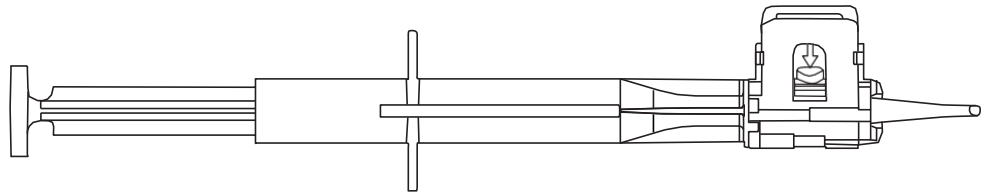


GALAXY

GALAXY^{TORIC}



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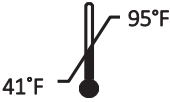
Prescription device: Federal U.S. law restricts this device to sale by, or on the order of, a physician.

RayOne Galaxy US eIFU PF000212, Version 1, Issue Date: 15th September 2026

 Rayner

EN

Symbol/Explanation

	Single use, do not reuse		Do not re-sterilize
	Steam Sterilized		Do not use if the sterile barrier system or packaging is damaged
	Store between 41-95°F temperature		Keep away from sunlight
	Keep dry		Consult Instructions for use
	Model Number		Consult electronic instructions for use
	Batch code		Serial Number
	Manufacturer		Use-by date
	Date of Manufacture		Country of Manufacture
	Caution		Unique Device Identifier
	Medical Device		Double sterile barrier system
	MR safe		Patient Name
	Date of Implant		Hospital

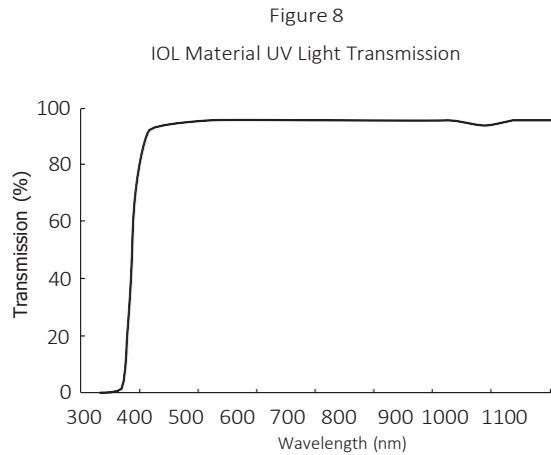
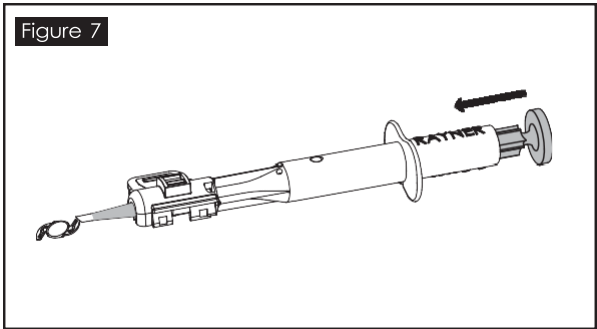
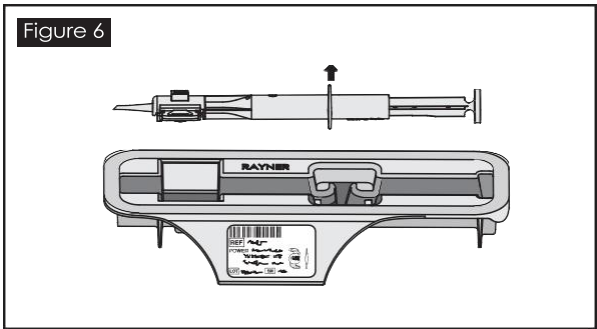
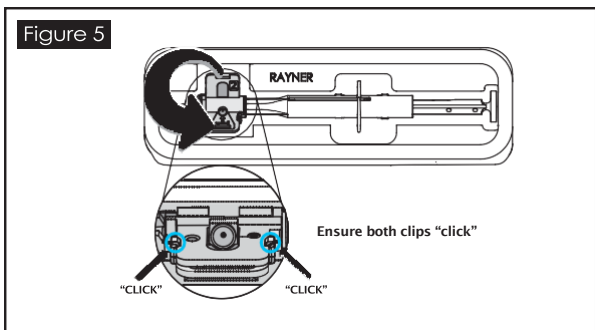
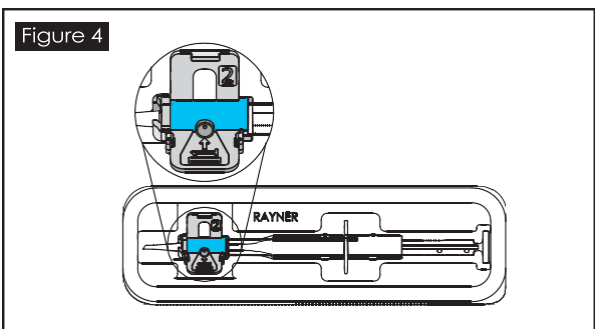
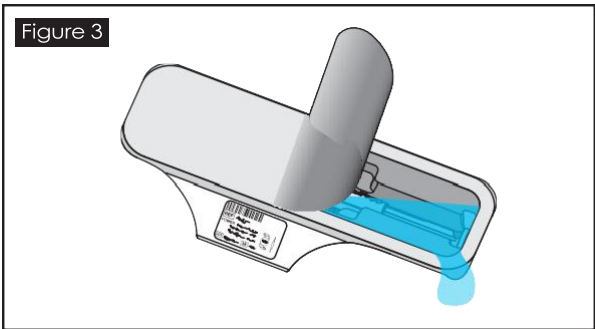
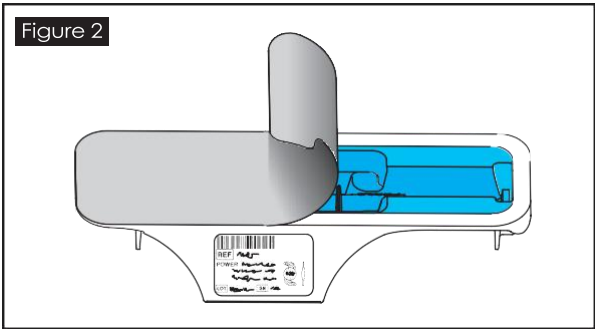
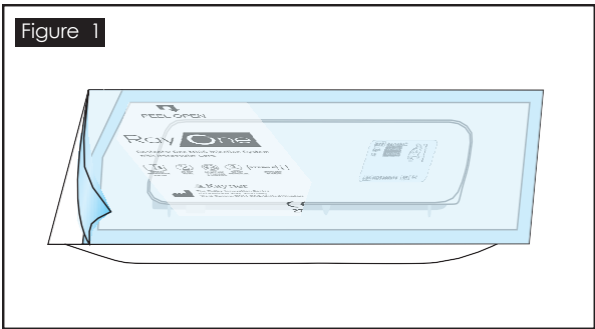


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Loading Instructions



Device Description

The RayOne Galaxy (RAO605G) and RayOne Galaxy Toric (RAO615X) consist of a Galaxy IOL preloaded within the RayOne injection system.

Galaxy IOLs are single piece optical devices, manufactured from hydrophilic Rayacryl (hydroxyethyl methacrylate/methyl methacrylate copolymer with UV blocker).

These devices are designed to be surgically implanted in the human eye as a replacement for the crystalline lens, and are intended for placement in the capsular bag.

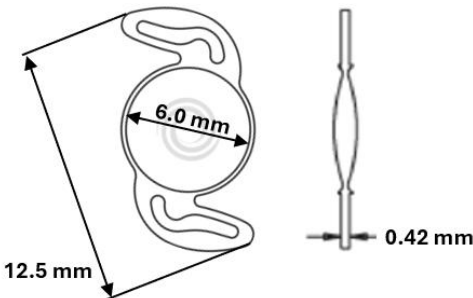
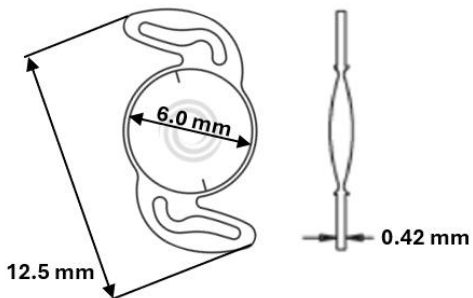
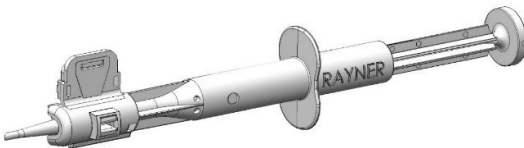
The Galaxy IOL optic is designed to mitigate the effects of presbyopia by extending the range of vision from distance to near. The optic is biconvex and consists of a refractive spiral anterior optical surface and aspheric posterior surface, for the toric IOL the posterior surface is toric.

The spiral optic extends from a radius of 0.55 mm to 1.6 mm and provides intermediate and near add powers of +1.5 D and +3.0 D, respectively, at the IOL plane.

The RayOne injection system is a Fully Preloaded system that delivers a 6 mm optic diameter lens into the eye through a micro incision. The RayOne injector is designed to mechanically fold a lens and insert it into the eye during routine cataract surgery.

The physical characteristics of RayOne Galaxy and RayOne Galaxy Toric are shown in **TABLE 1**.

TABLE 1 RAYONE GALAXY AND GALAXY TORIC PHYSICAL CHARACTERISTICS

Parameter	RayOne Galaxy	RayOne Galaxy Toric
Lens image		
Injector image		
Lens material	Rayacryl	
Injector material	Polypropylene & TPE	
Design features	Refractive spiral, multifocal, capsular bag fixated	Refractive spiral, toric, multifocal, capsular bag fixated
Injection system	Fully preloaded	
Overall diameter (mm)	12.5 ± 0.2	
Optic diameter (mm)	6.0 ± 0.1	
Limb width (mm)	0.38 ± 0.1	
Limb thickness (mm)	0.41 ± 0.15	
Haptic style	Closed C-loop	
Square edge	360° posterior Enhanced Square Edge	
Power range (increments)	+5.0 to +30.0 D (0.5 D)	N/A
Spherical equivalence (increments)	N/A	+6.0 to +30.0 D (0.5 D)
Cylinder power range (increments)	N/A	+1.5 to +3.75 D (0.75 D)
Index of refraction	1.46	

RayOne Galaxy Toric is available from:

SE: +6.0 D to +30.0 D in 0.5 D increments

Cylinder: +1.50 D to +3.75 D in 0.75 D increments

The effective corneal powers for each of the test lens plane cylindrical powers of the test IOLs are shown in **TABLE 2**.

TABLE 2 CYLINDER POWER AND CORNEAL ASTIGMATISM CORRECTION RANGE

IOL Type	IOL Power at IOL Plane (D)	Cyl Power on Corneal Plane (D)	Specified Range (D) Lower	Specified Range (D) Upper
T3	1.5	1.03	1.03	1.53
T4	2.25	1.54	1.54	2.04
T5	3	2.05	2.05	2.56
T6	3.75	2.57	2.57	3.07

Suggested “A” Constant

The source of the A-constant is a theoretical constant.

Optical Biometry 118.6

Contact Ultrasound Biometry 118.0

Barrett Toric Calculator constants LF=1.67, DF=0

For optimized refractive results, the A-constant used for IOL calculations should be personalized by the surgeon.

IOL Material (Rayacryl) Characteristics

- Water content: 26% in equilibrium
- Refractive index: 1.46
- UV light transmission: shown in Figure 8 (UV 10% cut-off is 380 nm)
- Nd: YAG laser compatible

Indications for Use

RayOne Galaxy (Model RAO605G) is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia, in adult patients in whom a cataractous lens has been removed.

The IOL mitigates the effects of presbyopia by providing improved intermediate and near visual acuity while maintaining comparable distance visual acuity to a monofocal IOL.

RayOne Galaxy is intended for implantation in patients with less than 1.00 diopter of pre-existing corneal astigmatism. The RayOne injection system is used to fold and assist in inserting the IOL into the eye.

RayOne Galaxy Toric (Model RAO615X) is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia, in adult patients in whom a cataractous lens has been removed.

The IOL mitigates the effects of presbyopia by providing improved intermediate and near visual acuity while maintaining comparable distance visual acuity to a monofocal IOL.

In addition, RayOne Galaxy Toric is intended to provide reduction of residual refractive astigmatism in patients with corneal astigmatism greater than or equal to 1.03 diopter, up to 3.07 diopter. The RayOne injection system is used to fold and assist in inserting the IOL into the eye.

Contraindications

There are no known contraindications.

Adverse Events

Cataract surgery for IOL implantation presents risks which the surgeon must evaluate. Potential complications of cataract surgery are:

- Secondary glaucoma
- IOL replacement or extraction
- Precipitates

- Reduced vision
- Vitreous herniation
- Excessive intraoperative vitreous loss
- IOL decentration
- Secondary membrane
- Expulsive hemorrhage
- IOL dislocation and subluxation
- Retrolenticular membrane
- Corneal edema
- Endophthalmitis and panophthalmitis
- Retinal detachment
- Corneal dystrophy
- Hemorrhage
- Iris atrophy
- Pupillary block
- Cystoid macular edema
- Severe ametropia and aniseikonia
- Iridocyclitis and hyalitis
- Deviation from target refraction
- Fibrin reaction
- Elevated IOP
- Best-corrected visual acuity loss of 2 lines (10 letters) or more on the ETDRS chart measured at 3-4 months or later from any prior post-operative visit
- Anterior chamber cells grade 0.5 or greater at 7-14 days or later
- Posterior vitreous detachment
- Subconjunctival hemorrhage
- Anterior chamber cells greater than grade 2 at Day 1-2
- Keratoconjunctivitis sicca or worsening, not specified as Sjogren's
- Double/multiple images
- Meibomian gland dysfunction
- Progression of diabetic retinopathy.

Warnings

- RayOne Galaxy cannot be reused, as it is not designed to perform as intended after the first and only usage. Changes in mechanical, physical or chemical characteristics, under conditions of repeated use, cleaning and resterilization, will compromise the integrity of the device.
- Non-toothed, polished instruments must be used if handling the IOL.
- Do not allow the IOL to dehydrate during the procedure.
- Do not use balanced salt solution (saline) as the sole lubricating agent, always use in combination with an ophthalmic viscosurgical device (OVD).
- Do not attempt to disassemble, modify or alter this device or any of its components, as this can significantly affect the function and/or structural integrity of the design.

- The sterility of the contents is guaranteed only if the outer tray has not been opened or damaged.
- Do not use if the pack has been damaged.
- Do not store in direct sunlight.
- Do not store the pack outside of the recommended storage conditions; store between 41°F - 95°F.
- Do not use after the expiration date.
- Do not attempt to reuse this device.
- Do not resterilize.
- Do not use system at temperature below 70°F (equilibration takes approximately 90 minutes from an initial temperature of 41°F).
- The IOL should not be partially injected and left in the injector tip for any amount of time.
- The IOL should remain folded in the injector for a maximum of 3 minutes.
- Posterior capsule opacification (PCO) can affect visual quality after cataract surgery. Patients implanted with multifocal intraocular lenses may be more sensitive to the visual effects of PCO than patients implanted with monofocal intraocular lenses, including effects on contrast sensitivity and overall quality of vision. As a result, clinically significant visual symptoms associated with PCO may be reported at a lesser degree of opacification, and Nd:YAG laser capsulotomy may be performed earlier or more frequently in patients with multifocal intraocular lenses.
- As with any intraocular lens other lenses which mitigate the effects of presbyopia, some visual disturbances may be expected following implantation. These may include the perception of halos, glare, or other visual phenomena, particularly under low-illumination conditions such as nighttime. In a small proportion of patients, these effects may be severe and interfere with distance vision indoors and outdoors and night driving. These symptoms may be significant enough that a patient may request removal of the lens.
- Do not use if the device appears damaged.

Precautions

- Healthcare professionals considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:
 - Active or recurrent ocular disease (e.g. uveitis, diabetic retinopathy, pars planitis, chronic glaucoma not responsive to medication)
 - Corneal endothelial compromise, including corneal decompensation, edema, endothelial insufficiency
 - Previous ocular surgery or conditions to complicate cataract extraction (e.g. iris atrophy or pseudo exfoliation)
 - Severe aniseikonia
 - Macular degeneration or other retinal pathologies, need for retinal laser treatment, potentially limiting postoperative visual performance
 - Zonular weakness or dehiscence (consider a capsular tension ring (CTR) to support the capsular bag)
 - Ruptured posterior capsule or planned posterior capsulotomy
 - Patients with ocular comorbidities that may prevent stable visual acuity or require frequent posterior segment interventions
 - Patients in whom the intraocular lens may affect the ability to observe, diagnose or treat posterior segment diseases
 - Surgical complications at the time of cataract extraction which might increase the potential for complications (e.g. persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss or ocular hemorrhage)
 - Anatomic abnormalities of the eye, such as microphthalmia, trauma, distorted eye or developmental

defect preventing adequate IOL fixation

- Circumstances that could cause endothelial trauma during implantation
 - Suspected or active ocular microbial infection or inflammation
 - Children under the age of 21 years
 - Patients with ocular disorders, other than cataract, could potentially cause future acuity losses to a level of 20/30 or worse in either eye
 - Patients unlikely to adapt to simultaneous multiple retinal images
- The lens should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned.
 - Rotation of the IOL away from the intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, IOL positioning should occur prior to capsule fibrosis and IOL encapsulation.
 - The clinical study of the RayOne Galaxy was conducted with the lens implanted into the capsular bag only. There are no clinical data to demonstrate its safety and effectiveness for placement in the ciliary sulcus.

