A New Intraocular Lens Design to Reduce Spherical Aberration of Pseudophakic Eyes

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ABSTRACT

PURPOSE: The aim of this study was to design and evaluate in the laboratory a new intraocular lens (IOL) intended to provide superior ocular optical quality by reducing spherical aberration.

METHODS: Corneal topography measurements were performed on 71 cataract patients using an Orbscan I. The measured corneal surface shapes were used to determine the wavefront aberration of each cornea. A model cornea was then designed to reproduce the measured average spherical aberration. This model cornea was used to design IOLs having a fixed amount of negative spherical aberration that partially compensates for the average positive spherical aberration of the cornea. Theoretical and physical eye models were used to assess the expected improvement in optical quality of an eye implanted with this lens.

RESULTS: Measurements of optical quality provided evidence that if this modified prolate IOL was centered within 0.4 mm and tilted less than 7 degrees, it would exceed the optical performance of a conventional spherical IOL. This improvement occurred without an apparent loss in depth of focus.

CONCLUSION: A new IOL with a prolate anterior surface, designed to partially compensate for the average spherical aberration of the cornea, is intended to improve the ocular optical quality of pseudophakic patients. [*J Refract Surg* 2002;18: 683-691]

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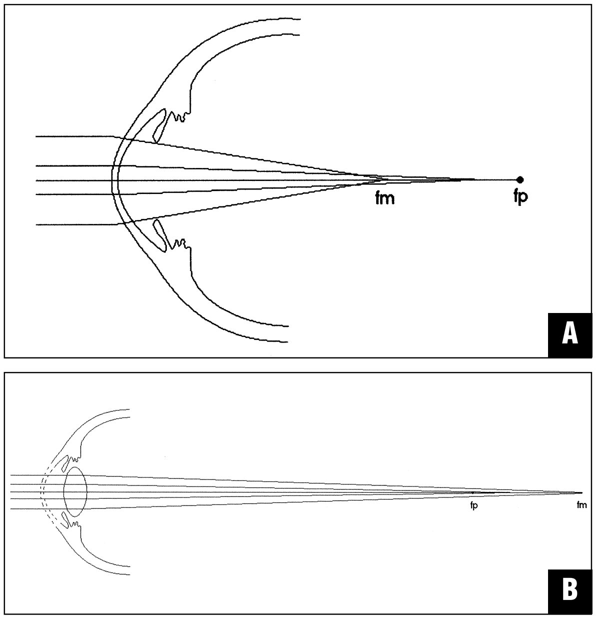
The optical quality of individual intraocular lenses (IOLs) has been analyzed[1,2] and standardized[3], but little research has been directed toward improvement of the optical interaction between IOLs and the cornea. Recent studies of pseudophakic eyes have shown that patients implanted with spherical IOLs have a spatial vision[4] and retinal image quality that is comparable with a healthy control population of the same age (Or H, Soylu T. The enhancement of contrast sensitivity in cataract surgery patients with a preoperative visual acuity of 0.4 to 0.7 and its comparison with the normals. International Congress of Ophthalmology, Sydney, Australia, April 21-25, 2002). This occurs despite the fact that the aging human crystalline lens is optically inferior to an IOL. The explanation for these observations may lie in the optical aberrations of the human cornea and spherical IOLs.

In recent years, significant technological advances and the quest to improve the quality of vision after refractive surgery have stimulated a renewed interest in the study of the aberrations of the normal human eye and the altered human eye after refractive and/or cataract surgery. The average positive spherical aberration introduced by the cornea in the young human eye is partially corrected by compensating negative spherical aberration introduced by the crystalline lens.[5-8] Major changes that occur in the lens with age, such as hardening of the nucleus[9], changes in the internal refractive index gradient[10] and the equivalent refractive index[11], and changes in lens shape[11] also cause the spherical aberration of the lens to increase with age. As these structural changes occur, the aberration compensation is gradually lost, leading to an increase in total ocular aberrations and a corresponding loss in optical[12] and visual quality[13] with age. An increase in ocular aberrations has been shown to both reduce scotopic contrast sensitivity[14,15] and increase optical side effects such as glare and haloes.



