Scientific Article



Sodium Hypochlorite Pulpotomies in Primary Teeth: A Retrospective Assessment

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Abstract: Purpose: In 2007, the University of Iowa's advanced training program in pediatric dentistry replaced the traditional formocresol vital pulpotomy technique with a 5% sodium hypochlorite (NaOCI) technique. The purpose of this study was to evaluate the clinical/radiographic success over 21 months of 5% NaOCI as the medicament in primary molar pulpotomies compared to published data for formocresol and ferric sulfate pulpotomies. **Methods:** A retrospective chart audit was performed to evaluate results for all primary molar pulpotomies completed during a 12-month period using NaOCI. Dental records were reviewed for clinical and radiographic findings subsequent to pulp therapy. Clinical and radiographic criteria used to determine pulpotomy success were based on scientific literature. **Results:** One hundred ninety-two NaOCI primary molar pulpotomies were completed in 118 patients; 131 (68%) primary molars from 77 children were available for follow-up examination (mean time since pulpotomy=10.5 months). NaOCI pulpotomies had a 95% clinical and 82% overall radiographic success rate. External root resorption was the most common pathologic finding. Pulpotomy success diminished over time. **Conclusions:** Clinical and radiographic success rates in this study on NaOCI pulpotomies are comparable to formocresol and ferric sulfate pulpotomies reported in the literature. Further study with longer observation periods is warranted. (Pediatr Dent 2011;33:327-32) Received December 7, 2009 I Last Revision October 18, 2010 I Accepted November 11, 2010

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One of the primary objectives for the pediatric patient is the preservation of the primary dentition until the permanent successors normally erupt. Pulpotomies, a mainstream procedure in pediatric dentistry, serve this purpose by preventing teeth with carious pulp exposures from being extracted, thus maintaining arch integrity until natural exfoliation occurs.¹

Practiced for over a century, the "therapeutic pulpotomy" is defined in the 2008-09 AAPD Reference Manual as a clinical procedure to remove the infected coronal pulpal tissue in order to preserve the vitality and function of the radicular pulp.² Although controversial, formocresol has been the "gold standard" for pulp therapy for the past 100 years, and continues to be the most widely used and advocated treatment for pulpally involved primary molars.³⁻⁶ Studies have reported clinical success rates for formocresol pulpotomies ranging be tween 70- 97%.7-12 Histologic results, however, have been problematic. In stark contrast to the goal of preserving vital radicular pulp tissue, no healing attributes have been found with formocresol.¹³ In fact, formocresol has been found to be cytotoxic, devitalizing the pulp and causing chronic inflammation and tissue necrosis.¹³⁻²² Other concerns include possible diffusion of formocresol from the pulpal site into the systemic circulation.14-18

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Despite its overall success as a pulpotomy agent, formocresol has come under recent scrutiny both in the public and the scientific arena due to the potentially mutagenic and carcinogenic effects of formaldehyde in humans.^{11,16,17,22-25} In June 2004, the International Agency for Research on Cancer (IARC) classified formaldehyde as carcinogenic to humans stating "there is now sufficient evidence that formaldehyde causes nasopharyngeal cancer in humans, limited evidence for cancer of the nasal cavity and paranasal sinuses, and 'strong but not sufficient evidence' for leukemia."^{6,25} Growing concerns have led to discontinuing the use of formocresol in at least 2 countries.^{6,27}

Further complicating matters is the fact that the 1:5 dilution of Buckley's formocresol that is most universally advocated for use in pediatric dentistry is not commercially available.²⁸ An investigation by King et al., surveyed practicing pediatric dentists to discover if the practitioner used fullstrength or diluted formocresol, and how that dilution was acquired. The results showed that only 2% of the respondents were using the correct dilution of formocresol and 32% mistakenly believed they were purchasing a diluted form. Another major concern, besides the preparation of the correct formulation of diluted formocresol, is the uncertainty related to shelf life. A full-strength formocresol solution is considered to have a 2-month shelf life.²⁹ Yet, due to the speculative volatile nature of formocresol in the diluted form, one is required to dilute immediately before use, making compliance unrealistic.

Safety concerns about formocresol have led to other proposed treatment alternatives for pulp therapy—most recently ferric sulfate.⁶ Fei et al., introduced the use of ferric sulfate

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(FS) in 1991, showing a higher clinical and radiographic success rate after 1 year in human primary teeth than formocresol.³⁰ The authors attributed the success of FS to its promising hemostatic properties and the encouraging response of the pulpal tissue. Although clinical success rates reported in the literature range from 81% to 97%,^{12,30-36} similar to formocresol, FS is not without its shortcomings.

