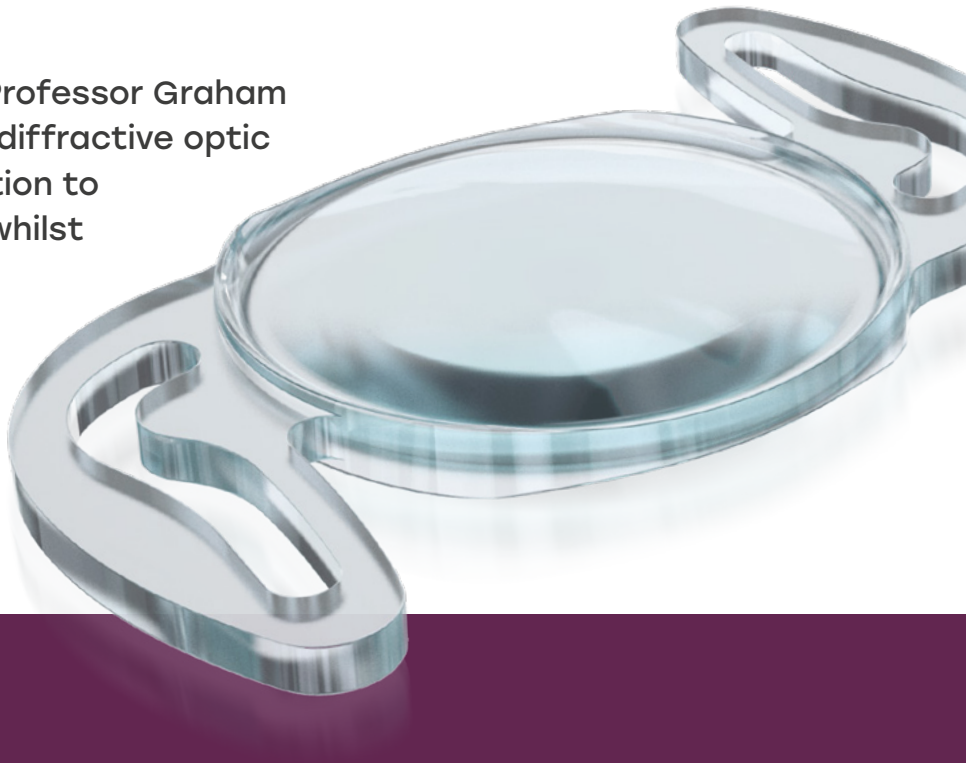
Extending range without compromise

RayOne™ EMV

Rayner

Developed in collaboration with Professor Graham Barrett, RayOne EMV's truly non-diffractive optic utilizes positive spherical aberration to slightly extend range of focus[1,2] whilst avoiding the problems that can arise with diffractive lenses.[2]



RayOne EMV offers:

Increased range of focus: 1.5 D[3,5] with an emmetropic target.

High quality vision: Truly non-diffractive IOL with monofocal levels of contrast sensitivity[3], dysphotopsia[4,6], and high levels of patient satisfaction.[7]

"RayOne EMV is a solution that gives patients increased satisfaction with the least compromise in their quality of vision."

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.[4]

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).[3,5]

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).

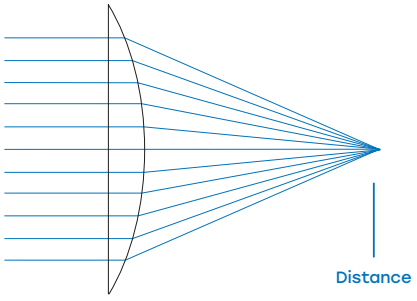


Figure 1
Standard monofocal IOL
with zero spherical aberration

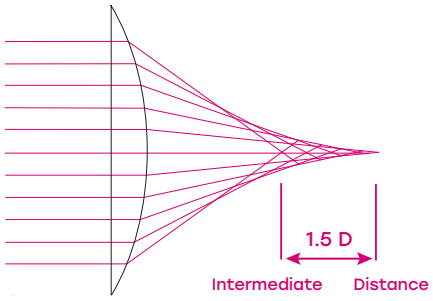


Figure 2
RayOne EMV with positive
spherical aberration

For illustrative purposes only; refer to clinical data for real world outcomes.

