ARTICLE

First results with a new intraocular lens design for the individual correction of spherical aberration

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Purpose: To assess the feasibility of individual compensation of corneal spherical aberration with a custom intraocular lens (IOL).

Setting: Department of Ophthalmology, Rudolf Virchow Klinikum Glauchau, Glauchau, Germany.

Design: Prospective case series.

Methods: Cataract patients were randomized to receive an individual aberration-correcting IOL (Invidua-aA; Group A) or a standard aspheric aberration-free IOL of otherwise identical design (Aspira-aA; Group B). In Group A, the IOL was designed according to preoperative calculation of the corneal spherical aberration Z(4,0). The aim was to achieve an overall postoperative ocular spherical aberration close to zero. Four weeks and 3 months postoperatively, the refraction, visual acuity (far, intermediate, and near distance), photopic and mesopic contrast sensitivities (with and without glare), defocus curve, corneal and ocular spherical aberration, and pupil size were measured.

Results: Group A, 57 eyes of 42 patients and Group B, 29 eyes of 27 patients. Preoperatively, there was no difference in corneal spherical aberration between groups ($P > .05$). Three months postoperatively, residual ocular spherical aberration Z(4,0) was significantly lower in Group A ($P < .001$). Photopic and mesopic contrast sensitivities (with and without glare) were significantly higher in Group A at most spatial frequencies. Monocular defocus curve and distance, intermediate, and near visual acuity outcomes did not differ significantly between groups.

Conclusions: Implantation of a custom monofocal aspheric IOL effectively reduced overall ocular spherical aberration. Clinical outcomes indicate that IOLs with an individual spherical aberration correction improve functional vision, especially contrast sensitivity, compared with standard aberration-free IOLs.

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Higher-order wavefront aberrations (HOAs) are complex refractive errors preventing light from focusing accurately on the fovea. Of all types of HOAs, spherical aberration is the only on-axis and rotationally symmetric aberration that is well understood and intraocular lenses (IOLs) might be suitable for practical compensation of corneal spherical aberration.[1–8]

In the young human eye, spherical aberration is a combination of the positive spherical aberration of the cornea and the negative spherical aberration of the crystalline lens.[9,10] Although the cornea usually shows a relatively stable spherical aberration over one's lifetime, the spherical aberration of the lens increases with age. Clinical studies[2–7] found that disregarding corneal spherical aberration in cataract or refractive lens surgery can significantly reduce visual performance, especially under mesopic light conditions.

Implanting spherical IOLs increases positive corneal spherical aberration as well because of the positive spherical aberration in these IOLs.[2] Aspheric IOLs, which are increasingly recognized as the current standard in IOL surgery, have a modified prolate anterior surface and can be divided into 2 groups. Although aspheric aberration-free IOLs are designed to correct the intrinsic spherical aberration of the IOL,[11] aspheric aberration-correcting IOLs are aimed at compensating for the corneal spherical aberration of an average pseudophakic eye with the goal of a leaving minimal postoperative total spherical aberration.[1,2]

Clinical results have confirmed that compared with spherical IOLs, implantation of aberration-correcting IOLs (with a fixed average value) can result in a significant improvement in visual acuity,[2,3] photopic contrast sensitivity,[2–4,8] and mesopic contrast sensitivity[2–6,8] and a lower incidence of subjective photic phenomena.[7] Today,

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different aberration-correcting IOL models with fixed amounts of negative spherical aberration are available. This approach offers effective spherical aberration compensation, but only for eyes that match the specific model parameters.

Analytic reviews have shown large variability in the amount of corneal spherical aberration. In 696 eyes, Beiko et al.[12] found spherical aberration values ranging from 0.017 µm to 0.639 µm at an optical zone of 6.0 mm. In 2014, de Sanctis et al.[13] reported that the variability of the total corneal spherical aberration might be even higher than previous studies had indicated.

Until now, the only way to control postoperative ocular spherical aberration is selecting the aspheric IOL model that best fits the preoperative measured corneal spherical aberration. This strategy results in better outcomes than the random use of aspheric IOLs,[14] but it can reduce only the individual corneal spherical aberration using an approximation.

Adaptive optics vision simulators allow investigation into the potential improvement in visual quality associated with custom correction of spherical aberration.[15] In 2007, Piers et al.[15] reported that contrast sensitivity peaked when spherical aberration was fully corrected. Furthermore, it was shown that spherical aberration also affects visual acuity.[16] Theoretic studies based on pseudophakic eye models support these findings.[17,18]

The aim of this study was to evaluate the visual performance of a new custom-designed aspheric IOL to compensate for individual corneal spherical aberration and thus minimize overall ocular spherical aberration.

