Original Article

# A Comparative Evaluation of Formocresol and Sodium Hypochlorite as Agents for Pulpotomy in Primary Molars: A Pilot Study

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## Abstract

**Aim:** This *in vivo* study was carried out to assess the clinical and radiographic evaluation of pulpotomy in primary molars, following the use of formocresol (FC) versus sodium hypochlorite (NaOCl) 5%. **Materials and Methods:** In the present study, pulpotomies were conducted on sixty primary molars of 5–8-year-old children who referred to the Department of Pediatric Dentistry. The selected teeth were equally distributed and randomly assigned into two groups of FC and NaOCl 5%. After taking the initial radiographs, standard pulpotomy was carried out using FC and NaOCl 5%; pulp chamber was filled with intermediate restorative material and restored with stainless steel crown cemented with glass ionomer cement. **Results:** The control (FC) and experimental (NaOCl 5%) groups demonstrated 96.3% clinical success at 3 and 6 months. The NaOCl group had 88.9% radiographic success at 3 months and 88.4% at 6 months. The FC group had 76.9% and 72% radiographic success at 3 and 6 months, respectively. No significant differences were found in clinical and radiological outcomes between two groups at 3 and 6 months (Pearson's test, Fishers exact test; $P = 0.02$ and $P = 0.05$, respectively). **Conclusion:** Based on the results of this study, NaOCl demonstrated clinical and radiological success comparable to FC.

**Keywords:** Formocresol, primary molars, pulpotomy, sodium hypochlorite

## Introduction

Pulpotomies in the primary teeth continues to be one of the most common treatments in pediatric dentistry. The main objective of the pulpotomy is to maintain radicular pulp asymptomatic without adverse clinical signs or symptoms, such as sensitivity, pain, or swelling.[1] Only in this way could early root resorption be preserved and teeth enter into exfoliative process at the appropriate time.[2] Hence, the ideal requisites of any pulpotomy material should be bactericidal, harmless to pulp and surrounding structures, should promote healing of remaining radicular pulp without interfering with the physiologic root resorption, and should not possess any toxicity.[3]

Formocresol (FC) [Figure 1], a devitalizing agent, has been a popular pulpotomy medicament for many years.[4] Despite its high success rate over the past years, FC's use as a pulpotomy agent has been challenged due to pulpal inflammatory response,[5] systemic disturbances,[6] cytotoxicity,[7] immunologic responses,[8] and mutagenic and carcinogenic potential.[9]

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These findings have led researchers to look for an alternative to FC. Accordingly, various pulpotomy medicaments such as glutaraldehyde, calcium hydroxide, adhesive liners, ferric sulfate, enamel matrix derivative, mineral trioxide aggregate, bioactive glass, bone morphogenic protein, pulpotec, collagen, and other techniques such as electrosurgery and lasers have been tried out with variable clinical and radiological success in both primary and permanent dentition.[10]

Sodium hypochlorite (NaOCl) [Figure 2] seems to be a suitable alternative for FC. Used for over four decades[11] as the most popular endodontic irrigant available, it has been shown to be a very good antimicrobial[12] and hemostatic agent,[13] two important factors in primary teeth pulpotomy.

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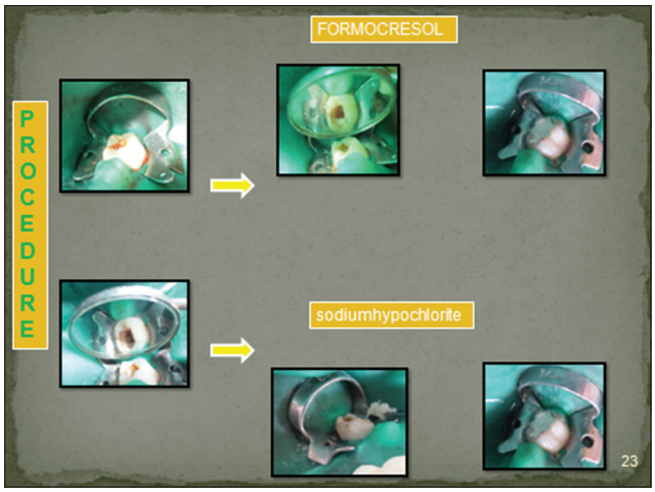


**Figure 1:** Pulpotomy procedure.


**Figure 2:** FMC (Kayvee Aero Pharmaceutics) to (Sultan Health care; Inc, Newyork, USA).

Consequently, the aim of this study has been undertaken to evaluate and compare 5% NaOCl and FC as pulpotomy medicaments in the deciduous teeth by clinical and radiographic methods.

