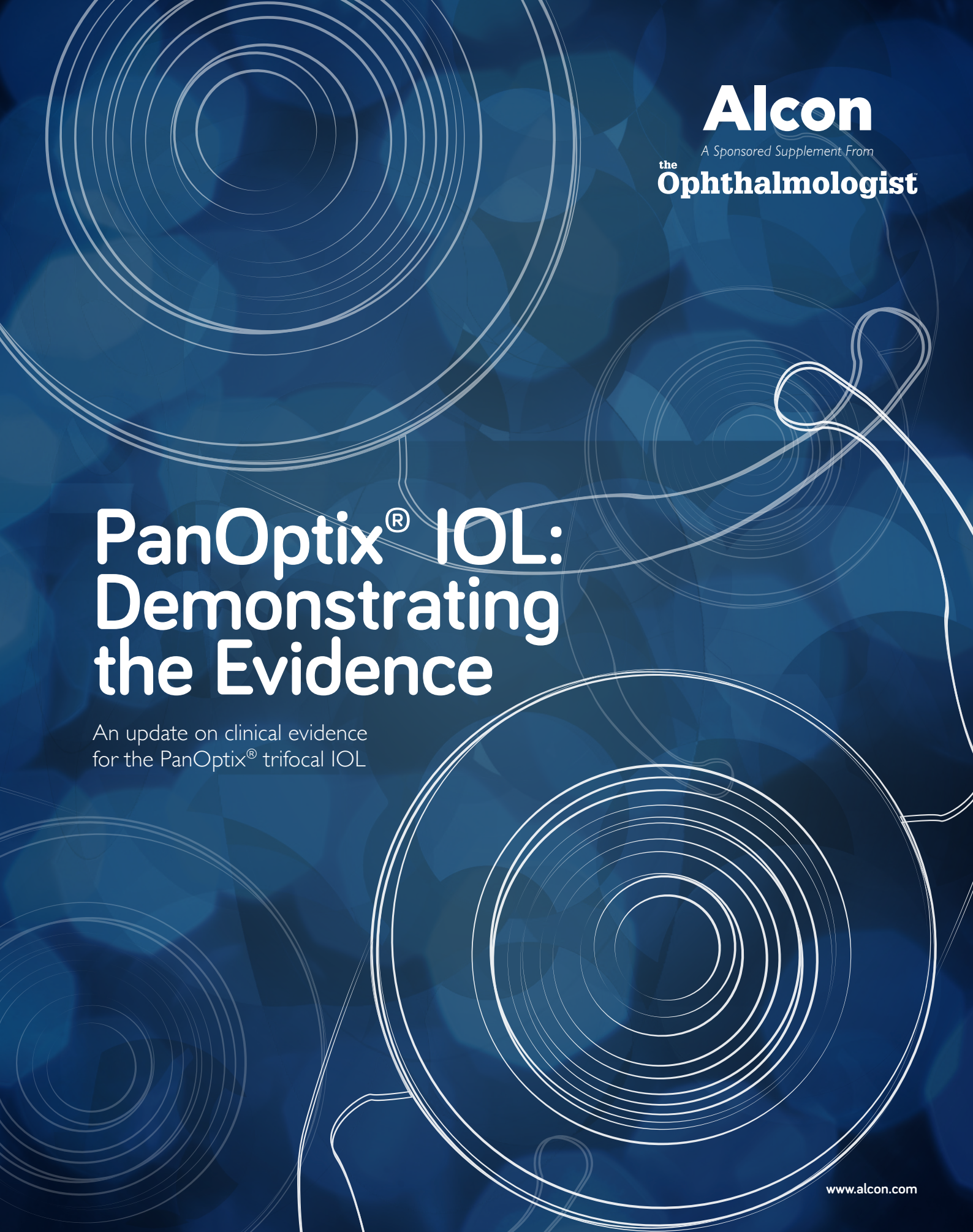

Alcon

A Sponsored Supplement From

the Ophthalmologist

PanOptix® IOL: Demonstrating the Evidence

An update on clinical evidence for the PanOptix® trifocal IOL

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PanOptix® IOL: Demonstrating the Evidence

AcrySof® IQ PanOptix® IOL®, featuring innovative ENLIGHTEN® optical technology, was launched in the US last year, having previously been approved globally. The innovative lens design in this presbyopia-mitagating IOL allows optimized light utilization and provides patients with a comfortable range of near to intermediate vision that is less dependent on pupil size.[1] But in the years since its global launch, how has this multifocal IOL performed in the clinic? And how do visual outcomes compare with other currently available multifocal IOLs? This feature presents clinical studies that support the safety and efficacy of PanOptix®.

