SCIENTIFIC ARTICLE

# Preliminary Evaluation of Sodium Hypochlorite for Pulpotomies in Primary Molars

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## Abstract

**Purpose:** The purpose of this study was to compare the effectiveness of 5% sodium hypochlorite (NaOCl) to that of ferric sulfate ($FeSO_4$) as a pulpotomy medicament in decayed primary molars.

**Methods:** Healthy subjects between 4 and 9 years with at least 2 primary molars needing pulpotomy consented to receive either NaOCl or $FeSO_4$ and restoration with IRM base/stainless steel crown in a prospective, randomized design. Clinical and radiographic signs/symptoms were recorded at 0, 6, and 12 months.

**Results:** Twenty-three subjects were recruited. Six-month results are based on the first 32 teeth in the NaOCl group and 28 teeth in the $FeSO_4$ group. Twelve-month results are based on 13 teeth in the $FeSO_4$ group and 14 in the NaOCl group. Results show 100% restoration retention in both groups and no signs/symptoms of pain at 6 and 12 months. At 6 months, 100% clinical success was found with both $FeSO_4$ and NaOCl. Radiographic success for $FeSO_4$ was 68%, with internal resorption being the most common finding. The NaOCl group showed 91% radiographic success, $P$=.050. At 12 months, $FeSO_4$ had 85% clinical success and 62% radiographic success. NaOCl had 100% clinical success and 79% radiographic success.

**Conclusion:** Preliminary evidence shows that NaOCl can be used successfully as a pulpotomy medicament. (Pediatr Dent 2006;28:511-517)


KEYWORDS: PULPOTOMY, FERRIC SULFATE, SODIUM HYPOCHLORITE, PRIMARY MOLARS

*Received April 20, 2006 Revision Accepted May 24, 2006*

Caries, if left untreated, has profound physiological and social effects.[1] In children, caries can reduce food intake, alter sleep habits, and increase the number of school days missed and parental work loss.[2] In young children, extraction of the carious molars is not recommended due to subsequent space loss, blocked out permanent teeth, and difficulty eating.[2] The treatment of choice, therefore, is a pulpotomy of the carious molar.

Over the past 20 years, the use of formocresol as a pulpotomy agent has been challenged due to its: (1) systemic distribution; (2) pulpal inflammatory response; (3) cytotoxicity; and (4) carcinogenic potential.[3-5] In 1991, Fei proposed the use of ferric sulfate ($FeSO_4$) as an alternative medicament to formocresol.[6] Since then, several other studies have been found in the literature.[7-11] Even though high clinical success rates have been found using both formocresol and $FeSO_4$, histologic studies have shown that both produce severe inflammatory responses.[12-13] Fuks found 40% of pulps treated with either formocresol or $FeSO_4$ had severe inflammation.[12] Similarly, Salako et al found complete pulpal destruction with $FeSO_4$ and pulpal necrosis with formocresol pulpotomies performed on rat molars.[13] Vargas and Packham found that teeth treated with formocresol and $FeSO_4$ also had a high incidence of premature loss due to resorption or abscess formation leading to pain, swelling, and space loss.[14] Thus, the potential for these chronic inflammatory responses to affect tooth exfoliation and succedaneous tooth formation must not be discounted.

One promising alternative to pulpotomy medicament is sodium hypochlorite (NaOCl), which has been used as an irrigant in permanent tooth root canal treatment since the 1920s[15] and has been shown to be a very good antimicrobial without being a significant pulpal irritant.[16,17] Rosenfeld et al showed that placement of 5% NaOCl on noninstrumented vital pulp tissue acted only at the surface, with minimal effects on deeper pulpal tissue.[18] Although NaOCl has not been used as a pulpotomy medicament in primary teeth, Hafez et al showed no pulpal inflammation after hemorrhage control was obtained with 3% NaOCl in pulpotomized adult monkey teeth. In contrast, significant

