TECNIS® Sym*f*ony Extended Range of Vision IOL

Rx Only

DESCRIPTION

The **TECNIS® Sym*f*ony Extended Range of Vision Intraocular Lenses (IOLs), lens model ZXR00 and toric lens models ZXT150, ZXT225, ZXT300, and ZXT375,** are ultraviolet light-absorbing posterior chamber IOLs which are intended to mitigate the effects of presbyopia and provide a continuous range of high-quality vision by extending the depth of focus. In addition, the toric IOLs compensate for corneal astigmatism.

The TECNIS® Sym*f*ony Extended Range of Vision IOLs are designed to be positioned in the lens capsule to replace the optical function of the natural crystalline lens. The biconvex optic incorporates a proprietary wavefront-designed aspheric or toric-aspheric anterior optic, designed to compensate for corneal spherical aberration. The anteriorly located cylinder axis marks in the toric-aspheric optic denote the meridian with the lowest power and is to be aligned with the steep corneal meridian. The squared posterior edge of the aspheric and toric aspheric anterior optic is designed to provide a 360-degree barrier and has a frosted design to reduce potential edge glare effects. The posterior optic of the TECNIS® Sym*f*ony Extended Range of Vision IOLs has a proprietary achromatic diffractive surface designed to correct chromatic aberration and a unique echelette feature to extend the range of vision, including far, intermediate, and near, while maintaining the corneal spherical aberration compensation. TECNIS® Sym*f*ony IOLs are designed to have pupil-independent lens performance in any lighting condition.

INDICATIONS FOR USE

The TECNIS® Sym*f*ony Extended Range of Vision IOL, Model ZXR00, is indicated for primary implantation for the visual correction of aphakia, in adult patients with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The Model ZXR00 IOL is intended for capsular bag placement only.

The TECNIS® Sym*f*ony Toric Extended Range of Vision IOLs, Models ZXT150, ZXT225, ZXT300, and ZXT375, are indicated for primary implantation for the visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients with greater than or equal to 1 diopter of preoperative corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The Model Series ZXT IOLs are intended for capsular bag placement only.

WARNINGS

Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:

1. Patients with any of the following conditions may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition, or may pose an unreasonable risk to the patient's eyesight:

   a) Patients with recurrent severe anterior or posterior segment inflammation or uveitis of unknown etiology, or any disease producing an inflammatory reaction in the eye.
   b) Patients in whom the intraocular lens may affect the ability to observe, diagnose or treat posterior segment diseases.
   c) Surgical difficulties at the time of cataract extraction, which may increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss).
   d) A compromised eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible.
   e) Circumstances that would result in damage to the endothelium during implantation.
   f) Suspected microbial infection.
   g) Patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL.
   h) Children under the age of 2 years are not suitable candidates for intraocular lenses.
   i) Congenital bilateral cataracts.
   j) Previous history of, or a predisposition to, retinal detachment.
   k) Patients with only one good eye with potentially good vision.
   l) Medically uncontrollable glaucoma.
   m) Corneal endothelial dystrophy.
   n) Proliferative diabetic retinopathy.

2. The TECNIS® Sym*f*ony IOL should be placed entirely in the capsular bag and should not be placed in the ciliary sulcus.

3. The TECNIS® Symfony IOL may cause a reduction in contrast sensitivity under certain conditions, compared to an aspheric monofocal IOL. The physician should carefully weigh the potential risks and benefits for each patient, and should fully inform the patient of the potential for reduced contrast sensitivity before implanting the lens in patients. Special consideration of potential visual problems should be made before implanting the lens in patients with macular disease, amblyopia, corneal irregularities, or other ocular disease which may cause present or future reduction in acuity or contrast sensitivity.

4. Because the TECNIS® Sym*f*ony IOL may cause a reduction in contrast sensitivity compared to a monofocal IOL, patients implanted with the lens should be informed to exercise special caution when driving at night or in poor visibility conditions.

5. Some visual effects associated with the TECNIS® Sym*f*ony IOL may be expected due to the lens design that delivers elongation of focus. These may include a perception of halos, glare, or starbursts around lights under nighttime conditions. The experience of these phenomena will be bothersome or very bothersome in some people, particularly

in low-illumination conditions. On rare occasions, these visual effects may be significant enough that the patient may request removal of the IOL.

6. Patients with a predicted postoperative astigmatism greater than 1.0 diopter may not be suitable candidates for implantation with the TECNIS® Symfony and TECNIS® Symfony Toric IOLs, Models ZXR00, ZXT150, ZXT225, ZXT300, and ZXT375, as they may not obtain the benefits of reduced spectacle wear or improved intermediate and near vision seen in patients with lower astigmatism.

7. The effectiveness of TECNIS® Sym*f*ony Toric IOLs in reducing postoperative residual astigmatism in patients with preoperative corneal astigmatism < 1.0 diopter has not been demonstrated.

8. Rotation of TECNIS® Symfony 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.

9. AMO IOLs are single-use devices only. Do not reuse this IOL.

PRECAUTIONS

1. Prior to surgery, the surgeon must inform prospective patients of the possible risks and benefits associated with the use of this device and provide a copy of the patient information brochure to the patient.

2. When performing refraction in patients implanted with the TECNIS® Sym*f*ony IOL, interpret results with caution when using autorefractors or wavefront aberrometers that utilize infrared light, or when performing a duochrome test. Confirmation of refraction with maximum plus manifest refraction technique is recommended.

3. The ability to perform some eye treatments (e.g. retinal photocoagulation) may be affected by the TECNIS® Sym*f*ony IOL optical design.

4. Recent contact lens usage may affect the patient's refraction; therefore, in contact lens wearers, surgeons should establish corneal stability without contact lenses prior to determining IOL power.

5. Do not resterilize the lens. Most sterilizers are not equipped to sterilize the soft acrylic material without producing undesirable side effects.

6. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.

7. Do not store the lens in direct sunlight or at a temperature greater than 113°F (45°C). Do not autoclave the intraocular lens.

8. The surgeon should target emmetropia as this lens is designed for optimum visual performance when emmetropia is achieved.

9. Care should be taken to achieve IOL centration, as lens decentration may result in a patient experiencing visual disturbances under certain lighting conditions.

10. When the insertion system is used improperly, TECNIS® Sym*f*ony IOLs may not be delivered properly (i.e., haptics may be broken). Please refer to the specific instructions for use provided with the insertion instrument or system.

11. The safety and effectiveness of TECNIS® Sym*f*ony IOLs have not been substantiated in patients with preexisting ocular conditions and intraoperative complications (see below for examples). 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

- Pupil abnormalities
- Prior corneal refractive or intraocular 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
- Amblyopia
- Macular disease
- Pregnancy

During Surgery

- Excessive vitreous loss
- Non-circular capsulotomy/capsulorhexis
- The presence of radial tears known or suspected at the time of surgery
- Situations in which the integrity of the circular capsulotomy/capsulorhexis cannot be confirmed by direct visualization
- Cataract extraction by techniques other than phacoemulsification or liquefaction
- Capsular rupture
- Significant anterior chamber hyphema
- Uncontrollable positive intraocular pressure
- Zonular damage

12. Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case. Residual viscoelastic and/or overinflation of the capsular bag may allow the lens to rotate, causing misalignment of the TECNIS® Sym*f*ony Toric IOL with the intended axis of placement.

13. The use of methods other than the TECNIS Toric Calculator to select cylinder power and appropriate axis of implantation were not assessed in the parent TECNIS® Toric IOL U.S. IDE study and may not yield similar results. Accurate keratometry and biometry, in addition to the use of the TECNIS Toric Calculator (www.TecnisToricCalc.com), are recommended to achieve optimal visual outcomes for the TECNIS® Sym*f*ony Toric IOL.

14. All preoperative surgical parameters are important when choosing a TECNIS® Sym*f*ony Toric IOL for implantation, including preoperative keratometric cylinder (magnitude and axis), incision location, surgeon's estimated surgically induced astigmatism (SIA) and biometry. Variability in any of the preoperative measurements can influence patient outcomes, and the effectiveness of treating eyes with lower amounts of preoperative corneal astigmatism.

15. All corneal incisions were placed temporally in the parent TECNIS® Toric IOL U.S. IDE study. If the surgeon chooses to place the incision at a different location, outcomes may be different from those obtained in the clinical study for the parent TECNIS® Toric IOL. Note that the TECNIS Toric Calculator incorporates the surgeon's estimated SIA and incision location when providing IOL options.

16. Potential adverse effects (e.g., complications) associated with the use of the device include the following:

- Infection (endophthalmitis)
- Hypopyon
- IOL dislocation
- Cystoid macular edema
- Corneal edema
- Pupillary block
- Iritis
- Retinal detachment/tear
- Raised IOP requiring treatment
- Visual symptoms requiring lens removal
- Tilt and decentration requiring repositioning
- Residual refractive error resulting in secondary intervention.

Secondary surgical interventions include, but are not limited to:

- Lens repositioning (due to decentration, rotation, subluxation, etc.)
- Lens replacement
- Vitreous aspirations or iridectomy for pupillary block
- Wound leak repair
- Retinal detachment repair
- Corneal transplant
- Lens replacement due to refractive error
- Unacceptable optical/visual symptoms
- Severe inflammation.

CLINICAL STUDY RESULTS

Data from a recent clinical study of the TECNIS Symfony IOL, Model ZXR00, and data from other relevant prior clinical studies are included to support the safety and effectiveness of the TECNIS Symfony IOLs, Model ZXR00, and TECNIS Symfony Toric IOLs, Models ZXT150, ZXT225, ZXT300, and ZXT375:

1. A clinical study of the TECNIS Symfony IOL, Model ZXR00, demonstrated the safety and effectiveness of the Symfony IOL. Results from the Model ZXR00 clinical study also apply to the TECNIS Symfony Toric IOL, Models ZXT150, ZXT225, ZXT300, and ZXT375.

2. A prior clinical study of the toric parents of the TECNIS Symfony Toric IOLs, the TECNIS Toric 1-Piece IOLs (Models ZCT150, ZCT225, ZCT300 and ZCT400), demonstrated the safety and effectiveness of the TECNIS Toric IOLs. Except for the difference in cylinder power between the clinically studied parent toric model ZCT400 and the TECNIS Symfony Toric IOL Model ZXT375, the toric feature on the anterior optic of the of the TECNIS Symfony Toric IOLs is the same as that of the TECNIS® Toric 1-Piece IOL; therefore, results of the TECNIS Toric 1-piece IOL also apply to the TECNIS Symfony Toric IOL. The safety data from this study provided supplemental information on the safety profile expected of the TECNIS Symfony Toric IOLs.

3. Two prior clinical studies of the multifocal parent of the TECNIS Symfony IOLs, the TECNIS Multifocal IOL, Model ZM900, demonstrated the safety and effectiveness of the TECNS Multifocal IOL. The posterior optic design of the TECNIS Symfony IOL and TECNIS Symfony Toric IOLs was derived from that of the TECNIS Multifocal IOL.

4. A prior clinical study of the material and mechanical parent, the SENSAR 1-Piece IOL, Model AAB00, demonstrated the safety and effectiveness of the 1-piece platform and SENSAR acrylic material. The clinical study results of the Model AAB00 apply to the TECNIS Symfony IOL, Model ZXR00, and TECNIS Symfony Toric IOLs, Models ZXT150, ZXT225, ZXT300, and ZXT375.

CLINICAL STUDY RESULTS: TECNIS SYMFONY IOL, MODEL ZXR00

A prospective, 6-month, multicenter, bilateral, randomized, evaluator- and subject-masked, clinical investigation was conducted at 15 investigative sites in the US to evaluate the safety and effectiveness of the TECNIS® Symfony Extended Range of Vision IOL, Model ZXR00. The control IOL was the TECNIS 1-Piece IOL, Model ZCB00. The primary effectiveness endpoints were mean monocular, photopic, distance corrected and uncorrected intermediate visual acuities at 66 cm; and the primary safety endpoint was the rates of adverse events vs. ISO SPE rates. Secondary endpoints included monocular depth of focus, overall spectacle wear via binocular questionnaire response, monocular photopic distance corrected near visual acuity at 40 cm, and monocular best corrected distance contrast sensitivity under mesopic conditions with and without glare at 12 cycles per degree.

The clinical study results achieved at 6 months postoperatively demonstrate that the TECNIS® Symfony IOL is safe and effective for the visual correction of aphakia, provides improved uncorrected and distance-corrected intermediate and near vision, an increased depth of focus, and decreased spectacle wear when compared to the monofocal control IOL, while demonstrating distance vision non-inferior to the monofocal control lens, and low rates of adverse events. For the rest of the clinical summary section including the data tables, "*Symfony*" refers to the TECNIS Symfony IOL, Model ZXR00, and "*Monofocal control*" refers to the TECNIS 1-Piece IOL, Model ZCB00.

Note: For consistency, results are presented for the overall safety population of all treated subjects unless otherwise noted (e.g., intent-to-treat, ITT, population). The primary analysis group consists of first eyes implanted (monocular tests) or binocular data as appropriate.

Subject Population

Of the 299 subjects enrolled and implanted in the study, 148 were in the Symfony IOL group (148 bilaterally implanted) and 151 were in the monofocal control group (150 bilaterally implanted). Subject demographics were similar between the Symfony and monofocal control groups. The mean age was 68.0 ± 7.5 years for the Symfony group and 67.9 ± 7.9 years for the control group. Females represented more than half of the subjects in both groups

(61.5% Symfony; 57.0% monofocal). Most Symfony subjects (>96%) and control subjects (>86%) were White. The remainder of subjects were African American (2.7% Symfony; 10.6% monofocal), Asian (0.7% Symfony; 2.0% monofocal) and American Indian/Alaska Native (1.3% monofocal only).

Distance High-Contrast Photopic Visual Acuities

Table 1 presents monocular, uncorrected and best corrected, photopic (85 cd/m^2) distance visual acuity results for Symfony and monofocal control first eyes at 6 months. As all Symfony eyes met best case criteria, the proportion of Symfony first eyes achieving monocular best corrected distance visual acuity (BCDVA) of 20/40 or better (100.0%) was above the ISO BCDVA Safety and Performance Endpoint (SPE) rates for overall (92.5%) and best-case (96.7%). The distribution of binocular distance visual acuity results for Symfony and monofocal control subjects at 6 months are presented in **Table 2**.

