

PATIENT INFORMATION LEAFLET

Rayner RayOne Galaxy and RayOne Galaxy Toric

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Terms to remember:

Aspheric IOL	A small artificial acrylic lens with a slightly curved surface. This design helps you see more clearly in low levels of light, as well as better differentiate between colors (contrast sensitivity), objects and their background.
Astigmatism	When the front surface of your eye (cornea) is not perfectly round like a basketball. Instead, it's shaped more like a football, causing blurred or distorted vision at all distances.
Cataract	When the natural lens inside your eye becomes cloudy or loses its transparency, from the introduction of natural proteins that build up over time. This can make vision blurry, colors look faded, and night driving harder.
Cornea	The protective clear layer at the front of your eye that helps bend and focus light as it enters the eye.
Crystalline lens	The clear, natural lens behind the colored part of your eye (iris) changes shape to focus light onto the back of the eye.
Diopter	Number that shows the strength of a lens. Also tells how much the lens bends light to help focus your vision. The higher the diopter, the stronger the lens must be to focus vision clearly.
Glare	A possible visual side effect after cataract surgery. Lights are dazzling and appear brighter than usual.
Halo	A possible visual side effect after cataract surgery. Rings of light are seen around headlights or lamps, especially at night.
Intraocular Lens (IOL)	A small artificial lens placed in the eye during cataract surgery after the natural cloudy lens is removed.
Iris	A flat colored membrane at the front of the eye that changes size to let light in; the amount of light let into the eye also depends on how bright the environment is.
Monofocal IOL	A small artificial lens that typically only provides distance vision (seeing things far away) after cataract surgery. Glasses are often still needed for reading or close work.
Patient	A person who is receiving or may receive medical care, like you as the reader of this leaflet.
Retina	The thin layer at the back of the eye that senses light, and sends signals to the brain where images are formed.
Starburst	A possible visual side effect after cataract surgery. Lights appear to have streaks or spikes coming out from them.
Subject	A person who takes part in a clinical study.

Introduction:

This patient leaflet provides information about the Rayner RayOne Galaxy and RayOne Galaxy Toric intraocular lenses (IOL) – models RAO605G and RAO615X. These IOLs are designed to improve your vision from distance to near after cataract surgery, and to correct corneal astigmatism (RayOne Galaxy Toric only).

Please read this leaflet carefully and talk about it with your eye surgeon.

Your eye surgeon will explain the potential risks and benefits of cataract removal and IOL implantation. Be sure to ask any questions you may have, and confirm with your surgeon whether the RayOne Galaxy or RayOne Galaxy Toric is right for you.

An overview of cataracts

A cataract occurs when the natural lens inside your eye becomes cloudy or loses its transparency, from the introduction of natural proteins that build up over time. When you have a cataract, your vision may look blurry, hazy or less colorful. A common sign of when a cataract has developed is when your vision isn't as clear or bright as it used to be.

Cataracts are very common and mostly develop naturally with age. Around the world, cataracts are one of the leading causes of vision problems, with over 94 million people affected¹. Cataract surgery is a common, safe, and effective procedure to restore your vision². There are more than 33 million cataract surgeries performed worldwide each year³.

1. <https://www.who.int/news-room/fact-sheets/detail/blindness-and-visual-impairment>
2. Cataract Surgery. National Eye Institute, May 2019
3. Market Scope IOL Report, 2014

An overview of astigmatism

Astigmatism is a common condition where the front surface of your eye (cornea) is not perfectly round like a basketball. Instead, it's shaped more like a football. This uneven shape causes light to bend unevenly, which can make your vision blurry or distorted at all distances.

Wearing glasses or contact lenses can help correct the vision issues caused by astigmatism. However, if the condition has stabilized in adulthood and you want a more permanent solution, your eye surgeon may recommend a special type of IOL called a toric lens. Toric IOLs are designed to reduce astigmatism and improve your vision as part of the surgical treatment.

Types of available IOLs

There are different types of IOLs available, and each provides different visual outcomes after cataract surgery. Your eye surgeon will review the IOL options and help decide which is best for you.

Rayner IOLs available in the United States include:

- **RayOne Aspheric**

The RayOne Aspheric is a monofocal IOL designed to provide high quality distance vision after cataract surgery. The RayOne Aspheric IOL has an aspheric surface, which means it is slightly curved, and is designed to enhance distance vision under low light conditions, such as indoors or at dusk, when wearing full correction glasses. This IOL is designed for people who have a normal corneal shape.

