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ARTICLE

Evaluating the small aperture intraocular lens: depth of focus and the role of refraction and preoperative corneal astigmatism in visual performance

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Purpose: To evaluate depth of focus (DOF) and visual acuities (VAs) by manifest refractive spherical equivalent (MRSE) and degree of preoperative corneal astigmatism with the IC-8 small aperture intraocular lens (SA IOL) (Apthera).

Setting: 21 investigational sites in the United States.

Design: Prospective, multicenter, open-label, parallel-group, nonrandomized, examiner-masked, 1-year clinical study.

Methods: Included patients had cataract and ≤1.5 diopters (D) preoperative corneal astigmatism. Patients received either the SA IOL in 1 eye targeted to −0.75 D and a monofocal or monofocal toric IOL in the other targeted to plano (SA IOL group) or bilateral monofocal/monofocal toric IOLs targeted to plano (control group). Monocular and binocular assessments included defocus curves and uncorrected VAs (distance, intermediate, and near) by postoperative MRSE; monocular VAs were assessed by degree of preoperative corneal astigmatism.

Results: The SA IOL group (n = 343) achieved 0.82 D additional binocular DOF vs the control group (n = 110), and SA IOL eyes achieved 0.91 D additional monocular DOF over fellow eyes. Across all MRSEs, the SA IOL group achieved monocular uncorrected VAs of 20/40 or better and binocular uncorrected VAs of 20/32 or better across all distances. In addition, SA IOL eyes with higher (1.0-1.5 D) vs lower (<1.0 D) preoperative corneal astigmatism achieved equivalent monocular uncorrected VAs.

Conclusions: The SA IOL provides increased DOF vs monofocal/monofocal toric IOLs and consistent monocular and binocular vision across several postoperative MRSEs and up to 1.5 D of preoperative corneal astigmatism, giving patients with cataract and mild astigmatism the potential for an extended range of vision and reliable visual outcomes.

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As one of the most common procedures performed worldwide, cataract surgeries have evolved from solely the removal of opacified crystalline lenses to the removal of an opacified crystalline lens and an opportunity to correct refractive errors.[1] Despite these innovations in intraocular lens (IOL) technologies, patients may continue to experience residual refractive error after cataract surgery.[1] Presbyopia, a common condition in patients with cataracts, introduces an additional layer of complexity. After successful cataract surgery, patients typically require spectacles to achieve clear vision at multiple distances. In addition, for complete refractive correction, surgeons often need to treat corneal astigmatism, which is estimated to be ≤1.5 diopters (D) in 82% of patients who present for cataract surgery.[2,3] Astigmatism correction with toric IOLs comes with the challenges of achieving precise and stable alignment, which is further complicated by several contributing factors—either alone or in combination—including potential inaccuracies in preoperative corneal imaging, calculation of IOL powers, calculation of surgically induced astigmatism, marking of the reference axis, surgical placement, and possible postoperative IOL rotation.[4] IOL misalignment by 10 degrees can reduce the effective astigmatism correction by a third.[4]

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According to one study, 19% of monofocal toric IOLs and 18% of multifocal toric IOLs had >10-degree rotation at 1 month after cataract surgery.[5]

Current options for managing presbyopia in patients who undergo cataract surgery include multifocal, accommodating, extended depth-of-focus IOLs, and full visual range IOLs.[6,7] One new IOL option to simultaneously manage presbyopia and mild corneal astigmatism in patients with up to 1.5 D of astigmatism is the small aperture IOL (SA IOL), the IC-8 Apthera IOL (Bausch & Lomb, Inc.). The SA IOL is a 1-piece, hydrophobic, acrylic, posterior-chamber IOL with a circular opaque mask (FilterRing, Bausch & Lomb, Inc.).[8] The SA IOL capitalizes on pinhole optics, a concept in which light shone through a small hole decreases blur in the resulting image by blocking unfocused peripheral light while allowing through more focused central and paracentral light. In the SA IOL, the circular, opaque mask creates a small, 1.36 mm aperture that functions like a pinhole, reducing the degree of blur on the retinal image.[8,9] In addition, by restricting the light rays that reach the retina, the small aperture extends the available depth of focus (DOF) to a wider range of distances; previous research indicates that the SA IOL provides an extended DOF.[8–10]

The SA IOL is a monocular implant for the nondominant eye that is combined with a distance-corrected monofocal IOL in the dominant eye to improve DOF and functional range of vision.[10] The SA IOL has previously demonstrated good centration, stability, and vision in eyes with up to 1.5 D of preoperative corneal astigmatism.[11,12] If the SA IOL performs well across both multiple degrees of postoperative manifest refraction spherical equivalent (MRSE)—defined as a lens' sphere power plus half its cylindrical power—and levels of preoperative corneal astigmatism, it could serve as a viable treatment option for patients with presbyopia who may or may not have astigmatism.

