Zinc Oxide−Eugenol Pulpotomy in Primary Teeth: A 24-Month Follow-up

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Objective: *The purpose of the present study was to evaluate the clinical and radiographic effectiveness of zinc oxide−eugenol (ZOE) as the only pulp capping agent in pulpotomies carried out on decayed primary molars after a follow-up period of 24 months.* ***Study design:*** *In total, 60 pulpotomies were performed on 38 patients aged 3 to 11 years. Pulpotomy treatment consisted of the removal of the coronal pup tissue, subsequent hemostasis, irrigation with saline solution, drying and pressure with sterile cotton pellets, and placement of a thick regular ZOE base with a minimal amount of eugenol directly over the vital radicular pulp. Additionally, a histopathologic study was carried out on some of the molars treated.* ***Results:*** *After a 24-month follow-up, we considered 51 procedures to be successful and 9 failures using clinical and radiographic criteria; most of the failures occurred between the 12th and 18th month.* ***Conclusions:*** *Results suggest that the proposed pulpotomy treatment with ZOE as the only capping agent may be considered as an alternative technique in the pulp treatment of primary molars.*

Key words: *Pulpotomy, primary molars, zinc oxide-eugenol*

INTRODUCTION

Dental caries in primary teeth is the most common chronic disease in childhood, having become an important worldwide public health problem.[1] It is considered an infectious process that is preventable and reversible in its initial stages, but without prompt treatment it may seriously affect the pulp tissue. Consequently, it may result in pain, premature loss of the affected teeth with consequent occlusal, arch-length, mastication, and esthetics abnormalities, speech disorders, harm to the permanent dentition and periodontal tissues, bacteremia, reduced growth and development, loss of self-esteem, and high cost of dental treatment.[1,2]

Untreated or inadequately treated carious lesions in primary teeth may result in bacterial invasion into the coronal pulp, with the subsequent inflammation and infection of this tissue. Pulpotomy is a mainstream procedure indicated for the treatment of primary teeth with coronally reversible inflammation and vital pulp, provided there is no involvement of the radicular pulp or characteristic signs or symptoms of pulp degeneration.[2] Treatment success depends on carrying out a precise diagnosis based on clinical findings, pain history, and radiographic evidence; besides, the prognosis is better when the restoration, such as the preformed metallic crown, supplies adequate coronal sealing against microleakage.[2,3]

Protocols for pulpotomy treatment in primary teeth vary according to the material or agent employed for capping the remnant radicular pulp tissue, as well as the treatment objectives.[3,4] The ideal capping agent must (1) be bactericidal, (2) be innocuous to the pulp and periodontal tissues, (3) promote healing of the radicular pulp, and (4) not interfere with the process of physiologic root resorption.[3,5] However, at the present time, such an agent has not been

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found.[2–6] Formocresol has been widely employed as a capping agent for more than 4 decades due to its excellent bactericidal and fixative properties. It also has a high clinical success rate, varying from 81% to 98%.[2,7–9] Nevertheless, the use of formocresol in pediatric dentistry has considerably decreased; studies have shown that it has a toxic effect on the radicular pulp, periodontium, and permanent tooth germ, as well as potentially teratogenic, mutagenic, and carcinogenic properties.[10–16]

For these reasons, researchers have sought to find a substitute for formocresol as a capping agent in primary teeth pulpotomies.[2] Several studies have been conducted, with appropriate methodologies, to evaluate the effectiveness of alternative materials having a higher histocompatibility; these materials include glutaraldehyde,[17–19] ferric sulfate,[20,21] calcium hydroxide,[22,23] mineral trioxide aggregate (MTA),[24–27] enamel matrix derivative,[28] collagen,[29] lyophilized dried bone,[30] and bone morphogenetic protein.[31] Other techniques, such as electrosurgery[32] and laser[33,34] have met with varied clinical and radiographic success.