TABLE 1
Monocular Distance Visual Acuity at 6 Months

Monocular	Symfony		Monofocal Control	
Visual Acuity	Uncorrected	Best Corrected	Uncorrected	Best Corrected
20/20 or better	38.8%	83.7%	47.3%	88.5%
20/25 or better	65.3%	98.0%	71.6%	96.6%
20/32 or better	87.8%	100.0%	85.1%	98.6%
20/40 or better	**96.6%**	**100.0%**	**93.9%**	**100.0%**
20/50-20/80	2.7%	0.0%	6.1%	0.0%
20/100 or worse	0.7%	0.0%	0.0%	0.0%
Total	**147**	**147**	**148**	**148**

TABLE 2
Binocular Distance Visual Acuity at 6 Months

Binocular	Symfony		Control	
Visual Acuity	Uncorrected	Best Corrected	Uncorrected	Best Corrected
20/20 or better	62.6%	93.2%	71.6%	95.3%
20/25 or better	91.2%	98.6%	84.5%	98.6%
20/32 or better	97.3%	100.0%	95.9%	100.0%
20/40 or better	**99.3%**	**100.0%**	**100.0%**	**100.0%**
20/50-20/80	0.7%	0.0%	0.0%	0.0%
20/100 or worse	0.0%	0.0%	0.0%	0.0%
Total	**147**	**147**	**148**	**148**

Table 3 presents mean monocular and binocular distance visual acuities at 6 months for Symfony and monofocal control first eyes. Mean monocular uncorrected distance visual acuity (UCDVA) and BCDVA outcomes were comparable between IOL groups at 20/25 and 20/20, respectively. Additionally, the lower limit of the 90% confidence interval (CI) of the mean difference in BCDVA between IOL groups was less than a half a line, demonstrating that the Symfony IOL is non-inferior to the control lens in providing best corrected distance visual acuity. It was hypothesized that Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated by trying to demonstrate that for eyes with residual manifest spherical equivalent ≥0.50 D at 6 months, the Symfony arm had statistically superior UCDVA compared to the control. Results did not confirm that Symfony eyes had greater "tolerance to refractive error." There were not enough eyes with residual hyperopic

refractive error (+0.50 D spherical equivalent; Symfony N=1, Monofocal N=4) to evaluate outcomes for these subsets.

TABLE 3:
Monocular and Binocular Distance Visual Acuity at 6 Months

Distance Visual Acuity	Lens Group	Monocular N	Monocular Mean LogMAR	Monocular Snellen Line Equiv.	Monocular Line Change vs. Control	Binocular N	Binocular Mean LogMAR	Binocular Snellen Line Equiv.	Binocular Line Change vs. Control
Uncorrected	Symfony	147	0.114	20/25	-0.3 lines	147	0.034	20/20	-0.2 lines
	Control	148	0.088	20/25		148	0.013	20/20	
Corrected	Symfony	147	-0.021	20/20	-0.2 lines[a]	147	-0.045	20/20	-0.3 lines
	Control	148	-0.040	20/20		148	-0.075	20/16	

[a] 90% Confidence Interval around mean difference: [-0.036; -0.003]

All statements apply only to high-contrast photopic visual acuities, as low-contrast distance visual acuities were not assessed in this study.

Intermediate High-Contrast Photopic Visual Acuities

Intermediate visual acuities (primary effectiveness endpoints) were tested at 66 cm under photopic (85 cd/m^2) lighting conditions. Mean monocular and binocular intermediate visual acuities at 6 months for both Symfony and monofocal control IOL groups are presented in **Table 4.** There were statistically significant improvements (**p<0.0001**; ITT population) in mean uncorrected intermediate visual acuity (UCIVA) and distance corrected intermediate visual acuity (DCIVA) at 6 months in favor of the Symfony lens with improvements of 1.7 and 2.4 lines, respectively. Additionally, as shown in **Table 5**, there were clinically significant improvements in favor of the Symfony IOL with 76.9% and 70.1% of Symfony eyes achieving UCIVA and DCIVA of 20/25 or better, respectively, compared to 33.8% and 13.5% of monofocal eyes. Binocular distribution results are presented in **Table 6**. Overall, intermediate visual acuity results demonstrate the effectiveness of the Symfony to provide improved intermediate vision compared to the monofocal control lens.

TABLE 4
Mean Monocular and Binocular Uncorrected and Distance Corrected Intermediate Visual Acuity at 66 cm at 6 Months

Visual Acuity[a]	Lens Group	Monocular N	Monocular Mean LogMAR	Monocular Snellen Line Equiv.	Monocular Line Change vs. Control	Binocular N	Binocular Mean LogMAR	Binocular Snellen Line Equiv.	Binocular Line Change vs. Control
Uncorrected	Symfony	147	0.087[a]	20/25	1.7 lines	147	0.002	20/20	1.3 lines
	Control	148	0.256[a]	20/40		148	0.134	20/25	
Distance Corrected	Symfony	147	0.104[a]	20/25	2.4 lines	147	0.032	20/20	1.9 lines
	Control	148	0.342[a]	20/40		148	0.227	20/32	

[a] The primary study endpoints are uncorrected and distance corrected intermediate VA for first eyes. Symfony had significantly better mean UCIVA and DCIVA compared to Control with **p<0.0001** (from one-sided two-sample t-test).

TABLE 5
Monocular Uncorrected and Distance Corrected Intermediate Visual Acuity at 66 cm at 6 Months

Monocular Visual Acuity	Symfony Uncorrected	Symfony Distance Corrected	Control Uncorrected	Control Distance Corrected
20/20 or better	40.8%	34.7%	12.8%	4.7%
20/25 or better	**76.9%**	**70.1%**	**33.8%**	**13.5%**
20/32 or better	92.5%	90.5%	54.7%	31.8%
20/40 or better	98.6%	97.3%	69.6%	53.4%
20/50-20/80	1.4%	2.7%	29.1%	42.6%
20/100 or worse	0.0%	0.0%	1.4%	4.1%
Total	**147**	**147**	**148**	**148**

TABLE 6
Binocular Uncorrected and Distance Corrected Intermediate Visual Acuity at 66 cm at 6 Months

Binocular Visual Acuity	Symfony Uncorrected	Symfony Distance Corrected	Control Uncorrected	Control Distance Corrected
20/20 or better	74.8%	61.9%	31.1%	8.1%
20/25 or better	**96.6%**	**92.5%**	**60.1%**	**35.1%**
20/32 or better	100.0%	100.0%	83.1%	62.8%
20/40 or better	100.0%	100.0%	91.9%	79.7%
20/50-20/80	0.0%	0.0%	8.1%	20.3%
20/100 or worse	0.0%	0.0%	0.0%	0.0%
Total	**147**	**147**	**148**	**148**

All statements apply only to high-contrast photopic visual acuities, as low-contrast intermediate visual acuities were not assessed in this study.

Near High-Contrast Photopic Visual Acuities

Near visual acuities (secondary effectiveness endpoint) were tested at 40 cm under photopic (85 cd/m^2) lighting conditions. Mean monocular and binocular near visual acuities at 6 months for both Symfony and monofocal control lens groups are presented in **Table 7**. There was a statistically significant improvement (**p<0.0001**; ITT population) in mean monocular DCNVA at 6 months in favor of the Symfony lens, with an improvement of 2.2 lines. Distributions of monocular and binocular near visual acuity for both lens groups are presented in **Tables 8** and **9**, respectively. As shown in **Table 8**, there were clinically significant improvements in favor of the Symfony IOL, with 61.9% of Symfony eyes achieving DCNVA of 20/40 or better monocularly compared to 16.2% of monofocal eyes. Near visual acuity results demonstrate the effectiveness of the Symfony to provide substantially improved near vision compared to the monofocal control lens.

TABLE 7
Mean Monocular and Binocular Uncorrected and Distance Corrected Near Visual Acuity at 40 cm at 6 Months

		Monocular				Binocular			
Visual Acuity	Lens Group	N	Mean LogMAR	Snellen Line Equiv.	Line Change vs. Control	N	Mean LogMAR	Snellen Line Equiv.	Line Change vs. Control
Uncorrected	Symfony	147	0.241	20/32	2.2 lines	147	0.146	20/25	1.8 lines
	Control	148	0.459	20/63		148	0.328	20/40	
Distance Corrected	Symfony	147	0.323[a]	20/40	2.2 lines	147	0.229	20/32	2.0 lines
	Control	148	0.544[a]	20/63		148	0.426	20/50	

[a] The secondary endpoint is distance corrected near VA for first eyes. Symfony had significantly better VA compared to Control with a p value of <0.0001 (from one-sided two-sample t-test)

TABLE 8
Monocular Uncorrected and Distance Corrected Near Visual Acuity at 40 cm at 6 Months

Monocular	Symfony		Control	
Visual Acuity	Uncorrected	Distance Corrected	Uncorrected	Distance Corrected
20/20 or better	9.5%	3.4%	0.0%	0.0%
20/25 or better	28.6%	10.9%	2.7%	0.7%
20/32 or better	55.8%	33.3%	17.6%	3.4%
20/40 or better	**81.0%**	**61.9%**	**31.1%**	**16.2%**
20/50-20/80	19.0%	36.7%	54.1%	56.1%
20/100 or worse	0.0%	1.4%	14.9%	27.7%
Total	**147**	**147**	**148**	**148**

TABLE 9
Binocular Uncorrected and Distance Corrected Near Visual Acuity at 40 cm at 6 Months

Binocular	Symfony		Control	
Visual Acuity	Uncorrected	Distance Corrected	Uncorrected	Distance Corrected
20/20 or better	21.8%	8.2%	4.7%	1.4%
20/25 or better	55.1%	23.8%	12.8%	4.7%
20/32 or better	84.4%	52.4%	33.8%	12.8%
20/40 or better	**95.9%**	**90.5%**	**62.8%**	**34.5%**
20/50-20/80	4.1%	9.5%	32.4%	58.8%
20/100 or worse	0.0%	0.0%	4.7%	6.8%
Total	**147**	**147**	**148**	**148**

All statements apply only to high-contrast photopic visual acuities, as low-contrast near visual acuities were not assessed in this study.

Depth of Focus

Monocular and binocular defocus curve testing was performed at 8 sites on a subset of subjects from each lens group who achieved BCDVA of 20/25 or better. Mean monocular

defocus range for which acuity was 20/32 or better was a secondary study endpoint. Monocular results were also analyzed for three pupil size ranges: ≤2.5 mm; >2.5 mm and <4.0 mm; and ≥4.0 mm. The defocus secondary effectiveness endpoint was met, with >0.5 D of increased range of focus (**p<0.0001**; ITT population) of 20/32 or better visual acuity for Symfony subjects vs. the monofocal control.

Figures 1 and 2 present the monocular defocus curve for the Symfony and monofocal control groups with mean values and error bars for confidence intervals and standard deviations, respectively, while **Figure** 3 represents the binocular defocus curves for the Symfony and monofocal groups (with mean values and error bars for confidence intervals). **Figure 4** presents monocular defocus curves by pupil size for the Symfony group. Mean monocular visual acuities were 20/32 or better for the Symfony group through intermediate defocus values of -1.5 D (66 cm); mean binocular acuities were 20/32 or better for the Symfony group through -2.0 D (50 cm). Both monocular and binocular defocus curves demonstrate that visual acuity monotonically decreased while maintaining a 1-2 line acuity difference over the monofocal group through -4.0 D of defocus. Visual inspection of the defocus curves yielded an improvement in the range of defocus with visual acuity of 20/32 or better in favor of the Symfony IOL by approximately 1 D. When monocular results were analyzed by pupil size, no appreciable pupil size effect was observed. Because visual acuity improves in monofocal subjects with pupil sizes ≤2.5 mm, the improvements in depth of focus between Symfony and monofocal groups are less pronounced in this subset of subjects. Some individual eyes showed drops in acuity below 20/32 between far and intermediate/near distances that are believed to be related to measurement noise when using the FrACT automated test system used in the study.

FIGURE 1
Monocular Defocus Curves at 6 Months
Symfony and Monofocal Control
(with 95% Confidence Intervals)

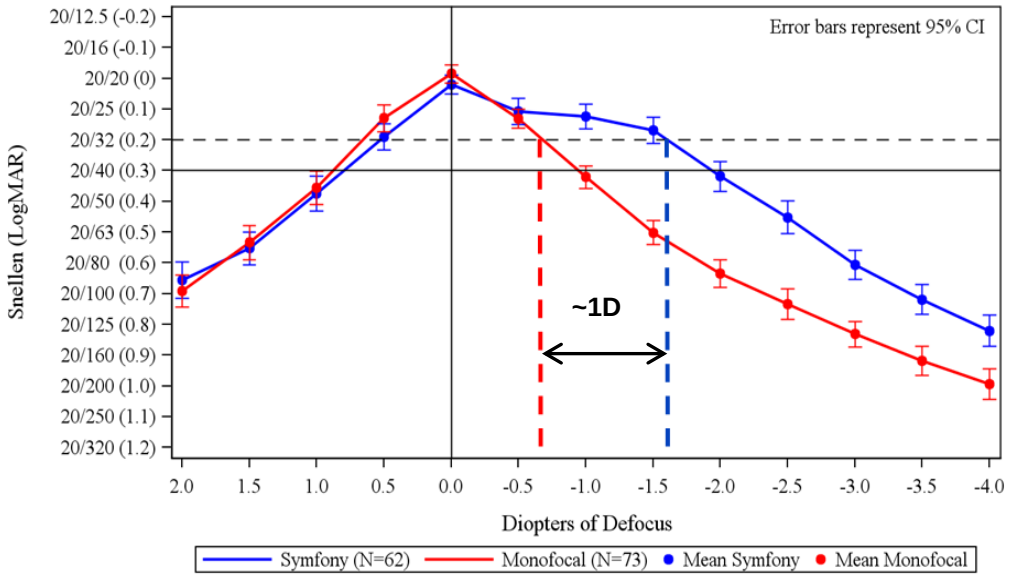


FIGURE 2
Monocular Defocus Curve at 6 Months
Symfony and Monofocal Control
(with Error Bars Representing 1 Standard Deviation)

