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Iodoform Vs Calcium Hydroxide/Zinc Oxide based pastes: 12-month findings of a Randomized Controlled Trial

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Abstract: This study evaluated clinical and radiographic twelve-month outcomes of root canal treatments (CT) with smear layer removal, performed in primary teeth, using two different root canal filling materials. Pulpectomy was performed on 27 primary teeth with necrosis or irreversible pulpitis, caused by dental caries or trauma, in 23 children (2-7 years old). A single trained operator performed the CT in a single visit in cases without periapical or interradicular radiolucency (PIR) or in multiple visits in cases with PIR. Participants were selected based on specific inclusion and exclusion criteria, and randomly allocated into two groups: Group 1 (G1) – iodoform paste (iodoform + camphorated parachlorophenol + ointment comprising prednisolone acetate 5.0 mg and rifamycin 1.5 mg); Group 2 (G2) – Calen®/ZO paste. Treated teeth were restored with composite resin immediately after the root canal filling. The outcomes were evaluated clinically and radiographically according to specific criteria. Two blinded and standardized evaluators assessed the radiographic outcomes. We used descriptive analyses due to the small sample size. CTs were performed due to caries lesions in 70.4% of the cases and due to trauma in 29.6%. Only one tooth of G1 was unsuccessful; hence, pulpectomy performance in both groups was not influenced by the filling material, nor by any other analyzed variable. The level of the root canal filling was better in the Calen®/ZO group. The clinical and radiographic twelve-month outcomes indicated successful treatment, independently of the root filling material used.

Keywords: Tooth; Deciduous; Root Canal Obturation; Dental Materials; Clinical Study.

Introduction

The success of root canal treatment (CT) depends completely on the accurate accomplishment of all operative steps,[1] including removal of irreversibly inflamed or necrotic radicular pulp tissue, cleaning of the root canal system, and filling with a resorbable filling material.[2] Furthermore, smear layer removal during the canal chemomechanical preparation is believed to improve pulpectomy outcomes in primary teeth.[3]

Given the complex root canal system of primary molars, the reduction or elimination of bacteria depends not only on the chemomechanical preparation, but also on the filling material, which should possess some

antimicrobial properties.[4] In addition, filling materials should be biocompatible with periapical tissues, and should prevent canal reinfection.[1] The guidelines for primary pulpectomies recommend the use of pure zinc oxide eugenol (ZOE), non-setting calcium hydroxide paste, or calcium hydroxide and iodoform paste.[2,5]

The use of ZOE has decreased as it can delay natural exfoliation.[6] In addition, the poor resorption ability of ZOE[7] and the ectopic eruption of permanent teeth due to this material[8] are some factors that contribute to the search for alternative materials, such as iodoform and calcium hydroxide-based pastes.[9] There are many available filling materials for this purpose; however, none of them possesses all the ideally required characteristics and properties.[10]

In the consulted literature, there is no randomized controlled clinical trial, with adequate methodology, conducted to evaluate the performance of root filling materials after smear layer removal in pulpectomy of primary teeth. Therefore, this study aimed to investigate the clinical and radiographic performance of pulpectomies using 1) iodoform paste and 2) calcium hydroxide/zinc oxide (Calen®/ZO) paste (thickened by the manufacturer) in primary teeth with irreversible pulpitis or pulp necrosis caused by dental caries or trauma.

Methodology

Study design

The present study was designed as a controlled, double blind, randomized clinical trial conducted in Rio de Janeiro, Brazil. The investigation was designed, analyzed, and interpreted according to the Consolidated Standards of Reporting Trials (CONSORT).[11,12]

Participants and recruitment

This trial was conducted at the Department of Pediatric Dentistry and Orthodontics, School of Dentistry, Universidade Federal do Rio de Janeiro, Rio de Janeiro, RJ, Brazil, from June, 2015 to June, 2017. The Research Ethics Committee approved the study (CAAE: 36760614.0.2001.5257). Participation in the study was voluntary, and the parents/guardians received all information regarding the pulpectomy procedure, such as the advantages and the possible risks or discomfort associated with the required treatment. Informed written consent was obtained.

