COHORT STUDY

Longitudinal Study Comparing Pulpectomy and Pulpotomy Treatments for Primary Molars of Alaska Native Children

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Abstract: ***Purpose:*** *The purpose of this study was to determine which pulp treatment technique, performed at the Alaska Native Medical Center, is most successful by comparing failure rates of primary molars treated with ferric sulfate (FS) pulpotomy, sodium hypochlorite (SH) pulpotomy or pulpectomy between January 2005 and January 2016.* ***Methods:*** *All data were abstracted from the dental records of Alaska Native children aged 2-13 years, retrospectively. Clinical and radiographic failures up to five years after treatment were assessed. Cox proportional hazards models using random effects to account for correlated failure time were adjusted for age, sex, molar tooth position, and visit type. A total of 1,149 procedures in 830 children met the inclusion criteria: 490 pulpectomies, 111 SH Pulpotomies and 548 FS Pulpotomies.* ***Results:*** *Teeth treated with FS pulpotomy had 3.7 times higher risk of radiographic failure (adjusted hazard ratio [aHR]=3.73, 95% confidence interval [CI]= 2.25–6.16), and teeth treated with SH pulpotomy had 2.5 times higher risk of failure (aHR=2.57, 95% CI= 1.17–5.64) than those treated with pulpectomy.* ***Conclusions:*** *The findings from this large cohort study suggest that molar teeth treated with pulpectomies survive significantly longer than those treated with either FS or SH pulpotomies. Randomized trials are warranted to confirm findings.* *(Pediatr Dent 2019; 41(3):214-20) Received June 14, 2018 | Last Revision January 28, 2019 | Accepted March 14, 2019*

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Dental caries is the most prevalent chronic disease in children and considered to be the most common unmet health care need among those from the lowest socioeconomic strata. If left untreated, the disease can have broad dental, medical, social, and quality-of-life consequences, including pain, infection, premature loss of teeth, a decrease in self-confidence, arch-length loss, a loss of masticatory function, and permanent tooth impaction.[1-3]

Alaska Native children are reported to have a significantly higher caries experience than the non-Alaska Native pediatric population.[4] In addition, 60 percent of Alaska Native children are reported to have severe early childhood caries.[5] Though early intervention is recommended, many Alaska Native children go untreated until disease has significantly progressed to where more invasive therapies are necessary, including vital and nonvital primary tooth pulp therapy.

Primary tooth pulp therapy is performed to restore the health and function of primary teeth in children with severe caries. When caries is confirmed to approximate the pulp, any definitive treatment plan must address treatment of the pulp, directly or indirectly. A recent review of the literature found a higher success for indirect pulp capping than for pulpotomies, regardless of the pulpotomy medicament used.[6]

By convention, any primary molar demonstrating a short duration of stimulus-related pain with caries approximating the pulp is treated with vital pulp therapy. A tooth that is observed with symptoms, including spontaneous pain, sinus tract, localized soft tissue inflammation, pathologic mobility, radiographic evidence of abscess, and/or limited internal/external resorption, represents a progressed pathology requiring treatment with non-vital pulp therapy.[7]

While a number of small clinical studies have compared the success of pulp therapy treatments, findings have largely been inconsistent.[8-13] A common shortcoming among these contrasting reports is the lack of appropriate statistical methods used to compare rates of failure (or success) across treatments. Reporting survival as a binary outcome (i.e., percent success or failure) tends to overestimate survival of teeth, because long-term failures are diluted by the early success of recently treated teeth.[14] Another important limitation among these studies is the incorrect assumption that teeth are independent observations when clustered dental data are analyzed using classic statistical techniques. Often, multiple teeth are treated per patient, and this creates correlated observations. Ignoring the correlated structure of tooth data can lead to inflated type one errors that impact hypothesis testing.

The purpose of this study was to compare the survival of treated primary molar teeth across Vitapex pulpectomies, sodium hypochlorite pulpotomies, and ferric sulfate pulpotomies. These data address methodological shortcomings of previous studies using multivariable survival analyses that account for important covariates and control for the correlated nature of teeth measured within mouths. Additionally, the robust sample size of this study, along with the lengthy data range, add considerably to its strength.

Methods

This is a retrospective cohort study of clinical data that were reviewed from charts of children receiving care from the Alaska Native Medical Center on the Southcentral Foundation campus in Anchorage, Alaska, an affiliate of NYU Langone Hospitals. Alaska Natives refer to themselves as customer-owners (**COs**) rather than patients, as the former describes individuals seeking ownership and involvement in their health care. Included in the study were two- to 13-year-olds who received a

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pulpectomy or pulpotomy treatment in primary molar teeth between January 2005 and January 2016 and whose charts demonstrated proper preoperative documentation and notation of the treatment provided.