To explore the effect of postoperative MRSE and preoperative corneal astigmatism in visual outcomes with the SA IOL, this study assessed VA and DOF in subgroups of patients treated contralaterally with an SA IOL and a monofocal/monofocal toric IOL compared with those treated with binocular monofocal/monofocal toric IOLs.

METHODS

This was a prospective, multicenter, open-label, parallel-group, nonrandomized, examiner-masked, 1-year clinical study (NCT03633695) conducted at 21 investigational sites in the United States and involved 22 principal investigators. It was performed in accordance with the HIPAA and the tenets of the Declaration of Helsinki and was approved by the Institutional Review Board of each participating center. Patients provided informed consent after passing eligibility screening.

Full inclusion criteria were discussed previously.[13,14] In brief, included patients (N = 453) were 22 years or older and could understand and were willing to sign a statement of informed consent and agreed to all study visits. Included patients had cataractous lens changes causing a corrected distance visual acuity (CDVA) of 20/40 or worse (either with or without a glare source present), with clear intraocular media other than the cataract, and the potential for postoperative CDVA of 20/25 or better in each eye.

Select exclusion criteria were a spherical power range not available in the SA IOL (ie, outside the range of +10.0 D through +30.0 D), pharmacologically dilated pupil size <6 mm, irregular astigmatism, or preoperative anterior corneal astigmatism >1.5 D in either eye as measured by optical biometry, which included corneal topography and biometric keratometry collected using one of the studies' approved devices: the IOLMaster (Carl Zeiss Meditec AG), LenStar (Haag-Streit, Bern, Switzerland), or through ultrasound. In addition, patients with any pathological condition that could affect future visual acuity (VA) predicted to be worse than 20/25 CDVA, such as macular degeneration, were excluded.[14]

Preoperative corneal astigmatism was evaluated by biometry, including axial length, anterior chamber depth, and keratometry. Manual or auto keratometry were not used to ensure accuracy and consistency. If an eye not receiving the SA IOL had a predicted residual refractive cylinder of ≥0.75 D, and a toric IOL was not indicated, limbal relaxing incisions were permitted during surgery to help resolve residual astigmatism, but only in monofocal eyes in the test and the control groups. Limbal relaxing incisions were not permitted in eyes implanted with the SA IOL.

In addition, sighting dominance was established through 3 consistent trials of the "hole-in-the-card" test in which the patient holds a rectangular card with a circular hole in the middle and, through the aperture, reads a single letter on the 4-m-distance logMAR ETDRS with 1 eye closed. After alternating which eye is closed, the dominant eye is recorded as the one that continued to see the letter when the fellow eye was covered.

Group assignments and surgical procedures were described previously.[13] Patients were assigned to receive the SA IOL contralaterally with a monofocal/monofocal toric lens (SA IOL group) or bilateral monofocal/monofocal toric lenses (control group) based on patient preference or investigator determination. For patients in the SA IOL group, the investigator determined which eye received the SA IOL or the monofocal/monofocal toric IOL based on patient preference and their assessment of the best predictive outcome, which could include the investigator's assessment of the degree of cataract in each eye, the patient's occupational and/or recreational needs, history of monovision contact lens wear, habitual spectacle prescription, or if the eye required a lens outside the available power range of the SA IOL.

All patients underwent crystalline lens removal by phacoemulsification, with or without femtosecond laser–assisted cataract surgery, followed by posterior chamber IOL implantation. For the monofocal/monofocal toric IOLs, patients received IOLs that corrected for spherical aberrations: AcrySof IQ (SA60WF, Alcon Laboratories, Inc.) or TECNIS aspheric monofocal IOLs (ZCB00, Johnson & Johnson Vision) or monofocal toric IOLs (AcrySof SA6AT3 or SA6AT4 IOLs; TECNIS ZCT150 or ZCT225 IOLs).

For both groups, the first eye implanted received a monofocal/monofocal toric IOL targeted to plano. If the first eye achieved satisfactory visual outcomes at postoperative week 1 (UDVA 20/32 or better and CDVA 20/25 or better), the second eye received either the SA IOL (SA IOL group) targeted to −0.75 D or a monofocal/monofocal toric IOL (control group) targeted to plano.

