Author's response to reviews

Title: Effects of a Novel Magnetic Orthopedic Appliance (MOA-III) on Dentofacial Complex in Mild Skeletal Class III Children

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Author's response to reviews: see over
Dear Editor,

Thank you for considering the revised version of our manuscript. We are thankful to the reviewers for pointing out some important modifications needed in our manuscript. We have thoughtfully taken into account these comments. The explanation of what we have changed in response to the reviewers' concerns is given point by point in the following pages.
Reviewer: Adriano CRISMANI
Reviewer's report:
Major compulsory revisions:

1) In the Chapter "Introduction" the train of thought is not clear: why did the authors do the investigation? One aim of the investigation cannot be "the development" of an intraoral class-III-appliance.

We have rewrite the Introduction section to make the train of thought clearly and clarified that “the aim of this study was to examine the craniofacial and dentoalveolar changes in subjects with mild to moderate skeletal class III malocclusion after a new magnetic orthopedic appliance (MOA-III) treatment”.

2) The explanation of the appliance’s acting system is not clear: how can originate attractive magnetic forces such vector’s directions (Fig. 5)?

We have explained the appliance’s acting system in the “appliance design” part and gave the reason why we use attractive magnetic forces in Discussion section.
We modified the Fig.5 to present the force direction created by MOA-III using attractive magnetic forces when the patients were at maximal mouth closure and opening position(1/3 offset) under attractive and repelling status..

3) The upper jaw’s center of resistance is not situated between the roots of the molars (Fig. 5)

In the book of “Biomechanics and esthetic strategies in clinical orthodontics”, it shows that the center of resistance for a maxilla to be slightly inferior to the orbitale for the maxilla, and distal to the lateral incisor roots for intrusive movements of maxillary anterior teeth. But in most of orthodontic textbooks in China, the center of resistance for a maxilla horizontally positioned inferior to the orbitale, but in sagittal direction, it is positioned in the root apex between upper 1st and 2nd molars (attached below). The results was calculated through three-dimensional finite element by Dr. Zhihe Zhao. The center of resistance for the maxilla might be controversial at this time point.
4) The chapter "Discussion" is too long winded in part and deals also with the erroneous assumption mentioned above.

We have rewrite the discussion part. And we tried to clarify the biological safety of magnets' application in orthodontics, the reason we use attractive magnetic forces in class III treatment and the results from MOA-III treatment.

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

Quality of written English: Needs some language corrections before being Published

We have rewrite all this manuscript and corrected the grammar, syntax and spelling by the person who is familiar with the good scientific writing in English.

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: Mohammad Y Hajeer
Reviewer's report:
Major Compulsory Revisions

The English language here in this manuscript needs to be improved thoroughly. In several occasions, the meanings are not clearly given because of the poor language. Understanding of the ideas being given is dependent on the good interpretation of the reader. I believe that the authors should re-write the whole manuscript again making use of person who is very familiar with the good scientific writing in English.

We have rewrite the whole manuscript and tried to clarify the ideas we want to present in this study. We also corrected the grammar, syntax and spelling by the person who is familiar with the good scientific writing in English.

One of the objectives of this research project is to 'develop an intraoral Class III magnetic orthopedic appliance (MOA-III), and to investigate ... '. However, this papers presents the results of comparing a treated group with an untreated group of patients. So, the first aim should be deleted.

We have deleted the first aim according to the reviewer`s suggestion. The objective has been changed to “the aim of this study was to examine the craniofacial and dentoalveolar changes in subjects with mild to moderate skeletal class III malocclusion after a new magnetic orthopedic appliance (MOA-III) treatment”.

Regarding the objectives of this study, I don't believe that it is ethical to consider conducting a research project on human subjects using a new form of a magnetic orthopedic device without doing proper investigations on few subjects and evaluating its effects before commencing an original study involving a relatively large number of patients (i.e. 36 patients). The authors admitted that an early version was applied on monkeys. Then the design was modified and was immediately applied on 36 patients. How did the authors convince their patient to be included in this trial if they had never tested it on previous few cases?

Thanks for this good question about the sample size estimation. We calculate the sample size by using the formula below:

\[ n = \left[ \left( Z_{\alpha/2} + Z_{\beta/2} \right)^2 \times \left\{ \frac{(\bar{\sigma})^2}{\mu_1 - \mu_2} \right\} \right] \]


8-10 patients in one group should be enough for this pilot study.

In our study, we collected 36 patients for MOA-III treatment and 20 patients for control. This might raises ethical issues as more subjects were exposed to this clinical trial. But the magnets has been used in orthodontic practice for some time. The review of the literature also showed the biological safety of both the magnets and static magnetic fields.

