

RayOne EMV Toric First-in-Eye Multicentre Real World Clinical Results

By Rayner

ABSTRACT

Purpose

To evaluate the visual and refractive outcomes and patient satisfaction after implantation of RayOne EMV Toric, an enhanced monofocal toric intraocular lens (IOL).

Setting

Multicentre, 8 countries worldwide.

Methods

This was a non-interventional multicentre case series of astigmatic patients diagnosed with cataract and implanted unilaterally or bilaterally with the RayOne EMV Toric RAO210T (Rayner Intraocular Lenses Limited, Worthing, UK, "Rayner"). Outcomes measures included manifest refraction, monocular and binocular uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), uncorrected intermediate visual acuity (UIVA), and uncorrected near visual acuity (UNVA). Rotational stability was also assessed. Patient satisfaction was recorded using a surgeon-administered patient satisfaction questionnaire.

Results

This analysis included 89 eyes of 56 patients treated by 16 surgeons. Average follow-up was 1-month. After surgery, the mean manifest spherical equivalent was -0.47 ± 0.58 D, with 96% of eyes within ± 1.00 D of target. Manifest cylinder was reduced from -1.32 ± 0.91 D preoperatively to -0.35 ± 0.44 D postoperatively ($p < 0.001$), with 74% of eyes with equal or less than 0.50 D of residual refractive astigmatism. Binocularly, mean UDVA was 0.00 ± 0.07 logMAR with 82% of patients 0.0 logMAR or better and 100% 0.2 logMAR or better. Mean binocular UIVA was 0.07 ± 0.14 logMAR with 73% of patients 0.1 logMAR or better. 94% of patients reported being satisfied or very satisfied. Complete spectacle independence was achieved for distance and intermediate in 91% of patients and at all distances in 51% of patients.

Conclusion

This first-in-eye multicentre real-world evaluation demonstrated that implantation of the enhanced monofocal toric RayOne EMV Toric IOL provided excellent uncorrected distance vision, similar to that of a standard monofocal IOL, excellent uncorrected intermediate vision, and very good functional near vision. Refractive outcomes were very predictable with a statistically significant reduction in cylinder. Patient satisfaction was high; spectacle independence at distance and intermediate was excellent.

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INTRODUCTION

The continuous development of presbyopia correcting IOLs has been driven by the increase in patients' expectations after cataract surgery, and in particular the increased demand for spectacle independence at all distances, from far to near. Increased spectacle independence contributes to increased patient satisfaction.^{1,2,3}

Standard monofocal IOLs provide excellent distance visual acuity; however, they do not fulfil the patient's wish for spectacle independence at intermediate and near distances. On the other hand, multifocal technology, mainly refraction and diffraction, used in bifocal, trifocal or extended depth of focus (EDOF) IOLs increases spectacle independence but often leads to unwanted photic phenomena and reduced contrast sensitivity.^{4,5,6,7}

Further advancements in IOL technology have yielded non-diffractive optics that extend the range of focus and offer a wider range of vision compared to standard monofocal IOLs. These lenses are also intended to result in less dysphotopsia than diffractive IOLs. Instead of splitting the focusing light into separate focal points, these non-diffractive enhanced monofocal IOLs elongate the range of focus by using positive or negative spherical aberration.^{8,9} The advantage of the enhanced monofocal IOLs over standard monofocal IOLs is that they provide additional vision at intermediate distance,¹⁰ without compromising distance vision and while limiting dysphotopsia.^{11,12}

In order to achieve excellent visual acuity, reliable reduction of astigmatism must also be considered, as uncorrected refractive astigmatism is known to degrade visual acuity. It is generally accepted that eyes with corneal astigmatism of 1.0 D or greater benefit from a toric IOL. These eyes represent a significant proportion of patients undergoing cataract surgery: it is estimated that the overall prevalence of corneal astigmatism greater than 1.0 D ranges from 30% to 39%.^{13,14} For these patients, toric IOLs allow the effective correction of astigmatism and therefore enable the achievement of excellent visual acuity, postoperative spectacle independence and optimal patient satisfaction.

The CE-marked and FDA-approved RayOne EMV lenses (Rayner) are non-diffractive enhanced monofocal aspheric IOLs. They are designed to extend the range of vision beyond that of a standard monofocal IOL, while minimising visual disturbances compared to diffractive IOLs. The toric version of the RayOne EMV became available in September 2022, offering a wide range of cylinder correction for treating patients with astigmatism. The RayOne EMV IOLs differ from other enhanced monofocal IOLs by intentionally introducing controlled positive spherical aberration to spread light along the visual axis and elongate the focal range from far into intermediate distances. In contrast,

most other technologies primarily employ negative spherical aberration. The RayOne EMV delivers up to 1.5 D of high-quality vision, without compromise. Moreover, the range of focus provided by RayOne EMV can be further extended by customising the offset, enabling enhanced monovision outcomes.

The aim of this evaluation was to assess the visual and refractive outcomes as well as patient satisfaction after unilateral or bilateral implantation of the enhanced monofocal toric IOL, RayOne EMV Toric (RAO210T).

MATERIALS AND METHODS

Design

This was a non-interventional multicentre evaluation of first eyes implanted with the RayOne EMV Toric across 16 surgeons in eight countries worldwide. Data was collected retrospectively at each centre, in a pseudonymised way, after informed patient consent was obtained.

