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## Clinical Evaluation of the Success Rate of Formocresol Pulpotomy in Children's Primary Molars

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### Abstract

**Introduction and Purpose:** The present study clinically evaluated the success rate of formocresol pulpotomy in the primary molars of children referred to the pediatric department of Shahid Dental Faculty from 2002 to 2005

**Methods:** The present cross-sectional study was conducted among all children treated with formocresol by pulpotomy and responded positively to the call for re-examination. The required data were obtained from the patient's medical records and 67 patients were rejected. The collected data were analyzed using descriptive statistical tests such as dispersion indices, frequency percentages, and correlational tests.

**Results:** 67 examined patients had 141 teeth pulpotomy. In the remaining 106 teeth, 6 cases of fistula, 2 cases of impact sensitivity, and 5 cases of pain were observed. Clinical success was observed in 123 teeth (82.2%) and clinical failure was observed in 18 teeth (12.8%). The total restored cases were 139 and 2 cases of pulpotomies were not restored ( $P < 0.6-2$ ). In addition, concerning the materials related to clinical failures, most cases were related to fistula, which included 6 cases (30%) of the cases.

**Keywords:** Formocresol pulpotomy, Primary molars, Failure, Success

### Introduction

The pulpotomy involves removing the pulp of the coronal area and placing a medicinal substance. The pulpotomy aims at removing the swollen coronal pulp so the pulp can survive in the root canal and the tooth is preserved in the dental arch (8). The ideal

covering material for the pulp should be bactericidal, not be harmful to the pulp and its structures, stimulate the restoration of the root pulp, and not interfere with the physiological process of root resorption (9). The pulpotomy success signs are lack of pain, fistula swelling, laxity, impact sensitivity, and internal and external resorption, 4K radiolucency, and the absence of injury and damage to the tooth bud. Various materials have been investigated in pulpotomy (7). Formocresol (a solution of bacilli formaldehyde, cresol, glycerol, and water) is the most common of these materials.

The application of formocresol is simple and the results of its application are excellent despite the systemic release of this substance and its toxicity, sensitizing, carcinogenic, and mutagenic potential. However, studies have shown that the applied concentration in pulpotomy does not cause the mentioned complications (6). The commonly used formula of Buckley formocresol contains 19% formaldehyde, 35% cresol, and 15% glycerin in water. Formocresol, formaldehyde, and cresol are its active compounds (10). The application of radioactive formocresol on the pulp incision site has indicated that the substance is quickly absorbed. Formocresol disrupts the microcirculation of vascular thrombus, leading to more limitations in systemic accumulation (1). By reviewing several studies, the researchers concluded that formocresol pulpotomy does not cause specific immunological sensitivity to homologous pulp antigens or pulp antigens that have been changed due to formocresol treatment.

The appropriate clinical application of formocresol in pulpotomy does not cause a clear reaction. (2). Examining the systemic effect of formocresol revealed the possibility of toxic effects on the fetus and teratogenicity. After the systemic administration of formocresol to the tested animals, it was released in the body and the metabolism, and a part of the absorbed formocresol was secreted in the lungs and kidneys. The remaining amount is bound to the kidneys, liver, and lungs. Thus, acute toxic effects of cardiovascular changes, changes in urinary and plasma enzymes, and histological signs of cellular damage to vital organs are observed with the systemic administration of high doses (3).

Before any treatment, the patient is systemically reviewed. Then, the tooth is examined clinically and radiographically. In addition, the time the tooth will be in the mouth, the patient's cooperation, the treatment cost, and the condition of the adjacent teeth should be considered (4). Children susceptible to subacute endocarditis, patients with leukemia, solid tumors, and idiopathic neutropenia are not candidates for this treatment and should not be exposed to the possibility of developing an acute infection following pulp treatment (12). Histological studies on the effect of formocresol on the pulp of primary and permanent human teeth indicated that when the cotton ball impregnated with formocresol contacts with the pulp tissue, the surface tissue becomes fibrous and acidophilic within a few minutes (11). After 60 days to one year, the pulp becomes progressively fixed and gradually the entire pulp tissue becomes fibrotic. Other studies have indicated that the effect of Formocresol on the pulp depends on the time the drug is in contact with the pulp tissue. After 5 minutes, a surface fixation is created (5). A study reported the histological success of pulpotomy with formocresol at 92% (8).

Pulpotomy with formocresol is applied in primary teeth when the pulp is exposed to decay and does not have an infection, otherwise, the success rate is reduced and there is a possibility of damage to the permanent tooth. Hence, the correct diagnosis is vital. After the correct diagnosis, local anesthesia is applied and the Rubberdam is closed. Then, the decays are removed and the pulp chamber roof is removed with a turbine and plenty of water. All the crown pulp is removed with a low-speed process mill or a spoon excavator. Then, the pulp chamber is washed thoroughly with saline and dried with cotton. Bleeding is mostly controlled within a few minutes. There are two reasons why bleeding continues and does not stop within 5 minutes, either all the pulp tissue has not been removed from the pulp chamber, or the swelling has penetrated the pulp inside the root. When the swelling spreads to the pulp inside the root, more extensive treatment will be required. In addition, the pulp tissue should be removed completely after stopping the bleeding if the entire pulp is not removed.