Expected vision with a standard monofocal IOL

Expected vision with RayOne EMV

Illustrative images to simulate expected and potential outcomes

Why positive spherical aberration is good for extending depth of focus [20]

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 substantially 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.

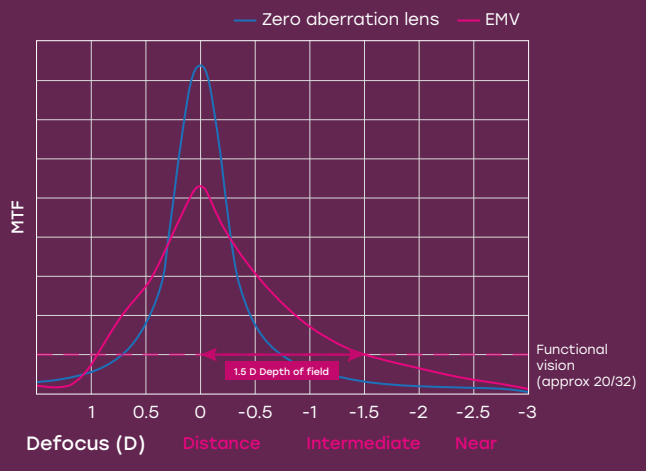


Figure 3

Clinical results with RayOne EMV

Since the launch of RayOne EMV in 2020, real world clinical data from across Europe has demonstrated that:

- RayOne can provide spectacle independence for distance and intermediate vision.[8]
- RayOne EMV provides improvement in intermediate vision without compromising binocular distance vision.[5,8,9]
- Contrast sensitivity levels similar to standard monofocals in both photopic and mesopic conditions.[3]

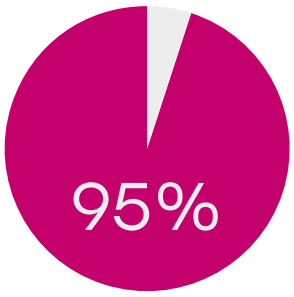
The following clinical results are from a prospective, single-center, observational, noncomparative study conducted at San Carlos Hospital, Madrid, Spain. The study aimed to evaluate visual and refractive outcomes, as well as patient satisfaction, following bilateral implantation of RayOne EMV (IOL) in 50 eyes, with emmetropia as the target refraction.[9]

EMMETROPIA

Outcomes reveal excellent binocular CDVA and good DCIVA, with a high level of patient satisfaction.[9]

Value	Acuity @ 3 months LogMAR
Binocular UDVA	0.01 ± 0.08
Binocular CDVA	-0.07 ± 0.05
Binocular UIVA	0.13 ± 0.07
Binocular DCIVA	0.24 ± 0.09

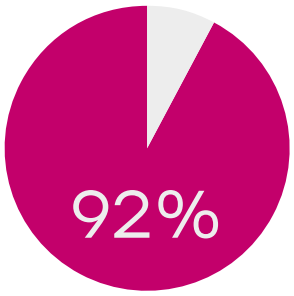
Binocular UDVA



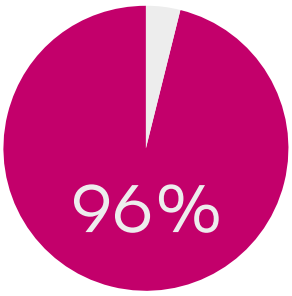
Of patients could read 0.2 logMAR or better

