Author's response to reviews

Title: Efficacy, predictability, and safety of small incision lenticule extraction: prospective cohort study

Authors:

Jae Ryun Kim (oindiano99@gmail.com)
Hyung Bin Hwang (leoanzel@catholic.ac.kr)
Su Joung Mun (moons-6@daum.net)
Young Taek Chung (eyegreen@eyegreen.com)
Hyun Seung Kim (Sara514@catholic.ac.kr)

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Author's response to reviews: see over
Dear Editorial team of the BMC Ophthalmology

Enclosed please find a revised version of original manuscript entitled “Efficacy, predictability, and safety of small incision lenticule extraction: prospective cohort study” by Jae Ryun Kim, Hyung Bin Hwang, Su Joung Mun, Young Taek Chung, Hyun Seung Kim, which we wish to submit to BMC Ophthalmology for publication again.

We heartily thank you the editor and referees of the BMC Ophthalmology for taking their valuable time to review our article. We have made some corrections and clarifications in the manuscript after going over the referee’s comments. The changes are summarized below:

Reviewer 1 (Dear Walter Sekundo)

1. The authors claim this study to be a prospective cohort study. However, this study has neither a study design nor a hypothesis to prove. Moreover, it is not clear, why they decided to choose the time between May 2012 and November 2013? Why did the have 447 eyes and not 500 or merely 100 eyes?

Corrections:

We understand the reviewer’s concern about the study design. This work was designed as a prospective study. First, the study was designed to evaluate the refractive and visual outcomes at 6 months and to identify predictors of the outcome after SMILE with 500 eyes. Because of the several previous reports of SMILE outcomes, we intended to enroll as many eyes as possible and to observe for as long as possible to differentiate our study from those reported previously. However, enrolling 500 eyes would have taken too long. Consequently, we abandoned our attempt to enroll 500 eyes because of shortage of time and excessive expense.

2. There is no randomisation of the incision groups. Moreover the number of eyes in the 2.5mm incision group is 3 times the 2mm incision. In my opinion it looks very much like a retrospective case review study, where the surgeon started with a slightly larger incision and - as his/her experience
increased the incision length shortened. Alternatively, there were different surgeons and we have a comparison between them. In any case a conclusion that a smaller incision produces a better 1st day outcome is scientifically not supported, but might be a result of biased data.

Corrections:

We accept that there are some weaknesses in our comparison of incision groups. Although all eyes were treated by one surgeon, there was no randomization of the incision groups and the number of eyes differed significantly among the groups. The analysis of the effect of incision size was, in fact, retrospective, because we had not planned to analyze the effects of incision size on visual outcomes when the study was designed. We also accept that there is a possibility that the surgeon may have become more skillful by the time the smaller incision group was treated compared with when the larger incision group was treated, in the relatively early period.

Nevertheless, we expect that use of the smaller incision in the SMILE procedure has certain benefits, such as increased corneal stability and more rapid epithelial healing. Our results showing better first-day outcomes in the smaller incision group seem to demonstrate a benefit, albeit limited. We added discussion of these limitations to the manuscript.

3. It also strikes because there are published papers from Japan and Turkey comparing SMILE and FLEex and showing no difference in refractive and visual outcome. The reviewer cannot appreciate a statement (see Discussion) that small incision leads to less manipulation. On contrary, the smaller the incision the larger the stretching of the wound edges during lenticule dissection.

Page 11, line 207. ".. smaller incision...helped shorten ist duration" This is another unsupported claim. You did not measure the duration of the procedure. "Experience" cannot substitute scientific data. Indeed, how an 0.5mm difference in the incision length shortens a procedure? I believe, that your procedure was shorter with a smaller incision, because you gained more experience when progressing from 2.5 to 2.0mm.

Corrections:

In our experience, as the surgeon became more adept at the smaller incision, manipulations could be performed more readily, as with a larger incision, during the SMILE procedure. Thus, this allows the benefits of a smaller incision, such as increased corneal stability and rapid epithelial healing. Presently, we cannot exclude the possibility of a better initial visual outcome because of the smaller incision.
Our data were also consistent with previous studies of SMILE and FLEX in that there was no difference in UDVA among the incision groups at 1 week after surgery.

We hope that more surgeons will be challenged to reduce the incision size to improve results for their patients, such as more rapid visual recovery.

4. It is not clear, why a 20/25 value is discussed in this paper. The usual way in the modern publications is to pay attention to the 20/20 vision. In the old days an UDVA of 20/40 used to be considered important, but is meanwhile outdated.

Corrections:

We have added the 20/20 value to the abstract and the main text of the manuscript. Because several previous SMILE papers used 20/25 values to present their results, we discussed the 20/25 values for comparison. We also added a discussion of the recent 1-year results of a SMILE study (Sekundo W., Gertnere J et al. Graefes Archives of Ophthalmology) using the 20/20 value.

The following other corrections were made:

Page 3, line 44: corrected “refractive stability”

Page 3, line 48: added citation No. 9

Page 8, line 146: added discussion regarding comparison with a recent 1-year follow-up SMILE study (Sekundo W., Gertnere J et al. Graefes Archives of Ophthalmology)

Page 8, line 147: corrected to [10-12]

Page 11, line 195-199: the paragraph was deleted.


Page 11. Line 207: add the discussion about the limitation of this analysis

Reviewer 1( Dear gary foster)

Major
1. Line 109 references 54.4% and 79.8% 20/20 on day one but figure one shows different values.

Corrections:

We have corrected Figure 1.

2. Line 122 references 86.1%. The fig 2 values in the bar graph don't seem to add up to 86.1%.

Corrections:

We have corrected Figure 2.

Minor

1. I infer from line 57 that data is presented on all consecutive SMILE patients with no qualifying patients' data omitted. If this is true, then should it be stated?

Corrections:

We revised the text to avoid confusion. “From May 2012 to November 2013, 447 eyes from 224 patients with myopia (with and without astigmatism) who were treated consecutively with SMILE at the Onnuri Eye Clinic, Jeonju, Korea, fulfilled these criteria. Patients were followed for 6 months.”

2. In line 168 you mention that the results appeared clinically insignificant while line 36 declares the result was clinically insignificant. The addition of appears seems more appropriate.

Corrections:

We have revised this.

3. The figures are not labeled in the current format, but the labeling is included in other parts of the publication (lines 293-300). I assume these will be married in the final publication

Corrections:

This has been corrected.
We hope the revised manuscript will better meet the requirements of the BMC Ophthalmology for publication. We thank earnestly you once again for the valuable and constructive review by the referees. We look forward to hearing your response again.

Sincerely yours,
Hyun Seung Kim, M.D.
Professor

Department of Ophthalmology and Visual Science, Yeouido St. Mary’s Hospital, College of Medicine, The Catholic University of Korea, Seoul, Korea

62 Yeouido-dong, Youngdeungpo-ku,
Seoul 150-713, Korea

Tel.: 82-2-3779-1848
FAX: 82-2-761-6869
E-mail: sara514@catholic.ac.kr