Patients

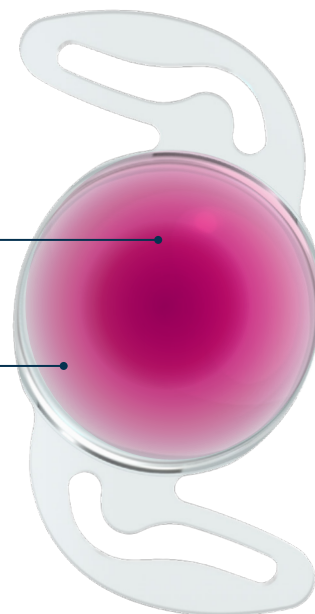
Eligible patients included individuals who presented at the participating centres with cataract and suitable for cataract surgery with monocular or binocular implantation of the RayOne EMV Toric IOL.

Intraocular Lens

The RayOne EMV Toric IOL is made of a hydrophilic acrylic copolymer (Rayacryl) with a refractive index of 1.46 and includes a benzophenone-based ultraviolet absorbing agent. RayOne EMV Toric is available in powers from 10.0 to 25.0 D for spherical equivalent in 0.5 D increments, and cylinder powers 0.75 D, 1.5 D, 2.25 D, 3.0 D, 3.75 D and 4.5 D. It is a single-piece, injectable, preloaded IOL with delivery through a 2.2 mm incision.

Centre region: Induced positive spherical aberration

Blended edge region: Reduced longitudinal spherical aberration designed to maintain visual acuity and contrast sensitivity under mesopic conditions



The lens features proven anti vaulting haptic technology for centration and stabilisation, and a square edge design with a 360° optimised barrier to reduce the epithelial cell migration including at the haptic-optic junction and reduce posterior capsular opacification (PCO).

It is designed with an optimised aspheric surface, that induces controlled positive spherical aberration across the aspheric surface to extend depth of focus compared to a standard monofocal lens, without compromising visual acuity under low light conditions.

The induction of spherical aberration to achieve monocular extended depth of focus is a promising strategy to enhance visual outcomes following cataract surgery. This approach aims to improve binocular vision compared to standard monofocal IOLs, while also preserving binocular stereoacuity and reducing asthenopia in a monovision set-up. Furthermore, this technique is expected to provide high-quality, spectacle-free distance vision, improving the patient's overall visual experience post-surgery.

Surgical Procedure

The surgery was performed according to each surgeon's routine for micro-incision cataract surgery. The chosen IOL was then implanted into the capsular bag with the single-use RayOne injection system. Surgeons were asked to complete a questionnaire on usability of the RayOne EMV Toric and the RayOne fully preloaded injector.

Preoperative and Postoperative Assessments

Preoperative data collected included preoperative biometry (axial length and anterior chamber depth) and keratometry, information on IOL power calculation and selection. The preferred IOL power calculation method was the Barrett toric calculator. Target refraction was either bilateral emmetropia, or emmetropia in one eye and -1.0 D in the fellow eye.

Preoperative sphere, cylinder and target refraction were recorded, as well as monocular uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA).

At one month after surgery of the second eye, postoperative sphere, cylinder, and spherical equivalent, as well as monocular CDVA, monocular UDVA, binocular uncorrected intermediate visual acuity (UIVA) and binocular uncorrected near visual acuity (UNVA) were recorded. Rotational stability was also assessed, and patient satisfaction recorded using a surgeon-administered patient satisfaction questionnaire.

Statistical Analysis

Data analysis was performed in Microsoft Office Excel software for Windows (version 2304). The data were analysed using descriptive statistics, including mean and standard deviation (SD) for each parameter assessed in this evaluation. When parametric analysis was possible, 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 a given parameter across visits. For all statistical tests, a p-value of less than 0.05 was considered to be statistically significant.

RESULTS

Demographics

Data was collected on 89 eyes of 56 patients; 33 patients (66 eyes) were implanted bilaterally, and 23 patients (23 eyes) were implanted unilaterally.

Preoperative Data

Mean implanted IOL power spherical equivalent was 20.7 ± 2.1 D, ranging from 15.5 D to 25.0 D. Mean cylindrical power was 1.58 ± 0.76 D, ranging from 0.75 D to 4.5 D. The distribution of spherical equivalent power is shown in Figure 1 and the distribution of cylindrical power is shown in Figure 2.

