

A DECADE OF PANOPTIX: HOW DOES TECNIS SYNERGY STACK UP?



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The advancement of intraocular lens (IOL) technology provides cataract patients the opportunity to recover from a blinding condition and to alleviate troublesome presbyopia to better enjoy their life, unfettered by glasses. Among currently available lenses, full range of vision IOLs that use either diffractive trifocal technology or a combination of diffractive extended depth of focus (EDOF) and bifocal technology are designed to provide high rates of spectacle independence.^{1,2,3} Do all these lenses provide the same visual outcomes and patient satisfaction? Is there solid clinical data to support our recommendation to patients? In collaboration with several surgeons, we recently completed a large prospective, randomized (1:1), patient- and examiner-masked multi-center study to compare the visual performance of AcrySof® IQ PanOptix® to TECNIS Synergy* IOL.^{4,5}

The PanOptix® trifocal IOL utilizes a unique non-apodized diffractive design on the central 4.5 mm zone surrounded by an outer refractive rim to form a 6 mm fully usable optic.^{1,6} The proprietary ENLIGHTEN® technology (Figure 1) redistributes the light energy at 120 cm to ensure high energy utilization (88% at 3 mm pupil size) for distance, intermediate (60cm) and near (40 cm).^{1,6} The unique intermediate focal point (60 cm) allows average height people to more comfortably perform intermediate tasks such as computer usage as compared to traditional trifocal IOLs.^{1,6} The large 4.5 mm diffractive zone enables PanOptix® patients to be less pupil dependent on lighting conditions.^{1,6}

It has been almost 10 years since the first implantation of an AcrySof® IQ PanOptix® trifocal IOL in the world.⁶ Meta-analysis studies show that PanOptix® provides full range of vision ($\geq 20/25$) from far to intermediate and near at 33 cm.⁷ Nine

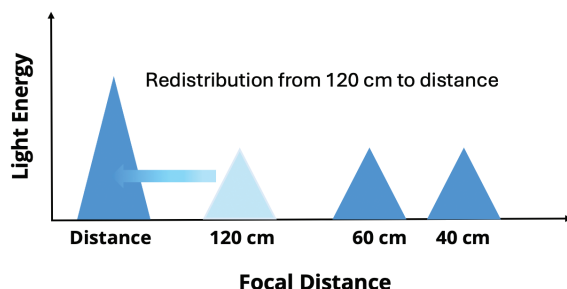


Figure 1. The ENLIGHTEN® Technology on the PanOptix optical design allows light redistributing to form 3 focal points at distance, intermediate (60 cm) and near (40 cm).

out of ten PanOptix® implanted patients can achieve complete spectacle independence⁸ with low rates of bothersome visual disturbances.⁹

TECNIS Synergy* IOL was first launched in Europe in 2019 and received US FDA approval in mid 2021. It combines a diffractive EDOF and bifocal optical design to provide full range of vision including near at 33 cm.¹⁰ It corrects corneal spherical and chromatic aberration as in other TECNIS* IOLs to improve image contrast.¹¹ Violet light filtering is also incorporated with the aim to mitigate dysphotopsia.¹¹ Synergy* FDA registration study showed that it provided continuous 20/32 or better vision from distance to near at 33 cm.¹⁰

The purpose of this prospective head-to-head study was to provide statistically powered comparative data on the visual performance including the range of vision, patient reported visual disturbances (VD) and spectacle usage using validated questionnaires (QUVID & IOLSAT). Visual disturbances are the main factors that affect refractive cataract patients' satisfaction after presbyopia correcting IOL implantation.¹²

It is essential to rule out the influence of residual refractive error by measuring distance corrected visual outcomes to ensure a fair comparison of visual benefits each IOL provides. In our study,⁴ one hundred thirty-eight randomized patients in each group completed 6-month follow-up after bilateral cataract removal and either PanOptix® or Synergy* implantation. **Compared to the Synergy* group, the PanOptix® group demonstrated non-inferior binocular distance corrected and uncorrected visual acuities (VA) at distance, intermediate (60 cm) and near (40 & 33 cm) in both photopic and mesopic conditions** (Table 1). The maximum difference of mean values between the two groups was ≤ 2 letters (0.04 logMAR) among

