Author’s response to reviews

Title: Association between gingival bleeding and gingival enlargement and Oral health-related quality of life (OHRQoL) of subjects under fixed orthodontic treatment: A cross-sectional study

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Author’s response to reviews: see over
November 05th, 2012

Dear Editor,

Thank you very much for your kind attention with our manuscript entitled "Association between gingival bleeding and gingival enlargement on Oral health-related quality of life (OHRQoL) of subjects under fixed orthodontic treatment: A cross-sectional study" As you have suggested, we are presenting a revised version to be considered for publication.

We are aware that we have received two excellent reviews, and the new manuscript we are resubmitting now took all these reviewers’ comments into consideration. Please find at the end of this letter a list explaining, point-by-point, the changes made in response to the comments that we received. In this response letter, all sentences typed in blue color were added in the manuscript. In manuscript file, the sentences inserted are typed in red.

We thank you and the reviewers for the excellent suggestions given to us. We firmly believe that your comments and suggestions improved significantly our manuscript.

Sincerely,

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This study attempts to delineate the association between OHRQoL and gingival enlargement and gingival bleeding in subjects receiving fixed orthodontic treatment. The study is well written, but the following points should be considered before a decision for publication can be reached.

Major compulsory revisions

1. Study aim is not clear. Did the authors try to investigate the association between OHRQoL and periodontal conditions (as stated in the last sentence in p3) or association between OHRQoL and variables in patients receiving orthodontic treatment? Whether the main focus was placed on periodontal condition or orthodontic treatment (or both) is not clear, and it appears as if the conclusion was made before the actual results were in.

   Answer: Thank you for the comment. We understand the reviewer point of view. We have stated more clearly our objective (Please see the introduction). Our main objective was to verify the association between OHRQoL and periodontal conditions in subjects under orthodontic treatment. However, this association can be confound by other variables. For instance, it’s well established that socioeconomic status and other dental clinical status (such as malocclusion, clinical attachment loss, etc.) have a negative impact on OHRQoL. Therefore, these variables were collected and analysed as a possible confounders for our main objective. This is also now better explained in the discussion: “...It’s well established that socioeconomic status and other dental clinical variables have a negative impact on OHRQoL. Therefore, the associations between gingival bleeding and gingival enlargement with OHRQoL were assessed taking into account the possible confounding effects of these variables...”

2. The selection of OHRQoL instrument. The rationale behind the selection of OHIP-14 to assess the association the authors wish to delineate is not shown.

   Answer: Assessment of OHRQoL is a subject of several contradictions. The selection of and an index has been widely advocated and used as an adjunct to clinical examination documenting the full impact of oral diseases. There is a range of instruments designed and validated for adult populations. The OHIP_14 is one of these instruments; It has been widely used in several cross-sectional and longitudinal studies. Information about OHIP_14 were included in the introduction (P1 second paragraph) and methods (P7 L11).

3. Diagnosis and types of orthodontic treatment

   In relation to the comment 1, clinical (periodontal) diagnoses for the subjects are not shown. I feel that types and stages of fixed orthodontic treatments may significantly influence the patients’ quality of life. Regarding this, the authors only included ‘time receiving’ orthodontic treatment into the analysis, and in my opinion, this is not sufficient.

   Answer: In relation to the periodontal diagnosis, this focus has been described in another study that has been published last year (Zanatta FB, Moreira CH, Rosing CK: Association between dental floss use and gingival conditions in orthodontic patients. Am J Orthod Dentofacial Orthop 2011, 140(6):812-821.) Considering this
Considering the periodontal diagnosis, based on patient ages and periodontal data explored in another study [1] (2.06 mm ± 0.18 and 1.6 ± 0.11 for mean probing depth and clinical attachment levels in proximal sites, respectively) most patients have only periodontal diagnosis of gingivitis.

Considering the information of orthodontic treatment stages, we completely agree and this issue was a cause of concern in the planning process of the study. However, some information about this topic is above:

1) Most patients have little occlusal problems (See data about Dental aesthetic index in table 3, where almost 72% of individuals have DAI < 30). Thus, after 6 months of orthodontic treatment we consider that treatment was able to reduce substantially occlusal problems like crowding, then reducing confounding factors that could interfere on OHRQoL.

