INTRA ORAL EFFECTS OF FLUORIDE RELEASING DEVICE IN PREVENTION OF DENTAL CARIES

Running title: Intraoral effects of fluoride releasing devices

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Abstract: Fluoride has been used to combat dental caries using a number of different clinical approaches. An exciting relatively new development is fluoride slow-releasing devices that consistently elevate intra-oral fluoride levels of plaque and saliva for prolonged periods of up to two years. An intra-oral fluoride-releasing device that can elevate fluoride levels in the mouth for up to 6 months has been developed for the prevention of dental caries. Slow-release fluoride devices were developed based on the inverse relationship existing between intra-oral fluoride levels and dental caries experience.

Keywords: fluoride, dental caries

Introduction:-
Dental caries is caused by acids produced by the bacteria on the dental biofilm which will progressively lead to demineralisation of enamel[1]. There are multiple factors involved in the formation of dental caries that allow pathogenic microorganisms to colonise in the mouth [2].

As in all ecosystems, bacteria living in the dental plaque are influenced by the nutritional conditions and surrounding oral environment, and they develop various defense mechanisms that result in the dominance of certain organisms [3,4]. The ability of fluoride to retard or prevent the development of dental caries appears to involve several mechanisms including a reduction in the acid solubility of enamel. Fluoride has been the most widely studied anti-caries material since the 1930s due to its antimicrobial effect and ability to create protective changes on the tooth surface [5,6]. Although the rise and therefore the later decline of decay from the 1950's to the first 1990's is common all over economically developed countries, at a similar time that tooth decay prevalence has diminished it’s become powerfully polarised, showing a bimodal distribution [7,8]. Knowledge from western countries showed that around eighty percent of all affected surfaces corresponded to solely twenty fifth children and adolescents implying that the bulk of children don't have any or little or no decay to be treated. On the opposite hand, there's still a fraction of the population within which the traditional fluoride regimens appears to own very little or no impact on decay prevalence [9,10,11]. In countries within which decay is thought to be polarised, there has been a promotion of insecure methods, rather than the traditional population-based prevention systems, in an effort to overcome this drawback [12,13]. However, the result of such a modification remains questionable. the most drawback is that notwithstanding what's performed all prevention strategies targeted at high caries-risk teams eventually fail owing to the shortage of patient compliance. For countries wherever it's unattainable to promote such speculative methods, the image becomes even worse. As the current scientific accord regards a continuing supply of low levels of fluoride, particularly at the biofilm/saliva/dental interface, as being of the foremost benefit in preventing decay, it’s reasonable to expect a positive impact on dental caries prevalence of a treatment able to raise intra-oral F concentrations at constant rates, while not looking forward to patient compliance. this idea is strengthened by the findings of Shields, et al.47 (1987) [14], World Health Organization showed that no matter water fluoridization status, caries-free children had secretion F levels of 0.04 ppm or a lot of whereas those with unhealthy dentitions had 0.02 ppm or less. different investigators conjointly found secretion F levels of caries-free people area unit more than those found for caries-active subjects, regardless the exposure to fluoridated drink [15,16,17]. Generally, baseline F levels in secretion area unit best-known to be around 0.02 ppm or less, keen about the F level in drink and also the use of F products [18] and area unit considered adequate for low or medium dental caries challenge people, however not for prime dental caries challenge[19]. Considering that intra-oral levels of, F play a key role within the dynamics of cavity, it's been recommended that the utilization of controlled and sustained delivery systems - like those used for contraception, treatment of eye
disease and interference of sickness - will be thought of as a way of controlling cavity incidence in risky individuals[20]. Thereafter, a topical system of slow and constant F release began to be investigated in in vitro, in place and in vivo study. Hence the aim of the review is to find out the intra oral effects of fluoride releasing device in the prevention of dental caries.

Types of devices:-
Copolymer membrane devices:-
This type of slow-release fluoride device was developed by Cowsar, et al. [21] (1976), consisting of a little pellet that may be connected on or close to the tooth surface. This technique was designed as a membrane-controlled reservoir-type and has an inner core of hydroxyethyl methacrylate (HEMA)/methyl methacrylate (MMA) polymer (50:50 mixture), containing a particular quantity of sodium fluoride (NaF). This core is encircled by a 30:70 HEMA/MMA polymer membrane that controls the speed of halide release, because the saturation of NaF is 3.3 x 10^{-3} g/cm^3, and 1.32 x 10^{-4} g/cm^3, severally for the inner core and also the outer membrane, F moves spontaneously from the matrix through the membrane and into saliva. The device is just about 8 metric long unit, 3 mm in breadth, and 2 mm in thickness [25,26]. The device is connected to the buccal surface of the primary permanent molar by means that of stainless-steel retainers that are spot welded to plain, normal dentistry bands7 or are secured to the tooth surfaces using adhesive resins [26].

