PATIENT INFORMATION BROCHURE

Alcon AcrySof® Toric

High Cylinder Power Intraocular Lenses

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Alcon AcrySof® Toric High Cylinder Power Intraocular Lenses

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Glossary

Aspheric IOL:	An artificial lens with an optic surface designed to enhance distance vision under low light conditions when a person wears full correction glasses. The lens is designed to benefit a person with an average corneal shape.
Astigmatism:	Astigmatism is a focusing error in the eye that results in blurred distance and/or near vision.
Cataract:	A clouding of the natural crystalline lens of the eye that interferes with vision.
Cornea:	The clear front part of the eye that focuses light into the eye.
Corneal Astigmatism:	The inability of the eye to focus clearly at any distance because of different curvatures on the cornea.
Crystalline lens:	The clear natural structure in the eye that helps to focus light on the back of the eye. The crystalline lens functions like the lens of a camera.
High Cylinder Power Toric IOL:	An artificial lens with an optic surface designed to correct high amounts of corneal astigmatism.
Intraocular Lens (IOL):	An artificial lens that replaces the natural crystalline lens of the eye after cataract surgery.

Iris:	The colored membrane in front of the natural crystalline lens that controls the size of the pupil and the amount of light entering the eye.
Monofocal IOL:	An artificial lens designed to restore only distance vision.
Retina:	The light-sensitive layer in the back part of the eye that receives images (light) and sends them to the brain for interpretation.
Toric IOL:	An artificial lens with an optic surface designed to correct corneal astigmatism.

Introduction

This brochure provides information about the Alcon AcrySof® Toric High Cylinder Power Intraocular Lenses (IOLs). These IOLs are designed to correct high corneal astigmatism, and restore distance vision after cataract surgery. Please read this entire brochure carefully and discuss the information with your eye doctor. Your eye doctor will advise you about the potential risks and benefits of cataract removal and IOL implantation. You should make sure that all of your questions are answered to your satisfaction. Please discuss with your eye doctor to determine if an AcrySof® Toric High Cylinder Power IOL would be the right lens for you.

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 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. High levels of corneal astigmatism may also be associated with visual distortions (e.g. objects

appear tilted or misshapen or floors appear curved). During your eye examination, your eye doctor will be able to tell you if you have corneal astigmatism.

What is a cataract?

Your eye functions much like a camera. Your natural crystalline lens focuses light onto the retina so you can see clearly, much like the lens of a camera focusing light onto film for a clear picture. At birth, your natural lens is clear. However, as you age, the lens becomes "cloudy" and eventually affects your ability to see clearly. This condition is called a cataract, and usually gets worse over time.

Surgery is the only way that a cataract can be removed. You should consider surgery when a cataract affects your vision enough to interfere with your daily activities.

What types of IOLs are available for cataract surgery?

The Alcon AcrySof® Toric High Cylinder Power IOL is one option for correcting high corneal astigmatism and distance vision after cataract surgery. There are other IOLs to choose from for distance vision, but some are not designed to correct astigmatism. Your eye doctor will discuss the IOL options available to you.

AcrySof® Toric High Cylinder Power IOL

The AcrySof® Toric High Cylinder Power IOL is designed to optically correct high corneal astigmatism and restore distance vision. There are different models of AcrySof® Toric High Cylinder Power IOL for varying levels of corneal astigmatism.

AcrySof® IQ Monofocal IOL

The AcrySof ® IQ Monofocal IOL is designed to restore distance vision but does not optically correct corneal astigmatism. This IOL also has an aspheric surface designed to enhance distance vision under low light conditions, when a person wears full correction glasses. The lens is designed to benefit a person with an average corneal shape.

Monofocal IOL

A monofocal IOL is designed to restore distance vision but does not optically correct corneal astigmatism.

IOL Performance Expectations

Performance expectations of each IOL are described in Table 1 below:

Table 1: Expected IOL Performance for Patients With High Astigmatism

Characteristic	Monofocal IOL	AcrySof® IQ Monofocal IOL	AcrySof® Toric High Cylinder Power IOL
Pre-existing Corneal Astigmatism	Is not designed to correct your pre-existing corneal astigmatism	Is not designed to correct your pre-existing corneal astigmatism	Designed to optically correct your pre-existing corneal astigmatism
Distance Vision	Your uncorrected distance vision will likely be blurred due to your uncorrected corneal astigmatism. You will likely need prescription glasses or contact lens correction to see clearly at distance.	Your uncorrected distance vision will likely be blurred due to your uncorrected corneal astigmatism. You will likely need prescription glasses or contact lens correction to see clearly at distance.	Your uncorrected distance vision will likely be clearer if your astigmatism is corrected.
Near Vision	A monofocal IOL is not designed to provide near vision. You will need astigmatism correcting prescription reading to clearly see objects up close or to read.	An aspheric monofocal IOL is not designed to provide near vision. You will need astigmatism correcting prescription reading glasses to clearly see objects up close or to read.	A toric IOL is not designed to provide near vision. You are less likely to need astigmatism correcting prescription glasses, but will still need reading glasses to clearly see objects up close or to read.

Enhanced Distance Vision	A monofocal IOL is not designed to provide the additional benefit of enhanced distance vision in low light environments.	An aspheric monofocal IOL is designed to provide the additional benefit of enhanced distance vision in low light environments, when a person wears full correction glasses. The lens is designed to benefit a person with an average corneal shape. However, you will need glasses or contact lens correction for your high corneal astigmatism to obtain this benefit.	A Toric IOL is not designed to provide the additional benefit of enhanced distance vision in low light environments.
Visual Distortions (i.e. straight lines look tilted and / or flat surfaces look curved)	You may experience visual distortions due to the optical correction of high astigmatism with glasses or contact lenses.	You may experience visual distortions due to the optical correction of high astigmatism with glasses or contact lenses.	You may experience visual distortions in the event that the toric IOL rotates, is improperly positioned, or if you require distant vision glasses for uncorrected astigmatism.
Glasses Use	You will likely need prescription glasses or contact lenses for most daily tasks due to uncorrected high corneal astigmatism. You will likely also need prescription glasses to clearly see objects up close or to read.	You will likely need prescription glasses or contact lenses for most daily tasks due to uncorrected high corneal astigmatism. You will likely also need prescription glasses to clearly see objects up close or to read.	You may be able to function without glasses or contact lens correction for many daily tasks requiring distance vision. You will likely still need prescription glasses to clearly see objects up close or to read.

Please discuss the IOL options with your eye doctor to determine which type 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 risk that you should be aware of.

Warnings

1. Your eye doctor may not be able to implant the AcrySof® Toric High Cylinder Power IOL into your eye if you have complications during surgery (e.g. tissue damage that may cause the lens to rotate after surgery). Depending on your specific surgical complications your doctor may or may not be able to implant a different IOL during the same surgical procedure.

2. 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. These symptoms could indicate a potential serious eye infection.

Precautions

1. As with any surgical procedure, there is risk involved. Possible complications from cataract surgery include infection, damage to the lining of the cornea, separation of the retina from the layer of tissue at the back of the eye (retinal detachment), inflammation or swelling inside or outside the eye, damage to the iris (the colored part of your eye), and an increase in eye pressure. You may need additional surgery to reposition or replace the IOL, or to treat other surgery complications. Toric IOLs require surgical repositioning more often than non-toric IOLs.

2. Tell your eye doctor if you have been diagnosed with any eye disease. The safety and effectiveness of the AcrySof® Toric IOL has not been established in patients with pre-existing eye conditions and complications during surgery, 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.

3. You will need to wear glasses to benefit from an aspheric IOL designed to enhance distance vision under low light conditions, if you have any of the following:

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a. *Nearsightedness or farsightedness after surgery*: These conditions may result from errors in measurements before surgery, wrong lens power, or changes in the cornea in response to the surgery;
b. *Uncorrected astigmatism after surgery*: This condition may result from the same reasons as stated above. In addition, uncorrected astigmatism could also result from improper position of the IOL or if your corneal astigmatism is greater than the amount that can be corrected with the IOL.

4. 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.

5. Avoid any activity that could harm your eye while you are recovering from surgery.

Potential Risks

There are risks associated with cataract surgery. You may have reactions to medicines, and side effects include redness, scratchiness of the eye, and sensitivity to light. Possible complications from cataract surgery include infection, bleeding, inflammation, tissue damage, tissue swelling of the front or back of the eye, or an increase in eye pressure. If your lens is not in the correct position, your vision may also be affected and the normal flow of fluid within the eye may be blocked. Your vision may not improve or may get worse if these complications occur. You may require additional surgery to treat these side effects.

If you have high corneal astigmatism, you may notice that some objects appear tilted or misshapen or floors appear curved. These visual distortions may be present before cataract surgery but may remain after surgery if your astigmatism is not fully corrected or if the IOL is not in the proper position in your eye. It may take some time to adapt to your new IOL(s) and any changes in your astigmatism. Please discuss with your eye doctor about your vision and any symptoms after surgery.

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Your eye doctor may advise that you have a second surgery if the toric IOL is not properly positioned in your eye.

The overall risks associated with cataract surgery, compared to other types of surgeries, is relatively low. Toric IOLs require surgical repositioning more often than non-toric IOLs. Discuss any questions about the possible risks and benefits of cataract surgery and the AcrySof® Toric High Cylinder Power IOL with your eye doctor.

What to expect during cataract surgery?

Cataract surgery is a procedure to replace your cloudy natural crystalline lens with an intraocular lens implant. You should expect the following before, during, and after surgery.

Before Surgery

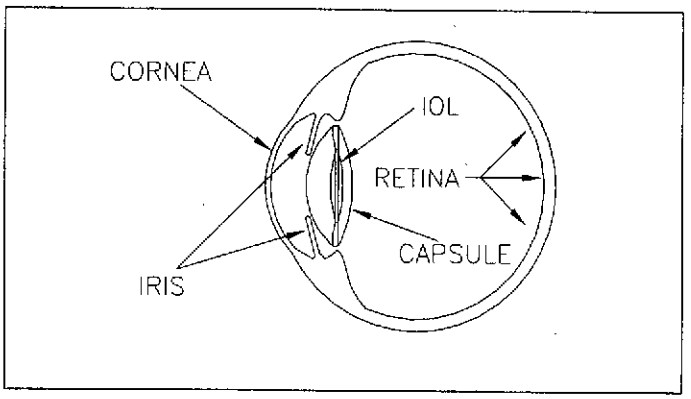
You will need a thorough eye examination. Be sure to tell your eye doctor about any problems about your vision or general health. Your eye will be measured after you and your eye doctor have decided that you will have your cataract removed. This will determine your amount of corneal astigmatism and the IOL power that will be right for you. You should plan to have someone else drive you home.

Day of 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 to properly position the toric IOL. Your natural 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 on the clear front part of your eye (cornea) to reach and remove the cataract. An IOL is then placed into the capsule to replace your natural lens. The IOL will act in the same way as your natural lens to restore your distance vision. The eye doctor will usually place a shield over your eye to protect it after surgery. After a short stay in the outpatient recovery area you will be ready to go home. Your eye doctor will let you know when your vision is good enough to drive again.

Below in Figure 1 shows the basic parts of the eye with an implanted IOL.

Figure 1 – Drawing of Eye with an Implanted IOL



After Surgery

After surgery, your eye doctor should give you a wallet card that identifies the type of implant in your eye. Typically, your eye doctor will examine you the following day. Many patients may see better within 1 to 2 days, most are stable at10 to 14 days, but some may take 4 to 6 weeks to fully recover from the surgery. Improvements in vision are different for each individual.

Take all prescribed medicines and apply antibiotic eye drops as instructed by your eye doctor. Be sure to consult your eye doctor if you have any questions or concerns as a result of cataract surgery.

Key points to remember regarding your choice

1. The Monofocal IOL, AcrySof® IQ Monfocal IOL and AcrySof® Toric High Cylinder Power IOLs all restore distance vision following cataract surgery. However, the AcrySof® Toric High Cylinder Power IOL is designed to also optically correct your high corneal astigmatism.

2. If reduced dependence on glasses is your desired outcome, you should consider the AcrySof® Toric High Cylinder Power IOL to correct high corneal astigmatism during cataract surgery.

3. Discussing your lifestyle or visual needs with your eye doctor can help determine which IOL is best for you.

Thank you for considering the AcrySof® Toric High Cylinder Power IOL.

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Fort Worth, Texas 76134-4630

PATIENT INFORMATION BROCHURE

Alcon AcrySof® IQ Toric

High Cylinder Power Intraocular Lenses

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Alcon AcrySof® IQ Toric High Cylinder Power Intraocular Lenses

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Glossary

Aspheric IOL: An artificial lens with an optic surface designed to enhance distance vision under low light conditions when a person wears full correction glasses. The lens is designed to benefit a person with an average corneal shape.

Astigmatism: Astigmatism is a focusing error in the eye that results in blurred distance and/or near vision.

Cataract: A clouding of the natural crystalline lens of the eye that interferes with vision.

Cornea: The clear front part of the eye that focuses light into the eye.

Corneal Astigmatism: The inability of the eye to focus clearly at any distance because of different curvatures on the cornea.

Crystalline lens: The clear natural structure in the eye that helps to focus light on the back of the eye. The crystalline lens functions like the lens of a camera.

High Cylinder Power Toric IOL: An artificial lens with an optic surface designed to correct high amounts of corneal astigmatism.

Intraocular Lens (IOL): An artificial lens that replaces the natural crystalline lens of the eye after cataract surgery.

Iris:	The colored membrane in front of the natural crystalline lens that controls the size of the pupil and the amount of light entering the eye.
Monofocal IOL:	An artificial lens designed to restore only distance vision.
Retina:	The light-sensitive layer in the back part of the eye that receives images (light) and sends them to the brain for interpretation.
Toric IOL:	An artificial lens with an optic surface designed to correct corneal astigmatism.

Introduction

This brochure provides information about the Alcon AcrySof® IQ Toric High Cylinder Power Intraocular Lenses (IOLs). These IOLs are designed to correct high corneal astigmatism, and restore distance vision after cataract surgery. Please read this entire brochure carefully and discuss the information with your eye doctor. Your eye doctor will advise you about the potential risks and benefits of cataract removal and IOL implantation. You should make sure that all of your questions are answered to your satisfaction. Please discuss with your eye doctor to determine if an AcrySof® IQ Toric High Cylinder Power IOL would be the right lens for you.

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 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. High levels of corneal astigmatism may also be associated with visual distortions (e.g. objects

appear tilted or misshapen or floors appear curved). During your eye examination, your eye doctor will be able to tell you if you have corneal astigmatism.

What is a cataract?

Your eye functions much like a camera. Your natural crystalline lens focuses light onto the retina so you can see clearly, much like the lens of a camera focusing light onto film for a clear picture. At birth, your natural lens is clear. However, as you age, the lens becomes "cloudy" and eventually affects your ability to see clearly. This condition is called a cataract, and usually gets worse over time.

Surgery is the only way that a cataract can be removed. You should consider surgery when a cataract affects your vision enough to interfere with your daily activities.

What types of IOLs are available for cataract surgery?

The Alcon AcrySof® IQ Toric High Cylinder Power IOL is one option for correcting high corneal astigmatism and distance vision after cataract surgery. There are other IOLs to choose from for distance vision, but some are not designed to correct astigmatism. Your eye doctor will discuss the IOL options available to you.

AcrySof® IQ Toric High Cylinder Power IOL

The AcrySof® IQ Toric High Cylinder Power IOL is designed to optically correct high corneal astigmatism and restore distance vision. There are different models of AcrySof® IQ Toric High Cylinder Power IOL for varying levels of corneal astigmatism. This IQ Toric IOL, also, incorporates an aspheric surface designed to enhance distance vision under low light conditions, when a person wears full correction glasses. The lens is designed to benefit a person with an average corneal shape.

AcrySof® IQ Monofocal IOL

The AcrySof ® IQ Monofocal IOL is designed to restore distance vision but does not optically correct corneal astigmatism. This IOL also has an aspheric surface designed to enhance distance vision under low light conditions, when a person wears full correction glasses. The lens is designed to benefit a person with an average corneal shape.

Monofocal IOL

A monofocal IOL is designed to restore distance vision but does not optically correct corneal astigmatism.

IOL Performance Expectations

Performance expectations of each IOL are described in Table 1 below:

Table 1: Expected IOL Performance for Patients With High Astigmatism

Characteristic	Monofocal IOL	AcrySof® IQ Monofocal IOL	AcrySof® IQ Toric High Cylinder Power IOL
Pre-existing Corneal Astigmatism	Is not designed to correct your pre-existing corneal astigmatism	Is not designed to correct your pre-existing corneal astigmatism	Designed to optically correct your pre-existing corneal astigmatism
Distance Vision	Your uncorrected distance vision will likely be blurred due to your uncorrected corneal astigmatism. You will likely need prescription glasses or contact lens correction to see clearly at distance.	Your uncorrected distance vision will likely be blurred due to your uncorrected corneal astigmatism. You will likely need prescription glasses or contact lens correction to see clearly at distance.	Your uncorrected distance vision will likely be clearer if your astigmatism is corrected.
Near Vision	A monofocal IOL is not designed to provide near vision.	An aspheric monofocal IOL is not designed to provide near vision.	An aspheric toric IOL is not designed to provide near vision.

Near Vision continued…	You will need astigmatism correcting prescription reading glasses to clearly see objects up close or to read.	You will need astigmatism correcting prescription reading glasses to clearly see objects up close or to read.	You are less likely to need astigmatism correcting prescription glasses, but will still need reading glasses to clearly see objects up close or to read.
Enhanced Distance Vision	A monofocal IOL is not designed to provide the additional benefit of enhanced distance vision in low light environments.	An aspheric monofocal IOL is designed to provide the additional benefit of enhanced distance vision in low light environments, when a person wears full correction glasses. The lens is designed to benefit a person with an average corneal shape. However, you will need glasses or contact lens correction for your high corneal astigmatism to obtain this benefit.	An aspheric toric IOL is designed to provide the additional benefit of enhanced distance vision in low light environments, when a person wears full correction glasses. The lens is designed to benefit a person with an average corneal shape. However, if you still need glasses for distance vision you will need to wear them to obtain this benefit.
Visual Distortions (i.e. straight lines look tilted and / or flat surfaces look curved)	You may experience visual distortions due to the optical correction of high astigmatism with glasses or contact lenses.	You may experience visual distortions due to the optical correction of high astigmatism with glasses or contact lenses.	You may experience visual distortions in the event that the toric IOL rotates, is improperly positioned, or if you require distant vision glasses for uncorrected astigmatism.
Glasses Use	You will likely need prescription glasses or contact lenses for most daily tasks due to uncorrected high corneal astigmatism.	You will likely need prescription glasses or contact lenses for most daily tasks due to uncorrected high corneal astigmatism.	You may be able to function without glasses or contact lens correction for many daily tasks requiring distance vision.

	You will likely also need prescription glasses to clearly see objects up close or to read.	You will likely also need prescription glasses to clearly see objects up close or to read.	You will likely still need prescription glasses to clearly see objects up close or to read.

Please discuss the IOL options with your eye doctor to determine which type 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 risk that you should be aware of.

Warnings

1. Your eye doctor may not be able to implant the AcrySof® IQ Toric High Cylinder Power IOL into your eye if you have complications during surgery (e.g. tissue damage that may cause the lens to rotate after surgery). Depending on your specific surgical complications your doctor may or may not be able to implant a different IOL during the same surgical procedure.

2. 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. These symptoms could indicate a potential serious eye infection.

Precautions

1. As with any surgical procedure, there is risk involved. Possible complications from cataract surgery include infection, damage to the lining of the cornea, separation of the retina from the layer of tissue at the back of the eye (retinal detachment), inflammation or swelling inside or outside the eye, damage to the iris (the colored part of your eye), and an increase in eye pressure. You may need additional surgery to reposition or replace the IOL, or to treat other surgery complications. Toric IOLs require surgical repositioning more often than non-toric IOLs.

2. Tell your eye doctor if you have been diagnosed with any eye disease. The safety and effectiveness of the AcrySof® IQ Toric IOL has not been established in patients with pre-

existing eye conditions and complications during surgery, 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.

3. You will need to wear glasses to benefit from an aspheric IOL designed to enhance distance vision under low light conditions, if you have any of the following:
   a. *Nearsightedness or farsightedness after surgery*: These conditions may result from errors in measurements before surgery, wrong lens power, or changes in the cornea in response to the surgery;
   b. *Uncorrected astigmatism after surgery*: This condition may result from the same reasons as stated above. In addition, uncorrected astigmatism could also result from improper position of the IOL or if your corneal astigmatism is greater than the amount that can be corrected with the IOL.

4. 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.

5. Avoid any activity that could harm your eye while you are recovering from surgery.

Potential Risks

There are risks associated with cataract surgery. You may have reactions to medicines, and side effects include redness, scratchiness of the eye, and sensitivity to light. Possible complications from cataract surgery include infection, bleeding, inflammation, tissue damage, tissue swelling of the front or back of the eye, or an increase in eye pressure. If your lens is not in the correct position, your vision may also be affected and the normal flow of fluid within the eye may be blocked. Your vision may not improve or may get worse if these complications occur. You may require additional surgery to treat these side effects.

If you have high corneal astigmatism, you may notice that some objects appear tilted or misshapen or floors appear curved. These visual distortions may be present before cataract surgery but may remain after surgery if your astigmatism is not fully corrected or if the IOL is not in the proper position in your eye. It may take some time to adapt to your new IOL(s) and any changes in your astigmatism. Please discuss with your eye doctor about your vision and any symptoms after surgery.

Your eye doctor may advise that you have a second surgery if the toric IOL is not properly positioned in your eye.

The overall risks associated with cataract surgery, compared to other types of surgeries, is relatively low. Toric IOLs require surgical repositioning more often than non-toric IOLs. Discuss any questions about the possible risks and benefits of cataract surgery and the AcrySof® IQ Toric High Cylinder Power IOL with your eye doctor.

What to expect during cataract surgery?

Cataract surgery is a procedure to replace your cloudy natural crystalline lens with an intraocular lens implant. You should expect the following before, during, and after surgery.

Before Surgery

You will need a thorough eye examination. Be sure to tell your eye doctor about any problems about your vision or general health. Your eye will be measured after you and your eye doctor have decided that you will have your cataract removed. This will determine your amount of corneal astigmatism and the IOL power that will be right for you. You should plan to have someone else drive you home.

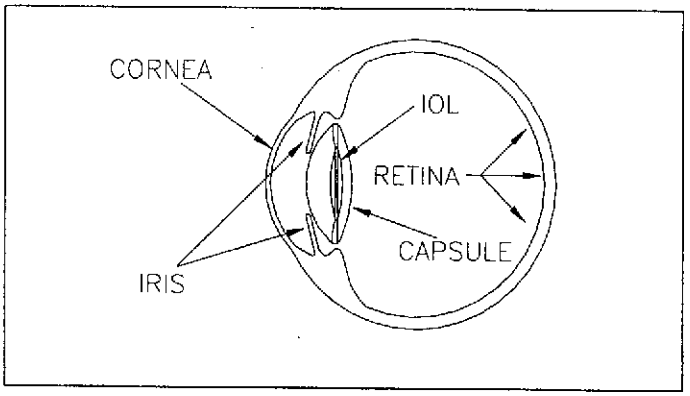
Day of Surgery

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 to properly position the toric IOL. Your natural 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 on the clear front part of your eye (cornea) to reach and remove the cataract. An IOL is then placed into the capsule to replace your natural lens. The IOL will act in the same way as your natural lens to restore your distance vision. The eye doctor will usually place a shield over your eye to protect it after surgery. After a short stay in the outpatient recovery area you will be ready to go home. Your eye doctor will let you know when your vision is good enough to drive again.

Below in Figure 1 shows the basic parts of the eye with an implanted IOL.

Figure 1 – Drawing of Eye with an Implanted IOL



After Surgery

After surgery, your eye doctor should give you a wallet card that identifies the type of implant in your eye. Typically, your eye doctor will examine you the following day. Many patients may see better within 1 to 2 days, most are stable at10 to 14 days, but some may take 4 to 6 weeks to fully recover from the surgery. Improvements in vision are different for each individual.

