

**PATIENT
INFORMATION
BROCHURE**

Alcon AcrySof® IQ ReSTOR®
Intraocular Lens (IOL)

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This brochure has been written to assist you and your surgeon to make an informed decision regarding the best intraocular lens (IOL) for your cataract surgery. Your surgeon will advise you about the potential risks and benefits of the surgical procedure for cataract removal and IOL implantation. This brochure will aid you in deciding if an Alcon AcrySof® IQ ReSTOR® IOL (an IOL designed to provide distance, intermediate, and near vision) would be a more appropriate choice compared to a traditional, monofocal IOL (an IOL designed to provide distance vision).

What is a cataract?

Your eye functions much like a camera. Your natural lens focuses images onto the back of your eye so you can see clearly, much like the lens of a camera focusing images onto film for a clear picture. At birth, your natural lens is clear. However, as you age, the lens may begin to gradually become “cloudy.” This condition is called a cataract, and is usually a result of the natural aging process. As the lens becomes cloudier, your vision becomes slowly more blurred.

A cataract can progress until eventually there is a complete loss of vision in your eye. Surgery is the only way a cataract can be removed. You should consider surgery when cataracts cause enough loss of vision to interfere with your daily activities.

What is the surgical procedure to restore my vision?

Your eye will be measured after you and your eye doctor have decided that you will have your cataract removed. This will determine the proper power of the IOL that will be placed in your eye during surgery.

You will be given eyedrops and perhaps medicines to help you relax when you arrive for surgery.

Cataract surgery techniques vary widely. However, the eye is always numbed to make the operation painless. To perform surgery, your doctor will use a microscope to have a magnified view of your eye. Your lens sits in a bag-like structure called the capsule. The capsule is located just behind the colored part of your eye (iris). A small incision is made in the outer surface of the eye (cornea) to reach and remove the cataract. An IOL is then usually placed into the capsule to replace your lens. The IOL will act in the same way as your natural lens once did to focus images clearly onto the back of your eye (retina), to allow clear vision once again. The surgeon will usually place a shield over your eye after surgery. You will be ready to go home after a short stay in the outpatient recovery area. Plan to have someone else drive you home. Below is a diagram showing the basic parts of the eye with an implanted IOL.

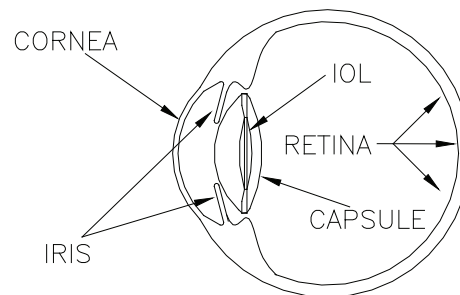


Figure 1 – Drawing of Eye with Implanted IOL

Potential Risks

Surgery risks include reactions to medicines and vision changes. Common side effects include redness, scratchiness of the eye, and light sensitivity. There is a small chance that your vision could be made worse by the operation, especially if bleeding or infection occurs. These risks are rare and may be outweighed by the potential benefits of restoring your vision.

In addition, you may have some side effects with the AcrySof® IQ ReSTOR® IOL. The percent of patients who have experienced severe side effects for the AcrySof® IQ ReSTOR® IOLs (Model SN6AD3

and Model SN6AD1) and the Monofocal IOL (Model MA60BM) are shown in the table below. Side effects that you may have include glare, rings around lights, and blurred vision. These side effects may make it more difficult to see while driving at night. These side effects may also make it more difficult for you to complete other tasks in a room with low lighting. Generally, higher rates of severe visual disturbances have been observed at earlier post operative intervals. In the clinical study, 1 of 304 AcrySof® IQ ReSTOR® patients encountered severe visual disturbances and requested to have the IOL removed.

	Model MA60BM (6-Months after Surgery)	Model SN6AD3 (3-Months after Surgery)	Model SN6AD1 (3-Months after Surgery)
Glare/Flare (trouble seeing street signs due to bright light or oncoming headlights)	1.9 %	7.6 %	8.0 %
Problems with Night Vision (trouble seeing at night)	1.9 %	5.3 %	5.1 %
Halos (rings around lights)	1.3 %	13.7 %	10.1 %
Blurred Near Vision	3.8 %	3.1 %	4.3 %
Blurred Far Vision	0.0	0.0	2.9 %
Double Vision with both eyes (seeing multiple images)	0.0	0.0	1.4 %

You should be aware that you may have some difficulty seeing “low contrast” objects (distinguishing “shades of gray”). You may notice this more under poor lighting conditions, such as in fog or when driving at night.

