

ORIGINAL RESEARCH

# Visual Outcomes and Patient Satisfaction of Two Continuous Range of Vision Intraocular Lenses

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Purpose: To determine if visual outcomes with PanOptix are non-inferior to visual outcomes with Synergy.

**Methods:** This was an ambispective, single center, comparative, bilateral, observational study. Patients received bilateral implantation with either PanOptix or Synergy intraocular lenses (IOLs) and were enrolled at least 5 months after surgeries. Patients with postoperative spherical equivalent  $\pm$  0.50D and astigmatism  $\leq$  0.75D in both eyes were enrolled. Postoperatively, patients were tested for binocular uncorrected and distance corrected visual acuities at distance, intermediate (60cm), and near (40cm and 33cm), binocular defocus curve, and were administered questionnaires about quality of vision (QUVID) and spectacle independence (IOLSAT).

**Results:** A total of 230 subjects completed the study, 153 in the PanOptix group and 77 in the Synergy group. Non-inferiority of visual acuities were confirmed for all testing distances, with and without distance correction in place. No significant differences were observed for the binocular defocus curves (p > 0.05). Severity of starburst, halo, and glare were rated as "None" in 65% (98/150), 38% (58/152), and 48% (72/151) of subjects with the PanOptix Group, compared to 49% (37/76), 38% (29/77), and 55% (42/77) for the Synergy Group, respectively. The percentage of patients "Satisfied" or "Very Satisfied" with their vision was 89% (136/153) in the PanOptix group and 94% (72/77) in the Synergy group.

**Conclusion:** The results of this study suggest excellent visual acuities at distance, intermediate, and near, high spectacle independence, and high patient satisfaction with both the PanOptix and Synergy IOLs. The incidence of starbursts and blurred vision, as well as visual acuities at extreme near (33 cm), may be higher with the Synergy IOL.

Keywords: panoptix, synergy, cataract surgery, continuous range of vision

#### Introduction

An increasing number of patients have expectations of clear vision at distance, intermediate, and near following cataract surgery and intraocular lens (IOL) implantation. Monofocal IOLs are the most often implanted type of IOL, however, subjects may only be able to see clearly at distance. Bifocal IOLs are designed for clarity at distance and near, however, patients may still require spectacles for intermediate vision.<sup>1</sup> In contrast, trifocal IOLs are designed to provide clear vision at all ranges: distance, intermediate, and near.<sup>2</sup> Extended depth of focus (EDOF) IOLs are distinct from multifocal (bifocal and trifocal) IOLs as they attempt to create a continuous focal point, rather than separate focal points, for good visual outcomes at distance, intermediate, and functional near.<sup>3</sup> However, because these technologies modify incoming light, both multifocal and diffractive EDOF IOLs have been reported to increase visual disturbances compared to monofocal IOLs.<sup>4-7</sup>

The AcrySof PanOptix (Alcon Vision LLC) was the first trifocal IOL approved by the US Food and Drug Administration (FDA). The PanOptix is a diffractive IOL, which distributes 50% of the incoming light for distance vision, 25% for intermediate, and 25% for near.<sup>8</sup> Studies to date have reported good clinical outcomes with the PanOptix IOL.<sup>2,9,10</sup> However, visual disturbances have also been observed.<sup>4,5,11,12</sup>

The Tecnis Synergy IOL (Johnson & Johnson Vision) is a hybrid presbyopia correcting IOL. It combines multifocal and EDOF technologies in a proprietary diffractive surface.<sup>13</sup> The Synergy IOL has been reported to provide good

clinical outcomes, including extreme near vision (33 cm). <sup>13–15</sup> However, visual disturbances have also been noted with this IOL. <sup>13–15</sup>

A few studies to date have compared visual outcomes after implantation with the PanOptix and Synergy IOLs. <sup>13,16–18</sup> Results have been mixed, with a large sample study by Dick et al <sup>13</sup> reporting significantly higher DCNVA at 40 cm and 33 cm with the Synergy IOL compared to the PanOptix IOL. However, the mean differences were 2.5 letters and 4 letters respectively, which may not be clinically relevant (less than 1 line). <sup>19</sup> In addition, the study used nondirected patient reports of quality of vision to assess dysphotopsias and did not report on spectacle independence. Other studies to date have had relatively low sample sizes or reported monocular outcomes. <sup>16–18</sup>

The purpose of this study is to determine if the binocular visual outcomes with the PanOptix are non-inferior to the visual outcomes with the Synergy, and to compare patient-reported dysphotopsias and spectacle independence in a large sample.