Take all prescribed medicines and apply antibiotic eye drops as instructed by your eye doctor. Be sure to consult your eye doctor if you have any questions or concerns as a result of cataract surgery.

Key points to remember regarding your choice

1. Both the AcrySof® IQ Monofocal and AcrySof® IQ Toric High Cylinder Power IOLs restore distance vision following cataract surgery. However, the AcrySof® IQ Toric High Cylinder Power IOL is designed to also optically correct your high corneal astigmatism.

2. If reduced dependence on glasses or enhanced distance vision is your desired outcome, you should consider the AcrySof® IQ Toric High Cylinder Power IOL to correct high corneal astigmatism during cataract surgery.

3. Discussing your lifestyle or visual needs with your eye doctor can help determine which IOL is best for you.

Thank you for considering the AcrySof® IQ Toric High Cylinder Power IOL.

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PRODUCT INFORMATION

Alcon Laboratories, Inc.

AcrySof TORIC
Single-Piece Natural IOL

STERILE UV and Blue Light Filtering Acrylic Foldable Toric Optic Single-Piece Posterior Chamber Lenses

CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

DESCRIPTION

The AcrySof® Toric Posterior Chamber Intraocular Lens (IOL) is a UV-absorbing foldable intraocular lens (IOL). These IOLs have a biconvex toric optic with cylinder axis marks to denote the flat meridian (plus cylinder axis). The single-piece design (see Figure 1 and Table 1) consists of a high refractive index material with proprietary blue light filtering chromophore which filters light in a manner that approximates the human crystalline lens in the 400-475 nm blue light wavelength range (Boettner and Wolter, 1962). In addition to standard UV-light filtering, the blue-light filtering chromophore reduces transmittance of blue light wavelengths (see Table 2). The biconvex toric optic consists of a high refractive index soft acrylic material capable of being folded prior to insertion, allowing placement through an incision smaller than the optic diameter of the lens. After surgical insertion into the eye, the lens gently unfolds to restore the optical performance. The supporting haptics provide for proper positioning and fixation of the IOL optic within the eye.

Figure 1: Physical Characteristics of AcrySof® Toric IOLs
(All dimensions in millimeters)

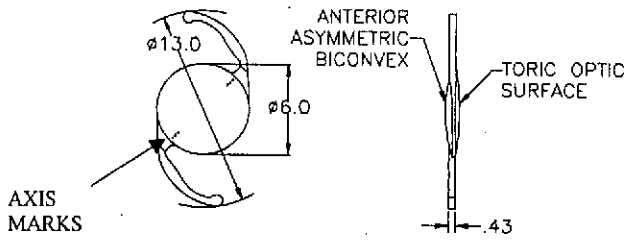
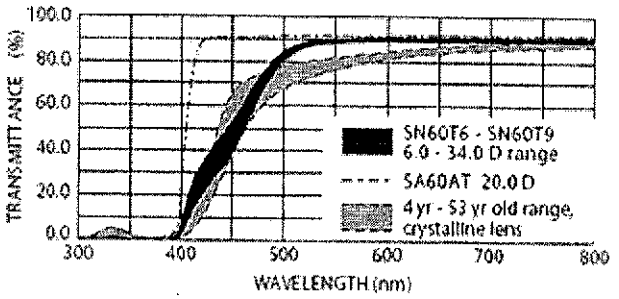


Table 1:
Physical Characteristics of AcrySof® Toric IOLs

Characteristics	Model			
	SN60T6	SN60T7	SN60T8	SN60T9
Optic Type	Biconvex Toric Optic			
Optic / Haptic Material	Ultraviolet and blue light filtering Acrylate/Methacrylate Copolymer UV cutoff at 10% T: 399 nm (+6.0 diopter lens) 407 nm (+34.0 diopter lens)			
IOL Powers (spherical equivalent diopters)	For available power range see Alcon Product Guide			
IOL Cylinder Power (Diopters)	3.75 D	4.50 D	5.25 D	6.00 D
Index Of Refraction	1.55			
Haptic Configuration	STABLEFORCE®			
Optic Diameter (mm)	6.0			
Overall Length (mm)	13.0			
Haptic Angle	0°			

Figure 2
SPECTRAL TRANSMITTANCE CURVES
(PERCENTAGE OF ULTRAVIOLET TRANSMITTANCE)



NOTE:
• Human lens data from Boettner and Wolter (1962).

Table 2
Average % Transmittance Comparison

Model	400 nm	425 nm	450 nm	475 nm
SA60AT	21	86	88	88
SN60T9	6	31	47	67
Transmittance Difference (SA60AT –SN60T9)	15	55	41	21
Transmittance Reduction with SN60T9 (% of SA60AT)	71	64	47	24

MODE OF ACTION

AcrySof® Toric IOLs are intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. These IOLs have a biconvex toric optic with cylinder axis marks to denote the flat meridian (plus cylinder axis). Alignment of the toric IOL cylinder axis marks with the post-operative steep corneal meridian allows the lens to correct astigmatism.. The astigmatic correction at the corneal plane for AcrySof® Toric intraocular lenses is shown in Table 3:

Table 3

Model	IOL Cylinder Power (diopters)	Cylinder Power at Corneal Plane (diopters)*
SN60T6	3.75	2.57
SN60T7	4.50	3.08
SN60T8	5.25	3.60
SN60T9	6.00	4.11

*Based on an average pseudophakic human eye

INDICATIONS

The AcrySof® Toric posterior chamber intraocular lenses are intended for primary implantation in the capsular bag of the eye for visual correction of aphakia and pre-existing corneal astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia, who desire improved uncorrected distance vision, reduction of residual refractive cylinder and increased spectacle independence for distance vision.

WARNINGS

1. This lens should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned.
2. Rotation of AcrySof® Toric IOLs away from their intended axis can reduce their astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, lens repositioning should occur as early as possible prior to lens encapsulation. Some clinical cases suggest encapsulation is complete within four weeks of implantation.
3. Carefully remove all viscoelastic from both the anterior and posterior sides of the lens. Residual viscoelastic may allow the lens to rotate causing misalignment of the AcrySof® Toric IOL with the intended axis of placement.

PRECAUTIONS

1. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon for this product informing them of possible risks and benefits associated with the AcrySof® Toric High Cylinder Power IOLs
2. A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.
3. As with any surgical procedure, there are risks involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, transient or persistent glaucoma and secondary surgical intervention. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspirations or iridectomy for pupillary block, wound leak repair, and retinal detachment repair.

4. The safety and effectiveness of the Toric intraocular lens have not been substantiated in patients with the following preexisting ocular conditions and intraoperative complications (see below). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions.

Before Surgery
- Choroidal hemorrhage
- Chronic severe uveitis
- Concomitant severe eye disease
- Extremely shallow anterior chamber
- Medically uncontrolled glaucoma
- Microphthalmos
- Non-age-related cataract
- Proliferative diabetic retinopathy (severe)
- Severe corneal dystrophy
- Severe optic nerve atrophy
- Irregular corneal astigmatism
- Color vision deficiencies

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g. glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optical nerve diseases) has not been studied.

During Surgery
- Excessive vitreous loss
- Capsulotomy by any technique other than a circular tear
- The presence of radial tears known or suspected at the time of surgery
- Situations in which the integrity of the circular tear cannot be confirmed by direct visualization
- Cataract extraction by techniques other than phacoemulsification or liquefaction
- Situations where the need for a large capsulotomy can be anticipated (e.g., diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.)
- Capsular rupture
- Significant anterior chamber hyphema
- Uncontrollable positive intraocular pressure
- Zonular damage

5. Some adverse reactions which have been associated with the implantation of intraocular lenses are: hypopyon, intraocular infection, acute corneal decompensation and secondary surgical intervention. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration or iridectomy for pupillary block, wound leak repair and retinal detachment repair.
6. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such problems. The physician must determine the benefits to be derived from lens implantation when such conditions exist.
7. DO NOT store the IOL at temperatures over 45° C (113° F).
8. DO NOT reuse the IOL. This IOL is for single use only.
9. DO NOT resterilize the IOL by any method.
10. Use only sterile intraocular irrigating solutions such as BSS® or BSS PLUS® to rinse and/or soak lenses.
11. Accurate keratometry and biometry in addition to the use of the Toric Calculator (www.acrysoftoriccalculator.com) are recommended to achieve optimal visual outcomes.
12. Optical theory suggests that high astigmatic patients may experience spatial distortions. Possible toric IOL related factors may include residual cylindrical error or axis misalignments.

CALCULATION OF LENS POWER

Accurate keratometry and biometry is essential to successful visual outcomes. Preoperative calculation of the required spherical equivalent lens power for these posterior chamber intraocular lenses should be determined by the surgeon's experience, preference, and intended lens placement. The A-constant listed on the outer label is presented as a guideline and is a starting point for implant power calculations. This provisional A-constant has been theoretically derived. Lens constants must be "personalized" to compensate for the differences in instrumentation, measurement technique, and IOL power calculation methods. A convenient initial estimate can be obtained by referencing to the personalized lens constant for a similar lens model (e.g. AcrySof® Toric IOL Models SN60T3, SN60T4, or SN60T5).

AcrySof® Toric IOLs are labeled with the IOL spherical equivalent power. The results obtained from the calculation formulas listed below should not be modified, as they result in the appropriate power consistent with the labeling of the AcrySof® Toric IOL. Lens power calculation methods are described in the following references:

Hoffer, K.J. The Hoffer Q formula: A comparison of theoretic and regression formulas. *J. Cataract Refract. Surg.* 19:700-712, 1993.

Holladay, J.T., *et al.* A three-part system for refining intraocular lens power calculations. *J. Cataract Refract. Surg.* 14:17-24, 1988.

Holladay, J.T., et al., Standardizing constants for ultrasonic biometry, keratometry, and IOL power calculations, *J. Cataract Refract. Surg.* 23:1356-1370, 1997.

Retzlaff, J.A., Sanders, D.R., and Kraff, M. *Lens Implant Power Calculation*, 3rd ed., Slack, Inc., Thorofare, N.J., 1990.

DIRECTIONS FOR USE

1. Examine the label on the unopened package for model, power (spherical equivalent and cylinder), and expiration date.
2. After opening the cardboard storage container verify lens case information (model, power, and serial number) is consistent with information on outer package labeling.
3. This device is sterile until the inner pouch is opened. Inspect the pouch carefully for tears, cuts, punctures or other signs that the pouch has been opened or damaged. DO NOT implant the IOL if the sterility has been compromised. (See RETURNED GOODS POLICY).
4. To remove the lens, open the undamaged pouch and transfer the case to a sterile environment. Carefully open the case to expose the lens.
5. To minimize the occurrence of marks on the lens due to handling, all instrumentation should be scrupulously clean. Any forceps used for lens handling must have round edges and smooth surfaces.
6. When removing the lens from the case, DO NOT grasp the optical area with forceps. The IOL should only be handled by the haptics. Handle the lenses carefully to avoid damage to lens surfaces or haptics. DO NOT attempt to reshape haptics in any way.
7. Rinse the lens thoroughly using sterile intraocular irrigating solution such as BSS® or BSS PLUS®. DO NOT rinse the IOL in solutions other than sterile intraocular irrigating solution. Prior to insertion, the IOL should be carefully examined to ensure that particles have not adhered during handling.
8. Alcon recommends using the MONARCH® III delivery system, or equivalent Alcon approved delivery system.
9. There are various surgical procedures that can be utilized, and the surgeon should select a procedure that is appropriate for the patient. Current techniques, appropriate instrumentation, and a list of their equivalents for delivery and implantation are available from Alcon. Surgeons should verify that appropriate instrumentation is available prior to surgery.

Selection and Placement of the AcrySof® Toric

The astigmatism to be corrected should be determined from keratometry and biometry data rather than refractive data since the presence of lenticular astigmatism in the crystalline lens to be removed may influence results. The size and location of the surgical incision may affect the amount and axis of corneal astigmatism. In order to optimize IOL selection and axis placement, Alcon provides a proprietary web-based tool (www.acrysoftoriccalculator.com) for the surgeon. Pre-operative keratometry and biometry data, incision location, and the surgeon's estimated surgically induced corneal astigmatism are used to determine the appropriate AcrySof® Toric IOL model, spherical equivalent lens power, and axis of placement in the eye.

For optimal results, the surgeon must ensure the correct placement and orientation of the lens within the capsular bag. The posterior surface of the IOL is marked with indentations (three at each end) at the haptic/optic junction that identify the flat meridian of the AcrySof® Toric optic. These indentations form an imaginary line representing the plus cylinder axis (note: IOL cylinder steep meridian is 90° away). The AcrySof® Toric IOL cylinder axis marks should be aligned with the post-incision steep corneal meridian (intended axis of placement).

Prior to surgery the operative eye should be marked with at least two reference points (e.g. three o'clock and nine o'clock positions) while the patient is sitting upright to prevent cyclotorsion. Using these marks as reference points, an axis marker can be used immediately prior to or during surgery to mark the axis of lens placement following the use of the Toric IOL calculator to determine the optimal axis of placement.

After the lens is inserted, precisely align the axis marking indentations on the AcrySof® Toric IOL with the marked axis of lens placement. Carefully remove all viscoelastic from both the anterior and posterior sides of the lens. This may be accomplished by manipulating the IOL optic with the I/A tip and using standard irrigation/aspiration techniques to remove all viscoelastic from the eye. Bimanual techniques may be used, if preferred, to ensure removal of viscoelastic from behind the lens implant. Special care should be taken to ensure proper positioning of the AcrySof® Toric IOL at the intended axis following viscoelastic removal. Residual viscoelastic may allow the lens to rotate causing misalignment of the AcrySof® Toric IOL with the intended axis of placement.

Misalignment of the axis of the lens with the intended axis of placement may compromise its astigmatic correction. Such misalignment can result from inaccurate keratometry or marking of the cornea, inaccurate placement of the AcrySof® Toric IOL axis during surgery, an unanticipated surgically induced change in the cornea, or physical rotation of the AcrySof® Toric IOL after implantation. In order to minimize this effect, the surgeon should be careful to ensure that preoperative keratometry and biometry is accurate and that the IOL is properly oriented prior to the end of surgery.

PATIENT REGISTRATION AND REPORTING

FDA requirement for US implanting surgeons only: Each patient must be registered with Alcon Laboratories, Inc. immediately following implantation of one of these lenses. Registration is accomplished by completing the prepaid Implant Registration Card that is enclosed in the lens box and mailing it to Alcon Laboratories, Inc. Patient registration is essential for Alcon Laboratories, Inc. long-term patient follow-up program and will assist us in responding to adverse event reports. The Patient Identification Card included in the package 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 care practitioner the patient consults in the future.

Adverse events 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 Alcon Laboratories, Inc. This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation. Surgeons should use the following address and telephone number for reporting adverse events involving these intraocular lenses:

Alcon Laboratories, Inc., Medical Safety (AB2-6)
6201 South Freeway, Fort Worth, Texas 76134.
Call Toll-Free (800) 757-9780 or Collect: (817) 551-4445.

Outside the United States, contact local Alcon offices or distributors regarding any reports of adverse events.

OVERVIEW OF AcrySof® SINGLE-PIECE STUDIES

The following clinical studies were conducted on the AcrySof® Single-Piece Intraocular Lenses:

1. AcrySof® NATURAL SINGLE-PIECE IOL CLINICAL STUDY

A clinical study was conducted on patients receiving the AcrySof® Natural Single Piece IOL as compared to the AcrySof® UV Single Piece IOL. The results achieved by the patients successfully followed for a minimum of one year postoperatively provided reasonable assurance of safety and effectiveness for the visual correction of aphakia. For information pertaining to the results obtained in this clinical study, please reference the corresponding Physicians Labeling or that provided with other AcrySof® Natural monofocal IOLs.

2. AcrySof® NATURAL SINGLE-PIECE IOL COLOR PERCEPTION

Color perception testing using the Farnsworth D-15 Panel Test was conducted at the 120 to 180 day postoperative period. Of the 109 subjects with normal color vision implanted with the AcrySof® Natural IOL in the first operative eye and examined at the 120-180 day postoperative visit, 107 (98.2%) passed the color perception test. Of the 102 subjects with normal color vision implanted with a AcrySof® UV IOL in the first operative eye and examined at the 120-180 day postoperative visit, 97 (95.1%) passed the color perception test. There were no statistically significant differences between AcrySof® Natural IOL and AcrySof® UV IOL for the percent of subjects that passed the color perception test at the 120 to 180 day postoperative visit. Therefore, the addition of the proprietary chromophore does not negatively affect color vision in patients with normal color vision.

OVERVIEW OF AcrySof® TORIC INTRAOCULAR LENS CLNICAL STUDIES

The following clinical studies have been conducted on AcrySof® Toric Intraocular Lenses. In addition to the data from the recent high cylinder power clinical study, the clinical data from the original study of the AcrySof® Toric IOLs are also included in order to provide data intended to help you make an informed decision as to whether or not to implant a Toric IOL:

1. AcrySof® Toric Intraocular Lens Original Study, and
2. AcrySof® Toric High Cylinder Power Intraocular Lens Clinical Study

Summaries of each of the above clinical studies are provided below.

1. AcrySof® TORIC INTRAOCULAR LENS ORIGINAL CLINICAL STUDY

A clinical study was conducted to demonstrate the safety and effectiveness of the AcrySof® Toric Posterior Chamber Lens Model SA60TT (Models SA60T3, SA60T4, and SA60T5). This was a randomized clinical study that included the AcrySof® Model SA60AT as a control lens. Only data from the first operative eye from those subjects who received either a Model SA60TT or Model SA60AT intraocular lens are included.

Three different lens models of varying cylinder correction were evaluated in this clinical study. Collectively, the three models are referred to as Model SA60TT. The three different models evaluated and their applicable cylinder powers are listed below.

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Table 4

Model	Cylinder Power at IOL plane	Cylinder Power at corneal plane	Toric Web-based Calculator Recommended Corneal Astigmatism Correction Ranges
SA60T3	1.50	1.03	0.75 - 1.54 D
SA60T4	2.25	1.55	1.55 - 2.05 D
SA60T5	3.00	2.06	2.06 - 2.56 D

The recommended corneal astigmatism correction ranges are based on the preoperative corneal astigmatism and the predicted effect of 0.5 diopter surgically induced astigmatism for a standardized temporal incision. To obtain the IOL cylindrical powers and the orientation of the surgical placement of the axes, for each operative eye the preoperative keratometry values and axes, IOL spherical power (as determined by the surgeon's preferred formula) and the anticipated surgically induced astigmatism (SIA) at the standard temporal incision location are entered into Alcon's proprietary web-based AcrySof Toric IOL calculator. The combination of these parameters are used in Alcon provided software to select the appropriate Toric IOL model and recommended axis of placement. As such, the recommended range of corneal astigmatism to be corrected, while not identical, is directly related to, the preoperative keratometric cylinder.

The results achieved by the patients followed to six months postoperatively demonstrate that the AcrySof® Toric Posterior Chamber Lens Model SA60TT is a safe and effective device for the visual correction of aphakia. The following clinical results illustrate minimal rotation with excellent rotational stability leading to significant reduction or elimination of residual refractive cylinder and significantly improved uncorrected distance visual acuity which results in increased distance spectacle independence.

AcrySof® TORIC INTRAOCULAR LENS CLINICAL STUDY PATIENT POPULATION

The subject population implanted with a Model SA60TT in the first operative eye consists of 53.3% females and 46.7% males. The subject population implanted with the Model SA60AT (control) intraocular lens consists of 57.2% females and 42.8% males. Stratifying by race for the Model SA60TT population, 97.6% are Caucasian, 2.0% are Black and 0.4% are other. The control (SA60AT) population is 95.6% Caucasian, 1.6% Black, 1.2% Asian and 1.6% other. The mean age for the population receiving the Model SA60TT was 70.0 years. Similarly, the mean age for the population receiving the Model SA60AT (control) was 72.4 years.

AcrySof® TORIC INTRAOCULAR LENS UNCORRECTED DISTANCE VISUAL ACUITY

A summary of uncorrected distance visual acuity achieved for Models SA60TT and SA60AT at six months postoperatively is presented in Tables 5A and 5B respectively. These tables show 38.4% of subjects implanted with a Model SA60TT achieved uncorrected distance visual acuities of 20/20 or better compared to only 19.0% of those subjects implanted with the control lens Model SA60AT. Also, of the 211 subjects implanted with a Model SA60TT and examined at the Form 5 visit, 140 (66.4%) achieved an uncorrected distance visual acuity of 20/25 or better, compared to only 86 subjects (40.9%) implanted with the control Model SA60AT.

Table 5A

Uncorrected Distance Visual Acuity by Age Category, Status at Form 5 - Lens Model SA60TT, All Implanted

	Sample size	Acuity: 20/20 or better		20/25		20/32		20/40		Worse than 20/40		20/40 or better	
	N	n	%	n	%	n	%	n	%	n	%	n	%
Age Category													
<60	33	15	45.5	11	33.3	2	6.1	4	12.1	1	3.0	32	97.0
60-69	56	25	44.6	11	19.6	14	25.0	6	10.7	0	0	56	100.0
70-79	90	32	35.6	29	32.2	15	16.7	7	7.8	7	7.8	83	92.2
≥80	32	9	28.1	8	25.0	5	15.6	5	15.6	5	15.6	27	84.4
Total	211	81	38.4	59	28.0	36	17.1	22	10.4	13	6.2	198	93.8

Table 5B

Uncorrected Distance Visual Acuity by Age Category, Status at Form 5 - Lens Model SA60AT, All Implanted

	Sample size	Acuity: 20/20 or better		20/25		20/32		20/40		Worse than 20/40		20/40 or better	
	N	N	%	n	%	n	%	n	%	n	%	n	%
Age Category													
<60	15	2	13.3	6	40.0	2	13.3	1	6.7	4	26.7	11	73.3
60-69	54	14	25.9	10	18.5	13	24.1	5	9.3	12	22.2	42	77.8
70-79	92	18	19.6	16	17.4	12	13.0	28	30.4	18	19.6	74	80.4
≥80	49	6	12.2	14	28.6	10	20.4	5	10.2	14	28.6	35	71.4
Total	210	40	19.0	46	21.9	37	17.6	39	18.6	48	22.9	162	77.1

At the Form 5 visit, shown in Figure 3A, 93.8% of Model SA60TT subjects achieved 20/40 or better UCDVA (first operative eye of the All Implanted data set) compared to 77.1% of the subjects implanted with the control Model SA60AT. The difference in UCDVA between Models SA60TT and SA60AT was statistically significant (all p-values ≤ 0.0001) in favor of Model SA60TT.

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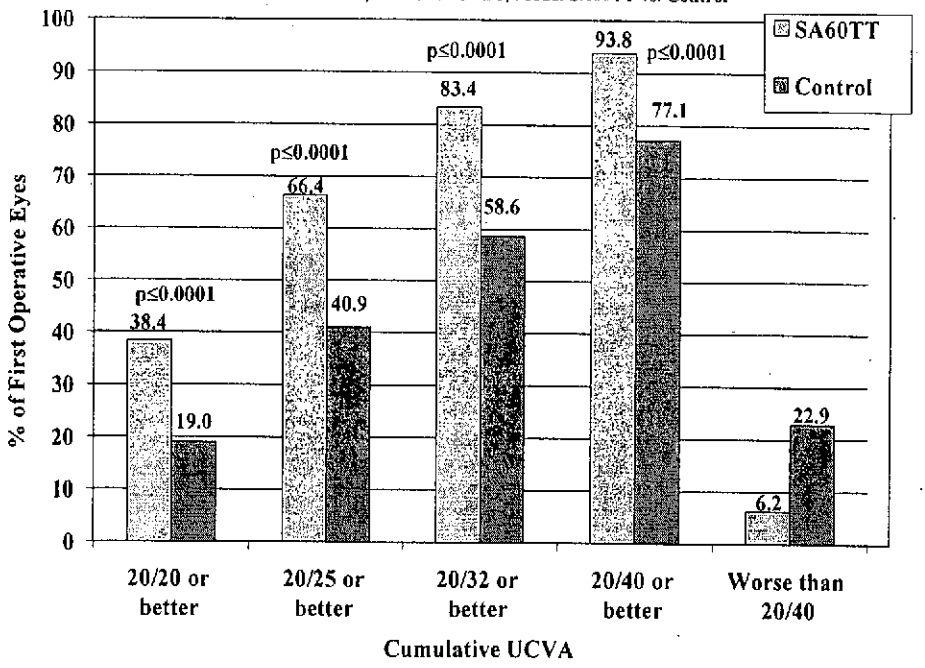
Figure 3A
Cumulative UCDVA, Status at Form 5, Model SA60TT vs. Control



Figures 3B – 3D show a summary of cumulative uncorrected distance visual acuities for each Toric IOL model compared to the control subjects in the same cylinder range. Figure 3B shows that the difference in cumulative UCDVA between Models SA60T3 and SA60AT was statistically significant (all p-values ≤ 0.0115) for each visual acuity category (20/20 or better, 20/25 or better, 20/32 or better and 20/40 or better) in favor of Model SA60T3.

