Two-year Outcomes of Primary Molar Ferric Sulfate Pulpotomy and Root Canal Therapy

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Abstract

Purpose: The objective of this outcome study was to compare ferric sulfate pulpotomy (FS) and primary tooth root canal therapy (RCT) on cariously exposed vital pulps of primary molars.
Methods: A total of 291 molars were treated in 130 children—182 molars received FS and 109 received RCT by random selection.
Results: At 2-year reassessment, 116 molars (73 FS, 43 RCT) were available for clinical and radiographic examination. There was no clinical evidence of pathosis in 96% of FS and 98% of RCT molars. Two independent pediatric dentists evaluated periapical radiographs of the treated molars. Molars were classified into 1 of 4 outcomes: (1) N—normal treated molar, (2) H—nonpathologic radiographic change present, (3) P_O—pathologic change present, follow-up in 6 months, and (4) P_X—pathologic change present, extract immediately. Survival analysis was applied. A good level of agreement between raters was found for molars with outcome P_X (κ=0.745). Intrarater reliability was good for molars with outcome P_X (κ=0.710). Significantly greater numbers of FS than RCT molars were rated P_X at the 2-year recall (χ^2=5.8; P=.02). No significant difference in survival between the 2 types of vital pulp treatments was detected in log rank tests (P=.22).
Conclusions: Outcomes for FS were poorer than RCT outcomes at 2 years; however, at 2 years, the survival rates were not statistically different. (*Pediatr Dent*. 2003:25:97-102)

KEYWORDS: FERRIC SULFATE, PULPOTOMY, ROOT CANAL THERAPY, PRIMARY MOLARS

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In North America, the most popular treatment for cariously exposed vital primary molars is the formocresol pulpotomy.[1] In the past 2 decades, concerns about the safety of formocresol for vital pulp therapy have led to investigations of pulp treatments that employ alternative techniques and materials.[2-4] Ferric sulfate pulpotomy (FS) has demonstrated comparable outcomes to formocresol pulpotomy.[5-8] Outcome investigations of primary tooth root canal treatment (RCT) have produced similar outcomes as well.[9,10] However, there are no prospective outcome investigations that directly compared RCT and FS treatments for vital pulp exposures in primary molars. This investigation compared 2-year outcomes of ferric sulfate pulpotomy (FS) and root canal treatment (RCT) in primary molars.

Methods

The subjects selected for this investigation were treated at The Hospital for Sick Children, Toronto, Canada, under general anesthesia between October 1998 and March 1999. Healthy children with 1 or more carious primary molars where removal of dental caries was likely to produce a vital pulp exposure were invited to participate in this study. The procedures and possible discomforts, risks, and benefits were explained fully to the subjects and their parents/guardians and informed consent was obtained and recorded prior to their participation in this investigation. The Research Ethics Board at The Hospital for Sick Children approved this investigation.

The total enrolment in this investigation was 291 primary molars in 130 subjects (83 males; 47 females). The

Table 1. Demographics of Subjects That Returned for Recall Examination and Those Lost to Follow-up (N=130)

	Recalled	Lost to follow-up
N	65	65
Males	41	41
Females	24	24
Mean age (y±SD)	4.4±1.3	4.5±1.4

FS group consisted of 182 primary molars in 86 subjects (52 males; 24 females). The RCT group consisted of 109 primary molars in 54 subjects (31 males; 23 females). Subjects that could not be located or were unwilling to return for evaluation were categorized as "lost to follow-up." At the conclusion of the investigation, 52% of the enrolled subjects returned for at least 1 evaluation. The demographic profile of all subjects is presented in Table 1. The final sample was 116 molars (73 FS; 43 RCT) in 65 subjects that had clinical and radiographic data available for analysis from the 2-year reassessment.

Periapical radiographs were acquired for each molar tooth that was likely to have a carious pulp exposure after induction of general anesthesia. Molars included in the study exhibited no radiographic evidence of physiological or pathological root resorption, periapical or furcation radiolucencies or pulp stones. Molars that presented with an associated swelling or sinus tract were excluded.

