

Aspheric microincision intraocular lens implantation with biaxial microincision cataract surgery: Efficacy and reliability

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PURPOSE: To evaluate the efficacy and reliability of a microincision intraocular lens (IOL) and its use in biaxial microincision cataract surgery (MICS).

SETTING: Atatürk Training and Research Hospital, Ankara, Turkey.

DESIGN: Prospective clinical study.

METHODS: A microincision IOL (Akreos MI60) was implanted after cataract extraction by the biaxial MICS technique. Over a postoperative follow-up of 12 months or more, visual acuity, contrast sensitivity, surgically induced astigmatism (SIA), corneal and ocular aberrations, and early and late complications were recorded.

RESULTS: The IOLs were implanted in the capsular bag in all 100 eyes. The mean final incision size was $1.82 \text{ mm} \pm 0.09$ (SD). Postoperatively, the mean corrected distance visual acuity was 0.06 ± 0.10 logMAR; the mean spherical equivalent, -0.48 ± 0.91 diopter (D); and the mean calculated SIA, 0.20 ± 0.22 D. Contrast sensitivity with and without glare was within normal limits. There was no statistically significant difference in the root mean square of total corneal aberrations between preoperatively and postoperatively. Ocular wavefront analysis 3 months postoperatively showed mean values of $0.15 \pm 0.2 \mu\text{m}$ for spherical aberration, $0.38 \pm 0.16 \mu\text{m}$ for higher-order aberrations, $0.18 \pm 0.14 \mu\text{m}$ for coma, and $0.14 \pm 0.08 \mu\text{m}$ for trefoil. The 4 cases (4.0%) of membranous anterior chamber reaction resolved with treatment. None of the 20 eyes (20.0%) with posterior capsule opacification required neodymium:YAG capsulotomy. All IOLs remained well centered.

CONCLUSION: The aspheric microincision IOL was safely implanted through a 1.8 mm or smaller incision during biaxial MICS and gave good postoperative outcomes.

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Advances in surgical technique and technology have significantly changed cataract surgery methods in the past decade. Cataract extraction can now be performed through incisions smaller than 2.0 mm using biaxial microincision cataract surgery (MICS)^{1–3} or microcoaxial phacoemulsification^{4,5} methods. These techniques require intraocular lenses (IOLs) that can be implanted through a very small incision. Until recently, the microincision IOLs on the market had disadvantages and did not have the positive features of standard conventional and existing IOLs.^{6–8}

The ideal IOL for MICS can be implanted through incisions smaller than 2.0 mm without incurring permanent structural or optical changes when compressed or rolled for implantation. The IOL should

also have high biocompatibility, be stable in the capsular bag, and not increase the risk for posterior capsule opacification (PCO). Its optical performance should continue in vivo, and it should not induce positive or negative dysphotopsia, light scattering, or aberrations. In short, it must have similar or better visual results than conventional IOLs. Paralleling the developments in cataract surgery is the availability of new-generation IOLs acceptable for implantation through microincisions.^{9,10}

Biaxial MICS can be performed through clear corneal incisions (CCIs) smaller than 1.8 mm. The 2 goals are to reduce intraoperative trauma and improve optical outcomes. There are several advantages to the MICS technique. It reduces the amount of surgically

induced astigmatism (SIA),¹¹⁻¹³ results in early visual rehabilitation, and separates the irrigation and aspiration functions. The latter improves the fluidics because the fluid inflow works as an instrument, reducing turbulence and making surgery less invasive.^{14,15}

Visual function after cataract surgery is determined by a combination of corneal and internal aberrations created by the IOL and surgical factors.¹⁶ Therefore, acceptance of the biaxial MICS technique by surgeons principally depends on the success of microincision IOLs. In this study, the aim was to evaluate the visual outcomes and optical quality of an aspheric microincision IOL and its suitability for use in biaxial MICS.

PATIENTS AND METHODS

This prospective study evaluated eyes that had biaxial MICS and implantation of an aspheric microincision IOL. All patients enrolled in the study agreed to participate, met the inclusion criteria, and signed an informed consent agreement before any procedures were performed. The study was approved by the hospital's ethics committee and was performed in accordance with the ethical principles described in the Declaration of Helsinki. Patients who had previous eye surgery or eye disease that might affect final visual acuity (eg, amblyopia, retinal or macular abnormalities, corneal pathology, glaucoma) were not included in the study.

