SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Multifocal intraocular lens
Device Trade Name:	SBL-3™ Multifocal Intraocular Lens
Device Procode:	Multifocal intraocular lens (MFK)
Applicant's Name and Address:	Lenstec Inc 1765 Commerce Avenue North, St. Petersburg, FL 33716

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P200020

Date of FDA Notice of Approval: July 22, 2022

II. INDICATIONS FOR USE

The SBL-3™ multifocal intraocular lens is indicated for primary implantation for the visual correction of aphakia, in adult patients with 1 diopter or less of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing a bifocal correction. Compared to an aspheric monofocal IOL, the lens provides improved near visual acuity, while maintaining comparable distance and intermediate visual acuity. The lens promotes the less frequent use of vision correction choices at near distance (including glasses, contact lenses, magnifying glasses, and digital adjustments on electronic devices), compared to an aspheric monofocal IOL. The SBL-3 ™ multifocal IOL is intended for capsular bag placement only.

III. CONTRAINDICATIONS

Outside of general contraindications for ocular surgery, the following specific contraindications apply:

Uncontrolled glaucoma, microphthalmia, chronic severe uveitis, retinal detachment, corneal decompensation, diabetic retinopathy, iris atrophy, perioperative complications, potentially foreseeable post-operative complications and other conditions which an ophthalmic surgeon might identify based on their experience.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the SBL-3 labeling.

V. DEVICE DESCRIPTION

The SBL-3™ Multifocal Intraocular Lens (MIOL) is an ultraviolet absorbing, single-piece closed loop/modified plate intraocular lens intended for the replacement of the human crystalline lens following phacoemulsification cataract removal. The SBL-3 possesses a rotationally asymmetric aspheric multifocal optic with a +3.00 add on the anterior surface. It is offered in the dioptric power range of +15.0 to +25.0 in quarter (0.25) diopter increments and 25.5 to 30.0 in half (0.50) diopter increments. The SBL-3 ™ is manufactured with a tolerance ±0.11 diopters at both the base power and the add power, between +15.0 and +25.0.The lens features, specifications, power offereings and tolerances are described in **Tables 1 and 2**.

Table 1: SBL-3 ™ Specifications

Lens Feature	Specifications
Optic Size	5.75 mm
Optic Type	Refractive, equiconvex, aspheric
Haptic Type	Closed loop/modified plate
Add power	+3.00D at the IOL plane +2.40D at the spectacle plane
Length	11.00 mm
Angulation	0 Degrees
Construction	1 Piece
Optic Material	Hydrophilic acrylic (26% water content)
Haptic Material	Hydrophilic acrylic (same as optic)
Index of refraction	1.456
A Constant*	118.00 mm*
A/C Depth*	5.10 mm*

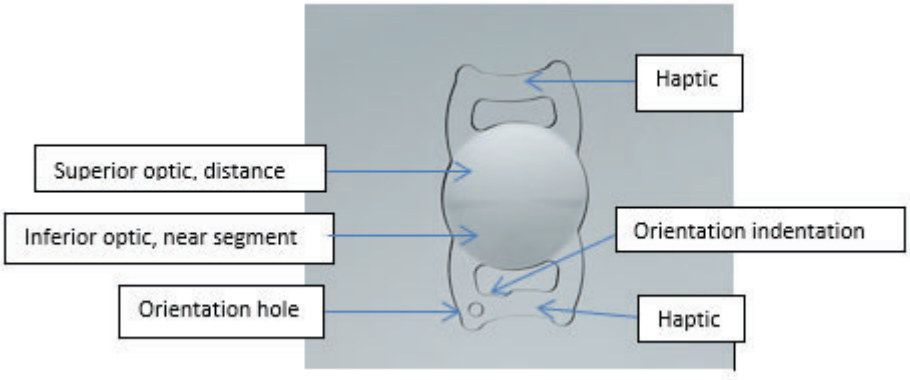
*NOTE: The 'A' Constant and ACD values printed on the outside of the package, are estimates only. It is recommended that the surgeon determine his/her own values based on individual clinical experience

Table 2: SBL-3™ Power Offering and Tolerances

SBL-3 Power Ranges (D)	Diopter Increments Offered In (D)	Tolerances Applied (D)**
+15.0 to +25.0	0.25	± 0.11
+25.5 D to +30.0	0.50	± 0.25

The SBL-3 ™ is designed with a segmented optic, rather than the concentric zonal approach used in currently available MIOLs (**Figure 1**). The optic is designed with two distinct power zones, with the superior aspect powered for distance and the inferior powered for near. The 'near' zone possesses 3.0 diopters (D) of additional (ADD) power at the IOL plane, which corresponds to approximately 2.4D at the spectacle plane, depending on corneal power and anterior chamber depth. The add portion is placed on the anterior MIOL surface.

Figure 1: SBL-3™ Multifocal Intraocular Lens



The SBL-3™ is manufactured from a medical grade co-polymer of Hydrophilic Acrylic, with a polymerizable UV blocker. The hydrophilic nature of the lens material (hydrophilic acrylic) reduces the problems associated with silicone oil adhesion and silicone oil induced opacification. Each MIOL has a 360° square edge design.

The IOL is designed with a half power ring at the very bottom of the optic portion. This is depicted in the **Figure 2** below, in which the green color represents the distance portion, the red portion represents the near add portion and the adjacent white colored portion represents this half power portion. In eyes with large pupils, it is possible that patients may see a resultant arcuate half-halo. No patient in the clinical trial noted such a concern, but the theoretical possibility exists that such an issue could occur.

Figure 2: SBL-3™ IOL Optic

Currently available MIOLs are designed in a concentric ring fashion in which powers change from the base power to the near power in alternating fashion, from one central ring all the way to the periphery of the optic. The number of rings varies by manufacturer/lens/design.

Although the design appears similar to bifocal spectacles in concept, the patient implanted with the SBL-3 ™ does not need to move his/her head up and down to gain the advantage of the near add (as is required with bifocal spectacles). Just as with approved two-power MIOLs in the US, the patient's brain adapts to the available images and suppresses the out of focus image associated with those objects not being focused on by the patient.

The SBL-3 ™ is manufactured from the same material approved for use with the Applicant's Softec family of IOLs (P090022). The SBL-3 ™ is lathe and mill cut from a 'button' of material and subsequently hydrated, polished, checked for acceptability, final cleaned/inspected, packaged in a pouch, labeled, sterilized, packed and then shipped.

Table 3, below, describes the injection systems which are approved for use with the SBL-3.

Table 3: IOL Injection System Compatibility Guide

	IOL Injection Systems			
IOL Model	LC Injection System (K122848) (Lenstec Inc)		Softip Injection System (K103495) (Asico LLC)	
	Validated for Use	Power range (D)	Validated for Use	Power range (D)
SBL-3	✓	I-9011S/ LC16: 15.0 to 22.0	✓	AS-9300/ LC1620I: 15.0 to 22.0
	✓	I-9011S/ LC1620: 15.0 to 22.0	✓	AS-9310/ LC2420I: 15.0 to 30.0
	✓	I-9011S/ LC2420: 15.0 to 30.0		
	✓	I-9012/ LC16: 10.0 to 26.0		

	✓	I-9012/ LC2420: 26.5 to 30.0		

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of of aphakia resulting from surgical cataract removal (i.e., for patients who have had a cataractous lens removed). Non-surgical options include special cataract glasses or contact lenses. Surgical options such as monofocal, multifocal, extended depth of focus or accommodative IOLs are also available. 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 SBL-3 ^{TM} has been marketed in the following countries: Argentina, Barbados/Caribbean, Belgium, Canada, China/Hong Kong, Colombia, Czech Republic/ Slovakia, Georgia, Germany, Iraq, Ireland, New Zealand, Panama, South Korea, Switzerland, Taiwan, United Kingdom, and Zimbabwe. The SBL-3^{TM} has never been withdrawn from marketing for any reason related to its 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.

- lens epithelial cell down-growth
- corneal endothelial damage
- infection (endophthalmitis)
- retinal detachment/tear
- vitritis
- cystoid macular edema
- corneal edema
- pupillary block
- cyclitic membrane
- iris prolapse
- hypopyon
- anterior uveitis
- hyphema
- pigment dispersion
- posterior capsule opacification
- transient or persistent glaucoma
- IOL dislocation, tilt, or decentration requiring repositioning
- residual refractive error resulting in secondary intervention

- increased visual symptoms (compared to a monofocal IOL) related to the optical characteristics of the IOL, including bothersome stray-light artifacts such as halo, starbursts, or glare

Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration, iridotomy for pupillary block, wound leak repair, and retinal detachment repair.

For the specific adverse events that occurred in the clinical study, please see Section X below.

IX. SUMMARY OF NONCLINICAL STUDIES

The SBL-3 ™ is made of the same material as the approved Softec HD Posterior Chamber Intraocular Lens IOL (P090022). Therefore, please refer to P090022, which is incorporated by reference into this PMA.

A. Laboratory Studies

Physicochemcial testing

The SBL-3 ™ is manufactured from the identical Hydroxyethylmethacrylate (HEMA) material as the Softec HD monofocal IOL (P090022). The materials used for the SBL-3 ™ has been previously tested to meet the recommendations in 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.

B. Animal Studies

Biologicial Testing

The animal studies were conducted using the Softec HD Posterior Chamber Intraocular Lens (P090022). The materials used for the SBL-3™ were identified as the same as what was evaluated in P090022 and leveraged. Biocompatibility testing (see **Table 4**) was performed in accordance with International Standard Organization (ISO) 10993-1 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity, - Part 5: Tests for in vitro cytotoxicity, - Part 6: Tests for local effects after implantation, - Part 10: Tests for irritation and skin sensitization, and - Part 11: Tests for systemic toxicity. All biocompatibility testing were conducted in accordance with the provisions of 21 CFR 58, Good Laboratory Practice for Nonclinical Laboratory Studies. The toxicology studies were conducted in accordance with the requirements of International Standard Organization (ISO) 11979-5, Ophthalmic implants – Intraocular lenses – Part

5: Biocompatibility. All acceptance criteria for biocompatibility were met.

Table 4: Biocompatability Testing

Test	Purpose	Acceptance Criteria	Results
MEM Elution with L-929 Mouse Fibroblast Cells	Evaluate the potential for cellular toxicity	Non-cytotoxic	Negative for cytotoxicity
Agarose Overlay (Direct Contact) with L-929 Mouse Fibroblast (solid)	Evaluate the potential for cellular toxicity	Non-cytotoxic	Negative for cytotoxicity
Agarose Overlay (Direct Contact) with L-929 Mouse Fibroblast (liquid)	Evaluate the potential for cellular toxicity	Non-cytotoxic	Negative for cytotoxicity
Cell Growth Inhibition Assay with L-929 Mouse Fibroblast Cells	Evaluate the potential for cellular toxicity	Non-cytotoxic	Negative for cytotoxicity
Guinea Pig Maximization Sensitization	Evaluate the potential of sensitization	Non-sensitizing	Negative for contact sensitization
Rabbit Muscle Implantation/ Intracutaneous Study (2, 4 week implant)	Evaluate the local effects in skeletal muscle tissue	Non-irritant	No significant biologicial local response
Acute Systemic Toxicity	Evaluate toxicity in muscle tissue	Non-toxic	No significant biologicial response
Bacterial Reverse Mutation Mutagenicity Test (DMSO, saline extract)	Evaluate the mutagenic potential	Non-mutagenic	Negative mutagenic potential
Chromosomal Aberration Study	Evaluate the genotoxicity potential	Non-genotoxic	Negative genotoxic potential
Mouse Peripheral Blood Micronucleus Study	Evaluate potential to cause gene mutations	Non-mutagenic	Negative mutagenic potential
Hemolysis Study	Evaluate potential to cause hemolysis	Non-hemolytic	Neagtive for hemolysis

Ocular Implantation Study in Rabbits (1 year study)	Evaluate local effects in ocular tissue	No significant biological local response.	No significant biologicial response

C. Additional Studies

Optical/Mechanical Testing

The **Table 5** below provides results of optical and mechanical testing following aging. The acceptance criteria are either the LensTec specifications, the specifications in the ISO 11979 series of IOL standards, or a determination that there was no significant change from the baseline values, as applicable. All acceptance criteria for optical and mechanical attributes were met after aging. The preclinical optical and mechanical testing were performed with the SBL-3 and measured in accordance with ISO 11979-2 Ophthalmic Implants – Intraocular Lenses – Part 2: Optical Properties and Test Methods and ISO 11979-3 Ophthalmic Implants – Intraocular Lenses – Part 3: Mechanical Properties and Test Methods.

Table 5: Optical and Mechanical Testing following Real/Accelerated Aging

Test	**Purpose**	**Acceptance Criteria**	**Results**
Tolerances and Dimensions	To characterize the tolerance of the IOL	N/A	Characterized
Compression Force	To characterize the force to compression the IOL	N/A	Characterized
Axial Displacement in Compression	To characterize the axial displacement in compression	N/A	Pass
Optic Decentration	To assess optic decentration under compression	Mean and 2 SD not greater than 10% of clear optic	Pass
Optic Tilt	To assess optic tilt under compression	Mean and 2 SD not greater than 5 degrees	Pass

Angle of Contact	To characterize haptic contact with ocular tissues	N/A	Characterized
Compression Force Decay	To characterize the force to compress the IOL after 24 hours decay	N/A	Characterized
Dynamic Fatigue Durability	To assess the ability of the haptics to withstand cyclic compressive loading	No haptic breakage	Pass
Surgical Manipulation/ Haptic Strength	To assess the force to separate the haptic from the optic	Greater than or equal to 0.25 N	Pass
Surface and Bulk Homogeneity	To assess conformance to dimensional tolerances and free of surface defects	Multiple acceptance criteria described in ISO 11979-3	Pass
Spectral Transmittance	To characterize the spectral transmittance of the IOL	Multiple acceptance criteria described in ISO 11979-2	Characterized
Dioptric Power[1]	To assess accuracy of optical power, meet minimum image quality specifications	Acceptance criteria described in ISO 11979-2	Pass
Image Quality	To assess image quality of the IOL by modulation transfer function (MTF)	Multiple acceptance criteria described in ISO 11979-2	Pass
Optical Evaluation After	To assess the ability of the IOL to	Multiple acceptance	Pass

Simulated Surgical Manipulation	withstand simulated surgical implantation without damage	criteria described in ISO 11979-3	

[1]Note: the SBL-3 is available in 0.25 diopter increments from 15.0 diopter to 25.0 diopter. Those IOLs have a required tolerance tighter than those for IOLs available in 0.5 diopter increments through that range. The SBL-3 is required to be within ±0.11 diopters in this range whereas the national standards require the 0.5 diopter IOLs to be within ±0.4 diopters. All SBL-3 tested were noted as "Pass" if they met this tightened tolerance.

The MTF through focus response at 50 lp/mm for a 2.0, 3.0, and 4.5 mm aperture is shown in **Figure 3.**

Figure 3: Through-focus MTF Values at 50 cyc/mm

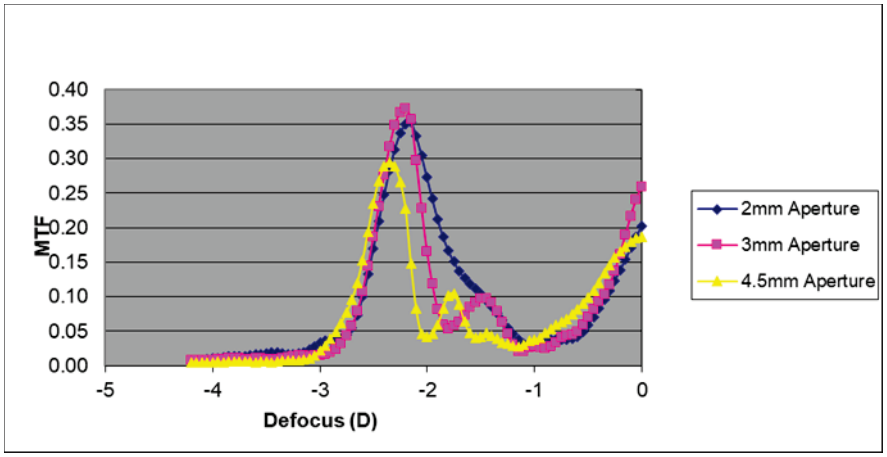
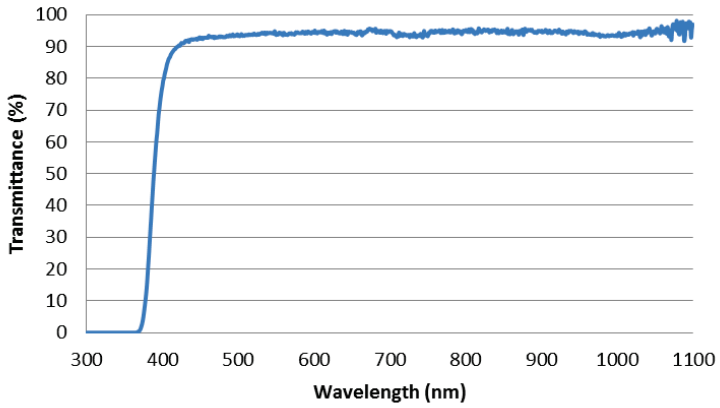


Figure 4 describes the SBL-3 spectral transmittance over the 300 nm to 1100 nm wavelengths. The % UV transmittance from 300-360 nm is 0% and the 10% cut off is 374 nm.

Figure 4: Spectral transmittance



Microbiology, Sterilization, and Shelf-Life Testing

The IOL material, sterilization method, packaging materials and packaging configuration of the SBL-3 ™ Multifocal IOLs are the same as those of Lenstec's approved Softec HD Posterior Chamber Intraocular Lens (P090022). Differences in the manufacturing process, including initial manufacturing location, manufacturing methods and manufacturing equipment have been evaluated and are considered acceptable with respect to microbiology, sterilization and shelf life/transport stability. As a result, stability, packaging integrity, and transport stability data supporting this reference Softec HD monofocal IOL lens model was used to support the application for the SBL-3 ™ multifocal IOL lens model. In addition, both accelerated aging and real-time aging studies were performed. As a result of reference and current stability testing, the SBL-3 ™ IOLs will be labeled with a 5-year shelf life.

Validation of the steam sterilization process was conducted on the SBL-3 ™ IOLs and assures a minimum sterility assurance level of 10^{-6}. The SBL-3 ™ IOLs were successfully adopted into the existing validated steam sterilization cycle per the appropriate standard operating procedures and passed all acceptance criteria for bioburden and bacterial endotoxin.

These tests were conducted in accordance with the current versions of the following standards:

- ISO 17665-1, Sterilization of health care products – Moist Heat – Part 1:
- Requirements for the development, validation, and routine control of a sterilization process for medical devices
- ISO 17665-2, Sterilization of health care products – Moist Heat – Part 2: Guidance on the application of ISO 17665-1
- ISO 11737-1, Sterilization of health care products—Microbiological
- methods—Part 1: Determination of a population of microorganisms on products

- ISO 11979-6, Ophthalmic Implants – Intraocular Lenses – Part 6: Shelf-life and transport stability
- ISO 11979-8, Ophthalmic Implants – Intraocular Lenses – Part 8: Fundamental requirements
- USP <85>, Bacterial Endotoxins Test
- ASTM F88-15, Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM D3078-02(2013), Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
- ASTM F1929-15, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

The results of the sterilization, packaging, shelf life and transport stability studies are summarized in **Table 6** below:

Table 6: Microbiology, Sterilization, and Shelf-Life Testing: SBL-3™ Multifocal IOL

Test	Purpose	Acceptance Criteria	Results
Pre-sterilization Bioburden Testing	Determine natural bioburden prior to sterilization to ensure a sterility assurance level (SAL) of 10^{-6} can be met per ANSI/AAMI/ISO 11737-1: 2018 Section 6	Achieve SAL of 10^{-6}	Pass
Steam sterilization requalification	Validates that the steam sterilization cycle is effective per EN ISO 17665-1: 2006/(R)2013 Section 12	Achieve SAL of 10^{-6}	Pass
Bacterial Endotoxin Testing	Confirm product is non-pyrogenic per USP <85>	≤0.12 EU/ml	Pass
Package Integrity Testing – Legibility of Labeling	Confirm that product labeling remains legibile after sterilization during stability studies per ISO 11979-6 Section 4.3	Label remains legible	Pass
Packaging Integrity Testing – Seal Strength	Confirm that product seal strength is maintained after sterilization during stabiilty studies per ISO	Minimum seal strength is 1 lb/in	Pass

	11979-6 Section 4.3 and ASTM F88-15		
Packaging Integrity Testing – Bubble Emission	Confirm that product seal integrity is maintained after sterilization during stabiilty studies per ISO 11979-6 Section 4.3 and ASTM D3078-02(2013)	Fluid in package after 30 seconds of submission	Pass
Packaging Integrity Testing – Dye Penetration	Confirm that product seal integrity is maintained after sterilization during stabiilty studies per ISO 11979-6 Section 4.3 and ASTM F1929-15	No leaks detected at four (4) distinct seal edge points	Pass

X. SUMMARY OF PRIMARY CLINICAL STUDY(IES)

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of cataract surgery and intraocular lens (IOL) implantation with the SBL-3 ™ ultifocal IOL for primary implantation for the visual correction of aphakia in the US under IDE G140134. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

Patients were treated between August 19, 2015 and August 15, 2019. The database for this Original PMA Application reflected data collected through August of 2019 and included 495 implanted subjects. There were 18 investigational sites in the U.S. The study was enrolled in two phases (Phase 2 and Phase 3).

The study was a prospective, multi-center, pivotal, two-arm/parallel group, subject masked, randomized (2:1 ratio) cohort study. Subjects were masked from knowing the type of IOL they received, either multifocal SBL-3 ™ or monofocal IOL control. The study was intended to include pre-operative visits and extend to 1-year post-operative. The subjects were enrolled following signing informed consent and meeting inclusion and exclusion criteria and randomized at the time of surgery into either the test or control group. Once the primary eye was treated, the fellow eye was to be implanted with the same type IOL between 7 and 30 days from the primary eye implantation date. Both eyes were required to meet inclusion/exclusion

criteria for this reason. The statistical plan was based upon the use of frequentist statistics. Sample size was based upon adequate power to test key effectiveness hypotheses comparing the SBL-3 ™ arm to the monofocal control arm, with regard to distance-corrected visual acuity at 4 m and 70 cm (to show non-inferiority, using a 0.10 logMAR margin), and at 40 cm (to show superiority).

