

PRODUCT INFORMATION

Alcon Laboratories, Inc.

ACRY TORIC

STERILE UV-Absorbing 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 ACRYSOFTM Toric Posterior Chamber Intraocular Lens (IOL) is a UV-absorbing foldable intraocular lens (IOL). 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 original size. 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)

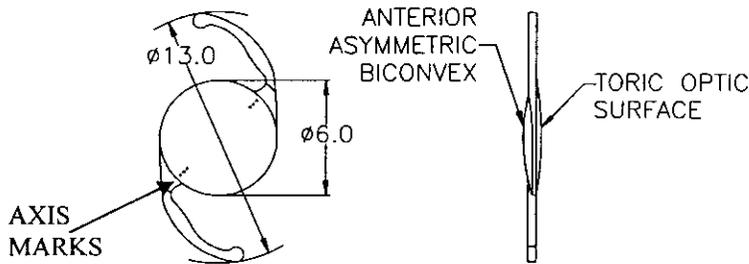
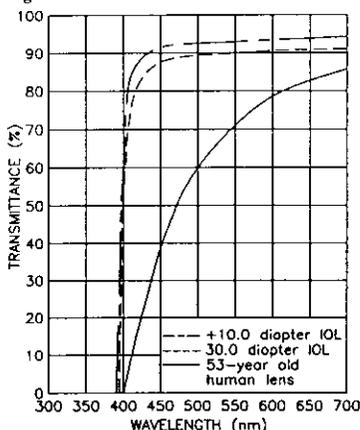


Table 1: Physical Characteristics of AcrySof® Toric IOLs

Characteristics	Model		
	SA60T3	SA60T4	SA60T5
Optic Type	Biconvex Toric Optic		
Optic / Haptic Material	Ultraviolet-absorbing Acrylate/Methacrylate Copolymer UV cutoff at 10% T: 398 nm (+10.0 diopter lens) 400 nm (+30.0 diopter lens)		
IOL Powers (spherical equivalent diopters)	For available power range see Alcon Product Guide		
IOL Cylinder Power (diopters)	1.50 diopter	2.25 diopter	3.00 diopter
Index Of Refraction	1.55		
Haptic Configuration	STABLEFORCE®		
Optic Diameter (mm)	6.0		
Overall Length (mm)	13.0		
Haptic Angle	0°		

**SPECTRAL TRANSMITTANCE CURVES
(PERCENTAGE OF ULTRAVIOLET TRANSMITTANCE)**

Figure 2



NOTES:

- The cutoff wavelength and the spectral transmittance curves presented here represent the range of transmittance values of IOLs made from acrylate/methacrylate copolymer with bonded UV-absorber.
- Measurements were direct transmittance using a 6 mm aperture and a disc of thickness equivalent to the optic center.
- UV cutoff at 10% T is 398 nm (+10 diopter lens).
UV cutoff at 10% T is 400 nm (+30 diopter lens).
- Human lens data from Boettner and Wolter (1962).

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 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 2:

Table 2

Model	IOL Cylinder Power (diopters)	Cylinder Power at Corneal Plane (diopters*)
SA60T3	1.50	1.03
SA60T4	2.25	1.55
SA60T5	3.00	2.06

*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. 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.

2. 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.
3. 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
 - Uncontrollable positive pressure
 - Irregular corneal astigmatism
 - 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
4. 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.
5. 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.
6. DO NOT store the IOL at temperatures over 45° C (113° F).
7. DO NOT reuse the IOL. This IOL is for single use only.
8. DO NOT resterilize the IOL by any method.
9. Use only sterile intraocular irrigating solutions such as BSS® or BSS PLUS® to rinse and/or soak lenses.
10. Accurate keratometry and biometry in addition to the use of the Toric Calculator (www.acrysoftoriccalculator.com) are recommended to achieve optimal visual outcomes.

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 estimated from lens design data and confirmed by clinical results. 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® IOL model SA60AT or SN60AT).

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.* V23:1356-1370, 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 outer 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. The IOL 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 IOL, open the undamaged pouch and transfer the case to a sterile environment. Carefully open the case to expose the IOL.
5. To minimize the occurrence of marks on the IOL due to handling, all instrumentation should be scrupulously clean. Any forceps used for handling the IOL must have round edges and smooth surfaces.
6. When removing the IOL from the case, DO NOT grasp the optical area with forceps. The IOL should only be handled by the haptics. Handle the IOL carefully to avoid damage to optic surface or haptics. DO NOT attempt to reshape haptics in any way.
7. Rinse the IOL 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® B cartridge with 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.