Participants were healthy patients aged between two and nine years, with one, or at most, two anterior or posterior primary teeth with irreversible pulp inflammation or pulp necrosis caused by dental caries or trauma. Participants were eligible for inclusion if they met the following criteria: a) teeth with deep caries lesions and associated interradicular and/or periapical radiolucencies; b) caries-affected teeth with abnormal mobility due to periapical pathosis, but not associated with normal exfoliation; c) history of spontaneous pain; d) teeth presenting with intra-oral swelling or draining sinus tract; e) continuous bleeding after amputation of coronal pulp tissue; and f) teeth with external physiological or pathological resorption involving less than one third of the root length.[3]

Children were not eligible if they presented with: a) systemic pathosis (medically compromising conditions and special health-care needs); b) history of allergic reaction to local anesthetics or to the components of the test materials; c) antibiotic therapy in the 30 days prior to the intervention or during the CT; d) tooth unable to be restored or impossibility of adequate rubber dam isolation; tooth that had previously been handled; e) interradicular or periapical radiolucency involving more than half of the shortest root measured vertically; f) internal root resorption; g) physiological or pathological external root resorption of more than one third of its length; h) obliteration of the root canal; or i) inadequate bone support evidenced by non-physiological tooth mobility compared with the contralateral tooth.[3]

Sample determination and randomization

All children who visited the clinic during the recruitment period and met the inclusion criteria without any exclusion criteria were included in this study. Randomization was performed by coin toss by a third person not involved with the clinical assessment or with data analysis, previously to the root canal filling procedure.

Intervention

To confirm the need for pulpectomy, a single investigator (D.C.) performed a detailed interview, a clinical examination, and a standard periapical radiographic evaluation with pediatric radiographic films and film-positioning devices. When indicated, a conservative procedure was adopted and the tooth was excluded from the final sample.

For teeth with irreversible pulpitis or necrosis without interradicular or periapical radiolucency, endodontic treatment was performed in a single visit. Multiple sittings were required only in cases of necrosis with interradicular or periapical radiolucency.

Following local anesthesia with 2% lidocaine and 1:100,000 epinephrine (Alphacaine, DFL, Rio de Janeiro, Brazil) and rubber dam isolation, a diamond bur mounted on a high-speed hand piece was used to create the access to the pulp chamber. Following removal of carious tissue, chemomechanical preparation was carried out using an adapted protocol (Figure 1) for primary teeth pulpectomy with smear layer removal described by Barcelos et al.[3] For all cases, a single trained operator (D.C.) performed the CT. Root canals were dried with sterile paper points and randomly filled with one of the materials using a lentulo spiral (Maillefer, Balaigues, Switzerland) calibrated at the working length. Teeth assigned to Group 1 received iodoform paste as filling material (iodoform + camphorated parachlorophenol + ointment comprising 5.0 mg prednisolone acetate and 1.5 mg rifamycin); those allocated to Group 2 received Calen®/ZO paste; S.S.White Artigos Dentários Ltda., Rio de Janeiro, Brazil) as filling material. The entry of the root canal was sealed with heated gutta-percha, and the tooth was restored with composite resin in the same sitting in which the roots were filled. Children and care providers were blinded to the filling material used. Immediately after the completion of treatment, a post-operative standardized periapical radiograph was taken.

In cases where two sittings were required, after the root canals were dried, a cotton pellet slightly moistened with camphorated paramonochlorophenol (Biodinamica, Parana, Brazil) was placed into the pulp chamber and coated with heated gutta-percha. A temporary restoration was carried out with conventional glass ionomer cement (Riva Self Cure, SDI, Victoria, Australia). One week later, in the absence of any signs and symptoms, using local anesthesia and rubber dam isolation, the root canals were irrigated with 10 mL of 0.9% physiologic solution, dried with sterile paper points, and randomly filled as previously described. If any sign or symptom of infection (pain, swelling, fistula or sensitivity to percussion) were still present, chemomechanical preparation would be repeated and a third appointment would be scheduled a week later to complete the treatment. If any signs or symptoms of infection remained, tooth extraction would be planned, and space maintenance would be considered.