For SA IOL eyes, the appropriate IOL power was calculated after biometric assessment using the Barrett Universal II formula.[15] Power calculations for monofocal/monofocal toric IOLs were left to the surgeon's discretion. Patients completed up to 12 study visits over 12 months, including preoperative, operative, day 1, week 1, and months 1, 3, 6, and 12 visits.

Primary effectiveness and safety outcomes of the trial are reported in a separate publication. Here, we explore the effectiveness of the SA IOL in monocular and binocular conditions. Assessments include monocular (SA eye vs fellow eye) and binocular (SA group vs control group) DOF, postoperative MRSE of SA and fellow eyes (SA group) and first and second eyes (control group), VA by degree of SA IOL-eye MRSE, and by low (<1.0 D) vs high

(1.0 to 1.5 D) preoperative corneal astigmatism. We also explore VAs when both groups are corrected to plano in 1 eye and +0.75 D in the fellow eye.

Visual Acuity

VA was measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) chart presented on a self-calibrating monitor in the Clinical Trial Suite (CTS, M&S Technologies, Inc.). Monocular and binocular distance-corrected and uncorrected VA data were collected in distance (4 m), intermediate (66 cm), and near (40 cm) conditions at postoperative month 3. The CTS automatically randomized letter presentation to avoid memorization.

For distance-corrected VAs with +0.75 D correction measured at 6 months, all eyes in both groups were corrected with the manifest refraction, then a +0.75 D lens was added in front of SA IOL eyes in the SA IOL group and in front of second eyes in the control group.

Defocus Curves

Defocus curves were collected monocularly and binocularly at postoperative month 3 using ETDRS charts in the CTS calibrated for a 4 m test distance in standard photopic conditions, with the corrected distance manifest refraction in place. VA was recorded between +2.00 D and −5.00 D in 0.5 D defocus steps, except in the region from +0.50 D through −0.50 D, which was assessed in 0.25-D steps.

Manifest Refraction Spherical Equivalent

MRSE was measured at month 6 at 4 m using the CTS. The middle point of the emmetropic range was determined through the duochrome technique. Manifest refraction was measured using the same technique in all eyes to maintain masking by the refractionist and to avoid between-group bias.[14]

Preoperative Corneal Astigmatism

SA IOL eyes were assessed preoperatively for corneal astigmatism using optical biometry and then grouped by degree of astigmatism (lower astigmatism group 1: <1.0 D [n = 273]; higher astigmatism group 2: 1.0 to 1.5 D [n = 70]). At month 3, UDVA, uncorrected intermediate VA (UIVA), and uncorrected near VA (UNVA) data from SA IOL eyes were stratified by the astigmatism group.

Statistical Analyses

Study sample sizes were based on Annex B of ISO 11979-7:2014.[16]

As a secondary effectiveness endpoint of patients in the SA IOL group, the effect of preoperative corneal astigmatism in patients who achieved CDVA 20/25 or better on all distances of uncorrected VA in SA IOL eyes was assessed at 3 months. Patients from the SA IOL group were divided according to degree of preoperative corneal astigmatism in the SA IOL eye: astigmatism group 1 had <1.0 D astigmatism and astigmatism group 2 had 1.0 to 1.5 D. Data from astigmatism group 1 and astigmatism group 2 were compared using a 2-sample *t* test with a noninferiority margin of 0.12 logMAR.

RESULTS

Patient Disposition

Full patient disposition and demographics data are presented in a separate publication.[13] Overall, 469 patients met the inclusion criteria and were enrolled provisionally, while 79 patients were excluded at screening. Of the total study population, fully enrolled with both eyes operated (N = 453), 343 patients were enrolled in the SA IOL group, and 110 patients were enrolled in the control group. The between-group difference in mean pupil size was not clinically meaningful. Compared with the control group, a greater percentage of eyes in the SA IOL group had photopic pupil size ≥4 mm and dilated pupil size ≥9 mm.

Although no specific instruction was provided on whether to place the SA IOL in the dominant or nondominant eye, almost all patients in the SA IOL group (92.1% [316/343]) received the SA IOL in the nondominant eye based on surgeon preference to use sighting dominance as the determining factor for implanting the monofocal or monofocal toric IOL in the dominant eye.

Rates of surgical complications were low: 3 eyes experienced a surgical complication, all of which were lens dislocations. Of the 3 eyes that had surgical complications, 1 was an SA IOL eye, 1 was the fellow eye in an SA IOL-group patient, and 1 was the first eye of a patient in the control group.