Eyes in the study had grade II to IV nuclear or corticonuclear cataract according to the Lens Opacities Classification System (LOCS) III scale.¹⁷ Preoperatively, all patients had a complete clinical and biomicroscopic ophthalmic examination. Nuclear hardness was evaluated by biomicroscopy and the LOCS III scale. Refraction and corrected distance visual acuity (CDVA) were determined by Early Treatment Diabetic Retinopathy Study (ETDRS) charts and transformed into logMAR units for statistical analysis. Corneal toricity was assessed by corneal topography (Keratron Scout Corneal Analyzer, Optikon 2000 SpA), and corneal aberrations were derived by converting the corneal elevation profile into corneal wavefront data with a 6.0 mm aperture diameter using Zernike polynomials. The root mean square (RMS) of higher-order aberrations (HOAs) (RMS value of 3rd to 6th Zernike modes), total RMS, primary coma Z(3,±1), primary trefoil Z(3,±3), and spherical aberration Z(4,0) were calculated from corneal wavefront data. Central corneal thickness was measured with an ultrasound pachymeter (B.V. International) as the patient gazed straight ahead and fixated on a continuously visible target point. Biometry was performed by an immersion method (CineScan Ultrasound, Quantel Medical). Intraocular lens power was calculated targeting emmetropia.

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Intraocular Lens

All eyes in the study had implantation of an Akreos MI60 microincision IOL (Bausch & Lomb) (Figure 1). The aspheric IOL is of hydrophilic acrylic with a 26% water content. The total length is 10.5 to 11.0 mm and the optic diameter 5.6 to 6.2 mm depending on the dioptric power. The IOL has a neutral aspheric optic that, according to the manufacturer, was designed to provide good image transmission even if the IOL decenters or tilts. The IOL has 4 haptics, a design the manufacturer says resists vitreous pressure and provides anteroposterior stability to prevent pseudoaccommodation. The thin haptic provides 4 zones for capsule sealing around the optic to promote early and stable centration. The progressive resistance of the haptics was designed to prevent capsular bag contraction and optic displacement. The IOL can be implanted in the capsular bag in eyes with posterior capsule rupture smaller than 1 quadrant. The optic pushes the IOL backward; this, along with the 10-degree haptic angle and 360-degree square-edged design, are intended to prevent PCO.

Surgical Technique

The same surgeon (I.C.) performed all operations using a standard dilation regimen, topical anesthesia, and a Stellaris 11110 phacoemulsification system with a venturi pump (Bausch & Lomb). After two 1.2 to 1.4 mm trapezoidal incisions were made with a 19-gauge steel knife and a capsulorhexis created, nucleofractis was performed using a half-moon supracapsular technique.¹⁸ The phaco mode was micropulse on for 20 milliseconds and off for 40 milliseconds. After quadrant, cortex, and epinucleus removal, the anterior capsule was thoroughly polished. The incision closer to the steep axis was enlarged to 1.7 mm with a knife and the IOL implanted with a lens injection system (Viscoject LP604350, Medical AG). The incision size after IOL implantation (final incision size) was measured with a microcoaxial gauge (Tsuneoka, American Surgical Instruments Corp.).

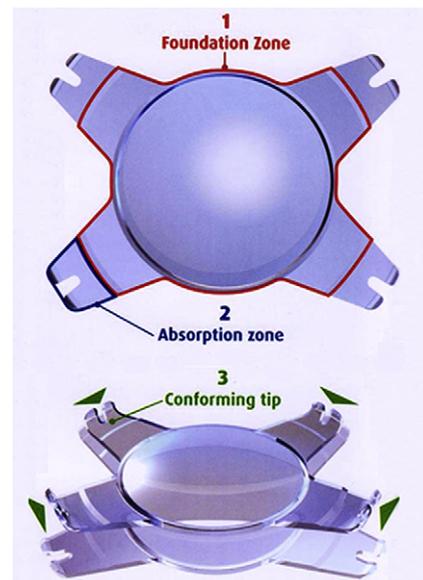


Figure 1. Aspheric microincision IOL.

In all cases, the surgical time, phaco time, mean phaco power (%), and effective phaco time were recorded. Intraoperative complications (eg, Descemet membrane detachment, incision burn, posterior capsule rupture, zonular dialysis, iris damage) were noted.

