Clinical Ophthalmology

Dovepress
Taylor & Francis Group

Open Access Full Text Article

CLINICAL TRIAL REPORT

Visual Outcomes Following Cataract Surgery and Implantation of a Small-Aperture Intraocular Lens in Post-Refractive Surgery Patients

Robert Edward T Ang

Asian Eye Institute, Makati City, Philippines

Correspondence: Robert Edward T Ang, Asian Eye Institute, 9th Floor PHINMA Plaza, Rockwell Center, Makati City, 1200, Philippines, Tel +639178888806, Email angbobby@hotmail.com

Purpose: To evaluate visual outcomes following small-aperture intraocular lens (IOL) implantation in post-refractive surgery patients undergoing cataract surgery.

Patients and Methods: This is a prospective, single-arm, interventional study. Post-corneal refractive surgery cataract patients (N=16), desiring spectacle independence at all distances, underwent phacoemulsification, and IC-8 Apthera IOL (Bausch+Lomb) implantation in one eye with targeted postoperative manifest refraction spherical equivalent (MRSE) of −0.75 D. Study parameters were uncorrected/corrected/distance-corrected visual acuity at distance (UDVA and CDVA), intermediate (UIVA and DCIVA), and near (UNVA and DCNVA), defocus curve, and patient-reported outcomes.

Results: At 12 months postoperatively, the mean MRSE was −0.55 ± 0.70 D in the small-aperture eyes. The mean monocular UDVA, UIVA, and UNVA were 0.05±0.06 (Snellen equivalent, 20/22.4), 0.04±0.14 (20/21.9), and 0.09±0.13 logMAR (20/24.6), and the mean monocular CDVA, DCIVA, and DCNVA were 0.02±0.05 (20/20.9), 0.03±0.12 (20/21.4) and 0.11±0.14 logMAR (20/25.7), respectively. All eyes achieved a CDVA of 20/40 or better by 1 month and maintained it until 12 months. The monocular defocus curve revealed a broad range of vision of 3.50 D at a visual acuity of 0.2 logMAR (20/31.6) or better. Over 92% (12/13) of the subjects responded that they would have the procedure done again. At 12 months postoperatively, mean patient satisfaction was 3.7 (measured on a scale of 1–5, with 1 being very dissatisfied to 5 being very satisfied) for overall vision. The incidence of mild to moderate posterior capsular opacification (PCO) was 93.8% (15/16) in the small-aperture IOL eyes and 69.2% (9/13) in the fellow eyes. All eyes with PCO (15/15) in the small-aperture IOL group required Nd:YAG capsulotomy, compared to 53.8% (7/13) of the fellow eyes.

Conclusion: The IC-8 Apthera small-aperture IOL provided a wide range of vision from distance to near and good spectacle independence in patients with prior corneal refractive surgery.

Trial Registration: ClinicalTrials.gov (NCT05574270).

Keywords: post-refractive surgery, small-aperture IOL, IC-8 Apthera IOL, cataract surgery

Introduction

Worldwide, tens of millions of patients have undergone corneal refractive surgery since the 1980s. As these patients age, a growing share of the patients presenting for cataract surgery have a history of refractive surgery. This population presents unique challenges to the cataract surgeon due to high expectations for the same high level of spectacle independence they enjoyed after their corneal refractive surgery. However, appropriate intraocular lens (IOL) selection and IOL power calculation for eyes with prior corneal refractive surgery is challenging.

Refractive treatments, such as LASIK (laser in situ keratomileusis) and PRK (photorefractive keratectomy), significantly alter the cornea's biomechanical properties.[1,2] The changes in the cornea's architecture, stability, and refractive index can make biometric calculations, especially keratometry, unreliable.[3] Although IOL power calculation formulas have been developed for post-refractive surgery eyes, refractive surprises are not uncommon after cataract surgery in such patients, which can negatively impact patient satisfaction.

https://doi.org/10.2147/OPTH.S571174
Received: 17 October 2025
Accepted: 10 February 2026
Published: 19 February 2026

Post-refractive surgery patients undergoing cataract surgery have high expectations of spectacle independence not only at far, but also at intermediate and near distances. They are often interested in multifocal IOL implantation; however, most surgeons tend to avoid multifocal IOL implantation in such patients. Corneal higher-order aberrations (HOAs) tend to increase after corneal refractive surgery and are associated with increased dysphotopsia and decreased contrast sensitivity.[4] Multifocal IOL implantation in such patients may further deteriorate the contrast sensitivity and tolerance to dysphotopsia.[5] In contrast to multifocal IOLs, extended depth of focus (EDOF) IOLs provide excellent distance vision, good intermediate vision, and functional near vision without the dysphotopsias associated with multifocal IOLs and are believed to be more suitable in post-refractive surgery patients.[6]

A small-aperture IOL (IC-8 Apthera IOL, Bausch + Lomb, Inc., Irvine, CA) is one such EDOF IOL. It achieves increased depth of focus by incorporating an annular opaque mask with a central 1.36 mm aperture. The increased depth of focus makes it potentially forgiving in the case of refractive misses and the small aperture increases tolerance of up to 1.5 D of astigmatism.[7–10] The ability of the small aperture to block defocused peripheral light also provides an opportunity to reduce the impact of aberrations and potentially improve vision in eyes with corneal irregularities.[11–14] The central mask of the small-aperture IOL, while beneficial for focus, can affect mesopic visual acuity and can be very sensitive to any ocular surface problems in the visual axis. For this reason, it is typically implanted unilaterally, paired with a monofocal IOL in the fellow eye.

Previous studies of small-aperture IOL implantation in patients with virgin corneas have documented good uncorrected vision at all distances, minimal photic phenomena, and good contrast sensitivity.[7,8] The objective of the present study was to evaluate outcomes following small-aperture IOL implantation in post-refractive surgery patients who desired spectacle independence at all distances.