To be included in the analysis: (1) teeth had to be restored with a stainless steel crown; (2) the stainless steel crown needed to be intact for the follow-up evaluation or until the tooth exfoliated naturally; (3) the patient had to have returned for a minimum of one six-month follow-up with a radiograph; and (4) pre- and postoperative radiographs had to be diagnostic. For teeth treated with pulpectomies to be included in the analysis, they needed to demonstrate, prior to the procedure: (1) a history of spontaneous pain; (2) presence of a sinus tract; (3) gingival abscess; (4) hemorrhagic radicular pulp tissue; (5) no pulp tissue remaining when the pulp chamber was accessed; (6) purulent discharge from the canals; (7) evidence of a radicular pathologic lesion with or without caries involvement; or (8) presence of interradicular or periapical radiolucency. For teeth treated with pulpotomies to be included in the analysis, they needed to be free of clinical or radiographic signs of pulpal or periapical pathosis (i.e., severe mobility, fistula, pain, external/internal root resorption, bone loss) prior to therapy.

All participants provided written consent prior to treatment; our project received approval from the Institutional Review Board (**IRB**) of New York University, New York, N.Y., USA, the Alaska Area IRB, the Alaska Native Tribal Health Consortium, and the Southcentral Foundation of Anchorage, Alaska, USA.

Treatment methodology. Patients were classified into three treatment modalities—pulpectomy, sodium hypochlorite pulpotomy, and ferric sulfate pulpotomy—depending on the condition and relative symptoms of the tooth on/up to the date of treatment. For illustrative purposes to describe the data at the individual level, those with multiple teeth treated by different modalities (N equals four) were classified according to the treatment performed on most teeth or were randomly chosen if there was no clear majority.

Though this is a retrospective study, it is important to understand that, at the Alaska Branch of the NYU Langone Hospitals Pediatric Dental Residency located in Anchorage, Alaska it is the intention of the providers to follow protocol when treating a tooth with pulpotomy or pulpectomy, as described next.

After a diagnostic preoperative radiograph is taken, rubber dam isolation, removal of caries, and tooth preparation for a stainless steel crown (**SSC**) is completed. Access into the pulp chamber is achieved using a no. 330, 245, or 557 carbide bur in a high-speed handpiece and then refined with sterile round burs in a slow-speed handpiece. The coronal pulp is carefully amputated with a round bur or sharp sterile spoon excavator. In the case of pulpotomy, once the coronal pulp is amputated and chamber dried, hemostasis of the radicular pulp is achieved within five minutes using dry, sterile cotton pellets and pressure over the root pulp orifices. After hemostasis is achieved, a cotton pellet soaked with either ferric sulfate, placed over the orifices for 10 to 15 seconds, or five percent sodium hypochlorite, placed over the orifices for 30 seconds. The cotton pellet is removed, the chamber is rinsed, gently dried, and filled with a dry mix of zinc oxide eugenol (Temrex Cement, Temrex Corp, Freeport, N.Y., USA), and each tooth is immediately restored with an SSC (using Rely-X Glass Ionomer Cement, 3M, Saint Paul, Minn., USA).

Table 1. DISTRIBUTION OF CUSTOMER-OWNER-LEVEL CHARACTERISTICS BY TREATMENT MODALITY*

Characteristic	Overall	Pulpectomies	Pulpotomies		*P*-value†
			Sodium hypochlorite	Ferric sulfate	
Total	**830**	**350**	**84**	**369**	
Age, mean±(SD)	5.0±1.2	5.3±1.6	4.7±1.5	4.5±1.3	<0.0001
Gender, N (%)					0.4137
Boys	456 (54.9)	184 (52.6)	45 (53.6)	227 (57.3)	
Girls	374 (45.1)	166 (47.4)	39 (46.4)	169 (42.7)	
Provider type, N (%)					0.0141
Attending	289 (34.8)	114 (32.6)	20 (23.8)	155 (39.1)	
Resident	541 (65.2)	236 (67.4)	64 (76.2)	241 (60.9)	
No. of teeth treated, N (%)					0.6682
1	581 (70.0)	246 (70.3)	62 (73.8)	273 (68.9)	
2	193 (23.3)	77 (22.0)	17 (20.2)	99 (25.0)	
3	44 (5.3)	21 (6.0)	4 (4.8)	19 (4.8)	
4	11 (1.3)	5 (1.4)	1 (1.2)	5 (1.3)	
5	1 (0.1)	1 (0.3)	0 (0.0)	0 (0.0)	

* Customer-owners with multiple teeth treated with different treatment modalities (N=4) were assigned to the procedure type performed on the most number of teeth, or randomly chosen in cases with one of each procedure type; the same approach was taken to classify provider type among those with a resident and attending operating on different teeth in the same customer-owner (N=19).

† *P*-values derived from analysis of variance or Pearson's chi-squared tests, as appropriate.

