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Prediction of the small aperture intraocular lens on visual acuity in patients with keratoconus

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Purpose: To investigate the impact of corneal higher-order aberrations (HOAs) on predicted corrected distance visual acuity (CDVA) in patients with keratoconus at varying simulated pupil apertures.

Setting: Ophthalmology Clinics, Medical University of South Carolina, Charleston, South Carolina.

Design: Retrospective chart review study.

Methods: 56 eyes with keratoconus were examined using Scheimpflug tomography during routine examinations before medical intervention. The severity of keratoconus was graded using the Amsler-Krumeich classification. Zernike analysis was used to obtain corneal aberrations using simulated pupil diameters of 6 mm, 4 mm, and 2 mm. These data were extrapolated to obtain the total root mean square HOAs for a 1.6 mm simulated pupil to evaluate the potential effect of a small aperture intraocular lens (IOL). Correlation analysis was used to study the impact and relative contributions of HOAs on CDVA. Convolution of HOAs from OPD-Scan III provided a clinical method to predict CDVA with different simulated pupil sizes in corneas with irregular astigmatism.

Results: There were statistically significant positive correlations between photopic CDVA and the magnitude of total and individual (coma, spherical aberration, and trefoil) HOAs in this cohort of keratoconus participants. A keratoconus case with the small aperture IOL confirms the improvement in vision due to the pinhole effect.

Conclusions: The small aperture IOL is expected to markedly reduce aberrations in patients with keratoconus up to Amsler-Krumeich class 4 severity to levels consistent with the levels seen in healthy patients. Convolution of corneal HOAs with the Early Treatment Diabetic Retinopathy Study chart provides a useful simulation of the impact of pinhole optics in aberrated eyes.

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Keratoconus is a noninflammatory, often progressive, bilateral ocular disease characterized by stromal thinning and corneal protrusion. The rate of progression is often greatest in the youth, and progression is variable in time and asymmetrical. The eventual severity of keratoconus is variable; a significant proportion of cases progress to an advanced stage requiring management to maintain tissue integrity and functional vision. As its name suggests, keratoconus produces cone-like bulges in the cornea, predominantly in the inferior periphery, but the apex of the cone can also occur centrally and superiorly.[1] These corneal shape changes result in irregular astigmatism that degrades visual acuity. Although a number of management techniques have been used to mitigate the optical distortions, including rigid and scleral contact lenses and intracorneal ring segments, the application of corneal crosslinking that aims to halt the progression of keratoconus has been a significant advance in the treatment of keratoconus.[2] The use of keratoconus screening systems developed for corneal topographers and corneal tomographers has improved early detection so that progression can be arrested with cross-linking before a significant reduction in visual acuity has occurred.[3–5]

The characteristics of irregular astigmatism in keratoconus have been studied with wavefront analysis, and as expected, significant amounts of coma dominate the aberrations.[6] These authors showed that rigid contact lenses significantly improved visual acuity but could not entirely compensate for the large amount of coma. Currently, advances in scleral contact lens design may have overcome this limitation, and results of current clinical trials with wavefront-guided scleral lenses are underway.[7] Although this advance may provide functional vision for many patients with keratoconus, the more severe cases with greatly

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increased aberrations may provide a challenge for this modality.

It has been well established that the size of the pupil correlates with ocular aberrations: The larger the pupil, the larger the amount of higher-order aberrations (HOAs) even in normal healthy eyes.[8] The majority of these aberrations arise from the air–tear interface on the corneal surface. In the evolution of keratorefractive surgery, it has long been recognized that large optical zones created by laser ablation were essential to reduce nighttime visual disturbances such as glare and halos.[9]

