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Original Article

Ineffectiveness of Antibiotic-Based Pulpotomy for Primary Molars: a Survival Analysis

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Abstract

Objective: To investigate the two-year survival rate of primary molars treated with non-instrumentation endodontic treatment with mixed antibiotic paste containing chloramphenicol, tetracycline, zinc oxide and eugenol (CTZ pulpotomy), and compare it to the conventional root canal treatment with calcium hydroxide paste. **Material and Methods:** Thirty-six children, mean age 6.2 years old (standard deviation, SD=1.5), presenting at least one primary molar with irreversible pulpitis or necrotic pulp, were included in this prospective clinical study. Teeth were assigned to CTZ pulpotomy (Group I) or calcium hydroxide pulpectomy (Group II) and assessed clinically and radiographically for up to 26 months. Data were analyzed using descriptive statistics, Chi-square test, Kaplan-Meier survival analysis and Log-rank test. **Results:** Fifty-three primary molars were treated in Group I (n=37) or Group II (n=16). Children were followed up for 1 to 26 months (mean=12.0; SD=7.1). Treatment failure rates were 73.0% in Group I and 31.3% in Group II. Overall, mean survival time was 15.2 months (95% confidence interval, CI 12.6–17.9); Group I (mean 13.2; 95% CI 10.2-16.3) had a lower survival rate than Group II (mean 18.9; 95% CI 14.5-23.2) (p=0.02). Necrotic pulp treatments had significantly lower survival rates (p=0.01) than pulpitis treatments. **Conclusion:** Non-instrumentation endodontic treatment of primary molars with CTZ paste resulted in a low survival rate in a two-year follow-up; its radiographic ineffectiveness discourages its use instead of conventional root canal endodontic treatment.

Keywords: Anti-Bacterial Agents; Tooth, Deciduous; Root Canal Therapy, Pulpotomy.

Introduction

The endodontic approach to infected or inflamed pulp in primary molars should focus on the repair of remaining tissue, which means the absence of signs and symptoms of infection in clinical and radiographic assessments following pulp therapy. The question is: what is the best technique and/or medicament to reach this objective? Over 10 years there was no evidence in systematic reviews showing superiority of one type of pulp treatment for extensive tooth decay in children's primary teeth [1,2].

In the last decade, studies [3-6] have demonstrated the success of the concept of Lesion Sterilization and Tissue Repair (LSTR) for pulpotomies of infected primary molars. The LSTR aims to repair damaged tissues by disinfecting affected pulp and periapical regions with a mixture of antibacterial drugs and no mechanical instrumentation. Those studies [3-6] concluded that pulpotomies with 3Mix, a mixture of three antibacterial drugs (ciprofloxacin, metronidazole and minocycline), were clinically successful for 75.0% to 100.0% of the infected primary molars investigated. However, while LSTR clinical success rates are usually high, its overall radiographic success rate can be as low as 36.7% [7].

Several methods of locally applying antibiotic-based agents for the management of pulp bacterial infections have been well reviewed [8]. In Latin America, an antibiotic-based paste containing a mixture of chloramphenicol, tetracycline, zinc oxide and eugenol, named CTZ, has been used for years as a pulpotomy agent in infected or inflamed pulp, also precluding root canal instrumentation [9]. All components of CTZ paste are approved by the Brazilian National Agency of Sanitary Control (ANVISA) [10]. Despite showing good *in vitro* activity against *Staphylococcus aureus*, *Enterococcus faecalis*, *Pseudomonas aeruginosa*, *Bacillus subtillis*, and *Candida albicans* [11], this mixture presents no consensus concern biocompatibility levels [12,13].

On the other hand, according to classical endodontic philosophy, proper pulp infection control includes root canal preparation, with careful disinfection and use of intracanal substances with good antimicrobial efficacy, tissue dissolution capacity and acceptable biocompatibility [14]. Calcium hydroxide is a popular root canal filling material for primary teeth due its favorable properties [15], mainly due to its resorbability, antibacterial effects, and ability to heal periapical lesions. Calcium hydroxide pulpectomy presents overall success rate of 92.3% for up to 36 months after treatment based on both clinical and radiographic assessments [16].

This prospective clinical study aimed to investigate the two-year survival rate of primary molars treated with non-instrumentation endodontic treatment with a mixed antibiotic paste (CTZ), and to compare with calcium hydroxide pulpectomy.