Figure 3B
0 Cumulative UCDVA, Model SA60T3 vs. Control, Form 5, All Implanted

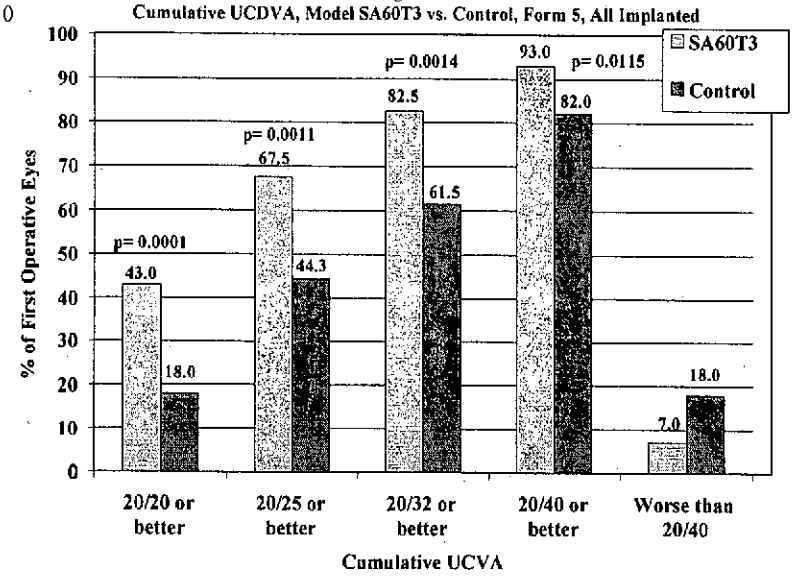


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Figure 3C shows that the difference in cumulative UCDVA between Models SA60T4 and SA60AT was statistically significant (all p-values ≤ 0.0082) for each visual acuity category (20/25 or better, 20/32 or better and 20/40 or better) in favor of Model SA60T4 with the exception of the 20/20 or better category.

Figure 3C
Cumulative UCDVA, Model SA60T4 vs. Control, Form 5, All Implanted

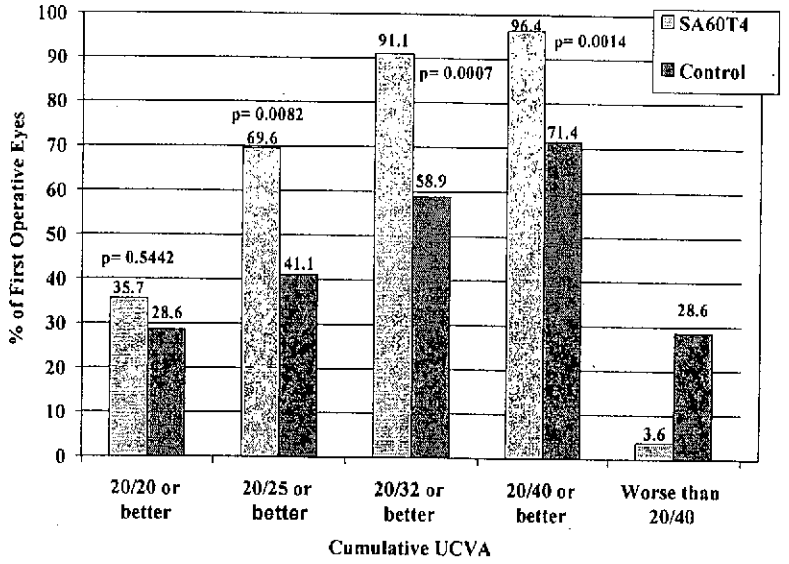
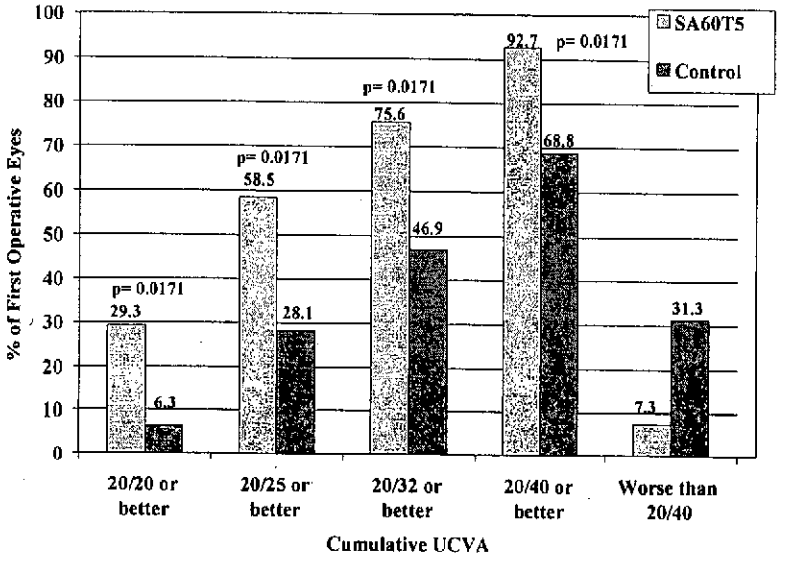


Figure 3D shows that the difference in cumulative UCDVA between Models SA60T5 and SA60AT was statistically significant (all p-values ≤ 0.0171) for each visual acuity category (20/20 or better, 20/25 or better, 20/32 or better and 20/40 or better) in favor of Model SA60T5.

Figure 3D
Cumulative UCDVA, Model SA60T5 vs. Control, Form 5, All Implanted



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AcrySof® TORIC INTRAOCULAR LENS BEST SPECTACLE DISTANCE CORRECTED VISUAL ACUITY

A summary of best spectacle corrected distance visual acuity (BSCDVA) achieved at six months postoperatively among subjects who did not have any visually significant preoperative pathology or macular degeneration at any time (Best Case) is presented in Table 6A. Visual acuity achieved by the overall subject population is shown in Table 6C. Control data are found for the same data sets in Tables 6B and 6D, respectively.

Of the first operative eyes implanted with a Model SA60TT and examined at the Form 5 visit, 100.0% achieved a BSCDVA of 20/40 or better in the Best Case dataset. These rates exceed the FDA grid rates of 96.7%.

Table 6A
BSCDVA by Age Category, Status at Form 5 - Lens Model SA60TT, Best Case

Age Category	Sample size	Acuity											
		20/20 or better		20/25		20/32		20/40		Worse than 20/40		20/40 or better	
	N	n	%	n	%	n	%	n	%	n	%	n	%
<60	29	27	93.1	1	3.4	1	3.4	0	0	0	0	29	100.0
60-69	51	42	82.4	7	13.7	2	3.9	0	0	0	0	51	100.0
70-79	73	57	78.1	13	17.8	3	4.1	0	0	0	0	73	100.0
≥80	20	14	70.0	4	20.0	1	5.0	1	5.0	0	0	20	100.0
Total	173	140	80.9	25	14.5	7	4.0	1	0.6	0	0	173	100.0

Table 6B
BSCDVA by Age Category, Status at Form 5 - Lens Model SA60AT, Best Case

Age Category	Sample size	Acuity											
		20/20 or better		20/25		20/32		20/40		Worse than 20/40		20/40 or better	
	N	n	%	n	%	n	%	n	%	n	%	n	%
<60	15	13	86.7	1	6.7	1	6.7	0	0	0	0	15	100.0
60-69	49	38	77.6	11	22.4	0	0	0	0	0	0	49	100.0
70-79	75	48	64.0	21	28.0	6	8.0	0	0	0	0	75	100.0
≥80	32	19	59.4	8	25.0	2	6.3	3	9.4	0	0	32	100.0
Total	171	118	69.0	41	24.0	9	5.3	3	1.8	0	0	171	100.0

Of the first operative eyes implanted with a Model SA60TT and examined at the Form 5 visit, 100.0% achieved a BSCDVA of 20/40 or better in the All Implanted dataset. These rates exceed the FDA grid rates of 92.5%.

Table 6C
BSCDVA by Age Category, Status at Form 5 - Lens Model SA60TT, All Implanted

Age Category	Sample size	Acuity											
		20/20 or better		20/25		20/32		20/40		Worse than 20/40		20/40 or better	
	N	n	%	n	%	n	%	n	%	n	%	n	%
<60	33	30	90.9	2	6.1	1	3.0	0	0	0	0	33	100.0
60-69	56	47	83.9	7	12.5	2	3.6	0	0	0	0	56	100.0
70-79	90	72	80.0	15	16.7	3	3.3	0	0	0	0	90	100.0
≥80	32	22	68.8	5	15.6	4	12.5	1	3.1	0	0	32	100.0
Total	211	171	81.0	29	13.7	10	4.7	1	0.5	0	0	211	100.0

Table 6D
BSCDVA by Age Category, Status at Form 5 - Lens Model SA60AT, All Implanted

Age Category	Sample size	Acuity											
		20/20 or better		20/25		20/32		20/40		Worse than 20/40		20/40 or better	
	N	n	%	n	%	n	%	n	%	n	%	n	%
<60	15	13	86.7	1	6.7	1	6.7	0	0	0	0	15	100.0
60-69	54	41	75.9	12	22.2	1	1.9	0	0	0	0	54	100.0
70-79	91	59	64.8	22	24.2	10	11.0	0	0	0	0	91	100.0
≥80	49	28	57.1	13	26.5	2	4.1	3	6.1	3	6.1	46	93.9
Total	209	141	67.5	48	23.0	14	6.7	3	1.4	3	1.4	206	98.6

Figures 4A – 4C show a summary of cumulative best corrected visual acuities for each Toric model compared to the control subjects in the same cylinder range for the All Implanted dataset.

Figure 4A
Cumulative BSCDVA, Model SA60T3 vs. Control, Form 5, All Implanted

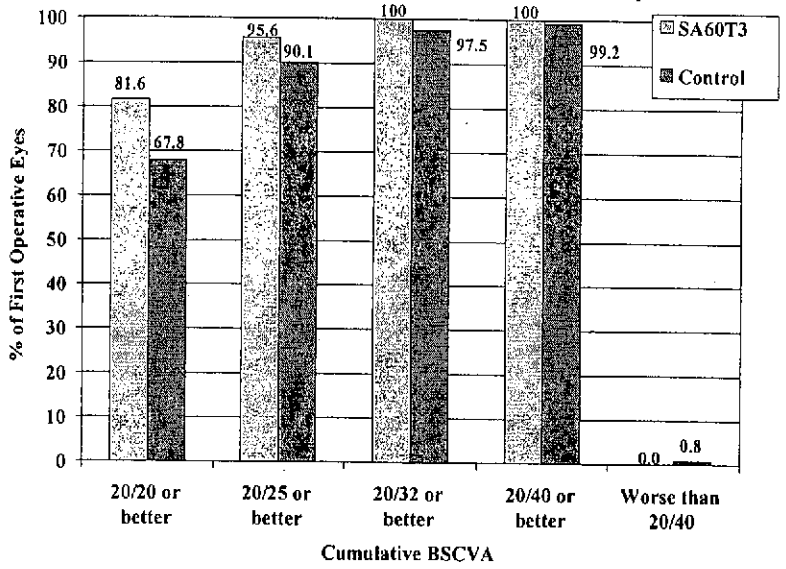

Figure 4B
Cumulative BSCDVA, Model SA60T4 vs. Control, Form 5, All Implanted

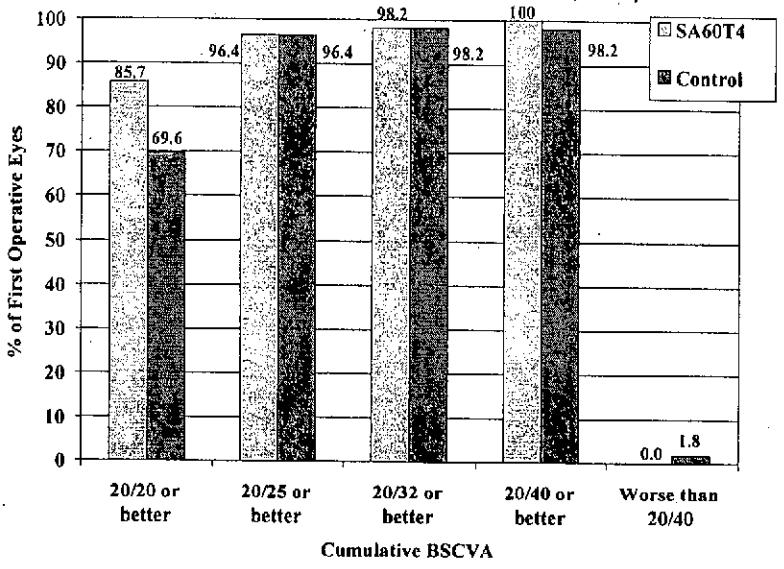

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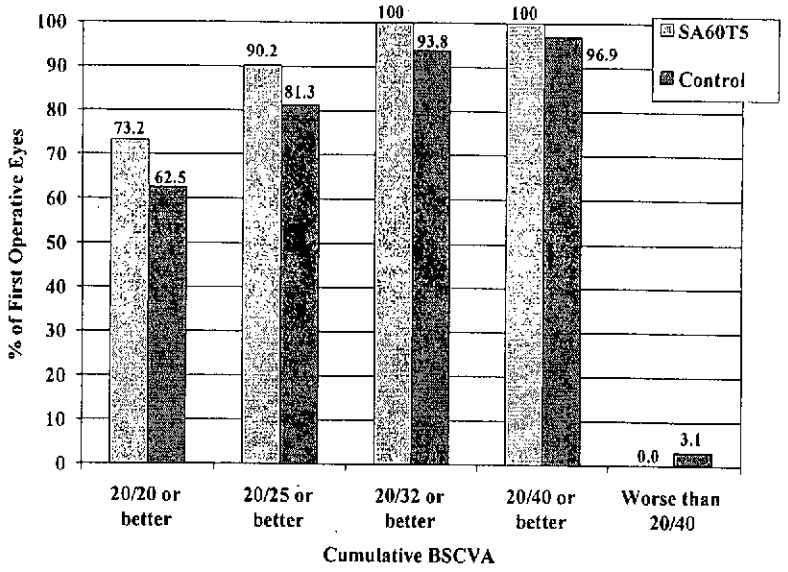
Figure 4C
Cumulative BSCDVA, Model SA60T5 vs. Control, Form 5, All Implanted



AcrySof® TORIC INTRAOCULAR LENS ABSOLUTE RESIDUAL REFRACTIVE CYLINDER

Figures 5A through 5C demonstrate that residual refractive cylinder values were statistically significantly lower among those subjects implanted with either an AcrySof® Toric Model SA60T3, SA60T4 or SA60T5 IOL when compared to the corresponding subjects implanted with the control Model SA60AT. Subjects implanted with an AcrySof® Toric Model SA60T3 showed a 62.4% mean reduction in refractive cylinder from the preoperative visit (keratometric cylinder) as compared to the 10.8% mean reduction for subjects implanted with the concurrent control Model SA60AT. Subjects implanted with an AcrySof® Toric Model SA60T4 or SA60T5 showed similar results with a mean reduction in refractive cylinder of 54.8 % and 67.8%, respectively, as compared to subjects implanted with the concurrent control model who had a mean reduction in refractive cylinder of 22.1% and 27.7%, respectively. Each of the AcrySof® Toric Lens Models SA60T3, SA60T4 and SA60T5 had at least a 3-fold increase in the likelihood of achieving residual refractive cylinder of 0.5 D or less as compared to the corresponding control model.

Figure 5A
Absolute Residual Refractive Cylinder,
Model SA60T3 vs. Control, Form 5, All Implanted

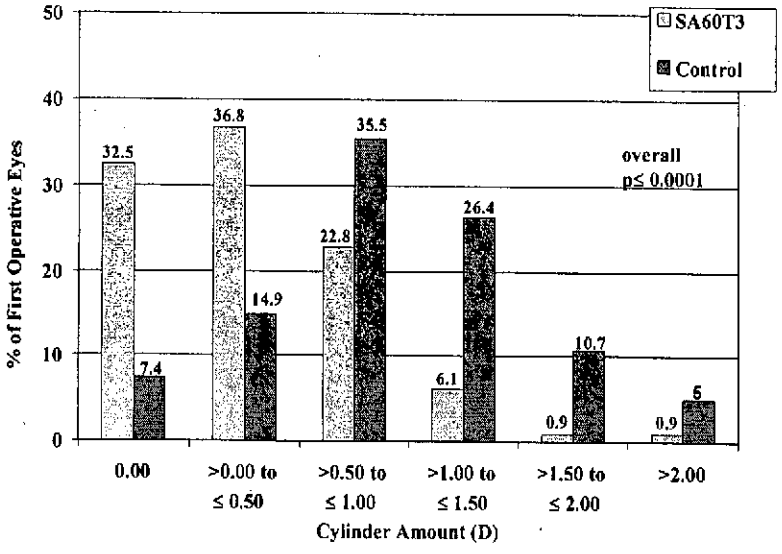


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Figure 5B
Absolute Residual Refractive Cylinder,
Model SA60T4 vs. Control, Form 5, All Implanted

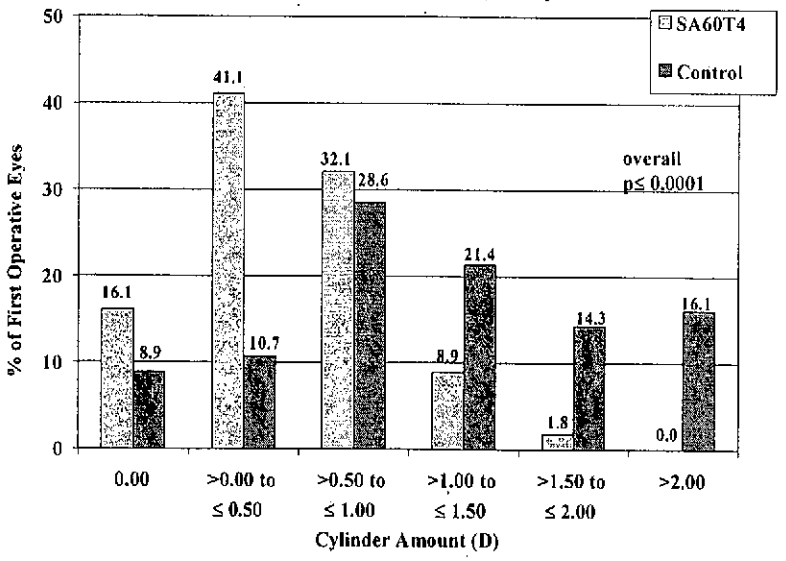
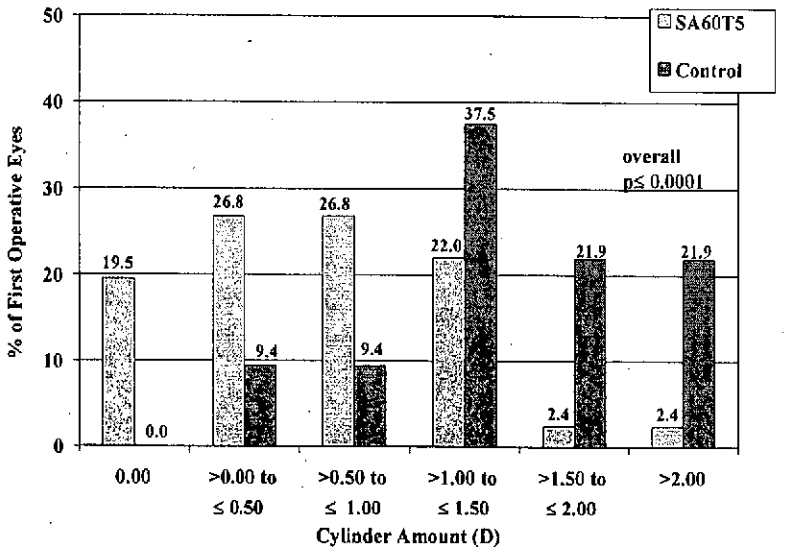


Figure 5C
Absolute Residual Refractive Cylinder,
Model SA60T5 vs. Control, Form 5, All Implanted



AcrySof® TORIC INTRAOCULAR LENS STABILITY OF CYLINDER

Subjects implanted with lens Model SA60TT exhibited stability of cylinder at Form 4 (3 months) with greater than 90% of all subjects changing less than or equal to 1.00 diopter at consecutive visits between Form 3 (one month) and Form 6 (twelve months).