Three pediatric dentists (DJK, DHJ, PLJ) completed all treatment over a 22-week period. All molars were treated under rubber dam isolation. Pulp therapy techniques were randomly assigned to children whose molars met the inclusion criteria. Treatment data was recorded daily on preprinted data collection sheets and entered into a computer database program. Quality assurance checks were performed by one of the investigators (MAL) who did not provide treatment or review postoperative radiographs to ensure that the investigators who provided treatment complied with the randomization protocol.

Primary tooth root canal therapy procedure

The technique used was as described by Payne et al.[10] Access into the pulp chamber was achieved using a sterile #56 fissure bur in a high-speed handpiece and then refined with sterile round burs in a slow-speed handpiece. The coronal pulp was amputated with a round bur, and the entrances into the root canals were identified at the floor of the pulp chamber. Radicular pulp tissue was removed by inserting two #15 or #20 Hedström files, one at a time, down opposite sides of the root canal to a point close to, but short, of the apex. The files were then rotated 2 or 3 times to engage the pulp tissue and removed together. In most cases, the pulp tissue was removed *en bloc* on the first attempt. If the first attempt was unsuccessful, then the procedure was repeated until all of the pulp tissue was removed. The canals were then irrigated and gently air dried using an air-water syringe. The canals were obturated using a viscous mixture of Sedanol (Dentsply DeTrey, Addlestone, UK), a fine-grained, nonreinforced zinc oxide-eugenol preparation. The paste was delivered to the root canal with a spiral paste filler (Lentulo, Dentsply DeTrey, Addlestone, UK) inserted into the canal to a point just short of the apex. Upon completion of canal obturation, the molar was immediately restored with a stainless steel crown (3M Ion Ni-Chro, 3M Dental Products, St. Paul, Minn) and cemented with polycarboxylate cement (Durelon, 3M Dental Products, St. Paul, Minn).

Ferric sulfate pulpotomy procedure

The ferric sulfate pulpotomy procedure was identical to the technique described by Fuks et al.[5] Access to the pulp chamber was achieved using a sterile #56 fissure bur mounted in a high-speed handpiece. The access was refined with round burs in a slow-speed handpiece. The coronal pulpal tissue was then removed using a sterile slow-speed round bur (#6 or #8). A 16% ferric sulfate equivalent in an aqueous vehicle (Astringedent, Ultradent Products Inc, Salt Lake City, Utah) was gently burnished on the pulp stumps for 15 seconds with the syringe applicator supplied by the manufacturer. The pulp chamber was then flushed with water supplied by an air-water syringe. If the bleeding had not stopped after the initial application of ferric sulfate, the molar was eliminated from the study. If hemostasis was achieved, the pulp chamber was sealed with a fortified zinc oxide-eugenol mixture supplied in premeasured capsules (Dentsply Caulk, Milford, Del) The molar was then immediately restored with a stainless steel crown cemented with polycarboxylate cement.

Clinical and radiographic evaluation

All subjects were offered clinical and radiographic assessments at 12 and 24 months after treatment with an investigator (MAL) who did not perform any of the pulp therapy or rate any of the radiographs. Subjects who returned for a follow-up examination were asked to report any history of pain related to the treated molars. Each molar was classified as present, exfoliated, lost to trauma, or extracted. If the molar was still present, the following observations were recorded if present: missing restoration, recurrent caries, mobility, and percussion sensitivity. The surrounding gingiva and mucosa was also examined for any signs of erythema, swelling, parulis, or the presence of a fistulous tract.

Periapical radiographs were taken of all treated molars. The radiographs were taken on size 0 film using a Rinn holder (Dentsply Rinn, Elgin, Ill) and bisecting angle technique. All radiographs taken during the follow-up sessions were screened for their diagnostic quality prior to being included in the radiographic evaluation. Acceptable radiographs had nondistorted images of the treated molars and the osseous structures immediately adjacent to the roots. Radiographs that did not meet these criteria were excluded from the radiographic evaluation. Two independent pediatric dentists who were not otherwise involved in the

Table 2. Pathological Radiographic Findings for FS and RCT Molars at the 2-year Recall Examination

	FS (N=31)		RCT (N=22)	
	N	%	N	%
Pulp canal obliteration	22	71	N/A*	N/A
Widened periodontal ligament space	19	61†	7	32
Furcation radiolucency	9	29	9	18
Periapical radiolucency	3	10	3	5
Internal resorption	17	55	N/A	N/A
External resorption	5	16‡	2	9

*Not applicable.
†χ^2=4.5; P>.05.
‡χ^2=10.7; P>.05.