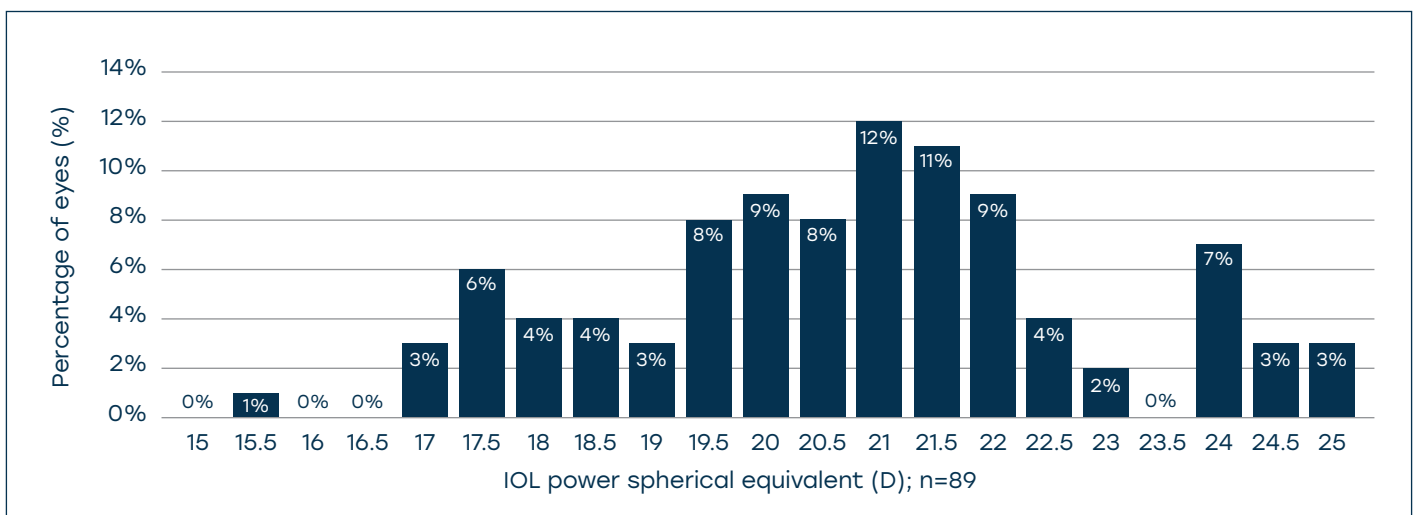


Figure 1. Distribution of spherical equivalent (SE) IOL power (in D)

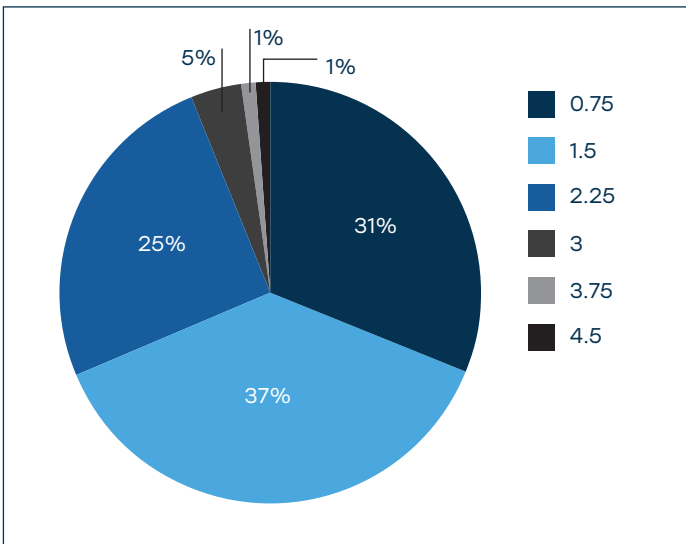


Figure 2. Distribution of cylindrical IOL power (in D)

Target refraction was emmetropia in 57% of patients, and monovision in 43% of patients. Mean predicted target spherical equivalent was -0.23 ± 0.38 D, ranging from -1.41 D to $+0.30$ D.

Preoperative biometry is shown in Table 1. Incision size was on average 2.35 mm, ranging from 2.0 mm to 2.7 mm.

	AL (mm)	ACD (mm)	Corneal astigmatism (D)
Mean \pm SD	23.62 \pm 0.89	3.17 \pm 0.38	1.41 \pm 0.75
Median	23.67	3.18	1.32
Range	21.58 ; 25.85	2.31 ; 4.01	0.17 ; 4.23

Intraoperative Data

The results of the usability questionnaire shown in Table 2 demonstrate excellent outcomes regarding manipulation during surgery. Visibility of the toric markings and intraoperative stability were rated as excellent in 99% of cases.

Refractive Outcomes

Mean manifest refraction spherical equivalent was reduced from 0.77 ± 1.92 D preoperatively to -0.47 ± 0.58 D postoperatively. Mean manifest astigmatism was statistically significantly reduced from -1.32 ± 0.91 D preoperatively to -0.35 ± 0.44 D postoperatively ($p < 0.001$).

The distribution of postoperative spherical equivalent showed that 74% of eyes were within ± 0.50 D of target refraction and 94% of eyes were within ± 1.0 D of target refraction (Figure 3A).

As shown on Figure 3B, after surgery, 63% of eyes had less than 0.25 D of manifest astigmatism, 74% of eyes had less than 0.50 D of manifest astigmatism, and 96% of eyes less than 1.00 D of astigmatism. This demonstrated excellent refractive outcomes.

TABLE 2
Usability and Surgical Questionnaire

	Excellent (4)	Good (3)	Fair (2)	Poor (1)
Ease of opening: IOL/injector packaging (blister packs)	96%	4%	0%	0%
Ease of preparing the RayOne Injector (OVD insertion/cartridge closing)	95%	5%	0%	0%
Injector movement required during IOL implantation	99%	1%	0%	0%
Smoothness of IOL transition through the injector	98%	2%	0%	0%
IOL delivery into the capsular bag	95%	5%	0%	0%
Control of IOL during insertion	95%	4%	1%	0%
Speed of IOL unfolding after insertion	93%	6%	1%	0%
Ease of manipulation of IOL within the capsular bag	91%	9%	1%	0%
Ease of positioning IOL at the targeted axis	96%	4%	0%	0%
Centration	99%	1%	0%	0%
Visibility of toric markings	99%	1%	0%	0%
Intraoperative stability	99%	1%	0%	0%
Clarity of the optic following implantation	99%	1%	0%	0%

