

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

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Academic Editor: Ana Maria Gondim Valença

Received: 07 July 2022 / **Review:** 26 September 2022 / **Accepted:** 24 October 2022

How to cite: Duarte ML, Siqueira M, Cassol DV, Scarparo A, Primo LG, Barcelos R. Pulpectomies with iodoform *versus* calcium hydroxide-based paste: a preliminary randomised controlled clinical trial. *Pesqui Bras Odontopediatria Clín Integr*. 2023; 23:e220119. <https://doi.org/10.1590/pboci.2023.058>

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 pulpctomy failure. Teeth considered as pulpctomy 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).

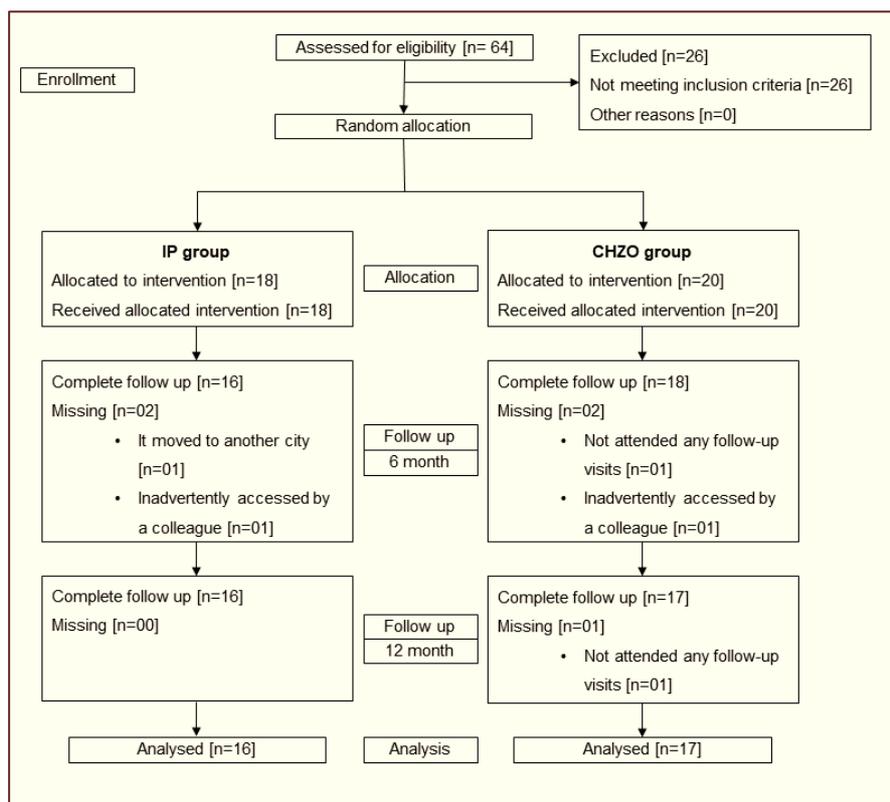


Figure 1. CONSORT flowchart demonstrating for each group the number of teeth randomly assigned and analyzed for each study period.

The mean age was 4.95 ± 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) [†] | | | | | | | | | | |
| 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) [‡] | | | | | | | | | | |
| 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) [§] | | | | | | | | | | |
| 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) |

[†]Total evaluated teeth in 06-month evaluation (34) = all treated teeth (38) - losses until 6-month evaluation (4); [‡]Total evaluated teeth in 12-month evaluation (27) = all successful teeth in 6-month evaluation (28) - losses between 6- and 12-month evaluation (1); [§]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.

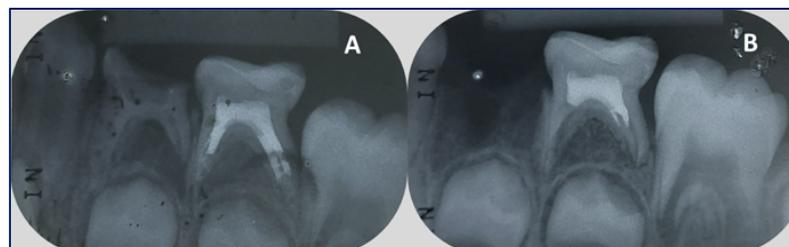


Figure 2. A) Post-obturation radiograph of tooth 75, IP group. B) 12-month follow-up radiograph.



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

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|-----|---|---|--|
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Financial Support

This study was financed in part by the Fundação Carlos Chagas Filho de Amparo à Pesquisa do Estado do Rio de Janeiro (FAPERJ) – APQ1 2010.352/2019 – Finance Code 111 550/2013 and Universidade Federal Fluminense (UFF) – Edital PROPPI FOPIN/2015, Brazil. This study is part of the master's Dissertation of the primary author.

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.

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