PATIENT INFORMATION BROCHURE

AcrySof® IQ PanOptix® Trifocal IOL
Model TFNT00

AcrySof® IQ PanOptix® Toric Trifocal IOLs
Models TFNT30, TFNT40, TFNT50, TFNT60

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Introduction

This brochure is intended to help you and your surgeon decide what type of intraocular lens (IOL) to choose for your cataract surgery. If the lens in your eye gets so cloudy that it makes your vision worse, it is called a cataract. Cataract surgery can restore good vision by removing the cloudy lens from your eye and replacing it with a clear artificial lens or IOL. Your surgeon will explain the risks and possible benefits of cataract surgery and will describe the different kinds of IOL that are available. This brochure can help you to decide whether an Alcon AcrySof® IQ PanOptix® Trifocal IOL would be a good choice for you. You can also read about other possible choices in the section called "What types of IOLs are available for this procedure?".

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 quality of vision may decrease.

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 corneal astigmatism?

Astigmatism is a focusing error in the eye that results in blurred distance and/or near vision. In a normal eye, the cornea (front of the eye) has a round shape (like a basketball); therefore, the light rays entering the eye focus at a single point on the back of the eye (retina) to form a clear image. In an eye with corneal astigmatism, the cornea has an oblong shape (like an American football). As a result, the light rays do not focus at the same point on the retina and parts of an object may not appear clear. During your eye examination, your eye doctor will be able to tell you if you have corneal astigmatism.

What is an Intraocular Lens (IOL)?

An intraocular lens, commonly referred to as an IOL, is an artificial lens that is implanted into the eye to replace the natural lens when a cataract is removed. Figure 1, below, shows the basic parts of the human eye with an IOL.

In general, IOLs have two basic features. The optic portion is the round part of the IOL that focuses an image onto the back of your eye. Two arm-like structures called haptics are attached to the edge of the optic. The haptics help to maintain the location of the IOL in the eye.

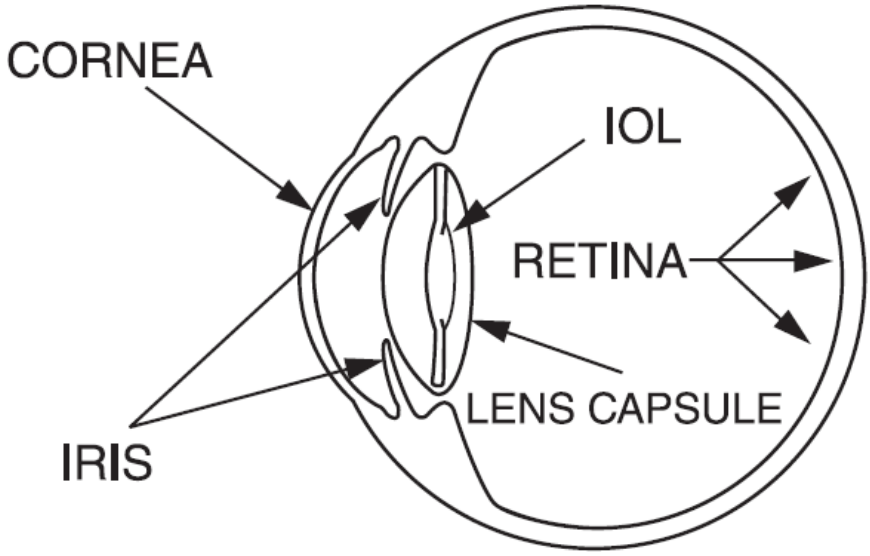

Figure 1 – Drawing of the Human Eye with an IOL

What is the surgical procedure to restore my vision?

After you and your eye doctor have decided that you will have your cataract removed, your eye will be measured (commonly referred to as biometry). This will help to determine the suitable IOL for you that will be placed in your eye during surgery.

