

Clinical evaluation of new designs for intraoral fluoride-releasing systems

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Abstract

Purpose: *Intraoral fluoride-releasing (IFR) devices provide elevated levels of fluoride in the mouth for extended periods of time. However, retention and protection of the devices have posed major challenges for clinical applications. The objectives of this study were to develop new methods for retaining and protecting IFR devices in the mouth and to assess their effects on salivary fluoride levels and distribution in adolescents.*

Methods: *Four different IFR systems (combinations of an IFR device and its retainer) were evaluated in four groups of 10 adolescents each, 12–15 years of age, for a period of six months. Each child wore two IFR systems of a given type affixed to the buccal surface of each permanent maxillary first molar. Unstimulated saliva samples were collected at each clinical examination and analyzed for fluoride.*

Results: *A significant increase in salivary fluoride concentration from a baseline mean of 0.07–0.69 $\mu\text{g}/\text{mL}$ was observed on day 14 postinsertion. IFR system retention was 85% after 6 months and, of the systems retained, 100% were functional.*

Conclusions: *These findings suggest that IFR devices can be successfully protected and retained in the mouth for prolonged periods of time. (Pediatr Dent 20:1 17–24, 1998)*

An intraoral 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.^{1,2} Pharmacologic evaluations of these devices have been carried out in adults³ and in children.⁴ Both groups of investigators reported significantly elevated levels of salivary fluoride while the devices were being worn, without major elevation of serum or urine fluoride concentration. In addition, Mirth et al.³ showed elevated levels of fluoride in dental plaque while the devices were in situ. These studies demonstrated that, in principle at least, it is possible to elevate the levels of fluoride in saliva and plaque using controlled-release devices attached intraorally.

The durability of intraoral devices was studied by Davidson et al.⁵ in 40 children 12–18 years of age during a 6-month period. Only eight of the 40 children studied retained both original devices for the duration of the study. In addition, excessive wear on 10 of the devices necessitated their replacement before the end of the study. There remains a need for a simple method of placing and replacing these devices, as required, while at the same time protecting them from wear. Provisions for such a method would open the way for a clinical trial to study the anticaries efficacy of an intraoral fluoride-releasing device in an appropriate human population. The objectives of this study were: 1) to develop and apply new methods for safely retaining and protecting IFR devices in the mouth, 2) to determine the effects on salivary fluoride levels in adolescents, and 3) to measure the distribution of salivary fluoride within the oral cavity.

Methods

Design of IFR device retainers

The IFR devices used in this study were membrane-controlled, reservoir-type devices with a central core containing sodium fluoride (NaF) intimately mixed with a 50:50 hydroxyethyl methacrylate (HEMA):methyl methacrylate (MMA) copolymer. The core was surrounded by a 30:70 HEMA:MMA copolymer membrane that controlled the rate of fluoride release from the device. All IFR devices were supplied by Southern Research Institute, Birmingham, Alabama, and have been previously described.¹ They were similar to devices used in previous clinical trials.^{3,4}

The IFR systems (combinations of an IFR device and its retainer) for this project consisted of four different stainless-steel IFR device retainers spot welded to plain, standard orthodontic bands selected to match individual permanent maxillary first molars or second premolars. Each IFR device could be inserted into its retainer prior to or after band cementation.

IFR devices were of three types: a small "peanut" shape (type 1a) with dimensions 2.5 X 1.6 X 6.1 mm; a large "peanut" shape (type 1b) with dimensions 3.3 X 2.1 X 8.2 mm; and a "heel" shape (type 2) with dimensions 4.2 X 1.9 X 4.2 mm. The combination of an IFR device with a specific retention mechanism resulted in the four separate IFR systems that were used in this study.

Retention of IFR device types 1b (system 1) and 2 (system 2) was accomplished by ligatures (Figs 1 and 2). Encapsulating retainers were used for IFR device type 1a and had either a hinged lid (system 3) or a sliding drawer (system 4) (Figs 3 and 4). System 3 was exclusively for individuals undergoing orthodontic treatment. IFR devices could be placed or removed in all four designs using cotton pliers or small hemostats. It was not necessary to remove the IFR systems to replace the IFR devices.