How Supplied

Rayner Galaxy IOLs (605G and 615X) are supplied in a 0.9% saline solution preloaded in the RayOne (RAO) injection system within the blister pack terminally sterilized with moist heat and should only be opened under aseptic conditions.

Expiration Date

The expiration date on the lens package is the sterility expiration date. Do not use the IOL after the expiration date.

Directions for Use

The RayOne preloaded injector should only be used for the placement of Rayner IOLs into the eye.

To ensure optimum injection performance of the IOLs, the blister pack should be allowed to equilibrate to a temperature of 70°F or above before use. The use of a sodium hyaluronate based OVD is recommended. Insert the IOL into the eye within 3 minutes of closing the cartridge.

Use of RayOne

Fig 1 Peel open the outer pouch as directed. Prior to implanting, examine the lens label on the unopened inner package for model, type, power, proper configuration and expiration date. The lens may be soaked in sterile balanced salt solution until ready for implantation.

Fig 2 Carefully peel back the lid halfway down the second blister pack.

Fig 3 Carefully drain the saline from the blister tray and peel off remaining lid. Do not remove the injector from the blister tray. Do not wait more than 3 minutes before adding OVD - Dehydration risk. Non-toothed, polished instruments must be used when handling the IOL. Rayner recommends that saline is not used as the sole lubricating agent, but in combination with a viscoelastic solution. The use of a sodium hyaluronate-based viscoelastic is recommended. Insert the viscoelastic cannula into the opening marked with an arrow on the cartridge and apply sufficient OVD to completely fill the cartridge.

Fig 4 Insert the viscoelastic cannula into the opening marked with an arrow on the cartridge and apply sufficient OVD to completely fill the cartridge. **NOTE:** Rayner's patented "lock and roll" injector technology uses the mechanical force of OVD inserted into the indicated port to move the IOL from 'storage' to 'roll ready' position at the bottom of the cartridge; do not add OVD directly via the nozzle tip.

Fig 5 Keep the injector in the tray and close the cartridge firmly together by pushing the moving half of the cartridge (Labelled 2) against the fixed half until you hear it click closed. Check both clips have "clicked" shut and secured the cartridge.

Fig 6 Gently lift out the injector from the tray.

Fig 7 Press the plunger in a slow and controlled manner. If excessive resistance is felt this could indicate a blockage; discontinue use of the product and return the product and all packaging to Rayner. In the case of IOL rotation during

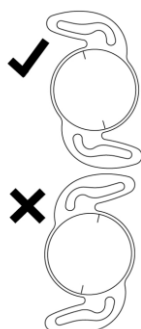
ejection from the nozzle, gently rotate the injector in the opposite direction to counteract any movement. Stop depressing the plunger when the IOL exits the nozzle. Discard the injector after use. Following implantation, irrigate/aspirate to eliminate any OVD residues from the eye, especially between the IOL and posterior capsule. The anterior continuous curvilinear capsulorhexis should be 360° and just cover the anterior edge of the IOL optic by 0.5 to 1.0 mm.

IOL Placement

Ensure that the IOL is implanted in the capsular bag with the correct anterior/posterior placement. Correct anterior/posterior placement is achieved when the haptics sweep away from the optic in a counterclockwise direction (anterior view Figure 10). The IOL can be dialed clockwise as is usual for posterior chamber IOLs. The anterior continuous curvilinear capsulorhexis should be positioned just covering the 360° anterior edge of the IOL optic by 0.5 to 1.0 mm.

Figure 10

IOL Haptic Orientation



Correct rotational orientation for toric IOLs is achieved when the IOL's axis marks (the lowest IOL power meridian) aligns with the cornea's highest power meridian. The IOL axis marks are therefore oriented in parallel to (or on) the steeper corneal meridian.

Calculation of IOL Power

The surgeon should preoperatively determine the power of RayOne Galaxy to be implanted by using established Barrett Universal II Formula. Barrett Universal II Formula power calculation method are described in the following references:

1. Barrett GD. An improved universal theoretical formula for intraocular lens power prediction. J Cataract Refract Surg. 1993 Nov;19(6):713-20. doi: 10.1016/s0886-3350(13)80339-2. PMID: 8271166.
2. Reitblat O, Assia EI, Kleinmann G, Levy A, Barrett GD, Abulafia A. Accuracy of predicted refraction with multifocal intraocular lenses using two biometry measurement devices and multiple intraocular lens power calculation formulas. Clin Exp Ophthalmol. 2015 May-Jun;43(4):328-34. doi: 10.1111/ceo.12478. Epub 2015 Jan 14. PMID: 25491591
3. Abulafia A, Barrett GD, Rotenberg M, Kleinmann G, Levy A, Reitblat O, Koch DD, Wang L, Assia EI. Intraocular lens power calculation for eyes with an axial length greater than 26.0 mm: comparison of formulas and methods. J Cataract Refract Surg. 2015 Mar;41(3):548-56. doi: 10.1016/j.jcrs.2014.06.033. Epub 2015 Feb 21. PMID: 25708208

The surgeon should preoperatively determine the power of the Galaxy Toric IOL to be implanted by using the Barrett Toric Calculator. The Barrett constants for RayOne Galaxy Toric calculation are LF=1.67, DF=0 ("A" constant Optical Biometry 118.6 and Contact Ultrasound Biometry 118.0). Barrett Toric Calculator IOL power calculation methods are described in the following references:

1. Abulafia A, Hill WE, Franchina M, Barrett GD. Comparison of Methods to Predict Residual Astigmatism After Intraocular Lens Implantation. J Refract Surg. 2015 Oct;31(10):699-707. doi: 10.3928/1081597X-20150928-03. PMID: 26469077.
2. Abulafia A, Barrett GD, Kleinmann G, Ofir S, Levy A, Marcovich AL, Michaeli A, Koch DD, Wang L, Assia EI. Prediction of refractive outcomes with toric intraocular lens implantation. J Cataract Refract Surg. 2015 May;41(5):936-44. doi: 10.1016/j.jcrs.2014.08.036. Epub 2015 Apr 30. PMID: 25936681.
3. Barrett GD, Abulafia A, "Improving Outcomes With Toric Intraocular Lenses," presented at the XXXII Congress of the European Society of Cataract and Refractive Surgeons, London, United Kingdom, September 2014

Patient Registration and Reporting

A Patient Identification Card is included in the package. This is to be completed and given to the patient, together with instructions to keep the card as a permanent record to be shown to any eye practitioner the patient consults in future.

Self-adhesive lens identification labels are provided for use on the Patient Identification Card, Implant Tracking Card and other clinical records.

Adverse events/complaints that may reasonably be regarded as lens related and that were not previously expected in nature, severity, or degree of incidence, should be reported to Rayner Intraocular Lenses Limited, 10 Dominion Way, Worthing, West Sussex, BN14 8AQ, United Kingdom.

Tel. +44 (0) 1903 258900, Fax. +44 (0) 1903 258901, Email: feedback@rayner.com through the Rayner U.S. Distribution Center, 1255 Lynnfield Road, Suite 257 Memphis, TN 38119, United States, Tel: 844-RAYNER1.

The intraocular lens in this pack is for implantation into the capsular bag. A non-exhaustive list of risks, instructions for use, cautions and precautions and warnings are provided in this IFU which should be given to the patient prior to surgery. Rayner hereby disclaims all liability associated with any injuries or harm that may be suffered by the patient caused by: The method or technique of implantation used by the surgeon if the manufacturer's recommendations and instructions were not followed; an unsuitable prescription, selection or implantation of an unsuitable intraocular lens.

References

- Kane JX, Connell B. A Comparison of the Accuracy of 6 Modern Toric Intraocular Lens Formulas. *Ophthalmology*. 2020 Nov;127(11):1472-1486. doi: 10.1016/j.ophtha.2020.04.039. Epub 2020 May 1. PMID: 32371252 <https://www.iolformula.com/>
- Abulafia A, Hill WE, Franchina M, Barrett GD. Comparison of Methods to Predict Residual Astigmatism After Intraocular Lens Implantation. *J Refract Surg*. 2015 Oct;31(10):699-707. doi: 10.3928/1081597X-20150928-03. PMID: 26469077
- Liu C, Wang M, Long D, Zhang Y, Chen Y, Wu Q. Comparison of the Accuracy of Toric Intraocular Lens Formulas Used by the Online Calculator of the European Society of Cataract and Refractive Surgeons. *J Refract Surg*. 2025 Feb;41(2):e120-e130. doi: 10.3928/1081597X-20241219-01. Epub 2025 Feb 1. PMID: 39937979
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- Melles RB, Holladay JT, Chang WJ. Accuracy of intraocular lens calculation formulas. *Ophthalmology*. 2018 Feb;125(2):169-178. doi:10.1016/j.ophtha.2017.08.027. PMID:28951074.
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- Yuan H, Zhang J, Han X, Ye J, et al. Accuracy of 11 intraocular lens calculation formulas in shallow anterior chamber eyes. *Acta Ophthalmologica*. 2024 Feb;102(5).Doi:10.1111/aos.16654]. PMID:37698825.

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Summary of Clinical Studies

Clinical studies have been conducted on the C-flex 570C IOL, the RayOne EMV Toric (Model RAO210T) and RayOne Galaxy (Model RAO605G). The RayOne EMV Toric is a combination of the optical design of the C-flex and RayOne EMV parents, RayOne Galaxy Toric (Model RAO615X) is a combination of the optical design of the RayOne Galaxy and RayOne EMV Toric. Clinical data from a clinical trial of the RayOne Galaxy Toric IOL are not available.

This IFU includes a summary limited to findings directly relevant to the performance and safety of the RayOne Galaxy and RayOne Galaxy Toric IOLs.

Clinical Data on the C-flex

The Rayner C-flex 570C intraocular lens IDE study was a multicenter clinical trial, with historical control designed to assess safety and efficacy. Three hundred and one (301) C-flex patients were enrolled (unilateral implants) in this investigation. Additionally, data from one hundred and eighty-two (182) model Centerflex IOL patients was used as supportive data. The Centerflex IOL is identical to the C-flex model in all aspects except that the C-flex additionally features an Enhanced Square Edge. This feature is a 360° raised ridge encircling the periphery of both the anterior and posterior surfaces of the optic body (including the optic-haptic junction). The Rayner C-flex IOL met or exceeded historical controls for posterior chamber IOLs in all areas, for best corrected visual acuity at the 12 months post-operative examination. Safety was evaluated regarding specific cumulative adverse event rates and persistent adverse events rates as specified in the FDA Intraocular Lens Guidelines, 19997 and ISO 11979-7. Primary safety analyses were based on data from all enrolled procedures with follow-up to at least one-year post implantation. The pooled C-flex[™] and Centerflex accumulative and persistent adverse event rates at 12-months are lower than the FDA historical control grid in all areas except persistent macular edema, persistent corneal edema and cumulative pupillary block. These rates were higher than the grid rate, but the differences were not statistically significant. The results achieved by 283 patients in the C-flex 570C study and 166 patients in the Centerflex IOL study followed for one year, provide the basis for the data which were used to support that the EMV IOL (200E) design can be used for the visual correction of aphakia. Clinical studies were not conducted with the EMV IOL (200E) to assess the effect of its aspheric surface or increased optic size and overall diameter on spherical aberration, visual acuity or contrast sensitivity.

Clinical Data on RayOne EMV Toric

Study Description

The U.S. IDE clinical trial of the RayOne EMV Toric was conducted as a prospective, multicenter, randomized, active controlled, masked investigation to determine the safety and performance of the 1.50 D toric IOL compared to an aspheric monofocal control. Key assessments included manifest refraction, visual acuity, IOL axis misalignment and orientation stability which were evaluated at follow-up visits. A total of 238 eligible subjects were randomized 1:1 to receive either the RayOne EMV Toric (n=118, Toric IOL group) or the RayOne Aspheric (n=120, Monofocal IOL group) in one eye following cataract extraction. Subjects underwent preoperative baseline assessments and postoperative follow-up visits at predefined intervals through Visit 4 (Day 120–180). The primary effectiveness endpoints were mean magnitude of residual manifest cylinder (as measured by manifest refraction) at Visit 4 (Day 120–180), toric IOL axis misalignment from pre-operatively marked intended axis at Visit 4, and rotational stability between Visit 3 (Day 30–60) and Visit 4. The primary effectiveness endpoints were assessed against the ANSI Z80.30 performance criteria. The primary safety endpoints included rates of cumulative and persistent adverse events listed in ISO 11979-7 at Visit 4, rates of all other adverse events not included in IOL adverse events from ISO 11979-7 at Visit 4, rates of secondary surgical interventions for IOL repositioning due to IOL misalignment at Visit 4, and rate of BCDVA 0.30 logMAR or better at Visit 4. Adverse events and safety outcomes were assessed against ISO 11979-7 criteria.

RayOne EMV Toric Clinical Trial Study Results

The clinical trial results provide reasonable assurance that the RayOne EMV Toric is safe and effective for the visual correction of aphakia and residual refractive astigmatism following cataract extraction.

Subject Population

A total of 274 subjects were enrolled (consented) in the study across 9 clinical sites in the United States. Of these, 238 subjects met the criteria for randomization. 233/274 (85.0%) subjects were available for analysis at study completion, the 6-month postoperative visit (Day 120–180). Visit accountability was high in both Toric and Monofocal groups, with ≥94% (minimum 113/120, 94.2%) of eyes available for analysis at all postoperative time points and minimal discontinuations or missed visits.

The demographics of the study population were typical for an IOL study performed in the U.S. Subjects ranged in age from

48 to 85 years in the Toric group (Mean: 67.7 ± 7.4 years) and 44 to 85 years in the Monofocal group (Mean: 69.4 ± 7.0 years). Females comprised 56% (66/118) of the Toric group and 58% (70/120) of the Monofocal group, and demographics were generally comparable across groups, with similar age ranges, sex distribution, and study eye laterality; the slightly higher proportion of subjects aged ≥ 65 years in the Monofocal group was not considered clinically meaningful.

Baseline ocular characteristics were well balanced between the Toric (N=118) and Monofocal (N=120) IOL groups, with similar axial length and keratometric cylinder distributions. Cataract severity by LOCS III (nuclear, cortical, and posterior subcapsular) was comparable across groups, with no meaningful differences in grade distributions.

Effectiveness Results

The Intent to Treat Analysis Set (ITT) was the primary set for the analyses of the effectiveness endpoints and included all randomized subjects. The analysis of effectiveness was based on the 238 evaluable patients at the 6-month time point (Day 120-180, Visit 4).

Visual Acuity

Photopic distance visual acuity testing was performed with the Early Treatment of Diabetic Retinopathy Study (ETDRS) charts using the M&S Clinical Trial Suite system (M&S Technologies, Niles, IL) at 4 meters.

All three co-primary effectiveness endpoints were met according to the ANSI Z80.30 performance criteria: the adjusted mean difference in magnitude of residual manifest cylinder between the randomized groups was -0.430 D (95% CI $[-0.544, -0.316]$), which was statistically ($P < 0.0001$) and clinically significant, meeting the minimum clinically important difference (MCID) of -0.40 D recommended by FDA (**TABLE 3**); the percentages of Toric IOL axis misalignment (from pre-operatively marked intended axis) under 10 degrees and 20 degrees exceeded the minimum percentages of 90% and 95%, respectively, (93.1%, 95% CI $[86.1\%, 96.8\%]$ less than 10 degrees and 99.99%, 95% CI $[96.9\%, 100\%]$ less than 20 degrees) per the primary imputation analysis (**TABLE 4**) and the percentage of Toric IOLs that rotated $\leq$ five degrees between Visit 3 (Day 30-60) and Visit 4 (Day 120-180) was 99.0% (95% CI $[93.5\%, 99.9\%]$), and exceeded the pre-specified success criteria of 90% for rotational stability using the primary imputation strategy (**TABLE 5**).

The results of the secondary effectiveness endpoints are as follows: at Visit 4, residual manifest cylinder stratified by preoperative keratometric cylinder was described for the Toric group compared with the Monofocal group, with between-group differences of 0.381 D $\pm$ 0.078 D in the 1.00 to <1.25 D subgroup and 0.478 D $\pm$ 0.088 D in the 1.25 to 1.50 D subgroup. Percent reduction in absolute cylinder at Visit 4 was 68.6% in the Toric group versus 36.1% in the Monofocal group (**TABLE 6** and **TABLE 7**).

In addition to the co-primary and secondary effectiveness endpoints, several additional cylinder reduction effectiveness analyses were performed to further characterize refractive outcomes. These included accuracy of cylinder to target (**TABLE 8**), lens axis misalignment (**TABLE 9**), mean reduction in cylinder power overall and by preoperative keratometric cylinder subgroup (**TABLE 10** and **TABLE 11**) and the percentage of eyes with reduction in cylinder within 0.50 D and 1.00 D of intended (**TABLE 12**) These analyses were evaluated descriptively using summary statistics.

