Author’s response to reviews

Title: Comparison of Visual Results and Higher-order Aberrations After Small Incision Lenticule Extraction (SMILE): High Myopia vs. Mild to Moderate Myopia

Authors:

hongying jin (hongyingj@163.com)

Ting Wan (64230519@qq.com)

Fang Wu (fangwuu@126.com)

Ke Yao (xlren@zju.edu.cn)

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Author’s response to reviews:

Dear editor,

We have modified the paper according to the review’s suggestions. We use red and blue fonts in the paper to highlight the modification.

Manuel Rodríguez-Vallejo (Reviewer 1):

1. Page 3. Line 47. It has not been clinically demonstrated yet that SMILE is biomechanically superior than LASIK or FS-LASIK therefore I suggest to modify by "SMILE theoretically has benefits…” and to cite a recent paper about corneal biomechanics in SMILE and the problem of confounding variables such as intraocular pressure or corneal thickness.

Answer: We cited two recent papers about corneal biomechanics in SMILE. Please see reference 5 and 6.

Answer: The Kolmogorov–Smirnov test was used to test for normality. The data of Pre-SE and HOAs in Group-H and Group-M are normality distributed. The differences between Pre-SE and Post-SE in each group are normality distributed. The differences between Pre-HOAs and Post-HOAs are also normality distributed.

3. Please specify in the table title (mean±SD and range). Furthermore change "center cornea thickness" by "central corneal thickness" and "introocular pressure" by "intraocular pressure".

Answer: We specified “mean ± SD and range” in the table title. And modified the change "central corneal thickness" and “intraocular pressure”

4. Page 8. Line 138. Modify "log MAR" by "logMAR" and along the text each time that is repeated.

Page 8. As the authors include visual acuities at 1 day and 10 days it would be interesting to include a new section named visual recovery on which they include the percentage of eyes that achieve UDVA and CDVA of different levels at one day and ten days and if there were differences among groups.

Answer: Considering the opinions of another reviewer, we removed the logMAR visual acuity and the table 2. If it is better for the paper, we will modify and add on the table again.

5. Page 8. Line 155. Exactly the same mean and standard deviation for safety in both groups?.

Please, recheck for ensuring that this is not a mistake.

Answer: We recheck the mean and standard deviation for safety in two groups. The mean and standard deviation for safety is 1.0586 ± 0.0918 in Group-H and 1.0563 ± 0.0946 in Group-M, respectively. It is not a mistake.
6. Page 9. Line 159. Authors report "None of the patients had severe corneal complications". Please include any adverse event without qualifying the severity that has happened as it is later detailed in the discussion.

Answer: We have added adverse event in this part of the paper.

7. Page 10. Line 178. According to the table 1, I understand that there was an increase of coma and spherical aberration in comparison to preoperative values in both groups, but differences between groups were only significant for the spherical aberration but not for the horizontal coma. Despite of including this information in the table, please include in the text what happens specifically for coma and spherical aberration which are the most important aberrations for which you can apply comparison with other papers in the discussion.

Answer: We modified this section in the paper.

8. Page 15. Line 261. Correct FELx by FLEx in this line. This mistake is repeated along the text.

Answer: Yes, we corrected FELx by FLEx.

9. Page 16. Line 275. Another limitation of the study is that both eyes have been included in the statistical analysis. This is a common mistake in ophthalmology research since the variance between eyes is usually less than that between subjects, the overall variance of a sample of measurements combined from both eyes is likely to be an underestimate of the true variance resulting in an increased risk of a Type 1 error. Please, specify this limitation in the text and cite this reference.


Answer: A type 1 error has been specified in the paper, please see reference 28.
10. Page 16. Line 277. I suggest to compute the statistical power almost for high order aberrations, which is the most valuable information of the paper, instead of specify that a larger sample size is required in order to demonstrate that sample size is enough for the hypothesis of differences in the increase of high order aberrations, especially for coma and spherical aberration.

Answer: UDVA is main information of the paper. The statistical power was set to be 0.8, and the results indicated that a total of 64 Group-H subjects and 64 Group-M subjects should be involved in our study. In our future work, we prepare to report longer follow-up results of SMILE.

Mercè Morral (Reviewer 2):

1. Methods section of the abstract: describe type of study
Answer: Yes, This is a prospective study.

2. Results section of the abstract should include p-values. Also, specify the level of UDVA reported in "It was found that 77% and 98% had an UDVA...."
Answer: P-values were included in the abstract.

It was found that 77% and 98% had an UDVA of 20/20, 98% and 99% had a CDVA of 20/20 in group-H and group-M, respectively, while 87% and 95% had a SE within ⊳0.5 D and ⊳1.0 D in group-H, and 98% and 100% in group-M.

3. Introduction needs a rewrite in terms of English language. Also, references on HOAs studies after SMILE are missing.
Answer: I rewrite the introduction of aberrations.

References on HOAs studies after SMILE were added in the paper. Please see references 12, 13, 14.
4. The authors state that only patients that attended the 3-month postop appointment were included. How many patients were lost to follow-up?

Answer: 17 eyes of 8 patients were lost to follow-up.

5. "Only measurements in eyes with a pupil of 6.0 mm or larger were included" How many eyes were excluded for the HOAs analysis? Did the authors consider dilating the pupil to measure ocular aberrations?

Answer: We measure ocular aberrations in a dark room without dilating the pupil. No eyes were excluded for the HOAs analysis.

6. Statistical analysis: considering that this is, in theory, a prospective comparative study, sample size calculation should be performed for the main outcome measure, at least. Which one is the main outcome measure? Was sample size calculation performed? Please, clarify and discuss.

Answer: The main outcome is UDVA. We used G-Power software (https://www.gpower.hhu.de/) to estimate the sample size. The statistical method is independent-samples T test. The $\alpha$ (the Type I error probability for a two sided test) was set to be 0.05, the power (the probability of correctly rejecting the null hypothesis) was set to be 0.8, the effect size was set to be 0.5, and the allocation ratio (the ratio of control to experimental subjects) was set to be 1. And the results indicated that a total of 64 Group-H subjects and 64 Group-M subjects should be involved in our study.

7. Table 2 may be omitted. Cumulative UDVA and CDVA graph is more relevant when reporting visual acuity after refractive surgery.

Answer: We omitted Table 2.
8. As mentioned before, the authors intend to perform a comparative study. The statistical analysis to compare the induction of HOAs between groups should be more clearly reported, including p-values. Moreover, table 3 is too crowded and there is too much data. In my opinion, preoperative and 3-month postop values are enough. Title of table describes "aberration changes". Does this mean that the value depicted under 1-month and 3-months postop is the change in HOAs or the mean value at that time-point? Please, clarify.

Answer: We modified the table 3. The mean value is the value at that time-point.

9. Page 14, lines 233-239: "In this study, mild DLK (diffuse lamellar keratitis) was observed only in four eyes at one day, postoperatively. After using topical fluorometholone 0.1% ophthalmic solution, DLK .... at the 3-month follow-up" belongs to the results section.

Answer: We modified this section of the paper.

10. Figures are of poor quality and difficult to review

Answer: Figures were modified and the quality was improved.

Yours Sincerely

Yao Ke, MD
Professor and Chief
Eye Institute of Zhejiang University
Eye Center, Second Affiliated Hospital, College of Medicine, Zhejiang University
Address: No. 88 Jiefang Road, Hangzhou 310009, China
E-mail address: xlren@zju.edu.cn.