

CAUTION:

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

Description

Tecnis® multifocal foldable acrylic intraocular len, Model ZMA00 is an ultraviolet light-absorbing posterior chamber intraocular lens. It is designed to be positioned posterior to the iris where the lens should replace the optical function of the natural crystalline lens. The Tecnis® multifocal foldable acrylic lens incorporates the squared OptiEdge® design. The lens is designed to provide both near 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 represents a +4 diopter add in actual lens power. However, accommodation will not be replaced.

INDICATIONS FOR USE:

Tecnis® multifocal intraocular lenses 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 phacemulsification 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:

- 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.
- Under low-contrast conditions, 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.
- 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:
 - Patients in whom the intraocular lens may interfere with the ability to observe, diagnose or treat posterior segment diseases.
 - 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).
 - A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
 - Circumstance that would result in damage to the endothelium during implantation.
 - Suspected microbial infection.
 - Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.
 - Congenital bilateral cataracts.
 - Recurrent severe anterior or posterior segment inflammation of unknown etiology, or any disease producing an inflammatory reaction in the eye.
 - Previous history of, or a predisposition to, retinal detachment.
 - Patients with only one eye with potentially good vision.
 - Medically uncontrollable glaucoma.
 - Corneal endothelial dystrophy.
 - Proliferative diabetic retinopathy.
- Because the clinical study was conducted with the lens implanted in the capsular bag, there are insufficient clinical data to demonstrate the safety and effectiveness for placement in the ciliary sulcus.
- The splitting of the light into more than one focus may affect image quality and lead to some reduction of contrast sensitivity.
- Well-informed patients with well-defined visual needs and preferences should be selected for Tecnis® multifocal foldable 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.
- Patients with a predicted postoperative astigmatism 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.

PRECAUTIONS:

- 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.
- There were no patients 21 years old or younger included in the clinical study; therefore there are insufficient clinical data to demonstrate safety and effectiveness in this age group.
- The central one millimeter area of the Tecnis® multifocal 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.
- Autorefractors may not provide optimal postoperative refraction of multifocal patients. Manual refraction is strongly recommended.
- 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.
- 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.
- 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.
- 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.
- Do not sterilize this intraocular lens by any method.
- Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.
- Do not store the lens in direct sunlight or at a temperature greater than 45°C (113°F). Do not autoclave the intraocular lens.
- Prior to implanting, examine the lens package for proper lens model, dioptric power, and expiration date.
- 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.
- AMO recommends using The UNFOLDER® Emerald Series Insertion System to insert the Tecnis® multifocal foldable acrylic lens. Only insertion systems that have been validated and approved for use with this lens should be used. Please refer to the specific instructions for use provided with the insertion instrument or system for additional information.

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 118 bilateral multifocal subjects and 116 bilateral monofocal subjects; no subjects in the expansion study had reached the one-year visit at the time of data analyses.

Distance Visual Acuties

Photopic (85 cd/m²) distance visual acuity results for both lens groups are presented in **Tables 1-4**. **Tables 1 and 2** present monocular uncorrected and best corrected distance visual acuity results for subjects' first eyes at 4-6 months and one year, respectively. **Table 3** shows binocular results at 4-6 months. 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 1 and 2**). Additionally, all best case Tecnis® ZM900 first eyes (100%, 327/327 at 4-6 months and 113/113 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.

Mean monocular and binocular distance visual acuities for both lens groups are presented in **Table 4**. 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.

Near Visual Acuties

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/m²) and mesopic (3 cd/m²) lighting conditions. Mean monocular and binocular near visual acuities at 4-6 months for both lens groups are presented in **Table 5**. 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.

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, 2-3 cm greater than the means for multifocal subjects.

Distributions of near visual acuity results for both lens groups are presented in **Tables 6-8**. **Tables 6 and 7** present 4-6 month and one-year results, respectively, for first-eye monocular photopic uncorrected and distance corrected near visual acuities. **Table 8** presents 4-6 month results 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 test 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, 97-99% 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 6-8**).

