Clinical evaluation of a new monofocal IOL with enhanced intermediate function in patients with cataract

Gerd U. Auffarth, MD, PhD, FEBO, Matthias Gerl, MD, Linda Tsai, MPH, D. Priya Janakiraman, OD, FAAO, Beth Jackson, PhD, Aixa Alarcon, PhD, H. Burkhard Dick, MD, PhD, FEBOS-CR, Quantum Study Group

Purpose: To evaluate the effectiveness and safety of 2 enhanced monofocal intraocular lenses (IOLs). The TECNIS Eyhance IOL (Model ICB00) was compared with a standard monofocal IOL (TECNIS Monofocal, Model ZCB00).

Setting: European multicenter study.

Design: Prospective, bilateral, randomized, comparative/evaluator-masked, controlled study.

Methods: Adult subjects scheduled to undergo bilateral, primary phacoemulsification cataract extraction and posterior IOL implantation were randomized to receive the enhanced monofocal ICB00 IOL or the monofocal ZCB00 IOL in both eyes. Monocular endpoints at 6 months included distance-corrected intermediate visual acuity (DCIVA), photopic corrected distance visual acuity, and uncorrected intermediate visual acuity (UIVA). Binocular visual acuities, monocular corrected distance contrast sensitivity (first eyes), patient-reported outcomes, and safety were assessed at 6 months.

Results: Overall, 139 patients were bilaterally implanted with the enhanced monofocal IOL (n = 67) or standard monofocal IOL (n = 72) and available for the 6-month visit. The enhanced monofocal IOL significantly improved mean monocular and binocular DCIVA and UIVA by at least 1-line logarithm of the minimum angle of resolution vs the standard monofocal IOL (all P < .0001). Distance vision for the enhanced monofocal IOL was 20/20 or better and comparable with that of the standard monofocal lens at 6 months. Contrast sensitivity, photic phenomena outcomes, and rates of adverse events were similar between the 2 groups.

Conclusions: In patients undergoing cataract surgery, TECNIS Eyhance IOL Model ICB00 provided enhanced intermediate vision and similar distance performance and photic phenomena compared with a standard monofocal IOL, along with improved functional performance in daily life.

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Cataract surgery with intraocular lens (IOL) implantation is one of the most commonly performed surgical procedures worldwide. The World Health Organization predicts that an estimated 32 million cataract surgeries will be performed globally in 2020.1,2

Current IOL options after cataract surgery include monofocal, multifocal, accommodating, and extended depth-of-focus (EDOF) IOLs. Standard monofocal IOLs only allow a patient’s vision to focus at 1 distance (ie, distance or near); thus, patients receiving monofocal IOLs often require spectacles postoperatively to improve their near and/or intermediate vision.3 Multifocal IOLs are designed to split incident light into 2 or more points of focus, but these IOLs are limited by the demands of minimizing optical aberration and balancing the focused and out-of-focus images.1,2 Although offering the advantage of improved near vision and spectacle independence, multifocal IOLs are associated with glare or halos.3,4 Accommodating IOLs produce a dynamic change in the dioptric power of the eye with accommodative effort to provide good vision across a variety of distances.5 In contrast to monofocal and multifocal IOLs, EDOF IOLs are those that provide an extended range of focus above a defined functional visual acuity threshold to provide useful distance and intermediate vision with monotonically decreasing visual acuity.
from the best distance focal point.\textsuperscript{8} Therefore, EDOF IOLs should provide functional vision over a range of distances while ideally reducing the incidence of bothersome halos or glare, which offer advantages to accommodate a patient’s lifestyle. Intermediate vision is becoming more essential because the use of computers or equivalent handheld electronic devices (eg, smartphones and tablets) has become more prevalent among older individuals.\textsuperscript{6,7}

The TECNIS Eyhance IOL, Model ICB00, is designed to enhance intermediate vision while providing distance vision comparable with an aspheric monofocal IOL.\textsuperscript{5} The overall lens design is refractive and leverages on the geometry, material, and corneal spherical aberration correction feature found in all IOLs of the TECNIS series, with a higher-order aspheric profile included on the anterior optic surface. Because this lens is designed to keep the benefits of a monofocal IOL and to add intermediate vision, the ICB00 IOL is considered an enhanced monofocal IOL designed to provide additional benefits of improved intermediate vision. This is a report of the clinical study that was designed to evaluate the effectiveness and safety of the TECNIS Eyhance IOL ICB00, compared with the standard TECNIS monofocal IOL ZCB00.