Outcomes and analyzed variables

The outcomes were evaluated clinically at one, three, six, and twelve months post-treatment, and clinically and radiographically at six and twelve months post-treatment. Two blinded and trained evaluators (Kappa = 1.0) independently examined the pre-operative and post-treatment radiographs, and this information was added to the patient's dental records with a consensus on the treatment outcome. If there was any disagreement, the lower category was used. The assessors were blind to the material used.

Treatment outcomes (dependent variables) were judged as success or failure according the criteria described by Barcelos et al.[3] (Figure 2). Clinical success was deemed the absence of signs or symptoms of infection, such as pain, swelling, fistula, or sensitivity to percussion. The radiographic criteria for success included a reduction in the size of the previous radiolucent area, or no new radiolucency. Teeth would be excluded from the study and endodontically retreated if total loss of root canal seal (restorative material and coating of gutta-percha) occured without clinical symptomatology or radiographic alteration.

The primary independent variable analyzed in relation to treatment outcome was root canal filling paste – iodoform (G1) or Calen®/ZO-based (G2). The following variables were also evaluated: a) patient age at the time of therapy; b) region of

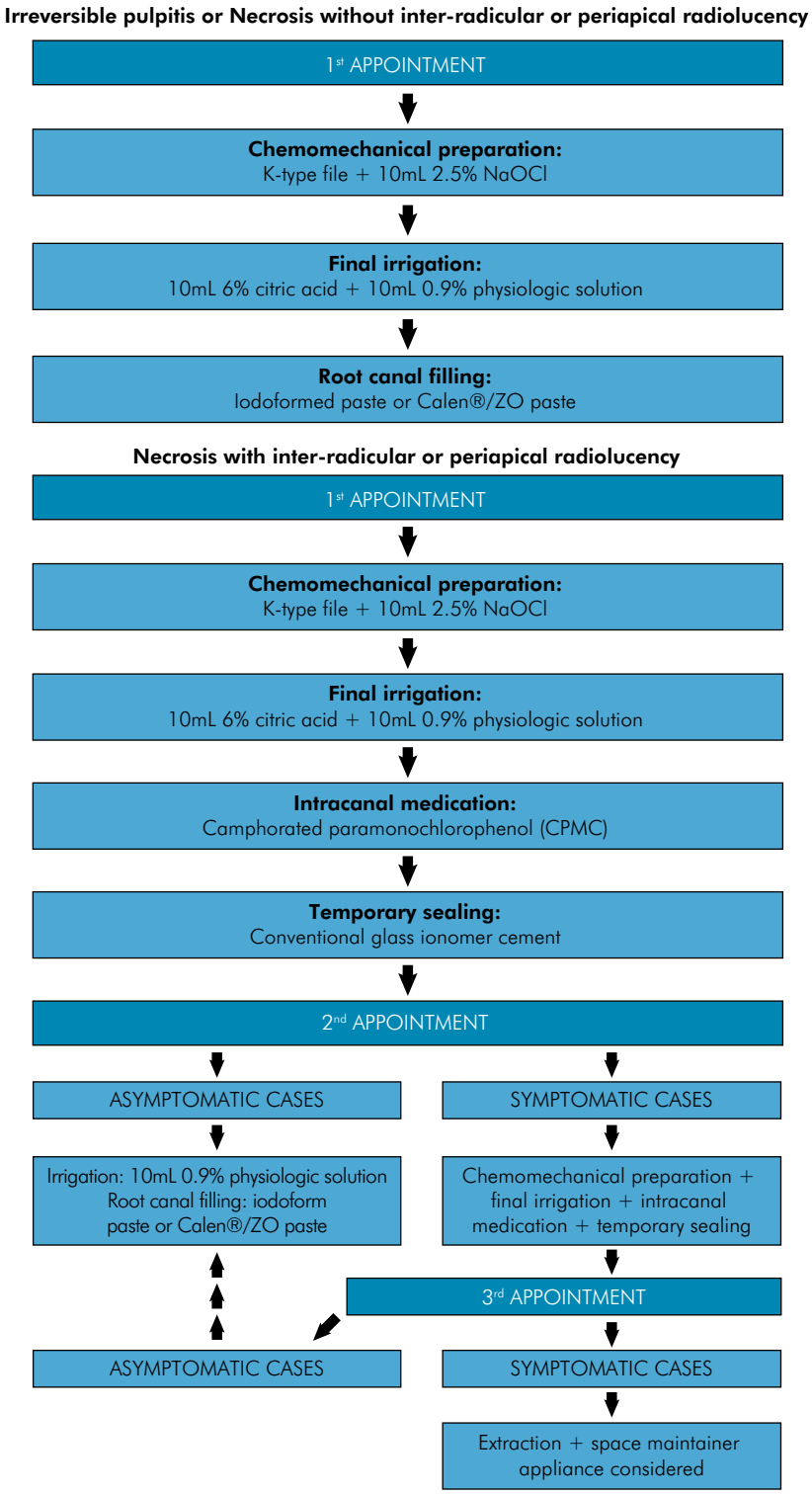

Figure 1. Protocol for pulpectomy in primary teeth with smear layer removal

treated teeth (anterior or posterior); c) arch of treated teeth (maxillary or mandibular); d) initial pulp condition (irreversible pulpitis, necrosis without periapical or interradicular radiolucency, necrosis with periapical or interradicular radiolucency); e) cause of pulp pathology (caries or trauma);

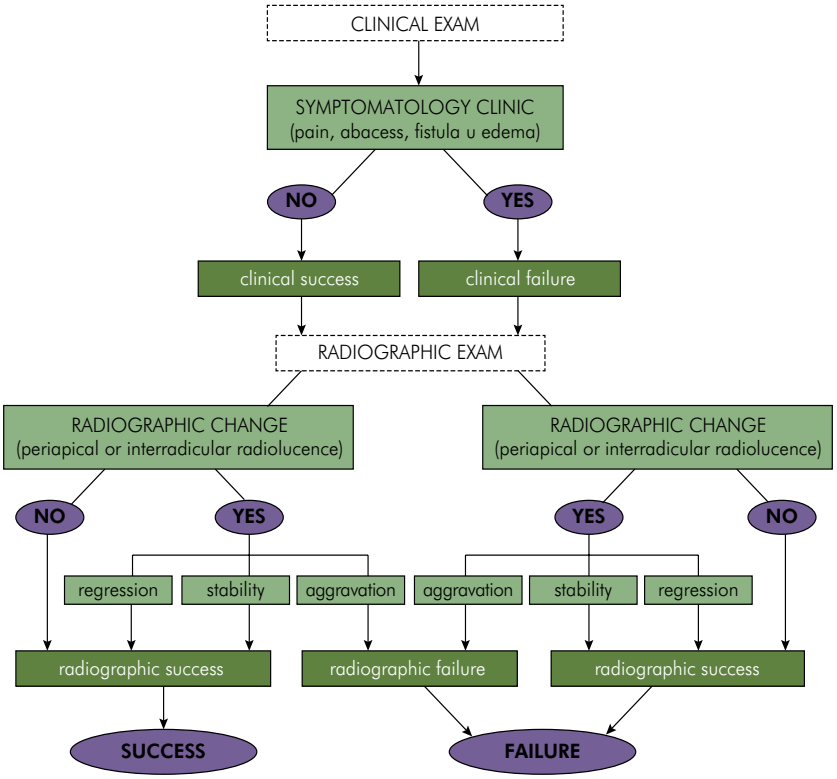

Figure 2. Clinical and radiographic criteria for monitoring pulpectomy.

