



Clinical Performance After Implantation of a New Purely Refractive Extended Depth of Field Intraocular Lens in Cataract Patients

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Purpose: To evaluate the functional outcomes including visual performance and patient reported outcomes after implantation of a refractive Extended Depth of Field (EDoF) intraocular lens (IOL) in a post-approval prospective, non-controlled study.

Patients and Methods: Fifty-eight eyes of 29 patients (mean age: 71 ± 11 years) that underwent phacoemulsification cataract surgery with implantation of a DEN00V or DET100-600 IOL (TECNIS PureSee, Johnson & Johnson Vision Inc. Jacksonville, Florida, USA) were included in this prospective study. Postoperative follow-up at 3 months included uncorrected and corrected distance visual acuity (UDVA/CDVA), uncorrected and distance corrected intermediate visual acuity at 80 cm (UIVA/DCIVA), and uncorrected and distance corrected near visual acuity at 40 cm (UNVA/DCNVA), as well as binocular corrected defocus curve analysis (range +2 to -4 dioptres), contrast sensitivity under photopic and mesopic conditions (CSV-1000, VectorVision, Greenville, USA) and patient-reported outcome (Heidelberg Daily Task Evaluation (DATE) Questionnaire and halo and glare evaluation).

Results: Mean binocular visual acuity in logMAR at 3 months was UDVA/ CDVA (-0.02/ -0.07), UIVA/ DCIVA (0.03/ 0.02) and UNVA/ DCNVA (0.16/ 0.16). The defocus curve analysis showed a visual acuity of 0.20 logMAR or better up to -2.25 D. Contrast sensitivity under photopic and mesopic conditions was within normal age limits. The study IOL was non-inferior to standard monofocal lenses in terms of halo/glare. Eighty-three percent of participants were fully satisfied with the outcome of the IOL implantation and ninety-six percent of patients would repeat the surgery with the same IOL and recommend the IOL to friends or acquaintances.

Conclusion: The TECNIS PureSee IOL yielded good visual performance with high patient satisfaction. Patients received a good EDoF-effect with a low probability of disturbing photopic phenomena in terms of halo and glare.

Keywords: EDOF, non-diffractive, intraocular lens, simultaneous vision

Introduction

Modern cataract and refractive lens exchange (RLE) surgeries offer a variety of intraocular lens (IOL) options, each with specific strengths and limitations in visual outcomes, spectacle independence, and visual disturbances such as halo and glare.¹⁻³ Standard monofocal IOLs remain the most commonly implanted, providing excellent vision in one distance, which is usually the far, but requiring spectacles for intermediate and near tasks.^{1,4} In contrast, multifocal IOLs enhance spectacle independence across all distances but are often associated with an increased likelihood of photic phenomena and reduced contrast sensitivity.^{1,5,6}

The first Extended Depth of Field (EDoF) IOLs were developed to improve intermediate visual acuity by distributing the light across a continuous and elongated focal zone, while reducing dysphotopsias compared to multifocal lenses.^{1,3,7,8} However, due to their diffractive design, these lenses remained prone to certain dysphotopsias.^{9,10} Recently, non-diffractive EDoF IOLs were developed to retain the intermediate vision benefits of traditional EDoF lenses while aiming to significantly reduce the risk of

visual side effects.^{9,11} To date, a number of EDoF IOLs utilizing various refractive principles are available. For example, the Mini Well (SIFI SpA, Catania, Italy)¹² and the LuxSmart (Bausch + Lomb Inc., Rochester, USA)¹³ employ alternating positive and negative spherical aberration zones to induce an extended range of vision.^{3,14} In contrast, the Vivity (Alcon Inc., Fortworth, USA)^{8,14} IOL incorporates a proprietary design called “wavefront-shaping technology”, while the Lentis Comfort (Teleon Surgical GmbH, Leverkusen, Germany)¹⁵ is designed as a low-add (+1.5 diopters) bifocal IOL. Another EDoF IOL, the IC-8 (Bausch + Lomb Inc., Rochester, USA), operates on a refractive-diffractive principle and is distinguished by its small-aperture with a pinhole effect.^{3,16,17}

A new IOL was recently introduced into the category of refractive EDoF IOLs.^{2,8} The lens is officially designated as TECNIS ZEN00V/DEN00V or DET100-600 for the toric version, and is branded as PureSee™ (Johnson & Johnson Vision Inc., Jacksonville, USA).^{2,8} It is a foldable single-piece lens made of a hydrophobic acrylic with a 6.0 mm optic diameter and a 13.0 mm total diameter, and it is also available as a toric version (DET100-600).² The lens utilizes a biconvex design with a wavefront-modified anterior aspheric surface, intended to compensate for the mean corneal spherical aberration ($-0.27 \mu\text{m}$), and a posterior refractive surface characterized by a continuously changing power profile.^{2,8,18} The smooth power distribution on the posterior curvature is intended to expand the range of clear vision while minimizing halo and glare to a level comparable to monofocal IOLs.^{2,18,19}

The objective of the present study is to assess the clinical performance of a new purely refractive extended depth of field IOL in a group of bilaterally implanted cataract patients following phacoemulsification over a follow-up period of three months.