- **RayOne EMV**

The RayOne EMV is similar to the RayOne Aspheric. It is designed to restore clear distance vision and has an aspheric (slightly curved) surface to enhance distance vision under low light conditions such as indoor

or at dusk. The RayOne EMV is designed to provide consistent vision results across a wide range of cornea shapes.

- **RayOne EMV Toric**

The RayOne EMV Toric can provide the same clear distance vision as the RayOne EMV but in addition, it is designed to correct any astigmatism on your cornea, which can reduce blurry or distorted vision caused by an uneven cornea.

- **RayOne Galaxy**

The RayOne Galaxy is designed to provide you with distance, intermediate and near vision after cataract surgery without the need for glasses. This IOL is designed for people who have a normal corneal shape.

- **RayOne Galaxy Toric**

The RayOne Galaxy Toric can provide the same distance, intermediate and near vision as the RayOne Galaxy but in addition, it is designed to correct any astigmatism on your cornea, which can reduce blurry or distorted vision caused by an uneven cornea.

What to expect from your IOL

Characteristic	RayOne Aspheric	RayOne EMV	RayOne EMV Toric	RayOne Galaxy	RayOne Galaxy Toric
Vision	This IOL is designed to provide you with high quality distance vision without the need for glasses.	This IOL is designed to provide you with high quality distance vision without the need for glasses.	This IOL is designed to provide you with high quality distance vision without the need for glasses.	This IOL is designed to provide you with high quality distance, intermediate and near vision without the need for glasses.	This IOL is designed to provide you with high quality distance, intermediate and near vision without the need for glasses.
Glasses use	You will likely need prescription glasses to clearly see objects up close or to read.	You will likely need prescription glasses to clearly see objects up close or to read.	You will likely need prescription glasses to clearly see objects up close or to read.	You may need to wear prescription glasses for small print reading.	You may need to wear prescription glasses for small print reading.
Astigmatism	This IOL is not designed to correct any corneal astigmatism.	This IOL is not designed to correct any corneal astigmatism.	This IOL <u>is</u> designed to correct corneal astigmatism.	This IOL is not designed to correct any corneal astigmatism.	This IOL <u>is</u> designed to correct corneal astigmatism.

Please talk with your eye surgeon to decide which intraocular lens (IOL) is right for you.

Cataract surgery is one of the most common surgical procedures performed; however, as with all surgeries there are warnings, precautions, and risks you should be aware of.

Warnings

- Pre-existing diseases or conditions may put you at higher risk of experiencing complications (e.g., more difficult recovery) after routine cataract surgery. Examples of pre-existing diseases or conditions are diabetes, heart disease, and previous trauma to your eye.
- Contact your eye doctor immediately if you have any of the following symptoms after surgery: a significant decrease in vision; a significant increase in pain in the implanted eye; significant itching, redness, and/or watering of your eye; significant eye discharge; or increased sensitivity to light. These symptoms could indicate postoperative complications including a potentially serious eye infection.
- If glaucoma or retinal conditions develop, some difficulty with conducting examinations and/or administering treatments is possible. In rare cases, the eye doctor may decide to remove the lens.
- Although cataracts do not grow back, some patients may experience blurry vision after cataract surgery due to the membrane behind the lens becoming cloudy. In those instances, a secondary procedure may be necessary to improve vision. Damage to the lens is possible during the procedure which may result in increased visual effects, and in rare cases, the IOL may need to be exchanged.
- If you are expected to have a large amount of astigmatism after surgery, you may not fully benefit from RayOne Galaxy Toric. You may need prescription glasses or your vision may not improve as well as patients with lower astigmatism.
- Unexpected results after surgery may result in you needing prescription glasses or another surgery to adjust or replace the IOL.
- Please discuss all risks and benefits with your eye doctor before your surgery.

Precautions

- If your eye is not healthy, as with all IOLs, your vision may not be good even after your cataract is removed.
- In this case, you may not get the full benefit of RayOne Galaxy or RayOne Galaxy Toric. Before surgery, your eye doctor will check if you have any eye diseases that may influence your IOL selection.
- RayOne Galaxy and RayOne Galaxy Toric have not been evaluated for use in patients younger than 21 years of age.
- After surgery, you may need prescription glasses when reading some small print or looking at small objects.