Table 2. DISTRIBUTION OF TOOTH-LEVEL CLINICAL CHARACTERISTICS BY TREATMENT MODALITY

Characteristic	Overall	Pulpectomies	Pulpotomies		*P*-value*
			Sodium hypochlorite	Ferric sulfate	
Total teeth treated (N)	**1,149**	**490**	**111**	**548**	
Molar teeth, N (%)					0.0149
First molars	641 (55.8)	255 (52.0)	74 (66.7)	312 (56.9)	
Second molars	508 (44.2)	235 (48.0)	37 (33.3)	236 (43.1)	
Dental arch, N (%)					0.4757
Maxillary	448 (39.0)	191 (39.0)	49 (44.1)	208 (38.0)	
Mandibular	701 (61.0)	299 (61.0)	62 (55.9)	340 (62.0)	
Dental arch and molar tooth type, N (%)					0.1198
First molars					
Maxillary first molars	279 (24.5)	109 (22.2)	35 (31.5)	135 (24.6)	
Mandibular first molars	362 (31.7)	146 (29.8)	39 (35.1)	177 (32.3)	
Second molars					
Maxillary second molars	169 (14.8)	82 (16.7)	14 (12.6)	73 (13.3)	
Mandibular second molars	331 (29.0)	153 (31.2)	23 (20.7)	163 (29.7)	
Visit type, N (%)					**<0.0001**
Operating room (with general anesthesia)	902 (78.5)	349 (71.2)	98 (88.3)	455 (83.0)	
Clinical setting (no sedation)	173 (15.1)	101 (20.6)	13 (11.7)	59 (10.8)	
Sedation appointment	74 (6.4)	40 (8.2)	0 (0.0)	34 (6.2)	

* *P*-values derived from Pearson's chi-squared tests.

In the case of a pulpectomy, after the coronal pulp is amputated, the radicular pulp is removed using a size 10-, 15-, 20-, or 25-mm endodontic k-file, instrumenting to the point of constriction. Per the recommendations of the American Academy of Endodontics, during instrumentation the canals are treated with copious and gentle sodium hypochlorite irrigation and then dried with paper points.[14,15] The canals are then obturated as Vitapex (Neo Dental International, Inc., Federal Way, Wash., USA) is gently injected into the canals until they were completely filled. The chamber is then filled with Temrex and the tooth is definitively restored with an SSC.

For pulpectomies, success was concluded, at the time of follow-up visits, if: (1) the treated tooth was asymptomatic and free of pathological mobility and signs or symptoms of infection; (2) the final radiograph demonstrated that the initial radiolucency had either decreased in size or resolved; (3) a fistula was present preoperatively that showed resolution, as noted in the clinical records; (4) the tooth remained asymptomatic until exfoliation; and (6) the radiographs taken were free of any pathologic external or internal resorption. For pulpotomies, success was defined, at the time of follow-up visits, if: (1) the treated tooth was asymptomatic and free of pathological mobility and signs or symptoms of infection; and (2) there was no evidence on follow-up radiographs of internal or external resorption or bone destruction.

Study endpoints. Treatment failure was determined independently by two dental examiners who were calibrated on study procedures; Interrater reliability showed that Cohen's Kappa was 73.7 percent (95 percent confidence interval [**CI**] equals 54.0 to 93.4 percent) for pulpectomy-treated teeth and 87.2 percent (95% CI equals 76.4 to 98.1 percent) for pulpotomy-treated teeth. The primary endpoint was radiographic failure, defined if a treated tooth: (1) developed a radiographic radiolucency (either periapical or furcal) that was not seen on preoperative radiographs; (2) demonstrated a radiolucency that remained unchanged or increased in size from the initial radiograph; and/or (3) revealed internal or external resorption that has led to bone destruction, even if the tooth was not extracted. A secondary endpoint was clinical failure, defined if a treated tooth: (1) was clinically symptomatic with signs or symptoms of infection requiring additional root treatment or was extracted; and/or (2) clinically demonstrated pathological mobility. We did not count exfoliation (at normal time, early, nor delayed) as an endpoint, since time-to-event analysis accounts for timing to the failure.

