Abstract: Purpose: This study’s purpose was to compare the clinical and radiographic success rates of 5.25 percent Sodium Hypochlorite (NaOCl) pulpotomies to Formocresol (FC) and Ferric Sulfate (FS) in decayed primary molars. Methods: Eighty-one primary molars, randomly divided into three groups, were treated with one of three different pulpotomy materials; NaOCl, FC, and FS. The outcomes of the different groups were assessed clinically and radiographically every six months over 18 months. Chi-square test was used to detect differences in outcome measures in all groups. Results: At six months, clinical and radiographic success rates were 100 percent for each group (27/27). At 12 months, clinical success was 100 percent (24/24), 96 percent (24/25), and 95.7 percent (22/23) for NaOCl, FC, and FS respectively. The radiographic success was 95.8 percent (23/24) for NaOCl group, and 100 percent for FC (25/25), and FS (23/23). At 18 months, the clinical success was 83.3 percent (20/24), 96 percent (24/25), and 87 percent (20/23) for NaOCL, FC, and FS respectively. The 18 month radiographic success was 91.7 percent (22/24), 100 percent (25/25), and 95.7 percent (22/23) for NaOCl, FC, and FS respectively. No significant differences were found in clinical or radiographic outcomes between the three groups at six, 12, and 18 months. Conclusion: The three pulpotomy medications yielded similar outcomes. (Pediatr Dent 2015;37(7):535-40) Received March 5, 2015  Last Revision September 17, 2015  Accepted September 17, 2015

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Sodium Hypochlorite Versus Formocresol and Ferric Sulfate Pulpotomies in Primary Molars: 18-month Follow-up
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A pulpotomy, which is the most common treatment modality for carious pulp-exposed and symptom-free primary molars, aims to preserve the vitality of the radicular pulp, limit pain and inflammation, and maintain the tooth in the oral cavity until the successor tooth erupts.1,2 Fuks noted that the ideal dressing material in a pulpotomy should be bactericidal, remain harmless to the pulp and surrounding structures, promote healing of the radicular pulp, and allow the physiological process of root resorption.2 Many medicaments with varying degrees of success have been introduced, but none are considered ideal.3,4 In a Cochrane review by Nadin et al., it was concluded that there was no reliable evidence supporting the use of a particular agent or technique over others in pulpotomies of primary teeth.5

The most commonly used pulp medicament is formocresol (FC), which was first introduced by Buckley in 1904.6 Buckley’s FC formulation consisted of 19 percent formaldehyde, 35 percent cresol, 17.5 percent glycerin, and water. Studies have reported clinical success rates of 87 to 100 percent with FC pulpotomies in the primary molar.7–10 Despite its popularity, use of FC has been challenged because of the potential cytotoxic, mutagenic, and carcinogenic effects of formaldehyde in humans and the reports of enamel defects in succedaneous teeth of those treated with FC pulpotomies.11,12 The Interna-
Methods
The protocol of this randomized clinical trial was approved by the ethics committee of the Faculty of Dentistry at King Abdulaziz University, Jeddah, Saudi Arabia. The study sample was recruited from the faculty's pediatric dentistry clinics over two months. Eighty children who had deep carious lesions in their primary molars were screened for study eligibility.

As per the clinical inclusion criteria, children were recruited for the study if they were healthy, four to eight years old, and had restorable primary molars with deep carious lesions with no pain (or pain only upon provocation), no mobility, no tenderness to percussion or palpation, no swelling, and no sinus-draining fistulas or chronic abscesses.

Radiographically, the inclusion criteria were as follows: normal periodontal tissues; no widening of the periodontal ligament space; no internal or external root resorption; and no apical or furcation radiolucencies.

