Author's response to reviews

Title: The Orthopaedic Trauma Literature: An Evaluation of Statistically Significant Findings in Orthopaedic Trauma Randomized Trials

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RESPONSE TO REVIEWS

1) It is a problem that 52 trials were excluded because of lacking data. This constitutes a high proportion of trials (52/(52+76)=41%), and it is likely that such trials reported lower treatment effects than the trials included. Did the trials excluded because of lacking data differ from the other trials? If the excluded trials with lacking data tended to have lower effect sizes how would that effect the result of the review?

Response: We have reviewed and appended our discussion section to include: “Fifty-two studies were excluded for this reason. We realize that excluding so many studies is a limitation. However, review of these studies suggests that they were similar in sample size, geographic location, funding status and number of centers to our included studies.”

2) I am somewhat uncomfortable with the wording of the aims of the study. The first aim was to examine ‘whether the statistically significant effects represented a clinically meaningful treatment effect’. What constitute a meaningful clinical effect depend very much on the clinical situation and the nature of the outcome. Furthermore, even if it was possible to uncontroversially compare RR or effect size in one setting with a RR in another setting there is no consensus of an appropriate threshold. I think this predicament could be more clearly pointed out in the discussion and also emphasised in the aims section by inserting a parenthesis with the operationalisation of ‘clinically meaningful effects’. The second aim was to examine ‘whether those small studies with large effects may be overestimates of the true treatment effect’. It seems too loose to include in an aims section whether large effects ‘may be overestimates’. I suggest that the aim is reformulated, e.g. to study whether there was an association between large effects and few number of events.

Response: We understand this reviewer’s concerns and have modified our aims as follows: Our study had 2 objectives: 1) To determine the magnitude of treatment effects in a sample of orthopaedic randomized trials with statistically significant results and 2) to examine the association between the number of outcome events (a measure of study sample size) and the size of the treatment effect.

3) The review identifies 76 trials with 62 binary outcomes. Were there any trials with more than one binary outcome? The review also identified 122 continuous outcomes. Again, there must have been some trials that reported more than one outcome. How were such correlated outcomes handled? If correlated outcomes simply were regarded as independent that should be made explicit and commented on.

Response: For each study, we documented what we believed to be the key outcome measures as reported by the authors. In those cases in which outcomes were not
defined as primary by the authors, we made judgments about the key outcomes based upon the interventions being tested. We have appended this information to our methods section.

4) Trials with binary outcomes were analysed for the association between total number of events and treatment effect. Why was a similar analysis not conducted for trials with continuous effects, i.e. a study of the association between effect size and some measure of study precision (e.g. 1/standard error)?

Response: Our decision was based upon a recent study that evaluated outcome events in binary outcomes. We wanted the ability to compare our findings in surgery with findings in the medical literature.

Minor Points Raised by Reviewer.

Response: We have reviewed the comments and shortened the introduction, and discussion, as well as provide definitions for clinical importance to ensure clarity of the message.