Indirect pulp treatment in primary teeth: 4-year results

LUCIANO CASAGRANDE, DDS, MS, PhD, LETICIA WESTPHALEN BENTO, DDS, MS, DÉBORA MARTINI DALPIAN, DDS, MS, FRANKLIN GARCÍA-GODOY, DDS, MS & FERNANDO BORBA DE ARAÚJO, DDS, MS, PhD

ABSTRACT: Purpose: To evaluate clinical and radiographic outcomes of indirect pulp treatment (IPT) in primary molars after long-term function (up to 60 months). Methods: Teeth with deep carious lesions without signs and symptoms of irreversible pulpitis were divided by random allocation into two groups, according to the capping material utilized over demineralized dentin: experimental group (1): self-etching adhesive system (Clearfil SE Bond); and control group (2): calcium hydroxide liner (Dycal). Both groups were filled with resin composite (Z250) and submitted to a clinical and radiographic monitoring period until exfoliation. Results: After the follow-up period (up to 60 months), no statistical difference was found between groups (P= 0.514). The overall success rate reached 78%. The failures occurred after the first year period recall. (Am J Dent 2010;23:34-38).

CLINICAL SIGNIFICANCE: The IPT provides an alternative treatment of primary teeth with deep carious lesions representing a simple and effective technique to maintain the pulp vitality.

Introduction

According to the guidelines of the American Academy of Pediatric Dentistry (AAPD), the indirect pulp treatment (IPT) is a procedure in which the caries closest to the pulp tissue is left in place and covered with a biocompatible material, and the tooth is restored to prevent microleakage. The main goal of this minimal intervention technique is to preserve dental substrate while maintaining pulp vitality, avoiding direct intervention on the pulp tissue. Besides, IPT showed higher rates of clinical and radiographic success when compared with other conservative pulp treatments, such as pulpotomy.

The IPT is clearly not indicated when the pulp tissue is exposed by caries or when the teeth present irreversible pulp pathology, based on a thorough clinical and radiographic examination.

Despite the indication of using a biocompatible material over the remaining demineralized tissue, clinical, radiographic, and bacteriologic studies have shown the inactivation of active carious lesion, even when inert materials (i.e. wax or gutta-percha) were used as capping materials. Other studies have shown that an acid-resistant tissue resulting from the interdiffusion of adhesive resin within the area of carious dentin does not affect the clinical performance of the restoration.

The restorative material should completely seal the involved dentin from the oral environment avoiding nutrient influx and compromising the bacteria metabolism. Glass-ionomer cement and resin composite have shown to provide adequate marginal sealing in primary teeth submitted to IPT.

The present study evaluated clinically and radiographically the long-term function of primary teeth submitted to IPT when a self-etching primer or a calcium hydroxide was used under resin-based composite restorations.

Materials and Methods

This clinical study was conducted at the Federal University of Rio Grande do Sul, Pediatric Dentistry Unit (Porto Alegre, Brazil), using a protocol that was reviewed and approved by the institutional review board. The parents/legal guardians read and signed an informed consent form for this study (No. 08/04 according to the resolution 196/96 of the National Health Council). Forty primary molars were selected from 21 healthy children (4-8 years old). The inclusion criteria were: (1) active carious lesion in deep dentin (occlusal or occluso-proximal surface); (2) absence of clinical diagnosis of pulp exposure, fistula, swelling of periodontal tissues, and abnormal tooth mobility; (3) absence of clinical symptoms of irreversible pulpitis, such as spontaneous pain or sensitivity to pressure; (4) the extension of the carious lesion should be such that complete caries removal would risk pulp exposure, as determined by clinical and radiographic assessment; (5) absence of radiolucencies at the interradicular (furcation) or periapical regions, or thickening of the periodontal spaces, that would indicate the presence of the irreversible pulp pathologies or necrosis; (6) absence of internal or external root resorption; and (7) 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 arrest, including extractions, pulp treatments, and restoration of carious lesions, fluoride therapy, oral hygiene and dietary instructions.