Fuks et al., after placing a 15.5% FS solution in the pulpotomized primary teeth of baboons, reported that 35% of the group experienced severe inflammatory changes.³⁷ Casas et al., observed the radiographic failure of FS over a 2-year period, reporting that 55% of treated molars experienced periapical radiolucencies and internal resorption.³⁸ Furthermore, under histological analysis, Salako et al., found acute inflammatory infiltrates, widespread necrosis and complete pulpal destruction in both formocresol- and FS-treated teeth.³⁹ Vargas et al., reported how chronic pulpal degradation from FS led to a higher incidence of premature exfoliation and abscess formation.⁴⁰

Alternative medicaments continue to be explored for use in primary molar pulpotomies, including sodium hypochlorite (NaOCI), which has been successfully used for decades in endodontic therapy as an irrigant for permanent teeth.^{41,42} Since the 1950s, studies have verified that NaOCl is biocompatible and nonirritating to exposed pulpal tissue and is an effective hemostatic agent. 43-47 Hafez and others have demonstrated that the application of NaOCl selectively dissolves the superficial necrotic pulp tissue while leaving the deeper healthy pulp tissue unharmed.⁴⁸⁻⁵³ Cox et al., whose study evaluated the pulpal response in primate teeth, maintains that hemostasis is the most critical factor for clinical success, and that it is best achieved with NaOCl.43 Yet, unlike the medicament FS, which demonstrates only hemostatic properties,^{38,54} NaOCl has other desirable qualities, including being an effective antiseptic without being a significant pulpal irritant.41-43,49-51,53

In 2006, Vargas et al., reported promising results from a pilot study using 5% NaOCl as a primary molar pulpotomy agent.⁵⁵ Their study revealed preliminary evidence that NaOCl had favorable results when compared to results from FS. Chompu-Inwai et al. compared vital pulpotomy techniques in primary molars using NaOCl with a resin modified glass ionomer base to the traditional diluted formocresol with a zinc oxide eugenol base. The 3-month clinical and radiographic evaluation indicated no symptoms and similar effectiveness when comparing the 2 medicaments.⁵⁶

As a result of these preliminary findings and due to the growing concern about formocresol, on April 1, 2007, the advanced training program in pediatric dentistry at the University of Iowa, Iowa City, Iowa, replaced the traditional 1:5 diluted formocresol/zinc oxide eugenol vital pulpotomy with 5% NaOCl/zinc oxide eugenol as the medicament of choice for vital pulpally involved primary molars.

The purpose of this retrospective study was to evaluate clinical and radiographic data from patients receiving 5% sodium hypochlorite pulpotomies performed by pediatric dentistry faculty and residents at the University of Iowa during a 12 month period and followed for up to 21 months and to compare this data to published data for pulpotomies performed with traditional formocresol and ferric sulfate.

Methods

Following approval from the University of Iowa's Institutional Review Board, a computer-assisted search of patient records was conducted for the time period between April 1, 2007 and March 31, 2008, to identify all primary tooth pulpotomy procedures. After an initial list of patient chart numbers was obtained, patient records were included in the study based on the following inclusion criteria:

- 1. Chart entry specified that 5% NaOCl solution was the sole medicament utilized to treat the pulp.
- 2. No clinical signs of pulpal degeneration (spontaneous pain, fistula, mobility) prior to treatment were noted.
- 3. Preliminary radiographs indicated absence of pathologic internal or external root resorption, or any evidence of inter-radicular bone destruction.
- 4. Following removal of coronal pulp tissue, hemostasis was readily achieved by applying pressure using dry cotton pellets.
- 5. The tooth was restored with a permanent restoration, upon completion of the pulpotomy, that remained intact over the course of follow-up until natural exfoliation.
- 6. Chart entries that revealed a pulpectomy procedure or that instrumentation entered into the pulp canal were excluded from the study.

