SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Intraocular Lens
Device Trade Name:	TECNIS PureSee™ IOL with TECNIS SIMPLICITY™ Delivery System TECNIS PureSee™ Toric II IOLs with TECNIS SIMPLICITY™ Delivery System
Device Procode:	HQL, POE, and MJP
Applicant's Name and Address:	Johnson & Johnson Surgical Vision, Inc. 31 Technology Drive, Suite 200, Irvine, CA 92618 USA
Date(s) of Panel Recommendation:	None
Premarket Approval Application (PMA) Number:	P980040/S176
Date of FDA Notice of Approval:	March 11, 2026

The original PMA (PMA #P980040) was approved on February 3, 2000, for the AMO® SENSAR™ Soft Acrylic UV Light-Absorbing, Posterior Chamber IOL, Model AR40, and is indicated for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens is intended to be placed in the capsular bag. The SSED to support the indication is available on the CDRH website and is incorporated by reference here (https://www.accessdata.fda.gov/cdrh_docs/pdf/P980040B.pdf). The current supplement was submitted to expand the indications and include the TECNIS PureSee™ IOL with TECNIS SIMPLICITY™ Delivery System (Model DEN00V) and the TECNIS PureSee™ Toric II IOL with TECNIS SIMPLICITY™ Delivery System (Models DET150, DET225, DET300, DET375).

The TECNIS PureSee™ Intraocular Lenses (IOLs), consist of toric and non-toric configurations and are preloaded in TECNIS SIMPLICITY™ Delivery System. Model DEN00V is the non-toric TECNIS PureSee™ IOL, while Model Series DET150, DET225, DET300 and DET375 are the toric versions of TECNIS PureSee™ IOLs with cylinder powers of 1.50D, 2.25D, 3.00D and 3.75D, respectively. Like their parent lenses, the TECNIS PureSee™ IOLs are indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by phacoemulsification and are intended to be placed in the capsular bag.

The TECNIS PureSee™ IOLs are a modification of existing FDA-approved lenses, including the SENSARTM 1-Piece IOL, Model AAB00 (P980040/S015), the TECNIS™ IOL, Model Z9000

(P990080/S001) and the TECNIS™ 3-Piece OptiBlue™ IOL, Model ZV9003 (P980040/S035). The TECNIS™ Toric 1-Piece IOL, Models ZCT150, ZCT225, ZCT300, and ZCT400 (P980040/S039; approved on April 15, 2013) is the toric parent.

II. INDICATIONS FOR USE

TECNIS PureSee™ IOL with TECNIS SIMPLICITY™ Delivery System

The TECNIS SIMPLICITY™ Delivery System is used to fold and assist in inserting the TECNIS PureSee™ IOL, which is indicated for primary implantation for the visual correction of aphakia in adult patients with less than 1 diopter of pre-existing corneal astigmatism in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the TECNIS PureSee™ IOL provides improved intermediate visual acuity, while maintaining comparable distance visual acuity. The lens is intended for capsular bag placement only.

TECNIS PureSee™ Toric II IOLs with TECNIS SIMPLICITY™ Delivery System

The TECNIS SIMPLICITY™ Delivery System is used to fold and assist in inserting the TECNIS PureSee™ Toric II IOLs, which are indicated for primary implantation for the visual correction of aphakia and for reduction of refractive astigmatism in adult patients with greater than or equal to 1 diopter of preoperative corneal astigmatism in whom a cataractous lens has been removed. The lenses mitigate the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the TECNIS PureSee™ Toric II IOLs provide improved intermediate visual acuity, while maintaining comparable distance visual acuity. The lenses are intended for capsular bag placement only.

III. CONTRAINDICATIONS

There are no known contraindications.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the labeling for the TECNIS PureSee™ IOLs.

V. DEVICE DESCRIPTION

The TECNIS PureSee™ IOLs, non-toric lens model DEN00V and toric lens Models DET150, DET225, DET300, DET375, are ultraviolet light-absorbing posterior chamber IOLs that provide extended depth of focus to mitigate the effects of presbyopia. Compared to an aspheric monofocal IOL, the lens provides substantially improved and clinically significant intermediate vision while maintaining distance visual acuity, contrast sensitivity, and low levels of visual symptoms.

The lens material blocks UV and violet radiation up to a 10%T cutoff wavelength of 420 nm to 440 nm. TECNIS PureSee™ IOLs are to be positioned in the lens capsule to replace the optical function of the natural crystalline lens. Accommodation will not be restored. **Table 1** below

describes the physical characteristics of the lenses. The biconvex optic incorporates the proprietary wavefront-designed aspheric or toric-aspheric TECNIS anterior optic, designed to compensate for corneal spherical aberration. The anteriorly located cylinder axis marks in the toric-aspheric optic denote the meridian with the lowest power and are to be aligned with the steep corneal meridian. The toric IOLs achieved the ANSI Standard for Toric IOLs, Z80.30, rotational stability requirement (>90% of eyes having ≤5° axis change between consecutive visits). The TECNIS PureSee™ IOLs share the same one-piece lens platform, the same material, lens geometry, general dimensions, overall manufacturing process, and packaging configuration as their parent lens models, and incorporate the purely refractive OptiCurve™ technology on the posterior optic of the lens to create a modulated power profile that extends the depth of focus. The TECNIS PureSee™ IOLs demonstrated pupil-independent lens performance among the pupil sizes tested.

The optic is 6.0 mm in diameter and the lens has an overall diameter of 13.0 mm. The toric lenses incorporate perpendicular maximum and minimum radii of curvature and two sets of four (total of eight) axis orientation marks on their anterior optic surfaces that correct astigmatic refractive error when aligned properly with the patient's corneal astigmatism (predicted postoperative steep corneal meridian). The physical properties of this lens are shown in **Figure 1** and the packaging configurations are shown in **Figure 2**. The TECNIS PureSee™ IOLs packaged with the TECNIS SIMPLICITY™ Delivery System (Models DEN00V, DET150-375) are preloaded to provide a sterile, single-use, controlled and touch-free disposable system that functions as both the primary packaging and as part of an insertion system for IOL insertion into the eye during cataract surgery.

The conversion table for cylinder powers is provided in the TECNIS PureSee™ IOL labeling.

Light Transmittance: UV cut-off at 10% T for a spherical equivalent (SE) +5.0 diopter lens (thinnest), SE +20.0 diopter lens and a SE +34.0 diopter lens (thickest) are shown in **Figure 3**.

The JJSV TECNIS™ Toric Calculator is a web-based calculator tool that can be used to select the most appropriate TECNIS PureSee™ Toric II IOL that best suits the visual needs of the patient. The TECNIS™ Toric Calculator is developed and controlled by JJSV's Software Development Procedures.

Table 1
Summary of Technical Specifications

Attribute	TECNIS PureSee™ IOL, Model DEN00V	TECNIS PureSee™ Toric II IOLs, Models DET150-375
Lens Configuration	1-piece lens	1-piece lens
Anterior Optic Profile	TECNIS wavefront-designed aspheric surface	TECNIS wavefront-designed toric-aspheric surface
Posterior Optic Profile	Purely refractive OptiCurve™ Technology	
Lens Material	Soft foldable hydrophobic acrylic with UVAM and proprietary violet light-filtering chromophore*	
Index of Refraction	1.47 at 35°C	
Light Transmittance	UV cut-off at 10% T for a spherical equivalent (SE) +5.0 D lens (thinnest), SE +20.0 D lens and a SE +34.0 D lens (thickest) are shown in **Figure 3**.	
Optic Center Thickness	0.7 mm (+20.0 D)	
Optic Edge Design	PROTEC 360 square posterior edge	
Haptic Configuration	TRI-FIX design Modified C, integral with optic	TRI-FIX design Modified C, integral with optic
Haptic Thickness	0.46 mm	
Cylinder Power (Diopter), IOL Plane	Spherical Equivalent (SE) Power: +5.0 D to +34.0 D in 0.5 D increments	Spherical Equivalent (SE) Power: +5.0 D to +34.0 D in 0.5 D increments Cylinder Power: Model DET150: 1.50 D Model DET225: 2.25 D Model DET300: 3.00 D Model DET375: 3.75 D (as measured at the IOL plane)
Cylinder Power (Diopter), Corneal Plane, approximate	0.0	Cylinder Power: Model DET150: 1.03 D Model DET225: 1.54 D Model DET300: 2.06 D Model DET375: 2.57 D (as calculated based on the average pseudophakic eye)

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

Figure 1
Product Drawing and photographs

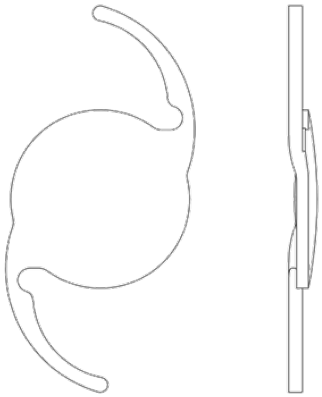
Product Drawing	TECNIS PureSee™ IOL, Model DEN00V	TECNIS PureSee™ Toric II IOLs, Model Series DET
		

Figure 2
TECNIS SIMPLICITY™ Packaging

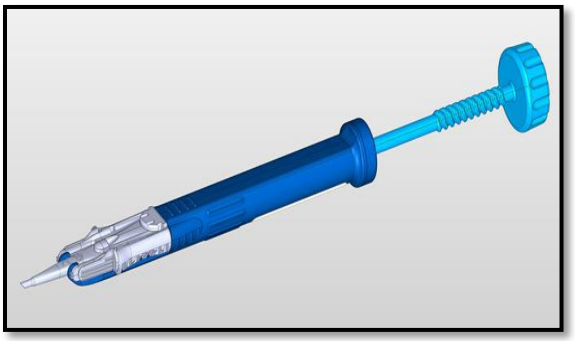
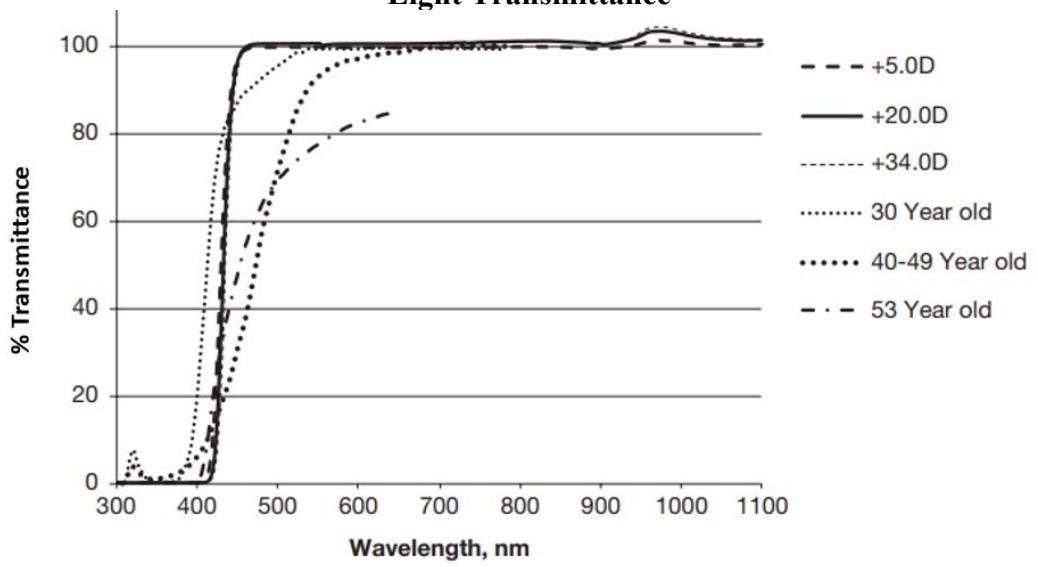


Figure 3
Light Transmittance



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

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of aphakia resulting from surgical cataract removal (i.e., for patients who have had a cataractous lens removed). Nonsurgical options include eyeglasses or contact lenses. Surgical options come in the form of intraocular lenses, which may be monofocal, multifocal, extended depth of focus, full visual range, toric or accommodative, depending on the patient's needs, expectations, and lifestyle. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The TECNIS PureSee™ IOLs in select models are currently commercially available in Australia, Canada, European Union, India, New Zealand, Singapore, and many other countries in Latin America, the Middle East-Africa region, and Asia Pacific. The lenses have not been withdrawn or recalled from any country for any reason related to safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

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

For the specific adverse events that occurred during the TECNIS PureSee™ IOL clinical study, please see Section X below.

IX. SUMMARY OF NON-CLINICAL STUDIES

Preclinical studies performed on either parent devices or subject devices demonstrate the safety and effectiveness of the TECNIS PureSee™ IOLs. The results of these studies are summarized below.

A. Laboratory Studies

Physicochemical Testing

The TECNIS PureSee™ IOLs use the same lens material as the material parent, the TECNIS™ 3-Piece OptiBlue™ IOL, Model ZV9003 (P980040/S035); therefore, physicochemical and biological data for these associated lenses are deemed applicable to the subject devices. All physicochemical reports pertaining to the SENSAR™ violet-light filtering soft acrylic material were previously submitted to FDA in 2006 as part of the 180-Day PMA Supplement for the material parent TECNIS™ 3 Piece OptiBlue™ IOL, Model ZV9003 (P980040/S035). P980040 served as the parent lens for the P980040/S035 submission for which an SSED is available. The physicochemical characterization of the TECNIS PureSee™ IOL material met the requirements of ISO 11979-5, Ophthalmic Implants – Intraocular Lenses – Part 5: Biocompatibility and EN ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process. The physicochemical tests are summarized in **Table 2**. All acceptance criteria for physicochemical testing were met.

Table 2
Physicochemical Test Summary: TECNIS PureSee™ IOLs, Indicating Relationship to the SENSAR™ AR40e IOL

Physicochemical Tests	Results of Testing
Exhaustive Extraction	Pass. Equivalent to SENSAR™ soft acrylic IOL, Model AR40e (P980040)
Leachables	Pass. Equivalent to SENSAR™ soft acrylic IOL, Model AR40e (P980040)
Insoluble Inorganics	Pass. No hazardous components identified
Hydrolytic Stability	Pass. Stable to 5 years equivalent age
Photostability	Pass. Stable to 20 years equivalent age
Nd:YAG laser	Pass. Equivalent to SENSAR™ soft acrylic IOL, Model AR40e (P980040)

Note: The SENSAR™ AR40e IOL has the OptiEdge™ design and was approved in the same PMA (P980040) as the SENSAR™ AR40 IOL, which has a rounded optic edge design.

B. Animal Studies

Biological Testing

The TECNIS PureSee™ IOLs are made of the same soft acrylic violet-filtering material and have the same manufacturing contact materials previously qualified with the material parent, the TECNIS™ 3-Piece OptiBlue™ IOL, Model ZV9003 (P980040/S035). All physicochemical reports pertaining to the SENSAR™ violet-light filtering soft acrylic material was previously submitted to FDA in 2006 as part of the 180-Day PMA Supplement for the material parent TECNIS™ 3 Piece OptiBlue™ IOL, Model ZV9003 (P980040/S035). P980040 served as the parent lens for the P980040/S035 submission for which an SSED is available. The biocompatibility studies were performed in accordance with the requirements in ISO 10993, Biological Evaluation of Medical Devices, and 11979-5 Ophthalmic Implants – Intraocular Lenses – Part 5: Biocompatibility guidelines, to establish a complete profile of the IOL material. The results are summarized in **Table 3**. All acceptance criteria for biocompatibility were met.