Potential Risks

Complications after cataract surgery are uncommon, but as with any surgical procedure, risks are involved. While almost any complication after surgery can be treated successfully, primary risks include inflammation, infection, swelling, and dislocation of the IOL amongst others.

Your risk of complications is greater if you have another eye disease or associated medical condition. On rare occasions, cataract surgery does not improve your vision to the level that was expected due to other eye conditions unrelated to the cataract, such as glaucoma (abnormally high intraocular pressure) or macular degeneration (a wearing down of the macula, the central portion of the eye). Your eye surgeon will evaluate these conditions prior to surgery to ensure the best possible outcome for you.

Discuss any questions about the possible risks and benefits of cataract surgery and the Rayner IOLs with your eye surgeon.

Cataract surgery, explained

Cataract surgery is an outpatient procedure. This means you go home the same day. During surgery, your natural lens is removed and replaced with a new intraocular lens (IOL).

- **Before surgery**

Your eye surgeon will examine your eyes and take several measurements to help you choose the best option for your vision. Your lifestyle and daily activities will also be discussed to make sure the right solution is recommended for you. You should plan to have someone else drive you home after surgery.

Your eye surgeon will also review your personal risk/benefit ratio to determine whether you are a good fit for a Rayner IOL. Factors include whether you have ongoing eye disease, a history of eye surgery, or other factors that may affect your outcome.

The results of cataract surgery and an IOL implantation cannot be guaranteed. It is important to be aware of possible side effects on vision after surgery, and not all patients are good candidates for every type of IOL. Be sure to discuss possible risks and side effects with your eye surgeon, who at the time of your consultation, will tell you whether a particular type of IOL is suitable for you. During this discussion, inform your eye surgeon if you have been diagnosed with any eye disease.

Please note that you may still need to wear glasses to benefit from an aspheric IOL when using your distance vision under low light conditions; the RayOne Aspheric, RayOne EMV and RayOne EMV Toric are not designed to provide functional (useful) vision in the near range for activities such as reading a book or sending a text message. Uncorrected (without glasses or contacts) near-sightedness, far-sightedness, and astigmatism (irregularly shaped cornea) may increase the likelihood that you will need glasses for various distances after surgery.

RayOne Galaxy and Galaxy Toric are designed to provide you with glasses-free vision at distance, intermediate and near; however, you may still need to wear prescription glasses for some small print activities – for example, reading a newspaper. Additionally, with RayOne Galaxy and Galaxy Toric you may experience mild visual side effects like halo, glare and starbursts around light sources in low light conditions – for example, around car headlights when driving at nighttime.

- **Day of surgery**

Before surgery you will be given a patient gown to change into for surgery.

Your eye surgeon will place eye drops in your eye to make your pupils larger (dilate the pupil), followed by sterilizing the skin around your eye and applying a local anesthetic (typically in the form of eye drops) to numb the eye. If needed, a mild sedative may also be provided to help you relax.

Cataract surgery is often a short procedure. If your eye is otherwise healthy, it can take between 10 to 15 minutes to remove the natural lens and replace it with the new IOL. The procedure should not be painful. During surgery, you will simply be asked to look at a bright light.

Immediately after the surgery, your eye will be covered with a protective dressing. You can usually return home after a short rest. Someone must accompany you on the day of surgery to drive you home, as you cannot drive straightaway. Your eye surgeon will also give you a small card that identifies the type of IOL implant placed in your eye.

- **After surgery**

While your eyesight may begin to recover straight after surgery, the total recovery time varies from patient to patient. Full recovery may take a few weeks, but you can normally resume day-to-day activities after a couple of days. Please be patient as your eyes adjust to the new IOL.

Remember to apply any eye drops provided by your eye surgeon to support your recovery after the surgery.

During the recovery process after surgery, be sure to avoid any activity that could harm your eye.

The Results of the US Clinical Studies

In this leaflet, we use the word subject when we talk about people who took part in the study.

RayOne EMV Toric

RayOne Galaxy Toric is a combination of the optical design of the RayOne Galaxy with the toric design of the RayOne EMV Toric.

