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One-Year Outcomes after implantation of an Extended Depth of Focus Intraocular Lens in Cataract patients

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Abstract

Purpose: To evaluate the clinical outcomes of a new extended depth of focus (EDF) intraocular lens (IOL) in patients with cataracts.

Setting: *("Masked by journal requirement")*

Design: Retrospective observational.

Methods: Data was retrospectively reviewed for a cohort of 51 consecutively operated cataract patients implanted with the ELON (Medicontur) IOL and followed over a 12-month period. The variables collected for analysis included visual acuities (VAs) at various distances (far, intermediate, and near), light distortion index (LDI), defocus curves (DC), and prediction error. Additionally, patient-reported outcomes were gathered to assess spectacle dependence, satisfaction with vision, positive dysphotopsia, difficulties in daily activities, and patients' willingness to undergo the same IOL procedure again.

Results: Monocular data for efficacy was available for 36 patients at the 3-month follow-up and 23 patients at the 12-month follow-up. Median monocular distance-corrected VAs were 0, 0.1, and 0.3 logMAR at 4 m, 66 cm, and 40 cm, respectively, at 3 and 12 months. Correlations between VAs and pupil diameter were found but only at near for binocular uncorrected (rho=0.38, p=0.02) and monocular distance corrected (rho=0.31, p=0.07). The median LDI reduced up to 9% at 12-month. No significant differences were found between follow-up visits for VAs and LDI ($p>0.05$); however, satisfaction, positive dysphotopsia, and willingness to undergo the same IOL procedure significantly improved from 3 to 12 months ($p<0.05$).

Conclusions: The ELON IOL extended the depth of field from far to intermediate distances, with some patients with smaller pupil diameters also achieving near vision restoration.

Keywords: intraocular lens, extended depth of focus, safety, efficacy, defocus curves, patient reported outcomes

1. Introduction

The development of cataracts requires surgical intervention, which involves replacing the opacified crystalline lens with a monofocal intraocular lens (IOL). Over the years, advances in cataract surgery technology have made it possible to increasingly maximize spectacle independence compared to conventional monofocal IOLs. Surgeons now have access to variety of simultaneous vision IOL technologies (Multifocal, Extended Depth of Focus and Full Visual Range IOLs), allowing them to select the options that best meet patient needs.[1] From these categories, patients looking for a high probability of complete spectacle independence at far and intermediate distances but who do not mind using spectacles for near (<50 cm) may opt for the optically known as Extended Depth of Focus (EDF) IOLs.[2]

The EDF with the highest volume of scientific publications among those based on the modification of the central optical profile is the Acrysof IQ Vivity DFT015 (Alcon Laboratories, USA).[3–19] Interestingly, despite more than 15 studies being published to date on binocular implantation targeted to emmetropia,[3–19] to the best of our knowledge, no authors have reported outcomes for follow-up times longer than 6 months. Although a six-month follow-up can be considered sufficient for assessing stable outcomes, longer durations are recommended to capture additional changes over time, such as posterior capsular opacification, Nd-YAG laser capsulotomy rates and some patient reported outcomes.[20] Besides Vivity, other EDFs based on the modification of the central optical profile have also published outcomes, such as Synthesis PLUS (CuttingEdge)[21], PureSee (Johnson and Johnson Surgical Vision, Irvine, CA, USA),[22] and Asqelio EDF IOL (ASTVisionCare Inc.),[23] although these studies are also limited to short-term follow-up. Similarly, a small-sample study with the ELON IOL (877PEY, Medicontur Medical Engineering Ltd. Inc., Zsámbék, Hungary) has been published, reporting results at 3 months postoperatively.[24]

The ELON is a refractive EDF IOL also based on the modification of the central optical profile. The primary aim of this study is to report, the safety, predictability, efficacy, and patient-reported outcomes in cataract patients implanted with the ELON lens. Furthermore, this observational study represents the longest follow-up (12 months) reported up to date for EDF IOLs based on the modification of the central optical profile.

2. Materials and methods

2.1. Subjects

The historical database of cataract patients consecutively implanted with ELON IOL from November 2021 to February 2024 at "*Masked by journal requirement*" was retrospectively reviewed. Supplemental Figure A summarizes the availability of data for each of the analyses and follow-ups. Inclusion criteria were limited to preoperative anterior corneal astigmatism < 1.20 D and irregular astigmatism <0.5 mm at 4 mm, both measured with Pentacam (Oculus Optikgeräte GmbH,Wetzlar, Germany). Patients with eye comorbidities were also included according to surgeon criteria, such as pre-perimetric open-angle glaucoma, previous corneal laser refractive surgery and blepharospasm. Exclusion criteria were corneal ectasia, retinal diseases, uveitis, dry eye or amblyopia. The study was approved by the Ethics Committee of Research, Almería Center, Torrecardenas Hospital Complex and performed in adherence with the tenets of the Declaration of Helsinki. Subjects provided express consent authorizing the use of medical record data for biomedical research purposes.

