European Journal of Orthodontics 21 (1999) 695–701

A retentive system for intra-oral fluoride release during orthodontic treatment

I. Marini, G. A. Pelliccioni, F. Vecchiet, G. Alessandri Bonetti and L. Checchi
Department of Oral Surgery, School of Dentistry, University of Bologna, Italy

SUMMARY The aim of this study was to test a particular type of intra-oral fluoride releasing device (IFRD), designed to release 0.04 mg/day of fluoride over a period of 6 months, using customized holders, in patients receiving orthodontic treatment.

Discomfort, holder detachment, plaque accumulation near the device, and the presence of gingivitis, bleeding, white spot lesions, and/or decay was recorded in 76 orthodontic patients (53 experimental and 23 controls) before and after wearing the device for 12 months.

The system proved to be easy and quick to use, and did not cause discomfort. There were no significant differences between the treated and the control groups for plaque index, bleeding, or the presence of gingivitis. In addition, no carious and/or white spot lesions occurred during the duration of this study in the test group.

Introduction

The preventive effects of fluoride against caries, as well as its ability to remineralize early lesions of the enamel, are well-known (Brown *et al*., 1977; Zero *et al*., 1988; Burt, 1992; Levy *et al*., 1995; Linton, 1996).

The white spot lesion 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. These lesions occur in approximately 6–8 per cent of subjects during orthodontic treatment with fixed appliances (Ingervall, 1962; Mizrahi, 1983; Årtun and Brobakken, 1986).

Fluoride supplements and good oral hygiene have been shown to be effective in reducing or eliminating white spot lesions (Ten Cate *et al*., 1985; Geiger *et al*., 1988; Ten Cate and Featherstone, 1996), due to the presence of fluoride ions, which promote the replacement of soluble apatite crystals with less soluble crystals (LeGeros and Silverstone, 1983; LeGeros and Tung, 1983; LeGeros, 1990). However, high levels of fluoride may cause surface precipitation and, in such cases, the lesion will not be reduced. Low levels of fluoride in solution form promote the formation of (F_2OH) apatite and the increase in fluoride ion levels lead to the formation of calcium fluoride (CaF_2), which produce a reservoir of F ions for the formation of (F_2OH) apatite (Linton, 1996). These low levels of fluoride occurring with frequent applications would result in the remineralization of the entire depth of the white spot lesions (Hicks *et al*., 1985; Ten Cate *et al*., 1985; Mellberg, 1988). Similarly, experimental studies have shown that the constant presence of low levels of fluoride in saliva reduces the incidence of caries (Mirth *et al*., 1983, 1985).

A new system for achieving a constant rate of continuous fluoride release in the oral cavity is the intra-oral fluoride releasing device (IFRD). This is a membrane-reservoir type system, which is formed by an internal element (the matrix), and contains granulated sodium fluoride and an external housing (the membrane fluoride retainer).

These devices are manufactured with copolymers designed to contain predetermined quantities of hydrophilic (hydroxyethylmethacrylate) and

Figure 1 'CIPI' with IFRD inserted.

Figure 2 'CIPI' with IFRD inserted in the hook of a molar tube for orthodontic patients.

hydrophobic (methylmetha-crylate) substances. This allows them to absorb a predictable (and repeatable) quantity of water and, at the same time, work as hydrogels. The hydration of the device leads to fluoride release according to Fick's first law of diffusion (Mirth *et al*., 1982; Mirth, 1987).

Once placed inside the mouth, the IFRD becomes hydrated by saliva and its characteristics lead it to release a constant rate of sodium fluoride of 0.02–1.0 mg per day for up to 4 or 6 months, depending on the size of the device.

The 'CIPI' (IDECO, Linear r.l., Bolanzo, Italy) is a new IFRD holder made of a biocompatible elastic alloy which is specifically designed for orthodontic patients and consists of a retentive four wire cage provided with a cannula and a clasp (Figure 1). The cage contains the IFRD, and is secured by the cannula and a clasp to the molar tube (Figure 2). The canula is inserted into the hook of the molar tube and works as a hinge to open and close the cage. A distal stop prevents the 'CIPI' from sliding out of the hook. The clasp allows the cage to be blocked on the headgear tube and prevents opening during mastication (Figure 3).

