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Innovative trifocal (quadrifocal) presbyopia-correcting IOLs: 1-year outcomes from an international multicenter study

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Purpose: To evaluate visual acuity (VA) and safety of the new AcrySof IQ PanOptix presbyopia-correcting IOL at 12 months postimplantation.

Setting: Seventeen sites in Europe, Australia, and South America.

Design: Prospective, single-arm, nonmasked, nonrandomized study.

Methods: Of 167 patients enrolled, 149 received study IOLs in both eyes; 145 completed the study. Binocular uncorrected distance VA (UDVA; 4 m), monocular corrected distance VA (CDVA), binocular distance-corrected intermediate VA (DCIVA; 60 cm and 80 cm), binocular uncorrected near VA (UNVA; 40 cm), and binocular defocus curves were evaluated. Safety was assessed by monitoring adverse events (AEs).

Results: Of 149 patients, 92 patients (62%) were women and 139 patients (93%) were white; mean ± SD age was 68.9 ± 9.3 years. At 12 months, mean binocular UDVA was 0.02 ± 0.11 logarithm of the minimum angle of resolution (logMAR); monocular CDVA was 0.01 ± 0.13 logMAR (first eye) and 0.01 ± 0.10 logMAR (second eye); binocular DCIVA was 0.04 ± 0.12 logMAR and 0.08 ± 0.14 logMAR at 60 cm and 80 cm, respectively; and binocular UNVA was 0.07 ± 0.11 logMAR. At 6 months, mean binocular defocus curve VA (0.00 diopter [D] to −3.00 D) ranged from −0.04 to 0.13 logMAR. Binocular VA at distance (0.00 D), intermediate (−1.50 D), and near (−2.50 D) was −0.04 ± 0.11 logMAR, 0.07 ± 0.13 logMAR, and 0.07 ± 0.13 logMAR, respectively. Serious ocular AE rates were 1.4% or less in first and second eyes. Posterior capsulotomy rates were 3.4% (first eye) and 2.7% (second eye).

Conclusions: The study IOL provided good VA outcomes. Defocus curve showed VA of 20/25 Snellen or better from near to intermediate distance. Rates of serious and nonserious AEs were low.

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Cataract is the leading cause of blindness worldwide and is expected to affect 30.1 million individuals by 2020. The standard of care for the treatment of patients with cataract is the implantation of an intraocular lens (IOL) after phacoemulsification.[1] Although monofocal IOLs provide good distance vision with few complications postimplantation, additional visual correction (eg, spectacles) is often needed for near and intermediate vision.[2]

Presbyopia is characterized by loss in accommodation and the resulting inability to focus on near objects and can be corrected by multifocal IOLs with 2 (bifocals) or 3 (trifocals) optical focal points for distance and near vision.[3] First-generation multifocal IOLs were apodized diffractive bifocal lenses designed to provide vision over a range of distances and decrease spectacle dependence compared with conventional monofocal IOLs.[2,4,5] A number of studies

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reported that patients who received multifocal IOLs such as AcrySof IQ ReSTOR +2.5 diopters (D) IOL (Alcon Vision LLC) had improved visual acuity (VA) and were more likely to achieve spectacle independence compared with patients who receive monofocal IOLs.[6–8] However, while improving near vision and increasing the depth of vision, multifocal IOLs have shown limited improvement for intermediate vision.[2,9,10]

The AcrySof IQ PanOptix (Alcon Vision LLC) presbyopia-correcting multifocal IOL was developed for visual correction of aphakia secondary to removal of the cataractous lens in adults with or without presbyopia who desire near, intermediate, and distance vision with increased spectacle independence. This IOL is a single-piece posterior chamber ultraviolet– and blue light–filtering IOL with a biconvex optic and a central anterior multifocal optic diffractive structure. The PanOptix IOL optical design is based on a nonapodized quadrifocal technology with 3 addition powers at 40 cm, 60 cm, and 120 cm that functions as a trifocal IOL with 3 main foci (far, intermediate, and near distance). The light from the 120 cm focal point is diffracted to the distance focus of the IOL, leading to optimized light use toward distance vision.[11,12] Functionally, the diffractive structure of the IOL divides incoming light to create intermediate and near add powers of +2.17 D and +3.25 D, respectively. Based on standard bench measurements such as through-focus Badal images, through-focus modulation transfer function curves, and headlight images, the PanOptix multifocal IOL had improved performance at intermediate distance (60 to 80 cm) compared with the ReSTOR +3.0 D multifocal IOL.[13] Initial results in 3 patients demonstrated good visual outcomes, including uncorrected distance, intermediate, and near VA.[11] A 3-month study in 27 patients similarly found good visual outcomes at near, intermediate, and far distances and high spectacle independence.[12]

The objective of this study was to evaluate visual outcomes and safety of the AcrySof IQ PanOptix presbyopia-correcting IOL more than a 1-year period after bilateral implantation in a large international cohort. This report includes VA results at 12 months postimplantation and binocular defocus curves at 6 months postimplantation.

