



Alternative method of hemorrhage control in full strength formocresol pulpotomy

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Abstract

Purpose: This investigation evaluated the success of a formocresol pulpotomy technique in which hemostasis was obtained with the same formocresol dampened cotton pellet used to medicate the root pulp stumps and to compare the findings of this investigation with data of published formocresol pulpotomy studies in which hemorrhage was controlled by traditional means.

Methods: Clinical and radiographic data were available for 194 primary molars in 112 patients with follow up times ranging from 5 to 109 months (mean=38 months).

Results: Overall radiographic success was 87%. The most frequently observed pulpal responses were calcific metamorphosis (34%) and internal resorption (10%). Overall clinical success was 98%. Only 7 of 194 molars were extracted due to radiographic and/or clinical failure. Overall cumulative probability of survival remained high over time with a cumulative survival rate of over 94% over 4 years.

Conclusions: The success rates for this variation of the formocresol technique are comparable to those success rates in the literature where hemostasis was obtained in a separate step using a nonmedicated cotton pellet. The results of this study suggest that using the same cotton pellet dampened with full strength formocresol to obtain hemorrhage control and medicate the root pulp is an acceptable variation of the traditional formocresol pulpotomy technique. (*Pediatr Dent* 23:217-222, 2001)

For primary teeth with carious pulp exposure, successful pulp therapy is one of the most valuable services a child patient can receive, since there is no better space maintainer than the retained primary tooth.¹ With the advent of the "Sweet technique"² in the 1930s, formocresol pulpotomies have been the popular choice of pulp therapy for primary teeth presenting with coronal pulpitis. Modifications of the first formocresol pulpotomy have included reduction in time of application of the medicament,^{2,3} reduction in concentration of the formocresol,⁴ and deletion of formocresol in the zinc oxide eugenol (ZOE) sub base.⁵ All of the modifications have produced clinically successful results as reported in the literature.

One aspect of the pulpotomy procedure which has not been modified is that hemorrhage of the root pulp stumps is controlled in a timely manner without the aid of a hemostatic agent. The ability to accomplish this step is purported to be indicative that the remaining pulp tissue is healthy and free

from infection. If hemostasis is difficult, the pulp tissue is described as "hyperemic" and indicates inflammatory changes are present in the radicular pulp and pulpotomy procedure should be abandoned in favor of pulpectomy or extraction.⁶ Dental textbooks advise that no vasoconstrictive or hemostatic medicaments be placed onto the root pulp stumps that might mask whether or not the pulp can clot on its own.^{7,8} However, no references are listed to substantiate this proposed requirement for successful pulpotomy treatment. The formocresol studies found in the published literature all obtain hemostasis of the pulp stumps using nonmedicated cotton pellets.

This concept of allowing the root pulp to clot on its own is disregarded with the use of the proposed alternatives to formocresol. Ferric sulfate, the agent receiving the most attention recently, facilitates the formation of a blood clot by chemical reactions with the blood.⁹ The reported success of the ferric sulfate pulpotomy has been comparable to that of formocresol pulpotomies¹⁰⁻¹³ and does not support the notion that the root pulp must clot without the aid of a medicament to predict successful outcome for the pulpotomy procedure.

In fact, anecdotal evidence suggests that private practitioners routinely omit the separate step of obtaining hemostasis with a nonmedicated cotton pellet but achieve control of hemorrhage with the same cotton pellet used to medicate the pulp with formocresol. A survey of 220 randomly selected members of District 5 of the American Academy of Pediatric Dentistry sought to determine how private practitioners control hemorrhage of the root pulp for their formocresol pulpotomies. Analysis of the 132 surveys returned indicated that 50% of the practitioners who perform formocresol pulpotomies use the same formocresol dampened cotton pellet to obtain hemorrhage control as is used to medicate the pulp.¹⁴ However, to date there are no reports in the literature concerning the effect this modification to the traditional formocresol pulpotomy has on the success of the procedure. Therefore, the purpose of this investigation was to examine a formocresol technique in which hemostasis with a nonmedicated cotton pellet was omitted prior to applying a cotton pellet dampened with full strength formocresol.