In the SA-IOL eye that had a lens dislocation, the IOL vaulted forward with a Y tilt 7 days after implantation, which was deemed to be unrelated to the device and more likely related to the procedure. The event was considered moderate in severity, nonserious, and resolved without sequelae.

The SA IOL-group patient who experienced lens dislocation in the fellow eye was deemed to actually have had a lens rotation, which was considered not related to either the device or the procedure. The eye received a toric lens (IOL model ZCT225) which, at 190 days, was found to have rotated to a 45-degree axis, which was corrected to 164 degrees. The event was considered moderate in severity, nonserious, and resolved without sequelae.

The patient in the control group who experienced a lens dislocation in the first eye (IOL model SA6AT3), the lens was found to be at an axis of 60 degrees at 1-day postimplantation, although the preoperative target was 122 degrees. The event was considered unrelated to either the device or the procedure, and the IOL was repositioned. The surgical complication was considered moderate in severity nonserious and resolved without sequelae.

Distance-Corrected Monocular and Binocular Defocus Curves

At postoperative month 3, SA IOL eyes demonstrated VA of 0.2 logMAR or better at the defocus range of +1 D to approximately −2 D, and fellow eyes at the range of +1 D to approximately −1 D. The negative intercepts of the defocus curves on the 0.2 logMAR threshold line were −1.99 D for SA IOL eyes and −1.08 D for fellow eyes, yielding an additional 0.91 D DOF for SA IOL eyes vs fellow eyes (Figure 1, A). This extended DOF exceeded the clinical success threshold of at least a 0.5 D between-eye difference.

For binocular vision, the negative intercepts of the defocus curves on the 0.2 logMAR (20/32) threshold line were −2.21 D for the SA IOL group and −1.38 D for the control group, yielding a difference of 0.82 D favoring the SA IOL group. This translates to 0.82 D additional range of vision for patients in the SA IOL group vs the control group (Figure 1, B).

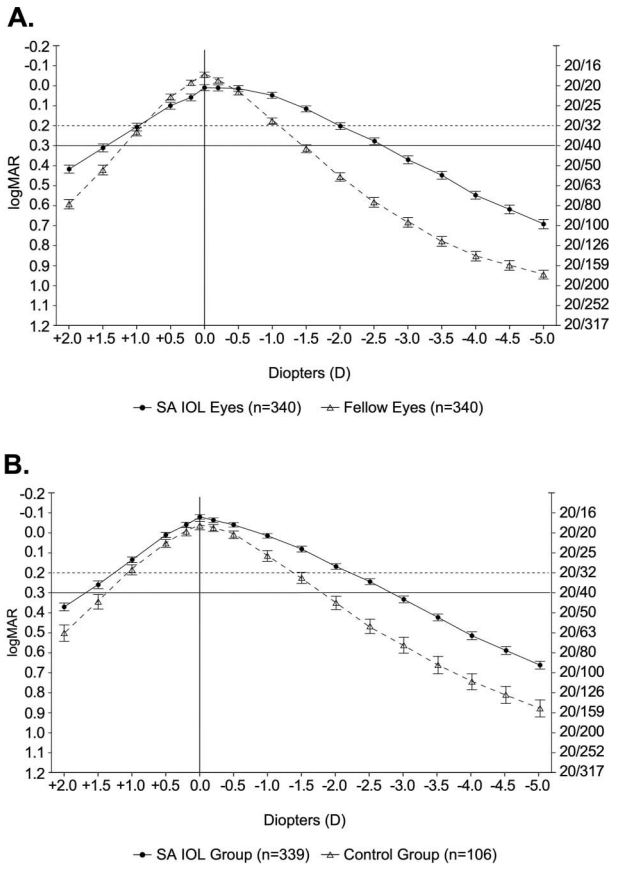

Figure 1. Monocular and binocular defocus curves at postoperative month 3. *A*: Monocular defocus curves assessed in eyes receiving the SA IOL vs fellow eyes with a monofocal/monofocal toric IOL. *B*: Binocular defocus curves assessed in patients in the SA IOL group vs control group. Error bars represent 95% CI. All eyes, whether implanted with the SA IOL or monofocal IOL, were corrected to plano. SA = small aperture

Manifest Refraction Spherical Equivalent

Through postoperative month 6, the SA IOL provided consistent refraction. In the SA IOL group, the mean (±SD) MRSE at 6 months was −0.314 (±0.4637) for SA IOL eyes and 0.073 (±0.3679) for fellow eyes (Figure 2).