Safety Results

Safety Set (SAF) consisting of all ITT subjects who underwent surgery was the pre-specified primary analysis set for safety endpoints. Among 234 subjects included in the SAF, 117 subjects received the test Toric IOL and 116 received the control Monofocal IOL. In addition, the rate of BCDVA of 0.30 logMAR or better at Month 6 was also planned to be evaluated based on the Best Case Set (BCS) consisting of all SAF subjects who were successfully implanted with a study lens, without major protocol deviations, and also met the following criteria: no clinically significant pre-operative ocular pathology; no macular degeneration detected at any time; and no previous surgery for the correction of refractive errors, which would have resulted in exclusion of the subject from the study. Among 222 subjects included in the Best-Case Set (BCS), 111 subjects received the test Toric IOL and 111 received the control Monofocal IOL.

The first co-primary safety endpoint was to evaluate rates of cumulative and persistent adverse events in first operative eyes at Month 6 (Visit 4) in comparison to ISO 11979-7 Safety and Performance Endpoints grid (SPE rates). Of the AEs

listed in the ISO grid, the two cumulative AEs observed in this study were cystoid macular edema (2/117 subjects, 1.7%) and secondary surgical interventions (SSIs) (2/117 subjects, 1.7%). At Visit 4, no rates of the adverse events in the Toric group were identified to be statistically higher than the ISO grid at one-sided 0.05 significance level, and this endpoint was successfully met according to the ISO performance criteria.

The second co-primary safety endpoint was to evaluate the rates of all other adverse events not included in the IOL adverse event list from ISO 11979-7 through Visit 4. The most common adverse events reported (out of an N=117) were posterior capsular opacification (14 subjects, 12.0%), posterior vitreous detachment (7 subjects, 6.0%) and corneal edema (7 subjects, 6.0%). No unexpected safety concerns were identified with the RayOne EMV Toric.

The third co-primary safety endpoint was to evaluate the rates of secondary surgical interventions for IOL repositioning due to IOL misalignment through Visit 4. One toric subject (1/117, 0.9%) underwent IOL repositioning surgery within the first few weeks. The need for repositioning was not attributed to the device itself, but to the initial placement.

The fourth co-primary safety endpoint was to evaluate the rate of BCDVA of 0.30 logMAR or better at Month 6 compared to the ISO SPE rates as described in ISO 11979-7. All Toric subjects achieved BCDVA of 0.30 logMAR (20/40) or Month 6 post-operatively based the Safety set (117/117, 100%, 95% CI [96.9%, 100%]) and the Best Case set (111/111, 100%, 95% CI [96.7%, 100%]). The rate of BCDVA of 0.30 logMAR or better at Visit 4 for the test Toric group was not identified to be statistically significantly lower than the corresponding ISO SPE rate based on both the Safety (ISO SPE rate: 92.5%) and Best Case sets (ISO SPE rate: 96.7%), therefore this endpoint was successfully met per the ISO performance criteria.

Therefore, all co-primary safety endpoints were met.

TABLE 3 RESIDUAL MANIFEST CYLINDER (D) AT VISIT 4 - PRIMARY IMPUTATION STRATEGY (ITT SET)

Statistic	Result
Observed Data	
RayOne EMV Toric IOL	117/118
Mean ± SD	0.368 ± 0.334
Median	0.25
Min, Max	0.00, 1.25
Q1, Q3	0.00, 0.50
Monofocal (Control) IOL	116/120
Mean ± SD	0.780 ± 0.532
Median	0.75
Min, Max	0.00, 2.50
Q1, Q3	0.38, 1.25
Difference in Means ± SE	-0.413 ± 0.0582
With Imputation	
Number of Imputations ^[1]	50
LS Mean Difference ± SE	-0.430 ± 0.058 ^[2]
95% Confidence Interval	[-0.544, -0.316]
t Value	-7.39
P-value	<.0001

Results are presented in absolute cylinder (D); more negative differences are more favorable for the **RayOne EMV** Toric lens.

One toric IOL subject underwent an SSI for IOL repositioning; Per ANSI Z80.30, the last Residual Manifest cylinder (1.25 D) prior to the SSI was carried forward to subsequent Visits 3 and 4.

^[1] Missing values imputed with the Markov chain Monte Carlo (MCMC) method. Following imputation, the primary hypothesis was tested using an Analysis of Covariance (ANCOVA) model with randomized treatment as factor and preoperative keratometric cylinder as covariate.

^[2] Meets the minimum clinically significant difference of -0.40 D

TABLE 4 ABSOLUTE IOL AXIS MISALIGNMENT (DEGREES) AT VISIT 4 - PRIMARY IMPUTATION STRATEGY (ITT SET)

	< 10 Degrees Misalignment at V4	< 20 Degrees Misalignment at V4
Absolute Misalignment (degrees), at Visit 4		
% (n/N), observed	93.9% (92/98)	100% (98/98)
%, with imputation ^[1]	93.1% (5492/5900)	99.99% (5899/5900)
95% Confidence Interval ^[2] , with imputation ^[1,3]	[86.1%, 96.8%]	[96.9%, 100%]

IOL Axis Misalignment is the difference in intended axis of orientation, marked pre-operatively on the day of surgery (Day 0), and the IOL axis at the postoperative visit.

One subject underwent an SSI for IOL repositioning; Per ANSI Z80.30, the last IOL Misalignment (9.04°) prior to the SSI was carried forward to subsequent Visits 3 and 4.

The IOL axis misalignment endpoint is successful if IOL axis misalignment is less than 10 degrees for 90% of eyes and less than 20 degrees for 95% of eyes from the Toric test group in the fifty imputed datasets.

^[1] Missing values were handled through multiple imputations (50 sets) using with the Markov chain Monte Carlo (MCMC) method.

^[2] 95% Exact (Clopper-Pearson) confidence interval (CI), without multiplicity adjustment.

^[3] All Missing data were imputed as <20 degrees misalignment in 49/50 imputations. The 95% CI presented for the percent of eyes with <20 degrees misalignment is based on a single imputation with 118/118 successes.

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 Toric; N=120 Monofocal)

TABLE 5 STABILITY OF RAYONE EMV TORIC IOL AXIS ORIENTATION (DEGREES) AT VISIT 4 - PRIMARY IMPUTATION STRATEGY

	Absolute IOL Axis Rotation ≤ 5 degrees between Visit 3 and Visit 4
Stability of RayOne EMV Toric IOL Axis Orientation (degrees) at Visit 4	
% (n/N), observed	99.0% (100/101)
%, with imputation ^[1]	99.0% (5839/5900)
95% Confidence Interval ^[2] , with imputation ^[1]	[93.5%, 99.9%]

Absolute IOL Axis Rotation is the absolute difference in the actual IOL axis at the postoperative visits

The IOL axis stability endpoint is successful if at least 90% of all toric lenses in the fifty imputed datasets rotate less than or equal to five degrees between Visits 3 and 4.

^[1] Missing values were handled through multiple imputations (50 sets) using the Markov chain Monte Carlo (MCMC) method.

^[2] 95% Exact (Clopper-Pearson) confidence interval (CI), without multiplicity adjustment.

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 RayOne EMV Toric; N=120 Monofocal)

TABLE 6 RESIDUAL MANIFEST CYLINDER (D) AT VISIT 4 STRATIFIED BY PREOPERATIVE KERATOMETRIC CYLINDER

Pre-operative Keratometric cylinder	Residual Manifest Cylinder (D) at Visit 4		
	RayOne EMV Toric IOL Mean ± SD	Monofocal IOL Mean ± SD	Difference Difference in means (± SD) [95% CI of difference]
1.00 to < 1.25 D			
n	75	62	
	0.413 ± 0.333	0.794 ± 0.535	-0.381 (± 0.078)
1.25 to 1.50 D			
n	42	54	
	0.286 ± 0.325	0.764 ± 0.533	-0.478 (± 0.088)

Abbreviations: D=Diopter; SD=Standard deviation; SE=Standard Error

Results are presented in absolute cylinder (D); more negative differences are more favorable for the RayOne EMV Toric lens.

For one subject who underwent an SSI for IOL repositioning, the last Residual Manifest cylinder (1.25 D) prior to the SSI was carried forward to subsequent Visits 3 and 4, per ANSI Z80.30.

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 RayOne EMV Toric; N=120 Monofocal)

TABLE 7 PERCENT REDUCTION IN ABSOLUTE CYLINDER (ITT SET)

Percent Reduction in cylinder at Visit 4	RayOne EMV Toric IOL Mean ± SD	Monofocal IOL Mean ± SD
n	117	116
Mean ± SD	68.59% ± 29.17 %	36.11% ± 45.69 %
Difference		
Difference in means (± SE)	32.48 (± 5.03) %	

Abbreviations: SD=Standard deviation; SE=Standard Error

Percent Reduction in absolute cylinder is calculated for each eye as $(1 - |\text{residual manifest cylinder}| / (\text{preoperative keratometric cylinder})) \times 100\%$.

For one subject who underwent an SSI for IOL repositioning, the last Residual Manifest cylinder (1.25 D) prior to the SSI was carried forward to subsequent Visits 3 and 4, per ANSI Z80.30.

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 Toric; N=120 Monofocal); subjects implanted with the **RayOne EMV** Toric IOL (N=117) and Monofocal IOL (N=116).

TABLE 8 ACCURACY OF CYLINDER TO TARGET (ITT SET)

Randomized Lens	Accuracy of Cylinder to Target	Visit 4 (Day 120-180)
RayOne EMV Toric IOL	±0.25 D	66/117 (56.4%)
	±0.50 D	100/117 (85.5%)
	±0.75 D	110/117 (94.0%)
	>0.75 D	7/117 (6.0%)
Monofocal IOL	±0.25 D	32/116 (27.6%)
	±0.50 D	56/116 (48.3%)
	±0.75 D	76/116 (65.5%)
	>0.75 D	40/116 (34.5%)

Accuracy of Cylinder is calculated for each eye as the difference between the magnitude of the postoperative manifest refraction cylinder and the magnitude of the target postoperative residual astigmatism per the Toric IOL calculator.

One subject underwent an SSI for IOL repositioning; Per ANSI Z80.30, the last Residual Manifest cylinder (1.25 D) prior to the SSI was carried forward to subsequent Visits 3 and 4.

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 **RayOne EMV** Toric; N=120 Monofocal)

TABLE 9 IOL AXIS MISALIGNMENT (DEGREES) BY VISIT (ITT SET)

	Statistic	Op	Visit 1 (Day 1-2)	Visit 2 (Day 7-14)	Visit 3 (Day 30-60)	Visit 4 (Day 120-180)
Absolute Misalignment (degrees)	N	106	99	97	97	98
	Mean ± SD	3.101 ± 3.787	3.086 ± 3.598	3.125 ± 3.306	3.071 ± 3.261	3.481 ± 3.418
	Median	1.88	1.94	1.93	1.90	2.61
	Min, Max	0.01, 20.33	0.01, 18.07	0.05, 16.67	0.02, 16.40	0.01, 16.50
	Q1, Q3	0.59, 4.25	0.68, 4.22	0.62, 3.88	0.86, 4.24	1.18, 4.29
	Ungradable Op Image	11	NA	NA	NA	NA
	Ungradable Op Image and Ungradable Postop Image	NA	4	4	4	4
	Ungradable Op Image and Gradable Postop Image	NA	6	6	7	7
	Gradable Op Image and Ungradable Postop Image	NA	5	7	5	8
	Data Not Available	NA	3	2	3	0
Absolute	< 5 degrees	84 (79.2%)	82 (82.8%)	77 (79.4%)	78 (80.4%)	76 (77.6%)

	Statistic	Op	Visit 1 (Day 1-2)	Visit 2 (Day 7-14)	Visit 3 (Day 30-60)	Visit 4 (Day 120-180)
Misalignment (degrees), n (%)	< 10 degrees	101 (95.3%)	95 (96.0%)	92 (94.8%)	93 (95.9%)	92 (93.9%)
	< 20 degrees	105 (99.1%)	99 (100%)	97 (100%)	97 (100%)	98 (100%)
	≤ 30 degrees	106 (100%)	99 (100%)	97 (100%)	97 (100%)	98 (100%)
	> 30 degrees	0	0	0	0	0
Signed IOL Misalignment	N	106	99	97	97	98
	Mean ± SD	1.583 ± 4.639	1.345 ± 4.554	1.183 ± 4.403	1.104 ± 4.351	1.041 ± 4.778
	Median	0.64	0.68	0.57	0.61	0.16
	Min, Max	-9.54, 20.33	-10.62, 18.07	-10.83, 16.67	-10.93, 16.40	-10.95, 16.50
	Q1, Q3	-0.57, 3.60	-0.73, 2.82	-1.01, 3.09	-1.11, 2.88	-1.55, 3.16

IOL Axis Misalignment is the difference in intended axis of orientation, marked pre-operatively on the day of surgery (Day 0), and the IOL axis at the postoperative visit

One subject underwent an SSI for IOL repositioning; Per ANSI Z80.30, the last IOL Misalignment (9.04°) prior to the SSI was carried forward to subsequent Visits 3 and 4.

^[1] The image was gradable but Operative visit image was not gradable / not done.

^[2] For signed misalignment, Clockwise=Negative, Counterclockwise=Positive

N = total number of Toric eyes analyzed at the specified visit

n = total number of eyes meeting each absolute misalignment threshold

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 RayOne EMV Toric; N=120 Monofocal)

TABLE 10 REDUCTION IN CYLINDER POWER (D) (ITT SET)

Randomized Lens	Statistic	Visit 4 (Day 120-180)
RayOne EMV Toric IOL	n	117
	Mean ± SD	0.839 ± 0.385
	Median	0.84
	Min, Max	-0.24, 1.48
	Q1, Q3	0.60, 1.13
Monofocal IOL	n	116
	Mean ± SD	0.466 ± 0.565
	Median	0.52
	Min, Max	-1.40, 1.49
	Q1, Q3	0.08, 0.92
	Difference in Means ± SE	0.373 ± 0.0634

Reduction in Cylinder Power is calculated for each eye as the difference between the magnitude of the preoperative keratometric cylinder and the magnitude of the postoperative manifest refraction cylinder.

One subject underwent an SSI for IOL repositioning; Per ANSI Z80.30, the last Residual Manifest cylinder (1.25 D) prior to the SSI was carried forward to subsequent Visits 3 and 4.

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 RayOne EMV Toric; N=120 Monofocal)

TABLE 11 REDUCTION IN CYLINDER POWER (D) BY PREOPERATIVE KERATOMETRIC CYLINDER (ITT SET)

Preoperative Keratometric Cylinder	Randomized Lens	Statistic	Visit 4 (Day 120-180)
1.0 to <1.25 D	RayOne EMV Toric IOL	n	75
		Mean ± SD	0.699 ± 0.342
		Median	0.73
		Min, Max	-0.24, 1.24
		Q1, Q3	0.51, 0.95

Preoperative Keratometric Cylinder	Randomized Lens	Statistic	Visit 4 (Day 120-180)
	Monofocal IOL	n	62
		Mean $\pm$ SD	0.346 $\pm$ 0.547
		Median	0.46
		Min, Max	-1.40, 1.21
		Q1, Q3	-0.03, 0.73
	Difference in Means $\pm$ SD		0.353 $\pm$ 0.0799
1.25 to 1.5 D	RayOne EMV Toric IOL	n	42
		Mean $\pm$ SD	1.089 $\pm$ 0.330
		Median	1.23
		Min, Max	0.00, 1.48
		Q1, Q3	0.92, 1.34
	Monofocal IOL	n	54
		Mean $\pm$ SD	0.604 $\pm$ 0.558
		Median	0.65
		Min, Max	-0.72, 1.49
		Q1, Q3	0.25, 1.02
	Difference in Means $\pm$ SD		0.486 $\pm$ 0.0914

Reduction in Cylinder Power is calculated for each eye as the difference between the magnitude of the preoperative keratometric cylinder and the magnitude of the postoperative manifest refraction cylinder.

One subject underwent an SSI for IOL repositioning; Per ANSI Z80.30, the last Residual Manifest cylinder (1.25 D) prior to the SSI was carried forward to subsequent Visits 3 and 4.

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 RayOne EMV Toric; N=120 Monofocal)

TABLE 12 PERCENTAGE OF EYES WITH REDUCTION OF CYLINDER POWER (D) (ITT SET)

Randomized Lens	Reduction of Cylinder Power within Intended	Visit 4 (Day 120-180)
RayOne EMV Toric IOL	≤ 0.50 D	100/117 (85.5%)
	≤ 1.00 D	113/117 (96.6%)
	> 1.00 D	4/117 (3.4%)
Monofocal IOL	≤ 0.50 D	56/116 (48.3%)
	≤ 1.00 D	92/116 (79.3%)
	> 1.00 D	24/116 (20.7%)

Reduction in Cylinder Power is calculated for each eye as the difference between the magnitude of the preoperative keratometric cylinder and the magnitude of the postoperative manifest refraction cylinder. Intended Reduction in Cylinder Power is calculated for each eye as the difference between the magnitude of the preoperative keratometric cylinder and the magnitude of the target postoperative residual astigmatism per the Toric IOL calculator.

One subject underwent an SSI for IOL repositioning; Per ANSI Z80.30, the last Residual Manifest cylinder (1.25 D) prior to the SSI was carried forward to subsequent Visits 3 and 4.

