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REVIEW ARTICLE

Intraoral Fluoride-Releasing Devices: A Literature Review

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ABSTRACT

Dental caries still continues to be a problem for majority of the individuals and it can be a serious problem for medically compromised, developmentally disabled and elderly individuals. Water fluoridation, systemic and topical fluorides are used for past many years to supply supplemental fluoride in order to combat dental caries. The latest fluoride research is investigating the use of slow-release devices for the long-term intraoral provision of fluoride. The present review addresses two main types of intraoral fluoride-releasing devices like the copolymer membrane device, glass device containing fluoride and some variations of these devices. These devices can significantly increase the salivary fluoride concentration without substantially affecting the urinary fluoride levels. A significant number of studies have confirmed that intraoral fluoride-releasing devices have great potential for use in preventing dental caries in children, high-caries-risk groups, and irregular dental attenders in addition to a number of other applications. As most of the studies done on these devices are *in vitro* and *in vivo* studies, more well-designed clinical trials are necessary to evaluate the results so that these devices can be used clinically.

Keywords: Dental caries, Fluoride, Intraoral, Devices, Prevention.

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INTRODUCTION

Dental caries is one of the most common diseases occurring in humans which is prevalent in developed, developing and underdeveloped countries and is distributed unevenly among the populations.[1-4] More than 60% of the children aged from 5 to 17 years in the United States have decayed, missing or filled permanent teeth because of dental caries.[5] In epidemiological surveys in Scotland, it has been seen that 50% of the disease can be accounted for by including only 11% of 5-year-old and only 6% of 14-year-old.[6] Currently various caries preventive strategies are in use like oral health education, chemical and mechanical control of plaque but fluoride (F), an efficient functional ingredient has been shown to be most effective not only in the prevention of caries[7-9] but also in reversal and remineralization of enamel lesions.[10-13] There are number of ways for administering supplemental fluoride including the fluoridation of drinking water, the ingestion of fluoride tablets or liquids, the incorporation of fluoride into mouth washes, dentifrices and foods, the topical application of fluoride solutions, gels and varnishes. These have a variable effect on caries which can be unpredictable on an individual basis and is dependent on patient compliance in following the prescribed regimen. Several of these have been the subject of various Cochrane reviews.[14,15]

The history of the importance of fluoride in caries control can be divided into two phases: Before its use for water fluoridation in the 1950s, and before the widespread use of fluoride dentifrices in the 1980s. Today, there is consensus that the predominant effect of fluoride is not systemic, pre-eruptively changing enamel structure, but mainly local, interfering with the caries process. Hence, fluoride must be present in the right place (biofilm fluid, saliva) and at the right time (sugar exposure) to interfere with demineralization and remineralization events. For this effect, even sub-ppm values of available fluoride are effective.[16] Thus, frequent applications of topical fluoride are advised to maximize the effects of preventive regimes. Therefore any method of fluoride use, to be effective, should be able to maintain a constant fluoride concentration in the oral environment.

The purpose of this review is to explore various types of intraoral fluoride-releasing devices (IFRD) similar to the ones used for birth control, treatment of glaucoma and prevention of motion sickness which can provide constant low levels of fluoride in saliva in order to control the incidence of dental caries in high-risk individuals. The most important point for preferring controlled release systems to conventional fluoride applications is their ability to increase salivary fluoride levels without substantially increasing serum and urinary fluoride concentrations during the treatment period.[17]

Various Methods of Fluoride Application in High-Risk Individuals

Any method of fluoride application in high-risk individuals should adhere to the properties that are listed in Table 1.[18] Most of the presently available methods have some limitations and do not satisfy all the criteria and most of them rely on patient compliance and do not release fluoride on long-term basis.

Types of Intraoral Fluoride-Releasing Devices

The various types of intraoral fluoride-releasing devices described in the present review are:

- Copolymer membrane device
- Glass device containing fluoride

Table 1: Requirements of the ideal application method to impart fluoride

1.	Safe to administer
2.	Cheap and cost-effective
3.	Easily manufactured
4.	Easy and quick in application
5.	Robust
6.	Long-term fluoride release
7.	Continuous intraoral availability of fluoride
8.	Acting topically at the tooth surface
9.	Not relying on patient compliance
10.	Preventing dental caries clinically

- Hydroxyapatite-Eudragit RS 100 diffusion controlled fluoride system
- Slow-fluoride release tablets for intrabuccal use.