Selection and Placement of the AcrySof® 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 web-based tool (www.acrysofioriccalculator.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 in the following manner:

With the patient sitting upright, precisely mark the twelve o'clock and/or the six o'clock position with a T marker, a surgical skin marker, or a marking pencil. 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 web-based www.acrysofioriccalculator.com 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., Technical Consumer Affairs (S3-14)
6201 South Freeway, Fort Worth, Texas 76134.
Call Collect: (817) 551-4445.

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

AcrySof® TORIC FOLDABLE POSTERIOR CHAMBER SINGLE-PIECE INTRAOCULAR LENS MODEL(S) SA60TT CLINICAL STUDIES

A clinical study was conducted to demonstrate the safety and effectiveness of the AcrySof® Toric Posterior Chamber Lens Model SA60TT (which consist of 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 amounts are listed below.

Table 3

Model	Cylinder Power		Recommended Corneal Astigmatism Correction Ranges
	at IOL plane	at corneal plane	
SA60T3	1.50	1.03	0.75 - 1.50 D
SA60T4	2.25	1.55	1.50 - 2.00 D
SA60T5	3.00	2.06	2.00 D & up

The recommended corneal astigmatism correction ranges are based on 1) the preoperative corneal astigmatism and 2) the predicted effect of 0.5 diopter surgically induced astigmatism for a standardized temporal incision. The combination of these two parameters is 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 4A and 4B 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 4A
Uncorrected Distance Visual Acuity by Age Category, Status at Form 5 - Lens Model SA60TT, All Implanted

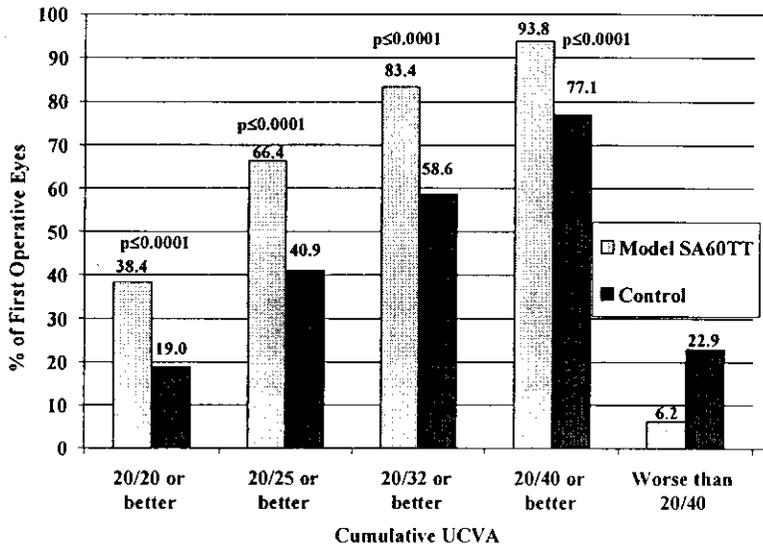
Age Category	Sample size N	Acuity										20/40 or better	
		20/20 or better		20/25		20/32		20/40		Worse than 20/40		n	%
		n	%	n	%	n	%	n	%	n	%		
<60	33	15	45.5	11	33.3	2	6.1	4	12.1	1	3.0	32	97.0
60-69	56	25	44.6	11	19.6	14	25.0	6	10.7	0	0	56	100.0
70-79	90	32	35.6	29	32.2	15	16.7	7	7.8	7	7.8	83	92.2
≥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 4B
Uncorrected Distance Visual Acuity by Age Category, Status at Form 5 - Lens Model SA60AT, All Implanted

Age Category	Sample size N	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	%		
<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, 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 SA60TT and SA60AT was statistically significant (all p-values ≤ 0.0001) in favor of SA60TT.

Figure 4A
Cumulative UCDVA, Status at Form 5, Model SA60TT vs. Control



Figures 4B – 4D 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 4B shows that the difference in cumulative UCDDVA between 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 SA60T3.