Materials and Methods

In this prospective, single-arm, one-year interventional study, subjects who had previous keratorefractive procedures (eg, LASIK, LASEK, PRK, RK, SMILE) and needed cataract surgery were screened for eligibility. The study was conducted in compliance with the study protocol and followed the tenets of the Declaration of Helsinki and its amendments. Institutional review board (IRB) approval was secured from the SCMC-AEI Ethics Review Committee and all participating patients provided written informed consent using the IRB-approved informed consent forms. The study was registered with ClinicalTrials.gov (NCT05574270).

To be included in the study, patients had to be older than 45 years of age, have had a prior corneal refractive procedure, desire spectacle independence at all distances, and have corrected distance visual acuity (CDVA) of 20/40 or worse or significant visual complaints as a result of cataract in the study eye. Projected visual acuity of 0.8 or better (Snellen 20/25) following cataract surgery was required, along with a willingness to return for scheduled follow-up examinations for 12 months after IOL implantation surgery. Fellow eyes could be phakic or pseudophakic.

Exclusion criteria included the requirement for an IOL outside the available power range for the small-aperture IOL (+15.5 D to +27.5 D); prior intraocular surgery; pupil abnormalities or a pharmacologically dilated pupil size <6 mm; marked microphthalmos; preoperative corneal astigmatism >1.5 diopters (D); corneal abnormalities such as stromal, epithelial, or endothelial dystrophies; or diagnosed degenerative visual disorders (eg, macular degeneration or other retinal disorders) that were predicted to cause visual acuity losses to a level of 20/25 or worse during the study. Subjects with active or recurrent anterior segment pathology, uncontrolled systemic disease, previous retinal pathology in either eye, suspected glaucoma, uncontrolled ocular hypertension, or history of glaucomatous changes were also excluded.

The IC-8 Apthera single-piece IOL has a 6 mm diameter biconvex optical design with an embedded opaque annular mask. It has modified C-loop haptics with an overall length of 12.5 mm. The anterior optical surface is aspheric, incorporating negative spherical aberration to compensate for the cornea's positive spherical aberration. The posterior surface of the intraocular lens has a 360° square edge for mitigating posterior capsular opacification (PCO). The embedded mask has an outer diameter of 3.23 mm, a central aperture of 1.36 mm, and contains 3200 micro-perforations along its annulus (sparing the edges), ranging in diameter from 7 to 10 microns. The IOL is indicated for contralateral implantation in the non-dominant eye in conjunction with an aspheric monofocal IOL implantation in the fellow eye.

All patients underwent a comprehensive preoperative examination, including assessment of cataract grade, pupil size, biometry (IOLMaster 700, Carl Zeiss Meditec Inc, Dublin, CA), corneal topography (Oculus Pentacam Wave, OCULUS, Inc., Arlington, WA), dilated fundus examination, and visual potential assessment. Following enrollment, phacoemulsification and small-aperture IOL implantation were performed in one eye. In most cases, the worse-seeing eye was selected as the study eye. If both eyes had similar cataract severity, the more aberrated eye or, if both had higher-order aberrations, the non-dominant eye, was chosen as the study eye. IOL lens power was calculated using the Barrett True-K formula and the A-constant provided by the manufacturer (120.5). IOL power selection was based on a postoperative refractive target of −0.75 D manifest refraction spherical equivalent (MRSE) for the study eye, as recommended by the manufacturer.

Postoperatively, subjects were followed at 1-, 3-, 6-, and 12-month intervals. Uncorrected and distance-corrected distance (6 m), intermediate (80 cm) and near (40 cm) were measured using the Optec 6500 Vision Tester (Stereo Optical Company, Inc.) with Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity charts.

Subjective depth of focus was assessed at 4 m using an ETDRS lightbox in photopic conditions, with the best-corrected distance manifest refraction in place. The examiner progressively changed the defocus lens in 0.50 D increments from +2.00 to −5.0 D, while visual acuity was measured at each successive defocus step.

Monocular and binocular contrast sensitivity was measured with the Functional Acuity Contrast Test chart in the Optec 6500 Vision Tester in mesopic conditions, with or without a glare source, at the screening visit and postoperative months 3, 6, and 12.

Visual symptoms were assessed through a questionnaire. Subjects reported “yes” or “no” regarding whether they experienced each assessed symptom; if “yes”, they were also asked to report the severity (on a scale of 1–5, with 1 being “very mild” to 5 being “very severe”) and the degree of bothersomeness (on a scale of 1–3, with 1 being “a little” to 3 being “very bothersome”) of the visual symptoms they experienced.

Statistical Analysis

This pilot study was designed to explore the outcomes of Apthera IOL implantation in a niche population of post-refractive surgery patients. Since no hypothesis was tested, a sample size calculation was not applicable. Descriptive statistics were used to summarize all clinical parameters, questionnaire data, demographics, and baseline variables. Means, standard deviations, medians, and minimum and maximum values were used to report continuous data. Frequency counts and percentages were used to report categorical outcomes. No data imputation was performed, and the descriptive analyses were conducted with all available data.

Results

Of 20 subjects who signed the informed consent form, 4 did not meet eligibility criteria and were considered screen failures. The remaining 16 subjects were enrolled and implanted with the small-aperture IOL in the study eye. One subject withdrew consent at Month 12 secondary to the COVID-19 pandemic travel restrictions; as such, 15 subjects completed the study. The mean age of the subjects was 62.2 ± 6.97 years; 56.3% (9/16) were female. Subjects were of either Asian (87.5%, 14/16) or White (12.5%, 2/16) race. Additional baseline characteristics are shown in Table 1. Among the 16 eyes implanted with a small-aperture IOL, 14 eyes had prior LASIK, and 2 eyes had prior radial keratotomy (RK). Thirteen subjects had a monofocal or monofocal toric IOL in the pseudophakic fellow eye; 3 subjects had phakic fellow eyes. In addition to monocular results for the 15 subjects who completed the study, binocular results for a subset of subjects with pseudophakic fellow eyes (N = 13) were also analyzed.

