PRELIMINARY REPORT OF THE VISUAL OUTCOMES AND PATIENT SATISFACTION OF AN ENHANCED MONOFOCAL IOL (RAYONE EMV): A PROSPECTIVE MULTICENTRE STUDY

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ABSTRACT

Purpose:
To evaluate the visual outcomes and patient satisfaction after implantation of an enhanced monofocal intraocular lens (IOL) for monovision.

Setting:
Clinica Baviera-AIER Eye Hospital Group, Spain

Method:
This prospective, multicentre interventional case series included patients with bilateral primary cataract surgery and implantation of an enhanced monofocal IOL (RayOne EMV IOL RAO200E, Rayner Intraocular Lenses Ltd., Worthing, UK). Target refraction was -1.00 D in the non-dominant eye and emmetropia in the dominant eye. The primary outcomes were binocular uncorrected distance visual acuity (UDVA) at 4 m, binocular uncorrected intermediate visual acuity (UIVA) at 66 cm and binocular uncorrected near visual acuity (UNVA) at 40 cm at 1, 3 and 6 months postoperatively. Patient reported outcomes (PRO) were also assessed using the Spanish version of the CAT-QUEST 9SF. A sample of 134 eyes of 67 patients is targeted for this ongoing study.

Results:
In this interim analysis, results were available for 42 eyes of 21 patients with 1-month follow-up and 38 eyes of 19 patients with 3-months follow-up. One month after surgery, mean logMAR binocular UDVA, UIVA and UNVA were 0.09 ± 0.13, 0.24 ± 0.19 and 0.31 ± 0.11, respectively. These visual acuity outcomes remained stable at 3 months. Three months postoperatively, mean manifest refraction spherical equivalent was -0.53 D for all eyes and -0.05 ± 0.34 D and -0.51 ± 0.55 D for the dominant and non-dominant eye, respectively. All respondents reported spectacle independence for distance and intermediate vision at 3 months with more than one-quarter of patients not requiring glasses for near tasks. All patients also reported being satisfied with their vision and 86% claimed no difficulty driving. No adverse event was reported to date.

Conclusion:
Implantation of the enhanced monofocal RayOne EMV IOL provided excellent distance vision and a high quality of overall vision. Spectacle independence was achieved for far and intermediate distances.

Introduction

The quest for providing cataract patients with spectacle independence has resulted in the development of various forms of intraocular lenses (IOLs). Despite providing excellent visual acuity at distance, standard monofocal intraocular lenses do not satisfy this growing patient desire for spectacle independence at intermediate and near distances. To address patients' needs in satisfactory distance, intermediate and near vision, trifocal diffractive optics have been designed. These however can result in unwanted dysphotopsia.[1,2] To overcome these issues, extended depth of focus (EDOF) IOLs were further introduced to achieve a wider range of vision compared to standard monofocal IOLs while aiming to minimize photic phenomena.

Currently, several pure and hybrid EDOF technologies have been developed including diffractive and refractive multifocal, small aperture and more recently non-diffractive intraocular lenses. Earlier, diffractive EDOF technology had significant limitations in terms of unwanted positive dysphotopsia.[3] Newer enhanced monofocal IOLs with non-diffractive optics have been recently introduced to provide a wide range of functional vision without undesirable photic effects associated with diffractive IOL technology.[4-6] The RayOne EMV RAO200E (Rayner Intraocular Lenses Ltd., Worthing, UK) is a non-diffractive enhanced monofocal IOL. According to the manufacturer the RayOne EMV is designed to extend the range of vision with less visual disturbances compared to a diffractive IOL, e.g. diffractive trifocal or diffractive EDOF IOL. The RayOne EMV's patented optic design is aiming to provide a dysphotopsia profile comparable to a standard monofocal IOL.

This interim analysis has been conducted to evaluate visual outcomes and patient satisfaction after bilateral implantation of the RayOne EMV with monovision targeting plano and -1.0 D in the dominant eye and non-dominant eye, respectively.

Materials and Methods

Patient and Study Design

This prospective, multicentre interventional case series evaluated the outcomes of patients who underwent bilateral primary cataract surgery with implantation of an enhanced monofocal IOL (RayOne EMV IOL, Rayner Intraocular Lenses Ltd. Worthing, UK). A sample of 134 eyes of 67 patients was targeted. In this interim analysis, results were available for 42 eyes of 21 patients with 1-month follow-up and 38 eyes of 19 patients with 3-months follow-up. The CAT-QUEST 9SF standardised questionnaire was used to evaluate patient reported quality of vision.

The study was compliant with the tenets of the Declaration of Helsinki and was prospectively approved by the local institutional review board/ethics committee, Medico Legal Committee of Clinica Baviera and the Ethical Committee of the San Carlos University Hospital of Madrid (CEI: LIO_EMV21 - 21/301-O_P). Written informed consent for the surgery and participation in the research was obtained from all patients.

