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Higher-order aberrations and visual outcomes of a new refractive extended depth-of-focus intraocular lens with a target of slight myopia

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In this single-center retrospective study, we compared visual performance and optical quality between a new refractive extended depth-of-focus intraocular lens (EDoF IOL, Model ZEN00V, n = 44), with a slightly myopic target, and an enhanced monofocal IOL (Model ICB00, n = 44), with the target refraction closest to emmetropia on the myopic side. The IOL power for the EDoF IOL was selected to achieve postoperative refraction of -0.50 to -1.00 D. Monocular distance visual acuity (VA) and iTrace aberrometry were assessed. Bilateral cases were analyzed to evaluate intermediate and near VA, and photic phenomena. Preoperative target diopter and postoperative spherical equivalent were more myopic in the EDoF IOL group than in the monofocal IOL group (all $p < 0.001$). Uncorrected and corrected distance VA were comparable between the two groups (all $p > 0.05$). Higher order aberrations were comparable between the two groups (all $p > 0.05$) except for spherical aberrations, which were lower in the monofocal group ($p = 0.002$). Subgroup analysis revealed superior near VA ($p = 0.02$) and an extended range of defocus in the EDoF IOL group with comparable photic phenomena. Implantation of the new refractive EDoF IOL, the TECNIS PureSee™, with myopic target diopter may be a viable option for improving intermediate and near visual performance while preserving distance vision and visual quality.

Abbreviations

ACD	Anterior chamber depth
AL	Axial length
CCT	Central corneal thickness
CDVA	Corrected distance visual acuity
D	Diopter
ETDRS	Early treatment diabetic retinopathy study
EDoF IOL	Extended depth-of-focus intraocular lens
HOA	High-order aberration
IOL	Intraocular lens
logMAR	Logarithm of the minimum angle of resolution
RMS	Root mean square

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UDVA	Uncorrected distance
VA	Visual acuity
WTW	White-to-white
SE	Spherical equivalent

Cataracts are among the leading causes of vision loss worldwide[1,2]. Advances in cataract surgery, ocular biometry, and intraocular lens (IOL) power calculations have shifted the focus of surgeons from merely restoring clarity to optimizing refractive and functional visual outcomes[3–6]. While monofocal IOLs provide excellent distance vision with minimal visual disturbances, increasing patient demand for spectacle independence at intermediate and near distances has driven the development of presbyopia-correcting IOLs[7–11].

Multifocal IOLs (MFIOLs), based on the principle of simultaneous vision, were introduced to address presbyopia by providing multiple focal points through distinct optical zones[8–11]. Due to intrinsic characteristics of their optical design, MFIOLs are frequently associated with drawbacks related to the superimposition of retinal images and light dispersion, leading to reduced contrast sensitivity and a higher incidence of photic phenomena such as glare, halos, and starbursts; however, the frequency and severity of these symptoms vary considerably across published series[8,10–13]. A proportion of incident light is inevitably defocused and projected as a blurred image, even when the MFIOL is correctly centered and positioned[14]. In such context, the influence of chord μ magnitude—particularly when exceeding certain thresholds—and its relationship to the alignment between the IOL optical center and the visual axis remain subjects of ongoing debate[15,16]. Additionally, patients implanted with MFIOLs may exhibit reduced tolerance to postoperative residual refractive error, particularly residual astigmatism[12].

Extended Depth-of-Focus (EDoF) IOLs were introduced to address the limitations of traditional MFIOLs. EDoF lenses are designed to enhance the depth-of-focus by elongating a single focal zone[14,17]. Previous studies have demonstrated that EDoF provides distance vision comparable to a standard monofocal IOL, with enhanced intermediate and near vision[6,7,18]. Moreover, EDoF IOLs are associated with fewer visual disturbances and optical aberrations, making them practical options for presbyopia correction[19–21]. Nevertheless, current evidence from systematic reviews and comparative studies consistently indicates that EDoF IOLs do not achieve the near visual acuity obtained with trifocal IOLs. Trifocal IOLs demonstrate a significant advantage in uncorrected and corrected near visual acuity, as well as in spectacle independence for near tasks, when compared with EDoF IOLs[22].

TECNIS PureSee™ (ZEN00V, Johnson & Johnson Surgical Vision, Irvine, CA, USA) is a fully refractive EDoF IOL using a continuous power gradient on the posterior surface to elongate the focal zone; the TECNIS Eyhance™ (ICB00/DIB00, Johnson & Johnson Surgical Vision, Irvine, CA, USA) is an enhanced monofocal using subtle power modulation for improved intermediate vision while maintaining monofocal characteristics[23]. The PureSee™ IOL has been reported to provide comparable distance visual acuity and superior intermediate visual acuity compared with the enhanced monofocal IOL. Defocus curves and subjective questionnaires showed improved tolerance to refractive errors and a low incidence of photic phenomena[23–25]. In contrast to these subjective evaluations, the objective quantitation of optical quality remains limited. Given that high-order aberrations (HOAs) can significantly affect postoperative visual quality and patient satisfaction, research on HOA in EDoF lenses may provide valuable insights into surgical outcomes.

