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Randomised trial of resin-based restorations in Class I and Class II beveled preparations in primary molars: 48-Month results

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ABSTRACT

Objective: This randomised clinical trial evaluated the survival rate of resin-based restorations in Class I and Class II beveled preparations in primary molars, over 48 months.

Methods: Forty-eight children received 141 restorations in beveled cavosurface margin preparations in primary molars randomly assigned by a lottery method: 46 received treatment with Vitremer™ Tri-Cure Glass Ionomer System (33 Class I and 13 Class II restorations); 51 received treatment with Freedom™ (36 Class I and 15 Class II restorations); 44 received treatment with TPH Spectrum™ (30 Class I and 14 Class II restorations). Two calibrated examiners (weight $\kappa \geq 0.85$) evaluated the restorations using the modified USPHS criteria and visible plaque index score at baseline and after 12, 24, 36 and 48 months. Cox regression with survival analysis and logistic regression evaluated the clinical performance of restorations.

Results: After 48 months, 11 teeth had exfoliated, 16 restorations were dropouts, 83 restorations were clinically successful of which 26 had used Vitremer™, 32 had used Freedom™ and 25 had used TPH Spectrum™. Thirty-one restorations failed because of secondary caries, fractures and loss of retention. The cumulative survival was 73.9%, 83.4% and 79.6%, respectively for Vitremer™, Freedom™ and THP Spectrum™ with no differences among materials (Log Rank Mantel-Cox, $p > 0.05$). However, the Class II cavity preparation reduced the survival of the restorations (OR = 5.1) for all materials evaluated ($p > 0.05$).

Conclusions: The life expectancy of Vitremer™, Freedom™ and THP Spectrum™ in Class I and Class II restorations could be comparable after 48 months.

1. Introduction

If clinical longevity is the primary criterion in material selection, dental amalgam would be preferable to composite restorations.[1–3] However, due to unaesthetic colour and also environmental concerns there are controversial discussions concerning the use of amalgam as a contemporary restorative material.[4]

In parallel, tooth-coloured restorative materials have been widely used for restoring primary teeth[5–7] not only to reflect the concept of minimal intervention in dentistry which implies conservative cavity preparations, but also due to

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differences in morphology and wear behaviour of the primary teeth in comparison with permanent teeth.[8] Moreover, the limited life span of deciduous teeth allows a greater diversity in the choice of adhesive restorative material. Specifically taking this latter point into account, resin-modified glass ionomer cements, polyacid modified composite resins (compomers) and composite resins have been shown to be more suitable because of light-induced cure and the improvements in their mechanical properties.[9] Otherwise, the survival order of restorations in paediatric dentistry is not straight forward.[5,10–12]

Many clinical trials have been published[5,10,11] in which secondary caries, bulk and or marginal fractures are of major concerns.[13] However, it is difficult to analyse and compare the results because of the different clinical protocols used.[14] A previous clinical trial showed that there was no difference among the survival rates of light-cured resin-based restorations in Class I and Class II beveled preparations in primary molars. However, the results of this clinical trial reported a medium-term period follow-up.[15]

Under the auspices of evidence-based dentistry,[14] randomised controlled trials with long-term period to follow-up the clinical outcomes of the materials is highly recommended. This study design has long been recognized as the 'gold standard' for evidence research related to clinical practice.[16] Thus, the present study aimed to evaluate the survival rates of restorations made with a resin-modified glass ionomer cement, a compomer and a composite restoration in Class I and Class II beveled preparations in primary molars after 48 months. The null hypothesis was there is no difference among restorative materials.

2. Materials and methods

2.1. Study design and participants

This randomised clinical trial (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 and was carried out at the School of Dentistry of the Federal University of Rio de Janeiro, after obtaining the children's and guardian's agreement and signed terms of informed consent.

2.2. Subjects

From March 2003 to October 2004, all children scheduled to start the dental treatment in paediatric dental clinic were screened by one instructor according to these criteria: be mentally and physically healthy with at least two occlusal (O) and/or occluso-proximal (MO or DO) primary caries lesions on primary molars in a split-mouth design, with no clinical or radiographic signs of pulpal or periradicular pathology and pathological wear; have all primary molars with occlusal and proximal contacts.

After clinical and bitewing radiographic examination, 48 healthy children between 3 and 9 years of age (mean 5 years and 9 months) were selected. The subjects were treated with local anaesthesia and rubber dam isolation by two trained paediatric dentists. Each child was treated by the same operator to avoid behaviour problems. Each patient received at least two types of restorative materials, which were randomly chosen by the lottery method.

Table 1 – Esthetic restorative materials investigated and technique used.

Material	Brand name	Batch number	Basic composition	Adhesive protocol	Technique
RMGIC	Vitremer™ Tri-Cure Glass ionomer System™	3303MPA3	Fluoroaluminosilicate glass; potassium persulphate, ascorbic acid, aqueous solution of polycarboxylic acid, water, hydroxyethyl methacrylate, photoinitiators, ethanol	Vitremer™ Primer[a]	Applied for 15 s, then light-cured for 20 s
PMCBR	Freedom™	033808	Strontium glass, non-BISGMA	Total etch 37% phosphoric acid Stae™ dentin/ enamel adhesive[b]	Total acid etch for 30 s (condition enamel for 15 s and dentin for 15 s). Washed with water then dried with air spray. Applied Stae adhesive system; gently dried with air spray and light-cured for 20 s
RBC	TPH Spectrum™	555055	Borosilicate glass/pyrogenic silica potassium persulphate and ascorbic acid; BISGMA, UDMA e TEDMA	Total etch 37% phosphoric acid/ Prime & Bond NT™[c]	Total etched for 30 s (condition enamel for 15 s and dentin for 15 s). Washed with water then dried with air spray. Applied Prime & Bond NT adhesive system; gently dry with air spray, reapplied and light-cured for 20 s

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[c] Manufactured by Dentsply, Petropolis, Rio de Janeiro, Brazil.