Table 7A
AcrySof® Toric IOL: Stability of Cylinder
(Eyes that had 2 consecutive exams, but not necessarily every follow-up exam)

Recommended Corneal Astigmatism Correction Ranges	Toric IOL Model	Magnitude of Vector Change in Cylinder	1 and 3 Months n/N,%	3 and 6 Months n/N,%	6 and 12 Months n/N,%
< 1.5 D	SA60T3	≤ 1.00 D	106/107,99.07%	101/105,96.19%	55/55,100.00%
		Mean Change	0.28	0.29	0.20
		SD	0.32	0.33	0.25
≥ 1.5 - < 2.0 D	SA60T4	≤ 1.00 D	54/56,96.43%	53/54,98.15%	25/27,92.59%
		Mean Change	0.40	0.27	0.46
		SD	0.35	0.22	0.45
≥ 2.0 D	SA60T5	≤ 1.00 D	40/45,88.89%	35/40,87.50%	27/30,90.00%
		Mean Change	0.43	0.42	0.41
		SD	0.44	0.45	0.38
Combined	SA60TT	≤ 1.00 D	200/208,96.15% (93.54,98.77)	189/199,94.97% (91.94,98.01)	107/112,95.54% (91.71,99.36)
		Mean Change	0.35	0.31	0.32
		SD	0.36	0.34	0.36
		95% CI	0.30,0.39	0.26,0.36	0.25,0.39
n/N,%,(%CI) are for percent with change between ± 1.00D					

Table 7B
AcrySof® Toric IOL: Stability of Cylinder
(Eyes that had every follow-up exam up to Form 6, 12 months)

Recommended Corneal Astigmatism Correction Ranges	Toric IOL Model	Magnitude of Vector Change in Cylinder	1 and 3 Months n/N,%	3 and 6 Months n/N,%	6 and 12 Months n/N,%
< 1.5 D	SA60T3	≤ 1.00 D	34/34,100.00%	34/34,100.00%	34/34,100.00%
		Mean Change	0.25	0.24	0.21
		SD	0.23	0.22	0.24
≥ 1.5 - < 2.0 D	SA60T4	≤ 1.00 D	17/17,100.00%	16/17,94.12%	16/17,94.12%
		Mean Change	0.27	0.25	0.35
		SD	0.25	0.26	0.33
≥ 2.0 D	SA60T5	≤ 1.00 D	17/19,89.47%	15/19,78.95%	16/19,84.21%
		Mean Change	0.44	0.56	0.52
		SD	0.47	0.50	0.43
Combined	SA60TT	≤ 1.00 D	68/70,97.14% (93.23,100.00)	65/70,92.86% (86.82,98.90)	66/70,94.29% (88.84,99.73)
		Mean Change	0.31	0.33	0.33
		SD	0.32	0.35	0.34
		95% CI	0.23,0.38	0.24,0.41	0.25,0.41
n/N,%,(%CI) are for percent with change between ± 1.00D					

Table 7C
AcrySof® Toric IOL: Stability of Absolute Cylinder
(Eyes that had 2 consecutive exams, but not necessarily every follow-up exam)

Recommended Corneal Astigmatism Correction Ranges	Toric IOL Model	Magnitude of Change in Absolute Cylinder	1 and 3 Months n/N,%	3 and 6 Months n/N,%	6 and 12 Months n/N,%
< 1.5 D	SA60T3	≤ 1.00 D	107/107,100.00%	104/105,99.05%	55/55,100.00%
		Mean Change	0.04	0.02	0.05
		SD	0.32	0.38	0.29
≥ 1.5 - < 2.0 D	SA60T4	≤ 1.00 D	54/56,96.43%	54/54,100.00%	27/27,100.00%
		Mean Change	0.18	0.05	-0.12
		SD	0.42	0.27	0.41
≥ 2.0 D	SA60T5	≤ 1.00 D	44/45,97.78%	37/40,92.50%	29/30,96.67%
		Mean Change	0.09	0.06	0.00
		SD	0.38	0.49	0.45
Combined	SA60TT	≤ 1.00 D	205/208,98.56% (96.93,100.00)	195/199,97.99% (96.04,99.94)	111/112,99.11% (97.36,100.00)
		Mean Change	0.09	0.03	-0.01

Recommended Corneal Astigmatism Correction Ranges	Toric IOL Model	Magnitude of Change in Absolute Cylinder	1 and 3 Months n/N,%	3 and 6 Months n/N,%	6 and 12 Months n/N,%
		SD	0.37	0.38	0.37
		95% CI	0.04,0.14	-0.02,0.09	-0.08,0.06
n/N,%,(%CI) are for percent with change between ± 1.00D					

Table 7D
AcrySof® Toric IOL: Stability of Absolute Cylinder
(Eyes that had every follow-up exam up to Form 6, 12 months)

Recommended Corneal Astigmatism Correction Ranges	Toric IOL Model	Magnitude of Change in Absolute Cylinder	1 and 3 Months n/N,%	3 and 6 Months n/N,%	6 and 12 Months n/N,%
< 1.5 D	SA60T3	≤ 1.00 D	34/34,100.00%	34/34,100.00%	34/34,100.00%
		Mean Change	0.01	-0.01	0.07
		SD	0.28	0.31	0.28
≥ 1.5 - < 2.0 D	SA60T4	≤ 1.00 D	17/17,100.00%	17/17,100.00%	17/17,100.00%
		Mean Change	0.06	0.19	-0.04
		SD	0.30	0.21	0.42
≥ 2.0 D	SA60T5	≤ 1.00 D	18/19,94.74%	17/19,89.47%	18/19,94.74%
		Mean Change	0.17	0.05	0.01
		SD	0.45	0.54	0.55
Combined	SA60TT	≤ 1.00 D	69/70,98.57% (95.78,100.00)	68/70,97.14% (93.23,100.00)	69/70,98.57% (95.78,100.00)
		Mean Change	0.07	0.05	0.03
		SD	0.34	0.38	0.40
		95% CI	-0.01,0.15	-0.04,0.14	-0.07,0.12
n/N,%,(%CI) are for percent with change between ± 1.00D					

AcrySof® TORIC INTRAOCULAR LENS ROTATIONAL STABILITY

A summary of the change in axis orientation (rotation) from the operative visit to the Form 5 visit (120-180 days postoperative) is presented in Figures 6A and 6B. The rotational stability of the AcrySof® Toric Model SA60TT is established with the majority of the lenses rotating ≤ 5°. Figure 6A also demonstrates that the amount of rotation seen in each AcrySof® Toric IOL model is independent of the amount of cylinder power present on the lens.

Figure 6A
Change in Axis Orientation from Operative Visit to Form 5, All Implanted

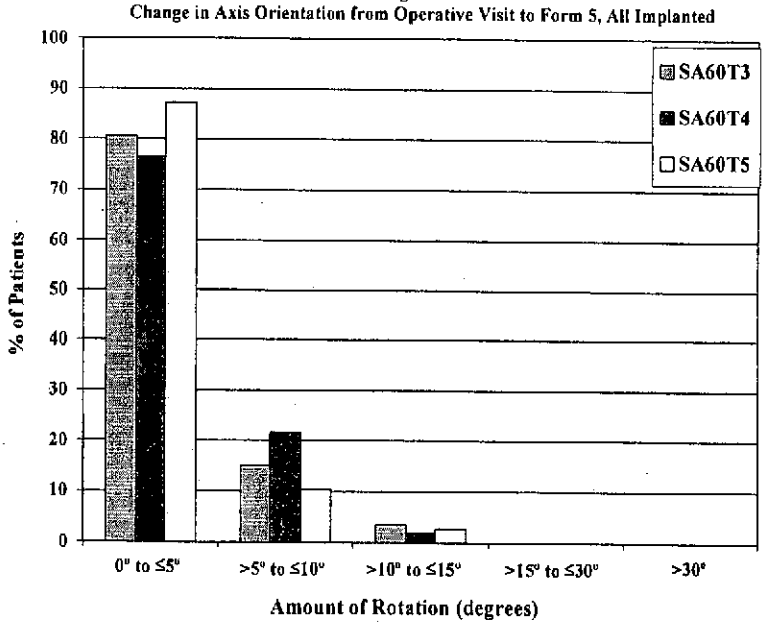


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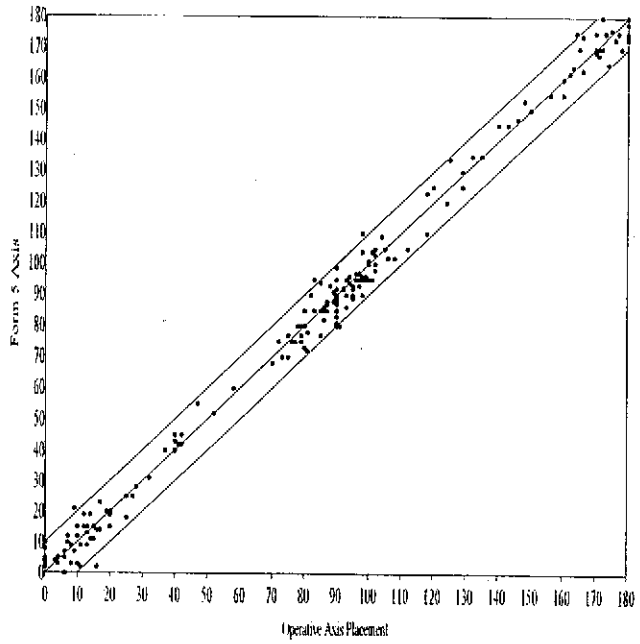
Figure 6B
Orientation of Lens Axis, Operative Visit versus Form 5,
Model SA60TT, All Implanted



AcrySof® TORIC INTRAOCULAR LENS ADVERSE EVENTS

The incidence of cumulative adverse events for the Model SA60TT compared favorably to the FDA historical grid rates. Only the rates for retinal detachment/repair and surgical reintervention exceeded the FDA historical grid. However, neither of these rates were statistically significant (p=0.5196 and p= 0.1336, respectively). No occurrences of persistent adverse events were observed in any patients implanted with the AcrySof® Toric IOL.

Table 8
Adverse Events Incidence Rates
First Eye – Safety

	Model SA60TT N=244		FDA Grid Rate
Cumulative Adverse Events	**N**	**%**	**%**
Retinal Detachment/Repair	1	0.4	0.3
Surgical Reintervention	4[a]	1.6	0.8
IOL Reposition Due to Rotation	1	0.4	NA
IOL Replacement Due to Rotation	1	0.4	NA
Laser Treatment	2	0.8	NA
Paracentesis	1	0.4	NA

The incidence rates in this table are based upon the number of eyes with an event divided by the number of eyes implanted.
Cumulative adverse events are those events that have occurred at any time during the clinical study.
FDA Grid Rate = FDA Grid of Adverse Events with Posterior Chamber Intraocular Lens Historical Controls, FDA Intraocular Lens Guidance Document, Annex B (October 14, 1999)
[a] There were 5 occurrences of surgical reintervention in 4 eyes for Model SA60TT first eye

The incidence of cumulative adverse events for the Model SA60TT also compared favorably to the concurrent control.

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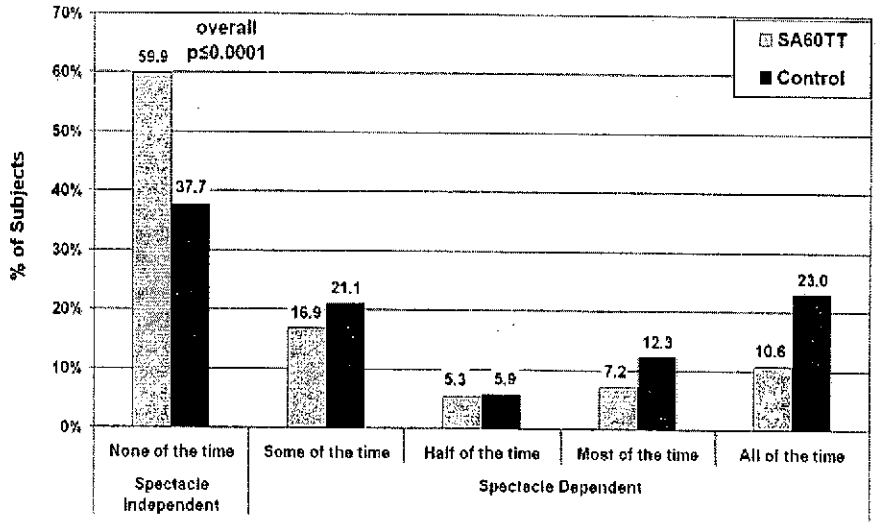
AcrySof® TORIC INTRAOCULAR LENS DISTANCE-VISION SPECTACLE INDEPENDENCE

Statistically significantly more Model SA60TT subjects reported postoperative distance-vision spectacle independence compared to Model SA60AT subjects (59.9% versus 37.7%, respectively) when unilaterally implanted. Distance-vision spectacle independence was defined as the percentage of subjects who selected the "none of the time" response for distance-vision frequency-of-spectacle-wear. Spectacle dependence was defined as subjects indicating any reliance on glasses for distance-vision and represents the summation of the "some of the time", "half of the time", "most of the time" and "all of the time" frequency-of-spectacle-wear responses. Consequently, fewer Model SA60TT subjects were spectacle dependent at 40.1% compared to 62.3% of the Model SA60AT subjects. Figure 7 illustrates the distance-vision frequency-of-spectacle-wear distributions between Model SA60TT and Model SA60AT groups. Implantation of an AcrySof® Toric Intraocular lens in astigmatic subjects provides significantly improved distance-vision spectacle independence relative to a conventional monofocal IOL.

Figure 7
Distance-Vision Spectacle Independence:
Frequency-of-Spectacle-Wear, Form 5, All Implanted



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2. AcrySof® TORIC HIGH CYLINDER POWER INTRAOCULAR LENS CLINICAL STUDY

A clinical study was conducted to investigate the rates of spatial distortions related to axial misalignment of the AcrySof® Toric Posterior Chamber High Cylinder Power Intraocular Lenses shown in Table 9.

Table 9

Model	Cylinder Power		Toric Calculator Recommended Corneal Astigmatism Correction Ranges
	at IOL plane	at corneal plane	
SN60T6	3.75	2.57	2.57 - 3.07 D
SN60T7	4.50	3.08	3.08 – 3.59 D
SN60T8	5.25	3.60	3.60 – 4.10 D
SN60T9	6.00	4.11	4.11 D and up

These recommended corneal astigmatism correction ranges are based on the preoperative corneal astigmatism and the predicted effect of surgically induced astigmatism. To obtain the IOL cylindrical powers and the orientation of the surgical placement of the axes, for each operative eye the preoperative keratometry values and axes, IOL spherical power (as determined by the surgeon's preferred formula) and the surgeon's estimated surgically induced astigmatism (SIA) at the standard temporal incision location are entered into Alcon's proprietary web-based AcrySof Toric IOL calculator. The combination of these parameters are used in the Alcon provided software to select the appropriate Toric IOL model and recommended axis of placement. As such, the recommended range of corneal astigmatism to be corrected while not identical, is directly related to, the preoperative keratometric cylinder.

The results achieved by the patients followed to six months (Visit 5A) postoperatively demonstrate that the AcrySof® Toric high cylinder intraocular lens models are safe and effective for the visual correction of aphakia. The following clinical results illustrate the AcrySof® Toric high cylinder power IOL's effectiveness in significantly reducing pre-existing corneal astigmatism and the IOL's excellent rotational stability following implantation in the capsular bag

AcrySof® TORIC HIGH CYLINDER POWER INTROCULAR LENS CLINICAL STUDY PATIENT POPULATION

This study focused on the highest cylinder power IOL Model SN60T9; however, due to the rarity of this level of astigmatism IOL Model SN60T8 was included to expand the inclusion criteria for the second eye. The subject population implanted with an IOL Model SN60T9 in the first operative eye consists of 80% (12/15) females and 20% (3/15) males. For the fellow eye, 3 subjects were implanted with IOL Model SN60T9, while 12 were implanted with IOL Model SN60T8. All 15 (100%) of the implanted subjects were white. The mean age for the population was 67 years old (range of 43 to 82 years) at the time of surgery.

AcrySof® TORIC HIGH CYLINDER POWER INTRAOCULAR LENS ABSOLUTE RESIDUAL REFRACTIVE CYLINDER

Refractive cylinder six months postoperatively was reduced for all subjects implanted with either an AcrySof® Toric IOL Model SN60T8 or SN60T9 compared to preoperative baseline. Results show a statistically significant reduction (p-value <.0001) in residual refractive cylinder in eyes implanted with IOL Model SN60T9 [85.7% in first eyes (n=15), 87.8% in second eyes (n=3) and IOL Model SN60T8 [87.3% (n=12)]..

AcrySof® TORIC HIGH CYLINDER POWER INTRAOCULAR LENS ROTATIONAL STABILITY

A summary of the change in axis orientation (rotation) from the operative visit to Visit 5A (six months postoperative) is presented in Figure 8A and 8B. The AcrySof® Toric high cylinder power IOLs demonstrated rotational stability with the majority of the lenses rotating ≤ 5°.

Figure 8A
Change in Lens Axis Orientation - Visit 5A (Final Visit) versus Target

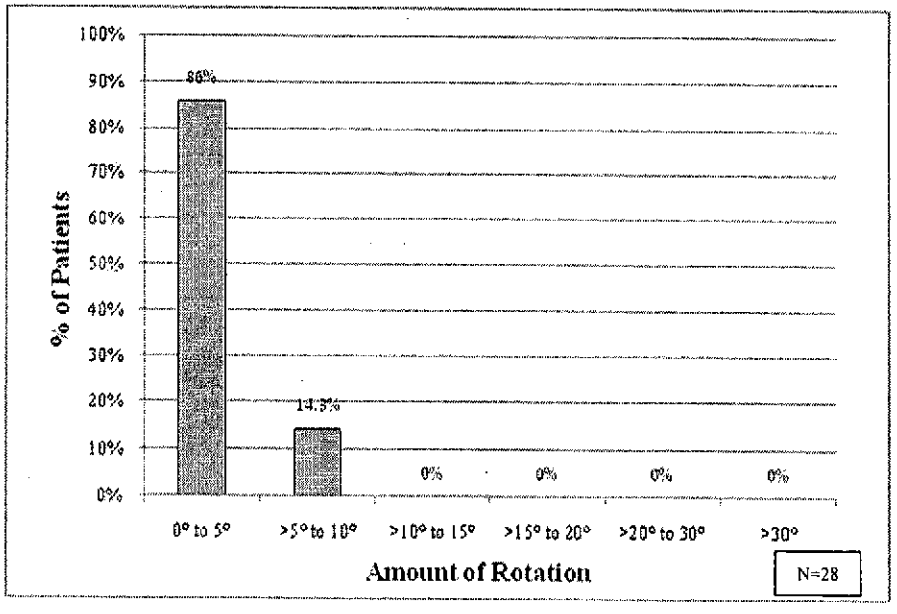

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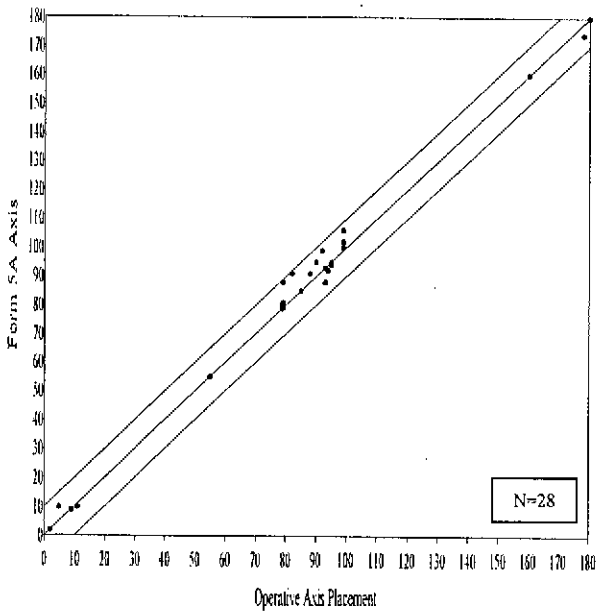
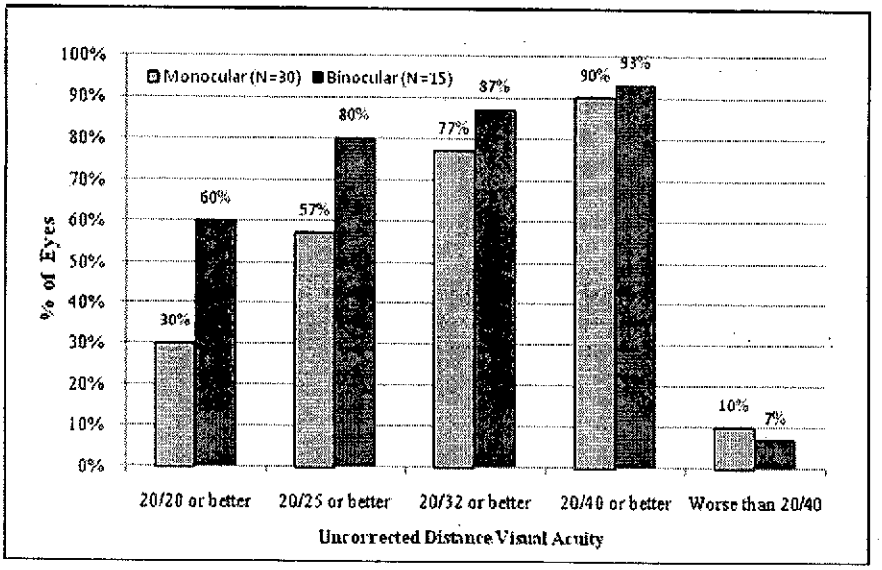
Figure 8B
Orientation of Lens Axis, Operative Visit versus Visit 5A (Final Visit)
IOL Models SN60T9 and SN60T8



AcrySof® TORIC HIGH CYLINDER POWER INTRAOCULAR LENS UNCORRECTED DISTANCE VISUAL ACUITY

All Subjects implanted bilaterally with the AcrySof® Toric IOL Models SN60T8 or SN60T9 achieved improved binocular uncorrected distance visual acuity six months postoperatively. Figure 10 demonstrates that 60% of subjects achieved 20/20 or better binocular uncorrected distance visual acuity compared to 30% for monocular eyes, while 93% of subjects achieved 20/40 or better binocular uncorrected distance visual acuity compared to 90% of monocular eyes. Less than 10% of subjects had monocular or binocular uncorrected distance visual acuity worse than 20/40 six months postoperatively.

Figure 10
Cumulative UCDVA Monocular versus Binocular



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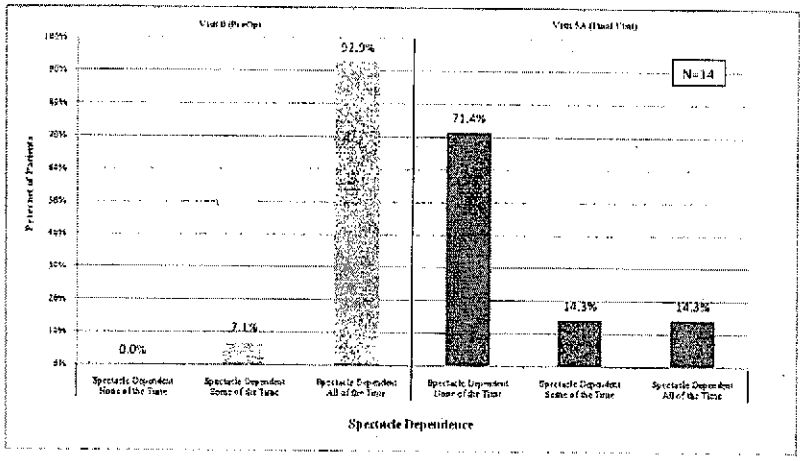
AcrySof® TORIC HIGH CYLINDER POWER INTRAOCULAR LENS BILATERAL DISTANCE-VISION SPECTACLE INDEPENDENCE

Preoperatively all subjects were spectacle dependent, either all-the-time (92.9%) or some-of-the-time (7.1%). Six months postoperatively, 71.4% of subjects were spectacle independent (Figure 9).

Figure 9
Bilateral Distance Vision Spectacle Independence
Frequency-of-Spectacle-Wear Visit 0 (PreOp) versus Visit 5A (Final Visit)



AcrySof® TORIC HIGH CYLINDER POWER POWER INTRAOCULAR LENS RATE OF SPATIAL DISTORTIONS

A Visual Distortion Questionnaire was administered preoperatively (Visit 0) and at six months postoperatively (Visit 5A) to evaluate the rate of spatial distortions of the AcrySof® Toric IOL Models SN60T8 and SN60T9. The overall rate of spatial distortions decreased postoperatively (Table 10A).

Table 10A:
Visual Distortion Questionnaire Results by Visit

During the past 4 weeks, have you had		PreOp (N = 14)		Final Visit (N = 14)	
		n	%	n	%
1) ...trouble with things appearing distorted?	No	3	21.4	12	85.7
	Yes	11	78.6	2[a,b]	14.3
2) ...trouble with flat surfaces (like floors) appearing curved?	No	12	85.7	13	92.9
	Yes	2	14.3	1[c]	7.1
3) ...trouble with straight lines (like door or window frames) appearing tilted?	No	10	71.4	14	100
	Yes	4	28.6	0	0.0
4) ...trouble with feeling sick to your stomach due to distortion of your vision?	No	14	100	14	100
	Yes	0	0.0	0	0.0

[a] Reported with or without glasses at Preop and Final Visit.
[b] Reported with or without glasses at Preop but only with glasses (progressive lenses) at Final Visit.
[c] Same subject as in (b). Reported only with glasses (progressive lenses) at Final Visit. Not reported at Preop.

Based on these questions spatial distortions associated with high pre-existing corneal astigmatism may not completely resolve postoperatively. Two subjects at Visit 5A continued to report "trouble with things appearing distorted" versus 11 subjects preoperatively. One of these subjects also had "trouble with flat surfaces appearing curved," which was noted only postoperatively, but no longer experienced the preoperative visual phenomena of straight lines appearing tilted. Neither subject had IOL misalignment requiring secondary surgical intervention to address problems of spatial distortion. There were no reports of subjects feeling sick to their stomachs due to distortion of vision.

Responses to visual distortion sub-questions related to spectacle wear, frequency of experiencing distortion, and degree of bother are presented in Tables 10B through 10D.