Before this study, both clinical and experimental research have been
performed to show the effects of magnets using in class III treatment. This is the reason why we include more patients in present study.

The authors mentioned several times that they were treating mild skeletal Class III patients although it is well known that a range of ANB values from 0 to -3 degrees means that the sample contained a group of mild, moderate and probably few cases of severe skeletal Class III patients. They should mention that their group of patients contained some moderate to severe cases. Or at least, this appliance was used to treat mild to moderate cases of skeletal Class III deformity.

Yes, a range of ANB values from 0 to -3 degrees should present mild to moderate cases of skeletal Class III deformity. We have changed the “mild skeletal Class III” to “mild to moderate skeletal Class III” in the revised manuscript. Thanks for your suggestion.

The protocol of screw activation was not mentioned. This should be given clearly in order to allow understanding of the changes that were observed in the treated group.

We have rewrite appliance design part and try our best to describe the protocol of screw activation clearly.

Sample size calculations was not performed.

We calculated the sample size by using the formula as mentioned before:

\[ n = \left[ \left( \frac{Z_{\alpha}}{\alpha} + \frac{Z_{\beta}}{\beta} \right)^2 \times \{2(\delta)^2\} \right] / (\mu_1 - \mu_2)^2 \]


8-10 patients should be enough for this pilot study.

Details of the control group was not given. No information was given whether sex- or age-matching was conducted. A table giving some demographic characteristics and clinical features of the both groups (the experimental vs. the control) was not given. It is very important to have some information about both groups before the commencement of the treatment. Also, the authors did not justify the inclusion of patients in the control group. They mentioned that the reason of postponing the treatment for the control group was due to the presence of primary molars. This is not a reason for delaying the treatment. They could have mentioned simply that patients in this group were informed that they would receive their treatment after six months because they were serving as a control group parallel to another group being treated. Many researchers may pose some ethical questions regarding this intentional delay of treatment in the control group.

We added the sex and aging data for treatment and control group. We performed a comparison of chronological and skeletal ages between treatment and control group as well.

For the inclusion of the control group, most of the patients had the problem of primary teeth alteration. At the same time, we did informed the
patients that they would receive their treatment after six months because they were serving as a control group parallel to another group being treated.

Radiography.

The authors did not justify the use of the hand-wrist radiograph. This treatment was labeled 'early', so there was no need to take hand-wrist radiographs. This kind of irradiation is not justified.

For the early treatment, the hand-wrist radiograph could be used for skeletal age assessment. In this experiment, we compared the chronological and skeletal ages between treatment and control group using hand-wrist radiograph estimation.

Of course, we can also use the maturation of cervical vertebrae for developmental stage evaluation. It could reduce radiological doses for the patients.

Statistics.

Paired t tests were used to evaluate intra-group differences. But nothing was mentioned regarding testing the significance of inter-group differences.

Error of the method was not evaluated. Intra-observer reliability was not evaluated too.

We added the evaluation of Error of the method. At the same time, we added the statistical analysis data between treatment and control group (table 4).

Results.

All the results were given in the body of the text. The author should have highlighted only the important findings. This section needs to be trimmed dramatically. Also, it was not written in paragraph-based style. Many headings and subheading!

We have rewrite the results part. The body of text has been trimmed dramatically. At the same time, we changed the style according your suggestion, thanks.

Any number given in the Results section should be mentioned as 'an average' or as 'a mean' because numbers coming from tables are generated from samples of patients and not from individual patients.

We rewrite the Results section and used P value to present the changes for different parameters instead of average or mean value.

A table representing the comparisons made between the Experiment group and the Control group was not given. We need to see the testing of changes observed in the main group compared to the changes observed in the control group in conjunction with the associated P values.

We have added the statistical data to show the changes between the Experiment group and the Control group.

Minor Essential Revisions

Any abbreviation mentioned in the body of the manuscript should be explained at its first appearance. The authors gave a table of the abbreviations
used at the end of the manuscript. This is not the ordinary way to deal with abbreviations.

We have explained all the abbreviations in this manuscript at its first appearance.

Discretionary Revisions
None.

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

Quality of written English: Not suitable for publication unless extensively edited

We have rewrite the whole manuscript and corrected the grammar, syntax and spelling by the person who is familiar with the good scientific writing in English.

Statistical review: Yes, and I have assessed the statistics in my report.
We have added the statistical data according to the reviewer’s comments.

Declaration of competing interests:
I declare that I have no competing interests