

# One-year follow-up of a multifocal intraocular lens with optimized elevated phase shift



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**Purpose:** To evaluate the standard outcomes of a multifocal intraocular lens (mIOL) with optimized elevated phase shift (EPS).

**Setting:** Qvision, Ophthalmology Department, VITHAS Almería, Spain.

**Design:** Retrospective observational.

**Methods:** 41 patients, consecutively operated on cataracts or refractive lens exchange with the implantation of the Liberty 640PM (EPS 2.0) and followed during 12 months, were included in the analysis. Retrieved variables were visual acuities at far, intermediate, and near distances; defocus curves (VADC); and prediction error of 4 formulas optimized for IOLMaster 500 and Pentacam AXL Wave. Patient-reported outcomes were also obtained for assessing spectacle independence, satisfaction, bothersome to dysphotopsia, difficulties in daily life tasks, and decision to be operated with the same mIOL.

**Results:** The median monocular efficacy with best distance correction was 0, 0.1, and 0.1 logMAR at far, intermediate, and near distances, respectively, with patients achieving binocularly a median of 0 logMAR at the 3 distances. VADC showed a depth of field of 3 diopters (D) above 0.2 logMAR with a median increase of 0.07 logMAR from  $-1.5$  to  $-2.5$  D. Complete spectacle independence was achieved at far distance, whereas 97.6% and 85.4% was achieved at intermediate and near distances, respectively. 7.3% of patients were bothered by dysphotopsia, and 92.6% of patients were likely to be operated again.

**Conclusions:** EPS 2.0 restored patients' vision in the full range of the depth of field with a nearly monotone decrease of visual performance from far to near, achieving high rates of spectacle independence at all distances and with low positive dysphotopsia rates (ClinicalTrials.gov Identifier: NCT05735990).

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**M**ultifocal intraocular lens (mIOL) implantation is an option to reestablish not only far distance vision after cataract surgery but also a solution for presbyopia correction. Trifocal IOLs are the most used option by surgeons to achieve this purpose because they allow restoration of vision across the full depth of field with comparable results to extended depth-of-focus IOLs at intermediate vision and bifocal IOLs at near vision.<sup>1–3</sup> Trifocal IOLs are based on refractive or diffractive technologies; the latter was early designed with 2 combined periodic structures of echelettes that vary in width and height, although new patterns with different shape structures and periodicities have emerged in the recent years.<sup>4,5</sup> In contrast to these methods for achieving the multifocality, elevated phase shift (EPS) technology maintains a single diffractive periodic structure and obtains constructive

interference at intermediate vision by modifying the refractive structure of the IOL in the central zone to achieve constructive interference between the far and near foci.<sup>6</sup> Clinical results with the EPS technology have been widely reported for the Liberty 677MY (EPS 1.0), but a new optimized EPS version for increasing light intensity distribution at intermediate distance has been designed (EPS 2.0), decreasing far and near light intensity, in such a low degree, that this optimization could have a clinically negligible decrease on far and near distance visual acuities but a clinically relevant increase at intermediate visual acuity (VA).<sup>7–11</sup> The aim of this study was to evaluate the safety, predictability, and efficacy of the implantation of a mIOL with this optimized EPS. The secondary aim was to assess the defocus curves (DCs) and patient-reported outcomes at 1 year postoperatively.

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## METHODS

### Patients

Data of 47 consecutive patients who underwent cataract or refractive lens exchange surgery between May 2021 and January 2022 at Qvision, Ophthalmology Department, VITHAS Almería, Spain were retrospectively reviewed from our historical database. The inclusion criteria were adults older than 18 years, binocularly implanted with the nontoric Q-Flex 640PM IOL (Medicontur Ltd.), who participated in at least 2 follow-up visits before the 12 months postoperatively (1 month  $\pm$  2 weeks, 3 months  $\pm$  1 month, and 12 months  $\pm$  3 months), for whom the retrospective data for the corrected distance visual acuity (CDVA) were available, and for whom at least half of all the secondary endpoints (available at ClinicalTrials.gov Identifier: NCT05735990) were measured in the time ranges specified in the protocol. Exclusion criteria were patients with any eye condition that could affect vision (corneal ectasia, retinal diseases, glaucoma, uveitis, dry eye or amblyopia, or corneal refractive surgery) and regular anterior corneal astigmatism  $\geq 1.20$  diopters (D) or irregular astigmatism  $\geq 0.5$   $\mu\text{m}$  at 4 mm measured with Pentacam AXL Wave (Oculus Optikgeräte GmbH). This retrospective observational study (ClinicalTrials.gov number: NCT05735990) 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. Patients provided express consent authorizing the use of medical record data for biomedical research purposes.