In 2023-2024, Rayner conducted a clinical study in the United States to evaluate the safety and effectiveness of the RayOne EMV Toric for correcting vision after cataract surgery. The study compared the RayOne EMV Toric to a standard monofocal IOL. The main goals were to check how well the IOL stayed centered (centration), how stable it was in position (rotational stability), and to measure how well it performed in improving vision and reducing astigmatism. The study included 234 subjects who were implanted, each randomly assigned to receive one IOL after cataract surgery. One hundred and seventeen subjects received the RayOne EMV Toric and 116 subjects received the FDA-approved RayOne Aspheric monofocal IOL. Eye surgeons followed subjects at several study visits over 4 to 6 months. Subjects who received the RayOne EMV Toric showed better astigmatism correction, stable vision, and low risk of complications. Key findings from the study are listed below:

Vision and Astigmatism Correction

- **100%** (117/117) of subjects with the RayOne EMV Toric were able to see 20/40 or better with correction (glasses or contact lenses) at 4 to 6 months after surgery.
- **68.6% ± 29.2%** was the average percent drop in absolute astigmatism 4 to 6 months after surgery for subjects with a RayOne EMV Toric, compared to **36.1% ± 45.7%** for those with the monofocal IOL.
- **85.5%** (100/117) of RayOne EMV Toric subjects had astigmatism reduced to within 0.50 diopters of their intended target (the level of vision correction your surgeon planned for you) 4 to 6 months after surgery, compared to **48.3%** (56/116) of subjects with the monofocal IOL.
- **96.6%** (113/117) of RayOne EMV Toric subjects had astigmatism reduced to within 1.00 diopters of their intended target (the level of vision correction your surgeon planned for you) 4 to 6 months after surgery, compared to **79.3%** (92/116) with the monofocal IOL.

Lens Rotational Stability:

- The average rotation of the IOL between 1 and 6 months after surgery was minimal, indicating the IOL stayed in the correct position over time.

- **99%** (100/101 subjects with evaluable data) of the RayOne EMV Toric IOLs stayed within 5 degrees of their original position between 1 to 6 months after surgery, also indicating that the IOL was able to stay close to the correct position during that time.

Safety and Side Effects:

The rate of serious side effects with the RayOne EMV Toric was similar to or lower than what is typically expected for cataract surgery in most cases, per internationally recognized safety benchmarks for intraocular lenses (ISO 11979-7).

The most common serious side effect was cystoid macular edema (swelling in the back of the eye), which occurred in 1.7% (2/117) of cases.

One subject (0.9%, 1/117) needed a second surgery for a minor IOL position adjustment due to how the IOL was positioned during the first surgery; however, this was not caused by a problem with the IOL itself. Another subject (0.9%, 1/117) required a cataract lens fragment removal, due to incomplete removal of the cataract at the time of the first surgery, also not caused by the IOL.

There were no cases of the following ISO-defined serious side effects:

- Endophthalmitis (infection inside the eye)
- Hypopyon (fluid build-up of white blood cells in the front of the eye)
- Retinal detachment (the layer at the back of the eye pulls away)
- IOL dislocation (the IOL shifts out of place)
- Pupillary block (fluid is unable to flow properly through the eye)

Rates of Side Effects Defined by Previous Cataract Research

As part of the study, researchers also monitored side effects defined by previous cataract research known as Masket criteria¹. These included swelling, pressure changes, and IOL repositioning.

Among 117 subjects, 5 (4.3%) experienced one or more of these events.

- Increased IOP (elevated eye pressure): 3/117 subjects (2.6%)
- Clinically significant macular edema (swelling in the back of the eye affecting vision): 1/117 subjects (0.9%)
- Secondary surgical intervention (IOL repositioning procedure): 1/117 subjects (0.9%)

1. Masket S. Recommended Standard for Reporting Adverse Events for Intraocular Lenses and Cataract Surgery. J Cataract Refract Surg. 2002.

Other Reported Side Effects

The study also tracked other side effects after cataract surgery. Among 117 subjects:

- Posterior capsular opacification (clouding behind the IOL) requiring laser treatment: 14/117 subjects (12.0%)
- Posterior vitreous detachment (gel inside eye separated from retina): 7/117 subjects (6.0%)
- Cornea edema (corneal swelling): 7/117 subjects (6.0%)
- Anterior chamber cells (mild inflammation shortly after surgery): 5/117 subjects (4.3%)
- Corneal abrasions or epithelial defects (abrasions or scratches on the eye): 5/117 subjects (4.3%)
- Eye redness or bleeding (e.g., subconjunctival hemorrhage): 3/117 subjects (2.6%)
- Epiretinal membrane (thin film that can form on retina): 2/117 (1.7%)