Table 3. Outcome Classification for FS and RCT Molars at 2-year Follow-up

	FS (N=31)		RCT (N=22)	
N	1	3%	10	45%
H	5	16%	1	5%
P_O	13	42%	9	41%
P_X	12	39%	2	9%

investigation evaluated the radiographs. The raters participated in a calibration exercise prior to the radiograph review. Sample radiographs of molars that had received FS and RCT were included in the calibration exercise. The raters were encouraged to come to a consensus on radiographic assessment. After the calibration exercise, the raters were separated and evaluated the radiographs alone under standardized viewing conditions. The raters' scores were subjected to interrater reliability testing. One reviewer reassessed a subset of the radiographs 2 weeks after the initial assessment so that measures of intrarater reliability could be calculated.

All radiographs included in this investigation were subjected to identical criteria for evaluation regardless of the vital pulp treatment performed. The raters were asked to determine the presence or absence of widened periodontal ligament space, furcation or periapical radiolucency, pulp canal obliteration (PCO), and pathologic internal or external root resorption. The raters classified each molar into 1 of 4 outcomes:

1. N—normal molar without evidence of radiographic change;
2. H—radiographic changes associated with normal physiologic molar resorption;
3. P_O—pathologic radiographic change not requiring immediate extraction;
4. P_X—pathologic radiographic change recommended for immediate extraction.[10]

Data analysis

In subjects with more than 1 treated molar, a single molar was randomly selected for analysis of radiographic outcomes, treatment outcomes, and survival to preserve the statistical independence of the observations. Discrete variables for radiographic findings and treatment outcomes were tested for statistical differences by the chi-square statistic. Percentages were used to summarize categorical data. A log-rank test was conducted to compare the survival of FS and RCT molars. Graphical representations of survival were produced for both groups using the Kaplan-Meier method. Interrater and intrarater agreement for dichotomous responses were measured with the kappa statistic.

Results

Clinical and radiographic findings

The average age of the 38 subjects that presented for recall with FS treated molars was 4.4 years±1.4. The average recall interval was 21.4±6.1 months. Thirty-eight subjects that had a follow-up visit at any point in this investigation were included in the survival analysis. To ensure statistical independence of the observations, each subject contributed only 1 molar to the 2-year outcome and survival analyses. In subjects with multiple treated molars, a single molar was randomly selected for the analysis. Thirty-one subjects (73 molars) returned for recall when contacted at 2 years after treatment (N=31). The average recall interval at 2-year recall was 25.2±3.1 months. Four percent (3/73) of FS molars had an associated gingival swelling or parulis upon clinical examination. One subject reported pain from a single FS molar (1/73) at the 2-year recall appointment.

The average age of subjects (N=27) recalled with RCT molars was 4.2±1.1 years. The average recall interval was 21.7±5.3 months. Twenty-seven subjects that had a follow-up visit at any point in this investigation were included in the survival analysis. Twenty-two subjects (43 molars) attended a recall examination when contacted at 2 years after initial treatment. The average recall interval at this point in time was 24.1±2.0 months. Forty-three molars were examined clinically and radiographically. As with the FS molars, each subject contributed 1 molar to the treatment outcome analysis (N=22) by random selection. One molar (1/43; 2%) elicited pain upon percussion. There were no soft tissue swellings or fistulae associated with any of the RCT-treated molars. Radiographic findings for FS and RCT molars are listed in Table 2.

FS molars had a significantly higher prevalence of periapical radiolucencies (P=.01) and widened periodontal ligament space (P=.05) than RCT molars on radiographic examination 2 years following treatment. No statistically significant differences in radiographic observations of furcation radiolucencies or pathological external root resorption were detected.

