TECNIS Synergy™ IOL with TECNIS Simplicity™ Delivery System
TECNIS Synergy™ Toric II IOL with TECNIS Simplicity™ Delivery System

Rx Only

DEVICE DESCRIPTION:

The TECNIS Synergy™ IOL with the TECNIS Simplicity™ Delivery System in Model DFR00V, and the TECNIS Synergy™ Toric II IOL with the TECNIS Simplicity™ Delivery System in Models DFW150, DFW225, DFW300 and DFW375 are ultraviolet (UV) and violet light-filtering posterior chamber IOLs that are to be positioned in the lens capsule to replace the optical function of the natural crystalline lens. Accommodation will not be restored. In addition, the toric IOLs compensate for corneal astigmatism.

The TECNIS Synergy™ IOLs mitigate the effects of presbyopia by providing far vision comparable to an aspheric monofocal IOL, and continuous 20/32 or better visual acuity through at least -3.0 D of defocus, which corresponds to distances ranging from approximately 33 cm to infinity. Compared to an aspheric monofocal IOL, the lens provides significantly improved near vision, including in low-light conditions. The TECNIS Synergy™ IOLs demonstrated pupil-independent lens performance among the pupil sizes tested (>2.5 mm). In addition, the toric IOLs achieved the ANSI Standard for Toric IOLs, Z80.30, rotational stability requirement (>90% of eyes having ≤5° axis change between consecutive visits).

The lens has an overall diameter of 13.0 mm and an optic diameter of 6.0 mm. The lens consists of a soft acrylic material with UVAM (a supplemental UV light-absorbing material) and proprietary violet light-filtering chromophore, which reduces transmittance of violet light wavelengths. The biconvex optic incorporates a proprietary wavefront-designed aspheric or toric-aspheric anterior surface to reduce corneal spherical aberration to near-zero. The posterior edge of the anterior optic is squared to provide a 360-degree barrier and is frosted to reduce potential edge glare effects. In addition, the haptics of the TECNIS Synergy™

Toric II IOL Model Series ZFW have a squared and frosted design. The posterior optic of the lens has a proprietary diffractive surface derived from a combination of extended depth of focus and multifocal technologies and is designed to correct chromatic aberration and to provide a range of vision from distance to intermediate to near.. The anteriorly located cylinder axis marks in the toric-aspheric optic denote the meridian with the lowest power and are to be aligned with the steep corneal meridian.

The TECNIS Simplicity™ Delivery System is designed to provide a sterile, controlled and touch-free method of delivering the lens into the eye. The lens is preloaded and preassembled in the delivery system. This reduces the number of steps required to prepare the IOL for insertion into the eye, when compared to a non-preloaded device. The lens with the delivery system is available in the full diopter range (5.0 D to 34.0 D) and is compatible with micro-incision surgical techniques. Sodium hyaluronate (HA) used in the cartridge coating is produced by a microbiological fermentation method.

INDICATIONS FOR USE:

TECNIS Synergy IOL with TECNIS Simplicity Delivery System, Model DFR00V

The TECNIS Simplicity™ Delivery System is used to fold and assist in inserting the TECNIS Synergy™ IOL which 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. Compared to an aspheric monofocal lens, the TECNIS Synergy IOL mitigates the effects of presbyopia by

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providing improved visual acuity at intermediate and near distances to reduce eyeglass wear, while maintaining comparable distance visual acuity. The lens is intended for capsular bag placement only.

TECNIS Synergy Toric II IOL with TECNIS Simplicity Delivery System, Models DFW150, DFW225, DFW300, DFW375

The TECNIS Simplicity™ Delivery System is used to fold and assist in inserting the TECNIS Synergy™ Toric II IOLs that are indicated for primary implantation for the visual correction of aphakia and for reduction of 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. Compared to an aspheric monofocal lens, the TECNIS Synergy Toric II IOLs mitigate the effects of presbyopia by providing improved visual acuity at intermediate and near distances to reduce eyeglass wear, while maintaining comparable distance visual acuity. The lens is intended for capsular bag placement only.

CONTRAINDICATIONS

There are no known contraindications.

PRECAUTIONS

1. This is a single use device. Do not resterilize the lens or the delivery system. Most sterilizers are not equipped to sterilize the soft acrylic material and the preloaded inserter material without producing undesirable side effects.
2. Do not store the device in direct sunlight or at a temperature under 5°C (41°F) or over 35°C (95°F).
3. Do not autoclave the delivery system.
4. Do not advance the lens unless ready for lens implantation.
5. The contents are sterile unless the package is opened or damaged.
6. The recommended temperature for implanting the lens is at least 17°C (63°F).
7. The use of balanced salt solution (BSS) or viscoelastics is required when using the delivery system. For optimal performance when using OVD, use the HEALON® family of viscoelastics. The use of BSS with additives has not been studied for this product.
8. Do not use if the delivery system has been dropped or if any part was inadvertently struck while outside the shipping box. The sterility of the delivery system and/or the lens may have been compromised.
9. When performing refraction in patients implanted with the lens, 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 strongly recommended.
10. The ability to perform some eye treatments (e.g., retinal photocoagulation) may be affected by the IOL optical design.
11. 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.
12. The surgeon should target emmetropia as this lens is designed for optimum visual performance when emmetropia is achieved.
13. Care should be taken to achieve centration of the intraocular lens in the capsular bag.
14. Prior to surgery, the surgeon must inform prospective patients of the possible risks and benefits associated with the use of the device and provide them a copy of the patient information brochure.
15. Children under the age of 2 years are not suitable candidates for intraocular lenses.
16. The lens should not be placed in the ciliary sulcus.
17. Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case. Residual viscoelastic and/or over-inflation of the capsular bag may allow the lens to rotate, causing misalignment of the toric lens with the intended axis of placement.

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18. The TECNIS® Toric IOL Calculator includes a feature that accounts for posterior corneal astigmatism (PCA). The PCA is based on an algorithm that combines published literature (Koch, et al., 2012) and a retrospective analysis of data from a TECNIS® Toric multi-center clinical study. The PCA algorithm for the selection of appropriate cylinder power and axis of implantation was not assessed in the prospective TECNIS® Toric IOL U.S. IDE study and may yield results different from those in the TECNIS Synergy™ Toric II IOL labeling. Please refer to the TECNIS® Toric IOL Calculator user manual for more information.
19. The use of methods other than the TECNIS® Toric IOL Calculator to select cylinder power and appropriate axis of implantation were not assessed in the 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 IOL Calculator (www.TecnisToricCalc.com) are recommended to achieve optimal visual outcomes for the toric lens.
20. All preoperative surgical parameters are important when choosing a toric lens for implantation, including preoperative keratometric cylinder (magnitude and axis), incision location, the 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. The effectiveness of TECNIS Synergy™ Toric II IOLs in reducing postoperative residual astigmatism in patients with preoperative corneal astigmatism <1.0 diopter has not been demonstrated.
21. Patients with a predicted postoperative astigmatism greater than 1.0 D may not be suitable candidates for implantation with the TECNIS Synergy and TECNIS Synergy Toric IOLs, as they may not obtain the benefits of reduced spectacle wear or improved intermediate and near vision seen in patients with lower astigmatism.
22. All corneal incisions were placed temporally in the 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 for the TECNIS® Toric IOL. Note that the TECNIS® Toric IOL Calculator incorporates the surgeon's estimated SIA and incision location when providing IOL options.
23. Do not reuse.
24. The safety and effectiveness of the TECNIS Synergy IOL have not been substantiated in patients under the age of 22 or those with preexisting ocular conditions and intraoperative complications, including those specified in the Warnings and Precautions, such as pupil abnormalities, prior corneal refractive or intraocular surgery, acute or chronic ophthalmic diseases or conditions (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.

<u>Before Surgery</u>

- 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

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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

Potential complications generally associated with cataract surgery include, but are not limited to: endophthalmitis/intraocular infection, hypopyon, hyphema, IOL dislocation, persistent cystoid macular edema, pupillary block, retinal detachment/tear, persistent corneal stromal edema, persistent uveitis, persistent raised intraocular pressure (IOP) requiring treatment (e.g., AC tap), retained lens material, or toxic anterior segment syndrome, or any other adverse event that leads to permanent visual impairment or requires surgical or medical intervention to prevent permanent visual impairment. Adverse events that may be associated with use of the device include: IOL dislocation, tilt or decentration, visual symptoms requiring lens removal, residual refractive error, secondary surgical intervention (including IOL repositioning or removal).

25. Do not leave the lens in a folded position more than 10 minutes.
26. When the delivery system is used improperly, the lens may not be delivered properly, (i.e., haptics may be broken). Please refer to the specific instructions for use provided.

WARNINGS

1. Intraocular lenses may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition or may pose an unreasonable risk to the eyesight of patients with:
    a. Recurrent severe anterior or posterior segment inflammation of unknown etiology
    b. Posterior segment diseases of which monitoring or treatment ability may be limited by an intraocular lens
    c. Surgical difficulties at the time of cataract extraction and/or intraocular lens implantation that might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss)
    d. Compromised posterior capsule or zonules due to previous trauma or developmental defect in which appropriate support of the IOL is not possible
    e. Risk of damage to the endothelium during implantation
    f. Suspected microbial infection
    g. Congenital bilateral cataracts
    h. Previous history of, or a predisposition to, retinal detachment
    i. Potentially good vision in only one eye
    j. Medically uncontrollable glaucoma
    k. Corneal endothelial dystrophy
    l. Proliferative diabetic retinopathy.
2. Patients should have well-defined visual needs and be informed of possible visual effects (such as a perception of halo, starbursts or glare around lights), which may be expected in nighttime or poor visibility conditions. Patients may perceive these visual effects as bothersome, which, on rare occasions, may be significant enough for the patient to request removal of the IOL.

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3. A reduction in contrast sensitivity compared to an aspheric monofocal IOL may be experienced by some patients under certain conditions. The physician should carefully weigh the potential risks and benefits for each patient, with special consideration of potential visual problems before implanting the lens in patients including those with macular disease, amblyopia, corneal irregularities, or other ocular disease that may cause present or future reduction in acuity or contrast sensitivity, and should fully inform the patient of the potential for reduced contrast sensitivity and to exercise caution when driving at night or in poor visibility conditions after implantation.
4. Patients with a predicted postoperative residual astigmatism greater than 1.0 diopter, with or without a toric lens, may not fully benefit in terms of reducing spectacle wear.
5. Rotation of the toric lens from its intended axis can reduce its 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.
6. Do not attempt to disassemble, modify or alter the delivery system or any of its components, as this can significantly affect the function and/or structural integrity of the design.
7. Do not use if the cartridge of the delivery system is cracked or split prior to implantation.
8. Do not implant the lens if the rod tip does not advance the lens or if it is jammed in the delivery system.
9. During initial lens advancement (Figure 11), quick advancement of the plunger is needed. Do not stop or reverse while advancing the plunger. Doing so may result in improper folding of the lens.
10. After initial lens advancement (Figure 11) and the half turn rotation step (Figure 12), do not move the plunger forward until ready for lens implantation. Doing so may result in the lens being stuck in the cartridge.
11. The lens and delivery system should be discarded if the lens has been folded within the cartridge for more than 10 minutes. Not doing so may result in the lens being stuck in the cartridge.
12. Johnson & Johnson Surgical Vision, Inc. single-use medical devices are labeled with instructions for use and handling to minimize exposure to conditions which may compromise the product, patient, or the user. When used according to the directions for use, the delivery system minimizes the risk of infection and/or inflammation associated with contamination.
13. The reuse/resterilization/reprocessing of Johnson & Johnson Surgical Vision, Inc. single-use devices may result in physical damage to the medical device, failure of the medical device to perform as intended, and patient illness or injury due to infection, inflammation, and/or illness due to product contamination, transmission of infection, and lack of product sterility.

TECHNICAL SPECIFICATIONS:

Lens Optic

- Material: Optically clear, soft foldable hydrophobic acrylic with UVAM and UV and violet light-filtering chromophores*.
- Power: +5.0 to +34.0 diopter powers in 0.5-diopter increments.
- Cylinder Power, toric models DFW150, DFW225, DFW300 and DFW375: 1.50 diopters, 2.25 diopters, 3.00 diopters, and 3.75 diopters (as measured at the IOL plane).
- Optic Center Thickness: 0.7 mm (+20.0D)
- Optic Edge Design: PROTEC 360 square posterior edge
- Index of Refraction: 1.47 at 35°C
- Light Transmittance: UV cut-off at 10% T for a spherical equivalent (SE) +5.0 diopter lens (thinnest) and a SE +34.0 diopter lens (thickest) are shown in **Figure 1.**

*The TECNIS Synergy™ IOLs may appear slightly blue on the anterior surface under slit lamp examination, which is not detectable by patients. The violet light filter has not been shown to provide retinal phototoxicity protection.

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Conversion table for cylinder powers:

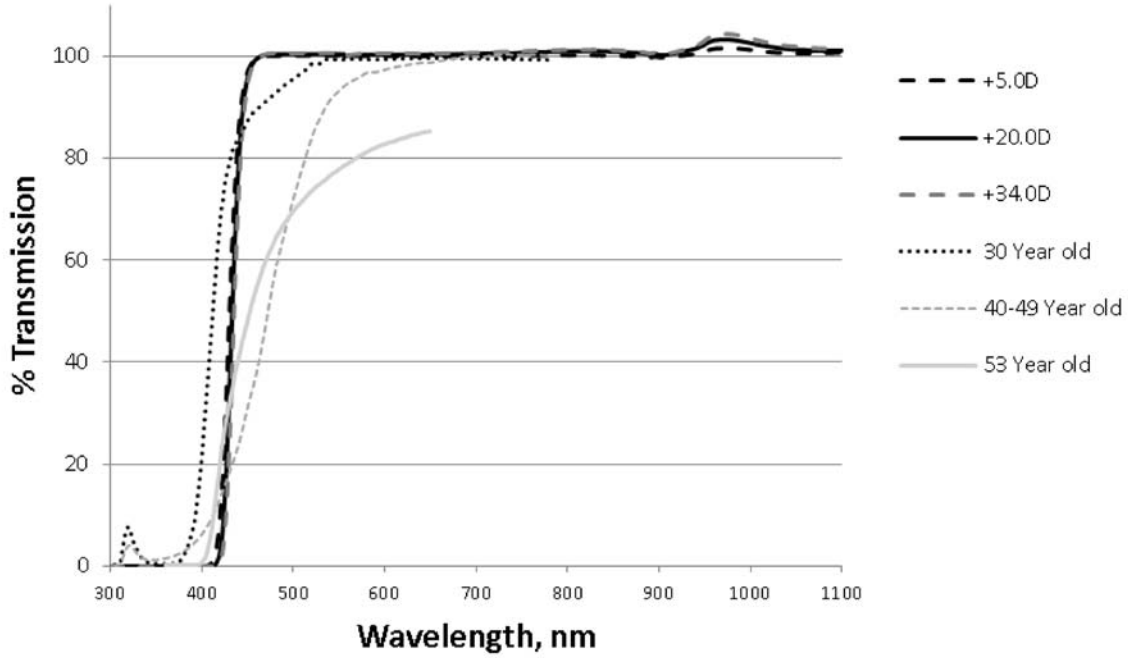
Model	Cylinder Power (D)	
	IOL Plane (Labeled)	Corneal Plane*
DFW150	1.50	1.03
DFW225	2.25	1.54
DFW300	3.00	2.06
DFW375	3.75	2.57

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

Haptics

1. Material: Soft foldable acrylic with UVAM and UV and violet light-filtering chromophores.
2. One-piece lens.
3. Configuration: TRI-FIX design Modified C, integral with optic.
4. Haptic thickness: 0.46 mm.

Figure 1



Legend:

Spectral transmittance curve of a typical 5-diopter IOL (thinnest). UV(420): UV cut-off at 10%T is 420 nm.
Spectral transmittance curve of a typical 20-diopter IOL. UV(424): UV cut-off at 10%T is 424 nm.
Spectral transmittance curve of a typical 34-diopter IOL (thickest). UV(426): UV cut-off at 10%T is 426 nm.
Spectral transmittance curve of crystalline lenses: 30 year old and 40-49 year old from Artigas, J.M., Felipe, A., Navea, A., Fandino, A., & Artigas, C. Spectral transmission of the human crystalline lens in adult and elderly persons: color and total transmission of visible light. Invest Ophthalmol Vis Sci (2012);53(7):4076-4084. 53 year old from Boettner, E.A., and Wolter J.R. Transmission of the Ocular Media. Investigative Ophthalmology. 1962;1:776-783.

CLINICAL STUDY RESULTS FOR THE TECNIS SYNERGY™ IOL, MODEL ZFR00V

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 Synergy™ IOL, Model ZFR00V, compared to the aspheric monofocal control IOL, TECNIS® 1-Piece IOL, Model ZCB00. The primary effectiveness endpoint was the mean monocular, photopic, distance-corrected near visual acuity (VA) at 40 cm. The five secondary effectiveness endpoints were mean monocular, photopic, distance-corrected intermediate VA at 66 cm, distance-corrected near VA at 33 cm, best-corrected distance (far) VA, distance-corrected defocus curve, and spectacle wear at distance (far),

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intermediate, near and overall, reported via questionnaire. The safety endpoints were the rates of secondary surgical interventions related to optical properties of the lens, adverse events vs. ISO Safety Performance and Effectiveness (SPE) rates, rate of monocular best-corrected distance VA of 20/40 or better vs. ISO SPE rates as well as monocular and binocular best-corrected distance contrast sensitivity.

The clinical study results achieved at 6-months postoperative demonstrate that the TECNIS Synergy™ IOL was safe and effective for the visual correction of aphakia and provided improved distance-corrected intermediate and near vision while demonstrating distance vision to be non-inferior to that of the aspheric monofocal control lens, an increased range of vision (distance to intermediate to near), decreased spectacle wear when compared to the monofocal control IOL, and low rates of adverse events.

NOTE: For this clinical summary and the associated data tables, "Synergy" or "TECNIS Synergy" refers to the TECNIS Synergy™ IOL, Model ZFR00V, and "control" or "TECNIS monofocal" refers to the TECNIS® Monofocal 1-Piece IOL, Model ZCB00. "N" denotes the total number of eyes/subjects who were present at a given visit, and "n" denotes the number of eyes/subjects with measurement data available.

Subject Population

Of the 272 subjects enrolled and implanted in the study, 135 were in the Synergy group (135 bilaterally implanted) and 137 were in the control group (137 bilaterally implanted). Subject demographics were similar between the Synergy and control groups. The mean age was 68.5 ±7.1 years for the Synergy group and 68.5 ±7.7 years for the control group. The majority of subjects in both lens groups were female (69.6% Synergy; 65.7% control), and most subject in both lens groups identified as White (84.4% of Synergy subjects and 84.7% of control). The remainder of subjects identified as African American (11.1% Synergy; 13.9% control), Asian (2.2% Synergy; 0.7% control), Native Hawaiian/Pacific Islander (0.7% Synergy only) and Other Race (1.5% Synergy; 0.7% control). There were no statistically significant differences in demographics between lens groups.

Distance (Far) Visual Acuity

Distance visual acuities were tested at 4.0 m under photopic (85 cd/m^2) lighting conditions. **Table 1** presents mean monocular and binocular distance visual acuities at 6 months for Synergy and control groups. Monocular BCDVA was comparable between the Synergy and control groups, with mean Snellen equivalents of 20/19 and 20/18, respectively. Additionally, the lower limit of the 95% confidence interval (CI) of the mean difference in BCDVA between IOL groups was -0.053 LogMAR (-0.1 LogMAR non-inferiority margin), demonstrating that the Synergy IOL is non-inferior to the control lens in providing best-corrected distance visual acuity.

TABLE 1
Mean Distance (Far) Visual Acuity at 6 Months

		Monocular					Binocular				
Distance Visual Acuity	**Lens Group**	**N**	**n**	**Mean LogMAR**	**Snellen Equiv.**	**Line Change vs. Control[a]**	**N**	**n**	**Mean LogMAR**	**Snellen Equiv.**	**Line Change vs. Control[a]**
Uncorrected	TECNIS Synergy	131	131	0.090	20/25	**-0.4 lines**	131	131	0.023	20/21	**-0.5 lines**
	TECNIS monofocal	131	130	0.052	20/23		131	130	-0.028	20/19	
Best Corrected	TECNIS Synergy	131	131	-0.014	20/19	**-0.3 lines[b]**	131	131	-0.056	20/18	**-0.3 lines**
	TECNIS monofocal	131	130	-0.045	20/18		131	130	-0.086	20/16	

[a] Line difference (control minus Synergy) is converted directly from LogMAR difference.

[b] Synergy met the secondary study endpoint for statistically non-inferiority to the control (Safety population).

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The distributions of monocular distance visual acuity for Synergy and control first eyes at 6 months are presented in **Tables 2A** and **2B**. The proportion of Synergy first eyes achieving monocular best-corrected distance visual acuity (BCDVA) of 20/40 or better (100.0%) was above the ISO Safety and Performance Endpoint (SPE) rates for BCDVA. The distributions of binocular distance visual acuity for Synergy and control subjects at 6 months are presented in **Tables 3A** and **3B**.

TABLE 2A
Distribution of Monocular Distance (Far) Visual Acuity at 6 Months

Monocular Snellen Visual Acuity	TECNIS Synergy				TECNIS monofocal			
	Uncorrected N=131		Best Corrected N=131		Uncorrected N=131		Best Corrected N=131	
	n	%	n	%	n	%	n	%
20/20^{-2} or better	50	38.2%	105	80.2%	72	55.4%	115	88.5%
20/25^{-2} or better	93	71.0%	127	96.9%	107	82.3%	126	96.9%
20/32^{-2} or better	115	87.8%	130	99.2%	121	93.1%	130	100.0%
20/40^{-2} or better	128	97.7%	131	100.0%	126	96.9%	130	100.0%
Worse than 20/40^{-2}	3	2.3%	0	0.0%	4	3.1%	0	0.0%
Total n	**131**		**131**		**130**		**130**	

%=(n/Total n) * 100

TABLE 2B
Distribution of Monocular Distance (Far) Visual Acuity at 6 Months

Monocular LogMAR Visual Acuity	TECNIS Synergy				TECNIS monofocal			
	Uncorrected N=131		Best Corrected N=131		Uncorrected N=131		Best Corrected N=131	
	n	%	n	%	n	%	n	%
0.00 LogMAR or better	33	25.2%	88	67.2%	55	42.3%	102	78.5%
0.10 LogMAR or better	76	58.0%	122	93.1%	92	70.8%	121	93.1%
0.20 LogMAR or better	106	80.9%	130	99.2%	116	89.2%	129	99.2%
0.30 LogMAR or better	126	96.2%	131	100.0%	124	95.4%	130	100.0%
Worse than 0.30 LogMAR	5	3.8%	0	0.0%	6	4.6%	0	0.0%
Total n	**131**		**131**		**130**		**130**	

%=(n/Total n) * 100

TABLE 3A
Distribution of Binocular Distance (Far) Visual Acuity at 6 Months

Binocular Snellen Visual Acuity	TECNIS Synergy				TECNIS monofocal			
	Uncorrected N=131		Best Corrected N=131		Uncorrected N=131		Best Corrected N=131	
	n	%	n	%	n	%	n	%
20/20^{-2} or better	88	67.2%	118	90.1%	105	80.8%	119	91.5%
20/25^{-2} or better	113	86.3%	130	99.2%	123	94.6%	129	99.2%
20/32^{-2} or better	127	96.9%	130	99.2%	127	97.7%	130	100.0%
20/40^{-2} or better	129	98.5%	131	100.0%	129	99.2%	130	100.0%
Worse than 20/40^{-2}	2	1.5%	0	0.0%	1	0.8%	0	0.0%
Total n	**131**		**131**		**130**		**130**	

%=(n/Total n) * 100

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TABLE 3B
Distribution of Binocular Distance (Far) Visual Acuity at 6 Months

Binocular LogMAR Visual Acuity	TECNIS Synergy				TECNIS monofocal			
	Uncorrected N=131		Best Corrected N=131		Uncorrected N=131		Best Corrected N=131	
	n	%	n	%	n	%	n	%
0.00 LogMAR or better	67	51.1%	108	82.4%	88	67.7%	116	89.2%
0.10 LogMAR or better	105	80.2%	130	99.2%	118	90.8%	128	98.5%
0.20 LogMAR or better	123	93.9%	130	99.2%	126	96.9%	130	100.0%
0.30 LogMAR or better	129	98.5%	131	100.0%	128	98.5%	130	100.0%
Worse than 0.30 LogMAR	2	1.5%	0	0.0%	2	1.5%	0	0.0%
Total n	**131**		**131**		**130**		**130**	

%=(n/Total n) * 100

Intermediate Visual Acuity

Intermediate visual acuities 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 Synergy and control IOL groups are presented in **Table 4**. There was a statistically significant improvement ($p<0.0001$) in mean monocular distance-corrected intermediate visual acuity (DCIVA; secondary effectiveness endpoint) at 6 months in favor of the Synergy group, with an improvement of 2.8 lines. Monocular intermediate visual acuity distributions for both lens groups are presented in **Tables 5A** and **5B**; binocular intermediate visual acuity distributions are presented in **Tables 6A** and **6B**. Overall, the intermediate visual acuity results demonstrate the effectiveness of the Synergy lens to provide improved intermediate vision compared to the monofocal control lens.