Eligibility criteria included patients who were at least 21 years of age and scheduled for cataract surgery with phacoemulsification and posterior capsule IOL implantation with IOL power within +10.0 D to +30.0 D, and astigmatism less than 1.00 D. Cataract surgeries were performed by five surgeons of the Clinica Baviera-AIER Eye Hospital Group in Spain. Target refraction was -1.00 D in the non-dominant eye while emmetropia was targeted for the dominant eye.

Intraocular Lens

The IOL studied was the RayOne EMV (RAO200E), a single-piece hydrophilic acrylic non-diffractive enhanced monofocal IOL. The patented aspheric IOL induces controlled positive spherical aberration across an aspheric surface to achieve an extended depth of field. Owing to its diffraction-free optic design, the IOL appears identical to a standard monofocal IOL, without zones or rings, thereby potentially avoiding visual disturbances or photic phenomena.[7] This new non-diffractive design was developed to widen the focus of the IOL without splitting or losing any light. It is designed to reduce patient spectacle dependence without inducing dysphotopsia. The RayOne EMV IOL has a total length of 12.5 mm and an optical diameter of 6.0 mm. Other key features include the Amon-Apple enhanced 360° square edge design, anti-vaulting haptic (AVH) technology, and delivery via the fully preloaded RayOne injector.

Outcome Measures

Binocular uncorrected distance visual acuity (UDVA) at 4 m, binocular uncorrected intermediate visual acuity (UIVA) at 66 cm, binocular uncorrected near visual acuity (UNVA) at 40 cm and manifest refraction spherical equivalent were evaluated at 1 and 3 months postoperatively.

Patients were monitored for any intraoperative and postoperative adverse events. Three months postoperatively, patient reported outcomes (PRO) including patient satisfaction, visual difficulties, alteration of night vision, and spectacle independence were assessed at three months using the Spanish version of the CAT-QUEST 9SF.[8]

Results

Table 1 outlines visual outcomes at all time points. One month after surgery, mean logMAR binocular UDVA, UIVA and UNVA were 0.09 ± 0.13, 0.24 ± 0.19 and 0.31 ± 0.11, respectively. Three months postoperatively, mean manifest refraction spherical equivalent was -0.05 ± 0.34 D and -0.51 ± 0.55 D for the dominant and non-dominant eye, respectively (Table 2).

One month after surgery, mean logMAR binocular UDVA, UIVA and UNVA were 0.09 ± 0.13, 0.24 ± 0.19 and 0.31 ± 0.11, respectively. Visual acuity outcomes remained stable at 3 months. Based on the CAT-QUEST 9SF at 3-months follow-up, all respondents (100%) reported spectacle independence for intermediate and distance with 29% patients not requiring glasses for near tasks (Figure 1).

All patients also reported being satisfied with their vision, with 86% indicating that they had no difficulty driving at night. There were no adverse events reported to date.

Table 1. LogMAR visual acuity outcomes at all timepoints.

	Preoperative						Day 30						Day 90					
Statistic	n	Mean (SD)	Median	Min, Max	[95% CI]	K-W p-value*	n	Mean (SD)	Median	Min, Max	[95% CI]	K-W p-value*	n	Mean (SD)	Median	Min, Max	[95% CI]	K-W p-value*
UDVA																		
Dominant	24	0.76 (0.353)	0.8	0.1, 1.4	[0.63; 0.88]	0.6691	22	0.13 (0.135)	0.1	0.0, 0.5	[0.08; 0.18]	0.0108	19	0.11 (0.133)	0.1	0.0, 0.5	[0.06; 0.16]	0.0208
Non-dominant	24	0.73 (0.358)	0.7	0.1, 1.4	[0.60; 0.85]		22	0.29 (0.219)	0.3	0.0, 0.7	[0.21; 0.37]		19	0.23 (0.192)	0.2	0.0, 0.7	[0.16; 0.31]	
Binocular	24	0.69 (0.374)	0.6	0.1, 1.4	[0.56; 0.82]		22	0.09 (0.131)	0.0	0.0, 0.5	[0.04; 0.14]		19	0.07 (0.100)	0.0	0.0, 0.3	[0.03; 0.11]	
UIVA																		
Dominant	24	0.77 (0.163)	0.8	0.3, 1.1	[0.71; 0.83]	0.9490	22	0.38 (0.177)	0.4	0.0, 0.6	[0.31; 0.44]	0.0697	19	0.43 (0.133)	0.4	0.2, 0.6	[0.37; 0.48]	0.0080
Non-dominant	24	0.78 (0.179)	0.8	0.3, 1.2	[0.72; 0.84]		22	0.29 (0.160)	0.3	0.0, 0.6	[0.23; 0.35]		19	0.28 (0.169)	0.3	0.0, 0.6	[0.21; 0.35]	
Binocular	24	0.75 (0.167)	0.8	0.3, 1.1	[0.70; 0.81]		22	0.24 (0.187)	0.3	0.0, 0.6	[0.17; 0.31]		19	0.26 (0.174)	0.2	0.0, 0.6	[0.19; 0.33]	
UNVA																		
Dominant	24	0.86 (0.222)	0.8	0.5, 1.4	[0.78; 0.94]	0.6802	22	0.46 (0.159)	0.4	0.2, 0.9	[0.41; 0.52]	0.0205	19	0.55 (0.178)	0.6	0.2, 0.8	[0.48; 0.62]	0.0073
Non-dominant	24	0.83 (0.266)	0.8	0.3, 1.4	[0.74; 0.93]		22	0.35 (0.114)	0.4	0.2, 0.5	[0.31; 0.40]		19	0.39 (0.131)	0.4	0.2, 0.7	[0.34; 0.45]	
Binocular	24	0.80 (0.256)	0.8	0.3, 1.4	[0.71; 0.89]		22	0.31 (0.111)	0.3	0.1, 0.5	[0.27; 0.35]		19	0.34 (0.130)	0.3	0.2, 0.7	[0.29; 0.39]	