Monocular and Binocular Uncorrected VA by Postoperative MRSE

Both monocular and binocular uncorrected VA data were grouped and analyzed by degree of postoperative SA IOL eye MRSE at postoperative month 3. Regardless of MRSE, pairing the SA IOL with a monofocal/monofocal toric IOL was associated with consistent monocular and binocular UDVA, UIVA, and UNVA (Figure 3, A). All 3 distances of monocular uncorrected VA in SA IOL eyes remained 20/40 or better regardless of MRSE. Binocular UDVA in the SA IOL group remained between 0.1 and −0.1 logMAR (20/25 or better) regardless of postoperative MRSE (Figure 3, B). UIVA in the SA IOL group remained just above 0.1 logMAR (20/25) in both monocular and binocular conditions regardless of postoperative MRSE. SA IOL-group binocular UNVA remained 0.2 logMAR (20/32) or better across all MRSEs.

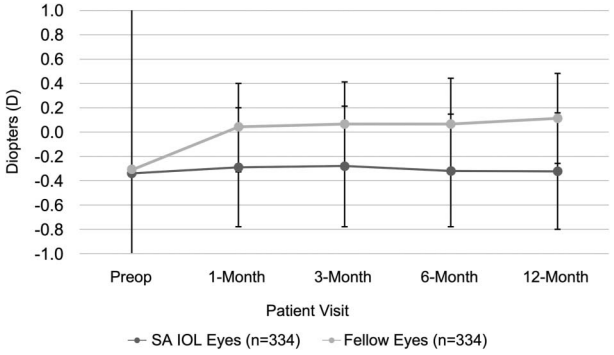

Figure 2. MRSE at each patient visit. Mean MRSE in SA IOL eyes vs fellow eyes in the SA IOL group. Error bars represent the SD. MRSE = manifest refraction spherical equivalent; SA = small aperture

Monocular SA IOL-Eye Uncorrected VA by Degree of Preoperative Corneal Astigmatism

Uncorrected VAs were analyzed for SA IOL eyes achieving CDVA or 20/25 or better grouped by degree of preoperative astigmatism. At 3 months, noninferiority of astigmatism group 2 (SA IOL eyes with higher preoperative astigmatism, 1.0 to 1.5 D) compared with astigmatism group 1 (SA IOL eyes with lower preoperative astigmatism, <1.0 D) was established based on a difference in mean monocular UDVA of 0.023 logMAR, with a 0.052-logMAR 95% UCL, which was below the 0.12-logMAR noninferiority margin ($P < .0001$) (Figure 4). Although not statistically analyzed at intermediate and near, astigmatism groups 1 and 2 were within 0.1 logMAR of each other in UIVA and UNVA.

+0.75 D Distance-Corrected Visual Acuities

At postoperative month 6, monocular +0.75 D distance-corrected VAs in SA IOL eyes were better than in control group eyes at intermediate and near, demonstrating that the SA IOL provides an additional 1.6 lines of intermediate VA and 2.1 lines of near VA over +0.75 D-corrected monofocal eyes (Figure 5, A).

Binocular +0.75 D distance-corrected VAs in the SA IOL group were also better than in the control group at intermediate and near (Figure 5, B). These data indicate that when both groups were corrected to the same amount of monovision, the SA IOL group had an additional 1.3 lines of intermediate VA and 1.5 lines of near VA over the control group (Figure 5, B).

Contrast sensitivity and safety data are presented in a separate publication.

DISCUSSION

The SA IOL represents an advancement in presbyopia-correcting IOLs. The wavefront-filtering central small aperture of the SA IOL mitigates the reduction in VA caused by unfocused peripheral light rays, allowing only central light rays to focus on the retina. Because of this design, the SA IOL can correct up to 1.5 D of astigmatism in patients and may help those with corneal irregularities due to medical conditions or trauma.[17]