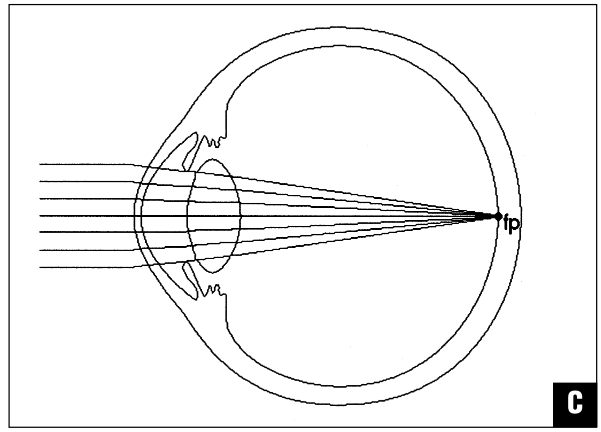


Figure 1. Illustration of ocular spherical aberration. The symbol fp signifies the paraxial focal length (the focal length of on-axis rays) while fm signifies the marginal (peripheral) focal length. **A)** The average cornea has positive spherical aberration. The rays in the periphery are focused in front of the rays near the center (paraxial) of the cornea. **B)** The young healthy crystalline lens exhibits negative spherical aberration. The rays in the periphery are focused behind the rays near the center. Note that the cornea in this picture does not provide any focal power (for simplicity of illustration). **C)** In the young healthy eye the positive spherical aberration of the cornea is compensated by the negative spherical aberration of the lens to yield a system with little or no spherical aberration. All rays come to a common focus at a single focal point (fp).

This paper demonstrates that it is possible to use knowledge of the spherical aberration of the average cornea from wavefront analysis to design IOLs that will reduce ocular aberrations and thereby improve the optical quality of the pseudophakic eye. Because cataract surgery is predominantly performed in older eyes and uncertainty exists in the literature as to whether corneal spherical aberration changes with age (Oshika et al[16] have shown no change; Guirao et al[17] have shown that it increases slightly with age), it was necessary in this study to develop a corneal model that represented the corneas of the cataract patient population. This corneal model was then used to design a spherical, aberration-correcting IOL designed to improve optical quality when combined with the model cornea.

Spherical Aberration of the Eye and IOLs

Higher order wavefront aberrations can be divided into a number of different types: astigmatism, coma, trefoil, and spherical aberration, each of which has its own characteristic effect on the image quality of an optical system. Of these types of aberrations, spherical aberration is the only on-axis, rotationally symmetric wavefront aberration, for which the origins in the eye are well understood.

The spherical aberration contributed by the corneal surface is well understood in terms of the shape of the corneal surfaces. In particular, the cornea in most optical eye models is described as a rotationally symmetric conicoid specified by two descriptors; the radius of curvature (R) and the conic constant (Q) of the surface (see Equation 1 where r is the radial distance from the vertex of the surface). The type of conicoid is determined by the value of the conic constant. Keily et al[18] have published population mean values for the radius of curvature and conic constant of the anterior corneal surface of 7.72 ± 0.27 mm and -0.26 ± 0.18; respectively. Based on this measured average value for the conic constant of the average anterior cornea, we know that it is a prolate ellipsoid surface (steeper in the center and flatter in the periphery) that contributes positive spherical aberration (Fig 1A). The average corneal spherical aberration measured by both Oshika et al[16] and Guirao et al[17] were both positive, meaning that rays entering the periphery of the pupil are focused in front of rays entering near the center of the pupil.

$$z = \frac{(1/R)r^2}{1 + \sqrt{1 - (Q+1)(1/R)^2(r^2)}} \qquad (1)$$

The lenticular spherical aberration has been determined by Glasser and Campbell[19] by in vitro measurements of human lenses of varying age. They showed that the spherical aberration of the young healthy lens is negative and that it increases steadily throughout life, becoming positive at around the age of 40. In a separate study, Smith et al[8] measured the spherical aberration of both the anterior corneal surface and the whole eye (in vivo) in order to estimate the lenticular contribution. By varying the radius of curvature and conic constant of the posterior corneal surface to determine a range of possible lenticular spherical aberration values, Smith et al confirmed that the spherical aberration of the relaxed non-cataractous lens is negative (cf. Fig 1B). Based on the results of these experiments, it is known that the spherical aberration of the cornea and the lens partially compensate for each other to reduce the spherical aberration of the eye before age 40 (Fig 1C).

An elegant analysis of the effects of different lens shapes on ocular image quality of PMMA lenses was performed by Atchison.[20] Because standard spherical IOLs have one or two spherical surfaces, they contribute positive spherical aberration[21] to the already positive spherical aberration of the cornea, thereby increasing the total positive ocular spherical aberration of the average patient after cataract extraction. In this paper, a new foldable IOL design is proposed that provides negative spherical aberration similar to the young crystalline lens. Because spherical aberration is a rotationally symmetric aberration, the new lens design is also rotationally symmetric about the optical axis.

PATIENTS AND METHODS

The study population included 71 eyes of 71 patients. These subjects were selected from cataract patients to be treated at St. Erik's Eye Hospital in Stockholm, Sweden. Their ages ranged from 35 to 94 years, with a mean of 74 years. All patients were caucasian and the ratio of males to females was 23 to 48.

