



## Evaluation and Comparison between Formocresol and Sodium Hypochlorite as Pulpotomy Medicament: A Randomized Study

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### ABSTRACT

**Introduction:** Pulpotomy is the most common treatment to preserve vitality of cariously exposed molars. Various pulpotomy medicaments used should be antimicrobial, should help in healing without damaging surrounding tissue, and should not affect eruption of permanent teeth. Thus, this study was conducted to evaluate and compare the clinical and radiographic outcomes of formocresol (FC) and sodium hypochlorite (NaOCl) in primary molars. The aim of this randomized study was to compare the clinical and radiographic success rate of FC and 5% NaOCl as a pulpotomy medicament in primary molars.

**Materials and methods:** Forty children aged 4 to 9 years with primary carious molar were selected and randomly assigned into two groups: FC and NaOCl. Pulpotomy procedure was then performed followed by restoration with stainless steel crowns. Clinical and radiographic evaluation was done at an interval of 3 to 6 months.

**Results:** Clinical success rate at 3 and 6 months was 100% for both groups. Radiographic success rate for FC was 95% at 3 months and 90% at 6 months, whereas for NaOCl, it was 90% at 3 months and 85% at 6 months.

**Conclusion:** Based on this study, result of 5% NaOCl and FC showed no significant difference in their success rate. Hence, NaOCl can be used as pulpotomy medicament; however, further clinical trials with long follow-up period are required.

**Clinical significance:** Sodium hypochlorite is a potential clinical substitute of FC for vital pulpotomy treatment in primary teeth because of its exceptional biological compatibility and to evade carcinogenic effect of FC.

**Keywords:** Formocresol, Primary molars, Pulpotomy, Sodium hypochlorite.

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### INTRODUCTION

Preservation of vitality of primary tooth whose pulp has been endangered by caries or trauma is a challenging treatment. Pulpotomy is one of the most common procedures used in pediatric dentistry. Pulpotomy is defined as "the surgical removal of the coronal portion of a vital pulp as a means of preserving the vitality of the remaining radicular portion."<sup>1</sup> The objective is to maintain the primary teeth until permanent teeth erupt. Various materials have been used as pulpotomy medicaments which include FC, ferric sulfate, glutaraldehyde, laser, and mineral trioxide aggregate. Pulpotomy medicaments have been classified as devitalizing agent, preservative, and regenerative.<sup>2</sup> Formocresol was introduced by Buckley in the year 1904.<sup>2</sup> Formocresol is a devitalizing agent, also called as mummifying agent. Despite its popularity, it was classified as carcinogenic for humans

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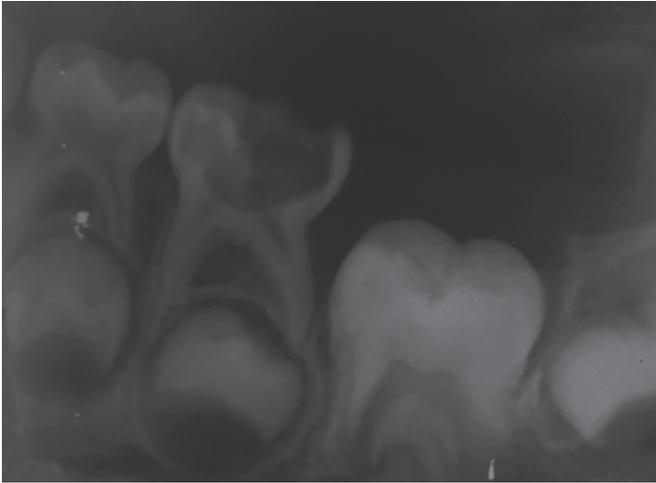