Table 3. ASSOCIATION OF TREATMENT MODALITY WITH RISK OF RADIOGRAPHIC FAILURE IN CRUDE AND ADJUSTED MODELS

	Unadjusted*					Adjusted†		
	N	Failures (%)	Hazard ratio	95% CI	*P*-value	Hazard ratio	95% CI	*P*-value
Treatment								
Pulpectomy	490	26 (5)	1	(Referent)		1	(Referent)	
Sodium hypochlorite pulpotomy	111	13 (12)	2.63	1.22, 5.68	0.0136	2.57	1.17, 5.64	0.0187
Ferric sulfate pulpotomy	548	136 (25)	3.56	2.22, 5.73	<.0001	3.73	2.25, 6.16	<.0001
Sex								
Male	642	102 (16)	1	(Referent)		1	(Referent)	
Female	507	73 (14)	1.11	0.79, 1.54	0.5543	1.18	0.84, 1.65	0.3467
Age (years)	1149	175 (15)	0.94	0.82, 1.09	0.4252	1.12	0.94, 1.34	0.2118
Molar teeth								
First molars	641	116 (18)	1	(Referent)		1	(Referent)	
Second molars	508	59 (12)	0.54	0.40, 0.75	0.0002	0.47	0.33, 0.66	<.0001
Dental arch‡								
Maxillary	448	46 (10)	1	(Referent)		1	(Referent)	
Mandibular	701	129 (18)	1.64	1.16, 2.33	0.0056	1.81	1.26, 2.59	0.0013
Provider type								
Attending	425	78 (18)	1	(Referent)		1	(Referent)	
Resident	724	97 (13)	0.95	0.68, 1.34	0.7854	0.98	0.69, 1.39	0.9071
Visit type								
Operating room (with general anesthesia)	902	147 (16)	1	(Referent)		1	(Referent)	
Clinical setting: no sedation	173	15 (9)	0.89	0.53, 1.49	0.6515	0.79	0.44, 1.43	0.4423
Sedation appointment	74	13 (18)	1.36	0.75, 2.45	0.3088	1.22	0.61, 2.43	0.5816

* Values are hazard ratios (HR) and 95 percent confidence intervals (95% CIs) derived from Cox proportional hazards regression models with robust sandwich covariance matrix estimation to account for clustering within customer-owners.

† Models adjusted for treatment type, age, gender, molar tooth type, dental arch location, provider type, and visit type.

‡ Proportional hazards assumption not satisfied; the association of dental arch with radiologic failure presented for model completeness and should be interpreted with caution.

Covariates. Sociodemographic information included sex and age. We categorized molar teeth as either first or second, their location as maxillary or mandibular, the dental provider as attending or resident, and the visit type as the operating room (**OR**), at a sedation appointment, or at standard operative appointment (with/without nitrous oxide). All clinical information was attained using EagleSoft dental management software (v.17.00.49, Patterson Dental, Saint Paul, Minn, USA).

Statistical analysis. Associations between person- and tooth-level characteristics with treatment were assessed in contingency tables using analysis of variance for continuous variables and Pearson's chi-square or Fisher exact tests for categorical variables. Time-to-event analysis was performed to evaluate the relationship between treatment and failure time, with follow-up restricted to 60 months of observation. To account for clustering of teeth, marginal Cox proportional hazards models were fit where the regression parameters were calculated using maximum partial likelihood estimates under an independent working assumption and with a robust sandwich covariance matrix estimate to account for the intracluster dependence.[16]

Subsequent multivariable models were adjusted for strong predictors of failure and for potential confounding factors determined a priori, including age, sex, molar tooth type, dental arch location, provider type, and visit type. Confounding was assessed by considering the association between each covariate of interest and treatment as well as risk for failure. In secondary analyses, we restricted to clinical failures only. The proportional hazards assumption was assessed for each variable using plots of Schoenfeld residuals derived for treatment effects from crude (unadjusted) models over follow-up and by visual inspection of log(-log[survival]). No evidence of departure from proportionality was found except for dental arch; Schoenfeld residuals for dental arch were significantly correlated with follow-up time (*P*=0.0183). Therefore, subsequent sensitivity analyses were performed in which the interaction between dental arch and continuous time was included in the final multivariable model. Because the interaction did not appreciably change the results of the main effect, we kept dental arch in the model for consistency.

To identify whether the effect of treatment on rate of failure is different in groups of patients with different demographic and clinical characteristics, separate marginal Cox models were fit that contained terms for the interaction between treatment and each covariate of interest while adjusting for the same variables as those from the main effect models. Subtypes of pulpotomy were combined for interaction analyses, due to small cell sizes in some groups. All statistical tests were two-sided, with a significance level at 0.05, and performed using SAS 9.4 software (SAS Institute Inc., Cary, N.C., USA).

Results

Study population. A total of 830 COs were recruited into the study, of whom roughly half (N equals 350) were treated with pulpectomies. Table 1 provides the overall distribution of person-level characteristics by treatment modality. The population had an approximately equal proportion of boys and girls with an average age of roughly five years. Children who received pulpectomies were slightly older (less than one year old) than those who received other treatments (*P*<0.0001). All treatments were largely performed by pediatric residents (65 percent). Thirty percent (30 percent) of COs had more than one tooth treated with a modality, up to a maximum of five treated teeth (N equals one); notably, the distribution of COs with more than one treated tooth did not vary significantly across treatment modalities.