Table 3
Biocompatibility Test Summary: TECNIS PureSee™ IOL

Biological Tests	Results of Testing
Cytotoxicity: (MEM) Agar Diffusion Solid Contact & Saline Extract)	**Pass** Non-cytotoxic
Percentage Inhibition of Cell Growth Method	**Pass** Non-inhibitory to cell growth
Guinea Pig Maximization a. Saline Extract b. Sesame Oil Extract	**Pass** Non-sensitizing
Non-Ocular Implant Study (Six-Week Subcutaneous Implantation in Rabbits)	**Pass**
Six-Month Rabbit Intraocular Study	**Pass**
Genotoxicity Testing *(Salmonella typhimurium* and *Escherichia coli* reverse mutation assay)	**Pass** Non-genotoxic, non-mutagenic
Genotoxicity testing (chromosomal aberration assay in Chinese hamster ovary cells) Genotoxicity Testing (Mouse Lymphoma Forward Mutation Assay)	**Pass** Non-clastogenic Non-mutagenic under short and long exposure conditions

C. Additional Studies

Dimensional, optical, and mechanical tests were conducted on finished, sterilized, TECNIS PureSee™ IOLs to verify the conformance to applicable sections of ISO 11979-2, Ophthalmic Implants-Intraocular Lenses-Part 2: Optical Properties and Test Methods; ISO 11979-3, Ophthalmic Implants-Intraocular Lenses Part 3: Mechanical Properties and Test Methods; and ANSI Z80.30, American National Standard for Ophthalmics: Toric Intraocular Lenses, and ANSI Z80.35, American National Standard for Ophthalmics: Extended Depth of Focus Intraocular Lenses. As part of mechanical assessment, folding and insertion testing was also performed to verify recovery of lens properties (e.g., optical, etc.) following simulated insertion. Here, the TECNIS PureSee™ IOLs passed all predetermined requirements established in the aforementioned standards where applicable and internal product specifications. **Table 4** summarizes the results of the dimensional, optical, and mechanical testing. Testing for the TECNIS SIMPLICITY™ Delivery System was completed on representative lenses and was focused on optical and mechanical testing on attributes that can be impacted by a change in the storage and delivery of the device; specifically, the recovery of properties following simulated surgical manipulation pertinent to the preloaded IOLs, according to testing requirements from ISO 11979-2 and ISO 11979-3. Here, the lenses met the acceptance criteria and met all predetermined requirements established in the aforementioned standards where applicable and internal product specifications. **Table 5** summarizes the results of the recovery of properties following simulated surgical manipulation for the TECNIS SIMPLICITY™ Delivery System.

Table 4
Dimensional, Optical and Mechanical Test Results

Requirements	Results
Optical Requirements	
Diopter Power	**Pass**
Image Quality	**Pass**
Spectral Transmittance	**Pass**
Cylinder Power (TECNIS PureSee™ Toric II IOLs only)	**Pass**
Axis Orientation Mark(s) (TECNIS PureSee™ Toric II IOLs only)	**Pass**
Mechanical and Dimensional Testing	
Overall Diameter	**Pass**
Vault Height	**Pass**
Sagitta	**Pass**
Clear Optic diameter	**Pass**
Optic Body Diameter	**Pass**
Central Optic Thickness	**Pass**
Axial Displacement in Compression	**Pass**
Optic Decentration	**Pass**
Optic Tilt	**Pass**
Haptic Width	**Pass**
Haptic Thickness	**Pass**
Angle of Contact	**Pass**
Compression Force and Decay	**Pass**
Dynamic Fatigue Durability	**Pass**
Pull Strength	**Pass**

Table 5
Recovery Properties Following Simulated Surgical Manipulation Test Results

Requirements	Results
Recovery of Properties Following Simulated Surgical Manipulation	
Diopter Power	**Pass**
Cylinder Power (TECNIS PureSee™ Toric II IOLs only)	**Pass**
Image Quality	**Pass**
Axis Orientation Mark(s) (TECNIS PureSee™ Toric II IOLs only)	**Pass**
Overall Diameter	**Pass**
Sagitta	**Pass**
Surface and Bulk Homogeneity	**Pass**

Microbiology, Sterilization, and Shelf-Life Adoption / Testing

The lens material and platform, geometry, dimensions, manufacturing method, materials and equipment, sterilization method, and packaging materials and configuration of the TECNIS PureSee™ IOLs packaged in the TECNIS SIMPLICITY™ Delivery System are the same as those of the recent FDA-approved JJSV's one-piece soft acrylic IOLs preloaded with the TECNIS SIMPLICITY™ Delivery System, such as TECNIS Synergy™ IOLs (P980040/S124), TECNIS Symfony™ OptiBlue™ IOLs (P980040/S142) and TECNIS Odyssey™ IOLs (P980040/S156/ S159). The TECNIS Sterilization validations performed the TECNIS SIMPLICITY™ Delivery System are deemed applicable to the subject lenses and assure a minimum sterility assurance level of 10^{-6}. A 3-year shelf life was established for the TECNIS PureSee™ IOLs packaged in the TECNIS SIMPLICITY™ Delivery System based on a 3-year shelf life approved by FDA for the TECNIS SIMPLICITY™ Delivery System in P980040/S098. These tests were conducted in accordance with the following standards, FDA Guidance, and United States Pharmacopeia (USP) chapter:

- ANSI/AAMI/ISO 11135-1, Sterilization of Healthcare Products – Ethylene Oxide – Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process

- ISO 10993-7, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

- ANSI/AAMI/ISO 11737-1, Sterilization of health care products—Microbiological methods—Part 1: Determination of a population of microorganisms on products

- ANSI/AAMI ST72, Bacterial endotoxins—Test methods, routine monitoring, and alternatives to batch testing

- USP<85>, Bacterial Endotoxin Test

- FDA Guidance on Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices (2015)

- ISO 11979-6, Ophthalmic Implants – Intraocular Lenses – Part 6: Shelf-life and transport stability.

- ANSI/AAMI/ISO 11607-1, Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems

X. SUMMARY OF PRIMARY CLINICAL STUDY(IES)

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of the TECNIS PureSee™ IOL with TECNIS SIMPLICITY™ Delivery System, Model DEN00V for the visual correction of aphakia in adult patients with less than 1 diopter of pre-existing corneal astigmatism in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the TECNIS PureSee™ IOL provides improved intermediate visual acuity, while maintaining comparable distance visual acuity in the US under IDE #G240043. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

The TECNIS PureSee™ Toric II IOLs with TECNIS SIMPLICITY™ Delivery Systems (Models DET150, DET225, DET300, DET375) involved imposing the toric feature from the toric design parents (P980040/S039): TECNIS™ Toric 1-Piece IOL, Models ZCT150, ZCT225, ZCT300 and ZCT400. Since the study for TECNIS PureSee™ IOL Model DEN00V established safety and effectiveness, and the applicant has approved toric parent IOLs, additional clinical data was not required to support safety and effectiveness of the toric models. Because of the potential for an interaction between the toric and extended depth-of-focus (EDF) elements, an optical-bench study was conducted. In the optical-bench study of imaging quality, the highest-power toric IOL (DET375) was misaligned at the highest tilt, decentration, and rotation observed in the parent toric IOL study (G090251) and those modulation transfer function (MTF) measurements at appropriate spatial frequencies and defocus levels were compared to the non-toric device (DEN00V) and to a monofocal parent device. The results of the optical-bench study, as well as ray-tracing simulations performed on the highest toric power IOL (DET375), in the presence of the clinically relevant amounts of tilt, decentration and rotation expected for the TECNIS PureSee™ Toric II IOLs demonstrated that the EDF effect of the TECNIS PureSee™ IOLs is maintained in the presence of misalignment.

A. Study Design

Patients were treated between June 3, 2024, and April 23, 2025. The database for this Panel-Track Supplement reflected data collected through May 9, 2025, and included 245 enrolled subjects. There were 9 investigational sites.

The study was a prospective, multicenter, bilateral, controlled, masked (sponsor, subject, and evaluator), randomized 6-month clinical study of the TECNIS PureSee™ IOL, with TECNIS SIMPLICITY™ Delivery System, Model DEN00V. The control group was the TECNIS™ 1-Piece IOL, with TECNIS SIMPLICITY™ Delivery System, Model DCB00. This study was designed according to ISO 11979-7:2024 and ANSI Z80.35:2018 to demonstrate the safety and effectiveness of the investigational TECNIS PureSee™ IOL in comparison to a monofocal control IOL. The TECNIS™ 1-Piece IOL, Model DCB00 used as the monofocal control is a legally marketed alternative with similar indications for use, except that it is not intended to provide improved vision at intermediate distance.

Up to 250 subjects were to be enrolled to achieve approximately 224 bilaterally implanted subjects, to obtain approximately 200 evaluable subjects (100 subjects per IOL group) at 6 months. This was to account for a screen failure rate of approximately 10% and a dropout rate of about 10% through 6 months.

The clinical hypotheses were that the investigational device TECNIS PureSee™ IOL, Model DEN00V would provide improved distance-corrected intermediate visual acuity (DCIVA, 66 cm) without compromising distance vision, when compared to the monofocal control, TECNIS™ 1-Piece IOL, Model DCB00, and that adverse event rates associated with the DEN00V IOL would be within the rates for posterior chamber IOLs given in ISO 11979-7:2024.

The study sample size satisfied the requirements for a Level B modification of a parent lens per ISO 11979-7:2024 and ANSI Z80.35-2018 which requires a minimum of 100 bilaterally implanted evaluable subjects in each IOL group. In addition to satisfying the ISO sample size requirement, a total of 200 subjects evaluable at 6 months provided over 90% statistical power for comparing the IOL groups on the co-primary effectiveness endpoints of monocular DCIVA and best-corrected distance visual acuity (BCDVA) while controlling for the study Type I error rate of 0.05.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the Clinical Investigation of the Safety and Effectiveness of an Investigational Model of the TECNIS PureSee™ Intraocular Lens (Model DEN00V) study was limited to subjects who met the following inclusion criteria in each study eye:

- Adults (Minimum 22 years of age or older at the time of participation in the study),
- Clear intraocular media other than cataract, with BCDVA of 20/40 or worse and <1.0 D of preoperative keratometric astigmatism,
- Potential BCDVA of 20/30 Snellen or better,
- Availability, ability, willingness and sufficient cognitive awareness to comply with examination procedures and complete all required postoperative visits,
- Signed informed consent and HIPAA authorization or equivalent documentation necessary to comply with applicable privacy laws pertaining to medical treatment in the governing countries, and
- Ability to understand and respond to a questionnaire in English.

Subjects were not permitted to enroll in the TECNIS PureSee™ Intraocular Lens (Model DEN00V) study if they, or either eye, met any of the following exclusion criteria:

- Clinically significant ocular surface disease that would affect study measurements based on Investigator medical opinion,
- Irregular corneal astigmatism,
- History of intraocular surgery, including prophylactic peripheral iridotomies and peripheral laser retinal repairs,
- Recent ocular trauma that is not resolved/stable or may affect visual outcomes or increase risk to the subject,
- Pregnancy, planned pregnancy, presently lactating or another condition associated with hormonal fluctuation that could lead to refractive changes,

- Concurrent participation or participation within 30 days prior to preoperative visit in any other clinical trial, and
- Desire for monovision correction.

In addition, there were general exclusions at the time of surgery that precluded implantation of a study lens (per ISO 11979-7:2024, Section 6.10.4.2, *General exclusion criteria at the time of surgery*). If any such complications occurred during surgery, the subject was discontinued from the study (if first eye affected) or would only be followed per the protocol for the first eye (if second eye affected).

2. Follow-up Schedule

All subjects were scheduled to return for follow-up examinations as described in **Table 6**.

Table 6
Clinical Study Visit Schedule

Visit	Eyes Evaluated	Exam	Visit Window
1	Both Eyes	Preoperative Exam	Within 60 days prior to 1st surgery
2	First Eye	Operative	0-60 days after preoperative exam
3	First Eye	1 day	1-2 days after 1st eye surgery
4	First Eye	1 week	7-14 days after 1st eye surgery
5	Second Eye	Operative	7-30 days after 1st eye surgery
6	Second Eye	1 day	1-2 days after 2nd eye surgery
7	Second Eye	1 week	7-14 days after 2nd eye surgery
8	First Eye	1 month[a]	30-60 days after 1st eye surgery
9	Second Eye	1 month[a]	30-60 days after 2nd eye surgery
10	Both Eyes	6 months[b,c]	120 - 180 days after 2nd eye surgery

Shaded rows indicate study visits where both eyes are evaluated at the same visit

[a] If the 1-month visit window for first and second eye overlap, both eyes may be examined at a single visit.

[b] If for any reason the second eye is not implanted, the first eye should be examined at the 6-month study visit 120 to 180 days following the first-eye surgery.

[c] A second 6-month visit (if needed) must be scheduled within 1-14 days of the first 6-month visit. Both visits must fall within the specified 6-month window (120-180 days).

Following study enrollment and informed consent procedure, the preoperative assessments, included distance visual acuity, potential acuity, anterior and posterior segment examination, intraocular pressure, biometry and IOL power calculations, subject questionnaires, and ocular/medical history.

Postoperatively, only the most recently operated eye was evaluated at the 1-day, 1-week and 1-month visits. Both eyes were evaluated at the 6-month visits. Postoperative measurements included

manifest refraction, uncorrected and corrected visual acuities under photopic and mesopic conditions, depth of focus testing, pupil size, contrast sensitivity, keratometry, IOP measurement, dilated fundus examination, and subject questionnaires. In addition, biomicroscopic slit-lamp examination (including IOL assessment) and ocular/visual symptoms were to be assessed at all postoperative visits.

Preoperatively and postoperatively, the objective parameters measured during the study are presented in Table 7.

Table 7
Summary of Procedures Required at Each Visit

Examination (Shaded lines indicate masked testing)	Preop Both eyes	Op 1st eye, 2nd eye	1 day 1st eye, 2nd eye	1 week 1st eye, 2nd eye	1 Month 1st eye, 2nd eye	6 Month Both eyes [f,h]
Informed consent, demographics, medical and ocular history, potential visual acuity, axial length, anterior chamber depth, targeted refraction, IOL power calculations	X					
Inclusion/exclusion criteria and randomization if required	X					
Lens power/serial number (masked)/operative procedures		X				
Keratometry	X					X
Corneal Topography	X					
UCDVA - photopic, monocular (each eye), binocular	X		X	X	X	X
Manifest refraction (Snellen preop; ETDRS postop)	X			X	X	X
BCDVA - photopic monocular (each eye), binocular	X			X	X	X
UCIVA – photopic monocular (each eye), binocular at 66 cm					X	X
DCIVA – photopic, monocular (each eye), binocular at 66 cm					X	X
Depth of focus testing, monocular (first eye), binocular						X
UCNVA – photopic, monocular (each eye), binocular at 40 cm					X	X
DCNVA – photopic, monocular (each eye), binocular at 40 cm					X	X
Photopic pupil size – monocular (first eyes)						X
Mesopic pupil size (with and without glare) – monocular (first eyes)						X
BCDVA- mesopic monocular (first eye), binocular						X
DCIVA – mesopic, monocular (first eye), binocular at 66 cm						X
Far Contrast sensitivity – monocular (first eye), binocular (mesopic with and without glare condition)						X
Biomicroscopic slit-lamp exam	X		X	X	X	X
Lens Stability (Tilt/Decentration)			X	X	X	X
Gonioscopy	X					
Intraocular pressure	X		X	X	X	X
Dilated Fundus Exam with fundus visualization and findings	X		X	X	X	X
Adverse event assessment	X	X	X	X	X	X
Ocular medications	X	X	X	X	X	X
Ocular/visual symptoms (non-directed)	X		X	X	X	X
Lens recommendation (self-administered)					X	X
Subject questionnaires (PRVSQv2) (self-administered)	X				X	X

3. Clinical Endpoints

For the remainder of the clinical summary section, "TECNIS PureSee™" refers to the TECNIS PureSee™ IOL, Model DEN00V, and "control" refers to the TECNIS™ 1-Piece IOL, Model DCB00. Of note, the numbering of endpoints below is intended to facilitate ease of reference to the results below and does not connote any statistical hierarchy.

With regards to safety, the primary safety endpoints and success criteria were:

1. The incidence of secondary surgical interventions (SSIs) related to optical properties of the lens for eyes in the test lens group.
2. The incidence of all Safety and Performance Endpoints (SPE) Rates, including total SSIs as defined in ISO 11979-7:2024 for eyes in the test lens group. Success was achieved if TECNIS PureSee™ rates were not statistically significantly higher than ISO SPE rates.
3. The percentage of eyes that achieves monocular best corrected distance visual acuity (BCDVA) 0.30 LogMAR or better acuity in the test lens group, as described in ISO 11979-7:2024, at the 6-month visit. Success was achieved if the rate of eyes achieving BCDVA 0.30 LogMAR or better for the PureSee group was not statistically significantly lower than ISO SPE rates.
4. Mean monocular BCDVA at 4 meters (first eyes and all eyes). Statistical success was achieved if the PureSee group mean was statistically significantly non-inferior to that of the control by a -0.10 LogMAR margin.
5. Incidence of all other non-SPE serious adverse events (SAEs) and/or device-related adverse events (ADEs) for eyes in the test lens group. There was no success criteria as descriptive statistics were used for this endpoint.
6. Monocular mesopic contrast sensitivity without glare at 6 months (first eyes): Clinical success was achieved if the mean difference between lens groups at any spatial frequency was ≤ 0.3 log units.
7. Investigator's assessment of his/her ability to clinically visualize fundus at 6 months. There was no success criteria as descriptive statistics were used for this endpoint.

