



## Outcome of formocresol/ZOE sub-base pulpotomies utilizing alternative radiographic success criteria

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### Abstract

**Purpose:** The purposes of this investigation were to 1) measure success of a primary tooth pulpotomy technique that applies formocresol in the sub-base without the common five-minute application of a formocresol impregnated cotton pellet; and 2) compare success rates of the pulpotomy procedure using traditional criteria found throughout the literature with new criteria recently established, excluding internal resorption as a radiographic failure.

**Methods:** Clinical and radiographic data were collected from a retrospective chart review of patients receiving formocresol pulpotomies with the application of formocresol in the zinc oxide-eugenol sub-base.

**Results:** Clinical and radiographic data were available for 196 primary molars in 122 children (followup = six to 103 months; mean = 49 months). Traditional assessment of radiographic success and failure yielded a success rate of 79%. Alternative assessment excluding internal resorption as a failure yielded a 99% success rate. Most frequently observed pulpal responses were calcific metamorphosis and internal resorption. Overall clinical success was 99%. Two of the 196 teeth were extracted due to failure. A survival analysis demonstrated that the overall probability of survival remained high over time with a cumulative survival of over 95% after six years.

**Conclusions:** The overall success rates in this study indicate that the formocresol pulpotomy technique incorporating formocresol in the zinc oxide-eugenol sub-base is a very successful treatment modality for primary molars requiring pulp therapy. (*Pediatr Dent* 23:331-336, 2001)

A primary concern of pediatric dentistry is to maintain the dental arch in an intact state until the permanent dentition erupts into the oral cavity. The formocresol pulpotomy is one of the most frequently used treatments for maintaining cariously involved primary molars that would otherwise be destined for extraction. The formocresol pulpotomy technique has undergone a lengthy evolution to shorten the formocresol application time and reduce the concentration of formocresol exposure to the remaining pulpal tissue.

One such technique modification intended to reduce formocresol exposure involves applying formocresol in the sub-base only and eliminating the common five-minute application of a formocresol impregnated cotton pellet prior to placement

of the sub-base. Barefield, in 1985, reported that formocresol in the sub-base alone exerted the same pulpal effect as the initial five-minute formocresol application and offered the possible advantage of lower levels of formocresol exposure systemically.<sup>1</sup> Hicks et al conducted a radiographic study of formocresol pulpotomies using this same technique in 164 human primary molars observed over 24 to 87 months.<sup>2</sup> Radiographic success was found to be 89%. Internal resorption was noted in approximately 11% of the cases. However, only 2.4% of those teeth with internal resorption were considered failures, as the integrity of the root structure was not compromised. The area of resorption appeared to be confined primarily to the root canal orifices adjacent to the pulpotomy paste and did not compromise the root structure.<sup>2</sup>

In 1999, Smith et al further addressed the role of internal resorption in pulpotomy success criteria.<sup>3</sup> They collected clinical and radiographic data from a retrospective chart review of patients receiving ferric sulfate pulpotomies over a five-year period and originally used 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, dental and osseous. An osseous resorptive change involved supporting bone and was pathologic. The other resorptive process, internal resorption, was of dental origin. It appeared to be a pulpal response secondary to the procedure and/or medication, such as ZOE, was not clinically significant in that it was confined to the tooth, the adjacent bone was not involved, and the patient remained asymptomatic. Smith suggested that new radiographic criteria to determine the success of a pulpotomy procedure be developed to reflect these dental and osseous changes that would support what clinicians have anecdotally suggested. If there are no osseous changes adjacent to a pulpotomized tooth and the changes are limited to the tooth itself, the procedure is a success.<sup>3</sup>

Because there is still controversy surrounding the formocresol pulpotomy, techniques that reduce formocresol exposure should be more thoroughly examined. Further studies evaluating the success of formocresol applied to the pulpal tissue through the sub-base alone should be conducted using the criteria set forth by Smith et al.<sup>3</sup> The purpose of this investigation was two-fold: 1) to measure the success of a primary