Combination Visual Acuties

Combination visual acuities represent the proportion of subjects that achieved a specific distance acuity and a specific near acuity at the same visit. **Figures 1 and 2** present combined uncorrected distance and near (tested at 33 cm) visual acuities for binocular subjects at 4-6 months. **Figure 1** presents the proportions of subjects that achieved 20/40 or better both at distance and near for both lens groups; **Figure 2** presents the proportions of subjects that achieved 20/25 or better distance and 20/32 or better near for both lens groups. 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 (**Figure 2**).

Reading Ability

Binocular reading acuity and speed were evaluated in the initial study under photopic lighting conditions at the subject's best distance using the MNRead chart. **Table 9** presents the results for both lens groups at one year. Statistically significant differences in mean binocular reading acuity (p<0.0001*), critical print size (p<0.0001*) and maximum reading speed (p=0.0007*) 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.

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.

Multifocal subjects were found to have a significantly increased measured depth of focus compared to monofocal subjects overall (**Figure 3**) with a prominent near peak around -3.0 D essentially equivalent to the distance peak or plano refraction.

The depth of focus performance for the Tecnis® multifocal IOL strongly illustrates the multifocality of the optic design at any pupil size (**Figure 4**). Little 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.

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 10**). 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.

Driving Performance

A night driving performance substudy was conducted to assess functional performance differences between multifocal and monofocal IOL subjects in the initial study. 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 11 and 12** for the rural road and in **Tables 13 and 14** 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.

Fundus Visualization

At the 4-6 month study visit, 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.

Figures 5-7 present the frequency of spectacle wear for bilaterally implanted monofocal subjects at 4-6 months. 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*). Similar statistically significant results were noted at one year as well.

Table 15 presents subjects' ability to function comfortably without glasses. Statistically significant differences were found between lens groups (p<0.0001*) with more multifocal subjects reporting the ability to function comfortably at near without glasses at both 4-6 months and one year.

Satisfaction of vision without glasses (**Table 16**) was assessed on a scale of 1-5, with 1 being "not at all satisfied" and 5 being "completely satisfied". At both 4-6 months and one year, statistically significant differences were found between lens groups for overall (p≤0.0052*) and during the day (p<0.0001*) with mean ratings for multifocal subjects closer to "completely satisfied" and mean ratings for monofocal subjects closer to "mostly satisfied". At night, there were no statistically significant differences between lens groups with mean ratings for both lens groups "mostly satisfied" or better.

Subjects also rated the degree of trouble with vision without glasses in the day and at night (**Table 17**) 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*) during the day with lower mean trouble ratings. At night, a significant difference (p=0.0047*) was noted in favor of the multifocal lens at one year. However, postoperative scores for both lens groups were generally low with mean ratings between "no trouble" and "a little bit of trouble".

Subjects also rated their vision in general without glasses (**Table 18**) 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*).

Subjects were asked about their desire to elect the same IOL again, if given the opportunity. As shown in **Table 19**, 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.

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 20**. 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, the observed proportion of lens-related surgical re-interventions in first eyes is not statistically higher than the FDA grid rate (p=0.575) with only three subjects out of 348 experiencing such events (3/348; 0.9%). A third subject also experienced a lens-related surgical re-intervention in a second eye (due to halos/glare); however, the rate for second eye lens-related surgical re-interventions was also not statistically above the grid rate (p=0.4432). The rate of non-lens-related surgical re-interventions was statistically higher than the grid rate for multifocal first eyes (p=0.0022); Secondary surgical re-intervention events for multifocal first eyes are specified in **Table 21**.

Medical complications at 4-6 months and one year (persistent) are presented for Tecnis® ZM900 first eyes in **Table 22**. 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). The rate for raised IOP requiring treatment at one year was not statistically higher than the FDA grid rate (p=0.3743). Some medical complications were reported at 4-6 months, however, none of the rates were statistically higher than the one-year grid rates.

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 23** presents the incidence of non-directed responses for optical/visual symptoms for first eyes in both lens groups at 4-6 months and 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". Lower rates were reported at the one-year visit compared to earlier study time points. Across both studies, three multifocal subjects (0.9%) underwent study lens removal; two resulting from halos/glare and one from dissatisfaction with image quality (blurry/hazy vision).

