Two novel extended depth-of-focus intraocular lenses targeted for mini-monovision: A prospective randomized controlled trial

JOUKJE C. WANTEN, NOËL J.C. BAUER, TOS T.J.M. BERENDSCHOT, FRANK J.H.M. VAN DEN BIGGELAAR, AND RUDY M.M.A. NUIJTS

• PURPOSE: To compare the visual outcomes of two extended depth-of-focus (EDOF) intraocular lenses (IOLs).
• DESIGN: Single-center prospective randomized controlled trial.
• METHODS: Patients undergoing bilateral cataract surgery were randomly assigned to receive either the Acunex Vario IOL (Teleon Surgical B.V., Spankeren, The Netherlands) or the AcrySof IQ Vivity IOL (Alcon Laboratories Inc., Fort Worth, United States of America); both Vario-group and Vivity-group were targeted for mini-monovision. The primary outcome was the uncorrected intermediate visual acuity (UIVA, measured at 66cm). Secondary outcome parameters were uncorrected distance visual acuity (UDVA), uncorrected near visual acuity (UNVA), defocus curves, reading speed, contrast sensitivity, spectacle independence and quality of vision.
• SETTING: University Eye Clinic, Maastricht University Medical Center+, the Netherlands.
• RESULTS: A total of 31 subjects (62 eyes) were included, 16 patients were enrolled into the Vario-group and 15 patients into the Vivity-group. At three months postoperatively, no statistically significant differences were found for the binocular visual acuities between the groups after adjustment for covariates. The mean and standard deviation for the binocular UIVA was 0.04±0.11 and 0.15±0.11 logMAR (adjusted-P=0.264) for the Vario-group and Vivity-group, respectively. The binocular UDVA was 0.00±0.14 and 0.08±0.10 logMAR (adjusted-P=0.753), and UNVA was 0.22±0.17 and 0.31±0.14 logMAR (adjusted-P=0.235), for both groups, respectively. While the Vario-group had a larger range of defocus, no significant differences were found for patient satisfaction and spectacle independence. Contrast sensitivity and reading speed were comparable, and there were no statistically significant differences in optical side effects between the groups.
• CONCLUSION: Bilateral implantation of the Acunex Vario IOL and the AcrySof IQ Vivity IOL targeted for mini-monovision had comparable results for binocular visual acuity outcomes, contrast sensitivity, optical side effects, and reading speed. The Vario-group showed a larger continuous range of defocus. (Am J Ophthalmol 2025;276: 286–296. © 2025 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/))

INTRODUCTION

Ideally, cataract surgery should provide perfect vison at all distances without optical complaints. Advances in intraocular lens (IOL) technology using multifocal designs offer expanding possibilities for achieving spectacle independence after cataract surgery. Although multifocal IOLs (mIOLs) may offer good visual performance at all distances, they carry risks of contrast sensitivity loss and photic phenomena.[1] Recently, extended-depth-of-focus (EDOF) IOLs have been developed that primarily focus on good uncorrected distance and intermediate vision.[2] The range of vision with EDOF IOLs can be increased by targeting for mini-monovision, wherein the dominant eye is targeted for emmetropia and the non-dominant eye targeted for -0.25 to -0.75D, improving the binocular uncorrected near visual acuity and thus increasing spectacle independency.[3,4] Furthermore, recent reports demonstrated that EDOF IOLs have an optical disturbance profile similar to monofocal IOLs, which assumedly contributes to the shifting popularity from multifocal to EDOF IOLs.[2,5] Various EDOF IOLs are available, either with a small aperture, aspherical continuous, refractive zonal or diffractive optical design.[6] For the current study the Acunex Vario IOL AN6V (+1.5D addition) (Teleon Surgical B.V., Spankeren, the

AJO.com Supplemental Material available at AJO.com.

Meeting presentations: - Free paper at annual Dutch Ophthalmological Association Congress (NOG congress) 2023 in Maastricht, the Netherlands - Poster at European Society of Cataract and Refractive Surgeons Congress (ESCRS) 2023 in Vienna, Austria
Accepted for publication April 20, 2025.

From the University Eye Clinic Maastricht, Maastricht University Medical Center+, Maastricht, The Netherlands
Inquiries to: Joukje C. Wanten, MD, University Eye Clinic Maastricht, Maastricht University Medical Center+, P.O. Box 5800, 6202 AZ Maastricht, the Netherlands. Tel.: +31 (0)43 387 1594; e-mail: joukje.wanten@mumc.nl

0002-9394/$36.00
https://doi.org/10.1016/j.ajo.2025.04.024

Netherlands), and the AcrySof IQ Vivity IOL DFT015 (Alcon Laboratories Inc., Fort Worth, United States of America) are explored.[2,3,7] The purpose of this study was to evaluate and compare the visual outcomes of these two EDOF IOLs when targeting for mini-monovision.

METHODS

For this study, patients with bilateral cataracts were invited for participation if they expressed an unsolicited interest in an EDOF IOL, had a power calculation between +10.0 Diopters (D) and +30.0D, and an expected postoperative refractive astigmatism of ≤1.0D. Exclusion criteria were previous eye surgery, any significant ocular pathology that would limit the postoperative visual acuity <0.3 logMAR, extensive visual field loss, and cognitive or concentration disorders. Between May and December 2022, 32 participants from the University Eye Clinic of the Maastricht University Medical Center+ were enrolled. All patients signed informed consent before enrollment. This study was approved by the local medical ethics committee and executed in accordance with the principles of the Helsinki Declaration. The trial registration can be accessed at ClinicalTrials.gov under the identifier NCT05335408. We used the CONSORT checklist when writing our report.[8]

Patients were randomized for bilateral implantation of the AN6V (Vario-group; intervention) or bilateral implantation of the DFT015 (Vivity-group; control). The randomization was performed using the algorithm of the data management platform (Castor, Amsterdam, the Netherlands) in blocks of 2 and 4. Patients and clinicians performing the postoperative assessments were blinded. Both IOLs are one-piece, foldable EDOF IOLs made of hydrophobic acrylic with a diopter range between +10.0 and +30.0D. The AN6V optic offers the extended depth of focus by a sector-shaped near vision segment of +1.5D located on the inferior IOL surface. The DFT015 provides extended depth of focus by its wavefront-shaping design. Power calculations were performed using the IOLMaster700 optical biometry (Carl Zeiss, Jena, Germany), the Barrett Universal-II (BU-II) formula, and the manufacturer recommended lens factor. All patients were targeted for mini-monovision, with the postoperative refraction in the dominant eye aimed closest to emmetropia and the non-dominant eye targeted for 0.25 to 0.75D of myopia.

