Three-year performance of a calcium-, fluoride-, and hydroxyl-ions-releasing resin composite

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Secondary caries is the main reason for replacement of restorations in cross-sectional studies. To prevent demineralization, the use of ion-releasing materials has been suggested. The purpose of this study was to evaluate the durability of a new resin composite that releases calcium-, fluoride- and hydroxyl ions at low pH. Sixty-nine posterior restorations were placed in 36 patients and were evaluated at baseline, 6 months, 1, 2, and 3 years with slightly modified USPHS criteria. Postoperative sensitivity was observed in 2 teeth directly after placement and in another 8 teeth after 6–12 months. Absence of the use of an adhesive bonding technique explained the symptoms. A total of 26% failures was observed during the follow-up: 13 cusp fractures, 2 partial fractures of the resin composite, 1 secondary caries and 1 endodontic treatment due to prolonged sensitivity. The cusp fractures occurred during the second part of the follow-up and may be explained by expansion of the composite material due to water expansion and/or hydrolytic degradation of the alkaline glass filler. It can be concluded that the new ion-releasing resin composite showed, despite promising pH stabilizing properties, a clinically unacceptable failure rate. □ *Caries; clinical study; fracture; restorative material*

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Secondary caries is the most frequent reason for replacement or repair of restorative materials in cross-sectional studies and comprises an important part of restorative dental treatment. The proximal cervical margin lesions are often overlooked and are mostly not recognized until the lesions are large enough to observe clinically (1–4). Secondary caries occurs, as primary caries, due to disturbance of the demineralization-remineralization balance after frequent intake of fermentable carbohydrates, which are metabolized by cariogenic bacteria into organic acids (5, 6).

The popularity of tooth-colored posterior restorations has increased during the past few years because of a growing demand for aesthetics and concerns about the bioactivity of amalgam. The use of directly placed resin composite fillings has increased and good durability has been reported when they are placed in smaller cavities and under ideal conditions (7–11). Some of the clinical problems associated with the resin composites are related to the shrinkage that occurs during conversion of the monomer molecules into a polymer network. The polymerization shrinkage of the rigid resin composite materials results in a relatively high shrinkage stress in the restorative, causing debonding from the cavity walls or cohesive fracture of the filling material or tooth structure (12, 13). Particularly in the deep parts of the proximal box of Class II cavities, the shrinkage can result in lack of adaptation to the cavity wall and increased susceptibility to caries (14–16).

Since the introduction of silicate cements, fluoride release from restorative materials has been advocated to enhance the rate of remineralization and have the ability to prevent secondary caries. When fluoride ions are released of dental materials they can saturate the liquid phase in and around the restoration-tooth surface, resulting in precipitation of CaF_2 crystals, which reduce the possibilities of demineralization and accelerate the process of remineralization. High concentrations of fluoride will also influence bacterial metabolism and growth (17). Conventional and resin-modified glass ionomers (GIC, RMGIC) are the main fluoride-releasing materials used today. Their powder consists of fluoride compounds, and the amount of fluoride released from GIC and RMGIC is high initially during the first days, and decline fairly rapidly over the next months finally to stabilize at a lower level. The release may be increased under acidic conditions and by hydrolysis in saliva (18, 19). Fluoride has been added to resin composites and poly-acid modified resin composites, but these materials release little fluoride (20).

Recently, a new posterior resin composite was developed containing additional alkaline glass fillers, a calcium silicate glass that releases fluoride and calcium ions acting as a reservoir providing ions to prevent demineralization contiguous to the restoration. After contact with water, hydroxyl ions are formed on the surface of the material. These ions can act like a buffer and neutralize part of the organic acid produced by the cariogenic bacteria. It has been suggested that in this way they can also reduce the growth of these bacteria (21). In vitro studies have shown that the ion release was still present after 2 years (21). Suggesting a demineralization-inhibiting effect by the ion release of the material, a simplified non-adhesive application was recommended (22).

The aim of this study was to evaluate the durability of the new ion-releasing resin composite in vivo in posterior restorations over the course of 3 years.

