

# No clear evidence of superiority regarding pulp medicaments in primary molars

## Abstracted from

**Smaïl-Faugeron V, Courson F, Durieux P, Muller-Bolla M, Glenny AM, Fron Chabouis H.**

Pulp treatment for extensive decay in primary teeth. *Cochrane Database Syst Rev* 2014; 8: Art. No. CD003220. DOI: 10.1002/14651858.CD003220.pub2.

Address for correspondence: Luisa Fernandez Mauleffinch, Review Group Co-ordinator, Cochrane Oral Health Group, School of Dentistry, The University of Manchester, Coupland III Building, Oxford Road, Manchester, M13 9PL, UK. E-mail: luisa.fernandez@manchester.ac.uk

## Question: In primary teeth with extensive decay what is the best pulp treatment?

**Data sources** Cochrane Oral Health Group's Trials Register, the Cochrane Central Register of Controlled Trials (CENTRAL), Medline, Embase, the Web of Science, OpenGrey, the US National Institutes of Health Trials Register and the World Health Organization (WHO) Clinical Trials Registry Platform.

**Study selection** Two reviewers independently selected studies. Randomised controlled trials comparing different pulp interventions combining a pulp treatment technique and a medicament in primary teeth were considered.

**Data extraction and synthesis** Data abstraction and risk of bias assessment were carried out independently by two reviewers. The primary outcomes were clinical failure and radiological failure, as defined in trials, at six, 12 and 24 months. Pairwise meta-analysis using fixed-effect models was conducted with statistical heterogeneity being assessed using I<sup>2</sup> coefficients.

**Results** Forty-seven trials involving 3910 teeth were included. All were small single centre studies. The overall level of evidence was low with only one trial having a low risk of bias, 20 a high risk and 26 unclear risk of bias.

The 47 trials examined 53 different comparisons: 25 for pulpotomy, 13 for pulpectomy, 13 for direct pulp capping and two comparisons between pulpotomy and pulpectomy.

Regarding pulpotomy, 14 trials compared mineral trioxide aggregate (MTA) with formocresol (FC). MTA reduced both clinical and radiological failures at six, 12 and 24 months, although the difference was not statistically significant. MTA also showed favourable results for all secondary outcomes measured, although again, differences between MTA and FC were not statistically significant (with the exception of pathological root resorption at 24 months and dentine bridge formation at six months). MTA showed favourable results compared with calcium hydroxide (CH) (two trials) for all outcomes measured, but the differences were not statistically significant (with the exception of radiological failure at 12 months). When comparing MTA with ferric

sulphate (FS) (three trials), MTA had statistically significantly fewer clinical, radiological and overall failures at 24 months. This difference was not shown at six or 12 months.

FC was compared with CH in seven trials and with FS in seven trials. There was a statistically significant difference in favour of FC for clinical failure at six and 12 months, and radiological failure at six, 12 and 24 months. FC also showed favourable results for all secondary outcomes measured, although differences between FC and CH were not consistently statistically significant across time points. The comparisons between FC and FS showed no statistically significant difference between the two medicaments for any outcome at any time point.

For all other comparisons of medicaments used during pulpotomies, pulpectomies or direct pulp capping, the small numbers of studies and the inconsistency in results limits any interpretation.

**Conclusions** We found no evidence to identify one superior pulpotomy medicament and technique clearly. Two medicaments may be preferable: MTA or FS. The cost of MTA may preclude its clinical use and therefore FS could be used in such situations. Regarding other comparisons for pulpectomies or direct pulp capping, the small numbers of studies undertaking the same comparison limits any interpretation.

## Commentary

This systematic review is an update of a previous Cochrane review done in 2003<sup>1</sup> including only three randomised controlled trials in contrast to this review which added 44 studies. The objective was to assess the effectiveness of pulp treatment techniques; direct pulp capping, pulpotomy and pulpectomy in the treatment of extensive decay in primary teeth. Further, the effectiveness of pulpotomy medicaments namely; mineral trioxide aggregate (MTA), formocresol (FC), ferric sulphate (FS), calcium hydroxide (CH), enamel matrix derivative (EMD), Portland cement (PC), calcium enriched mixture (CEM) and glutaraldehyde were assessed. Furthermore, the effectiveness of diode laser, Erbium:yttrium-aluminium garnet (Er:YAG) and electrosurgical pulpotomy were evaluated. Finally, pulpectomy medicaments namely; pre-mixed calcium hydroxide and iodoform paste (Vitapex, Metapex), zinc oxide and eugenol (ZOE), calcium hydroxide (CH), Endoflas (CH + ZOE + iodoform), Sealapex (eugenol-free CH) were assessed. The primary outcomes were clinical failure and radiological failure at six, 12 and 24 months.