Attachment and removal of IFR systems

IFR device retainers were attached to custom-fitted, plain, standard orthodontic bands by spot welding. The resulting IFR systems were attached to permanent maxillary first molars by cementation with a nonfluoride-containing type 1 zinc-phosphate cement (Schein). IFR systems used in the orthodontic group were attached to one of the unused tubes of triple tube brackets affixed to orthodontically banded permanent maxillary molars. An approximate 90% offset bend was made in the stainless-steel arch wire attached to the IFR System housing. The arch wire was then placed such that the IFR system housing, when inserted into the molar bracket tube, was positioned in the buccal vestibule gingival to the second premolar bicuspid. The arch wire was then crimped just distal to the tube to secure the IFRS in the tube. Once the IFR systems were attached, cotton pliers were used to place and replace IFR devices in their retainers. IFR systems 1, 2, and 4 (non orthodontic systems) were removed using band-removing pliers. The orthodontic system (system 3) was removed by first cutting the retaining arch wire with

wire cutters and then removing the IFR device retainer and the remaining arch wire. These latter two tasks could be accomplished using hemostats or cotton pliers.

Study participants

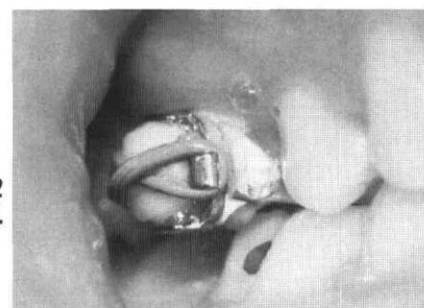
A group of 40 noninstitutionalized community-dwelling children, 12–15 years of age, were recruited from Rochester, NY, metropolitan-area schools for this project. Ten of the children were undergoing active orthodontic treatment. Informed consent was obtained for children who participated in this investigation, and of their parent/guardian. A detailed health history was obtained and all children received an oral examination, including bite-wing radiographs as necessary. To participate in the study, all children were required to be in good general health, good dental health, and to have two fully erupted permanent maxillary first molars and second premolars. Subsequently, all eligible children were assigned to four groups of 10 subjects each. One group consisted of those 10 children undergoing orthodontic treatment. The remaining 30 children were stratified by gender and age, and randomly assigned to one of the three remaining groups. Group 1 children were fitted with system 1, group 2 with system 2, group 3 (the orthodontic group) with system 3, and group 4 with system 4 designs.

Study schedule

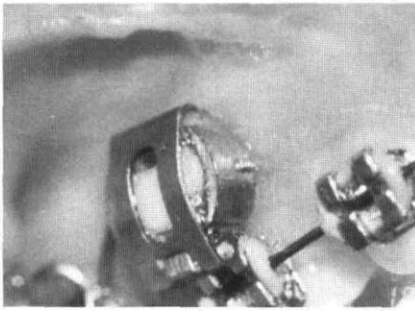
Clinical examinations and saliva collections (described below) were carried out on study days 1, 8, 22, 36, 64, 92, 120, 148, 183, and 190 according to the following protocol. Pretrial data were collected on study day 1. On study day 8, each participant received a rubber cup prophylaxis using a nonfluoride containing prophylaxis paste, immediately after which identical IFR systems were attached to the buccal surface of the maxillary first molars. Therefore, study day 22 corresponds to day 14 after insertion. Clinical and laboratory data were then collected over a 25 week period (study days 8–183). All sys-



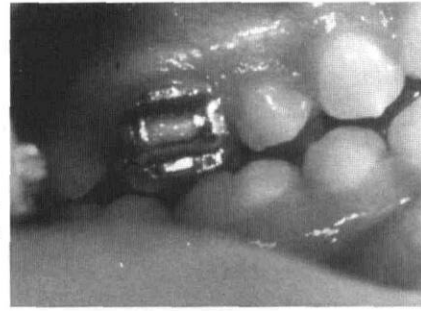
◀ Fig 1. IFR device type 1b (system 1).



▶ Fig2. IFR device type 2 (system 2).



◀ Fig 3. Encapsulating retainer, hinged lid (system 3).



▶ Fig 4. Encapsulating retainer, sliding drawer (system 4).

tems were removed on day 183, immediately after which a second dental prophylaxis was performed, again using a nonfluoride-containing prophylaxis paste. Post-trial data were collected 1 week later, on study day 190.

All participants were allowed to continue their normal oral hygiene procedures throughout this study, except that they were asked to use an American Dental Association-approved fluoride-containing dentifrice. Colgate MFP, containing 1000 ppm fluoride as sodium monofluorophosphate (Colgate-Palmolive Company), was distributed or made available to participants and their families on study days 1, 22, 36, 64, 92, 120, 148, and 183. No attempt was made to conceal the identity of the dentifrice. A variety of soft-bristled toothbrushes were given to all participants and their immediate families on study days 1, 64, and 148, and at other times as requested.

