Reviewer's report

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

Version: 2 Date: 8 May 2014

Reviewer: Walter Sekundo

Reviewer's report:

This paper has several weaknesses that have to be addressed:

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 they have 447 eyes and not 500 or merely 100 eyes?

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. It also strikes because there are published papers from Japan and Turkey comparing SMILE and FLEX 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.

2. 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 In the old days an UDVA of 20/40 used to be considered important, but is meanwhile outdated.

Step-by-step comments:

Page 3, line 44: Past decade ist efficacy and REFRACTIVE stability are proven.

Page 3, line 48: Recently, small incision has been proposed...potential side effects. Here you have to put the citation No 9 as you have to name those who proposed/develped this new treatment modality Page 8, line 146 and in the following discussion you compare your results to other short-term (3-6 months) studies. I believe, you should also compare your results to mid-term (at least 1 year) studies (e.g. Sekundo W., Gertnere J et al. Graefes Archives of Ophthalmology) Page 8, line 147: There is a typing error [10-12] Page 11, line 195 till 199: This paragraph can be omitted without any harm to the manuscript.

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.