Surgeries were performed by three experienced surgeons using a standard divide-and-conquer phacoemulsification technique or by performing femtosecond laser-assisted cataract surgery, with a 2.2 mm clear corneal incision. For cases of with-the-rule (WTR) astigmatism, the corneal incision was made superiorly, while for against-the-rule (ATR) astigmatism, the corneal incision was made temporally. The choice between immediate sequential bilateral or delayed sequential bilateral cataract surgery was based on the patient's preference.[9]

Preoperatively, patients underwent routine ophthalmological examination, including manifest subjective refraction, visual acuity measurements, slit lamp and funduscopy, optical biometry, and corneal topography (Pentacam HR, Oculus, Wetzlar, Germany). Postoperative assessments were planned at one week, one month, and three months. The three-month postoperative visit included a comprehensive ophthalmological assessment, with manifest refraction, uncorrected and corrected monocular and binocular visual acuities for distance (UDVA and CDVA), intermediate (UIVA and DCIVA), and near (UNVA and DCNVA). Visual acuity measurements were performed using the Early Treatment Diabetic Retinopathy Study (ETDRS) charts, at distances of 4 m, 66 cm, and 40 cm. The last attempted line on the ETDRS chart was determined, until no further optotypes could be distinguished. The logMAR score was identified by adding the total number of correctly identified optotypes added to the score of the last attempted line. Functional vision assessment included binocular uncorrected and distance-corrected defocus curves, ranging from +2.0D to -4.0D with +0.50D increments, in photopic conditions. The defocus equivalent (DEQ) was calculated using: |Sphere + ½*Cylinder| + |½*Cylinder|. Contrast sensitivity was measured using the CSV-1000 (Greenville, Ohio, United States of America) in photopic and mesopic conditions, with and without glare. Reading speed (binocular uncorrected) was tested at 40 cm with the Radner reading chart in photopic conditions.[10] Aberrometry measurements were conducted with the KR-1W Wavefront analyser (Topcon, Tokyo, Japan), and tilt and decentration analyses with the CASIA2 (Tomey Corp., Nagoya, Japan). At three months postoperatively, patient satisfaction, spectacle independence, and optical complaints were assessed using the Catquest-9SF, IOLSAT (Alcon Laboratories Inc., Fort Worth, United States of America), and QoV questionnaires with Likert scales ranging from zero (none/never) to four (severe/always).[11,12] Questionnaires were completed by patients at home, without involvement from surgeons or researches, to minimize bias.

• **SAMPLE SIZE AND STATISTICAL ANALYSES:** A sample size of 32 participants was determined based on the assumption of no UIVA difference in logMAR at three months postoperatively, with an expected standard deviation (SD) of 0.09 logMAR and a non-inferiority margin of 0.10 logMAR. A significance level of 0.05, power of 90%, and a 10% loss to follow-up were used in this calculation. Data analysis was conducted using SPSS (IBM Corp. Released 2021. IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY).

Qualitative variables were summarized as frequencies and percentages, while descriptive statistics, including mean and SD, were calculated for quantitative variables. Preoperative keratometric astigmatism, postoperative corneal

TABLE 1. Baseline characteristics.
Baseline characteristics of the study groups. Vectors, marked with an asterisk (*), are calculated using vector analyses.

		Vario-group (n=16, 32 eyes) Mean ± SD	Vivity-group (n=15, 30 eyes) Mean ± SD
Age (y)	All patients	64.1 ± 9.6	71.7 ± 7.6
CDVA (LogMAR)	Dominant eyes	0.27±0.18	0.19±0.14
	Non-dominant eyes	0.27±0.33	0.21±0.23
SEQ (D)	Dominant eyes	0.10±2.20	-1.61±3.01
	Non-dominant eyes	0.98±2.91	0.00±3.38
AL (mm)	Dominant eyes	23.46±1.02	24.35±1.43
	Non-dominant eyes	23.51±1.05	24.23±1.43
ACD (mm)	Dominant eyes	3.16±0.41	3.25±0.47
	Non-dominant eyes	3.14±0.42	3.30±0.48
Keratometric astigmatism (D)*	Dominant eyes	0.40±0.56	0.20±0.75
	Non-dominant eyes	0.22±0.69	0.16±0.70
Target (D)	Dominant eyes	-0.02±0.10	-0.04±0.11
	Non-dominant eyes	-0.35±0.09	-0.41±0.13
IOL Power (D)	Dominant eyes	22.1±3.1	18.7±4.3
	Non-dominant eyes	22.5±3.3	19.7±4.2

ACD=Anterior Chamber Depth, AL=Axial Length, CDVA=Corrected Distance Visual Acuity, D=Diopter, IOL=Intraocular Lens, SD=Standard Deviation, SEQ=Spherical Equivalent

astigmatism, and tilt and decentration measurements were analyzed using vector analysis. The comparison of vector values between the study groups were performed using Hotelling's T-squared test. The binocular visual acuity outcomes were assessed for non-inferiority (Vario-group – Vivity-group), with a 90% confidence interval (CI). For postoperative analyses of the quantitative outcomes, linear regression analyses were carried out. Logistic regression analyses were performed to compare the qualitative outcomes between the two study groups. A significance level of ≤0.05 was applied.

RESULTS

A total of 32 patients (64 eyes) were randomly assigned to the Vario-group or Vivity-group. One patient withdrew from the study because of anxiety for the cataract surgery. In total, 22 patients underwent ISBCS and 9 underwent DSBCS. The Vario-group comprised 16 patients (8 males and 8 females) and the Vivity-group comprised 15 patients (3 males and 12 females). Table 1 presents baseline characteristics. Baseline imbalances were observed for age, IOL power, and preoperative keratometric values of the dominant eye. In the statistical analyses of postoperative outcomes, age and IOL power were found to significantly influence the results and were included as covariates. Consequently, all P-values were adjusted for these covariates and reported as adjusted P-values (adjusted-P).

Table 2 summarizes the refraction and visual acuity outcomes at three months postoperatively subdivided into dominant and non-dominant eyes. The unstandardized B-coefficients, including standard error (SE) represent the difference between the two study groups after adjusting for covariates. The primary outcome parameter, UIVA, was non-inferior, with a 90%CI of -0.026 to 0.091. All other binocular visual acuity outcomes showed non-inferior outcomes as well, the 90% CI levels can be found in Supplemental Table 1. The postoperative refractive astigmatism was analyzed using double-angle plots shown in Figure 1. An additional analysis of the monocular and binocular uncorrected visual acuity outcomes was conducted, shown in Table 3, comparing the data excluding the outlier eyes with a postoperative corneal astigmatism >1.0D. This sensitivity analysis showed non-inferior binocular uncorrected visual acuity outcomes for the Vario-group compared to the Vivity-group.

The postoperative prediction error (PE) was statistically significantly different between the two study groups for the dominant eyes. The percentage of dominant eyes within ±0.50D of the target was 82% for the Vario-group and 73% for the Vivity-group at three months postoperatively. For the non-dominant eyes these values were respectively 88% and 80%. Vector analyses were performed for all operated eyes using preoperative and postoperative Scheimpflug topography scans. Mean surgically induced astigmatism (SIA) for the Vario-group and the Vivity-group of the dominant eyes was 0.19±0.38D at 5° and 0.19±0.37D at 30° (adjusted-P=0.673), and for the non-

TABLE 2. Refractive state and visual acuity outcomes.

Refractive state and visual acuity outcomes at 3 months postoperatively. Vectors, marked with a ×, are calculated using vector analyses and further analyzed using Hotelling's T-squared tests. The outcomes are corrected for the covariates age and IOL power, offering the unstandardized coefficient B, standard error, and adjusted P-value marked with an asterisk (*).