Before starting treatment, the risks and benefits were discussed with the parents and written consent for treatment was obtained. Of the 80 screened children, 67 met the aforementioned inclusion criteria. Exclusion was based on the non-removability of the teeth (five children), radiographic pathology (six children), and refusal to participate in the study (two children). Among the 67 included children, 81 teeth were eligible for the pulpotomy procedure (Figure). The teeth were randomly assigned to groups and treated with NaOCl, FC, or FS. A parallel design was used, because only some of the children had more than one molar requiring pulpotomy. The tooth was considered the unit for randomization. The teeth were randomly allocated into three equal groups of 27 molars with the Researcher Randomizer program (Version 4, Urbania, G.C., & Plous, S.)39 On the day of the procedure before the pulpotomy was performed, the surgeon was given a sealed envelope that contained a letter denoting the medicament group. The patients were not informed about their group allocation. Randomization occurred after the consents were obtained.

Surgical technique. Two of the coauthors, who were pediatric dentists and who did not perform the randomization, performed all pulpotomies. The surgical techniques were calibrated and standardized with a detailed rubric for the pulpotomy. The surgeons were not blinded to the technique, as the technique used for each medicament differed slightly. All of the carious molars were properly anesthetized and isolated with a rubber dam. After caries removal, coronal access was obtained with a sterile no. 330 high-speed carbide bur (Hager & Meisinger GmbH, Neuss, Germany) under water spray to deroof the pulp chamber. The coronal pulp was removed with a sterile no. 330 high-speed carbide round bur (Hager & Meisinger GmbH), and hemostasis was obtained by applying light pressure with a moist sterile cotton pellet over the pulp stumps for five minutes. Hemostasis was successfully achieved in all of the cases.

In the NaOCl group, a sterile cotton pellet soaked in 5.25 percent NaOCl (Karamji Chemical Industries, Noida, Uttar Pradesh, India) was placed over the pulp stumps for 15 seconds. In the FC group, a dried cotton pellet damped with a one-to-five-ratio Buckley’s FC formulation was placed for five minutes. In the FS group, a sterile cotton pellet saturated with 15.5 percent FS was placed over the pulp stumps for 15 seconds. In all groups, the medicament was not rinsed off the pulp stumps and the pulp was covered with zinc oxide-eugenol cement and then restored with a well-fitting stainless steel crown cemented with a glass ionomer cement.

The treated children were evaluated clinically and radiographically at six, 12, and 18 months after surgery. Periapical radiographs were taken by applying the bisecting angle technique with a Rinn XCP (Dentsply International, Inc., York, Pa., USA) in order to enhance reproducibility. The clinical and radiographic follow-up examinations were performed by two experienced dentists (other than the original operators) who were blinded to the groups. The interexaminer reliability, which was assessed at each follow-up period, was strong (kappa equals 0.83). The intra-examiner reliability, which was assessed on 20 patients examined on two occasions over a one-week interval, was almost perfect (kappa equals 0.91). In case of any disagreement, a consensus was reached by re-examining the radiograph and coming to an agreement.

The treatment was considered a clinical failure if the tooth presented with any of the following clinical signs or symptoms: pain; swelling; sinus tract; mobility; or pain on percussion. The treatment was considered a radiographic failure if the periapical radiograph showed: internal root resorption; furcation radiolucency; periapical radiolucency; or widening of the periodontal ligament space. Any tooth that had a treatment failure received proper treatment tailored to that particular tooth. Pulp canal obliteration was not considered to be a failure.

Statistical analysis. Statistical analysis was conducted with Statistical Package for the Social Sciences (SPSS, Version 16;
IBM Corporation, Armonk, N.Y., USA). Chi-square tests were used to detect the differences in the outcome measures in the three groups at each follow-up examination. Differences in the performance of each material over time were tested via McNemar’s test. The significance level was set to less than 0.05.