The safety objective was to characterize the rates of all adverse events in the SBL-3 ™ arm and to statistically compare these to rates seen in with a monofocal IOL. For types of adverse events listed in the ISO 11979-7 (2018) (Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations), SBL-3 ™ adverse event rates were compared to the ISO historical control rates found in monofocal IOLs. Statistically, SBL-3 ™ rates were compared to the historical control rates to determine whether the observed rates were significantly greater than the historical control rates. Secondary surgical intervention due to the optical properties of the IOL (which is not a type of event mentioned in this ISO historical control) was part of the primary safety endpoint. The analysis was to compare the rates in the SBL-3 and active monofocal IOL control arms using a 2- sided 90% confidence interval constructed around the estimate of the rate difference between the arms. (The group rates wound be considered comparable if the confidence interval contains zero. Similar statistical comparisons were the analyses used for any types of serious adverse events not found in the historical control.)

The control group was the subjects implanted with a legally marketed aspheric monofocal IOL with indications for primary implantation for the visual correction of aphakia (the Akreos AO60 (Bausch + Lomb, NJ, USA)). (For the types of safety and performance endpoints (SPEs) specified in ISO 11979-7, the ISO historical control was used for statistical comparisons.)

A total of up to 510 subjects were allowed to be enrolled, in order to ultimately have 300 study subjects and 150 control subjects available at the 1-year postoperative. Enrollment was closed after the 499th subject was included in the study.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the IDE study for the SBL-3™ was limited to patients who met the following inclusion criteria:

- ≥ 22 years of age, of any race and either gender
- Operable, age related cataract grade in both eyes
- Patients who require an IOL power in the range of 15 D – 30 D only.
- Able to comprehend and sign a statement of informed consent
- Planned cataract removal by phacoemulsification

- Potential postoperative visual acuity of 0.2 logMAR or better in both eyes
- In good general and ocular health
- Patients with preoperative astigmatism ≤1.0 D
    - Note: Corneal incisions made to reduce astigmatism will not be allowed during the course of the study.
- Clear intraocular media other than cataract in study eyes
- Preoperative Best Corrected Distance Visual Acuity worse than 0.20 logMAR with or without medium BAT (Brightness Acuity Test)
- The subject must be able to undergo second eye surgery between 7 days and 30 days of the first eye surgery
- Able to competently complete testing
- Willing and able to attend study visits

Patients were not permitted to enroll in the IDE study for the SBL-3™ if they met any of the following exclusion criteria:

- Previous intraocular surgery
- Preoperative photopic pupil size of < 2.75 mm
- Previous corneal refractive surgery
- Any inflammation or edema (swelling) of the cornea
- Pterygium with corneal involvement or has the potential of corneal involvement (in the opinion of the Investigator) during the course of the study
- Subjects with diagnosed degenerative visual disorders (e.g. macular degeneration or other retinal disorders) that are predicted to cause future acuity losses to a level worse than 0.2 LogMAR
- Subjects who may reasonably be expected to require a secondary surgical intervention at any time during the study (other than YAG capsulotomy)
- Amblyopia
- Clinically significant ptosis
- Clinically severe corneal dystrophy (e.g., epithelial, stromal, or endothelial dystrophy), keratitis, keratoconjunctivitis, keratouveitis, keratopathy, or kerectasia
- Diabetic Retinopathy
- Extremely shallow anterior chamber, not due to swollen cataract
- Microphthalmia
- Previous retinal detachment
- Previous corneal transplant
- Severe dry eye
- Recurrent severe anterior or posterior segment inflammation of unknown etiology
- Systemic medications that may confound the outcome or increase the risk to the subject in the opinion of the Investigator [tamsulosin

hydrochloride (Flomax) or other medications with similar side effects (floppy iris syndrome)]
- Rubella or traumatic cataract
- Iris neovascularization
- Glaucoma (medically controlled or uncontrolled)
- Aniridia
- Chronic severe uveitis
- Optic nerve atrophy
- Corneal decompensation
- Greater than 1.0 D of astigmatism
- History of corneal disease (e.g., herpes simplex, herpes zoster keratitis, etc.)
- Pseudoexfoliation syndrome
- Iris atrophy
- Pupil abnormalities (e.g., corectopia)
- Aniseikonia
- An acute or chronic disease or illness that may confound the results of this investigation (e.g., immunocompromised, connective tissue disease, clinically significant atopic disease, diabetes, and any other such disease or illness)
- Pregnant, lactating, or planning to become pregnant during the course of the trial
    - Note: Subjects who become pregnant during the study will not be discontinued; however, data may be excluded from the effectiveness analyses because pregnancy can alter refraction and visual acuity results. Participation in another clinical trial within 30 days of study start
- Participation in another clinical trial within 30 days of study start

The following were criteria for not implanting the study device (after enrollment and during surgical visit)

- Other planned ocular surgery procedures, including but not limited to, LASIK, astigmatic keratotomy and limbal relaxing incisions for the duration of the study
- Significant vitreous loss
- Mechanical or surgical manipulation required to enlarge the pupil; pupil size must be at least 4.5 mm or larger just prior to implantation
- Excessive iris mobility
- Capsular rent or tear
- Significant anterior chamber hyphema
- Uncontrollable intraocular pressure
- Iris damage
- Detached Descemet's Membrane
- Zonular or capsular rupture

- Bag-sulcus, sulcus-sulcus or unknown placement of the haptics

2. Follow-up Schedule

The visit schedule and clinical evaluations are presented in **Table 7**, below. All patients were scheduled to return for follow-up examinations as follows:

Table 7: Schedule of Visits for Subjects in the SBL-3 IDE Study

Activity	Visit 0/0A	Visit 00	Visit 1*	Visit 2*	Visit 3*	Visit 00A*	Visit 1A*	Visit 2A*	Visit 3A*	Visit 4A*	Visit 5A*
	Preop	Op	1-2 Days Postop	7-14 Days Postop	30-60 Days Postop	Op[a]	1-2 Days Postop	7-14 Days Postop	30-60 Days Postop	120-180 Days Postop	330-420 Days Postop
Informed Consent	X										
Demographics	X										
General Information / Medical History	X										
Manifest Refraction	X		X	X	X		X	X	X	X	X
Inclusion/Exclusion Criteria	X	X[b]				X[b]					
Urine Pregnancy Test	X										
Device Deficiencies		X	X	X	X	X	X	X	X	X	X
Adverse Events	X	X	X	X	X	X	X	X	X	X	X
Light Measurements	X		X	X	X		X	X	X	X	X
Photopic Pupil Size at Near, Intermediate and Distance	X									X	X

Activity	Visit 0/0A	Visit 00	Visit 1*	Visit 2*	Visit 3*	Visit 00A*	Visit 1A*	Visit 2A*	Visit 3A*	Visit 4A*	Visit 5A*
	Preop	Op	1-2 Days Postop	7-14 Days Postop	30-60 Days Postop	Op[a]	1-2 Days Postop	7-14 Days Postop	30-60 Days Postop	120-180 Days Postop	330-420 Days Postop
Distance Visual Acuity											
Mesopic Pupil Size at Near, Intermediate and Distance	X									X	X
Uncorrected Distance Visual Acuity	X		X	X	X		X	X	X[c]	X[c]	X[c]
Best Corrected Distance Visual Acuity Using Original Manifest Refraction	X		X	X	X		X	X	X[c]	X[c]	X[c]
Best Corrected Distance Visual Acuity Using Additional -0.25 D	X		X	X	X		X	X	X[c]	X[c]	X[c]
Mesopic Low Contrast Acuity Testing										X[f]	
Near Visual Acuity at 40 cm											
Uncorrected Near Vision at 40 cm			X	X	X		X	X	X[c]	X[c]	X[c]

Activity	Visit 0/0A	Visit 00	Visit 1*	Visit 2*	Visit 3*	Visit 00A*	Visit 1A*	Visit 2A*	Visit 3A*	Visit 4A*	Visit 5A*
	Preop	Op	1-2 Days Postop	7-14 Days Postop	30-60 Days Postop	Opa	1-2 Days Postop	7-14 Days Postop	30-60 Days Postop	120-180 Days Postop	330-420 Days Postop
Distance Corrected Near Vision at 40 cm					X				X[c]	X[c]	X[c]
Mesopic Distance Corrected Near Vision at 40 cm										X[c]	X[c]
Best Corrected Near Vision at 40 cm					X				X[c]	X[c]	X[c]
Near Visual Acuity at Best Distance											
Uncorrected Near Visual Acuity at Best Distance					X				X[c]	X[c]	X[c]
Distance Corrected Near Visual Acuity at Best Distance					X				X[c]	X[c]	X[c]
Intermediate Visual Acuity at 70 cm											
Uncorrected Intermediate Visual Acuity at 70 cm					X				X[c]	X[c]	X[c]

Activity	Visit 0/0A	Visit 00	Visit 1*	Visit 2*	Visit 3*	Visit 00A*	Visit 1A*	Visit 2A*	Visit 3A*	Visit 4A*	Visit 5A*
	Preop	Op	1-2 Days Postop	7-14 Days Postop	30-60 Days Postop	Opa	1-2 Days Postop	7-14 Days Postop	30-60 Days Postop	120-180 Days Postop	330-420 Days Postop
Distance Corrected Intermediate Visual Acuity at 70 cm						X			X[c]	X[c]	X[c]
Corneal Topography	X										
Target Residual Refractive Error	X										
Contrast Sensitivity Photopic (with and without glare)										X[d]	X[d]
Contrast Sensitivity Mesopic (with and without glare)										X[d]	X[d]
Binocular Defocus										X[d]	
Anterior Chamber Depth	X										
Axial Length	X										
Keratometry	X									X	
Intraocular Pressure	X			X	X	X	X	X	X	X	X
PRO Questionnaires	X		X[g]						X[e]	X	X
Concomitant Medications	X		X	X	X	X	X	X	X	X	X
Activity	Visit 0/0A	Visit 00	Visit 1*	Visit 2*	Visit 3*	Visit 00A*	Visit 1A*	Visit 2A*	Visit 3A*	Visit 4A*	Visit 5A*
	Preop	Op	1-2 Days Postop	7-14 Days Postop	30-60 Days Postop	Opa	1-2 Days Postop	7-14 Days Postop	30-60 Days Postop	120-180 Days Postop	330-420 Days Postop
Operative Eye			X				X				
Surgical Problems			X				X				
Other Procedures at surgery			X				X				
Folding and Insertion Instrument			X				X				

Incision Site and Size		X				X					
Haptic Placement		X				X					
Lens Information		X				X					
Slit Lamp Exam	X		X	X	X		X	X	X	X	X
Dilated Fundus Exam	X				X				X	X	X
Secondary Surgical Interventions			X	X	X		X	X	X	X	X
IOL Observations			X	X	X		X	X	X	X	X
IOL Position Change			X	X	X		X	X	X	X	X
Posterior Capsulotomy			X	X	X		X	X	X	X	X
Subjective Posterior Capsule Opacification			X	X	X		X	X	X	X	X
Lens Orientation		X	X	X	X	X	X	X	X	X	X
Functional Performance										X[d]	

*: Visit and Testing performed on All Subjects
a. Second Implantation can be done within 7-30 days of first implantation
b. Review of Inclusion/Exclusion criteria prior to surgery
c. Monocular and Binocular testing
d. Binocular testing only
e. Administration of PRO twice at Form 3A (once at beginning of visit and once prior to dilation) for up to an additional 100 Phase 3 subjects only
f. Only administered if the subject has a ≥ 10 letter loss in visual acuity or is complaining of visual disturbances
g. PRO is administered prior to sedation and dilation for up to an additional 100 Phase 3 subjects only

Subgroup populations:

There were two sub-studies involved in the IDE study associated with the SBL-3™. These were defocus evaluation and functional performance (driving simulator). These were both performed at the Form 4A (120-180 days post-operative) visit.

3. Clinical Endpoints

With regards to safety, the primary endpoint was the rates of observed adverse events of various types, including the rate of secondary surgical intervention (SSIs) due to the optical properties of the IOL. As mentioned above, the rate of SSIs due to optical properties of the IOL was to be considered acceptable if it was not statistically, significantly higher than the rate for the active monofocal control. For types of serious adverse events listed (among the "safety and performance endpoints) in the ISO 11979-7(2018), the outcome for each type of adverse event was considered successful if the SBL-3™ rate was not statistically significantly higher than the historical control rate.

There was one secondary safety endpoint: binocular distance contrast sensitivity. and 'other' safety endpoints, as listed below, and as noted in the statistical analysis plan (SAP).

- PRO Visual Disturbance Questionnaire (to include patient visual symptoms)
- Slit Lamp Examination
- Dilated Fundus Examination (to include adequacy of fundus visualization and clarity of retinal image)
- Subjective Posterior Capsule Opacification (PCO)
- Posterior Capsulotomy
- IOL Observations
- IOL Position Change (Tilt and Decentration)
- Intraocular Pressure
- Surgical Problems
- Device Deficiencies
- A loss of $\geq$ 10 letters in Best Corrected Visual Acuity (LogMar) between any form evaluation and a later form evaluation
- Failure to achieve a Best Corrected LogMar acuity of 0.30 LogMAR (20/40) at any postoperative visit

The effectiveness objective was to compare the legally marketed monofocal to the study article and the ISO historical grid, for visual acuity outcomes.

a. There were three co-primary effectiveness endpoints at the 1-year post-operative visit:
    - Photopic monocular Distance Corrected Near Visual Acuity at 40 cm at visit 5A (330-420 days). The hypothesis tested for the co-primary effectiveness endpoint #1 was to demonstrate superiority of the SBL-3™ IOL to the control monofocal IOL.
    - Photopic monocular Distance Corrected Intermediate Visual Acuity at 70 cm at visit 5A (330-420 days). The hypothesis tested for the co-primary effectiveness endpoint #2 was to demonstrate non-inferioirty of the SBL-3™ IOL to the control monofocal IOL (using a non-inferiority margin of 0.10 logMAR).
    - Photopic monocular best corrected distance visual acuity at 4m at visit 5A (330-420 days). The hypothesis tested for the co-primary effectiveness endpoint #3 was to demonstrate non-inferioirty of the SBL-3™ IOL to the control monofocal IOL (using a non-inferiority margin of 0.10 logMAR).
b. Secondary Endpoints
    - The same three co-primary acuity endpoints/analyses, as above, but evaluated at visit 4A (120-180 days, postop)

- Patient reported use (as reported on a patient questionnaire) of the frequency of use of vision correction (glasses/contact lenses) and spectacle independence at visit 5A (330-420 days)

There were other supportive effectiveness endpoints, including defocus curve characterization, and patient questionnaire assessment of patient satisfaction.

Note: The clinical protocol initially contained an error in the instructions for how to perform the testing for best corrected distance visual acuity (BCDVA). For discussion of this, see the portion of Section X under "Effectiveness Results" concerning the third co-primary effectiveness endpoint of BCDVA (see below, **Table 38**). (This discussion is also pertinent to the "other" safety endpoint of "Proportion of Eyes Achieving Best Corrected Distance Visual Acuity (BCDVA) of 0.30 LogMar (or better).")

B. Accountability of PMA Cohort

At the time of database lock, of 499 patients enrolled in the PMA study, 95.4% (476) patients are available for analysis at the completion of the study, the 12 month post-operative visit.

A total of 499 subjects were randomized into this study and randomized to receive either the test or control IOL. Of the 499 subjects randomized into the study, 333 were test subjects and 166 were control subjects. Of the 499 subjects randomized into the study, 495 had at least one operative eye implanted (329 in the SBL-3 group and 166 in the control group). Of the 495 implanted subjects, 476 (96.2%; 476/495) (315 in the SBL-3 group and 161 in the control group) completed the study at the Form 5A (1-year post-operative) visit. **Table 8** describes the subject accountability.

Table 8: Subject Accountability (Intent to Treat Population, ITT) (Primary Eyes)

	SBL-3					Control				
	Form 1	Form 2	Form 3A	Form 4A	Form 5A	Form 1	Form 2	Form 3A	Form 4A	Form 5A
Expected[1] (E)	333	333	333	333	333	166	166	166	166	166
Not Due[2](ND)	3	3	3	3	3	0	0	0	0	0
Missed (M)	0	1	3	2	0	0	1	3	0	0
Discontinued (D)	1	1	3	5	10	0	0	0	1	2
Lost-to-Follow up (L)	0	0	0	2	5	0	0	0	2	3
Visit in Window (VW)	329	322	317	289	302	166	163	159	148	154
Visit Not in Window (VN)	0	6	7	32	13	0	2	4	15	7
Total Accountability (%)[3]	100.0	99.7	99.1	98.8	98.4	100.0	99.4	98.2	98.8	98.2
1. Expected = all eyes randomized (ITT)										
2. Not Due = not attempted. Attempted but aborted are discontinued by the Form 1 Visit										
3. Total Accountability = (VW+VN)/(E-ND-D) displayed as a percentage.										

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for this type of study performed in the US, as shown in **Table 9**. Those subjects having cataractous natural lenses tend to be 60 years or older in age. Historically, a greater proportion of women enroll in these types of clinical trials. Also, they tend to be dominated by white, non-Hispanic individuals.

Table 9: Subject Demographics (ITT Population)

Characteristic	Statistics	SBL3 (N=333)	Control (N=166)	p-value[1]
Age	n	333	166	
	Mean (Std)	67.7 (7.54)	67.9 (6.94)	0.7583
	Median	68.3	68.8	
	Range	34.6, 88.8	45.2, 82.0	
< 60 yr	n (%)	54 (16.2)	19 (11.4)	0.2681
60 - <70 yr	n (%)	137 (41.1)	78 (47.0)	
≥ 70 yr	n (%)	142 (42.6)	69 (41.6)	
Gender				
Male	n (%)	111 (33.3)	58 (34.9)	0.7209
Female	n (%)	222 (66.7)	108 (65.1)	
Race				
Black or African American	n (%)	20 (6.0)	7 (4.2)	0.1594
American Indian or Alaska Native	n (%)	0 (0.0)	0 (0.0)	
Asian	n (%)	1 (0.3)	0 (0.0)	
Native Hawaiian/Pacific Islander	n (%)	0 (0.0)	0 (0.0)	
White	n (%)	312 (93.7)	157 (94.6)	
Other	n (%)	0 (0.0)	2 (1.2)	
Ethnicity				
Hispanic or Latino	n (%)	11 (3.3)	5 (3.0)	0.8619
Not Hispanic or Latino	n (%)	322 (96.7)	161 (97.0)	

1. **P-value associated with Chi-Square tests for categorical variables, and 2-sample t-tests for continuous variables**
2. **Observed rate % = (N/n)*100**

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the safety cohort of 496 subjects which had the IOL come into contact with the eye (330 in the SBL-3™ group and 166 in the control group). The post-operative adverse event rates are based upon the number of eyes implanted. The key safety outcomes for this study are presented below in Tables 10 to 24.

Adverse effects that occurred in the PMA clinical study:

Cumulative and Persistent Adverse Events- Safety Population- All Eyes

Table 10 outlines the incidences of cumulative and persistent adverse events for the SBL-3™ and Akreos AO (control) monofocal IOL as compared to the ISO 11979-7:2018 for the safety population- All Eyes, the entire study cohort.

The incidence rates of cumulative adverse events for the SBL-3™ compared favorably to the specified ISO SPE (historical control) rates, as the observed rates for SBL-3™ were within or not statistically significantly higher than the specified ISO SPE rates, except for Secondary Surgical Intervention rate which is explained below. There were twelve observed cases of Secondary Surgical Interventions (1.8%; 12/656) which is statistically inferior to the historical control SPE rate. However, only six of the SSI were related to the optical properties of the IOL (0.9%; 6/656). Subsequently, the remaining 6 SSI (0.9%; 6/656) were not related to the IOL optical properties at all and were treatments for SAE's.
The incidence rates of persistent adverse events for the SBL-3™ also compared favorably to the specified ISO SPE rates. There was one case of corneal stromal edema (0.2%; 1/628), however, this rate was not statistically significantly higher than the ISO SPE rate of 0.3%. Furthermore, the SBL-3™ had one case of cystoid macular edema (0.2%; 1/628), and this rate was not statistically significantly higher than the ISO SPE rate of 0.5%

Table 10: Cumulative and Persistent Adverse Events, All Eyes, Safety Population, Primary Safety Endpoint

[a] Per ISO 11979-7 2018 Ophthalmic Implants- Intraocular Lenses (Part 7): The SPE rate is the safety and performance endpoint.

[b] The maximum number of cases that would not be significantly higher than the historical SPE rate, based upon a 1-sided hypothesis test using an alpha of 0.05.

[c] The observed rate for Secondary Surgical Intervention is statistically inferior ($p < 0.05$) to the historical control SPE rate.

[d] Observed rate % = (N/n)*100

	SBL-3™ N=656			Akreos N=332		
ISO[a] SPE Rate (%)	**Max[b] No. of Cases allowed before SPE rate exceeded**	**Observed Number (n)**	**Observed[d] Rate (%)**	**Max[b] No. of Cases allowed before SPE rate exceeded**	**Observed Number (n)**	**Observed Rate (%)**
3	27	13	2	15	9	2.7
0.3	4	0	0	3	0	0
0.1	2	0	0	1	0	0
0.1	2	0	0	1	0	0
0.1	2	1	0.2	1	0	0
0.3	4	1	0.2	3	0	0
0.8	9	12	1.8[c]	6	3	0.9
	SBL-3™ n=628			**Akreos n=322**		
0.3	4	1	0.2	3	0	0
0.5	6	1	0.2	4	0	0
0.3	4	0	0	3	0	0
0.4	5	0	0	3	0	0

Secondary Surgical Intervention Related to Optical Properties of the IOL

The cumulative rate of secondary surgical interventions (SSIs) related to the optical properties of the IOL were reported during the clinical trial. The results are based on the safety population- All Eyes. A total of 6 SBL-3^{TM} SSIs related to and not related to the optical properties of the IOL out of 656 SBL-3^{TM} implanted are shown below in **Tables 11-13.** Two subjects had explants (both eyes for one subject, primary eye for second subject) due to the subjective complaints of dissatisfaction with visual symptoms (or level of vision). Two additional subjects (both eyes for one subject, primary eye for second subject) had IOL rotation due to dissatisfaction with vision (visual disturbances and decreased vision). The confidence interval on the difference in the rates includes zero, and therefore there was no statistically significant difference between the arms in the rates for the SSIs related to optical properties.

Table 11: Secondary Surgical Interventions (SSI) Related to the Optical Properties of the IOL, All Eyes, Safety Population

Eye	Statistic	SBL3^{TM}	Akreos	SBL3^{TM} - Akreos
All Eyes	**N**	**656**	**332**	
	n	6	0	6
	%	0.91	0	0.91
	90% CI	0.40, 1.80	0.00, 0.90	-0.01, 1.76
Percentages are calculated as (n/N)*100;CI=Confidence Interval (exact)				
N and % for treatment difference column are based on observed differences between groups				

There were six (6) SBL-3^{TM} cases of SSI not related to the optical properties of the IOL during this study. The SSIs were treatments for SAE's; there were no SSIs as the original event.