Materials and Methods

In this prospective, non-controlled post-approval study, 29 patients with age-related cataract scheduled for bilateral phacoemulsification with IOL implantation were enrolled to the study following written informed consent for both the surgical procedure and study participation. Additional inclusion criteria were the participant’s availability, willingness, and sufficient cognitive ability to comply with examination procedures, as well as an uneventful surgical procedure. The participants were between 46 and 88 years old.

Exclusion criteria included higher-order aberrations exceeding 0.3 as measured by Pentacam (Oculus Optikgeräte, Wetzlar, Germany) and the presence of clinically significant ocular pathologies or ocular comorbidities likely to affect postoperative clinical outcomes.

All patients underwent bilateral phacoemulsification with subsequent implantation of a TECNIS PureSee IOL into the capsular bag. Depending on individual refractive needs, either a spherical (ZEN00V/DEN00V) or toric (DET100-600) model was used.

The study was approved by the Ethics Committee of the Medical Faculty of Heidelberg University (S-392/2011) and registered in the German Clinical Trials Register (Deutsches Register Klinischer Studien; reference number: DRKS00007837). The study was conducted in accordance with the Declaration of Helsinki.

IOL and Surgical Procedure

Preoperative optical biometry was conducted using the IOL Master 700 (Carl Zeiss Meditec AG, Jena, Germany). IOL power was calculated targeting emmetropia using the Barrett Universal II formula and selecting the first minus spherical equivalent.

Depending on the patient’s preference and cost considerations, cataract surgery was performed either manually or with femtosecond laser assistance using the LensAr Laser system (Alcon Inc., Fort Worth, USA). To manage preexisting corneal astigmatism, a digital image-guided system (Callisto Eye, Carl Zeiss Meditec AG, Jena, Germany) was used to precisely align the toric IOL axis and/or position the clear corneal incision on the steepest meridian. All surgeries were performed under standardized conditions by one of three experienced ophthalmic surgeons. All patients were bilaterally implanted with the PureSee IOL.

Pre- and Postoperative Evaluations

Prior to surgery, all patients underwent a comprehensive ophthalmologic examination which included manifest refraction, visual acuity testing, slit-lamp biomicroscopy (Haag Streit 900, Haag-Streit GmbH, Mannheim, Germany), funduscopy, biometry, cornea tomography, and optical coherence tomography (OCT) of the optic nerve and macula.

The main outcome measure was the 3-month follow-up, during which participants completed a standardized examination protocol consisting of manifest refraction; uncorrected and distance-corrected visual acuity testing at far (4 m; UDVA/CDVA), intermediate (80 cm; UIVA/DCIVA), and near (40 cm; UNVA/DCNVA) distances; slit-lamp biomicroscopy; funduscopy; contrast sensitivity assessment; halo and glare simulation testing; and completion of a subjective patient questionnaire.

Visual acuity (VA) was assessed using the logMAR scale under photopic conditions (85 cd/m^2) and 100% contrast, using Early Treatment Diabetic Retinopathy Study (ETDRS) charts appropriate for each test distance. All VA measurements were carried out separately for monocular and binocular viewing. Defocus curve testing was conducted binocularly using distance correction. ETDRS charts were alternated throughout the test to prevent memorization effects.

Contrast sensitivity was evaluated postoperatively using the CSV-1000 chart (VectorVision Inc., Greenville, USA) at 2.5 meters under both photopic ($\sim 85 \text{ cd/m}^2$) and mesopic ($\sim 3 \text{ cd/m}^2$) conditions. Testing was performed with best spectacle correction, as determined by manifest refraction, and under binocular conditions only. Patients were presented with four rows of sine-wave gratings corresponding to spatial frequencies of 3, 6, 12, and 18 cycles per degree (cpd). For mesopic testing, appropriate neutral density filters were inserted into the trial frame.

Photopic phenomena were assessed using the Halo and Glare Simulator (HGS) (Eyeland Design Network GmbH, Vreden, Germany), which provides a visual depiction and allows adjustment of halo and glare size and intensity on a scale from 0 to 100. The patients were asked to adjust the level of halo and glare size and intensity in the simulator (showing an image of a highway during night-time, see Figure 1) to create the most accurate depiction of their subjective perception in day-to-day life.