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 RayOne EMV Toric; N=120 Monofocal)

Clinical Data on RayOne Galaxy

Study Description

The U.S. IDE clinical trial of the RayOne Galaxy was conducted as a prospective, multicenter, randomized, active controlled, masked investigation to determine the safety and performance of the RayOne Galaxy (Model RAO605G) in comparison with the RayOne Aspheric (Model RAO600C) monofocal IOL following approximately 6 months (120 to 180 days) of post-operative assessment. Key assessments compared monocular distance-corrected visual acuity of the RayOne Galaxy IOL with a monofocal lens to demonstrate improved intermediate and near vision while maintaining comparable distance

visual acuity.

Enrolled and randomized subjects underwent preoperative baseline assessments and postoperative follow-up visits at predefined intervals through Visit 4. Subjects underwent preoperative baseline assessments and postoperative follow-up visits at predefined intervals through Visit 4 (Day 120–180). The primary effectiveness endpoints at Visit 4 were mean photopic monocular best corrected distance visual acuity (BCDVA) at 4 meters in first implanted eyes, and photopic monocular distance-corrected near visual acuity (DCNVA) at 40 cm in first implanted eyes. The primary safety endpoints through Visit 4 were the rates of device-related secondary surgical interventions related to the optical properties of the investigational device, the rate of BCDVA of 0.30 logMAR or better, the rates of IOL adverse events compared to the ISO Safety and Performance Endpoint (SPE) rates as described in ISO 11979-7 (2024), the rates of all other adverse events not included in IOL adverse events from ISO 11979-7 (2024), and the rates of adverse events defined in Masket et al¹. The primary effectiveness and safety endpoints were assessed against the ISO 11979-7:2024 performance and safety criteria.

RayOne Galaxy Clinical Study Trial Study Results

Subject Population

Subjects’ enrolment was limited to patients who met the defined inclusion criteria and none of the exclusion criteria in both eyes. A total of 254 subjects were enrolled (consented) in the study across 10 clinical sites in the United States. Of these, 230 subjects met the criteria for randomization and constituted the Intent-to-Treat (ITT) set (114 subjects in the Multifocal group and 116 in the Monofocal group). At the 6-month postoperative visit (Day 120–180, Visit 4), accountability was 98.2% in both groups (220/224 Multifocal eyes and 221/225 Monofocal eyes) (TABLE 13).

The demographics of the study population were typical for an IOL study performed in the U.S (TABLE 14). Subjects ranged in age from 46 to 81 years in the Multifocal group (Mean: 67.3 ± 7.3 years) and 34 to 81 years in the Monofocal group (Mean: 67.7 ± 7.4 years). Females comprised 64.0% (73/114) in the Multifocal group, and 61.2% (71/116) of the subjects enrolled in the Monofocal group. The distribution of axial length, pre-operative keratometry cylinder, and the grade of cataract were similar between randomized groups. (TABLE 15).

TABLE 13 - ACCOUNTABILITY - MULTIFOCAL AND MONOFOCAL EYES (ITT SET)

Eye	Accountability	Visit 1 (Day 1-2)	Visit 2 (Day 7-14)	Visit 3 (Day 30-60)	Visit 4 (Day 120-180)
Multifocal Eyes					
First Eye (N=114)	Available for Analysis (In Window)	112 (98.2%)	107 (93.9%)	104 (91.2%)	110 (96.5%)
	Available for Analysis (Out of Window)	0	5 (4.4%)	5 (4.4%)	0
	Missed Visit	0	0	1 (0.9%)	0
	Discontinued	2 (1.8%)	2 (1.8%)	2 (1.8%)	2 (1.8%)
	Lost to Follow-up	0	0	2 (1.8%)	2 (1.8%)
	% Accountability	112/112 (100%)	112/112 (100%)	109/112 (97.3%)	110/112 (98.2%)
Second Eye (N=114)	Available for Analysis (In Window)	109 (95.6%)	107 (93.9%)	107 (93.9%)	110 (96.5%)
	Available for Analysis (Out of Window)	1 (0.9%)	2 (1.8%)	1 (0.9%)	0
	Missed Visit	1 (0.9%)	2 (1.8%)	2 (1.8%)	0
	Discontinued	2 (1.8%)	2 (1.8%)	2 (1.8%)	2 (1.8%)
	Lost to Follow-up	1 (0.9%)	1 (0.9%)	2 (1.8%)	2 (1.8%)
	% Accountability	110/112 (98.2%)	109/112 (97.3%)	108/112 (96.4%)	110/112 (98.2%)
All RAO605G Multifocal Eyes (N=228)	Available for Analysis (In Window)	221 (96.9%)	214 (93.9%)	211 (92.5%)	220 (96.5%)
	Available for Analysis (Out of Window)	1 (0.4%)	7 (3.1%)	6 (2.6%)	0
	Missed Visit	1 (0.4%)	2 (0.9%)	3 (1.3%)	0

¹ Masket S, Rorer E, Stark W, et al. Special Report: The American Academy of Ophthalmology Task Force Consensus Statement on Adverse Events with Intraocular Lenses. Ophthalmology. 2017;124(1):142-144.

Eye	Accountability	Visit 1 (Day 1-2)	Visit 2 (Day 7-14)	Visit 3 (Day 30-60)	Visit 4 (Day 120-180)
Multifocal Eyes					
	Discontinued	4 (1.8%)	4 (1.8%)	4 (1.8%)	4 (1.8%)
	Lost to Follow-up	1 (0.4%)	1 (0.4%)	4 (1.8%)	4 (1.8%)
	% Accountability	222/224 (99.1%)	221/224 (98.7%)	217/224 (96.9%)	220/224 (98.2%)
Monofocal Eyes					
First Implanted Eye (N=116)	Available for Analysis (In Window)	113 (97.4%)	112 (96.6%)	109 (94.0%)	109 (94.0%)
	Available for Analysis (Out of Window)	2 (1.7%)	2 (1.7%)	4 (3.4%)	2 (1.7%)
	Missed Visit	0	0	0	0
	Discontinued	1 (0.9%)	1 (0.9%)	2 (1.7%)	3 (2.6%)
	Lost to Follow-up	0	1 (0.9%)	1 (0.9%)	2 (1.7%)
	% Accountability	115/115 (100%)	114/115 (99.1%)	113/114 (99.1%)	111/113 (98.2%)
Second Implanted Eye (N=116)	Available for Analysis (In Window)	113 (97.4%)	111 (95.7%)	109 (94.0%)	108 (93.1%)
	Available for Analysis (Out of Window)	1 (0.9%)	2 (1.7%)	2 (1.7%)	2 (1.7%)
	Missed Visit	0	0	1 (0.9%)	0
	Discontinued	2 (1.7%)	2 (1.7%)	3 (2.6%)	4 (3.4%)
	Lost to Follow-up	0	1 (0.9%)	1 (0.9%)	2 (1.7%)
	% Accountability	114/114 (100%)	113/114 (99.1%)	111/113 (98.2%)	110/112 (98.2%)
All RAO600C Monofocal Eyes (N=232)	Available for Analysis (In Window)	226 (97.4%)	223 (96.1%)	218 (94.0%)	217 (93.5%)
	Available for Analysis (Out of Window)	3 (1.3%)	4 (1.7%)	6 (2.6%)	4 (1.7%)
	Missed Visit	0	0	1 (0.4%)	0
	Discontinued	3 (1.3%)	3 (1.3%)	5 (2.2%)	7 (3.0%)
	Lost to Follow-up	0	2 (0.9%)	2 (0.9%)	4 (1.7%)
	% Accountability	229/229 (100%)	227/229 (99.1%)	224/227 (98.7%)	221/225 (98.2%)

Abbreviations: n = number of eyes in the specified accountability category; N = total number of eyes in the respective treatment and eye group. Accountability-category results are presented as n (%). Percentages for the individual accountability categories are calculated as n/N using the applicable N for the respective treatment and eye group. **Available for Analysis (In Window):** Total number of eyes for whom data are available at the visit and within the visit window. **Available for Analysis (Out of Window):** Total number of eyes that were seen at the scheduled visit, but before or after the time window associated with the visit. **Missed Visit:** Total number of eyes that did not attend the scheduled visit. **Discontinued:** Total number of eyes that discontinued study participation prior to the visit for any reason, not including subjects that are lost to follow-up. **Lost to Follow-up:** Total number of eyes that missed the visit and for whom there is no information available. **% Accountability:** Available for Analysis / (N - Discontinued)

TABLE 14 SUBJECT DEMOGRAPHICS (ITT SET)

		Randomized Lens	
Demographic Parameter	Outcome	RAO605G Multifocal IOL, (N=114)	RAO600C Monofocal IOL, (N=116)
Age (years)	N	114	116
	Mean ± SD	67.3 ± 7.3	67.7 ± 7.4
	Median	68	69
	Min, Max	46, 81	34, 81
	Q1, Q3	64, 72	63, 73
Age Group: n (%)	< 65 years	30 (26.3%)	36 (31.0%)
	≥ 65 years	84 (73.7%)	80 (69.0%)
Sex: n (%)	Male	41 (36.0%)	45 (38.8%)
	Female	73 (64.0%)	71 (61.2%)
Race: n (%)	American Indian or Alaska Native	0	1 (0.9%)
	Asian	4 (3.5%)	1 (0.9%)
	Black or African American	3 (2.6%)	3 (2.6%)

Demographic Parameter	Outcome	Randomized Lens	
		RAO605G Multifocal IOL, (N=114)	RAO600C Monofocal IOL, (N=116)
	Native Hawaiian or Other Pacific Islander	0	1 (0.9%)
	White	106 (93.0%)	109 (94.0%)
	Multiple	1 (0.9%)	1 (0.9%)
	Other	0	0
Ethnicity: n (%)	Hispanic or Latino	4 (3.5%)	8 (6.9%)
	Not Hispanic or Latino	110 (96.5%)	108 (93.1%)
First Eye: n (%)	OD	70 (61.4%)	56 (48.3%)
	OS	44 (38.6%)	60 (51.7%)

Abbreviations: n = number of subjects in the specified category; N = total number of subjects in the respective randomized treatment group. Categorical results are presented as n (%). Percentages are calculated as n/N using the applicable N for the respective randomized treatment group.

TABLE 15 BASELINE PARAMETERS (ITT SET)

		RAO605G Multifocal IOL			RAO600C Monofocal IOL		
Parameter	Statistic	First Eye ^[1]	Second Eye	All Eyes	First Eye ^[1]	Second Eye	All Eyes
	n	114	114	228	116	116	232
Axial Length (mm)	Mean ± SD	23.975 ± 1.219	23.936 ± 1.215	23.956 ± 1.215	24.243 ± 1.226	24.194 ± 1.181	24.218 ± 1.201
	Median	23.80	23.71	23.77	24.07	24.07	24.07
	Min, Max	22.01, 28.27	21.91, 28.63	21.91, 28.63	21.57, 27.33	21.68, 26.94	21.57, 27.33
Anterior Chamber Depth (mm)	Mean ± SD	3.355 ± 0.395	3.321 ± 0.378	3.338 ± 0.386	3.394 ± 0.403	3.383 ± 0.398	3.389 ± 0.399
	Median	3.32	3.32	3.32	3.41	3.39	3.40
	Min, Max	2.27, 4.34	2.30, 4.30	2.27, 4.34	2.50, 4.63	2.53, 4.60	2.50, 4.63
Photopic BCDVA (logMAR)	Mean ± SD	0.244 ± 0.180	0.102 ± 0.112	0.173 ± 0.166	0.281 ± 0.236	0.138 ± 0.188	0.209 ± 0.224
	Median	0.21	0.10	0.14	0.22	0.10	0.18
	Min, Max	-0.08, 0.92	-0.18, 0.40	-0.18, 0.92	-0.04, 1.10	-0.20, 1.10	-0.20, 1.10
MRSE (D)	Mean ± SD	-0.9594 ± 2.5021	-0.6009 ± 2.4603	-0.7802 ± 2.4823	-1.6239 ± 3.1324	-1.1056 ± 2.8376	-1.3648 ± 2.9934
	Median	-0.375	0.000	-0.250	-1.000	-0.250	-0.625
	Min, Max	-9.750, 3.250	-10.000, 2.625	-10.000, 3.250	-9.875, 3.500	-9.250, 3.000	-9.875, 3.500
Target Residual Spherical Equivalent (D)	Mean ± SD	-0.007 ± 0.113	-0.000 ± 0.095	-0.003 ± 0.104	-0.006 ± 0.108	-0.002 ± 0.093	-0.004 ± 0.101
	Median	-0.01	0.00	0.00	-0.02	0.00	-0.01
	Min, Max	-0.50, 0.18	-0.17, 0.16	-0.50, 0.18	-0.18, 0.18	-0.17, 0.17	-0.18, 0.18
Keratometric Cylinder (D)	n	114	114	228	116	116	232
	Mean ± SD	0.521 ± 0.255	0.530 ± 0.209	0.525 ± 0.233	0.586 ± 0.244	0.533 ± 0.230	0.559 ± 0.238
	Median	0.50	0.52	0.51	0.58	0.52	0.54
	Min, Max	0.00, 0.99	0.00, 0.98	0.00, 0.99	0.06, 0.99	0.00, 0.99	0.00, 0.99

^[1]For implanted subjects, First Eye is the First-Implanted Eye and Second Eye is the Second-Implanted Eye. For subjects who were not implanted, the First and Second eyes were determined according to the methods described in the study protocol.

Effectiveness Results

A total of 230 subjects were randomized in the study and constituted the Intent-to-Treat (ITT) set (114 Multifocal, 116 Monofocal). Of the 230 ITT subjects, 227 underwent surgery and comprised the Safety set. Of these, 209 subjects had no major protocol deviations and thus comprised the Per-Protocol (PP) set; all but two (2) PP subjects were included in the Best Case Set (BCS; n = 207). Eventually, the Multifocal IOL was implanted in 112 subjects, and the Monofocal IOL in 115

subjects. The effectiveness analysis was based on 110 evaluable subjects in the Multifocal group and 109 evaluable subjects in the Monofocal group, considering First Implanted Eyes at the Visit 4 time point in the IIT population.

Visual acuity testing was performed with the Early Treatment of Diabetic Retinopathy Study (ETDRS) charts using the M&S Clinical Trial Suite system (M&S Technologies, Niles, IL).

The first and second co-primary effectiveness endpoints were both met according to the ISO 11979-7:2024 performance criteria.

- The first co-primary effectiveness endpoint was the mean photopic monocular BCDVA at 4 meters in First Implanted eyes at Visit 4 (**TABLE 16**). The success criterion was that the mean photopic monocular BCDVA at 4 meters in First Implanted eyes in the Multifocal group would be better than or equal to 0.20 logMAR (i.e., mean logMAR $\leq$ 0.20 without rounding). The estimated mean (SE) monocular BCDVA was 0.031 (0.0076) logMAR ($n = 114$) in the First Implanted Multifocal eyes, and -0.035 (0.0078) logMAR ($n = 116$) in the First Implanted Monofocal eyes.
- The second co-primary effectiveness endpoint was the difference in mean photopic monocular DCNVA at 40 cm between IOL groups (Multifocal – Monofocal) in First Implanted eyes at Visit 4 (**TABLE 17**). The endpoint was considered successful if the mean monocular DCNVA in Multifocal group was statistically superior to the Monofocal group. The estimated mean [95% CI] difference between groups was -0.275 [-0.309, -0.241] logMAR in favor of the Multifocal group ($p < 0.0001$). Therefore, the Multifocal IOL was successful in this co-primary endpoint, with an improvement of 0.275 logMAR or 2.75 lines over the Monofocal group at a near distance of 40 cm.

The results of the secondary effectiveness endpoints, assessed at 120 to 180 days post-operatively (Visit 4) are as follows:

- The mean difference [95% CI] between groups in mean photopic monocular BCDVA in First Implanted eyes was 0.066 [0.045, 0.087] logMAR ($p = 0.0018$), demonstrating non-inferiority of the Multifocal IOL over the Monofocal IOL (**TABLE 16**).
- The mean difference [95% CI] between groups in mean photopic monocular DCIVA at 66 cm in First Implanted eyes (Multifocal - Monofocal) was -0.206 [-0.238, -0.173] logMAR ($p < 0.0001$) in favor of the Multifocal group, corresponding to an improvement of 0.2 logMAR over the Monofocal group at the intermediate distance of 66 cm (**TABLE 18**).
- The mean (SE) photopic monocular DCIVA at 66 cm in First Implanted eyes was 0.129 (0.0112) logMAR in Multifocal eyes (**TABLE 18**).
- The mean $\pm$ SD photopic monocular DCVA in First Implanted eyes in the Multifocal IOL group was 0.141 ± 0.129 logMAR at 1.0 m, and 0.194 ± 0.171 logMAR at 50 cm. In the Monofocal group, the mean $\pm$ SD DCVA was 0.198 ± 0.123 logMAR at 1.0 m and 0.452 ± 0.194 logMAR at 50 cm, corresponding to differences in means [95% CI] of -0.057 [-0.091, -0.023] at 1.0 m and -0.258 [-0.307, -0.209] at 50 cm in favor of the Multifocal group (**TABLE 19**).
- The mean photopic monocular DCNVA at 40 cm in First Implanted eyes was 0.252 (0.0101) logMAR in the Multifocal eyes and 0.527 (0.0139) logMAR in the Monofocal eyes (**TABLE 17**).
- Binocular best-corrected distance defocus curves were obtained by defocusing each subject with spherical lenses ranging from -4.00 D to +2.00 D, applied in randomized order over the subject's manifest distance correction. Lens power was adjusted in 0.50 D increments, except between -0.50 D and +0.50 D, where 0.25 D steps were used. In both lens groups, the defocus curves peaked at 0.00 D, with a mean acuity of 0.0 logMAR or better. In the Multifocal group, visual acuity better than 0.20 logMAR was maintained through -2.50 D of defocus, corresponding to approximately 40 cm. In contrast, visual acuity in the Monofocal group declined below the 0.20 logMAR threshold between -1.00 and -1.50 D. Refer to **FIGURE 1**. Subjects were also subdivided by photopic pupil size. Those with the smallest pupil sizes ≤ 3.0 mm (Multifocal IOL group, $n=6$; Monofocal IOL group, $n=4$), those with medium pupil > 3.0 mm and < 4 mm (Multifocal IOL group, $n=25$; Monofocal IOL group, $n=30$) and those with large

pupil size > 4 mm (Multifocal IOL group, n=78; Monofocal IOL group, n=76). The global poolability statistic demonstrated no effect of preoperative pupil size on the difference between IOL groups in binocular defocus outcomes ($p = 0.7019$).