Material and Methods

This study was conducted in the pediatric dental clinic of the Federal University of Goias (UFG) Dental School, in accordance with the Declaration of Helsinki (World Medical Association)

and approved by the UFG Research Ethics Board (unnumbered protocol approval, 12/2000). The children's parents signed the informed consent form.

Subjects were 36 healthy children referred by community dental services, having primary molars with extensive decay without previous treatment and indicated to endodontic intervention (inclusion criteria). Indicators for endodontic intervention due to pulp involvement were: clinical signs and symptoms, described as history of spontaneous toothache, facial or intra-oral swelling with or without fistulae tract, tooth tenderness to vertical and/or horizontal percussion and light or moderate pathological tooth mobility; and radiographic aspects: furcation or periapical radiolucency without involvement of permanent tooth germ or one or more roots presenting widening of periodontal ligament space. A parent's refusal to participate or a child's non-compliance was considered exclusion criteria.

Groups and interventions

Children who met the inclusion criteria randomly received one of the following interventions: CTZ pulpotomy (Group I) and calcium hydroxide pulpectomy (Group II). Random allocation was done opening consecutive opaque envelopes throughout the study. Parents were blinded to the group assignment of their children. Power analysis was performed based on success rates and samples included in each group to detect a difference at the significance level of 0.05 (95% confidence level).

Two general practitioners with extensive experience in pediatric dentistry performed the pulp therapies, using local anesthesia with 3% Citanest (Dentsply, Rio de Janeiro, RJ, Brazil) and rubber dam isolation. Caries removal and pulp chamber cleaning were done the same way in the two groups. Primary molars from Group I were given the treatment using CTZ paste with one portion of the powder containing chloramphenicol (25%), tetracycline (25%), and zinc oxide (50%) (Formula & Ação, São Paulo, SP, Brazil) plus one drop of eugenol (SSWhite, Rio de Janeiro, RJ, Brazil). This mixture was inserted onto the radicular pulp stumps with a sterile excavator with slight pressure from a sterile cotton pellet. Group II teeth were given conventional root canal treatment, which included chemomechanical preparation of the root canals with three sequences of K-files and irrigation with 1% hypochlorite solution, intracanal medication with calcium hydroxide paste in cases of canal exudate and/or fistulae, and filling of root canals by packing a calcium hydroxide paste (one portion of pure calcium hydroxide, one-third zinc oxide for radiopacity, and propylene glycol).

After pulp treatments, teeth in both groups received a lining of Vidrion glass ionomer cement (SSWhite, Rio de Janeiro, RJ, Brazil) and adhesive composite restoration with Single Bond and Z-100 Restorative (3M ESPE, Saint Paul, MN, USA). Occlusal checking and adjustment were performed. Systemic antimicrobials were not prescribed in any of the cases as no children had systemic symptoms of infection such as fever, trismus or sickness.

Follow-up

Follow-up assessments (clinical and radiographic) were set at predetermined intervals, similar to those used by Trairatvorakul and Detsomboonrat [7]: 30, 90 and 180 days, and 12, 18 and 24 months after the endodontic treatment, or until tooth exfoliation. At each follow-up appointment, children were examined in a dental chair with a dental mirror and a probe. Radiographic exams were performed using pediatric E-Speed films (Kodak Ektaspeed film, Kodak, France) positioned with a straight hemostat for the parallel technique. Treatment was deemed a failure if a child presented any of the following symptoms, as based on an adaptation of Strindberg's criteria [17] and in accordance with a core set of component outcomes to define failure of a pulp treatment in primary teeth proposed by Smaïl-Faugeron et al. [18]: persistent pain, pathological tooth mobility, presence of fistulae and/or swelling, unchanged or new appearance of periradicular radiolucency, pathological external resorption or internal root resorption. In these cases the tooth was extracted and a space maintainer was inserted. A checklist was used to ensure that all criteria (clinical or radiographic) were properly assessed. Visible restoration failure led to the end of a tooth's follow-up regardless of subsequent treatment, whether endodontic re-treatment or extraction, and was also considered as treatment failure due to the real possibility of canal contamination.

Statistical analysis

Primary treatment effectiveness outcomes were the proportion of teeth recovering from baseline symptoms in each group and maintenance of primary molars until their expected exfoliation time (tooth survival). Association of the initial pulp diagnosis (irreversible pulpitis or pulp necrosis) and treatment options (CTZ pulpotomy or calcium hydroxide pulpectomy) was assessed.