METHODS

Study Design

This prospective, single-arm, nonmasked, nonrandomized international study was conducted at 17 sites including Australia (4 sites), Chile (3 sites), Germany (2 sites), Italy (2 sites), Spain (2 sites), Belgium (1 site), Great Britain (1 site), France (1 site), and the Netherlands (1 site) from September 2015 to June 2017. Study visits included a preoperative screening visit; 2 operative visits (first- and second-eye surgeries; second-eye surgery was conducted 7 to 9 days after first-eye surgery); postimplantation visits conducted at 1 day and 8 to 10 days after each surgery; and postimplantation visits conducted 20 to 40, 120 to 180, and 330 to 420 days after the second-eye surgery. The study (ClinicalTrials.gov identifier, NCT02529488) was conducted in accordance with the tenets of the Declaration of Helsinki and in compliance with good clinical practice (ISO 14155:2011). Institutional review board or ethics committee approval was obtained. Patients provided voluntary written informed consent before any screening or trial-related procedures.

Patients

Included in the study were patients aged 22 years or older with bilateral cataracts with planned cataract extraction by phacoemulsification. Additional inclusion criteria were preoperative corrected distance visual acuity (CDVA) worse than 0.20 logarithm of the minimum angle of resolution (logMAR) in both eyes, potential postoperative CDVA equal to or better than 0.20 logMAR in both eyes, and preoperative regular corneal astigmatism less than 1.00 D in both eyes.

Key exclusion criteria were any clinically significant ocular abnormalities or diseases; degenerative eye disorders; glaucoma or ocular hypertension; rubella, congenital, traumatic, or complicated cataracts, or any conditions expected to cause intraocular inflammation; known color vision deficiencies; anterior chamber depth of 2.5 mm or less; history of or planned refractive surgeries; or previous corneal transplant. If any of the mentioned criteria were discovered during the first-eye surgery before the IOL came into contact with the eye, implantation was not performed, and the patient was discontinued from the study: any additional procedures during phacoemulsification and IOL implantation because of intraoperative complications or incision site or haptic placement not in accordance with the protocol. If these criteria were discovered during the second-eye surgery before the IOL came into contact with the eye, implantation of the second eye was not performed.

IOL Implantation

After cataract removal by phacoemulsification, patients were implanted with the AcrySof IQ PanOptix presbyopia-correcting IOL (model TFNT00). Surgery was performed using temporal clear corneal incisions and continuous curvilinear capsulorhexis. Other IOL implantation procedures were performed according to physicians' standard of care. For IOL power calculation and selection, investigators aimed to target emmetropia (±0.50 D) in both eyes. SRK/T formula was used with the A constant of 119.1 to calculate IOL power, as recommended by the manufacturer.[14]

The study IOL is a single-piece hydrophobic aspheric IOL with a 6.0-mm optical zone composed of a 4.5 mm large diffractive area with 15 diffractive zones and an outer refractive rim (Figure 1, A and B) and provides +2.17 D intermediate add power and +3.25 D near add power. It is available in a diopter range of 13.0 to 30.0 D in 0.5 D increments and 31.0 to 34.0 D in 1.0 D increments. The anterior surface is designed with negative spherical aberration (−0.10 μm) to compensate for the positive spherical aberration of the cornea.

Outcomes

Effectiveness endpoints included binocular uncorrected distance VA (UDVA) and monocular CDVA at 4 m, binocular distance-corrected intermediate VA (DCIVA) at 60 cm and 80 cm, binocular uncorrected near VA (UNVA) at 40 cm (at 12 months), and binocular defocus curve (at 6 months). Distance-corrected near VA (DCNVA) at 40 cm was assessed under mesopic conditions (VA chart luminance of ~3 cd/m^2). Manifest refraction was performed under photopic lighting conditions (VA chart luminance of ~85 cd/m^2) using a phoropter or trial frames and a 100% contrast Early Treatment Diabetic Retinopathy Study (ETDRS) chart at 4 m.