Copolymer Membrane Device

This type of slow-release intraoral fluoride release device (IFRD) was developed in USA.[19] This consists of a small pellet which could be attached on or near the tooth surface. This system was designed as a membrane-controlled reservoir type and has an inner core of hydroxyethyl methacrylate (HEMA)/methyl methacrylate (MMA) copolymer (50:50 mixture), containing a precise amount of sodium fluoride (NaF). This core is surrounded by a 30:70 HEMA/MMA copolymer membrane which controls the rate of fluoride release from the device.[20] When the matrix becomes hydrated, small quantities of granulated NaF are diluted until the matrix itself becomes saturated. The precise water absorption rates by the inner and the outer cores enables the devices to act accurately and reliably as a release controlling mechanism. Once placed inside the mouth, the IFRD becomes hydrated with saliva and its characteristics lead it to release a constant rate of sodium fluoride of 0.02 to 1.0 mg per day for up to 4 or 6 months, depending upon the size of the device.[21]

The standard form of the device is approximately 8 mm in length, 3 mm in width and 2 mm in thickness[22] as shown in Figure 1 and is usually attached to the buccal surface of the first permanent molar by means of stainless steel retainers that are spot welded to plain, standard orthodontic bands[23] or are bonded to the tooth surfaces using adhesive resins.[24] A new IFRD holder known as 'CIPI' made of biocompatible elastic alloy is specifically designed for orthodontic patients and consists of a retentive four wire cage provided with a cannula and a clasp. The cage contains the IFRD, and is secured by the cannula and a clasp to the molar tube.[21]

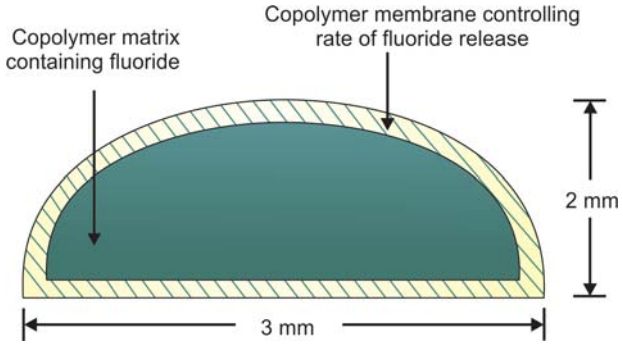

Fig. 1: Diagrammatic cross-sectional view of the copolymer device which was initially 8 mm in length, 3 mm in width and 2 mm in thickness

Glass Device Containing Fluoride

Initially, the glass device that could contain inorganic radicals was developed for use in animal husbandry to combat pasture and feed deficiencies of various trace elements, such as selenium, copper and cobalt.[25] Due to the association of a number of trace elements with caries inhibition, a modification of this device was developed in Leeds, United Kingdom, for use in dentistry in order to evaluate its caries preventive effects.[26] The fluoride glass device dissolves slowly when moist in saliva, releasing fluoride without significantly affecting the device's integrity.

The original device was dome shape, with a diameter of 4 mm and about 2 mm thick[26-28] being usually attached to the buccal surface of the first permanent molar using adhesive resins. Due to the low retention rates of the original device, it was further substantially changed to a kidney-shaped device, being 6 mm long, 2.5 mm in width and 2.3 mm in depth, and it was proven to be effective regarding both fluoride release and retention rate.[29] A new modification was introduced, in order to facilitate device handling, attachment and replacement. This new device has been shaped in the form of a disk that is placed within a plastic bracket, so a new device can be easily installed without the need for debonding, removing remnants of composite resin and performing a new acid etch and bonding the device.

Hydroxyapatite-Eudragit RS 100 Diffusion Controlled fluoride System

This is the newest type of slow-release fluoride device, which consists of a mixture of hydroxyapatite, NaF and Eudragit RS 100; it contains 18 mg of NaF and is intended to release 0.15 mg fluoride/day. It was demonstrated that hydroxyapatite-Eudragit RS 100 matrix tablets increased the salivary fluoride concentrations at optimal caries preventive levels while urinary fluoride concentrations were kept at an acceptable level in a 1-month treatment period.[30] Not much information is available in the literature about this device.

Slow-Fluoride Release Tablets for Intrabuccal Use

Controlled release fluoride delivering system for intrabuccal use was developed, permitting to reach high enough local concentrations for desirable therapeutic effect with minimal

side effects. Tablets of 160 to 200 mg were formulated which were intended to be fixed on a tooth. These tablets have a granular matrix composed of pure hydroxyapatite, Eudragit® and/or ethylcellulose. NaF is added either by a mechanical mixing or an impregnation method.[31] Such a mode of fluoride administration can be extended to all chronic pathologies of the buccal cavity.

Various Applications of Intraoral Fluoride-Releasing Devices

Prevention of Caries

The most important function of intraoral fluoride-releasing devices is the prevention of caries by significantly increasing the salivary fluoride levels for a prolonged period of time. According to the results of the study conducted on 174 children in England, the test group developed 67% fewer new carious teeth after 2 years of placement of the devices.[26] Some authors suggested that the low fluoride levels in saliva allow the slow mineral uptake in the base of the carious lesion, and not only on enamel surface, as frequently occurs when high fluoride vehicles are applied.[32] Another study reported that there were 55% fewer new occlusal fissure carious cavities, showing that occlusal surfaces were also protected by these intraoral devices.[33] The copolymer membrane device was also shown to be a similar effect on enamel remineralization and fluoride uptake when compared to a fluoridated chewing gum.[34]

Prevention of Root Caries

Fewer studies have been conducted to demonstrate the preventive effect of fluoride-releasing devices in root caries. *In situ* studies demonstrated that the use of a slow-release fluoride device was able to increase fluoride uptake in root specimens (with subsurface lesions) to a higher extent when compared to fluoridated mouthrinses and dentifrices[35] and a fluoridated chewing gum.[36] Further studies in this regard are needed to establish a preventive role of these fluoride-releasing devices in the control of root caries.

