Reviewer’s report

Title: Small incision lenticule extraction (SMILE) versus Laser In-situ Keratomileusis (LASIK): A Randomized, Non-inferiority Trial

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Reviewer: lawrence friedman

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This protocol manuscript is generally quite well written and includes most of the necessary information. I have several questions/comments, however.

a) How was the margin of noninferiority selected? Why 0.50 diopters? What evidence is there that that amount is clinically unimportant?

b) A key eligibility criterion listed in the table, but that probably should also be mentioned in the text is that all subjects must have bilateral myopia.

c) What has been done to insure that all surgeons are equally adept at performing both procedures? Has each surgeon performed a certain number satisfactorily?

d) What is the status of the trial?

e) The Discussion indicates that SMILE is reversible. If this procedure turns out to be worse than LASIK, can it be reversed and LASIK performed in the eye that received SMILE?

f) There are a couple of grammatical errors: on the top line of page 5, “are” is used twice, but is needed only once; on page 13, line 8, “proving” should be “prove”

g) Many of the ophthalmology clinical trials prefer to use the term “masked” rather than “blinded.” The authors might consider changing that in the various places it occurs in the text.