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Clinical performance of a resin-modified glass-ionomer and two polyacid-modified resin composites in cervical lesions restorations: 1-year follow-up

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SUMMARY **The aim of this study was to assess the clinical performance of a resin-modified glass–ionomer cement (Vitremer™) and two polyacid-modified resin composites (F2000™ and Freedom™) over 1 year. Nineteen patients with at least three cervical lesions were selected, providing an initial sample size of 87 restorations (29 per material), being 78 to non-carious and nine to carious lesions. Restorations were evaluated at baseline, 6 months and 1 year after placement, using modified US Public Health Service criteria: colour match, marginal discoloration, caries, anatomical form, marginal integrity and surface texture. At baseline, restorations were considered as acceptable for all criteria. At 1-year recall, 21 restorations per material were re-examined. Freedom™ was rated Bravo or Charlie for all the examined criteria and Vitremer™ earned an Alfa rating solely for the criterion caries. On the contrary, F2000™ showed the best overall results, although presenting significant alteration in colour match. Statistical analysis of data was performed using chi-square and Mc Nemar tests. As to the evaluated periods, significant difference was observed solely between baseline and 1-year recall. Freedom™ and Vitremer™ were statistically different ($P < 0{\cdot}01$) as to anatomical form and surface texture. For F2000™, significant difference ($P < 0{\cdot}05$) was noticed as to colour match and anatomical form. After 1-year follow-up, F2000™ showed the most acceptable results as to the analysed criteria.**

KEYWORDS: **glass–ionomer cement, resin composite, clinical evaluation**

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Introduction

The conventional glass–ionomer cements (GICs) were first introduced to dentistry in the 1970s (1) as two-component materials comprising powder, usually a fluoroaluminunsilicate glass, and liquid consisting of one or more polyalkenoic acids. On mixing, the GIC results from an acid-base reaction of the aqueous polymeric acid and the ion-leachable glass powder (2). However, only up from the 1980s, the characteristics and properties of the commercially available glass–ionomers were greatly improved, thus extending their applicability and indications (3). Several features contributed to their acceptance, including biocompatibility, good adhesion to dental substrate, ability to take up and release fluoride, minimal shrinkage on setting and a coefficient of thermal expansion similar to that of tooth structure (2). On the contrary, the GICs provide aesthetics less good than resin composites, deficient physical properties and, in addition, they are susceptible to water loss and uptake in the first few hours after placement and dissolution, which may compromise finishing and polishing (4).

In an attempt to overcome the disadvantages of conventional glass–ionomers, a further evolution combined light-cured composite resin and GIC technology. The term 'resin-modified glass–ionomer cement' (RMGIC) defines a material with the main characteristics of the GICs, but modified by the presence of resin molecules, usually 2-hydroxyethyl methacrylate (HEMA). Therefore, this material undergoes a second curing process normally initiated by visible-light

activation in addition to the acid–base reaction (3, 5). The so-called hybrid ionomers have been claimed to possess improved physical properties, decreased sensitivity to water loss and sorption, enhanced aesthetics and longer working time (3). Clinically, the hybrid ionomers present optimal behaviour immediately after placement while the conventional GICs improve their properties with time (3, 5, 6).

In the 1990s, another category of light-cured restorative materials, which contain glass–ionomer components and release fluoride, was introduced to market. However, the polyacid-modified resin composites (PMRC) may not be considered as glass–ionomers, as they are single-component resin materials and do not exhibit the characteristic acid–base reaction (4).

Although there is a great number of reported laboratory researches evaluating the physical properties of adhesive restorative materials, there is a lack of short- and long-term clinical studies assessing their clinical performance.

Therefore, the aim of this trial was to evaluate the clinical performance of one RMGIC (Vitremer™) and two PMRCs (F2000™ and Freedom™) in cervical lesions cavities, over 1-year.