The subjects were anesthetized and under rubber dam isolation, received occlusal or occluso-proximal cavity preparations. The carious tissue was removed completely by the peripheral excavation of the cavity followed by a central excavation removing the outermost necrotic and infected demineralized dentin. Teeth were then randomly assigned into experimental (N =19, Clearfil SE Bond), or control (N=21, Dycal calcium hydroxide) groups. In the experimental 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/cm² for 20 seconds (Elipar Highlight). In the control group, a calcium hydroxide cement liner was applied over the carious dentin, before the self-etching system application. The cavities were filled with resin composite (Filtek Z250) by incremental technique. To restore the Class II cavities, a metal...
were considered significant if \( P < 0.05 \). The software SPSS survival followed by Log Rank and tooth type and cavity were statistically analyzed using Kaplan-Meier.

One blind examiner performed the clinical and radiographic follow-up examinations.

The groups were statistically analyzed using Kaplan-Meier survival followed by Log Rank and tooth type and cavity configurations were analyzed by Fisher’s exact test. All results were considered significant if \( P < 0.05 \). The software SPSS 13.0 was used for these analyses.

**Results**

After a long-term follow-up (up to 60 months), 15 children from a total of 21 were reexamined for the final evaluation. Six subjects dropped from the study: three quit the program and the other three moved to another city; these occurred in 24 months and represented eight teeth out of the initial sample (two from the Clearfil SE Bond group and six from the Dycal group). Thirty-two teeth, from a total baseline of 40, were evaluated. Twenty-five cases met the criteria for clinical and radiographic success, reaching an overall success rate of 78\% with no statistical difference between the groups (Table 1, Figs. 1-5).

**Discussion**

According to the AAPD, the indications for IPT and pulpotomy are very similar for primary teeth with deep caries and reversible pulpitis, when the pulp is judged to be vital from clinical and radiographic criteria. The difference is that if during caries excavation a pulp exposure occurs, a pulpotomy is performed. IPT purposely avoids an exposure by leaving in place the deepest decay in place, adjacent to the pulp. Studies have shown that the pulpotomy success significantly decreases over time. Another concern is the early exfoliation of pulpotomized teeth, compared to IPT. Further, even when dental students with different abilities perform IPT, the success rate did not decrease significantly.

At a meeting sponsored by the American Association of Endodontists (AAE) and the American Academy of Pediatric Dentistry (AAPD) in 2007, pre-symposium and post-symposium tests were given to endodontists and pediatric dentists to compare the level of agreement in terms of conservative pulp treatment of primary and young permanent teeth. The results indicated that the pediatric dentistry and endodontic communities agree that formocresol will be replaced as a primary tooth pulpotomy agent, that IPT in primary teeth holds hope as a replacement for pulpotomy, and that IPT is an acceptable technique for cariously involved young permanent teeth.

Interestingly, a survey conducted among pediatric program directors in U.S. dental schools and pediatric dentists, regarding deep caries removal in primary molars, reported the pulpotomy as treatment of choice, for 70\% and 80\%, respectively.

Follow-up studies have demonstrated the effectiveness of treating deep carious lesions by using a less invasive...
approach, independent of the capping material used over the
demineralized dentin. The placement of a high-quality adhesive
restoration seems to be a requirement to seal completely the
involved dentin from the oral environment. Absence of
marginal defects limits the nutrient influx to support bacteria
and their proliferation besides facilitating the recovery of dental
pulp health.4,10

Long-term recall (2- to 4-year) studies29,12,13 showed a high
success rate for IPT, ranging from 70-90%. This present
clinical trial showed high percentages of clinical and
radiographic success of IPT after long-term follow-up and
corroborates with previous studies.6,9,13,20

The results of the first period evaluation, a 2-year clinical
and radiographic follow-up study, were previously published,
with successful rate of 87%.20 The overall proportion of teeth
that had a successful outcome with IPT after the final
evaluation (up to 60 months) was 78%.

