PHYSICIAN LABELING
SBL-3™ MULTIFOCAL INTRAOCULAR LENS

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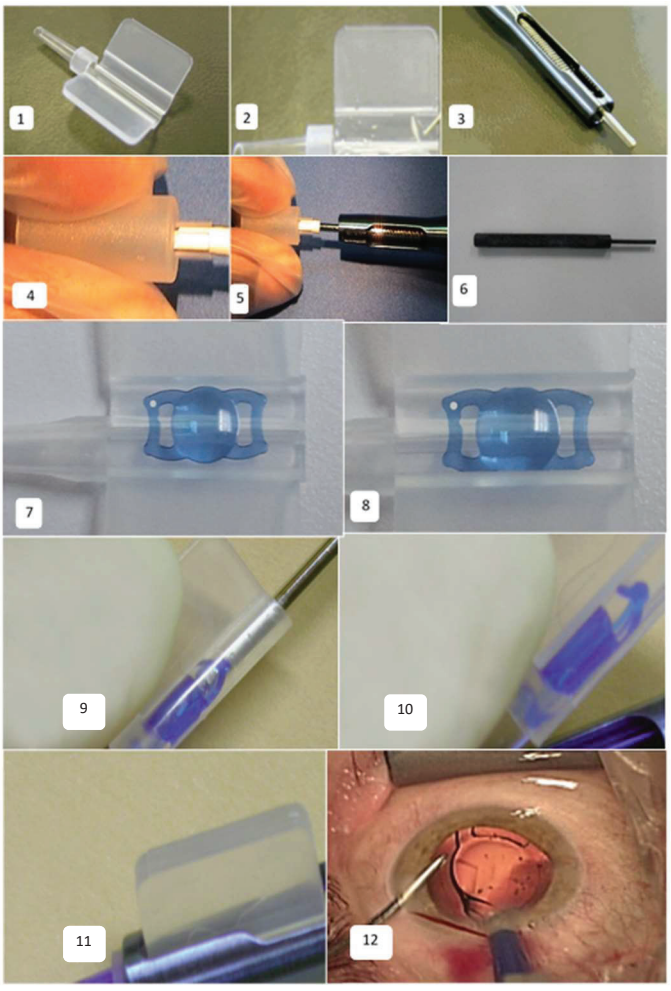


Acronyms or abbreviations used throughout this Physician Labeling

AAO	**American Academy of Ophthalmology**
A/C	**Anterior Chamber**
ACD	**Anterior Chamber Depth**
ADE	**Adverse Device Effect**
AE	**Adverse Event**
ASADE	**Anticipated Serious Adverse Device Effect**
BCVA, BCDVA	**Best Corrected Distance Visual Acuity**
C°	**Celsius**
CI	**Confidence Interval**
CM	**Centimeter**
CPD	**Cycle Per Degree**
CYC/MM	**Cycle per Millimeter**
D	**Diopter**
DCIVA	**Distance Corrected Intermediate Visual Acuity**
DCNVA	**Distance Corrected Near Visual Acuity**
DMEK	**Descemet Membrane Endothelial Keratoplasty**
eEDTRS	**Electronic Early Treatment Diabetic Retinopathy Study**
F°	**Fahrenheit**
FDA	**Food and Drug Administration**
IDE	**Investigational Device Exemption**
IOL	**Intraocular Lens**
ISO	**International Organization for Standardization**
ITT	**Intent to Treat**
LASIK	**Laser-Assisted In Situ Keratomileusis**
LogMAR	**Logarithm of the Minimum Angle of Resolution**
mmHG	**Millimeter of Mercury**
MIOL	**Multifocal Intraocular Lens**
MRSE	**Manifest Refraction Spherical Equivalent**
MTF	**Modular Transfer Function**
ND:YAG, YAG	**Neodymium-Doped Yttrium Aluminum Garnet**
PCO	**Posterior Capsule Opacity**

PMA	**Pre-Market Approval**
PRO	**Patient Reported Outcome**
SAE	**Serious Adverse Event**
SE	**Spherical Equivalent**
SAP	**Statistical Analysis Plan**
SSI	**Secondary Surgical Intervention**
SPE	**Safety and Performance End Point**
STD	**Standard**
UV	**Ultra-Violet**
UCDVA	**Uncorrected Distance Visual Acuity**
UCNVA	**Uncorrected Near Visual Acuity**

IMPORTANT NOTICE

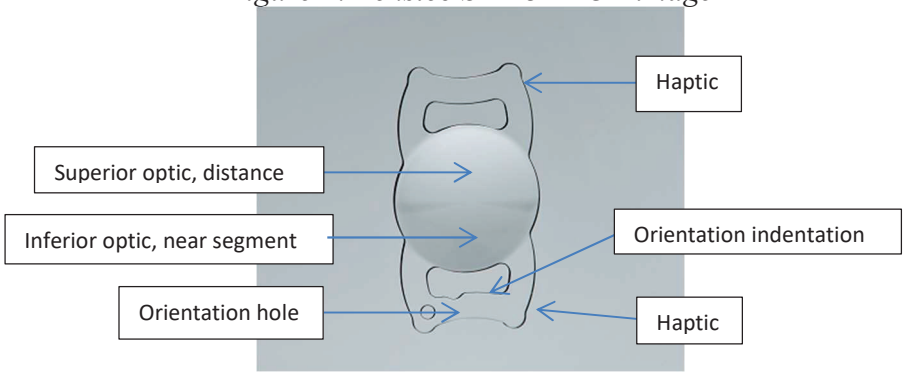
It is highly recommended that the surgeon adheres to the recommendations, precautions, contraindications and warnings outlined in these instructions.

CAUTION: Federal (U.S.) law restricts this device to the sale by or on the order of a physician.

DETAILED DEVICE DESCRIPTION

The SBL-3™ Multifocal Posterior Chamber 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[1] 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.

Figure 1: Lenstec SBL-3 MIOL image



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 [2-4]. Each MIOL has a 360° square edge design [5].

Table 1: SBL-3™ characteristics

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 their 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

Figure 2: Through-focus MTF values at 50 cyc/mm

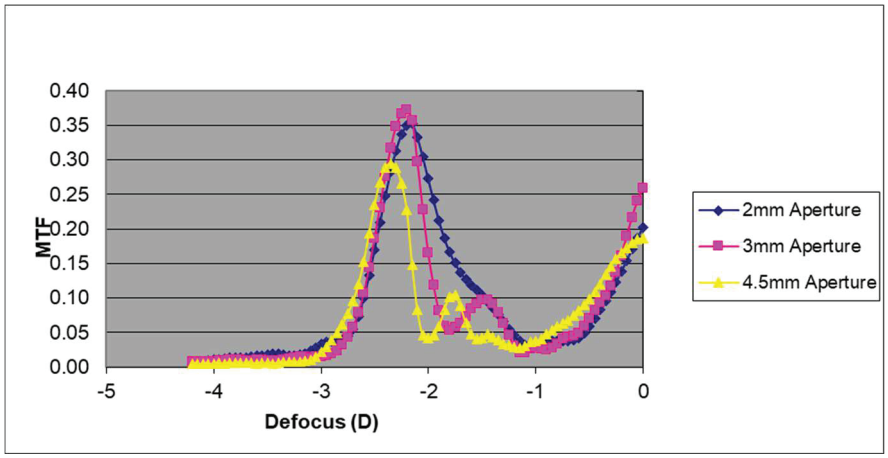


Figure 2 describes the SBL-3™ MIOLs MTF/optical performance at differing pupil sizes in a standardized eye model at 50 cyc/mm. In the image, focus is directed from distance through near. NOTE: Higher MTF values indicate better performance.