Pupil Size

The mean photopic and mesopic pupil sizes were 3.9 ± 0.74 mm and 4.6 ± 0.8 mm, respectively, in the small-aperture eyes at screening. At postoperative 12 months, these measurements were 3.9 ± 0.73 mm and 4.5 ± 0.8 mm, respectively.

Visual and Refractive Outcomes

Mean MRSE improved from −1.49 ± 1.96 D preoperatively to −0.55 ± 0.70 D at 12 months in the small-aperture eyes and from −1.30 ± 1.70 D to −0.14 ± 0.66 D in the fellow eyes.

 https://doi.org/10.2147/OPTH.S571174

Table 1 Demographics and Baseline Characteristics

Demographics		
N	16	
Age (years) (Mean ± SD)	62.2 ± 6.97	
Gender		
Male	43.8%	
Female	56.3%	
Race		
Asian	87.5%	
White	12.5%	
Baseline characteristics	**Apthera eyes**	**Fellow eyes**
Axial length (mm) (Mean ± SD)	25.97 ± 1.66	26.40 ± 1.68
Anterior chamber depth (mm) (Mean ± SD)	3.25 ± 0.38	3.96 ± 0.93
White to white (mm) (Mean ± SD)	12.08 ± 0.45	11.93 ± 0.38
Lens thickness (mm) (Mean ± SD)	4.56 ± 0.41	4.66 ± 0.34
Potential acuity assessment (%)		
20/25 or better	100.0%	92.3%
Worse than 20/25	0.0%	7.7%

Abbreviation: SD, Standard deviation.

At 12 months postoperatively, the mean monocular uncorrected distance (UDVA), intermediate (UIVA), and near (UNVA) visual acuities in the small-aperture IOL-implanted eyes (N = 15) were 0.05 ± 0.06 logMAR (Snellen equivalent 20/22.4), 0.04 ± 0.14 logMAR (20/21.9), and 0.09 ± 0.13 logMAR (20/24.6), respectively. The CDVA was 0.02 ± 0.05 logMAR (20/20.9), and the distance-corrected visual acuity at intermediate (DCIVA) and near (DCNVA) was 0.03 ± 0.12 logMAR (20/21.4) and 0.11 ± 0.14 logMAR (20/25.7), respectively. All small-aperture eyes (100%, 15/15) achieved CDVA of 0.3 logMAR (20/40) or better by 1 month and maintained that acuity until the last follow-up visit at 12 months.

At 12 months, bilateral pseudophakic subjects (N = 13) achieved good binocular uncorrected and distance-corrected visual acuities across all distances (Figure 1A and B). All subjects (13/13) had binocular UDVA of 20/25 or better, 92.3% (12/13) of subjects had UIVA of 20/25 or better, and 76.9% (10/13) had UNVA of 20/25 or better.

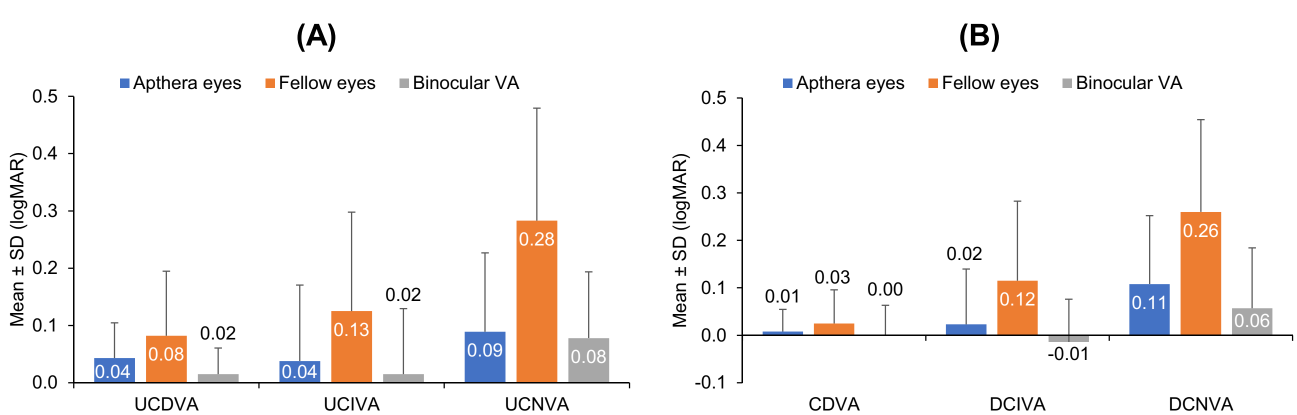


Figure 1 The mean monocular (**A**) uncorrected and (**B**) distance-corrected visual acuity of Apthera eyes, fellow eyes, and mean binocular visual acuity for the patients with pseudophakic fellow eyes (N = 13) (Only positive error bars are shown).

The mean MRSE at Months 1, 3, 6, and 12 was −0.53 ± 0.47, −0.58 ± 0.39, −0.62 ± 0.60, and −0.55 ± 0.70 D. Similarly, the mean visual acuities across all distances were stable from 1 to 12 Months.

Defocus Curve

Defocus curves for the 13 bilateral pseudophakic subjects showed that visual acuity of 0.2 logMAR or better was achieved in the small-aperture IOL eyes at a defocus range of +1.5 D to over −2.0 D (3.5 D range) at 12 months, compared to a defocus range of +1.0 D to −1.5 D (2.5 D range) in the fellow eyes (Figure 2). Binocularly, visual acuity of 0.2 logMAR or better was achieved at a defocus range of +2.0 D to −2.5 D (4.5 D range).

Contrast Sensitivity

Mean monocular contrast sensitivity in the small-aperture IOL eyes compared to the fellow eyes was comparable across mid to high spatial frequencies in mesopic conditions, with and without glare, at 12 months (Figure 3A and B). Binocular logCS results were similar or better than the corresponding monocular logCS results from either eye across all tested conditions (Figure 3A and B).