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pulpal necrosis was found with formocresol.[19,20] Accorinte et al evaluated $FeSO_4$, NaOCl, calcium hydroxide ($Ca(OH)_2$), and saline as hemostatic agents in pulpotomized human premolars restored with adhesive and composite resin. Their results showed that 60% of subjects with $FeSO_4$ pulpotomies had sensitivity to cold, and histological analysis showed intense inflammatory response. On the other hand, no subjects receiving either sodium hypochlorite or $Ca(OH)_2$ reported any pain or sensitivity. Histological assessment also showed comparable chronic inflammation for both of these medicaments.[21]

These findings lend support to the purpose of this pilot study, which was to compare the effectiveness of 5% NaOCl as a pulpotomy medicament in severely decayed primary molars to $FeSO_4$. The authors' null hypothesis was that the long-term radiographic and clinical success of primary teeth treated with NaOCl is the same for teeth treated with $FeSO_4$.

## Methods

### Participants

Following approval by the Internal Review Board of The University of Iowa, Iowa City, IA, healthy children who met the following inclusion criteria were invited to participate in this study:

1. between the ages of 4 and 9;
2. in need of at least 2 or more pulpotomies on primary molars (if the subjects had odd numbers of teeth requiring pulpotomies, only even numbers of teeth were used) which were asymptomatic and restorable with a cariously exposed vital pulp; and
3. who were able to cooperate for periapical radiographs.

If the child had an odd number of teeth requiring pulpotomies, the odd tooth received a formocresol pulpotomy, as this is the standard at the Department of Pediatric Dentistry, The University of Iowa, Iowa City, Iowa, and was not included in the study.

Teeth were excluded from the study if they had: (1) clinical mobility; (2) spontaneous pain; (3) swelling; (4) tenderness to percussion; or (6) unsuccessful hemorrhage control. Similarly, radiographic exclusion of teeth was based upon the presence of: (1) internal resorption; (2) furcal radiolucency; (3) widened periodontal ligament space; or (4) physiological root resorption of more than one third.

### Treatment

Fifteen-and-a-half percent $FeSO_4$ (control group; Astringident, Ultradent Products, Salt Lake City, Utah) or 5% NaOCl (Regal Liquid Bleach, IPI, Anamosa, Iowa) were used as parallel treatment methods. In all groups, after local anesthesia and rubber dam placement, caries was removed with a no. 330 carbide bur (Brasseler USA, Savannah, GA) with water spray in a high-speed handpiece (KaVo Dental Corp, Lake Zurich, Ill). After chamber access, coronal pulp tissue was removed using a slow-speed handpiece (KaVo Dental Corp., Lake Zurich, IL) with a no. 6 round carbide bur (Brasseler USA, Savannah, Ga). Control of complete removal of the pulp tissue down to the canal orifices was done by visual inspection.

Initial hemorrhage control was done by placing sterile cotton pellets on the radicular pulp stumps under slight pressure for no more than 5 minutes to ensure that the pulp was healthy. The 5-minute mark was chosen because this is the midpoint of the normal bleeding time range (1-9½ minutes[22]). At this stage, the achievement of complete hemostasis was an inclusion criterion. In the control $FeSO_4$ group, a syringe with a brush tip using a rubbing motion but with no pressure was used to deliver the medicament to the pulp chamber for 15 seconds. For the experimental group, a cotton pellet soaked in 5% NaOCl was placed in the chamber for 30 seconds. The cotton pellet was not expressed(dried) before placement in the chamber. In both groups, the solutions were rinsed with water making sure that no clot was present in the pulp chamber before final restoration. If bleeding started again, at this point, the tooth was eliminated from the study.

A zinc oxide eugenol base (Caulk-Denstply, Milford, Del) was then placed in the chamber of both treatment and control groups, and a stainless steel crown (3M/ESPE, St. Paul, Minn) was fitted and cemented with a glass ionomer cement (Ketac-Cem, 3M/ESPE). All procedures were performed by the principal investigator (KV).

### Follow-up

Clinical and radiographic evaluations were performed, immediately after the pulpotomy procedure was completed at 6 and 12 months. The clinical examination was performed by the principal investigator without immediate knowledge of which treatment had been rendered on which tooth. Clinical success at follow-up visits met the following criteria:

1. no spontaneous pain;
2. restoration intact;
3. no mobility;
4. no swelling;
5. no fistula;
6. no gingival inflammation—represented by pain, redness, or bleeding—around the tooth/crown.