After the bleeding stopped, Buckley diluted formocresol (1.5) is placed on a cotton ball in direct contact with the pulp opening. The cotton ball is compressed to remove the extra formocresol. Formocresol is caustic and causes severe tissue burns. It should not be in contact with the gum. It is placed in contact with the pulp opening for 5 minutes. After removing the cotton, the canal entrance should be dark brown. A ZOE cement is placed on the pulp opening. Then, the tooth is permanently restored (13). The selective restoration of primary molars is SSC. In using formocresol, a dentine barrier is not created as seen in calcium hydroxide. The formocresol pulpotomy failure can mostly be detected by radiography (14). The first sign of failure is mostly the internal resorption of the root adjacent to the place where formocresol was used. This condition may also be associated with external resorption, especially when the failure progresses. In primary molars, a radiolucency is sometimes created in the 4K or fistula area. The occurrence of pain during the formocresol pulpotomy failure is rare. Thus, if the patient does not visit the dentist to check formocresol pulpotomy, pulpotomy failure is not diagnosed, and when the tooth is loose and lost, the child and his parents consider this phenomenon normal.

Some studies have reported the creation of a cystic lesion after pulp therapy in primary molars. In a study that examined primary molars with a failed pulpotomy, cysts were observed in most of the samples. These results highlight the importance of follow-up examinations after endodontic treatments of primary molars (15) Loss and Han stated that a one-fifth diluted solution produces a favorable response similar to the full concentration of formocresol and allows faster healing of the affected cells. They recommended that concentration 15 is a safe drug that has fewer postoperative complications and has similar and good results compared to pure formocresol (16).

The two-session formocresol pulpotomy technique in primary teeth is the same as the one-session pulpotomy in the treatment of primary teeth with opening due to caries. The procedure steps are similar to the one-step technique, but the bleeding is not controlled within 5 minutes and cotton impregnated with formocresol is placed on the pulp tissue incision site for one week, and the tooth is temporarily bandaged. After seven days, the next steps of the treatment are taken based on the one-step method if there are no symptoms. Thus, the healthy

pulp tissue inside the canals is fixed to formocresol after 7 days in contact with cotton in this technique (17). If after a week the signs of tissue fixation are not observed and there is bleeding in the area, the tooth undergoes pulpectomy since the swelling has penetrated the root canals. Most researchers nowadays believe in one-session pulpotomy (18). In this study, the pulpotomy success rate with formocresol and the symptoms of its failure were examined.

**Materials and Methods**

The statistical population of the present cross-sectional study included all children treated with formocresol by pulpotomy and responded positively to the call for re-examination. Those patients who received pulpotomy treatment between 2002 and 2005 were included. Since the medical records of the patients in 2002 were removed from the archive, the study was conducted in the years 2003, 2004, and 2005. During this period, 173 patients underwent pulpotomy, 34 (19.7%) in 2003, 53 (30.6%) in 2004, and 86 (49.7%) in 2005. After reviewing the medical records and making phone calls with them, 67 people (38.7%) responded positively to the call. Among them, 44.1% were from 2003, 34% were from 2004, and 38.4% were from 2005. The examination form of these people was completed from September to February 2007. This examination was performed using a mirror and a disposable catheter and on the dental chair with the unit lamp light. In each case, the tooth was examined in clinical, toothache, pathological loosening, abscess, fistula, and impact sensitivity aspects. Additionally, the state of filling and the presence of teeth were recorded. The collected data were analyzed using descriptive statistical tests such as dispersion indices, frequency percentages, and correlational tests.

**Results**

In the 67 examined patients, 141 teeth had been pulpotomized. In this regard, 35 teeth (24.8%) were not present in the mouth of the pulpotomized teeth, of which 27 had been lost naturally and their replacement teeth had grown. One tooth was extracted by the dentist for orthodontic treatment and 5 teeth were extracted due to pain. Two cases were not restored and the patient had to extract them. In the remaining 106 teeth, six cases of fistula, two cases of impact sensitivity, and 5 cases of pain were observed. Clinical success was observed in 123 teeth (82.2%) and clinical failure in 18 teeth (12.8%) (Table 1).

Table 1. The frequency and percentage of pulpotomy success and failure

Percentage	Frequency	
12.8	18	Clinical failure
87.2	123	Clinical success
100	141	

Table 2. Distribution of children undergoing pulpotomy based on clinical success separately by related factors (p<0.9).

Clinical failure	No	Yes
Clinical success		

Number of sessions		
1 session	103 (83.7%)	15 (83.3%)
2 sessions	20 (16.3%)	3 (16.7%)
Age during treatment		
4-7 years	69 (56.1%)	10 (55.6%)
7-11 years	54 (43.9%)	8(43.9%)
Gender		
Male	69 (56.1%)	9 (50%)
Female	54 (43.9%)	9 (50%)
Restoration type		
Class I Amalgam	2 (1.6%)	-
Class II Amalgam	70 (56.9%)	8 (50%)
Class III Amalgam	5 (4.1%)	3 (19%)
SSC	46 (34.7%)	5 (31%)

Based on Table 2, the total restored cases was 139 cases (two cases of pulpotomies were not restored)  $P < 0.6-2$ .

