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RayOne EMV: First Clinical Results

Rayner Intraocular Lenses Limited (Worthing, UK) were delighted to launch the newest addition to their preloaded IOL portfolio on October 2, 2020. RayOne EMV is the first and only IOL designed to enhance patient outcomes in a monovision setting, providing up to 2.25 D depth of focus when used with a 1.0 D offset. The non-diffractive RayOne EMV is designed to induce positive spherical aberration across a controlled aspheric surface. The lens is designed to provide superior intermediate vision when compared with standard monofocals. RayOne EMV is compatible with RayPRO, the contactless telehealth solution that collects three years' worth of patient-reported outcomes data after cataract surgery, free to Rayner customers.

RayOne EMV received CE mark in June 2020. A first-in-eye case series of twenty eyes of ten patients were 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). Following the first-in-eye, surgeons in CE mark accepting countries were invited to implant a minimum of three patients bilaterally and evaluate the outcomes in their own practices. Assessments were performed per standard care and post-market data was sought via audit results and post market surveillance data capture. To date, more than sixty RayOne EMV IOLs have been implanted bilaterally across ten countries in Europe and Asia-Pacific.

This white paper summarises the initial clinical results of twenty patients implanted bilaterally with RayOne EMV in the months leading up to the commercial launch. The first clinical results were collated at one month.

Patient Selection & IOL Calculation

RayOne EMV is designed to be used in a modest monovision setting with approximately 0.75 - 1.5 D offset between the dominant to the non-dominant eye. The Modulation Transfer Function graph (**Figure 1**), modelled with a 3.0 mm pupil in a Liou & Brennan eye model, shows the binocular optical performance for RayOne EMV and a competitor's negatively aberrated aspheric IOL, with a distance target of emmetropia at 22.0 D (dotted black line) and targeted for a monovision offset of +1.0 D. The hyperopic tail of the non-dominant eye gives binocular vision at distance and improved stereoacuity versus competitor lenses. Due to the extended depth of vision, the dominant eye will be more forgiving of post-operative myopic shift when compared to aberration negative aspheric IOLs, shown by the dominant eye hyperopic tail.

RayOne EMV is suitable for any patient in which a monovision setting is desired. The RayOne EMV optic is non-diffractive and dysphotopsia-free with no zonal demarcation on the IOL surface, and there are no contraindications for any specific profession.

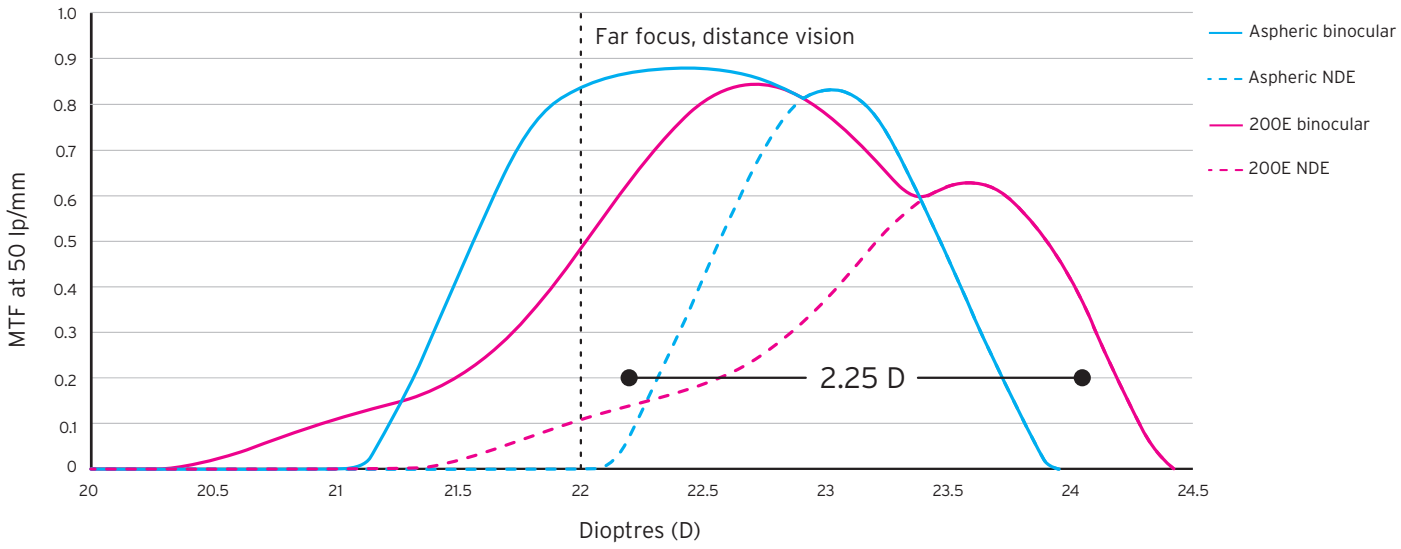

Figure 1. MTF Curve

In practice, patient selection is determined by the surgeon and it is recommended that the closest negative to zero is targeted in the dominant eye with approximately 1.0 D of offset in the non-dominant eye in order to gain the greatest benefit for binocular distance vision. The approach of the first implanters was primarily plano in the dominant eye with an offset ranging from 0.5 D to 1.0 D. Patients in the first-in-eye series did not undergo a contact lens trial nor have a significant level of ocular dominance testing but were assessed for suitability per the surgeon's standard practice. IOL calculation and corneal topography were performed. RayOne EMV is a monofocal aspheric IOL (meeting all applicable ISO standards for monofocal IOLs) with the following manufacturer suggested constants (**Figure 2**).