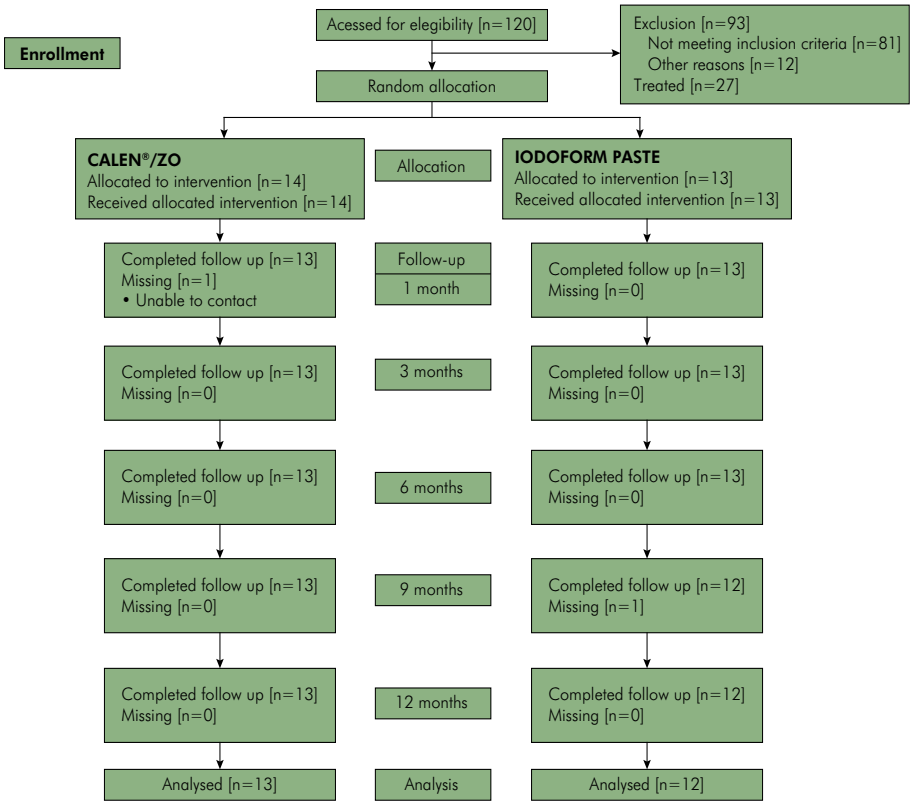

Figure 3. CONSORT flowchart.

Table 1. Baseline characteristics of the sample for each group (n = 27).

Characteristics	G1 (filled with iodoform paste)	G2 (filled with Calen®/ZO)	Total
	n (% per group)	n (% per group)	G1 + G2
Tooth region			
Anterior	10 (76.9)	10 (71.4)	20 (74.1)
Posterior	3 (23.1)	4 (28.6)	7 (25.9)
Total	13 (100)	14 (100)	27 (100)
Tooth arch			
Maxillary arch	12 (92.3)	12 (85.7)	24 (88.9)
Mandibular arch	1 (7.7)	2 (14.3)	3 (11.1)
Total	13 (100)	14 (100)	27 (100)
Cause			
Dental caries	8 (61.5)	11 (78.6)	19 (70.4)
Trauma	5 (38.5)	3 (21.4)	8 (29.6)
Total	13 (100)	14 (100)	27 (100)
Pulpal diagnosis			
Irreversible pulpitis	4 (30.8)	7 (50.0)	11 (40.7)
Pulp necrosis without periapical radiolucency	3 (23.0)	3 (21.4)	6 (22.3)
Pulp necrosis with periapical radiolucency	6 (46.2)	4 (28.6)	10 (37.0)
Total	13 (100)	14 (100)	27 (100)
Clinical signs or symptoms			
Absent	7 (53.8)	4 (28.6)	11 (40.7)
Present	6 (46.2)	10 (71.4)	16 (59.3)
Total	13 (100)	14 (100)	27 (100)

f) pre-operative clinical signs and symptoms (present or absent); g) pre-operative periapical or interradicular radiolucency (present or absent); h) level of root canal filling; and (i) integrity of crown restoration at follow-up visits. Level of the root canal filling was documented from the immediate post-treatment radiograph as under-filled (when the filling paste ended 1 mm or more short of the apex), flush-filled (when the filling paste appeared to end at the radiographic apex), or overfilled (when the filling paste extruded past the radiographic apex). Results were recorded and analyzed using the statistical package SPSS v. 21.0 (SPSS Inc, Chicago, IL, USA). We used descriptive analyses due to the small sample size.