2.2. Intraocular Lens

The ELON is a single-piece, preloaded, foldable acrylic lens featuring Medicontur's 'Wavefront Linking' technology, which uses wavefront transition-smoothing to achieve a monotonous decreased of visual acuity from far to near.[25] This design incorporates three concentric refractive zones with varying curvatures linked by 20-micron wide zones, creating a single extended focus. This approach aims to provide an EDF and reduce photic phenomena compared to diffractive IOLs. This reduction can be assessed in clinical practice by measuring the size of photic phenomena and/or collecting patient-reported outcomes related to positive dysphotopsia.[26] The lens platform includes a doubled c-loop haptic (Bi-Flex platform) with an overall diameter of 13 mm and a 6 mm biconvex aspheric optic with

neutral spherical aberration. The single-piece is made of hydrophobic acrylic copolymer SEMTEY^{TD} (Medicontur Medical Engineering Ltd. Inc., Zsámbék, Hungary) with an ultraviolet blocker, blue-light filter, and a refractive index of 1.47 (58 Abbe number).[27]

2.3. Surgery

The decision regarding the IOL power to be implanted was determined using two formulae with the Pentacam AXL Wave biometer. These formulae were the Barrett Universal II and the Qvision thick-lens formula.[28] Eyes were targeted for emmetropia or the first myopic predicted refraction closest to emmetropia. In cases where there was a lack of agreement in IOL power between the formulae (which was rare and always ≤0.50 D), the IOL with the highest power was selected. For three eyes, the Barrett True K formula in Pentacam AXL Wave was used: two eyes with a myopic corneal history of photorefractive keratectomy and one with Supracor for Hyperopia.

Eyes were also measured with the IOL Master 500 (Carl Zeiss Meditec AG, Jena, Germany), but these measurements were used solely as a double-check method to prevent refractive surprises and minimize prediction errors. In rare cases where there was a high degree of inconsistency between biometry readings from both devices, the surgeon, drawing on their knowledge and experience, carefully evaluated additional criteria such as ocular surface dryness, axial length, and spherical aberration to determine the final IOL power. This decision-making process favored a tendency toward myopic rather than hyperopic refractive surprise and aimed to balance the risk of potential residual refractive errors between the two eyes.

The constant used with both formulas in the Pentacam was 118.59. When IOL Master measurements were considered, the Barrett online calculator was used with the constant of 118.9 recommended for ELON by the manufacturer calculator (https://toriccalculator.net/).

Patients underwent either phacoemulsification or femtosecond laser-assisted cataract surgery, performed by the same surgeon (*name masked as per journal requirements*). Clear corneal incisions of 2.2 mm were made manually or 2.5 mm with femtosecond assistance, all at the temporal location. Capsulotomies were programmed at 5.5 mm if conducted by femtosecond, or approximated to that size if manually achieved. Postoperative treatment for all patients included 500 mg of oral Levofloxacin twice daily for three days, 250 mg of Acetazolamide three times daily for one day, 0.1% Dexamethasone drops tapered over 21 days (starting from five times daily to once daily), 0.3% Ofloxacin drops five times daily for five days, and 0.9% Bromfenac drops twice daily for one month.

2.4. Procedures

The pupil diameter was measured using the Pentacam device under both daytime and nighttime conditions, corresponding to photopic and mesopic states, respectively, as defined by the device.[29] Postoperatively, the subjective refraction was taken by a single experimented optometrist at a distance of 4 meter and fitted to infinity adding -0.25 D to the sphere.[30]

Monocular and binocular uncorrected and distance-corrected VAs were evaluated at 3 and 12 months postoperatively at three distances: far (4 meters), intermediate (66 cm), and near (40 cm). A standardized ETDRS chart was displayed on an iPad with a background luminance of 85 cd/m² (VisionC App, QvisionAcademy, Spain). The VA threshold was determined as the last line where the patient could read 3 out of 5 letters correctly. Light distortion index (LDI) was also measured at 3-month and 12-month monocularly with best distance correction and binocularly at 12-month without correction.[31] Previous to the measurement, a +0.50 D lens was used to correct vergence distance of the light distortion analyzer device located at 2 meters from the eye (CEORLab, University of Minho, Portugal).[32] This index is based on measuring the percentage of the area in which a central high-intensity light distorts the

visibility of surrounding lower-intensity lights, which are distributed radially along 24 semi-meridians within an angular limit of 4.6º. The surrounding lights are explored in a manner similar to a visual field perimeter test, assessing the extent to which the central light source interferes with the detection of peripheral targets.[32]

