TECNIS® Multifocal 1-Piece Intraocular Lens (IOL) – Models ZKB00 (+2.75 D) and ZLB00 (+3.25 D)

Rx Only

DESCRIPTION:

The TECNIS® Multifocal foldable acrylic 1-Piece lenses, Model ZKB00 and Model ZLB00, are ultraviolet-light absorbing posterior chamber intraocular lenses (IOLs). They are designed to be positioned in the lens capsule to replace the optical function of the natural crystalline lens. The TECNIS® Multifocal 1-Piece lenses incorporate a proprietary wavefront-designed aspheric optic with a squared posterior edge designed to provide a 360-degree barrier. The edge of the optic has a frosted design to reduce potential edge glare effects.

The lenses incorporate a diffractive multifocal optic pattern designed to provide near, intermediate and distance vision and thereby reduce spectacle dependency. The light distribution between the distance and near focus is approximately 50/50. The labeled power of the lens is the distance power. The near power for Model ZKB00 represents a +2.75 diopter add in actual lens power and the near power for Model ZLB00 represents a +3.25 diopter add in actual lens power; however, accommodation will not be restored.

INDICATIONS FOR USE:

The TECNIS® Multifocal 1-Piece intraocular lenses, Models ZKB00 (+2.75 D) and ZLB00 (+3.25 D), are indicated for primary implantation for the visual correction of aphakia in adult patients with and without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire near, intermediate, and distance vision with increased spectacle independence. The intraocular lenses are intended to be placed in the capsular bag.

WARNINGS:

1. Some visual effects associated with multifocal IOLs may be expected because of the superposition of focused and unfocused images. These may include a perception of halos or glare around lights under nighttime conditions. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions. On rare occasions these visual effects may be significant enough that the patient will request removal of the multifocal IOL.

2. Contrast sensitivity is reduced with a multifocal lens compared to a monofocal lens. Therefore, subjects with multifocal lenses should exercise caution when driving at night or in poor visibility conditions.

3. Patients with any of the following conditions may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition or may pose an unreasonable risk to the patient's eyesight:
    a. Patients in whom the intraocular lens may interfere with the ability to observe, diagnose or treat posterior segment diseases.
    b. 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).
    c. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
    d. Circumstance that would result in damage to the endothelium during implantation.
    e. Suspected microbial infection.
    f. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support for the IOL.

g. Congenital bilateral cataracts.
h. Recurrent severe anterior or posterior segment inflammation of unknown etiology, or any disease producing an inflammatory reaction in the eye.
i. Previous history of, or a predisposition to, retinal detachment.
j. Patients with only one eye with potentially good vision.
k. Medically uncontrollable glaucoma.
l. Corneal endothelial dystrophy.
m. Proliferative diabetic retinopathy.

4. The TECNIS® Multifocal 1-Piece IOL should be placed entirely in the capsular bag. Do not place the lens in the ciliary sulcus.

5. The splitting of the light into more than one focus may affect image quality and lead to some reduction of contrast sensitivity.

6. Well-informed patients with well-defined visual needs and preferences should be selected for TECNIS® Multifocal 1-Piece lens implantation. The patients should be informed about the possibility that a decrease in contrast sensitivity and an increase of visual disturbances may affect their ability to drive a car under certain environmental conditions, such as driving at night or in poor visibility conditions.

7. Patients with a predicted postoperative astigmatism greater than 1.0 diopter may not be suitable candidates for multifocal IOL implantation since they may not fully benefit from a multifocal IOL in terms of potential spectacle independence.

8. Care should be taken to achieve IOL centration, as lens decentration may result in patients experiencing visual disturbances, particularly in patients with large pupils under mesopic conditions.

9. Multifocal IOL implants may be inadvisable in patients where central visual field reduction may not be tolerated, such as macular degeneration, retinal pigment epithelium changes, and glaucoma.

PRECAUTIONS:

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

2. There were no patients 21 years old or younger included in the clinical studies; therefore there are insufficient clinical data to demonstrate safety and effectiveness in this age group.

3. The central one millimeter area of the TECNIS® Multifocal 1-Piece IOL creates a far image focus in accordance with the labeled power of the IOL, so patients with abnormally small pupils (~1mm) should achieve, at a minimum, the prescribed distance vision under photopic conditions; however, because this multifocal design has not been tested in patients with abnormally small pupils, it is unclear whether such patients will derive any near vision benefit.

4. Autorefractors may not provide optimal postoperative refraction of patients with multifocal lenses. Manual refraction is strongly recommended.

5. 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.

6. When performing wavefront measurements on a patient with a multifocal lens, two different wavefronts are produced. One wavefront will be in focus (either far or near) and the other

wavefront will be out of focus. In this situation, incorrect interpretation of the wavefront measurements is possible.

7. The long-term effects of intraocular lens implantation have not been determined. Therefore the physician should continue to monitor implant patients postoperatively on a regular basis.

8. Secondary glaucoma has been reported occasionally in patients with controlled glaucoma who received lens implants. The intraocular pressure of implant patients with glaucoma should be carefully monitored postoperatively.

9. Do not resterilize this intraocular lens by any method.

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

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

12. Prior to implanting, examine the lens package for proper lens model, dioptric power, and expiration date.

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

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

15. 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. When the insertion system is used improperly, the haptics of the TECNIS® Multifocal 1-Piece lens may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system.

CLINICAL STUDY RESULTS for the TECNIS® Multifocal 1-Piece IOL, Models ZKB00 (+2.75 D) and ZLB00 (+3.25 D)

The clinical trial of the TECNIS® Multifocal IOL, Models ZKB00 (+2.75 D) and ZLB00 (+3.25 D) was a prospective, multicenter, bilateral, open-label, evaluator-masked, modified-parallel group trial conducted at 18 investigative sites in the United States and one investigative site in the United Kingdom.

The clinical study results achieved through 6 months postoperatively demonstrate that the TECNIS® Multifocal IOL, Models ZKB00 (+2.75 D) and ZLB00 (+3.25 D) are safe and effective for the visual correction of aphakia. The following clinical results demonstrate that the TECNIS® Multifocal IOL, Models ZKB00 (+2.75 D) and ZLB00 (+3.25 D) provide improved near visual acuity, improved simultaneous distance and near (combination) vision, improved depth of focus, and decreased spectacle use compared to a monofocal control IOL (TECNIS® 1-Piece, Model ZCB00).

Note: The primary analysis group for the primary and secondary study endpoints (distance-corrected near vision, depth of focus, simultaneous/combination visual acuity and spectacle independence) was an intent-to-treat (ITT) population; however, as only 4 subjects (2 ZKB00 and 2 ZCB00 controls) were unavailable for analysis at 6 months, the outcomes for the ITT population and the overall safety population (all implanted subjects with available data) were very similar. As such, outcomes for the safety population are presented for all study endpoints.

Subject Population

A total of 445 subjects were enrolled and implanted (441 bilaterally implanted). Of these, 147 were in the ZKB00 IOL group, 150 were in the ZLB00 group and 148 were in the monofocal control group. There were no statistically significant differences between the multifocal IOL groups and the control group for age, gender, race or eye color. The mean age of all three IOL groups was approximately 68 years (67.6 ± 6.9 years for ZKB00 subjects; 67.9 ± 6.8 years for ZLB00 subjects; 68.5 ± 6.8 years for ZCB00 control subjects). In each IOL group, most subjects were Caucasian (≥93%) and the majority of subjects were female (≥50%). The 6-month study results are presented for 145 ZKB00 subjects (143 bilaterally implanted), 150 ZLB00 subjects (all bilaterally implanted) and 146 ZCB00 control subjects (all bilaterally implanted).

Distance Visual Acuities

Distance visual acuities were tested using 100% ETDRS charts at 4.0 m. **Tables 1** and **2** present photopic (85 cd/m^2) monocular and binocular uncorrected and best corrected distance visual acuity results at 6 months for all three lens groups. At 6 months, monocular best corrected distance visual acuity results for first eyes implanted with TECNIS® Multifocal IOL, Models ZKB00 (+2.75 D) and ZLB00 (+3.25 D), were above the ISO Safety and Performance Endpoints (SPE) criterion for percent of eyes with best-corrected distance visual acuity achieving 20/40 or better (92.5%; see **Table 1**). Additionally, 99.3% (143/144) of the ZKB00 best-case first eyes and 100% (149/149) of the ZLB00 best-case eyes achieved 20/40 or better best corrected distance visual acuity at 6 months, exceeding the ISO SPE rate for best-case (96.7%) as well.

Table 1:
Monocular Distance Visual Acuity at 6 Months

	ZKB00(+2.75) N=145		ZLB00(+3.25) N=150		ZCB00 N=146	
Visual Acuity	**Uncorrected**	**Best Corrected**	**Uncorrected**	**Best Corrected**	**Uncorrected**	**Best Corrected**
20/20 or better	41.4%	84.8%	40.0%	82.7%	48.6%	87.7%
20/25 or better	70.3%	97.2%	67.3%	94.0%	80.8%	97.9%
20/32 or better	86.2%	99.3%	84.7%	100.0%	89.7%	99.3%
20/40 or better	93.1%	99.3%	96.0%	100.0%	95.2%	100.0%
20/50-20/80	6.9%	0.7%	4.0%	0.0%	4.8%	0.0%
20/100 or worse	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table 2:
Binocular Distance Visual Acuity at 6 Months

	ZKB00(+2.75) N=143		ZLB00(+3.25) N=150		ZCB00 N146	
Visual Acuity	**Uncorrected**	**Best Corrected**	**Uncorrected**	**Best Corrected**	**Uncorrected**	**Best Corrected**
20/20 or better	73.4%	94.4%	72.0%	94.0%	75.3%	95.9%
20/25 or better	93.0%	99.3%	92.0%	100.0%	91.1%	100.0%
20/32 or better	97.9%	100.0%	98.7%	100.0%	96.6%	100.0%
20/40 or better	99.3%	100.0%	99.3%	100.0%	99.3%	100.0%
20/50-20/80	0.7%	0.0%	0.7%	0.0%	0.7%	0.0%
20/100 or worse	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Mean monocular and binocular distance visual acuities at 6 months for all three lens groups are presented in **Table 3.** Mean distance visual acuities were clinically comparable between lens groups with mean LogMAR differences within one half line or less for both the ZKB00 and ZLB00 IOLs as compared to the ZCB00 control IOL. Additionally, the upper limits of the confidence intervals of the mean difference between multifocal and control groups for BCDVA were less than half a line, demonstrating non-inferiority of the ZKB00 (+2.75 D) and ZLB00 (+3.25 D) lenses for providing distance visual acuity compared to the monofocal control.

Table 3:
Mean Distance Visual Acuity at 6 Months

		Monocular				Binocular			
Distance Visual Acuity	**Lens Group**	**N**	**Mean LogMAR**	**Snellen Line Equiv.**	**Line Change vs. ZCB00**	**N**	**Mean LogMAR**	**Snellen Line Equiv.**	**Line Change vs. ZCB00**
Uncorrected	ZKB00(+2.75)	145	0.102	20/25	-0.2	143	0.008	20/20	-0.1
	ZLB00(+3.25)	150	0.112	20/25	-0.3	150	0.016	20/20	-0.2
	ZCB00	146	0.078	20/25		146	-0.005	20/20	
Best Corrected	ZKB00(+2.75)	145	-0.022	20/20	-0.1	143	-0.073	20/16	-0.1
	ZLB00(+3.25)	150	-0.012	20/20	-0.2	150	-0.062	20/16	-0.2
	ZCB00	146	-0.036	20/20		146	-0.085	20/16	

Near Visual Acuities

Near visual acuities were tested using 100% ETDRS charts at the fixed test distance of 40 cm and at the subjects' best distance, with and without distance correction under photopic (85 cd/m^2) lighting conditions and with distance correction under mesopic (3 cd/m^2) lighting conditions. Mean monocular and binocular near visual acuities at 6 months for all three lens groups are presented in **Table 4.** The true test of a multifocal optic is the evaluation of near vision with distance correction in place eliminating any effects from residual refractive error. Mean monocular distance corrected near visual acuity as measured at 40 cm was statistically significantly better (**p<0.0001**) for the ZKB00 (+2.75 D) and ZLB00 (+3.25 D) models compared to the monofocal control by 3.3 lines for the ZKB00 IOL and by 4.0 lines for the ZLB00 IOL**.** Near visual acuity results demonstrate the effectiveness of the TECNIS® Multifocal 1-Piece IOLs, Models ZKB00 (+2.75 D) and ZLB00 (+3.25 D) in providing substantial near vision compared to the monofocal control lens.

Table 4:
Mean Near Visual Acuity at 6 Months

			Monocular				Binocular			
Near Visual Acuity	**Test Distance**	**Lens Group**	**N**	**Mean LogMAR**	**Snellen Line Equiv.**	**Line Gain vs. ZCB00**	**N**	**Mean LogMAR**	**Snellen Line Equiv.**	**Line Gain vs. ZCB00**
Uncorrected Photopic	40 cm	ZKB00 (+2.75)	145	0.238	20/32	3.3	143	0.135	20/25	3.1
		ZLB00 (+3.25)	150	0.185	20/32	3.8	150	0.097	20/25	3.5
		ZCB00	146	0.568	20/80		146	0.443	20/50	
	Best[a]	ZKB00 (+2.75)	145	0.148	20/25	3.3	143	0.079	20/25	2.7
		ZLB00 (+3.25)	150	0.141	20/25	3.3	150	0.068	20/25	2.8
		ZCB00	146	0.476	20/63		146	0.346	20/40	
Distance Corrected Photopic[b]	40 cm	ZKB00 (+2.75)	145	0.252[b]	20/40	3.3	143	0.170	20/32	3.2
		ZLB00 (+3.25)	150	0.179[b]	20/32	4.0	150	0.106	20/25	3.8
		ZCB00	146	0.582	20/80		146	0.488	20/63	
	Best[a]	ZKB00 (+2.75)	145	0.154	20/32	3.5	143	0.093	20/25	3.2
		ZLB00 (+3.25)	150	0.141	20/25	3.6	150	0.077	20/25	3.3
		ZCB00	146	0.503	20/63		146	0.408	20/50	
Distance Corrected Mesopic	40 cm	ZKB00 (+2.75)	145	0.447	20/50	3.3	143	0.362	20/50	3.4
		ZLB00 (+3.25)	150	0.375	20/50	4.0	150	0.282	20/40	4.2
		ZCB00	146	0.773	20/126		146	0.698	20/100	
	Best[a]	ZKB00 (+2.75)	145	0.367	20/50	3.2	143	0.292	20/40	3.3
		ZLB00 (+3.25)	150	0.330	20/40	3.6	150	0.259	20/40	3.6
		ZCB00	146	0.692	20/100		146	0.624	20/80	

[a] Best test distance is the distance at which the subject can read the smallest letters with the most ease.

