

Clinical Article

Long-term Outcomes of Primary Tooth Pulpectomy With and Without Smear Layer Removal: A Randomized Split-mouth Clinical Trial

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Abstract: ***Purpose:** The aim of this study was to evaluate, via clinical and radiographic assessment, pulpectomy outcomes performed on primary anterior teeth both with and without a citric acid solution to enhance smear layer removal. **Methods:** Patients with a matched pair of primary incisors (split-mouth design) with irreversible pulp changes were selected. A total of 36 teeth (18 children) received pulpectomies and were followed for 36 months. Pulpectomies were performed using sodium hypochlorite and saline solution as canal irrigants; during the last irrigation, the tooth was randomly selected to receive (Group 1) or not receive (Group 2) the citric acid solution for smear layer removal. The roots were filled with ZOE paste. **Results:** Overall pulpectomy success was 90.6%. Cases with smear layer removal were successful 82.3% of the time; those without smear layer removal, 88.2%, and there were no statistical differences ($P=1.00$). **Conclusion:** Pulpectomy with smear layer removal in primary incisors exhibited, after 36 months, a high success rate; however, comparable results were obtained when the smear layer was not removed. (Pediatr Dent 2011;33:316-20) Received December 2, 2009 | Last Revision March 9, 2010 | Accepted April 1, 2010*

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Despite the emphasis on caries prevention and a worldwide decrease in the number of carious lesions, some population groups continue to experience a high prevalence of caries,¹ resulting in premature loss of primary teeth and associated negative consequences. Another contributing factor in premature loss of primary teeth is dental trauma. Children often experience traumatic dental injuries, especially in their early years, and pulp necrosis has been found to be the most common post-traumatic complication.^{2,3} Primary tooth pulpectomy is a successful means of maintaining teeth with irreversible pulpitis or necrotic pulps in terms of function, esthetics, arch length, and symmetry until exfoliation.⁴

To overcome the limitations of the peculiar anatomy of primary teeth and their greater need for root canal disinfection, various irrigating solutions have been used during pulpectomies. In permanent teeth, sodium hypochlorite solution (NaOCl) is highly recommended because of its broad antimicrobial spectrum and capacity to dissolve necrotic tissue remnants.⁵ Although NaOCl is efficient in dissolving organic components of the smear layer, its ability to remove inorganic components is limited.⁶ Citric acid, a demineralizing agent,

has been recommended as an adjunctive irrigant for permanent teeth⁵ because of its good results in endodontics for both permanent^{7,8} and primary teeth.⁹ Götze et al.,¹⁰ has reported the association of 6.0% citric acid with 1.0% NaOCl as an effective alternative to enhance smear layer removal, increase dentin permeability, and permit better disinfection of primary teeth.

Zehnder⁷ reported that there is no randomized, controlled clinical trial in the endodontic literature on the effect of irrigating solutions on treatment outcome. Moreover, no clinical studies have evaluated the effectiveness of irrigating solutions in primary tooth pulpectomy.

Consequently, the purpose of this study was to evaluate, via clinical and radiographic assessment over 36 months, pulpectomy outcomes performed on primary anterior teeth both using and not using a chelating solution to enhance smear layer removal.

Methods

This study was approved by the Ethics Committee of the Institute of Public Health Studies, Federal University of Rio de Janeiro, Rio de Janeiro, Brazil. Informed consent was obtained from all participating parents and legal guardians.

We selected for the study only patients who had a matched pair of primary incisors with irreversible pulp changes from caries or trauma. We used a split-mouth design, and each patient received pulpectomies with (Group 1) and without (Group 2) smear layer removal. A total of 18 healthy children (11 boys and 7 girls), ranging from 3 to 5 years old, were included for the clinical investigation of pulpectomy efficacy

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using citric acid solution irrigation among patients attending the Pediatric Dentistry Department Clinic at the Federal University of Rio de Janeiro. Pulpectomies on primary anterior teeth were performed by 1 pediatric dentist. Two blinded examiners, who were not involved in performing the therapy, evaluated the pulpectomies at 15 days, and at 1, 6, 12, 18, 24, 30, and 36 months.

Inclusion criteria to perform a pulpectomy were as follows: (1) irreversible pulpitis; (2) pulpal necrosis; (3) root at least two thirds intact^{11,12}; and (4) adequate tooth structure remaining for an appropriate restoration.¹³ Teeth meeting any of the following criteria were excluded: (1) anatomical anomalies; (2) radiographic evidence of calcifying changes; (3) evidence of internal or external pathologic root resorption; and (4) previous canal manipulation.