TABLE 4
Mean Intermediate Visual Acuity at 66 cm at 6 Months

Intermediate Visual Acuity	Lens Group	Monocular					Binocular				
		N	n	Mean LogMAR	Snellen Equiv.	Line Change vs. Control[a]	N	n	Mean LogMAR	Snellen Equiv.	Line Change vs. Control[a]
Uncorrected	TECNIS Synergy	Not Tested					131	131	0.022	20/21	1.8 lines
	TECNIS monofocal						131	130	0.199	20/32	
Distance Corrected	TECNIS Synergy	131	131	0.060	20/23	2.8 lines[b]	Not Tested				
	TECNIS monofocal	131	130	0.335	20/43						

[a] Line difference (control minus Synergy) is converted directly from LogMAR difference.

[b] Synergy met the secondary study endpoint of significantly better mean DCIVA than control ($p<0.0001$, one-sided two-sample t-test) and a mean DCIVA of 0.060 LogMAR (Safety population).

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TABLE 5A
Distribution of Monocular Distance-Corrected Intermediate Visual Acuity at 66 cm at 6 Months

Monocular Snellen Visual Acuity	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	%	n	%
20/20^{-2} or better	72	55.0%	8	6.2%
20/25^{-2} or better	105	80.2%	17	13.1%
20/32^{-2} or better	125	95.4%	37	28.5%
20/40^{-2} or better	129	98.5%	68	52.3%
Worse than 20/40^{-2}	2	1.5%	62	47.7%
Total n	**131**		**130**	

Monocular UCIVA was not tested
%=(n/Total n) * 100

TABLE 5B
Distribution of Monocular Distance-Corrected Intermediate Visual Acuity at 66 cm at 6 Months

Monocular LogMAR Visual Acuity	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	%	n	%
0.00 LogMAR or better	47	35.9%	4	3.1%
0.10 LogMAR or better	97	74.0%	10	7.7%
0.20 LogMAR or better	117	89.3%	24	18.5%
0.30 LogMAR or better	127	96.9%	55	42.3%
Worse than 0.30 LogMAR	4	3.1%	75	57.7%
Total n	**131**		**130**	

Monocular UCIVA was not tested
%=(n/Total n) * 100

TABLE 6A
Distribution of Binocular Uncorrected Intermediate Visual Acuity at 66 cm at 6 Months

Binocular Snellen Visual Acuity	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	%	n	%
20/20^{-2} or better	84	64.1%	18	13.8%
20/25^{-2} or better	117	89.3%	44	33.8%
20/32^{-2} or better	130	99.2%	96	73.8%
20/40^{-2} or better	131	100.0%	114	87.7%
Worse than 20/40^{-2}	0	0.0%	16	12.3%
Total n	**131**		**130**	

%=(n/Total n) * 100

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TABLE 6B
Distribution of Binocular Uncorrected Intermediate Visual Acuity at 66 cm at 6 Months

Binocular LogMAR Visual Acuity	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	%	n	%
0.00 LogMAR or better	64	48.9%	8	6.2%
0.10 LogMAR or better	107	81.7%	31	23.8%
0.20 LogMAR or better	127	96.9%	78	60.0%
0.30 LogMAR or better	131	100.0%	106	81.5%
Worse than 0.30 LogMAR	0	0.0%	24	18.5%
Total n	**131**		**130**	

%=(n/Total n) * 100

Near Visual Acuity at 40 cm

Near visual acuities were tested at 40 cm under photopic (85 cd/m^2) and mesopic (3 cd/m^2) lighting conditions. Mean monocular near visual acuities at 6 months for both Synergy and control groups are presented in **Table 7**. There was a statistically significant improvement ($p<0.0001$) in mean monocular distance-corrected near visual acuity (DCNVA at 40 cm; primary effectiveness endpoint) at 6 months in favor of the Synergy group, with an improvement of 4.2 lines. Monocular near (40 cm) visual acuity distributions for both lens groups are presented in **Tables 8A** and **8B**; binocular near (40 cm) visual acuity distributions are presented in **Tables 9A** and **9B**. Near (40 cm) visual acuity results demonstrate the effectiveness of the Synergy lens in providing improved near vision compared to the monofocal control lens.

TABLE 7
Mean Near Visual Acuity at 40 cm at 6 Months

Near (40 cm) Visual Acuity	Lens Group	Monocular					Binocular				
		N	n	Mean LogMAR	Snellen Equiv.	Line Change vs. Control[a]	N	n	Mean LogMAR	Snellen Equiv.	Line Change vs. Control[a]
Uncorrected	TECNIS Synergy	Not tested					131	131	0.060	20/23	3.3 lines
	TECNIS monofocal						131	130	0.393	20/49	
Distance Corrected	TECNIS Synergy	131	131	0.104	20/25	4.2 lines[b]	131	131	0.047	20/22	3.6 lines
	TECNIS monofocal	131	130	0.522	20/67		131	130	0.403	20/51	
Mesopic Distance Corrected	TECNIS Synergy	131	131	0.315	20/41	3.4 lines	131	131	0.244	20/35	3.5 lines
	TECNIS monofocal	131	130	0.654	20/90		131	130	0.591	20/78	

[a] Line difference (control minus Synergy) is converted directly from LogMAR difference.

[b] Synergy met the primary study endpoint of significantly better mean DCNVA than control ($p<0.0001$, one-sided two-sample t-test) and a mean DCNVA of 0.104 LogMAR (Safety population).

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TABLE 8A
Distribution of Monocular Distance-Corrected Near Visual Acuity at 40 cm at 6 Months

Monocular Snellen Visual Acuity	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	%	n	%
20/20^{-2} or better	44	33.6%	2	1.5%
20/25^{-2} or better	92	70.2%	7	5.4%
20/32^{-2} or better	119	90.8%	10	7.7%
20/40^{-2} or better	124	94.7%	25	19.2%
Worse than 20/40^{-2}	7	5.3%	105	80.8%
Total n	**131**		**130**	

%=(n/Total n) * 100

TABLE 8B
Distribution of Monocular Distance-Corrected Near Visual Acuity at 40 cm at 6 Months

Monocular LogMAR Visual Acuity	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	%	n	%
0.00 LogMAR or better	33	25.2%	0	0.0%
0.10 LogMAR or better	76	58.0%	6	4.6%
0.20 LogMAR or better	110	84.0%	9	6.9%
0.30 LogMAR or better	123	93.9%	19	14.6%
Worse than 0.30 LogMAR	8	6.1%	111	85.4%
Total n	**131**		**130**	

%=(n/Total n) * 100

TABLE 9A
Distribution of Binocular Uncorrected Near Visual Acuity at 40 cm at 6 Months

Binocular Snellen Visual Acuity	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	%	n	%
20/20^{-2} or better	61	46.6%	0	0.0%
20/25^{-2} or better	114	87.0%	158	6.2%
20/32^{-2} or better	122	93.1%	25	19.2%
20/40^{-2} or better	127	96.9%	57	43.8%
Worse than 20/40^{-2}	4	3.1%	73	56.2%
Total n	**131**		**130**	

%=(n/Total n) * 100

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TABLE 9B
Distribution of Binocular Uncorrected Near Visual Acuity at 40 cm at 6 Months

Binocular LogMAR Visual Acuity	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	%	n	%
0.00 LogMAR or better	43	32.8%	0	0.0%
0.10 LogMAR or better	101	77.1%	2	1.5%
0.20 LogMAR or better	120	91.6%	14	10.8%
0.30 LogMAR or better	126	96.2%	42	32.3%
Worse than 0.30 LogMAR	5	3.8%	88	67.7%
Total n	**131**		**130**	

%=(n/Total n) * 100

Near Visual Acuity at 33 cm

Near visual acuities were tested at 33 cm under photopic (85 cd/m^2) lighting conditions. Mean monocular distance-corrected near visual acuities at 6 months for both Synergy and control groups are presented in **Table 10**. There was a statistically significant improvement ($p<0.0001$) in mean monocular distance-corrected near visual acuity (DCNVA at 33 cm; secondary effectiveness endpoint) at 6 months in favor of the Synergy group, with an improvement of 4.5 lines.

TABLE 10
Mean Monocular Near Visual Acuity at 33 cm at 6 Months

Lens Group	N	n	Mean LogMAR	Snellen Equivalent	Line Change vs. Control[a]
TECNIS Synergy	131	131	0.154	20/29	4.5 lines[b]
TECNIS monofocal	131	130	0.608	20/81	

[a] Line difference (control minus Synergy) is converted directly from LogMAR difference.

[b] Synergy met the secondary study endpoint of significantly better mean DCNVA at 33 cm than control ($p<0.0001$, one-sided two-sample t-test) and a mean DCNVA of 0.154 LogMAR (Safety population).

Defocus Curve

Distance-corrected defocus testing was performed monocularly at 6 months and binocularly at 1 month. Mean monocular defocus curve at 0.2 LogMAR was a secondary effectiveness study endpoint, and results for each lens group at 6 months are presented in **Figure 2.** The defocus curve shows that Synergy achieved the secondary study endpoint with 0.2 LogMAR or better VA from 0.0 D to -2.5 D of defocus; 0.2 LogMAR visual acuity on the Synergy defocus curve continued beyond -3.0 D, which corresponds to a range of distances from approximately 33 cm to infinity.

Figure 3A presents monocular defocus curves for the Synergy group by pupil size. The curves for medium and large pupils are essentially indistinguishable with 0.2 LogMAR visual acuity sustained to beyond -3.0 D. It should be noted that there were no eyes in the small pupil size category for the Synergy group. Therefore, the TECNIS Synergy IOLs demonstrated pupil-independent lens performance between 0 and -3.0 D of defocus among the pupil sizes available (>2.5 mm). Monocular defocus curves for the Synergy and control groups are presented by small, medium, and large pupil sizes in **Figures 3B** and **3C**, respectively. The range of defocus for medium and large pupils in the Synergy group are greater than that for the control group by approximately 2.5 D and 2.0 D, respectively.

Figure 4 presents the binocular defocus curves for the Synergy and control groups at 1 month. The binocular defocus curves show results similar to the monocular 6 month defocus results, with a difference

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in the range of defocus of approximately 2.5 D between the IOL groups, favoring the Synergy group over the control group.

FIGURE 2
Mean Monocular Distance-Corrected Defocus Curve at 6 Months
TECNIS Synergy (N=131) and TECNIS monofocal (N=131)

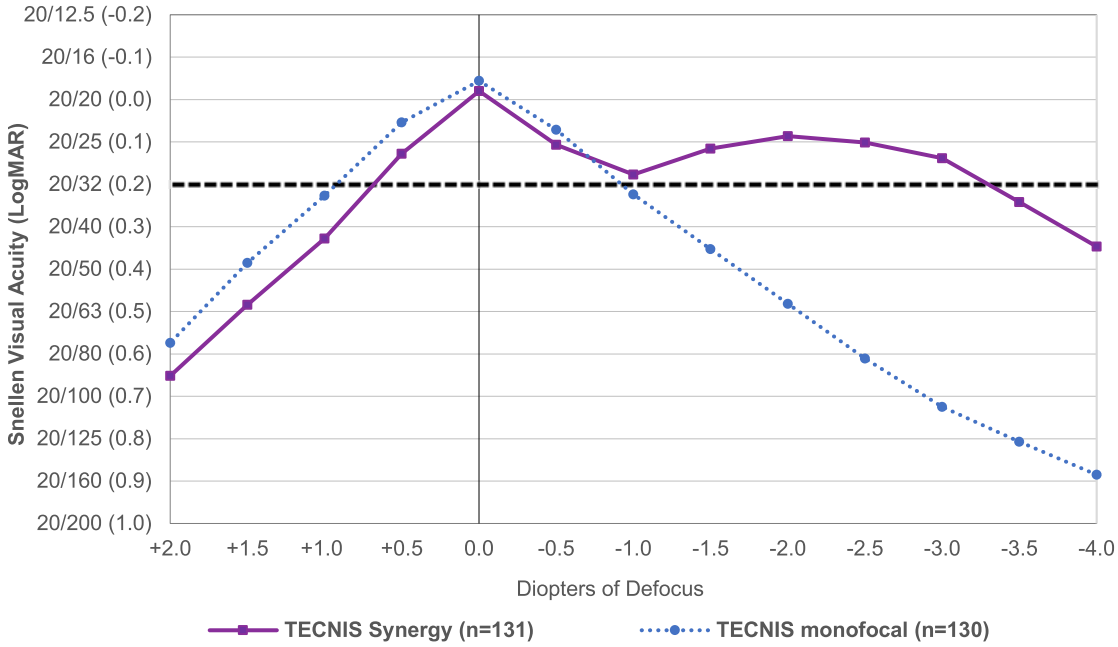

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FIGURE 3A
Mean Monocular Distance-Corrected Defocus Curve By Pupil Size at 6 Months
TECNIS Synergy

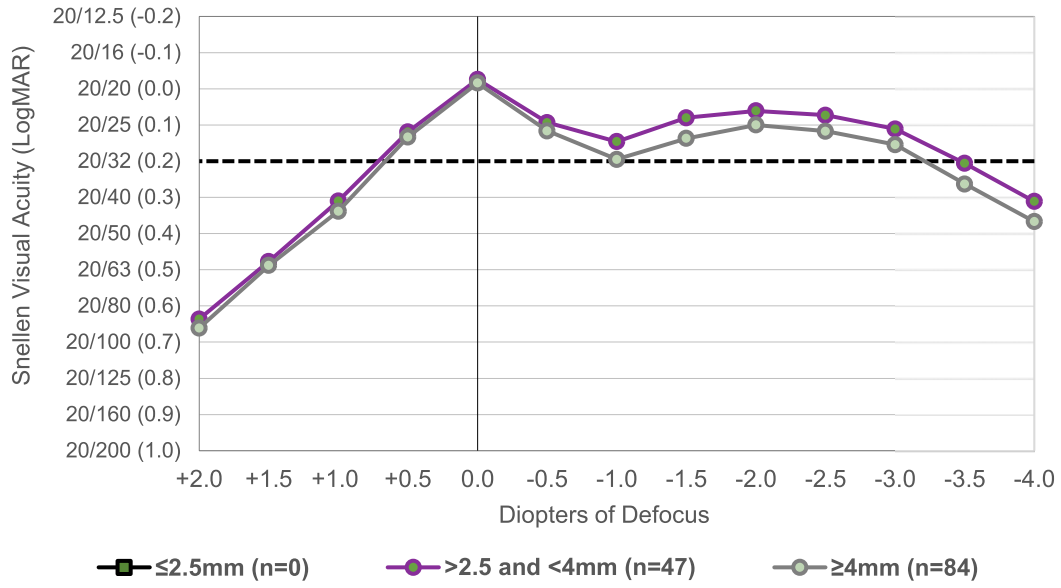

FIGURE 3B
Mean Monocular Distance-Corrected Defocus Curve for
Medium Pupils (>2.5 and <4 mm) at 6 Months
TECNIS Synergy and TECNIS monofocal

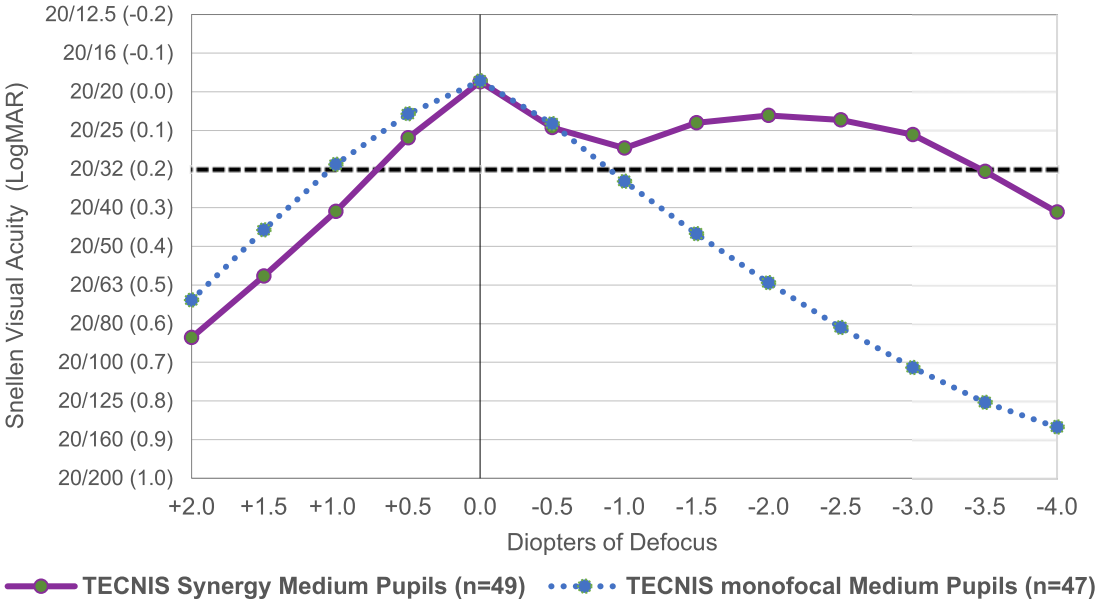

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FIGURE 3C
Mean Monocular Distance-Corrected Defocus Curve for Large Pupils (≥4 mm) at 6 Months
TECNIS Synergy and TECNIS monofocal

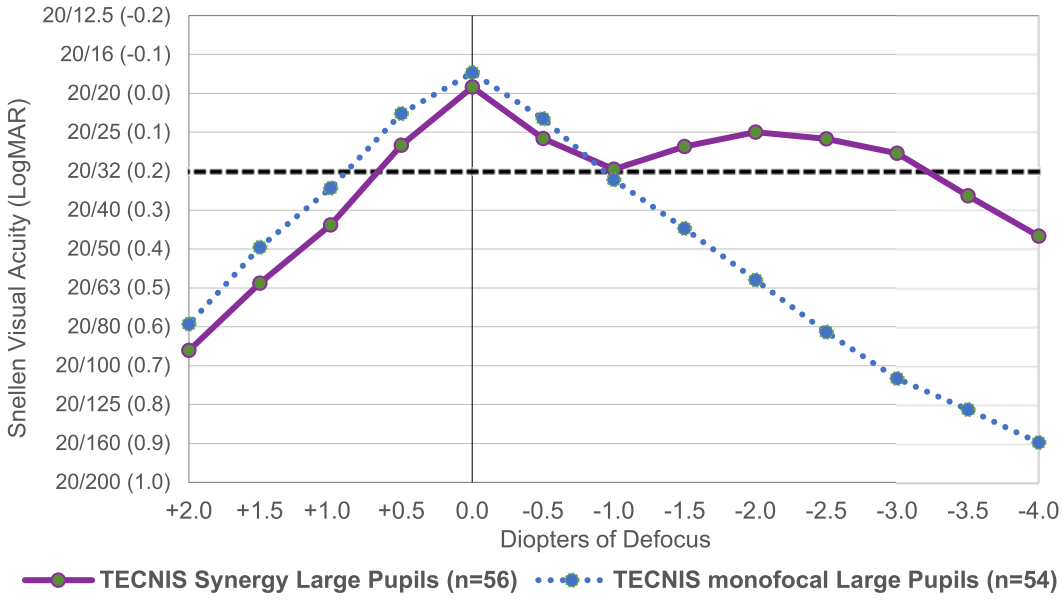
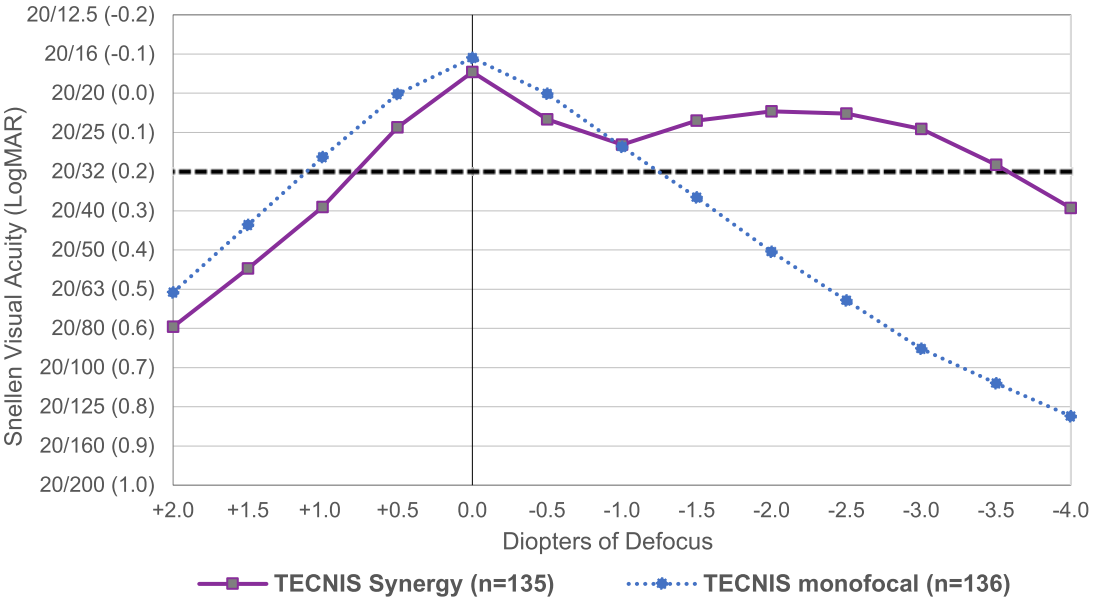


FIGURE 4
Mean Binocular Distance-Corrected Defocus Curve at 1 Month
Bilateral TECNIS Synergy (N=135) and TECNIS monofocal (N=136)



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Contrast Sensitivity

Monocular best-corrected distance contrast sensitivity was evaluated under three lighting conditions: mesopic without glare, mesopic with glare, and photopic with glare. The median monocular contrast sensitivity measurements at all spatial frequencies and all lighting conditions at 6 months were generally lower for the Synergy group than the control group (**Figures 5A, 5B,** and **5C**) but were not clinically significant. The illuminance of the glare source used for testing (150 lux) was high enough to reduce mesopic contrast sensitivity in the monofocal control group by at least 0.2 log units and further reduced that of the Synergy group by up to 0.11 log units; however, the clinical significance of the measured differences in contrast sensitivity was not evident in patient-reported experiences. In addition, median binocular contrast sensitivity measurements at all spatial frequencies and all lighting conditions at 1 month are presented in **Figures 6A, 6B,** and **6C**.