Materials and methods

The research protocol was initially submitted to appreciation of Ethics Committee (Ethics Committee of Ribeirão Preto School of Dentistry, University of São Paulo). As the method was approved, patients of the ambulatory clinic at Ribeirão Preto School of Dentistry-University of São Paulo, with cervical dentinal hypersensitivity or aesthetic complaints, were examined.

To participate in the trial, patients were required to present at least three carious or typical non-carious wedge/saucer-shaped cervical lesions resulting from abrasion, erosion, and abfraction. After the medical and dental histories were assessed, a detailed thorough visual inspection was accomplished using dental mirror and probe. The investigators ruled out as participants all individuals with high plaque index and improper oral health care, and selected 19 patients of both sexes, ranging in age from 25 to 50 years. Subjects were required to be willing and able to return at specified study intervals for follow-up examinations. The nature and objectives of the trial were fully explained and all participants signed the appropriate, approved informed consent documents.

For each patient, at least three restorations – one of each tested material – were placed in anterior and/or posterior teeth, providing an initial sample size of 87 restorations (29 per material). Seventy-eight restorations were placed to treat non-carious lesions and nine restorations were provided to treat carious lesions. The tested materials, specifications and manufacturers are listed in Table 1; their compositions are listed in Table 2.

All restorations were placed under isolation with a rubber dam, appropriate retainer or cheek retractor and cotton rolls to prevent salivary contamination and facilitate the restorative procedures. A local anaesthetic was previously used when needed to prevent discomfort during operative proceeding. The dental surfaces were carefully polished with water/pumice slurry in dental prophylactic cups to remove the biofilm and stains. Then, careful visual inspection was carried out under good illumination on a clean and dry tooth surface. Cavity preparation was limited to the removal of previous restorations or carious tissue using small, round burs at low-speed. An additional retention was accomplished on the axio-occlusal angle, using no. 1/4 round carbide bur (ISO: 500 314 001 001 005) at high-speed with air–water spray. For teeth restored with PMRC, the occlusal cavosurface angle was bevelled with a no. 2134 diamond point (ISO: 806 314 198 524 014).

The materials were manipulated and placed following the manufacturers' instructions. For the PMRCs, cavity

Table 1. Tested materials

Material	Batch no.	Pre-treatment	Batch no.	Manufacturer	Type
F2000™	23038	Single Bond™	7AY	3M Dental Products, St Paul, MN, USA	PMRC
Freedom™	2256	Stae™	70812	Southern Dental Industries, LTD (SDI), Victoria, Australia	PMRC
Vitremer™	Powder – 19970717 Liquid – 199770709	Vitremer Primer™	199770925	3M Dental Products, St Paul, MN, USA	RMGIC

PMRC: polyacid-modified resin composites; RMGIC: resin-modified glass–ionomer cement.

Table 2. Composition of restorative materials and primer/adhesive systems evaluated

Material	Composition	Pre-treatment	Composition
F2000™	FAS glass, colloidal silica, CDMA oligomer (dimethactylate functional oligomer derived from citric acid), GDMA, hydrophilic polymer, camphoroquinone/amine	Single Bond™	HEMA, BisGMA, dimethacrylates, methacrylate functional copolymer (polyacrilic and polyitaconic acids = polyalkenoic acid copolymer), photoinitiator, ethanol, water
Freedom™	Modified dimethacrylates, silica, strontium glass, sodium fluoride, initiators	Stae™	HEMA, TEG-DMA, initiators dimethacrylates, water, acetone
Vitremer™	Powder: FAS glass Liquid: HEMA, photosensible aqueous solution of modified polyalkenoic acid, water	Vitremer Primer™	HEMA, methacrylated polycarbixilic acids, water, ethanol, photoinitiator

FAS, fluoroaluminunsilicate; CDMA, cycloaliphatic dimethacrylate; GDMA, glyceryl dimethacrylate; HEMA; BisGMA, biphenol glycidyl methacrylate; TEG-DMA, tetraethylene glycol dimethacrylate.

preparations were etched with a 37% phosphoric acid gel for 15 s, thoroughly rinsed for 20 s and water excess was removed with absorbing paper to keep the tooth surface moist. Two coats of Single-Bond™ or Stae™ were applied before placing either F2000™ or Freedom™ restorations, respectively. The one-bottle adhesive systems were slightly thinned with a mild oil-free air stream and light-cured for 20 s with a visible light-curing unit with a 450 mW cm^2 output (XL 3000™; 3M Dental Products). The materials were inserted into cavities with appropriate instruments according to an incremental placement technique and each increment was polymerized for 40 s.

