Evaluation of Visual Outcomes in Patients With Aberrated Corneas Implanted With the IC-8 Small-Aperture IOL

Zhen Ling Teo, MBBS, MRCSEd, FRCOphth; Nicole Ming Sie, MMED(Ophthal), FRCOphth, FAMS; Jodhbir S. Mehta, FRCS(Ed), FAMS, PhD

ABSTRACT

PURPOSE: To assess the visual outcomes in patients with cataract implanted with a small-aperture intraocular lens (IOL) in eyes with aberrated corneas.

METHODS: This prospective, non-interventional, single-center clinical study was conducted at Singapore National Eye Centre, Singapore. Twenty-one patients with aberrated corneas had IC-8 IOL (Bausch & Lomb, Inc) implantation. An aberrated cornea was defined as from natural causes: keratoconus (n = 1, 4.8%), high coma (n = 2, 9.5%), corneal scar (n = 1, 4.8%), or iatrogenic causes: keratorefractive procedure (n = 17, 86%). Uncorrected and corrected visual acuities were measured at distance (600 cm) (UDVA and CDVA), intermediate (66.7 cm) (UIVA and CIVA), and near (40 cm) (UNVA and CIVA). Defocus curve was tested monocularly and binocularly. Contrast sensitivity (CS) was measured under photopic and mesopic conditions with and without glare.

RESULTS: In IC-8 eyes, the mean ± standard deviation UDVA, UIVA, and UNVA was 0.24 ± 0.18, 0.19 ± 0.18, and 0.14 ± 0.14 logMAR, respectively. Mean CDVA, CIVA, and CNVA in IC-8 eyes was 0.12 ± 0.17, 0.16 ± 0.15, and 0.19 ± 0.13 logMAR, respectively. Binocular mean UDVA, UIVA, and UNVA was 0.07 ± 0.10, 0.07 ± 0.10, and 0.13 ± 0.12 logMAR, respectively. Defocus curve testing yielded a depth of focus of 1.50 D monocularly and 2.00 D binocularly at a 0.2 logMAR threshold. Photopic binocular CS with and without glare improved over monocular CS of IC-8 and fellow eyes under all spatial frequencies. Mesopic binocular CS with and without glare were similar among monocular IC-8 and fellow eyes across spatial frequencies. Most patients reported low levels of visual symptoms.

CONCLUSIONS: The IC-8 IOL provides good monocular and binocular visual outcomes for patients with cataract who had aberrated corneas.

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Patient expectations for spectacle independence at all distances following cataract surgery has increased in recent years.[1] Multifocal and trifocal intraocular lenses (IOLs) provide good functional vision but have disadvantages such as reduced quality of vision, undesirable visual disturbances, and discrete non-continuous range of vision.[2-4] In addition, irregular corneal astigmatism and significant corneal higher order aberrations are not addressed by multifocal or trifocal IOLs and are often considered to be contraindicated in patients with aberrated corneas.[5]

Aberrated corneas with various types of corneal irregularities present unique challenges to achieving optimal visual outcomes after cataract surgery. A main challenge is potentially inaccurate corneal power measurements despite improved IOL formulas and improved optical instruments for corneal curvature and power measurements.[6] This can lead to refrac-

From Singapore National Eye Centre, Singapore Eye Research Institute, Singapore (ZLT, NMS, JSM); the Cornea and Refractive Surgery Group, Tissue Engineering and Cell Therapy Group, Singapore Eye Research Institute, Singapore (JSM); the Department of Cornea and External Eye Disease, Singapore National Eye Centre, Singapore (NMS, JSM); and the Ophthalmology and Visual Sciences Academic Clinical Program, Duke-NUS Medical School, Singapore (JSM).

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Address correspondence to Jodhbir S. Mehta, Singapore Eye Research Institute, The Academia, 20 College Road, Discovery Tower Level 6, 169856 Singapore. Email: jodhbir.s.mehta@singhealth.com.sg.

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tive surprises after cataract surgery, requiring subsequent surgical correction or enhancement and patient dissatisfaction.[7] Cornea irregularities may arise from preexisting natural causes such high astigmatism or keratoconus, or induced causes such as previous surgical procedures, trauma, and other diseases. With the increasing cumulative prevalence of refractive surgery rates,[8] predominantly keratorefractive procedures, the population of patients who have had refractive surgery undergoing cataract surgery will rise along with the demand to optimize visual and refractive outcomes after cataract surgery in this population.

Extended depth of focus IOLs are designed to provide more continuity from far to intermediate or near distances. The IC-8 IOL (Bausch & Lomb, Inc) is a small-aperture IOL that reduces defocus by decreasing the size of the blur circle to achieve extended depth of focus and has been shown to provide good uncorrected intermediate and near vision with fewer visual symptoms.[9-11] The IC-8 IOLs have potentially greater tolerance to spherocylindrical residual refractive errors due to its extended depth of focus.[10] This is important for patients with aberrated corneas, especially those who have received refractive surgery, where the broad depth of focus may also make it rather forgiving for postoperative refractive accuracy. Reports have suggested that small-diameter aperture optics such as the IC-8 IOL may improve visual acuity in patients with significant higher order aberrations.[12-14]

In this study, we prospectively evaluated visual outcomes in patients with aberrated corneas who had been implanted with the IC-8 IOL after cataract removal. We hypothesized that patients with aberrated corneas implanted with the IC-8 IOL would achieve a good distance, intermediate, and near visual acuity postoperatively.

PATIENTS AND METHODS

Study Design

A prospective, non-randomized, single-arm, single-visit, single-center clinical study was conducted in Singapore National Eye Centre, Singapore, from February to December 2022. This study was approved by the SingHealth centralized institutional review board and was conducted in accordance with applicable Good Clinical Practices, U.S. Code of Federal Regulations pertaining to international clinical study, International Conference on Harmonization guidelines, and the tenets of the Declaration of Helsinki. All participants provided written informed consent prior to study-specific examinations to meet all inclusion and exclusion criteria.

Definition of Aberrated Cornea and Study Eyes

In this study, an aberrated cornea was defined as corneal irregularity due to preexisting natural causes including irregular astigmatism, keratoconus, scarring from previous infection, or induced causes including previous keratorefractive surgery. The study eye was defined as the eye with a history of an "aberrated cornea" and underwent IC-8 IOL implantation following cataract removal. The fellow eye was defined as the contralateral eye of the same patient that was not implanted with an IC-8 IOL. Although IC-8 IOL implantation was based on the clinical decision by a senior corneal specialist, in patients with bilateral cornea aberrations including keratoconus, the eye with the worse aberration was chosen for IC-8 implantation. IC-8 implantation in keratoconic eyes is off-label use.

Inclusion and Exclusion Criteria for Study Eye

This study included eyes with baseline "aberrated corneas" that were implanted with the IC-8 IOL after cataract removal. The following inclusion criteria were applied to the study eye and patient: age 22 years and older; able to comprehend and signed informed consent; availability, willingness, and sufficient cognitive awareness to comply with study examination procedures and visits; aberrated cornea prior to cataract surgery, defined above; and underwent cataract surgery and IC-8 IOL implantation at least 3 months prior to recruitment.

We excluded eyes that had baseline corrected distance visual acuity (CDVA) worse than 20/25 in either eye; presence of ocular abnormalities other than corneal irregularities that may confound the study outcomes including strabismus, amblyopia, retinal/macular abnormalities, history of ocular inflammation, or any ocular pathology identified that may affect visual acuity to a level worse than 20/25 baseline CDVA; previous intraocular surgery (except cataract surgery); previous corneal cross-linking with residual corneal haze; ocular conditions requiring planned ocular surgical intervention (except Nd:YAG capsulotomy); severe dry eye or other conditions including hormonal fluctuations that may lead to unstable refraction or visual acuity measurements or significant eye discomfort; and patients who were pregnant or nursing.

Ophthalmic Assessment

All participants underwent a comprehensive eye examination at the Singapore National Eye Centre clinic according to a standardized protocol and test setting at all visits. Monocular and binocular uncorrected and corrected distance (600 cm) (UDVA and CDVA), intermediate (66.7 cm) (UIVA and CIVA, and near (40 cm)

(UNVA and CNVA) visual acuities were measured under photopic lighting conditions with the Optec 6500 Vision Tester (Stereo Optical Company, Inc) with Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity charts. Manifest refraction was measured at 6 m using an ETDRS chart. The midpoint refraction technique was in view of the extended depth of focus provided by the small-aperture optics. Defocus curves were performed monocularly and binocularly using ETDRS charts calibrated for 4 m in standard photopic conditions, with best-corrected distance manifest refraction. For manifest refraction between +2.00 and -2.00 diopters (D), 0.50-D defocus steps were used, whereas -0.25-D steps were used in the region from +0.50 through -0.50 D. Patients were instructed to read the chart from left to right for one test followed by right to left in the subsequent test to avoid chart memorization. Monocular and binocular contrast sensitivity were measured under photopic and mesopic conditions with and without glare using the Functional Acuity Contrast Test (FACT) chart with sine wave gratings in the Optec 6500 Vision Tester. The spatial frequencies tested under mesopic conditions were 1.5 to 12 cycles/degree (cpd) and were 3 to 18 cpd under photopic conditions. Pupil size was measured in photopic, mesopic, and pharmacologically dilated conditions up to the nearest 0.50 mm using a pupillometer.