A thorough search (to 25 October 2013) for relevant articles was performed both electronically and manually by two independent

This paper is based on a Cochrane Review published in the Cochrane Library 2014, issue 8 (see [www.thecochranelibrary.com](http://www.thecochranelibrary.com) for information). Cochrane Reviews are regularly updated as new evidence emerges and in response to feedback, and the Cochrane Library should be consulted for the most recent version of the review.

authors. No restrictions on language or date of publication were placed. As for electronic search, four trial registries, three databases and OpenGrey were explored. Meanwhile, handsearching included five relevant journals. Selection of studies, data extraction and risk of bias assessment were independently performed by two review authors to avoid bias. Disagreements were resolved by discussion.

During data synthesis, the authors combined results of different types of MTA (white, grey and unspecified). This combination of white and grey MTA assumed both possess the same effect following pulpotomy in primary teeth. This assumption cannot be justified since one study with 84 months follow-up found that grey MTA induced a higher percentage of dentine bridge formation than white MTA and this result was statistically significant.<sup>2</sup>

The authors included 47 trials with 3910 randomised teeth. Ten trials were split mouth design, while the rest of 37 trials were parallel-arm design. None of these 47 trials was registered in ClinicalTrials.gov, thus it was not possible for the authors to detect within-study selective outcome reporting. Risk of bias assessment was performed using Cochrane handbook for systematic review of interventions (5.1.0) tool. The resultant risk of bias for included trials was low in only one trial with the rest of 46 studies being at unclear or high risk of bias. This poses uncertainty on the result of meta-analyses in the review.

The authors performed 47 meta-analyses comparing different pulp treatments regarding medicaments/techniques. Although the total number of randomised teeth was 3910, quite a few meta-analyses were 'under powered' with a small number of teeth not exceeding 40 teeth per arm. This can be attributed to inherent differences between included studies regarding the outcomes measured, the medicament/technique used and the time of measurement (six, 12 and 24 months). All these factors posed clinical heterogeneity with subsequent difficulty to combine studies in many instances.

The review authors did not find clear evidence to identify one superior pulpotomy medicament or technique, possibly due to high/unclear risk of bias in most included studies. However, they

suggested the use of either MTA or FS due to their proven clinical success in comparison to FC. Another limitation that faced the authors in pertaining a definitive conclusion was the diversity of reported outcomes in included trials reaching to 78 different outcomes (39 clinical outcomes and 39 radiological outcomes). This difference in outcome reporting posed difficulties in performing meta-analysis. In a trial to limit the outcomes to be used in assessment of clinical and radiological failure of pulpotomy in primary teeth, a core set of outcomes was proposed which is composed of five main domains; soft-tissue pathology, pain, pathologic mobility, pathologic radiolucency and pathologic root resorption.<sup>3</sup> The use of this core set of outcomes by researchers studying the effectiveness of a medicament/technique in treatment of extensive decay of primary molars would increase the power of future meta-analyses.

Although the authors have made substantial effort in synthesising this systematic review, it is still difficult to reach a definitive conclusion regarding the 'best' pulp medicament/technique in the treatment of extensive decay in primary teeth. We concur with the review authors in recommending the execution of a 'network meta-analysis' to unravel the efficacy hierarchy existing between different pulpotomy medicaments.

**Ahmed Elkhadem<sup>1</sup>, Inas Sami<sup>2</sup>**

<sup>1</sup>*Evidence Based Dentistry Centre*, <sup>2</sup>*Department of Dental Biomaterials, Faculty of Oral and Dental Medicine, Cairo University, Egypt*

1. Nadin G, Goel BR, Yeung CA, Glenn AM. Pulp treatment for extensive decay in primary teeth. *Cochrane Database Syst Rev* 2003; (1): CD003220.
2. Cardoso-Silva C, Barberia E, Maroto M, Garcia-Godoy F. Clinical study of Mineral Trioxide Aggregate in primary molars. Comparison between Grey and White MTA – a long term follow-up (84 months). *J Dent* 2011; **39**: 187–193.
3. Smail-Faugeron V, Fron Chabouis H, Durieux P, Attal JP, Muller-Bolla M, Courson F. Development of a core set of outcomes for randomized controlled trials with multiple outcomes – example of pulp treatments of primary teeth for extensive decay in children. *PLoS One* 2013; **8**: e51908.

*Evidence-Based Dentistry* (2014) **15**, 100–101. doi:10.1038/sj.ebd.6401056