For teeth restored with the RMGIC, a thin layer of Vitremer Primer™ was applied to the entire dentine surface with a disposable brush and light-cured for 20 s. Vitremer™ Powder and Liquid were dosed (1:1) and mixed within 45 s. The resultant material was injected into the cavities in a single increment using a Centrix™ injector to prevent air-entrapment, void or bubble formation and polymerized for 20 s.

Restorations were finished at the placement visit by removing the roughest excesses with a sharp scalpel blade. For RMGIC restorations, Vitremer Finishing Gloss™ was applied and light-cured for 20 s. In a subsequent appointment, after 1 week, wet polishing was carried out using 12-bladed finishing burs and aluminium oxide disks (Sof-Lex™; 3M Dental Products) of decreasing abrasive order.

Two experienced, previously calibrated examiners evaluated restorations at baseline, 6 months and 1 year after placement, using modified US Public Health Service (USPHS) criteria (2, 7) to assess: caries, anatomical form, marginal integrity, marginal discoloration, colour match and surface texture (this criterion was added to the USPHS criteria proposed by Ryge). The methods for the criteria evaluation are described in Table 2. If disagreement occurred between the examiners, a third equally calibrated expert was asked for evaluation. Photographs of all restorations were taken at 1:1 magnification on colour slide film at baseline and at each recall, for retrospective comparison. Data were submitted to statistical analysis using Chi-square and Mc Nemar tests.

Results

At baseline, 29 restorations of each material were evaluated. However, at the further recalls, some patients did not show up for re-examination and the number of restorations per material was 23 after 6 months and 21 after 1 year. The data for the tested materials are described in Table 3. At baseline, the restorations showed no alteration with respect to criteria assessed. At the 6-month evaluation, the restorations presented few alterations and showed similar satisfactory results.

After 1 year, no loss of restorations was noticed. Freedom™ restorations showed alterations in higher (Charlie rating) or lower degree (Bravo rating) for all the clinical aspects examined. At the 1-year examination, 4·5% of the Freedom™ restorations were rated Charlie for colour match, marginal discoloration, caries and anatomical form. Additionally, 86·4% of Freedom™ restorations received Bravo ratings for surface

Table 3. Evaluation of restorations at baseline, 6 months and 1 year

	Baseline			6 Months			1 Year		
	A (%)	B (%)	C (%)	A (%)	B (%)	C (%)	A (%)	B (%)	C (%)
Colour match (method of evaluation: visual inspection)									
F2000™	100	0	0	100	0	0	66·6	28·6	4·8
Freedom™	100	0	0	100	0	0	90·9	4·5	4·5
Vitremer™	100	0	0	100	0	0	95	0	5
Marginal discoloration (method of evaluation: visual inspection)									
F2000™	100	0	0	100	0	0	100	0	0
Freedom™	100	0	0	96·2	3·8	0	90·9	4·5	4·5
Vitremer™	100	0	0	100	0	0	85	10	5
Caries (method of evaluation: visual inspection)									
F2000™	100	0	0	100	0	0	100	0	0
Freedom™	100	0	0	100	0	0	95·5	0	4·5
Vitremer™	100	0	0	100	0	0	100	0	0
Anatomical form (method of evaluation: visual inspection and explorer)									
F2000™	100	0	0	88·5	11·5	0	71·4	28·6	0
Freedom™	100	0	0	88·5	11·5	0	63·7	31·8	4·5
Vitremer™	100	0	0	91·6	4·2	0	40	60	0
Marginal integrity (method of evaluation: visual inspection and explorer)									
F2000™	100	0	0	92·3	7·7	0	100	0	0
Freedom™	100	0	0	100	0	0	95·5	4·5	0
Vitremer™	100	0	0	100	0	0	95	5	0
Surface texture (method of evaluation: explorer)									
F2000™	100	0	0	100	0	0	76·2	23·8	0
Freedom™	100	0	0	88·5	11·5	0	13·6	86·4	0
Vitremer™	100	0	0	91·7	8·3	0	55	45	0