Table 12: Secondary Surgical Interventions (SSI) Not Related to the Optical Properties of the IOL, All Eyes, Safety Population

Secondary Surgical Interventions: Not Device Related	Treatments for SAE's
SBL-3™	Yag iridotomy for pupillary block
SBL-3™	Haptic malposition at surgery lead to IOL repositioning
SBL-3™	Vitrectomy for retinal detachment
SBL-3™	DMEK for corneal edema
SBL-3™	IOL explant for IOL incorrect power
SBL-3™	Yag vitreolysis

Table 13: Characterization of SSI based on the Modified Version of AAO Consensus (Masket, 2017) Safety Population.

All Eyes	Statistic	SBL-3™	Akreos	SBL-3™ - Akreos
Exchange	**N**	**656**	**332**	
	n	1	0	1
	%	0.15	0.00	0.05
	95% CI	0.00, 0.28	0.00, 0.37	-0.05, 0.15
Removal	**N**	**656**	**332**	
	n	3	0	3
	%	0.46	0.00	0.15
	95% CI	0.03, 0.44	0.00, 0.37	-0.02, 0.32
Repositioning	**N**	**656**	**332**	
	n	4	1	3
	%	0.61	0.30	0.10
	95% CI	0.06, 0.52	0.00, 0.56	-0.18, 0.38
	Percentages are calculated as (n/N)*100;CI=Confidence Interval (exact)			
	N and % for treatment difference column are based on observed differences between groups			

Cumulative and Persistent Adverse Events- Safety Population-Primary Eyes

Table 14 outlines the incidences of cumulative and persistent adverse events for the SBL-3™ and Akreos AO (control) monofocal IOL as compared to the ISO 11979-7:2018 for the safety population- Primary Eyes.

The incidence rates of cumulative adverse events for the SBL-3™ (primary eyes) compared favorably to the specified ISO SPE rates, as the observed rates for SBL-3™ were within or not statistically significantly higher than the specified ISO SPE rates, except for Secondary Surgical Intervention rate which is explained below. There were seven observed cases of Secondary Surgical Interventions (2.1%, 7/330) which is statistically inferior to the historical control SPE rate. However, only 3 of the SSI were related to the optical properties of the IOL (0.9%; 3/330) and are discussed below.

The incidence rates of persistent adverse events for the SBL-3™ (primary eyes) also compared favorably to the specified ISO SPE rates. There was one case of cystoid macular edema (0.3%; 1/315), however, this rate was not statistically significantly higher than the ISO SPE rate of 0.5%.

Table 14: Cumulative and Persistent Adverse Events, Primary Eyes, Safety Population, Primary Safety Endpoint

		SBL-3™ N=330			Akreos N=166		
	ISO SPE[a] Rate (%)	Max No. of Cases[b] allowed before SPE rate exceeded	Observed Number (n)	Observed[d] Rate (%)	Max No. of Cases[b] allowed before SPE rate exceeded	Observed Number (n)	Observed[d] Rate (%)
Cumulative Serious Adverse Events							
Cystoid Macular Edema	3	15	7	2.1	9	4	2.4
Hypopyon	0.3	3	0	0	2	0	0
Endophthalmitis	0.1	1	0	0	1	0	0
Lens Dislocated from Posterior Chamber	0.1	1	0	0	1	0	0
Pupillary Block	0.1	1	0	0	1	0	0
Retinal Detachment	0.3	3	1	0.3	2	0	0
SSI (excluding posterior capsulotomy)	0.8	6	7	2.1[c]	3	0	0
Persistent Serious Adverse Events		SBL-3™ N=315			Akreos N=161		
Corneal Stromal Edema	0.3	3	0	0	2	0	0
Cystoid Macular Edema	0.5	4	1	0.3	2	0	0

Iritis	0.3	3	0	0	2	0	0
Raised IOP Requiring Treatment	0.4	3	0	0	2	0	0

[a] Per ISO 11979-7 2018 Ophthalmic Implants- Intraocular Lenses (Part 7): The SPE rate is the safety and performance endpoint.

[b] The maximum number of cases that would not be significantly higher than the historical SPE rate, based upon a 1-sided hypothesis test using an alpha of 0.05.

[c]The observed rate for Secondary Surgical Intervention is statistically inferior ($p < 0.05$) to the historical control SPE rate.

[d] Observed rate % = (N/n)*100

Secondary Surgical Intervention Related to Optical Properties of the IOL-Primary eyes

The cumulative rate of secondary surgical interventions (SSIs) related to the optical properties of the IOL were reported during the clinical trial. The results are based on the safety population- Primary Eyes. A total of 3 SBL-3^{TM} SSIs related to the optical properties of the IOL out of 330 SBL-3^{TM} implanted are shown below in **Table 15**. The confidence interval on the difference in the rates includes zero, and therefore there was no statistically significant difference between the arms in the rates for the SSIs related to optical properties. This confirms a successful outcome.

Table 15: Secondary Surgical Interventions Related to the Optical Properties of the IOL, Primary Eyes, Safety Population

Secondary Surgical Intervention Due to Optical Properties of the IOL Safety Population				
Eye	**Statistic**	**SBL-3^{TM}**	**Akreos**	**SBL-3^{TM} - Akreos**
Primary Eye	**N**	**330**	**166**	
	n	3	0	3
	%	0.91	0	0.91
	90% CI	0.25, 2.33	0.00, 1.79	-0.78, 2.25
Percentages are calculated as (n/N)*100;CI=Confidence Interval (exact)				
N and % for treatment difference column are based on observed differences between groups				

Another characterization of this is provided below in **Table 16**.

Table 16: Supportive Characterization of Secondary Surgical Interventions Based on a Modified Version of AAO Consensus (Masket,2017) Safety Population-Primary Eyes

Primary Eye	Statistic	SBL-3™	Akreos	SBL-3™ - Akreos
Exchange	N	330	166	
	n	1	0	1
	%	0.30	0.00	0.30
	95% CI	0.01, 1.68	0.00, 2.20	-0.29, 0.90
Removal	N	330	166	
	n	1	0	1
	%	0.30	0.00	0.30
	95% CI	0.01, 1.68	0.00, 2.20	-0.29, 0.90
Repositioning	N	330	166	
	n	3	0	3
	%	0.91	0.00	0.91
	95% CI	0.19, 2.63	0.00, 2.20	-0.11, 1.93
Percentages are calculated as (n/N)*100;CI=Confidence Interval (exact)				
N and % for treatment difference column are based on observed differences between groups				

Proportion of Eyes Achieving Best Corrected Distance Visual Acuity (BCDVA) of 0.30 LogMar (or better)

An 'other' supportive safety endpoint was the proportion of SBL-3™ eyes achieving BCDVA 0.3 LogMAR or better vs. ISO 11979-7:2018 (E) SPE (historical control) rate at 6 months and 1 year. Table E.4 historical grid summary for posterior chamber IOLs is presented in Table 15 for both treatment groups by primary eye, fellow eye and all eyes from the safety population for overall post-operative BCDVA 0.30 LogMar or better. **Table 17** is the best-case population. (This is defined as all patients/eyes from the All-Implanted population who have at least one postoperative visit without any clinically significant preoperative pathology or macular degeneration at any time.)

SBL-3™ eyes achieved BCDVA of 0.3 LogMAR or better at 6 months and 1 year exceeding the ISO rates for posterior chamber lenses (92.5% overall), with ranges of 98.1% (6-month primary eyes; 315/321) to 99.7% (1-year fellow eyes; 312/313).

Note: The clinical protocol initially contained an error in the instructions for how to perform the testing for BCDVA. See the discussion below "**Table 38**: Best Corrected Distance Visual Acuity (LogMar) (by analysis population)" in the "Effectiveness Results" section.

Table 17: Rates of Overall Post-Operative BCVA of 0.30 LogMAR or Better relative to Historical Grid noted at any Time, Safety Population

		SBL3				Akreos		
Visual Acuity[1]	**ISO SPE Rate (%)**	**Total (N)**	**Minimum No. of Cases allowed before less than SPE Rate**	**Observed Number (n)**		**Total (N)**	**Minimum No. of Cases allowed before less than SPE Rate**	**Observed Number (n)**
Overall post-operative BCVA 0.3 LogMar or better - Primary Eye								
Visit 4A	92.5	321	289	315		163	145	162
Visit 5A	92.5	315	283	313		161	143	160
Overall post-operative BCVA 0.3 LogMar or better - Fellow Eye								
Visit 4A	92.5	318	286	316		163	145	163
Visit 5A	92.5	313	282	312		161	143	161
Overall post-operative BCVA 0.3 LogMar or better - All Eyes								
Visit 4A	92.5	639	580	631		326	294	325
Visit 5A	92.5	628	570	625		322	290	321
Note: For subjects without a 4A or 5A visit due to early discontinuation, the last available visit after surgery is used.								
Note: % = (n/N)*100								

Table 18 shows best case SBL-3™ eyes achieved BCDVA of 0.30 LogMAR or better at 6 months and 1 year exceeding the ISO rates for posterior chamber lenses (96.7% best-case), with ranges of 98.1% (6-month primary eyes; 314/320) to 99.7% (1-year fellow eyes; 311/312).

Table 18: Rates of Overall Post-Operative BCDVA of 0.30 LogMAR or Better relative to Historical Grid noted at any Time, Best Case

		SBL3				Akreos		
Visual Acuity[1]	**ISO SPE Rate (%)**	**Total (N)**	**Minimum No. of Cases allowed before less than SPE Rate**	**Observed Number (n)**		**Total (N)**	**Minimum No. of Cases allowed before less than SPE Rate**	**Observed Number (n)**
Overall post-operative BCVA 0.3 LogMar or better - Primary Eye								
Visit 4A	96.7	320	304	314		162	153	161
Visit 5A	96.7	314	298	312		160	151	159
Overall post-operative BCVA 0.3 LogMar or better - Fellow Eye								
Visit 4A	96.7	317	301	315		162	153	162
Visit 5A	96.7	312	296	311		160	151	160
Overall post-operative BCVA 0.3 LogMar or better - All Eyes								
Visit 4A	96.7	637	608	629		324	308	323
Visit 5A	96.7	626	598	623		320	304	319
Note: For subjects without a 4A or 5A visit due to early discontinuation, the last available visit after surgery is used.								
Note: % = (n/N)*100								

Eyes Which Lost ≥ 10 Letters of BCDVA Between Postoperative Visits

The following Tables 19-20 present data on the number (and rates) in each arm of those eyes that had a loss of 10 or more letters, both in the all eyes group and the primary eyes group.

Table 19: Eyes which Presented with a Loss of 10 Letters or more- All Eyes

Visit	Finding	SBL3 n (%)	Akreos n (%)	Estimate of Treatment Difference (Diff Prop (SE))	90% CI of Difference	p-value[1]
At Any Visit	**N**	**655**	**332**			
	Loss of ≥ 10 letters in BCDVA between any form evaluation and a prior form visit	51 (7.8)	35 (10.5)	-0.03 (0.020)	-0.06, 0.01	0.1523
Form 4A	**N**	**643**	**326**			
	Loss of ≥ 10 letters in BCDVA between visit and any prior visit	20 (3.1)	11 (3.4)	-0.00 (0.012)	-0.02, 0.02	0.8474
Form 5A	**N**	**628**	**322**			
	Loss of ≥ 10 letters in BCDVA between	31 (4.9)	26 (8.1)	-0.03 (0.017)	-0.06, -0.00	0.0608

	visit and any prior visit					

1. P-value associated with Fisher's Exact Test

Note: Comparisons are between any post-operative visit after 1 month (3A) and any prior visit. Unscheduled visits occurring between visits are counted as occurring at the next scheduled visit.
Note: % = (n/N)*100

At the 1-year post-operative visit, a greater proportion of the control group (8.1%; 26/322) showed this loss in the primary eye than the SBL-3^{TM} group (4.9%; 31/628), but this difference was not significant.

Table 20: Eyes which Presented with a Loss of 10 Letters or More- Primary Eyes

Visit	Finding	SBL3 n (%)	Akreos n (%)	"Estimate of Treatment Difference (Diff Prop (SE))"	90% CI of Difference	p-value[1]
At Any Visit	N	329	166			
	Loss of > 10 letters in BCDVA between any form evaluation and a prior form visit	27 (8.2)	16 (9.6)	-0.01 (0.028)	-0.06, 0.03	0.6138
Form 4A	N	322	163			
	Loss of > 10 letters in BCDVA between visit and any prior visit	9 (2.8)	5 (3.1)	-0.00 (0.017)	-0.03, 0.02	1.0000
Form 5A	N	315	161			
	Loss of > 10 letters in BCDVA between	18 (5.7)	11 (6.8)	-0.01 (0.024)	-0.05, 0.03	0.6865

	visit and any prior visit					

1. P-value associated with Fisher's Exact Test
Note: Comparisons are between any post-operative visit after 1 month (3A) and any prior visit. Unscheduled visits occurring between visits are counted as occurring at the next scheduled visit.

Note: % = (n/N)*100

Similar to the primary eyes, the all eyes data identified that the control group (6.8%; 11/161) had more subjects lose 10 or more letters at the 1-year post-operative visit than the SBL-3^{TM} group (5.7%; 18/315). As with the primary eyes though, this difference was also not significant

Serious Adverse Events of Types Not in the ISO Historical Control

Serious adverse events (of types not in the ISO historial control grid) were also evaluated, as decribed below in **Table 21**.

Table 21: All Serious Non-Grid Rate Adverse Events

All Serious Non-Grid Adverse Events (Safety population - Either Eye)			
Category/Primary Term	SBL-3 (N-330) n (%)	Akreos (N-166) n (%)	P-Value
TOTAL	2 (0.6)	0 (0.0)	0.5538
CORNEAL STROMAL EDEMA	2 (0.6)	0 (0.0)	
EPITHELIOPATHY			
TOTAL	1 (0.3)	0 (0.0)	1.0000
EPITHELIAL DEFECT	1 (0.3)	0 (0.0)	
PUPIL OBSERVATIONS			
TOTAL	1 (0.3)	0 (0.0)	1.0000
PUPILLARY FINDINGS	1 (0.3)	0 (0.0)	
RETINOPATHY			
TOTAL	2 (0.6)	0 (0.0)	0.5538
EPIRETINAL MEMBRANE	1 (0.3)	0 (0.0)	
MACULOPATHY	1 (0.3)	0 (0.0)	
VITREOUS FINDINGS			
TOTAL	0 (0.0)	1 (0.6)	0.3347
SYNERESIS	0 (0.0)	1 (0.6)	

There were no significant differences between the test and control IOLs in this comparison.

Binocular Contrast sensitivity

Figures 5-12 present the secondary safety endpoint binocular contrast sensitivity performed under photopic and mesopic conditions with and without glare. Subjects were measured under photopic conditions with contrast sensitivity monitor luminance being calibrated with the M&S Technologies Spyder

photometer to approximately 85 cd/m^2 and mesopic conditions to approximately 3 cd/m^2 with the use of a neutral density filter.

Figure 5: Contrast Sensitivity Outcomes, Photopic, without Glare at the 6-month Post-operative Visit

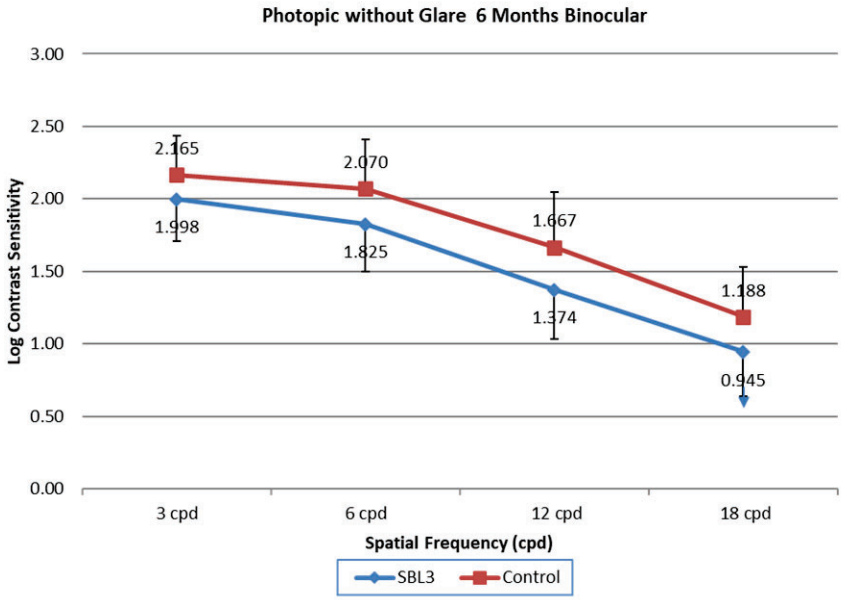


Figure 6: Contrast Sensitivity Outcomes, Photopic, without Glare at the 1-year Post-operative Visit

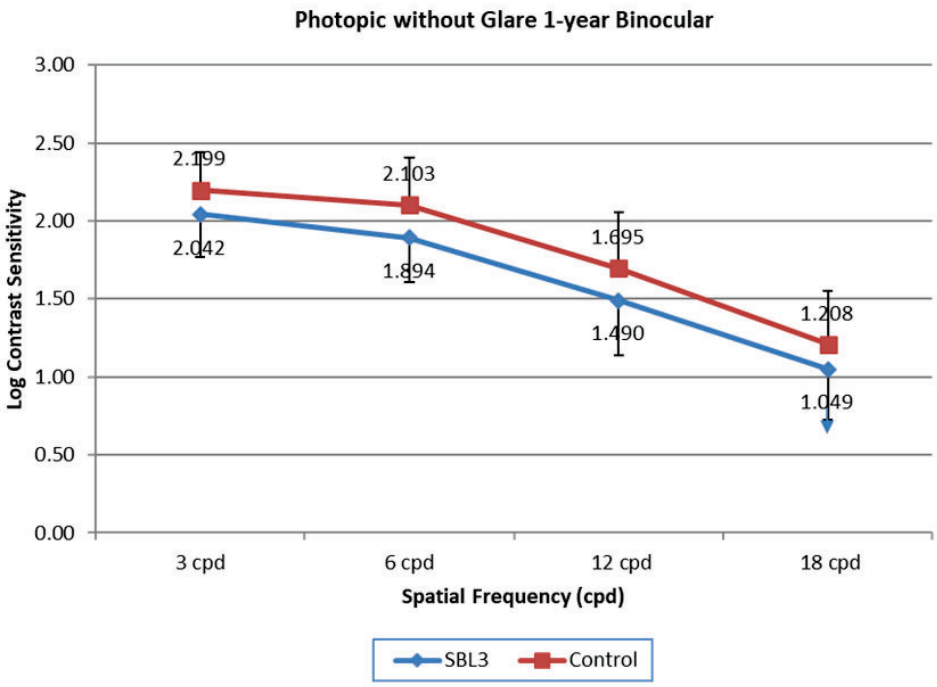


Figure 7: Contrast Sensitivity Outcomes, Photopic, with Glare at the 6-month Post-operative Visit

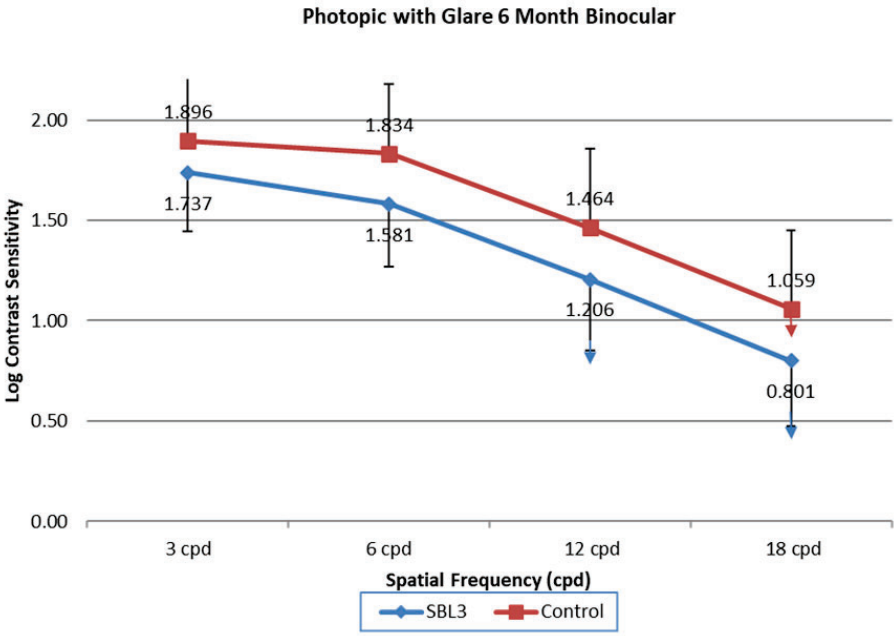


Figure 8: Contrast Sensitivity Outcomes, Photopic, with Glare at the 1-year Post-operative Visit

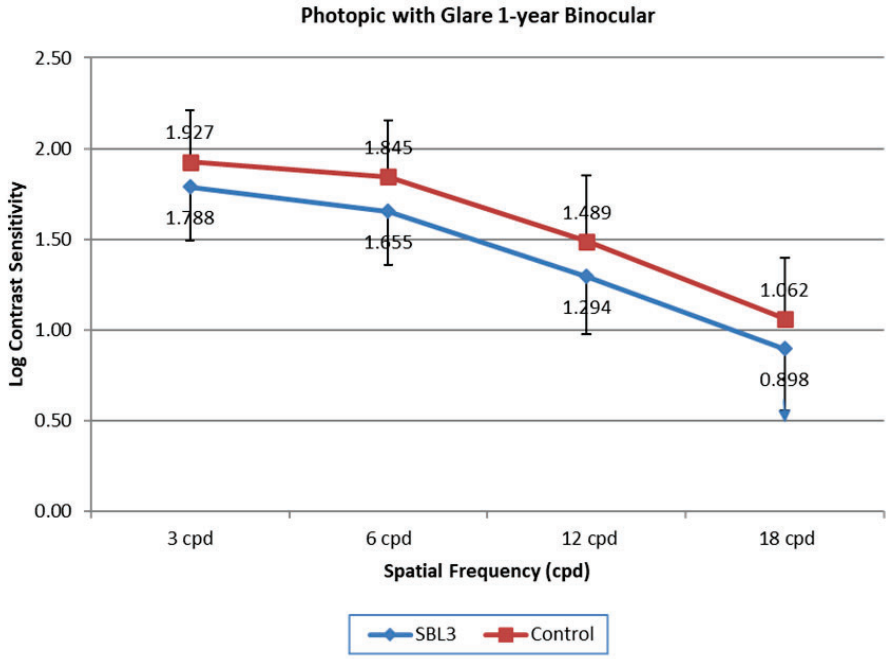


Figure 9: Contrast Sensitivity Outcomes, Mesopic, without Glare at the 6-month Post-operative Visit

