In vivo outcomes of Indirect Pulp Treatment using a Self-etching Primer versus Calcium Hydroxide over the Demineralized Dentin in Primary Molars

Luciano Casagrande * / Letícia Westphalen Bento ** / Simone Ossok Rerin ***/
Évelin de Resende Lucas ****/ Débora Martini Dalpian ***** / Fernando Borba de Araujo ******

Objective: *To evaluate the clinical and radiographic outcomes (24 months) of indirect pulp treatment (IPT) in primary teeth when a self-etching primer or a calcium hydroxide layer was used over the remaining carious dentin.* ***Study design:*** *Primary molar teeth with deep carious lesions without signs and symptoms of irreversible pulpitis were divided into two groups, according to the capping material: Experimental group (1): self-etching adhesive system (Clearfill SE Bond); and Control group (2): calcium hydroxide liner (Dycal). Both groups were followed up after application of a resin restoration (3M - Z250).* ***Results:*** *After 2 years of clinical and radiographic follow-up, no statistical difference was found between groups (p=1). The overall success rate reached 87%.* ***Conclusion:*** *These results demonstrate that IPT has a high clinical and radiographic performance in primary teeth and is not dependent on the capping material used over the demineralized dentin.*

Keywords: *primary teeth, indirect pulp treatment, self-etching primer, calcium hydroxide*
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INTRODUCTION

Indirect pulp treatment (IPT) is a technique indicated for the treatment of deep dentin active carious lesions in which the non-remineralizing tissue is removed and a thin layer of demineralized tissue is left at the deepest site of the cavity to avoid pulp exposure.[1-17] Composite resin and glass ionomer cement are generally used to restore primary teeth submitted to IPT due to their adequate marginal sealing.[11,12,15] Self-etching primers were developed in order to simplify clinical procedures and improve the quality of adhesive restorations. Systems that etch and infiltrate monomers simultaneously do not show a demineralized area in the bottom of hybrid layer.[18] Studies *in vitro* and *in vivo* have shown that self-etching primers advantage consist of a shallower area of demineralization promoted by the acidic monomers that can be easily filled by the bonding agent.[19,20]

Considering that the success of IPT is related to the marginal seal of the cavity and that the self-etching systems seems to promote an adequate hybridization, our study evaluated the clinical and radiographic outcome of indirect pulp treatment (IPT) in primary teeth when a self-etching primer or a calcium hydroxide layer was used over the remaining carious dentin.

MATERIALS AND METHOD

This clinical trial was conducted at the Pediatric Dentistry Unit (Federal University of Rio Grande do Sul – Brazil) using a protocol that was reviewed and approved by the institutional review board. (nº 08/04 according to the resolution 196/96 of the National Heatlh Council).

Forty primary molar teeth were selected from 21 healthy children (4 to 8 years old). The inclusion criteria were: (1) An active carious lesion in deep dentin limited to the

* Luciano Casagrande, DDS, MS, PhD Associate Professor School of Dentistry, Franciscan University Center (UNIFRA), Santa Maria RS, Brazil.
** Letícia Westphalen Bento, DDS, MS, PhD Student School of Dentistry, Department of Pediatric Dentistry, Federal University of Rio Grande do Sul (UFRGS), Porto Alegre RS, Brazil
*** Simone Ossok Rerin, DDS, Graduate student School of Dentistry, Department of Pediatric Dentistry, Federal University of Rio Grande do Sul (UFRGS), Porto Alegre RS, Brazil
**** Évelin de Resende Lucas, DDS** MS Student School of Dentistry, Department of Pediatric Dentistry, Federal University of Rio Grande do Sul (UFRGS), Porto Alegre RS, Brazil
***** Débora Martini Dalpian, DDS** MS Student School of Dentistry, Department of Pediatric Dentistry, Federal University of Rio Grande do Sul (UFRGS), Porto Alegre RS, Brazil
****** Fernando Borba de Araujo, DDS, MS, PhD** Associate Professor. School of Dentistry, Department of Pediatric Dentistry, Federal University of Rio Grande do Sul (UFRGS), Porto Alegre RS, Brazil