Table 10B:
Visual Distortion Questionnaire Results – Trouble with Things Appearing Distorted

1) For subjects who had trouble with things appearing distorted in the last 4 weeks:		PreOp (N = 11)		Final Visit (N = 2)	
		n	%	n	%
Do you notice this only when you wear your glasses?	No	10	90.9	1	50.0
	Yes	1	9.1	1	50.0
How often have you noticed this?	Rarely	2	18.2	0	0.0
	Sometimes	2	18.2	0	0.0
	Frequently	3	27.3	1	50.0
	All the time	4	36.4	1	50.0
How much does it bother you?	None	1	9.1	1	50.0
	A Little	4	36.4	0	0.0
	A Lot	6	54.5	1	50.0

Table 10C:
Visual Distortion Questionnaire Results – Trouble with Flat Surfaces Appearing Curved

2) For subjects who had trouble with flat surfaces (like floors) appearing curved in the last 4 weeks:		PreOp (N = 2)		Final Visit (N = 1)	
		n	%	n	%
Do you notice this only when you wear your glasses?	No	2	100	0	0.0
	Yes	0	0.0	1	100
How often have you noticed this?	Rarely	0	0.0	0	0.0
	Sometimes	0	0.0	0	0.0
	Frequently	1	50.0	1	100
	All the time	1	50.0	0	0.0
How much does it bother you?	None	0	0.0	0	0.0
	A Little	0	0.0	0	0.0
	A Lot	2	100	1	100

Table 10D
Visual Distortion Questionnaire Results – Trouble with Straight Lines Appearing Tilted

3) For subjects who had trouble with straight lines (like door or window frames) appearing tilted in the last 4 weeks:		PreOp (N = 4)		Final Visit (N = 0)	
		n	%	n	%
Do you notice this only when you wear your glasses?	No	3	75.0	0	0.0
	Yes	1	25.0	0	0.0
How often have you noticed this?	Rarely	0	0.0	0	0.0
	Sometimes	2	50.0	0	0.0
	Frequently	0	0.0	0	0.0
	All the time	2	50.0	0	0.0
How much does it bother you?	None	0	0.0	0	0.0
	A Little	1	25.0	0	0.0
	A Lot	3	75.0	0	0.0

AcrySof® TORIC HIGH CYLINDER POWER INTRAOCULAR LENS ADVERSE EVENTS

During the study, 1 of 15 subjects underwent a secondary surgical intervention in the first eye to resolve residual refractive cylinder due to an error in preoperative keratometry. One week postoperatively, the IOL was repositioned. At six months postoperatively the subject was satisfied with uncorrected distance vision and did not experience any spatial distortion after IOL repositioning. No other serious adverse events were reported in the study.

HOW SUPPLIED

The AcrySof® Toric IOL is supplied dry, in a package terminally sterilized with ethylene oxide, and must be opened only under aseptic conditions (See DIRECTIONS FOR USE).

EXPIRATION DATE

Sterility is guaranteed unless the pouch is damaged or opened. The expiration date is clearly indicated on the outside of the lens package. Any lens held after the expiration date should be returned to Alcon Laboratories, Inc. (See RETURNED GOODS POLICY).

RETURNED GOODS

In the United States, returned lenses will only be accepted in exchange for other products, not credit. All returns must be accompanied by an Alcon Laboratories, Inc. Returned Goods Number and be shipped via traceable means. A Returned Goods Number is obtained by contacting Alcon's Customer Service Department. Issuance of this number does not constitute final acceptance of the returned products. For detailed policy guidelines including exchange, please contact your Sales or Customer Service Representative. Outside the United States, Contact your local Alcon offices or distributors regarding returned goods policy

REFERENCES
Boettner, E.A. and Wolter, J.R. Transmission of the ocular media. *Invest. Ophthalmol.* 1:776-783, 1962

Symbols Used on Labeling

SYMBOL	ENGLISH
IOL	Intraocular lens
PC	Posterior chamber
PCL	Posterior chamber lens
UV	Ultraviolet
D	Diopter (spherical equivalent)
CYL	Cylinder Power
$Ø_B$	Body diameter (Optic diameter)
$Ø_T$	Overall diameter (Overall length)
	Do not reuse
or	Use by (YYYY-MM: year-month)
STERILE EO	Sterilized by ethylene oxide
SN or SN	Serial Number
	Attention: See instructions for use
LOT	Batch Code
EC REP	Authorized Representative in the European Community
	Manufacturer

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas, USA
76134-2099

U.S. Pat. No's. 5,403,901, 5,470,932, 5,543,504, 5,603,774, and 5,716,403.

PRODUCT INFORMATION

Alcon Laboratories, Inc.

ACRYSof IQ TORIC

ASTIGMATISM IOL

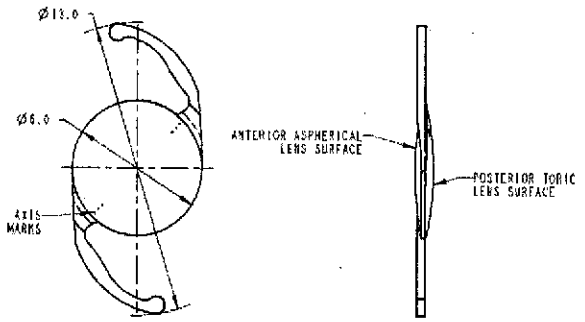
STERILE UV and Blue Light Filtering Acrylic Foldable Toric Aspheric Optic Single-Piece Posterior Chamber Lenses

CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

DESCRIPTION

The AcrySof® IQ Toric Posterior Chamber Intraocular Lens (IOL) is a UV-absorbing foldable intraocular lens (IOL). These IOLs have a biconvex toric aspheric optic with cylinder axis marks to denote the flat meridian (plus cylinder axis). The single-piece design (see Figure 1 and Table 1) consists of a high refractive index material with proprietary blue light filtering chromophore which filters light in a manner that approximates the human crystalline lens in the 400-475 nm blue light wavelength range (Boettner and Wolter, 1962). In addition to standard UV-light filtering, the blue-light filtering chromophore reduces transmittance of blue light (see Table 2). The biconvex toric aspheric optic consists of a high refractive index soft acrylic material capable of being folded prior to insertion, allowing placement through an incision smaller than the optic diameter of the lens. After surgical insertion into the eye, the lens gently unfolds to restore the optical performance. The supporting haptics provide for proper positioning and fixation of the IOL optic within the eye. The anterior surface of the AcrySof® IQ Toric IOL Model SN6ATT is designed with negative spherical aberration identical to the aspheric AcrySof® IQ IOL Model SN60WF to compensate for the positive spherical aberration of the cornea.*

Figure 1: Physical Characteristics of AcrySof® IQ Toric IOLs
(All dimensions in millimeters)

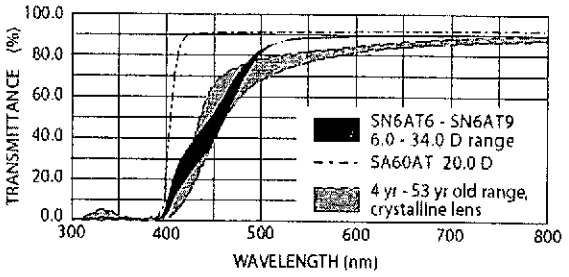


* The effects of this aspheric design feature have been clinically assessed on AcrySof® IQ IOL Model SN60WF.

Table 1: Physical Characteristics of AcrySof® IQ Toric IOLs

Characteristics	Model			
	SN6AT6	SN6AT7	SN6AT8	SN6AT9
	Collectively referred to as Model SN6ATT			
Optic Type	Biconvex Toric Aspheric Optic			
Optic / Haptic Material	Ultraviolet and blue light filtering Acrylate/Methacrylate Copolymer UV cutoff at 10% T: 399 nm (+6.0 diopter lens) 407 nm (+34.0 diopter lens)			
IOL Powers (spherical equivalent diopters)	For available power range see Alcon Product Guide			
IOL Cylinder Power (Diopters)	3.75 D	4.50 D	5.25 D	6.00 D
Index Of Refraction	1.55			
Haptic Configuration	STABLEFORCE® Haptic			
Optic Diameter (mm)	6.0			
Overall Length (mm)	13.0			
Haptic Angle	0°			

Figure 2: Spectral Transmittance Curves
(Percentage of Ultraviolet Transmittance)



NOTE:
• Human lens data from Boettner and Wolter (1962).

Table 2: Average % Transmittance Comparison

Model	400 nm	425 nm	450 nm	475 nm
SA60AT (20.0D)	21	86	88	88
SN6ATT (20.0D)	8	33	49	68
Transmittance Difference (SA60AT – SN6ATT)	13	53	39	20
Transmittance Reduction with SN6ATT (% of SA60AT)	62	62	44	23

MODE OF ACTION

AcrySof® IQ Toric IOLs are intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. These IOLs have a biconvex toric aspheric optic with cylinder axis marks to denote the flat meridian (plus cylinder axis): Alignment of the toric IOL cylinder axis marks with the post-operative steep corneal meridian allows the lens to correct astigmatism. The biconvex toric aspheric optic reduces spherical aberration as compared to a standard spherical toric optic in an average eye. The astigmatic correction at the corneal plane for AcrySof® IQ Toric intraocular lenses is shown in Table 3:

Table 3 Astigmatism Correction at the IOL and Cornea Plane

Model	Cylinder Power at IOL Plane (diopters)	Cylinder Power at Corneal Plane (diopters*)
SN6AT6	3.75	2.57
SN6AT7	4.50	3.08
SN6AT8	5.25	3.60
SN6AT9	6.00	4.11

*Based on an average pseudophakic human eye

INDICATIONS

The AcrySof® IQ Toric posterior chamber intraocular lenses are intended for primary implantation in the capsular bag of the eye for visual correction of aphakia and pre-existing corneal astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia, who desire improved uncorrected distance vision, reduction of residual refractive cylinder and increased spectacle independence for distance vision.

WARNINGS

1. This lens should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned.
2. Rotation of AcrySof® IQ Toric IOLs away from their intended axis can reduce their astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, lens repositioning should occur as early as possible prior to lens encapsulation. Some clinical cases suggest encapsulation is complete within four weeks of implantation.
3. Carefully remove all viscoelastic from both the anterior and posterior sides of the lens. Residual viscoelastic may allow the lens to rotate causing misalignment of the AcrySof® IQ Toric IOL from the intended axis of placement.

PRECAUTIONS

1. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon for this product informing them of possible risks and benefits associated with the AcrySof® IQ Toric High Cylinder Power IOLs
2. A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.
3. As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, transient or persistent glaucoma and secondary surgical intervention. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspirations or iridectomy for pupillary block, wound leak repair, and retinal detachment repair.
4. The safety and effectiveness of the Toric intraocular lens have not been substantiated in patients with the following preexisting ocular conditions and intraoperative complications (see below). Careful preoperative evaluation and sound clinical judgement should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions.

Before Surgery

- Choroidal hemorrhage
- Chronic severe uveitis

- Concomitant severe eye disease
- Extremely shallow anterior chamber
- Medically uncontrolled glaucoma
- Microphthalmos
- Non-age-related cataract
- Proliferative diabetic retinopathy (severe)
- Severe corneal dystrophy
- Severe optic nerve atrophy
- Irregular corneal astigmatism
- Color vision deficiencies

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g. glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optical nerve diseases) has not been studied.

During Surgery

- Excessive vitreous loss
- Capsulotomy by any technique other than a circular tear
- The presence of radial tears known or suspected at the time of surgery
- Situations in which the integrity of the circular tear cannot be confirmed by direct visualization
- Cataract extraction by techniques other than phacoemulsification or liquefaction
- Situations where the need for a large capsulotomy can be anticipated (e.g., diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.)
- Capsular rupture
- Significant anterior chamber hyphema
- Uncontrollable positive intraocular pressure
- Zonular damage

5. Some adverse reactions which have been associated with the implantation of intraocular lenses are: hypopyon, intraocular infection, acute corneal decompensation and secondary surgical intervention. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration or iridectomy for pupillary block, wound leak repair and retinal detachment repair.
6. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such problems. The physician must determine the benefits to be derived from lens implantation when such conditions exist.
7. DO NOT store the IOL at temperatures over 45° C (113° F).
8. DO NOT reuse the IOL. This IOL is for single use only.
9. DO NOT resterilize the IOL by any method.
10. Use only sterile intraocular irrigating solutions such as BSS® or BSS PLUS® solutions to rinse and/or soak lenses.
11. Accurate keratometry and biometry in addition to the use of the Toric Calculator (www.acrysoftoriccalculator.com) are recommended to achieve optimal visual outcomes.
12. Patients with postoperative refractive error may not receive the aspheric optical design benefit without spectacle correction.
13. Optical theory suggest, that, high astigmatic patients may experience spatial distortions. Possible toric IOL related factors may include residual cylindrical error or axis misalignments.

CALCULATION OF LENS POWER

Accurate keratometry, biometry, and targeting emmetropia are essential for optimal visual outcomes. Preoperative calculation of the required spherical equivalent lens power for these posterior chamber intraocular lenses should be determined by the surgeon's experience, preference, and intended lens placement. The A-constant listed on the outer label is presented as a guideline and is a starting point for implant power calculations. This provisional A-constant has been theoretically derived. Lens constants must be "personalized" to compensate for the differences in instrumentation, measurement technique, and IOL power calculation methods. A convenient initial estimate can be obtained by referencing to the personalized lens constant for a similar lens model (e.g. AcrySof® IQ Toric IOL Models SN6AT3, SN6AT4, or SN6AT5).

AcrySof® IQ Toric IOLs are labeled with the IOL spherical equivalent power. The results obtained from the calculation formulas listed below should not be modified, as they result in the appropriate power consistent with the labeling of the AcrySof® IQ Toric IOL. Lens power calculation methods are described in the following references:

Hoffer, K.J. The Hoffer Q formula: A comparison of theoretic and regression formulas. *J. Cataract Refract. Surg.* 19:700-712, 1993.

Holladay, J.T., *et al.* A three-part system for refining intraocular lens power calculations. *J. Cataract Refract. Surg.* 14:17-24, 1988.

Holladay, J.T., et al., Standardizing constants for ultrasonic biometry, keratometry, and IOL power calculations, *J. Cataract Refract. Surg.* 23:1356-1370, 1997.

Retzlaff, J.A., Sanders, D.R., and Kraff, M. *Lens Implant Power Calculation*, 3rd ed., Slack, Inc., Thorofare, N.J., 1990.

Selection and Placement of the AcrySof® IQ Toric IOL

The astigmatism to be corrected should be determined from keratometry and biometry data rather than refractive data since the presence of lenticular astigmatism in the crystalline lens to be removed may influence results. The size and location of the surgical incision may affect the amount and axis of corneal astigmatism. In order to optimize IOL selection and axis placement, Alcon provides a proprietary web-based tool (www.acrysoftoriccalculator.com) for the surgeon. Pre-operative keratometry and biometry data, incision location, and the surgeon's estimated surgically induced corneal astigmatism are used to determine the appropriate AcrySof® IQ Toric IOL model, spherical equivalent lens power, and axis of placement in the eye.

For optimal results, the surgeon must ensure the correct placement and orientation of the lens within the capsular bag. The posterior surface of the IOL is marked with indentations (three at each end) at the haptic/optic junction that identify the flat meridian of the AcrySof® IQ Toric optic. These indentations form an imaginary line representing the plus cylinder axis (note: IOL cylinder steep meridian is 90° away). The AcrySof® IQ Toric IOL cylinder axis marks should be aligned with the post-incision steep corneal meridian (intended axis of placement).

Prior to surgery the operative eye should be marked with at least two reference points (e.g. three o'clock and nine o'clock positions) while the patient is sitting upright to prevent cyclotorsion. Using these marks as reference points, an axis marker can be used immediately prior to or during surgery to mark the axis of lens placement following the use of the Toric IOL calculator to determine the optimal axis of placement.

After the lens is inserted, precisely align the axis marking indentations on the AcrySof® IQ Toric IOL with the marked axis of lens placement. Carefully remove all viscoelastic from both the anterior and posterior sides of the lens. This may be accomplished by manipulating the IOL optic with the I/A tip and using standard irrigation/aspiration techniques to remove all viscoelastic from the eye. Bimanual techniques may be used, if preferred, to ensure removal of viscoelastic from behind the lens implant. Special care should be taken to ensure proper positioning of the AcrySof® IQ Toric IOL at the intended axis following viscoelastic removal. Residual viscoelastic may allow the lens to rotate causing misalignment of the AcrySof® IQ Toric IOL with the intended axis of placement.

Misalignment of the axis of the lens from the intended axis of placement may compromise its astigmatic correction. Such misalignment can result from inaccurate keratometry or marking of the cornea, inaccurate placement of the AcrySof® IQ Toric IOL axis during surgery, an unanticipated surgically induced change in the

cornea, or physical rotation of the AcrySof® IQ Toric IOL after implantation. In order to minimize this effect, the surgeon should be careful to ensure that preoperative keratometry and biometry are accurate and that the IOL is properly oriented prior to the end of surgery.

DIRECTIONS FOR USE

1. Examine the label on the unopened package for model, power (spherical equivalent and cylinder), and expiration date.
2. After opening the cardboard storage container verify lens case information (model, power, and serial number) is consistent with information on outer package labeling.
3. This device is sterile until the inner pouch is opened. Inspect the pouch carefully for tears, cuts, punctures or other signs that the pouch has been opened or damaged. DO NOT implant the IOL if the sterility has been compromised. (See RETURNED GOODS POLICY).
4. To remove the lens, open the undamaged pouch and transfer the case to a sterile environment. Carefully open the case to expose the lens.
5. To minimize the occurrence of marks on the lens due to handling, all instrumentation should be scrupulously clean. Any forceps used for lens handling must have round edges and smooth surfaces.
6. When removing the lens from the case, DO NOT grasp the optical area with forceps. The IOL should only be handled by the haptics. Handle the lenses carefully to avoid damage to lens surfaces or haptics. DO NOT attempt to reshape haptics in any way.
7. Rinse the lens thoroughly using sterile intraocular irrigating solution such as BSS® or BSS PLUS®. DO NOT rinse the IOL in solutions other than sterile intraocular irrigating solution. Prior to insertion, the IOL should be carefully examined to ensure that particles have not adhered during handling.
8. Alcon recommends using the MONARCH® II delivery system, or equivalent Alcon approved delivery system.
9. There are various surgical procedures that can be utilized, and the surgeon should select a procedure that is appropriate for the patient. Current techniques, appropriate instrumentation, and a list of their equivalents for delivery and implantation are available from Alcon. Surgeons should verify that appropriate instrumentation is available prior to surgery.

PATIENT REGISTRATION AND REPORTING

FDA requirement for US implanting surgeons only: Each patient must be registered with Alcon Laboratories, Inc. immediately following implantation of one of these lenses. Registration is accomplished by completing the prepaid Implant Registration Card that is enclosed in the lens box and mailing it to Alcon Laboratories, Inc. Patient registration is essential for Alcon Laboratories, Inc. long-term patient follow-up program and will assist us in responding to adverse event reports. The Patient Identification Card included in the package 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 care practitioner the patient consults in the future.

Adverse events 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 Alcon Laboratories, Inc. This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation. Surgeons should use the following address and telephone number for reporting adverse events involving these intraocular lenses:

Alcon Research, Ltd. Medical Safety (AB 2-6)
6201 South Freeway, Fort Worth, Texas 76134.
Call Toll-Free (800) 757-9780 or Call Collect: (817) 551-4445.

Outside the United States, contact local Alcon offices or distributors regarding any reports of adverse events.

OVERVIEW OF AcrySof® TORIC INTRAOCULAR LENS CLNICAL STUDIES

The following clinical studies have been conducted on AcrySof® Toric Intraocular Lenses. In addition to the data from the recent high cylinder power clinical study, the clinical data from the original study of the AcrySof® Toric IOLs are also included in order to provide data intended to help you make an informed decision as to whether or not to implant a Toric IOL:

1. AcrySof® Toric Intraocular Lens Original Study, and
2. AcrySof® Toric High Cylinder Power Intraocular Lens Clinical Study

Summaries of each of the above clinical studies are provided below.

I, AcrySof® TORIC INTRAOCULAR LENS ORIGINAL CLINICAL STUDIES

AcrySof® IQ Toric IOL Models SN6AT6, SN6AT7, SN6AT8, and SN6AT9 are minor design modifications to the clinically studied AcrySof® Toric IOL Models SA60T3, SA60T4, and SA60T5.

A clinical study was conducted to demonstrate the safety and effectiveness of the AcrySof® Toric Posterior Chamber Lens Model SA60TT (Models SA60T3, SA60T4, and SA60T5). This was a randomized clinical study that included the AcrySof® Model SA60AT as a control lens. Only data from the first operative eye from those subjects who received either a Model SA60TT or Model SA60AT intraocular lens are included.

Three different lens models of varying cylinder correction were evaluated in this clinical study. Collectively, the three models are referred to as Model SA60TT. The three different models evaluated and their applicable cylinder powers are listed below in table 4.

Table 4: Cylinder Powers and Recommended Correction Ranges

Model	Cylinder Power at IOL plane	Cylinder Power at corneal plane	Toric Web-based Calculator Recommended Corneal Astigmatism Correction Ranges
SA60T3	1.50	1.03	0.75 - 1.54 D
SA60T4	2.25	1.55	1.55 - 2.05 D
SA60T5	3.00	2.06	2.06 -2.56 D

The recommended corneal astigmatism correction ranges are based on the preoperative corneal astigmatism and the predicted effect of 0.5 diopter surgically induced astigmatism for a standardized temporal incision. To obtain the IOL cylindrical powers and the orientation of the surgical placement of the axes, for each operative eye the preoperative keratometry values and axes, IOL spherical power (as determined by the surgeon's preferred formula) and the anticipated surgically induced astigmatism (SIA) at the standard temporal incision location are entered into Alcon's proprietary web-based AcrySof Toric IOL calculator. The combination of these parameters are used in Alcon provided software to select the appropriate Toric IOL model and recommended axis of placement. As such, the recommended range of corneal astigmatism to be corrected, while not identical, is directly related to, the preoperative keratometric cylinder.

The results achieved by the patients followed to six months postoperatively demonstrate that the AcrySof® Toric Posterior Chamber Lens Model SA60TT is a safe and effective device for the visual correction of aphakia. The following clinical results illustrate minimal rotation with excellent rotational stability leading to significant reduction or elimination of residual refractive cylinder and significantly improved uncorrected distance visual acuity which results in increased distance spectacle independence.

AcrySof® TORIC INTRAOCULAR LENS CLINICAL STUDY PATIENT POPULATION

The subject population implanted with a Model SA60TT in the first operative eye consists of 53.3% females and 46.7% males. The subject population implanted with the Model SA60AT (control) intraocular lens consists of 57.2% females and 42.8% males. Stratifying by race for the Model SA60TT population, 97.6% are Caucasian, 2.0% are Black and 0.4% are other. The control (SA60AT) population is 95.6% Caucasian, 1.6% Black, 1.2% Asian and 1.6% other. The mean age for the population receiving the Model SA60TT was 70.0 years. Similarly, the mean age for the population receiving the Model SA60AT (control) was 72.4 years.

AcrySof® TORIC INTRAOCULAR LENS UNCORRECTED DISTANCE VISUAL ACUITY

A summary of uncorrected distance visual acuity achieved for Models SA60TT and SA60AT at six months postoperatively is presented in Tables 5A and 5B respectively. These tables show 38.4% of subjects implanted with a Model SA60TT achieved uncorrected distance visual acuities of 20/20 or better compared to only 19.0% of those subjects implanted with the control lens Model SA60AT. Also, of the 211 subjects implanted with a Model SA60TT and examined at the Form 5 visit, 140 (66.4%) achieved an uncorrected distance visual acuity of 20/25 or better, compared to only 86 subjects (40.9%) implanted with the control Model SA60AT.

