

# The Formocresol Pulpotomy, Should We Continue Its Use?

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**Abstract:** Formocresol as an obtundant pulpal therapy medication has been successfully utilized for over one hundred years. The safety of this drug therapy is presently controversial. Although formocresol has the potential for malignant transformation, it has a long term track record of safety. Decreased formocresol pulpal therapy utilization has the potential to limit tooth preservation globally, especially in pediatric patients. Issues regarding carcinogenicity, toxicology, and mutagenesis are discussed. Further issues such as expense, ease of administration, availability, and effectiveness are also discussed. A review of the published literature regarding formocresol case reports is investigated. In conclusion, although formocresol has several known problematic side-effects, it is the opinion of the authors that when properly utilized as a pulpal medicament, formocresol is safe, inexpensive, readily available, easily administered, and effective.

**Keywords:** Formocresol, toxicity, pulpotomy, pulpectomy.

The utilization of the formocresol pulpotomy is an important public health consideration for the treatment of pulpally compromised primary teeth in the pediatric population [1-5]. Formocresol (FC) as a pulpal medicament is efficacious, inexpensive, relatively easy to utilize, and readily available. Other materials and techniques such as mineral trioxide aggregate (MTA), electrosurgery, calcium hydroxide, and ferric sulfate (FC), are either more technique sensitive, less efficacious, more expensive, or less available. Specifically, MTA is more expensive, and more technique sensitive; electrosurgery is less available; calcium hydroxide is less efficacious; and FC is less available [1-4,7,8]. The major attack against FC has been with regard to safety, particularly with respect to carcinogenic potential [8,9]. The purpose of this paper is to demonstrate and educate that concerns regarding safety considerations for the utilization of FC as a pulpal medicament are unfounded. Furthermore, it is our opinion that decreasing the use of formocresol as a pulpal medicament has the potential to adversely effect maintaining pulpally involved teeth, leading to a greater number of tooth extractions and mutilated dentitions.

FC was introduced as an obtundant to treat non-vital permanent teeth by Buckley in 1904. Obtund is defined as: to reduce the edge or violence of: dull [10]. Obtunded is defined as having diminished arousal and awareness, often as the result of intoxication, metabolic illness, infection, or neurological catastrophe. Sweet

introduced the primary tooth pulpotomy in 1930 [11]. In 1960, Dummett and co-workers proposed the single visit formocresol pulpotomy primary tooth procedure [12]. In 1991, Fei *et al.*, [13] declared that the FC primary tooth pulpotomy was the gold standard for therapeutic comparison. The utilization of FC as a pulpotomy medicament has had a long and successful clinical history [1]. Over the last thirty years or so, its use has become controversial as its safety has been questioned due to known toxic, mutagenic, and carcinogenic potential [1,5].

The Sargenti N2 paste root canal therapy technique was introduced to the USA dental community by the 1970s. The Sargenti root canal technique provided a quicker, less rigorous clinical procedure that could be accomplished less expensively, and required less clinical expertise compared to the endodontic standard gutta percha root canal procedures [13,14]. The utilization of the Sargenti technique by non-endodontist dentists provided an economic threat to the endodontic specialist community. The USA endodontic community critically evaluated the Sargenti technique and reported concerning negative therapeutic issues particularly with regard to formaldehyde and paraformaldehyde [15-17]. Well-founded issues regarding problems concerning the long-term effectiveness of the Sargenti technique also contributed to endodontists' arguments against the utilization of the Sargenti technique by general dentists. The Sargenti technique proved to be an unreliable endodontic procedure, and certainly endodontists' opinions of the technique appear to be justified [18,19]. It appears that relevant endodontic specialists' concerns such as 1) economic competition from Oral & Maxillofacial Surgeons and General Dentists utilizing

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this less expensive endodontic technique, and 2) the Sargenti technique's questionable long term root canal therapy efficacy, coalesced to influence the endodontists' concerns regarding the safety of formaldehyde, formocresol, and arsenic as a pulpal medicaments.