Fig. 1: Preoperative intraoral radiograph with respect to 85

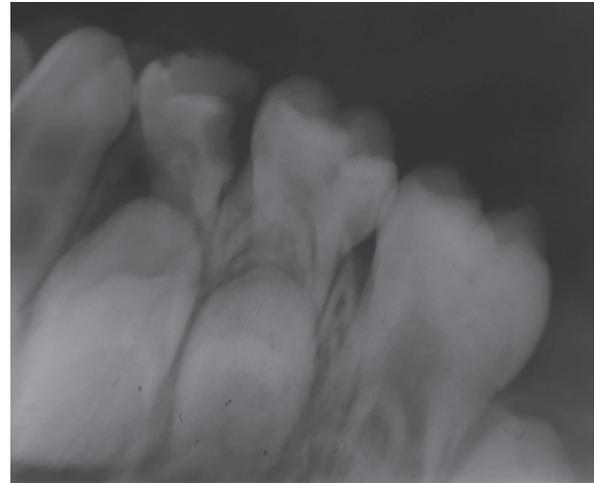


Fig. 2: Preoperative intraoral radiograph with respect to 64

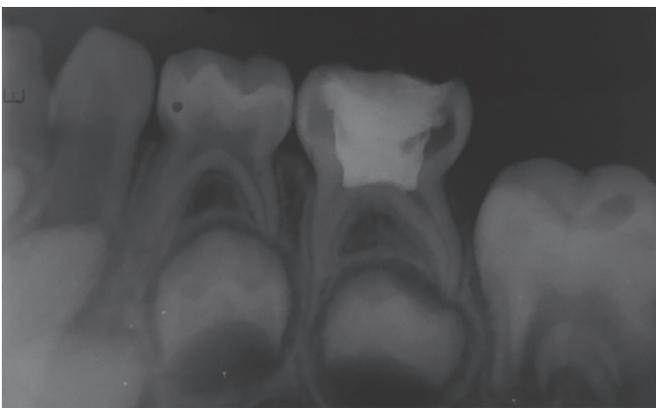


Fig. 3: Pulp chamber filled with ZOE after fixation with FC with respect to 85

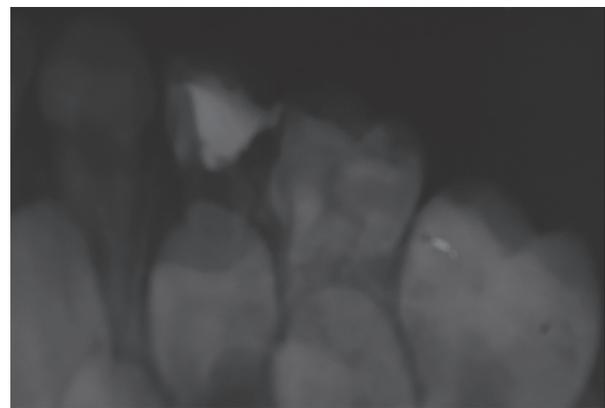


Fig. 4: Pulp chamber filled with ZOE after fixation with NaOCl with respect to 64

in June 2004 by the International Agency for Research on Cancer.<sup>3</sup>

These findings have led researchers to find an alternative to FC. Sodium hypochlorite can be an alternative to FC. It is one of the best irrigants used for decades in endodontics, and it has gained its popularity for being antimicrobial agent. At 6% concentration, it kills almost all microorganisms or completely removes the biofilm from the root canals which chlorhexidine alone cannot do.<sup>4</sup> Histological studies conducted by Hafez et al<sup>5</sup> reported its use as a hemostatic agent in pulp therapy.

The purpose of this study was to evaluate and compare 5% NaOCl with FC as a pulpotomy agent in primary molar.

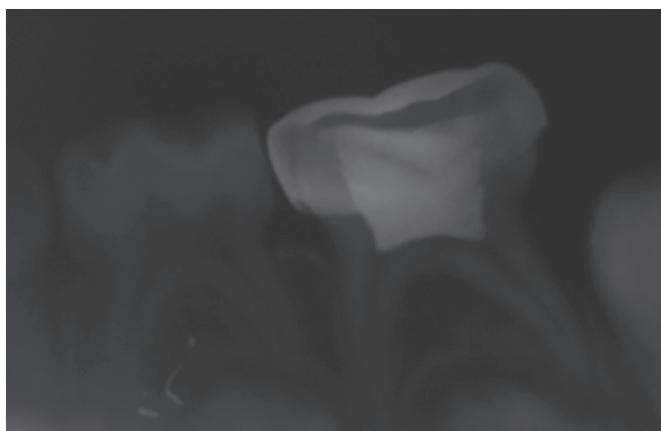
## MATERIALS AND METHODS

This randomized clinical trial was approved by the Institutional Ethical Committee. The participants selected for this study were healthy children aged between 4 and 9 years, 22 males and 18 females (Table 1). Teeth selected were primary molars which met following inclusion criteria:

- Exposure of pulp during caries excavation
- No signs of pulpal infection, i.e., mobility, sinus/fistula

- No pulpal necrosis
- Hemostasis achieved after compression with a sterile cotton pellet
- The absence of radiographic pathology, such as furcal abscess and widening of periodontal ligament (PDL)

Periapical radiographs were taken with size 0 ultra-speed dental film (Eastman Kodak Co.) A total of 40 children were randomly allocated to one of the groups: FC (control group) (Figs 1 and 2) or 5% NaOCl (experimental group) as listed in Table 2. Local anesthesia was administered; the selected teeth were isolated with a rubber dam. Caries was excavated using a sterile low-speed bur; coronal access was obtained. A sterile no. 6 carbide round bur was used for coronal pulp amputation, and hemostasis was achieved by a water-moistened cotton pellet. After obtaining hemostasis, pulpotomy medicament was placed in both groups with the help of cotton pellet: Group I—FC for 5 minutes (n = 20) and group II—5% NaOCl for 30 seconds (n = 20). Cotton pellet was removed and cavity was rinsed with saline. In both groups, a layer of 2 mm zinc oxide eugenol (ZOE) was placed over the amputated pulp (Figs 3 and 4) and tooth was restored with miracle mix cement followed by placement of stainless steel