[b] The primary study endpoint was photopic distance corrected near VA for first eyes. ZKB00 & ZLB00 showed statistically significantly better VA compared to ZCB00 with **p <0.0001** (from one sided two sample t-test).

Distributions of near visual acuity results at 6 months for all three lens groups are presented in **Tables 5-8**. **Table 5** and **6** present monocular (first eye) photopic uncorrected and distance corrected near visual acuities. **Tables 7** and **8** present binocular photopic uncorrected and distance corrected near visual acuities. In all cases, larger proportions of the ZKB00 and ZLB00 multifocal subjects achieved better near visual acuities compared to monofocal subjects, with or without correction, monocularly or binocularly, at the fixed test distance of 40 cm or at the subject's best distance (distance at which the subject could read the smallest letters with the most ease). With

distance correction in place eliminating any effects from residual refractive error, 93-100% of ZKB00 (+2.75 D) and ZLB00 (+3.25 D) subjects achieved 20/40 or better at near at best distance, monocularly or binocularly, compared to 17-39% of monofocal subjects (**Tables 6 and 8**).

Table 5: Monocular Photopic Uncorrected Near Visual Acuity at 6 Months

	ZKB00(+2.75)		ZLB00(+3.25)		ZCB00	
Visual Acuity	**40 cm N=145**	**Best N=145**	**40 cm N=150**	**Best N=150**	**40 cm N=146**	**Best N=146**
20/20 or better	7.6%	17.2%	14.0%	20.0%	0.0%	0.0%
20/25 or better	30.3%	52.4%	49.3%	52.0%	0.7%	4.1%
20/32 or better	61.4%	82.1%	72.7%	84.7%	3.4%	13.0%
20/40 or better	77.2%	93.1%	88.0%	93.3%	17.8%	30.1%
20/50-20/80	21.4%	6.9%	11.3%	6.7%	45.9%	49.3%
20/100 or worse	1.4%	0.0%	0.7%	0.0%	36.3%	20.5%

Table 6: Monocular Photopic Distance Corrected Near Visual Acuity at 6 Months

	ZKB00(+2.75)		ZLB00(+3.25)		ZCB00	
Visual Acuity	**40 cm N=145**	**Best N=145**	**40 cm N=150**	**Best N=150**	**40 cm N=146**	**Best N=146**
20/20 or better	6.9%	21.4%	12.7%	26.0%	0.0%	0.0%
20/25 or better	26.2%	50.3%	51.3%	58.0%	0.7%	2.1%
20/32 or better	51.0%	75.9%	75.3%	82.0%	4.1%	7.5%
20/40 or better	80.0%	93.8%	90.7%	90.7%	11.0%	17.1%
20/50-20/80	18.6%	6.2%	9.3%	9.3%	56.8%	65.1%
20/100 or worse	1.4%	0.0%	0.0%	0.0%	32.2%	17.8%

Table 7: Binocular Photopic Uncorrected Near Visual Acuity at 6 Months

	ZKB00(+2.75)		ZLB00(+3.25)		ZCB00	
Visual Acuity	**40 cm N=143**	**Best N=143**	**40 cm N=150**	**Best N=150**	**40 cm N=146**	**Best N=146**
20/20 or better	24.5%	39.9%	34.7%	42.7%	0.0%	4.1%
20/25 or better	63.6%	74.8%	78.7%	82.0%	4.1%	11.0%
20/32 or better	83.9%	93.0%	94.7%	96.7%	15.8%	32.9%
20/40 or better	95.1%	98.6%	98.7%	99.3%	33.6%	50.7%
20/50-20/80	4.9%	1.4%	1.3%	0.7%	56.8%	45.2%
20/100 or worse	0.0%	0.0%	0.0%	0.0%	9.6%	4.1%

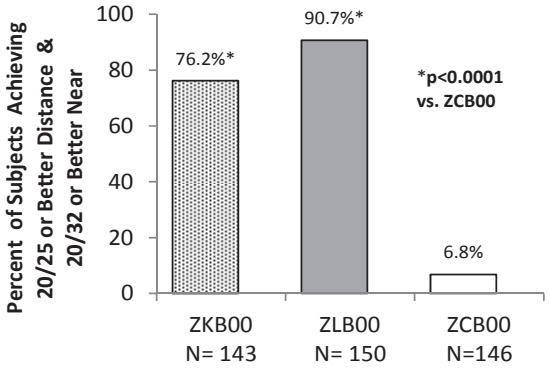
Table 8: Binocular Photopic Distance Corrected Near Visual Acuity at 6 Months

	ZKB00(+2.75)		ZLB00(+3.25)		ZCB00	
Visual Acuity	**40 cm N=143**	**Best N=143**	**40 cm N=150**	**Best N=150**	**40 cm N=146**	**Best N=146**
20/20 or better	11.2%	30.1%	31.3%	37.3%	0.0%	1.4%
20/25 or better	50.3%	75.5%	74.0%	80.0%	1.4%	4.1%
20/32 or better	76.2%	93.0%	90.7%	90.0%	6.8%	12.3%
20/40 or better	97.2%	99.3%	97.3%	98.7%	23.3%	37.7%
20/50-20/80	2.8%	0.7%	2.7%	1.3%	60.3%	52.7%
20/100 or worse	0.0%	0.0%	0.0%	0.0%	16.4%	9.6%

Combination Visual Acuities

Combination visual acuities represent the proportion of subjects that achieved a specific distance acuity and a specific near acuity at the same visit, and as such represents the ability to achieve simultaneous vision provided by multifocal optics. **Figure 1** presents the proportions of subjects that achieved 20/25 or better binocular best corrected distance and 20/32 or better distance-corrected near visual acuity at 6 months for all three lens groups. Statistically significantly (**p<0.0001**) more ZKB00 and ZLB00 multifocal subjects achieved the specified combined visual acuities compared to monofocal subjects. With distance correction in place eliminating any effect from residual refractive error, 76.2% of ZKB00 (+2.75 D) subjects and 90.7% of ZLB00 (+3.25 D) subjects achieved 20/25 or better binocular distance and 20/32 or better binocular near visual acuity compared to only 6.8% of monofocal subjects.

Figure 1:
Combined 20/25 or Better Binocular Best Corrected Distance and 20/32 or Better Binocular Distance-Corrected Near Visual Acuity at 6 Months



Depth of Focus

Defocus curve testing was performed on a subset of approximately 60 subjects from each lens group at the 6-month study exam to evaluate binocular best corrected distance visual acuity defocus curves, and any effects of pupil size. The substudy was a non-randomized, modified parallel-group comparison of the binocular best corrected visual acuity depth of focus. Results were also analyzed for three pupil size ranges: ≤2.5 mm; >2.5 mm and <4.0 mm; and ≥4.0 mm.

Figure 2 presents the defocus curves for all three lens groups combined; results were adjusted for cases with residual refractive error following manifest refraction. Prominent near peaks are shown in **Figure 2** at approximately -2.0 D for the ZKB00 (+2.75 D) IOL and -2.5 D for the ZLB00 (+3.25 D) IOL. Both ZKB00 (+2.75 D) and ZLB00 (+3.25 D) multifocal subjects were found to have a statistically significantly increased (**p<0.0001**) range of defocus with visual acuity of 20/40 or better compared to monofocal subjects (**Figure 2 and Table 9**).

Figure 2:
Binocular Defocus Curves at 6 Months
Bilateral Subjects- ZKB00, ZLB00, and ZCB00

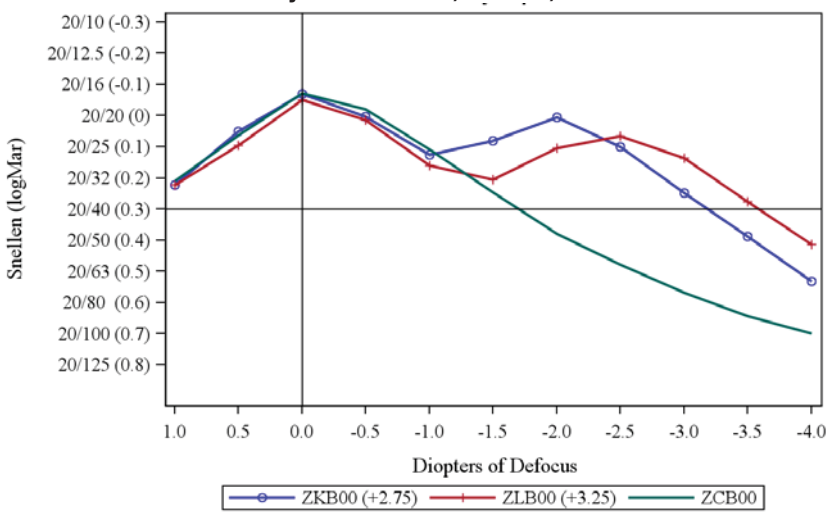


Table 9:
Mean of Diopter Range With Visual Acuity of 20/40 or Better at 6 Months
Defocus Testing[a] Using Range of 0 to -4 Diopters

IOL	N	Mean (D)	Std Dev.	P-value[b]
ZKB00 (+2.75)	59	3.16	0.50	
ZCB00	61	1.75	0.70	
Difference		1.42		**<0.0001**
ZLB00 (+3.25)	63	3.30	0.69	
ZCB00	61	1.75	0.70	
Difference		1.56		**<0.0001**

[a] Adjusted for cases with residual refractive error following manifest refraction
[b] P-value is from one-sided two-sample t-test

The defocus results of the ZKB00 (+2.75 D) and ZLB00 (+3.25 D) multifocal IOLs strongly illustrate the multifocality of the optic design at any pupil size (**Figures 3-4**). Minimal pupil size effect was observed. Even at intermediate distances (~1.5 D of defocus), depth of focus curves for all pupil size groups displayed visual acuity of 20/40 or better. In summary, depth of focus was significantly increased for the ZKB00 (+2.75 D) and ZLB00 (+3.25 D) multifocal subjects compared to monofocal subjects with an increased range of vision at which visual acuity was 20/40 or better.

Figure 3: Binocular Defocus Curve by Average Pupil Size at 6 Months Bilateral Subjects—ZKB00

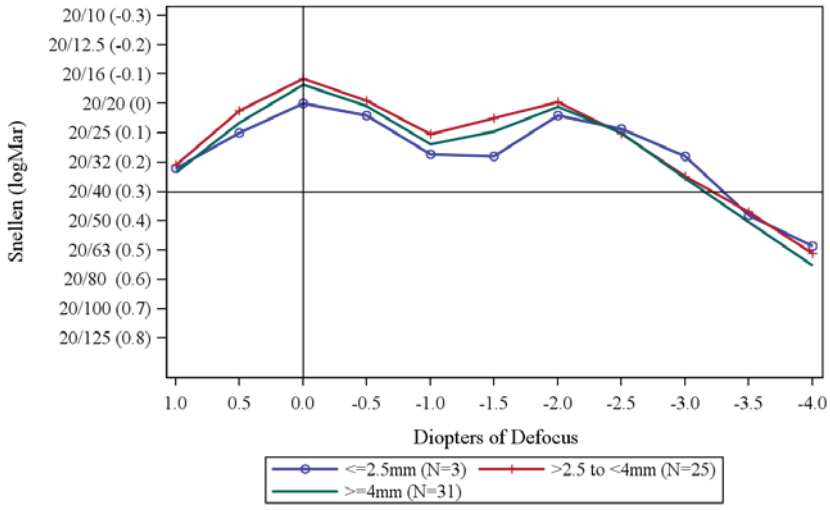
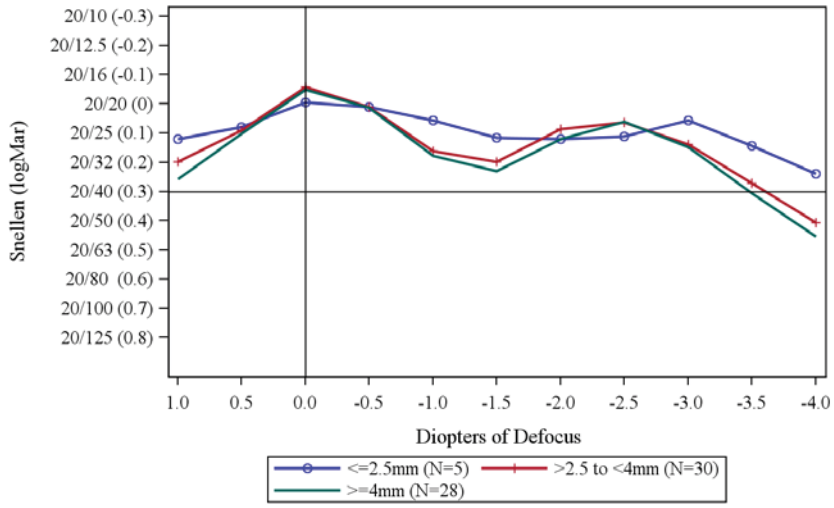


Figure 4: Binocular Defocus Curve by Average Pupil Size at 6 Months Bilateral Subjects—ZLB00



Contrast Sensitivity

Binocular best corrected distance contrast sensitivity testing was performed using the Vector Vision ETDRS light box and contrast sensitivity charts under three lighting conditions: mesopic without glare (**Table 10**), mesopic with glare (**Table 11**), and photopic with glare (**Table 12**). As expected with multifocality, median contrast scores for both the ZKB00 and ZLB00 multifocal subject groups were somewhat reduced compared to the monofocal control group under each lighting condition and spatial frequency (**Tables 10-12**). The most challenging condition was mesopic lighting with glare as median scores were slightly lower for all IOL groups for most conditions and median differences between IOL groups were the most prominent. However, with the exception of the mesopic 12 cpd conditions, median differences between IOL groups were generally within -0.15 log units. The largest median differences were between the ZKB00 (+2.75 add) multifocal lens and the ZCB00 monofocal control lens (-0.250 and -0.255 for the 12 cpd mesopic without glare and mesopic with glare conditions, respectively). Assignment of reference patch scores to unmeasurable values would bias the mean values higher and parametric variability estimates lower. The medians (50th percentile values) in **Tables 10-12** are unbiased, because less than 25% of the values were un-measurable (i.e. subjects not seeing the reference pattern) for any condition. The 25th and 75th percentiles are also

reported to give unbiased estimates of the variability of the results. Additionally, no appreciable pupil-size effects were seen when results were analyzed by pupil size; this was expected due to the optic design of the TECNIS® Multifocal IOLs.