Although elimination of HOAs from the optical zone can improve vision, when this is not possible or practical, another approach to reduce the impact of corneal aberrations on visual acuity is the pinhole effect. This is a well-studied phenomenon where, as the pupil constricts, the optical system is less influenced by anterior segment aberrations, and the depth of focus increases.[10,11] A surgical pinhole pupilloplasty technique has been developed, and reports showed a significant improvement in visual acuity in cases with corneal HOAs.[12,13] Trindade et al. published a cases series with a pinhole lens (Xtrafocus, Morcher GmbH) implanted in the ciliary sulcus in a piggyback configuration of eyes with irregular corneal astigmatism (keratoconus, postradial keratotomy, postpenetrating keratoplasty, and traumatic corneal laceration) demonstrating improved corrected distance visual acuity (CDVA) postoperatively.[14] This strategy was also used in the design of a corneal inlay (KAMRA, Acufocus, Inc.) providing a small 1.6 mm aperture to extend the depth of focus in 1 eye of presbyopes to improve near vision.[15] The same inlay was subsequently embedded in an intraocular lens (IOL) for patients needing cataract surgery—the IC-8 Apthera (Bausch & Lomb, Inc.). This device was constructed with a 1.36 mm aperture, providing the same optical aperture at the corneal plane of 1.6 mm as the corneal inlay.[16] In a clinical trial, enhancement of depth of focus was demonstrated in a monovision trial with nearly all eyes (N = 12) achieving 20/32 or better uncorrected binocular vision for distance, intermediate and near at 1 year. All eyes in the same study maintained 20/40 or better vision over a +0.5 to −1.50-diopter (D) defocus range.[17] In a separate study, uncorrected intermediate and near visions were maintained at 20/25 and 20/32, respectively, with as much as 1.5 D of uncorrected astigmatism illustrating improved tolerance to low-order aberrations.[18] The small aperture IOL is approved in the United States for unilateral implantation to provide monovision in aphakes with up to 1.5 D of cylinder with a refractive target of −0.75 D.[19]

The small aperture devices have not been studied extensively in patients with keratoconus. Although safety and effectiveness data of this technology for corneas with significant aberrations are not currently available, it is of interest to investigate the influence that the pinhole effect may have on keratoconus aberrations to determine whether these lenses should be considered for visual correction. This study evaluates the impact of simulated small aperture optics on HOAs in varying degrees of keratoconus severity to study whether these lenses could be expected to provide therapeutic benefit. A surgical case is presented to illustrate its use in a patient with keratoconus.

METHODS

This retrospective chart review study included patients with keratoconus who were seen at ophthalmological clinics at the Storm Eye Institute, Medical University of South Carolina. Data were obtained from July 2016 to October 2022 records, and the study was approved by the Medical University of South Carolina Institutional Review Board. The study adhered to the tenets of the Declaration of Helsinki.

Patients with keratoconus were examined in the clinic and classified as mild, moderate, and severe groups according to the Amsler-Krumeich classification system. In brief, the Amsler-Krumeich classification is based on mean keratometry and has 4 stages of progressing severity.[20] The mild group included stage 1 (Amsler-Krumeich), the moderate group included stage 2, and the severe group consisted of stages 3 and 4 due to a paucity of patients qualifying for stage 3. Exclusion criteria included patients with a history of corneal disorders other than keratoconus (eg, corneal dystrophies, ocular surface disease, ocular trauma, herpetic keratitis, corneal melt, recurrent corneal erosion, corneal scarring, and nystagmus).

Refractive data, including manifest refraction spherical equivalent, uncorrected visual acuity (UDVA), and CDVA, were collected from electronic medical records along with examinations with the Scheimpflug device (Pentacam HR, Oculus Optikgeräte GmbH). For this study, lower-order aberrations (LOAs) and HOAs up to sixth order were obtained from the instrument's Zernike analysis for the natural photopic pupil, and for apertures of 6 mm, 4 mm, and 2 mm for the total cornea. Calculations of aberrations followed the guidance provided by "Methods of Reporting Optical Aberrations of Eyes" provided in ANSI Z80.28-2017. These data were used to estimate the HOAs within a 1.6 mm aperture calculated by second-order polynomial fit of the measured data extrapolated to 1.6 mm for each participant.

The dynamic sciascopy device (OPD-Scan III, Nidek, Inc.) was used to illustrate the potential improvement in CDVA in keratoconics that could be obtained with the 1.6 mm aperture at the corneal plane with the small aperture IOL.