We also hypothesized that the new refractive EDoF IOL, the TECNIS PureSee™, would demonstrate robust performance under low uncorrected refractive error, extending the range of vision when implanted with a slightly myopic target. Therefore, the current study aimed to retrospectively investigate the optical quality and visual performance of TECNIS PureSee™ implanted with a low myopic target, compared with an enhanced monofocal IOL with an emmetropic target.

Materials and methods

Study design and ethics approval

This retrospective case–control study was performed at Severance Eye Hospital, Yonsei University College of Medicine (Institutional Review Board approval no. 4-2025-1135). The requirement for written informed consent was waived because of the retrospective nature of the analysis of anonymized data. This study adhered to the tenets of the Declaration of Helsinki.

Study population

Medical records of patients who underwent cataract surgery between September 2023 and July 2024 were retrospectively reviewed to collect relevant clinical data.

The inclusion criteria were as follows: (1) diagnosis of senile cataract, (2) preoperative astigmatism less than 1.0 diopter (D), and (3) age ranging from 50 to 80 years. The exclusion criteria were as follows: (1) a history of ocular surgery, trauma, ocular abnormalities, or any disease other than cataracts that would affect postoperative VA, (2) any intraoperative or postoperative complications, and (3) an axial length (AL) of less than 22.5 mm or greater than 26.0 mm. Patients with an AL greater than 26.0 mm were excluded based on previous studies that reported a relationship between elongated AL and increased prediction error[26,27]. When both eyes met the inclusion criteria, one eye was randomly selected, and were included for the subgroup analyses. Propensity score matching (age and sex) was performed to adjust for potential selection bias.

Surgical technique

All surgeries were performed by a single surgeon (T-I Kim) under topical anesthesia using 0.5% proparacaine hydrochloride. A main incision was made along the steepest corneal meridian, followed by a 20-G paracentesis. Using the Centurion Vision System (Alcon Laboratories, Inc.), phacoemulsification was performed using the

following standard steps: lens fragmentation, irrigation and aspiration of the cortical material, and polishing of the posterior capsule. Subsequently, an IOL was implanted into the capsular bag, and stromal hydration was used to secure all incisions.

IOLs and refractive targeting

The current study compared the TECNIS PureSee™ EDoF IOL (Model ZEN00V) with the TECNIS Eyhance™ Enhanced Monofocal IOL (Models ICB00/DIB00), both manufactured by Johnson & Johnson Vision, USA. Both IOLs are single-piece, aspheric, foldable posterior chamber lenses with 6.0 mm optics and a 13.0 mm overall length, with an A-constant of 119.3 (based on the SRK/T formula). They are available in D ranges from + 5.0 D to + 34.0 D in 0.5 D increments.

The ZEN00V was made of SENSAR UV2 (OptiBlue) (Abbe 55, n = 1.47). The lens features an aspheric anterior surface design to compensate for the mean corneal spherical aberration, whereas the posterior refractive surface gradually varies in power, thereby providing an extended depth of focus.

Preoperative and postoperative evaluation

All participants underwent a detailed chart review and comprehensive ophthalmological evaluation before surgery. Baseline ophthalmic evaluations included VA assessment, manifest refraction, intraocular pressure measurement, slit-lamp biomicroscopy, optical biometry, specular microscopy, and dilated fundus examination.

Uncorrected distance VA (UDVA at 4 m) and corrected distance VA (CDVA) were measured using an early treatment diabetic retinopathy study (ETDRS) chart (Precision Vision, Woodstock, IL, USA) and were converted to the logarithm of the minimum angle of resolution (logMAR) for statistical analysis. VA was assessed under photopic conditions (85 candelas/square meter) with 100% contrast. Keratometry was performed using a Topcon KR 8800 auto-kerato-refractometer (Topcon Corporation, Tokyo, Japan), and the refractive status was evaluated through manifest refraction. Spherical equivalent (SE) and defocus equivalent, defined as the absolute value of the SE plus the absolute value of half of the cylinder, was calculated from the refractive components[28]. Optical biometry was performed using an IOL Master 700 (Carl Zeiss Meditec AG, Jena, Germany) to measure the AL, anterior chamber depth (ACD), central corneal thickness (CCT), and white-to-white (WTW) distance. Specular microscopy was performed using the EM-4000 microscope (Tomey GmbH, Nuremberg, Germany). The IOL power was calculated using the Barrett Universal II; A-constants were used as per the manufacturer's recommendations without individualized lens constant optimization. The IOL power was selected to achieve the lowest myopic refraction closest to emmetropia in eyes implanted with the TECNIS Eyhance™ Enhanced Monofocal IOL, whereas a target refraction between − 0.50 D and − 1.00 D was used for the TECNIS PureSee™ EDoF IOL.