In addition to the co-primary and secondary effectiveness endpoints, several additional effectiveness analyses were performed to further characterize visual and refractive outcomes. These included:

Categorical summaries of photopic monocular distance-corrected visual acuity at distance (BCDVA), intermediate (DCIVA) and near (DCNVA) in first implanted eyes (TABLE 20), mean photopic binocular distance-corrected visual acuity (logMAR) at distance (BCDVA), intermediate (DCIVA) and near (DCNVA) (TABLE 21), mesopic monocular distance-corrected visual acuity at distance (BCDVA), intermediate (DCIVA) and near (DCNVA) in first implanted eyes (TABLE 22), mesopic binocular distance-corrected visual acuity at distance (BCDVA), intermediate (DCIVA) and near (DCNVA) (TABLE 23), photopic binocular uncorrected visual acuity (TABLE 24). These analyses were evaluated descriptively using summary statistics.

TABLE 16. PHOTOPIC MONOCULAR BCDVA (LOGMAR) AT 4M IN FIRST-IMPLANTED EYES AT VISIT 4 (ITT SET)

Statistic	RAO605G Multifocal IOL (N=114)	RAO600C Monofocal IOL (N=116)	Multifocal - Monofocal
Available for Analysis (In Window) at Visit 4	110/114 (96.5%)	109/116 (94.0%)	
Imputed at Visit 4	4/114 (3.5%)	7/116 (6.0%)	
Estimated Mean $\pm$ SE ^[1]	0.031 $\pm$ 0.0076	-0.035 $\pm$ 0.0078	0.066 $\pm$ 0.0109
95% Confidence Interval	(0.0161, 0.0460)	(-0.0502, -0.0195)	(0.0445, 0.0873)
Min, Max	0.028, 0.034	-0.038, -0.031	0.060, 0.070
t Value			-3.13
P-value ^[2]			0.0018

Missing values were imputed using 50 imputed datasets. The Markov chain Monte Carlo method was used to compute monotone imputations using treatment and the corresponding visual acuity assessment(s) at all scheduled visits prior to Visit 4. As Visit 4 is the final assessment of visual acuity (excluding potential unscheduled visits following Visit 4), data was imputed using a monotone regression method.

^[1]The Primary Effectiveness Endpoint of mean photopic monocular best corrected distance visual acuity (BCDVA) at 4 meters in first implanted eyes is successful if the mean meets or exceeds 0.20 logMAR (i.e. mean logMAR $\leq$ 0.20 without rounding).

^[2]A non-inferiority t-test with a non-inferiority margin of 0.10 is used to evaluate the Secondary Effectiveness Endpoint of photopic monocular best corrected distance visual acuity (BCDVA) at 4 meters.

TABLE 17. PHOTOPIC MONOCULAR DCNVA (LOGMAR) AT 40 CM IN FIRST-IMPLANTED EYES AT VISIT 4 (ITT SET)

Statistic	RAO605G Multifocal IOL (N=114)	RAO600C Monofocal IOL (N=116)	Multifocal - Monofocal
Available for Analysis (In Window) at Visit 4	110/114 (96.5%)	109/116 (94.0%)	
Imputed at Visit 4	4/114 (3.5%)	7/116 (6.0%)	
Estimated Mean $\pm$ SE ^[1]	0.252 $\pm$ 0.0101	0.527 $\pm$ 0.0139	-0.275 $\pm$ 0.0172
95% Confidence Interval	(0.2324, 0.2718)	(0.4999, 0.5545)	(-0.3089, -0.2414)
Min, Max	0.248, 0.255	0.518, 0.533	-0.285, -0.267
t Value			-15.98
P-value ^[2]			<0.0001

Missing values were imputed using 50 imputed datasets. The Markov chain Monte Carlo method was used to compute monotone imputations using treatment and the corresponding visual acuity assessment(s) at all scheduled visits prior to Visit 4. As Visit 4 is the final assessment of visual acuity (excluding potential unscheduled visits following Visit 4), data was imputed using a monotone regression method.

^[1]The Secondary Effectiveness Endpoint of mean photopic monocular distance-corrected near visual acuity (DCNVA) at 40 cm is successful if the mean meets or exceeds 0.20 logMAR (i.e. mean logMAR $\leq$ 0.20 without rounding).

^[2]The Primary Effectiveness Endpoint of difference in mean photopic monocular distance-corrected near visual acuity (DCNVA) at 40 cm is successful if the mean DCNVA of Multifocal group is significantly better than that of Monofocal group using a one-sided t-test at alpha of 0.025.

TABLE 18. PHOTOPIC MONOCULAR DCIVA (LOGMAR) AT 66 CM IN FIRST-IMPLANTED EYES AT VISIT 4 (ITT SET)

Statistic	RAO605G Multifocal IOL (N=114)	RAO600C Monofocal IOL (N=116)	Multifocal - Monofocal
Available for Analysis (In Window) at Visit 4	110/114 (96.5%)	109/116 (94.0%)	
Imputed at Visit 4	4/114 (3.5%)	7/116 (6.0%)	
Estimated Mean $\pm$ SE ^[1]	0.129 $\pm$ 0.0112	0.335 $\pm$ 0.0119	-0.206 $\pm$ 0.0164
95% Confidence Interval	(0.1073, 0.1510)	(0.3113, 0.3581)	(-0.2377, -0.1735)
Min, Max	0.124, 0.134	0.330, 0.340	-0.212, -0.200
t Value			-12.56
P-value ^[2]			<.0001

Missing values were imputed using 50 imputed datasets. The Markov chain Monte Carlo method was used to compute monotone imputations using treatment and the corresponding visual acuity assessment(s) at all scheduled visits prior to Visit 4. As Visit 4 is the final assessment of visual acuity (excluding potential unscheduled visits following Visit 4), data was imputed using a monotone regression method.

^[1] The Secondary Effectiveness Endpoint of mean photopic monocular distance-corrected intermediate visual acuity (DCIVA) at 66cm is successful if the mean meets or exceeds 0.20 logMAR (i.e. mean logMAR $\leq$ 0.20 without rounding).

^[2] A one-sided t-test is used to evaluate the Secondary Effectiveness Endpoint of photopic monocular distance-corrected intermediate visual acuity (DCIVA) at 66 cm.

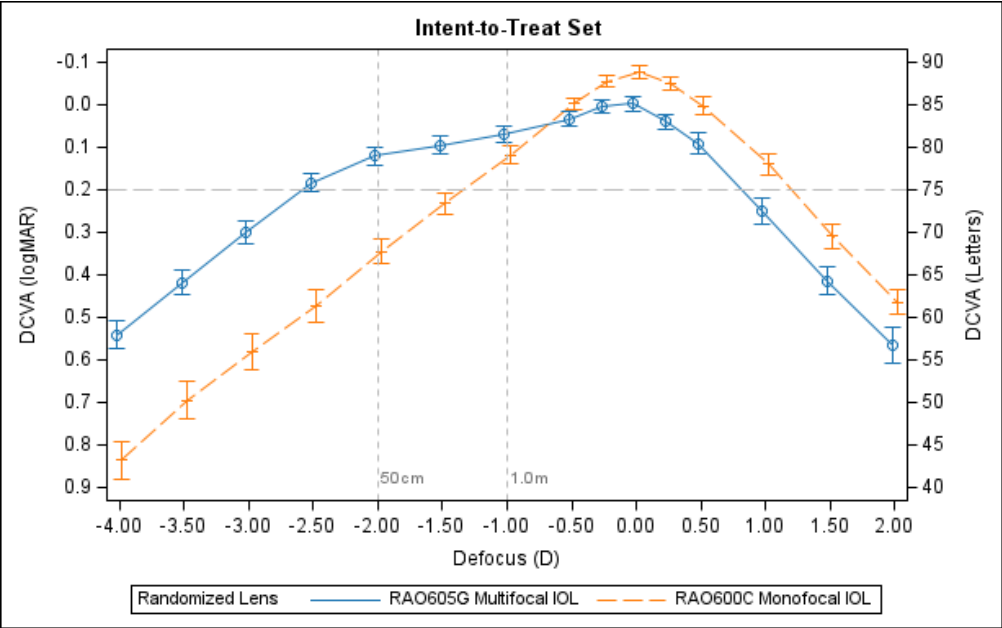
TABLE 19. PHOTOPIC MONOCULAR DCVA (LOGMAR) IN FIRST-IMPLANTED EYES AT VISIT 4 (ITT SET)

Randomized Lens	Statistic	Focal Length	
		1.0 m	50 cm
RAO605G Multifocal IOL	n	110	110
	Mean $\pm$ SD	0.141 $\pm$ 0.129	0.194 $\pm$ 0.171
	Median	0.12	0.16
	Min, Max	-0.12, 0.48	-0.04, 0.94
	Q1, Q3	0.04, 0.24	0.10, 0.24
RAO600C Monofocal IOL	n	109	109
	Mean $\pm$ SD	0.198 $\pm$ 0.123	0.452 $\pm$ 0.194
	Median	0.20	0.44
	Min, Max	-0.14, 0.50	0.04, 1.10
	Q1, Q3	0.12, 0.30	0.32, 0.58
	Difference in Means $\pm$ SE	-0.057 $\pm$ 0.0171	-0.258 $\pm$ 0.0247
	95% CI for Diff in Means	(-0.0905, -0.0233)	(-0.3067, -0.2092)

Abbreviations: n = number of First Implanted Eyes with non-missing photopic monocular distance-corrected visual acuity data at the applicable focal length. Note: Focal Length (m) = 1/D, where D is the defocus step in negative power.

The Secondary Effectiveness Endpoint of Photopic monocular distance-corrected visual acuity (DCVA) at 1.0 m and 50 cm is successful if both the mean DCVA at 1.0 m, and the mean DCVA at 50 cm, of Multifocal group first-implanted eyes at Visit 4 are $\leq$ 0.20 logMAR

FIGURE 1. PHOTOPIC BINOCULAR DEFOCUS CURVES AT VISIT 4 (ITT SET)



Error bars represent a 95% confidence interval about the mean

TABLE 20. PHOTOPIC MONOCULAR DISTANCE-CORRECTED VISUAL ACUITY IN FIRST IMPLANTED EYES (ITT SET) AT VISIT 4 (DAY 120-180)

Distance	Statistic	RAO605G Multifocal IOL n (%)	RAO600C Monofocal IOL n (%)
BCDVA, 4 m	N (eyes)	110	111
	0.00 (20/20) logMAR or better	48 (43.6%)	88 (79.3%)
	0.10 (20/25) logMAR or better	94 (85.5%)	107 (96.4%)
	0.20 (20/32) logMAR or better	107 (97.3%)	109 (98.2%)
	0.30 (20/40) logMAR or better	110 (100%)	111 (100%)
	Worse than 0.30 logMAR	0	0
DCIVA, 66 cm	N (eyes)	110	111
	0.00 (20/20) logMAR or better	12 (10.9%)	0
	0.10 (20/25) logMAR or better	54 (49.1%)	5 (4.5%)
	0.20 (20/32) logMAR or better	91 (82.7%)	22 (19.8%)
	0.30 (20/40) logMAR or better	104 (94.5%)	44 (39.6%)
	Worse than 0.30 logMAR	6 (5.5%)	67 (60.4%)
DCNVA, 40 cm	N (eyes)	110	111
	0.00 (20/20) logMAR or better	2 (1.8%)	0
	0.10 (20/25) logMAR or better	7 (6.4%)	0
	0.20 (20/32) logMAR or better	39 (35.5%)	2 (1.8%)
	0.30 (20/40) logMAR or better	83 (75.5%)	8 (7.2%)
	Worse than 0.30 logMAR	27 (24.5%)	103 (92.8%)

Abbreviations: n = number of eyes meeting the specified visual acuity criterion; N = total number of First Implanted Eyes with non-missing visual acuity data at the respective testing distance in each treatment group. Categorical results are presented as n (%). Percentages are calculated as n/N using the applicable N for the respective testing distance and treatment group.

TABLE 21. MEAN PHOTOPIC BINOCULAR DISTANCE-CORRECTED VISUAL ACUITY (LOGMAR) (ITT SET) AT VISIT 4 (DAY 120-180)

		4 m	66 cm	40 cm
RAO605G Multifocal IOL	Mean (SE)	-0.020 (0.083)	0.059 (0.074)	0.172 (0.081)
RAO600C Monofocal IOL	Mean (SE)	-0.081 (0.072)	0.234 (0.115)	0.425 (0.137)
Difference	Mean ± SD	0.061 ± 0.0105	-0.175 ± 0.0131	-0.253 ± 0.0153
	95% CI	0.0403; 0.0819	-0.2012; -0.1496	-0.2832; -0.2229

TABLE 22. MESOPIC MONOCULAR DISTANCE-CORRECTED VISUAL ACUITY IN FIRST IMPLANTED EYES (ITT SET) AT VISIT 4 (DAY 120-180)

Distance	Statistic	RAO605G Multifocal IOL n (%)	RAO600C Monofocal IOL n (%)
4 m	N (eyes)	110	111
	0.00 (20/20) logMAR or better	2 (1.8%)	11 (9.9%)
	0.10 (20/25) logMAR or better	23 (20.9%)	50 (45.0%)
	0.20 (20/32) logMAR or better	55 (50.0%)	89 (80.2%)
	0.30 (20/40) logMAR or better	94 (85.5%)	104 (93.7%)
	Worse than 0.30 logMAR	16 (14.5%)	7 (6.3%)
66 cm	N (eyes)	110	111
	0.00 (20/20) logMAR or better	2 (1.8%)	0
	0.10 (20/25) logMAR or better	4 (3.6%)	0
	0.20 (20/32) logMAR or better	19 (17.3%)	1 (0.9%)
	0.30 (20/40) logMAR or better	57 (51.8%)	7 (6.3%)
	Worse than 0.30 logMAR	53 (48.2%)	104 (93.7%)
40 cm	N (eyes)	110	110
	0.00 (20/20) logMAR or better	0	0
	0.10 (20/25) logMAR or better	1 (0.9%)	0
	0.20 (20/32) logMAR or better	4 (3.6%)	0
	0.30 (20/40) logMAR or better	15 (13.6%)	0
	Worse than 0.30 logMAR	95 (86.4%)	110 (100%)

Abbreviations: n = number of eyes meeting the specified visual acuity criterion; N = total number of First Implanted Eyes with non-missing mesopic distance-corrected visual acuity data at the respective testing distance in each treatment group. Categorical results are presented as n (%). Percentages are calculated as n/N using the applicable N for the respective testing distance and treatment group.

TABLE 23. MESOPIC BINOCULAR DISTANCE-CORRECTED VISUAL ACUITY (ITT SET) AT VISIT 4 (DAY 120-180)

Distance	Statistic	RAO605G Multifocal IOL n (%)	RAO600C Monofocal IOL n (%)
4 m	N (subjects)	109	109
	0.00 (20/20) logMAR or better	6 (5.5%)	26 (23.9%)
	0.10 (20/25) logMAR or better	36 (33.0%)	80 (73.4%)
	0.20 (20/32) logMAR or better	80 (73.4%)	98 (89.9%)
	0.30 (20/40) logMAR or better	104 (95.4%)	108 (99.1%)
	Worse than 0.30 logMAR	5 (4.6%)	1 (0.9%)

Distance	Statistic	RAO605G Multifocal IOL n (%)	RAO600C Monofocal IOL n (%)
66 cm	N (subjects)	109	109
	0.00 (20/20) logMAR or better	1 (0.9%)	0
	0.10 (20/25) logMAR or better	7 (6.4%)	1 (0.9%)
	0.20 (20/32) logMAR or better	42 (38.5%)	6 (5.5%)
	0.30 (20/40) logMAR or better	87 (79.8%)	23 (21.1%)
	Worse than 0.30 logMAR	22 (20.2%)	86 (78.9%)
40 cm	N (subjects)	109	109
	0.00 (20/20) logMAR or better	0	0
	0.10 (20/25) logMAR or better	1 (0.9%)	0
	0.20 (20/32) logMAR or better	10 (9.2%)	0
	0.30 (20/40) logMAR or better	40 (36.7%)	0
	Worse than 0.30 logMAR	69 (63.3%)	109 (100%)

Abbreviations: n = number of subjects meeting the specified visual acuity criterion; N = total number of subjects with non-missing mesopic binocular distance-corrected visual acuity data at the respective testing distance in each treatment group. Categorical results are presented as n (%). Percentages are calculated as n/N using the applicable N for the respective testing distance and treatment group.

