Ferric sulfate pulpotomy in primary molars: A retrospective study

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Abstract

Purpose: This investigation collected clinical and radiographic data from a retrospective chart review of patients receiving ferric sulfate pulpotomies with a sub-base of zinc oxide eugenol in a clinical practice over a five-year period.

Methods and Materials: Clinical and radiographic data were available for 242 primary molars in 171 children with follow-up times ranging from 4-57 mos (mean=19 mos).

Results: The overall radiographic success rate ranged from 74-80%. The frequency of normal appearing pulps decreased over time. The most frequently observed pulpal responses were calcific metamorphosis (6-33%) and internal resorption (7-18%). Overall clinical success was 99%. Only 9 of the 242 teeth were extracted due to radiographic and/or clinical failure. A survival analysis demonstrated that the overall cumulative probability of survival remained high over time with a cumulative survival of over 90% after 3 years.

Conclusions: The overall success rates in this study are lower than those reported previously in the literature for ferric sulfate pulpotomies, but are comparable with those reported for 1:5 dilution, 5-min formocresol pulpotomies. (Pediatr Dent 22:192-199, 2000)

A major goal in pediatric dentistry is to maintain the primary dentition in an intact state until the permanent successors erupt. Pulpotomies help maintain arch integrity by allowing preservation of teeth that would otherwise be destined for extraction. Many techniques have been advocated for use in treatment of pulpally involved primary teeth. The formocresol pulpotomy technique is considered the most universally taught and preferred pulp therapy for primary teeth at the present time[1], and since it was introduced in 1904 by Buckley[2], it has undergone a lengthy evolution to shorten the application time and reduce the concentration of the agent used. The technique has a long history of overall clinical success ranging from 55% to 98%, and many studies have used variations of the technique, and defined success and failure using a variety of criteria.[3-11] These are summarized in Table 1A. Despite years of apparent successful use as a pulpotomy agent, formocresol has come under attack for the research and documentation in the literature which have shown formaldehyde to be toxic, mutagenic and carcinogenic.[12-15] The response to the controversy has been a quest for alternative agents and techniques. Currently, the technique receiving the most attention is ferric sulfate.

Ferric sulfate (Fe2[SO4]3) as a 15.5% solution (AstringedentTM, Ultradent Products, Inc., Salt Lake City, UT), has been used commonly as a coagulative and hemostatic retraction agent for crown and bridge impressions and is slightly acidic.[16] The mechanism of action of ferric sulfate is still debated, but agglutination of blood proteins results from the reaction of blood with both the ferric and sulfate ions. The agglutinated protein forms plugs to occlude the capillary orifices.[17] Thus, unlike traditional hemostatic agents, ferric sulfate affects hemostasis through a chemical reaction with blood.[17] Ferric sulfate is proposed as a pulpotomy agent on the theory that its mechanism of controlling hemorrhage might minimize the chances for inflammation and internal resorption believed by some investigators (Schroeder)[18] to be associated with physiologic clot formation.[19] Investigators have not explained how clotting itself could curtail these activities. Ranly proposes the possibility that the metal-protein clot at the surface of the pulp stumps may act as a barrier to the irritative components of the sub-base and in that capacity, functions solely in a passive manner.[19]

Landau and Johnson were the first to study the pulpal response from ferric sulfate in monkey teeth.[20] The two human clinical studies using ferric sulfate are summarized in Table 1B and have reported success rates similar to formocresol.[21-22]

Currently, an exact mechanism explaining why ferric sulfate would be expected to be superior to previous pulpotomy agents, such as formocresol, has yet to be provided. In fact, the technique is quite similar to performing ZOE pulpotomies. The human studies with ferric sulfate are limited in time and have small sample sizes. Additional long-term studies with increased sample sizes should be conducted before ferric sulfate can be recommended as a substitute for the "gold standard" formocresol technique.

The purpose of this investigation was to collect clinical and radiographic data from a retrospective chart review of patients receiving ferric sulfate pulpotomies in a clinical pediatric dental practice over a five-year period and compare those data to the widely published data of the formocresol technique.