## Materials and Methods

A randomized clinical trial was reviewed and approved by the Institutional Human Ethical Committee in accordance with the Declaration of Helsinki. The procedure and the possible discomforts or risks versus benefits were explained to the subjects and their parents/guardians, and informed consent was obtained before the initiation of the CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomized trials.[14]

### Participants

Experimental participants selected for this study were cooperative, healthy children aged between 5–8 years who were being treated in the Department of Pedodontics and Preventive dentistry, Mamata Dental College and Hospital, Khammam. The selection criteria for the patients and teeth are as follows.

### Patient selection criteria[15,16]

1. Absence of systemic disease such as bacterial endocarditis, kidney disease, leukemia, diabetes, neutropenia, and bleeding problems
2. Absence of any type of medical treatment or continues use of any medication
3. Absence of drug allergies, anesthetics, and environmental allergies
4. Patients' compliance with the treatment.[15,16]

### Teeth selection criterion[17]

Teeth with no clinical or radiographic pulpal degeneration.[17]

### Clinical selection criteria

1. Teeth with deep decay lesions and no symptoms
2. Teeth with vital pulp exposed by decay; no spontaneous pain; and absence of edema, pain, and fistula
3. Absence of sensitivity on percussion
4. Teeth with manageable pulpal hemorrhage.

### Radiographic selection criteria

1. Teeth with code 3 decay (radiographic spread to one-third of the dentine) and code 4 decay (radiolucency spread to one-third of the pulp) according to the codes for decay lesion grade and severity used by Ekstrand *et al.*[18]
2. Teeth with no pathological root resorption
3. Teeth with no periradicular or furcal radiolucency
4. Teeth with no periradicular or furcal radiolucency
5. Teeth with less than one-third physiological root resorption (no resorption or one-fourth resorption of the root).[19]

All radiographs were taken with size 0 ultraspeed dental film (Eastman Kodac Co. Rochester, NY, USA) using a Planmeca prostyle intra-X-ray unit (Helsinki, Finland) set at 70 kV, 8 mA with an exposure time of 0.32 s; patients were fitted with a lead apron and thyroid collar before radiation exposure. The dental film was positioned intraorally with a Rinn Snap-A-Ray (Dentsply Rinn, Elgin, IL, USA).

The primary molar teeth were divided into FC and NaOCl 5% according to the random number table. The caries were removed by a high-speed diamond hand-piece (NSK-Japan). After removing the pulp chamber roof, the coronal pulp tissue was removed by a round carbide bur size 0.25 and a low-speed hand-piece (NSK-Japan).

The initial hemostasis of coronal pulp occurred using a cotton saturated with normal saline (NaOCl 5%) for 1 min to ensure the healthiness of the pulp [Figure 3].

In the first group FC [Figure 4] – saturated cotton (Sultan Health Care, Inc, India) 1.5% was diluted, and in the second group [Figure 5], the cotton moistened with NaOCl 5% (Vishal company, India) was put in the pulp chamber for 1 min to perform fixation in both groups, and if bleeding was continued, the tooth would be excluded from the study. Having ensured the pulp tissue fixation. Two millimeters zonalin was placed on

the pulp chamber floor. After 1 week, the tooth was prepared for stainless steel crown (SSC) (Poly-F plus Germany).

The clinical and radiographic evaluation was performed at 3 and 6 months follow-up. The clinical success was examined in the absence of spontaneous pain, mobility, swelling, fistula, gum inflammation (pain, redness, and bleeding around the teeth or SSC) and in the case of healthy SSC. Furthermore, the radiographic success was evaluated by a blind radiologist in case there were no internal or external resorption and inter-root bone damage, respectively (It should be noted that the radiographies were performed as the same condition as the initial radiography).