Among 830 charts reviewed, 2,159 pulpectomy-treated teeth and 2,127 pulpotomy-treated teeth were reviewed. A total of 1,149 teeth were included in the analysis, of which 490 were treated with pulpectomies and 659 were treated with pulpotomies (83 percent were ferric sulfate pulpotomies, and 17 percent were sodium hypochlorite pulpotomies). Table 2 displays the distribution of tooth-level characteristics by treatment modality. First molar teeth comprised the majority (56 percent) of all teeth that were treated; 61 percent of all teeth treated were mandibular, and nearly 79 percent of treatments were completed in the operating room. Pulpotomies were significantly more likely than pulpectomies to be completed at an operating room visit (*P*<0.0001).

Associations between treatment and risk of failure. A total of 175 radiographic and 59 clinical failures were documented over the course of follow-up. The median length of follow-up was 30 months for pulpotomies and 42 months for pulpectomies. Table 3 shows the crude and adjusted hazard ratios in models that accounted for clustering of teeth. After controlling for age, sex, molar tooth, dental arch, provider type, and visit type, teeth treated with sodium hypochlorite and

Table 4. ASSOCIATION OF TYPE OF TREATMENT MODALITY WITH TOOTH SURVIVAL BY CLINICAL ENDPOINT *

Independent variable	Unadjusted					Adjusted †		
	N	Failures	Hazard ratio	95% CI	*P*-value	Hazard ratio	95% CI	*P*-value
Treatment								
Pulpectomy	490	10	1	(Referent)		1	(Referent)	
Sodium hypochlorite pulpotomy NaOCl	111	3	1.58	0.43, 5.80	0.4905	1.82	0.49, 6.67	0.3696
Ferric sulfate pulpotomy	548	46	2.85	1.42, 5.73	0.0033	2.71	1.32, 5.55	0.0064
Sex								
Male	642	35	1	(Referent)		1	(Referent)	
Female	507	24	1.15	0.66, 2.01	0.6259	1.16	0.66, 2.06	0.6071
Age (in 1-year increments)	1149	59	0.91	0.70, 1.17	0.4579	0.96	0.71, 1.30	0.8092
Tooth								
First molars	641	36	1	(Referent)		1	(Referent)	
Second molars	508	23	0.69	0.41, 1.16	0.1589	0.66	0.38, 1.15	0.1411
Dental arch								
Maxillary	448	11	1	(Referent)		1	(Referent)	
Mandibular	701	48	2.42	1.26, 4.66	0.0082	2.55	1.28, 5.06	0.0076
Provider								
Attending	425	32	1	(Referent)		1	(Referent)	
Resident	724	27	0.67	0.38, 1.15	0.1474	0.64	0.36, 1.13	0.1213
Appointment								
Operating room (with general anesthesia)	902	46	1	(Referent)		1	(Referent)	
Clinical setting: no sedation	173	7	1.44	0.66, 3.12	0.3598	1.69	0.69, 4.13	0.2509
Sedation appointment	74	6	1.89	0.79, 4.49	0.1519	1.88	0.73, 4.84	0.1923

* Values are hazard ratios and 95% confidence intervals (95% CI) derived from Cox proportional hazards regression models with robust sandwich covariance matrix estimation to account for clustering within customer-owners.

† Models adjusted for treatment type, age, gender, first versus second molars, location (maxillary versus mandibular), provider (attending versus resident), and appointment location.

ferric sulfate pulpotomies had significantly higher risks of failure versus those treated with pulpectomies (adjusted hazard ratio [**aHR**] equals 2.57, 95% CI equals 1.17, 5.64; and aHR equals 3.73, 95% CI equals 2.25, 6.16, respectively). We further tested pulpotomy treatments to each other in pairwise analysis. Compared to sodium hypochlorite pulpotomies, ferric sulfite pulpotomies had a higher risk of failure; however, estimates did not reach statistical significance due to smaller number of failures (unadjusted hazard ratio [**HR**] equals 1.80, 95% CI equals 0.55, 5.87, P=0.3286; and aHR equals 1.49, 95% CI equals 0.45, 4.96, P=0.5127). We observed no confounding for each covariate tested.

In this multivariable model, molar tooth position and dental arch remained significant predictors of failure (i.e., second molars had a 53 percent lower risk of failure than first molars (aHR equals 0.47, 95% CI equals 0.33, 0.66) and mandibular teeth had an 81 percent higher risk of failure than maxillary teeth (aHR equals 1.81, 95% CI equals 1.26, 2.59). Sensitivity analyses that stratified models by dental arch confirmed no appreciable differences in associations from main effects (data not shown). In addition, when a clinical rather than radiographic endpoint was considered, we found similar associations (Table 4).