Clinical examinations

In situ IFR system retention, IFR device retention, soft-tissue health, and personal adaptation to the systems were monitored. This study was not designed to assess dental caries during the 6 month trial period. Four examiners were used in the study. One examiner (RJB) served as the "gold standard" for calibration which was performed prior to initiation of the study and at each subsequent examination during the 6-month study period.

The gingival index of Loe and Silness,⁶ using the modified criteria described by Loe,⁷ was used to monitor gingival health in the immediate vicinity of the IFR system and at appropriate control sites. Scores were recorded from the buccal, lingual, and mesial approximal surfaces of each erupted maxillary and mandibular posterior tooth, except third molars, using a standard Michigan periodontal probe (Hu Friedy[®] CPA-PCP 8). The oral soft tissues, particularly those tissues in the vicinity of the IFR system, were carefully inspected initially and at each subsequent examination through the end of the study. In addition, each IFR system was inspected at each ex-

amination for retention of the IFR system and for loose or damaged systems. Finally, all patients were interviewed at each examination regarding their comfort and attitudes toward wearing the systems.

Saliva collection

Two samples of unstimulated whole saliva were provided by each participant on each clinical examination day during the course of the study for fluoride analysis. The first sample was obtained immediately upon rising on the morning of each clinical examination and brought to the examination site at school by the participant. The second sample was obtained under supervision immediately prior to each clinical examination. Each child was instructed to expectorate 3 mL of saliva into a marked 50-mL, screw-cap plastic centrifuge tube both at home and at school. Tubes for home use were given to each child at school on each examination day. All saliva samples were refrigerated and were analyzed within 24 h of collection or were frozen until analyzed.

Saliva fluoride analysis

Saliva fluoride concentration was analyzed as acid-diffusible fluoride according to the Taves method.⁸ A calibration curve using appropriate standards similarly diffused was constructed each time and the fluoride content of the sample was then calculated in absolute $\hat{\text{E}}\text{g}$ of fluoride. The fluoride concentration in $\mu\text{g}/\text{mL}$ of original sample was then calculated.

Measurement tu patterns of fluoride distribution

Fluoride distribution in the mouths of subjects wearing IFR systems was evaluated using a modification of the method described by Weatherell et al.⁹ Samples of unstimulated whole saliva were collected from each quadrant in each subject on study days 64 and 92 using acid-washed cotton swabs.¹⁰ The swab stems were shortened to fit each swab into 1.5-mL plastic tubes. Each tube and its accompanying swab was numbered and weighed. Saliva was collected by removing a swab from its preweighed container with a surgical hemostat and passing it once around the

facial tooth surfaces and soft tissues of the designated quadrant. The saliva-coated swab was returned to its tube, tightly sealed, reweighed, and analyzed for fluoride concentration as described above.

IFR device wear analysis

Following their removal from the mouth, all IFR devices were examined for signs of wear or damage with the aid of a stereo microscope (5–10x magnification). IFR devices observed to be worn or damaged at the lower magnification were examined in greater detail at higher magnification. Each IFR device was positioned under a video camera connected to an Olympus® (Olympus, Inc., Tokyo, Japan) Image Analysis System with Optimus™ (Bioscan, Inc., Edmonds, WA) software. Each sample was “shadow lit” from one side, highlighting the outer shell and enabling the relief to be observed and measured. With the aid of a mouse, a line was drawn on the video image screen on the edge of the IFR device to mimic the original surface. In this way, surface wear or damage relative to the original contour of the IFR device outer shell could be qualitatively estimated.

Data management and analysis

Analysis of the in situ fluoride data was performed using a split-plot analysis of variance (ANOVA). The gingival index data were analyzed using repeated-measures ANOVA, with separate analyses also performed using the data from each quadrant in the mouth. A level of significance of 0.05 was employed in all statistical tests.

Results

The study subjects are presented in Table 1. The groups were balanced with respect to age and gender distribution. Of the 40 subjects enrolled in the study, 29 had both IFR systems in place at the end

of the 6-month study interval. About 45% (5 of 11) of those not completing the study with both systems in place were from the orthodontic group (system 3). However, in terms of age and sex, the individuals that did not complete the study with both systems in place were not different from those that did complete the study with both systems.

