Long-term Outcomes of Primary Molar Ferric Sulfate Pulpotomy and Root Canal Therapy

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Abstract

Purpose: The purpose of this study was to compare long-term outcomes of ferric sulfate pulpotomy (FS) and primary tooth root canal therapy (RCT) in vital pulps of deciduous molars exposed to caries lesions.
Methods: A total of 291 molars were treated in 130 children. One hundred and eighty-two molars received FS and 109 received RCT by random selection.
Results: At 3-year re-assessment, 29 molars (15 FS, 14 RCT) were available for clinical and radiographic examination. Two independent pediatric dentists evaluated periapical radiographs of the treated molars. Molars were classified 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; (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=0.79). No difference in radiographic outcomes was demonstrated 3 years after treatment (χ^2=1.4). Survival analysis demonstrated a 3-year survival probability of 0.62 for FS-treated molars and 0.92 for RCT molars. Survival of RCT molars was significantly greater than for FS molars (Wilcoxon: P=.01; log-rank: P=.02).
Conclusions: RCT-treated molars demonstrated significantly greater survival than FS-treated molars 3 years after treatment. (*Pediatr Dent.* 2004;26:44-48)

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In North America, the most popular treatment for vital primary molars exposed to caries lesions 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]

A recent Cochrane Review of pulp therapy criticized the body of primary pulp therapy literature for the paucity of appropriately designed, statistically-assessed investigations and the lack of long-term outcomes.[11] This prospective, random, controlled trial provides long-term outcomes (greater than 3 years) for vital molars treated with ferric sulfate (FS) pulpotomy and root canal therapy (RCT). Two-year outcomes from this investigation were reported previously.[12]

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 primary molars with carious lesions, where removal of dental caries was likely to produce a vital pulp exposure, were invited to participate in this study. The procedures, possible discomforts or risks, as well as possible benefits were explained fully to the subjects and their parents/guardians, and informed consent was obtained and recorded prior to their participation in this

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

	Assessed at 3 yrs	Lost to follow-up
N	29	101
Males	21	62
Females	8	39
Mean Age (±SD) yrs	4.5 ±1.2	4.5±1.4

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 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.

Periapical radiographs were acquired for each molar tooth that was likely to have a caries lesion 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 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.

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 No. 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 No. 15 or No. 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, non-reinforced, 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) 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 No. 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 (No. 6 or No. 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 least 36 months after treatment with an investigator 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: (1) missing restoration; (2) recurrent caries lesions; (3) mobility; and (4) percussion sensitivity. The surrounding gingiva and mucosa were 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.

Table 2. Pathological Radiographic Findings for Ferric Sulfate Pulpotomy (FS) and Vital Primary Root Canal Therapy (RCT) Molars at the 3-year Recall Examination

	FS (N=15)		RCT (N=14)	
	N	%	N	%
Pulp canal obliteration	9	60	NA*	NA
Widened periodontal ligament space	4	27	4	29
Periapical radiolucency	3	20	2	14
Furcation radiolucency	4	27	2	14
Internal resorption	5	33	NA	NA
External resorption	5	33	1	7

*NA=not applicable.

Two independent pediatric dentists who were not otherwise involved in the 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 they evaluated the radiographs alone under standardized viewing conditions. The raters' scores were subjected to inter-rater 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

Subjects assessed 2 years after treatment were invited for re-assessment when the previously examined molars had aged at least 1 additional year. In subjects with more than one 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. The final sample was 29 molars (15 FS; 14 RCT) in 29 subjects that had clinical and radiographic data available for analysis from the 3-year reassessment.

Discrete variables for radiographic findings and treatment outcomes were tested for statistical differences via the chi-square statistic. Percentages were used to summarize categorical data. Wilcoxon and log-rank tests were conducted to compare the survival of FS and RCT molars. Graphical representations of survival were produced for both groups using the Kaplan-Meier method. Inter-rater and intra-rater agreement for dichotomous responses were measured with the kappa statistic.