TABLE 1: BINOCULAR VISUAL ACUITIES UNDER PHOTOPIC OR MESOPIC CONDITION AT 6 MONTHS AFTER SURGERIES⁴

	PanOptix (n=138)	Synergy (n=138)
Photopic Binocular VAs (logMAR)		
BCDVA	-0.02 $\pm$ 0.08	-0.01 $\pm$ 0.09
DCIVA (60 cm)	0.12 $\pm$ 0.14	0.12 $\pm$ 0.14
DCNVA (40 cm)	0.13 $\pm$ 0.12	0.13 $\pm$ 0.12
DCNVA (33 cm)	0.21 $\pm$ 0.13	0.19 $\pm$ 0.12
UDVA	0.02 $\pm$ 0.11	0.05 $\pm$ 0.09
UIVA (60 cm)	0.09 $\pm$ 0.14	0.09 $\pm$ 0.12
UNVA (40 cm)	0.15 $\pm$ 0.15	0.14 $\pm$ 0.11
UNVA (33 cm)	0.22 $\pm$ 0.13	0.23 $\pm$ 0.11
Mesopic Binocular VAs (logMAR)		
DCIVA (60 cm)	0.29 $\pm$ 0.23	0.33 $\pm$ 0.24
DCNVA (40 cm)	0.32 $\pm$ 0.23	0.35 $\pm$ 0.25
DCNVA (33 cm)	0.4 $\pm$ 0.24	0.41 $\pm$ 0.25

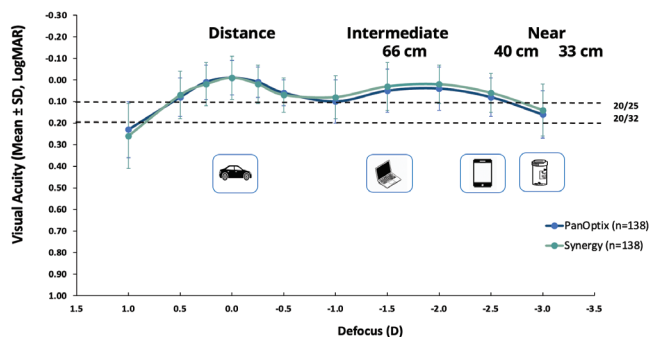


Figure 2. Binocular Distance Corrected Defocus Curve at 6 Months after Implantation.⁴

all tested conditions, suggesting no clinically relevant differences between the two groups. Consistently, binocular distance corrected defocus curve measurement showed that the two IOLs provided no significant differences on range of vision from distance to near at 33 cm ($P>0.05$, Figure 2).

For diffractive presbyopia correcting IOLs, the common concern is visual phenomena and decreased contrast sensitivity. The Synergy[®] IOL is designed to include chromatic aberration correction to increase the image contrast. However, binocular distance corrected contrast sensitivity measurements showed similar results between the two groups at 3 months post-op.⁴ When patients were presented with images of commonly experienced visual phenomena, significantly more PanOptix[®] patients reported "not experienced" ($P<0.05$, Figure 3) and "not bothered by Starbursts and Glare" ($P<0.05$),⁵ suggesting that the PanOptix IOL provides a superior visual disturbance profile (Starbursts and Glare) vs. Synergy.

Overall, this prospective, randomized large study showed that both PanOptix[®] and Synergy[®] provided similar full range of vision in both bright and dim light conditions. Patients from both groups reported high spectacle independence and high overall satisfaction, while patients in the PanOptix[®] group presented better tolerance to visual phenomena (Starbursts and Glare) compared to the Synergy[®] group,^{4,5} possibly related to

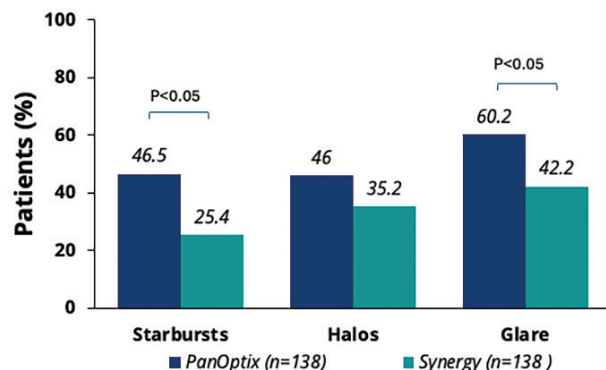


Figure 3. Patient reported not experiencing visual disturbances at 6 months.⁵

differences of optical design. We hope such clinical and statistically significant evidence will provide more confidence when we preoperatively counsel our cataract patients. ■

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AcrySof[®] IQ PanOptix[®] Family of Trifocal IOLs

IMPORTANT PRODUCT INFORMATION

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 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 IOLs, 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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