Extending range without compromise

RayOne EMV

RayOne EMV TORIC

Rayner

An **enhanced** monofocal IOL delivering **up to 1.5 D of high quality** vision

Developed in collaboration with Professor Graham Barrett, RayOne EMV's truly non-diffractive optic utilises positive spherical aberration to uniquely extend vision whilst avoiding the problems that can arise with diffractive lenses.

RayOne EMV's range of focus can be extended further with a customisable offset for Enhanced Monovision outcomes.

RayOne EMV and RayOne EMV Toric offers:

Increased range of focus: Up to 1.5 D[1,4,6] with an emmetropic target.

High quality vision: Truly non-diffractive IOL with monofocal levels of contrast sensitivity[1], dysphotopsia[2,5] and high levels of patient satisfaction.[3]

Enhanced Monovision: Unique positive spherical aberration design provides a smoother transition between distance and near eyes.[2,4]

Now available on the rotationally stable RayOne toric platform.[8]

"For many years I have worked on optimising a lens for monovision, given that it accounts for nearly 30% of all surgeries. I collaborated with Rayner on bringing this lens to market as RayOne EMV, an exciting new product for all surgeons looking to treat presbyopia reliably"

Professor Graham Barrett, president of the Australasian Society of Cataract & Refractive Surgeons

How does RayOne EMV work?

RayOne EMV is a truly non-diffractive IOL which does not use light splitting technology like many IOLs which increase depth of focus, resulting in low levels of dysphotopsia, similar to standard monofocal lenses.[1]

RayOne EMV has a unique patented aspheric optic that induces controlled positive spherical aberration.

Compared to a lens with zero spherical aberration, the carefully controlled positive spherical aberration induced by RayOne EMV spreads light along the visual axis, elongating the focal range from far into intermediate with up to 1.5 D of depth of focus (per lens on the spectacle plane).

Below shows an illustration of a lens with zero aberration and a small focal range (Figure 1), shown together with RayOne EMV with positive spherical aberration and a larger focal range (Figure 2).

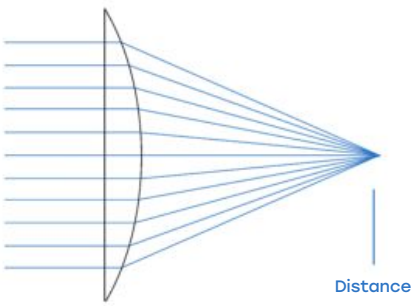


Figure 1
Standard monofocal IOL with zero spherical aberration

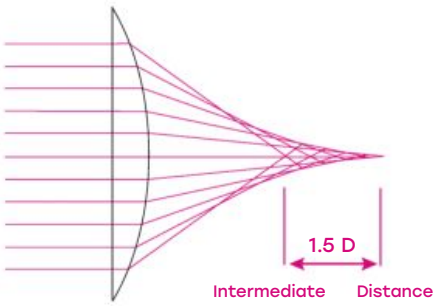


Figure 2
RayOne EMV with positive spherical aberration

Expected vision with a standard monofocal IOL

Expected vision with RayOne EMV

Why is positive spherical aberration good for extending depth of focus?[4]

The positive spherical aberration induced by RayOne EMV complements the natural spherical aberration of the human cornea and gently increases depth of focus into the intermediate range - see illustrative Figure 3.

An equivalent negative spherical aberration IOL needs to first negate the positive spherical aberration of the cornea, 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, and the RayOne EMV optical surface remains closer to spherical in form, thus making performance more consistent under normal tilt and decentration conditions.