5% NaOCl pulpotomy technique. The 5% NaOCl pulpotomy procedure used in this study has been taught at the University of Iowa's advanced training program in pediatric dentistry and used by selected faculty members since 2004. The technique used for all NaOCl pulpotomies in this study consisted of the following:

- 1. Local anesthesia was administered and a rubber dam was placed that ensured good isolation of the treated teeth.
- 2. Pulp chambers were accessed using a no. 330 carbide bur in a high-speed handpiece with water coolant.
- 3. Pulp amputation was performed using either a spoon excavator or a no. 6 round bur in a slow-speed hand-piece.
- 4. Hemorrhage control was obtained within 5 minutes using dry, sterile cotton pellets placed with light pressure over the pulpal stumps.
- 5. Following hemostasis, a cotton pellet saturated in 5% NaOCl was placed over the vital pulp tissue for 30 to 35 seconds.
- 6. The pellet was removed, and the pulp chamber was filled with IRM^{*}, a polymer-reinforced zinc-oxideeugenol restorative material (Caulk-Dentsply, Milford, Del).
- 7. The tooth was restored with a stainless steel crown (3M/ESPE, St. Paul, Minn) cemented with glass ionomer cement (Ketac-Cem, 3M/EPSE).

Follow-up. Upon completion of the pulpotomy procedure, patients were scheduled for 6-month recall exams or for a follow-up restorative appointment when applicable. In addition to the chart entry, a standardized clinical and radiographic evaluation form was completed by the clinician who examined the patient at each scheduled return visit to ensure collection of a standard set of criteria when determining clinical and radiographic success or failure. Clinical and radiographic success was based on criteria used by Smith et al., and Vargas et al.^{11,55}

Table 1. SODIUM HYPOCHLORITE PULPOTOMY SUCCESS OVER TIME								
	3-12 mos		13- 21 mos		Overall 3-21 mos			
Radiographic	N	%	N	%	N	%		
Success	52	85	20	74	72	82		
Failures	9	15	7	26	16	18		
Total	61	100	27	100	88	100		
Clinical								
Success	90	95	35	97	125	95		
Failures	5	5	1	3	6	5		
Total	95	100	36	100	131	100		

Clinical criteria used on the evaluation form to determine clinical success included the absence of: (1) spontaneous pain; (2) abscess or draining fistula; (3) mobility; (4) gingival inflammation; and (5) any other indications for extraction including lack of intact restoration. The radiographic criteria for success set forth included: (1) no external root resorption; (2) no internal root resorption; (3) no inter-radicular bone destruction; and (4) absence of any other abnormalities compared to the contralateral tooth. All faculty members (N=5) and residents (N=12) performing the follow-up examinations were trained to record a clinical failure on the evaluation form if the tooth presented 1 or more symptoms previously described. If no clinical signs or symptoms were evident, yet the patient revealed radiographic pathology, then only a "radiographic failure" was reported.

Postoperative radiographs were made either using standard film or digital radiographs. For each patient, a clinician (N=17) and the principal investigator (N=1) independently reviewed and interpreted radiographic findings. Clinicians in this study consisted of all full-time pediatric dentistry faculty members (N=5) and all pediatric dentistry residents (N=12). The principal investigator was blinded to the follow-up clinician's interpretation of the radiographic findings of success or failure.

Data recorded from each chart included: (1) identity of tooth/teeth treated; (2) clinical and radiographic pretreatment condition of tooth; (3) date of treatment; (4) date of follow-up(s); (5) clinical condition of pulpotomized tooth at follow-up; and (6) postoperative radiographic findings, if available.

Results

A total of 192 NaOCl primary molar pulpotomies on 118 patients were completed between April 1, 2007 and March 31, 2008 at the University of Iowa. All pulpotomies were completed by either pediatric dentistry faculty members or residents. A total of 4 faculty members and 8 residents completed at least 1 NaOCl pulpotomy during that time period. A total of 131 primary molars (68%) met the inclusion criteria for this study. Most excluded pulpotomies (47/192) never returned for a follow-up visit, or returned only once prior to the minimum 3-month follow-up period (8/192). Six pulpotomies (6/192) were excluded from the study for not adhering to the following inclusion criteria: the final restorations on 2 treated teeth did not remain intact over the course of observation; clinical signs of pulpal degeneration and evidence of pathosis from preliminary radiographs were documentated for 2 teeth; and NaOCl pulpectomies had been performed on 2 teeth.

Table 2. DISTRIBUTION OF FINDINGS OVER TIME*							
Radiographic findings	N	3-12 mos	13-21 mos				
Normal	72	52	30				
External root resorption	10	7	3				
Internal root resorption	8	4	4				
Inter-radicular bone destruction	8	5	3				
Other abnormalities	1	0	1				
Clinical findings	N	3-12 mos	13-21 mos				
Clinical findings Normal	N 125	3-12 mos 90	13-21 mos 35				
Clinical findings Normal Spontaneous pain	N 125 0	3-12 mos 90 0	13-21 mos 35 0				
Clinical findings Normal Spontaneous pain Abscess or draining fistula	N 125 0 5	3-12 mos 90 0 4	13-21 mos 35 0 1				
Clinical findings Normal Spontaneous pain Abscess or draining fistula Mobility	N 125 0 5 5	3-12 mos 90 0 4 4	13-21 mos 35 0 1 1				
Clinical findings Normal Spontaneous pain Abscess or draining fistula Mobility Gingival inflammation	N 125 0 5 5 1	3-12 mos 90 0 4 4 1	13-21 mos 35 0 1 1 0				

* Some teeth demonstrated more than 1 reportable pulpal response over time.