Table 5A
Uncorrected Distance Visual Acuity by Age Category, Status at Form 5 - Lens Model SA60TT, All Implanted

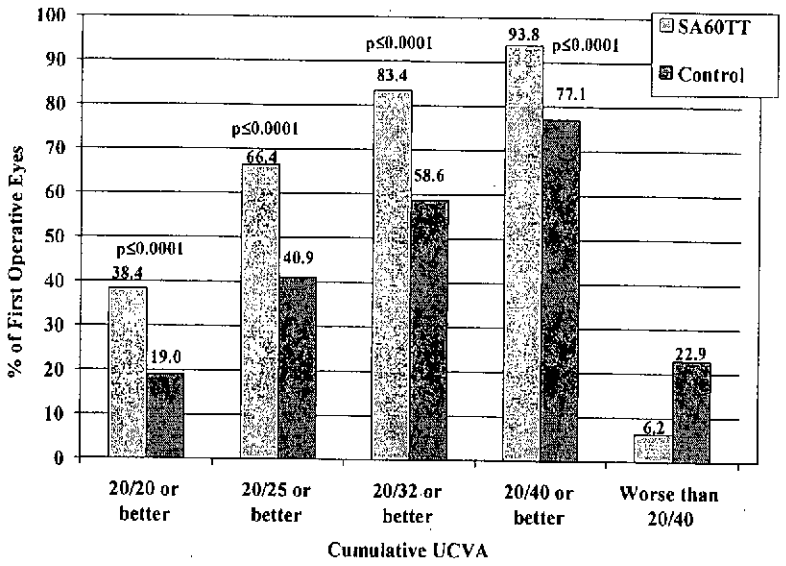
	Sample size	Acuity											
		20/20 or better		20/25		20/32		20/40		Worse than 20/40		20/40 or better	
	N	n	%	n	%	n	%	n	%	n	%	n	%
Age Category													
<60	33	15	45.5	11	33.3	2	6.1	4	12.1	1	3.0	32	97.0
60-69	56	25	44.6	11	19.6	14	25.0	6	10.7	0	0	56	100.0
70-79	90	32	35.6	29	32.2	15	16.7	7	7.8	7	7.8	83	92.2
≥80	32	9	28.1	8	25.0	5	15.6	5	15.6	5	15.6	27	84.4
Total	211	81	38.4	59	28.0	36	17.1	22	10.4	13	6.2	198	93.8

Table 5B
Uncorrected Distance Visual Acuity by Age Category, Status at Form 5 - Lens Model SA60AT, All Implanted

	Sample size	Acuity											
		20/20 or better		20/25		20/32		20/40		Worse than 20/40		20/40 or better	
	N	N	%	n	%	n	%	n	%	n	%	n	%
Age Category													
<60	15	2	13.3	6	40.0	2	13.3	1	6.7	4	26.7	11	73.3
60-69	54	14	25.9	10	18.5	13	24.1	5	9.3	12	22.2	42	77.8
70-79	92	18	19.6	16	17.4	12	13.0	28	30.4	18	19.6	74	80.4
≥80	49	6	12.2	14	28.6	10	20.4	5	10.2	14	28.6	35	71.4
Total	210	40	19.0	46	21.9	37	17.6	39	18.6	48	22.9	162	77.1

At the Form 5 visit, shown in Figure 3A, 93.8% of Model SA60TT subjects achieved 20/40 or better UCDVA (first operative eye of the All Implanted data set) compared to 77.1% of the subjects implanted with the control Model SA60AT. The difference in UCDVA between Models SA60TT and SA60AT was statistically significant (all p-values < 0.0001) in favor of Model SA60TT.

Figure 3A
Cumulative UCDVA, Status at Form 5, Model SA60TT vs. Control



Figures 3B – 3D show a summary of cumulative uncorrected distance visual acuities for each Toric IOL model compared to the control subjects in the same cylinder range. Figure 3B shows that the difference in cumulative UCDVA between Models SA60T3 and SA60AT was statistically significant (all p-values < 0.0115) for each visual acuity category (20/20 or better, 20/25 or better, 20/32 or better and 20/40 or better) in favor of Model SA60T3.

Figure 3B
Cumulative UCDVA, Model SA60T3 vs. Control, Form 5, All Implanted

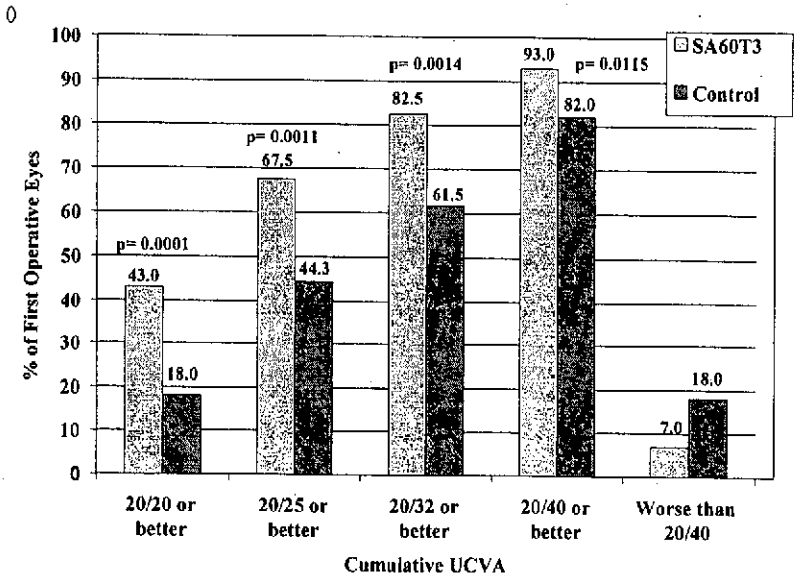


Figure 3C shows that the difference in cumulative UCDVA between Models SA60T4 and SA60AT was statistically significant (all p-values ≤ 0.0082) for each visual acuity category (20/25 or better, 20/32 or better and 20/40 or better) in favor of Model SA60T4 with the exception of the 20/20 or better category.

Figure 3C
Cumulative UCDVA, Model SA60T4 vs. Control, Form 5, All Implanted

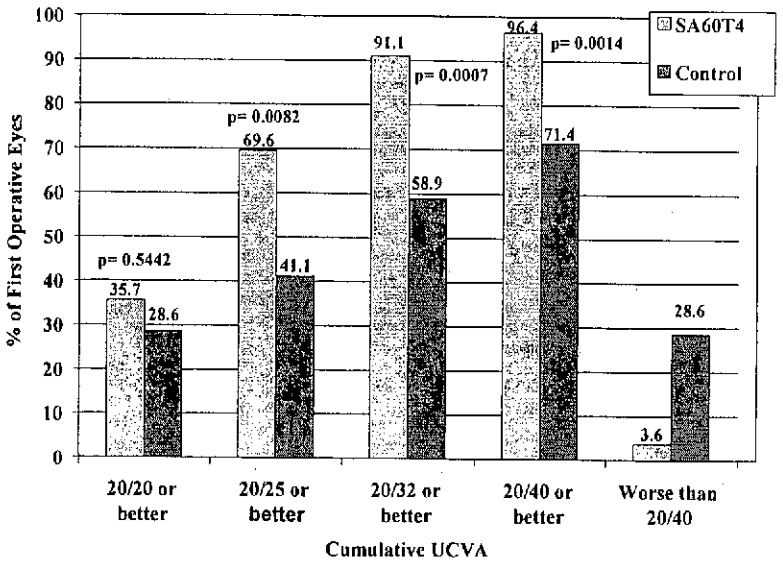
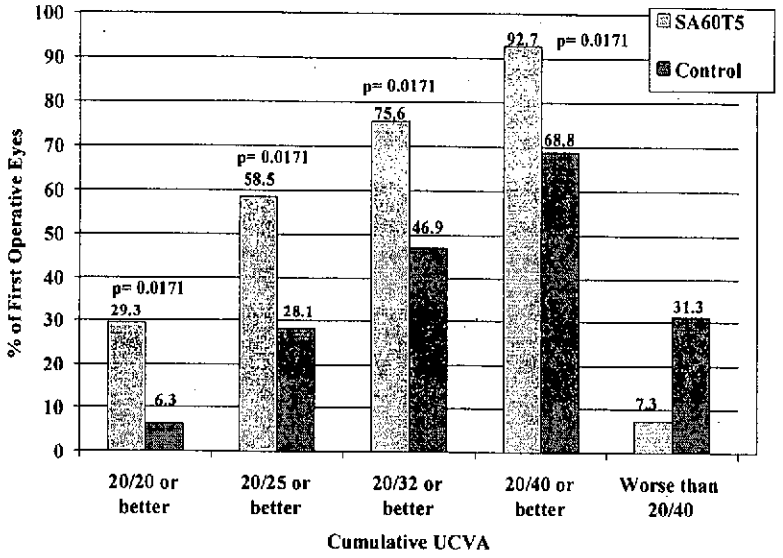


Figure 3D shows that the difference in cumulative UCDVA between Models SA60T5 and SA60AT was statistically significant (all p-values < 0.0171) for each visual acuity category (20/20 or better, 20/25 or better, 20/32 or better and 20/40 or better) in favor of Model SA60T5.

Figure 3D
Cumulative UCDVA, Model SA60T5 vs. Control, Form 5, All Implanted



AcrySof® TORIC INTRAOCULAR LENS BEST SPECTACLE DISTANCE CORRECTED VISUAL ACUITY

A summary of best spectacle corrected distance visual acuity (BSCDVA) achieved at six months postoperatively among subjects who did not have any visually significant preoperative pathology or macular degeneration at any time (Best Case) is presented in Table 6A. Visual acuity achieved by the overall subject population is shown in Table 6C. Control data are found for the same data sets in Tables 6B and 6D, respectively.

Of the first operative eyes implanted with a Model SA60TT and examined at the Form 5 visit, 100.0% achieved a BSCDVA of 20/40 or better in the Best Case dataset. These rates exceed the FDA grid rates of 96.7%.

Table 6A
BSCDVA by Age Category, Status at Form 5 - Lens Model SA60TT, Best Case

Age Category	Sample size	Acuity										20/40 or better	
		20/20 or better		20/25		20/32		20/40		Worse than 20/40			
	N	n	%	n	%	n	%	n	%	n	%	n	%
<60	29	27	93.1	1	3.4	1	3.4	0	0	0	0	29	100.0
60-69	51	42	82.4	7	13.7	2	3.9	0	0	0	0	51	100.0
70-79	73	57	78.1	13	17.8	3	4.1	0	0	0	0	73	100.0
≥80	20	14	70.0	4	20.0	1	5.0	1	5.0	0	0	20	100.0
Total	173	140	80.9	25	14.5	7	4.0	1	0.6	0	0	173	100.0

Table 6B
BSCDVA by Age Category, Status at Form 5 - Lens Model SA60AT, Best Case

Age Category	Sample size	Acuity										20/40 or better	
		20/20 or better		20/25		20/32		20/40		Worse than 20/40			
	N	n	%	n	%	n	%	n	%	n	%	n	%
<60	15	13	86.7	1	6.7	1	6.7	0	0	0	0	15	100.0
60-69	49	38	77.6	11	22.4	0	0	0	0	0	0	49	100.0
70-79	75	48	64.0	21	28.0	6	8.0	0	0	0	0	75	100.0
≥80	32	19	59.4	8	25.0	2	6.3	3	9.4	0	0	32	100.0
Total	171	118	69.0	41	24.0	9	5.3	3	1.8	0	0	171	100.0

Of the first operative eyes implanted with a Model SA60TT and examined at the Form 5 visit, 100.0% achieved a BSCDVA of 20/40 or better in the All Implanted dataset. These rates exceed the FDA grid rates of 92.5%.

Table 6C
BSCDVA by Age Category, Status at Form 5 - Lens Model SA60TT, All Implanted

Age Category	Sample size	Acuity										20/40 or better	
		20/20 or better		20/25		20/32		20/40		Worse than 20/40			
	N	n	%	n	%	n	%	n	%	n	%	n	%
<60	33	30	90.9	2	6.1	1	3.0	0	0	0	0	33	100.0
60-69	56	47	83.9	7	12.5	2	3.6	0	0	0	0	56	100.0
70-79	90	72	80.0	15	16.7	3	3.3	0	0	0	0	90	100.0
≥80	32	22	68.8	5	15.6	4	12.5	1	3.1	0	0	32	100.0
Total	211	171	81.0	29	13.7	10	4.7	1	0.5	0	0	211	100.0

Table 6D
BSCDVA by Age Category, Status at Form 5 - Lens Model SA60AT, All Implanted

Age Category	Sample size	Acuity										20/40 or better	
		20/20 or better		20/25		20/32		20/40		Worse than 20/40			
	N	n	%	n	%	n	%	n	%	n	%	n	%
<60	15	13	86.7	1	6.7	1	6.7	0	0	0	0	15	100.0
60-69	54	41	75.9	12	22.2	1	1.9	0	0	0	0	54	100.0
70-79	91	59	64.8	22	24.2	10	11.0	0	0	0	0	91	100.0
≥80	49	28	57.1	13	26.5	2	4.1	3	6.1	3	6.1	46	93.9
Total	209	141	67.5	48	23.0	14	6.7	3	1.4	3	1.4	206	98.6

Figures 4A – 4C show a summary of cumulative best corrected visual acuities for each Toric model compared to the control subjects in the same cylinder range for the All Implanted dataset.

Figure 4A
Cumulative BSCDVA, Model SA60T3 vs. Control, Form 5, All Implanted

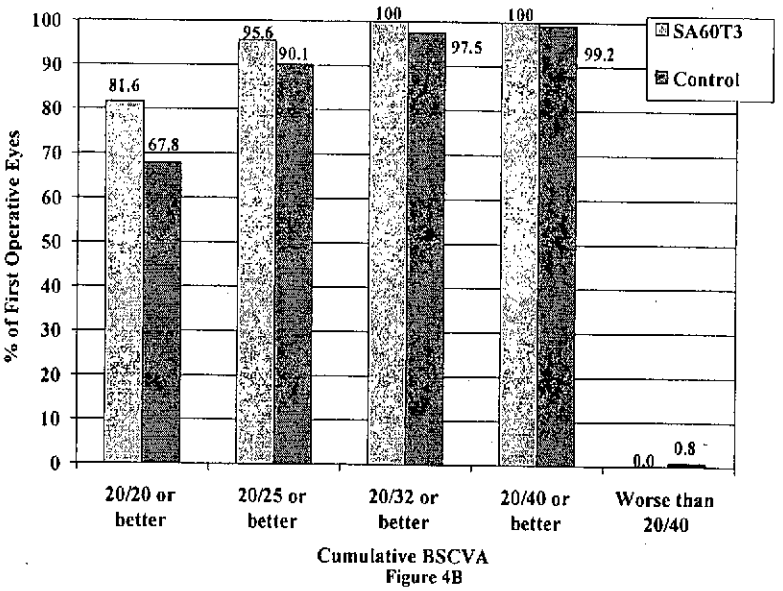


Figure 4B
Cumulative BSCDVA, Model SA60T4 vs. Control, Form 5, All Implanted

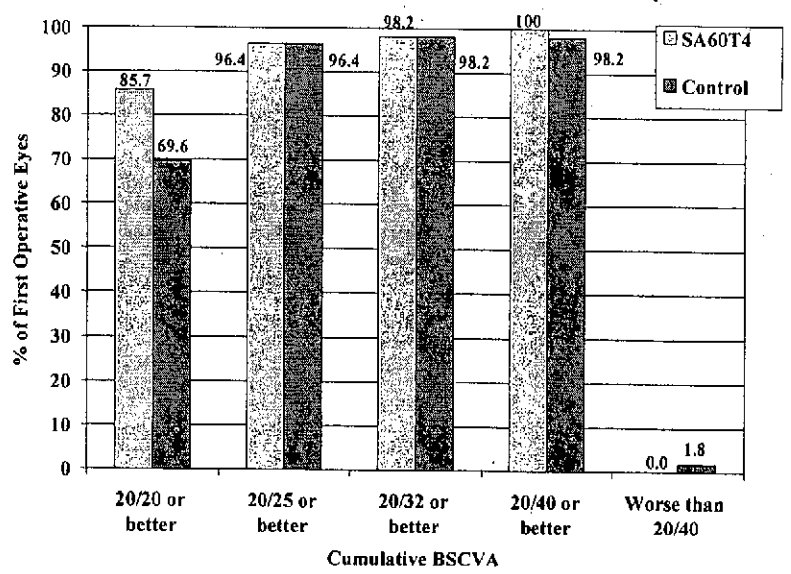
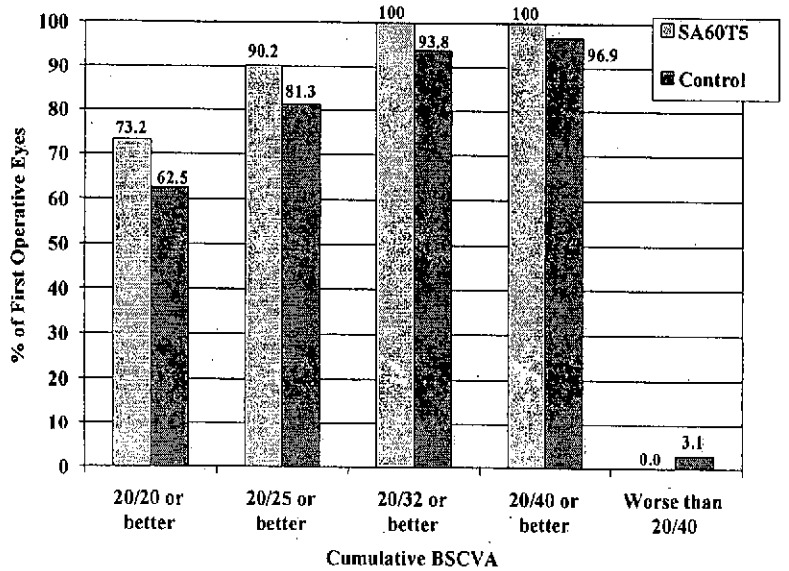


Figure 4C
Cumulative BSCDVA, Model SA60T5 vs. Control, Form 5, All Implanted



AcrySof® TORIC INTRAOCULAR LENS ABSOLUTE RESIDUAL REFRACTIVE CYLINDER

Figures 5A through 5C demonstrate that residual refractive cylinder values were statistically significantly lower among those subjects implanted with either an AcrySof® Toric Model SA60T3, SA60T4 or SA60T5 IOL when compared to the corresponding subjects implanted with the control Model SA60AT. Subjects implanted with an AcrySof® Toric Model SA60T3 showed a 62.4% mean reduction in refractive cylinder from the preoperative visit (keratometric cylinder) as compared to the 10.8% mean reduction for subjects implanted with the concurrent control Model SA60AT. Subjects implanted with an AcrySof® Toric Model SA60T4 or SA60T5 showed similar results with a mean reduction in refractive cylinder of 54.8 % and 67.8%, respectively, as compared to subjects implanted with the concurrent control model who had a mean reduction in refractive cylinder of 22.1% and 27.7%, respectively. Each of the AcrySof® Toric Lens Models SA60T3, SA60T4 and SA60T5 had at least a 3-fold increase in the likelihood of achieving residual refractive cylinder of 0.5 D or less as compared to the corresponding control model.

Figure 5A
Absolute Residual Refractive Cylinder,
Model SA60T3 vs. Control, Form 5, All Implanted

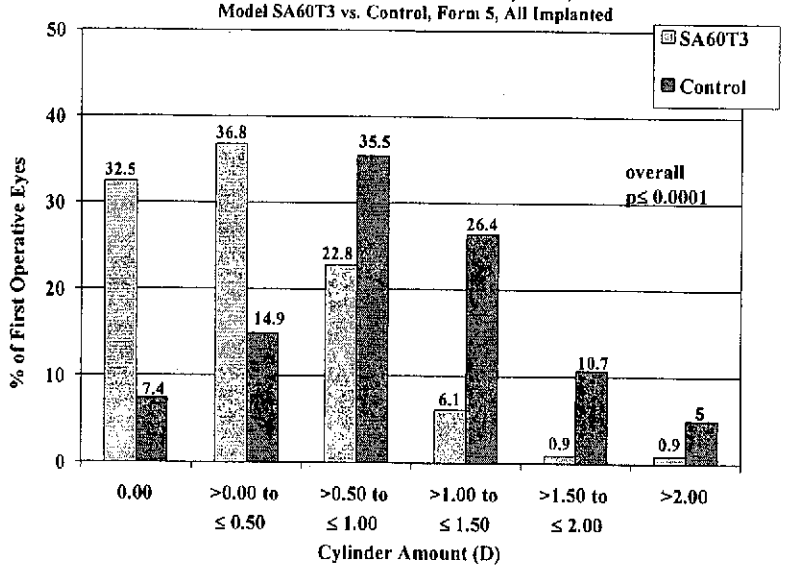


Figure 5B
Absolute Residual Refractive Cylinder,
Model SA60T4 vs. Control, Form 5, All Implanted

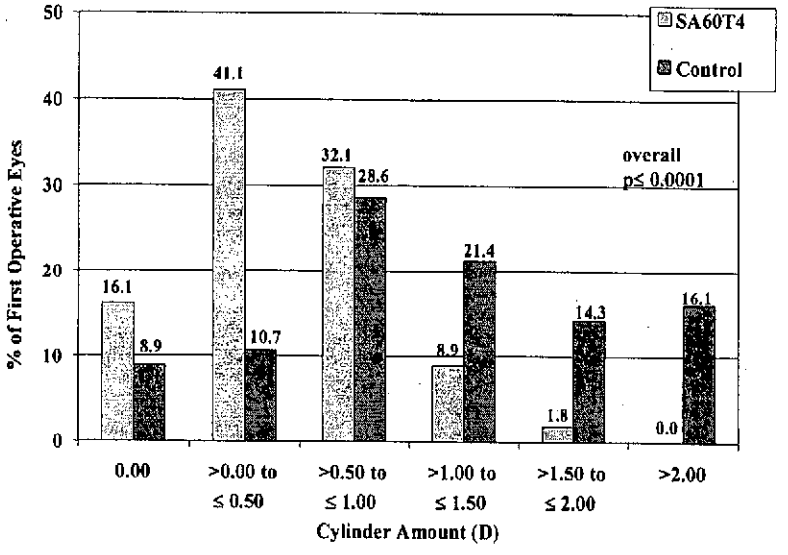
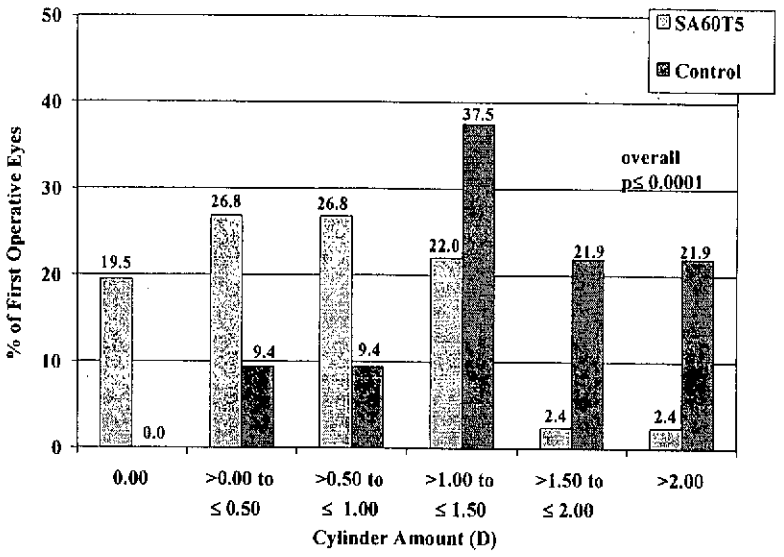


Figure 5C
Absolute Residual Refractive Cylinder,
Model SA60T5 vs. Control, Form 5, All Implanted



AcrySof® TORIC INTRAOCULAR LENS STABILITY OF CYLINDER

Subjects implanted with lens Model SA60TT exhibited stability of cylinder at Form 4 (3 months) with greater than 90% of all subjects changing less than or equal to 1.00 diopter at consecutive visits between Form 3 (one month) and Form 6 (twelve months).

