Subjective evaluation of intraocular lenses by visual acuity measurement using adaptive optics

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We present a new method for subjectively evaluating intraocular lenses (IOLs) without implantation surgery. To illustrate the method, three types of single-piece IOL (equispherical monofocal, rotational symmetric aspheric monofocal, and diffractive bifocal) were assembled into a model eye and evaluated using an ocular adaptive optics system by a single subject. To separate the spherical aberration of the crystalline lens, the subject's corneal topography and wavefront aberrations were measured and modeled. Three levels of Zernike spherical aberration were generated and superposed on the IOLs and the subject's eye. The corrected distance visual acuity was measured by psychophysical visual procedure. © 2012 Optical Society of America

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In cataract surgery, the lens of the eye is replaced by an intraocular lens (IOL). IOL optical designs are becoming increasingly sophisticated, not only providing the appropriate power and astigmatism correction but also compensating the average spherical aberration (SA) induced by the cornea. In the future, it is likely that personalized IOLs will be used, each one customized for the precise optical aberrations of the patient's eye. There is a challenge of predicting and evaluating the IOL's optical effect in the pseudophakic eye. The current usual ways are (1) objective optical testing, e.g., Kim *et al.* [1] and Guo *et al.* [2], which is a physical test of the IOL's optical quality; and (2) clinical visual performance evaluation after the IOL implantation into pseudophakic eyes, e.g., Nanavaty *et al.* [3] and Ernest and Potvin [4]. The objective evaluation by the first does not provide direct information on the patient's subjective vision, and the second is only a postoperative method. It would be useful for both research and clinics to have subjective IOL evaluation before the implantation surgery. In this letter, we describe a method for doing this and provide an illustrative example.

The two main refractive elements of the human eye, the cornea and the crystalline lens, both have optical imperfections causing the retinal image to be blurred. In normal eyes there might be an aberration compensation mechanism, depending on the accommodation and age, between the two elements [5–7]. The measurement of the whole eye's aberration and the corneal aberration (usually derived from the corneal topography) makes it possible to separate the aberration contribution of the crystalline lens from the cornea (mostly anterior surface). This offers the opportunity to optically simulate the implantation of an IOL. Adaptive optics (AO) has the ability to manipulate the aberrations and therefore is an attractive option for the simulation. Many studies have used AO to investigate the visual system with aberrations (see a comprehensive review in Roorda [8]). A recent study by Artal *et al.* [9] combined an achromatizer plate into an AO system to investigate the effects of chromatic and SA correction. Real IOLs, however, have not been subjectively evaluated with AO. We propose a method that can directly evaluate a subject's visual performance to different IOLs with AO to remove the aberration compensation of the crystalline lens. We designed a model eye containing different types of IOLs and combined it with an ocular AO system for psychophysical visual acuity measurements.

To simulate the implanted IOL and the aberration compensation of the crystalline lens, the following requirements need to be met: (1) the IOL under evaluation should be optically conjugated with the implanted IOL position, which is close to the human pupil (with the assumption that the optical propagation of wavefront aberration is negligible), (2) the optical magnification of the IOL projected into the eye should be unity to mimic the real IOL's optical functional area, (3) the optical beam from the visual stimulus should have the appropriate convergence angle on the implanted IOL, (4) the IOL should be immersed into liquid to simulate its natural environment in the eye, (5) the IOL should be conveniently and effectively assembled into the AO system, and, finally, (6) the subject under test should be able to see the visual stimulus with proper magnification and brightness through the whole optical system.

A model eye has been designed to achieve these six requirements, which are shown in Fig. 1 near the eye position. The main parts include an adjustable aperture, an artificial cornea doublet lens L1 ($f = 35$ mm, $D =$ 25.4 mm), wet cell with IOL, and another doublet lens L2 ($f = 16$ mm, $D = 8$ mm). L1 provides the approximate convergence angle on the IOL and L2 conjugates the IOL with the pupil of the eye. The IOL, mounted into a disc with a 5 mm opening, is inserted into the wet cell filled with water at room temperature. Located at twice the focal length of L2, the IOL and the eye pupil are optically conjugated with unit magnification. The wet cell is mounted onto a 6 degrees of freedom movement stage to assist IOL alignment or to simulate misalignments.

The model eye with the IOL is coaxially placed in front of the ocular AO system (Fig. 1) and the IOL is conjugated with the system aperture (A), the deformable mirror (DM), and the Hartmann–Shack (HS) wavefront sensor. The AO system has been modified and updated from an