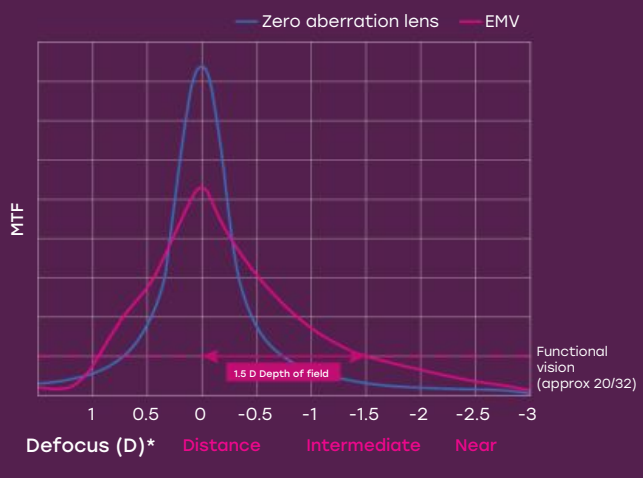


Figure 3

Clinical results with RayOne EMV

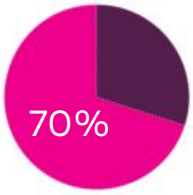
Since the launch of RayOne EMV in 2020, clinical data from across Europe has demonstrated that:[1,2,3,6,7]

- RayOne EMV can provide spectacle independence in the distance to intermediate vision.
- RayOne EMV provides improvement in intermediate vision without compromising the binocular distance vision.
- RayOne EMV can help to improve your patients' near vision, particularly when used with monovision.

The following clinical results are from patients in the UK, Spain and Portugal during the months leading up to the commercial launch of RayOne EMV.[2]

MONOVISION

Value		Acuity @ 1 month (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



of patients reported spectacle independence at distance, intermediate and near

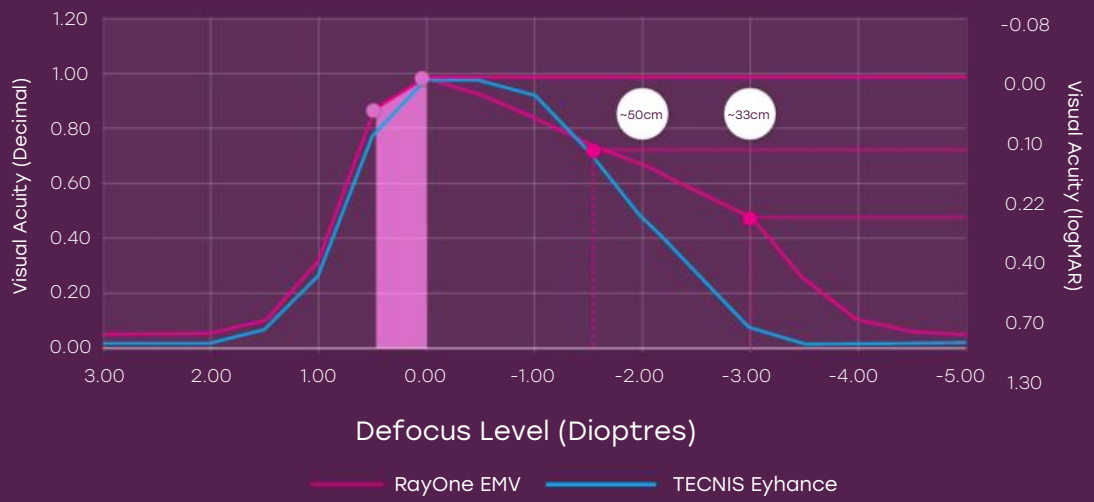
of patients reported no difficulty negotiating steps, stairs or curbs with no depth perception or contrast sensitivity issues reported

of patients reported no incidence of halo, glare, starbursts or haze

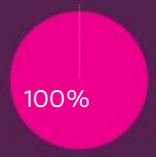
of patients reported being dysphotopsia free

EMMETROPIA

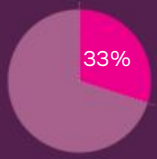
Dr. Mariano Royo, Director of Ophthalmology at the Hospital San Rafael in Madrid, shared his clinical results of 22 eyes of 11 patients implanted with RayOne EMV at six months post-op and 70 eyes of 35 patients implanted with TECNIS Eyhance (Johnson & Johnson Vision). Bilateral emmetropia was targeted for all patientsin both groups. The defocus curve below reports the binocular vision obtained using the best distance correction.[6]