Results

Clinical and radiographic findings

The average age at time of pulp treatment of the 15 subjects that presented for 3-year recall with FS-treated molars was 4.8 years±1.1 (SD). Fifteen subjects returned for recall when contacted 3 years after treatment (N=15). The average recall interval at 3-year recall was 46.7±3 months. Thirty independent observations for FS-treated molars that had a follow-up visit at any point in this investigation were included in the survival analysis.

The average age at time of pulp treatment of subjects recalled with RCT molars was 4.5±1 years. Fourteen subjects attended a recall examination when contacted 3 years after initial treatment (N=14). The average recall interval at this point was 44.4±2 months. Twenty-three independent observations of RCT-treated molars that had a follow-up visit at any point in this investigation were included in the survival analysis.

No statistically significant differences in radiographic observations of widened periodontal ligament space, periapical radiolucencies, furcation radiolucencies, or pathological external root resorption between FS and RCT molars were detected. Radiographic findings for FS and RCT molars are listed in Table 2.

No difference in the prevalence of P_X outcomes between FS and RCT molars was detected at 3 years post-treatment. Outcomes for FS and RCT molars are found in Table 3.

Measures of reliability

Inter-rater agreement was good for molars classified P_X (κ=0.79) using Fleiss' interpretation of reliability.[13]

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-three observations for subjects with RCT molars were available for the survival analysis. Ninety-one percent of the observations (21/23 observations) in RCT molars were censored (molar survived until the completion of the investigation). Thirty observations for FS molars were available for the survival analysis. Fifty-three percent of the observations (16/30 observations) in FS molars were censored. The probability of survival for FS molars at 36 months was 0.62. Primary molars treated with RCT exhibited a probability

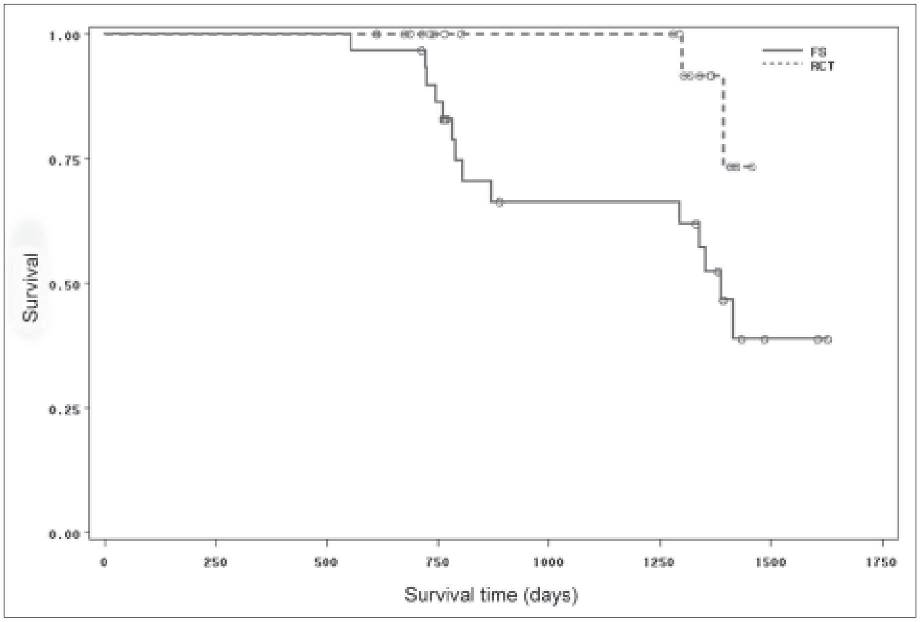

Figure 1. Kaplan-Meier survival plots for molars treated with ferric sulfate pulpotomy (FS) and vital root canal therapy (RCT). RCT demonstrated a higher probability of survival than FS molars (Wilcoxon: *P*=.01; log-rank: *P*=.02).

of survival of 0.92 at 36 months. Kaplan-Meier curves for FS and RCT-treated molars are shown in Figure 1. RCT molars demonstrated a higher probability of survival at 3 years post-treatment than FS molars (Wilcoxon: *P*=.01; log-rank: *P*=.02)