Less common events (each in 1/117 subjects, or 0.9%) included:

IOL decentration/malposition (off-center IOLs requiring adjustment), iris pigment epithelium loss (loss of pigment in the colored part of the eye), progression or onset of diabetic retinopathy (diabetes-related retinal changes), retained lens material (small piece of IOL left after surgery), wound burp / paracentesis (fluid release to lower eye pressure), surgical removal of retained lens fragment (minor procedure to remove leftover lens piece), choroidal nevus (benign freckle at the back of the eye), conjunctival injection (eye redness), corneal dellen (dry or sunken area on the eye surface), dermatochalasis (sagging upper eyelid skin), epiretinal membrane (thin scar tissue on the retina), subconjunctival hemorrhage (small bleed on the white of the eye), worsening dry eye disease (increased dryness or irritation), central capsular wrinkle (fold behind the IOL), chemosis (swelling of clear eye tissue), double vision after surgery (temporary double vision due to visual adjustment), dry eye disease (gritty or dry feeling in the eyes), epithelial basement membrane dystrophy (irregular surface of the eye), intraretinal hemorrhage (small bleed within the retina), iritis (inflammation inside the front part of the eye), keratoconjunctivitis sicca (non-autoimmune dry eye), photophobia (light sensitivity), retinal pigment epithelial changes (minor pigment changes in the retina), retinal pigment epithelial mottling, irregular coloring in the retina), superficial punctate keratitis (small spots of irritation on the eye's surface), trace punctate epithelial erosions (tiny surface scratches on the eye), visually significant corneal edema (swelling that temporarily reduced vision), worsening punctate epithelial erosion (progression of small surface damage on the eye).

The US clinical trial proved that the RayOne EMV Toric is effective in improving vision while reducing astigmatism and providing excellent IOL stability, with a safety profile comparable to other toric IOLs used in cataract surgery.

The results of the US clinical study for the RayOne Galaxy are summarized below. Based on the results of this study and the results of the RayOne EMV Toric clinical study described above, no additional clinical studies were needed to support the safety and effectiveness of the RayOne Galaxy Toric IOL.

RayOne Galaxy

In 2024-2025, Rayner conducted a clinical study in the United States at 10 study sites to evaluate the safety and effectiveness of the RayOne Galaxy for correcting vision after cataract surgery. The study compared the RayOne Galaxy to a standard monofocal IOL which is commonly used in cataract surgery. The main goals of the study were to understand how well the RayOne Galaxy helps people see at different distances. Doctors looked at distance vision (such as looking at a street sign), intermediate vision (such as seeing a computer screen) and near vision (such as reading). The study also monitored safety and side effects after surgery. The study enrolled 254 subjects. Of these, 230 subjects met the study requirements and were randomly assigned to receive either the RayOne Galaxy or a monofocal IOL. Cataract surgery was planned in both eyes; however, a few subjects did not proceed with surgery in the second eye. As a result, the study included 227 subjects who were implanted, most of who received lenses in both eyes. One hundred and twelve (112) subjects received the RayOne Galaxy, and 115 subjects received the FDA-approved RayOne Aspheric monofocal IOL. Eye surgeons followed subjects at several study visits over 4 to 6 months after surgery.

Subjects who received the RayOne Galaxy showed stable vision, and low risk of complications. Key findings from the study are listed below:

Vision Correction

Distance

- **100%** (110/110) of subjects with the RayOne Galaxy in **one eye** were able to see 20/40 or better with correction (glasses or contact lenses) at far distance (4 meters), 4 to 6 months after surgery.
- **98.2%** (107/109) of subjects with the RayOne Galaxy in **both eyes** were able to see 20/40 or better without correction (glasses or contact lenses) at far distance (4 meters), 4 to 6 months after surgery.
- **100%** (109/109) of subjects with the RayOne Galaxy in **both eyes** were able to see 20/40 or better with correction (glasses or contact lenses) at far distance (4 meters), 4 to 6 months after surgery.

Intermediate

- **94.5%** (104/110) of subjects with the RayOne Galaxy in **one eye** were able to see 20/40 or better with correction (glasses or contact lenses) at intermediate distance (66 centimeters), 4 to 6 months after surgery.
- **100%** (109/109) of subjects with the RayOne Galaxy in **both eyes** were able to see 20/40 or better without correction (glasses or contact lenses) at intermediate distance (66 centimeters), 4 to 6 months after surgery.
- **100%** (109/109) of subjects with the RayOne Galaxy in **both eyes** were able to see 20/40 or better with correction (glasses or contact lenses) at intermediate distance (66 centimeters), 4 to 6 months after surgery.