TABLE 24. PHOTOPIC BINOCULAR UNCORRECTED VISUAL ACUITY (ITT SET) AT VISIT 4 (DAY 120-180)

Distance	Statistic	RAO605G Multifocal IOL n (%)	RAO600C Monofocal IOL n (%)
4 m	N (subjects)	109	109
	0.00 (20/20) logMAR or better	32 (29.4%)	75 (68.8%)
	0.10 (20/25) logMAR or better	74 (67.9%)	98 (89.9%)
	0.20 (20/32) logMAR or better	101 (92.7%)	109 (100%)
	0.30 (20/40) logMAR or better	107 (98.2%)	109 (100%)
	Worse than 0.30 logMAR	2 (1.8%)	0
66 cm	N (subjects)	109	109
	0.00 (20/20) logMAR or better	35 (32.1%)	12 (11.0%)
	0.10 (20/25) logMAR or better	87 (79.8%)	35 (32.1%)
	0.20 (20/32) logMAR or better	105 (96.3%)	69 (63.3%)
	0.30 (20/40) logMAR or better	109 (100%)	95 (87.2%)
	Worse than 0.30 logMAR	0	14 (12.8%)
40 cm	N (subjects)	109	109
	0.00 (20/20) logMAR or better	7 (6.4%)	1 (0.9%)
	0.10 (20/25) logMAR or better	48 (44.0%)	4 (3.7%)
	0.20 (20/32) logMAR or better	94 (86.2%)	13 (11.9%)
	0.30 (20/40) logMAR or better	109 (100%)	42 (38.5%)
	Worse than 0.30 logMAR	0	67 (61.5%)

Abbreviations: n = number of subjects meeting the specified visual acuity criterion; N = total number of subjects with non-missing photopic binocular uncorrected visual acuity data at the respective testing distance in each treatment group. Categorical results are presented as n (%). Percentages are calculated as n/N using the applicable N for the respective testing distance and treatment group.

Safety Results

Safety Set (SAF) consisting of all ITT subjects who underwent surgery and were exposed to the IOL was the pre-specified primary analysis set for safety endpoints. Among 227 subjects included in the SAF, 123 subjects were exposed to the Multifocal IOL and 115 to the control Monofocal IOL. In addition, the rate of BCDVA of 0.30 logMAR or better at Month 6 was also planned to be evaluated based on the Best Case Set (BCS) consisting of all SAF subjects who were successfully implanted with a study lens, without major protocol deviations, and also met the following criteria: no clinically significant pre-operative ocular pathology; no macular degeneration detected at any time; and no previous surgery for the correction of refractive errors, which would have resulted in exclusion of the subject from the study. Among 207 subjects included in the Best-Case Set (BCS), 101 subjects received the Multifocal IOL and 106 received the control Monofocal IOL.

All co-primary safety endpoints assessed at 120 to 180 days post-operatively (Visit 4) were met.

- The first co-primary safety endpoint was the rates of device-related secondary surgical interventions related to the optical properties of the investigational lens (**TABLE 25**). SSIs were considered to be related to optical properties of IOL if these were associated with subject intolerance of visual symptoms, not adequately improved by spectacle correction. No First Implanted eyes in either lens group required a secondary surgical intervention due to the optical properties of the IOL. And no Second Implanted eyes in the Multifocal group required a secondary surgical intervention due to the optical properties of the lens. One (0.88%) second eye in the Monofocal group required secondary surgical intervention due to optical properties of the IOL. And no Second Implanted eyes in either group required a secondary surgical intervention due to the optical properties of the lens. There was no observed difference in rates between the two treatment groups (0% in both groups); the p-value was not applicable (NA), and this endpoint was considered successful.
- The second co-primary safety endpoint was the frequency and percentage of eyes which achieved a BCDVA of 0.30 logMAR or better at 4 meters (**TABLE 26**). All (110/110, 100%) First Implanted eyes in both lens groups achieved BCDVA of 0.30 logMAR or better at the final study visit. For Second Implanted eyes, 98.2% (108/110) and 99.1% (109/110) of patients achieved a BCDVA of 0.30 logMAR or better at the final visit in the Multifocal and Monofocal groups, respectively, in the Safety Set; corresponding rates were 99.0% (100/101) and 100% (106/106) in the Best-Case Set. Compared with the historical control specified in ISO 11979-7 (2024), no statistically significant difference was observed in either the Safety Set or the Best-Case Set. Similarly, when compared with the SPE rate, differences for both lenses were not statistically significant ($p > 0.05$).
- The third co-primary safety endpoint was the rates of adverse events compared to the ISO Safety and Performance Endpoint (SPE) rates as described in ISO 11979-7 (2024) (**Table 27** and **Table 28**). The rate of adverse events in the Multifocal First Implanted were not statistically higher than the ISO grid ($p > 0.05$) and this endpoint was successfully met. The supportive analyses using Second Implanted eyes and All Implanted eyes were successful for all AEs listed in the ISO grid, except Secondary Surgical Interventions which were statistically significant compared to the ISO grid. In the Monofocal control group, there were no cumulative or persistent AEs in First Implanted Monofocal eyes. In the Second Implanted Monofocal eyes, the only cumulative adverse event was secondary surgical intervention, occurring in 1 of 114 subjects (0.9%). No persistent adverse events were reported in a Second Implanted Monofocal eye. No adverse event rates in Monofocal First Implanted or Second Implanted eyes were statistically higher than those specified in the ISO grid ($p > 0.05$).
- The fourth co-primary safety endpoint was the rates of all adverse events not included in the IOL adverse event list from ISO 11979-7 for First Implanted and Second Implanted eyes in both lens groups (**Table 29** and **Table 30**).
- The fifth co-primary safety endpoint was the frequency and percentage of eyes with adverse events meeting the definition(s) put forth by the AAO Task Force (i.e., Masket et al.) for First Implanted and Second Implanted eyes in both lens groups (**Table 31**).

TABLE 25 - RATES OF DEVICE-RELATED SECONDARY SURGICAL INTERVENTIONS RELATED TO THE OPTICAL PROPERTIES OF THE IOL (SAFETY SET)

RAO605G Multifocal IOL n/N (%)	RAO600C Monofocal IOL n/N (%)	Difference (Multifocal - Monofocal)	Z-value	P-value ^[1]	95% Confidence Interval ^[2]
First-Implanted Eyes					
0/112	0/115	0.0000	NA	NA	NA
Second-Implanted Eyes					
0/111	0/114	0.0000	NA	NA	NA

Abbreviations: n=number of eyes that experienced a device-related secondary surgical intervention related to the optical properties of the IOL; N = total number of eyes in the applicable implanted-eye and treatment group.

Secondary Surgical Interventions with a Relationship to Device of 'Definitely Related', 'Probably Related', or 'Possibly Related' and associated with subject intolerance of visual symptoms, or in consultation with Medical Monitor, are considered to be SSIs related to the optical properties of the device.

^[1] One-sided Farrington-Manning superiority test comparing the difference in proportions to 0.014.

^[2] Two-sided 95% Wald confidence interval for the difference in AE Rates.

TABLE 26 - RATE OF BCDVA OF 0.30 LOGMAR OR BETTER IN FIRST-IMPLANTED EYES AND SECOND-IMPLANTED EYES AT VISIT 4

Analysis Set	Implanted Lens	n/N (%)	SPE Rate (%)	P-value ^[1]	95% Confidence Interval ^[2]
First-Implanted Eyes					
Safety Set	RAO605G Multifocal IOL	110/110 (100.0%)	92.5	>.9999	(96.70%, 100%)
	RAO600C Monofocal IOL	111/111 (100.0%)	92.5	>.9999	(96.73%, 100%)
Best Case Set	RAO605G Multifocal IOL	101/101 (100.0%)	96.7	>.9999	(96.41%, 100%)
	RAO600C Monofocal IOL	106/106 (100.0%)	96.7	>.9999	(96.58%, 100%)
Second-Implanted Eyes					
Safety Set	RAO605G Multifocal IOL	108/110 (98.2%)	92.5	0.9981	(93.59%, 99.78%)
	RAO600C Monofocal IOL	109/110 (99.1%)	92.5	0.9998	(95.04%, 99.98%)
Best Case Set	RAO605G Multifocal IOL	100/101 (99.0%)	96.7	0.9663	(94.61%, 99.97%)
	RAO600C Monofocal IOL	106/106 (100.0%)	96.7	>.9999	(96.58%, 100%)

Abbreviations: n = number of eyes achieving BCDVA of 0.30 logMAR or better; N = total number of eyes with evaluable BCDVA data at Visit 4 in the applicable analysis set, implanted-eye group, and treatment group; SPE = Safety and Performance Endpoint. Results are presented as n/N (%). Percentages are calculated as n/N using the applicable N.

^[1]One-sided Exact Binomial Test comparing the proportion of eyes to the SPE Rate.

^[2]Two-sided 95% Exact Binomial (Clopper-Pearson) confidence interval for the AE Rate.

TABLE 27 - RATES OF MULTIFOCAL IOL ADVERSE EVENTS IN FIRST-IMPLANTED EYES COMPARED TO ISO GRID (SAFETY SET)

Adverse Event	n/N (%)	SPE Rate (%)	P-value ^[1]	95% Confidence Interval ^[2]
Cumulative				
Cystoid Macular Edema	0/112	3.0	>.9999	(0%, 3.24%)
Hypopyon	0/112	0.3	>.9999	(0%, 3.24%)
Endophthalmitis	0/112	0.1	>.9999	(0%, 3.24%)
Lens Dislocated from Posterior Chamber	0/112	0.1	>.9999	(0%, 3.24%)
Pupillary Block	0/112	0.1	>.9999	(0%, 3.24%)
Retinal Detachment	1/112 (0.9%)	0.3	0.2857	(0.02%, 4.87%)
Secondary Surgical Intervention ^[3]	2/112 (1.8%)	0.8	0.2259	(0.22%, 6.30%)
Persistent				
Corneal Stroma Edema	0/110	0.3	>.9999	(0%, 3.30%)
Cystoid Macular Edema	0/110	0.5	>.9999	(0%, 3.30%)

Adverse Event	n/N (%)	SPE Rate (%)	P-value ^[1]	95% Confidence Interval ^[2]
Anterior Uveitis (Iritis)	0/110	0.3	>.9999	(0%, 3.30%)
Raised IOP Requiring Treatment	0/110	0.4	>.9999	(0%, 3.30%)

Abbreviations: n=number of eyes that experienced the event; SPE=Safety and Performance Endpoints

The denominator (N) for cumulative AEs is the total number of first-implanted Multifocal eyes in the Safety Set.

The denominator (N) for persistent AEs is the total number of first-implanted Multifocal eyes who had a follow-up visit on or after the beginning of the Visit 4 visit window (120 days after implantation).

^[1] One-sided Exact Binomial Test comparing the proportion of Multifocal eyes to the SPE Rate from Table E.2 of ISO 11979-7(2024).

^[2] Two-sided 95% Exact Binomial (Clopper-Pearson) confidence interval for the Multifocal IOL AE Rate.

^[3] Excludes posterior capsulotomies and wound burp.

TABLE 28 - RATES OF MULTIFOCAL IOL ADVERSE EVENTS IN SECOND-IMPLANTED EYES COMPARED TO ISO GRID (SAFETY SET)

Adverse Event	n/N (%)	SPE Rate (%)	P-value ^[1]	95% Confidence Interval ^[2]
Cumulative				
Cystoid Macular Edema	0/111	3.0	>.9999	(0%, 3.27%)
Hypopyon	0/111	0.3	>.9999	(0%, 3.27%)
Endophthalmitis	0/111	0.1	>.9999	(0%, 3.27%)
Lens Dislocated from Posterior Chamber	0/111	0.1	>.9999	(0%, 3.27%)
Pupillary Block	0/111	0.1	>.9999	(0%, 3.27%)
Retinal Detachment	0/111	0.3	>.9999	(0%, 3.27%)
Secondary Surgical Intervention ^[3]	4/111 (3.6%)	0.8	0.0125	(0.99%, 8.97%)
Persistent				
Corneal Stroma Edema	0/110	0.3	>.9999	(0%, 3.30%)
Cystoid Macular Edema	0/110	0.5	>.9999	(0%, 3.30%)
Anterior Uveitis (Iritis)	0/110	0.3	>.9999	(0%, 3.30%)
Raised IOP Requiring Treatment	0/110	0.4	>.9999	(0%, 3.30%)

Abbreviations: n=number of eyes that experienced the event; SPE=Safety and Performance Endpoints

The denominator (N) for cumulative AEs is the total number of second-implanted Multifocal eyes in the Safety Set.

The denominator (N) for persistent AEs is the total number of second-implanted Multifocal eyes who had a follow-up visit on or after the beginning of the Visit 4 visit window (120 days after implantation).

^[1] One-sided Exact Binomial Test comparing the proportion of Multifocal eyes to the SPE Rate from Table E.2 of ISO 11979-7(2024).

^[2] Two-sided 95% Exact Binomial (Clopper-Pearson) confidence interval for the Multifocal IOL AE Rate.

^[3] Excludes posterior capsulotomies and wound burp.

TABLE 29 - RATES OF ALL OTHER ADVERSE EVENTS IN FIRST-IMPLANTED EYES (SAFETY SET)

Adverse Event	RAO605G Multifocal IOL (N=112)		RAO600C Monofocal IOL (N=115)	
	n/N (%) e	95% Confidence Interval ^[1]	n/N (%) e	95% Confidence Interval ^[1]
Anterior Uveitis	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Corneal Edema	10 (8.9%) 10	(4.4%, 15.8%)	17 (14.8%) 17	(8.9%, 22.6%)
Elevated IOP	4 (3.6%) 4	(1.0%, 8.9%)	5 (4.3%) 5	(1.4%, 9.9%)
Best-corrected visual acuity loss of 2 lines (10 letters) or more on the ETDRS chart measured at Visit 4 or later from any prior post-operative visit	2 (1.8%) 2	(0.2%, 6.3%)	0	(0%, 3.2%)
Progression or onset of diabetic retinopathy	1 (0.9%) 1	(0.0%, 4.9%)	1 (0.9%) 1	(0.0%, 4.7%)
Retained lens material	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)

	RAO605G Multifocal IOL (N=112)		RAO600C Monofocal IOL (N=115)	
Adverse Event	n/N (%) e	95% Confidence Interval ^[1]	n/N (%) e	95% Confidence Interval ^[1]
Secondary Surgical Intervention	24 (21.4%) 24	(14.2%, 30.2%)	9 (7.8%) 9	(3.6%, 14.3%)
Nd:YAG laser capsulotomy	24 (21.4%) 24	(14.2%, 30.2%)	8 (7.0%) 8	(3.1%, 13.2%)
Wound burp (aqueous tap, or paracentesis)	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Other	54 (48.2%) 66	(38.7%, 57.9%)	48 (41.7%) 59	(32.6%, 51.3%)
Anterior chamber cells grade 0.5 or greater at visit 2 or later	31 (27.7%) 31	(19.6%, 36.9%)	37 (32.2%) 37	(23.8%, 41.5%)
Posterior capsule opacification requiring YAG capsulotomy	24 (21.4%) 24	(14.2%, 30.2%)	8 (7.0%) 8	(3.1%, 13.2%)
Posterior vitreous detachment	3 (2.7%) 3	(0.6%, 7.6%)	3 (2.6%) 3	(0.5%, 7.4%)
Subconjunctival hemorrhage	2 (1.8%) 2	(0.2%, 6.3%)	2 (1.7%) 2	(0.2%, 6.1%)
Anterior chamber cells greater than grade 2 at visit 1	2 (1.8%) 2	(0.2%, 6.3%)	1 (0.9%) 1	(0.0%, 4.7%)
Keratoconjunctivitis sicca, not specified as Sjogrens	1 (0.9%) 1	(0.0%, 4.9%)	1 (0.9%) 1	(0.0%, 4.7%)
Worsening of dry eye disease	0	(0%, 3.2%)	2 (1.7%) 2	(0.2%, 6.1%)
Chalazion	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Corneal edema	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Double/Multiple images	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Epithelial defect	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Hypotony	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Meibomian gland dysfunction	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Ocular pain	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Worsening of keratoconjunctivitis sicca	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)

Abbreviations: n=number of eyes that experienced the event; N = total number of first-implanted eyes in the Safety Set for each IOL; e = total number of events.

Excludes Cumulative AEs from Table E.2 of ISO 11979-7 (2024).

^[1]Two-sided 95% Exact Binomial (Clopper-Pearson) confidence interval for the AE Rate.