RayOne EMV patients reporting spectacle independence:

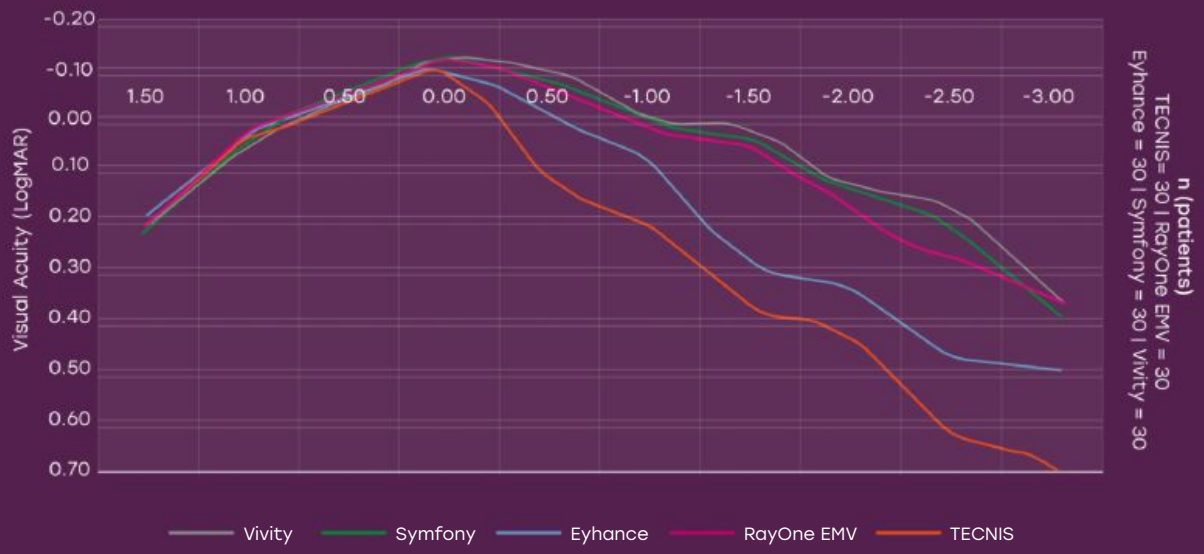


distance & intermediate vision



functional near vision

In a double-arm, non-randomised prospective case series, RayOne EMV demonstrated excellent visual outcomes for distance and intermediate vision, and good visual acuity for near vision.[1]



"RayOne EMV can easily be the lens that helps surgeons go from being a standard lens surgeon to a premium lens surgeon. It is a natural, easy transition for most surgeons to make, and it provides patients with good quality distance and intermediate vision along with useful near vision for many, particularly with a mini-monovision approach."

Mr Allon Barsam, Consultant Ophthalmic Surgeon & Director at OCL Vision

Uncorrected distance visual acuity at 2 weeks postoperative[7]

Binocular UDVA LogMAR	Cumulative %
-0.1	41.70%
0	100%

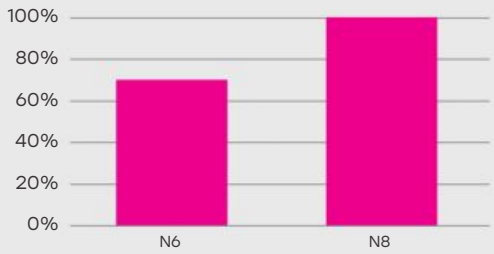
n=24 eyes

Mean Binocular UDVA (LogMAR) -0.04 ±0.05

Uncorrected intermediate visual acuity at 2 weeks postoperative[7]