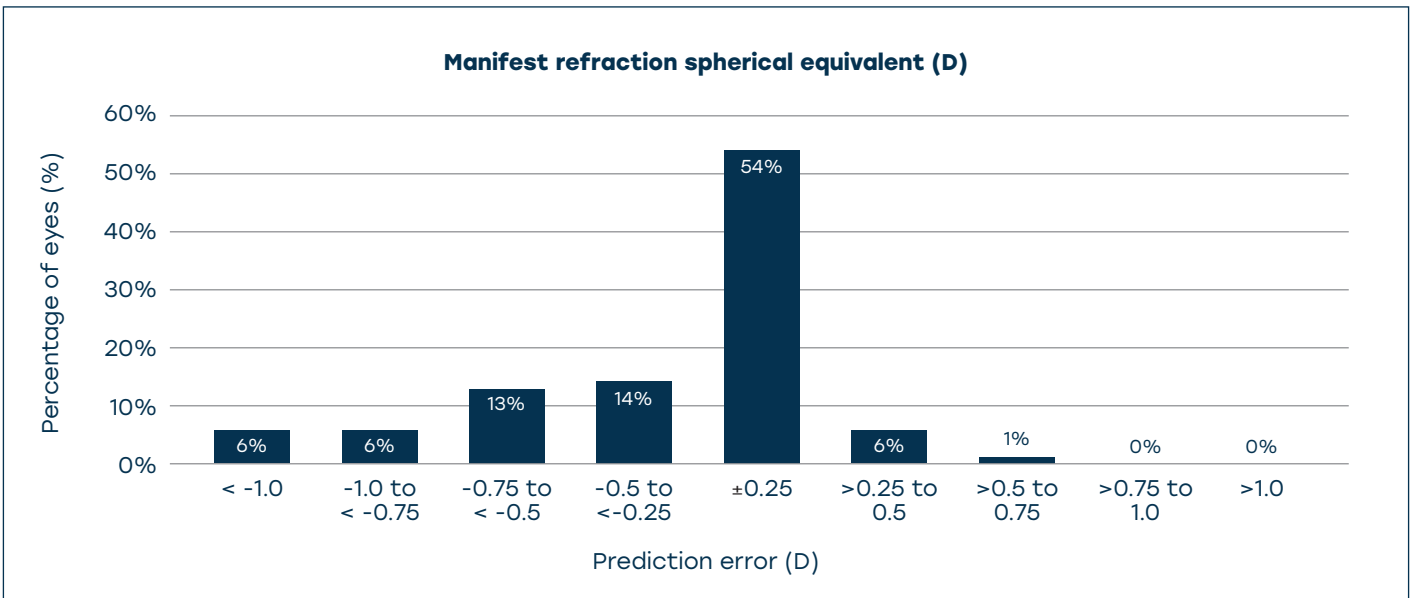


Figure 3A. Distribution of refractive predictability

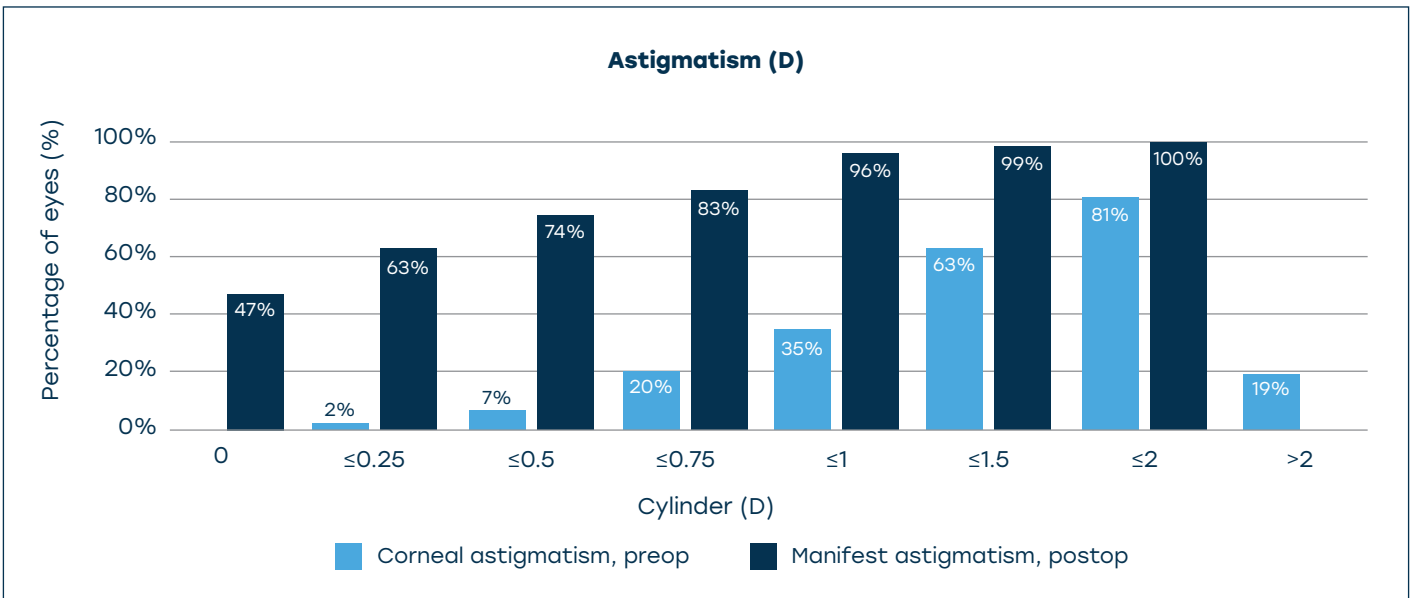


Figure 3B. Distribution of postoperative refractive astigmatism (dark blue bars) and preoperative corneal astigmatism (light blue bars)

Visual Outcomes

Mean preoperative and postoperative visual acuities are presented in Table 3. Postoperatively, there was a statistically significant improvement in monocular UDVA and CDVA ($p < 0.001$) as well as binocular UDVA and CDVA ($p = 0.005$) compared to preoperatively. Postoperatively, mean monocular UDVA was 0.10 ± 0.16 logMAR and mean monocular CDVA was -0.01 ± 0.11 logMAR. Mean binocular UDVA was 0.00 ± 0.07 logMAR and mean binocular CDVA was -0.03 ± 0.08 logMAR.