### **Methods**

This was a non-interventional, ambispective, bilateral, single center multi-surgeon study of visual outcomes and patient satisfaction with the PanOptix and Synergy IOLs. The study was reviewed and approved by an institutional review board (WCG IRB, approval 1329473). The study was conducted in agreement with the tenets of the Declaration of Helsinki, good clinical practice, and international harmonization guidelines, and was registered in a clinical trials database (NCT06041139). All subjects gave written informed consent.

Four surgeons from a single private practice performed all surgeries using their standard extraction technique, phacoemulsification, and IOL implantation. The IOL was decided by each subject before surgery after discussion with the surgeon. Implantation in the second eye was performed two weeks after the first eye.

Inclusion criteria were age 45 years or older, uncomplicated bilateral cataract surgeries with either bilateral PanOptix or Synergy implantation, and postoperative residual refractive error up to  $\pm$  0.50 spherical equivalent with  $\leq$  0.75 residual refractive astigmatism in each eye. Subjects were excluded with corneal dystrophies or degenerations, conditions that might affect cataract removal, strabismus with or without amblyopia in either eye, previous ocular surgery of any kind, history of retinal detachment, diagnosed degenerative visual disorders, corneal abnormality, other than regular corneal astigmatism, or glaucoma.

Consecutive charts that met implantation criteria were retrospectively reviewed from June 2021 to February 2024 to identify patients that met the inclusion/exclusion criteria. Eligible subjects were prospectively assessed at least 5 months or more postoperatively from their last cataract surgery and IOL implantation. Binocular uncorrected and distance corrected visual acuities were measured at distance (UDVA, CDVA), intermediate (UIVA, DCIVA; 60 cm), and near (UNVA, DCNVA; 40 and 33 cm). Visual acuities were assessed using Early Treatment Diabetic Retinopathy Study (ETDRS) charts, recorded in Snellen equivalent, then converted to logMAR for statistical analysis. Data on postoperative refractive outcomes and binocular defocus curves (from –3.0 D to 1.0 D) were collected. Subjects were also administered a questionnaire about satisfaction with their vision (IOLSAT) and a questionnaire about quality of vision (QUVID). The QUVID questionnaire is a proprietary Alcon questionnaire that asks subjects to rate the frequency, severity, and bothersomeness of dysphotopsias. The IOLSAT is a proprietary Alcon questionnaire that asks subjects to rate their spectacle independence, satisfaction, and visual performance at distance, intermediate, and near under different lighting conditions. Both the QUVID and IOLSAT are validated questionnaires.

We estimated that 112 subjects per arm (224 total) would be required, assuming the difference in DCNVA (40 cm) between groups was 0.05 logMAR, standard deviation of 0.15 logMAR, non-inferiority margin of 0.1 logMAR, power 80%, and alpha of 0.05. It was also estimated that 142 subjects per arm (282 total) would be required, assuming the difference of 13.4% of subjects reporting "not bothered by halo" between groups, power 80%, and alpha of 0.05. To account for dropout, 155 per arm (310 total) were targeted. The software R (version 4.3.2; The R Foundation for Statistical Computing, Vienna, Austria) was used for all statistical analysis. Normality was assumed if skewness was  $\pm$  2 and kurtosis was  $\pm$  7. Comparisons for parametric data were performed using the Welch two sample *t*-test and comparisons for non-parametric data were performed using the Wilcoxon rank-sum test. A non-inferiority margin of 0.1 logMAR was used for non-inferiority testing. Categorical data were compared using the 2-sample test for equality of

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proportions. Defocus curves were compared using a linear mixed effect model, which was adjusted for multiple measurements with the same subject at different levels of defocus. In all cases, a p < 0.05 was considered significant.