A night driving simulation study was conducted on both multifocal and monofocal IOL patients to assess the effects of various lighting conditions on vision performance. The ability of multifocal IOL patients to detect and identify road signs and hazards at night was similar to the monofocal patients under normal visibility conditions. However, sign identification in fog and glare conditions were more challenging for the multifocal patients compared to monofocal patients. The ability to detect hazards was also lower for multifocal patients than monofocal patients, especially when glare was present. These findings further emphasize the caution that multifocal IOL patients should exercise when driving at night.

Warnings

- You may have some visual effects such as halos (circles around lights) or glare. (Such problems are usually worse at night.) This is because a multifocal IOL, unlike a traditional monofocal IOL, provides both a focused and an unfocused image of each light source.
- You may have some difficulty seeing “low contrast” objects (distinguishing “shades of gray”). This may be more noticeable in areas with less light. Therefore, you should take extra care when driving at night.
- Your eye doctor should consider the following points that are unique before implanting the AcrySof® IQ ReSTOR® IOL:
 - To achieve your best vision after cataract surgery, your doctor must use the lens power that will give you the best chance of not needing glasses after surgery.
 - The front surface of your eye may be irregular in shape (astigmatism) before and after cataract surgery. You may not get the best results if you have more than a small amount (less than or equal to 1 diopter) of

astigmatism measured in your eye before surgery or estimated in your eye after cataract surgery.

- Contact your eye doctor immediately if you have any of the following symptoms while using the antibiotic eye drops prescribed by your doctor: itching, redness, watering of your eye, sensitivity to light.
- You should avoid any activity that could harm your eye while you are recovering from surgery.

Precautions

- The safety and effectiveness of the AcrySof® IQ ReSTOR® IOL has not been established in patients with eye conditions, such as an increase in eye pressure (glaucoma) or complications of diabetes in the eye (diabetic retinopathy). The outcome of cataract surgery will depend on the health of your eye before surgery. You should tell your doctor if you have been diagnosed as having amblyopia (lazy eye) or any eye disease.
- The bag-like structure (posterior capsule) that your IOL is placed in may become cloudy after cataract surgery. If this condition develops, it may affect your vision earlier if you are implanted with the AcrySof® IQ ReSTOR® IOL compared to someone implanted with a traditional monofocal IOL.
- As with any surgical procedure, there is risk involved. These risks may include infection, the layer which lines the inside back wall of your eye may become separated from the tissue next to it (retinal detachment), and an increase in eye pressure. Your eye doctor will discuss all risks and benefits to you before your surgery.
- Take all prescribed medicines and apply eye drops as instructed.
- Before surgery, your eye doctor will check to see if you have any eye diseases or swelling. Be sure to tell your eye doctor if you have any health conditions that may affect your surgery or vision.

What types of IOL's are available for this procedure?

There are many different IOLs to choose from. Your eye doctor will discuss your options including this IOL and other IOLs.

In general, IOLs have two basic features. The optic portion is the round part of the IOL, which focuses an image. Two arm-like structures called haptics are attached to edge of the optic. The haptics help maintain the location of the IOL in the eye. The basic design allows for clear distance vision. Let's look at the basic ideas behind a traditional (monofocal) IOL and the AcrySof® ReSTOR® IOLs.

Alcon AcrySof® Single-piece Monofocal IOL

A monofocal IOL is designed to provide clear distance vision. This means you will be able to see objects far away. However, you will most likely need glasses for reading and any type of "close" detailed work. Monofocal IOLs, like the Alcon AcrySof® Single-Piece, have been the standard implant used after a cataract is removed. Millions of monofocal IOLs have been successfully implanted providing cataract patients with clear distance vision.

Alcon AcrySof® IQ ReSTOR® IOL

The design of the Alcon AcrySof® IQ ReSTOR® IOL allows for clear distance vision (watching children playing in the backyard). The center of the IOL also allows for near (reading) and intermediate (computer work) vision. You may therefore be more independent of glasses for daily tasks. There are two types of AcrySof® IQ ReSTOR® IOLs that provide distance, intermediate and near vision. Both of these IOLs provide quality near vision but at different reading distances. The larger the add power value, the closer you may have to hold materials for reading or other near vision tasks. In this case, the AcrySof® IQ ReSTOR® +4.0 D Add Power IOL provides reading distance (about 12 inches) that is closer than the AcrySof® IQ ReSTOR® +3.0 D Add Power IOL (about 15 inches).

See pages 7-10 for a "side by side" comparison for these lenses compared to a monofocal IOL.

As with many things, there may be a trade off. This possible decrease in use of glasses may come at the cost of losing some of the sharpness of your vision. Even with glasses, this loss of sharpness may become worse in dim light or fog. There may also be some visual side effects. These may include rings or circles around lights at night.