Postoperative Protocol

Patients had a follow-up of 1 year or longer. The examinations at 1 day, 1 week, and 1, 3, 6, and 12 months included uncorrected distance visual acuity (UDVA), CDVA, uncorrected near acuity (UNVA), and corrected near visual acuity (CNVA) measurements (ETDRS chart); detailed slit-lamp biomicroscopy, and corneal pachymetry. At 3 months, corneal topographic measurements, the SIA calculated by vector analysis, total ocular aberrations, and corneal aberrations were evaluated. Total ocular wavefront aberrations were measured with a wavefront analyzer (ORK, Schwind Eye-Tech-Solutions GmbH & Co. KG) using a Hartmann-Shack wavefront sensor. The RMS for HOAs (Zernike 3rd to 6th), primary coma Z(3,±1), primary trefoil Z(3,±3), and spherical aberration Z(4,0) were calculated for a 6.0 mm pupil diameter. Long-term complications (eg, PCO) were evaluated at 6 months and 12 months.

Statistical Analysis

Statistical analysis was performed using SPSS for Windows software (version 16.0, SPSS, Inc.). The paired-samples *t* test was used for comparisons. A *P* value less than 0.05 was considered statistically significant.

RESULTS

This study comprised 100 eyes of 81 patients. Table 1 shows the patients' characteristics and Table 2, the surgical parameters. The final incision width was 1.7 mm

in 25 eyes (25.0%), 1.8 mm in 37 eyes (37.0%), 1.9 mm in 33 eyes (33.0%), and 2.0 mm in 5 eyes (5.0%).

Table 3 shows the postoperative visual acuity and refraction 3 months postoperatively. The UDVA and CDVA were statistically significantly better than preoperatively (*P* < .01). Regarding predictability, the SE was within ±0.50 D in 38 eyes (38.0%) and within ±1.00 D in 73 eyes (73.0%).

Figure 2 and Table 3 show the contrast sensitivity 3 months postoperatively. There were no statistically significant differences between contrast sensitivity with glare and contrast sensitivity without glare at any spatial frequency (all *P* > .05).

Table 4 shows the preoperative and postoperative corneal and postoperative ocular aberration values. There were no statistically significant differences in any corneal aberration between preoperatively and postoperatively. Although the mean coma aberration decreased slightly after surgery, the mean trefoil increased (*P* = .625).

Complications

Intraoperative complications were posterior capsule rupture in 1 eye (1.0%), partial zonular dialysis in 1 eye (1.0%), and iris prolapse through the incision site related to intraoperative floppy-iris syndrome in 2 eyes (2.0%).

Postoperatively, membranous inflammation in the anterior chamber occurred in 4 eyes (4.0%); 2 cases were relatively severe. The inflammation resolved with topical corticosteroid treatment within 15 days in the cases of severe membrane and within 3 days in other cases. At the 12-month follow-up, anterior capsule fibrosis was seen in 3 eyes (3.0%) and PCO in 20 eyes (20%). The mean CDVA in the PCO cases was 0.089 ± 0.13 logMAR; no eye with PCO required a neodymium:YAG (Nd:YAG) laser capsulotomy. All IOLs were well positioned, with no change in IOL position, no decentration, and no tilt up to 12 months postoperatively (Figure 3).

DISCUSSION

In this study, we evaluated advantages and disadvantages of biaxial MICS with implantation of an Akreos MI60 aspheric microincision IOL. Previous generation

Table 1. Patient characteristics and preoperative data.

Parameter	Value
Patients/eyes (n)	81/100
Mean age (y) ± SD	64.2 ± 13.0
Sex, n (%)	
Female	41 (50.6)
Male	40 (49.4)
Eye, n (%)	
Right	49 (49.0)
Left	51 (51.0)
Mean CDVA ± SD	
Decimal	0.34 ± 0.19
LogMAR	0.56 ± 0.36
Mean UDVA ± SD	
Decimal	0.23 ± 0.15
LogMAR	0.75 ± 0.39
Mean CCT (µm) ± SD	547.9 ± 37.7
Nuclear hardness (LOCS III)	NO2-4

CCT = central corneal thickness; CDVA = corrected distance visual acuity; LOCS = Lens Opacities Classification System; UDVA = uncorrected distance visual acuity

Table 2. Surgical parameters.