Radiographic criteria used for this study was based on the criteria used by Strange et al.[23] Radiographic success at follow-up visits met the following criteria:

1. no external root resorption;
2. no internal root resorption;
3. no inter-radicular bone destruction.

All radiographs were read using the same standard view box by 2 co-investigators who were blinded to the technique used and who had been previously calibrated. If a discrepancy occurred between examiners, a consensus was reached by having both examiners view the radiographs again and come to an agreement. The inter- and intraexaminer reproducibility was calculated by Cohen's unweighted kappa statistic (0.73; $P<.001$)

**Table 1. Distribution of Primary Molar Pulpotomies by Tooth Type**

| Treatment | 6 mos | | | | | | 12 mos | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Tooth* | | | | | | Tooth | | | | | |
| | First molar | | | Second molar | | | First molar | | | Second molar | | |
| $FeSO_4$ | U | L | T | U | L | T | U | L | T | U | L | T |
| | 3 | 9 | 12 | 6 | 10 | 16 | 2 | 4 | 6 | 2 | 5 | 7 |
| NaOCl | 6 | 10 | 16 | 7 | 9 | 16 | 1 | 6 | 7 | 4 | 3 | 7 |

*U=upper; L=lower; T=total number of teeth. There were no significant differences between treatment groups for tooth type.

### Randomization

An allocation sequence was computer generated for the 2 treatments. $FeSO_4$ was assigned the no. 1 and NaOCl the no. 2. This allocation sequence was concealed until the day of the restorative visit. The random table was generated to correlate with the subject number. For example, subject number 1 may have been randomly assigned to have a $FeSO_4$ pulpotomy on the first tooth needing such a treatment. The other tooth received the other treatment. Subject assignment was made at the consent appointment, but allocation of the tooth according to the allocation sequence was made the day of the treatment visit. If a subject had more than 2 pulpotomies (4 or 6), then each subsequent pair of teeth was considered separately for reasons of treatment allocation. This randomization and allocation followed the current guidelines for randomized clinical trials put forth by CONSORT (consolidated standards for reporting clinical trials).[24]

### Statistical analysis

During follow-up, a clinical failure was recorded if the tooth presented mobility, swelling, fistula, or history of spontaneous pain. If the tooth presented only radiographic changes with no clinical symptom, then the classification was made as "radiographic failure" only. SigmaStat version 3.0 (Systat Software, Inc, Richmond, Calif) was used to perform statistical analysis with the Fisher exact test. Tooth type and location were also analyzed.

### Sample size

The sample size for this pilot study was determined from prior literature.[6,7,9] Data from this pilot study will be used to perform a power analysis for the subsequent larger scale trial.

## Results

### Demographic characteristics

Sixty primary molars were randomly allocated to the 2 treatment groups in 23 subjects (13 females, 10 males with a median age of 5 years [range=4-9 years]). No teeth were excluded from the study for failure to meet clinical or radiographic inclusion criteria. Thirty-two teeth received NaOCl pulpotomies, and 28 teeth received $FeSO_4$ pulpotomies. All 60 teeth had 6-month follow-up data, and 29 teeth had 12-month data (13 $FeSO_4$ and 16 NaOCl), including 28 first molars and 32 second molars. Tooth type was distributed in the following manner: 9 (15%) upper first molars, 19 (33%) lower first molars, 13 (22%) upper second molars, and 19 (33%) lower second molars (Table 1). Using the Fisher exact test, no significant differences were found between groups for the variables age, sex, tooth type, or tooth location for either 6 or 12 months.