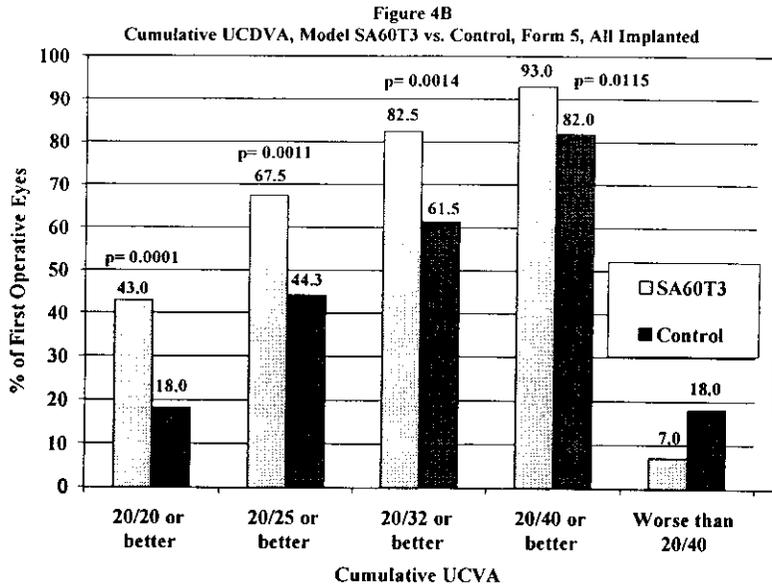


Figure 4C shows that the difference in cumulative UCDDVA between SA60T4 and SA60AT was statistically significant (all p-values ≤ 0.0082) for each visual acuity category (20/25 or better, 20/32 or better and 20/40 or better) in favor of SA60T4 with the exception of the 20/20 or better category.

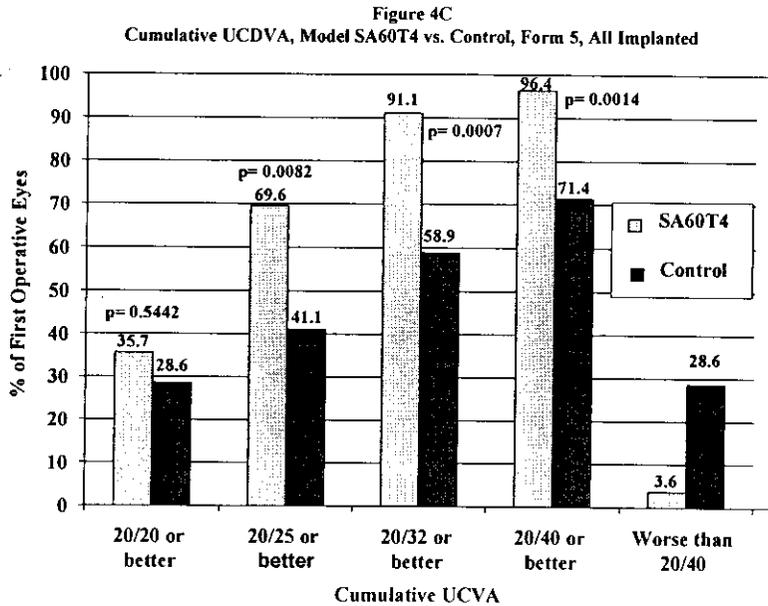
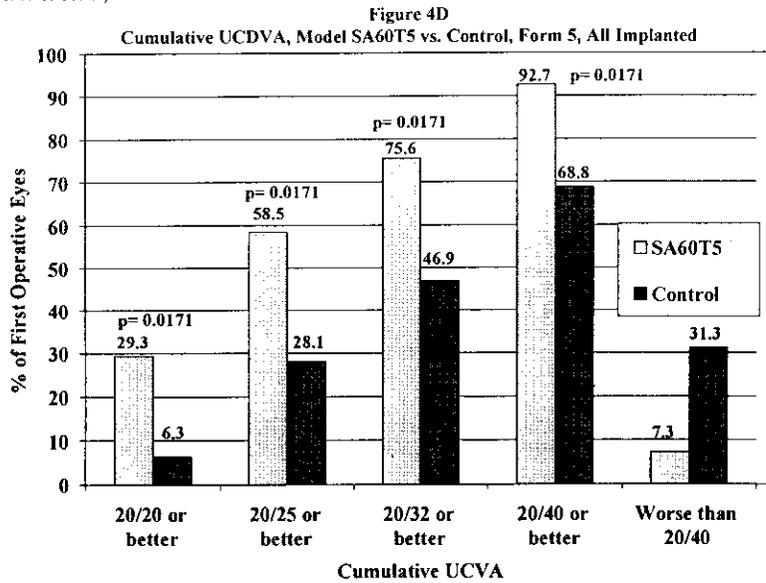


Figure 4D shows that the difference in cumulative UCDVA between SA60T5 and SA60AT was statistically significant (all p-values ≤ 0.0171) for each visual acuity category (20/20 or better, 20/25 or better, 20/32 or better and 20/40 or better) in favor of SA60T5.