You will get the full benefit of the AcrySof® IQ ReSTOR® IOL when it is implanted in both eyes. Results from a clinical study showed that patients can see better for distance, intermediate, and near vision with the AcrySof® IQ ReSTOR® IOL implanted in both eyes. Please discuss with your eye doctor whether this is the right IOL for you.

Postoperative Care Instructions

You will return home after surgery. Typically, your eye doctor will examine you the following day. Your eye doctor will give you eyedrops to speed up the healing process and to prevent infection.

Your vision almost always improves greatly within 4 to 6 weeks. Many patients may see better within 1 to 2 weeks or less. The specifics of surgery may be different for each individual. Be sure to consult your eye doctor.

The AcrySof® IQ ReSTOR® IOL is designed to provide you with a full range of vision allowing you to see objects far away, up close, and in between. It may take you some time to get accustomed to your new IOL(s). Always consult with your eye doctor if you have any questions or concerns as a result of cataract surgery.

Key points to remember regarding your choice

Both the Alcon AcrySof® Monofocal and AcrySof® IQ ReSTOR® IOLs can restore your vision following cataract surgery. Discussing your lifestyle or visual needs with your eye doctor can help determine which IOL is best for you.

If freedom from glasses is your desired outcome, the Alcon AcrySof® IQ ReSTOR® IOLs may be your

best choice. These IOLs give you the best possibility to have clear distance vision and be able to read and perform computer work without the need for glasses. However, there is a slightly greater chance of having severe difficulty with halos or rings around lights (10-14 out of 100) and glare (8 out of 100) compared to a monofocal IOL (1 or 2 out of 100). You may grow accustomed to them or continue to notice them. If you drive a considerable amount at night, or perform delicate, detailed, “up-close” work requiring closer focus than just reading, perhaps a monofocal IOL would be a better choice. Alcon offers a variety of monofocal IOLs for your surgeon to choose from.

Thanks for considering the Alcon AcrySof® IQ ReSTOR® IOL.

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**Comparison of Study Results between Alcon AcrySof® Monofocal and
AcrySof® IQ ReSTOR® +3.0 D and +4.0 D Add Power IOLs**

Characteristic	Alcon AcrySof® Monofocal IOL^ (N=172)	Alcon AcrySof® IQ ReSTOR® +4.0 D Add Power IOL* (N=131)	Alcon AcrySof® IQ ReSTOR® +3.0 D Add Power IOL* (N=138)
Distance Vision (20/40 or better) without glasses**	The majority of patients (97 out of 100) had good distance vision	Similarly, a majority of patients (99 out of 100) had good distance vision	Similarly, a majority of patients (99 out of 100) had good distance vision
Distance Vision (20/40 or better) with glasses**	All patients (100 out of 100) have good distance vision with glasses	All patients (100 out of 100) have good distance vision with glasses	Almost all patients (99 out of 100) have good distance vision with glasses
Intermediate Vision without glasses (20/40 or better)	More than half of these patients (59 out of 100) had intermediate acceptable vision at 50 cm (approximately 20 inches). A small number (63 of 100) patients had intermediate vision at 70 cm	A large number (73 out of 100) had acceptable intermediate vision at approximately 20 inches (50 cm). More than half (60 out of 100) of the subjects had intermediate vision without glasses at about 27.5 inches (70 cm)	A much large number (96 out of 100) had acceptable intermediate vision at approximately 20 inches (50 cm). A larger number (89 out of 100) of the subjects had intermediate vision without glasses at about 27.5 inches (70 cm)
Average intermediate vision with glasses designed for distance vision (at 20 inches)	20/50	20/40	20/25
Near Vision (20/40 or better) without reading glasses**	A small number (41 out of 100) have good near vision; many (over 50) require reading glasses more than half of the time for “close-work” like reading	A much larger number (95 out of 100) had good near vision; few (less than 6 out of 100) require reading glasses more than half of the time for “close-work.” Reading glasses may be needed in low lighting for your best focus.	A much larger number (96 out of 100) had good near vision; few (less than 6 out of 100) require reading glasses more than half of the time for “close-work.” Reading glasses may be needed in low lighting for your best focus.
Near Vision (20/40 or better) with glasses designed for Distance Vision**	A small number of patients (34 out of 100) have good near vision with glasses designed for distance vision	A much larger number (99 out of 100) had good near vision with glasses designed for distance vision	A much larger number (97 out of 100) had good near vision with glasses designed for distance vision

**Comparison of Study Results between Alcon AcrySof® Monofocal and
AcrySof® IQ ReSTOR® +3.0 D and +4.0 D Add Power IOLs**