Results

The trial included 39 teeth in 35 children; however, a conservative procedure was performed on 12 teeth. The pulpectomy procedure was performed on 27 teeth of 23 children (69.6% boys and 30.4% girls). The mean age of the patients was 3.68 ± 1.67 years. The present study is summarized in a CONSORT flowchart (Figure 3). Description of the teeth in each group regarding the jaw, tooth type, cause of pulp pathology, pulp diagnosis, radiographic signs and the clinical signs and symptoms is shown in Table 1. In 19 teeth (70.4%), the CT was performed due to caries lesions and in eight teeth (29.6%), due to trauma.

Table 2. Clinical, radiographical, and overall pulpectomy outcome at 6, 9, and 12 months compared by groups.

Pulpectomy outcome	G1 (Iodoform paste n=13)		G2 (Calen®/ZO paste n=14)	
	Success	Failure	Success	Failure
	n (%)	n (%)	n (%)	n (%)
6 months (missing = 1 [G2])				
Clinical	13 (100.0)	0 (0.0)	13 (100.0)	0 (0.0)
Radiographical	13 (100.0)	0 (0.0)	13 (100.0)	0 (0.0)
Overall	13 (100.0)	0 (0.0)	13 (100.0)	0(0.0)
9 months (missing = 1 [G1])				
Clinical	12 (100.0)	0 (0.0)	13 (100.0)	0 (0.0)
Radiographical	12 (100.0)	0 (0.0)	13 (100.0)	0 (0.0)
Overall	12 (100.0)	0 (0.0)	13 (100.0)	0 (0.0)
12 months				
Clinical	12 (100.0)	0 (0.0)	13 (100.0)	0 (0.0)
Radiographical	11 (91.7)	1 (8.3)	13 (100.0)	0 (0.0)
Overall	11 (91.7)	1 (8.3)	13 (100.0)	0 (0.0)

Table 3. Level of the root filling material for each group.

Extension	G1 (filled with iodoform paste) n (% per group)	G2 (filled with Calen®/ZO) n (% per group)	Total
Under-filled	5 (83.3)	1 (16.7)	6 (100)
Flush-filled	4 (30.8)	9 (69.2)	13 (100)
Overfilled	4 (50.0)	4 (50.0)	8 (100)

Two teeth were excluded from the analysis: one (G2) because the patient did not attend any follow-up visits and one (G1) because it was mistakenly treated by a dental student, after the six-month assessment. The remaining 25 teeth complete the follow-up period. At six- and nine-month evaluation, no failure was found. At 12 months, no clinical failure as recorded although a radiographic failure was counted for G1, yielding an overall success rate of 97.1% and 100.0% for G1 and G2, respectively (Table 2). The distribution of overall pulpectomy (dependent variable) compared by group (primary independent variable) and some secondary independent variables (cause of tooth pathology, clinical or radiographic previous signs and symptoms, pulp condition, and the level of root canal obturation) are presented in Table 3. No measure of association was computed for the cross tabulation of any independent variables versus the dependent variable, as there was one tooth classified as failure. No tooth had total loss of root canal seal.

Discussion

We attributed the high success rate in this study to several factors. First, besides performing an effective reduction of bacterial load in the cases of infection or necrosis and the maintenance of asepsis in cases of vital pulps,[2] we used two root filling materials that have shown positive properties in several studies.[13,14,15] Second, smear layer removal was performed on all treated teeth. Third, we ensured a good crown seal in the same visit in which the root canals were filled. Finally, treatment was performed by a highly skilled operator. Other factors that might have influenced our results are stringent case selection, as this can play an important role in the outcome of pulpectomies,[16] as well as the strict follow-up of patients during the post-operative period. Rigorous selection criteria and the high technical skill of the operator in a clinical trial usually leads to higher prevalence of success. However, this may not reflect usual clinical practice.[17]

All treatments were performed with smear layer removal in association with the chemomechanical preparation, as this has been shown to improve the pulpectomy outcome in primary teeth[3,7]. This step increases dentine permeability, promoting better adaptation of the filling materials and improves disinfection and sealing of root canals.[18] Although a recent systematic review was inconclusive regarding the most effective intra-canal irrigant for smear layer removal,[19] we chose 6% citric acid as it has been shown to have the best efficacy without damaging the normal dentinal structures.[18] In addition, it has been shown to have antibacterial effects in infected root canals,[20] less toxicity then other solutions such as ethylenediaminetetraacetic acid (EDTA)[21] and to be quite effective in primary teeth in a short period of time.[22] For all teeth, we performed the last irrigation with saline solution because washing out the citric acid from the root canal system is indicated for safe endodontic clinical practice.[23]