"The clinical evidence base for PanOptix® has grown considerably and proved the predictions at launch to be true."

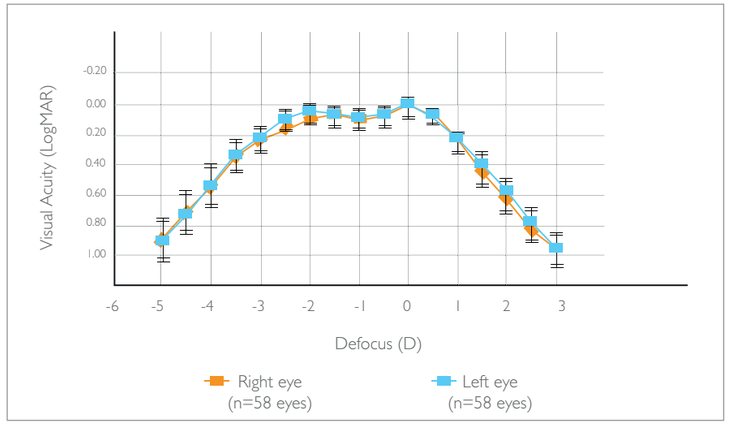


Figure 1. Monocular distance-corrected PanOptix IOL defocus curve given in LogMAR 1 month after surgery.[1]

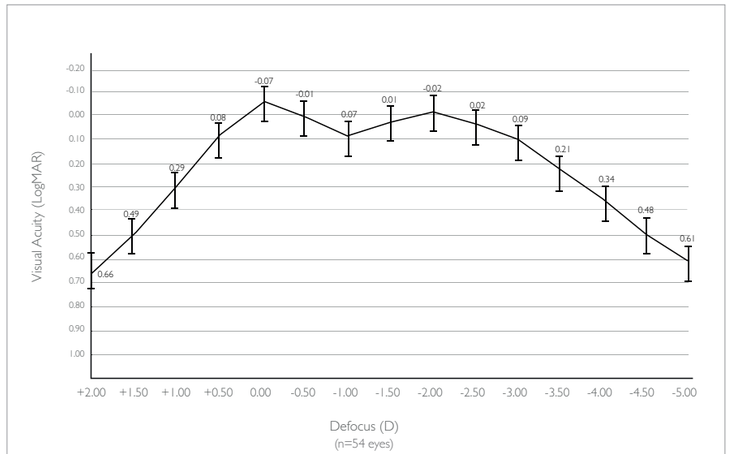


Figure 2. Binocular distance-corrected PanOptix IOL defocus curve given in logMAR 3 months after surgery.[2]

With several prospective clinical studies now complete, and the number of surgeons with experience of the platform increasing, the evidence base for PanOptix® has grown considerably. In this clinical update, recently published and presented PanOptix® clinical data from experienced surgeons are overviewed.

PanOptix® IOL clinical outcomes

Two recent publications describe short-term visual outcomes with PanOptix®: Garcia-Perez et al.[1] reported visual outcomes one month after surgery in 58 patients (116 eyes) who underwent bilateral implantation at the Clínica Rementería Madrid, Spain; and a prospective study by Kohnen et al.[2] assessed visual performance at 3 months in 27 bilaterally implanted patients (54 eyes) at a single center in Germany. In addition, a prospective study by Akman[4] (2019) evaluated vision-related quality of life in 48 bilaterally implanted patients 3 months after the second implant (or 3 months after the first implant, if the gap between implants was ≥ 3 months), at a single centre in Turkey. A summary of the quality of life findings from the Akman study[4] is given in Figure 3.