Figure 5A
Monocular Best-Corrected Distance Contrast Sensitivity at 6 Months
Mesopic Without Glare
Medians with 5th and 95th Percentile Error Bars

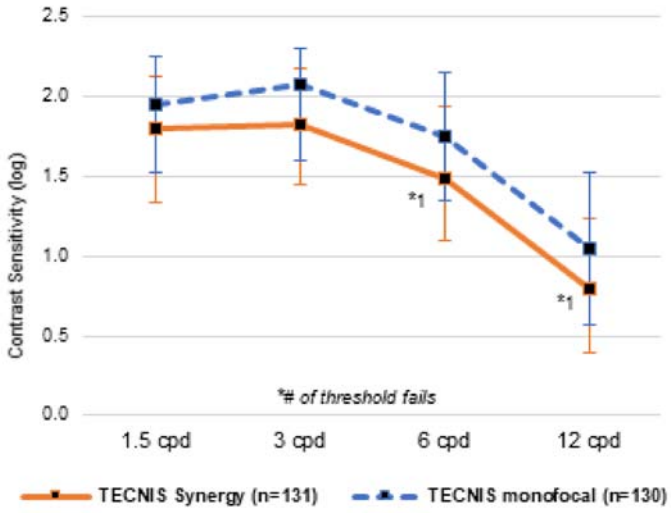

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Figure 5B
Monocular Best-Corrected Distance Contrast Sensitivity at 6 Months
Mesopic With Glare
Medians with 5th and 95th Percentile Error Bars

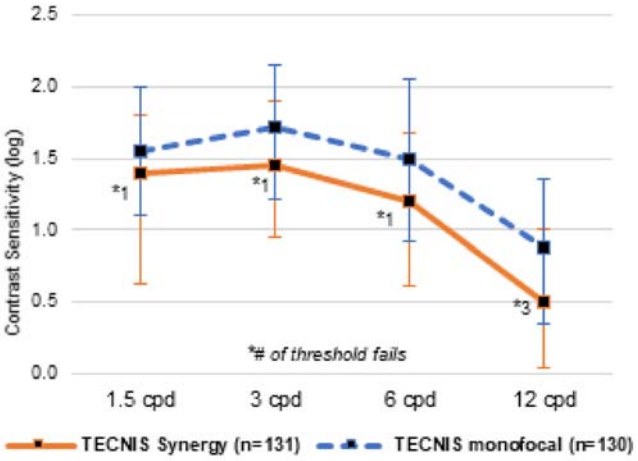

Figure 5C
Monocular Best-Corrected Distance Contrast Sensitivity at 6 Months
Photopic With Glare
Medians with 5th and 95th Percentile Error Bars

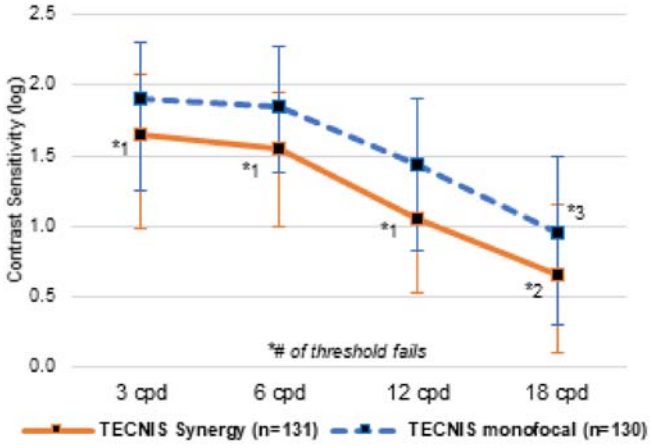

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FIGURE 6A
Binocular Best-Corrected Distance Contrast Sensitivity at 1 Month
Mesopic without Glare
Medians with 5th and 95th Percentile Error Bars

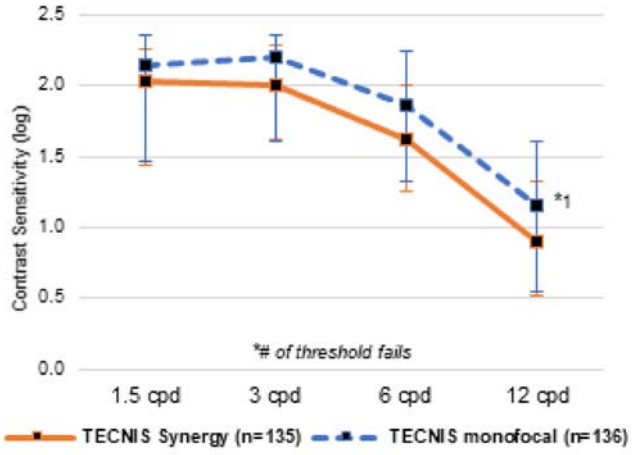

FIGURE 6B
Binocular Best-Corrected Distance Contrast Sensitivity at 1 Month
Mesopic with Glare
Medians with 5th and 95th Percentile Error Bars

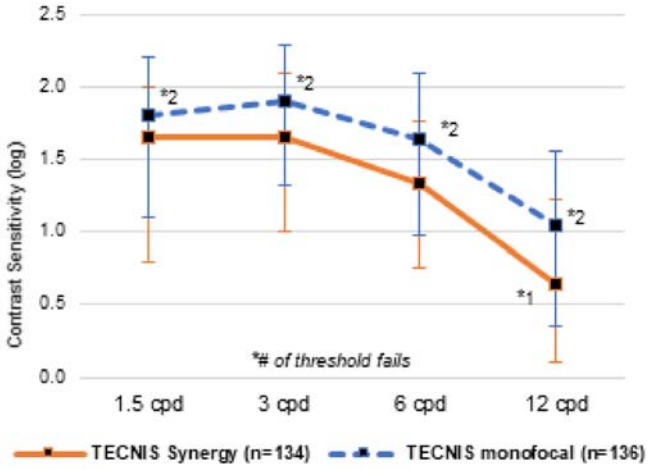

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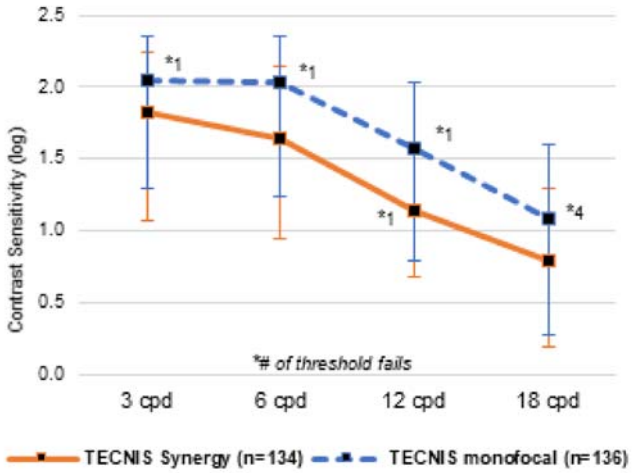
FIGURE 6C
Binocular Best-Corrected Distance Contrast Sensitivity at 1 Month
Photopic with Glare
Medians with 5th and 95th Percentile Error Bars



Patient-Reported Spectacle Independence Questionnaire Results
Spectacle wear and other related items were assessed by subject responses obtained from 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. The questionnaire includes questions about the need for glasses, wear of glasses, and straining to see without them. The study results showed that the Synergy group achieved the secondary effectiveness endpoint of reduced spectacle wear compared to the control group.

Spectacle wear (secondary effectiveness endpoint) was based on the proportion of subjects who reported wearing glasses or contacts "none of the time" for all four conditions: distance, intermediate, near, and overall. **Figure 7** presents the frequency of spectacle wear for bilaterally implanted subjects at 6 months. There was a statistically significantly greater ($p<0.0001$) proportion of subjects in the Synergy group (87.8%; 115/131) who reported wearing glasses "none of the time" in all four conditions (distance, intermediate, near, and overall vision) compared to the control group (3.1%; 4/131); the 84.7 percentage point difference between the two IOL groups was clinically significant. Similarly, 82.4% (108/131) of subjects in the Synergy group reported no need for glasses for distance, intermediate and near vision compared to the control (5.3%, 7/131).

Responses to these questions at the 6-month visit indicated that the Synergy IOL provided freedom from eyeglasses to implanted subjects.

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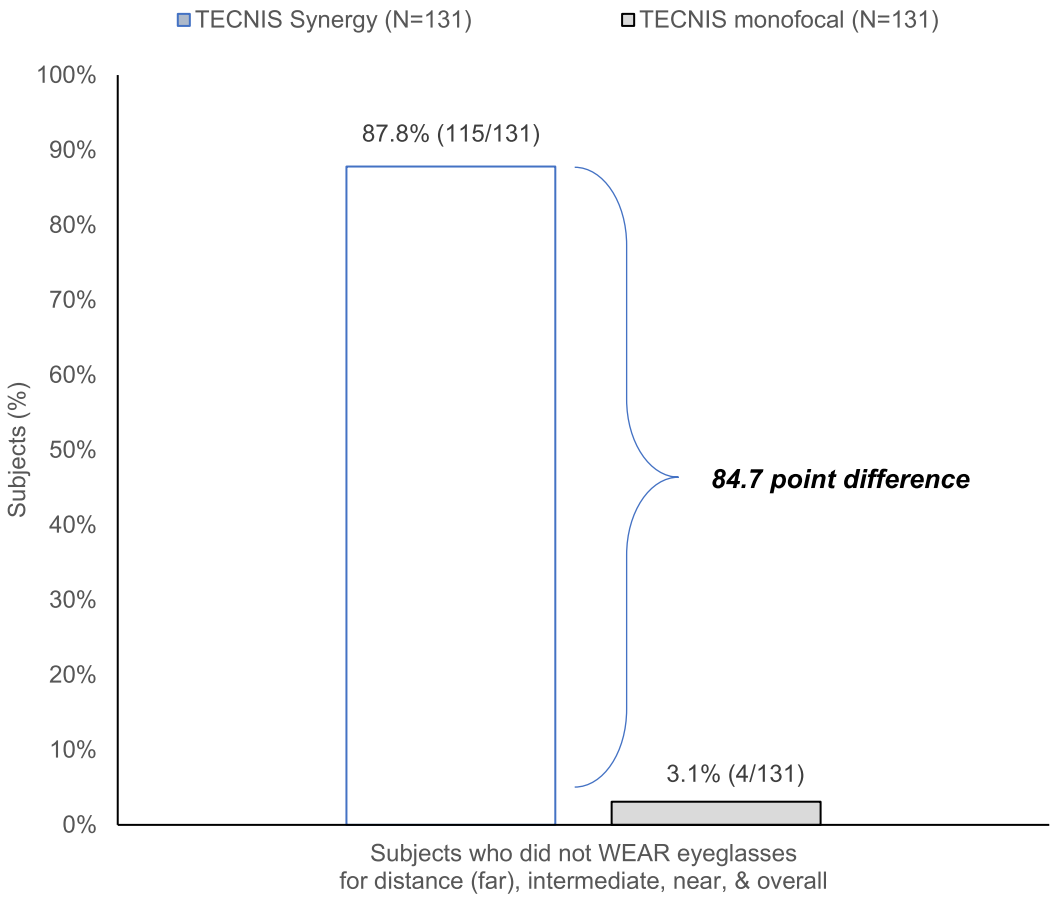
FIGURE 7
Patient Reported Spectacle Independence Questionnaire Results at 6 Months



Each subject reported "None of the time" for all four conditions.

Optical/Visual Symptoms

Optical/visual symptoms that were spontaneously reported by subjects (non-directed) and questionnaire-directed reports of experience/bother/difficulty with visual problems (directed) were evaluated. Non-directed reports of optical/visual symptoms included halos, night glare, and starbursts, of which there were few reports of severe symptoms for both Synergy and control groups (**Table 11**). As shown in the responses to the directed questionnaire (**Table 12)**, reports of bothersome visual disturbances were generally acceptable for the Synergy group at 6 months. The highest rate of the most bothersome reports ("extremely bothersome") of optical/visual symptoms at 6 months was for starbursts, at 5.3% for Synergy and 0.0% for the control.

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TABLE 11
Spontaneous (Non-directed[a]) Reports of Optical/Visual Symptoms (First Eyes) at 6 Months

	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	**%**	**n**	**%**
Halos[b]	30	22.9	5	3.8
○ Mild	8	6.1	3	2.3
○ Moderate	17	13.0	2	1.5
○ Severe	5	3.8	0	0.0
Night Glare[b]	11	8.4	2	1.5
○ Mild	1	0.8	0	0.0
○ Moderate	7	5.3	2	1.5
○ Severe	3	2.3	0	0.0
Starbursts[b]	13	9.9	2	1.5
○ Mild	3	2.3	2	1.5
○ Moderate	5	3.8	0	0.0
○ Severe	5	3.8	0	0.0
Photophobia	2	1.5	3	2.3
Day glare	2	1.5	1	0.8
Night vision difficulty	6	4.6	1	0.8

% = (n/N)*100
Subjects may report multiple symptoms.
[a] Responses to the question, “Are you having any difficulties with your eyes or vision?”
[b] Severity collected in follow-up response

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TABLE 12
Experience/Bother With Visual Symptoms at 6 Months
(Directed Questionnaire)

		TECNIS Synergy N=131		TECNIS monofocal N=131	
		n	%	n	%
Halos	Did not experience or NR	24	18.3	79	60.3
	Not at all bothered	19	14.5	23	17.6
	Slightly bothered	40	30.5	22	16.8
	Moderately bothered	30	22.9	6	4.6
	Very bothered	13	9.9	1	0.8
	Extremely bothered	5	3.8	0	0.0
Starbursts	Did not experience or NR	46	35.1	102	77.9
	Not at all bothered	18	13.7	17	13.0
	Slightly bothered	27	20.6	4	3.1
	Moderately bothered	25	19.1	6	4.6
	Very bothered	8	6.1	2	1.5
	Extremely bothered	7	5.3	0	0.0
Multiple or Double Vision	Did not experience or NR	113	86.3	116	88.5
	Not at all bothered	2	1.5	5	3.8
	Slightly bothered	10	7.6	4	3.1
	Moderately bothered	2	1.5	5	3.8
	Very bothered	2	1.5	1	0.8
	Extremely bothered	2	1.5	0	0.0
Sensitivity to Light	Did not experience or NR	63	48.1	71	54.2
	Not at all bothered	13	9.9	9	6.9
	Slightly bothered	30	22.9	32	24.4
	Moderately bothered	19	14.5	11	8.4
	Very bothered	5	3.8	6	4.6
	Extremely bothered	1	0.8	2	1.5
Glare Related to Scattered Light	Did not experience or NR	69	52.7	110	84.0
	Not at all bothered	9	6.9	4	3.1
	Slightly bothered	23	17.6	12	9.2
	Moderately bothered	19	14.5	3	2.3
	Very bothered	5	3.8	2	1.5
	Extremely bothered	6	4.6	0	0.0
Occlusions	Did not experience or NR	127	96.9	128	97.7
	Not at all bothered	1	0.8	1	0.8
	Slightly bothered	1	0.8	2	1.5
	Moderately bothered	0	0.0	0	0.0
	Very bothered	2	1.5	0	0.0
	Extremely bothered	0	0.0	0	0.0
Poor Low Light Vision	Did not experience or NR	79	60.3	80	61.1
	Not at all bothered	9	6.9	6	4.6
	Slightly bothered	25	19.1	34	26.0
	Moderately bothered	15	11.5	6	4.6
	Very bothered	3	2.3	4	3.1
	Extremely bothered	0	0.0	1	0.8

% = (n/N)*100
NR = Not Reported

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Adverse Events

The incidence rates of persistent and cumulative adverse events for Synergy eyes at 6 months compared to the ISO SPE (safety and performance endpoint) rates at 12 months are presented in **Tables 13** and **14**, respectively. The incidence rates for the Synergy IOL group compared favorably to the specified ISO SPE rates, as the observed rates for the Synergy group were either lower than or not statistically significantly higher than the specified ISO SPE rates (primary safety endpoint). Secondary surgical interventions (SSI) by IOL group are presented in **Table 15**. Of the three second eye SSIs, only one was device related.

TABLE 13
6-Month Persistent Adverse Events vs. ISO 11979-7 SPE 12-Month Rates
TECNIS Synergy

	ISO SPE Rate	First Eyes N=131		Second Eyes N=132	
Persistent Medical Complication/Adverse Event	**%**	**n**	**%**	**n**	**%**
Corneal edema	0.3	0	0.0	0	0.0
Cystoid macular edema	0.5	0	0.0	0	0.0
Iritis	0.3	0	0.0	0	0.0
Raised IOP requiring treatment	0.4	0	0.0	0	0.0

TABLE 14
6-Month Cumulative Adverse Events vs. ISO 11979-7 SPE 12 Month Rates
TECNIS Synergy

	ISO SPE Rate	First Eyes N=135		Second Eyes N=135	
Cumulative Medical Complication/Adverse Event	**%**	**n**	**%**	**n**	**%**
Cystoid macular edema	3.0	1	0.7	1	0.7
Hypopyon[a]	0.3	0	0.0	1	0.7 [b]
Endophthalmitis[c]	0.1	0	0.0	0	0.0
Lens dislocated from posterior chamber[c]	0.1	0	0.0	0	0.0
Pupillary block[c]	0.1	0	0.0	0	0.0
Retinal detachment[c]	0.3	0	0.0	0	0.0
Eyes with secondary surgical intervention[c]	0.8	1	0.7	3	2.2 [b]

% = (n/N) *100

[a] Associated with a single report of toxic anterior segment syndrome (TASS), which occurred in same eye.

[b] Rate is not statistically significantly higher than ISO SPE rate (p>0.05).

[c] As defined by AAO IOL Task Force (Masket *et al.*, 2016). Cystoid macular edema was defined by clinical examination and adjunct testing (OCT). Hypopyon was defined as an accumulation of white blood cells in the anterior chamber.

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TABLE 15
Secondary Surgical Interventions by IOL Group

	TECNIS Synergy				TECNIS monofocal			
	First Eyes N=135		Second Eyes N=135		First Eyes N=137		Second Eyes N=137	
	n	%	n	%	n	%	n	%
Secondary Surgical Interventions (SSIs)								
○ Lens Removal	1[a]	0.7	0	0.0	0	0.0	0	0.0
○ Aspiration (Removal) of Lens Fragments	0	0.0	1[b]	0.7	0	0.0	0	0.0
○ Retinal Repair	0	0.0	1[c]	0.7	0	0.0	1[e]	0.7
○ Treatment Injection	0	0.0	1[d]	0.7	0	0.0	0	0.0
Total Eyes with SSIs	**1**	**0.7**	**3**	**2.2**	**0**	**0.0**	**1**	**0.7**

% = (n/N) *100
[a]SSI related to visual symptoms (optical properties of the lens). The second-eye lens for same subject was removed after study exit for similar reason.
[b]Due to retained lens material
[c]Due to macular hole
[d]Due to hypopyon and TASS in same eye
[e]Due to retinal detachment/tear

Table 16 presents the incidence of serious and non-serious medical findings/adverse events at 6-months for all Synergy and monofocal control eyes.

Table 16
Medical Findings/Adverse Events at 6 Months
TECNIS Synergy and TECNIS Monofocal
Pooled (First and Second) Eyes
Safety Population

	TECNIS Synergy N=263		TECNIS Monofocal N=262	
Medical Findings	**n**	**%**	**n**	**%**
Posterior capsule opacification (any)	116	44.1	106	40.5
Posterior vitreous detachment	76	28.9	76	29.0
Dermatochalasis	56	21.3	49	18.7
Dry eye/superficial punctate keratopathy/ epithelial erosion/tear film insufficiency	50	19.0	46	17.6
Blepharitis/meibomianitis	40	15.2	48	18.3
Posterior capsular striae/wrinkles (any)	16	6.1	10	3.8
Periorbital fat herniation	14	5.3	10	3.8
Pinguecula	14	5.3	15	5.7
Ptosis	6	2.3	4	1.5
Chorioretinal atrophy	5	1.9	5	1.9
Congenital optic nerve anomaly	5	1.9	0	0.0
Epiretinal membrane	5	1.9	1	0.4
Corneal dystrophy	4	1.5	4	1.5
Drusen	4	1.5	5	1.9
Eye nevus	4	1.5	1	0.4
Guttata	4	1.5	2	0.8
Corneal scar	3	1.1	6	2.3
Optic nerve cup/disc ratio increased	3	1.1	0	0.0
Pterygium	3	1.1	2	0.8
Retinal degeneration	3	1.1	0	0.0

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Medical Findings	TECNIS Synergy N=263 n	%	TECNIS Monofocal N=262 n	%
Retinal pigment epithelium (RPE) changes	3	1.1	2	0.8
Arcus	2	0.8	9	3.4
Conjunctival hyperemia/injection	2	0.8	0	0.0
Conjunctivitis	2	0.8	0	0.0
Conjunctivochalasis	2	0.8	0	0.0
Corneal disorder	2	0.8	0	0.0
Corneal pigmentation[b]	2	0.8	2	0.8
Heterophoria	2	0.8	0	0.0
Macular degeneration	2	0.8	0	0.0
Optic nerve cupping	2	0.8	0	0.0
Optic nerve hypoplasia	2	0.8	0	0.0
Telangiectasia	2	0.8	0	0.0
Anterior chamber cells (if any)	1	0.4	4	1.5
Chorioretinal scar	1	0.4	1	0.4
Corneal opacity	1	0.4	1	0.4
Eyelid cyst	1	0.4	2	0.8
Lagophthalmos	1	0.4	0	0.0
Macular hole	1	0.4	0	0.0
Retinal anomaly congenital	1	0.4	1	0.4
Retinal scar	1	0.4	0	0.0
Vitreous degeneration	1	0.4	0	0.0
Anterior chamber flare (if any)	0	0.0	3	1.1
Cornea verticillata	0	0.0	2	0.8
Corneal edema (if any)[b]	0	0.0	2	0.8
Iris transillumination defect[b]	0	0.0	2	0.8
Madarosis	0	0.0	2	0.8
Presumed ocular histoplasmosis syndrome	0	0.0	2	0.8
Retinal hemorrhage	0	0.0	2	0.8
Elevated IOP/ocular hypertension[b]	0	0.0	1	0.4
Hyalosis asteroid	0	0.0	1	0.4
Retinal exudates	0	0.0	1	0.4
Retinal tear[b]	0	0.0	1	0.4
Strabismus	0	0.0	1	0.4
Other	0	0.0	2[a]	0.8[a]

[a] Other includes orbital fat prolapse and negative dysphotopsia.
[b] As defined by AAO IOL Task Force (Masket *et al*., 2016).

Bother or difficulty with a visual symptom that caused interference with daily activity lasting more than 3 months and was deemed related to the IOL by the investigator was considered an Adverse Device Effect (ADE). Eleven ADEs of undesirable optical phenomena occurred in 8.1% (11/135) of Synergy subjects and none for control subjects; one resulted in a lens removal due to optical properties of the lens (0.7%, 1/135).

Overall lens findings in Synergy subjects included lens decentration (0.7%, 1/135) in both eyes, inflammatory deposits on IOL (0.7%, 1/135), and implant positioned minimally nasal in pupil (0.7%, 1/135) during the study.

RELATED CLINICAL STUDIES

Data from other relevant clinical studies are included to support the safety and effectiveness of the TECNIS Synergy™ IOLs, Model ZFR00V, and the TECNIS Synergy™ Toric II IOLs, Models ZFW150, ZFW225,

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ZFW300, and ZFW375. Clinical data to support the TECNIS Synergy™ Toric II IOLs (Models ZFW150, ZFW225, ZFW300, and ZFW375) are from the toric design parents (P980040/S039; TECNIS Toric 1-Piece IOLs, Models ZCT150, ZCT225, ZCT300 and ZCT400) onto the anterior optic surface of the TECNIS Synergy™ IOL, Model ZFR00V (non-toric).

The TECNIS Symfony® Extended Range of Vision IOL, Model ZXR00, approved under P980040/S065, and TECNIS® Multifocal IOL, Model ZM900, approved under P080010 serve as the optical parents to TECNIS Synergy™ IOLs, Models ZFR00V and ZFW (non-toric and toric). The posterior optic design of the TECNIS Synergy™ IOLs was derived from the diffractive technology of Models ZXR00 and ZM900, whereas the anterior optic surface contains a modified prolate (aspheric) design identical to that of its monofocal analog, the TECNIS 1-Piece IOL, Model ZCB00, approved under P980040/S015. The SENSAR® 1-Piece IOL, Model AAB00, which was approved under P980040/S015, served as the mechanical parent to support the safety and effectiveness of the 1-piece platform and SENSAR acrylic material used for the TECNIS Synergy™ IOLs (non-toric and toric models). In addition, the TECNIS Synergy™ IOLs, Models ZFR00V and ZFW, are made of the same soft acrylic material of the clinically studied TECNIS 3-Piece OptiBlue™ IOL, Model ZV9003, approved under P980040/S035, which also serves as the material parent.

CLINICAL STUDY RESULTS FOR THE 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 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.

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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 (standard deviation [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**	**SD**	**P-Value**	**Lens Model**	**N[a]**	**Mean**	**SD**	**P-Value**
Preop Keratometric Cylinder (K_{cyl}; 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[1,2] and up to 20° for axis[2]) and any potential errors in surgeon-estimated SIA are contributing factors to prediction errors of postoperative keratometry.

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.

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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 K_{cyl} 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 K_{cyl} alone and by predicted K_{cyl} (i.e., vector sum of preoperative K_{cyl}, magnitude and axis, SIA, and incision axis) in 0.25 D increments as shown in **Tables 19, 20,** and **21**.

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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)	Percent Reduction in Cylinder (ANSI)[a] N	Mean	SD	Predicted Keratometric Cylinder (D)[b] (Preop K_{cyl} + SIA)	Percent Reduction in Cylinder (ANSI)[a] N	Mean	SD
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 to 0.99	22	32.32	111.09	0.75 to 0.99	23	7.39	48.81
ZCT150		30	69.20	87.53		21	55.38	58.57
ZCB00	1.00 to 1.24	34	41.06	68.41	1.00 to 1.24	31	43.44	59.77
ZCT150		38	94.88	52.09		36	61.88	49.80
ZCB00	1.25 to 1.49	27	32.31	60.95	1.25 to 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 K_{cyl})/(Target Ref. Cyl. minus Preop K_{cyl}); 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	SD	Predicted Keratometric Cylinder (D)[a] (Preop K_{cyl} + SIA)	Residual Refractive Cylinder (D) N	Mean	SD
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 to 0.99	22	0.56	0.50	0.75 to 0.99	23	1.03	0.51
ZCT150		30	0.50	0.40		21	0.43	0.33
ZCB00	1.00 to 1.24	34	0.80	0.55	1.00 to 1.24	31	0.84	0.68
ZCT150		38	0.36	0.36		36	0.48	0.45
ZCB00	1.25 to 1.49	27	1.09	0.59	1.25 to 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.