**Fig. 5:** Postoperative X-ray with stainless steel crown with respect to 85



**Fig. 6:** Postoperative X-ray with stainless steel crown with respect to 64

**Table 1:** Patient demographic data

Mean age	5.9 (4–9 years)
Male (%)	22 (55)
Female (%)	18 (45)
Total	40

**Table 2:** Distribution of primary molars in 3 and 6 months

	3 months		6 months	
	First molar	Second molar	First molar	Second molar
FC	10	10	10	10
NaOCl	10	10	10	10
Total	n = 40		n = 40	

crown (Figs 5 and 6). Patients were recalled after 3 and 6 months for clinical and radiographic evaluation.

**Clinical and Radiographic Evaluation**

Clinical success was based on the absence of following sign and symptoms, pain, mobility, and tender on percussion, sinus, or fistula. The criteria for radiographic success were met in the absence of internal and external root resorption, furcal abscess, and widening of PDL.

**Statistical Analysis**

Formocresol and NaOCl groups were analyzed separately. Both groups showed 100% clinical success rate. The radiographic data collected were compiled, tabulated, analyzed, and subjected to statistical tests. Analysis was done using Statistical Package for the Social Sciences. Wilcoxon’s signed-rank test with significance level  $p < 0.05$  was used.

**RESULTS**

Forty primary molars in 40 children were randomly divided into two groups: FC (n = 20) and NaOCl (n = 20). After 3 and 6 months, out of 40 patients treated with pulpotomy, all 40 were available for the evaluation (Table 2). The clinical success rate for FC and NaOCl was 100% at 3 and 6 months. The absence of pain, mobility, sinus, or fistula led to the conclusion of 100% clinical success (Table 3). At 3 months radiographic evaluation, pathological changes in the development of furcal radiolucency, internal resorption, or excessive external root

resorption were seen in 5% (1/20) of teeth treated with FC and 10% (2/20) of teeth treated with NaOCl ( $p > 0.05$ ). At 3 months evaluation, one tooth from FC was assessed as radiographic failure (bifurcation radiolucencies). At the same time, two teeth from NaOCl were considered as failure (two teeth had internal resorption). The overall radiographic success rate at 3 months for FC group was 95% and NaOCl was 90% (Table 4).

At 6 months follow-up, radiographic changes as furcal radiolucency in one case and external root resorption in another case were seen (total two teeth) out of 20 samples, indicative of radiographic failure. This failure rate was 10% (2/20) of teeth treated with FC group. At the same time, three teeth from NaOCl were considered a failure (two teeth had internal resorption and one had widening of PDL). Hence, the failure rate was 15% (3/20) in the NaOCl group (Table 4). There was no significant difference in radiographic outcome. The overall

**Table 3:** Comparison of FC and NaOCl clinical treatment outcome in 3 and 6 months

Groups	At 3 months n (%)	At 6 months n (%)
<i>Group I</i>		
Success	20	20
Failure	–	–
<i>Group II</i>		
Success	20	20
Failure	–	–
p-value <sup>#</sup>	1.000 <sup>NS</sup>	1.000 <sup>NS</sup>

<sup>#</sup>Wilcoxon’s signed-rank test; NS:  $p > 0.05$ , nonsignificant

**Table 4:** Comparison of FC and NaOCl radiographic treatment outcome in 3 and 6 months

Groups	At 3 months n (%)	At 6 months n (%)
<b>Group I</b>		
Success	19 (95)	18 (90)
FFR	1 (5)	1 (5)
FIR	–	–
FER	–	1 (5)
FPDL	–	–
<b>Group II</b>		
Success	18 (90)	17 (85)
FPR	–	–
FIR	2 (10)	2 (10)
FER	–	–
FPDL	–	1 (5)
p-value <sup>#</sup>	0.586 <sup>NS</sup>	0.348 <sup>NS</sup>

FFR: Failure due to furcal radiolucency; FIR: Failure due to internal resorption; FER: Failure due to external root resorption; FPDL: Failure due to periodontal ligament widening; <sup>#</sup>Wilcoxon's signed-rank test; NS: p>0.05, nonsignificant

radiographic success rate at 3 months for FC group was 95% and NaOCl was 90% and at 6 months 90% for FC group and 85% for NaOCl.