#### **Results**

A total of 230 subjects completed the study, 153 in the PanOptix group and 77 in the Synergy group. The study was terminated early as recruitment was difficult in the Synergy group. Of 504 patient charts reviewed that included bilateral Synergy implantation, 128 patients were identified as potential candidates, but another 51 were excluded due to new enhancements, falling out of the range of SE or astigmatism on presentation for screening, or declining to participate. As there was considerable uncertainty in our assumptions for the expected pooled standard deviation for DCNVA (40 cm) with the two groups, sample size re-estimation was performed prior to stopping the study to confirm there was sufficient sample size for meaningful analysis. We estimated that 28 subjects per arm (56 total) would be required using the original assumed DCNVA (40 cm) difference of 0.05 logMAR, actual pooled standard deviation of 0.075 logMAR, non-inferiority margin of 0.1 logMAR, power 80%, and alpha of 0.05. Baseline characteristics and demographic data were comparable between groups and are summarized in Table 1. The proportion of female subjects was 57% (87/153) in the PanOptix group and 66% (51/77) in the Synergy group. The proportion of toric lenses was 55% (168/306) in the PanOptix group and 64% (99/134) in the Synergy group.

Binocular uncorrected and distance-corrected visual acuities are summarized in Table 2. Non-inferiority of PanOptix to Synergy was confirmed for all distances in Table 2, as none of the 95% confidence intervals for the difference in means contained the non-inferiority margin of 0.1 logMAR. The visual acuities were similar between groups. The largest mean difference was 0.07 logMAR at uncorrected extreme near (33 cm). For DCNVA at extreme near, the mean difference was 0.05 logMAR. The cumulative percentage of patients 20/xx or better for binocular uncorrected and distance-corrected visual acuities are summarized in Figure 1. Generally, the percentages of patients 20/20 or better at distance and intermediate were similar, while the Synergy group had higher percentages 20/20 or better for UNVA (33 cm), DCNVA (40 cm), and DCNVA (33 cm).

Table I Patient Demographics and Baseline Data

Parameter	PanOptix (n=306 eyes) Mean ± SD (Range)	Synergy (n=154 eyes) Mean ± SD (Range)	P value
Age (years)	65.6 ± 8.3 (21 to 82)	65.9 ± 10.2 (18 to 84)	0.85
ACD (mm)	3.33 ± 0.35 (2.41 to 4.33)	$3.33 \pm 0.35$ (2.41 to 4.33) $3.19 \pm 0.42$ (2.15 to 4.17)	
Axial Length (mm)	24.11 ± 1.12 (20.92 to 27.36)	24.08 ± 1.23 (21.44 to 27.63)	0.79
KI (D)	43.56 ± 1.30 (39.4 to 47.61)	43.38 ± 1.86 (38.5 to 46.84)	0.27
K2 (D)	44.38 ± 1.42 (40.48 to 48.6)	44.19 ± 1.82 (39.53 to 48.90)	0.28
Astigmatism (D)	0.82 ± 0.57 (-1.50 to 2.88)	0.82 ± 0.57 (0.00 to 3.09)	0.99
Average K (D)	43.97 ± 1.33 (39.94 to 47.82)	43.78 ± 1.82 (39.02 to 47.47)	0.28
Pupil Size (mm)	3.87 ± 1.00 (2.10 to 7.30)	3.87 ± 0.95 (1.80 to 6.50)	0.93
Sphere (D)	(D) $-1.43 \pm 3.15 (-15.50 \text{ to } 4.25)$ $-1.38 \pm 3$		0.88
Cylinder (D)	0.86 ± 0.72 (0.00 to 3.75)	0.99 ± 0.83 (0.00 to 4.25)	0.10
MRSE (D)	-1.00 ± 3.05 (-14.75 to 4.25)	-0.88 ± 3.25 (-12.63 to 8.38)	0.72
Lens Power (D)	19.17 ± 3.54 (8.00 to 31.00)	19.53 ± 4.11 (7.00 to 27.50)	0.37

**Abbreviations**: ACD, anterior chamber depth; Astigmatism K, corneal astigmatism; Average K, average corneal power (average of K1 and K2); MRSE, mean residual spherical equivalent. Significant differences are highlighted in bold.