The final study sample consisted of 77 children (28 females, 49 males) with a mean age of 5 years, 10 months at the time of pulpotomy treatment (age range=2 years, 0 months to 11 years, 3 months). Follow-up times ranged from 3 to 21 months, with a mean of 10.5 months. Observation times were grouped into 2 follow-up time increments for the purpose of reporting the findings. Patients who returned for multiple observations were recorded once and grouped into their final observation period. The first time increment was 3 to 12 months, and the second time increment was 13 to 21 months. Once a tooth was identified as a failure, it was no longer included for future evaluation time frames.

Radiographic findings. Follow-up radiographs were available for 88 of the 131 treated molars. On the radiographs reviewed, 82% (72/88) of treated molars were radiographically successful. External root resorption (n=10) was the most commonly detected radiographic finding (Table 2). Internal resorption (n=8) and inter-radicular bone destruction (n=8) were the next most common findings. Many teeth demonstrated more than 1 pulpal response over time, as indicated in Table 2. Radiographic findings revealed that successful pulpotomies decreased over time (Table 1).

Clinical findings. Chart entries and clinical evaluation forms were reviewed for clinical findings at each follow-up visit. The overall clinical success rate for sodium hypochlorite pulpotomies shown in Table 1 was 95% (125/131). Some teeth demonstrated multiple findings (Table 2). Abscesses (N=5), mobility (N=5), and teeth requiring extraction (N=4) were the most common clinical pathology found. Of the 6 clinical failures, 4 were abscessed and required extraction. The remaining 2 teeth presented clinical failures, but were radiographically acceptable. Of these 2 teeth, 1 had mobility and gingival inflammation leading to bleeding around the margins of the crown, and the other showed previous signs of fistula, yet was currently asymptomatic and nearing normal exfoliation. Both teeth remain under observation. Most clinical failures occurred during the first 12 months (5 of 6). Clinical findings of success/failure rates over time are summarized in Table 1.

Discussion

Since its introduction by Buckley in 1904, formocresol has remained one of the most popular treatment medicaments for pulpally involved primary molars.³⁻⁵ Yet, despite the overall success as a pulpotomy agent, formocresol remains controversial due to the recent International Agency for Research on Cancer press release and its potential cytotoxic, mutagenic, and carcinogenic effects in humans.^{15-18,22-25} Due to these concerns, alternative medicaments have been proposed to treat vital primary molar pulps exposed to carious lesions.

According to Fuks,⁵⁷ the ideal dressing material to preserve the radicular pulp should: (1) be bactericidal; (2) be harmless to the pulp and surrounding structures; (3) promote healing of the radicular pulp; and (4) not interfere with the physiological process of root resorption.

Although the ideal pulpotomy medicament has yet to be determined, NaOCI, as reported in the literature, has several favorable characteristics, as aforementioned. For nearly a century, NaOCl has been an effective agent for the removal of infected tissue from wounds and dissolving necrotic pulp tissue.⁵⁸ Leonardo et al., reported its long-term success in endodontics as a root canal irrigant due to its antimicrobial activity and low toxicity.42 Ranley and Garcia-Godoy reported that NaOCl's favorable attributes, beyond hemorrhage control, stem from its "ability to purge bacteria, superficial inflamed tissue, and dentine debris from the exposure site."27 Rosenfeld et al., showed that a 5% NaOCl solution can superficially dissolve tissue when it comes in contact with vital pulp tissue, with minimal deep tissue changes.⁵¹ Hafez et al., found that, after using 3% NaOCl on the teeth of Rhesus monkeys, ample healing of the radicular pulp occurred with proper hemorrhage control and an adequate seal.48

The purpose of this retrospective study was to present the University of Iowa's early experience using 5% NaOCl as the medicament of choice in primary molar pulpotomies and to compare its clinical and radiographic success rates with previously published data on pulpotomies performed with formocresol or ferric sulfate.

