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# "IS FORMOCRESOL OBSOLETE?"

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**ABSTRACT**

The use of formocresol is ubiquitous. Its use in pediatric dentistry over the century has been well established. Formaldehyde, a primary component in formocresol, is a hazardous substance and is considered a probable carcinogen by the International Agency for Research on Cancer Health, Canada. Humans inhale and ingest formaldehyde during cellular metabolism. The human body is physiologically equipped to handle formaldehyde through multiple conversion pathways. The purpose of this review was to examine more recent research about formaldehyde metabolism, pharmacokinetics, and carcinogenicity, results indicate formaldehyde is probably not a potent human carcinogen under low exposure conditions.

**KEY WORDS:. Formocresol, Metabolism, Pharmacokinetics, Carcinogenicity**

## INTRODUCTION

It has been suggested recently that formocresol use in pediatric dentistry is unwarranted because of safety concerns, and consequently, formocresol use in pediatric pulp therapy is obsolete. The alternatives to formocresol, which have been shown to be equivalent as efficacy have been studied and investigated. This article will demonstrate that the evidence for banning this medicament because of safety concerns has been either misinterpreted or replaced by better science.

Daily formaldehyde exposure is a fact of life. Formaldehyde is found in the air we breathe, the water we drink and the food we eat. The WHO (World Health Organization) has estimated that daily consumption of formaldehyde approximated 1.5-1.4 mg/day. Second hand cigarette smoke might contain up to 0.4ppm of formaldehyde.[1] The National Institute for Occupational Safety and Health in the United States has stated that formaldehyde is immediately dangerous to health and life at concentrations of 20 parts per million (ppm) and at present there are no estimates of pediatric exposure, although it is likely that children are exposed to lower amounts because of lower food intake. The estimate formaldehyde dose associated with 1 pulpotomy procedure, assuming a 1:5 dilution of formocresol placed on a no. 4 cotton pellet that has been squeezed dry, is approximately 0.02-0.10 mg.[2]

### SOURCES OF HUMAN FORMALDEHYDE EXPOSURE

**Atmospheric formation:**

- Photochemical oxidation
- Internal combustion engine exhaust
- Fertilizer productions

**Hydrogen Sulfide Scavenger:**

- Oil separation

**Household products:**

- Dish washing Liquid
- Antiseptics and Disinfectants
- Carpet Cleaners
- Carpets

Preservatives and Inflaming Solutions, Cosmetics, Finger Nail Hardner, Paper Products, Adhesives, Tyre and Rubber Manufacturers, Latex paints, Resins production, Permanent Press Fabrics, Manufactured Wood Products, Forest and Bush fired and Tobacco products.[3]

### History

In 1874, Nitzel applied a tricresol formalin tanning agent to 8000 exposed pulps. The technique appeared unpopular until Buckley's method of treating putrescent pulps was published in 1904. In 1908, the use of mummifying paste with a preparation including solid formaldehyde was advocated. By the late 1920's, there was disagreement between clinicians from Europe and United States of America(USA) on treatment criteria

and medicaments. In general, clinicians from Europe favoured Gysi's Triopaste with paraformaldehyde, and in the USA, pulp amputation was followed by application of Buckley's Formocresol solution.[5] The defining time for pulpotomy for the extensively carious primary tooth was the work published during a period of 25years by Sweet.[6] During this time, multiple applications of Buckley's formocresol was reduced to 2, and an additional application of fomocresolized Zinc-oxide Eugenol cement was suggested. Since then, the technique for a single visit 5 minute application formocresol pulpotomy was developed using an effective but weaker strength solution.[7,8] It was reported that the formocresol addition to Zinc-oxide Eugenol cement could be omitted.[9]

Despite formocresol's undoubted clinical record of success and its position as the gold standard medicament in both vital and non-vital pulp therapy techniques in the primary dentition is a recent survey of 184 specialists in Pediatric Dentistry, 54% expressed concern over the safety of formocresol.[10]

**Discussion**

As clinicians, we all know from our own experience and from reported literature that a pulpotomy performed with a 5 minute application of a 20% dilution of Buckley's formocresol has a good prognosis, irrespective of whether the radicular pulp is viable. By virtue of the formaldehyde and cresol moieties, the solution has a tissue fixative and anti-microbial properties and will fix and devitalize an irreversibly inflamed radicular pulp. According to data sheets and a large base of published evidence for animal and human studies, formaldehyde, a volatile, organic compound, is toxic and corrosive particularly local to th point of contact.