The aim of this study was to assess the effectiveness of the 'CIPI' in orthodontic patients, evaluating its influence on periodontal health, caries formation, and the possible increase in plaque accumulation in the adjacent areas.

Materials and methods

In order to estimate the quantity of *in vivo* fluoride released by the IFRD, an *in vitro* procedure suggested by the Southern Research Institute, Birmingham, Alabama, USA, was used.

Method for determining fluoride release in vitro

The release of fluoride ion from the IFRD was determined by equilibrating a device in deionized

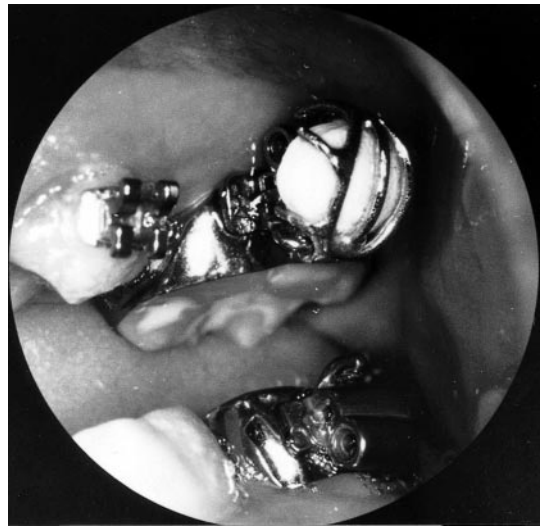

Figure 3 'CIPI' with IFRD in the mouth.

water at 37°C. Although other aqueous solutions, such as a synthetic saliva, can be used to simulate the ionic strength of real saliva, deionized water is suitable when the intent of the assay is for quality control to determine device-to-device variability. The fluoride ion release was quantified using an ion-selective electrode (ISE) and an appropriate total ionic strength adjustment buffer (TISAB). An Orion 960900 combination fluoride ion-selective electrode and TISAB II were used in this investigation. A general outline of the procedure is provided below. Only plastic laboratory ware was used in the study since fluoride ion adsorbs onto glass, especially at low concentrations. Aluminium cap liners should therefore be avoided as aluminium ion interferes with the detection of fluoride by the ISE.

For each IFRD to be tested, 20 ml of deionized water was placed in a plastic scintillation vial and equilibrated at 37°C. The IFRDs were immersed in the pre-warmed water, the vials replaced in the incubator and the time recorded. After 24 hours, the vials were removed from the incubator and the IFRDs transferred to the vials of fresh deionized water (pre-warmed, and labelled with device number and time designator), and the time recorded. The water was allowed to cool and assay for fluoride ion release was carried out. Steps 3 and 4 were repeated on days 2, 3, 4, 7, 9, 11, 14, 16, 18, 21, 23, and 25, and then at 14-day intervals (a total of 150 days). For each IFRD, the amount of fluoride ion released during each interval (concentration × volume × dilution factor) was calculated and divided by the interval (in days) to determine the release rate at each sample time. The group average and standard deviation at each time was determined.

The study was carried out on 76 patients, 41 female and 35 male, 8–18 years of age, (average 13.01 years) who had been undergoing orthodontic treatment for at least 4 months. All patients were from the city of Brescia and its province. Fluoride concentration in drinking water was 0.12 µg/l in the city and 0.05 µg/l in the province. No patient received antibiotic treatment or had any periodontal therapy during the 3 months preceding the study, except for routine scheduled professional oral hygiene procedures. The subjects involved were fully informed of possible discomfort or benefits of the procedure, and their permission was obtained prior to application of the IFRD and of radiographic examination.

For each patient, a full mouth intra-oral radiographic examination was undertaken. A complete intra-oral and dental examination was performed, and the presence/absence, and the number of caries and white spot lesions, the presence/absence of gingivitis, the gingival index, and the level of plaque accumulation on all molars and on upper incisors using the banded-bracket index, where: 0 = absence of plaque on attachment or tooth surface; 1 = plaque only on the attachment; 2 = plaque on attachment and tooth, not extending to gums; 3 = plaque on attachment and tooth, extending to papilla; 4 = plaque on attachment and tooth, gums partially involved; 5 = plaque on attachment and tooth, and involving all gums (Ciancio *et al*., 1984) were recorded.