Methods

Clinical and radiographic data were collected from a retrospective chart review in a private pediatric dentist's office located

in Sherman, Texas. The practitioner has used the described formocresol pulpotomy technique since January 1980. The study sample was comprised of patients who presented during the period of January 1980 to January 1995 with at least one primary molar treatment planned for a vital pulpotomy. Patient charts were made available from the practitioner's active and inactive files. Permission to perform this investigation was obtained from the private practitioner. The primary investigator screened the patient records to evaluate if the following criteria were met for acceptance into the study: 1) primary teeth with 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, were present prior to performing the pulpotomy; 3) primary teeth were treated with the described five minute formocresol technique; 4) a tooth restorable with a posterior stainless steel crown that remained intact at future recalls until the tooth exfoliated or was extracted; and 5) patients who returned for at least one recall visit that included radiographs following the pulpotomy. Radiographs were determined to be of diagnostic quality (i.e. proper exposure, processing and appropriate angulation) and bitewing radiographs displayed a minimum of 2.0 mm of the furcation area.

All molars were treated with the following technique: rubber dam isolation, caries removal, and coronal pulp access using a high-speed handpiece with a #4 round carbide bur and water spray. A spoon excavator was used for coronal pulp amputation. A cotton pellet that had been wetted with full strength formocresol and then blotted dry was placed over the root pulp stumps for five minutes and removed. The pulp chamber was filled with zinc-oxide eugenol cement (Temerex: Temerex Corporation, Freeport, New York). The tooth was restored with a stainless steel crown cemented with Temerex.

The principal investigator and co-investigator were calibrated for radiographic interpretation of pulpotomies using the criteria developed for this study. The criteria included the assignment of the following codes describing radiographic findings: 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, delayed eruption compared to contralateral tooth, and root perforation. The calibration session included having both investigators read the radiographs of 57 primary molars with 192 observations. Following the calibration, the principal investigator scored all radiographs, and the co-investigator randomly selected 40 primary molars with 65 radiographic observations to score independently. All radiographs were viewed on a standard viewbox (Star Xray, Model DE100) with the aid of a viewing device that eliminated extraneous light and magnified the image (Viewscope 2X, Flow Xray). The Kappa statistic indicated a significant reproducibility between the two examiners with a measurement of agreement of 0.637 ($P < 0.0001$).

The following clinical codes were developed for chart review: no chart entry, unremarkable soft tissue, draining fistula, abscess/swelling, spontaneous pain, mobility, and assessment of decalcification, abnormal morphology, or defect noted on the succeeding premolar. In addition, extraction codes were developed to identify the reason for extraction.

Data collected for each patient included: patient name, date of birth, tooth number, treatment date, follow up time in months, radiographic codes for each recall visit, clinical codes for each recall visit, extraction code and date of extraction, and tooth exfoliation. All data were then entered into an Excel software (Microsoft Corp, Redmond, WA) 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. To explore whether radiographic failure rates varied over time, a logistic regression model was fit using the method of generalized estimate equations (GEE) with an exchangeable working correlation. The time until clinical failure (tooth loss prior to exfoliation) was considered for analysis using multivariate survival techniques. It was necessary to use multivariate survival analysis to account for the difference in failure times among teeth, to take into account the difference in periods of time that each tooth was followed, regardless of failure, and to adjust for the lack of independence among observations. In multivariate survival analysis, the outcome variable is the time until either a failure occurs or the last period of followup for the tooth. A "failure" (in this case, tooth loss because of clinical pathology) in sur-

Table 1. Radiographic Success Rates for Primary Molars Over Time by Molar Type and Arch Location*

	5-12 mos (N = 33)	> 1-2 yrs (N = 81)	> 2-3 yrs (N = 60)	> 3-4 yrs (N = 59)	> 4-5 yrs (N = 48)	> 5 yrs (N = 38)	Total (N = 319)
1st Molars	87% (13/15)	83% (39/47)	80% (24/30)	83% (29/35)	86% (19/22)	95% (21/22)	85% (145/171)
2nd Molars	94% (17/18)	88% (30/34)	90% (27/30)	92% (22/24)	80% (21/26)	100% (16/16)	90% (133/148)
	$P = 0.364$	$P = 0.206$	$P = 0.163$	$P = 0.202$	$P = 0.269$	$P = 0.579$	$P = 0.222$
Maxillary	91% (10/11)	91% (21/23)	91% (10/11)	89% (16/18)	90% (9/10)	100% (6/6)	91% (10/11)
Mandibular	91% (20/22)	83% (48/58)	84% (41/49)	85% (35/41)	82% (31/38)	97% (31/32)	86% (206/240)
	$P = 0.466$	$P = 0.187$	$P = 0.336$	$P = 0.310$	$P = 0.334$	$P = 0.842$	$P < 0.283$
All molars	91%	85%	85%	86%	83%	97%	87%

*GEE modeling of radiographic failure over time reveals no significant association between time period and failure rate ($P = 0.322$). GEE modeling also indicates that the radiographic failure rate during the first year is not significantly different than during other time periods ($P = 0.246$).