Legend:

CI: confidence interval
K-W: Kruskal-Wallis
SD: standard deviation
UDVA: uncorrected distance visual acuity
UIVA: uncorrected intermediate visual acuity
UNVA: uncorrected near visual acuity
*p-value of the non-parametric Kruskal-Wallis test for the comparison of dominant versus non-dominant eye

Discussion

Spectacle independence is nowadays a high demand in modern cataract and refractive surgery. Despite providing excellent distance vision, standard monofocal IOLs are not designed to provide spectacle independence for near and intermediate vision.[9,10] Multifocal refractive or diffractive IOLs in contrast, were designed to provide a wider range of focus and greater spectacle independence. The term 'EDOF' was first used to describe diffractive and refractive multifocal IOLs, with a lower power addition providing spectacle independent distance and intermediate vision. However, the use of multifocal technology in bifocal, trifocal or EDOF IOLs frequently results in unwanted photic phenomena and loss of contrast sensitivity. Further advancements in IOL technology have yielded non-diffractive optics that extend the depth of focus and offer a wider range of vision compared to standard monofocal IOLs. These lenses are also intended to result in less dysphotopia than diffractive IOLs.

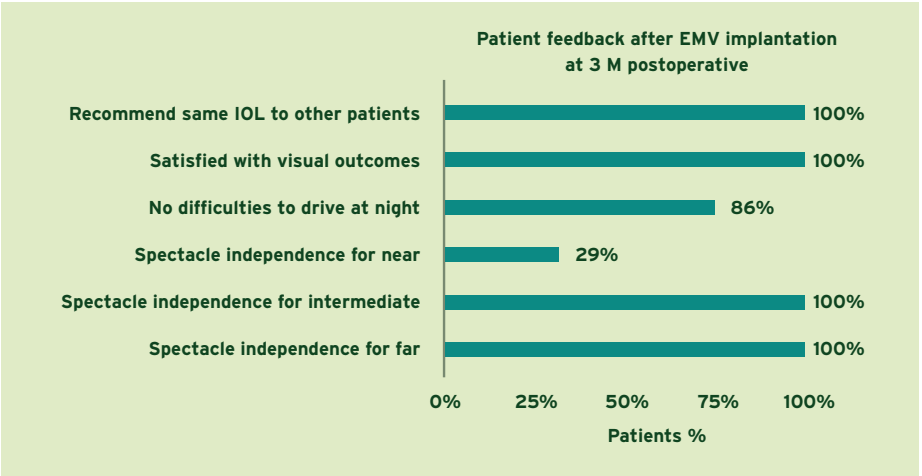
Table 2. Spherical equivalent results at all timepoints.

	Preoperative						Day 30						Day 90					
Statistic	n	Mean (SD)	Median	Min, Max	[95% CI]	K-W p-value*	n	Mean (SD)	Median	Min, Max	[95% CI]	K-W p-value*	n	Mean (SD)	Median	Min, Max	[95% CI]	K-W p-value*
Dominant	24	1.135 (2.4484)	1.63	-4.00, 4.25	[0.279; 1.992]	0.9095	22	-0.080 (0.3810)	0.00	-1.00, 0.75	[-0.219; 0.060]	0.0001	19	-0.053 (0.3393)	0.00	-0.75, 1.00	[-0.188; 0.082]	0.0034
Non-dominant	24	0.969 (2.7949)	1.63	-8.00, 4.75	[-0.009; 1.947]		22	-0.682 (0.4308)	-0.75	-1.25, 0.00	[-0.840; -0.524]		19	-0.513 (0.5557)	-0.50	-1.50, 0.50	[-0.734; -0.292]	