Binocular UIVA

Of patients could read 0.2 logMAR or better



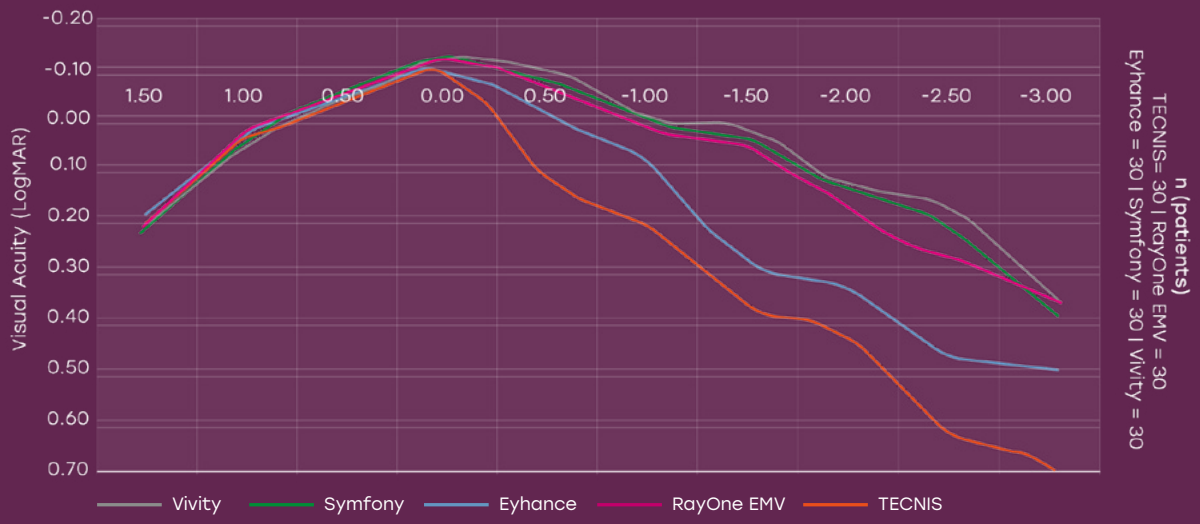
Of patients reported no difficulty with their vision in their everyday life (CatQuest-9SF-questionnaire)



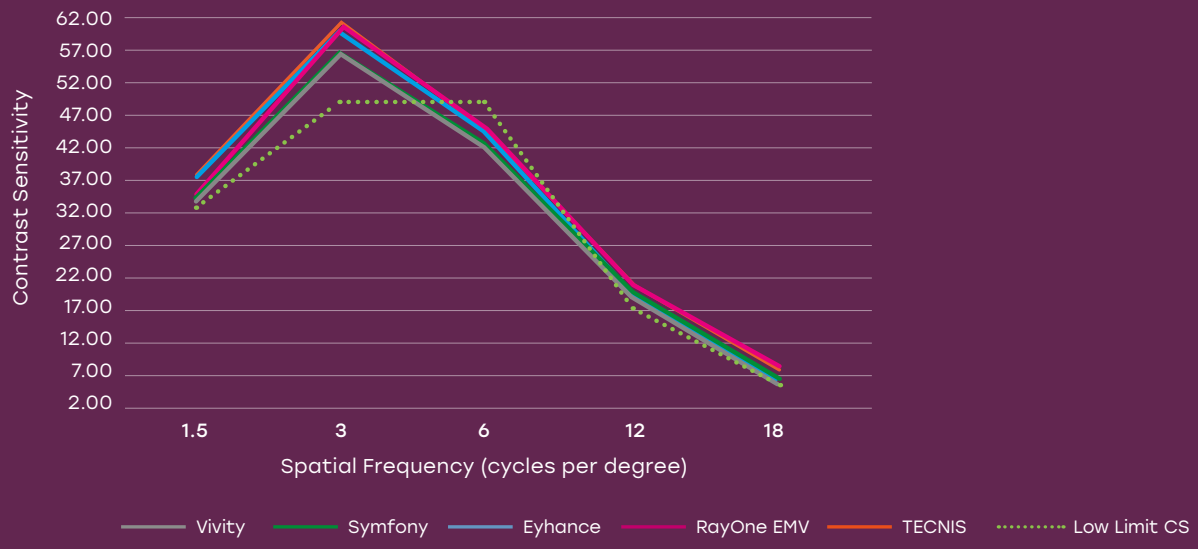
Of patients were (very) satisfied with their sight after surgery (CatQuest-9SF-questionnaire)

EMMETROPIA

At the Hospital da Luz Lisboa in Lisbon, Professor Filomena Ribeiro and Professor Tiago Ferreira led a 150 patient double-arm, non-randomized prospective case series where RayOne EMV demonstrated excellent visual outcomes for distance and intermediate vision, and good visual acuity for near vision.[3]



No statistical difference in contrast sensitivity from a standard monofocal and slightly better contrast sensitivity levels than extended depth of vision (EDOF) IOLs under photopic conditions.[4]



Patients in the RayOne EMV group experienced a high level of spectacle independence and a photic phenomena profile similar to standard monofocals.[4]

Lens	Spectacle independence
TECNIS	3.3%
Eyhance	26.7%
Symfony	63.3%
RayOne EMV	**66.7%**
Vivity	70.8%