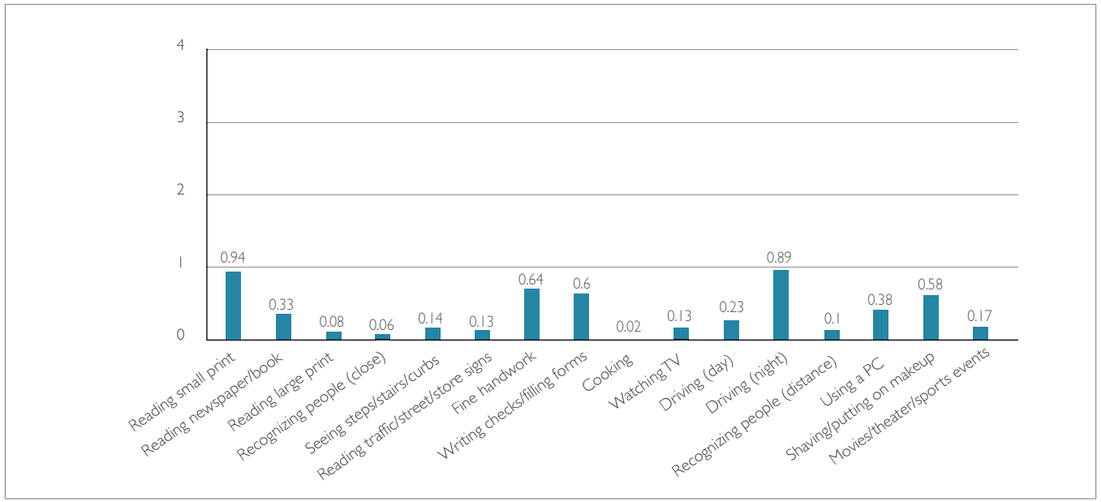


Figure 3. Quality of life after bilateral PanOptix® implantation.[4] 0=no difficulty, 1=a little difficulty, 2=moderate difficulty, 3=quite difficult, 4=impossible (n=48 patients).

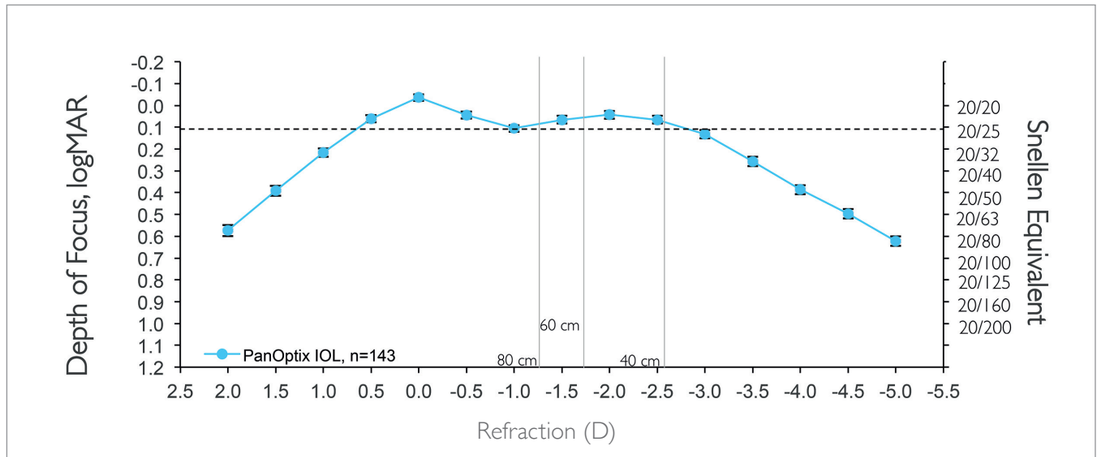


Figure 4. Binocular defocus curve for PanOptix® at 6 months.[6] Binocular defocus testing was performed under photopic conditions (~85 cd/m2) using a 100% ETDRS chart at 4 m. Subjects were defocused from manifest refraction using a -5.00 D and +2.00 D spherical correction in 0.5 D increments. Data reflect mean and 90% confidence intervals (n=143 patients).

