

Optical modeling of a corneal inlay in real eyes to increase depth of focus: Optimum centration and residual defocus

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PURPOSE: To determine the optimum position to center a small-aperture corneal inlay and the effect of residual defocus in the surgical eye to maximize depth of focus.

SETTING: Laboratorio de Óptica, Universidad de Murcia, Murcia, Spain.

DESIGN: Cohort study.

METHODS: Personalized eye models were built using actual data (corneal topography, eye length, ocular aberrations, and eye alignment). A small aperture 1.6 mm in diameter was placed at the corneal plane in each model. The monochromatic and polychromatic Strehl ratios were calculated as a function of the pinhole position. Different residual defocus values were also incorporated into the models, and the through-focus Strehl ratios were calculated.

RESULTS: Sixteen eye models were built. For most subjects, the optimum location of the aperture for distance vision was close to the corneal reflex position. For a given optimized centration of the aperture, the best compromise of depth of focus was obtained when the eyes had some residual myopic defocus (range -0.75 to -1.00 diopter [D]). Strehl ratio values were over 0.1 for far distance, which led to visual acuities better than 20/20. The depth of focus was 2.50 D with a mean near visual acuity of Jaeger 1 or better.

CONCLUSIONS: In eyes with little astigmatism and aberrations, the optimum centration of the small aperture was near the corneal reflex position. To improve optical outcomes with the inlay, some small residual myopia and correction of corneal astigmatism might be required.

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At present, there are many optical solutions to improve near vision in presbyopic patients. These include the classic approaches of progressive-power spectacles or contact lenses and a variety of surgical procedures, including diffractive or refractive multifocal intraocular lenses and corneal refractive procedures to increase depth of focus. However, there is no perfect method of fully correcting presbyopia. Every technique has intrinsic pros and cons that should be carefully evaluated case by case before surgery or before choosing a prescription.

A relatively new technique is implantation of an intrastromal corneal inlay with a small aperture to increase depth of focus. Theoretically, a small-aperture pinhole placed into the cornea should produce an extended range of tolerance to defocus,

improving the quality of near vision. One small-aperture inlay is the Kamra (Acufocus, Inc.), a polyvinylidene fluoride ring that contains particles of carbon to make it opaque. It is 0.01 mm thick and has a central aperture of 1.6 mm and an outer diameter of 3.8 mm. The surface of the inlay is perforated with 25 μ m holes arranged in a random pattern to allow nutritional flow through the corneal tissue. It has a 1600 random-hole pattern with an average light transmission of 7.5%. The surgical implantation technique has been described.^{1,2} To minimize the impact of the reduction in light intensity reaching the retina, the technique has been applied monocularly to the nondominant eye. Recently, using an adaptive optics instrument^{3,4} in the laboratory, we found that this binocular configuration improves depth of focus. We measured

through-focus visual acuity monocularly and binocularly with pupil diameters of 4.0 mm and 1.6 mm.⁵

A potential problem of the small-aperture technique is decentration of the inlay. In practice, the surgeon attempts to align the inlay with the coaxially sighted corneal reflex.¹ This is probably the best way to ensure that the center of the aperture overlaps the patient's visual axis at the corneal plane. Nevertheless, it remains unclear whether another position would improve optical quality with respect to centration of the corneal reflex. In addition, it would be of practical use to know the maximum amount of decentration that would allow good image quality and thus good vision. Another important issue is to know the through-focus image quality in the eye with the inlay in the presence of residual spherocylindrical refractive errors or higher-order aberrations (HOAs).

We assessed these 2 optical problems (centration and combination with refractive errors) using a set of individualized eye models to realistically simulate the retinal image quality when a small aperture inlay was virtually implanted.

SUBJECTS AND METHODS

In this study of normal subjects, all eyes had a monocular corrected distance visual acuity of 20/25 or better and were nearly emmetropic (ie, ± 2.00 diopters (D) or less of mean defocus and 1.5 D or less of astigmatism on subjective refraction). No eye had a history of ocular surgery, and all had a complete ophthalmologic examination to rule out disease or abnormality in the ocular media. All measurements were performed under natural viewing conditions; that is, no eye required pharmacologic dilation to reach a pupil diameter of 5.0 mm. All participants provided informed consent before the measurements. The study protocol adhered to the guidelines of the Declaration of Helsinki.

