Clinical Evaluation of Three Restorative Materials Applied in a Minimal Intervention Caries Treatment Approach

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Abstract

Objectives: *This paper reports on a longitudinal evaluation of three materials (glass ionomer, zinc oxide-eugenol cement, and composite) employed in a minimal restorative intervention approach of 81 high caries-active pregnant women selected for a preventive oral health program in Brazil. The aim of the study was to evaluate the clinical behavior of the glass ionomer cement, currently indicated in programs for control of carious lesions.* ***Methods:*** *The patients were randomly divided into two groups. Both groups were engaged in an oral health promotion approach. In Group 1, 417 glass ionomer restorations were placed in 43 individuals, involving all types and sizes of cavities. In the second group, 213 posterior zinc oxide-eugenol (ZOE) restorations and 127 anterior composite restorations were placed in 38 patients. Minimal cavity preparations were made, in which only soft or infected dentin was removed, on the basis of clinical judgment.* ***Results:*** *After two years, the restorations were clinically evaluated by two examiners for marginal integrity, amount of wear, presence of fracture, carious lesions, and lost restorations. Statistical analysis (chi-square test) identified statistically significant difference between glass ionomer and ZOE (90.6% vs 9.2%). Comparing glass ionomer and composite, similar survival rates were observed. The success rate observed for the glass ionomer cement ranged from 77.1 percent to 92.5 percent, depending on the type and size of cavity in which it was applied. Four teeth restored with glass ionomer cement and one tooth restored with composite showed caries signs. Regarding the ZOE restorations, caries was always associated with other causes of failure such as excessive wear, restoration loss, or marginal defects, with no possibility of separate evaluation. Despite the preventive and therapeutic measurements employed, a mean increase of 2.15 new surfaces with cavities was observed in Group 1, as well as 2.83 surfaces presenting the same status in Group 2.* ***Conclusions:*** *This study demonstrated that highly viscous glass ionomer cement applied in a minimal intervention approach provided high-quality preventive and restorative care after two years to a population at high risk for caries. The composite was employed in cavities exposed to lower stress, such as in the anterior teeth, and its behavior was comparable to that of the glass ionomer cement. The reinforced ZOE presented a high failure rate, thus contraindicating its use for such purpose. [J Public Health Dent 2003;63(4):221-26]*

Key Words: atraumatic restorative treatment, caries excavation, composite, dental caries, glass ionomer cement, minimal cavity preparation, preservative dentistry, restoration.

Although dental caries has decreased substantially in the industrialized countries over the last two decades, from a global perspective it remains a widespread problem. Despite huge developments in the prevention and management of dental caries, this disease tends to go untreated in people living in underprivileged communities (1,2). Globally, dental caries ranks among the most prevalent diseases of humans and it is a public health problem in most countries (3,4).

In communities without access to traditional dental treatment, alternative measures for treating caries are being used. One alternative is the atraumatic restorative treatment (ART) (4), which fits with modern concepts of preventive and restorative oral care in that it emphasizes prevention and minimal invasiveness in treatment (5,6).

In patients with great treatment needs, an attempt is made to improve the oral status with a view to arrest the destructive process of the disease and favorably alter the microbiota. This approach includes a fast restorative treatment employing a material that does not predispose to bacterial recolonization. Currently, glass ionomer cement is indicated for this purpose throughout the world.

Jendresen and Phillips (7), in a controlled clinical study using the US Public Health Service criteria, observed a success rate above 80 percent over 12 months in 50 preparations in posterior teeth (both class I and II) restored with reinforced ZOE cement. Also, the manufacturer's instructions of the material employed in that study (IRM—Dentsply) indicate its application for long-term intermediate restorations and for caries control, especially in public health programs.

The aim of this study was to carry out a longitudinal clinical evaluation of three different dental materials employed in the restorative therapy (minimal cavity preparation—MCP) of 81 caries-active pregnant women of low socioeconomic background who were selected for a basic preventive oral health program in Brazil, with a

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view to evaluate the clinical behavior of glass ionomer cement placed in multiple-surface restorations.

Methods

The study design was approved by the Ethics Committee of Bauru Dental School, and by the Municipal Health Office. Written consent was obtained from the patients included in the study or from their parents. Eighty-one pregnant women, with a mean age of 19.1 (±3.7) years and presenting with several carious lesions, were engaged in an oral health promotion program.