On the day of their surgery, corneal topography was performed on all patients using the Orbscan I (Bausch & Lomb, Salt Lake City, UT), a scanning slit-based, corneal and anterior segment topographer/tomographer. The corneal elevation and position in the pupil (relative to the line of sight) were used as the first input for determining the optical properties of the cornea. Although the Orbscan provided elevation data for both the front and back surfaces of the cornea, it was decided due to previously reported inaccuracies in the back surface information[22], to use only the front surface data to develop a one-surface cornea model. This one-surface model replaced the surfaces of the cornea and aqueous with one effective medium with the keratometric refractive index of 1.3375.

The calculation of the wavefront aberrations of the single-surface cornea model of each patient was performed using the computational method previously described by Guirao and Artal.[23] The surface was described by fitting the elevation height data with a series of Zernike polynomials using Gram-Schmidt orthogonalization.[24] These polynomials are commonly used to describe wavefront aberrations in the field of optics. The first 36 (up to 7th order) of these polynomials were used in the fit. Knowing the precise shape of the anterior corneal surface, it was possible to determine the wavefront aberration contributed by this surface using a ray trace procedure. Like the surface shape, the wavefront aberration was represented as a sum of Zernike polynomials. Surface fits and aberration calculations were performed for a 6-mm aperture diameter, approximating the pupil diameter under mesopic and scotopic (but not photopic) conditions.

For every patient, the radius of curvature (R) and conic constant (Q) value of the anterior corneal surface were determined from the Zernike coefficients describing this surface, as was the spherical aberration of the anterior corneal surface. The radius of curvature of this model cornea was the average radius determined from the Zernike fit data; the conic constant was tuned to yield a spherical aberration (fourth-order) that was equal to the average for the 71 patients.

The resulting model cornea was used in an eye model to design a new IOL that compensates for the average corneal spherical aberration measured in the cataract population investigated. Using the optical design package OSLO SIX, an equi-biconvex lens made from high refractive index polysiloxane was placed 4.5 mm behind the anterior corneal surface. This anterior chamber depth was chosen based on measurements of IOL positioning in pseudophakic eyes[25-28]; the refractive indices used in the eye model were consistent with accepted values for the refractive indices of the ocular optical media at 546 nm. The anterior surface of the lens was then modified in such a way that the optical path lengths of all on-axis rays within the design aperture were the same. Lenses with powers of 5 to 30 diopters (D) (in 1-D steps between 5 and 10 D and 0.50-D steps between 10 and 30 D) were designed in this way, such that every lens power contributed the same amount of negative spherical aberration to the eye.

Knowing the corneal spherical aberration of the individual patients and the average spherical aberration of the population, it was possible to estimate if a lens with a single anterior contour that was designed to compensate for the average spherical aberration would provide reduced spherical

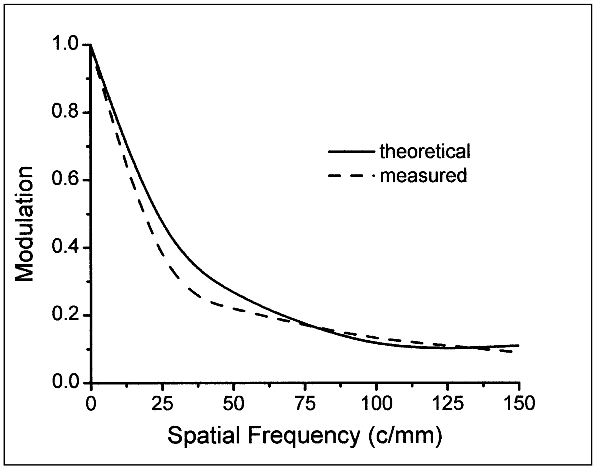


Figure 2. The theoretical and measured through-frequency modulation transfer function (MTF) of the physical cornea model (for a 5-mm pupil diameter).

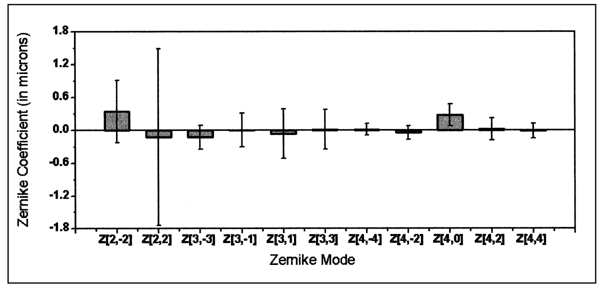


Figure 3. Average values of Zernike aberration coefficients for the cornea for a 6-mm aperture diameter (in microns). The error bars are representative of ± 1 standard deviation.

aberration in each of the individual patients. An estimate of the total ocular spherical aberration can be derived from the sum of the corneal aberration and the aberration of the IOL. Furthermore, to provide a reference, the new lenses were compared with an equi-biconvex lens of the same power, made from the same material but having spherical surfaces (a spherical lens). The spherical aberration of 22-D models of both lenses were calculated in a pseudophakic eye model using OSLO SIX for a 6-mm aperture at the cornea ($SA_{lens} = SA_{eye} - SA_{cornea}$). A simple eye model was used to determine how many of the 71 individual patients would have reduced ocular spherical aberration (absolute value of the Z[4,0] coefficient) if implanted with the new lens, as opposed to a spherical lens ($SA_{eye} = SA_{individual\ cornea} + SA_{lens}$).