Received September 13, 1999   Revision Accepted March 27, 2000

Table 1. Summary of Pulpotomy Studies

Authors	Year	Agents/Sample Size	Observation Time	Clinical Findings/ Success	Radiographic Findings/ Success
A. FORMOCRESOL AND ZINC OXIDE EUGENOL PULPOTOMY STUDIES					
Berger	1965	5 min FC+ZOE–30 teeth ZOE–17 teeth	3-38 wks	No clinical signs or symptoms	FC: 97% ZOE: 58%
Beaver	1966	5 min FC+ZOE/FC–30 teeth 5 min FC+ZOE–30 teeth	1-3 mo	No clinical signs or symptoms	FC+FC/ZOE: 93% Furc radiolucency 2 teeth FC/ZOE: 96%
Redig	1968	5 min FC+ZOE/FC–20 teeth 2 appt FC+ZOE–20 teeth	3-18 mo	Both groups: Abscess = 4 teeth Pain = 1 tooth	5-min=85% succ 2 appt=90% succ
Magnusson	1971	ZOE-40 mand molars	3-39 mo	No clinical signs	Peri radiolucency=3 roots or symptoms Int root resorption=45% 1st molars – 10 teeth 2nd molars – 8 teeth
Hansen	1971	ZOE–14 teeth Ledermix–14 teeth	1-42 mo	No clinical signs or symptoms	ZOE: 57% Int root resorption 6 teeth Ledermix: 79% Int root resorption 3 teeth
Morawa	1975	5 min. 1:5 Dil FC+ ZOE/FC –125 molars	6 mo–5 yrs		2 molars - failures
Rolling	1975	5 min FC+ZOE/FC -98 molars	3-36 mo	Survival rate–36 mo 77% max 67% mand	Survival Rates: 3 mo–91% 12 mo–83% 24 mo–78% 36 mo–70%
Willard	1976	4 min FC+ZOE-30 teeth	6-36 mo		Furc radiolucency 1 tooth Peri radiolucency 2 teeth Ext root resorption 2 teeth Int root resorption 2 teeth Calcif metamorph 24 teeth
Magnusson	1977	5 min FC+ZOE–48 mand molars 3-5 day FC+ZOE-36 mand molars	6-36 mo	No clinical signs or symptoms	Both groups: Internal root resorption 37% Furc or peri radioluc 10%
Fuks	1981	5 min 1:5 Dil FC+ZOE-70 teeth	4-36 mo	No clinical signs or symptoms	FC: 94% Furc or Peri radiolucency 3 teeth Int root resorption 1 tooth
Verco	1984	2 appt FC+ZOE/FC–240 teeth 5 min FC+ZOE/FC–1006 teeth	6 mo – 5 yrs	Both groups: 98%	Both groups: 92% Int root resorption 12 teeth
B.FERRIC SULFATE PULPOTOMY STUDIES					
Fei	1991	15.5% FS+ZOE: 29 human molars or 1:5 Dil 5 min FC+ZOE: 27 human molars	3-12 mo	FS–100% FC–96%	FS: 97% Calcific metamorphosis 48% FC: 78% Calcific metamorphosis 44%
Fuks	1997	15.5% FS+ZOE –55 human molars 1:5 Dil 5 min FC+ZOE –37 human molars	6-34 mo		FS: 93% Calcific metamorphosis 18% Furcation radiolucency 4% Internal root resorption 7% FC: 84% Calcific metamorphosis 11% Furc radiolucency 8% Peri radioolucency 8% Int root resorption 5%

FC=Full Strength Formocresol
1:5 Dil FC=1 to 5 Dilution of Full Strength Formocresol
ZOE=Zinc Oxide Eugenol
FS=Ferric Sulfate
ZOE=Zinc Oxide Eugenol
PCX=Polycarboxylate
FC=Formocresol

Table 2. Radiographic Success Rates Over Time by Tooth Type and Arch Location

317 Observations* of 242 Molars	4-12 mo N=12	13-24 mo N=117	25-36 mo N=57	>36 mo N=31
1st molars	78% (52/67)	74% (43/53)	78% (21/27)	80% (12/15)
2nd molars	84% (33/45)	73% (43/59)	83% (25/30)	69% (11/16)
	P=0.3722	*P*=0.8776	*P*=0.5956	*P*=0.4744
Max molars	89% (46/52)	76% (38/50)	90% (18/20)	91% (10/11)
Mand molars	73% (44/60)	72% (48/67)	76% (28/37)	65% (13/20)
	P=0.0445	*P*=0.5972	*P*=0.1909	*P*=0.1147
All molars	80%	74%	81%	74%

*Total observations > total teeth in the sample, because teeth were observed in multiple observation periods.