**Figure 3:** Sodium hypochlorite 5% (Vishal dental care pvt, Gujarat, India).

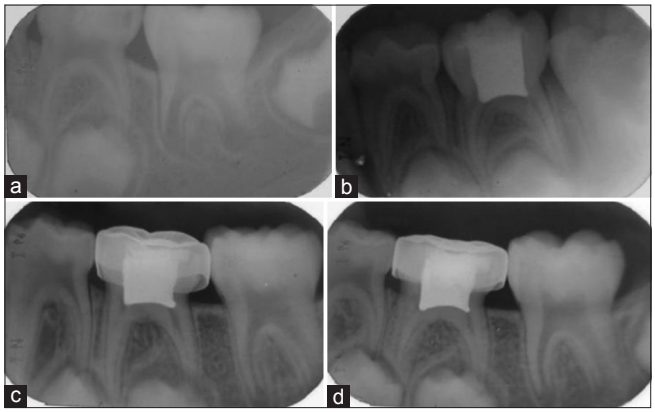


**Figure 4:** Formolcresol group: (a) Preoperative photograph, (b) postoperative photograph, (c) 3 months follow-up, (d) 6 months follow-up.

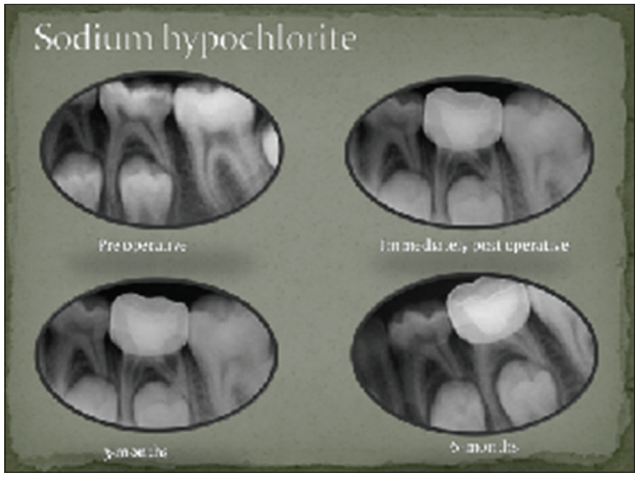


**Figure 5:** Sodium hypochlorite group.

### Statistical analysis

Data evaluation was performed using the SPSS 15.0 (IBM Corporation USA) program. Number and percentage values were used for data identification, and comparisons among groups were performed with Pearson's Chi-square test and Fisher's exact test. Values of $P < 0.005$ were considered statistically significant.

## Results

### Demographic characteristics

Sixty primary molar teeth in 55 children were randomly allocated into two treatment groups.

Table 1 represents samples available for follow-up giving a total sum of 25 (FC group) and 26 (NaOCl group) subjects at 6-month interval.

The percentage of sample loss was 16.6% for FC group and 13.3% in NaOCl group at the end of 6-month interval as shown in Table 2.

### Clinical findings

Clinical evaluation of all two groups at 3 and 6 months interval is represented in Table 3. The inference obtained was that in FC group, none of the cases reported with pain, draining sinus, swelling, and premature exfoliation, except for two cases where mobility was observed at the end of 3 months. At the end of 6 months, one case reported with draining sinus, two cases showed presence of swelling, mobility was in one case, and two cases showed premature exfoliation resulting in failure.

NaOCl group showed no signs of clinical pathology, except in one case each showing formation of buccal abscess at the end of 3 and 6 months interval. Thus, the clinical success rates (%) obtained in subjects reviewed after 3 and 6 months have been represented in Table 4.