Contrast Sensitivity (CS) and VA Defocus Curves (DC) were recorded using the Multifocal Lens Analyzer (MultifocalLA App, QvisionAcademy, Spain). Crowded Sloan letters were randomly presented across a defocus range of +1.50 D to -3.00 D in 0.50 D steps to prevent memorization.[33] An automated psychophysical procedure was utilized. Monocular visual acuity DC were measured in a randomly selected eye at the 3-month follow-up. Binocular contrast sensitivity DC were evaluated without distance correction at the 12-month follow-up. All VA and DC measurements were conducted with an iPad background luminance of 85 cd/m², verified using a Spyder5Elite colorimeter (Datacolor Imaging Solutions, Lawrenceville, NJ), under ambient lighting conditions of 120 lux (LX1010B digital luxmeter). At the 12-month follow-up, patients completed two standardized questionnaires: the Visual Function Index and the Patient Reported Spectacle Independence Questionnaire.[34,35] Additionally, they responded to five single questions at 3 and 12-month to report the cumulative percentage of patients satisfied with postoperative uncorrected vision, experiencing bothersome photic phenomena (positive dysphotopsia), and willing to undergo the same procedure again.[20]

2.5. Statistical analysis

For monocular efficacy and predictability, a single eye per patient was included in the analysis.[20] This eye corresponded to the one evaluated at 3 months during randomization to measure DC. Descriptive statistics of mean ± standard deviation and median [interquartile range] were used to summarize variables. Distributions were assessed by histogram

inspection and tested with the Shapiro-Wilk test. Correlations were evaluated with Spearman rho and standard plots for reporting results of presbyopia-correcting IOLs and recommendations for manuscript writing were followed.[20,36] Areas under the curve (AUCs) for the far range (+0.50 to −0.50 D) and the intermediate range (−1.00 to −1.50 D) over 0.3 logMAR or 0.3 logCS were computed.

Sample size was calculated for the null hypothesis of non-inferiority of 0.2 logMAR for monocular DCIVA plus a margin point (δ) of 0.1 logMAR. This was assessed with GPower 3.1.9.2 (Düsseldorf University). A two-sided test was used, with the alpha risk set at 5%. The estimated mean DCIVA was 0.15 and a standard deviation of 0.09 logMAR based on previous evidence of a similar IOL.[3] To achieve a power of 0.8, a sample size of at least 22 subjects was required. Considering the imbalance between the 3 and 12-month follow-up samples, a mixed model analysis was used to test differences between both follow-up measurements.[37] Data analysis was carried out using the IBM SPSS for windows statistical software (version 26.0; SPSS, Inc., Chicago, IL).

3. Results

Supplemental Figure A shows the characteristics of the included sample and the sample size for each of the analyses. Four of the 40 patients who completed the 3-month follow-up were excluded from the efficacy analysis but were reported in the safety analysis due to adverse events occurring during the follow-up. The sample included not only eyes without comorbidities, but also six eyes with pre-perimetric open-angle glaucoma (n=2), previous corneal laser refractive surgery (n=3), and blepharospasm (n=1). These cases were included in the efficacy analysis because their results aligned with the overall sample. However, cases with a history of corneal laser refractive surgery were excluded from the predictability analysis only, as they required the use of different calculation formulas. These cases were

individually described in the corresponding section on predictability. Finally, the study was completed before 13 subjects could achieve the 12-month follow-up, thus 23 eyes were available for this visit, 2 of them submitted to monocular surgery.

3.1. Safety

The four patients excluded from the efficacy analysis were due to the following reasons: one patient required vitrectomy during the follow-up; their CDVA, DCIVA, and DCNVA were 0.3, 0.5, and 0.4 logMAR, respectively, at the 12-month follow-up after treatment. Another patient experienced posterior capsular opacification limiting intermediate vision and was scheduled for Nd-YAG laser capsulotomy, with distance-corrected visual acuities of 0, 0.3, and 0.6 logMAR at the 12-month follow-up before treatment, respectively. Two patients followed only for 3-months suffered from: 1) recurrent viral conjunctivitis, achieving 0.3 logMAR at the three distances, and 2) aponeurotic ptosis, achieving 0.3, 0.5, and 0.8 logMAR, respectively. Only the Nd-YAG laser capsulotomy case was an IOL related adverse event. No more eyes presented a loss of 2 lines of visual acuity in comparison to the preoperative period or a CDVA poorer or equal than 0.3 logMAR.

3.2. Predictability

Three eyes were excluded from the prediction error analysis shown in Figure 1E due to previous laser refractive surgery, specifically two with photorefractive keratectomy and one with Supracor. These eyes exhibited postoperative spherical equivalent of 0, -0.75, and -0.25 D, respectively. Among the 33 eyes analyzed, 90.9% and 100% were within ±0.50 D and ±1.00 D, respectively, for the preoperative predicted refraction using Pentacam and a constant of 118.59.