With regards to effectiveness, the primary effectiveness endpoints and success criteria were:

1. Monocular (first eyes) photopic distance-corrected intermediate visual acuity (DCIVA) at 66 cm at 6 months. The mean value for TECNIS PureSee™ group was to be statistically significantly superior to that of control group. Clinical success was achieved if the median and mean DCIVA for the PureSee group were 0.20 LogMAR or better.
2. Monocular (first eyes) distance-corrected depth of focus at 6 months. Clinical success was achieved if the intercept of the depth of focus curves at the 0.20 LogMAR threshold for the PureSee group was at least 0.50 D greater than that for the control group.
3. Monocular (first eyes) photopic BCDVA at 4 m at 6 months. The mean value for the TECNIS PureSee™ group was to be statistically significantly non-inferior to that of the control group by a 0.10 LogMAR margin.
4. Monocular (first eyes) photopic distance-corrected distance visual acuity (DCVA) at 100 cm at 6 months. Clinical success was achieved if the mean DCIVA for the TECNIS PureSee™ group was 0.20 LogMAR or better.

With regard to success/failure criteria, the study success will be demonstrated if all success criteria for all primary effectiveness and primary safety endpoints are simultaneously met.

Additional Study Endpoints Discussed in the Results Section Below:
Manifest refraction
Photopic monocular and binocular UCDVA at 4 m, UCIVA at 66 cm, UCNVA at 40 cm
Photopic binocular BCDVA at 4 m, DCIVA at 66cm, DCNVA at 40 cm
Photopic monocular DCNVA at 40 cm
Mesopic monocular and binocular BCDVA at 4 m and DCIVA at 66 cm
Binocular distance-corrected depth of focus
Monocular mesopic contrast sensitivity with glare
Binocular mesopic contrast sensitivity with and without glare
Non-serious, non-device related adverse events
Medical Findings, Lens findings
Increases in Intraocular Pressure (IOP)
PRO instrument (Patient Reported Visual Symptoms Questionnaire, PRVSQv2)
Ocular/visual symptoms (non-directed responses as obtained from the open-ended question "Are you having any difficulties with your eyes or vision?")
PRO instrument (Patient Reported Spectacle Independence Questionnaire, PRSIQv2)

The Analysis Populations were:

- **Intent-to-treat (ITT) Population:** All subjects randomized with a study lens implanted in the first eye. As there were some general exclusion criteria at the time of surgery, per ISO 11979-7:2024 Section 6.10.4.2, the ITT population excluded subjects who experienced such exclusion criteria during the first-eye surgery. Subjects were analyzed per the planned randomization schema.
- **Safety Population (SP):** All subjects for whom a study IOL touched the eye. Subjects were analyzed per IOL received.
- **Per-Protocol (PP) Population:** Subjects implanted with a study lens, evaluated within the proper 6-month study interval and without clinically relevant protocol deviations (deviations that could potentially impact the primary endpoints), as determined prior to database lock.
- **Best-Case Population:** Eyes in the safety population with no preoperative ocular pathology, no macular degeneration detected at any time, and no previous surgery for the correction of refractive error, as determined prior to database lock.

The ITT Population was the primary analysis set for the primary effectiveness endpoints and the SP was the primary analysis set for the primary safety endpoints and other endpoints. In addition, the PP Population was also the primary analysis set for a primary effectiveness BCDVA endpoint. First eyes were considered the primary eyes and presented in the tables for monocular endpoints, unless specified otherwise. All results presented are based on the SP with observed case (i.e., available data with no data imputation) unless specified otherwise.

B. Accountability of PMA Cohort

At the time of database lock, a total of 245 subjects enrolled in the PMA study, 97.8% (223 out of the 228 bilaterally implanted) are available for analysis at the completion of the study, the 6-month

post-operative visit. The study was conducted between June 2024 and April 2025 across 9 investigational sites in the USA.

Of the 228 bilaterally implanted subjects in the SP population, 115 subjects were in the TECNIS PureSee™ group and 113 in the control group. Subject accountability at 6 months was 98.3% (113/115) in the TECNIS PureSee™ group (**Table 8**) and 97.3% (110/113) in the control group (**Table 9**). The PP population included 218 of 228 subjects (95.6% of SP), with 111 subjects in the TECNIS PureSee™ group and 107 in the control group.

While the ITT and SP populations were comprised of 228 subjects each, the number of subjects in the TECNIS PureSee™ and control groups differed due to 1 subject who was randomized to the TECNIS PureSee™ group but was inadvertently implanted with the control lens in both eyes. All other subjects were bilaterally implanted according to the randomization schedule.

Table 8
Accountability First Eyes – TECNIS PureSee™

	1 Day		1 Week		1 Month		6 Months[a]	
Status	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Treated (N)	**115**		**115**		**115**		**115**	
Available for Analysis	115	100.0%	115	100.0%	114	99.1%	113	98.3%
In Interval	115	100.0%	115	100.0%	112	97.4%	111	96.5%
Out of Interval	0	0.0%	0	0.0%	2	1.7%	2	1.7%
Missing Data	0	0.0%	0	0.0%	1	0.9%	2	1.7%
○ Discontinued/ early study exit	0	0.0%	0	0.0%	1	0.9%	2	1.7%
○ Lost-to-follow-up	0	0.0%	0	0.0%	0	0.0%	0	0.0%
○ Not seen but accounted for (missed visit)	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Active	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Percent Accountability (ISO 11979-7:2024)[b]	-	100.0%	-	100.0%	-	100.0%	-	100.0%

[a] Based on the first day of the 6-month visit if the visit was conducted over 2 days.
[b] Percent accountability = (available for analyses * 100)/(treated - discontinued - active)

Table 9
Accountability First Eyes – Control

	1 Day		1 Week		1 Month		6 Months[a]	
Status	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Treated (N)	**113**		**113**		**113**		**113**	
Available for Analysis	113	100.0%	113	100.0%	110	97.3%	110	97.3%
In Interval	113	100.0%	110	97.3%	106	93.8%	108	95.6%
Out of Interval	0	0.0%	3	2.7%	4	3.5%	2	1.8%
Missing Data	0	0.0%	0	0.0%	3	2.7%	3	2.7%
o Discontinued/ early study exit	0	0.0%	0	0.0%	3	2.7%	3	2.7%
o Lost-to-follow-up	0	0.0%	0	0.0%	0	0.0%	0	0.0%
o Not seen but accounted for (missed visit)	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Active	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Percent Accountability (ISO 11979-7:2024)[b]	-	100.0%	-	100.0%	-	100.0%	-	100.0%

[a] Based on the first day of the 6-month visit if the visit was conducted over 2 days.
[b] Percent accountability = (available for analyses * 100)/(treated - discontinued - active)

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a cataract surgery and IOL implantation study performed in the US. **Table 10** shows the demographic results for the SP population. The population was on average 68.5 (Standard Deviation [SD] of 6.7) years of age with 77.2% (176/228) of subjects 65 years or older. Most subjects were female (61.8%; 141/228) and white (81.1%; 185/228) with brown/black irises (54.4%; 124/228). Similar demographic characteristics were observed for age, sex, race, ethnicity, or iris color between lens groups. Additionally, the demographic characteristics were similar for the ITT and PP populations.

Table 10
Demographics – TECNIS PureSee™ and Control Subjects

		TECNIS PureSee™ N=115		Control N=113		Total (N=228)	
Age (years)	N	115		113		228	
	Mean	69.0		68.0		68.5	
	SD	6.9		6.4		6.7	
	Median	70.0		68.0		69.0	
	Min	45		44		44	
	Max	82		84		84	
		n	**%**	**n**	**%**	**n**	**%**
Age Group	<65 years	25	21.7%	27	23.9%	52	22.8%
	>=65years	90	78.3%	86	76.1%	176	77.2%
	Total n	115	100.0%	113	100.0%	228	100.0%
Sex	Male	44	38.3%	43	38.1%	87	38.2%
	Female	71	61.7%	70	61.9%	141	61.8%
	Total n	115	100.0%	113	100.0%	228	100.0%
Race	American Indian/Alaska Native	0	0.0%	1	0.9%	1	0.4%
	Asian (Includes Indian)	5	4.3%	3	2.7%	8	3.5%
	Black or African American	13	11.3%	16	14.2%	29	12.7%
	Native Hawaiian/Other Pacific Islander	1	0.9%	0	0.0%	1	0.4%
	White	93	80.9%	92	81.4%	185	81.1%
	Other	3	2.6%	1	0.9%	4	1.8%
	Total n	115	100.0%	113	100.0%	228	100.0%
Ethnicity	Hispanic/Latino	18	15.7%	10	8.8%	28	12.3%
	Not Hispanic/Latino	97	84.3%	103	91.2%	200	87.7%
	Total n	115	100.0%	113	100.0%	228	100.0%
Iris Color	Blue/Gray	35	30.4%	23	20.4%	58	25.4%
	Brown/Black	61	53.0%	63	55.8%	124	54.4%
	Green/Hazel	19	16.5%	27	23.9%	46	20.2%
	Total n	115	100.0%	113	100.0%	228	100.0%

%=n/N *100 (Total N - Not Reported)

Table 11 presents the preoperative MRSE and Keratometric Cylinder for TECNIS PureSee™ and control subjects in the SP population. The mean differences between lens groups for preoperative intended MRSE and preoperative keratometric cylinder were small and not clinically significant (difference of 0.02 D and -0.01 D, respectively). These results were similar for the ITT and PP populations.

Table 11
Mean Intended MRSE and Preoperative Keratometric Cylinder
First Eyes

Variable	IOL	n	Mean	Standard Deviation	Median	Minimum	Maximum
Intended MRSE (D)	TECNIS PureSee™	115	-0.06	0.104	-0.04	-0.32	0.19
	Control	113	-0.08	0.111	-0.08	-0.35	0.23
	Difference		0.02				
Keratometric Cylinder (D)	TECNIS PureSee™	115	0.51	0.244	0.54	0.00	0.98
	Control	113	0.51	0.232	0.51	0.00	1.00
	Difference		-0.01				

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety results was based on the SP cohort of 228 subjects treated, 223 were available for the 6-month evaluation. The primary analysis sets for all primary safety endpoints were the SP first eyes and all eyes, except for contrast sensitivity which was SP first eyes only. The SP was also the primary analysis set for the other safety endpoints reported. In addition, the Best-Case population first eyes was also a primary analysis set for the BCDVA vs ISO Safety and Performance (SPE) rate endpoint. The success criteria for all primary safety endpoints were met for the TECNIS PureSee™ lens. The key safety outcomes for this study are presented below in **Tables 12-24**, **Figures 4-7**. Adverse effects are reported in **Tables 12-18**.

Adverse effects that occurred in the PMA clinical study:

The second co-primary safety endpoint was persistent (present at the final visit) and cumulative rates of ISO 11979-7 SPE AEs among first eyes and all eyes in the TECNIS PureSee™ lens group. This primary safety endpoint met the study success criteria because the rates were below or not statistically significantly higher than the ISO SPE rates (**Table 12 and Table 13**). Overall, there were 2 SAEs in first eyes and 3 SAEs in all eyes associated with ISO SPEs.

Table 12
6-Month Persistent Adverse Events vs. ISO 11979-7 SPE[a] Rates
TECNIS PureSee™ Group

Persistent Medical Complication/Adverse Event	ISO SPE Rate %	First Eyes N=113 n (%)	First Eyes N=113 Lower Bound of 1-sided 95% CI	All Eyes N=226 n (%)	All Eyes N=226 Lower Bound of 1-sided 95% CI
Corneal edema	0.3	0 (0.0%)	0.00	0 (0.0%)	0.00
Cystoid macular edema	0.5	1 (0.9%)	0.05	2 (0.9%)	0.16
Iritis	0.3	0 (0.0%)	0.00	0 (0.0%)	0.00
Raised IOP requiring treatment	0.4	0 (0.0%)	0.00	0 (0.0%)	0.00

[a] SPE: Safety and Performance Endpoint.
Confidence intervals were calculated using the Clopper-Pearson method.

Table 13
6-Month Cumulative Adverse Events vs. ISO 11979-7 SPE[a] Rates
TECNIS PureSee™ Group

Cumulative Medical Complication/Adverse Event	ISO SPE Rate %	First Eyes N=115 n (%)	First Eyes N=115 Lower Bound of 1-sided 95% CI	All Eyes N=230 n (%)	All Eyes N=230 Lower Bound of 1-sided 95% CI
Cystoid macular edema[b]	3.0	1 (0.9%)	0.04	3 (1.3%)	0.36
Hypopyon	0.3	0 (0.0%)	0.00	0 (0.0%)	0.00
Endophthalmitis	0.1	0 (0.0%)	0.00	0 (0.0%)	0.00
Lens dislocated from posterior chamber	0.1	0 (0.0%)	0.00	0 (0.0%)	0.00
Pupillary block	0.1	0 (0.0%)	0.00	0 (0.0%)	0.00
Retinal detachment	0.3	0 (0.0%)	0.00	0 (0.0%)	0.00
Eyes with secondary surgical intervention[c]	0.8	1 (0.9%)	0.04	1 (0.4%)	0.02
o Device related	-	0 (0.0%)	0.00	0 (0.0%)	0.00
o Not device related	-	1 (0.9%)	0.04	1 (0.4%)	0.02

% = (n/N) *100
[a] SPE: Safety and Performance Endpoint.
[b] All incidence of cystoid macular edema reported per ISO, regardless of clinical significance as defined by Masket et al. AAO Task Force criteria.
[c] Excluding wound burp.
Confidence intervals were calculated using the Clopper-Pearson method.

The first co-primary safety endpoint was SSIs related to the optical properties of the IOL and during the pivotal trial there were zero SSIs related to the optical properties of the IOL (i.e., "Eyes with secondary surgical intervention, device related") (**Table 14**). In addition, SSIs not related to the optical properties of the IOL, including non-ISO SPE SSIs procedures (such as tap, wound burp, and paracentesis) are listed in **Table 14**.

Table 14
Secondary Surgical Interventions by IOL Group

	TECNIS PureSee™				Control			
	First Eyes N=115		All Eyes N=230		First Eyes N=113		All Eyes N=226	
	n	%	n	%	n	%	n	%
Secondary Surgical Interventions (SSIs)								
○ Anterior chamber washout for retained lens material	1	0.9%	1	0.4%	0	0.0%	0	0.0%
○ Wound burp	0	0.0%	2	0.9%	2	1.8%	3	1.3%
○ Pars plana vitrectomy for vitreous in the anterior chamber	0	0.0%	0	0.0%	0	0.0%	1	0.4%
○ Related to Optical Properties	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Total Eyes with SSIs	**1**	**0.9%**	**3**	**1.3%**	**2**	**1.8%**	**4**	**1.8%**

% = (n/N) *100

The incidence of all other non-SPE serious AEs and/or device-related adverse events for eyes in the test lens group was the fifth co-primary safety endpoint. A summary of the results is described below and in **Table 15** and **Table 16.** In the TECNIS PureSee™ group, the incidence rates of non-SPE ocular serious and/or device-related adverse events were 4.3% (5/115) for first eyes and 4.8% (11/230) for all eyes.

- Non-SPE SAEs: 1.7% (2/115) of TECNIS PureSee™ first eyes and 2.6% (6/230) of all eyes experienced increased intraocular pressure (IOP), deemed as serious but non-device related; all events were resolved without sequelae.

- Non-SPE ADEs: 2.6% (3/115) of TECNIS PureSee™ first eyes and 2.2% (5/230) of all eyes reported undesirable optical phenomena (or inadequate visual clarity) deemed device-related but non-serious; of these, 4 (from 2 subjects) from the all-eyes set were ongoing at study end. Only 1 of 115 (0.9%) subject in the TECNIS PureSee™ group reported optical phenomena to cause bother or difficulty that interfered with daily activity for more than 3 months.