Postoperative outcome measures

Clinical data were obtained 3 months after cataract surgery. Monocular CDVA and UDVA were assessed using the same methods used for preoperative evaluation. HOAs were quantified using the iTrace aberrometer (Tracey Technologies, Houston, TX, USA). Total and internal ocular aberrations, encompassing the root mean square (RMS, μm) of total HOA, trefoil, coma, tetrafoil, and spherical aberration, were assessed at a 3 mm pupil diameter.

Patients who underwent bilateral cataract surgery, either simultaneously or within a 1-week interval, according to patient preference, were enrolled and those whose eyes both met the inclusion criteria were included in the subgroup analysis. Monocular uncorrected intermediate VA (UIVA) and uncorrected near VA (UNVA) were measured in both eyes by using handheld ETDRS vision cards (Precision Vision).

Binocular defocus curves and patient-reported outcomes were obtained for each group. For binocular defocus curves, the same trial frame used for CDVA assessment was used to minimize the influence of vertex distance. Negative spherical trial lenses were sequentially added in 0.5 D steps from + 1.50 D to − 4.00 D, and binocular VA was measured at each step using an ETDRS chart at 4 m.

The postoperative patient-reported outcomes were evaluated using a questionnaire addressing photic phenomena (halo, glare, and starburst), spectacle independence in daily activities (distance, intermediate, and near vision), and overall patient satisfaction. Questionnaire responses were recorded as binary outcomes. A detailed version of the questionnaire is provided in the Supplementary information (Table S1).

Statistical analysis

For monocular UDVA, a sample size of 50 participants was required to achieve 95% power with one-sided alpha of 0.05 and a non-inferiority margin of 0.10 logMAR, assuming a standard deviation of 0.12 logMAR.

Baseline characteristics are presented as mean ± standard deviation for continuous variables and numbers with percentages for categorical variables. Differences between measurement indicators were analyzed using Student's independent t-test for continuous variables and Pearson's chi-square test for categorical variables. In the subgroup analysis, a generalized estimating equation with an exchangeable correlation structure was used to compare monocular measurements to adjust for inter-eye correlation. Fisher's exact test was applied instead when the expected frequency in any cell was less than 5 in the analysis of the subjective questionnaire. All tests were two-tailed, and a p-value < 0.05 was considered statistically significant. Statistical analyses were performed using R version 4.3.3 (R Foundation for Statistical Computing, Vienna, Austria) and Statistical Package for the Social Sciences software (version 26.0; IBM Corp., Armonk, NY, USA).

Results

Baseline demographics and ocular biometry results are shown in Table 1. In total, 53 patients in the ICB00 group and 56 patients in the ZEN00V group who underwent HOA evaluations at 3-months postoperatively, who had no perioperative complications, and were not lost to follow-up were evaluated. Five patients from the ICB00

Variable	Eyhance (n = 44)	Puresee (n = 44)	p-value
Age (years)	69.41 ± 7.21	67.20 ± 3.97	0.08[a]
Sex (Female, %)	33 (75.0%)	34 (77.3%)	> 0.99 [b]
Axial length (mm)	23.63 ± 1.04	23.82 ± 1.11	0.41[a]
ACD (mm)	3.12 ± 0.37	3.18 ± 0.45	0.50[a]
CCT (μm)	534.36 ± 30.66	542.14 ± 29.12	0.23[a]
LT (mm)	4.52 ± 0.35	4.49 ± 0.36	0.69[a]
WTW (mm)	11.69 ± 0.37	11.83 ± 0.44	0.11[a]
Preop UDVA (logMAR)	0.61 ± 0.45	0.48 ± 0.35	0.13[a]
Preop CDVA (logMAR)	0.33 ± 0.29	0.29 ± 0.33	0.59[a]
Preop SE (D)	− 0.47 ± 4.34	− 0.29 ± 4.35	0.85[a]
Preop DE (D)	3.51 ± 3.17	2.67 ± 1.62	0.13[a]
K1 (D)	44.09 ± 1.56	43.95 ± 1.27	0.65[a]
K2 (D)	44.82 ± 1.59	44.52 ± 1.31	0.33[a]
Target diopter	**− 0.33 ± 0.21**	**− 0.64 ± 0.31**	**< 0.001**[a]***

Table 1. Baseline demographics and ocular biometry according to intraocular lens (IOL) groups. Values are presented as mean ± standard deviation. ACD, Anterior Chamber Depth; CCT, Central Corneal Thickness; LT, Lens Thickness; WTW, White-to-White distance; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; SE, spherical equivalent; DE, defocus equivalent, D, diopters; logMAR, logarithm of the minimal angle of resolution. [a] Independent t-test; [b] Pearson Chi-squared test. *p < 0.05, ***P < 0.001, Significant values are indicated in bold font.