Photic Phenomena

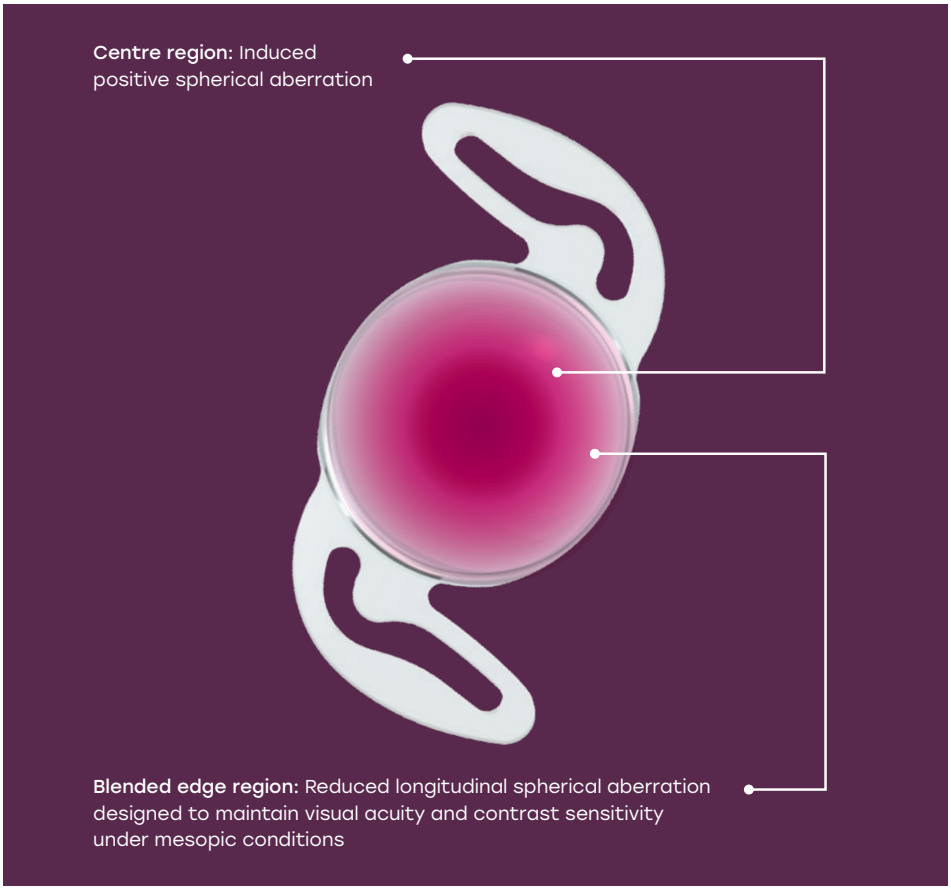
RayOne EMV

KEY INFORMATION

- RayOne EMV is classified as a conventional monofocal IOL by the US FDA.
- 1.5 D increased range of focus with an emmetropic target.[3,5]
- High levels of contrast sensitivity[3] and low levels of dysphotopsia[4], similar to standard monofocal lenses.
- Positive spherical aberration design provides a natural range of vision.[2]

DESIGNED TO PROVIDE:

- High quality spectacle-free distance vision.[4,8]
- Reduced pupil dependency, for optimised performance under low light conditions.[2,3]
- Reduced sensitivity to decentration and tilt compared to other IOL designs.[11]
- Complements the eye's natural level of spherical aberration.[2]
- Fully preloaded across the entire power range.



VACUOLE FREE MATERIAL FOR A GLISTENING FREE IOL

- Single piece IOL created from a homogeneous material free of Microvacuoles.[12]
- Compressible material for delivery through a 2.2 mm micro incision.[13]
- Excellent handling characteristics with controlled unfolding within the capsular bag.[14]
- Low silicone oil adherence.[15]
- Excellent uveal biocompatibility.[16]
- Hydrophilic acrylic material with low inflammatory response.[17]

