Effect of Adhesive Restorations Over Incomplete Dentin Caries Removal: 5-year Follow-up Study in Primary Teeth

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ABSTRACT

Purpose: The purpose of this study was to evaluate the effect of the materials used for indirect pulp treatment (IPT) on the long-term outcome of primary molar teeth.
Methods: Forty-eight teeth with deep carious lesions, but without signs and symptoms of irreversible pulpitis, were randomly divided into 2 groups, according to the material placed on the demineralized dentin remain: (1) experimental group, adhesive system (Scotchbond Multipurpose); and (2) control group, calcium hydroxide liner (Dycal). Both groups were followed by a resin restoration application.
Results: After 4 to 5 years, the clinical and radiographic success rates between groups were similar (group 1=14 of 15; group 2=8 of 10; *P*=0.350). Subsequent to exfoliation, scanning electron microscopy revealed the presence of a hybrid layer at the resin-dentin interface and a microtensile bond strength of 9.63 MPa (group 1). Histological analysis showed that the pulp health status was similar in both groups.
Conclusions: Indirect pulp treatment has a high clinical and radiographic long-term success rate in primary teeth and is not material-dependent.
(J Dent Child 2009;76:117-22)

Received October 18, 2007; Last Revision December 31, 2007; Revision Accepted December 31, 2007.

KEYWORDS: DENTAL MATERIALS, BIOMATERIALS, CARIOLOGY, PULP THERAPY, ENDODONTICS

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Maintenance of pulpal vitality is the primary objective of the conservative treatment of deep carious lesions. With indirect pulp treatment (**IPT**), the nonremineralizable carious tissue is removed and a thin layer of caries is left at the deepest sites of the cavity.[1,2] The complete removal of all carious tissue from the lateral walls of the cavity preparation is traditionally required to improve the marginal seal and adequately control microleakage. Clinical, radiographic, and bacteriologic studies have shown that carious lesions can be arrested if the restoration's margins remain sealed.[3-5]

Total dentinal caries excavation is typically performed to enhance the restoration's long-term performance. The hardness criteria used for determination of the extent

of caries removal, however, does not assure bacteria-free dentinal tubules. Bacteria usually remain even when all soft tissue is removed.[6,7]

Commercially available caries detector dyes are used to help the dentist differentiate infected dentin, but these dyes are not specific for infected dentin once they also stain the circumpulpal dentin and the sound dentin of the amelodentinal junction.[8]

Although there are no precise methods to determine how much carious tissue should be removed, most would agree that dentin that is obviously necrotic and amorphic should be eliminated.[9] This leaves dentin that is firmer and still has the appearance of being intact.[10-12]

The use of IPT is limited to teeth that have no signs or symptoms of irreversible pulp pathology.[3,13] In primary teeth, IPT and the tooth's final restoration can be performed in one appointment.[14,15] This procedure is based on data from previous studies, which demonstrated that the remaining dentin is mostly remineralized and hardened with significantly less bacteria. No signs of caries progression have been found in the absence of marginal defects in teeth that received IPT and were later reopened.[9,12,16]

Materials such as calcium hydroxide, zinc oxide eugenol, glass ionomer cement, and an adhesive system have been used to cover the remaining demineralized and infected dentin after IPT. The traditional IPT technique uses a calcium hydroxide liner (bacteriostatic/bactericidal) over carious dentin to induce lesion inactivation and protect the pulp. Studies have shown that an acid-resistant tissue resulting from the interdiffusion of adhesive resin within the area of carious dentin (modified hybrid layer) does not affect the clinical performance of the restoration.[5,17]

Even though many studies have focused on the clinical and radiographic outcomes of IPT, few of these studies have described the results of long-term evaluations. The objectives of this clinical trial were to:

1. compare the clinical and radiographic outcome of primary molar teeth treated with indirect pulp treatment where either a calcium hydroxide liner or only an adhesive resin system was used to protect the dentin-pulp complex;
2. measure the bond strength at the adhesive/carious dentin interface of the exfoliated primary molars;
3. characterize the micromorphology of the adhesive/carious dentin interface by scanning electron microscopy (SEM); and
4. describe the histological characteristics of the pulp in exfoliated deciduous teeth with IPT after a 5-year follow-up.

METHODS

SAMPLE AND INCLUSION CRITERIA

This clinical trial was conducted in the Pediatric Dentistry Unit at the Federal University of Rio Grande do Sul, Porto Alegre, Brazil, using a protocol that was reviewed and approved by the Institutional Review Board. All parents/legal guardians read and signed an informed consent form for this study. Forty-eight primary molar teeth from 3- to 5-year-old children were treated by IPT. The inclusion criteria were: absence of spontaneous pain; swelling or fistula; and tooth mobility not compatible with chronological age. Radiographic criteria were: caries lesions at the dentin's internal half, absence of pulp contact with the lesion, and alterations suggesting degenerative pulp conditions.

