ARTICLE

Visual and refractive outcomes after bilateral implantation of an enhanced monofocal intraocular lens: prospective study

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Purpose: To evaluate visual and refractive outcomes, as well as patient satisfaction after bilateral implantation of an enhanced monofocal intraocular lens (IOL) with emmetropia as a target refraction.

Setting: San Carlos Hospital, Madrid, Spain.

Design: Prospective, monocentric, noncomparative study.

Methods: Adults 21 years or older suitable for cataract surgery and with corneal astigmatism <1.50 diopters (D) were bilaterally implanted with the RayOne EMV IOL and followed up for 3 months. Outcomes measures included refraction, monocular and binocular uncorrected distance visual acuity, corrected distance visual acuity (CDVA), uncorrected intermediate visual acuity, distance-corrected intermediate visual acuity (DCIVA), and defocus curve, aberrometry, and satisfaction. Visual symptoms were assessed using the CatQuest-9SF questionnaire.

Results: 50 eyes of 25 patients were included. At month 3, the mean manifest spherical equivalent was −0.39 ± 0.28 D, with all eyes within 1.00 D. Binocularly, uncorrected, at distance, 68% of patients could read ≤0.0 logMAR and 95% ≤0.2 logMAR; at intermediate 59% of patients could read ≤0.1 and 100% ≤0.2 logMAR. Mean monocular CDVA was −0.03 ± 0.06 logMAR and mean monocular DCIVA was 0.28 ± 0.07 logMAR. Binocular defocus curve demonstrated a visual acuity ≤0.2 logMAR over a 2 D range from +1.00 D to −1.25 D. Satisfaction was good in 96% of patients.

Conclusions: Bilateral implantation of an enhanced monofocal IOL with emmetropia as a target provided excellent binocular CDVA and good DCIVA, with a high level of satisfaction.

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The standard of care in cataract surgery is changing with the continuous development of presbyopia-correcting intraocular lenses (IOLs) and the increasing patients' demand for restoration of functional vision at all distances. Increased spectacle independence has resulted in an increase in quality of life after surgery and increased patient satisfaction.[1–4]

Monofocal IOLs are commonly implanted and provide good distance vision and minimal visual disturbances; however, monofocal IOLs are not designed to offer spectacle independence at near or intermediate. On the other hand, multifocal IOLs have been shown to provide acceptable visual acuity from distance to near; however, their main disadvantages remain a loss in contrast sensitivity and increased visual disturbances such as halos and glare.[5]

Extended depth-of-focus (EDOF) IOLs have been developed with the aim of providing patients with a continuous range of good vision from distance to intermediate while limiting dysphotopsia.[6,7] Instead of splitting the focusing light into separate focal points, these lenses create a single elongated focal point to enhance the depth of focus, improving intermediate vision without compromising distance vision.[8,9] However, the performance of diffractive EDOF IOLs still has limitations, including reduced quality of vision.

Nondiffractive enhanced monofocal IOLs share a similar objective of primarily optimizing distance vision while extending the range of vision toward the intermediate range, but without compromising quality of vision and binocular distance vision. Nondiffractive elongation of the depth of focus can be achieved through various methods such as small apertures, wavefront shaping technologies, or manipulations of spherical aberrations.[10]

Among these, the RayOne EMV RAO200E lens (Rayner Intraocular Lenses Ltd.) is a nondiffractive, monofocal aspheric lens, designed to extend the range of vision by inducing a

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controlled amount of positive spherical aberrations, unlike other technologies using negative spherical aberration. The aim of this study was to evaluate refractive and visual outcomes as well as patient satisfaction after bilateral implantation of the RayOne EMV RAO200E.

METHODS

This prospective, single-center, observational, noncomparative study was performed at San Carlos Hospital, Madrid, Spain. The study was reviewed and approved by the hospital's Ethics Committee (Reference 21/664-O_P). Written informed consent was obtained from all patients preoperatively, after they were fully informed about the purpose of the study. The study followed the tenets of the Declaration of Helsinki.