Binocular defocus testing was performed under photopic conditions (~85 cd/m^2) using a 100% contrast ETDRS chart at 4 m. Patients were defocused from manifest refraction using −5.00 D and +2.00 D spherical corrections. Minus or plus power was decreased in 0.5 D increments until only the corrected distance remained (0.0 D defocus); VA was recorded in logMAR. Safety was assessed by monitoring adverse events (AEs), including secondary surgical interventions, slitlamp examination, fundus visualization, dilated fundus examination, IOL observations and damage, subjective posterior capsule opacification, posterior capsulotomy, IOL decentration and tilt, intraocular pressure, surgical problems, and device deficiencies.

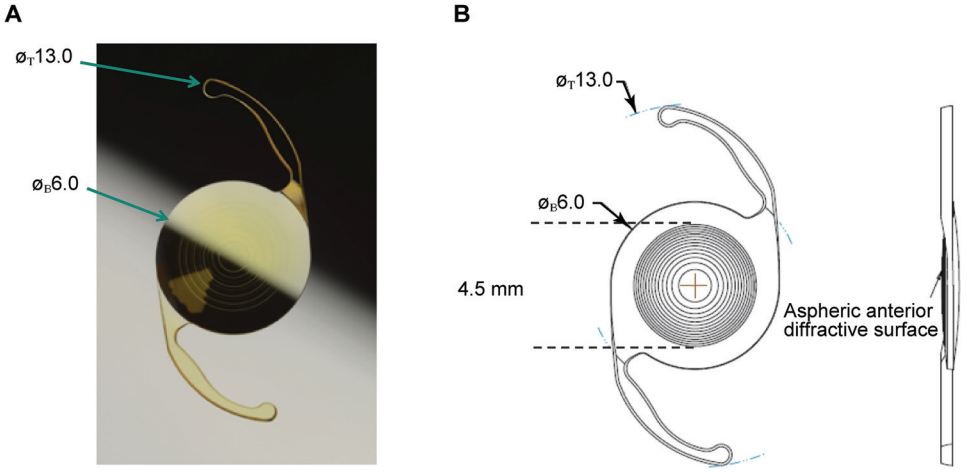

Figure 1. *(A)* Study intraocular model TFNT00 IOL image and *(B)* physical characteristics and dimensions ($Ø_T$ = overall diameter; $Ø_B$ = optic diameter).

Statistical Analyses

Because this is a single-arm, open-label study, no formal statistical hypothesis testing was planned for any endpoints; data were summarized using descriptive statistics. Categorical data were summarized using sample size, number in the category, and percentage in the category. Continuous data were summarized using sample size, mean, SD, range, and 2-sided 90% CIs based on Student *t* statistics.

All eyes with successful implantation with the study IOL were included in the all-implanted analysis set. All eyes with attempted implantation with the study IOL (ie, successful implantation or implantation aborted after contact with the eye) were included in the safety analysis set. Planned enrolment included 156 patients who were to receive the study IOL bilaterally to ensure that at least 140 evaluable patients completed the study, assuming a dropout rate of approximately 10%.

RESULTS

Patients

Of the 167 patients enrolled in the study, 149 received the study IOL and 145 completed the study (Figure 2). Four patients discontinued the study: 3 patients died because of systemic conditions (myocardial infarction, acute myocardial infarction, and multiple organ failure resulting in a fatal outcome; all were assessed as unrelated to the IOL by the investigators), and 1 patient discontinued the study because of an AE (patient underwent IOL exchange of the first and only implanted eye because of blurred vision). In addition, 2 patients discontinued from the study before implantation because of AEs (posterior capsule rupture during surgery).

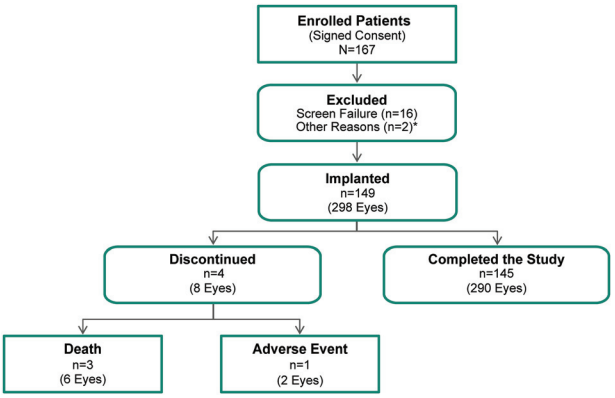

Figure 2. Patient disposition. *Patients passed screening but were not implanted.