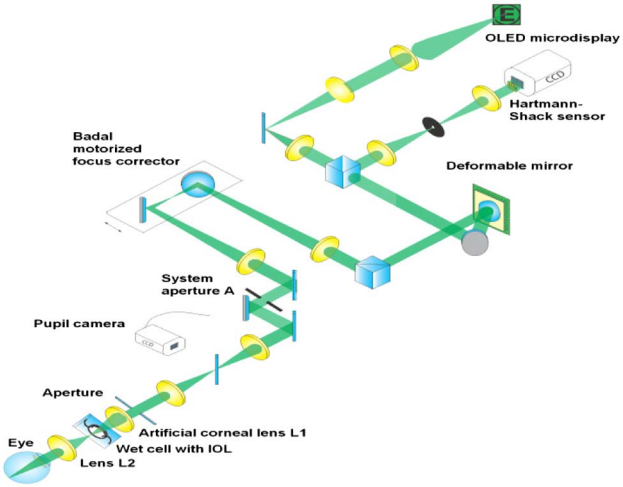

Fig. 1. (Color online) Ocular AO system with a model eye. The model eye consists of an aperture, artificial corneal L1, wet cell, an IOL, and lens L2 in front of the eye. The pupil of the eye and the IOL locate at double optical focus length of lens L2.

original design described in Dalimier *et al.* [10]. The focus corrector, the Badal subsystem, is mounted on a motor stage controlled by a Universal Motion Controller/Driver (Newport). The visual target is a green organic light emission diode (OLED) microdisplay (eMagin Inc.), which has a 15 μm × 15 μm pixel size and 800 × 600 resolution. The psychophysical visual path includes the subject's eye, the model eye with the IOL, the Badal corrector, the DM, and the OLED microdisplay. The display spectrum bandwidth is ~70 nm full width at half-maximum and peak at 540 nm; it provides ~50 cd/m^2 to the eye and a 5 arc min *E* letter that covers about 25 pixels × 25 pixels. The AO system aperture diameter is 6 mm, projecting 4 mm on the IOL and the pupil of the eye.

The software controlling the DM and the HS sensor has been programmed in Microsoft Visual C++ 6.0. The plane wavefront slope reference for the HS sensor is computationally modified to include the predesigned Zernike SA Z(4,0). A 635 nm collimated laser beam is used to calibrate the DM in closed loop. After several iterations, a certain amount of SA is induced as a result of targeting the predesigned slope reference. Then the sequence of the high-voltage commands to the DM is saved as files for later selective loading to restore the calibrated DM's shape. Using this open-loop procedure, any required wavefront aberration could be calibrated as long as it was within the stroke range of the DM's actuators.

To measure the aberration contribution, especially SA of the crystalline lens, the eye's wavefront aberration and the corneal topography were measured with an iDesign Mx measurement instrument (Wavefront Sciences, AMO). Within a few seconds after aligning the subject's eye, this equipment sequentially measured the wavefront aberrations and anterior corneal topography referring to the same axis. See the description in Nowakowski *et al.* [11] of this instrument.

The wavefront aberrations were decomposed into Zernike polynomials. The anterior corneal elevation data (deviation from a best fit sphere) were also fitted by Zernike polynomials in a maximum circle area. An optical ray-tracing model was created using the optical design software Zemax (Radiant Zemax Inc., USA). The anterior cornea was modeled with a single Zernike standard sag surface that included the fitted corneal Zernike coefficients. The SA coefficient, C(4,0) was calculated under 4 mm pupil locating 3.6 mm back from the cornea, which corresponds to the 4.6 mm diameter area near the corneal vertex. These values were chosen to match the following visual experiment settings for the subject. The crystalline lens was estimated from the corneal SA subtracted by the whole eye's SA at the same pupil size.

The psychophysical visual acuity test software has been programmed in MATLAB (version R2009b, MathWorks). Different sizes and directions of *E* letters, with equal stroke and gap spaces, are randomly shown on the microdisplay. A four-option forced choice (up, down, left, and right) of the tumbling *E* letter gap is made by the subject. The subject's input device is a number keypad on which only the four arrow keys are activated. As the result of one visual acuity test, the fraction of correct choices is plotted as a function of LogMAR letter size. The maximum likelihood estimation is used to estimate the most possible LogMAR determined at a certain threshold of the correct judgments. Under the same test conditions, the average of several tests estimates the subject's visual acuity.

To illustrate the principle of the method, one experienced subject (age 46, right eye, 0D.S.–0.5D.C. × 89) carried out the tests on three IOLs. The research has been approved by the ethics committee of the university. The corneal topography and wavefront aberration of the eye were measured six times, and the results and calculations were averaged. Three types of IOLs were evaluated: a 20.5D equispherical monofocal (AcrySof, Alcon), a 20D anterior rotational symmetric aspheric monofocal (Tecnis, AMO), and a 20D anterior diffractive bifocal (ReSTOR, Alcon).

The subject's right eye was instilled with one drop of 1% tropicamide 20 min before the experiment and another drop every hour during the experiment. The DM was driven in open loop to the predesigned shapes. A bite bar was used to fix the subject's head and eye. The bite bar was mounted on an XYZ translation stage for aligning the subject's line of sight with the optical axis of the AO system. The alignment was performed using the pupil camera while the subject was looking at the center of the microdisplay showing an ~0.5 deg *E* letter. The subject then adjusted the motorized Badal stage to search for his best visual focus. The stage moved at 2.5 or 5 mm/s speed with 1 mm movement corresponding to 0.31D power change. After the subject found the best focus, the operator recorded the current position of the Badal corrector; 6 to 10 times judgments were recorded and the average was set on the Badal corrector. This procedure was performed every time the SA was altered to ensure that the experimental conditions correspond to the clinical corrected distance visual acuity (CDVA).