Send all correspondence to: Luciano Casagrande, School of Dentistry, Franciscan University Center (UNIFRA), Andradas 1614, Santa Maria, RS; ZIP: 97010-032, Brazil

Telephone: 0XX(55)32201200
Fax: 0XX(55)32226484

E-mail: lucianocasagrande@hotmail.com
lucianocasagrande@unifra.br

occlusal or occluso-proximal surface of the teeth; (2) absence of clinical diagnosis of pulp exposure, fistula, swelling, and abnormal tooth mobility; (3) absence of clinical symptoms of irreversible pulpits, such as spontaneous pain or sensitivity to pressure; (4) absence of radiolucencies at the furcation or periapical regions, or thickening of the periodontal spaces, which would indicate the presence of irreversible pulp pathology or necrosis; (5) absence of internal or external root resorption. Cases were selected based on the color and consistency of the caries in the lesion by one trained examiner, whose reliability was tested by the kappa test with an index of 0,80 and 0,75 respectively. All the subjects received treatment for caries activity arrestment, including extractions, pulp treatments, restoration of carious lesions, fluoride therapy, oral hygiene and dietary instructions.

The sample was submitted to IPT using the following protocol: The patient was anesthetized and under rubber dam isolation, received occlusal or occluso-proximal cavity preparations. The carious tissue was removed completely from the lateral walls of the cavity. On the pulp/axial wall, the most superficial infected and necrotic carious dentin was removed at sites where there was greatest "pulp exposure risk". A thin layer of demineralized dentin (Figure 1) was left. Teeth were then randomly assigned by assortment into experimental (CSE) (19 teeth, Clearfil SE Bond, Kuraray, Toquio - Japan), or control (21 teeth, Dycal Calcium Hydroxide, Caulk Dentsply, Milford DE - USA) groups, according to the capping material applied on the remaining carious dentin. In CSE group, the self- etching primer was applied for 20 seconds to the entire cavity and then the adhesive was placed and polymerized by light-curing with 500 mw/cm^2 for 20 seconds (Elipar Highlight ESPE – 3M). In the control group, a thin layer of calcium hydroxide was applied over the demineralized dentin intentionally left before the self-etching system application. The cavities were filled with resin composite (Filtek Z250) by incremental technique and the polymerization was achieved by the soft-start polymerization technique,[21] using a visible light source (Elipar Highlight ESPE – 3M). To restore the Class II cavities, a metal matrix (AutoMatrix) was adapted to the cervical margin with an interproximal wedge. The teeth were clinically re-examined after 1, 6, 12, and 24 months and radiographically after 6, 12, and 24 months (Figures 2 and 3).

The criteria used to determine the clinical and radiographic outcome of IPT were: absence of spontaneous pain and/or sensitivity to pressure, absence of fistula, edema, abnormal mobility, absence of radiolucencies at inter-radicular and/or periapical regions, absence of internal or external root resorption that was not compatible with biological resorption due to the exfoliation process. Any tooth that presented with irreversible pulpitis or symptoms at clinical or/and radiographic evaluation (Figures 4 and 5) was recorded as a treatment failure and either pulpectomized or extracted. One blind examiner performed the clinical (1, 6, 12, and 24) and radiographic (6, 12, and 24) follow-up examinations. The groups were statistically compared by the Fisher exact test with a significance level of 5%.

