

Indirect Pulp Capping in the Primary Dentition: a 4 Year Follow-up Study

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Purpose: Evaluate clinical and radiographic changes in primary teeth submitted to indirect pulp capping (IPC) over a 48-month-period.

Methods: Twenty seven primary molars with deep caries, but without preoperative signs of irreversible pulpitis, were treated with IPC. The teeth were randomly divided into two groups, according to the material used for protection of the dentin-pulp complex: (1) a calcium hydroxide liner (Dycal®) and (2) glass ionomer cement (Vitremer®).

Results: After 48 months, Group-1 showed a success rate of 88.8% and Group-2 of 93%. No statistical significant difference between the groups was observed ($P = 0.62$).

CLINICAL SIGNIFICANCE: The results of this study suggested that indirect pulp capping in primary teeth arrests the progression of the underlying caries, regardless of the material used as a liner.

Key words: Pulp capping, indirect, primary dentition

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INTRODUCTION

Indirect pulp capping has been described as a conservative alternative treatment of the dentin-pulp complex, for primary and permanent teeth, since 1859 by John Tomes. In his textbook, the author affirms: "It is preferable to maintain a layer of discolored dentin for the protection of the pulp rather than run the risk of sacrificing the tooth. Supposing that the walls near the caries lesion are strong and sound, it does not appear that the maintenance of a little slightly-softened dentin at the bottom of the cavity interferes seriously in the durability of the plug."¹ The technique consists of removing only the softened and humid dentin, which does not offer resistance to the manual excavation, and leave intentionally the deepest dentin of the pulp wall. Several studies already showed that this dentin can get remineralized, through the observation of harder texture, darkened color and with smaller quantity of unviable bacteria.²⁻⁸

The great advantage of this technique is the possible prevention of pulp exposures. Some studies showed a higher index of success of this technique when compared with others complex treatments, such as direct pulp capping and pulpotomies.⁹⁻¹² In infants, this technique can be considered definite, since the primary tooth has a defined biological cycle in the oral cavity.^{7,11,13,14}

The more frequent question about the technical approach is a precise distinction between the infected and affected zones. Massara *et al* (2002) described that the texture of the dentin (leathery, coming out in form of scales or chips) constitutes itself a reliable clinical criteria to stop scooping out dentin. The softened, humid, yellow or light-brown dentin, that does not offer resistance to the manual excavation should be removed, while the less softened, darker and harder consistency, coming out in scales or chips, can remain since the technique creates conditions for a physiological remineralization process.¹⁵

The indirect pulp capping is not considered a material-dependent technique. The role of the lining material is not essential, but a good marginal seal, preventing, first, bacterial substrate infiltrating the dentin, and, second the control of the carious activity in the infant, guarantees a high success of this restorative treatment.^{6,8,14,16}

The purpose of this randomized controlled study was to compare the clinical and radiographic outcomes of primary molars treated with the indirect pulp capping technique when either a calcium hydroxide liner or a glass ionomer cement was used for protection of the dentin-pulp complex.

METHODS

Seventeen children of both sexes with good general health and ages ranging from 4 to 9 years were selected. These children had primary molars with deep active carious lesions in the dentin. X-rays showed the proximity of the carious lesion to the pulp, where a great risk of pulp exposure existed. These children were included in a therapeutic program that consisted of: Oral hygiene program, diet

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and rational use of fluoride, restoration of carious lesions and pulp treatment, when necessary, extraction of those teeth that could not be restored. The patients were only included in this study if their relatives or guardian read and signed informed consent forms. The design of this study and the consent forms were reviewed and approved by the ethics committee.

The clinical criteria of inclusion were: 1-active carious lesion deep into dentin, involving occlusal and/or proximal surfaces of primary molars, without clinical observation of pulp exposure; 2-Absence of cavitated lesions at the buccal or lingual surfaces, as determined by clinical and radiographic examination; 3-Absence of clinical symptoms of irreversible pulpitis, such as spontaneous pain or sensitivity to pressure; 4- Absence of clinical diagnosis of pulp exposure, fistula, swelling of soft and periodontal tissues, and abnormal tooth mobility; 5- Possibility of restoration.