Legend :
CI: confidence interval
K-W: Kruskal-Wallis
SD: standard deviation
SE: spherical equivalent
*p-value of the non-parametric Kruskal-Wallis test for the comparison of dominant versus non-dominant eye

Previous studies as Ferreira et al already compared the defocus curves of different EDOF IOLs and enhanced monofocal IOLs and showed a very similar defocus curve of the RayOne EMV compared to two EDOF IOLs - TECNIS Symfony and AcrySof IQ Vivity.[16]
The results from this ongoing study at Clinica Baviera AIER Eye Hospital Group in Spain demonstrated excellent postoperative UDVA with notable improvements in monocular and binocular intermediate vision for RayOne EMV IOL targeted for monovision.
The spectacle independence results assessed in this study with the standardised CAT-QUEST 9SF questionnaire further underline the good VA results with RayOne EMV. Based on recent literature, despite providing some degree of spectacle independence, some of the marketed non-diffractive EDOF lenses are not completely free from photic phenomena. Specifically, the implantation with AcrySof IQ Vivity IOL was found to result in slightly worse halo complaints compared to the benchmark AcrySof SN60WF monofocal IOL.[11] Moreover, Kohnen and associates have observed that up to 6% of patients experienced double vision symptoms, 25% of patients reported halo and 25% of patients reported glare following bilateral implantation with AcrySof IQ Vivity.[12] These findings were further supported by a recent study by Gundersen et al. wherein the

Figure 1. Post-operative CATQUEST 9-SF results found that all patients reported spectacle independence for distance and intermediate vision.



AcrySof IQ Vivity was associated with hazy vision, blurred vision, focusing difficulties, halos and glare symptoms.[13] According to the manufacturer the AcrySof IQ Vivity optic features a wavefront shaping design element in the 2.2 mm optic centre that extends the depth of focus.[12] In contrast, a first-in-eye case series with RayOne EMV implanted in 20 eyes of 10 patients performed by three surgeons in England (Mr Allon Barsam, Ophthalmic Consultants of London), Spain (Dr Laureano Rementeria, Clinica Baviera, Madrid) and Portugal (Dr Manuel Domingues, Clipovoa, Porto) demonstrated excellent distance and intermediate vision with 70% of patients reporting spectacle independence at all distances. No patient reported dysphotopsia and 100% reported no difficulty with depth perception or contrast sensitivity.[14]
In further independent examinations where RayOne EMV IOL was implanted binocularly targeted for emmetropia, the RayOne EMV IOL also shows monofocal IOL-comparable distance and improved intermediate VA with a broad landing zone of vision, keeping a dysphotopsia and contrast sensitivity profile within a normal range.[17]
The patient satisfaction results for day and night vision quality captured in this analysis (using the CAT-QUEST 9SF questionnaire) were further consistent with global real-world data analysis provided by RayPRO (digital patient-engagement PROM platform).

Of the RayOne EMV patients who have recorded their experience through RayPRO three months after surgery (n=74), 91% reported that they no longer required glasses for distance vision (Figure 2A), while 87% and 63% reported they no longer required glasses for intermediate and near tasks, respectively (Figure 2B & 2C). Overall, 89% of patients were satisfied with the results (Figure 2D), with no reports of dysphotopsia (Figure 2E). [15]

These results demonstrate that as an enhanced monofocal IOL, RayOne EMV can provide a unique option for patients desiring more spectacle independence without causing dysphotopsia, particularly at night. With its patented non-diffractive optic profile, RayOne EMV is likely to enhance the depth of focus and improve both visual acuity and quality of vision.

Figure 2A-E. RayPRO data from patients receiving RayOne EMV implantation (n=74 at 3-months post-operative.

Legend:

(A). Percentage of time patients no longer needed glasses for distance.
(B) Percentage of time patients no longer needed glasses for intermediate vision.
(C) Percentage of time patients no longer needed glasses for near vision.
(D) Percentage of patients satisfied with their vision.
(E) Percentage of patients reporting nighttime dysphotopsia.

Conclusion

In this interim report, the bilateral implantation of the enhanced monofocal RayOne EMV provided excellent uncorrected binocular distance and intermediate vision results with more than one-quarter of patients not requiring glasses for near tasks. The results of the quality of vision questionnaire demonstrate high levels of patient satisfaction with uncompromised quality of vision.

The initial results reported here are preliminary, but it is expected that the visual results will be maintained as additional patients are enrolled and followed-up. RayOne EMV, used in a monovision set-up, may represent not only an alternative to standard monofocal IOL implants, but also to EDOF IOLs by providing an enhanced depth of focus with minimal dysphotopsia.

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