Patients included in the study were men and women aged 21 years or older who presented with bilateral cataract and suitable for cataract surgery with bilateral implantation of the RayOne EMV IOL. Other inclusion criteria were preoperative corneal astigmatism <1.50 diopters (D), potential for corrected distance visual acuity (CDVA) of 0.18 logMAR or better postoperatively, and calculated IOL power in the range of +10.0 to +30.0 D. Participants were excluded from participation if they suffered from other comorbidity such as other medical or ocular conditions that could affect the outcome. Eyes with preoperative corneal positive spherical aberration greater than 0.40 μm for a 6 mm pupil were excluded.

Patients attended a preoperative visit and 3 postoperative visits: 1 to 2 days postoperatively (day 1), 30 to 60 days postoperatively (month 1), and 100 to 120 days postoperatively (month 3).

Intraocular Lens

The CE-marked RayOne EMV RAO200E lens is made of Rayacryl hydrophilic acrylic; it is a nondiffractive enhanced monofocal aspheric IOL. The center of the optics induces controlled positive spherical aberration (maximum 0.15 μm across the 6 mm optic) to spread light along the visual axis and elongate the focal range from far into intermediate, and the blended edge reduces longitudinal spherical aberration to maintain visual acuity and contrast sensitivity in mesopic conditions. It has a refractive index of 1.46 and an Abbe number of 56.[11]

The IOL is fully preloaded in the RayOne injector in the full power range (+10.0 to +30.0 D in 0.5 D increments) and allows implantation through a 2.2 mm incision. The injector features a syringe-shaped design to allow for a one-handed IOL placement technique.

Surgical Procedure

The surgery was performed as per the surgeon preferred a microincision surgical technique under topical anesthesia, using standard phacoemulsification and a 2.2 mm incision.

Biometry was measured using the IOL master 700 (Carl Zeiss Meditec AG). IOL power was calculated using the Barrett Universal II formula (lens factor 1.67; design factor 3.5), and the manufacturer suggested A-constant of 118.6. The target refraction was emmetropia for both eyes; the IOL power was selected as the IOL power resulting in the smallest postoperative myopic refraction (ie, the closest myopic refraction to zero), rather than resulting in the refraction closest to zero.

Postoperative medication was prescribed according to the hospital protocol, including topical antibiotics and steroids.

Preoperative and Postoperative Assessments

Visual acuity was measured using Early Treatment Diabetic Retinopathy Study charts, with 100% contrast, under photopic conditions and reported in logMAR. Uncorrected distance visual acuity (UDVA) and CDVA were measured monocularly and binocularly at 4 meters. Uncorrected intermediate visual acuity (UIVA) and distance corrected intermediate visual acuity (DCIVA) were measured monocularly and binocularly at 66 cm. DCIVA was measured with the distance manifest refraction in place as per recommended published standards.[12] Visual acuities were measured at 1-month and 3-month visits.

The defocus curve was performed with the manifest refraction in place, monocularly (at the 1-month visit) and binocularly (at the 3-month visit) under photopic conditions (85 cd/m^2), with defocus values between +1.00 D and −2.50 D in 0.50 D steps. Pupillometry was measured using the KR-1W wavefront analyzer (Topcon Corp.).

Preoperatively, corneal aberrations were measured with the Pentacam (Oculus Optikgeräte GmbH) for the 6 mm pupil diameter. Postoperatively, corneal and ocular aberrations were measured with the Hartmann-Shack KR-1W wavefront analyzer.

Patient satisfaction and spectacle independence were measured using the validated CatQuest-9SF questionnaire. Aberrometry and questionnaires were performed at 3-month visit. Adverse events were recorded at all visits.

Statistical Analysis

Sample size was calculated using the published results related to UIVA by Kang et al.[13] Given an α risk of 0.05 and a β risk of 0.2 in a 2-sided test, it was calculated that 25 participants were required to achieve a statistically significant difference greater than or equal to 0.06 logMAR units. The SD was assumed to be 0.1. It had been anticipated a drop-out rate of 10%.

