Comparison of Visual Acuity Outcomes of Enhanced Monofocal Versus Standard Monofocal Intraocular Lenses from a Randomized, Multicenter, Active-Controlled Trial

Robert Edward T. Ang, MD; Ramin Khoramnia, MD; Harvey S. Uy, MD; Peter Hoffmann, MD; Robert D. Anello, MA; Dominik Zalewski, MD; Kai Januschowski, MD; Pablo de Arriba Palomero, MD; Daniel Böhringer, MD; Marta Ibarz Barberá, MD; Eckart Bertelmann, MD; Slawomir Cisiecki, MD; H. Burkhard Dick, MD; Katrin Lorenz, MD; Gerd U. Auffarth, MD; Ramón Ruiz-Mesa, MD; Alvin S. Relucio, MD

ABSTRACT

PURPOSE: To compare visual performance of the Vivinex Impress enhanced monofocal intraocular lens (IOL) (HOYA Surgical Optics) with the Acrysof IQ monofocal IOL (Alcon Laboratories, Inc).

METHODS: In this multicenter, active-controlled trial, participants were randomized 2:1 to bilateral implantation with the enhanced monofocal (test) or standard monofocal (control) IOL and examined through 12 months postoperatively for visual acuities, refractive outcomes, defocus curves, and pupil diameters.

RESULTS: Ninety-eight test and 46 control participants completed testing for the first implanted eye. The test arm demonstrated a statistically significant benefit in monocular distance-corrected intermediate visual acuity (DCIVA) (photopic: 1.2 lines, $P < .001$; mesopic: 0.7 lines, $P = .01$) and uncorrected intermediate visual acuity (0.8 lines; $P < .001$) but no significant difference in monocular corrected distance visual acuity ($P = .07$). Using a stepwise regression analysis for DCIVA, the final model (adjusted R-square, 0.31) identified three significant predictor variables (age, pupil diameter, and treatment arm). Photopic defocus curves showed the test arm produced better monocular visual acuity from -1.00 through -2.50 D than the control arm. The intermediate vision benefit of the test IOL is independent of pupil size and axial length. Cumulative and persistent adverse events for the test IOL did not exceed the Safety and Performance Endpoint rates per International Organization for Standardization 11979-7.

CONCLUSIONS: Compared to a standard monofocal IOL, the Vivinex Impress enhanced monofocal IOL offers an extended range of vision, with significant improvements in intermediate vision and a DCIVA benefit unaffected by pupil size and axial length. This IOL is safe and effective for patients seeking improved intermediate vision following cataract surgery.

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From Asian Eye Institute Rockwell, Makati, The Philippines (RETA); Universitäts-Augenklinik Heidelberg, Heidelberg, Germany (RK); University of the Philippines, Manila, The Philippines, and Peregrine Eye and Laser Institute, Makati, The Philippines (HSU); Augen- und Laserklinik Castrop-Rauxel, Castrop-Rauxel, Germany (PH); HOYA Surgical Optics, Irvine, California (RDA, ASR); Centrum Diagnostyki I Mikrochirurgii Oka LENS, Olsztyn, Poland (DZ); MVZ Augenklinik Petrisberg, Trier, Germany (KJ); University Hospital Ramón y Cajal, Madrid, Spain (PAP); Universitätsklinikum Freiburg, Freiburg Im Breisgau, Germany (DB); Clínica Oftalvist Madrid, Madrid, Spain (MIB); Charité Berlin, Berlin, Germany (EB); Centrum Medyczne "JULIANOW" S.C., Łódz, Poland (SC); Universitätsklinikum Knappschaftskrankenhaus Bochum, Bochum, Germany (HBD); Universitätsmedizin Mainz, Mainz, Germany (KL); Universitäts-Augenklinik Heidelberg, Heidelberg, Germany (GUA); and Clínica Oftalvist Jerez, Jerez De La Frontera, Spain (RR-M).

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Address correspondence to Robert D. Anello, HOYA Surgical Optics, 110 Progress, Suite 175, Irvine, CA 92618; email: bob.anello@hoya.com.

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Using aspheric optics to enhance postoperative range of vision has emerged alongside modern trifocal and extended depth of focus intraocular lenses (IOLs). One approach to extending range of vision using refractive monofocal optics is to redirect a minimal amount of incoming light to enhance intermediate vision while maintaining international monofocal IOL standards for distance image quality. Current enhanced monofocal design approaches include the use of hybrid polynomial asphere (Vivinex Impress IOL; HOYA Surgical Optics), central steepening (Tecnis Eyhance IOL; Johnson & Johnson Vision), and positive spherical aberration (RayOne EMV IOL; Rayner).

Another strategy redistributes more incoming light away from distance image formation to further extend range of vision, sacrificing distance image quality, and therefore does not meet monofocal IOL standards but still meets American National Standards Institute standards for extended depth of focus IOLs.[1] This added range of vision comes at the expense of corrected distance visual acuity (CDVA) and contrast sensitivity and still does not provide a full range of vision as do trifocal IOLs.[2]

The current study examines a new enhanced monofocal IOL to add to the body of knowledge surrounding the performance of this lens class. This study compared the Vivinex Impress enhanced monofocal (test) IOL to a well-characterized monofocal (control) IOL (AcrySof IQ; Alcon Laboratories, Inc). The objectives of this post-market study were to compare the performance of the test lens to the International Organization for Standardization (ISO) Safety and Performance Endpoint rates and to compare monocular distance-corrected intermediate visual acuity (DCIVA) of test and control lenses.

PARTICIPANTS AND METHODS

Study Design

This was a randomized, multicenter, participant- and evaluator-masked, surgeon-unmasked, controlled trial, which compared bilateral implantation of enhanced monofocal (test) to standard monofocal (control) IOLs. Randomization was performed for treatment (2:1; test vs control IOL) and the first (study) eye (first vs second eye implanted). The study was conducted at 14 sites throughout Germany (n = 7), Spain (n = 3), Poland (n = 2), and the Philippines (n = 2). A full list of study investigators is provided in **Table A.** All participants were examined through 12 months postoperatively across 10 study visits. A study visit included preoperative examination of both eyes up to 90 days before first surgery; first-eye surgery within 90 days after the preoperative examination; postoperative examinations of the first eye at 1 day and 1 week postoperatively; second-eye surgery up to 30 days after the first-eye surgery; postoperative examinations of the second eye at 1 day and 1 week postoperatively; and postoperative examinations of both eyes at 1, 6, and 12 months after the second-eye surgery.