### Intraocular Lens

The Liberty Q-Flex 640PM mIOL consists of 1, single-piece, semipreloaded, foldable acrylic IOL with a diffractive apodized structure in the anterior surface of the lens based on the 7 rings EPS 2.0 patented technology.<sup>6</sup> The platform consists of 4 closed loops around a 6 mm biconvex aspheric optic of hydrophilic-hydrophobic acrylic copolymer material Benz-25 (Benz Research & Development) with labelled addition power at the IOL plane of +3.50 D for the near vision and +1.75 D for the intermediate vision.

### Surgery

IOL implanted power was calculated as the mean between the Qvision thick lens formula personalized for the surgeon, IOL, and biometer (Pentacam) and the Barrett formula. This formula considers both surfaces of the cornea with a fitted refractive index and the real characteristics of the IOL, such as curvature radii, refractive index, and IOL thickness.<sup>12</sup> The decision criteria for selecting the implanted IOL power was generally targeted to emmetropia or first myopic predicted refraction closest to emmetropia except in cases of discrepancies between Qvision and Barrett formulas, in that case the mean of 2 IOL powers was calculated. Retrospective calculation of prediction error was also computed for Barrett, Kane, and EVO formulas after constant optimization for both biometers, IOLMaster 500 and Pentacam, excluding lens thickness and white to white in the calculation.<sup>13</sup>

Patients were submitted either to manual or femtosecond laser cataract surgery, according to their desire, by the same surgeon (JF). Manual or femtosecond laser-assisted clear corneal incisions of 2.2 and 2.5 mm were uniformly conducted, respectively, at the temporal location. Capsulotomy size was approximately sized or programmed at 5.5 mm. No additional corneal incisions were conducted for correcting corneal astigmatism. All patients were treated postoperatively with 500 mg of oral levofloxacin, twice a day for 3 days; 250 mg of acetazolamide, 3 times a day during 1 day; dexamethasone 0.1% drops, 21 days decreasing from 5 times, 3 times, and once a day each 7 days; ofloxacin 0.3% drops, 5 times a day during 5 days; and bromfenac 0.9% drops twice a day during 1 month.

### Procedures

Subjective refraction was measured at 4 meters and fitted to infinity adding  $-0.25$  D to the sphere. Pupil diameter was measured with the Keratograph 5M (Oculus Optikgeräte GmbH) under photopic and mesopic conditions. Posterior capsule opacification (PCO) density at the pupil area was graded by an experienced ophthalmologist during slitlamp evaluation using a scale from 0 to 4 (0 = none, 1 = minimal, 2 = mild, 3 = moderate, and 4 = severe).<sup>14</sup> Uncorrected and distance-corrected visual acuities were measured at 12-month follow-up for distance (4 m), intermediate (66 cm), and near (40 cm) distances with a standardized Early Treatment Diabetic Retinopathy Study chart (VisionC App, www.qvisionacademy.com) presented on an iPad with a background luminance of 85 Candelas ( $\text{cd}/\text{m}^2$ ) (calibrated with a SpyderX Elite colorimeter, Datacolor Imaging Solutions).<sup>15</sup> The VA threshold (logMAR) was defined as the last VA row for which the patient read 3/5 letters. DCs were measured with the Multifocal Lens Analyzer (MultifocalLA App, www.qvisionacademy.com) using random crowded Sloan letters to avoid memorization and an automated psychophysical procedure.<sup>16</sup> Monocular distance-corrected visual acuity DCs (VADCs) were measured for 1 random eye at 3-month follow-up. Binocular contrast sensitivity DCs (CSDCs) without distance correction were measured at the 12-month visit. Either visual acuities at all distances or DCs were measured with a background iPad luminance of 85  $\text{cd}/\text{m}^2$ , checked with a Spyder5Elite colorimeter, and environmental light conditions of 120 lux (LX1010B digital luxmeter). Patients answered to 2 standardized questionnaires at the 12-month visit, the visual function index (VF-14), the Patient-Reported Spectacle Independence Questionnaire (PRSIQ), and 5 single questions to report the cumulative percentage of patients achieving satisfaction with postoperative uncorrected vision, bothersome to photic phenomena (positive dysphotopsia), and likely to be operated on with the same procedure.<sup>17</sup>