Table 2 Postoperative Visual Acuities

Parameter	PanOptix (n=306 eyes) Mean ± SD (Range)	Synergy (n=154 eyes) Mean ± SD (Range)	95% CI for Difference in Mean*	Non-Inferiority	P value
UDVA	-0.01 ± 0.08 (-0.20 to 0.24)	0.00 ± 0.08 (-0.30 to 0.20)	-0.03 to 0.02	Х	0.72
UIVA 60cm	0.00 ± 0.08 (-0.20 to 0.20)	0.00 ± 0.08 (-0.20 to 0.20)	-0.03 to 0.01	Х	0.44
UNVA 40cm	0.03 ± 0.08 (-0.10 to 0.24)	0.03 ± 0.08 (-0.10 to 0.24)	-0.02 to 0.03	Х	0.64
UNVA 33cm	0.11 ± 0.10 (-0.10 to 0.34)	0.04 ± 0.08 (-0.10 to 0.24)	0.04 to 0.08	Х	< 0.001
CDVA	-0.06 ± 0.06 (-0.20 to 0.10)	$-0.07 \pm 0.07 \ (-0.30 \text{ to } 0.04)$	-0.01 to 0.03	Х	0.36
DCIVA 60cm	0.00 ± 0.08 (-0.30 to 0.30)	0.00 ± 0.07 (-0.20 to 0.20)	-0.02 to 0.02	Х	0.91
DCNVA 40cm	0.03 ± 0.08 (-0.10 to 0.24)	0.01 ± 0.07 (-0.10 to 0.20)	0.00 to 0.04	Х	0.13
DCNVA 33cm	0.09 ± 0.09 (-0.10 to 0.34)	0.04 ± 0.08 (-0.10 to 0.24)	0.03 to 0.07	Х	< 0.001

Notes: \*PanOptix - Synergy. Significant differences are highlighted in bold.

Abbreviations: CDVA, corrected distance visual acuity; DCIVA, distance corrected intermediate visual acuity; DCNVA, distance corrected near visual acuity; SD, standard deviation; UDVA, uncorrected distance visual acuity; UIVA, uncorrected intermediate visual acuity; UNVA, uncorrected near visual acuity.

The postoperative binocular defocus curves are shown in Figure 2. There were no significant differences observed at any level of defocus from -3.0 D to 1.0 D (p > 0.05). Postoperative mean residual astigmatism were  $0.24 \pm 0.26$  D and  $0.23 \pm 0.26$  D in the PanOptix and Synergy groups, respectively (p = 0.73). Postoperative mean MRSE were  $-0.02 \pm 0.27$  D and  $-0.01 \pm 0.27$  D in the PanOptix and Synergy groups, respectively (p = 0.59).

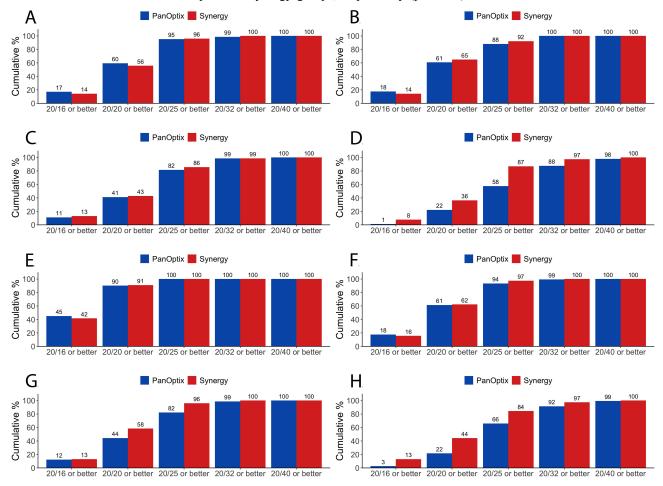


Figure I Cumulative postoperative binocular uncorrected visual acuities at (A) distance, (B) intermediate, (C) near 40 cm, and (D) near 33 cm and binocular distance-corrected visual acuities at (E) distance, (F) intermediate, (G) near 40 cm, and (H) near 33 cm.