Discussion

No statistical differences were demonstrated between RCT and FS molars for pathological radiographic findings or radiographic outcomes at 3 years. PCO was the most common radiographic finding for FS-treated molars at 3-year assessment, as reported at the 2-year assessment.[12]

Unacceptable P_X outcomes at 3 years for FS-treated molars and RCT molars were 33 and 14%, respectively. These results were similar to 39% for FS-treated molars and 9% for RCT-treated molars at 2 years. At 2-year assessment, the prevalence of unacceptable outcomes was statistically greater for molars treated with FS than for molars treated with RCT.[12] No statistical difference for P_X outcomes was demonstrated at 3-year reassessment. A sample size estimate projected that 64 molars with FS pulpotomy and 147 molars with RCT would be required to demonstrate a statistical difference based on the 3-year findings (α=0.05; power=0.8).

Table 3. Outcome Classification for Ferric Sulfate Pulpotomy (FS) and Vital Primary Root Canal Therapy (RCT) Molars at 3-year Follow-up

	FS (N=15)		RCT (N=14)	
N	2	14%	7	50%
H	3	20%	3	22%
P_O	5	33%	2	14%
P_X	5	33%	2	14%

The level of agreement between the raters was good when classifying molars in the P_X category (κ=.79).[14] Raters agreed, as they did at the 2-year assessment, on combinations of radiographic features that indicated when the extraction of a treated molar was indicated.[2] 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 post-treatment. Beyond 24 months, the curve for the FS molars demonstrated decreased survival that was statistically significant. Ninety-one percent of RCT molar and 53% of FS molar observations were censored (survived to the end of the investigation). At 2 years, the large proportion of censored observations provided little information about the future status of treated molars.[2] Mean estimates of survival time cannot be accurately calculated in a survival analysis where a large proportion of observations are censored.[5] Consequently, this sample was followed for an additional year with the effect that some molars from both FS and RCT groups were followed for more than 4 years. Survival of RCT-treated molars was significantly greater than FS-treated molars (Wilcoxon: *P*=.01; log-rank: *P*=.02).

RCT produced more favorable 2-year (fewer P_X ratings) and 3-year (greater survival) outcomes than FS pulpotomy for treatment of vital primary molar teeth. However, RCT has not gained favor among clinicians for treatment of vital primary molars despite good outcome evidence that supports its efficacy.[9-10,12] Lack of utilization of RCT by clinicians may be due to the additional effort and time to complete RCT compared with a pulpotomy. Clinicians are unlikely to change their primary vital pulp treatment modalities unless alternative treatments offer distinct and immediate (time) advantages over conventional therapy. Many clinicians continue to perform the formocresol pulpotomy because it produces predictable outcomes, materials are readily available, and the technique is simple.[4]

The recent Cochrane Review of pulp therapy for primary teeth reported in depth on 3 investigations that met its inclusion criteria as random controlled trials of primary tooth pulp therapy. Additional long-term random controlled trials of pulp therapy are needed, as only 3 of 82 studies reviewed met the inclusion criteria for the Cochrane

Review. The reviewers noted the logistic difficulty of amassing large, randomly selected samples with independent observations over long follow-up periods. Two investigations of FS pulpotomy met the Cochrane Review criteria for inclusion.[11]

Based on the best available evidence, clinicians can infer that ferric sulfate and formocresol produce equivalent outcomes and RCT produces more favorable outcomes than FS.[8,12] Dentists who wish to avoid aldehydes in vital molar pulp therapy now have 2 alternatives that have been investigated in random controlled trials with appropriate statistical analysis: (1) FS pulpotomy; and (2) RCT. Based on long-term survival data from this investigation, clinicians who require a nonaldehyde vital pulp technique for primary molar that must be retained long-term (greater that 3 years) should recommend RCT.

Conclusions

RCT-treated vital primary molars had greater survival than vital primary molars treated with FS pulpotomy beyond 3 years post-treatment.

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