

# Pulpectomies with Iodoform *Versus* Calcium Hydroxide-Based Paste: A Preliminary Randomised Controlled Clinical Trial

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## ABSTRACT

**Objective:** To compare clinical and radiographical pulpectomy outcomes in primary teeth filled with different pastes. **Material and Methods:** The sample included thirty-eight teeth indicated for pulpectomy due to irreversible pulp inflammation or necrosis from thirty patients (2 to 9 years old). The first appointment comprised chemomechanical preparation (2.5% sodium hypochlorite), smear layer removal (6% citric acid), intracanal dressing and temporary restoration. Seven days later, teeth were randomly assigned to filling with iodoform (IP) or calcium hydroxide with zinc oxide (CHZO) based pastes and temporarily restored. Final restoration (composite resin) occurred at the 3rd appointment. Data from baseline, 6 and 12 months were analysed using descriptive and inferential statistics ( $p \leq 0.05$ ). **Results:** The overall frequency of success was 63.6% ( $n=21$ ), with no significant difference between groups (IP=62.5%  $n=10$ ; CHZO=64.7%  $n=11$ ,  $p=0.59$ ). Multiradicular teeth, overfilled canals and teeth whose coronal restoration have been lost were significantly associated with failure ( $p=0.01$ ,  $p=0.04$  and  $p<0.001$ , respectively). **Conclusion:** After 12 months, both pastes showed similar outcomes and can be used as good options for pulpectomies in primary teeth. Moreover, tooth location, extent of the root canal filling, and integrity of final restoration during the follow-up influenced the outcome of pulpectomies.

**Keywords:** Pulpectomy; Tooth, Deciduous; Root Canal Filling Materials; Clinical Trial.

## Introduction

Despite the advantages and good clinical results presented by the different root filling materials for primary teeth [1-3], none of them has all the requirements for an ideal material [4,5]. There is a trend in the literature to use materials that combine calcium hydroxide and iodoform [1-3], with no quality evidence about the superiority of a specific material [1].

Iodoform-based pastes (IP) have bactericidal and bacteriostatic effects, are biocompatible with periapical tissues and show good resorption capacity [6,7]. Similarly, calcium hydroxide-based pastes have antimicrobial potential [8,9] and are easily resorbed [10]. In primary teeth, thickening of calcium hydroxide-based paste with zinc oxide (CHZO paste) has been indicated to increase the time for paste resorption [11] – approaching physiological resorption – and with the additional benefit of improving radiopacity [5,12].

Although a previous study compared these root canal filling, multiple sessions were performed only on teeth with lesions and with a sample predominantly of anterior teeth [13]. Even though there is a scarcity of studies comparing calcium hydroxide-based pastes versus iodoform-based pastes. Therefore, this study aimed to evaluate, both clinically and radiographically, the outcomes of primary teeth pulpectomies filled with an iodoform-based paste or a calcium hydroxide-based paste, thickened with zinc oxide. The null hypothesis was that there would be no significant difference in the pulpectomy outcome using these root canal filling materials.

## Material and Methods

### Study Design and Ethical Considerations

A randomised and double-blind trial was analysed and interpreted following the Consolidated Standards of Reporting Trials (CONSORT) recommendations. The two reference centers enrolled were in different cities in Rio de Janeiro, Brazil. The Research Ethics Committee of both centers approved this study (CAAE: 36760614.0.1001.5626 and CAAE: 36760614.0.2001.5257). All those responsible for the children who participated in this study expressed their written permission by signing the free and informed consent form. Children whose developmental stage allowed an understanding of the treatment also agreed to participate in the study by signing the assent form.

### Participants and Sample Determination

The sample was a non-probabilistic one or convenience. All children of both sexes aged from 2 to 9 years old without systemic disease and in need of pulpectomy in one or more primary teeth [14] who attended the centers during an 11-month period were eligible for the study.

Patients underwent anamnesis, clinical and radiographic examinations to determine whether they could participate in the study. Inclusion criteria were primary teeth presenting caries or dental trauma associated with signs or symptoms of irreversible pulp inflammation or pulp necrosis as: spontaneous pain, presence of abscesses, fistulas, and periapical or interradicular radiolucency. Primary teeth with pre-preparation of root canals, remaining crown insufficient to allow rubber dam isolation and subsequent final restoration, drilling of chamber floor pulp, radiographic evidence of calcific metamorphosis, pathological or physiological resorption involving more than one-third of the length of the root and bone resorption involving the crypt of the permanent tooth were not eligible [14].

Periapical radiographs taken by the paralleling technique using standardized positioners were used to set up radiographic inclusion criteria and were later used to determine the working length (WL), which was obtained by reducing the radiographic apex measurement by 1 mm.

## Interventions

The pulpectomies were conducted in two sessions by two operators previously trained by the study director of each center. All procedures were performed under local anaesthesia and rubber dam isolation.