3.3. Efficacy

Table 2 and Figures 1A to 1C show the monocular and binocular VAs at the 3 and 12-month follow-up. DCIVA was significantly better than 0.2 logMAR ($p<0.0005$), with values of 0.11 and 0.14 logMAR at 3 and 12-months, respectively. No significant differences were found for all endpoints except for monocular UNVA, which decreased from 0.25 to 0.29 logMAR ($p=0.02$), and binocular UIVA, which increased from 0.13 to 0.07 logMAR ($p=0.03$). Monocular UNVA (rho=0.38, $p=0.02$) and DCNVA (rho=0.31, $p=0.07$) increased with photopic pupil diameter. DCNVAs equal to or better than 0.2 logMAR (27% in Figure 1C) were only achieved in eyes with photopic pupil diameter < 3 mm. On the other hand, no significant correlations were found for CDVA and DCIVA, nor for binocular UNVA and DCNVA. Supplemental figure B shows the procedure efficacy plots for binocular vision at 3-month. Finally, the monocular LDI with best distance correction was 9.07% at 12-month and decreased up to 7.27% in binocular vision despite taking the measurement without distance correction.

3.4. Defocus Curves

Figure 2A shows the monocular visual acuity DC with a monotonous decrease of visual acuity from far to near. Figure 2B shows the monocular distance corrected contrast sensitivity DC and Figure 2C the binocular uncorrected contrast sensitivity DC. Far AUC for visual acuity DC was inversely related to patient's age, showing that older patients achieved a poorer far distance quality of vision (-0.40, $p=0.015$), this correlation was also shown but without significance for contrast sensitivity DC (-0.29, $p=0.09$). Interestingly, no relationships were found with age and intermediate AUC.

3.5. Patient Reported Outcomes

Table 3 presents the responses to the questionnaire about satisfaction with vision without spectacles, bothersome photic phenomena, and likelihood of being operated on again with the same IOL. The median responses for the five questions improved by one level. For instance, the median for bothersome photic phenomena at 3 months decreased from 2 ("Slightly") to 1 ("Not at all"). The weakest response was attributed to satisfaction with near vision, which improved from a median of 3 ("Neutral") to 4 ("Satisfied") between the 3 and 12-month follow-ups. This explains why tasks showing greater difficulties, with responses of "A little" or "Moderate," were associated with reading small print or newspapers and knitting (Supplemental Figure C), while the remaining activities, including driving at night, were conducted without difficulties. Regarding bothersome to photic phenomena, no patients were bothered or very bothered by dysphotopsia at 12-month. To confirm that the improvement at 12-month was not due to the differences between the 3- and 12-month follow-up sample sizes, a sub-analysis was conducted including only the 21 patients that completed both visits (Table 3).

Spectacle independence was completely achieved for far and intermediate distances (Table 4), but nearly all patients required near spectacles. However, the median comfortability without wearing spectacles was 2 ("Most of the time"), and no patients reported being comfortable only a little or none of the time. No significant correlations were found between pupil diameter, either photopic or mesopic, and any of the patient-reported outcomes.

4. Discussion

In this study, the standard outcomes with a new EDF IOL were evaluated in a sample followed at 3 months, and a subset who also completed a 12-month visit. Cataract surgery with implantation of the new ELON IOL demonstrated to be a safe procedure with posterior capsular opacification as the only IOL-related adverse event requiring of Nd-YAG laser

capsulotomy before 12-month (4.35%). Regarding IOL efficacy, the mean monocular corrected distance VAs at 3-month were 0.01, 0.11, and 0.29 logMAR for far, intermediate, and near distances, respectively. These outcomes were practically the same as those reported by other authors for Vivity, particularly for CDVA and DCNVA, but slightly superior for DCIVA.[3,8] For instance, monocular DCIVA for Vivity has been reported to be between 0.15 and 0.18 logMAR at 3 and 6-months.[3,4,7,8] In our study, DCIVA was 0.11 logMAR at 3-months but decreased to 0.14 logMAR at 12-months. However, these differences are very small and may not be clinically relevant, likely due to differences in sample characteristics since the 95% confidence interval for DCIVA in our study ranged from 0.08 to 0.15 logMAR. These similarities were also found in the percentage of eyes achieving a CDVA of 20/20, or a DCIVA and DCNVA of 20/25, reported as 84%, 53%, and 9% for Vivity, and 87%, 63%, and 8% in our study, respectively.[3] Our study also showed superior outcomes than the previously described for ELON by Gil et al.[24] Supplemental table 1 includes a summary of these outcomes for easier comparison.

One interesting finding was the correlation between near visual acuities and pupil size, suggesting that to achieve a monocular DCNVA equal to or better than 0.2 logMAR, a pupil diameter of ≤ 3 mm, as measured with Pentacam, is required. This finding aligns well with previous results reported for Vivity,[12] on which although no significant correlation was found with photopic pupil measured with Pentacam, a significant correlation was observed with Anterion (Heidelberg Engineering, Heidelberg, Germany) measurements. For achieving 0.2 logMAR with Vivity, a pupil diameter around 4.75 mm was required. However, it is important to note that according to the authors, this corresponds to around 3 mm when measured with Pentacam.[12] The reason why Sohee et al. reported significant correlations with Anterion and not with Pentacam could be due to differences in the environmental light conditions during vision testing, which could differ from the 120 lux environmental light in our study. Thus, both IOLs showed pupil-dependence, mainly affecting near VA.