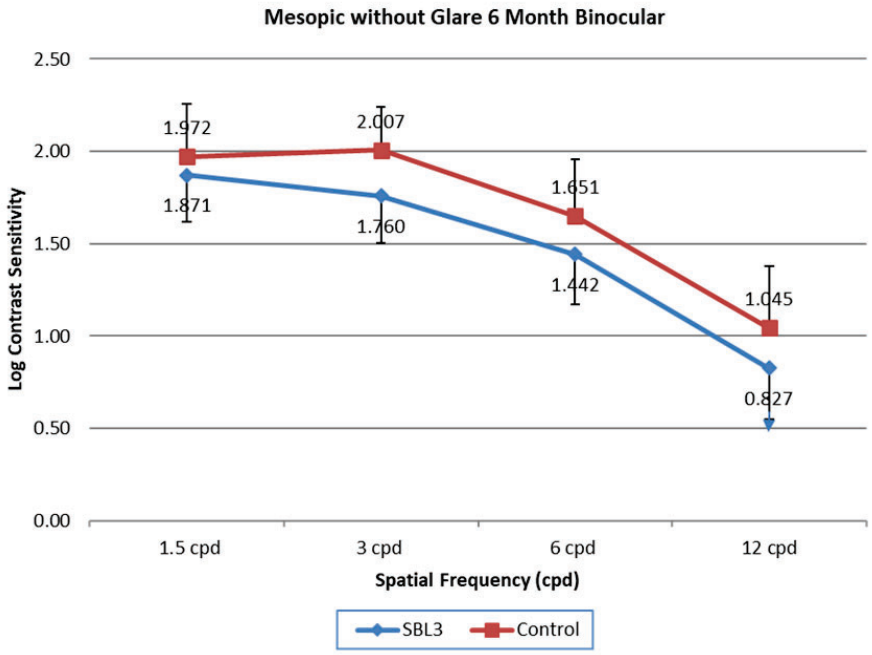


Figure 10: Contrast Sensitivity Outcomes, Mesopic, without Glare at the 1-year Post-operative Visit

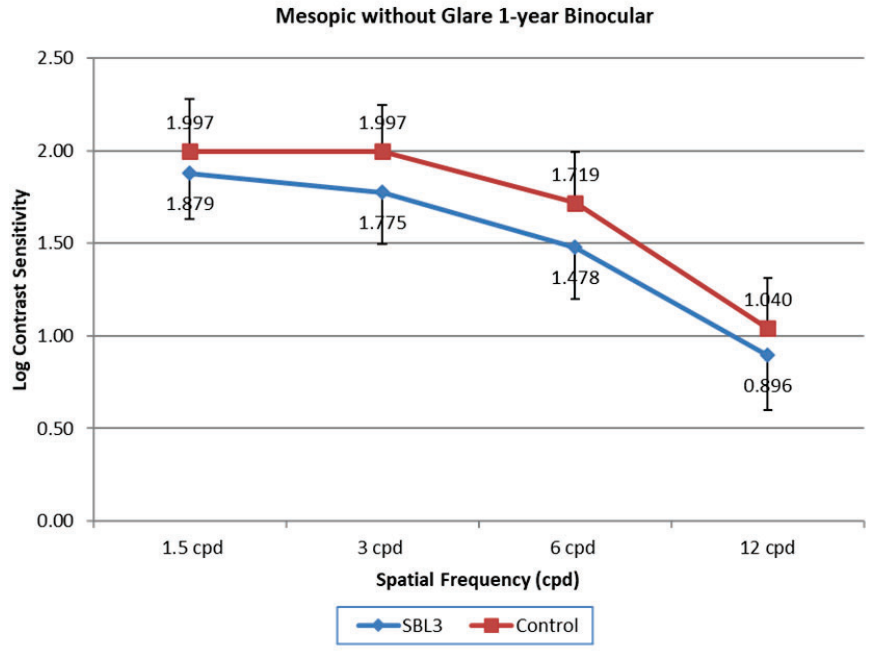


Figure 11: Contrast Sensitivity Outcomes, Mesopic, with Glare at the 6-month Post-operative Visit

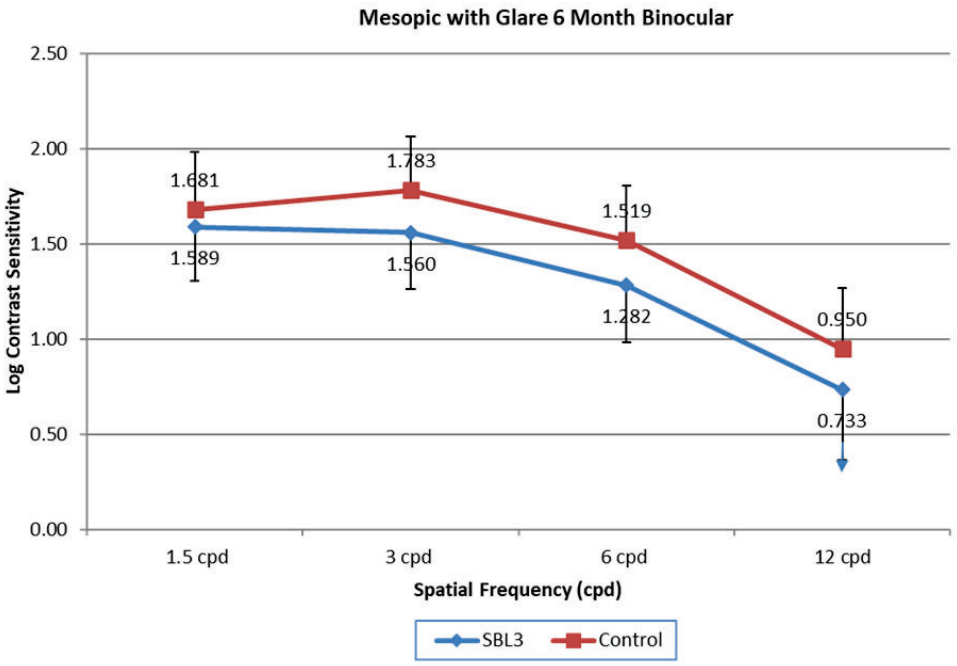
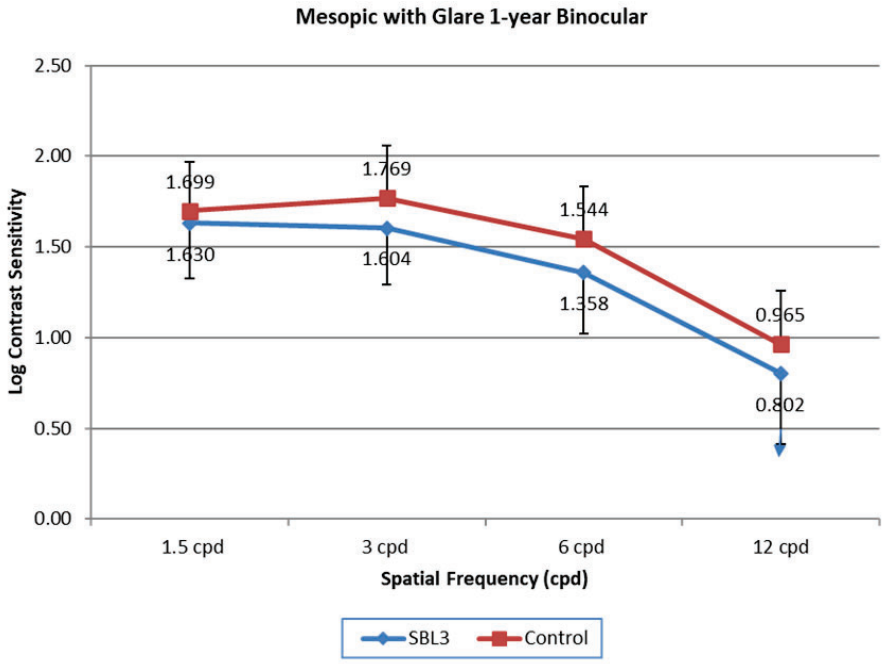


Figure 12: Contrast Sensitivity Outcomes, Mesopic, with Glare at the 1-year Post-operative Visit



Below are descriptions of these outcomes in tabular form.

Table 22: Photopic Contrast Sensitivity Outcomes without and with Glare at the 1-year Post-operative Visit

Spatial Frequency	IOL Model	N	Photopic without Glare			N	Photopic w/Glare		
			Mean	Subjects who did not see the reference pattern			Mean	Subjects who did not see the reference pattern	
				n	%			n	%
1.5	SBL		Not Tested	Not Tested			Not Tested	Not Tested	
	Akreos								
	Difference								
3	SBL	313	2.042	0	0	312	1.788	0	0
	Akreos	158	2.199	0	0	158	1.927	0	0
	Difference		-0.157				-0.139		
6	SBL	313	1.894	0	0	312	1.655	0	0
	Akreos	158	2.103	0	0	158	1.845	0	0
	Difference		-0.209				-0.19		
12	SBL	313	1.49	0	0	312	1.294	0	0
	Akreos	158	1.695	0	0	158	1.489	0	0
	Difference		-0.205				-0.195		
18	SBL	311	1.056	2	0.6	309	0.907	3	1
	Akreos	158	1.208	0	0	158	1.062	0	0
	Difference		-0.152				-0.155		

Note: % = (n/N)*100

Table 23: Mesopic Contrast Sensitivity Outcomes without and with Glare at the 1-year post-operative Visit

Spatial Frequency	IOL Model	N	Mesopic w/o Glare			N	Mesopic w/Glare		
			Mean	Subjects who did not see the reference pattern			Mean	Subjects who did not see the reference pattern	
				n	%			n	%
1.5	SBL	314	1.879	0	0	312	1.63	0	0
	Akreos	158	1.997	0	0	158	1.699	0	0
	Difference		-0.118				-0.069		

3	SBL	314	1.775	0	0	312	1.604	0	0
	Akreos	158	1.997	0	0	158	1.769	0	0
	Difference		-0.222				-0.165		
6	SBL	314	1.478	0	0	312	1.358	0	0
	Akreos	158	1.719	0	0	158	1.544	0	0
	Difference		-0.241				-0.186		
12	SBL	314	0.896	0	0	310	0.808	2	0.6
	Akreos	158	1.04	0	0	158	0.965	0	0
	Difference		-0.144				-0.157		
18	SBL		Not Tested	Not Tested			Not Tested	Not Tested	
	Akreos								

Note: % = (n/N)*100

Tables 22 and 23 show that under photopic and mesopicwithout glare, the mean difference between the SBL-3 and the Akreos AO is 0.181 log units and with glare, 0.140 log units. Under mesopic without glare, the mean difference is 0.181 log units and with glare, 0.144 log units.

Multifocal IOLs generally show somewhat reduced levels of contrast sensitivity compared to monofocal IOLs. All of the differences between the SBL-3^{TM} and control arms for mean contrast sensitivity results, appear to be within within the general levels seen in other studies of marketed multifocal IOLs.

Other Safety Endpoint Outcomes

Visual disturbances

Visual disturbances were assessed using a patient reported outcomes tool, which specifically asked subjects about their experience with blurry vision, vision in dim light, vision in bright light, seeing colors, seeing halos, seeing streaks, seeing glare and seeing double images. Subjects implanted with the SBL-3^{TM} multifocal IOL reported higher rates of "severe" levels for halos, glare, streaks of light and multiple images, than subjects implanted with the monofocal control (See Tables 24 and 25).

The table below describes the outcomes at the pre-operative visit and the 6-month and 1-year post-operative visits.

Table 24: Visual Disturbances Reported by Visit

Visual Disturbance over the past 7 Days at Each Visit Safety Population				
Form 0	SBL-3		Akreos AO	
	N	Mean	N	Mean
Blurry Vision	330	6.27	165	6.44
Dim Light	330	6.14	165	6.44
Bright Light	330	5.74	165	6.61
Colors	330	3.84	165	4.07
Halos	330	5.35	165	5.66
Streaks of Light	330	5.13	165	5.47
Glare	330	6.20	165	6.75
Double Images	330	6.20	165	6.75
Form 4A	SBL-3		Akreos AO	
	N	Mean	N	Mean
Blurry Vision	319	2.83	163	2.16
Dim Light	320	1.81	163	2.07
Bright Light	320	3.56	163	3.71
Colors	320	0.78	163	0.67
Halos	320	2.93	163	1.38
Streaks of Light	320	2.75	163	1.41
Glare	320	3.03	163	1.65
Double Images	320	1.69	163	0.42
Form 5A	SBL-3		Akreos AO	
	N	Mean	N	Mean
Blurry Vision	314	2.43	161	2.43
Dim Light	314	1.69	161	2.03
Bright Light	314	3.30	161	3.43
Colors	314	0.70	161	0.76
Halos	314	2.43	161	1.47

Streaks of Light	314	2.38	161	1.60
Glare	314	2.81	1.61	1.78
Double Images	314	1.42	161	0.49

Subjects reported their visual symptoms on the visual disturbance questionnaire as 'None' (0), 'Mild' (1-3), 'Moderate' (4-6) and 'Severe' (>6). Overall, the rate of test subjects reporting their symptoms as 'none' increased between 4A and 5A for all visual disturbance questions (sensitivity to light remained similar between 4A and 5A) while the control subjects experienced a decreased rate across 7 of the 8 questions posed.

Additionally, the opposite trend was noted for the rate of test subjects reporting their symptoms as 'severe' decrease between 4A and 5A visits for 6 of the 8 visual disturbance questions (with their rates decreasing) while the control group generally showed an increase in severe symptoms for 6 of the 8 visual disturbance questions.

This data was also tabulated for each of the potential responses for each group, at the 4A and 5A visits.

Table 25: Visual Disturbances Data for all Subjects who Responded with each Possible Response Option for each Item

Visual Disturbance Questionnaire (PRO-VDS) at 4A Safety Population			Visual Disturbance Questionnaire (PRO-VDS) at 5A Safety Population		
	SBL3 n (%)	Akreos n (%)		SBL3 n (%)	Akreos n (%)
	Overall	Overall		Overall	Overall
Question 1 Blurry Vision			Question 1 Blurry Vision		
N	319	163	N	314	161
None (0)	86 (26.96)	58 (35.58)	None (0)	99 (31.53)	50 (31.06)
Mild (1-3)	130 (40.75)	68 (41.72)	Mild (1-3)	129 (41.08)	67 (41.61)
Moderate (4-6)	63 (19.75)	24 (14.72)	Moderate (4-6)	49 (15.61)	27 (16.77)

Severe (>6)	40 (12.54)		13 (7.98)	Severe (>6)	37 (11.78)		17 (10.56)
	SBL3 n (%)		Akreos n (%)		SBL3 n (%)		Akreos n (%)
	Overall		Overall		Overall		Overall
Question 2 Difficulty in Low Light				Question 2 Difficulty in Low Light			
N	320		163	N	314		161
None (0)	156 (48.75)		72 (44.17)	None (0)	160 (50.96)		73 (45.34)
Mild (1-3)	101 (31.56)		55 (33.74)	Mild (1-3)	98 (31.21)		55 (34.16)
Moderate (4-6)	37 (11.56)		18 (11.04)	Moderate (4-6)	27 (8.60)		17 (10.56)
Severe (>6)	26 (8.13)		18 (11.04)	Severe (>6)	29 (9.24)		16 (9.94)
	SBL3 n (%)		Akreos n (%)		SBL3 n (%)		Akreos n (%)
	Overall		Overall		Overall		Overall
Question 3 Sensitivity to Bright Light				Question 3 Sensitivity to Bright Light			
N	320		163	N	314		161
None (0)	82 (25.63)		30 (18.40)	None (0)	81 (25.80)		38 (23.60)
Mild (1-3)	101 (31.56)		59 (36.20)	Mild (1-3)	119 (37.90)		59 (36.65)
Moderate (4-6)	64 (20.00)		36 (22.09)	Moderate (4-6)	45 (14.33)		26 (16.15)
Severe (>6)	73 (22.81)		38 (23.31)	Severe (>6)	69 (21.97)		38 (23.60)
	SBL3 n (%)		Akreos n (%)		SBL3 n (%)		Akreos n (%)
	Overall		Overall		Overall		Overall
Question 4 Difficulty to see colors				Question 4 Difficulty to see colors			

N	320		163	N	314		161
None (0)	227 (70.94)		122 (74.85)	None (0)	234 (74.52)		120 (74.53)
Mild (1-3)	71 (22.19)		32 (19.63)	Mild (1-3)	60 (19.11)		27 (16.77)
Moderate (4-6)	12 (3.75)		7 (4.29)	Moderate (4-6)	12 (3.82)		10 (6.21)
Severe (>6)	10 (3.13)		2 (1.23)	Severe (>6)	8 (2.55)		4 (2.48)
	SBL3 n (%)		Akreos n (%)		SBL3 n (%)		Akreos n (%)
	Overall		Overall		Overall		Overall
Question 5 Disruption due to Halos				Question 5 Disruption due to Halos			
N	320		163	N	314		161
None (0)	102 (31.88)		103 (63.19)	None (0)	125 (39.81)		93 (57.76)
Mild (1-3)	119 (37.19)		33 (20.25)	Mild (1-3)	104 (33.12)		43 (26.71)
Moderate (4-6)	42 (13.13)		16 (9.82)	Moderate (4-6)	41 (13.06)		12 (7.45)
Severe (>6)	57 (17.81)		11 (6.75)	Severe (>6)	44 (14.01)		13 (8.07)
	SBL3 n (%)		Akreos n (%)		SBL3 n (%)		Akreos n (%)
	Overall		Overall		Overall		Overall
Question 6 Seeing streaks or rays of light				Question 6 Seeing streaks or rays of light			
N	320		163	N	314		161
None (0)	118 (36.88)		100 (61.35)	None (0)	142 (45.22)		82 (50.93)
Mild (1-3)	106 (33.13)		37 (22.70)	Mild (1-3)	91 (28.98)		55 (34.16)
Moderate (4-6)	37 (11.56)		15 (9.20)	Moderate (4-6)	30 (9.55)		12 (7.45)
Severe (>6)	59 (18.44)		11 (6.75)	Severe (>6)	51 (16.24)		12 (7.45)

	SBL3 n (%)		Akreos n (%)		SBL3 n (%)		Akreos n (%)
	Overall		Overall		Overall		Overall
Question 7 Glare from headlights/streetlights				Question 7 Glare from headlights/streetlights			
N	320		163	N	314		161
None (0)	94 (29.38)		87 (53.37)	None (0)	108 (34.39)		69 (42.86)
Mild (1-3)	120 (37.50)		49 (30.06)	Mild (1-3)	113 (35.99)		67 (41.61)
Moderate (4-6)	47 (14.69)		14 (8.59)	Moderate (4-6)	34 (10.83)		13 (8.07)
Severe (>6)	59 (18.44)		13 (7.98)	Severe (>6)	59 (18.79)		12 (7.45)
	SBL3 n (%)		Akreos n (%)		SBL3 n (%)		Akreos n (%)
	Overall		Overall		Overall		Overall
Question 8 Seeing double or multiple images				Question 8 Seeing double or multiple images			
N	320		163	N	314		161
None (0)	192 (60.00)		139 (85.28)	None (0)	204 (64.97)		134 (83.23)
Mild (1-3)	67 (20.94)		17 (10.43)	Mild (1-3)	62 (19.75)		20 (12.42)
Moderate (4-6)	29 (9.06)		5 (3.07)	Moderate (4-6)	20 (6.37)		5 (3.11)
Severe (>6)	32 (10.00)		2 (1.23)	Severe (>6)	28 (8.92)		2 (1.24)

Note: % = (n/N)*100

The same trends were noted for this tabulation as well. More test subjects reported noticing halo, glare and double images

Fundus Visulation

At the 1-year post-operative visit, the safety population included 628 SBL-3™ eyes and 322 control IOL eyes. In that group, it was noted that the

fundus was adequately visible through the respective IOL optic in 100% (322/322) of either group.

Driving Simulation Substudy

A subgroup of the bilaterally implanted subjects in both groups were put through a driving simulation substudy, to assess functional performance in sign-reading and low-contrast object-detection abilities. The testing was performed using a nighttime driving scenario with a condition that simulates headlight glare. The primary endpoints were reading distance for signs and recognition distance for roadway hazards.

The study found that the ability to safely respond to signs and hazards on the road is similar for both groups in most cases, though the control group reacted sooner than the SBL-3™ group. The worst case was regulatory sign recognition without glare, in which the mean difference was 286.98 feet. There was, however, adequate time to stop for the cone if necessary.

A number of the signs for both lenses have average reading distances of less than the 30 feet per inch of letter height assumed by the Federal Highway Administration, though the control was able to recognize the signs sooner. This is mitigated to some extent by the increase in availability and use of in-vehicle maps and turn-by-turn navigation.

The ability to detect and read signs is similar for both groups under glare conditions. Under the no glare condition, the distance at which guide signs could be read for the SBL-3™ was less than for the control but still allowed the sign to be read before passing it.

Manifest Refraction Spherical Equivalent (MRSE) Fluctuations >1.0D

There were 30 (thirty) instances in which SBL-3™ eyes (vs. 0 control eyes) were found to have a fluctuation of manifest refraction spherical equivalent of >1.0D after the Form 3A (30-60 day post-operative) visit from any prior visit. **Table 26**, below, describes these outcomes.

Table 26: Change in MRSE of >1.0 D after 3A from any Prior Visit (Safety Population) - All Eyes

Visit	Finding	SBL3 n (%)	Akreos n (%)	Estimate of Treatment Difference (Diff Prop [SE])	90% CI of Difference	p-value[1]
At Any Visit	N	645	326			
	> 1.0D Fluctuation in MRSE between any form evaluation and a prior form visit	30 (4.7)	0 (0.0)	0.05 (0.008)	0.03, 0.06	<.0001

Note: % = (n/N)*100

The causes of these changes were often not clear. Some of these eyes with substantial refractive changes had associated significant uncorrected distance acuity changes. Of the 30 SBL-3™ eyes in question, the following levels of changes in UCDVA:

- ≥10 letters (2 lines) change: 12 eyes
- ≥15 letters (3 lines) change: 9 eyes
- ≥20 letters (4 lines) of change: 4 eyes

Unintended Myopic Outcomes

There were a number of instances in which subjects in either study group presented with unintended myopic outcomes. **Table 27**, below, describes these outcomes. Rates of substantial myopic outcomes were substantially higher in the SBL-3™ arm than in the control arm.