Figure 3: Spectral transmittance

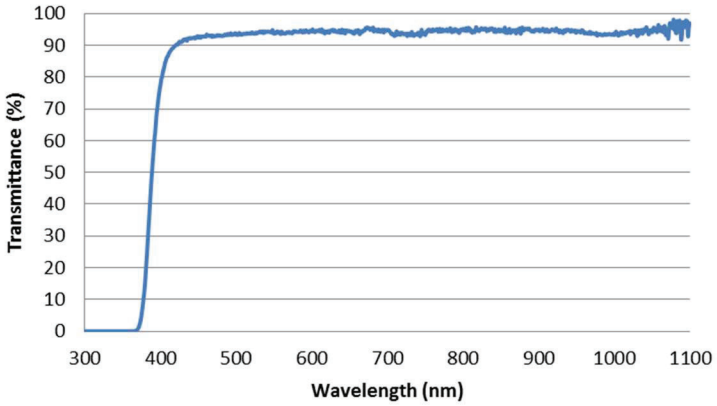


Figure 3 describes the SBL-3™ spectral transmittance over the 300 nm to 1100 nm wavelengths. The % UV transmittance from 300-360 nm is 0% and the 10% cut off is 374 nm.

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.

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.

WARNINGS

The implanting ophthalmic surgeon shall consider the following warnings, and identify a risk/benefit ratio prior to surgery:

1) Failure to follow the implantation instructions supplied with this lens could lead to mishandling and subsequent IOL damage prior to or during implantation.
2) There is no clinical data to support placing this lens in the ciliary sulcus.
3) The overall posterior capsule opacification (PCO) rate was similar to the control monofocal IOL, however, clinically significant PCO did occur earlier in the post-operative period with the SBL-3 group.
4) Clinically significant PCO requiring ND:YAG occurred at a higher rate when compared to the control monofocal IOL. This is consistent with other multifocal IOLs.
5) Any posterior capsulotomy opening should be limited to approximately 5 mm. Consistent with other IOLs, there is an increased risk of lens dislocation and/or secondary surgical intervention with early or large YAG capsulotomies.
6) The IOLs should not be implanted if the capsular bag is not intact or if there is significant zonular rupture/dehiscence.
7) The effectiveness of ultraviolet light absorbing lenses in reducing the incidence of retinal disorders has not been established. As a precaution, patients should be informed that they should wear sunglasses with UV protection when in sunlight.
8) The rate of cystoid macular edema may increase with extracapsular bag placement of the haptics.
9) Patients with any of the following could be at increased risk for complication(s) following implantation of the SBL-3: previous ocular surgery, those meeting any of the listed factors in the 'Contraindications' section of this document, non-age related cataract, vitreous loss, iris atrophy, severe aniseikonia, ocular hemorrhage, macular degeneration or suspected microbial infection.
10) Patients who present complications at the time of cataract extraction could be at increased risk for complication(s) following implantation of any IOL. This may include but is not limited to any of the following: persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss.
11) The implanting surgeon shall consider whether patients in who intraocular lens implantation would affect the ability to observe, diagnose or treat posterior segment diseases, should have the SBL-3 implanted.
12) The implanting surgeon shall consider whether patients who have a distorted eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible, should have the SBL-3 implanted.
13) The implanting surgeon shall consider whether patients who have recurrent severe anterior or posterior segment inflammation or uveitis, should have the SBL-3 implanted.
14) Any circumstances which could lead to damage to the corneal endothelium during implantation should be avoided.
15) The SBL-3 lens has only been studied in adult patients. Children are likely to have special issues with the SBL-3 lenses related to larger pupil size, more

reactive pupils, and difficulty in articulating problems with visual disturbances. Implantation in children is not recommended.

16) Reuse of the IOL is strictly prohibited, as it raises serious safety and effectiveness concerns.
    a. LENSTEC does not provide cleaning/sterilization instructions. An improperly cleaned and/or sterilized IOL can cause significant damage to a patient's vision, due in part to cross contamination induced infection.
    b. Once removed from its original packaging, the IOL can lose traceability. In the event an IOL is re-used, it is unlikely the user will know the correct expiry date, serial number or dioptric power.
    c. LENSTEC cannot guarantee stability or proper function of either haptic or optic portions in the event that an IOL is re-used. Failure of either of these components can render the IOL ineffective.
17) The SBL-3 was only studied bilaterally. Monocular results may vary.
18) Patients should exercise caution when driving at night or in poor visibility conditions. In the driving simulation portion of the clinical trial, patients in the control group were able to recognize signs and road hazards sooner than in the multifocal group. This is consistent with previously approved multifocal IOLs.
19) The IOL is designed with a half power ring at the very bottom of the optic portion. This is depicted in the figure 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 4: SBL-3 IOL optic

20) In pupil sizes that exceed 6mm, the possibility exists of some portion of incoming light to miss the optic altogether. This light will not be focused on the retina, and ultimately could contribute to potential visual disturbances that present themselves to IOL recipients. This is consistent with other IOLs.
21) Theoretically, the type of blur associated with the segmented multifocal design is different than that of the concentric ring design, and therefore, the visual disturbance profiles could be different. Patients should be informed that there is a possibility that this blur pattern could impact the types of visual disturbances seen in the post-operative environment. There was no evidence that this occurred during the clinical trial for the SBL-3, but the possibility exists.
22) Substantial changes in manifest refraction spherical equivalent (>1.0D) occurred at a higher frequency in the SBL-3 arm than in the control. In many cases no reason could be identified as to why this occurred. These refractive changes may be associated with substantial changes in uncorrected distance visual acuity.

23) The pivotal clinical study for the SBL-3 included only a small number of subjects with small pupils. One separate study found that smaller pupil size was associated with worse subjective visual disturbances using a specific quality of vision survey[6].
24) In the pivotal clinical trial for the SBL-3, there was a higher rate of severe visual disturbances in the SBL-3 arm than the control arm, for several categories.
25) Failure to ensure the lens haptic or optic is properly placed in the cartridge can lead to damage during injection/implantation.
26) Visual symptoms may be expected due to the superposition of focused and unfocused multiple images. In the pivotal study, the SBL-3-implanted patients showed higher rates of severe glare, halos, double/multiple images, and streaks of light (starbursts). As with other multifocal IOLs, there is a possibility that visual symptoms may be significant enough that the patient will request explant of the multifocal IOL. Patients should be cautioned that some of these visual symptoms may contribute to difficulties with driving, under certain conditions.
27) The pivotal clinical study found that the SBL-3 IOL was associated with a loss of contrast sensitivity and poorer mesopic low-contrast acuity, as compared to a monofocal IOL. Therefore, patients implanted with the SBL-3 IOL should exercise caution when driving at night or in poor visibility conditions.
28) The pivotal clinical study found that a greater proportion of SBL-3 subjects had a manifest refraction spherical equivalent > 1.0D of myopia, which could increase the possibility for the need to explant the IOL.

PRECAUTIONS

- The IOL must be stored in dry conditions between 0°C (32°F) and 45°C (113°F).
- Do not attempt to re-use the lens. Do not autoclave or attempt to re-sterilize the lens. Lenses requiring re-sterilization should be returned to LENSTEC Inc.
- Do not use the device if sterile packaging has been damaged or if there are traces of leakage on the bottle or pouch.
- Do not soak the intraocular lens with any solution other than a sterile balanced salt solution or saline solution.
- Once packaging has been opened, the intraocular lens must be used immediately. The hydrophilic nature of the lens can cause the lens to absorb substances with which it comes into contact, such as disinfectants, medicines, blood cells, etc. This may cause a “Toxic Lens Syndrome”. Rinse the lens carefully once removed from the glass vial.
- The lens must be implanted within 2 minutes following removal from its saline bath, as dehydration causes the lens material to become brittle.
- The lens must be implanted in the capsular bag.
- The lens must be implanted using only injection systems validated for use with the IOLs. These are listed in Table 3 below.
- Do not use the intraocular lens after the expiration date shown on the outside package label.