The monocular defocus curves reported by Garcia-Perez et al. showed a LogMAR acuity ≤0.1 between +0.50 and -2.00 D (Figure 1). Mean post-operative spherical equivalent (SE) was found to be -0.10 ± 0.26 at one month postoperatively[2] and 0.08 ± 0.25 D up to two months follow-up.[3]

Kohnen's study[2] on the visual performance of PanOptix® 3 months after surgery suggests (Figure 2) that VA peaks at 0D (-0.07 log MAR) and -2.00 D (-0.02 logMAR), with the lowest value between these peaks at -1.00 D (0.07 logMAR). With a defocus of -1.50 D (67 cm) and -2.00 D (50 cm), the intermediate VA ranged from 0.01 to -0.02 logMAR, respectively (Figure 2). Key findings included the demonstration that PanOptix® provided

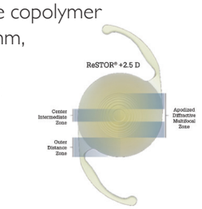
Box 1. IOL Characteristics

AcrySof® IQ PanOptix® trifocal multifocal IOL (Alcon)[7]

- Hydrophobic acrylate/methacrylate copolymer
- Optic 6.0 mm, overall diameter 13.0 mm; 4.5 mm diffractive optic zone
- Non-apodized trifocal design
- Intermediate +2.17 D add
- Near +3.25 D add
- Spherical range: +6.0 to +34.0 D

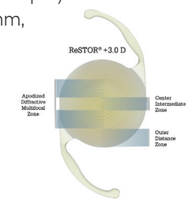
AcrySof® IQ ReSTOR® +2.5 D multifocal IOL (Alcon)

- Hydrophobic acrylate/methacrylate copolymer
- Optic 6 mm, overall diameter 13 mm, 3.0 mm optic zone
- Apodized diffractive aspheric optic with central refractive zone
- Spherical range: +6.0 to +34.0 D



AcrySof® IQ ReSTOR® +3.0 D multifocal IOL (Alcon)

- Hydrophobic acrylate/methacrylate copolymer
- Optic 6 mm, overall diameter 13 mm, diffractive optic zone 3.0 mm
- Intermediate add powers: none
- Spherical range: +6.0 to +34.0 D



TECNIS Symfony EDOF IOL (Johnson & Johnson Vision)[8]

- Hydrophobic acrylate
- Optic 6.0 mm, overall diameter 13.0 mm
- Diffractive optics
- Spherical range: +5.0 to +34.0 D
- Pupil independent

Table 1. Visual outcomes of PanOptix®, Symfony* and AcrySof® monofocal IOLs

	Monaco et al.[9]		
Mean ± SD, LogMAR	*PanOptix® (n=40 eyes)*	*Symfony (n=40 eyes)*	*AcrySof® monofocal (n=40 eyes)*
UDVA	0.00 ± 0.04	0.03 ± 0.05	0.02 ± 0.06
CDVA	-0.01 ± 0.01	-0.01 ± 0.02	-0.01 ± 0.02
UIVA	0.23 ± 0.07 (p=0.04 vs. Symfony; p=0.001 vs. AcrySof monofocal)	0.27 ± 0.08 (p=0.001 vs. AcrySof monofocal)	0.42 ± 0.09
DCIVA (80 cm)			
DCIVA (67 cm)	0.13 ± 0.01 (p=0.001 vs. AcrySof monofocal)	0.16 ± 0.07 (p=0.001 vs. AcrySof monofocal)	0.29 ± 0.11
DCIVA (60 cm)			
UNVA	0.02 ± 0.06 (p=0.05 vs. Symfony; p=0.001 vs. AcrySof monofocal)	0.07 ± 0.08 (p=0.001 vs. AcrySof monofocal)	0.38 ± 0.10
DCNVA	0.01 ± 0.04 (p=0.005 vs. Symfony; p=0.001 vs. AcrySof monofocal)	0.07 ± 0.07 (p=0.001 vs. Acrysof monofocal)	0.32 ± 0.09

Visual acuity values are expressed as mean ± SD in LogMAR units. CDVA, corrected distance visual acuity; DCIVA, distance-corrected intermediate visual acuity; DCNVA, distance-corrected near visual acuity; UDVA, uncorrected distance visual acuity; UIVA, uncorrected intermediate visual acuity; UNVA, uncorrected near visual acuity.