All participants provided written informed consent, and Independent Ethics Committee approval was obtained. The study was conducted in accordance with Good Clinical Practice, ISO 14155:2011, the tenets of the 1964 Declaration of Helsinki, and all other applicable laws and regulations of the countries in which the study was conducted. The study is registered at the World Health Organization International Clinical Trials Registry Platform (ID: DRKS00026617).

Eligibility Criteria

Participants were included in the study if they were age 22 years or older, scheduled for bilateral cataract extraction and implantation of the test or control IOLs, and had the following baseline characteristics: minimal (less than 1.00 diopter [D] postoperative) and regular corneal astigmatism; clear intraocular media; expected postoperative binocular CDVA of 0.2 logarithm of the minimum angle of resolution (logMAR) or better; and eligibility for a spherical equivalent lens power from +6.00 to +30.00 D.

Key exclusion criteria (for each eye) included intraocular inflammation or recurrent ocular inflammatory condition and previous intraocular or corneal surgery. **Table B** lists full inclusion and exclusion criteria.

IOL Descriptions

The test lens was the Vivinex Impress IOL (model XY1-EM; Hoya Medical Singapore Pte. Ltd.), a modified version of the Vivinex IOL designed to provide comparable far vision and better intermediate vision compared to standard monofocal IOLs. XY1-EM, delivered via the multiSert preloaded injector system, is a foldable, single-piece, hydrophobic acrylic, blue light–filtering, monofocal IOL with a 13-mm overall length and 6-mm optic diameter with a full 6-mm effective optical zone.

The control lens was the AcrySof IQ IOL (model SN60WF [AU00T0]; Alcon Laboratories, Inc), a foldable, single-piece, hydrophobic acrylic, monofocal IOL with a 13-mm overall length and 6-mm optic diameter.

Preoperative Assessments

Preoperative assessments included corneal topography, pachymetry, biometry, keratometry, subjective refraction and visual acuity, pupil diameter, and in-

traocular pressure. Lens spherical power calculation was determined by the investigator's personalized A-constant using their formula of choice. Emmetropia (±0.30 D) was targeted for all eyes.

Surgical Technique

Investigators used their own standard, small-incision, phacoemulsification, cataract extraction surgical techniques. Self-sealing incisions were preferred. IOL placement entirely in the bag was mandatory.

Endpoints and Postoperative Assessments

The primary performance endpoint was comparison of Safety and Performance Endpoint rates associated with the test IOL with those outlined in ISO 11979-7:2018. The secondary performance endpoint was postoperative mean monocular DCIVA for first eyes implanted.

Visual acuity measurements were performed using the M&S Clinical Trial Suite (M&S Technologies), a computer-based testing system using self-illuminated Early Treatment Diabetic Retinopathy Study (ETDRS) charts at 4 m (far) and 66 cm (intermediate) with chart luminance of 85 cd/m^2 for photopic testing or 3 cd/m^2 for mesopic testing. Room illumination is 50 lux or less under photopic conditions and as close to 0 lux as possible under mesopic conditions.

Photopic monocular defocus testing was performed at 4 m using the M&S Clinical Trial Suite. Defocus testing ranged from +1.00 to -2.50 D in 0.50-D increments, and visual acuity measurement was obtained at each defocus increment (dVA).

Pupil diameter of the first eye was measured using the NeurOptics infrared pupillometer (model VIP-300; NeurOptics), under photopic and mesopic conditions at 4 m (far) and 66 cm (intermediate) with the non-occluded fellow eye fixated on the ETDRS visual acuity chart. Contrast sensitivity and patient-reported outcome questionnaires were also administered and will be reported separately.

Sample Size

The primary Safety and Performance Endpoint required a sample size of 100 participants as per ISO 22979; therefore, 125 test participants were targeted assuming 20% attrition.

The secondary performance endpoint was based on the hypothesis of superior mean monocular DCIVA with the test lens over the control lens. Prior results suggested a mean DCIVA of 0.230 logMAR for the test lens and 0.327 logMAR for the control lens (ie, approximately 0.1 logMAR difference) and a standard deviation (SD) of 0.10 for each lens. Choosing an alpha error of 0.05 and a power of 90%, a sample size of 46 participants/arm was necessary to prove the hypothesis with a two-sided *t*-test; therefore, 58 participants were targeted for enrollment to account for 20% attrition.

Statistical Analysis

Descriptive statistics including number, mean ± SD, and range were used for continuous variables. For categorical data, frequency and proportion were computed. A two-sample *t*-test with equal or unequal variances of first-eye visual acuities, cylinder, spherical equivalent, and pupil diameter results was used to compare arms, depending on results of the F-test of treatment arm variances. Fisher's exact test was used to test differences in categorical data between treatment arms—namely, the percentage of cases with spherical equivalent within 0.50 D of emmetropia and posterior capsule status. For all statistical analyses, a *P* value less than .05 was considered significant. No statistics were used to compare defocus curves of the two arms because defocus testing was not a study endpoint.

To identify study variables predictive of DCIVA (covariates), multiple linear regression analysis was conducted using the Data Analysis ToolPak of Microsoft Excel for Microsoft 365 (MSO Version 2406 Build 16.0.17726.20078 64-bit). Monocular DCIVA in the first eye was the dependent variable and sex, age, photopic pupil size, axial length, and treatment arm were explored as independent variables. Stepwise regression was performed where non-significant covariates ($P > .05$) were sequentially removed to arrive at the final set of significant predictor variables of DCIVA or final regression model. The adjusted R-square was monitored after each iteration to ensure that predictability of the final model was not affected by removal of non-significant covariates. R-square is indicative of the percent of overall variation accounted for by the model, whereas the adjusted R-square further considers the number of variables to prevent using a large number of variables to "over-fit" the model.