Table 10:
Contrast Sensitivity[a] at 6 Months Mesopic Without Glare

Spatial Frequency	Lens Model	N	Mesopic Without Glare				
			25th percentile	Median[b] 50th percentile	75th percentile	Subjects who did not see the reference pattern[a] n	%
1.5 cpd	ZKB00 (+2.75)	143	1.445	1.595	1.745	0	0.0
	ZLB00 (+3.25)	150	1.370	1.595	1.745	0	0.0
	ZCB00	146	1.520	1.670	1.745	0	0.0
3.0 cpd	ZKB00 (+2.75)	143	1.415	1.635	1.780	0	0.0
	ZLB00 (+3.25)	150	1.485	1.705	1.855	0	0.0
	ZCB00	146	1.415	1.630	1.780	1	0.7
6.0 cpd	ZKB00 (+2.75)	143	1.380	1.625	1.700	5	3.5
	ZLB00 (+3.25)	150	1.380	1.550	1.770	3	2.0
	ZCB00	146	1.465	1.700	1.770	3	2.1
12.0 cpd	ZKB00 (+2.75)	143	0.610	0.995	1.250	17	11.9
	ZLB00 (+3.25)	150	0.760	1.080	1.395	17	11.3
	ZCB00	146	0.995	1.245	1.470	13	8.9

[a] All subjects analyzed; Note: reference scores assigned for subjects who did not see the reference pattern for a spatial frequency.
[b] $Log_{10}(Contrast^{-1})$

Table 11:
Contrast Sensitivity[a] at 6 Months Mesopic With Glare

Spatial Frequency	Lens Model	N	Mesopic With Glare				
			25th percentile	Median[b] 50th percentile	75th percentile	Subjects who did not see the reference pattern[a] n	%
1.5 cpd	ZKB00 (+2.75)	143	1.370	1.595	1.745	1	0.7
	ZLB00 (+3.25)	150	1.370	1.595	1.820	0	0.0
	ZCB00	146	1.445	1.670	1.745	0	0.0
3.0 cpd	ZKB00 (+2.75)	143	1.415	1.560	1.780	1	0.7
	ZLB00 (+3.25)	150	1.490	1.705	1.855	1	0.7
	ZCB00	146	1.490	1.630	1.780	0	0.0
6.0 cpd	ZKB00 (+2.75)	143	1.380	1.550	1.700	9	6.3
	ZLB00 (+3.25)	150	1.380	1.625	1.700	6	4.0
	ZCB00	146	1.465	1.700	1.840	3	2.1
12.0 cpd	ZKB00 (+2.75)	143	0.610	0.995	1.325	26	18.2
	ZLB00 (+3.25)	150	0.610	1.080	1.375	22	14.7
	ZCB00	146	0.910	1.250	1.540	13	8.9

[a] All subjects analyzed; Note: reference scores assigned for subjects who did not see the reference pattern for a spatial frequency.
[b] $Log_{10}(Contrast^{-1})$

Table 12:
Contrast Sensitivity[a] at 6 Months Photopic With Glare

Spatial Frequency	Lens Model	N	Photopic With Glare				
			25th percentile	Median[b] 50th percentile	75th percentile	Subjects who did not see the reference pattern[a] n	%
3.0 cpd	ZKB00 (+2.75)	143	1.485	1.705	1.780	1	0.7
	ZLB00 (+3.25)	150	1.490	1.705	1.855	1	0.7
	ZCB00	146	1.630	1.743	1.855	0	0.0
6.0 cpd	ZKB00 (+2.75)	143	1.625	1.770	1.915	4	2.8
	ZLB00 (+3.25)	150	1.625	1.770	1.990	5	3.3
	ZCB00	146	1.770	1.915	2.065	2	1.4
12.0 cpd	ZKB00 (+2.75)	143	1.165	1.400	1.615	7	4.9
	ZLB00 (+3.25)	150	1.250	1.470	1.690	9	6.0
	ZCB00	146	1.325	1.540	1.690	8	5.5
18.0 cpd	ZKB00 (+2.75)	143	0.640	0.960	1.180	9	6.3
	ZLB00 (+3.25)	150	0.725	0.995	1.175	14	9.3
	ZCB00	146	0.885	1.100	1.250	9	6.2

[a] All subjects analyzed; Note: reference scores assigned for subjects who did not see the reference pattern for a spatial frequency.
[b] $Log_{10}(Contrast^{-1})$

Fundus Visualization
At the 6-month study visit, investigators evaluated the ability to visualize the fundus during the dilated fundus exams. In all cases (100%; 145/145 ZKB00 (+2.75 D), 150/150 ZLB00 (+3.25 D) multifocal first eyes and 146/146 monofocal first eyes), fundus visualization was deemed “adequate”. During the study, no difficulties were reported in evaluating or treating retinal complications in multifocal eyes; however, only 3 multifocal eyes underwent a surgical retinal procedure.

Spectacle Independence and Other Questionnaire Items
A subjective questionnaire was administered that consisted of sponsor-developed questions, regarding visual quality and subject satisfaction, as well as spectacle usage and other questions from the Modified TyPE Specification for Cataracts. The questionnaire was administered via telephone by third-party, masked interviewers following the clinical study exams at 6 months. The questionnaire was not determined to be a psychometrically valid assessment of the concept of spectacle independence.

Figures 5-7 present the frequency of spectacle wear for bilaterally implanted subjects at 6 months. Overall rates of “never” using spectacles for the ZKB00 (+2.75 D) and ZLB00 (+3.25 D) lens groups were statistically significantly higher (**p<0.0001**) than the monofocal control group (**Figure 5**).

Figure 5: Overall Spectacle Use at 6 Months
Bilateral Subjects - ZKB00, ZLB00 and ZCB00

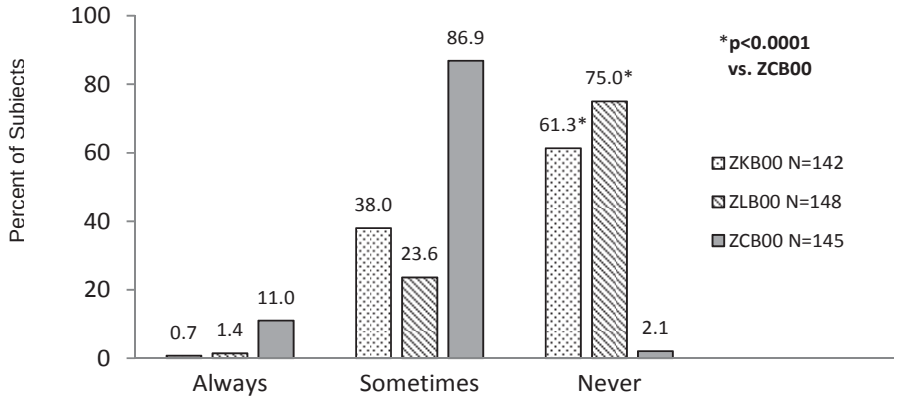


Figure 6: Spectacle Use for Distance Vision at 6 Months
Bilateral Subjects - ZKB00, ZLB00 and ZCB00

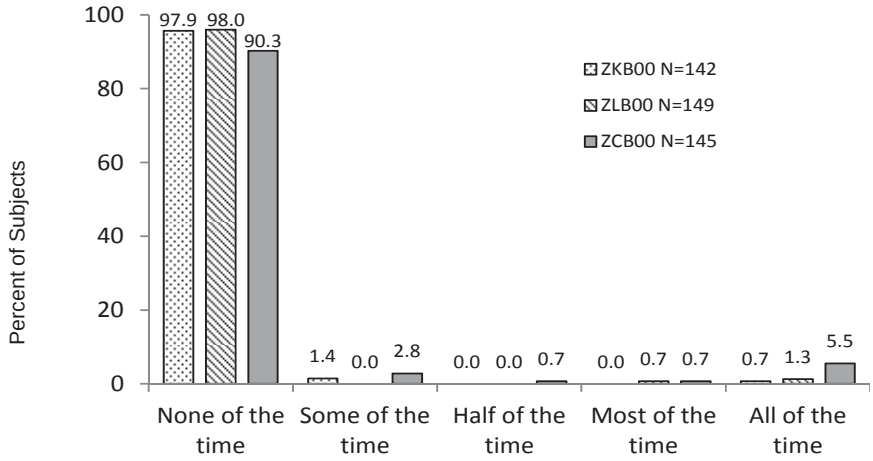


Figure 7: Spectacle Use for Near Vision at 6 Months
Bilateral Subjects - ZKB00, ZLB00 and ZCB00

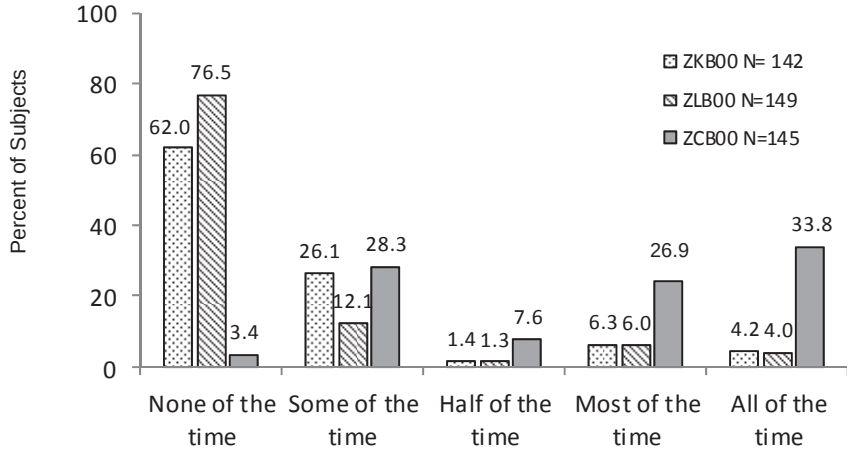
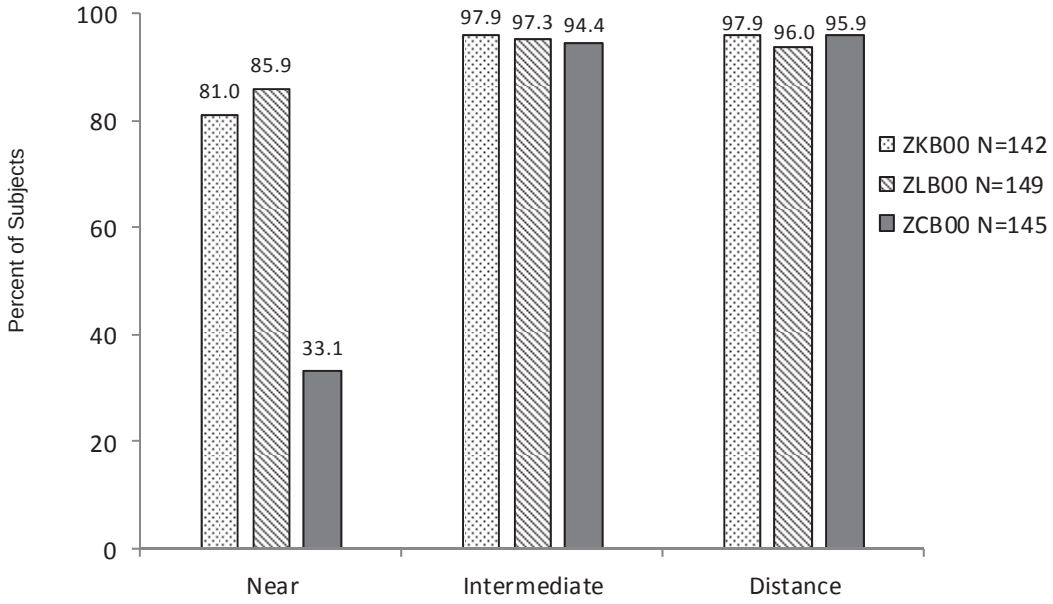


Figure 8 presents the subjects' ability to function comfortably without glasses at near, intermediate and distance.

Figure 8: Ability to Function Comfortably Without Glasses at 6 Months
Bilateral Subjects - ZKB00, ZLB00 and ZCB00



Tables 13-15 present additional subjective results collected in the questionnaire at 6 months. These results include satisfaction with vision without glasses, trouble with vision without glasses, and overall rating of vision.

Table 13:
Satisfaction With Vision Without Glasses at 6 Months

		ZKB00 (+2.75) N=142		ZLB00 (+3.25) N=149		ZCB00 N=145	
		n	%	n	%	n	%
Overall	**Not at all satisfied**	0	0.0	2	1.3	4	2.8
	A little satisfied	0	0.0	0	0.0	6	4.1
	Moderate satisfied	4	2.8	8	5.4	11	7.6
	Mostly satisfied	51	35.9	46	30.9	53	36.6
	Completely satisfied	87	61.3	93	62.4	71	49.0
	Not Reported	0	-	0	-	0	-
During the Day	**Not at all satisfied**	0	0.0	2	1.3	4	2.8
	A little satisfied	0	0.0	1	0.7	7	4.8
	Moderate satisfied	3	2.1	7	4.7	9	6.2
	Mostly satisfied	42	29.6	37	24.8	49	33.8
	Completely satisfied	97	68.3	102	68.5	76	52.4
	Not Reported	0	-	0	-	0	-
At Night	**Not at all satisfied**	0	0.0	5	3.4	5	3.4
	A little satisfied	3	2.1	1	0.7	7	4.8
	Moderate satisfied	12	8.5	14	9.4	11	7.6
	Mostly satisfied	50	35.2	44	29.5	45	31.0
	Completely satisfied	77	54.2	85	57.0	77	53.1
	Not Reported	0	-	0	-	0	-

%=n/N excluding Not Reported

Table 14:
Trouble With Vision Without Glasses at 6 Months

		ZKB00 N=142		ZLB00 N=149		ZCB00 N=145	
		n	%	n	%	n	%
During the Day	**No trouble at all**	108	76.1	121	81.2	101	70.1
	A little bit of trouble	30	21.1	24	16.1	24	16.7
	Moderate trouble	4	2.8	1	0.7	12	8.3
	Considerable trouble	0	0.0	2	1.3	3	2.1
	Major or overwhelming trouble	0	0.0	1	0.7	4	2.8
	Not Reported	0	-	0	-	1	-
At Night	**No trouble at all**	93	65.5	88	59.1	111	76.6
	A little bit of trouble	31	21.8	40	26.8	15	10.3
	Moderate trouble	15	10.6	12	8.1	13	9.0
	Considerable trouble	3	2.1	7	4.7	3	2.1
	Major or overwhelming trouble	0	0.0	2	1.3	3	2.1
	Not Reported	0	-	0	-	0	-

Table 15:
Mean Rating of Vision Without Glasses at 6 Months on a Scale of 0-10

IOL	N	Mean
ZKB00 (+2.75)	142	9.1
ZLB00 (+3.25)	149	9.0
ZCB00	145	8.3

0=worst score, 10=best score

Subjects were also asked in the questionnaire about their desire to elect the same IOL again, if given the opportunity (**Table 16**). The primary reasons subjects would not elect the IOL again were dissatisfaction with visual outcomes for all three lens groups as well as optical/visual effects for the multifocal subjects and the need for glasses at intermediate and near for monofocal subjects.