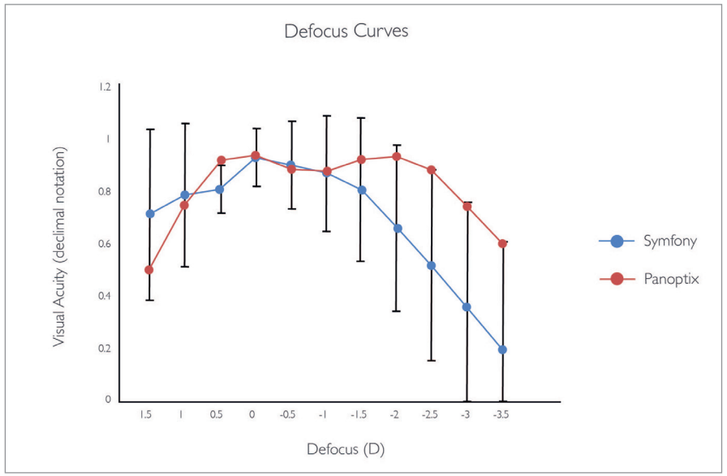


Figure 5. Defocus curves. y axis = visual acuity in decimal; x axis = diopters (blur test) for the two IOLs: AcrySof IQ PanOptix (Alcon Laboratories, Inc., TX), and TECNIS Symfony (Abbott Medical Optics, Inc., IL); n=20 patients.[10]

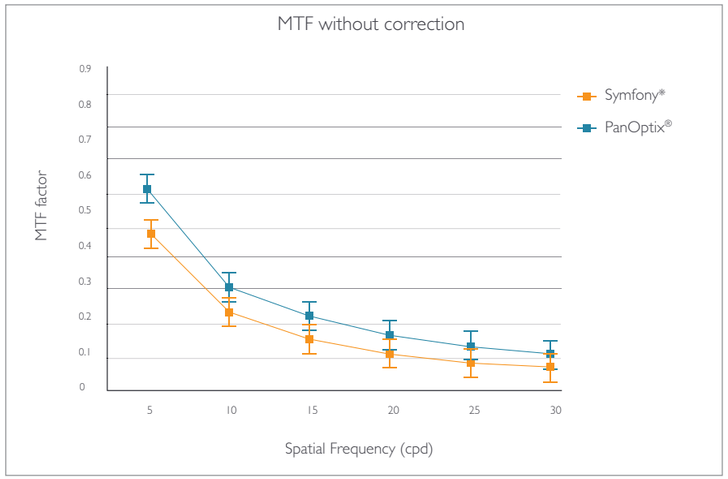


Figure 6: Modulation transfer functions for Symfony and PanOptix. The two IOLs exhibit comparable MTF values; for all IOLs, contrast sensitivity decreases without correction versus with correction, with acceptable decreases under mesopic conditions; n=20 patients.[10]

patients with high visual performances at all distances and very good intermediate visual acuity. This validates the findings from bench studies.[5] Furthermore, 93 percent of patients showed SE accuracy of +/- 0.5 D.[2] Thus, recent clinical experience with PanOptix® indicates high visual performance at all distances – in particular, very good intermediate visual acuity – and demonstrates that a high proportion of patients achieve spectacle independence.[2]

In Akman's study,[4] patients reported a high overall satisfaction rate and high vision-related quality of life. Notably, the responses to each question in the VF-14 QoL questionnaire had mean values of <1.00, indicating little or no difficulty in each activity. Furthermore, bilateral PanOptix® implantation was associated with improved vision-related QoL versus monocular IOL implantation; in particular significant differences were found in tasks requiring near and intermediate vision (such as computer use). This provides further evidence for the real-world benefits of PanOptix® – not least vision-related QoL.