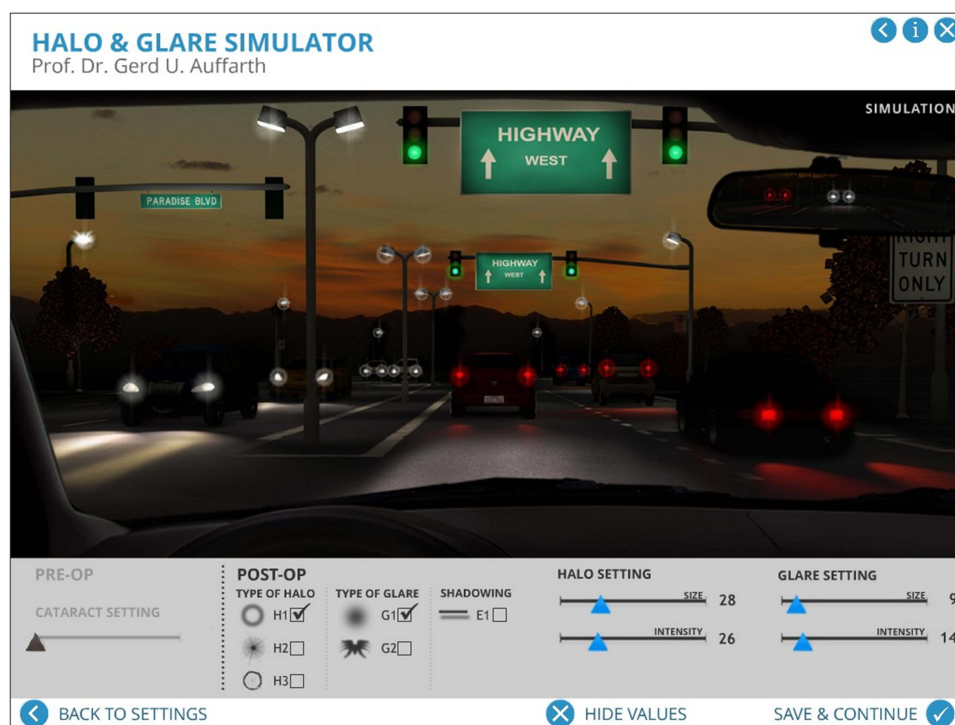


Figure 1 Image generated with the Halo and Glare Simulator (Eyeland Design Network GmbH, Vreden, Germany) by entering the mean values for size and intensity for the halo and glare parameters (see Table 4).

Patient-reported outcomes regarding functional vision and spectacle independence were assessed postoperatively using the Heidelberg Daily Task Evaluation (DATE) Questionnaire,²⁰ which evaluates patients' reliance on spectacles for various daily activities, with responses ranging from complete independence to complete dependence. Adverse events, serious adverse events, and changes in concomitant medication were recorded at each study visit.

Statistical Analysis

Based on published data for EDOF IOLs we expected a mean binocular UIVA of approximately 0.0 to 0.1 logMAR with a standard deviation of about 0.10 to 0.12 logMAR. Using an a priori precision-based sample size approach, a total of 25 patients will enable estimation of the mean binocular UIVA with a 95% confidence interval half-width of ± 0.05 to 0.06 logMAR. Statistical analyses were conducted using Microsoft Excel (version 16.32 for Microsoft Windows) and IBM SPSS Statistics (version 27 for Microsoft Windows). For all quantitative variables, mean values and standard deviations (SD) were calculated. The Shapiro–Wilk test was applied to assess the normality of data distribution. A P-value of less than 0.05 was considered statistically significant.

Results

Safety

Of the 29 patients enrolled into the study, 25 completed the 3-month follow-up evaluation. Of the 58 surgeries, 32 were performed conventionally and 26 were femtosecond laser-assisted. There were no IOL-related complications except for one eye requiring toric IOL rotation. Table 1 shows a summary of the demographic data and preoperative ophthalmological assessments.

Visual Acuity Outcomes

Three months after surgery, mean binocular visual acuity at far and intermediate distance was 20/20 Snellen (0.0 logMAR) or better for both uncorrected and distance-corrected vision. Mean uncorrected binocular near visual acuity was better than 20/32 Snellen (0.16 logMAR) (Table 2).

Table 1 Demographics and Preoperative Characteristics

Parameter	Mean \pm SD	Median	Min	Max
Gender				
Female	N = 11 (45.8%)			
Male	N = 13 (54.2%)			
Age				
Female	72.3 \pm 8.2	73	57	86
Male	68.9 \pm 12.9	75	46	87
Keratometry				
R1 (mm)	7.91 \pm 0.32	7.87	7.39	8.71
R2 (mm)	7.75 \pm 0.32	7.71	7.34	8.53
Astigmatism (D)	-0.88 \pm 0.97	-0.61	-4.75	0.0
Ocular biometry (mm)				
Anterior chamber depth	3.11 \pm 0.33	3.03	2.45	3.88
Axial length	23.90 \pm 1.45	23.59	21.69	27.81
Target refraction (D)				
Expected target refractive error* IOL (D)	-0.14 \pm 0.16	-0.17	-0.46	0.18
Dioptric power	21.08 \pm 3.25	21.50	13.00	27.00

Note: *IOL power was calculated using the Barrett Universal II formula.

Abbreviations: SD, standard deviation; D, diopters; R1, steep corneal radius of curvature; R2, flat corneal radius of curvature; IOL; intraocular lens.