RESULTS

Participant Disposition

A total of 172 participants were enrolled and implanted bilaterally with the test (n = 118) or control (n = 54) IOL. Eight participants (n = 4, per arm) were lost to follow-up, leaving 114 test and 50 control participants examined at 12 months postoperatively or later, for a 95.3% (164/172) accountability rate. Five test arm participants with concomitant ocular pathologies and 6 participants (test, n = 4; control, n = 2) not completing all required visual acuity, defocus, and pupil diameter testing were excluded from analysis. Nine participants

TABLE 1

Demographics and Baseline Characteristics by Treatment Arm

Characteristic	Test IOL (n = 98)	Control IOL (n = 46)
Age, years		
Mean ± SD	68.8 ± 7.0	69.0 ± 5.9
Range	43.2 to 83.2	53.1 to 81.8
Sex, %		
Female	61.2	69.6
Male	38.8	30.4
Axial length of first eyes, mm		
Mean ± SD	23.4 ± 0.9	23.5 ± 0.9
Range	21.6 to 25.9	21.7 to 26.1

IOL = intraocular lens; SD = standard deviation

(test, n=7; control, n = 2) were excluded from analysis due to uncertain reliability of baseline refractions (ie, dVA at ±0.50 D defocus was > 0.5-line better than at 0.00 D).

Thus, 98 test and 46 control best case participants completing all first-eye visual acuity, defocus, and pupil diameter testing at the 12-month postoperative or later visit are included in this analysis. One participant in each arm was not implanted as randomized (received IOL from the other arm in error); these 2 participants were included for analysis in the arm of actual, not intended, implantation.

Demographics and Baseline Characteristics

In the test arm, mean ± SD participant age was 68.8 ± 7.0 years with 61% being women. In the control arm, mean ± SD age was 69.0 ± 5.9 years with 70% being women (**Table 1**). Mean ± SD first-eye axial length (AL) was 23.4 ± 0.9 mm in the test arm and 23.5 ± 0.9 mm in the control arm.

Refractive Outcomes

Mean ± SD follow-up time from first-eye surgery was 429.8 ± 55.6 days in the test arm and 437.1 ± 52.8 days in the control arm. First-eye refractive outcomes at 12 months postoperatively or later were similar between arms (cylinder, $P = .65$; spherical equivalent, $P = .24$; eyes within 0.50 D emmetropia, $P = .61$; **Table 2**).

Visual Acuity

All participants in both treatment arms (100%) had monocular first-eye CDVA of 0.3 logMAR or better compared with the ISO Safety and Performance Endpoint rate of 92.5%.

TABLE 2

Refractive Outcomes of First Eyes by Treatment Arm

Refractive Outcome	Test IOL (n = 98)	Control IOL (n = 46)
Follow-up from first-eye surgery, days		
Mean ± SD	429.8 ± 55.6	437.1 ± 52.8
Range	333.0 to 621.0	351.0 to 606.0
Sphere, D		
Mean ± SD	0.12 ± 0.36	0.18 ± 0.41
Range	-0.75 to 1.25	-0.75 to 1.00
Cylinder, D		
Mean ± SD	-0.55 ± 0.41	-0.52 ± 0.37
Range	-1.75 to 0.00	-1.50 to 0.00
P	.65	
Spherical equivalent, D		
Mean ± SD	-0.15 ± 0.34	-0.08 ± 0.36
Range	-0.88 to 1.13	-0.88 to 0.75
P	.24	
Eyes within 0.25 D emmetropia, %	62.2	69.6
Eyes within 0.50 D emmetropia, %	84.7	89.1
P	.61	

D = diopters; IOL = intraocular lens; SD = standard deviation

Mean monocular DCIVA demonstrated a significant 1.2-line benefit for the test arm under photopic conditions ($P < .001$) and a significant 0.7-line benefit for the test arm under mesopic conditions ($P = .01$; **Figure 1**). Mean monocular uncorrected intermediate visual acuity also demonstrated a significant benefit for the test arm (0.8 lines; $P < .001$). Mean monocular CDVA was not significantly different between arms (test, -0.01 logMAR; control, -0.04 logMAR; $P = .07$).

To identify variables that may affect intermediate vision, monocular DCIVA was investigated using a stepwise multiple linear regression analysis. The model summary (**Table 3**) demonstrates the stepwise approach progressing from left to right, with the sequential removal of non-significant variables (sex and AL). Using final significant coefficients ($P < .05$), model-estimated monocular DCIVA (first eye) is = -0.228 + 0.003*Age + 0.065*Pupil size + -0.122*Treatment arm. Age and pupil size coefficients are positive, indicating that younger participants and smaller pupils are more likely to have better DCIVA (smaller logMAR value) irrespective of treatment arm. The treatment arm coefficient is negative, demonstrating better

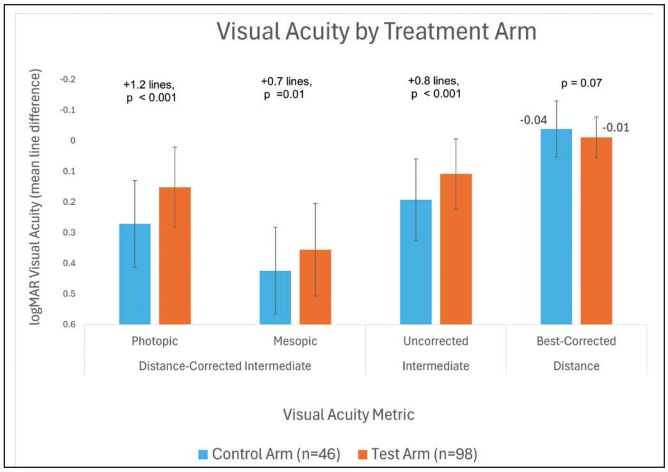


Figure 1. Mean ± standard deviation (SD) monocular visual acuities in the first eye by treatment arm.