Optical Measurements

The same protocol was used to measure the optical and geometric properties of each subject's eyes. The protocol included corneal topography and aberrations, axial length (AL), anterior chamber depth (ACD), total eye aberrations, and ocular alignment (angle κ). The corneal aberrations

were estimated with a ray-tracing procedure⁶ from the shape of the cornea measured with a clinical topographer (Atlas, Carl Zeiss Meditec AG). The AL and ACD were assessed using a low-coherence interferometry instrument (IOLMaster, Carl Zeiss Meditec AG). The last 2 series of measurements used purpose-designed instrumentation. A Hartmann-Shack wavefront sensor built in the Laboratorio de Óptica, Universidad de Murcia,⁷ was used to measure aberrations in the total eye. It was designed to perform clinical measurements in an easy and comfortable way for untrained subjects. The device includes a super-luminescent diode emitting at 780 nm to illuminate the retina and an array of microlenses (200 μm pitch with an effective focal length of 8.05 mm). The procedure to measure the angle κ is similar to the one described previously.⁸ The angle κ is defined as the angular distance in the object space between the pupillary axis (the line perpendicular to the cornea that intersects the center of the entrance pupil) and the principal line of sight. Briefly, an extended source of light (a semicircular array of infrared light-emitting diodes) coaligned with a telecentric objective coupled to a charge-coupled device camera generates a corneal reflex that is registered in an image of the anterior segment of the eye (iris, pupil, and reflection). Digital analysis of this image shows the position of the corneal reflex (the center of the semicircular reflex) with respect to the pupil center (this is the reference to center the corneal small aperture inlay) and angle κ , calculated as the angle subtended by the particular point of the illuminating source overlapping the center of the pupil.

Optical Modeling and Calculations

Using the data collected for each subject, personalized models were built.^{9,10} The anterior corneal surface geometry obtained from topography was used as the first surface of a computer model based on ray-tracing software (Zemax Corp.). The exact surface, including all HOAs, was incorporated into the model. Initially, the Le Grand crystalline lens model¹¹ was placed at a distance from the cornea according to the measured ACD and the image plane (retina) was placed at the particular AL in each eye. The common axis of the model was the line of sight. The value of angle κ was also included by tilting both surfaces according to the measured values (commonly on the temporal direction). The refractive index was taken to be 1.3375 for the aqueous and 1.376 for the vitreous. Each personalized eye model was optimized by changing the curvature and asphericity of the lens to match the values of spherical aberration and defocus measured with the Hartmann-Shack wavefront sensor in the complete eye. The whole series of calculations were first performed in monochromatic light (wavelength 555 nm).

Two studies were performed using the resulting models. First, the optical quality of the eye as a function of the inlay position was predicted. A circular aperture of 1.6 mm diameter was placed at the corneal plane, simulating the small-aperture inlay. This aperture could be moved to any position in the corneal plane. For these simulations, the AL of each model was modified to obtain the best-focus position that minimized the spherical equivalent in the subjects, all of whom were considered emmetropic. Figure 1 shows a schematic of 1 eye model with the inlay centered and with the inlay decentered. An image-quality metric, the Strehl ratio, was calculated as the quotient of the peak value of the eye's point-spread function (PSF) and that corresponding to a perfect diffraction-limited system

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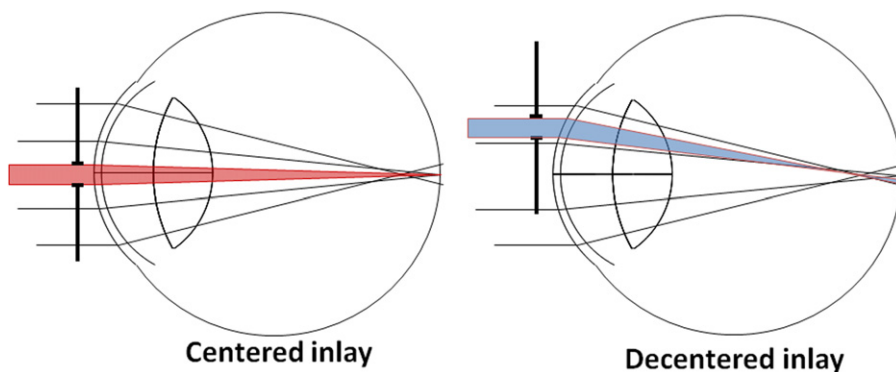