At distance, 82% of patients had a binocular UDVA of 0.0 logMAR (20/20) or better, and all patients had a UDVA of 0.2 logMAR (20/32) or better (Figure 4A). At intermediate, 73% of patients had a binocular UIVA of 0.1 logMAR (20/25) or better, and all patients had a binocular UIVA of 0.3 logMAR (20/40) or better (Figure 4B). At near, 77% of patients had a binocular UNVA of 0.3 logMAR (20/40) or better, and 87% of patients had a binocular UNVA of 0.4 logMAR (20/50) or better (Figure 4B).

		Preoperatively	1-Month
CDVA	Monocular	0.24 ± 0.19	-0.01 ± 0.11
	Binocular	0.18 ± 0.11	-0.03 ± 0.08
UDVA	Monocular	0.58 ± 0.30	0.10 ± 0.16
	Binocular	0.47 ± 0.20	0.00 ± 0.07
UIVA	Monocular	-	0.14 ± 0.14
	Binocular	-	0.07 ± 0.14
UNVA	Monocular	-	0.30 ± 0.24
	Binocular	-	0.22 ± 0.23

CDVA: corrected distance visual acuity; UDVA: uncorrected distance visual acuity; UIVA: uncorrected intermediate visual acuity; UNVA: uncorrected near visual acuity)

	Yes	No
Is the IOL centred and stable in the bag?	100%	0%
Is there any change in the placement of the IOL from the targeted axis?	1%	99%
Has the patient experienced any increase in intraocular pressure (IOP)?	1%	99%
Any adverse events since the surgery?	3%	97%
Was it necessary to explant the IOL?	0%	100%

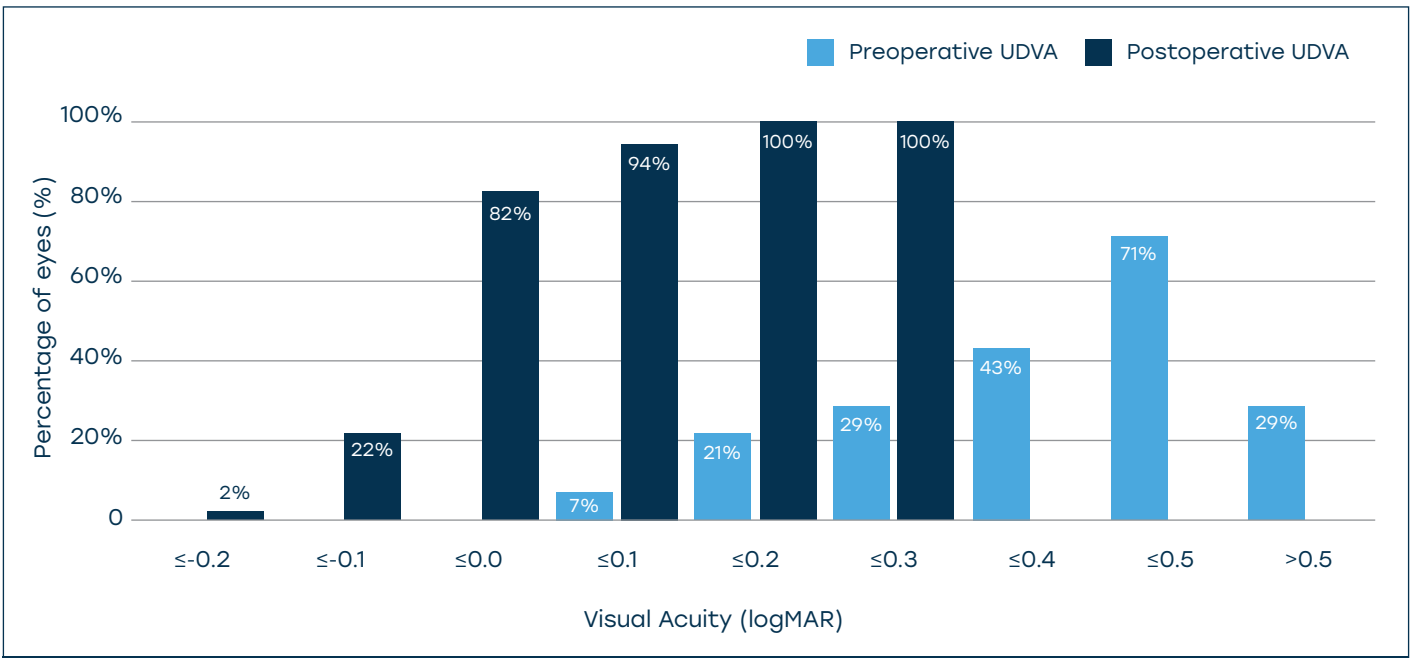


Figure 4A. Cumulative distribution of binocular uncorrected distance visual acuity (UDVA)