The patients were randomly divided into two groups:

Group 1: fifty-three individuals were fitted with an IFRD of a larger size, releasing 0.04 mg/day of fluoride during 6 months. In patients with orthodontic bands on all upper and lower molars it was possible to use the holder. The study ran for 12 months and IFRDs were replaced at their date of expiry.
Group 2: Twenty-three individuals forming the control group received no device and were followed for 12 months.

An examination was performed every month by the same person and the following data were recorded:

(1) the (banded-bracket) plaque index;
(2) holder detachments;
(3) the gingival index (Löe and Silness, 1963) in the immediate vicinity of the IFRD. Scores were recorded from the buccal, lingual, and mesial approximal surfaces of each erupted maxillary and mandibular posterior tooth using a periodontal probe;
(4) bleeding on probing (Löe, 1967) in the immediate vicinity of the IFRD holder;

Table 1 The mean of banded-bracket index for two groups during 1 year.

	Before IFRD	Time (months) 1	2	3	4	5	6	7	8	9	10	11	12
Holder group	2.52	1.81	1.83	1.58	1.53	1.04	1.55	1.53	1.53	1.13	1.31	1.38	1.23
Control group	2.50	1.90	1.91	1.63	1.63	1.54	1.54	1.01	1.53	1.23	1.37	1.38	1.40

(5) the presence of caries and/or white spot lesions.

Each tooth was checked for the presence of carious or spot lesions. The white spots were determined by visual inspection and then photographed from two different projections to obtain colour slides, according to a standardized macrophotographic procedure to minimize reflection on the tooth surface.

All patients were asked to report any speaking or chewing discomfort, as well as lesions on the buccal mucosa.

Data were compared using the ANOVA test. The significance level was selected as $P < 0.001$.

Results

Over the 12-month period, one out of 53 holders became detached. Three patients reported opening of the holder during oral hygiene procedures. The IFRDs were recovered by the patients themselves and re-applied by the dentist.

No adverse reactions were observed in the oral tissue, such as inflammation or lesions. All the patients stated they wore the device without any pain or stress.

The plaque index values on the molars were similar in the two groups, as shown in Table 1. There were no significant differences between groups 1 and 2. The plaque index values for the upper incisors were lower than the molars, but not significantly ($P = 0.05$).

Gingival index scores were analysed, but there were no significant differences found between the two groups.

Table 2 shows the IFRD fluoride ion release *in vitro* and Figure 4 the temporal pattern of *in vivo* fluoride release. At the end of the study, one showed tooth decay (tooth 85) and one a white spot lesion (tooth 12) in the control group, but no lesions were observed in the study group.

Discussion

The results show that the 'CIPI' does not cause oral hygiene problems and the quantity of plaque accumulated on the holder was no different from that found with any other system of direct orthodontic attachment on the molars. Discomfort (such as pain, nausea, and vomiting or lesions of the mucosa) were absent. All patients on being informed of the anticarious effects of fluoride, requested replacement of the device on its expiry as they considered it to be of great help and did not cause any problems.

Recent studies have shown that between 50 and 75 per cent of orthodontic patients develop demineralization on the buccal surfaces during fixed appliance therapy (Gorelick *et al*., 1982; Øgaard *et al*., 1997). Various systems have been proposed to prevent this problem, such as fluoride mouth-rinses, fluoride-releasing bonding materials and ionomer cements, and fluoridated toothpastes (Ciancio *et al*., 1984; Duckworth *et al*., 1987; Bruyn *et al*., 1988; Sonis and Snell, 1989; Banks and Richmond, 1994; Marcusson *et al*., 1997). In the case of mouth-rinses collaboration by the patient is needed and compliance is often poor.

The use of a fluoride-releasing adhesive in combination with fluoridated toothpaste does not increase the fluoride level in saliva after

Table 2 IFRD fluoride ion release with respect to time. Data obtained with 20 devices.