Table 15
Ocular Non-SPE Related Serious and/or Device-Related Adverse Events
Safety Population - First Eyes

	DEN00V N=115		Control N=113	
Adverse Event	**n (%)**	**95% CI**	**n (%)**	**95% CI**
Inadequate visual clarity	1 (0.9)	(0.02, 4.75)	0 (0.0)	(0.00, 3.21)
Increased IOP	2 (1.7)	(0.21, 6.14)	3 (2.7)	(0.55, 7.56)
Undesirable optical phenomena	2 (1.7)	(0.21, 6.14)	3 (2.7)	(0.55, 7.56)
Total[a]	5 (4.3)	(1.43, 9.85)	6 (5.3)	(1.97, 11.20)

Confidence intervals are calculated using the Clopper-Pearson method.
[a] Total represents the number of unique eyes with at least 1 event.

Table 16
Ocular Non-SPE Related Serious and/or Device-Related Adverse Events
Safety Population - All Eyes

	DEN00V N=230		Control N=226	
Adverse Event	**n (%)**	**95% CI**	**n (%)**	**95% CI**
Inadequate visual clarity	2 (0.9)	(0.11, 3.11)	0 (0.0)	(0.00, 1.62)
Increased IOP	6 (2.6)	(0.96, 5.59)	4 (1.8)	(0.48, 4.47)
Undesirable optical phenomena	3 (1.3)	(0.27, 3.76)	6 (2.7)	(0.98, 5.69)
Total[a]	11 (4.8)	(2.41, 8.40)	10 (4.4)	(2.14, 7.99)

Confidence intervals are calculated using the Clopper-Pearson method.
[a] Total represents the number of unique eyes with at least 1 event.

Additional safety measurements based on the modified consensus definitions as set forth by the American Academy of Ophthalmology's Task Force (Masket et al., Ophthalmology 2017) are shown in **Table 17**.

Table 17
Ocular Adverse Events Based on a Modified Version of the AAO Task Force Consensus (Masket, et al 2017 reference)

	First Eyes		All Eyes		Subjects	
Adverse Event	TECNIS PureSee™ N=115 n (%)	Control N=113 n (%)	TECNIS PureSee™ N=230 n (%)	Control N=226 n (%)	TECNIS PureSee™ N=115 n (%)	Control N=113 n (%)
Increased IOP	3 (2.6)	7 (6.2)	7 (3.0)	9 (4.0)	6 (5.2)	8 (7.1)
Chronic anterior uveitis	2 (1.7)	0 (0.0)	3 (1.3)	0 (0.0)	3 (2.6)	0 (0.0)
Clinically significant cystoid macular edema	0 (0.0)	1 (0.9)	0 (0.0)	2 (0.9)	0 (0.0)	2 (1.8)
Corneal edema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toxic anterior segment syndrome	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Endophthalmitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mechanical pupillary block	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhegmatogenous RD	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Secondary IOL intervention	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Exchange	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Removal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reposition	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

% = n/N
Adverse Events are presented in descending order by the incidence rate of TECNIS PureSee™ first eyes.
n=Number of unique eyes or unique subject.

Table 18 presents the incidence rates of medical findings/general AEs for the TECNIS PureSee™ and control all-eyes at 6 months. The most reported medical findings for all eyes in both IOL groups were posterior vitreous detachment/floaters and posterior capsule opacification (PCO). Of the reports of PCO (any), most were of trace severity and there were no cases of moderate or severe PCO were reported in either IOL group.

Table 18
Medical Findings/Adverse Events at 6 Months
All Eyes (First and Second)

	TECNIS PureSee™ N=226		Control N=220	
Medical Finding	n	%	n	%
Posterior vitreous detachment/floaters	99	43.8%	77	35.0%
Posterior capsule opacification (any)	69	30.5%	80	36.4%
o Trace	65	28.8%	73	33.2%
o Mild	4	1.8%	7	3.2%
o Moderate	0	0.0%	0	0.0%
o Severe	0	0.0%	0	0.0%
Blepharitis/meibomianitis	60	26.5%	54	24.5%
Dermatochalasis	56	24.8%	48	21.8%
Dry eye/superficial punctate keratopathy/punctate epithelial erosion/tear film insufficiency	29	12.8%	16	7.3%
Pinguecula	19	8.4%	25	11.4%
Arcus	16	7.1%	15	6.8%

Medical Finding	TECNIS PureSee™ N=226		Control N=220	
	n	%	n	%
Posterior capsule striae/wrinkles	15	6.6%	11	5.0%
Peripapillary atrophy	9	4.0%	7	3.2%
Meibomian gland dysfunction	8	3.5%	4	1.8%
Corneal scar	5	2.2%	9	4.1%
Epiretinal membrane	5	2.2%	8	3.6%
Ptosis	5	2.2%	5	2.3%
Drusen	4	1.8%	14	6.4%
Intra-ocular injection	4	1.8%	0	0.0%
Retinal pigment epithelium (RPE) changes	4	1.8%	9	4.1%
Telangiectasia	4	1.8%	4	1.8%
Corneal dystrophy	3	1.3%	2	0.9%
Corneal pigmentation	3	1.3%	2	0.9%
Eye naevus	3	1.3%	2	0.9%
Posterior capsule reticulation	3	1.3%	9	4.1%
Pterygium	3	1.3%	2	0.9%
Strabismus	3	1.3%	0	0.0%
Blepharal papilloma	2	0.9%	0	0.0%
Cystoid macular edema	2	0.9%	1	0.5%
Diabetic retinopathy	2	0.9%	0	0.0%
Guttata	2	0.9%	1	0.5%
Lens disorder	2	0.9%	0	0.0%
Melanosis	2	0.9%	0	0.0%
Optic disc pigmentation	2	0.9%	0	0.0%
Punctal plug insertion	2	0.9%	0	0.0%
Retinal aneurysm	2	0.9%	0	0.0%
Retinal degeneration	2	0.9%	5	2.3%
Retinal detachment/tear	2	0.9%	0	0.0%

Medical Finding	TECNIS PureSee™ N=226		Control N=220	
	n	%	n	%
Rosacea	2	0.9%	0	0.0%
Choroidal dystrophy	1	0.4%	0	0.0%
Corneal deposits	1	0.4%	0	0.0%
Cranial nerve paralysis	1	0.4%	0	0.0%
Hyalosis asteroid	1	0.4%	0	0.0%
Iris atrophy/abnormality	1	0.4%	0	0.0%
Retinal scar	1	0.4%	1	0.5%
Scleral disorder	1	0.4%	0	0.0%
Chorioretinal scar	0	0.0%	1	0.5%
Conjunctivochalasis	0	0.0%	2	0.9%
Cornea verticillata	0	0.0%	2	0.9%
Macular atrophy	0	0.0%	1	0.5%
Macular degeneration	0	0.0%	4	1.8%
Maculopathy	0	0.0%	1	0.5%
Optic atrophy	0	0.0%	1	0.5%
Pigment	0	0.0%	2	0.9%
Retinal pigmentation	0	0.0%	1	0.5%
Retinal vascular disorder	0	0.0%	1	0.5%
Steatoblepharon	0	0.0%	2	0.9%
Vitreous adhesions	0	0.0%	1	0.5%
Vitreous degeneration	0	0.0%	3	1.4%

Only findings reported with an incidence >0 are presented.
% = (n/N) *100
N=Number of all eyes (first and second).

Visual Acuity Related Primary Safety Endpoints

The third co-primary safety endpoint was the percentage of eyes achieving BCDVA 0.30 logMAR or better acuity in the test lens group, as described in ISO 11979-7:2024, at the 6-month visit. The success criterion for the primary safety endpoint was achieved, as 100% of first eyes and all eyes in the safety population and 100% of first eyes in the best-case population achieved BCDVA 0.30 LogMAR (**Table 19)**.

Table 19
Monocular Best-Corrected Distance Visual Acuity of 0.30 LogMAR or Better at 6 Months vs ISO 11979-7 SPE[a] Rates

Analysis Population	Cohort	LogMAR Threshold	ISO SPE (%)	n (%)	Upper bound of 1-sided 95% CI
Safety Population	First Eyes (N=113)	≤0.30	92.5	113 (100.0)	100.00
	All Eyes (N=226)	≤0.30	92.5	226 (100.0)	100.00
Best Case Population	First Eyes (N=112)	≤0.30	96.7	112 (100.0)	100.00

[a] SPE: Safety and Performance Endpoint.
Confidence intervals are calculated using the Clopper-Pearson method.

The fourth co-primary endpoint was mean monocular photopic BCDVA where distance is defined as 4 meters. The results demonstrated that the test lens group was non-inferior to the control lens group by -0.10 logMAR margin, at the 6-month visit. Among first eyes in the SP at 6 months, the difference in mean monocular BCDVA between lens groups was -0.04 LogMAR. The lower limit of the 2-sided 90% CI of the mean difference was -0.06, which was greater than the -0.10 LogMAR non-inferiority margin; thus, the statistical success criterion of this primary safety endpoint was met. Similar to the first-eye results, for all eyes in the SP at 6 months, the difference in mean monocular (all-eye) BCDVA between lens groups was -0.04 LogMAR. The lower limit of the 2-sided 90% CI of the mean difference was -0.05, which was greater than the -0.10 LogMAR non-inferiority margin; thus, the statistical success criterion of this primary safety endpoint was also met (**Table 20**).

Table 20
Monocular Best-Corrected Distance Visual Acuity at 4 m at 6 Months
Safety Population

Cohort	Lens Group	N	Mean Monocular LogMAR	Monocular Snellen Equiv.	90% CI
First Eyes	TECNIS PureSee™	113	-0.04	20/18	(-0.05, -0.03)
	Control	110	-0.08	20/16	(-0.09, -0.06)
	Difference		-0.04	-0.4 lines[a]	(-0.06, -0.02)
All Eyes (first and second)	TECNIS PureSee™	226	-0.04	20/18	(-0.05, -0.03)
	Control	220	-0.08	20/16	(-0.09, -0.07)
	Difference		-0.04	-0.4 lines[a]	(-0.05, -0.03)

[a] Line difference (Control minus TECNIS PureSee™) converted directly from LogMAR difference.
Non-inferiority margin of -0.10 LogMAR.

Mesopic Contrast Sensitivity

The between-lens groups differences (**Figure 4** and **Table 21**) in mean monocular (first eye) contrast sensitivity (CS) values under mesopic conditions without glare were ≤0.3 log units at all spatial frequencies, meeting the clinical success criterion of the sixth co-primary safety endpoint according to ISO 11979-7:2024. Likewise, the median differences were ≤0.3 log units at all spatial

frequencies. All subjects (100.0%) in both lens groups were able to see the reference pattern for the contrast sensitivity tests at all tested conditions.

Similar to the monocular mesopic without glare CS outcomes, the between-lens group mean and median differences in both monocular CS with glare (**Figure 4** and **Table 21**) and binocular CS with and without glare (**Figure 5**) under mesopic conditions were ≤0.3 log units at all spatial frequencies.

Table 21
Monocular Best Corrected Distance Mesopic Contrast Sensitivity (Log Unit) at 6 Months

			Without Glare		With Glare	
Spatial Frequency	**Lens Model**	**N**	**Mean**	**Did not see reference pattern %**	**Mean**	**Did not see reference pattern %**
1.5 cpd	TECNIS PureSee™	113	1.95	0.0%	1.73	0.0%
	Control	110	1.91	0.0%	1.75	0.0%
	Difference		0.04		-0.02	
3.0 cpd	TECNIS PureSee™	113	2.00	0.0%	1.81	0.0%
	Control	110	2.01	0.0%	1.88	0.0%
	Difference		-0.01		-0.08	
6.0 cpd	TECNIS PureSee™	113	1.65	0.0%	1.50	0.0%
	Control	110	1.75	0.0%	1.70	0.0%
	Difference		-0.10		-0.20	
12.0 cpd	TECNIS PureSee™	113	0.98	0.0%	0.88	0.0%
	Control	110	1.11	0.0%	1.06	0.0%
	Difference		-0.13		-0.18	

cpd = Cycles per degree

Figure 4
Mean (±1 SD) Monocular Best Corrected Distance Mesopic Contrast Sensitivity (Log Unit) at 6 Months

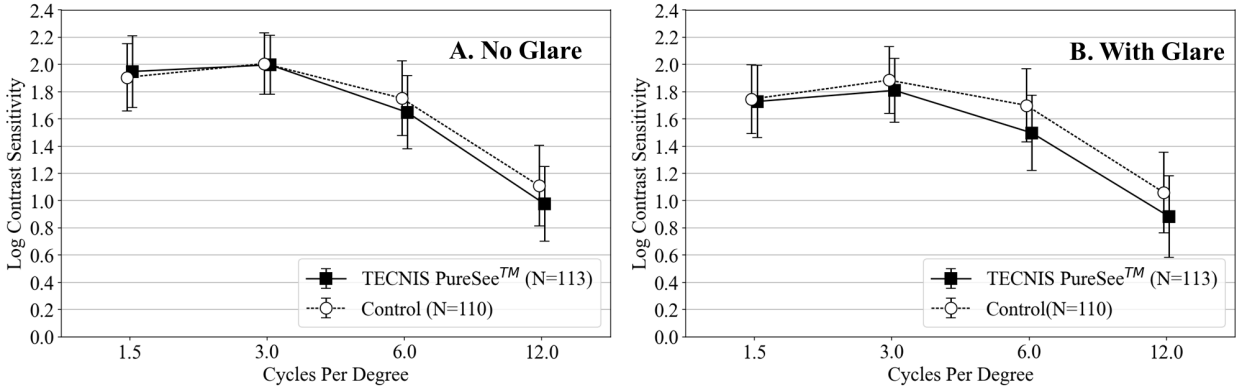
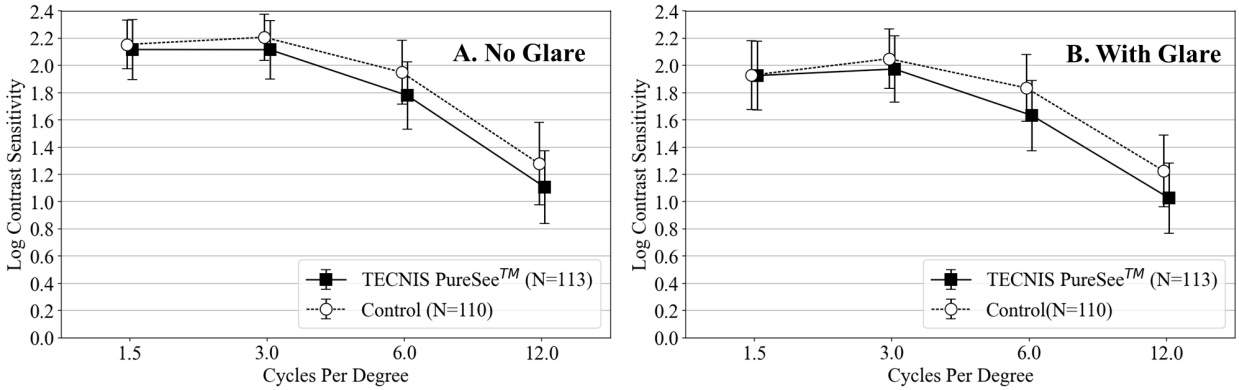


Figure 5
Mean (±1 SD) Binocular Best Corrected Distance Mesopic Contrast Sensitivity (Log Unit) at 6 Months



Monocular best corrected distance CS results were stratified by pupil size categories of "small" (≤3.0 mm), "medium" (>3.0 mm to <4.0 mm) or "large" (≥4.0 mm) where pupil size was measured under mesopic conditions. **Figure 6** and **Figure 7** show that the results for monocular mesopic CS without glare and with glare are consistent for all pupil size categories for the TECNIS PureSee™ and control group. There were no clinically meaningful differences (≤0.3 log units) between lens groups or between pupil size categories.

