A randomized trial of resin-based restorations in Class I and Class II beveled preparations in primary molars

24-month results

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In pediatric dentistry, the range of restorative procedures performed in primary molars differs slightly from that of those performed in permanent teeth, owing to the characteristics of primary teeth, such as dental wear and limited life span.[1] Thus, resin-modified glass ionomer cements (RMGICs), polyacid-modified resin-based composites (PMRBCs) and resin-based composites (RBCs) have been shown to be suitable materials for filling primary molars[2-6] because of their advantages and physical properties. Among these are their ability to bond to dental substrate, their pleasing esthetic qualities and, in some of these materials, the fluoride release potential.[7] In addition, there is controversy in both scientific and lay communities about the use of amalgam.[4] Moreover, to date, no consistent guidelines have been published in the pediatric dental literature for either cavity design or material selection, and choices in these areas appear to be based on clinical preference.[6]

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ABSTRACT

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Purpose. The authors conducted a randomized clinical trial to evaluate the survival rate of esthetic restorations in Class I and Class II beveled preparations in primary molars 24 months after placement. The null hypothesis was that there is no difference among survival rates of the restorative materials used.

Methods. Forty-eight children (mean age, 5 years 9 months) received 141 restorations in beveled cavosurface margins in primary molars randomly assigned by lottery method: 46 received treatment with Vitremer Tri-Cure Glass Ionomer System (3M ESPE Dental Products, St. Paul, Minn.) (33 Class I and 13 Class II restorations), 51 received treatment with Freedom (SDI, Bayswater, Victoria, Australia) (36 Class I and 15 Class II restorations); 44 received treatment with TPH Spectrum (Dentsply, Petropolis, Rio de Janeiro, Brazil) (30 Class I and 14 Class II restorations). Two examiners whose technique had been calibrated (weight $\kappa > 0.85$) evaluated the restorations using modified U.S. Public Health Service criteria and Visible Plaque Index score at baseline and at 12, 18 and 24 months.

Results. After two years, the authors censored data for 17 restorations, considered 101 restorations to be clinically successful and deemed 23 restorations failed because of loss of marginal integrity, anatomical form discrepancies and secondary caries. For Class I and Class II restorations, the cumulative survival rates were higher than 80 percent and 55 percent, respectively, for all materials (life table, Gehan-Wilcoxon Test, $P > .05$; $P > .05$).

Conclusions. At the 24-month clinical recall, the authors found no differences among materials in Class I ($P > .05$) or Class II beveled preparations ($P > .05$) in primary molars, but all materials showed higher survival rates in Class I than in Class II restorations.

Key Words. Randomized controlled trial; dental materials; survival rate; molar; primary teeth; dental cavity preparation.

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bonding procedures has been studied extensively in permanent teeth,[8] researchers have merely extrapolated the results of these studies to primary teeth. In permanent teeth, clinicians do not use bevels along occlusal enamel because bevels make the restorations more prone to marginal fracture at points of occlusal contact or functional slides. In primary teeth, differently from permanent teeth, clinicians could improve the bond quality by carrying out a mechanical treatment, such as removal of the prismless enamel by grinding, before performing acid etching. Under these conditions, a clinician could achieve a constant and regularly distributed loss of interprismatic and intraprismatic substances.[9] Moreover, in primary dentition, researchers have reported that beveled cavity margins should be the preferred configuration for adhesive restorative treatment because they reduce marginal microleakage.[10,11] Furthermore, children's bite force is less than that of adults,[12] and the primary teeth experience physiological wear at the same rates as those of the RBCs, therefore minimizing the possibility of marginal fractures.[11] However, in clinical trials,[13-19] investigators rarely adopted this beveled cavity configuration for Class I and Class II preparations in primary molars.

Restorative material assessment should be based on findings from practice-based clinical trials, because this is the most appropriate evidence to use in qualifying and understanding the behavior of restorative materials.[20] Indeed, the ability to evaluate the interaction of factors such as operator, design, material properties, site and patient conditions,[21] all modulated by time, can occur only in in vivo studies.[22] In contrast, laboratory studies provide only partial information, generally regarding the physical properties of restorative materials.[23,24]

Nevertheless, in the dental literature we consulted, we found no report that simultaneously compared the clinical performance of restorations made with RMGIC, PMRBC and RBC, mainly in Class I and Class II cavity preparations in children. Thus, we conducted a randomized clinical trial (RCT) to evaluate the survival rate of esthetic restorations done with three types of adhesive restorative materials, in Class I and Class II beveled preparations in primary molars, after 24 months. The null hypothesis was that there is no difference among survival rates of the restorative materials.

METHODS

This RCT was approved by the local human research ethics committee of Clementino Fraga Filho University Hospital of the Federal University of Rio de Janeiro, Brazil. We performed it at the Federal University of Rio de Janeiro School of Dentistry after obtaining the children's and guardians' agreement and signed terms of informed consent.

Subjects. During a period of 12 months, one instructor (L.C.M.) screened all children scheduled to start the dental treatment at the pediatric dental clinic according to these criteria:

- good mental and physical health;
- presence of at least two primary carious lesions—occlusal, occlusoproximal (mesio-occlusal or disto-occlusal) or both—on primary molars in a split-mouth design, with no clinical or radiographic signs of pulpal or periradicular disease and pathological wear;
- presence of all primary molars with occlusal and proximal contacts.

After performing clinical and bitewing radiographic examinations, we selected 48 healthy children between the ages of 3 and 9 years (mean, 5 years 9 months). Two trained pediatric dentists (M.P. and another dentist) who had participated in a pilot study that preceded this study treated the subjects, using local anesthetic and rubber dam isolation. Each child was treated by the same operator at each visit to avoid behavior problems on the part of the child. Each patient received at least two types of restorative materials, which the dentists chose randomly via the lottery method after completing the cavity preparations.

The study consisted of 141 restorations in total: 46 with RMGIC (Vitremer Tri-Cure Glass Ionomer System, 3M ESPE Dental Products, St. Paul, Minn.); 51 with PMRBC (Freedom, SDI, Bayswater, Victoria, Australia); and 44 with RBC (TPH Spectrum, Dentsply, Petropolis, Rio de

ABBREVIATION KEY. AC: Axial contour. **AF:** Anatomical form. **DO:** Disto-occlusal. **MA:** Marginal adaptation. **MO:** Mesio-occlusal. **MS:** Marginal staining. **NA:** Not available. **NS:** Not significant. **O:** Occlusal. **PC:** Proximal contact. **PMRBC:** Polyacid-modified resin-based composite. **RBC:** Resin-based composite. **RCT:** Randomized clinical trial. **RMGIC:** Resin-modified glass ionomer cement. SC: Secondary caries. **USPHS:** U.S. Public Health Service.