Table 5 presents the findings from exploratory analyses that evaluated the data for effect modification. We found no evidence that the associations varied by age, sex, molar teeth type, dental arch, provider, or visit type (all P-values for interaction were >0.05). Nevertheless, we found that after controlling for age, gender, dental arch, provider type, and appointment location, first molars treated with pulpotomies were roughly 3.5 times more likely to fail than first molars treated with pulpectomies (aHR equals 3.46, 95% CI equals 1.99, 6.03).

Table 5. EFFECT MODIFICATION OF THE ASSOCIATION BETWEEN TREATMENT AND FAILURE

Independent variable	Pulpectomy*				Sodium hypochlorite/ferric sulfate pulpotomy*				
	N	Failures	Hazard ratio	95% CI	N	Failures	Hazard ratio	95% CI	P-value
Sex									0.9619
Male	257	14	1	(Referent)	385	88	3.45	1.76, 6.78	
Female	233	12	0.84	0.36, 1.98	274	61	2.98	1.49, 5.96	
Age (years)									0.6058
<5	253	18	1	(Referent)	476	110	3.22	1.79, 5.78	
≥5	237	8	1.12	0.47, 2.67	183	39	4.66	2.39, 9.11	
Molar tooth									0.9607
First molars	255	17	1	(Referent)	386	99	3.46	1.99, 6.03	
Second molars	235	9	0.49	0.22, 1.05	273	50	1.72	0.94, 3.12	
Dental arch†									0.4120
Maxillary	299	21	1	(Referent)	402	108	3.14	1.84, 5.36	
Mandibular	191	5	0.37	0.13, 1.03	257	41	1.83	0.99, 3.36	
Provider type									0.5090
Resident	326	17	1	(Referent)	398	80	3.04	1.77, 5.22	
Attending	164	9	0.78	0.29, 2.06	261	69	3.35	1.90, 5.91	
Visit type									0.6625
Operating room (with general anesthesia)	349	22	1	(Referent)	553	125	3.33	1.97, 5.64	
Clinical setting‡	141	4	0.78	0.26, 2.32	106	24	3.38	1.72, 6.63	

* Values are hazard ratios and 95% confidence intervals (95% CIs) derived from Cox proportional hazards regression models with robust sandwich covariance matrix estimation to account for clustering within customer-owners; models adjusted for age, gender, first or second molars, location (maxillary versus mandibular), provider (attending versus resident), and appointment location.

† Proportional hazards assumption not satisfied; the association of dental arch with radiologic failure presented for model completeness and should be interpreted with caution.

‡ With or without sedation.

Discussion

To date, this is the largest longitudinal study comparing tooth survival across these pulp therapy treatments in children. The results showed that ferric sulfate and sodium hypochlorite pulpotomies were significantly more likely to fail than Vitapex pulpectomies. This association was independent of potential confounders such as age, sex, provider type, and number of treated teeth. Consistency was found in the direction and magnitude of estimates when the outcome was restricted to clinical failures, suggesting that the findings are robust.

These findings are consistent with previous studies that suggest higher success for teeth treated with pulpectomies.[8,18-20] For instance, a longitudinal study of 130 children found that molar teeth treated with pulpectomies had significantly higher percent survival than teeth treated with ferric sulfate pulpotomies after three years of follow-up.[12] Ozalp and Chen demonstrated the success of pulpectomies over their sample period of 100 percent; however, due to small sample sizes and short follow-ups, diminished weight has been given to their findings.[17,18] Although these findings are supportive of literature regarding the positive effects of pulpectomies in primary teeth, they do not explain why a pulpectomy might be more successful than a pulpotomy.

The rationale behind completing a pulpotomy relies on the natural healing ability of healthy radicular pulp tissue. Once all the compromised pulp has been removed and the healthy pulp is treated with a medicament, sealed, and then definitively restored, the tooth will heal and remain in the mouth until it is exfoliated naturally.[3] Because of the difficulty in determining the extent of pulpal compromise, however, misdiagnosis may be attributed, in part, to the higher failures observed in pulpotomy-treated teeth.

Children, especially the very young, are generally not reliable reporters of tooth symptoms; they have a lower threshold for pain, their responses may be exaggerated due to anxiety, and they struggle with accurate recall sufficient to answer the questions required to make an accurate pulpal diagnosis. Children often lack the ability to understand and differentiate between acute and chronic symptoms, reversible and nonreversible symptoms, and stimulated and non-stimulated pain; therefore, they may be delayed in reporting symptoms or simply report symptoms incorrectly.[19]

Assuming a vital pulpal diagnosis is accurately reached, the provider's next challenge is to determine which type of medicament to use for treating the radicular pulp.

Because of its biocompatibility, bactericidal nature, ability to seal, and ability to induct cementogenesis, dentinogenesis, and osteogenesis, mineral trioxide aggregate has consistently demonstrated high success as a pulpotomy agent; however, due to comparatively fewer studies, its much higher cost, relatively difficult workability, and delayed setting time result in continued use of other pulpotomy medicaments.[3] Other medicaments used in pulpotomies, including ferric sulfate, formocresol, glutaraldehyde, and, to a degree, sodium hypochlorite, can artificially contribute to hemostasis of a pulp, unfortunately masking the true condition of the pulp.