Several studies exist comparing the radiographic and clinical results of FS to the "gold standard" of traditional formocresol.^{11,28,31} Formocresol and FS have been shown in both retrospective and prospective studies to have equivalent clinical and radiographic success rates for carious teeth with pulp exposures when the diagnosis is reversible pulpitis.^{11,21,22,31,33,36,54,59-61} Over the course of the last 3 decades, the clinical success rates of formocresol and FS in the literature have ranged between 84% to 100% and 89% to 100%, respectively. The radiographic success rates have ranged between 73% and 96% for formocresol and 74% to 97% for FS. Our findings of 95% clinical and 82% radiographic success in the present study fall within the range of these previously published data.

Two similarly designed retrospective studies comparing FS to formocresol by Smith et al., and Burnett and Walker had similar findings over the same time intervals.^{11,54} Clinical success rates over a comparable time interval were reported to be 99% by Smith and coworkers (FS) and 98% by Burnett and Walker (formocresol), compared with 95% for NaOCl in the present study (Tables 1). Observing the radiographic success of the present study presented in Table 1 (85% at 3-12 months

and 74% at 13-21 months), the results were more similar to the FS results reported by Burnett and Walker at 1 year (86%) and Smith et al., at 13-24 months (74%) than the FC results from Burnet and Walker (76% at 1 year and 90% at 13-24 months). Interestingly, the present study reported results more similar to the formocresol pulpotomies of Fei et al.,³⁰ (96% clinical and 81% radiographic at 12- month interval) than the FS findings in the previously noted studies. Additionally, the current study's findings can be substantiated by data reported by Vargas et al. using NaOCI for primary tooth pulpotomies.⁵⁵

The 2 most common pathologic findings reported in the literature for pulpotomized primary teeth treated with formocresol and FS are internal root resorption and inter-radicular bone destruction. The current study, however, found that internal resorption, inter-radicular bone destruction, and external root resorption occurred in near equal frequency, with external root resorption being slightly more frequently observed (Table 2). Although not often noted in other published data, many of the failures in the current study demonstrated more than one pathological response (Table 2). Previous investigations suggested that similar failures were the result of inadequate coronal seal,^{48,60} inflammatory response from the zincoxide eugenol base,¹¹ inconsistency in techniques from utilizing multiple operators,⁵⁴ or improper selection of the teeth.^{30,35,60}

It has been acknowledged that pulpotomy success or failure is dependant upon accurate diagnosis at the time of treatment.^{34,35,60,62} Considering the fact that more clinical failures occurred within the first time interval (3 to 12-months), it is plausible that improper diagnosis may have contributed to these failures. Premature exfoliation in relation to formocresol and FS pulpotomy was evaluated by Vargas et al.⁴⁰ The authors concluded that 11% were lost prematurely due to abscess formation in the FS group, and 10% in the formocresol group. The current study revealed a more favorable 3% loss due to abscess formation, with the majority occurring within the first 12 months (4 of 5). One additional asymptomatic tooth was charted as a radiographic failure due to premature natural exfoliation compared to its contralateral tooth.

The current study's findings should be considered regarding its study design limitations. The pulpotomies evaluated in this study were completed by multiple operators. Additionally, operators performing the pulpotomies consisted primarily of residents with various ranges of initial experience. Because no comparable control group was utilized during the same time period, this retrospective study was inherently biased. The ideal research design would be a prospective, randomized, double-blind study, where 2 or more pulpotomy techniques could be compared. Finally, the role of zinc oxide and eugenol as a dressing placed directly over the pulp tissue was not explored in this study. While zinc oxide and eugenol is a common medicament placed over the treated pulp tissue in multiple pulpotomy techniques (formocresol, FS, and NaOCl), it is possible that other medicaments would result in different success rates. Nevertheless, the present study demonstrates an outcome for NaOCl that is comparable to both formocresol and FS pulpotomies in primary molar teeth, as reported in the literature. The results of this investigation reveal that pulpotomies performed with NaOCl can result in a favorable outcome with high tooth survival rates.

Conclusions

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

- 1. This study's results concur with previously reported data utilizing sodium hypochlorite (NaOCl) for pulp therapy.
- 2. Overall clinical and radiographic success rates for NaOCl pulpotomies are comparable to ferric sulfate and formocresol pulpotomies reported in the literature with equivalent follow-up intervals.
- 3. Radiographic findings of pulpotomy success diminished over time.
- 4. External root resorption was the most common pathologic finding.
- 5. Further study with longer observation periods utilizing NaOCl as a pulpotomy medicament is warranted.

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