TABLE 30 - RATES OF ALL OTHER ADVERSE EVENTS IN SECOND-IMPLANTED EYES (SAFETY SET)

	RAO605G Multifocal IOL (N=111)		RAO600C Monofocal IOL (N=114)	
Adverse Event	n/N (%) e	95% Confidence Interval ^[1]	n/N (%) e	95% Confidence Interval ^[1]
Anterior Uveitis	0	(0%, 3.3%)	2 (1.8%) 2	(0.2%, 6.2%)
Corneal Edema	7 (6.3%) 7	(2.6%, 12.6%)	12 (10.5%) 12	(5.6%, 17.7%)
Elevated IOP	4 (3.6%) 4	(1.0%, 9.0%)	4 (3.5%) 4	(1.0%, 8.7%)
IOL decentration/malposition resulting in secondary surgical intervention	0	(0%, 3.3%)	1 (0.9%) 1	(0.0%, 4.8%)
Best-corrected visual acuity loss of 2 lines (10 letters) or more on the ETDRS chart measured at Visit 4 or later from any prior post-operative visit	3 (2.7%) 3	(0.6%, 7.7%)	0	(0%, 3.2%)
Secondary Surgical Intervention	27 (24.3%) 27	(16.7%, 33.4%)	10 (8.8%) 10	(4.3%, 15.5%)
Nd:YAG laser capsulotomy	27 (24.3%) 27	(16.7%, 33.4%)	9 (7.9%) 9	(3.7%, 14.5%)
Wound burp (aqueous tap, or paracentesis)	0	(0%, 3.3%)	1 (0.9%) 1	(0.0%, 4.8%)
Other	61 (55.0%) 82	(45.2%, 64.4%)	41 (36.0%) 53	(27.2%, 45.5%)
Anterior chamber cells grade 0.5 or greater at visit 2 or later	31 (27.9%) 31	(19.8%, 37.2%)	28 (24.6%) 28	(17.0%, 33.5%)
Posterior capsule opacification requiring YAG capsulotomy	27 (24.3%) 27	(16.7%, 33.4%)	9 (7.9%) 9	(3.7%, 14.5%)
Anterior chamber cells greater than grade 2 at visit 1	4 (3.6%) 4	(1.0%, 9.0%)	2 (1.8%) 2	(0.2%, 6.2%)
Posterior vitreous detachment	3 (2.7%) 3	(0.6%, 7.7%)	3 (2.6%) 3	(0.5%, 7.5%)
Subconjunctival hemorrhage	2 (1.8%) 2	(0.2%, 6.4%)	2 (1.8%) 2	(0.2%, 6.2%)
Corneal abrasion	1 (0.9%) 1	(0.0%, 4.9%)	1 (0.9%) 1	(0.0%, 4.8%)

	RAO605G Multifocal IOL (N=111)		RAO600C Monofocal IOL (N=114)	
Adverse Event	n/N (%) e	95% Confidence Interval ^[1]	n/N (%) e	95% Confidence Interval ^[1]
Corneal edema	1 (0.9%) 1	(0.0%, 4.9%)	1 (0.9%) 1	(0.0%, 4.8%)
Keratoconjunctivitis sicca, not specified as Sjogrens	1 (0.9%) 1	(0.0%, 4.9%)	1 (0.9%) 1	(0.0%, 4.8%)
Superficial punctate keratitis	2 (1.8%) 2	(0.2%, 6.4%)	0	(0%, 3.2%)
Allergic conjunctivitis	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Anterior chamber debris	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Capsular bag distension syndrome	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Chalazion	0	(0%, 3.3%)	1 (0.9%) 1	(0.0%, 4.8%)
Double vision	0	(0%, 3.3%)	1 (0.9%) 1	(0.0%, 4.8%)
Double/Multiple images	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Dry eye	0	(0%, 3.3%)	1 (0.9%) 1	(0.0%, 4.8%)
Ecchymosis	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Hyphema	0	(0%, 3.3%)	1 (0.9%) 1	(0.0%, 4.8%)
Macular edema	0	(0%, 3.3%)	1 (0.9%) 1	(0.0%, 4.8%)
Meibomian gland dysfunction	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Skin laceration	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Vitreous floaters	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Vitreous syneresis	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Worsening of dry eye disease	0	(0%, 3.3%)	1 (0.9%) 1	(0.0%, 4.8%)
Worsening of keratoconjunctivitis sicca	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)

Abbreviations: n=number of eyes that experienced the event; N = total number of first-implanted eyes in the Safety Set for each IOL; e = total number of events.

Excludes Cumulative AEs from Table E.2 of ISO 11979-7 (2024).

^[1]Two-sided 95% Exact Binomial (Clopper-Pearson) confidence interval for the AE Rate.

TABLE 31 - RATES OF ADVERSE EVENTS DEFINED IN MASKET ET AL IN FIRST-IMPLANTED EYES AND SECOND-IMPLANTED EYES (SAFETY SET)

	RAO605G Multifocal IOL		RAO600C Monofocal IOL	
Adverse Event	n/N (%) e	95% Confidence Interval ^[1]	n/N (%) e	95% Confidence Interval ^[1]
First-Implanted Eyes	N=112		N=115	
Anterior Uveitis	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Clinically Significant Cystoid Macular Edema	0	(0%, 3.2%)	0	(0%, 3.2%)
Visually Significant Corneal Edema	0	(0%, 3.2%)	0	(0%, 3.2%)
Endophthalmitis	0	(0%, 3.2%)	0	(0%, 3.2%)
Mechanical Pupillary Block	0	(0%, 3.2%)	0	(0%, 3.2%)
Increased IOP	3 (2.7%) 3	(0.6%, 7.6%)	3 (2.6%) 3	(0.5%, 7.4%)
Rhegmatogenous Retinal Detachment	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Toxic Anterior Segment Syndrome	0	(0%, 3.2%)	0	(0%, 3.2%)
IOL Exchange	0	(0%, 3.2%)	0	(0%, 3.2%)
IOL Removal	0	(0%, 3.2%)	0	(0%, 3.2%)
IOL Reposition	0	(0%, 3.2%)	0	(0%, 3.2%)
Second-Implanted Eyes	N=111		N=114	
Anterior Uveitis	0	(0%, 3.3%)	2 (1.8%) 2	(0.2%, 6.2%)
Clinically Significant Cystoid Macular Edema	0	(0%, 3.3%)	0	(0%, 3.2%)
Visually Significant Corneal Edema	0	(0%, 3.3%)	0	(0%, 3.2%)

	RAO605G Multifocal IOL		RAO600C Monofocal IOL	
Adverse Event	n/N (%) e	95% Confidence Interval ^[1]	n/N (%) e	95% Confidence Interval ^[1]
Endophthalmitis	0	(0%, 3.3%)	0	(0%, 3.2%)
Mechanical Pupillary Block	0	(0%, 3.3%)	0	(0%, 3.2%)
Increased IOP	2 (1.8%) 2	(0.2%, 6.4%)	3 (2.6%) 3	(0.5%, 7.5%)
Rhegmatogenous Retinal Detachment	0	(0%, 3.3%)	0	(0%, 3.2%)
Toxic Anterior Segment Syndrome	0	(0%, 3.3%)	0	(0%, 3.2%)
IOL Exchange	1 (0.9%) 1	(0.0%, 4.9%)	1 (0.9%) 1	(0.0%, 4.8%)
IOL Removal	1 (0.9%) 1	(0.0%, 4.9%)	1 (0.9%) 1	(0.0%, 4.8%)
IOL Reposition	0	(0%, 3.3%)	0	(0%, 3.2%)

Abbreviations: n=number of eyes that experienced the event; N = total number of eyes in the applicable implanted-eye and treatment group in the Safety Set; e = total number of events.

^[1]Two-sided 95% Exact Binomial (Clopper-Pearson) confidence interval for the AE Rate.

Anterior Uveitis = Anterior segment inflammation characterized by grade 1+ cell or greater (using the Standardization of Uveitis Nomenclature criteria) that is persistent for greater than 3 months after surgery, or relapses in less than 3 months after discontinuation of therapy, or the subject is maintained on therapy for more than 3 months to control inflammation.

Clinically significant cystoid macular edema = Macular edema diagnosed by clinical examination and adjunct testing (e.g., OCT, FA) resulting in BCDVA of $\leq 20/40$ at ≥ 1 month

Visually Significant Corneal edema = Corneal swelling (stromal or epithelial) resulting in CDVA of 20/40 or worse at Form 3 or later.

Endophthalmitis = Intraocular inflammation requiring diagnostic vitreous tap and intraocular antibiotics

Mechanical pupillary block = Shallowing of anterior chamber due to obstruction of aqueous humor flow from the posterior to anterior chamber through the pupil by the crystalline lens, vitreous face, or implanted device

Increased IOP = Elevation of IOP greater than or equal to 10 mmHg above baseline to a minimum of 25mmHg.

Rhegmatogenous RD = Partial or complete RD associated with retinal tear

Toxic anterior segment syndrome = Acute, non-infectious inflammation of the anterior segment that starts within 24 to 48 hrs after surgery, usually resulting in hypopyon and commonly presenting with corneal edema, that improves with steroid treatment

IOL Exchange = The investigational device is replaced with the same lens model.

IOL Removal = The investigational device is removed and replaced with a non-investigational lens or no lens is implanted.

IOL Reposition = The existing IOL is surgically moved to another location or rotated.

Quality of Vision (QoV) Patient Reported Outcome

Visual disturbances were assessed by the Quality of Vision (QoV) Patient Reported Outcome (PRO) Instrument and Patient Vision Questionnaire. **Table 32**, **Table 33** and **Table 34** present the frequency severity and bothersomeness, respectively, of visual disturbances at 120-180 days post-operatively (Visit 4). **Table 32** presents the frequency of each visual disturbance for subjects who provided a frequency response. **Table 33** and **Table 34** present the severity and bothersomeness, respectively, among subjects who also reported experiencing the applicable visual disturbance. The highest ratings of frequency, severity, and bothersomeness were reported by few subjects in either group, indicating good quality of vision for most subjects. Most symptoms, including glare, starbursts, hazy vision, blurred vision, distortion, double images, fluctuation, focusing difficulty, and difficulty judging distance or depth, occurred at similar rates in both groups. Halos were reported more frequently in the Multifocal group; among subjects who reported halos, most rated them not at all or only a little bothersome, and this pattern is consistent with the published literature on multifocal lenses. Rasch-modeled analyses of questionnaire data showed comparable Frequency, Severity and Bothersome scores between the Multifocal group and the Monofocal group, with overlapping distributions and confidence intervals.

Patient Vision Questionnaire (PVQ) Patient Reported Outcome

The Patient Vision Questionnaire (PVQ) assessed patient-reported visual experience following intraocular lens implantation. **Table 35** presents descriptive summaries of responses for each PVQ item at Visit 4 (120 to 180 days postoperatively) by treatment group. Responses were generally comparable between the two groups, with the following exceptions. The largest between-group differences in "Always" responses were for Questions 4, 5, 6, and 8, which concerned trouble with near vision in daylight, outdoors at night or in dark situations, and indoors; 2% to 3% of Multifocal subjects responded "Always" compared with 15% to 24% of Monofocal subjects. The next largest difference was for Question 7, blurred vision at distance, for which 8% of Multifocal subjects responded "Always" compared with 1% of Monofocal subjects. Differences were smaller for Question 9, night vision, and Question 10, night driving, with

"Always" responses of 9% versus 5% and 9% versus 4% in the Multifocal and Monofocal groups, respectively. Approximately 90% of subjects in each group reported they would again elect to be implanted with the same lens. The PVQ was a secondary exploratory measure. The PVQ was not developed or validated in accordance with current guidance for patient-reported outcome measures. Accordingly, the PVQ results are presented as descriptive item-level results only and should be interpreted with caution. Accordingly, the PVQ results are presented as descriptive item-level results only and should be interpreted with caution. No measure-level statistics or formal comparative statistical analysis are presented. These results should be interpreted alongside objective clinical measures of visual function. Because visual symptoms may affect patient satisfaction and could influence decisions regarding lens exchange, a procedure associated with the risks of secondary intraocular surgery, the findings are presented with this limitation in mind

TABLE 32 QUALITY OF VISION (QOV) CATEGORICAL SUMMARY OF THE FREQUENCY OF EACH VISUAL DISTURBANCE AT VISIT 4 (DAY 120–180), (SAFETY SET)

	RAO605G Multifocal IOL						RAO600C Monofocal IOL					
Visual Disturbance	N	Never	Occasionally	Quite Often	Very Often	Not Done	N	Never	Occasionally	Quite Often	Very Often	Not Done
Glare	110	38/110 (34.5%)	61/110 (55.5%)	9/110 (8.2%)	2/110 (1.8%)	0	111	57/109 (52.3%)	46/109 (42.2%)	6/109 (5.5%)	0	2
Halos	110	45/110 (40.9%)	40/110 (36.4%)	13/110 (11.8%)	12/110 (10.9%)	0	111	67/109 (61.5%)	37/109 (33.9%)	4/109 (3.7%)	1/109 (0.9%)	2
Starbursts	110	45/110 (40.9%)	44/110 (40.0%)	16/110 (14.5%)	5/110 (4.5%)	0	111	62/109 (56.9%)	39/109 (35.8%)	4/109 (3.7%)	4/109 (3.7%)	2
Hazy Vision	110	83/110 (75.5%)	22/110 (20.0%)	4/110 (3.6%)	1/110 (0.9%)	0	111	80/109 (73.4%)	23/109 (21.1%)	4/109 (3.7%)	2/109 (1.8%)	2
Blurred Vision	110	58/110 (52.7%)	43/110 (39.1%)	7/110 (6.4%)	2/110 (1.8%)	0	111	51/109 (46.8%)	46/109 (42.2%)	8/109 (7.3%)	4/109 (3.7%)	2
Distortion	110	97/110 (88.2%)	10/110 (9.1%)	1/110 (0.9%)	2/110 (1.8%)	0	111	96/109 (88.1%)	12/109 (11.0%)	1/109 (0.9%)	0	2
Double/Multiple Images	110	92/110 (83.6%)	15/110 (13.6%)	2/110 (1.8%)	1/110 (0.9%)	0	111	95/109 (87.2%)	12/109 (11.0%)	1/109 (0.9%)	1/109 (0.9%)	2
Fluctuation	110	49/110 (44.5%)	52/110 (47.3%)	9/110 (8.2%)	0	0	111	59/109 (54.1%)	44/109 (40.4%)	5/109 (4.6%)	1/109 (0.9%)	2
Focusing	110	36/110 (32.7%)	64/110 (58.2%)	9/110 (8.2%)	1/110 (0.9%)	0	111	34/109 (31.2%)	62/109 (56.9%)	9/109 (8.3%)	4/109 (3.7%)	2
Distance/Depth Perception	110	71/110 (64.5%)	32/110 (29.1%)	4/110 (3.6%)	3/110 (2.7%)	0	111	80/109 (73.4%)	20/109 (18.3%)	8/109 (7.3%)	1/109 (0.9%)	2

Note: N represents the number of subjects who completed the QoV frequency assessment for the applicable treatment group at Visit 4. Percentages are based on subjects who provided a frequency response for the applicable visual disturbance. Two Monofocal subjects had “Not Done” responses; therefore, the Monofocal percentage denominator is 109.

TABLE 33 QUALITY OF VISION (QOV) CATEGORICAL SUMMARY OF THE BOTHERSOMENESS OF EACH VISUAL DISTURBANCE AT VISIT 4 (DAY 120–180), (SAFETY SET)

	RAO605G Multifocal IOL						RAO600C Monofocal IOL					
Visual Disturbance	N	Not at All	Mild	Moderate	Severe	Not Done	N	Not at All	Mild	Moderate	Severe	Not Done
Glare	72	4/72 (5.6%)	51/72 (70.8%)	14/72 (19.4%)	3/72 (4.2%)	0	52	1/52 (1.9%)	40/52 (76.9%)	10/52 (19.2%)	1/52 (1.9%)	0
Halos	65	2/65 (3.1%)	41/65 (63.1%)	15/65 (23.1%)	7/65 (10.8%)	0	42	2/42 (4.8%)	37/42 (88.1%)	3/42 (7.1%)	0	0
Starbursts	65	4/65 (6.2%)	45/65 (69.2%)	11/65 (16.9%)	5/65 (7.7%)	0	47	4/47 (8.5%)	37/47 (78.7%)	2/47 (4.3%)	4/47 (8.5%)	0
Hazy Vision	27	1/27 (3.7%)	21/27 (77.8%)	4/27 (14.8%)	1/27 (3.7%)	0	29	0	25/29 (86.2%)	3/29 (10.3%)	1/29 (3.4%)	0
Blurred Vision	52	4/52 (7.7%)	35/52 (67.3%)	12/52 (23.1%)	1/52 (1.9%)	0	58	3/58 (5.2%)	42/58 (72.4%)	9/58 (15.5%)	4/58 (6.9%)	0
Distortion	13	2/13 (15.4%)	8/13 (61.5%)	2/13 (15.4%)	1/13 (7.7%)	0	13	0	12/13 (92.3%)	1/13 (7.7%)	0	0
Double/Multiple Images	18	2/18 (11.1%)	11/18 (61.1%)	4/18 (22.2%)	1/18 (5.6%)	0	14	0	13/14 (92.9%)	0	1/14 (7.1%)	0
Fluctuation	61	5/61 (8.2%)	46/61 (75.4%)	10/61 (16.4%)	0	0	50	5/50 (10.0%)	39/50 (78.0%)	6/50 (12.0%)	0	0
Focusing	74	6/74 (8.1%)	57/74 (77.0%)	10/74 (13.5%)	1/74 (1.4%)	0	75	3/75 (4.0%)	58/75 (77.3%)	11/75 (14.7%)	3/75 (4.0%)	0
Distance/Depth Perception	39	1/39 (2.6%)	33/39 (84.6%)	5/39 (12.8%)	0	0	29	3/29 (10.3%)	22/29 (75.9%)	4/29 (13.8%)	0	0

Note: N represents the number of subjects who reported a frequency of “Occasionally,” “Quite often,” or “Very often” for the applicable visual disturbance. Because the number of subjects reporting each visual disturbance varied, N varies by visual disturbance. Percentages are based on these subjects.