Table 7A
AcrySof® Toric IOL: Stability of Cylinder
(Eyes that had 2 consecutive exams, but not necessarily every follow-up exam)

Recommended Corneal Astigmatism Correction Ranges	Toric IOL Model	Magnitude of Vector Change in Cylinder	1 and 3 Months n/N,%	3 and 6 Months n/N,%	6 and 12 Months n/N,%
< 1.5 D	SA60T3	≤ 1.00 D	106/107,99.07%	101/105,96.19%	55/55,100.00%
		Mean Change	0.28	0.29	0.20
		SD	0.32	0.33	0.25
≥ 1.5 - < 2.0 D	SA60T4	≤ 1.00 D	54/56,96.43%	53/54,98.15%	25/27,92.59%
		Mean Change	0.40	0.27	0.46
		SD	0.35	0.22	0.45
≥ 2.0 D	SA60T5	≤ 1.00 D	40/45,88.89%	35/40,87.50%	27/30,90.00%
		Mean Change	0.43	0.42	0.41
		SD	0.44	0.45	0.38
Combined	SA60TT	≤ 1.00 D	200/208,96.15% (93.54,98.77)	189/199,94.97% (91.94,98.01)	107/112,95.54% (91.71,99.36)
		Mean Change	0.35	0.31	0.32
		SD	0.36	0.34	0.36
		95% CI	0.30,0.39	0.26,0.36	0.25,0.39
n/N,%,(%CI) are for percent with change between ± 1.00D					

Table 7B
AcrySof® Toric IOL: Stability of Cylinder
(Eyes that had every follow-up exam up to Form 6, 12 months)

Recommended Corneal Astigmatism Correction Ranges	Toric IOL Model	Magnitude of Vector Change in Cylinder	1 and 3 Months n/N,%	3 and 6 Months n/N,%	6 and 12 Months n/N,%
< 1.5 D	SA60T3	≤ 1.00 D	34/34,100.00%	34/34,100.00%	34/34,100.00%
		Mean Change	0.25	0.24	0.21
		SD	0.23	0.22	0.24
≥ 1.5 - < 2.0 D	SA60T4	≤ 1.00 D	17/17,100.00%	16/17,94.12%	16/17,94.12%
		Mean Change	0.27	0.25	0.35
		SD	0.25	0.26	0.33
≥ 2.0 D	SA60T5	≤ 1.00 D	17/19,89.47%	15/19,78.95%	16/19,84.21%
		Mean Change	0.44	0.56	0.52
		SD	0.47	0.50	0.43
Combined	SA60TT	≤ 1.00 D	68/70,97.14% (93.23,100.00)	65/70,92.86% (86.82,98.90)	66/70,94.29% (88.84,99.73)
		Mean Change	0.31	0.33	0.33
		SD	0.32	0.35	0.34
		95% CI	0.23,0.38	0.24,0.41	0.25,0.41
n/N,%,(%CI) are for percent with change between ± 1.00D					

Table 7C
AcrySof® Toric IOL: Stability of Absolute Cylinder
(Eyes that had 2 consecutive exams, but not necessarily every follow-up exam)

Recommended Corneal Astigmatism Correction Ranges	Toric IOL Model	Magnitude of Change in Absolute Cylinder	1 and 3 Months n/N,%	3 and 6 Months n/N,%	6 and 12 Months n/N,%
< 1.5 D	SA60T3	≤ 1.00 D	107/107,100.00%	104/105,99.05%	55/55,100.00%
		Mean Change	0.04	0.02	0.05
		SD	0.32	0.38	0.29
≥ 1.5 - < 2.0 D	SA60T4	≤ 1.00 D	54/56,96.43%	54/54,100.00%	27/27,100.00%
		Mean Change	0.18	0.05	-0.12
		SD	0.42	0.27	0.41
≥ 2.0 D	SA60T5	≤ 1.00 D	44/45,97.78%	37/40,92.50%	29/30,96.67%
		Mean Change	0.09	0.06	0.00
		SD	0.38	0.49	0.45
Combined	SA60TT	≤ 1.00 D	205/208,98.56% (96.93,100.00)	195/199,97.99% (96.04,99.94)	111/112,99.11% (97.36,100.00)
		Mean Change	0.09	0.03	-0.01
		SD	0.37	0.38	0.37
		95% CI	0.04,0.14	-0.02,0.09	-0.08,0.06
n/N,%,(%CI) are for percent with change between ± 1.00D					

Table 7D
AcrySof® Toric IOL: Stability of Absolute Cylinder
(Eyes that had every follow-up exam up to Form 6, 12 months)

Recommended Corneal Astigmatism Correction Ranges	Toric IOL Model	Magnitude of Change in Absolute Cylinder	1 and 3 Months n/N,%	3 and 6 Months n/N,%	6 and 12 Months n/N,%
< 1.5 D	SA60T3	≤ 1.00 D	34/34,100.00%	34/34,100.00%	34/34,100.00%
		Mean Change	0.01	-0.01	0.07
		SD	0.28	0.31	0.28
≥ 1.5 - < 2.0 D	SA60T4	≤ 1.00 D	17/17,100.00%	17/17,100.00%	17/17,100.00%
		Mean Change	0.06	0.19	-0.04
		SD	0.30	0.21	0.42
≥ 2.0 D	SA60T5	≤ 1.00 D	18/19,94.74%	17/19,89.47%	18/19,94.74%
		Mean Change	0.17	0.05	0.01
		SD	0.45	0.54	0.55
Combined	SA60TT	≤ 1.00 D	69/70,98.57% (95.78,100.00)	68/70,97.14% (93.23,100.00)	69/70,98.57% (95.78,100.00)
		Mean Change	0.07	0.05	0.03
		SD	0.34	0.38	0.40
		95% CI	-0.01,0.15	-0.04,0.14	-0.07,0.12
n/N,%,(%CI) are for percent with change between ± 1.00D					

AcrySof® TORIC INTRAOCULAR LENS ROTATIONAL STABILITY

A summary of the change in axis orientation (rotation) from the operative visit to the Form 5 visit (120-180 days postoperative) is presented in Figures 6A and 6B. The rotational stability of the AcrySof® Toric Model SA60TT is established with the majority of the lenses rotating ≤ 5°. Figure 6A also demonstrates that the amount of rotation seen in each AcrySof® Toric IOL model is independent of the amount of cylinder power present on the lens.

Figure 6A
Change in Axis Orientation from Operative Visit to Form 5, All Implanted

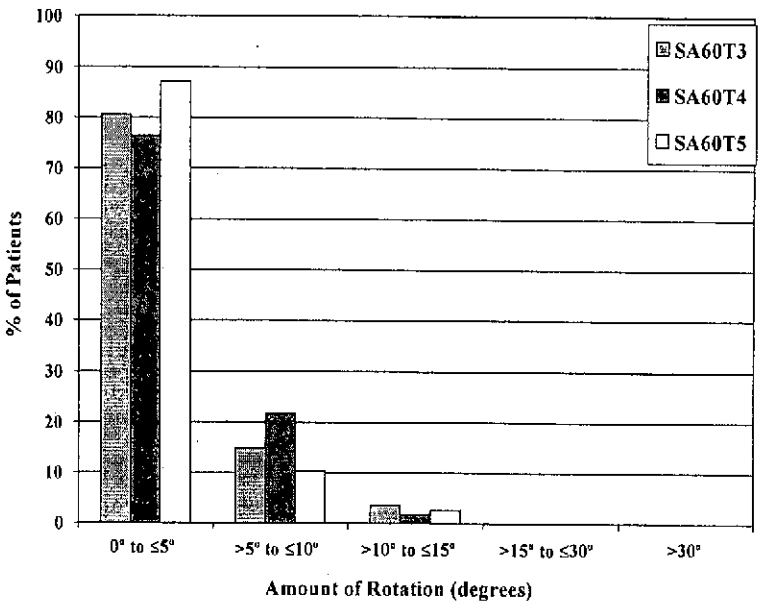
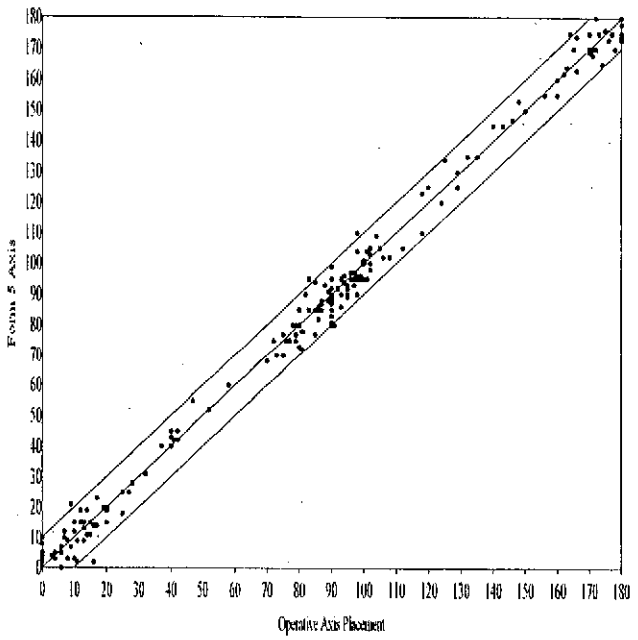


Figure 6B
Orientation of Lens Axis, Operative Visit versus Form 5,
Model SA60TT, All Implanted



AcrySof® TORIC INTRAOCULAR LENS ADVERSE EVENTS

The incidence of cumulative adverse events for the Model SA60TT compared favorably to the FDA historical grid rates. Only the rates for retinal detachment/repair and surgical reintervention exceeded the FDA historical grid. However, neither of these rates were statistically significant (p=0.5196 and p= 0.1336, respectively). No occurrences of persistent adverse events were observed in any patients implanted with the AcrySof® Toric IOL.

Table 8
Adverse Events Incidence Rates
First Eye – Safety

	Model S60TT N=244		FDA Grid Rate
Cumulative Adverse Events	N	%	%
Retinal Detachment/Repair	1	0.4	0.3
Surgical Reintervention	4[a]	1.6	0.8
IOL Reposition Due to Rotation	1	0.4	NA
IOL Replacement Due to Rotation	1	0.4	NA
Laser Treatment	2	0.8	NA
Paracentesis	1	0.4	NA

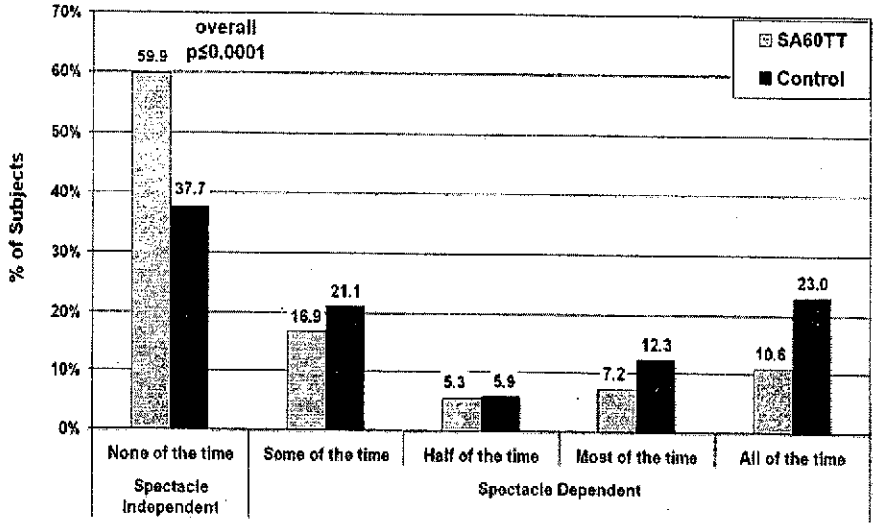
The incidence rates in this table are based upon the number of eyes with an event divided by the number of eyes implanted.
Cumulative adverse events are those events that have occurred at any time during the clinical study.
FDA Grid Rate = FDA Grid of Adverse Events with Posterior Chamber Intraocular Lens Historical Controls, FDA Intraocular Lens Guidance Document, Annex B (October 14, 1999)
[a] There were 5 occurrences of surgical reintervention in 4 eyes for Model SA60TT first eye

The incidence of cumulative adverse events for the Model SA60TT also compared favorably to the concurrent control.

AcrySof® TORIC INTRAOCULAR LENS DISTANCE-VISION SPECTACLE INDEPENDENCE

Statistically significantly more Model SA60TT subjects reported postoperative distance-vision spectacle independence compared to Model SA60AT subjects (59.9% versus 37.7%, respectively) when unilaterally implanted. Distance-vision spectacle independence was defined as the percentage of subjects who selected the "none of the time" response for distance-vision frequency-of-spectacle-wear. Spectacle dependence was defined as subjects indicating any reliance on glasses for distance-vision and represents the summation of the "some of the time", "half of the time", "most of the time" and "all of the time" frequency-of-spectacle-wear responses. Consequently, fewer Model SA60TT subjects were spectacle dependent at 40.1% compared to 62.3% of the Model SA60AT subjects. Figure 7 illustrates the distance-vision frequency-of-spectacle-wear distributions between Model SA60TT and Model SA60AT groups. Implantation of an AcrySof® Toric Intraocular lens in astigmatic subjects provides significantly improved distance-vision spectacle independence relative to a conventional monofocal IOL.

Figure 7
Distance-Vision Spectacle Independence:
Frequency-of-Spectacle-Wear, Form 5, All Implanted



AcrySof® TORIC HIGH CYLINDER POWER INTRAOCULAR LENS CLINICAL STUDY

A clinical study was conducted to investigate the rates of spatial distortions related to axial misalignment of the AcrySof® Toric Posterior Chamber High Cylinder Power Intraocular Lenses. The cylinder power at the IOL plane and corneal plane and the recommended correction ranges are shown in Table 9.

Table 9 High Cylinder Powers and Recommended Correction Ranges

Model	Cylinder Power		Toric Calculator Recommended Corneal Astigmatism Correction Ranges
	at IOL plane	at corneal plane	
SN60T6	3.75	2.57	2.57 - 3.07 D
SN60T7	4.50	3.08	3.08 – 3.59 D
SN60T8	5.25	3.60	3.60 – 4.10 D
SN60T9	6.00	4.11	4.11 D and up

These recommended corneal astigmatism correction ranges are based on the preoperative corneal astigmatism and the predicted effect of surgically induced astigmatism. To obtain the IOL cylindrical powers and the orientation of the surgical placement of the axes, for each operative eye the preoperative keratometry values and axes, IOL spherical power (as determined by the surgeon's preferred formula) and the surgeon's estimated surgically induced astigmatism (SIA) at the standard temporal incision location are entered into Alcon's proprietary web-based AcrySof Toric IOL calculator. The combination of these parameters are used in the Alcon provided software to select the appropriate Toric IOL model and recommended axis of placement. As such, the recommended range of corneal astigmatism to be corrected while not identical, is directly related to, the preoperative keratometric cylinder.

The results achieved by the patients followed to six months (Visit 5A) postoperatively demonstrate that the AcrySof® Toric high cylinder intraocular lens models are safe and effective for the visual correction of aphakia. The following clinical results illustrate the AcrySof® Toric high cylinder power IOL's effectiveness in significantly reducing pre-existing corneal astigmatism and the IOL's excellent rotational stability following implantation in the capsular bag

AcrySof® TORIC HIGH CYLINDER POWER INTROCULAR LENS CLINICAL STUDY PATIENT POPULATION

This study focused on the highest cylinder power IOL Model SN60T9; however, due to the rarity of this level of astigmatism IOL Model SN60T8 was included to expand the inclusion criteria for the second eye. The subject population implanted with an IOL Model SN60T9 in the first operative eye consists of 80% (12/15) females and 20% (3/15) males. For the fellow eye, 3 subjects were implanted with IOL Model SN60T9, while 12 were implanted with IOL Model SN60T8. All 15 (100%) of the implanted subjects were white. The mean age for the population was 67 years old (range of 43 to 82 years) at the time of surgery.

AcrySof® TORIC HIGH CYLINDER POWER INTRAOCULAR LENS ABSOLUTE RESIDUAL REFRACTIVE CYLINDER

Refractive cylinder six months postoperatively was reduced for all subjects implanted with either an AcrySof® Toric IOL Model SN60T8 or SN60T9 compared to preoperative baseline. Results show a statistically significant reduction (p-value <.0001) in residual refractive cylinder in eyes implanted with IOL Model SN60T9 [85.7% in first eyes (n=15), 87.8% in second eyes (n=3) and IOL Model SN60T8 [87.3% (n=12)]..

AcrySof® TORIC HIGH CYLINDER POWER INTRAOCULAR LENS ROTATIONAL STABILITY

A summary of the change in axis orientation (rotation) from the operative visit to Visit 5A (six months postoperative) is presented in Figure 8A and 8B. The AcrySof® Toric high cylinder power IOLs demonstrated rotational stability with the majority of the lenses rotating ≤ 5°.

Figure 8A
Change in Lens Axis Orientation - Visit 5A (Final 6-Month Visit) versus Target

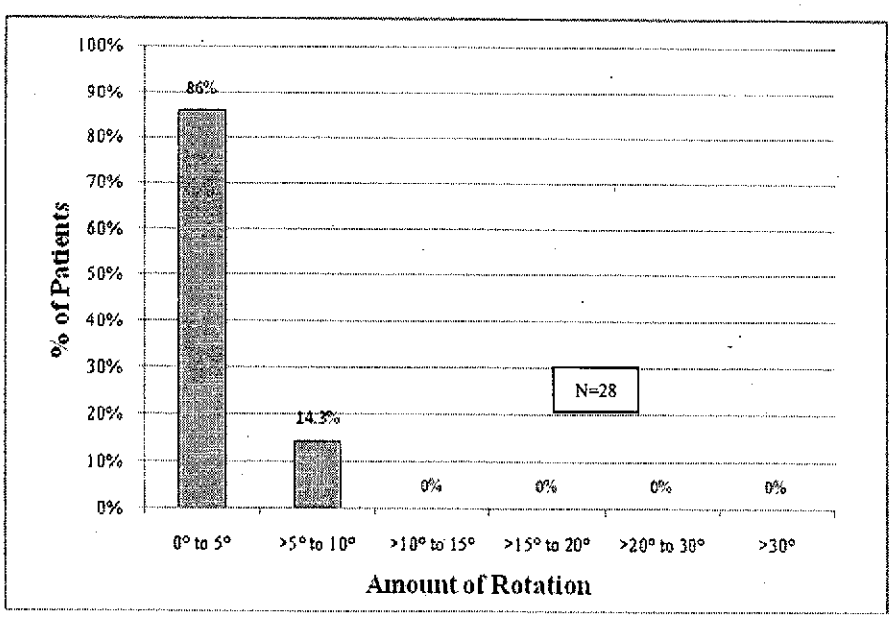
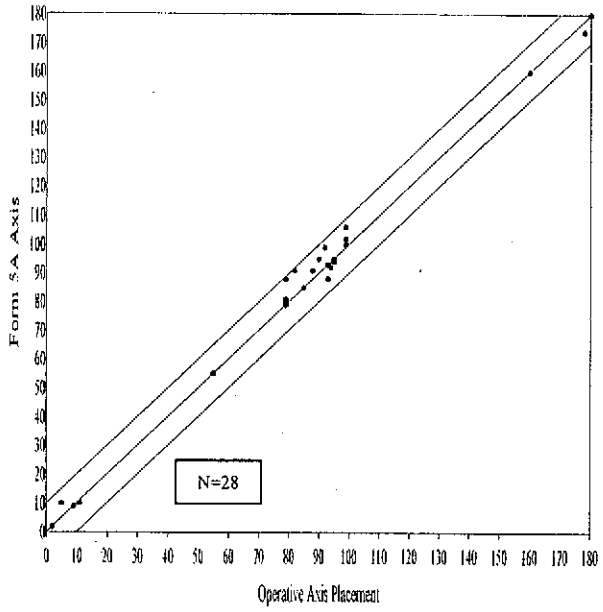


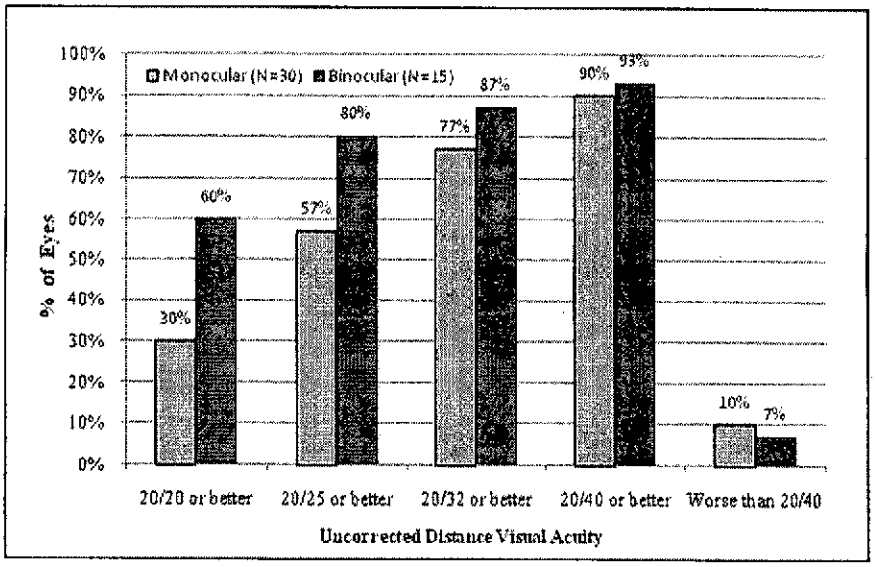
Figure 8B
Orientation of Lens Axis, Operative Visit versus Visit 5A (Final Visit)
IOL Models SN60T9 and SN60T8



AcrySof® TORIC HIGH CYLINDER POWER INTRAOCULAR LENS UNCORRECTED DISTANCE VISUAL ACUITY

All Subjects implanted bilaterally with the AcrySof® Toric IOL Models SN60T8 or SN60T9 achieved improved binocular uncorrected distance visual acuity six months postoperatively. Figure 9 demonstrates that 60% of subjects achieved 20/20 or better binocular uncorrected distance visual acuity compared to 30% for monocular eyes, while 93% of subjects achieved 20/40 or better binocular uncorrected distance visual acuity compared to 90% of monocular eyes. Less than 10% of subjects had monocular or binocular uncorrected distance visual acuity worse than 20/40 six months postoperatively.

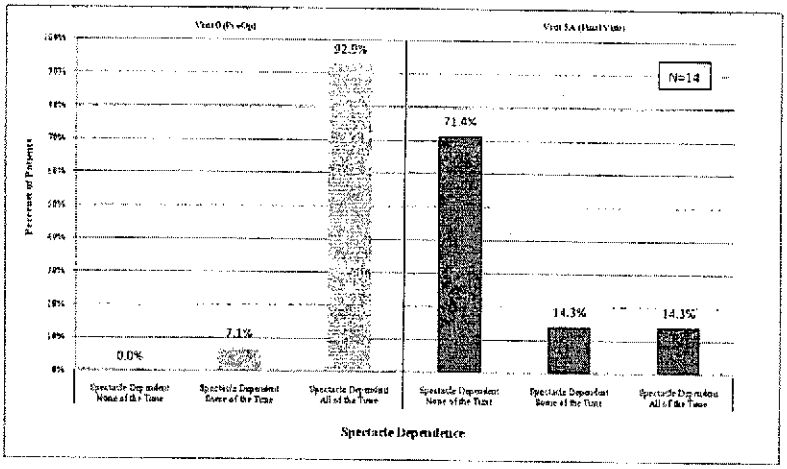
Figure 9
Cumulative UCDVA Monocular versus Binocular



AcrySof® TORIC HIGH CYLINDER POWER INTRAOCULAR LENS BILATERAL DISTANCE-VISION SPECTACLE INDEPENDENCE

Preoperatively all subjects were spectacle dependent, either all-the-time (92.9%) or some-of-the-time (7.1%). Six months postoperatively, 71.4% of subjects were spectacle independent (Figure 10).

Figure 10
Bilateral Distance Vision Spectacle Independence
Frequency-of-Spectacle-Wear Visit 0 (PreOp) versus Visit 5A (Final Visit)



AcrySof® TORIC HIGH CYLINDER POWER INTRAOCULAR LENS RATE OF SPATIAL DISTORTIONS

A Visual Distortion Questionnaire was administered preoperatively (Visit 0) and at six months postoperatively (Visit 5A) to evaluate the rate of spatial distortions of the AcrySof® Toric IOL Models SN60T8 and SN60T9. The overall rate of spatial distortions decreased postoperatively (Table 10A).