Then the visual acuity test software was launched. The highest contrast of the microdisplay was used to present the letters, which had dark strokes with bright surrounding. Six letter sizes were selected and 20 *E* letters for each size were presented to the subject. Each letter was shown for 0.3 s (18 frames at a screen refresh rate

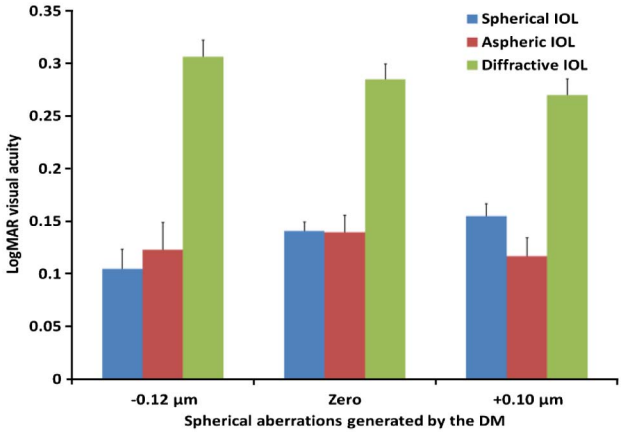

Fig. 2. (Color online) Visual acuity results of spherical (first bar of each group), aspheric (second bar), and diffractive (third bar) IOLs under three Zernike SAs generated by the AO system.

of 60 Hz) and then the subject had to make a choice. The subject's choices were recorded and the next random E letter was presented. Sound beeps indicated when each letter was presented and a long beep indicated the end of one test. Altogether 120 letters in one test usually took 2.5 to 3 min. The correct answer threshold was 80%. At least three tests were run for each type of IOL with each SA condition. All the experiments were done within one day, and all repeated on another day with a random order of IOL assembling and SA condition.

The subject's anterior cornea had 0.11 μm SA at 4 mm pupil predicted by the ray-tracing eye model. The whole eye's SA at this pupil size was 0.015 μm. That is to say about 0.095 μm corneal SA had been compensated by the crystalline lens. To cancel the compensation, positive 0.10 μm of Zernike SA was induced by the AO. As a contrast, zero and negative 0.12 μm SAs were included with all three types of IOLs.

Figure 2 shows the experimental results. Three levels of SA are shown at the horizontal axis, and the vertical axis shows the visual acuity in LogMAR for each type of IOL. The error bar represents standard error of all tests in 2 days. For the equispherical IOL (left, blue bars), the level of SA played a significant role (one-way analysis of variance, $F = 5.17$, $p = 0.019$), but it was not significant for the other two types of IOLs ($F = 0.29$, $p = 0.76$ for the aspheric IOL and $F = 1.36$, $p = 0.29$ for the multifocal IOL). For this subject, implantation of aspheric IOL could give better CDVA (~0.05 LogMAR) than spherical IOL at a barely significant level ($p = 0.15$). The multifocal IOL (right, green bars) had the worst CDVA ($p < 0.001$).

The spherical IOL is sensitive to the level of SA possibly because the spherical IOL has intrinsic SA. For example, for a 1.13 mm central thickness 21.5D equispherical IOL (CeeOn 911A), $C(4, 0) = 0.04$ μm at 4 mm (the AcrySof spherical IOL used in this study should have similar value), and for a 22.0D Tecnis Z9000 aspheric IOL, $C(4, 0) = -0.1$ μm. In our case, the cornea $C(4, 0) = 0.1$ μm and the aspheric IOL closely compensated this so that the subject got, on average, a better CDVA than with the spherical IOL, however, not in significant way, possibly because of the relatively small pupil size. This finding is consistent with many clinical pseudophakic eye studies showing that an aspheric IOL may have no significant improvement in acuity although possibly more significant improvement in contrast sensitivity (see review paper by Montes-Mico *et al.* [12]).

Besides the manipulation of spherical aberration, AO is potentially able to generate other aberrations, such as astigmatism, trefoil, and coma [13,14], which the next generation IOLs may include in their optical design. The individual IOL is optimally required to treat relative high and individual-dependent corneal aberrations, especially for a growing group of post—corneal laser refractive surgery patients who are reaching their age for cataract.

One potential limitation of the current experimental illustration is that other aberrations of the crystalline lens might play a role. Although, they should be constant for different IOLs, they may still bias the results. The challenges of fully removing the aberration of the crystalline lens over extended central field still remain. As the SA is usually dominating other nonrotational symmetrical aberrations, however, the effect of the latter was considered small. Cataract surgery—induced aberration was not considered to have a big effect because of the modern small incision [15].

In summary, we developed a methodology to subjectively evaluate and compare different types of IOLs. We believe this is the first report of the measurement of the CDVA for different types of IOLs in a single eye.

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