A standardized manual chemomechanical technique with endodontic K-files at the same WL was used at the first appointment. The first file was the one whose caliber best coupled to the WL, followed by the next two files in the series until at least #45 for the anterior teeth and #35 for the posterior teeth. The movement performed was the balanced force technique using clockwise rotation to engage dentin and counterclockwise rotation to cut dentin. In at each exchange of the files, the canals were irrigated with 2.5% sodium hypochlorite (NaOCl) (10 mL/60 seconds). At the end, each canal was irrigated with 2.5% NaOCl (10 mL/60 seconds), followed by 6.0% citric acid (10 mL/60 seconds) to remove the smear layer and then saline solution 0.9% (10 mL/60 seconds) was applied [14]. After drying the canals with sterile absorbent paper points, a sterile cotton pellet with camphor paramonochlorophenol (CPMC) was placed into the pulp chamber, followed by a temporary restorer composed of zinc oxide without eugenol. This clinical protocol was conducted according to Barcelos et al. [14].

In the second appointment, seven days later, the temporary restoration was removed, and each canal was irrigated with saline solution 0.9% (10 mL/60 seconds) and then dried with sterile absorbent paper points. After that, patients were randomised. The unit of randomization was the patient, meaning that all teeth in the same patient were treated according to the same regimen. All patients and their responsible were blinded to the filling material used. A person not involved with the investigation performed the randomization by tossing a coin and the patients were divided into two groups: the iodoform-based paste (IP) and the calcium hydroxide-based paste thickened with zinc oxide (CHZO). Canals in the IP group were filled with an iodoform-based paste composed by CPMC, iodoform and an ointment containing sodium Rifamycin 1.5 mg and 5.0 mg prednisolone acetate [6,7]. Canals in the CHZO group were filled with calcium hydroxide-based paste (Calen®) thickened with zinc oxide in proportion (volume: volume) 1:0.65 [5] prepared by the fabricant [13] (S.S.White Artigos Dentários Ltda., Rio de Janeiro, Brazil). Root canals were filled using a lentulo spiral in the WL. The entrance of the root canal was sealed with a thin layer of heated insulating material. The tooth received a temporary restoration with conventional glass ionomer cement. Then, a periapical radiograph was taken to determine the extent of filling: flush-filled – filling material up to the WL boundary; underfilled – filling material below the WL boundary; overfilled – filling material beyond the WL boundary.

At the third appointment, seven days after the second visit, the teeth received a final restoration with light-cured composite resin [4,13,14], while the cases that remained symptomatic were indicated for extraction and space maintainers.

## Outcomes and Analysed Variables

The clinical follow-up was carried out every three months and radiographic follow-up every six months. The X-ray exams were evaluated by two researchers ( $k = 0.89$ ) who did not participate in treatment, ensuring blind assessments. In addition, zinc oxide powder was added in such an amount that the radiopacity of the CHZO paste was similar to the IP paste. Any discrepancies between the two evaluators were discussed until reaching a consensus. If divergence continued, the treatment performance was judged as a failure. The pulpectomy outcome evaluation followed the Barcelos et al. [14] criteria. Clinical success was determined by the absence of signs and symptoms, such as pain, gingival abscess, fistula, and edema. And radiographic success by the absence of periapical or inter-radicular radiolucency and/or maintenance or regression of periapical or inter-radicular

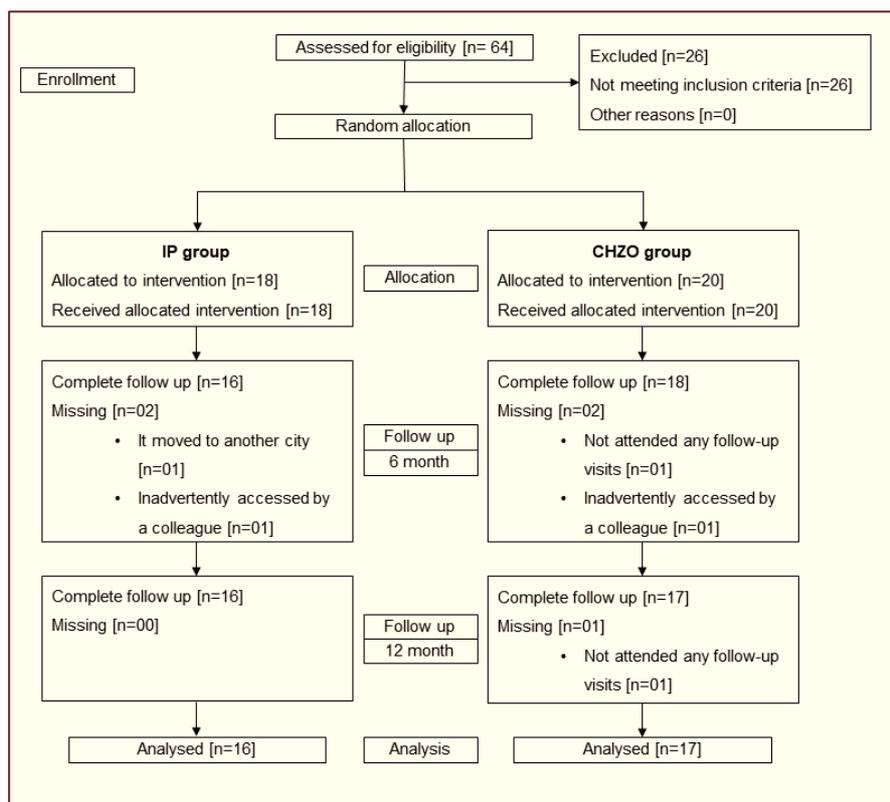
radiolucency present at the initial examination. Cases with both clinical and radiographic success were considered complete success [14]. At the follow-up appointments, the coronal restoration was also evaluated. When there was loss or fracture that required a reintervention, the teeth were classified as coronal restoration failure and not pulpectomy failure. Teeth considered as pulpectomy failure during the follow-up visits were extracted, and space maintainers were installed.