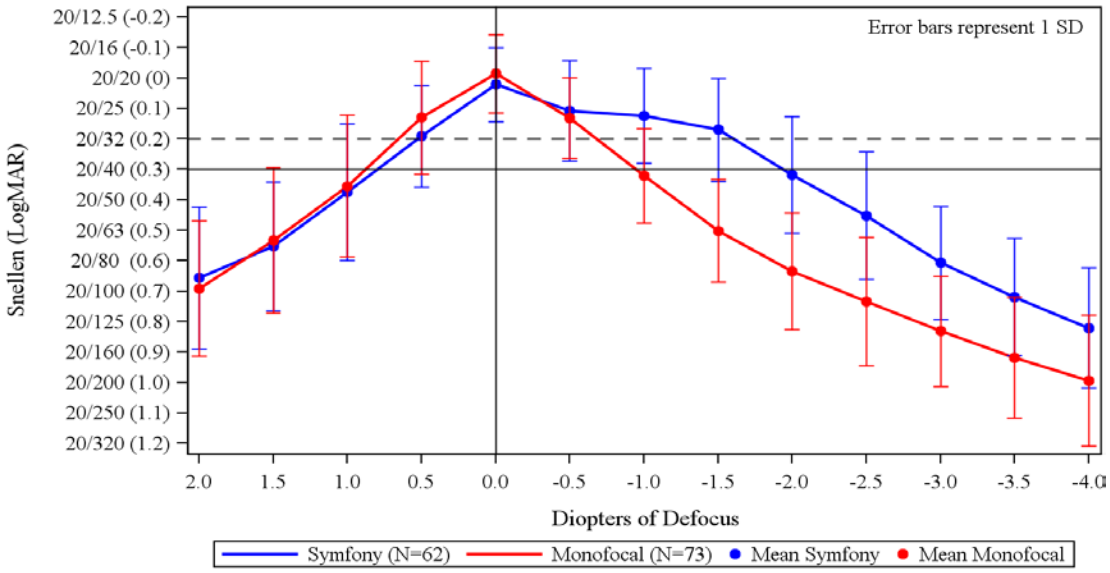


FIGURE 3
Binocular Defocus Curve at 6 Months
Bilateral Subjects—Symfony and Monofocal Control

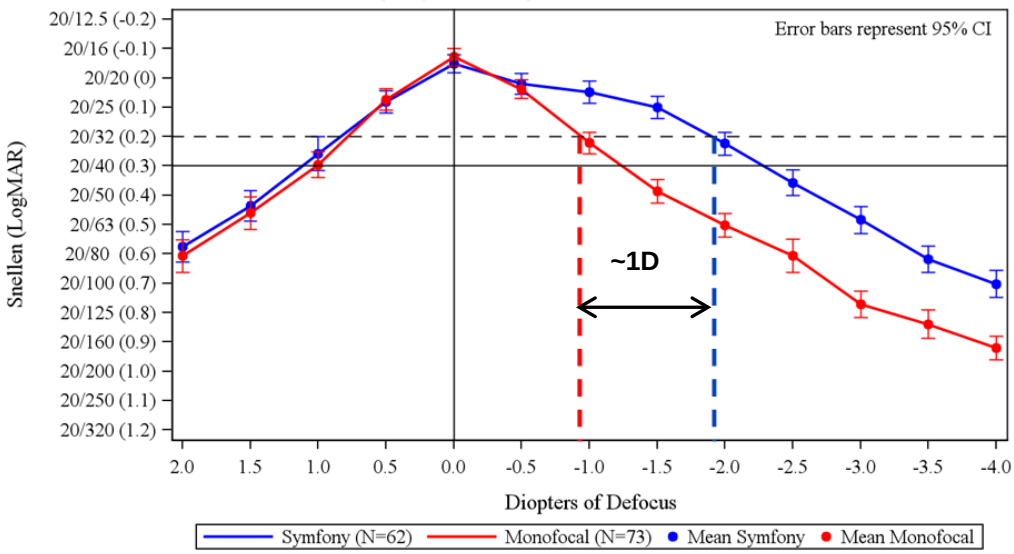
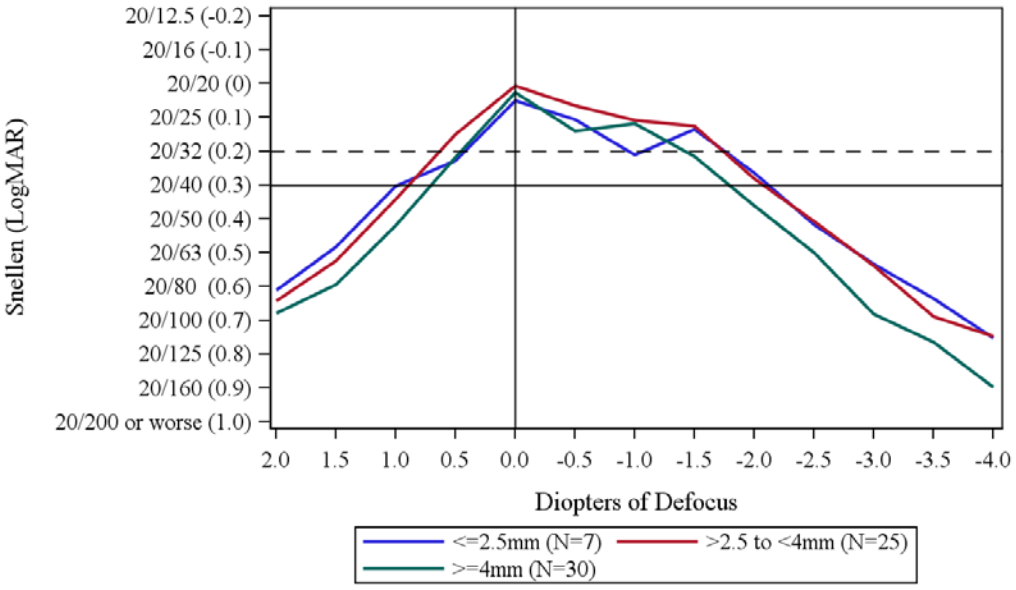


FIGURE 4
Monocular Defocus Curve at 6 Months By Pupil Size
Symfony Subjects



Contrast Sensitivity

Monocular best corrected distance contrast sensitivity testing was performed under three lighting conditions: mesopic with glare, mesopic without glare, and photopic with glare. Median contrast scores for the Symfony IOL group were reduced compared to the monofocal control group under each lighting condition and spatial frequency (**Table 10**). The lower 90% confidence interval (CI) of the median differences between IOL groups at 12.0 cycles per degree (cpd) under mesopic with and without glare were below -0.15 log units, at -0.165 log units and -0.265 log units, respectively (ITT population); the secondary endpoint of non-inferior mesopic contrast sensitivity at the 12 cpd spatial frequency was not achieved. Hypothesis tests were conducted using the Hodges-Lehmann method, utilizing a pre-assigned score for subjects who could not see the reference pattern. This may introduce potential bias, which would tend to cause underestimation of the difference in contrast sensitivity between the arms. An alternative analysis method that avoids this bias is a simple comparison of the medians of the two arms. Differences between Symfony and control medians at 12 cpd were -0.170 log units under mesopic without glare conditions and -0.320 log units under mesopic with glare conditions. No statistically significant difference in contrast sensitivity across pupil size groups was observed; however, the sample size may not have been sufficient to detect differences for subgroup analyses.

TABLE 10
Monocular Best Corrected Distance Contrast Sensitivity at 6 Months

Spatial Frequency	Lens Model	N	Mesopic Without Glare Median[a]	Mesopic Without Glare Subjects who did not see the reference pattern n	Mesopic Without Glare Subjects who did not see the reference pattern %	Mesopic With Glare Median[a]	Mesopic With Glare Subjects who did not see the reference pattern n	Mesopic With Glare Subjects who did not see the reference pattern %	Photopic With Glare Median[a]	Photopic With Glare Subjects who did not see the reference pattern n	Photopic With Glare Subjects who did not see the reference pattern %
1.5 cpd	Symfony	146	1.520	0	0.0	1.520	0	0.0	Not tested		
	Control	147	1.595	1	0.7	1.520	1	0.7	Not tested		
	Difference		-0.075			0.00			Not tested		
3.0 cpd	Symfony	146	1.415	0	0.0	1.445	1	0.7	1.560	0	0.0
	Control	147	1.490	3	2.0	1.490	3	2.0	1.705	1	0.7
	Difference		-0.075			-0.045			-0.145		
6.0 cpd	Symfony	146	1.380	16	11.0	1.380	19	13.0	1.700	4	2.7
	Control	147	1.540	6	4.1	1.550	7	4.8	1.840	5	3.4
	Difference		-0.160			-0.170			-0.140		
12.0 cpd	Symfony	146	0.910	38	26.0	0.760	44	30.1	1.325	12	8.2
	Control	147	1.080	23	15.6	1.080	28	19.0	1.540	9	6.1
	Difference		-0.170			-0.320			-0.215		
18.0 cpd	Symfony	146	Not tested			Not tested			0.885	14	9.6
	Control	147	Not tested			Not tested			1.100	8	5.4
	Difference		Not tested			Not tested			-0.215		

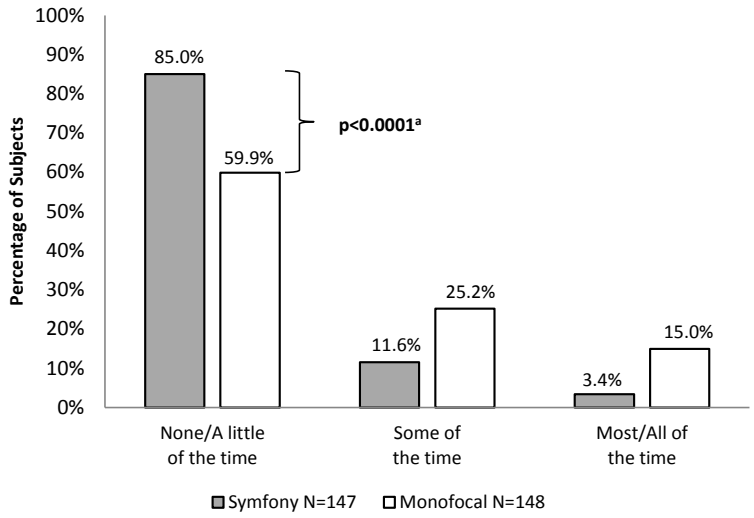
cpd = Cycles per degree
[a] In log units.

Overall Spectacle Wear

Spectacle wear and other related items were assessed by directed subject responses obtained from a self-reported, binocular subjective questionnaire: the Patient Reported Spectacle Independence Questionnaire (PRSIQ). This questionnaire was developed and evaluated following the US FDA guidance document "*Patient-Reported Outcomes Measures: Use in Medical Product Development to Support Labeling Claims*" dated December 2009. Although the questionnaire was not determined to be a psychometrically valid assessment of the concept of spectacle independence, data showed that the Symfony IOL achieved the secondary effectiveness endpoint of reduced overall spectacle wear compared to the control monofocal IOL.

The spectacle wear secondary effectiveness endpoint is based on the proportion of subjects who reported wearing glasses or contacts "none of the time" or "a little of the time" for overall vision, collected from a single question in the PRSIQ. **Figure 5** presents the frequency of overall spectacle wear for bilaterally implanted subjects at 6 months. There was a statistically significantly higher (**p<0.0001**; modified ITT population) proportion of subjects in the Symfony group compared to the monofocal group who reported wearing glasses "none of the time" or "a little of the time". Clinical significance was achieved with 85% of Symfony subjects vs. 59.9% of control subjects reporting wearing glasses "none of the time" or "a little of the time" for overall vision. Additionally, 62.6% (92/147) of Symfony subjects vs. 32.0% (47/148) of monofocal subjects indicated wearing glasses or contacts "none of the time" for overall vision.

FIGURE 5
Overall Spectacle Wear at 6 Months



[a] "None of the time" and "A little of the time" combined; 1-sided Fisher's exact test.

Lens Findings

There were no reports of lens decentration or IOL glistenings at 6 months for Symfony or control IOLs.

Adverse Events

Overall, 2.7% (4/148) of Symfony subjects experienced serious adverse events during the study and none (0%; 0/148) experienced device-related or unanticipated events.

The incidence rates of persistent and cumulative serious adverse events for Symfony eyes compared to the ISO SPE (safety and performance endpoint) rates are presented in **Tables 11 and 12**, respectively. The incidence rates for the Symfony IOL compared favorably to the specified ISO SPE rates, as the observed rates for Symfony were within or not statistically significantly higher than the specified ISO SPE rates (primary safety endpoint). Additionally, there were no secondary surgical interventions related to the optical properties of the Symfony IOL. Secondary surgical intervention events for the Symfony IOL are specified in **Table 13**.

TABLE 11
6-Month Persistent Serious Adverse Events for the Symfony IOL Group

Persistent Medical Complications/ Adverse Events	ISO SPE Rate[a]	First Eyes N=148		Second Eyes N=148		All Eyes N=296	
		n	%	n	%	n	%
Corneal edema	0.3	0	0	0	0	0	0
Cystoid macular edema	0.5	0	0.0	1	0.7[b]	1	0.3
Iritis	0.3	0	0	0	0	0	0
Raised IOP requiring treatment	0.4	0	0	0	0	0	0
Other:							
- Pupillary capture	NA	0	0.0	1	0.7	1	0.3

[a] Per ISO 11979-7: 2006/Amd. 1:2012 (E) ophthalmic Implants – Intraocular Lenses (Part 7): The SPE rate is the safety and performance endpoint.
[b] Incidence rate for "Cystoid Macular Edema-Second Eye" is not statistically significantly higher than ISO SPE rate (p = 0.5238) using 1-sided exact test.

TABLE 12
6-Month Cumulative Serious Adverse Events for the Symfony IOL Group

Cumulative Medical Complications/ Adverse Events	ISO SPE Rate[a]	First Eyes N=148		Second Eyes N=148		All Eyes N=296	
		n	%	n	%	n	%
Cystoid macular edema	3	1	0.7	1	0.7	2	0.7
Hypopyon	0.3	0	0	1	0.7[b]	1	0.3[f]
Endophthalmitis	0.1	0	0	1	0.7[c]	1	0.3[g]
Lens dislocated from posterior chamber	0.1	0	0	0	0	0	0
Pupillary block	0.1	0	0	0	0	0	0
Retinal detachment	0.3	0	0	0	0	0	0
Eyes with secondary surgical intervention	0.8	0	0	2	1.4[e]	2	0.7
-- Device related	NA	0	0	0	0	0	0
-- Not device related	NA	0	0	2[d]	1.4	2	0.7
Other:							
- Pupillary capture	NA	0	0.0	1	0.7	1	0.3

[a] Per ISO 11979-7: 2006/Amd. 1:2012 (E) ophthalmic Implants – Intraocular Lenses (Part 7): The SPE rate is the safety and performance endpoint.
[b] Incidence rate for "Hypopyon-Second Eye" is not statistically significantly higher than ISO SPE rate (p = 0.3590) using 1-sided exact test.
[c] Incidence rate for "Endophthalmitis-Second Eye" is not statistically significantly higher than ISO SPE rate (p = 0.1376) using 1-sided exact test.
[d] Treatment injections for endophthalmitis (Subject 1314) and CME (Subject 1425).
[e] Incidence rate for secondary surgical interventions is not statistically significantly higher than ISO SPE rate (p = 0.3318) using 1-sided exact test.
[f] Incidence rate for "Hypopyon--All Eyes" (0.34)is not statistically significantly higher than ISO SPE rate (p = 0.5891) using 1-sided exact test.
[g] Incidence rate for "Endophthalmitis-All Eyes" is not statistically significantly higher than ISO SPE rate (p = 0.2563) using 1-sided exact test.