PATIENTS AND METHODS

This prospective randomized double-masked study comprised patients between 50 and 84 years of age scheduled for standard phacoemulsification in age-related cataract. All patients provided written informed consent before enrollment. The study was approved by the local ethics committee and followed the tenets of the Declaration of Helsinki.

Patients were randomized to receive an individual spherical aberration-correcting IOL (Invidua-aA; Group A) or a standard aspheric aberration-free IOL with an otherwise identical lens design (Aspira-aA; Group B).

Inclusion criteria were an expected postoperative visual acuity of 20/25 or better and a corneal astigmatism of 1.00 diopter (D) or less. Exclusion criteria comprised irregular corneal astigmatism, disease that might impair vision, comorbidity that could affect IOL stability in the bag, and previous ocular surgery or trauma.

Intraocular Lenses

The Invidua-aA (Humanoptics AG) is a monofocal 1-piece hydrophilic acrylic (n = 1.46) IOL with an optic diameter of 6.0 mm and an overall length of 12.5 mm. It has a C-loop haptic design with a 360-degree lens epithelial cell barrier on the posterior surface. The anterior surface of the IOL optic is individually aspheric, which means it is designed according to the patient's preoperative corneal spherical aberration Z(4,0). The aberration-free Aspira-aA (Humanoptics AG) was implanted in Group B. Apart from the anterior IOL surface, both IOLs are of identical material and design.

Intraocular Lens Power Calculation

For both IOL models, IOL power was based on optical biometry by partial coherence interferometry (PCI) (IOLMaster, Carl Zeiss Meditec AG); the target was emmetropia. The aberration-free IOL power was calculated using the department's standard procedure and the Holladay formula built into the PCI device.[A] For the aberration-correcting IOL, an individual ray-tracing calculation was performed by the manufacturer using detailed corneal data from preoperative high-resolution Scheimpflug tomography (Pentacam HR, Oculus Optikgeräte GmbH). The manufacturer received the export files (U12 files) of 3 high-resolution Scheimpflug tomography measurements and used optical design software (Opticstudio, Zemax, LLC) to derive an individual eye model for calculation of the design for the custom IOL surface. The design process implies an objective function that takes a certain amount of decentration into account.[19] The goal was a postoperative plano refraction and an overall ocular spherical aberration close to zero.

Preoperative and Postoperative Examinations

Preoperatively, all patients had an ophthalmologic examination including medical history, slitlamp evaluation, measurement of eye length and the corneal radii of curvature (with PCI), and corneal high-resolution Scheimpflug tomography.

Postoperative follow-up examinations were performed at 4 weeks and 3 months. They included subjective refraction, uncorrected (UDVA) and corrected (CDVA) distance visual acuities, uncorrected near and intermediate visual acuities, distance-corrected near (DCNVA) and intermediate (DCIVA) visual acuities, slitlamp evaluation, corneal high-resolution Scheimpflug tomography, wavefront measurement including total ocular spherical aberration Z(4,0) using ray-tracing aberrometry (iTrace, Tracey Technologies), monocular defocus curve, contrast sensitivity, and mesopic pupil diameter (ray-tracing aberrometry).

Visual acuity for far distance (5 m) was evaluated monocularly with numerical optotypes (sizes according to ISO 8596[20]), and Early Treatment Diabetic Retinopathy Study charts (Precision Vision) were used for intermediate (1 m and 0.63 m) and near (0.40 m) vision.

Wavefront data were collected preoperatively from corneal tomography with high-resolution Scheimpflug tomography and postoperatively for the whole eye with ray-tracing aberrometry.

To determine monocular defocus curves, visual acuity was measured with logarithm of the minimum angle of resolution (logMAR) charts at 5 m under photopic conditions. The defocus curve was obtained with distance correction through different levels of defocus induced with trial lenses (between 2.00 D and −3.00 D in steps of 0.50 D).

Monocular contrast sensitivity was measured under photopic (85 candelas [cd]/m^2) and mesopic (3 cd/m^2) conditions with and without glare source (Functional Vision Analyzer, Stereo Optical Co., Inc.).

All postoperative examinations were performed by the same investigator (J.S.) who was unaware of the implanted IOL model. Patients were also masked to their study group.

Statistical Analysis

Data analysis was performed using SPSS software for Windows (version 22, IBM Corp.). For statistical analysis, log base 10 values were used for contrast sensitivity and logMAR notation for visual acuity. The Wilcoxon rank-sum test was used for comparisons between preoperative data and postoperative data. For comparison between independent groups, the Mann-Whitney test was applied. Furthermore, the chi-square test was used for comparing percentages of categorical data between IOL models. For all statistical tests, a P value less than 0.05 was considered statistically significant.