Time (days)	Mean (mg/day)	SD (mg/day)	Time (days)	Mean (mg/day)	SD (mg/day)
0.72	0.009	0.004	34.05	0.04	0.01
1.73	0.032	0.008	37.05	0.04	0.01
2.7	0.036	0.009	39.15	0.039	0.01
3.73	0.037	0.009	51.1	0.04	0.01
4.68	0.038	0.009	66.06	0.041	0.011
5.87	0.042	0.011	79.96	0.042	0.011
8.78	0.041	0.01	93.73	0.041	0.011
11.72	0.044	0.01	107.68	0.041	0.01
13.69	0.042	0.01	121.77	0.041	0.01
17.81	0.041	0.01	136	0.041	0.011
20.06	0.042	0.011	149.76	0.041	0.011
22.79	0.04	0.01	163.69	0.041	0.011
25.08	0.04	0.01	177.71	0.041	0.011
27.74	0.04	0.01	192.08	0.042	0.011
30.04	0.04	0.01	205.95	0.042	0.011
32.12	0.04	0.01			
Mean					0.041
SD					0.01

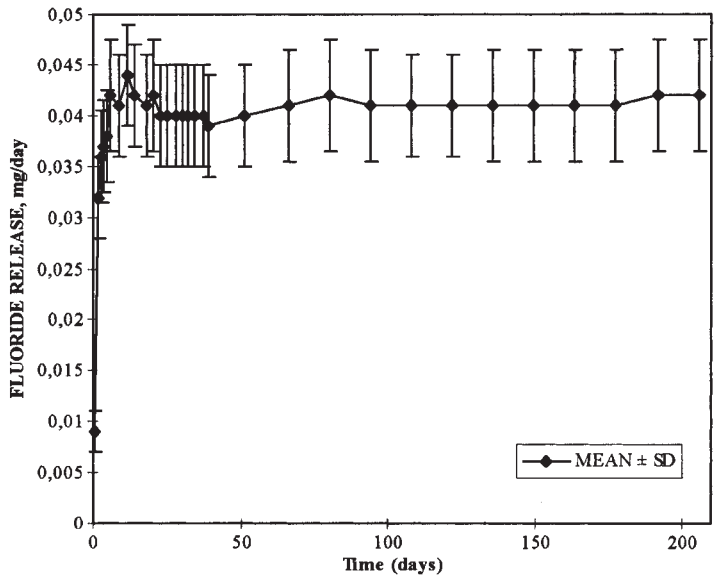

Figure 4 Measurement of *in vivo* release of fluoride ion from IFRD.

bonding. The adhesive inhibits lesion development only in areas adjacent to the bracket (Øgaard *et al*., 1992; Hallgren *et al*., 1993).

Although a number of authors have reported a considerable increase of fluoride concentration in saliva following glass ionomer cement (GIC) restoration (Koch and Hatibovi'c-Kofman, 1990; Hatibovi'c-Kofman and Koch, 1991), when GIC is used as an orthodontic adhesive its fluoride release (Hallgren *et al*., 1990) occurs within the first 24 hours and falls to a low plateau after several weeks (Bilgin and Ozalp, 1998). On the

basis of the salivary fluoride concentrations observed at each examination day, all the children in the study presented a significant increase in fluoride concentration.

The fluoride concentration in the whole saliva increased from a pre-treatment value of 0.05 μg/ml to 0.46 μg/ml during the treatment phase. IFRDs release fluoride continuously over time, 24 hours a day over 6 months, so that ionic fluoride is present in saliva, at a very low concentration, shortly after its application (Duxbury *et al*., 1982). This appears to be a very good system both to avoid white spots and to prevent areas of demineralization. Moreover, some studies show that the daily release rate of 0.04 mg of fluoride is sufficient to lower the incidence of caries in children (Mirth *et al*., 1985; Mirth, 1987; Billings *et al*., 1998). Furthermore, the dosage being extremely low means that there is no risk of fluorosis even if it is administered in association with other fluoride containing substances. These additional sources of fluoride include: tablets, toothpaste, dietary supplementation, mouthrinses, processed food and beverages, and pesticides (Morgon *et al*., 1998).

