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European, Multicenter, Prospective, Non-comparative Clinical Evaluation of an Extended Depth of Focus Intraocular Lens

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ABSTRACT

PURPOSE: To evaluate clinical and safety results obtained with an extended depth of focus (EDOF) intraocular lens (IOL).

METHODS: In this European, multicenter, prospective, uncontrolled, interventional study, 77 patients were enrolled in the study, 71 patients received bilateral implantation of the Mini Well Ready EDOF IOL (SIFI S.p.A.), and 68 patients completed the study and were evaluated 2 to 4 months postoperatively. Each clinical examination recorded uncorrected (UDVA) and corrected (CDVA) distance visual acuity, uncorrected (UIVA) and distance-corrected (DCIVA) intermediate visual acuity, and uncorrected (UNVA), distance-corrected (DCNVA), and corrected (CNVA) near visual acuity. A defocus curve from +2.00 to -5.00 diopters (D) was obtained, contrast sensitivity and reading ability were assessed, and the perception of dysphotopsia was evaluated.

RESULTS: Mean binocular visual results showed UDVA, UIVA, and UNVA values of -0.01 ± 0.15, 0.03 ± 0.10, and 0.10 ± 0.11 logMAR, respectively. Mean binocular defocus curve demonstrated a visual acuity of 0.30 logMAR or better from +2.00 to -3.00 D. Mean photopic contrast sensitivity values were 1.86, 2.18, 1,97, 1.51, and 1.17 at 1.5, 3.0, 6.0, 12.0, and 18.0 cycles per degree, respectively. A fluent reading speed of 80 words per minute was reached at 0.5 logRAD by 95.31% of patients without distance correction. The mean halo size was 33.06 ± 14.25, mean halo intensity was 38.00 ± 18.51, mean glare size was 23.85 ± 10.43, and mean glare intensity was 42.23 ± 13.22. One postoperative complication, a moderate photophobia, was observed and classified as related to the lens.

CONCLUSIONS: The Mini Well Ready EDOF IOL provides good visual acuity across various distances and functional reading ability provided at a near range, and delivers an enhanced contrast sensitivity while causing a low incidence of photic phenomena.

[*J Refract Surg*. 2020;36(7):426-434.]

A primary aim of modern cataract surgery and refractive lens exchange is the restoration of sight at all distances. Early multifocal intraocular lens (IOL) designs were bifocal, providing functional visual restoration at far and near distances.[1,2] Recent technological advances in multifocal IOL design aim to improve the patient's intermediate vision, to help in the performance of daily tasks. Trifocal IOLs,[3-5]

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Submitted: December 30, 2019; Accepted: June 2, 2020

Dr. Khoramnia has received grants from AcuFocus, Alcon Laboratories, Inc, Anew, Bausch & Lomb, Contamac, Johnson & Johnson, Kowa, Oculus Optikgeräte, PhysIOL, Presbia, Rayner, Santen, and SIFI, and has received financial support from Alcon Laboratories, Inc, Johnson & Johnson, and SIFI. Dr. Auffarth has received grants from AcuFocus, Alcon Laboratories, Inc, Alimera, Anew, Biotech, Carl Zeiss Meditec AG, Contamac, EyeYon, Glaukos, Hoya, Johnson & Johnson, Kowa, Oculentis/Teleon, Oculus Optikgeräte GmbH, PhysIOL, Rayner, Rheacell, Santan, SIFI, and URSAPHARM GmbH, and is a consultant for Johnson & Johnson. The remaining authors have no financial or proprietary interest in the materials presented herein.

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doi:10.3928/1081597X-20200603-01

extended depth of focus (EDOF) lenses,[6-8] and low-add bifocal IOLs[9,10] are all reported to enhance vision successfully at intermediate distances. However, the diffractive-refractive optic designs are associated with optical side effects such as incidence of halo and glare that may debilitate the visual quality.[11]

The Mini Well Ready (SIFI S.p.A.) is a new type of EDOF IOL that is "wavefront engineered." In contrast to conventional diffractive-refractive multifocal lenses, it uses spherical aberrations to increase the depth of focus, ensuring continuous and progressive (from far to near) vision while minimizing the perception of optical side effects.

We evaluated the visual performance of the Mini Well Ready IOL in qualitative and quantitative terms of progressive vision and assessed its safety in patients undergoing cataract surgery or refractive lens exchange.

PATIENTS AND METHODS

Five sites participated in this prospective, interventional, uncontrolled, multicenter European trial (Clinicaltrials.gov NCT02838004): Ruprecht-Karls-Universitats-Augenklinik Heidelberg, Heidelberg, Germany (GUA, RK, HSS); Oculus Eye Clinic Bucharest, Bucharest, Romania (OM); Prof. Dr. Munteanu Ophthalmology Center, Timisoara, Romania (MM); Clinica Oculistica, Azienda Sanitaria Universitaria Integrata di Trieste Ospedale Maggiore, Trieste, Italy (DT); and Ospedale Mater Salutis di Legnago, Legnago, Italy (PB). The study was conducted in compliance with the protocol, principles of the Declaration of Helsinki, Good Clinical Practices, and International Organization for Standardization (ISO) 14155:2011. All patients received information on cataract surgery and Mini Well Ready lenses and signed an informed consent before being included in the study. The inclusion criteria were as follows: any gender and age older than 18 years; patients had a conventional phacoemulsification or femtosecond laser procedure; and patients were willing to have surgery in both eyes in a short period of time (within 2 weeks). The exclusion criteria were as follows: previous corneal surgery; eye diseases likely to limit postoperative visual acuity to worse than 20/40 Snellen; pseudoexfoliation; abnormal pupil size and position; contact lens use 30 days before the preoperative visit; corneal warpage; and predicted postoperative corneal astigmatism greater than 1.00 diopter (D).

IOL AND SURGICAL TECHNIQUE

The Mini Well Ready is a one-piece, preloaded, aspheric IOL that provides an extended depth of focus by inducing an appropriate spherical aberration at the pupil's center while controlling higher order aberrations (HOAs) at the pupil's periphery (**Figure A**, available in the online version of this article). There are three annular, optical zones: an outer monofocal zone and two inner zones with spherical aberrations of opposite signs and an equivalent addition of +3.00 D, corresponding to an addition of +2.40 D at the spectacle plane. It has four closed-loop haptics angulated 5° with an optic diameter of 6 mm and an overall diameter of 10.75 mm.

The lens is made of a hydrophilic-hydrophobic acrylic material with 25% water content and has a chromophore that filters ultraviolet radiation. The refractive index is 1.46 at 35 °C. The IOL is commercially available in power ranges from 0.00 to 30.00 D.

The Hoffer Q formula was used for axial lengths of 22 mm or less; the SRK/T or Holladay I or Hoffer Q formula was used for axial lengths greater than 22 mm to 24.5 mm or less; and the SRK/T formula was used for axial lengths greater than 24.6 mm. The targeted refraction for emmetropia was used in IOL power calculations (Haigis = 15 eyes, Hoffer Q = 14 eyes, Holladay 1 = 25 eyes, SRK/T = 82 eyes).