Of the 80 IFR systems placed, 12 systems were dislodged or damaged as a result of cement failure or mechanical problems and were not replaced. In addition, 20 IFR devices (in seven different children) were dislodged during the course of the study as a result of ligature failure or other mechanical problems not associated with the basic integrity or retention of the IFR device retainer. Dislodged IFR devices were replaced as necessary during the study (20 devices). Thirty-nine children retained at least one IFR system for the duration of the study and 29 children retained both IFR systems for the duration of the study. Of these 29, 23 retained the original IFR system without need for replacement.

IFR system integrity

No children withdrew from the study and no adverse reactions were observed or reported during the 6 months of the clinical trial. No IFR systems were removed from the study because of irritation or at the request of participants or their parent/guardian. No children experienced any serious or untoward soft-tissue reactions or any other reactions attributable to the presence of the IFR systems. A mild inflammatory response accompanied by mild soreness or discomfort was noted on the day following placement in six children. Both resolved after 48–72 h.

All study participants responded to questions on comfort and acceptance of the IFR systems. Overall, the children adapted well to wearing the IFR systems. After the first week, the majority of children

TABLE 1. SUBJECTS BY SYSTEM GROUP

System	All subjects (N = 40)			Subjects with two IFR systems (N = 29)		
	Male	Female	Mean Age (SD)	Male	Female	Mean Age (SD)
1	6	4	14.2 (0.75)	5	3	14.0 (0.71)
2	5	5	14.1 (0.94)	5	5	14.1 (0.94)
3	4	6	12.9 (0.83)	1	4	13.0 (0.89)
4	5	5	13.7 (1.00)	3	3	13.3 (0.94)

Subjects not completing the study with both IFR systems (n = 11, 6 male, 5 female, mean age 13.7) were similar to those who completed the study with both IFR systems (n = 29, 14 male, 15 female, mean age 13.7).

commented that they were no longer aware of the presence of the IFR systems and indicated that they would be willing to wear them indefinitely.

Clinical examinations

Gingival index scores were analyzed using repeated-measures ANOVA. As the purpose of these analyses was to assess the effect of the presence of an IFRS on the gingival tissues after various, specified lengths of time, only data obtained from those subjects who retained both IFR systems for the duration of the 6 month trial period were analyzed. Preliminary analyses of the day 1 GI scores indicated the presence of a significant difference between system 3 (the orthodontic group) and the other three groups. There were no significant differences among systems 1, 2, and 4. This pattern continued throughout the study, as was indicated by the

lack of any significant "System by Day" interaction. No significant difference in mean GI scores was observed between days 1 and 8; however, significant increases in scores were subsequently observed between days 8 and 22, and between days 22 and 36. After day 36, no significant changes were observed throughout the remainder of the study, except for a significant decrease in scores between days 183 and 190 in the maxillary quadrants only. Table 2 summarizes the patterns described above more generally as Pre-trial, Trial, and Post-Trial levels for each system.

IFR system wear

IFR devices held in place by elastic or wire ligatures (systems 1 and 2) showed visual evidence of wear. The outer membrane appeared to be worn through in areas directly exposed to the oral environment. No wear of IFR devices contained in the encapsulated retainers (systems 3 and 4) was observed. IFR devices retained by ligatures were also deformed as a result of the restraining forces generated by the ligatures. There was no deformation of IFR devices contained in encapsulated retainers. There was no discernible wear of the IFR device retainers or their accompanying orthodontic bands. The wire ligatures demonstrated no wear. Although the elastic liga-

TABLE 2. GI SCORES (MEAN ± SD) BY IFRS GROUP AND TRIAL PERIOD FOR ALL INDIVIDUALS (N = 40).

System	Pre-Trial	Trial	Post-Trial
	(Mean ± SD) (Days 1 & 8)	(Mean ± SD) (Days 22-183)	(Mean ± SD) (Day 190)
1	0.42 ± 0.18	0.85 ± 0.14	0.77 ± 0.22
2	0.40 ± 0.15	0.82 ± 0.15	0.74 ± 0.12
3	0.76 ± 0.19	1.01 ± 0.06	1.03 ± 0.05
4	0.37 ± 0.16	0.75 ± 0.19	0.77 ± 0.21

TABLE 3. IN SITU FLUORIDE DISTRIBUTION (MEAN ± SD) IN µG/G BY SYSTEM GROUP AND QUADRANT.