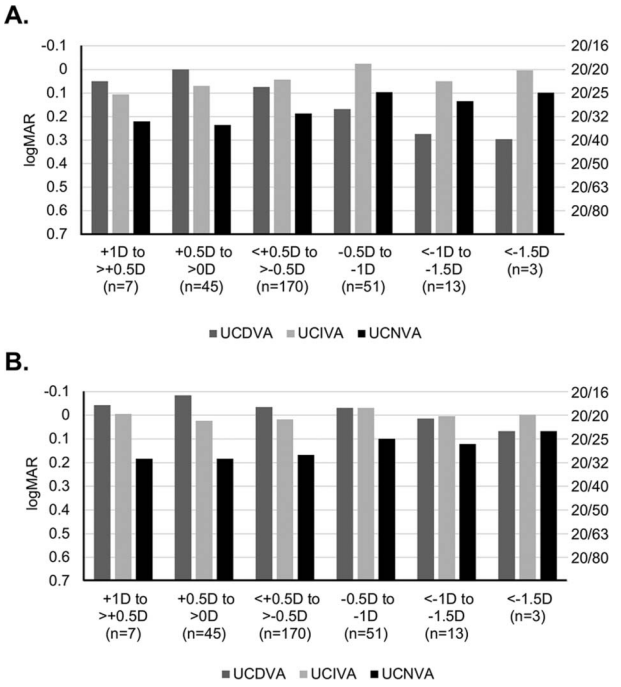

Figure 3. Mean monocular and binocular uncorrected VA data at postoperative month 3 grouped by postoperative SA IOL-eye MRSE. *A*: Mean monocular uncorrected VAs by postoperative SA IOL MRSE. *B*: Mean binocular uncorrected VAs by postoperative SA IOL MRSE. Monocular vision was measured in the SA IOL eye; binocular vision in the SA IOL group was evaluated by vision in both eyes (SA IOL in the study eye; monofocal/monofocal toric IOL in the fellow eye). MRSE = mean refraction spherical equivalent; SA = small aperture

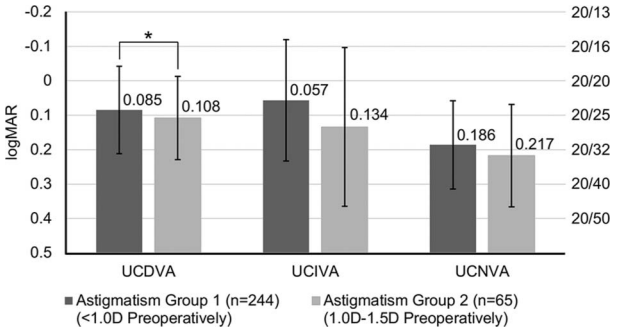

Figure 4. Mean monocular uncorrected VA at 3 months in SA IOL eyes by degree of preoperative corneal astigmatism. Noninferiority of UDVA data was established using a 2-sample *t* test and a 0.12-logMAR noninferiority margin. *Below the 0.12-logMAR noninferiority margin. Error bars represent the SD. SA = small aperture

Overall, previous work on monocular implantation of the SA IOL has demonstrated positive VA, DOF, safety, and patient satisfaction outcomes across a variety of studies, both small and large. Across several small-scale studies, the SA IOL provided substantial improvements in binocular uncorrected VA at all distances, with significant improvements at all distances in both the short and long terms. One study of 12 patients saw significant improvements beginning at month 1, while another small-scale study found meaningful improvements at month 3.[11,18] In the longer term, 2 studies found that nearly all patients who receive the SA IOL had uncorrected VAs 20/32 or better across all distances at 12 months.[18,19]

Some of the smaller, initial studies of the SA IOL examined its use when implanted either contralaterally or bilaterally. Two such studies, both prospective case series, examined visual outcomes with the SA IOL in patients with the SA IOL implanted either contralaterally or bilaterally, though in smaller populations.[19,20] Dick et al. (N = 17) evaluated SA IOL performance in the short term, with the bilateral SA IOL group demonstrating significantly improved uncorrected binocular VA at all distances vs the contralateral SA IOL group at 6 months, but reduced overall satisfaction and an increased incidence of halo at 3 months.[20] In the work of Ang et al. (N = 22), 12-month data demonstrated 20/32 or better uncorrected binocular VA in both groups across all distances, although the bilateral SA IOL group had improved UNVA. Overall satisfaction was similar in both the contralateral and bilateral SA IOL groups, but similar to the work of Dick et al., bilateral SA IOL implantation was associated with increased visual symptoms such as glare, halos, and night vision problems.[19,20]

Larger studies of the SA IOL found similar visual outcomes, with excellent VA across all distances, often 20/32 or better.[10,21] In the work of Dick et al., a prospective, multicenter case series of 105 patients implanted contralaterally with the SA IOL and an aspheric monofocal IOL, binocular DOF was evaluated with the SA IOL targeted to −0.75 D and with a simulation of bilateral IOL targeting to plano, as described above in this study. In the prospective case series, the SA IOL targeted to −0.75 D provided nearly 1.0 D additional depth of focus vs the simulated bilateral plano DOF.[21]

In addition, Dick et al. demonstrated that contralateral implantation of the SA IOL with a monofocal IOL provided 20/32 or better uncorrected binocular VA in 99% of patients at distance, 95% at intermediate, and 79% at near at 6 months.[21] Although the present article does not present data on mean uncorrected VAs for the patient population overall, it does include an analysis of uncorrected VA by the MRSE range (Figure 3). Here, the SA IOL provided a mean of 20/32 or better binocular uncorrected VA across all distances in all MRSE groups; furthermore, for UDVA and UIVA, the mean VA was 20/25 or better (Figure 3, B).