### Statistical Analysis

Descriptive statistics of mean  $\pm$  standard deviation (SD) was used to summarize variables after a normal distribution. For non-normal distributions, the median (interquartile range [IQR]) was used instead. Distributions were assessed by histogram inspection and tested with the Shapiro-Wilk test. Standard plots for reporting results of presbyopia-correcting IOLs and recommendations for manuscript writing were followed.<sup>17</sup> DCs were inspected and corrected for defocus shifts before averaging. Areas under the curve (AUCs) for the total measured range from +1.00 to  $-4.00$  D (TAUC), the far range (FAUC: +0.50 to  $-0.50$  D), the intermediate range (IAUC:  $-1.00$  to  $-1.50$  D), and the near range (NAUC:  $-2.00$  to  $-4.00$  D) over 0.3 logMAR or 0.3 log contrast sensitivity (logCS) were computed by means of the trapezoidal numerical integration method by normalizing the 0.5 D defocus steps to the unit.<sup>17</sup> The sample size calculation was computed for the null hypothesis of noninferiority: postoperative CDVA at 12 months was poorer or equal to the obtained preoperatively plus a margin safety point ( $\delta$ ) of 0.2 logMAR. The sample size was assessed with the GPower 3.1.9.2 (Düsseldorf University). A 2-sided test was used, an alpha risk was set at 5%, and an estimated SD of the preoperative CDVA was 0.26 and postoperatively 0.07 considering the previous evidence of a trifocal IOL.<sup>18</sup> For achieving a power of 0.8, a sample size of at least 21 patients was required. Data analysis was performed using the IBM SPSS for windows statistical software (v. 24.0, SPSS, Inc.).

## RESULTS

Six from the 47 available consecutive patients were not included in the analysis because of accomplishing the following exclusion criteria: 3 had signs of eye dryness, 1 had an intraoperative history of corneal burn, 1 had

**Table 1.** Demographic and biometric characteristics of the sample

| Parameter                       | Mean $\pm$ SD    | Median (IQR) | Min, max     |
|---------------------------------|------------------|--------------|--------------|
| Sex (M/F), n (%)                | 9 (22)/32 (78)   |              |              |
| Lens type (phaco/femto), n (%)  | 12 (15)/70 (85)  |              |              |
| Age                             | 62.02 $\pm$ 7.8  | 59 (11.5)    | 48, 80       |
| IOLMaster 500                   |                  |              |              |
| Mean corneal power (D)          | 43.55 $\pm$ 1.07 | 42.74 (1.01) | 40.96, 45.28 |
| Corneal astigmatism (D)         | 0.58 $\pm$ 0.29  | 0.63 (0.36)  | 0, 1.2       |
| Anterior chamber depth (mm)     | 3.1 $\pm$ 0.32   | 3.12 (0.36)  | 2.46, 3.84   |
| Axial length (mm)               | 23.08 $\pm$ 0.76 | 23.07 (1.09) | 21.50, 24.61 |
| Implanted IOL power (D)         | 22.70 $\pm$ 1.97 | 23 (2.5)     | 18, 26.5     |
| Target spherical equivalent (D) | -0.04 $\pm$ 0.26 | -0.02 (0.38) | -0.78, 0.46  |
| Photopic pupil diameter (mm)    | 2.87 $\pm$ 0.65  | 2.7 (0.91)   | 1.77, 4.99   |
| Mesopic pupil diameter (mm)     | 4.80 $\pm$ 0.95  | 4.78 (1.29)  | 2.50, 6.67   |
| CDVA (logMAR)                   | 0.1 $\pm$ 0.18   | 0 (0.2)      | 0, 1         |

blepharitis during the 12-month visit, and 1 was submitted to photorefractive keratectomy (+0.25) (-1.00) @ 100 degrees at 6 months postoperatively. A total of 41 patients who accomplished the inclusion criteria were finally included in the analysis (Table 1). Some data of these patients were not available in the database: the monocular intermediate and near visual acuities at 12 months for 1 patient, the monocular VADC at 3 months for 3 patients, the monocular CSDC at 3 months for 2 patients, and the binocular CSDC for 3 patients.

### Safety

Five patients presented nonserious adverse events during the follow-up. These were included in the analysis because no

clinically relevant decrease of CDVA was presented in comparison with the remaining sample. Two patients presented vitreous detachment in 1 eye, a patient with epiphora in 1 eye, and 1 eye of 2 patients (2.43%) were submitted to Nd:YAG capsulotomy before the 12-month follow-up. The median postoperative CDVA was 0 logMAR, better than the median preoperative CDVA of 0.1 logMAR ( $z = -5.29$ ,  $P < .0005$ ). No eyes presented 2 lines of CDVA loss in comparison with the preoperative visit, and no eyes presented a CDVA equal to or poorer than 0.3 logMAR. PCO was graded as none in 82.9% of eyes, minimal in 13.4%, and middle in 2.5%. The latter was one of the eyes submitted to Nd:YAG capsulotomy.