System	Day 64*		Day 92†	
	(Mean ± SD)		(Mean ± SD)	
	Upper Left / Lower Left	Upper Right / Lower Right	Upper Left / Lower Left	Upper Right / Lower Right
1	1.73 ± 1.28	1.63 ± 1.06	0.99 ± 0.40	0.80 ± 0.38
	1.45 ± 0.77	1.54 ± 0.85	0.69 ± 0.42	0.76 ± 0.75
2	2.26 ± 1.21	2.12 ± 1.58	1.58 ± 1.79	1.27 ± 0.65
	1.77 ± 1.54	1.35 ± 1.36	0.91 ± 0.55	1.21 ± 1.04
3	2.37 ± 1.63	2.92 ± 1.56	1.09 ± 1.18	1.43 ± 1.34
	2.02 ± 0.77	1.45 ± 0.92	0.54 ± 0.68	0.67 ± 0.63
4	1.62 ± 0.81	2.20 ± 1.96	1.05 ± 0.72	0.88 ± 0.57
	1.92 ± 1.05	1.55 ± 1.35	0.70 ± 0.44	0.60 ± 0.42

* Day 64 fluoride distribution between the maxillary and mandibular arch is significant (P = 0.002).

† Day 92 fluoride distribution between the maxillary and mandibular arch is significant (P = 0.003).

tures lost both resiliency and elasticity, and were somewhat brittle upon removal, they nevertheless retained IFR devices satisfactorily.

Saliva fluoride concentration

With respect to fluoride concentration there were no differences when all of the systems were compared with one another (Fig 5). The mean salivary fluoride concentration prior to placement of the IFR devices was $0.07 (\pm 0.09 \text{ SD}) \mu\text{g/mL}$. On day 14 postinsertion (study day 22), the mean salivary fluoride concentration measured in the samples collected at home was $0.69 (\pm 0.42 \text{ SD}) \mu\text{g/mL}$ ($P = 0.0001$). This level of salivary fluoride was maintained until the IFR systems were removed (day 183). Salivary fluoride concentration returned to baseline levels 1 week following IFR device removal (day 190). Salivary fluoride concentration, as expected, was greater immediately upon rising (home sample) than at the supervised collections at school later in the morning. There was greater interperiod variation in the fluoride concentration from samples of saliva obtained by the children at home (immediately upon rising) compared to the samples obtained at school under supervision.

In situ fluoride distribution

As shown in Table 3, analysis of the data revealed no significant differences in fluoride concentration between the maxillary right and left quadrants on days 64 or 92 among those 29 children who retained both IFR systems for the duration of the 6-month trial period. Similarly, there were no significant differences in fluoride concentration between the mandibular right and left quadrants. However, there was a significant difference between

the maxillary and mandibular arch on day 64 ($P = 0.002$) and on day 92 ($P = 0.003$) which indicates a greater distribution of fluoride in the maxillary arch relative to the mandibular arch. Wear of IFR devices was greater in systems 1 and 2 than in the encapsulated systems (systems 3 and 4), however, this did not seem to be reflected in the group-specific fluoride levels in situ.

Discussion

The first purpose of this project was to develop and apply new methods for retaining IFR devices safely and securely in the mouth. Four different mechanical IFR systems were evaluated in four groups of 10 children for 6 months. All of the children readily acclimated to the presence of the IFR systems. No adverse reactions were noted. Oral tissue soreness and inflammation associated with the placement of the bands were transient and disappeared completely within 72 h. Gingival irritation due to the presence of the orthodontic bands, though present, was mild and clinically insignificant.

Close inspection of each dislodged IFR device did not reveal the underlying cause of dislodgement, although oral habits were suspected in at least one case. Minor modification of the tie-wings for the ligatures in system 1 and 2 would likely prevent IFR device dislodgement due to oral habits such as chewing gum or sticky candies. Ten systems were dislodged as a result of preventable mechanical problems; use of a stronger cement or directly bonding the brackets to the tooth surface would overcome this type of system retention problem. Polycarboxylate cement was not used in this study because of the concern that its high fluoride content would interfere with

in situ fluoride measurements. The consequences of wear and deformation observed in system 1 and 2 IFR devices on fluoride release, or on their ultimate longevity or durability, is unknown. However, on the basis of the salivary fluoride concentrations observed on each study examination day, the net effect on fluoride releasing patterns in situ appeared to be negligible.