	Vario-group (n=16) Mean ± SD [range]	Vivity-group (n=15) Mean ± SD [range]	P	Unstandardized coefficient B (SE (B))*	Adjusted-P*
Binocular outcomes					
UDVA (logMAR)	0.00 ± 0.14 [-0.20, 0.34]	0.08 ± 0.10 [-0.06, 0.22]	0.056	-0.014 (0.045)	0.753
UIVA (logMAR)	0.04 ± 0.11 [-0.10, 0.24]	0.15 ± 0.11 [-0.02, 0.36]	0.011	-0.052 (0.045)	0.264
UNVA (logMAR)	0.22 ± 0.17 [-0.10, 0.50]	0.31± 0.14 [0.14, 0.60]	0.104	-0.086 (0.071)	0.235
CDVA (logMAR)	-0.07 ± 0.09 [-0.20, 0.12]	0.00 ± 0.10 [-0.16, 0.18]	0.059	-0.028 (0.037)	0.459
DCIVA (logMAR)	0.06 ± 0.12 [-0.08, 0.34]	0.14 ± 0.14 [-0.04, 0.40]	0.105	-0.042 (0.056)	0.453
DCNVA (logMAR)	0.26 ± 0.12 [-0.10, 0.42]	0.35 ± 0.14 [0.12, 0.64]	0.055	-0.061 (0.059)	0.313
Monocular outcomes: Dominant eyes					
Sphere (D)	0.09 ± 0.38 [-0.75, 0.75]	0.57 ± 0.51 [-0.25, 1.50]	0.006	-0.452 (0.197)	0.030
Cylinder (D)×	-0.27 ± 0.54 [-1.25, 0.00]	-0.73 ± 0.79 [-1.75, 0.00]	0.001	NA	0.008
SEQ (D)	-0.12 ± 0.44 [-1.12, 0.75]	0.10 ± 0.48 [-0.50, 0.88]	0.181	-0.360 (0.202)	0.086
DEQ (D)	0.48 ± 0.46 [0.00, 1.50]	0.87 ± 0.31 [0.50, 1.50]	0.012	-0.110 (0.141)	0.442
UDVA (logMAR)	0.01 ± 0.09 [-0.16, 0.20]	0.18 ± 0.12 [0.04, 0.50]	<0.001	-0.104 (0.044)	0.027
CDVA (logMAR)	-0.02 ± 0.08 [-0.16, 0.14]	0.03 ± 0.09 [-0.16, 0.16]	0.106	-0.022 (0.033)	0.499
Prediction error (D)	0.11 ± 0.45 [-0.73, 1.12]	-0.14 ± 0.44 [-0.85, 0.50]	0.121	0.443 (0.192)	0.029
Monocular outcomes: Non-dominant eyes					
Sphere (D)	-0.03 ± 0.35 [-0.75, 0.75]	0.05 ± 0.45 [-0.75, 1.00]	0.576	-0.111 (0.176)	0.535
Cylinder (D)×	-0.15 ± 0.57 [-1.25, 0.00]	-0.67 ± 0.84 [-1.75, -0.25]	0.006	NA	0.141
SEQ (D)	-0.22 ± 0.33 [-0.75, 0.63]	-0.42 ± 0.41 [-1.25, 0.13]	0.131	0.072 (0.158)	0.651
DEQ (D)	0.50 ± 0.37 [0.00, 1.25]	0.95 ± 0.46 [0.25, 2.00]	0.005	-0.207 (0.166)	0.221
UDVA (logMAR)	0.04 ± 0.14 [-0.14, 0.34]	0.20 ± 0.12 [0.04, 0.48]	0.002	-0.088 (0.052)	0.098
CDVA (logMAR)	-0.02 ± 0.10 [-0.16, 0.22]	0.06 ± 0.11 [-0.08, 0.34]	0.039	-0.063 (0.046)	0.178
Prediction error (D)	-0.14 ± 0.34 [-1.02, 0.29]	0.01 ± 0.36 [-0.58, 0.72]	0.246	0.016 (0.145)	0.915

CDVA=Corrected Distance Visual Acuity, D=Diopter, DCIVA=Distance Corrected Intermediate Visual Acuity, DCNVA=Distance Corrected Near Visual Acuity, DEQ=Defocus Equivalent, IOL=Intraocular Lens, SD=Standard Deviation, SE=Standard Error, SEQ=Spherical Equivalent, UDVA=Uncorrected Distance Visual Acuity, UIVA=Uncorrected Intermediate Visual Acuity, UNVA=Uncorrected Near Visual Acuity.