Fig 1. Tooth #T at 25 months followup demonstrating normal radiographic appearance.

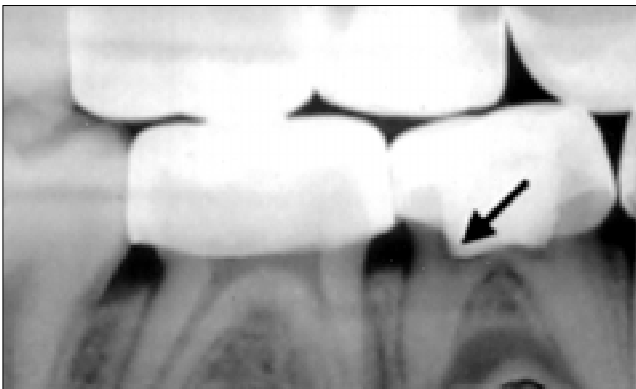


Fig 2. Tooth #S at 42 months followup exhibiting internal resorption (arrow) with calcification of the root canals.

vival analysis is considered to be an “event” while the period of last followup for a “success” (a tooth that is clinically asymptomatic) is considered to be a “censored observation” since only the state of the tooth until that point in time is known. It is only with survival analysis that these “censored observations” can be taken into account in the analysis. 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 112 patients (48 females and 64 males). The ages at treatment ranged from one year, 10 months to 9 years, 9 months, with a mean of 5 years. A total of 194 primary molars were observed with the following composition: first molars = 100; second molars = 94; maxillary molars = 62; mandibular molars = 132. The followup times ranged from 5 to 109 months with a mean of 38 months. Observation times were grouped into 12-month intervals for the purpose of reporting.

Radiographic findings

There were a total of 319 radiographs available from 194 treated molars followed from 5 to 109 months. Total observations were 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. Radiographic success was defined as absence of pathologic internal or external resorption, interradiolar or periapical radiolucency, and no root perforation. The radiographic success rates over time are summarized in Table 1. These ranged from 91% at 5-12 months to 97% at >5 years. Additional radiographic findings recorded included calcific metamorphosis and uneven root resorption compared to the contralateral molar. The frequencies of these pulpal responses over time are summarized in Table 2.

Radiographic failure rates over time were analyzed using a GEE logistic regression model to adjust for the lack of independence of observations over time. When followup time was considered as a continuous variable for predicting radiographic failure, no significant association was found between time of followup and radiographic failure ($P=0.322$). When the radiographic rate for the first 12 months was compared to the radiographic failure rate for all time periods, no significant difference in failure rates was found between the early radiographic failures (up to 12 months) and the later radiographic failures (over a year) ($P=0.246$).

The frequency of normal-appearing pulps (Fig 1) remained fairly constant over time. The most frequently observed pulpal responses were calcific metamorphosis (34%) and internal resorption (10%). This practitioner chose to observe teeth that displayed internal resorption, which was confined to the tooth, rather than extract the teeth. Most often the internal resorption was confined adjacent to the sub base (Fig 2). Also of note in Figure 2 is that the root canals exhibit considerable calcific metamorphosis.

