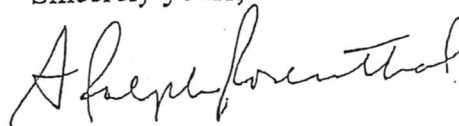


Although it is not required, you may decide to study the change in accommodation anyway; if you do this study, you should use the same subjects as those enrolled in the contrast sensitivity study. You should also keep in mind that in your proposed test, a subject with a multifocal cornea may accommodate, for several reasons: perhaps the infinity point provides more power than the near point, or perhaps the subject is simply accustomed to accommodating under near viewing conditions. Also, you are only proposing to measure two points (infinity and near). A more informative test would be a depth of focus test under cycloplegic conditions, which would measure acuity at many potential planes of focus. This test would have to be performed with an artificial pupil held close to the eye, because the cycloplegic pupil usually would be larger than the diameter ablated.

We continue to be concerned that your ablation is likely to have multifocal properties, which means that some light will be out of focus even at the best focal plane. It is possible that your proposed mesopic contrast sensitivity study will help resolve some of these concerns. Also, any claims you may wish to assert regarding advantages of multifocality may not be supported by your change in accommodation study.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,



A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic Devices

Office of Device Evaluation

Center for Devices and Radiological Health