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

		Absolute Cylinder								Absolute Cylinder						
			Reduction >0.50 D		Change ≤±0.50 D[b]		Increase >0.50 D				Reduction >0.50 D		Change ≤±0.50 D[b]		Increase >0.50 D	
Model	Preoperative Keratometric Cylinder (D)	N	n	%	n	%	n	%	Predicted Keratometric Cylinder (D)[c] (Preop K_{cyl}+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 to 0.99	22	7	31.82	13	59.09	2	9.09	0.75 to 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 to 1.24	34	12	35.29	19	55.88	3	8.82	1.00 to 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 to 1.49	27	9	33.33	16	59.26	2	7.41	1.25 to 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 K_{cyl}

[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.

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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 to 30	0	0.0	0	0.0	0	0.0	0	0.0
10 to 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 to 9	9	6.1	6	4.1	9	5.8	6	3.9
0 to 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]		Toric Eyes with Data at One Day and Six Months	
	1 Day vs. 6 Months		1 Day vs. 6 Months	
	n	%	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).

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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]			Toric Eyes with Data at Two or More Visits[b]		
	N	Mean (degrees)	SD	N	Mean (degrees)	SD
1 Month vs. 3 Month	148	0.24	2.82	156	0.25	2.77
3 Month vs. 6 Month	148	-0.06	2.94	152	-0.09	2.96
Baseline (1 Day) vs. 6 Month	148	-1.35	6.13	156	-1.33	5.99
Abs. Value: 1 Month vs. 3 Month	148	1.82	2.17	156	1.79	2.12
Abs. Value: 3 Month vs. 6 Month	148	1.85	2.28	152	1.89	2.27
Abs. Value: Baseline (1 Day) vs. 6 Month	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 SSIs. 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.

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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%

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	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 K_{cyl} in second eyes
[b] As control subjects had ≤1.5 D of preoperative K_{cyl}, 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 FOR THE TECNIS Symfony® Extended Range of Vision IOL, Model ZXR00

A prospective, 6-msonth, 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® Monofocal 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 this clinical summary section including the data tables, “Symfony” refers to the TECNIS Symfony® IOL, Model ZXR00, and “control” refers to the TECNIS® Monofocal 1-Piece IOL, Model ZCB00.

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 control group (150 bilaterally implanted). Subject demographics were similar between the Symfony and 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% control). Most Symfony subjects (>96%) and control subjects (>86%) were White. The remainder of subjects were African American (2.7% Symfony; 10.6% control), Asian (0.7% Symfony; 2.0% control) and American Indian/Alaska Native (1.3% control only).

Distance Visual Acuities

Table 27 presents monocular, uncorrected and best-corrected, photopic (85 cd/m^2) distance visual acuity results for Symfony and 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%).

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TABLE 27
Monocular Distance Visual Acuity at 6 Months

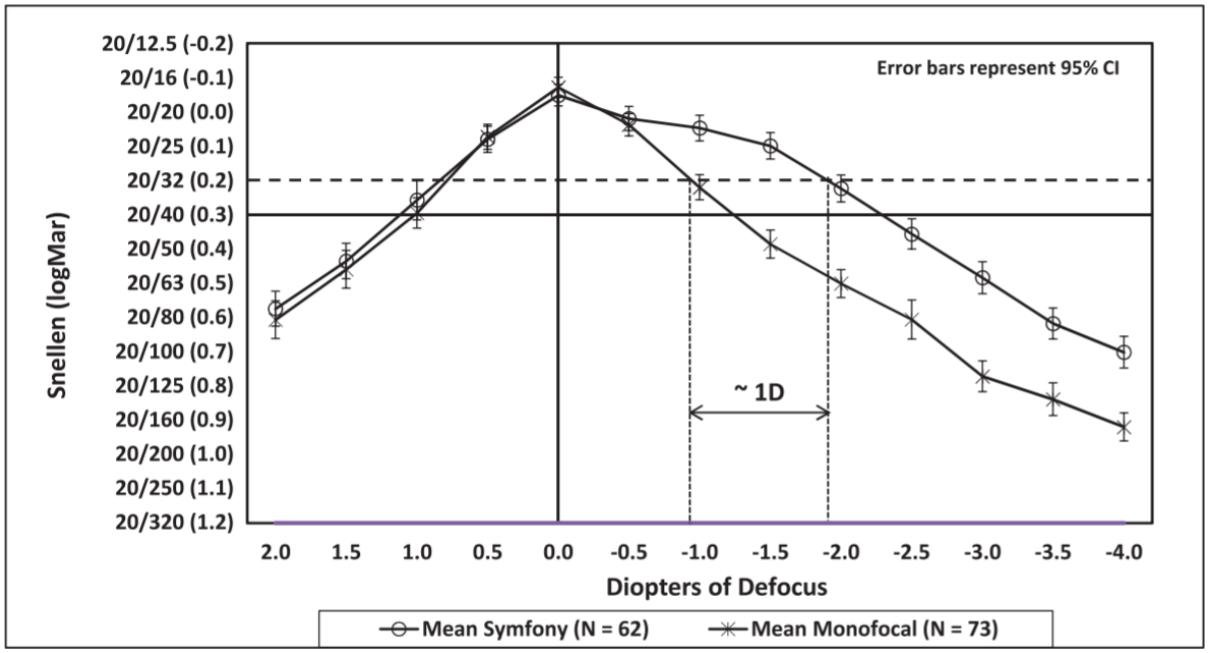
Monocular Visual Acuity	Symfony		Control	
	Uncorrected	Best Corrected	Uncorrected	Best Corrected
20/20 or better	38.8%	83.7%	47.3%	88.5%
20/25 or better	65.3%	98.0%	71.6%	96.6%
20/32 or better	87.8%	100.0%	85.1%	98.6%
20/40 or better	96.6%	100.0%	93.9%	100.0%
20/50 to 20/80	2.7%	0.0%	6.1%	0.0%
20/100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

%=(n/Total n) * 100

Depth of Focus

Figure 8 presents the binocular defocus curves for the Symfony and control groups with mean values and confidence intervals. Mean binocular acuities were 20/32 or better for the Symfony group through -2.0 D (50 cm). The binocular defocus curves demonstrate that visual acuity for the Symfony group monotonically decreased while maintaining a 1-2 line acuity difference over the control 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.

FIGURE 8
Binocular Defocus Curves at 6 Months
Symfony and Monofocal Control



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 28** and **29**, respectively.

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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 30**.

TABLE 28
6-Month Persistent Serious Adverse Events for the Symfony IOL Group

Persistent Medical Complications/ Adverse Events	ISO SPE Rate (%)	First Eyes N=147		Second Eyes N=147	
		n	%	n	%
Corneal edema	0.3	0	0.0	0	0.0
Cystoid macular edema	0.5	0	0.0	1	0.7
Iritis	0.3	0	0.0	0	0.0
Raised IOP requiring treatment	0.4	0	0.0	0	0.0

[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 is not statistically significantly higher than ISO SPE rate (p = 0.5238) using 1-sided exact test.

TABLE 29
6-Month Cumulative Serious Adverse Events for the Symfony IOL Group

Cumulative Medical Complications/ Adverse Events	ISO SPE Rate (%)	First Eyes N=148		Second Eyes N=148	
		n	%	n	%
Cystoid macular edema	3.0	1	0.7	1	0.7
Hypopyon	0.3	0	0.0	1	0.7[c]
Endophthalmitis	0.1	0	0.0	0	0.0
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	0.0	2[b]	1.4[d]
○ Device related	N/A	0	0.0	-	-
○ Not device related	N/A	0	0.0	2[b]	1.4[d]
Other: Pupillary Capture	N/A	0	0.0	1	0.7

[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] Treatment injections for Vitritis (Subject 1314) and CME (Subject 1425).
[c] Incidence rate is not statistically significantly higher than ISO SPE rate (p = 0.3590) using 1-sided exact test.
[d] Incidence rate is not statistically significantly higher than ISO SPE rate (p = 0.3318) using 1-sided exact test.

TABLE 30
Secondary Surgical Interventions for the Symfony IOL Group

Secondary Surgical Interventions[a] Not Device-Related	First Eyes N=148		Second Eyes N=148	
	n	%	n	%
Treatment injections for medical complications:	0	0.0	2	0.7
○ Cystoid macular edema	0	0.0	1	0.3
○ Endophthalmitis	0	0.0	1	0.3

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

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Optical/Visual Symptoms

The most commonly reported directed symptoms at 6 months based on a direct questionnaire (**Table 31**) were halos, starbursts, and glare for both IOL groups; halos and starbursts were reported with increased bother in the Symfony group compared with the control group.

TABLE 31
Experience/Bother with Visual Symptoms Over the Past 7 Days at 6 Months (Directed Reports)

		Symfony N=147		Control 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
	Very bothered	12	8.2	6	4.1
Glare[a]	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[a]	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)[a]	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[a]	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[a]	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 “Does not apply” and “Not Reported”.

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

[a] “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.

CLINICAL STUDY RESULTS FOR THE 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

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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 (Model CeeOn® 911A silicone IOL) 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 32** and **33** for the rural road and in **Tables 34** and **35** 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 32

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

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TABLE 33
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 34
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 35
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

CLINICAL STUDY RESULTS FOR THE TECNIS OPTIBLUE™ IOL, MODEL ZV9003

A multi-center, bilateral and double-masked study compared the clinical outcomes of the TECNIS OptiBlue™ IOL, Model ZV9003 and the control, TECNIS® Foldable Acrylic IOL, Model ZA9003. The mean best-corrected distance visual acuity, mean binocular contrast sensitivity, and color vision data were

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comparable between subjects implanted with the Model ZV9003 lens and those implanted with the control lens. Statistically significant improvements were observed 4-6 months and one year postoperatively in favor of the Model ZV9003 lens in subjective ratings for reduced difficulty with daytime driving.

A total of 250 subjects (ZV9003 lens group=126, control lens group=124) were enrolled. The subject population consisted of more females than males in both lens groups, with 61.9% females in the test group and 54.8% females in the control group. The subjects in the ZV9003 group were slightly older (mean age=73.3 years) than those in the control group (mean age=71.5 years). Majority of subjects were Caucasian in both lens groups (96.0% in the ZV9003 group, 96.8% in the control group). The remainder of subjects were Black (2.4% in the ZV9003 group, 2.4% in the control group), Asian (0.0% in the ZV9003 group, 0.8% in the control group), and 'Other' (1.6% in the ZV9003 group, 0.0% in the control group).

Best-Corrected Distance Visual Acuity

At one year, 100% of ZV9003 first eyes and 99.2% of ZV9003 second eyes were 20/40 or better for best-corrected distance visual acuity, exceeding the FDA grid rate of 92.5%. At one year, all best-case ZV9003 first eyes achieved a best-corrected visual acuity of 20/40 or better, exceeding the FDA grid rate of 96.7%. The postoperative best-corrected distance visual acuity results for the best-case patients at one year are provided in **Table 36**. In addition, the data 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
ZV9003 First Eyes, Best-Case Subjects[a] (N=113)

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	4	4	100.0	0	0.0	0	0.0	0	0.0
60 to 69	32	30	93.8	2	6.3	0	0.0	0	0.0
70 to 79	51	41	80.4	10	19.6	0	0.0	0	0.0
>80	26	18	69.2	8	30.8	0	0.0	0	0.0
Total	**113**	**93**	**82.3**	**20**	**17.7**	**0**	**0.0**	**0**	**0.0**

[a] Best-case was defined as eyes without clinically significant preoperative pathology, sulcus implantation, contralateral implantation, macular degeneration at any time, or other significant macular pathology (e.g., macular hole).

TABLE 37
Best-Corrected Distance Visual Acuity (Snellen Equivalent) at 1 Year
ZV9003 Best-Case Subjects[a] (N = 113) vs. FDA Grid

Age Decade	N	Total %	20/40 or Better N	20/40 or Better %	FDA Grid %
< 60	4	3.54%	4	100.0	98.5
60 to 69	32	28.32%	32	100.0	96.5
70 to 79	51	45.13%	51	100.0	97.5
> 80	26	23.01%	26	100.0	94.8
Total	**113**	**100.0**	**110**	**100.0**	**96.7**

[a] Best-case was defined as eyes without clinically significant preoperative pathology, sulcus implantation, contralateral implantation, macular degeneration at any time, or other significant macular pathology (e.g., macular hole).

Color Vision

As part of the inclusion criteria, all subjects underwent binocular color vision testing using the Ishihara color test and the Farnsworth-Munsell D-15 color vision test. Farnsworth-Munsell D-15 color testing was performed again at the 4-6 month and one-year postoperative visits. At 4-6 months, 98.3% (119/121) of subjects implanted with the ZV9003 lens and 99.2% (118/119) of subjects implanted with the control lens

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passed the color vision test. At one year, 99.2 (118/119) of subjects implanted with the ZV9003 lens and 95.8% (115/120) of subjects implanted with the control lens passed the color vision test (**Table 38**).

TABLE 38
Farnsworth-Munsell D-15 Color Vision Test at 4-6 Months and One Year

Color Vision Test	ZV9003 4-6 Months (N=121)	ZV9003 One Year (N=119)	Control 4-6 Months (N=119)	Control One Year (N=120)
Pass	98.3%	99.2%	99.2%	95.8%
Perfect (no errors)	95.0%	97.5%	93.2%	96.5%
Not Perfect (1 major error and minor errors)	5.0%	2.5%	6.8%	3.5%
Fail (≥2 major errors)	1.7%	0.8%	0.8%	4.2%

A statistically significant difference was observed between lens groups for driving during the day at 4-6 months (p=0.0044) and at one year (p=0.0330). Subjects implanted with ZV9003 reported less difficulty driving during the day, compared to subjects implanted with the control lens (**Table 39**).

TABLE 39
Subject Assessment of Driving During Daytime, 4-6 Months and One Year Directed Responses to a Subjective Questionnaire

Driving During Daytime	4 to 6 Months[a] ZV9003 N=121	4 to 6 Months[a] Control N=120	One Year[b] ZV9003 N=119	One Year[b] Control N=120
No difficulty at all	100.0%	92.9%	98.1%	91.7%
A little difficulty	0.0%	5.4%	0.9%	8.3%
Moderate difficulty	0.0%	1.8%	0.0%	0.0%
Extreme difficulty	0.0%	0.0%	0.9%[c]	0.0%

[a] Statistically significant difference (p=0.0044) at 4-6 months, based on Wilcoxon Rank-Sum test
[b] Statistically significant difference (p=0.0330) at one year, based on Wilcoxon Rank-Sum test
[c] One subject implanted with ZV9003 had difficulty driving during the daytime preoperatively and at one year, which may not be lens-related. The subject's visual acuity was excellent at the one-year visit, and there were no other issues.

Adverse Events

The incidence of adverse events reported during the clinical trial for the TECNIS OptiBlue™ IOL is similar to or less than that of the historic control population (FDA Grid for posterior chamber IOLs) as shown in **Tables 40** and **41**. There were no persistent adverse events reported during the study. The incidence rates for the Model ZV9003 lens compared favorably to the specified FDA rates.

TABLE 40
Adverse Events, TECNIS OptiBlue™ IOL, Model ZV9003, First Eyes (N = 126)

Cumulative Adverse Event	Study Eyes n	Study Eyes %	FDA Grid Rate %
Subjects with no Adverse Events	**126**	**100.0**	**N/A**
Subjects with Adverse Events	**0**	**0.0**	**N/A**
○ Cystoid Macular Edema (CME)	0	0.0	3.0
○ Secondary Surgical Intervention	0	0.0	0.8
○ Endophthalmitis	0	0.0	0.1
○ Hyphema	0	0.0	2.2
○ Hypopyon	0	0.0	0.3
○ Lens Dislocation	0	0.0	0.1
○ Pupillary Block	0	0.0	0.1
○ Retinal Detachment	0	0.0	0.3

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TABLE 41
Adverse Events, TECNIS OptiBlue™ IOL, Model ZV9003, Second Eyes (N = 126)

Cumulative Adverse Event	Study Eyes		FDA Grid Rate
	n	%	%
Subjects with no Adverse Events	**125**	**99.2**	**N/A**
Subjects with Adverse Events	**1**	**0.8**	**N/A**
○ Cystoid Macular Edema (CME)	0	0.0	3.0
○ Secondary Surgical Intervention	1	0.8	0.8
○ Endophthalmitis	0	0.0	0.1
○ Hyphema	0	0.0	2.2
○ Hypopyon	0	0.0	0.3
○ Lens Dislocation	0	0.0	0.1
○ Pupillary Block	0	0.0	0.1
○ Retinal Detachment	0	0.0	0.3

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 42**. In addition, the results compared to the FDA Grid values (historical control) are presented in **Table 43**.

TABLE 42
SENSAR Model AAB00 IOL (upon which TECNIS Synergy IOL is based)
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 to 69	35	29	82.9	6	17.1	0	0.0	0	0.0
70 to 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 43
SENSAR Model AAB00 IOL (upon which TECNIS Synergy IOL is based):
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 to 69	35	31.8	35	100.0	96.5
70 to 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.

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CLINICAL STUDY RESULTS FOR THE SENSAR® IOL, MODEL AAB00

The acrylic SENSAR® 1-piece IOL, 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 SENSAR® 1-piece IOL, 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.

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 44**.

TABLE 44
SENSAR Model AAB00 IOL (upon which TECNIS Synergy IOL is based):
Adverse Events
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).

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, and the range of near vision with TECNIS Synergy IOL allows for the selection of an IOL power that predicts the least hyperopic residual refraction. Accuracy of IOL power calculation is particularly important with the TECNIS Synergy™ IOLs and TECNIS Synergy™ Toric II IOLs, as reduced eyeglass wear is the goal of IOL implantation. The A-constants listed on the outer label are presented as a guideline and serve as a starting point for power calculations. The physician should preoperatively determine the spherical equivalent and cylindrical power of the lens to be implanted.

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For TECNIS Synergy™ IOLs: Use of the Johnson & Johnson Surgical Vision, Inc. provided TECNIS® Toric IOL Calculator tool is recommended for determining the appropriate TECNIS Synergy™ Toric II IOL model, optimal axis of IOL placement and cylinder power. The TECNIS Synergy™ Toric II IOL is labeled with the IOL distance spherical equivalent power. Physicians requiring additional information on lens power calculations may contact the local Johnson & Johnson Surgical Vision, Inc. representative.

Lens power calculation methods are described in the following references:

- Barrett, Graham D. "An improved universal theoretical formula for intraocular lens power prediction." *Journal of Cataract & Refractive Surgery* 19.6 (1993): 713-720.
- Canovas, Carmen, and Pablo Artal. "Customized eye models for determining optimized intraocular lenses power." *Biomedical optics express* 2.6 (2011): 1649-1662.
- Haigis Wolfgang. "The Haigis Formula." Shammas, H. John. *Intraocular Lens Power Calculations*. Slack Incorporated, 2004.
- Hoffer, Kenneth J. "The Hoffer Q formula: a comparison of theoretic and regression formulas." *Journal of Cataract & Refractive Surgery* 19.6 (1993): 700-712.
- Holladay, Jack T., et al. "A three-part system for refining intraocular lens power calculations." *Journal of Cataract & Refractive Surgery* 14.1 (1988): 17-24.
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- Norrby, Sverker NE. "Unfortunate discrepancies." *Journal of Cataract & Refractive Surgery* 24.4 (1998): 433.
- Olsen T. "The Olsen formula." Shammas, H. John. *Intraocular Lens Power Calculations*. Slack Incorporated, 2004.
- Retzlaff, John A., Donald R. Sanders, and Manus C. Kraff. "Development of the SRK/T intraocular lens implant power calculation formula." *Journal of Cataract & Refractive Surgery* 16.3 (1990): 333-340.

- Barrett, Graham D. "An improved universal theoretical formula for intraocular lens power prediction." *Journal of Cataract & Refractive Surgery* 19.6 (1993): 713-720.
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- Norrby, Sverker NE. "Unfortunate discrepancies." *Journal of Cataract & Refractive Surgery* 24.4 (1998): 433.
- Olsen T. "The Olsen formula." Shammas, H. John. *Intraocular Lens Power Calculations*. Slack Incorporated, 2004.
- Retzlaff, John A., Donald R. Sanders, and Manus C. Kraff. "Development of the SRK/T intraocular lens implant power calculation formula." *Journal of Cataract & Refractive Surgery* 16.3 (1990): 333-340.

SELECTION AND PLACEMENT OF THE TECNIS SYNERGY™ TORIC II IOLS

The astigmatism to be corrected should be determined from keratometry and biometry rather than refractive data since the presence of lenticular astigmatism in the crystalline lens to be removed may influence results. The size and location of the surgical incision may affect the amount and axis of corneal astigmatism. To facilitate IOL selection and placement, Johnson & Johnson Surgical Vision, Inc. provides a web-based proprietary tool, the TECNIS® Toric IOL Calculator (www.TecnisToricCalc.com) for the surgeon. The corneal astigmatism to be corrected at the time of surgery is calculated by the TECNIS® Toric IOL Calculator using vector summation of the preoperative corneal astigmatism and the expected surgically

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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.

The TECNIS® Toric Calculator also provides an option for including the Posterior Corneal Astigmatism (PCA) (where available). The predetermined value for posterior corneal astigmatism can be included in the calculation by checking the box labeled “Include Posterior Corneal Astigmatism (PCA)”. The option to include the predetermined value of PCA is based on an algorithm that combines published literature (Koch, et al. “Contribution of posterior corneal astigmatism to total corneal astigmatism.” J Cataract Refract Surg. 2012 Dec;38(12):2080-7) with a retrospective analysis of existing clinical data.

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 Synergy™ Toric II IOL 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 Synergy™ Toric II 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 IOL 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 Synergy™ Toric II 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 IOL 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 Synergy™ Toric II 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 Synergy™ Toric II 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 Synergy™ Toric II 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 Synergy™ Toric II IOL axis during surgery, an unanticipated surgically induced change in the cornea, or physical rotation of the TECNIS Synergy™ Toric II 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.

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DIRECTIONS FOR USE:

1. Prior to opening the outer box, examine the outer box label for lens model, dioptric power or dioptric spherical equivalent (SE) and cylinder power, proper configuration and expiration date.
2. After opening the outer box of the TECNIS Synergy™ IOL with TECNIS Simplicity™ Delivery System, examine the device package for any damage, and verify that information on the device (lens model, dioptric power or dioptric (SE) and cylinder power, and serial number) is consistent with the information on the outer box label.
3. Open the peel pouch and remove the delivery system in the tray. Place the tray on the sterile environment. Do not use the device if the pouch is damaged or the seal is broken. If the device is defective in any way, use another delivery system.
4. Use BSS or OVD as a hydration method using a cannula. Insert the cannula into the hydration port and fill the cartridge completely from cartridge tip to hydration port without filling the lens case (Figures 9 & 10). Proceed to step 5 once completed.
5. Carefully remove the delivery system from the tray. Do not touch the tip of the delivery system during removal as this may damage the tip. Inspect the tip to ensure that it is not damaged.
6. Quickly advance the plunger forward in a continuous motion (for example less than 1 second) until it stops at the threads (Figure 11). Do not stop or reverse while advancing the plunger.
7. Rotate the knob half a turn clockwise to place the lens in the holding position (Figure 12). Do not move the plunger forward until ready for lens implantation. Dwell the lens in this position for 0 to 10 minutes. To minimize haptic release time, a minimum of 3 minutes is recommended. If left for more than 10 minutes, then do not use device.
8. Proceed with the lens implantation by inserting the delivery system tip into the incision with the bevel of the tip oriented downwards. Rotate the knob of the plunger clockwise to slowly advance the lens forward. Lens must be delivered within 1 minute. Continue to rotate the plunger knob until the lens is fully released from the delivery system tip.
9. Rotate the knob of the plunger counter-clockwise to slowly retract the plunger.
10. Discard the device. Do not re-use the delivery system.
11. 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 in the capsular bag.
12. Carefully remove all viscoelastic from the capsular bag and if implanting a TECNIS Synergy™ Toric II IOL, align the lens with the intended axis of placement, following the recommendations provided in the “Selection and Placement” section for the TECNIS Synergy™ Toric II IOLs.

<u>Factors to consider in deciding whether to implant a TECNIS Synergy™ Toric II IOL:</u>
Effectiveness of implanting a toric IOL 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.
- The clinical data presented in Table 17 represent outcomes that include the sources of variation listed above.

CAUTION:

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

PATIENT REGISTRATION (U.S. Only)
Each patient who receives a TECNIS Synergy™ IOL must be registered with Johnson & Johnson Surgical Vision. Inc. 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 Johnson & Johnson Surgical Vision, Inc. Patient registration is essential for Johnson & Johnson Surgical Vision's long term patient follow-up program and will assist Johnson & Johnson Surgical Vision, Inc. 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 his/her implant and to show the card to any eye care practitioner he/ she may see 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 Johnson & Johnson Surgical Vision, Inc. 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
Each lens is supplied sterile and preloaded in the delivery system within a single aseptic transfer peel pouch. The single 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 pouch are not sterile. The recommended storage temperature is 25°C (77°F).

EXPIRATION DATE
The use-by date on the device is the sterility expiration date. The delivery system shall not be used, and the lens shall not be implanted after the indicated sterility expiration date.