\section*{METHODS}

\subsection*{Study Design}

This prospective, bilateral, randomized, comparative/evaluator-masked, multicenter study was conducted at 10 sites throughout Europe (World Health Organization International Clinical Trials Registry Platform ID: DRKS00010603). All patients were examined through 6 months postoperatively, which comprised the following examinations: a preoperative examination of both eyes within 60 days of the first surgery; an operative examination of the first eye; postoperative examinations of the first eye at 1 day and 1 week to 2 weeks postoperatively; an operative examination of the second eye 30 to 90 days after first-eye surgery; postoperative examinations of the second eye at 1 day and 1 week to 2 weeks postoperatively; and postoperative examinations at 1 month and 6 months after second-eye surgery. All patients provided written informed consent, and Independent Ethics Committee approval was obtained. The study was conducted in accordance with Good Clinical Practices, ISO14155:2011, the tenets of Declaration of Helsinki, and all other applicable laws and regulations of the countries in which the study was conducted.

\subsection*{Inclusion and Exclusion Criteria}

Patients were included in the study if they were aged 50 years or older; were scheduled to undergo bilateral, primary phacoemulsification cataract extraction, and posterior IOL implantation; were candidates for postoperative corrected distance visual acuity (CDVA) of Snellen 20/25 (decimal 0.8) or better in both eyes; and a preoperative corneal astigmatism of 1.00 diopter (D) or less in both eyes; had clear intraocular media (other than cataract) in a preoperative corneal astigmatism of 1.00 diopter (D) or less in both eyes; and had provided signed informed consent.

Key exclusion criteria that applied to each eye included pupil abnormalities; any ocular trauma or ocular surgery that was not resolved/stable or could affect visual outcomes or increase risk to the patient; previous corneal refractive surgery; corneal irregularities or abnormalities, or degenerative disorders predicted to cause visual acuity losses; an endothelial cell count of less than 2000 cells/mm\textsuperscript{2}; requirement for an IOL power outside the available range of +16.0 D to +28.0 D; conditions associated with increased risk for zonular rupture; or the use of systemic or ocular medications that could affect vision, including miotic agents.

\subsection*{IOL Device Description}

The 2 IOLs that were compared in this study were the enhanced monofocal TECNIS Eyhance IOL ICB00 and the standard TECNIS 1-piece monofocal IOL, Model ZCB00. The enhanced monofocal IOL is a 1-piece acrylic aspheric refractive foldable posterior chamber IOL designed for placement in the capsular bag. This IOL is made of the same hydrophobic SENSAR acrylic material and has the same overall geometry/dimensions (13 mm overall length and 6.0 mm optic diameter) as the standard 1-piece monofocal IOL. Both the enhanced and standard monofocal IOLs are based on refractive technology, are visually indistinguishable, and have the same IOL constant. The enhanced monofocal IOL has a refractive optical design with a higher-order aspheric anterior surface that creates a continuous power progression. This refractive profile increases the power of the enhanced monofocal IOL continuously from the periphery to the center of the IOL. Therefore, the IOL is designed to effectively improve intermediate vision while maintaining distance vision comparable with a standard monofocal IOL, hence, the denomination of enhanced monofocal. The higher-order aspheric design of the enhanced monofocal IOL enables the power progression for enhancing intermediate vision and, at the same time, compensates corneal spherical aberration similar to the standard 1-piece monofocal ZCB00 IOL, adding a spherical aberration of \(-0.27 \mu\text{m}\). This is because the higher-order aspheric surface minimally changes the surface profile, being more than 85\% of the enhanced monofocal IOL surface is indistinguishable from the standard 1-piece monofocal ZCB00 IOL.