Table 16:
Desire to Elect IOL at 6 Months

	ZKB00 (+2.75) N=142		ZLB00 (+3.25) N=149		ZCB00 N=145	
	n	%	n	%	n	%
Yes	136	96.5	140	94.0	128	88.3
No	5	3.5	9	6.0	17	11.7
Not Reported	1[a]	-	0	-	0	-

%=n/N excluding not reported.
[a] One subject was inadvertently not asked the question by the interviewer.

Adverse Events

The incidence rates of cumulative adverse events for the ZKB00 (+2.75 D) and ZLB00 (+3.25 D) multifocal first eyes compared to the ISO SPE (safety and performance endpoint) rates are presented in **Table 17**. The incidence rates for the Multifocal IOL Models ZKB00 (+2.75 D) and ZLB00 (+3.25 D) compared favorably to the specified ISO SPE rates. Only the rate of surgical re-interventions in the ZLB00 (+3.25 D) lens group were statistically higher than the FDA grid rate of 0.8% (**p=0.0075** for both first and second eyes). Secondary surgical intervention events for the TECNIS® Multifocal IOL Models ZKB00 (+2.75 D) and ZLB00 (+3.25 D) are specified in **Table 18**.

Table 17:
6-Month Cumulative Medical Complications/Adverse Events vs. ISO 11979-7 SPE[a] Rates

Cumulative Medical Complications/ Adverse Events	ISO SPE[a] Rate	ZKB00 First Eyes N=147		ZKB00 Second Eyes N=145		ZLB00 First Eyes N=150		ZLB00 Second Eyes N=150	
	%	n	%	n	%	n	%	n	%
Cystoid macular edema[b]	3.0	2	1.4	1	0.7	0	0.0	0	0.0
Hypopyon	0.3	0	0.0	0	0.0	0	0.0	1	0.7[c]
Endophthalmitis	0.1	0	0.0	0	0.0	0	0.0	1	0.7[d]
Lens dislocated from posterior chamber	0.1	0	0.0	0	0.0	0	0.0	0	0.0
Pupillary block	0.1	0	0.0	0	0.0	0	0.0	0	0.0
Retinal detachment	0.3	0	0.0	0	0.0	0	0.0	1	0.7[c]
Eyes with secondary surgical intervention	0.8	0	0.0	3	2.1[e]	5[f]	3.3[g]	5[h]	3.3[g]
-Lens related		0	0.0	1	0.7	1	0.7	0	0.0
-Not lens related		0	0.0	2	1.4	4[f]	2.7	5[h]	3.3[g]

[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] Includes all cases of CME, regardless of investigator opinion regarding AE status.
[c] Incidence rate is not statistically significantly different than ISO SPE rate (p=0.3628)
[d] Incidence rate is not statistically significantly different than ISO SPE rate (p=0.1394)
[e] Incidence rate is not statistically significantly different than ISO SPE rate (p=0.1112)
[f] One incident was reported after database lock.
[g] Incidence rate is statistically significantly different than ISO SPE rate (**p=0.0075**)
[h] One of these 5 eyes underwent 3 SSIs for a total of 7 SSI procedures in 5 eyes.

Table 18:
Secondary Surgical Interventions

	ZKB00				ZLB00			
	First Eyes N=147		Second Eyes N=145		First Eyes N=150		Second Eyes N=150	
Secondary Surgical Interventions	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Secondary Surgical Interventions: Lens-Related	***0***	***0.0***	***1***	***0.7***	***1***	***0.7***	***0***	***0.0***
IOL exchange (halos)	*0*	*0.0*	*0*	*0.0*	*1*	*0.7*	*0*	*0.0*
IOL repositioning (decentration)	0	0.0	1	0.7	0	0.0	0	0.0
Secondary Surgical Interventions: Not Lens-Related	**0**	**0.0**	**2**	**1.4**	**4**	**2.7**	**5**	**3.3**
Blepharoplasty	0	0.0	0	0.0	2	1.3	2	1.3
Retinal repair -Endophthalmitis	0	0.0	0	0.0	0	0.0	1[a]	0.7
-Retinal detachment	0	0.0	0	0.0	0	0.0	1	0.7
- Retinal tear	0	0.0	0	0.0	1	0.7	0	0.0
Removal of residual cortex	0	0.0	1	0.7	0	0.0	0	0.0
Ruptured globe repair & iridoplasty	0	0.0	0	0.0	0	0.0	1[b]	0.7
Treatment injections for medical complications:								
-Endophthalmitis (with vitreous tap)	0	0.0	0	0.0	0	0.0	2[a]	1.3
-Episcleritis	0	0.0	0	0.0	1	0.7	0	0.0
-Diabetic retinopathy	0	0.0	1	0.7	0	0.0	0	0.0
TOTAL Eyes	**0**	**0.0**	**3**	**2.1**	**5**	**3.3**	**5**	**3.3**

[a] Same eye.
[b] Orbital fracture due to fall.

Medical complications persistent at 6 months for ZKB00 (+2.75 D) and ZLB00 (+3.25 D) first eyes and second eyes were within ISO SPE rates (**Table 19)**.

Table 19:
6-Month Persistent Medical Complications/Adverse Events vs. ISO 11979-7 SPE[a] Rates

		ZKB00				ZLB00			
	ISO SPE[a] Rate	First Eyes N=147		Second Eyes N=145		First Eyes N=150		Second Eyes N=150	
Persistent Medical Complications/ Adverse Events	**%**	n	**%**	**n**	**%**				
Corneal edema	0.3	0	0.0	0	0.0	0	0.0	0	0.0
Cystoid macular edema	0.5	0	0.0	0	0.0	0	0.0	0	0.0
Iritis	0.3	0	0.0	0	0.0	0	0.0	0	0.0
Raised IOP requiring treatment	0.4	0	0.0	0	0.0	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.

Optical/Visual Symptoms
Non-directed subject responses were obtained from the open-ended question “Are you having any difficulties with your eyes or vision” as asked at the clinical study exams. **Table 20** presents the incidence of non-directed responses for key optical/visual symptoms for first eyes in all three lens groups at 6 months. These include symptoms common to multifocal IOLs (halos, night glare, starbursts, and night vision difficulties) as well as any findings reported with an incidence of 10% or more at 6 months.

Table 20:
Ocular Symptoms (First Eyes) at 6 Months

Ocular Symptoms	ZKB00 N=145		ZLB00 N=150		ZCB00 N=146	
	n	%	n	%	n	%
Image Quality						
Blurred vision	28	19.3	25	16.7	38	26.0
- Overall	4	2.8	7	4.7	2	1.4
- Distance	5	3.4	2	1.3	3	2.1
- Intermediate	3	2.1	3	2.0	2	1.4
- Near	18	12.4	14	9.3	33	22.6
Optical/Visual						
Halos	29	20.0	37	24.7	6	4.1
- Mild	20	13.8	20	13.3	4	2.7
- Moderate	8	5.5	11	7.3	2	1.4
- Severe	1	0.7	6	4.0	0	0.0
Night Glare	7	4.8	8	5.3	2	1.4
- Mild	5	3.4	2	1.3	1	0.7
- Moderate	2	1.4	3	2.0	1	0.7
-Severe	0	0.0	3	2.0	0	0.0
Starbursts	3	2.1	6	4.0	0	0.0
- Mild	1	0.7	3	2.0	0	0.0
- Moderate	2	1.4	1	0.7	0	0.0
-Severe	0	0.0	2	1.3	0	0.0
Night vision difficulty (overall)	0	0.0	4	2.7	2	1.4
Sensation						
Irritated/itchy/scratchy/burning/gritty	7	4.8	20	13.3	13	8.9
Dryness	16	11.0	22	14.7	18	12.3

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

Directed subject responses for optical/visual symptoms were also obtained from a sponsor-developed questionnaire administered by a third-party over the telephone in which bilaterally implanted subjects were asked to rate their degree of “difficulty” for specific visual disturbances. It should be noted that directed questionnaires may contain inherent over-reporting as directed questioning is more subjective and is designed to elicit responses whether or not these would be deemed by the subject significant enough to voluntarily discuss with the investigator and study staff (non-directed response). **Table 21** presents the difficulty reported for night vision, glare/flare and halos at 6 months for ZKB00 (+2.75 D), ZLB00 (+3.25 D) and ZCB00 subjects and **Table 22** presents the trouble with glare reported when driving toward the sun or oncoming headlights. In general, ZKB00 (+2.75 D) and ZLB00 (+3.25 D) subjects reported more difficulty with glare/flare and halos than monofocal subjects and reported more difficulty when driving toward oncoming headlights without glasses; however, overall levels of subject satisfaction remained high for the TECNIS® multifocal subjects (as 96.5% of ZKB00 (+2.75 D) subjects and 94% of ZLB00 (+3.25 D) subjects would choose the same lens again, as shown in **Table 16**).

Table 21:
Degree of Difficulty[a] with Night Vision, Glare/Flare and Halos at 6 Months (With Glasses if You Need Them)

	ZKB00 N=142		ZLB00 N=149		ZCB00 N=145	
	n	%	n	%	n	%
Night Vision						
No difficulty (1, 2)	129	90.8	125	83.9	125	86.2
Moderate difficulty (3, 4, 5)	12	8.5	20	13.4	14	9.7
Severe difficulty (6, 7)	1	0.7	4	2.7	6	4.1
Glare/Flare						
No difficulty (1, 2)	109	76.8	103	69.1	117	80.7
Moderate difficulty (3, 4, 5)	31	21.8	38	25.5	18	12.4
Severe difficulty (6, 7)	2	1.4	8	5.4	10	6.9
Halos						
No difficulty (1, 2)	98	69.0	85	57.0	122	84.1
Moderate difficulty (3, 4, 5)	36	25.4	48	32.2	20	13.8
Severe difficulty (6, 7)	8	5.6	16	10.7	3	2.1

%=n/N

[a] On a scale of 1-7

Table 22:
Degree[a] of Trouble with Glare at 6 Months (Without Glasses)

	ZKB00 N=142		ZLB00 N=149		ZCB00 N=145	
	n	%	n	%	n	%
Driving towards the sun						
No trouble at all (0)	84	60.0	94	65.3	87	61.7
A little bit of trouble (1)	24	17.1	16	11.1	23	16.3
Moderate trouble (2)	20	14.3	18	12.5	17	12.1
Considerable trouble (3)	10	7.1	12	8.3	11	7.8
Major or overwhelming trouble (4)	2	1.4	4	2.8	3	2.1
I do not perform this activity for reasons unrelated to my vision (5)	2	-	5	-	3	-
Not reported	0	-	0	-	1	-
Driving toward oncoming headlights						
No trouble at all (0)	70	51.9	66	48.5	84	64.1
A little bit of trouble (1)	30	22.2	30	22.1	22	16.8
Moderate trouble (2)	19	14.1	23	16.9	13	9.9
Considerable trouble (3)	13	9.6	13	9.6	8	6.1
Major or overwhelming trouble (4)	3	2.2	4	2.9	4	3.1
I do not perform this activity for reasons unrelated to my vision (5)	7	-	13	-	13	-
Not reported	0	-	0	-	1	-

%=n/N excluding Not reported and Do Not Perform this activity.

[a] On a scale of 0-4 (5 = I do not perform this activity for reasons unrelated to my vision)

Table 23 presents the rating of the quality of near and far vision while indoors. Over 90% of subjects reported good vision indoors overall; however, fewer multifocal subjects reported good vision while indoors under dim lighting.

The questionnaire administered was not validated according to FDA's guidance document entitled "Patient-reported outcome measures: use in medical product development to support labeling claims", dated December 2009.

Table 23:
Rating of the Quality[a] (Sharpness, Clarity) of Near and Far Vision at 6 Months (With Glasses if Needed)

	Near Vision						Far Vision					
	ZKB00 N=142		ZLB00 N=149		ZCB00 N=145		ZKB00 N=142		ZLB00 N=149		ZCB00 N=145	
	n	%	%	%	n	%	n	%	n	%	n	%
Indoors												
Poor Vision (1,2)	0	0.0	1	0.7	2	1.4	0	0.0	0	0.0	0	0.0
Fair Vision (3,4,5)	12	8.5	9	6.0	9	6.2	8	5.6	8	5.4	8	5.5
Good Vision (6,7)	130	91.5	139	93.3	134	92.4	134	94.4	140	94.6	137	94.5
Not Reported	0	-	0	-	0	-	0	-	1	-	0	-
Indoors with dim lighting												
Poor Vision (1,2)	3	2.1	2	1.3	2	1.4	0	0.0	1	0.7	0	0.0
Fair Vision (3,4,5)	48	33.8	53	35.6	35	24.1	27	19.0	29	19.7	20	13.8
Good Vision (6,7)	91	64.1	94	63.1	108	74.5	115	81.0	117	79.6	125	86.2
Not Reported	0	-	0	-	0	-	0	-	2	-	0	-

%=n/N excluding Not Reported
[a] On a scale of 1-7

CLINICAL STUDY RESULTS for the Silicone TECNIS® Multifocal Lens, Model ZM900:

Two clinical studies were conducted in the United States with the silicone version of the TECNIS® multifocal IOL, Model ZM900. The diffractive multifocal optic design of the silicone lens is identical to that of the TECNIS® multifocal acrylic IOL, Model ZMA00. The initial clinical study of the TECNIS® multifocal silicone IOL, Model ZM900 was a one-year, multicenter, evaluator-masked, bilateral, parallel-group comparative clinical evaluation conducted at 13 investigational sites; the second study was a one-year, multicenter, open-label, unilateral or bilateral, expansion study conducted at 16 investigational sites. Across both studies, a total of 347 TECNIS® ZM900 subjects (306 bilaterally implanted) and 123 monofocal control subjects (122 bilaterally implanted) were enrolled. In the initial study, subjects' lens group assignment was not randomized; each subject was implanted with either TECNIS® multifocal ZM900 lenses or monofocal control lenses according to the subject's preference.