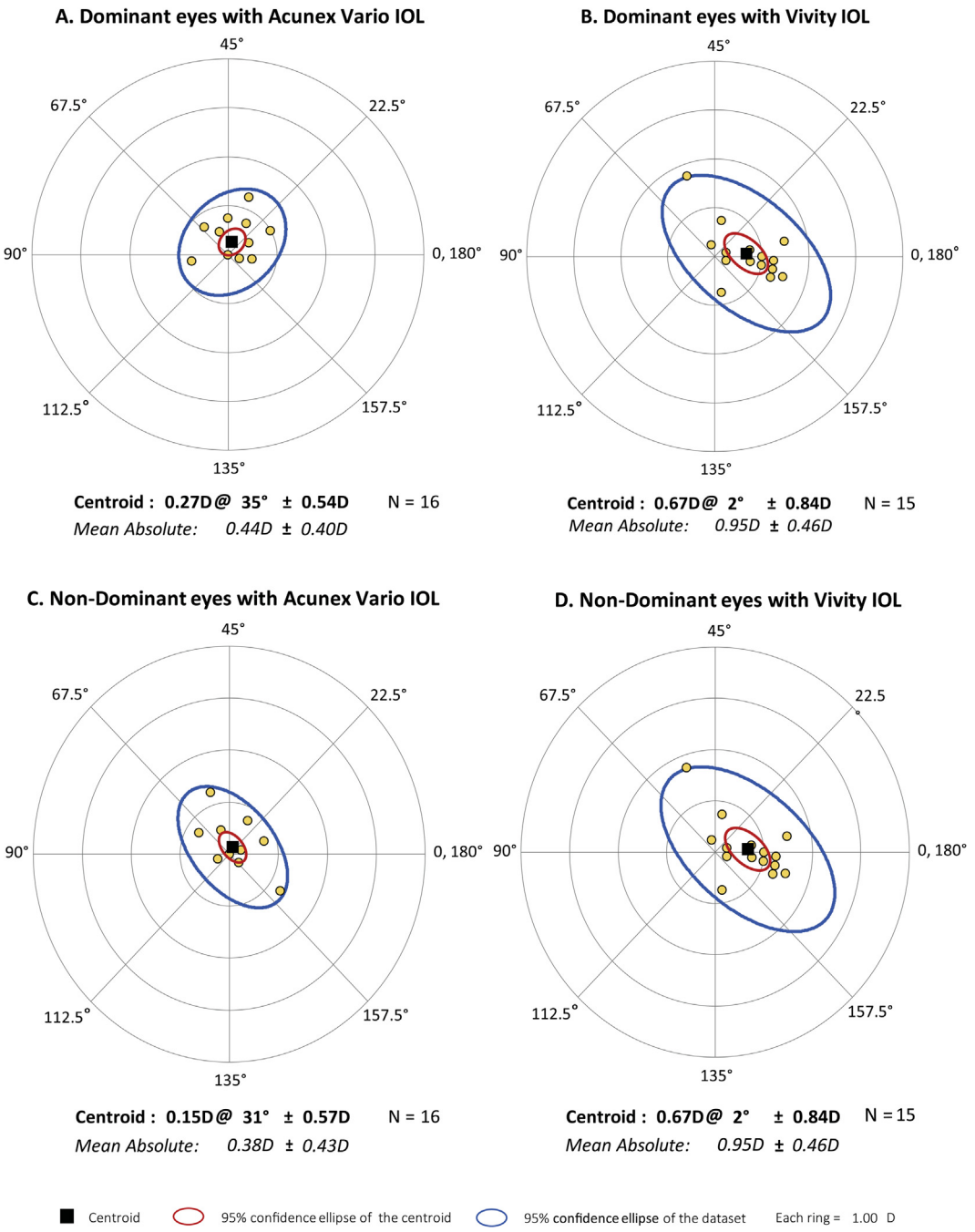

FIGURE 1. Double angle plots of postoperative refractive astigmatism at three months postoperatively. The centroid is represented by the black square, the red ellipse encompasses the 95% confidence interval of the centroid. The blue ellipse represents the 95% confidence interval of the entire dataset. Each concentering ring in the double angle plot corresponds to a 1.0D increment. *D=Diopter*.

dominant eyes 0.35±0.39D at 2° and 0.128±0.34D at 10° (adjusted-P=0.453).

Figure 2 shows the binocular UDVA defocus curve and binocular UDVA defocus curve without the outlier eyes with a postoperative residual astigmatism >1.0D. The Vario-group showed significantly better results for the uncorrected defocus curve at -2.0D (adjusted-P=0.034; B=0.118; SE(B)=0.053), -2.5D (adjusted-P=0.024; B=0.241; SE(B)=0.068), -3.0D (adjusted-P=0.003; B=0.257; SE(B)=0.077), and -3.5D (adjusted-P<0.001; B=0.251; SE(B)=0.066). The defocus curve without outliers showed no differences between the two study groups. The binocular CDVA defocus curve can be found in Supplemental Figure 1.

TABLE 3. Sensitivity analysis visual acuity outcomes.
Sensitivity analysis of uncorrected monocular and binocular visual outcomes at 3 months postoperatively. Outlier-eyes with a corneal astigmatism >1.0D were excluded before analysis. The outcomes are corrected for covariates age and IOL power, offering the unstandardized coefficient B, standard error (SE), and adjusted P-value marked with an asterisk (*). For binocular visual acuity outcomes, one sided P-values are given and for monocular visual acuity outcomes two-sides P-values are used.

	Vario-group Mean ± SD (n=Eyes)	Vivity-group Mean ± SD (n=Eyes)	P	Unstandardized coefficient B (SE (B))*	Adjusted-P*
Binocular outcomes					
UDVA (logMAR)	-0.03 ± 0.11 (28)	0.01 ± 0.07 (14)	0.241	-0.013 (0.049)	0.794
UIVA (logMAR)	0.05 ± 0.11 (28)	0.07 ± 0.06 (14)	0.273	-0.003 (0.052)	0.956
UNVA (logMAR)	0.24 ± 0.17 (28)	0.23 ± 0.11 (14)	0.460	-0.010 (0.087)	0.911
Monocular outcomes					
UDVA (logMAR) Dominant eyes	0.00 ± 0.08 (15)	0.14 ± 0.08 (10)	<0.001	-0.092 (0.036)	0.018
UDVA (logMAR) Non-Dominant eyes	0.02 ± 0.12 (14)	0.15 ± 0.09 (9)	0.013	-0.069 (0.053)	0.215

SD=Standard Deviation, SE=Standard Error, UDVA=Uncorrected Distance Visual Acuity, UIVA=Uncorrected Intermediate Visual Acuity, UNVA=Uncorrected Near Visual Acuity

Tilt and decentration analyses were performed at one month postoperatively, showing a mean tilt for the dominant eyes of 3.4±3.6° for the Vario-group and 4.4±2.3° for the Vivity-group (adjusted-P=0.079). The non-dominant eyes had values of 3.5±3.2° and 4.5±2.1° for the Vario-group and Vivity-group, respectively (adjusted-P=0.0124). Mean decentration for the dominant eyes was 0.11±0.16 mm for the Vario-group and 0.06±0.20 mm for the Vivity-group (adjusted-P= 0.718). Non-dominant eyes had a decentration of 0.13±0.1 8mm for the Vario-group and 0.02±0.20 mm for the Vivity-group (adjusted-P=0.667).

Both study groups had comparable reading speed scores in relation to visual acuity in logRAD. Contrast sensitivities are presented in Figure 3. Only at 12cpd in mesopic conditions with glare there was significant difference in favor of the Vario-group (adjusted-P=0.024; B=0.124, SE(B)=0.052).

At three months postoperatively, the total higher-order aberrations were measured in pupils of 4 mm and 6 mm, respectively. For dominant eyes with 4mm pupils, values were 0.19±0.11 µm and 0.16±0.05 µm for the Vario-group and Vivity-group, respectively (adjusted-P=0.366). In 6 mm pupils, the values were 0.49±0.21 µm and 0.47±0.11 µm (adjusted-P=0.334). Non-dominant eyes of the Vario-group and Vivity-group showed values of 0.23±0.16 µm and 0.17±0.04 µm in 4 mm pupils (adjusted-P=0.430) and 0.52±0.17 µm of and 0.49±0.09 µm in 6 mm pupils (adjusted-P=0.651), respectively.

No statistically significant difference in patient satisfaction was found between the groups with 93.8% (n=15) in the Vario-group and 86.7% (n=13) in the Vivity-group being satisfied. Similarly, the Catquest-9SF questionnaire outcomes did not reveal significant differences between the groups (detailed results available in Supplemental Figure 2). The presence of photic phenomena and the spectacle independence at three months postoperatively can be found in Supplemental Figure 3 and Supplemental Table 2, where the results were comparable between the study groups. In bright light conditions, 93.8% of the Vario-group and 86.7% of the Vivity-group never or rarely used glasses. For near vision, reading glasses were required by 62.5% of patients in the Vario-group and 73.3% in the Vivity-group. Patients reported halos, glare, and starbursts never or only sometimes in 75% (n=12), 75% (n=12), and 81% (n=13) of cases in the Vario-group and 93% (n=14), 86% (n=13), and 93% (n=14) in the Vivity-group, respectively. Two patients in the Vario-group reported bothersome halos and glare, while one experienced starburst complaints. In the Vivity-group, one patient reported bothersome glare.