The standard IOL is a 1-piece acrylic monofocal IOL with a modified prolate (aspheric) design on the anterior optic surface to reduce spherical aberration to near zero.\textsuperscript{7} Commercially available in a preloaded configuration in the TECNIS iTec Delivery System, the preloaded standard monofocal IOL product is designated as Model PCB00. Either Model PCB00 or Model ZCB00 was used as the control IOL in this study; control IOLs will be referred to as the standard aspheric monofocal IOL in this article.

\subsection*{Randomization}

Patients were randomly assigned to bilaterally receive either the enhanced monofocal IOL or the standard 1-piece monofocal IOL using a centralized electronic randomization system (Merge eClinical OS). All patients and study technicians performing the postoperative vision tests and refractions remained masked throughout the study.

\subsection*{Surgical Technique}

Preoperative calculation of the required diopter power for the study IOL to be implanted was determined by each surgeon based on his or her experience, preference, and intended lens placement. Emmetropia (±0.5 D) was targeted for all eyes in the study. Each surgeon used his or her standard, small-incision, phacoemulsification cataract extraction surgical technique to implant the enhanced or standard monofocal IOL. Using a validated insertion system, IOLs were folded for implantation and inserted into the capsule bag through a clear-corneal, limbal, or scleral-tunnel incision ranging in size from 2.2 to 3.0 mm, as per the surgeon’s standard technique. Anterior capsulotomies were to be a continuous, curvilinear capsulorhexis approximately 5.0 to 5.5 mm in diameter made by manual (rhexis) or laser-assisted methods. Lens removal was to be performed using phacoemulsification only or through laser fragmentation and phacoemulsification/aspiration. Ophthalmic viscosurgical device materials and preoperative and intraoperative medications were used as customary for each investigator, and wound closure was left to the surgeon’s discretion.

Surgeons were to manage surgical outcomes to minimize total postoperative refractive astigmatism. Astigmatism was managed intraoperatively at the discretion of the surgeon using intraoperative astigmatism treatment procedures (ie, limbal relaxing incision, opposite clear corneal incision, and astigmatic keratotomy); these were only performed during the operative procedure. A capsular tension ring could be placed during the surgery at the surgeon’s discretion.
Endpoints and Assessments

Postoperative visual acuities were measured using Early Treatment Diabetic Retinopathy Study (ETDRS) acuity charts designed for use at test distances of 4 m (distance) and 66 cm (intermediate), which was in line with recent intermediate visual acuity testing recommendations by the Near Vision and Accommodation Committee of the American-European Congress of Ophthalmology. Lighting conditions for visual acuity testing were either photopic (85 cd/m²) with 100% contrast or mesopic (3 ± 0.5 cd/m²) with 10% low contrast.

Monocular visual acuity endpoints for all eyes at 6 months included mean (logarithm of the minimum angle of resolution [logMAR]) monocular, photopic CDVA (measured at 4 m); mean (logMAR) monocular, photopic uncorrected distance visual acuity (UDVA); mean (logMAR) monocular, photopic, distance-corrected intermediate visual acuity (DCIVA) (measured at 66 cm); and mean (logMAR) monocular, photopic uncorrected intermediate visual acuity (UIVA) (measured at 66 cm).

Binocular visual acuity endpoints included binocular CDVA, DCIVA, UDVA, and UIVA under photopic lighting conditions at 6 months. Low-contrast (10%) binocular UDVA under mesopic lighting conditions was also assessed at 1 month.

Monocular, corrected distance contrast sensitivity was measured in first eyes only at 6 months under both mesopic and photopic lighting conditions with glare (subgroup of patients only). This was measured using the M&S system and sine-wave grating charts under mesopic (1.5, 3, 6, and 12 cycles per degree [cpd]) and photopic (3, 6, 12, and 18 cpd) lighting conditions at a distance of 2.5 m; a refraction adjustment was used.