Standard cataract surgical procedures were used at all sites and optimized to each investigator's experience and routine surgical practice. Generally, phacoemulsification and IOL implantation were performed through a temporal near-to-clear corneal incision of approximately 2.2 mm, under topical and intracameral anesthesia (1% preservative-free lidocaine). At the principal investigator's (GUA) site, a clear corneal incision was made at the 12-o'clock position, followed by a manual curvilinear or a femtosecond laser–assisted capsulorhexis. The Mini Well Ready IOL was implanted into the capsular bag using the preloaded Accuject injector system (Medicel AG).

PREOPERATIVE AND POSTOPERATIVE ASSESSMENTS

All patients underwent comprehensive preoperative examination of ocular biometry evaluated using partial coherence interferometry (PCI) (IOLMaster; Carl Zeiss Meditec AG) and optical low-coherence interferometry (OLCI) (Aladdin; Topcon).

Patients were evaluated 2 to 4 months after surgery for manifest refraction, monocular and binocular uncorrected (UDVA) and corrected (CDVA) distance visual acuity, uncorrected (UIVA) and distance-corrected (DCIVA) intermediate visual acuity at 80 cm, and uncorrected (UNVA), distance-corrected (DCNVA), and corrected (CNVA) near visual acuity at 40 cm. The visual acuity was tested with Early Treatment Diabetic Retinopathy Study (ETDRS) (Precision Vision) charts under photopic conditions.

Binocular defocus curve was investigated, under photopic conditions, by assessing the binocular vi-

sual acuity at 4 m with steps of 0.50 D (from +2.00 to -5.00 D). Defocus curves of patients with short axial length (< 23.5 mm) were compared to defocus curves of patients with long axial lengths (> 23.5 mm). Defocus curves of patients with low anterior corneal radius/steep keratometry (> 43.50 D) were compared to defocus curves of patients with high anterior corneal radius/flat keratometry (< 43.50 D).

Binocular distance-corrected contrast sensitivity function under photopic conditions (85 candelas [cd]/m^2) was evaluated with the Yang Smart (SIFI S.p.A.) at 3 m. Binocular reading performance was assessed with and without distance correction at 40 cm using the Radner Reading Charts. The Radner Reading Charts use sentence optotypes that take into account the characteristics of each language and are logarithmically scaled in logRAD units, which is the reading equivalent of logMAR units. Halos and glare were evaluated with the Halos and Glare Simulator (Eyeland-Design Network GmbH), which allows the patient to classify the halo perceived into three types: H1 (diffuse halo ring), H2 (starburst type), and H3 (distinct halo ring), and the glare into two types: G1 (diffuse glare) and G2 (irregularly shaped glare). The patient can adjust the size and intensity of both halo and glare from 0 (none) to 100 (extremely disturbing).

Quality of life and vision were evaluated using the National Eye Institute Visual Functioning Questionnaire 25 (NEI VFQ-25) (**Table A**, available in the online version of this article). The patient satisfaction, subjective perception of visual disturbances, light dependence, and spectacles required for far, intermediate, and near vision were evaluated using the Revised Heidelberg Daily Task Evaluation (DATE) questionnaire.[12]

Safety was assessed through summary of adverse events and compliance with study treatment. Events were summarized by system organ class for the following: all adverse events, all serious adverse events, events judged to be related to study treatment, and events leading to discontinuation of study treatment. The severity of adverse events was classified as mild (awareness of a sign or symptom that does not interfere with the patient's activity or is transient and is resolved without treatment or sequelae), moderate (may interfere with the patient's activity and require additional intervention and/or treatment, and may have additional sequelae), and severe (significant discomfort to the patient and/or interferes with the patient's activity; additional intervention and/or treatment are necessary; additional sequelae occur).

Statistical Analysis

Statistical analysis was performed using the free software R version 3.5 (https://www.r-project.org). All statistical methods are basic descriptive analyses. Mean, median, and standard deviation were obtained for continuous variables, whereas frequency and percentage were obtained for discrete variables. All hypothesis tests were two sided. All statistical tests were performed at a 5% significance level ($P < .05$).

Sample Size Calculation

In the medical literature,[13] the mean binocular UDVA at month 4 of other presbyopia-correcting IOLs was -0.053 ± 0.104 logMAR. Considering a power of 80% and an alpha level of 0.05, and under the hypothesis of a minimum clinical acceptable difference of 0.037 logMAR with previously published data (a difference of 9% in logMAR) and a common standard deviation of ±0.104, a sample size of 64 evaluable patients has been calculated. Considering a drop-out rate of 15%, at least 76 patients should have been enrolled in the study (one group *t* test that a mean equals user-specified value, nQuery Advisor 4.0).

RESULTS

Seventy-seven patients were enrolled in the study. Three patients withdrew their consent before the surgery and were excluded from the study. There were three drop-outs after the IOL implantation in the first eye and another three patients were lost to follow-up after the second eye implantation. Sixty-eight patients (136 eyes; 24 men and 44 women) completed the study and were evaluated for effectiveness at the final visit performed 2 to 4 months postoperatively. Sixty-six patients underwent conventional cataract surgery and 2 patients received femtosecond laser–assisted surgery. A summary of the demographic data and preoperative ophthalmological examinations is presented in **Table 1**.

Visual Acuity Outcome

Table B (available in the online version of this article) summarizes the results of mean monocular and binocular visual acuity (distance, intermediate, and near) at 2 to 4 months postoperatively.

The threshold of 20/40 Snellen (0.30 logMAR) was reached by 96.32% of patients for monocular UDVA, 100% of patients for monocular CDVA, 97.06% of patients for binocular UDVA, and 100% of patients for binocular CDVA (**Figures 1A-1B**). Results of intermediate vision acuity showed that the 20/40 Snellen threshold was reached by 98.48% of patients for monocular UIVA, 97.73% of patients for monocular DCIVA, and all patients (100%) for binocular UIVA and DCIVA. The percentages of patients reaching a monocular near visual acuity of 20/40 Snellen were 83.33% (UNVA),

TABLE 1

Main Demographic and Preoperative Characteristics of the Sample

Parameter	N (%)	Mean	SD	Median	Min	Max
Gender						
Female	44 (64.71)					
Male	24 (35.29)					
Age (y)						
Female		68.25	8.51	69.50	48	83
Male		67.83	11.07	71.50	46	83
Keratometry (D)						
K1	136	43.27	1.65	43.28	39.87	48.35
K2	136	43.94	1.63	43.93	40.24	49.34
K average	136	43.61	1.63	43.59	40.12	48.85
Astigmatism	136	-0.67	0.37	-0.62	-1.80	0.00
Ocular biometry (mm)						
Anterior chamber depth	136	3.02	0.34	3.04	2.21	3.85
Axial length	136	23.24	0.85	23.25	21.24	25.69
Aberrometry and corneal asphericity (μm)						
Spherical aberration 5 mm	133	0.11	0.20	0.18	-1.71	0.68
Coma 5 mm	133	0.22	0.29	0.17	-0.23	2.34
Q-value 6 mm	101	-0.31	0.16	-0.31	-0.74	0.27
Target refraction (D)						
Expected target refractive error	136	-0.10	0.14	-0.08	-0.56	0.44
IOL (D)						
Dioptric power	136	22.17	2.18	22.00	17.00	29.00

SD = standard deviation; D = diopters; K1 = steep keratometry; K2 = flat keratometry; IOL = intraocular lens

97.73% (CNVA), and 84.09% (DCNVA); for binocular near visual acuity, the percentages were 95.59% (UNVA), 100% (CNVA), and 96.97% (DCNVA).