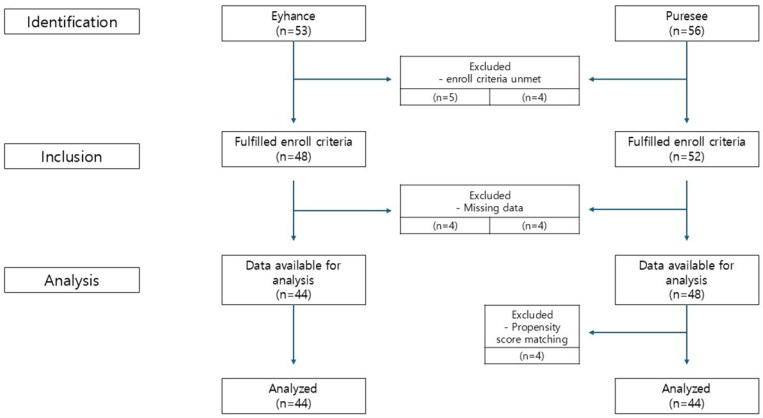

Fig. 1. Flow chart for population selection.

group and four patients from the ZEN00V group who did not meet the inclusion criteria were excluded from the analysis. Four patients from the ICB00 and four patients from the ZEN00V group were excluded due to missing data. If both eyes met the inclusion criteria, one eye was randomly selected for the primary analysis. After propensity score matching, 88 eyes from 44 patients in each of the ICB00 and ZEN00V group were included in this study (Fig. 1).

Patient demographics were comparable between the two groups. The mean (± SD) age was 68.3 (± 8.8) years in the ICB00 group and 66.1 (± 5.2) years in the ZEN00V, with no statistically significant difference (p = 0.08). Both groups included a higher proportion of female patients (ICB00, 34/44 [77.3%] vs. ZEN00V, 33/44 [75.0%]; p > 0.99). Ocular biometry, including ACD, CCT, lens thickness, and WTW, was comparable between the two groups (all p > 0.05). Preoperative UDVA and CDVA were comparable between the two groups (all p > 0.05). Notably, the mean target refraction was set more myopic in the ZEN00V group than that of the ICB00 group (-0.33 ± 0.21 D vs. -0.64 ± 0.31 D, p < 0.001).

Refractive and visual outcomes

The refractive and visual outcomes at 3 months after cataract surgery are shown in Table 2. The postoperative SE was − 0.50 (± 0.49) in the ICB00 group and − 1.30 (± 0.68) in the ZEN00V group (p < 0.001). Both groups achieved favorable postoperative UDVA and CDVA without significant differences (all p > 0.05). Moreover, the lower bound of the two-sided 90% confidence interval for the mean difference in postoperative UDVA between ZEN00V and ICB00 was − 0.08 logMAR, which was above the non-inferiority margin of − 0.1 logMAR. The ZEN00V group also showed outcomes in clinical settings comparable to those of the ICB00 group. The

Variable	Eyhance (n = 44)	Puresee (n = 44)	p-value
Postop UDVA (logMAR)	0.16 ± 0.22	0.16 ± 0.23	0.97
Postop CDVA (logMAR)	0.06 ± 0.21	0.11 ± 0.26	0.37
Postop SE (D)	**-0.50 ± 0.49**	**-1.30 ± 0.68**	**< 0.001*****
Postop DE (D)	**0.90 ± 0.49**	**1.61 ± 0.74**	**< 0.001*****

Table 2. Postoperative visual acuity and refractive index. Values are presented as mean ± standard deviation. UDVA, Uncorrected distance visual acuity; CDVA, corrected distance visual acuity; SE, spherical equivalent; DE, defocus equivalent; D, diopters; ***P < 0.001, Significant values are indicated in bold font.