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*) 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 24**). Although more difficulty was noted with the multifocal lens with respect to nighttime visual symptoms, overall levels of subject satisfaction remained high (95% or more would choose the same lens again when asked one year postoperatively) and exceeded that of the monofocal lens (as shown in **Table 19**). With respect to other optical/visual symptoms, subject questionnaire results also yielded some statistically significant differences between groups for distorted near vision, distorted distance vision and blurred distance vision; however, the large majority of subjects in both lens groups reported no difficulty with these symptoms.

CLINICAL STUDY RESULTS for the Sensor® Monofocal Lens, Model AR40

The soft acrylic optic material was clinically studied in the US clinical trial of the monofocal Sensor® acrylic lens Model AR40, conducted between July 1996 and May 1998. The incidences of complications experienced during the clinical trial (**Table 25**) were comparable to or less than those of the historic control (FDA Grid) population. In the clinical study, there were 382 subjects implanted monocularly and the overall incidence of reported adverse events was 1.6%.

DETAILED DEVICE DESCRIPTION:

The Tecnis® multifocal lens is a three-piece foldable posterior chamber lens. The optic is made of hydrophobic soft acrylic and the haptics are made of polymethylmethacrylate (PMMA). This lens has 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 is +4 diopters, corresponding to +3 diopters in the spectacle plane.

LENS OPTIC:

- Material: hydrophobic soft acrylic with a covalently bound UV absorber
- UV transmittance: for a typical 10 D lens, UV cut-off at 10% T is 379 nm; for a typical 30 D lens, UV cut-off at 10% T is 383 nm
- Index of refraction: 1.47 at 35°C
- Diopter power: 5.0 D to 34.0 D in 0.5 D increments.

HAPTICS:

- Material: Blue core polymethylmethacrylate (PMMA) monofilament

Dimensions (i.e., overall diameter, optic diameter, etc.) and loop shape of specific lens model is provided on the outside of the lens box.

Throughout the visible and near infrared regions (400-1100nm), the lenses are highly transmissive with %T values generally exceeding 90%. **Figure 8** shows the overlay of the average percent transmission spectra for the 20 D acrylic Tecnis® Multifocal lenses.

DIRECTIONS FOR USE:

- Prior to implanting, examine the lens package for proper lens model, dioptric power, and expiration date.
- Open the package and remove the lens in a sterile environment.
- Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens optical surfaces for other defects.
- The lens may be soaked in sterile balanced salt solution until ready for implantation.
- 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.
- AMO recommends using The UNFOLDER® Emerald Series Insertion System (handpiece model EmeraldT or EmeraldXL, and Cartridge model EmeraldC) to insert the acrylic Tecnis® multifocal lens. Only insertion systems 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.
- Norrry NES. Unfortunate discrepancies. Letter to the editor and reply by Holladay JT. J. Cataract Refract Surg. 24:433-434, 1998.
- Norrry 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/euilb/index/htm is in particular useful for Zeiss IOLMaster users.

PATIENT CARD: An implant identification card, to be supplied to the patient, is included in the package. The patient should be instructed to keep the card as a permanent record of his/her implant and to show the card to any eye care practitioner he/she may see in the future.

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

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

HOW SUPPLIED: Each Tecnis® multifocal foldable acrylic posterior chamber intraocular 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 sterilize the lens.

Symbol/Explanation:

SYMBOL	ENGLISH
	Sterilized by Ethylene Oxide
	DO NOT REUSE
	USE BY (YYYY-MM: year-month)
	SEE INSTRUCTIONS FOR USE

The AMO Logo, Tecnis, Sensor, OptiEdge and the UNFOLDER are registered trademarks of Advanced Medical Optics, Inc. .

Manufactured by:
AMO Groningen BV, 9728 NX Groningen, The Netherlands for Advanced Medical Optics, Inc., Santa Ana, CA, USA.
The CE marked IOLs comply with the European Council Directive 93/42/EEC of June 14, 1993.

^a P-value was not adjusted for multiplicity.