Alfa (A), no clinically detectable alteration; Bravo (B), restoration slightly altered without need for replacement; Charlie (C), restoration altered with need for replacement.

texture. Vitremer™ restorations also presented alterations for most criteria, mainly regarding the anatomical form (loss of material). Sixty per cent of Vitremer™ restorations received Bravo ratings and 5% of the restorations received Charlie ratings with respect to colour match and marginal discoloration. Nevertheless, no carious lesion was observed. F2000™ showed no alteration with respect to marginal discoloration, marginal integrity and caries. However, 4·8% of F2000™ restorations were rated Charlie for colour match. Although, comparing the tested restorative systems as to their overall clinical performance, F2000™ showed the best results for the criteria evaluation after 1 year.

Comparing the restorative materials, statistical analysis using Chi-square test showed significant difference concerning colour match, anatomical form, surface texture and marginal discoloration. As to the evaluated periods, Mc Nemar test revealed significant difference solely between baseline and 1-year evaluation. Freedom™ and Vitremer™ were statistically different ($P < 0{\cdot}01$) as to anatomical form and surface texture. For F2000™, significant difference ($P < 0{\cdot}05$) was observed with regard to colour match and anatomical form.

Discussion

The oral cavity is a complex environment from chemical and technological points of view. Therefore, *in vitro*-experiments cannot conceivably copy every important detail of an *in vivo*-situation. Important and clinically relevant information can of course be obtained from *in vitro* experiments, but ultimate information about the clinical feasibility of a particular dental material or technique can only be retrieved from *in vivo* studies.

Studies (8, 4) have stated the clinical performance of hybrid restorative materials. Some of these studies evaluated the clinical performance of RMGIC or PMRC

in non-carious or carious cervical lesions. Restorations of cervical abrasion or erosion lesions are subjected to continuous loss of tooth structure or the occurrence of small fracture of the materials at the margin, which might have adversely affected marginal integrity and resulted in increased rate of marginal discoloration (8). Marginal discoloration indicates a lack of adhesion of the material and penetration of stain around the margins (9).

The RMGICs and PMRCs have a setting stress, which starts immediately after the start of light curing. Feilzer *et al*. (10) showed setting stress values of 2·5 MPa for a RMGIC after a 1-min exposure time. The extent of the curing shrinkage determines creation of marginal gaps if the filling material does not adhere enough to tooth structure or it can cause cohesive failures in the material. The marginal adaptation is probably affected by dimensional changes occurring during setting. A study (11) showed curing shrinkage to appear within 5 min after polymerization, and to proceed for the next 24 h. This shrinkage gives rises to contraction stress that can damage the adhesive interface and create marginal gaps. After immersion in water, this shrinkage is followed by expansion to water sorption (10–15).

The findings of this trial disclosed that, except for colour match, F2000^{TM} restorations appeared clinically superior to the RMGIC (Vitremer^{TM}). These results corroborate those of an earlier investigation (4), which concluded that RMGIC and PMRC restoratives showed acceptable performance when placed in cervical carious cavities. However, according to those authors, PMRC demonstrated better clinical performance than RMGIC.