**Results**

The children’s age at the beginning of the study ranged from four to eight years old, with a mean age of 7.00±1.40 (standard deviation) years old for the NaOCl group, 7.50±1.42 years old in the FC group, and 6.70±0.98 years old in the FS group. The sample consisted of 81 teeth in 36 boys and 31 girls. All of the treated children returned for the six-month follow-up, while some children were lost for the consecutive follow-up appointments despite repetitive phone calls (Figure). At the 12-month follow-up, nine teeth (five children) were lost to follow-up: three, two, and four teeth in the NaOCl, FC, and FS groups, respectively. The guardians of three children refused to come for further follow-up appointments after the comprehensive dental treatment was completed. Two children had moved to distant cities. These teeth were dropped from the data for the 12- and 18-month follow-up examinations.

The Table shows the clinical and radiographic outcomes at the three follow-up clinical and radiographic examinations. At six months, 100 percent clinical and radiographic success rates were observed in all three groups.

At the 12-month visit, 24 teeth remained in the NaOCl group, 25 teeth remained in the FC group, and 23 teeth remained in the FS group. No teeth showed clinical failure in the NaOCl group. However, in the FC group, one tooth out of 25 (four percent) displayed grade one mobility, and one tooth out of 23 (4.3 percent) in the FS group was sensitive to percussion. The extracted tooth that had presented with a history of spontaneous pain at 12 months (four percent) in the FS group showed furcation radiolucency. This was the same tooth that had presented with grade one mobility in the FC group at 12 months still displayed grade one mobility at 18 months.

In the NaOCl group, four teeth had clinical signs of treatment failure (16.7 percent). Two teeth displayed grade one mobility, one showed sensitivity to percussion, and one displayed spontaneous pain. The tooth with grade one mobility in the FC group at 12 months still displayed grade one mobility at 18 months (four percent). In the FS group, two teeth displayed clinical signs of failure: one presented with spontaneous pain, while the other one was sensitive to percussion. The extracted molar in the FS group at 12 months was still considered a failure, resulting in a total failure rate of 13 percent. The differences in the success rates of the three groups were not statistically significant.

Radiographically, at 18 months two teeth out of 24 (8.3 percent) in the NaOCl group showed internal root resorption. One was the tooth that had presented with a history of spontaneous pain while the other was one of the teeth with grade one mobility. No radiographic pathology was noted in any of the teeth in the FC group. One tooth out of 25 (4.3 percent) in the FS group showed furcation radiolucency. This was the same tooth that had presented with a history of spontaneous pain at 18 months. The radiographic success rates were 91.7 percent for the NaOCl group, 100 percent for the FC group, and 91.3 percent for the FS group. No statistically significant differences were noted in the radiographic success rates of the three groups.

The total number of teeth with clinical or radiographic failure at 18 months was eight. These teeth were treated by monitoring (four out of eight), pulpectomy (two out of eight), or extraction (two out of eight), including the tooth extracted at 12 months.

| Table. CLINICAL AND RADIOGRAPHIC PERFORMANCE OVER 18 MONTHS OF SODIUM HYPOCHLORITE, FORMOCRESOL, AND FERRIC SULFATE WHEN USED AS PULPOTOMY MEDICAMENTS |
|-------------------------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Clinical performance                            | NaOCL            | FC              | FS              | P-value*        |
| Follow-up period                                | Success          | Failure         | Success         | Failure         | Success         | Failure         | Success         | Failure         |                 |
| N                                               | N %              | N %             | N %             | N %             | N %             | N %             | N %             | N %             |                 |
| 6 mos                                           | 27               | 0               | 27              | 100             | 0               | 0               | 27              | 27              | 100             |
| 12 mos                                          | 24               | 0               | 25              | 96              | 1               | 4               | 23              | 22              | 95.7            |
| 18 mos                                          | 24               | 4               | 25              | 96              | 1               | 4               | 23              | 20              | 87              |
| P-value†                                        | 0.341            | 0.567           | 0.317           |                 |                 |                 |                 |                 |                 |
| Radiographic performance                        |                  |                 |                 |                 |                 |                 |                 |                 |                 |
| 6 mos                                           | 27               | 0               | 27              | 100             | 0               | 0               | 27              | 27              | 100             |
| 12 mos                                          | 24               | 1               | 25              | 95.8            | 1               | 4.2             | 25              | 25              | 100             |
| 18 mos                                          | 24               | 1               | 25              | 91.7            | 2               | 8.3             | 25              | 25              | 100             |
| P-value†                                        | 0.299            |                 | 0.317           |                 |                 |                 |                 |                 |                 |