RETURN/EXCHANGE POLICY
Contact the local Johnson & Johnson Surgical Vision, Inc. 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, including information on different IOL options available to them, prior to the decision to implant an intraocular lens.

SYMBOL/EXPLANATION:

SYMBOL	EXPLANATION
	Sterilized using ethylene oxide Do not re-use Use-by (YYYY-MM-DD: Year-Month-Day)

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	Consult instructions for use
	Manufacturer
	Do not resterilize
35°C (95°F) 5°C (41°F)	Temperature limit
	Keep away from sunlight
	Date of manufacture (YYYY-MM-DD: Year-Month-Day)
	Do not use if package is damaged
REF	Catalogue number
SN	Serial number

PRODUCT OF THE NETHERLANDS
AMO Groningen B.V., van Swietenlaan 5, 9728 NX Groningen, The Netherlands

Johnson & Johnson Surgical Vision, Inc.,
1700 E. St. Andrew Place
Santa Ana, CA 92705 USA
Toll-free (800) 366-6554

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Figure 9

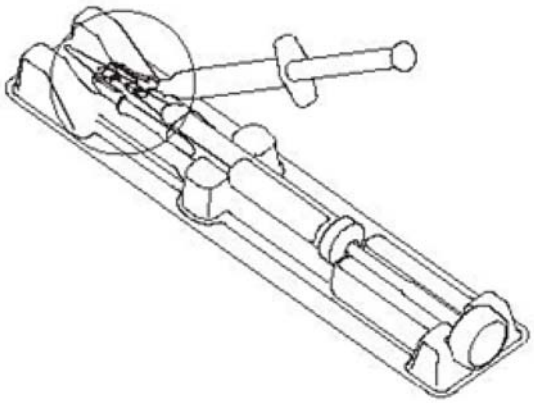

Figure 10

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Figure 11

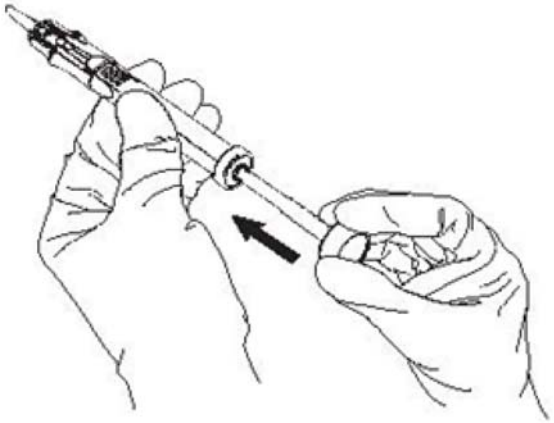
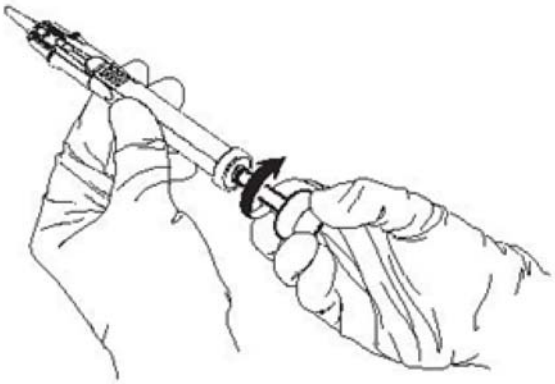


Figure 12



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TECNIS Synergy™ Intraocular Lens
TECNIS Synergy™ Toric II Intraocular Lens

Z311413E Rev. A

Revision Date: MM/YYYY

Rx Only

DEVICE DESCRIPTION

The TECNIS Synergy™ Intraocular Lens (IOL), Model ZFR00V, and the TECNIS Synergy™ Toric II IOL, Model Series ZFW (ZFW150, ZFW225, ZFW300, and ZFW375), are ultraviolet (UV) and violet light-filtering posterior chamber IOLs that are to be positioned in the lens capsule to replace the optical function of the natural crystalline lens. Accommodation will not be restored. In addition, the toric IOLs compensate for corneal astigmatism.

The TECNIS Synergy™ IOLs mitigate the effects of presbyopia by providing far vision comparable to an aspheric monofocal IOL, and continuous 20/32 or better visual acuity through at least -3.0 D of defocus, which corresponds to distances ranging from approximately 33 cm to infinity. Compared to an aspheric monofocal IOL, the lens provides significantly improved near vision, including in low-light conditions. The TECNIS Synergy™ IOLs demonstrated pupil-independent lens performance among the pupil sizes tested (>2.5 mm). In addition, the toric IOLs achieved the ANSI Standard for Toric IOLs, Z80.30, rotational stability requirement (>90% of eyes having ≤5° axis change between consecutive visits).

The lens has an overall diameter of 13.0 mm and an optic diameter of 6.0 mm. The lens consists of a soft acrylic material with UVAM (a supplemental UV light-absorbing material) and proprietary violet light-filtering chromophore, which reduces transmittance of violet light wavelengths. The biconvex optic incorporates a proprietary wavefront-designed aspheric or toric-aspheric anterior surface to reduce corneal spherical aberration to near-zero. The posterior edge of the anterior optic is squared to provide a 360-degree barrier and is frosted to reduce potential edge glare effects. In addition, the haptics of the TECNIS Synergy™ Toric II IOL Model Series ZFW have a squared and frosted design. The posterior optic of the lens has a proprietary diffractive surface derived from a combination of extended depth of focus and multifocal technologies and is designed to correct chromatic aberration and to provide a range of vision from distance to intermediate to near. The anteriorly located cylinder axis marks in the toric-aspheric optic denote the meridian with the lowest power and are to be aligned with the steep corneal meridian.

INDICATIONS FOR USE

TECNIS Synergy™ IOL, Model ZFR00V

The TECNIS Synergy™ IOL, Model ZFR00V, 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. Compared to an aspheric monofocal lens, the TECNIS Synergy IOL mitigates the effects of presbyopia by providing improved visual acuity at intermediate and near distances to reduce eyeglass wear, while maintaining comparable distance visual acuity. The lens is intended for capsular bag placement only.

TECNIS Synergy™ Toric II IOL, Models ZFW150, ZFW225, ZFW300, ZFW375

The TECNIS Synergy™ Toric II IOL, Models ZFW150, ZFW225, ZFW300, ZFW375, are indicated for primary implantation for the visual correction of aphakia and for the reduction of 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. Compared to an aspheric monofocal lens, the TECNIS Synergy Toric II IOLs mitigate the effects of presbyopia by providing improved visual acuity at intermediate and near

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distances to reduce eyeglass wear, while maintaining comparable distance visual acuity. The lens is intended for capsular bag placement only.

CONTRAINDICATIONS

There are no known contraindications.

PRECAUTIONS

1. When performing refraction in patients implanted with the TECNIS Synergy™ IOLs, 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 strongly recommended.
2. The ability to perform some eye treatments (e.g., retinal photocoagulation) may be affected by the IOL optical design.
3. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution.
4. Do not store the lens in direct sunlight or at a temperature greater than 113°F (45°C).
5. Please refer to the specific instructions for use provided with the insertion instrument or system for the amount of time the IOL can remain folded before the IOL must be discarded. In addition, if the insertion system is used improperly, the haptics of the IOL may become broken.
6. 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.
7. The surgeon should target emmetropia as this lens is designed for optimum visual performance when emmetropia is achieved.
8. Care should be taken to achieve centration of the intraocular lens in the capsular bag.
9. Prior to surgery, the surgeon must inform prospective patients of the possible risks and benefits associated with the use of the device and provide them a copy of the patient information brochure.
10. Children under the age of 2 years are not suitable candidates for intraocular lenses.
11. The TECNIS Synergy™ IOLs should not be placed in the ciliary sulcus.
12. Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case. Residual viscoelastic and/or over-inflation of the capsular bag may allow the lens to rotate, causing misalignment of the TECNIS Synergy™ Toric II IOL with the intended axis of placement.
13. The TECNIS Toric IOL Calculator includes a feature that accounts for posterior corneal astigmatism (PCA). The PCA is based on an algorithm that combines published literature (Koch, et al., 2012) and a retrospective analysis of data from a TECNIS® Toric IOL multi-center clinical study. The PCA algorithm for the selection of appropriate cylinder power and axis of implantation was not assessed in the prospective TECNIS® Toric IOL U.S. IDE study and may yield results different from those in the TECNIS Synergy™ Toric II IOL labeling. Please refer to the TECNIS Toric IOL Calculator user manual for more information.
14. The use of methods other than the TECNIS Toric IOL Calculator to select cylinder power and appropriate axis of implantation were not assessed in the 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 IOL Calculator (www.TecnisToricCalc.com) are recommended to achieve optimal visual outcomes for the TECNIS Synergy™ Toric II IOL.
15. All preoperative surgical parameters are important when choosing a TECNIS Synergy™ Toric II IOL for implantation, including preoperative keratometric cylinder (magnitude and axis), incision location, the 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. The effectiveness of TECNIS Synergy™ Toric II

IOLs in reducing postoperative residual astigmatism in patients with preoperative corneal astigmatism < 1.0 diopter has not been demonstrated.

16. Patients with a predicted postoperative astigmatism greater than 1.0 D may not be suitable candidates for implantation with the TECNIS Synergy and TECNIS Synergy Toric IOLs, as they may not obtain the benefits of reduced spectacle wear or improved intermediate and near vision seen in patients with lower astigmatism.
17. All corneal incisions were placed temporally in the 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 for the TECNIS® Toric IOL. Note that the TECNIS Toric IOL Calculator incorporates the surgeon's estimated SIA and incision location when providing IOL options.
18. Do not reuse and do not resterilize.
19. The safety and effectiveness of the TECNIS Synergy IOL have not been substantiated in patients under the age of 22 or those with preexisting ocular conditions and intraoperative complications, including those specified in the Warnings and Precautions, such as pupil abnormalities, prior corneal refractive or intraocular surgery, acute or chronic ophthalmic diseases or conditions (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

Potential complications generally associated with cataract surgery include, but are not limited to: endophthalmitis/intraocular infection, hypopyon, hyphema, IOL dislocation, persistent cystoid macular edema, pupillary block, retinal detachment/tear, persistent corneal stromal edema, persistent uveitis, persistent raised intraocular pressure (IOP) requiring treatment (e.g., AC tap), retained lens material, or toxic anterior segment syndrome, or any other adverse event that leads to permanent visual impairment or requires surgical or medical intervention to prevent permanent visual impairment.

Adverse events that may be associated with use of the device include: IOL dislocation, tilt or decentration, visual symptoms requiring lens removal, residual refractive error, secondary surgical intervention (including IOL repositioning or removal).

WARNINGS

1. Intraocular lenses may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition or may pose an unreasonable risk to the eyesight of patients with:
    a. Recurrent severe anterior or posterior segment inflammation of unknown etiology
    b. Posterior segment diseases of which monitoring or treatment ability may be limited by an intraocular lens
    c. Surgical difficulties at the time of cataract extraction and/or intraocular lens implantation that might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss)
    d. Compromised posterior capsule or zonules due to previous trauma or developmental defect in which appropriate support of the IOL is not possible
    e. Risk of damage to the endothelium during implantation
    f. Suspected microbial infection
    g. Congenital bilateral cataracts
    h. Previous history of, or a predisposition to, retinal detachment
    i. Potentially good vision in only one eye
    j. Medically uncontrollable glaucoma
    k. Corneal endothelial dystrophy
    l. Proliferative diabetic retinopathy.
2. Patients should have well-defined visual needs and be informed of possible visual effects (such as a perception of halo, starbursts or glare around lights), which may be expected in nighttime or poor visibility conditions. Patients may perceive these visual effects as bothersome, which, on rare occasions, may be significant enough for the patient to request removal of the IOL.
3. A reduction in contrast sensitivity compared to an aspheric monofocal IOL may be experienced by some patients under certain conditions. The physician should carefully weigh the potential risks and benefits for each patient, with special consideration of potential visual problems before implanting the lens in patients including those with macular disease, amblyopia, corneal irregularities, or other ocular disease that may cause present or future reduction in acuity or contrast sensitivity, and should fully inform the patient of the potential for reduced contrast sensitivity and to exercise caution when driving at night or in poor visibility conditions after implantation.
4. Johnson & Johnson Surgical Vision, Inc. single-use medical devices are labeled with instructions for use and handling to minimize exposure to conditions that may compromise the product, patient, or the user. The re-use/resterilization/reprocessing of Johnson & Johnson Surgical Vision, Inc. single-use devices may result in failure of the medical device to perform as intended.
5. Patients with a predicted postoperative residual astigmatism greater than 1.0 diopter, with or without a toric lens, may not fully benefit in terms of reducing spectacle wear.
6. Rotation of the TECNIS Synergy™ Toric II IOL from its intended axis can reduce its 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.

TECHNICAL SPECIFICATIONS

Lens Optic

- Material: Optically clear, soft foldable hydrophobic acrylic with UVAM, UV, and violet light-filtering chromophores*
- Power: +5.0 to +34.0 diopter powers in 0.5-diopter increments
- Cylinder Power, toric lens models ZFW150, ZFW225, ZFW300, and ZFW375: 1.50 diopters, 2.25 diopters, 3.00 diopters, and 3.75 diopters (as measured at the IOL plane)
- Optic Center Thickness: 0.7 mm (+20.0D)
- Optic Edge Design: PROTEC 360 square posterior edge
- Index of Refraction: 1.47 at 35°C
- Light Transmittance: UV cut-off at 10% T for a spherical equivalent (SE) +5.0 diopter lens (thinnest), SE +20.0 diopter lens and a SE +34.0 diopter lens (thickest) are shown in **Figure 1**

*The TECNIS Synergy™ IOLs may appear slightly blue on the anterior surface under slit lamp examination, which is not detectable by patients. The violet light filter has not been shown to provide retinal phototoxicity protection.

Conversion table for cylinder powers:

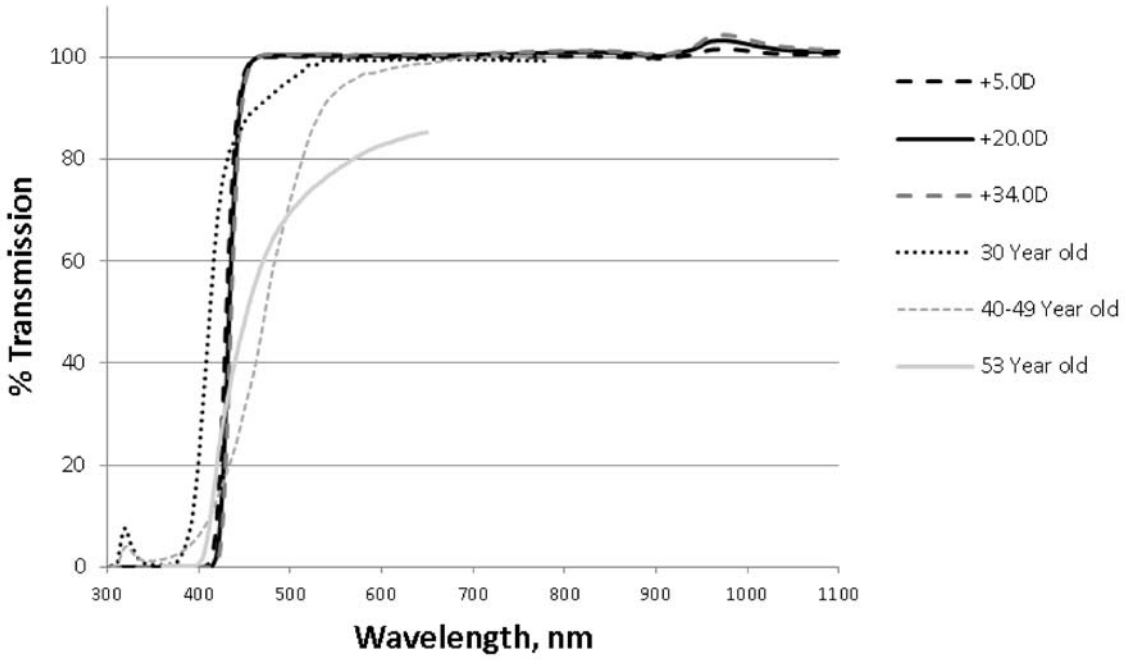
IOL Model	Cylinder Power (D)	
	IOL Plane (Labeled)	Corneal Plane*
ZFW150	1.50	1.03
ZFW225	2.25	1.54
ZFW300	3.00	2.06
ZFW375	3.75	2.57

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

Haptics

1. Material: Soft foldable acrylic with UVAM, UV, and violet light-filtering chromophores
2. One-piece lens
3. Configuration: TRI-FIX design Modified C, integral with optic
4. Haptic thickness: 0.46 mm

Figure 1



Legend:
Spectral transmittance curve of a typical 5-diopter IOL (thinnest). UV(420): UV cut-off at 10%T is 420 nm.
Spectral transmittance curve of a typical 20-diopter IOL. UV(424): UV cut-off at 10%T is 424 nm.
Spectral transmittance curve of a typical 34-diopter IOL (thickest). UV(426): UV cut-off at 10%T is 426 nm.
Spectral transmittance curve of crystalline lenses: 30 year old and 40-49 year old from Artigas, J.M., Felipe, A., Navea, A., Fandino, A., & Artigas, C. Spectral transmission of the human crystalline lens in adult and elderly persons: color and total transmission of visible light. Invest Ophthalmol Vis Sci (2012);53(7):4076-4084. 53 year old from Boettner, E.A., and Wolter J.R. Transmission of the Ocular Media. Investigative Ophthalmology. 1962;1:776-783.

CLINICAL STUDY RESULTS FOR THE TECNIS SYNERGY™ IOL, MODEL ZFR00V

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 Synergy™ IOL, Model ZFR00V, compared to the aspheric monofocal control IOL, TECNIS® Monofocal 1-Piece IOL, Model ZCB00. The primary effectiveness endpoint was the mean monocular, photopic, distance-corrected near visual acuity (VA) at 40 cm. The five secondary effectiveness endpoints were mean monocular, photopic, distance-corrected intermediate VA at 66 cm, distance-corrected near VA at 33 cm, best-corrected distance (far) VA, distance-corrected defocus curve, and spectacle wear at distance (far), intermediate, near and overall, reported via questionnaire. The safety endpoints were the rates of secondary surgical interventions related to optical properties of the lens, adverse events vs. ISO Safety Performance and Effectiveness (SPE) rates, rate of monocular best-corrected distance VA of 20/40 or better vs. ISO SPE rates as well as monocular and binocular best-corrected distance contrast sensitivity.

The clinical study results achieved at 6-months postoperative demonstrate that the TECNIS Synergy™ IOL was safe and effective for the visual correction of aphakia and provided improved distance-corrected intermediate and near vision while demonstrating distance vision to be non-inferior to that of the aspheric monofocal control lens, an increased range of vision (distance to intermediate to near), decreased spectacle wear when compared to the monofocal control IOL, and low rates of adverse events.

NOTE: For this clinical summary and the associated data tables, “Synergy” or “TECNIS Synergy” refers to the TECNIS Synergy™ IOL, Model ZFR00V, and “control” or “TECNIS monofocal” refers to the TECNIS®

Monofocal 1-Piece IOL, Model ZCB00. "N" denotes the total number of eyes/subjects who were present at a given visit, and "n" denotes the number of eyes/subjects with measurement data available.

Subject Population

Of the 272 subjects enrolled and implanted in the study, 135 were in the Synergy group (135 bilaterally implanted) and 137 were in the control group (137 bilaterally implanted). Subject demographics were similar between the Synergy and control groups. The mean age was 68.5 ±7.1 years for the Synergy group and 68.5 ±7.7 years for the control group. The majority of subjects in both lens groups were female (69.6% Synergy; 65.7% control), and most subject in both lens groups identified as White (84.4% of Synergy subjects and 84.7% of control). The remainder of subjects identified as African American (11.1% Synergy; 13.9% control), Asian (2.2% Synergy; 0.7% control), Native Hawaiian/Pacific Islander (0.7% Synergy only) and Other Race (1.5% Synergy; 0.7% control). There were no statistically significant differences in demographics between lens groups.

Distance (Far) Visual Acuity

Distance visual acuities were tested at 4.0 m under photopic (85 cd/m^2) lighting conditions. **Table 1** presents mean monocular and binocular distance visual acuities at 6 months for Synergy and control groups. Monocular BCDVA was comparable between the Synergy and control groups, with mean Snellen equivalents of 20/19 and 20/18, respectively. Additionally, the lower limit of the 95% confidence interval (CI) of the mean difference in BCDVA between IOL groups was -0.053 LogMAR (-0.1 LogMAR non-inferiority margin), demonstrating that the Synergy IOL is non-inferior to the control lens in providing best-corrected distance visual acuity.

TABLE 1
Mean Distance (Far) Visual Acuity at 6 Months

		Monocular					Binocular				
Distance Visual Acuity	**Lens Group**	**N**	**n**	**Mean LogMAR**	**Snellen Equiv.**	**Line Change vs. Control[a]**	**N**	**n**	**Mean LogMAR**	**Snellen Equiv.**	**Line Change vs. Control[a]**
Uncorrected	TECNIS Synergy	131	131	0.090	20/25	**-0.4 lines**	131	131	0.023	20/21	**-0.5 lines**
	TECNIS monofocal	131	130	0.052	20/23		131	130	-0.028	20/19	
Best Corrected	TECNIS Synergy	131	131	-0.014	20/19	**-0.3 lines[b]**	131	131	-0.056	20/18	**-0.3 lines**
	TECNIS monofocal	131	130	-0.045	20/18		131	130	-0.086	20/16	

[a] Line difference (control minus Synergy) is converted directly from LogMAR difference.

[b] Synergy met the secondary study endpoint for statistically non-inferiority to the control (Safety population).

The distributions of monocular distance visual acuity for Synergy and control first eyes at 6 months are presented in **Tables 2A** and **2B**. The proportion of Synergy first eyes achieving monocular best-corrected distance visual acuity (BCDVA) of 20/40 or better (100.0%) was above the ISO Safety and Performance Endpoint (SPE) rates for BCDVA. The distributions of binocular distance visual acuity for Synergy and control subjects at 6 months are presented in **Tables 3A** and **3B**.

TABLE 2A
Distribution of Monocular Distance (Far) Visual Acuity at 6 Months

Monocular Snellen Visual Acuity	TECNIS Synergy				TECNIS monofocal			
	Uncorrected N=131		Best Corrected N=131		Uncorrected N=131		Best Corrected N=131	
	n	%	n	%	n	%	n	%
20/20^{-2} or better	50	38.2%	105	80.2%	72	55.4%	115	88.5%
20/25^{-2} or better	93	71.0%	127	96.9%	107	82.3%	126	96.9%
20/32^{-2} or better	115	87.8%	130	99.2%	121	93.1%	130	100.0%
20/40^{-2} or better	128	97.7%	131	100.0%	126	96.9%	130	100.0%
Worse than 20/40^{-2}	3	2.3%	0	0.0%	4	3.1%	0	0.0%
Total n	**131**		**131**		**130**		**130**	

%=(n/Total n) * 100

TABLE 2B
Distribution of Monocular Distance (Far) Visual Acuity at 6 Months

Monocular LogMAR Visual Acuity	TECNIS Synergy				TECNIS monofocal			
	Uncorrected N=131		Best Corrected N=131		Uncorrected N=131		Best Corrected N=131	
	n	%	n	%	n	%	n	%
0.00 LogMAR or better	33	25.2%	88	67.2%	55	42.3%	102	78.5%
0.10 LogMAR or better	76	58.0%	122	93.1%	92	70.8%	121	93.1%
0.20 LogMAR or better	106	80.9%	130	99.2%	116	89.2%	129	99.2%
0.30 LogMAR or better	126	96.2%	131	100.0%	124	95.4%	130	100.0%
Worse than 0.30 LogMAR	5	3.8%	0	0.0%	6	4.6%	0	0.0%
Total n	**131**		**131**		**130**		**130**	

%=(n/Total n) * 100

TABLE 3A
Distribution of Binocular Distance (Far) Visual Acuity at 6 Months

Binocular Snellen Visual Acuity	TECNIS Synergy				TECNIS monofocal			
	Uncorrected N=131		Best Corrected N=131		Uncorrected N=131		Best Corrected N=131	
	n	%	n	%	n	%	n	%
20/20^{-2} or better	88	67.2%	118	90.1%	105	80.8%	119	91.5%
20/25^{-2} or better	113	86.3%	130	99.2%	123	94.6%	129	99.2%
20/32^{-2} or better	127	96.9%	130	99.2%	127	97.7%	130	100.0%
20/40^{-2} or better	129	98.5%	131	100.0%	129	99.2%	130	100.0%
Worse than 20/40^{-2}	2	1.5%	0	0.0%	1	0.8%	0	0.0%
Total n	**131**		**131**		**130**		**130**	

%=(n/Total n) * 100

TABLE 3B
Distribution of Binocular Distance (Far) Visual Acuity at 6 Months

Binocular LogMAR Visual Acuity	TECNIS Synergy				TECNIS monofocal			
	Uncorrected N=131		Best Corrected N=131		Uncorrected N=131		Best Corrected N=131	
	n	%	n	%	n	%	n	%
0.00 LogMAR or better	67	51.1%	108	82.4%	88	67.7%	116	89.2%
0.10 LogMAR or better	105	80.2%	130	99.2%	118	90.8%	128	98.5%
0.20 LogMAR or better	123	93.9%	130	99.2%	126	96.9%	130	100.0%
0.30 LogMAR or better	129	98.5%	131	100.0%	128	98.5%	130	100.0%
Worse than 0.30 LogMAR	2	1.5%	0	0.0%	2	1.5%	0	0.0%
Total n	**131**		**131**		**130**		**130**	

%=(n/Total n) * 100

Intermediate Visual Acuity

Intermediate visual acuities 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 Synergy and control IOL groups are presented in **Table 4**. There was a statistically significant improvement ($p<0.0001$) in mean monocular distance-corrected intermediate visual acuity (DCIVA; secondary effectiveness endpoint) at 6 months in favor of the Synergy group, with an improvement of 2.8 lines. Monocular intermediate visual acuity distributions for both lens groups are presented in **Tables 5A** and **5B**; binocular intermediate visual acuity distributions are presented in **Tables 6A** and **6B**. Overall, the intermediate visual acuity results demonstrate the effectiveness of the Synergy lens to provide improved intermediate vision compared to the monofocal control lens.