Monocular subjective best near and intermediate distances are shown in **Figure 2**. Mean subjective best near and intermediate distances were 45 ± 9 cm (range: 30 to 80 cm) and 68 ± 10 cm (range: 40 to 100 cm), respectively.

Refractive Outcome

Refraction results are shown in **Figures 1C-1D**. The almost bell-shaped histogram with a slight deviation from the 0.00 D emmetropic target (**Figure 1C**) shows the accuracy of the spherical equivalent to the intended target. Most of the data range from -0.14 to -0.50 D, which is close to the mean attempted spherical equivalent target of the study (-0.10 D). **Figure 1D** shows that most eyes (91%) had a refractive cylinder in the range of 0.26 to 1.00 D postoperatively. A small percentage of eyes (9%) had postoperative astigmatism in the range of 1.01 to 2.00 D.

Regarding refractive predictability, presented as the percentage of eyes reaching a specific postoperative spherical equivalent, only 16.18% (22 eyes of 136) had a postoperative spherical equivalent of greater than 0.75 D.

Defocus Curve

Figure 3 shows binocular defocus curves at 4 m, described through a graph of visual acuity (logMAR) versus diopters of defocus measured using optical corrections from +2.00 to -5.00 D. Defocus curve revealed that the best performance (better than 0.00 logMAR), was reached at the border of far and intermediate vision (0.00 to -1.00 D).

Defocus curves in relation to patients' axial length and keratometry are shown in **Figure B** (available in the online version of this article).

Halos and Contrast Sensitivity

Halos were reported after direct questioning by 17 patients (25%) and glare by 13 patients (19%) (**Table C**, available in the online version of this article). The analysis with the Halo and Glare Simulator revealed a mean halo size of 33.06 ± 14.25 and mean halo intensity of 38.00 ± 10.43. Mean glare size was 23.85 ±

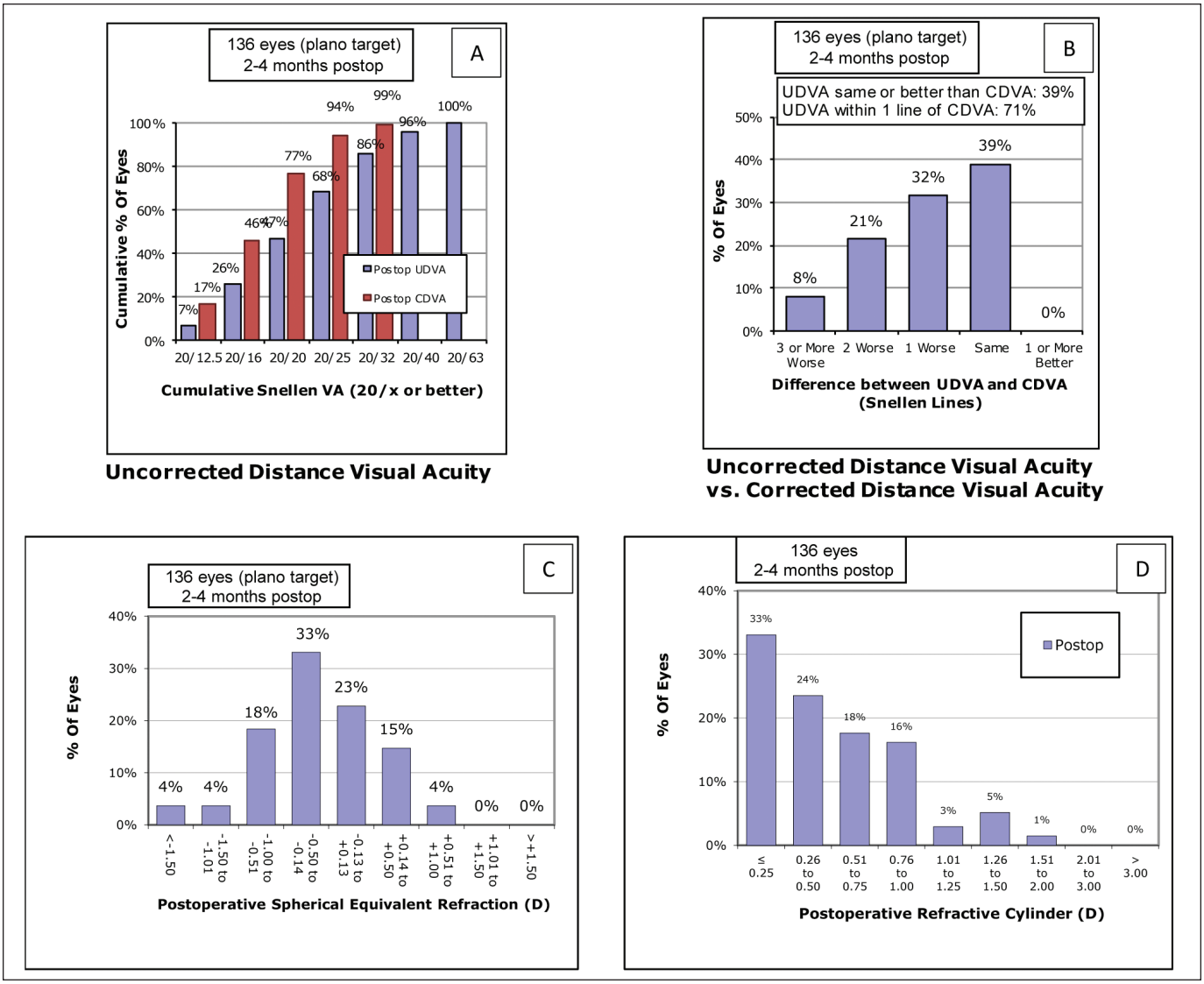

Figure 1. Refractive outcomes 2 to 4 months following cataract surgery. (A) Postoperative uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA). (B) Differences between UDVA and CDVA. (C) Postoperative spherical equivalent refractive accuracy in diopters (D). (D) Postoperative refractive cylinder values (D).

10.43 and mean glare intensity was 42.23 ± 13.22. Halos were classified as H1 in 58.82%, H2 in 29.41%, and H3 in 11.77% of eyes, whereas only G1 glare type (100%) was manifested by the above-mentioned 13 patients. Fifty-one patients (75%) did not report any presence of halos 2 to 4 months after the eye surgeries.

The results of photopic contrast sensitivity testing are shown in **Figure 4**.

Reading Performance

A minimum accepted speed for fluent reading of 80 wpm was reached at 0.5 logRAD by 95.31% of the patients without correction for distance and by 93.44% with distance correction. A total of 68.75% of patients uncorrected for distance and 63.93% with distance correction were able to read fluently at 0.3 logRAD. Mean reading speed was 129 ± 35 wpm (uncorrected) and 127 ± 34 wpm (distance-corrected) at 0.5 logRAD, and 93 ± 42 wpm (uncorrected) and 90 ± 46 wpm (distance-corrected) at 0.3 logRAD (**Figure 5**).

