ORIGINAL RESEARCH
Pediatric Dentistry

Shortening of etching time of the dentin in primary teeth restorations: a randomized clinical trial

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Declaration of Interests: The authors certify that they have no commercial or associative interest that represents a conflict of interest in connection with the manuscript.

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https://doi.org/10.1590/1807-3107bor-2020.vol34.0081

Submitted: March 5, 2020
Accepted for publication: May 18, 2020
Last revision: June 2, 2020

Abstract: The aim of this study was to investigate the influence of shortening of etching time for dentin on the restoration survival after selective carious tissue removal in primary molars. This two-arm randomized clinical trial included sixty-two subjects (5–8 year-old) and 100 primary molars presenting moderate dentin carious lesions on occlusal surface. The sample was randomly assigned into groups previously to adhesive application (Adper Single Bond 2; 3M ESPE): etching time recommended by manufacturer (15 s) or reduced (7 s). Resin composite (Filtek Bulk Fill Posterior Restorative; 3M ESPE) was inserted in a single increment for all restorations. Restorations were evaluated at 1, 6, 12, and 18 months using FDI criteria. Survival estimates for restorations' longevity were evaluated with Kaplan-Meier method. Multivariate Cox regression analysis with shared frailty was used to assess the factors associated with failures ($p < 0.05$). The etching time did not influence the restorations' survival (HR 0.35 95%CI 0.11–1.12; $p = 0.06$). Mean estimated time of survival was 17.6 months (95%CI, 17.2–17.9). The survival rates at the 18-month follow-up were 75.7% and 91.4% (AFR: 16.9% and 5.7%) when primary dentin was acid etched for 15 and 7 s, respectively (log-rank $p = 0.06$). In conclusion, the etching time for dentin did not influence the clinical behavior of adhesives restorations. However, there was a tendency for better clinical outcome when using etching time of 7 s.

Keywords: Clinical Trial; Pediatric Dentistry; Acid Etching, Dental; Tooth, Deciduous.

Introduction

Resin composite has been widely used to restore decayed primary teeth because of its superior esthetics and lesser removal of sound tissue as compared to conventional treatments, thus allowing minimal intervention approaches such as selective carious tissue removal. Even though this material has shown satisfactory properties, a significant number of failures have been reported.[1,2] Factors associated with children such as caries risk,[3] oral hygiene,[4] age,[3,4] and behavior, as well as cavity-related features such as number of restored surfaces[3,5] and presence of endodontic treatment[1] could affect the restoration survival.

Although the choice of the type of composite material seems to have a minor effect on restoration survival,[6] there is evidence of

superior performance of etch-and-rinse adhesives in comparison with self-etch systems for restoring primary teeth[7], being the most used by clinicians. However, it has been known that chemical[8] and microstructural[9] differences between primary and permanent dentin may jeopardize the adhesion in this substrate.[10,11] Greater tubular density and larger diameter[9] result in a reduced area of intertubular dentin available for bonding. Chemically, the lower mineral content[8] reduces the buffering capacity and increases the reactivity of primary tooth dentin to acidic solutions. This is more critical while performing restorative procedures in cavity preparations involving residual carious tissue due to lesser mineral content in this substrate.[12]

Deeper demineralization of the dentinal substrate and subsequent incomplete penetration of resin monomers into the demineralized area results in a non-impregnated zone at the bottom of the hybrid layer, which creates sites more prone to degradation over time.[13] Thus, a previous *in vitro* study[14] stated that acid etching for half the time recommended by the manufacturer improves the bond stability with sound and carious primary dentin when etch-and-rinse adhesives are employed. Unfortunately, there is a lack of clinical evidence for the same.

Since randomized clinical trials provide the necessary support to clinicians in an evidence-based decision-making process, the aim of this study was to investigate the influence of shortening of etching time for dentin on the restoration survival after selective carious tissue removal in primary molars.

Methodology

Study design and ethical concern

This was a two-arm, parallel, randomized clinical trial that followed the CONSORT (Consolidated Standards of Reporting Trials) statement, and the study has been registered on the website www.clinicaltrials.gov (#NCT02969538). The local Ethics Committee on Investigations Involving Human Subjects of the Federal University of Santa Maria reviewed and approved the protocol and consent form for this study (protocol 1.320.844). Written informed consent was obtained from the guardians of the participants prior to starting the treatment.

The study was carried out in the Pediatric Dentistry Clinic of the School of Dentistry, Federal University of Santa Maria, Santa Maria, Rio Grande do Sul, Brazil, from April 2016 to October 2018. The participants and their guardians received detailed information about the study, but they were not aware of the treatment provided by the specific restoration under evaluation.

Sample calculation

To perform the sample size calculation, the expected success rate of occlusal resin composite restorations in primary molars was considered 95% in 18 months[15]. It was considered that a clinically significant difference was 15% in the success rate between the groups. Therefore, considering a significance level of 0.05 and a power of 0.80, using a one-tailed test for non-inferiority studies, with a 20% increase due to a possible sample loss and 30% by cluster of more than one tooth per children, we reached the final rounded number of 48 teeth per group, resulting in 96 teeth in total.

Sample selection

A total of 130 children (aged 5–8 years) were examined by two dentists (R.O.R. and T.M.A.) check the inclusion and exclusion criteria (Figure 1). The participants were recruited in the order that they attended the screening appointment. The clinical evaluations were performed using a plain mouth mirror and a ballpoint probe (Hu-Friedy Manufacturing Co., Chicago, USA). Children presenting good general health with cooperative behavior that did not refuse with the completion of clinical procedure with at least one primary molar with a moderate occlusal dentinal carious lesion, and with antagonist tooth were included in the study. The depth of the lesions was confirmed by bitewing radiographic examinations, *i.e.*, the caries lesions should involve the middle third of dentin radiographically. Moreover, the inclusion criteria also required that the participants presented teeth with the following clinical and radiographic features: absence of sensitivity and/or spontaneous pain, swelling, fistula, and mobility incompatible with the root resorption stage, absence of any radiographic signs suggesting pulp necrosis. Participants requiring