Corneal HOAs up to sixth order and the whole eye HOAs were assessed using the Scheimpflug and raytracing (iTrace, Tracey Technologies) devices, respectively, in 1 patient with keratoconus who underwent cataract surgery with the implantation of the pinhole IOL. Patient informed consent was obtained for the case report.

Statistical Analysis

A P value less than or equal to 0.05 was considered statistically significant. Quantitative variables were represented as mean and SD. Pearson correlation analyses were obtained with Excel for MAC (v. 18.78.3, Microsoft Corp.).

RESULTS

In the 6-year single-site chart review, 56 patients with keratoconus were identified meeting the inclusion criteria for the study. The demographic data are presented in Table 1. Their age, sex, and keratoconus severity graded with the Amsler-Krumeich classification system are presented in Table 1. There was no statistically significant difference between age groups ($P > .05$). The participants were evenly divided overall by sex; the differences within each classification were not meaningful. By design, maximum keratometry values were significantly different between the groups, increasing substantially with an increasing Amsler-Krumeich stage.

Table 1. Patient with keratoconus demographics by severity			
Variable/group	**Mild: A-K1 (n = 21)**	**Moderate: A-K2 (n = 19)**	**Severe: A-K3, 4 (n = 16)**
Sex (F/M)	8/13	9/10	11/5
Age (y)	39.6 ± 13.8 (14, 67)	43.2 ± 16.5 (14, 73)	35.3 ± 14.3 (16, 72)
Kmax (D)	44.8 ± 1.9 (40.3, 47.9)	50.5 ± 1.4 (48.3, 52.7)	60.9 ± 5.9 (53.2, 72.4)

A-K = Amsler-Krumeich severity grade; Kmax = maximum keratometry
Age and Kmax data are means ± SD (range). The severe group comprised 4 A-K stage 3 and 12 A-K stage 4.

The magnitude of HOAs in the patients with keratoconus was correlated with CDVA under normal photopic conditions (Figure 1). It is noted that each type of aberration is interdependent within the whole set of Zernike coefficients, the result of the Zernike wavefront surface fitting routine. The impact of the total HOAs and the individual components are evident in Figure 1. Statistically significant correlations were found between CDVA and spherical aberration, coma, and trefoil.

To estimate the HOAs that could be expected with the IC-8 Apthera IOL with its 1.6 mm effective aperture at the corneal plane, data from the HOAs obtained from 6 mm, 4 mm, and 2 mm apertures were fit individually with a second-order polynomial regression (Spearman rank correlation coefficient = 1 for all patients). The data for the keratoconus group are shown in Figure 2. The average root mean square (RMS) values for the HOAs expected for a 1.6 mm aperture for these patients are shown to be 0.12 μm (Figure 2, A) with the complete data distribution shown in Figure 2, B. As the patients with keratoconus were graded using the Amsler-Krumeich classification scheme, these groups were evaluated separately, and the results are shown in Figure 3.

The magnitude of the low-order aberrations in the patients with keratoconus was also correlated with CDVA under normal photopic conditions (Figure 4). In this cohort of highly aberrated corneas, CDVA measured with the phoropter cannot compensate for even all the low-order aberrations.

The potential for improvement in CDVA with the pinhole optics provided by the small aperture IOL is confirmed by the estimates illustrated in Figure 3. The impact of reducing peripheral corneal HOAs can also be demonstrated visually by convolving the measured HOAs with a standard Early Treatment Diabetic Retinopathy Study (ETDRS) chart. An example of a patient with keratoconus so analyzed is shown in Figure 5 in which the anticipated pinhole effect is clearly demonstrated.

The predicted improvement in vision is illustrated by a 66-year-old woman with keratoconus and visually significant posterior subcapsular cataract in the left eye with preoperative UDVA of 20/150, CDVA of 20/40 (corrected with scleral lenses), and uncorrected near visual acuity (UNVA) of 20/200. The patient underwent cataract surgery with an IC-8 Apthera IOL implantation in the left eye. At 3 months postoperatively, the UDVA was 20/30, CDVA was 20/30 + 1(without scleral lenses), and UNVA was 20/20. Corneal RMS HOAs were reduced from 0.72 μm preoperatively (for the natural photopic pupil of 3.0 mm) to 0.05 μm estimated for the 1.6 mm aperture at the corneal plane (Supplemental Figure 1, available at http://links.lww.com/JRS/B140). Total eye RMS HOA through the IOL's small aperture (1.36 mm) was 0.039 μm, measured by the iTrace aberrometer close to prediction (0.05 μm).