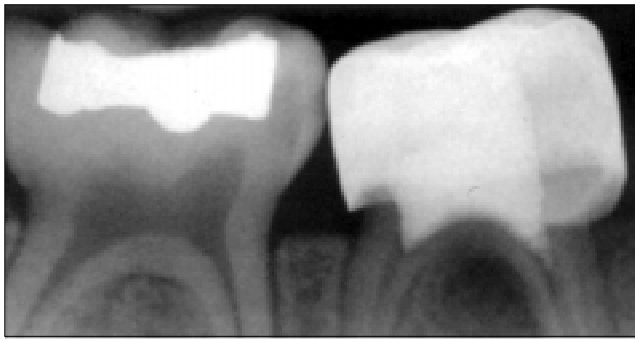


Fig 1. Tooth #5 at 13 months followup demonstrating normal radiographic appearance.

tooth pulpotomy technique that applied formocresol in the sub-base and avoided the common five-minute application of a formocresol impregnated cotton pellet prior to placement of the treatment paste; and 2) compare the success rates of the pulpotomy procedure using traditional criteria found throughout the literature and the new criteria recently suggested by Smith et al<sup>3</sup>

## Methods

Clinical and radiographic data were collected from the records of patients treated in a private pediatric dental office in Denver, Colorado. The practitioner has used the pulpotomy technique using formocresol only in the sub-base exclusively from 1985 to present. The study sample included patients who presented between 1985 and 1996 with at least one primary molar treatment planned for a vital pulpotomy. Criteria for inclusion included: 1) primary tooth 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. Patient records had to be complete, and all radiographs met the following prescribed subjective criteria: acceptable diagnostic quality, proper film density and contrast, used the paralleling technique, and displayed a minimum of 2.0 mm of bone in the furcation area

All primary molars were treated with the following technique: rubber dam isolation, caries removal, and coronal access using a high-speed handpiece with a #330 carbide bur and water spray, and removal of coronal pulp using a slow-speed handpiece with a #6 round bur. After hemostasis with a water-moistened cotton pellet, the pulp chamber was filled with zinc oxide-eugenol cement incorporating one drop of full strength formocresol. The tooth was restored with a stainless steel.

Radiographic criteria developed for this study included: unremarkable, external root resorption, internal root resorption, inter-radicular bone destruction, calcific metamorphosis, periapical bone destruction, uneven root resorption compared to the contralateral tooth, early eruption compared to the contralateral tooth, and root perforation. All radiographs were read using the same standard view box illuminator with a 2x-viewscope magnifier that masked extraneous ambient light (Flow X-ray, West Hempstead, NY).

Clinical categories developed for chart review included: no chart entry, soft tissue-unremarkable, 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: gender, chart number, date of birth, tooth number, treatment date, followup time (in months), radiographic codes for each recall visit, extraction code and date of extraction, clinical codes for each recall visit, and tooth exfoliation. All data were then entered into an Excel software format for statistical analyses (Microsoft Corporation, Redmond, WA).

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 122 children. The ages of the children at treatment ranged from 1.4 years to 10.2 years with a mean age at treatment of 5.2 years (SD = 1.8 years, median = 4.8 years). A total of 196 primary molars were studied with the following composition: first molars = 118, second molars = 78, maxillary molars = 66, and mandibular molars = 130. The followup times ranged from six to 103 months (mean = 49 months or 4.1 years, SD = 1.8 years, median = 3.9 years). Observation times were grouped into 12-month increments for the purpose of reporting findings.

### Radiographic findings

There was a total of 532 radiographs available from 196 treated primary molars followed from six to 103 months. The principal investigator scored all radiographs. A second investigator, who had been previously calibrated with the principal investigator, independently evaluated 139 randomly selected radiographs of the 532. The Kappa statistic used to test the reproducibility of the scoring by examiners indicated highly

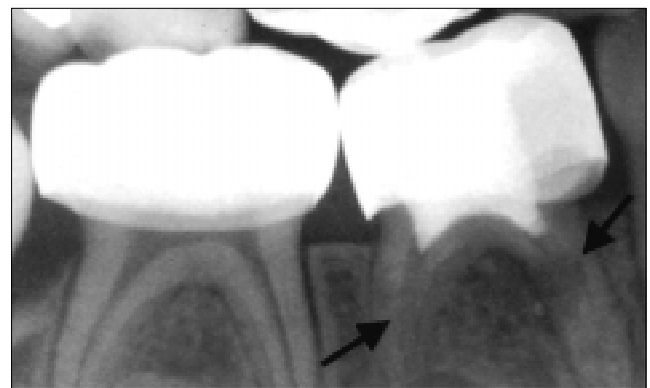


Fig 2. Tooth #5 with internal resorption in the mesial root (arrow) and onset of calcification in the distal root (arrow) at 25 months followup.