TABLE 4
Mean Intermediate Visual Acuity at 66 cm at 6 Months

Intermediate Visual Acuity	Lens Group	Monocular					Binocular				
		N	n	Mean LogMAR	Snellen Equiv.	Line Change vs. Control[a]	N	n	Mean LogMAR	Snellen Equiv.	Line Change vs. Control[a]
Uncorrected	TECNIS Synergy	Not Tested					131	131	0.022	20/21	1.8 lines
	TECNIS monofocal						131	130	0.199	20/32	
Distance Corrected	TECNIS Synergy	131	131	0.060	20/23	2.8 lines[b]	Not Tested				
	TECNIS monofocal	131	130	0.335	20/43						

[a] Line difference (control minus Synergy) is converted directly from LogMAR difference.

[b] Synergy met the secondary study endpoint of significantly better mean DCIVA than control ($p<0.0001$, one-sided two-sample t-test) and a mean DCIVA of 0.060 LogMAR (Safety population).

TABLE 5A
Distribution of Monocular Distance-Corrected Intermediate Visual Acuity at 66 cm at 6 Months

Monocular Snellen Visual Acuity	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	%	n	%
20/20^{-2} or better	72	55.0%	8	6.2%
20/25^{-2} or better	105	80.2%	17	13.1%
20/32^{-2} or better	125	95.4%	37	28.5%
20/40^{-2} or better	129	98.5%	68	52.3%
Worse than 20/40^{-2}	2	1.5%	62	47.7%
Total n	**131**		**130**	

Monocular UCIVA was not tested
%=(n/Total n) * 100

TABLE 5B
Distribution of Monocular Distance-Corrected Intermediate Visual Acuity at 66 cm at 6 Months

Monocular LogMAR Visual Acuity	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	%	n	%
0.00 LogMAR or better	47	35.9%	4	3.1%
0.10 LogMAR or better	97	74.0%	10	7.7%
0.20 LogMAR or better	117	89.3%	24	18.5%
0.30 LogMAR or better	127	96.9%	55	42.3%
Worse than 0.30 LogMAR	4	3.1%	75	57.7%
Total n	**131**		**130**	

Monocular UCIVA was not tested
%=(n/Total n) * 100

TABLE 6A
Distribution of Binocular Uncorrected Intermediate Visual Acuity at 66 cm at 6 Months

Binocular Snellen Visual Acuity	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	%	n	%
20/20^{-2} or better	84	64.1%	18	13.8%
20/25^{-2} or better	117	89.3%	44	33.8%
20/32^{-2} or better	130	99.2%	96	73.8%
20/40^{-2} or better	131	100.0%	114	87.7%
Worse than 20/40^{-2}	0	0.0%	16	12.3%
Total n	**131**		**130**	

%=(n/Total n) * 100

TABLE 6B
Distribution of Binocular Uncorrected Intermediate Visual Acuity at 66 cm at 6 Months

Binocular LogMAR Visual Acuity	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	%	n	%
0.00 LogMAR or better	64	48.9%	8	6.2%
0.10 LogMAR or better	107	81.7%	31	23.8%
0.20 LogMAR or better	127	96.9%	78	60.0%
0.30 LogMAR or better	131	100.0%	106	81.5%
Worse than 0.30 LogMAR	0	0.0%	24	18.5%
Total n	**131**		**130**	

%=(n/Total n) * 100

Near Visual Acuity at 40 cm

Near visual acuities were tested at 40 cm under photopic (85 cd/m^2) and mesopic (3 cd/m^2) lighting conditions. Mean monocular near visual acuities at 6 months for both Synergy and control groups are presented in **Table 7**. There was a statistically significant improvement ($p<0.0001$) in mean monocular distance-corrected near visual acuity (DCNVA at 40 cm; primary effectiveness endpoint) at 6 months in favor of the Synergy group, with an improvement of 4.2 lines. Monocular near (40 cm) visual acuity distributions for both lens groups are presented in **Tables 8A** and **8B**; binocular near (40 cm) visual acuity distributions are presented in **Tables 9A** and **9B**. Near (40 cm) visual acuity results demonstrate the effectiveness of the Synergy lens in providing improved near vision compared to the monofocal control lens.

TABLE 7
Mean Near Visual Acuity at 40 cm at 6 Months

Near (40 cm) Visual Acuity	Lens Group	Monocular					Binocular				
		N	n	Mean LogMAR	Snellen Equiv.	Line Change vs. Control[a]	N	n	Mean LogMAR	Snellen Equiv.	Line Change vs. Control[a]
Uncorrected	TECNIS Synergy	Not tested					131	131	0.060	20/23	3.3 lines
	TECNIS monofocal						131	130	0.393	20/49	
Distance Corrected	TECNIS Synergy	131	131	0.104	20/25	4.2 lines[b]	131	131	0.047	20/22	3.6 lines
	TECNIS monofocal	131	130	0.522	20/67		131	130	0.403	20/51	
Mesopic Distance Corrected	TECNIS Synergy	131	131	0.315	20/41	3.4 lines	131	131	0.244	20/35	3.5 lines
	TECNIS monofocal	131	130	0.654	20/90		131	130	0.591	20/78	

[a] Line difference (control minus Synergy) is converted directly from LogMAR difference.

[b] Synergy met the primary study endpoint of significantly better mean DCNVA than control ($p<0.0001$, one-sided two-sample t-test) and a mean DCNVA of 0.104 LogMAR (Safety population).

TABLE 8A
Distribution of Monocular Distance-Corrected Near Visual Acuity at 40 cm at 6 Months

Monocular Snellen Visual Acuity	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	%	n	%
20/20^{-2} or better	44	33.6%	2	1.5%
20/25^{-2} or better	92	70.2%	7	5.4%
20/32^{-2} or better	119	90.8%	10	7.7%
20/40^{-2} or better	124	94.7%	25	19.2%
Worse than 20/40^{-2}	7	5.3%	105	80.8%
Total n	**131**		**130**	

%=(n/Total n) * 100

TABLE 8B
Distribution of Monocular Distance-Corrected Near Visual Acuity at 40 cm at 6 Months

Monocular LogMAR Visual Acuity	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	%	n	%
0.00 LogMAR or better	33	25.2%	0	0.0%
0.10 LogMAR or better	76	58.0%	6	4.6%
0.20 LogMAR or better	110	84.0%	9	6.9%
0.30 LogMAR or better	123	93.9%	19	14.6%
Worse than 0.30 LogMAR	8	6.1%	111	85.4%
Total n	**131**		**130**	

%=(n/Total n) * 100

TABLE 9A
Distribution of Binocular Uncorrected Near Visual Acuity at 40 cm at 6 Months

Binocular Snellen Visual Acuity	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	%	n	%
20/20^{-2} or better	61	46.6%	0	0.0%
20/25^{-2} or better	114	87.0%	158	6.2%
20/32^{-2} or better	122	93.1%	25	19.2%
20/40^{-2} or better	127	96.9%	57	43.8%
Worse than 20/40^{-2}	4	3.1%	73	56.2%
Total n	**131**		**130**	

%=(n/Total n) * 100

TABLE 9B
Distribution of Binocular Uncorrected Near Visual Acuity at 40 cm at 6 Months

Binocular LogMAR Visual Acuity	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	%	n	%
0.00 LogMAR or better	43	32.8%	0	0.0%
0.10 LogMAR or better	101	77.1%	2	1.5%
0.20 LogMAR or better	120	91.6%	14	10.8%
0.30 LogMAR or better	126	96.2%	42	32.3%
Worse than 0.30 LogMAR	5	3.8%	88	67.7%
Total n	**131**		**130**	

%=(n/Total n) * 100

Near Visual Acuity at 33 cm

Near visual acuities were tested at 33 cm under photopic (85 cd/m^2) lighting conditions. Mean monocular distance-corrected near visual acuities at 6 months for both Synergy and control groups are presented in **Table 10**. There was a statistically significant improvement ($p<0.0001$) in mean monocular distance-corrected near visual acuity (DCNVA at 33 cm; secondary effectiveness endpoint) at 6 months in favor of the Synergy group, with an improvement of 4.5 lines.

TABLE 10
Mean Monocular Near Visual Acuity at 33 cm at 6 Months

Lens Group	N	n	Mean LogMAR	Snellen Equivalent	Line Change vs. Control[a]
TECNIS Synergy	131	131	0.154	20/29	4.5 lines[b]
TECNIS monofocal	131	130	0.608	20/81	

[a] Line difference (control minus Synergy) is converted directly from LogMAR difference.

[b] Synergy met the secondary study endpoint of significantly better mean DCNVA at 33 cm than control ($p<0.0001$, one-sided two-sample t-test) and a mean DCNVA of 0.154 LogMAR (Safety population).

Defocus Curve

Distance-corrected defocus testing was performed monocularly at 6 months and binocularly at 1 month. Mean monocular defocus curve at 0.2 LogMAR was a secondary effectiveness study endpoint, and results for each lens group at 6 months are presented in **Figure 2.** The defocus curve shows that Synergy achieved the secondary study endpoint with 0.2 LogMAR or better VA from 0.0 D to -2.5 D of defocus; 0.2 LogMAR visual acuity on the Synergy defocus curve continued beyond -3.0 D, which corresponds to a range of distances from approximately 33 cm to infinity.

Figure 3A presents monocular defocus curves for the Synergy group by pupil size. The curves for medium and large pupils are essentially indistinguishable with 0.2 LogMAR visual acuity sustained to beyond -3.0 D. It should be noted that there were no eyes in the small pupil size category for the Synergy group. Therefore, the TECNIS Synergy IOLs demonstrated pupil-independent lens performance between 0 and -3.0 D of defocus among the pupil sizes available (>2.5 mm). Monocular defocus curves for the Synergy and control groups are presented by small, medium, and large pupil sizes in **Figures 3B** and **3C**, respectively. The range of defocus for medium and large pupils in the Synergy group are greater than that for the control group by approximately 2.5 D and 2.0 D, respectively.

Figure 4 presents the binocular defocus curves for the Synergy and control groups at 1 month. The binocular defocus curves show results similar to the monocular 6-month defocus results, with a difference in the range of defocus of approximately 2.5 D between the IOL groups, favoring the Synergy group over the control group.

FIGURE 2
Mean Monocular Distance-Corrected Defocus Curve at 6 Months
TECNIS Synergy (N=131) and TECNIS monofocal (N=131)

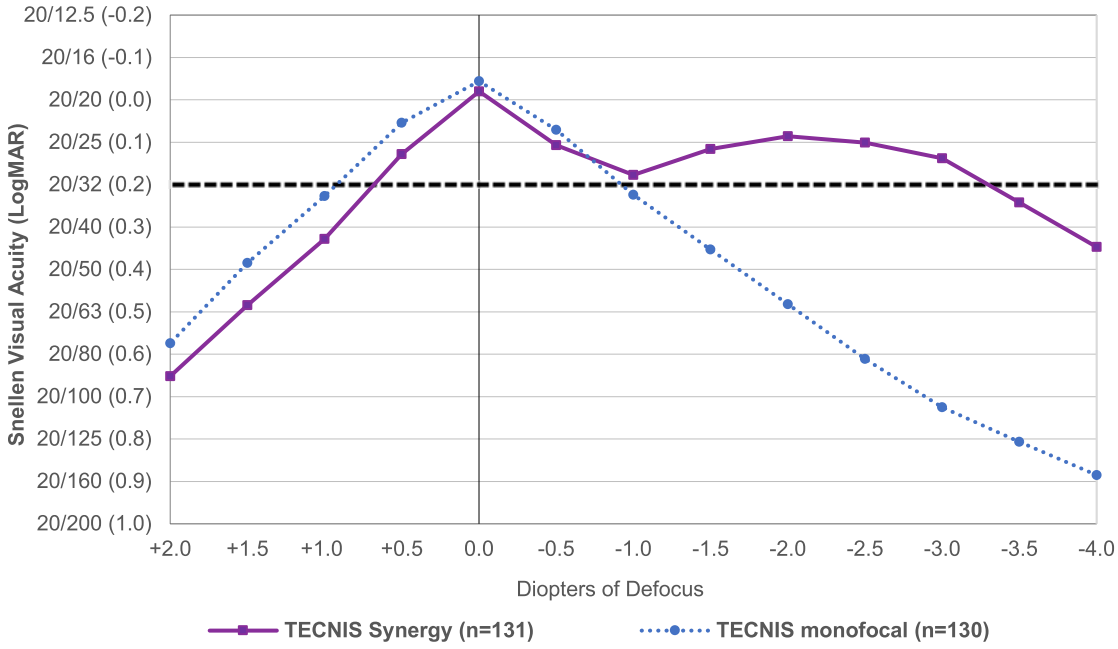


FIGURE 3A
Mean Monocular Distance-Corrected Defocus Curve By Pupil Size at 6 Months
TECNIS Synergy

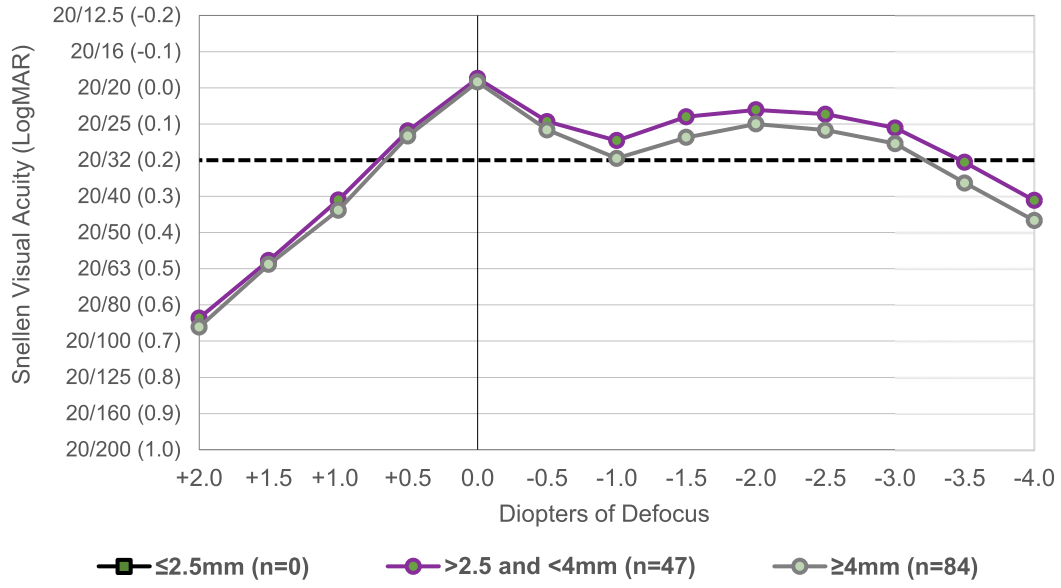


FIGURE 3B
Mean Monocular Distance-Corrected Defocus Curve for
Medium Pupils (>2.5 and <4 mm) at 6 Months
TECNIS Synergy and TECNIS monofocal

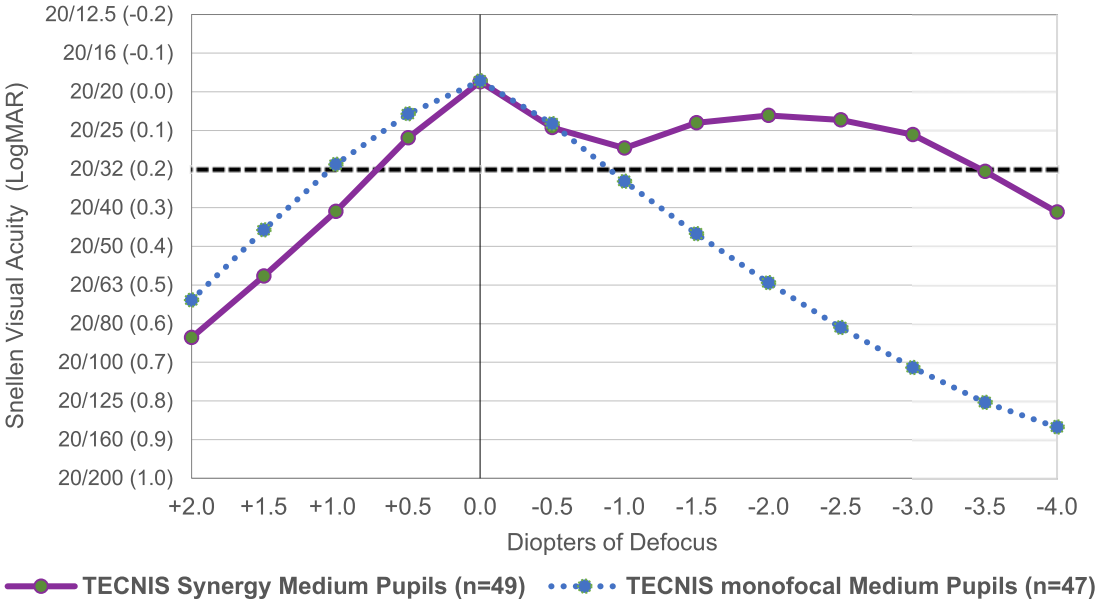


FIGURE 3C
Mean Monocular Distance-Corrected Defocus Curve for Large Pupils (≥4 mm) at 6 Months
TECNIS Synergy and TECNIS monofocal

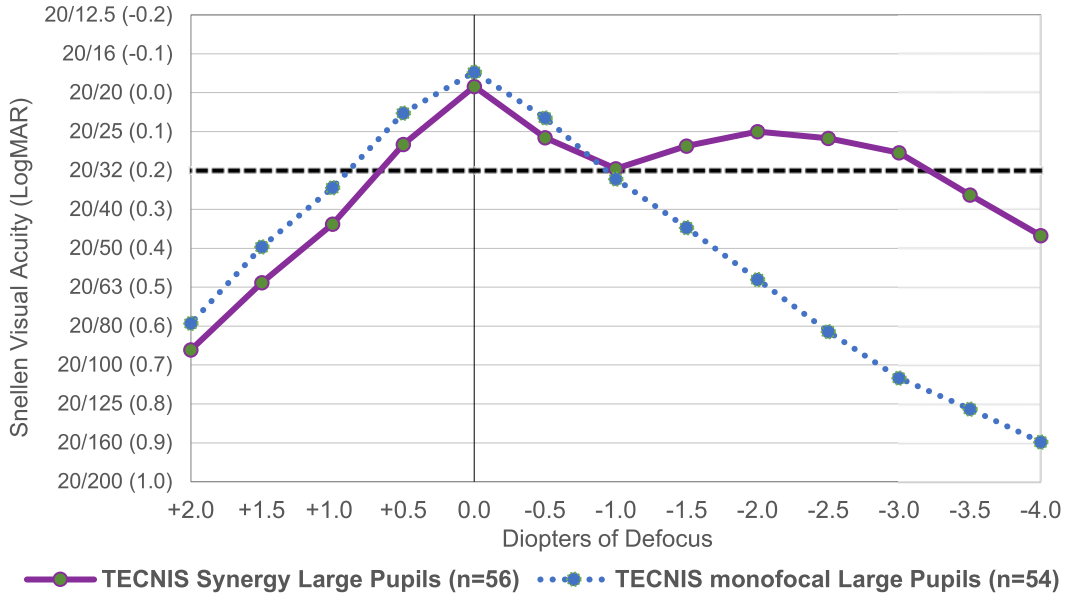
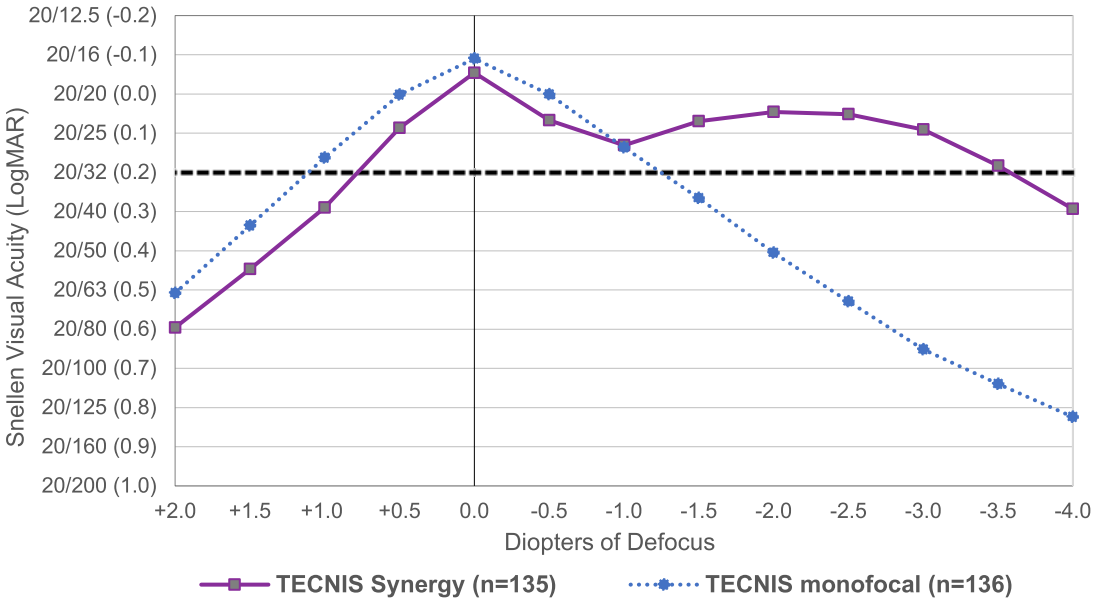


FIGURE 4
Mean Binocular Distance-Corrected Defocus Curve at 1 Month
Bilateral TECNIS Synergy (N=135) and TECNIS monofocal (N=136)



Contrast Sensitivity

Monocular best-corrected distance contrast sensitivity was evaluated under three lighting conditions: mesopic without glare, mesopic with glare, and photopic with glare. The median monocular contrast sensitivity measurements at all spatial frequencies and all lighting conditions at 6 months were generally lower for the Synergy group than the control group (**Figures 5A, 5B,** and **5C**) but were not clinically significant. The illuminance of the glare source used for testing (150 lux) was high enough to reduce mesopic contrast sensitivity in the monofocal control group by at least 0.2 log units and further reduced that of the Synergy group by up to 0.11 log units; however, the clinical significance of the measured differences in contrast sensitivity was not evident in patient-reported experiences. In addition, median binocular contrast sensitivity measurements at all spatial frequencies and all lighting conditions at 1 month are presented in **Figures 6A, 6B,** and **6C**.