The program was carried out from 1997 to 1999 in eight Public Health Centers located in suburban areas of Bauru City. Besides the restorative care, the basic preventive program included dietary counseling; oral hygiene instructions; donation of toothbrushes, dental floss, and toothpaste; professional prophylaxis; fluoride and iodine topical applications; and extraction.

Restorative Care. The restorations were made by quadrants because the mean number of decayed surfaces (DS) was 14.0. All restorations were completed by one dentist in a mobile dental unit, during pregnancy, and immediately postdelivery.

Patients were divided randomly into two groups. In Group 1 (n=43) all types of cavities (class I, II, III, IV, and V) were restored with a type II glass ionomer cement specifically developed for ART (Fuji IX—GC Dental Co., Japan). Lesions larger than two-thirds of the entire tooth crown with involvement of the two proximal surfaces or involving destroyed cusps were classified as a coronal reconstruction.

In Group 2 (n=38), posterior cavities (class I, II, and reconstruction) were restored with a reinforced ZOE cement (IRM—Dentsply). The class III, IV, and anterior and posterior class V cavities were restored with a universal hybrid composite (Fill Magic—Vigodent, Brazil) because the ZOE cement sustained immediate failure and its nonesthetic appearance was rejected by most patients.

Cotton wool rolls and suction were used for moisture control during restorative treatment. Access to dentin lesions in the proximal surfaces was performed with a high-speed bur. The entrance of small lesions was also widened using high-speed burs. Excavators were used to remove soft carious dentin, preserving the partially demineralized dentin as much as possible (modified ART approach). Particular care was taken to remove all carious tissue at the dentin-enamel junction. Partial excavations were performed in deep carious lesions that were considered likely to result in pulp exposure if they were completely excavated. A base material containing calcium hydroxide (Hydro C, Dentsply) was placed when necessary.

No conventional cavity preparations were made, but conservative ones, with minimal invasiveness (minimal cavity preparation), for removal of soft carious tissue. After preparation, the cavities were washed and treated depending on the type of restorative material to be employed. The materials were used according to the manufacturers' instructions. After removal of carious tissue, the preparations to be restored with Fuji IX glass ionomer cement were cleaned with the cement liquid by means of a 15-second rubbing procedure with a cotton pellet moistened in water and dipped into the liquid. Afterwards, the preparations were washed for 20 seconds and dried with another cotton pellet. The standard powder and liquid ratio was followed, measuring one level spoonful of powder and one drop of liquid, which were mixed for 30 seconds. The glass ionomer mixture was inserted into the cavity using a flat no. 1 applicator to push the mixture into deeper parts of the cavity and under any unsupported enamel. Additional material was spread on the occlusal surface covering all the fissures adjacent to the cavity. After the glossy aspect had disappeared, finger pressure was applied over the restoration, allowing the excess material to overflow the surface, avoiding air bubble inclusion. The finger, rubbed with petroleum jelly, was removed sideways from the tooth surface after 30 seconds. The excess glass ionomer cement displayed along the outer margins was removed with either the carver instrument or blades. When the glass ionomer had partially hardened, the occlusion was checked and adjusted. Surface protection was accomplished with Fuji Varnish after occlusal adjustment.

The ZOE cement required no dentin pretreatment. The powder and liquid were measured according to the manufacturer's instructions and mixed for up to 1 minute. The mixture was inserted into cavities in a similar way, but with no fissure sealing. No surface protection was required and the occlusion was adjusted with round steel burs. For restoring posterior proximal surfaces, metal strips and wedges were used with both materials.

For anterior restorations, plastic strips were used with glass ionomer (Group 1) and composite (Group 2) restorations. For composite, carious tissue was removed, an enamel bevel was made and the enamel conditioner, dentin primer, and adhesive were applied according to the manufacturer's instructions. The adhesive system employed required enamel etching with phosphoric acid. The dentin was submitted to application of a mixture of primers (Primer 1 and 2; one of them contains sodium fluoride) for 30 seconds. After evaporation of the excess primer, the adhesive was applied to the enamel and dentinal surfaces for 20 seconds, light cured for 20 seconds, followed by insertion of the composite. Light curing was performed incrementally in large restorations. Whenever an occlusal adjustment was required, it was completed with diamond burs. Traditional polishing was not performed.