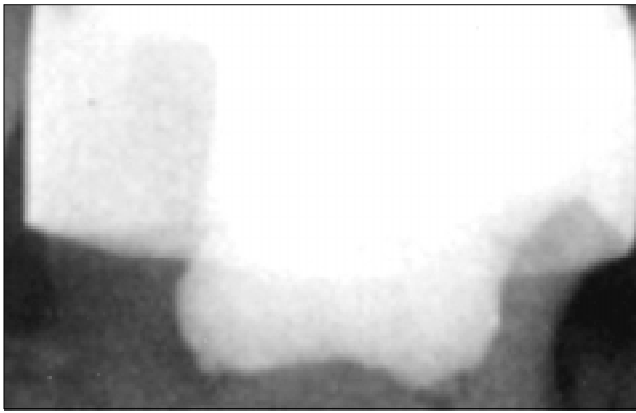


Fig 3. Tooth #L at 29 months followup demonstrating complete calcification of the mesial and distal canals and the mesial and distal roots appearing to become indistinguishable from bone.

significant reproducibility between the two examiners with a measurement of agreement of 0.73 ( $P < 0.001$ ).

Using traditional assessment of radiographic success and failure for pulpotomies on primary molars, there was a 79% success rate (419/532) for all observations over time (Tables 1 and 3-A). When the method of assessment for radiographic success and failure was modified to exclude internal resorption,<sup>3</sup> there was a 99% success rate (529/532) for all observations over time (Tables 2 and 3-A). Two of these three failures correspond to the two failures observed clinically. The one radiographic failure that was not classified as a clinical failure was determined to have external resorption at 3.4 years after treatment. This was the last point of observation for this tooth and, at that point, the tooth was clinically asymptomatic. No teeth failed clinically as a result of internal resorption alone.

Kaplan-Meier survival plots were also constructed for radiographic success. Robust log-rank tests were conducted to compare failure rates of the traditional method of radiographic failure according to molar type (first molar vs. second molar) and according to arch (maxillary vs. mandibular). Robust tests were used to take into account multiple pulpotomies within a child. This technique enabled use of survival methods of statistical analysis to analyze these data, although there is a lack of independence among some of the observations. Based on the robust log-rank test, there was not a statistically significant difference in radiographic success found for molar type. However, there was a statistically significant difference in

radiographic success over time between the maxillary and mandibular arch ( $P = 0.013$ ). The reason for this difference may be related to the difficulty of reading radiographs taken for the maxillary arch where the maxillary sinuses may tend to obscure radiographic changes. In fact, the survival analysis comparing the radiographic success using traditional assessment of radiographic success indicates that mandibular radiographic failures were about 1.6 times more likely to be detected compared to maxillary radiographic failures over time. No testing was conducted to compare differences in actual clinical success (tooth survival) between molar types or between arches because of the lack of sufficient failures available for testing purposes. Similarly, testing was not conducted to compare molar types or arches for the modified method of assessing radiographic success because of the limited number of failures according to Smith's modified definition.<sup>3</sup>

Additional radiographic findings recorded included: calcific metamorphosis, uneven root resorption compared to the contralateral molar, and early eruption compared to the contralateral molar. It should be noted that radiographs reviewed demonstrated continual change over time. In other words, it was not unusual to encounter calcific metamorphosis in one radiograph and then find the subsequent radiographs to present with greater and greater amounts of calcific metamorphosis.

Based on a GEE logistic regression model with calcific metamorphosis as the outcome variable, it was also determined that the probability of detecting calcific metamorphosis increased with increased time of followup ( $P < 0.0001$ ). In fact, for each year of followup, the likelihood of detecting calcific metamorphosis increased by a factor of 1.3. However, there was no association between time of followup and detection of internal resorption ( $P = 0.255$ ). Furthermore, when detection of internal resorption during the first year was compared to all other followup times, it was found that it was no more likely to detect internal resorption during the first year of followup than at later followup times either ( $P = 0.893$ ).