Data analysis was performed with the SPSS software for Windows, v. 26.0 (IBM Corp.). The study data were analyzed using descriptive statistics including mean and SD for each parameter. For each study metric, normality was analyzed using the Shapiro-Wilk test. When parametric analysis was possible, the *t* test for paired data was used to compare results between consecutive visits. When parametric analysis was not possible, the Wilcoxon test was used to compare parameters across visits. For all statistical tests, a *P* value of less than 0.05 was considered to be statistically significant.

Only the right eye of each patient was included in the analysis of refraction and monocular visual acuity.

RESULTS

A total of 25 patients (50 eyes) were included and bilaterally implanted with the EMV IOL. All patients completed the 3-month follow-up. Mean preoperative characteristics are summarized in Table 1.

Refractive Results

Postoperative mean spherical equivalent (SEQ) was −0.47 ± 0.39 D (−1.75 to 0.00 D) at month 1 and −0.39 ± 0.28 D (−1.00 to 0.25 D) at month 3. Figure 1A shows the distribution of the SEQ at month 3: 87.0% of eyes were within ±0.50 D and 100% of eyes within ±1.00 D of emmetropia.

Postoperative astigmatism was −0.50 ± 0.44 D (−1.50 to 0.00 D) at month 1 and −0.52 ± 0.44 D (−1.25 to 0.00 D) at month 3. Figure 1B shows the distribution of refractive astigmatism at month 3: 60.9% of eyes were within ±0.50 D and 87.0% of eyes within ±1.00 D of target.

Visual Acuity Results

Mean visual acuity values are summarized in Table 2. All eyes had a monocular CDVA of 0.06 logMAR or better, except 1 eye had macular edema at the 1-month visit and persisting at the 3-month visit with a CDVA of 0.3

Table 1. Mean preoperative demographics

Parameter	Mean ± SD (range)
Age (y)	69.2 ± 8.1 (50, 81)
Sex (F/M) (%)	72/28
SEQ (D)	−0.50 ± 2.94 (−8.50, +3.50)
Mean keratometry (D)	43.61 ± 1.53 (41.08, 47.10)
Corneal astigmatism (D)	0.63 ± 0.35 (0.00, 1.36)
Refractive astigmatism (D)	−0.81 ± 0.54 (0.25, 2.25)
AL (mm)	23.41 ± 1.53 (22.34, 25.12)
ACD (mm)	3.11 ± 0.30 (2.58, 3.90)
Pupil diameter (mm)	
Photopic	3.6 ± 0.7 (2.3, 4.6)
Mesopic	5.4 ± 1.0 (2.8, 6.6)
Corneal spherical aberration (Z_4^0) for the 6 mm pupil (μm)	0.33 ± 0.06 (0.20, 0.39)
IOL power (D)	21.38 ± 2.02 (16.00, 25.50)

ACD = anterior chamber depth; AL = axial length; SEQ = spherical equivalent

logMAR. Figure 1C shows the distribution of the difference between postoperative monocular UDVA and postoperative monocular CDVA; UDVA was within 1 line of CDVA for 92% of eyes.

Mean monocular UDVA (at 4 m) was 0.06 ± 0.11 logMAR at month 3. As shown in Figure 2A, at month 3, UDVA was 0.0 logMAR or better in 58% of eyes, 0.1 logMAR or better in 88% of eyes, and 0.2 logMAR or better in 96% of eyes. Binocularly, UDVA was 0.1 logMAR or better in 95% of patients and 0.2 logMAR or better in all patients (Figure 2C).

At month 3, mean monocular UIVA (at 66 cm) was 0.19 ± 0.09 logMAR; UIVA was 0.1 logMAR or better in 35% of eyes, 0.2 logMAR or better in 78%, and 0.3 logMAR or better in 96% of eyes (Figure 2B). Binocularly, UIVA was 0.1 logMAR or better in 59% of patients and 0.2 logMAR or better in all patients (Figure 2D).