Table 2 Visual Acuity Results, 3 months Postoperative

Visual acuity	Monocular	Binocular
UDVA (4m)	0.03 ± 0.10	-0.02 ± 0.09
CDVA (4m)	-0.04 ± 0.09	-0.07 ± 0.07
UIVA (80 cm)	0.07 ± 0.10	0.03 ± 0.08
DCIVA (80 cm)	0.06 ± 0.09	0.02 ± 0.07
UNVA (40 cm)	0.22 ± 0.14	0.16 ± 0.12
DCNVA (40 cm)	0.22 ± 0.12	0.16 ± 0.09

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

A Snellen threshold of 20/32 (0.20 logMAR) was achieved by 90% of eyes for UDVA, and 98% for CDVA. A monocular UDVA and CDVA of 20/20 (0.0 logMAR) was achieved by 44% and 69% of eyes, respectively. For monocular intermediate vision, 88% of eyes reached a threshold of 20/32 Snellen (0.20 logMAR) for UIVA, and 92% for DCIVA. Near visual acuity was 20/32 or better in 38% for UNVA and 42% for DCNVA, respectively (Figure 2A and B). 90% of eyes were within 1 line of CDVA (Figure 2C). In a post hoc sensitivity analysis, using the observed standard deviation of binocular UIVA at 80 cm (0.08 logMAR) and the final analyzed cohort of 25 patients, the study had approximately 90% power to detect a difference of about 0.05 logMAR in mean binocular UIVA at a two-sided significance level of 0.05.

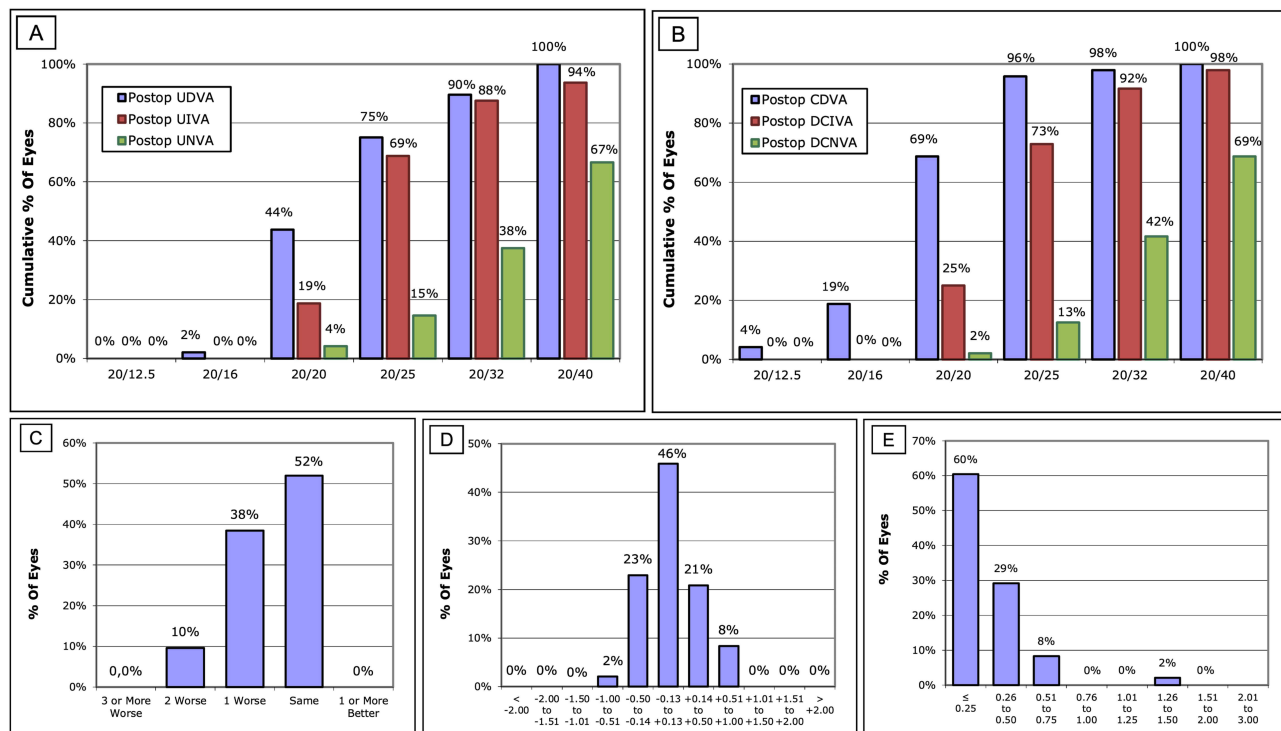


Figure 2 (A) Postoperative uncorrected distance (UDVA), intermediate (UIVA) and near (UNVA) as cumulative Snellen Visual Acuity (20/x or better). (B) Postoperative corrected distance (CDVA), intermediate (DCIVA) and near (DCNVA) as cumulative Snellen Visual Acuity (20/x or better). (C) Postoperative UDVA vs CDVA (difference in Snellen lines). (D) Postoperative spherical equivalent refractive accuracy (D = diopters). (E) Postoperative refractive astigmatism. Graphs show monocular results without correction for bilateral inclusion.