Manifest refractions were performed in all eyes at 6 months using ETDRS charts at a fixed test distance of 4 m using the maximum plus refraction technique. The maximum plus (or minimum minus) is a subjective refraction technique that involves initially adding positive power until the visual acuity is reduced (also called fogging effect), then reducing the positive power until the patient achieves the best visual acuity. As a result, the refraction of the patient will be the maximum plus sphere (or the minimum negative sphere) that provides the best visual acuity. Manifest refractive outcomes assessed in this study included refractive sphere, cylinder, and spherical equivalent (manifest refractive spherical equivalent [MRSE]), which were reported for all eyes. Results were converted to plus cylinder format and adjusted for optical infinity (−0.25 D of sphere).

Binocular corrected distance defocus curve testing was performed at 1 month using a visual acuity testing system with 100% contrast ETDRS distance acuity charts at a test distance of 4 m. Testing was conducted from +1.00 D through −2.00 D of defocus.

Information on patient-reported visual symptoms was collected at 6 months (before ETDRS visual acuity testing) using the self-administered Patient-Reported Visual Symptoms Questionnaire. In addition, the validated Catquest-SF9 questionnaire data were reported for subjects who have received the same test IOLs or same control IOLs in both eyes. Subject questionnaires were tabulated with the frequency and proportion for each response by IOL group. Comparison between IOL groups for categorical data were performed using Fisher exact test with the null hypothesis that there is no difference between responses and the alternative hypothesis that there is a difference between responses. Comparisons for ordinal data were performed using the Wilcoxon rank-sum test with the null hypothesis that there is no difference in scores between IOL groups and with the alternative hypothesis that there is a difference in scores between IOL groups. Two-sided testing and α of 0.05 were used to evaluate questionnaire data.

RESULTS

Disposition and Baseline Characteristics

The study was initiated on June 22, 2016, and completed on June 29, 2018. Overall, 151 patients were enrolled with 142 implanted with a study IOL: 68 (47.8%) with the enhanced monofocal IOL and 74 (52.1%) with the standard monofocal IOL (ie, safety population). Of these, 139 (67/142 [47.2%] enhanced monofocal and 72/142 [50.7%] standard monofocal) were bilaterally implanted and were available for the 6-month visit. The remaining 3 patients discontinued from the study prior to the 6-month visit; 2 patients in the monofocal IOL group discontinued prior to the 1-month visit owing to unilateral IOL implantation, and 1 patient in the enhanced monofocal IOL group was lost to follow-up at the 1-month visit.

Demographics and baseline characteristics of the safety population were well balanced in both treatment arms and are summarized in Table 1. The mean (±SD) age was 69.3 ± 8.7 and 72.0 ± 6.8 years in the enhanced monofocal IOL and standard monofocal IOL groups, respectively, and more patients were women in both IOL groups (40/68 [58.8%] and 44/74 [59.5%] patients, respectively). Four eyes from 3 subjects in the enhanced monofocal IOL group and 1 eye in the standard monofocal IOL group had laser-assisted astigmatism correction.

Statistical Analysis

Sample size calculations were based on analyses of visual acuity. For intermediate vision, a sample size of 70 patients per group provided more than 98% power to detect a 1-line or greater difference in mean visual acuity between the enhanced and standard monofocal IOL groups assuming 1-sided testing, an α of 0.05, and an SD of 1.5 lines. For distance vision, a sample size of 70 patients per group provided more than 99% power to detect a 1-line noninferiority margin between the enhanced and standard monofocal control IOL groups assuming an SD of 1.2 lines. The safety population was defined as all eyes implanted with the enhanced or standard monofocal control IOL that had data available at the time of analysis.
Visual Acuity

**Monocular Uncorrected and Corrected Visual Acuities** Mean (±SE) monocular, photopic DCIVA for all eyes at 6 months was 0.19 ± 0.02 logMAR (Snellen 20/31) in the enhanced monofocal IOL group, compared with 0.31 ± 0.02 logMAR (Snellen 20/41) in the standard monofocal IOL group, resulting in a significant improvement in DCIVA of 0.11 ± 0.02 logMAR (1.1 lines in Snellen equivalent; \( P < .0001 \)), favoring the enhanced monofocal IOL group (Figure 1). Mean (±SE) monocular, photopic UIVA for all eyes at 6 months was 0.16 ± 0.02 logMAR (Snellen 20/29) in the enhanced monofocal IOL group, compared with 0.27 ± 0.02 logMAR (Snellen 20/37) in the standard monofocal IOL group, resulting in a significant improvement in UIVA of 0.11 ± 0.03 logMAR (1.1 lines in Snellen equivalent; \( P < .0001 \)), favoring the enhanced monofocal IOL group (Figure 1), thus confirming the enhanced monofocal IOL group, resulting in a difference of 0.01 logMAR (Snellen 20/17) in the standard monofocal IOL group, compared with 0.06 ± 0.09 logMAR (Snellen 20/17) in the enhanced monofocal IOL group, resulting in a significant improvement in UIVA of 0.10 ± 0.14 logMAR (1.0 line in Snellen equivalent; \( P < .0001 \)), favoring the enhanced monofocal IOL group.