At month 3, mean monocular DCIVA was 0.28 ± 0.07 logMAR. As shown in Figure 2B, DCIVA was 0.1 logMAR or better in 4% of eyes, 0.2 logMAR or better in 39%, and 0.3 logMAR or better in 91% of eyes. Binocularly, DCIVA was 0.1 logMAR or better in 23% of patients, 0.2 logMAR or better in 59% of patients, and 0.3 logMAR or better in 86% of patients (Figure 2D).

Defocus Curve

The distance-corrected monocular and binocular defocus curves showed a peak at defocus 0.00 D (4 m) and, as expected, a gradual continuous reduction in visual acuity with the increase in negative defocus (near vision) (Figure 3). For a defocus of −1.50 D (equivalent to a 66 cm viewing distance), mean visual acuity was 0.36 ± 0.12 logMAR monocularly and 0.24 ± 0.09 binocularly.

Questionnaires

Figure 4 shows the results of the CatQuest-9SF questionnaire obtained at month 3. Most patients (92%) reported that their vision did not cause any difficulty in their everyday life. Regarding satisfaction, 58% of patients reported being very satisfied with their present vision and 38%

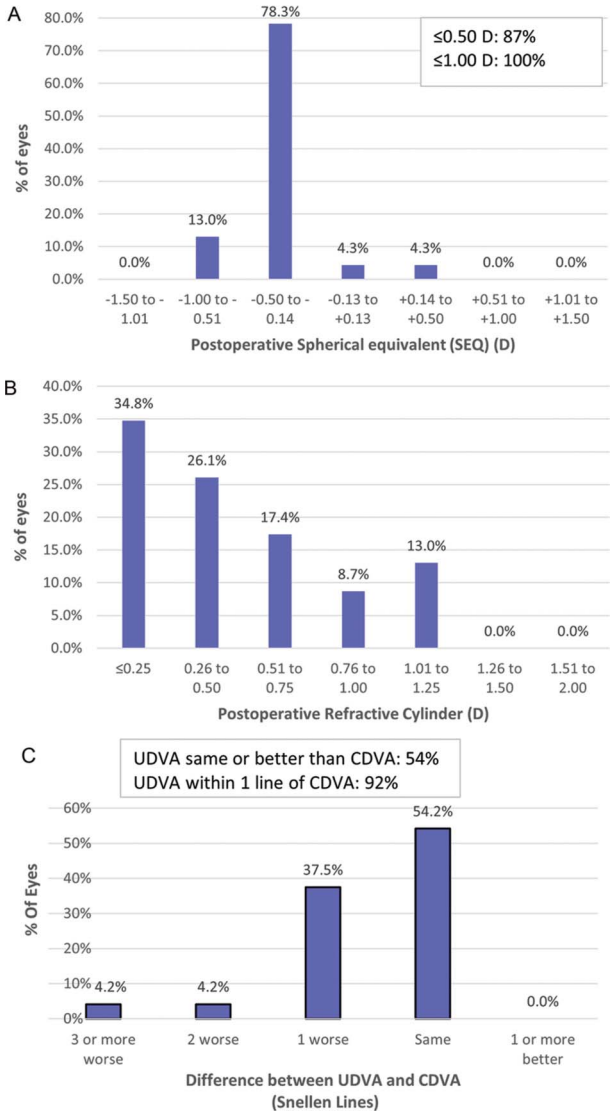

Figure 1. Standard graphs for reporting refractive outcomes after IOL implantation (25 eyes, 3 months postoperatively). *A*: Distribution of postoperative SEQ refraction. *B*: Distribution of postoperative refractive cylinder. *C*: Change in Snellen lines between postoperative CDVA and postoperative UDVA. SEQ = spherical equivalent

of patients reported being fairly satisfied. For difficulties with everyday tasks, most patients (between 80% and 96%) reported no difficulty with recognizing faces, seeing prices of goods when shopping, seeing to walk on uneven ground, seeing to do needlework and handicraft, reading text on television, and seeing to perform a preferred hobby. For reading text in newspaper, 58% of patients reported no difficulty, 37% reported some difficulty, and 4% reported great difficulties. No patient reported being very dissatisfied or having very great difficulties for any questions.