Slit-lamp biomicroscopy (model BQ-900; Haag-Streit) was performed by a single experienced corneal specialist (JSM) to detect abnormalities of the anterior segment including aqueous cells and flare, corneal edema, posterior capsule striae, posterior capsule opacification, and IOL position. Tear break-up time was measured and intraocular pressure measured by Goldmann applanation tonometry. Dilated fundus examination was performed with slit-lamp biomicroscopy and a +90.00 D lens, as well as binocular indirect ophthalmoscopy. Corneal tomography was measured with the Pentacam (Oculus Optikgeräte GmbH). All aberrometry measurement, corneal higher order aberrations, and surface regularity index scores were recorded from the tomographer.

To obtain information on potential visual disturbances, the Quality of Vision (QoV) questionnaire[15] followed by the Small Aperture Patient Questionnaire (SAPQ) (**Table A**) were administered by trained study personnel at baseline (before any tests were performed) and at follow-up. Visual symptoms were assessed by both the QoV questionnaire and SAPQ. Driving task performance and patient satisfaction were assessed by the SAPQ. Patients reported "yes" or "no" to the experience of the assessed symptoms; if the answer was yes, then they reported the severity (0 = not at all, 1 = very mild, 2 = mild, 3 = moderate, 4 = severe, and 5 = very severe) and the degree of bothersomeness (0 = not at all, 1 = a little, 2 = quite, 3 = very) of the visual symptoms that they experienced. Under informed consent, source documents were used to obtain information on patient demographics, ocular and medical history, and history of posterior capsulotomy.

Patients discontinued the study if at their own request; if the patient was uncontactable; if the patient was uncooperative or refused to return; and if the patient was deceased, ill, unable to travel for visit, or institutionalized.

Outcome Measures and Statistical Analysis

Primary outcome measures included mean monocular UDVA of the study eye and if it achieved 0.3 logarithm of the minimum angle of resolution (logMAR) or better; mean monocular UIVA of the study eye and if it achieved 0.3 logMAR or better; and mean monocular UNVA of the study eye and if it achieved not worse than 0.3 logMAR. Further analyses for binocular UDVA and CDVA, CIVA, and CNVA, manifest refraction and cylinder, and subjective satisfaction will be reported by descriptive statistics. For monocular and binocular photopic distance-corrected defocus curves, the mean depth of focus was evaluated at 0.2 and 0.3 logMAR visual acuity thresholds. All statistical analyses were performed using the statistical software SAS/BASE and ASA/STAT (version 9.4 for Windows; SAS Institute, Inc) and statistical software R (version 3.4.1; The R Foundation for Statistical Computing). A *P* value less than .05 was considered statistically significant.

RESULTS

A total of 21 patients were enrolled in this study and the study included 21 study eyes implanted with the IC-8 IOL and 21 fellow eyes. Baseline characteristics of the 21 patients enrolled are seen in **Table B**. The mean age was 60.7 ± 7.3 years, and 52.4% were male.

Among the 21 study eyes enrolled, the most common cause of "aberrated cornea" was a previous keratorefractive procedure (n = 17, 81.0%), of which 15 study eyes underwent laser in situ keratomileusis (LASIK), 1 underwent photorefractive keratotomy (PRK), and 1 underwent radial keratotomy (RK) (**Figure A**). One patient had a history of cornea inlay explanted before IC-8 IOL implantation (**Figure B**). The remaining study eyes had aberrated corneas due to corneal scarring (n = 1, 4.8%) (**Figure C**), keratoconus (n = 1, 4.8%), and irregular astigmatism with high coma aberration (n = 2, 9.5%). Among the 15 eyes that underwent LASIK, 14 had myopic correction and 1 eye had hyperopic correction. The mean keratometric cylinder was 1.40 ± 1.30 D, mean total higher order aberration was 1.3 ±

TABLE 1

Monocular Uncorrected and Corrected Visual Acuities (Mean ± SD) in IC-8 Eyes (n = 20)

	Uncorrected			Corrected		
Visual Acuity	**Mean ± SD**	**Snellen Equivalent**	**Range**	**Mean**	**Snellen Equivalent**	**Range**
Distance	0.24 ± 0.18	20/35	0.16 to 0.32	0.12 ± 0.17	20/26	0.04 to 0.20
Intermediate	0.19 ± 0.18	20/31	0.11 to 0.28	0.16 ± 0.15	20/29	0.09 to 0.23
Near	0.14 ± 0.14	20/28	0.08 to 0.21	0.19 ± 0.13	20/31	0.12 to 0.25

logMAR = logarithm of the minimum angle of resolution; SD = standard deviation
The IC-8 intraocular lens is manufactured by Bausch & Lomb, Inc.

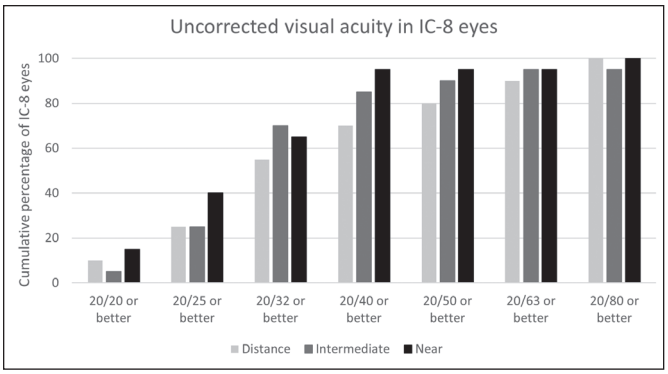

Figure 1. Monocular uncorrected visual acuities achieved in eyes implanted with the IC-8 intraocular lens (Bausch & Lomb, Inc).

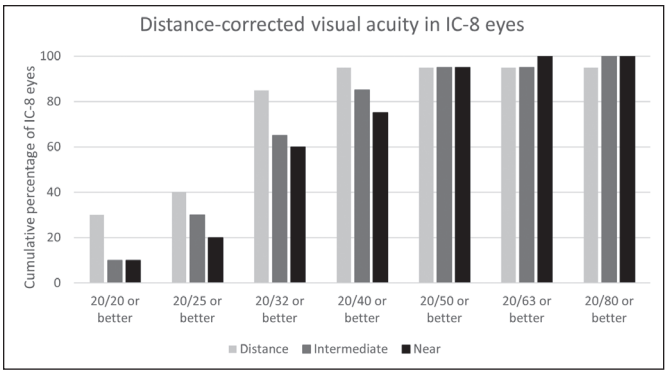

Figure 2. Monocular distance-corrected visual acuities achieved in eyes implanted with the IC-8 intraocular lens (Bausch & Lomb, Inc).

0.9 µm, mean surface regularity index was 0.2 ± 0.7, and mean corneal spherical aberration was 0.5 ± 0.4 µm (**Table B**). The mean duration of follow-up since IC-8 IOL implantation was 19.2 months (range: 3.2 to 35.9 months) with a minimum follow-up duration of 3.2 months (97 days).

Among the 21 fellow eyes enrolled, 18 eyes had previous corneal refractive procedures and 1 had dysfunctional lens syndrome with internal aberrations. Of 21 fellow eyes, 18 eyes (85.7%) had irregular astigmatism. The mean keratometric cylinder among fellow eyes was 1.10 ± 0.90 D, mean total higher order aberration was 1.2 ± 0.6 µm, mean surface regularity index was 0.5 ± 0.8, and mean corneal spherical aberration was 0.6 ± 0.4 µm. Of the 21 fellow eyes, 13 had a monofocal IOL, 1 had a monofocal toric IOL, and 7 were phakic. Paired *t*-tests performed showed that baseline surface regularity index was higher in fellow eyes than in IC-8 eyes, but there was otherwise no statistically significant difference in baseline mean keratometric cylinder, mean total higher order aberrations, and mean corneal spherical aberrations between IC-8 and fellow eyes. (**Table C**).

One patient (n = 1, 5%) withdrew during the study due to fatigue. The remaining study population (n = 20) was used for outcome analysis.

Visual Acuity and Manifest Refraction

The mean UDVA, UIVA, and UNVA in IC-8 eyes was 0.24 ± 0.18, 0.19 ± 0.18, and 0.14 ± 0.14 logMAR, respectively (**Table 1**). The mean best CDVA, CIVA, and CNVA were 0.12 ± 0.17, 0.16 ± 0.15, and 0.19 ± 0.13 logMAR, respectively. Of the 20 IC-8 eyes evaluated, the cumulative percentage of eyes that achieved 0.3 logMAR or better was 70% (n = 14), 85% (n = 17), and 95% (n = 19) for UDVA, UIVA, and UNVA, respectively (**Figure 1**). The cumulative percentage of IC-8 eyes that achieved 0.3 logMAR or better was 95% (n = 19), 85% (n = 17), and 75% (n = 15) for CDVA, CIVA, and CNVA, respectively (**Figure 2**). The mean manifest refraction spherical equivalent was -0.79 D in IC-8 eyes and -0.44 D in fellow eyes. The mean refractive cylinder in IC-8 eyes was 0.88 and 0.60 D in fellow eyes (**Table D**).