### Clinical findings

Of the 60 teeth followed for 6 months, 100% (32/32) of the NaOCl and 100% (28/28) of the $FeSO_4$ pulpotomies were clinically successful. No teeth showed signs of mobility,

**Table 2. Clinical and Radiographic Success Rates for NaOCl and $FeSO_4$ Pulpotomies at 6 and 12 Months**

| Treatment | Clinical | | | | Radiographic | | | | Overall* | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 6 mos | | 12 mos | | 6 mos | | 12 mos | | 6 mos | | 12 mos | |
| | S | F | S | F | S | F | S | F | S | F | S | F |
| $FeSO_4$ | 28 (100%) | 0 | 11 (85%) | 2 (15%) | 19 (68%) | 9† (32%) | 8 (62%) | 5‡ (38%) | 84% | 16% | 74% | 27% |
| NaOCl | 32 (100%) | 0 | 14 (100%) | 0 | 29 (91%) | 3 (9%) | 11 (79%) | 3§ (21%) | 96% | 5% | 90% | 11% |
| Total | 60 | 0 | 25 | 2 | 48 | 12 | 19 | 8 | | | | |

S=success; F=failure.

*% clinical success+% radiographic success÷2.

†Significantly different, Fischer's exact, P=.050.

‡2 of the 5 radiographic failures were new.

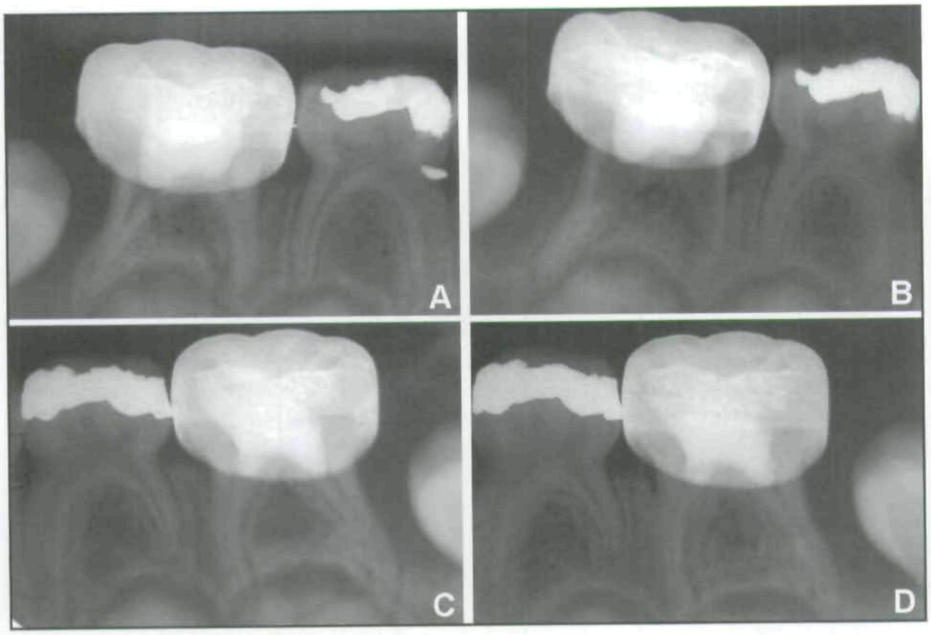


Figure 1. Ferric sulfate ($FeSO_4$) and sodium hypochlorite (NaOCl) pulpotomy on teeth T and K from the same subject. (A) Tooth T immediately after pulpotomy treatment with $FeSO_4$. (B) Tooth T at 6-month recall. Note internal resorption of mesial and distal roots. (C) Tooth K immediately after NaOCl pulpotomy. (D) Tooth K at 6-month recall. Note normal root structure.

fistula, swelling, or inflammation of the gingival tissue surrounding the tooth, as judged by: (1) redness; (2) tenderness to touch; or (3) bleeding around the crown/tooth (Table 2). Of the 29 teeth followed for 12 months, 2 teeth exfoliated in the same 8-year-old patient (she was 9 at the time of exfoliation), both of which were in the NaOCl group.

These 2 teeth were eliminated from further follow-up, leaving 27 teeth at 12 months (13 $FeSO_4$ and 14 NaOCl). Of these 27 teeth, 100% (14/14) of the NaOCl-treated teeth presented no clinical pathology and 85% (11/13) of the $FeSO_4$-treated teeth were asymptomatic. One tooth in the $FeSO_4$ group had gingival inflammation with bleeding around the crown due to the inflammation, and the other had a fistula on the buccal mucosa. Both of these teeth were second primary molars. The tooth with the fistula was treated with a pulpectomy, and the tooth with gingival inflammation is under observation.