Parameter	Mean ± SD
Effective phaco time (s)	5.31 ± 3.77
Total operation time (min)	14.91 ± 3.79
Used fluid volume (mL)	102.07 ± 31.42
Final incision width (mm)	1.82 ± 0.09

Table 3. Postoperative visual acuity, refraction, and contrast sensitivity at 3 months.

Parameter	Mean ± SD
UDVA	
Decimal	0.49 ± 0.22
LogMAR	0.35 ± 0.21
CDVA	
Decimal	0.89 ± 0.17
LogMAR	0.06 ± 0.10
UNVA	
Jaeger	3.02 ± 2.14
LogMAR	0.16 ± 0.16
DCNVA	
Jaeger	4.70 ± 1.77
LogMAR	0.29 ± 0.13
CNVA	
Jaeger	1.09 ± 0.35
LogMAR	0.008 ± 0.03
Required near add power* (D)	2.24 ± 0.57
SE refraction (D)	-0.48 ± 0.91
SIA by vector analysis (D)	0.20 ± 0.22
Contrast sensitivity (log units)	
Without glare	
3 cpd	1.59 ± 0.18
6 cpd	1.86 ± 0.17
12 cpd	1.56 ± 0.25
18 cpd	1.15 ± 0.27
With glare	
3 cpd	1.56 ± 0.17
6 cpd	1.77 ± 0.19
12 cpd	1.47 ± 0.21
18 cpd	1.08 ± 0.22

add = addition; CDVA = corrected distance visual acuity; CNVA = corrected near visual acuity; cpd = cycles per degree; DCNVA = distance-corrected near visual acuity; SE = spherical equivalent; SIA = surgery induced astigmatism; UDVA = uncorrected distance visual acuity; UNVA = uncorrected near visual acuity
 *Calculated to assess pseudoaccommodation

small-incision IOLs were associated with significant PCO and IOL tilting and decentration,⁶⁻⁸ problems that were overcome with newer IOL designs.^{10,19-21}

The biaxial MICS technique has several advantages. One is that it minimizes SIA. In our study, the IOLs were implanted through incisions that were 2.0 mm or smaller (mean 1.82 mm) and the mean SIA was 0.20 D, which indicates that the surgical technique and the IOL complement each other. Studies of the biaxial MICS technique report SIA values of 0.36 D with 1.7 mm incisions,¹² 0.15 D with 1.5 to 1.7 mm incisions,²² and 0.23 D with 1.7 mm incisions.²³ These findings show that with even with small incisions, the SIA is almost zero when the proper technique and IOL are used.

Another advantage of biaxial MICS is that it protects the optical quality of the cornea and does not increase corneal HOAs.^{16,24} To our knowledge, a study by Tong

Contrast Sensitivity

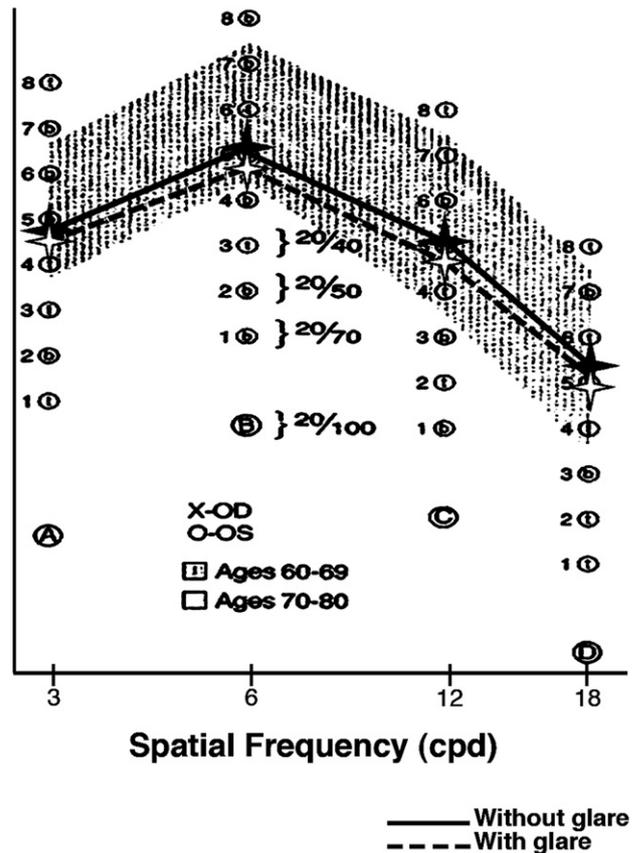


Figure 2. Contrast sensitivity results with and without glare (cpd = cycles per degree).