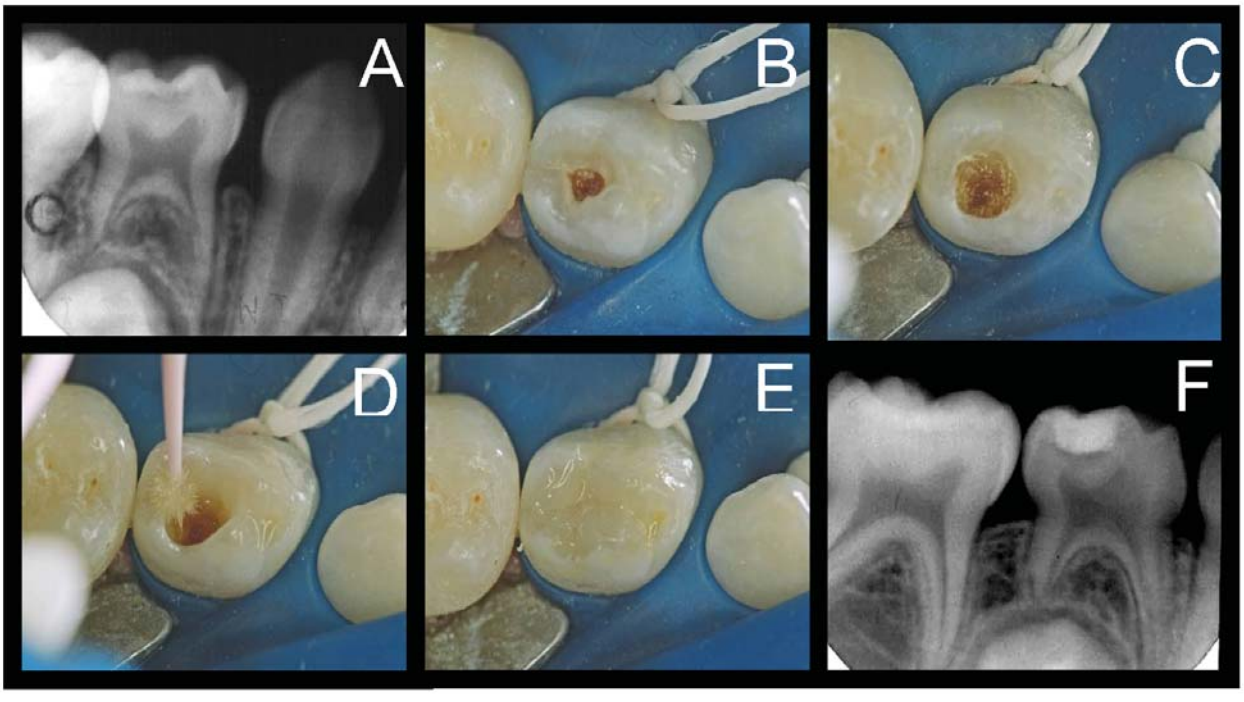

Figure 1. Clinical pictures describing the Indirect Pulp Treatment. (A) Pre-operative radiographic of a lower first primary molar with a deep carious lesion; (B) Caries lesion aspect after rubber dam isolation; (C) The most necrotic and infected dentin was removed by dentin excavators from the pulpal floor of the cavity, and a partially demineralized tissue was left at the deepest site; (D) Self-etching system application; (E) and resin composite restoration. (E) Post-operative radiographic.

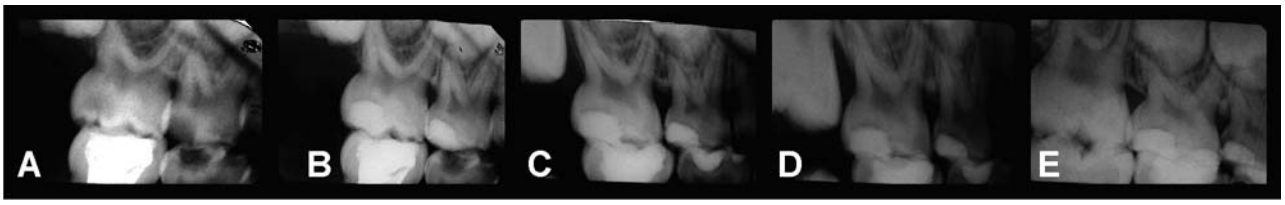

Figure 2. Radiographic evaluation of an upper second primary molar, which received indirect pulp treatment, with a self-etching primer over the remaining carious dentin. Pre-operative (A), post-operative (B), 6 months (C), 12 months (D) and 24 months (E) of radiographic follow-up. The procedure was considered successful after 2-year evaluation.