Good oral hygiene and improved dietary habits are essential prerequisites to initiate the healing process of white spot lesions. Nevertheless, it has long been demonstrated that fluoride is the most common element used for the remineralization of white spot lesions and for preventing caries (Brown *et al*., 1977; Ten Cate *et al*., 1985; Burt, 1992; Levy *et al*., 1995; Linton, 1996; Ten Cate and Featherstone, 1996).

The 'CIPI' is an easy, fast, and cost-effective procedure for the application of IFRDs in orthodontic patients. However, unlike fluoride gels, which can often cause nausea and vomiting following accidental ingestion during application (Beal and Rock, 1976; Duxbury *et al*., 1982), IFRDs have no flavour and none of the patients in this study reported any of these symptoms.

This technique may also be suitable for disabled subjects as it does not require any collaboration from the patient, who simply returns to the dental practice every 6 months to receive a new device.

Long-term follow-up studies and investigations will be necessary to further evaluate the system IFRD-'CIPI'.

Address for correspondence

Ida Marini
Via Sant'Angela Merici 60 – 25100
Brescia
Italy

Acknowledgements

The authors wish to thank the SBS Southern BioSystems, Inc., Birmingham, AL, USA, for their collaboration.

References

Årtun J, Brobakken B O 1986 Prevalence of caries white spots after orthodontic treatment with multi-bonded appliances. European Journal of Orthodontics 8: 229–234

Banks P A, Richmond S 1994 Enamel sealants: a clinical evaluation of their value during fixed appliance therapy. European Journal of Orthodontics 16: 19–25

Beal J F, Rock W P 1976 Fluoride gels: a laboratory and clinical study. British Dental Journal 140: 307–310

Bilgin Z, Ozalp N 1998 Fluoride release from three different types of glass ionomer cements after exposure to NOF solution and APF gel. Journal of Clinic Pediatric Dentistry 22: 237–241

Billings R J, Adair S A, Shields C P, Moss M E 1998 Clinical evaluation of new design of intra-oral fluoride releasing systems. Pediatric Dentistry 20: 17–24

Brown W E, Gregory T M, Chow L C 1977 Effects of fluoride on enamel solubility and cariostasis. Caries Research 11: 118–124

Bruyn H D, Van Rijn L J, Purdell-Lewis D J, Arends A 1988 Influence of various fluoride varnishes on mineral loss under plaque. Caries Research 22: 76–83

Burt B A 1992 The changing patterns of systemic fluoride intake. Journal of Dental Research 71: 1228–1237

Ciancio S, Cunat J, Mather M, Harvey D J 1984 A comparison of plaque accumulation in bonded vs. banded teeth. Journal of Dental Research 64: 359 (Abstract)

Duckworth R M, Morgan S N, Murray A M 1987 Fluoride in saliva and plaque following use of fluoride-containing mouthwashes. Journal of Dental Research 66: 1730–1734

Duxbury A J, Leach F N, Duxbury J T 1982 Acute fluoride toxicity. British Dental Journal 153: 64–66

Geiger A M, Gorelik L, Gwinnett A J, Groswold P G 1988 The effect of a fluoride program on white spot formation during orthodontic treatment. American Journal of Orthodontics and Dentofacial Orthopedics 93: 29–37

Gorelick L, Geiger A M, Gwinnett A J 1982 Incidence of white spot formation after bonding and banding. American Journal of Orthodontic 81: 93–98

Hallgren A, Oliveby A, Twetman S 1990 Salivary fluoride concentration in children with glass ionomer cement orthodontic appliances. Caries Research 24: 239–241

Hallgren A, Oliveby A, Twetman S 1993 Fluoride concentration in plaque adjacent to orthodontic appliances retained with glass ionomer cement. Caries Research 27: 51–54

Hatibovi'c-Kofman S, Koch G 1991 Fluoride release from glass ionomer cement *in vivo* and *in vitro*. Swedish Dental Journal 15: 253–258

Hicks M J, Flaitz C M, Silverstone L M 1985 Initiation and progression of caries-like lesions of enamel: effect of periodic treatment with synthetic saliva and sodium fluoride. Caries Research 19: 481–489