Clinical findings

Chart entries were reviewed for clinical findings at each followup period. Teeth were scored as clinical success if they had no symptoms of pain, tenderness to percussion, swelling, fistulation, or pathologic tooth mobility. Clinical findings associated with the pulp treatment performed were not frequently found and there were no significant differences between first and second molars or maxillary and mandibular molars over time. Therefore, all molars were combined and success rates reported for all molars together. The overall clinical success rate was 98%. Only 4 of 194 treated molars presented with clinical

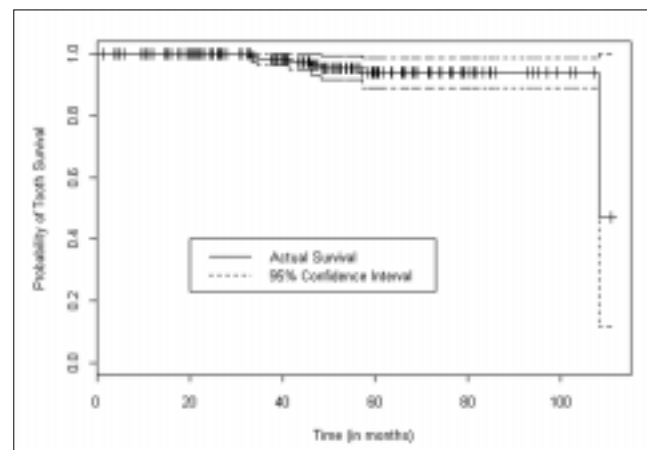


Fig 3. Survival plot for tooth survival over time for all formocresol pulpotomies evaluated.

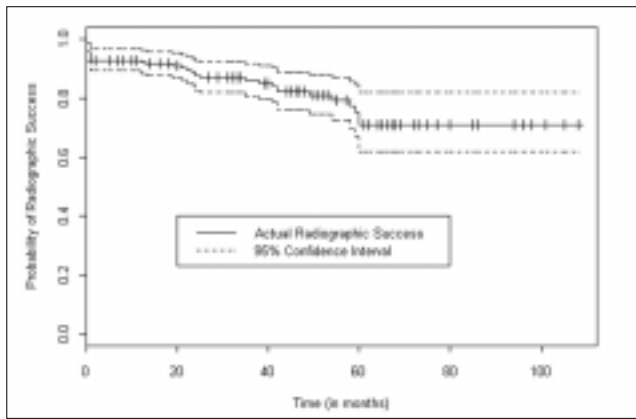


Fig 4. Survival plot for radiographic success over time for all formocresol pulpotomies evaluated.

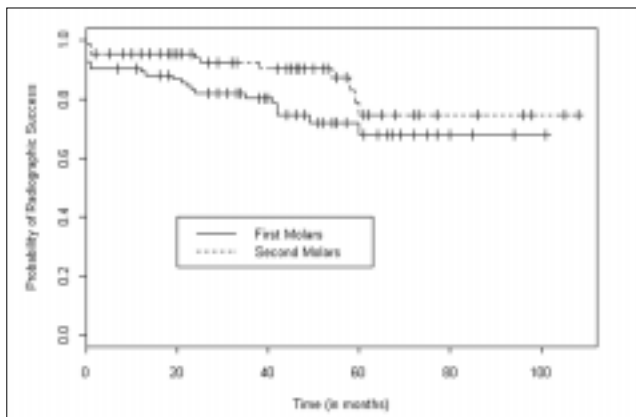


Fig 5. Survival plot for radiographic success over time according to molar type.

cal signs and/or symptoms. The frequencies of specific clinical findings and clinical success rates over time are summarized in Table 3.

A total of 28 teeth were deemed failures in this study due to advanced radiographic findings, and 4 failed due to clinical signs and symptoms. Table 4 presents a summary of the clinical and radiographic failures according to study criteria.

A total of 7 teeth (4%) were extracted as failures in the study. Three of the 7 were extracted due to advanced radiographic findings but did not present with any clinical signs and/or

symptoms. Four teeth were extracted due to clinical signs and/or symptoms.

Six of the 194 treated molars were observed to exfoliate prematurely when compared to contralateral teeth that had not been treated. This was not found to be of clinical significance in that the eruption of the permanent premolar followed and space maintenance was not required in any case. There were no hypoplastic or hypocalcified areas noted for the premolars that succeeded the treated primary molars.

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 the use of survival techniques to analyze these data, although there is a lack of independence between some observations (Table 5 and Fig 3). 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: $P=0.66$; for molar type: $P=0.91$).

Radiographic success was also evaluated using robust log-rank tests. Since tooth loss may not always provide an accurate view of “successful” pulpotomies, radiographic followup of these pulpotomies was evaluated as “success” or “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 4). Again, robust log-rank tests were used to compare the “success” rate according to arch and according to molar type over time. Little difference was indicated for radiographic success over time according to arch type. Similarly, the robust log-rank test failed to be statistically significant for the difference in radiographic success over time between the maxillary and mandibular arch ($P=0.28$). Although the survival plot for radiographic success over time according to molar type appeared to show better radiographic success for second molars compared to first molars, the robust log-rank test failed to be statistically significant ($P=0.056$) (Fig 5).