Medically Compromised Individuals

Dental caries is also a major problem in individuals with special needs who are unable to maintain their oral health because of any disease, disability and old age. Intraoral fluoride-releasing devices have substantial potential to inhibit caries development in populations with special needs especially for medically compromised, developmentally disabled and elderly individuals.[37]

People of Low Socioeconomic Status

Intraoral fluoride-releasing systems can go a long way in preventing dental caries in high-risk individuals like ethnic groups and people of low socioeconomic status.[20]

Conditions of Xerostomia and Individuals on Irradiation Therapy

Xerostomia is often a contributing factor for both minor and serious health problems. Patients experiencing xerostomia from radiation therapy or cancer chemotherapy are at particular risk of infections from normal oral flora as well as dental caries.[38] These devices are helpful in prevention of caries in radiation induced xerostomia patients and in adults with head and neck cancer undergoing irradiation therapy.[39]

Orthodontic Patients

A significant problem in patients undergoing orthodontic treatment is white spot lesion (WSL) demineralization. A cross-sectional study found that 50% of individuals undergoing brace treatment had a nondevelopmental WSL compared with 25% of controls.[40] Another study found that, even 5 years after treatment, orthodontic patients had a significantly higher incidence of WSLs than a control group of patients who had not had orthodontic treatment.[41] These lesions occur in approximately 6 to 8% of subjects during orthodontic treatment with fixed appliances.[42,43] WSL is considered to be the precursor of enamel caries and has been attributed to the effect of prolonged accumulation and retention of bacterial plaque on the enamel surfaces. It is demonstrated that a copolymer device, intended to release fluoride for 6 months, was able to avoid the development of WSL after 1 year of using the devices by patients under orthodontic treatment.[21]

Fluoride-Releasing Dental Materials

There are numerous dental materials from many different manufacturers that have the ability to release fluoride to adjacent tooth structure and into the oral environment.[44-47] Some of the known materials are fluoridated amalgams, glass ionomer cements, resin-modified glass ionomer cements, light cured composite resins, etc. Fluoride-releasing dental materials provides for improved resistance against primary and secondary caries in coronal and root surfaces. Plaque and salivary fluoride levels are elevated to a level that facilitates remineralization. In addition, the fluoride released to dental plaque adversely affects the growth of lactobacilli and mutans streptococci by interference with bacterial enzyme systems.[48] Fluoride recharging of these dental materials is readily achieved with fluoridated toothpastes, fluoride mouthrinses and other sources of topical fluoride. This allows fluoride-releasing dental materials to act as intraoral fluoride reservoirs.

Toxicity and Side Effects related to Fluoride Devices

One of the important concerns that are raised with the use of these devices is the possibility of debonding of the fluoride devices and subsequent swallowing which can lead to the development of acute toxic effects in adults and especially in children. Hence, studies were conducted to verify the safety of these devices so that children do not suffer from any toxic effects even if they are accidentally ingested. Initial studies[49] conducted on dogs reported that dogs ingested devices containing 6 months' supply of fluoride which amounted to 485 mg of fluoride following which there were no signs of toxicity. Subsequent studies conducted on humans[50] reported that the fluoride glass devices were found to be entirely safe from the possibility of developing fluoride toxicity following their ingestion when compared with the plasma levels achieved from swallowing one tablet of 2.2 mg of sodium fluoride. The fluoride devices either passed through stomach or small intestine very quickly or remain insoluble. Further clinical studies also reported elevated fluoride concentration in saliva but no changes in fluoride concentrations in serum and urine of human subjects after fitting copolymer devices.[5,24] In some studies, mucosal irritation, eythema or small ulcers were reported as local side effects[24,51] while some other study reported no adverse effects on the oral studies during the period of study.[21]

CONCLUSION

From the evidence accumulated from the above discussion, it can be concluded that intraoral fluoride-releasing devices can play a vital role in reducing dental caries in populations. Relatively low but elevated levels of fluoride can be maintained for prolonged periods in the oral cavity with the use of such devices. Devices like the copolymer membrane device and the glass device can easily be used in children especially in the mixed dentition stage. These types of devices seem ideal for targeting the high-caries risk groups who are bad dental attenders with very poor oral hygiene and motivation. In addition, it is worth mentioning that the use of such devices is also very favorable in terms of cost benefit and cost-effectiveness.[52] These devices can be easily attached to the teeth, are robust and they effectively raise the saliva fluoride concentration approaching that deemed necessary for caries inhibition. Moreover, these devices were found to be completely safe from the possibility of developing fluoride toxicity in case they are accidently swallowed or ingested. The provision of fluoride-releasing devices for each individual must be tailor-made to suit varying social and working circumstances. As most of the studies evaluating the effect of slow release fluoride devices on intraoral fluoride levels are *in vitro* and *in situ* investigations, further well-designed clinical trials are required to add to the evidence that these have substantial potential in preventing dental caries.

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