Table 27: Distribution of Myopic Results for Different Levels of Postoperative MRSE by Visit (Safety Population)- All Eyes

Visit	Category	SBL3 n (%)	Akreos n (%)
Form 3A	N	648	326
	>=0 D	319 (49.2)	221 (67.8)
	-0.5 - < 0 D	238 (36.7)	97 (29.8)
	-1.0 - < -0.5 D	67 (10.3)	8 (2.5)
	-1.5 - < -1.0 D	19 (2.9)	0 (0.0)
	-2.0 - < -1.5 D	3 (0.5)	0 (0.0)
	-2.5 - < -2.0 D	0 (0.0)	0 (0.0)
	-3.0 - < -2.5 D	2 (0.3)	0 (0.0)
	-3.5 - < -3.0 D	0 (0.0)	0 (0.0)
	-4.0 - < -3.5 D	0 (0.0)	0 (0.0)
	< -4.0 D	0 (0.0)	0 (0.0)
Form 4A	N	639	326
	>=0 D	327 (51.2)	244 (74.8)
	-0.5 - < 0 D	232 (36.3)	78 (23.9)
	-1.0 - < -0.5 D	62 (9.7)	4 (1.2)
	-1.5 - < -1.0 D	13 (2.0)	0 (0.0)
	-2.0 - < -1.5 D	2 (0.3)	0 (0.0)
	-2.5 - < -2.0 D	3 (0.5)	0 (0.0)
	-3.0 - < -2.5 D	0 (0.0)	0 (0.0)
	-3.5 - < -3.0 D	0 (0.0)	0 (0.0)
	-4.0 - < -3.5 D	0 (0.0)	0 (0.0)
	< -4.0 D	0 (0.0)	0 (0.0)
Form 5A	N	628	322
	>=0 D	343 (54.6)	254 (78.9)
	-0.5 - < 0 D	221 (35.2)	65 (20.2)
	-1.0 - < -0.5 D	47 (7.5)	3 (0.9)
	-1.5 - < -1.0 D	10 (1.6)	0 (0.0)
	-2.0 - < -1.5 D	6 (1.0)	0 (0.0)
	-2.5 - < -2.0 D	0 (0.0)	0 (0.0)
	-3.0 - < -2.5 D	1 (0.2)	0 (0.0)
	-3.5 - < -3.0 D	0 (0.0)	0 (0.0)
	-4.0 - < -3.5 D	0 (0.0)	0 (0.0)
	< -4.0 D	0 (0.0)	0 (0.0)

Note: % = (n/N)*100

IOL Rotational Stability

The SBL-3™ was implanted so that the near segment was oriented with an inferonasal position. To ensure this, a visual line was drawn across the transition zone of the IOL and this line was to intersect an axis between 41° to 49° and 221° to 229° for the right eye and 131° to 139° and 311° to 319° for the left eye. Below are the results of the rotational stability for the right and left eyes (Tables 28 and 29). It is worth noting that all subjects/eyes (2 subjects/3 eyes) who underwent an SSI of IOL rotation have been excluded from this analysis. In addition to the eyes that had these SSIs, several other eyes showed substantial IOL rotation over time.

Table 28: SBL-3 IOL Rotation at Each Visit: Right Eye

SBL3 IOL Rotation at Each Visit **Right Eyes** **Safety Population**				
Visit	**Statistic**	**Surgery**	**Visit**	**Change from Surgery to Visit**
Visit 1	N	326	326	326
	Mean (Std)	45.42 (7.523)	46.56 (11.65)	1.85 (8.868)
	Std Err	0.42	0.65	0.49
	Median	45	45	0
	Range	35.00,145.0	38.00,163.0	0.00,118.0
Rotation > 15	n (%)			3 (0.92)
Rotation > 30	n (%)			3 (0.92)
Rotation > 45	n (%)			2 (0.61)
Rotation > 60	n (%)			2 (0.61)
Visit 2	N	324	324	324
	Mean (Std)	45.42 (7.546)	46.73 (12.71)	2.21 (10.15)
	Std Err	0.42	0.71	0.56
	Median	45	45	0
	Range	35.00,145.0	35.00,160.0	0.00,115.0
Rotation > 15	n (%)			7 (2.15)
Rotation > 30	n (%)			5 (1.53)
Rotation > 45	n (%)			3 (0.92)
Rotation > 60	n (%)			3 (0.92)
Visit 3A	n	322	322	322
	Mean(Std)	45.42 (7.569)	46.48 (12.47)	2.34 (9.627)
	Std Err	0.42	0.7	0.54

	Median	45	45	0
	Range	35.00,145.0	33.00,161.0	0.00,116.0
Rotation > 15	n (%)			4 (1.24)
Rotation > 30	n (%)			4 (1.24)
Rotation > 45	n (%)			3 (0.93)
Rotation > 60	n (%)			2 (0.62)
Visit 4A	N	318	318	318
	Mean(Std)	45.43 (7.617)	46.27 (10.94)	1.93 (7.673)
	Std Err	0.43	0.61	0.43
	Median	45	45	0
	Range	35.00,145.0	34.00,161.0	0.00,116.0
Rotation > 15	n (%)			3 (0.94)
Rotation > 30	n (%)			3 (0.94)
Rotation > 45	n (%)			2 (0.63)
Rotation > 60	n (%)			1 (0.31)
Visit	**Statistic**	**Surgery**	**Visit**	**Change from Surgery to Visit**
Visit 5A	n	312	312	312
	Mean(Std)	45.44 (7.689)	46.40 (11.33)	2.00 (7.837)
	Std Err	0.44	0.64	0.44
	Median	45	45	0
	Range	35.00,145.0	30.00,160.0	0.00,115.0
Rotation > 15	n (%)			4 (1.28)
Rotation > 30	n (%)			3 (0.96)
Rotation > 45	n (%)			2 (0.64)
Rotation > 60	n (%)			1 (0.32)
Endpoint[2]	n	326	326	326
	Mean(Std)	45.42 (7.523)	46.29 (11.21)	2.13 (7.790)
	Std Err	0.42	0.62	0.43
	Median	45	45	0
	Range	35.00,145.0	30.00,160.0	0.00,115.0
Rotation > 15	n (%)			4 (1.23)
Rotation > 30	n (%)			3 (0.92)
Rotation > 45	n (%)			2 (0.61)
Rotation > 60	n (%)			1 (0.31)

Note: The change is the absolute value of the difference between these two values.

1. P-value from paired t-test
2. 2. Endpoint is the last available IOL observation with at an IOL Tilt assessment

Note: % = (n/N)*100

The right eye showed a maximum mean change from surgery of 2.34° which occurred at the 3A Form visit. The level of rotation was stratified by >15°, >30°, >45° and >60° from initial surgery for each visit. The largest rotation for >15° was Visit 2, °, >30° was Visit 2, >45° was Visit 3 and >60° was Visit 2. The above analysis excludes one (1) eye that underwent a Secondary Surgical Procedure of an IOL rotation.

Table 29: SBL-3 IOL Rotation at Each Visit: Left Eye

SBL3 IOL Rotation at Each Visit **Left Eyes** **Safety Population**				
Visit	**Statistic**	**Surgery**	**Visit**	**Change from Surgery to Visit**
Visit 1	N	321	321	321
	Mean(Std)	134.3 (8.266)	134.1 (12.73)	2.11 (9.492)
	Std Err	0.46	0.71	0.53
	Median	135	135	0
	Range	45.00,145.0	35.00,164.0	0.00,100.0
Rotation > 15	n (%)			7 (2.15)
Rotation > 30	n (%)			3 (0.92)
Rotation > 45	n (%)			3 (0.92)
Rotation > 60	n (%)			3 (0.92)
Visit 2	n	325	325	325
	Mean(Std)	134.3 (8.215)	134.3 (11.99)	2.23 (8.309)
	Std Err	0.46	0.67	0.46
	Median	135	135	0
	Range	45.00,145.0	37.00,156.0	0.00,98.00
Rotation > 15	n (%)			10 (3.08)

Rotation > 30	n (%)			2 (0.62)
Rotation > 45	n (%)			2 (0.62)
Rotation > 60	n (%)			2 (0.62)
Visit 3A	N	321	321	321
	Mean(Std)	134.3 (8.266)	135.1 (13.61)	2.68 (10.50)
	Std Err	0.46	0.76	0.59
	Median	135	135	0
	Range	45.00,145.0	43.00,225.0	0.00,92.00
Rotation > 15	n (%)			7 (2.17)
Rotation > 30	n (%)			4 (1.24)
Rotation > 45	n (%)			4 (1.24)
Rotation > 60	n (%)			4 (1.24)
Visit 4A	n	319	319	319
	Mean(Std)	134.3 (8.291)	134.9 (10.47)	1.99 (6.199)
	Std Err	0.46	0.59	0.35
	Median	135	135	0
	Range	45.00,145.0	45.00,225.0	0.00,90.00
Rotation > 15	n (%)			6 (1.88)
Rotation > 30	n (%)			1 (0.31)
Rotation > 45	n (%)			1 (0.31)
Rotation > 60	n (%)			1 (0.31)
Visit 5A	N	313	313	313
	Mean(Std)	134.3 (8.367)	134.3 (11.08)	2.20 (7.034)
	Std Err	0.47	0.63	0.4
	Median	135	135	0

	Range	45.00,145.0	32.00,156.0	0.00,103.0
Rotation > 15	n (%)			7 (2.24)
Rotation > 30	n (%)			1 (0.32)
Rotation > 45	n (%)			1 (0.32)
Rotation > 60	n (%)			1 (0.32)
Endpoint[2]	N	326	326	326
	Mean(Std)	134.3 (8.202)	134.4 (10.86)	2.15 (6.910)
	Std Err	0.45	0.6	0.38
	Median	135	135	0
	Range	45.00,145.0	32.00,156.0	0.00,103.0
Rotation > 15	n (%)			7 (2.15)
Rotation > 30	n (%)			1 (0.31)
Rotation > 45	n (%)			1 (0.31)
Rotation > 60	n (%)			1 (0.31)

Note: The change is the absolute value of the difference between these two values.
1. P-value from paired t-test
2. Endpoint is the last available IOL observation with at an IOL Tilt assessment
Note: % = (n/N)*100

The left eye showed a maximum mean change from surgery of 2.68° which occurred at the 3A Form visit. The level of rotation was stratified by >15°, >30°, >45° and >60° from initial surgery for each visit. The largest rotation for >15° was Visit 2, °, >30° was Visit 3, >45° was Visit 3 and >60° was Visit 3. The above analysis excludes two (2) eyes that underwent a Secondary Surgical Procedure of an IOL rotation.

Intraocular pressure (IOP) Changes

The **Table 30**, below, describes the rate of clinically significant changes in IOP during the course of the clinical trial (as per Masket S, et al.; see references).

Table 30: IOP Changes Over Time

Visit		Statistic[1]	SBL3	Akreos
After Operative and up to Form 1	Increased by 10mmHg	O n/N (%)	35 35/655 (5.34)	20 20/331 (6.04)
After Form 1 and up to Form 2	Increased by 10mmHg	O n/N (%)	5 5/654 (0.76)	1 1/331 (0.30)
After Form 2 and up to Form 3A	Increased by 10mmHg	O n/N (%)	3 3/646 (0.46)	1 1/326 (0.31)
At Any time through 3A	Increased by 10mmHg	O n/N (%)	43 41/655 (6.26)	22 21/332 (6.33)
Note: All occurrences of IOP increases of >= 10mmHg were before Form 3A.				
1. O = Number Occurrences, n = number of eyes with increases, N = total number of eyes represented in that interval.				

In **Table 30** , the following are noted:

The number of instances of IOP increase were similar between both groups. It was worth noting that there was no occurrence fitting this table which happened at the Form 3A or later.

In a small number of cases, IOP was required to be reduced using ocular decompression (or 'wound burp'), in which the surgeon presses a small instrument on the posterior lip of the paracentesis causing some amount of aqueous fluid or viscoelastic to be released, and thereby allowing the IOP to rapidly decrease. The SBL-3^{TM} group had 1 instance (1/656 total SBL-3^{TM} implanted= 0.15%) whereas the control group had 4 (4/332 total control implanted= 1.2%). No subject which underwent this procedure had any associated adverse reaction.

Lens Findings

There were five (5) IOL observations noted during the study, in the form of decentration for the SBL-3^{TM} group and two (2) for the Akreos AO group as shown in **Table 31**, below. There were no discoloration, opacities, deposits or tilt

noted for the SBL-3™ group. The two IOL observations noted for the Akreos AO group were for optic opacities. This was however an error and was mistakenly marked in reference to posterior capsule opacity.

There were nine (9) eyes (1.4%; 9/655) of the SBL-3™ group that were identified as to not having the near add segment placed with an inferonasal orientation.

Table 31: IOL Observations Noted Post-operatively, All Eyes

Observation	Statistic	SBL3	Akreos	Estimate of Treatment Difference	90% CI of Difference
N		655	332		
Any Observation	n (%)	5 (0.8)	2 (0.6)	0.00 (0.005)	-0.01, 0.01
IOL Opacities	n (%)	0 (0.0)	2 (0.6)	-0.01 (0.004)	-0.01, 0.00
IOL Optic Discoloration	n (%)	0 (0.0)	0 (0.0)		
Deposits on IOL	n (%)	0 (0.0)	0 (0.0)		
IOL Tilt > 10º	n (%)	0 (0.0)	0 (0.0)		
Optic Decentration > 0.5mm	n (%)	5 (0.8)	0 (0.0)	0.01 (0.003)	0.00, 0.01
Near Add still placed infero-nasal?					
Yes	n(%)	619 (98.6)			
No	n(%)	9 (1.4)			

Note: % = (n/N)*100

Cumulative Rate of YAG Capsulotomy

Those eyes having a YAG capsulotomy prior to and/or on the date of their Form 5 visit
was 48.4% for the SBL-3 and 29.3% (90% CI 0.13, 0.24) for the control lens.

Surgical Problems

Table 32 describes surgical problems and procedures encountered in the pivotal trial.

Table 32: Summary of Surgery Problems and Procedures

Summary of Surgery Problems and Procedures ITT Population - Primary Eyes			
Category	**Sub-Category**	**SBL3 (N=333) n (%)**	**Akreos (N=166) n (%)**
Due to Surgical Procedure	Iris Damage	1 (0.30)	0 (0.00)
	Zonular Damage	3 (0.90)	0 (0.00)
	IOL Damage	3 (0.90)	1 (0.60)
	Wound Leak	2 (0.60)	1 (0.60)
	Surgeon Error	3 (0.90)	0 (0.00)
	Anterior Chamber Bleeding	0 (0.00)	0 (0.00)
	Anterior Capsule Rent	0 (0.00)	1 (0.60)
	Posterior Capsular Damage	4 (1.20)	0 (0.00)
	Corneal Abrasion	1 (0.30)	0 (0.00)
Due to Subject Physiology	Decentered Pupil	0 (0.00)	0 (0.00)
Intraoperative Explants	Explantation of IOL	2 (0.60)	0 (0.00)
Summary of Surgery Problems and Procedures ITT Population - Fellow Eyes			
Category	**Sub-Category**	**SBL3 (N=333) n (%)**	**Akreos (N=166) n (%)**
Due to Surgical Procedure	Iris Damage	3 (0.90)	0 (0.00)
	Zonular Damage	0 (0.00)	4 (2.41)
	IOL Damage	1 (0.30)	3 (1.81)
	Wound Leak	1 (0.30)	0 (0.00)
	Surgeon Error	0 (0.00)	0 (0.00)
	Anterior Chamber Bleeding	1 (0.30)	0 (0.00)
	Anterior Capsule Rent	0 (0.00)	0 (0.00)

	Posterior Capsular Damage	0 (0.00)	2 (1.20)
	Corneal Abrasion	1 (0.30)	0 (0.00)
Due to Subject Physiology	Decentered Pupil	1 (0.30)	0 (0.00)
Intraoperative explants	Explantation of IOL	2 (0.60)	0 (0.00)
Summary of Surgery Problems and Procedures ITT Population - All Eyes			
Category	**Sub-Category**	**SBL3 (N=666)** n (%)	**Akreos (N=332)** n (%)
Due to Surgical Procedure	Iris Damage	4 (0.60)	0 (0.00)
	Zonular Damage	3 (0.45)	4 (1.20)
	IOL Damage	4 (0.60)	4 (1.20)
	Wound Leak	3 (0.45)	1 (0.30)
	Surgeon Error	3 (0.45)	0 (0.00)
	Anterior Chamber Bleeding	1 (0.15)	0 (0.00)
	Anterior Capsule Rent	0 (0.00)	1 (0.30)
	Posterior Capsular Damage	4 (0.60)	2 (0.60)
	Corneal Abrasion	2 (0.30)	0 (0.00)
Due to Subject Physiology	Decentered pupil	1 (0.15)	0 (0.00)
Intraoperative explants	Explantation of IOL	4 (0.60)	0 (0.00)

Each group had a number of surgical problems. In primary eyes, posterior capsule damage (1.2%; 4/333) was the largest proportion for the SBL-3™ group. In fellow eyes, the largest proportion of problems involved iris damage (0.9%; 1/333). In all eyes, iris damage, IOL damage and posterior

capsule damage shared the highest occurrence rate (0.60%; 2/333). In the control's primary eyes, IOL damage, wound leak and anterior capsular rhent shared the highest occurrence rate (0.60%; 2/333). In fellow eyes, the largest proportion of problems involved zonular damage (2.41%; 4/166). In all eyes, zonular damage and IOL damage shared the highest occurrence rate (1.20%; 2/166).

Device Deficiencies

During the trial, the investigators were required to report device deficiencies to the sponsor. Device Deficiencies included any lens that was not successfully implanted or a lens that was returned after an explant. All SBL-3^{TM} lenses returned underwent an investigation as required by the quality management system. No product or manufacturing issues were found. Back up lenses were provided and used in the cases were required. No patient injury was recorded for any device returned. **Table 33** reflects the number of devices returned and reasons.

Table 33: Device Deficiencies Reported

Reason Returned (Device Deficiency)	**SBL-3**	**Akreos AO (Control)**
Loading Error	7	1
Lens Damage (broken haptic, debris, haptic issue)	1	2
Opened in Error	3	0

Subjects that Dropped Out of Study

Twenty-four (24) subjects left the study early: nineteen (19) in the SBL-3^{TM} groups and five (5) in the control group. These subjects left for the following reasons:

In the SBL-3^{TM} groups, two (2) subjects discontinued under their own will and decided to be followed up for safety only. This had to do with an SSIs in both cases. Five (5) were lost to follow up and never responded to a number of attempts made to have them return for follow up visits. None of these had an AE associated with the discontinuation. Four (4) subjects decided they did not want to continue participation at all, with no reasons provided. Three (3) subjects passed away during the trial, unrelated to the

study article. Three (3) subjects met all inclusion and exclusion criteria, but had intraoperative complications which excluded them from participation in the trial (damaged capsular bag, zonular damage during phacoemulsification). These subjects received approved, non-study IOLs. One (1) subject had unsuccessful implantation of a study lens, in which the surgeon failed in the attempt to implant the IOL. That subject received an approved, non-study IOL. One (1) subject opted to have their study IOLs explanted by a non-study surgeon and remove themself from the study.

In the control group, three (3) subjects were lost to follow up and never responded to a number of attempts made to have them return for follow up visits. None had an AE associated with this discontinuation. One (1) subject decided that they did not want to continue participation. Finally, one (1) subject passed away during the trial, and the death was unrelated to the study article.

2. Effectiveness Results

The analysis of effectiveness was (primarily) based on 475 evaluable patients at the 1-year post-operative study visit. Key effectiveness outcomes are presented in **Tables 34 to 41 and Figures 13 to 15**.

Primary effectiveness endpoints

The first primary effectiveness endpoint was associated with photopic monocular Distance Corrected Near Visual Acuity (DCNVA) at 40 cm for the first implanted eye at visit 5A (ITT Population). Table 33, below, has specific results.

Table 34: Distance Corrected Near Visual Acuity (LogMar) at 5A - (by Analysis Population)

Population	Statistic	SBL3	Control	p-value[1]
ITT Population[2]	N	314	161	<.0001
	Mean (Std)	0.109 (0.124)	0.569 (0.175)	
	Std Error	0.007	0.014	
	Median	0.100	0.600	
	Range	-0.120, 1.000	0.100, 1.000	
All Implanted Population	N	314	161	<.0001
	Mean (Std)	0.109 (0.124)	0.569 (0.175)	
	Std Error	0.007	0.014	
	Median	0.100	0.600	
	Range	-0.120, 1.000	0.100, 1.000	
Best Case Population	N	313	160	<.0001
	Mean (Std)	0.108 (0.124)	0.570 (0.175)	
	Std Error	0.007	0.014	
	Median	0.100	0.600	
	Range	-0.120, 1.000	0.100, 1.000	
Per Protocol Population	N	313	160	<.0001
	Mean (Std)	0.109 (0.124)	0.569 (0.176)	
	Std Error	0.007	0.014	
	Median	0.100	0.590	
	Range	-0.120, 1.000	0.100, 1.000	
1. P-value associated with a 2-sample t-test				
2. The ITT Population is the primary analysis population				

The SBL-3™ was found to be statistically superior to the control in this endpoint ($p<0.0001$). The mean visual acuity in the SBL-3™ group was 0.109 LogMar (~20/25 Snellen equivalent) while the control group was

0.569 LogMar (~20/80 Snellen equivalent). This difference, 0.46 LogMar, represents **23** letters on the vision chart or **4.6 lines** on the vision chart. This represents a clinically meaningful difference. Similar levels of statistical and clinically meaningful levels of difference were seen in each available population. Cumulative monocular DCNVA is presented in **Figure 13**, below.