Technique. One pediatric dentist performed the single-visit pulpectomy together with composite resin restoration at the same visit. The teeth were isolated with a rubber dam after local anesthesia. Periapical radiographs were taken of all eligible teeth on Kodak Insight films (size 0, F-speed) using a radiographic film holder. Time exposure was adjusted for the tooth type, and processing was performed manually and adjusted by time/temperature. Chemical-surgical preparation was performed through instrumentation by using K-files at 1 mm short of the apex. Each tooth was randomly selected, by tossing a coin, for an irrigation group as follows:

- Group 1—irrigation with 10 mL 1% NaOCl during every instrument change. After the last instrumentation, a final irrigation was performed with 10 mL 6% citric acid followed by 10 mL 0.9% saline solution.
- Group 2—irrigation with 10 mL 1% NaOCl during every instrument change. After the last instrumentation, a final irrigation was performed with 20 mL 0.9% saline solution.

Next, the root canals were dried with sterile paper points and filled with ZOE paste using clockwise-rotating lentulo spirals to standardize the obliteration technique. The canal orifice was sealed with glass ionomer cement. All pulpectomized teeth were restored with composite resin. A final periapical radiograph was taken to verify obturation quality according to the following definitions: underfilled (more than 2 mm short of the radiographic apex), ideal (at the radiographic apex or up to 2 mm short of the apex), and overfilled (extravasation through the radiographic apex). The patients returned for clinical and radiographic evaluation at 2-week, 1-month, and 6-month intervals for 36 months.

A successful pulpectomy should satisfy the following criteria¹³:

1. Pretreatment clinical signs and symptoms should be resolved within 2 weeks.
2. The infectious process should be resolved radiographically within 6 months, as evidenced by bone deposition in the pretreatment radiolucent areas.
3. No pathologic root resorption or apical radiolucency should occur.

From the post-treatment radiographs, we determined whether the ZOE had resorbed faster than, slower than, or at the same rate as the root. The alveolar area was examined radiographically for signs of retained ZOE—that is, whether there was

evidence of radiopaque material in the vicinity of the succedaneous teeth. Reasons for tooth loss included: (1) exfoliation; (2) extraction due to pulpectomy failure; (3) extraction due to over-retention; and (4) extraction for other reasons. In addition, we tabulated the frequency of ectopic eruption and enamel defects of the succedaneous teeth.

Descriptive frequencies and the McNemar test were used for statistical analysis with a significance level of 95% ($P \leq .05$).

Results

Pulpectomies were performed on 32 primary maxillary incisors (14 centrals and 18 laterals) and 4 primary mandibular incisors (2 centrals and 2 laterals). Pulp necrosis was observed in 21 (~62%) teeth. Table 1 also describes clinical and radiographic findings observed before pulpectomy. At 12 months' evaluation, 2 teeth (1 in each group) were excluded from the analysis because 1 patient failed his follow-up appointments. After 36 months, 17 patients remained for clinical and radiographic evaluation ($n=34$ pairs of primary teeth). The overall pulpectomy success rate was approximately 91%. Cases with and without smear layer removal were successful, respectively, approximately 82% and 88% of the time. The success rates for both groups were not significantly different ($P=1.00$; Table 2).

Table 1. ABSOLUTE FREQUENCIES OF CLINICAL AND RADIOGRAPHIC FINDINGS OBSERVED BEFORE PULPECTOMY AND AFTER ROOT CANAL FILLING

Variable	Group 1 (N=18)	Group 2 (N=18)	Total (N=36)
Clinical findings*			
Pain	4	1	5
Gingival swelling	4	4	8
Sinus tract/exudate	1	1	2
No alteration	11	14	25
Radiographic findings			
Periapical lesion	2	2	4
No alteration	16	16	32
Pulp diagnosis			
Necrosis	11	10	21
Vital	7	8	15
Extent of root filling material			
Underfilled	9	7	16
Ideal	5	6	11
Overfilled	2	7	9

* Some teeth presented more than 1 clinical finding.

Table 2. COMPARISON OF SUCCESS AND FAILURE IN G1 AND G2 CONSIDERING A MATCHED PAIR OF PRIMARY INCISORS

		Group 1		Total	P-value
		Success	Failure		
Group 2	Success	14	1	15	1.00*
	Failure	0	2	2	
Total		14	3	17	

* McNemar test.

