Author's response to reviews

Title: Clinical Evaluation of Short 6-mm Implants alone, Short 8-mm Implants combined with osteotome sinus floor elevation and Standard 10-mm Implants combined with osteotome sinus floor elevation in posterior maxillae: study protocol for a randomized controlled clinical trial.

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Response to reviewer
Firstly, I want to appreciate reviewer's constructive and useful advice. It helps me to improve the present study protocol. I have revise the manuscript according to your advice and all changes have been highlighted in red. Here is the point-to-point response:

Major Compulsory Revisions:
(1) P.3, Abstract and P.9, Methods: The selection of a single implant for each participant for statistical evaluation does not seem to be appropriate, as long as some information could be considered in statistical analysis by using different methods. I strongly recommend to change planned methods and get a statistician to provide support for planning this part. Some statistical methods (such as generalized estimating equations) may be used for taking every implant placed into account with considering the paired effect of having two or more in a single participant. This will lead to a more precise testing protocol and avoid loosing relevant data from study participants. Revising tests will be useful, as exemplified by saying that an ANOVA would be used for the study (if some outcomes are binary, an ANOVA would not be employable; other methods should have been taken into account).

Response: Thanks for the advice. I have consulted a statistician. GEE (generalized estimating equations) will be used to take every implant placed into account with considering.

Text Change: Pg. 10, 11

(2) Considering that sample size was based on a binary outcome, I consider that 225 participants may not suffice for detecting a difference of 1.6%. Please clearly
state what the minimally important difference considered is, and revise this estimation with a statistician.

Response: I have performed a search in the pubmed and found a RCT study (Esposito et al. 2014) reporting more similar study design. In addition, the implant survival rates of 98.6% for group short and 97% for group long in Thoma et al. 2015 was just for the worst case scenario. In that study, all 132 implants in 97 patients were osseointegrated and clinically stable. One implant in group long and two implants in group short were not followed-up and therefore considered as being lost. So I decide to use the implant survival rates of 85.7% for group short and 92.0% for group long in Esposito et al. 2014 to estimate the sample size with the formula \( n = \frac{2 \times \sin^{-1} P_{\text{max}} - 2 \sin^{-1} P_{\text{min}}}{K - 1} = 12.65 \).

Text change: Pg.10

(3) The Methods section provides too little details regarding several procedures. They must be dealt with in order to achieve a reproducible study protocol.

Response: The term “systemically healthy adults” has been deleted, and all patients excluding Medically compromised patients (ASA classification #-) will be included in the study. Partial edentulism is defined as participants presenting all incisors and canines. Panoramic and peri-apical radiograph will be taken to assess the initial bone height and width. If necessary, cone-beam computed tomography will be taken.

Text change: Pg.7

Minor Essential Revisions:

(1) The expression “randomized controlled clinical trial” can be reduced to “randomized controlled trial” in the title and further appearances.

Response: The expression has been changed.

(2) In the background: “recent”, not “resent”; you must mention “success rate” or survival rate” on the 3rd line. On 4th line: “are less technically demanding”. I recommend citing which level of evidence is missing for the mentioned comparison; rewrite the sentence “which is the focus of the proposed study”.

Response: The clerical mistakes have been corrected. The level of evidence has been described as high evidence (# Ib: evidence from at least one randomized controlled trial). The last sentence has been deleted.

Text change: Pg.2

(3) Methods: simplify the sentence “using randomization tables allocating the patient a number with a corresponding envelope” by mentioning something like “according to a table of random numbers”. You should mention which are the patient-reported outcomes considered, the term refers to a category of outcomes, not to a specific construct. It is “3” groups, not “43” for ANOVA.
Response: The sentence has been simplified. The explain of patient-reported outcomes has been supplemented. And the clerical mistake has been corrected.
Text change: Pg.2-3

(4) Discussion: I suggest rewriting this part in order to make it clearer. My suggestion is something like “The results of the trial will support better decision-making for dental implant treatment in atrophic posterior maxillary ridges. If favorable, the use of short implant may avoid adjunct procedures used of implant insertion, thus reducing operative time, complexity and postoperative discomfort.”

Response: The discussion section has been revised according to reviewer’s advice.
Text change: Pg.3

(5) Background, P.4:
Mention the meaning of the acronym “OSFE” in the 1st paragraph. The 3rd paragraph only mentions a “similar rate” but does not say if it is a success rate or something else.
You should be clearer regarding how you can affirm that there are only two randomized trials comparing shorter versus longer implants in the atrophic posterior maxilla. Please explicitly say that those studies were found by the two systematic reviews cited in this section; if not, please describe how you can say that there are only two RCT, .e.g, by explaining that you have run a structured search in some databases and selected studies by using systematic methods.