Figure 5A
Monocular Best-Corrected Distance Contrast Sensitivity at 6 Months
Mesopic Without Glare
Medians with 5th and 95th Percentile Error Bars

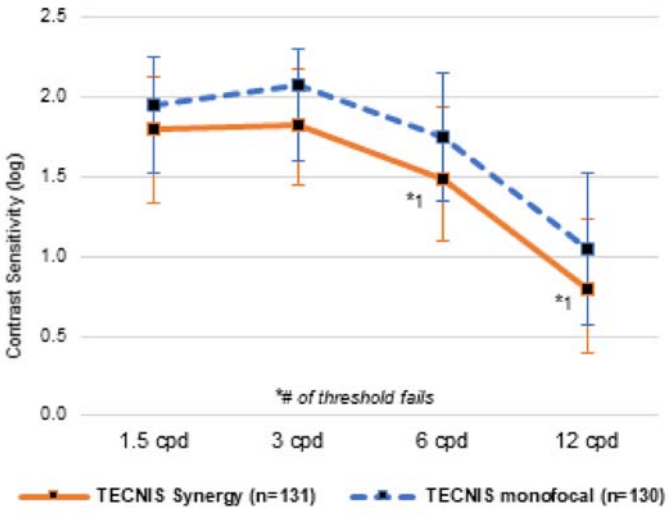


Figure 5B
Monocular Best-Corrected Distance Contrast Sensitivity at 6 Months
Mesopic With Glare
Medians with 5th and 95th Percentile Error Bars

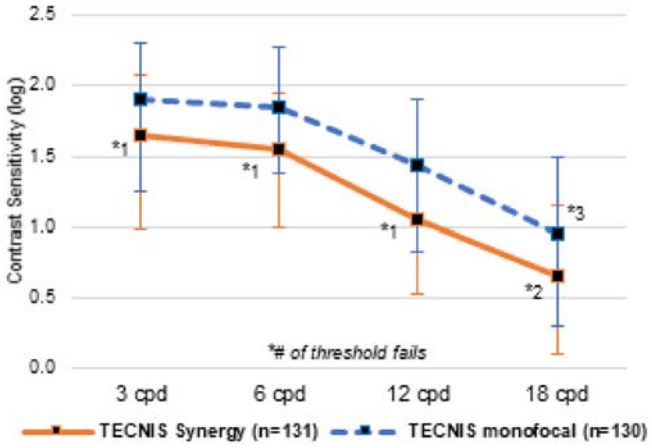


Figure 5C
Monocular Best-Corrected Distance Contrast Sensitivity at 6 Months
Photopic With Glare
Medians with 5th and 95th Percentile Error Bars

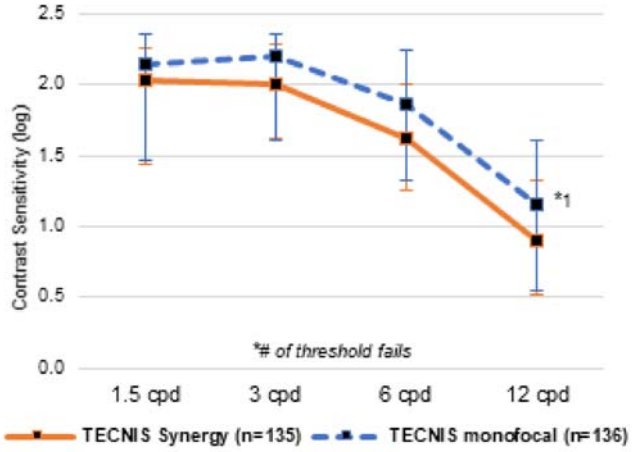


FIGURE 6A
Binocular Best-Corrected Distance Contrast Sensitivity at 1 Month
Mesopic without Glare
Medians with 5th and 95th Percentile Error Bars

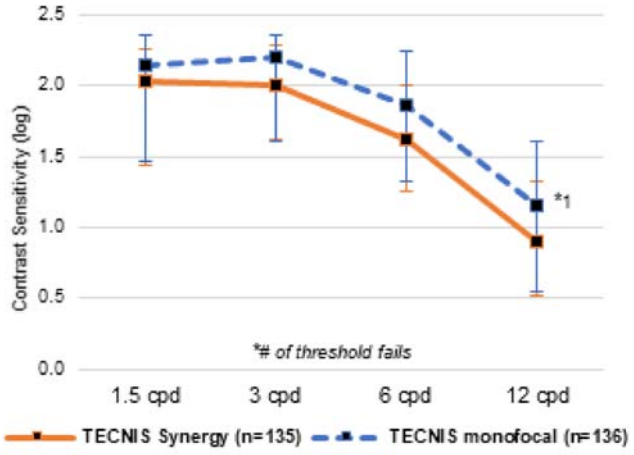


FIGURE 6B
Binocular Best-Corrected Distance Contrast Sensitivity at 1 Month
Mesopic with Glare
Medians with 5th and 95th Percentile Error Bars

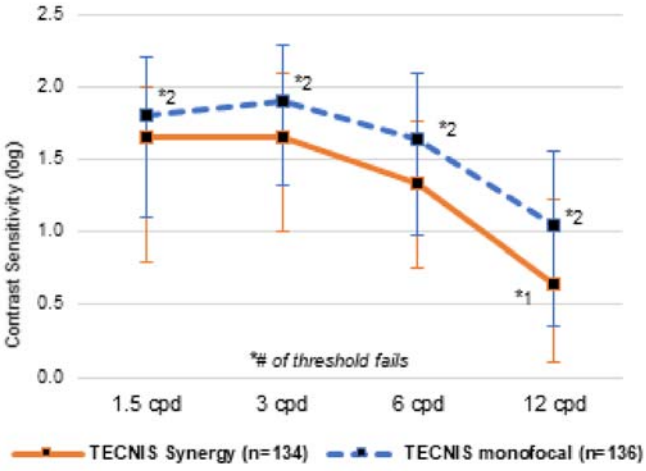
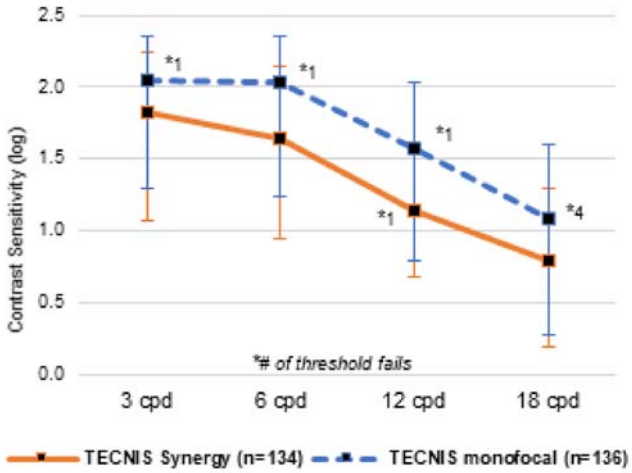


FIGURE 6C
Binocular Best-Corrected Distance Contrast Sensitivity at 1 Month
Photopic with Glare
Medians with 5th and 95th Percentile Error Bars

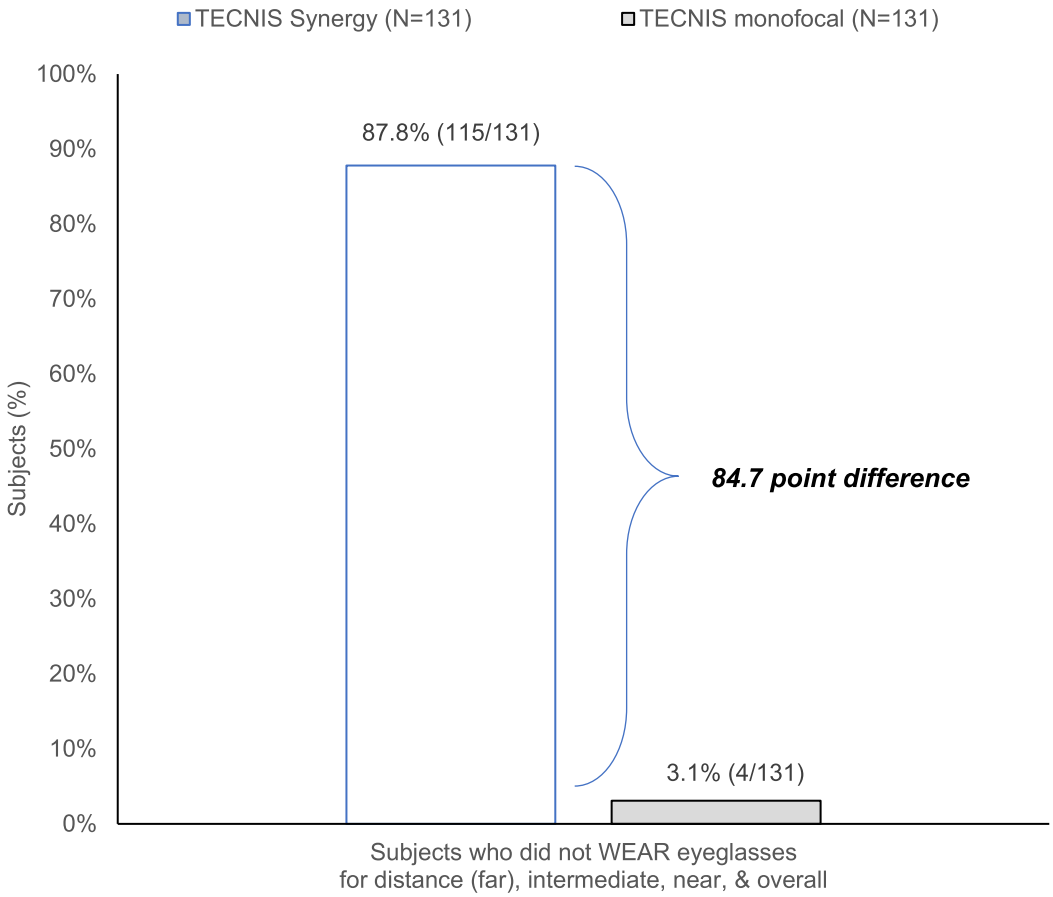


Patient-Reported Spectacle Independence Questionnaire Results
Spectacle wear and other related items were assessed by subject responses obtained from the Patient Reported Spectacle Independence Questionnaire (PRSIQ). This questionnaire was developed and evaluated following the US FDA guidance document "Patient-Reported Outcomes Measures: Use in Medical Product Development to Support Labeling Claims" dated December 2009. The questionnaire includes questions about the need for glasses, wear of glasses, and straining to see without them. The study results showed that the Synergy group achieved the secondary effectiveness endpoint of reduced spectacle wear compared to the control group.

Spectacle wear (secondary effectiveness endpoint) was based on the proportion of subjects who reported wearing glasses or contacts "none of the time" for all four conditions: distance, intermediate, near, and overall. **Figure 7** presents the frequency of spectacle wear for bilaterally implanted subjects at 6 months. There was a statistically significantly greater ($p<0.0001$) proportion of subjects in the Synergy group (87.8%; 115/131) who reported wearing glasses "none of the time" in all four conditions (distance, intermediate, near, and overall vision) compared to the control group (3.1%; 4/131); the 84.7 percentage point difference between the two IOL groups was clinically significant. Similarly, 82.4% (108/131) of subjects in the Synergy group reported no need for glasses for distance, intermediate and near vision compared to the control (5.3%, 7/131).

Responses to these questions at the 6-month visit indicated that the Synergy IOL provided freedom from eyeglasses to implanted subjects.

FIGURE 7
Patient Reported Spectacle Independence Questionnaire Results at 6 Months



Each subject reported "None of the time" for all four conditions.

Optical/Visual Symptoms

Optical/visual symptoms that were spontaneously reported by subjects (non-directed) and questionnaire-directed reports of experience/bother/difficulty with visual problems (directed) were evaluated. Non-directed reports of optical/visual symptoms included halos, night glare, and starbursts, of which there were few reports of severe symptoms for both Synergy and control groups (**Table 11**). As shown in the responses to the directed questionnaire (**Table 12)**, reports of bothersome visual disturbances were generally acceptable for the Synergy group at 6 months. The highest rate of the most bothersome reports ("extremely bothersome") of optical/visual symptoms at 6 months was for starbursts, at 5.3% for Synergy and 0.0% for the control.

TABLE 11
Spontaneous (Non-directed[a]) Reports of Optical/Visual Symptoms (First Eyes) at 6 Months

	TECNIS Synergy N=131		TECNIS monofocal N=131	
	n	**%**	**n**	**%**
Halos[b]	30	22.9	5	3.8
○ Mild	8	6.1	3	2.3
○ Moderate	17	13.0	2	1.5
○ Severe	5	3.8	0	0.0
Night Glare[b]	11	8.4	2	1.5
○ Mild	1	0.8	0	0.0
○ Moderate	7	5.3	2	1.5
○ Severe	3	2.3	0	0.0
Starbursts[b]	13	9.9	2	1.5
○ Mild	3	2.3	2	1.5
○ Moderate	5	3.8	0	0.0
○ Severe	5	3.8	0	0.0
Photophobia	2	1.5	3	2.3
Day glare	2	1.5	1	0.8
Night vision difficulty	6	4.6	1	0.8

% = (n/N)*100
Subjects may report multiple symptoms.
[a]Responses to the question, “Are you having any difficulties with your eyes or vision?”
[b]Severity collected in follow-up response

TABLE 12
Experience/Bother With Visual Symptoms at 6 Months
(Directed Questionnaire)

		TECNIS Synergy N=131		TECNIS monofocal N=131	
		n	%	n	%
Halos	Did not experience or NR	24	18.3	79	60.3
	Not at all bothered	19	14.5	23	17.6
	Slightly bothered	40	30.5	22	16.8
	Moderately bothered	30	22.9	6	4.6
	Very bothered	13	9.9	1	0.8
	Extremely bothered	5	3.8	0	0.0
Starbursts	Did not experience or NR	46	35.1	102	77.9
	Not at all bothered	18	13.7	17	13.0
	Slightly bothered	27	20.6	4	3.1
	Moderately bothered	25	19.1	6	4.6
	Very bothered	8	6.1	2	1.5
	Extremely bothered	7	5.3	0	0.0
Multiple or Double Vision	Did not experience or NR	113	86.3	116	88.5
	Not at all bothered	2	1.5	5	3.8
	Slightly bothered	10	7.6	4	3.1
	Moderately bothered	2	1.5	5	3.8
	Very bothered	2	1.5	1	0.8
	Extremely bothered	2	1.5	0	0.0
Sensitivity to Light	Did not experience or NR	63	48.1	71	54.2
	Not at all bothered	13	9.9	9	6.9
	Slightly bothered	30	22.9	32	24.4
	Moderately bothered	19	14.5	11	8.4
	Very bothered	5	3.8	6	4.6
	Extremely bothered	1	0.8	2	1.5
Glare Related to Scattered Light	Did not experience or NR	69	52.7	110	84.0
	Not at all bothered	9	6.9	4	3.1
	Slightly bothered	23	17.6	12	9.2
	Moderately bothered	19	14.5	3	2.3
	Very bothered	5	3.8	2	1.5
	Extremely bothered	6	4.6	0	0.0
Occlusions	Did not experience or NR	127	96.9	128	97.7
	Not at all bothered	1	0.8	1	0.8
	Slightly bothered	1	0.8	2	1.5
	Moderately bothered	0	0.0	0	0.0
	Very bothered	2	1.5	0	0.0
	Extremely bothered	0	0.0	0	0.0
Poor Low Light Vision	Did not experience or NR	79	60.3	80	61.1
	Not at all bothered	9	6.9	6	4.6
	Slightly bothered	25	19.1	34	26.0
	Moderately bothered	15	11.5	6	4.6
	Very bothered	3	2.3	4	3.1
	Extremely bothered	0	0.0	1	0.8

% = (n/N)*100
NR = Not Reported

Adverse Events

The incidence rates of persistent and cumulative adverse events for Synergy eyes at 6 months compared to the ISO SPE (safety and performance endpoint) rates at 12 months are presented in **Tables 13** and **14**, respectively. The incidence rates for the Synergy IOL group compared favorably to the specified ISO SPE rates, as the observed rates for the Synergy group were either lower than or not statistically significantly higher than the specified ISO SPE rates (primary safety endpoint). Secondary surgical interventions (SSI) by IOL group are presented in **Table 15**. Of the three second eye SSIs, only one was device related.

TABLE 13
6-Month Persistent Adverse Events vs. ISO 11979-7 SPE 12-Month Rates
TECNIS Synergy

	ISO SPE Rate	First Eyes N=131		Second Eyes N=132	
Persistent Medical Complication/Adverse Event	**%**	**n**	**%**	**n**	**%**
Corneal edema	0.3	0	0.0	0	0.0
Cystoid macular edema	0.5	0	0.0	0	0.0
Iritis	0.3	0	0.0	0	0.0
Raised IOP requiring treatment	0.4	0	0.0	0	0.0

TABLE 14
6-Month Cumulative Adverse Events vs. ISO 11979-7 SPE 12-Month Rates
TECNIS Synergy

	ISO SPE Rate	First Eyes N=135		Second Eyes N=135	
Cumulative Medical Complication/Adverse Event	**%**	**n**	**%**	**n**	**%**
Cystoid macular edema	3.0	1	0.7	1	0.7
Hypopyon[a]	0.3	0	0.0	1	0.7 [b]
Endophthalmitis[c]	0.1	0	0.0	0	0.0
Lens dislocated from posterior chamber[c]	0.1	0	0.0	0	0.0
Pupillary block[c]	0.1	0	0.0	0	0.0
Retinal detachment[c]	0.3	0	0.0	0	0.0
Eyes with secondary surgical intervention[c]	0.8	1	0.7	3	2.2 [b]

% = (n/N) *100

[a] Associated with a single report of toxic anterior segment syndrome (TASS), which occurred in same eye.

[b] Rate is not statistically significantly higher than ISO SPE rate (p>0.05).

[c] As defined by AAO IOL Task Force (Masket *et al*., 2016). Cystoid macular edema was defined by clinical examination and adjunct testing (OCT). Hypopyon was defined as an accumulation of white blood cells in the anterior chamber.

TABLE 15
Secondary Surgical Interventions by IOL Group

	TECNIS Synergy				TECNIS monofocal			
	First Eyes N=135		Second Eyes N=135		First Eyes N=137		Second Eyes N=137	
	n	%	n	%	n	%	n	%
Secondary Surgical Interventions (SSIs)								
○ Lens Removal	1[a]	0.7	0	0.0	0	0.0	0	0.0
○ Aspiration (Removal) of Lens Fragments	0	0.0	1[b]	0.7	0	0.0	0	0.0
○ Retinal Repair	0	0.0	1[c]	0.7	0	0.0	1[e]	0.7
○ Treatment Injection	0	0.0	1[d]	0.7	0	0.0	0	0.0
Total Eyes with SSIs	**1**	**0.7**	**3**	**2.2**	**0**	**0.0**	**1**	**0.7**

% = (n/N) *100
[a]SSI related to visual symptoms (optical properties of the lens). The second eye-lens for same subject was removed after study exit for similar reason.
[b]Due to retained lens material
[c]Due to macular hole
[d]Due to hypopyon and TASS in same eye
[e]Due to retinal detachment/tear

Table 16 presents the incidence of serious and non-serious medical findings/adverse events at 6-months for all Synergy and monofocal control eyes.

TABLE 16
Medical Findings/Adverse Events at 6 Months
TECNIS Synergy and TECNIS Monofocal
Pooled (First and Second) Eyes
Safety Population

	TECNIS Synergy N=263		TECNIS Monofocal N=262	
Medical Findings	**n**	**%**	**n**	**%**
Posterior capsule opacification (any)	116	44.1	106	40.5
Posterior vitreous detachment	76	28.9	76	29.0
Dermatochalasis	56	21.3	49	18.7
Dry eye/superficial punctate keratopathy/ epithelial erosion/tear film insufficiency	50	19.0	46	17.6
Blepharitis/meibomianitis	40	15.2	48	18.3
Posterior capsular striae/wrinkles (any)	16	6.1	10	3.8
Periorbital fat herniation	14	5.3	10	3.8
Pinguecula	14	5.3	15	5.7
Ptosis	6	2.3	4	1.5
Chorioretinal atrophy	5	1.9	5	1.9
Congenital optic nerve anomaly	5	1.9	0	0.0
Epiretinal membrane	5	1.9	1	0.4
Corneal dystrophy	4	1.5	4	1.5
Drusen	4	1.5	5	1.9
Eye nevus	4	1.5	1	0.4
Guttata	4	1.5	2	0.8
Corneal scar	3	1.1	6	2.3
Optic nerve cup/disc ratio increased	3	1.1	0	0.0
Pterygium	3	1.1	2	0.8
Retinal degeneration	3	1.1	0	0.0

Medical Findings	TECNIS Synergy N=263		TECNIS Monofocal N=262	
	n	%	n	%
Retinal pigment epithelium (RPE) changes	3	1.1	2	0.8
Arcus	2	0.8	9	3.4
Conjunctival hyperemia/injection	2	0.8	0	0.0
Conjunctivitis	2	0.8	0	0.0
Conjunctivochalasis	2	0.8	0	0.0
Corneal disorder	2	0.8	0	0.0
Corneal pigmentation[b]	2	0.8	2	0.8
Heterophoria	2	0.8	0	0.0
Macular degeneration	2	0.8	0	0.0
Optic nerve cupping	2	0.8	0	0.0
Optic nerve hypoplasia	2	0.8	0	0.0
Telangiectasia	2	0.8	0	0.0
Anterior chamber cells (if any)	1	0.4	4	1.5
Chorioretinal scar	1	0.4	1	0.4
Corneal opacity	1	0.4	1	0.4
Eyelid cyst	1	0.4	2	0.8
Lagophthalmos	1	0.4	0	0.0
Macular hole	1	0.4	0	0.0
Retinal anomaly congenital	1	0.4	1	0.4
Retinal scar	1	0.4	0	0.0
Vitreous degeneration	1	0.4	0	0.0
Anterior chamber flare (if any)	0	0.0	3	1.1
Cornea verticillata	0	0.0	2	0.8
Corneal edema (if any)[b]	0	0.0	2	0.8
Iris transillumination defect[b]	0	0.0	2	0.8
Madarosis	0	0.0	2	0.8
Presumed ocular histoplasmosis syndrome	0	0.0	2	0.8
Retinal hemorrhage	0	0.0	2	0.8
Elevated IOP/ocular hypertension[b]	0	0.0	1	0.4
Hyalosis asteroid	0	0.0	1	0.4
Retinal exudates	0	0.0	1	0.4
Retinal tear[b]	0	0.0	1	0.4
Strabismus	0	0.0	1	0.4
Other	0	0.0	2[a]	0.8[a]

[a] Other includes orbital fat prolapse and negative dysphotopsia.
[b] As defined by AAO IOL Task Force (Masket *et al*., 2016).

Bother or difficulty with a visual symptom that caused interference with daily activity lasting more than 3 months and was deemed related to the IOL by the investigator was considered an Adverse Device Effect (ADE). Eleven ADEs of undesirable optical phenomena occurred in 8.1% (11/135) of Synergy subjects and none for control subjects; one resulted in a lens removal due to optical properties of the lens (0.7%, 1/135).

Overall lens findings in Synergy subjects included lens decentration (0.7%, 1/135) in both eyes, inflammatory deposits on IOL (0.7%, 1/135), and implant positioned minimally nasal in pupil (0.7%, 1/135) during the study.

RELATED CLINICAL STUDIES

Data from other relevant clinical studies are included to support the safety and effectiveness of the TECNIS Synergy™ IOLs, Model ZFR00V, and the TECNIS Synergy™ Toric II IOLs, Models ZFW150, ZFW225, ZFW300, and ZFW375. Clinical data to support the TECNIS Synergy™ Toric II IOLs (Models ZFW150, ZFW225, ZFW300, and ZFW375) are from the toric design parent, TECNIS® Toric 1-Piece IOLs, Models ZCT150, ZCT225, ZCT300 and ZCT400 (P980040/S039).

The TECNIS Symfony® Extended Range of Vision IOL, Model ZXR00, approved under P980040/S065, and TECNIS® Multifocal IOL, Model ZM900, approved under P080010 serve as the optical parents to TECNIS Synergy™ IOLs, Models ZFR00V and ZFW (non-toric and toric). The posterior optic design of the TECNIS Synergy™ IOLs was derived from the diffractive technology of Models ZXR00 and ZM900, whereas the anterior optic surface contains a modified prolate (aspheric) design identical to that of its monofocal analog, the TECNIS® Monofocal 1-Piece IOL, Model ZCB00, approved under P980040/S015. The SENSAR® 1-Piece IOL, Model AAB00, which was approved under P980040/S015, served as the mechanical parent to support the safety and effectiveness of the 1-piece platform and SENSAR acrylic material used for the TECNIS Synergy™ IOLs (non-toric and toric models). In addition, the TECNIS Synergy™ IOLs, Models ZFR00V and ZFW, are made of the same soft acrylic material of the clinically studied TECNIS 3-Piece OptiBlue™ IOL, Model ZV9003, approved under P980040/S035, which also serves as the material parent.

CLINICAL STUDY RESULTS FOR THE 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® Monofocal 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 1-Piece 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 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 (standard deviation [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**	**SD**	**P-Value**	**Lens Model**	**N[a]**	**Mean**	**SD**	**P-Value**
Preop Keratometric Cylinder (K_{cyl}; 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[1,2] and up to 20° for axis[2]) and any potential errors in surgeon-estimated SIA are contributing factors to prediction errors of postoperative keratometry.

[1] Zadnik K, Mutti D, Adams A. The repeatability of measurement of the ocular components. Invest Ophthalmol Vis Sci. 1992 Jun; 33(7): 2325-33.