TABLE 13
Secondary Surgical Interventions for the Symfony IOL Group

Secondary Surgical Interventions[a]: Not Device-Related	First Eyes N=148		Second Eyes N=148		All Eyes N=296	
	n	%	n	%	n	%
Treatment injections for medical complications:	0	0	2	1.4	2	0.7
- Cystoid macular edema	0	0	1	0.7	1	0.3
- Endophthalmitis (with AC tap)	0	0	1	0.7	1	0.3

[a] All SSIs were treatments for SAEs; there were no SSIs as the original event.

Optical/Visual Symptoms

Optical/visual symptoms spontaneously reported by subjects (non-directed reports; **Table 14**) were typically noted with lower incidences than when subjects were specifically asked about experience/bother with visual problems via a questionnaire (directed reports; **Table 15**). Reports of severe symptoms for Symfony and control eyes were rare (**Table 14**). The most commonly reported directed symptoms at 6 months based on a direct questionnaire (**Table 15**) were halos, starbursts, and glare for both IOL groups; halos and starbursts were reported with increased bother in the Symfony group compared with the monofocal control group. The rates of subjects expressing some desire to have lenses removed or replaced due to visual symptoms or other problems with vision are shown in **Table 16**.

TABLE 14
Spontaneous (Non-directed[a]) Reports of Ocular Symptoms (First Eyes) at 6 Months

Ocular Symptoms		Symfony N=147		Control N=148	
		n	%	n	%
Image Quality					
Blurred vision		25	17.0	35	23.6
	Overall	6	4.1	8	5.4
	Distance	9	6.1	3	2.0
	Intermediate	1	0.7	2	1.4
	Near	13	8.8	26	17.6
Optical/Visual					
Halos		24	16.3	2	1.4
	Mild	9	6.1	1	0.7
	Moderate	11	7.5	0	0.0
	Severe	4	2.7	1	0.7
Night Glare		4	2.7	0	0.0
	Mild	1	0.7	0	0.0
	Moderate	3	2.0	0	0.0
	Severe	0	0.0	0	0.0
Starbursts		13	8.8	2	1.4
	Mild	6	4.1	1	0.7
	Moderate	5	3.4	1	0.7
	Severe	2	1.4	0	0.0
Night vision difficulty (overall)		4	2.7	0	0.0
Sensation					
Dryness		12	8.2	16	10.8

%=n/N (Total)

Note: Includes reports of optical/visual symptoms common to traditional multifocal IOLs (halos, night glare, starbursts, and night vision difficulties) as well as any findings reported with an incidence of 10% or more at 6 months.

[a] Non-directed, spontaneously-reported subject responses were obtained from the open-ended question “Are you having any difficulties with your eyes or vision?”.

TABLE 15
Experience/Bother with Visual Symptoms over the Past 7 Days at 6 Months (Directed Reports)

		Symfony N=147		Monofocal N=148	
		n	%	n	%
Halos	None	60	40.8	105	70.9
	Bother a little bit	46	31.3	24	16.2
	Bother somewhat	18	12.2	13	8.8
	Bother quite a bit	13	8.8	2	1.4
	Very bothered	10	6.8	4	2.7
Starbursts	None	62	42.2	110	74.3
	Bother a little bit	42	28.6	18	12.2
	Bother somewhat	18	12.2	12	8.1
	Bother quite a bit	13	8.8	2	1.4

		Symfony N=147		Monofocal N=148	
		n	%	n	%
	Very bothered	12	8.2	6	4.1
Glare[b]	None	62	42.8	85	57.4
	Bother a little bit	53	36.6	35	23.6
	Bother somewhat	12	8.3	18	12.2
	Bother quite a bit	10	6.9	5	3.4
	Very bothered	8	5.5	5	3.4
Streaks of Light[b]	None	122	84.7	126	85.1
	Bother a little bit	11	7.6	10	6.8
	Bother somewhat	5	3.5	7	4.7
	Bother quite a bit	2	1.4	1	0.7
	Very bothered	4	2.8	4	2.7
Occlusions (Shadows)[b]	None	139	95.2	140	94.6
	Bother a little bit	4	2.7	4	2.7
	Bother somewhat	1	0.7	2	1.4
	Bother quite a bit	0	0.0	0	0.0
	Very bothered	2	1.4	2	1.4
Sensitivity to Light[b]	None	65	44.5	75	50.7
	Bother a little bit	53	36.3	38	25.7
	Bother somewhat	15	10.3	18	12.2
	Bother quite a bit	9	6.2	6	4.1
	Very bothered	4	2.7	11	7.4
Poor Low Light Vision[b]	None	60	41.1	60	40.5
	Bother a little bit	64	43.8	56	37.8
	Bother somewhat	13	8.9	21	14.2
	Bother quite a bit	7	4.8	8	5.4
	Very bothered	2	1.4	3	2.0

%=n/N (total) excluding not reported

[a] None includes “did not experience symptom” and “experienced symptom but not bothered”.

[b] “Not Reported” - Two Symfony subjects did not respond to the glare question, three Symfony subjects did not respond to the streaks of light question, and one Symfony subject did not respond to the occlusion question, to the sensitivity to light question and to the poor low light vision question.

TABLE 16
Would Want to Have Lens(es) Removed and Replaced due to Visual Symptoms or Other Problems with Vision at 6 Months

		Symfony N=147		Monofocal N=148	
		n	%	n	%
Lens removed and replaced	Yes	5[a]	3.4	13[a]	8.8
	No	119	81.0	108	73.0
	NA[b]	23	15.6	27	18.2

%=n/N(Total) excluding not reported.

[a] One Symfony subject (0.7%; 1/147) and one monofocal subject (0.7%; 1/148) indicated a desire to have the lenses removed/replaced and the investigator determined the subject reason(s) to be related to optical lens design, i.e., a potential secondary surgical intervention.

[b] NA = NOT APPLICABLE, did not experience any visual symptoms

Clinical Study Results: TECNIS® Toric 1-Piece IOLS, MODELS ZCT150, ZCT225, ZCT300, AND ZCT400

A clinical investigation of the TECNIS Toric 1-Piece IOLs, Models ZCT150, ZCT225, ZCT300 and ZCT400, was conducted at 14 sites in the United States and Canada between March 2010 and September 2011. This pivotal, prospective, multicenter, two-armed, bilateral, 6-month clinical study was designed to evaluate the safety and effectiveness, including the ability to reduce astigmatism, of the TECNIS Toric 1-Piece lenses. The first arm of the study, referred to as the Randomized Control Arm (RCA), was a randomized, comparative, subject- and technician-masked evaluation of the TECNIS® Toric 1-Piece IOL, Model ZCT150, compared to a monofocal control, the TECNIS 1-Piece IOL, Model ZCB00. The second arm of the study, referred to as the Open Label Arm (OLA), was an open-label, non-comparative clinical trial of the TECNIS Toric 1-Piece IOL, Models ZCT225, ZCT300, and ZCT400. In order to facilitate toric IOL selection and axis placement, a web-based, proprietary TECNIS® Toric Calculator was used to determine the appropriate TECNIS Toric IOL model and axis of placement for each eye.

The 6-month results demonstrated that the TECNIS Toric 1-Piece IOLs, Models ZCT150, ZCT225, ZCT300 and ZCT400, are safe and effective for the visual correction of aphakia. The results demonstrated that the TECNIS Toric 1-Piece IOLs exhibit minimal rotation with sound rotational stability, leading to a significant reduction or elimination of residual refractive cylinder in most cases. As a result, subjects implanted with the TECNIS Toric 1-Piece IOLs experienced improved uncorrected distance visual acuity compared to control values. In the data summary, all results presented are for the safety population of all treated subjects.

Subject Population

A total of 269 subjects were enrolled and implanted: 197 were in the RCA and 72 in the OLA. Of the 197 in the RCA, 102 were implanted in the first eye with a TECNIS Model ZCT150 toric lens and 95 were implanted in the first eye with the control lens. Of the 72 in the OLA, 17 were implanted with the ZCT225 lens in the first eye and 55 with either ZCT300 or ZCT400. Overall, 174 first eyes were implanted with a TECNIS® Toric 1-Piece IOL.

In the RCA, the ZCT150 population consisted of 53.9% females and ZCB00 control population consisted of 57.9% females; in the OLA, the study population consisted of 55.6% females. Stratifying by race, the ZCT150 population consisted of 94.1% Caucasian, 3.9% African American, and 2.0% Asian; the ZCB00 control population consisted of 95.8% Caucasian, 3.2% African American and 1.1% Asian; and the OLA group consisted of 94.4% Caucasian, 4.2% African American and 1.4% Asian. The mean ages were 69.9 years for the ZCT150 population, 71.3 years for the ZCB00 control population and 68.8 years for the OLA population.

Reduction in Cylinder

No statistically significant differences were observed in preoperative keratometric cylinder or target refractive cylinder between ZCT150 toric and ZCB00 control eyes in the RCA; however, statistically significant differences were observed for mean refractive cylinder and the mean percent reduction in cylinder in favor of the ZCT150 lens group compared to the ZCB00 control at 6 months postoperative (**Table 17**). Additionally, the mean percent reduction in cylinder for OLA first eyes at 6 months was statistically significantly higher than the target value of 25%. For all toric first eyes in the RCA and OLA safety populations combined (N=171), the mean percent reduction in cylinder was 75.24 (SD=59.29).

TABLE 17
Mean Cylinder and Percent Reduction in Cylinder at Six Months
First Eyes[a] - Randomized Control Arm and Open Label Arm

	Randomized Control Arm					Open Label Arm				
VARIABLE	**Lens Model**	**N[a]**	**Mean**	**Std. Dev.**	**P-Value**	**Lens Model**	**N[a]**	**Mean**	**Std. Dev.**	**P-Value**
PreopKeratometric Cylinder (Kcyl; D)	Control	91	1.11	0.24	0.3436	Pooled	70	2.16	0.66	N/A
	ZCT150	101	1.08	0.28		ZCT225	17	1.58	0.28	
						ZCT300	24	1.91	0.46	
						ZCT400	29	2.70	0.55	
Target Refractive Cylinder (D)	Control	91	0.26	0.18	0.6267	Pooled	70	0.26	0.30	N/A
	ZCT150	101	0.25	0.17		ZCT225	17	0.12	0.10	
						ZCT300	24	0.19	0.12	
						ZCT400	29	0.41	0.40	
Refractive Cylinder (D)	Control	91	0.85	0.57	**<0.0001**	Pooled	70	0.67	0.47	N/A
	ZCT150	101	0.45	0.41		ZCT225	17	0.49	0.37	
						ZCT300	24	0.62	0.43	
						ZCT400	29	0.82	0.52	
Percent Cylinder Reduction[b]	Control	91	31.61	78.73	**<0.0001**	Pooled	70	76.27	33.09	**<0.0001[c]**
	ZCT150	101	74.53	72.25		ZCT225	17	73.78	27.17	
						ZCT300	24	72.03	38.57	
						ZCT400	29	81.23	31.78	

[a] Eyes with both preoperative and postoperative data
[b] Percent Reduction ANSI Formula=(Postop Ref. Cyl. minus Preop K. Cyl.)/(Target Ref. Cyl. minus Preop K. Cyl.); ANSI formula used except for a few eyes in the RCA with very small denominators (within ±0.1); for these eyes the ANSI formula was used but without the target value.
[c] Versus OLA target of 25% reduction

The TECNIS Toric Calculator utilizes preoperative keratometry and a surgeon-estimated surgically-induced astigmatism (SIA) value to calculate the expected postoperative keratometry and provide options for toric IOL selection. An analysis of the errors in the calculation of postoperative keratometry was performed using vector arithmetic. Results showed that error in magnitude prediction was on average 0.32 D (with a median value of 0.25 D due to bias toward lower values) and error in meridian prediction was on average 16° (with a median value of 8°, again with bias toward lower values). It is important to note that measurement noise in keratometry (estimated from 0.20 D to 0.83 D for magnitude[Zadnik,Visser] and up to 20° for axis[Visser]) and any potential errors in surgeon-estimated SIA are contributing factors to prediction errors of postoperative keratometry.

- Zadnik K, Mutti D, Adams A. The repeatability of measurement of the ocular components. Invest Ophthalmol Vis Sci. 1992 Jun; 33(7): 2325-33
- Visser N, Berendschot T, Verbakel F, de Brabander J, Nuijts R. Comparability and repeatability of corneal astigmatism measurements using different measurement technologies. J. Cataract Refract Surg. 2012 Oct; 38(1): 1764-70

The absolute difference between refractive cylinder at 6 months vs. the target is presented in **Table 18**. In the RCA, 72.3% (73/101) of ZCT150 eyes compared to 49.5% (45/91) of ZCB00 eyes were within 0.50 D of target refractive cylinder; additionally, 94.1% (95/101) of ZCT150 eyes compared to 70.3% (64/91) of ZCB00 eyes were within 1.00 D of target refractive cylinder. In the OLA, 52.9% (37/70) were within 0.50 D and 84.3% (59/70) were within 1.00 D of target refractive cylinder.