- Handle the intraocular lens carefully. Rough handling or excessive handling may damage the lens.
- The surgeon must be aware of the risk of opacification of the intraocular lens, which may necessitate lens removal[7].
    - NOTE: Although the LENSTEC hydrophilic intraocular lens has a satisfactory history regarding lens opacification, there is a history of lens opacification with lenses from other manufacturers. The material used by LENSTEC, unlike the materials used by other manufacturers has not had any reported 'Adverse Events' due to material discoloration, opacification and/or other material related deficiencies, which have caused post-operative patient problems. Ophthalmic surgeons should keep in mind that there have been cases of reported opacification of hydrophilic IOLs. Most, if not all, of these types of cases required explantation.
- All cases of lens removal must be reported to LENSTEC.
- Patients who did not meet the inclusion/exclusion criteria from the pivotal clinical trial were not studied with the IOL and therefore the safety and effectiveness of use of the SBL-3 device in these types of patients is not known. These are listed below, in the section regarding study design.
- Patients with clinically significant ptosis were not included in the primary clinical study used to approve this device and may have trouble using both parts of the optic.

ADVERSE EVENTS

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 the clinical study safety outcomes section.

HOW SUPPLIED

The Lenstec SBL-3 is supplied in a 0.9% saline solution in a lens bottle contained within a sealed Tyvek sterilizable peel pouch and should only be opened under aseptic conditions.

DIRECTIONS FOR USE

Each LENSTEC SBL-3™ is autoclave sterilized in a lens bottle contained within a sealed Tyvek sterilizable peel pouch. The lens is held in a glass vial containing sterile 0.9% saline solution. The contents of the pouch/bottle are sterile unless the package is damaged or opened. Perform standard phacoemulsification technique. Ensure that the capsulorhexis is between 5.0 and 5.5 mm in diameter. Prior to implanting, examine the lens package for IOL, power, and expiration date. The lens should be implanted using the Directions for Folding and Inserting the Lens, listed below. If more specific instructions for use are available in the insertion system packaging, consult it. NOTE: Only folders/injectors validated for use with the Lenstec SBL-3 should be used. Also, neither the orientation indentation or orientation hole is intended to be used to manipulate or maneuver the SBL-3 once it is inserted in the eye.

INSTRUCTIONS FOR IMPLANTATION OF THE SBL-3
CALCULATION OF LENS POWER:
It is recommended that the surgeon uses a power calculation method with which they are most comfortable. In general, the power of the lens for each patient can be calculated from the keratometry measurements and axial length of the eye according to formulas in relevant literature. An A Constant of 118.00 and an anterior chamber depth (ACD) of 5.22 are the manufacturer suggested values for the LENSTEC SBL-3 when using Optical Coherence Tomography. Additional reference to this topic can be found at http://www.doctor-hill.com/iol-master/lens_constants.htm

NOTE: These manufacturers suggested values are estimates. It is recommended that the surgeon determine their own values based on their own individual clinical experience.

PRE-SURGICAL PREPARATION:

a. Determine the lens power from preferred IOL formula IOL Refractive Calculation Equation.
b. Determine the Expected Post-operative Target Refraction (SE).
c. Measure the patient's mesopic pupil size after at least 5 minutes of dark adaptation and determine if large pupils could impact potential post-operative vision or have adverse consequences. The patient should be counselled on the possibility that that out of focus images could lead to post-operative visual disturbances/ghost images and that in some cases, some patients are unable to tolerate these visual symptoms.

DIRECTIONS FOR FOLDING AND INSERTING THE LENS: (Refer to diagrams on the cover of this DFU document):

1. Prepare injector cartridge (1) by opening the cartridge wings and injecting viscoelastic down the barrel, both channels on each side and across the ridge between them channels (2).
2. Obtain the Injector (3). Expose its plunger tip and use the applicator (4) to affix the silicone tip onto the plunger tip (5) and then retract the plunger as far as it will go.
3. Remove the lens bottle from the Tyvek pouch. Firmly hold the bottle in one hand and unscrew the cap. Remove the stopper and then carefully remove the lens holder from the vial. Retract the plunger to release the holding pins from the lens. Using toothless forceps grasp the lens by the haptic and place the lens on the cartridge as shown in figure (7). Inspect the lens for debris and damage. The SBL-3 has an orientation indentation and orientation hole in one of the haptics, which signifies the side closest to the 'add' portion. The 'add' is found on the anterior IOL surface, so it is important that, when implanted, it is placed as seen in (7).
4. Using a partially open pair of sterile angled toothless forceps, gently compress the lens (including both haptics and the full optic) into the chamber channels of the cartridge below the level of the flaps (8).
5. Slowly close the cartridge, keeping gentle pressure on the optic with the forceps, and ensure that the optics and haptics are not pinched in the flaps of the cartridge as it closes. Visually inspect the closed cartridge to ensure that the lens is not trapped between the flaps. Introduce the plunger end of the Lens Loader II into the back of the closed cartridge chamber (9), and slowly advance the lens from the Chamber to the Barrel (feel for any resistance which could indicate the lens is trapped between the flaps). Ensure that the Lens Loader II is advanced to its farthest depth, so that the lens is in the tip of the nosecone (10). The lens should move freely. If it does not, one (or both) of the haptics or optic is pinched by the wings of the cartridge. If the lens does not move freely, open the cartridge and repeat steps 4 and 5. If the lens moves freely, the cartridge is ready to load in the injector.
6. Place the cartridge into the housing of the injector and push it in as far as it will go (11). Depress the Injector Plunger so that the Silicone Tip fits into the back of

the cartridge chamber and advance it forward until you can just see the tip in the Barrel.

7. Carefully introduce the loaded injector tip into the anterior chamber with the bevel facing down, assisting with delivery into the capsular bag, until the tip of the cartridge is near the mid-pupil margin. Gently inject the lens into the anterior chamber. If the IOL is twisting, rotate the injector, if necessary, to ensure the IOL remains orientated correctly as it emerges from the cartridge. Ensure the leading haptic is in the bag. Gently withdraw the cartridge from the eye as the trailing haptic emerges from the cartridge (12). Reconfirm that the anterior chamber is deep, and if not, introduce additional saline or viscoelastic. Using a tapered "pusher", insert the trailing haptic into the capsular bag if needed.
8. Immediately after lens insertion, visually confirm correct placement of the four footplates by manipulating the lens once it is fully inside the capsule. The SBL-3 should be carefully manipulated (rotated) within the capsular bag to such that a line intersecting both transition zones would be aligned on the axis of 45° and 225° for the right eye and 135° and 315° for the left eye. This allows for the near segment of the SBL-3 to be oriented inferonasal. The amount of manipulation will depend on where the surgical incision was made and if any rotation has occurred during implantation.
9. Irrigate and aspirate the saline or viscoelastic from the anterior chamber and from behind the lens.
10. Close the wound as desired.

The table 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		

SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of the SBL-3 Multifocal Intraocular Lenses. This study was conducted 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.

STUDY DESIGN

Subjects 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 in two phases (Phase 2 and Phase 3).

The study was a prospective, multi-center, pivotal, two-arm/parallel group, subject masked, randomized (in a 2:1 manner) cohort study. Subjects were masked from knowing the type of IOL they received, either the multifocal SBL-3 or the monofocal control. Both groups were enrolled concurrently at one of 18 total clinical sites across the United States. 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 receive the identical IOL type from 7 to 30 days from the primary eye implantation date. Both eyes were required to meet inclusion/exclusion criteria for this reason.

The safety objective was to characterize the rates of adverse events in the SBL-3 arm and to statistically compare these to rates seen in with a monofocal IOL. From a statistical standpoint, the primary safety endpoint was the presence or absence of all adverse events whether or not listed in the FDA historical grid found in ISO 11979-7: Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations. Secondary surgical intervention due to the optical properties of the SBL-3 was part of the primary safety endpoint. The analysis was to compare the rates in the SBL-3 and control arms, using a 2- sided 90% confidence interval constructed around the estimate of the rate difference for the SSI rate due to optical properties. (The group rates would 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.)

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

There were three co-primary effectiveness endpoints at the 1-year post-operative visit:

a. 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.
b. 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-inferiority of the SBL-3 IOL to the control monofocal IOL (using a non-inferiority margin of 0.10 logMAR).
c. 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-inferiority of the SBL-3 IOL to the control monofocal IOL (using a non-inferiority margin of 0.10 logMAR).

There were several secondary and supportive effectiveness endpoints, but only use of vision correction was studied for a label claim.

A total of 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.