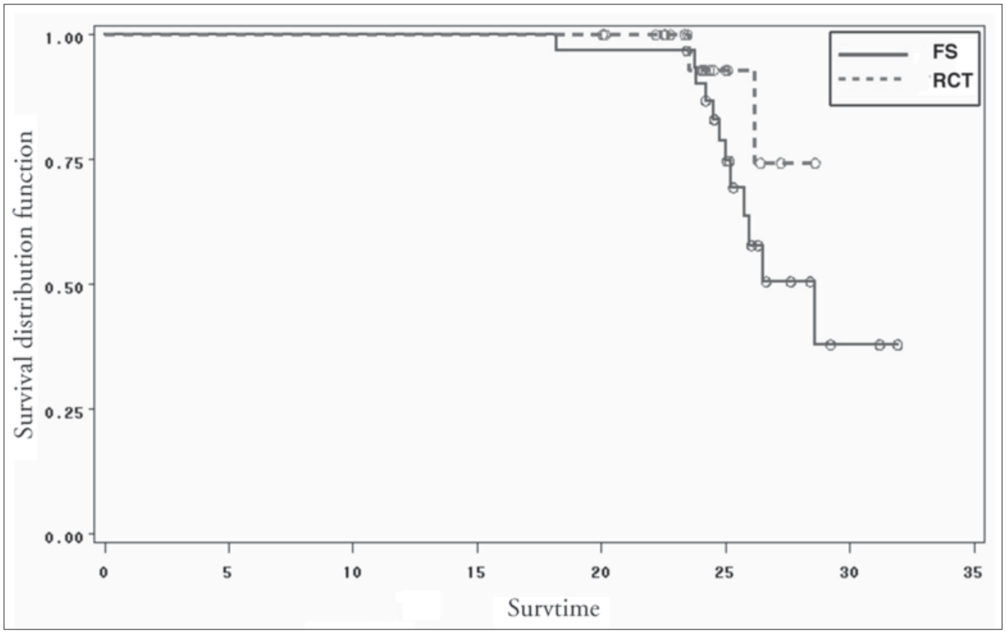

Figure 1. Kaplan-Meier survival curves for FS and RCT molars. Molars selected randomly within patients.

RCT demonstrated statistically fewer P_X outcomes than FS at 2 years following treatment (χ^2=5.8; *P*=.02). Outcomes for FS and RCT molars are found in Table 3.

Measures of reliability

Interrater agreement was good for molars classified P_X (κ=0.745) using Fleiss' interpretation of reliability.[11] Intrarater agreement also was good (κ=0.710) for molars rated P_X.

Survival analysis

Any molar rated as P_x, exfoliated prematurely, or extracted during the recall interval of the investigation was classified as not meeting the criteria for survival. Twenty-seven observations for subjects with RCT molars were available for the survival analysis. Seventy-four percent of the observations (20/27 observations) in RCT molars were censored (molar survived until the completion of the investigation). Thirty-eight observations for FS molars were available for the survival analysis. Forty-two percent of the observations (16/38 observations) in FS molars were censored. The probability of survival for FS molars at 24 months was 0.86. Primary molars treated with RCT exhibited a probability of survival of 0.92 at 24 months. Kaplan-Meier curves for FS- and RCT-treated molars are shown in Figure 1. No statistical difference in survival of FS and RCT molars was detected in log rank tests (*P*=.5).

Discussion

In this investigation, RCT was chosen as the control group based upon its demonstrated efficacy as a treatment for vital carious pulp exposures in primary molars.[9,10] This investigation also provided an opportunity to replicate the treatment outcomes of Payne et al, for RCT using an identical prospective study design and evaluation method for outcome classification.[10] Ferric sulfate pulpotomy has recently received attention as a potential alternative to the formocresol pulpotomy.[5-8] This investigation is the only known prospective longitudinal clinical outcome study that provides a comparison of the ferric sulfate pulpotomy to another nonaldehyde form of primary molar pulp treatment.