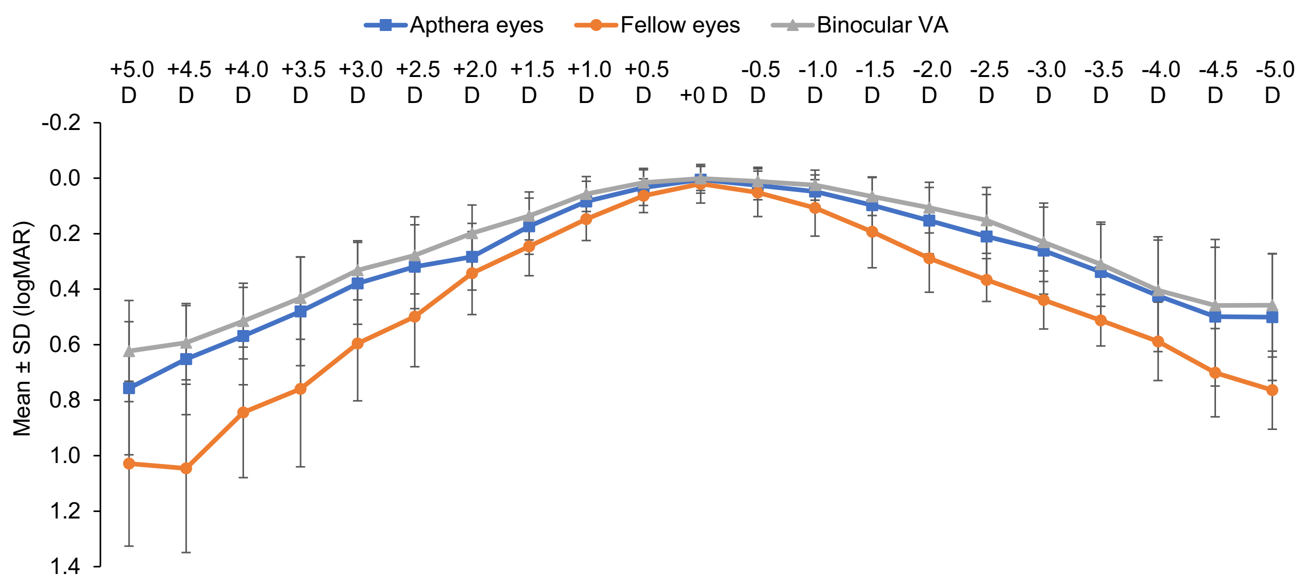
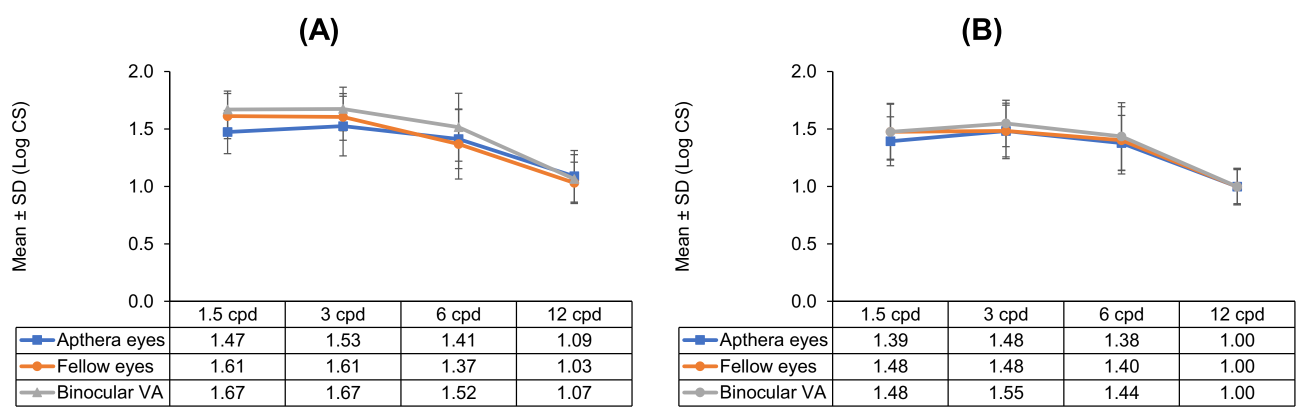


Figure 2 Monocular defocus curve (logMAR) of study and fellow eyes, and binocular defocus curve for the patients with pseudophakic fellow eyes (N = 13).



(A)

	1.5 cpd	3 cpd	6 cpd	12 cpd
Apthera eyes	1.47	1.53	1.41	1.09
Fellow eyes	1.61	1.61	1.37	1.03
Binocular VA	1.67	1.67	1.52	1.07

(B)

	1.5 cpd	3 cpd	6 cpd	12 cpd
Apthera eyes	1.39	1.48	1.38	1.00
Fellow eyes	1.48	1.48	1.40	1.00
Binocular VA	1.48	1.55	1.44	1.00

Figure 3 (**A**) Mean mesopic contrast sensitivity without glare and (**B**) Mean mesopic contrast sensitivity with glare measured monocularly for Apthera and fellow eyes and measured binocularly for the patients with pseudophakic fellow eyes (N = 13).

https://doi.org/10.2147/OPTH.S571174

Patient-Reported Outcomes

Patient Satisfaction with Vision

At 12 months postoperatively, the mean score for patient satisfaction (measured on a scale of 1–5, with 1 being very dissatisfied to 5 being very satisfied) was 3.7 for overall vision. At far and intermediate distances, the mean satisfaction score was 4.1, and at near it was 3.5 (Figure 4A).

At 3 and 6 months, 86.7% (13/15) of the subjects responded that they would have this procedure done again. At 12 months, this proportion increased to 92.3% (12/13). The mean frequency of corrective lens wear (assessed on a scale of 1–5 where 1 is all or most of the time and 5 is rarely to never) was 3.9 overall, 4.5 for far distance, and 3.9 for near (Figure 4B).