Mean (±SE) binocular, photopic UDVA at 6 months was 0.03 ± 0.12 logMAR (Snellen 20/16) in the standard monofocal IOL group, compared with 0.05 ± 0.02 logMAR (Snellen 20/17) in the enhanced monofocal IOL group, resulting in a significant improvement of 0.11 ± 0.03 logMAR (1.1 lines in Snellen equivalent; \( P < .0001 \)), favoring the enhanced monofocal IOL group (Figure 1), thus confirming the intermediate improvement provided by the enhanced monofocal IOL when compared with the standard version.

Mean (±SE) monocular, photopic CDVA for all eyes at 6 months was −0.02 ± 0.01 logMAR (Snellen 20/19) in the enhanced monofocal IOL group, compared with −0.06 ± 0.01 logMAR (Snellen 20/17) in the standard monofocal IOL group, resulting in a difference of −0.05 ± 0.02 logMAR (0.5 lines in Snellen equivalent); the lower 90% CI of the treatment difference was −0.07 logMAR, thus confirming that the monocular distance vision provided by the enhanced monofocal IOL was noninferior to the standard monofocal IOL (Figure 1).

**Binocular Uncorrected and Corrected Visual Acuities** Figure 2 summarizes mean binocular visual acuity outcomes at 6 months for patients who underwent bilateral cataract surgery. Mean (±SD) binocular, photopic DCIVA at 6 months was 0.09 ± 0.11 logMAR (Snellen 20/25) in the enhanced monofocal IOL group, compared with 0.20 ± 0.13 logMAR (Snellen 20/32) in the standard monofocal IOL group, resulting in a significant improvement of 0.11 ± 0.12 logMAR (1.1 lines in Snellen equivalent; \( P < .0001 \)), favoring the enhanced monofocal IOL group. Mean (±SD) binocular, photopic UIVA at 6 months was 0.07 ± 0.09 logMAR (Snellen 20/23) in the enhanced monofocal IOL group, compared with 0.17 ± 0.16 logMAR (Snellen 20/30) in the standard monofocal IOL group, resulting in a significant improvement of 0.10 ± 0.14 logMAR (1.0 line in Snellen equivalent; \( P < .0001 \)), favoring the enhanced monofocal IOL group.

Mean (±SD) binocular, photopic CDVA at 6 months was −0.06 ± 0.09 logMAR (Snellen 20/17) in the enhanced monofocal IOL group, compared with −0.10 ± 0.08 logMAR (Snellen 20/16) in the standard monofocal IOL group, resulting in a difference of −0.04 ± 0.09 logMAR (−0.4 lines in Snellen equivalent). Mean (±SD) binocular, photopic UDVA at 6 months was 0.03 ± 0.12 logMAR (Snellen 20/21) in the enhanced monofocal IOL group, compared with −0.03 ± 0.11 logMAR (Snellen 20/19) in the standard monofocal IOL group, resulting in a difference of −0.06 ± 0.11 logMAR (−0.6 lines in Snellen equivalent). Mean (±SD) binocular, mesopic low-contrast CDVA at 1 month was 0.44 ± 0.17 logMAR (Snellen 20/55) in the enhanced monofocal IOL group, compared with 0.43 ± 0.17 logMAR (Snellen 20/54) in the standard monofocal IOL group, resulting in a difference of −0.01 ± 0.17 logMAR (0 lines in Snellen equivalent).