The control group received the Akreos AO60 (Bausch + Lomb, NJ, USA) aspheric monofocal IOL, which is a legally marketed alternative for the correction of aphakia. It was selected due to its similarity in appearance and physical characteristics to the test article.

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 0.20 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 0.20 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

All patients were scheduled to return for follow-up examinations as follows:

- Visit 0- preoperative visit for both eyes
- Visit 00- 1st Eye Op Visit
- Visit 1- 1-2 days post-operative (1st eye)
- Visit 2- 7-14 days post-operative (1st eye)
- Visit 00A- 2nd eye operative visit (7-30 days from Visit 00)
- Visit 3- 30-60 days post-operative (1st eye)
- Visit 1A- 1-2 days post-operative (2nd eye)
- Visit 2A- 7-14 days post-operative (2nd eye)
- Visit 3A- 30-60 days post-operative (2nd eyes)
- Visit 4A- 120-180 days post-operative (each eye monocular and binocular)
- Visit 5A- 330-420 days post-operative (each eye monocular and binocular)

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.

Adverse events and complications were recorded at all visits. The key timepoints are shown below in the tables summarizing safety and effectiveness.

3. Clinical Study Results

i. Accountability of PMA cohort

A total of 499 subjects were randomized into this study and randomized to receive either the test or control IOL. Of those, 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 4 describes the subject accountability.

Table 4: 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.											

ii. 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 5. 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 5: 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				
Note: % = (n/N)*100				

CLINICAL OUTCOMES

SAFETY OUTCOMES

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 6 to 17.**

CUMULATIVE AND PERSISTENT ADVERSE EVENTS- Safety Population- All Eyes

Table 6 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 6: Cumulative and Persistent Adverse Events, All Eyes, Safety Population, primary safety endpoint

		SBL-3 N=656			Akreos N=332		
	ISO[a] SPE Rate (%)	**Max[b] No. of Cases allowed before SPE rate exceeded**	**Observed**	**Observed[d] Rate**	**Max[b] No. of Cases allowed before SPE rate exceeded**	**Observed Number**	**Observed Rate**
			Number (n)	**(%)**		**(n)**	**(%)**
Cumulative Serious Adverse Events							
Cystoid Macular Edema	3	27	13	2	15	9	2.7
Hypopyon	0.3	4	0	0	3	0	0
Endophthalmitis	0.1	2	0	0	1	0	0
Lens Dislocated from Posterior Chamber	0.1	2	0	0	1	0	0
Pupillary Block	0.1	2	1	0.2	1	0	0
Retinal Detachment	0.3	4	1	0.2	3	0	0
SSI (excluding posterior capsulotomy)	0.8	9	12	1.8[c]	6	3	0.9
Persistent Serious Adverse Events		**SBL-3 N628**			**Akreos N=322**		
Corneal Stromal Edema	0.3	4	1	0.2	3	0	0
Cystoid Macular Edema	0.5	6	1	0.2	4	0	0
Iritis	0.3	4	0	0	3	0	0
Raised IOP Requiring Treatment	0.4	5	0	0	3	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

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 SSIs related to the optical properties of the IOL out of 656 SBL-3 implanted are shown below in Table 7. 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. This confirms a successful outcome.

Table 7: Secondary Surgical Interventions Related to the Optical Properties of the IOL, All Eyes, Safety Population

Eye	**Statistic**	**SBL3**	**Akreos**	**SBL3 - Akreos**
All Eyes	**N**	**656**	**332**	
	n	6	0	6
	%	0.91	0.00	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				

Secondary Surgical Intervention Not Related to Optical Properties of the IOL

There were 6 SBL-3 cases of SSI not related to the optical properties of the IOL during this study. The SSIs were treatments for SAEs; there were no SSIs as the original event.

Table 8: Secondary Surgical Interventions 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 9: Supportive Characterization of Secondary Surgical Interventions Based on a Modified Version of AAO Consensus (Masket,2017) Safety Population- All Eyes

All Eyes	Statistic	SBL3	Akreos	SBL3 - 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 Eye

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- 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 10: 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 SSIs related to the optical properties of the IOL out of 330 SBL-3 implanted are shown below in Table 11. 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 11: Secondary Surgical Interventions Related to the Optical Properties of the IOL, Primary Eyes, Safety Population

Eye	**Statistic**	**SBL3**	**Akreos**	**SBL3 - Akreos**
Primary Eye	**N**	**330**	**166**	
	n	3	0	3
	%	0.91	0.00	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 12.

Table 12: Supportive Characterization of Secondary Surgical Interventions Based on a Modified Version of AAO Consensus (Masket,2017) Safety Population- Primary Eyes

Primary Eye	Statistic	SBL3	Akreos	SBL3 - 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				

SUBJECTS ACHIEVING BEST CORRECTED DISTANCE VISUAL ACUITY (BCDVA) of 0.30 LogMar

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 13 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 14 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 0.30 LogMAR or better at 6 months, 1 year and endpoint 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).

Table 13: 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 14 shows best case SBL-3 eyes achieved BCDVA of 0.30 LogMAR or better at 6 months, 1 year and endpoint 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 14: 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 LETTER OF BCDVA BETWEEN POSTOPERATIVE VISITS

The following table presents 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 15: 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 visit and any prior visit	31 (4.9)	26 (8.1)	-0.03 (0.017)	-0.06, -0.00	0.0608

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 group (4.9%; 31/628), but this difference was not significant.

Table 16: 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-value1
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 visit and any prior visit	18 (5.7)	11 (6.8)	-0.01 (0.024)	-0.05, 0.03	0.6865

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%; 11/166) had more subjects lose 10 or more letters at the 1-year post-operative visit than the SBL-3 group (5.7%; 18/329). 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 historical control "grid") were also evaluated.

Table 17: 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)	

Note: % = (n/N)*100

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/m2 and mesopic conditions to approximately 3 cd/m2 with the use of a neutral density filter.

Figure 5: Contrast sensitivity outcomes, photopic, without glare at the 6-month post-operative visit

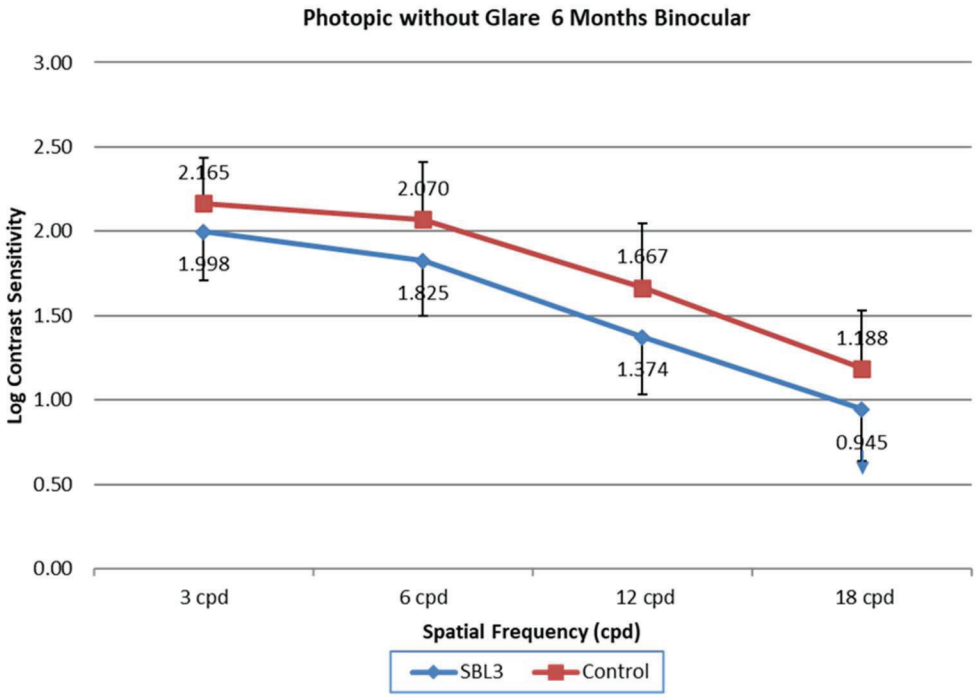


Figure 6: Contrast sensitivity outcomes, photopic, without glare at the 1-year post-operative visit