The calculation technique described above is a simplification of what happens in the actual pseudophakic eye. A more accurate method for estimating whether each patient would benefit from the implantation of a new lens would be to use the precise shape of the individual's cornea (the Zernike polynomial description described previously) along with their axial eye length (measured with A-scan ultrasound) and the correct lens power (calculated using the SRK/T formula with a refractive goal of emmetropia) to construct individual pseudophakic eye models. The spherical aberration of each individual eye model (implanted with either a new lens of the correct power or a spherical lens of the correct power) was calculated using OSLO SIX. Individual eye models were constructed for 25 random patients plus the two subjects with the highest and lowest (emmetropic) lens powers and the three subjects with the highest and lowest corneal spherical aberration (35 patients in total, 49% of the population).

Lenses designed (as described) were manufactured and a physical eye model was used to test their optical properties. The cornea in this physical model was designed to simulate the on-axis optical performance of the average cornea model for an aperture size of 6-mm. (Figure 2 shows the theoretical and measured through-frequency modulation transfer functions (MTFs) for a 5-mm pupil. The manufactured physical cornea model displays similar optical quality to the theoretical average cornea model.) The modified prolate (conicoid with negative Q-values + additional terms) lenses were measured in this model and compared with the same measurements for a lens of the same power and made of the same material, but having spherical surfaces. In addition, the through-focus and through-frequency modulation transfer functions were measured for different conditions of tilt and decentration.

RESULTS

Figure 3 presents the average and standard deviation of each Zernike aberration term (2nd, 3rd and 4th order polynomials) calculated for a 6-mm diameter aperture. These values are ordered according to the recently standardized double-index format for Zernike coefficients.[29] There are three aberrations that are significantly different from zero on average in our population: astigmatism (Z[2,-2]), trefoil (Z[3,-3]), and fourth-order spherical aberration (Z[4,0]). Spherical aberration is on average the dominant higher order (3rd or 4th order) aberration in the cornea of the measured cataract population (Z[4,0] = 0.27 ± 0.02 µm). Furthermore, because spherical aberration is the only rotationally symmetric aberration, it is the only aberration that can be corrected with a rotationally symmetric IOL.

Based on these results, the model eye used in designing the prolate-surfaced IOL incorporates a model cornea that reproduces Z(4,0) and the average refractive power of the corneas measured for a 6-mm aperture diameter. The model eye consists of the design cornea, plus an intraocular lens 4.5 mm behind the anterior corneal surface. The new IOLs are designed to balance the spherical aberration of the model cornea in the optical system of the model eye. As a result these IOLs have an anterior surface that is modified prolate (MP) described by Equation 2. This equation is very similar to Equation 1, but is not a simple conicoid (ad and ae are higher order polynomial terms describing the surface shape, while R is the radius of curvature, Q is the conic constant of the surface, and r is the radial distance from the vertex of the surface). Each lens that is designed in this way contributes negative spherical aberration to the cornea-lens system. The specific values of the parameters vary with the power of the lens.

$$z = \frac{(1/R)r^2}{1 + \sqrt{1 - (Q+1)(1/R)^2(r^2)}} + \mathbf{ad}r^4 + \mathbf{ae}r^6 \qquad (2)$$

Figure 4 shows a histogram of the distribution of the spherical aberration (Z[4,0]) values measured in the population studied. The Z(4,0) coefficient for the 22-D spherical lens was determined to be 0.178 mm while the Z(4,0) coefficient for the 22-D modified prolate lens was -0.27 mm. The line labeled modified prolate benefit in Figure 4 represents the dividing line where patients have reduced ocular spherical aberration with the modified prolate lens. A reduction in the total ocular spherical aberration is estimated to occur in 64 of the 71 patients (90% of the population).

Figure 5 shows the spherical aberration of the estimate calculated using the simple eye model plotted against the spherical aberration calculated using the eye model constructed with anatomical data (for models containing both the spherical lenses [Fig 5A] and the modified prolate lenses [Fig 5B]). Implanting a spherical lens with a high power (higher than 22 D) results in a higher overall ocular spherical aberration while a low power lens contributes lower values of spherical aberration, a fact not considered in the simple eye model. In contrast, the modified prolate lens has the same spherical aberration for every lens power. This contributes to the fact that the spherical lens estimates are less correlated with the modeled values than the modified prolate lens estimates. For the 35 cases investigated one patient (implanted with a low power lens) went from having higher absolute values of ocular spherical aberration with a spherical lens than with a modified prolate lens, and in another patient (implanted with a high power lens) the opposite occurred. The fact that the spherical aberration values in the anatomical eye model and the simple eye models are so closely correlated and that in the 35 cases investigated only two patients had different outcomes with respect to whether the modified prolate lens would reduce ocular spherical aberration makes us confident that the results found with the simple eye model are a reasonable prediction of what would occur in a cataract population.