Corneal and Ocular Aberrations

Mean preoperative and 3-month postoperative corneal and ocular spherical aberrations are presented in Supplemental Table 1 (available at http://links.lww.com/JRS/B98). There was no statistically significant change in corneal spherical

Table 2. Mean monocular and binocular UDVA, CDVA, UIVA, and DCIVA preoperatively, at month 1 and month 3 postoperatively

logMAR		Preop	Month 1	Month 3	*P* value (1 mo vs 3 mo)
UDVA	Monocular	0.59 ± 0.23 (0.00, 0.60)	0.13 ± 0.20 (−0.10, 0.74)	0.06 ± 0.11 (−0.10, 0.42)	0.047
UDVA	Binocular	0.38 ± 0.22 (0.10, 0.94)	0.06 ± 0.16 (−0.08, 0.72)	0.01 ± 0.08 (−0.08, 0.20)	0.203
CDVA	Monocular	0.20 ± 0.16 (0.02, 0.66)	−0.01 ± 0.07 (−0.20, 0.16)	−0.03 ± 0.06 (−0.20, 0.06)	0.137
CDVA	Binocular	0.09 ± 0.10 (−0.10, 0.40)	−0.05 ± 0.07 (−0.18, 0.04)	−0.07 ± 0.05 (−0.18, 0.02)	0.355
UIVA	Monocular	0.62 ± 0.26 (0.20, 1.24)	0.17 ± 0.06 (0.06, 0.26)	0.19 ± 0.09 (0.00, 0.36)	0.241
UIVA	Binocular	0.40 ± 0.24 (0.10, 1.04)	0.13 ± 0.05 (0.02, 0.24)	0.13 ± 0.07 (0.00, 0.24)	0.949
DCIVA	Monocular	0.39 ± 0.16 (0.10, 0.82)	0.25 ± 0.12 (0.00, 0.56)	0.28 ± 0.07 (0.12, 0.40)	0.217
DCIVA	Binocular	0.26 ± 0.12 (0.06, 0.62)	0.21 ± 0.05 (0.10, 0.32)	0.24 ± 0.09 (0.10, 0.38)	0.116

aberrations after surgery for the 4 mm pupil ($P = .105$) and 6 mm pupil ($P = .057$). There was a statistically significant increase in ocular spherical aberrations ($P < .001$) for both the 4 mm pupil (from 0.04 ± 0.11 μm to 0.10 ± 0.04 μm) and the 6 mm pupil (from 0.07 ± 0.40 μm to 0.38 ± 0.17 μm) induced by the RayOne EMV IOL.

Adverse Events

Three nonserious adverse events were identified, all cystoid macular oedema. One was experienced monocularly, and the other 2 occurred in the same patient. Two adverse events resolved before the 1-month visit. In the third eye, despite apparent resolution on OCT, loss of CDVA persisted at month 1 and month 3 (CDVA of 0.30 logMAR). A subsequent visit showed improvement in CDVA, suggesting unresolved CME at month 3. Consequently, this eye was excluded from the visual and refractive outcomes analysis. There were no intraoperative adverse events.

DISCUSSION

The RayOne EMV is the only enhanced monofocal IOL on the market using positive spherical aberration rather than negative spherical aberration to increase depth of focus. Regarding presbyopic correction strategies using induced aberrations for increased depth of focus, Bakaraju et al. reported that both positive and negative spherical aberration has equal potential.[14] The IOL was designed so that the induced positive spherical aberration complements the natural positive spherical aberration of the human cornea. An equivalent negative spherical aberration IOL needs to first negate the positive spherical aberration of the cornea and then add even more negative spherical aberration to induce any required depth-of-focus improvements. The total spherical aberration used on the RayOne EMV is therefore designed to be significantly less than for equivalent negative spherical aberration extended depth IOLs. Using optical bench analysis, Schmid et al. confirmed a positive increase in