The second purpose of this study was to determine the effects of the IFR Devices on salivary fluoride levels. All children demonstrated a significantly elevated

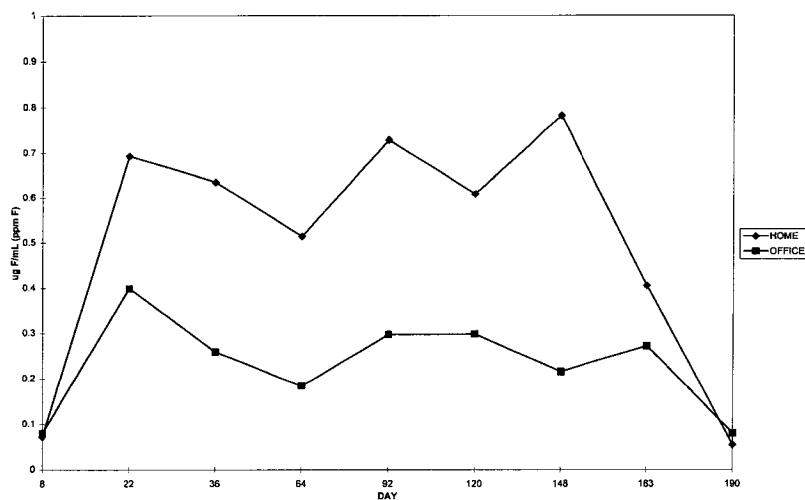


Fig 5. Mean salivary F concentration.

salivary fluoride concentration during the trial phase of this study (day 8–183). These observations were consistent with those of Mirth et al.³ and Kula et al.⁴ Salivary fluoride concentration returned to baseline within 1 week following removal of the IFR systems.

The interperiod variation in the fluoride concentration from samples of saliva obtained by the children at home (immediately upon rising) on each examination day compared to the samples obtained at school under supervision was anticipated and provided the rationale for obtaining the additional supervised saliva sample immediately preceding each clinical examination. The most likely cause of the interperiod variation in the home samples was poor compliance with the request to obtain the sample immediately upon rising, before drinking, eating, or brushing.

The third objective of this study was to assess the intraoral distribution of the fluoride released by the IFR devices. The finding that fluoride was concentrated more highly in the maxillary arch, in the vicinity of the IFR devices, than in the mandibular arch is in agreement with the oral fluoride clearance patterns reported by Weatherell et al.⁹ However, the clinical significance of this observation regarding caries prevention remains to be elucidated; fluoride levels in the mandibular arch were still well above the concentration generally regarded as necessary for optimal protection against caries.¹¹

One of the problems encountered during this study was the damage to IFR systems in orthodontic patients (system 3). Apparently, the arch wires for system 3 attracted a great deal of curiosity from attending orthodontists, such that a relatively large proportion of IFR system failures in this group occurred immediately following an orthodontic appointment. This was unfortunate, as system 3 appeared to be superior to the other three designs in many respects. System 3 retainers, designed to hold IFR devices within the retainer by using a hinged perforated lid, were easy to attach and remove; IFR devices could be inserted and removed from them quickly without special instruments. These retainers could be custom-positioned for comfort and access in orthodontic patients, or could be fastened to plain, standard bands or direct bonded for use in patients not undergoing orthodontic treatment. Also, system 3 retainers were less bulky, accumulated less plaque and debris than other systems, and offered greater protection from abrasion and damage to the IFR device than systems 1 and 2. Undoubtedly, methods of attaching and protecting IFR devices in the mouth can be refined further.

Conclusions

The results of this study clearly show

1. Relatively low but elevated levels of fluoride can be maintained for prolonged periods in the mouth with all four of the tested IFR systems. Salivary levels of 0.2 µg/mL fluoride or greater would be expected to inhibit the development of dental caries, based on both in vitro and in situ studies.^{11–13} However, long-term clinical studies assessing the true anticariogenic efficacy of IFR devices in humans are needed.
2. Intraoral fluoride-releasing devices have substantial potential to inhibit caries development in these and other populations with special needs. Dental caries continues to be a problem for many of the world's children and it can be a serious problem for medically compromised, developmentally disabled, and elderly individuals.

Dr. Billings is professor and director, Ms. Shields is assistant professor, and Dr. Moss is assistant professor, all at the Eastman Dental Center, Rochester, New York. Dr. Adair is professor and chairman, Department of Pediatric Dentistry, Medical College of Georgia, Augusta, Georgia.

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