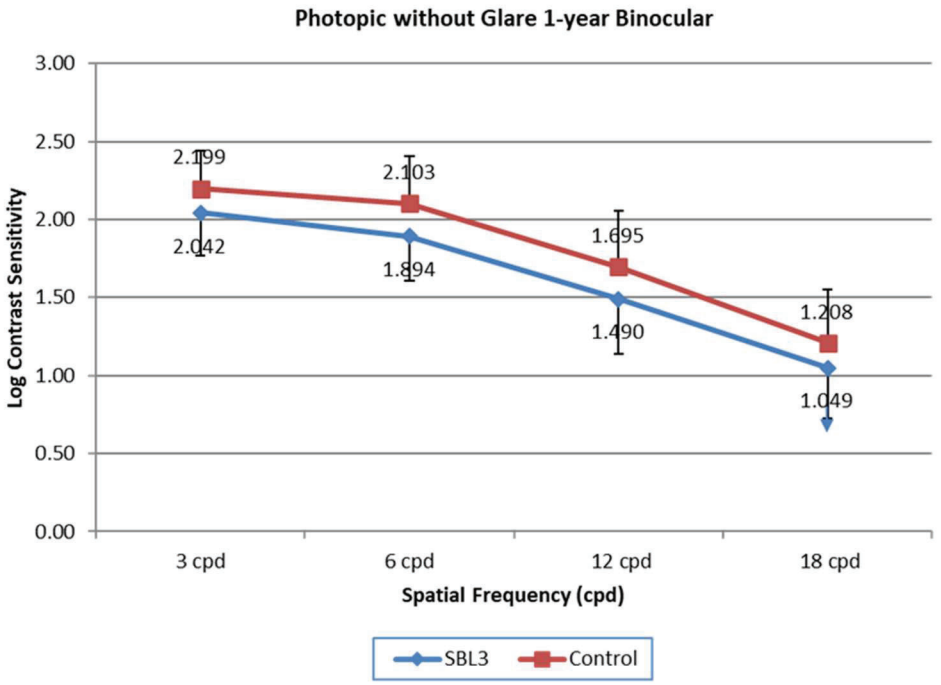


Figure 7: Contrast sensitivity outcomes, photopic, with glare at the 6-month post-operative visit

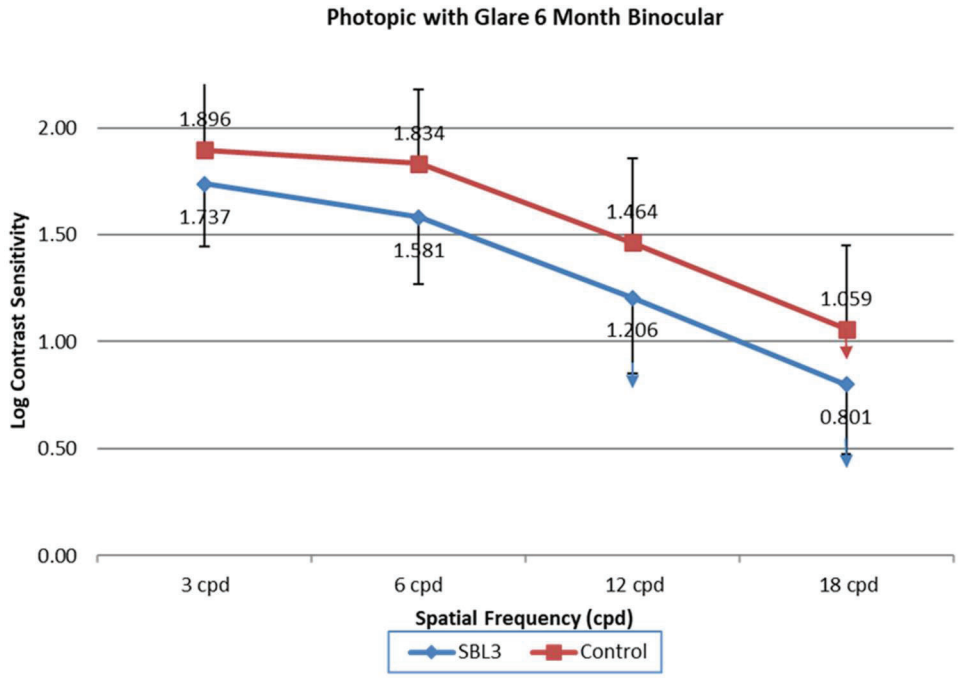


Figure 8: Contrast sensitivity outcomes, photopic, with glare at the 1-year post-operative visit

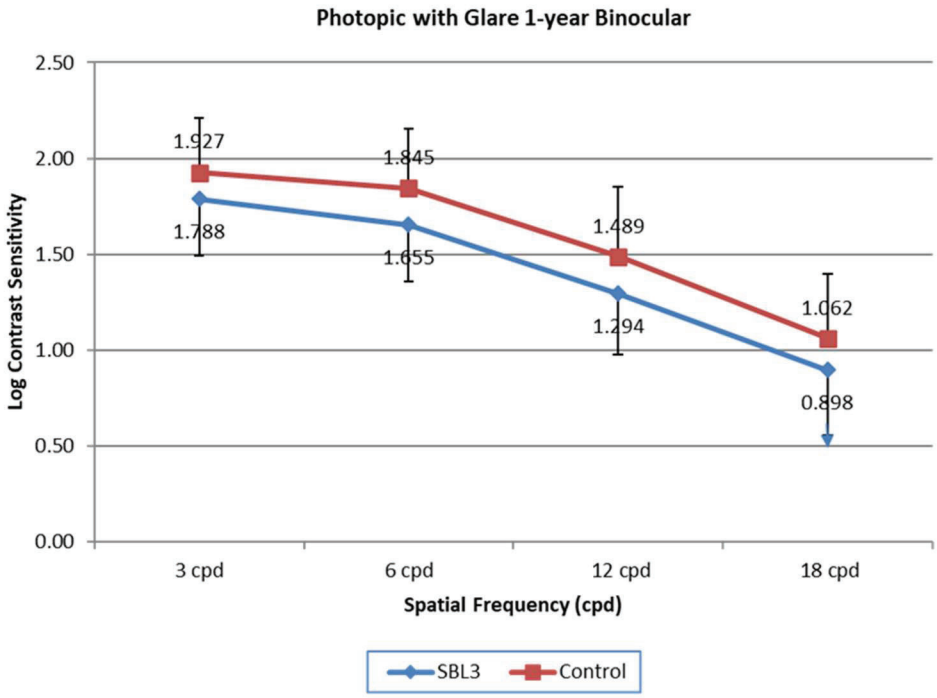


Figure 9: Contrast sensitivity outcomes, mesopic, without glare at the 6-month post-operative visit

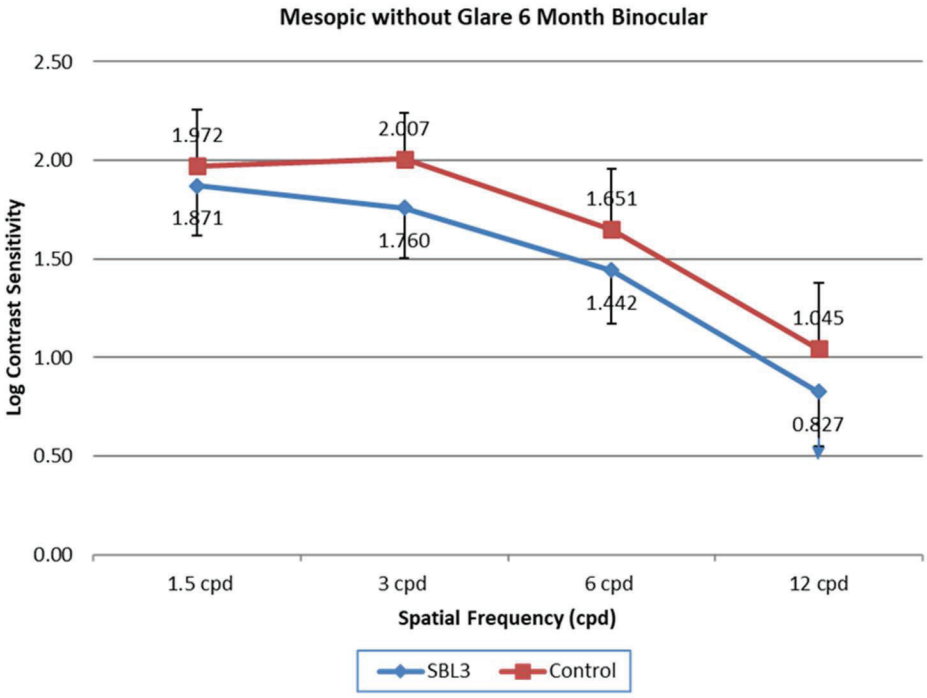


Figure 10: Contrast sensitivity outcomes, mesopic, without glare at the 1-year post-operative visit