Estimated Constants for Optical Biometry								
SRK/T	Haigis			HofferQ	Holladay	Holladay II	Barrett Universal II	
A-constant	a0	a1	a2	pACD	SF	pACD	LF	DF
118.6	1.17	0.40	0.10	5.32	1.56	5.32	1.67	0

Figure 2. Manufacturer Suggested Constants for RayOne EMV.

Surgeon Experience & Visual Acuity Data

Surgeon experience was rated excellent throughout with surgeons experiencing a smooth lens transition through the preloaded RayOne injector, fine IOL control during insertion and excellent stability and centration of the IOL seen in the capsular bag. All surgeons reported reaching their targeted subjective refractive outcome and no intraoperative or postoperative adverse events were reported. At one-month postoperative, visual acuity and refractive data showed excellent results (**Table 1**).

Value		Acuity (LogMAR)	Snellen Approximation
Binocular UDVA	(n=18)	-0.03 ± 0.05	6/6 20/20
Dominant Eye UDVA	(n=18)	-0.02 ± 0.07	6/6 20/20
Binocular UIVA	(n=17)	0.08 ± 0.12	N8 @ 100 cm J1 / J2 @ 40 cm
Binocular UNVA	(n=5)	N6 Range N4 - N10	6/9 20/32

Table 1. Visual Acuity at one month postoperative.

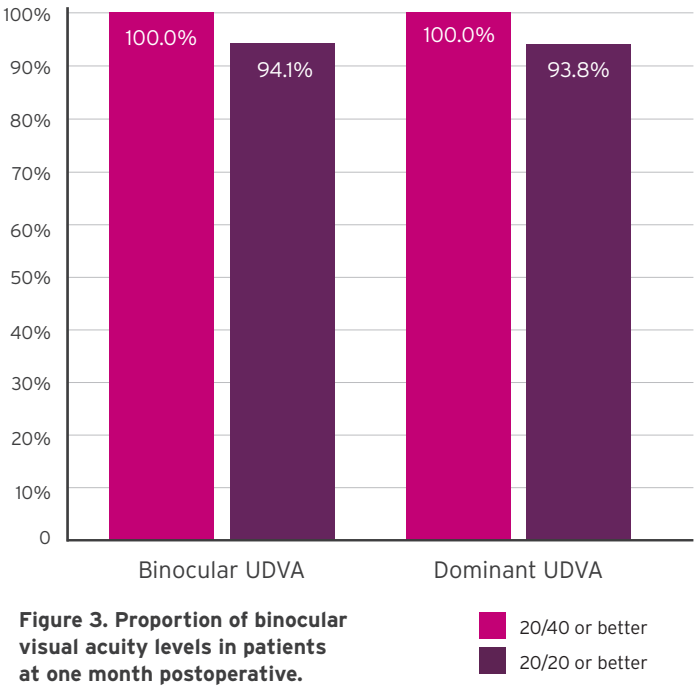

Figure 3. Proportion of binocular visual acuity levels in patients at one month postoperative.

Patient Satisfaction

In the one-month postoperative period, patients reported high satisfaction with their refractive outcome, with 70% reporting spectacle independence at distance, intermediate and near. Patients were entirely dysphotopsia-free; 100% reported no incidence of halo, glare, starbursts or haze one month postoperatively (n=18). 100% of patients reported no difficulty negotiating steps, stairs or curbs with no depth perception or contrast sensitivity issues reported.

A small sample of five bilateral patients completed a spectacle independence and visual functioning questionnaire as part of standard care at one practice. Aspects of visual functioning including reading medicine bottles, taking part in sports such as bowling or golf, watching television and driving during the day or night all scored zero in difficulty.

RayOne EMV has provided excellent early clinical results. Patient-reported outcomes will be further gathered for three years postoperatively by RayPRO, the free contactless telehealth solution for Rayner customers that collects three years' worth of patient-reported outcomes data after cataract surgery. Additional prospective clinical studies are planned to further grow the evidence base for this new, first-of-its-kind technology, the only IOL designed to provide enhanced visual outcomes in a monovision setting.

To experience the patient benefits offered by RayOne EMV, we encourage all surgeons to evaluate RayOne EMV in their own practice. For more information:

- Visit the Rayner website **www.rayner.com/EMV**
- For clinical or data questions, contact **eyescience@rayner.com**
- For sales and all other questions, contact your **local Rayner representative**.

RayOne EMV is not approved by the US FDA

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