Figure 13: Cumulative Monocular DCNVA at 1-year Post-operative Visit (All Implanted Population)

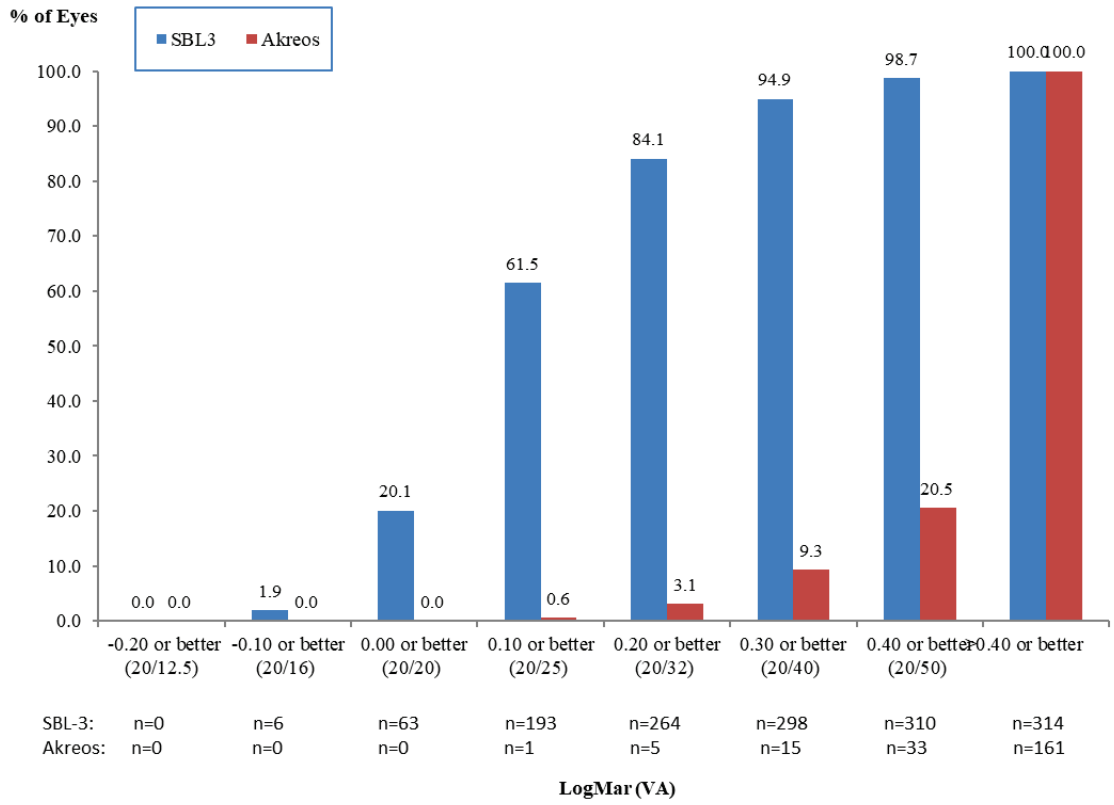


Table 35, below, corresponds to Figure 13, above. It provides the sample sizes and rates described in the Figure 13 .

Table 35: Cumulative Monocular DCNVA at 1-year Post-operative Visit (All Implanted Population)

Parameter	Statistic	SBL3	Akreos
Primary Eye			
At 40 cm (LogMar)	**N**	314	161
-0.2 or better (20/12.5)	n (%)	0 (0.0)	0 (0.0)
-0.1 or better (20/16)	n (%)	6 (1.9)	0 (0.0)
0.0 or better (20/20)	n (%)	63 (20.1)	0 (0.0)
0.1 or better (20/25)	n (%)	193 (61.5)	1 (0.6)
0.2 or better (20/32)	n (%)	264 (84.1)	5 (3.1)
0.3 or better (20/40)	n (%)	298 (94.9)	15 (9.3)
0.4 or better (20/50)	n (%)	310 (98.7)	33 (20.5)
> 0.4 or better	n (%)	314 (100.0)	161 (100.0)
Note: % = (n/N)*100			

The difference shown here also demonstrated clinical meaningful improvement in the SBL-3 group. For example, 61.5% (193/314) of SBL-3 subjects were able to read the 0.10 LogMar (20/25 Snellen equivalent) line or better, whereas the control group was only able to see the same line in 0.6% (1/161) of cases.

The second primary effectiveness endpoint was associated with photopic monocular Distance Corrected Intermediate Acuity (DCIVA) at 70 cm for the first implanted eye at visit 5A (ITT Population). **Table 36**, below, has specific results.

Table 36: Distance Corrected Intermediate Visual Acuity (LogMar) at 5A - (by Analysis Population)

Population	Statistic	SBL3	Control	Difference (SBL3 - Control)	90% CI[1]
ITT Population[2]	N	315	161		
	Mean (Std)	0.120 (0.139)	0.301 (0.151)	-0.181 (0.143)	-0.204, -0.158
	Std Error	0.008	0.012	0.014	
	Median	0.1	0.3		
	Range	-0.160, 0.900	-0.060, 0.700		
All Implanted Population	N	315	161		
	Mean (Std)	0.120 (0.139)	0.301 (0.151)	-0.181 (0.143)	-0.204, -0.158
	Std Error	0.008	0.012	0.014	
	Median	0.1	0.3		
	Range	-0.160, 0.900	-0.060, 0.700		
Best Case Population	N	314	160		
	Mean (Std)	0.120 (0.139)	0.301 (0.151)	-0.181 (0.144)	-0.204, -0.158
	Std Error	0.008	0.012	0.014	
	Median	0.1	0.3		
	Range	-0.160, 0.900	-0.060, 0.700		
Per Protocol Population	N	314	160		
	Mean (Std)	0.120 (0.140)	0.302 (0.151)	-0.182 (0.143)	-0.205, -0.159
	Std Error	0.008	0.012	0.014	
	Median	0.1	0.3		
	Range	-0.160, 0.900	-0.060, 0.700		

1. 2-sided confidence interval based on a normal distribution. The upper bound will be compared to 0.1
non-inferiority margin.

2. The ITT Population is the primary analysis population

As the statistical endpoint was seeking non-inferiority, it is obvious the SBL-3™ is not worse than the control for visual acuity for intermediate. Cumulative monocular DCIVA is presented in **Figure 14**, below.

Figure 14: Cumulative Monocular DCIVA at 1-year Post-operative Visit (All Implanted Population

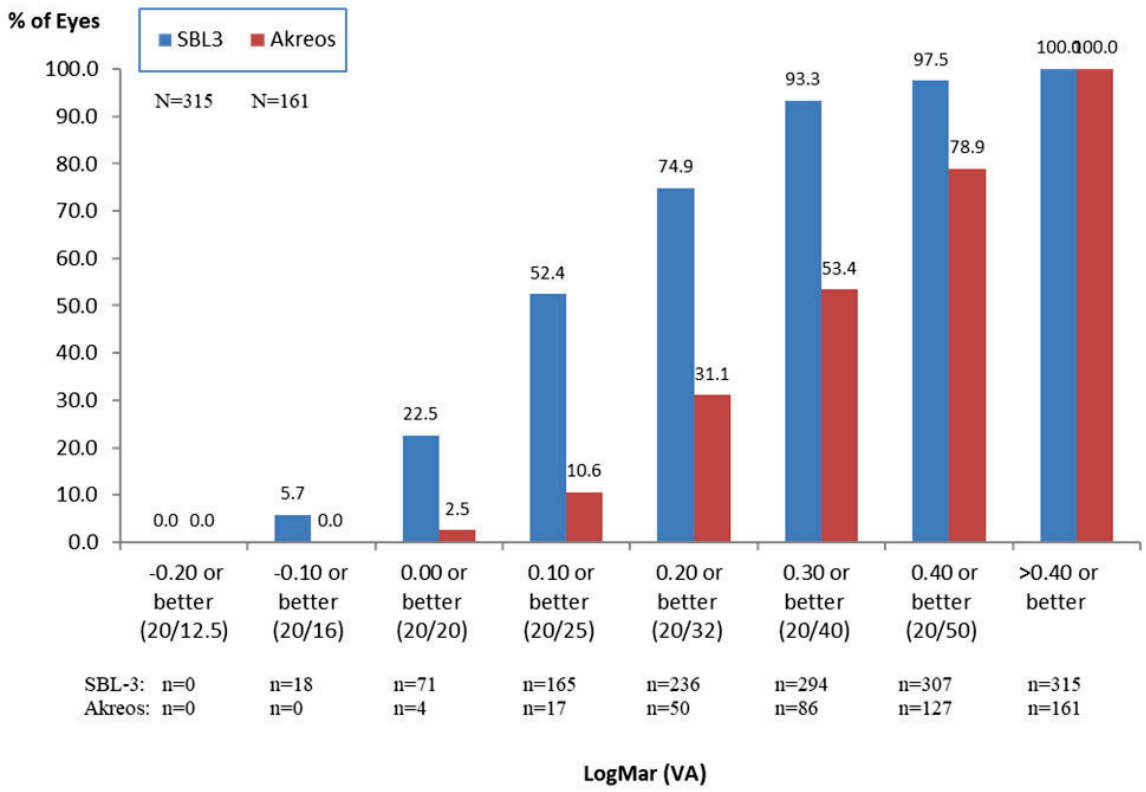


Table 37, below, corresponds to **Figure 14**, above. It provides the sample sizes and rates described in the figure.

Table 37: Cumulative Monocular DCIVA at 1-year Post-operative Visit (All Implanted Population)

Parameter	Statistic	SBL3	Akreos
Primary Eye (LogMar)	**N**	**315**	**161**
-0.2 or better (20/12.5)	n (%)	0 (0.0)	0 (0.0)
-0.1 or better (20/16)	n (%)	18 (5.7)	0 (0.0)
0.0 or better (20/20)	n (%)	71 (22.5)	4 (2.5)
0.1 or better (20/25)	n (%)	165 (52.4)	17 (10.6)
0.2 or better (20/32)	n (%)	236 (74.9)	50 (31.1)
0.3 or better (20/40)	n (%)	294 (93.3)	86 (53.4)
0.4 or better (20/50)	n (%)	307 (97.5)	127 (78.9)
> 0.4 or better	n (%)	315 (100.0)	161 (100.0)
Note: % = (n/N)*100			

The third primary effectiveness endpoint was associated with photopic monocular BCDVA for the first implanted eye at visit 5A (ITT Population). **Table 38**, below, has specific results.

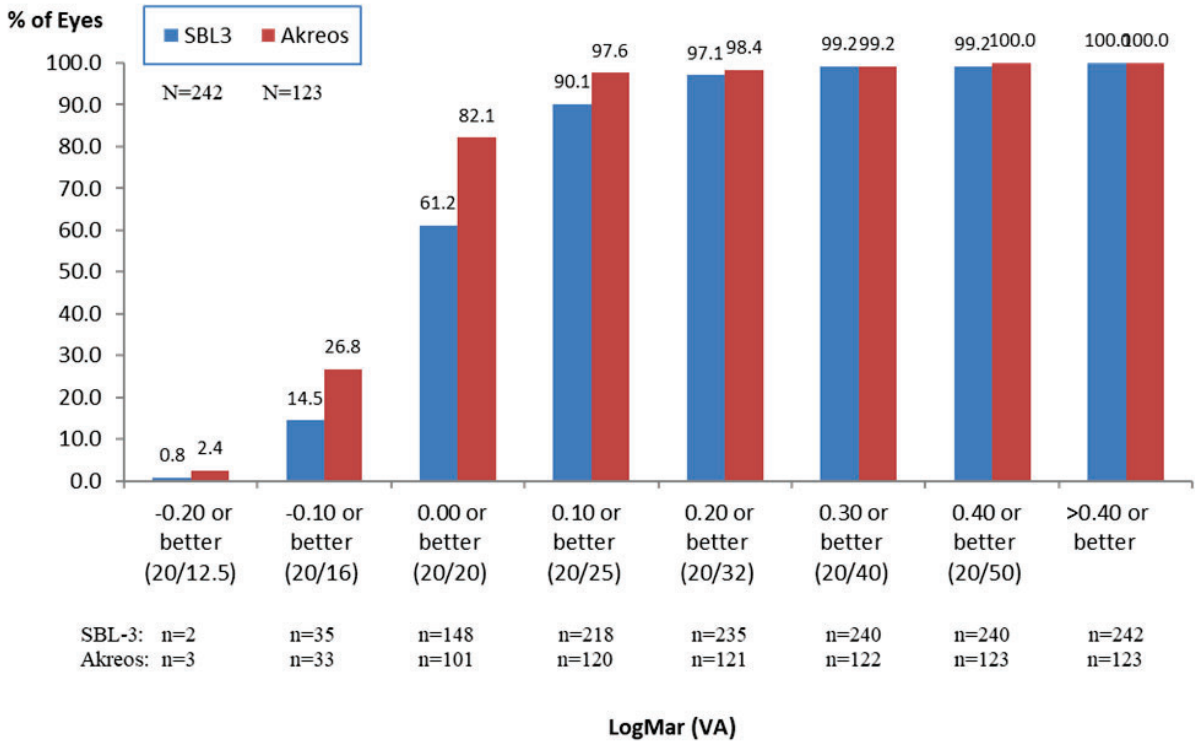
Table 38: Best Corrected Distance Visual Acuity (LogMar) (by analysis population)

Population	Statistic	SBL3	Control	Difference (SBL3 - Control)	90% CI[1]
ITT Population[2]	N	242	123		
	Mean (Std)	0.003 (0.105)	-0.039 (0.082)	0.042 (0.098)	0.024, 0.060
	Std Error	0.007	0.007	0.011	
	Median	0.000	-0.040		
	Range	-0.200, 0.860	-0.200, 0.400		
All Implanted Population	N	242	123		
	Mean (Std)	0.003 (0.105)	-0.039 (0.082)	0.042 (0.098)	0.024, 0.060
	Std Error	0.007	0.007	0.011	
	Median	0.000	-0.040		
	Range	-0.200, 0.860	-0.200, 0.400		
Best Case Population	N	241	123		
	Mean (Std)	0.003 (0.106)	-0.039 (0.082)	0.042 (0.098)	0.024, 0.059
	Std Error	0.007	0.007	0.011	
	Median	0.000	-0.040		
	Range	-0.200, 0.860	-0.200, 0.400		
Per Protocol Population	N	241	122		
	Mean (Std)	0.002 (0.105)	-0.039 (0.082)	0.041 (0.098)	0.023, 0.059
	Std Error	0.007	0.007	0.011	
	Median	0.000	-0.030		
	Range	-0.200, 0.860	-0.200, 0.400		
1. 2-sided confidence interval based on a normal distribution. The upper bound will be compared to 0.1 non-inferiority margin.					
2. The ITT Population is the primary analysis population					

NOTE: The above table shows that a significant number of eyes were not included in this analysis. This is because, the clinical protocol initially contained an error in the instructions for how to perform the testing for BCDVA. Although the manifest refraction was performed at 4 meters for all eyes, in the protocol erroneously instructed investigators to add an extra -0.25 D lens to the resulting refraction, when measuring "BCDVA." Because of this, a significant number of subjects did not have a correct measurement of BCDVA at each visit, including the 12 month visit (about 23%; 33/123). After the error in the methodology was discovered, the applicant instructed investigators to measure this outocome, both with and without the extra -0.25 D lens. Analysis for eyes with both measurements showed that the mean within-eye difference was only about 2 letters (.04 logMAR) worse for the measurement with the extra -0.25 D. The applicant performed similar non-inferiority analyses (at 12 months and 6 months postop visits) for the acuity measured through the manifest refraction with the additional -0.25 D lens. These supportive non-inferiority analyses both found the SBL-3^{TM} results to be non-inferior to the control monofocal. Due to the small mean within-eye difference observed using the different methods, a conclusion of non-inferiority at both 12 months and 6 months was justified. (It is noted that since the extra -0.25 D lens is expected to reduce acuity results, it was considered appropriate to include this acuity within the analysis of the proportion of eyes achieving BCDVA of 0.30 or better, if there was no measurement made using the original manifest refraction. For this endpoint, if an eye had both acuity measurements taken at the same visit, the poorer of the two acuity resuls was used as a worst-case analysis.)

As the statistical endpoint was seeking non-inferiority, it is clear the SBL-3^{TM} is not inferior to the control for visual acuity for best corrected distance. Clinically, the control had slightly better vision than the SBL-3^{TM} in each of the populations. The mean visual acuity in the SBL-3^{TM} group was 0.003 LogMar (~20/20 Snellen equivalent) while the control group was -0.039 LogMar (~20/20 Snellen equivalent). This difference, 0.042 LogMar, represents 2.1 letters on the vision chart. This does not represent a statistical or clinically meaningful difference. Cumulative monocular BCDVA is presented in **Figure 15**, below.

Figure 15: Cumulative Monocular Best Corrected Distance Visual Acuity (LogMar) at 5A (ITT population)



The difference shown here also demonstrated a lack of inferiority or clinical meaningful difference in the SBL-3 group. For example, 90.1% (218/242) of SBL-3 subjects were able to read the 0.1 LogMar (20/25 Snellen equivalent) line or better, whereas the control group was able to see the same line in 97.6% (120/123) of cases.

Table 39, below, corresponds to **Figure 15**, above. It provides the sample sizes and rates described in the figure.

Table 39: Cumulative monocular BCDVA at 1-year post-operative visit (ITT Analysis population)

Parameter	Statistic	SBL3	Akreos
Primary Eye (LogMar)	**N**	242	123
-0.2 or better (20/12.5)	n (%)	2 (0.8)	3 (2.4)
-0.1 or better (20/16)	n (%)	35 (14.5)	33 (26.8)
0.0 or better (20/20)	n (%)	148 (61.2)	101 (82.1)
0.1 or better (20/25)	n (%)	218 (90.1)	120 (97.6)
0.2 or better (20/32)	n (%)	235 (97.1)	121 (98.4)
0.3 or better (20/40)	n (%)	240 (99.2)	122 (99.2)
0.4 or better (20/50)	n (%)	240 (99.2)	123 (100.0)
> 0.4 or better	n (%)	242 (100.0)	123 (100.0)
Note: % = (n/N)*100			

Secondary effectiveness endpoints

The first secondary effectiveness endpoint was associated with photopic monocular DCNVA at 40 cm for the first implanted eye at visit 4A (120-180 post-operative) (All Implanted Population). **Table 40**, below, has specific results.

Table 40: Distance Corrected Near Visual Acuity (LogMar) at 4A (by analysis population)

Population	Statistic	SBL3	Control	p-value[1]
All Implanted Population	N	321	161	<.0001
	Mean (Std)	0.116 (0.121)	0.558 (0.186)	
	Std Error	0.01	0.01	
	Median	0.1	0.58	
	Range	-0.100, 0.800	0.080, 1.000	
Best Case Population	N	320	160	<.0001
	Mean (Std)	0.116 (0.121)	0.558 (0.186)	
	Std Error	0.01	0.01	
	Median	0.1	0.58	
	Range	-0.100, 0.800	0.080, 1.000	
Per Protocol Population	N	320	160	<.0001
	Mean (Std)	0.115 (0.121)	0.557 (0.185)	
	Std Error	0.01	0.01	
	Median	0.1	0.58	
	Range	-0.100, 0.800	0.080, 1.000	
1. P-value associated with a 2-sample t-test				

The SBL-3™ was found to be statistically superior to the control in this endpoint in each population ($p<0.0001$). In the All Implanted data set, the mean visual acuity in the SBL-3™ group was 0.116 LogMar (~20/25 Snellen equivalent) while the control group was 0.558 LogMar (~20/80 Snellen equivalent). This difference, 0.442 LogMar, represents **22.1** letters on the vision chart or **~4.4 lines** on the vision chart. This represents a clinically meaningful difference. Similar levels of statistical and clinically meaningful levels of difference were seen in each available population. This is nearly identical to the same data set in the Form 5A (one-year post-operative) visit.

The second secondary effectiveness endpoint was associated with photopic monocular DCIVA at 70 cm for the first implanted eye at visit 4A (120-180 post-operative) (All Implanted Population). That data is presented in **Table 41**, below.

Table 41: Distance Corrected Intermediate Visual Acuity (LogMar) at 4A - (by analysis population)

Population	Statistic	SBL3	Control	Estimate of Treatment Difference	90% CI of Difference
All Implanted Population	N	321	162		
	Mean (Std)	0.124 (0.129)	0.294 (0.156)	-0.170 (0.139)	-0.192, -0.148
	Std Error	0.007	0.012	0.013	
	Median	0.12	0.3		
	Range	-0.220, 0.620	-0.080, 0.660		
Best Case Population	N	320	161		
	Mean (Std)	0.124 (0.129)	0.294 (0.156)	-0.170 (0.139)	-0.193, -0.148
	Std Error	0.007	0.012	0.013	
	Median	0.12	0.3		
	Range	-0.220, 0.620	-0.080, 0.660		
Per Protocol Population	N	320	161		
	Mean (Std)	0.123 (0.129)	0.293 (0.156)	-0.170 (0.138)	-0.192, -0.148
	Std Error	0.007	0.012	0.013	
	Median	0.12	0.3		
	Range	-0.220, 0.620	-0.080, 0.660		

As the statistical endpoint was seeking non-inferiority, it is obvious the SBL-3^{TM} is not worse than the control for visual acuity for intermediate.

The third secondary effectiveness endpoint was associated with photopic monocular BCDVA for optical infinity at 4 m for the first implanted eye at visit 4A (120-180 post-operative) (All Implanted Population). That data is presented in **Table 42**, below.

Table 42: Best Corrected Distance Visual Acuity (LogMar) at 4A (by analysis population)

Population	Statistic	SBL3	Control	Estimate of Treatment Difference	90% CI of Difference
All Implanted Population	N	239	124		
	Mean (Std)	0.006 (0.092)	-0.034 (0.075)	0.040 (0.087)	0.024, 0.056
	Std Error	0.006	0.007	0.01	
	Median	0	-0.04		
	Range	-0.180, 0.380	-0.220, 0.260		
Best Case Population	N	238	124		
	Mean (Std)	0.006 (0.093)	-0.034 (0.075)	0.040 (0.087)	0.024, 0.056
	Std Error	0.006	0.007	0.01	
	Median	0	-0.04		
	Range	-0.180, 0.380	-0.220, 0.260		
Per Protocol Population	N	238	123		
	Mean (Std)	0.005 (0.092)	-0.033 (0.075)	0.039 (0.087)	0.023, 0.055
	Std Error	0.006	0.007	0.01	
	Median	0	-0.04		
	Range	-0.180, 0.380	-0.220, 0.260		

Note: See the discussion under **Table 38,** concerning a protocol error in methodology causing reduced sample sizes in the above **Table 38**.

As the statistical endpoint was seeking non-inferiority, it is clear the SBL-3™ is not inferior to the control for visual acuity for best corrected

distance through the original manifest refraction. Clinically, the control had slightly better vision than the SBL-3 ™ in each of the populations. The mean visual acuity in the SBL-3™ group was 0.006 LogMar (~20/20 Snellen equivalent) while the control group was -0.034 LogMar (~20/20 Snellen equivalent). This difference, 0.040 LogMar, represents 2 letters on the vision chart. This does not represent a statistical or clinically meaningful difference.

The final two secondary endpoints were associated with the patient reported outcomes (PRO) questionnaire at the 5A visit: use of vision correction options (including glasses, contact lenses, magnifying glasses, and digital adjustments on electronic devices) and patient satisfaction. The only label claim is associated with use of vision correction options. Use of vision correction options outcomes are presented in **Table 43,** below.