The UK'S Health and Safety Executive (HSE) presently rates exposure limits for formaldehyde for both long term and short term periods in the work place to be 2ppm or 2.5mg per cubic meter.[11]

Disrupting cell membranes might potentiate further local toxic effects. Alternatively, formaldehyde can enter a rapid metabolic pathway, converting ultimately to formate that is excreted in urine as formic acid, or enters normal metabolic pathways, or is oxidized to carbon dioxide and exhaled.[12] Concentrations of 3ppm of formaldehyde gas can saturate detoxification pathways in nasal epithelial cells, thus allowing "free" formaldehyde to cause damage locally. Fomaldehyde's acute toxic effects are considered real and can occur in humans from both vapour and solution.[13] Formaldehyde is an irritant to the eyes and respiratory tract in amounts as low as 0.1ppm in some humans. Workers chronically exposed to mean levels of 0.2-2ppm formaldehyde exhibited mild nasal epithelial lesions (loss of cilia, goblet cell hyperplasia, and mild dysplasia) when compared with non-exposed controls.[14] Repeat dose inhalation studies with rodents and monkeys demonstrated that length of exposure and the concentration of formaldehyde vapor (ppm) are related to the degree of histopathologic change observed, ranging from slight hyperplasia to squamous cell metaplasia of ciliated and non-ciliated respiratory epithelium.[15] It is generally accepted that formaldehyde is genotoxic invitro, inducing mutations and DNA damage in bacteria and in humans, monkeys, and rodent cells.[16] Results from human and animal in vivo studies showed that findings indicate that formaldehyde acts as a mutagen at the site of contact. Formaldehyde has been shown to be an experimental animal carcinogen in rats, producing nasal tumors at high levels of exposure (time and concentrations).[17]

With respect to humans, many different regulatory authorities have assessed the data published before 2004. Since the IARC findings, the HSE has appraised the epidemiologic studies considered within the IARC report and stated that "sufficient evidence" exists that formaldehyde has caused nasopharyngeal cancer in humans.[18] On the basis of the classification system of Ranly, the treatment of the extensively carious primary tooth can be divided into devitalization, preservation, and remineralization. The latter two are where we can move away from formocresol and reflect a more modern, biologic approach to treatment, irrespective of whether formocresol is carcinogenic.[19]

To present the alternatives that are presently clinically viable as succinctly as possible, the techniques are tabulated by using a single example of related clinical research (Table 1). These alternative techniques for vital pulp therapy might provide such good success rates if used when radicular pulps are irreversibly inflamed. In such a situation other than pulpectomy, there is not an equivalently successful pulpotomy medicament as formocresol solution.[20]

| Table.1 overview of some alternatives to formocresol for vital pulp therapy | | | | |
|---|---|---|---|---|
| **Material** | **Clinical Success** | **Human clinical studies** | **Tested against formocresol** | **Effect (animal studies)** |
| Indirect pulp therapy | 94% over mean (3.4yrs) | Yes | Yes | Preservation and Remineralization |
| Ferric sulfate | 92% 4yrs | Yes | Yes | Preservation |
| MTA | 100% 1yr (gray) 84% 1yr (white) | Yes | Yes | Preservation |
| Calcium hydroxide | 77% at 22.5 mos | Yes | Yes | Preservation and Remineralization |
| Lasers | 100% 90 days | Yes | | Preservation |

We concur that it is in this area where formocresol, if removed completely would be missed the most and, in addition, for teeth exhibiting hyperalgia or those without local analgesia where in the past one would have used a paraformaldehyde preparation such as Miller's paste to devitalize the tooth over time. If we wish to move away from such preparations, then the treatment of such teeth needs further research and development.

## CONCLUSION

In the lights of the findings presented, I would recommend that pediatric dentists should be engaged in further good quality research and debate relating to vital and non-vital pulp therapy for the primary dentition. At the beginning of this 21st century, we have greater understanding of the pulp biology, pathophysiology, and its powers of healing; we should reflect this in our approach to clinical management and aim to preserve what pulp we can.

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