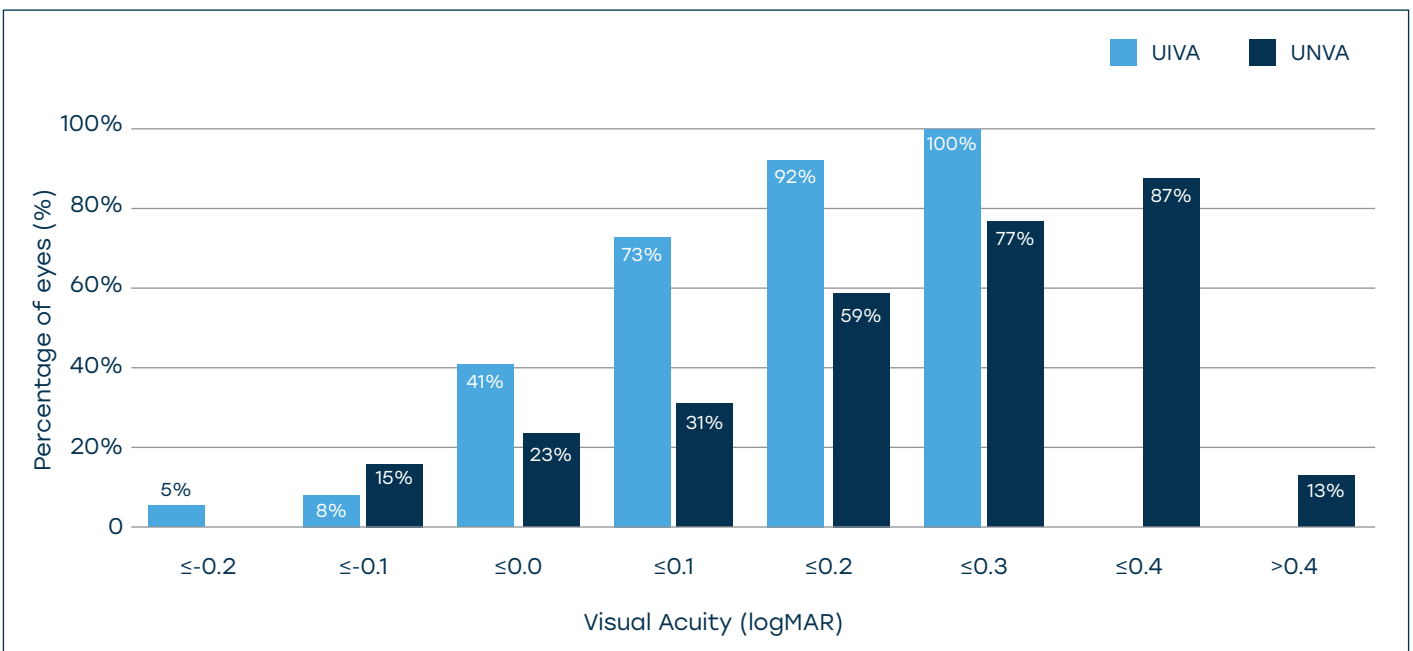


Figure 4B. Cumulative distribution of postoperative binocular uncorrected intermediate visual acuity (UIVA) and binocular uncorrected near visual acuity (UNVA)

QUESTIONNAIRES

Results of the postoperative surgeon questionnaire are shown in Table 4.

Rotational Stability and Adverse Events

The surgeons were asked whether they observed any rotation of the IOL from the target axis and in 99% of cases they reported observing no rotation. There were three reported adverse events in three eyes: one eye with raised IOP at two weeks after surgery, one eye with asteroid bodies, and one eye with anterior lens capsule tear with nasal zonular dehiscence. None of these adverse events were considered related to the IOL and no IOL was explanted during this evaluation.

Visual Disturbances

96% of patients reported no visual disturbances at daytime and 89% of patients reported no visual disturbances at nighttime. Visual disturbances were reported at daytime in both eyes of one patient who noticed a left temporal shadow and one eye of a second patient who reported slight flaring of lights. At nighttime, visual disturbances were reported in nine eyes of seven patients; halos and starburst in one eye of one

patient, halos in one eye of one patient, slight flaring or reflection of light in one eye of one patient, a little bit of ghosting but improving in both eyes of the same patient. One patient (both eyes) stated needing spectacle correction for night driving, and there was no additional information for two eyes of two patients.

Patient Satisfaction

Patient satisfaction after surgery was excellent with 94% of patients reporting being satisfied or very satisfied (Figure 5). Only one patient expressed dissatisfaction for both eyes. This particular patient had a pre-existing corneal scar and experienced fluctuations in vision after surgery. Three patients implanted monocularly (three eyes) reported being neutral.

Spectacle Independence

Complete spectacle independence was achieved for distance and intermediate in 91% of patients and 51% of patients stated not requiring any spectacle correction at all distances (Figure 6). Only one patient required spectacle correction for intermediate, and 37% of patients required spectacle aid for near tasks only.