• **COMPLICATIONS AND ADVERSE EVENTS:** Three surgical complications were reported: one case of corneal erosion and partial zonulolysis in the Vario-group, and one posterior capsule rupture necessitating anterior vitrectomy in the Vivity-group. Postoperatively, one patient in the Vario-group developed bilateral uveitis anterior, while one patient in the Vivity group had bilateral cystoid macular edema, and another had stromal edema. These conditions had all resolved with standard treatment at the final postoperative visit. Thereafter, one patient was scheduled to receive additional laser-assisted sub-epithelial keratectomy (LASEK) to correct the residual ametropia.

DISCUSSION

The purpose of this study was to compare the visual outcomes of two EDOF IOLs (AN6V and DFT015) when targeted for a mini-monovision approach. At three months postoperatively, after correcting for the covariates age and IOL power, non-inferiority was observed for the primary

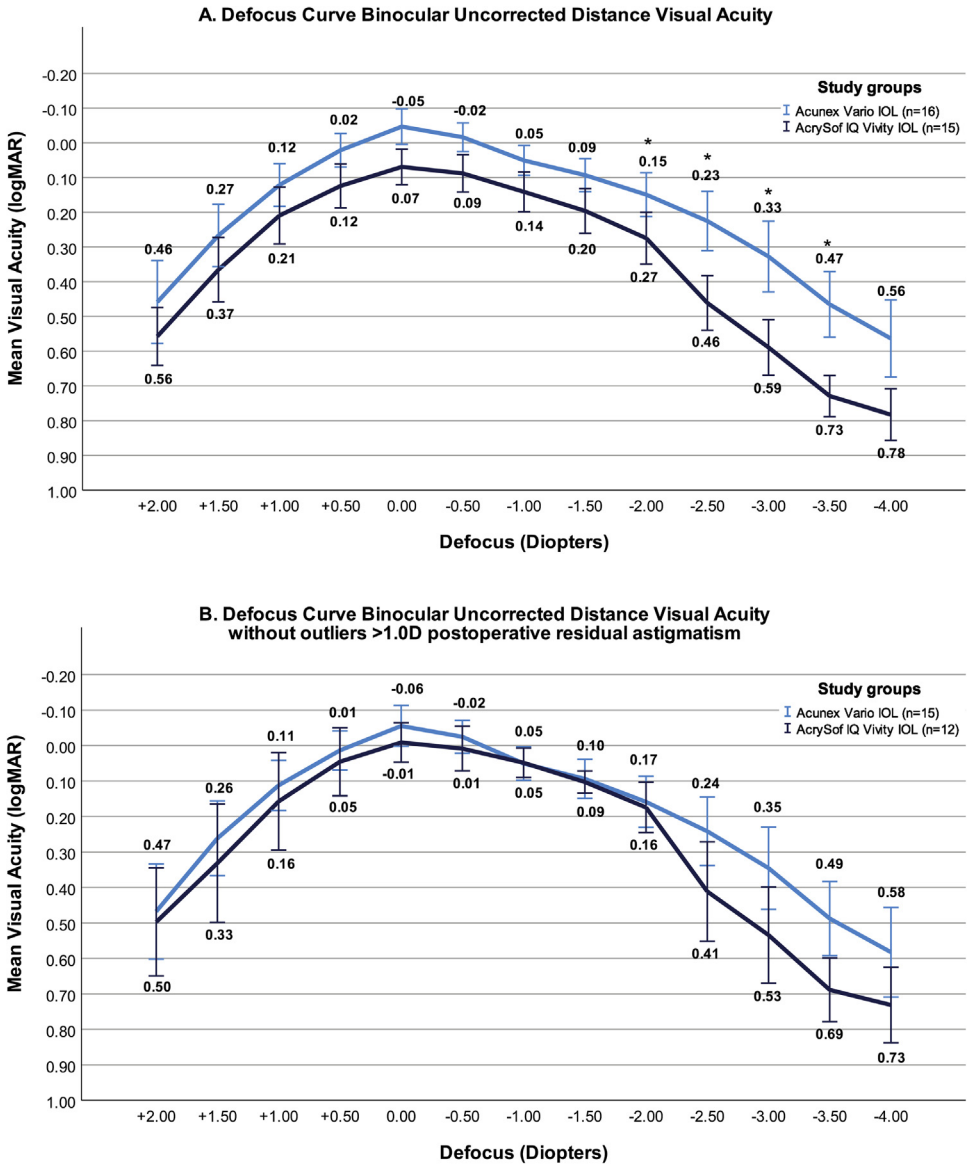

FIGURE 2. Binocular defocus curves at three months postoperatively. A. Binocular UDVA defocus curve. B. Binocular UDVA defocus curve without outliers having >1.0D postoperative residual astigmatism. The statistically significant differences between group, after adjusting for the covariates age and IOL power, are denoted by an asterisk (*).
D=Diopter, UDVA=Uncorrected Distance Visual Acuity.

outcome binocular UIVA in the Vario-group compared to the Vivity-group. The correction for these covariates was applied to all quantitative outcomes to mitigate bias arising from the imbalances between the groups at baseline and to ensure the objectivity of our comparisons between the study groups.

The refractive outcomes at three months demonstrated significant differences for sphere, cylinder and UDVA for the dominant eyes between the study groups. These disparities were primarily attributed to higher residual astigmatism outcomes in the Vivity-group compared to the Vario-group. Although our study aimed for a postoperative residual astigmatism of ≤1.0D, postoperative refractive astigmatism clearly demonstrated higher centroid values and an increased prevalence of outliers (>1.0D) in the Vivity-group. The sensitivity analysis without these >1.0D outliers indicated comparable binocular visual acuity outcomes between the groups, which emphasizes the importance of postoperative residual astigmatism <1.0D on uncorrected visual acuity outcomes. This is in line with previous research showing that residual astigmatism of ≥1.0D significantly decreases UDVA.[13] In retrospect, targeting a residual astigmatism lower than the ≤1.0D aim might have been preferable to limit the amount of residual postoperative astigmatism due to the wide range and individual variability of SIA.[14] Therefore, IOL calculations aiming for a residual postoper-

