Author’s response to reviews

Title: Clinical and radiographic evaluation of pulpectomy in primary teeth: a 18-months clinical randomized controlled trial

Authors:

Xiaoxian Chen (chenxiaox2007@126.com)
Xinggang Liu (iceworlds0033@126.com)
Jie Zhong (77704994@qq.com)

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Author’s response to reviews:

Reviewer reports:

Reviewer #1: It is well written article.

Abstract:

Please state the statistical method in the Methods part, shortly.

Answer: We stated the statistical method in the methods part which is in red as the reviewer suggested.

Introduction:

Well designed.

Subjects:

Please give details about the randomization procedure and sample size calculations for patients.

Answer: We described details about the randomization procedure and sample size calculations for patients in the subjects and treatment part which is in red.

Treatment-Radiography and follow up:
Please state why the proportions prepared 0.21 g zincoxide, 0.07 eugenol and 0.18 g iodoform. Do you have any pilot investigations about these ratios.

Answer : The 0.21 g zincoxide and 0.07g eugenol were according to the manufacturers guidance for one primary molar use. The ratios was decided by the setting time and consistency. We had tried many ratios of ZOE and iodoform, finally found when the 1:1 in volume, the consistency was suitable for clinical usage. If more iodoform was added, the paste was too viscous. So the amount of iodoform was 0.18 g for one tooth. Five different weight of calcium hydroxide, 0.01g, 0.02g, 0.03g, 0.04g and 0.05g, was added and the applicable setting time of mixture ( 0.28g ZOE and 0.18g iodoform) was recorded. Calcium hydroxide could accelerate the setting process and the more calcium hydroxide added, the shorter the setting time. The final amount of calcium hydroxide was determined in as low as 0.01g. The eventual proportion of ZOE: iodoform: calcium hydroxide in the MPRCF was 0.28g: 0.18g: 0.01g. We had done some in vitro test of the property of this mixture root filling material, such as pH, working time and setting time. We had applied the mixing pattern of ZOE, iodoform, and calcium hydroxide in our clinic for one year and showed no adverse reactions, and then we started the present RCT study.

Please state if you completed any in-vitro antibacterial effects of this combination (for example on E.faecalis) compared to the previous published materials. If not, please state such synergistic and/or additive effects of combined drugs as antibacterial therapies in the discussion part. Please clearly discuss in the discussion part with the similar products in the literature.

Answer : We had not completed any in-vitro antibacterial effect of this combination yet. The objective of present study was initially evaluation of the clinical performance of the mixture of these three materials. Before this material was applied in clinic, we evaluated its microbiological by means of consulting literature about similar material and found there were different antimicrobial activity of ZOE, iodoform and calcium hydroxide. The next step of our study will be doing microbiological tests and histological evaluation of the biocompatibility of this mixture.

Interestingly, Endoflas, produced in South America, also comprising of triiodomethane, zinc oxide eugenol, calcium hydroxide, has been reported having the resorption limited to the excess material and resorbs at the same pace as the physiological resorption of root. The antimicrobial efficacy in-vitro study showed Endoflas had good antimicrobial potential against eight microbial strains including E. faecalis compared to other primary root canal filling materials.

In the experimental in vitro study of Sapna Hegde et al, six materials were tested for antimicrobial efficacy against eight microbial strains. Their results showed that zinc oxide eugenol paste exhibited the strongest antimicrobial potential followed by Endofla, zinc oxide-calcium hydroxide-sodium fluoride mixture, zinc oxide-calcium hydroxide mixture and calcium hydroxide paste (Apexcal ™). (Sapna Hegde , Priti Kamlesh Lala ,Dinesh Rao B, Shubha AB. An in vitro Evaluation of Antimicrobial Efficacy of Primary Root Canal Filling Materials. J Clin Pediatr Dent, 2012;37(1): 59–64) . In another study assessing the antimicrobial efficacy against E. faecalis (ATCC 29212), the antimicrobial activity of obturating materials according to results obtained from the present study can be summarized as follows: Endoflas > ZOE >Calcium hydroxide %20 Chlorhexidine > Calcium hydroxide %20 Iodoform
We added these two literatures in the discussion part.

Discussion:

Please give detailed explanation by using schematic figure in the Method part including the chemical and/or physical reactions about the favourable absorbability.

Answer: We added explanation by using schematic figure in the method part about the favorable absorbability as the reviewer suggested.

Reviewer #2: Language review - very good

Reviewer #4: The aim of this study was to compare the success rates of a mixed primary root canal filling (MPRCF, ingredients: zinc oxide eugenol [ZOE], iodoform, calcium hydroxide) to those of ZOE and Vitapex in pulpectomised primary molars. Below are recommendations for this manuscript:

In the Background, the problem/hypothesis is not significant and concise. An Introduction should be briefly focused on the context needed to put the study into perspective in the area of interest.

Answer: We had modified and make clear our hypothesis in the background part as the reviewer suggested.

Articles reporting the results of randomized controlled trials (RCTs) should follow the guidelines of the CONSORT statement. Authors should complete both the CONSORT flow diagram and checklist. The complete CONSORT guidelines can be found at http://www.consort-statement.org.

Answer: We had the CONSORT flow diagram as the figure 1 in this manuscript.

The results are not clear. The description of the results in the text does not comply. I suggest that this section is rewritten.

In discuss, the authors should discuss and address study limitations.

Answer: We had rewritten the results part and added discussion about the limitations in the end of the manuscript.