DCIVA in the test arm. The coefficients translate to a 0.30-line DCIVA change per decade of age, a 0.65-line DCIVA change per millimeter of pupil size, and a 1.2-line DCIVA benefit of test arm over control arm.

R-square indicates the final three-variable model accounts for 32% of DCIVA variability, comparing favorably with other similar IOL regression models (17%).[3] Adjusted R-square shows little change across stepwise iterations; that is, the three-variable model captures approximately 31% of DCIVA variation, nearly identical to the 32% with the five-variable model, confirming the validity of removing non-significant sex and AL.

Site effects on DCIVA were explored by adding SITE and SITE × ARM to the model. One site demonstrated a half-line better DCIVA for all participants, whereas another site showed a significant interaction with study ARM; the 3 control participants enrolled at the latter site showed one line of reduced DCIVA. Model results (significant predictor variables and corresponding coefficients) were unchanged when controlling for site effects, meaning that the magnitude of the DCIVA benefit of the test lens (ARM), pupil effect, and age effect were unaffected by SITE. The multiple correlation coefficient improved slightly to 0.61, whereas the adjusted R-square improved to 0.35.

Defocus Curves

Photopic distance-corrected defocus curves show the test IOL had better monocular dVA from -1.00 through -2.50 D compared with the control IOL (**Figure 2**).

Pupil Size and Axial Length

Photopic mean ± SD distance-fixed pupil size was 4.00 ± 0.83 mm in the test arm and 3.96 ± 0.91 mm in the control arm (P = .77); mean ± SD intermediate-fixed pupil sizes were smaller in both arms (test, 3.38 ± 0.69 mm; control, 3.36 ± 0.74 mm; P = .92; **Table 4**).

Mesopic mean ± SD distance-fixed pupil size was 4.95 ± 0.93 mm in the test arm and 4.79 ± 0.91 mm in the control arm (P = .33); again, mean ± SD intermediate-fixed pupil sizes were smaller in both arms (test, 4.34 ± 0.92 mm; control, 4.23 ± 0.93 mm; P = .48).

First eyes were divided into three photopic distance-fixed pupil size subgroups (small, < 3.5 mm; medium, 3.5 to < 4.5 mm; large, ≥ 4.5 mm) and mean DCIVA was presented by arm for each subgroup (**Figure 3A**). Mean DCIVA benefit favoring the test arm was +1.1, +0.9, and +1.4 lines in the small, medium, and large pupil subgroups, respectively. To control the impact of significant predictor variables on DCIVA, subgroups were then examined using regression model–adjusted mean DCIVA. Results demonstrated a consistent DCIVA benefit favoring the test arm of +1.2, +1.2, and +1.4 lines in the small, medium, and large subgroups, respectively (**Figure 3B**).

First eyes were also divided into three AL subgroups (short: ≤ 23 mm; medium: > 23 to < 24 mm; long: ≥ 24 mm) and mean DCIVA was presented by arm for each subgroup (**Figure 4A**). Mean DCIVA benefit favoring the test arm was +0.9, +1.1, and +1.6 lines in the short, medium, and long subgroups, respectively. To control the impact of significant predictor variables on DCIVA, subgroups were then examined using regression model–adjusted mean DCIVA. Results demonstrated a consistent DCIVA benefit favoring the test arm of +1.1, +1.2, and +1.6 lines in the short, medium, and long subgroups, respectively (**Figure 4B**).

Posterior Capsule Status

There was no statistically significant difference in posterior capsule status between treatment arms (P = .43); 91.7% of control eyes and 84.7% of test eyes had no or trace posterior capsule opacification reported, whereas 8.7% of control eyes and 15.3% of test eyes had an yttrium aluminum garnet (YAG) capsulotomy performed during the study.

Safety

No cumulative or persistent adverse events for the test IOL exceeded the corresponding Safety and Performance Endpoint rate.

Six participants experienced 7 ocular adverse events categorized as serious, including 4 first-eye serious adverse events (test: n = 1 serious adverse event; control: n = 3 serious adverse events). The test-arm serious adverse event, choroidal neovascularization, was ongoing at study completion. The control-arm serious adverse events were retinal detachment, sud-

TABLE 3

Distance-Corrected Intermediate Visual Acuity Stepwise Multiple Linear Regression Model Results[a]

Parameter	DCIVA Five-Variable Model		DCIVA Four-Variable Model		DCIVA Three-Variable Model	
Multiple R	0.588		0.574		0.566	
R-square	0.346		0.329		0.321	
Adjusted R-square	0.322		0.310		0.306	
Standard error	0.119		0.120		0.121	
Observations	144		144		144	
ANOVA	**Degrees of Freedom**	**Significance F**	**Degrees of Freedom**	**Significance F**	**Degrees of Freedom**	**Significance F**
Regression	5	< .0001	4	< .0001	3	< .0001
Residual	138		139		140	
Total	143		143		143	
Predictor Variable	**Coefficient**	***P***	**Coefficient**	***P***	**Coefficient**	***P***
Intercept	-0.794	.0137	-0.607	.0482	-0.228	.0515
Sex	0.041	.0637		NS		NS
Age	0.004	.0094	0.004	.0148	0.003	.0224
Photopic pupil size	0.055	< .0001	0.060	< .0001	0.065	< .0001
Axial length	0.023	.0661	0.016	.1809		NS
Treatment arm	-0.117	< .0001	-0.121	< .0001	-0.122	< .0001

ANOVA = analysis of variance; DCIVA = distance-corrected intermediate visual acuity; NS = not significant; R = correlation coefficient; VA = visual acuity
[a]Treatment arm reference category = control arm.