### Radiographic findings

At the 6-month recall, pathologic changes were seen in 32% (9/28) of the teeth treated with $FeSO_4$ and in 9% (3/32) of the teeth treated with NaOCl ($P$=.050; Table 2). Internal resorption was the most common radiographic finding, regardless of treatment type (Figures 1 to 3). More specifically, 8 of the teeth treated with $FeSO_4$ had internal resorption and 1 had furcation involvement. Two of the teeth treated with NaOCl had internal resorption, and 1 had furcation involvement. Regardless of treatment, 6 radiographic failures were first primary molars and 6 were second primary molars, with no statistically significant differences. At 12 months, 2 of the 5 $FeSO_4$ failures noted were new (they had not been observed at the 6-month evaluation) and were due to internal resorption, but none of the NaOCl radiographic failures were new.

The overall success rates for $FeSO_4$ at 6 and 12 months were 84% and 74%, respectively. The overall success rates for NaOCl at 6 and 12 months were 96% and 90%, respectively (Table 2).

## Discussion

Pulp treatments for severely decayed primary molars have been conducted with success since the introduction of Buckley's formocresol in 1904.[25] Much controversy exists, however, due to the mutagenic and carcinogenic potential of formocresol.[26,27] For this reason, many other medicaments have been evaluated, with differing degrees of success and cost, as alternative treatments[6,9,12,26,28-31]: (1) glutaraldehyde; (2) electrosurgery; (3) lasers; (4) $Ca(OH)_2$; (5) mineral trioxide aggregate (MTA); and (6) $FeSO_4$. A consensus has not been reached on the ideal intrapulpal medicament, however, as the majority of the research published has not involved randomized clinical trials.[11,32] After conducting a search through the Cochrane Library of Clinical Trials, Nadin et al concluded that, given the available data, no assessment could be made regarding superiority of one pulp treatment over another and that no conclusion could be made as to the optimum treatment due to the scarcity of reliable scientific information.[32]

Given the existing paucity of information, conflicting evidence for success of current pulpotomy medicaments, and the need to find an alternative to formocresol, this research was designed to evaluate the effectiveness of 5% NaOCl. Thus far, the results have shown 100% clinical success and 91% radiographic success with NaOCl at 6 months and 100% clinical and 79% radiographic success at 12 months.

This is drastically different from what Vargas and others have found for $FeSO_4$. For example, Burnett and Walker found a 50% failure rate for $FeSO_4$[8] and Casas et al also observed internal resorption in 55% of $FeSO_4$ treated teeth.[33] In a retrospective study, Vargas and Packham looked at radiographic changes in $FeSO_4$ vs formocresol pulpotomies and found radiographic failure in 40% of teeth treated with $FeSO_4$.[14] These numbers compare well with the current findings of 32% radiographic failure at 6 months and 38% at 12 months for $FeSO_4$ in this study.

NaOCl has been used since 1915, when Dakin reported its successful use as an antiseptic for wound cleansing during World War I,[34] and has been used extensively as an endodontic irrigant[35]. Histologic studies have shown that