Binocular UIVA	Cumulative %
N6	**70%**
N8	100%

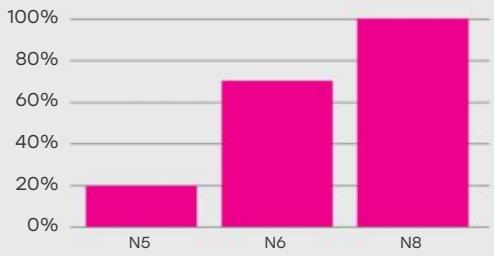
n=20 eyes



Uncorrected near visual acuity at 2 weeks postoperative[7]

Binocular UNVA	Cumulative %
N5	20%
N6	**70%**
N8	100%

n=20 eyes



RayOne EMV & EMV Toric

ENHANCED TORIC MARKINGS

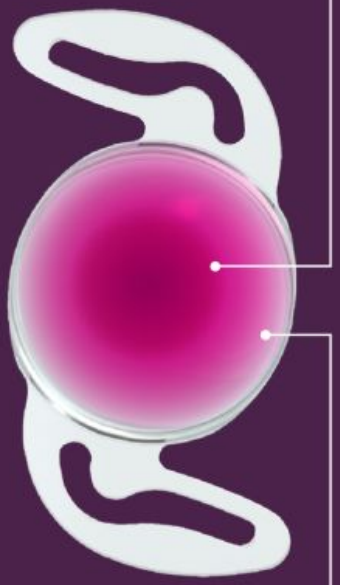
KEY INFORMATION

- Up to 1.5 D increased range of focus with an emmetropic target.[1,4,6]
- High levels of contrast sensitivity[1] and low levels of dysphotopsia[2,5], similar to standard monofocal lenses.
- Positive spherical aberration design provides a natural range of vision.[2,4]

DESIGNED TO PROVIDE:

- Smoother, blended transition between the eyes when compared to monovision with standard monofocals, maintaining binocular stereoacuity and reducing asthenopia.
- High quality spectacle-free distance vision.
- Reduced pupil dependency, for optimised performance under low light conditions.
- Reduced sensitivity to decentration and tilt compared to other IOL designs.
- Complements the eye's natural level of spherical aberration.
- Fully preloaded across the entire power range.

Centre region: Induced positive spherical aberration



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

CORRECT MORE OF YOUR PATIENTS, EVEN THOSE WITH SIGNIFICANT CORNEAL ASTIGMATISM

- Proven rotational stability and centration[8] with predictable, sustainable and accurate visual results
- Average offset of only 0.08 mm 3 to 6 months after surgery[8]
- 1.83° mean IOL rotation 3 to 6 months after surgery[8]
- Available in a wide range of IOL plane cylinders: +0.75 D to +4.5 D, in +0.75 D increments

VACUOLE FREE MATERIAL FOR A GLISTENING FREE IOL

- Single piece IOL created from a homogeneous material free of microvacuoles[9]
- Compressible material for delivery through a 2.2 mm micro incision[10]
- Excellent handling characteristics with controlled unfolding within the capsular bag[11]
- Low silicone oil adherence[12]
- Excellent uveal biocompatibility[13]
- Hydrophilic acrylic material with low inflammatory response[14]

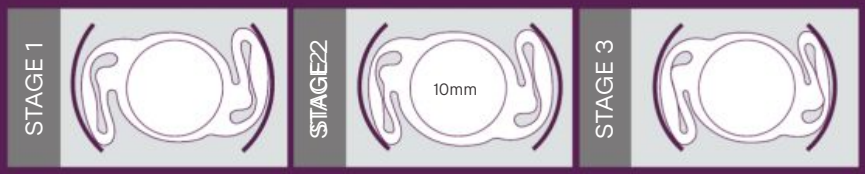
360° Optimised barrier to reduce PCO

Rayner's 360° Amon-Apple Enhanced Square Edge creates an optimum barrier to reduce epithelial cell migration including at the haptic-optic junction.[15,16]

ND:YAG CAPSULOTOMY RATES[15]		MEAN TIME TO ND:YAG CAPSULOTOMY[15]
At 12 months	0.6%	9.3 ± 5.5 mths (range 2.6 - 22.7 mths)
At 24 months	1.7%	Follow-up period: 5.3 - 29 mths