Figure 6
Mean Monocular Best Corrected Distance Mesopic Contrast Sensitivity Without Glare (Log Unit) By Pupil Size at 6 Months

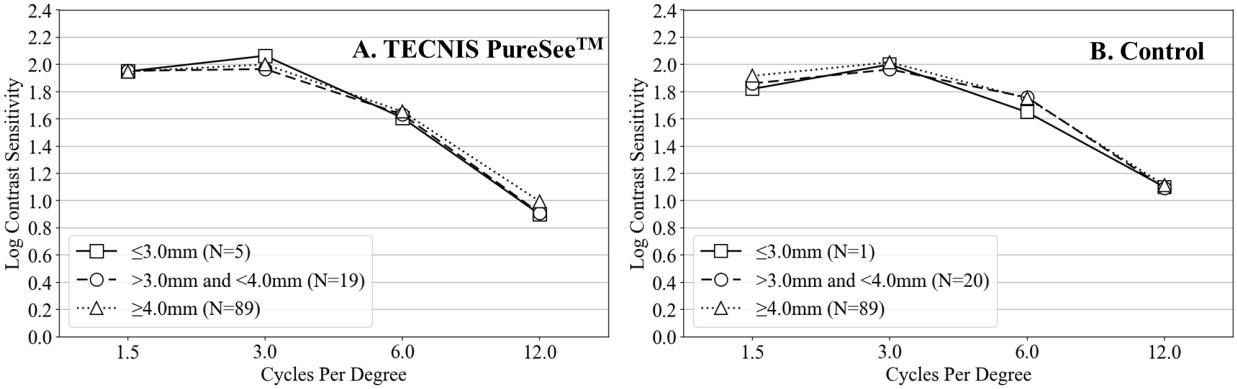
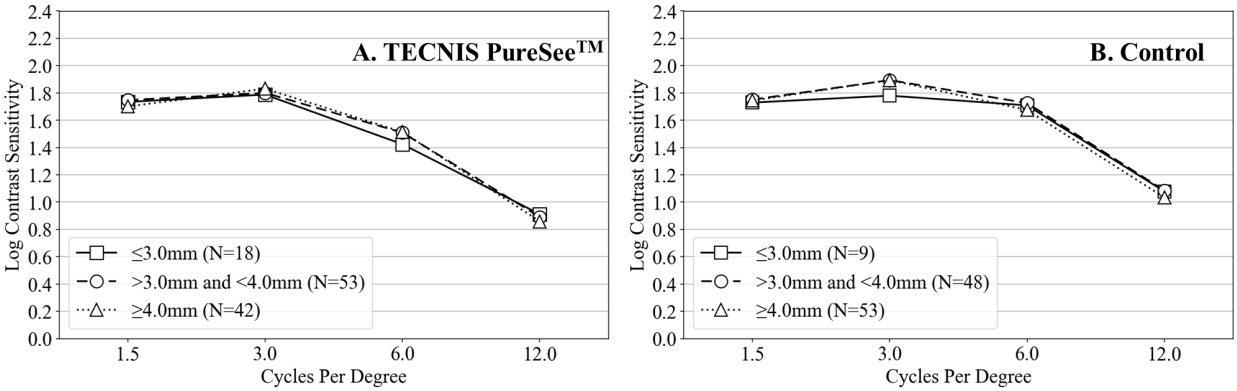


Figure 7
Mean Monocular Best Corrected Distance Mesopic Contrast Sensitivity With Glare (Log Unit) By Pupil Size at 6 Months



Ocular/Visual Symptoms

The study pre-identified some "additional endpoints" as supportive clinical information, including ocular/visual symptoms. The study was not designed for statistical comparison of this endpoint. Therefore, only descriptive statistics are presented here. At 6 months, subjects in both lens groups spontaneously reported ocular/visual symptoms in response to the open-ended question, “Are you having any difficulties with your eyes or vision?”. These subject-reported outcomes for both lens groups are in **Table 22**. The spontaneous reports of halos, night glare, and starbursts ranged from 4.4% (5/113) to 5.3% (6/113) among PureSee™ subjects and 0.9% (1/110) to 4.5% (5/110) among control subjects. When queried in follow-up to the spontaneous report, none of the subjects in the PureSee™ group reported severe halos, night glare, or starbursts. In the control group, one subject reported severe halos and none reported severe night glare or starbursts.

Table 22
Spontaneous (Non-directed[a]) Reports of Ocular/Visual Symptoms (First Eyes) at 6 Months

	TECNIS PureSee™ N=113		Control N=110	
	n	%	n	%
Blurred Vision[b]				
Overall	5	4.4%	1	0.9%
Distance	3	2.7 %	0	0.0 %
Intermediate	3	2.7%	7	6.4%
Near	19	16.8%	22	20.0%
Decreased Vision[b]				
Overall	0	0.0%	0	0.0%
Distance	0	0.0%	0	0.0%
Intermediate	0	0.0%	0	0.0%
Near	1	0.9%	0	0.0%
Halos[b]	6	5.3%	5	4.5%
Mild	3	2.7%	4	3.6%
Moderate	3	2.7%	0	0.0%
Severe	0	0.0%	1	0.9%
Night Glare[b]	5	4.4%	2	1.8%
Mild	0	0.0%	1	0.9%
Moderate	5	4.4%	1	0.9%
Severe	0	0.0%	0	0.0%
Starbursts[b]	6	5.3%	1	0.9%
Mild	2	1.8%	1	0.9%
Moderate	4	3.5%	0	0.0%
Severe	0	0.0%	0	0.0%
Photophobia	8	7.1%	6	5.5%
Day glare	2	1.8%	1	0.9%
Night vision difficulty (overall)	2	1.8%	1	0.9%

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

In addition to spontaneous (non-directed) reports of visual symptoms, the validated Patient Reported Visual Symptoms Questionnaire (PRVSQv2) was included in the study as another "additional endpoint." The study was not designed for statistical comparison of this endpoint Therefore, only descriptive statistics are presented here. Subjects were asked about seven specific visual symptoms in the PRVSQv2 that were defined. For example, "occlusions" were defined as "fixed dark or light blocked areas within your vision" and "glare related to scattered light" was defined as "decreases the ability to distinguish differences between objects and their background."

A subject could report multiple symptoms. As shown in Table 23, the most frequently reported questionnaire-directed symptoms at 6 months were sensitivity to light and poor low light vision. In the PureSee™ group, 38 subjects reported experiencing sensitivity to light "sometimes" or more frequently, and 40 subjects reported experiencing poor low light vision "sometimes" or more frequently. In the control group, 37 subjects reported experiencing sensitivity to light "sometimes" or more frequently, and 25 subjects reported experiencing poor low light vision "sometimes" or more frequently. The frequencies of experiencing other symptoms assessed in the PRVSQv2 are below in Table 23.

Table 23
Visual Symptoms at 6 Months
(Directed Questionnaire)

		PureSee™ N=113		Control N=110	
		n	**%**	**n**	**%**
Halos	Not Reported	0	0.0%	0	0.0%
	Never	83	73.5%	75	68.2%
	Rarely	8	7.1%	14	12.7%
	Sometimes	14	12.4%	13	11.8%
	Often	3	2.7%	5	4.5%
	Always	5	4.4%	3	2.7%
Starbursts	Not Reported	0	0.0%	0	0.0%
	Never	80	70.8%	81	73.6%
	Rarely	7	6.2%	11	10.0%
	Sometimes	12	10.6%	8	7.3%
	Often	6	5.3%	7	6.4%
	Always	8	7.1%	3	2.7%
Multiple or Double Vision	Not Reported	0	0.0%	0	0.0%
	Never	97	85.8%	103	93.6%
	Rarely	4	3.5%	1	0.9%
	Sometimes	10	8.8%	3	2.7%
	Often	0	0.0%	2	1.8%
	Always	2	1.8%	1	0.9%
Sensitivity to Light	Not Reported	0	0.0%	0	0.0%
	Never	62	54.9%	61	55.5%
	Rarely	13	11.5%	12	10.9%
	Sometimes	26	23.0%	26	23.6%
	Often	6	5.3%	8	7.3%
	Always	6	5.3%	3	2.7%
Glare Related to Scattered Light	Not Reported	0	0.0%	0	0.0%
	Never	92	81.4%	91	82.7%
	Rarely	8	7.1%	4	3.6%
	Sometimes	8	7.1%	10	9.1%
	Often	3	2.7%	3	2.7%
	Always	2	1.8%	2	1.8%
Occlusions	Not Reported	0	0.0%	0	0.0%
	Never	110	97.3%	109	99.1%
	Rarely	1	0.9%	0	0.0%

	Sometimes	0	0.0%	0	0.0%
	Often	0	0.0%	1	0.9%
	Always	2	1.8%	0	0.0%
Poor Low Light Vision	Not Reported	0	0.0%	0	0.0%
	Never	62	54.9%	72	65.5%
	Rarely	11	9.7%	13	11.8%
	Sometimes	29	25.7%	17	15.5%
	Often	7	6.2%	5	4.5%
	Always	4	3.5%	3	2.7%

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

If subjects reported experiencing a particular symptom, they were then asked to rate how bothered they were by the symptom (**Table 24**) and if there was anything they had a lot of difficulty with, or did not do, because of the symptom (**Table 25**). Among subjects reporting sensitivity to light or poor low light vision in the PureSee™ group, 7 reported very or extremely bothered for sensitivity to light and 5 reported very or extremely bothered for poor low light vision. In the control group, 7 reported very or extremely bothered for sensitivity to light and 3 reported very or extremely bothered for poor low light vision. Among subjects reporting halos, glare, or starbursts in the PureSee™ group, 3 reported very or extremely bothered for each symptom at 6 months. In the control group, 3 reported very or extremely bothered for halos and starbursts, and 6 reported very or extremely bothered for glare at 6 months. Among subjects reporting a particular symptom, the number of subjects reporting there was anything they had a lot of difficulty with or did not do because of that symptom at 6 months ranged from 0 to 7 subjects in the PureSee™ group and 1 to 8 subjects in the control group.

Table 24
Experience/Bother With Visual Symptoms at 6 Months
(Directed Questionnaire)

		TECNIS PureSee™ N=113		Control N=110	
		n	**%**	**n**	**%**
Halos	Did not experience or NR	83	73.5%	75	68.2%
	Not at all bothered	10	8.8%	14	12.7%
	Slightly bothered	10	8.8%	13	11.8%
	Moderately bothered	7	6.2%	5	4.5%
	Very bothered	3	2.7%	3	2.7%
	Extremely bothered	0	0.0%	0	0.0%
Starbursts	Did not experience or NR	80	70.8%	81	73.6%
	Not at all bothered	8	7.1%	9	8.2%
	Slightly bothered	11	9.7%	12	10.9%
	Moderately bothered	11	9.7%	5	4.5%
	Very bothered	2	1.8%	3	2.7%

	Extremely bothered	1	0.9%	0	0.0%
Multiple or Double Vision	Did not experience or NR	97	85.8%	103	93.6%
	Not at all bothered	2	1.8%	0	0.0%
	Slightly bothered	7	6.2%	3	2.7%
	Moderately bothered	4	3.5%	2	1.8%
	Very bothered	3	2.7%	1	0.9%
	Extremely bothered	0	0.0%	1	0.9%
Sensitivity to Light	Did not experience or NR	62	54.9%	61	55.5%
	Not at all bothered	5	4.4%	3	2.7%
	Slightly bothered	28	24.8%	19	17.3%
	Moderately bothered	11	9.7%	20	18.2%
	Very bothered	6	5.3%	4	3.6%
	Extremely bothered	1	0.9%	3	2.7%
Glare Related to Scattered Light	Did not experience or NR	92	81.4%	91	82.7%
	Not at all bothered	2	1.8%	2	1.8%
	Slightly bothered	12	10.6%	10	9.1%
	Moderately bothered	4	3.5%	1	0.9%
	Very bothered	3	2.7%	6	5.5%
	Extremely bothered	0	0.0%	0	0.0%
Occlusions	Did not experience or NR	110	97.3%	109	99.1%
	Not at all bothered	1	0.9%	1	0.0%
	Slightly bothered	1	0.9%	0	0.0%
	Moderately bothered	1	0.9%	0	0.0%
	Very bothered	0	0.0%	1	0.9%
	Extremely bothered	0	0.0%	0	0.0%
Poor Low Light Vision	Did not experience or NR	62	54.9%	72	65.5%
	Not at all bothered	7	6.2%	8	7.3%
	Slightly bothered	31	27.4%	16	14.5%
	Moderately bothered	8	7.1%	11	10.0%
	Very bothered	4	3.5%	3	2.7%
	Extremely bothered	1	0.9%	0	0.0%

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

Table 25
Difficulty With Activity Due to Visual Symptoms at 6 Months

(Directed Questionnaire)		TECNIS PureSee™ N=113		Control N=110	
		n	%	n	%
Halos	Did not experience or NR	83	73.5%	75	68.2%
	No	26	23.0%	34	30.9%
	Yes	4	3.5%	1	0.9%
Starbursts	Did not experience or NR	80	70.8%	81	73.6%
	No	28	24.8%	27	24.5%
	Yes	5	4.4%	2	1.8%
Multiple or Double Vision	Did not experience or NR	97	85.8%	103	93.6%
	No	12	10.6%	5	4.5%
	Yes	4	3.5%	2	1.8%
Sensitivity to Light	Did not experience or NR	62	54.9%	61	55.5%
	No	46	40.7%	42	38.2%
	Yes	5	4.4%	7	6.4%
Glare Related to Scattered Light	Did not experience or NR	92	81.4%	91	82.7%
	No	16	14.2%	15	13.6%
	Yes	5	4.4%	4	3.6%
Occlusions	Did not experience or NR	110	97.3%	109	99.1%
	No	3	2.7%	0	0.0%
	Yes	0	0.0%	1	0.9%
Poor Low Light Vision	Did not experience or NR	62	54.9%	72	65.5%
	No	44	38.9%	30	27.3%
	Yes	7	6.2%	8	7.3%

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

Lens Findings

Lens findings was another pre-identified "additional endpoint" for supportive clinical information. The study was not designed for statistical comparison of this endpoint. Therefore, only descriptive statistics are presented here. There were no reports of any lens findings (e.g. lens instability, glistenings) at 6 months for TECNIS PureSee™ or control IOLs.

Fundus Visualization

The investigator's assessment of his/her ability to clinically visualize the fundus at 6 months (seventh co-primary safety endpoint), was adequate for all first eyes (100.0%) and all-eyes (100.0%) in the study.

2. Effectiveness Results

The analysis of effectiveness was based on the 223 evaluable subjects at the 6-month time point. The Intent-To-Treat (ITT) population was the primary analysis set for all primary effectiveness endpoints. In addition, the Per-Protocol (PP) population first eyes was a primary analysis set for the BCDVA primary effectiveness endpoint. All other effectiveness results are shown for the Safety Population (SP) with observed case (i.e., available data with no imputation) unless specified otherwise. First eyes were primary eyes and presented in the monocular data tables, unless specified otherwise. All success criteria for all primary effectiveness endpoints were met for the TECNIS PureSee™ lens. Key effectiveness outcomes are presented in **Tables 26 to 50** and **Figures 8 to 11**.

IOL Power Selection and Postoperative Refractive Outcomes

Surgeons were instructed to select the IOL power to achieve emmetropia in both eyes (closest to plano spherical equivalent). Both the TECNIS PureSee™ and control first eyes had mean manifest refraction spherical equivalent outcomes at 6 months within emmetropia (±0.25 D); although, the TECNIS PureSee™ group was slightly hyperopic (0.04 D), and the control group was slightly myopic (-0.06 D). There were no clinically meaningful differences in refractive outcomes between lens groups for first and second eyes. Mean refractive cylinder did not exceed 0.50 D for first eyes in either lens group.

Distance Photopic Visual Acuity

At 6 months, using the ITT population (first eyes) and the PP population, the difference in mean monocular (first eye) best-corrected distance visual acuity (BCDVA) between lens groups was −0.04 LogMAR in both populations. The lower limit of the 2-sided 90% CI of the mean difference was −0.06 in both populations, which was greater than the −0.10 LogMAR non-inferiority margin; indicating TECNIS PureSee™ is non-inferior to the Control. Thus, the statistical success criterion of the third co-primary effectiveness endpoint for BCDVA was achieved **Table 26**.

Table 26
Monocular Best-Corrected Distance Visual Acuity (LogMAR) at 6 Months
Intend-To-Treat (ITT) and Per-Protocol (PP) Population

Population	Lens Group	N	Mean Monocular LogMAR	Monocular Snellen Equiv.	90% CI
ITT [a]	TECNIS PureSee™	116	-0.04	20/18	(-0.05, -0.03)
	Control	112	-0.08	20/17	(-0.10, -0.07)
	Difference		-0.04	-0.4 lines [b]	(-0.06, -0.02)
PP	TECNIS PureSee™	111	-0.04	20/18	(-0.06, -0.03)
	Control	107	-0.08	20/16	(-0.10, -0.07)
	Difference		-0.04	-0.4 lines [b]	(-0.06, -0.02)

[a] Intent-To-Treat population was used with multiple imputation approach to handle missing data.
[b] Line difference (Control minus TECNIS PureSee™) was converted directly from LogMAR difference.
Non-inferiority margin of -0.10 LogMAR.