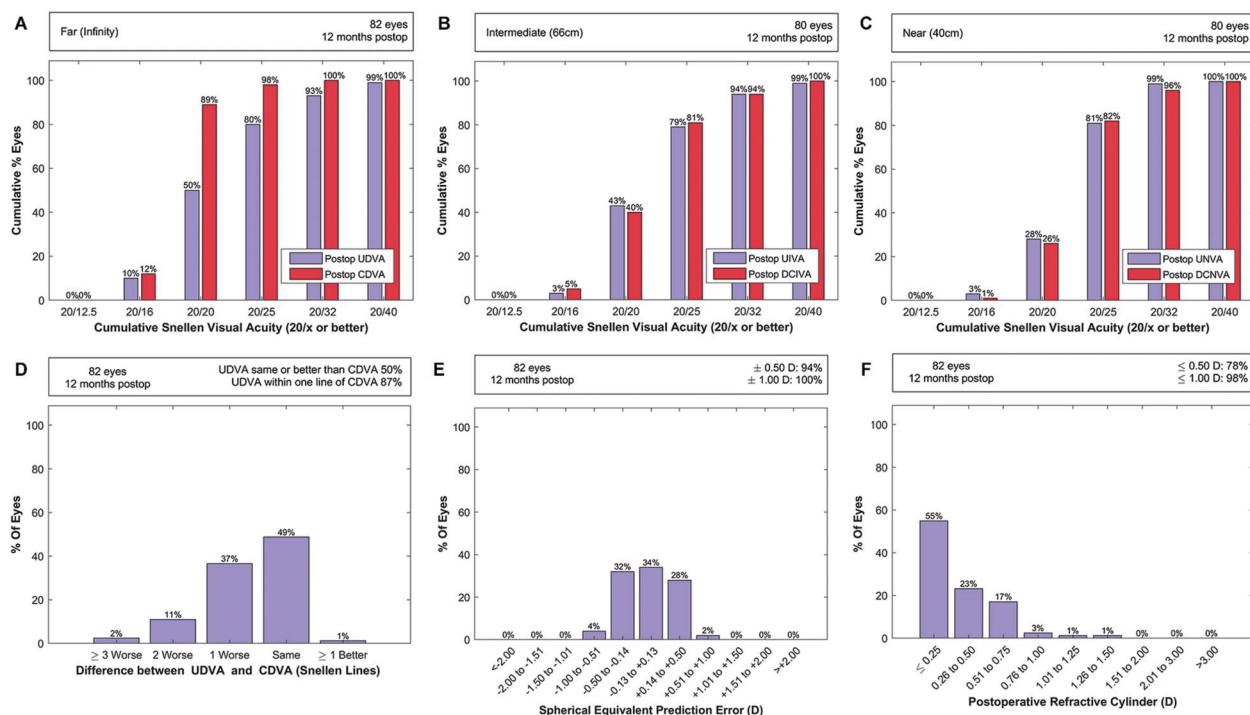


**Figure 1.** Cumulative percentage of eyes achieving monocular CDVA and UDVA at (A) far, (B) intermediate, and (C) near distances. (D) The difference on lines in far distance between postoperative UDVA and CDVA. (E) Spherical equivalent prediction error distribution and (F) postoperative refractive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

**Table 2.** Efficacy at 12-month follow-up for 80 eyes and 40 patients

| Visual acuity | Monocular Mean $\pm$ SD; median (IQR) | Binocular Mean $\pm$ SD; median (IQR) |
|---------------|---------------------------------------|---------------------------------------|
| UDVA (4 m)    | 0.07 $\pm$ 0.1; 0.00 (0.1)            | 0.01 $\pm$ 0.07; 0 (0)                |
| CDVA (4 m)    | 0.00 $\pm$ 0.06; 0.00 (0.0)           | −0.01 $\pm$ 0.06; 0 (0)               |
| UIVA (66 cm)  | 0.08 $\pm$ 0.10; 0.10 (0.1)           | 0.02 $\pm$ 0.08; 0 (0)                |
| DCIVA (66 cm) | 0.08 $\pm$ 0.09; 0.10 (0.1)           | 0.02 $\pm$ 0.08; 0 (0.05)             |
| UNVA (40 cm)  | 0.09 $\pm$ 0.08; 0.10 (0.1)           | 0.04 $\pm$ 0.08; 0 (0.1)              |
| DCNVA (40 cm) | 0.09 $\pm$ 0.08; 0.10 (0.1)           | 0.05 $\pm$ 0.08; 0 (0.1)              |

### Predictability

The prediction error obtained with the Qvision formula showed 85% of eyes in  $\pm 0.375$  D and 94% in  $\pm 0.50$  D (Figure 1, E). A similar percentage of 82% was obtained for Barrett after constant optimization (118.59), 85% for EVO (118.61), and 85% for Kane (118.6) when Pentacam biometric data were used. Percentages of 74%, 79%, and 77% of eyes in  $\pm 0.375$  D were obtained for Barrett (118.92), EVO (118.9), and Kane (118.89), respectively, after constant optimization when IOLMaster 500 biometric data were used. Differences between IOLMaster and Pentacam were obtained for the mean corneal power ( $0.27 \pm 0.29$  D,  $P < .0005$ ), anterior chamber depth ( $-0.05 \pm 0.13$  D,  $P < .0005$ ), and axial length ( $0.009 \pm 0.019$  D,  $P = .001$ ).