### Statistical Analysis

The results were recorded and analysed using SPSS software (SPSS Inc., Chicago, IL, USA) version 21, by descriptive and inferential analysis using chi-square and Fisher's exact tests. The level of significance was 5% ( $p \leq 0.05$ ). As the number of observations was small, no attempt was made to adjust other factors that would influence the results as univariate logistic regression, as these methods can fail to produce sensible results or they produce unreliable results when used with a small sample size [15].

### Results

Fifty-one eligible patients ( $n = 64$  teeth) were assessed for inclusion and exclusion criteria over a period of 11-month period. Of these, 38 teeth in 30 patients were included according to the inclusion and exclusion criteria (Figure 1).



**Figure 1. CONSORT flowchart demonstrating for each group the number of teeth randomly assigned and analyzed for each study period.**

The mean age was  $4.95 \pm 1.7$ , and 56.7% were female and 43.3% male. All molars presented lesions on multiple faces, being considered as class II. The sample's baseline characteristics are shown in Table 1 and did not differ significantly between groups.

**Table 1. Baseline characteristics of the sample per group.**

Variables	IP N (%)	CHZO N (%)	Total N (%)	p-value*
Tooth region				
Anterior	8 (44.4)	7 (35.0)	15 (100.0)	
Posterior	10 (55.6)	13 (65.0)	23 (100.0)	0.396
Tooth arch				
Maxillary arch	10 (55.6)	7 (35.0)	17 (100.0)	
Mandibular arch	8 (44.4)	13 (65.0)	21 (100.0)	0.172
Cause				
Dental caries	16 (88.9)	17 (85.0)	33 (100.0)	
Trauma	2 (11.1)	3 (15.0)	5 (100.0)	0.552
Pulpal diagnosis				
Irreversible pulpitis	10 (55.6)	7 (35.0)	17 (100.0)	
Pulp necrosis	8 (44.4)	13 (65.0)	21 (100.0)	0.172
Clinical signs or symptoms				
Absent	13 (72.2)	13 (65.0)	26 (100.0)	
Present	5 (27.8)	7 (35.0)	12 (100.0)	0.450
Periapical radiolucency				
Absent	11 (61.1)	12 (60.0)	23 (100.0)	
Present	7 (38.9)	8 (40.0)	15 (100.0)	0.604

\*Fisher's exact test.

Clinical, radiographic, and overall outcome of the pulpectomy in each period is presented in Table 2. At the six-month evaluation, three patients (n=4) were lost: one moved to another city; one did not attend the follow-up visits; and one patient had two teeth inadvertently accessed by a colleague. As the research was conducted in a University clinic, with an average of 180 appointments per week, mismatching information sometimes occurred. Six failures happened within six months and the overall success of pulpectomy was 82.4% (n=28): 81.3% (n=13) in the IP group and 83.3% (n=15) in the CHZO group (p=0.611). In the period between six and 12 months, another patient (n=1) was lost since the patient missed the follow-up visits. At the 12-month follow-up, there were six more failures giving 77.8% (n=21) overall success, 76.9% (n=10) in the IP group and 78.6% (n=11) in the CHZO group (p=0.638).

At the end of the experimental period, 27 patients (n=33) were evaluated, giving a 90.0% return. The overall success was 63.6% (n=21): 62.5% (n=10) in the IP group and 64.7% (n=11) in the CHZO group. There was no significant difference in the overall success between groups (p=0.590). In addition, treatment performance was not influenced by the operator (p=0.486).

The results of the pulpectomy in both groups were not significantly influenced by the secondary variables: dental arch, cause of pulp pathology, pulpal diagnosis, clinical signs and symptoms and periapical radiolucency. However, the region of the tooth (p=0.013), extent of filling (p=0.040) and the integrity of the coronal restoration (p<0.001) had a significant influence on the pulpectomy outcome (Table 3). A higher frequency of success was found in the anterior teeth, with only one failure (8.3%). The three teeth classified as overfilled failed at the 12 months follow-up. Of the 14 coronal restoration failures, 11 (78.6%) were considered unsuccessful pulpectomy procedures during the follow-up period (Table 3).