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).

The 4-6 month study results are presented for 335 TECNIS® multifocal subjects (297 bilaterally implanted) and 119 bilaterally implanted monofocal subjects. One-year study results are presented for 331 multifocal subjects (292 bilaterally implanted) and 114 bilateral monofocal subjects.

Distance Visual Acuities

Photopic (85 cd/m^2) distance visual acuity results for both lens groups are presented in **Tables 24-27**. **Tables 24** and **25** present monocular uncorrected and best corrected distance visual acuity results for subjects' first eyes at 4-6 months and one year, respectively. **Tables 26** and **27** show binocular results at 4-6 months and one year, respectively. At both 4-6 months and one year, monocular best corrected distance visual acuity results for TECNIS® ZM900 first eyes were above the FDA grid rates for safety (92.5%; **Tables 24** and **25**). Additionally, all best case TECNIS® ZM900 first eyes (100%, 327/327 at 4-6 months and 32/3323 at one year) achieved 20/40 or better best corrected distance visual acuity exceeding the FDA grid rate for best case (96.7%) as well.

Table 24:
Monocular Distance Visual Acuity at 4-6 Months

Visual Acuity	TECNIS ZM900 N=335		Monofocal Control N=119	
	Uncorrected	Best Corrected	Uncorrected	Best Corrected
20/20 or better	31.2%	75.1%	39.5%	82.4%
20/25 or better	62.2%	94.3%	68.9%	94.1%
20/32 or better	82.6%	98.2%	90.8%	99.2%
20/40 or better	92.8%	99.7%	97.5%	100.0%
20/50 – 20/80	6.9%	0.3%	2.5%	0.0%
20/100 or worse	0.3%	0.0%	0.0%	0.0%

Table 25:
Monocular Distance Visual Acuity at One Year

Visual Acuity	TECNIS ZM900 N=331		Monofocal Control N=114	
	Uncorrected	Best Corrected	Uncorrected	Best Corrected
20/20 or better	29.6%	71.6%	49.1%	84.2%
20/25 or better	58.6%	93.1%	77.2%	93.9%
20/32 or better	79.2%	98.5%	86.8%	100.0%
20/40 or better	90.9%	99.4%	97.4%	100.0%
20/50 – 20/80	7.9%	0.6%	2.6%	0.0%
20/100 or worse	1.2%	0.0%	0.0%	0.0%

Table 26:
Binocular Distance Visual Acuity at 4-6 Months

Visual Acuity	TECNIS ZM900 N=294		Monofocal Control N=119	
	Uncorrected	Best Corrected	Uncorrected	Best Corrected
20/20 or better	56.1%	84.7%	75.6%	87.4%
20/25 or better	83.3%	98.0%	91.6%	98.3%
20/32 or better	95.9%	100.0%	98.3%	100.0%
20/40 or better	98.6%	100.0%	99.2%	100.0%
20/50 – 20/80	1.4%	0.0%	0.8%	0.0%
20/100 or worse	0.0%	0.0%	0.0%	0.0%

Table 27:
Binocular Distance Visual Acuity at One Year

Visual Acuity	TECNIS ZM900 N=291		Monofocal Control N=114	
	Uncorrected	Best Corrected	Uncorrected	Best Corrected
20/20 or better	56.7%	88.0%	77.2%	93.9%
20/25 or better	83.5%	98.6%	86.0%	99.1%
20/32 or better	95.2%	99.3%	98.2%	100.0%
20/40 or better	98.6%	100.0%	100.0%	100.0%
20/50 – 20/80	1.4%	0.0%	0.0%	0.0%
20/100 or worse	0.0%	0.0%	0.0%	0.0%

Mean monocular and binocular distance visual acuities for both lens groups at 4-6 months and one year, respectively are presented in **Tables 28** and **29**. Mean distance visual acuities were clinically comparable between lens groups with mean differences between lens groups within one line or less. The lower limits of the confidence intervals of the mean differences between groups were one line or less for uncorrected distance visual acuities and approximately one-half line or less for best corrected distance visual acuities, demonstrating non-inferiority of the TECNIS® ZM900 lens for distance visual acuity compared to the monofocal control.

Table 28:
Mean Distance Visual Acuities at 4-6 Months

Distance Visual Acuity	Lens Group	Monocular			Binocular		
		N	Mean Snellen Equivalent	Mean Diff. (ETDRS lines)	N	Mean Snellen Equivalent	Mean Diff. (ETDRS lines)
Uncorrected	ZM900	333	20/27	-0.38	294	20/22	-0.50
	Monofocal	119	20/25		119	20/20	
Best Corrected	ZM900	333	20/20	-0.25	294	20/18	-0.21
	Monofocal	119	20/19		119	20/17	

Table 29:
Mean Distance Visual Acuities at One Year

Distance Visual Acuity	Lens Group	Monocular N	Monocular Mean Snellen Equivalent	Monocular Mean Diff. (ETDRS lines)	Binocular N	Binocular Mean Snellen Equivalent	Binocular Mean Diff. (ETDRS lines)
Uncorrected	ZM900	331	20/28	-0.62	291	20/22	-0.47
	Monofocal	114	20/24		114	20/20	
Best Corrected	ZM900	331	20/20	-0.25	291	20/18	-0.24
	Monofocal	114	20/19		114	20/17	

Near Visual Acuities Near visual acuities were tested at the fixed test distance of 33 cm and at the subjects' preferred or "best" test distance, with and without distance correction, under both photopic (85 cd/m^2) and mesopic (3 cd/m^2) lighting conditions. Mean monocular and binocular near visual acuities at 4-6 months and at one year for both lens groups are presented in **Tables 30** and **31.** All mean near visual acuities were significantly better ($p<0.0001$) for multifocal subjects compared to monofocal subjects by approximately four or more lines of acuity. Near visual acuity results demonstrate the effectiveness of the TECNIS® multifocal lens in providing substantial near vision compared to the monofocal control lens.

Table 30:
Mean Near Visual Acuities at 4-6 Months

Near Visual Acuity	Test Distance	Lens Group	Monocular N	Monocular Mean Snellen Equivalent	Monocular Diff. in Means (ETDRS lines)	Binocular N	Binocular Mean Snellen Equivalent	Binocular Diff. in Means (ETDRS lines)
Uncorrected Photopic	33 cm	ZM900	333	20/30*	4.3	294	20/25*	4.0
		Monofocal	119	20/81		119	20/65	
	Best	ZM900	332	20/28*	4.0	292	20/23*	3.6
		Monofocal	119	20/69		119	20/53	
Distance Corrected Photopic	33 cm	ZM900	332	20/28*	4.9	294	20/24*	4.6
		Monofocal	119	20/86		119	20/69	
	Best	ZM900	331	20/26*	4.6	291	20/23*	4.5
		Monofocal	119	20/76		119	20/64	
Distance Corrected Mesopic	33 cm	ZM900	332	20/45*	4.8	294	20/37*	4.7
		Monofocal	119	20/134		119	20/111	
	Best	ZM900	330	20/42*	4.7	291	20/35*	4.7
		Monofocal	119	20/123		119	20/104	

*Statistically significant difference in mean ETDRS scores versus monofocal control ($p<0.0001$)

Table 31:
Mean Near Visual Acuities at One Year

Near Visual Acuity	Test Distance	Lens Group	Monocular N	Monocular Mean Snellen Equivalent	Monocular Diff. in Means (ETDRS lines)	Binocular N	Binocular Mean Snellen Equivalent	Binocular Diff. in Means (ETDRS lines)
Uncorrected Photopic	33 cm	ZM900	331	20/32*	4.3	291	20/25*	4.1
		Monofocal	113	20/84		113	20/63	
	Best	ZM900	331	20/29*	4.2	291	20/24*	3.7
		Monofocal	113	20/76		113	20/57	
Distance Corrected Photopic	33 cm	ZM900	331	20/29*	4.8	291	20/24*	4.5
		Monofocal	113	20/87		113	20/70	
	Best	ZM900	329	20/27*	4.7	290	20/23*	4.4
		Monofocal	113	20/80		113	20/64	
Distance Corrected Mesopic	33 cm	ZM900	331	20/46*	4.5	291	20/37*	4.6
		Monofocal	113	20/130		113	20/104	
	Best	ZM900	331	20/42*	4.5	291	20/35*	4.5
		Monofocal	113	20/120		113	20/99	

*Statistically significant difference in mean ETDRS scores versus monofocal control (p<0.0001)

Mean best test distances for multifocal subjects were close to the theoretical value of 33.0 cm both monocularly and binocularly, with and without distance correction in place. Mean best test distances for monofocal subjects were, on average, 2 cm greater than the means for multifocal subjects.

Distributions of near visual acuity results for both lens groups are presented in **Tables 32-35**. **Tables 32** and **33** present 4-6 month and one-year results, respectively, for first-eye monocular photopic uncorrected and distance corrected near visual acuities. **Tables 34** and **35** present 4-6 month and one-year results, respectively, for binocular photopic uncorrected and distance corrected near visual acuities. In all cases, much larger proportions of multifocal subjects achieved better near visual acuities compared to monofocal subjects, with or without correction, monocularly or binocularly, at the fixed text distance of 33 cm or at the subject's preferred test distance. The true test of a multifocal optic is the evaluation of near vision with distance correction in place eliminating any effects from residual refractive error. With distance correction in place, 95-99% of TECNIS® ZM900 subjects achieved 20/40 or better at near at best distance, monocularly or binocularly, compared to 7-19% of monofocal subjects (**Tables 32-35**).

Table 32:
Monocular Photopic Uncorrected and Distance Corrected
Near Visual Acuity at 4-6 Months

	Uncorrected				Distance Corrected			
	TECNIS ZM900		Monofocal		TECNIS ZM900		Monofocal	
Near Visual Acuity	**33 cm N=333**	**Best N=332**	**33 cm N=119**	**Best N=119**	**33 cm N=332**	**Best N=331**	**33 cm N=119**	**Best N=119**
20/20 or better	17.1%	26.2%	0.0%	0.0%	22.3%	31.4%	0.0%	0.0%
20/25 or better	44.4%	56.3%	1.7%	3.4%	56.0%	64.4%	0.0%	0.0%
20/32 or better	76.0%	85.8%	2.5%	7.6%	84.9%	89.1%	1.7%	3.4%
20/40 or better	91.0%	95.8%	7.6%	16.8%	94.9%	97.0%	5.0%	6.7%
20/50 – 20/80	8.4%	4.2%	49.6%	53.8%	4.5%	2.7%	43.7%	56.3%
20/100 or worse	0.6%	0.0%	42.9%	29.4%	0.6%	0.3%	51.3%	37.0%

Table 33:
Monocular Photopic Uncorrected and Distance Corrected
Near Visual Acuity at One Year

	Uncorrected				Distance Corrected			
	TECNIS ZM900		Monofocal		TECNIS ZM900		Monofocal	
Near Visual Acuity	33 cm N=116	Best N=116	33 cm N=113	Best N=113	33 cm N=116	Best N=116	33 cm N=113	Best N=113
20/20 or better	17.8%	27.5%	0.0%	0.0%	21.8%	32.8%	0.0%	0.0%
20/25 or better	38.4%	49.5%	0.9%	1.8%	52.9%	62.6%	0.0%	0.9%
20/32 or better	69.2%	76.4%	2.7%	5.3%	79.8%	83.3%	2.7%	4.4%
20/40 or better	84.3%	92.4%	6.2%	14.2%	93.1%	95.4%	6.2%	10.6%
20/50 – 20/80	13.9%	6.6%	46.0%	45.1%	6.0%	3.6%	42.5%	43.4%
20/100 or worse	1.8%	0.9%	47.8%	40.7%	0.9%	0.9%	51.3%	46.0%

Table 34:
Binocular Photopic Uncorrected and Distance Corrected
Near Visual Acuity at 4-6 Months

	Uncorrected				Distance Corrected			
	TECNIS ZM900		Monofocal		TECNIS ZM900		Monofocal	
Near Visual Acuity	33 cm N=294	Best N=292	33 cm N=119	Best N=119	33 cm N=294	Best N=291	33 cm N=119	Best N=119
20/20 or better	33.3%	45.9%	0.0%	0.8%	42.9%	49.8%	0.0%	0.0%
20/25 or better	75.5%	82.2%	1.7%	6.7%	79.6%	84.9%	0.0%	0.8%
20/32 or better	94.9%	96.6%	7.6%	17.6%	96.3%	97.3%	5.0%	8.4%
20/40 or better	99.0%	99.0%	21.0%	38.7%	98.3%	98.6%	13.4%	18.5%
20/50 – 20/80	0.7%	0.7%	63.9%	52.9%	1.7%	1.4%	59.7%	60.5%
20/100 or worse	0.3%	0.3%	15.1%	8.4%	0.0%	0.0%	26.9%	21.0%

Table 35:
Binocular Photopic Uncorrected and Distance Corrected
Near Visual Acuity at One Year

	Uncorrected				Distance Corrected			
	TECNIS ZM900		Monofocal		TECNIS ZM900		Monofocal	
Near Visual Acuity	33 cm N=291	Best N=291	33 cm N=113	Best N=113	33 cm N=291	Best N=290	33 cm N=113	Best N=113
20/20 or better	38.1%	43.6%	0.0%	1.8%	39.9%	49.7%	0.0%	0.0%
20/25 or better	70.4%	76.6%	1.8%	6.2%	78.0%	81.7%	0.9%	0.9%
20/32 or better	93.1%	94.8%	6.2%	15.9%	92.4%	94.1%	3.5%	6.2%
20/40 or better	99.0%	99.0%	21.2%	31.0%	97.9%	99.0%	11.5%	18.6%
20/50 – 20/80	0.7%	0.7%	58.4%	53.1%	2.1%	1.0%	57.5%	58.4%
20/100 or worse	0.3%	0.3%	20.4%	15.9%	0.0%	0.0%	31.0%	23.0%

Combination Visual Acuities

Combination visual acuities represent the proportion of subjects that achieved a specific distance acuity and a specific near acuity at the same visit. **Figures 9 and 10** present combined uncorrected distance and near (tested at 33 cm) visual acuities for binocular subjects at 4-6 months. **Figures 11 and 12** present combined uncorrected distance and near (tested at 33 cm) visual acuities for binocular subjects at one year. **Figures 9** and **11** present the proportions of subjects that achieved 20/40 or better both at distance and near for both lens groups, at 4-6 months and one year, respectively. **Figures 10** and **12** present the proportions of subjects that achieved 20/25 or better distance and 20/32 or better near for both lens groups, at 4-6 months and one year, respectively. In both comparisons, significantly more multifocal subjects ($p<0.0001$) achieved the combined visual acuities compared to monofocal subjects with or without distance correction. The best test of multifocal optic performance is the evaluation of simultaneous good distance and near acuity with distance correction in place eliminating any effect from residual refractive error. With distance correction in place, 94% of TECNIS® ZM900 subjects achieved 20/25 or better distance and 20/32 or better near visual acuity compared to only 5.0% of monofocal subjects at 4-6 months (**Figure 10**). With distance correction in place, 92.1% of TECNIS® ZM900 subjects achieved 20/25 or better distance and 20/32 or better near visual acuity compared to only 3.5% of monofocal subjects at one year (**Figure 12**).