Based on a clinical examination alone, both FS and RCT molars had very favorable outcomes. No pathosis was detected for 96% of FS and 98% of RCT molars by clinical examination at 2-year follow-up. However, radiographic examination produced favorable outcomes for 61% of FS and 91% of RCT molars. This finding suggests that radiographic follow-up of primary molar pulp therapy is indicated, as the postoperative clinical appearance of pulp-treated molar may not be representative of its actual status.

The most common radiographic observation for ferric sulfate pulpotomy-treated molars was PCO. This was found in 71% of the treated molars in this study. Other investigators have reported varying prevalence of PCO in FS-treated molars at 18% to 48%.[5-7] PCO is not an indicator of an unfavorable outcome to pulpotomy treatment.[5] Calcific metamorphosis is produced by odontoblastic activity within the treated molar and is indicative of ongoing pulp vitality.[12]

Internal resorption was observed in 55% of FS molars in this investigation. Although this type of resorption was not always indicative of an unacceptable outcome, it was found in approximately 70% of the molars classified as P_X. Several molars exhibited both PCO and internal resorption in the same molar. Fuks et al, and Ibricevic and Al-Jame reported internal resorption in 7% and 3% of FS molars, respectively, while Smith et al, reported 17% of FS molars exhibited internal resorption after 57 months follow-up.[5,7,8] Ferric sulfate is not a tissue fixative like formocresol. Ferric sulfate produces hemostasis at the amputated pulp stumps site by mechanical sealing of cut blood vessels. This leaves vital pulp tissue at the site of pulp amputation in contact with the zinc-oxide eugenol base. The irritating properties of eugenol have been shown to produce internal resorption when applied to the vital pulps of primary molars.[13,14] Fixation of pulpal tissue by formocresol may prevent pulpal reaction to the eugenol in zinc-oxide eugenol and thereby reduce the prevalence of internal resorption. Future investigations of the ferric sulfate pulpotomy would benefit from the use of alternative base materials that do not stimulate internal resorption.

Nonpathological radiographic outcomes (N+H) were observed in only 19% of the molars treated with ferric sulfate. Teeth with radiographic evidence of pathosis were classified into P_O and P_X outcomes, as clinicians do not regard all pathologic changes as an absolute indication for extraction of molars. Pediatric dentists are likely to leave pulp-treated primary molars that exhibit a limited degree of radiolucency or pathologic root resorption in the absence of clinical signs and symptoms in situ. Pathosis confined within the tooth such as internal resorption or PCO should not be considered harmful to the underlying permanent tooth and are acceptable outcomes following pulp therapy.[5,7] Protocols that classify molar outcomes as acceptable (normal or minor pathosis present) or unacceptable (major pathosis present) are more clinically relevant than protocols that classify outcomes as normal vs pathological or "successful" vs "unsuccessful," as they more closely mimic clinical decision making.[10]

The proportion of FS molars with acceptable outcomes was lower than reported in previous investigations within a similar follow-up period.[5] Fuks et al, reported 93% acceptable outcomes at 6 to 34 months posttreatment of FS-treated molars.[5] In the current investigation, 61% of molars had acceptable radiographic outcomes ($N+H+P_O$) after 25 months. The difference in outcomes between the 2 investigations may be due to differences in data analysis and potential for rater bias. All teeth that were included in 2-year results had been treated a minimum of 24 months prior to assessment of outcomes. More that half of the subset of the sample (26/51) classified as "total success" in Fuks et al, was not aged 2 years following treatment. Thus, many teeth classified as a "total success" by Fuks et al, may not have yet demonstrated pathosis that may have been present at a 2-year follow-up. In addition, as some subjects contributed more than 1 tooth to the analyses (96 molars in 72 subjects) statistical independence of the observations was not assured.[5] Additionally, this investigation used independent expert raters to minimize observer bias. It is unclear, but assumed, that the authors reviewed the experimental material in Fuks et al.