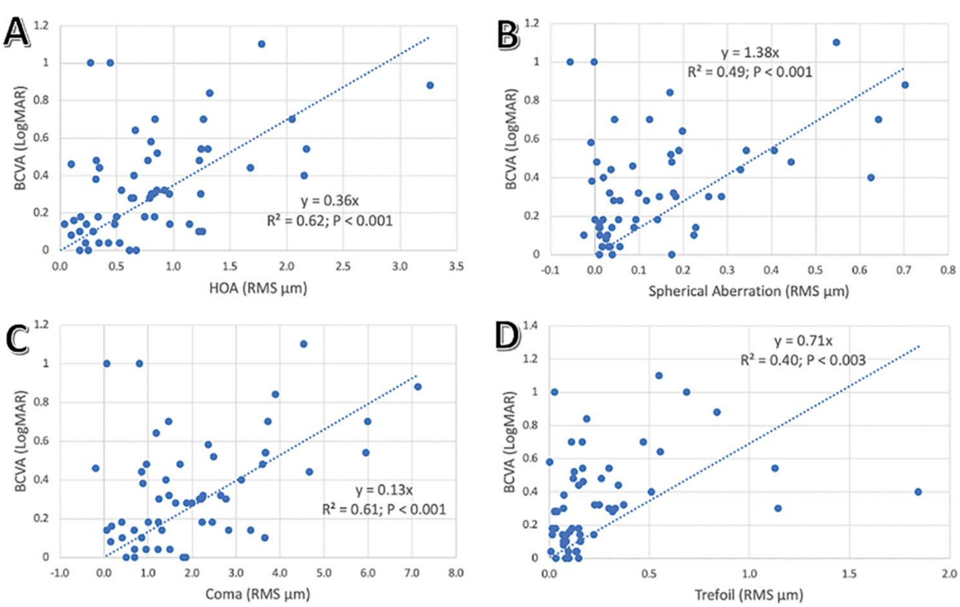

Figure 1. Correlations of HOAs in the patients with keratoconus under natural pupil photopic conditions with CDVA. Correlations *A–D* were statistically significant (assuming linearity: Pearson correlation coefficient was calculated). *A*: Total HOAs. *B*: Spherical aberration HOAs. *C*: Coma aberrations. *D*: Trefoil aberrations.

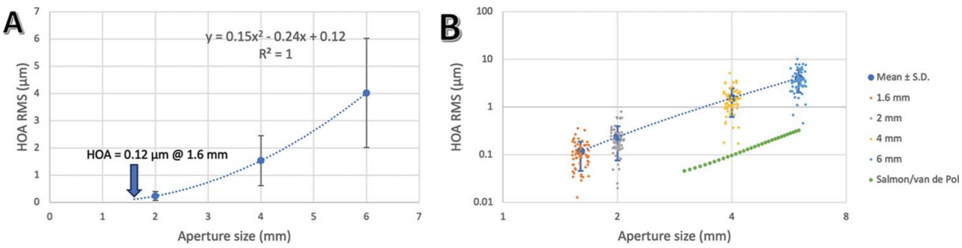

Figure 2. Estimation of HOAs with a 1.6 mm aperture in the keratoconus group. *A*: Mean ± SD of the measured HOAs for 6 mm, 4 mm, and 2 mm and HOAs extrapolated for 1.6 mm IC-8 aperture. *B*: HOAs are nearly linear on a log–log plot. The green dotted line indicates average HOAs for normal participants over the pupil sizes of 3 to 6 mm.[8]

