Author’s response to reviews

Title: A prospective study of quality of life related to oral health after immediately loaded implant treatment in the atrophic edentulous maxilla, 3-year results

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Responses and changes on Erkapers et al submission:

Reviewer reports:

Reviewer #1: Language review - ok

Response: Thank you.

Reviewer #2: The manuscript could be considered for publication because provide meaningful (albeit non so innovative) information about the patient quality of life in this type of rehabilitation.

Response: Thank you for your opinion. We hope our publication will contribute to further knowledge about patient’s experience/quality of life, for patients with atrophic maxillae receiving essential implant treatment.
Notes:

Class D and E of L&Z could often require bone augmentation (not allowed by the protocol) or use of narrow / short implants, were they used? This could affect some prosthetic outcomes, perceptible by the patient and have to be reported and evaluated.

Response: Thank you for your observation. We have added supplement information about implant diameters, lengths and surgical procedures in the section “Clinical protocol”.

The denture extension may be worthy to be considered. This parameter could influence the quality of life score value.

Response: Thank you for pointing out this important parameter. Additional information about the denture extension has been added in the section “Clinical protocol”.

The Discussion may be considered too long. Same initial parts repeat the procedures performed. It may be suitable to move it in the Methods or erase it.

Response: Thank you for your opinion. Some text in the Discussion has been excluded preventing repetition of what has already been described in the Clinical protocol.

Reviewer #3: This paper reports 3-year results for a clinical trial on a very relevant topic in oral rehabilitation, i.e. immediate loading of dental implants in edentulous maxillae. This paper is well written and interesting.

Response: Thank you for the positive feedback.

At this point, I have the following three comments/suggestions for the improvement of this paper:

1) The sequence of information in the Methods section could be better, and reordering it would make the paper easier/more interesting to read. Authors can present the (a) centers at the beginning, followed by (b) the paragraph with eligibility criteria and sample composition, and (c) the clinical protocol section; the description of dependent/outcome variables can be placed in a separate section and (d) united with the text about the OHIP-49. Then the paper can finish with (e) the sample size estimation and (f) statistical analysis sections.
Response: Thank you for your suggestions to make the paper more interesting to read.

a) The centers are presented in the beginning of the Material and Method section.

b) The paragraph with eligibility criteria and sample composition has been moved as suggested by reviewer.

c) and d) The description of dependent/outcome variables has been united with the text about the OHIP-49 in a separate section.

e) the sample size estimation has been joined with the f) statistical analysis section to make the section easier to read.

(2) The statistical analysis may need revision. Authors mention to have used the Wilcoxon to compare centers, which have different participants; probably other test was used? Moreover, running multiple tests to compare different time points for the same variable without correcting the level of significance may not be the most appropriate approach (e.g. some p values lower than 0.05 would not be significant following Bonferroni correction). My suggestion is to focus on the OHIP-49 as the primary outcome and use appropriate correction and/or different test.

Response: Thank you for your comment. The Wilcoxon rank sum test, that gives equal p-values as the Mann-Whitney U-test, is used here to compare as the data are not necessarily normal distributed and as the centers are independent of each other. If the data could be assumed to be normal distributed, the Student’s t-test could have been used. The Wilcoxon signed rank test is used to test if there is a change over time within patients and should not be mixed up with the Wilcoxon rank sum test.

The significance level is not corrected as the hypotheses tested were not defined a priori and then there is no way to correctly adjust the significance level. We do not consider defining a primary hypothesis when data are available as a proper way to handle the multiplicity issue as then this definition could have been driven by the data – even though we agree the OHIP-49 seems quite natural as the primary variable. There is still a problem defining which time points that are the primary. In our text we adress this problem (line 157-159): " No adjustment for multiplicity was conducted since the risk for multiplicity should be taken into account in the clinical conclusion (but as the results showed no statistically significant difference this was not applicable). " We hope the added sentence above will address the issue well enough.

(3) Figure 1 and 2: Some type of dispersion (e.g. SD) measure would be important to add.
Response: Thank you for your suggestion. SD for OHIP-improvement (expressed with p-values) between consecutive visits for the domains and OHIP total is presented in Table 3.

Other minor comments include:

- Page 3, line 36: delete patient before OHQoL (it is redundant).
- Page 4, line 32: the word "Economic" seems displaced (it seems to have a part of this sentence placed after the figure legends). Please correct it.
- Page 6, line 13: 'respective' instead of 'respectively'.
- Page 9: no need to explain the acronym OHQoL again.
- Page 11, 1st line: 'adaptation', not 'adaption'.

Response: The above suggested changes have been made.