

# The development of formocresol as a medicament for primary molar pulpotomy procedures

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**T**he first mention of pulp treatment in the literature was in 1756, when a Philip Pfalt attempted capping exposed pulps with small pieces of gold carefully adapted to the base of the cavity. In the following century, Leonard Koeker in 1826 advocated cauterizing the exposed portion of the pulp with a red hot iron wire, after which the wound was covered with a piece of lead foil. Early attempts at pulp healing utilized the placement of metal foil against the exposed pulp to promote healing. The use of medicaments came later: for example, asbestos, cork, beeswax, pulverized glass, a variety of calcium compounds, as well as others based on eugenol. While the search for the ideal material went on, the debate swung between those believing that the pulp was capable of healing and those who felt strongly that it was not.<sup>1</sup>

The first recorded use of a formaldehyde-containing medicament came in 1874, when Nitzel used a tricresol-formalin tanning agent for 8,000 cases.<sup>2</sup> With a shift in emphasis to the concept of focal infection, however, the technique fell from favor some thirteen years later.

In 1904 Buckley put forward his rationale for the treatment of putrescent pulps.<sup>3</sup> After isolation of the

tooth by rubber dam and removal of the coronal pulp, a mixture of equal parts of Tricresol and Formalini (an aqueous solution of formaldehyde gas generally found to be equivalent to 38 percent W/W formaldehyde) on a cotton wool pledget was hermetically sealed into the pulp chamber. This remained in situ for either one day or one week, depending on the operator. At the second visit the dressing was removed, the tooth dried with alcohol and the mixture placed again over each canal and hermetically sealed for a further three days. He attributed the success of the procedure to the conversion of chemically irritating gases and poisonous ptomaines into nonirritating and nonpoisonous liquids and solids. Thus in a hermetically sealed cavity there was no risk of pain from the evolution of gases causing pressure in a confined space. In addition, the chemicals he used were antiseptic and germicidal in nature. Buckley also proposed an alternative formula composed of Creosote (1 drachm), Formalini (1 drachm) and Alcoholis (20 minims). The latter compound was added to 'clear' the formalin and creosote mixture. Buckley himself apparently felt, however, that the former mixture was the most advantageous, due to the disposition of the fatty constituents of the pulp by the tricresol. The mixture could also be made into a paste by adding precipitated calcium phosphate.

In 1908 Bennette in the *British Journal of Dental Science* advocated a mummifying paste for teeth where full pulpal extirpation was impossible.<sup>4</sup> The paste consisted

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of dried alum, zinc oxide, thymol and glycerine (the formula of a Dr. Soderberg), to which Bennette added formaldehyde in the solid form. This addition apparently ensured a symptomless outcome. No reference was made in this work to Buckley's formulations.

At the International Dental Congress of 1909, the pathology of the pulp was a major topic of discussion and Boennecken discussed his conversion from being an advocate of full pulpal extirpation to the technique of amputation: in 1891, on returning to Prague from the United States he investigated the effects of formaldehyde on the pulp, and by 1893 had conceived the idea of using it in amputation.<sup>5</sup> He advocated its use both in primary teeth, and in permanent teeth where the pulp was difficult to extirpate. Boennecken's most effective formulation was 40 percent formalin, thymol and 1 percent cocaine for analgesia. After two to three minutes of pulpal contact the mummification paste was covered with heated asbestos wool and cement. Boennecken considered Buckley's tricresol-formalin mix inferior, due to its poorer penetrative properties.<sup>3</sup>

By the late 1920s much of the debate in Europe centered around terminology. Bonsack defined mummification as "amputation and fixation", but there was disagreement between Europe and the U.S.A. on treatment criteria and medicaments.<sup>6</sup> In Europe the favored technique was one advocated by Professor Gysi. This involved placing cobalt and a sedative like creosote or eucalyptol on the pulp. If there was a clinical pulpal exposure the mixture was left in situ for two days. If a local anaesthetic had been applied to the pulp, or there was a clinical exposure after cleaning the cavity with alcohol and carbolic acid, then the mixture was left for 1 week. At the end of this time the mixture was removed and the pulp 'stumps' dressed with Trio paste - Tricresol (10 ml), Creolin (Pearson) (20 ml), Glycerin (4 ml), Paraformaldehyde (20 ml), Zinc Oxide (60g). This paste was often mixed with asbestos fibers sterilized by passing through a hot flame. A medicated cement was then placed without pressure into the access cavity. In the U.S.A. pulps in a similar condition were treated primarily by Buckley's Formocresol, although an alternative technique using calcium hydroxide had its advocates.<sup>1,7-9</sup> Interestingly, the use of calcium hydroxide is again experiencing a resurgence of interest along with other alternative medicaments and techniques for pulp treatment.<sup>9-13</sup>

In the middle of this century, there followed many discussions on the merits of different medicaments, such as calcium hydroxide and glutaraldehyde; several variations on formocresol emerged, each with its advocates.