Extremely low Nd:YAG capsulotomy rates, comparable with hydrophobic acrylic lenses with square-edge optics.[15]

Stability of RayOne IOLs



Outer haptics begin to take up the compression forces of post-operative capsule contraction

Outer haptics engage the inner haptics

Haptic tips gently meet the IOL optic and are effectively locked into position

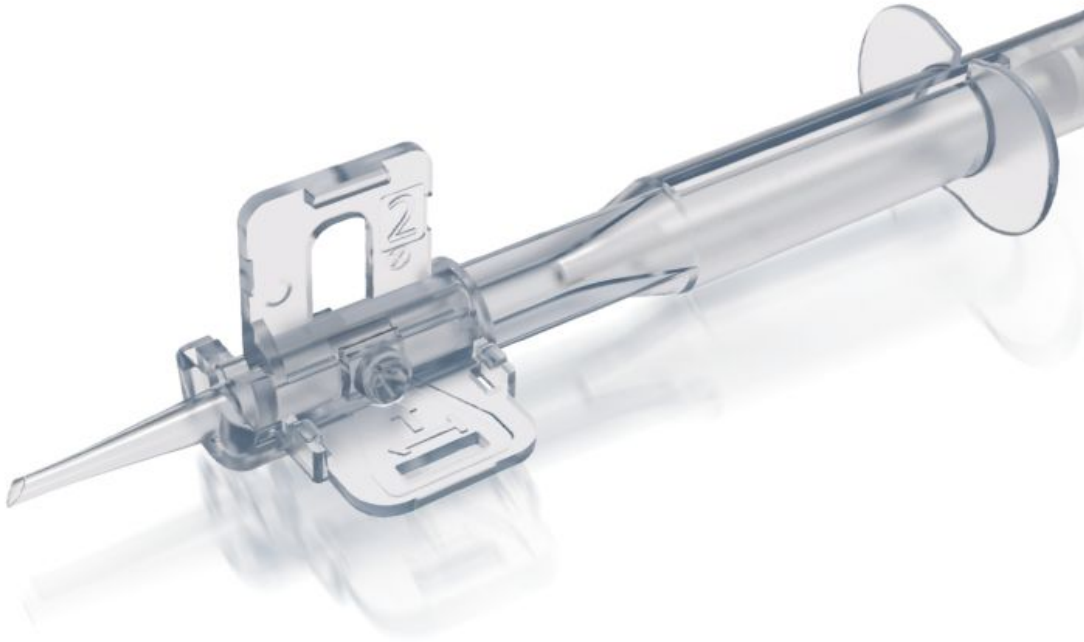
Comparison of preloaded IOLs

Company	Rayner	Alcon	Alcon	J&J
Lens platform	**EMV**	Acrysof IQ	Clareon	Tecnis1
Injector	**RayOne**	UltraSert	AutonoMe	iTec
Nd:YAG rate / PCO*	**1.7%[1]**	7.5%[7]	5.4%[14]	3.7%[7]
Miyata grade (glistenings)	**0[2] (None)**	1[8] (Glistenings)	0[15] (None)	0[12] (None)
Abbe value	**56[2]**	37[9]	Unknown	55[9]
Refractive index	**1.46[3]**	1.55[10]	1.55[12]	1.47[12]
Mean decentration	**0.08 mm[4]**	0.78 mm[11]	0.06 mm[13]	0.27 mm[13]
Nozzle diameter	**1.65 mm[5]**	2.08 mm[5]	3.0 mm[15]	1.86 mm[5]
Injector preparation steps	**2[6]**	3[10]	3[15]	4[12]