Adding to the complexity of achieving an accurate pulpal diagnosis, current research suggests that, even if hemostasis is achieved within five minutes, hemostasis at the canal orifices might not provide accurate assessment of inflammation; therefore, it may be misleading for diagnosing vital pulp treatment in primary teeth with a carious pulp exposure.[20]

Furthermore, significant anatomical and physiological differences exist between mature permanent teeth and primary teeth. Specifically, an underdeveloped plexus of Raschkow in the pulp-dentin complex results in a decreased density of innervation in primary teeth, causing certain vitality diagnostic tests to have little value in primary teeth.[19]

When planning for a pulpectomy, the concern of a pulpal misdiagnosis due to inaccurate subjective reporting, anatomical differences, or occult hyperemia is eliminated. By performing pulpectomies, clinicians have been able to successfully preserve the teeth in the arch as a natural space maintainer; despite an increase in research supporting this technique, as of 2005 only 85 percent of dental schools in the United States teach any form of pulpectomy technique. Additionally, 52 percent of American Academy of Pediatric Dentistry diplomates who responded to the survey and 47 percent of the directors of school programs advocated the extraction of a primary mandibular second molar with a draining fistula but no root resorption.[21] The findings from this study demonstrate that the tooth survival benefit from a pulpectomy did not vary by sex, age, provider type, visit type, or whether the treatment was complete on a first or second molar or in the maxillary or mandibular arch. This is helpful to the provider or institution unfamiliar with a pulpectomy technique, as it supports the idea that, although there are additional steps and training required to treat a molar with a pulpectomy, even the less-practiced clinician should be able to expect a high level of success.

In comparing pulpectomies and pulpotomies performed on first versus second molars, the data from the present study indicate that second molar pulpectomies were 51 percent less likely to fail than first molar pulpectomies . This association, while strong, did not reach statistical significance, similar to findings from studies by Holan and Fuks.[26,27] Since a difference in success of treatment by molar teeth has not been clearly established thus far, providers should not be dissuaded from treating first molars with a pulpectomy.

The authors believed that the findings of this study are likely an underrepresentation of the true potential for pulpectomy's success in comparison to a pulpotomy. Generally, pulpectomies are performed on teeth with significant loss of tooth structure and with pulpal compromise far beyond those teeth treated with pulpotomies.

The authors note several limitations to the study. These results do not account for other potential variables not assessed in the study, including comorbidities and environmental characteristics such as socioeconomic status, social circumstances, water fluoridation, and behavioral factors like oral hygiene. An attempt at determining the potential for influence of these particular variables was beyond the scope of this study. Regarding the assessment of effect modification across variables that we did have, we may not have been sufficiently powered to detect statistical (multiplicative) interaction. Nevertheless, it is reassuring that there is consistency in the association of the main effect across levels of these variables. Furthermore, selection bias may have occurred if children who were lost to follow-up experienced failures at a percent that was different than those who remained in the cohort, particularly by treatment status. Lastly, because this is an observational study, a causal inference from the findings cannot be verified.

Taken together, the findings from the current study suggest that the outcomes of pulpectomies are better than sodium hypochlorite and ferric sulfate pulpotomies. This study benefits from the added statistical control for correlated teeth within mouths that is present in dental data but not often addressed. Nevertheless, randomized clinical trials are needed to confirm these findings.

Conclusions

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

1. First and second primary molar pulpectomies demonstrate better radiographic survival than ferric sulfate and sodium hypochlorite pulpotomies. Ferric sulfate pulpotomy is 3.7 times more likely to fail than pulpectomy. Sodium hypochlorite pulpotomy is 2.5 times more likely to fail than pulpectomy.
2. First and second primary molar pulpectomies demonstrate better clinical survival than ferric sulfate and sodium hypochlorite pulpotomies. Ferric sulfate pulpotomy is 2.7 times more likely to fail than pulpectomy. Sodium hypochlorite pulpotomy is 1.8 times more like to fail than pulpectomy.
3. Second molar pulpectomies had better survival than first molar pulpectomies (though the difference was not significant).
4. Better survival of pulpectomies was statistically independent of tooth type (first molar versus second molar), provider type (attending versus resident), visit type (OR versus sedation versus no sedation/ N2O/non-N2O appointment), and arch (maxillary versus mandibular).