The radiographic criteria were: 1-The extension of the carious lesion should be such that complete caries removal would risk pulp exposure; 2-Absence of radiolucencies at the interradicular or periapical regions, or thickening of the periodontal spaces, that should indicate the presence of irreversible pulp pathologies or necrosis; 3-Absence of internal and/or external dentin resorption.

The methods used for this investigation were as follows: All patients received a prophylaxis prior to the clinical examination. Standardized periapical and posterior bitewings were taken and evaluated to complete the assessment for inclusion in the study. In a follow-up appointment, the patients were anesthetized with local anesthesia and rubber dam isolation was placed. Class I cavity preparations and pulp protection were performed as follows. Undermined enamel was removed with carbide bur #245 at high speed with copious air/water spray. Caries were removed completely from the cavosurface margins and all lateral walls of the cavity preparation with carbide burs #2 to #8 at low speed. Caries removal at the site of "risk for pulp exposure" was performed with a #6 or #8 carbide bur at low speed, and the cavity was thoroughly rinsed with phosphate-buffered saline (pH 7.4). Teeth were excluded from the study if a pulp exposure occurred or if the caries was completely removed at the end of cavity preparation.

Teeth were randomly assigned for the experimental (15 first and second molars) or control groups (12 first and second molars). In both groups, the total-etch technique was carried out for enamel and dentin by applying 10% phosphoric acid gel (Acigel® – SS White, Rio de Janeiro, Brazil) for 15 and 8 seconds, respectively.^{17,18} The acid was removed by rinsing with water for 15 seconds and the cavity was gently dried with air and cotton pellets, to maintain the remaining dentin, humid.

The experimental group received an application of a primer (Vitremer®, 3M Dental Products, St. Paul, MN), followed by gentle drying and subsequent light cure for 20 seconds. The material was manipulated with a plastic spatula on a mixing paper pad and the insertion of the material in the cavity was performed in increments with aid of a squirt centrix, with subsequent light cure for 40 seconds. Techniques for finishing and polishing the glass ionomer cement were employed. Subsequently the finishing gloss (Vitremer® - 3M Dental Products, St. Paul, MN) was applied with photopolymerization for 20 seconds. Following the removal of the rubber dam, occlusion was checked.

In the control group a thick layer of the calcium hydroxide liner (Dycal® - Caulk – Dentsply Petrópolis, BR) was applied to the

remaining carious dentin. The cavity preparation was etched with 10% phosphoric acid. The primer Scotchbond MultiPurpose (Scotchbond Multi Purpose® – 3M Dental Products, St. Paul, MN) was applied to the entire cavity followed by an adhesive resin system Scotchbond MultiPurpose as instructed by the manufacturer. All teeth of this group were restored with the composite resin Z250® (3M Dental Products, St. Paul, MN) using the incremental technique, and each increment was light cured for 40 seconds. Standard techniques for finishing and polishing composite resins were employed. Immediately after the restoration, a postoperative periapical radiograph was taken for each tooth. One operator (AMF) performed all the indirect pulp capping, restorations and radiographs included in this study.

All teeth incorporated in the study were examined at 1, 3, 6, 9, 12, 18, 24, 36 and 48 months after restoration. These teeth were not reopened for evaluation of the status of the remaining carious dentin. The criteria used for determination of clinical and radiographic successful outcome of the indirect pulp capping were: (1) Absence of spontaneous pain and/or sensitivity to pressure; (3) Absence of fistula and/or edema; (4) Absence of a pathological mobility; (5) Absence of radiolucencies at the interradicular and/or periapical regions, as determined by periapical radiographs; (6) Absence of increase of the periodontal space; (7) Absence of internal and/or external dentin resorption that was not compatible with the expected resorption due to the exfoliation process. Any tooth that presented clinical radiographic signs or symptoms of irreversible pulp pathologies or necrosis were either pulpectomized or extracted and recorded as treatment failures.

STATISTICAL ANALYSIS

The data obtained was analyzed by Fisher exact test to compare the materials used for protection of the dentin-pulp complex (calcium hydroxide and glass ionomer cement) on the outcome of primary molars treated by indirect pulp capping. The statistical significance of the data was determined at $p < 0.05$. The software used for these analyses was SigmaStat 2.0 (SPSS Science, Chicago, Ill).