TABLE REFERENCES: 1. Mathew RG and Coombes AGA. Ophthalmic Surg Lasers Imaging. 2010 Nov-Dec; 41(6):651-5. **2**. Rayner. Data on File. White paper. **3**. Ferreira T et al. J of Refract Surg. 2019; 35(7): 418-25 **4**. Bhogal-Bhamra GK et al. Journal of Refractive Surgery. 2019;35(1):48-53. **5**. Nanavaty MA and Kubrak-Kisza M. J Cataract Refract Surg 2017; 43:558-563. **6**. www.rayner.com. **7**. Cullin F et al. Acta Ophthalmol. 2014; 92(2): 179-83. **8**. Yildirim TM et al. PLoS ONE. 2021; 16(4): e0250860. **9**. Zhao H et al. Br J Ophthalmol. 2007; 91(9): 1225-29. **10**. www.myalcon.com. **11**. Humbert G et al. FR J Ophthalmol. 2013; 36(4): 352-61. **12**. jnjvisionpro.com. **13**. Baumeister M et al. J of Refract Surg. 2009; 35(6): 1006-12. **14**. FDA Summary of Safety and Effectiveness Data PMA P190018 (2020). **15**. Clareon IOL: A New Monofocal Platform. The Ophthalmologist. 2017.

*Follow-up: RayOne=YAG at 24mths, Acrysof IQ=YAG at 41.4mths, Clareon=PCO at 12mths, Tecnis1=YAG at 41.5mths.

RayOne injector



TWO-STEP SYSTEM

- Easy to use[10]
  - i. Minimal learning curve
  - ii. Minimises error
- Efficient IOL delivery time[10]
  - i. Designed for repeatability
  - ii. Reduces operating time
- **Step 1:** Insert OVD into cartridge via port
- **Step 2:** Lock cartridge ready for implantation

FEATURES & BENEFITS

- 1.65 mm nozzle for 2.2 mm incision
- Small fully preloaded injector nozzle
  - i. Ease of insertion
  - ii. Enables true micro incision
- Parallel sided for minimal stretch
  - i. 2.2 mm delivery
  - ii. Maintains incision architecture
- Ergonomic design for ease of handling
- Single handed plunger with minimal force required

Unique patented Lock & Roll technology for consistent delivery

- Rolls the lens to under half its size before injection
  - i. Consistent, smoother delivery
  - ii. Reduces insertion forces
- Fully enclosed cartridge with no lens handling
  - i. Reduces the risk of lens damage
  - ii. Minimises chance of contamination

Lock & Roll technology

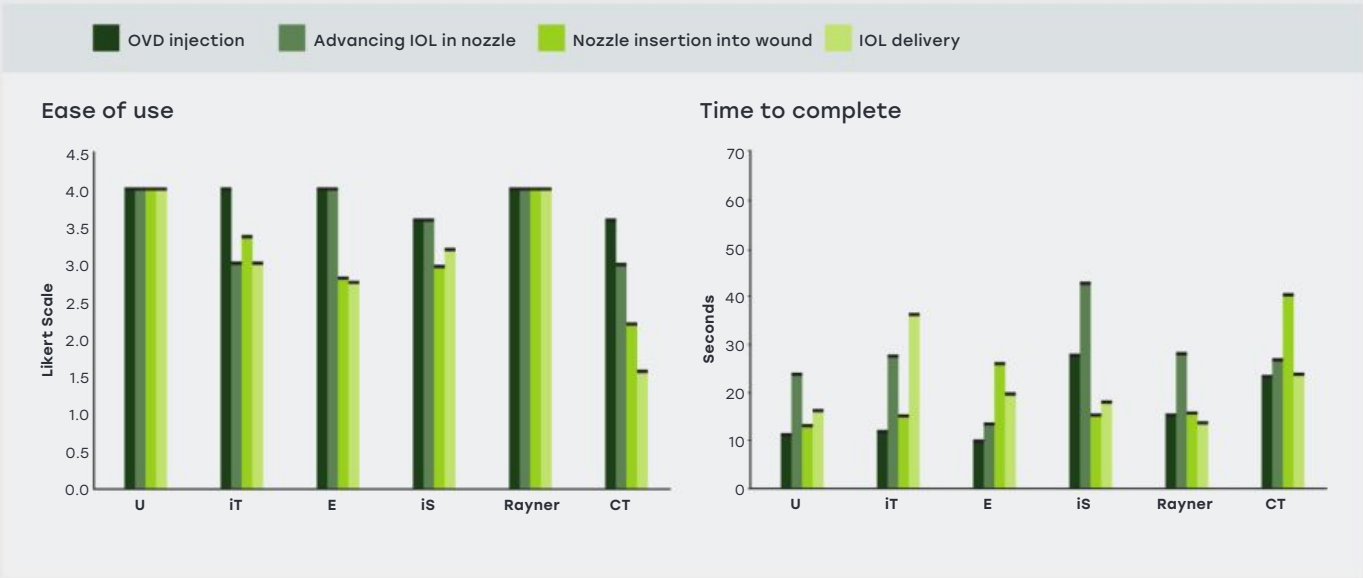
Consistently locked and rolled to under half its size in one simple action