Zinc oxide−eugenol (ZOE) is one of the most frequently used materials in dentistry, due to its sedative and palliative properties, in cases of pulpal pain. It has been employed as an intermediate and thermal insulating base in restorative procedures, as well as a primary pulp canal obturating paste and periodontal antimicrobial; however, diverse toxic effects have been reported when ZOE is applied directly over the pulp since eugenol induces a chronic inflammatory response and, at the same time, inhibits the immune reaction in defense of the dental pulp.[26,35–37] Limited reports of direct pulp capping of primary teeth with ZOE have been made, with controversial results.[38–41]

The purpose of the present study was to evaluate the clinical and radiographic results of pulpotomy treatments carried out on primary molars employing ZOE as the only capping material, placed directly over the remnant root pulp tissue, with a 24-month follow-up.

MATERIALS AND METHOD

This was a prospective and longitudinal study conducted in accordance with the Declaration of Helsinki. The Ethics Committee of our institution approved the study, whose objective was explained to the parents/legal guardians and for which written informed consent was obtained. This study included 38 patients of both sexes between 3 and 11 years old who had no systemic conditions that would contraindicate pulp therapy. Periapical radiographs were taken; each child was treated with pulpotomy in one or more carious primary molars following these selection criteria[42]: (1) vital teeth with carious pulp exposure or during caries removal; (2) no clinical signs or symptoms of irreversible pulpitis or pulp degeneration (spontaneous pain, pain on percussion, abnormal mobility, swelling, or sinus tract); (3) no radiographic evidence of external or internal root resorption, periradicular radiolucency, or widening of the periodontal space; (4) bright red hemorrhage from the amputation site and total hemostasis after removing the coronal pulp; (5) teeth restorable with a stainless steel crown; and (6) no more than half of any root exhibiting physiologic resorption.

Conventional pulpotomy treatment and restorative crown placement were carried out by only one clinical operator after locally anesthetizing (lidocaine with 2% epinephrine, 1:100,000) and rubber dam isolating. Caries and overhanging enamel were removed with a No. 3 high-speed bur with water spray. Access to the pulp chamber and amputation of the coronal pulp were achieved with the same bur, with no tags remaining on the pulpal floor. Hemostasis was gained after washing with sterile solution and drying the cavity chamber with sterile cotton pellets placed under light pressure over the radicular pulp stumps for 5 minutes. The pulp chamber was immediately filled with a thick, homogeneous mix of regular ZOE (Caulk-Dentsply, Milford, DE, USA) with the least possible amount of eugenol, placing it directly over the pulp stumps with a moistened cotton pellet. All molars were restored immediately or during the following 7 days (in this case, IRM was placed provisionally) with a stainless steel crown (3M-ESPE, St. Paul, MN, USA), which was cemented with glass ionomer (Ketac-Cem, 3M-ESPE).

The patients were clinically and radiographically assessed at 1, 3, 6, 12, 18, and 24 months posttreatment by an experienced and blinded pediatric dentist not involved in the investigation, who evaluated the pulpotomies. The outcomes were categorized as successful or failed by the following criteria[42]: history of pain, tenderness to percussion, pathologic mobility, gingival swelling or sinus tract, internal or external root resorption, and periradicular radiolucency. The pediatric dentist had previously been calibrated; intra- and inter-rater reliability were calculated using Cohen's kappa coefficient, obtaining 0.85 and 0.90 scores, respectively, considered good. Evaluation radiographs were taken using size 0 standard films in a Rinn film holder, using the bisecting angle technique with a long tube. Those patients who did not return to any of the assessment appointments were eliminated from the study.

Additionally, a histopathologic analysis, previously reported by Odabas *et al*,[33] was carried out on some treated molars at the end of the 12-18 month-follow-up period, that had nearly exfoliated and so were extracted. Briefly, after extraction, the teeth were immediately preserved in 10% buffered formalin. Then they were decalcified in a formic acid solution under constant agitation. Once decalcified, the teeth were embedded in paraffin blocks, and serial sections were cut at a setting of 5 μm in the buccolingual direction. The slides were H & E-stained and observed under conventional light microscope; histopathologic evaluations were performed by an oral pathologist, blinded as to the study purposes.

A descriptive analysis was carried out to consider clinical and demographic variables of the selected sample of pediatric patients. Also, success and failure rates were calculated as rates, from the total of pulpotomies performed.