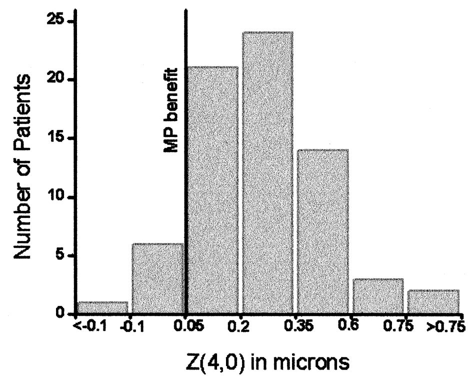


Figure 4. The distribution of the fourth-order corneal spherical aberration values (Z[4,0]) for a 6-mm aperture diameter (at the cornea) in the 71 cataract patients. Using the simple eye model ($SA_{eye} = SA_{individual\ cornea} + SA_{lens}$) it was determined whether patients would have reduced ocular spherical aberration if a modified prolate lens was implanted. The line labeled modified prolate benefit is the dividing line for this improvement—patients with greater values of corneal spherical aberration will have reduced ocular spherical aberration.

The optical quality of a prolate lens is more sensitive to misalignments than a conventional spherical lens. In order to determine whether tilt and decentration would negatively affect the optical quality of an eye implanted with one of these lenses, ray tracing was performed in the model eye using an optical simulation package (OSLO SIX). Once again the new modified prolate lenses were compared with the spherically surfaced equi-biconvex lens of the same power. The comparison was made for 5-D, 20-D, and 30-D lenses, using a 5-mm pupil.

Figure 6 presents the calculated ocular MTF at 50 c/mm for lens tilts up to and including 10 degrees. (The MTF considered is the average of the MTF in the sagittal and meridional directions.) From these results, it is seen that the modified prolate lens is sensitive to tilt for medium and high power lenses. However, the modified prolate lens

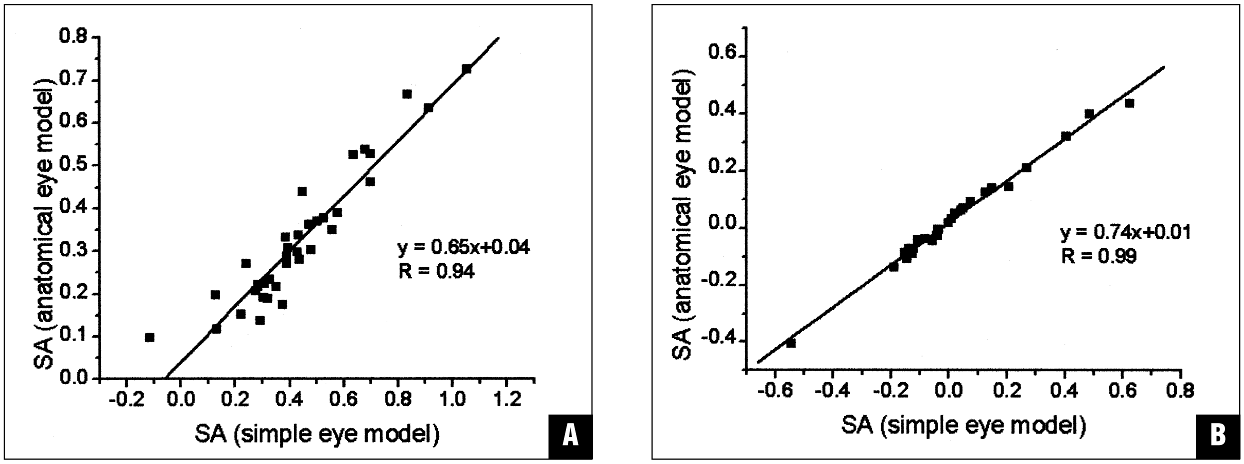
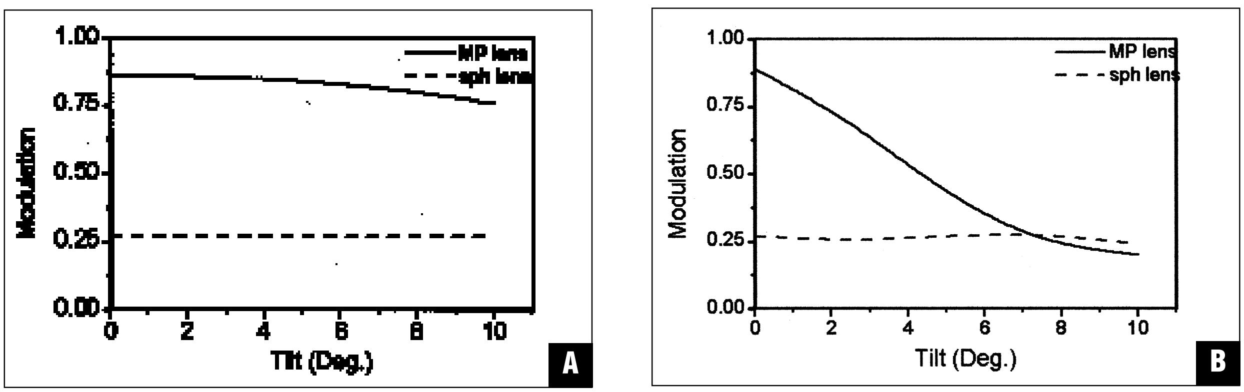