Table 4. Preoperative and postoperative corneal aberrations and postoperative ocular aberrations.

Aberration	Mean (µm) ± SD		P Value*
	Preoperative	Postoperative (3 Mo)	
Corneal			
HO RMS	0.57 ± 0.24	0.62 ± 0.26	.658
Total RMS	1.28 ± 0.67	1.24 ± 0.44	.764
Spherical	0.18 ± 0.17	0.17 ± 0.15	.925
Coma	0.42 ± 0.23	0.34 ± 0.26	.525
Trefoil	0.32 ± 0.15	0.37 ± 0.18	.625
Ocular			
HO RMS	—	0.38 ± 0.16	—
Spherical	—	0.15 ± 0.20	—
Coma	—	0.18 ± 0.14	—
Trefoil	—	0.14 ± 0.08	—

HO RMS = higher-order root mean square; RMS = root mean square
 *Comparison between preoperative and postoperative (paired-samples t test)

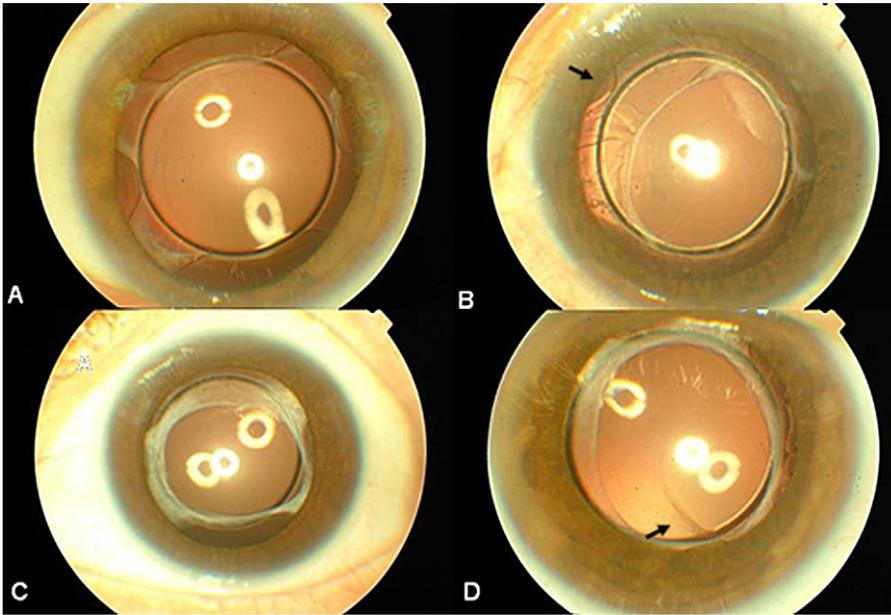


Figure 3. A: The IOL is well centered 9 months postoperatively in an eye with no intraoperative complications. B: The IOL remains well centered 6 months postoperatively in an eye with partial zonular dialysis (*arrow*) as a result of traumatic cataract. C: The IOL is well centered at 6 months in an eye with anterior capsule fibrosis that developed a severe membranous anterior chamber reaction. D: The IOL is centered 6 months postoperatively in an eye in which the IOL was implanted in the capsular bag despite posterior capsule rupture (*arrow*).

et al.²⁵ is the only one to report a significant increase in trefoil after biaxial MICS; there was no significant difference in total HOA between preoperatively and postoperatively. In our study, the trefoil induced by the CCI increased after surgery, but not significantly. In addition, there were no significant changes in coma, spherical aberration, total HOA, or total RMS, all of which would decrease the optical and visual quality of the cornea. In addition to surgical technique, retinal image quality is affected by IOL-induced aberrations, light scattering, and optical quality degradation.

The increased positive spherical aberration in the eye induced by conventional spherical IOLs can be prevented and the positive spherical aberration of the cornea reduced or unchanged by the implantation of aspheric IOLs. Of the aberrations of the Zernike pyramid, IOLs can only address spherical aberration. This is because it is the only aberration that is rotationally symmetric and therefore does not require any specific rotation of the correcting IOL inside the eye.²⁶ Several studies²⁷⁻³⁰ report the positive effects of negative aspheric conventional IOLs on visual quality. In contrast, some studies suggest that complete correction of spherical aberration may have unfavorable effects. Johansson et al.³¹ found that a maximum reduction in spherical aberration did not maximize subjective visual quality. Rocha et al.³² report that the correction of total spherical aberration might degrade DCNVA and depth of focus. Thus, a certain amount of residual spherical aberration might have benefits. In our study, the mean spherical aberration 3 months postoperatively was $0.15 \pm 0.2 \mu\text{m}$.

