Author’s response to reviews

Title: Oral Health Related Quality of Life of Patients with Class III Skeletal Malocclusion Before and After Orthognathic Surgery

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Author’s response to reviews:

Dear Editor in Chief

Thank you very much for the valuable comments. Please find our responses to reviewers’ comments as follows:

Reviewer reports:
Clarissa Drummond, Ph.D. (Reviewer 1): Dear authors,
Considering the relevance of the topic, the quality of the study, and all the questions duly answered by authors, I recommend the manuscript for publication.

Response: Thank you very much.

Ramon Targino Firmino, Ph.D. (Reviewer 2): The authors have satisfactorily responded to all my previous comments and have made the necessary amendments to the manuscript. I have no further suggestions or comments.

Response: Thank you very much.

Reviewer 3): PEER REVIEWER ASSESSMENTS:

OBJECTIVE - Full research articles: is there a clear objective that addresses a testable research question(s) (brief or other article types: is there a clear objective)?
Yes - there is a clear objective

DESIGN - Is the current approach (including controls and analysis protocols) appropriate for the objective?
No - there are major issues

EXECUTION - Are the experiments and analyses performed with technical rigor to allow confidence
in the results?
No - there are major issues

STATISTICS - Is the use of statistics in the manuscript appropriate?
No - there are issues with the statistics in the study

INTERPRETATION - Is the current interpretation/discussion of the results reasonable and not overstated?
No - there are major issues

OVERALL MANUSCRIPT POTENTIAL - Is the current version of this work technically sound? If not, can revisions be made to make the work technically sound?
Maybe - with major revisions

PEER REVIEWER COMMENTS:

GENERAL COMMENTS:
The authors aim to investigate "oral health-related quality of life of patients with class III skeletal malocclusion before and after orthognathic surgery." This is a clear goal. The research question is important and interesting.
The authors used three instruments to answer the research question: 1) oral health impact profile-14 (OHIP-14), 2) multidimensional body self-relations questionnaire (MBSRQ), and 3) orthognathic quality of life questionnaire (OQLQ). They conclude "Orthognathic surgery significantly improves most of the quality of life domains in skeletal class III patients. The improvement in the quality of life and satisfaction after surgery was significantly greater in female patients in our study compared to males."

REQUESTED REVISIONS:
The conclusions need to be modified and the methods and results should be changed accordingly.
Response: The methods, results and conclusions were all modified according to your comment (Abstract, lines 35-39, Page 2).
I recommend that the authors declare one on the used instruments as their primary measure of interest.
Response: We mentioned the OHIP-14 as our primary outcome measure (Materials and Methods, line 123, Page 6).
According to the aim, the authors want to investigate oral health-related quality of life (OHRQoL). Therefore, the OHIP should be used because it is an OHRQoL. Body self-relations are not OHRQoL. This questionnaire should be omitted because it does not measure OHRQoL.
Response: According to your comment, we omitted the body self-relations questionnaire and the related results were omitted from the results section as well.
The orthognathic quality of life questionnaire is a specific dental patient-reported outcomes measures. It measures OHRQoL; however, because the OHIP is more widely used and its psychometric properties are better investigated, OHIP results should be the primary results. OQLO results can accompany them, but there are less important.
Response: According to your comment, we revised the results section. We first reported the results of OHIP, and then the results of OQLO were reported (Results section, Page 9).
If the authors chose OHIP as the primary outcome measure, the analyses need to be modified The authors apply a scoring system for OHIP-14 that is not recommended anymore. OHIP-14's seven
domain scores should be avoided. According to John 2014 (J Oral Rehabil), the original 7 domains are not valid and OHIP-14 results should be presented with one summary score only.

Response: We modified this part and only reported the summary score as recommended by John 2014 (Materials and Methods, lines 123 and 128, Page 6). The table regarding the OHIP-14 domain scores in males and females was also truncated accordingly (the domains were deleted and only the summary score was reported for males and females in the three groups (Table 2). Also, the Discussion section was truncated accordingly.

From Table 2, it can be seen that one summary score is sufficient to describe the results because all domain score analyses show an effect and are statistically significant (which is to be expected when only the summary score is valid.) As a next step to simplify the paper, the OHIP domain score analyses should be deleted (Table 2 in particular). Only the last line of Table 2 should be retained because it describes the summary score analyses. Results can be presented in the text.

Response: Table 2 was deleted and only the summary scores (last line of Table 2) were reported in the text.

Next, the clinical relevance of the findings it not clear. Unfortunately, the authors focus on statistical significance; however, this has nothing to do with clinical relevance. Therefore, I recommend to interpret OHIP change scores in relationship to the minimal important difference. I recommend to consult Locker 2003 (Assessing the responsiveness of measures of oral health-related quality of life) and Reissmann German Dental Journal 2009 (Assessment of clinically significant changes in oral health - Results from the German short version of the Oral Health Impact Profile (OHIP-G14)). According to both benchmarks, OHRQoL change is clinically relevant. This demonstrates that orthognathic surgery matters to patients.

Response: It would be ideal if we could do that. However, we did not use the questionnaire required for minimal important difference in our study. So, at this point, we do not have the required data to clinically interpret our findings based on minimal important difference. However, this would be a great idea for a future study and we mentioned this at the end of our discussion section as a limitation of our study and called for further studies in this respect. “This study had some limitations. We mainly focused on statistical significance of the findings and did not address their clinical relevance. Future studies are required to interpret the change in OHIP scores in relationship to the minimal important difference as described by Locker et al, and Reissmann et al.” (Discussion, Lines 286-289, Page 13).

Right now the authors have a lengthy results section that does not address the aim and does not interpret the magnitude of changes."Results: Significant differences were found in fitness evaluation (P=0.042), body areas satisfaction (P=0.031), functional limitation (P=0.041), psychological discomfort (P=0.001), physical disability (P=0.001), social disability (P=0.002), handicap (P=0.050), dentofacial esthetics (P=0.008), and oral function (P=0.001). The mean score of the following parameters was significantly different between males and females: fitness orientation, self-classified weight, body areas satisfaction, physical pain, psychological discomfort, social disability, facial esthetics, oral function and awareness of facial esthetics. Differences in other parameters were not statistically significant among the groups (P>0.05)."

The results section would simply read: "OHRQoL changed from 14.5 prior to orthodontic treatment to 23.4 prior to surgery and during orthodontic treatment to 5.4 after surgery. These OHRQoL changes were clinically relevant according to the Oral Health Impact Profile's Minimal Important Difference and they were statistically significant (P<0.001)."

Response: The results section was totally revised according to your comment (Results, Page 9).

Conclusions would be straightforward. "Orthognathic surgery matters to patients with class III skeletal malocclusion. It improves oral health-related quality of life to a clinically relevant degree."

Response: The conclusion section was totally revised according to your comment (Conclusion, Pages
I would recommend omitted the term quality of life because you did not investigate this concept. You should also omit the term satisfaction. This is a different concept and you have not investigated this. The gender difference does not seem to exist for OHRQoL.

Response: The terms quality of life and satisfaction were both omitted. No emphasis was placed on gender difference.

Thank you very much for your time and consideration.