Figure 5. The correlation between the spherical aberration calculated using the simple eye model and the spherical aberration calculated using the eye model constructed with anatomical data. **A)** Pseudophakic eye models containing spherical IOLs; **B)** Pseudophakic eye model containing the modified prolate IOLs.



has higher MTF performance than the reference lens for tilts up to and including 7 degrees.

Figure 7 presents the MTF at 50 c/mm for lens decentrations up to and including 1 mm. From these results, it is seen that the modified prolate lens is most sensitive to decentration for low and medium powers lenses. In particular, for the 5-D and 20-D lenses, the modified prolate lens has higher MTF performance for decentrations up to and including 0.4 mm; for the 30-D lenses the modified prolate lens offers higher MTF performance for decentrations up to and including 0.5 mm.

Experimental comparisons of the optical quality of reference spherical lenses and the new modified prolate lenses were performed using a physical eye model mounted on an optical bench. The through-focus and through-frequency MTFs of 20-D lenses for a 3-mm pupil diameter are shown in Figure 8; the MTF results for a 5-mm pupil are shown in

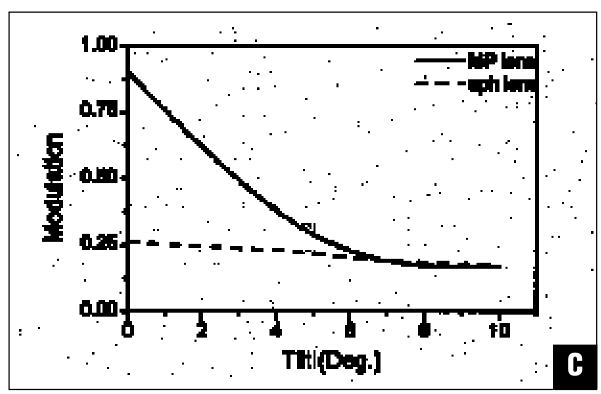


Figure 6. The ocular MTF as a function of lens tilt for the modified prolate (MP) and spherical lenses. MTF was calculated in the model eye at 50 c/mm for a 5-mm pupil diameter (average values for the meridional and sagittal directions). **A)** 5-D lenses; **B)** 20-D lenses; **C)** 30-D lenses.