Patients were anesthetized and, under rubber dam isolation, received Class I cavity preparations and pulp protection. Caries was removed completely from the cavosurface margins and all lateral walls of the cavity preparation. The most superficial, infected, and necrotic dentin was removed at sites of "pulp exposure risk," and the cavity was thoroughly rinsed with phosphate-buffered saline (pH 7.4).

Teeth were randomly assigned to 2 groups—group 1 (experimental group=25 teeth; Scotchbond Multipurpose Adhesive System, 3M, Minneapolis, Minn) or group 2 (control group=23 teeth; Dycal Calcium Hydroxide, Caulk Dentsply, Milford, Del)—according to the capping material placed on the remaining carious dentin. The teeth were restored with a composite resin restoration (Z100, 3M). The tooth was considered the experimental unit of evaluation, and the number of teeth per subject was based on the invasive/restorative necessity as well as fulfilling the IPT criteria.

CLINICAL AND RADIOGRAPHIC EVALUATION

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 the interradicular and/or periapical regions as determined by periapical radiographs, and absence of internal or external root resorption that was not compatible with the expected resorption due to the exfoliation process. Any tooth that presented clinical or radiographic signs or symptoms of irreversible pulp pathologies or necrosis was either pulpectomized or extracted and recorded as a treatment failure. Two examiners performed the clinical and radiographic follow-up examinations. The clinical and radiographic outcomes were statistically analyzed using Fisher's exact test. The student *t* test was used to compare the mean time of follow-up between groups.

MICROTENSILE BOND STRENGTH TEST

After exfoliation, group 1 teeth were stored in distilled water at 4°C for no more than 1 month. The resin-filled cavities

Table 1. Distribution of Tooth Type According to Outcome and Follow-up Period

	Group 1 (Scotchbond Multipurpose)		Group 2 (Dycal)	
	First molar	Second molar	First molar	Second molar
Part 1 (0-2 ys)	13	12	5	8
Part 2 (2-5 ys)	5	10	2	8

Table 2. Distribution of Patients and Teeth Between Groups (Part 2)*

	Group 1 (Scotchbond Multipurpose)	Group 2 (Dycal)
No. of patients after 4-5 ys	6	5
No. of teeth after 4-5 ys	15	10
Rate of clinical and radiographic successes	93	80
Mean time of follow-up (mos)	57 (3)†	50 (7)†
Bond strength (MPa) N=15	10 (3)	–

** There is no difference in clinical and radiographic success between groups. The mean time of follow-up was higher in group 1 (P=.01). The mean bond strength (MPa) obtained in the microtensile bond testing of the Scotchbond Multipurpose adhesive system applied to the demineralized dentin of deciduous teeth. The adhesive resin system group had a longer mean time of follow-up compared with the Dycal group † (P=.01).*

were sectioned perpendicular to the adhesive interface in the pulp floor (demineralized zone) by means of a diamond saw with water coolant. One or 2 resin-dentin bonded sections (0.7 mm thickness) were obtained from each tooth. These slices were carefully trimmed and shaped with a super-fine diamond point (3122 FF KG, Sorensen, São Paulo, Brazil) to produce an hourglass shape with a gentle curve along the bonded interface (1.0 mm constriction width) from both sides until 0.7 mm of bonded surface remained. These specimens were then attached to a testing apparatus (Instron 4411 testing machine, Instron Corp, Canton Mass), and a tensile load was applied at a crosshead speed of 0.5 mm/minute. The bond strength values were obtained in MPa.

SCANNING ELECTRON MICROSCOPY

Group 1 specimens were prepared for morphological characterization of the adhesive/carious dentin interface via SEM (Jeol 5600 LV, JEOL Tokyo, Japan). Each flat surface was polished using silicon carbide papers of decreasing abrasiveness (600-1,200 grip) and soft cloths with alpha-alumina powder (6, 3, 1, and 0.25 μm, Metadi II, Buehler, Lake Bluff, Ill) suspended in distilled water, and cleaned in an ultrasonic bath (10 minutes). Each specimen was immersed (5 seconds) in a 50% phosphoric acidsolution, washed with distilled water, and submerged for 15 minutes in 10% NaOCl to remove the organic content. The specimens were treated with absolute alcohol for 15 minutes followed by hexamethyldisilazane solution ($[(CH_3)_3SiNHSi(CH_3)]_3$ Sematech Technology, Austin, Tex) for 15 minutes and sputter-coated with gold for examination with a field-emission SEM. The qualitative evaluation of the adhesive interface was based on the analysis related to the presence/absence of gaps and the formation of the hybrid layer and resin tags.