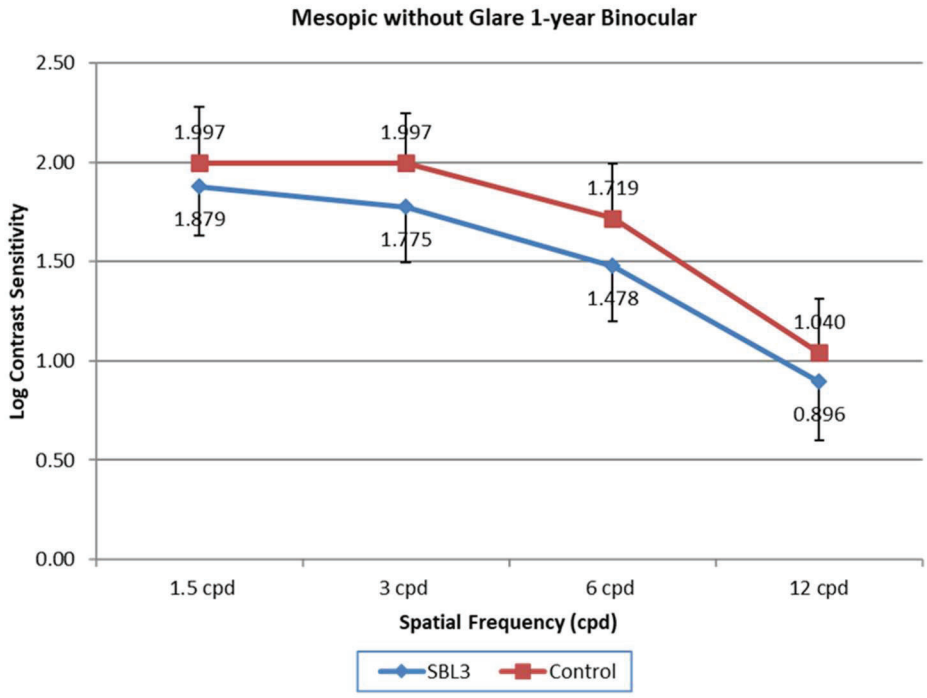


Figure 11: Contrast sensitivity outcomes, mesopic, with glare at the 6-month post-operative visit

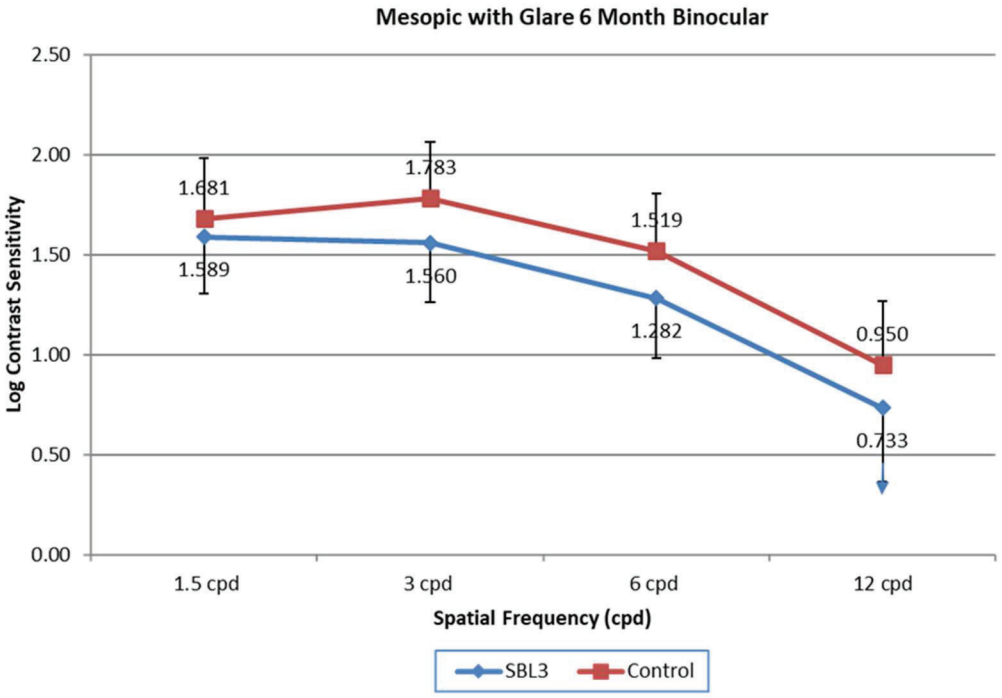
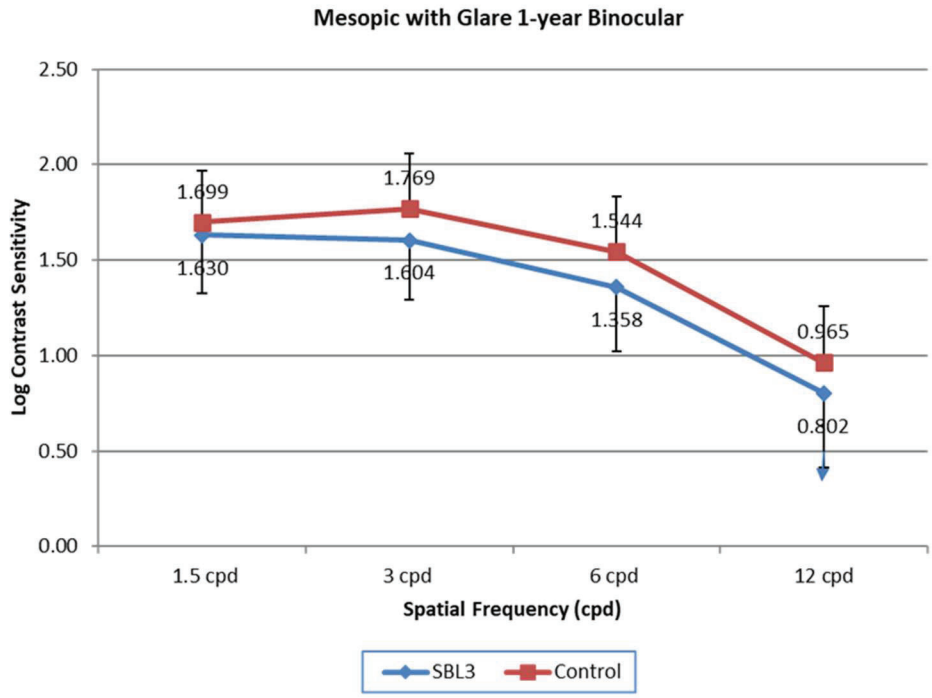


Figure 12: Contrast sensitivity outcomes, mesopic, with glare at the 1-year post-operative visit



Below are descriptions of these outcomes in tabular form.

Table 18: 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 19: 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 18 and 19 show that under photopic without 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.

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

Table 20: 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 21: 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 VISUALIZATION

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% of either group (628/628 in SBL-3 and 322/322 in control).