Table 43: Use of Vision Correction Options Rates at the 5A visit (by analysis population)

Population[1]	Statistic	SBL3	Control	Row Mean Score Differ Statistic	p-value[2]
Near Vision					
ITT Population	n/N (%)	293/314 (93.3)	41/161 (25.5)	234.22	<.0001
All Implanted Population	n/N (%)	292/313 (93.3)	41/161 (25.5)	233.53	<.0001
Best Case Population	n/N (%)	291/312 (93.3)	41/160 (25.6)	231.47	<.0001
Per Protocol Population	n/N (%)	291/312 (93.3)	41/160 (25.6)	231.47	<.0001
Intermediate Vision[3]					
ITT Population	n/N (%)	295/314 (93.9)	73/161 (45.3)	143.78	<.0001
All Implanted Population	n/N (%)	294/313 (93.9)	73/161 (45.3)	143.3	<.0001
Best Case Population	n/N (%)	293/312 (93.9)	73/160 (45.6)	141.3	<.0001
Per Protocol Population	n/N (%)	293/312 (93.9)	73/160 (45.6)	141.3	<.0001
Distant Vision[4]					
ITT Population	n/N (%)	295/314 (93.9)	137/161 (85.1)	10.12	0.0015
All Implanted Population	n/N (%)	294/313 (93.9)	137/161 (85.1)	10.04	0.0015
Best Case Population	n/N (%)	293/312 (93.9)	136/160 (85.0)	10.12	0.0015
Per Protocol Population	n/N (%)	293/312 (93.9)	136/160 (85.0)	10.12	0.0015
1. Rates of spectacle independence (never or only some of the time requiring spectacles)					
2. P-value associated with the Cochran-Mantel-Haenzel Mean Score Test					
3. Intermediate Vision statistical test to be evaluated only if Near Vision results are significant ($p < 0.05$)					
4. Distant vision statistical test to be evaluated only if Near and Intermediate Vision results are significant ($p < 0.05$)					
Note: % = (n/N)*100					

Reduced use of vision correction options was defined as subjects reporting either *never* using vision correction (spectacles, contact lenses, increasing font size on electronic devices etc.) or using those things *some of the time*. Based on the results, it is clear that the SBL-3™ was not statistically inferior to the control IOL. In the ITT population, patients reported less frequent use of vision correction options in the SBL-3™ group (93.3%; 291/312) at a much higher rate than the control (25.5%; 41/161). Similarly, with regards to intermediate vision, SBL-3™ subjects (93.9%;

293/312) also reported a large improvement over the control (45.3%; 73/161). Regarding distance vision, SBL-3™ subjects (93.9%; 293/312) saw a slight improvement relative to the control (85.1%; 137/161). The final secondary effectiveness endpoint was associated with patient satisfaction. Data on this topic is presented in **Table 44**, below.

Table 44: Overall Patient Satisfaction at 5A (by analysis population)

Population[1]	Statistic	SBL3	Control	Row Mean Score Differ Statistic	p-value[2]
Near Vision					
ITT Population	n/N (%)	280/314 (89.2)	76/161 (47.2)	99.62	<.0001
All Implanted Population	n/N (%)	280/313 (89.5)	76/161 (47.2)	101.3	<.0001
Best Case Population	n/N (%)	279/312 (89.4)	76/160 (47.5)	99.49	<.0001
Per Protocol Population	n/N (%)	279/312 (89.4)	76/160 (47.5)	99.49	<.0001
Intermediate Vision[3]					
ITT Population	n/N (%)	280/314 (89.2)	107/161 (66.5)	36.3	<.0001
All Implanted Population	n/N (%)	280/313 (89.5)	107/161 (66.5)	37.44	<.0001
Best Case Population	n/N (%)	279/312 (89.4)	106/160 (66.3)	37.69	<.0001
Per Protocol Population	n/N (%)	279/312 (89.4)	106/160 (66.3)	37.69	<.0001
Distant Vision[4]					
ITT Population	n/N (%)	240/314 (76.4)	146/161 (90.7)	14.16	0.0002
All Implanted Population	n/N (%)	240/313 (76.7)	146/161 (90.7)	13.77	0.0002
Best Case Population	n/N (%)	240/312 (76.9)	145/160 (90.6)	13.18	0.0003
Per Protocol Population	n/N (%)	239/312 (76.6)	145/160 (90.6)	13.68	0.0002
1. Rates of overall satisfaction (satisfied or extremely satisfied)					
2. P-value associated with the Cochran-Mantel-Haenzel Mean Score Test					
3. Intermediate Vision statistical test to be evaluated only if Near Vision results are significant ($p < 0.05$)					
4. Distant vision statistical test to be evaluated only if Near and Intermediate Vision results are significant ($p < 0.05$) **Note: % = (n/N)*100**					

Satisfaction was defined as subjects reporting being *satisfied* or *extremely satisfied*. The satisfaction results at near again favor the SBL-3™, in that 89.2% (280/314) of subjects in that group were either *satisfied* or *extremely satisfied*, compared to the control groups value of 47.2% (76/161). Similarly, the difference in intermediate reporting was also favoring the SBL-3™ group (89.2%; 280/314 for SBL-3™ vs 66.5%; 107/161 for the control). Based on this, it is clear that SBL-3™ is not statistically inferior to the control IOL. Regarding distant vision, however, the control (90.7%; 146/161) had a greater percentage of subjects report satisfaction than the SBL-3™ group (76.4%; 240/314). This difference was statistically significant in favor of the control (p=0.0002).

Supportive effectiveness endpoints

There were several supportive effectiveness endpoints. Uncorrected visions were evaluated. In addition, binocular defocus curves, and the use of vision correction were evaluated. In patients with visual symptoms, mesopic, binocular low- contrast distance visual acuities were evaluated.

Uncorrected Visual Acuity Measurements

Photopic uncorrected visual acuities for monocular vision (primary and all eyes separately), and binocular vision will be summarized at each visit and distance (near, intermediate and distance). Table 44 through Table 52 show these data.

Uncorrected Distance Visual Acuity

Uncorrected distance visual acuity in primary eyes is presented below in **Table 45**. At the 1-year post-operative visit, the control IOL has a lower mean score than the SBL-3™ by 0.054, which accounts for less than 3 letters on the vision chart. This difference between the two groups was similar to that seen in the BCDVA data, presented previously, both in the means and cumulative proportions. The differences were not clinically meaningful.

Table 45: Uncorrected Distance Visual Acuity Adjusted for Optical Infinity (LogMar) at Each Visit, All Implanted Population - Primary Eyes

Visit	Statistic	SBL3	Akreos	Estimate of Treatment Difference	90% CI of Difference
All Available Data					
Preop	N	308	153		
	Mean(Std)	0.662 (0.321)	0.682 (0.317)	-0.020 (0.320)	-0.073, 0.032
	Std Error	0.018	0.026	0.032	
	Median	0.620	0.640		
	Range	0.100, 1.400	0.100, 1.400		
Form 1	N	309	158		
	Mean(Std)	0.290 (0.283)	0.180 (0.191)	0.110 (0.256)	0.069, 0.152
	Std Error	0.016	0.015	0.025	
	Median	0.200	0.160		
	Range	-0.120, 1.280	-0.160, 0.940		
Form 2	N	312	158		
	Mean(Std)	0.126 (0.171)	0.052 (0.110)	0.074 (0.153)	0.049, 0.098
	Std Error	0.010	0.009	0.015	
	Median	0.100	0.030		
	Range	-0.180, 0.880	-0.200, 0.460		
Form 3A	N	318	160		
	Mean(Std)	0.114 (0.163)	0.029 (0.108)	0.085 (0.147)	0.062, 0.109
	Std Error	0.009	0.009	0.014	
	Median	0.080	0.020		
	Range	-0.140, 0.940	-0.180, 0.380		
Form 4A	N	320	163		
	Mean(Std)	0.095 (0.154)	0.030 (0.100)	0.064 (0.138)	0.043, 0.086

	Std Error	0.009	0.008	0.013	
	Median	0.060	0.020		
	Range	-0.160, 1.000	-0.200, 0.300		
Form 5A	N	315	161		
	Mean(Std)	0.092 (0.158)	0.039 (0.109)	0.054 (0.143)	0.031, 0.077
	Std Error	0.009	0.009	0.014	
	Median	0.060	0.020		
	Range	-0.200, 0.840	-0.180, 0.420		

Uncorrected distance visual acuity (in All Eyes) is presented below in **Table 46**. At the 1-year post-operative visit, the control IOL has a lower mean score than the SBL-3^{TM} by 0.044, which accounts for ~2 letters on the vision chart. This difference between the two groups was similar to that seen in the BCDVA data, presented previously, both in the means and cumulative proportions. The differences were not clinically meaningful.

Table 46: Uncorrected Distance Visual Acuity Adjusted for Optical Infinity (LogMar) at Each Visit, All Implanted Population - All Eyes

Visit	Statistic	SBL3	Akreos	Estimate of Treatment Difference	90% CI of Difference
All Available Data					
Preop	N	613	307		
	Mean(Std)	0.620 (0.308)	0.628 (0.314)	-0.009 (0.310)	-0.045, 0.027
	Std Error	0.012	0.018	0.022	
	Median	0.580	0.560		
	Range	-0.040, 1.400	0.040, 1.400		
Form 1	N	618	316		
	Mean(Std)	0.252 (0.267)	0.149 (0.177)	0.103 (0.240)	0.076, 0.131
	Std Error	0.011	0.010	0.017	
	Median	0.180	0.120		
	Range	-0.160, 1.280	-0.200, 0.940		
Form 2	N	622	318		
	Mean(Std)	0.115 (0.165)	0.041 (0.109)	0.075 (0.149)	0.058, 0.092
	Std Error	0.007	0.006	0.010	
	Median	0.080	0.020		
	Range	-0.180, 1.040	-0.200, 0.460		
Form 3A	N	636	320		
	Mean(Std)	0.106 (0.154)	0.031 (0.108)	0.075 (0.140)	0.059, 0.091
	Std Error	0.006	0.006	0.010	
	Median	0.080	0.020		
	Range	-0.180, 0.940	-0.180, 0.500		
Form 4A	N	639	326		
	Mean(Std)	0.087 (0.145)	0.028 (0.100)	0.059 (0.131)	0.045, 0.074
	Std Error	0.006	0.006	0.009	
	Median	0.060	0.010		
	Range	-0.220, 1.000	-0.200, 0.380		
Form 5A	N	628	322		
	Mean(Std)	0.082 (0.148)	0.038 (0.109)	0.044 (0.136)	0.029, 0.060
	Std Error	0.006	0.006	0.009	
	Median	0.060	0.020		
	Range	-0.200, 0.900	-0.180, 0.420		

Binocular uncorrected distance visual acuity is presented below in **Table 47**. At the 1-year post-operative visit, the control IOL has a lower mean score than the SBL-3™ by 0.041, which accounts for ~2 letters on the vision chart. This difference between the two groups was similar to that seen in the BCDVA data, presented previously, both in the means and cumulative proportions. The differences were not clinically meaningful.

Table 47: Uncorrected Distance Visual Acuity (LogMar) at Each Visit - Optical Infinity Adjusted, All Implanted Population - Binocular Vision

Visit	Statistic	SBL3	Akreos	Estimate of Treatment Difference	90% CI of Difference
Form 3A	N	319	160		
	Mean(Std)	0.035 (0.123)	-0.033 (0.081)	0.068 (0.111)	0.051, 0.086
	Std Error	0.007	0.006	0.011	
	Median	0	-0.02		
	Range	-0.240, 0.720	-0.240, 0.220		
Form 4A	N	319	162		
	Mean(Std)	0.012 (0.103)	-0.041 (0.079)	0.052 (0.096)	0.037, 0.067
	Std Error	0.006	0.006	0.009	
	Median	0	-0.04		
	Range	-0.200, 0.600	-0.240, 0.220		
Form 5A	N	313	161		
	Mean(Std)	0.009 (0.110)	-0.032 (0.088)	0.041 (0.103)	0.024, 0.057
	Std Error	0.006	0.007	0.01	
	Median	0	-0.04		
	Range	-0.300, 0.740	-0.200, 0.220		

Uncorrected Near Visual Acuity

Uncorrected near visual acuity in primary eyes is presented below in **Table 48**. Uncorrected near vision outcomes in the primary eye were considerably better in the test group than in the control group. The approximate difference between the two groups was similar to that seen in the DCNVA data, presented previously, both in the means and cumulative proportions. The differential between the two groups grew up through the 1-year post-operative visit. The differences were clinically meaningful.

Table 48: Other Effectiveness Uncorrected Near Visual Acuity at Each Visit, All Implanted Population - Primary Eyes

Parameter	Statistic	SBL3	Akreos	Estimate of Treatment Difference	90% CI of Difference
At 40 cm (LogMar)					
Visit 1	N	328	166		
	Mean(Std)	0.237 (0.200)	0.575 (0.214)	-0.338 (0.205)	-0.371,-0.306
	Std Error	0.011	0.017	0.019	
	Median	0.2	0.6		
	Range	-0.100, 1.200	0.100, 1.200		
Visit 2	N	328	165		
	Mean(Std)	0.116 (0.125)	0.519 (0.186)	-0.403 (0.148)	-0.426,-0.379
	Std Error	0.007	0.015	0.014	
	Median	0.1	0.52		
	Range	-0.200, 0.740	0.080, 1.000		
Visit 3A	N	324	163		
	Mean(Std)	0.109 (0.133)	0.540 (0.182)	-0.430 (0.151)	-0.454,-0.406
	Std Error	0.007	0.014	0.014	
	Median	0.1	0.54		
	Range	-0.180, 1.000	0.100, 1.200		
Visit 4A	N	321	163		
	Mean(Std)	0.089 (0.110)	0.548 (0.216)	-0.459 (0.154)	-0.483,-0.434
	Std Error	0.006	0.017	0.015	
	Median	0.08	0.56		
	Range	-0.180, 0.700	-0.580, 1.000		
Visit 5A	N	315	161		
	Mean(Std)	0.101 (0.125)	0.574 (0.187)	-0.473 (0.149)	-0.497,-0.449
	Std Error	0.007	0.015	0.014	
	Median	0.1	0.58		
	Range	-0.220, 1.200	0.060, 1.000		

Uncorrected near visual acuity (All Eyes) is presented below in **Table 49**. These outcomes were better (lower LogMar scores) in both groups than the respective monocular groups. The magnitude of difference between the two was similar to that of the unilateral uncorrected visions above. The approximate difference between the two groups was similar to that seen in the DCNVA data, presented previously, both in the means and cumulative proportions. The differences were clinically meaningful.

Table 49: Other Effectiveness Uncorrected Near Visual Acuity at Each Visit, All Implanted Population - All Eyes

Parameter	Statistic	SBL3	Akreos	Estimate of Treatment Difference	90% CI of Difference
At 40 cm (LogMar)					
Visit 1	N	654	331		
	Mean(Std)	0.215 (0.189)	0.549 (0.206)	-0.333 (0.195)	-0.355,-0.312
	Std Error	0.007	0.011	0.013	
	Median	0.18	0.56		
	Range	-0.140, 1.200	0.000, 1.200		
Visit 2	N	654	331		
	Mean(Std)	0.107 (0.139)	0.517 (0.185)	-0.410 (0.156)	-0.427,-0.393
	Std Error	0.005	0.01	0.011	
	Median	0.1	0.52		
	Range	-0.200, 1.000	-0.280, 1.000		
Visit 3A	N	648	326		
	Mean(Std)	0.099 (0.124)	0.537 (0.180)	-0.438 (0.145)	-0.454,-0.422
	Std Error	0.005	0.01	0.01	
	Median	0.1	0.54		
	Range	-0.180, 1.000	0.100, 1.200		
Visit 4A	N	639	326		
	Mean(Std)	0.086 (0.110)	0.558 (0.204)	-0.472 (0.149)	-0.489,-0.456
	Std Error	0.004	0.011	0.01	
	Median	0.08	0.59		
	Range	-0.200, 0.700	-0.580, 1.200		
Visit 5A	N	628	322		
	Mean(Std)	0.095 (0.118)	0.569 (0.183)	-0.475 (0.143)	-0.491,-0.458
	Std Error	0.005	0.01	0.01	
	Median	0.1	0.58		
	Range	-0.220, 1.200	0.060, 1.000		

Binocular uncorrected near visual acuity is presented below in **Table 50**. These outcomes were better (lower LogMar scores) in both groups than the respective monocular groups. The magnitude of difference between the two was similar to that of the unilateral uncorrected visions above. The approximate difference between the two groups was similar to that seen in the DCNVA data, presented previously, both in the means and cumulative proportions. The differences were clinically meaningful.

Table 50: Other Effectiveness Uncorrected Near Visual Acuity at Each Visit, All Implanted Population - Binocular

Parameter	Statistic	SBL3	Akreos	Estimate of Treatment Difference	90% CI of Difference
At 40 cm (LogMar)					
Visit 3A	N	324	163		
	Mean(Std)	0.043 (0.098)	0.412 (0.160)	-0.369 (0.122)	-0.388,-0.350
	Std Error	0.005	0.013	0.012	
	Median	0.04	0.4		
	Range	-0.180, 0.440	0.100, 0.880		
Visit 4A	N	319	163		
	Mean(Std)	0.031 (0.088)	0.429 (0.169)	-0.397 (0.121)	-0.417,-0.378
	Std Error	0.005	0.013	0.012	
	Median	0.02	0.42		
	Range	-0.220, 0.320	0.020, 0.840		
Visit 5A	N	313	161		
	Mean(Std)	0.037 (0.091)	0.425 (0.161)	-0.388 (0.119)	-0.407,-0.369
	Std Error	0.005	0.013	0.012	
	Median	0.04	0.4		
	Range	-0.200, 0.400	0.060, 0.820		

Uncorrected Intermedicate Visual Acuity

Uncorrected intermediate visual acuity in primary eyes is presented below in **Table 51**.

Table 51: Other Effectiveness Uncorrected Intermediate Visual Acuity (LogMar) at Each Visit, All Implanted Population - Primary Eyes

Parameter	Statistic	SBL3	Akreos	Estimate of Treatment Difference	90% CI of Difference
At 70 cm					
Visit 3A	N	322	162		
	Mean(Std)	0.114 (0.139)	0.260 (0.161)	-0.146 (0.147)	-0.169,-0.123
	Std Error	0.008	0.013	0.014	
	Median	0.1	0.24		
	Range	-0.400, 0.780	-0.080, 0.660		
Visit 4A	N	320	163		
	Mean(Std)	0.109 (0.130)	0.298 (0.160)	-0.189 (0.141)	-0.212,-0.167
	Std Error	0.007	0.013	0.014	
	Median	0.11	0.28		
	Range	-0.280, 0.640	-0.080, 0.800		
Visit 5A	N	315	161		
	Mean(Std)	0.114 (0.142)	0.293 (0.158)	-0.179 (0.148)	-0.202,-0.155
	Std Error	0.008	0.012	0.014	
	Median	0.1	0.3		
	Range	-0.260, 0.840	-0.120, 0.840		

Uncorrected intermediate visual acuity (All Eyes) is presented below in **Table 52**.

Table 52: Other Effectiveness Uncorrected Intermediate Visual Acuity (LogMar) at Each Visit, All Implanted Population - All Eyes

Parameter	Statistic	SBL3	Akreos	Estimate of Treatment Difference	90% CI of Difference
At 70 cm					
Visit 3A	N	644	324		
	Mean(Std)	0.112 (0.134)	0.247 (0.163)	-0.134 (0.144)	-0.151,-0.118

	Std Error	0.005	0.009	0.01	
	Median	0.1	0.23		
	Range	-0.400, 0.780	-0.100, 0.820		
Visit 4A	N	639	325		
	Mean(Std)	0.104 (0.129)	0.294 (0.163)	-0.190 (0.142)	-0.206,-0.174
	Std Error	0.005	0.009	0.01	
	Median	0.1	0.28		
	Range	-0.300, 0.640	-0.100, 0.800		
Visit 5A	N	628	322		
	Mean(Std)	0.106 (0.132)	0.293 (0.162)	-0.187 (0.143)	-0.203,-0.171
	Std Error	0.005	0.009	0.01	
	Median	0.1	0.3		
	Range	-0.260, 0.840	-0.120, 0.840		

Binocular intermediate visual acuity in primary eyes is presented below in **Table 53**.

Table 53: Other Effectiveness Uncorrected Intermediate Visual Acuity (LogMar) at Each Visit, All Implanted Population - Binocular Vision

Parameter	Statistic	SBL3	Akreos	Estimate of Treatment Difference	90% CI of Difference
At 70 cm					
Visit 3A	N	322	162		
	Mean(Std)	0.025 (0.107)	0.144 (0.136)	-0.119 (0.117)	-0.138,-0.100
	Std Error	0.006	0.011	0.011	
	Median	0.02	0.13		
	Range	-0.280, 0.380	-0.160, 0.620		
Visit 4A	N	319	163		
	Mean(Std)	0.010 (0.099)	0.179 (0.140)	-0.169 (0.115)	-0.188,-0.151
	Std Error	0.006	0.011	0.011	
	Median	0	0.16		
	Range	-0.300, 0.300	-0.100, 0.600		
Visit 5A	N	313	161		
	Mean(Std)	0.018 (0.105)	0.185 (0.133)	-0.167 (0.115)	-0.185,-0.149
	Std Error	0.006	0.011	0.011	
	Median	0.02	0.18		
	Range	-0.280, 0.400	-0.140, 0.600		

Binocular Defocus Curve

Figures 16-18 presents binocular defocus curve testing that was performed on a randomized subset of subjects from each lens group. Defocus testing was performed using a phoropter or trial frames, 100% contrast eETDRS monitor at 4 meters and photopic lighting conditions at approximately 85 cd/m^2. Binocular defocus results were analyzed for all eyes, and by two photopic pupil size ranges: >2.75 mm and <4.0 mm; and ≥4.0 mm, shown on **Figure 16**.