Figure 3. Radiographic evaluation of a lower first primary molar that received indirect pulp treatment with calcium hydroxide over the remaining carious dentin. Pre-operative (A), post-operative (B), 6 months (C), 12 months (D) and 24 months (E) after indirect pulp treatment indicated the successful outcome after 2 years.

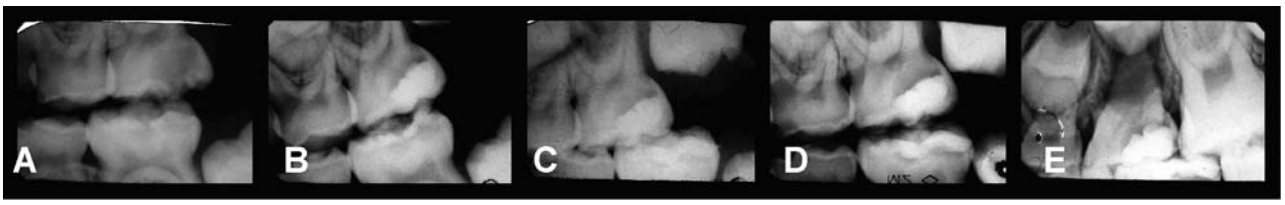

Figure 4. Radiographic evaluation of an upper second primary molar that received indirect pulp treatment with a self-etching primer on the remaining carious dentin. The treatment was considered a failure outcome after 2 years. Preoperative (A), postoperative (B), 6 months (C), 12 months (D) and 24 months (E) of radiographic follow-up.

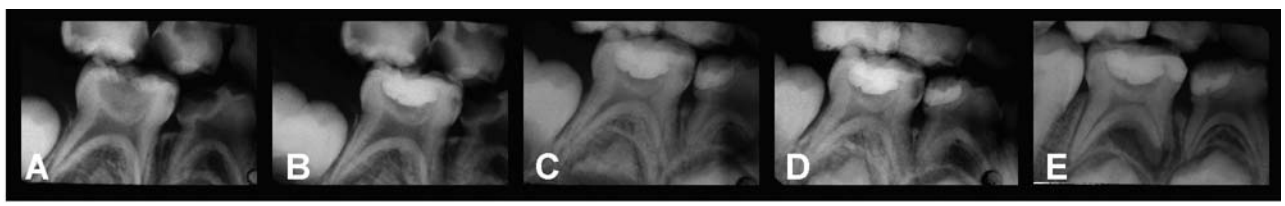

Figure 5. Radiographic evaluation of a lower second primary molar which received indirect pulp treatment with calcium hydroxide on the remaining carious dentin. Pre-operative (A), post-operative (B), 6 months (C), 12 months (D) and 24 months (E) of radiographic follow-up. The failure was detected by resorption of the mesial root.

RESULTS

Table 1. Results of clinical and radiographic evaluation (24 months) of indirect pulp treatment in the groups evaluated.

Group	Sample	Success	Failures	
			Clinical	Radiographic
I Clearfil[a]	16(19)	14(87,5%)	-	2(12,5%)
II Calcium hydroxide[a]	15(21)	13(86,6%)	-	2(13,4%)
Total	31(40)	27(87,1,%)	-	4(12,9%)

No statistically difference between groups[a] (p=1)

After a 2-year follow-up period, 15 children from a total of 21 were examined for the 24 month evaluation. The other 6 patients moved to another city and were dropped out from the study. Thirty-one teeth, from a total baseline of 40, were evaluated (Table 1). Twenty-seven cases had met the criteria for clinical and radiographic success, reaching an overall success rate of 87% with no statistical difference between the groups. Failures occurred after twelve months follow-up, and were detected by radiographic evaluation.

DISCUSSION

The present study aimed to evaluate the clinical and radiographic outcome of indirect pulp treatment in primary teeth, when a self-etching primer or a calcium hydroxide

layer was used over the remaining carious dentin. After 2 years follow-up, no statistical difference was found between groups, and the overall rate success for both groups reached 87%.