Variable	Eyhance (n = 44)	Puresee (n = 44)	p-value
Total RMS (μm)	0.45 ± 0.57	0.47 ± 0.36	0.85
Higher Order Aberration RMS (μm)	0.34 ± 0.49	0.33 ± 0.25	0.89
Third Order RMS (μm)	0.20 ± 0.32	0.22 ± 0.17	0.72
Fourth Order RMS (μm)	0.16 ± 0.25	0.20 ± 0.14	0.45
Primary Coma ($Z^{\pm 1}_{3}$) RMS	0.13 ± 0.20	0.14 ± 0.10	0.74
Trefoil ($Z^{\pm 3}_{3}$) RMS	0.15 ± 0.25	0.15 ± 0.17	0.94
Tetrafoil ($Z^{\pm 4}_{4}$) RMS	0.11 ± 0.21	0.10 ± 0.14	0.91
Primary Spherical RMS (Z^{0}_{4})	**0.08 ± 0.07**	**0.13 ± 0.08**	**0.002****

Table 3. Ocular higher-order aberration at 3 months postoperatively. Values are presented as mean ± standard deviation. RMS = root mean square or square root of the mean of the squared coefficients; HOA = higher-order aberration. *p < 0.05, **P < 0.01, Significant values are indicated in bold font.

Variable	Eyhance (n = 12)	Puresee (n = 14)	p-value
Age (years)	71 ± 7.09	66.2 ± 6.39	0.09
Sex (Female, %)	9 (75%)	10 (66.7%)	0.92
Variable	Eyhance (n = 24)	Puresee (n = 28)	p-value
Axial length (mm)	23.20 ± 0.64	23.59 ± 0.97	0.2
Preop UDVA (logMAR)	**0.31 ± 0.18**	**0.48 ± 0.33**	**0.04***
Preop CDVA (logMAR)	0.13 ± 0.18	0.18 ± 0.18	0.33
Preop SE (D)	0.51 ± 1.11	− 0.43 ± 2.14	0.12
Preop DE (D)	1.49 ± 0.77	1.85 ± 1.46	
K1 (D)	44.55 ± 1.77	44.31 ± 1.12	0.54
K2 (D)	45.23 ± 1.83	45.05 ± 1.10	0.66
Goal diopter	**− 0.33 ± 0.12**	**− 0.75 ± 0.28**	**< 0.001*****

Table 4. Baseline characteristics for subgroup analysis. Values are presented as mean ± standard deviation. LogMAR, logarithm of the minimal angle of resolution; UDVA, Uncorrected distance visual acuity; CDVA, corrected distance visual acuity; SE, spherical equivalent; DE, defocus equivalent; D, diopters. *p < 0.05, ***P < 0.001, Significant values are indicated in bold font.

proportion of participants who achieved monocular UDVA better than 0.20 logMAR was 70.5% (31/44) in the ZEN00V group and 72.7% (32/44) in the ICB00 group.

HOAs

The analysis of internal ocular HOA is presented in Table 3. Total HOA RMS, third-order RMS, fourth-order RMS, coma, trefoil, and tetrafoil did not differ between the groups (all p > 0.05). Primary spherical aberration (Z4, 0) was significantly greater in the ZEN00V group (0.13 ± 0.08 μm) than in the ICB00 group (0.08 ± 0.07 μm, p = 0.002).

Subgroup analysis

Baseline demographics of the subgroup analyses are presented in Table 4. In total, 28 eyes from 14 patients in the ZEN00V group and 24 eyes from 12 patients in the ICB00 group were included in the subgroup analysis. Participants with missing data were excluded. The subgroup analysis included participants whose eyes met the inclusion criteria for the entire dataset before matching. Age and sex distributions were comparable between groups. Preoperative ocular biometry results showed no statistically significant differences (p > 0.05).

Variable	Eyhance (n = 24)	Puresee (n = 28)	p-value
UDVA (logMAR)	0.10 ± 0.11	0.10 ± 0.10	0.91
CDVA (logMAR)	0.02 ± 0.05	0.01 ± 0.06	0.64
UIVA (logMAR)	0.14 ± 0.11	0.10 ± 0.09	0.25
UNVA (logMAR)	**0.27 ± 0.11**	**0.13 ± 0.12**	**< 0.001*****
Postop SE (D)	**-0.35 ± 0.49**	**-0.96 ± 0.67**	**< 0.001*****
Postop DE (D)	**0.66 ± 0.59**	**1.29 ± 0.83**	**0.002****

Table 5. Postoperative visual acuity and refractive index for subgroup analysis at 3 months. Values are presented as mean ± standard deviation. LogMAR, logarithm of the minimal angle of resolution; D diopters; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity; SE = spherical equivalent; DE, defocus equivalent; D = diopters. **P < 0.01, ***P < 0.001, Significant values are indicated in bold font.