Ingervall B 1962 The influence of orthodontic appliances on caries frequency. Odontologisk Revy 13: 175–190

Koch G, Hatibovi'c-Kofman S 1990 Glass ionomer cements as a fluoride release system *in vivo*. Swedish Dental Journal 14: 267–273

LeGeros R Z 1990 Chemical and crystallographic events in the caries process. Journal of Dental Research 69: 567–574

LeGeros R Z, Tung M S 1983 Chemical stability of carbonate and fluoride containing apatites. Caries Research 17: 419–429

LeGeros R Z, Silverstone L 1983 *In vitro* caries-like lesion formation in F-containing tooth enamel. Journal of Dental Research 62: 138–144

Levy S M, Kiritsy M C, Warren J J 1995 Sources of fluoride intake in children. Journal of Dental Public Health 55: 39–52

Linton J L 1996 Quantitative measurements of remineralization of incipient caries. American Journal of Orthodontics and Dentofacial Orthopedics 110: 590–597

Löe H 1967 The gingival index, the plaque index, and the retention index systems. Journal of Periodontology 38: 610–616

Löe H, Silness J 1963 Periodontal disease in pregnancy. I. Prevalence and severity. Acta Odontologica Scandinavica 21: 533–551

Marcusson A, Norevall L T, Persson M 1997 White spot reduction when using glass ionomer cement for bonding in orthodontics: a longitudinal and comparative study. European Journal of Orthodontics 19: 233–242

Mellberg J 1988 Remineralization: a status report. Part 1. American Journal of Dentistry 1: 39–43

Mirth D B 1987 Controlled-release therapeutic systems: technology applicable to the treatment of oral disease. Advances in Dental Research 1: 109–118

Mirth D B, Shern R J, Emilson C G 1982 Clinical evaluation of an intra-oral device for the controlled release of fluoride. Journal of the American Dental Association 105: 791–797

Mirth D B, Adderly D D, Amsbaugh S M, Monell-Torrens E, Li S H, Baren W H 1983 Inhibition of experimental dental caries using an intra-oral fluoride releasing device. Journal of the American Dental Association 107: 55–58

Mirth D B, Adderly D D, Monell-Torrens E, Amsbaugh S M, Li S H, Baren W H 1985 Comparison of cariostatic effect of topically and systemically administered controlled-release fluoride in the rat. Caries Research 19: 466–474

Mizrahi E 1983 Surface distribution of enamel opacities following orthodontic treatment. American Journal of Orthodontic 84: 323–331

Morgon L, Albred E, Tavares M, Bellinger D, Needleman H 1998 Investigation of the possible associations between fluorisis, fluoride exposure, and childhood behaviour problems. Pediatric Dentistry 20: 244–252

Øgaard B, Rezk-Lega F, Ruben J, Arends J 1992 Cariostatic effect of fluoride release from a visible light-curing adhesive for bonding of orthodontic brackets. American Journal of Orthodontics and Dentofacial Orthopedics 101: 303–307

Øgaard B, Arends J, Helseth H, Dijkman G, Van der Kuif M 1997 Fluoride level in saliva after bonding orthodontic brackets with a fluoride containing adhesive. American Journal of Orthodontics and Dentofacial Orthopedics 111: 199–202

Sonis A L, Snell W 1989 An evaluation of a fluoride-releasing, visible light-activated bonding system for orthodontic bracket placement. American Journal of Orthodontics and Dentofacial Orthopedics 95: 306–311

Ten Cate J M Featherstone J D B 1996 Physico-chemical aspects of fluoride enamel interactions. In: Fejerskov O, Ekstrand J, Burt A (eds) Fluoride in dentistry. Munksgaard, Copenhagen, pp. 252–272

Ten Cate J M, Shariati M, Featherstone J D B 1985 Enhancement of (salivary) remineralization by 'dipping' solutions. Caries Research 19: 335–341

Zero D, Fu J, Espeland M, Featherstone J 1988 Comparison of fluoride concentrations in unstimulated whole saliva following the use of a fluoride dentifrice and a fluoride rinse. Journal of Dental Research 67: 1257–1262