Figure 1. An eye model with a centered corneal inlay and a decentered corneal inlay. The parameters for the model include corneal aberrations, total eye spherical aberration, angle κ , and interocular distances.

with the same pupil diameter. The Strehl ratio was determined as a function of inlay decentration by moving the aperture every 0.25 mm in a 2.0 mm \times 2.0 mm grid as long as overlapping with a 5.0 mm pupil diameter did not generate vignetting. The actual pupil diameter of the participants in the study was larger than this value.

Polychromatic calculations of the Strehl ratio were also performed. The chromatic dispersion of the ocular medium was incorporated into the models from values in the literature.¹² The ocular PSF was computed for 5 wavelengths covering the visible spectrum (ie, 470 nm, 510 nm, 550 nm, 610 nm, 650 nm). The polychromatic Strehl ratio was calculated as the peak of the mean PSF weighted by the spectral sensitivity of the eye; the weights were 0.091, 0.503, 1.000, 0.503, 0.107, corresponding with the above-mentioned wavelengths. The calculations considered longitudinal chromatic aberration and transverse chromatic aberration induced by the angle κ in the eye and by the pupil position. A 2-dimensional map of the Strehl ratio values versus aperture decentration was obtained for each subject, and the best Strehl ratio position with respect to the pupil center was

determined for monochromatic (550 nm) and polychromatic calculations. This optimum centration position was compared later with the position of the corneal reflex taken with respect to the pupil center. Figure 2 shows an example of this procedure (monochromatic case) for 3 subjects.

A second series of simulations were performed to study the effect of residual defocus on the eye with the inlay. The emmetropic models were used again with the inlay now placed at the position providing the best Strehl ratio (optimum centration). Then, a simulated spectacle was placed in front of the eye, adding defocus in 0.25 D steps from -0.50 D to 1.50 D. For each defocus value, the Strehl ratio was calculated as a function of the viewing distance, from infinity to 333 mm from the eye (3.00 D object vergence). These calculations were performed in monochromatic light. To define the optimum range, a Strehl ratio of 0.05 served as the threshold value. The value was chosen to serve as a reference because of its association with a Jaeger (J) 1 visual acuity value in photopic measurements and of J3 under mesopic conditions. This value was determined experimentally in a previous study using an adaptive optics