Task Performance

At 12 months, the mean near/intermediate vision task performance ratings ranged from 2.8 to 4.1 in bright lighting and from 2.7 to 2.9 in dim lighting when assessed on a scale of 1 to 5 (with 1 being "very difficult" and 5 being "very easy") (Table 2). Task performance ratings for distance tasks were 3.1 to 4.4 at 12 months (Figure 4C).

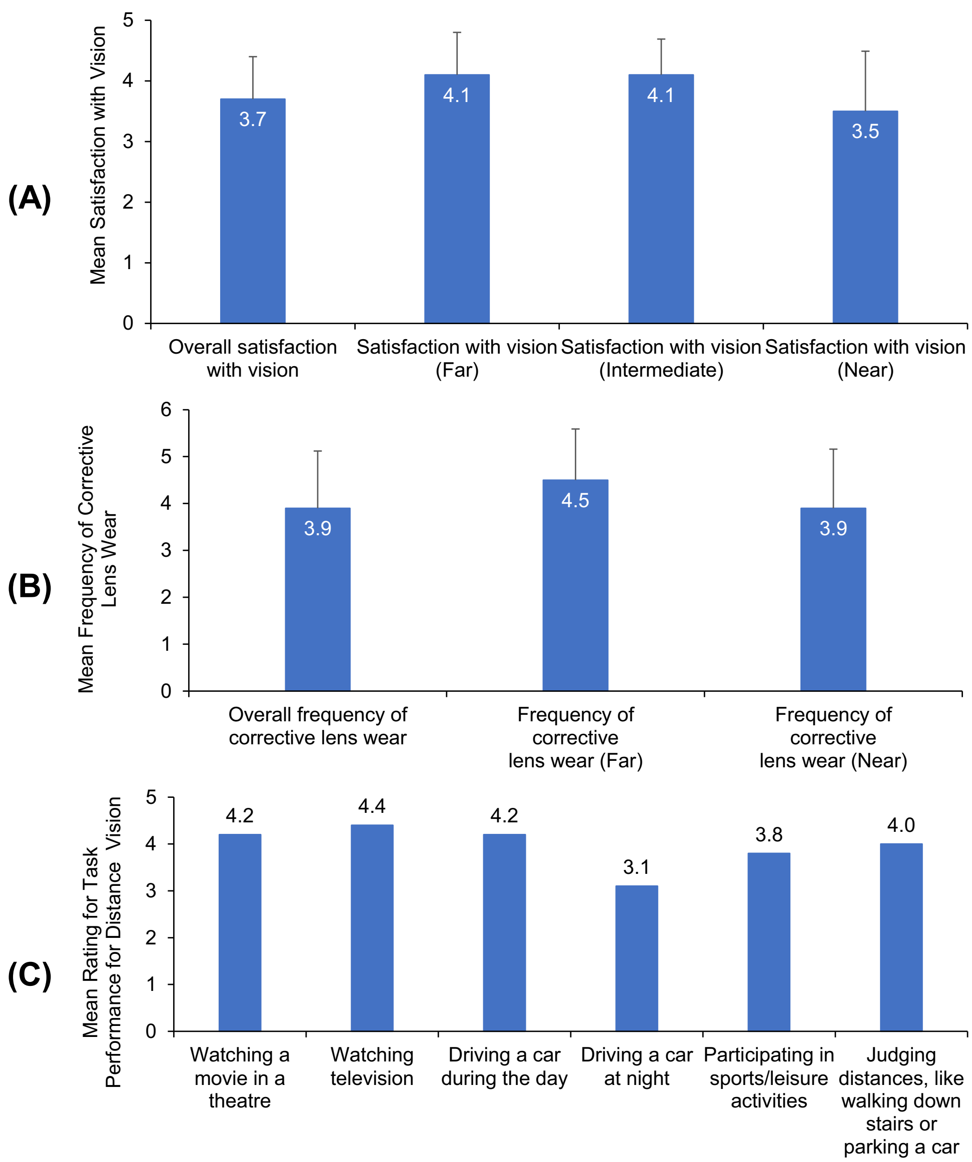


Figure 4 (**A**) Satisfaction with vision scores, (**B**) Frequency of corrective lens wear, and (**C**) Distance task performance at postoperative 12 months (Only positive error bars are shown).

Table 2 Task Performance Ratings for Bright and Dim Lighting

Task Performance	Bright Lighting (Mean ± SD)	Dim Lighting (Mean ± SD)
Reading newspaper or magazine	3.7 ± 1.16	2.7 ± 1.11
Reading a menu or restaurant bill	3.8 ± 1.15	2.9 ± 1.03
Reading a book	3.5 ± 1.30	2.7 ± 1.05
Working on a computer	3.8 ± 0.93	2.9 ± 1.07
Seeing numbers on a mobile phone, tablet or watch	4.1 ± 0.62	2.9 ± 1.16
Seeing small print such as stock quotes or medicine labels	2.8 ± 1.32	–
Performing small item tasks such as sewing	2.9 ± 1.25	–

Notes: Scale 1 to 5: 1=Very Difficult, 2=Difficult, 3=Possible, 4=Easy, and 5=Very Easy.

Patients' ability to judge distances and shave or put on makeup without wearing corrective lenses was also evaluated. At 12 months, the mean score for both task limitations (assessed on a scale of 1–5, with 1 being extreme limitation to 5 being no limitation) was 4.2, indicating slightly reduced task limitation to the level between "a little limitation" and "no limitation."

Dysphotopsia

Table 3 shows the mean visual symptom severity and bothersomeness scores for various visual symptoms at 12 months postoperatively. Overall, most subjects reported that their visual symptoms were of "very mild" to "mild" severity, and these were only "a little bothersome" for patients.