Most patients were white (139 [93%] of 149 patients); 103 (69%) of 149 patients were aged 65 years or older, and 92 (62%) of 149 patients were women (Table 1). At baseline, the mean ± SD CDVA was 0.39 ± 0.19 logMAR for the first eye and 0.33 ± 0.13 logMAR for the second eye, and the mean corneal astigmatism was 0.48 ± 0.24 D for the first eye and 0.50 ± 0.24 D for the second eye.

Effectiveness Outcomes

At the 12-month visit, the mean binocular UDVA at 4 m was 0.02 ± 0.11 logMAR (all-implanted analysis set) (Figure 3, A) and 143 (99%) of 145 patients had binocular UDVA of 0.3 logMAR (20/40 Snellen) or better; 101 (70%) of 145 patients had binocular UDVA of 0.04 logMAR (20/20 Snellen) or better (Figure 3, B). The mean binocular CDVA (based on the defocus curve data at 6 months; 0.00 D) was −0.04 ± 0.11 logMAR. At 12 months, the mean monocular CDVA was 0.01 ± 0.13 logMAR for the first eye and 0.01 ± 0.10 logMAR for the second eye; 70% or more of patients had monocular CDVA of 0.04 logMAR (20/20 Snellen) or better in the first (n = 102/145) and second eyes (n = 106/145).

At the 12-month visit, the mean binocular DCIVA at 60 cm and 80 cm was 0.04 ± 0.12 logMAR and 0.08 ± 0.14 logMAR, respectively (Figure 3, A). Binocular DCIVA of 0.3 logMAR (20/40 Snellen) or better was achieved by 142 (98%) of 145 patients at 60 cm and 139 (96%) of 145 patients at 80 cm, and binocular DCIVA of 0.04 logMAR (20/20 Snellen) or better was achieved by 74 (51%) of 145 patients at 60 cm and 64 (44%) of 145 patients at 80 cm (Figure 3, B). The mean binocular UNVA at 40 cm was 0.07 ± 0.11 logMAR (Figure 3, A); 141 (97%) of 145 patients had binocular UNVA of 0.3 logMAR (20/40 Snellen) or better, and 64 (44%) of 145 patients had binocular UNVA of 0.04 logMAR (20/20 Snellen) or better (Figure 3, B). Under mesopic lighting conditions, the mean binocular DCNVA was 0.26 ± 0.16 logMAR; 109 (76%) of 144 patients had binocular DCNVA of 0.3 logMAR (20/40 Snellen) or better (Figure 4).

Table 1. Patient demographics and baseline characteristics (all-implanted dataset).

Demographic	Study IOL (n = 149)	
Age (y)		
Mean ± SD	68.9 ± 9.3	
Range	33, 88	
Age group, n (%)		
<65 y	46 (30.9)	
≥65 y	103 (69.1)	
Sex, n (%)		
F/M	92 (61.7)/57 (38.3)	
Race, n (%)		
White	139 (93.3)	
Asian	1 (0.7)	
Other	9 (6.0)	
Characteristic	**First Eye (n = 149)**	**Second Eye (n = 148)**
Corneal astigmatism (D)		
Mean ± SD	0.48 ± 0.24	0.50 ± 0.24
Range	0.00, 0.97	0.00, 0.99
CDVA (logMAR)	n = 146	n = 146
Mean ± SD	0.39 ± 0.19	0.33 ± 0.13
Range	0.18, 1.06	0.16, 0.88

CDVA = corrected distance visual acuity; logMAR = logarithm of the minimum angle of resolution

At the 6-month visit, the binocular defocus curve showed that patients had mean binocular VA of 0.1 logMAR (20/25 Snellen) or better from +0.50 to −2.50 D (Figure 5). The mean VA at distance (0.00 D), intermediate (−1.50 D), and near (−2.50 D) was −0.04 ± 0.11 logMAR, 0.07 ± 0.13 logMAR, and 0.07 ± 0.13 logMAR, respectively.

At 12 months, the mean manifest refractive sphere and cylinder were within 0.5 D of target in both eyes in the all-implanted analysis set. The mean manifest refractive spherical equivalent was −0.34 ± 0.36 D and −0.26 ± 0.36 D, the mean manifest refractive sphere was −0.15 ± 0.38 D and −0.10 ± 0.39 D, and the mean manifest refractive cylinder was 0.38 ± 0.43 D and 0.35 ± 0.37 D in the first and second eyes, respectively.