This study includes an analysis of the SA IOL in a large population, comparing an SA IOL group against a bilateral monofocal/monofocal toric IOL control group. Here, as in the prospective case series of Dick et al., the SA IOL provided additional DOF vs the control group, by 0.82 D at 3 months (Figure 1, B).[21] Taking both the smaller and larger prospective case series together, work to date has demonstrated that contralateral implantation of the SA IOL provides a wide range of focus, with DOF improvements up to 1.0 D over bilateral monofocal IOL implantation.[18,19,21,22] Patients reported low rates of visual symptoms such as halo or glare, and these were largely rated as low in severity.[10,18,21]

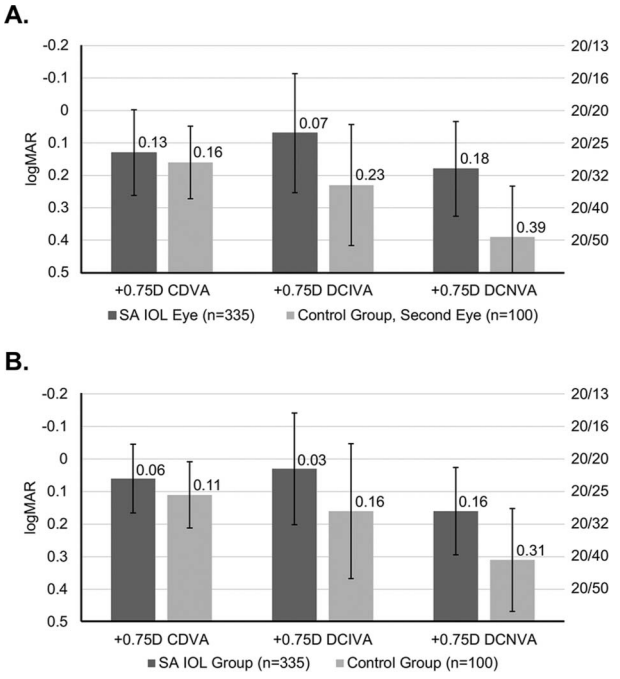

Figure 5. Mean +0.75 D-corrected VA at 6 months. *A*: Monocular VAs. *B*: Binocular VAs. Error bars represent the SD. SA = small aperture

Similarly, across clinical trials, the SA IOL was associated with a favorable safety profile and high patient satisfaction, although some cases of posterior capsular opacification (PCO) or elevated intraocular pressure have occurred.[10,11,18–22] PCO, the most common complication after cataract surgery, can lead to reduced VA and therefore could potentially affect mean VAs in this study.[23,24] In this study, PCO rates were similar across both test groups, with mild to moderate PCO occurring in approximately 15% of SA IOL eyes, 10% in fellow eyes, and 5% to 6% in control group eyes. In addition, SA IOL eyes with PCO had similar corrected and uncorrected VAs to SA IOL eyes without PCO regardless of PCO severity. Mean UDVA, however, was approximately 2 lines lower in eyes with moderate-to-severe PCO in both test groups, but only at the 6-month timepoint, UDVA was not significantly affected by PCO severity in either test group at any other timepoint.

This clinical study of the SA IOL conducted in the United States, described here and previously, was designed to compare the binocular visual outcomes in the SA IOL group, in which patients received an SA IOL in 1 eye and a monofocal/monofocal toric IOL in the fellow eye, with a control group, in which patients received monofocal/monofocal toric IOLs bilaterally.[13] The results demonstrated that when compared with the control group, the SA IOL group achieved comparable distance VA, enhanced intermediate and near VA, monofocal-like binocular contrast sensitivity, and a favorable safety profile.[13] To complement these data, the current analysis focuses on the mean photopic monocular and binocular DOF, the influence of refraction on the visual performance of eyes treated contralaterally with the SA IOL and a monofocal/monofocal toric IOL, and monocular uncorrected VA in SA IOL eyes with higher (1.0 to 1.5 D, astigmatism group 2) vs lower (<1.0 D, astigmatism group 1) preoperative corneal astigmatism. In addition, this study compared the effect of mini-monovision with SA IOL with a similar amount of mini-monovision in the control group. DOF assessments demonstrated that at 0.2 logMAR, the SA IOL provides a greater DOF by 0.91 D compared with fellow eyes, and binocularly, patients in the SA IOL group had a 0.81 D greater DOF compared with patients in the control group (Figure 1).