Among the 20 patients, 14 (70%) had either a monofocal or monofocal toric IOL implanted in the fellow eye. Two of the 14 pseudophakic fellow eyes had an IOL implanted less than 60 days before the study visit and were excluded from the binocular comparison subgroup analysis. A binocular comparison subgroup analysis was performed in the remaining 12 patients. Among these remaining 12 patients, the 12 IC-8 eyes included in this analy-

TABLE 2

Visual Acuity Comparison With Fellow Eyes With Monofocal Toric or Non-toric Lens (n = 12)

	IC-8 Eye		Fellow Eye			Binocular	
Parameter	Mean ± SD	Snellen Equivalent	Mean ± SD	Snellen Equivalent	*P*[a]	Mean ± SD	Snellen Equivalent
UDVA	0.21 ± 0.20	20/33	0.17 ± 0.20	20/30	.286	0.07 ± 0.10	20/23
UIVA	0.18 ± 0.21	20/31	0.24 ± 0.16	20/35	.566	0.07 ± 0.10	20/23
UNVA	0.12 ± 0.17	20/26	0.28 ± 0.20	20.38	.058	0.13 ± 0.12	20/27
CDVA	0.12 ± 0.21	20/27	0.07 ± 0.17	20/24	.359	-0.00 ± 0.09	20/20
CIVA	0.16 ± 0.16	20/29	0.26 ± 0.13	20/36	.083	0.10 ± 0.10	20/25
CNVA	0.18 ± 0.14	20/30	0.32 ± 0.14	20/41	.023	0.12 ± 0.11	20/26

CDVA = corrected distance visual acuity; CIVA = corrected intermediate visual acuity; CNVA = corrected near visual acuity; SD = standard deviation; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity
[a]Comparison between IC-8 and fellow eyes.
The IC-8 intraocular lens is manufactured by Bausch & Lomb, Inc.

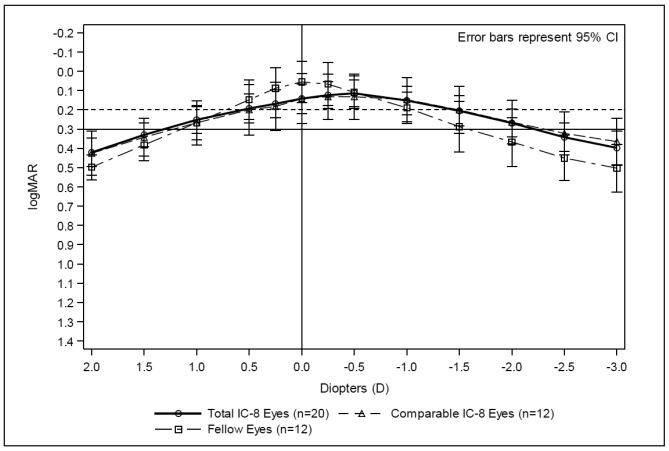

Figure 3. Monocular defocus curves in eyes implanted with the IC-8 intraocular lens (Bausch & Lomb, Inc) and fellow eyes (n = 20).

sis are: the eye with high coma aberration and 11 eyes that had LASIK. Mean binocular visual acuity was 0.07 ± 0.10 (20/23), 0.07 ± 0.10 (20/23) and 0.13 ± 0.12 (20/27) logMAR (Snellen equivalent) for UDVA, UIVA, and UNVA, respectively. We found that CNVA was statistically significantly better in IC-8 eyes compared to fellow eyes with a monofocal IOL (P = .023). There was no statistical difference between IC-8 and fellow monofocal IOL eyes in UDVA, UIVA, UNVA and baseline CDVA and DCIVA (**Table 2**) Mean binocular visual acuities were -0.003 ± 0.09 (20/20), 0.10 ± 0.10 (20/25), and 0.12 ± 0.11 (20/26) logMAR (Snellen equivalent) for CDVA, CIVA, and CNVA, respectively. **Table 2** shows the comparison between IC-8 eyes, fellow pseudophakic eyes, and binocular visual acuities. Binocular mean UDVA, UIVA, and UNVA were 0.07 ± 0.10 (20/23), 0.07 ± 0.10 (20/23), and 0.13 ± 0.12 (20/27) logMAR (Snellen equivalent), respectively.

Defocus Curves

Monocular defocus curve testing demonstrated that visual acuity of 0.2 logMAR or better was achieved in IC-8 eyes (n = 20, 100%) at the defocus range between +0.50 and -1.50 D, yielding 1.45 D in negative defocus range at the 0.2 logMAR threshold (**Figure 3**). Subgroup analysis was performed for the binocular comparison group (n = 12, 60%), and monocular defocus curve was compared between IC-8 eyes and fellow monofocal or monofocal toric IOL eyes. Monocular defocus curve testing showed that visual acuity of 0.2 logMAR or better was achieved in this subgroup of 12 IC-8 eyes at the defocus range between approximately +0.50 and -1.40 D, yielding 1.45 D in negative defocus range, similar to the above. Meanwhile, fellow monofocal eyes achieved visual acuity of 0.2 logMAR or better at the defocus range between approximately +1.00 to -1.00 D, yielding a smaller 1.05 D in negative defocus range. Binocular defocus curve testing was performed in this subgroup (n = 12, 60%) and demonstrated that visual acuity of 0.2 logMAR or better was achieved at the defocus range between +1.00 and -2.00 D, yielding 2.00 D in negative defocus range at the 0.2 logMAR threshold (**Figure D**). Paired *t*-tests performed to compare monocular defocus curve between the IC-8 eye and monofocal IOL eye showed no statistically significant difference (all $P > .104$) (**Figure E**).

Glare Contrast Sensitivity: Photopic and Mesopic

Under photopic conditions, 95% (n = 19), 85% (n = 17), 70% (n = 14), and 25% (n = 5) of IC-8 eyes were able to see at the highest contrast sensitivity level at 3, 6, 12, and 18 spatial frequencies (cpd), respectively. **Figure F** shows contrast sensitivity among IC-8 eyes, fellow monofocal eyes, and binocular comparison subgroup in photopic conditions. At all spatial frequencies, mean contrast sensitivity in IC-8 eyes was inferior

to monofocal fellow eyes in both photopic with glare and without glare conditions and this was statistically significant for photopic condition with no glare at 18 cpd (P = .02) (**Table E**). At this highest spatial frequency (18 cpd), a larger proportion of IC-8 eyes (without glare [83.3%], with glare [66.7%]) compared to fellow monofocal eyes (without glare [50.0%], and with glare [41.7%]) were unable to see at the highest contrast level.

Under mesopic conditions, 90% (n = 18), 90% (n = 18), 70% (n = 14), and 25% (n = 5) of IC-8 eyes were able to see at the highest contrast sensitivity level at 1.5, 3, 6, and 12 cpd, respectively. Among eyes that were able to see at the highest contrast sensitivity, the mean logCS was similar between glare and without glare at 1.5, 6, and 12 cpd. At 3 cpd, mean logCS was worse for mesopic contrast sensitivity with glare (mean < 1.3) than without glare (mean < 1.5) (**Figure F**). At all spatial frequencies, mean contrast sensitivity in IC-8 eyes was inferior to monofocal fellow eyes in both mesopic with and without glare conditions and this was statistically significant under mesopic conditions with glare at 1.5, 3, and 6 cpd (P < .04) and mesopic conditions without glare at 3, 6, and 12 cpd (P < .04) (**Table E**). At the highest spatial frequency (18 cpd), a larger proportion of IC-8 eyes (without glare [75.0%], with glare [75.0%]) compared to fellow monofocal eyes (without glare [33.3%], with glare [66.7%]) were unable to see at the highest contrast level.

Mean binocular photopic contrast sensitivity with and without glare was superior (> 0.15 logCS difference) to IC-8 eyes at all spatial frequencies (**Figure G**). In mesopic conditions, mean binocular contrast sensitivity with and without glare was superior to monocular IC-8 eyes at all spatial frequencies (**Figure G**).

Comparison of contrast sensitivity between binocular (one IC-8 eye and one monofocal eye) and monocular monofocal eyes showed that in photopic conditions, binocular contrast sensitivity was comparable to monocular monofocal contrast sensitivity in most situations and even statistically significantly superior in photopic conditions with glare at 6 cpd (P = .05), and without glare at 3 (P = .01) and 6 (P = .04) cpd (**Table F**). In mesopic conditions, binocular (one IC-8 eye and one monofocal eye) and monocular monofocal eyes had no statistically significant difference in contrast sensitivity (all P > .16) except at 1.5 cpd under mesopic with glare conditions, where monocular monofocal eyes had better contrast sensitivity than binocular testing (P = .04) (**Table F**).

Subgroup Analysis IC-8 Eyes With Previous Keratorefractive Procedure

We performed a subgroup analysis of eyes that had a prior keratorefractive procedure and IC-8 implantation (n = 17). The mean UDVA, UIVA, and UNVA in IC-8 eyes was 0.26 ± 0.17, 0.21 ± 0.19, and 0.14 ± 0.15 logMAR, respectively. The mean CDVA, CIVA, and CNVA was 0.15 ± 0.17, 0.18 ± 0.16 and 0.19 ± 0.14 logMAR, respectively (**Table G**). Monocular defocus curve testing in this subgroup demonstrated a similar 1.45 D in negative defocus range at the 0.2 logMAR threshold (**Figure H**). Contrast sensitivity in photopic and mesopic conditions in the IC-8 eyes for this subgroup was similar to the overall contrast sensitivity results with IC-8 eyes inferior to fellow monofocal eyes and binocular testing.