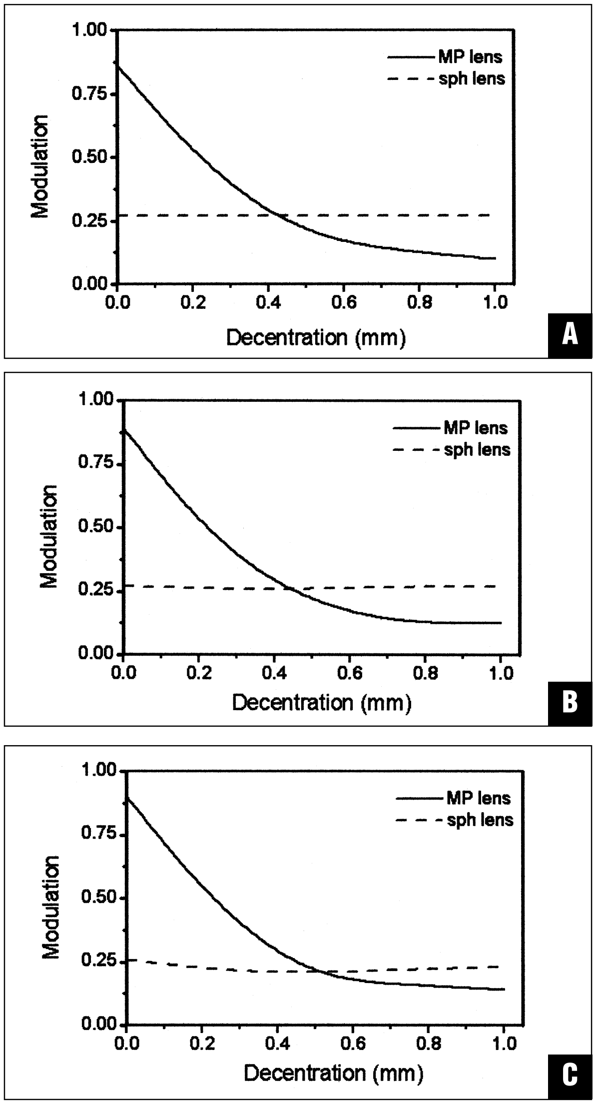


Figure 7. The ocular MTF as a function of lens decentration for the modified prolate and spherical lenses. MTF was calculated in the model eye at 50 c/mm for a 5-mm pupil diameter (average values for the meridional and sagittal directions). **A)** 5-D lenses; **B)** 20-D lenses; **C)** 30-D lenses.

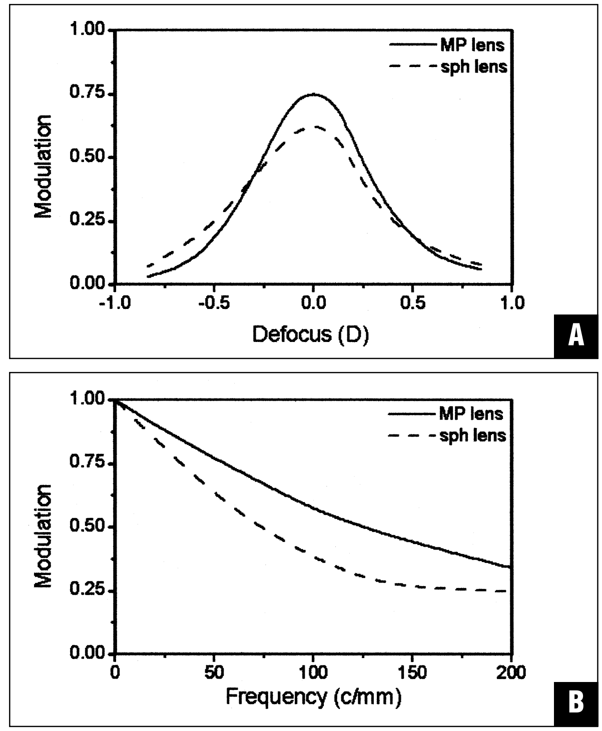


Figure 8. The MTF values for the 20-D modified prolate and spherical lenses measured in a physical eye model mounted on an optical bench. The meridional MTF was measured in the model eye for a 3-mm pupil diameter. **A)** Measured values of the Tecnis lens are significantly better than the spherical lens for defocus values of +0.25 and 0 D (at 50 c/mm). **B)** Measured values of the Tecnis lens are significantly better than the spherical lens for all spatial frequencies (25 to 200 c/mm; $P<.05$).

Figure 9. As expected from the previous calculations, the optical performance of the modified prolate lens in the physical eye model is better than that of the lenses, which have simple spherical surfaces (as measured by MTF performance). Figures 8A and 9A also show that although loss of depth of focus can be a concern when spherical aberration is eliminated from an optical system, the depth of focus obtained with the modified prolate lens is equivalent to that obtained with the spherical lenses. Also, although an equi-biconvex lens with spherical surfaces was used as a reference in this comparison, it should be noted that similar results are expected from all spherical lenses with significantly positive spherical aberration.

DISCUSSION

Evaluation of the optical performance and aberrations of the human eye has been an area of active research for many years. New advances in wavefront technology have allowed measurements that quantitatively describe the optical performance and aberrations of the cornea and the entire refractive system of the eye.

The normal prolate cornea exhibits about one-half the spherical aberration of a sphere. A Q-value of approximately -0.52 is necessary to completely eliminate any spherical aberration from the anterior surface of the cornea.

When a patient undergoes cataract surgery the cataractous lens is removed and replaced with a biconvex or convex-plano spherical intraocular lens