PanOptix®: clinical experiences at six months postoperatively

Thomas Kohnen of Goethe University, Frankfurt, Germany, presented a prospective, single-arm, non-randomized multicenter clinical study sponsored by Alcon[6] at the XXXV Congress of the European Society of Cataract and Refractive Surgeons (ESCRS), where the binocular defocus curve of PanOptix® at 6 months post-implantation was determined. A total of 143 patients who had received bilateral implantation of PanOptix® were followed up for 6 months. The binocular defocus curve for PanOptix® demonstrated an approximate VA of 20/25 or better from near (40 cm) through intermediate (60 cm) to distance (Figure 4).

PanOptix® compared with Symfony

In a study of patients after bilateral caratarct surgery with implantation of a PanOptix® or Symfony IOL (with postoperative examinations including assessing distance, intermediate and near VA, binocular defocus, intraocular and total aberrations, point-spread function, MTF, retinal straylight, and QoV and spectacle-dependence questionnaires), Monaco et al. reported that PanOptix® performed better than Symfony at vergences of -1.5 D to -4.0D ($p \leq 0.05$) in the binocular defocus curve, and that both and that both IOLs performed better than the monofocal

Table 2. Higher order aberrations (HOA) comparison between PanOptix® and Symfony IOLs. It shows fewer HOA with PanOptix® and less variability compared to Symfony, p>0.05.[10]

IOL	HOAs	Coma	Trefoil	Spherical Aberrations
TECNIS Symfony	0.28 ± 0.51 (0.04 to 2.73)	0.13 ± 0.27 (0.01 to 1.72)	0.12 ± 0.21 (0.01 to 1.03)	0.05 ± 0.13 (0.00 to 0.80)
AcrySof IQ PanOptix	0.16 ± 0.07 (0.05 to 0.31)	0.07 ± 0.04 (0.02 to 0.20)	0.08 ± 0.05 (0.01 to 0.18)	0.03 ± 0.02 (0.00 to 0.01)

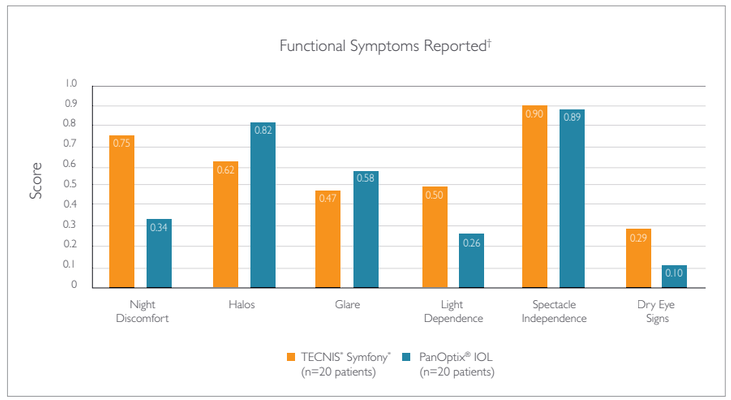


Figure 7. Functional symptoms of the PanOptix® and TECNIS Symfony IOLs.[10]
†Fewer than 1% of patients in each IOL group experienced night-time visual disturbances, dry eye, halos, and glare. Patients reported that visual symptoms had little or no impact on their daily functioning.

IOL for defocus vergences between -1.0 D to -4.0 D (Table 1), p≤0.05.[9]

VA at intermediate and far distances was found to be excellent for both PanOptix® and Symfony IOLs, with PanOptix® showing a significantly better performance UNVA and DCNVA (Table 1).[9] PanOptix® was found to have significantly better DCNVA at 40 cm.[9] Monaco et al.[9] reported that patients who had received PanOptix® showed better monocular DCNVA than those who received Symfony (p=0.005), with both groups showing better results than those who had received the AcrySof® monofocal IOL (p<0.001 for both PanOptix® and Symfony versus AcrySof®).