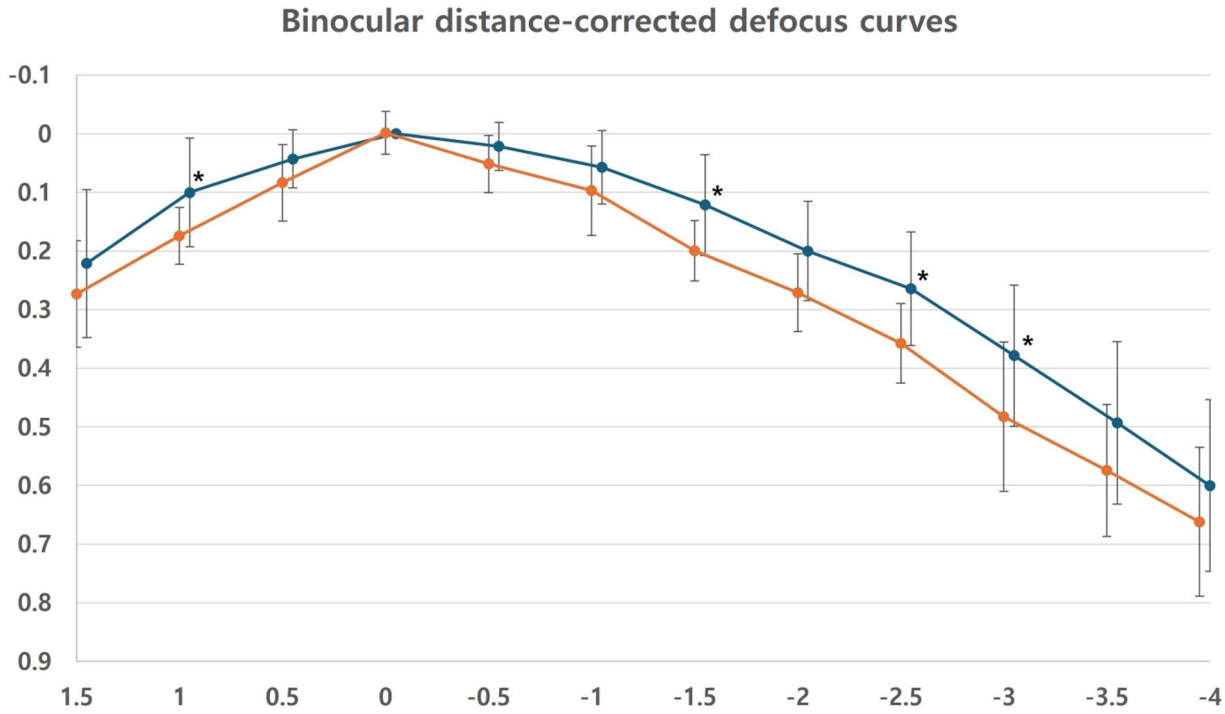

Fig. 2. Mean binocular, distance corrected defocus curves obtained at 3 months for the Puresee (ZEN00V) and Eyhance (ICB00) groups, ranging from + 1.5D to − 4.0 D. Vertical bars denote standard deviation. For visual clarity, the defocus curves were slightly offset by ± 0.05 D to reduce overlap of the standard deviation bars. D, diopters; LogMAR, logarithm of the minimal angle of resolution. *p < 0.05

Preoperative UDVA was better in the ICB00 group than in the ZEN00V group (0.31 ± 0.18 logMAR vs. 0.48 ± 0.33 logMAR, p = 0.04); however, preoperative CDVA was comparable between the two groups (0.13 ± 0.18 logMAR vs. 0.18 ± 0.18 logMAR, p = 0.33). The target diopter was more myopic in the ZEN00V group than that in the ICB00 group (-0.33 ± 0.12 vs. -0.75 ± 0.28, p < 0.001).

Postoperative 3-month visual outcomes are shown in Table 5. Monocular UDVA (0.10 ± 0.11 vs. 0.10 ± 0.10, p = 0.91) and CDVA (0.02 ± 0.05 vs. 0.01 ± 0.06, p = 0.64) were comparable between groups. The mean monocular photopic UIVA at 66 cm was 0.10 (± 0.09) logMAR in the ZEN00V group and 0.14 (± 0.11) in the ICB00 group, without a significant difference (p = 0.25). On the other hand, the mean monocular UNVA at 40 cm was 0.17 (± 0.11) in the ZEN00V group and 0.26 (± 0.11) in the ICB00 group, demonstrating a statistically significant improvement (p < 0.001).

Binocular defocus curves (Fig. 2) showed that ZEN00V maintained VA ≤ 0.2 logMAR from roughly + 1.0 D to − 2.0 D, while ICB00 maintained this level from approximately + 0.5 D to − 1.5 D.