**Table 2. Clinical, radiographic and overall performance of pulpectomy in the 6- and 12-month evaluation and in the complete period of study divided by group.**

Follow-up (Number of Evaluated Patients)	IP			CHZO			p-value*	Total Teeth		
	Success N (%)	Failure N (%)	Total N (%)	Success N (%)	Failure N (%)	Total N (%)		Success N (%)	Failure N (%)	Total N (%)
06 Months (n=34) <sup>†</sup>										
Clinical	14 (87.5)	2 (12.5)	16 (100.0)	16 (88.9)	2 (11.1)	18 (100.0)	0.652	30 (88.2)	4 (11.8)	34 (100.0)
Radiographical	13 (81.3)	3 (18.8)	16 (100.0)	15 (83.3)	3 (16.7)	18 (100.0)	0.611	28 (82.4)	6 (17.6)	34 (100.0)
Overall	13 (81.3)	3 (18.8)	16 (100.0)	15 (83.3)	3 (16.7)	18 (100.0)	0.611	28 (82.4)	6 (17.6)	34 (100.0)
12 Months (n=27) <sup>‡</sup>										
Clinical	12 (92.3)	1 (7.7)	13 (100.0)	13 (92.6)	1 (7.1)	14 (100.0)	0.741	25 (92.6)	2 (7.4)	27 (100.0)
Radiographical	11 (84.6)	2 (15.4)	13 (100.0)	11 (78.6)	3 (21.4)	14 (100.0)	0.538	22 (81.5)	5 (18.5)	27 (100.0)
Overall	10 (76.9)	3 (23.1)	13 (100.0)	11 (78.6)	3 (21.4)	14 (100.0)	0.638	21 (77.8)	6 (22.2)	27 (100.0)
Complete (n=33) <sup>§</sup>										
Clinical	12 (75.0)	4 (25.0)	16 (100.0)	13 (76.5)	4 (23.5)	17 (100.0)	0.619	25 (75.8)	8 (24.2)	33 (100.0)
Radiographical	10 (62.5)	6 (37.5)	16 (100.0)	10 (58.8)	7 (41.2)	17 (100.0)	0.556	20 (60.6)	13 (39.4)	33 (100.0)
Overall	10 (62.5)	6 (37.5)	16 (100.0)	11 (64.7)	6 (35.3)	17 (100.0)	0.590	21 (63.6)	12 (36.4)	33 (100.0)

<sup>†</sup>Total evaluated teeth in 06-month evaluation (34) = all treated teeth (38) - losses until 6-month evaluation (4); <sup>‡</sup>Total evaluated teeth in 12-month evaluation (27) = all successful teeth in 6-month evaluation (28) - losses between 6- and 12-month evaluation (1); <sup>§</sup>Total evaluated teeth in complete study (33) = all treated teeth (38) - total losses (5); \*Fisher's exact test.

**Table 3. Influence of variables on pulpectomy outcome, compared by group, after 12 months of follow-up (n=33).**

Variables	IP			CHZO			Success N (%)	Total		p-value
	Success N (%)	Failure N (%)	Total N (%)	Success N (%)	Failure N (%)	Total N (%)		Success N (%)	Failure N (%)	
Tooth region										
Anterior	6 (85.7)	1 (14.3)	7 (100.0)	5 (100.0)	0 (0.0)	5 (100.0)	11 (91.7)	1 (8.3)	12 (100.0)	0.013
Posterior	4 (44.4)	5 (55.6)	9 (100.0)	6 (50.0)	6 (50.0)	12 (100.0)	10 (47.6)	11 (52.4)	21 (100.0)	
Tooth arch										
Maxillary arch	6 (66.7)	3 (33.3)	9 (100.0)	5 (100.0)	0 (0.0)	5 (100.0)	11 (78.6)	3 (21.4)	14 (100.0)	0.122
Mandibular arch	4 (57.1)	3 (42.9)	7 (100.0)	6 (50.0)	6 (50.0)	12 (100.0)	10 (52.6)	9 (47.4)	19 (100.0)	
Cause										
Dental caries	9 (64.3)	5 (35.7)	14 (100.0)	8 (57.1)	6 (42.9)	14 (100.0)	17 (60.7)	11 (39.3)	28 (100.0)	0.388
Trauma	1 (50.0)	1 (50.0)	2 (100.0)	3 (100.0)	0 (0.0)	3 (100.0)	4 (80.0)	1 (20.0)	5 (100.0)	
Pulpal diagnosis										
Irreversible pulpitis	7 (77.8)	2 (22.2)	9 (100.0)	5 (71.4)	2 (28.6)	7 (100.0)	12 (75.0)	4 (25.0)	16 (100.0)	0.170
Pulp necrosis	3 (42.9)	4 (57.1)	7 (100.0)	6 (60.0)	4 (40.0)	10 (100.0)	9 (52.9)	8 (47.1)	17 (100.0)	
Clinical signs or symptoms										
Absent	7 (63.6)	4 (36.4)	11 (100.0)	9 (81.8)	2 (18.2)	11 (100.0)	16 (72.7)	6 (27.3)	22 (100.0)	0.125
Present	3 (60.0)	2 (40.0)	5 (100.0)	2 (33.3)	4 (66.7)	6 (100.0)	5 (45.5)	6 (54.5)	11 (100.0)	