Table 27 presents photopic distance visual acuity results for TECNIS PureSee™ and control groups in the SP at 6 months.

Table 27
Mean Distance Visual Acuity at 6 Months
Safety Population

		Monocular				Binocular			
Distance Visual Acuity	Lens Group	N	Mean LogMAR	Snellen Equiv.	Line Change vs. Control[a]	N	Mean LogMAR	Snellen Equiv.	Line Change vs. Control[a]
Best-Corrected[b]	TECNIS PureSee™	113	-0.04	20/18	**-0.4 lines**	113	-0.07	20/17	**-0.5 lines**
	Control	110	-0.08	20/16		110	-0.12	20/15	
Uncorrected	TECNIS PureSee™	113	0.05	20/22	**-0.5 lines**	113	-0.01	20/19	**-0.5 lines**
	Control	110	0.00	20/20		110	-0.06	20/17	

[a] Line difference (Control minus TECNIS PureSee™) was converted directly from LogMAR difference.
[b] Best-corrected distance visual acuity was a primary safety endpoint.

The distributions of monocular uncorrected and best-corrected distance visual acuities for TECNIS PureSee™ and control first eyes at 6 months are presented in **Table 28** and **Table 29**. The distributions of binocular distance visual acuity for TECNIS PureSee™ and control at 6 months are presented in **Table 30** and **Table 31**. Overall, distance visual acuity results demonstrated that the TECNIS PureSee™ lens provides distance visual acuity comparable to the monofocal control lens.

Table 28
Monocular Distance (Far) Visual Acuity (Snellen) at 6 Months

Monocular Snellen Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Best-Corrected N=113		Uncorrected N=110		Best-Corrected N=110	
	n	%	n	%	n	%	n	%
$20/20^{-2}$ or better	66	58.4%	100	88.5%	78	70.9%	102	92.7%
$20/25^{-2}$ or better	93	82.3%	110	97.4%	98	89.1%	107	97.3%
$20/32^{-2}$ or better	104	92.0%	113	100.0%	106	96.4%	109	99.1%
$20/40^{-2}$ or better	111	98.2%	113	100.0%	109	99.1%	110	100.0%
Worse than $20/40^{-2}$	2	1.8%	0	0.0%	1	0.9%	0	0.0%

%=(n/N) * 100

Table 29
Monocular Distance (Far) Visual Acuity (LogMAR) at 6 Months

Monocular LogMAR Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Best-Corrected N=113		Uncorrected N=110		Best-Corrected N=110	
	n	%	n	%	n	%	n	%
0.00 or better	50	44.3%	91	80.5%	66	60.0%	97	88.2%
0.10 or better	82	72.6%	110	97.4%	96	87.3%	105	95.5%
0.20 or better	102	90.3%	112	99.1%	103	93.6%	108	98.2%
0.30 or better	109	96.5%	113	100.0%	109	99.1%	110	100.0%
Worse than 0.30	4	3.5%	0	0.0%	1	0.9%	0	0.0%

%=(n/N) * 100

Table 30
Binocular Distance (Far) Visual Acuity (Snellen) at 6 Months

Binocular Snellen Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Best-Corrected N=113		Uncorrected N=110		Best-Corrected N=110	
	n	%	n	%	n	%	n	%
$20/20^{-2}$ or better	88	77.9%	106	93.8%	98	89.1%	107	97.3%
$20/25^{-2}$ or better	103	91.2%	111	98.2%	105	95.5%	109	99.1%
$20/32^{-2}$ or better	113	100.0%	112	99.1%	110	100.0%	110	100.0%
$20/40^{-2}$ or better	113	100.0%	113	100.0%	110	100.0%	110	100.0%
Worse than $20/40^{-2}$	0	0.0%	0	0.0%	0	0.0%	0	0.0%

%=(n/N) * 100

Table 31
Binocular Distance (Far) Visual Acuity (LogMAR) at 6 Months

Binocular LogMAR Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Best-Corrected N=113		Uncorrected N=110		Best-Corrected N=110	
	n	%	n	%	n	%	n	%
0.00 or better	77	68.1%	104	92.0%	92	83.6%	107	97.3%
0.10 or better	99	87.6%	110	97.4%	101	91.8%	108	98.2%
0.20 or better	110	97.4%	112	99.1%	109	99.1%	110	100.0%
0.30 or better	113	100.0%	113	100.0%	110	100.0%	110	100.0%
Worse than 0.30	0	0.0%	0	0.0%	0	0.0%	0	0.0%

%=(n/N) * 100

Photopic Visual Acuity at 100 cm

Monocular distance-corrected visual acuity was tested at 100 cm under photopic (85 cd/m^2) lighting conditions (**Table 32**). Mean monocular (DCVA) tested at 100 cm at 6 months was the fourth co-primary effectiveness endpoints. TECNIS PureSee™ achieved a mean pf 0.10 LogMAR for first eyes in the ITT population, meeting the success criteria of being ≤0.20 LogMAR.

Table 32
Mean Monocular Distance-Corrected Visual Acuity[a]
at 100 cm at 6 Months
Intend-To-Treat (ITT) Population

Distance Visual Acuity	Lens Group	N	Mean LogMAR	Snellen Equiv.	Line Difference vs. Control[b]
Distance-Corrected	TECNIS PureSee™	116	0.10	20/25	**0.6 lines**
	Control	112	0.16	20/29	

[a] Monocular distance-corrected visual acuity at 100cm was a primary effectiveness endpoint. Results were obtained from the Intent-to-Treat population with multiple imputation approach to handle missing data.
[b] Line difference (Control minus TECNIS PureSee™) was converted directly from LogMAR difference.

The distributions of monocular distance-corrected visual acuity tested at 100 cm for TECNIS PureSee™ and control first eyes at 6 months are presented in **Table 33** and **Table 34**. Results favored TECNIS PureSee™, with 88.5% of TECNIS PureSee™ subjects achieving monocular distance-corrected visual acuity at 100 cm of 0.20 LogMAR (20/32 Snellen) or better compared to 66.4% of control subjects (**Table 34**).

Overall, the visual acuity results demonstrated that the TECNIS PureSee™ IOL provides improved vision compared to the monofocal control lens at 100 cm.

Table 33
Monocular Distance-Corrected Visual Acuity (Snellen) at 100 cm at 6 Months

Monocular Snellen Visual Acuity	TECNIS PureSee™ Distance-Corrected N=113		Control Distance-Corrected N=110	
	n	%	n	%
20/20^{-2} or better	35	31.0%	21	19.1%
20/25^{-2} or better	84	74.3%	54	49.1%
20/32^{-2} or better	105	92.9%	80	72.7%
20/40^{-2} or better	110	97.4%	100	90.9%
20/50 to 20/80	2	1.8%	10	9.1%
20/100 or worse	1	0.9%	0	0.0%

%=(n/N) * 100

Table 34
Monocular Distance-Corrected Visual Acuity (LogMAR) at 100 cm at 6 Months

Monocular LogMAR Visual Acuity	TECNIS PureSee™ Distance-Corrected N=113		Control Distance-Corrected N=110	
	n	%	n	%
0.00 or better	20	17.7%	13	11.8%
0.10 or better	68	60.2%	40	36.4%
0.20 or better	100	88.5%	73	66.4%
0.30 or better	108	95.6%	93	84.6%
0.31 to 0.60	4	3.5%	17	15.5%
0.61 or worse	1	0.9%	0	0.0%

%=(n/N) * 100

Intermediate Photopic Visual Acuity

Intermediate visual acuities were tested at 66 cm under photopic (85 cd/m^2) lighting conditions. Mean intermediate visual acuities at 6 months for both the TECNIS PureSee™ and control IOL groups are presented in **Table 35**. Mean monocular first-eye distance-corrected intermediate visual acuity (DCIVA) was the first co-primary effectiveness endpoint. There was a statistically significant improvement ($p<0.0001$) in mean monocular distance-corrected intermediate visual acuity (DCIVA) at 6 months in favor of the TECNIS PureSee™ lens in the ITT population, with an improvement of 1.5 lines (0.15 LogMAR), meeting the statistical success criterion. The mean and median monocular distance-corrected intermediate visual acuity at 6 months was 0.15 and 0.14 LogMAR, respectively, which met the clinical success criteria of ≤0.20 LogMAR.

Table 35
Mean Intermediate Visual Acuity at 66 cm at 6 Months

		Monocular				Binocular[c]			
Intermediate Visual Acuity	**Lens Group**	**N**	**Mean LogMAR**	**Snellen Equiv.**	**Line Change vs. Control[b]**	**N**	**Mean LogMAR**	**Snellen Equiv.**	**Line Change vs. Control[b]**
Distance Corrected[a]	TECNIS PureSee™	116	0.15	20/28	**1.5 lines**	113	0.10	20/25	**1.0 lines**
	Control	112	0.31	20/40		110	0.19	20/30	
Uncorrected[c]	TECNIS PureSee™	113	0.17	20/29	**0.8 lines**	113	0.09	20/24	**0.4 lines**
	Control	110	0.25	20/35		110	0.13	20/26	

[a] Monocular distance corrected visual acuity was a primary effectiveness endpoint. Results were obtained from the Intent-to-Treat population with multiple imputation approach to handle missing data.
[b] Line difference (Control minus PureSee™) was converted directly from LogMAR difference.
[c] Uncorrected and binocular visual acuities were other endpoints and Safety Population with observed case was used for the analysis.

The distributions of monocular uncorrected and distance-corrected intermediate visual acuities for TECNIS PureSee™ and control first eyes at 6 months are presented in **Table 36** and **Table 37**. Results favored TECNIS PureSee™, showing a difference of 52.3% between groups, with 82.3% (93/113) of TECNIS PureSee™ subjects achieving monocular DCIVA of 0.20 LogMAR (20/32 Snellen) or better compared to 30.0% (33/110) of control subjects (**Table 37**). The distributions of binocular uncorrected and distance-corrected intermediate visual acuity for TECNIS PureSee™ and control at 6 months are presented in **Table 38** and **Table 39**. The intermediate visual acuity results demonstrated the TECNIS PureSee™ lens to provides overall improved intermediate vision compared to the monofocal control lens.

Table 36
Monocular Intermediate Visual Acuity (Snellen) at 66 cm at 6 Months

Monocular Snellen Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Distance-Corrected N=113		Uncorrected N=110		Distance-Corrected N=110	
	n	%	n	%	n	%	n	%
$20/20^{-2}$ or better	13	11.5%	12	10.6%	8	7.3%	3	2.7%
$20/25^{-2}$ or better	58	51.3%	69	61.1%	27	24.6%	16	14.6%
$20/32^{-2}$ or better	90	79.7%	103	91.2%	55	50.0%	46	41.8%
$20/40^{-2}$ or better	109	96.5%	110	97.4%	82	74.6%	67	60.9%
$20/50^{-2}$ to $20/80^{-2}$	3	2.7%	2	1.8%	27	24.5%	41	37.3%
$20/100^{-2}$ or worse	1	0.9%	1	0.9%	1	0.9%	2	1.8%

%=(n/N) * 100

Table 37
Monocular Intermediate Visual Acuity (LogMAR) at 66 cm at 6 Months

Monocular LogMAR Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Distance-Corrected N=113		Uncorrected N=110		Distance-Corrected N=110	
	n	%	n	%	n	%	n	%
0.00 or better	5	4.4%	6	5.3%	3	2.7%	1	0.9%
0.10 or better	29	25.7%	36	31.9%	23	20.9%	9	8.2%
0.20 or better	78	69.0%	93	82.3%	47	42.7%	33	30.0%
0.30 or better	104	92.0%	109	96.5%	71	64.6%	56	50.9%
0.31 to 0.60	8	7.1%	2	1.8%	38	34.5%	48	43.6%
0.61 or worse	1	0.9%	2	1.8%	1	0.9%	6	5.5%

%=(n/N) * 100

Table 38
Binocular Intermediate Visual Acuity (Snellen) at 66 cm at 6 Months

Binocular Snellen Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Distance-Corrected N=113		Uncorrected N=110		Distance-Corrected N=110	
	n	%	n	%	n	%	n	%
20/20^{-2} or better	38	33.6%	35	31.0%	33	30.0%	12	10.9%
20/25^{-2} or better	89	78.8%	92	81.4%	65	59.1%	42	38.2%
20/32^{-2} or better	109	96.5%	110	97.4%	90	81.8%	80	72.7%
20/40^{-2} or better	112	99.1%	111	98.2%	106	96.4%	99	90.0%
20/50^{-2} to 20/80^{-2}	0	0.0%	1	0.9%	4	3.6%	11	10.0%
20/100^{-2} or worse	1	0.9%	1	0.9%	0	0.0%	0	0.0%

%=(n/N) * 100

Table 39
Binocular Intermediate Visual Acuity (LogMAR) at 66 cm at 6 Months

Binocular LogMAR Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Distance-Corrected N=113		Uncorrected N=110		Distance-Corrected N=110	
	n	%	n	%	n	%	n	%
0.00 or better	21	18.6%	12	10.6%	20	18.2%	5	4.6%
0.10 or better	67	59.3%	68	60.2%	51	46.4%	29	26.4%
0.20 or better	106	93.8%	106	93.8%	83	75.5%	66	60.0%
0.30 or better	111	98.2%	111	98.2%	101	91.8%	92	83.6%
0.31 to 0.60	1	0.9%	1	0.9%	9	8.2%	18	16.4%
0.61 or worse	1	0.9%	1	0.9%	0	0.0%	0	0.0%

%=(n/N) * 100

Near Photopic Visual Acuity

The study pre-identified some "additional endpoints" as supportive clinical information, including near photopic visual acuity. The study was not designed for statistical comparison of this endpoint. Therefore, only descriptive statistics are presented here. As one of the "additional endpoints", near vision data were collected at 40 cm under photopic (85 cd/m2) lighting conditions. At 6 months, the mean monocular distance-corrected near visual acuity was 0.34 LogMAR for the TECNIS PureSee™ lens and 0.49 LogMAR for the control lens, with an observed mean difference of 1.5 lines between groups (**Table 40**).

Table 40
Mean Near Visual Acuity at 40 cm at 6 Months

Near Visual Acuity	Lens Group	Monocular N	Monocular Mean LogMAR	Monocular Snellen Equiv.	Monocular Line Change vs. Control[a]	Binocular N	Binocular Mean LogMAR	Binocular Snellen Equiv.	Binocular Line Change vs. Control[a]
Distance-Corrected	TECNIS PureSee™	113	0.34	20/43	**1.5 lines**	113	0.28	20/38	**1.1 lines**
	Control	110	0.49	20/61		110	0.39	20/49	
Uncorrected	TECNIS PureSee™	113	0.35	20/44	**1.2 lines**	113	0.25	20/35	**0.9 lines**
	Control	110	0.47	20/59		110	0.33	20/42	

[a] Line difference (Control minus TECNIS PureSee™) was converted directly from LogMAR difference.

The distributions of monocular uncorrected and distance-corrected near visual acuities for TECNIS PureSee™ and control first eyes at 6 months are presented in **Table 41** and **Table 42**. The distributions of binocular near visual acuity for TECNIS PureSee™ and control at 6 months are presented in **Table 43** and **Table 44**.