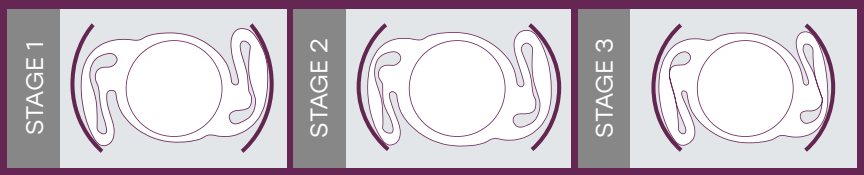
360° Optimised barrier to reduce PCO

Rayner's 360° Amon-Apple Enhanced Square Edge creates an optimum barrier to reduce epithelial cell migration including at the haptic-optic junction.[18,19]

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.[18]

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

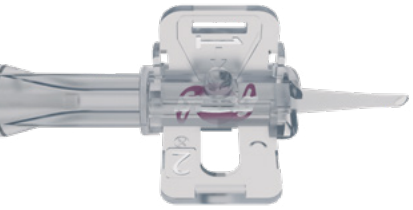
Comparison of preloaded IOLs

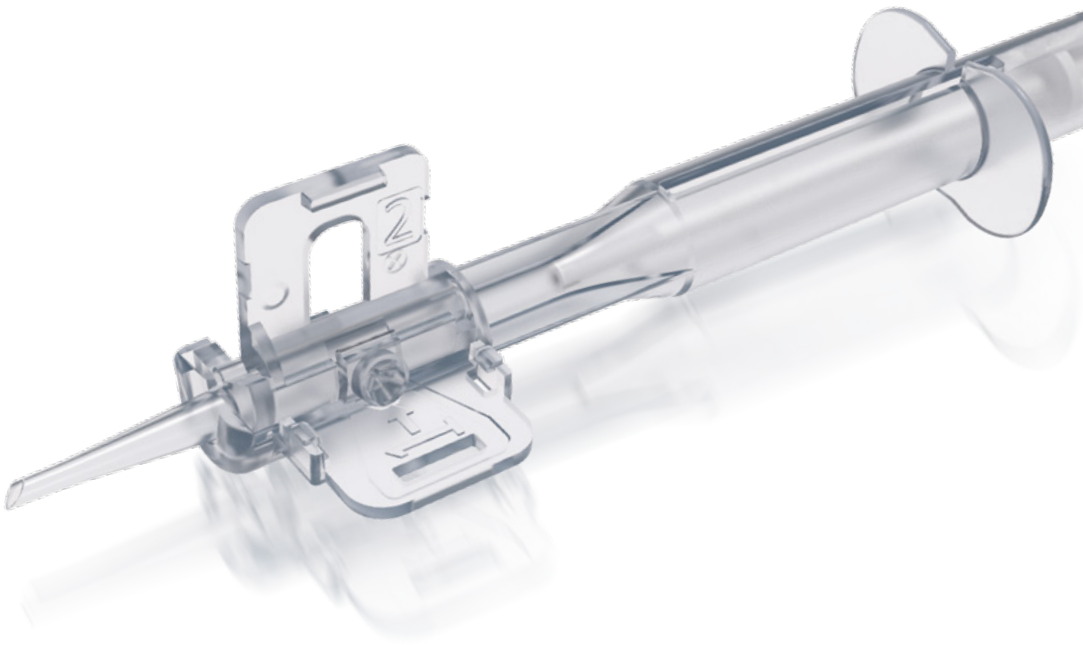
Company	Rayner	Alcon	B + L	J&J
Lens platform	**200E**	Acrysof™	enVista™	Tecnis™
Nd: YAG/PCO rate	**1.7%[18]**	3.2%[30]	2.2%[29]	8.1%[30]
Miyata grade (glistenings)	**0[21] (None)**	1[23] (Glistenings)	0[31] (None)	0[27] (None)
Abbe value	**56[21]**	37[24]	42[31]	55[24]
Refractive index	**1.46[22]**	1.55[25]	1.53[31]	1.47[27]
Mean decentration	**0.08 mm[11]**	0.78 mm[26]	0.33[33]	0.27 mm[28]
Injector prep steps	**2[13]**	3[25]	10[32]	4[27]
Nozzle diameter	**1.65mm[28]**	2.08mm[28]	NA	1.86[28]

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

 *Follow-up: RayOne=YAG at 24m, Acrysof =YAG at 365 days, B+L=PCO at 24m, Tecnis=YAG at 365 days.

