Lack of effect of fluoride releasing resin modified glass ionomer restorations on the contacting surface of adjacent primary molars. A clinical prospective study

N. KOTSANOS*, P. DIONYSOPOULOS**

ABSTRACT. Aim This prospective, split mouth control study was planned to clinically evaluate shown short-term caries protection of glass ionomer cement on tooth enamel placed in contact to it, as a result of fluoride release. Study design The sample consisted of 83 children, aged 4-7 years, visiting a private practice during the years 1999 and 2000. All subjects met the following criteria: a Class II restoration was needed to a maxillary or mandibular primary molar on both sides of the mouth, the adjacent molars being radiographically diagnosed as sound or with caries in the relative proximal enamel only. Methods A resin modified glass ionomer restoration (Vitremer, 3M) was placed at the test side chosen by chance, while an amalgam or composite restoration was placed at the control side. Lesion initiation or progression adjacent to each restoration was categorized in 5 stages radiographically. Statistics The non-parametric Marginal Homogeneity test for paired observations was used. Results Differences between test and control were not statistically significant (p>0.1). Two years after restorations were placed bitewings were taken from 36 children (41 pairs of restorations). Uncontrolled brushing with fluoride dentifrice was reported. Mean fluoride treatments performed were 2.2, initial visit included. Lesion progression was: 14 pairs - no progression in either side; 9 pairs - equal progression by 1 stage in both sides; 9 pairs - progression by 1 stage at test side, no progression at control side; 6 pairs - progression by 1 stage at control side, no progression at test side; 3 pairs - various other combinations of scores. Conclusions Under these clinical conditions, fluoride release from Class II Vitremer restorations did not affect the rate of caries progression at the adjacent enamel of proximal primary teeth.

KEYWORDS: Resin modified glass ionomer, Fluoride, Caries prevention, Clinical study.

Introduction

Daily use of low concentration fluoride (F) products combined with good oral hygiene is an effective means for preventing dental caries [Ogaard et al., 1986; Rolla et al., 1991]. This is widely documented and incorporated in the policies of preventive and pediatric dentistry organizations [Oulis et al., 2000]. The prevailing way of exposure of the teeth to such products is by means of fluoridated dentifrice [Clarkson et al., 1993]. Some focus has been laid upon the exposure of teeth to even lower concentrations of F by means of F releasing restorative materials, their main representatives being glass ionomer cement and its modifications. Currently there has been an increase of their use, especially in children. The daily amount of F released from these materials, at any time following the first weeks after mixing, is much lower than that released from the daily use of a dentifrice [Forsten, 1998] probably playing no significant role at remote areas in the mouth. In vivo evidence of this is the significant, but only short lasting, rise of salivary F following orthodontic bracket bonding with glass ionomer cement [Hallgren et al., 1990]. In the case of Class II restorations the released F is nevertheless present exactly where interproximal,
potentially cariogenic plaque thrives, in close proximity to the enamel of adjacent teeth in contact. However small the initial release, it can result in F incorporation in adjacent enamel and dentine [Skartveit et al., 1990; Mukai et al., 1993; Modesto et al., 1997]. Short term studies have also shown it to increase remineralization of carious enamel in vitro [Hatibovic-Kofman et al., 1997a] or previously demineralized enamel in vivo [Arai et al., 2000]. In other in vitro and intraoral studies, glass ionomer materials had a caries protective effect on enamel in contact or very close to them [Donly et al., 1999; Kotsanos, 2001]. This effect was enhanced when extra F was added to the glass ionomer [Donly and Segura, 2002].

However, the clinical significance of these findings is of more importance. Some clinical support has been provided by three studies [Derkson et al., 1989; Svanberg, 1992; Qvist et al., 1997] and disputed by one other [Kotsanos and Thanouri, 2001] that Class II glass ionomer or silicate cement restorations can exert a caries protective effect on the enamel of adjacent molars. The evidence is therefore not conclusive, especially in the light of the questioned clinical effect of F releasing materials, even on secondary caries [Randall and Wilson, 1999].

In vitro studies have shown that, at the phase following the initial ‘burst’ effect of F release [Forsten, 1998], glass ionomer cements can regain F when exposed to other F sources and release it hours or days later [Creanor et al., 1994; Donly and Nelson, 1997; Dionysopoulos et al., 2003]. This implies that the combined use of a proximal glass ionomer cement restoration with daily use of topical F agents could possibly enhance the F releasing potential of these materials and its caries preventive effect to other contacting tooth surfaces.