Posterior Capsular Opacification (PCO)

The incidence of mild to moderate PCO was 93.8% (15/16) in the small-aperture IOL eyes and 69.2% (9/13) in the fellow eyes during the 12 months of follow-up. Nd:YAG (neodymium-doped yttrium aluminum garnet) capsulotomy was performed when patients complained of a significant decrease in uncorrected distance vision, and posterior capsular opacity was confirmed as grade 2 or worse upon dilated slit lamp examination. All eyes with PCO (15/15) in the small-aperture IOL group required Nd:YAG capsulotomy, compared to 53.8% (7/13) of the fellow eyes with PCO. All the Nd:YAG capsulotomy procedures in the small-aperture IOL eyes (15/15, 100%) were performed before the 12-month

Table 3 Mean Visual Symptom Severity and Bothersomeness Scores for Various Visual Symptoms

Experience	Severity (Mean ± SD)	Bothersomeness (Mean ± SD)
Blurry Vision	1.2 ± 1.57	0.6 ± 0.91
Fluctuating Vision	1.7 ± 1.53	1.1 ± 0.96
Dry Eye	1.7 ± 1.28	1.1 ± 0.96
Glare	1.9 ± 1.46	1.1 ± 0.99
Halo	1.1 ± 1.30	0.7 ± 0.98
Double Vision	0.8 ± 1.52	0.5 ± 0.92
Ghost	0.6 ± 1.02	0.3 ± 0.61

Notes: Severity coding: 0=None, 1=Very Mild, 2=Mild, 3=Moderate, 4=Severe, and 5=Very Severe. Bothersomeness coding: 0=Never experienced/Not at all, 1=A Little, 2=Moderately, 3=Very.

postoperative visit, with one-third of the procedures performed between Months 3 and 6 and two-thirds between Months 6 and 12. On the other hand, in the fellow eyes, 57% (4/7) of the capsulotomy procedures were performed prior to 12 months, and 43% (3/7) were performed after the 12-month visit.

All Nd:YAG procedures were successful and were reported to be no more difficult than performing Nd:YAG in regular monofocal IOL patients. In a majority of eyes (93.3%), laser shots were performed both around the mask and through the center of the mask. The surgeon found both locations to be equally easy.

Adverse Events

Postoperatively, 5 ocular and 1 non-ocular adverse events (AE) were observed in 4 subjects. All 5 ocular AEs occurred in small-aperture-implanted eyes, and all were regarded as unrelated to the study device. The most reported ocular AE in the study was elevated IOP (defined as an increase of >10 mmHg postoperatively above the patient's preoperative levels) requiring treatment (all occurring on Day 1) (3/16, 18.8%), followed by blepharitis (1/16, 6.3%) and trichiasis (1/16, 6.3%).

Discussion

Implantation of presbyopia-correcting IOLs to enhance the range of vision is generally contraindicated in eyes with previous refractive surgery due to the increased risk of HOAs and refractive surprises after surgery. As such, IOLs that reduce the effect of aberrations, and are forgiving to residual refractive error are preferable for post-refractive surgery patients who desire to maintain or restore spectacle independence after cataract surgery. The small-aperture IOL simulates a smaller pupil size, providing an extended depth of focus and taking advantage of the reduced impact of HOAs on visual acuity.[15–17] Additionally, the small-aperture IOL is able to tolerate a wider range of spherical and cylindrical refractive errors.[8,9] It does not impede retinal fundus visualization or cause any impairment of the visual field.[17] As such, implantation of a small-aperture IOL is a good option for eyes with prior refractive surgery.

The small-aperture IOL is indicated for contralateral implantation in the non-dominant eye in conjunction with an aspheric monofocal IOL implantation in the fellow eye. However, a determination of dominance may be unreliable in the presence of cataract.[18] Additionally, patients may present for surgery with significantly worse cataract in one eye or with a monofocal IOL already implanted in one eye without regard for eye dominance. The results of the present study demonstrated that in real-world usage, post-refractive-surgery eyes implanted with the small-aperture lens achieved good visual outcomes at all distances, irrespective of eye dominance.

The postoperative monocular visual outcomes in this pilot study demonstrate that eyes implanted with the small-aperture IOL achieved a continuous, broad range of vision and excellent acuity across all distances. At 1 year post-operatively, the mean monocular UDVA in small-aperture eyes was 20/22 and 86.7% of eyes achieved UDVA of 20/25 or better. The mean monocular DCIVA at 1 year postoperatively was 20/21 and 86.7% of eyes achieved DCIVA of 20/25 or better. The mean monocular DCNVA was 20/26 at 1 year and 73.3% of eyes achieved DCNVA of 20/32 or better. The refractive target for the eyes implanted with the small-aperture IOL eyes was −0.75 D but, in this pilot study, the achieved MRSE was −0.55 D. The UNVA results might have been even better if the eyes implanted with the small-aperture eyes had been closer to the target refraction.

This study assessed the outcomes of small-aperture IOL implantation in post-refractive surgery patients seeking spectacle independence at all distances. A comparison of the uncorrected visual outcomes obtained in the present study with prior publications of EDOF IOL implantation in post-refractive surgery eyes demonstrated comparable UDVA. In contrast, UIVA and UNVA were better with the small-aperture IOLs than with other EDOF IOLs reported in the post refractive surgery population.[19–21]

Generally, the small-aperture IOL is implanted when the fellow eye has undergone successful implantation of a monofocal or monofocal toric IOL targeted for emmetropia. In this pilot study, 13 patients had pseudophakic fellow eyes already implanted with a monofocal or monofocal toric IOL. Good binocular uncorrected visual acuity results were demonstrated across all distances at all postoperative visits in these 13 patients. At 12 months postoperatively, more than 90% of subjects had binocular UDVA and UIVA 20/25 or better, and 76.9% had UNVA 20/25 or better.

Analysis of patient-reported outcomes data from a patient questionnaire showed that most subjects were satisfied with the outcomes, with a mean overall satisfaction score of 3.7 (Figure 4A). The frequency of corrective lens wear at 12 months demonstrates that most patients did not need spectacles (Figure 4B); however, they were required occasionally for near vision (Figure 4C). When asked (at various postoperative time points) if they would like to undergo this procedure again, all except 3 patients responded positively. All 3 of the patients who responded "no" at any postoperative time point were found to have developed PCO in the small-aperture eye. Following ND:YAG capsulotomy in these eyes, 2 of the 3 subjects changed their opinion from "no" to "yes" at the next follow-up visit and responded that they would like to have the same procedure again. One patient still responded "No" and reported experiencing haloes in the small-aperture eye despite uncorrected visual acuity of 0.00, −0.20, and 0.00 logMAR at distance, intermediate, and near.

