

Conference Paper

“New Age” Pulp Therapy: Personal Thoughts on a Hot Debate

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Abstract: *This article outlines the counterpoint delivered in the debate “Is Formocresol Obsolete?” It addresses the opinion supporting the need to move away from formaldehyde-containing preparations in the dental care of children. It is suggested that such a move should be made not just because of concerns relating to the possible toxicity of formaldehyde but to reflect a more contemporary, biologic approach to pulp therapy in the primary dentition. (Pediatr Dent 2008;30:247-52)*

KEYWORDS: FORMOCRESOL, PRIMARY TEETH, PULP THERAPY, PULPOTOMY

The debate over the use of formocresol solution and other formaldehyde-containing preparations in children’s dentistry continues. This is welcomed and should be regarded as a positive activity that will benefit ultimately those for whom we provide dental care. Discussion at meetings and within peer-reviewed and non–peer-reviewed publications has stimulated both specialist pediatric dentists and general dentists, not only on both sides of the Atlantic but worldwide, to consider their stance over this issue. Should we, as providers of healthcare in the 21st century, continue to use formaldehyde-containing medicaments in endodontic therapy?

This counterpoint will provide my personal thoughts on an undoubtedly controversial topic. These thoughts will be presented within the following sections:

- History: Where were we?
- A perspective from the United Kingdom (UK) on formocresol preparations
- Recent advances in primary tooth pulp biology
- Formocresol: Saint or sinner?
- Treatment
- Evidence-based practice
- The current UK guidelines.

History: Where Were We?

Debate centered on clinical technique is not a product of modern medicine. The varying treatments for the tooth pulp during the last 3 centuries illustrate this clearly. During the

1700s and early 1800s, metal foils were used to cap exposed pulp tissue,¹ which would one use, gold or lead? Would you also prefer to cauterize the exposed tissue with a red-hot iron wire before placing the foil?

From the mid-1800s to the early 1900s, the use of medicaments in pulp therapies emerged and involved wide-ranging substances such as asbestos fibers, cork, beeswax, pulverized glass, calcium compounds, and others based on eugenol. Interestingly, even at a relatively early time in medical and surgical knowledge, it is documented that there was great debate between those who believed a pulp was capable of healing and those who did not.²

During this period of innovation and discovery, the first recorded use of a formaldehyde-containing medicament was published. In 1874, Nitzel applied a tricresol-formalin tanning agent to 8000 exposed pulps.³ The technique appeared to be unpopular until Buckley’s method of treating putrescent pulps was published in 1904, suggesting the use of equal parts of tricresol and formalini (an aqueous solution of formaldehyde gas equivalent to 38% w/w formaldehyde).

In 1908, the use of a mummifying paste with a preparation including solid formaldehyde was advocated.⁴ One year later, the International Dental Congress was devoted to the pulp and its treatment, and it was here that Boennecken⁵ suggested his preparation of 40% formalin, thymol, and cocaine to be superior to Buckley’s solution in pulp amputation procedures.

By the late 1920s, there was disagreement between clinicians from Europe and the United States of America (USA) on treatment criteria and medicaments. In general, clinicians from Europe favored Gysi’s Triopaste with paraformaldehyde, and in the USA, pulp amputation was followed by application of Buckley’s formocresol solution.¹

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In the middle of the last century there were many debates on the merits of different medicaments, and several variations of formocresol existed. The defining time for pulpotomy for the extensively carious primary tooth was the work published during a period of 25 years by Sweet.^{6,7} During this time, multiple applications of Buckley's formocresol were reduced to 2, and an additional application of formocresolized zinc oxide–eugenol cement was suggested. Since then, the technique for a single visit, 5-minute application formocresol pulpotomy was developed by using an as effective but weaker strength solution.^{8,9} It was reported that the formocresol addition to zinc oxide–eugenol cement could be omitted.¹⁰

It has been suggested that these later developments were driven by the impetus from concerns regarding the safety of formocresol.¹

The UK Perspective on Formocresol Preparations

In the UK, Buckley's formocresol solution (38% w/w formaldehyde) and other formocresol preparations are not available for purchase on the general market. It is classed as a medicament, but it does not have a medicine license. It is prepared from its raw constituents in hospital-based pharmacy departments. In the late 1990s and early this century fewer and fewer hospital pharmacists were willing to prepare Buckley's formocresol solution, even in its diluted form.