Depending on the quantity of F within the inner core, the speed of F release of those devices are often between 0.02 and 1.0 mg F/day for up to 180 days. salivary F levels were demonstrated to stay considerably elevated throughout a 100-day check period [28,29]. Glass device
Historically, the glass device was utilized in animal husbandry to combat pasture and feed deficiencies of varied trace elements, like antioxidant, copper and cobalt [30], as a result of the association of variety of trace elements with dental caries inhibition, a variant of this device was developed in Leeds, uk, for use in dental medicine so as to assess its potential use in cavity control [31]. The F glass device dissolves slowly once wet in saliva, releasing F while not considerably affecting the device's integrity.

The original device was dome form, with a diameter of 4 mm and about 2 mm thick [32-34], being typically connected to the buccal surface of the primary permanent molar using adhesive resins, as a result of the low retention rates of the original device, it absolutely was more considerably modified to a simple device, being 6 mm long, 2.5 mm broad and 2.3 millimeter in depth, and it absolutely was proved to be effective relating to each F release and retention rate. a new modification was introduced more recently, so as to facilitate device handling, attachment and replacement. This new device has been formed within the sort of a disk that's placed inside a plastic bracket, thus a new device may be simply put in without the necessity for de-bonding, removing remnants of composite organic compound and performing a new acid etch and bonding the device.

Preliminary studies were conducted to evaluate the most effective F concentration to be employed in the glass devices, with F concentrations starting from 13.3% to 21.9. it had been found that devices containing thirteen, 3% F showed a better rate of F release compared to devices containing higher F concentrations (18.3% and 21.9%); this was explained by the presence of Al within the high F concentration devices that binds to F so reducing its release rate. In distinction to the polymer membrane device, the glass type has shown a extended life time, releasing F continuous for up to two years [35].

EFFECT ON INTRA-ORAL FLUORIDE CONCENTRATIONS
Several in vitro and in vivo studies were conducted so as to evaluate the resulting F levels in saliva and bacterial plaque that are the sites wherever the F particle will exert its cariostatic result throughout the cariogenic challenge. The results of studies involving the immersion of polymer devices each in human and artificial saliva recommended an interaction between F discharged by the devices and metallic element from saliva, which F release is directly proportional to the concentration of calcium present in saliva [36]. These laboratory results, however, weren't in line with those obtained during a further trial, after one month of placement of a glass device, salivary Ca levels weren't considerably completely different from baseline values[37].

Animal studies conjointly found important will increase in secretion F levels associated to the utilization of a polymer device[38,39,40,41]. Such increases were further verified in studies involving human subjects, for periods ranging from 270 minutes [42] to two years. Mean salivary F levels associated to the polymer membrane device unfold a wider vary when put next to the glass sort.

Significant increases were conjointly found in plaque F concentrations, both for the polymer membrane and glass devices. during a double-blind crossover study, it had been demonstrated that the glass device considerably elevated F levels in plaque (~ 10 fold) after one month of placement of the head. Similar findings were obtained during a study using the polymer membrane device, conjointly for a period of 1 month [43], further as in another study conducted with primates[45].
EFFECT ON DENTAL CARIES PREVALENCE REDUCTION

After proving that the utilization of the slow-release F devices was ready to considerably increase salivary F levels for prolonged periods of time, following step was to evaluate the clinical outcomes resulted from such will increase. the primary studies that aimed to verify the impact of the slow-release devices on tooth decay prevalence were conducted using animal models and therefore the polymer type. Mirth, et al. (1983) reported a [46] reduction in dental caries development in the check cluster (rats employing a device releasing 0.15 mg F/day) compared to the control group (no treatment) after one month. the foremost fascinating finding, however, was that the occlusal surfaces were conjointly protected in this study, since 400th fewer occlusal tooth decay lesions were found within the test group. Another study employing a similar protocol conjointly demonstrated that the polymer device considerably restricted the development of enamel dental caries on the sulcal-morsal surfaces in rats.

The only study involving humans was conducted using the glass device. it had been a double-blind clinical test that evaluated the event of caries in 174 children aged eight years. children were residents in a very underprivileged space of Leeds, uk, and used each halide (test group) and placebo devices (control group). when two years of placement of the devices, it had been found that the test group developed 67 fewer new unhealthy teeth and 76 fewer new carious surfaces. In agreement with the findings obtained by merriment, et al.[47] (1983), there have been fifty fifth fewer new occlusal fissures carious cavities, showing that the constant supply of low doses of F is able to safeguard not solely approximate and free surfaces, however conjointly those not usually protected by ancient fluoride regimens. However, as retention rates (discussed in a very specific topic on the current review) were low, the results were analyzed on the premise of head retention instead of associate degree intention-to-treat, that semiconductor diode recent reviews to conclude that the proof from this study wasn't strong[48,49]. Thus, though the results from this study give some proof on the clinical effectiveness of glass devices on tooth decay management, any investigations on the subject are still necessary.