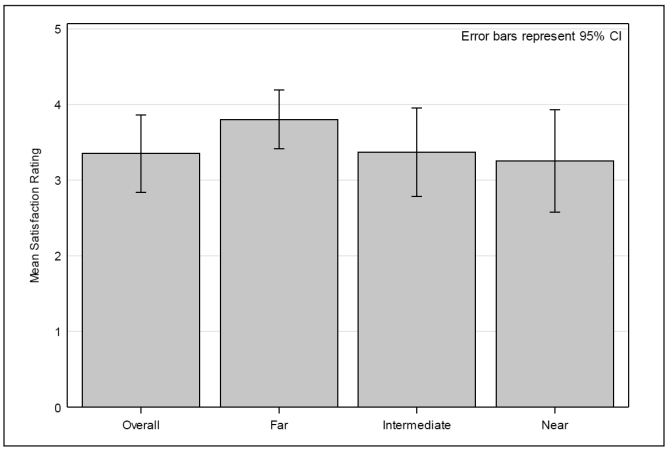

Figure 4. Mean patient satisfaction with vision (n = 20). Satisfaction coding: 1 = very dissatisfied, 2 = dissatisfied, 3 = neutral, 4 = satisfied, and 5 = very satisfied.

Subjective Visual Symptoms

The mean overall satisfaction score was 3.4 (of 5, where a higher score represents greater satisfaction), with a mean score of 3.28, 3.4, and 3.3 for distance, intermediate, and near vision, respectively (**Figure 4**). The mean rating of problematic driving was 1.1 during the day (of 5, where the higher score represents greater difficulty driving) and 1.7 during the night. The mean scores for severity and bothersomeness for all visual symptoms were less than 1. Across all visual symptoms assessed, most patients (n = 14, 70%) reported none (0) or very mild (1) for severity and 95% of patients (n = 19) reported none (0) or a little (1) for bothersomeness. Visual symptoms that received a severe rating were: double or multiple images (2 of 20, 10%), vision fluctuation (1 of 20, 5%), surroundings seem dimmer (1 of 20, 5%), and negative dysphotopsia (1 of 20, 5%). No visual symptom had a very severe rating. Visual symptoms that received a very bothersome rating were: hazy vision (1 of 20, 5%), blurry vision (1 of 20, 5%), double or multiple images (1 of 20, 5%), vision fluctuation (1 of 20, 5%), focusing difficulties (2 of 20, 10%), problem judging distance of moving objects (1 of 20, 5%), surround-

ings seem dimmer (1 of 19, 5.3%), and eye dryness (2 of 20, 10%).

Adverse Events

There were five ocular adverse events reported in 5 patients during the study that occurred postoperatively and were mild and unrelated to the study procedure. Three adverse events reported were posterior capsular opacification that affected vision and one was zonulysis resulting in subsequent IOL subluxation. All 3 eyes with posterior capsular opacification underwent successful Nd:YAG capsulotomy procedures. The eye with postoperative IOL subluxation underwent subsequent removal of the IC-8 IOL and secondary scleral fixation of a monofocal IOL. There were no other reported intraoperative adverse events (ocular and nonocular) during the study. At the time of study visit, with the exception of the eye with IOL subluxation, the remaining 19 IC-8 eyes showed good IOL status with good centration (no tilt, no pupillary capture, no dislocation), no optic discoloration, no nuclear or cortical remnants, no IOL opacities, and no epithelial cell growth on the anterior surface of the IOL. Mean intraocular pressure was similar in both groups at 12.4 mm Hg (IC-8 eye) and 13.6 mm Hg (fellow eye).

DISCUSSION

In this study, we evaluated outcomes in patients with aberrated corneas who had IC-8 IOL implantation following cataract removal. This study found that the IC-8 IOL provides good uncorrected and corrected visual acuities in eyes with corneal aberrations. Compared to fellow eyes that underwent monofocal or monofocal toric IOL, IC-8 eyes achieved comparable visual acuity at distance and superior visual acuity at intermediate and near with 70%, 85%, and 95% of IC-8 eyes achieving 0.3 logMAR or better unUDVA, UIVA, and UNVA, respectively. We observed that there was a trend toward better UNVA for IC-8 eyes, with a *P* value close to statistical significance at .058. The lack of statistical significance may be due to inadequate power from the small sample size, which is a limitation of this study. Of note, among the eyes that had postoperative CDVA worse than 0.1 logMAR (Snellen equivalent 20/25), 3 eyes had significant posterior capsule opacification, 1 eye had a fold in the posterior capsule involving the visual axis, 1 eye had significant dry eye disease, and 1 eye had zonulysis with intraocular lens subluxation. The 4 eyes with posterior capsular opacification and folds underwent successful Nd:YAG capsulotomy with subsequent CDVA of 0.1 logMAR or better. The eye with zonulysis and intraocular lens subluxation required subsequent removal of IC-8 IOL and secondary scleral-fixated IOL implant with CDVA of 0.1 logMAR. The eye with significant dry eye disease continued dry eye treatment with CDVA of 0.2 logMAR at last follow-up visit. In this study, the IC-8 eyes also demonstrated increased depth of focus (1.45 D in negative defocus range monocularly and 2.00 D in the negative defocus range binocularly) compared to traditional monofocal or monofocal toric IOLs (1.05 D negative defocus range monocularly).

This study evaluated the performance of the IC-8 IOL in a specific group of patients with aberrated corneas who are prone to postoperative visual phenomenon and have limited IOL choices to correct for both intermediate and near vision. Previous studies have shown that the IC-8 (Apthera) IOL can achieve good postoperative centration[16] and provides good postoperative visual acuity and contrast sensitivity among both eyes with normal and pathological corneas with severe irregularities due to keratoconus, previous corneal graft, or scarring after trauma.[10,11,14,16] In contrast, our study evaluated IC-8 performance in a population of which most cases of aberrated cornea were due to previous refractive surgery. This is important because with the increasing cumulative prevalence of refractive surgery, the population with aberrated corneas due to previous corneal refractive procedures will rise and thus it is beneficial to evaluate whether the IC-8 IOL can perform well for this subgroup of patients. Studies have also shown that the IC-8 IOL provides an extended depth of focus among eyes with normal cornea with visual acuity of 0.3 logMAR or better over a defocus range of +0.50 to -1.50 D.[10] There is limited existing evidence on whether this range remains so for patients with aberrated corneas and our study found that this subgroup can achieve similar extended depth of focus performance with visual acuity of 0.2 logMAR or better at the defocus range between +0.50 to -1.50 D.

In patients with bilateral aberrated corneas, binocular implantation of IC-8 IOL may be considered in view that bilateral IOL implantation had a marginally larger extended range of focus (by 0.25 D).[17] However, these patients often have asymmetric aberrations and there is evidence that patients with bilateral IC-8 IOL implantation had a higher perception of photic phenomena and lower overall satisfaction than monocular implantation.[18] Hence, considering the evidence, unilateral IC-8 IOL implantation may be better in patients with bilateral aberrated corneas.

There is also limited evidence on whether monocular IC-8 implantation with fellow eye monofocal IOL implantation will provide good binocular performance in patients with aberrated corneas. Hence the inclusion of a subgroup analysis of patients in our study with fellow monofocal IOL allows for the comparison between the IC-8 IOL and monofocal IOL, and evaluation of binocular visual performance in patients

with aberrated corneas. Our study found that although contrast sensitivity in IC-8 eyes was inferior to that in monofocal fellow eyes, binocular contrast sensitivity (where one eye is implanted with the IC-8 and the fellow eye with a monofocal IOL) was largely comparable to monofocal IOL levels of contrast sensitivity and even superior in certain photopic conditions. This provides a solution where the patient has one eye implanted with a monofocal IOL and the other eye with a IC-8 IOL, allowing the patient with aberrated corneas to have the benefits of both IOLs in a binocular state.

This study has a few limitations. First, contrast sensitivity results in this study have limited generalizability due to the exclusion from analysis of a significant proportion of patients that were unable to see the highest contrast of the testing chart. Second, the reporting of visual symptoms and driving ability may have inherent biases because patients may report these symptoms in a binocular state and it may be difficult to pinpoint symptoms and satisfaction to the monocular IC-8 eye. Third, there was inadequate statistical power due to the small sample size, because IC-8 implantation for aberrated corneas with good baseline visual acuity is not yet widely practiced in our setting. Finally, this study was conducted at a single site and the reported data may reflect the surgical techniques or preferences of the investigator thus limiting generalizability. Nonetheless, the standardized clinical measurements attempt to provide a good assessment of the clinical performance of the IC-8 IOL in patients with aberrated cornea.

This study shows that the IC-8 IOL not only assists in the management of presbyopia but is able to safely provide a good range of vision with increased spectacle independence and extended depth of focus in patients with aberrated corneas.

AUTHOR CONTRIBUTIONS

Study concept and design (ZLT, NMS, JSM); data collection (ZLT, NMS, JSM); analysis and interpretation of data (ZLT, NMS, JSM); writing the manuscript (ZLT, NMS, JSM); critical revision of the manuscript (ZLT, NMS, JSM)

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Small Aperture Patient Questionnaire (SAPQ)

Instructions:

- Answer the questions below about your eyesight in your **everyday life**.
- Please think about **the last 7 days** when you answer these questions.
- If you have had surgery, please respond based on **how you are now**, not before your surgery.
- Please check **one box** per line.

1. A) In the last 7 days, how often did you have a problem with judging the distance or closeness of moving objects (for example, a moving ball or a moving car seemed too near or too far from you)?

Never	Occasionally	Quite often	Very often
☐	☐	☐	☐

B) How severe was it?

Not at all	Mild	Moderate	Severe
☐	☐	☐	☐

C) How bothersome was it?

Not at all	A little	Quite	Very
☐	☐	☐	☐

2. A) In the last 7 days, how often did your surroundings, due to your eyesight, seem dimmer than usual?

Never	Occasionally	Quite often	Very often
☐	☐	☐	☐

B) How severe was it?