Materials and methods

Clinical and radiographic data were collected from a retrospective chart review in a solo private practitioner's office located in Fort Worth, TX, who has used the ferric sulfate pulpotomy technique exclusively since July 1994. The potential sample was generated from a computer search for pulpotomies performed in this office during the period of July 1994 to November 1998. The study sample was comprised of patients who presented with at least one primary molar treatment planned for a vital pulpotomy, and the patient records were screened to meet the following criteria for acceptance into the study: 1) primary teeth with a vital carious exposure with pulp tissue that bled upon entering the pulp chamber, 2) no clinical symptoms or evidence of pulpal degeneration, to include swelling or presence of a sinus tract, 3) a tooth restorable with a posterior stainless steel crown that remained intact at future recalls until the tooth exfoliated or was extracted, and 4) patients who returned for at least one recall visit following the pulpotomy.

All molars were treated with the following technique: Rubber dam isolation, caries removal, and coronal access performed with a #330 high-speed bur with water spray. A spoon excavator was used for coronal pulp amputation. Hemostasis was obtained by using a 15.5% solution of ferric sulfate (Astringedent™ Ultradent Products Inc., Salt Lake City, UT) on the pulpal stumps with the dental infuser supplied by the manufacturer for 10-15 seconds. The pulpal stumps were then rinsed thoroughly, dried with cotton pellets, and covered by zinc oxide-eugenol cement. The teeth were restored with stainless steel crowns.

Permission to perform this investigation was obtained from the private practitioner. Radiographs met the following prescribed criteria: demonstrated proper film density and contrast to determine if findings were present, were of diagnostic quality, used paralleling technique and displayed a minimum of 2.0 mm of the furcation area. The criteria used to describe radiographic findings included: unremarkable, external root resorption, internal root resorption, interradicular bone destruction, calcific metamorphosis, periapical bone destruction, uneven root resorption compared to contralateral tooth, early eruption compared to contralateral tooth, and root perforation. Radiographic success was defined as absence of pathologic internal or external resorption, furcation or periapical radiolucency, and root perforation.

The following clinical codes were developed for chart review: no chart entry, soft tissue-unremarkable, draining fistula, abscess/swelling, spontaneous pain, mobility, and assessment of succeeding premolar for decalcification, abnormal morphology, or defect. Teeth were coded by reason for extraction. Teeth were scored as clinical successes if they had no symptoms of pain, tenderness to percussion, swelling, fistulation, or pathologic tooth mobility.

The principal investigator and co-investigator were standardized to determine inter-rater reliability by independently reading radiographs of 50 molars with 76 observations. Following standardization, the principal investigator scored all radiographs, and the co-investigator randomly selected 95 molars with 153 radiographic observations to score independently. If a discrepancy occurred between examiners a consensus was reached. All radiographs were read by both investigators using a standard view box illuminator with a 2x viewscope magnifier (Flow X-ray, West Hempstead, NY). The same view box was used for all radiographs. The Kappa statistic indicated highly significant reproducibility between the two examiners with a measurement of agreement of .744 ($P<0.001$).

Data collected for each patient during the chart review included: a) gender, b) chart number, c) date of birth, d) tooth number, e) treatment date, f) follow-up time in months, g) radiographic codes for each recall visit, h) clinical codes for each recall visit, i) extraction code and date of extraction, and j) tooth exfoliation. All data were entered into an Excel format for statistical analyses. Preliminary analyses consisted of testing radiographic failures for each time period by arch and by molar type using chi-squared tests of independence. The time until clinical failure (tooth loss prior to exfoliation) was considered for analysis using multivariate survival techniques. A robust log-rank test was conducted to compare the survival rate of pulpotomies, and product limit estimators of survival were calculated based on the true clinical survival, as well as the radiographic survival. Kaplan-Meier plots were constructed to demonstrate graphically the clinical and radiographic survival over time.