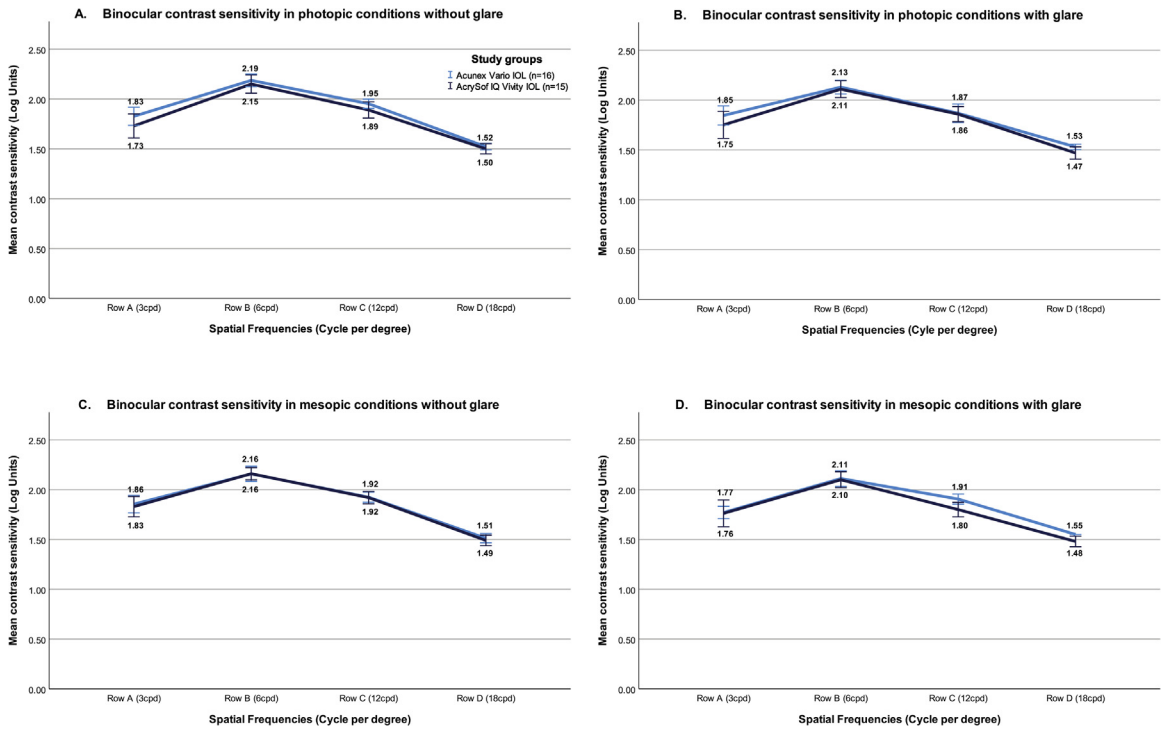

FIGURE 3. Binocular contrast sensitivity outcomes at three months postoperatively in different conditions. A. Photopic conditions without glare. B. Mesopic conditions without glare. C. Photopic conditions with glare. D. Mesopic conditions with glare.

ative astigmatism ≤0.75D may decrease the number of outliers >1.0D of astigmatism and reduce the postoperative PE.

For both monofocal and EDOF IOLs, the impact of refractive cylinder on UDVA shows a comparable change of 0.0425 logMAR per 0.25D cylinder.[15] Furthermore, toric monofocal IOLs in patients with low preoperative corneal astigmatism (0.75-1.5D) demonstrate significantly reduced postoperative residual astigmatism, leading to improved UDVA outcomes. Therefore, considering the use of a toric IOL is suggested for preoperative astigmatism at or above the 0.75D threshold.[16] Studies involving presbyopia-correcting IOLs also have recommended astigmatism correction ≥0.75D to ensure postoperative vision quality.[17] In our study, the IOLs of interest were expected to tolerate ≤1.0D astigmatism, although scientific validation is lacking for refractive EDOF IOLs. Previous research on the DFT015 has shown that low levels of induced ametropia (up to ±0.50D) are tolerated, with no significant difference in visual acuity compared to emmetropia (≤1 line loss).[18] Additionally, another study has demonstrated a tolerance for negative spherical aberrations up to -0.05 µm, which does not impact UDVA and may even provide slight improvements in UNVA and UIVA.[19] Higher levels of ametropia and spherical aberrations have not yet been reported.

Literature on the AN6V (+1.5D addition) is limited. The precursor of this IOL, the Lentis Comfort M15 IOL (currently Teleon Surgical B.V., Spankeren, The Netherlands), features a sector-shaped near vision zone with a +1.5D add power. When targeted for emmetropia, this IOL demonstrated monocular UDVA, UIVA and UNVA outcomes at three months postoperatively, with values of 0.12±0.13, 0.16±0.17, and 0.32±0.18 logMAR, respectively.[20] Another study reported bilateral outcomes for UDVA, UIVA, UNVA of 0.07±0.10, 0.21±0.15, and 0.53±0.15 logMAR at three months postoperatively.[21] Long-term results up to 5 years postoperatively showed stable distance and intermediate visual acuity.[22] A prospective study involving the implantation of the AN6V (+1.5D addition), targeted for emmetropia, reported binocular UDVA, UIVA, and UNVA at three months of -0.08±0.06, -0.03±0.06, and 0.16±0.06 logMAR, respectively. Additionally, the distance-corrected defocus curve demonstrated a visual acuity of 0.20 logMAR or better within +1.50D to -2.00D.[23] Our results with the AN6V targeted for mini-monovision, showed superior outcomes on all distances as compared to the previous studies using the Lentis Comfort M15 IOL, but slightly lower visual acuity outcomes and a narrower range of defocus (from +1.00D to -2.00D) as compared to the previous prospective AN6V study. The DFT015 has demonstrated good results both when targeting for emmetropia and mini-monovision.[2,3,24-30] In our earlier case series we bilaterally implanted DFT015 IOLs targeted for mini-monovision and reported binocular UDVA of -0.07±0.10, UIVA of 0.04±0.09, and UNVA of 0.23±0.12 logMAR at three months.[3] These results were comparable to those reported in the literature, which indicate that DFT015 implantation for mini-monovision provides good UDVA and UIVA, as well as functional UNVA.[3,24,27-30] In

the present study, the Vivity-group had a higher mean age and postoperative residual astigmatism, which contributed to inferior uncorrected visual acuity outcomes compared to our previous case series. This difference may be attributed to variations in corneal rigidity, which typically increases with age.[31]

Both study IOLs induced minimal or only occasional optical disturbances. Previous results with the Lentis Comfort M15 IOL showed that 9.1% of the eyes experienced dysphotopsia at three months postoperatively.[21] In an AN6V cohort study, 15% of patients reported halos or starbursts, and 20% reported glare.[23] In our study, the incidence of dysphotopsia in the Vario-group was higher. However, it is important to note that the previous AN6V study used a different questionnaire to assess these disturbances. The results for the DFT015 in the literature were comparable with our findings, reporting an incidence of no halos, and no starbursts ranging from 53% to 94% and 78% to 100%, respectively. Only the incidence of glare in our Vivity-group was higher, with 13% of the patients reporting no glare, compared to 53% to 97% in the literature.[3,5,7,24-26,32-36]

While our study revealed a significantly greater range of defocus in the Vario-group, no difference in spectacle independence was observed between the groups. Both study-groups demonstrated similar results in terms of near spectacle independence. A prospective study involving bilateral AN6V implantation targeted for emmetropia reports that 85% of the patients use reading glasses occasionally or for prolonged reading.[23] After DFT015 implantation, near vision spectacle independence ranges from 33% to 87%.[3,25,26] Following DFT015 implantation targeted for mini-monovision, only 32% of patients report complete spectacle independence.[3] Our findings aligned with those from other EDOF studies, suggesting that while a mini-monovision approach can improve spectacle independence, it does not guarantee complete spectacle independence.[3,36,37] Therefore, patients should be carefully counseled with respect to expectations of achieving full spectacle independency when applying EDOF IOLs.

Despite randomization, the main limitation of this study was the baseline imbalances between the groups, emphasizing the need for age stratification. Moreover, striving for a lower postoperative residual astigmatism by taking into account the wide individual variability in SIA, is crucial to minimize refractive outliers as much as possible. In addition, patients were treated by multiple surgeons, which could have led to bias. Lastly, it is important to note the scarcity of cohorts focused on mini-monovision in the existing EDOF literature, which makes comparisons challenging.

