Author’s response to reviews

Title: MINIMALLY-INFRINGEMENT VS. SURGICAL APPROACH FOR PERIODONTAL INTRABONY DEFECTS: A RANDOMISED CONTROLLED TRIAL

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TRIALS PAPER REBUTTAL

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Nibali L et al.
We would like to thank the reviewers for the comments provided, which have helped improve the paper. Track changes mode was used to prepare a revised version of the paper. A point-by-point response is provided below:

Reviewer #1: The study protocol is very well written and the topics are well delimited and according to a clinical research of excellence. The research question is clear and the way of conducting the study is appropriate to test the hypothesis. In times of more and more frequent use of bone substitutes, membranes and surgical techniques, testing a minimally invasive technique gains academic value.

My considerations are the following:

- PAGE 6, LINE 31: "measurements will be taken by the calibrated examiner (s)". Who / how many examiners? Please enter the initials of each of them.

- PAGE 6, LINE 31 AND 33: "six sites per tooth" is duplicate.

- PAGE 8, LINE 38: "use of anaesthetic", correct for anesthesia

- PAGE 26: improve image quality for publication of Fig 1.

Response: Thanks for the comments. Each suggested change has been made. A new figure 1 with better quality was provided.

Reviewer #2: Dear Authors,

the paper is well written and the findings will add some interesting insight to the literature. I just have few considerations
1- CAL "clinical attachment loss" should be changed to "clinical attachment level" gain (CAL gain)

2- small detail, why prescribe chlorhexidine 3 times a day, since its substantivity lasts for 12 hours, and therefore being recommended its use two times a day

Response: CAL was changed as suggested; chlorhexidine rinses will be advised 2/day, thanks for spotting the mistake, which has now been corrected.

Reviewer #3: Dear author,

Congratulations on the submission of your research protocol, I hope to value your work with some of the considerations listed below:

Background

Page 3

line 11: "... the most prevalent conditions in humans." is a very strong sentence, reminiscent of conventional literature. I suggest replacing it with another more conventional phrase, or include a bibliographical reference that is quite robust to support this sentence.

Response: We have now modified the sentence to read 'one of the most prevalent…'

Line 20-23: "... based on disease ..., based on risk of progression." Replace to avoid misunderstandings.

Response: We added ‘into’ before ‘grades’ to clarify the sentence. This is taken from the current classification.
Line 31-33: "... The objective of treatment is the elimination of periodontal inflammation ...". According to the literature, the purpose of periodontal treatment, at each particular stage, should treat biofilm infection, inflammation and residual sites. This sentence could better show this broader concept at this point in the text.

Response: the sentence was modified as suggested to reflect the importance of disruption of the subgingival biofilm in order to reduce periodontal inflammation, which is the ultimate aims of treatment ("The overall objective of the treatment is the elimination of periodontal inflammation through disruption of the subgingival biofilm, with reduction of gingival PPD and CAL, resulting in reduced risk of disease progression").

Line 44-47: "... radical surgical elimination of the defect by sacrificing adjacent healthy ...". Sacrificing is not a common term in scientific literature. I suggest replacing.

Response: the word ‘sacrificing’ has been removed as suggested.

Line 47-49: "... to more conservative ... to regenerative ...". I suggest replacing it to avoid misunderstandings in the text.

Response: We have now added ‘then’ to clarify the sentence.

Line 49-51: "... regeneration of periodontal attachment measurable clinically, radiographically and histologically." I suggest removing the "histologically" because it seems controversial, though correct. It may generate expectation of response to this issue in the case of your protocol.

Response: We believe it is important to stress that periodontal regeneration has been proven ‘histologically’. This word is not repeated anywhere else in the text. Therefore, we do not believe it could generate confusion.

Line 56-60: "The most recent introduction ... periodontal regeneration.". I think this is the presentation of his technique, the highlight of his introduction. I believe the reader needs to know more about this topic. I also suggest that you do not abbreviate the term "modified- MIST" in the first instance, to be clearer at the outset.

Response: This section was expanded as suggested.
Line 29: Review the text, it seems duplicate. Only the acronyms of the surgical techniques studied should be used here.

Response: The change was made as suggested.

Methods / Design

Line 49- I suggest replacing "examiner-blind" with the term "blind";

Line 51-54: Group names are confusing. I suggest rewriting, separating groups more clearly and objectively.

Response: We chose to keep ‘examiner-blind’ to specify that only the examiner (outcome assessor) and not the patient or the person delivering the intervention will be blind. We separated groups (MINST and M-MIST) more clearly as suggested.

Study Design Plan / Study visits

Cite the location where the study will be conducted.

Include ERB approval information here.

Response: The location was added (‘All the visits will take place in the clinics of Barts & The London Dental Hospital’). ERB approval details are provided under ‘Trial Status’ as requested by the journal.
Line 33: Cite the manufacturer of the periodontal probe.

Line 40: quote the manufacturer of the Nabers probe.
Response: Manufacturers for both probes were added

Page 7

Repeatability

Cite the bibliographic reference of the test that will be done.
Response: Two references were added for the statistical methods used (Bland-Altman & Lin’s concordance correlation coefficient):