Safety Outcomes

Serious ocular AEs included retinal detachment (first eye, 2 [1.3%] of 149 patients; second eye, 2 [1.4%] of 148 patients) and retinopexy (first eye, 2 [1.3%] of 149 patients; second eye, 1 [0.7%] of 148 patients). The rates of other serious ocular AEs were 1% or less (Table 2). Serious device-related AEs were IOL extraction (1 [0.7%] of 149 patients) and blurred vision (1 [0.7%] of 149 patients) in the first eye (both AEs reported from the same patient); no device-related AEs were reported for the second eye. The rates of nonocular serious AEs were less than 1%. There were 3 deaths from nonocular conditions that were assessed as unrelated to the IOL by the investigators.

The most common nonserious ocular AEs were dry eye (first eye, 15 [10.1%] of 149 patients; second eye, 13 [8.8%] of 148 patients) and posterior capsule opacification (first eye, 6 [4.0%] of 149 patients; second eye, 8 [5.4%] of 148 patients). Posterior capsule opacification onset ranged from 7 to 415 days postoperatively (Table 3).

Device-related nonserious AEs included halos (first eye, 4 [2.7%] of 149 patients; second eye, 3 [2.0%] of 148 patients) and posterior capsule opacification (first eye, 2 [1.3%] of 149 patients; second eye, 3 [2.0%] of 148 patients). Posterior capsulotomy rates were reported in 5 (3.4%) of 149 patients in the first eye and 4 (2.7%) of 148 patients in the second eye (5 of the posterior capsulotomy interventions were considered to be related to the procedure or the device and 4 were not related).

DISCUSSION

This prospective, nonrandomized, multicenter study assessed the visual outcomes and safety of a new trifocal PanOptix IOL in 149 patients. At 12 months postimplantation, most patients who received study IOLs had binocular distance, intermediate, and near VA equivalent to or better than 0.3 logMAR (20/40 Snellen). The mean binocular UDVA was 0.02 ± 0.11 logMAR, binocular DCIVA was 0.08 ± 0.14 logMAR (80 cm) and 0.04 ± 0.12 (60 cm) logMAR, and binocular UNVA was 0.07 ± 0.11 logMAR. The binocular defocus curve at 6 months postimplantation showed that patients had mean binocular VA of 0.1 logMAR (20/25 Snellen) or better from +0.50 to −2.50 D. Rates of serious ocular AEs in the first and second eyes were 1% or less.

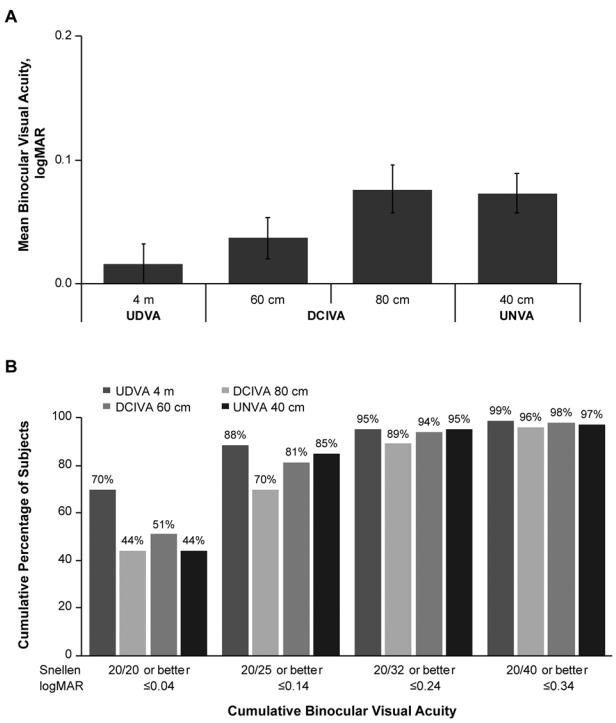

Figure 3. Visual acuity under photopic conditions. Mean binocular visual acuity (*A*) and cumulative distribution of binocular visual acuity (*B*) at 12 months in patients who received the study IOL; n = 145. Error bars represent 90% CIs (DCIVA = distance-corrected intermediate visual acuity; logMAR = logarithm of the minimum angle of resolution; UDVA = uncorrected distance visual acuity; UNVA = uncorrected near visual acuity).