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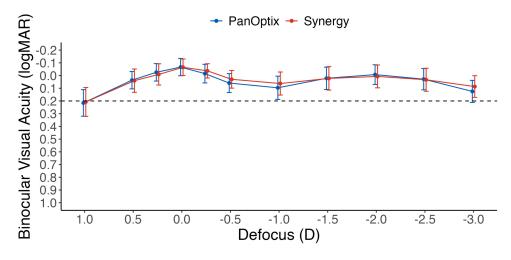


Figure 2 Binocular defocus curve.

Abbreviation: D, diopters; logMAR, log of minimum angle of resolution.

Table 3 summarizes the responses on the QUVID questionnaire. The percentage of subjects that answered "Never" for frequency, "None" for severity, and "Not bothered at all" for bothersomeness are shown and compared between groups. The proportion of subjects that answered "Never" for frequency and "None" for severity of starburst was significantly higher in the PanOptix group, as was the proportion of subjects that answered "Never" for frequency of blurred vision compared to the Synergy group. No other significant differences were observed.

Table 4 summarizes the responses on the IOLSAT questionnaire. Spectacle independence was defined as answering "Never" or "Rarely" on the IOLSAT, while good visual performance was defined as answering "Very good" or "Good" on the IOLSAT. There were no significant differences identified between the groups. The percentage of patients "Satisfied" or "Very Satisfied" with their vision was 89% (136/153) in the PanOptix group and 94% (72/77) in the Synergy group.

#### **Discussion**

This study compared the visual outcomes of the PanOptix IOL to the Synergy IOL. We observed that the PanOptix was non-inferior to the Synergy IOL at binocular UDVA, UIVA (60 cm), UNVA (40 and 33 cm), CDVA, DCIVA (60 cm), and DCNVA (40 and 33 cm). The 95% confidence intervals for binocular UNVA (33 cm) and DCNVA (33 cm) also did not contain 0.0, indicating significant differences favoring the Synergy group. However, the mean differences were 0.07 and 0.05 logMAR, respectively, which may not be clinically relevant (less than 1 line). Dick et al 13 reported significant

Table 3 Summary of QUVID Questionnaire Responses (n=150 to 153 PanOptix; n=76 to 77 Synergy)

Туре	Frequency			Severity		Bothersomeness			
	PanOptix (%) "Never"	Synergy (%) "Never"	P value	PanOptix (%) "None"	Synergy (%) "None"	P value	PanOptix (%) "Not Bothered at all"	Synergy (%) "Not Bothered at all"	P value
Starbursts	65	49	0.03	65	49	0.03	68	59	0.25
Halos	38	38	1.00	38	38	1.00	57	49	0.38
Glare	48	55	0.41	48	55	0.41	52	60	0.36
Haze	84	86	0.93	84	86	0.94	84	88	0.53
Blurred Vision	87	75	0.04	87	77	0.10	87	82	0.43
Double Vision	97	100	0.20	97	100	0.20	97	100	0.20
Dark Area	98	96	0.70	99	96	0.48	99	97	0.89

Note: Significant differences are highlighted in bold.

Table 4 Summary of IOLSAT Questionnaire Responses (n=153 PanOptix; n=77 Synergy)

Туре	Spectad	le Independen	ce	Good Vi	sual Performance		
	PanOptix (%)	Synergy (%)	P value	PanOptix (%)	Synergy (%)	P value	
Overall	92	97	0.18	-	-	-	
Distance (Overall)	99	100	1.00	_	_	-	
Distance (Bright Light)	97	100	0.31	89	88	0.87	
Distance (Dim Light)	99	100	1.00	74	71	0.72	
Intermediate (Overall)	99	100	1.00	-	-	-	
Intermediate (Bright Light)	99	100	1.00	98	96	0.69	
Intermediate (Dim Light)	99	100	0.78	86	89	0.61	
Near (Overall)	93	96	0.48	-	-	-	
Near (Bright Light)	97	99	0.87	94	95	1.00	
Near (Dim Light)	92	96	0.38	72	80	0.25	