HISTOLOGIC PROCESSING OF THE SPECIMENS

To characterize the histological pattern, 1 tooth from each group was fixed in 10% neutral buffered formalin and decalcified in equal portions of 45% aqueous formic acid and 20% aqueous sodium citrate solution (changed daily). After decalcification, specimens were submitted for paraffin embedding. From each tooth, an average of 15 sections with coronal pulp at 4 μm were obtained and stained with hematoxylin and eosin. Light microscopy was used to analyze the pulp tissue's histopathology. A "blinded" expert made the histopathologic examination of the samples. Other histological pulp specimens of sound primary teeth in the final stages of root resorption were used as reference controls.[18]

RESULTS

The results of the first evaluation, a 2-year clinical and radiographic follow-up study, were previously published.[5] The distribution of tooth type and time of evaluation according to outcome is presented in Table 1. After a 4- to 5-year follow-up, 11 children (5 girls and 6 boys) from an initial total of 21 (15 girls and 6 boys) participated in

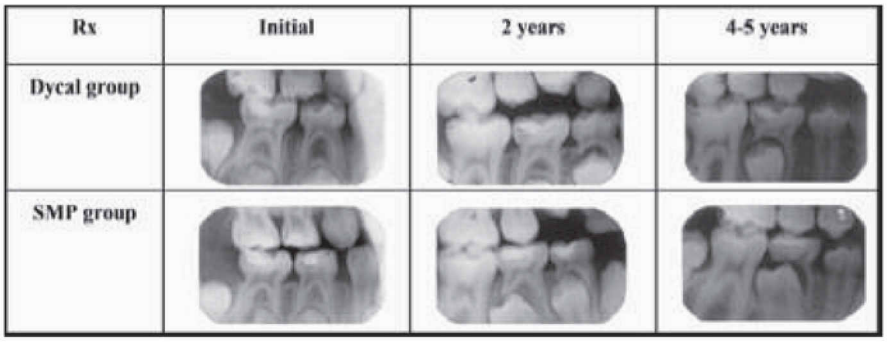

Figure 1. Radiographic follow-up evaluation of teeth (primary mandibular second molar in both groups) that received indirect pulp treatment with Scotch Multipurpose and calcium hydroxide was considered successful after 4 to 5 years.

the second evaluation (2- to 5-year follow-up). The other 10 patients moved to another city and were dropped from the study. Twenty-five teeth were available for the final examination (2- to 5-year follow-up). Ninety-three percent of the teeth (14 of 15) treated with an adhesive technique placed directly over the carious dentin and 80% (8 of 10) that received calcium hydroxide liner before application of the restoration were considered clinically and radiographically successful after 4 to 5 years (Table 2). Figure 1 shows one case of each group considered as a clinical/radiographic success after a 4- to 5-year follow-up. There is no statistical difference between groups (P=0.350). The adhesive resin system group had a longer mean time of follow-up compared with the Dycal group (P=0.01). Three failures were observed, two at 36 to 48 months (group 2), and one at 48 to 60 months (group 1). Radiographic evaluation revealed the presence of inter-radicular and/or apical lesions.

Histological evaluation of the dental pulp in both groups showed characteristics similar to that of the sound pulp at the time of exfoliation.[18] Histological analysis showed a preserved odontoblastic layer and fibrocellular matrix, with a hyalinized zone and a fibrotic pattern and absence of any degenerative process (Figure 2).

The microtensile bonding test (group 1) showed low values (9.63±2.62 MPa; Table 2), but no restoration was lost during the follow-up period. A hybrid layer was visible with resin tags on the demineralized zone (Figure 3).

DISCUSSION

This prospective and randomized clinical trial shows high percentages of clinical and radiographic success with IPT after a 4- to 5-year follow-up and coincides with results of other studies conducted to verify IPT's clinical and radiographic success.[17,19] The overall proportion of teeth that had a successful outcome with IPT after the clinical and radiographic follow-up in this study was 88% (group 1=93%; group 2=80%).

Deep caries may induce reversible or irreversible inflammatory changes in the pulpal tissue. Therefore, a thorough evaluation of symptoms and clinical/radiographic signs should be performed prior to any conservative pulp treatment.

