift in anti caries/anti gingivitis toothpaste to whitening toothpaste.<sup>[9]</sup> Neither a therapeutic benefit (in terms of less gingivitis or fewer caries) nor a societal benefit (in terms of less treatment demand) has been demonstrated due to the whitening effects of toothpaste.<sup>[9]</sup>

### Pregnancy toothpaste

Pregnant women across the world receive special care during their maternity period. This special care is given to make sure that both the mother and the developing newborn are



**Figure 1:** Image of the mouth freshener used for symptomatic treatment of halitosis



**Figure 2:** Dental stain remover marketed in Malaysia and South East Asian nations, which claims to remove stains, plaque, and calculus by rubbing action on the cervical margin of the tooth

safe and healthy. Perinatal oral health plays a crucial role in the overall health and well-being of pregnant women.<sup>[10]</sup> It is also needed for the health and well-being of developing new born.<sup>[10]</sup> Moderate to severe generalized periodontitis in pregnant women has been linked to adverse pregnancy outcomes including pre-eclampsia, preterm birth, and low birth weight babies.<sup>[11]</sup> However, more research is needed to confirm the pathogenesis of periodontitis relating to adverse pregnancy outcomes.<sup>[11]</sup> Pregnant women are at increased risk of developing caries due to their possible avoidance of brushing owing to increased chances of nausea and vomiting.<sup>[10]</sup> Maternity toothpaste are being marketed in Malaysia and South East Asian countries which are free from fluoride, sodium lauryl sulfate (SLS), and saccharin [Figure 3]. These toothpaste claim to be specially formulated for pregnant and lactating women. A wrong message is being sent out to the consumers that presence of SLS and saccharin in the toothpaste could lead to dry mouth in the pregnant lady (due to SLS) and harm the fetus (due to saccharin). These maternity toothpaste are being promoted, citing unrelated toxic effects of fluoride without sound scientific evidence. Ironically, instead of SLS, sarcosinate another foaming agent has been used in this maternity toothpaste [arrow mark in Figure 3].

Consumption of balanced nutritious diet and the use of fluoridated toothpaste has been recommended by the guidelines from the American Academy of Pediatric Dentistry.<sup>[10]</sup> Fluoridated toothpaste in pregnant women are highly recommended due to the increased risk of caries in pregnant women due to possible negligence in oral hygiene. The guidelines state that fluoride certainly helps prevent dental caries in pregnant women and nursing mothers pass on very little fluoride to their infants.<sup>[10]</sup> Research also suggests that fluoride exposure from community water or from products, such as mouthwashes and toothpaste, are most likely safe for both the mother and the unborn child during pregnancy. The dental practitioner should create awareness among the public regarding the safe ingredients in the toothpaste and

their benefits. This will help in reducing the patient's doubts about the safe usage of fluoride in dental consumer products.

### Charcoal toothpaste and charcoal brushes

A new OTC dental product marketed is toothpaste and brushes containing charcoal. The justification provided by the manufacturers is the ability of charcoal to kill microbes and absorb gases causing malodor. These claims need to be proved both *in-vitro* and *in-vivo*. However, the abrasive capacity of charcoal on the teeth has long been proven.<sup>[12]</sup> Hence, actually these charcoal toothpaste and brushes could be causing more harm than benefit to the patient.<sup>[13]</sup>

### Whitening agents/pastes

In the recent years, the use of whitening agents in the toothpaste has increased with a focus on the stain removal and whitening of teeth than the normal function of toothpaste. There are a number of OTC whitening toothpaste which are marketed with claims such as tobacco stain removal, coffee and tea stain removal, and advanced whitening formula. Patients with a history of smoking have more extrinsic stains due to tobacco. In such patients, toothpaste with more abrasives are marketed claiming to remove stains. These toothpastes claim to remove tobacco stains and are marketed as "smoker's toothpaste" [Figure 4]. These products claim to be 60% more effective in the removal of stain than other toothpaste and some of the brands have more than one type of abrasive compared to the normal toothpaste ingredients. New research has shown that there are other risks such as tooth surface roughening, softening, increased potential for demineralization, degradation of dental restorations, and unacceptable color change of dental restorations due to indiscriminate use of these whitening agents.<sup>[14]</sup>

## DISCUSSION

Various marketing strategies, tall and false claims by the vendors and dental suppliers have resulted in the increased use



**Figure 3:** Image of the marketed maternity toothpaste which is free from fluoride, sodium lauryl sulfate, and saccharine. Arrow mark shows the presence of another foaming agent sarcosinate



**Figure 4:** Image of smokers toothpaste which has more abrasive potential than regular toothpaste



of OTC products. According to the oral care products in USA 8<sup>th</sup> Edition, OTC dental products sales are increasing every year and generated 4.9 million USD in the year 2012 and by 2017 the retail sales will reach 6 billion USD.<sup>[15]</sup> In order to increase the sales many of the market leaders in oral care products, sell their products as a complete oral care package. The companies also market their products by projecting the dental products to achieve professional results at home. This has resulted in many consumers avoiding professional treatment since the OTC products are less costly compared to professional treatment.

Introduction of new dental products into the market should be evidence-based and supported by scientific studies. These studies must be ethical, avoid bias, and be suitably controlled. Where appropriate, new products should be compared with products already available and used by the general public. Awareness among patients regarding OTC products which are of dubious nature should be done. This should be included in the oral hygiene instructions of the patients.

## SUMMARY AND CONCLUSION

OTC dental products without any scientific evidence are a small part of a much bigger issue. The issue is of concern for dental esthetics over dental health. Focus, especially among OTC dental products has shifted from oral hygiene to esthetics. Esthetics, of course has its own vital importance, but should be evidence-based. The dental community should stress upon maintaining an oral cavity free of gingival/periodontal inflammation and dental caries. The indiscriminate use of OTC dental products should also be discouraged. OTC products without sound scientific evidence could actually risk the oral health of patients. Professional bodies of countries should initiate a seal of approval programs with stringent criteria for the manufacturers to meet. Regulatory agencies should be created which would help the professional bodies in this process. This would result in improving the quality and standard of OTC dental products entering the market. They also would put a cap on the dubious OTC products from entering the market.

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