Periapical radiolucency										
Absent	6 (60.0)	4 (40.0)	10 (100.0)	7 (63.6)	4 (36.4)	11 (100.0)	13 (61.9)	8 (38.1)	21 (100.0)	
Present	4 (66.7)	2 (33.3)	6 (100.0)	4 (66.7)	2 (33.3)	6 (100.0)	8 (66.7)	4 (33.3)	12 (100.0)	0.544
Extent of root canal filling										
Flush-filled	6 (66.7)	3 (33.3)	9 (100.0)	9 (81.8)	2 (18.2)	11 (100.0)	15 (75.0)	5 (25.0)	20 (100.0)	
Overfilled	0 (0.0)	1 (100)	1 (100.0)	0 (0.0)	2 (100.0)	2 (100.0)	0 (0.0)	3 (100)	3 (100.0)	
Underfilled	4 (66.7)	2 (33.3)	6 (100.0)	2 (50.0)	2 (50.0)	4 (100.0)	6 (60.0)	4 (40.0)	10 (100.0)	0.040**
Coronal restoration										
Adequate	9 (90.0)	1 (10.0)	10 (100.0)	9 (100)	0 (0.0)	9 (100.0)	18 (94.7)	1 (5.3)	19 (100.0)	
Failed	1 (16.7)	5 (83.3)	6 (100.0)	2 (25.0)	6 (75.0)	8 (100.0)	3 (21.4)	11 (78.6)	14 (100.0)	0.000

\*Fisher's exact test; \*\*Chi-squared test.

Figures 2 and 3 represent radiographs of successful and unsuccessful cases.

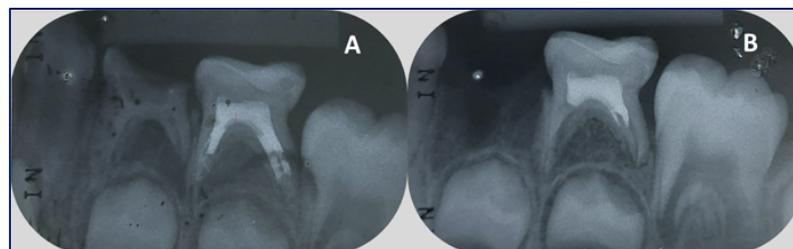


Figure 2. A) Post-obturation radiograph of tooth 75, IP group. B) 12-month follow-up radiograph.



Figure 3. A) Initial radiograph of tooth 85. B) Radiograph performed after filling, CHZO group, showing extravasation of root filling material. Tooth classified as overfilled. C) Failure observed in the 6-month follow-up.

## Discussion

The outcome of pulpectomies did not differ between the two groups, which corroborates the results of a previous study using similar root canal filling materials [13]. The choice of these two materials with antimicrobial properties [7-9] was based on their abilities to overcome cleaning difficulties during the chemomechanical preparation of root canals. A recent literature review evaluating research using iodoform paste showed good results similar to those described in the present study [3]. The calcium hydroxide-based paste is considered an antimicrobial agent. The addition of zinc oxide (ZO) has shown to reduce the speed of resorption of the filling material [11], which should ideally be similar to the physiological resorption of primary teeth. The adding does not impair its antimicrobial action, which has proved to be similar to the non-thickened material [8]. Although there was no statistical difference between the groups, there seemed to be a slight tendency for clinical superiority of the teeth filled with CHZO, as observed by Cassol et al. [13].

Only two clinical trials using calcium hydroxide-based paste thickened with zinc oxide have reported a success rate superior to ours [4,13]. In the first study [4], pulpectomy was conducted only in traumatized anterior teeth, which may have contributed to the good results, as treatment of traumatized permanent teeth with calcium hydroxide-based paste materials has a high success rate [16]. In the second study [13], more than 70% of the sample comprised anterior teeth, which could have favoured the superior result.

Dental caries is one of the most prevalent chronic diseases in children worldwide [17], which could explain why patients in this study have more teeth indicated for pulpectomy due to caries rather than trauma. Advanced dental caries was observed in the majority of examined patients. Most of the evaluated teeth were excluded since the structure of the remaining crown prevented further restoration and there was radiographic evidence of extensive inter-radicular radiolucency, affecting the structure of the primary teeth and even their permanent successors. This characteristic of the eligible population may have contributed to the small sample size, which is a limitation of the present study. However, it is noteworthy that the sample size was similar to that of previous studies [4,13].

Characteristics such as the arch, cause of pulp pathology, pulp diagnosis, clinical signs and symptoms, and preoperative radiolucency did not influence the outcome of the pulpectomy. Although not statistically significant, more than half of the cases with previous periapical lesions were classified as successful, which is consistent with Barcelos et al. [14], who observed that pulpectomy was significantly more successful when the smear layer was removed. This shows that chemomechanical preparation with adequate cleaning is particularly important for good results, especially in more difficult cases.