The most frequently observed radiographic findings were calcific metamorphosis 41% (220/532) and internal resorption 20% (105/532), which are summarized in Table 4. Sometimes, both responses were observed in the same tooth. There was a total of 45/532 observations and a total of 30/196 teeth that demonstrated both radiographic internal resorption and calcific metamorphosis. Figure 1 is a 13-month followup

Table 1. Radiographic Success Rates (Including Internal Resorption) for Primary Molars Over Time by Molar Type and Arch Location (N = 196 Molars)

	1–12 mos (N = 84)	> 1–2 yrs (N = 108)	> 2–3 yrs (N = 119)	> 3–4 yrs (N = 106)	> 4–5 yrs (N = 62)	> 5 yrs (N = 53)	Total (N = 532)
<b>1<sup>st</sup> Molars</b>	83% (39/47)	76% (48/63)	75% (53/71)	76% (48/63)	78% (32/41)	85% (22/62)	78% (242/311)
<b>2<sup>nd</sup> Molars</b>	78% (29/37)	80% (36/45)	79% (38/48)	81% (35/43)	90% (19/21)	74% (20/27)	80% (177/221)
	$P = 0.594$	$P = 0.639$	$P = 0.569$	$P = 0.523$	$P = 0.305$	$P = 0.344$	$P = 0.527$
<b>Maxillary</b>	91% (30/33)	89% (33/37)	86% (30/35)	96% (27/28)	83% (10/12)	85% (11/13)	89% (141/158)
<b>Mandibular</b>	75% (38/51)	72% (51/71)	73% (61/84)	72% (56/78)	82% (41/50)	78% (31/40)	74% (278/374)
	$P = 0.062$	$P = 0.051$	$P = 0.125$	$P = 0.007$	$P = 1.000$	$P = 0.711$	$P < 0.001$

**Table 2 . Radiographic Success Rates (Excluding Internal Resorption) for Primary Molars Over Time by Molar Type and Arch Location (N = 196 Molars)**

	1-12 mos (N = 84)	> 1-2 yrs (N = 108)	> 2-3 yrs (N = 119)	> 3-4 yrs (N = 106)	> 4-5 yrs (N = 62)	> 5 yrs (N = 53)	Total (N = 532)
<b>1<sup>st</sup> Molars</b>	100% (47/47)	100% (63/63)	100% (71/71)	100% (63/63)	100% (41/41)	96% (25/26)	100% (310/311)
<b>2<sup>nd</sup> Molars</b>	100% (37/37)	100% (45/45)	98% (47/48)	98% (42/43)	100% (21/21)	100% (27/27)	99% (219/221)
	<i>P</i> = 1.000	<i>P</i> = 1.000	<i>P</i> = 0.403	<i>P</i> = 0.406	<i>P</i> = 1.000	<i>P</i> = 0.491	<i>P</i> = 0.573
<b>Maxillary</b>	100% (33/33)	100% (37/37)	100% (35/35)	100% (28/28)	100% (12/12)	100% (13/13)	100% (158/158)
<b>Mandibular</b>	100% (51/51)	100% (71/71)	99% (83/84)	99% (77/78)	100% (50/50)	98% (38/40)	99% (371/374)
	<i>P</i> = 1.000	<i>P</i> = 1.000	<i>P</i> = 1.000	<i>P</i> = 1.000	<i>P</i> = 1.000	<i>P</i> = 1.000	<i>P</i> < 0.558

radiograph of a pulpotomy performed on the lower right first primary molar. This tooth began to demonstrate internal resorption at 19 months in both the mesial and distal root canals. Figure 2 reveals the onset of calcification in the distal root and internal resorption in the mesial root of the same tooth at 25 months.

### 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 in this study. There were no significant differences between first and second molars and maxillary versus mandibular molars over time.

The overall clinical success rate was 99% with only a total of two teeth extracted in this study due to severe radiographic findings and clinical symptoms (Table 3B). The followup times ranged from nine to 103 months from the time of treatment to extraction of these teeth, natural exfoliation, or loss to followup. There were no hypoplastic or hypocalcified areas

noted for the succedaneous teeth replacing the primary teeth that received the pulpotomies.

### Discussion

When traditional radiographic success criteria were applied to the findings reported in this study, the results of this investigation (78% success) are comparable to the results previously reported in the literature.<sup>4-6</sup> The radiographic success rate of 99%, found when the radiographs of this investigation were read using Smith's non-traditional radiographic criteria,<sup>1</sup> was high and similar to those reported by Hicks et al (94%) when they included those teeth with "questionable radiographs" because of internal resorption.<sup>2</sup> The role of internal resorption in the outcome of the current study deserves further discussion.

