correction of refractive error. The intended (theoretical) myopic ablation is flat (i.e., constant depth) over the central 2 mm, and decreases in depth in five linear segments of decreasing slope, with the five annular segments extending from diameters of 2 to 3 mm, 3 to 3.9 mm, 3.9 to 4.8 mm, 4.8 to 5.7 mm and 5.7 to 6.6 mm. The actual ablation is not flat in the central 2 mm, but shows a pronounced "central island" so that the ablation depth is up to 20% less at the center than at 2 mm diameter. The central 2 mm thus receives a hyperopic instead of a myopic correction. Outside the central 2 mm, the ablation produces a cornea with constantly changing curvature, i.e., constantly changing dioptric power. The amount of correction varies from overcorrection near 2 mm to undercorrection near 6.6 mm. Although the smoothing effect of the overlying corneal flap may modify this shape to some extent, it seems likely that the smoothing effects will be limited to distances no more than a few tenths of a mm from discontinuities in the ablation pattern. The predicted result of this type of ablation is a multifocal cornea, in which different portions of the cornea simultaneously focus portions of the "retinal" image at different positions in front of, on, or behind the retina. This multifocal property raises a number of safety and effectiveness issues that you will need to address:

a. An eye with a multifocal cornea generally will not have a well-defined best distance refraction. Uncorrected visual acuity as a function of distance may be nearly constant over an extended range, or it may be complex, with multiple peaks and troughs. Characterizing the refractive state may be difficult, requiring visual acuity assessments over a range of refractive corrections. Please provide a detailed description of the procedures you will use for measuring manifest refractions for postoperative subjects to take into account these concerns.

b. To document the clinical effects of this multifocal ablation, please propose substudies for mesopic contrast sensitivity (or low contrast acuity) with and without glare. The background luminance of the contrast sensitivity test should be reduced to less than 3 cd/m² (about 0.2 cd/m² preferred) and the ambient illumination should be even lower. The test targets may be either grating contrast sensitivity charts or low contrast letter acuity charts. In order to limit pupil constriction and maintain uniform glare conditions across the test chart, the glare source should be an array of two or more small spots symmetrically positioned around the chart. The glare source should be bright enough to significantly reduce the contrast sensitivity of young adult subjects with normal corneas and normal vision. If the above conditions cannot be implemented, the Brightness Acuity Test (BAT) may be used as an alternative glare source if the subject's pupil is dilated and the above brightness criterion is met. Control data may be obtained either from the preop LASIK subjects or (preferably) from a sample of normal subjects with the same age, gender and refractive error distributions as the postoperative test subjects. The subject population should be large enough to detect 0.1 log contrast sensitivity