Statistical analysis was performed using IBM SPSS 19.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics were used to describe frequency distributions and a chi-square test was used to study differences between groups and pulp condition at baseline and after treatment. Values of $p<0.05$ were accepted as statistically significant.

Life tables and Kaplan-Meier analysis were used to estimate the survival rates associated with pulp treatments and initial diagnosis. Survival curves were compared using the Log-rank test. Treatment failure was considered as the terminal event. Incomplete observations due to loss of follow-up or natural tooth exfoliation during follow-up were treated as censored cases.

Results

No parents refused to participate and all children collaborate with the dental treatment. One child left the study before the first recall appointment and was excluded from the analysis. Thirty-five children aged 3.6 to 9.4 years old (mean=6.2; standard deviation, SD=1.5), 21 boys and 14 girls, were included in the final sample, having 53 primary molars treated with CTZ pulpotomy (n=37) or calcium hydroxide pulpectomy (n=16). There were 4 (7.5%) maxillary first molars, 9 (17.0%) maxillary second molars, 24 (45.3%) mandibular first molars and 17 (30.2%) mandibular second

molars. Teeth had irreversible pulpitis or necrotic pulp with no differences between groups (p=0.61, Chi-square test) (Table 1); existing fistulae completely disappeared 30 days after treatment.

Table 1. Baseline pulp diagnosis and unsuccessful outcomes in primary molars treated with CTZ pulpotomy or pulpectomy.

Variables	Group I CTZ pulpotomy (n=37) n (%)	Group II Pulpectomy (n=16) n (%)
Pulp diagnosis at baseline		
Irreversible pulpitis	18 (48.7%)	9 (56.3%)
Pulp necrosis with fistulae	8 (21.6%)	2 (12.5%)
Pulp necrosis without fistulae	11 (29.7%)	5 (31.2%)
Unsuccessful outcomes		
Exclusively clinical	1 (3.7%)	0
Exclusively radiographic	18 (66.7%)	4 (80.0%)
Clinical and radiographic	8 (29.6%)	1 (20.0%)

Children were followed up for 1 to 26 months (mean=12.0; SD=7.1). Survival times of all cases are described in Figures 1 and 2. All successful cases in both groups were observed for at least 12 months, except for one tooth in Group I that exfoliated 10 months after treatment (case 51, Figure 1). Out of primary molars from Group I, 62.2% was rated as unsuccessful in the first year after intervention (Figure 1). In cases of treatment failure, tooth extraction was required and considered as the terminal event for survival analysis.