In the current study, internal resorption was found in 20% of the cases. One cause of internal resorption following pulpotomy is believed to be the irritating effects of the medicaments present in the treatment paste,<sup>2,7</sup> in this case zinc oxide and eugenol (ZOE).

Previous investigators reported that ZOE, used as a pulpotomy agent, results in internal resorption.<sup>8</sup> Direct placement

**Table 3. Overall Success Rates Over Time**

<b>A. Radiograph Success Rates* (N=532 Observations of 196 Molars)</b>							
	1-12 mos (N = 84)	> 1-2 yrs (N = 108)	> 2-3 yrs (N = 119)	> 3-4 yrs (N = 106)	> 4-5 yrs (N = 62)	> 5 yrs (N = 53)	Total (N = 532)
<b>Success rates with internal resorption</b>	81% (68/84)	78% (84/108)	76% (91/119)	78% (83/106)	82% (51/62)	79% (42/53)	79% (419/532)
<b>Success rates without internal resorption</b>	100% (84/84)	100% (108/108)	99% (118/119)	99% (105/106)	100% (62/62)	98% (52/53)	99% (529/532)
<b>B. Clinical Success Rates (N=590 Observations of 196 Molars)</b>							
	1-12 mos (N = 95)	> 1-2 yrs (N = 123)	> 2-3 yrs (N = 133)	> 3-4 yrs (N = 112)	> 4-5 yrs (N = 69)	> 5 yrs (N = 58)	Total (N = 590)
<b>Success rates</b>	100% (95/95)	100% (123/123)	99% (132/133)	100% (112/112)	100% (69/69)	98% (57/58)	99% (588/590)

\*GEE modeling of radiographic failure over time reveals no significant association between time period and failure rate for either failure rates, including internal resorption (*P* = 0.593) or failure rates excluding internal resorption (*P* = 0.249). GEE modeling also indicates that the radiographic failure rate during the first year is not significantly different than during other time periods for either failure rates including internal resorption (*P* = 0.661) or failure rates excluding internal resorption (*P* = 1.000).

**Table 4. Distribution of Radiographic Findings\* Over Time**  
(N = 532 observations of 196 Molars)

	Time of Follow-Up						Total (N = 532)
	1-12 mo (N = 84)	> 1-2 yrs (N = 108)	> 2-3 yrs (N = 119)	> 3-4 yrs (N = 106)	> 4-5 yrs (N = 62)	> 5 yrs (N = 53)	
Normal	56	56	48	41	23	19	243
External resorption	0	0	1	1	0	1	3
Internal resorption	16	22	26	21	11	9	105
Interradicular bone destruction	0	0	0	0	0	0	0
Calcific metamorphosis	14	37	53	55	34	27	220
Uneven root resorption	0	0	0	0	0	1	1
Early eruption	0	0	0	1	0	1	2

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

of eugenol over vital tissue causes a moderate to severe inflammatory response with resulting chronic inflammation and necrosis.<sup>9</sup> ZOE, when in contact with a highly perfused environment such as the pulp, undergoes a greater hydrolysis of the eugenolate to yield free eugenol and zinc hydroxide.<sup>10</sup> The pulpotomy treatment in the current study is more like a ZOE pulpotomy even though it has been considered in the literature to be a variant of the traditional formocresol pulpotomy. It may, therefore, be expected that the pulpotomized teeth in the current study behaved in a similar fashion to those teeth receiving ZOE pulpotomies reported in the literature.

Another common radiographic finding in this investigation, calcific metamorphosis, is one of the most commonly reported radiographic findings described by several investigators.<sup>11,12</sup> The occurrence of calcific metamorphosis in this study of 54% at > four to five year intervals was similar to the findings of Hicks et al who reported 60% calcific metamorphosis using a similar technique.<sup>2</sup> Radiographically, calcific metamorphosis appeared as an increased calcification of the root walls, resulting eventually in almost complete obliteration of the canals. It appeared to develop uniformly throughout the canals and is apparently the result of odontoblastic activity following treatment, suggesting that the pulp retains some degree of vitality and function over time.<sup>12</sup>