Near

- **75.5%** (83/110) of subjects with the RayOne Galaxy in **one eye** were able to see 20/40 or better with correction (glasses or contact lenses) at near distance (40 centimeters), 4 to 6 months after surgery.
- **100%** (109/109) of subjects with the RayOne Galaxy in **both eyes** were able to see 20/40 or better without correction (glasses or contact lenses) at near distance (40 centimeters), 4 to 6 months after surgery.
- **97.2%** (106/109) of subjects with the RayOne Galaxy in **both eyes** were able to see 20/40 or better with correction (glasses or contact lenses) at near distance (40 centimeters), 4 to 6 months after surgery.

Quality of Vision Symptoms Reported by Patients

People in the study were asked about visual symptoms such as glare, halos, starbursts, hazy vision, blurred vision, distorted vision, double vision, changes in vision, difficulty focusing, and difficulty judging distance or depth. They were asked how often they had each symptom, how severe it was, and how bothersome it was.

Most visual symptoms were reported at similar rates in people who received the RayOne Galaxy and people who received the monofocal lens. Among people with the RayOne Galaxy who reported halos, most said the halos were either not bothersome or only a little bothersome.

The tables below show how often each visual symptom was reported and, for people who experienced the symptom, how severe and how bothersome it was.

TABLE 1 - HOW OFTEN PATIENTS EXPERIENCED VISUAL SYMPTOMS

Visual Disturbance	RAO605G Multifocal IOL						RAO600C Monofocal IOL					
	N ¹	Never	Occasionally	Quite Often	Very Often	Not Done	N ¹	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

¹N is the number of patients who completed this part of the questionnaire. Percentages are based on patients who answered the question. Note: Two patients with the monofocal lens did not answer, so percentages for this group are based on 109 patients.

TABLE 2 - HOW SEVERE THE VISUAL SYMPTOMS WERE

Visual Disturbance	RAO605G Multifocal IOL						RAO600C Monofocal IOL					
	N ¹	Not at All	Mild	Moderate	Severe	Not Done	N ¹	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

Visual Disturbance	RAO605G						RAO600C					
	Multifocal IOL						Monofocal IOL					
	N ¹	Not at All	Mild	Moderate	Severe	Not Done	N ¹	Not at All	Mild	Moderate	Severe	Not Done
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

¹N is the number of patients who actually reported that they experienced an applicable symptom. Because not every patient had every symptom, the number of patients varies from row to row.

TABLE 3 - HOW BOTHERSOME THE VISUAL SYMPTOMS WERE

Visual Disturbance	RAO605G						RAO600C					
	Multifocal IOL						Monofocal IOL					
	N ¹	Not at All	A Little	Quite	Very	Not Done	N ¹	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

¹N is the number of patients who actually reported that they experienced an applicable symptom. Because not every patient had every symptom, the number of patients varies from row to row.

Patient Vision Questionnaire

Patients also answered questions about their vision during everyday activities. The Patient Vision Questionnaire was not developed or validated using current guidance for patient questionnaires. For this reason, the results should be interpreted with caution.

Overall, responses were generally similar between the two lens groups.

The largest differences were for near vision. Patients with the multifocal lens reported less trouble with near vision than patients with the standard (monofocal) lens. Depending on the question, about 2 to 3 out of 100 patients with the multifocal lens said they “Always” had trouble with near vision, compared with about 15 to 24 out of 100 patients with the standard lens.

For some distance and nighttime vision questions, the results went in the other direction, although the differences were smaller. About 8 out of 100 multifocal patients said they “Always” had blurred distance vision, compared with about 1 out of 100 standard-lens patients. For night vision, this was about 9 out of 100 compared with 5 out of 100, and for night driving, about 9 out of 100 compared with 4 out of 100, respectively.

About 90 out of 100 patients in each group said they would choose the same lens again.

Safety and Side Effects:

The rate of serious side effects with the RayOne Galaxy was similar to what’s typically expected for cataract surgery, based on internationally recognized safety benchmarks for intraocular lenses (ISO 11979-7). As noted earlier, most subjects were implanted in both eyes with the RayOne Galaxy.