RayOne injector





TWO-STEP SYSTEM

- Easy to use[13]
  - i. Minimal learning curve
  - ii. Minimises error
- Efficient IOL delivery time[13]
  - 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

34. RayOne Instructions for Use.

In a comparative study of six market-leading preloaded delivery systems[13]

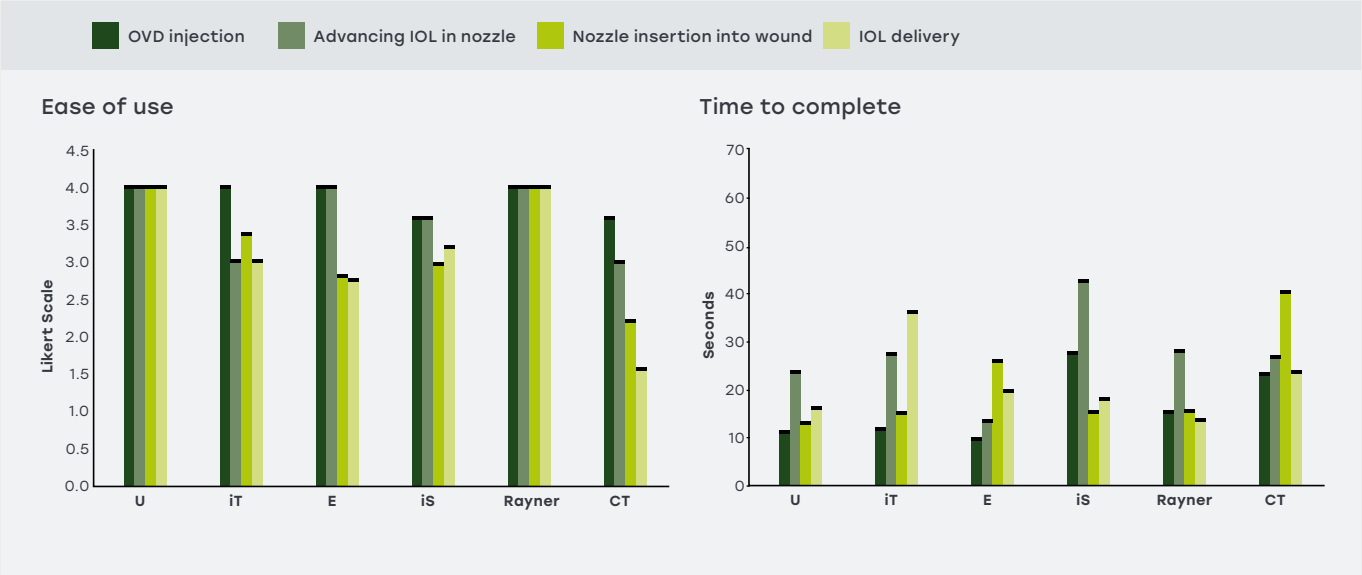
1. RayOne received the maximum score for ‘ease of use’ for all delivery steps:[13]

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[13]

3. RayOne showed less injector tip damage post-insertion than 50% of the tested delivery systems[13]

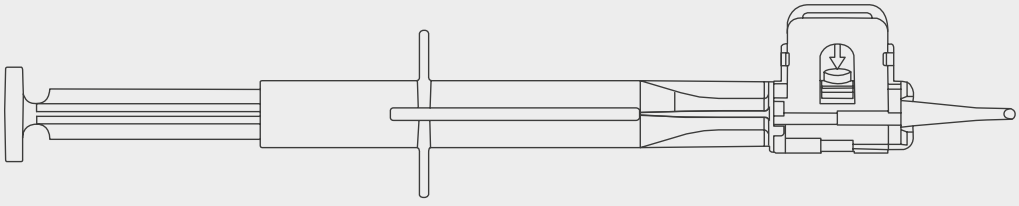
4. RayOne showed minimal wound stretch compared to other tested delivery systems when inserted through a 2.2 mm incision[13]