Characteristic	Alcon AcrySof® Monofocal IOL^ (N=172)	Alcon AcrySof® IQ ReSTOR® +4.0 D Add Power IOL* (N=131)	Alcon AcrySof® IQ ReSTOR® +3.0 D Add Power IOL* (N=138)
Near Vision (20/40 or better) with reading glasses	The majority of patients (97 out of 100) had good near vision with reading glasses	Similarly, a majority of patients (98 out of 100) had good near vision with reading glasses	Similarly, a majority of patients (99 out of 100) had good near vision with reading glasses
Time Spent Wearing Glasses	<ul style="list-style-type: none"> • Never 8 out of 100 • Sometimes 69 out of 100 • Always 23 out of 100 	<ul style="list-style-type: none"> • Never 76 out of 100 • Sometimes 22 out of 100 • Always 2 out of 100 	<ul style="list-style-type: none"> • Never 76 out of 100 • Sometimes 23 out of 100 • Always 1 out of 100
Dependency upon Glasses for Distance Vision	<ul style="list-style-type: none"> • None of the time 62 out of 100 • Some of the time 12 out of 100 • Half of the time 3 out of 100 • Most of the time 5 out of 100 • All of the time 17 out of 100 	<ul style="list-style-type: none"> • None of the time 96 out of 100 • Some of the time 0 out of 100 • Half of the time 0 out of 100 • Most of the time 2 out of 100 • All of the time 2 out of 100 	<ul style="list-style-type: none"> • None of the time 96 out of 100 • Some of the time 2 out of 100 • Half of the time 0 out of 100 • Most of the time 1 out of 100 • All of the time 1 out of 100
Dependency upon Glasses for Near Vision	<ul style="list-style-type: none"> • None of the time 8 out of 100 • Some of the time 23 out of 100 • Half of the time 3 out of 100 • Most of the time 26 out of 100 • All of the time 41 out of 100 	<ul style="list-style-type: none"> • None of the time 73 out of 100 • Some of the time 19 out of 100 • Half of the time 2 out of 100 • Most of the time 2 out of 100 • All of the time 4 out of 100 	<ul style="list-style-type: none"> • None of the time 75 out of 100 • Some of the time 17 out of 100 • Half of the time 2 out of 100 • Most of the time 4 out of 100 • All of the time 2 out of 100
Quality of Overall Vision (rating from 1/worst to 10/best) without glasses	Monofocal patients rated their overall vision quality at 7.9	Patients rated their overall vision quality at 8.3	Patients rated their overall vision quality at 8.6

**Comparison of Study Results between Alcon AcrySof® Monofocal and
AcrySof® IQ ReSTOR® +3.0 D and +4.0 D Add Power IOLs**

Characteristic	Alcon AcrySof® Monofocal IOL^ (N=172)	Alcon AcrySof® IQ ReSTOR® +4.0 D Add Power IOL* (N=131)	Alcon AcrySof® IQ ReSTOR® +3.0 D Add Power IOL* (N=138)
Visual effects, such as halos (rings around lights) and glare (trouble seeing street signs due to bright lights or oncoming headlights)	There is a slight chance that you may have severe difficulty with halos around lights (1 out of 100) or with glare (2 out of 100), especially when performing nighttime activities, like driving at night	There is a greater chance of having severe difficulty with halos (14 out of 100) and glare (8 out of 100) compared to someone with a Monofocal IOL. You may grow accustomed to them or continue to notice them. In rare instances (less than 1 out of 200), patients have requested that their IOL be removed	There is a greater chance of having severe difficulty with halos (10 out of 100) and glare (8 out of 100) compared to someone with a Monofocal IOL. You may grow accustomed to them or continue to notice them. In rare instances (less than 1 out of 200), patients have requested that their IOL be removed
Low contrast vision, especially driving in poor light conditions, like fog	Your vision for low contrast signs should be clear. Vision under poor lighting conditions, like fog, will not be as clear.	You may have more difficulty recognizing some traffic signs and hard-to-see objects in the road compared to someone with a Monofocal IOL.	You may have more difficulty recognizing some traffic signs and hard-to-see objects in the road compared to someone with a Monofocal IOL.
Percent of dissatisfied patients who would not have the same IOL implanted again	0%	1.4%	3.1%

*Results in the table are from a clinical study in which patients were implanted with the same Add Power IOL in both eyes

^Monofocal results in the table are from a clinical study between a Monofocal IOL compared to ReSTOR® spherical IOLs

** The improvement in near vision for AcrySof® IQ ReSTOR® patients was greater under normal light conditions than under low light conditions