differences for CDVA (0.05 logMAR), DCNVA 40 cm (0.05 logMAR), and DCNVA 33 cm (0.08 logMAR), favoring the Synergy IOL, however the differences may also not be clinically relevant (less than 1 line). Differences in our study compared to Dick et al<sup>13</sup> may be explained by the 1:2 enrollment of in the PanOptix group to the Synergy group in their study, compared to 2:1 in our study. In addition, Dick et al<sup>13</sup> implanted non-toric IOLs only, while our study implanted both toric and non-toric IOLs. Ferreira et al<sup>18</sup> reported no significant differences in binocular UDVA, UIVA, UNVA, CDVA, DCIVA, or DCNVA between the PanOptix and Synergy groups. However, the sample size was 30 subjects in each group. In a sample of 224 eyes, Moshirfar et al<sup>17</sup> reported significant differences for monocular UNVA (40 cm) in favor of the Synergy IOL (0.04 logMAR), however, the differences may not be clinically relevant (less than 1 line). In addition, the mean postoperative MRSE was 0.30 for the PanOptix group and 0.01 for the Synergy group. Finally, Nomura et al<sup>16</sup> observed a 0.05 logMAR difference for binocular UNVA (40 cm) in favor of the Synergy IOL, but again the differences may not be clinically relevant (less than 1 line) and there was a hyperopic shift in the PanOptix group compared to the Synergy group. The sample size was 27 subjects in each group, significantly smaller than our study. The results of our study and others suggest non-inferior visual acuity at all distances with the PanOptix IOL, and significant, but not clinically relevant, differences for near (33 cm) visual acuity compared to the Synergy IOL.

Visual acuity measurements are important when assessing the efficacy of cataract surgery and IOL implantation. However, spectacle independence and patient satisfaction are essential to understand as unhappy patients may have more frequent visits and require further intervention. Spectacle independence and patient satisfaction were high in both the PanOptix and Synergy groups with no significant differences observed. Ferreira et al<sup>18</sup> observed similarly high spectacle independence between the PanOptix and Synergy groups. In addition, Nomura et al<sup>16</sup> reported high satisfaction in both the PanOptix and Synergy groups. Other reports on each IOL in isolation have noted high spectacle independence and patient satisfaction.<sup>2,4,14,15</sup> The results of our study and others suggest high spectacle independence and patient satisfaction with both the PanOptix and Synergy IOLs.

Visual disturbances are of particular concern for diffractive IOLs. The proportion of subjects that answered "Never" for frequency and "None" for severity of starburst was significantly higher in the PanOptix group, as was the proportion of subjects that answered "Never" for frequency of blurred vision compared to the Synergy group. Dick et al<sup>13</sup> used nondirected patient reports of quality of vision and reported no significant differences between the PanOptix and Synergy groups. Ferreira et al<sup>18</sup> reported no significant differences in dysphotopsias between groups using the validated Quality of Vision questionnaire. Nomura et al<sup>16</sup> observed more symptoms of very and extreme glare and halos in the Synergy group compared to the PanOptix group, using a questionnaire. We acknowledge that comparisons between studies are difficult, especially given the use of different validated and unvalidated questionnaires. However, the results of our study and others suggest a potential increase in dysphotopsias with the Synergy IOL.

A limitation of this study was the restrictive inclusion/exclusion criteria which made recruitment in the Synergy group difficult and caused unequal sample sizes between groups. However, our results appear robust when compared to other

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reports. Another limitation was the ambispective nature of the study. A randomized study could lead to stronger conclusions, although using a retrospective chart review and 1 prospective visit enabled a large sample to be evaluated in a shorter period of time.

In conclusion, the results of this study suggest excellent visual acuities at distance, intermediate, and near, high spectacle independence, and patient satisfaction with both the PanOptix and Synergy IOLs. The incidence of starbursts and blurred vision, as well as visual acuities at extreme near (33 cm), may be higher with the Synergy IOL.

# **Data Sharing Statement**

Data are not available for sharing.

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#### **Disclosure**

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