In the conducted evaluation, none of the patients reported post-operative sensitivity. A previous histological study (6) evaluated PMRC restorations placed *in vivo* in primates' teeth and found good compatibility with pulp tissue, when bacterial microleakage is excluded by a proper clinical seal. Leakage pathways between the cavity walls and the restoration cause post-operative problems such as hypersensitivity, pulpal injury and recurrent caries (16). For light-cured restorative materials, in particular, polymerization shrinkage tends to generate contraction stresses at the cavity floor and cause deterioration of the adaptation. In an earlier investigation (17), the best adaptation was shown for the PMRC, while the RMGIC showed significantly more leakage. On the contrary, PMRC possess high coefficient of thermal expansion, superior to that of RMGIC (5), which is an important approach in gap formation at tooth/restoration interface thereby minimizing the deleterious effects of marginal microleakage.

Ferrari and Davidson (18) assessed the marginal sealing of RMGIC and PMRC cervical lesions restorations placed *in vivo* and reported equivalent results for all the tested restorative systems. The findings of the conducted research disclosed that solely F2000^{TM} provided complete marginal sealing at the 12-month recall, although this result was not statistically different to those of the other evaluated materials. A previous *in vitro* evaluation of microleakage on cervical restorations (19) revealed that the same materials tested in this study, showed statistically similar results at the enamel interface, and at the cervical margin, Vitremer^{TM} and F2000^{TM} provided better marginal sealing compared with Freedom^{TM}.

Hygroscopic expansion is also one of the factors in reducing the leakage (11, 20). Measurements after longer storage in water will show the better adaptation. Nevertheless, adaptation of the top surface may be better than the other sites of the cavity as the bond between the restoratives and tooth substrates can be achieved as soon as the restorative is irradiated during photo polymerization (21).

Regardless of the tested restorative materials at the 1-year recall, the appearance of great number of restorations was seriously deteriorated, mainly because of loss of anatomical form, colour change and development of a rough surface. A criterion such as surface roughness of a material is an important parameter in determining its polishability and abrasive-wear rate (22). A measurement of surface-roughness (23) revealed that RMGICs were rougher than the PMRC, especially after toothbrush abrasion. The higher polishability of the PMRC is probably mainly because of its smaller particles and the absence of air bubbles, unlike the RMGIC, which contain multiple in-mixed air bubbles in the hand-mix. These intruding porosities, together with filler particles that became exposed by abrasion, contribute to the higher roughness of the RMGIC (23).

One of the factors that determine the clinical longevity of an aesthetic restorative material is its ability to maintain its original colour when functioning in the oral cavity (24). The conducted study is in agreement with a previous clinical investigation (25), which related that colour changes occurred in both evaluated RMGIC and PMRC over 1 year. However, it is not in accordance with another earlier investigation

(26), which disclosed that the mean colour match score of a PMRC at baseline and 1 year indicated a close colour match to tooth that remained unchanged over the observation period. A potential reason for the change in colour match can be the extent of polymerization reactions, water sorption, early disruption of both polymerization reactions and surface characteristics. The addition of a high concentration of hydrophilic monomers in these new materials can also lead to a continuing water sorption, resulting in degradation of its resin components and exposing its filler particles after *in vivo* wear, which affect the colour by increasing the scattering of incident light (5).

Another significant alteration noticed for the tested restorative materials concerned loss of anatomical form. Anatomical form indicates the early ease of finishing and then, later, the resistance to abrasion and erosion of material in cervical lesions (9). Such alteration would possibly be ascribed to the improper oral health care presented by most patients, who returned for the appointments with visible presence of biofilm, as it has been reported that restorative materials undergo significantly greater abrasion in an acidified oral environment (27). In the conducted research, the RMGIC showed higher degree of clinically visible wear than the PMRC. A possible explanation for such performance would be that, although the addition of resin components improved RMGIC properties, they still present higher wear rate when compared with resin composites (28).

Although the RMGIC and PMRC are claimed to successfully replace lost tooth structure, consistent improvements are still required to provide the desirable characteristics and properties of an aesthetic material. Moreover, further investigations on the long-term clinical behaviour of these materials will lead to more widespread indications and applicability in dental practice.

On the basis of this study, it may be concluded that, after a 1-year follow-up, F2000^{TM} showed the most acceptable overall clinical performance for the analysed criteria.

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