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 5A. Visual acuity achieved by the overall subject population is shown in Table 5C. Control data are found for the same data sets in Tables 5B and 5D, 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 5A
BSCDVA by Age Category, Status at Form 5 - Lens Model SA60TT, Best Case

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

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

Age Category	Sample size N	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	%			
<60	15	13	86.7	1	6.7	1	6.7	0	0	0	0	0	15	100.0
60-69	49	38	77.6	11	22.4	0	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	0	75	100.0
>80	32	19	59.4	8	25.0	2	6.3	3	9.4	0	0	0	32	100.0
Total	171	118	69.0	41	24.0	9	5.3	3	1.8	0	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 5C

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

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

Table 5D

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

Age Category	Sample size N	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	%		
<60	15	13	86.7	1	6.7	1	6.7	0	0	0	0	0	0	15	100.0
60-69	54	41	75.9	12	22.2	1	1.9	0	0	0	0	0	0	54	100.0
70-79	91	59	64.8	22	24.2	10	11.0	0	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	3	6.1	46	93.9
Total	209	141	67.5	48	23.0	14	6.7	3	1.4	3	1.4	3	1.4	206	98.6

Figures 5A - 5C 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 5A

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

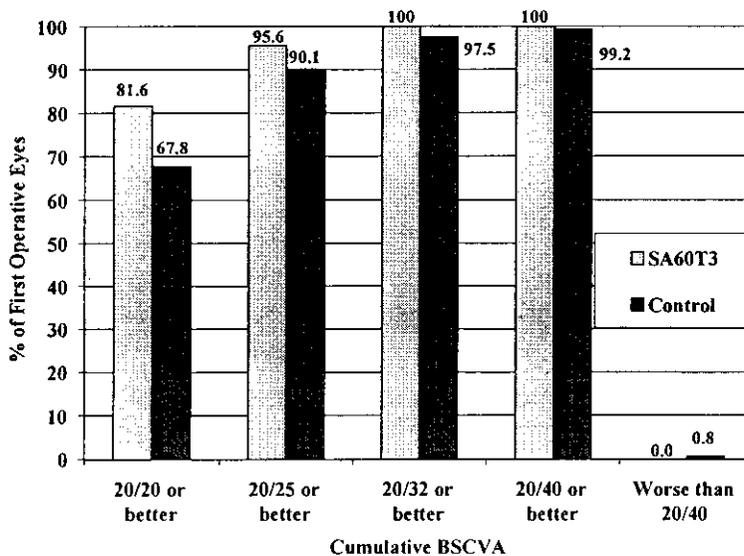


Figure 5B
 Cumulative BSCDVA, Model SA60T4 vs. Control, Form 5, All Implanted

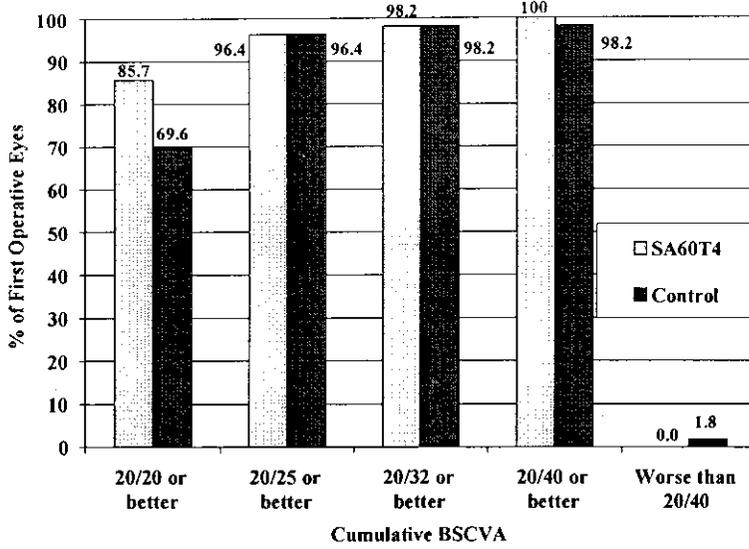
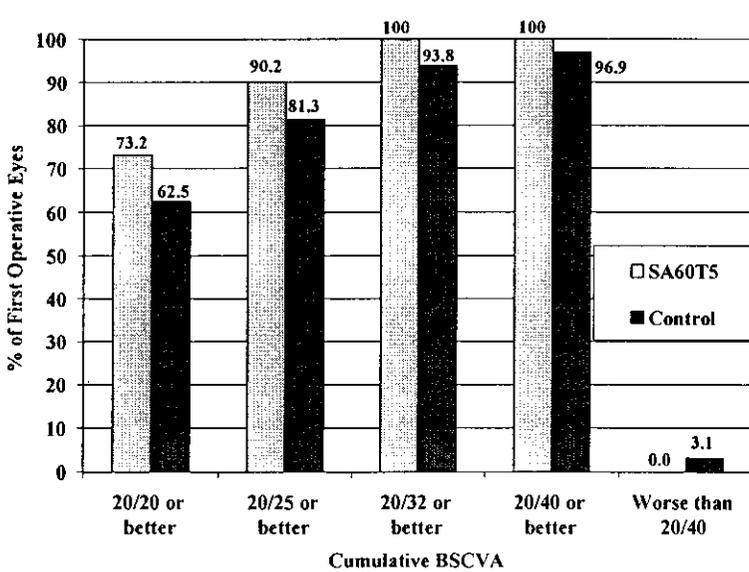


Figure 5C
 Cumulative BSCDVA, Model SA60T5 vs. Control, Form 5, All Implanted



AcrySof® TORIC INTRAOCULAR LENS ABSOLUTE RESIDUAL REFRACTIVE CYLINDER

Figures 6A through 6C demonstrate that residual refractive cylinder values were statistically significantly lower among those subjects implanted with either an ACRYSOFToric Model SA60T3, SA60T4 or SA60T5 IOL when compared to the corresponding subjects implanted with the control Model SA60AT. Subjects implanted with an ACRYSOFToric 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 6A
Absolute Residual Refractive Cylinder,
Model SA60T3 vs. Control, Form 5, All Implanted

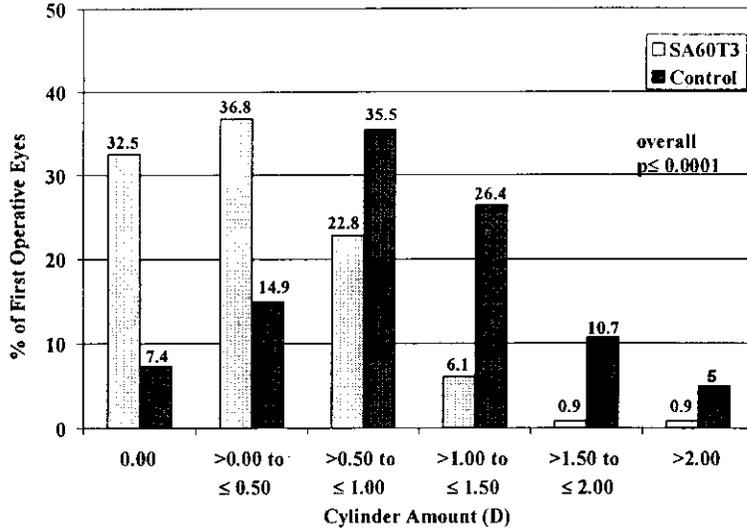


Figure 6B
Absolute Residual Refractive Cylinder,
Model SA60T4 vs. Control, Form 5, All Implanted