In Group 1, a total of 417 glass ionomer restorations were placed in 43 individuals. In Group 2 (n=38), 213 zinc oxide-eugenol and 127 composite restorations were placed.

Evaluations

Evaluations at baseline and at years one and two were performed by two independent, calibrated dentists, both examining each patient. The examiners were calibrated by means of clinical examination of 20 patients under supervision by an expert. Some inconsistency was observed in scoring restoration survival codes 1 and 2 (both considered acceptable), which means disagreement between examiners was observed frequently between restorations with perfect marginal adaptation (no change from baseline) and restorations with slight marginal defect and/or wear of less than 0.5 mm, not requiring repair. The other codes express more evident situations and differences between examiners were rare (interexaminer kappa=0.78). One week later, the patients were reexamined for intraexaminer concordance (intraexaminer kappa=0.87 and

0.91). The final assessment was based on consensus, with the worst clinical situation prevailing.

The dental examination was carried out with a dental mirror, in a dental office, without any radiographic examination, through recording of the decayed, missing, or filled surface (DMFS) index. Additionally, the initial carious lesions were counted, including demineralized areas or white spot lesions. At the pit and fissure areas, the visual detection of a whitish line along the lateral walls of the fissure, associated with a tactile diagnosis of softened tissue, suggests the development of a carious process. The tactile diagnosis was carried out by gentle probing with a periodontal probe. On the smooth surfaces, incipient lesions were visually diagnosed as a whitish opaque line, which usually followed the contour of the gingival tissue. The access to the proximal surfaces was quite limited, and temporary tooth separation was used as an auxiliary in cases presenting doubtful diagnoses.

Each restoration was assessed according to the codes given in Table 1. Frencken (6,9) designed these specific criteria, with some modifications, for the ART approach and we considered them suitable for the present MCP study, where different materials were used with the purpose of achieving restorative treatment. In analyzing the data, codes 1 and 2 were considered to be acceptable restorations and the other ones were considered unsatisfactory. Depth of marginal defects and gradual wear were measured using the CPI (Community Periodontal Index) probe with a 0.5 mm ball end.

Differences in results were statistically tested using the chi-square and log rank tests. The longevity of the restorations was determined by computing the estimated cumulative survival rates.

Results

The decayed surfaces (DS) constituted 41.3 percent and 50.8 percent of the DMFS scores for Groups 1 and 2, respectively. Caries was found predominantly on fissure surfaces (36.6%), followed by proximal surfaces of the anterior (33.0%) and posterior (24.6%) teeth. Cavitated lesions on buccal and lingual smooth surfaces represented 5.8 percent of the total number of cavitated surfaces, yet demineralizations were more frequently diagnosed on those surfaces (58% of the detected lesions). The mean DMFT and DMFS scores of the patients at baseline are shown in Table 2. After 2 years, a mean increase of 2.2 tooth surfaces with new cavitated lesions was observed in Group 1 and 2.8 in Group 2; thus, the mean DMFS score for the subjects at the end of 2 years was 38.4 for the Group 1 and 34.7 for Group 2. The mean increase in the number of demineralized surfaces (white spot lesions) was 3.0 and 3.4, respectively, for Groups 1 and 2 (t-test, not significant).

In the glass ionomer group, 417 restorations were placed in 43 pregnant women. After one year, 383 restorations were evaluated in 39 patients (90.7%), and after 2 years only 302 restorations could be reevaluated in 34 patients (79%).

In the second group, 213 ZOE cement restorations (class I, II, and reconstructions) and 127 composite restorations (class III, IV, V) were placed in 38 patients. After 1 year, a total of 183 and 111 restorations of these materials, respectively, were reevaluated in 31 patients (81.6%). After 24 months, 38 IRM restorations and 106 composite restorations were reevaluated in 30 patients (78.9%). The small number of IRM restorations evaluated after 2 years was because all restorations scored as unsatisfactory in the first evaluation were excluded from the second evaluation.