All failed pulpectomies ($N=5$) occurred in the first 12 months (4 cases after 6 months and 1 case after 12 months of evaluation) and were extracted. Clinical signs and symptoms of infection were not observed in children analyzed with pulpectomy failure. Twenty-one teeth presented pulp necrosis before treatment and 4 were judged failures. All teeth with underfilled ($N=6$) and ideally filled ($N=5$) canals were successful. At 36 months' evaluation, 19 primary teeth (~59%) had been lost, 18 permanent successors (~56%) had erupted, and only 2 presented opacity (Table 3). Clinical and radiographic follow-up examinations showed that ZOE resorption lagged behind root resorption in 12 cases, and 5 of them were removed because of either over-retention ($N=4$) or deflection of successor's path ($N=1$; Table 3).

Table 3. OBSERVED FINDINGS AFTER LONG-TERM EVALUATION OF GROUPS 1 AND 2 ($N=34$)

	Group 1	Group 2	Total
Reason for tooth loss ($N=19$)			
Exfoliation	5	4	9
Extraction due to infection	3	2	5
Extraction due to over-retention	2	2	4
Extraction due to deflection of successor's path	0	1	1
ZOE paste resorption compared with root resorption ($N=34$)			
Ideal	11	10	21
Early	1	0	1
Late	5	7	12
Overfilled cases ($N=9$)			
ZOE particle resorption during 3 months' post-treatment	1	1	2
ZOE particles retained in periapical area	2	5	7
First radiograph after tooth loss ($N=19$)			
ZOE particles retained in periapical area	4	3	7
ZOE resorbed completely	7	5	12
Permanent successors erupted ($N=18$)			
Ectopic eruption	0	1	1
Enamel defects (white opacities)	1	1	2
No defects in enamel or position	8	7	15

Discussion

The overall pulpectomy success rates observed in our study (~82% and 88%, with and without smear layer removal, respectively, with no statistically significant differences) were similar to other studies.^{11,14-19} Although various root canal irrigants^{11,12,15,19,20} were employed for primary tooth pulpectomies, no agreement exists regarding which root canal irrigants should be used during primary tooth pulpectomy. Moreover, no studies were found in the literature that used a chelating solution during treatment and compared the effectiveness of different solutions. We attempted to analyze important variables in this study, such as long-term clinical and radiographic outcomes.

An interaction exists between periapical diagnosis and endodontic treatment factors (level of root canal instrumentation and obturation and density of root filling), which exerts a significant effect on treatment outcome in permanent teeth.²¹ According to a previous descriptive study, the main factor associated with pulpectomy failure in primary teeth was the technical limitations associated with morphological irregularities created by external and inflammatory resorption.²² Our study presented only 5 teeth having treatment failure after a 36-month follow-up. We suggest that the low number of failures could be due to careful tooth selection, effective irrigating solutions, filling paste having good antimicrobial action, and rigorous success criteria.

In endodontic infection, bacteria located in areas such as isthmuses, ramification deltas, irregularities, and dentinal tubules are not eliminated by mechanical means alone.⁶ Therefore, 1% NaOCl, the main root canal irrigant for the primary dentition, was selected in our study because of its broad antimicrobial spectrum⁵ and acceptable biological compatibility.²³

Demineralizing agents such as ethylenediaminetetraacetic acid (EDTA) and citric acid have, therefore, been recommended as adjuvants in root canal therapy.²⁴ Although citric acid appears to be slightly more potent than EDTA at similar concentrations, both agents are highly efficient at removing the smear layer.²⁵ In addition, a previous study has related that citric acid solutions showed antibacterial effects on micro-organisms isolated from infected root canals²⁶ and were less cytotoxic than other solutions such as EDTA and EDTA-T.²⁷⁻²⁹ Because treatment successes observed in both groups (with and without smear layer removal) were comparable, we assume that the limited sample size might have influenced the treatment outcome.

ZOE is probably the most widely used root canal filling in the United States for primary teeth, with success rates ranging from 65% to 86%.^{11,14,18,30} Long-term studies,^{16,31-33} however, have revealed that overfilled canals displayed over-retained ZOE during follow-up and delayed resorption of the material when compared with physiologic radicular resorption. Other studies found that retained paste could deflect the eruption path of succedaneous teeth.^{19,32}

Sadrian and Coll³¹ have related that ZOE was retained at a rate of approximately 49% (38/77) based on the first radiograph after the pulpectomized tooth exfoliated or was extracted. An investigation by Mani et al.,³³ revealed that 67% of all overfilled canals showed over-retained ZOE at the 6-month follow-up. Our results showed that ZOE particles were retained after pulpectomized tooth loss. In overfilled cases ($N=9$), 7 presented ZOE particles retained in the periapical area after 3 months' follow-up.