Not at all	Mild	Moderate	Severe
☐	☐	☐	☐

C) How bothersome was it?

Not at all	A little	Quite	Very
☐	☐		☐

3. A) In the last 7 days, how often did you have a problem seeing when lighting conditions changed abruptly (for example, driving into a dark tunnel or walking into a dark movie theater)?

Never	Occasionally	Quite often	Very often
☐	☐	☐	☐

B) How severe was it?

Not at all	Mild	Moderate	Severe
☐	☐	☐	☐

C) How bothersome was it?

Not at all	A little	Quite	Very
☐	☐	☐	☐

4. A) In the last 7 days, how often did you see a dark or gray crescent-shaped or arc-shaped shadow to the side of your vision?

Never	Occasionally	Quite often	Very often
☐	☐	☐	☐

B) How severe was it?

Not at all	Mild	Moderate	Severe
☐	☐	☐	☐

C) How bothersome was it?

Not at all	A little	Quite	Very
☐	☐	☐	☐

5. A) In the last 7 days, how often did you have eye dryness (such as irritated, gritty, burning or watery eyes)?

Never	Occasionally	Quite often	Very often
☐	☐	☐	☐

B) How severe was it?

Not at all	Mild	Moderate	Severe
☐	☐	☐	☐

C) How bothersome was it?

Not at all	A little	Quite	Very
☐	☐	☐	☐

6. In the last 7 days, have there been any other issues with your eyes or eyesight?

Yes	No
☐	☐

If **Yes**, please describe the issues with your eyesight:

_____

_____

How often, how severe and how bothersome were the issues?

_____

_____

_____

Instructions:

- The questions below are about your eyesight in your **everyday life.**
- Please think about **the last 7 days** when you answer these questions.
- If you have had surgery, please respond based on **how you are now**, not before your surgery.
- Please check **one box** for each question.
- The questions below are about any problems you had with **driving** while using both eyes **without any corrective eyeglasses or contact lenses**.
- If you did not drive for reasons other than your eyesight (for example, if you didn't have a car), please check the **N/A box**.

T1. How much problem did you have driving **during the day,** due to your eyesight?	None	A little	Moderate	A Great deal	Unable to drive without eyeglasses or contact lenses
N/A ☐	☐	☐	☐	☐	☐

If you had problems driving **during the day,** please describe what eyesight issues caused this problem.

_____

_____

T2. How much problem did you have driving **at night,** due to your eyesight?	None	A little	Moderate	A Great deal	Unable to drive without eyeglasses or contact lenses
N/A ☐	☐	☐	☐	☐	☐

If you had problems driving **at night**, please describe what eyesight issues caused this problem.

_____

_____

Instructions:

- The questions below are about your eyesight in your **everyday life.**
- Please think about **the last 7 days** when you answer these questions.
- If you have had surgery, please respond based on how you are now, not before your surgery.
- Please check **one box** for each question.
- The questions below are about your **satisfaction** with your eyesight while using both eyes **without any corrective eyeglasses or contact lenses**.

S1. How satisfied are you with your vision overall?	Very Satisfied	Satisfied	Neutral	Dissatisfied	Very Dissatisfied
	☐	☐	☐	☐	☐

S2. How satisfied are you with your far vision (such as driving, reading street signs)?	Very Satisfied	Satisfied	Neutral	Dissatisfied	Very Dissatisfied
	☐	☐	☐	☐	☐

S3. How satisfied are you with your intermediate vision (at arm's length or slightly beyond, such as computer viewing)?	Very Satisfied	Satisfied	Neutral	Dissatisfied	Very Dissatisfied
	☐	☐	☐	☐	☐

S4. How satisfied are you with your near vision (within arm's length, such as reading or sewing)?	Very Satisfied	Satisfied	Neutral	Dissatisfied	Very Dissatisfied
	☐	☐	☐	☐	☐

S5. If you had to decide again, would you have this procedure done?	Yes ☐ No ☐ If you answered "no", please explain: _____ _____ _____ _____

Table B
Baseline Characteristics of Study Eyes (n = 21)

Demographics	Mean or Number (%)	Range (Minimum- Maximum)
Age, years	60.7 ± 7.3	49.0 – 78.0
Gender		
Male	11 (52.4)	
Female	10 (47.6)	
Study eye*		
Right		
Left		
Primary cause of complex cornea		
Cornea refractive procedure	17 (81.0)	
Keratoconus	1 (4.8)	
Irregular astigmatism	2 (9.5)	
Corneal scar	1 (4.8)	
Dry Eye	13 (61.9)	
Keratometric Cylinder (D)	1.4 ± 1.3	0.0 – 5.6
Total HOA (um)	1.3 ± 0.9	0.5 – 4.2
Surface Regularity Index	0.2 ± -0.7	-1.3 – 1.4
Corneal Spherical Aberration (um)	0.5 ± 0.4	-0.7 – 1.6
Duration since IC-8 implantation (days)	582.3 (333.2)	97.0 – 1078.0

D = diopters; HOA = higher order aberrations

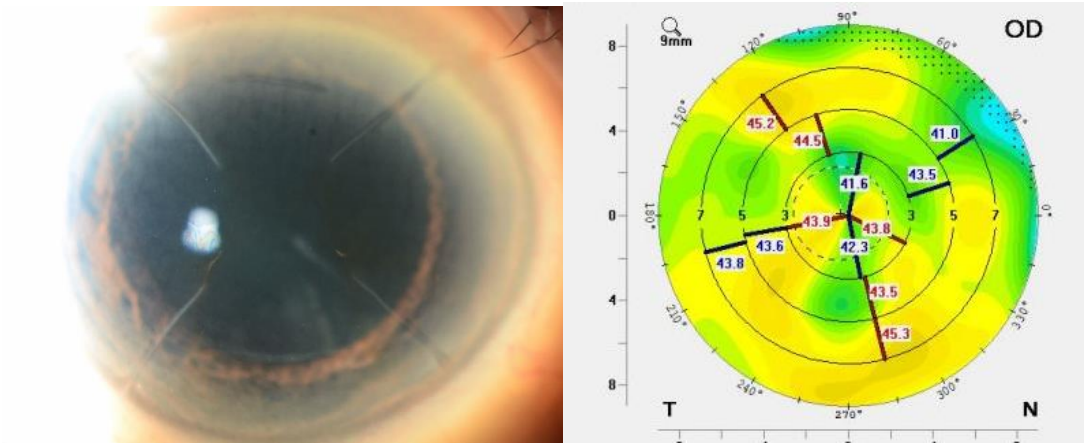


Figure A. Clinical photograph (*left)* and corneal topography axial curvature map *(right*) of study eye with previous radial keratotomy.

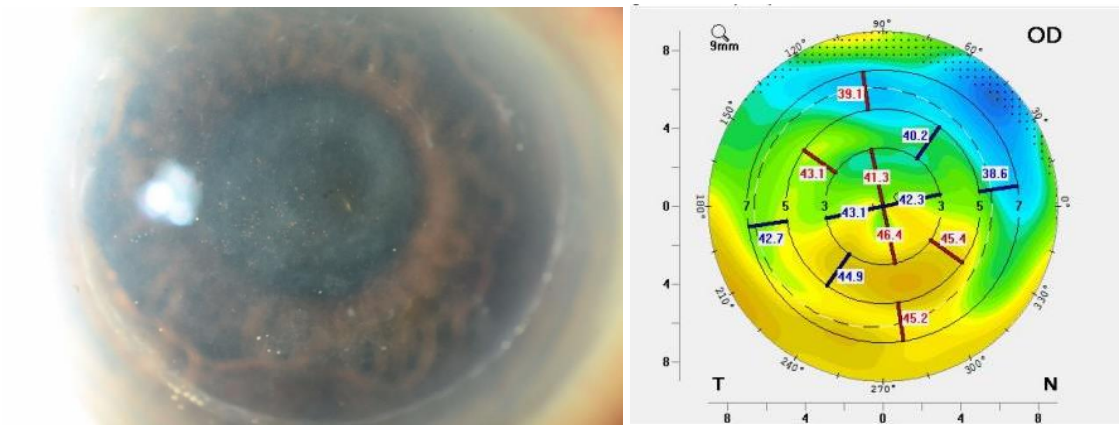


Figure B. Clinical photograph (*left)* and corneal topography axial curvature map *(right*) of study eye with previous corneal inlay explanted and subsequent IC-8 IOL.

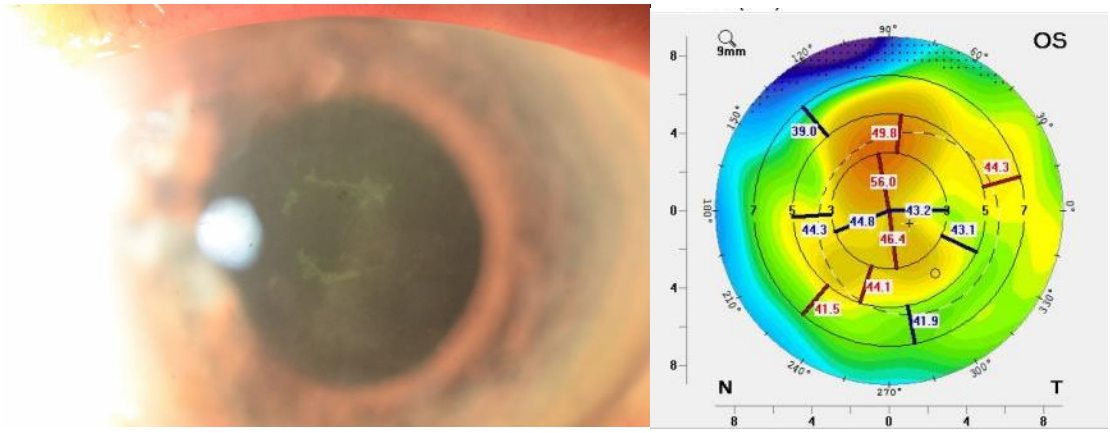


Figure C. Clinical photograph (*left)* and corneal topography axial curvature map *(right*) of study eye with irregular astigmatism due to cornea scarring.