Results

The final study sample consisted of 171 children (81 females and 90 males) ranging in age from 2 years 8 months to 12 years 5 months, with a mean age of 7 years 5 months. A total of 242 primary molars were studied with the following composition: 1st molars = 129, 2nd molars = 113, maxillary molars = 110, mandibular molars = 132. The follow-up times ranged from 4 to 57 months with a mean of 19 months. Observation times were grouped into 12-month increments for purpose of reporting findings.

Radiographic findings

There were a total of 317 radiographs available from 242 treated molars followed from 4-57 months. Total observations were

Table 3. Distribution of Radiographic Findings* over Time

	N=317 Observations of 242 Molars			
	4-12 mo N=112	13-24 mo N=117	25-36 mo N=57	>36 mo N=31
Normal	79	60	27	10
Internal resorption	13	21	4	3
External resorption	2	9	2	3
Interradicular bone destruction	7	14	6	5
Periapical bone destruction	3	2	0	1
Root perforation	3	2	2	2
Calcific metamorphosis	7	23	13	10
Unevenroot resorption	2	3	5	1
Early eruption	5	1	4	5

*Some teeth had multiple findings.

Table 4. Pathologic Clinical Findings for Primary Molars over Time by Tooth Type and Arch Location

	4-12 mo	13-24 mo	25-36 mo	>36 mo
	N=112	N=117	N=57	N=31
1st molars	1.2% (1/67)	0.0%	0.0%	0.0%
2nd molars	1.5% (1/45)	2.8% (2/59)	2.7% (1/30)	0.0%
	P=0.8548	*P*=0.1172	*P*=0.3274	*P*=0.0874
Max molars	2.7% (2/52)	2.7% (2/50)	0.0%	0.0%
Mand molars	0.0% (0/60)	0.0%	2.4% (1/37)	0.0%
	P=0.1517	*P*=0.1317	*P*=0.3947	*P*=0.9682

greater than the total number of teeth in the sample, because some teeth were observed in more than one observation time. There were no significant differences between first and second molars or between maxillary or mandibular molars for any observation period. Therefore, all molars were combined and success rates reported for all molars together. These ranged from 80% at 4-12 months to 74% at >36 months (Table 2). Some teeth demonstrated more than one pulpal response, and these radiographic pulpal responses over time are summarized in Table 3.

Fig 1. Tooth #K at 39 month follow-up demonstrating normal radiographic appearance.

The frequency of normal appearing pulps decreased over time (Fig 1). The most frequently observed pulpal responses were calcific metamorphosis and internal resorption. Sometimes, both responses were observed in the same tooth (N=5). Fig 2A is an example of the development of internal resorption at 7 months in the distal root of the mandibular left second primary molar. Fig 2B reveals the onset of calcification in this same tooth at 15 months, and continuing at 29 months (Fig 2C).

In other teeth, internal resorption continued, but did not jeopardize retention of the treated teeth until normal exfoliation. Fig 3A reveals significant internal resorption with perforation of the mesial root of the mandibular right first primary molar at 7 months; however, the lamina dura remained intact. Thirty months later (Fig 3B) the tooth is nearing exfoliation without pathologic root resorption, and Fig 3C reveals normal exfoliation at 45-months follow-up.

Compared to preoperative findings (Fig 4A), Fig 4B depicts a mandibular right first primary molar undergoing interradicular bone destruction at 16 months. This patient failed to return for the planned extraction of the first molar and was seen again for an emergency visit over two years later. This tooth had progressed to external root resorption and extensive bone loss at 43 months in Fig 4C. These same figures also depict the mandibular right second primary molar undergoing progressive internal resorption during the same time period, but without involvement of supporting bone.