On the other hand, some authors have reported no correlations between near VAs and pupil diameter for Vivity.[7] This discrepancy can be explained by the fact that these were tested against binocular VAs, which also did not show any correlation in our study, likely due to the noise introduced by binocular summation. Other authors have reported poorer patient-reported outcomes related to the quality of vision, such as dysphotopsia, with Vivity for larger pupil diameters.[38] However, this was not shown in our study and is not clearly demonstrated in optical bench studies.[6] In addition, it is important to note that our sample size of 21 subjects who completed the questionnaire at 12 months is not large enough for reliably testing correlations with patient-reported outcomes.

The predictability in our study for the calculation of ELON showed high percentages, with approximately 91% of eyes achieving within ±0.50 D using Pentacam AXL and an A constant of 118.59. It is important to note that this constant differs from the one recommended by the manufacturer 118.9. This can be partly explained due to the optimization of residual refractive error to infinity rather than to 6 meters (very small difference of 0.1 D) but mainly due to differences between Pentacam AXL in measuring simulated keratometry in comparison to IOL Master.[39,40] Therefore, we recommend that users select either constant depending on the biometer employed.

Regarding DC, the monocular visual acuity DC with best distance correction demonstrated an extended depth of field.[41,42] However, visual acuity at 0 D was underestimated (0.09 logMAR in Figure 1) in comparison to the monocular CDVA measured with the ETDRS (0.01 logMAR in Table 2). This can be explained by the fast method for measuring the defocus curve which revealed a testing method bias greater than that observed in previous studies multifocal IOLs.[33,43]

On the other hand, the binocular uncorrected contrast sensitivity DC showed poorer outcomes at 0 D of defocus compared to a previous study with Liberty IOLs.[43] However, it is important to note that far AUC decreased with age, and the median age of the sample in this study was 69 years with few comorbidities, whereas in our previous Liberty study, the median age was 59 years without comorbidities. Therefore, to determine if ELON provides equal or better far distance VA, a future comparison study without confounding factors such as age is required.

The most interesting finding in the study was that even though VA, refraction, and LDI remained stable at the 12-month compared to the 3-month, patient-reported outcomes improved significantly. Specifically, questions related to the quality of vision, bothersome dysphotopsia, and likelihood of undergoing surgery again improved by a median of one level. This suggests a variation in patient-reported outcomes in the long term. This should be especially taken into account when comparing patient-reported outcomes from studies with different follow-up durations. This should be also used for educating patients to alert them that the perception with their vision is able to improve with time and for taking decisions in a short period of time. The mean LDI at 3 months (13.82%) in our study was below the threshold typically associated with moderately bothersome positive dysphotopsia (≥15.20%) and was comparable to that of other refractive EDF IOLs,[26] such as 11.36% for the Asqelio EDF IOL,[23] and 13.81% and 14.36% for the Vivity IOL.[11,44] It was also lower than that of other diffractive EDF IOLs, including 29.18% for the AT Lara (Zeiss Meditec AG) and 23.54% for the Symfony (Johnson & Johnson Vision).[11]

Our study has some limitations that should be discussed. First and most importantly, due to the retrospective nature of the study, not all consecutively implanted patients were followed. Although this could be considered a limitation, it is important to note that retrospective studies with IOLs generally only include patients who were followed and may even exclude those with complications. In this study, all reasons for loss of follow-up and adverse events

from all implanted patients were described, allowing for a more complete critical appraisal of the study. Another limitation is that not all patients followed at 3 months were able to be followed at 12 months because the study was conducted before some patients could achieve this follow-up time. However, for the primary endpoint, which was to evidence the improvement of DCIVA, the sample size was sufficient for both the 3-month and the 12-month visits. Furthermore, the mixed model used in the statistical analysis allows testing repeated differences in non-uniform groups, as in the case of the current study. For some secondary outcomes, such as long-term patient-reported outcomes, a larger sample size will be recommendable in future studies.

In conclusion, our results demonstrated an EDF for ELON IOL. Compared to other IOLs with similar modifications to the central optical profile, the efficacy was quite similar, with pupil dependency affecting only near vision. In contrast to the disadvantages in near vision, which prevent surgeons from offering this IOL to avoid near spectacle dependence, the main advantage is its ability to reduce positive dysphotopsia, as evidenced by patient-reported outcomes and the light distortion index, compared to multifocal IOLs. This should be confirmed in future randomized clinical trials.