### Efficacy

Table 2 and Supplemental Tables S1 and S2 (available at <http://links.lww.com/JRS/A950>) show the efficacy by means of the monocular and binocular corrected and uncorrected visual acuities. Figure 1, A–C shows the monocular cumulative results of VA. Eighty-nine percent of eyes achieved a monocular CDVA of 20/20, whereas 81% and 82% achieved distance-corrected intermediate visual acuity (DCIVA) and distance-corrected near visual acuity (DCNVA) of 20/25, respectively. Supplemental Figure A (available at <http://links.lww.com/JRS/A940>) shows the binocular cumulative results of VA. Eighty percent of eyes achieved a binocular UDVA of 20/20, whereas 96% achieved uncorrected intermediate visual acuity and uncorrected near visual acuity of 20/25. No clinically relevant correlations

were found between photopic pupil diameter and monocular DCNVA ( $\rho = 0.07$ ,  $P = .5$ ) and CDVA ( $\rho = 0.23$ ,  $P = .04$ ), whereas a statistically significant correlation was obtained with DCIVA ( $\rho = 0.4$ ,  $P < .0005$ ). The median DCIVA was 0 logMAR (IQR = 0.1) for photopic pupils  $\leq 2.5$  mm, 0.1 logMAR (IQR = 0.1) for pupils between 2.5 mm and 4 mm, and 0.2 logMAR (IQR = 0.2) for pupils  $> 4$  mm. Only 8.5% of eyes had a photopic pupil diameter above 4 mm.

### Defocus Curves

Figure 2, A shows the monocular VADC measured at 3 months with best distance correction. The highest peak of vision was obtained for the VADC at infinity (0 D) with a value of 0.05 logMAR, and the slope of the DC decreased up to 0.17 logMAR at 66 cm ( $-1.5$  D) and increased again up to a second peak of 0.1 logMAR at 40 cm ( $-2.5$  D). Figure 2, B shows the monocular CSDC measured at 3 months with best distance correction, and Figure 2, C shows the binocular CSDC measured at 12 months without distance correction. Binocularly, the CSDC was increased along all ranges but especially at intermediate vision.

### Patient-Reported Outcomes

Figure 3 shows the stacked bar chart with the percentage of patients answering to the VF-14 questionnaire. All activities showed little or no difficulties except for reading small letters for which 2.43% showed moderate difficulty. 2.43%, 7.32%, and 14.63% reported not conducting activities of reading small letters, driving in day, and driving at night, respectively, but not related with vision difficulties. Table 3 shows the outcomes for the PRSIQ and the single questions. Total spectacle independence was achieved in 85.4% of patients, with only 2.4% requiring spectacles for intermediate vision. More than 90.2% of patients were satisfied or very satisfied with their vision without spectacles. Only 7.3% of patients were bothersome by photic phenomena, and 92.6% of patients were likely or very likely to be operated again with the same IOL.

### DISCUSSION

In this study, the standard outcomes of the Liberty mIOL with an optimized EPS (EPS 2.0) were evaluated at