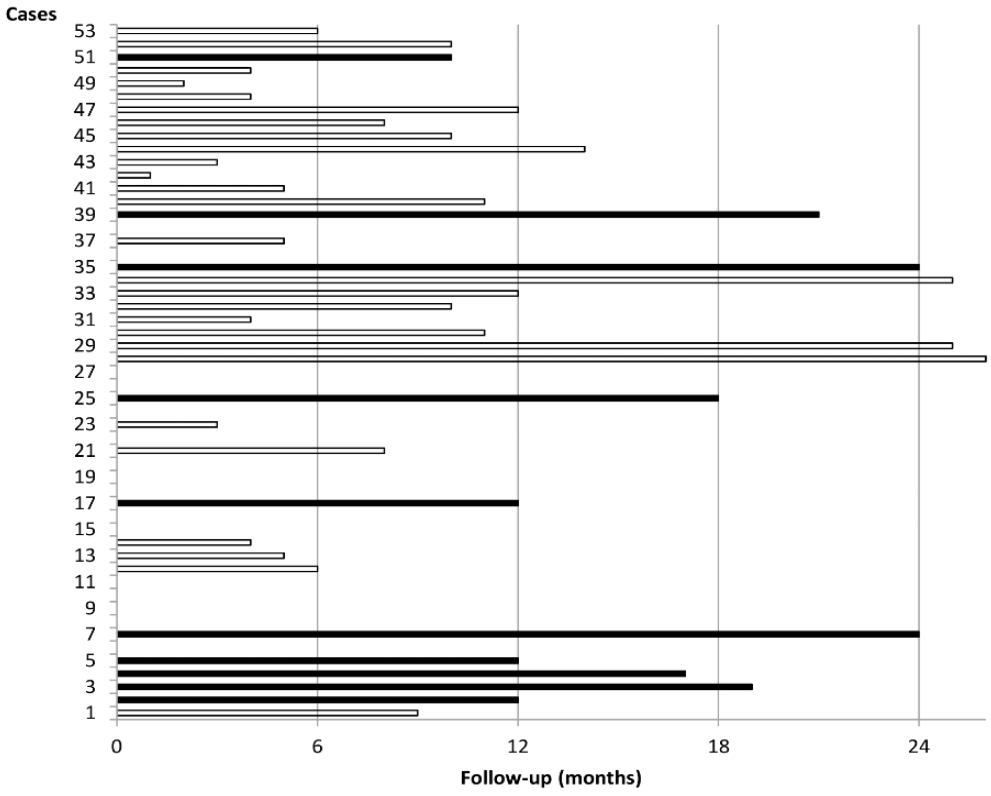

Figure 1. Survival times of cases from CTZ pulpotomy until the outcome. Empty bar: treatment failure described as terminal event; full bar: tooth exfoliation and loss to follow-up described as censored case.

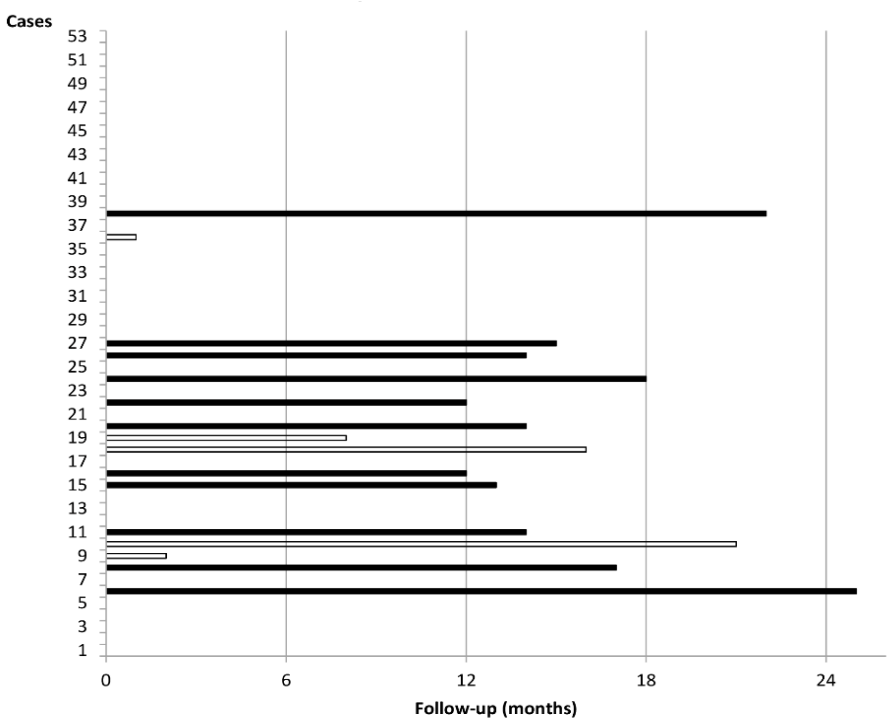

Figure 2. Survival times of cases from primary molars treated with calcium hydroxide pulpectomy until the outcome. Empty bar: treatment failure described as terminal event; full bar: tooth exfoliation and loss to follow-up described as censored case.

Overall rates of successful cases were 27.0% for CTZ pulpotomy and 68.7% for calcium hydroxide pulpectomy. Based on the difference of success rates, sample size was considered sufficient for explaining that the observed effect size is a good estimator of the true effect size with a power of 82% (two-sided 95% confidence interval). Cases were categorized as failures according to clinical and/or radiographic parameters and in 68.8% of unsuccessful outcomes (including both groups) the radiographic aspects that led to the decision that a treatment was a failure (Table 1). Causes of radiographic failures were: large radiolucency in the furcation area (n=31), extensive external root resorption (n=23) and internal root resorption (n=7). The most evident clinical aspect was pain while chewing (n=10) and there was one case in the Group I with a new fistula. Also, 12 cases from Group I had yellowish coronary stains already visible in the first three months, and there was restoration failure with marginal leakage in 6 teeth (Group I) and 1 tooth (Group II).

The overall mean survival time of all treated molars was 15.2 months (95% CI=12.6–17.9). Descriptive analysis of treatment outcomes and survival time as influenced by treatment group and previous pulp diagnosis is summarized in Table 2. Kaplan-Meier survival curves (Figures 3 and 4) showed significantly lower survival rates for the mixed antibiotic paste used for CTZ pulpotomy (P = 0.024, Log-rank test) and necrotic pulp initial diagnosis (P = 0.010, Log-rank test). Censored cases included exfoliated teeth (n=4) and cases which did not reach the terminal event (n=17) during the follow-up period.