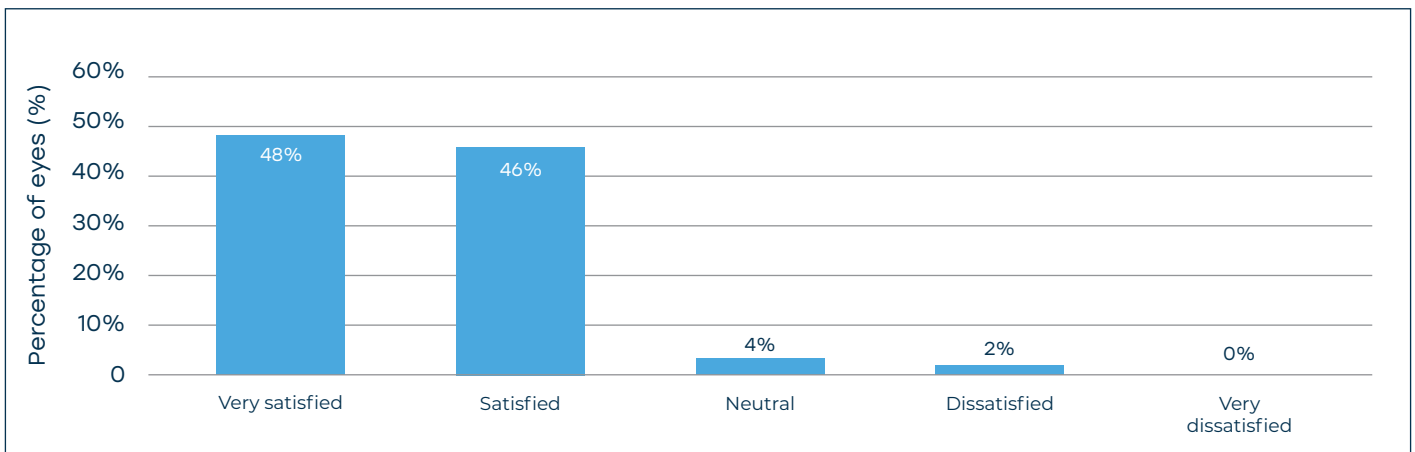


Figure 5. Patient satisfaction at 1-month after implantation with the RayOne EMV Toric

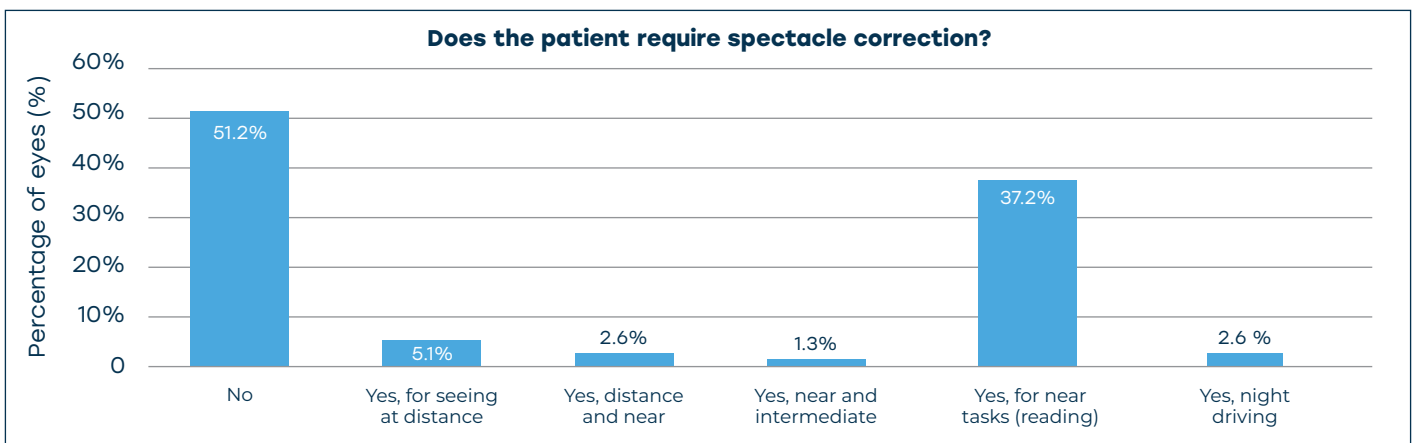


Figure 6. Spectacle independence at 1-month after implantation with the RayOne EMV Toric

DISCUSSION

Traditionally, the primary goal of cataract surgery with standard monofocal lenses has been to attain optimal distance visual acuity. However, advancements in IOLs have expanded patients' and surgeons' aspirations, now aiming to offer a sense of well-being and enable patients, even those with astigmatism, to comfortably engage in various daily activities like driving, using electronic devices, and pursuing hobbies like reading and sewing, all without the need for glasses.

The RayOne EMV stands out amongst other enhanced monofocal IOLs on the market due to the utilisation of controlled positive spherical aberration, as opposed to negative spherical aberration, to increase depth of focus. The RayOne EMV is designed so that the controlled positive spherical aberration induced by the IOL optic complements the natural positive spherical aberration of the human cornea. By employing the same sign of spherical aberration as the cornea, the RayOne EMV utilises lower overall spherical aberration compared to equivalent enhanced monofocal IOLs that utilise negative spherical aberration. This unique design gives the RayOne EMV the advantage of being less sensitive to decentration and tilt than IOLs using negative spherical aberration.

This real-world evaluation presents the first clinical outcomes of the RayOne EMV Toric, providing insights into its safety and performance.

The outcomes after implantation of the RayOne EMV Toric IOL demonstrate reliable cylinder correction, resulting in excellent uncorrected distance vision similar to that of a standard monofocal IOL. Additionally, patients experienced excellent intermediate vision and very good functional near vision. Refractive outcomes were accurate and patient satisfaction was very high. All patients achieved spectacle independence for distance and 91% for intermediate vision. Moreover, in 51% of patients, complete spectacle independence was attained across all distances, including near vision.

The lens design and preloaded injector system demonstrated excellent usability as assessed by the participating surgeons. All surgeons rated the usability of the injector, as well as the IOL delivery and positioning, as excellent or good. Moreover, the intraoperative stability of the IOL was consistently assessed as excellent and the alignment markings on the toric IOL were highly visible to the surgeons, aiding in accurate placement.