5. What was known

- Intraocular lenses (IOLs) based on the modification of the central optical profile have shown an extended depth of field at the 6-month or shorter follow-ups.
- Visual performance with these lenses can vary with pupil diameter, and high rates of spectacle independence can be achieved at far and intermediate distances.

6. What this paper adds

- A new IOL named ELON provides an extended depth of field comparable to other IOLs based on the modification of the central optical profile.
- Despite the similarity in visual acuity at short and longer follow-ups, patient-reported outcomes improved over time.
- Visual acuities better than 0.2 logMAR can also be achieved at near distances, but only in a few cases and with pupil diameters below 3 mm.

Supplemental Data File A--http://links.lww.com/JRS/B411

Supplemental Figure A--http://links.lww.com/JRS/B412

Supplemental Figure B--http://links.lww.com/JRS/B413

Supplemental Figure C--http://links.lww.com/JRS/B414

Supplemental Table 1--http://links.lww.com/JRS/B415

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36.–44. References 36–44 are listed in Supplemental Data File 1

8. Figure captions

Figure 1. Cumulative percentage of eyes achieving monocular CDVA and UDVA at (A) far, (B) intermediate, and (C) near distances. (D) Difference on lines in far distance between postoperative UDVA and CDVA. (E) Spherical equivalent prediction error distribution and (F) postoperative refractive cylinder distribution.

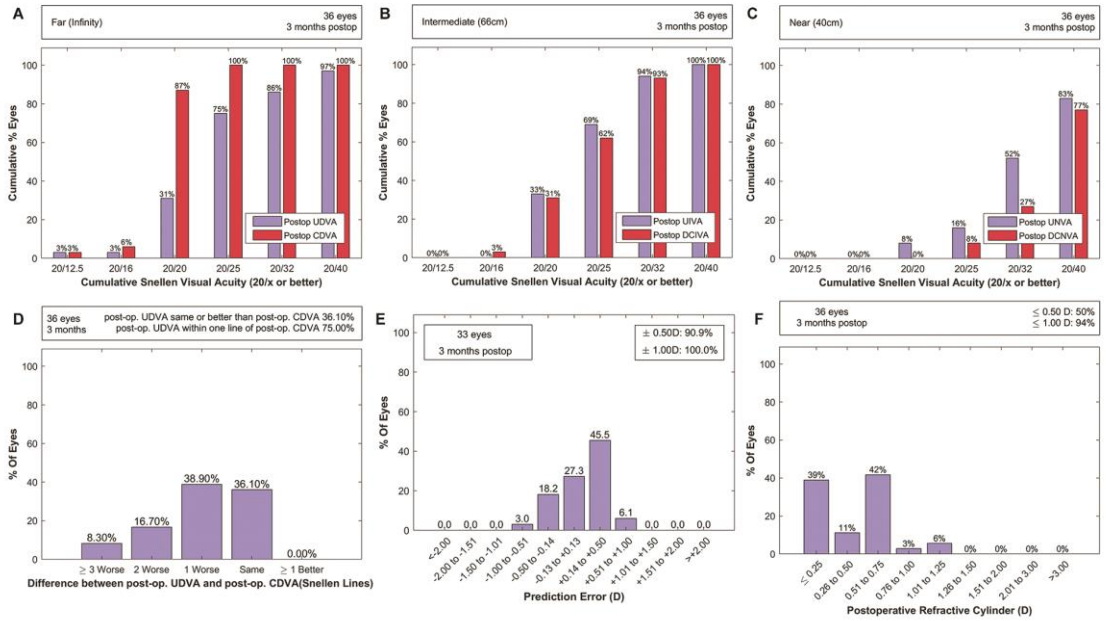
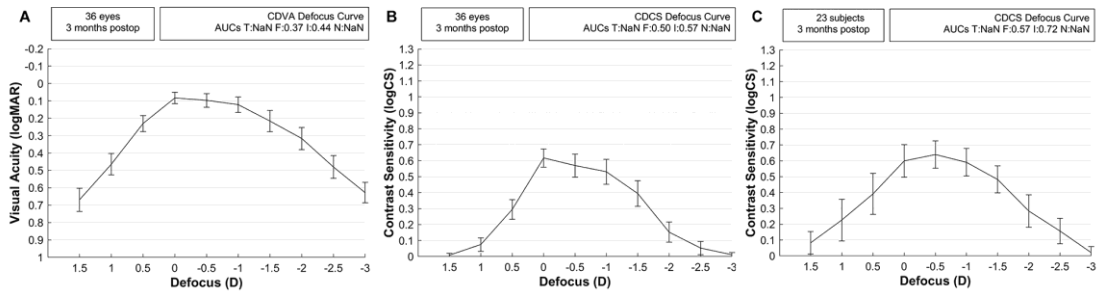


Figure 2. (A) Monocular visual acuity defocus curve with best distance correction, (B) Monocular contrast sensitivity defocus curve with best distance correction and (C) Binocular contrast sensitivity defocus curve without distance correction. AUCs correspond to the areas under the curve computed for total range [T], far [F], intermediate [I], and near [N] distances. Error bars represent the 95% confidence interval.