Table 10A:
Visual Distortion Questionnaire Results by Visit

During the past 4 weeks, have you had		PreOp (N = 14)		Final Visit (N = 14)	
		n	%	n	%
1) ...trouble with things appearing distorted?	No	3	21.4	12	85.7
	Yes	11	78.6	2[a,b]	14.3
2) ...trouble with flat surfaces (like floors) appearing curved?	No	12	85.7	13	92.9
	Yes	2	14.3	1[c]	7.1
3) ...trouble with straight lines (like door or window frames) appearing tilted?	No	10	71.4	14	100
	Yes	4	28.6	0	0.0
4) ...trouble with feeling sick to your stomach due to distortion of your vision?	No	14	100	14	100
	Yes	0	0.0	0	0.0

[a] Reported with or without glasses at Preop and Final Visit.
[b] Reported with or without glasses at Preop but only with glasses (progressive lenses) at Final Visit.
[c] Same subject as in (b). Reported only with glasses (progressive lenses) at Final Visit. Not reported at Preop.

Based on these questions spatial distortions associated with high pre-existing corneal astigmatism may not completely resolve postoperatively. Two subjects at Visit 5A continued to report "trouble with things appearing distorted" versus 11 subjects preoperatively. One of these subjects had "trouble with flat surfaces appearing curved," which was noted only postoperatively, but no longer experienced the preoperative visual phenomena of straight lines appearing tilted. Neither subject had IOL misalignment requiring secondary surgical intervention to address problems of spatial distortion. There were no reports of subjects feeling sick to their stomachs due to distortion of vision.

Responses to visual distortion sub-questions related to spectacle wear, frequency of experiencing distortion, and degree of bother are presented in Tables 10B through 10D.

Table 10B:
Visual Distortion Questionnaire Results – Trouble with Things Appearing Distorted

1) For subjects who had trouble with things appearing distorted in the last 4 weeks:		PreOp (N = 11)		Final Visit (N = 2)	
		n	%	n	%
Do you notice this only when you wear your glasses?	No	10	90.9	1	50.0
	Yes	1	9.1	1	50.0
How often have you noticed this?	Rarely	2	18.2	0	0.0
	Sometimes	2	18.2	0	0.0
	Frequently	3	27.3	1	50.0
	All the time	4	36.4	1	50.0
How much does it bother you?	None	1	9.1	1	50.0
	A Little	4	36.4	0	0.0
	A Lot	6	54.5	1	50.0

Table 10C:
Visual Distortion Questionnaire Results – Trouble with Flat Surfaces Appearing Curved

2) For subjects who had trouble with flat surfaces (like floors) appearing curved in the last 4 weeks:		PreOp (N = 2)		Final Visit (N = 1)	
		n	%	n	%
Do you notice this only when you wear your glasses?	No	2	100	0	0.0
	Yes	0	0.0	1	100
How often have you noticed this?	Rarely	0	0.0	0	0.0
	Sometimes	0	0.0	0	0.0
	Frequently	1	50.0	1	100
	All the time	1	50.0	0	0.0
How much does it bother you?	None	0	0.0	0	0.0
	A Little	0	0.0	0	0.0
	A Lot	2	100	1	100

Table 10D
Visual Distortion Questionnaire Results – Trouble with Straight Lines Appearing Tilted

3) For subjects who had trouble with straight lines (like door or window frames) appearing tilted in the last 4 weeks:		PreOp (N = 4)		Final Visit (N = 0)	
		n	%	n	%
Do you notice this only when you wear your glasses?	No	3	75.0	0	0.0
	Yes	1	25.0	0	0.0
How often have you noticed this?	Rarely	0	0.0	0	0.0
	Sometimes	2	50.0	0	0.0
	Frequently	0	0.0	0	0.0
	All the time	2	50.0	0	0.0
How much does it bother you?	None	0	0.0	0	0.0
	A Little	1	25.0	0	0.0
	A Lot	3	75.0	0	0.0

AcrySof® TORIC HIGH CYLINDER POWER INTRAOCULAR LENS ADVERSE EVENTS

During the study, 1 of 15 subjects underwent a secondary surgical intervention in the first eye to resolve residual refractive cylinder due to an error in preoperative keratometry. One week postoperatively, the IOL was repositioned. At six months postoperatively the subject was satisfied with uncorrected distance vision and did not experience any spatial distortion after IOL repositioning. No other serious adverse events were reported in the study.

OVERVIEW OF AcrySof® SINGLE-PIECE STUDIES

AcrySof® NATURAL SINGLE-PIECE IOL CLINICAL STUDY

A clinical study was conducted on patients receiving the AcrySof® Natural Single Piece IOL as compared to the AcrySof® UV Single Piece IOL. The results achieved by the patients successfully followed for a minimum of one year postoperatively provided reasonable assurance of safety and effectiveness for the visual correction of aphakia. For information pertaining to the results obtained in this clinical study, please reference the corresponding Physicians Labeling or that provided with other AcrySof® Natural monofocal IOLs.

AcrySof® NATURAL SINGLE-PIECE IOL COLOR PERCEPTION

Color perception testing using the Farnsworth D-15 Panel Test was conducted at the 120 to 180 day postoperative period. Of the 109 subjects with normal color vision implanted with the AcrySof® Natural IOL in the first operative eye and examined at the 120-180 day postoperative visit, 107 (98.2%) passed the color perception test. Of the 102 subjects with normal color vision implanted with a AcrySof® UV IOL in the first operative eye and examined at the 120-180 day postoperative visit, 97 (95.1%) passed the color perception test. There were no statistically significant differences between AcrySof® Natural IOL and AcrySof® UV

IOL for the percent of subjects that passed the color perception test at the 120 to 180 day postoperative visit. Therefore, the addition of the proprietary chromophore does not negatively affect color vision in patients with normal color vision.

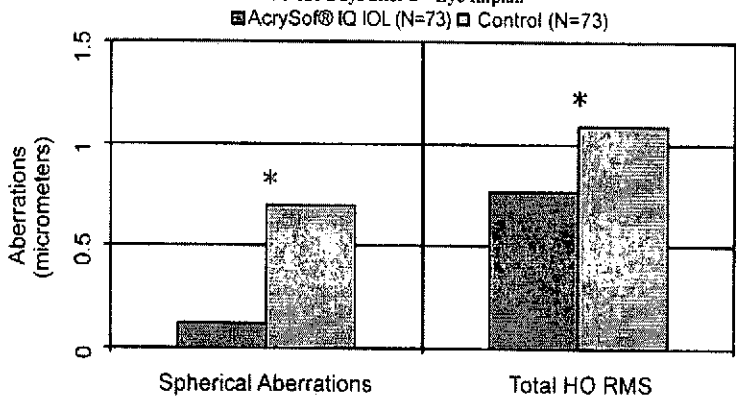
AcrySof® IQ LENS CLINICAL STUDY

Consistent with the design of similar previously conducted IOL studies, adult subjects in good general ocular health (e.g. no prior ocular surgery, degenerative visual disorder which would significantly impact visual acuity, or severe acute or chronic condition that may increase patient risk) having bilateral cataracts were enrolled in a controlled, randomized, double-masked, multi-center, contralateral implant clinical investigation of the AcrySof® IQ lens versus a spherical control lens. Ocular spherical aberrations were statistically significantly less with the AcrySof® IQ lens than the control lens. Contrast sensitivity results demonstrated a statistically significant postoperative (at 3 months) improvement in favor of AcrySof® IQ implanted eyes. Eyes implanted with the AcrySof® IQ lens also experienced statistically and clinically significant improvements in a functional vision measurement, simulated night driving, under several conditions tested - especially glare and fog. These results reflect that the AcrySof® IQ IOL (an aspheric optic on a material platform containing a blue-light filtering chromophore) provides beneficial clinical performance as compared to the monofocal AcrySof® IOL (without an aspheric optic and blue-light filtering chromophore).

AcrySof® IQ LENS – SPHERICAL AND TOTAL HIGHER ORDER ABERRATIONS

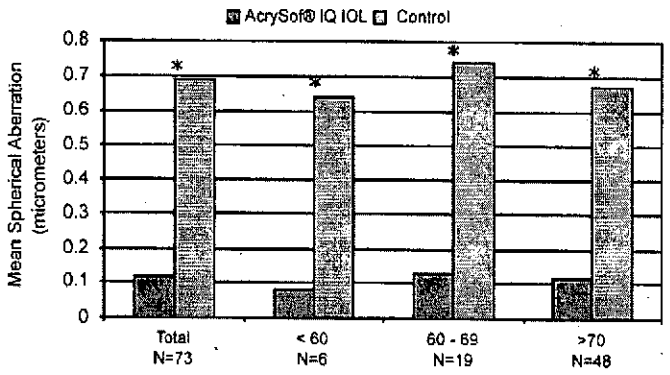
The mean ocular spherical aberration of the AcrySof® IQ eyes was approximately 0.1 micrometers. Figure 11 represents the statistically significant reduction in spherical and total higher order aberrations observed in favor of the AcrySof® IQ lens. Figure 12 provides the mean spherical aberration measurements of all eyes with wavefront aberrometer measurements by lens and age group. As depicted in this chart, the reduction in spherical aberration of the AcrySof® IQ eyes was independent of age.

Figure 11
Spherical and Total Higher Order RMS
90-120 Days after 2nd Eye Implan



* Differences favor AcrySof® IQ IOL overall and at each visit (p<0.0001)

Figure 12
Mean Spherical Aberration Overall and by Age Group
90-120 Days after 2nd Eye Implant

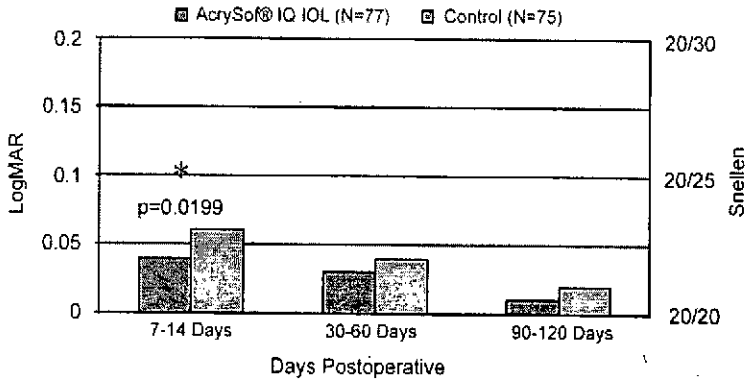


* Denotes statistical significance between lenses (p<0.0001)

AcrySof® IQ LENS – DISTANCE VISUAL ACUITY

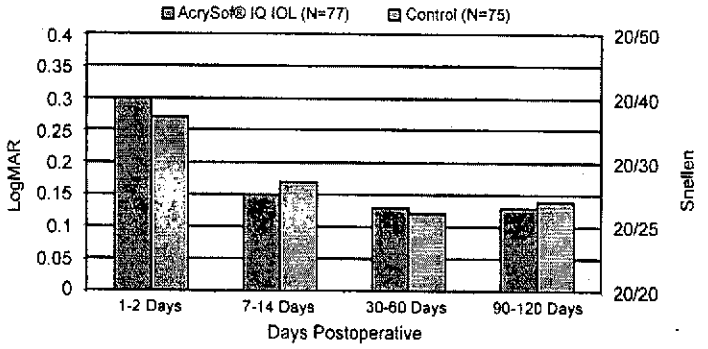
The AcrySof® IQ lens and the control lens provided clinically similar postoperative visual acuity. Monocular visual acuity results are presented in Figures 13 and 14.

Figure 13
LogMAR BCVA



* Quantitative Lens Model Main Effect (p=0.0214)

Figure 14
LogMAR UCVA



Differences are not statistically significant

AcrySof® IQ LENS - CONTRAST SENSITIVITY

The primary objective of the clinical investigation was to demonstrate superiority of the AcrySof® IQ lens over the control lens via mean contrast sensitivity measured postoperatively under mesopic conditions with or without glare at either of two spatial frequencies (3 or 6 cycles per degree) using the Vector Vision CSV-1000 (with chart luminance of 3 cd/m2). In a subset of patients, the Functional Acuity Contrast Test (FACT) was also performed (with chart luminance of 3 cd/m2). In this clinical investigation, superiority of the AcrySof® IQ lens over the control lens under mesopic conditions was demonstrated at 6 cycles per degree both with and without glare (CSV-1000) and at 3 and 6 cycles per degree without glare (FACT). Figures 15 and 16 depict the mesopic contrast sensitivity results at all spatial frequencies tested for both the AcrySof® IQ lens and control lens.

Figure 15
Mesopic Contrast Sensitivity (CSV-1000)
90-120 Days after 2nd Eye Implant

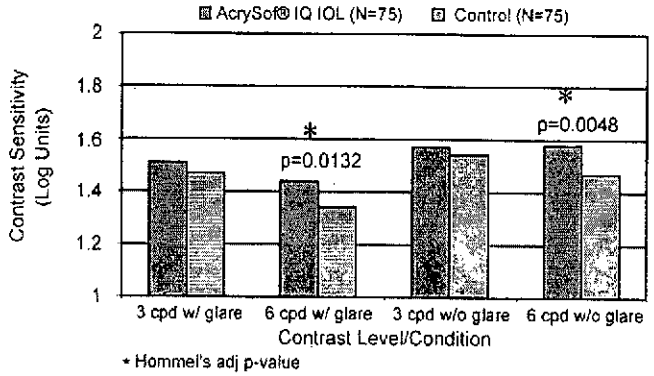
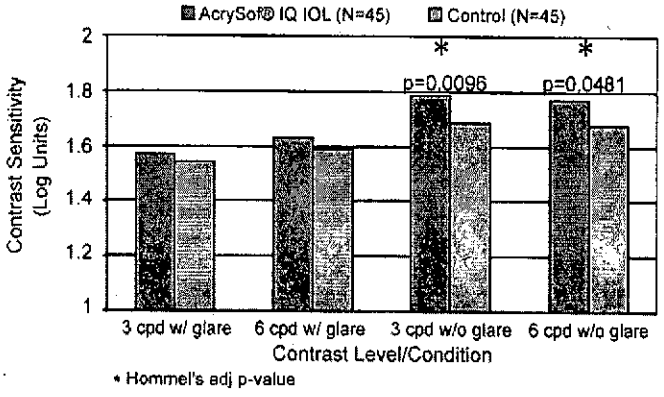


Figure 16
Mesopic Contrast Sensitivity (FACT) Substudy
Minimum of 90 days after 2nd Eye Implant



AcrySof® IQ LENS – NIGHT DRIVING SIMULATION

A subset of patients underwent testing in a validated night driving simulator. Patients were tested monocularly under conditions which simulate city and rural settings under normal, glare and fog conditions.

The nighttime city driving scene employs a variety of street lights, car lights, store lights and signs to recreate the high level of ambient lighting typical under these conditions. The nighttime rural driving scene uses a minimal amount of ambient lighting. Simulated driving speeds of approximately 35 mph and 55 mph were used for the city and rural scenes, respectively.

Patients were asked to detect and identify a series of targets in each scene, including white-green highway information signs, black-yellow warning signs and pedestrians. Patients were asked to respond when they saw the first target, allowing a detection distance to be recorded. Patients were then asked to respond when they could distinguish the target (e.g., what the sign says, which direction the pedestrian was walking, etc.) so that an identification distance could be recorded.

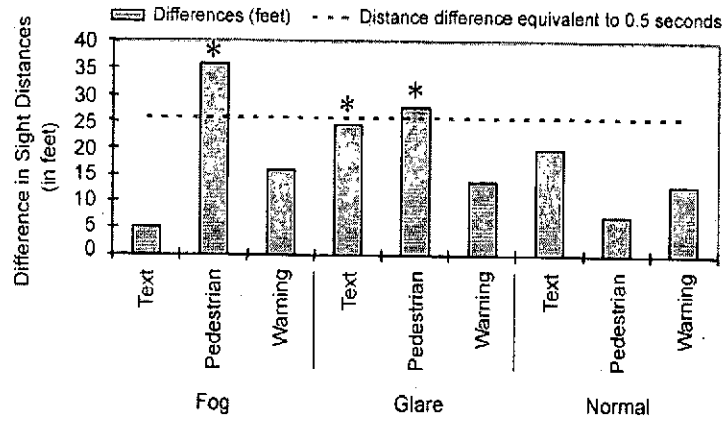
Figures 17 through 20 present the average differences between the AcrySof® IQ lens and control lens in city and rural driving scenes for both detection and identification distances (e.g., the mean of the intra-individual differences).

The AcrySof® IQ lens performed functionally better than the control in 34 of the 36 conditions tested, reflecting improvement in both detection and identification distances in both city and rural driving scenes under the various driving conditions tested (normal, glare, fog). Furthermore, the AcrySof® IQ lens performed statistically significantly better than the control in 12 of these conditions, with the most significant impact and greatest advantage observed in detection and identification of city pedestrians (under glare and fog conditions) and rural warning signs (under glare and fog conditions). Under reduced visibility conditions (glare,

fog) in the city scene, the increased visibility distance at 35 mph provides the AcrySof® IQ lens greater than 0.5 second additional time to respond to a pedestrian target, a hazard more commonly encountered in city settings. This 0.5 second increase is functionally significant in allowing for greater time to take appropriate actions such as stopping, avoidance, etc. (Green, 2000; McBride and Matson, 2004). Under all conditions in the rural scene, the increased visibility distance at 55 mph provides the AcrySof® IQ lens more than 1 second additional time to identify warning signs, a situation frequently encountered in rural areas. A 0.5 second increase is functionally significant in allowing for greater time to take appropriate action while driving, which becomes critical at night in unfamiliar rural areas where ambient lighting is often absent. There were 6 patients in the substudy who postoperatively experienced macular degeneration or PCO. When these patients were removed from the driving analysis, the difference between IOLs for detection and identification of pedestrian targets under glare conditions in the city location fell short of the 0.5-second threshold for clinical relevance. When the original analyses were adjusted for multiplicity, the difference between IOLs was no longer statistically significant for city detection of text under glare (Hommel's p-value = 0.0539) or for rural detection of pedestrian under glare (Hommel's p-value=0.0507).

These results demonstrate improved functional vision and likely meaningful safety benefits to elderly drivers with the AcrySof® IQ lens and to other drivers and pedestrians with whom they share the road. The results of this test demonstrate that the AcrySof® IQ lens improves functional vision, which in turn may improve patient safety for other life situations under low visibility conditions.

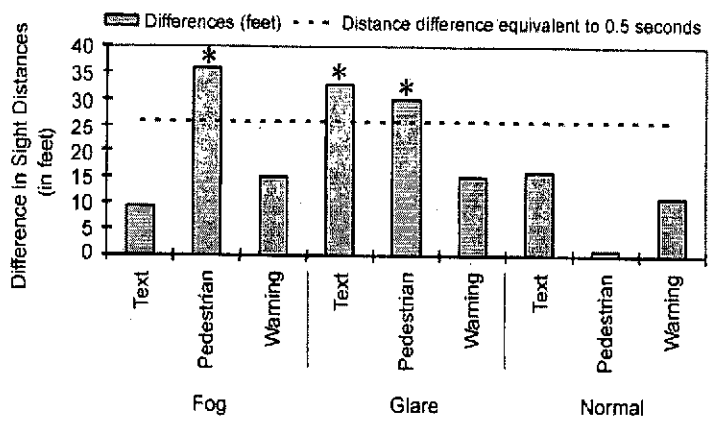
Figure 17
Night Driving Simulator
Mean Intra-individual Differences in Detection Sight Distances, City
Minimum of 90 days Postoperatively
AcrySof® IQ IOL –Control (n=44)



Distances for both lens groups were normalized

* Denotes statistical significance (p<0.05) in favor of AcrySof® IQ IOL.

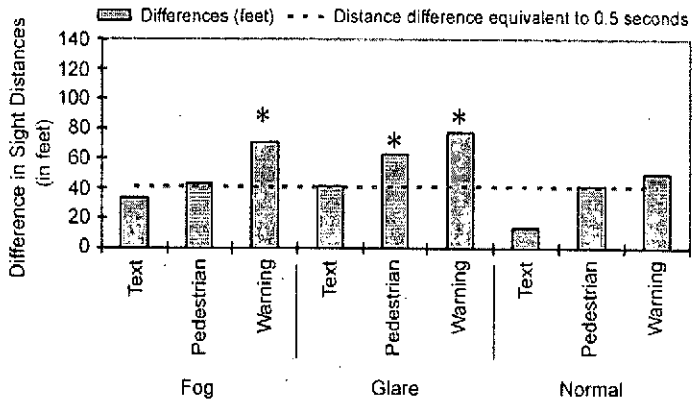
Figure 18
Night Driving Simulator
Mean Intra-individual Differences in Identification Sight Distances, City
Minimum of 90 days Postoperatively
AcrySof® IQ IOL–Control (n=44)



Distances for both lens groups were normalized.

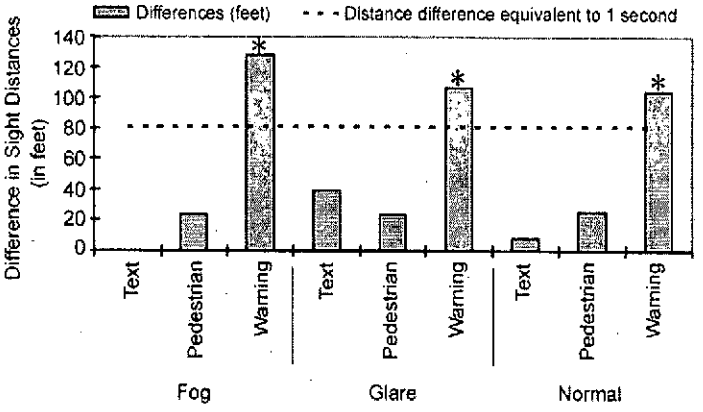
* Denotes statistical significance (p<0.05) in favor of AcrySof® IQ IOL.

Figure 19
Night Driving Simulator
Mean Intra-individual Differences in Detection Sight Distances, Rural
Minimum of 90 days Postoperatively
AcrySof® IQ IOL –Control (n=44)



Distances for both lens groups were normalized.
* Denotes statistical significance ($p<0.05$) in favor of AcrySof® IQ IOL.

Figure 20
Night Driving Simulator
Mean Intra-individual Differences in Identification Sight Distances, Rural
Minimum of 90 days Postoperatively
AcrySof® IQ IOL –Control (n=44)



Distances for both lens groups were normalized.
* Denotes statistical significance ($p<0.05$) in favor of AcrySof® IQ IOL.

HOW SUPPLIED

The AcrySof® IQ Toric IOL is supplied dry, in a package terminally sterilized with ethylene oxide, and must be opened only under aseptic conditions (See DIRECTIONS FOR USE).

EXPIRATION DATE

Sterility is guaranteed unless the pouch is damaged or opened. The expiration date is clearly indicated on the outside of the lens package. Any lens held after the expiration date should be returned to Alcon Laboratories, Inc. (See RETURNED GOODS POLICY).

RETURNED GOODS

In the United States, returned lenses will only be accepted in exchange for other products, not credit. All returns must be accompanied by an Alcon Laboratories, Inc. Returned Goods Number and be shipped via traceable means. A Returned Goods Number is obtained by contacting Alcon's Customer Service Department. Issuance of this number does not constitute final acceptance of the returned products. For detailed policy guidelines including exchange, please contact your Sales or Customer Service Representative. *Outside the United States, contact local Alcon offices or distributors regarding returned goods policy.*

REFERENCES

Boettner, E.A. and Wolter, J.R. Transmission of the ocular media. Invest. Ophthalmol. 1:776-783, 1962.

Symbols Used on Labeling

SYMBOL	ENGLISH
IOL	Intraocular lens
PC	Posterior chamber
PCL	Posterior chamber lens
UV	Ultraviolet
D	Diopter (spherical equivalent)
CYL	Cylinder Power
$Ø_B$	Body diameter (Optic diameter)
$Ø_T$	Overall diameter (Overall length)
	Do not reuse
or	Use by (YYYY-MM: year-month)
STERILE EO	Sterilized by ethylene oxide
SN or SN	Serial Number
	Attention: See instructions for use
LOT	Batch Code
	Manufacturer

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