When you arrive for surgery, you will be given eye drops and perhaps medicines to help you relax. Cataract surgery techniques vary widely. However, the eye is always numbed to make the operation painless. To perform surgery, your eye doctor will use a microscope to have a magnified view of your eye. Your natural lens sits in a bag-like structure called the lens capsule. The lens capsule is located just behind the colored part of your eye (iris). A small incision is made in the outer surface of the eye. Through this opening, the eye doctor removes the center part of the front of the lens capsule and then inserts a tiny instrument to break-up and remove the cataract. An IOL is then placed into the capsule to replace your natural lens that your eye doctor has just removed. The IOL will focus light inside the eye to allow you to see. 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.

Potential Risks Associated with Cataract Surgery

As with any surgery, there are risks and potential problems associated with routine cataract surgery and IOL placement. General surgery risks include reactions to medicines, bleeding, infection, inflammation, redness, scratchiness of the eye, sensitivity to light, and increased eye pressure. There is a small chance that your vision could be made worse by the operation. Please discuss these general risks associated with cataract surgery with your eye doctor.

What types of IOLs are available for this procedure?

There are many different lOLs to choose from. Some of the main types are described below. Your eye doctor will discuss your options, including AcrySof® IQ PanOptix® Trifocal IOLs and other IOLs. Discuss all of your IOL options with your eye doctor.

Monofocal IOLs

A monofocal IOL is designed to provide clear distance vision. This means you will usually be able to see objects far away, but there is still a small chance that you may need glasses for distance vision. You will most likely need glasses for near vision activities such as reading, writing, and sewing, as well as intermediate vision activities such as applying makeup or shaving, and working on a computer. These lenses do not correct for corneal astigmatism. Patients who have larger amounts of corneal astigmatism and who are implanted with a monofocal IOL may need glasses for distance vision.

Monofocal Toric IOLs

A monofocal toric IOL is designed to provide clear distance vision and correct corneal astigmatism. There are different models of monofocal toric IOLs for varying levels of corneal astigmatism. With a monofocal toric IOL, you will be able to see objects far away, but there is still a small chance that you may need glasses for distance vision. However, you will most likely still need glasses for near distance activities such as reading, writing, sewing as well as intermediate distance activities such as viewing a cell phone, applying makeup or shaving or working on a computer.

Multifocal IOLs

Multifocal IOLs allow for clear distance vision (e.g., for watching children playing in the backyard). The design of the IOL also allows for better near (reading) and intermediate (computer work) vision than a monofocal lens would provide. Different multifocal IOLs have different optical strengths for near vision. There is a chance you may still need glasses for distance, intermediate, and/or near vision. These lenses do not correct for corneal astigmatism.

Multifocal Toric IOLs

In addition to the benefits of the Multifocal IOLs, the Multifocal Toric IOLs provide corneal astigmatism correction. Most Multifocal IOLs are available in a non-toric and a toric version to allow for the full range of patients without or with pre-existing astigmatism. Like the other types of IOLs, there is a chance you may still need glasses for distance, intermediate, and/or near vision with a Multifocal Toric IOL.

Alcon AcrySof® IQ PanOptix® Trifocal IOLs

The AcrySof® IQ PanOptix® Trifocal IOL is a type of multifocal IOL and has the same basic shape and identical materials as Alcon AcrySof® monofocal and monofocal toric IOLs. Like a monofocal lens, the purpose of the AcrySof® IQ PanOptix® Trifocal IOL is to focus images clearly onto the back of your eye (retina) to allow clear vision after the cataract removal. In addition, the center

of the AcrySof® IQ PanOptix® Trifocal IOL allows for better near (reading) vision and intermediate (computer work) vision versus what a monofocal lens would provide.

The AcrySof® IQ PanOptix® Trifocal IOL is offered in five models (TFNT00, TFNT30, TFNT40, TFNT50, TFNT60). All models provide similar distance, better intermediate, and better near vision compared to monofocal IOLs.
The most appropriate model will be chosen by your surgeon based on the amount of your corneal astigmatism, including Model TFNT00 if you have no corneal astigmatism (this model does not correct for corneal astigmatism).

There is a chance that you still may need glasses for distance, intermediate, and/or near vision. You will get the full benefit of the AcrySof® IQ PanOptix® Trifocal IOL when it is placed in both eyes. Please discuss with your eye doctor whether this is the right IOL for you.