In conclusion, the findings of this randomized controlled trial illustrate that bilateral Acunex Vario IOL (AN6V +1.5D addition) implantation offers non-inferior visual outcomes compared to bilateral AcrySof IQ Vivity IOL (DFT015) implantation, when targeted for mini-monovision. Furthermore, the study reveals comparable visual quality and high levels of patient satisfaction in both study groups.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

Joukje C. Wanten: Writing – review & editing, Writing – original draft, Visualization, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Noël J.C. Bauer:** Writing – review & editing, Supervision, Methodology, Investigation, Conceptualization. **Tos T.J.M. Berendschot:** Writing – review & editing, Supervision. **Frank J.H.M. van den Biggelaar:** Writing – review & editing, Funding acquisition, Conceptualization. **Rudy M.M.A. Nuijts:** Writing – review & editing, Supervision, Methodology, Investigation, Funding acquisition, Conceptualization.

Funding/Support: This investigator-initiated trial was funded by Teleon Surgical B.V. (Spankeren, The Netherlands).
Financial Disclosures: N.J.C.B is a consultant for Alcon; has received lecture fees from Teleon Surgical B.V.; and has received research support of Alcon, OPHTEC, and Chiesi. R.M.M.A.N. is a consultant for Alcon; has received lecture fees from Alcon and OPHTEC; and has received research support from Alcon, Carl-Zeiss Meditec, and Johnson & Johnson. All other authors have no financial disclosures. All authors attest that they meet the current ICMJE criteria for authorship.
Declaration of competing interest: The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

REFERENCES

1. Sudhir RR, Dey A, Bhattacharrya S, Bahulayan A. AcrySof IQ PanOptix Intraocular Lens Versus Extended Depth of Focus Intraocular Lens and Trifocal Intraocular Lens: A Clinical Overview. *Asia Pac J Ophthalmol (Phila)*. 2019;8(4):335–349 Jul-Aug. doi:10.1097/APO.0000000000000253.
2. Bala C, Poyales F, Guarro M, Mesa RR, Mearza A, Varma DK, Jasti S, Lemp-Hull J. Multicountry clinical outcomes of a new nondiffractive presbyopia-correcting IOL. *J Cataract Refr Surg*. 2022;48(2):136–143. doi:10.1097/j.jcrs.0000000000000712.
3. van Amelsfort T, Webers VSC, Bauer NJC, Clement LHH, van den Biggelaar F, Nuijts R. Visual outcomes of a new nondiffractive extended depth-of-focus intraocular lens targeted for minimonovision: 3-month results of a prospective cohort study. *J Cataract Refract Surg*. 2022;48(2):151–156 Feb 1. doi:10.1097/j.jcrs.0000000000000825.

4. Sandoval HP, Lane S, Slade S, Potvin R, Donnenfeld ED, Solomon KD. Extended depth-of-focus toric intraocular lens targeted for binocular emmetropia or slight myopia in the nondominant eye: Visual and refractive clinical outcomes. *J Cataract Refr Surg*. 2019;45(10):1398–1403. doi:10.1016/j.jcrs.2019.05.019.
5. Guarro M, Sararols L, Londono GJ, Goni I, Vazquez M, Ruiz S, Lopez S. Visual disturbances produced after the implantation of 3 EDOF intraocular lenses vs 1 monofocal intraocular lens. *J Cataract Refract Surg*. 2022;48(12):1354–1359 Dec 1. doi:10.1097/j.jcrs.0000000000000988.
6. Rampat R, Gatinel D. Multifocal and Extended Depth-of-Focus Intraocular Lenses in 2020. *Ophthalmology*. 2021;128(11):e164–e185 Nov. doi:10.1016/j.ophtha.2020.09.026.
7. Arrigo A, Gambaro G, Fasce F, Aragona E, Figini I, Bandello F. Extended depth-of-focus (EDOF) AcrySof® IQ Vivity® intraocular lens implant: a real-life experience. *Graefes Arch Clin Exp Ophthalmol*. 2021 May 29. doi:10.1007/s00417-021-05245-6.
8. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel group randomized trials. *BMC Med Res Methodol*. 2001;1:2. doi:10.1186/1471-2288-1-2.
9. Spekreijse L, Simons R, Winkens B, van den Biggelaar F, Dirksen C, Bartels M, de Crom R, Goslings O, Joosse M, Kasanardjo J, Lansink P, Ponsioen T, Reus N, Schouten J, Nuijts R. Safety, effectiveness, and cost-effectiveness of immediate versus delayed sequential bilateral cataract surgery in the Netherlands (BICAT-NL study): a multicentre, non-inferiority, randomised controlled trial. *Lancet*. 2023;401(10392):1951–1962 Jun 10. doi:10.1016/S0140-6736(23)00525-1.
10. Maaijwee K, Mulder P, Radner W, Van Meurs JC. Reliability testing of the Dutch version of the Radner Reading Charts. *Optom Vis Sci*. 2008;85(5):353–358 May. doi:10.1097/OPX.0b013e31816bf58b.
11. Visser MS, Dieleman M, Klijn S, Timman R, Lundstrom M, Busschbach JJ, Reus NJ. Validation, test-retest reliability and norm scores for the Dutch Catquest-9SF. *Acta Ophthalmol*. 2017;95(3):312–319 May. doi:10.1111/aos.13287.
12. Makhotkina NY, Nijkamp MD, Berendschot T, van den Borne B, Aelen-van Kruchten M, van Vught L, Beenakker JM, Krijgh E, Aslam T, Pesudovs K, Nuijts R. Measuring quality of vision including negative dysphotopsia. *Acta Ophthalmol*. 2023 Sep 12. doi:10.1111/aos.15762.
13. Wolffsohn JS, Bhogal G, Shah S. Effect of uncorrected astigmatism on vision. *J Cataract Refract Surg*. Mar 2011;37(3):454–460. doi:10.1016/j.jcrs.2010.09.022.
14. Langenbucher A, Szentmary N, Cayless A, Casaza M, Weisensee J, Hoffmann P, Wendelstein J. Surgically Induced Astigmatism after Cataract Surgery - A Vector Analysis. *Curr Eye Res*. Sep 2022;47(9):1279–1287. doi:10.1080/02713683.2022.2052108.
15. Berdahl JP, Hardten DR, Kramer BA, Potvin R. Effect of astigmatism on visual acuity after multifocal versus monofocal intraocular lens implantation. *J Cataract Refract Surg*. Oct 2018;44(10):1192–1197. doi:10.1016/j.jcrs.2018.06.048.
16. Hienert J, Ruiss M, Hirnschall N, Findl O. Assessing the astigmatism reducing effect of toric intraocular lenses in eyes with low astigmatism: a randomized masked bilateral comparison. *J Cataract Refract Surg*. 2023 May 3. doi:10.1097/j.jcrs.0000000000001211.
17. Hayashi K, Yoshida M, Igarashi C, Hirata A. Effect of Refractive Astigmatism on All-Distance Visual Acuity in Eyes With a Trifocal Intraocular Lens. *Am J Ophthalmol*. Jan 2021;221:279–286. doi:10.1016/j.ajo.2020.07.051.
18. Rementeria-Capelo LA, Contreras I, Moran A, Lorente-Hevia P, Marinas L, Ruiz-Alcocer J. Visual Performance of Eyes with Residual Refractive Errors after Implantation of an Extended Vision Intraocular Lens. *J Ophthalmol*. 2023;2023:7701390. doi:10.1155/2023/7701390.
19. Shetty N, Shetty R, Ranade R, Narasimhan R, Artal P, Nuijts R, Sinha Roy A. Using adaptive optics to optimize the spherical aberration of eyes implanted with EDOF and enhanced monofocal intraocular lenses. *J Cataract Refract Surg*. 2024;50(1):30–36 Jan 1. doi:10.1097/j.jcrs.0000000000001315.
20. Song X, Liu X, Wang W, Zhu Y, Qin Z, Lyu D, Shentu X, Xv W, Chen P, Ke Y. Visual outcome and optical quality after implantation of zonal refractive multifocal and extended-range-of-vision IOLs: a prospective comparison. *J Cataract Refract Surg*. 2020;46(4):540–548 Apr. doi:10.1097/j.jcrs.0000000000000088.
21. Vounotrypidis E, Diener R, Wertheimer C, Kreutzer T, Wolf A, Priglinger S, Mayer WJ. Bifocal nondiffractive intraocular lens for enhanced depth of focus in correcting presbyopia: Clinical evaluation. *J Cataract Refract Surg*. 2017;43(5):627–632 May. doi:10.1016/j.jcrs.2017.01.024.
22. Oshika T, Arai H, Inoue Y, Fujita Y. Five-Year Clinical Outcomes of Low-Add-Power Segmented Rotationally Asymmetrical Intraocular Lens. *Ophthalmol Ther*. 2023;12(3):1649–1656 Jun. doi:10.1007/s40123-023-00703-2.
23. Rua Amaro D, Bertelmann E, von Sonnleithner C. Clinical outcomes and optical performance of a new segmental refractive extended depth-of-focus intraocular lens. *BMC Ophthalmol*. 2024;24(1):320 Aug 1. doi:10.1186/s12886-024-03586-4.
24. Coassin M, Mori T, Di Zazzo A, Poddi M, Sgrulletta R, Napolitano P, Bonini S, Orfeo V, Kohnen T. Effect of minimonovision in bilateral implantation of a novel non-diffractive extended depth-of-focus intraocular lens: Defocus curves, visual outcomes, and quality of life. *Eur J Ophthalmol*. 2022;32(5):2942–2948 Sep. doi:10.1177/11206721211064018.
25. McCabe C, Berdahl J, Reiser H, Newsom TH, Cibik L, Koch D, Lemp-Hull J, Jasti S. Clinical outcomes in a U.S. registration study of a new EDOF intraocular lens with a non-diffractive design. *J Cataract Refract Surg*. 2022;48(11):1297–1304 Nov 1. doi:10.1097/j.jcrs.0000000000000978.
26. Shafer BM, McCabe C, Reiser H, Newsom TH, Berdahl J. The REVIVE Study: Long Term Outcomes of a Novel Non-Diffractive Extended Vision IOL versus Monofocal Control IOL. *Clin Ophthalmol*. 2022;16:3945–3950. doi:10.2147/OPTH.S390380.
27. Fernandes MC, Nunomura CY, Messias A. Visual performance and photic disturbances with diffractive and non-diffractive EDOF intraocular lenses using mini-monovision: randomized trial. *J Cataract Refract Surg*. 2024;50(2):153–159 Feb 1. doi:10.1097/j.jcrs.0000000000001330.