Patient Satisfaction

Two quality of life type questionnaires were used to measure patients' satisfaction with the outcome of the IOL implantation. The NEI VFQ-25 revealed a high satisfaction global score of 92.15 (out of 100) (**Table 2**). The Glasses Independence Questionnaire (Revised Date) showed that 85.29% of the study participants were fully satisfied with the outcome of their IOL im-

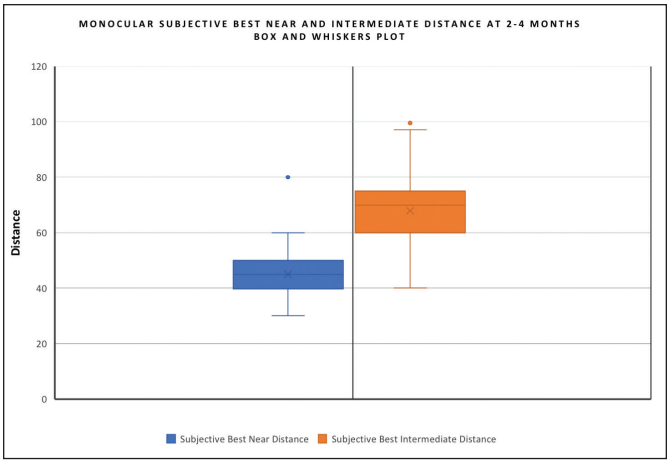

Figure 2. Monocular subjective best distance for near and intermediate vision (cm).

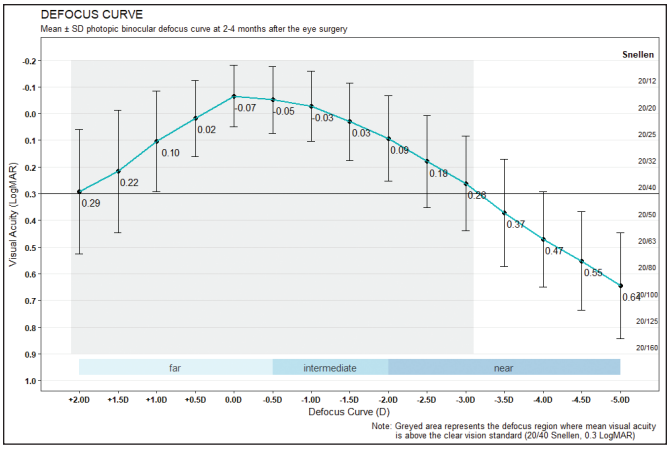

Figure 3. Mean binocular defocus curves at 2 to 4 months after surgery. D = diopters

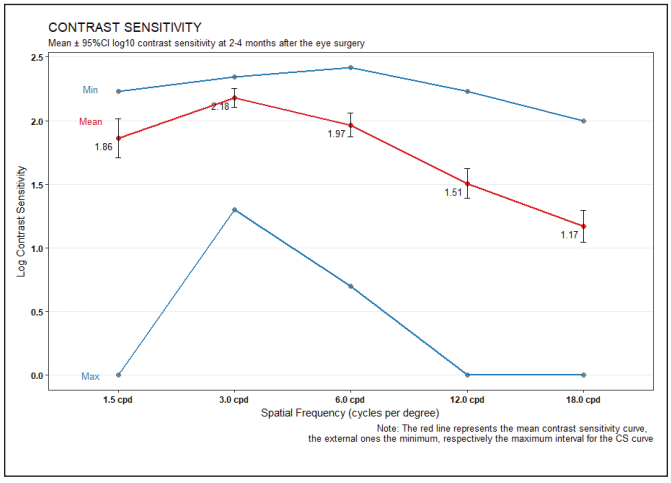

Figure 4. Mean contrast sensitivity outcomes under photopic conditions, curve with mean ± standard deviation and $Log_{10}CS$ values.

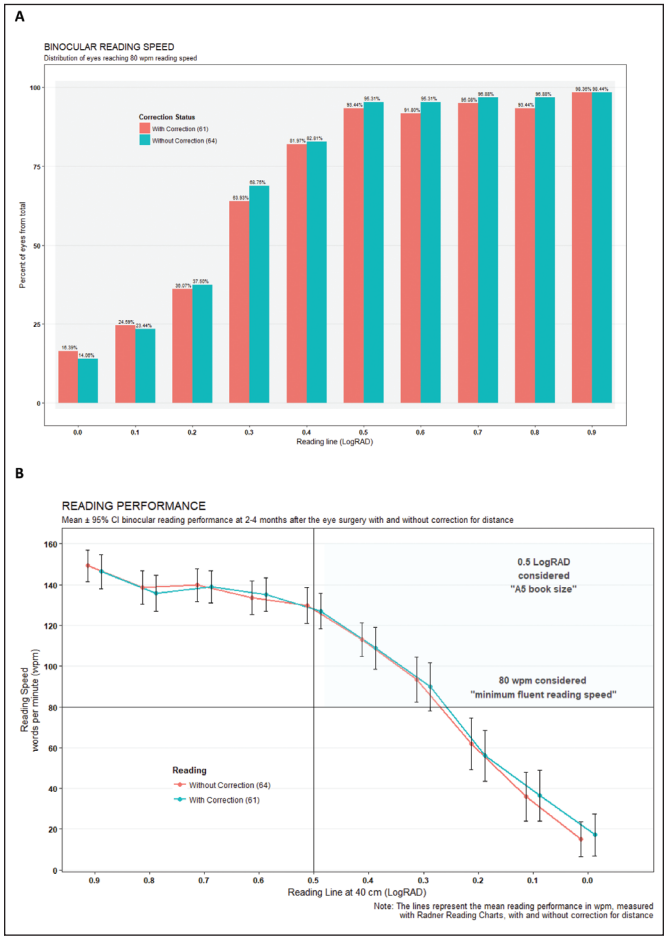

Figure 5. (A) Distribution of eyes reaching a reading speed of 80 words per minute (wpm) or greater. (B) "Trade-off" graphic between fluent reading speed (higher than 80 wpm) and A5 book character size (less than 0.50 diopters [D] logRAD) (Radner Reading Chart, Precision Vision).

plantations (**Figure C**, available in the online version of this article).

Safety

Seventy-four patients were analyzed for safety during the study and for 2 to 4 months after surgery. Two intraocular pressure values above the normal ranges were recorded as adverse events and were considered mild and not device related (data not shown). There were 6 adverse device effects; 5 of these were classified as intraoperative complications (intensity mild for 2 cases and moderate for 3) and consisted of IOLs that got stuck in the injector during the lens injection. There was an adverse device effect of moderate photophobia (light sensitivity) that was classified as the only postoperative complication related to the lens. No cases of posterior capsule opacification or posterior capsulotomies were reported in the study. Besides that, no patients required an IOL explantation.