Compounding this problem, there appears to have been confusion within pharmacy services when preparing the medicament in its dilute form.¹ In particular, which formulation should be used to produce a 1:5 dilution? This is reinforced by the Extra Pharmacopoeia stating that "there is often confusion about the terminology and strength of formaldehyde."¹

Buckley's original formula appears to have contained 50% of a 38% solution of formaldehyde (equivalent to 19% formaldehyde). In Newcastle, since 1979 the following formulation has been used: formaldehyde solution BP (formalin), 19 mL; tricresol, 35 mL; glycerol, 15 mL; and water to 100 mL. This contains 19% of a 38% solution of formaldehyde (equivalent to 7% formaldehyde) and is then diluted to a 1:5; thus the final product contains 1/13 the concentration of formaldehyde (gas). This is inarguably a small amount of formaldehyde.

The apparent confusion over its formulation might make comparison of studies problematic. Further uncertainty related to shelf life was raised. "Laboratories making up these solutions have not only a certain reticence in handling these relatively toxic materials, but also have difficulty in determining a shelf-life for the product."¹

Full-strength Buckley's formocresol solution is considered to have a shelf life of approximately 2 months if stored in brown glass bottles, but in its diluted form it is considered unstable and should be diluted just before use, which is impractical. Despite this, the use of pharmacy-diluted Buckley's formocresol was effective, even under strict criteria for success.¹¹ I believe that in the UK the move away from Buckley's formocresol has,

in part, been driven by increasing difficulties in obtaining the medicament and the increasing reticence of pharmacy staff to prepare the formulation.^{1,12}

Recent Advances in Primary Tooth Biology

Dental pulp is a richly innervated tissue, and recent research has evaluated neuropeptide-containing nerve fibers. Nerves that express substance P have provided insight into pulp nerve function. Studies have shown that within a tooth the nerve fibers are predominantly nociceptive. These have an obvious pain receptive role, but they also play a primary role in immunoregulation and healing.¹³ Both the permanent and primary dentitions show similar increases in innervation density with caries progression, and Substance P is increased in painful caries cases.

In addition to this, during my own undergraduate days, despite few published data, I was taught that in response to caries, primary tooth pulps present a more pronounced and widespread inflammatory reaction compared with permanent teeth and might have been instrumental in continuing with the amputation procedures.¹⁴ This response is refuted by more recent immunohistochemical work that demonstrates equality between dentitions for the degree of vasodilation and angiogenesis in relation to caries insult, with responses predominantly in the region of the pulp horns. Although primary teeth contain more immune cells in both intact and carious states, they appear to localize in a manner similar to permanent teeth.¹²

It appears that the primary tooth pulp has good potential for tissue repair and healing. In light of these contemporary findings, we as a collective professional body should be re-evaluating our approaches to pulp therapy in the primary dentition as our colleagues within adult restorative dentistry have already begun to do. We should be directing our research energies toward compiling a sound evidence base for therapies that favor pulp regeneration.

Formocresol: Saint or Sinner?

Despite formocresol's undoubted clinical record of success and its position as the gold standard medicament in both vital and nonvital pulp therapy techniques in the primary dentition, in a recent British survey of 184 specialists in pediatric dentistry, 54% expressed concern over the safety of formocresol.¹⁵

As clinicians, we all know from our own experience and from the 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 tissue fixative and antimicrobial properties and will fix and devitalize an irreversibly inflamed radicular pulp.

I agree with other pediatric dentists in that the overall amount of formaldehyde in a working solution is small, but whether that amount might cause problems should be explored further.