In a comparative study of six market-leading preloaded delivery systems[10]

1. RayOne received the maximum score for ‘ease of use’ for all delivery steps:

OVD priming → Advancing OVD in the nozzle → Nozzle insertion into the wound → IOL delivery

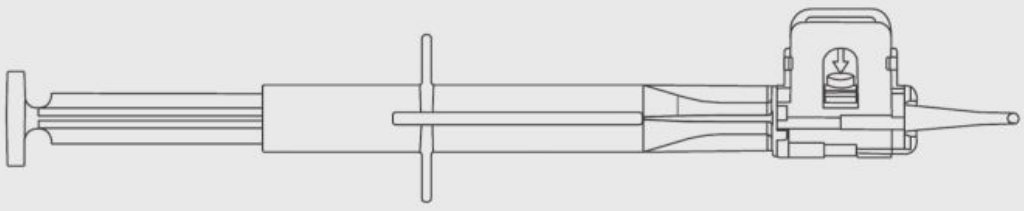
2. RayOne was the least time consuming system for delivering the IOL
3. RayOne showed less injector tip damage post-insertion than 50% of the tested delivery systems
4. RayOne showed minimal wound stretch compared to other tested delivery systems when inserted through a 2.2 mm incision



Ultrasert (U) (Alcon Laboratories, Inc.), iTec (iT) (Abbott Medical Optics, Inc.), Eyecee (E) (Bausch & Lomb, Inc.), iSert (iS) (Hoya Surgical Optics, Inc.), and CT Lucia (CT) (Carl Zeiss Meditec AG). All trademarks are property of their respective owners

RAYONE FULLY PRELOADED
INJECTOR SYSTEM:

THE QUEEN’S AWARDS
FOR ENTERPRISE:
INNOVATION
2020



RayPRO

Long-term, real-time, patient-led reported insights

RayPRO is a comprehensive Patient Reported Outcome Measurements (PROMs) platform that allows clinics to gain essential data on patient outcomes which can be used to inform.

- A truly unique patient-reported outcomes (PROMs) platform which has the ability to track patients over 3 years post-surgery.
- Giving actionable feedback and insight from patients on their experiences and perspectives post-surgery.
- Supporting all IOL brands and models as well as validated clinical questionnaires.
- Utilising a unique multiple-patient upload feature to quickly and effectively add patients.

Cat-PROM5 integrated
Clinically validated questionnaire designed by Sparrow JM, Frost NA, Donovan JL et al.

Comparison view
This unique feature within RayPRO allows users to directly compare the performance of up to four different IOLs patient data.

Multiple patient upload
Supporting fast and efficient upload of patients via an intuitive multiple patient upload system. In some cases, this can be automated with scripts.

Automated collection & reporting
RayPRO sends patient follow-up questionnaires automatically at predefined time points and displays the results in real-time.

DPIA/GDPR/HIPPA compliant
RayPRO cooperates with all national data protection standards.