As with any study, this evaluation of the SA IOL comes with some limitations. This study was nonrandomized, which could lead to selection biases in the treatment group assignments; however, the study was designed according to the ISO standard for multifocal lens studies, which do not recommend randomization.[16] In addition, there was a propensity score analysis included as a sensitivity analysis to address this. In this analysis, the statistical success criteria were still met for all coprimary endpoints. However, because of the permanent nature of IOLs, it was important to consider patient preference and the investigator's assessment of the best predictive outcome when selecting which IOL to use. Further refinement on lens calculation is needed to achieve targeted endpoint refraction and minimize aim error.

Because MRSE can be a factor in postoperative outcomes, this analysis evaluated VAs in the SA IOL group by SA IOL-eye MRSE. The data determined that MRSE in both eyes remained stable over time and that degree of MRSE did not affect monocular (SA IOL eye) or binocular uncorrected VAs at any distance (Figures 2 and 3). In addition, VAs in all MRSE ranges were high—20/25 or better for SA IOL eyes and 20/32 or better for SA IOL-group binocular vision—and the SA IOL often outperformed monofocal/monofocal toric IOLs across a variety of conditions, refractive errors, and degrees of astigmatism.

In addition, patients with up to 1.5 D of preoperative corneal astigmatism experienced consistent visual performance at distance, intermediate, and near without astigmatism correction. Eyes with both high (1.0 to 1.5 D, astigmatism group 2) and low (<1.0 D, astigmatism group 1) preoperative corneal astigmatism achieved equivalent UDVA, UIVA, and UNVA (Figure 4).

To compare visual performance of the SA IOL and monofocal/monofocal toric IOLs at the same refractive mini-monovision target, a +0.75 D lens was used to simulate the SA IOL's intended refractive target of −0.75 D. For monocular vision, SA IOL eyes achieved 1.6 lines better intermediate VA and 2.1 lines better near VA over control group second eyes (Figure 5, A). Binocularly, the SA group achieved 1.3 and 1.5 lines better intermediate and near VA, respectively, over the control group (Figure 5, B). These results provide evidence that eyes with the SA IOL have additional range of vision over traditional mini-monovision with monofocal/monofocal toric IOLs.

These results represent the largest study to date on the SA IOL, and they align well with previously published results. Previous studies show that the SA IOL is associated with an extended DOF and reliable vision in eyes with preoperative

corneal astigmatism.[11,12,19,20] This study demonstrates that contralateral implantation of the SA IOL and a monofocal/monofocal toric IOL provides excellent uncorrected binocular VA across a range of distances. These results are seen regardless of degree of postoperative MRSE in eyes with up to 1.5 D of preoperative corneal astigmatism and that a target correction of −0.75 D for the SA IOL yields additional intermediate and near VA vs monofocal IOLs. Thus, eyes with the SA IOL, in addition to having enhanced DOF, benefit from reliable visual outcomes across multiple degrees of postoperative residual refractive error and up to 1.5 D of preoperative corneal astigmatism.

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WHAT WAS KNOWN

- Previous studies on the small aperture (SA) IOL indicate that it provides improved DOF when implanted contralaterally with a traditional monofocal or monofocal toric IOL vs bilateral monofocal/monofocal toric IOLs.
- Despite these previous, more descriptive assessments of the SA IOL, there have not yet been large enough studies to confirm its effects statistically, and no assessments as yet have examined the effects of preoperative corneal astigmatism and postoperative refractive error on the visual performance of the SA IOL.

WHAT THIS PAPER ADDS

- This analysis provides large-scale (N = 453) characterization of the SA IOL and its visual performance with higher vs lower preoperative corneal astigmatism and across a range of refractive errors.
- Defocus curves demonstrated that patients with the SA IOL have a difference of 1.0 D additional monocular (SA IOL eye) and binocular DOF over those in the control group.
- This large-scale analysis confirms that initial studies showing increased DOF with the SA IOL vs monofocal/monofocal toric IOLs as statistically significant.

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