In the 12-month evaluation, 95 percent of the glass ionomer restorations, 98.2 percent of the composite restorations, and 21.9 percent of the ZOE cement restorations were scored as satisfactory. Tables 3, 4, and 5 demon-

TABLE 1
Criteria Used for Evaluation of Restorations

Score	Criteria	Definition
1	Present, no change.	Successful
2	Present, slight defect at the margin and/or wear of the restoration of less than 0.5 mm; no repair is needed.	Successful
3	Present, marginal defect deeper than 0.5 mm. Repair is needed.	Failed
4	Present, wear over larger parts of the restoration deeper than 0.5 mm. Repair is needed.	Failed
5	Caries presence at the restoration margin. Repair is needed.	Failed
6	Partially present, restoration and/or tooth breakdown. Repair is needed.	Failed
7	Not present, restoration has completely disappeared. Treatment is needed.	Failed
8	Not present, other restorative treatment has been performed.	Excluded
9	Not present, tooth has been extracted.	Excluded
10	Sensitivity or pulpal involvement.	Failed

TABLE 2
Mean Number of Decayed, Missing, or Filled Tooth Surfaces (DMFS) and Teeth (DMFT) in Patients Included in Preventive Program

	DMFS Mean (SD)	Decayed Surfaces Mean (SD)	DMFT Mean (SD)	Decayed Teeth Mean (SD)
Group 1	36.2 (23.2)	14.3 (9.2)	15.5 (6.5)	9.8 (5.5)
Group 2	27.0 (12.3)	13.6 (4.7)	11.2 (4.6)	8.2 (3.8)
Total	31.9 (19.8)	14.0 (8.1)	13.5 (6.0)	9.0 (4.8)

TABLE 3
Success Rate of Fuji IX Glass Ionomer Cement Restorations after 2 Years, by Class of Restoration

Class of Restoration	Number of Restorations Placed	Evaluated at 1 Year (*n*)	Evaluated at 2 Years (*n*)	Success Rate % (Cumulative)
I	143	125	103	92.45
II	92	84	67	87.56
III	138	134	103	92.21
IV	5	5	5	100
V	24	21	14	88.44
Reconstruction	15	14	10	77.14
Total	417	383	302	90.63

TABLE 4
Success Rate of ZOE Cement Restorations—IRM after 2 Years, by Class of Restoration

Class of Restoration	Number of Restorations Placed	Evaluated at 1 Year (*n*)	Evaluated at 2 Years (*n*)	Success Rate % (Cumulative)
I	134	114	29	12.71
II	75	67	9	3.32
Reconstruction	4	2	0	0
Total	213	183	38	9.21

TABLE 5
Success Rate of Fill Magic Composite Restorations after 2 Years, by Class of Restoration

Class of Restoration	Number of Restorations Placed	Evaluated at 1 Year (*n*)	Evaluated at 2 Years (*n*)	Success Rate % (Cumulative)
III	104	90	87	92.16
IV	9	9	8	100
V	14	12	11	100
Total	127	111	106	93.56

TABLE 6
Cumulative Survival Rates of Glass Ionomer Restorations, by Class of Restorations

		Evaluations			
Class of Restoration	Baseline No. of Restorations	1 Year % (95% CI)	χ^2	2 Years % (95% CI)	χ^2
I, III, V	305	96.4 (94.3, 98.6)	*P*=.07	92.0 (88.7, 95.4)	*P*=.85
II, IV, and reconstruction	112	91.3 (85.8, 96.7)		86.8 (80.1, 93.5)	

strate the cumulative success rate of each material after 24 months of clinical function. A statistically significant difference ($P \leq .0001$) was observed in both evaluations. Glass ionomer restorations performed better than class I and class II ZOE restorations. For class III, IV, and V, glass ionomer was compared with a microhybrid fluoride-containing composite and no statistically significant difference was found ($P=.52$). The clinical performance of the glass ionomer cement in more conservative preparations (class I, III, and V) was compared to its performance in preparations with a larger loss of tooth structure (class II, IV, and reconstruction) (Table 6).

For glass ionomer cement, failures were related to unacceptable marginal defects (3.0%), excessive wear (0.3%), tooth and/or restoration fracture (1.2%), and total material loss (2.4%). Four teeth showed signs of caries at restoration margin (1.2%). Tooth sensitivity was observed in four restorations in different patients. None of the glass ionomer restorations were substituted for another restorative treatment.

For the ZOE cement, the failure percentage after two years was 87.3 percent for one-surface restorations and 96.7 percent for two or more surface restorations. Loss of the entire restoration was the most frequent cause observed (39.3%), followed by restoration and/or tooth fracture in 32.4 percent (most common for class II) and by excessive wear in 24.5 percent (most common for class I restorations).