Task performance ratings at far and intermediate/near distances were very good overall, corresponding to the degree of spectacle independence reported. However, as expected with the design of the small-aperture IOL, ratings were slightly lower for tasks performed in dim lighting (Table 2). Visual symptoms, including those associated with night vision, such as glare and halo, were of mild or low severity (mean severity score of 0.6 to 1.9, Table 3) and the patients were only a little or minimally bothered by them (mean bothersomeness score of 0.3 to 1.1, Table 3).

In this pilot study, we observed that the mean monocular mesopic contrast sensitivity (logCS) in the small-aperture IOL eyes was comparable to mean logCS in the fellow eyes, with and without glare, at all spatial frequencies. Subjects demonstrated binocular mesopic contrast sensitivity similar to that reported in previously published studies with monofocal IOLs.[22] Comparison of contrast sensitivity following the implantation of other EDOF IOLs in post-refractive surgery eyes could not be performed, as none of the previously published studies reported mesopic contrast sensitivity outcomes.[19–21,23]

In this pilot study, PCO occurred more frequently in the small-aperture IOL eyes than in fellow eyes. While the Apthera IOL features a 360° posterior square edge and is made of hydrophobic acrylic material, capsule dynamics or population characteristics may have contributed to the observed differences. As the small-aperture IOL directs light through the small central opening, slight opacities and folds in the capsule behind the aperture may affect vision more quickly and necessitate an early Nd:YAG laser procedure. In this study, when a posterior capsulotomy was performed, there was no additional technical difficulty introduced by the presence of the small aperture and the Nd:YAG procedure was rated "easy" by the surgeon regardless of whether laser shots were needed only around the annular mask or also through the center of the aperture. Posterior capsulotomy improved the mean UDVA and UNVA from 20/26 to 20/24, while UIVA was unchanged (20/23) before and after the Nd:YAG procedure.

Although conventional monovision is a simple and effective approach to managing presbyopia, it may cause a loss in stereopsis that can negatively affect patient outcomes.[24–28] It has been shown previously that a small-aperture IOL can yield stereoacuity similar to that attained under normal binocular vision in photopic conditions.[25] In this pilot study, task performance for tasks that might be expected to be affected by stereoacuity, such as ability to judge distances, walking down stairs or parking a car, were rated highly. This suggests that "monovision" with a small-aperture IOL in one eye does not degrade vision in the same way that conventional monovision does.

This pilot study was conducted at a single site to explore the outcomes of a small-aperture IOL in the niche population of post-refractive surgery patients; as such, some of the reported data may reflect the investigator's surgical techniques or preferences and may be limited in terms of generalizability. Nevertheless, the findings of this pilot study may help calculate an appropriate sample size for future comparative studies. A larger study with longer follow-up may validate the present study's findings. Another limitation of the study is that HOA data for these post-refractive eyes were not evaluated. In the future, a detailed analysis of HOA profiles would be helpful in understanding the extent to which a small-aperture may improve quality of vision in aberrated eyes.

Conclusion

In conclusion, the results of this pilot study suggest that the IC-8 Apthera small-aperture IOL may provide a full range of vision from distance to near, with high spectacle independence and a reasonable assurance of safety in patients with a history of prior corneal refractive surgery.

Abbreviations

IOL, intraocular lens (IOL); MRSE, manifest refraction spherical equivalent; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; UIVA, uncorrected intermediate visual acuity; DCIVA, distance-corrected intermediate visual acuity; UNVA, uncorrected near visual acuity; DCNVA, distance-corrected near visual acuity; HOAs, higher-order aberrations; EDOF, Extended depth of focus; IRB, Institutional review board; ETDRS, Early Treatment Diabetic Retinopathy Study; LASIK, laser in situ keratomileusis; RK, radial keratotomy; PCO, Posterior capsular opacification; Nd:YAG, neodymium-doped yttrium aluminum garnet; AE, adverse event; IOP, Intraocular pressure.

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author (Ang) upon reasonable request.

Acknowledgments

The author wishes to thank Jan Beiting (Wordsmith Consulting) and Raman Bedi, MD (IrisARC - Analytics, Research & Consulting) for providing editorial assistance in preparing the manuscript.

Funding

This study was funded through an independent study grant from Bausch + Lomb.

Disclosure

The author has received research grants from ACE Vision, Bausch + Lomb, BVI, Glaukos, Hoya, Staar Surgical, Spyglass, and Vialase. The author has received lecture honoraria from Alcon, Bausch + Lomb, BVI, Glaukos, Heidelberg Engineering, Johnson & Johnson, and Santen.