In comparison, 91% of the molars in this investigation treated with root canal therapy had acceptable radiographic outcomes. These results are similar to the 90% acceptable outcomes reported by Payne et al, using the same radiographic criteria in an identical RCT technique in a previous study.[10] In this investigation, FS-treated molars had 61% acceptable radiographic outcomes, significantly less than the 91% acceptable outcomes for RCT molars (χ^2=5.8; *P*=.02). These results once again provide support for the use of primary tooth root canal therapy as a nonaldehyde alternative to the formocresol pulpotomy.

The level of agreement between the raters was good when classifying molars in the P_X category (κ=.745). Raters agreed on combinations of radiographic features that indicated when the extraction of a treated molar was indicated. Intrarater reliabilities were good when classifying a molar as P_X (κ=0.710). This result demonstrated that radiographic interpretation remained consistent when deciding whether the outcome of a treated molar indicated extraction. Clinicians were consistent with each other and over time when classifying molars with unacceptable treatment outcomes.

Survival curves for both RCT and FS molars were similar until approximately 24 months following treatment. Beyond 24 months, the curve for the FS molars demonstrated a trend of decreased survival that was not statistically significant. The standard error for both treatments at this time interval was greater than for earlier time intervals. The large standard error was produced by the high proportion of molars that survived (censored observations) until the end of the follow-up period. Eighty-six percent of RCT-molar observations and 70% of FS-molar observations were censored in this investigation. Censored observations (surviving molars) provided no information about the future status of treated molars. In a survival analysis in which a large proportion of observations are censored, mean estimates of survival time cannot be accurately calculated.[15] The large proportion of censored observations in this investigation indicates that survival analysis may not be an appropriate statistical method to compare FS and RCT molars at 2 years following treatment. Investigations of primary pulp therapy using survival analysis would benefit from longer periods of follow-up to ensure that censored observations do not make up the bulk of the data. It is conceivable that a stronger statistical relationship between the 2 survival curves may be obtained if these molars were observed over longer periods of follow-up. Consequently, this sample will be followed for an additional year to allow assessment of 3-year treatment outcomes and survival.

RCT produced more acceptable treatment outcomes than FS (χ^2=5.8; *P*=.02) in vital pulp treatment of primary molars at 2-year follow-up. RCT has not gained favor among clinicians for treatment of carious exposures in vital primary molars, despite good outcome evidence documenting its efficacy.[1,9,10] This lack of utilization of RCT among clinicians may be due to the additional effort and time when compared to a pulpotomy procedure. Clinicians will not change their primary vital pulp treatment modalities unless alternative treatments offer distinct advantages over their conventional therapy. In primary pulp therapy, many clinicians continue to use formocresol pulpotomy because it is the technique they learned as students, it produces predictable outcomes, the materials are readily available, and the technique is simple.

Four outcome investigations have demonstrated similar outcomes for FS and formocresol pulpotomy.[5-8] This investigation replicated the findings of 2 previous outcome studies of RCT.[9,10] RCT and FS have the advantage of avoiding the use of aldehydes in children. Clinicians who wish to avoid aldehydes in vital molar pulp therapy for children have 2 alternatives.

Conclusions

RCT produced more acceptable outcomes than FS at 2 years following treatment. No difference in the survival of FS and RCT molars was detected.

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Abstract of the Scientific Literature

Troubleshooting the Herbst Appliance

The Herbst appliance is fixed, durable, popular, and commonly used for Class II dental correction. It is typically cemented posteriorly to the maxillary molars and anteriorly in the cuspid region and consists of a telescoping mechanism that exerts forces during function. The purpose of this study was to review prevention of possible problems with and management of the Herbst appliance. This involved reviewing factors such as model distortion, improper band placement, midline, overjet, and overbite errors, tooth eruption during appliance fabrication, loose bands, cement failure, loose screws, inadequate maxillary molar control, appliance components impinging on soft and hard tissues, twisted and broken appliance parts, and parental expectations. The report stresses the clinical efficiency resultant of these precautions.

Comments: This article demonstrates each stage and problem solution pictorially and presents valuable tips on Herbst clinical techniques. **AW**

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Rogers M. Troubleshooting the Herbst appliance. ***J Clin Orthod.*** **2002;36:268-274.**

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