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 OF >1.0D

There were 30 (thirty) instances in which 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 22, below, describes these outcomes.

Table 22 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. Rates of substantial myopic outcomes were substantially higher in the SBL-3 arm than in the control arm. Table 23, below, describes these outcomes.

Table 23 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. 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, as shown in Tables 24 and 25.

Table 24 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 25 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.

IOP CHANGES

The table below describes the rate of changes in IOP during the course of the clinical trial.

Table 26 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 in IOP, N = total number of eyes represented in that interval.				

In the table, the following are noted:

- N n/N (%) where the first N is the number of occurrences in that interval, n is the number of eyes with at least one occurrence, and the second N is the number of eyes in the interval with the percentage (rate).

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 group had 1 instance (1/656 total SBL-3 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 group and two (2) for the Akreos AO group as shown in Table 27, 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 27 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 > 10^{o}	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% (304/628) for the SBL-3 and 29.8% (96/322) (90% CI 0.13, 0.24) for the control lens.

SURGICAL PROBLEMS

The following table describes surgical problems and procedures encountered in the pivotal trial.

Table 28 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)

Note: % = (n/N)*100

Each group had a number of surgical problems. In primary eyes, posterior capsule damage (1.2%; 4/133) was the largest proportion for the SBL-3 group. In fellow eyes, the largest proportion of problems involved iris damage (0.9%; 3/333). In all eyes, iris damage, IOL damage and posterior capsule damage shared the highest occurrence rate (0.60%; 4/666). In the control's primary eyes, IOL damage, wound leak and anterior capsular rent shared the highest occurrence rate (0.60%; 1/166). 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%; 4/332).

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 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. The below table reflects the number of devices returned and reasons.

Table 29: 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 groups and five (5) in the control group. These subjects left for the following reasons:

In the SBL-3 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.

EFFECTIVENESS OUTCOMES

EFFECTIVENESS RESULTS:

The analysis of effectiveness was based on 475 evaluable patients at the 1-year post-operative study visit. Key effectiveness outcomes are presented in Tables 30 to 36 and Figures 10 to 13.

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 30, below, has specific results.

Table 30: 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	
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)

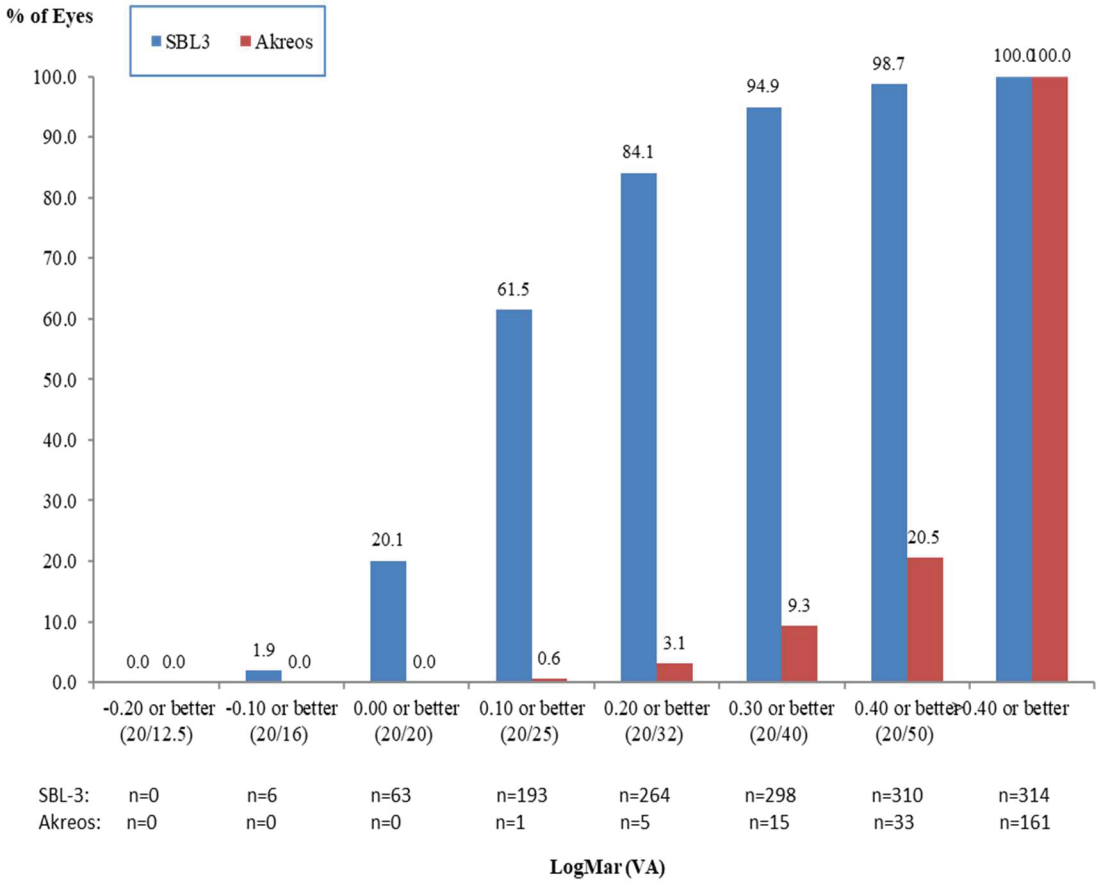


Table 31, below, corresponds to Figure 13, above. It provides the sample sizes and rates described in the figure.

Table 31: 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)
-0.1 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 32, below, has specific results.

Table 32: 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					
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 at intermediate distance. Cumulative monocular DCIVA is presented in Figure 14, below.

Figure 14: Cumulative monocular DCIVA at 1-year post-operative visit (all implanted population)

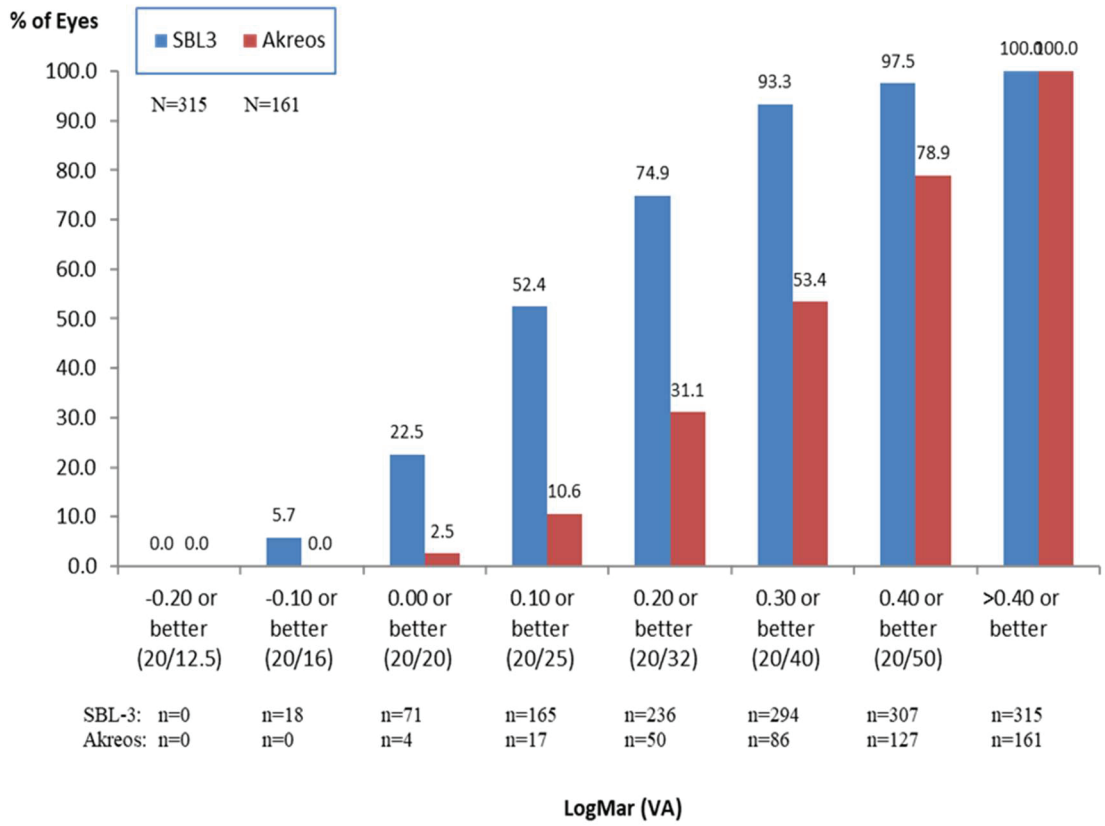


Table 33, below, corresponds to Figure 14, above. It provides the sample sizes and rates described in the figure.