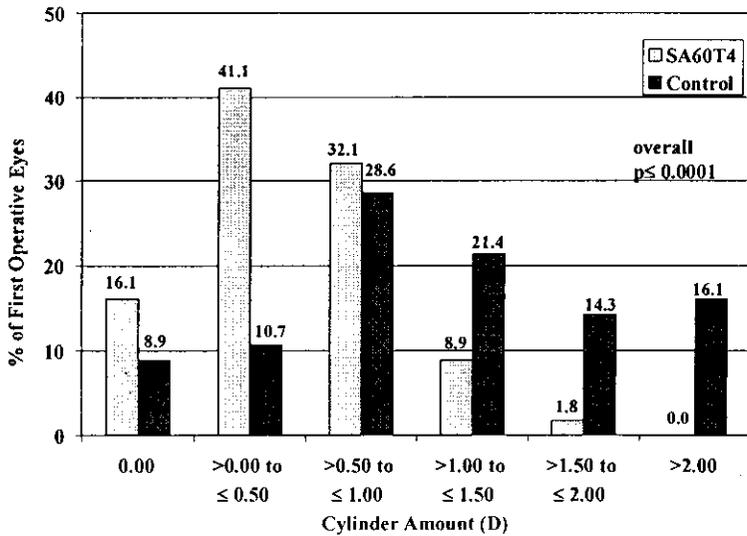
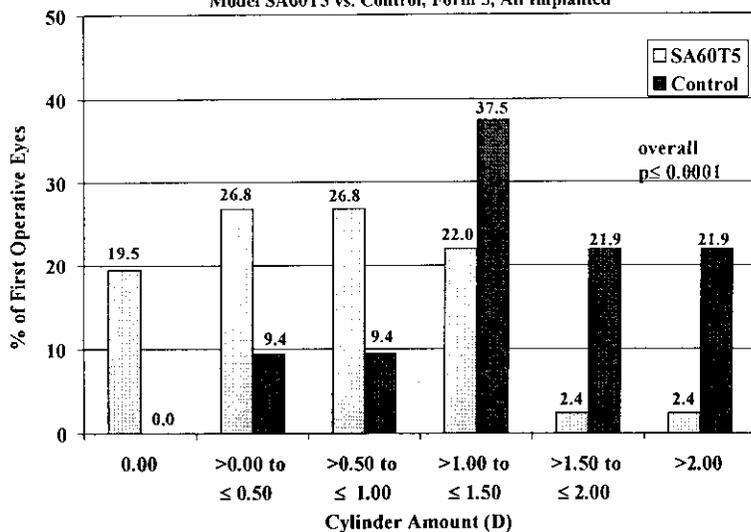


Figure 6C
Absolute Residual Refractive Cylinder,
Model SA60T5 vs. Control, Form 5, All Implanted



AcrySof® TORIC INTRAOCULAR LENS MODELS - 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).

Figure 7A
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

Figure 7B
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

Figure 7C
Stability of Absolute Cylinder for TT Lens Models
(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

Figure 7D
Stability of Absolute Cylinder for TT Lens Models
(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,%,(95%CI) are for percent with change between ± 1.00D

AcrySof® TORIC INTRAOCULAR LENS MODEL SA60TT - 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 8A and 8B. The rotational stability of the ACRYSOFToric Model SA60TT IOL is established with the majority of the lenses rotating ≤ 5°. Figure 8A also demonstrates that the amount of rotation seen in each Toric IOL model is independent of the amount of cylinder power present on the lens.

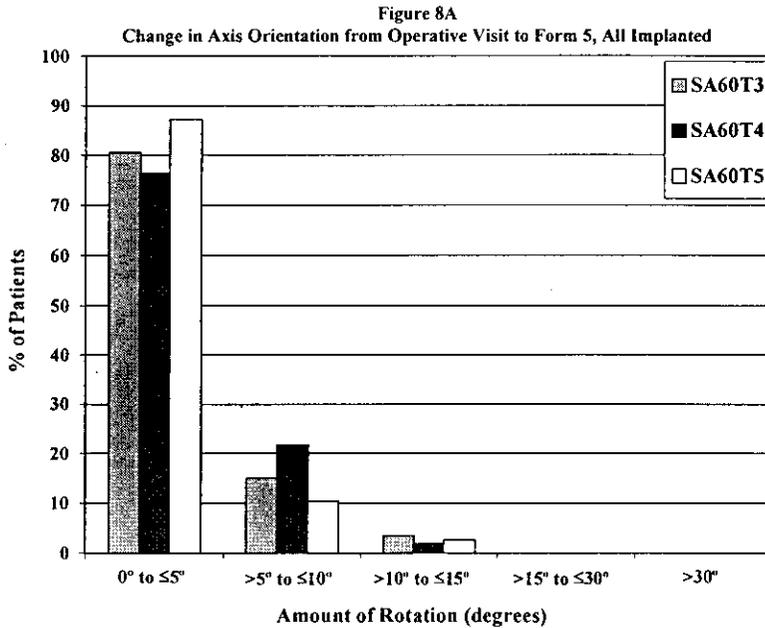
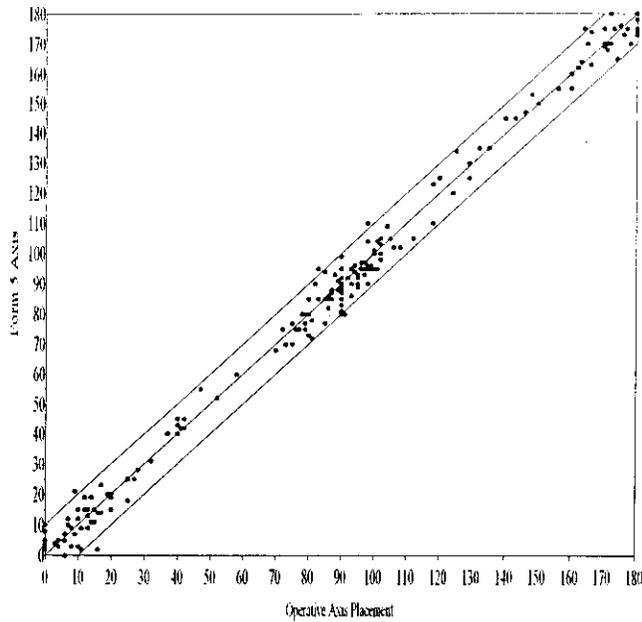