Table 1: Monocular Distance Visual Acuity at 4-6 Months

Visual Acuity	Tecnis ZM900 N=333		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 2: Monocular Distance Visual Acuity at One Year

Visual Acuity	Tecnis ZM900 N=116		Monofocal Control N=114	
	Uncorrected	Best Corrected	Uncorrected	Best Corrected
20/20 or better	26.7%	69.8%	49.1%	84.2%
20/25 or better	60.3%	93.1%	77.2%	93.9%
20/32 or better	81.0%	99.1%	86.8%	100.0%
20/40 or better	91.4%	100.0%	97.4%	100.0%
20/50 - 20/80	6.9%	0.0%	2.6%	0.0%
20/100 or worse	1.7%	0.0%	0.0%	0.0%

Table 3: 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 4: Mean Distance Visual Acuties

Distance Visual Acuity	Time point	Lens Group	Monocular			Binocular		
			N	Mean Snellen Equivalent	Mean Diff. (ETDRS lines)	N	Mean Snellen Equivalent	Mean Diff. (ETDRS lines)
Uncorrected	4-6 Months	ZM900 Monofocal	333 119	20/27 20/25	-0.38	294 119	20/22 20/20	-0.50
	1 Year	ZM900 Monofocal	116 114	20/28 20/24	-0.68	114 114	20/22 20/20	-0.45
Best Corrected	4-6 Months	ZM900 Monofocal	333 119	20/20 20/19	-0.25	294 119	20/18 20/17	-0.21
	1 Year	ZM900 Monofocal	116 114	20/21 20/19	-0.30	114 114	20/18 20/17	-0.33

Table 5: Mean Near Visual Acuties at 4-6 Months

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

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

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

Near Visual Acuity	Uncorrected				Distance Corrected			
	Tecnis ZM900		Monofocal		Tecnis ZM900		Monofocal	
	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%	0.9%
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 7: Monocular Photopic Uncorrected and Distance Corrected Near Visual Acuity at One Year

Near Visual Acuity	Uncorrected				Distance Corrected			
	Tecnis ZM900		Monofocal		Tecnis ZM900		Monofocal	
	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	16.4%	27.6%	0.0%	0.0%	24.1%	34.5%	0.0%	0.0%
20/25 or better	37.1%	47.4%	0.9%	1.8%	53.4%	66.4%	0.0%	0.8%
20/32 or better	69.8%	75.9%	2.7%	5.3%	79.3%	81.9%	2.7%	4.4%
20/40 or better	83.6%	90.5%	6.2%	14.2%	95.7%	97.4%	6.2%	10.6%
20/50 - 20/80	14.7%	9.5%	46.0%	45.1%	4.3%	2.6%	42.5%	43.4%
20/100 or worse	1.7%	0.0%	47.8%	40.7%	0.0%	0.0%	51.3%	46.0%

Table 8: Binocular Photopic Uncorrected and Distance Corrected Near Visual Acuity at 4-6 Months

Near Visual Acuity	Uncorrected				Distance Corrected			
	Tecnis ZM900		Monofocal		Tecnis ZM900		Monofocal	
	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%

Figure 1: Combined 20/40 or Better Binocular Distance and Near Photopic Visual Acuity at 4-6 Months

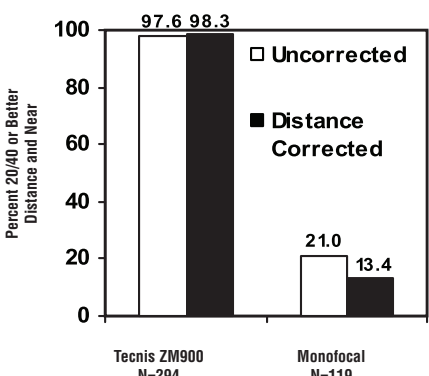
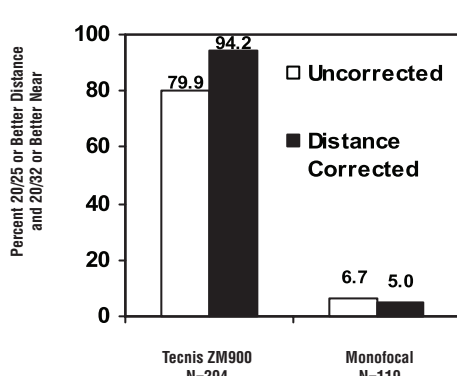


Figure 2: Combined 20/25 or Better Binocular Distance and 20/32 or Better Binocular Near Photopic Visual Acuity at 4-6 Months



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Table 9: 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

Figure 3: Mean Visual Acuity at Each Defocus Level for All Subjects at Their Natural Pupil Size