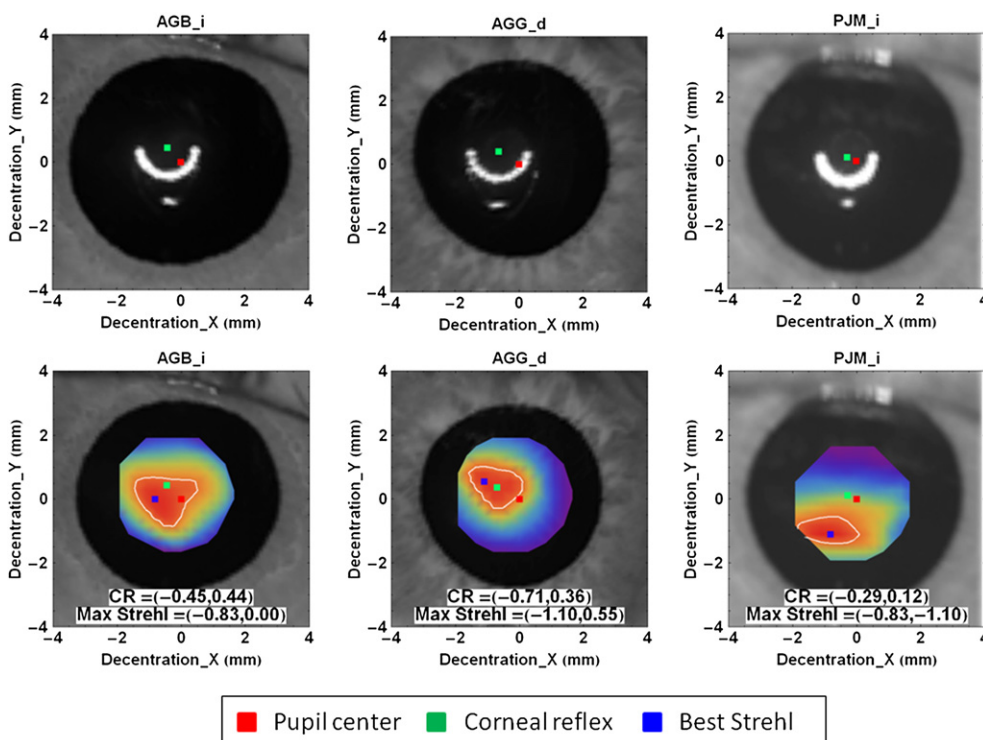


Figure 2. Upper row: Purkinje images in 3 eyes. The corneal reflex (CR) is shown as a semicircular light pattern with its center marked with a green square. The red squares show the pupil center. Lower row: The same images but with the Strehl ratio as a function of the pinhole position and superimposed over the image. The blue squares show the position of the Strehl ratio maximum value. The white circles indicate the region that decays down to 10% of the maximum value of the Strehl ratio peak.

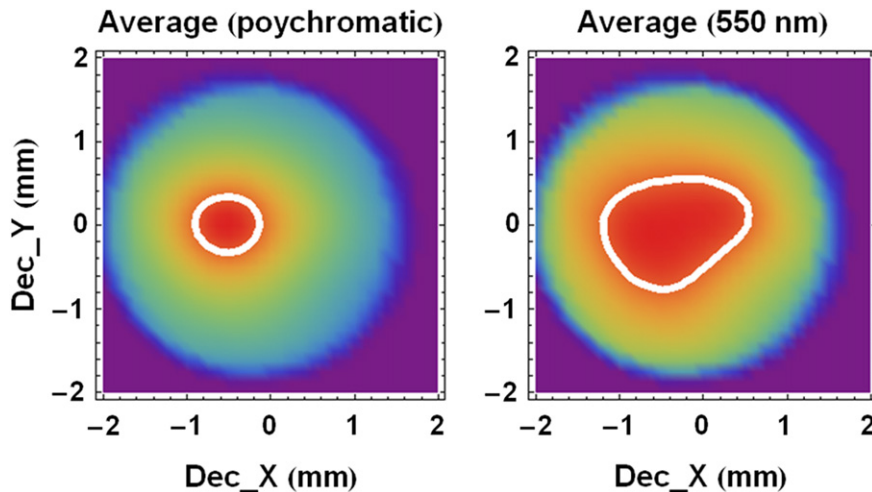


Figure 3. The mean Strehl ratio as a function of the inlay decentration for the 16 eye models (*left panel* = monochromatic calculations; *right panel* = polychromatic calculations). The white lines indicate the limit of 10% variation from the maximum Strehl ratio value (Dec = decentration).

visual simulator.³ In addition, to ensure that the retinal image quality for distance objects was not compromised, a security threshold doubling this value was considered (ie, Strehl ratio = 0.10).

RESULTS

The study enrolled 16 subjects. The mean age of the subjects was 58 years \pm 7 (SD) (range 47 to 67 years).

Best Centration Position of the Inlay

Figure 3 shows the mean Strehl ratio as a function of inlay decentration in the 16 eye models. The white line indicates the limit of 10% variation from the maximum Strehl ratio value in each plot. These variations were more restricted in the polychromatic case, covering an approximately circular area of 0.90 mm diameter and centered 0.43 mm nasal from the pupil center.