2) Several clinical variables were collected. If were added orthodontic variables, the time of examination would difficult the feasibility of the study.

Answer: The term quality of life was replaced to OHRQoL in the whole manuscript.

Introduction
p3 L1 “…QOL is a reflection of the degree of satisfaction with one’s family and social life.” I do not feel that the notion is appropriate. Please specify the reference.

Answer: A reference was inserted.

p3 L6
There was no basic explanation of the basic concept of OHRQoL in this paper.

Answer: It was added in the second paragraph of introduction (L6) the sentence: “ Oral health-related quality of life (OHRQoL) is defined by a self-report specifically pertaining to oral health, capturing both the functional, social and psychological impacts of oral disease (Gift and Redford, 1992).”

p3 L13
This review on the impact of periodontal disease and OHRQoL is not very sufficient.

Answer: We chose to make a synthetic style about this topic in the introduction, highlighting all relevant papers about periodontal disease and OHRQoL. After, in the discussion section (second paragraph) we detailed again the pertinent publications. We decided not to include this in the introduction not to be repetitive. In the discussion P11 L5 the following information was added: “In the last years, the OHIP instrument has been used to verify associations between OHQoL and periodontal conditions...”

p4 L1
There is a wide range in the age group for subjects included in the study. The life stage is vastly different; juveniles, young adults and adults. Please provide information that shows the use of the particular instrument (OHIP) is valid in these age groups receiving this type of treatment.
**Answer:** It was added in the second paragraph of the introduction studies that used OHIP	extsubscript{14} in adolescents and Young adult populations under orthodontic treatment. The references are below cited:


**p4 L9**
Please provide more detailed information regarding the orthodontic treatment.

**Answer:** It was added in the “Study sample” section the following explanation about orthodontic treatment: “In general, the orthodontic treatment consisted of fixed straight-wire appliances used in all subjects, the first treatment phase consisted in alignment and leveling of the teeth with NiTi and stainless steel archwires; following, the space closure was proceeded by sliding mechanics with a 0.019x0.025” stainless steel archwires and elastomeric ligatures; and last, in the finalization phase 0.018” stainless steel archwires was used to promote adequate intercuspidation...”

**p4 L9**
Inclusion criteria are extremely broad. This could potentially include patients with various degrees of periodontitis and other oral complications.

**Answer:** I think this concern was clarified in question 3.

**p5 L7**
Describe what ‘PD’ stands for.

**Answer:** It was inserted

**p5 L9**
Describe what ‘BOP’ stands for

**Answer:** It was inserted

**p5 L10**
I am puzzled as to this description regarding periodontal status. What do the authors mean by ‘most participants’? If the authors try to delineate the relationship between periodontal condition and OHRQoL, they need to provide values for PD and CAL. If a patient has gingival enlargement, there is a possibility that he or she has deep periodontal pocket. This problem relates to the lack of appropriate diagnosis of periodontal disease.

**Answer:** This point was clarified in the sentence inserted on results section. “Considering the periodontal diagnosis, based on patient ages and periodontal data explored in another study [1] (2.06 mm ± 0.18 and 1.6 ± 0.11 for mean probing depth and clinical attachment levels in proximal sites, respectively) most patients have only periodontal diagnosis of gingivitis”. We used “Most participants” due to mean values of PD and CAL and low values of standard deviation. Then, we could concluded that almost all participants had little mens of PD and CAL.
Define ‘PPD’ and ‘CAL’. Does this ‘PPD’ differ from ‘PD’?
Answer: We apologize for the mistake. It’s exactly the same meaning. We changed all terms PPD for PD in the manuscript.

What is the significance of calculating both gingival bleeding and bleeding on probing?
Answer: Gingival bleeding refers to marginal bleeding, in other words, bleeding due to a gingivitis process. This bleeding can be caused by manual stimulation like dental floss or even manual toothbrush. Then, it could be caused and seen by the patients in their routine dental cleaning process and it could impact the OHRQoL. On the other hand, bleeding on probing is a bleeding caused by a periodontal probe after probing the entire pocket depth. Sometimes, periodontal patients can have little marginal bleeding (if they have little gingivitis) and high levels of bleeding on probing. We measured both bleedings.

Please check if this description of OHIP14 is appropriate (OHIP-14)?
Answer: We added a detailed description of OHIP14. This point was answered in question 2.