Discussion

Numerous studies have assessed the clinical outcomes of different EDOF IOLs, but most of these have

TABLE 2
NEI VFQ-25 Mean Scores

Parameter	Score
Global score	92.2
General health	73.3
General vision	85.7
Ocular pain	89.9
Near vision	92.6
Distance vision	93.9
Social functioning	97.9
Mental health	92.2
Role limitation	97.7
Dependency	98.8
Color vision	98.1
Peripheral vision	94.3

NEI VFQ-25 = National Eye Institute Visual Functioning Questionnaire 25

concerned the evaluation of the visual performance of the Symfony IOL (J&J Vision). Cochener et al[14] observed mean binocular UDVA, UIVA (at 70 cm), and UNVA (at 40 cm) values of 0.03 ± 0.09, 0.13 ± 0.16, and 0.21 ± 0.16 logMAR, respectively (598 eyes in the non-monovision group, 4- to 6-month follow-up). Similarly, Ruiz-Mesa et al[15] reported mean binocular UDVA, UIVA (at 60 cm), and UNVA (at 40 cm) values of 0.01 ± 0.02, 0.09 ± 0.08, and 0.17 ± 0.06 logMAR, respectively (40 eyes, 1-year follow-up), whereas Pedrotti et al[16] found mean monocular UDVA, UIVA (60 cm), and UNVA (at 40 cm) values of 0.08 ± 0.12, 0.24 ± 0.11, and 0.27 ± 0.11 logMAR, respectively (50 eyes, 3-month follow-up). Dick et al[17] also studied the clinical performance of the IC-8 EDOF IOL (AcuFocus) and noted mean binocular UDVA, UIVA (at 67 cm), and UNVA (at 40 cm) values of 0.06 ± 0.05, 0.00 ± 0.16, and 0.04 ± 0.11 logMAR, respectively (12 eyes in the bilateral group, 6-month follow-up).[17] In a recent study, Giers et al[18] reported the functional results of the MiniWell Ready IOL and observed median postoperative UDVA, UIVA (at 80 cm), and UNVA (at 40 cm) values of 0.13 logMAR (range: -0.08 to 0.42 logMAR), -0.05 logMAR (range: -0.18 to 0.58 logMAR), and 0.14 logMAR (range: -0.10 to 0.64 logMAR), respectively (28 bilateral implantations, up to 4 months of follow-up).

The clinical outcomes obtained in this study were comparable to the results observed in the aforementioned studies. The bilateral implantation of the Mini Well Ready IOL not only led to good visual restoration at far and near (at 40 cm) distances with mean binocular UDVA and UNVA values of -0.01 ± 0.15 and 0.10 ± 0.11 logMAR, respectively, but it also provided functional intermediate (at 80 cm) visual performance with a mean binocular UIVA value of 0.03 ± 0.10 logMAR. Overall, a binocular UDVA of 0.30 logMAR or better was reached by 97.06% of patients, a binocular UIVA of 0.30 logMAR or better in 100% of patients, and a binocular UNVA of 0.30 logMAR or better in 95.59% of patients. The mean binocular defocus curve also confirmed this visual outcome, with a visual acuity of 0.30 logMAR or better measured from +2.00 to -3.00 D.

The differences in the recorded visual acuity values between various studies evaluating the different EDOF lenses may be ascribable to the differences in the distances at which the intermediate and near visual outcomes were measured and the differences in the studied IOLs' optical principles. The Symfony IOL features a diffractive-refractive optic on its posterior surface with concentrically aligned diffractive steps that determine the allocation of incident light energy,[14] whereas the IC-8 lens uses the optical effect of a pinhole to extend the range of vision.[8] In contrast, the Mini Well Ready IOL design exploits the wavefront aberrations to provide a continuum of foci: positive and negative spherical aberrations are induced in the optical center to allow for intermediate and near vision, respectively, whereas the outermost zone is designed to control the higher order aberrations and provide distance vision.

Such an innovative optic design also led to low perception of photic phenomena, a complication commonly seen after implantation of multifocal IOLs[19,20] that can lead to considerable patient dissatisfaction.[11] In our study, we observed that only 17 (25%) and 13 (19%) patients reported experiencing halo and glare, respectively, in daily life. Among these patients, the mean halo size and intensity values were 33.06 ± 14.25 and 38.00 ± 18.51, respectively, and mean glare size and intensity values were 23.85 ± 10.43 and 42.23 ± 13.22, respectively. Currently, a direct subjective comparison of photic phenomena cannot be made among different studies because there is no standardized means of measurement for evaluation of such optical side effects. To the authors' knowledge, only one other study used the same Halo and Glare Simulator, which observed higher levels of dysphotopsia after implantation of a diffractive, trifocal toric AT LISA Tri toric 939MP IOL (Carl Zeiss Meditec AG), with mean halo size and intensity values of 50.67 ± 15.69 and 54.89 ± 17.86, respectively, and mean glare size and intensity values of 39.67 ± 3.51 and 44.67 ± 15.01, respectively.[21]

Reduced retinal image contrast is another complication that is often associated with the intrinsic optical properties of multifocal IOLs.[22,23] Generally, the sine wave contrast sensitivity is used to quantify and compare the patients' contrast vision.[23] Haughom et al[24] de-

fined the normal range of photopic binocular contrast sensitivity values (in logCS) in healthy individuals as 1.75 ± 0.16, 2.01 ± 0.13, 2.18 ± 0.10, 1.83 ± 0.21, and 1.55 ± 0.23 for 1.5, 3, 6, 12, and 18 cpd, respectively. Mencucci et al[25] evaluated the photopic contrast sensitivity results of the Symfony IOL compared to two diffractive trifocal IOLs (PanOptix, Alcon Laboratories, Inc; and AT LISA Tri 839MP, Carl Zeiss Meditec AG), and found statistically significantly superior performance with the EDOF lens, with mean logCS values of 1.70, 1.72, 1.73, 1.33, and 0.77 at 1.5, 3, 6, 12, and 18 cpd, respectively. Our results also showed that the Mini Well Ready IOL is able to provide enhanced contrast sensitivity, with mean logCS values of 1.86, 2.18, 1,97, 1.51, and 1.17 at 1.5, 3, 6, 12, and 18 cpd, respectively.

When evaluating the visual performance, it is also crucial to assess the postoperative reading acuity because this measure better reflects the patients' actual reading ability in daily life. The reading acuity is often slightly worse than the visual acuity measured at the same distance because patients may skip letters or even read a smaller letter size when reading the ETDRS optotypes.[6] In contrast, when reading sentences, every word that is difficult to read impairs the overall reading performance, slowing down the reading speed. In general, text read at a speed of at least 80 words per minute is considered to be read with ease.[26,27] Previous studies have found slower reading speed with refractive multifocal lenses than with diffractive ones,[28,29] most likely owing to the pupil dependency of the former.[30] Our reading acuity results were in agreement with the excellent near visual acuity results obtained, with 95.31% of patients reading without distance correction (at 40 cm) at a speed of at least 80 words per minute at a 0.5 logRAD print size, equivalent to A5 book size.

In terms of quality of life, the NEI VFQ-25 resulted in a global score of 92.15 (out of 100) and The Glasses Independence Questionnaire showed that 85.29% of patients were fully satisfied with the visual outcomes of this IOL.

The bilateral implantation of the Mini Well Ready EDOF IOL is an effective treatment solution for the correction of presbyopia, with good visual acuity across various distances and functional reading ability provided at a near range. The innovative multifocal optic design, one that does not rely on a conventional diffractive-refractive optic, also led to a low incidence of photic phenomena and an enhanced contrast sensitivity.