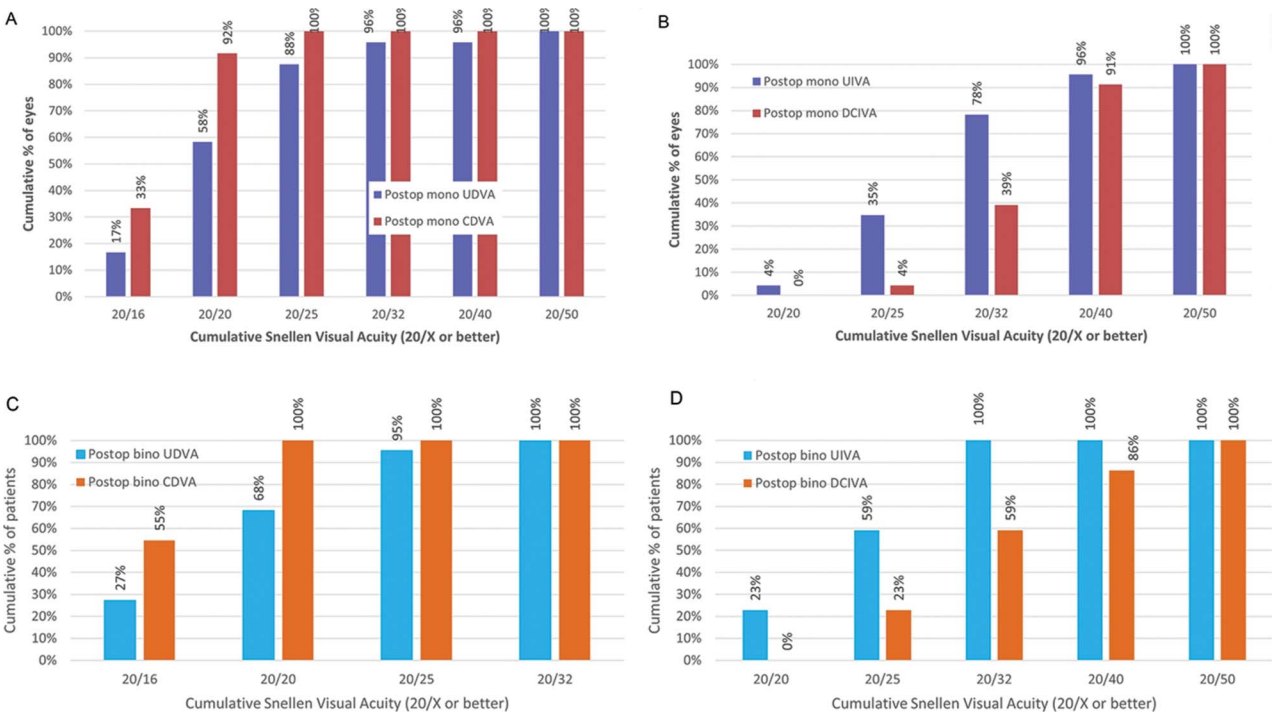

Figure 2. *A*: Cumulative distribution of monocular UDVA and CDVA. *B*: Cumulative distribution of monocular UIVA and DCIVA. *C*: Cumulative distribution of binocular UDVA and CDVA. *D*: Cumulative distribution of binocular UIVA and DCIVA

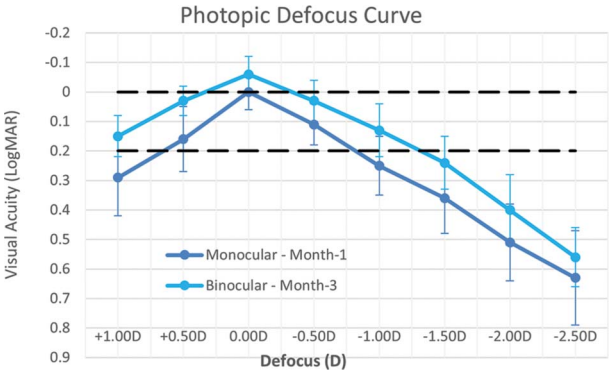

Figure 3. Photopic monocular and binocular defocus curves (measured with the best distance correction in place).