The results corroborate with other trials conducted to verify clinical and radiographic success of IPT.[11, 12, 15, 22] Also, failures were detected after the first year of follow-up by radiographic evaluation but without clinical signs.[12] Several studies have been shown the arrestment of caries progression when demineralized dentin is left under sealed restoration.[3,6,8,10,13,16,21,23,24]

After 24 months of clinical and radiographic follow-up, the rate of drop out was 22.5%, which was considered acceptable for a long-term study. According to the literature, the rate of clinical and radiographic success is associated with correct selection of cases.[12, 17] Since the IPT does not directly intervene into the pulp tissue, the information about pain or sensitivity associate with clinical and radiographic signs, are essentials to achieve the correct pulp condition diagnostic. However, in pediatric dentistry, is difficulty to obtain precise information related to symptoms from children, so parents' participation is essential to help the diagnosis. The failures observed could be explained by the difficulty in the diagnosis of pulp viability using radiographic signs, child and parents report of symptoms.

Calcium hydroxide is one of the most successful pulp treatment materials for inducing repair of the dentin-pulp complex. Calcium hydroxide liner provides a beneficial effect to the dentin-pulp complex from its bactericidal effect and stimulation of the dentin remineralization.[2] According to Graham *et al.*,[25] calcium hydroxide exerts its effects on dentin by mechanisms involving cell signaling resulted from release of bio-active molecules from the dentin matrix. There is a satisfactory rate of success with its use as capping material for IPT technique, in both permanent [3, 24] and primary teeth. [12, 17]

Adhesive restorative materials offer good marginal sealing, which is a requirement for the IPT success.[9, 12] A sealed marginal adaptation of the restorative material in the cavity limits the nutrient influx to maintain bacteria and therefore their proliferation. Absence of marginal defects will facilitate the recovery of dental pulp health.[26, 27] To improve the quality of adhesive restorations, the resin monomers must be diffused into the demineralized dentin.[19, 20] According to some studies, the application of an adhesive restorative system on the irreversibly infected dentin did not affect the clinical performance of the restoration.[9, 12] An "ideal" hybrid layer should be large enough to allow a stable interlocking of the bonding agent around the exposed collagen network. Self-etching primers have been used to prevent the occurrence of demineralized dentin collapse. The acidic monomers act through smear layer to the subjacent dentin, incorporating it in the union process.[19] Theoretically, this prevents the excessive loss of dentin matrix and solubilized apatite crystals around the collagen network, permitting good infiltration of the adhesive monomer in the substrate. The performance of these materials could provide a better interaction with the carious dentin in the indirect pulp treatment, once the demineralized zone produced by the self-etching primers is thinner compared to conventional systems, which use phosphoric acid. Increased thickness of the demineralized zone and subsequent incomplete impregnation of the bonding system in the collagen network result in an area of collagen fibers without support, susceptible to the hydrophilic degradation and a consequent reduction of the adhesive strength over time.[28, 29] After a long-term function, primary molars restored with a self-etching primer showed higher values of bond strength compared with a conventional bonding system.[19] These results are attributed to the interaction between the bonding system and the dentin. Considering that carious processes already altered the dentin in indirect pulp treatment, the use of a self-etching primer would prevent the over-etching of dentin.

In this study, the success rates after 2 years of clinical and radiographic IPT follow-up were similar between the calcium hydroxide group and the one that used the self-etching system on the remaining carious dentin. This result confirms that the techniques success is not dependent on the material used to recover the remaining carious dentin. The failures found after the first year of follow-up by radiographic signs emphasizes the importance of the radiographic follow-up when the IPT is the treatment of choice. As primary teeth undergo physiologic resorption, it has been suggested that there is no need to reopen the lesion as proposed by stepwise excavation technique,[12, 15, 16, 17, 30] hence IPT has been considered definitive for primary teeth.

CONCLUSIONS

The present study showed that the IPT has a high clinical and radiographic long-term success rate in primary teeth, independently of capping materials used over the remaining carious dentin. IPT provides a conservative alternative treatment of primary teeth with deep carious lesions.

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