With respect to issues against the utilization of FC, Lewis [20-30] has written over a half dozen articles concerning formaldehyde, paraformaldehyde, and FC and lumped several of these chemicals together in an effort to have FC discontinued within the realm of clinical dentistry. Lewis [20-30] has written a number of articles against the utilization of FC as a pulpal medication. Lewis [20-30] appears to be particularly concerned regarding the malignant potential of FC. Lewis [20-30] focused on issues of carcinogenicity, mutagenicity, and the superiority of other pulpal medicaments. However, it appears that Lewis has a bias against the clinical utilization of FC, particularly with respect to toxicology, mutagenesis, and carcinogenesis. Within these articles, Lewis [20-30] presents several misstatements [1-3,32]. Lewis [20-30] utilized a technique referred to as "cherry picking" in that he reported on studies that supported his viewpoints and disregarded studies that did not support his viewpoint. This was particularly apparent with regard to studies which demonstrated either FC mutagenicity or FC-induced genetic damage, or lack of FC mutagenicity, or FC-induced genetic damage [32-36]. Lewis [20-30] disregarded similar toxicity issues related to other endodontic medicaments such as Sodium hypochloride which has a similar mutagenicity profile compared to FC [32-36]. Lewis [21] provided a false statement that the American Academy of Pediatric Dentistry had opposed the use of FC for pediatric pulpotomies [7].

Casas *et al.*, [31] reported that 54% of the pediatric dentists in North America utilize FC pulpotomy for vital primary tooth therapy, and 42% of these specialists had concerns regarding FC. They reported that only 2% of USA pediatric dentists use an accurate dilution of FC. They reported medical concerns regarding mutagenicity, carcinogenicity, and immune sensitization

In 2003, Nadin *et al.*, [37] reported a Cochrane Database System review regarding treatment techniques to manage asymptomatic and symptomatic teeth with carious pulpal involvement. They compared FC pulpotomy, ferric sulphate (FS) pulpotomy, electrosurgical pulpotomy studies and determined that

there were only three acceptable studies which met the appropriate criteria and did not demonstrate the superiority of any one of the pulpal therapies. Scrivivan *et al.*, [4] in 2006, concluded that further long-term studies with a high level of evidence (randomized controlled trials) are necessary to identify alternative therapeutics to replace FC. In a subsequent Cochrane Database systemic review in 2014, Smail-Faurgeron *et al.*, [4] came up with virtually the exact same conclusion as the 2003 review, that there was no evidence to identify the superiority of one of the three pulpotomy medicaments (FC, FS, mineral trioxide aggregate - MTA) over any of the others. Both Lewis [20-30] and Casas *et al.*, [31] also suggested that other pulpotomy medicaments were better compared to FC, although to date these opinions appear to be clearly biased and not readily supported, as FC, FS, and MTA all appear to be essentially equal with regard to efficacy, and FC is more readily available, cheaper, and more easily utilized [1-4,7,37].

However, MTA has been noted for favorable pulp responses as a pulpal medicament [38].

Calcium hydroxide (Ca(OH)<sub>2</sub>) has been utilized as a pulp capping agent since 1938. Many studies have been accomplished with success ranges from 30 to 98 percent [38]. However, in 2010, Aminabadi reported the superiority of FC compared to Ca(OH)<sub>2</sub> with respect to efficacy pulp capping of human primary molars [39]. The evidence supporting the utilization of Ca(OH)<sub>2</sub> as a pulpal medicament remains limited despite its longterm history [38]

Walton and Keiser [40] reported that chemical medicaments such as FC, Cresatin, eugenol, or saline were believed to be necessary in the past for controlling and preventing post-endodontic procedure pain. They reported that a dry cotton pellet alone is just as effective. There is no argument concerning the correctness of such a belief. However, they also noted that a pulpotomy procedure is usually as effective as a pulpectomy when minimal time is available. Furthermore, they noted with respect to a pulpectomy procedures, that the dry cotton pellet is placed after irrigation with Sodium hyperchlorite (presumably after the canal has been dried).