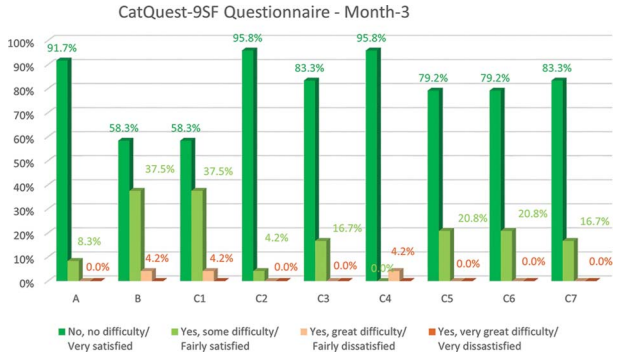

Figure 4. Results of the CatQuest-9SF questionnaire at the 3-month postoperative visit. A: Do you find that your sight at present causes you difficulty in your everyday life? B: Are you satisfied or dissatisfied with your sight at present? Do you have difficulties with the following activities because of your sight? C1: Reading text in newspapers. C2: Recognizing faces of people you meet. C3: Seeing the process of goods when shopping. C4: Seeing to walk on uneven surfaces. C5: Seeing to do handicrafts, woodwork. C6: Reading subtitles on TV. C7: Seeing to engage in an activity/hobby that you are interested in.

spherical aberration, as per the manufacturer's claim.[15] Our clinical study corroborated that the RayOne EMV IOL induces positive spherical aberration in implanted eyes. Corneal aberrations remained unchanged after surgery; however, ocular spherical aberrations positively increased postoperatively, averaging 0.38 ± 0.17 μm (range: 0.02 μm to 0.72 μm) for the 6 mm pupil.

The increase in spherical aberration was also significant for the 4 mm pupil, increasing from 0.04 ± 0.11 μm before surgery to 0.10 ± 0.04 μm after surgery. This is important as a 4 mm pupil diameter closely aligns with the average pupil size of 3.6 mm measured under photopic conditions in our study. This supports the finding that the improvement in intermediate vision is due to the increased depth of field resulting from the increase in spherical aberration.

At the time of writing, there are only published studies assessing the optical quality of the RayOne EMV using optical bench evaluation. To our knowledge, this is the first humans' study reporting the visual and refractive outcomes of patients implanted with the RayOne EMV. Schmid et al. compared 4 enhanced monofocal IOLs in an optical bench study and concluded that for a small aperture, the peak modulation transfer function was best for the Eyhance IOL (Johnson & Johnson Vision, Santa Ana, CA) and RayOne EMV indicating excellent distance quality of vision.[16] Alarcon et al. also performed optical bench testing to evaluate the distance image quality of 3 enhanced monofocal IOLs including the RayOne EMV.[17] The simulated visual acuity demonstrated that the RayOne EMV provided as good distance vision as that of a standard monofocal; both papers are in good agreement with the clinical findings in our study where mean CDVA was excellent and slightly better than 20/20 (−0.03 ± 0.06 logMAR).

In the absence of previously published clinical data on the RayOne EMV, we compared our results with published literature on other nondiffractive enhanced monofocal IOLs, also offering an increased range of vision, including the Tecnis Eyhance ICB00 (Johnson & Johnson Vision, Santa Ana, CA) and the ISOPURE 1.2.3 (PhysIOL S.A, Liege, Belgium).[18] Given that the spherical aberration of any optical system is dependent on the height of incoming light rays regarding the optic axis, and therefore on the diameter of the entrance pupil of the system, it is important to understand the strategies used by the manufacturers to increase the depth of focus with these IOLs. It should be considered that positive spherical aberration induces an extra positive power in the lens periphery compared with its central zone. Conversely, negative spherical aberration leads to greater power in the central zone.