Table 2. Survival characteristics according to the pulp therapy performed and pulp condition at baseline.

Group*	Pulp condition at the baseline	n	Failures	Censored cases (%)	Survival (months)		
					Mean	Std. Error	95% CI
I	Pulpitis	18	11	7 (38.9)	16.1	2.2	11.7–20.5
	Necrosis	19	16	3 (15.8)	10.4	2.0	6.4–14.4
	Overall	37	27	10 (27.0)	13.2	1.6	10.2–16.3
II	Pulpitis	9	1	8 (88.9)	23.0	1.4	20.2–25.8
	Necrosis	7	4	3 (42.9)	12.4	3.2	6.1–18.7
	Overall	16	5	11 (68.8)	18.9	2.2	14.5–23.2
Total		53	32	21 (39.6)	15.2	1.4	12.6–17.9

*Group I = CTZ pulpotomy; Group II = Calcium hydroxide pulpectomy.

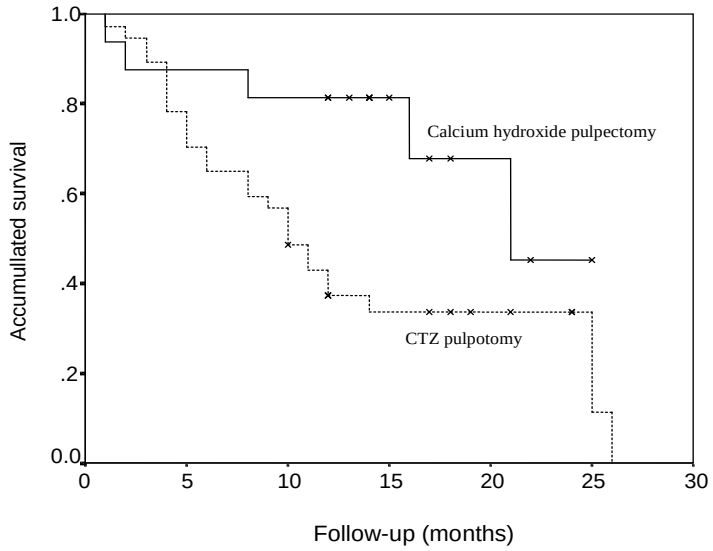

Figure 3. Kaplan-Meier curves of survival rates of CTZ pulpotomy (Group I, dotted line) and calcium hydroxide pulpectomy (Group II) in a 26 months period (p= 0.024).

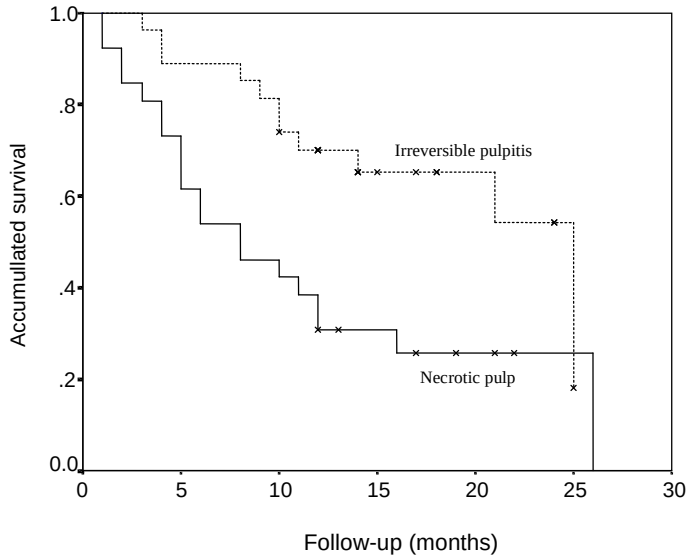

Figure 4. Kaplan-Meier curves of survival rate of primary molars receiving pulp therapy according to pulp diagnosis at baseline (p= 0.010).

Discussion

This prospective study showed that pulpotomy with CTZ paste was less effective than calcium-hydroxide pulpectomy for pulp therapy in infected primary molars. One major finding that had to be highlighted is that low survival rate as well as the high proportion of radiographic failure of CTZ-treated primary molars is an undeniable fact.