**Contrast Sensitivity**

Monocular, corrected distance contrast sensitivity results at 6 months under mesopic and photopic conditions with glare for first eyes in subgroup patients are presented in Figure 3. Mean values for contrast sensitivity were similar between the enhanced monofocal IOL and standard monofocal IOL groups, and the differences between IOL groups were all within 0.15 log units for all the cycles per degree measured at both mesopic and photopic conditions with glare.

**Manifest Refractive Outcomes**

No statistically significant differences (\( P > .05 \)) in mean refractive outcomes (refractive sphere, cylinder, MRSE, adjusted MRSE [adjusted for target], and target MRSE) were observed between the enhanced monofocal and standard monofocal IOL groups at 6 months for all eyes (Figure 4). At 6 months, mean refractive cylinder outcomes were approximately 0.50 D for both IOL groups, and mean MRSE was within emmetropia (±0.50 D) for both IOL groups. First-eye refractive results indicated that most eyes in both the enhanced monofocal and standard monofocal IOL groups were within ±0.5 D (50/67 [74.6%] and 60/72 [83.3%, respectively] and ±1.0 D (63/67 [94.0%] and 70/72 [97.2%]) of absolute spherical equivalent. In addition, most patients in both the enhanced monofocal and standard monofocal IOL groups had absolute refractive cylinder within ±0.5 D (41/67 [61.2%] and 45/72 [62.5%] of first eyes, respectively) and ±1.0 D (65/67 [97.0%] and 65/72 [90.3%], respectively).

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Table 1. Subject demographics and baseline characteristics (safety population).

| Characteristic | Enhanced Monofocal IOL (n = 68) | Standard Monofocal IOL (n = 74) |
|---------------|---------------------------------|---------------------------------|
| Age (y)       | Mean ± SD 69.3 ± 8.7 (50-86)    | 72.0 ± 6.8 (55-86)              |
| Age group (y), n (%) | <60 (14.7) | (2.7) |
| 60-69         | 17 (25.0) | 23 (31.1) |
| 70-79         | 38 (55.9) | 39 (52.7) |
| ≥80           | 3 (4.4) | 10 (13.5) |
| Sex, n (%)    | Men 28 (41.2) | 30 (40.5) |
| Race, n (%)   | White 67 (98.5) | 72 (97.3) |
|               | Black 1 (1.5) | 0 |
|               | Asian 0 | 1 (1.4) |
|               | Other 0 | 1 (1.4) |
| Ethnicity, n (%) | Hispanic/Latino 1 (1.5) | 2 (2.7) |

IOL = intraocular lens

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Defocus Curve

Binocular defocus curves showed that the enhanced monofocal IOL had better mean visual acuity from -0.5 through -2.0 D when compared with the standard monofocal IOL (Figure 5). The stratification by pupil size showed no pupil dependency of the enhanced monofocal IOL, compared with the standard monofocal for pupils more than 2.5 mm. The sample size for pupils smaller than 2.5 mm was too small for between-group comparisons.

Patient-Reported Outcomes

Catquest-SF9 In response to the questions “Sight at present causes difficulty in everyday life” and “Satisfaction with sight at present,” there were no significant differences between the enhanced monofocal and standard monofocal IOL groups at 6 months (P > .35). In response to the question “Seeing to walk on uneven surfaces, eg cobblestones,” significantly more subjects who received ICB00 IOL showed improvement when compared with subjects who received ZCB00 IOL (P = .046).

Visual Symptoms There were no statistically significant differences in direct assessment asking the patients how often they experience halos (P = .7334), glare (P = .1534), or starbursts (P = .3088) for enhanced monofocal IOL when compared with the standard monofocal IOL at 6 months. Furthermore, when patients were asked how much they were bothered by the visual symptoms, more than 80% of patients in both study groups reported that they did not experience, were not bothered, or were slightly bothered by glare, halos, or starbursts during the past 7 days. At 6 months, nondirected assessment of visual symptoms indicated that more than 90% of patients in both study groups reported having no problems with their vision during the past 7 days related to glare, halos, or starbursts.