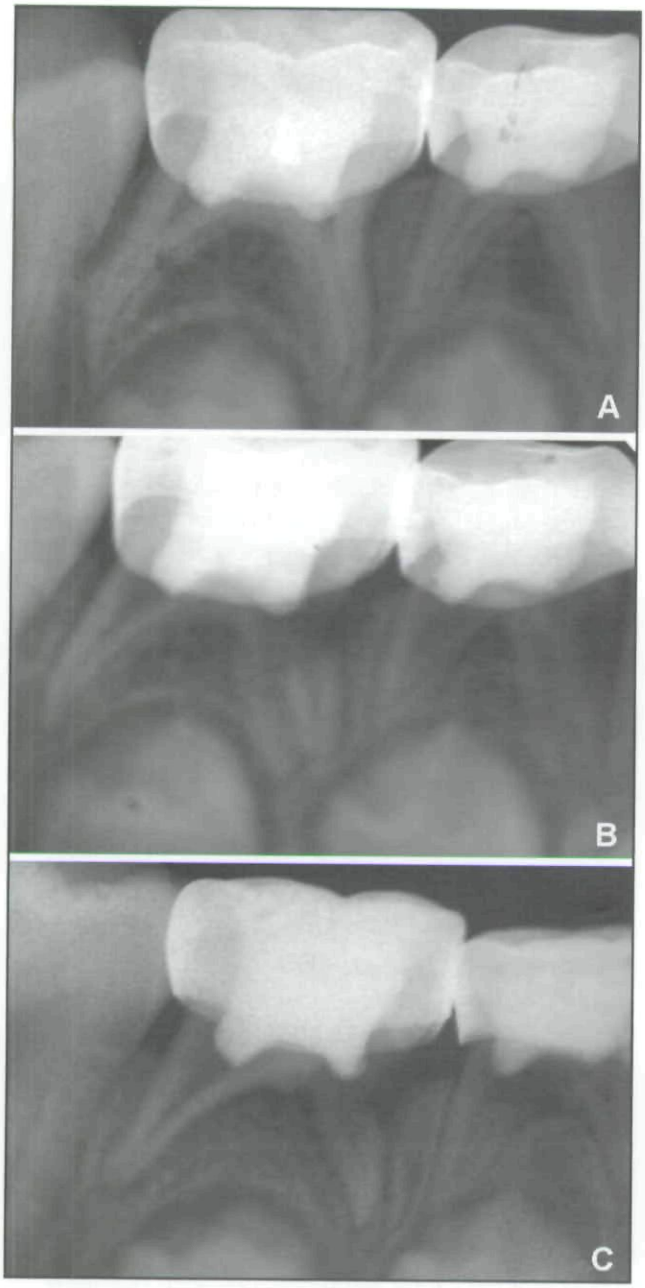

Figure 2. Teeth S and T from same patient. S had a NaOCl pulpotomy, and T had a $FeSO_4$ pulpotomy. (A) S and T immediately after pulp treatment. (B) S and T at 6-month recall. note internal resorption on both teeth. (C) S and T at 12-month recall. Internal resorption advancing. Both teeth are being monitored, with no clinical signs of inflammation.