Table C
Comparison of Baseline Keratometry Parameters in IC-8 and Fellow Eyes (n = 20)

Parameter	Difference in Means (IC-8 – Fellow)	95% CI	Paired t-test p-value	Wilcoxon Signed-Rank
Keratometric Cylinder	0.329	(-0.380, 1.04)	0.3447	0.5084
HOA	0.131	(-0,272, 0.534)	0.5045	0.9599
Corneal Spherical Aberration	-0.143	(-0.308,0.022)	0.0852	0.1429
SRI	-0.227	(-0.418, -0.036)	**0.0220**	**0.0132**

HOA = higher order aberrations

Table D
Manifest Refraction Parameters in IC-8 and Fellow Eyes (n = 20)

	IC-8 eye		Fellow eye	
Parameter	**Mean ± SD**	**Range (min – max)**	**Mean ± SD**	**Range (min – max)**
Spherical Equivalent	-0.79 ± 0.83	-2.50 - 0.75	-0.44 ± 1.21	-1.00 – 0.13
Refractive cylinder	0.88 ± 1.13	0.35 – 1.40	0.60 ± 0.48	0.37 – 0.83

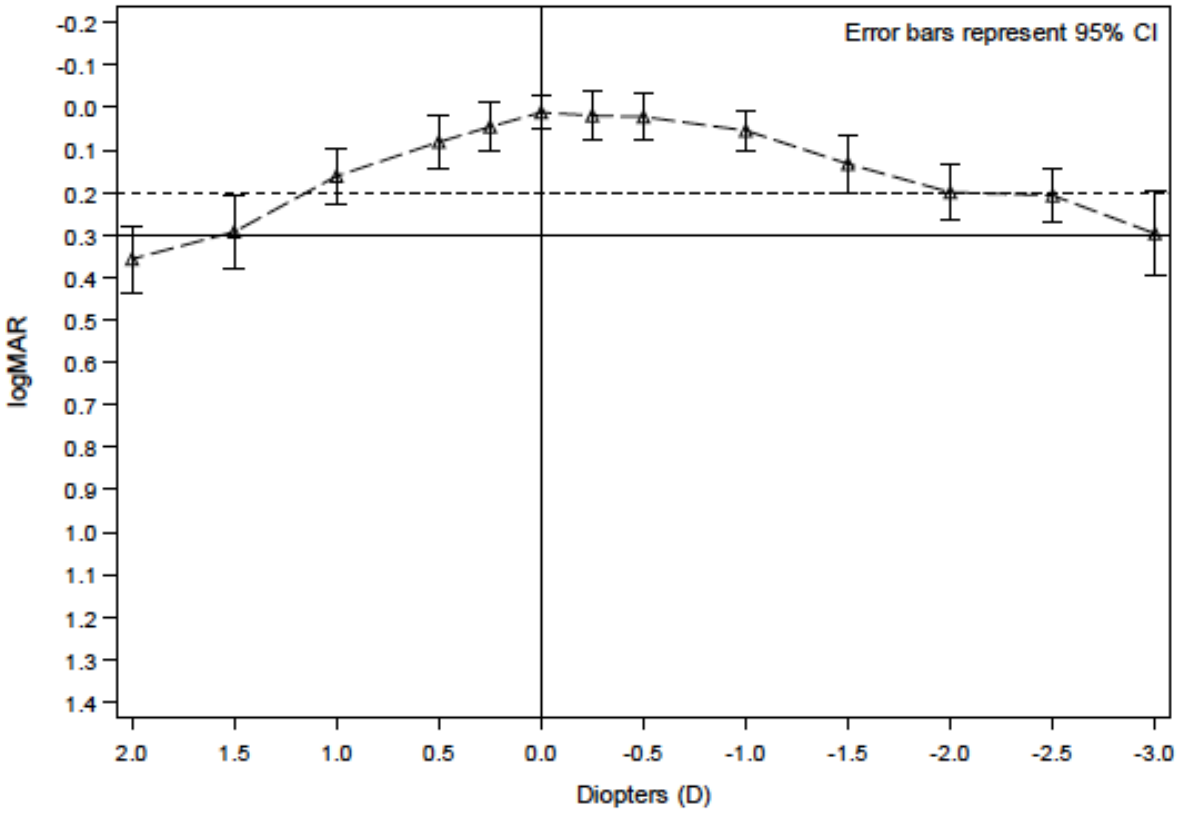


Figure D. Binocular defocus curves (n = 12).

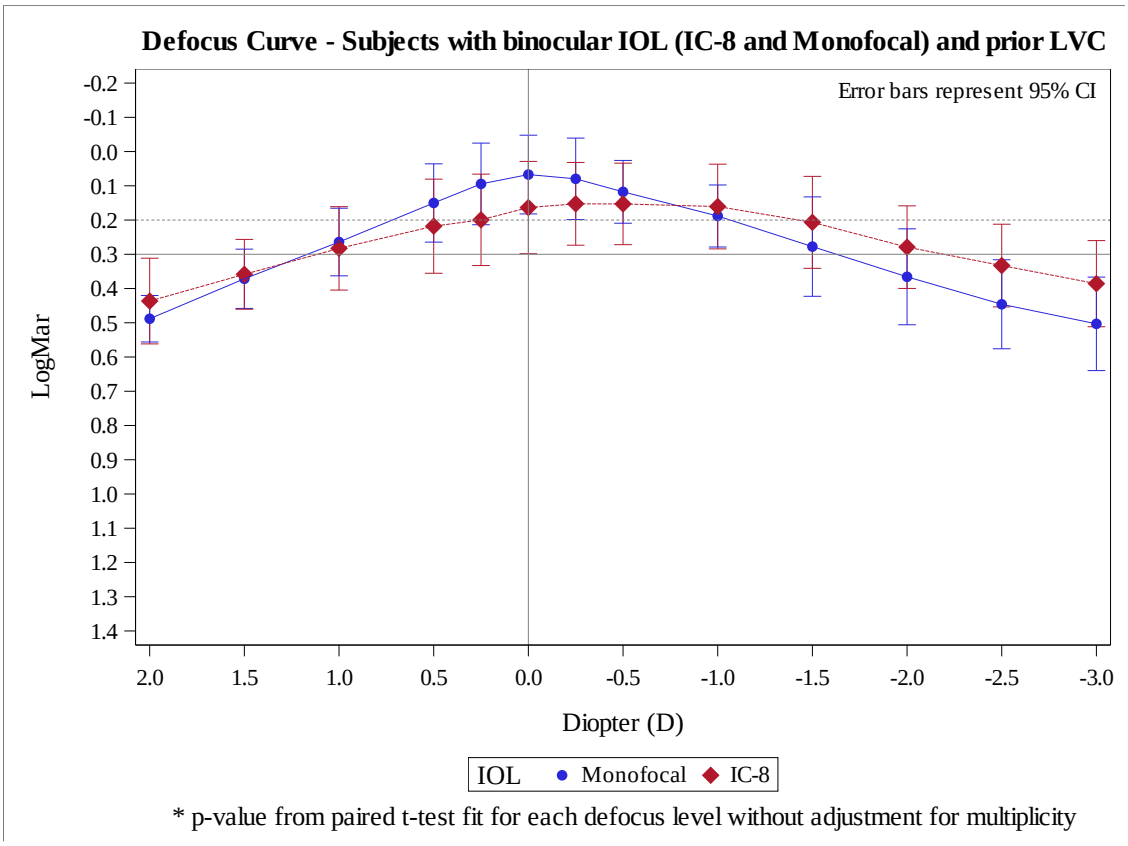
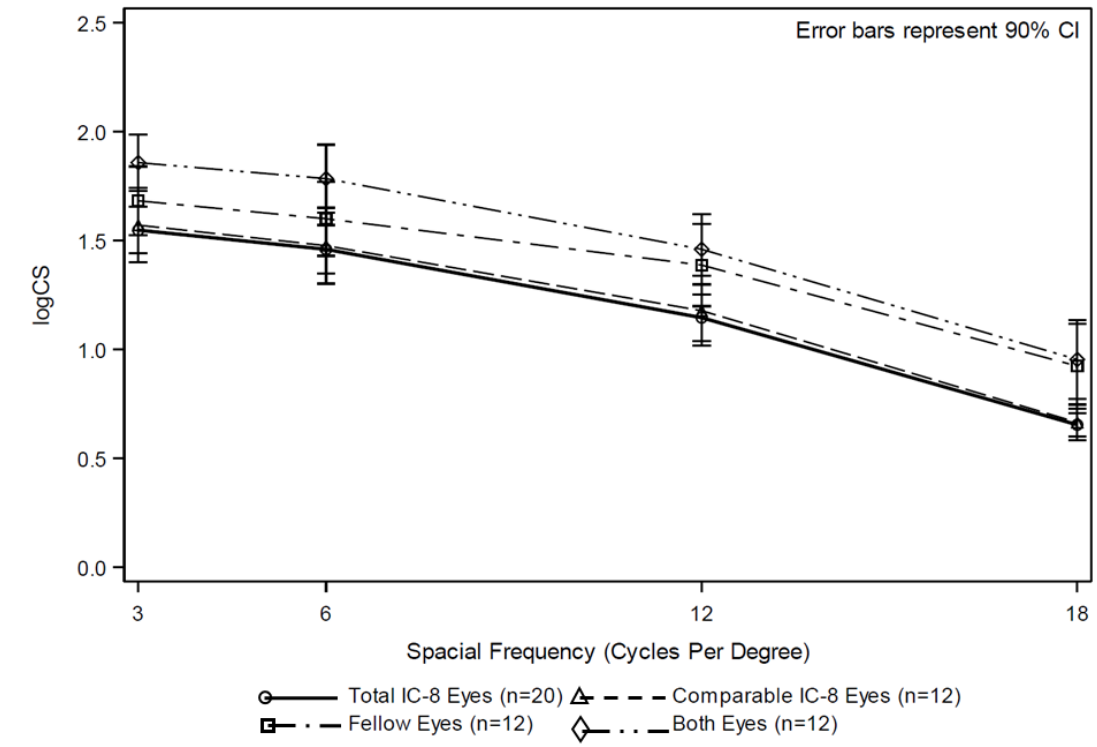