Results
Is it appropriate to direct the readers to Table 4 without first noting Tables 1 to 3?
Answer: We understand your concern. Normally demographic characteristics are described in a standard table 1. However, in table 3 and 4 these informations were described in the first column. Thus, we decided to remove a standard table 1 and conducted the readers to table 3 to read these informations. This strategy allowed to reduce 1 table of our manuscript.

What are the suspected causes for the gingival enlargement observed in these subjects? This can potentially have significant impact on the relationship with OHRQoL.
Answer: We inserted a topic about this issue on third paragraph of discussion (P12 L9): “GE associated with orthodontic treatment is a hypertrophic form of gingivitis. The exact mechanism for the development of GE is not completely understood, but probably involves increased production by fibroblasts of amorphous ground substances with a high level of glycosaminoglycans. Increases in the mRNA expression of type I collagen and up-regulation of the keratinocyte growth factor receptor could play important role in the excessive proliferation of epithelial cells and the development of GE [2]. In some studies, poor oral hygiene enhanced GE [3, 4], while other clinical studies concluded that overall gingival changes during orthodontic treatment are transient with no permanent damage to the periodontal supporting tissues [5, 6]”.

Define ‘whole mouth bleeding’.
Answer: It was added (percentage mean of gingival marginal gingival bleeding) in the sentence.

Table II? Table 2?
Answer: It was corrected to table 2.

From bottom ‘…periodontal status is associated with OHRQoL.’ The notion of periodontal status is too broad.
Answer: Periodontal status was replaced by gingival enlargement to clarify the association found.
In this study, no criteria or definition of periodontal disease are shown. Answer: This point was clarified in the sentence inserted on results section. "Considering the periodontal diagnosis, based on patient ages and periodontal data explored in another study [1] (2,06 mm ± 0,18 and 1,6 ± 0,11 for mean probing depth and clinical attachment levels in proximal sites, respectively) most patients have only periodontal diagnosis of gingivitis.”

Here, the authors provide another version of study aim, which is different from those described elsewhere. Now the authors’ focus is placed on the aesthetic aspect, which is not exactly the same as ‘periodontal condition or status’.

Answer: In the beginning, our study aimed to verify associations between different aspects periodontal conditions (Bleeding, gingival enlargement, probing depth, clinical attachment level) and OHRQoL. However, considering periodontal status, we found an independent association only between anterior gingival enlargement and OHRQoL and the aesthetic aspect was the main explanation reason of this association.

No clinical diagnosis is presented in the results or method section. Answer: I think this point have already been clarified.

Young subjects refers to individuals with more than 14 years and less than 30 years.

Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:
I declare that I have no competing interests.

Reviewer's report
Title: Impact of gingival bleeding and gingival enlargement on Oral health-related quality of life (OHRQoL) of subjects under fixed orthodontic treatment: A cross-sectional study
Version: 1 Date: 24 October 2012
Reviewer: Kerstin Öhrn
Reviewer's report:
I have reviewed the article and have the following comments

My major concerns are:
1. The title include the word impact, which also is mentioned in the conclusion. However, this is a cross-sectional study and it is only association that is assessed not impact. To use the word impact an experimental study is necessary. In addition gingival bleeding is mentioned in the title and it is reported that gingival bleeding was assessed using a condensed version of Löe & Silness index, but this is not used in any analyses.

Answer: We agree that association is more appropriate than impact. So, the title was changed to: “Association between gingival bleeding and gingival enlargement and Oral health-related quality of life (OHRQoL) of subjects under fixed orthodontic treatment: A cross-sectional study”.

Regard to Gingival bleeding, first was collected a gingival index (Loe 1967) and after that it was dichotomized in presence or absence of bleeding. This explanation is described in methods section: “...PlI and GI were dichotomized as visible plaque (present / absent) and gingival bleeding (present / absent), respectively with scores 0 and 1 of each index being considered “absent” and scores 2 and 3 being considered “present”. The percentages of sites per person with visible plaque, gingival bleeding and bleeding on probing were calculated...”. The marginal bleeding refers to a bleeding due to a gingivitis process. This bleeding can be caused by manual stimulation like dental floss or even manual toothbrush. Then, it could be caused and seen by the patients in their routine dental cleaned process and it could impact the OHRQoL. Gingival Index proposed by Loe (1967) also use visual alterations in the index (i.e. contour, texture, edema and color). However, it was done a gingival enlargement index. So, we used only the bleeding information of GI

2. In the sample there is no information of the reasons for the non response.

Answer: It was added in “study sample” section the phrase: “...The main reason of non response subjects was due to abandonment of orthodontic treatment....”