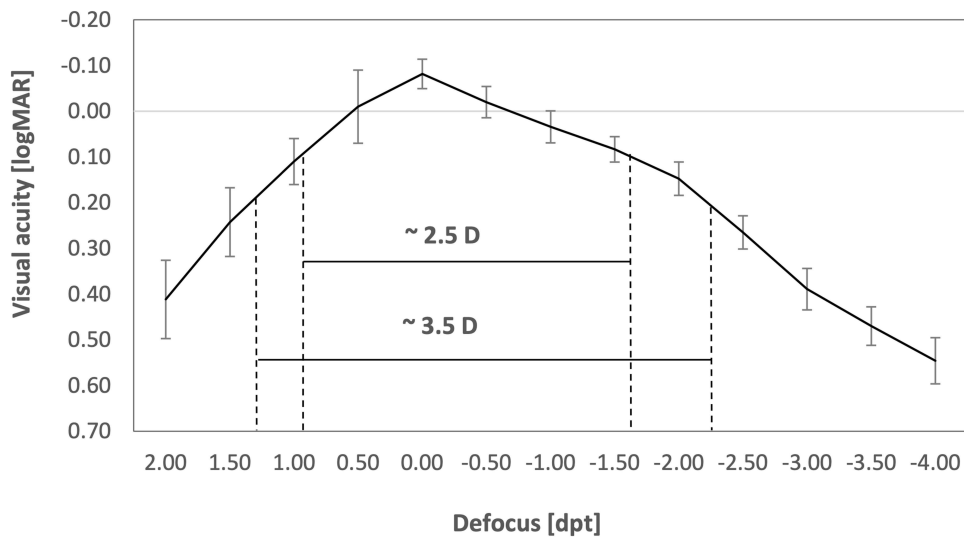


Figure 3 Binocular distance-corrected defocus curve at 3 months postoperatively. A continuous visual acuity (VA) of 0.10 logMAR or better was observed over approximately 2.5 diopters (D) of defocus, while a continuous VA of 0.20 logMAR or better was maintained over around 3.5D of defocus.

Refractive Outcomes

Figure 2D and E show the refractive outcomes 3 month after implantation. 90% of eyes had a spherical equivalent within ± 0.50 D, and all eyes within ± 1.0 D. 90% of eyes showed a refractive astigmatism of 0.50 D or less, 98% of eyes of 0.75 D or less.

Defocus Curve

Figure 3 presents the binocular distance-corrected defocus curve 3 months after surgery at 4 meters, from +2.00 to -4.00 D. The defocus curve shows a continuous binocular visual acuity of 0.10 logMAR or better in the range from +1.0 to -1.5 D, and of 0.20 logMAR or better in the range up to -2.25 D.

Halo and Contrast Sensitivity

At the 3-month follow-up, contrast sensitivity testing under photopic and mesopic conditions showed results within the normal range of the examined age group, which are shown in Figure 4 and Table 3. During the same visit, patients were questioned about the perception of halos and glare. With the HGS, 7 (29%) reported no halos, and 17 (71%) reported no

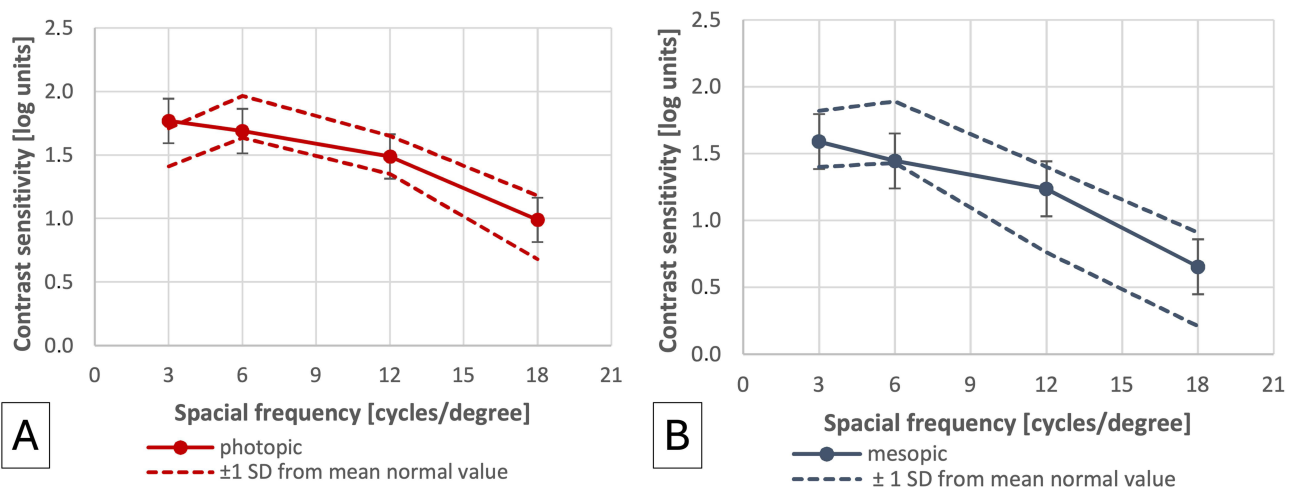


Figure 4 Contrast sensitivity testing under (A) photopic (red) and (B) mesopic (blue) conditions. Mean normal values as defined by VectorVision for the CSV-1000 test (<https://www.vectorvision.com/csv1000-norms>).

Table 3 Contrast Sensitivity at 3 months Postoperative

Spatial Frequency	Photopic	Mesopic
	Mean ± SD	Mean ± SD
3 cpd	1.77 ± 1.04	1.59 ± 1.09
6 cpd	1.69 ± 1.17	1.44 ± 1.31
12 cpd	1.49 ± 0.94	1.24 ± 1.11
18 cpd	0.99 ± 0.50	0.65 ± 0.65

Abbreviation: cpd, cycles per degree.