Potential Side Effects Associated with AcrySof® IQ PanOptix® Trifocal IOLs

Due to the design of multifocal IOLs, there are some side effects that can be associated with the AcrySof® IQ PanOptix® Trifocal IOL models. These may be worse than with a monofocal IOL, including visual disturbances such as glare, rings around lights, starbursts (rays around light sources), and reduced contrast sensitivity (decrease in ability to distinguish objects from their background, especially in dim lighting). These side effects may make it more difficult to see while driving at night or completing tasks in low lighting conditions such as at night or in fog, or in a dimly lit room after surgery as compared to before surgery**.**

Further, a toric IOL corrects astigmatism only when it is placed in the correct position in the eye. There is a possibility that the toric IOL could be placed incorrectly or could move within the eye. If the toric lens is not positioned correctly following surgery, the change in your astigmatism correction by the IOL, along with any necessary correction with glasses, may cause visual distortions. If the lens rotates in your eye, you may need additional surgery to reposition or replace the IOL.

Clinical study results

A human clinical study comparing AcrySof® IQ PanOptix® Trifocal IOL Model TFNT00 (without the toric feature for correcting corneal astigmatism) against a monofocal lens, the AcrySof Monofocal IOL Model SN60AT was conducted in the United States. Important results from this study are provided are described below:

Overall Impact on Vision:
The clinical study involved testing with both eyes as well as testing on each eye one at a time. Results from are provided in Table 1.

Table 1. Comparison of Study Results between AcrySof® IQ PanOptix® IOL Model TFNT00 and AcrySof® Monofocal IOL Model SN60AT at 6 months After Surgery.

	PanOptix® IOL		Monofocal IOL	
	Percentage of patients who achieved approximately 20/25 or better vision*		Percentage of patients who achieved approximately 20/25 or better vision*	
	One eye tested alone	Both eyes tested together	One eye tested alone	Both eyes tested together
Distance Vision without glasses (driving, playing golf, etc.)	72%	92%	84%	100%
Distance Vision with glasses (driving, playing golf, etc.)	98%	100%	99%	100%
Intermediate Vision without glasses eyes (computer work, cooking, etc.) at approximately 26 inches.	71%	94%	28%	51%
Intermediate Vision with glasses for distance (computer work, cooking, etc.) at approximately 26 inches.	81%	98%	7%	26%
Near Vision without glasses (reading, threading a needle, etc.) at approximately 16 inches.	65%	92%	2%	9%
Near Vision with glasses for distance (reading, threading a needle, etc.) at approximately 16 inches.	76%	96%	0%	0%

* On an eye chart, reading all the letters on the 20/25 line with no mistakes means you have 20/25 or better vision. Reading the majority of the 20/25 line correctly means you have approximately 20/25 or better vision.

Need for Eyeglasses*: Patients were asked about how often they needed glasses overall and their responses are presented in Table 2.

Table 2.Need for Eyeglasses*

Frequency	**Percentage of patients who reported wearing glasses Overall**	
	PanOptix® IOL 129 patients	**Monofocal IOL 114 patients**
Never	80.5%	8.2%

* "Eyeglasses" also mean bifocals, "readers", contact lenses or prescription sunglasses.

Adverse events: Collective serious adverse events in the eye for the AcrySof® IQ PanOptix® Trifocal IOL and the AcrySof® Monofocal IOL Model SN60AT are presented in table 3.

Table 3.

PanOptix® IOL	**Monofocal IOL**
4 out of 129 patients reported having serious adverse events: Adverse events related to cataract surgery but not the PanOptix® IOL: • One patient had swelling in the retina which was treated with medication and recovered. This patient also required a second surgical procedure to reposition the IOL due to a tilted IOL, which recovered after the surgery. • One patient had a tear of the retina that recovered without any treatment. • One patient had vitreous (gelatinous tissue filling the eyeball behind the lens) enter the front part of the eye, which needed to be removed with a second surgical procedure. The patient recovered after surgery. Adverse event related to PanOptix® IOL but not the cataract surgery: • One patient required a second surgery to remove the IOL due to complaints of dissatisfaction with level of vision. The patient recovered after surgery.	2 out of 114 patients reported having serious adverse events: Adverse events not related to the Monofocal IOL or cataract surgery: • One patient had age-related macular degeneration and needed medication injected in both eyes to treat abnormal blood vessel growth in the back of the eye. The patient recovered after the procedure. Adverse events related to cataract surgery but not the Monofocal IOL: • One patient needed a second surgical procedure to remove the IOL from the eye because a tear in the capsule (bag-like structure) holding the IOL caused the IOL to not be centered in the eye. The patient recovered after the surgery.