Materials and methods

Clinical procedure

During the period January–March 1998, all patients, who needed posterior restorations and attending the author's clinic at the Dental School, University of Umeå, Sweden, were asked to participate in the follow-up study. All patients (12 M and 24 F; mean age 50.7 years, range 20–81) responded positively and were included in the study. Each patient provided informed consent to participation in the study, which was approved by the ethics committee of the University of Umeå. In 40 premolars and 29 molars, 6 Class I and 63 Class II restorations of moderate sizes were placed by the author. Reasons for placement of the resin composite restorations were secondary caries, fracture of old amalgam fillings or replacement for aesthetic reasons. After removal of the amalgam restoration and/or caries excavation, the cavities were cleaned by rinsing in water. Cotton rolls and a saliva suction device isolated the operative field. A steel matrix was applied followed by proper wedging. The material was applied in accordance with the instructions of the manufacturer. The cavity was not conditioned with an acid. A resinous dentin liner (Ariston Liner, Vivadent, Schaan, Liechtenstein) was applied for 20 sec, air-thinned and light-cured for 20 sec. The liner contained a methacrylate modified polyacrylic acid, HEMA, ethanol and maleic acid. The resin composite used, Ariston pHc (pHc = pH control; Vivadent) contains Bis-GMA, urethane dimethacrylate and dimethacrylate monomers. Filler types included are ytterbium trifluoride, Ba-Al-fluorosilicate glass, highly dispersed silica and 48 wt% silanized alkaline glass filler. The resin composite was applied in layers of maximally 3 mm. The first layer in the proximal box was 2 mm. Each layer was light-cured for at least 40 sec. Normally, 2 or 3 layers were required to restore the cavity. The final finishing was performed after checking of occlusion/articulation.

Evaluation

The restorations were evaluated by slightly modified USPHS criteria at baseline, 6 months, 1, 2, and 3 years (23; Table 1). The following parameters were evaluated: anatomical form, marginal adaptation, colour stability, marginal discoloration, surface roughness and secondary caries. The restorations were evaluated regularly by two calibrated observers. Disagreement was resolved by consensus. Postoperative sensitivity was analysed according to the system used by Borgmeijer et al. (24). Bitewing radiographs were taken regularly and in addition colour slides were made of selected cases. The author estimated the caries risk for each patient by means of clinical and socio-demographic information routinely available at the annual clinical examinations, e.g. incipient caries lesions and former caries histories (25, 26).

Statistical analysis

The characteristics of the restorations were described by descriptive statistics using relative cumulative frequency distributions of the scores.

Results

All except 2 patients with 4 Class II restorations who died between the recalls were registered at all recalls during the 3 years. A total of 65 restorations were evaluated.

Postoperative sensitivity

Postoperative sensitivity was reported by 10 patients during the study. Two patients had slight symptoms after cold or masticatory forces during the first months. After 6–12 months, functioning time in the mouth, 8 additional restorations previously without symptoms reported sensitivity, 3 after cold and/or air stimuli, 4 during mastication and 1 during mastication and air/cold stimuli. Sealing of the proximal margins by an adhesive after etching with phosphoric acid of 4 of the restorations with symptoms caused by cold or air stimuli decreased the symptoms, but minor sensitivity remained at the 2 years' recall. No operative treatment was performed in the other cases after discussion with the involved patients.

Reasons for failure

Seventeen non-acceptable restorations (26%) were observed during the 3 years' follow-up. Thirteen teeth showed cusp fracture (6 molars and 7 premolars). Eight fractures occurred between the 12 and 24 months' recall, and the others between 24 and 36 months. All cusp fractures were repaired with resin composite. During the continued follow-up of these repaired teeth, a second cusp fracture occurred in 4 teeth (3 premolars and 1 molar) between 6 and 12 months after repair of the first cusp fracture. Most of the tooth cusp fractures occurred without complaints of the patients about initial symptoms. In two patients with cusp fracture, who had previously reported symptoms during masticatory forces, the symptoms disappeared. One patient with previously reported air/cold sensitivity reported acute pain at 2 years and an endodontic treatment was performed on the premolar. Horizontal cusp cracks were observed in another 7 teeth. A partial resin composite fracture was observed in 1 molar restoration at 2 years and an isthmus fracture after 26 months in a premolar restoration. In 4 other restorations (2 molars and 2 premolars), small defects in the form of

Table 1. Criteria for direct clinical evaluation (23)