In the present study, there was a significant difference in pulpectomy success regarding the type of treated teeth. These data are consistent with a previous study [18] which also reported that the molars success rate was lower than the incisors'. Pulpectomy failures may be related to the presence of aberrant connections between the periodontium and the pulp, such as accessory channels commonly present in the furcation region of primary molars. Their presence makes proper treatment and disinfection more difficult [19].

Regarding the filling limit, all three cases classified as overfilled were evaluated as failures and two belonged to the group filled with CHZO. Despite this, a previous study showed that the apical and periapical regions of dog teeth filled with the same paste used in this study appeared normal, with a large number of cells and the absence of mineralized tissue reabsorption [20]. In addition, a higher frequency of success was found in teeth classified as flush-filled [21]. In our sample, most teeth were classified as flush-filled, highlighting the importance of care when filling root canals in pulpectomies of primary teeth. However, the results should be interpreted with caution as it is a preliminary study with a convenience sample.

In the present study, the integrity of the coronal restoration significantly influenced the success of pulpectomy, as previously reported [22,23]. Few studies have described the influence of final restoration on the pulpectomy outcome in primary teeth [22-25]. This relationship has already been elucidated in permanent teeth, where the success of endodontic treatment can be equally attributed to hermetic closure of the ducts and adequate coronal restoration [26]. Although this relationship remains unclear in primary teeth, retrospective studies have reported that restorations in posterior teeth with previous pulp intervention have a higher risk of failure compared to those with no previous intervention [24]. Likewise, class II restorations, like most cases of our sample, fail more than class I restorations [27]. In addition, restorations in vital teeth have less risk of failure than those in non-vital teeth [25]. Furthermore, unfavourable results related to bond strength in laboratory studies have been reported when using mixed paste (Metapex) [28] or irrigation with NaOCl [29], the substance used in the present methodology. Thus, more studies should be carried out, primarily controlled clinical trials with long follow-up.

Prefabricated stainless-steel crowns are indicated as the final restoration option after endodontic treatment [30,31]. Another option indicated are composite restorations, that have been used in several clinical studies [4,13,14,23] because this material has a low annual failure rate in primary teeth, especially if placed under a rubber dam [27]. Furthermore, a recent controlled clinical trial concluded that it is not possible to say that restorations made with bulk-fill composites after endodontic treatment in primary teeth with endodontic treatment are inferior to restorations made with stainless-steel crowns [23]. However, some factors can influence the performance of composite resin, such as high caries activity [24] and high index of visible plaque [25]. We emphasize the strong presence of these factors in the present sample.

A point to be highlighted is the recent tendency to use pastes like Vitapex [1,3,32] and Endoflas; [1,2,3,22], which combine both iodoform and calcium hydroxide. The comparison with studies that use only iodoform-based paste or only calcium hydroxide-based paste is challenging. Most studies use mixed pastes, making it difficult to compare the success of these studies with those using a single component. It is not possible to determine the direct influence of the material on treatment outcome. Despite this propensity, a thorough review of the literature and meta-analysis evaluating various root canal filling materials reported that in this regard, there is no conclusive evidence about the superiority of any material over another [1]. Although it was not possible to make this comparison, previous studies using combined pastes have reported clinical [2] and radiographic [32] success similar to ours. Thus, both materials used in this study can be considered options for root canal filling materials of primary teeth.

According to the American Academy of Pediatric Dentistry [30], after pulpectomy, clinical signs and symptoms should disappear within weeks and radiographic within six months. A large variation in follow-up time is observed in clinical studies [10,13,14,21,32]. It is considered that the success of endodontic therapy is only obtained when the treated tooth is preferably kept in the mouth until the moment of exfoliation. However, the survival rate of teeth that received pulpectomy is still poorly studied, and this rate has not yet been established [33,34]. As the primary tooth is the best space maintainer, it is considered worth keeping a primary tooth as long as possible, even for a short period of time.

## Conclusion

Based on our results, the null hypothesis that there is no significant difference in the pulpectomy outcome using these root canal filling materials was confirmed. In addition, the region of the tooth, the extent of the root canal filling and the integrity of the final restoration during the follow-up visits negatively influenced

the outcome of pulpectomies. The data provided here are valuable to pediatric dentists since the quality of the final restoration is a challenge in clinical practice.

### Authors' Contributions

MLD		<a href="https://orcid.org/0000-0002-8067-2733">https://orcid.org/0000-0002-8067-2733</a>	Methodology, Formal Analysis, Investigation, Data Curation, Writing - Original Draft and Writing - Review and Editing.
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### Conflict of Interest

The authors declare no conflicts of interest.

### Data Availability

The data used to support the findings of this study can be made available upon request to the corresponding author.