SAsEs and Device-Related AESE Medical complications/adverse events were similar between both the enhanced monofocal and standard monofocal IOL groups and compared favorably to the ISO 11979-9 SPE rates. However, cumulative incidence rates of cystoid macular edema (CME) for first eyes in both the enhanced monofocal and standard monofocal IOL groups were higher, compared with ISO SPE rates (7.4% [5/68] and 5.4% [4/74] vs 3.0%, respectively); no cases were considered related to the study IOLs. For second eyes, CME rates in the enhanced monofocal and standard monofocal IOL groups were 1.5% (1/68) and 1.4% (1/72), respectively.

DISCUSSION

This study demonstrates the safety and effectiveness of the enhanced monofocal Eyhance ICB00 IOL, compared with the standard aspheric monofocal ZCB00 IOL. The results from this 6-month clinical study confirmed the intended performance of the Eyhance, providing improved intermediate vision while maintaining distance vision and photic phenomena when compared with an aspheric monofocal IOL.

At 6 months, the enhanced monofocal IOL provided significant improvements in intermediate vision (monocular and binocular DCIVA and UIVA) by at least 1-line vs the standard monofocal IOL. Eyhance monofocal IOL provided a binocular intermediate vision of 20/25, whereas distance visual acuity was 20/17 at 6 months. Binocular distance vision under mesopic, low-contrast lighting conditions for the enhanced monofocal IOL was maintained at comparable levels with that of the standard monofocal IOL. Mean monocular, corrected distance contrast sensitivity was similar between the enhanced monofocal IOL and the standard monofocal IOL.
the standard monofocal IOL. Patient-reported outcomes indicated that photic phenomena outcomes (halos, glare, and starbursts) were similar in both groups, and both IOLs were generally well tolerated, with similar rates of SAEs.

Given the importance of intermediate vision for common daily tasks, such as walking upstairs and downstairs and using computers or electronic devices (eg, tablets and smartphones), the restoration of intermediate vision is a desired outcome for many individuals who undergo cataract surgery. In the literature to date, clinical evidence demonstrating improvements in intermediate vision with monofocal IOLs has been lacking. Recently, a prospective case series comparing the enhanced monofocal Eyhance IOL and the standard monofocal IOL reported similar visual outcomes to the results of this study, with the Eyhance IOL providing similar levels of distance/near visual acuities and significant improvements in intermediate vision relative to the standard monofocal IOL. Taken together, the findings of this study and that of the prospective case series indicate that the enhanced monofocal IOL is the first monofocal IOL to demonstrate an improvement in intermediate vision.

Furthermore, there seems to be no correlation between the improvement at intermediate vision and refractive error. Manifest refractive outcomes at 6 months were similar between the enhanced monofocal IOL and the standard monofocal IOL, indicating that refractive outcomes did not influence the significant improvement in UIVA observed with the enhanced monofocal IOL, thus further highlighting the excellent visual performance of the enhanced monofocal IOL at intermediate distances. Because the study was performed using the same IOL constant for both IOL models, the similarity on refractive outcomes between both IOL models confirms that the Eyhance ICB00 IOL shares the same IOL constant as the monofocal ZCB00 or PCB00 IOL. In this current study, an increased depth of focus was observed with the enhanced monofocal IOL, compared with the standard monofocal IOL. Therefore, the enhanced monofocal IOL provides improved visual performance over the standard monofocal IOL at an increased depth of focus.

It is also important to note that the maximum plus refraction technique was used in this study. This consists of refracting patients with the maximum plus (or least minus) power through which the best distance visual acuity is achieved. This refraction procedure is similar to that used for young phakic patients who still retain their accommodation. This method is strongly recommended for IOL with an extended depth of focus, such as Eyhance IOL. As Figure 5 shows, the enhanced monofocal IOL provided a sustained visual acuity through different defocus values because of the continuous change in power provided by its optical design, unlike standard monofocal IOLs that show a clear maximum in the defocus curve. Therefore, refracting patients by pushing plus (ie, adding spherical power) helps maximizing both distance and intermediate vision with this technology. In addition, the use of autorefractors is not
recommended for the enhanced monofocal IOL. Because autorefractors use the central part of the pupil to estimate refraction, they might not be able to capture the continuous power progression of the enhanced monofocal IOL. Therefore, autorefractors might not provide optimal postoperative refraction in patients implanted with this technology because of its optical design.