Figure E. Monocular defocus curve of IC-8 eyes vs fellow monfoocal eyes (n = 11).



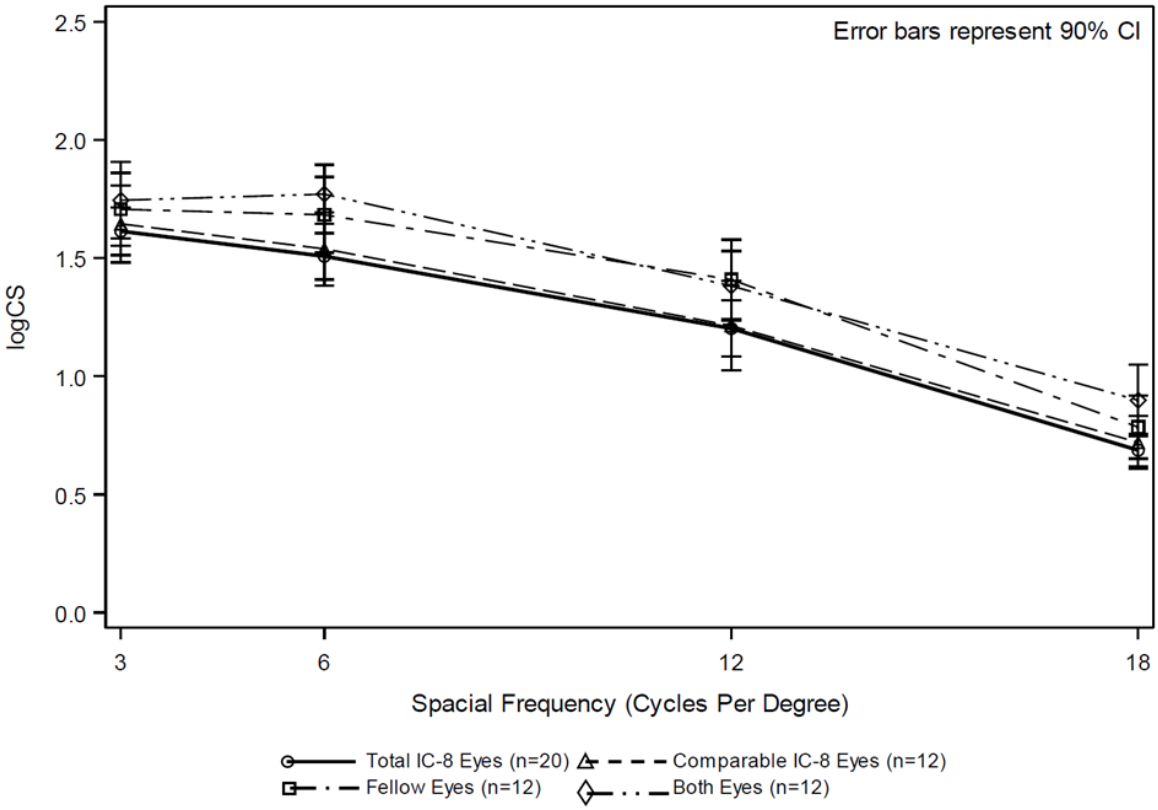


Figure F. Monocular and binocular photopic without (*top)* and with (*bottom)* glare contrast sensitivity, mean and 90% CI (n = 20).

Table E
Contrast Sensitivity Between IC-8 Eye and Monofocal Fellow Eye

			Mean (95%CI)		Mean Difference (95%CI)	
Condition	**Glare**	**Spatial Frequency**	**IC-8**	**Monofocal**	**(IC-8 - Monofocal)**	**p-value***
Mesopic	Glare	1.5	1.251 (1.027, 1.475)	1.462 (1.282, 1.641)	-0.211 (-0.405, -0.017)	**0.0360**
Mesopic	Glare	3	1.340 (1.111, 1.569)	1.645 (1.453, 1.838)	-0.305 (-0.485, -0.126)	**0.0035**
Mesopic	Glare	6	1.214 (0.995, 1.432)	1.462 (1.264, 1.659)	-0.248 (-0.484, -0.013)	**0.0407**
Mesopic	Glare	12	1.019 (0.840, 1.199)	1.139 (0.918, 1.360)	-0.120 (-0.289, 0.049)	0.1438
Mesopic	No Glare	1.5	1.385 (1.145, 1.624)	1.570 (1.347, 1.793)	-0.185 (-0.407, 0.036)	0.0914
Mesopic	No Glare	3	1.473 (1.242, 1.703)	1.796 (1.582, 2.010)	-0.324 (-0.472, -0.176)	**0.0006**
Mesopic	No Glare	6	1.262 (1.023, 1.500)	1.579 (1.374, 1.784)	-0.317 (-0.580, -0.054)	**0.0228**
Mesopic	No Glare	12	0.993 (0.815, 1.170)	1.189 (0.983, 1.395)	-0.196 (-0.379, -0.014)	**0.0374**
Photopic	Glare	3	1.649 (1.428, 1.870)	1.702 (1.493, 1.911)	-0.053 (-0.321, 0.215)	0.6703
Photopic	Glare	6	1.529 (1.320, 1.738)	1.686 (1.469, 1.904)	-0.157 (-0.316, 0.001)	0.0512
Photopic	Glare	12	1.190 (0.940, 1.440)	1.403 (1.174, 1.631)	-0.213 (-0.439, 0.013)	0.0622
Photopic	Glare	18	0.687 (0.557, 0.818)	0.758 (0.588, 0.928)	-0.071 (-0.228, 0.086)	0.3371
Photopic	No Glare	3	1.553 (1.324, 1.782)	1.675 (1.461, 1.888)	-0.122 (-0.354, 0.110)	0.2691
Photopic	No Glare	6	1.472 (1.236, 1.708)	1.595 (1.364, 1.826)	-0.123 (-0.379, 0.133)	0.3108
Photopic	No Glare	12	1.163 (0.948, 1.377)	1.378 (1.123, 1.633)	-0.215 (-0.472, 0.041)	0.0906
Photopic	No Glare	18	0.671 (0.562, 0.780)	0.895 (0.640, 1.151)	-0.225 (-0.407, -0.042)	**0.0210**