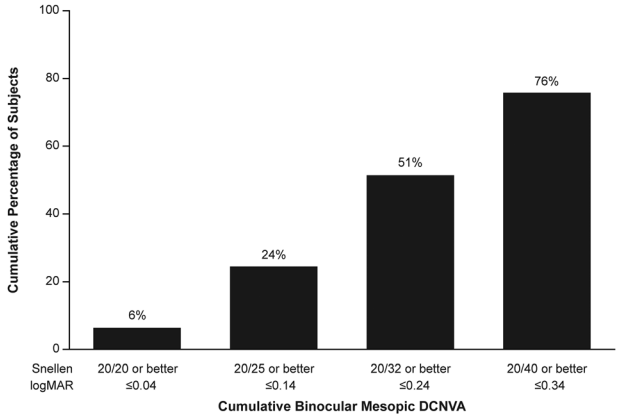

Figure 4. Cumulative distribution of binocular DCNVA at 12 months under mesopic conditions in patients who received the study IOL; n = 144. Error bars represent 90% CIs (DCNVA = distance-corrected near visual acuity; logMAR = logarithm of the minimum angle of resolution).

These results confirmed findings from a previous study in 27 patients with PanOptix IOLs, which assessed outcomes at 3 months postimplantation and reported mean binocular UDVA of 0.00 ± 0.09 logMAR, binocular DCIVA of 0.10 ± 0.13 logMAR (80 cm) and 0.01 ± 0.12 (60 cm) logMAR, binocular uncorrected intermediate visual acuity (UIVA) of 0.00 ± 0.11 logMAR, and binocular UNVA of 0.01 ± 0.09 logMAR.[12] In a separate study (n = 33 with mean follow-up of 5.7 weeks) where VA was measured in Snellen and Revised American Point-Type and then converted to logMAR, the mean UDVA was 0.01 ± 0.10 logMAR, UIVA (60 cm) was 0.30 ± 0.14 logMAR, and UNVA (40 cm) was 0.18 ± 0.10 logMAR.[15] Differences in UNVA and UIVA among these studies could be the result of variations in study methodologies or postoperative follow-up duration.

Previous studies in patients receiving multifocal AcrySof ReSTOR IOLs demonstrated binocular UNVA comparable with that reported here.[5,16,17] However, our results suggest that the PanOptix IOL provided improved VA at intermediate distances compared with the AcrySof IQ ReSTOR IOL. For example, mean binocular DCIVA at 60 cm was 0.23 ± 0.12 logMAR in 25 patients with the AcrySof IQ ReSTOR

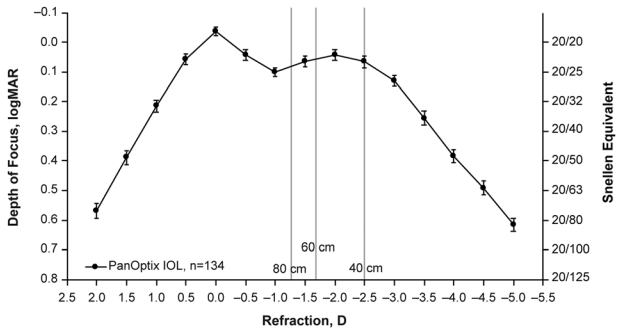

Figure 5. Depth of focus. Visual acuity in logMAR and Snellen equivalent at 6 months are shown (best case analysis set). Data reflect mean and 90% CIs (logMAR = logarithm of the minimum angle of resolution).

IOL compared with 0.04 ± 0.12 logMAR achieved with the PanOptix IOL in this study.[16] Another study of multifocal AcrySof IQ ReSTOR IOLs +2.5 D in 155 patients reported mean DCIVA (60 cm) of 0.33 ± 0.17 logMAR and 0.32 ± 0.16 logMAR in the first and second eyes, respectively.[6] In addition, the binocular defocus curve with the AcrySof IQ ReSTOR IOL demonstrated VA equal or better than 20/25 Snellen for a relatively small range, approximately 1.0 to −1.0 D, compared with +0.50 to −2.50 D reported in this study.[6]

A comparative study of optical bench performance found that the PanOptix IOL had similar or better performance compared with other trifocal IOLs, such as the AT LISA tri 839MP IOL (Carl Zeiss Meditech AG) and FineVision Micro F IOL (PhysIOL s.a.), as assessed using modulation transfer function measurements at focal distances of 20/20 and 20/40 VA. Evaluation of the Badal images of the ETDRS chart demonstrated that all 3 IOLs provided good distance, near, and intermediate resolutions. Simulated headlight images resulted in similar background halo intensity for the 3 IOLs.[18]