Discussion

This retrospective study intended to examine clinical and radiographic success rates of a formocresol pulpotomy technique in which hemostasis was obtained with the same formocresol

Table 2. Distribution of Radiographic Findings* over Time $N = 319$ of 194 Molars

Radiographic pathology	Time of follow-up						Total ($N=319$)
	5-12 mo ($N=33$)	>1 -2 yrs ($N=81$)	>2 -3 yrs ($N=60$)	>3 -4 yrs ($N=59$)	>4 -5 yrs ($N=48$)	>5 yrs ($N=38$)	
Normal	22	55	30	36	23	33	199
External resorption	0	5	3	1	0	0	9
Internal resorption	3	7	7	6	8	1	32
Interradicular bone destruction	0	4	2	2	2	0	10
Calcific metamorphosis	11	23	23	22	20	8	107
Uneven root resorption	0	3	4	2	6	1	16
Root perforation	0	2	2	1	2	0	7

*Total of pathologic findings > than number of observations because some teeth had more than one finding.

cotton pellet used to medicate the root pulp and to compare them with published data for traditional formocresol pulpotomy techniques. However, comparison of the current success rates with those found in the literature is somewhat complicated because three versions of the traditional formocresol pulpotomy procedure have been recognized and accepted over time.

The earliest single-appointment formocresol pulpotomy technique used full strength formocresol applied for five minutes and placed a ZOE sub base following the formocresol application.³ Variations of this technique used diluted and full-strength formocresol with and without incorporating formocresol in the ZOE sub base.^{4,5}

Despite variations in formocresol concentration and sub base content, all of the described techniques include obtaining hemostasis of the radicular root stumps with cotton pellets prior to the placement of the medicament. Comparing the results of this study with those already published for pulpotomies using traditional methods of hemostasis lends scientific support to the experience-based evidence from private practitioners who describe that the method of hemorrhage control in formocresol pulpotomy can vary from that as previously believed necessary for successful pulpotomy.

The radiographic success rate of 87% found in the current investigation is comparable to radiographic success rates that have been previously reported in the literature for formocresol pulpotomies. Earlier investigations have reported radiographic success rates ranging from 85 – 98%.^{2,3,4,5,15}

In the current investigation, the frequency of normal-appearing pulps remained fairly constant over time, which can be correlated with overall radiographic success rate. This finding differs from many of the published reports of formocresol pulpotomies in that older formocresol studies have found normal pulps and success rates to decrease over time.^{2-5,12} Fei reported a success rate of 85% at 3 months that decreased to 71% at 12 months while observing 27 human molars.¹¹ A more recent study by Farooq et al reported that formocresol pulpotomy success decreased with time with the largest number of failures observed in 0-2 years.¹⁶ Also of note in the current study is that there was no increased risk of failure over time compared to the first 12 months. Redig reported that the radiographic failures of his study occurred in the first six months.²

The most common radiographic observations of this study were calcific metamorphosis (34%) and internal resorption (10%). The frequency of these pulpal reactions in the current investigation is comparable to those of previously published reports for traditional formocresol pulpotomies.^{11,12,15,17,18}

The probability for radiographic success for first molars was lower than the probability of radiographic success for second molars; however, the difference was not statistically significant. The difference might be explained by considering the earlier eruption into the oral cavity of the first molars. The first molars are susceptible to the carious attack for a longer period of time than the second molars and it is possible that the first molars may present with a more advanced disease state at the first dental visit.