For composite, four restorations showed marginal defects (3.8%) and one of them exhibited secondary caries (0.9%). Tooth sensitivity was observed in two class III restorations, in the same patient.

Discussion

Disease control in patients needing urgent care related to dental caries in populations with scarce resources remains a challenge. Currently, the minimal intervention techniques (MITC) combined with educational and preventive programs are the most commonly advocated approach in the literature (5).

The ART approach has been validated for single-surface restorations using highly viscous glass ionomer cements. Nevertheless, caution is recommended when extending this indica-

tion to larger restorations. This does not necessarily mean that these restorations should not be placed where there is no better alternative. In this study, three different materials were evaluated in an attempt to enhance the assistance to patients with high caries risk.

It is not standard practice to use glass ionomer cement as a restorative material for multiple-surface caries lesions due to the weakness of glass ionomer in stress-bearing situations, such as in posterior restorations (5,6,8,9). It is therefore surprising that only a low percentage of restorations (9.3%) failed after two years (Table 3, Figures 1 and 2). In particular, the 86.8 percent success rate for multiple-surface cavities in the permanent dentition makes this material very promising for use in the ART approach and other MITC for restorations greater than one surface.

In the present study the glass ionomer was placed in areas for which it had not been designed, and it was expected that this material would exhibit problems of excessive wear or fracture; however, the two-year survival percentage did not differ between more conservative or more extensive restorations, even though the statistical analysis reveals values close to significance, which in the long term may be regarded as a tendency toward a more favorable behavior for restoration with smaller loss of dental structure (Table 6).

The Fuji IX one-surface restorations, both occlusal and nonocclusal, presented a success rate after two years of 92.5 percent and 88.4 percent, respectively. Frencken et al. (8) employed the same material in similar preparations and observed a success rate of 94 percent and 88 percent after two and three years, respectively. In the study conducted by Frencken et al. (8), carious tissue adjacent to the restoration was observed in one tooth (0.5%), fewer than the four teeth in this situation observed in our study (1.18%). Yet, in the cited study the initial caries experience (mean DMFS=0.95) was also less than that of the present group (DMFS=31.9).

Phantumvanit and others (9) observed a low rate of caries progression surfaces adjacent to acceptable restorations; however, a significantly higher number of carious surfaces were observed next to the restorations evaluated as not acceptable. This also occurred in the present study, mainly for the ZOE restorations.

FIGURE 1
Two-year Occlusal Glass Ionomer Restoration (Score 1)

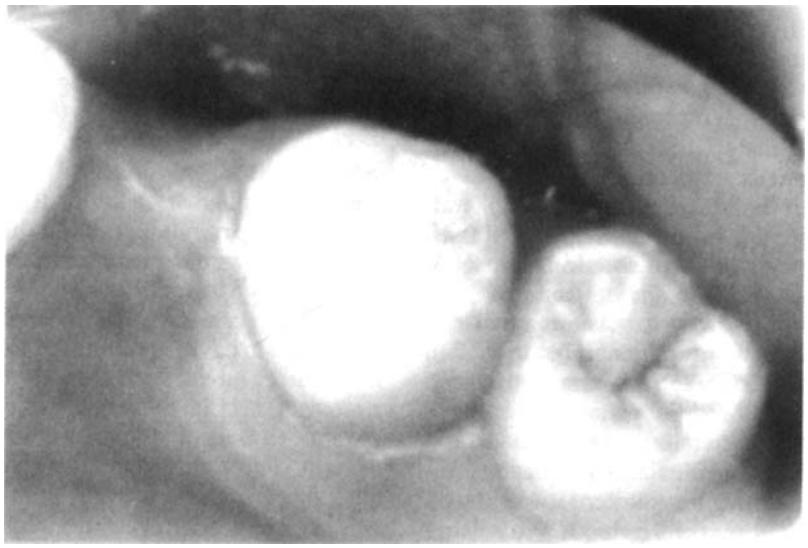
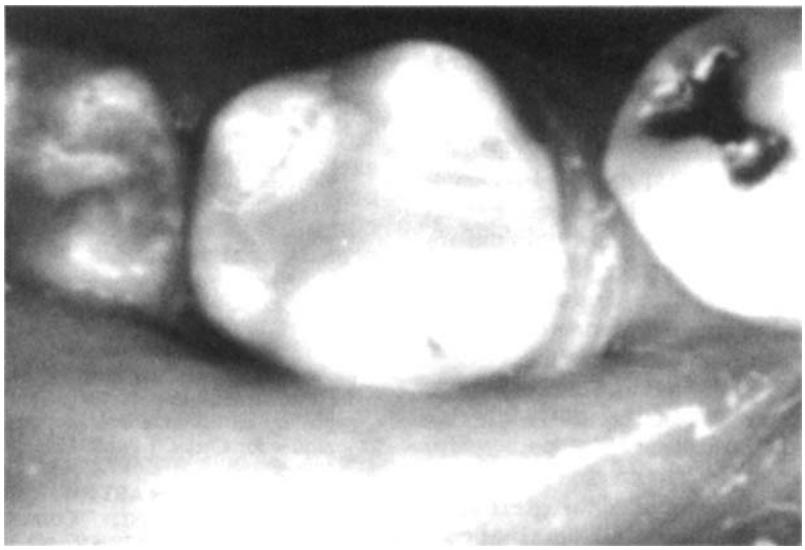