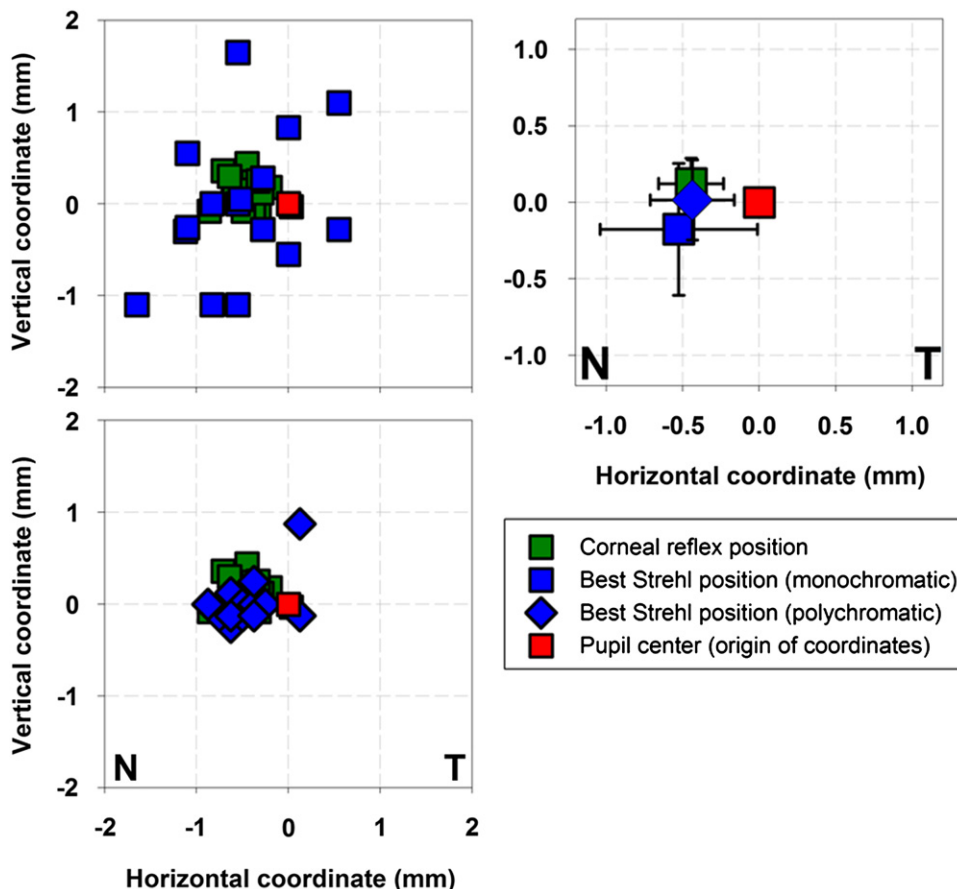


Figure 4. Positions of the corneal reflex and best Strehl ratio with respect to the pupil center position for the 16 subjects in the study (*left panel*) and the mean data (*right panel*) (N = nasal; T = temporal).

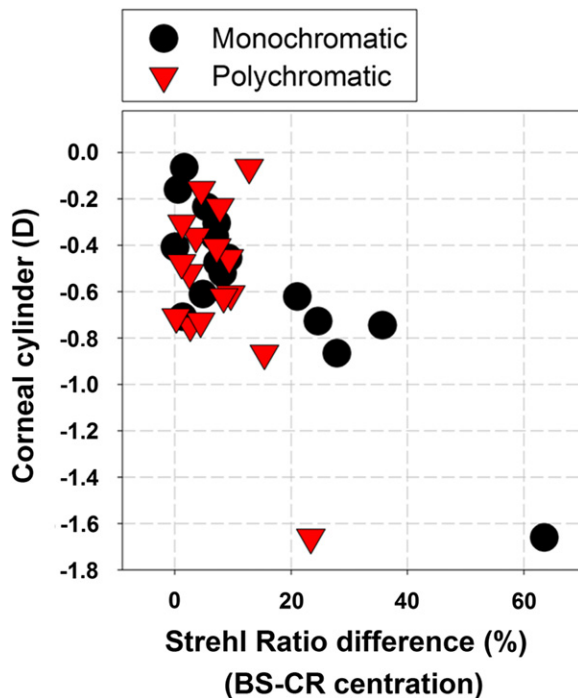


Figure 5. Astigmatism values as a function of the Strehl ratio difference for monochromatic and polychromatic calculations (BS = best Strehl ratio; CR = corneal reflex).

Figure 4 shows the position of the best Strehl ratio and the corneal reflex with respect to the pupil center for the 16 eyes in the study. The mean horizontal position of the corneal reflex was 0.45 ± 0.21 mm nasal from the pupil center. The mean position of the optimum Strehl ratio value was at 0.52 ± 0.60 mm nasal for the monochromatic case and 0.44 ± 0.27 mm nasal for the polychromatic case. Vertically, the corneal reflex was located a mean of 0.12 ± 0.17 mm from the pupil center, while the best Strehl position was at a mean of -0.18 ± 0.43 mm (monochromatic) and 0.01 ± 0.26 mm (polychromatic).