Figure 16: Defocus Curve Outcomes, Binocular, All Eyes at the 6-month Post-operative Visit

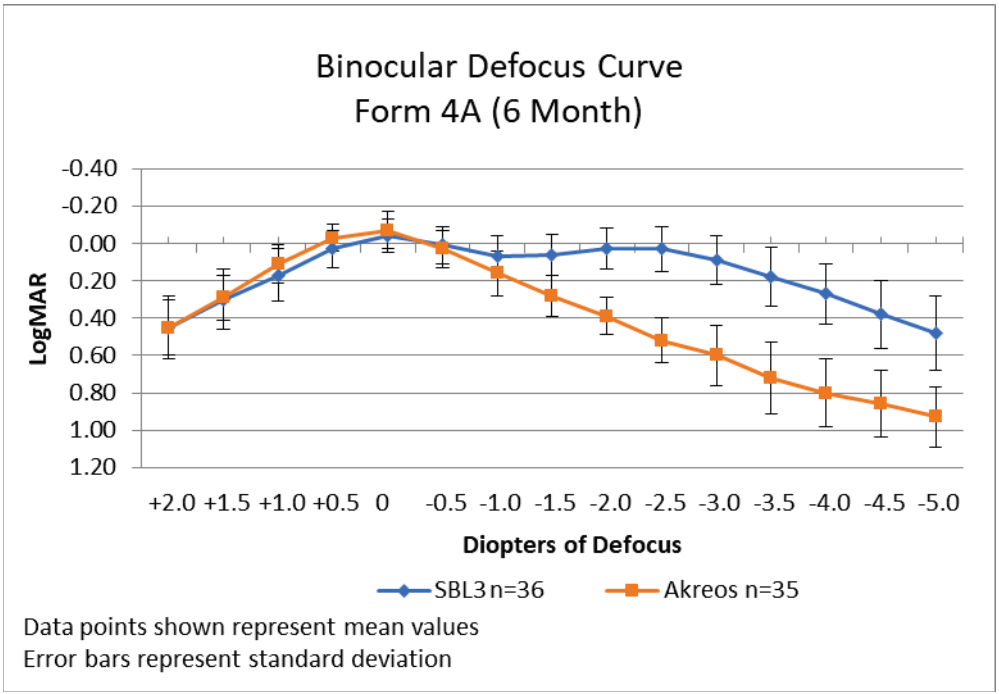


Figure 17: Defocus Curve Outcomes, Binocular, Stratified by Pupil Size at the 6-month Post-operative Visit (Smaller Pupil Group)

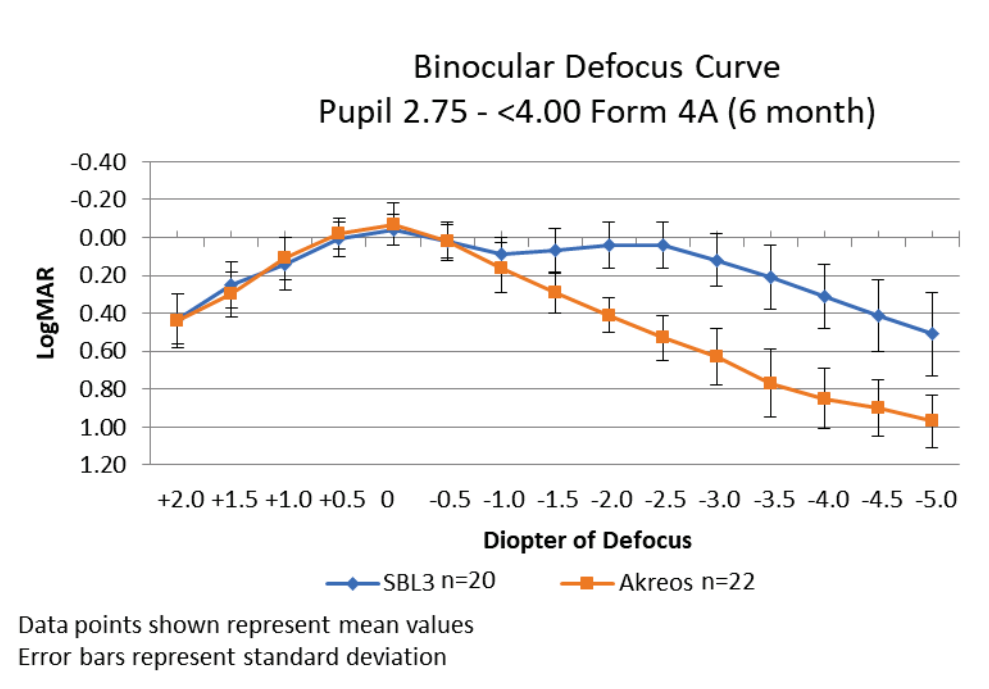
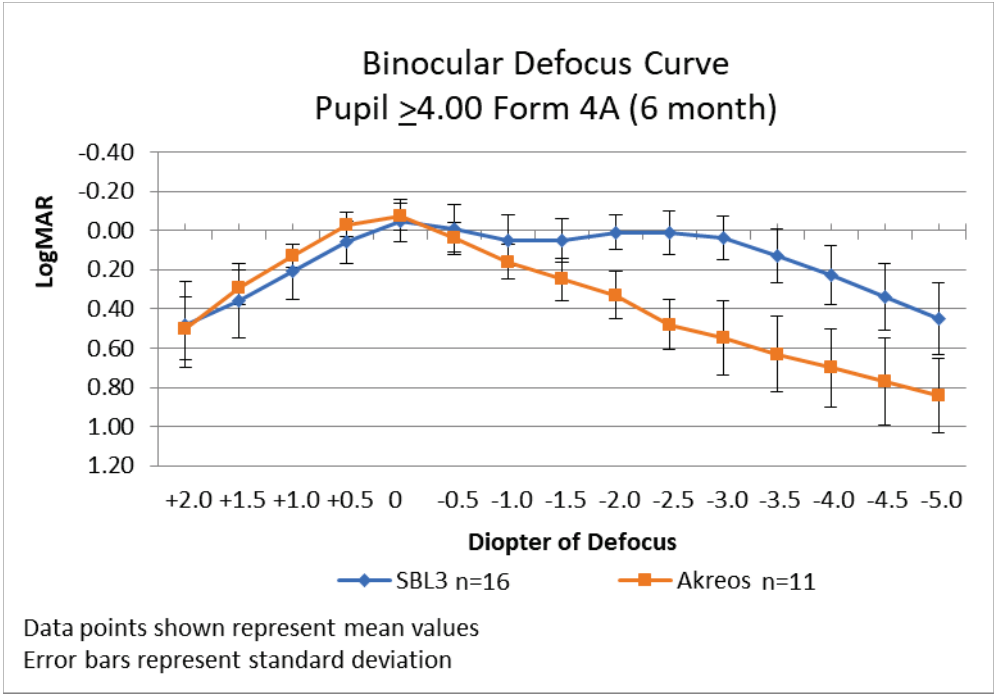


Figure 18: Defocus Curve Outcomes, Binocular, Stratified by Pupil Size at the 6-month Post-operative Visit (Larger Pupil Group)



Defocus evaluation showed that both IOLs performed well around the zero (0) defocus level. The control IOL suffered loss in both directions from there, whereas the SBL-3™ performed well at the -2.5 diopter evaluation level, due to that correlating with the add power. Both sets of pupil groups performed similarly. The defocus secondary effectiveness endpoint was met.

Mesopic Low Contrast Visual Acuity Outcomes at the 6- month Post-Operative Visit

Mesopic low contrast visual acuity was performed at the 6-month visit in subjects that reported visual disturbances or had a 10 or more-letter loss of (high contrast) BCDVA between the 1-month and 6-month visits, **Table 54**, below. The viewing distance used for low contrast testing was 4 meters. The test performed was 10% low contrast best-correcteddistance visual acuity.

Table 54: Other Effectiveness: Binocular Mesopic Low Contrast Visual Acuity (4 meters) Outcomes at the 6-month Post-operative Visit (LogMAR visual acuity) (in eyes with visual disturbance or loss of high contrast)

Other Effectiveness Mesopic Low Contrast Visual Acuity (In eyes with visual disturbance or loss of high contrast acuity)					
Visit	**Statistic**	**SBL3 (LogMAR)**	**Akreos (LogMAR)**	**Estimate of Treatment Difference (LogMAR)**	
Form 4A	N	122	19		
(All values)	Mean(Std)	0.792 (0.259)	0.638 (0.247)	0.154 (0.258)	
	Std Error	0.023	0.057	0.064	
	Median	0.810	0.600		
	Range	0.000, 1.100	0.120, 1.100		
Values > 1 LogMar	n (%)	29 (31.18)	1 (5.56)		

Note: % = (n/N)*100

There were more subjects in the SBL-3™ group due to the nature of the need for this test. Both groups had poor vision outcomes under these test conditions, with the SBL-3™ group being

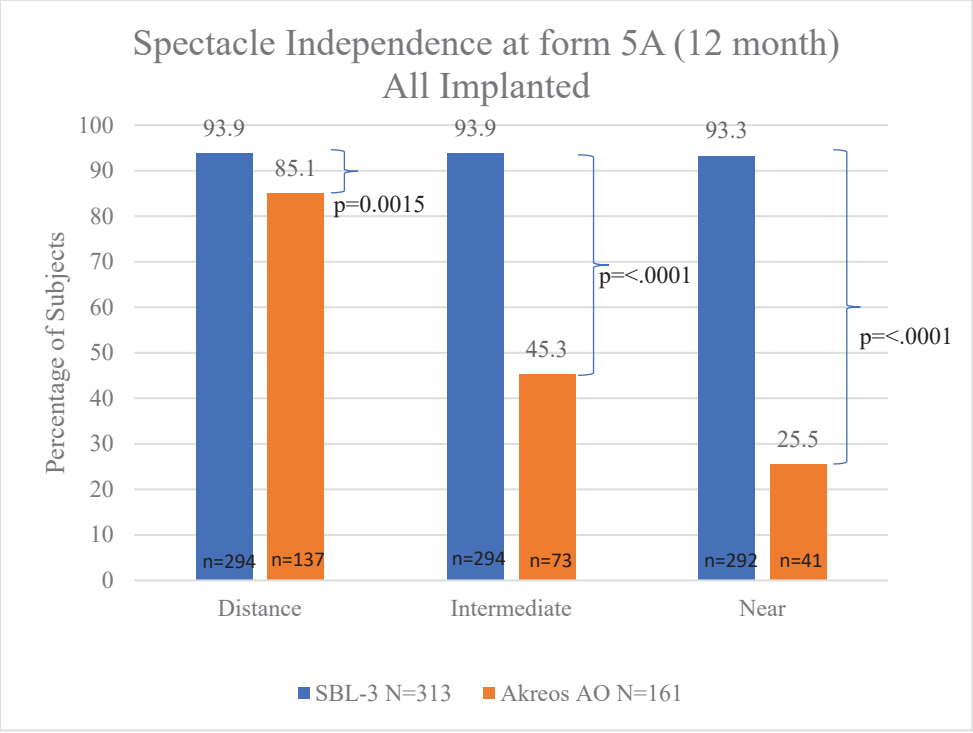
worse by ~1.5 lines on the vision chart. Both groups performed worse than healthy young individuals.

Use of Vision Correction

The SBL-3™ was found to be superior to the Akreos AO in use of vision correction at the 5A (330-420 days) visit. The P-values listed below are associated with the Cochran-Mantel-Haenzel Mean Score Test. Intermediate Vision statistical testing was evaluated only when Near Vision results were significant ($p < 0.05$). Distant vision statistical testing was evaluated only when Near and Intermediate Vision results were significant ($p < 0.05$). P-values associated with this testing were ≤ 0.0015. **Figure 19**, below, clearly demonstrates statistical and clinical significance for the use of vision correction of SBL-3™ subjects as compared to the Akreos AO at near distance.

Clinically, the SBL-3™ had ≥ 93.3% (291/312) of subjects opting to not use vision correction in all four (4) populations listed below and at all three (3) distances compared to ≥ 25.5% (41/161; for near vision), 45.3% (73/161; for intermediate vision) and 85.1% (137/161; for distance vision) for the Akreos AO. Therefore, the SBL-3™ had almost 3 times the amount for near vision, more than twice the amount for intermediate vision and roughly 9% higher for the distance vision in this aspect.

Figure 19: Subjects Opting to not use Vision Correction at the 1-year Post-operative Visit



3. Subgroup Analyses

The following preoperative characteristics were evaluated for potential association with outcomes and the results show sites, baseline characteristics and co-primary endpoints at the 1-year post-operative visit DCNVA at 40 cm, DCIVA at 70 cm and BCDVA at 4 m to be poolable. An evaluation of each of the co-primary effectiveness endpoints was completed by site. There was minimal difference between the sites and their outcomes.

Regarding gender, DCNVA, DCIVA and BCDVA were also evaluated. The same between group difference was seen as that of the overall population.

An evaluation by age (<60, 60 - <70 and ≥70) identified that the youngest age group had slightly better outcomes than the other two groups for BCDVA with -0.25 diopters added to the manifest refraction and DCIVA. For DCNVA, the difference between the SBL-3^{TM} and control group was (minimally) less for the oldest group.

Serious adverse events, whether cumulative or persistent, were also evaluated by age group, and it was shown that there were no differences by age group, for either primary eyes, fellow eyes or either eye or subject. Similarly, the groups were similar for treatments emergent adverse events, with a few sites having an increased proportion of visual disturbances in the SBL-3^{TM} group relative to the control.

Since the majority of the trial consisted of white (93.7%; 312/333) and non-Hispanic Caucasian (96.7%; 322/333) subjects, subgroup analyses were not conducted on this subset. Historically, IOL trials in the US have similar proportions of subjects which participate.

4. Pediatric Extrapolation

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

E. 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 1 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
- Significant payment of other sorts: 0
- Proprietary interest in the product tested held by the investigator: 0
- Significant equity interest held by investigator in sponsor of covered study: 1

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.

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

No relevant studies have been conducted on the SBL-3™ IOL which impact this PMA. The Applicant's Softec HD Posterior Chamber Intraocular Lens was approved under P090022. The material used to manufacture both IOLs is identical and some strictly-material related testing (i.e., physicochemical and biocompatibility testing) was omitted from this PMA.

XII. 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 Devices Panel an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The primary effectiveness endpoints identified that the SBL-3™ provided improved near visual acuity and non-inferior intermediate and distance visual acuity at the 1-year post-operative visit. This was supported by the secondary effectiveness endpoints at the 6-month post-operative visit. SBL-3™ subjects statistically and clinically meaningfully less frequently used vision correction choices at near distance (including glasses, contact lenses, magnifying glasses, and digital adjustments on electronic devices), compared to the aspheric monofocal control IOL. All other vision testing performed similar to the primary endpoints, whereas near vision was superior and intermediate and distance was non-inferior. Defocus testing showed similar results, with the SBL-3™ having better outcomes than the control at most

tested visions. This effectiveness dataset provides a reasonable assurance of the effectiveness of the SBL-3™ Multifocal Intraocular Lens (MCIOL).

B. Safety Conclusions

The risks of the device are based on nonclinical laboratory studies as well as data collected in the clinical study conducted to support PMA approval as described above.

The primary safety endpoint was the adverse event rates for different categories of events. For the ISO 11979-7 historical control categories of adverse events (SPE categories of cumulative and persistent adverse events), the SBL-3™ was found to not be statistically significantly inferior to the historical control rates, with the exception of cumulative total secondary surgical interventions. This SSI rate 12/656 (1.8%) was inferior to the historical control rate of 0.8%. However, it is known that other multifocal IOLs, once on the market, tend to have somewhat higher reported SSI rates than monofocal IOLs, because multifocal IOLs generally have higher incidences of SSIs associated with patient intolerance of visual symptoms (e.g., explants) In this study, the SSIs related to optical properties of the IOL (for which no historical control is available) occurred at a higher rate than in the control, but when statistically compared to the active monofocal control, using a 2-sided 90% confidence interval on the difference in the rates, the confidence interval contained zero. Thus, the rates were not statistically, significantly different. The most common type of more serious adverse event seen were cystoid macular edema which occurred at a rate 2% (13/656), and corneal stomal edema which occurred at a rate of 0.6% (2/656). Other serious adverse events occurred at lower rates. With the exception of the SSIs, other types of adverse events were observed to occur at rates similar to those commonly seen in cataract surgery with IOL implantation. The only categories of ISO persistent serious adverse events (present at the 12 month visit) were cystoid macular edema and corneal stromal edema, both occurring at a rate of 0.2% (1/656). The SBL-3™ arm also showed increased risk of significant myopic outcomes (occurring at a rate > 1.0 diopter of myopia at 12-months of 10/648 or 1.6%). And there were 30 instances in which SBL-3™ eyes (vs. 0 control eyes) were found to have a fluctuation of manifest refraction spherical equivalent of >1.0D after the Form 3A (30-60-day post-operative) visit from any prior visit. The cause for these fluctuations was not determined, but in some was sometimes associated with significant variation in uncorrected distance visual acuity.

There was an increased rate of visual disturbances in the SBL-3™ group, relative to the control, and contrast sensitivity results were somewhat worse in the SBL-3™ group. These types of results are commonly seen with other marketed multifocal

IOLs, due to the splitting of the light between "far" and "near" foci. Driving simulation outcomes identified that the control IOL performed somewhat better than the SBL-3™.

C. Benefit-Risk Determination

The probable benefits of the SBL-3™ are based on data collected in a clinical study conducted to support PMA approval as described above. Subjects that received the SBL-3™ had statistically significant and clinically meaningfully improved near visual acuity outcomes when viewing a conventional vision chart. The subjects also had statistically significant and clinically meaningfully improved near vision outcomes, with respect to use of vision correction options.

The probable risks of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. Secondary surgical intervention for reasons associated with the optical properties of the SBL-3™ was greater than the control IOL, but not statistically greater than the control rate. Although not considered to be key safety outcomes, there were unexpected increased risks of significantly myopic outcomes, and of significant fluctuations in refractive error after month 1. There was an increased incidence of visual disturbances in the SBL-3™ group.

Additional factors to be considered in determining probable risks and benefits for the SBL-3™ device include:

- The risks associated with the optical design include visual symptoms related to stray light, such as glare, halos and starbursts. Some of these may make some tasks such as driving, more difficult under certain circumstances. These issues are mitigated by labeling which informs users of these risks and quantifies them
- The unexpected risk of significant myopic outcomes, may prove to be less than seen in the clinical study, as the sponsor has modified the recommended A-constant to be used in calculating appropriate IOL power selection. However, this may also be related to other factors. This risk is mitigated by an approopriate Warning in the labeling, and a postapproval study will attempt to ascertain contributing factors.
- The unexpected risk of substantial refractive fluctuation does not have an established cause and may result in unexpected vision fluctuation. This is risk is partially mitigated by an approopriate Warning in the labeling, and a postapproval study will attempt to ascertain contributing factors.

- The risk of SSIs related to the optical properties of a multifocal IOL are often seen to be higher in the marketed product than in the preapproval study. This risk will be further evaluated in a postapproval study, which will also attempt to ascertain contributing factors.

Patient perspectives: The study collected patient reported outcome (PRO) measures (using a questionnaire) that evaluated patient reports of visual symptoms, frequency of vision correction use, and satisfaction with the IOL.

In conclusion, given the available information above, the data support that for the SBL-3™'s indication for use:

> "The SBL-3™ multifocal intraocular lens is indicated for primary implantation for the visual correction of aphakia, in adult patients with 1 diopter or less of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing a bifocal correction. Compared to an aspheric monofocal IOL, the lens provides improved near visual acuity, while maintaining comparable distance and intermediate visual acuity. The lens promotes the less frequent use of vision correction choices at near distance (including glasses, contact lenses, magnifying glasses, and digital adjustments on electronic devices), compared to an aspheric monofocal IOL. The SBL-3™ multifocal IOL is intended for capsular bag placement only", the probable benefits outweigh the risks;"

the probable benefits outweigh the risks.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of the SBL-3™ when used in accordance with the indications for use. Key effectiveness endpoints related to near, intermediate, and distance visual acuity were met, demonstrating the ability of the SBL-3™ to provide statistically significant and clinically meaningful improvements in near visual acuity when viewing vision charts, compared to the control aspheric monofocal IOL. Intermediate visual acuity and distance visual acuity when viewing vision charts were not inferior to the control. Subjects implanted with the SBL-3™ lens used vision correction choices at near distance (including glasses, contact lenses, magnifying glasses, and digital adjustments on electronic devices) less frequently than those implanted with the monofocal IOL. Adverse events compared favorably to ISO IOL historical control rate established in the grid found in ISO 11979-7: Ophthalmic implants - Intraocular

lenses - Part 7: Clinical investigations (with the exception of total SSIs). Also, the number of eyes which did not achieve 0.30 LogMar were also shown to be favorable relative to historical data and the control IOL. Higher percentages of subjects reported having visual disturbance. However, subjects who reported having disturbance issues still rated their satisfaction as high in a large proportion of cases.

Based on all available data, the benefits of using the SBL-3™ outweigh the risks. A significant portion of the patient population achieved clinically meaningful results.

XIV. CDRH DECISION

CDRH issued an approval order on July 22, 2022. The final clinical conditions of approval cited in the approval order are described below.

The Lenstec SBL-3™ Post Approval Study is a 2:1 randomized controlled clinical trial per the agreed post-approval study (PAS) outline on February 19, 2021 (email). The objectives of this PAS are: (1) to verify the safety of the SBL-3 multifocal intraocular lens (MIOL) and (2) to determine the risk factors that may be associated with key study endpoints. The test group will enroll up to 330 subjects in order to obtain 300 at the final evaluation. The control group (another approved MIOL) will enroll up to 170 subjects in order to obtain 150 subjects at the final evaluation.

The study endpoints (discussed below) will be evaluated for each group and a comparison made at the appropriate time points. The primary safety endpoints are rates of secondary surgical interventions (SSI) within 6-months related to visual symptoms or refractive error, rate of eyes with absolute manifest refraction spherical equivalent (MRSE) ≥ 1 diopter (D) from the intended target starting at any visit at 21 days postoperatively, or required SSI related to refractive error at any time in the study (cumulative over the 6-month study), rate of eyes with changes between any two postoperative visits, of absolute MRSE ≥1 D, starting at any visit at 21 days postoperatively (cumulative over the 6-month study), rate of eyes with changes between any two postoperative visits monocular uncorrected distance visual acuity UCDVA) ≥ 10 letters (plus or minus) starting at any visit at 21 days post-operatively (cumulative over the 6-month study), rate of subjects with significant difficulty due to variations in distance vision on a questionnaire (given at every visit, including unscheduled, starting at any visit at 21 days postoperatively over the 6-month study) defined as a “severe” level of difficulty, and rate of eyes with UCDVA worse than 20/40 at any single visit starting at the 3A visit or later. The scheduled follow up visits will be 1-day post-operative, 1-week post-operative, 1-month post-operative, 3-month post-operative and 6-month post-operative. The 6-month post-operative visit will have a scheduled window of +/-3 weeks from the initial surgical date.

The secondary endpoints include the rate of eyes with other types of serious adverse events (ISO 11979-7 historical grid Table E.2 - Posterior chamber IOL adverse event rates). The collection of the following parameters is required to meet the second objective of the study: UCDVA, baseline angle kappa measured objectively (biometry) and subjectively (e.g., using a penlight), post-op angle kappa measured objectively (biometry) and subjectively (e.g., using a penlight), baseline pupil size, segment line orientation measured at surgery and at each postop visit, post-op percent of pupil coverage by near zone of SBL-3 (objectively measured using slit lamp photographs), and preoperative lid position. The scheduled follow-up visits will be 1-day post-operative, 1-week post-operative, 1-month post-operative, 3-month post-operative and 6-month post-operative. The 6-month post-operative visit will have a scheduled window of +/-3 weeks from the initial surgical date.

From the time of study protocol approval, you must meet the following timelines for

- First subject enrolled within 6 months
- 20% of subjects enrolled within 12 months
- 50% of subjects enrolled within 18 months
- 100% of subjects enrolled within 24 months
- Submission of Final study report: 3 months from study completion (i.e. last subject, last follow-up date)

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XV. 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.

XVI. REFERENCES

International Standard Organization 10993, Biological Evaluation of Medical Devices

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

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

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

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

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.