Table 41
Monocular Near Visual Acuity (Snellen) at 40 cm at 6 Months

Monocular Snellen Visual Acuity	TECNIS PureSee™ Uncorrected N=113 n	TECNIS PureSee™ Uncorrected N=113 %	TECNIS PureSee™ Distance-Corrected N=113 n	TECNIS PureSee™ Distance-Corrected N=113 %	Control Uncorrected N=110 n	Control Uncorrected N=110 %	Control Distance-Corrected N=110 n	Control Distance-Corrected N=110 %
20/20^{-2} or better	0	0.0%	0	0.0%	1	0.9%	0	0.0%
20/25^{-2} or better	2	1.8%	4	3.5%	1	0.9%	0	0.0%
20/32^{-2} or better	28	24.8%	21	18.6%	6	5.5%	7	6.4%
20/40^{-2} or better	63	55.8%	56	49.6%	29	26.4%	23	20.9%
20/50^{-2} to 20/80^{-2}	47	41.6%	55	48.7%	70	63.6%	70	63.6%
20/100^{-2} or worse	3	2.7%	2	1.8%	11	10.0%	17	15.5%

%=(n/N) * 100

Table 42
Monocular Near Visual Acuity (LogMAR) at 40 cm at 6 Months

Monocular LogMAR Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Distance-Corrected N=113		Uncorrected N=110		Distance-Corrected N=110	
	n	%	n	%	n	%	n	%
0.00 or better	0	0.0%	0	0.0%	1	0.9%	0	0.0%
0.10 or better	0	0.0%	1	0.9%	1	0.9%	0	0.0%
0.20 or better	17	15.0%	13	11.5%	4	3.6%	2	1.8%
0.30 or better	41	36.3%	39	34.5%	19	17.3%	15	13.6%
0.31 to 0.60	68	60.2%	72	63.7%	70	63.6%	69	62.7%
0.61 or worse	4	3.5%	2	1.8%	21	19.1%	26	23.6%

%=(n/N) * 100

Table 43
Binocular Near Visual Acuity (Snellen) at 40 cm at 6 Months

Binocular Snellen Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Distance-Corrected N=113		Uncorrected N=110		Distance-Corrected N=110	
	n	%	n	%	n	%	n	%
$20/20^{-2}$ or better	1	0.9%	0	0.0%	0	0.0%	0	0.0%
$20/25^{-2}$ or better	28	24.8%	19	16.8%	7	6.4%	3	2.7%
$20/32^{-2}$ or better	62	54.9%	45	39.8%	42	38.2%	21	19.1%
$20/40^{-2}$ or better	93	82.3%	91	80.5%	63	57.3%	46	41.8%
$20/50^{-2}$ to $20/80^{-2}$	19	16.8%	21	18.6%	45	40.9%	60	54.5%
$20/100^{-2}$ or worse	1	0.9%	1	0.9%	2	1.8%	4	3.6%

%=(n/N) * 100

Table 44
Binocular Near Visual Acuity (LogMAR) at 40 cm at 6 Months

Binocular LogMAR Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Distance-Corrected N=113		Uncorrected N=110		Distance-Corrected N=110	
	n	%	n	%	n	%	n	%
0.00 or better	0	0.0%	0	0.0%	0	0.0%	0	0.0%
0.10 or better	11	9.7%	4	3.5%	3	2.7%	1	0.9%
0.20 or better	50	44.3%	33	29.2%	23	20.9%	11	10.0%
0.30 or better	81	71.7%	72	63.7%	55	50.0%	36	32.7%
0.31 to 0.60	31	27.4%	40	35.4%	50	45.5%	66	60.0%
0.61 or worse	1	0.9%	1	0.9%	5	4.5%	8	7.3%

%=(n/N) * 100

Mesopic Visual Acuity

Mesopic visual acuity was another pre-identified additional endpoint for supportive clinical information. The study was not designed for statistical comparison of this endpoint. Therefore, only descriptive statistics are presented here. Best-corrected distance (far) and distance-corrected intermediate (66 cm) visual acuities were also tested under mesopic (3 cd/m^2) lighting conditions. Mean mesopic visual acuities at 6 months for both TECNIS PureSee™ and control groups are presented in **Table 45**. The difference in mean monocular mesopic BCDVA between lens groups was -0.05 LogMAR. The mean monocular mesopic DCIVA for the TECNIS PureSee™ lens was 0.32 LogMAR, showing a difference of 1.5 lines between the two groups. Differences in mesopic BCDVA and DCIVA between TECNIS PureSee™ and control are consistent in both lighting conditions tested (mesopic and photopic conditions). The distributions of mesopic BCDVA for both lens groups at 6 months are presented in **Table 46** and **Table 47**. The distributions of mesopic DCIVA for both lens groups at 6 months are presented in **Table 48** and **Table 49**.

Table 45
Mean Mesopic Distance (Far) and Intermediate (66 cm) Visual Acuity at 6 Months

Visual Acuity	Lens Group	Monocular				Binocular			
		N	Mean LogMAR	Snellen Equiv.	Line Change vs. Control[a]	N	Mean LogMAR	Snellen Equiv.	Line Change vs. Control[a]
Best- Corrected Distance	TECNIS PureSee™	113	0.11	20/25	**-0.5 lines**	113	0.07	20/23	**-0.7 lines**
	Control	110	0.06	20/22		110	0.00	20/20	
Distance-Corrected Intermediate	TECNIS PureSee™	113	0.32	20/41	**1.5 lines**	113	0.24	20/34	**1.5 lines**
	Control	110	0.47	20/59		110	0.39	20/39	

[a] Line difference (Control minus TECNIS PureSee™) was converted directly from LogMAR difference.

Table 46
Mesopic Best Corrected Distance Visual Acuity (Snellen) at 6 Months

Best-Corrected Distance Snellen Visual Acuity	TECNIS PureSee™				Control			
	Monocular N=113		Binocular N=113		Monocular N=110		Binocular N=110	
	n	%	n	%	n	%	n	%
20/20^{-2} or better	29	25.7%	51	45.1%	59	53.6%	88	80.0%
20/25^{-2} or better	82	72.6%	104	92.0%	93	84.6%	108	98.2%
20/32^{-2} or better	107	94.7%	111	98.2%	106	96.4%	109	99.1%
20/40^{-2} or better	111	98.2%	111	98.2%	107	97.3%	109	99.1%
Worse than 20/40^{-2}	2	1.8%	2	1.8%	3	2.7%	1	0.9%

%=(n/N) * 100

Table 47
Mesopic Best Corrected Distance Visual Acuity (LogMAR) at 6 Months

Best-Corrected Distance LogMAR Visual Acuity	TECNIS PureSee™				Control			
	Monocular N=113		Binocular N=113		Monocular N=110		Binocular N=110	
	n	%	n	%	n	%	n	%
0.00 or better	13	11.5%	27	23.9%	35	31.8%	63	57.3%
0.10 or better	60	53.1%	82	72.6%	84	76.4%	99	90.0%
0.20 or better	99	87.6%	109	96.5%	104	94.6%	109	99.1%
0.30 or better	110	97.4%	111	98.2%	107	97.3%	109	99.1%
Worse than 0.30	3	2.7%	2	1.8%	3	2.7%	1	0.9%

%=(n/N) * 100

Table 48
Mesopic Distance-Corrected Intermediate Visual Acuity (Snellen) at 66 cm at 6 Months

Distance-Corrected Intermediate Snellen Visual Acuity	TECNIS PureSee™				Control			
	Monocular N=113		Binocular N=113		Monocular N=110		Binocular N=110	
	n	%	n	%	n	%	n	%
20/20^{-2} or better	0	0.0%	1	0.9%	0	0.0%	0	0.0%
20/25^{-2} or better	2	1.8%	13	11.5%	0	0.0%	3	2.7%
20/32^{-2} or better	33	29.2%	71	62.8%	4	3.6%	11	10.0%
20/40^{-2} or better	78	69.0%	104	92.0%	23	20.9%	46	41.8%
20/50^{-2} to 20/80^{-2}	33	29.2%	8	7.1%	77	70.0%	62	56.4%
20/100^{-2} or worse	2	1.8%	1	0.9%	10	9.1%	2	1.8%

%=(n/N) * 100

Table 49
Mesopic Distance-Corrected Intermediate Visual Acuity (LogMAR) at 66cm at 6 Months

Distance-Corrected Intermediate LogMAR Visual Acuity	TECNIS PureSee™				Control			
	Monocular N=113		Binocular N=113		Monocular N=110		Binocular N=110	
	n	%	n	%	n	%	n	%
0.00 or better	0	0.0%	1	0.9%	0	0.0%	0	0.0%
0.10 or better	2	1.8%	4	3.5%	0	0.0%	1	0.9%
0.20 or better	22	19.5%	47	41.6%	2	1.8%	6	5.5%
0.30 or better	60	53.1%	93	82.3%	11	10.0%	24	21.8%
0.31 to 0.60	50	44.2%	19	16.8%	84	76.4%	82	74.5%
0.61 or worse	3	2.7%	1	0.9%	15	13.6%	4	3.6%

%=(n/N) * 100

Depth of Focus

Mean monocular (first eye) distance-corrected depth of focus was the second co-primary effectiveness endpoint; measurements were plotted using the ITT population with the multiple imputation approach to handle missing data (**Figure 8**). The curves demonstrated that the TECNIS PureSee™ group maintained 0.20 LogMAR or better visual acuity from 0.0 D to -1.77 D and the control group from 0.0 D to -1.13 D. The depth of focus at the 0.20 LogMAR threshold (horizontal line) for the TECNIS PureSee™ group was 0.64 D greater than that for the control, meeting the clinical success criterion of a between-lens difference of at least a 0.50 D.

Binocular depth of focus (with 0.20 LogMAR or better) was maintained through -2.15 D for the TECNIS PureSee™ group and through -1.54 D for the control group, yielding a similar difference (0.61 D), in favor of the TECNIS PureSee™ group (**Figure 9**).

Figure 8
Monocular Distance-Corrected Depth of Focus Curve at 6 Months
Intent-to-Treat Population with Multiple Imputation

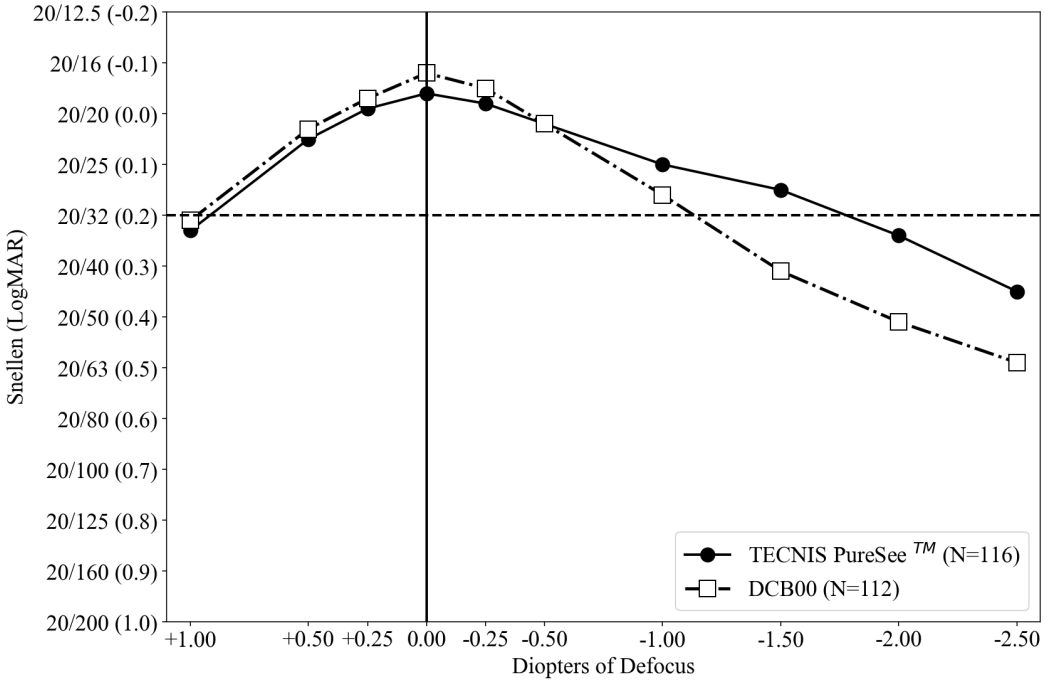
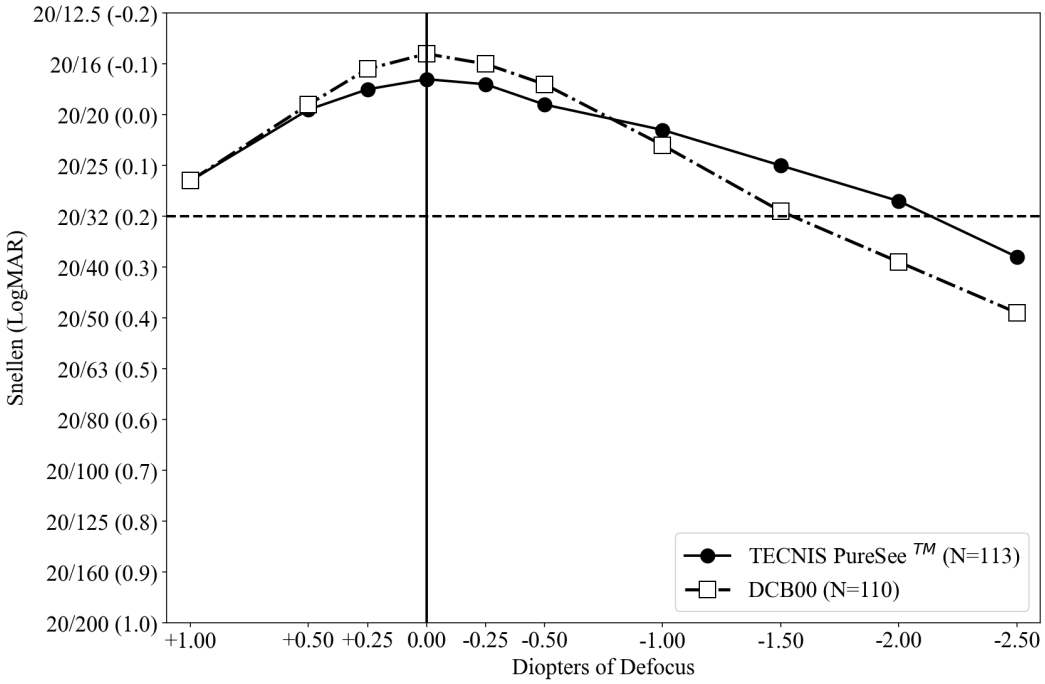
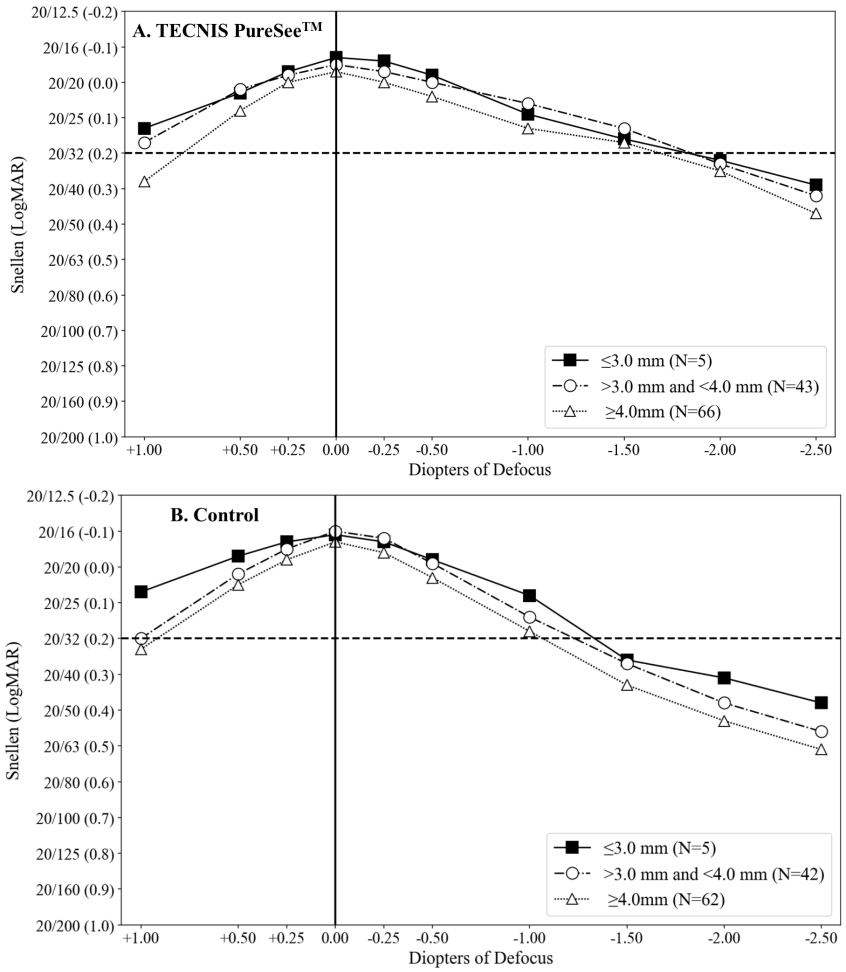


Figure 9
Binocular Distance-Corrected Depth of Focus Curve at 6 Months
Safety Population



Greater depth of focus was observed for the TECNIS PureSee™ group than the control group across all pupil size categories of "small" (≤3.0 mm), "medium" (>3.0 mm to <4.0 mm) or "large" (≥4.0 mm), where pupil size was measured under photopic conditions (**Figure 10**). The curves indicate no noticeable effect of pupil size on TECNIS PureSee™ performance.