The present study was designed as a prospective, split mouth controlled clinical study to investigate the existence of a clinically measurable caries preventive effect of glass ionomer restorations under daily use of topical F on the contacting enamel of the adjacent primary teeth.

Material and methods

Sample population. The initial number of patients that entered the study was 83 children, aged 4-7 years, all visiting a private practice during the calendar years 1999 and 2000 and meeting the following criteria: one of the two primary molars on each side of the mouth to be radiographically sound or with enamel caries only at the interproximal surface, while the other to have need for a Class II restoration involving the surface of their common interproximal contact.

Restorations. A glass ionomer restoration (Vitremer, 3M) was placed at the test side chosen at random, while an amalgam (Dispersalloy, J&J) or composite (Spectrum, Dentsply) restoration was placed at the control side, always following the manufacturer’s instructions. The operator’s (NK) choice for the control restorative material was amalgam, unless the parent and/or the patient required a ‘tooth coloured filling’. The parents were informed that all three materials were clinically appropriate for this use [Ostlund et al., 1992; Croll et al., 2001; Hübel and Mejàre, 2003] and gave oral consent that new radiographs would be required in 24 months time [Murray and Majid, 1978], as these children were considered risk patients for caries (deft ≥ 2 for age 4-7 years, mean deft: 4.2, SD±2.3). Dental treatment was always performed under local anaesthesia and rubber dam isolation. Cavity preparation involved both high and low speed and possibly hand instruments. In case of deep cavities in the control group, a small quantity of lining material (Vitrebond, 3M) was placed at the pulp horn area, away from the cavo-surface margin. In either group a formocresol pulpotomy was performed when required. Heavy occlusal contacts were checked and relieved.

Prevention. Oral hygiene instructions were given prior to the restoration appointments and the children were required to brush teeth twice a day with a F-dentifrice under parental supervision. All children were recalled by mail twice annually for check-ups and F treatment. The latter was performed with cotton roll isolation after professional flossing and small quantities of Duraphat® (Colgate) placement both buccally and lingually at the interdental areas of all rear teeth [Peterson et al., 1991].

Follow-up. Two years following restoration placement (mean: 2 years 3 months, range: 1 year 8 months to 2 years 8 months), 36 children (mean age 5.9 years, SD±0.81) with 41 pairs of restorations had their final radiographs taken under the same conditions. Follow-up for the study purposes was completed. Recording of the extent of carious lesions on the bitewing radiographs was based on the method of Pitts [1984], after Solanki and Sheiham’s [1992] validation of his radiographic scores in primary teeth (Fig. 1). The modification was the absence of 3 categories in our study, namely secondary caries, filled surfaces and unerupted teeth. No progression received score 0, progression by 1 stage received score 1 and progression by 2 stages
received score 2. If a relevant restoration failed before study completion, it was immediately replaced and the tooth pair excluded from the study. Other needs not influencing study outcome were met accordingly.

The radiographs were viewed on an opal glass illuminated box, their interpretation being aided by a x3 magnifying glass. The radiographic examiner (PD) was blind to study design. His diagnostic accuracy was checked by randomly selecting 15% of the radiographs (12 pairs of them in total), which he scored again 2 days later. Intraexaminer reliability was 96%.

Statistics. An extension of the common non-parametric McNemar test from binary responses to multinomial responses was applied to all the observations. This test is called Marginal Homogeneity test and it is appropriate to detect changes in responses due to experimental intervention in paired ordinal variables [Agresti, 1984]. The degree of progression in the present study is the ordinal variable with four levels (reversal, no progression, progression 1 and progression 2). The significance level of the test was computed by the Monte-Carlo simulation method using the statistical package SPSS v.10 [Mehta and Patel, 1996].

Results

The mean number of F treatments performed was 2.2, initial visit included and final visit excluded. Average time interval between actual check-ups was 12 months. Toothbrushing with a F-dentifrice was reported by parents to be not every day for 9 children, once a day for 20 children and twice a day for 7 children of the study.

One Vitremer and one Dispersalloy restorations from different children were judged as failed according to modified United States Public Health Service criteria [Hübel and Mejäre, 2003]. In 4 other children, at least one primary molar initially being part of the study was exfoliated before final examination. A total of 41 children did not show up for final examination, despite a reminder by telephone in addition to the mail recall. All these 47 children were excluded from the study.