Sealing of the root canal system is an essential step in successful endodontic treatments as it avoids the penetration of microorganisms and their toxins, helps periapical repair, and prevents reinfection.[24] It has been confirmed that an optimal filling level directly influences the successful outcome of a CT.[25] In contrast, in our study, the extent of the root canal filling material did not influence success rate, in agreement with previous study. As the high frequency of ideal level of the root canal filling was in the Calen®/ZO group, we believe that the slight thickening of the paste improved its consistency and favored its insertion, facilitating this important step of the treatment. Moreover, an important condition for CT success is the protection of the filling material with a well-sealed crown restoration,[1] which aims to prevent microleakage.[5] This can be accomplished by placing a permanent restoration as soon as possible after the completion of the treatment;[26] delay in the placement of final restorations may result in contamination of the filled root canals.[27] Considering this, we restored the teeth in the same visit in which the roots were filled.

There is some evidence that suggests that single and multiple visits present similar clinical and radiographic success.[28,29,30] In this sense, the two-visit protocol used only for the necrotic pulp conditions[3] with periapial radiolucence might probably have not impaired the results. Multiple visits should be viewed as an endodontic therapy option, since the circumstances of each case should be carefully considered.[28] Nevertheless, the American Academy of Pediatric Dentistry Guideline does not have a specific recommendation for single-visit or multiple-visit protocols for the pulpectomy procedure in primary teeth.[5]

In this study, only one failure occurred, limiting the accomplishment of statistical inferences about the possible variables related to treatment outcome. However, it occurred in a tooth with a previous periapical alteration due to caries lesion and that presented loss of coronary restoration. These factors had already been related to endodontic treatment failure. RCT seems to have a higher success rate when performed in symptomless teeth with no or minimal root resorption and/or periapical infection.[31] Breakdown, fracture or loss of the temporary/permanent restoration can also contribute to the failure of endodontic treatment.[27] Therefore, we can infer that a successful CT can be achieved regardless of such factors if great attention is given to the selection and follow-up of the cases, the chemomechanical preparation of the root canal system, the smear layer removal, and the coronal sealing; all filled root canals had their entries protected with gutta-percha. In addition, fractured or lost restorations were immediately replaced, because children's guardians were in close contact with the operator.

Iodoform pastes have excellent antibacterial and anti-inflammatory properties, as well as good radiopacity and easy resorption when extruded to periapical tissues.[13] However, iodoform-based products can lead to discoloration of the dental crown,[32] which may limit their use in anterior teeth. Calcium hydroxide pastes do not cause such impairment and are widely used, mainly due to their low toxicity and antibacterial, antifungal, and biocompatibility properties.[14] On the other hand, they have rapid resorption and low radiopacity, which can be improved by the addition of zinc oxide to their composition.[33] Therefore, we believe

that newer preparations of filling materials, such as the Calen®/ZO paste, are interesting.

Despite the small sample size, we believe that the rigorous selection criteria minimized bias in our study. Another limitation of the study is the clustering of teeth within individuals, considering that a single patient could have more than one tooth treated. No attempt was made to account for clustering as the results were presented solely in a descriptive form and no inferential statistics was applied. This trial aimed to conduct an initial exploratory analysis, considering that an unsuccessful root canal treatment usually shows clinical or radiographic signs of failure during the first six months[34]. However, more trials should be performed with multiple operators, a larger sample size, and longer follow-ups to verify the clinical and radiographic long-term success rates, and follow the development of the successor permanent teeth.

Conclusion

The clinical and radiographic twelve-month outcomes indicated successful treatment, independently of the root filling material used, iodoform based paste or Calen®/ZO, although the frequency of ideal level of the root canal filling was higher in Calen®/ZO group.

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