No significant differences were found between PanOptix® and Symfony binocular contrast sensitivity under mesopic and photopic conditions. These studies showed that PanOptix® and Symfony provided comparable visual outcomes at far and intermediate distances, with PanOptix® providing significantly better VA at 40 cm as well as showing a more continuous range of vision.

In another, prospective peer-reviewed study, Cochener et al.[10] (2018) compared the performance of PanOptix®, and Symfony IOLs at 6 months post-surgery. This prospective study at a single center in France (40 eyes / 20 patients per group) showed that PanOptix® provided significantly better UNVA than Symfony (p=0.002), and no statistical difference for distance and intermediate VA (p>0.05) (defocus curves shown in Fig 5). PanOptix® had fewer higher order aberrations (HOA) and less variability compared to Symfony IOL and there was no statistical difference, p>0.05 (see Table 2).[10] In this study, overall there was no significant difference in visual disturbance occurrence, however, night discomfort values mean scores, based on patient questionnaire responses, were lower for PanOptix® than for Symfony.

In summary, Cochener et al.[10] show that PanOptix® provides better near vision than Symfony, and similar distance and intermediate vision; these data therefore are in agreement with those of Monaco et al.[9]

Summary

Clinical evidence obtained so far continues to demonstrate that PanOptix® provides good visual outcomes for patients across all distances. One month after implantation, PanOptix® has shown good refractive and visual outcomes, and high rates of spectacle independence. Clinical evidence obtained with PanOptix® beyond one month post-surgery has shown that visual outcomes and incidence of photic phenomena improved over time. PanOptix® has also shown very predictable results. The PanOptix® IOL performed well at an intermediate distance of 60 cm. With an increasing number of surgeons using PanOptix® and a growing number of patients receiving it, as well as an increasing duration of postoperative follow up, the clinical evidence for this innovative presbyopia-mitigating IOL is only set to grow.

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IMPORTANT PRODUCT INFORMATION

AcrySof® IQ PanOptix® Family of Trifocal IOLs

CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

INDICATIONS: The AcrySof® IQ PanOptix® Trifocal IOLs include AcrySof® IQ PanOptix® and AcrySof® IQ PanOptix® Toric and are indicated for primary implantation in the capsular bag in the posterior chamber of the eye for the visual correction of aphakia in adult patients, with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity with a reduced need for eyeglasses, compared to a monofocal IOL. In addition, the AcrySof® IQ PanOptix® Toric Trifocal IOL is indicated for the reduction of residual refractive astigmatism.

WARNINGS/PRECAUTIONS: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Physicians should target emmetropia and ensure that IOL centration is achieved. For the AcrySof® IQ PanOptix® Toric Trifocal IOL, the lens should not be implanted if the posterior capsule is ruptured, if the zonules are damaged or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction. If necessary, lens repositioning should occur as early as possible prior to lens encapsulation. Some visual effects may be expected due to the superposition of focused and unfocused multiple images. These may include some perceptions of halos or starbursts, as well as other visual symptoms. As with other multifocal IOLs, there is a possibility that visual symptoms may be significant enough that the patient will request explant of the multifocal IOL. A reduction in contrast sensitivity as compared to a monofocal IOL may be experienced by some patients and may be more prevalent in low lighting conditions. Therefore, patients implanted with multifocal IOLs should exercise caution when driving at night or in poor visibility conditions. Patients should be advised that unexpected outcomes could lead to continued spectacle dependence or the need for secondary surgical intervention (e.g., intraocular lens replacement or repositioning). As with other multifocal IOLs, patients may need glasses when reading small print or looking at small objects. Posterior capsule opacification (PCO) may significantly affect the vision of patients with multifocal IOLs sooner in its progression than patients with monofocal IOLs. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure, available from Alcon, informing them of possible risks and benefits associated with the AcrySof® IQ PanOptix® Trifocal IOLs.

ATTENTION: Reference the Directions for Use labeling for each IOL for a complete listing of indications, warnings and precautions.

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