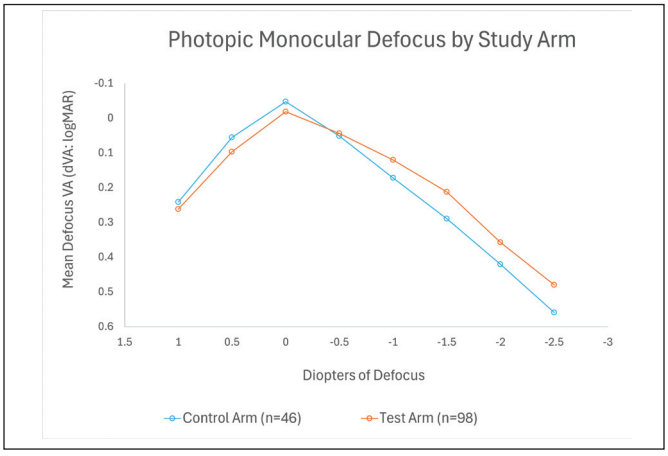


Figure 2. Photopic mean monocular defocus curve in the first eye by treatment arm.

TABLE 4

Pupil Diameter in the First Eye by Lighting, Fixation, and Treatment Arm

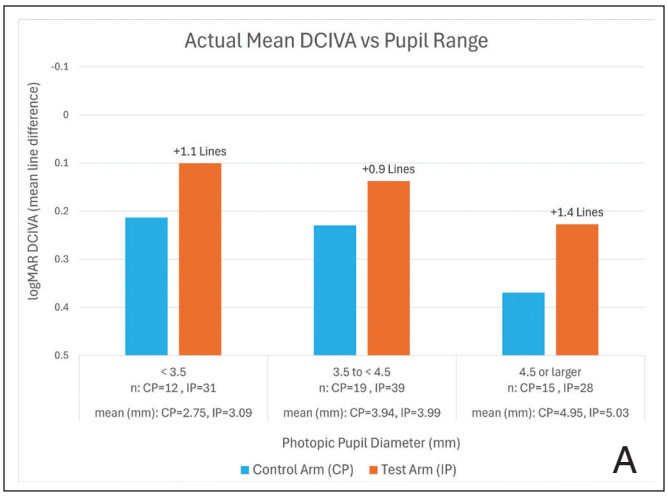
Pupil Diameter, mm	Test IOL (n = 98)	Control IOL (n = 46)
Photopic, distance fixation		
Mean ± SD	4.00 ± 0.83	3.96 ± 0.91
Range	2.50 to 6.51	1.97 to 5.55
P	.77	
Photopic, intermediate fixation		
Mean ± SD	3.38 ± 0.69	3.36 ± 0.74
Range	1.95 to 5.70	1.97 to 4.89
P	.92	
Mesopic, distance fixation		
Mean ± SD	4.95 ± 0.93	4.79 ± 0.91
Range	2.53 to 6.95	2.70 to 6.15
P	.33	
Mesopic, intermediate fixation		
Mean ± SD	4.34 ± 0.92	4.23 ± 0.93
Range	2.18 to 6.47	2.37 to 5.98
P	.48	

IOL = intraocular lens; SD = standard deviation

den loosening of capsular tension ring, and elevated intraocular pressure. None of the 4 first-eye serious adverse events were judged as related to either study lens.

DISCUSSION

This randomized controlled study met both its primary endpoint, demonstrating that all test participants achieved CDVA of 0.3 logMAR or better, and its secondary endpoint, demonstrating a statistically



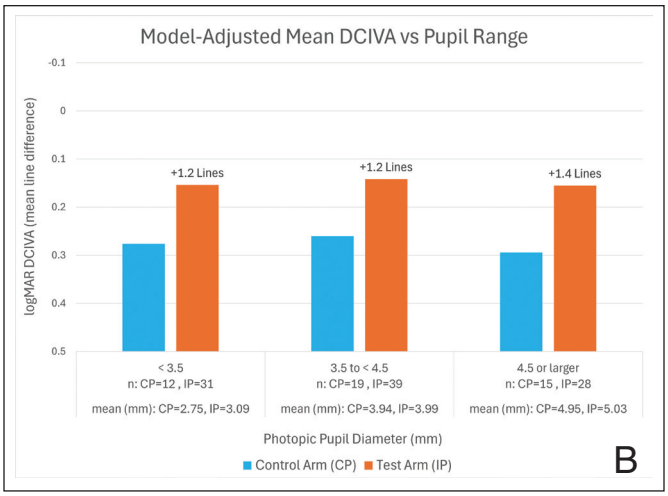
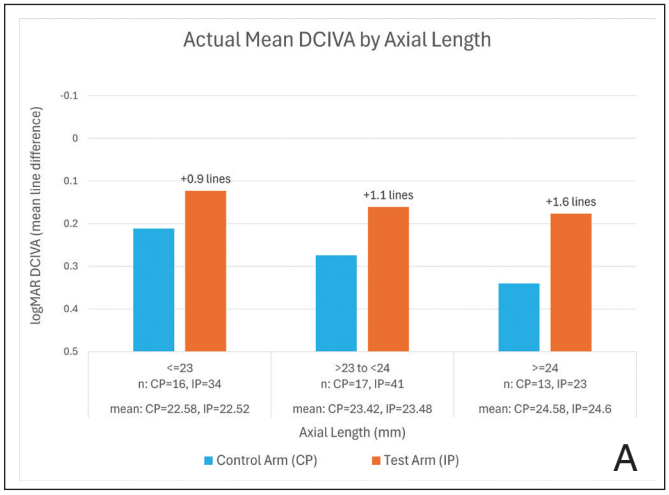


Figure 3. Mean monocular photopic distance-corrected intermediate visual acuity (DCIVA) in the first eye by treatment arm across a range of photopic distance-corrected pupil sizes. (A) Mean of the measured (actual) DCIVA by treatment arm and pupil subgroup. (B) Mean of the multiple regression model–adjusted DCIVA by treatment arm and pupil subgroup.



