Author’s response to reviews

Title: Evaluation of the levels of pain and discomfort of piezocision-assisted flapless corticotomy when treating severely crowded lower anterior teeth: a single-center, randomized controlled clinical trial

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Response to the Reviewers

Denis Bourgeois (Reviewer 1):

1. Presentation of VAS tables

They are relatively confused.

Since you are doing a study on different periods, it would be useful to have an analysis at 14, 28 days (Appendix absent, I am mistaken) because the active group requires a longer healing process. Which raises the question of the point date of your study. A summary chart would make reading easier. Which could lead you to a multifactorial type analysis applied to VAS 'case vs. control''

Response: Thanks very much for your questions regarding our tables. The descriptive statistics of the VAS scores obtained at one day and seven days following the onset of treatment are given in Tables 2 and 3. We have mentioned in the main text that all the values of the assessed variables dropped to zero at the 14-day and 28-day assessment times. Therefore, there is no benefit of showing tables full of zero values for all the examined variables at the third and fourth assessment times. Accordingly, we decided to show only two tables (Table 2 and Table 3) which included the main findings of the study.
Summarizing the VAS scores of the six variables was given in this manuscript in a tabulated manner instead of a visual way (i.e., a chart as suggested by Dr Denis Bourgeois). It is well-known that charts are very easy to interpret but do not give the author or the researcher the ability to convey the whole amount of summary measures performed in the statistical analysis. In other words, when the results of this research project was announced in local research meeting, the principal researcher presented all of his results in the form of line charts and bar charts. However, in the context of publishing these results, tables are usually more informative and much condensed than using graphical displays.

Regarding the final assessment time, we found all values of the assessed variables going to the zero level at 14 and 28 days following the onset of treatment which indicated that any further assessment times would be a waste of time and labor. Therefore, we are satisfied by our selected ‘last assessment time’ located at 28 days following the onset of treatment despite the presence of a group of patients undergoing a surgical intervention. We would have announced the ‘final assessment time’ as a source of limitation in the current study if the VAS scores appeared relatively high at the last assessment time (i.e., 28 days following the onset of treatment) but this was not the case in the current trial.

Regarding the performed statistical analysis. Since we have ended up with only two assessment times (i.e., the one-day and seven-day assessment times) in a parallel-group RCT study design, we preferred to choose the simplest way to compare the two groups at each assessment time. Table 4 came with six comparisons made at one day following the beginning of treatment between the two groups (using two-sample t tests) and another six comparisons made at seven days following the onset of orthodontic treatment. I think this would be enough since there was only one factor being compared between the two groups (i.e., accelerated method of decrowding vs. non-accelerated method).

2. Choice of VAS

The literature recommends an odd number of values. You have taken the option of a variable from 0 to 100. Can you explain this choice? Would not it make sense to create categories of value judgments (0-4) and thus allow a synthesized visibility and a more efficient analysis.

Did you use CI or SE? Why?

Are you sure of the relevance of the choice of the X2 test with regard to the small number of people?
Response: I have just made a quick search of the recent papers in the field of orthodontics that evaluated levels of pain, discomfort, swelling, and mastication problems using PubMed databases and found hundreds of papers employing VAS scores instead of Likert-type scales. I am not against the idea of using Likert-type scales, actually our early research projects between 1999 and 2008 included many questionnaires with answers that incorporated different types of Likert-type scales. However, recently there is a great tendency toward using VAS-based questionnaires in the orthodontic literature when evaluating patient-centered outcomes. Many authors claim that VAS scores are reliable and informative in revealing patients’ perceptions and impressions towards different oral sensations and impairments. I agree with Dr Denis Bourgeois that converting patients’ responses into several categories would give another picture about their status at T1 and T2. However, this suggesting requires an additional data analysis which would unnecessarily lengthen this paper and exceed the reasonable word limit.

The Chi-square test appeared in Table 1 to show that there was no sex-difference in the distribution of males and females between the two groups. Of course, the number of observations in this 2-by-2 table was relatively small. But we obtained a similar P-value when Fisher’s exact test was employed. Therefore, we decided to keep it as it is.

3. Are there other criteria for judgment than others involved in VAS (bleeding, smoking, etc....?)

Response: The chosen variables are the most common ones in the literature when evaluating patient-centered outcomes following any orthodontic treatment with/without surgical intervention. We have mentioned at the end of the Discussion section (i.e. at the Limitation section) that other variables could have been evaluated such periodontal tissues and tooth vitality.

4. Not sure that clinical photography is of interest

Response: Yes, we believe that the figure showing the surgical intervention is very important to the reader in order to understand the concept of flapless corticotomy by piezosurgery.

5. Unless I am mistaken, appendix II only targeted the active group. If so, my advice is to remove it
Response: You are right that Appendix II was the questionnaire given to patients at the last assessment time in the surgical group only (i.e. the experimental group). However, in order to make the picture very clear to the reader, we prefer to keep this Appendix at the end of the paper since we have also kept Appendix I that shows the questionnaire that was administered to both groups. Again if the Editor-in-Chief does not feel that Appendix II is important, I am very happy to be deleted by your Editorial team.