* Difference between the follow-up periods using McNemar’s test.  
† Difference between materials using chi-square test.
Discussion

Although FC is still considered the most frequently used pulpotomy medicament in dental schools,\(^9\) the American Academy of Pediatric Dentistry (AAPD) encourages additional research on new techniques and biologically compatible medicaments.\(^8\) These recommendations motivated us to conduct this study to investigate the effectiveness of 5.25 percent NaOCl as a pulpotomy dressing material.

As a pulpotomy agent, histological studies have shown that NaOCl aids in the removal of blood clots and stops hemorrhage that compromises healing of the pulp.\(^7\) Bacteria may remain in the pulp canal orifices after pulp amputation, causing an inflammatory reaction. The antimicrobial properties of NaOCl enhance the capacity of the pulp to heal and increase the treatment success rates.\(^9\)

The results of this prospective randomized clinical trial revealed no significant differences in the success rates of NaOCl, FC, and FS as pulp dressing materials. All three materials showed 100 percent clinical and radiographic success rates at the six-month follow-up. These findings suggest accurate selection of the sample, as the improper selection of teeth at the time of treatment has been reported as the main cause of the early failure of pulpotomy treatments.\(^9,\)\(^10,\)\(^36\)

The results at the six-month follow-up demonstrated clinical success rates consistent with those of previous studies. In 2002, a study by Ibricevic et al. recorded a 100 percent clinical success rate for both FC and FS pulpotomies on a nine-month recall visit.\(^11\) Two studies conducted by Farsi et al. and Ruby et al. have also demonstrated favorable results, with a 100 percent clinical success rate observed with FC at the six-month recall visits.\(^12,\)\(^13\) The 100 percent success rate of NaOCl at the six-month visit was similar to the results of previous reports.\(^9,\)\(^10,\)\(^36\)

Similar to our 12-month results, 100 percent clinical success rates with NaOCl were demonstrated by Ruby et al. and Vargas et al.\(^9,\)\(^10,\)\(^24,\)\(^23\) In a 2001 retrospective study by Vostatek et al., the success rate of NaOCl pulpotomies was 95 percent. Although a similar concentration of NaOCl (five percent) was used in that study, the authors claimed that the failures could have been due to improper diagnosis of the cases in addition to the limited clinical experience of the surgeons.\(^9\)

In the FS group, only one tooth presented with sensitivity to percussion. Although percussion is one of the most reliable pulpal tests in primary teeth,\(^7\) it is still very subjective and variable in children. Despite that clinical finding, there was no radiographic pathology. This discrepancy might have been the result of an early pulpal pathology detectable at a histological level but that had not yet materialized into a pathological radiographic finding.

At the 18-month recall visit, the FC group showed the best clinical results, with a 96 percent success rate, but the difference was not significant. Therefore, these results do not support the use of FC over the other two materials. The previous studies on NaOCl reported follow-up examinations for only 12 months.\(^9,\)\(^10,\)\(^23,\)\(^24\) Only Vostatek et al., who investigated the cases for 21 months, reported a 95 percent clinical success rate over this period, but their study design was retrospective and only investigated NaOCl.\(^9\)

The 100 percent radiographic success rates of all three materials at six months in the present study were higher than most previous reports of follow-up examinations that were conducted for less than 12 months. In a study by Ibricevic et al., the radiographic success rates for FS and FC at the nine-month recall were both 97 percent.\(^11\) Furthermore, in contrast to the results of the present study, a less favorable radiographic success rate of 86 percent was demonstrated by Ruby et al., in which two teeth showed internal root resorption with NaOCl at six months.\(^9\)