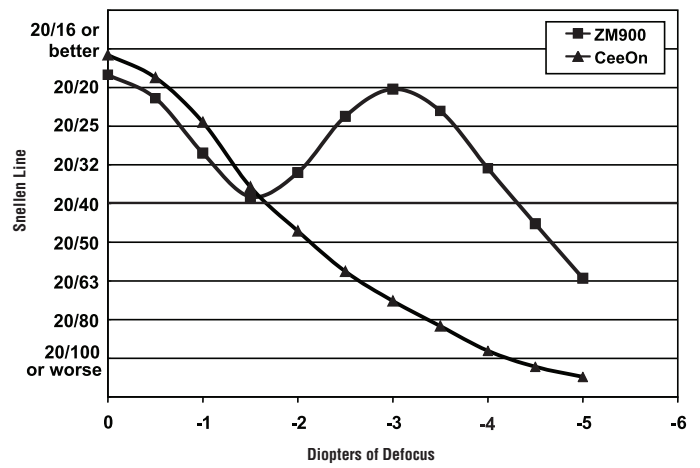


Figure 4: Mean Visual Acuity at Each Defocus Level for Tecnis Multifocal Subjects by Pupil Size Groups: Small: $\leq 2.5\text{ mm}$; Medium: <math>> 2.5\text{ mm}, < 4.0\text{ mm}</math>; Large: $\geq 4.0\text{ mm}$

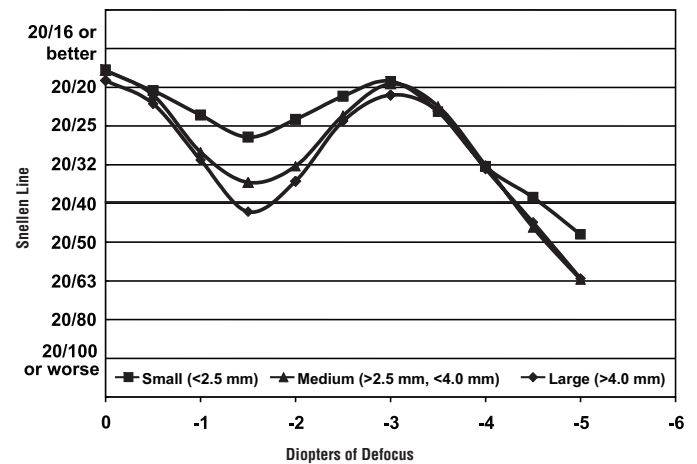


Table 10: Mean Best Case Binocular Log Contrast Sensitivity Scores at 4-6 Months

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

Table 11: 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	5.94
	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 12: 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 13: 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 14: Visibility Distance and Time for City Identification

Visibility Condition	Target	Mean Visibility Distance (feet)		Difference (feet)	Mean % Loss	Mean Visibility Time (sec)	
		ZM900	Monofocal				

Figure 5: Spectacle Usage for Bilateral Subjects at 4-6 Months

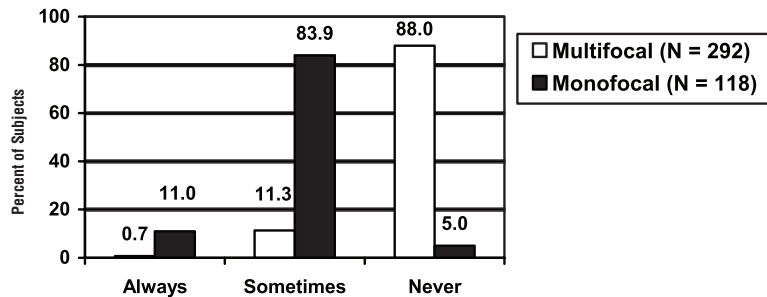


Figure 6: Spectacle Usage for Distance Vision for Bilateral Subjects at 4-6 Months