Clinical findings

Chart entries were reviewed for clinical findings at each follow-up period. There were no significant differences between first and second molars or between maxillary or mandibular molars over time for clinical findings (Table 4). Therefore, all molars were combined and success rates reported for all mo-

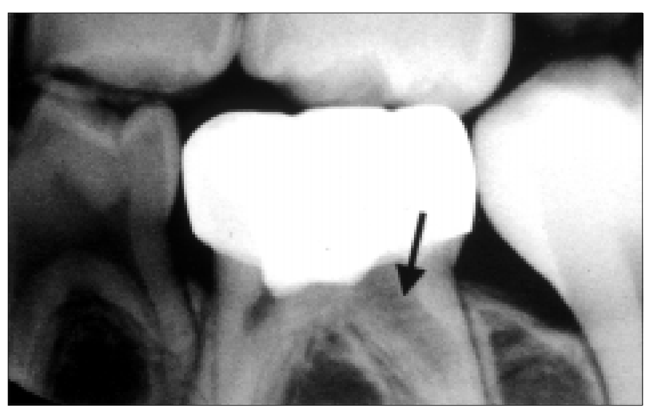

Fig 2a. Tooth #K with internal resorption (arrow) at 7 months follow-up.

Table 5. Distribution of Clinical Findings/ Success Rates Over Time

	N=410 Observations of 242 Molars			
	4-12 mo N=149	13-24 mo N=157	25-36 mo N=72	>36 mo N=32
Abscess	1	1	1	0
Mobility	0	1	0	0
Other	1	0	0	0
Total failures	2	2	1	0
% Success	99%	99%	99%	100%

Table 6. Estimated Survival by Time

Time (in months)	Probability of Survival	95% CI
5	0.996	(0.989,1.000)
7	0.992	(0.982,1.000)
10	0.988	(0.974,1.000)
21	0.979	(0.956,1.000)
26	0.966	(0.934,1.000)
30	0.933	(0.879,0.990)
39	0.901	(0.823,0.986)
43	0.806	(0.674,0.964)

lars together. The overall clinical success rate was 99%, with only 5 teeth extracted due to clinical symptoms. The follow-up time ranged from 7 to 44 months from time of treatment to extraction of these teeth (Table 5). An additional 4 teeth were extracted due to pathologic radiographic findings. Therefore, a total of 9 teeth were removed due to clinical or radiographic failure. There were no hypoplastic or hypocalcified areas noted for the succedaneous teeth replacing the primary teeth that received pulpotomies. Based on Wilcoxin Rank Sum Test, there was not a significant difference in the average age of patients who had successful pulpotomies and those who experienced one or more failures (P=0.7246).

Tooth survival analysis

Robust log-rank tests were used to compare tooth survival by arch (maxillary vs. mandibular) and by molar type (first molar vs. second molar). Robust tests were used to take into account multiple pulpotomies within a child. This technique enabled us to use survival techniques to analyze these data, although there is a lack of independence between some observations (Table 5, Fig 4). The robust log rank tests demonstrated that there was not a statistically significant difference in survival rates between either arch type or molar type (for arch type: P=0.84; for molar type: P=0.48).

Radiographic success was also evaluated using robust log-rank tests. Since tooth loss may not always provide an accurate view of "successful" pulpotomies, radiographic follow-up of these pulpotomies was evaluated as a "success" or a "failure" at each time point. For pulpotomies that were radiographic "failures" but became radiographic "successes" at a later point in time, the observation was treated as "censored" at the point where the failure was noted (Fig 6). Again, robust log-rank tests were used to compare the "success" rate according to arch and according to molar type over time. Although the survival plot for radiographic success over time according to arch type appeared to show better radiographic success for the maxillary arch, the robust log-rank test failed to be statistically significant (P=0.14). The survival plot for radiographic success over time according to molar type indicated little difference in radiographic success between first and second molars. Similarly, the robust log-rank test failed to be statistically significant for the difference in radiographic success over time between first and second molars (P=0.80).