Figure 9:
Combined 20/40 or Better Binocular Distance and Near Photopic Visual Acuity at 4-6 Months

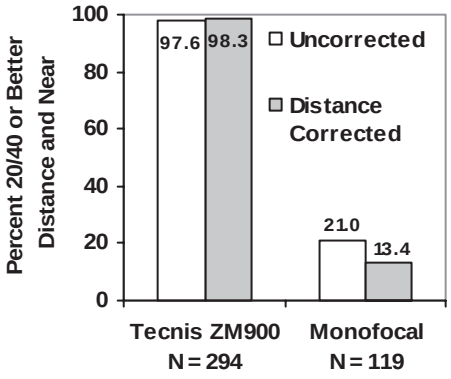


Figure 10:
Combined 20/25 or Better Binocular Distance and 20/32 or Better Binocular Near Photopic Visual Acuity at 4-6 Months

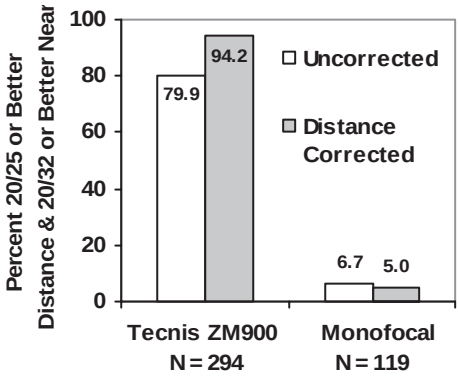


Figure 11:
Combined 20/40 or Better Binocular Distance and Near Photopic Visual Acuity at One Year

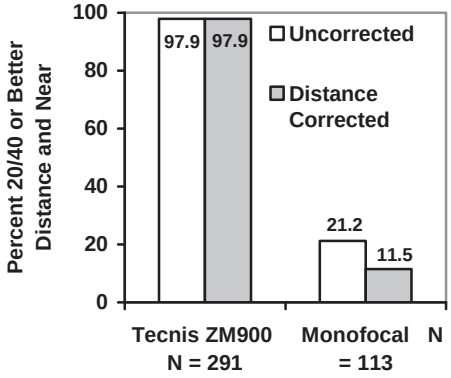
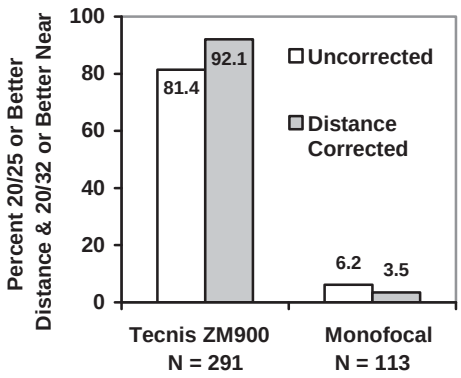


Figure 12:
Combined 20/25 or Better Binocular Distance and 20/32 or Better Binocular Near Photopic Visual Acuity at One Year



Reading Ability

Binocular reading acuity and speed were evaluated in the initial study at one year under photopic lighting conditions at the subject's best distance using the MNRead chart. **Table 36** presents the results for both lens groups at one year. Statistically significant differences in mean binocular reading acuity ($p<0.0001$[a]), critical print size ($p<0.0001$[a]) and maximum reading speed ($p=0.0007$[a]) were found between lens groups with multifocal subjects having better reading acuity, smaller critical print size (smallest print a subject can read near their maximum reading speed) and faster reading speed. Critical print size results indicate that on average, multifocal subjects were able to read near their maximum reading speed at three lines better than monofocal control subjects.

Table 36:
Mean Binocular Distance Corrected Reading Acuity and Speed at One Year

Lens Group	N	Reading Acuity		Reading Speed	
		Mean Snellen Equivalent	Mean Test Distance (cm)	Mean Critical Print Size Snellen Equivalent	Mean Words Per Minute
ZM900	114	20*	34.4*	30*	148*
Monofocal	113	47	41.1	63	117

* Statistically significant difference vs. monofocal control

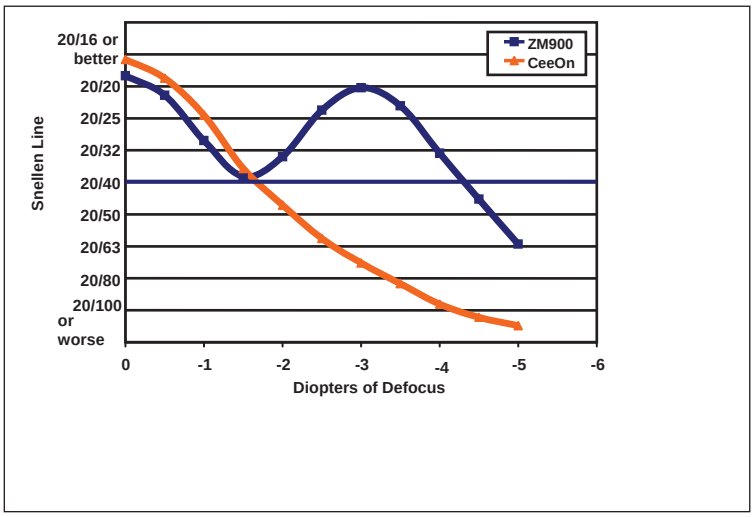
Depth of Focus

Defocus curve testing was performed on a subset of 30 subjects from each lens group at the 4-6 month study exam in the initial study to evaluate binocular best corrected distance visual acuity defocus curves, and any effects of pupil size. The substudy was a non-randomized, parallel-group comparison of the binocular best corrected visual acuity depth of focus at three pupil size ranges: ≤2.5 mm; >2.5 mm and <4.0 mm; and ≥4.0 mm.

[a] P-value was not adjusted for multiplicity.

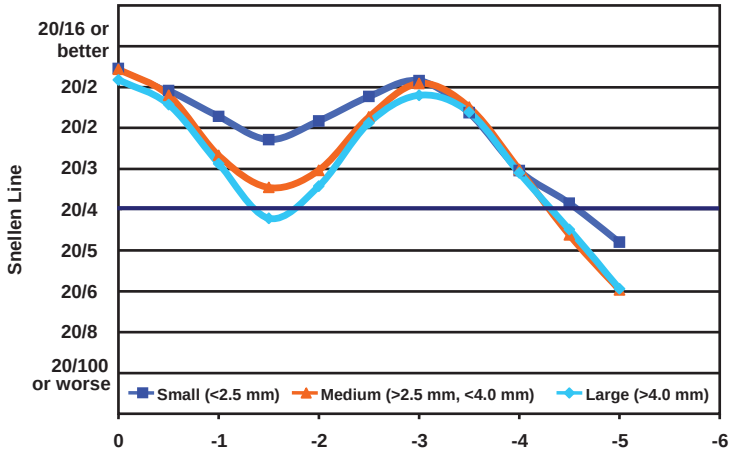
Multifocal subjects were found to have a significantly increased measured depth of focus compared to monofocal subjects overall (**Figure 13**) with a prominent near peak around -3.0 D essentially equivalent to the distance peak or plano refraction.

Figure 13:
Mean Visual Acuity at Each Defocus Level for All Subjects at Their Natural Pupil Size



The depth of focus performance for the TECNIS® multifocal IOL strongly illustrates the multifocality of the optic design at any pupil size (**Figure 14**). Minimal pupil size effect was observed. Even at intermediate distances (~1.5 D of defocus), depth of focus curves for all pupil size groups were generally 20/40 or better indicating a large range of functional vision. In summary, depth of focus was significantly increased for multifocal subjects compared to monofocal subjects with a substantial near peak evident for multifocal subjects for all pupil size groups.

Figure 14:
Mean Visual Acuity at Each Defocus Level for TECNIS Multifocal Subjects by Pupil Size Groups: Small: ≤2.5 mm; Medium: >2.5 mm, <4.0 mm; Large: ≥4.0 mm



Contrast Sensitivity
Binocular best corrected distance contrast sensitivity testing was performed on subjects in the initial study at the 4-6 month study exam under three lighting conditions: mesopic with glare, mesopic without glare, and photopic with glare. Testing was performed using the Functional Acuity Contrast Test (FACT) sine wave grating charts with the Optec 6500 Vision Tester.

Mean contrast scores for the multifocal group were less than that for the monofocal IOL group under each lighting condition and spatial frequency (**Table 37**). Mean differences between IOL groups ranged between 0.10 to 0.26 log units, with the majority under 0.20 log units. Except in one case, the lower limits of the confidence intervals of the mean differences did not exceed 0.30 log units. When results were analyzed by pupil size, no noticeable pupil size effects were found for either lens group under any lighting condition.

Table 37:
Mean Best Case Binocular Log Contrast Sensitivity Scores at 4-6 Months

Spatial Frequency	Lens Model	N	Mesopic Without Glare	Mesopic With Glare	Photopic With Glare
1.5 cpd	ZM900	110	1.54	1.25	Not tested
	Monofocal	109	1.64	1.36	Not tested
3.0 cpd	ZM900	110	1.63	1.29	1.60
	Monofocal	109	1.75	1.50	1.75
6.0 cpd	ZM900	110	1.56	1.23	1.64
	Monofocal	109	1.70	1.49	1.80
12.0 cpd	ZM900	110	0.95	0.85	1.23
	Monofocal	109	1.14	0.99	1.43
18.0 cpd	ZM900	110	Not tested	Not tested	0.77
	Monofocal	109	Not tested	Not tested	0.96

Driving Performance
A night driving performance substudy was conducted to assess functional performance differences between multifocal and monofocal IOL subjects in the initial study at 4-6 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. Driving simulation substudy results are presented for 26 multifocal subjects and 31 monofocal subjects.

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 38** and **39** for the rural road and in **Tables 40** and **41** 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 38:
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 39:
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 40:
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 41:
Visibility Distance and Time for City Identification

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

Fundus Visualization
At the 4-6 month study visit in both studies, investigators evaluated the ability to visualize the fundus during the dilated fundus exams. In all cases (100%; 333/333 multifocal first eyes and 119/119 monofocal first eyes), fundus visualization was deemed "adequate". During the studies, no difficulties were reported in evaluating or treating retinal complications in multifocal eyes; however, only one multifocal eye underwent a surgical retinal procedure.

Subject Satisfaction/Quality of Life Evaluation
Two subjective questionnaires were administered to subjects to assess the impact of the lens on vision-related quality of life: a sponsor-developed questionnaire collected information regarding visual quality and subject satisfaction, and the Modified TyPE Specification for Cataracts (developed by Jonathan Javitt, M.D., M.P.H., in 1994) measured multifocal-specific quality of life impact information. The questionnaires were administered via telephone by masked, trained interviewers following the clinical study exams preoperatively, at 4-6 months and one year. The questionnaire was not determined to be a psychometrically valid assessment of the concept of spectacle independence.

Figures 15-20 present the frequency of spectacle wear for bilaterally implanted subjects at 4-6 months and at one year. Spectacle independence rates for the TECNIS® ZM900 lens group were statistically higher than the monofocal control group for overall, distance and near spectacle use ($p<0.0001^{a}$).

Figure 15:
Spectacle Usage for Bilateral Subjects at 4-6 Months

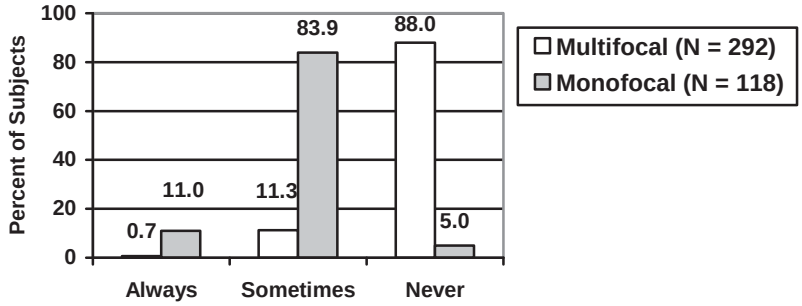


Figure 16:
Spectacle Usage for Bilateral Subjects at One Year

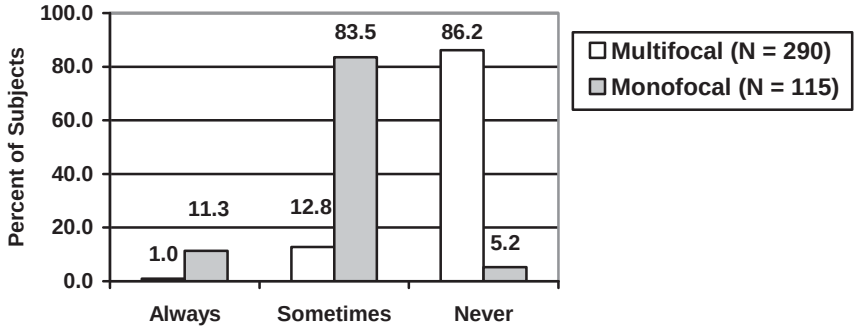


Figure 17:
Spectacle Usage for Distance Vision for Bilateral Subjects at 4-6 Months

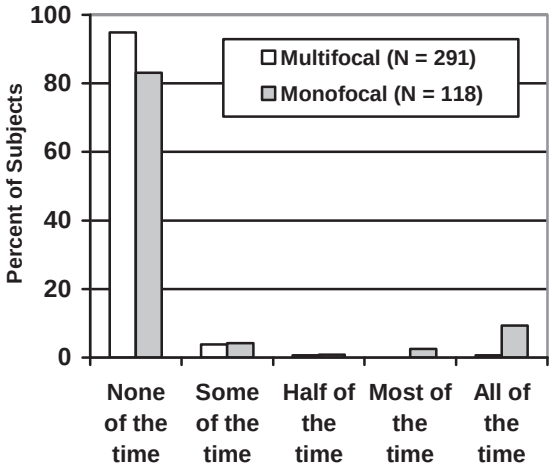


Figure 18:
Spectacle Usage for Distance Vision for Bilateral Subjects at One Year