Category	Score: Acceptable	Score: Unacceptable	Criteria
Anatomical form	0		The restoration is continuous with tooth anatomy
	1		Slightly under- or over-contoured restoration; marginal ridges slightly undercontoured; contact slightly open (may be self-correcting); occlusal height reduced locally
		2	Restoration is undercontoured, dentin or base exposed; contact is faulty, not self-correcting; occlusal height reduced; occlusion affected
		3	Restoration is missing, partially fractured or shows traumatic occlusion; restoration causes pain in tooth or adjacent tissue; tooth fracture
Marginal adaptation	0		Restoration is continuous with existing anatomic form, explorer does not catch
	1		Explorer catches, no crevice is visible into which explorer will penetrate
	2		Crevice at margin, enamel exposed
		3	Obvious crevice at margin, dentin or base exposed
		4	Restoration mobile, fractured or missing
Colour match	0		Very good colour match
	1		Good colour match
	2		Slight mismatch in colour, shade or translucency
		3	Obvious mismatch, outside the normal range
		4	Gross mismatch
Marginal discoloration	0		No discoloration evident
	1		Slight staining, can be polished away
	2		Obvious staining cannot be polished away
		3	Gross staining
Surface roughness	0		Smooth surface
	1		Slightly rough or pitted
	2		Rough, cannot be refinished
		3	Surface deeply pitted, irregular grooves
Caries	0		No evidence of caries contiguous with the margin of the restoration
		1	Caries is evident contiguous with the margin of the restoration

chip fractures were observed. Relative cumulative frequencies of the scores for the evaluated variables at 3 years are shown in Table 2.

Thirty-eight percent of the patients were estimated as caries-risk patients. One case of recurrent caries contiguous with an experimental restoration was observed in a caries-active patient. No clinical signs of extreme occlusal wear were seen during the follow-up.

Discussion

In vitro research has shown the cariostatic effect of fluoride-releasing materials. Clinically, its effect has been more difficult to prove because of the complexity and multi-factorial character of the caries process. Fluoride release decreases significantly during the first weeks, as does the antimicrobial effect of the cement (20, 27). The ions most frequently associated with increasing the resistance of tooth tissue to acid attack are calcium, phosphate, and fluoride. The release of fluoride and calcium from glass ionomer cements and the studied resin composite increase at lower pH. These materials can therefore act as reservoir, providing ions directly after a pH drop in the plaque. However, for glass ionomer cements it is well known that the fluoride release level of the aged restoration depends to a high degree on the ability of the cement to take up fluoride in the oral environment from sources such as dentifrices and diet (28). In patients with additional fluoride prophylaxis the continuous fluoride release from the cement into the liquid phase, around and in the tooth, will be higher potentially. Consequently, in patients with low fluoride intake, the cariostatic effect of the GIC will be decreased.

The term ‘smart materials’ has been introduced for materials that release ions as the local pH of the oral plaque drops after consumption of fermentable carbohydrates (29). Glass ionomer cements were the second restorative materials after the silicate cements to release fluoride into the environment, especially during the first days after the restorations were inserted. Geurtsen et al. (19) showed in vitro that the fluoride release varied significantly in different storage media. Conventional glass ionomer cements were subject to a susceptible erosion and disintegration at low pH. Fluoride release in vivo of glass ionomer cements may be increased under acidic conditions and by hydrolysis in saliva (18).

The Ariston pHc material was suggested to leach, besides fluoride and calcium, also hydroxyl ions in response to the drop in pH after intake of fermentable carbohydrates. These ions may act as a buffer, reversing the demineralization process. The buffering effect of the resin composite after a pH drop was shown by the research department of the manufacturer and confirmed recently in a plaque study (microtouch method) (30). After rinsing with a sucrose solution, the proximal plaque pH of Ariston

Table 2. The relative scores of the evaluated criteria for the 65 Class II and Class I Ariston pHc resin composite fillings at the 36-month recall (%)

	0	1	2	3	4
Anatomical form*	69.2	4.6	13.9	12.4	
Marginal adaptation*#	53.9	16.9	4.6	13.9	10.7
Colour match	0	7.7	56.9	35.4	0
Marginal discoloration	87.6	6.2	6.2	0	
Surface roughness	84.6	15.4	0	0	
Caries	98.5	1.5			

* Relative cumulative scores.
# The cervical margins of 4 of the restorations with postoperative sensitivity were sealed during the study.

restorations included in this study measured at either 1 or 3 years of age remained significantly more stable than those on non-filled, enamel surfaces acting as control.