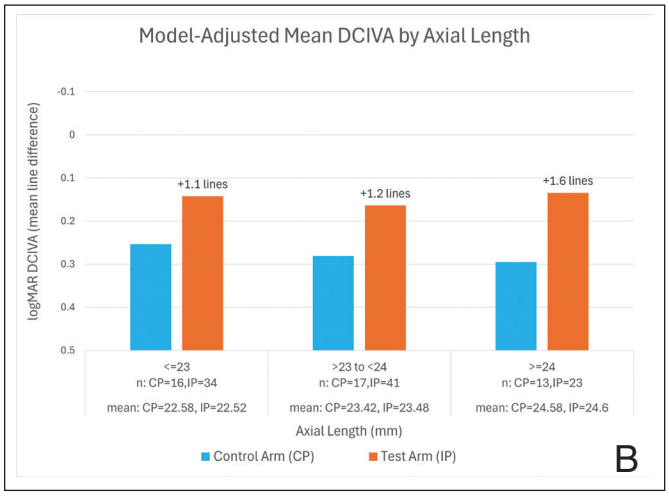


Figure 4. Mean monocular photopic distance-corrected intermediate visual acuity (DCIVA) in the first eye by treatment arm across a range of axial lengths. (A) Mean of the measured (actual) DCIVA by treatment arm and axial length subgroup. (B) Mean of the multiple regression model–adjusted DCIVA by treatment arm and axial length subgroup.

significant 1.2-line improvement in DCIVA of the test IOL compared with the control IOL. No cumulative or persistent adverse events for the test IOL exceeded the corresponding Safety and Performance Endpoint rate nor were any ocular serious adverse events considered related to either study IOL. Thus, this study confirms the safety and effectiveness of the test IOL.

There was no statistically significant difference in CDVA between the test and control IOLs (-0.01 vs -0.04 logMAR, respectively; $P = .07$). Regression analysis of DCIVA identified age, pupil size, and treatment arm as significant DCIVA predictors. In this study, younger participants, smaller pupil sizes, and test IOL implantation were all associated with better DCIVA outcomes. Younger age has been determined to be an independent predictor of improved visual outcomes after cataract surgery.[4-6] It is well established that small pupil sizes are associated with better uncorrected visual acuity by mitigating the effect of residual refractive error. However, pupillary effects on corrected visual acuity must arise from mitigation of higher order aberrations by a smaller aperture. It is important to note that the intermediate vision benefit of the test IOL over the control IOL is not dependent upon pupil size, with **Figure 3** clearly showing that DCIVA benefit (using actual or model-adjusted DCIVA values) is maintained across pupil size subgroups. Furthermore, separate regression modeling applied to the test and control arms confirmed nearly identical pupil diameter coefficients (0.59 vs 0.62 lines/mm, respectively).

TABLE 5

Intermediate Visual Acuity From Randomized Controlled Trials Comparing an Enhanced Monofocal IOL to a Monofocal IOL

Author, Year	Enhanced Monofocal IOL	Monofocal IOL	Mean IVA, logMAR	*P*
Micheletti et al, 2023[3]	TECNIS Eyhance ICB00	Clareon CCA0T0/CNA0T0 monofocal	Binocular DCIVA: 0.19 vs 0.24	< .0001
Auffarth et al, 2021[7]	TECNIS Eyhance ICB00	TECNIS monofocal ZCB00	Monocular UIVA: 0.16 vs 0.27 Monocular DCIVA: 0.19 vs 0.31	< .0001 < .0001
Choi et al, 2023[8]	TECNIS Eyhance ICB00	TECNIS monofocal ZCB00	Monocular UIVA: 0.05 vs 0.12 Binocular UIVA: 0.04 vs 0.10	.001 .026
Nanavaty et al, 2022[9]	TECNIS Eyhance	RayOne monofocal	Monocular UIVA: 0.29 vs 0.38 Binocular UIVA: 0.13 vs 0.26 Monocular DCIVA: 0.27 vs 0.37 Binocular DCIVA: 0.14 vs 0.29	.02 < .01 .01 < .01
Donoso et al, 2023[10]	TECNIS Eyhance ICB00	TECNIS monofocal ZCB00	Binocular UIVA: 0.37 vs 0.45	< .01
Goslings et al, 2023[11]	TECNIS Eyhance ICB00	Vivinex iSert monofocal	Monocular UIVA: 0.24 vs 0.32 Binocular UIVA: 0.12 vs 0.22 Monocular DCIVA: 0.23 vs 0.33 Binocular DCIVA: 0.12 vs 0.24	.001 < .001 .002 < .001
Giglio et al, 2024[12]	TECNIS Eyhance ICB00	TECNIS monofocal PCB00	Monocular UIVA: 0.20 vs 0.32 Monocular DCIVA: 0.17 vs 0.29 Binocular UIVA: 0.17 vs 0.32 Binocular DCIVA: 0.13 vs 0.29	< .001 < .001 < .001 < .001
	TECNIS Eyhance ICB00	Clareon monofocal CNA0T0	Monocular UIVA: 0.20 vs 0.34 Monocular DCIVA: 0.17 vs 0.31 Binocular UIVA: 0.17 vs 0.31 Binocular DCIVA: 0.13 vs 0.29	< .001 < .001 < .001 < .001
Pérez-Sanz et al, 2024[13]	ISOPure enhanced	MicroPure monofocal	Monocular UIVA: 0.19 vs 0.29 Monocular DCIVA: 0.22 vs 0.30	.03 .04

DCIVA = distance-corrected intermediate visual acuity; IOL = intraocular lens; IVA = intermediate visual acuity; logMAR = logarithm of the minimum angle of resolution; UIVA = uncorrected intermediate visual acuity

The outcomes of the current study are consistent with previous randomized studies of enhanced monofocal IOLs, in which intermediate vision is improved compared to conventional monofocal IOLs.[7-13] In a study presenting results of multiple regression modeling for Eyhance, Micheletti et al[3] reported that both pupil diameter and AL were predictive of monocular DCIVA with Eyhance. This contrasts with results of the current study, in which AL was not a significant predictor of DCIVA, illustrating the Vivinex Impress intermediate vision benefit is independent of AL. The apparent 1.6-line benefit achieved in the current study in test arm eyes with ALs 24 mm or longer, although interesting, did not reach the level of statistical significance using regression modeling, possibly due to the small number (test: n = 23; control: n = 13) in this subgroup. Further investigation would be useful to confirm this finding.