28. Newsom TH, Potvin R. Evaluation of Quality of Vision and Visual Outcomes with Bilateral Implantation of a Non-Diffractive Extended Vision Intraocular Lens with a Target of Slight Myopia in the Non-Dominant Eye. *Clin Ophthalmol*. 2022;16:183–190. doi:10.2147/OPTH.S350850.
29. Won YK, Choi SH, Chung TY, Lim DH. Clinical Outcomes after Bilateral Implantation of a Wavefront-Shaping Extended Depth of Focus (EDOF) IOL with Mini-Monovision. *J Clin Med*. 2024;13(11) May 30. doi:10.3390/jcm13113225.
30. Zeilinger J, Kronschlager M, Schlatter A, Georgiev S, Ruiss M, Pilwachs C, Findl O. Comparing an Advanced Monofocal With a Non-diffractive Extended Depth of Focus Intraocular Lens Using a Mini-Monovision Approach. *Am J Ophthalmol*. Mar 2025;271:86–95. doi:10.1016/j.ajo.2024.10.014.
31. Knox Cartwright NE, Tyrer JR, Marshall J. Age-related differences in the elasticity of the human cornea. *Invest Ophthalmol Vis Sci*. 2011;52(7):4324–4329 Jun 17. doi:10.1167/iovs.09-4798.
32. Hovanesian JA, Jones M, Allen Q. The Vivity Extended Range of Vision IOL vs the PanOptix Trifocal, ReStor 2.5 Active Focus and ReStor 3.0 Multifocal Lenses: A Comparison of Patient Satisfaction, Visual Disturbances, and Spectacle Independence. *Clin Ophthalmol*. 2022;16:145–152. doi:10.2147/OPTH.S347382.
33. Nowik KE, Ordon A, Pielak K, Izdebska J, Kamińska A, Szaflik J. Clinical and functional assessment of Acrysof Alcon Vivity extended depth of focus intraocular lenses. *Klinika Oczna /Acta Ophthalmologica Polonica*. 2024;126(1):23–26 2024. doi:10.5114/ko.2023.133447.
34. Sabur H, Unsal U. Visual outcomes of non-diffractive extended-depth-of-focus and enhanced monofocal intraocular lenses: A case-control study. *Eur J Ophthalmol*. Jan 2023;33(1):262–268. doi:10.1177/11206721221125004.
35. Howes F, Rementeria-Capelo LA, Poyales F, Borovik A, Khoramnia R, Perez-Vives C, Nuijts R. Visual Performance and Patient Satisfaction of Bilaterally Implanted Extended Depth of Focus Intraocular Lens: Outcomes of a Multicenter Registry. *J Refract Surg*. Feb 2025;41(2):e131–e143. doi:10.3928/1081597X-20241230-01.
36. Teus MA, Kohnen T, Ball J, Saelens IEY, Sutton G, Lawless M, Vives CP. Lapid-Gortzak R. Visual and subject-reported outcomes of a wavefront shaping extended depth of focus intraocular lens implanted bilaterally with monovision. *J Cataract Refract Surg*. 2025 Feb 18. doi:10.1097/j.jcrs.0000000000001636.
37. Vasavada V, Vasavada SA, Shastri L, Nath V, Vasavada AR, Srivastava S. Visual outcomes comparing emmetropia vs mini-monovision after bilateral implantation of a nondiffractive extended vision intraocular lens: randomized trial. *J Cataract Refract Surg*. 2024;50(8):799–804 Aug 1. doi:10.1097/j.jcrs.0000000000001458.