AUTHOR CONTRIBUTIONS

Study concept and design (GUA, MM, DT, RB, RK); data collection (GUA, OM, MM, DT, PB, RK, HSS); analysis and interpretation of data (GUA, RK); writing the manuscript (HSS); critical revision of the manuscript (GUA, OM, MM, DT, PB, RB, RK); administrative, technical, or material support (GUA); supervision (GUA, RB)

REFERENCES

1. Calladine D, Evans JR, Shah S, Leyland M. Multifocal versus monofocal intraocular lenses after cataract extraction. *Cochrane Database Syst Rev*. 2012;12(9):CD003169. doi:10.1002/14651858.CD003169.pub3
2. Leyland M, Zinicola E. Multifocal versus monofocal intraocular lenses in cataract surgery: a systematic review. *Ophthalmology*. 2003;110(9):1789-1798. doi:10.1016/S0161-6420(03)00722-X
3. Attia MS, Auffarth GU, Khoramnia R, Linz K, Kretz FT. Near and intermediate reading performance of a diffractive trifocal intraocular lens using a reading desk. *J Cataract Refract Surg*. 2015;41(12):2707-2714. doi:10.1016/j.jcrs.2015.06.038
4. Cochener B, Vryghem J, Rozot P, et al. Clinical outcomes with a trifocal intraocular lens: a multicenter study. *J Refract Surg*. 2014;30(11):762-768. doi:10.3928/1081597X-20141021-08
5. Gundersen KG, Potvin R. Trifocal intraocular lenses: a comparison of the visual performance and quality of vision provided by two different lens designs. *Clin Ophthalmol*. 2017;11(11):1081-1087. doi:10.2147/OPTH.S136164
6. Attia MSA, Auffarth GU, Kretz FTA, et al. Clinical evaluation of an extended depth of focus intraocular lens with the Salzburg Reading Desk. *J Refract Surg*. 2017;33(10):664-669. doi:10.3928/1081597X-20170621-08
7. Akella SS, Juthani VV. Extended depth of focus intraocular lenses for presbyopia. *Curr Opin Ophthalmol*. 2018;29(4):318-322. doi:10.1097/ICU.0000000000000490
8. Dick HB, Piovella M, Vukich J, Vilupuru S, Lin L; Clinical Investigators. Prospective multicenter trial of a small-aperture intraocular lens in cataract surgery. *J Cataract Refract Surg*. 2017;43(7):956-968. doi:10.1016/j.jcrs.2017.04.038
9. Linz K, Attia MS, Khoramnia R, Tandogan T, Kretz FT, Auffarth GU. Clinical evaluation of reading performance using the Salzburg Reading Desk with a refractive rotational asymmetric multifocal intraocular lens. *J Refract Surg*. 2016;32(8):526-532. doi:10.3928/1081597X-20160603-02
10. Thomas BC, Auffarth GU, Philips R, et al. Clinical results after implantation of a new segmental refractive multifocal intraocular lens. *Ophthalmologe*. 2013;110(11):1058-1062. doi:10.1007/s00347-013-2810-5
11. Woodward MA, Randleman JB, Stulting RD. Dissatisfaction after multifocal intraocular lens implantation. *J Cataract Refract Surg*. 2009;35(6):992-997. doi:10.1016/j.jcrs.2009.01.031
12. Kretz FT, Son H, Liebing S, Tandogan T, Auffarth GU. Impact of an aspherical aberration correcting monofocal intraocular lens on patient satisfaction for daily life activities: the Heidelberg Daily Task Evaluation (DATE) questionnaire. *Klin Monbl Augenheilkd*. 2015;232(8):940-946.
13. Pepose JS, Qazi MA, Chu R, Stahl J. A prospective randomized clinical evaluation of 3 presbyopia-correcting intraocular lenses after cataract extraction. *Am J Ophthalmol*. 2014;158(3):436-46.e1. doi:10.1016/j.ajo.2014.06.003
14. Cochener B; Concerto Study Group. Clinical outcomes of a new extended range of vision intraocular lens: International Multicenter Concerto Study. *J Cataract Refract Surg*. 2016;42(9):1268-1275. doi:10.1016/j.jcrs.2016.06.033
15. Ruiz-Mesa R, Abengózar-Vela A, Aramburu A, Ruiz-Santos M. Comparison of visual outcomes after bilateral implantation of

extended range of vision and trifocal intraocular lenses. *Eur J Ophthalmol*. 2017;27(4):460-465. doi:10.5301/ejo.5000935

16. Pedrotti E, Bruni E, Bonacci E, Badalamenti R, Mastropasqua R, Marchini G. Comparative analysis of the clinical outcomes with a monofocal and an extended range of vision intraocular lens. *J Refract Surg*. 2016;32(7):436-442. doi:10.3928/1081597X-20160428-06
17. Dick HB, Elling M, Schultz T. Binocular and monocular implantation of small-aperture intraocular lenses in cataract surgery. *J Refract Surg*. 2018;34(9):629-631. doi:10.3928/1081597X-20180716-02
18. Giers BC, Khoramnia R, Varadi D, et al. Functional results and photic phenomena with new extended-depth-of-focus intraocular lens. *BMC Ophthalmol*. 2019;19(1):197. doi:10.1186/s12886-019-1201-3
19. Alba-Bueno F, Vega F, Millán MS. Halos and multifocal intraocular lenses: origin and interpretation. *Arch Soc Esp Oftalmol*. 2014;89(10):397-404. doi:10.1016/j.oftal.2014.01.002
20. Vega F, Alba-Bueno F, Millán MS, Varón C, Gil MA, Buil JA. Halo and through-focus performance of four diffractive multifocal intraocular lenses. *Invest Ophthalmol Vis Sci*. 2015;56(6):3967-3975. doi:10.1167/iovs.15-16600
21. Kretz FTA, Breyer D, Klabe K, et al. Clinical outcomes after implantation of a trifocal toric intraocular lens. *J Refract Surg*. 2015;31(8):504-510. doi:10.3928/1081597X-20150622-01
22. Williamson W, Poirier L, Coulon P, Verin P. Compared optical performances of multifocal and monofocal intraocular lenses (contrast sensitivity and dynamic visual acuity). *Br J Ophthalmol*. 1994;78(4):249-251. doi:10.1136/bjo.78.4.249
23. Eppig T, Filser E, Goeppert H, Schroeder AC, Seitz B, Langenbucher A. Index of contrast sensitivity (ICS) in pseudophakic eyes with different intraocular lens designs. *Acta Ophthalmol*. 2015;93(3):e181-e187. doi:10.1111/aos.12538
24. Haughom B, Strand TE. Sine wave mesopic contrast sensitivity—defining the normal range in a young population. *Acta Ophthalmol*. 2013;91(2):176-182. doi:10.1111/j.1755-3768.2011.02323.x
25. Mencucci R, Favuzza E, Caporossi O, Savastano A, Rizzo S. Comparative analysis of visual outcomes, reading skills, contrast sensitivity, and patient satisfaction with two models of trifocal diffractive intraocular lenses and an extended range of vision intraocular lens. *Graefes Arch Clin Exp Ophthalmol*. 2018;256(10):1913-1922. doi:10.1007/s00417-018-4052-3
26. Dexl AK, Seyeddain O, Riha W, et al. Reading performance after implantation of a modified corneal inlay design for the surgical correction of presbyopia: 1-year follow-up. *Am J Ophthalmol*. 2012;153(5):994-1001.e2. doi:10.1016/j.ajo.2011.08.044
27. Whittaker SG, Lovie-Kitchin J. Visual requirements for reading. *Optom Vis Sci*. 1993;70(1):54-65. doi:10.1097/00006324-199301000-00010
28. Hütz WW, Eckhardt HB, Röhrig B, Grolmus R. Intermediate vision and reading speed with array, Tecnis, and ReSTOR intraocular lenses. *J Refract Surg*. 2008;24(3):251-256. doi:10.3928/1081597X-20080301-06
29. Alió JL, Grabner G, Plaza-Puche AB, et al. Postoperative bilateral reading performance with 4 intraocular lens models: six-month results. *J Cataract Refract Surg*. 2011;37(5):842-852. doi:10.1016/j.jcrs.2010.11.039
30. Kawamorita T, Uozato H, Aizawa D, Kamiya K, Shimizu K. Optical performance in rezoom and array multifocal intraocular lenses in vitro. *J Refract Surg*. 2009;25(5):467-469. doi:10.3928/1081597X-20090422-10

