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Efficacy of sealing occlusal caries with a flowable composite in primary molars: A 2-year randomized controlled clinical trial

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ABSTRACT

Objectives: This randomized controlled clinical trial evaluated the efficacy of sealing carious dentin in controlling the progression of lesions in primary molars for 2-year follow-up.

Materials and methods: Children (6.79 ± 1.81 years, n = 28) presenting primary molars with occlusal caries in the outer half of dentine were randomized and allocated into 2 groups: test (sealing caries with a flowable resin – SC) and control (partial removal of caries followed by restoration – PRC). The primary outcomes were: the clinical success of restorations evaluated by USPHS criteria and the radiographic analysis of caries progression. The children anxiety was evaluated by a Facial Image Scale; and the time required to perform the treatments was registered.

Results: In 21 patients evaluated after 2 years, 48 primary molars were analyzed. Clinically, there was no difference between the groups. There was no difference between treatments ($p = 0.848$) considering lesion progression. The anxiety level did not change after the two interventions ($p = 0.650$). The treatment time of SC (9.03 ± 1.91 min) was lower ($p = 0.002$) than the PRC time (17.13 ± 5.26 min).

Conclusion: Sealing carious dentin may be used in dentistry since it did not alter the children anxiety, reduced the chair time and demonstrated clinical success rate and no radiographic difference in relation to the partial caries removal followed by restoration.

1. Introduction

Studies have shown that the conventional restorative technique where carious dentine is totally removed, should be replaced by a more conservative removal of decayed tissue followed by the restoration [1,2]. Moreover, there is a growing demand, especially in children, for even less invasive techniques [3], due to difficulties in the management of children's behavior during restorative dental appointments [4]. Thus, a restorative treatment that requires less time during its clinical procedure would become interesting for these patients. Some clinical studies [3–6] have already investigated less invasive treatments of carious deciduous teeth. Among them, sealing of caries [4,7] is a technique that recommends covering the carious tissue extending up to the outer half of dentin with resin-based sealants [8].

There is scientific evidence for the benefits of sealing caries as a preventive approach [9–11]. However, when indicated as a therapeutic treatment [4,7,8], more clinical studies are need. In a recent clinical trial [4], the authors observed the efficacy of a pit and fissure resin-based sealant in arresting dentinal caries lesions compared to partial excavation (control) and restorative treatment in primary molars. However, although they stated that no caries progression was registered on the radiographic evaluations of teeth that have their caries sealed, the control group showed significantly better clinical survival rate after 18 months of follow-up. Truly, while the sealant remains adhered to the tooth surface, the lesion is arrested [4].

According to Feigal and Donly [12] there is a failure rate of sealants range from 5% to 10% each year. Without appropriate clinical follow-up, previously sealed surfaces will be equally susceptible to caries as

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surfaces that were never sealed [12,13]. Thus, a more resistant sealant to masticatory wear would benefit the sealing caries treatment. Recently, Shinkai et al. [14] affirmed that flowable are resin materials indicated as cavity liners, fissure sealants and restorative material for small cavities. According to a recent study [14], flowable resin is equivalent to universal resin composites in resistance to tooth wear. Therefore, the aim of this study was to investigate the efficacy of sealing dentin caries with a flowable resin by comparison with partial caries removal followed by composite restoration in primary molars. The null hypotheses of this study were that the clinical and radiographic success of sealing caries with a flowable resin would not be different from partial caries removal followed by restoration in children with dentin caries lesion in deciduous molars.

2. Materials and methods

2.1. Ethics

The Research Ethics Committee of the Clementino Fraga Filho Hospital of the Federal University of Rio de Janeiro gave the approval of the present study (protocol #244-14; trial registration no. NCT02584218). Parents gave also written consent for children to participate after being informed of the aims of the study.

2.2. Study design

This controlled randomized clinical trial was conducted in the pediatric dental unit of the Federal University of Rio de Janeiro (UFRJ). Between September 2014 and June 2015, one trained examiner recruited 28 children (3–8 years old) with primary molars (n = 57) showing occlusal caries extending up to the outer half of dentin tissue, confirmed by interproximal radiograph exam. Children were randomized by a block design using a coin tossing system, with allocation concealment (through a sequentially numbered, white, sealed envelopes) into 2 arms: the test group (children who received the sealing caries treatment with a flowable resin), and the control group (children where partial caries removal was followed by composite restoration and flowable resin). When more than one tooth per child fulfilled the inclusion criteria, all of them received the same treatment, keeping the parallel design of the study. This trial followed the CONSORT recommendations [15]. Moreover, this is an interim study with a 24 months follow-up. Details of primary and secondary outcomes criteria are presented in Table 1.