Contrast Sensitivity:

Contrast sensitivity, an important measure of visual function, is the ability to distinguish objects from their background, especially in dim lighting. In patients who received the AcrySof® IQ PanOptix® Trifocal IOL Model TFNT00, contrast sensitivity was well maintained, regardless of lighting conditions or the presence of glare. Results of this study indicate that contrast sensitivity was slightly worse in patients receiving the AcrySof® IQ PanOptix® Trifocal IOL Model TFNT00 compared to those who received the monofocal IOL.

Visual Disturbances:

Patients were asked "How Severe was your worst Experience?" Table 4 below shows the number of patients who reported their visual disturbances such as glare, rings around lights, starbursts to be severe. The rates of severe halos, starbursts, and glare were higher in the PanOptix® IOL group compared to the Monofocal IOL group. Patients were also asked to rate how much specific visual symptoms bothered them. Table 5 below shows the number of patients who reported being most bothered ("Bothered very much") by visual disturbances. Note that fewer patients were most bothered by the visual disturbance (less than 5%) than rated it severe.

Table 4. Rates of patients reporting their Visual Disturbances to be severe, per 100 patients, 6 months After Surgery

	PanOptix® IOL	**Monofocal IOL**
	6 Months	**6 Months**
Halos (rings around lights)	13%	1%
Starbursts (rays around light sources)	16%	2%
Glare	3%	2%
Blurred Vision (reduced sharpness in vision)	0%	0%
Hazy Vision (reduced contrast sensitivity)	0%	0%
Double Vision	0%	0%
Dark Areas	0%	0%

Table 5. Rates of patients reporting "Bothered very much" by certain Visual Disturbances, per 100 patients, 6 months After Surgery

	PanOptix® IOL	Monofocal IOL
	6 Months	6 Months
Halos (rings around lights)	2%	1%
Starbursts (rays around light sources)	5%	1%
Glare	2%	1%
Blurred Vision (reduced sharpness in vision)	0%	2%
Hazy Vision (reduced contrast sensitivity)	0%	1%
Double Vision	0%	0%
Dark Areas	0%	0%

Effect of Astigmatism remaining after cataract surgery

Some patients may have some level of astigmatism remaining after IOL placement, especially if they had a lot of astigmatism before surgery or if their AcrySof® IQ PanOptix® Toric Trifocal IOL was placed incorrectly or moved within the eye after surgery. The effect of this was studied by artificially creating astigmatism for patients using glasses. As with other multifocal IOLs, patients with large artificial levels of residual astigmatism showed reduced vision.

As with any multifocal toric IOL, if the IOL is not placed correctly in your eye or if the amount of remaining astigmatism after the surgery was calculated incorrectly :

- Your may have poor vision
- You may need to wear eye glasses to see clearly (for far, intermediate, and near distances)
- You may need a second surgical procedure to correct the position of your IOL

Other Clinical studies:

Alcon multifocal (AcrySof ReSTOR IOL Models MA60D3 and SA60D3) and multifocal toric IOLs (AcrySof IQ ReSTOR +3.0 D Multifocal Toric IOL Models SND1T3 to SND1T6) have been clinically studied. AcrySof® IQ PanOptix® Trifocal IOL and AcrySof® IQ PanOptix® Toric Trifocal IOL are modifications of these multifocal models. Therefore, the study completed on the previous models are applicable to AcrySof® IQ PanOptix® Trifocal IOLs with regards to the results described below.