Although several studies have assessed visual outcomes in patients with trifocal IOLs, differences in the design and methods make it difficult to compare VA outcomes from different studies. The AT LISA tri 839MP IOL has been reported to provide good uncorrected distance, intermediate, and near VA and high spectacle independence and provided better VA at intermediate distances (2 to 67 cm) compared with a blended-vision approach using the AcrySof IQ ReSTOR +2.5/+3.0 D multifocal IOL.[19,20] A study in 25 patients assessing AT LISA tri 839MP IOL reported mean binocular UDVA of −0.01 ± 0.06 logMAR, DCIVA (80 cm) of 0.03 ± 0.06 logMAR, and UNVA of 0.02 ± 0.04 logMAR at 12 months.[21] Defocus curve showed the corrected VA at 0.00 D and −2.0 D. In a study of 27 patients with AT LISA tri 839MP IOL, VA at 3 months postimplantation was 0.10 logMAR or better at far, intermediate, and near distances.[20] These data suggest that AT LISA tri 839 MP IOL provides VA that is comparable with PanOptix IOL. However, AEs for AT LISA tri 839 MP IOL included posterior capsule opacification in 5 (10%) of 50 eyes resulting in Nd:YAG capsulotomy.[21] Approximately 3% of first and second eyes needed surgical intervention for posterior capsule opacification in this study, and less than 1% of first and second eyes had clinically significant posterior capsule opacification that required Nd:YAG.

Evaluation of the trifocal FineVision Micro F IOL in 15 patients demonstrated mean binocular UDVA of −0.01 ± 0.11 logMAR, DCIVA (70 cm) of 0.31 ± 0.11 logMAR, and UNVA of 0.15 ± 0.13 logMAR. Comparable with the PanOptix IOL defocus curve data in this study, the FineVision Micro F IOL had VA of 0.1 logMAR or better (20/25 Snellen or better) from +1.00 to −3.0 D.[22]

One comparative study assessing visual outcomes 4 months after implantation of PanOptix, Tecnis Symfony (Abbot Laboratories), or AcrySof monofocal IOLs reported mean UDVA (3 m) of 0.00 ± 0.04 logMAR, DCIVA (67 cm) of 0.13 ± 0.07 logMAR, and UNVA (40 cm) of 0.02 ± 0.06 logMAR in 40 eyes with the PanOptix IOL.[23] Patients with the PanOptix IOL had statistically significantly better VA for the defocus

Table 2. Serious ocular AEs (safety dataset).

AEs, n (%)	Study IOL	
	First Eye (n = 149)	Second Eye (n = 148)
Retinal detachment	2 (1.3)	2 (1.4)
Retinopexy	2 (1.3)	1 (0.7)
Eye operation	1 (0.7)	0
IOL extraction	1 (0.7)	0
IOL repositioning	0	1 (0.7)
Increased IOP	1 (0.7)	0
Blurred vision	1 (0.7)	0
Visual field defect	1 (0.7)	1 (0.7)
Device dislocation	0	1 (0.7)
Optic nerve cup-to-disc ratio increase	1 (0.7)	1 (0.7)
Vitrectomy	0	1 (0.7)

AE = adverse event; IOL = intraocular lens; IOP = intraocular pressure

levels of −2.5 to −4.0 D compared with Tecnis Symfony IOL; in addition, patients in both the PanOptix and Tecnis Symfony extended depth-of-focus IOL groups had statistically significantly better VA for the defocus levels of −1.0 to −4.0 D compared with the AcrySof monofocal IOL.[23]

This study of 149 patients reported low rates of serious and nonserious AEs. Serious ocular AEs were reported at a rate of 1% or less and included retinal detachment and retinopexy. One patient experienced blurred vision, requested explantation of the PanOptix IOL, and subsequently received a monofocal IOL with no further complications. Posterior opacification was a nonserious ocular AE reported at a rate of 5% or less; the rate of device-related posterior opacification was 2% or less. Serious nonocular AEs were reported at a rate of less than 1%. There were 3 deaths from myocardial infarction, acute myocardial infarction, and multiple organ failure reported in this study; these deaths were assessed as unrelated to the IOL by the investigators. The patient with myocardial infarction had a history of noninsulin-dependent diabetes mellitus, asthma, hypertension, hepatic cirrhosis, chronic obstructive pulmonary disease, prostate carcinoma, and atrial fibrillation. The patient with acute myocardial infarction had a history of prostate cancer. The patient with multiple organ failure had a history of anemia, hypertension, obesity, kidney disease, noninsulin-dependent diabetes mellitus, chronic neuralgia, and atrial fibrillation.