Discussion

This retrospective study intended to examine clinical and radiographic success rates of ferric sulfate pulpotomies in primary molars and compare the findings with those of previous clini-

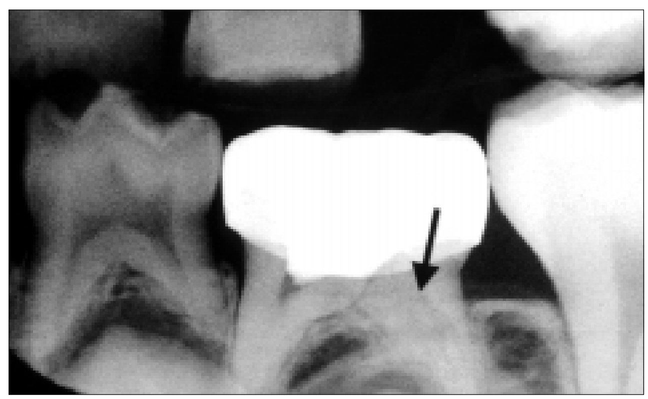

Fig 2c. Tooth #K with continuing calcification (arrow) at 29 months follow-up.

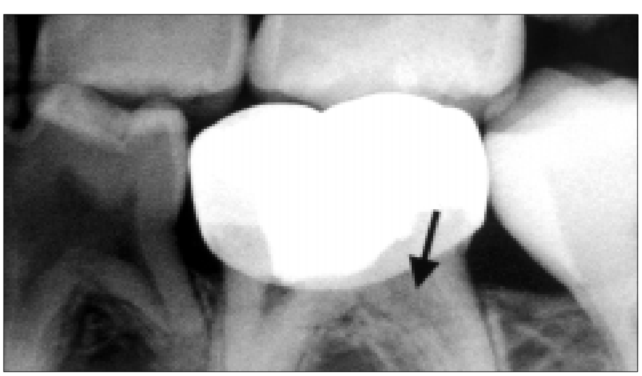

Fig 2b. Tooth #K with onset of calcification (arrow) at 15 months follow-up.

Fig 3a. Tooth #S with internal resorption (arrow) at 7 months follow-up.

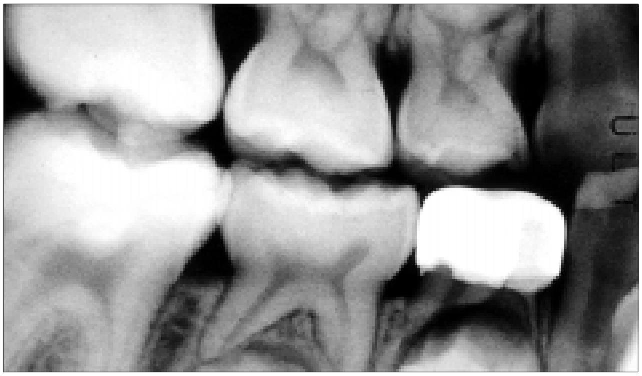

Fig 3b. Physiologic resorption of tooth #S at 37 months follow-up.

Fig 3c. Physiologic resorption of tooth #S at 45 months follow-up.

Fig 4a. Pre-operative radiograph teeth #S and #T.

cal studies of ferric sulfate pulpotomies and those using formocresol. The radiographic success rates for the ferric sulfate pulpotomies evaluated in this study are lower than those reported at corresponding time periods for ferric sulfate pulpotomies in the only two clinical studies available. Fei et al. in 1991, reported a 96% radiographic success rate after one year compared with an 80% success rate in the current study at one year.[21] Fuks and coworkers, in 1997, reported a radiographic success rate of 93% at 24-34 months compared with the current study's success rate of 81% at 25-36 months.[22] These differences in success rates may be due to the larger sample size

Fig 4b. Tooth #S with interradicular bone destruction (arrow) and tooth #T with internal resorption (arrow) at 16 months follow-up.