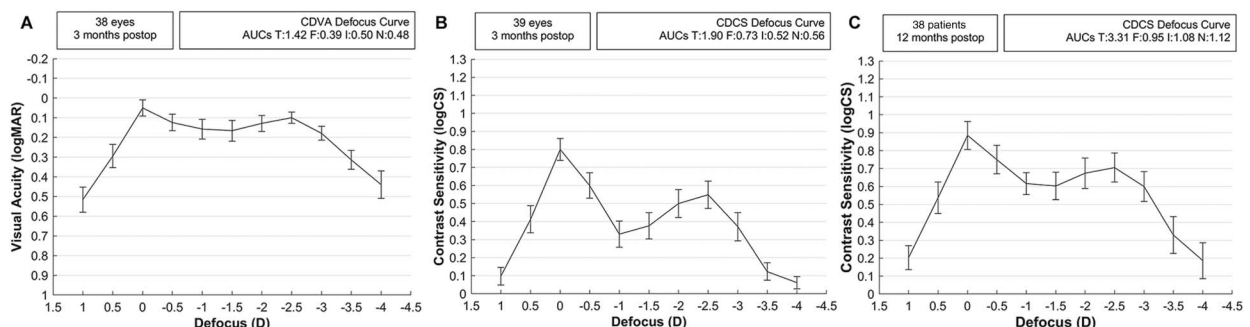


**Figure 2.** (A) Monocular visual acuity defocus curve with best distance correction, (B) monocular contrast sensitivity defocus curve with best distance correction, and (C) binocular contrast sensitivity defocus curve without distance correction. AUCs correspond to the areas under the curve computed for total range (T), far (F), intermediate (I), and near (N) distances. Error bars represent the 95% CI. AUC = area under the curve

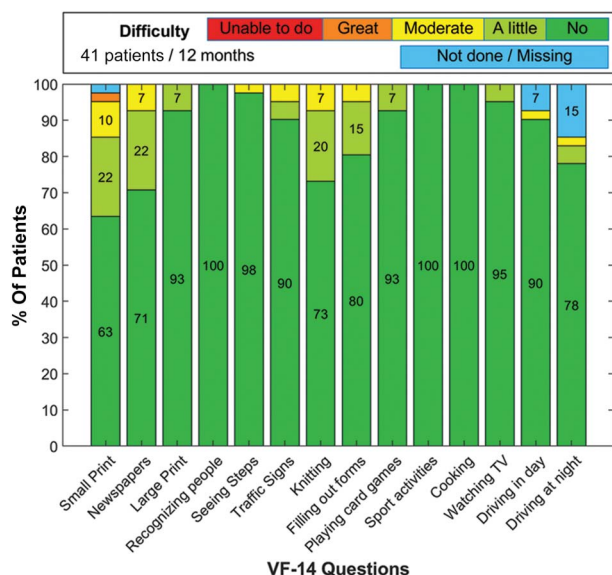


**Figure 3.** Percentages for each 1 of the 5 possible answers from the 14 questions of the Visual Function Questionnaire (VF-14).

the 12-month follow-up. Several studies have been conducted for the Liberty 677MY (EPS 1.0), but, to our knowledge, this is the first study that evaluates the optimized EPS 2.0.<sup>7-11</sup> The procedure with the Liberty Q-Flex 640PM was safe with no IOL-related adverse events beyond a laser corneal refractive surgery retreatment to achieve emmetropia and the required Nd:YAG for 2.43% of eyes. This Nd:YAG rate was close to the 6.9% previously reported for the

Liberty 677MY in the same follow-up.<sup>14</sup> The predictability after constant optimization was considerably better than the 78% of eyes in  $\pm 0.50$  D achieved by the major part of surgeons.<sup>19</sup> In fact, this percentage was achieved in  $\pm 0.375$  D with IOLMaster 500 (between 74% and 79% depending on the formula), and better outcomes were achieved for all the optimized formulas and Pentacam AXL with a threshold of 85% of eyes in  $\pm 0.375$  D. These outcomes, above the normal accuracy reported in studies comparing the accuracy of formulas for calculating IOL power, can be explained by the sample of eyes in the normal range of axial length (between 21.50 and 24.61 mm), because of the use of a mIOL with higher tolerance of far distance defocus during the subjective refraction and because of the use of a formula optimized for the surgeon, IOL, and biometer.<sup>12,19,20</sup> Moreover, the Barrett formula using an optimized constant of 118.59 achieved similar outcomes (82% in  $\pm 0.375$  D) with the Pentacam AXL biometer. Thus, it is important to note that the constant recommended by the manufacturer of 118.9 for this IOL is only recommended for IOLMaster, and other biometers, such as Pentacam AXL, might require optimization for the constant used by the same formula.

In comparison with 677MY efficacy, for which the monocular DCIVA at 66 cm has been reported between 0.22 and 0.28 logMAR, the monocular DCIVA for the 640PM in our study was 0.08 logMAR, around 2 lines more of VA.<sup>9,21</sup> On the other hand, the monocular CDVA in our study was 0 logMAR in comparison with the 0.01 and -0.01 logMAR reported in previous studies for EPS 1.0, and DCNVA was 0.08 logMAR vs the 0.09 and 0.13