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, incorporating a validated clinical questionnaire.
- 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 three 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. Gatinel D. Presented at ESCRS 2023. **2.** Barrett G. Presented at ESCRS 2023. **3.** Ferreira TB. Presented at ESCRS 2022 [Paper]. **4.** Ferreira TB. Presented at ESCRS 2022 [Symposia]. **5.** Royo, M. Presented at ESCRS 2023. **6.** Findl O. et al. (2022, Sept 28). *Rayner ESCRS 2022 Symposium: challenges in cataract surgery and advanced technology IOLs* [Webinar]. Peer2Peer https://www.youtube.com/watch?v=FJzV9Grwshk. **7.** Data on file. Rayner. RayPRO. **8.** Royo Presented at ESCRS 2022. **9.** García-Bella J. et al. J Cataract Refract Surg. 2024 Jun 1;50(6):585-590. **10.** Barsom A. et al. CRSTE. 2021 April; 10-12. **11.** Bhogal-Bhamra GK. et al. J Refract Surg. 2019;35(1):48-53. **12.** Data on file. Rayner. RDTR 1937. **13.** Nanavaty M. et al. J Cataract Refract Surg 2017; 43:558-563. **14.** Data on file. Rayner. PMCF. **15.** McLoone E. et al. J Ophthalmol. 2001; 85:543-545. **16.** Tomlins PJ, et al. J Cataract Refract Surg. 2014; 40:618-625. **17.** Data on file. Rayner. **18.** Mathew RG. et al. Ophthalmic Surg Lasers Imaging. 2010 Nov-Dec; 41(6):651-5. **19.** Vyas AV, et al. J Cataract Refract Surg 2007; 33:81-87 **20.** Auffarth GU. Presented at DGII 2022. **21.** Data on file. Rayner. **22.** Ferreira T. et al. J of Refract Surg. 2019; 35(7): 418-25. **23.** Yildirim TM. et al. PLoS ONE. 2021; 16(4): e0250860. **24.** Zhao H. et al. Br J Ophthalmol. 2007; 91(9): 1225-29. **25.** Data on file. Alcon. **26.** Humbert G. et al. FR J Ophthalmol. 2013; 36(4): 352-61. **27.** Data on file. Johnson & Johnson Surgical Vision, Inc. **28.** Baumeister M. et al. J of Refract Surg. 2009; 35(6): 1006-12. **29.** Ton V. Et al. J Fr Ophtalmol. 2018 Dec;41(10):899-903. **30.** Horn JD. et al. Clin Ophthalmol. 2022 Jun 1;16:1721-1730. **31.** EnVista Directions for Use, Bausch & Lomb – Clinical Results. May 2017. **32.** Data on file. Bausch + Lomb. INJ100 Inserter. **33.** Buckhurst PJ. et al. Clin Ophthalmol. 2022 Nov 15;16:3763-3774. **34.** RayOne Instructions for Use.

Technical information

Model Name	RayOne EMV
Model Number	RAO200E
Power Range	+10.0 to +30.0 D (0.5 D increments)
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	118.6	1.044	0.40	0.10	5.32	1.56	5.32	1.51	0
IOLcon.org Optimised Constants for EMV	118.416	0.1481	0.237	0.1612	5.178	1.437	N/A	1.51	0

34. RayOne Instructions for Use.

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

Search for **#Peer2Peer**

PRECAUTION: The safety and effectiveness of the RayOne EMV (RAO200E) has not been substantiated in clinical trials. The effects of the RayOne EMV IOL optical design on quality of vision, contrast sensitivity, and subjective visual disturbances (glare, halo, etc.) have not been evaluated clinically. Certain lab-based testing of the RayOne EMV IOL may aid surgeons in understanding the theoretical image quality expected with the RayOne EMV IOL compared to other Rayner FDA approved lenses, but such testing does not fully assess all aspects of clinical difficulties under all conditions. Surgeons must weigh the potential benefits of the modified optical design of RayOne EMV against the potential for risks associated with a degradation in vision quality and the lack of clinical data to characterize the impact of RayOne EMV optical design on contrast sensitivity and subjective visual disturbance. These considerations may be especially relevant to patients with certain pre-existing ocular conditions (prior corneal refractive surgery, irregular corneal astigmatism, severe corneal dystrophy, macular disease, optic nerve atrophy, etc.) or intraoperative conditions (posterior capsular rupture, complications in which the IOL stability could be compromised, inability to place IOL in capsular bag, etc.).

CAUTION: United States Federal Law restricts this device to sale and distribution by or on the order of a physician and its use is restricted to a properly licensed physician.

For Full Instructions for Use please visit: rayner.com/ifu

Not all Rayner products are approved for sale in every country.

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EC 2024-104 US 09/24

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