### References

- [1] Smaïl-Faugeron V, Glenny AM, Courson F, Durieux P, Muller-Bolla M, Fron Chabouis H. Pulp treatment for extensive decay in primary teeth. *Cochrane Database Syst Rev* 2018; 5(5):CD003220. <https://doi.org/10.1002/14651858.CD003220.pub3>
- [2] Najjar RS, Alamoudi NM, El-Housseiny AA, Al Tuwirqi AA, Sabbagh HJ. A comparison of calcium hydroxide/iodoform paste and zinc oxide eugenol as root filling materials for pulpectomy in primary teeth: a systematic review and meta-analysis. *Clin Exp Dent Res* 2019; 5(3):294-310. <https://doi.org/10.1002/cre2.173>
- [3] Silva Junior MF, Wambier LM, Gevert MV, Chibinski ACR. Effectiveness of iodoform-based filling materials in root canal treatment of deciduous teeth: a systematic review and meta-analysis. *Biomater Investig Dent* 2022; 9(1):52-74. <https://doi.org/10.1080/26415275.2022.2060232>
- [4] Pinto DN, de Sousa DL, Araujo RB, Moreira-Neto JJS, Araújo RBR, Moreira-Neto JJS. Eighteen-month clinical and radiographic evaluation of two root canal-filling materials in primary teeth with pulp necrosis secondary to trauma. *Dent Traumatol* 2011; 27(3):221-4. <https://doi.org/10.1111/j.1600-9657.2011.00978.x>
- [5] Segato RA, Pucinelli CM, Ferreira DC, Daldegan Ade R, Silva RS, Nelson-Filho P, et al. Physicochemical properties of root canal filling materials for primary teeth. *Braz Dent J* 2016; 27(2):196-201. <https://doi.org/10.1590/0103-6440201600206>
- [6] Cerqueira DF, Mello-Moura AC, Santos EM, Guedes-Pinto AC. Cytotoxicity, histopathological, microbiological and clinical aspects of an endodontic iodoform-based paste used in pediatric dentistry: a review. *J Clin Pediatr Dent* 2008; 32(2):105-10. <https://doi.org/10.17796/jcpd.32.2.k1wx5571h2w85430>
- [7] Marques RPS, Moura-Netto C, Oliveira NM, Bresolin CR, Mello-Moura ACV, Mendes FM, et al. Physicochemical properties and filling capacity of an experimental iodoform-based paste in primary teeth. *Braz Oral Res* 2020; 34:1-8. <https://doi.org/10.1590/1807-3107bor-2020.vol34.0089>
- [8] Queiroz AM, Nelson-Filho P, Silva LA, Assed S, Silva RA, Ito IY. Antibacterial activity of root canal filling materials for primary teeth: zinc oxide and eugenol cement, Calen paste thickened with zinc oxide, Sealapex and EndoREZ. *Braz Dent J* 2009; 20(4):290-6. <https://doi.org/10.1590/s0103-64402009000400005>
- [9] Moness AM, Khattab NN, Waly NG. Evaluation of three root canal filling materials for primary teeth (in vivo and in vitro study). *Egypt Dent J* 2012; 59:1-13.
- [10] Mani SA, Chawla HS, Tewari A, Goyal A. Evaluation of calcium hydroxide and zinc oxide eugenol as root canal filling materials in primary teeth. *ASDC J Dent Child* 2000; 67(2):83,142-7.
- [11] Queiroz AM, Assed S, Consolaro A, Nelson-Filho P, Leonardo MR, Silva RA, et al. Subcutaneous connective tissue response to primary root canal filling materials. *Braz Dent J* 2011; 22(3):203-11. <https://doi.org/10.1590/S0103-64402011000300005>