References

1. Nieto-Bona A, González-Mesa A, Villa-Collar C, Lorente-Velázquez A. Biomechanical properties in corneal refractive therapy during adaptation period and after treatment interruption: a pilot study. *J Optom*. 2012;5(4):164–170. doi:10.1016/j.optom.2012.06.006
2. Raevdal P, Grauslund J, Vestergaard AH. Comparison of corneal biomechanical changes after refractive surgery by noncontact tonometry: small-incision lenticule extraction versus flap-based refractive surgery - a systematic review. *Acta Ophthalmol*. 2019;97(2):127–136. doi:10.1111/aos.13906
3. Bethke W. A cataract surgeon's guide to post-refractive surgery patients. *Rev Ophthalmol*. 2003;10(3):34–36.
4. Jung HH, Ji YS, Oh HJ, Yoon KC. Higher order aberrations of the corneal surface after laser subepithelial keratomileusis. *Korean J Ophthalmol*. 2014;28(4):285–291. doi:10.3341/kjo.2014.28.4.285
5. Sachdev GS, Sachdev M. Optimizing outcomes with multifocal intraocular lenses. *Indian J Ophthalmol*. 2017;65(12):1294–1300. doi:10.4103/ijo.IJO_1072_17
6. Kanclerz P, Toto F, Grzybowski A, Alio JL. Extended depth-of-field intraocular lenses: an update. *Asia Pac J Ophthalmol*. 2020;9(3):194–202. doi:10.1097/APO.0000000000000296
7. Grabner G, Ang RE, Vilupuru S. The Small-aperture IC-8 intraocular lens: a new concept for added depth of focus in cataract patients. *Am J Ophthalmol*. 2015;160(6):1176–1184e1171. doi:10.1016/j.ajo.2015.08.017
8. Dick HB, Piovella M, Vukich J, Vilupuru S, Lin L, Clinical I. Prospective multicenter trial of a small-aperture intraocular lens in cataract surgery. *J Cataract Refract Surg*. 2017;43(7):956–968. doi:10.1016/j.jcrs.2017.04.038
9. Ang RE. Small-aperture intraocular lens tolerance to induced astigmatism. *Clin Ophthalmol*. 2018;12:1659–1664. doi:10.2147/OPTH.S172557
10. Ang RE. Comparison of tolerance to induced astigmatism in pseudophakic eyes implanted with small aperture, trifocal, or monofocal intraocular lenses. *Clin Ophthalmol*. 2019;13:905–911. doi:10.2147/OPTH.S208651
11. Dick HB. Small-aperture strategies for the correction of presbyopia. *Curr Opin Ophthalmol*. 2019;30(4):236–242. doi:10.1097/ICU.0000000000000576
12. Agarwal S, Thornell EM. Cataract surgery with a small-aperture intraocular lens after previous corneal refractive surgery: visual outcomes and spectacle Independence. *J Cataract Refract Surg*. 2018;44(9):1150–1154. doi:10.1016/j.jcrs.2018.06.028
13. Hooshmand J, Allen P, Huynh T, et al. Small aperture IC-8 intraocular lens in cataract patients: achieving extended depth of focus through small aperture optics. *Eye*. 2019;33(7):1096–1103. doi:10.1038/s41433-019-0363-9
14. Son HS, Khoramnia R, Mayer C, Labuz G, Yildirim TM, Auffarth GU. A pinhole implant to correct postoperative residual refractive error in an RK cataract patient. *Am J Ophthalmol Case Rep*. 2020;20:100890. doi:10.1016/j.ajoc.2020.100890
15. Langer J, Shajari M, Kreutzer T, Priglinger S, Mayer WJ, Mackert MJ. Predictability of refractive outcome of a small-aperture intraocular lens in eyes with irregular corneal astigmatism. *J Refract Surg*. 2021;37(5):312–317. doi:10.3928/1081597X-20210222-03
16. Ogle KN, Schwartz JT. Depth of focus of the human eye. *J Opt Soc Am*. 1959;49(3):273–280. doi:10.1364/JOSA.49.000273
17. Franco F, Branchetti M, Vicchio L, et al. Implantation of a small aperture intraocular lens in eyes with irregular corneas and higher order aberrations. *J Ophthalmic Vis Res*. 2022;17(3):317–323. doi:10.18502/jovr.v17i3.11568

18. Mapp AP, Ono H, Barbeito R. What does the dominant eye dominate? A brief and somewhat contentious review. *Percept Psychophys*. 2003;65 (2):310–317. doi:10.3758/BF03194802
19. Micheletti JM, Hall B. Satisfaction and visual outcomes with a non-diffractive EDOF IOL in post-myopic LASIK and PRK patients with high corneal spherical aberration. *Clin Ophthalmol*. 2026;Volume 20:1–9. doi:10.2147/OPTH.S566800
20. Carreras H, Renones J, Carreras MDR, Canto C, Pinero DP. Clinical performance of an extended range of vision intraocular lens after LASIK. *J Refract Surg*. 2024;40(10):e742–e753. doi:10.3928/1081597X-20240903-01
21. Ferreira TB, Pinheiro J, Zabala L, Ribeiro FJ. Comparative analysis of clinical outcomes of a monofocal and an extended-range-of-vision intraocular lens in eyes with previous myopic laser in situ keratomileusis. *J Cataract Refract Surg*. 2018;44(2):149–155. doi:10.1016/j.jcrs.2017.11.007
22. FDA. Summary of safety and effectiveness data (SSED) IC-8® Apthera™ IOL. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf21/P210005B.pdf. Accessed March 22, 2024.
23. Christopher KL, Miller DC, Patnaik JL, Lynch AM, Davidson RS, Taravella MJ. comparison of visual outcomes of extended depth of focus lenses in patients with and without previous laser refractive surgery. *J Refract Surg*. 2020;36(1):28–33. doi:10.3928/1081597X-20191204-01
24. Agarwal S, Thornell E. Spectacle independence in patients with prior radial keratotomy following cataract surgery: a case series. *Int Med Case Rep J*. 2020;13:53–60. doi:10.2147/IMCRJ.S230863
25. Fernandez EJ, Schwarz C, Prieto PM, Manzanera S, Artal P. Impact on stereo-acuity of two presbyopia correction approaches: monovision and small aperture inlay. *Biomed Opt Express*. 2013;4(6):822–830. doi:10.1364/BOE.4.000822
26. Abdelrazek Hafez T, Helaly HA. Spectacle independence and patient satisfaction with pseudophakic mini-monovision using aberration-free intraocular lens. *Clin Ophthalmol*. 2019;13:2111–2117. doi:10.2147/OPTH.S215229
27. Hayashi K, Ogawa S, Manabe S, Yoshimura K. Binocular visual function of modified pseudophakic monovision. *Am J Ophthalmol*. 2015;159 (2):232–240. doi:10.1016/j.ajo.2014.10.023
28. Xun Y, Wan W, Jiang L, Hu K. Crossed versus conventional pseudophakic monovision for high myopic eyes: a prospective, randomized pilot study. *BMC Ophthalmol*. 2020;20(1):447. doi:10.1186/s12886-020-01694-5