## DISCUSSION

Dental caries is infectious and multiple factors are involved for the initiation and progression of the disease in human.<sup>2</sup> The pulp of a tooth can be exposed due to several causes, including dental caries, trauma, and during cavity preparation. Caries penetration of the pulp can cause bacteria invasion of the pulp, resulting in pulpal inflammation. The goal of vital pulp therapy is to treat reversible pulpal injury and maintain pulp vitality.

This randomized clinical trial compares the clinical and radiographic success rate of FC and 5% NaOCl as a pulpotomy medicament in primary molars. The clinical success rate at 3 and 6 months was 100% for both groups. Radiographic success rate for FC was 95% at 3 months and 90% at 6 months, whereas for NaOCl it was 90% at 3 months and 85% at 6 months. Our results are similar to those of Vargas et al<sup>6</sup> and they compared the effectiveness of 5% NaOCl with that of ferric sulfate (FeSO<sub>4</sub>) as a pulpotomy medicament in decayed primary molars. At 6 months, 100% clinical success was found in both FeSO<sub>4</sub> and NaOCl groups. Radiographic success for FeSO<sub>4</sub> was 68%. The NaOCl group showed 91% radiographic success. At 12 months, FeSO<sub>4</sub> had 85% clinical success and 62% radiographic success. NaOCl had 100% clinical success and 79% radiographic success. Vostatek et al<sup>7</sup> evaluated the clinical/radiographic success over 21 months of 5% NaOCl as the medicament in primary

molar pulpotomies. The NaOCl pulpotomies had a 95% clinical and 82% overall radiographic success rate.

Pulpotomy is one of the simple and commonly used treatments in the management of extensive caries in primary molars. Formocresol remains the “gold standard” for therapeutic pulpotomy in human primary teeth at a 1:5 dilution. Formocresol contains 19% formaldehyde, 35% cresol in a vehicle of 15% glycerine and 31% water (Buckley's FC).<sup>8</sup> The active ingredients of FC are formaldehyde and cresol. The first clinical success of FC was reported by Sweet<sup>8</sup> in the 1920s who introduced a five appointment pulpotomy procedure using arsenic followed by FC as the devitalizing agent. Redig<sup>9</sup> reported good success rate with 5-minute single visit pulpotomy in human teeth, after which the 5-minute treatment with FC has remained, the standard against which all new modalities are compared. Doyle et al<sup>10</sup> compared the FC pulpotomy technique with the calcium hydroxide technique in primary canines and found the FC technique to be 95% clinically successful at the end of 1 year.

Question regarding carcinogenicity and mutagenicity is raised by various researchers. Meyers et al<sup>11</sup> reported that 14C-labeled formaldehyde used in pulpotomy of primates has been found in PDL, bone, dentin, and urine. Small amounts of labeled formaldehyde were detected in liver, kidney, lungs, skeletal muscle, and cerebrospinal fluid within minutes of the medicament being placed at the pulpotomy site. These findings were confirmed by Pashley et al.<sup>12</sup> However, Ranly et al calculated that over 3,000 pulpotomies would have to be performed in the same individual at the same time for FC to reach the toxin levels systemically.<sup>13</sup>

Sodium hypochlorite is also called as Dakin's solution. It was first used in the First World War as an anti-septic agent to clean wound.<sup>14</sup> Grossman used 0.5 to 5.25% of NaOCl for root canal irrigations in the year 1961; since then, it has become a very popular medicament for such treatment in both the primary and permanent dentition.<sup>14</sup>

Hafez et al<sup>5</sup> have performed two histological studies and reported NaOCl to be biologically compatible with exposed pulp tissue when used as a hemostatic agent in direct pulp capping. Rosenfeld et al demonstrated that using 5% NaOCl had superficial effects on pulpal tissue, and its effects on deeper tissues were minimal.<sup>15</sup>

The radiographic success rate of NaOCl in the present study is similar to that observed in a number of previous studies.<sup>7,16</sup> The primary cause of radiographic failure in the present study in the NaOCl group was internal root resorption, which was seen in three cases, which could be explained by the concentration used or the ZOE base. Hemostasis is a critical factor for clinical success of pulpotomies and is best achieved with NaOCl.

Thus, NaOCl has been found to have promising results as a pulpotomy agent in primary teeth with results comparable to the agent of choice for maintaining vital pulp tissue, i.e., calcium hydroxide (the associated internal resorption being the major problem with calcium hydroxide). Coupled with the easy availability of NaOCl in each and every clinical scenario, it can be stated that for preservation pulpotomies, NaOCl is one of the best materials available at easy disposal to every dentist.

## CONCLUSION

The 5% NaOCl and FC showed no significant difference in their success rate. Hence, NaOCl can be used as pulpotomy medicaments; nonetheless, further clinical trials with long follow-up period are required.

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