DISCUSSION

HOAs are known to be significantly increased in patients with keratoconus. Although coma-like aberrations are pronounced because of the normally offset steepening with keratoconus, spherical aberration and trefoil make significant correlations with the HOAs as shown in Figure 1. These optical aberrations are well acknowledged to be the key factors causing visual impairment in keratoconus eyes, although, as shown in Figure 4, the low-order aberrations also affect vision even with spectacle correction.[6] As such, reduction in total corneal aberrations is central to all optical treatments offered to such patients. In this study, the impact of simulated small aperture optics in patients with varying degrees of keratoconus severity showed a statistically significant improvement of HOAs in mild, moderate, and severe cases. The magnitude of HOAs correlated with CDVA under normal photopic conditions, supporting the hypothesis of an expected therapeutic benefit of small aperture optics IOLs in aberrated corneas.

The average RMS value for the HOAs estimated for 1.6 mm at the corneal plane (1.36 mm central aperture in the IOL plane) was 0.12 ± 0.07 µm compared with 0.81 ± 0.63 µm for the natural pupil size (3.16 ± 0.54 mm) in keratoconus eyes ranging from Amsler-Krumeich stages 1 to 4. The value of 0.12 ± 0.07 µm for the 1.6 mm aperture approximates the total RMS HOAs measured in 1,433 normal participants by Salmon and Van de Pol for a 4 mm pupil (0.10 µm RMS).[8] Even when analyzed for the subset of most advanced keratoconics (Amsler-Krumeich stages 3 and 4), the average simulated HOAs through the small aperture were estimated to be 0.20 µm. This was equivalent to the aberrations seen in the normal population for a 5 mm pupil.[8] Hence, even for the most advanced keratoconus in this study, the simulated HOAs through an aperture of 1.6 mm in the corneal plane would provide normal CDVA. One caveat should be noted. Simply reducing total RMS HOAs does not guarantee crisp high contrast vision. As shown in Figure 5, vision in a keratoconic with a 1.6 mm aperture should enable 20/20 vision, but residual HOAs over the entrance pupil can decrease contrast acuity. Nevertheless, the improvement in functional vision for such patients is evident.

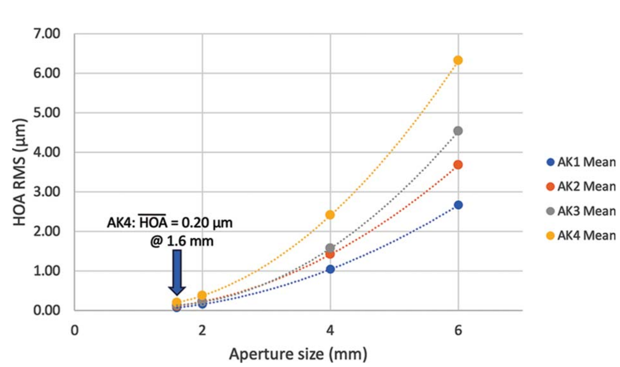

Figure 3. Mean RMS HOAs for the Amsler-Krumeich classification groups in the study. RMS = root mean square

The impact of pinhole optics on aberrations and visual acuity, as demonstrated in Figure 5 with the convolution of the cornea's HOAs with the ETDRS chart, is a useful clinical adjunct to the measurement of HOAs. This approach demonstrates not only the anticipated distance corrected visual acuity for an aberrated eye but also the quality of that acuity that cannot be easily understood with metrics often used for this purpose, such as the modulation transfer function or visual Strehl formulations.