**Table 3.** Descriptive results for the PRSIQ and the additional questions

| PRSIQ                                                                                                                                                                                                                                                                               | Mean $\pm$ SD; median (IQR) | Category 1 | Category 2 | Category 3 | Category 4 | Category 5 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|------------|------------|------------|------------|------------|
| Need spectacles                                                                                                                                                                                                                                                                     |                             |            |            |            |            |            |
| Distance                                                                                                                                                                                                                                                                            | 2 $\pm$ 0; 2 (0)            | 0          | 100        |            |            |            |
| Intermediate                                                                                                                                                                                                                                                                        | 1.98 $\pm$ 0.16; 2 (0)      | 2.4        | 97.6       |            |            |            |
| Near                                                                                                                                                                                                                                                                                | 1.85 $\pm$ 0.36; 2 (0)      | 14.6       | 85.4       |            |            |            |
| Often wear                                                                                                                                                                                                                                                                          |                             |            |            |            |            |            |
| Distance                                                                                                                                                                                                                                                                            | 4.8 $\pm$ 0.87; 5 (0)       | 4.9        | 0          | 0          | 0          | 95.1       |
| Intermediate                                                                                                                                                                                                                                                                        | 4.76 $\pm$ 0.92; 5 (0)      | 4.9        | 0          | 2.4        | 0          | 92.7       |
| Near                                                                                                                                                                                                                                                                                | 4.58 $\pm$ 0.97; 5 (0)      | 2.4        | 4.9        | 4.9        | 7.3        | 80.5       |
| Comfortably without wear                                                                                                                                                                                                                                                            |                             |            |            |            |            |            |
| Distance                                                                                                                                                                                                                                                                            | 1.15 $\pm$ 0.42; 1 (0)      | 87.8       | 9.8        | 2.4        | 0          | 0          |
| Intermediate                                                                                                                                                                                                                                                                        | 1.20 $\pm$ 0.51; 1 (0)      | 85.4       | 9.8        | 4.9        | 0          | 0          |
| Near                                                                                                                                                                                                                                                                                | 1.39 $\pm$ 0.77; 1 (0.5)    | 75.6       | 12.2       | 9.8        | 2.4        | 0          |
| Coding: "yes" (category 1) and "no" (category 2). Wear and function items used verbal response labels of "all of the time" (category 1), "most of the time" (category 2), "some of the time" (category 3), "a little of the time" (category 4), and "none of the time" (category 5) |                             |            |            |            |            |            |
| Additional questions (X)                                                                                                                                                                                                                                                            |                             |            |            |            |            |            |
| Satisfaction (satisfied)                                                                                                                                                                                                                                                            |                             |            |            |            |            |            |
| Distance                                                                                                                                                                                                                                                                            | 4.73 $\pm$ 0.45; 5 (1)      | 0          | 0          | 0          | 26.8       | 73.2       |
| Intermediate                                                                                                                                                                                                                                                                        | 4.66 $\pm$ 0.66; 5 (1)      | 0          | 2.4        | 2.4        | 22         | 73.2       |
| Near                                                                                                                                                                                                                                                                                | 4.46 $\pm$ 0.87; 5 (1)      | 0          | 7.3        | 2.4        | 26.8       | 63.4       |
| Photoc phenomena (bothersome)                                                                                                                                                                                                                                                       | 1.73 $\pm$ 1.05; 2 (1)      | 48.8       | 43.9       | 0          | 0          | 7.3        |
| Operated again (likely)                                                                                                                                                                                                                                                             | 4.51 $\pm$ 0.64; 5 (1)      | 0          | 0          | 7.3        | 34.1       | 58.5       |
| Coding for main words (X = satisfied or bothersome or likely): "not at all X" (category 1), "slightly X" (category 2), "neutral" (category 3), "X" (category 4), and "very X" (category 5)                                                                                          |                             |            |            |            |            |            |

IQR = interquartile range; PRSIQ = Patient-Reported Spectacle Independence Questionnaire

Centrality and variation indices in the first column and the percentage of answers for each category (frequency) in category columns

logMAR previously reported.<sup>9,21</sup> These VA outcomes at several distances suggest an improvement at intermediate vision without decreasing VA at far and near distances. These findings were also in agreement with the monocular DC reported by Law et al. and by our research group for 677MY.<sup>7,10</sup> In the current study for 640PM, the monocular DC was above 0.2 logMAR for  $-1.0$  D and  $-1.5$  D of defocus, whereas the previous studies have reported to be close to or below 0.2 logMAR.<sup>7,10</sup> This improvement at intermediate vision appeared even the background luminance of the chart in the current study was  $85 \text{ cd/m}^2$ , considerably lower than the  $250 \text{ cd/m}^2$  used in our previous study for 677MY.<sup>7</sup> It is important to note that despite the 7 rings apodized technology, patients with photopic pupil diameters above 4 mm maintained a median DCIVA of 0.2 logMAR, and no decrease of DCNVA was detected with the increase of pupil diameter. Moreover, the best performance with the IOL in all ranges was obtained for photopic pupils below 4 mm, especially for pupils equal to and smaller than 2.5 mm.