Supplemental Figure A. Flow-chart about the characteristics of the sample and the availability of the data at each one of the follow-up visits.

Supplemental Figure B. Cumulative percentage of eyes achieving binocular CDVA and UDVA at (A) far, (B) intermediate, and (C) near distances.

Supplemental Figure C. Percentages for each one of the five possible answers from the 14 questions of the visual function questionnaire.

Table 1. Demographic and biometric characteristics of the sample.

n (%) of Men / Woman		13 (36%) / 23 (64%)	
n (%) of Phaco / Femto		24 (67%) / 12 (33%)	
	Mean ± SD	**Median [IQR]**	**[min, max]**
Age	67.78 ± 7.78	69 [10]	[47, 83]
Pentacam AXL			
Average corneal power (D)	42.89 ± 1.44	42.8 [2.20]	[40.1, 45.61]
Corneal astigmatism (D)	0.54 ± 0.24	0.6 [0.30]	[0.20, 1.10]
Anterior Chamber Depth (mm)	3.28 ± 0.36	3.31 [0.60]	[2.49, 3.86]
Axial length (mm)	23.87 ± 0.99	23.70 [1.28]	[21.96, 26.37]
Implanted IOL Power (D)	20.57 ± 2.70	20.5 [2.5]	[14.00, 29.00]
Target Barrett Universal II (D)	0.02 ± 0.19	0.04 [0.3]	[-0.35, 0.4]
IOL Master 500			
Average corneal power (D)	43.42 ± 1.29	43.58 [2.23]	[40.89, 45.61]
Corneal astigmatism (D)	0.70 ± 0.30	0.7 [0.25]	[0.00, 1.67]
Anterior Chamber Depth (mm)	3.23 ± 0.42	3.19 [0.56]	[2.43, 4.02]
Axial length (mm)	23.91 ± 0.98	23.74 [1.27]	[21.97, 26.36]
Photopic Pupil Diameter (mm)	3.01 ± 0.65	2.83 [0.74]	[2.02, 5.14]
Mesopic Pupil Diameter (mm)	4.60 ± 0.91	4.70 [1.08]	[2.68, 6.54]
CDVA (logMAR)	0.33 ± 0.24	0.3 [0.27]	[0, 1.10]

Table 2. Efficacy at 3 and 12-month follow-up described as mean ± standard deviation and median (interquartile-range).

	3-month	12-month	p-value
Monocular	n=36	n=23	
UDVA (4 m)	0.11 ± 0.12	0.10 ± 0.10	0.568, 0.58
	0.10 (0.18)	0.10 (0.20)	
CDVA (4 m)	0.01 ± 0.05	0.02 ± 0.05	-1.15, 0.26
	0.00 (0.00)	0.00 (0.10)	
UIVA (66 cm)	0.10 ± 0.09	0.12 ± 0.08	-0.465, 0.65
	0.10 (0.20)	0.10 (0.10)	
DCIVA (66 cm)	0.11 ± 0.10	0.14 ± 0.09	1.75, 0.18
	0.10 (0.20)	0.10 (0.10)	
UNVA (40 cm)	0.25 ± 0.13	0.29 ± 0.10	-2.51, 0.02
	0.20 (0.10)	0.30 (0.10)	
DCNVA (40 cm)	0.29 ± 0.10	0.28 ± 0.13	0.41, 0.68
	0.30 (0.10)	0.30 (0.10)	
SE (D)	-0.21 ± 0.23	-0.18 ± 0.27	0.94, 0.34
	-0.25 (0.38)	-0.19 (0.38)	
Astigmatism (D)	-0.47 ± 0.41	-0.51 ± 0.41	-0.05, 0.96
	-0.63 (0.75)	-0.63 (0.75)	
LDI (%) Distance	13.82 ± 8.09	11.69 ± 10.72	1.35, 0.26
Corrected	10.66 (8.68)	9.07 (7.60)	
Binocular	n =32	n =21	
UDVA (4 m)	0.08 ± 0.13	0.08 ± 0.09	0.53, 0.60
	0.05 (0.18)	0.10 (0.10)	
CDVA (4 m)	0.01 ± 0.05	-0.01 ± 0.06	0.67, 0.51
	0.00 (0.00)	0.00 (0.00)	
UIVA (66 cm)	0.13 ± 0.10	0.07 ± 0.08	2.35, 0.03
	0.10 (0.18)	0.10 (0.10)	
DCIVA (66 cm)	0.09 ± 0.10	0.11 ± 0.07	-1.17, 0.25
	0.10 (0.20)	0.10 (0.10)	
UNVA (40 cm)	0.21± 0.15	0.23 ± 0.15	-1.55, 0.14
	0.30 (0.20)	0.20 (0.25)	
DCNVA (40 cm)	0.24± 0.12	0.23± 0.14	0.42, 0.68
	0.25 (0.20)	0.20 (0.15)	
LDI (%) Distance	-	9.74 ± 6.63	-
Uncorrected		7.27 (6.07)	

UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; UIVA: Uncorrected intermediate visual acuity; DCIVA: Distance corrected intermediate visual acuity; UNVA: Uncorrected near visual acuity; DCNVA: Distance corrected near visual acuity; LDI: Light distortion index; SE: Spherical equivalent

Table 3. Descriptive results for Additional Questions. Centrality and variation indices in first column and percentage of answers for each category (frequency) in Cat. columns. Coding for main words described at the bottom of the table.

Additional Questions (X) at 3-month (n=32)		Cat. 1	Cat. 2	Cat. 3	Cat. 4	Cat. 5	Cat. 4 or 5
Satisfaction (Satisfied)							
Distance	4.03 ± 1.05;* 4 [1]	0	15	7.5	37.5	40	77.5
Intermediate	3.85 ± 0.98;* 4 [2]	0	12.5	17.5	42.5	27.5	70
Near	3.13 ± 1.02;* 3 [2]	5	22.5	35	30	7.5	37.5
Photic phenomena (Bothersome)	1.98 ± 0.77;* 2 [0]	22.5	65	5	7.5	0	7.5
Operated again (Likely)	4.08 ± 0.89;* 4 [1]	2.5	2.5	12.5	50	32.5	82.5
Additional Questions (X) at 3-month (n=21)		Cat. 1	Cat. 2	Cat. 3	Cat. 4	Cat. 5	Cat. 4 or 5
Satisfaction (Satisfied)							
Distance	4.34 ± 0.79;* 4 [1]	0	6.3	0	46.9	46.9	93.8
Intermediate	4.03 ± 0.86;* 4 [1]	0	6.3	15.6	46.9	31.3	78.2
Near	3.31 ± 0.86;* 3 [1]	0	18.8	37.5	37.5	6.3	43.8
Photic phenomena (Bothersome)	1.81 ± 0.59;* 2 [0.75]	25	71.9	0	3.1	0	3.1
Operated again (Likely)	4.22 ± 0.66;* 4 [1]	0	0	12.5	53.1	34.4	87.5
Additional Questions (X) at 12-month (n=21)		Cat. 1	Cat. 2	Cat. 3	Cat. 4	Cat. 5	Cat. 4 or 5
Satisfaction (Satisfied)							
Distance	4.76 ± 0.44;* 5 [0.5]	0	0	0	23.8	76.2	100
Intermediate	4.71 ± 0.46;* 5 [1]	0	0	0	28.6	71.4	100
Near	4.14 ± 0.57;* 4 [0.5]	0	0	9.5	66.7	23.8	90.5
Photic phenomena (Bothersome)	1.29 ± 0.56;* 1 [0.5]	76.2	19	4.8	0	0	0
Operated again (Likely)	4.62 ± 0.50;* 5 [1]	0	0	0	38.1	61.9	100

Coding for main words (X = Satisfied or Bothersome or Likely): ''Not at all X" (Cat. 1), ''Slightly X" (Cat. 2), "Moderate for bothersome and Neutral for remaining questions" (Cat. 3), ''X" (Cat. 4), and ''Very X" (Cat. 4).
*$p<0.05$ in the comparison between 3 and 12-month.

Table 4. Descriptive results for the Patient Reported Spectacle Independence Questionnaire. Centrality and variation indices in first column and percentage of answers for each category (frequency) in Cat. columns. Coding for main words described at the bottom of the table.

	Mean ± SD; median [IQR]	Cat. 1	Cat. 2	Cat. 3	Cat. 4	Cat. 5
Need Glasses						
Distance	2 ± 0; 2 [0]	0	100			
Intermediate	2 ± 0; 2 [0]	0	100			
Near	1.04 ± 0.22; 1 [0]	95.2	4.8			
Often wear						
Distance	5 ± 0; 5 [0]	0	0	0	0	100
Intermediate	5 ± 0; 5 [0]	0	0	0	0	100
Near	3.14 ± 0.96; 3 [1]	4.8	14.3	52.4	19	9.5
Comfortably without wear						
Distance	1 ± 0; 1 [0]	100	0	0	0	0
Intermediate	1 ± 0; 1 [0]	100	0	0	0	0
Near	2.38 ± 0.59; 2 [1]	4.8	52.4	42.9	0	0

Coding: ''Yes'' (Cat. 1) and ''No'' (Cat. 2). Wear and Function items used verbal response labels of ''All of the time'' (Cat. 1), ''Most of the time'' (Cat. 2), ''Some of the time'' (Cat. 3), ''A little of the time'' (Cat. 4), and ''None of the time'' (Cat. 5).