Table 4 Results of Halo and Glare Simulation at 3 months Postoperatively*

Variable	Type					
	None	Classic	Starburst	Asymmetric	Size	Intensity
Halo	29.2%	54.2%	16.6%	0%	28.0 ± 24.4	26.6 ± 21.6
Glare	70.8%	29.2%	NA	0%	8.5 ± 16.0	13.7 ± 23.2

Notes: *Percentages indicate the proportion of patients perceiving each effect, regardless of severity. Size and intensity are adjusted according to the patient's own perception (range 0–100) and are shown as mean values ± SD. A value of 0 indicates no effect; size 100 represents the largest depiction, and intensity 100 the highest brightness.

Abbreviation: NA, not applicable.

glare (Table 4). The HGS showed a mean halo size of 28 ± 24 and a mean halo intensity of 26 ± 22 . For glare, a mean size of 9 ± 16 and intensity of 14 ± 23 were reported (Table 4 and Figure 1). Halos were categorized as H1 in 83.3% and H2 in 16.7% of eyes, while all patients reported G1 glare type (Table 4).

Patient Satisfaction

Figure 5 shows a subjective evaluation of the patients' ability to perform various daily tasks, as assessed by the DATE Questionnaire 3 months postoperatively. Furthermore, 83% of participants were fully satisfied with the outcome of the IOL implantation, and 96% would repeat the surgery with the same IOL and recommend the IOL to friends or acquaintances.

Can you perform the following task without using spectacles?

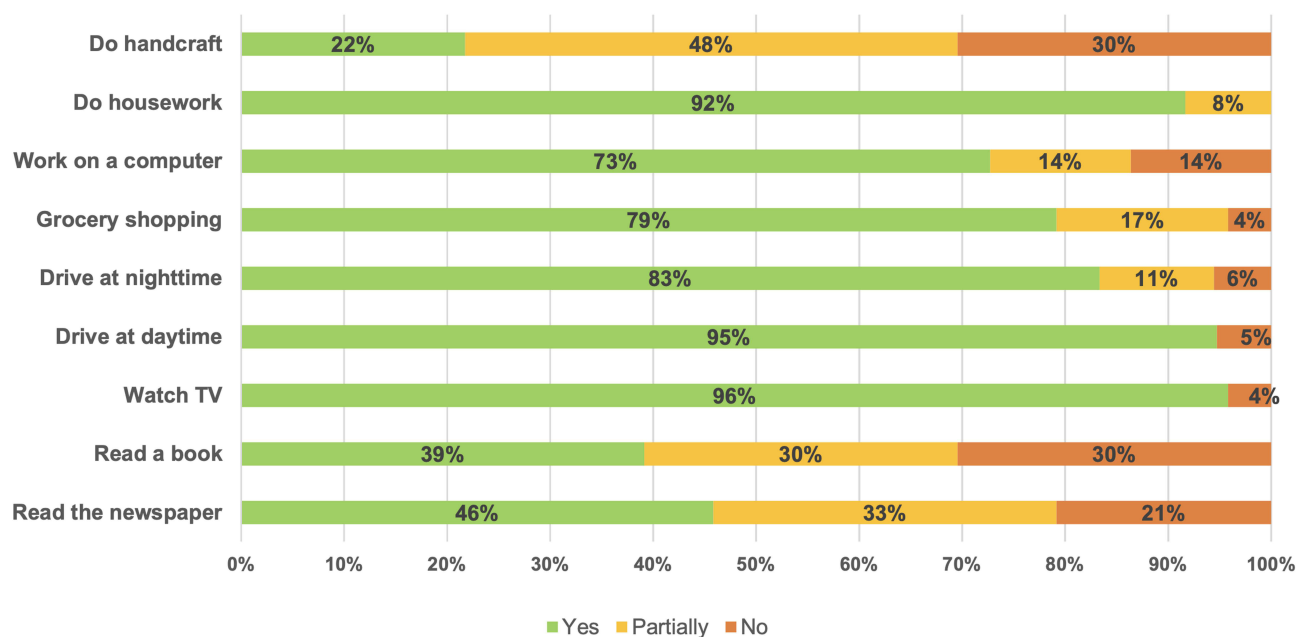


Figure 5 Results of the Heidelberg Daily Task Evaluation Questionnaire at 3 months postoperative (percentage of patients responding with “yes”, “partially” or “no”).