An important additional feature with pinhole optics embedded in an IOL is the increase the depth of focus it provides. The small aperture IOL incorporates an opaque annular mask with an outer diameter of 3.80 mm and a central aperture of 1.36 mm embedded within the 6 mm optic of the 1-piece hydrophobic acrylic IOL. This embedded mask blocks peripheral aberrated light from entering the eye allowing only central focused light to reach the retina. Although this small aperture optics IOL has been approved by the FDA as a presbyopia-correcting IOL to improve reading vision, the findings of this study show that the same optical principle can be used to significantly reduce HOAs and improve functional vision in keratoconic eyes. Although this study is confined to the impact of the pinhole IOL on keratoconics, other conditions with corneal irregular astigmatism should also show an improved reduction in HOAs and improved vision. For example, Ang reported that the same small aperture IOL provided 20/25 or better CDVA with up to 1.5 D of induced astigmatic defocus when implanted in the nondominant eye.[21] With 2.50 D of astigmatic defocus, 10 of 11 participants were 20/40 or better. As shown in Figure 4, LOAs even when corrected for refractive sphere and cylinder also degrade CDVA. Ezzeldin et al. described a pinhole IOL implantation in a keratoconus case with excellent outcomes, representing a safe and effective option to improve the quality of vision. The uncorrected distance visual acuity (Decimal) improved from 0.2 (20/100) preoperatively to 0.5 (20/40) at postoperative 4 months; corrected distance visual acuity (Decimal) improved from 0.3 (20/63) preoperatively

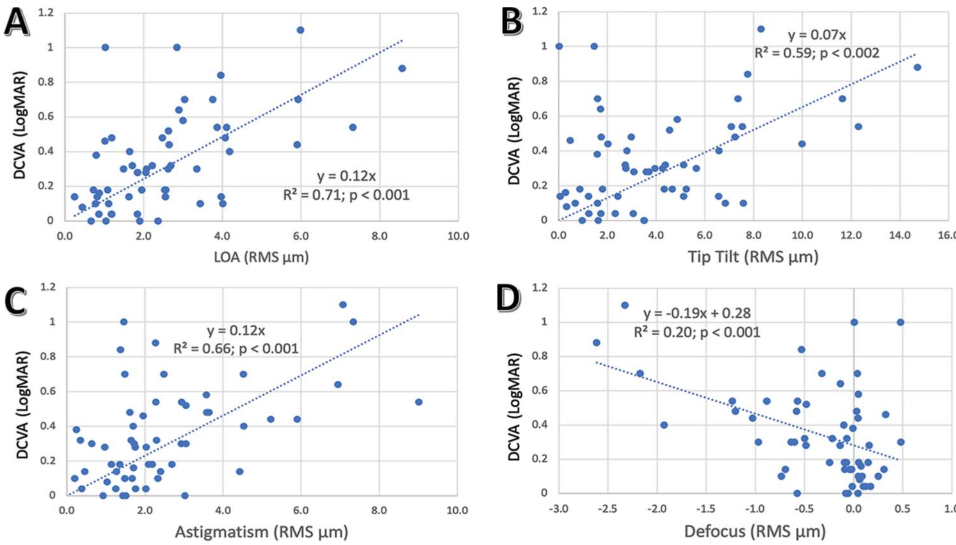

Figure 4. Correlations of low-order aberrations in the patients with keratoconus under natural pupil photopic conditions with CDVA. Correlations *A*–*D* were statistically significant (assuming linearity: Pearson correlation coefficient was calculated). *A*: Total LOAs. *B*: Tip tilt. *C*: Astigmatism. *D*: Defocus.

to 0.9 (20/20+) at postoperative 4 months.[22] Langer et al. published a study with 17 eyes with irregular corneal astigmatism followed by IC-8 Apthera implantation and also presented good visual results and patient performance. Mean logMAR CDVA improved from 0.37 ± 0.09 (20/40+) to 0.19 ± 0.06 (20/32) at 3 months postoperatively ($P < .0001$).[23] These results are comparable with our case report and with our visual simulations.

Limitations of the small aperture optics approach have been noted.[24] Among these are included difficulty with fundus examinations. However, the IOL has not been found to interfere with the visualization of the retinal fundus while improving visual function in eyes with abnormally aberrated corneas. Furthermore, it has been shown that the reduction in retinal illumination caused by the light masking with the corneal implanted pinhole inlay seems to be overcome by neural adaptation.[25] Finally, uneven retinal illumination can cause distortion of object motion (the Pulfrich effect) and possibly cause problems with driving. However, in the Trindade case series, none of the participants reported this phenomenon when tested.[14]

This study measures the HOAs for 6 mm, 4 mm, and 2 mm apertures. The extrapolation to the 1.6 mm aperture provided by the pinhole optics is theoretical, and at the time of writing, only 1 operated participant was available to confirm the reduced aberrations and improvement in vision predicted.