TABLE 18
Absolute Difference between Refractive Cylinder at Six Months vs. Target
First Eyes - Randomized Control Arm and Open Label Arm

Diopter Group	Randomized Control Arm				Open Label Arm		All Toric Eyes[a]	
	ZCT150 N=101		ZCB00 Control N=93		ZCT225, ZCT300, ZCT400 N=71		ZCT150, ZCT225, ZCT300, ZCT400 N=172	
	n	%	n	%	n	%	n	%
>2.0	0	0.0	0	0.0	0	0.0	0	0.0
1.51-2.00	1	1.0	6	6.6	2	2.9	3	1.8
1.01-1.50	5	5.0	21	23.1	9	12.9	14	8.2
(≤1.00)	**95**	**94.1**	**64**	**70.3**	**59**	**84.3**	**154**	**90.0**
0.51-1.00	22	21.8	19	20.9	22	31.4	44	25.7
(≤0.50)	**73**	**72.3**	**45**	**49.5**	**37**	**52.9**	**110**	**64.3**
Total Tested	101	100.0	91	100.0	70	100.0	171	100.0
Not Reported	0		2		1		1	

%=n/Total Tested

[a] As control eyes had ≤1.5 D of preoperative Kcyl only, results for all toric eyes pooled are not to be compared to control values

Subgroup Analysis

Cylinder outcomes in the RCA were stratified by preoperative Kcyl alone and by predicted Kcyl (i.e., vector sum of preoperative Kcyl, magnitude and axis, SIA, and incision axis) in 0.25 D increments as shown in **Tables 19, 20, and 21.**

Table 19
Achieved Cylinder Reduction as a Percentage of Intended Reduction
(Percent Reduction in Cylinder ANSI formula[a])
at 6 Months Stratified by Keratometric Cylinder
First Eyes Randomized Control Arm ZCT150 and ZCB00

Model	Preoperative Keratometric Cylinder (D)	N	Percent Reduction in Cylinder (ANSI)[a] Mean	Std Dev	Predicted Keratometric Cylinder (D)[b] (Preop Kcyl + SIA)	N	Percent Reduction in Cylinder (ANSI)[a] Mean	Std Dev
ZCB00	<0.75	4	-45.26	80.51	<0.75	13	-1.28	136.54
ZCT150		5	-79.77	51.59		16	78.20	122.83
ZCB00	0.75-0.99	22	32.32	111.09	0.75-0.99	23	7.39	48.81
ZCT150		30	69.20	87.53		21	55.38	58.57
ZCB00	1.00-1.24	34	41.06	68.41	1.00-1.24	31	43.44	59.77
ZCT150		38	94.88	52.09		36	61.88	49.80
ZCB00	1.25-1.49	27	32.31	60.95	1.25-1.49	20	45.09	73.00
ZCT150		22	74.82	45.78		26	100.27	63.21
ZCB00	≥1.50	4	19.43	17.23	≥1.50	4	118.57	50.01
ZCT150		6	99.88	32.32		2	139.43	31.58
ZCB00	**All**	91	31.61	78.73	**All**	91	31.61	78.73
ZCT150		101	74.53	72.25		101	74.53	72.25

[a] Percent Cylinder Reduction (ANSI Formula)=(Postop Ref. Cyl. minus Preop Kcyl)/(Target Ref. Cyl. minus Preop Kcyl); Percent cylinder reduction (ANSI formula) adjusted for eyes (3) with small denominators (±0.10) where target value was not used.

[b] Predicted keratometric cylinder is the vector combination of preoperative keratometric cylinder (magnitude and axis), estimated SIA and incision axis.

Table 20
Residual Refractive Cylinder at 6 Months Stratified by Keratometric Cylinder
First Eyes Randomized Control Arm ZCT150 and ZCB00

Model	Preoperative Keratometric Cylinder (D)	Residual Refractive Cylinder (D) N	Mean	Std Dev	Predicted Keratometric Cylinder (D)[a] (Preop Kcyl + SIA)	Residual Refractive Cylinder (D) N	Mean	Std Dev
ZCB00	<0.75	5	0.85	0.42	<0.75	14	0.77	0.49
ZCT150		5	0.91	0.14		16	0.55	0.43
ZCB00	0.75-0.99	22	0.56	0.50	0.75-0.99	23	1.03	0.51
ZCT150		30	0.50	0.40		21	0.43	0.33
ZCB00	1.00-1.24	34	0.80	0.55	1.00-1.24	31	0.84	0.68
ZCT150		38	0.36	0.36		36	0.48	0.45
ZCB00	1.25-1.49	27	1.09	0.59	1.25-1.49	21	0.84	0.52
ZCT150		22	0.48	0.49		26	0.39	0.43
ZCB00	≥1.50	5	1.35	0.28	≥1.50	4	0.43	0.42
ZCT150		6	0.34	0.44		2	0.38	0.18
ZCB00	**All**	93	0.86	0.57	**All**	93	0.86	0.57
ZCT150		101	0.45	0.41		101	0.45	0.41

[a] Predicted keratometric cylinder is the vector combination of preoperative keratometric cylinder (magnitude and axis), estimated SIA and incision axis.

Table 21
Change in Absolute Cylinder[a] at Six Months Stratified by Keratometric Cylinder
First Eyes Randomized Control Arm ZCT150 and ZCB00

			Absolute Cylinder Change								Absolute Cylinder Change					
			Reduction >0.50 D		≤ +/-0.50 D[b]		Increase >0.50 D				Reduction >0.50 D		≤ +/-0.50 D[b]		Increase >0.50 D	
Model	Preoperative Keratometric Cylinder (D)	N	n	%	n	%	n	%	Predicted Keratometric Cylinder (D)[c] (Preop Kcyl + SIA)	N	n	%	n	%	n	%
ZCB00	<0.75	5	0	0.00	4	80.00	1	20.0	<0.75	14	2	14.29	10	71.43	2	14.29
ZCT150		5	0	0.00	4	80.00	1	20.0		16	5	31.25	9	56.25	2	12.50
ZCB00	0.75-0.99	22	7	31.82	13	59.09	2	9.09	0.75-0.99	23	2	8.70	18	78.26	3	13.04
ZCT150		30	10	33.33	19	63.33	1	3.33		21	15	71.43	6	28.57	0	0.00
ZCB00	1.00-1.24	34	12	35.29	19	55.88	3	8.82	1.00-1.24	31	12	38.71	17	54.84	2	6.45
ZCT150		38	29	76.32	9	23.68	0	0.00		36	22	61.11	14	38.89	0	0.00
ZCB00	1.25-1.49	27	9	33.33	16	59.26	2	7.41	1.25-1.49	21	10	47.62	10	47.62	1	4.76
ZCT150		22	18	81.82	4	18.18	0	0.00		26	19	73.08	7	26.92	0	0.00
ZCB00	≥1.50	5	1	20.00	4	80.00	0	0.00	≥1.50	4	3	75.00	1	25.00	0	0.00
ZCT150		6	6	100.0	0	0.00	0	0.00		2	2	100.0	0	0.00	0	0.00
ZCB00	**All**	93	29	31.18	56	60.22	8	8.60	**All**	93	29	31.18	56	60.22	8	8.60
ZCT150		101	63	62.38	36	35.64	2	1.98		101	63	62.38	36	35.64	2	1.98

[a] Change in Absolute Cylinder=Postop Ref. Cyl minus Preop Kcyl

[b] Not all eyes were targeted for a reduction in absolute cylinder greater than 0.50 D; therefore, some eyes that achieved the intended cylinder change will be included in the ± 0.50 D column

[c] Predicted keratometric cylinder is the vector combination of preoperative keratometric cylinder (magnitude and axis), estimated SIA and incision axis.

Distance Visual Acuities

In the RCA, a statistically significant improvement (**p=0.0009**) in mean monocular UCDVA at 6 months was found in favor of ZCT150 (0.10 LogMAR, SD 0.14; Snellen equivalent 20/25) over the ZCB00 control group (0.16 LogMAR, SD 0.16; Snellen equivalent 20/29) by 0.6 lines. In the OLA, mean UCDVA was 0.11 LogMAR (SD 0.12; Snellen equivalent 20/26). For all toric eyes in the RCA and OLA combined (N=172), mean UCDVA was 0.10 LogMAR (SD 0.13; Snellen equivalent 20/25).

In the RCA, statistically significant differences in the distribution of monocular UCDVA results were observed at 6 months group with higher proportions of ZCT150 eyes achieving 20/20 or better (43.6%; **p=0.0026**) and 20/40 or better (97.0%; **p=0.0092**) vs. ZCB00 control eyes (23.7% and 87.1%, respectively). In the OLA, a statistically significantly (**p<0.0001**) greater proportion of eyes achieved UCDVA of 20/20 or better (38.0%) vs. target (6%); additionally 97.2% of OLA eyes achieved UCDVA of 20/40 or better.

At 6 months, 100% of all toric first eyes and 100% of best-case toric first eyes in the RCA and OLA combined achieved BCDVA of 20/40 or better, exceeding the ISO BCDVA Safety and Performance Endpoint (SPE) rates for overall (92.5%) and best case (96.7%). Additionally, 88.4% of all toric eyes achieved BCDVA of 20/20 or better.

Rotational Stability

The degree of lens axis rotation between time points was measured using a direct photographic method. **Table 22** presents the change in axis rotation between stability time points (1 to 3 months and 3 to 6 months) for toric first eyes. The TECNIS® Toric 1-Piece IOLs achieved the Z80.30 ANSI Standard for Toric IOLs, rotational stability requirement (>90% of eyes having ≤5° axis change between consecutive visits approximately three months apart) as ≥93% of toric first eyes had a change in axis of ≤5° between stability visits approximately three months apart.

TABLE 22
Absolute Difference in Axis Alignment Between Visits
First Eyes - All Toric ZCT150, ZCT225, ZCT300, ZCT400 Pooled

Axis Shift (degrees)	Toric Eyes: Consistent Cases[a]				Toric Eyes with Data at Two or More Consecutive Visits[b]			
	1 Month vs. 3 Months		3 Months vs. 6 Months		1 Month vs. 3 Months		3 Months vs. 6 Months	
	n	%	n	%	n	%	n	%
>30	0	0.0	0	0.0	0	0.0	0	0.0
16-30	0	0.0	0	0.0	0	0.0	0	0.0
10-15	2	1.4	3	2.0	2	1.3	3	2.0
(<10)	146	98.6	145	98.0	154	98.7	149	98.0
6-9	9	6.1	6	4.1	9	5.8	6	3.9
0-5	**137**	**92.6[c]**	**139**	**93.9[c]**	**145**	**92.9[c]**	**143**	**94.1[c]**
Total	**148**	**100.0**	**148**	**100.0**	**156**	**100.0**	**152**	**100.0**

[a] Eyes with photographic axis data at all visits through six months.
[b] Eyes with photographic axis data at two or more consecutive visits but not necessarily all visits.
[c] Results achieved the ANSI Standard for Toric IOLs, Z80.30 rotational stability requirements (>90% of eyes having ≤5° axis change between consecutive visits approximately three months apart)

Table 23 presents the axis change for toric eyes between the baseline (1-day) and 6-month visits. Of toric first eyes, 97% had <10° of axis change between baseline and six months.

TABLE 23
Absolute Difference in Axis Alignment between 1 Day and 6 Months
First Eyes - All Toric ZCT150, ZCT225, ZCT300, ZCT400 Pooled

Axis Shift (degrees)	Toric Eyes: Consistent Cases[a] 1 Day vs. 6 Months n	%	Toric Eyes with Data at One Day and Six Months 1 Day vs. 6 Months N	%
>30	2[b]	1.4	2[b]	1.3
16-30	3[c,d]	2.0	3[c,d]	1.9
10-15	0	0.0	0	0.0
(<10)	**143**	**96.6**	**151**	**96.8**
6-9	4	2.7	4	2.6
0-5	139	93.9	147	94.2
Total	**148**	**100.0**	**156**	**100.0**

[a] Eyes with photographic axis data at all visits through six months
[b] Two ZCT400 eyes with calculated rotation of 40° and 45° underwent repositioning procedures
[c] Two ZCT300 eyes with calculated rotation of 18° and 21° underwent repositioning procedures
[d] One ZCT150 eye with calculated lens rotation 24° was not repositioned.

Table 24 presents mean axial rotation between stability time points (1 to 3 months and 3 to 6 months) as well as overall (baseline to 6 months). Mean axial rotation was minimal (<3°) whether taking direction of axis shift into account or regardless of direction (absolute value).

TABLE 24
Mean Change in Axis
Difference Taking Direction into Account (+/- Sign Included)
and Degree Shift Regardless of Direction (Absolute Value)
First Eyes - All Toric ZCT150, ZCT225, ZCT300, ZCT400 Pooled

Change in Axis Between Visits	Toric Eyes: Consistent Cases[a] N	MEAN (degrees)	STD. DEV.	Toric Eyes with Data at Two or More Visits[b] N	MEAN (degrees)	STD. DEV.
1 Mon. vs. 3 Mon.	148	0.24	2.82	156	0.25	2.77
3 Mon. vs. 6 Mon.	148	-0.06	2.94	152	-0.09	2.96
Baseline (1 Day) vs. 6 Mon.	148	-1.35	6.13	156	-1.33	5.99
Abs. Value-1 Mon. vs 3 Mon.	148	1.82	2.17	156	1.79	2.12
Abs. Value-3 Mon. vs 6 Mon.	148	1.85	2.28	152	1.89	2.27
Abs. Value-Baseline (1 Day) vs. 6 Mon.	148	2.74	5.65	156	2.70	5.51

[a] Eyes with photographic axis data at all visits through six months
[b] Eyes with photographic axis data at two or more visits but not necessarily all visits

Adverse Events

The cumulative adverse event incidence rates for the TECNIS® Toric ZCT IOL first eyes compared favorably to the ISO SPE rates (**Table 25**). The rate of secondary surgical interventions (SSIs, 3.4%; 6/174) was statistically significantly higher than the ISO SPE rate of 0.8%. Four lens-related repositioning procedures were performed in toric eyes to correct a rotated IOL; however, the rate for lens-related SSIs (2.3%; 4/175) was not statistically significantly higher than the ISO SPE rate for SSI's. The lens repositioning procedures occurred in ZCT300 and ZCT400 first eyes only (7.3%; 4/55); no ZCT300 or ZCT400 second eyes underwent lens repositioning procedures, thereby yielding an overall rate of 4.7% (4/85)

for all ZCT300 and ZCT400 eyes. The rate of non-lens-related SSIs (two retinal repair procedures; 1.1%, 2/174) was not statistically significantly higher than the ISO SPE rate for surgical re-intervention.

TABLE 25
Cumulative Adverse Events through 6 Months
TECNIS® Toric ZCT First Eyes: ZCT150, ZCT225, ZCT300 and ZCT400

Cumulative Adverse Event	ZCT Eyes N=174		ISO SPE[a] Rate
	n	%	%
Cystoid macular edema	5	2.9	3.0
Hypopyon	0	0.0	0.3
Endophthalmitis	0	0.0	0.1
Lens dislocation	0	0.0	0.1
Pupillary block	0	0.0	0.1
Retinal detachment	1	0.6[b]	0.3
Secondary Surgical Intervention	6	3.4[c]	
Lens-related: repositioning procedures	4	2.3[d]	0.8
Not lens-related: retinal repair procedures	2	1.1[e]	

[a] ISO 11979-7 Safety and Performance Endpoint (SPE).
[b] p=0.4071 compared to cumulative ISO SPE rate of 0.3%
[c] **p=0.0030** compared to cumulative ISO SPE rate of 0.8%
[d] p=0.0521 compared to cumulative ISO SPE rate of 0.8%
[e] p=0.4059 compared to cumulative ISO SPE rate of 0.8%

There were no persistent complications/adverse events present at 6 months for toric first eyes (0%; 0/174) in comparison to the ISO SPE rates for persistent complications/adverse events.