In the same Eyhance study, the authors segmented results of 110 bilaterally implanted participants into an enhanced (61 patients achieving binocular DCIVA of 0.2 logMAR or better) versus a non-enhanced group (41 patients having binocular DCIVA worse than 0.2 logMAR).[3] These data show a potentially strong gender effect, with 60.7% of male enhanced patients versus only 30.6% of male non-enhanced patients (ie, males appear to be associated with better DCIVA) (**Table 1**).[3] These potential gender and AL effects with Eyhance merit further scientific investigation.

The choice of control IOL in the current study is a potential weakness, due to differences in material and overall IOL design that may differentially impact posterior capsule opacification and glistenings. Two randomized, contralateral comparisons demonstrated that the Vivinex XY1 monofocal IOL has lower rates of YAG capsulotomy, posterior capsule opacification, and glistenings than the Acrysof IQ IOL at 3 years postoperatively, and such differences could bias the observed intermediate visual acuity benefit.[14,15] In the current study, there was no statistically significant difference in posterior capsule status at the 1-year examination, making the likelihood of such bias small, and glistenings are generally not associated with significant impact on visual acuity, particularly within 1 year after implantation.

The Vivinex XY1 monofocal IOL also has a unique aspheric optic that mitigates the induction of higher order aberrations in the presence of decentration or non-zero angle alpha. Because the effect of this optic on depth of focus had not been demonstrated clinically at the time the current study was designed, the Acrysof IQ was selected as a more suitable choice of the control lens, due to the extensive history of published results.

In the current study, the Vivinex Impress IOL demonstrated a monocular dVA of 0.21 logMAR at -1.50 D versus 0.30 logMAR with the AcrySof IQ control IOL. The Clareon IOL (also from Alcon Laboratories, Inc) was not readily available at study initiation and thus was not a suitable monofocal control. Recently reported binocular defocus results for Clareon demonstrate mean dVAs of approximately 0.35 and 0.30 logMAR at -1.50 D for Clareon models CNA0T0 and CCA0T0/CNA0T0, respectively.[16,17] Therefore, the optical performance of Clareon and AcrySof IQ appear to be similar, as illustrated by the nearly identical modulation transfer functions published for AcrySof IQ monofocal and Clareon monofocal IOLs.[18]

In addition to the publication of this current study's results, 9 clinical trials have now been published comparing intermediate vision in participants bilaterally implanted with enhanced monofocal IOLs to those with standard monofocal IOLs. Eight of these studies are randomized controlled trials, and each one confirms a significant intermediate vision benefit with the enhanced monofocal lens (**Table 5**);[3,7-13] a ninth trial was not randomized and demonstrated a 0.5-line intermediate vision benefit with the Eyhance over the Clareon, although no difference in dVAs was observed.[18]

Multiple regression modeling by the current authors and by Micheletti et al[3] demonstrates that DCIVA may be affected by demographic and biometric variables, thereby underscoring the importance of randomization to the scientific value of comparative trials. Furthermore, defocus testing may not be the most appropriate endpoint, given that resulting dVA can be influenced by image minification of minus defocus trial lenses, and the technique avoids physiological pupil size elicited by the near reflex. Therefore, distance-corrected visual acuity measured at a fixed distance with a calibrated chart may be a more relevant endpoint.

CONCLUSION

This randomized, multicenter, active-controlled trial demonstrated that the Vivinex Impress enhanced monofocal IOL offers significant improvements in intermediate vision compared to a standard aspheric monofocal IOL, for both photopic and mesopic conditions and with extended range of vision demonstrated on defocus testing from -1.00 to -2.50 D. The intermediate vision benefit afforded by the Vivinex Impress IOL is independent of pupil diameter and axial length, and thus offers a robust option for patients desiring extended range of vision. Altogether, these results confirm that this enhanced monofocal IOL is safe and effective for a wide range of patients seeking improved intermediate vision following cataract surgery.

AUTHOR CONTRIBUTIONS

Study concept and design (RK, HSU, RDA, KJ, GUA); data collection (RETA, RK, HSU, PH, RDA, DZ, KJ, PAP, DB, MIB, EB, SC, KL, GUA, RR-M); analysis and interpretation of data (RETA, RK, HSU, PH, RDA, KJ, HBD, KL, ASR, RR-M); writing the manuscript (RETA, HSU, RDA, KJ, ASR); critical revision of the manuscript (RETA, RK, HSU, PH, RDA, DZ, KJ, PAP, DB, MIB, EB, SC, HBD, KL, GUA, ASR, RR-M); statistical expertise (RK, RDA); administrative, technical, or material support (RK); supervision (RK, HSU, CS, HBD)

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Table A
Principal Investigator List, COMP Study