Table 3. Distribution of Clinical Findings Over Time
N = 335 Observations of 194 Molars

	5 – 12 mo N = 35	>1 – 2 yrs N = 81	>2 – 3 yrs N = 64	>3 – 4 yrs N = 60	>4 – 5 yrs N = 48	>5 yrs N = 45
Spontaneous pain	0	0	1	0	0	0
Abscess	0	0	2	0	0	1
Total failures	0	0	3	0	0	1
% Success	100%	100%	95%	100%	100%	98%

Clinical success in the current study of 98% is comparable with Verco, who reported a 98% clinical success rate.¹⁵ Other studies have reported clinical success rates ranging from 88% - 100%.^{2,3,5,11}

One criticism of the formocresol technique as described in this study could be that placing a formocresol dampened cotton pellet onto a bleeding surface of pulp tissue may dilute the concentration of formocresol affecting the tissues. This practitioner chose to use full strength formocresol. Therefore, dilution of the formocresol should not have an effect on the outcome of the procedure as it has been shown that a 1:5 dilution of formocresol is clinically effective.⁴ Additionally, formocresol is traditionally applied over a blood clot, which may filter the agent and render it less concentrated as it penetrates the clot, even in traditional pulpotomy techniques.

An additional criticism of this pulpotomy technique might be that, without first allowing a blood clot to form over the radicular pulp tissue, the potential for increased absorption of the formocresol into the blood stream could exist. Although the current study was not designed to address this issue, previous studies have focused on the amount of systemic absorption of formocresol following pulpotomy procedures. Myers et. al. reported that radioactive formocresol used during pulpotomy procedures in rhesus monkeys showed little difference in total absorption whether the material was left in the pulp chamber for five minutes or for 120 minutes. It was described that when formaldehyde contacts the pulp tissue, vessel thrombosis results and thereby limits further systemic accumulation. This statement was further supported when radioactive iodine was placed over the pulp tissue after treatment with formocresol. Only moderate absorption of the isotope was observed from the formocresol-treated sites whereas large, cumulative absorptions of the radioactive iodine were found from nontreated sites.

These data are consistent with the view that there is an impaired microcirculation in formocresol-treated tissue relative to that of nonformocresol-treated controls.¹⁹ One could also speculate that the active bleeding of the tissue would tend to wash the formocresol away from the vessels, thus inhibiting uptake into the vessels. However, this issue, in light of the recognized harmful side effects of formocresol, does warrant future investigation.

Table 4. Summary of Clinical and Radiographic Failures (N= 194)

Failure type	Number of teeth
Radiographic finding	28
Abscess or swelling	3
Spontaneous pain	1

No previous formocresol pulpotomy investigation has questioned the mechanism by which hemorrhage of the root pulp stumps is controlled. But a very early formocresol pulpotomy procedure, proposed in 1935, described that hemorrhage should be controlled "by the application of formocresol for about two to three minutes."²⁰ Although, the question as to whether a specific method of hemostasis is required for the successful outcome of a formocresol pulpotomy has never been answered in the literature, it has been addressed in private practice. The 50% of District 5 AAPD practitioners who reported that they control hemorrhage and medicate the pulp in the same step¹⁴ would not have continued to do so if the procedure had not proven itself successful in practice. Albeit the evidence available from private practitioners has not been scientifically obtained, the corroboration of the results of this study with the anecdotal evidence provided by the practitioners indicates that more attention should be paid to the procedures that are tested in private practice.

The formocresol pulpotomy as an overall technique, though developed largely on empirical evidence, has been practiced through the years with great success. The outcome of the current investigation indicates that it might be appropriate to question other aspects of the formocresol pulpotomy technique such as whether or not hemorrhage control of the root pulp stumps is necessary at all for the success of the procedure.

The results of this investigation indicate that the technique of obtaining hemorrhage control with the same formocresol-dampened cotton pellet that is used to medicate the pulp is as clinically effective as and comparable with any other formocresol procedure presented in the literature. Thus, one could conclude that a separate step of obtaining hemostasis before applying formocresol may be eliminated.

Conclusions

The results of this study suggest that using the same cotton pellet dampened with formocresol to obtain hemorrhage control and medicate the root pulp is an acceptable variation of the traditional formocresol pulpotomy technique.

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Table 5. Estimated Clinical Survival by Time (in months)

Time (in months)	Teeth at risk	Probability of survival	95% CI
0.0 to <33.1	194	1.000	-
33.1 to <34.5	129	0.992	(0.977,1.000)
34.5 to <41.4	126	0.984	(0.963,1.000)
41.4 to <46.0	111	0.976	(0.948,1.000)
46.0 to <48.3	97	0.965	(0.933,1.000)
48.3 to <57.2	89	0.955	(0.916,0.995)
57.2 to <108.2	63	0.939	(0.892,0.989)
≥108.2	2	0.470	(0.117,1.000)

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