**Table 1: Sample available for follow-up**

| Medicaments | 3 months | | 6 months | |
|---|---|---|---|---|
| | Total number | Follow-up | Total number | Follow-up |
| Formocresol | 30 | 26 | 30 | 25 |
| Sodium hypochlorite | 30 | 27 | 30 | 26 |

**Table 2: Percentage of sample loss**

| Medicaments | 3 months (%) | 6 months (%) |
|---|---|---|
| Formocresol | 4 (13) | 5 (17) |
| Sodium hypochlorite | 3 (10) | 4 (13) |

**Table 3: Evaluation of clinical parameter between formocresol and sodium hypochlorite**

| Clinical parameters | Formocresol | | Sodium hypochlorite | |
|---|---|---|---|---|
| | 3 months | 6 months | 3 months | 6 months |
| Pain | | | | |
| Present | 0 | 0 | 0 | 0 |
| Absent | 26 | 25 | 27 | 26 |
| Draining sinus | | | | |
| Present | 0 | 1 | 0 | 0 |
| Absent | 26 | 25 | 27 | 26 |
| Abscess/swelling | | | | |
| Present | 0 | 2 | 1 | 1 |
| Absent | 26 | 23 | 26 | 25 |
| Mobility | | | | |
| Present | 2 | 1 | 0 | 0 |
| Absent | 24 | 24 | 27 | 26 |
| Premature exfoliation | | | | |
| Present | 0 | 2 | 0 | 0 |
| Absent | 26 | 33 | 26 | 27 |

**Table 4: Clinical success rates of two groups at 3 and 6 months**

| Clinical success | Formocresol (%) | Sodium hypochlorite (%) | *P* |
|---|---|---|---|
| Success rate at 3 months | 92.3 | 96.3 | 0.72 |
| Success rate at 6 months | 86 | 96.3 | 0.021 |

Pearson's Chi-square test; *P*>0.005 statistically not significant

**Table 5: Evaluation of radiological parameters between formocresol and sodium hypochlorite**

| Radiological parameters | Formocresol | | Sodium hypochlorite | |
|---|---|---|---|---|
| | 3 months | 6 months | 3 months | 6 months |
| Interradicular radiolucency | | | | |
| Present | 2 | 3 | 1 | 1 |
| Absent | 24 | 22 | 26 | 25 |
| Periodontal ligament widening | | | | |
| Present | 1 | 2 | 1 | 1 |
| Absent | 25 | 23 | 26 | 25 |
| Periapical radiolucency | | | | |
| Present | 0 | 2 | 1 | 1 |
| Absent | 26 | 23 | 26 | 25 |
| Interradicular resorption | | | | |
| Present | 0 | 0 | 0 | 0 |
| Absent | 25 | 25 | 27 | 26 |

**Table 6: Radiological success rate of two groups at 3 months and 6 months**

| Radiological success | Formocresol (%) | Sodium hypochlorite (%) | *P* |
|---|---|---|---|
| Success rate at 3 months | 76.9 | 88.9 | 0.051 |
| Success rate at 6 months | 72 | 88.4 | 0.055 |

Pearson's Chi-square test; *P*>0.005 statistically not significant

### Radiographic findings

In Table 5, the radiographic evaluation of all groups have been represented which demonstrates signs of pathology in four cases of FC group, wherein two cases showed interradicular radiolucency, one case had periodontal ligament (PDL) widening, and one case reported with periapical radiolucency. At the end of 3 months, seven cases showed signs of radiographic failure in FC group. Three cases in NaOCl group showed pathosis as PDL widening, interradicular and periradicular radiolucency by the end of 3 months and the same cases continued to show failure after 6 months observation also.

Thereby the success rate for FC, NaOCl group was 76.9% at 3 months period and 72% at the end of 6 months, respectively, as depicted in Table 6 which represents the comparison of *P* value for radiographic success rates among the two groups, indicating statistically significant *P* = 0.055 between FC and NaOCl group.

## Discussion

Children aged 5 to 8 years were selected as per the inclusion and exclusion criteria for the study, irrespective of their sex. The age group was selected taking into consideration the lack of cooperation of children <5 years of age and physiologic root resorption (greater than three-fourth of root). Above 8 years of age. The first and second molars of both arches were included in the present study.