The pulpotomy technique described by Sweet in 1937 was one procedure.<sup>14</sup> This was a modification of an earlier procedure by Sweet, first advocated for primary molar pulpotomies, but involving five visits.<sup>15</sup> The later technique involved removal of coronal pulp tissue and the application of formocresol or Beechwood creosote to the pulp stumps. After two to three days, this was repeated and on a third visit the pulp chamber was filled with a mix of zinc oxide and eugenol, followed by crown and bridge cement and an amalgam restoration. Sweet later modified this to include a layer of zinc oxide and eugenol cement containing some formocresol over the treated pulp stumps and although this technique was widely adopted, there now seems little rationale for this particular modification.<sup>16</sup>

While formocresol as a pulpotomy medicament has a long clinical history, its safety has often been questioned.<sup>17</sup> Many authors consider that if alternative medicaments are not to be investigated, then at least a dilution of the normal working strength of formaldehyde should be used.<sup>18,19</sup> In view of the evidence against formaldehyde and the disadvantages associated with the alternatives this would seem a sensible move, especially since *in vivo* studies indicate comparable clinical effectiveness with the weaker strength solution.<sup>20,21</sup> When pharmacy departments come to prepare the medicament in its dilute form, however, a problem is identified, precisely which formulation to dilute?

Drummond and Curzon detail the dilution required to be clinically effective: a mixture of 30ml formocresol with 90ml glycerol and 30ml water.<sup>21</sup> Most papers and text books quote Buckley's solution to be approximately as follows:

|                |      |
|----------------|------|
| Formaldehyde   | 19%  |
| Tricresol      | 35%  |
| Glycerol       | 15%  |
| Water          | 50%  |
| Apparent Total | 119% |

For this to be sensible, the formaldehyde gas must be dissolved in the water, so that a more meaningful formula would be:

|  |       |
|--|-------|
| Formaldehyde Solution BP/USP equiv 38 percent<br>HCHO) | 50ml  |
| Tricresol  | 35ml  |
| Glycerol   | 15ml  |
| TOTAL  | 100ml |

Note that the above preparation is equivalent to about 19 percent of formaldehyde gas.

The 29th edition of The Extra Pharmacopeia (Martindale) makes the observation "There is often confusion about the terminology and strength of formaldehyde". In practice, the term formaldehyde is used to describe Formaldehyde Solution also known as formalin. The formula used at this and some other local hospitals since 1979 is:

|                          |       |
|--------------------------|-------|
| Formaldehyde Solution BP | 19ml  |
| Tricresol                | 35ml  |
| Glycerol                 | 15ml  |
| Water to                 | 100ml |

Buckley's original formula appears to have contained 50 percent of a 38 percent solution of formaldehyde (equivalent to approximately 19 percent HCHO). The Buckley's formocresol in current use by many authorities, however, is much less concentrated than this. Our formula contains 19 percent of a 38 percent solution of formaldehyde (equivalent to approximately 7 percent HCHO), if subsequently this is to be diluted as indicated by Morawa and others to 1 in 5, the final product will contain 1/13th the concentration of formaldehyde (gas) shown.<sup>20,22</sup>

Quite apart from the difficulties in formulation, formocresol, in whatever guise, is a medicine and should have a product license, which it currently does not, if it is to be manufactured in bulk for sale on the market. In addition, 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. Anecdotal evidence suggests that the shelf life is approximately two months when stored in a brown bottle. While the diluted formula is considered unstable, forming a precipitate in a few hours, and necessitating, therefore, dilution at the chairside, this has not been our experience.

The dental profession, and in this instance, those within the profession most likely to ask for this product, need to decide exactly what formula of the solution they are asking pharmacy departments to prepare.

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