In our study, refractive accuracy was excellent with 87% of eyes within ±0.50 D and all eyes within ±1.00 D of target. These results are consistent with published data on other enhanced monofocal IOLs. In our study, most eyes were slightly myopic postoperatively (mean postoperative SEQ, −0.36 ± 0.28 D) aligning with the preference for a small myopic postoperative target over a hypermetropic one while targeting emmetropia in all eyes. The small postoperative myopic SEQ did not greatly affect uncorrected visual acuity; mean binocular uncorrected distance vision at 3 months postoperatively was good (0.01 ± 0.08 logMAR), with 68% of patients reaching 0.0 logMAR or better, and 95% reaching 0.1 logMAR or better.

Binocular UDVA in our study (0.01 ± 0.08 logMAR) was comparable with previously reported for other IOLs: 0.03 ± 0.12 logMAR for the Eyhance and −0.02 ± 0.13 logMAR for the Isopure.[18,19]

At intermediate distance measured at 66 cm, monocular outcomes were similar between the different IOLs. Mean monocular DCIVA was 0.27 ± 0.11 logMAR for the Eyhance, 0.27 ± 0.13 logMAR for the Isopure, and 0.28 ± 0.07 logMAR for the RayOne EMV in our study.[19,20] The percentage of eyes with a monocular DCIVA of 0.3 logMAR or better was 83.3% with the Isopure and 91% with the RayOne EMV. Mean binocular DCIVA was 0.20 ± 0.11 logMAR for the Isopure, 0.15 ± 0.08 logMAR for the Eyhance, and 0.24 ± 0.09 logMAR for the RayOne EMV showing 59% of patients with binocular DCIVA of 0.2 logMAR or better.[19,20] Randomized trials would be necessary to further evaluate whether there are any differences and conclude with certainty on the comparative performance of these lenses.

Patient satisfaction was high, with 96% of patients reporting satisfaction with their sight after surgery. Although the mean refractive error postoperatively was slightly myopic, the satisfaction level was high for all viewing distances, showing a good tolerance to small refractive errors. The spectacle independence results assessed in this study with the standardized Cat-Quest 9SF questionnaire further underline the good visual acuity results with RayOne EMV.

Some limitations of our study include the fact that the defocus curve was only measured up to a defocus of +1.00 D; it would be beneficial to extend to a wider range of positive defocus to capture the full extended range of vision of the RayOne EMV. Furthermore, preoperatively, eyes with corneal spherical aberration greater than 0.4 μm were excluded to ensure that the maximum spherical aberration postoperatively remained below the 0.6 μm threshold, with the aim of avoiding any potential impact on visual quality.[21,22] Our approach leaned toward caution in the absence of previously published clinical studies on the RayOne EMV. Based on the findings from this study, future research may benefit from extending the inclusion criteria to encompass patients with higher spherical aberration to evaluate the clinical threshold beyond which the lens advantages in extending the depth of focus become indiscernible. It is expected that most eyes will be suitable for implantation with the RayOne EMV given that the average corneal spherical aberration for virgin eyes is approximately +0.27 ± 0.10 μm for a diameter of 6 mm.[23,24]

In conclusion, bilateral implantation of the enhanced monofocal RayOne EMV provided excellent binocular CDVA and good DCIVA. It was confirmed that the RayOne EMV induced positive spherical aberration resulting in an increased range of vision. The results of the quality of vision questionnaire demonstrated high levels of patient satisfaction with 92% of patients reporting no difficultly with their vision in their everyday life.

WHAT WAS KNOWN

- Nondiffractive enhanced monofocal IOLs provide patients a continuous range of good vision from distance to intermediate vision compared with monofocal IOLs.

WHAT THIS PAPER ADDS

- Bilateral implantation of the RayOne EMV–enhanced monofocal IOL, which induces controlled positive spherical aberration, provides excellent binocular corrected distance and good intermediate visual acuity with high levels of patient satisfaction.

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