Table 3: Distribution of children undergoing pulpotomy based on treatment success separately by tooth type ( $p < 0.6$ )

Position Tooth type	Yes	No	Total
E	50 (41%)	50 (41%)	59
D	73 (59%)	9 (50%)	82
Total	123	18	141

Table 4. Distribution of pulpotomized children based on the treatment success separately by pulpotomy duration ( $p < 0.04$ ).

Position Tooth type	Yes	No	
E	66 (53.7%)	5 (27.8%)	59
D	57 (46.3%)	13 (72.2%)	82
Total	123	18	141

According to the results of Tables 3 and 4, most cases of clinical failures were related to fistula with 6 cases (30%). The rest are:

- Impact sensitivity: 10%

- Pain: 25%
- Lack of restoration: 10%
- Tooth extraction due to pain: 25%

## Discussion and Conclusion

Pulpotomy is the most common method of primary teeth pulp exposed to decay. This treatment involves cutting the coronal area pulp and placing a medicinal substance. The purpose of pulpotomy is to preserve the primary tooth until it is lost naturally (19). Pulpotomy treatment is one of the most common methods of pulp treatment in primary teeth. It aims to preserve this tooth's health and function until they are lost and replaced teeth erupt. Various materials and methods for pulp treatment have been developed since Witzel described the pulpotomy method, Buckley presented his research on the effectiveness of pulpotomy with formocresol, and Sweet registered the multi-session method of pulpotomy with formocresol until now. Formocresol was one of the first substances used in the treatment of pulpotomy. Nowadays, pulpotomy treatment with formocresol is commonly used, especially in educational centers. Pulpotomy with Formocresol is still one of the selected methods in the treatment of live primary teeth exposed to decay, swelling, and degeneration limited to the coronal pulp. The pulpotomy with formocresol used today is a modified type of method introduced by Sweet in 1930 (20).

This study investigated the clinical success rate of formocresol pulpotomy performed on the primary teeth of children referred to the pediatric department of the Faculty of Dentistry of Shahid University. The results of this study indicate a clinical success rate of 2.87%. These results are consistent with those of a study by Waterhouse (7). A study reported the pulpotomy success rate as 99.3%. This high success rate can be attributed to the difference in the type of study and observing the complete isolation using Ruberdam and SSC restoration (16). Farooq reported the success rate of one-session pulpotomy at 74% (21). In a data analysis, Farooq examined the treatment after 2-7 years and the lower success rate of the pulpotomy reported in this study could be due to the long follow-up period, as the study by Rolling reported that the pulpotomy success rate decreases over time (18).

In separate studies conducted in Zahedan and Qazvin, the pulpotomy success rate was reported at 94 (25 and 24). The follow-up period of these two studies was six months, and this difference can be involved in the difference between the results of these studies and the present study. In addition, the accuracy level of students in observing the principles of sterilization and pulpotomy prescriptions can be involved in the higher success of formocresol pulpotomy by the students of the above faculties. In this study, the highest failure rate was observed within two years or longer duration of pulpotomy treatment, indicating that the pulpotomy success rate may decrease over time. The present study revealed that gender is not involved in pulpotomy success, which is consistent with the results of a study by Boeve (26). No significant relationship was observed between the pulpotomy success rate and the restoration type in this study (23). No correlation was also found between the pulpotomy success rate and the tooth type. This study is consistent with the results of the study by Olan

(22). Furthermore, the success rate of the one-session treatment was not significantly different from that of the two-session treatment, which is consistent with the results of a study by Reding (5).

In previous studies conducted in the dental school of Maryland, USA, in 2000, Farooq reported the success rate of one-session pulpotomy on 78 primary teeth at 74% after 2 to 7 years clinically and radiographically (21). Holan et al. (2002) examined 341 pulpotomy primary teeth, 284 of which were restored by SSC and 54 teeth by amalgam. The success of this treatment was reported to be ? in the SSC group and 80% in the amalgam group (22). Additionally, Eskandarian et al. examined 72 primary molars treated in two sessions between the years 1989 and 2001. The patients underwent clinical radiographic evaluation after 2 to 4 years of treatment. The clinical success rate was 3.94% and the radiographic success rate was reported at 80% (23). The high success of pulpotomy with formocresol still raises this substance as a standard material in pulpotomy. From another viewpoint, formocresol use is doubted due to its toxicity and carcinogenic potential. Since the toxic effects of formocresol depend on the amount of its use, it is possible to carefully select the tooth and create ideal conditions during the treatment, and limit the use of formocresol to a one-session pulpotomy to prevent imposing problems resulting from high amounts of formocresol on the patient while performing a successful treatment.

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