IOL rotation was noted by investigators at one day postoperatively in four toric first eyes; these were the four eyes (two ZCT300 and two ZCT400) mentioned above that underwent IOL repositioning procedures. IOL rotation at one day was estimated by the investigators to be 10° in both ZCT300 eyes, 35° in one ZCT400 eye, and 40° in the other ZCT400 eye. The repositioning procedures were performed early in the postoperative period, between the 1-day and 1-month study visits. Photographic analyses showed good lens stability following the repositioning procedures with only 2° to 5° of calculated rotation at 6 months vs. following the repositioning procedures.

Optical/Visual Symptoms

Table 26 presents the degree of bother/trouble with ocular/visual symptoms at 6 months as collected from a questionnaire. Overall, most toric and ZCB00 control subjects reported “no trouble at all” for most items, including those that may be related to a toric IOL (things appearing distorted, judging distances when going up or down steps, objects appearing tilted, floors or flat surfaces appearing curved). Reports of ocular symptoms for toric eyes with >2.0 D of cylinder correction at the corneal plane (ZCT300 and ZCT400) did not appear different from the lower cylinder models, indicating no impact on the ocular/visual profile with higher cylinder correction.

TABLE 26:
Degree of Bother/Trouble with Key Ocular/Visual Symptoms at 6 Months from a Directed Questionnaire
Bilateral Subjects[a] in the Randomized Control Arm and the Open Label Arm

During the past month, how bothered have you been by each of the following, using correction if needed?		Randomized Control Arm		Open Label Arm		All Toric Subjects[b]
		ZCT150 N=72	ZCB00 Control N=78	ZCT225 N=17	ZCT300/ ZCT400[c] N=54	ZCT150, ZCT225, ZCT300, ZCT400 N=143
Changes in your vision during the day	No trouble at all	93.1%	80.8%	94.1%	87.0%	90.9%
	A little trouble	5.6%	19.2%	5.9%	11.1%	7.7%
	Moderate trouble	1.4%	0.0%	0.0%	1.9%	1.4%
	Severe trouble	0.0%	0.0%	0.0%	0.0%	0.0%
Glare (reflections off shiny surfaces, snow)	No trouble at all	68.1%	50.0%	58.8%	51.9%	60.8%
	A little trouble	22.2%	33.3%	29.4%	27.8%	25.2%
	Moderate trouble	9.7%	14.1%	5.9%	20.4%	13.3%
	Severe trouble	0.0%	2.6%	5.9%	0.0%	0.7%
Things looking different out of one eye vs. the other	No trouble at all	84.7%	70.5%	100.0%	70.4%	81.1%
	A little trouble	12.5%	19.2%	0.0%	18.5%	13.3%
	Moderate trouble	2.8%	9.0%	0.0%	7.4%	4.2%
	Severe trouble	0.0%	1.3%	0.0%	3.7%	1.4%
Seeing in dim light	No trouble at all	84.7%	65.4%	70.6%	63.0%	74.8%
	A little trouble	15.3%	29.5%	23.5%	22.2%	18.9%
	Moderate trouble	0.0%	5.1%	5.9%	13.0%	5.6%
	Severe trouble	0.0%	0.0%	0.0%	1.9%	0.7%
Your depth perception	No trouble at all	98.6%	85.9%	82.4%	90.7%	93.7%
	A little trouble	1.4%	10.3%	17.6%	5.6%	4.9%
	Moderate trouble	0.0%	2.6%	0.0%	3.7%	1.4%
	Severe trouble	0.0%	1.3%	0.0%	0.0%	0.0%
Things appearing distorted	No trouble at all	97.2%	93.6%	94.1%	96.3%	96.5%
	A little trouble	1.4%	1.3%	0.0%	3.7%	2.1%
	Moderate trouble	1.4%	5.1%	5.9%	0.0%	1.4%
	Severe trouble	0.0%	0.0%	0.0%	0.0%	0.0%
Judging distance when going up or down steps (stairs, curbs)	No trouble at all	90.3%	87.2%	100.0%	88.9%	90.9%
	A little trouble	8.3%	9.0%	0.0%	9.3%	7.7%
	Moderate trouble	1.4%	2.6%	0.0%	1.9%	1.4%
	Severe trouble	0.0%	1.3%	0.0%	0.0%	0.0%
Objects appearing tilted	No trouble at all	100.0%	98.7%	100.0%	98.1%	99.3%
	A little trouble	0.0%	1.3%	0.0%	1.9%	0.7%
	Moderate trouble	0.0%	0.0%	0.0%	0.0%	0.0%
	Severe trouble	0.0%	0.0%	0.0%	0.0%	0.0%
Floors or flat surfaces appearing curved	No trouble at all	97.2%	100.0%	100.0%	98.1%	97.9%
	A little trouble	2.8%	0.0%	0.0%	1.9%	2.1%
	Moderate trouble	0.0%	0.0%	0.0%	0.0%	0.0%
	Severe trouble	0.0%	0.0%	0.0%	0.0%	0.0%

[a] Subjects bilaterally implanted with either toric or control lenses and with ≥0.75 D preoperative Kcyl in second eyes
[b] As control subjects had ≤1.5 D of preoperative Kcyl, results for all toric subjects pooled are not to be compared to control values
[c] ZCT IOL models with >2.0 D of cylinder correction at corneal plane presented separately

CLINICAL STUDY RESULTS: TECNIS® MULTIFOCAL IOL, MODEL ZM900

Two clinical studies were conducted in the United States with the silicone version of the TECNIS® Multifocal IOL, Model ZM900, between 2004 and 2007. The initial clinical study of the TECNIS® multifocal IOL, Model ZM900, was a 1-year, multicenter, evaluator-masked, bilateral, parallel-group comparative clinical evaluation conducted at 13 investigational sites; the second study was a 1-year, multicenter, open-label, unilateral or bilateral, expansion study conducted at 16 investigational sites. Across both studies, a total of 347 TECNIS® ZM900 subjects (306 bilaterally implanted) and 123 monofocal control subjects (122 bilaterally implanted) were enrolled.

The subject population across both studies consisted of more females than males in both lens groups: 60.8% females in the multifocal lens group and 65.9% in the monofocal lens group. The mean age for multifocal subjects was 65.9 years (ranging from 29 to 87 years); the mean age for monofocal control subjects was slightly older at 68.7 years (ranging from 35 to 84 years). The majority of subjects were Caucasian in both lens groups: 95.7% in the multifocal group and 94.3% in the monofocal group. The remainder of subjects were Black (2.0% in the multifocal group; 5.7% in the monofocal group), Asian (0.9% in the multifocal group; 1.6% in the monofocal group) and “Other” (1.4% in the multifocal group and none in the monofocal group).

Driving Performance

A night driving performance substudy of 26 bilateral multifocal subjects and 31 bilateral monofocal subjects was conducted to assess functional performance differences between multifocal and monofocal IOL subjects in the initial study at 6 months. Binocular visual performance was measured while driving under low visibility conditions such as night driving and with headlight glare conditions. The Night Driving Simulator developed and validated by Vision Sciences Research Corporation (VSRC) was used to measure night driving visibility distances and evaluate driving safety in terms of critical stopping sight distance.

The Night Driving Simulator included two driving scenes, a nighttime rural road and a nighttime city street. Six visual test targets were used: two different road warning signs, two text signs and two road hazards. The size and content of the signs and hazards varied requiring different detection and identification distances. The simulated visibility conditions for nighttime driving in rural and city roads were clear weather, inclement weather (fog), and glare conditions.

The night driving visibility results are presented in **Tables 27** and **28** for the rural road and in **Tables 29** and **30** for the city street. In general, mean night driving visibility distances for detection and identification of text, warning and pedestrian targets was lower for multifocal subjects than for monofocal subjects. However, the mean percent loss in visibility detection and identification distances for TECNIS multifocal subjects compared to the monofocal control group was within 25% loss for most distances, even in city roads with visual clutter and background interaction.

TABLE 27
Visibility Distance and Time for Rural Detection

Visibility Condition	Target	Mean Visibility Distance (feet)		Difference (feet)	Mean % Loss	Mean Visibility Time (sec)	
		ZM900	Monofocal			ZM900	Monofocal
Normal	Text	715 ± 33	734 ± 19	19	2.6%	8.86	9.09
	Warning	668 ± 36	703 ± 29	35	5.0%	8.28	8.72
	Pedestrian	630 ± 39	667 ± 22	37	5.6%	7.81	8.27
Fog	Text	690 ± 32	709 ± 23	19	2.7%	8.55	8.79
	Warning	623 ± 32	658 ± 29	35	5.3%	7.73	8.16
	Pedestrian	616 ± 31	642 ± 38	26	4.1%	7.64	7.96
Glare	Text	645 ± 35	678 ± 28	33	4.8%	8.00	8.41
	Warning	591 ± 34	635 ± 27	44	6.9%	7.32	7.87
	Pedestrian	546 ± 75	621 ± 39	75	12.0%	6.77	7.70

TABLE 28
Visibility Distance and Time for Rural Identification

Visibility Condition	Target	Mean Visibility Distance (feet)		Difference (feet)	Mean % Loss	Mean Visibility Time (sec)	
		ZM900	Monofocal			ZM900	Monofocal
Normal	Text	353 ± 85	479 ± 76	126	26.3%	4.38	5.94
	Warning	502 ± 70	583 ± 40	81	14.0%	6.22	7.23
	Pedestrian	455 ± 103	583 ± 67	128	21.9%	5.64	7.23
Fog	Text	281 ± 73	393 ± 65	112	28.5%	3.48	4.87
	Warning	426 ± 75	529 ± 69	103	19.5%	5.28	6.56
	Pedestrian	387 ± 109	495 ± 96	108	21.7%	4.80	6.14
Glare	Text	253 ± 82	392 ± 67	139	35.6%	3.13	4.86
	Warning	396 ± 95	526 ± 59	130	24.7%	4.90	6.52
	Pedestrian	335 ± 111	465 ± 91	130	27.9%	4.16	5.76

TABLE 29
Visibility Distance and Time for City Detection

Visibility Condition	Target	Mean Visibility Distance (feet)		Difference (feet)	Mean % Loss	Mean Visibility Time (sec)	
		ZM900	Monofocal			ZM900	Monofocal
Normal	Text	279 ± 37	333 ± 44	54	16.2%	5.43	6.48
	Warning	297 ± 31	320 ± 32	23	7.1%	5.79	6.23
	Pedestrian	348 ± 89	358 ± 92	10	2.6%	6.78	6.97
Fog	Text	255 ± 49	300 ± 41	45	15.0%	4.97	5.85
	Warning	276 ± 28	303 ± 30	27	9.0%	5.37	5.90
	Pedestrian	326 ± 80	358 ± 88	32	8.9%	6.36	6.98
Glare	Text	229 ± 42	279 ± 32	50	17.8%	4.46	5.43
	Warning	266 ± 32	295 ± 32	29	9.9%	5.17	5.74
	Pedestrian	291 ± 69	326 ± 82	35	10.7%	5.66	6.35

TABLE 30
Visibility Distance and Time for City Identification

Visibility Condition	Target	Mean Visibility Distance (feet)		Difference (feet)	Mean % Loss	Mean Visibility Time (sec)	
		ZM900	Monofocal			ZM900	Monofocal
Normal	Text	255 ± 30	312 ± 37	57	18.3%	4.96	6.07
	Warning	293 ± 33	320 ± 32	27	8.4%	5.70	6.23
	Pedestrian	324 ± 72	348 ± 82	24	7.1%	6.31	6.79
Fog	Text	219 ± 40	273 ± 32	54	19.7%	4.27	5.32
	Warning	269 ± 32	300 ± 30	31	10.2%	5.25	5.85
	Pedestrian	305 ± 65	343 ± 71	38	11.0%	5.95	6.68
Glare	Text	199 ± 57	263 ± 39	64	24.3%	3.88	5.12
	Warning	261 ± 35	293 ± 31	32	11.1%	5.08	5.71
	Pedestrian	276 ± 53	310 ± 65	34	10.9%	5.38	6.04

Fundus Visualization

At 6 months, investigators evaluated the ability to visualize the fundus during the dilated fundus exams. In all cases (100%; 333/333 multifocal first eyes and 119/119 monofocal first eyes), fundus visualization was deemed “adequate”. During the studies, no difficulties were reported in evaluating or treating retinal complications in multifocal eyes; however, only one multifocal eye underwent a surgical retinal procedure.

Adverse Events

The incidences of cumulative complications/adverse events for the TECNIS ZM900 multifocal first eyes compared to the US FDA historical grid are presented in **Table 31**. The incidence rates for the TECNIS ZM900 lens compared favorably to the specified FDA rates. At 1 year, only the rate of secondary surgical interventions (SSIs) in the TECNIS ZM900 lens group was statistically higher than the FDA grid rate of 0.8% ($p<0.0001$). However, with only three subjects out of 348 experiencing lens-related events (3/348; 0.9%), the observed proportions of lens-related SSIs for first and second eyes were not statistically higher than the FDA grid rate ($p=0.4725$ for first eyes; $p=0.4432$ for second eyes). The rate of non-lens-related SSIs was statistically higher than the grid rate for multifocal first eyes ($p=0.0001$). SSIs for multifocal first eyes are specified in **Table 32**.

TABLE 31
Cumulative Adverse Events for TECNIS ZM900 First Eyes at 1 Year

Cumulative Adverse Event	ZM900 N=348[a]		FDA Grid Rate
	n	%	%
Hyphema	0	0.0	2.2
Macular edema	9	2.6	3.0
Retinal detachment	0	0.0	0.3
Pupillary block	0	0.0	0.1
Lens dislocation	0	0.0	0.1
Endophthalmitis	1[b]	0.3	0.1
Hypopyon	1[b]	0.3	0.3
Surgical re-intervention	13	3.7	
Lens-related	2[c]	0.6	0.8
Not lens-related	11[b]	3.2	

[a] Excluded subject with lens exchange due to incorrect lens type included in study population for adverse events only: 348 first eyes instead of 347.

[b] One eye experienced endophthalmitis and hypopyon followed by non-lens-related surgical re-interventions (trabeculectomy and two filtration bleb revisions).