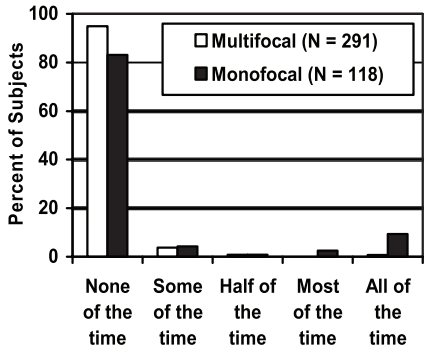


Figure 7: Spectacle Usage for Near Vision for Bilateral Subjects at 4-6 Months

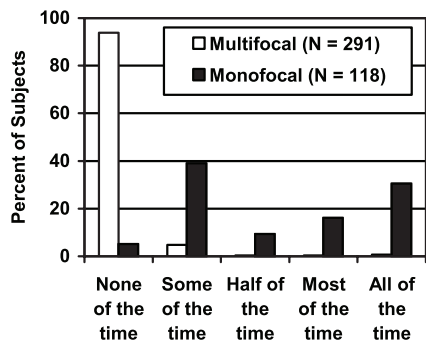


Table 15: Ability to Function Comfortably Without Glasses for Bilateral Subjects

Ability to Function Comfortably at:	4-6 Months		One Year	
	Tecnis ZM900 N=292	Monofocal N=118	Tecnis ZM900 N=112	Monofocal N=115
Near	94.2%*	16.9%	96.4%*	30.4%
Intermediate	85.3%	94.9%	93.8%	84.2%
Distance	90.4%	94.9%	96.4%	98.3%

*Statistically significant difference vs. monofocal control

Table 16: 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=112	Monofocal N=115
Overall	4.46*	4.20	4.59*	4.25
During the day	4.53*	4.19	4.65*	4.24
At Night	4.09	4.11	4.37	4.19

*Statistically significant difference vs. monofocal control

Table 17: 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=112	Monofocal N=115
During the day	1.44*	1.80	1.23*	1.86
At Night	1.97	1.89	1.63*	2.00

*Statistically significant difference vs. monofocal control

Table 18: Mean Rating of Vision Without Glasses for Bilateral Subjects (on a scale of 0-10, with 10 being best)

Rating of Vision	Tecnis ZM900		Monofocal	
	N	Mean Rating	N	Mean Rating
4-6 Months	292	8.67*	118	7.94
One Year	112	8.94*	115	7.86

*Statistically significant difference vs. monofocal control

Table 19: Desire to Elect IOL Again for Bilateral Subjects Directed Response to a Prompted Choice Questionnaire

Elect IOL Again?	Tecnis ZM900		Monofocal	
	4-6 Months N=292	One Year N=112	4-6 Months N=118	One Year N=115
Yes	255 87.3	106 94.6	100 84.7	103 89.6
No	30 10.3	5 4.5	15 12.7	12 10.4
Undecided	7 2.4	1 0.9	3 2.5	0 0.0

Table 20: 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	8	2.3	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	12	3.4	
Lens-related	2 [‡]	0.6	0.8
Not lens-related	10 [§]	2.9	

* 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).

‡ Following study completion, two subjects experienced lens-related events in the first eye; however, one of these had also 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%) - the same three subjects with lens-related events in second eyes during the study.

Table 21: 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	10	2.9%
Iris prolapse/wound repair	1	0.3
Lens exchange:		
- Lens power (refractive error)	3	0.9
- Incorrect lens type	1 [*]	0.3
Macular hole repair	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	12*	3.4%

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

† This subject also experienced a pupiloplasty 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

Table 22: 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=116		
	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 [#]	1.0	0.4

Same eye

Table 23: 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=116	4-6 Months N=119	One Year N=116
Visual Disturbances				
Day glare	3.9%	5.2%	1.7%	1.7%
Floaters	4.2%	5.2%	4.2%	2.6%
Halos[‡]	40.8%	22.4%	4.2%	8.6%
Mild = 16.5%		Mild = 12.1%		Mild = 2.5%
Moderate = 15.3%		Moderate = 5.2%		Moderate = 1.7%
Severe = 9.0%		Severe = 5.2%		Moderate = 2.6%
Night glare[‡]	14.1%	15.5%	4.2%	4.3%
Mild = 5.1%		Mild = 2.6%		Mild = 1.7%
Moderate = 5.4%		Moderate = 10.3%		Moderate = 0.9%
Severe = 3.6%		Severe = 2.6%		Severe = 1.7%
Starburst[‡]	8.1%	6.0%	0.8%	1.7%
Mild = 3.6%		Mild = 3.4%		Mild = 1.7%
Moderate = 3.3%		Moderate = 2.6%		
Severe = 1.2%				
Night vision difficulty	3.3%	0.0%	0.0%	0.0%
Entoptic phenomena [†]	4.2%	1.7%	1.7%	1.7%
Image Quality	19.5%	11.2%	14.3%	12.9%
Overall = 3.3%		Overall = 0.9%		Overall = 2.6%
Distance = 5.4%		Distance = 2.9%		Distance = 1.7%
Intermediate = 11.1%		Intermediate = 6.9%		Intermediate = 0.9%
Near = 2.4%		Near = 1.7%		Near = 7.8%
Blurred/difficulty with vision				
Cloudy/hazy/filmy/foggy vision	3.9%	2.6%	1.7%	2.6%
Decreased vision	3.9%	2.9%	1.7%	2.6%
Fluctuation in acuity	3.6%	2.6%	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% (8/116) of both first and second eyes.