Investigator	Country	City	Site Name	Responsible Ethics Committee	EC Process/ Application Number
Prof. Dr. Med. Gerd U. Auffarth	Germany	Heidelberg	Universitäts-Augenklinik Heidelberg	Ethikkommission der Medizinische Fakultät Heidelberg	S-869/2021
Prof. Dr. Dr. Katrin Lorenz	Germany	Mainz	Universitätsmedizin Mainz	Ethikkommission der Landesärztekammer Rheinland-Pfalz	2021-16230
Prof. Dr. Med. Burkhard Dick	Germany	Bochum	Universitätsklinikum Knappschaftskrankenhaus Bochum	Ethik-Kommission der Medizinischen Fakultät der Ruhr-Universität Bochum	22-7487-BR
Univ.-Prof. Dr. Med. Eckart Bertelmann	Germany	Berlin	Charité Berlin	Ethikkommission der Charité - Universitätsmedizin Berlin	NA
Dr. Med. Peter Hoffmann	Germany	Castrop-Rauxel	Augen- Und Laserklinik Castrop-Rauxel	Ethik-Kommission der Ärztekammer Westfalen-Lippe und der Westfälischen Wilhelms-Universität Münster	2021-720-f-s
Prof. Dr. Med. Daniel Böhringer	Germany	Freiburg Im Breisgau	Universitätsklinikum Freiburg	Ethikkommission der Albert-Ludwigs-Universität Freiburg	21-1702
Dra. Marta Ibarz Barberá	Spain	Madrid	Clínica Oftalvist Madrid	CEIm H Puerta de Hierro Majadahonda, Madrid	NA
Dr. Ramón Ruiz Mesa	Spain	Jerez De La Frontera	Clínica Oftalvist Jerez	CEIm H Puerta de Hierro Majadahonda, Madrid	NA
Dr. Francisco J. Muñoz Negrete	Spain	Madrid	University Hospital Ramon Y Cajal	CEIm H Puerta de Hierro Majadahonda, Madrid	NA
Dr N. Med. Slawomir Cisiecki	Poland	Łódź	Centrum Medyczne "JULIANOW" S.C.	Bioethics Committee at OIL in Łodz	2/2022
Dr N. Med. Dominik Zalewski	Poland	Olsztyn	Centrum Diagnostyki I Mikrochirurgii Oka LENS	Bioethics Committee at OIL in Łodz	2/2022
Dr. Harvey S. Uy	Philippines	Makati	Peregrine Eye and Laser Institute	Peregrine Eye and Laser Institute - Institutional Review Board	2022-03
Dr. Robert Ang	Philippines	Makati	Asian Eye Institute Rockwell	SCMC - AEI Ethics Review Committee	2022-012
Prof. Dr. Kai Januschowski	Germany	Trier	MVZ Augenklinik Petrisberg	Ethikkommission der Landesärztekammer Rheinland-Pfalz	2021-16230

Table B
Full Inclusion and Exclusion Criteria

Inclusion criteria

All patients of this clinical investigation shall be/have:

1. Adult patients with a minimum age of 22 years
2. Planned for bilateral lens extraction (cataract) and implantation of the investigational IOLs
3. Minimal (<1.0 D postop, see No. 6) and regular corneal astigmatism to be treated with the non-toric HOYA Vivinex™ Impress Monofocal Preloaded IOL (model XY1-EM) or non-toric Alcon AcrySof® IQ IOL (model SN60WF [AU00T0])
4. Clear intraocular media other than cataract
5. Expected postoperative binocular corrected distance visual acuity of 0.2 logMAR (0.67 decimal) or better as estimated by surgeon
6. Less than 1.0 D of expected postoperative corneal astigmatism
7. Eligible to receive a spherical equivalent lens power from +6.00 D to +30.00 D
8. Availability, willingness, ability and sufficient cognitive awareness to comply with examination procedures and clinical investigation visits
9. Ability to consent to the participation in clinical investigation
10. Signed informed consent

Exclusion criteria

All patients enrolled in this clinical investigation shall not be/ not have:

1. A legal representative or cannot read or understand the ICF
2. Surgery planned for one eye only
3. Intraocular inflammation or recurrent ocular inflammatory condition
4. Previous intraocular or corneal surgery (eg, LASIK, LASEK, RK, PRK, etc.) including corneal refractive surgery or retinal (laser) surgery, excluding laser treatment of peripheral retinal regions not affecting vision in the opinion of the investigator
5. Lentodonesis or other capsular bag pathologies (eg, after traumatic cataract)
6. Instability of keratometry or biometry measurements
7. Strabismus, amblyopia (defined as minimum CDVA of 0.63 decimal or 0.2 logMAR in one eye) or single eye status
8. Pupil abnormalities (eg, non-reactive, fixed pupils, or abnormally shaped pupils)
9. More than 1.0 D of expected postoperative corneal astigmatism
10. Irregular corneal astigmatism as estimated by surgeon (eg, angle steep/flat ≠ 90° in 3 mm zone; asymmetric power distribution)
11. Requiring an intraocular lens power outside the available range of +6.00 D to +30.00 D
12. Continuous contact lens wearing within 6 months of the preoperative, examination for PMMA contact lenses, within 1 month of the preoperative examination for gas permeable-wear and daily-wear soft contact lenses

13. Presence of corneal pathology affecting topography and vision (eg, stromal, epithelial or endothelial dystrophy)
14. Acute, chronic, or uncontrolled systemic or ocular disease or illness that in the opinion of the investigator would increase the operative risk or confound the outcome of the clinical investigation (eg, poorly controlled diabetes, immuno-compromised, connective tissue disease, uncontrolled ocular hypertension, glaucomatous changes in the retina, chronic iritis/uveitis, retinal vessel disease, etc.) or where healing process is compromised
15. Diagnosed degenerative visual disorders (eg, macular degeneration or other retinal disorders) that are predicted to cause visual acuity losses to a level of 0.2 logMAR or worse during the clinical investigation or known ocular disease or pathology that may affect visual acuity or that may be expected to require retinal laser treatment or other surgical intervention during the clinical investigation (macular degeneration, cystoid macular edema, diabetic retinopathy, etc.)
16. Systemic disease that could increase the operative risk or confound the outcome
17. Conditions associated with increased risk of zonular rupture, including capsular or zonular abnormalities that may lead to IOL decentration, including pseudoexfoliation, trauma, or posterior capsule defects
18. Use of systemic or ocular medications that may affect vision
19. Serious dry eye symptoms that could lead to refractive changes/ fluctuations and to significant patients' complaints
20. Prior or current use of tamsulosin or silodosin (eg, Flomax®, Flomaxtra®, Rapaflo®) likely, in the opinion of the investigator, to cause poor dilation or lack of adequate iris structure or floppy iris syndrome to perform standard cataract surgery in the opinion of the investigator
21. Inability to focus, fixate or do vision tests for prolonged periods of time (eg, due to strabismus, nystagmus, Parkinson disease
22. Pregnant, plan to become pregnant, lactating or have another condition associated with the fluctuation of hormones that could lead to significant refractive changes
23. Concurrently participating in any other clinical trial or if they have participated in any other clinical trial during the last 30 days

Patients should be discontinued if following conditions are present at the time of surgery:

24. Zonular instability
25. Need for iris manipulation
26. Capsular fibrosis or other opacities which might influence the optical performance of the IOL
27. Inability to fixate the entire IOL in the capsular bag and ensure its stability