A night driving simulation study was previously conducted on AcrySof ReSTOR IOL Models MA60D3 and SA60D3. Patients who received Alcon multifocal and monofocal IOLs were asked to assess the effects of various lighting conditions on their vision. The ability of multifocal IOL patients to detect and identify road signs and hazards at night was similar to the monofocal IOL patients under normal visibility conditions. Sign identification in fog and glare conditions were more challenging for the multifocal IOL patients compared to monofocal IOL patients. The ability to detect hazards was also lower for multifocal patients than for monofocal patients, especially when glare was present.

Warnings

- As with other multifocal IOLs, there is a possibility that you may experience very bothersome visual disturbances such as starbursts, halos and glare. This may cause you to be dissatisfied to the point of requesting removal of the IOL.
- It may be more difficult to see while driving at night or completing tasks in low lighting conditions such as at night or in fog, after surgery. Therefore, you should take extra care when driving at night.
- Your vision may not be as good with a multifocal IOL if you have irregular astigmatism (if before surgery it is determined that the front surface of your eye is irregular in shape).
- Your vision may not be as good if you choose the non-Toric AcrySof® IQ PanOptix® Trifocal IOL and have large amount of astigmatism before surgery and/or are expected to have a large amount of astigmatism after surgery.
- Your vision may not be as good if you choose AcrySof® IQ PanOptix® Toric Trifocal IOL and have a large amount of astigmatism after surgery.
- As with other IOLs, if there are unexpected results, there is a chance you may need to continue wearing eye glasses or may need a second surgical procedure to reposition your IOL.
- 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, significant itching, significant redness, watering of your eye, double vision persisting more than a few days, significant eye discharge, and increased sensitivity to light. These symptoms could indicate potential serious postoperative complications including, but not limited to, eye infection, increased intraocular pressure, retinal detachment, wound leak, allergic reaction to medications, or lens dislocation.
- Patients with pre-existing retinal problems that reduce their vision, such as macular degeneration or diabetic edema, may not benefit from or may have a poorer visual outcome following cataract surgery with multifocal IOL placement.

Please discuss all risks and benefits with your eye doctor before your surgery.

Precautions

- 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 (e.g., breathing difficulties, heart trouble, allergies, previous eye surgery) that may affect your surgery or vision.
- The safety and effectiveness of the AcrySof® IQ PanOptix® Trifocal IOL has not been established in patients with certain eye conditions, such as glaucoma or diabetic retinopathy (an increase in eye pressure or complications of diabetes in the eye). The outcome of cataract surgery will depend on the health of your eye before surgery. You should tell your eye doctor if you have been diagnosed as having amblyopia (lazy eye) or any other eye disease.
- The capsule (bag-like structure) that your IOL is placed in may become cloudy after cataract surgery. If this condition develops, it may affect your vision earlier if you receive the AcrySof®

IQ PanOptix® Trifocal IOL compared to someone who receives with a standard monofocal IOL.

- AcrySof® IQ PanOptix® Toric Trifocal IOL have not been evaluated in a clinical study. However, the effects of astigmatism remaining after the surgery has been studied using simulation techniques. As with any multifocal toric IOL, you may need eyeglasses to see clearly (for far, intermediate, and near distances) if you have a large amount of astigmatism after surgery. You should avoid any activity that could harm your eye while you are recovering from surgery. Your eye doctor will tell you what activities you should avoid.
- Take all prescribed medicines and apply eye drops as instructed.

You should tell your eye doctor of any eye problems or if you have been diagnosed with any eye condition.

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 eye drops to speed up the healing process and to prevent infection.

Your vision should improve within 4 to 6 weeks after cataract surgery. 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 so you can fully understand the recovery process after the cataract surgery. It may take you some time to get accustomed to your new IOL(s). Always consult your eye doctor if you have any questions or concerns as a result of cataract surgery.

Key points to remember regarding your choice

- Monofocal, multifocal, including toric and non-toric IOLs can restore your vision following cataract surgery.
- It is important to discuss your lifestyle or visual needs with your eye doctor to help select the most suitable IOL for you.
- There is a greater chance of experiencing starbursts, halos and glare with a Multifocal IOL as compared to a Monofocal IOL.

Thank you for considering the Alcon AcrySof® IQ PanOptix® Trifocal family of IOLs.

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