The outcomes of the patient-reported subjective questionnaire at 3 months postoperatively are summarized in Table 6. The incidence of halo (2/12 [17%] vs. 3/14 [21%], p = 0.71), glare (0/12 [0%] vs. 1/14 [7%], p = 0.42), and starburst (1/12 [8%] vs. 2/14 [14%], p = 0.32) was comparable between the two groups. Spectacle dependence for distance (1/12 [8%] vs. 2/14 [14%], p = 0.62) and intermediate vision (1/12 [8%] vs. 0/14 [0%], p = 0.31)

	Eyhance (n = 24)	Puresee (n = 28)	p-value
Photic phenomena			
Halo	2 (17%)	3 (21%)	0.71
Glare	0 (0%)	1 (7%)	0.42
Starburst	1 (8%)	2 (14%)	0.32
Spectacle dependence			
Distance	1 (8%)	2 (14%)	0.62
Intermediate	1 (8%)	0 (0%)	0.31
Near	**6 (50%)**	**1 (7%)**	**0.02***
Overall satisfaction	11 (92%)	13 (93%)	1.00
Recommendation	11 (92%)	13 (93%)	1.00

Table 6. Results for the patient questionnaire regarding photic phenomena, spectacle dependence, overall satisfaction, and recommendations for each IOL. Values are presented as frequency (percentage). *$p < 0.05$, Significant values are indicated in bold font.

was low in both groups, without significant differences. Regarding near vision, the ICB00 group reported significantly higher spectacle dependence than the ZEN00V group (6/12 [50%] vs. 1/14 [7%]; $p < 0.001$). The overall satisfaction and proportion of patients willing to recommend the procedure were comparable, with 93% (11/12) in the ICB00 group and 93% (13/14) in the ZEN00V group.

Discussion

This study compared the visual performance and HOAs of a new refractive EDoF IOL implanted with a slightly myopic target to those of an enhanced monofocal IOL from the same manufacturer. The postoperative target diopter and postoperative SE were more myopic in the new refractive IOL, ZEN00V, than in the enhanced monofocal IOL, ICB00. Distance VA and HOAs except for spherical aberrations were comparable between the two groups. In subgroup analysis of bilateral cases, near VA and extended range of defocus was better in the ZEN00V than in the ICB00 group, and photic phenomenon was comparable between the two groups.

The target myopic range of − 0.50 to − 1.00 was determined based on the tolerance for refractive error reported in previous studies[23–25,29,30]. Previous clinical and optical bench trials have demonstrated that the new refractive EDoF IOL was well tolerated to low uncorrected refractive error and showed robust performance under natural HOA levels[23,24]. A previous prospective multicenter randomized trial and our previous retrospective study showed comparable UDVA and CDVA between the two groups, while intermediate and near VA were superior to the new refractive EDoF IOL compared to those of the enhanced monofocal IOL[24,25]. An optical bench study using a model eye with the new refractive EDoF IOL demonstrated a binocular negative defocus range, where VA of 0.20 logMAR or better was achieved, extending to − 2.2 D[23]. In another study, which simulated VA for the new refractive IOL, showed simulated VA better than 0.1 logMAR until a defocus of − 2.25 D, and better than 0.2 logMAR even until defocus of − 2.75 D[29]. The defocus curve range or intermediate VA at 66 cm obtained from the actual clinical data was less pronounced compared to aforementioned simulated outcomes. The prospective randomized trial showed that the monocular negative defocus range was − 1.6 D for the new refractive EDoF IOL compared to − 1.3 D for the enhanced monofocal IOL[24]. Another prospective study concluded that the monocular VA over a range of defocus of − 0.50 to + 0.50 D was better than 0.1 logMAR, and that VA remained better than 0.2 logMAR over a defocus range of − 0.75 D to − 1.75 D[30]. A defocus curve obtained from our previous retrospective study showed binocular negative defocus ranges to −1.50 D for the new refractive IOL compared to − 1.0 D for the enhanced monofocal IOL[25]. Based on these findings, the new refractive EDoF IOL offers good tolerance to refractive errors within ± 0.50 D from targeted emmetropia, a feature likely attributable to its capacity to extend the depth of focus. In this context, we investigated the clinical utility of setting a myopic target of -0.50 to -1.00 D at the time of implantation.

In our study, the preoperative target diopter calculated using Barrett Universal II and the postoperative SE were significantly more myopic in the new refractive EDoF IOL group than in the enhanced monofocal IOL group. However, the uncorrected distance vision was comparable between the two groups without significant differences. Subgroup analysis showed that uncorrected intermediate vision was comparable between the two groups, whereas uncorrected near vision was superior in the new refractive EDoF IOL group compared with the enhanced monofocal IOL group.

