Author’s response to reviews

Title: Comparative Study of Wave-front Aberration and Corneal Asphericity after SMILE and LASEK for Myopia: a short and long term study

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Version: 1 Date: 15 Feb 2019

Author’s response to reviews:

Dear Editor,

We really appreciate the editor’s advice and reviewers’ comments on our manuscript entitled “Comparative Study of Wave-front Aberration and Corneal Asphericity after SMILE and LASEK for Myopia: a short and long term study”, which were very helpful to the improvement of our article. In this article, we have revised the manuscript in accordance with the editor and reviewers’ comments and carefully proofread the manuscript to correct typographical, grammatical, and bibliographical errors. In addition, our point-by-point responses to the reviewers’ comments are listed below. We hope the revised manuscript will be more acceptable for publication in your journal. Thank you!

Yours Sincerely,

Manrong Yu & Jinhui Dai

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Editorial Office:

1. Please kindly make clear if the assignment of patients into SMILE or LASIK group is at the discretion of the investigator or not. If it was patients’ choice, then this study should be considered as observational (case control design). However, if patients were assigned to receive different surgical procedure by the doctors because of this research work, then this should considered as a clinical trial, and it should be registered in a public registry platform and the article should be prepared according to CONSORT guideline.

The assignment of patients into different groups was the patients’ choice, after the surgeons explained clearly to them the cons and pros of each kind of surgery, so the patients were assigned to receive different surgical procedures at their free will without the control of doctors.

2. It has come to our attention that throughout the manuscript there is significant text overlap with other publications. While we understand that you may wish to express some of the same ideas contained in these publications, please be aware that we cannot condone the use of text from previously published work. We would therefore be grateful if you could provide a justification for the overlap in text between your manuscript and other sources. Please be informed that we cannot proceed with handling your manuscript before this issue is resolved, and the sections of text in question have been reformulated.

Thank you for your kindly reminding. I have revised the manuscript to avoid overlap in the text. Hope the modified manuscript could more acceptable. Thank you!

3. In accordance with BioMed Central editorial policies, could you please ensure your manuscript reporting adheres to TREND guidelines for reporting of clinical trials. This is so your methodology can be fully evaluated and utilised. Can you please include a completed TREND checklist as an additional file when submitting your revised manuscript?

Thank you so much for your advice, I have included a completed TREND checklist in the supplementary material.
4. Please, rename the “Patients and Methods” section to “Methods”.

I have renamed the title to “Methods” as requested. Thank you!

5. We note that you have not included a ‘Funding’ section in the Declarations. All sources of funding for the research reported should be declared under this section. Please, also declare the role of the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

I have included the ‘Funding’ section in the Declarations, as well as the declaration of no role in the conduct of the study. Thank you!

6. Please, include the ethics approval reference number in the ethics declaration.

The ethics approval reference number was 2014012, which was included in the ethics declaration. Thank you!

Reviewer 1:

Do not use doesn't or isn't, always use does not, is not

I have changed all the “doesn't” or “isn't” to “does not” and “is not”, thank you.

Reviewer 2:

1. Abstract: In the results, please provide the values for corneal Q, HOA, SA and peripheral corneal power in parenthesis for the 2 groups.

I have provided the detailed values of corneal Q value, HOA, SA for the two groups, as there is a large number of information for peripheral corneal power, please allow me to present the data in the table.

2. Please do not start a sentence with a numerical.

Yes, I have revised the sentence into a proper way.
3. At 3 years, the differences in the SA were similar to 3 months results, it is surprising that, being a prospective study, authors do not report interim results at 1 and 2 years.

Thank you for this inspiring question, it is better to have the interim data to investigate the visual quality during the following-up, and the 1-2 years results have been reported in several previous publications. That’s why we aim to observe the short and long term visual quality and corneal shape change after refractive surgery, and the data was collected only at 3 months and 3 years postoperatively.

4. Referring to LASEK as essentially flapless is probably not advisable since there is an epithelial flap is created. Authors can reframe as "nearly flapless". Similarly, claiming that LASEK does not induce any HOA is also not correct. Please reframe.

Thank you for the advice, I have reframed the sentence. In terms of the HOA, as no stromal flap is created during LASEK, I reframed the sentence to claim that LASEK creates no stromal-flap-related HOA, which I think might be more appropriate. Thank you!

5. In participants, please mention how the type of procedure was allocated to each patient. Assuming that this was not randomized, how did authors choose which patient gets SMILE and who gets LASEK? Even though not randomized, masking can be done in a prospective study. This can immensely improve the strength of the study. Please mention whether any masking was done during the follow up?

Thank you for your considerable advice. The assignment of patients into different groups was the patients’ choice, after the surgeons clearly explained the cons and pros of each kind of surgery, so the patients were assigned to receive different surgical procedures at their free will without the control of doctors. During the follow-up, the examinations were operated by two independent technicians who were blind to the surgical procedures the patients received, as I have mentioned in the Method section.

6. Have the authors measured the Q value for the posterior corneal surface as well?

Thank you for the question; although I have not measured the Q value for the posterior corneal surface in this study, it is worthwhile investigation in the further research, as this data may have relationship with postoperative visual quality and the stability of the corneal shape.
7. Sample size calculation - authors assume a small difference between SMILE and LASEK, which is good, but the standard deviation assumed is larger than the assumed mean difference, which has shot down the sample size. Please provide a reference for these assumptions.

Thank you for the question. The assumed sample size was calculated by the formula below, with the level of significance as 5% and the power to 80%:

\[ N = \frac{2 \times (1.96 + 0.84)^2 \times SD^2}{\text{mean difference}^2} \]

Where the SD=0.25 and mean difference=0.2, so the larger the SD, the more patients we need to enroll. The formula was from a published article (Naduvilath TJ, John RK, Dandona L. Sample size for ophthalmology studies. Indian J Ophthalmol. 2000;48(3):245-50)

8. Did authors record patient related subjective symptoms during follow up? This may be substantiated the objective readings. Please acknowledge this as a limitation of the study if not recorded.

Thank you for the advice. As a fact, I have recorded the subjective symptoms at 3 months postoperative using a questionnaire, which was used in a previous study (Chan A, Manche EE. Effect of preoperative pupil size on quality of vision after wave-front-guided LASIK. Ophthalmology. 2011;118:736-741). The scores of the questionnaire showed that patients complained less night glare and halos after SMILE than after LASEK (SMILE: night glare=1.25 ± 1.22, halos=0.97 ± 1.12, LASEK: night glare=2.32 ± 1.99, halos=1.96 ± 1.77), but unfortunately, I haven’t recorded the subjective symptoms at 3-year follow-up.