A comparison of findings from initial with final radiographs (Fig. 2) showed what follows.
- One early enamel carious lesion in contact to a Vitremer restoration showed reversal from D1 to E2 (score: -1) while the paired surface in contact to amalgam restoration showed no progression (score: 0).
- Tooth surfaces contacting 23 pairs of restorations showed equal (9) or no progression (14) on both test and control sides.
- Of the other 17 pairs with unequal progression between the two sides, the ratio of Vitremer to amalgamComposite contacting tooth surfaces with increased lesion progression was 10:7 (Table 1).

The Marginal Homogeneity test was applied to the observations of Table 1 after these were cross tabulated to form Table 2. The difference between lesion progression in the radiographs of test and control sides was not statistically significant (Std. MH statistic = 0.471, p ≤ 0.813).

Discussion

A number of in vitro studies are unanimous in showing preventive properties on secondary caries-like demineralisation by the glass ionomer materials [Hicks et al., 1986; Forss and Seppa, 1990; Dionysopoulos et al., 1994, 1998; Tam et al., 1997; Pereira et al., 1998; Hicks and Flaitz, 2000]. This, together with earlier scarce clinical observations of reduced secondary caries [Wilson and McLean, 1988] and despite greater restoration failures [Ostlund et al., 1992;qvist et al., 1997], has led to the conclusion of their potential use in clinical practice.
clinicians to progressively increase the use of glass ionomer restorations. This tendency is more intense in restoring primary molars, especially after the established better mechanical performance of the resin modified as compared with other glass ionomer materials [Croll, 1998; Espelid et al., 1999; Hübel and Mejàre 2003], but extends into restoring small approximal cavities in permanent teeth in a minimally invasive technique [Axelsson, 1999]. However, a meta-analysis of clinical studies on secondary caries at the margins of glass ionomer restorations has not shown conclusive evidence in favour of a caries preventive effect of such materials [Randal and Wilson, 1999]. Most of these studies have dealt with Class V restorations with conventional glass ionomers in permanent teeth [Tyas, 1991; Welbury et al., 1991; Mjor, 1996; Wilson et al., 1997]. Loss of margin integrity due to mechanical forces, absent in the in vitro experiments, may have contributed to plaque retention and therefore to secondary caries, thus masking any possible preventive effect of the glass ionomers. This view agrees with findings that a resin modified glass ionomer showed microscopically less marginal

**TABLE 1** - **Paired ordinal variables of radiographically detected enamel lesion initiation or progression in interproximal contact with the restorative materials in the 41 children under study.**

<table>
<thead>
<tr>
<th></th>
<th>Vitremer</th>
<th>Dispersalloy, Spectrum</th>
<th>N=41</th>
</tr>
</thead>
<tbody>
<tr>
<td>-1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>14</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>0</td>
<td>9</td>
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<tr>
<td>0</td>
<td>1</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**TABLE 2** - **Cross tabulation of the ordinal variables of table 1 for statistical evaluation.**

<table>
<thead>
<tr>
<th></th>
<th>Reversal by 1</th>
<th>No progr.</th>
<th>Progr. by 1</th>
<th>Progr. by 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitremer</td>
<td>Reversal by 1</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>No progression</td>
<td>0</td>
<td>14</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Progression by 1</td>
<td>0</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Progression by 2</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

**FIG. 2** - Initial (upper) and final (lower) radiographs show how the child’s conservative needs were met. *T* = test material (Vitremer), *C* = control material (Spectrum). Lesion progression in the adjacent tooth surface in contact to them was: #54 distal 0→0, score 0; #64 distal E2→D1, score 1; #75 mesial 0→0, score 0 and #85 mesial E1→E1, score 0.
demineralisation at approximal sites than amalgam after 3 years of clinical use [Donly et al., 1999]. In general though, there seems to be a discrepancy between the outcomes from the short term in vitro and those from the much longer in time clinical studies.