First Implanted Eyes (112 subjects, RayOne Galaxy)

The most common serious side effect was a secondary surgical intervention (an additional eye procedure), which occurred in 1.8% (2/112) and of cases in first-implanted eyes.

No First Implanted eyes required a secondary surgical intervention due to the optical properties of the IOL.

Retinal detachment (the layer at the back of the eye pulls away) occurred in 0.9% (1/112) of cases in first-implanted eyes. This event was not related to the study device and resolved without additional complications.

There were no cases of the following ISO-defined serious side effects in the first-implanted eyes:

- Cystoid macular edema (swelling in the back of the eye)
- Endophthalmitis (infection inside the eye)
- Hypopyon (fluid buildup of white blood cells in the front of the eye)
- IOL dislocation (the IOL shifts out of place)
- Pupillary block (fluid is unable to flow properly through the eye)
- Corneal Stroma Edema (long-lasting corneal swelling)
- Anterior Uveitis (persistent inflammation inside the eye)
- Raised Intraocular Pressure Requiring Treatment (ongoing high eye pressure)

There were no persistent (remaining at the final visit) serious side effects in first-implanted eyes at the 4 to 6 months visit window.

Second-Implanted Eyes (111 subjects, RayOne Galaxy)

The only serious side effect observed was a secondary surgical intervention, which occurred in 3.6% (4/111) of cases.

No Second Implanted eyes required a secondary surgical intervention due to the optical properties of the lens.

There were no cases of the following ISO-defined serious side effects in the second-implanted eyes:

- Cystoid macular edema (swelling in the back of the eye)
- Endophthalmitis (infection inside the eye)
- Hypopyon (fluid buildup of white blood cells in the front of the eye)
- IOL dislocation (the IOL shifts out of place)
- Pupillary block (fluid is unable to flow properly through the eye)
- Retinal Detachment (the layer of the back of the eye pulls away)
- Corneal Stroma Edema (long-lasting corneal swelling)
- Anterior Uveitis (persistent inflammation inside the eye)
- Raised Intraocular Pressure Requiring Treatment (ongoing high eye pressure)

There were no persistent (remaining at the final visit) serious side effects in second-implanted eyes at the 4 to 6 months visit window.

Rates of Side Effects Defined by Previous Cataract Research

As part of the study, researchers also monitored side effects defined by previous cataract research known as Masket criteria¹. These include changes in eye pressure, inflammation, swelling, and the need for additional eye procedures.

First-Implanted Eyes (112 subjects, RayOne Galaxy)

Among 112 first-implanted eyes, the following Masket-defined side effects were observed:

- Increased IOP (elevated eye pressure): 3/112 (2.7%)
- Retinal detachment (the layer of the back of the eye pulls away): 1/112 (0.9%)

There were no cases of the following Masket-defined side effects in the first-implanted eyes:

- Anterior uveitis (persistent inflammation inside the eye)
- Clinically significant cystoid macular edema (swelling in the back of the eye affecting vision)
- Visually significant corneal edema (corneal swelling that affects vision)
- Endophthalmitis (serious infection inside the eye)
- Mechanical pupillary block (blocked fluid flow inside the eye)
- Toxic anterior segment syndrome (severe inflammation in the front of the eye after surgery)
- IOL exchange, removal, or repositioning

Second-Implanted Eyes (111 subjects, RayOne Galaxy)

Among 111 second-implanted eyes, the following Masket-defined side effects were observed:

- Increased IOP (elevated eye pressure): 2/111 (1.8%)
- IOL removal: 1/111 (0.9%)
- IOL exchange (IOL replaced with the same lens model): 1/111 (0.9%)

There were no cases of the following Masket-defined side effects in the second-implanted eyes:

- Anterior uveitis (persistent inflammation inside the eye)
- Clinically significant cystoid macular edema (swelling in the back of the eye affecting vision)
- Visually significant corneal edema (corneal swelling that affects vision)
- Endophthalmitis (serious infection inside the eye)
- Mechanical pupillary block (blocked fluid flow inside the eye)
- Retinal detachment (the layer of the back of the eye pulls away)
- Toxic anterior segment syndrome (severe inflammation in the front of the eye after surgery)

1. Masket S. Recommended Standard for Reporting Adverse Events for Intraocular Lenses and Cataract Surgery. J Cataract Refract Surg. 2002.

Other Reported Side Effects

The study also tracked other side effects after cataract surgery. The side effects listed below were reported in eyes that received the RayOne Galaxy.