The differences in optical quality when centering at the best optical position with respect to centering at the corneal reflex were estimated in terms of the Strehl ratio fraction of improvement (%) (best Strehl ratio – Strehl ratio (at CR position)/best Strehl ratio). For the monochromatic case, in general, subjects with a clear difference between the Strehl ratio from the peak value to the value obtained at the corneal reflex had a higher degree of corneal astigmatism (Figure 5). However, when chromatic aberrations were taken into consideration this tendency was less, although it was still present in the 2 subjects with the highest cylinder.

Optimum Residual Defocus

Figure 6 shows the through-focus Strehl ratio curves for the 16 subjects (ie, monochromatic Strehl ratio

versus the object distance to the eye in diopters from infinity to 333 mm). Each graph in the figure represents the same calculation but with an additional value of residual defocus incorporated (spectacle placed in front of the eye with the dioptric power changed for each simulation). When a residual defocus between -0.75 D and -1.00 D (myopic defocus) was present in the eye, optical quality for distance objects remained well above 0.1 Strehl ratio; for near objects, it just reached the 0.05 Strehl ratio value, ensuring an acceptable range of optical quality for a wide range of object distances. In the case of the purely emmetropic eye, the optical quality was practically limited by diffraction for far vision, but reached the 0.05 Strehl ratio value at approximately 2.00 D.

DISCUSSION

The coaxially sighted corneal reflex provides an easy reference to center some procedures, especially those performed over the corneal surface. Because of the angle κ of the eye, the corneal reflex is usually located on the nasal side with respect to the pupil center^{11,13} unless strong axial myopia is present. Strictly speaking, the position of the corneal reflex does not mark the intersection of the visual axis with the cornea; however, it can be considered a good approximation. This is because the theoretic concept that defines the visual axis (nodal points) is elusive and difficult to systematically localize in the real eye. For this reason, our intention was to determine whether there is a location over the cornea on which a 1.6 mm diameter inlay can be centered to provide the best optical quality. In addition, we wanted to determine the possible tolerance to potential inlay decentrations in terms of retinal image quality metrics.

The results of the simulations suggest that most subjects would obtain only a modest benefit from the most accurate centration. In practical terms, given the small difference between that position and the corneal reflex location, which is smaller when chromatic aberrations are considered, the surgeon would find it difficult to center the inlay with the required accuracy. This reinforces the clinical idea that correct centration of the inlay should be performed around the corneal reflex. However, when only monochromatic light was used in the calculations, 5 of the 16 subjects had a significant difference in the Strehl ratio that was also associated with a more peripheral best Strehl ratio centration position. The reason seems to be the presence of corneal astigmatism. Those 5 subjects had more corneal astigmatism than the mean of the rest of the subjects. Some additional simulations were performed by adding astigmatism to 1 of the models for which the best Strehl ratio position and the corneal