In this 3-year study, only 1 secondary caries lesion was observed contiguous with the Ariston pHc restorations. This is despite the high frequency of caries-risk patients involved who showed caries, although in a low frequency, on other teeth. The finding confirms the pH stabilizing properties of the material. However, the observation time of 3 years is fairly short for the development of secondary caries contiguous to modern resin composite restorations (9). In another in vivo 2 months' study, during which occlusal Ariston pHc restorations were placed in caries-active patients, the composite countered the pre-operative acidic pH of saliva, thereby protecting the tooth from demineralizing attacks (31). Schiffner (22) showed an inhibiting effect of Ariston pHc on the demineralization of enamel and root dentin in an artificial mouth device. He suggested that the release of ions neutralizes acids, promotes remineralization and provides in this way an environment less favorable for enhanced growth of mutans streptococci. Schuepbach et al. (32) compared the efficacy of Ariston pHc and the effect of the Ariston liner in an in situ model with that of a glass ionomer cement and a non-fluoride-releasing resin composite. The extent of demineralization was studied by confocal microscopy. Ariston pHc substantially reduced demineralization compared to the GIC, but the efficacy was markedly reduced by the application of the liner.

The manufacturer recommended applying the ion-leasing resin composite without the use of the total-etch technique. The liner, which contained maleic acid (3 wt%) and methacrylate modified polyacrylic acid (8.4 wt%), probably sealed the dentin tubuli initially like the self-etching primers. However, the frequency of teeth with delayed reported postoperative symptoms for warm and cold, which occurred after 4–12 months, suggested a marginal degradation and diminished interfacial adaptation of the liner resulting in marginal leakage. Sealing of these restoration margins with a low viscous resin-bonding agent relieved the symptoms of some of the treated teeth. In another series of posterior restorations with the ion-leaking resin composite, a total etch adhesive technique was used. No postoperative symptoms were observed for these bonded restorations. The reported symptoms clearly indicated the use of an adhesive restorative technique. The manufacturer recently changed its instructions and recommended using the total-etch technique with phosphoric acid. In a 1-year follow-up of posterior restorations of the same material, the main problem reported was an increase of hypersensitivity and enamel cracks, confirming the findings in this study (33). A microscopic margin analysis showed a significantly increased marginal deterioration and a 6% clinical failure rate after 1 year.

The acceptable posterior restorations at 3 years showed little occlusal wear. Gabrielli et al. (34) reported that the occlusal wear of the material was higher than that of resin composites, and nearly equal to amalgam. The clinical durability of the restorative material, however, was not acceptable because of the 26% failure rate mainly due to the high frequency of fractures observed. Most of these were cusp fractures, observed in the second part of follow-up. There are few reports in the literature describing the occurrence of tooth fractures (35). Bader et al. (36) recently reported the occurrence of cusp fracture to be 5 teeth per 100 adults per year. Heft et al. (35) examined 723 subjects over the course of 2 years and reported an incidence rate of 14 teeth with cusp/incisal edge fractures per 100 subjects per 24 months. Cusp fractures are a significant dental health problem, in many cases caused by the conventional preparation technique for amalgam restorations with large undercuts in posterior teeth in order to obtain macromechanical retention (37). A continuous occlusal loading of the weakened cusps will result in horizontal crack formation and cusp fractures. Adhesive bonding of the resin composite material to the cavity walls, in combination with the new amphiphilic bonding systems, decreased this problem (9, 38). The high-frequency-observed cusp fractures could also be caused by expansion of the resin composite restorative material. Most resin composites absorb low amounts of water for up to 120 days. Many of the cusp fractures were observed in the second part of the study, which suggests prolonged water absorption. Another explanation may be found in the aging of the newly developed alkaline glass filler particles in the oral environment. Owing to hydrolytic and/or chemical degradation of the glass fillers in the mouth, calcium oxides and calcium carbonates can be formed, where the in size increased calcium carbonates will have an expanding effect (E. Ruyter, 2001, pers. comm.).

Despite promising pH-stabilizing properties, it can be concluded that the new ion-releasing material showed non-acceptable clinical behaviour because of the high frequency of tooth fractures.

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