Although previous studies have reported monocular CSDC with 677MY, these have been conducted with a background luminance of  $250 \text{ cd/m}^2$ , and the results are not directly comparable with the CSDC at  $85 \text{ cd/m}^2$  measured in the current study.<sup>14,22</sup> However, monocular CSDC at  $85 \text{ cd/m}^2$  has been reported for AT LISA Tri (Carl Zeiss Meditec AG) at 6 years of follow-up, resulting in around 0.1 logCS higher CS at  $-1.5$  D for AT LISA Tri but better CS for 640PM in the range beyond  $-2.0$  D of defocus.<sup>23</sup> Of interest, binocular vs monocular CSDC with 640PM showed a considerable increase close to 0.3 logCS at  $-1.50$  D of defocus in comparison with the increase of far distance (0.1 logCS at 0 D of defocus) and near distance (0.15 logCS at  $-2.5$  D of defocus). These results suggest that the degree of binocular summation may depend on the modulation transfer function provided by the IOL at each defocus plane.

Little or no difficulty was reported for all the daily tasks, except for reading small letters, for which 2.43% showed moderate difficulty. Of interest, none of the patients reported difficulties during night driving, which is one of the tasks with usually poorer scores with mIOLs. In fact, in previous studies with AT LISA Tri, 15% and 8.3% of patients showed a great deal or inability to drive at night at 6 months and 6 years of follow-up, respectively.<sup>23,24</sup>

No patients needed spectacles at far distance, and visual performance at intermediate distance was enough to achieve 97.6% spectacle independence. Spectacle independence at intermediate vision was not lower than that reported for extended depth-of-focus (EDOF) IOLs such as Symphony (Johnson & Johnson Vision) (between 84% and 89.1%) and Vivity (Alcon Laboratories, Inc.) (88%).<sup>25–28</sup> On the other hand, near spectacle independence was 85.4%, although only 7.3% required near spectacle for all or most of the time. This rate of near spectacle independence was similar to that of other trifocal IOLs such as AT LISA Tri (80.6% at 6 years) or PanOptix (Alcon Laboratories, Inc.)

(86% at 3 months).<sup>23,29</sup> Other studies have also reported percentages of spectacle independence, but only those using the PRSIQ were included in this discussion. For instance, spectacle independence at near has been reported for the 677MY to be between 75% and 100% and between 93% and 100% for intermediate, but these percentages were not collected with the PRSIQ.<sup>10,11,21</sup>

The bothersome to photic phenomena or positive dysphotopsia and the decision to be submitted to the same surgery are also questions of great interest in patients implanted with mIOLs.<sup>17</sup> Patients bothered or very bothered by photic phenomena have been reported between the 3% and 8% of patients for 677MY, similar to the 7.3% of the current study.<sup>8,21</sup> Of interest, this rate was not higher than that reported by some refractive EDOF IOLs such as Lucidis (5%) (SAV-IOL), Comfort LS-313 MF15 (Teleon Surgical) (between 3% and 9%), and Vivity (between 0% and 8%).<sup>30–34</sup> On the other hand, a high percentage of patients (92.6%) were likely or very likely to be submitted to the implantation of the same IOL again; unfortunately, this question has not been included in previous studies of 677MY.

It is important to note that our study has a main limitation related to the discussion and comparison of outcomes with other studies because of the retrospective case series single-arm design. Thus, future randomized clinical trials are required to test the hypothesis for differences between Liberty 640PM (EPS 2.0) and refractive EDOF IOLs in terms of bothersome to dysphotopsia and intermediate vision spectacle independence.

In conclusion, to our knowledge, this study is the first to provide standard outcomes for an optimized EPS technology (EPS 2.0) implemented in a 640PM model. Our outcomes suggest better intermediate vision without affecting far and near distance vision in comparison with the previous EPS 1.0 technology implemented in the 677MY model. In addition, our results suggest that the outcomes of this mIOL in terms of positive dysphotopsia or spectacle independence at intermediate vision might not be clinically relevant in comparison with EDOF IOLs. However, this hypothesis should be tested in future studies with a randomized clinical trial.

### WHAT WAS KNOWN

- Elevated phase shift (EPS) technology of the Liberty mIOL (EPS 1.0) allows visual acuity to be covered in the full range of the depth of field.
- High levels of spectacle independence are achieved in patients undergoing cataract surgery or refractive lens exchange surgery.

### WHAT THIS PAPER ADDS

- Optimization of the EPS technology (EPS 2.0) resulted in an increase in intermediate visual performance compared with previous studies with EPS 1.0.
- Differences in visual acuity at far and near distances were not clinically relevant in comparison with EPS 1.0, and low positive dysphotopsia rates were maintained.

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