How many pulpotomies with formocresol would a child receive in 1 visit? How many pulpotomies with formocresol might a pediatric dentist undertake during the course of 1 day?

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 the point of contact. Fewer findings appear to be available for cresol, but it too is a known irritant and corrosive substance in its own right.¹⁶

The UK's Health and Safety Executive (HSE) presently rates exposure limits for formaldehyde for both long-term and short-term periods in the workplace to be 2 ppm or 2.5 mg per cubic meter. There appear to be no data published related to the possible levels of formaldehyde vapor and indeed cresol vapor in the dental working environment. The amount of vapor exposure (ppm) to a child undergoing a formocresol pulpotomy is unknown, and the degree and potential effect of accumulative formaldehyde exposure to dental professionals are unknown.

In the UK in 2005, the HSE's Working Group on Action to Control Chemicals (WATCH) published findings from an Advisory Committee on Toxic Substances (ACTS) related to the carcinogenicity of formaldehyde.¹⁷ In Annex 2 of the report the toxicologic profile of formaldehyde is discussed, and in Annex 3 the carcinogenicity of formaldehyde is presented by a summary of the human epidemiologic data mainly relied on by the International Agency for Research into Cancer (IARC) Working Group in reaching its conclusion relating to formaldehyde exposure and cancer.¹⁸

Formaldehyde is a known and accepted direct-acting irritant. But what happens once it has contacted a tissue? This has been investigated mainly in rats (which are obligate nasal breathers). Formaldehyde will pass into tissues such as mucous membranes rapidly, but uptake into skin is poor. Once within tissues, formaldehyde will react directly with proteins and nucleic acids. To put this into the context of formocresol, tricresol is said to decrease the solubility and diffusion properties of formaldehyde, thus reducing movement out of the root canal.¹⁹ However, tricresol has been shown to increase the permeability of cell membranes by disrupting cell membranes' lipid components.²⁰ 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.²¹⁻²³ However, studies have shown that concentrations of 3 ppm formaldehyde gas can saturate detoxification pathways in nasal epithelial cells, thus allowing "free" formaldehyde to cause damage locally.²⁴

Formaldehyde's acute toxic effects are considered real and can occur in humans from both the vapor and solution.²⁵ In 2005, a dental clinic in California was evacuated after spillage of a 1-ounce bottle of Buckley's formocresol solution and was

closed for the rest of the day. According to press reports, 10 people had difficulty breathing and required emergency room treatment.²⁶

Formaldehyde is an irritant to the eyes and respiratory tract in amounts as low as 0.1 ppm in some humans. Workers chronically exposed to mean levels of 0.2–2 ppm formaldehyde exhibited mild nasal epithelial lesions (loss of cilia, goblet cell hyperplasia, and mild dysplasia) when compared with nonexposed controls.²¹

Repeat dose inhalational 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. The levels that produced no observed adverse effect for long-term inhalation studies with rodents were in the range of 1–2 ppm.^{21,23} When formaldehyde was given to rats in drinking water, a 2-year study showed local effects on gastric tissue, but no signs of systemic toxicity were reported.^{22,25}

The WATCH group suggest that formaldehyde is toxic at the site of initial contact.

It is generally accepted that formaldehyde is genotoxic in vitro, inducing mutations and DNA damage in bacteria and in humans, monkeys, and rodent cells.²⁷⁻³¹

Results from human and animal in vivo studies showed that findings indicate that formaldehyde acts as a mutagen at the site of contact.¹⁷ Formaldehyde has been shown to be an experimental animal carcinogen in rats, producing nasal tumors at high levels of exposure (time and concentrations).³¹ The carcinogenic potential of formaldehyde is less evident in other rodents.