Studies using in situ models conjointly found positive results on F uptake and remineralisation of enamel slabs. Corpron, et al. (1986) demonstrated that enamel will be remineralised at intervals seven days after the use of a polymer membrane device, as a result of the constant release of F ions into the oral surroundings, a similar authors recommended that the low F levels in spit enable the slow mineral uptake within the base of the unhealthy lesion, and not solely on enamel surface, as often happens once high F vehicles square measure applied. The polymer membrane device was conjointly shown to be an identical impact on enamel remineralisation and F uptake when put next to a fluoridated mastication gum. additionally, a dose-response relationship was verified between F concentration free by the copolymer-type device and enamel remineralisation. concerning the situation of the device, Toumba demonstrated that the glass-type device additionally was ready to increase surface microhardness of enamel slabs, each within the same and therefore the opposite sides of the mouth from the location of the device.

Other studies, victimization in place and in vivo models, conjointly evaluated the potential use of slow-release devices for reduction of dental medicine white spots, dentine sensitivity and bar of root tooth decay. Marini, et al. (1999) incontestible that a polymer device, supposed to unharvest F for six months, was ready to avoid the event of white spot lesions when one year of victimization the devices by patients below treatment. Since organization procedures weren't thought of as adequate by a recent meta-analysis10, care should be taken once analysing these results. The glass device was conjointly tested to be effective for such purpose, when the treatment, the cluster of subjects that used the F cathartic device developed sixty six fewer white spots lesions when put next to the management group.

The use of a F cathartic device conjointly evidenced to be effective for treating dentine sensitivity. Subjects presenting dentine sensitivity each secondary to post-periodontal surgery and first sensitivity were fitted a polymer device for a amount of four months [50] when four weeks of treatment, the symptoms reduced considerably, remaining absent through the period of the treatment. concerning root tooth decay, in place studies incontestible that the employment of a slow-release F device was ready to increase F uptake in root specimens (with undersea lesions) to the next extent when put next to fluoridated mouthrinses and dentifrices and a fluoridated mastication gum . Any clinical studies square measure still required so as to check and validate the effectiveness of F cathartic devices for such functions.

TOXICITY AND SIDE-EFFECTS

One of the primary considerations regarding the utilization of the slow-release fluoride device was the likelihood of debonding and its resultant uptake, that could lead on to acute toxic effects. For this reason, since the event of the primary device (copolymer type), studies are conducted so as to verify the degree of safety when using these devices in humans, particularly in children [51].

Using an animal model, Mirth, et al [24], (1980) demonstrated that no signs of toxicity were verified in dogs once consumption of devices containing six months supply of fluoride (equivalent of 458 mg F). During a further clinical study, identical research group showed no changes in F concentrations in body fluid and urine of human subjects after fitting polymer devices, different investigators additionally incontestible that the utilization of the polymer device was ready to considerably increase secretion and plaque F concentrations while not will increase in urine and body fluids, each in primates and in humans.

For the glass devices, a pilot study compared F levels in plasm of five adult volunteers after ingesting either a glass device pellet or a sodium fluoride pill (2.2 mg NaF) in 2 separate occasions. whereas the uptake of the NaF pill promoted the rise of plasma F
concentrations from 0.01 (baseline) to ~0.1 mg F/mL, returning to baseline levels after one hundred twenty min, no changes were verified after the uptake of the glass device. This incontestible that if a tool is debonded or bust, there's no risk of F absorption into the blood stream.

Regarding local side-effects, some authors reported tissue layer irritation, erythroderma and/or small ulcers in a number of the subjects. On the other hand, a more recent study reported no adverse effects within the oral tissues throughout the study period; the volunteers failed to report discomfort or local irritation, nor found the device large. With relevancy animal tissue indices in children and adolescents, Andreadis, et al.[48](2006) showed no vital variations within the measurements done at days one, ninety and one hundred eighty after the position of a glass device, though there was a tendency for increased plaque retention on the highest of the devices.

RETENTION
Although the utilization of F releasing devices has been proved to be effective in raising salivary F concentrations at levels that cause important reductions in tooth decay prevalence, besides the absence of pharmacological medicine and side-effects, keeping the device in position has been the foremost challenge found by the investigators, no matter the type of the device used. the primary studies conducted with the polymer device showed terribly low retention rates, even in short-run trials. Mirth, et al.[23](1982) reported a sixty five percent of harm rate after thirty five days of placement of the devices. Similar findings were obtained in 50-days and 6-month trials[51], that were conducted so as to enhance the retention rates.