RESULTS

The enrolled subject sample included 19 female and 19 male patients, on which a total of 65 pulpotomies were performed; 2 children with partially missing crowns and 3 not available at the final of the follow-up period were eliminated from the study. The age range at the beginning of the study was between 3.2 and 11.0 years, with a mean age at the time of treatment of 7.1 ± 2.3 years. Distribution of treated teeth is described in Table 1.

After a follow-up period of 24 months, 9 pulpotomized primary molars were considered failures. At the first 3 evaluation periods (1, 3, and 6 months), all treatments were rated as clinically and radiographically successful. Posteriorly, 2 failures occurred between 6 and 12 months posttreatment; most failures (75%) occurred between 12 and 18 months, and an additional failure was noted after 24 months after treatment (Table 2).

Clinical and radiographic findings

Of the 9 pulpotomies rated as failures, 4 exhibited abscesses, sinus tract, or pathologic mobility. Radiographically, there was furcal or periapical radiolucency, and 3 of them showed internal root resorption. One of these failed molars was detected during at 12 month assessment period, and the others in the next period; all were subsequently extracted. Further, 3 molars were associated with gingivitis, marginal bleeding, and pathologic mobility, although without pain symptoms or radiographic evidence of abnormality; these molars were found in the assessment period corresponding to 18 months. Finally, 2 molars caused spontaneous pain, without clinical or radiographic anomalies, and were reported between 6 and 12 months, and between 18 and 24 months, respectively. All these teeth were extracted or treated endodontically and restored with stainless steel crowns.

Histopathologic findings

Among the molar samples having pulpotomies rated as successes (Figure 1-A), a root dentin tissue layer was observed with the presence of tubules over the pulp remnant; under this layer there was inflammatory tissue, considered normal because of the changes produced by the eruption of the succedaneous premolar. No stained bacteria were observed in any of these samples. However, in the sample obtained from the failed pulpotomy, we observed an upper layer composed of immature cells resembling primitive dentin tissue, probably reparative (Figure 1-B).

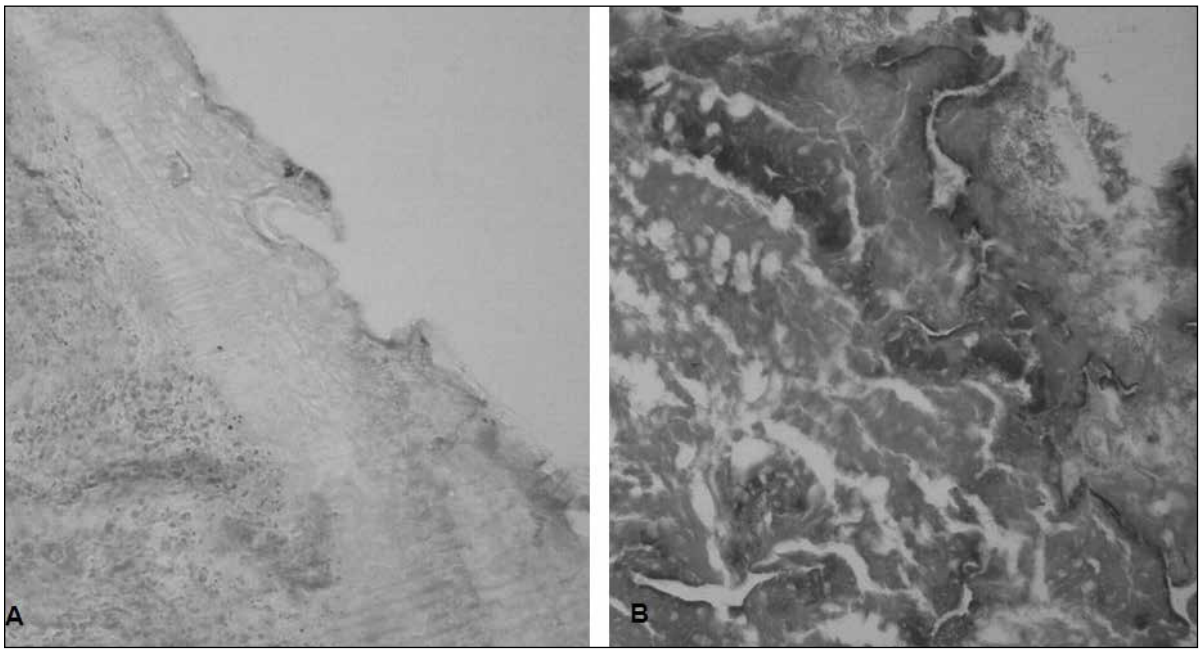
Table 1. Distribution of treated molars.