In light of today's knowledge, it is not biologically acceptable to leave necrotic tissue in a root canal [19]. Our results confirm that use of the LSTR concept for the treatment of infected primary molars is not justified, contrasting with other clinical studies [3-5] or recommended by experimental findings in animals [12]. Furthermore, in accordance to another study, this treatment cannot replace conventional root canal treatment over the long term [7].

Symptom remission, also found with other antibacterial mixtures a few days after pulp treatment [3-7], was observed in both groups in this study. However, our results agree with other investigation [7] that showed low success rates in the radiographic assessment of the outcomes using the LSTR pulpotomy conception, confirming that unsuccessful treatments are commonly associated with symptom-free teeth as observed in other studies of the effectiveness of different pulp therapies for primary teeth [20]. Accordingly with the American Academy of Paediatric Dentistry's guideline on pulp therapy [21], radiographic infectious process of pulpectomized teeth should resolve in 6 months, which is evidenced by bone deposition in the pretreatment radiolucent areas. However, in the present study none of the Group I cases presented bone deposition in the follow-up.

To allow comparison with the CTZ pulpotomy, we chose the traditional pulpectomy technique having calcium hydroxide paste as a filling agent, but a lower success rate was found compared with other studies that used calcium hydroxide and had shorter follow-up periods [16,22]. This probably happened because we included primary molar teeth with irreversible pulpitis or pulp necrosis. However, this study also found that pulpectomized primary molars showed significantly greater survival rates than pulpotomized teeth [23]. It seems that the unsuccessful pulpectomized cases might be due to the limited efficacy of chemomechanical instrumentation and calcium hydroxide-based paste to control root canal microorganisms of primary teeth with pulp necrosis [15].

Moreover, previous pulpal diagnosis at baseline influenced pulp therapy outcomes in both groups in this study, evidencing that pulpal necrosis significantly reduces the success rates of pulp therapy compared to the treatment of vital pulp. These findings could be a result of the presence of bacterial biofilm on the external root surface of primary teeth with necrotic pulps and periradicular pathosis, which may lead to the persistence of the inflammatory process, delaying or even precluding periapical healing [24].

Some study limitations should be pointed. In this clinical study, blinded practitioners performing the treatment as well as blinded observer for follow-up assessment were not used. This could be explained because the pastes and the techniques (pulpotomy vs. pulpectomy) were markedly distinct and present clear different radiological images in the root canals to blind it from the operator

and from the observer, respectively. Other limitation was that general practitioners performing pulp therapies instead of pediatric dentists could be questioned in a preliminary analysis. However, this situation is a realistic fact in public health settings where most child dental care takes place. This is also in agreement with the idea that pediatric dentists are not recognized as primary care providers, restricting access to pediatric dentists for children in some specific ages [25].

Restoration failure and consequent marginal leakage were observed in some unsuccessful cases and this could be another important limitation of the study. Results could have been different if we had used stainless steel crowns (SSCs) to restore the teeth, although some studies [16,26] have not demonstrated any statistically significant difference between different materials (SSCs, glass ionomer cement, compomer, amalgam, composite) used to restore primary molars after pulp therapy. Furthermore, in some studies in which primary teeth were treated successfully by the LSTR therapy [3,4], resin was also used. Our results support the concept that endodontic treatment in primary dentition should follow the same biological principles applicable to permanent teeth, and manual or rotary instrumentation techniques are safe procedures for primary molars without significant root resorption [27]. Advantages of the LSTR concept [5] such as less chair time, single-visit treatment and providing an option for poor-prognosis molars, might be considered in public service dentistry, but its cost-effectiveness deserves further investigation. In addition, if we consider the prevention of mesial migration of first permanent molars as mandatory [18], as well as the influence of early loss of primary teeth in the dental arch, like ectopic eruption, disturbance of the eruption sequence and space loss for successor permanent teeth [28], perhaps pulp therapies for infected primary molars should be recommended for young children, even bearing in mind that most pulpotomies or pulpectomies for those cases last no longer than 18 to 24 months [23,29]. Most importantly, a systematic clinical and radiographic follow-up cannot be neglected.

Conclusion

Non-instrumentation endodontic treatment with CTZ paste demonstrated a lower survival rate than calcium hydroxide conventional root canal treatment for primary molars with carious pulp involvement. Despite the apparently favorable clinical signs in most of the cases, the low success rate determined by radiographic evaluation provides evidence to discourage this procedure and to argue for future randomized clinical trials before it can be indicated safely.

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