In the permanent dentition, the prognosis for endodontic outcome is enhanced if teeth with a normal periapex are instrumented and obturated at a distance from the radiographic apex. Likewise, the prognosis of teeth with periapical disease is improved if they are instrumented closer to the radiographic apex.²¹ We observed that most cases, in which extent of obturation was considered ideal or underfilled, showed pulpectomy success. Some authors have stated that underfilling is better than overfilling because extruded ZOE

could initiate periapical irritation.^{12,34} Primosch et al.,²⁰ have reported a statistically significant increase in failure rates in pulpectomized vital incisors with grossly overfilled canals.

Only a few studies^{14,16,18,32,35} describe pulpectomy's effect on permanent successors, but our long-term evaluation permitted this analysis. Ectopic eruption of succedaneous teeth was observed in 1 permanent tooth that erupted during this study (Table 3). Periodic evaluation by periapical radiography allowed detection of the successors' deflection path so that the pulpectomized teeth could be extracted. For this reason, the frequency of ectopic eruption of succedaneous teeth in our study was lower than that found in the literature. We suggest that the main factor associated with ectopic eruption is unresorbed ZOE paste, as previously reported.^{20,32}

We observed enamel defects involving white opacities in 2 permanent incisor successors. Both predecessors presented pulp necrosis. No hypoplastic defects were observed, and none of the enamel opacities required treatment. It appears that the enamel defects resulted from pre-existing infection before pulpectomy and not because of the procedure itself. According to Coll and Sadrian,³² excessive preoperative root resorption might indicate extensive, pre-existing periradicular infection in the area with potential to damage the permanent tooth before therapy was ever performed. Our study selected only teeth with at least two thirds of the root intact, suggesting only a mild infection. Thus, we observed only white opacities in permanent successors; their prevalence was lower when compared with other studies.^{32,35}

Only a limited number of patients were available because of the difficulties of a split-mouth, long-term follow-up study. Another contributing factor was the socioeconomic status of the families attending the Federal University of Rio de Janeiro. For them, bringing in a child for periodic assessment is costly, and financial assistance to participate in a scientific study is prohibited by Brazilian ethics legislation. On the other hand, in a split-mouth design, divisions of the mouth constitute the experimental units randomly assigned to treatments. Because the patient serves as his or her own control (increasing statistical efficiency), fewer patients are needed.³⁶

In summary, as this was the first clinical evaluation of the influence of smear layer removal on primary pulpectomy, we recommend that further evaluation, using a larger sample that includes molars, be conducted to obtain strong evidence for adding citric acid to the canal disinfection protocol.

Conclusions

Based on this study's results, the following conclusions can be made:

1. After 36 months, pulpectomy with smear layer removal in primary incisors exhibited a high success rate.
2. Comparable results in pulpectomy outcomes were obtained when the smear layer was not removed.
3. All pulpectomy failures occurred within 12 months.

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Abstract of the Scientific Literature

Evaluating the impact of a Prenatal Dental Public Health Program

This paper describes findings from an evaluation of a prenatal dental public health program providing limited clinical care along with oral health education to pregnant women at increased risk for negative birth outcomes. Women are referred for these dental services from the Healthiest Babies Possible program serving low-income women at high-risk for preterm and low-birth-weight pregnancies. Referral is based upon women self-reporting a dental problem or if they have not seen a dentist in > 2 years. A one year evaluation was undertaken to assess the effects of the oral health counselling and periodontal care provided. Participants completed questionnaires, interviews, and clinical assessments during the different phases of the project. Visits 1 and 2 were during pregnancy, while visit 3 was postnatal. A total of 61 women were enrolled with a mean age of 27.7 years at an average of 22.8 weeks gestation. Gingival health improved significantly between visit 1 and 2 in all parameters like plaque, calculus, bleeding on probing, and mean pocket depth ($P < .01$). These clinical improvements in periodontal health were maintained over time as they were significantly better even at the postnatal visit when compared with the first study visit. Maternal oral health knowledge also improved after completing this study. Significantly more women believed that gingival bleeding during pregnancy is not normal ($P < .001$) and that baby's should not go to sleep with a bottle ($P = .019$). Further, 93% reported that they had begun to provide infant oral care for their newborn, and dental care for their other children significantly increased after taking part in this project ($P < .001$). Overall, participants found the oral health information useful and appreciated the fact that it was provided verbally from the dental hygienist rather than via a pamphlet.

Comments: This program provides simple and relatively low-cost examples on how to improve access to clinical care and counselling for high-needs pregnant women by dedicating time in the clinical schedule to accommodate referrals from the local prenatal support program. Such strategies could easily be adopted by other dental public health clinics that want to improve the oral health of women, their infants, and their other children. Such programs may improve family oral health for high-risk groups and may also reduce the dental disease burden among their children. *RJS*

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