RayPRO is FREE for users of Rayner IOLs. Subscription available for non-Rayner IOL users.

Learn more at rayner.com/raypro

RayOne EMV References:

1. Ferreira TB. Comparison of visual outcomes of a monofocal, two enhanced monofocals and two extended depth of focus intraocular lenses. Presented at ESCRS 2022. **2**. RayOne EMV: First Clinical Results, Rayner. Oct 2020. **3**. Rayner RayPRO, data on file. **4**. Rayner, data on file. **5**. Rayner Peer2Peer webinar. May 2022. **6**. Royo, M. RayOne EMV and TECNIS Eyhance: A Comparative Clinical Defocus Curve. Data on file. 2021. **7**. How to Choose the Right Solution for Your Patients, CRSTE April 2021. **8**. Bhogal-Bhamra GK, Sheppard AL, Kolli S, Wolffsohn JS. J Refract Surg. 2019;35(1):48-53. **9**. Rayner. Data on File (RDTR 1937). **10**. Nanavaty MA and Kubrak-Kisza M. J Cataract Refract Surg 2017; 43:558-563. **11**. Rayner, PMCF data on file. **12**. McLoone E, Mahon G, Archer D, Best R. Br J Ophthalmol. 2001; 85:543-545. **13**. Tomlins PJ, Sivaraj RR, Rauz S, Denniston AK, Murray PI. J Cataract Refract Surg. 2014; 40:618-625. **14**. Rayner, data on file. **15**. Mathew RG, Coombes AGA. Ophthalmic Surg Lasers Imaging. 2010 Nov-Dec; 41(6):651-5. **16**. Vyas AV, Narendran R, Bacon PJ, Apple DJ. J Cataract Refract Surg 2007; 33:81-87.

Technical information

Model Name	RayOne EMV	RayOne EMV Toric
Model Number	RAO200E	RAO210T
Power Range	+10.0 to +30.0 D (0.5 D increments)	SE: +10.0 D to +25.0 D (0.5 D increments) Cylinder: +0.75 D, +1.5 D, +2.25 D, +3.0 D, +3.75 D, +4.5 D
Delivery System Type	Fully preloaded IOL injection system	
Incision Size	2.2 mm	

Delivery System	
Injector Type	Single use, fully preloaded IOL injection system
Nozzle Size	1.65 mm
Bevel Angle	45°
Lens Delivery	Single handed plunger

Aspheric Monofocal IOL	
Material	Single piece Rayacryl hydrophilic acrylic
Water Content	26% in equilibrium
UV Protection	Benzophenone UV absorbing agent
UV Light Transmission	UV 10% cut-off is 380 nm
Refractive Index	1.46
ABBE	56
Overall Diameter	12.50 mm
Optic Diameter	6.00 mm
Optic Shape	Biconvex (positive powers)
Asphericity	Aspheric anterior surface
Optic Edge Design	Amon-Apple 360° enhanced square edge
Haptic Angulation	0°, uniplanar
Haptic Style	Closed loop with anti-vaulting haptic (AVH) technology

Estimated Constants for Optical Biometry									
	SRK/T	Haigis			HofferQ	Holladay	Holladay II	Barrett	
	A-constant	a0	a1	a2	pACD	SF	pACD	LF	DF
EMV & EMV Toric	118.6	1.044	0.40	0.10	5.32	1.56	5.32	1.51	0

For Contact Ultrasound, the estimated A-constant is 118.0

Please note that the constants indicated for all Rayner lenses are estimates and are for guidance purposes only. Surgeons must always expect to personalise their own constants based on initial patient outcomes, with further personalisation as the number of eyes increases.

Don’t miss what your peers are saying

Leading surgeons from around the world share their real-world experience with RayOne EMV - watch engaging webinars, listen to insightful interviews and podcasts, and read interesting case study articles.

Visit **www.rayner.com/peer2peer** to access videos and articles, download resources and join future events and discussions.

Peer 2 Peer

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