RESULTS

The results obtained with the indirect pulp capping were considered satisfactory. We observed an index of success of 93% for the group lined and restored with GIC(experimental group) and of 89% for the group lined with the calcium hydroxide cement (control group), after a minimum period of four years of clinical and radiographic examination. Through the Fisher's exact test, no statistical significance was observed between the groups ($p = 0.62$). In the experimental group ($n = 15$) fourteen teeth were considered successes in four years of clinical and radiographic follow up, and one tooth exfoliated in the period evaluated without any sign of technique failure. One tooth was considered a failure, after the appearance of a fistula at six months. In the control group ($n = 12$) two teeth were excluded from the study because of a fracture in the restoration and one because the child did not attend the control exams. In the control group eight teeth were considered successful. Also two teeth exfoliated in the period evaluated without any sign of technique failure and similar to the experimental group. Only one tooth failed with a presence of a fistula at 12 months follow up. (Table 1, Fig 1- 4).

Table 1: Clinical and radiographic evaluation of indirect pulp capping after 4 years.

Groups	N° teeth	Success Rate	Failure Rate		
			Periapical Lesion	Pathological Root Resorption	Total
Control (calcium hydroxide)	12 (44.5%)	08 (88.8%)	1	0	1 (11.2%)
Test (glass ionomer cement)	15 (55.5%)	14 (93.3%)	1	0	1 (6.7%)
Total	27 (100%)	22 (91.7%)	2 (8.3%)	0 (0%)	2 (8.3%)



Figure 1: Radiographic evaluation of a second mandibular right primary molar with indirect pulp capping using a layer of calcium hydroxide (control group). Successful treatment after 48-month follow-up. (a) Initial X-ray, (b) immediately after treatment and (c) 48 month follow up.

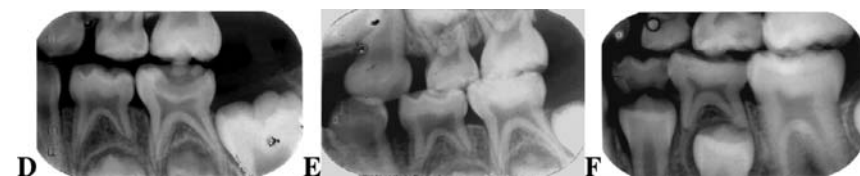


Figure 2: Radiographic evaluation of a second mandibular left primary molar with indirect pulp capping using the glass ionomer cement (test group). Successful treatment after 48 month follow-up. (d) Initial X-ray, (e) immediately after and (f) 48 months of follow up.

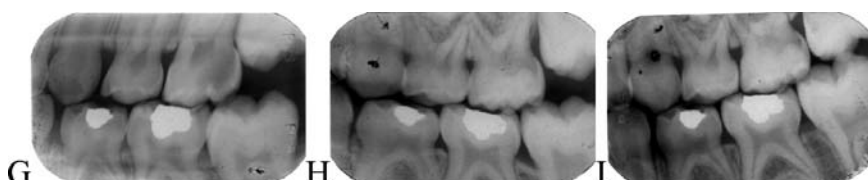


Figure 3: Radiographic examination of second maxillary primary left molar from the test group (GIC), considered as failure. (g) Initial X-ray, (h) after treatment and (i) 6 month follow up.

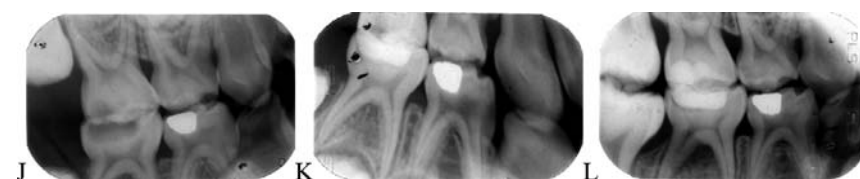


Figure 4: Radiographic examination of second mandibular right primary molar from the control group (CH), considered as failure. (j) Initial X-ray (k) immediately after treatment and (l) 6 month follow up.