Response: The meaning of OSFE and the success rate have been supplemented. I am sorry to use the improper statement. I have performed a search in pubmed again and another RCT study is found. In addition, the sentence has been revised to “To our knowledge, three randomized controlled clinical trials compared short implants versus longer implants in combination with sinus floor elevation procedures in posterior maxilla”

Text change: Pg.4-5

(6)Objective and hypotheses:
This part should provide the PICO components in a clearer form. Please consider the following structure: “The aim of the randomized controlled trial is to evaluate the efficacy of short implants (6mm) alone and short implants (8mm) combined with osteotome sinus floor elevation, compared to standard implants (10mm) combined with osteotome sinus floor elevation (OSFE) for treating atrophic posterior maxillary ridges of partially edentulous adults. Considered outcomes include … (then, mention each considered outcome).”

Response: The paragraph has been revised according to reviewer’s advice.
Text change: Pg.6

(7) Move “sample size” estimation to the end of the section, i.e., after the
“outcomes”. Authors should explicitly cite which the primary outcome is. Please provide more details about the surgical procedures. Which implant type (model, manufacturer…) will be used? The OSFE procedure needs more explanation or at least a reference for a detailed description. Please provide the name of the anti-inflammatory drugs, as well as prescription details (doses, time spam, etcetera) for all medications to be used. Which concentration of the chlorhexidine mouthrinse will be used, and what is the reason for 5-6 uses per day instead of twice/day as usual? Will authors use a single- or two-stage protocol with delayed load? What material will be used of fabricating crowns and bridges, as well as abutments? Authors could provide more details about the questions posed for the patients, such as an English translation with original files in Chinese in a supplementary material.

Response: The paragraph has been moved to the end of the section. The primary outcome is implant survival rates. More details of the treatment procedure have been supplemented.

Text change: Pg.8-9

(8) Follow-up: Please explain which criteria for success and survival will be used in this study. The same should be provided for the complications to be considered, instead of just saying biological and mechanical complications. Do you intend to evaluate bone level by using certain types of radiographs with/without positioning devices (please describe intended methods).

The Discussion section could become even more interesting if authors provide data regarding potential benefits associated with possible results. Moreover, the information regarding Straumann implants apparently contradicts the Introduction section. Please provide details regarding implant type used in the mentioned studies or other relevant aspects for both sections, so the reader can distinguish potential reasons for discrepant results.

“Trial status”: Please correct “clinicaltrials.org”.

Response: The description of survival rate, complications and radiographic assessment has been supplemented. The potential benefits associated with possible results have been described in the second paragraph of discussion section. The discrepant results may be caused by the different implant design and surface. Implants in Lai et al. 2013 were Straumann SLA Standard Plus short implants (6 or 8mm), while implants in French et al. 2014 were Straumann (Standard, Standard Plus, Tapered effect and Bone level) implants.

Text change: Pg.5,12

Discretionary Revisions:

(1)Background: Please consider the provision of a paragraph that briefly explains the epidemiological aspects of the clinical issue approached by your protocol.

You could mention that partial tooth loss is highly prevalent in different populations worldwide, that the posterior area is more vulnerable and the percent of cases that will not have sufficient ridge height for restoration by implants in the posterior maxilla. This will provide the reader with a better view of how important this clinical issue is.
Response: The percentage of insufficient ridge height in posterior area has been described in the first paragraph of background section.
Text change: Pg.4

(2) It would be interesting to cite a protocol number provided by the Shanghai Ninth People Hospital’s Ethics Committee.
Please use the term “participants” rather than “subjects” or other throughout the protocol, whenever applicable. The first is more accurate.
Response: The number has been supplemented and the term has been replaced.

(3) Item “d” of the exclusion criteria is redundant and could be removed. Perhaps authors might prefer to say that unfavorable prognosis/a possible indication of extractions that can result in anterior edentulism will lead to exclusion.
Withdrawals: you could add the sentence “requested by them” following “any treatment”.
The order of letters in the acronyms mentioned on the Authors’ contribution section could be the same used in the byline.
Response: Item “d” has been deleted. The term “requested by them” has been added. The order of letters in the acronyms has been corrected.
Text change: Pg.13