Figure 8B
Scatter Plot of Current Orientation of Lens Axis, Operative Visit versus Form 5,
Toric IOL-SA60TT, All Implanted



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 9A
Adverse Event Incidence Rates, Model SA60TT versus FDA Historical Grid
Rate, First Eye – Safety

	Model SA60TT N=244		FDA Grid Rate
	N	%	%
Cumulative Adverse Events			
Retinal Detachment/Repair	1	0.4	0.3
Surgical Reintervention	4*	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)

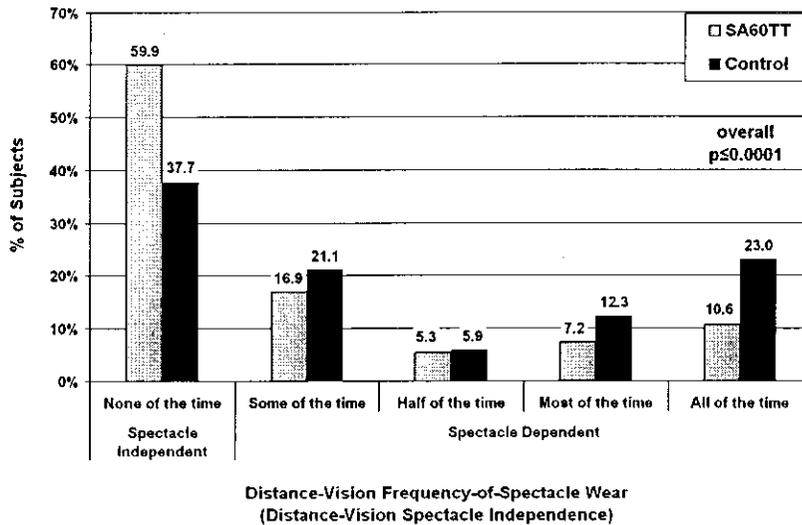
*There were 5 occurrences of surgical reintervention in 4 eyes for Model SA60TT first eye

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

AcrySof® TORIC INTRAOCULAR LENS MODEL SA60TT DISTANCE-VISION SPECTACLE DEPENDENCE

Statistically significantly more SA60TT subjects reported postoperative distance-vision spectacle independence compared to 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 SA60TT subjects were spectacle dependent at 40.1% compared to 62.3% of the SA60AT subjects. Figure 10A illustrates the distance-vision frequency-of-spectacle-wear distributions between the SA60TT and 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 10A
Distance-Vision Spectacle Independence:
Frequency-of-Spectacle-Wear, Form 5, All Implanted



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 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
UV	Ultraviolet
D	Diopter (Spherical Equivalent)
CYL	Cylinder Power
\varnothing_B	Body diameter (Optic diameter)
\varnothing_T	Overall diameter (Overall length)
	Do not reuse
	Use by (YYYY-MM: year-month)
STERILE EO	Sterilized by ethylene oxide
SN	Serial number
	Attention: See instructions for use

U.S. Pat. No's. 5,290,892, 5,470,932, 5,543,504 and 5,716,403

Manufacturer:

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

U.S. Patent Nos. 5,290,892, 5,403,901, 5,433,746, 5,674,960, and 5,861,031
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