TABLE 34 QUALITY OF VISION (QOV) CATEGORICAL SUMMARY OF THE BOTHERSOMENESS OF EACH VISUAL DISTURBANCE AT VISIT 4 (DAY 120–180), (SAFETY SET)

	RAO605G Multifocal IOL						RAO600C Monofocal IOL					
Visual Disturbance	N	Not at All	A Little	Quite	Very	Not Done	N	Not at All	A Little	Quite	Very	Not Done
Glare	72	10/72 (13.9%)	52/72 (72.2%)	9/72 (12.5%)	1/72 (1.4%)	0	52	14/52 (26.9%)	32/52 (61.5%)	4/52 (7.7%)	2/52 (3.8%)	0
Halos	65	17/65 (26.2%)	36/65 (55.4%)	6/65 (9.2%)	6/65 (9.2%)	0	42	14/42 (33.3%)	25/42 (59.5%)	2/42 (4.8%)	1/42 (2.4%)	0
Starbursts	65	17/65 (26.2%)	36/65 (55.4%)	9/65 (13.8%)	3/65 (4.6%)	0	47	17/47 (36.2%)	26/47 (55.3%)	1/47 (2.1%)	3/47 (6.4%)	0
Hazy Vision	27	5/27 (18.5%)	17/27 (63.0%)	4/27 (14.8%)	1/27 (3.7%)	0	29	3/29 (10.3%)	22/29 (75.9%)	2/29 (6.9%)	2/29 (6.9%)	0
Blurred Vision	52	8/52 (15.4%)	33/52 (63.5%)	9/52 (17.3%)	2/52 (3.8%)	0	58	3/58 (5.2%)	44/58 (75.9%)	7/58 (12.1%)	4/58 (6.9%)	0
Distortion	13	4/13 (30.8%)	6/13 (46.2%)	1/13 (7.7%)	2/13 (15.4%)	0	13	1/13 (7.7%)	11/13 (84.6%)	1/13 (7.7%)	0	0
Double/Multiple Images	18	0	14/18 (77.8%)	3/18 (16.7%)	1/18 (5.6%)	0	14	1/14 (7.1%)	10/14 (71.4%)	2/14 (14.3%)	1/14 (7.1%)	0
Fluctuation	61	15/61 (24.6%)	39/61 (63.9%)	7/61 (11.5%)	0	0	50	9/50 (18.0%)	37/50 (74.0%)	3/50 (6.0%)	1/50 (2.0%)	0
Focusing	74	17/74 (23.0%)	46/74 (62.2%)	10/74 (13.5%)	1/74 (1.4%)	0	75	5/75 (6.7%)	56/75 (74.7%)	10/75 (13.3%)	4/75 (5.3%)	0
Distance/Depth Perception	39	5/39 (12.8%)	29/39 (74.4%)	4/39 (10.3%)	1/39 (2.6%)	0	29	8/29 (27.6%)	17/29 (58.6%)	2/29 (6.9%)	2/29 (6.9%)	0

Note: N represents the number of subjects who reported a frequency of “Occasionally,” “Quite often,” or “Very often” for the applicable visual disturbance. Because the number of subjects reporting each visual disturbance varied, N varies by visual disturbance. Percentages are based on these subjects.

TABLE 35 PATIENT VISION QUESTIONNAIRE RESULTS AT VISIT 4 (DAY 120-180) (SAFETY SET)

	RAO605G Multifocal IOL n (%)	RAO600C Monofocal IOL n (%)
Question		
1. Do you have trouble with distance vision outdoors in daylight?		
N	110	111
Never	50 (45.5%)	71 (65.1%)
Rarely	45 (40.9%)	29 (26.6%)
Often	9 (8.2%)	7 (6.4%)
Always	6 (5.5%)	2 (1.8%)
Not Done	0	2
2. Do you have trouble with distance vision outdoors at night or in dark situations?		
N	110	111
Never	27 (24.5%)	47 (43.1%)
Rarely	52 (47.3%)	48 (44.0%)
Often	21 (19.1%)	7 (6.4%)
Always	10 (9.1%)	7 (6.4%)
Not Done	0	2
3. Do you have trouble with distance vision when indoors?		
N	110	111
Never	57 (51.8%)	82 (75.2%)
Rarely	42 (38.2%)	23 (21.1%)
Often	9 (8.2%)	2 (1.8%)
Always	2 (1.8%)	2 (1.8%)
Not Done	0	2
4. Do you have trouble with near vision outdoors in daylight?		
N	110	111
Never	65 (59.1%)	34 (31.2%)
Rarely	36 (32.7%)	34 (31.2%)
Often	6 (5.5%)	23 (21.1%)
Always	3 (2.7%)	18 (16.5%)
Not Done	0	2
5. Do you have trouble with near vision outdoors at night or in dark situations?		
N	110	111
Never	41 (37.3%)	24 (22.0%)
Rarely	52 (47.3%)	35 (32.1%)
Often	14 (12.7%)	25 (22.9%)
Always	3 (2.7%)	25 (22.9%)
Not Done	0	2
6. Do you have trouble with near vision when indoors?		
N	110	111
Never	57 (51.8%)	23 (21.1%)
Rarely	40 (36.4%)	36 (33.0%)
Often	11 (10.0%)	24 (22.0%)
Always	2 (1.8%)	26 (23.9%)
Not Done	0	2
7. Do you have trouble with blurred vision when looking at things in the distance?		
N	110	111
Never	35 (31.8%)	65 (59.6%)

	RAO605G Multifocal IOL n (%)	RAO600C Monofocal IOL n (%)
Question		
<u>Rarely</u>	<u>53 (48.2%)</u>	<u>33 (30.3%)</u>
<u>Often</u>	<u>13 (11.8%)</u>	<u>10 (9.2%)</u>
<u>Always</u>	<u>9 (8.2%)</u>	<u>1 (0.9%)</u>
<u>Not Done</u>	<u>0</u>	<u>2</u>
<u>8. Do you have trouble with blurred vision when looking at things that are near?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Never</u>	<u>49 (44.5%)</u>	<u>33 (30.3%)</u>
<u>Rarely</u>	<u>48 (43.6%)</u>	<u>23 (21.1%)</u>
<u>Often</u>	<u>10 (9.1%)</u>	<u>37 (33.9%)</u>
<u>Always</u>	<u>3 (2.7%)</u>	<u>16 (14.7%)</u>
<u>Not Done</u>	<u>0</u>	<u>2</u>
<u>9. Do you have trouble with night vision?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Never</u>	<u>24 (21.8%)</u>	<u>41 (37.6%)</u>
<u>Rarely</u>	<u>58 (52.7%)</u>	<u>47 (43.1%)</u>
<u>Often</u>	<u>18 (16.4%)</u>	<u>16 (14.7%)</u>
<u>Always</u>	<u>10 (9.1%)</u>	<u>5 (4.6%)</u>
<u>Not Done</u>	<u>0</u>	<u>2</u>
<u>10. Do you have trouble with night driving because of your vision?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Never</u>	<u>33 (30.0%)</u>	<u>49 (45.0%)</u>
<u>Rarely</u>	<u>42 (38.2%)</u>	<u>33 (30.3%)</u>
<u>Often</u>	<u>19 (17.3%)</u>	<u>13 (11.9%)</u>
<u>Always</u>	<u>10 (9.1%)</u>	<u>4 (3.7%)</u>
<u>N/A</u>	<u>6 (5.5%)</u>	<u>10 (9.2%)</u>
<u>Not Done</u>	<u>0</u>	<u>2</u>
<u>11. Do you have trouble with color disturbances in your vision?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Never</u>	<u>90 (81.8%)</u>	<u>84 (77.1%)</u>
<u>Rarely</u>	<u>19 (17.3%)</u>	<u>21 (19.3%)</u>
<u>Often</u>	<u>0</u>	<u>4 (3.7%)</u>
<u>Always</u>	<u>1 (0.9%)</u>	<u>0</u>
<u>Not Done</u>	<u>0</u>	<u>2</u>
<u>12. If given the opportunity, would you again elect to be implanted with the IOL?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Yes</u>	<u>100 (90.9%)</u>	<u>97 (89.8%)</u>
<u>No</u>	<u>10 (9.1%)</u>	<u>11 (10.2%)</u>
<u>Not Done</u>	<u>0</u>	<u>3</u>

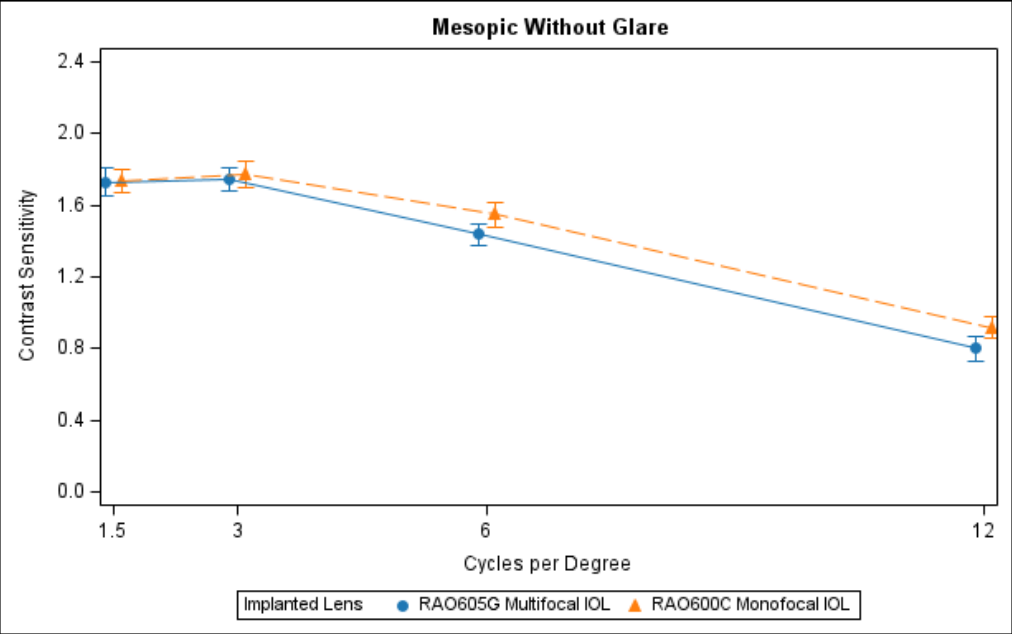
Abbreviations: n = number of subjects in the specified response category; N = total number of subjects with a recorded response status for the respective question, including subjects reported as Not Done. Response-category results are presented as n (%), except Not Done, which is presented as n. Percentages for the evaluable response categories are calculated as $n/(N - \text{Not Done})$.

Contrast Sensitivity

Monocular contrast sensitivity testing with best correction was measured under photopic and mesopic conditions using the M&S System for sine-wave gratings of 1.5, 3, 6, 12 and/or 18 cycles per degree (CPD) at a test distance of 2.5 meters. The mean monocular distance contrast sensitivity under 3 lighting conditions in First Implanted eyes at 120 to 180 days post-operatively (Visit 4) is presented in **FIGURE 2** to **FIGURE 4**. On each Figure, the error bars represent ± 1 standard error about the mean. Under mesopic conditions without

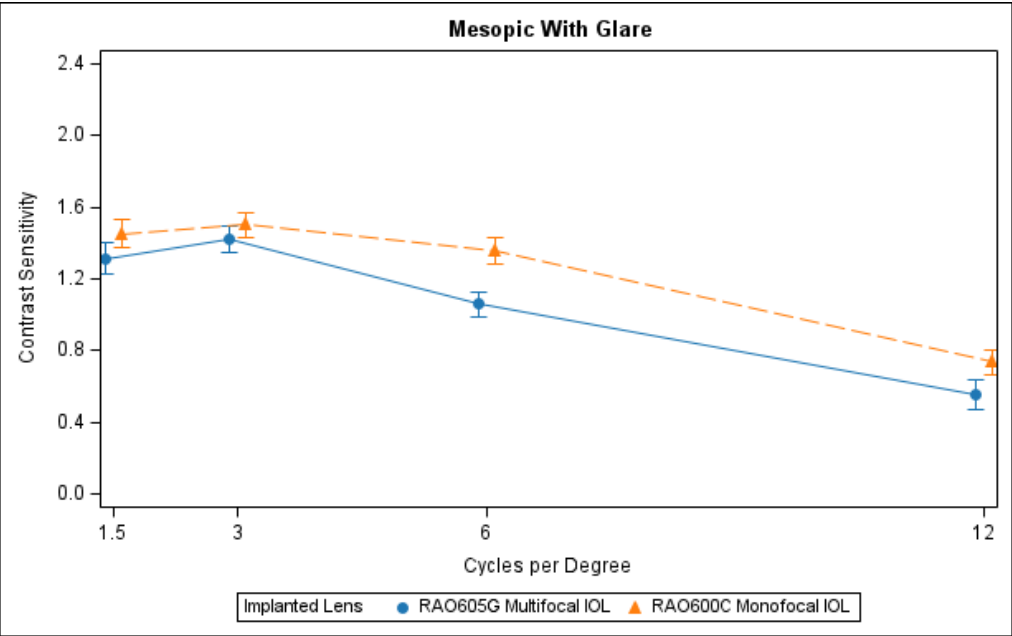
glare, the mean contrast sensitivity of eyes implanted with the Multifocal IOL was not more than 0.3 log units below that of the Monofocal control at each tested spatial frequency, thereby meeting the predefined ISO 11979-7:2024 criterion.

FIGURE 2- MONOCULAR BEST CORRECTED CONTRAST SENSITIVITY (MESOPIC WITHOUT GLARE) IN FIRST-IMPLANTED EYES (BEST CASE SET)



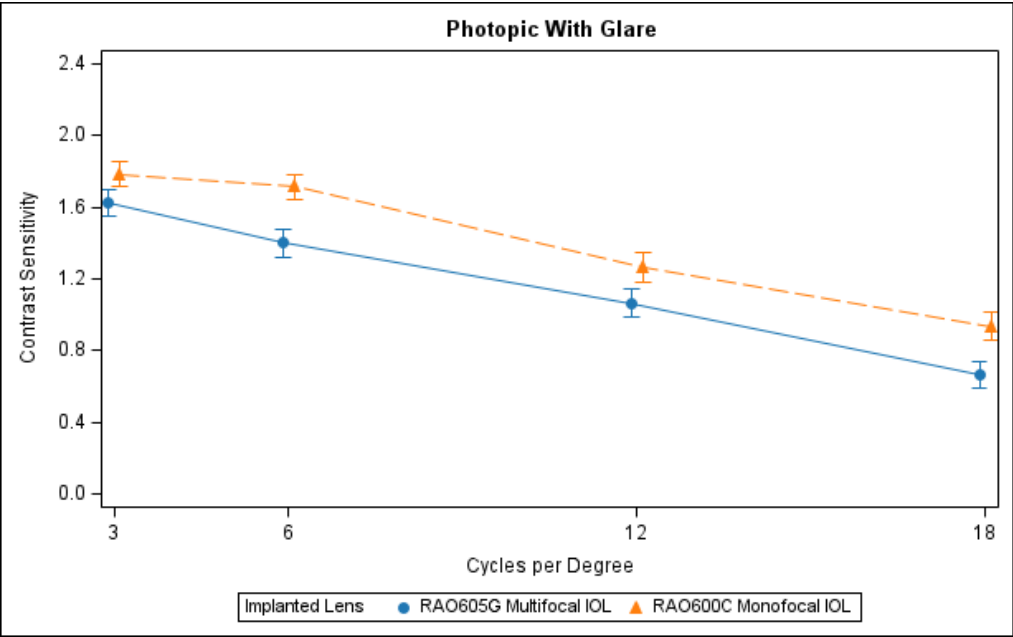
Error bars represent ±1 standard error about the mean.
Contrast Sensitivity is presented in log units ranging from 0.00 (100% contrast) to 2.4 (0.4% contrast).

FIGURE 3 - MONOCULAR BEST CORRECTED CONTRAST SENSITIVITY (MESOPIC WITH GLARE) IN FIRST-IMPLANTED EYES (BEST CASE SET)



Error bars represent ±1 standard error about the mean.
Contrast Sensitivity is presented in log units ranging from 0.00 (100% contrast) to 2.4 (0.4% contrast).

FIGURE 4 - MONOCULAR BEST CORRECTED CONTRAST SENSITIVITY (PHOTOPIC WITH GLARE) IN FIRST-IMPLANTED EYES (BEST CASE SET)



Error bars represent ±1 standard error about the mean.
Contrast Sensitivity is presented in log units ranging from 0.00 (100% contrast) to 2.4 (0.4% contrast).

Fundus Visualization

Across First and Second Implanted eyes in both the Multifocal and Monofocal groups, dilated fundus examination findings were generally stable over the course of study follow-up.