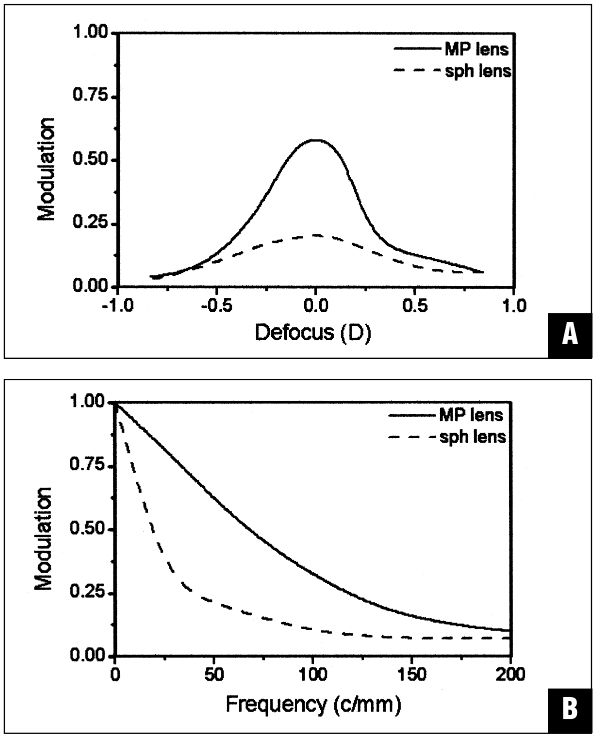


Figure 9. The MTF values for the 20-D modified prolate and spherical lenses measured in a physical eye model mounted on an optical bench. The meridional MTF was measured in the model eye for a 5-mm pupil diameter. **A)** Measured values of the Tecnis lens are significantly better than the spherical lens for defocus values of +0.25, -0.25, and 0 D (at 50 c/mm). **B)** Measured values of the Tecnis lens are significantly better than the spherical lens for spatial frequencies between 25 and 150 c/mm (*P*<.05).

(IOL). Spherical intraocular lenses have positive spherical aberration, resulting in a significant amount of spherical aberration in the pseudophakic eye following cataract surgery. It is possible to reduce the peripheral power of the IOL by making the front surface modified prolate (flatter curvature in the periphery), producing negative spherical aberration in the IOL, similar to that of the young crystalline lens. The result—on average—is an eye with reduced remaining spherical aberration in the entire optical system, although the outcome may vary because of the variable spherical aberration among human corneas, and the fixed-spherical aberration in the prolate IOL.

Optical compensation of a normal cornea with an IOL exhibiting negative spherical aberration requires precise alignment with the cornea (centration and tilt). Our data show that if the modified prolate IOL is decentered less than 0.4 mm and is tilted less than 7 degrees, it will exceed the optical performance of a spherical IOL, measured as modulation transfer function. For a 5-mm pupil the MTF for a centered modified prolate lens (at 50c/mm) is three times that of a centered spherical lens. The MTF is a measure of the ratio of object contrast to image contrast for a range of spatial frequencies. An improvement in the measured MTF therefore translates to an improvement in image contrast. It is expected that this increase in contrast should provide for an increase in contrast sensitivity in patients implanted with this lens.

Prior to 1991, consistently achieving the desired tolerances of lens placement could not have been expected. The study by Auran et al of lenses implanted in the ciliary sulcus or capsular bag or both demonstrated the average decentration was 0.64 mm and the average tilt was 6.75 degrees.[30] Kozaki et al found similar values of 0.68 mm and 7.53 degrees.[31] However, three more recent studies in which the continuous circular capsulorhexis technique with direct visualization of in-the-bag lens placement was used, found decentrations of 0.15 mm, 0.28 mm, and 0.30 mm and tilts of 1.13 degrees, 2.83 degrees, and 2.41 degrees.[32-34] These recent studies confirm that modern IOL implantation is well within the tolerances needed for decentration and tilt to benefit from the improved optical performance of a modified prolate IOL in the eye.

It is important to know the effect of reducing the spherical aberration on depth of focus. This question can be addressed using the through-focus modulation transfer function. At first, one might think that improving the optical performance (MTF) of an optical system may reduce its depth of focus. However, the width of the through-focus-MTF curve is 0.50 D of defocus for both the modified prolate lens and the spherical lens. The significant difference is that the peak is much higher with the modified prolate optic due to its enhanced optical performance, especially for wide pupils. These theoretical calculations were confirmed experimentally in an eye model. In practice, this result can only be confirmed by conducting clinical studies that measure the depth of focus using contrast thresholds.

The posterior surface of the cornea was not considered in the design of the modified prolate lens. The shape of the anterior corneal surface and an effective refractive index of 1.3375 were used as the cornea model. Dubbelman et al[35] determined that a one-surface and a two-surface cornea model differ by only ~3% in power and ~5% in spherical aberration. We therefore consider the one-surface model a reasonable model for corneal power and spherical aberration.

We have characterized a modified prolate IOL that compensates for the average spherical aberration of the human cornea in a cataract population. We have demonstrated, both theoretically and in an eye model, superior optical performance compared to a spherical IOL for systems with 5 to 6-mm pupils in which the optical quality is reduced due to the image degrading effects of aberrations. There appears to be no loss of depth of focus with this design. The requirements for centration and tilt are within the clinical tolerances of modern cataract surgery with continuous circular capsulorhexis and in-the-bag IOL implantation. These data support the need for manufacture and clinical evaluation of a modified prolate IOL to verify if it would improve the quality of vision following cataract surgery.[36]

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