Previous clinical studies employing an emmetropic target for the new refractive EDoF IOL demonstrated distance and intermediate visual performance comparable to our results. The previously reported postoperative monocular intermediate VA ranged from 0.08 to 0.13 logMAR, a range that encompassed our subgroup analysis findings[24,25]. For distance vision, UDVA was reported in a single previous study as 0.10 logMAR[30]. Notably, the UNVA in our study was measured to be 0.17 ± 0.11 logMAR, demonstrating a superior result compared with the previously reported range of 0.25–0.37 logMAR[24,25]. The binocular defocus curve obtained for the new refractive IOL obtained from the subgroup analysis is well aligned with the findings of previous studies, demonstrating a depth of field with visual acuity better than 0.2 logMAR over a range from + 1.00 to − 2.00 D, with a smooth decay at intermediate distances.

The continuous and elongated defocus curve of the EDoF IOLs was attributed to the elongation of the focus, which extended the incoming light wave to the longitudinal plane. The aspherical design of the new refractive

EDoF IOL achieves an extended focus by providing more negative asphericity than needed to compensate for corneal spherical aberration[31,32]. This principal mechanism of EDoF allows near-vision capability without overlapping near and far images; however, it involves a certain level of HOAs[7]. Because a myopic target diopter was set for the new refractive EDoF IOL in our study, the postoperative SE was expected to be lower. Previous studies have demonstrated an association between HOAs and refractive astigmatism; however, a relationship between SE and HOAs has also been reported[33–35].

High HOA levels can negatively affect a patient's subjective visual experience, even when VA is improved. Ocular wavefront aberrations can compensate for retinal image quality, which changes the degree of light-induced visual discomfort and photic phenomena[31,32]. Therefore, we evaluated postoperative HOAs using the iTrace system, which enables the assessment of internal aberrations after cataract surgery by subtracting corneal aberrations from total aberrations[36]. No significant differences were observed in HOA, coma, trefoil, or tetrafoil between the two groups. The spherical aberration (Z4, 0) was significantly higher in the new refractive IOL than in the enhanced monofocal IOL.

Spherical aberration (Z4, 0) is associated with the focal length difference between the central and marginal rays, where light enters the lens[31,32]. Therefore, our result showing a significant increase in the spherical aberration (Z4, 0) aligns with the underlying optical mechanism. Wavefront analysis in a previous optical bench evaluation of the new refractive EDoF IOL revealed that the only significant Zernike polynomials were increased spherical aberration and secondary spherical aberration[29]. Therefore, the compensation for visual quality by HOAs is limited, which is reflected in the findings of the subjective questionnaire.

In our study, 21%, 7%, and 14% of the patients who underwent implantation of the new refractive EDoF IOL bilaterally perceived halo, glare, and starburst, respectively. The overall frequency of the photic phenomena was comparable between the two groups. A patient-reported questionnaire from a previous randomized trial also demonstrated no significant differences between the two groups in the frequency of photic phenomena and contrast sensitivity under mesopic conditions[24]. A laboratory investigation also demonstrated that the new refractive EDoF IOL is expected to cause low levels of dysphotopsia, comparable to those of the monofocal IOL[23].

The limitations of our study included its retrospective design, modest sample size derived from a single center, and inclusion of a single ethnicity (Korean), which limits its generalizability. In addition, higher-order aberrations (HOAs) were measured at a single photopic pupil size (3.0 mm). Eyes with short AL (< 22.5 mm) or high myopia (AL > 26.0 mm) were excluded as well. Larger, prospective, multicenter studies incorporating mesopic pupil HOA assessment, contrast-sensitivity testing, wider spectrum of ocular biometric profiles, and longer follow-up periods are needed to better characterize optical quality and neuroadaptation over time.

The results from our study showed that implantation of the new refractive EDoF IOL with a slightly myopic target allowed patients to maintain a distance VA comparable to that of an enhanced monofocal IOL. The EDoF design increased primary spherical aberration but did not increase the overall HOAs. The subgroup analysis revealed a significant improvement in near VA with high spectacle independence across various distance ranges, without significant increase in dysphotopsia rates. Thus, implantation of the TECNIS PureSee™ with a myopic target diopter may be a viable option for improving intermediate and near visual performance while preserving distance vision and visual quality.

Data availability

The datasets used during the current study are available from the corresponding author on reasonable request. All data generated or analyzed during this study are included in this published article.

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Author contributions

Conceptualization with study design and hypothesis generation, H.L., D.Y.K., H.W.P., J.O., I.H.J., K.Y.S., A.E. and T.I.K.; Data collection and screening, H.L., D.Y.K., H.W.P., J.O. and T..K.; investigation including literature research and evidence synthesis, H.L., D.Y.K., A.E., and T.I.K., formal analysis, H.L., D.Y.K., and T.I.K.; writing—original draft preparation, H.L., D.Y.K., and T.I.K.; writing—review and editing with contributions from all co-authors. All authors have reviewed and agreed to the final version of the manuscript.

Declarations

Competing interests

The authors declare no competing interests.

Additional information

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