An interesting and unusual radiographic finding in this study, though not a part of the designed data collection criteria, was the phenomenon of some of the tooth roots appearing to become indistinguishable from the bone—i.e., the root of the tooth appeared to blend with the surrounding bone (Fig 3). The fact that formocresol is available from the pulpotomy paste to leach into the surrounding periodontal tissue may result in an inflammatory mediated response. In 1981, Fuks and Bimstein attributed accelerated root resorption to a chronic inflammatory reaction.<sup>13</sup> Perhaps the inflammatory reaction, instead of initiating a classic cellular response, is initiating a blastic cellular response, and additional bone is being deposited instead of resorbed. This finding is unique to this study, and has not been previously reported in primary tooth pulpo-

my literature. The obvious concern is whether or not this exaggerated bony response will lead to ankylosis of the involved primary tooth and possibly delay the eruption of the succedaneous tooth. Using delayed eruption as an indication for ankylosis, no ankylosis was found in this study.

An unusual aspect in this retrospective study is that the majority of the same teeth were followed on a consistent six-month interval for long periods of time, an aspect more common to prospective study design. The ability to observe these teeth frequently over time allowed the investigator to determine that the teeth appeared to be constantly changing, either undergoing internal resorption, chronic progressive pulpal calcification, or replacement resorption. These changes are radiographically relevant, as it has been experimentally determined that 20% to 40% of bone mass must be added or lost before it is visibly apparent on radiographs.<sup>14</sup> This is compelling evidence that the teeth in this study were maintaining their vitality.

A 1:5 dilution of formocresol is considered to be the current standard medicament for formocresol pulpotomy and is the most widely taught technique in dental schools. However, this practitioner chose to use full strength formocresol in his pulp paste. Perhaps he believed that the addition of the formocresol to the zinc-oxide and eugenol provided a level of dilution or believed that he needed to continue to use the full strength medicament since he was using an alternative form of application. Diluted formocresol is not available commercially, and practitioners who choose to use a diluted form must either dilute it themselves or have it diluted.

In this study, the success rates are high when internal resorption is excluded as a cause for failure. With only two teeth lost due to failure, the variation of the traditional formocresol pulpotomy technique that applies formocresol in the sub-base and avoids the common five-minute application of a formocresol impregnated cotton pellet prior to placement of the treatment paste must be considered a successful pulpotomy technique which can be recommended. It may also have the added advantage of minimizing exposure of the patient to

formocresol.<sup>1</sup> Accordingly, it may not be necessary to find a replacement for formocresol, but documentation of the safety of the technique under investigation was not a goal of this study.

## Conclusions

The results of this study indicate that the formocresol pulpotomy technique that incorporates formocresol in the zinc oxide-eugenol sub-base is a very successful treatment modality for primary molars requiring pulp therapy.

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## ABSTRACT OF THE SCIENTIFIC LITERATURE



### Weight Status, Parent Reaction, and Self-Concept in Five-Year-Old Girls

This study examined the relationship between weight status and self-concept in a sample of preschool-aged girls and whether parental concern about child overweight or restriction of access to food are associated with negative self-evaluations among girls. 197 5-year-old girls and their parents participated in this study. Girls' self-concept was assessed using an individually administered questionnaire. Parents' concern about their child's weight status and restriction of their child's access to food were assessed using a self-report questionnaire. Girls with higher weight status reported lower body esteem and lower perceived cognitive ability than did girls with lower weight status. Higher maternal concern about child overweight was associated with lower perceived physical and cognitive ability among girls. The authors conclude that at least as early as age 5 years, lower self-concept is noted among girls with higher weight status. In addition, parents' concern about their child's weight status and restriction of access to food are associated with negative self-evaluations among girls.

**Comments:** This study has shown that girls as young as five form negative self-images based on their weight. Traditionally, researchers have believed that at this young age, children express strong positive opinions about themselves and are usually free of concerns about body image. Pediatric dentists should consider the findings of this study when counseling parents who present a young child with anterior teeth decay or missing teeth and are in doubt whether treatment is necessary. Perhaps, a positive self-image can be encouraged through proper dental treatment. AK

**Weight Status, Parent Reaction, and Self-Concept in Five-Year-Old Girls.** Krahnstoever Davison K and Birch LL. *PEDIATRICS* Vol. 107 No. 1 January 2001, pp. 46-53