Primary first molar			Primary second molar			Total
Maxillary	Mandibular	Total	Maxillary	Mandibular	Total	
15 (25%)	21 (35%)	36 (60%)	9 (15%)	15 (25%)	24 (40%)	60 (100%)

Table 2. Outcomes of pulpotomies performed with ZOE, up to 24 months of follow-up.

Age group (years)	Number of pulpotomies performed	1, 3, and 6 months		12 months		18 months		24 months	
		Success	Failure	Success	Failure	Success	Failure	Success	Failure
3−4	5	5	0	5	0	5	0	5	0
5	7	7	0	7	0	7	0	7	0
6	13	13	0	12	1	11	2	11	2
7	11	11	0	11	0	11	2	11	2
8	9	9	0	9	0	8	1	7	2
9	8	8	0	8	0	7	1	7	1
10−11	7	7	0	6	1	5	2	5	2

Figure 1. Histological slides from samples of molars with pulpotomies; A, successful treatment; B, failed treatment (×40).



DISCUSSION

The final purpose of pulpotomy in primary teeth is to maintain the vitality and function of the remaining pulp tissue, and therefore to preserve the affected tooth in a functional state until natural exfoliation occurs.[2,3,6] However, a misdiagnosis of the state of the pulp can lead to an adverse prognosis. The correct diagnostic process in pediatric endodontics, particularly in cases of inflamed pulp, involves several stages which must be carefully carried out: initially, obtaining an adequate clinical history including detailed data about the history and characteristics of the pain, a precise evaluation of the clinical and radiographic findings, and finally, direct observation of the pulp tissue. After this diagnostic process, a definitive decision is made regarding the treatment plan. However, even with all the data obtained from this protocol, it is almost impossible to make an accurate diagnosis about the inflammation grade and the histopathologic state of the pulp.[33,43,44] According to some authors, the clinical signs and symptoms and the true histopathologic condition of pulp tissue do not fully correlate; also, the absence of pain does not preclude the presence of irreversible pulpal changes. These issues may complicate the diagnostic process when pulp tissue is exposed.[45,46]

Pulpotomy therapy for the primary dentition has been broadly classified according to the treatment effect on the remaining pulp tissue: devitalization (mummification or cauterization), preservation (minimal devitalization, noninductive), or regeneration (inductive or reparative).[2,6] In the present study, ZOE constituted the only capping agent applied over the remaining pulp, after profuse irrigation with saline solution and control of hemorrhage by means of pressure with sterile cotton pellets. According to the above classification, the main objective of using ZOE is as a preservative, which implies maintaining the vitality of most of the pulp tissue (minimal devitalization) without inducing reparative dentin formation.[26,35] In studies carried out in the 1960s and 1970s, ZOE was considered a less-than-ideal material for pulpotomy (about 55%) in relation to other experimental agents[47–49]; that success rate was significantly lower than the one obtained in this preliminary report. It has been mentioned that placing ZOE as a capping base during pulpotomy in primary teeth results in its hydrolization by the pulp tissue to produce zinc hydroxide, with the subsequent liberation of eugenol, which can cause pulpal inflammation and, later, internal root resorption.[35,37,50] The latter has also been reported in pulpotomies when ferric sulfate is used as a pulp sub-base agent.[51] In the present report, internal root resorption was noted in only about 5% of the pulpotomies, a lower rate than that of the 27% reported by Erdem *et al*[26] in their 24-month study, in which they compared 4 pulpotomy agents for primary teeth: MTA, formocresol, ferric sulfate, and regular ZOE, a rate only higher than the one from MTA (0%, in the same study), a material considered less irritating than ZOE; also, their results showed that ZOE exhibited the lowest pulpotomy success rate, although the difference was significant only when compared with MTA.