Nasal tumors in rats are thought to arise by a combination of severe chronic local irritation and local genotoxicity. It is clearly stated by WATCH, "By extrapolation, a combination of these circumstances in humans would be of concern in relation to cancer."¹⁷

With respect to humans, many different regulatory authorities have assessed the data published before 2004.^{22,23} 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.³² The HSE interpretation of the data from the studies considered is that they justify "increased concern" for the carcinogenic potential of formaldehyde in humans, particularly in relation to nasopharyngeal cancer, but that the data fall short of providing conclusive evidence. Doubts were raised concerning inconsistencies in some prominent new studies.¹⁷

In the context of formocresol vapor in a dental setting, what might the combined effect of formaldehyde and cresol be? Would the added local toxicity of cresol aid the local genotoxicity of formaldehyde? Are the levels of these substances so low

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 (3.4 ys) ³⁴ | Yes | Yes | Preservation and remineralization |
| Ferric sulphate | 92% 4 ys ³⁵ | Yes | Yes | Preservation |
| MTA | 100% 1y (gray), 84% 1 y (white) ³⁶ | Yes | Yes | Preservation |
| Calcium hydroxide | 77% at 22.5 mos ¹¹ | Yes | Yes | Preservation and remineralization |
| Lasers | 100% 90 days ³⁷ | Yes | - | Preservation |

in the air around a dental chair that this does not constitute a risk? Clearly, these need further investigation with models that replicate the nasal and oral breathing patterns of humans.

Treatment

Applying formocresol to the radicular pulp of a cariously exposed tooth will render the pulp in its most part nonvital. In many instances does this relate to our present understanding of primary pulp biology and pathophysiology? If one considers a carious exposure in a permanent tooth, it should be appreciated that much effort is directed at preserving the pulp. Recent UK-based publications are beginning to reflect this approach for the primary dentition. On the basis of the classification system of Ranly,³³ 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.

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).

With all the techniques/medicaments listed in Table 1 excluding indirect pulp therapy (IPT), care must be taken in assessing the status of the radicular pulp after coronal amputation. If the techniques are used on healthy or reversibly inflamed pulp tissue, then a high degree of success has been recorded. These alternative techniques for vital pulp therapy might not 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.^{38,39} I concur that it is in this area where formocresol, if removed completely, would be missed the most and, in addition, for teeth exhibiting hyperalgesia 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 treatment of such teeth needs further research and development.

IPT of symptom-free but extensively carious teeth shows great promise but should only be undertaken on teeth without signs of pulpal degeneration. Notwithstanding this, it is certainly an area worthy of further study.

Evidence-based Practice

Considering all the options we have, what works best? Unfortunately, the Cochrane Systematic Review of pulp treatment for the extensively decayed primary tooth showed a paucity of acceptable related clinical research but did draw conclusions,

despite including only 3 prospective randomized controlled trials.⁴⁰ From the review it was demonstrated that formocresol, ferric sulfate, electrosurgical pulpotomy, and zinc oxide–eugenol pulpectomy all performed equally well. A recent meta-analysis of formocresol versus ferric sulfate found ferric sulfate to be as effective as formocresol.⁴¹

The Current UK Guidelines

The British Society of Paediatric Dentistry has produced a range of clinical guidelines. The update reflects a shift in treatment modalities away from formocresol, discussing IPT, vital pulpotomy, desensitizing pulpotomy, and pulpectomy.¹² However, a 1:5 dilution of Buckley’s formocresol solution remains listed as a medicament within the guidelines. This is an acknowledgment that the debate is far from over.

Summary

In light of the findings presented, I would recommend that pediatric dentists should be engaged in further good quality research and debate relating to vital and nonvital pulp therapy for the primary dentition. This should include studies to increase our awareness of the possible formaldehyde and cresol vapor exposure in the clinical environment. In some instances, however, there might be difficulties obtaining ethical approval for such work in certain countries.

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. This in itself might lead to a natural reduction in the use of formocresol and herald a new age of pulp therapy.

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Conflict of Interest: Paula Jane Waterhouse, BDS, PhD, has research interests with Newcastle University through an internal fund and also supervises several graduate students at Newcastle University. She is also a Council Member of the British Society of Paediatric Dentistry.

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