3. In the description of the assessment there is no information on how the extent of encroachment was assessed only that is was a 4 graded scale.

Answer: It was added the following explanation: “...The extent of encroachment of the gingival tissues onto the adjacent crowns was also graded, using 0 (normal), 1 (up to 1mm in occlusal/medial direction), 2 (up to 2mm in occlusal/medial direction) and 3 (≥ to 3mm in occlusal/medial direction), on the labial and lingual surfaces...”

5. There is neither any descriptive statistics of the combined hyperplasia score.

In this manuscript, we choose use only the overall mean Anterior Gingival Enlargement (AGE) score as independent variable. This variable was treated statistically as a continuous variable where a point of increase in AGE we have the correspondent value fold increase in overall OHIP$_{14}$ average. The specific data about frequencies of different scores of gingival enlargement index were explored in another manuscript titled “Association between plaque control, oral habits and anterior gingival enlargement in orthodontic subjects”.

6. There are no information on the OHIP-14 scores in the method section

It was added on P7 L11 the following: “...This instrument is a questionnaire containing fourteen questions addressing the following dimensions, based on the theoretical and conceptual model of oral health [7]: Functional limitation, physical pain, psychological discomfort, physical disability, social disability and handicap. Each of the seven subscales has two questions graded on a five-point scale, for which patients choose an answer using the following codes: 0=never; 1=hardly ever; 2=occasionally; 3=fairly often; 4=very often. OHIP$_{14}$ total scores were calculated using an additive method.”
7. The result section has a main focus on sociodemographic variables, which is not the aim of the study. The focus should be on gingival hyperplasia and bleeding according to the aim.
   Answer: We understand your point of view. However, there is evidence that sociodemographic variables are associated with OHRQoL. Thus, it was explored all variables that could have independent association with OHRQoL.

8. However, it looks from the result as if the problem is more of aesthetic nature than a health issue and from that point of view the focus could be on appearance and not periodontal condition as such, then the aim need to be altered.
   Answer: In the beginning, our study aimed to verify associations between different aspects of periodontal conditions (Bleeding, gingival enlargement, probing depth, clinical attachment level) and OHRQoL. However, considering periodontal status, we found an independent association only between anterior gingival enlargement and OHRQoL and the aesthetic aspect was the main explanation reason of this association.

9. Among the sociodemographic variables there is an analysis of the association between age and OHIP-scores and 52% had an education less than 11 years and if Brasil do not differ substantially from other countries, people who are 14 years can not have an education more than 11 years.
   Answer: In our sample, 49% had between 14 and 19 years old and 48.1% had at least 11 years of education. In our tables, the exact number of subjects with 14 years old is not available.

My minor comments are:

1. In the abstract the result in regard to gingival enlargement should be presented before the result on sociodemographic variables (see comments on focus above)
   Answer: The suggestion was accepted.

2. It is unclear what the sentence "patient diagnosed with oral pathological conditions were advised to seek consultation and treatment" is about (method section).
   Answer: It was added in the sentence: “... Patients diagnosed with oral pathological conditions (i.e. gingivitis, periodontitis, active caries, semiological lesions, …) were advised to seek consultation and treatment.”

3. Please make sure that all abbreviations for example FOT are explained.
   Answer: Both points were corrected.

4. As table 4 is mentioned first in the text, the table should be table 1.
   Answer: We understand your concern. Normally demographic characteristics are described in a standard table 1. However, in table 3 and 4 these informations were described in the first column. Thus, we decide to remove a standard table 1 and conducted the readers to table 3 to read these informations. This strategy allowed to reduce 1 table of our manuscript.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable
Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests

Thank you very much for the suggestions. Having considered point by point the queries of the referees, we now think that the manuscript has improved in quality and that it can be considered for publication. Thank you very much for the careful review process.

Sincerely yours,

Fabricio Zanatta