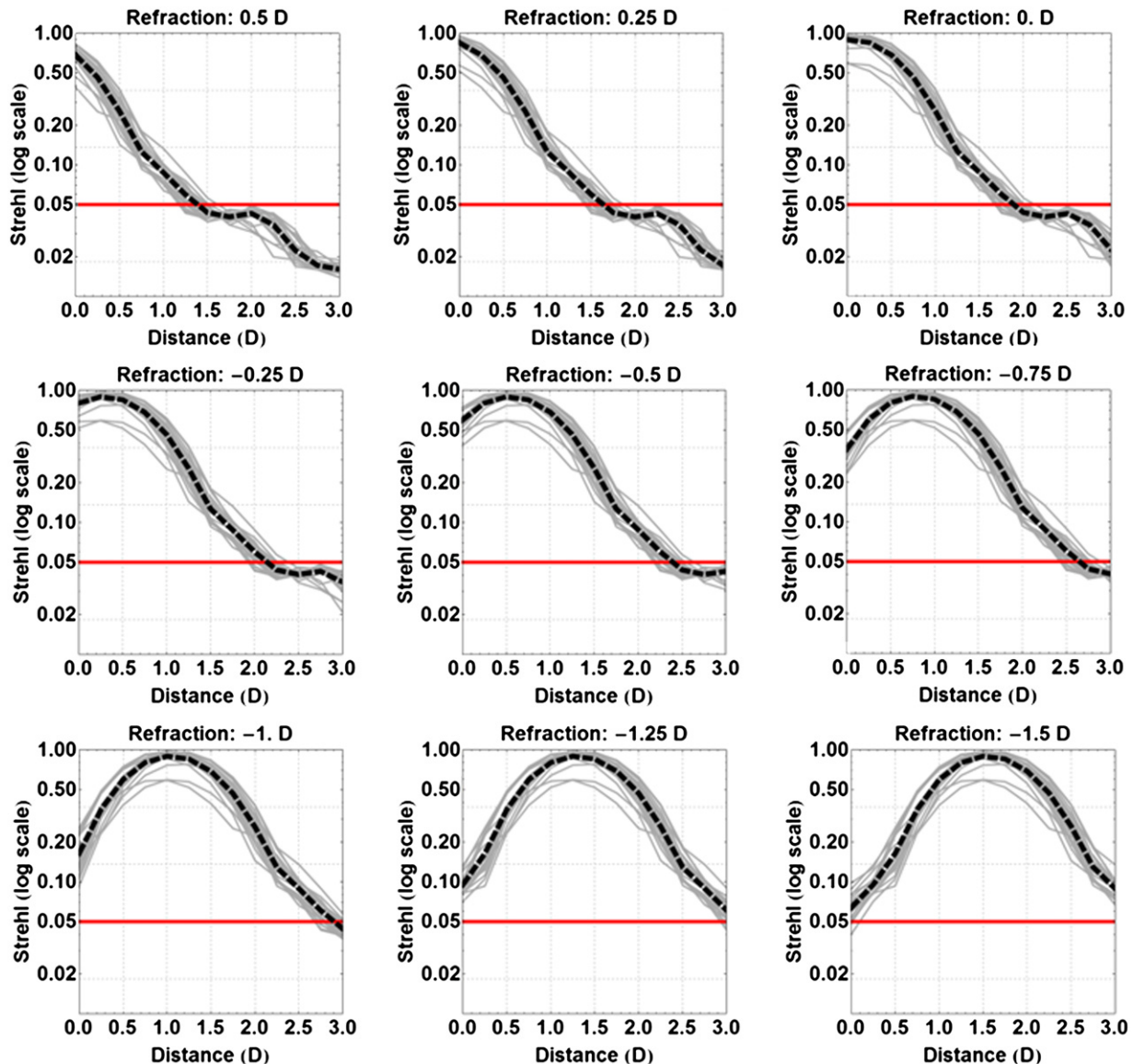


Figure 6. Strehl ratio as a function of the object distance for the 16 eye models when different amounts of residual defocus were added. The thick dashed line shows the mean data. The red line shows the Strehl ratio value of 0.05 as a reference.

reflex were nearly the same. [Figure 7](#) shows how the best Strehl ratio position changed toward peripheral locations when the amount of cylinder (at 0 degrees) increased. The association between astigmatism and the position of the best optical quality position was obvious. Although this tendency was greatly attenuated when chromatic aberrations were taken into account, it was still present in the 2 subjects with the highest amount of astigmatism. Clinically, this might indicate that the optimum result with the small-aperture corneal inlay would be in eyes with a modest amount of preexisting astigmatism and that when this is not the case, the preexisting astigmatism should be corrected to less than 1.00 D. Otherwise, the optimum location for the center of the pinhole might be too far from

the corneal reflex and the outcome of the technique (centered on the corneal reflex) would not be optimum. It is also possible that the presence of elevated corneal aberrations could affect the optimum centration.

Another important issue is the tolerance to decentration. The tolerance is clearly less when white light is considered in the calculations because of the increased impact of lateral chromatic aberration. Decentration from the optimum position of approximately 0.5 mm could significantly reduce the retinal image quality and overall vision.