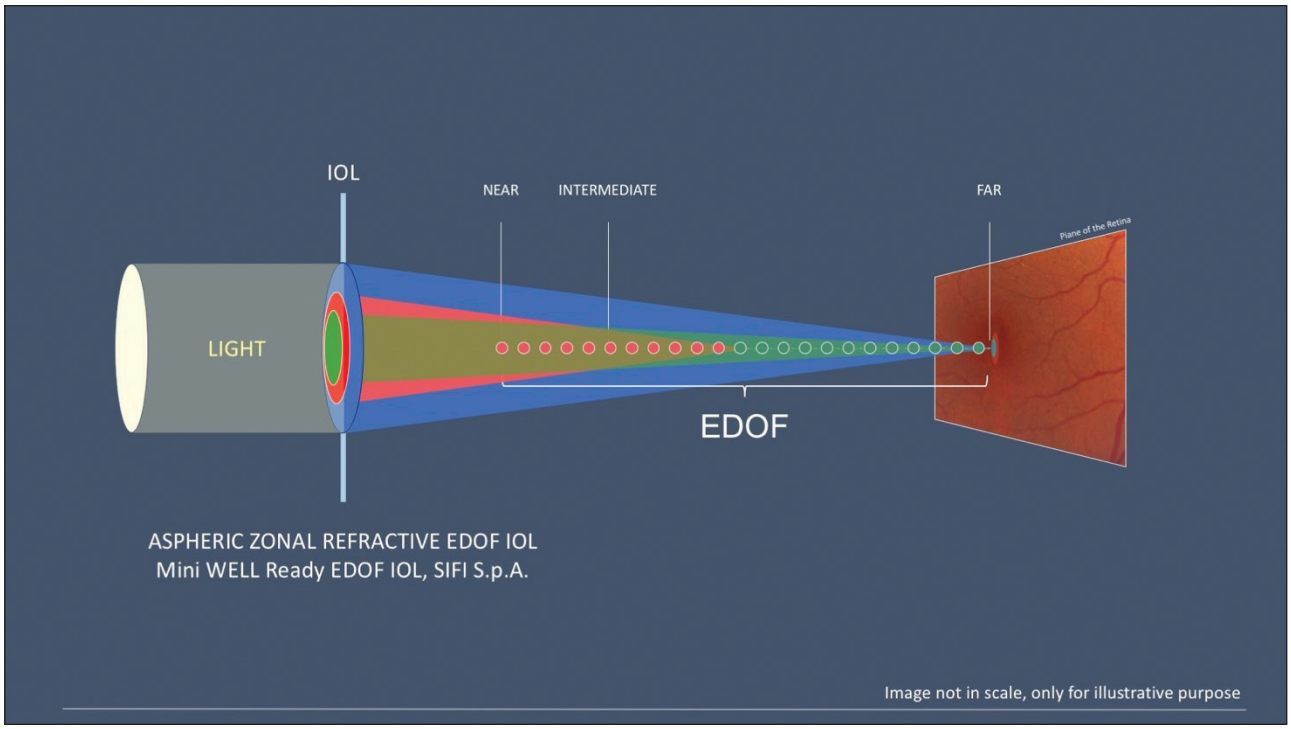

Figure A. Schematic illustration of the Mini Well Ready extended depth of focus (EDOF) intraocular lens (IOL). Image provided courtesy of Dr. Zuppardo.

TABLE A

Averaging of Items to Generate NEI VFQ-25+ Optional Items Subscales

Scale	No. of Items	Maximum
General Health	2	1, A1
General Vision	2	2, A2
Ocular Pain	2	4, 19
Near Activities	6	5, 6, 7, A3, A4, A5
Distance Activities	6	8, 9, 14, A6, A7, A8
Vision Specific		
Social Functioning	3	11, 13, A9
Mental Health	5	3, 21, 22, 25, A12
Role Difficulties	4	17, 18, A11a, A11b
Dependency	4	20, 23, 24, A13
Driving	3	15c, 16, 16a
Color Vision	1	12
Peripheral Vision	1	10

NEI VFQ-25 = National Eye Institute Visual Functioning Questionnaire 25

TABLE B

Summary of VA (logMAR) Measurement

Scale	N	Mean	SD	Median	Min	Max
Distance						
UDVA						
Monocular (OD + OS)	136	0.06	0.15	0.07	-0.20	0.50
Binocular (OU)	68	-0.01	0.15	0.00	-0.20	0.38
CDVA						
Monocular (OD + OS)	136	-0.05	0.11	-0.04	-0.20	0.22
Binocular (OU)	68	-0.08	0.11	-0.10	-0.22	0.18
Intermediate						
UIVA						
Monocular (OD + OS)	132	0.09	0.11	0.10	-0.20	0.40
Binocular (OU)	67	0.03	0.10	0.02	-0.20	0.40
DCIVA						
Monocular (OD + OS)	132	0.06	0.12	0.02	-0.24	0.40
Binocular (OU)	66	0.01	0.11	0.00	-0.20	0.30
Near						
UNVA						
Monocular (OD + OS)	132	0.18	0.14	0.18	-0.08	0.60
Binocular (OU)	68	0.10	0.11	0.10	-0.20	0.40
CNVA						
Monocular (OD + OS)	132	0.00	0.12	0.00	-0.20	0.50
Binocular (OU)	67	-0.01	0.09	0.00	-0.28	0.20
DCNVA						
Monocular (OD + OS)	132	0.18	0.14	0.20	-0.10	0.50
Binocular (OU)	66	0.12	0.11	0.10	-0.20	0.50

VA = visual acuity; SD = standard deviation; UDVA = uncorrected distance visual acuity; OD = right eye; OS = left eye; OU = both eyes; CDVA = corrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; DCIVA = distance corrected intermediate visual acuity; UNVA = uncorrected near visual acuity; CNVA = corrected near visual acuity; DCNVA = distance-corrected near visual acuity