DISCUSSION

Despite several studies verifying the success of the indirect pulp capping this technique is not widely used by pediatric dentists. Many studies showed success through the presence of a darkened and hardened dentin, suggesting a remineralization process in primary^{3,6-8,15} and permanent teeth.^{4,5,13,16} Beyond a higher preservation

of the dental structure, the maintenance of carious tissue in the pulpal wall also contributes for less aggression to the dentin-pulp complex, allowing a defense mechanism through the dentin sclerosis.³

This technique also prevents possible pulpal exposures in deep carious lesions, frequent during conventional cavity preparations.^{7,12} The common question of this technique is preserving demineralized and contaminated tissues, which could allow the progression of the carious lesion. Several studies were carried out to evaluate if bacteria could be viable under the restoration through a microbiologic analysis. They concluded that microorganisms are present in the contaminated layer in small quantities and are not viable, since these bacteria do not have access to the substrate for the process of cell metabolism.^{3,9} Therefore the progression of the carious lesion does not occur.^{2,5,7,19}

The primary tooth has a biological cycle defined in the oral cavity, hence the technique suggests that it is not necessary to reopen the tooth after indirect pulp capping. The success of the present study suggest that indirect pulp capping performed in one appointment, is viable in the primary dentition. This was also confirmed in several studies where the authors observed a hardened and remineralized tissue without aspects of progression of the lesion.^{3,6-8,14,15} Therefore in the primary dentition this technique can be considered definitive.^{7,11,14}

The results found in the present study using the calcium hydroxide cement as a lining material corroborates other studies carried out previously using the same material in the primary dentition.^{8,14,15} Calcium hydroxide has been considered as a gold standard for decades because literature has shown compatibility with the dentin-pulp complex. The use of the calcium hydroxide cement as a lining base provides a high index of success due to the biological characteristics such as its bactericide effect and stimulation of the remineralization process in the remaining carious dentin.²⁰

The high index of success also achieved in the present study with the use of the resin modified glass ionomer cement associated to the non-significant difference between the materials (p=0,62), indicates that this material could be appropriate in the pediatric clinic, since this material combines adhesive and biological properties. This material presents some advantages when compared with the conventional glass ionomer cement as a restorative material such as: Longer working time, less sensitivity to an humid environment and the polishing can be performed in the same session.²¹ This material can be considered definitive, mainly in the primary dentition, if the tooth remains in the oral cavity for

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a period of approximately 2-3 years.^{22,23,24}

Falster *et al.* (2002) evaluated for 2 years the clinical and radiographic performance of indirect pulp cappings in 48 primary molars, of which 23 teeth were lined with calcium hydroxide cement and 25 used only the adhesive system. The success found in the calcium hydroxide cement group was 83%, similar to the results observed in the present study. The literature offers different studies with clinical and radiographic follow up using different materials as line a base for the dentin-pulp complex such as: calcium hydroxide, adhesive system, inert material (wax and gutta percha) and glass ionomer cement. All the data from these studies suggests that the indirect pulp capping is not material dependent.

After 3 months of clinical observation, Massara *et al.* (2002) evaluated the atraumatic treatment restoration in primary molars, utilizing the glass ionomer cement, as capping and restorative material. No children presented symptoms of pain and/or signs of irreversible pulpitis in the three months follow up period. The authors also found an increase of the calcium content in the dentin sample after the treatment suggesting that the restorations provide conditions for remineralization of the remained carious dentin. The present study also observed a high index of success using the glass ionomer cement, corroborating the results of Massara *et al.* Nevertheless more longitudinal studies are necessary to evaluate the efficiency of this material in the indirect pulp capping.

There were two clinical failures (one in each group) both between 6-12 months through the clinical observation of a fistula. Falster *et al.* (2002), found that most failures occurred between 18 and 24 months, diagnosed only radiographically. The low percentage observed in the studies carried out with indirect pulp capping allow us to conclude that the proper diagnosis, the isolation of bacteria from the oral environment associated with the control of carious activity are an essential to achieve success in this technique.²⁵ However, more clinical studies need to be carried out to confirm this hypothesis.

CONCLUSIONS

- 1) In this clinical randomized controlled study, the clinical and radiographic success of a 48 month follow up of the indirect pulp capping was similar when the protection of the dentin-pulp complex was performed with a glass ionomer cement (93%) or with a layer of calcium hydroxide (89%) with no statistical significant difference between the materials.
- 2) The most frequent cause of failures in both groups was the clinical observation of a fistula in the period of a 6-12 month follow up, suggesting a misdiagnosis of the pulpal condition.
- 3) The indirect pulp capping can be done in one session and there is no need to reopen the cavities in the primary dentition.

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