Perhaps, the difference of opinion between endodontists and pediatric dentists and some general dentists regarding pulpal medication with FC is related to different patient treatment realities. Endodontists tend to perform an initial endodontic appointment which involves finding the canals, measurement of the canals,

irrigation of the canals with Sodium hyperchlorite, drying of the canals, and then placing a dry cotton pellet. Such procedures take time. While initial pain control appointments for pediatric dental patients and general dentists' patients are often treated with pulpotomy procedures. The treatment environment for general dentists and pediatric dentists with respect to painful pulpal emergency patients is somewhat different from that of endodontists. General dentists and pediatric dentists may have more situations requiring them to quickly treat their endodontic pulpal pain patients compared to endodontists. Endodontists are certainly correct with their treatment philosophy that secondary pulpal medicaments are unnecessary with respect to the way endodontists treat endodontic pulpal pain patients. However, it is quite possible, that the utilization of FC for pulpotomy procedures is also reasonable.

Both Lewis [20-30] and Casas *et al.*, [31] reported on the issue of formaldehyde's and FC's carcinogenic potential. There is no denying that formaldehyde and FC have carcinogenic potential. However, toxicity is relative; which means that causation of malignant transformation is dose dependent. The question with regard to pupal and peri-pulpal tissues transforming to malignancy is dependent upon a minimum baseline initiating concentration of the toxic material upon the affected tissues [41,42]. Accomplishing a randomized controlled studies to determine the therapeutic carcinogenic risk of a known carcinogenic is not easily attained to say the least. Scientific inquiry has determined the approximate carcinogenic risks for cigarettes and alcohol, and noted that the dosage (administration) of these products over time is significant in risk determination [43,44]. It is established that these products (tobacco and alcohol) have a significant risk with respect to causing cancer. The determination of these risks was made possible through epidemiologic cross-sectional evaluations.

If indeed FC pulpotomy procedures resulted in secondary oral cancer secondary to the utilization of FC, we would logically assume that there would be case report publications. In 2003 both Marx [45] and Migliorati [46] reported case reports of bisphosphonate-associated osteonecrosis of the jaw (BONJ). This secondary effect from bisphosphonate therapy is very rare, but nevertheless, reports continue to be published which support these two initial BONJ case reports [47]. However, when we look for case reports relating to FC-induced oral cancer, we find zero such cases, although historically there have most probably been millions of

FC pulpotomies performed. A boolean search on pubmed for the two terms "formocresol" and "case report" revealed 16 responses. The search was undertaken to determine if there were any case reports concerning an association between the use of FC and cancer. There were a total of 16 articles [48-63], 13 responses in English [48-56,58-60,63], and one each published in Spanish [57], Polish [61], and Croatian [62]. Of the responses, six concerned tissue necrosis [48,53,60,63], four concerned evaluation of therapy [50,54,61,62], three concerned cysts [51,57,59], and one each concerned allergy [49], paresthesia [55], and burn [52]. Further evaluation of the published literature revealed necrosis and allergy secondary to sodium hypochlorite [64-66], and serious allergy case reports concerning formaldehyde [67].

Although several side effects secondary to FC pulpotomy use are noted, there does not appear to be even a singular case report regarding malignant transformation secondary to FC pulpotomy procedures even though presumably hundreds of thousands if not millions of these procedures have been accomplished during the last hundred years. Therefore, it is completely logical to assume that cancer transformation risk secondary to the utilization of FC (even when used in inappropriate dosages) is not a relevant clinical concern. Other critical evaluations of the literature have also reached the same conclusion that FC as a pulpal medicament is both safe and effective [1-4,32,37]. Furthermore, with respect to adult emergency pulpal therapy, treatment perspectives are different for general dentists compared to endodontic specialists. Endodontists typically treat the initial endodontic pulpectomy by determining the working length of the canal system, filing and irrigating, drying, and placing dry cotton and temporary restorative material to seal the pulpal/canal system. With respect to such, it is not necessary to use a pulpal medicament [40,67,68]. However, the general dentists' concerns are to quickly treat the patient's pain complaint and either schedule the patient for the more involved next endodontic procedure, or refer the patient to a specialist for endodontic therapy.

In conclusion, several problematic side-effects to the dental utilization of formocresol have been reported in the literature. However, medication side-effects are expected to be found in virtually all medications. It is our opinion, that formocresol when properly utilized as a pulpal medicament is safe, inexpensive, readily available, easily administered, and effective. Decreasing the utilization of formocresol, particularly

with respect to primary pulpotomy procedures, has the potential to lead to increased primary tooth extractions in the pediatric patient population.

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