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References

1. Casamassimo PS, Thikkurissy S, Edelstein BL, Maiorini E. Beyond the dmft: the human and economic cost of early childhood caries. J Am Dent Assoc 2009;140(6):650-7.
2. Fontana M. The clinical, environmental, and behavioral factors that foster early childhood caries: evidence for caries risk assessment. Pediatr Dent 2015;37(3):217-25.
3. Parisay I, Ghoddusi J, Forghani M. A review on vital pulp therapy in primary teeth. Iran Endod J 2015;10(1):6-15.
4. Phipps KR, Ricks TL, Manz MC, Blahut P. Prevalence and severity of dental caries among American Indian and Alaska Native preschool children. J Public Health Dent 2012;72(3):208-15.
5. Sekiguchi E, Guay AH, Brown LJ, Spangler TJ. Improving the oral health of Alaska Natives. Am J Public Health 2005;95(5):769-73.
6. Coll JA, Seale NS, Vargas K, Marghalani AA, Al Shamali S, Graham L. Primary tooth vital pulp therapy: a systematic review and meta-analysis. Pediatr Dent 2017;39 (1):16-27.E15-E95.
7. American Academy of Pediatric Dentistry, Clinical Affairs Committee. Guideline on pulp therapy for primary and immature permanent teeth. Reference Manual 2016-2017 Pediatr Dent 2016;38(special issue):280-8.
8. Vostatek SF, Kanellis MJ, Weber-Gasparoni K, Gregorsok RL. Sodium hypochlorite pulpotomies in primary teeth: a retrospective assessment. Pediatr Dent 2011;33(4):327-32.
9. Erdem AP, Guven Y, Balli B, et al. Success rates of mineral trioxide aggregate, ferric sulfate, and formocresol pulpotomies: a 24 month study. Pediatr Dent 2011;33(2):165-70.
10. Ruby JD, Cox CF, Mitchell SC, Makhija S, Chompu-Inwai P, Jackson J. A randomized study of sodium hypochlorite versus formocresol pulpotomy in primary molar teeth. Int J Paediatr Dent 2013;23(2):145-52.
11. Li TY, Chuang LC, Tsai AI. A retrospective study of sodium hypochlorite pulpotomies in primary molars. J Dent Sci 2016;11(3):261-5.
12. Casas MJ, Kenny DJ, Johnston DH, Judd PL. Long-term outcomes of primary molar ferric sulfate pulpotomy and root canal therapy. Pediatr Dent 2004;26(1):44-8.
13. Shabbzendedar M, Mazhari F, Alami M, Talebi M. Sodium hypochlorite versus formocresol as pulpotomy in primary molars: 1-year follow up. Pediatr Dent 2013;35 (4):329-32.
14. Hannigan A, Lynch CD. Statistical methodology in oral and dental research: pitfalls and recommendations. J Dent 2013;41(5):385-92.
15. Torabinejad M. Endodontics: Root Canal Irrigants and Disinfectants. Chicago, Ill., USA: American Association of Endodontics; 2011:1-7.
16. Zehnder M. Root canal irrigants. J Endod 2006;32(5): 389-98.
17. Lin DY. Cox regression analysis of multivariate failure time data: the marginal approach. Stat Med 1994;13(21): 2233-47.
18. Garcia-Godoy F. Evaluation of an iodoform paste in root canal therapy for infected primary teeth. ASDC J Dent Child 1987;54(1):30-4.
19. Reyes AD, Reina ES. Root canal treatment in necrotic primary molars. J Pedod 1989;14(1):36-39.
20. Pramila R, Muthu MS, Deepa G, Farzan JM, Rodrigues SJ. Pulpectomies in primary mandibular molars: a comparison of outcomes using three root filling materials. Int Endod J 2016;49(5):413-21.
21. Ozalp N, Saroglu I, Sonmez H. Evaluation of various root canal filling materials in primary molar pulpectomies: an in-vivo study. Am J Dent 2005;18(6):347-50.
22. Chen XX, Lin BC, Zhong J, Ge LH. Degradation evaluation and success of pulpectomy with a modified primary root canal filling in primary molars. Beijing Da Xue Bao Yi Xue Ban 2015;47(3):529-35.
23. Gopakumar R, Gopakumar M. Diagnostic aids in pediatric dentistry. Int J Clin Pediatr Dent 2011;4(1):1-7.
24. Mutluay M, Arikan V, Sari S, Kisa U. Does achievement of hemostasis after pulp exposure provide an accurate assessment of pulp inflammation? Pediatr Dent 2018;40 (1):37-42.
25. Dunston B, Coll JA. A survey of primary tooth pulp therapy as taught in US dental school and practice by Diplomates of the American Academy of Pediatric Dentistry. Pediatr Dent 2008;30(1):42-8.
26. Holan G, Fuks AB. A comparison of pulpectomies using ZOE and KRI paste in primary molars: a retrospective study. Pediatr Dent 1993;15(6):403-7.
27. Holan G, Fuks AB, Keltz N. Success rate of formocresol pulpotomy in primary molars restored with stainless steel crown versus amalgam. Pediatr Dent 2002;24(3):212-6.