Secondary caries is not easy to diagnose clinically. It is well established in the literature that the secondary lesion may have the same origin as the primary lesion—plaque accumulation on the tooth surface, the difference is that the secondary caries is located in a dentin wall, next to a restoration.[20] According to Mjör,[21] narrow gaps, crevices, ditches, and "microleakage" do not lead to secondary caries, but wide voids may. We also know that the lesion activity should be judged in each patient. The main cause of IPT failure in the present study can be related to marginal defects (considerable size) of the restoration associated with the maintenance of high caries activity by the patient. 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.[4,5]

The degradation of the adhesive interface and consequent recurrent carious lesions may be accelerated by the maintenance of high caries activity. After a 4-year follow-up, one tooth from the adhesive resin system group had an inter-radicular lesion accompanied by a fistula, which was indicative of treatment failure. In group 2, two failures were observed in the same time period:

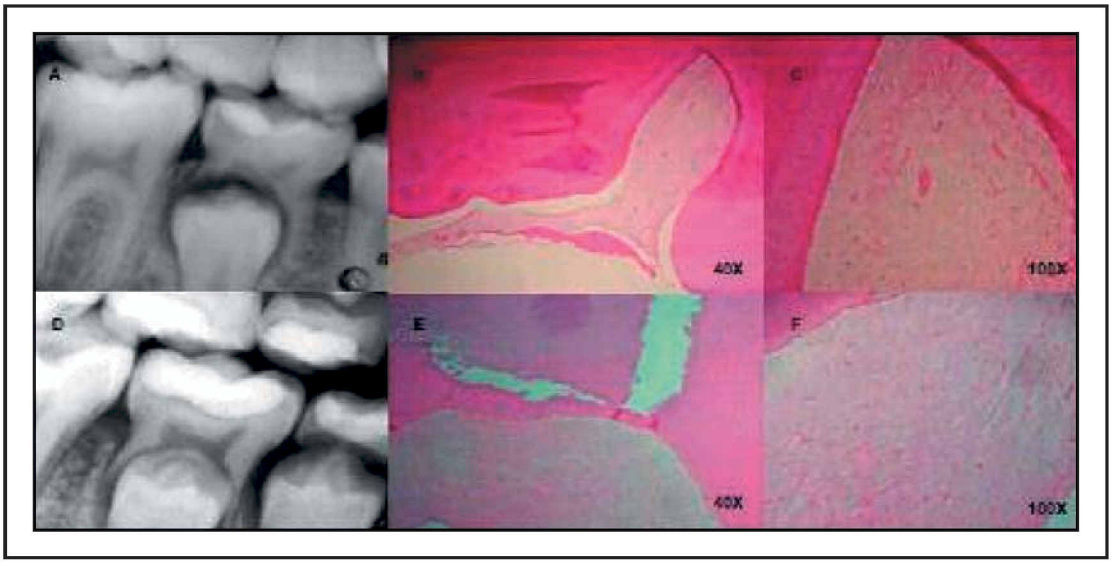

Figure 2. Radiographic evaluation of primary mandibular second molars that received indirect pulp treatment with calcium hydroxide (A) and with an adhesive resin (D) was considered successful after 4 to 5 years. Histological evaluation of the dental pulp in both groups showed similar characteristics, with absence of a degenerative process, preserved odontoblastic layer, and fibrocellular matrix, with a hyalinized zone and a fibrotic pattern (B, C, E, F).

the first presented external radicular periapical resorption (incompatible with the exfoliation time); and the other showed an inter-radicular lesion accompanied by internal root resorption. These findings agreed with a retrospective study that evaluated IPT's success rate in primary molar teeth, where treatment failures (5%) were observed after a follow-up period of up to 43 months.[22]

Despite the higher success rate in group 1, there are no statistical differences with group 2. Based on the sample size of this study, the results suggest that the 4- to 5-year clinical outcome was independent of material use on demineralized dentin. After exfoliation, group 1 specimens were submitted to a microtensile bonding test. They showed relatively low bond strength values (9.63 MPa), considering that polymerization shrinkage of the resin composite used in the present study (Z 100, 3M) is approximately 9 MPa.[23] Nevertheless, these restorations were retained in the oral environment until tooth exfoliation. Previous studies have already shown a dramatic reduction (70%) in the adhesion to sound dentin after 3 years under oral conditions.[24] Furthermore, the influence of demineralized dentin in lowering the bond strength values has been reported.[25] The adhesive bond strengths are not uniform inside a cavity. In general, the tensile bond strength to lateral walls is higher than to the pulpal floor.[26] Therefore, in the present study, the bond strength data alone does not represent the true retention condition of the IPT restorations, which could underestimate the clinical relevance.