- [12] Pilownic KJ, Gomes APN, Wang ZJ, Almeida LHS, Romano AR, Shen Y, et al. Physicochemical and biological evaluation of endodontic filling materials for primary teeth. *Braz Dent J* 2017; 28(5):578-86. <https://doi.org/10.1590/0103-6440201701573>
- [13] Cassol DV, Duarte ML, Pintor AVB, Barcelos R, Primo LG. Iodoform *vs* calcium hydroxide/zinc oxide based pastes: 12-month findings of a randomized controlled trial. *Braz Oral Res* 2019; 33(e002):1-10. <https://doi.org/10.1590/1807-3107bor-2019>
- [14] Barcelos R, Tannure PN, Gleiser R, Luiz RR, Primo LG. The influence of smear layer removal on primary tooth pulpectomy outcome: a 24-month, double-blind, randomized, and controlled clinical trial evaluation. *Int J Paediatr Dent* 2012; 22(5):369-81. <https://doi.org/10.1111/j.1365-263X.2011.01210.x>
- [15] Hackshaw A. Small studies: strengths and limitations. *Eur Respir J* 2008; 32(5):1141-3. <https://doi.org/10.1183/09031936.00136408>
- [16] Finucane D, Kinirons MJ. External inflammatory and replacement resorption of luxated, and avulsed replanted permanent incisors: a review and case presentation. *Dent Traumatol* 2003; 19(3):170-4. <https://doi.org/10.1034/j.1600-9657.2003.00154.x>
- [17] Tinanoff N, Baez RJ, Diaz Guillory C, Donly KJ, Feldens CA, McGrath C, et al. Early childhood caries epidemiology, aetiology, risk assessment, societal burden, management, education, and policy: Global perspective. *Int J Paediatr Dent* 2019; 29(3):238-48. <https://doi.org/10.1111/ipd.12484>
- [18] Coll J, Sadrian R. Predicting pulpectomy success and its relationship to exfoliation and succedaneous dentition. *Pediatr Dent* 1996; 18(1):57-63.
- [19] Poornima P, Subba Reddy VV. Comparison of digital radiography, decalcification, and histologic sectioning in the detection of accessory canals in furcation areas of human primary molars. *J Indian Soc Pedod Prev Dent* 2008; 26(2):49-52. <https://doi.org/10.4103/0970-4388.41615>
- [20] Silva LA, Leonardo MR, Oliveira DS, Silva RA, Queiroz AM, Hernández PG, et al. Histopathological evaluation of root canal filling materials for primary teeth. *Braz Dent J* 2010; 21(1):38-45. <https://doi.org/10.1590/S0103-64402010000100006>
- [21] Sari S, Okte Z. Success rate of Sealapex in root canal treatment for primary teeth: 3-year follow-up. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2008; 105(4):e93-96.
- [22] Moskovitz M, Sammara E, Holan G. Success rate of root canal treatment in primary molars. *J Dent* 2005; 33(1):41-7. <https://doi.org/10.1016/j.tripleo.2007.12.014>
- [23] Olegário IC, Bresolin CR, Pássaro AL, de Araujo MP, Hesse D, Mendes FM, et al. Stainless steel crown *vs* bulk fill composites for the restoration of primary molars post-pulpectomy: 1-year survival and acceptance results of a randomized clinical trial. *Int J Paediatr Dent* 2022; 32(1):11-21. <https://doi.org/10.1111/ipd.12785>
- [24] Pinto Gdos S, Oliveira LJ, Romano AR, Scharodosim LR, Bonow ML, Pacce M, et al. Longevity of posterior restorations in primary teeth: Results from a paediatric dental clinic. *J Dent* 2014; 42(10):1248-54. <https://doi.org/10.1016/j.jdent.2014.08.005>
- [25] Campagna P, Pinto LT, Lenzi TL, Ardenghi TM, De Oliveira Rocha R, Oliveira MDM. Survival and associated risk factors of composite restorations in children with early childhood caries: a clinical retrospective study. *Pediatr Dent* 2018; 40(3):210-4.
- [26] Gillen BM, Looney SW, Gu LS, Loushine BA, Weller RN, Loushine RJ, et al. Impact of the quality of coronal restoration versus the quality of root canal fillings on success of root canal treatment: a systematic review and meta-analysis. *J Endod* 2011; 37(7):895-902. <https://doi.org/10.1016/j.joen.2011.04.002>
- [27] Chisini LA, Collares K, Cademartori MG, de Oliveira LJC, Conde MCM, Demarco FF, et al. Restorations in primary teeth: a systematic review on survival and reasons for failures. *Int J Paediatr Dent* 2018; 28(2):123-39. <https://doi.org/10.1111/ipd.12346>
- [28] Şermet Elbay Ü, Tosun G. Effect of endodontic sealers on bond strength of restorative systems to primary tooth pulp chamber. *J Dent Sci* 2017; 12(2):112-20. <https://doi.org/10.1016/j.jds.2016.06.003>
- [29] Di Francescantonio M, Nurrohman H, Takagaki T, Nikaido T, Tagami J, Giannini M. Sodium hypochlorite effects on dentin bond strength and acid-base resistant zone formation by adhesive systems. *Brazilian J Oral Sci* 2015; 14(4):334-40. <https://doi.org/10.1590/1677-3225v14n4a15>
- [30] American Academy of Pediatric Dentistry (AAPD). Pulp Therapy for Primary and Immature Permanent Teeth. The Reference Manual of Pediatric Dentistry. Chicago, Ill.: American Academy of Pediatric Dentistry; 2021:399-407.
- [31] Coll JA, Dhar V, Vargas K, Chen CY, Crystal YO, AlShamali S, et al. Use of non-vital pulp therapies in primary teeth. *Pediatr Dent* 2020; 42(5):337-49.
- [32] Chen X, Liu X, Zhong J. Clinical and radiographic evaluation of pulpectomy in primary teeth: a 18-months clinical randomized controlled trial. *Head Face Med* 2017; 13(1):1-10. <https://doi.org/10.1186/s13005-017-0145-1>
- [33] Amin M, Nouri MR, Hulland S, ElSalhy M, Azarpazhooh A. Success rate of treatments provided for early childhood caries under general anesthesia: a retrospective cohort study. *Pediatr Dent* 2016; 38(4):317-24.
- [34] Songvejkasem M, Auychai P, Chankanka O, Songsiripradubboon S. Survival rate and associated factors affecting pulpectomy treatment outcome in primary teeth. *Clin Exp Dent Res* 2021; 7(6):978-86. <https://doi.org/10.1002/cre2.473>