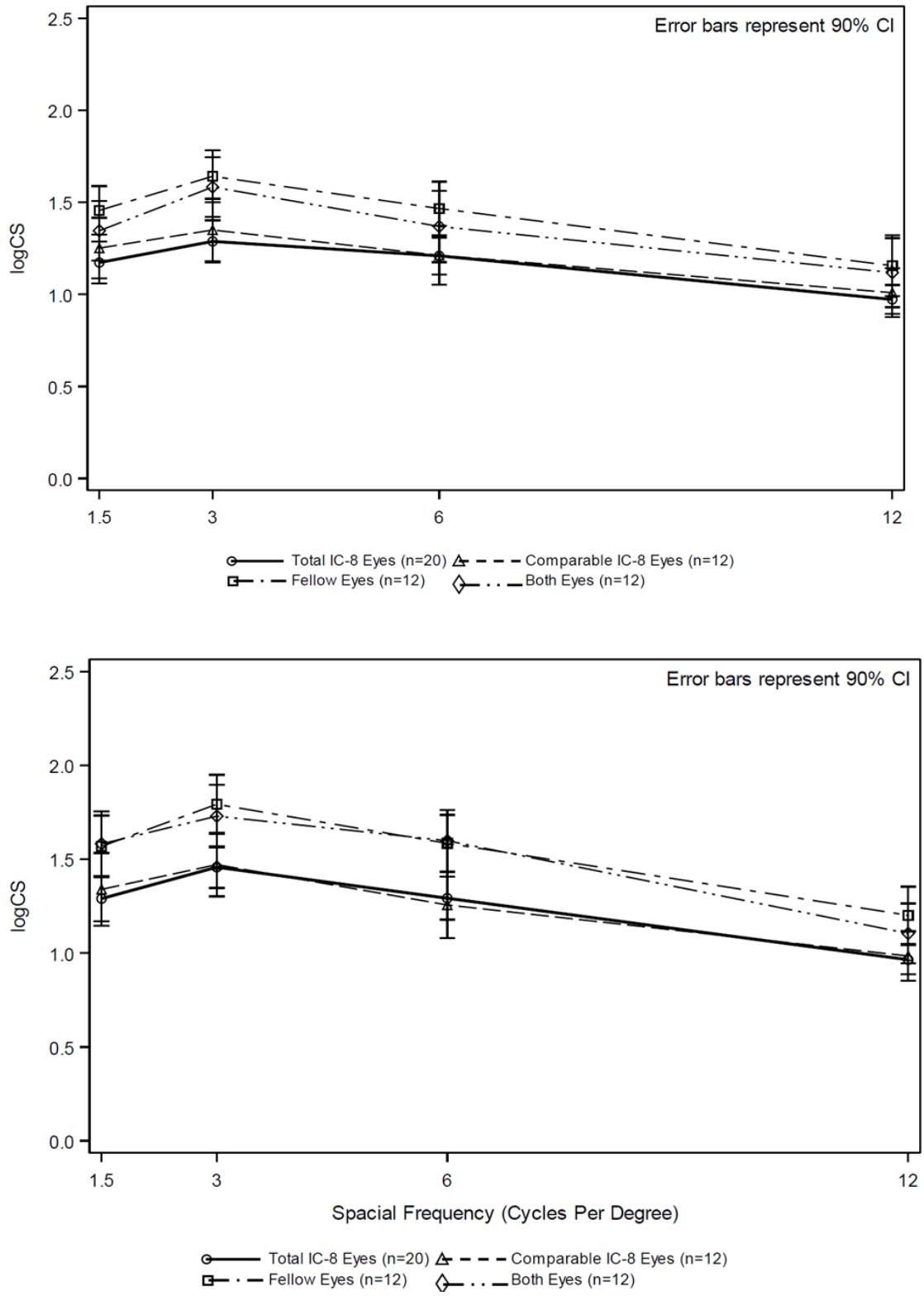


Figure G. Monocular and binocular mesopic without (*top)* and with (*bottom)* glare contrast sensitivity, mean and 90% CI (n = 20).

Table F
Binocular contrast Sensitivity Compared to Monocular Monofocal Contrast Sensitivity

			Mean (95%CI)		Mean Difference (95%CI)	
Condition	**Glare**	**Spatial Frequency**	**Monocular CS (Monofocal)**	**Binocular CS (IC-8 Monofocal)**	**(Binocular - Monocular)**	**p-value***
Mesopic	Glare	1.5	1.462 (1.282, 1.641)	1.326 (1.110, 1.543)	-0.135 (-0.260, -0.011)	**0.0354**
Mesopic	Glare	3	1.645 (1.453, 1.838)	1.567 (1.351, 1.783)	-0.078 (-0.206, 0.049)	0.2014
Mesopic	Glare	6	1.462 (1.264, 1.659)	1.355 (1.094, 1.617)	-0.106 (-0.315, 0.102)	0.2821
Mesopic	Glare	12	1.139 (0.918, 1.360)	1.113 (0.858, 1.367)	-0.026 (-0.149, 0.097)	0.6429
Mesopic	No Glare	1.5	1.570 (1.347, 1.793)	1.599 (1.369, 1.830)	0.029 (-0.152, 0.210)	0.7272
Mesopic	No Glare	3	1.796 (1.582, 2.010)	1.727 (1.502, 1.953)	-0.069 (-0.209, 0.071)	0.2979
Mesopic	No Glare	6	1.579 (1.374, 1.784)	1.595 (1.373, 1.816)	0.015 (-0.131, 0.162)	0.8193
Mesopic	No Glare	12	1.189 (0.983, 1.395)	1.098 (0.882, 1.314)	-0.091 (-0.223, 0.042)	0.1571
Photopic	Glare	3	1.702 (1.493, 1.911)	1.744 (1.523, 1.964)	0.042 (-0.167, 0.250)	0.6645
Photopic	Glare	6	1.686 (1.469, 1.904)	1.767 (1.598, 1.937)	0.081 (0.001, 0.161)	**0.0478**
Photopic	Glare	12	1.403 (1.174, 1.631)	1.374 (1.175, 1.573)	-0.029 (-0.143, 0.085)	0.5825
Photopic	Glare	18	0.758 (0.588, 0.928)	0.868 (0.675, 1.061)	0.110 (-0.062, 0.282)	0.1848
Photopic	No Glare	3	1.675 (1.461, 1.888)	1.865 (1.691, 2.040)	0.191 (0.063, 0.319)	**0.0078**
Photopic	No Glare	6	1.595 (1.364, 1.826)	1.781 (1.570, 1.992)	0.186 (0.012, 0.361)	**0.0384**
Photopic	No Glare	12	1.378 (1.123, 1.633)	1.444 (1.229, 1.658)	0.065 (-0.135, 0.266)	0.4845
Photopic	No Glare	18	0.895 (0.640, 1.151)	0.928 (0.690, 1.166)	0.033 (-0.112, 0.177)	0.6253

Table G
Monocular Uncorrected and Corrected Visual Acuities in IC-8 Eyes in the Post-keratorefractive Surgery Subgroup (n = 17)

Visual acuity	Uncorrected			Corrected		
	LogMar Mean ± SD	Snellen equivalent	LogMar Range (Min – max)	Mean ± SD	Snellen equivalent	Range (Min – max)
Distance	0.26 ± 0.17	20/36	0.00-0.60	0.15 ± 0.17	20/26	-0.06-0.72
Intermediate	0.21 ± 0.19	20/32	-0.06-0.76	0.18 ± 0.16	20/30	-0.10-0.54
Near	0.14 ± 0.15	20/28	-0.14-0.52	0.19 ± 0.14	20/31	0.00-0.42

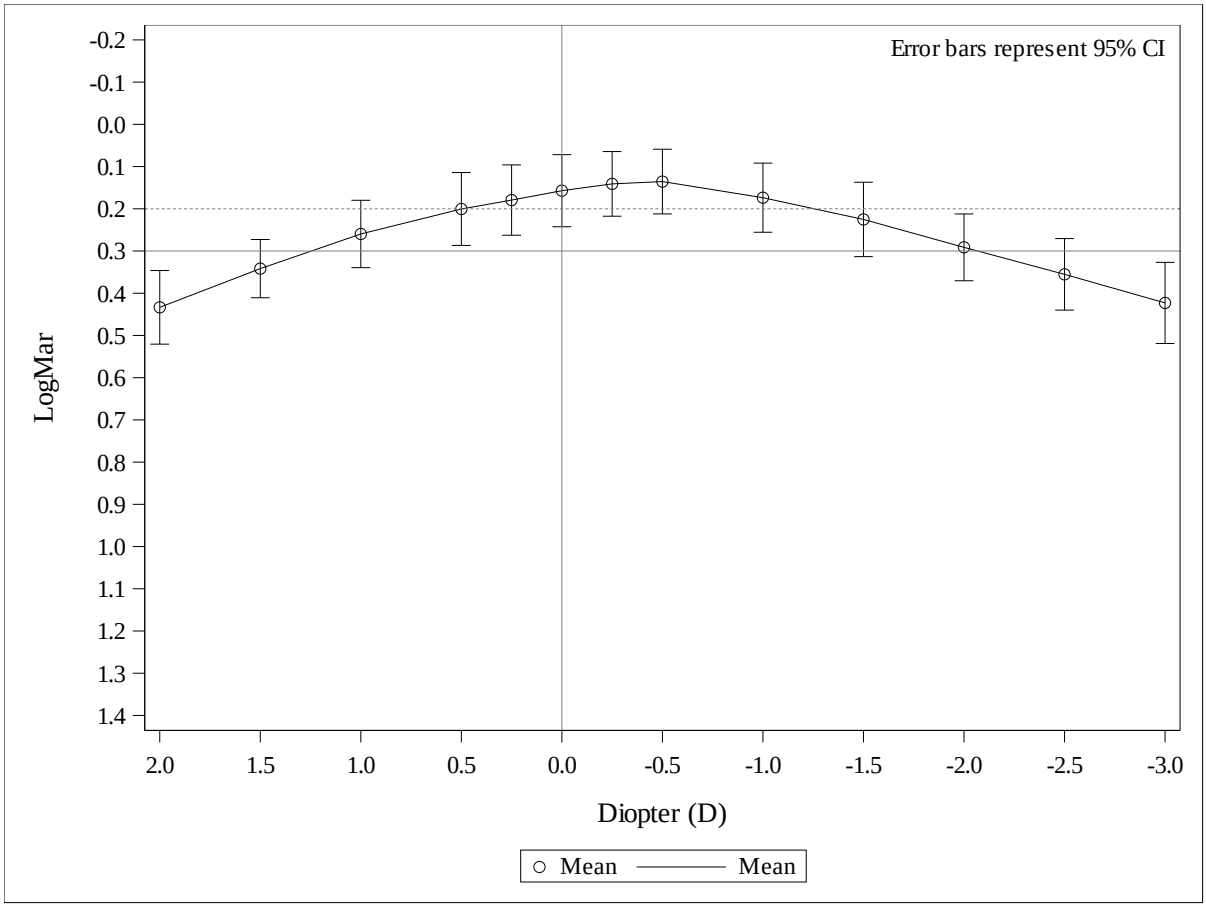


Figure H. Monocular defocus curve of IC-8 eyes in the post keratorefractive surgery subgroup (n =17).