2.3. Participants and recruitment

Children aged 3 to 8 years, who sought the first time dental care at the Pediatric Dental Unit of UFRJ, were selected after a complete anamnesis, clinical and radiographic examination by one operator (KRD), who was trained and calibrated for the caries assessment according to dmft/DMFT indexes [16] (inter examiner Kappa value = 0.91). Examinations were performed after a complete professional cleaning of the children's teeth. Inclusion criteria for the tooth were: opening of the occlusal cavity limited to 1.5 mm diameter measured with a millimeter probe, and lesion limited radiographically to the outer half of the dentin. Exclusion criteria at the tooth level were the presence of cavities or restorations in other surfaces. Children were also excluded if they had carious lesions affecting other teeth than the deciduous molars; signs or symptoms of pulpal or perirradicular pathology (including pain) in any tooth; or if they were unable to cooperate during the clinical appointments.

2.4. Sample size

Sample size was calculated based on the difference in the proportion of clinical success (one of the main outcome) observed in the only one previous similar study [4], since no caries progression (main outcome) was verified by these authors after 18-months follow-up. Assuming a difference of proportions of 35% between test and control groups, based on a two-sided test, considering a power of 80% and $\alpha = 0.05\%$, a sample size of 17 tooth allocated into each group of treatment was required to complete the study. With the estimative of 20% of drop out, at least 21 teeth for each group should be selected.

2.5. Baseline assessments

The selected children received a professionally tooth cleaning with pumice and rotating brushes, and air-dried before assessment of their caries status. The caries risk was performed by one trained and calibrated examiner (KRD), using the form based on Cariogram® software [17]. Thus, the patient's risk was classified as low, moderate, and high risk of caries [18], considering the following variables of assessment: dmft/DMFT index [16] (kappa inter value = 0.91); visible plaque index [19] (Kappa inter value = 0.73); dietary habits; and exposition to fluoride. The same examiner (KRD) interviewed the parents to assess the remaining data of the caries risk form.

Routinely, every child who presented clinically detected carious lesions was referred to radiographic examination. Radiographs were taken with individualized film-holders (Silicon bite registers) by a single operator using Express™ digital x-ray system (Instrumentarium, Finland) and Spectro 70× Seletronic equipment (Dabi Atlante, Brazil). After processing, the digital radiographic images were stored using CliniView™ software (Version 9.3.0).In this study, from 190 potentially eligible children aged 3–9 years diagnosed with occlusal caries that would be possibly included in the research, 152 were excluded because they did not meet the inclusion criteria (95 caries lesions presented the opening of occlusal cavity bigger than 1.5 mm; and 57 had cavities or restorations in other surfaces, which most of them were detected after the radiograph examination), 3 because their parents declined to participate, and 7 were excluded because they would not cooperate during the clinical appointments.

2.6. Randomization and intervention

In order to balance test (sealing) and control (partial caries removal + composite restoration) groups, patients were first stratified in two clusters paired by caries risk. Secondly, each cluster was allocated into test or control group using a coin tossing system. The allocation concealment was guaranteed by a sequentially numbered, white and sealed envelopes distributed by a third investigator (AL) not involved with the clinical assessment or with data analysis.

Children from both test and control groups and their parents were periodically (every three month) instructed regarding oral health care including dental floss usage, low sugar intake, and tooth brushing with fluoridated toothpaste after meals.

Patients from the test group had their teeth sealed according to the following protocol: (a) cleaning occlusal surface with pumice; (b) local anesthesia; (c) application of rubber dam; (d) 37% phosphoric acid application on the occlusal surface for 15 s; (e) rinsing and drying the surface; (f) application of adhesive system (Adper Single Bond 2, 3 M ESPE, Saint Paul, USA), following the manufacturer's instructions which was light cured for 20 s; (g) resin Filtek Flow (3 M ESPE, Saint Paul, USA) was applied on the whole occlusal surface and cured for 20 s; (h) occlusion checked and adjusted when necessary.

Patients from the control group had their teeth restored according to the following protocol: (a) cleaning occlusal surface with pumice; (b) local anesthesia; (c) application of rubber dam; (d) cavity was opened in enamel with a diamond bur in high speed (when it was necessary); then caries lesion was completely removed at the enamel/dentin junction, and dentin caries lesion was partially removed with hand instruments until the dentin started to become 'firm and leathery' [4]; (e) 37% phosphoric acid was applied in the cavity for 15 s; (f) rinsing