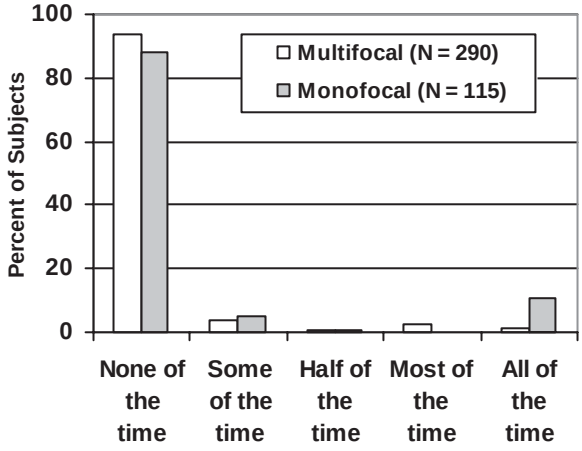


Figure 19:
Spectacle Usage for Near Vision for Bilateral Subjects at 4-6 Months

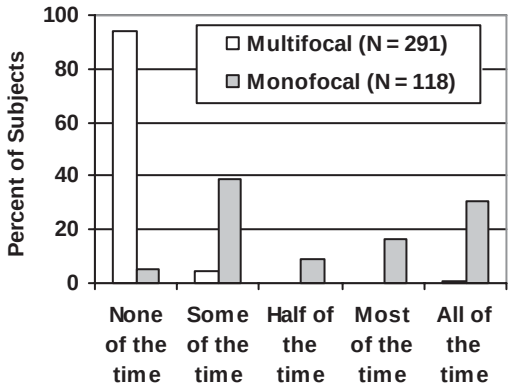


Figure 20:
Spectacle Usage for Near Vision for Bilateral Subjects at One Year

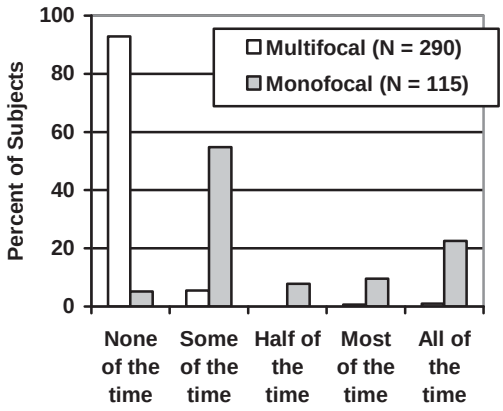


Table 42 presents subjects' ability to function comfortably without glasses. Statistically significant differences were found between lens groups ($p<0.0001^a$) with more multifocal subjects reporting the ability to function comfortably at near without glasses at both 4-6 months and one year.

Table 42:
Ability to Function Comfortably Without Glasses for Bilateral Subjects

Ability to Function Comfortably at:	4-6 Months		One Year	
	TECNIS ZM900 N=292	Monofocal N=118	TECNIS ZM900 N=290	Monofocal N=115
Near	94.2%*	16.9%	96.9%*	30.4%
Intermediate	85.3%	94.9%	89.7%	84.2%
Distance	90.4%	94.9%	95.5%	98.3%

* Statistically significant difference vs. monofocal control

Satisfaction of vision without glasses (**Table 43**) was assessed on a scale of 1-5, with 1 being "not at all satisfied" and 5 being "completely satisfied". Statistically significant differences were found between lens groups for overall ($p\leq0.0001^a$), during the day ($p<0.0001^a$), at both 4-6 months and one year, and at night at one year ($p=0.0141$) with mean ratings for multifocal subjects closer to "completely satisfied" and mean ratings for monofocal subjects closer to "mostly satisfied", in general.

Table 43:
Mean Rating of Satisfaction With Vision Without Glasses for Bilateral Subjects
(on a scale of 1-5, with 5 being best)

Satisfaction With Vision	4-6 Months		One Year	
	TECNIS ZM900 N=292	Monofocal N=118	TECNIS ZM900 N=289	Monofocal N=115
Overall	4.46*	4.20	4.59*	4.25
During the day	4.53*	4.19	4.66*	4.24
At Night	4.09	4.11	4.35*	4.19

* Statistically significant difference vs. monofocal control

Subjects also rated the degree of trouble with vision without glasses in the day and at night (**Table 44**) on a scale of 1 to 5, with 1 being "no trouble at all" and 5 being "major or overwhelming trouble". At both 4-6 months and one year, significant differences were found in favor of the TECNIS® ZM900 lens group ($p<0.0001^a$) during the day with lower mean trouble ratings. At night, a significant difference ($p=0.0045^a$) was noted in favor of the multifocal lens at one year as well. However, postoperative scores for both lens groups were generally low with mean ratings between "no trouble" and "a little bit of trouble".

Table 44:
Mean Rating of Trouble With Vision Without Glasses for Bilateral Subjects
(on a scale of 1-5, with 5 being worst)
Directed Responses to a Prompted Choice Questionnaire

Trouble With Vision	4-6 Months		One Year	
	TECNIS ZM900 N=292	Monofocal N=118	TECNIS ZM900 N=289	Monofocal N=115
During the day	1.44*	1.80	1.29*	1.86
At night	1.97	1.89	1.71*	2.00

* Statistically significant difference vs. monofocal control

Subjects also rated their vision in general without glasses (**Table 45**) on a scale of 0 to 10, with zero being “worst possible vision” and 10 being “best possible vision”. At both 4-6 months and one year, multifocal subjects rated their vision as significantly better than monofocal subjects overall ($p<0.0001$[a]).

Table 45:
Mean Rating of Vision Without Glasses for Bilateral Subjects
(on a scale of 0-10, with 10 being best)

	TECNIS ZM900		Monofocal	
Rating of Vision	**N**	**Mean Rating**	**N**	**Mean Rating**
4-6 Months	292	8.67*	118	7.94
One Year	290	8.93*	115	7.86

* Statistically significant difference vs. monofocal control

Subjects were asked about their desire to elect the same IOL again, if given the opportunity. As shown in **Table 46**, at both 4-6 months and one year, more multifocal subjects indicated they would elect the IOL again compared to monofocal subjects, although the difference was not statistically significant. The primary reasons subjects would not elect the IOL again were dissatisfaction with visual outcomes for both lens groups as well as optical/visual effects for the multifocal subjects and the need for glasses for monofocal subjects.

Table 46:
Desire to Elect IOL Again for Bilateral Subjects
Directed Response to a Prompted Choice Questionnaire

	TECNIS ZM900				Monofocal			
	4-6 Months N = 292		One Year N = 290		4-6 Months N = 118		One Year N = 115	
Elect IOL Again?	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Yes	255	87.3	266	91.7	100	84.7	103	89.6
No	30	10.3	23	7.94	15	12.7	12	10.4
Undecided	7	2.4	1	0.3	3	2.5	0	0.0

Adverse Events

The incidence of cumulative adverse events for the TECNIS® ZM900 multifocal first eyes compared to the US FDA historical grid are presented in **Table 47**. The incidence rates for the TECNIS® ZM900 lens compared favorably to the specified FDA rates. Only the rate of surgical re-interventions in the TECNIS® ZM900 lens group was statistically higher than the FDA grid rate of 0.8% ($p<0.0001$). However, with only three subjects out of 348 experiencing lens-related events (3/348; 0.9%), the observed proportion of lens-related surgical re-interventions in both first and second eyes were not statistically higher than the FDA grid rate ($p=0.4725$ for first eyes; $p=0.4432$ for second eyes). The rate of non-lens-related surgical re-interventions was statistically higher than the grid rate for multifocal first eyes ($p=0.0001$). Secondary surgical re-intervention events for multifocal first eyes are specified in **Table 48**.

Table 47:
Cumulative Adverse Events for TECNIS ZM900 First Eyes

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

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

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

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

Table 48:
Surgical Re-Interventions in TECNIS ZM900 First Eyes

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

* Includes excluded subject (lens exchange following implantation of non-study IOL) for adverse events only

[†] This subject also experienced a pupilloplasty and lens removal in the second eye due to halos and glare

[Δ] This subject eventually underwent lens removal in both eyes due to halos and glare

[‡] This subject eventually underwent lens removal in both eyes due to image quality (blurry/hazy vision)

[¥] Subsequent to endophthalmitis and hypopyon

Medical complications at 4-6 months and one year (persistent) are presented for TECNIS® ZM900 first eyes were below FDA grid rates and are presented in **Table 49**. There was only one persistent event; one first eye unilateral subject was diagnosed with secondary glaucoma/raised intraocular pressure (IOP) requiring treatment beginning approximately five months postoperatively through the one-year study timeframe.

Table 49:
Medical Complications and Adverse Events for TECNIS ZM900 First Eyes at 4-6 Months and One Year (Persistent)

Persistent Adverse Event	ZM900				FDA Grid Rate
	4-6 Months N=333		One Year N=331		
	n	%	n	%	%
Macular edema	1	0.3	0	0.0	0.5
Corneal edema	1	0.3	0	0.0	0.3
Iritis	2	0.6	0	0.0	0.3
Raised IOP requiring treatment	1[#]	0.3	1	0.3	0.4

[#] Same eye

Optical/Visual Symptoms

Non-directed subject responses were obtained from the open-ended question “Are you having any difficulties with your eyes or vision” as asked at the clinical study exams. **Table 50** presents the incidence of non-directed responses for optical/visual symptoms for first eyes in both lens groups at one year postoperatively. The most reported optical/visual symptoms noted in the TECNIS® multifocal lens group were halos, with most reports being “mild” to “moderate”. For monofocal first eyes, halos were also reported but with lower incidence and severity. Blurred/difficulty with vision was reported frequently in both lens groups; the majority of reports in the multifocal group were noted for intermediate distances whereas the majority of reports in the monofocal group were noted at near. Night glare and starbursts were reported with higher frequencies in the multifocal group; however, most reports were noted as “mild” to “moderate”. Across both studies, three multifocal subjects (0.9%; 3/348) underwent study lens removal; two resulting from halos/glare and one from dissatisfaction with image quality (blurry/hazy vision).

Table 50:
Optical/Visual Symptoms* Pertaining to Visual Disturbances and Image Quality for First Eyes, Non-directed Responses at 4-6 Months and One Year

Optical/Visual Symptoms	TECNIS ZM900		Monofocal Control	
	4-6 Months N=333	One Year N=331	4-6 Months N=119	One Year N=116
Visual Disturbances				
Day glare	3.9%	6.0%	1.7%	1.7%
Floaters	4.2%	5.7%	4.2%	2.6%
Halos[#]	40.8% Mild = 16.5% Moderate = 15.3% Severe = 9.0%	24.5% Mild = 12.7% Moderate = 6.3% Severe = 5.4%	4.2% Mild = 2.5% Moderate = 1.7%	8.6% Mild = 6.0% Moderate = 2.6%
Night glare[#]	14.1% Mild = 5.1% Moderate = 5.4% Severe = 3.6%	11.8% Mild = 3.3% Moderate = 5.7% Severe = 2.4%	4.2% Mild = 2.5% Moderate = 1.7%	4.3% Mild = 1.7% Moderate = 0.9% Severe = 1.7%
Starburst[#]	8.1% Mild = 3.6% Moderate = 3.3% Severe = 1.2%	6.3% Mild = 2.4% Moderate = 2.1% Severe = 1.8%	0.8% Mild = 0.8%	1.7% Mild = 1.7%
Night vision difficulty	3.3%	1.5%	0.0%	0.0%
Entoptic phenomena[†]	4.2%	2.1%	1.7%	1.7%
Other image quality[Ω]		1.8%		0.9%
Image Quality				
Blurred/difficulty with vision	19.5% Overall = 3.3% Distance = 5.4% Intermediate = 11.1% Near = 2.4%	18.4% Overall = 2.4% Distance = 5.7% Intermediate = 8.2% Near = 2.7%	14.3% Overall = 4.2% Distance = 0.0% Intermediate = 0.8% Near = 9.2%	12.9% Overall = 2.6% Distance = 1.7% Intermediate = 0.9% Near = 7.8%
Cloudy/hazy/filmy/foggy vision	3.9%	5.4%	1.7%	2.6%
Decreased vision	3.9%	4.5%	1.7%	2.6%
Fluctuation in acuity	3.6%	3.0%	5.9%	2.6%

* Reported with incidence rates of 3.0% or higher for at least one lens group
† Includes reports of arcs of light, rings (not halos) in vision, lens shimmer, light reflection/streaks, etc.
# Some subjects reported more than one visual disturbance. Reports of severe halos, night glare or starbursts were noted for 11.7% (39/333) of first eyes and 11.5% (34/296) of second eyes at 4-6 months. At one year, reports of severe halos, night glare or starbursts were noted for 6.9% (23/331) of first eyes and 6.8% (20/295) of second eyes.
Ω Includes reports of vision trembles, difficulty reading in dim/low light conditions, decreased reading distance, trouble reading for long periods, too much or too little contrast, color, etc.

Directed subject responses for optical/visual symptoms were also obtained from a sponsor-developed questionnaire administered by a third-party over the telephone in which bilaterally implanted subjects were asked to rate their degree of "difficulty" for specific visual disturbances. It should be noted that directed questionnaires may contain inherent over-reporting as directed questioning is more subjective and is designed to elicit responses whether or not these would be deemed by the subject significant enough to voluntarily discuss with the investigator and study staff (non-directed response). Nonetheless, when specifically asked, statistically significant differences ($p<0.0001^{a}$) were found between the two lens groups with more difficulty experienced with night vision, glare/flare and halos for multifocal subjects compared to monofocal subjects (**Table 51**). Although more difficulty was noted with the multifocal lens with respect to nighttime visual symptoms, overall levels of subject satisfaction remained high (92% would choose the same lens again when asked one year postoperatively) similar to that of the monofocal lens (as shown in **Table 46**). With respect to other optical/visual symptoms, subject questionnaire results also yielded some statistically significant differences between groups for distorted distance vision and blurred distance vision; however, the large majority of subjects in both lens groups reported no difficulty with these symptoms.