Fig 4c. Tooth #S with progressing bone destruction and external root resorption near permanent successor and tooth #T with progressing internal resorption at 43 months follow-up.

in the current study, with 112 molars in comparison with 28 molars observed at one year in the Fei et al. study, and 57 molars in comparison with 25 molars at 34 months in the Fuks et al. study.[21-22] Formocresol pulpotomies were the controls for both previous studies. Interestingly, the current study reported success rates for ferric sulfate more similar to the formocresol pulpotomies from both the Fei et al. (77% at one yr) and Fuks et al. (84% at 34 mos) studies.[21-22]

The two most common radiographic findings in the current study were internal resorption and calcific metamorphosis and are similar to those of Fuks et al.[22] The findings of internal resorption could be a result of the sub-base used in these studies. Both of the clinical ferric sulfate investigations, as well as this study, used zinc oxide and eugenol (ZOE) as the sub-base. Previous investigations of ZOE as a pulpotomy agent have reported internal resorption to be a common finding.[3, 23-24] ZOE, when used as a base in pulpotomies can come in contact with the highly perfused environment of pulp and

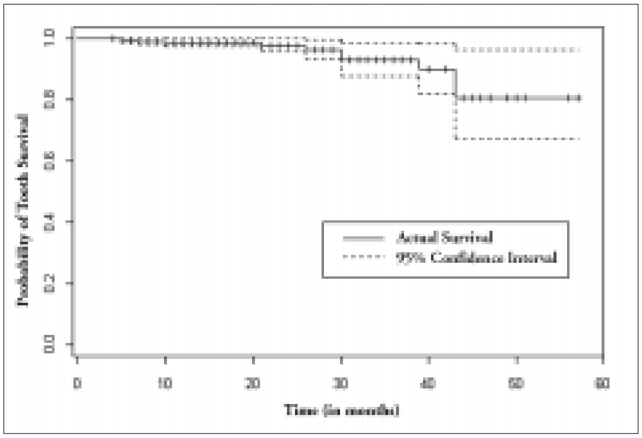

Fig 5. Tooth survival for all ferric sulfate pulpotomies evaluated.

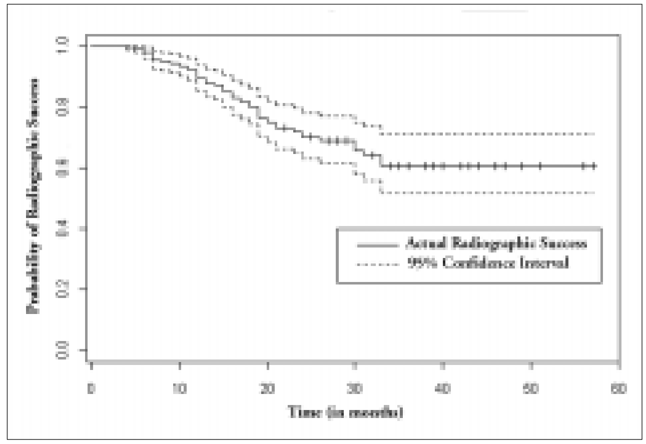

Fig 6. Radiographic success for all ferric sulfate pulpotomies evaluated.

undergo hydrolysis of the zinc eugenolate to yield free eugenol.[25] Direct placement of eugenol over vital tissue causes a moderate to severe inflammatory response with resulting chronic inflammation and necrosis.[26] One common response of the pulp to chronic inflammation is internal resorption. With formocresol, fixed tissue may act as a barrier to the eugenol, but with ferric sulfate, the clot is the only entity separating the eugenol from the vital tissue. Therefore, ZOE may not be an ideal base for ferric sulfate pulpotomies due to the inflammatory tissue response.

In this study, the private practitioner chose to observe teeth displaying internal resorption, instead of extracting these teeth as failures. This practice allowed observation of interesting radiographic changes over time not previously reported in teeth displaying internal resorption. For instance, in Fig 2A the mandibular left second primary molar at 7 months presented with radiographic internal resorption in the distal root. At 15 and 29 months follow-up, the internal resorption showed evidence of calcification. This phenomenon is similar to that found by Magnusson with ZOE pulpotomies, in which reparative new formation of hard tissue seen in areas of previous resorption was universally seen in histological analysis.[23] In other teeth (N=4) in the current study, internal resorption continued, but did not interfere with normal root resorption and the primary tooth remained until the normal exfoliation time (Figs 3A-3C). Both calcific metamorphosis and internal resorption are the result of odontoblastic and odontoclastic activity and suggest that the tooth is retaining some degree of vitality and function over time.[8] Although the cause of internal resorption is unknown, there is speculation that whatever the precipitating factor, it produces a vascular change in the pulp that involves an inflammation and the formation of granulation tissue.[27] There is an accompanying metaplasia of normal connective tissue and macrophages to form osteoclast-like giant multinuclear odontoclasts.[27]