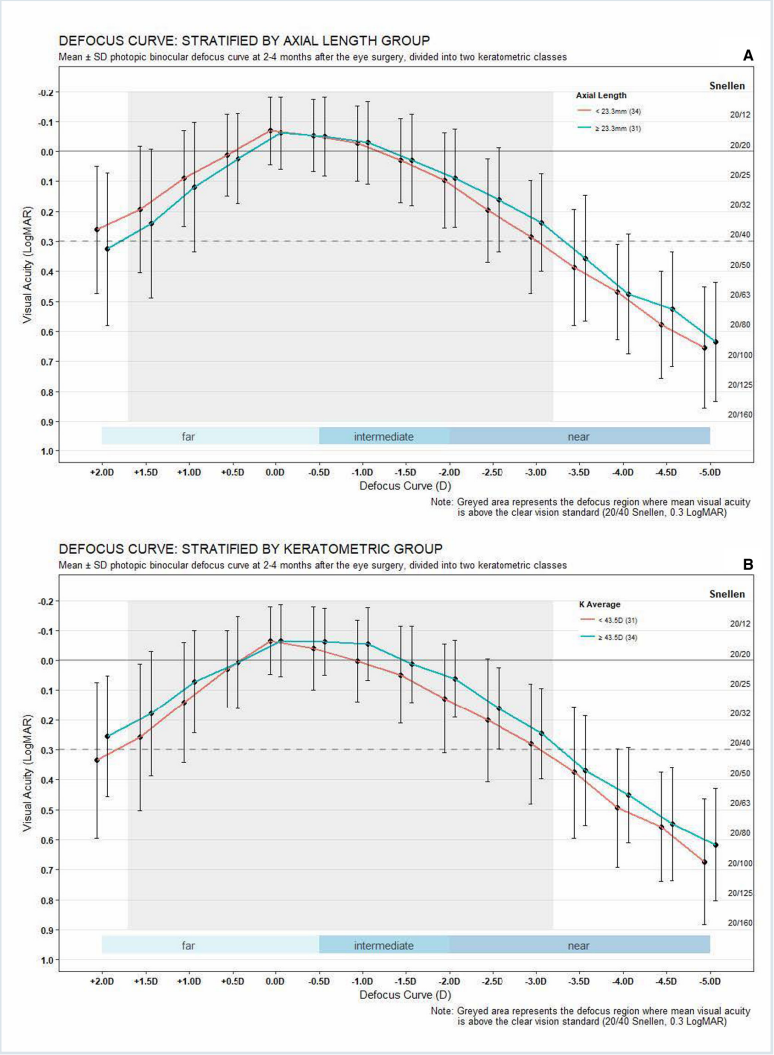

Figure B. Defocus curve at 2 to 4 months postoperatively (mean ± standard deviation [SD]) stratified by (A) axial group and (B) keratometric group. D = diopters

TABLE C

Halo and Glare Simulation Findings

Parameter	N (%)	Mean	SD	Median	Min	Max
Halo						
Patient without findings	51 / 68 (75%)					
Patient with findings	17 / 68 (25%)					
Size	17	33.06	14.25	30	16	65
Intensity	17	38.00	18.51	43	14	78
Type						
H1	58.82%					
H2	29.41%					
H3	11.77%					
Glare						
Patient without findings	55 / 68 (81%)					
Patient with findings	13 / 68 (19%)					
Size	13	23.85	10.43	26	10	44
Intensity	13	42.23	13.22	46	14	62
Type						
G1	100%					
G2	0%					
Halo and glare strength (Mini Well; SIFI S.p.A.)[a]						
None (0% to 25%)	80.88					
Mild (25% to 50%)	19.12					
Moderate (50% to 75%)	0.00					
Severe (75% to 100%)	0.00					
Mean strength	7.86					

SD = standard deviation; H1 = diffuse halo ring; H2 = starburst; H3 = distinct halo ring; G1 = diffuse glare; G2 = irregularly shaped glare

[a]The new strength function (developed by Hagen et al) allows study of dysphotopsia assessed using the Halo and Glare Simulator in a comparative manner. The function allows classification of halo and glare into four categories: none (0% to 25%), mild (25% to 50%), moderate (50% to 75%), and severe (75% to 100%). The mean strength value of halo and glare was 7.86% (none), with 55 patients (80.88%) reporting no halo and glare (0% to 25%).

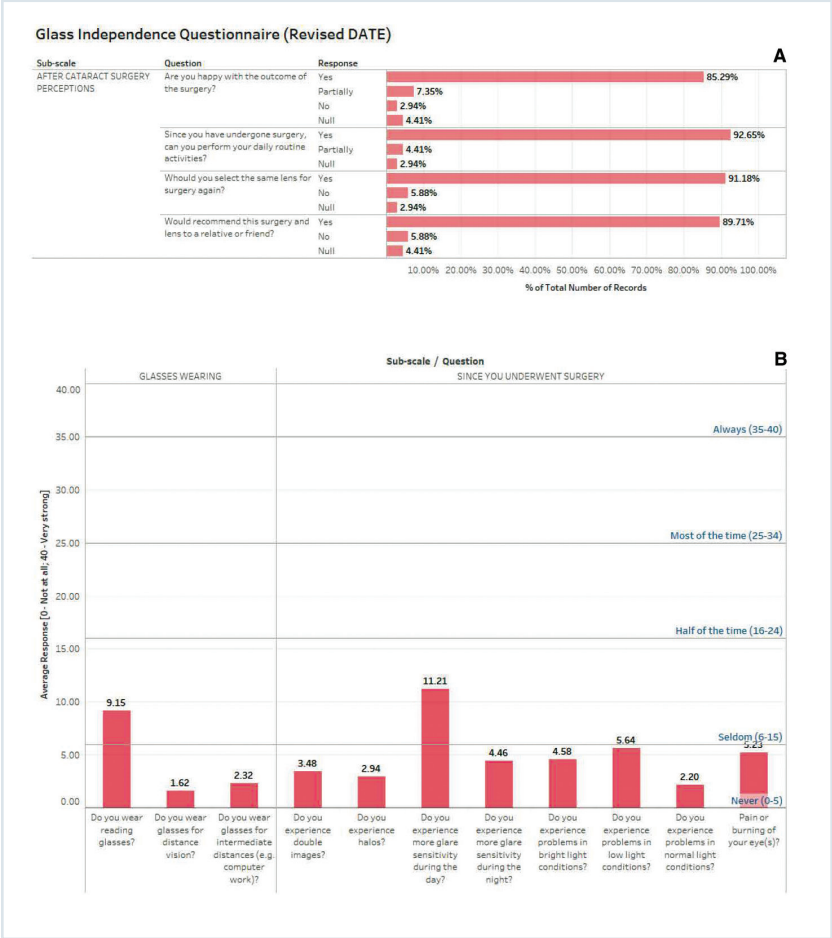

Figure C. Revised Heidelberg Daily Task Evaluation (DATE) questionnaire. (A) Postoperative perceptions after cataract surgery in percentage from total number of responders. (B) Average responses of frequency (from 0 = never to 40 = always) by question.