Table 51:
Degree of Difficulty* Experienced with Visual Symptoms Without Glasses†
As Reported by Bilateral Subjects to a Prompted Choice Questionnaire
at One Year**

Question	TECNIS ZM900 N =290	Monofocal Control N =115
Night Vision		
No Difficulty	60.2%	77.4%
Moderate Difficulty	32.9%	20.9%
Severe Difficulty	6.9%	1.7%
Glare/Flare		
No Difficulty	48.8%	72.2%
Moderate Difficulty	34.6%	24.3%
Severe Difficulty	16.6%	3.5%
Halos		
No Difficulty	45.0%	80.0%
Moderate Difficulty	36.7%	15.7%
Severe Difficulty	18.3%	4.3%

* Scale: No difficulty = score of 1 or 2, Moderate difficulty = score of 3, 4 or 5, Severe difficulty = score of 6 or 7
† For items with statistically significant ($p<0.0001$) distributions between lens groups.
** Note: Although more difficulty was noted (during third-party administered questionnaires) with the multifocal lens with respect to nighttime visual symptoms, overall levels of subject satisfaction remained high (92% would choose the same lens again when asked one year postoperatively) similar to that of the monofocal lens (please refer to **Table 38**).

CLINICAL STUDY RESULTS for the SENSAR® 1-Piece Lens, Model AAB00:
The clinical study results of the mechanical parent lens, Model AAB00 apply to that of lens Model ZKB00 and lens Model ZLB00. The SENSAR® acrylic 1-piece lens, Model AAB00 was clinically studied in a US clinical trial. The clinical trial was initiated on November 30, 2005. The purpose of the study was to evaluate the safety and effectiveness of lens model AAB00 in subjects undergoing cataract removal and intraocular lens implantation. Following routine cataract removal by extracapsular cataract extraction, all IOLs were implanted in the capsular bag with a continuous curvilinear capsulorhexis.

The results achieved by 117 patients followed for one year provide the basis for the data supporting the use of this lens design for visual correction of aphakia. In the total study population (123 patients), 56.9% of the patients were female and 43.1% were male; 93.5% were Caucasian, 4.1% were Black and 2.4% were Asian. The best corrected distance visual acuity results for the “best case” patients at 1 year (330-420 days) postoperatively are provided in **Table 52**. In addition the data compared to the FDA Grid values (historical control) are presented in **Table 53**.

Table 52:
Best Corrected Distance Visual Acuity (Snellen Equivalent) at 1 Year
Best Case Subjects[a] (N = 110)

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

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

Table 53:
Best Corrected Distance Visual Acuity (Snellen Equivalent) at 1 Year
Best Case Subjects[a](N = 110) vs. FDA Grid

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

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

Adverse Events
As of August 10, 2007, 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 54**.

Table 54:
Adverse Events Model AAB00
All Subjects (N = 123)

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

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

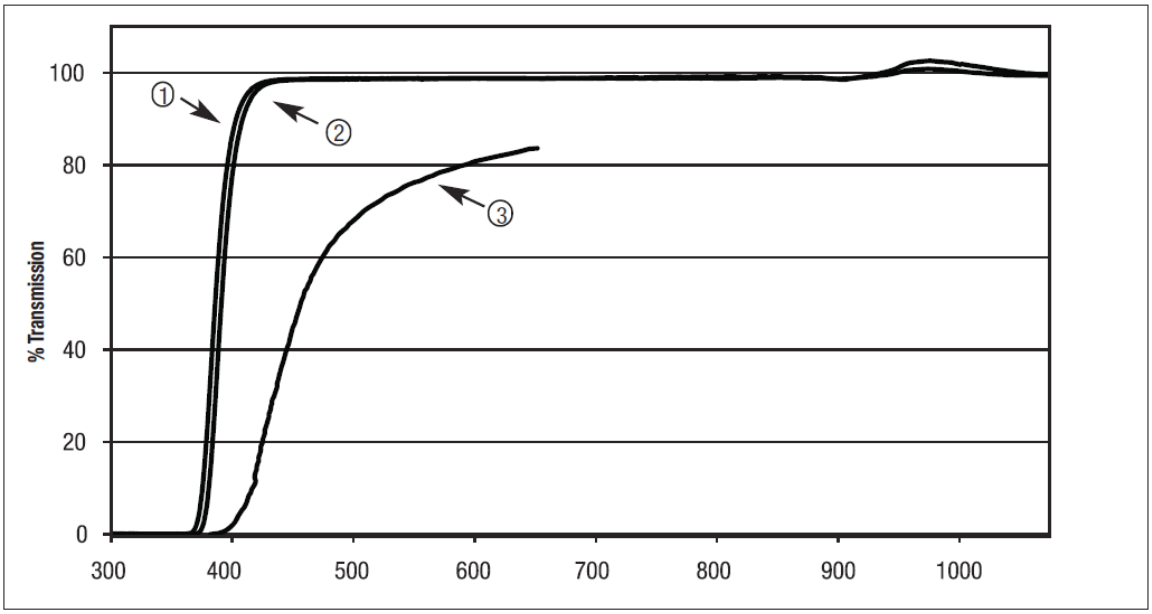
[b] This rate is not statistically significantly higher than the FDA Grid rate for posterior chamber IOLs of 0.5% (p=0.4437).

DETAILED DEVICE DESCRIPTION:
The TECNIS® Multifocal 1-piece lens, Model ZKB00 and Model ZLB00, are one-piece foldable posterior chamber lenses. The optic and haptics are made of soft acrylic. These lenses have a diffractive multifocal surface on the posterior side of the lens and a modified prolate (aspheric) surface on the anterior side. The optic is 6.0 mm in diameter and the lens has an overall diameter of 13.0 mm. The add power of Model ZKB00 is +2.75 diopters, corresponding to +2.01 diopters in the spectacle plane. The add power of Model ZLB00 is +3.25 diopters, corresponding to +2.37 diopters in the spectacle plane.

Lens Optic:
1. Optic Material: Optically clear, soft foldable hydrophobic acrylic with a covalently bound UV absorber
2. Power: +5.0 to +34.0 diopter powers in 0.5 diopter increments
3. Optic Center Thickness: 0.722 mm (+20.0D)
4. Optic Edge Design: PROTEC 360 Square posterior edge
5. Index of Refraction: 1.47 at 35°C
6. Light Transmittance: UV cut-off at 10%T for a +5.0 diopter lens (thinnest) and a +34.0 diopter lens (thickest) are shown in **Figure 21**.
7. Modulation Transfer Function (MTF) Through-Focus Response: MTF values are shown in **Figure 22**.

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

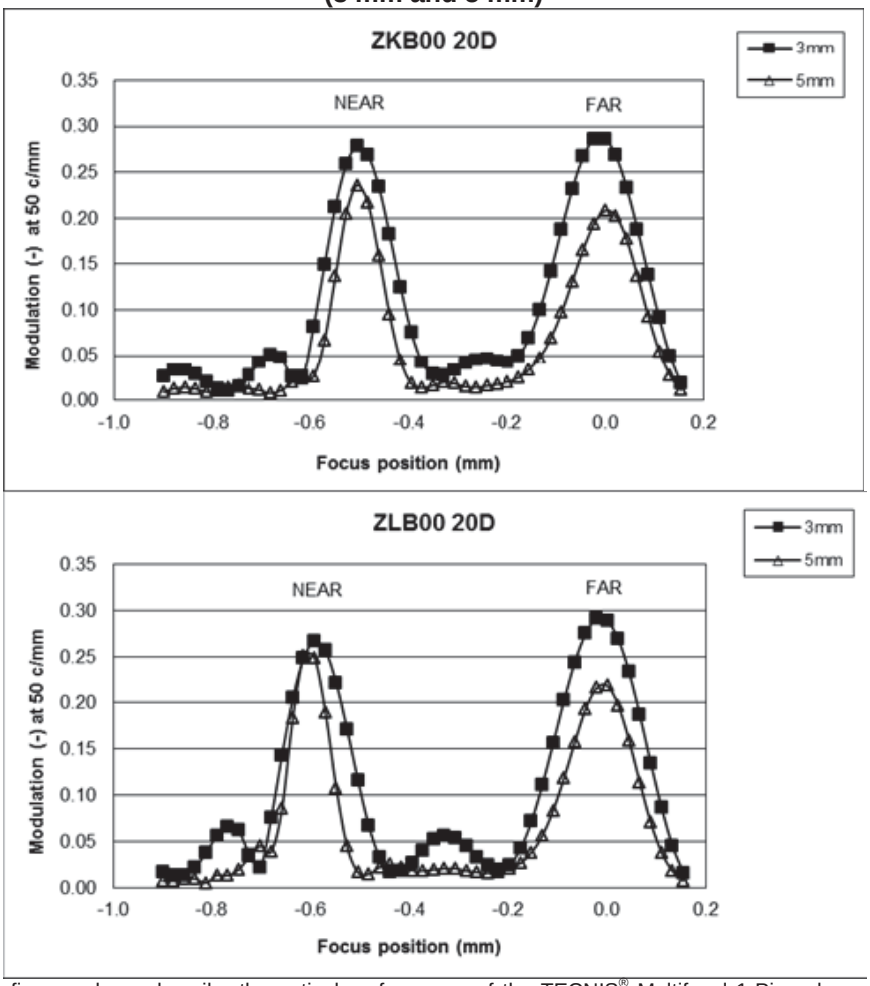
Figure 21:
Light Transmittance



LEGEND:
Curve 1: Spectral Transmittance curve of a typical 5 diopter IOL (thinnest), UV cut-off at 10% T is 375nm
Curve 2: Spectral Transmittance curve of a typical 34 diopter IOL (thickest), UV cut-off at 10% T is 380nm
Curve 3: Spectral Transmittance (T) Curve* Corresponding to 53 year-old Phakic Eye
Note: The cut-off wavelengths and the spectral transmittance curves represent the range of the transmittance of IOLs (5-34 diopter) made with this material. Spectral transmission measurements were taken in water at room temperature.

*Boettner, E.A., and Wolter J.R. Transmission of the Ocular Media. Investigative Ophthalmology. 1962; 1:776-783.

Figure 22:
Modulation Transfer Function (MTF) Through-Focus Response
(3 mm and 5 mm)



Note: The figures above describe the optical performance of the TECNIS® Multifocal 1-Piece lenses, Models ZKB00 and ZLB00, in the ACE* eyes at 50 cycles/mm measured in white light as the focus is gradually shifted from that of a far object to increasingly nearer objects, with higher numbers typically indicating better performance. However, this may not be true for an aberration-correcting IOL such as the TECNIS® lens. The natural cornea is not aberration-free. The ACE* model has the spherical aberration of an average natural cornea, which the TECNIS® lens is designed to compensate. The combination is aberration-free.

* Norrby S, Piers P, Campbell C, van der Mooren M. "Model eyes for evaluation of intraocular lenses."Appl Opt. 2007 Sep 10;46(26):6595-605.

DIRECTIONS FOR USE:

1. Prior to implanting, examine the lens package for proper lens model, dioptric power, and expiration date.
2. Open the package and remove the lens in a sterile environment.
3. Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens optical surfaces for other defects.
4. The lens may be soaked in sterile balanced salt solution or sterile normal saline 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 sterile technique, to an appropriate loading device.
7. The physician should consider the following points:
   - The surgeon should target **emmetropia** as this lens is designed for optimum visual performance when emmetropia is achieved.
   - Care should be taken to achieve **centration** of the intraocular lens.
8. AMO recommends using the ONE SERIES Ultra implantation system, the UNFOLDER Platinum 1 implantation system, or an equivalent qualified insertion instrument or system to insert these TECNIS® Multifocal 1-Piece lens models. 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.

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

LENS POWER CALCULATIONS: The physician should determine preoperatively the power of the lens to be implanted. **Emmetropia should be targeted.** The estimated A-constant for this lens is provided on the lens box; adjustments may be necessary if using IOLMaster. Accuracy of IOL power calculation is particularly important with multifocal IOLs as spectacle independence is the goal of multifocal IOL implantation.

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

- 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. 19:17-24 1988.
- Retzlaff JA, Sanders DR and Kraff MC. Development of the SRK/T intraocular lens implant power calculation formula. J. Cataract Refract Surg. 16:333-340, 1990; ERRATA, 16:528, 1990.
- Olsen T, Olesen H, Thim K and Corydon L. Prediction of pseudophakic anterior chamber depth with the newer IOL calculation formulas. J. Cataract Refract Surg. 18:280-285, 1992.
- Hoffer KJ. The Hoffer Q formula: A comparison of theoretic and regression formulas. J Cataract Refract Surg. 19:700-712, 1993; ERRATA 20:677, 1994.
- Holladay JT. Standardizing constants for ultrasonic biometry, keratometry and intraocular lens power calculations. J Cataract Refract Surg. 23; 1356-1370, 1997.
- Norrby NES. Unfortunate discrepancies. Letter to the editor and reply by Holladay JT. J Cataract Refract Surg. 24:433-434, 1998.
- Norrby S, Lydahl E, Koranyi G, Taube M. Reduction of trend errors in power calculation by linear transformation of measured axial lengths. J Cataract Refract Surg 2003; 29:100-105
- http://www.augenklinik.uni-wuerzburg.de/eulib/index/htm is in particular useful for Zeiss IOLMaster users.

PATIENT REGISTRATION SECTION
Each patient who receives a TECNIS® Multifocal IOL must be registered with AMO at the time of lens implantation.

Registration is accomplished by completing the Implant Registration Card that is enclosed in the lens package and mailing it to AMO. Patient registration is essential for AMO's long-term patient follow-up program and will assist AMO in responding to adverse event reports and/or potentially sight-threatening complications.

REPORTING: All adverse events, regardless of severity and whether or not attributed to the implant, are to be reported to AMO at (800) 366-6554. In the event of a life-threatening incident or serious adverse event, AMO must be notified immediately (no later than 48 hours upon detection) by phone and by faxing a completed adverse event form.

HOW SUPPLIED: Each TECNIS® Multifocal 1-Piece lens is 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.

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

RETURN/EXCHANGE POLICY: Contact the local AMO representative for the return lens policy. Return lens with proper identification and the reason for the return. Label the return as a biohazard.

Do not attempt to resterilize the lens.

Symbol/Explanation

SYMBOL	EXPLANATION
	Sterilized Using Ethylene Oxide
	Do Not Reuse
	Use By (YYY-MM: Year-Month)
	Consult Instructions for Use
	Manufacturer
	Authorized Representative in the European Community
	Do Not Resterilize
	Upper Limit of Temperature

Manufactured in the Netherlands:
AMO Groningen BV
Van Swietenlaan 5
9728 NX Groningen
The Netherlands

MANUFACTURED For:

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

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