This study was originally designed to use traditional radiographic criteria found throughout the literature. However, as data were collected and analyzed, it became apparent that radiographic changes could be classified as involving two resorptive processes, osseous and dental. Osseous resorptive changes involved supporting bone and included interradicular bone destruction, external root resorption and/or periapical bone destruction. These changes could lead to sinus tracts, cellulitis, pain and/or mobility. The dental resorptive process, internal resorption, was confined to the tooth and of dental origin. It was the result of a pulpal response to the procedure and/or medicament, such as ZOE, and appeared to show periods of activity and inactivity. It was not clinically significant in that it was confined to the tooth, remained that way and was asymptomatic. Internal resorption as a radiographic change by itself, was observed in 25 molars in this study. Because these dental radiographic findings do not involve osseous changes they would not affect the permanent successor. When internal resorption was observed over time (N=13), in no instance were osseous changes observed.

Therefore, the findings of this investigation could be reanalyzed using these new criteria for success: osseous changes would be defined as the radiographic failures in this study and include: interradicular bone destruction, periapical bone destruction and/or external root resorption. All other radiographic codes would be defined as successes and include: internal root resorption, root perforation, calcific metamorphosis, uneven root resorption compared to the contralateral tooth, and early eruption compared to the contralateral tooth. The radiographic success rates would then change from 80% to 92% at 4-12 months and from 74% to 84% at >36 months.

Many private practitioners today view that the ultimate goal for a pulpotomy is to maintain the primary tooth with no clinical signs or symptoms until the permanent successors erupt, with no harm occurring to the permanent successors. With this goal, some traditional radiographic failure criteria may not be important, as long as the permanent tooth is not affected. The permanent successor will only be affected if the radiographic pathology present involves an osseous change, versus a dental change confined to the primary tooth. In the current study, some dental radiographic "failures" were untreated due to failure of the patient to return for planned extractions, and there were no hypoplastic or hypocalcified areas noted in any succedaneous teeth replacing the primary teeth that received pulpotomies. The results of this study indicate that defining osseous changes versus dental changes may be a more realistic approach for developing criteria for success of a pulpotomy study, since in reality this is what clinicians have done for years when evaluating pulpotomies in a clinical setting.

The data were also analyzed to determine survival of the molars over time. The overall cumulative probability of survival remained high over time (Table 6) with cumulative survival rates all greater than 90% for all periods of time up to

39 months. The drop in cumulative survival rate at 43 months occurred because only a small number of treated teeth remained in any patient's mouth at this point. Only 22 treated teeth had clinical and/or radiographic observations for as long as 43 months.

The success rates found in this retrospective review of ferric sulfate pulpotomies are lower than those reported previously in the literature for ferric sulfate pulpotomies, but are comparable with those reported for 1:5 dilution, 5-minute formocresol pulpotomies.

Conclusions

1. Radiographic success rates ranged from 80% at 4-12 months to 74% at >36 months and are lower than those reported previously in the literature for ferric sulfate pulpotomies.
2. The most frequently observed pulpal responses were calcific metamorphosis and internal resorption. Sometimes (N=5) both responses were observed in the same tooth.
3. Clinical success rate was 99%, and only 9 of 242 primary molars were extracted due to radiographic or clinical failure.
4. Overall cumulative probability of survival remained high over time with a cumulative survival of over 90% after three years.
5. The results of this study suggest that defining osseous changes versus dental changes should be considered when developing criteria for success of pulpotomy.
6. The overall success rates in this study are lower than those reported previously in the literature for ferric sulfate pulpotomies, but are comparable with those reported for 1:5 dilution, 5-min formocresol pulpotomies.

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