Discussion

Extended depth of field (EDoF) IOLs were developed to enhance intermediate vision while maintaining distance VA similar to standard monofocal lenses. Early EDoF IOL models used diffractive technology, which offered good visual acuity and an extended range of vision but were frequently associated with significant halo and glare.^{8,20,21} Best known diffractive models include the TECNIS Symphony (Johnson & Johnson Vision Inc., Jacksonville, USA)²² and the AT Lara (Carl Zeiss Meditec AG, Jena, Germany).²³ With non-diffractive designs, a reduction regarding the frequency of photic phenomena was achieved while maintaining VA results comparable to diffractive EDoF models.³ Refractive IOLs such as Vivity (Alcon Laboratories Inc., Fort Worth, USA), MiniWell (SIFI SpA, Catania, Italy), LuxSmart (Bausch + Lomb Inc., Rochester, USA), Lentis Comfort (Teleon Surgical GmbH, Leverkusen, Germany) and the small aperture IC-8 (Bausch Lomb Inc., Rochester, USA) have already been compared in multiple studies and play an important role as premium IOL alternatives for cataracts surgery and presbyopia correction.^{3,14}

The more recent TECNIS PureSee IOL was designed as a purely refractive lens and has already been tested multiple times in laboratory studies. Existing literature shows good simulated optical quality, as well as an increased range of vision for the TECNIS PureSee IOL.^{2,8,18,19} The predicted halo induction was small in size and low in intensity, similar to that of a monofocal IOL, and lower than that observed with a diffractive EDoF IOL.^{8,18} Optical quality decreased with increasing pupil size and IOL-decentration, while the simulated effect of IOL-tilt was less pronounced.⁸

The clinical approval study for the TECNIS PureSee IOL was conducted by Corbett et al¹ and Black et al⁴ as a prospective multi-center randomized study which included highly selected patients and followed them for 6 months after implantation. The study compared a group of 62 patients implanted bilaterally the TECNIS PureSee (ZEN00V) IOL with a control group of 58 patients implanted bilaterally with the enhanced monofocal TECNIS Eyhance (ICB00) IOL. To date, and to the best of our knowledge, post-approval studies evaluating the clinical results of the TECNIS PureSee IOL are limited to the publication by Alfonso-Bartolozzi et al, who focus on optical bench analysis while also reporting clinical outcomes for 30 eyes of 15 patients 3 months after IOL implantation.² In our post-approval study, we focused on precise clinical outcome measures including visual acuity, defocus curve testing, contrast sensitivity, and halo/glare perception. Our findings corroborate the results reported in the initial approval study and show non-inferior outcomes to those reported by Alfonso-Bartolozzi et al.

For the TECNIS PureSee IOL, Corbett et al¹ found a mean monocular CDVA of -0.06 ± 0.08 logMAR at 6 months postoperative, while laboratory testing by Niknahad et al⁸ predicted a distance VA of -0.05 logMAR. In contrast, a CDVA of -0.06 ± 0.06 logMAR had been described for the TECNIS 1-piece monofocal ZCB00 IOL.²⁴ Furthermore, Black et al report a mean binocular UDVA of -0.03 logMAR at 6 months,⁴ while the study by Alfonso-Bartolozzi et al finds monocular UDVA and CVDA for the TECNIS PureSee of 0.10 ± 0.15 and 0.05 ± 0.09 logMAR, respectively, after 3 months. Our post-approval study found a mean monocular CDVA of -0.04 ± 0.09 logMAR and UDVA of -0.02 ± 0.09 logMAR at 3 months in our study cohort. While direct comparison of outcomes from different studies is limited due to factors such as different methodologies, patient populations, testing conditions and follow-up periods, results from the present study suggest non-inferior performance for distance vision to monofocal IOL designs and to earlier published evidence for the PureSee IOL.

For monocular DCIVA, Corbett et al report 0.13 ± 0.08 (20/32 Snellen) logMAR at 66 cm, while our study identified a monocular DCIVA 0.06 ± 0.09 logMAR (20/25 Snellen) at 80 cm. These results suggest an improvement in intermediate vision with the TECNIS PureSee IOL compared to standard monofocal lenses. For comparison, for the TECNIS ZCB00 1-piece monofocal, a monocular DCIVA of 0.30 ± 0.11 at 80 cm and of 0.38 ± 0.12 logMAR at 66 cm had been reported.^{1,24} While Corbett et al report 817% eyes achieving a VA for DCIVA (at 66cm) of 20/32 Snellen, in the presented study 92% of eyes reached 20/32 and 73% 20/25 Snellen (at 80 cm).

Notably, our study found very good mean monocular DCNVA at 40 cm of 0.22 ± 0.12 logMAR (20/32) with 42% of eyes reaching 20/32 Snellen or more. Corbett et al¹ report a mean monocular DCNVA (40 cm) of 0.37 ± 0.10 (Snellen 20/50) and Niknahad et al⁸ simulated a near VA of 0.24 logMAR for the PureSee IOL, while published results for the TECNIS ZCB00 monofocal IOL showed a DCNVA of 0.55 ± 0.14 logMAR at 40 cm.²⁴ Mean binocular UNVA in our patients was 0.16 logMAR (20/32 Snellen), which is sufficient for good functional near vision.²⁵ This correlates well

with the finding that about two thirds of patients reporting the ability able to read a book or newspaper without or partially without using glasses.