Figure 10
Monocular Distance-Corrected Depth of Focus Curve by Pupil Size at 6 Months
Intent-to-Treat Population with Observed Case



Spectacle Wear

Spectacle wear was another pre-identified additional endpoint for supportive clinical information. The study was not designed for statistical comparison of this endpoint. Therefore, only descriptive statistics are presented here. Spectacle wear and other related items were assessed by responses to a subject questionnaire, the Patient-Reported Spectacle Independence Questionnaire-v2 (PRSIQv2), which was developed and evaluated following the US FDA guidance document "Patient-Reported Outcomes Measures: Use in Medical Product Development to Support Labeling Claims" dated December 2009. In the questionnaire, subjects were asked how often they wore glasses (or other visual correction) during the last 7 days for four categories: distance, intermediate, near and overall vision. Table 50 presents the frequency of spectacle wear under each of these

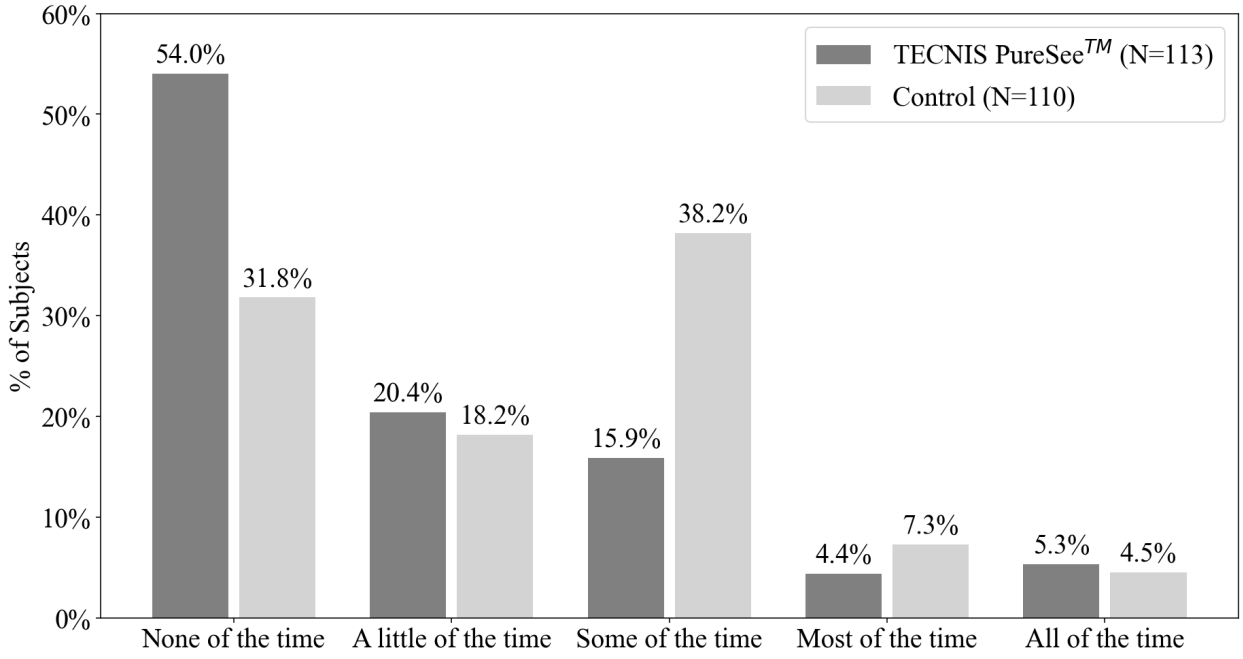
conditions. Figure 11 presents the frequency of overall spectacle wear at 6 months for bilaterally implanted subjects. Reports of wearing glasses "None/ A little of the time" for overall spectacle wear was 74.4% (84/113) of subjects in the TECNIS PureSee™ group and 50% (55/110) of subjects in the control group.

Table 50
Frequency of Spectacle Wear for Distance, Intermediate, Near and Overall Vision

Condition	Frequency	TECNIS PureSee™ N=113		Control N=110	
		n	%	n	%
Distance Vision	None of the time	106	93.8%	96	87.3%
	A little of the time	0	0.0%	2	1.8%
	Some of the time	1	0.9%	6	5.5%
	Most of the time	2	1.8%	4	3.6%
	All of the time	4	3.5%	2	1.8%
Intermediate Vision	None of the time	88	77.9%	69	62.7%
	A little of the time	3	2.7%	5	4.5%
	Some of the time	9	8.0%	11	10.0%
	Most of the time	4	3.5%	13	11.8%
	All of the time	9	8.0%	12	10.9%
Near Vision	None of the time	30	26.5%	9	8.2%
	A little of the time	19	16.8%	10	9.1%
	Some of the time	18	15.9%	19	17.3%
	Most of the time	25	22.1%	24	21.8%
	All of the time	21	18.6%	48	43.6%
Overall Vision	None of the time	61	54.0%	35	31.8%
	A little of the time	23	20.4%	20	18.2%
	Some of the time	18	15.9%	42	38.2%
	Most of the time	5	4.4%	8	7.3%
	All of the time	6	5.3%	5	4.5%

%=(n/N) * 100

Figure 11
Overall Spectacle Wear at 6 Months



3. Subgroup Analyses

The following baseline characteristics were evaluated for potential association with effectiveness outcomes; age group (< 65 years, ≥ 65 years), sex, race (white, non-white) and cataract severity (trace/mild, moderate/severe). The primary effectiveness endpoints DCIVA at 66 cm, BCDVA at 4 m, DCVA at 100 cm and defocus curve were stratified by the baseline characteristics described above. In addition, a model-based analysis was conducted to assess the potential impact of these baseline and demographic characteristics on the TECNIS PureSee™ performance as measured by DCIVA, and BCDVA. No covariates were found to have a significant impact on outcomes and the TECNIS PureSee™ lens performed consistently across subgroups. The study was not specifically powered for these subgroups.

4. Pediatric Extrapolation

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

XI. FINANCIAL DISCLOSURE

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 18 investigators of which none were full-

time or part-time employees of the sponsor and 4 had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: 0 investigators
- Significant payments of other sorts: 2 investigators
- Proprietary interest in the product tested held by the investigator: 0 investigators
- Significant equity interest held by investigator in sponsor of covered study: 0 investigators.

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data.

XII. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Primary clinical study outcomes for the parent lenses are provided in the TECNIS PureSee™ labeling in Tables 1-30; these tables are incorporated by reference from previous approvals. As a result, these tables were not repeated within this SSED. Below identify which tables are associated with each submission:

- Tables 38-47: TECNIS™ Toric 1-Piece IOLs, Models ZCT150, ZCT225, ZCT300 and ZCT400 (P980040/S039)
- Table 48: SENSAR™ 1-Piece IOL, Model AAB00
- Tables 49 to 56: TECNIS™ 3-Piece OptiBlue™ IOL, Model ZV9003 (P980040/S035)

In addition, another study of the TECNIS PureSee™ IOL (Model DEN00V) (IDE # G220225) was performed, with 243 subjects enrolled at 10 US sites. The study results were reviewed as part of the benefit-risk determination of this device.

XIII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIV. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The 6-month results of the IDE (#G240043) clinical investigation demonstrated the effectiveness of the TECNIS PureSee™ IOL with TECNIS SIMPLICITY™ Delivery System, Model DEN00V, as an extended depth-of-focus (EDF) IOL because all clinical and statistical success criteria for

the primary effectiveness endpoints were achieved. The primary effectiveness endpoints included monocular distance corrected intermediate visual acuity, monocular depth of focus, monocular best corrected distance visual acuity and mean monocular photopic DCVA (first eyes) at 100 cm. Intermediate visual acuity (first-eye DCIVA) at 66 cm was statistically superior to the monofocal control (1.5 lines difference) and 52.3% more TECNIS PureSee™ IOL subjects than control subjects achieved 0.20 LogMAR or better (82.3% [93/113] v. 30.0% [33/110]). The median and mean DCIVA for the DEN00V first eyes were 0.14 LogMAR and 0.15 LogMAR, respectively. Both met the clinical success criterion for the effectiveness endpoint of being equal to or better than 0.20 LogMAR (i.e., ≤0.20 LogMAR). Monocular depth of focus curves demonstrated that the TECNIS PureSee™ IOL lens provided an extended depth of focus by 0.64 D more than the monofocal control, providing 0.20 LogMAR or better acuity. There was no noticeable effect of pupil size on the TECNIS PureSee™ performance. Distance visual acuity (first-eye BCDVA) for the TECNIS PureSee™ IOL group was non-inferior to the monofocal control and nearly all subjects in both lens groups had 20/20 or better BCDVA (88.5% [100/113] for TECNIS PureSee™ v. 92.7% [102/110] for control). The mean monocular distance corrected visual acuity (DCVA) at 100cm for TECNIS PureSee™ was 0.10 LogMAR, which met the clinical criterion of better than the threshold of 0.20 LogMAR.

In summary, the study demonstrated the TECNIS PureSee™ IOL provided improved intermediate vision compared to the monofocal control, the TECNIS™ 1 Piece IOL, with TECNIS SIMPLICITY™ Delivery System, Model DCB00, and extended the depth of focus without compromising distance vision.

The effectiveness of the toric models (Models DET150, DET225, DET300, and DET375) to provide reduced postoperative refractive astigmatism is supported by: (1) the clinical data provided for the monofocal toric parent IOL in P980040/S039 (which has the same toric surface and mechanical design); and (2) optical-bench testing performed on the models DEN00V and DET375 and a monofocal parent device, as noted above.

B. Safety Conclusions

The risks of the device (TECNIS PureSee™ IOLs) are based on nonclinical laboratory studies and a primary clinical study conducted to support PMA approval in G240043 as described above, as well as a prior TECNIS PureSee™ clinical study (IDE# G220225) of 243 subjects at 10 sites. In addition, the clinical data from previous U.S. studies for the SENSAR™ 1-piece IOL, Model AAB00 (G050183, P980040/S015 – the mechanical parent lens) and the TECNIS OptiBlue 3 Piece IOL, Model ZV9003 (G060212, P980040/S035 – the material parent) provided data that are relevant to the TECNIS PureSee™ IOL device safety. These studies of the parent IOLs included up to 1 (one) year of follow-up and a minimum sample size of 300 subjects. The TECNIS PureSee™ IOL, Model DEN00V, is made of the same FDA-approved surface-treated SENSAR™ violet-light filtering soft acrylic material as its material parent and has a design that is derived from proven material, with mechanical and optical parents that have a long history of safe clinical use. The results of prior nonclinical laboratory testing, animal studies on the SENSAR™ violet-light filtering acrylic material and the one-piece lens design support safety of this lens model. In addition, the results of dimensional, optical cosmetic and folding/recovery properties of the TECNIS PureSee™ IOL demonstrated conformance to applicable sections of ISO 11979-2 and ISO 11979-9, ISO 11979-3, ANSI Z80.30, and internal product specifications.

The 6-month results of the IDE clinical investigation of the TECNIS PureSee™ IOL, Model DEN00V, provide reasonable assurance of the safety of this lens model, as the criteria for all primary safety endpoints were met. There were no SSIs related to optical properties of the IOL and rates of the SPE-related AEs of the TECNIS PureSee™ IOL subjects met the ISO cumulative and persistent SPE rates. All eyes in the TECNIS PureSee™ IOL arm met the SPE rate for monocular BCDVA of 0.30 LogMAR or better, and the mean BCDVA for TECNIS PureSee™ was statistically significantly non-inferior to the control.

No serious adverse device-related events (SADEs) occurred and rates of serious or device-related adverse events occurred in similar proportions for both lens groups. In addition, the rate of ocular non-SPE serious and/or device related events was ≤4.8% for both lens groups. Contrast sensitivity function for the TECNIS PureSee™ IOL was maintained and found to be pupil-independent, with no clinically meaningful differences compared to the monofocal control. Notably, all eyes in both lens groups were able to detect the threshold contrast sensitivity pattern which further supports the image quality of the lens. The study also demonstrated adequate fundus visualization after TECNIS PureSee™ IOL implantation.

C. Benefit-Risk Determination

The probable benefits of the device are also based on data collected in a clinical study conducted to support the PMA approval as described above. The clinical benefits of the TECNIS PureSee™ IOL are based on the data collected in this clinical study (IDE# G240043), of subjects bilaterally implanted with the TECNIS PureSee™ IOL in comparison to a monofocal control (the TECNIS™ 1 Piece IOL, with TECNIS SIMPLICITY™ Delivery System, Model DCB00), which demonstrated that the TECNIS PureSee™ IOL is safe and effective when used as intended and according to the instructions for use. The study has demonstrated statistically significant and clinically meaningful results in favor of the TECNIS PureSee™ IOL regarding visual correction of aphakia, improved intermediate vision and extended depth of focus while preserving corrected distance vision, and for the TECNIS PureSee™ Toric IOL, the supportive clinical and optical-bench data demonstrate reduction of residual refractive astigmatism in adult subjects with greater than or equal to 1.00 diopter (D) of preoperative corneal astigmatism.

The probable risks of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. Adverse events were comparable to those associated with other intraocular lenses and there were no SSIs secondary to optical properties of the IOL.

Additional factors to be considered in determining probable risks and benefits for the TECNIS PureSee™ IOL devices included:

1. Patient Perspective

   Patient perspectives considered during the review included:

   - Information on subjects' experience of visual symptoms using the Patient Reported Visual Symptoms Questionnaire (PRVSQv2), a patient reported outcome (PRO) measure.

   - Non-directed (spontaneous) ocular/visual symptoms reported by subjects were also collected to gather information on their experience during the study.

- Information on subjects' experiences with the use of spectacles using the Patient Reported Spectacle Independence Questionnaire (PRSIQv2), a patient reported outcome (PRO) measure.

In conclusion, given the available information above, the data support that for the visual correction of aphakia (and corneal astigmatism for subjects receiving a toric IOL) in subjects for whom a cataract lens has been removed, while providing improved intermediate visual acuity and maintaining comparable distance visual acuity compared to a monofocal IOL, the probable benefits of the TECNIS PureSee™ IOL and TECNIS PureSee™ Toric II IOL outweigh the probable risks.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of the TECNIS PureSee™ IOL and TECNIS PureSee™ Toric II IOL devices when used in accordance with the indications for use and labeled Directions for Use.

All primary safety and effectiveness endpoints success criteria were achieved, the study demonstrates the safety and effectiveness of the TECNIS PureSee™ IOL, Model DEN00V as an Extended Depth of Focus IOL. The Model DEN00V IOL provided improved intermediate vision and an increased depth of focus with visual acuity of 0.20 LogMAR or better compared to a monofocal IOL. The Model DEN00V achieved distance vision comparable to that of a monofocal IOL, maintained contrast sensitivity function, and demonstrated a low incidence of adverse events ISO SPE rates. These results provide adequate evidence of the safety and effectiveness of the investigational TECNIS PureSee™ IOL, Model DEN00V. These results provide adequate evidence of the safety and effectiveness of the investigational TECNIS PureSee™ IOL.

XV. CDRH DECISION

CDRH issued an approval order on March 11, 2026

The applicant's manufacturing facility was inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820), which was in effect at the time of the inspection. As of February 2, 2026, the revised part 820, referred to as the Quality Management System Regulation (QMSR), is effective.

XVI. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.

XVII. REFERENCES

International Organization for Standardization 10993, Biological Evaluation of Medical Devices

International Organization for Standardization 11979-2 Ophthalmic Implants – Intraocular Lenses – part 2: Optical Properties and Test Methods

International Organization for Standardization 11979-3 Ophthalmic Implants – Intraocular Lenses – Part 3: Mechanical Properties and Test Methods

International Organization for Standardization 11979-5, Ophthalmic Implants- Intraocular Lenses- Part 5: Biocompatibility

International Organization for Standardization 11979-7 -Intraocular Lenses – Part 7: Clinical Investigations

American National Standards Institute Z80.30, American National Standard for Ophthalmics: Toric Intraocular Lenses

American National Standards Institute Z80.35, American National Standard for Ophthalmics: Extended Depth of Focus Intraocular Lenses.

Masket S, Rorer E, Stark W, Holladay JT, MacRae S, Tarver ME, et al. Special Report: The American Academy of Ophthalmology Task Force Consensus Statement on Adverse Events with Intraocular Lenses. Ophthalmology. 2017 Jan;124(1):142-144.