Table 3. Nonserious ocular AEs (safety dataset).

AEs n (%)	Study IOL	
	First Eye (n = 149)	Second Eye (n = 148)
Ocular AEs with incidence ≥2% in either eye		
Dry eye	15 (10.1)	13 (8.8)
Posterior capsule opacification	6 (4.0)	8 (5.4)
Foreign body sensation	5 (3.4)	3 (2.0)
Corneal edema	4 (2.7)	4 (2.7)
Halo vision	4 (2.7)	4 (2.7)
Blepharitis	3 (2.0)	3 (2.0)
Glare	3 (2.0)	3 (2.0)
Punctate keratitis	3 (2.0)	3 (2.0)
Vitreous detachment	3 (2.0)	2 (1.4)
Increased intraocular pressure	2 (1.3)	3 (2.0)
Device-related ocular AEs		
Halo vision	4 (2.7)	3 (2.0)
Posterior capsule opacification	2 (1.3)	3 (2.0)
Glare	2 (1.3)	2 (1.4)
Visual impairment	2 (1.3)	1 (0.7)

AE = adverse event

This study also found that glare and halos reported as nonserious device-related AEs affected less than 2% and less than 3% of all eyes, respectively, which is similar to the rates of glare (3%) and halos (3%) reported for the bifocal AcrySof IQ ReSTOR IOL.[6] Previous studies reported that optic phenomena such as glare and halos occurred more frequently in patients with multifocal IOLs compared with monofocal IOLs.[24,25]

The strengths of this study include duration of follow-up and the number of patients assessed at multiple sites. The limitations of this study include its single-arm, nonmasked design and limited duration of follow-up. In addition, subjective visual quality data were not collected because an approved, validated patient-reported outcomes questionnaire was not available. Although there was only 1 report of discontinuation because of poor visual quality, future studies will need to address the effect of the PanOptix IOL on quality of vision. Patients with a history of refractive surgery were excluded from this study; these patients can present a challenge for accurate calculation of IOL power, potentially leading to residual refractive error.[26,27] Long-term analysis of VA and safety in patients with PanOptix IOLs representing the general patient population that undergoes cataract surgery, and quality of vision surveys, and additional comparative studies with other IOLs would be of interest. To help surgeons and patients make informed choices about IOLs, analyses of patient-reported outcomes are needed to assess the percentage of patients who observed optic phenomena and whether symptoms improved over time.

In patients with cataracts, implantation of a toric IOL is one of the approaches currently used to treat astigmatism, a common refractive error that increases in prevalence with age and can affect visual outcomes after cataract surgery.[28,29] Only a limited population of patients (those with preoperative regular corneal astigmatism <1.0 D) qualify for the nontoric PanOptix IOL. A new toric version of the PanOptix IOL is in development, and additional studies will be needed to address its efficacy and safety in patients with astigmatism.

In conclusion, this was an international multicenter study covering a diverse population of patients that addressed the visual outcomes and safety of PanOptix IOLs through 1 year of postimplantation follow-up. This study showed that PanOptix IOLs provided good VA at all tested distances, including intermediate (60 cm), and the binocular defocus curve demonstrated VA of 0.1 logMAR (20/25 Snellen) or better from near to intermediate distance. Future research exploring visual outcomes and safety at greater durations of

follow-up will provide value information regarding long-term performance of this trifocal presbyopia-correcting IOL.

WHAT WAS KNOWN

- Monofocal IOLs implanted during cataract surgery provide excellent distance vision but spectacles are often needed for near and intermediate vision.
- Multifocal IOLs can improve near vision but provide limited improvements for intermediate vision.
- A new trifocal IOL has 3 add powers (40 cm, 60 cm, and 120 cm) and functions as a trifocal lens with 3 main foci (far, intermediate, and near distance); early studies suggested good visual outcomes and high spectacle independence with this IOL.

WHAT THIS PAPER ADDS

- The new trifocal IOL provided an excellent safety profile with satisfactory visual acuity (VA) outcomes through 12 months of postimplantation follow-up.
- Good intermediate VA was achieved under photopic conditions; defocus curve demonstrated 20/25 Snellen or better VA at near to intermediate distance.

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