First-Implanted Eyes (112 subjects, RayOne Galaxy)**More common side effects**

- Anterior chamber cells, grade 0.5 or greater (mild inflammation inside the front of the eye seen during any exam): 31/112 (27.7%)
- Posterior capsular opacification requiring laser treatment (Nd:YAG capsulotomy) (clouding behind the lens treated with a laser): 24/112 (21.4%)
- Corneal edema (swelling of the clear front surface of the eye): 10/112 (8.9%)
- Elevated intraocular pressure (higher-than-normal eye pressure): 4/112 (3.6%)

- Posterior vitreous detachment (the gel inside the eye pulling away from the retina): 3/112 (2.7%)
- Anterior chamber cells greater than grade 2 at visit 1 (mild inflammation inside the front of the eye seen in the early postoperative period): 2/112 (1.8%)
- Subconjunctival hemorrhage (a small blood spot on the white of the eye): 2/112 (1.8%)
- Loss of two or more lines of best-corrected vision (temporary decrease in vision measured on an eye chart): 2/112 (1.8%)

Less common events (each in 1/112 subjects, or 0.9%) included:

Progression or onset of diabetic retinopathy (diabetes-related changes to the retina), double or multiple images (seeing more than one image), keratoconjunctivitis sicca (dry eye), meibomian gland dysfunction (blocked oil glands in the eyelids), and worsening of keratoconjunctivitis sicca (increase in dry eye symptoms).

Overall, the types and rates of other reported side effects in first-implanted eyes were similar between subjects who received the RayOne Galaxy and those who received the monofocal IOL. Most were mild, commonly seen after cataract surgery, and resolved without lasting effects.

Second-Implanted Eyes (111 subjects, RayOne Galaxy)

More common side effects

- Anterior chamber cells, grade 0.5 or greater (mild inflammation inside the front of the eye): 31/111 (27.9%)
- Posterior capsular opacification requiring laser treatment (Nd:YAG capsulotomy) (clouding behind the lens treated with a laser): 27/111 (24.3%)
- Corneal edema (swelling of the clear front surface of the eye): 7/111 (6.3%)
- Anterior chamber cells greater than grade 2 at visit 1 (mild inflammation inside the front of the eye seen in the early postoperative period): 4/111 (3.6%)
- Elevated intraocular pressure (higher-than-normal eye pressure): 4/111 (3.6%)
- Loss of two or more lines of best-corrected vision (temporary decrease in vision measured on an eye chart): 3/111 (2.7%)
- Posterior vitreous detachment (the gel inside the eye pulling away from the retina): 3/111 (2.7%)
- Subconjunctival hemorrhage (a small blood spot on the white of the eye): 2/111 (1.8%)
- Superficial punctate keratitis (small, irritated spots on the eye surface): 2/111 (1.8%)

Less common events (each in 1/111 subjects, or 0.9%) included:

Corneal abrasion (a scratch on the surface of the eye), corneal edema (swelling of the clear front surface of the eye), keratoconjunctivitis sicca (dry eye), allergic conjunctivitis (eye irritation caused by allergies), anterior chamber debris (small particles seen in the fluid inside the eye), capsular bag distension syndrome (fluid buildup behind the lens), double or multiple images (seeing more than one image), ecchymosis (bruising around the eye), meibomian gland dysfunction (blocked oil glands in the eyelids), skin laceration (small cut to the skin), vitreous floaters (small moving spots in vision), vitreous syneresis (normal age-related thinning of the eye's gel), worsening of dry eye disease (increase in eye dryness), and worsening of

keratoconjunctivitis sicca (worsening of chronic dry eye condition affecting the surface of the eye).

Overall, the RayOne Galaxy study concluded that the types and rates of other reported side effects in second implanted eyes were similar between subjects who received the RayOne Galaxy and those who received a monofocal IOL. The pattern of events was similar to that seen in first-implanted eyes, and most events resolved without lasting effects.

Important Points to Remember

1. The RayOne Aspheric, RayOne EMV and RayOne EMV Toric restore distance vision following cataract surgery.
2. The RayOne Galaxy and Galaxy Toric restore vision at all distances following cataract surgery.
3. Discuss your wants, needs, and lifestyle with your eye surgeon to help ensure you receive the right IOL for you.

For further information about this device, please refer to the device's professional labeling.

We appreciate your consideration of Rayner IOLs.