[c] A total of 3 subjects experienced lens-related events during the study (0.9%; 3/348); however only two of these experienced events in first eyes. Following study completion, two of the three subjects experienced lens-related events in the first eye (one of which experienced an event in the first eye during the study). Therefore, the total number of first eyes with lens-related events during and after the study is three (3/348; 0.9%)

TABLE 32
Secondary Surgical Interventions in TECNIS ZM900 First Eyes at 1 Year

Surgical Re-Interventions		TECNIS ZM900 N=348[a]	
		n	%
Lens-Related		**2**	**0.6%**
Lens removal due to halos/glare		1[b,c]	0.3
Lens repositioning (image quality: blurry/hazy vision)		1[d]	0.3
Not Lens-Related		**11**	**3.2%**
Iris prolapse/wound repair		1	0.3
Lens exchange:	- Lens power (refractive error)	3	0.9
	- Incorrect lens type	1[a]	0.3
Retinal repair	- Macular hole repair	1	0.3
	- Laser photocoagulation for retinal break	1	0.3
	- Vitrectomy/membrane peel for macular pucker	1	0.3
Trabeculectomy and two subsequent filtration bleb revisions		1[e]	0.3
Treatment injections for cystoid macular edema		2	0.6
TOTAL EYES		**13**[a]	**3.7%**

[a] Includes excluded subject (lens exchange following implantation of non-study IOL) for adverse events only
[b] This subject also experienced a pupilloplasty and lens removal in the second eye due to halos and glare
[c] This subject eventually underwent lens removal in both eyes due to halos and glare
[d] This subject eventually underwent lens removal in both eyes due to image quality (blurry/hazy vision)
[e] Subsequent to endophthalmitis and hypopyon

Medical complications at 6 months and 1 year (persistent) are presented for TECNIS ZM900 first eyes were below FDA grid rates and are presented in **Table 33**. There was only one persistent event; one first eye unilateral subject was diagnosed with secondary glaucoma/raised intraocular pressure (IOP) requiring treatment beginning approximately 5 months postoperatively through the 1-year study timeframe.

TABLE 33
Medical Complications and Adverse Events for TECNIS ZM900 First Eyes at 6 Months and 1 Year (Persistent)

Persistent Adverse Event	ZM900				FDA Grid Rate
	6 Months N=333		1 Year N=331		
	N	%	n	%	%
Macular edema	1	0.3	0	0.0	0.5
Corneal edema	1	0.3	0	0.0	0.3
Iritis	2	0.6	0	0.0	0.3
Raised IOP requiring treatment	1[a]	0.3	1[a]	0.3	0.4

[a] Same eye

Optical/Visual Symptoms

Non-directed, spontaneous subject responses were obtained from the open-ended question "Are you having any difficulties with your eyes or vision" as asked at the clinical study exams. **Table 34** presents the incidence of non-directed, spontaneous responses for optical/visual symptoms for first eyes in both lens groups at 1 year postoperatively. The most reported optical/visual symptoms noted in the TECNIS multifocal lens group were halos, with most

reports being “mild” to “moderate”. For monofocal first eyes, halos were also reported but with lower incidence and severity. Blurred/difficulty with vision was reported frequently in both lens groups. Night glare and starbursts were reported with higher frequencies in the multifocal group; however, most reports were noted as “mild” to “moderate”. Across both studies, three multifocal subjects (0.9%; 3/348) underwent study lens removal; two resulting from halos/glare and one from dissatisfaction with image quality (blurry/hazy vision).

TABLE 34
Optical/Visual Symptoms* Pertaining to Visual Disturbances and Image Quality for First Eyes, Non-directed Responses at 6 Months and 1 Year

Optical/Visual Symptoms	TECNIS ZM900		Monofocal Control	
	6 Months N=333	1 Year N=331	6 Months N=119	1 Year N=116
Visual Disturbances				
Day glare	3.9%	6.0%	1.7%	1.7%
Floaters	4.2%	5.7%	4.2%	2.6%
Halos[b]	40.8% Mild = 16.5% Moderate = 15.3% Severe = 9.0%	24.5% Mild = 12.7% Moderate = 6.3% Severe = 5.4%	4.2% Mild = 2.5% Moderate = 1.7%	8.6% Mild = 6.0% Moderate = 2.6%
Night glare[b]	14.1% Mild = 5.1% Moderate = 5.4% Severe = 3.6%	11.8% Mild = 3.3% Moderate = 5.7% Severe = 2.4%	4.2% Mild = 2.5% Moderate = 1.7%	4.3% Mild = 1.7% Moderate = 0.9% Severe = 1.7%
Starburst[b]	8.1% Mild = 3.6% Moderate = 3.3% Severe = 1.2%	6.3% Mild = 2.4% Moderate = 2.1% Severe = 1.8%	0.8% Mild = 0.8%	1.7% Mild = 1.7%
Night vision difficulty	3.3%	1.5%	0.0%	0.0%
Entoptic phenomena[a]	4.2%	2.1%	1.7%	1.7%
Other image quality[c]		1.8%		0.9%
Image Quality				
Blurred/difficulty with vision	19.5% Overall = 3.3% Distance = 5.4% Intermediate = 11.1% Near = 2.4%	18.4% Overall = 2.4% Distance = 5.7% Intermediate = 8.2% Near = 2.7%	14.3% Overall = 4.2% Distance = 0.0% Intermediate = 0.8% Near = 9.2%	12.9% Overall = 2.6% Distance = 1.7% Intermediate = 0.9% Near = 7.8%
Cloudy/hazy/filmy/foggy vision	3.9%	5.4%	1.7%	2.6%
Decreased vision	3.9%	4.5%	1.7%	2.6%
Fluctuation in acuity	3.6%	3.0%	5.9%	2.6%

Note: Includes any findings reported with an incidence of 3% or higher at 6 months.

[a] Includes reports of arcs of light, rings (not halos) in vision, lens shimmer, light reflection/streaks, etc.

[b] Some subjects reported more than one visual disturbance. Reports of severe halos, night glare or starbursts were noted for 11.7% (39/333) of first eyes and 11.5% (34/296) of second eyes at 4-6 months. At one year, reports of severe halos, night glare or starbursts were noted for 6.9% (23/331) of first eyes and 6.8% (20/295) of second eyes.

[c] Includes reports of vision trembles, difficulty reading in dim/low light conditions, decreased reading distance, trouble reading for long periods, too much or too little contrast, color, etc.

Directed subject responses for optical/visual symptoms were also obtained from a sponsor-developed, non-validated questionnaire administered by a third-party over the telephone in which bilaterally implanted subjects were asked to rate their degree of “difficulty” for specific visual disturbances. Note that directed questioning is designed to elicit responses whether or not these would be deemed by the subject significant enough to voluntarily discuss with the investigator and study staff (non-directed response), thus directed responses are likely to have higher response rates than non-directed rates. Nonetheless, when specifically asked, statistically significant differences (**p<0.0001**) were found between the two

lens groups with more difficulty experienced with night vision, glare/flare and halos for multifocal subjects compared to monofocal subjects (**Table 35**).

TABLE 35
Degree of Difficulty Experienced with Visual Symptoms without Glasses As Reported by Subjects to a Prompted Choice Questionnaire at 1 Year

Question	TECNIS ZM900 N =290	Monofocal Control N =115
Night Vision		
No Difficulty (1,2)	60.2%	77.4%
Moderate Difficulty (3, 4, 5)	32.9%	20.9%
Severe Difficulty (6, 7)	6.9%	1.7%
Glare/Flare		
No Difficulty (1,2)	48.8%	72.2%
Moderate Difficulty (3, 4, 5)	34.6%	24.3%
Severe Difficulty (6, 7)	16.6%	3.5%
Halos		
No Difficulty (1, 2)	45.0%	80.0%
Moderate Difficulty (3, 4, 5)	36.7%	15.7%
Severe Difficulty (6, 7)	18.3%	4.3%

Note: Includes any findings reported with a statistically significant (**p<0.0001**) difference in distribution between lens groups.

CLINICAL STUDY RESULTS: SENSAR® 1-PIECE LENS, MODEL AAB00:

The SENSAR® acrylic 1-piece lens, Model AAB00 was clinically studied in a US multicenter, unilateral, open-label, non-comparative clinical trial between November 2005 and June 2007. The purpose of the study was to evaluate the safety and effectiveness of lens Model AAB00 in subjects undergoing cataract removal and intraocular lens implantation. The 1-year results demonstrated that the SENSAR 1-Piece IOL, Model AAB00, is safe and effective for the visual correction of aphakia.

Study Population

A total of 123 subjects were enrolled and implanted with the SENSAR 1-Piece IOL, Model AAB00. In the study population, 56.9% of subjects were female and 43.1% were male; 93.5% were Caucasian, 4.1% were Black and 2.4% were Asian.

Best-case best corrected distance visual acuity

The best corrected distance visual acuity results for the “best case” subjects at 1 year postoperatively are provided in **Table 36**. In addition the results compared to the FDA Grid values (historical control) are presented in **Table 37**.

TABLE 36
Best Corrected Distance Visual Acuity (Snellen Equivalent) at 1 Year
Best Case Subjects[a] (N = 110)

Age Group	N	20/20 or Better		20/25 to 20/40		20/50 to 20/100		20/125 or Worse	
		n	%	N	%	n	%	n	%
< 60	11	11	100.0	0	0.0	0	0.0	0	0.0
60-69	35	29	82.9	6	17.1	0	0.0	0	0.0
70-79	46	39	84.8	7	15.2	0	0.0	0	0.0
≥ 80	18	14	77.8	4	22.2	0	0.0	0	0.0
TOTAL[b]	**110**	**93**	**84.5**	**17**	**15.5**	**0**	**0.0**	**0**	**0.0**

[a] Excludes subjects with macular degeneration at any time during the study.
[b] Includes three subjects who experienced a Nd:YAG posterior capsulotomy.

TABLE 37
Best Corrected Distance Visual Acuity (Snellen Equivalent) at 1 Year
Best Case Subjects[a] (N = 110) vs. FDA Grid

Age Group	TOTAL		VISUAL ACUITY 20/40 OR BETTER		FDA GRID
	N	%	N	%	%
< 60	11	10.0	11	100.0	98.5
60 – 69	35	31.8	35	100.0	96.5
70 – 79	46	41.8	46	100.0	97.5
> 80	18	16.4	18	100.0	94.8
TOTAL[b]	**110**	**100.0**	**110**	**100.0**	**96.7**

[a] Excludes subjects with macular degeneration at any time during the study.
[b] Includes three subjects who experienced a Nd:YAG posterior capsulotomy.

Adverse Events

The incidence of adverse events experienced during the clinical trial for Model AAB00 is similar to or less than those of the historic control population (FDA Grid for Posterior Chamber IOLs) as shown in **Table 38**.

TABLE 38
Adverse Events Model AAB00
All Subjects (N = 123)

ADVERSE EVENTS	Cumulative		Persistent at 1 Year		FDA Grid	
	N	%	N	%	Cumulative %	Per %
Persistent Corneal Edema	-	-	0	0.0	-	0.3
Cystoid Macular Edema (CME)	4	3.3[a]	1	0.9[b]	3.0	0.5
Endophthalmitis	0	0.0	-	-	0.1	-
Hyphema	0	0.0	-	-	2.2	-
Hypopyon	0	0.0	-	-	0.3	-
Persistent Iritis	-	-	0	0.0	-	0.3
Secondary Surgical Intervention – Pars Plana Vitrectomy with Membrane Peel	1	0.8	-	-	0.8	-
Lens Dislocation	0	0.0	-	-	0.1	-
Pupillary Block	0	0.0	-	-	0.1	-
Retinal Detachment	0	0.0	-	-	0.3	-
Persistent Raised IOP Requiring Treatment	-	-	0	0.0	-	0.4
Lens Exchange –Torn Haptic related to improper loading technique	1	0.8	-	-	-	-

[a] This rate is not statistically significantly higher than the FDA Grid cumulative rate for posterior chamber IOLs of 3.0% (p=0.5060).
[b] This rate is not statistically significantly higher than the FDA Grid rate for posterior chamber IOLs of 0.5% (p=0.4437).

DETAILED DEVICE DESCRIPTION:

The TECNIS® Sym*f*ony Extended Range of Vision IOLs (lens model ZXR00 and toric lens models ZXT150, ZXT225, ZXT300, and ZXT375) are one-piece, foldable, posterior chamber lenses with an overall diameter of 13.0 mm and an optic diameter of 6.0 mm. They incorporate a proprietary aspheric optic or toric aspheric optic design on the anterior optic surface that compensates for corneal spherical aberration, and a diffractive design on the posterior surface designed to compensate for the eye's chromatic aberrations and to extend the range of vision, improve intermediate and near visual acuities, and reduce how often patients wear glasses or contact lenses, compared to a standard monofocal IOL that does not have these design features. In addition, the TECNIS® Sym*f*ony Toric IOLs compensate for corneal astigmatism while achieving the ANSI Standard for Toric IOLs, Z80.30 rotational stability requirement (>90% of eyes having ≤5° axis change between consecutive visits approximately three months apart).

Lens Optic

1. Material: Optically clear, soft foldable hydrophobic acrylic with a covalently bound UV absorber.
2. Power: +5.0 to +34.0 diopter powers in 0.5-diopter increments.
3. Cylinder power, toric lens models ZXT150, ZXT225, ZXT300, and ZXT375: 1.50 diopters, 2.25 diopters, 3.00 diopters, and 3.75 diopters (as measured at the IOL plane).