Table 24: Degree of Difficulty* Experienced with Visual Symptoms Without Glasses[†] As Reported by Bilateral Subjects to a Prompted Choice Questionnaire at 4-6 Months and One Year**

Question	Tecnis ZM900		Monofocal Control	
	4-6 Months N=292	One Year N=112	4-6 Months N=118	One Year N=115
Night Vision				
No Difficulty	44.3%	50.0%	70.4%	77.4%
Moderate Difficulty	43.6%	42.0%	27.0%	20.9%
Severe Difficulty	12.1%	8.0%	2.6%	1.7%
Glare/Flare				
No Difficulty	33.6%	40.2%	59.0%	72.2%
Moderate Difficulty	41.4%	37.5%	34.2%	24.3%
Severe Difficulty	25.0%	22.3%	6.8%	3.5%
Halos				
No Difficulty	30.1%	42.0%	77.8%	80.0%
Moderate Difficulty	34.6%	31.3%	14.5%	15.7%
Severe Difficulty	35.3%	26.8%	7.7%	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 (95% or more would choose the same lens again when asked one year postoperatively) and exceeded that of the monofocal lens (please refer to Table 19).

Table 25: Adverse Events - Sensor[®] Monofocal Lens, Model AR40 All Subjects (N=382)

Adverse Events	Cumulative		Persistent at One Year		FDA Grid	
	N	%	N	%	Cum † (%)	Per †† (%)
Subjects with No Adverse Events	376	98.4	335	100.0	-	-
Subjects with Adverse Events*	6	1.6	0	0.0	-	-
- Corneal Edema	-	-	0	0.0	-	0.6
- Iritis	-	-	0	0.0	-	1.0
- HypHEMA	0	0.0	-	-	1.0	-
- Macular Edema	3	0.8	0	0.0	3.5	0.8
- Pupillary Block	0	0.0	-	-	0.3	-
- Raised IOP Requiring Treatment	-	-	0	0.0	-	0.5
- Cystic Membrane	0	0.0	0	0.0	0.0	0.1
- Vitritis	-	-	0	0.0	-	0.1
- Endophthalmitis	1	0.3 [∞]	-	-	<0.1	-
- Anterior Lens Tissue Ongrowth**	33	8.6	17	5.0	-	-
- Retinal Detachment	0	0.0	-	-	0.5	-
- Lens Dislocation	1	0.3	-	-	0.4	-
- Hypopyon	1	0.3	-	-	0.4	-
- Acute Corneal Decompensation	0	0.0	0	0.0	0.2	-
- Intraocular Infection	0	0.0	0	0.0	0.1	-
- Secondary Surgical Intervention (lens removal and replacement)	1	0.3	-	-	2.0	-

* One subject had both endophthalmitis and hypopyon.

† Cumulative incidence at one year visit.

†† Persistent incidence at one year visit.

∞ Incidence of endophthalmitis was not statistically different from the FDA grid.

** At the conclusion of the three-year clinical study, the cumulative and persistent incidences were 11.3% (43/382) and 7.4% (19/256) respectively; these incidences were not statistically different from the one year levels. Of the 17 cases reported at one year, 8 cases resolved; 10 new cases of ongrowth were seen at the year three visit. Adverse effect on these subjects' vision was not reported by the investigators. Tissue ongrowth has been previously reported in the literature on other IOL material types.

Figure 8: Average Percent Transmission Spectra for Model ZMA00