Regarding the best residual defocus to increase depth of focus in eyes with the inlay, an uncorrected myopic eye would benefit from an extended depth of

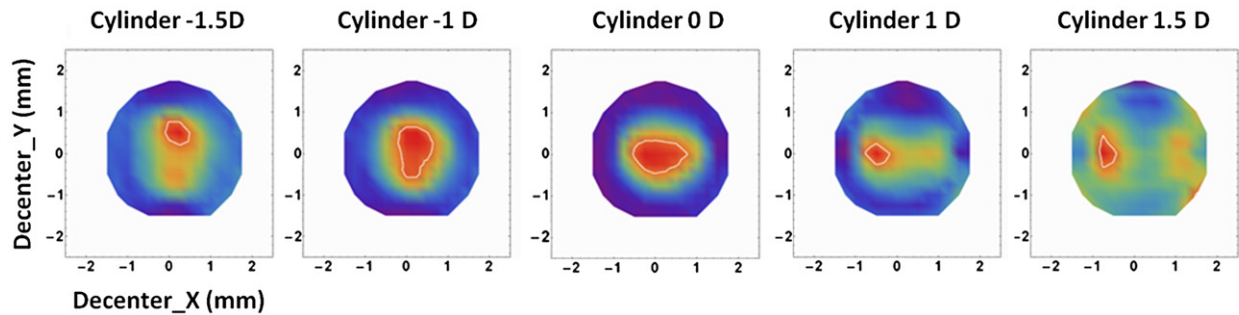


Figure 7. Strehl ratio as a function of the pinhole center position for 1 of the subjects participating in the study. For this particular subject, astigmatism was added at 0 degree, showing how the Strehl ratio peak moved from a relatively centered position to more peripheral places as the magnitude of astigmatism increased.

focus curve with respect to emmetropic eyes and hyperopic eyes. Near distance in hyperopia is compensated for at some distance by the residual myopia in the eye and generates a shift of the through-focus curve, which decreases optical quality for distance objects while improving it for near objects. Although this seems to be a well-known fact, it was still not clear how much myopia would be acceptable under far vision conditions for an eye that had implantation of a 1.6 mm corneal inlay. We quantified this by using a 0.05 Strehl ratio value as the acceptable threshold for near vision at 3.0 D (justified by the correlation with J1 acuity at photopic conditions⁵), and we increased twice this value (0.10 Strehl ratio) for far vision. Figure 6 shows that these 2 conditions could be simultaneously satisfied when the eye has a residual amount of myopia between -0.75 D and -1.00 D. Uncorrected myopic eyes with similar values might have a greater depth of focus than emmetropic eyes. However, no hyperopia should be left uncorrected because it would decrease the range of tolerance to defocus. With -0.75 D of myopia, the mean depth of focus was 2.50 D with a mean near visual acuity of J1 or better. In a perfectly emmetropic eye, without the addition of myopic defocus, the depth of focus decreased to approximately 1.75 D.

There are limitations of the modeling. Our optical modeling approach was powerful and realistic because it used actual data from the eyes of subjects. The predicted optical performance was in generally good agreement with the available clinical data in patients who have had implantation of the inlay. However, some limitations might be overcome in future studies. The inlay has an external diameter of 3.2 mm. In many cases, the natural pupil of the patient will be larger, in which case the optical system would have an effective annular pupil that produces different retinal image quality features. In this study, we concentrated on an eye with a single aperture of 1.6 mm on the corneal plane and assumed that the

eye's pupil would be smaller than 3.2 mm. For larger pupils, the results of the analysis could be different. A realistic analysis using annular pupils could also be performed.

In conclusion, the optical effect on retinal image quality of a small aperture to increase depth of focus was accurately evaluated using data from real eyes. This inlay approach may provide a simple and effective solution to improve near vision. In eyes with small amounts of astigmatism and aberrations, the optimum centration of the aperture was near the corneal reflex position. White-light calculations indicated that lateral chromatic aberration could be the main deleterious effect in terms of retinal image quality when the inlay is decentered. Cylinder values greater than 1.00 D can generate nonoptimized results. In the absence of astigmatism, the current strategy of corneal reflex centration seems adequate. For improved optical outcomes, some small residual myopia and correction of corneal astigmatism might be required. Hyperopic patients should not be selected. Residual myopia of approximately -0.75 to -1.00 D would further increase depth of focus without compromising distance vision. The results provide a better understanding of the optics behind the small-aperture corneal inlay, and we hope this will stimulate new clinical studies with the goal of obtaining better solutions and better quality of vision for presbyopic individuals.

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