Conversion table for cylinder powers:

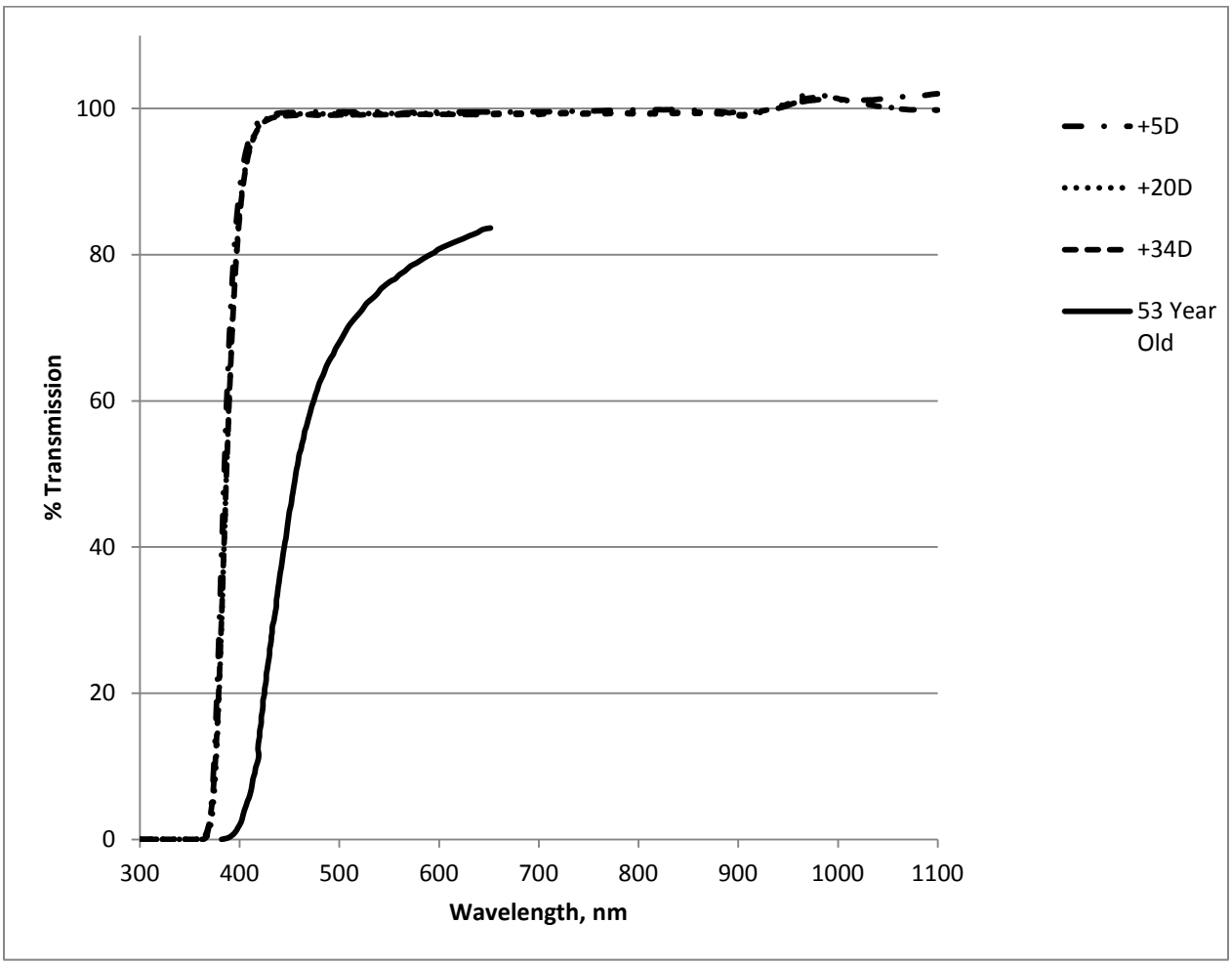
IOL Model	Cylinder Power (D)		Correction ranges based on combined corneal astigmatism (preop Kcyl + SIA)
	IOL Plane (Labeled)	Corneal Plane*	
ZXT150	1.50	1.03	0.75** – 1.50 D
ZXT225	2.25	1.54	1.50 – 2.00 D
ZXT300	3.00	2.06	2.00 – 2.50 D
ZXT375	3.75	2.57	2.50 – 3.00 D

*The corresponding cylinder values at the corneal plane have been calculated based on the average pseudophakic eye.

**Note that the effectiveness of the Model Series ZXT lens in eyes with preoperative corneal astigmatism <1.0 D has not been demonstrated.

4. Optic Center Thickness: 0.7 mm (+20.0D)
5. Optic Edge Design: PROTEC 360 square posterior edge
6. Index of Refraction: 1.47 at 35°C
7. Light Transmittance: UV cut-off at 10% T for a +5.0 diopter lens (thinnest) and a +34.0 diopter lens (thickest) are shown in **Figure 6**.

FIGURE 6
Light Transmittance



Legend:
Spectral transmittance curve of a typical 5-diopter IOL (thinnest), UV cut-off at 10%T is 374 nm
Spectral transmittance curve of a typical 20-diopter IOL, UV cut-off at 10%T is 376 nm
Spectral transmittance curve of a typical 34-diopter IOL (thickest), UV cut-off at 10%T is 375 nm
Spectral transmittance curve of a 53-year-old phakic eye, from *Boettner, E.A., and Wolter J.R. Transmission of the Ocular Media. Investigative Ophthalmology. 1962;1:776-783.*
Note: The cut-off wavelengths and the spectral transmittance curves represent the range of the transmittance of the IOLs (5-34D) made with this material. Spectral transmission measurements were taken in water at room temperature (ref: TR7475).

Haptics

1. Material: Soft foldable acrylic with a covalently bound UV absorber.
2. One-piece lens.
3. Configuration: TRI-FIX design Modified C, integral with optic.
4. Haptic thickness: 0.46 mm.

LENS POWER CALCULATIONS:

Accurate keratometry and biometry are 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. Emmetropia should be targeted. Accuracy of IOL power calculation is particularly important with TECNIS® Sym*f*ony IOLs, as reduced spectacle wear is a goal of TECNIS® Sym*f*ony IOL implantation. The A-constants listed on the outer label are presented as a guideline and serve as a starting point for implant power calculations. The physician should determine preoperatively the spherical equivalent and cylindrical power of the lens to be implanted.

For TECNIS® Sym*f*ony Toric lens models: Use of the AMO-provided toric calculator tool is recommended for determining the appropriate TECNIS® Sym*f*ony Toric IOL model, optimal axis of IOL placement and cylinder power. The TECNIS® Sym*f*ony Toric IOL is labeled with the IOL spherical equivalent power.

Physicians requiring additional information on lens power calculations may contact the local AMO representative. Lens power calculation methods are described in the following references:

- Haigis W. "The Haigis formula". In: Shammas HJ, ed, Intraocular Lens Power Calculations. Thorofare, NJ, Slack, 2004; 41-57.

- Hoffer K.J., "The Hoffer Q formula: a comparison of theoretic and regression formulas", J Cataract Refract Surg, 19, 700-712 (1993). Erratum in: *J Cataract Refract Surg* 1994;20:677. Erratum in: *J Cataract Refract Surg* 2007;33:2-3

- Holladay, J.T., Musgrove, K.H., Prager, T.C., Lewis, J.W., Chandler, T.Y., and Ruiz, R.S. "A three-part system for refining intraocular lens power calculations." *J Cataract Refractive Surg*. 1988; 14:17-24.

- Holladay, J.T. "Standardizing constants for ultrasonic biometry, keratometry and intraocular lens power calculations." *J Cataract Refractive Surg*. 1997; 23:1356-1370.

- Retzlaff J.A, Sanders D.R. and Kraff M.C., "Development of the SRK/T intraocular lens implant power calculation formula", *J Cataract Refract Surg*. 16, 333-340 (1990). Erratum in: *J Cataract Refract Surg*. 1990;16:528.

- Olsen T. "The Olsen formula". In: Shammas HJ, ed, Intraocular Lens Power Calculations. Thorofare, NJ, Slack, 2004; 27–40

- Norrby NES. Unfortunate discrepancies. Letter to the editor and reply by Holladay, J.T. *J Cataract Refractive Surg*. 1998; 24:433-434.

- Canovas C., Artal P. "Customized eye models for determining optimized intraocular lenses power". *Biomed. Opt. Express* 2011;2:1649-1662

SELECTION AND PLACEMENT: TECNIS® SYM*F*ONY TORIC IOL (MODELS ZXT150, ZXT225, ZXT300, AND ZXT375):

The astigmatism to be corrected should be determined from keratometry and biometry data rather than refractive data because 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 postoperative corneal astigmatism. In order to facilitate IOL selection and axis placement, AMO provides a web-based proprietary tool, the TECNIS Toric Calculator (www.TecnisToricCalc.com) for the surgeon. The corneal astigmatism to be corrected at the time of surgery is calculated by the TECNIS Toric Calculator using vector summation of the preoperative corneal astigmatism and the expected surgically induced astigmatism. The cylinder IOL power calculation is based on the Holladay 1 formula (Holladay JT, Musgrove KH, Prager TC, Lewis JW, Chandler TY, and Ruiz RS. "A three-part system for refining intraocular lens power calculations." *J Cataract Refract Surg*, 1988; 14:17-24). This yields an individual calculation instead of a fixed ratio based on average ocular parameters.

For optimal toric IOL calculations, it is recommended that surgeons customize their surgically induced corneal astigmatism values based upon individual surgical technique and past results. An example of this calculation can be found within the following reference (Holladay JT, Cravy TV, Koch DD. "Calculating the surgically induced refractive change following ocular surgery." *J Cataract Refract Surg*, 1992; 18:429-43).

Preoperative keratometry and biometry data, incision location, spherical equivalent IOL power, and the surgeon's estimated surgically induced corneal astigmatism are used as inputs for the TECNIS Toric Calculator. These inputs are used to determine the axis of placement in the eye and the predicted residual refractive astigmatism for up to three different TECNIS® Sym*f*ony toric lens models. In eyes with low levels of corneal astigmatism, the predicted residual refractive astigmatism for implantation of a TECNIS® 1-Piece lens, Model ZCB00, will be displayed for evaluation by the surgeon to determine the clinically meaningful benefit of implanting a TECNIS® Sym*f*ony Toric IOL.

For optimal results, the surgeon must ensure the correct placement and orientation of the lens within the capsular bag. The anterior surface of the IOL is marked with indentations (four at opposite sides) at the haptic/optic junction that identify the flat meridian of the toric TECNIS® Sym*f*ony optic. These "indentations," or axis marks, form an imaginary line representing the meridian with least power (note: IOL cylinder steep meridian is 90° away). The TECNIS® Sym*f*ony 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 indicated for ophthalmic use. 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 TECNIS Toric Calculator, www.TecnisToricCalc.com, to determine the optimal axis of placement.

After the lens is inserted, precisely align the axis marking indentations on the TECNIS® Sym*f*ony Toric IOL with the marked axis of lens placement. Carefully remove all viscoelastic from the capsular bag. 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 TECNIS®

Sym*f*ony Toric IOL at the intended axis following viscoelastic removal and/or inflation of the capsular bag at the end of the surgical case. Residual viscoelastic and/or over-inflation of the bag may allow the lens to rotate, causing misalignment of the TECNIS® Sym*f*ony 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 TECNIS® Sym*f*ony Toric IOL axis during surgery, an unanticipated surgically induced change in the cornea, or physical rotation of the TECNIS® Sym*f*ony 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.

DIRECTIONS FOR USE:

1. Prior to implanting, examine the lens package for IOL type, power, proper configuration and expiration date.

2. Open the peel pouches and remove the lens in a sterile environment. Verify the dioptric power of the lens. For the TECNIS® Sym*f*ony Toric IOL, verify the cylinder power of the lens as well.

3. Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens' optical surfaces for other defects.

4. If desired, the lens may be soaked or rinsed in sterile balanced salt solution until ready for implantation.

5. Handle the lens by the haptic portion. Do not grasp the optical area with forceps.

6. Transfer the lens, using a sterile technique, to an appropriate loading device.

7. The physician should consider the following points:

    - The surgeon should target emmetropia, as this lens is designed for optimum visual performance when emmetropia is achieved.

    - Care should be taken to achieve centration of the intraocular lens.

8. AMO recommends using The UNFOLDER Platinum 1 Series implantation system with the 1MTEC30 cartridge to insert the TECNIS® Sym*f*ony lenses. Alternate validated insertion systems that can be used to insert the TECNIS Sym*f*ony IOLs include the UNFOLDER® EMERALD-AR Series Implantation System (with the 1CART30 Cartridge), and the ONE SERIES Ultra Insertion System (the 1VIPR30 Cartridge and the DK7786 or DK7791 inserters). Only insertion instruments that have been validated and approved for use with this lens should be used. Please refer to the directions for use with the insertion instrument or system for additional information.

9. Carefully remove all viscoelastic from the capsular bag and if implanting a TECNIS® Sym*f*ony Toric IOL, align the lens with the intended axis of placement, following the recommendations provided in the 'Selection and Placement' section for the TECNIS Symfony Toric IOLs.

Factors to consider in deciding whether to implant a TECNIS® Sym*f*ony Toric IOL: effectiveness of implanting a TECNIS® Sym*f*ony Toric lens in reducing postoperative astigmatism is affected by many factors, including the following:

- The degree of mismatch between the postoperative magnitude of corneal astigmatism and effective IOL power in the corneal plane.
- Misalignment between the intended axial position and final IOL axial orientation.
- Error in prediction of the postoperative corneal cylinder axis and power. Error in prediction of cylinder axis is greatest for lower levels of preoperative corneal astigmatism.
- Manufacturing variation in power and axis markings can influence intended correction. Based on the tolerances set in the ANSI standard Z80.30, cylinder power variation may cause the intended correction at the corneal plane to vary by up to ±0.34 D, and cylinder axis tolerance may reduce intended correction by up to 16%.

Caution: Do not use the lens if the package has been damaged. The sterility of the lens may have been compromised.

PATIENT REGISTRATION SECTION (U.S, Only)

Each patient who receives a TECNIS Sym*f*ony IOL must be registered with AMO at the time of lens implantation. Registration is accomplished by completing the Implant Registration Card that is enclosed in the lens package and mailing it to AMO. Patient registration is essential for AMO's long-term patient follow-up program and will assist AMO in responding to adverse event reports and/or potentially sight-threatening complications.

PATIENT CARD

An implant identification card is included in the package and should be supplied to the patient. The patient should be instructed to keep the card as a permanent record of the implant and to show the card to any eye care practitioner that the patient consults in the future.

REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as lens-related and that were not previously expected in nature, severity, or rate of occurrence must be reported to AMO. This information is being requested from all surgeons in order to document potential long-term effects of IOL implantation, especially in younger patients.

Physicians are required to report these events to aid in identifying emerging or potential problems with posterior chamber lenses. These problems may be related to a specific lot of lenses or may be indicative of long-term problems associated with these lenses or with IOLs in general.

HOW SUPPLIED

The TECNIS® Sym*f*ony lenses are supplied sterile in a lens case within a double aseptic transfer peel pouch. The double aseptic transfer peel pouch is sterilized with ethylene oxide and should be opened only under sterile conditions. The pouch and product labels are enclosed in a shelf pack. The external surfaces of the outer pouch are not sterile.

EXPIRATION DATE

The expiration date on the lens package is the sterility expiration date. This lens should not be implanted after the indicated sterility expiration date.

RETURN/EXCHANGE POLICY

Contact your local AMO representative for the return/exchange policy. Return the lens with proper identification and the reason for the return. Label the return as a biohazard. Do not attempt to resterilize the lens.

PATIENT INFORMATION

Each patient should receive information regarding intraocular lenses prior to the decision to implant an intraocular lens.

Symbol/Explanation

SYMBOL	EXPLANATION
STERILE EO	Sterilized using Ethylene Oxide
	Do Not Reuse
	Use By (YYYY-MM-DD: Year-Month-Day)
	Consult Instructions for Use
	Manufacturer
	Do Not Resterilize
	Upper Limit of Temperature
	Keep Away from Sunlight
	Date of Manufacture (YYYY-MM-DD: Year-Month-Day)
	Do Not Use if Package Is Damaged
REF	Catalogue Number

PRODUCT OF THE NETHERLANDS
AMO Groningen BV, 9728 NX Groningen, Netherlands

 Abbott Medical Optics Inc., 1700 E. St. Andrew Pl., Santa Ana, CA 92705 USA, Toll-free (800) 366-6554