A second issue under investigation is a possible carries protective effect of glass ionomer materials to other teeth in their vicinity. There are some in vitro or intraoral studies of short duration (4-10 weeks) showing remineralisation of previously demineralised enamel or prevention of demineralization of sound enamel by proximal contact to glass ionomer materials [Hatibovic-Kofman et al., 1997a; Jang et al., 2001; Kotsanos, 2001]. In another 1 month in vitro study, a glass ionomer was found to be inferior to a F-mouthrinse in promoting remineralization to demineralized adjacent teeth, but similar to a F-dentifrice [Marinelli et al., 1997]. Again, there has been some previous clinical evidence supporting a carries preventive effect of F releasing materials to contacting tooth surfaces [Derkson et al., 1989; Svanberg, 1992; Qvist et al., 1997]. A recent controlled clinical study, however, did not show any such effect of the highly viscous glass-ionomer Ketac Molar (ESPE, Seafeld, Germany) on the contacting enamel of the adjacent primary molar [Kotsanos and Thanouri, 2001]. Such glass ionomers, however, are known to release significantly less F than conventional and resin modifying ones [Verbeeck et al., 1998; Dionysopoulos et al., 2003].

The present study was a prospective controlled blind study repeating that of Kotsanos and Thanouri [2001] with a resin modified glass ionomer that has shown high F release levels coming close to conventional glass ionomer materials [Forsten, 1998; Dionysopoulos et al., 2003]. Vitremer has shown in vitro short term (phase I) F release levels that are about 70% of those of the conventional glass ionomer Ketac Fil (3M-ESPE). For phase II F release, which is more relevant to the long term clinical studies, this percentage rose to 80% [Verbeeck et al., 1998]. The outcome was again that the two year radiographic follow-up of the enamel surfaces adjacent to Vitremer did not show any carries protection in relation to the non-F-releasing amalgam or composite materials.

There have been some earlier findings that glass ionomer is superior to other materials in absorbing and then releasing F [Suljak and Hatibovic-Kofman, 1996] and that F release may continue for a whole month [Hatibovic-Kofman et al., 1997b]. It seems though that neither the inherent F of the glass ionomer nor any possible release of F absorbed from dentifrice use (frequency only about once a day in our study) offered any radiographically measurable protection to adjacent tooth surfaces. This is not surprising in the light of more recent findings that this F release lasts only for a day or two depending on the F source [Toumba and Arizos, 2000] or even only for some hours when the liquid medium is changed every hour [Kotsanos et al., unpublished data]. The infrequent F varnish application in the present study (once a year on average) is not expected to have had any significant effect in this respect [Petersson et al., 1991].

The clinical impression of the 27-month follow-up of Vitremer was satisfactory. The one failed restoration out of 41 compares well with other clinical performance studies proving its suitability for Class II restorations in primary teeth [Donly et al., 1999; Espelid et al., 1999; Croll et al., 2001; Hübel and Mejäre, 2003]. Their established clinical success, apart from advantages like good adhesion to hard dental tissues and close to tooth colour, is partly owed to their F release. Both resin modified and conventional glass ionomers release a significant amount of F for a week or two, but continue to release small amounts for years [Forsten, 1998; Verbeeck et al., 1998; Williams et al., 2001]. It is difficult to define F release levels above which a measurable effect in adjacent enamel surfaces can be seen. The difficulty, except for possible differences between in vivo and in vitro media composition [Marks et al., 2000], lies in the continuous recycling of saliva which is not duplicated satisfactorily by changing the medium in the in vitro experiments every day or so. In a relevant in vitro F release study using Vitremer [Kotsanos et al., unpublished data] levels of 1 ppm were maintained only during the first two weeks after mixing and for a few days after treating the aged material with a 2% NaF solution when the storing medium (artificial saliva) was changed every day.

Such time periods seem very short when considering the total of the 2- or 3-year period of a clinical study, to allow the so-called F releasing restoration to have any effect on adjacent enamel. Two weeks is, however, a significant time period within a 4-week in vitro study, thus explaining the unanimous positive outcomes of relevant in vitro studies. This view of the discrepancy between in vitro and clinical results is further supported by findings of Papagiannoulis et al. [2002]. It seems that if F releasing properties continue to be considered as clinically important for dental restorative materials, ways of prolonging and enhancing their F release potential need to be explored.
References

Kotsanos N, Thanouri E. Effect of glass-ionomer Class II restorations to the approximal surface of the adjacent teeth. Two years clinical study in primary teeth. Pedodontia 2001;15:182-8 [in Greek].


Tam LE, Chan GP, Yim D. In vitro caries inhibition effects by conventional and resin-modified glass-ionomer restorations. Oper Dent 1997 Jan-Feb;22(1):4-14.