The mean postoperative CDVA in our study was 0.06 logMAR (0.89 decimal), which was significantly better

than preoperatively. This result agrees with findings in other studies of microincision IOLs.^{24,33} We evaluated the effects of reduced spherical aberration on visual quality and found that our contrast sensitivity results are comparable to those in other studies of conventional spherical IOLs and of aspheric IOLs.²⁸⁻³⁰ Kershner³⁴ compared the outcomes in eyes with conventional spherical IOLs and eyes with aspheric IOLs and found better night vision and fewer glare symptoms with aspheric IOLs. We found no significant differences between contrast sensitivity with glare and contrast sensitivity without glare, indicating that the aspheric microincision IOL we assessed will provide good night vision without a decrease in contrast sensitivity. Alió et al.³³ found that the mean ocular cutoff modulation transfer function (MTF) frequency with the Akreos MI60 IOL was better than with the UltraChoice 1.0 ThinOptX (ThinOptX, Inc.) and the Acri.Smart 48S (Acri.Tech) spherical microincision IOLs. The cutoff MTF is the maximum spatial frequency the human eye can detect. Therefore, the higher the cutoff frequency, the better the ocular system can detect fine details; this explains the good contrast sensitivity in our study with the aspheric microincision IOL.

A significant disadvantage of aspheric IOLs is that they are more sensitive to tilt and decentration than conventional IOLs.^{35,36} Decentration and a decreased resistance to capsule contraction have been reported with the ThinOptX, one of the first microincision IOLs.⁶ In our study, the aspheric microincision IOL remained centered and stable in the bag, indicating that the 4-haptic design resists asymmetric pressure postoperatively. The IOL remained centered without tilt in eyes with asymmetric forces caused by partial

zonular dialysis, posterior capsule rupture, or anterior capsule fibrosis. Coma aberration arising from imperfect IOL centration and from IOL tilt is the second most important HOA.³⁷ In our study, the mean coma was $0.18 \pm 0.14 \mu\text{m}$, which agrees with findings in a previous study.²⁴

In our study, the mean required near addition power to obtain good CNVA was 2.24 ± 0.57 D. This indicates that the aspheric microincision IOL provides limited pseudoaccommodation, so it does not have a significant advantage in this respect. It may also indicate that the 4-haptic design of this IOL model provides good anteroposterior stability, which helps prevent PCO.

Good uveal biocompatibility is important for all IOLs. Four eyes in our study developed postoperative membranous anterior chamber inflammation. Although all cases resolved with treatment, this complication should be kept in mind. We reviewed the recent literature related to this topic and found 1 case of capsulorhexis phimosis³⁸ in an eye with the aspheric microincision IOL model we used and 1 case of calcification in an eye with an Akreos Adapt Advanced Optics IOL,³⁹ which is of the same material as the IOL in our study. Therefore, more extensive studies or a metaanalysis should be performed.

One of the most significant complications of cataract surgery is PCO. We predicted that we would have a low rate of PCO in our study based on the IOL's 360-degree square-edged design and 10-degree haptic angulation, which pushes the IOL back to the posterior capsule. However, 20 eyes (20%) developed PCO, although none required an Nd:YAG laser capsulotomy during the follow-up. Alió et al.³³ report a PCO rate of 35% with the same IOL, which is higher than the percentages reported for previous-generation Akreos IOLs.⁴⁰

In conclusion, biaxial MICS combined with Akreos MI60 aspheric microincision IOL implantation gave good results. The use of a microincision protected the optical quality and functions of the cornea, and the asphericity of the IOL yielded a high quality of vision. Postoperative contrast sensitivity with and without glare was within normal levels, which indicates that patients with this IOL have good night vision. The IOL remained well centered, even in eyes with asymmetric capsule support. Additional studies with larger cohorts are needed to evaluate the uveal biocompatibility of the IOL and the tendency toward PCO in eyes with the IOL.

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