Studies on FC therapy have put the clinical success rate between 70% and 90%.[20] However, variable histological results were also reported in contrast to the clinical success rate. Instead of preserving vital pulpal tissue, chronic inflammation and necrotic tissue were found.[20,21] Another problem with FC is its systemic distribution from the pulpotomy site. Pruhs *et al*.[22] found a relationship between primary teeth treated with FC and enamel defects in the permanent successors. The allergenic and mutagenic properties of formaldehyde have been demonstrated in animal models, but not in humans. Cysts have also been found to be associated with the pulpotomized teeth.[20]

Furthermore, the WHO has estimated that the use of FC through air, water, and food is 1.5–14 mg/day (mean 7.8 mg/day). For one pulpotomy procedure, the estimated dose of formaldehyde associated, assuming a 1:5 dilution of FC placed on cotton pellet has been squeeze dried, is 0.02–0.1 mg. Thus, there is no consequential risk of carcinogenesis associated with the use of formaldehyde in pediatric pulp therapy. The potential systemic effects of FC have been shown to be minimal based

on a recent study that examined FC levels in the bloodstream of children having pulpotomies under general anesthesia.

Formaldehyde was undetectable above baseline plasma concentration, and cresol was undetectable in all samples.[23] Yet, Milnes[24] revealed the use of FC with 190,000 ppm formaldehyde safe for pulpotomy in the treatment in children.

In the present study, FC showed clinical success rates of 92.3% and 86% after 3 and 6 months, which is in accordance with the findings of Erdem *et al*.[25] The major clinical failure was due to formation of abscess (8%) and premature exfoliation (8%), which is in accordance with the study by Berger.[26] They reemphasized the fact that the fixation of pulp tissue using FC is never complete.

In the present study, after 6 months, in the FC group, two teeth showed periapical radiolucency and two other teeth showed intraradicular radiolucency. These findings of failure have also been reported in various previous studies.[27,28] The pathological radiolucency in the FC group may have been due to the smaller molecular size of FC, which may cause seepage into the apical region through the pulpal canals or into the furcation area through accessory canals or the pulpal floor, as it is thin, porous, and permeable in nature, in primary molars.[29,30] In addition, FC even in reduced concentration has the potential to result in negative immunologic, systemic, toxicological, and overt clinical consequences.

In a study done by Vargas *et al*. (2006), FC pulpotomies lead to premature exfoliation up to 13%, whereas in the present study, 8% cases were recorded.[31] The clinical success rate of FC pulpotomy in the present study was attributed to its germicidal action. The chemical bonding with the proteins of microorganisms is the basis for bactericidal action and fixative qualities of FC.[32]

Regarding the radiographic success rates of the present study, it was found to be 76.9% after 3 months and 72% after 6 months, which were similar to the results obtained by Vargas *et al*. (2006) and Zealand *et al*. (2010).[31,33] The major radiographic failures of the study were due to interradicular radiolucency (12%), followed by periapical radiolucency (8%) and PDL widening (8%). The probable reason is due to fixative effect of FC, ability of vapors to escape through apical foramen.[34]

According to the results of the present study, the clinical, radiographic success rate of pulpotomy by NaOCl 5% was 88.9% and 88.4%, respectively, 3 and 6 months follow-up, which are in line with the findings of Vargas *et al*.[31] In the present study, in 3 months follow-up, one case of PDL widening and interradicular and periradicular radiolucency was observed. However, in the 6 months follow-up, 1 case of PDL widening, interradicular radiolucency and periradicular radiolucency seen in 2 cases.

The findings of the present study indicated the clinical success rate of 96% for the medicament in the 3- and 6-month follow-up and radiographic success rate of 88.9% and 88.4% in the 3- and 6-month follow-up, which are in agreement with the results of Asgary and Ehsani[35] and Tabarsi *et al*.[36]

The results of a study similar to the retrospective study of NaOCl pulpotomies in primary molars was evaluated by a total of 131 primary molars from 77 children were available for follow-up examinations (3–21 months). NaOCl pulpotomy had 95% clinical and 82% radiographic success rate; root resorption was the most common pathological finding.

The present randomized clinical trial study was conducted to analyze the success rate of primary molar pulpotomy using FC and NaOCl in the 3 and 6 months follow-up.

The highest rate of therapeutics failure in the present study was reported for furcation involvement, as widening of PDL space, which is different than the studies, internal resorption has been reported as the main cause of treatment failure.[35,37]

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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