In 1998, Billings, et al.[50] evaluated new ways for retentive the polymer devices intra-orally, that consisted of devices with completely different completely different sizes and shapes combined to different orthodontic-type retainers. After 6 months of analysis, the retention rate was eighty percent , of that 100 percent were still practical. Even higher results were obtained within the study conducted by Giambattista Marino, et al.[34] (1999), during which a new holder referred to as CIPI was tested. This holder was made from a biocompatible elastic alloy designed specifically for odontology patients, consisting of a retentive four-wire cage supplied with a tube and a clasp. once twelve months, the retention rate was bigger than ninety eight. The results obtained from each studies show that it's potential to adequately defend and retain the devices within the mouth for prolonged periods of time.

Retention rates for the glass devices were additionally low within the initial clinical trials, though it had been reported as 100 percent within the initial pilot studies involving one and four subjects, for the amount of eighteen and seven months, respectively15. within the initial massive run, Toumba and Curzon[52] (2005) reported nearly a forty eight percent retention rate using the first “dome-shaped” devices in children. consistent with the authors, the potential reasons for such a coffee rate were associated with the lower co-operation found in kids as compared to adult volunteers; problem in moisture control; incomplete establishment of children's occlusion within the mixed dentition stage; and a deliberate dislodging of the devices by the kid volunteers.

Such low retention rates in kids prompted the event of recent shapes of glass devices and retention ways that would cause a rise in such rates. A simple glass device with circumferential retentive grooves was evaluated by Andreadis, et al.[48] (2006) to be used in kids and adults, as shown in Figure three. once half dozen months of placement, the retention rates were ninety three and eighty six, severally for kids and adults. Such associate improvement within the retention was attributed to the big quantity of composite organic compound used for the attachment of the devices, that provided a considerable bulk, that was ready to resist each masticatory and brushing forces. Besides, one issue that would make a case for the success obtained in kids was that this new form device had a shorter height (2.5 mm, against four millimeter for the recent shape), that is a very important issue once considering that children's molars area unit sometimes not absolutely erupted, therefore the area offered for placement of the device is crucial.

The most recent approach was the development of plastic brackets to be used with dome shaped glass beads. The principle for this new system is that such brackets would be connected just once, so facilitating handling and replacement, besides reducing the majority of the resultant connected device. For adults, eighty five percent of the devices were maintained once 6 months of placement, whereas in children but eight years recent the retention rates were 60 minutes and 1/3 after 1 and 6 months, respectively5. Thus, this new system for placement and replacement of glass devices appear to be a good alternative for adults, whereas the kidney shaped type could be a sensible alternative for children with developing occlusions.

FINAL CONSIDERATIONS:
Although there are a considerable range of studies addressing the consequences of slow-release F devices on intra-oral F levels, furthermore as its effects on de- and remineralisation processes, the good majority of those were in vitro and in place investigations[53]. One recent meta-analysis was conducted so as to evaluate the clinical impact of slow-release F devices on dental caries prevalence, however just one clinical trial fulfilled the standards adopted. However, as previously mentioned, the proof from this study was thought of as not robust as a result of the authors failed to associate degree allies the information on an intention-to-treat basis [52].Thus, it's evident that any clinical trials are still required so as to produce a considerable body of proof that the employment of such devices constitutes an efficient and viable measure for the management of caries. Future investigators ought to take into account the weaknesses noticed by the meta-analysis conducted by Bonner, et al.[53] (2006), that principally enclosed lack of organisation and/or inadequate study style. Besides the employment of those devices in children and alternative well-known patient groups that are non-compliant, have poor attendance and are principally from low socio-economic teams, it'd be instructive
to gauge their use for the interference of enamel and root dental caries in medially compromised groups, ethnic groups, patients undergoing treatment individuals with dentine sensitivity and xerostomia/irradiation patients[54].

In addition, it's value lightness that the employment of the slow-release devices are shown to own a really favourable benefit-cost and cost-effectiveness ratios [9]. Within the trial conducted by Toumba [55](1996), the cost-effectiveness of the glass device was 0.72, which means that the value for saving one dental surface over a amount of 2 years was £0.72.

According to Featherstone [56] (2006), there's a significant anti-caries impact for prime dental caries individuals if a "therapeutic level" of fluoride at a background level of around zero.1 ppm F in secretion is achieved day and night. Any extra fluoride delivery, like twice daily brushing with a fluoride dentifrice, would be a bonus. A sustained-release device that functions to produce identical protection because the glass device noted above should be targeted solely in an exceedingly a lot of acceptable kind to the patients. Such a tool would overcome compliance issues and will be targeted successfully to high caries-risk people. it should not eliminate all dental caries, however would result in dramatic reductions, and together with anti-bacterial treatments may so eliminate dental caries in these people.

**Conclusion:**
Hence fluoride releasing device have a major role in prevention of dental caries, there are major advances in now trendin in the current period, so this has a major role in the current society.

**References:**