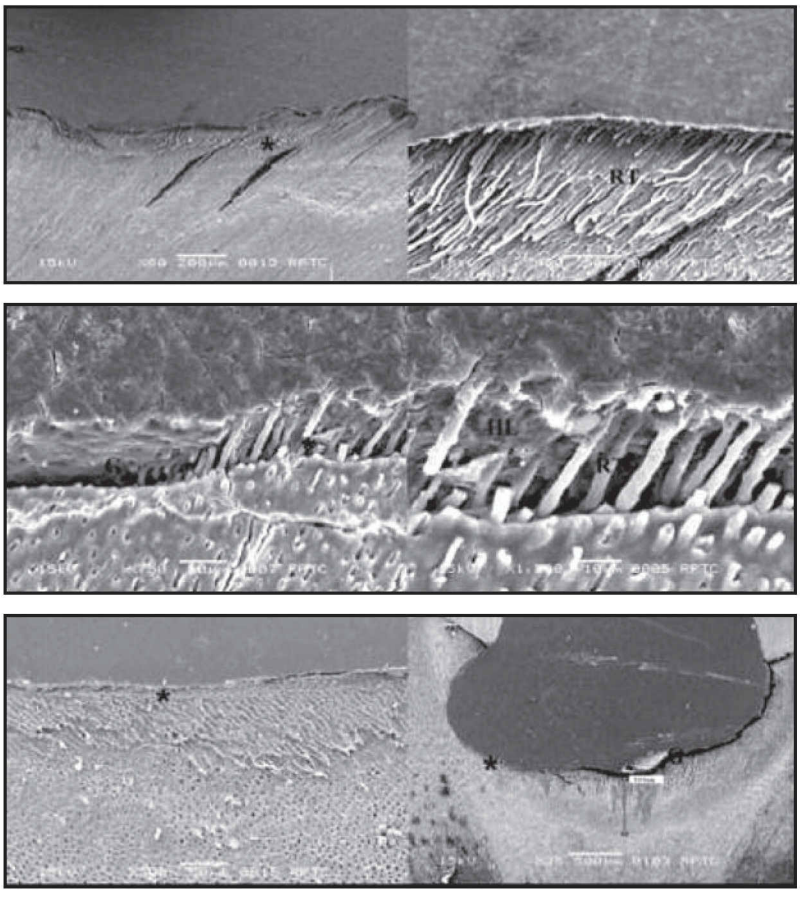

Figure 3. Photomicrographs of the union interface formed between carious dentin and the Scotchbond Multipurpose adhesive system. Note zones with an intimate relation of the restorative material with the dentin (*), presence of resin tags (RT), occurrence of the hybrid layer (HL), and other regions with occurrence of gaps in the adhesive interface (G).

SEM visualization of the adhesive/demineralized dentin interface showed the presence of a hybrid zone in the dentin. The demineralized zone was evident, but gaps were detected in several areas of the interface. This type of micromorphological finding may be due to several factors. A fragile tooth/restoration union can produce artifacts during processing of the specimens for SEM analysis and be subject to misinterpretations about the interaction between the dental substrate and the restorative material. The micromorphological finding was similar to a 1-year follow-up study, which described an "altered hybrid layer" with resin tags on the demineralized dentin. According to this study, the application of an adhesive restorative system to irreversibly infected dentin did not affect the restoration's clinical performance.[17]

Considering that there is no long-term histological follow-up study of IPT, the histological samples were included to illustrate vital tissue, knowing that these cases had met the criteria for success and implying that other successful cases may be histologically similar in appearance. The histomorphological characteristics of the coronal pulp tissue were similar in both conditions tested, showing pulp architecture similar to the normal pulp of primary teeth in the final stage of root resorption.

Evidence of IPT's success can be observed by the deposition of a tertiary dentin matrix (increasing the distance between the carious lesion and the pulp chamber) in radiographs. In mild grades of injury, the odontoblasts and other pulpal cells are stimulated production of a reactionary type of tertiary dentin matrix. It is different from pulp exposure injures where reparative dentinogenesis requires recruitment of progenitor cells from the pulp population, which differentiate into odontoblast-like cells and then stimulate matrix secretion. Growth factors provide the molecular signal for this induction of odontoblast differentiation and the subsequent stimulation of matrix production by these cells.[27]

Future studies should focus on the molecular and cellular events that play an important role in oral structures and conditions, contributing to better clinical dental practice. The clinical relevance of IPT as a conservative pulp treatment in pediatric dentistry is to provide a simple and effective approach to maintain the viability of teeth with deep carious lesions.

CONCLUSIONS

Based on the present study's results, it can be concluded that indirect pulp treatment has a high clinical and radiographic long-term success rate in primary teeth and provides a conservative, alternative treatment of teeth with deep carious lesions.

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