FIGURE 2
Two-year Posterior (Class II) Glass Ionomer Restoration (Score 1)



For both class I preparations and more extensive restorations in posterior teeth, a better clinical performance was observed for the glass ionomer cement. The obtained results are in disagreement with the findings of Jendresen and Phillips (7), who claimed satisfactory results (>80%) after one year, using a reinforced ZOE cement in posterior multiple-surface cavities. In the present study, after 12 months only 26.3 percent of the class I restorations and 14.9 percent of the class II restorations were rated as satisfactory. After 2 years, less than 10 percent of the restorations were satisfactory (Table 4).

The use of glass ionomer cement in the proximal surfaces of anterior teeth, class III restorations, and in free smooth surfaces was common in this study and the material behavior was similar to that of the composite resin tested. The composite used in this study (Fill-magic) was applied with a nontotal etching adhesive system (Magic Bond), and only the enamel was conditioned with phosphoric acid. It was interesting that, despite the high prevalence of untreated caries in the population, concern about es-

thetic restorations was evident. The universal Fuji IX color, dark yellow, was also unsatisfactory for some females, mainly for the adolescents.

In this study, the composite restorations showed excellent results. Considering that the sealing capacity of the filling material seems to be more important than its anticariogenic properties in the arrest of caries (10,11), and the superior mechanical properties of composite resin, it should be a useful material when enamel margins are present. However, glass ionomer cements have a superior ability to inhibit caries (12,13). Yet only one tooth restoration showed the presence of caries.

The progression of caries under restorations and sealants has been studied for a long time. Recent studies have reported marked reduction in microorganisms in carious dentin under glass ionomer, ZOE cement, and composite (10,14-16). Mertz-Fairhurst and others (11) reported positive results after 10 years for an atraumatic treatment with composite sealed restorations. The authors observed 14 percent of failure in 85 evaluated restorations, as well as the arrest of dentinal lesions sealed with composite in the presence of sound enamel margins. McDonald and Sheiham (17) observed progression of the dentinal lesions in a small percentage (11%) of deciduous molars restored with composite in an MITC approach, yet the authors did not describe the presence of enamel throughout the preparation margin.

Most of the studies on ART have been conducted on relatively low-risk populations. Alternative operative interventions in the treatment of caries should also be applied to high-risk patients, as in this study, before the benefit of the treatment can be ascertained (18).

The lost-to-follow-up rates of 20.9 percent and 21.1 percent for Groups 1 and 2, respectively, after two years are high, but apparently unavoidable, in longitudinal studies in disadvantaged societies, and they are in agreement with results of other studies (8,9).

The present study has demonstrated that high-viscosity glass ionomer applied in a minimal intervention approach provided high-quality preventive and restorative care after two years to a population at high risk for caries. The composite was employed in cavities submitted to less masticatory stress, such as in the anterior teeth, and its behavior was comparable to that of the glass ionomer cement. The reinforced ZOE cement exhibited a high failure rate, thus contraindicating its application for restorative care in oral health promotion program for caries arrestment.

Acknowledgments

The authors would like to thank the FAPESP foundation for the financial support of this study (grant 96/05299-7).

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