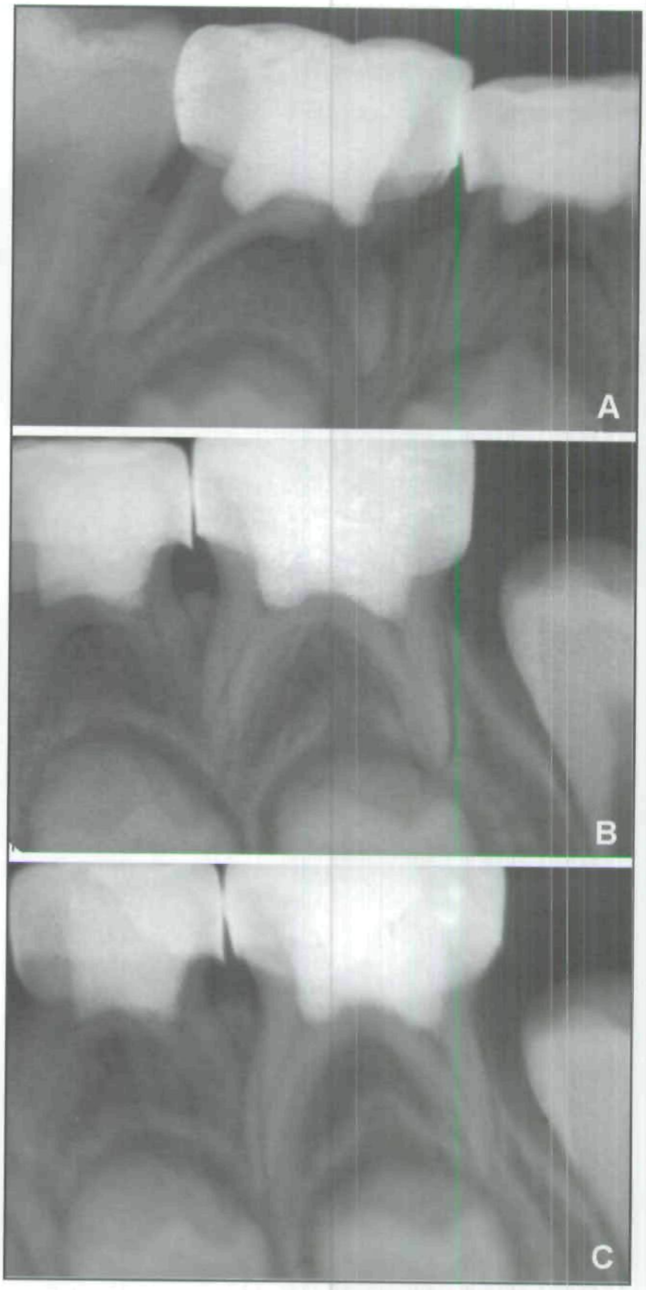

Figure 3. Successful $FeSO_4$ pulpotomy on tooth L and NaOCl pulpotomy on tooth K. (A) Immediately after pulpotomy. (B) Six-month recall. (C) Twelve-month recall.

NaOCl is compatible with pulp tissue and has only superficial effects on vital pulp tissue.

Rosenfeld et al found that, after placing 5% NaOCl intermittently on vital premolar pulp tissue for 15 minutes, only the first 3 or 4 layers of cells were digested by the irrigant while the underlying tissue remained unaffected.[18] Since the treatment in this study was only 30 to 40 seconds long, it stands to reason that the effects will be even more subtle. Hafez et al found that 86% of primate teeth irrigated with 3% NaOCl for 40 to 50 seconds had normal pulpal healing.[19] In a similar study, this group also found that a 40- to 50-second application of NaOCl was an effective hemostatic agent.[20] The evidence presented by these studies, along with the preliminary findings in this study, lends support to the use of NaOCl as a pulpotomy medicament in primary teeth.

The study presented here is unique in that it is it the first randomized clinical trial to use NaOCl as a pulpotomy medicament in primary molars. Also, the design was a prospective, randomized, partially blinded clinical trial following the guidelines set forth by the committee to standardize the reporting of clinical trials.[24]

## Conclusions

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

1. Preliminary evidence shows that sodium hypochlorite (NaOCl) is superior to ferric sulfate ($FeSO_4$) as a pulpotomy medicament in primary molars.
2. Internal resorption is the most common radiographic finding at 6 and 12 months for both $FeSO_4$ and NaOCl.


## Acknowledgement

This research was supported by the Obermann Center for Advanced Studies Spelman Rockefeller Grant from The University of Iowa, Iowa City, Iowa.


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## Abstract of the Scientific Literature

## Microstructure and Chemical Composition of Primary Teeth in Children with Down Syndrome and Cerebral Palsy.

If a sufficient stress is exerted on a developing permanent tooth, the location of the resulting imprint will reflect the timing and duration of the insult. The aim of this study was to investigate the timing and severity of growth insults expressed in the development of the lower mandibular primary secondary molars. Twenty-four exfoliated teeth from children with Down syndrome (DS), cerebral palsy (CP), and healthy controls were each divided into 48 ground sections for histological and chemical analysis using light microscope and energy dispersive X-ray spectrometer. In comparison to control teeth, the teeth from children with DS and CP had significantly less enamel produced prenatally, and less mineralization of the mesial cusps. The chemical analysis also showed that in comparison to the controls, the teeth from DS children had impaired mineralization and slower growth of all cusps . The authors concluded that prenatal growth insults of different etiologies leave permanent imprints in the developing dentition This may help in the differentiation between growth insults occurring in utero and those encountered during or after birth.

**Comments:** This interesting study highlights not only the chemical and structural differences between the teeth of children with DS and CP, but also that primary teeth are useful research tools for investigating the timing of severe systemic insults. **EKM**

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**Keinan D, Smith P, Zilberman. Microstructure and chemical composition of primary teeth in children with Down syndrome and cerebral palsy. Arch Oral Biol 2006; 51: 836-843.**

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