The RayOne EMV Toric platform has been shown to be very robust against both decentration and rotation. Bhogal-Bhamra et al.¹⁵ have previously demonstrated exceptional centration and rotational stability of the RayOne platform. In their study, mean rotations postoperatively were $1.60^\circ \pm 1.13^\circ$ at 1 to 3 days, $1.58^\circ \pm 1.36^\circ$ at 30 days, and $1.83^\circ \pm 1.44^\circ$ at 90 to 180 days,

with no lens rotating more than 5° . In this evaluation, 99% of the IOLs were found to be rotationally stable up to one month of follow-up.

The refractive outcomes of this real-world evaluation demonstrated excellent cylinder correction with 63% of eyes with less than 0.25 D of manifest astigmatism at 1-month after surgery and 74% of eyes with less than 0.50 D of manifest astigmatism. The cylindrical correction was shown to be effective across a broad range of corneal astigmatism, with cylindrical powers on the IOL plane between 0.75 D and up to 4.5 D used in this group of eyes. Overall sphero-cylindrical correction was also excellent, with 74% of eyes within ± 0.50 D of target refraction and 94% of eyes within ± 1.0 D of target refraction. This is above the proposed benchmark by Brogan et al.⁶ of 62% of patients achieving a final spherical equivalent within 0.5 D and 89% of patients achieving a final spherical equivalent within 1.0 D.

The visual outcomes obtained in this evaluation showed that implantation of the RayOne EMV Toric yields distance vision comparable to the published data for a standard monofocal IOL. Furthermore, RayOne EMV implantation exhibits enhanced performance in intermediate vision compared to a standard monofocal IOL.¹⁷ In this evaluation, mean binocular UDVA was 0.00 ± 0.07 logMAR and all patients could see 0.2 logMAR or better. Likewise, mean binocular UIVA was 0.07 ± 0.14 logMAR with 92% of patients with 0.2 logMAR or better.

The visual and refractive outcomes are consistent with individual surgeon evaluations of the RayOne EMV Toric.¹⁸ Royo et al. presented outcomes on 12 eyes implanted with the RayOne EMV Toric and reported 83% of eyes with postoperative astigmatism of 0.50 D or less, with all IOLs stable and no case of rotation. Uncorrected vision was excellent with 100% of patients with 0.1 logMAR or better at distance and 100% of patients with 0.2 logMAR or better at intermediate.¹⁹

In comparing the visual outcomes at intermediate distance with other enhanced monofocal IOLs, the RayOne EMV and RayOne EMV Toric appear to perform at least as well. In published studies, binocular UIVA was 0.08 ± 0.11 logMAR with the TECNIS Eyhance,^{20,21} and ranging between 0.13 ± 0.11 logMAR²² and 0.20 ± 0.14 logMAR²³ for the ISOPURE 123. With the LuxSmart, Campos et al.²⁴ reported a mean UIVA of 0.18 ± 0.12 logMAR, and Tahmaz et al.²⁵ obtained a UIVA of 0.08 ± 0.10 logMAR, but essentially due to a small myopic refraction postoperatively. In this evaluation, some eyes were targeted for emmetropia, and some for monovision. The overall mean postoperative refraction was slightly myopic (-0.47 ± 0.58 D) contributing to the excellent binocular vision at intermediate, but without compromising the distance vision.

Previous studies with the RayOne EMV have shown a broad range of focus. Royo et al.¹⁹ measured binocular defocus curve after implantation with the RayOne EMV and reported a defocus range of 0.2 logMAR or better from -1.5 D to +0.5 D. Salamun and Umari²⁶ conducted a prospective evaluation of the depth of focus of four IOLs: the RayOne EMV, the ISOPURE 123, the TECNIS Eyhance and the LuxSmart. They found that the RayOne EMV provided patients with the greatest range of focus, as it achieved the highest visual acuity across distance-corrected intermediate visual acuity (DCIVA) and distance-corrected near visual acuity (DCNVA) in both photopic and mesopic conditions. Ferreira et al. also 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 Symphony and AcrySof IQ Vivity.²⁷

In this evaluation, spectacle independence at distance and intermediate was very high, with 100% of patients reporting spectacle independence at distance and 91% at intermediate. This further supports the excellent mean visual acuity outcomes achieved at distance and intermediate. Over half of the patients additionally benefited from spectacle independence at near. Patient satisfaction after surgery was excellent with 94% of patients reporting being satisfied or very satisfied.

The vast majority of patients experienced no unwanted photic phenomena after the surgery. Only a small percentage of patients reported daytime visual disturbances (4%); they reported either a shadow or a slight flaring of the lights, and they did not necessarily report visual disturbances at night. At nighttime, 11% of patients reported visual disturbances. This is consistent with previously reported data by Llovet et al.,²⁸ where of the patients who have recorded their experience three months after bilateral implantation of the RayOne EMV, all patients were satisfied with the visual outcomes, and 86% reported no difficulty driving at night.

CONCLUSION

The RayOne EMV enhanced monofocal IOL reliably provides patients with excellent distance and intermediate vision and very good functional near vision. The optical design of the IOL with the induction of positive spherical aberration results in a broad range of focus as measured by the gain of intermediate vision and the reduced dependence on glasses compared to standard monofocal IOLs. The rotationally stable RayOne EMV Toric IOL offers the additional benefit of effective astigmatism correction with cylindrical power from 0.75 D to 4.5 D on the IOL plane, with the benefit of the enhanced monofocal optic. Compared to a standard monofocal toric lens, RayOne EMV Toric provides a greater opportunity for patients to achieve spectacle independence at both distance and intermediate, and high levels of satisfaction. It is an attractive choice for patients with astigmatism who desire spectacle independence but have low tolerance to visual disturbances.

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