Although most previous studies on NaOCl pulpotomies were concluded at six or 12 months, the present study showed a higher radiographic success rate of 91.7 percent at 18 months.\(^9,\)\(^10,\)\(^23,\)\(^24\) Only one case exhibited internal root resorption in the NaOCl group at 12 months. At 18 months, one additional tooth developed internal root resorption in the NaOCl group, and one tooth in the FS group developed furcation radiolucency. Similar to the findings of Ruby et al., the most common cause of radiographic failure in this study was internal root resorption.\(^9\) This type of resorption has been suggested to be the result of chronic pulpsitis.\(^37\) An explanation for the resorption noted in this study could be attributed to NaOCl’s nonspecific and non-coagulating digestive effect on vital human pulp tissue, which was reported by Rosenfeld.\(^38\)

The radiographic success rate of NaOCl in the present study was better than that observed in a number of previous studies.\(^9,\)\(^10,\)\(^23,\)\(^24\) In the present study, the primary cause of radiographic failure in the NaOCl group was internal root resorption, which was seen in three cases. These findings differed from those of Al-Mutairi and Bawazir, who reported that furcation radiolucency was the most commonly detected radiographic failure.\(^9\) Almost all of the previous studies considered internal root resorption a sign of radiographic failure, except for Holan et al., who considered internal resorption a failure only when it reached the bone; arrested internal resorption, calcific metaplasia, and pulp canal obliteration were not counted as failures.\(^38\)

The difference between the findings of the current study and those of other studies could be attributed to differences in the methodology, such as the use of a three percent concentration of NaOCl by Shabzandedar et al. and Ruby et al. in contrast to the 5.25 percent used in the present study.\(^9,\)\(^10\) Other differences, such as sample size, could explain the higher success rate of NaOCl found in the current study. In the current study, 24 teeth were observed in the NaOCl group at the last visit, while Ruby et al. and Vergas et al. examined, respectively, 15 and 14 teeth and reported 80 percent and 79 percent radiographic success rates.\(^9,\)\(^24\)

In this study, NaOCl was compared to FC and FS because of their high documented success rates. FC is still the gold standard agent for pulpotomies in primary molars. However, FS is also a successful pulpotomy medicament that has hemostatic properties similar to those of NaOCl. Despite the high success rate of MTA as a pulpotomy agent, its high cost discouraged us from using it in the current study as one of the control medicaments.\(^20,\)\(^21\)

One of the greatest challenges in randomized clinical trials with a long-term follow-up is the dropout of patients, especially pediatric patients, and this was the main limitation of this study. Another limitation was that a split-mouth design was not used. Split-mouth design was not attempted, as it is very difficult to find cases with contralateral primary molars in the same arch indicated for pulpotomy and that have the same clinical and radiographic criteria. Finally, the follow-up period of 18 months, although longer than previous studies, is still a short period because it is shorter than the expected lifespan of many primary molars.
These findings suggested that NaOCl can to be used as a pulpotomy agent. NaOCl has been reported to have therapeutic properties that expedite pulpal healing. It facilitates hemostasis, stimulates debridement of necrotic tissue, aids in the removal of the clots, has an antiseptic effect, and is inexpensive.\(^9\),\(^39\)

The results of the present study showed similar success rates for the three materials. Because FC has potential cytotoxicity and carcinogenicity, we suggest the use of NaOCl, because its superior properties and biocompatibility indicated that it is a suitable alternative for vital pulpotomies in primary molars.

**Conclusions**

Based on this study’s results, the following conclusions can be made:

1. Sodium hypochlorite, formocresol, and ferric sulfate pulpotomy medicaments showed no statistical differences in their success rates.

2. Further longitudinal studies with longer follow-up periods and larger sample sizes are encouraged.

**References**