Laboratory investigations report a wide simulated range of visual acuity for the TECNIS PureSee IOL. Niknahad et al⁸ predicted a defocus curve throughout the range of +1.0 to -2.25D of 0.2 logMAR or better, as derived from the modulation transfer function (MTF) at 3 mm aperture. MTF-based VA-simulation by Schmid and Borkenstein¹⁹ at 3 mm aperture had shown a VA of 0.1 logMAR or better up to a defocus of -2.25D and better than 0.2 logMAR even until a defocus of -2.75D.¹⁹ The defocus range narrowed considerably with larger apertures.^{8,19}

Clinical defocus curve results from our study demonstrate an extended range of functional vision with binocular VA of 0.1 logMAR or better from +1.0 to -1.50D and of 0.2 logMAR from +1.25 to -2.25D. Our results broadly align with optical bench predictions from Niknahad et al and are non-inferior to findings from the study by Alfonso-Bartolozzi et al, in which a VA of 0.2 logMAR was reached from 0.0 to -2.0D.^{2,8,19} What is more, our study found peak VA of -0.08 logMAR at 0.0D, while Alfonso-Bartolozzi report 0.0 logMAR at 0.0D.² It should be noted that the defocus curve in this study was assessed binocularly without stratification by pupil size or lighting conditions, and monocular defocus curves were not obtained. Given the known pupil dependence of refractive EDoF optics, these factors limit interpretation of the specific optical contribution of the lens design.

Despite significant advancements since the initial EDoF IOL models, evaluating contrast sensitivity remains essential for assessing the performance of newer lenses.²⁶⁻²⁸ To date, no publications have reported contrast sensitivity results for the TECNIS PureSee IOL using the CSV-1000 chart as in this study. One study comparing the TECNIS PureSee IOL with the TECNIS Eyhance (ICB00) IOL used a different chart (CTS, M&S Technologies) at 1.5, 3, 6, and 12 cpd under photopic and mesopic conditions,^{1,4} finding non-inferior contrast sensitivity outcomes for the TECNIS PureSee IOL. Our study found similar contrast sensitivity values for the TECNIS PureSee IOL within 1 SD of mean normal values for both mesopic and photopic conditions, as indicated by the CSV-1000 chart for the respective age group.²⁹ While these findings suggest preserved contrast sensitivity at three months, the study design did not include a preoperative baseline or a monofocal control group.

Photic phenomena are a crucial factor in assessing IOL performance and patient satisfaction. In our study, we observed low levels of halo and glare among patients using the HGS software, which enables adjustment of size and intensity with visual representation (Table 4 and Figure 1). Using this method, 29% of patients reported no halos and 71% no glare. To our knowledge, this is the first publication describing visual disturbances for the TECNIS PureSee IOL using this software. Previous clinical studies on the TECNIS PureSee IOL employed different assessment methods: Corbett et al used patient questionnaires without visual aids, reporting about 60% of patients experienced no halos and 87% no glare, while Alfonso-Bartolozzi et al used static images without adjustable parameters, finding 90% of patients with no halos and none reporting glare.^{1,2}

It should be considered that the method of evaluation can significantly influence the frequency with which patients report photic phenomena.²⁷ Moreover, the level of subjective disturbance is highly individual and the majority of patients report not being bothered by photic phenomena after successful neuroadaptation.³⁰⁻³² Recent work by Sulaiman et al demonstrates that different assessment methods yield varying results, highlighting that halo and glare simulation softwares provide a reproducible and more objective approach to characterising photic phenomena (such as halo, glare and starbursts) while reducing reliance on subjective recall inherent to questionnaires.³³ Other tools, such as real-time light source halometers, also show promise, underscoring the need for further studies comparing assessment techniques and their correlation with patient-reported outcomes.³³

Functional performance assessed using the DATE questionnaire suggested reduced dependence on spectacles for intermediate and near tasks. As with other patient-reported outcomes in this study, the absence of preoperative baseline measurements limits the ability to attribute functional changes specifically to the IOL rather than to cataract surgery itself.

The strengths of this study include its prospective design with its intention-to-treat approach as well as the use of multiple objective and subjective outcome measures. However, several limitations must be acknowledged. The study lacks a control group, so that outcomes are primarily descriptive. Visual acuity and refractive outcomes were analyzed at the eye level without statistical adjustment for within-subject correlation, which may overestimate precision. The follow-up duration of three months is relatively short for evaluating neuroadaptation, long-term dysphotopsia, and stability of

functional near vision. Accordingly, the results should be interpreted as exploratory and hypothesis-generating. Additional studies comparing the TECNIS PureSee IOL with other EDOF IOLs, along with refractive lens exchange research, could offer valuable complementary insights into its clinical outcomes.

Conclusion

In conclusion, implantation of the TECNIS PureSee IOL was associated with good distance and intermediate visual acuity and functional near visual acuity within the study cohort. Contrast sensitivity measurements remained within the expected physiological range under both mesopic and photopic conditions. Patient-reported outcomes, including dysphotopsia profile, indicated a high level of satisfaction and reduced reliance on spectacles for near and intermediate tasks. As this study did not include a control group, the findings should be interpreted as descriptive and exploratory. Further controlled studies are required to better contextualize these outcomes relative to other IOLs and to assess performance in refractive lens exchange procedures.

Data Sharing Statement

The datasets generated and analyzed during the current study are not publicly available, but individual deidentified participant data are available from the corresponding author on reasonable request.

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Disclosure

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