Since IPT requires no pulp entry, cases of failure are
expected to occur in a short period of time, and are reflected in
terms of clinical and/or radiographic evaluations. In addition,
the failure of IPT are more likely to be as a result of incorrect
diagnosis of the pulp condition. In the present study, the
majority of failures were observed after the first-year of clinical
and radiographic follow-up. However, it is important to state
that the sample constituted predominantly children belonging to
very low socioeconomic levels, living far from the pediatric
dentistry clinic. Once treated, achieving an adequate oral health condition, some children did not return for the scheduled recalls. Toothache and other invasive treatments were the reasons for returning after missing the scheduled research appointments. These subjects usually showed up with high caries activity and restorations with considerable marginal defects, which allowed for plaque accumulation and the recurrence of the carious lesion. Under these conditions, the restorations were replaced and the treatments recorded as failures.

According to the literature, IPT therapy has a higher success rate in second primary molars compared to first primary molars.\textsuperscript{15} Al-Zayer \textit{et al.}\textsuperscript{17} assessed retrospectively the clinical and radiographic success of IPT on primary posterior teeth. The results revealed that IPT performed on primary first molars failed more frequently than on second primary molars (P=0.045), however there was no significant difference between maxillary and mandibular primary molars.

Surprisingly, in the present study more cases of IPT failures were recorded in second primary molars, and in occlusal restorations compared to the first primary molars and occluso-proximal restorations, but without statistical differences. These were probably due to various events acting over the restorations after long-term function in the oral environment. During the restorative procedures, it was observed that the cavities' sizes of second molars were larger compared to the first molars, which needed considerably more resin composite to restore. Considering the cavity configuration (C-factor), especially for the occlusal cavity, it represents the greatest challenge for the composite adhesion, since a great number of adhesive surfaces were competing during the resin polymerization. The incremental technique was introduced to overcome the destructive influence of resin composite polymerization shrinkage and to achieve better marginal adaptation and seal, although another important factor that must be considered is the self-etching primer used in the present study.

The literature shows satisfactory results of bond strength in dentin of primary teeth,\textsuperscript{23} even after aging in the oral environment.\textsuperscript{22} However, when bonded to enamel, studies\textsuperscript{22,23} have shown contradictory results. The differences of mineral content between dentin and enamel suggest a lack of stable adhesion when a self-etching primer, with limited power of decalcification, is used in enamel.

Considering the strategic position in the dental arch during occlusion development, the second primary teeth undergo considerably higher mastication loads, which could negatively contribute to the restoration failures, once the fatigue associated with biofilm accumulation could accelerate the interfacial degradation formed by a self-etching primer and enamel. In summary, the association of these conditions, such as the tooth position in the arch, the restoration size with a high C-factor and a self-etching primer bonded to enamel, after a long-term function and perhaps, under high caries activity challenge, may possibly explain the failure rate of occlusal restorations of second primary molars observed in the present study.

Further knowledge in relation to stability of adhesion and quality of the restorations used in indirect pulp treatment is necessary to determine the clinical performance after long-term function in the oral environment.

The results suggest the possibility of arresting the caries process, independent of the capping material used over the demineralized dentin. The subjects’ compliance with the recall visits was decisive for caries control and IPT success. This less invasive approach provides an alternative treatment for primary teeth with deep carious lesions, representing a simple and effective technique to maintain pulp vitality.

\begin{itemize}
  \item Kuraray, Tokyo, Japan.
  \item Caulk Dentsply, Milford, DE, USA.
  \item 3M ESPE, St. Paul, MN, USA.
  \item Caulk Dentsply, York, PA, USA.
  \item SPSS, Chicago, IL, USA.
\end{itemize}

\textbf{Disclosure statement:} All authors have no conflict of interest.

Dr. Casagrande is Associate Professor, School of Dentistry, Franciscan University Center (UNIFRA), Santa Maria, Rio Grande do Sul, Brazil. Dr. Bento is a PhD student, Dr. Dalpian was a MS student, and is now in private practice, Dr. Araujo is Associate Professor, School of Dentistry, Department of Pediatric Dentistry, Federal University of Rio Grande do Sul (UFRGS), Porto Alegre, Rio Grande do Sul, Brazil. Dr. García-Godoy is Professor and Senior Executive Dean for Research, Director, Bioscience Research Center, College of Dentistry, University of Tennessee Health Science Center, Memphis, Tennessee, USA.

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