In summary, Zernike simulations and convolution analysis show the potential for marked improvement in CDVA and UNVA that can be provided with the small

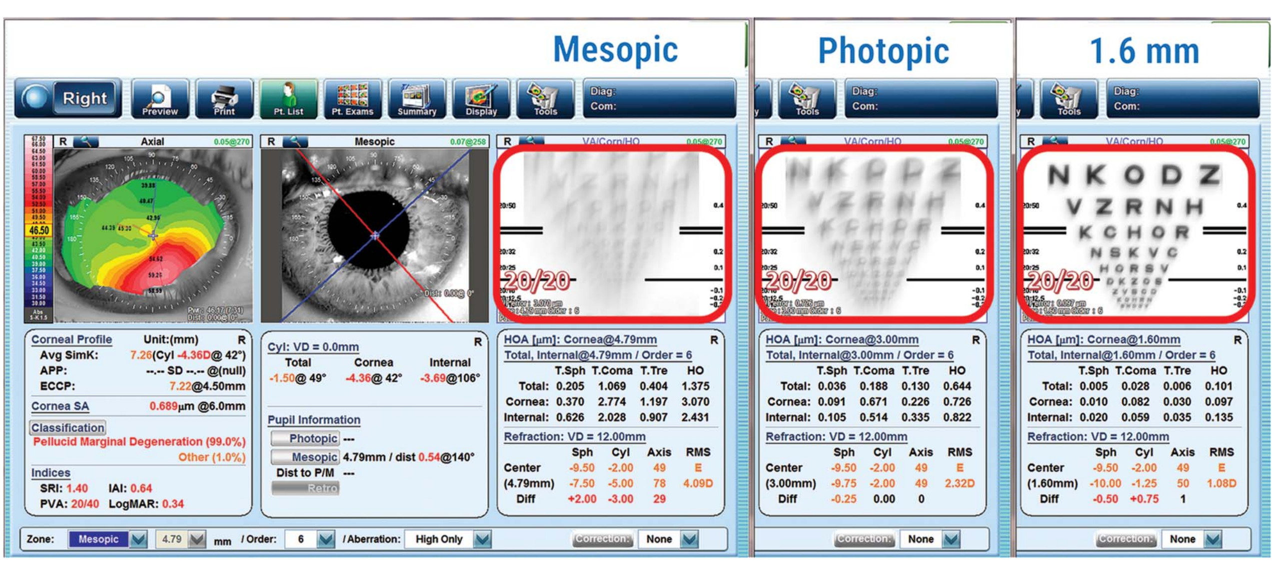

Figure 5. Nidek OPD-Scan topography and Zernike convolutions of corneal HOAs for different real and simulated pupil diameters (4.79 mm, 3.0 mm, and 1.6 mm). Although the contrast seems to be reduced, the simulation indicates the potential for CDVA 20/20 for this participant with pinhole optics.

aperture IOL in participants with keratoconus. The HOAs simulated for a 1.6 mm diameter were found to be substantially reduced, irrespective of the keratoconus disease stage. The decreased HOAs through the small aperture of the IOL can provide tolerance to fluctuations in refraction owing to large variation in curvature over entrance pupil in these patients. This technology can be a promising therapeutic option for highly aberrated corneas.

WHAT WAS KNOWN

- Keratoconic eyes have increased HOAs due to irregular astigmatism.
- Pinhole effect reduces the impact of HOAs in the optical system.
- Small aperture IOLs are currently approved to extend depth of focus after cataract and lens-based refractive surgery.

WHAT THIS PAPER ADDS

- Zernike simulations and convolution analysis showed the benefits of the small aperture optics in patients with keratoconus.
- For a 1.6 mm aperture diameter at the corneal plane (1.36 mm optical aperture simulated at the IOL plane), HOAs considerably decrease despite the keratoconus disease stage.
- Small aperture IOLs can be considered to reduce LOAs and HOAs in patients with keratoconus undergoing lens surgery.

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