The difference in these results can be explained by the fact that the ZOE mix employed in our study contained only a minimal amount of eugenol, thus being less cytotoxic yet preserving its antiseptic properties, as previously reported.[37] With further regard to internal root resorption, some authors have argued that this radiographic sign should be considered as indicative of failure only when the process has reached the root's outer surface, thereby inducing an inflammatory response in the periodontal ligament and surrounding bone.[35,52,53] On the other hand, Hui-Derksen *et al*[37] reported a very high global success rate of 94% in primary molars followed for an average time of 36.4 ± 21.8 months, and with a low incidence of furcal radiolucency and periapical abscesses (4%), when using a reinforced zinc oxide-eugenol, these authors speculated that the addition of polymethil methacrylate to the reinforced ZOE cement may decrease the irritant effects to the pulp tissue from eugenol. Chien et *al*[35] got a 100% of successes in 145 pulpotomised primary teeth with regular ZOE or ferric sulphate, but with a following period of only 3 months.

Recent studies have also evaluated the effects of ZOE as a direct capping agent in pulpotomies in primary teeth. Chédid *et al*[54] assessed clinically and radiographically the pulpotomy outcomes using unmodified ZOE on 25 healthy and carious primary canines at 1, 6, 12, and 24 months. Although no painful symptoms were reported throughout the follow-up, they found pathologic mobility, internal and external resorption, and abscesses or sinus tracts in up to 50% of the treatments performed. They therefore concluded that this technique is not promising because, in their opinion, chemical fixation does not occur in the pulp tissue, as in the case of formocresol. According to the literature, similar pulpotomy failures in primary teeth can be attributed to such factors—in addition to erroneous diagnosis at the time of treatment or an improperly selected case—as inflammatory response from the ZOE, active presence of previous subclinical pulpal inflammation, poor control of hemorrhage, and microleakage through the interface of the restorative material as a result of an inadequate coronal seal, allowing the entrance of pathogenic bacteria into the remnant pulp tissue. All these factors can explain the failures in the present study. Guelmann *et al*[55] also suggested that short- and medium-term pulpotomy failures in primary teeth are usually related to imprecise diagnosis or an elusive pulpal inflammatory process.

It has been demonstrated that the type of restoration placed on pulpally treated primary teeth has a great influence on the long-term prognosis of pulp therapy. Stainless steel crowns have been highly recommended for pulpotomized teeth—compared with those restored with amalgam or provisional materials like IRM—based on their durability, resistance, and the assumption that there is less microleakage.[3,56,57] In the present study, all restorative crowns were placed either immediately or in a lapse not exceeding 7 days after pulpotomy; a time longer than that was considered a cause for rejection because, in our clinic, sometimes it is not possible to place the crown at the same appointment the pulpotomy is performed, mainly for cost reasons.

The dental literature has also mentioned that bacterial contamination during treatment is one of the main factors in the failure of primary teeth pulpotomies, since the recovery of any tissue occurs only in absence of bacterial infection.[58] In this study, care was always taken to maintain aseptic conditions (sterile burs, instruments, and other materials; absolute isolation; profuse irrigation with saline solution) in order to reduce contamination to a minimum.

In this report, the success rate obtained with the pulpotomy treatment using regular ZOE as a capping agent was 84.5% , after a clinical and radiographic follow-up period of 24 months. Taking

into account the above information, we believe that any failures can be explained by 2 main factors, acting alone or in combination: (1) improper pulp diagnosis, (2) subclinical pulp inflammation. Although longer follow-up times are preferred, our success rates can be considered promising compared with those reported in other studies employing other capping agents: formocresol, 81% to 98%; MTA, 96%; glutaraldehyde, 90%; ferric sulfate, 74% to 97%; calcium hydroxide, 31% to 90%; and laser, 86%.[2,5,6,33,35,42]

CONCLUSION

Based on the outcomes reported in the present study, it can be cautiously assumed that pulpotomy with ZOE is an effective direct capping agent for primary molars. It can be considered a simple and economical alternative to present methods, provided the previously established protocols of diagnosis and treatment are strictly followed.

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