Patient-reported visual symptoms associated with the enhanced monofocal IOL were similar to those of the standard monofocal IOL, with most patients indicating that they had no problems with or were not bothered by photic phenomena outcomes. Similarly, no differences in glare and halo perception were noted between IOLs in the recently published prospective case series comparison of the enhanced and standard monofocal IOLs. Catquest-SF9 results also highlighted the functional benefits of improved intermediate vision with Model ICB00 IOL, with a significantly greater proportion of patients with Model ICB00 IOL indicating that they had no difficulty “Seeing to walk on uneven surfaces” compared with patients with Model ZCB00 IOL. Taken together, these findings indicate that the enhanced monofocal IOL will provide improved performance in the daily life of individuals seeking improved intermediate vision while keeping distance vision and photic phenomena comparable with that of a standard monofocal IOL.

The enhanced monofocal IOL had a similar safety profile to that of the standard monofocal IOL. However, an increased incidence of CME was observed in the enhanced monofocal IOL group, compared with ISO SPE rates, although no cases were considered related to the IOL. High CME incidence rates have been previously reported after cataract surgery when identified using optical coherence tomography (1% to 41%) or fluorescein angiography (16% to 60%) and in patients undergoing secondary IOL implantation (16.7%).

Eyhance ICB00 IOL is a higher-order aspheric monofocal IOL that shares the same material and base geometry as all other IOLs of the TECNIS IOL platform, with an optical profile designed to keep the same benefits as the TECNIS monofocal 1-piece IOL while improving intermediate vision. This clinical study demonstrated the comparable distance performance of both IOL models. In addition, the higher-order aspheric profile was designed to provide the tolerance to decentration as the monofocal version. Simulated visual acuity calculated using computational eye models shows that Eyhance IOL is expected to be as tolerant to decentralions as the monofocal 1-piece IOL, therefore at the level reported in the clinical practice for the TECNIS IOL platform.

In addition to comparable tolerance with decentration, the enhanced monofocal IOL is designed to provide a pupil-independent behavior comparable with that of the standard monofocal version. The same methodology as described earlier was used to simulate distance and intermediate vision for 2.0, 3.0, and 4.0 mm pupils. The results of these simulations indicate that the enhanced monofocal IOL is designed to provide a pupil-independent performance comparable with the standard monofocal IOL for both distance and intermediate vision. The pupil independency of the enhanced monofocal IOL when compared with the standard aspheric monofocal IOL was also supported by the results of this clinical study for pupils more than 2.5 mm.

As is expected with a controlled clinical trial setting, patients included in this study had healthier eyes, and surgeons who participated in the study were highly experienced, which might result in better outcomes than those observed in a more generalized clinical setting. These potential study limitations should be considered when interpreting the results of this study.

In conclusion, the results from this study demonstrated the safety and effectiveness of the enhanced monofocal IOL, Model ICB00, and it is the first monofocal IOL to show...
evidence of an improvement in intermediate vision with comparable distance vision and dysphotopsia profile similar to a standard monofocal IOL with the same base geometry, material, and corneal spherical aberration correction. As a result, the enhanced monofocal IOL will provide patients undergoing cataract surgery with an alternative to standard monofocal IOLs, which might offer improved functional performance in daily life.

WHAT WAS KNOWN
- The restoration of intermediate vision is an important outcome for many individuals who undergo cataract surgery, given that it is a requirement for common daily tasks, such as walking upstairs and downstairs and using computers or electronic devices.
- Standard monofocal IOLs effectively restore distance vision, but do not provide functional vision at other distances.

WHAT THIS PAPER ADDS
- The TECNIS Eyhance IOL, Model ICB00, was a safe and an effective alternative to standard monofocal IOLs in patients undergoing cataract surgery.
- It is the first monofocal IOL to demonstrate an improvement in intermediate vision with comparable distance vision and photic phenomena as a standard monofocal IOL.

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