[2] [2]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 K_{cyl} 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 K_{cyl} alone and by predicted K_{cyl} (i.e., vector sum of preoperative K_{cyl}, 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	SD	Predicted Keratometric Cylinder (D)[b] (Preop K_{cyl} + SIA)	N	Percent Reduction in Cylinder (ANSI)[a] Mean	SD
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 to 0.99	22	32.32	111.09	0.75 to 0.99	23	7.39	48.81
ZCT150		30	69.20	87.53		21	55.38	58.57
ZCB00	1.00 to 1.24	34	41.06	68.41	1.00 to 1.24	31	43.44	59.77
ZCT150		38	94.88	52.09		36	61.88	49.80
ZCB00	1.25 to 1.49	27	32.31	60.95	1.25 to 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 K_{cyl})/(Target Ref. Cyl. minus Preop K_{cyl}); 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)	N	Residual Refractive Cylinder (D) Mean	SD	Predicted Keratometric Cylinder (D)[a] (Preop K_{cyl} + SIA)	N	Residual Refractive Cylinder (D) Mean	SD
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 to 0.99	22	0.56	0.50	0.75 to 0.99	23	1.03	0.51
ZCT150		30	0.50	0.40		21	0.43	0.33
ZCB00	1.00 to 1.24	34	0.80	0.55	1.00 to 1.24	31	0.84	0.68
ZCT150		38	0.36	0.36		36	0.48	0.45
ZCB00	1.25 to 1.49	27	1.09	0.59	1.25 to 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								Absolute Cylinder						
			Reduction >0.50 D		Change ≤ ±0.50 D[b]		Increase >0.50 D				Reduction >0.50 D		Change ≤ ±0.50 D[b]		Increase >0.50 D	
Model	Preoperative Keratometric Cylinder (D)	N	n	%	n	%	n	%	Predicted Keratometric Cylinder (D)[c] (Preop K_{cyl}+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 to 0.99	22	7	31.82	13	59.09	2	9.09	0.75 to 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 to 1.24	34	12	35.29	19	55.88	3	8.82	1.00 to 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 to 1.49	27	9	33.33	16	59.26	2	7.41	1.25 to 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 K_{cyl}

[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 to 30	0	0.0	0	0.0	0	0.0	0	0.0
10 to 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 to 9	9	6.1	6	4.1	9	5.8	6	3.9
0 to 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]		Toric Eyes with Data at One Day and Six Months	
	1 Day vs. 6 Months		1 Day vs. 6 Months	
	n	%	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]			Toric Eyes with Data at Two or More Visits[b]		
	N	Mean (degrees)	SD	N	Mean (degrees)	SD
1 Month vs. 3 Month	148	0.24	2.82	156	0.25	2.77
3 Month vs. 6 Month	148	-0.06	2.94	152	-0.09	2.96
Baseline (1 Day) vs. 6 Month	148	-1.35	6.13	156	-1.33	5.99
Abs. Value: 1 Month vs. 3 Month	148	1.82	2.17	156	1.79	2.12
Abs. Value: 3 Month vs. 6 Month	148	1.85	2.28	152	1.89	2.27
Abs. Value: Baseline (1 Day) vs. 6 Month	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 SSIs. 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	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%

steps (stairs, curbs)	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 K_{cyl} in second eyes
[b] As control subjects had ≤1.5 D of preoperative K_{cyl}, 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 FOR THE TECNIS Symfony® Extended Range of Vision IOL, Model ZXR00

A prospective, 6-msonth, 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® Monofocal 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 this clinical summary section including the data tables, “Symfony” refers to the TECNIS Symfony® IOL, Model ZXR00, and “control” refers to the TECNIS® Monofocal 1-Piece IOL, Model ZCB00.

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 control group (150 bilaterally implanted). Subject demographics were similar between the Symfony and 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% control). Most Symfony subjects (>96%) and control subjects (>86%) were White. The remainder of subjects were African American (2.7% Symfony; 10.6% control), Asian (0.7% Symfony; 2.0% control) and American Indian/Alaska Native (1.3% control only).

Distance Visual Acuities

Table 27 presents monocular, uncorrected and best-corrected, photopic (85 cd/m^2) distance visual acuity results for Symfony and 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%).

TABLE 27
Monocular Distance Visual Acuity at 6 Months

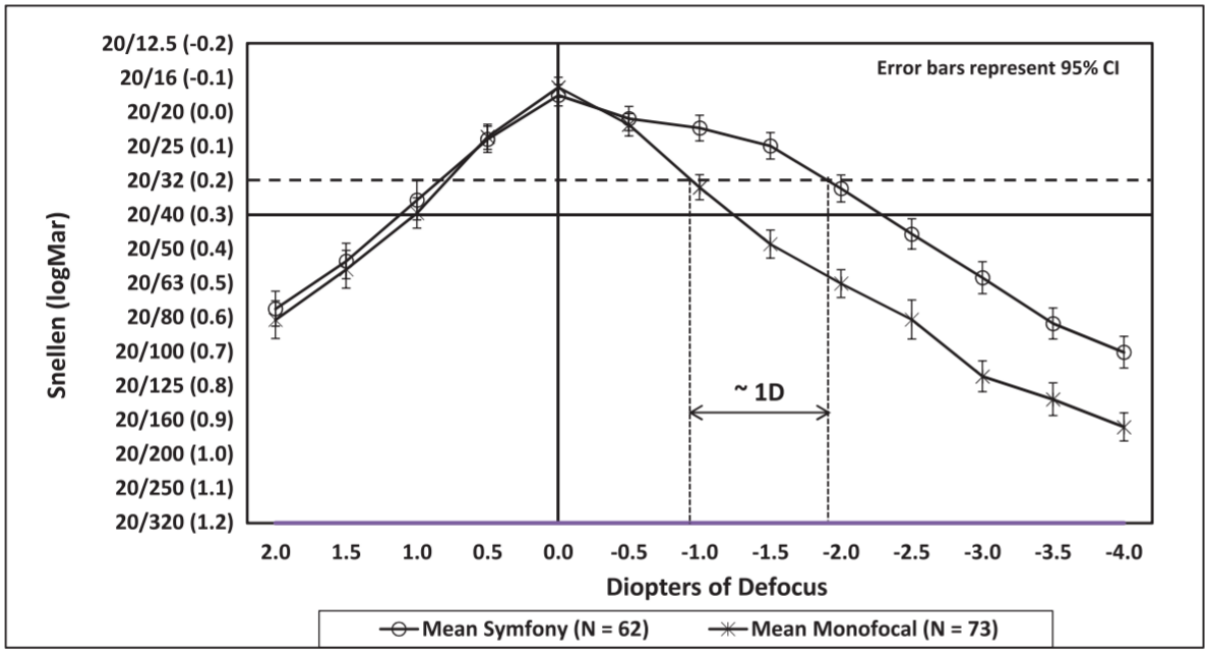
Monocular Visual Acuity	Symfony		Control	
	Uncorrected	Best Corrected	Uncorrected	Best Corrected
20/20 or better	38.8%	83.7%	47.3%	88.5%
20/25 or better	65.3%	98.0%	71.6%	96.6%
20/32 or better	87.8%	100.0%	85.1%	98.6%
20/40 or better	96.6%	100.0%	93.9%	100.0%
20/50 to 20/80	2.7%	0.0%	6.1%	0.0%
20/100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

%=(n/Total n) * 100

Depth of Focus

Figure 8 presents the binocular defocus curves for the Symfony and control groups with mean values and confidence intervals. Mean binocular acuities were 20/32 or better for the Symfony group through -2.0 D (50 cm). The binocular defocus curves demonstrate that visual acuity for the Symfony group monotonically decreased while maintaining a 1-2 line acuity difference over the control 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.

FIGURE 8
Binocular Defocus Curves at 6 Months
Symfony and Monofocal Control



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 28** and **29**, 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 30**.

TABLE 28
6-Month Persistent Serious Adverse Events for the Symfony IOL Group

Persistent Medical Complications/ Adverse Events	ISO SPE Rate (%)	First Eyes N=147		Second Eyes N=147	
		n	%	n	%
Corneal edema	0.3	0	0.0	0	0.0
Cystoid macular edema	0.5	0	0.0	1	0.7
Iritis	0.3	0	0.0	0	0.0
Raised IOP requiring treatment	0.4	0	0.0	0	0.0

[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 is not statistically significantly higher than ISO SPE rate (p = 0.5238) using 1-sided exact test.

TABLE 29
6-Month Cumulative Serious Adverse Events for the Symfony IOL Group

Cumulative Medical Complications/ Adverse Events	ISO SPE Rate (%)	First Eyes N=148		Second Eyes N=148	
		n	%	n	%
Cystoid macular edema	3.0	1	0.7	1	0.7
Hypopyon	0.3	0	0.0	1	0.7[c]
Endophthalmitis	0.1	0	0.0	0	0.0
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	0.0	2[b]	1.4[d]
○ Device related	N/A	0	0.0	-	-
○ Not device related	N/A	0	0.0	2[b]	1.4[d]
Other: Pupillary Capture	N/A	0	0.0	1	0.7

[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] Treatment injections for Vitritis (Subject 1314) and CME (Subject 1425).
[c] Incidence rate is not statistically significantly higher than ISO SPE rate (p = 0.3590) using 1-sided exact test.
[d] Incidence rate is not statistically significantly higher than ISO SPE rate (p = 0.3318) using 1-sided exact test.

TABLE 30
Secondary Surgical Interventions for the Symfony IOL Group

Secondary Surgical Interventions[a] Not Device-Related	First Eyes N=148		Second Eyes N=148	
	n	%	n	%
Treatment injections for medical complications:	0	0.0	2	0.7
○ Cystoid macular edema	0	0.0	1	0.3
○ Endophthalmitis	0	0.0	1	0.3

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

Optical/Visual Symptoms

The most commonly reported directed symptoms at 6 months based on a direct questionnaire (**Table 31**) were halos, starbursts, and glare for both IOL groups; halos and starbursts were reported with increased bother in the Symfony group compared with the control group.

TABLE 31
Experience/Bother with Visual Symptoms Over the Past 7 Days at 6 Months (Directed Reports)

		Symfony N=147		Control 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
	Very bothered	12	8.2	6	4.1
Glare[a]	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[a]	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)[a]	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[a]	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[a]	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 “Does not apply” and “Not Reported”.

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

[a] “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.

CLINICAL STUDY RESULTS FOR THE 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 (Model CeeOn® 911A silicone IOL) 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 32** and **33** for the rural road and in **Tables 34** and **35** 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 32

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 33

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 34

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 35

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

CLINICAL STUDY RESULTS FOR THE TECNIS OPTIBLUE™ IOL, MODEL ZV9003

A multi-center, bilateral and double-masked study compared the clinical outcomes of the TECNIS OptiBlue™ IOL, Model ZV9003 and the control, TECNIS® Foldable Acrylic IOL, Model ZA9003. The mean best-corrected distance visual acuity, mean binocular contrast sensitivity, and color vision data were comparable between subjects implanted with the Model ZV9003 lens and those implanted with the control

lens. Statistically significant improvements were observed 4-6 months and one year postoperatively in favor of the Model ZV9003 lens in subjective ratings for reduced difficulty with daytime driving.

A total of 250 subjects (ZV9003 lens group=126, control lens group=124) were enrolled. The subject population consisted of more females than males in both lens groups, with 61.9% females in the test group and 54.8% females in the control group. The subjects in the ZV9003 group were slightly older (mean age=73.3 years) than those in the control group (mean age=71.5 years). Majority of subjects were Caucasian in both lens groups (96.0% in the ZV9003 group, 96.8% in the control group). The remainder of subjects were Black (2.4% in the ZV9003 group, 2.4% in the control group), Asian (0.0% in the ZV9003 group, 0.8% in the control group), and 'Other' (1.6% in the ZV9003 group, 0.0% in the control group).

Best-Corrected Distance Visual Acuity

At one year, 100% of ZV9003 first eyes and 99.2% of ZV9003 second eyes were 20/40 or better for best-corrected distance visual acuity, exceeding the FDA grid rate of 92.5%. At one year, all best-case ZV9003 first eyes achieved a best-corrected visual acuity of 20/40 or better, exceeding the FDA grid rate of 96.7%. The postoperative best-corrected distance visual acuity results for the best-case patients at one year are provided in **Table 36**. In addition, the data 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
ZV9003 First Eyes, Best-Case Subjects[a] (N=113)

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	4	4	100.0	0	0.0	0	0.0	0	0.0
60 to 69	32	30	93.8	2	6.3	0	0.0	0	0.0
70 to 79	51	41	80.4	10	19.6	0	0.0	0	0.0
>80	26	18	69.2	8	30.8	0	0.0	0	0.0
Total	**113**	**93**	**82.3**	**20**	**17.7**	**0**	**0.0**	**0**	**0.0**

[a] Best-case was defined as eyes without clinically significant preoperative pathology, sulcus implantation, contralateral implantation, macular degeneration at any time, or other significant macular pathology (e.g., macular hole).

TABLE 37
Best-Corrected Distance Visual Acuity (Snellen Equivalent) at 1 Year
ZV9003 Best-Case Subjects[a] (N = 113) vs. FDA Grid

Age Decade	N	Total %	20/40 or Better N	20/40 or Better %	FDA Grid %
< 60	4	3.54%	4	100.0	98.5
60 to 69	32	28.32%	32	100.0	96.5
70 to 79	51	45.13%	51	100.0	97.5
> 80	26	23.01%	26	100.0	94.8
Total	**113**	**100.0**	**110**	**100.0**	**96.7**

[a] Best-case was defined as eyes without clinically significant preoperative pathology, sulcus implantation, contralateral implantation, macular degeneration at any time, or other significant macular pathology (e.g., macular hole).

Color Vision

As part of the inclusion criteria, all subjects underwent binocular color vision testing using the Ishihara color test and the Farnsworth-Munsell D-15 color vision test. Farnsworth-Munsell D-15 color testing was performed again at the 4-6 month and one-year postoperative visits. At 4-6 months, 98.3% (119/121) of subjects implanted with the ZV9003 lens and 99.2% (118/119) of subjects implanted with the control lens

passed the color vision test. At one year, 99.2 (118/119) of subjects implanted with the ZV9003 lens and 95.8% (115/120) of subjects implanted with the control lens passed the color vision test (**Table 38**).

TABLE 38
Farnsworth-Munsell D-15 Color Vision Test at 4-6 Months and One Year

	ZV9003		Control	
Color Vision Test	**4-6 Months (N=121)**	**One Year (N=119)**	**4-6 Months (N=119)**	**One Year (N=120)**
Pass	98.3%	99.2%	99.2%	95.8%
Perfect (no errors)	95.0%	97.5%	93.2%	96.5%
Not Perfect (1 major error and minor errors)	5.0%	2.5%	6.8%	3.5%
Fail (≥2 major errors)	1.7%	0.8%	0.8%	4.2%

A statistically significant difference was observed between lens groups for driving during the day at 4-6 months (p=0.0044) and at one year (p=0.0330). Subjects implanted with ZV9003 reported less difficulty driving during the day, compared to subjects implanted with the control lens (**Table 39**).

TABLE 39
Subject Assessment of Driving During Daytime, 4-6 Months and One Year Directed Responses to a Subjective Questionnaire

	4 to 6 Months[a]		One Year[b]	
Driving During Daytime	**ZV9003 N=121**	**Control N=120**	**ZV9003 N=119**	**Control N=120**
No difficulty at all	100.0%	92.9%	98.1%	91.7%
A little difficulty	0.0%	5.4%	0.9%	8.3%
Moderate difficulty	0.0%	1.8%	0.0%	0.0%
Extreme difficulty	0.0%	0.0%	0.9%[c]	0.0%

[a] Statistically significant difference (p=0.0044) at 4-6 months, based on Wilcoxon Rank-Sum test
[b] Statistically significant difference (p=0.0330) at one year, based on Wilcoxon Rank-Sum test
[c] One subject implanted with ZV9003 had difficulty driving during the daytime preoperatively and at one year, which may not be lens-related. The subject's visual acuity was excellent at the one-year visit, and there were no other issues.

Adverse Events
The incidence of adverse events reported during the clinical trial for the TECNIS OptiBlue™ IOL is similar to or less than that of the historic control population (FDA Grid for posterior chamber IOLs) as shown in **Tables 40** and **41**. There were no persistent adverse events reported during the study. The incidence rates for the Model ZV9003 lens compared favorably to the specified FDA rates.

TABLE 40
Adverse Events, TECNIS OptiBlue™ IOL, Model ZV9003, First Eyes (N = 126)

	Study Eyes		FDA Grid Rate
Cumulative Adverse Event	**n**	**%**	**%**
Subjects with no Adverse Events	**126**	**100.0**	**N/A**
Subjects with Adverse Events	**0**	**0.0**	**N/A**
○ Cystoid Macular Edema (CME)	0	0.0	3.0
○ Secondary Surgical Intervention	0	0.0	0.8
○ Endophthalmitis	0	0.0	0.1
○ Hyphema	0	0.0	2.2
○ Hypopyon	0	0.0	0.3
○ Lens Dislocation	0	0.0	0.1
○ Pupillary Block	0	0.0	0.1
○ Retinal Detachment	0	0.0	0.3

TABLE 41
Adverse Events, TECNIS OptiBlue™ IOL, Model ZV9003, Second Eyes (N = 126)

Cumulative Adverse Event	Study Eyes		FDA Grid Rate
	n	%	%
Subjects with no Adverse Events	**125**	**99.2**	**N/A**
Subjects with Adverse Events	**1**	**0.8**	**N/A**
○ Cystoid Macular Edema (CME)	0	0.0	3.0
○ Secondary Surgical Intervention	1	0.8	0.8
○ Endophthalmitis	0	0.0	0.1
○ Hyphema	0	0.0	2.2
○ Hypopyon	0	0.0	0.3
○ Lens Dislocation	0	0.0	0.1
○ Pupillary Block	0	0.0	0.1
○ Retinal Detachment	0	0.0	0.3

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 42**. In addition, the results compared to the FDA Grid values (historical control) are presented in **Table 43**.

TABLE 42
SENSAR Model AAB00 IOL (upon which TECNIS Synergy IOL is based)
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 to 69	35	29	82.9	6	17.1	0	0.0	0	0.0
70 to 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 43
SENSAR Model AAB00 IOL (upon which TECNIS Synergy IOL is based):
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 to 69	35	31.8	35	100.0	96.5
70 to 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.

CLINICAL STUDY RESULTS FOR THE SENSAR® IOL, MODEL AAB00

The acrylic SENSAR® 1-piece IOL, 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 SENSAR® 1-piece IOL, 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.

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 44**.

TABLE 44
SENSAR Model AAB00 IOL (upon which TECNIS Synergy IOL is based):
Adverse Events
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).

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, and the range of near vision with TECNIS Synergy™ IOL allows for the selection of an IOL power that predicts the least hyperopic residual refraction. Accuracy of IOL power calculation is particularly important with the TECNIS Synergy™ IOLs and TECNIS Synergy™ Toric II IOLs, as reduced eyeglass wear is the goal of IOL implantation. The A-constants listed on the outer label are a guideline and serve as a starting point for power calculations. The physician should preoperatively determine the spherical equivalent and cylindrical power of the lens to be implanted.

For TECNIS Synergy™ IOLs: Use of the Johnson & Johnson Surgical Vision, Inc. provided TECNIS Toric IOL Calculator tool is recommended for determining the appropriate TECNIS Synergy™ Toric II IOL model, optimal axis of IOL placement and cylinder power. The TECNIS Synergy™ Toric II IOL is labeled with the IOL distance spherical equivalent power. Physicians requiring additional information on lens power calculations may contact the local Johnson & Johnson Surgical Vision, Inc. representative.

Lens power calculation methods are described in the following references:

- Barrett, Graham D. "An improved universal theoretical formula for intraocular lens power prediction." *Journal of Cataract & Refractive Surgery* 19.6 (1993): 713-720.
- Canovas, Carmen, and Pablo Artal. "Customized eye models for determining optimized intraocular lenses power." *Biomedical optics express* 2.6 (2011): 1649-1662.
- Haigis Wolfgang. “The Haigis Formula.” Shammas, H. John. *Intraocular Lens Power Calculations*. Slack Incorporated, 2004.
- Hoffer, Kenneth J. "The Hoffer Q formula: a comparison of theoretic and regression formulas." *Journal of Cataract & Refractive Surgery* 19.6 (1993): 700-712.
- Holladay, Jack T., et al. "A three-part system for refining intraocular lens power calculations." *Journal of Cataract & Refractive Surgery* 14.1 (1988): 17-24.
- Holladay, Jack T. "Standardizing constants for ultrasonic biometry, keratometry, and intraocular lens power calculations." *Journal of Cataract & Refractive Surgery* 23.9 (1997): 1356-1370.
- Norrby, Sverker NE. "Unfortunate discrepancies." *Journal of Cataract & Refractive Surgery* 24.4 (1998): 433.
- Olsen T. “The Olsen formula.” Shammas, H. John. *Intraocular Lens Power Calculations*. Slack Incorporated, 2004.
- Retzlaff, John A., Donald R. Sanders, and Manus C. Kraff. "Development of the SRK/T intraocular lens implant power calculation formula." *Journal of Cataract & Refractive Surgery* 16.3 (1990): 333-340.

SELECTION AND PLACEMENT OF THE TECNIS SYNERGY™ TORIC II IOLS (MODELS ZFW150, ZFW225, ZFW300, AND ZFW375):

The astigmatism to be corrected should be determined from keratometry and biometry rather than refractive data since the presence of lenticular astigmatism in the crystalline lens to be removed may influence results. The size and location of the surgical incision may affect the amount and axis of corneal astigmatism. To facilitate IOL selection and placement, Johnson & Johnson Surgical Vision, Inc. provides a web-based proprietary tool, the TECNIS Toric IOL Calculator (www.TecnisToricCalc.com) for the surgeon. The corneal astigmatism to be corrected at the time of surgery is calculated by the TECNIS Toric IOL 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.

The TECNIS Toric Calculator also provides an option for including the Posterior Corneal Astigmatism (PCA) (where available). The predetermined value for posterior corneal astigmatism can be included in the calculation by checking the box labeled “Include Posterior Corneal Astigmatism (PCA)”. The option to include the predetermined value of PCA is based on an algorithm that combines published literature (Koch, et al. “Contribution of posterior corneal astigmatism to total corneal astigmatism.” J Cataract Refract Surg. 2012 Dec;38(12):2080-7) with a retrospective analysis of existing clinical data.

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 Synergy™ Toric II IOL models. In eyes with low levels of corneal astigmatism, the predicted residual refractive astigmatism for implantation of a TECNIS® Monofocal 1-Piece lens, Model ZCB00, will be displayed for evaluation by the surgeon to determine the clinically meaningful benefit of implanting a TECNIS Synergy™ Toric II 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 IOL 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 Synergy™ Toric II 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 IOL 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 Synergy™ Toric II 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 Synergy™ Toric II 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 Synergy™ Toric II 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 Synergy™ Toric II IOL axis during surgery, an unanticipated surgically induced change in the cornea, or physical rotation of the TECNIS Synergy™ Toric II 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 proper 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 Synergy™ Toric II 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:
    i. The surgeon should target emmetropia as this lens is designed for optimum visual performance when emmetropia is achieved.
    ii. Care should be taken to achieve centration of the intraocular lens in the capsular bag.

8. Johnson & Johnson Surgical Vision, Inc. recommends using The UNFOLDER® Platinum 1 Series implantation system with the 1MTEC30 cartridge to insert the TECNIS Synergy™ IOLs. Alternate validated insertion systems that can be used to insert the TECNIS Synergy™ 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 Synergy™ Toric II IOL, align the lens with the intended axis of placement, following the recommendations provided in the "Selection and Placement" section for the TECNIS Synergy™ Toric II IOLs.

Factors to consider in deciding whether to implant a TECNIS Synergy™ Toric II IOL:
Effectiveness of implanting a toric IOL 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.
- The clinical data presented in Table 17 represent outcomes that include the sources of variation listed above.

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

PATIENT REGISTRATION (U.S. Only)
Each patient who receives a TECNIS Synergy™ IOL must be registered with Johnson & Johnson Surgical Vision. Inc. 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 Johnson & Johnson Surgical Vision, Inc. Patient registration is essential for Johnson & Johnson Surgical Vision's long term patient follow-up program and will assist Johnson & Johnson Surgical Vision, Inc. 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 his/her implant and to show the card to any eye care practitioner he/ she may see 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 Johnson & Johnson Surgical Vision, Inc. 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
Johnson & Johnson Surgical Vision, Inc. IOLs 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

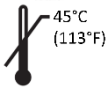
opened only under sterile conditions. The pouch and product labels are enclosed in a shelf pack. The external surfaces of the outer pouch are not sterile.

EXPIRATION DATE
The use-by date on the lens package is the sterility expiration date. The lens shall not be implanted after the indicated sterility expiration date.

RETURN/EXCHANGE POLICY
Contact the local Johnson & Johnson Surgical Vision, Inc. 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, including information on different IOL options available to them, prior to the decision to implant an intraocular lens.

SYMBOL/EXPLANATION:

SYMBOL	EXPLANATION
	Sterilized using ethylene oxide
	Do not re-use
	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
	Catalogue number
	Serial number

PRODUCT OF THE NETHERLANDS
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