Table 33: 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 Best Corrected Distance Acuity (BCDVA) for the first implanted eye at visit 5A (ITT Population). Table 34, below, has specific results.

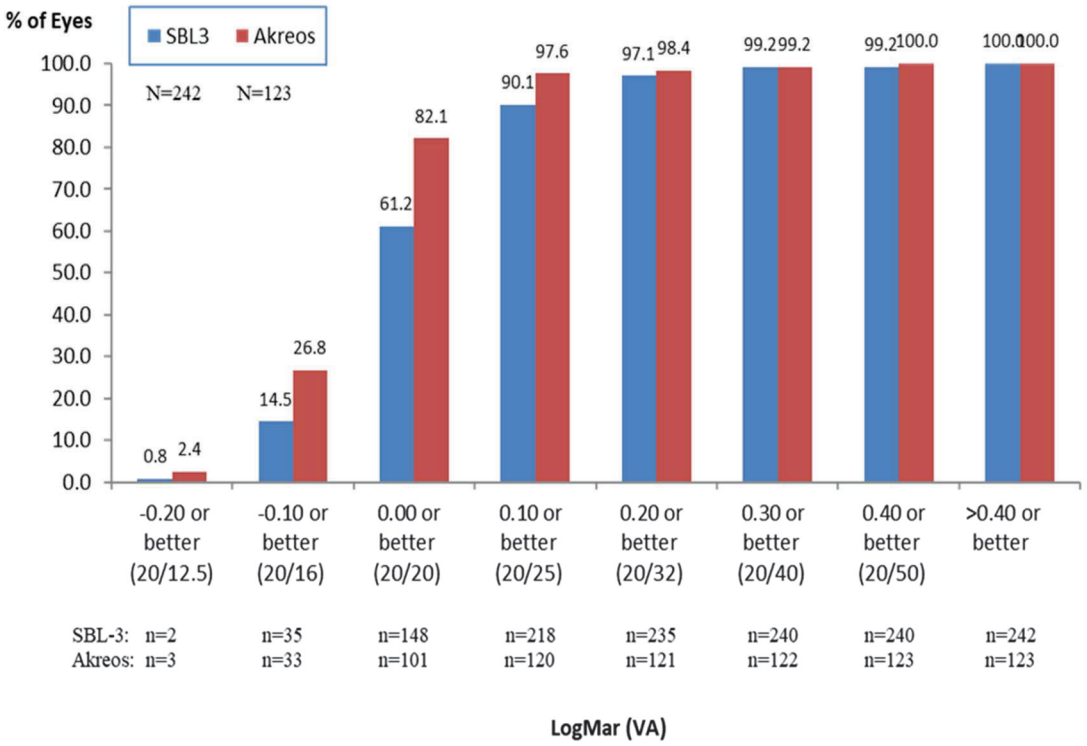
Table 34: Best Corrected Distance Visual Acuity (LogMar) at 5A (by analysis population)

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					

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. 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 0.003 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 Analysis 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 0.10 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 35, below, corresponds to Figure 15, above. It provides the sample sizes and rates described in the figure.

Table 35: 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 Distance Corrected Near Visual Acuity (DCNVA) at 40 cm for the first implanted eye at visit 4A (120-180 post-operative) (All Implanted Population). Table 36, below, has specific results.

Table 36: 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

Distance Corrected Intermediate Visual Acuity (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 37, below.

Table 37: 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 is not worse than the control for visual acuity for intermediate.

The third secondary effectiveness endpoint was associated with photopic monocular Best Corrected Distance Visual Acuity (BCDVA) at 4 m for the first implanted eye at visit 4A (120-180 post-operative) (All Implanted Population). That data is presented in Table 38 below.

Table 38: 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		

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. Clinically, the control had slightly better vision than the SBL-3 in each of the populations. In the All Implanted dataset, 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 39, below.

Table 39: Use of vision correction 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%; 293/314) at a much higher rate than the control (25.5%; 41/161). Similarly, with regards to intermediate vision, SBL-3 subjects (93.9%; 295/314) also reported a large improvement over the control (45.3%; 73/161). Regarding distance vision, SBL-3 subjects (93.9%; 295/314) 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 40, below.

Table 40: 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 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 41 through Table 49 show these data.

UNCORRECTED DISTANCE VISUAL ACUITY

Uncorrected distance visual acuity in primary eyes is presented below in Table 41. 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 41: 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 42. At the 1-year post-operative visit, the control IOL has a lower mean score than the SBL-3 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 42: 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 43. 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 43: 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 44. 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 44: 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 45. 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 45: 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 46. 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 46: 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 INTERMEDIATE VISUAL ACUITY

Uncorrected intermediate visual acuity in primary eyes is presented below in Table 47.

Table 47: 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 48.

Table 48: 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 49.

Table 49: 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/m2. Binocular defocus results were analyzed for all eyes (Figure 16), and by two photopic pupil size ranges: >2.75 mm and <4.0 mm (Figure 17); and ≥4.0 mm (Figure 18).

Figure 16: Defocus curve outcomes, binocular, all eyes at the 6-month post-operative visit

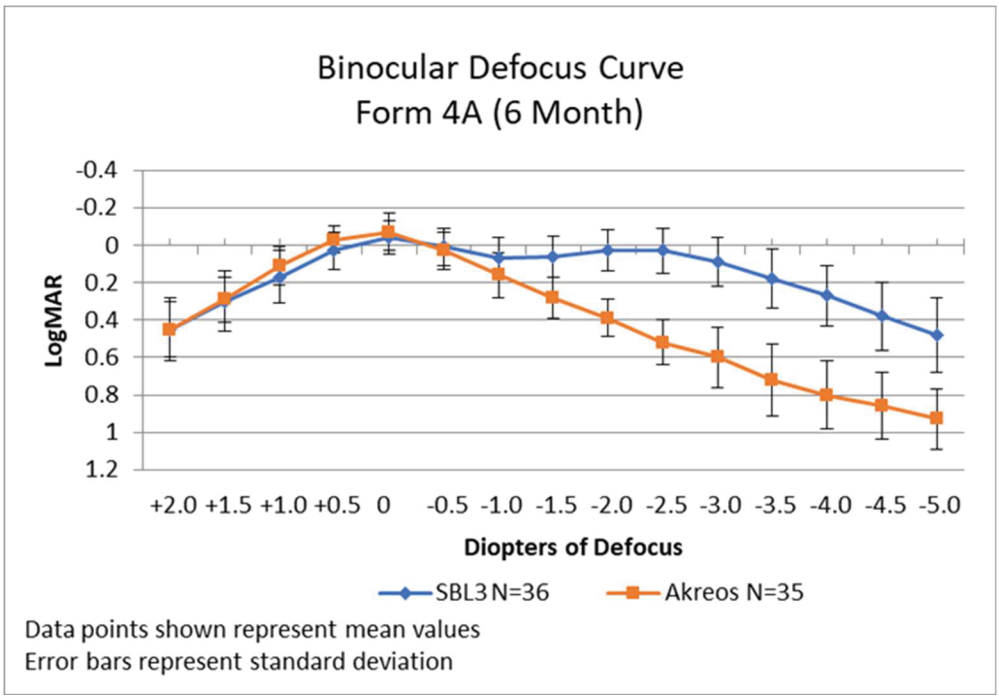


Figure 17: Defocus curve outcomes, binocular, stratified by pupil size at the 6-month post-operative visit (smaller pupil group)

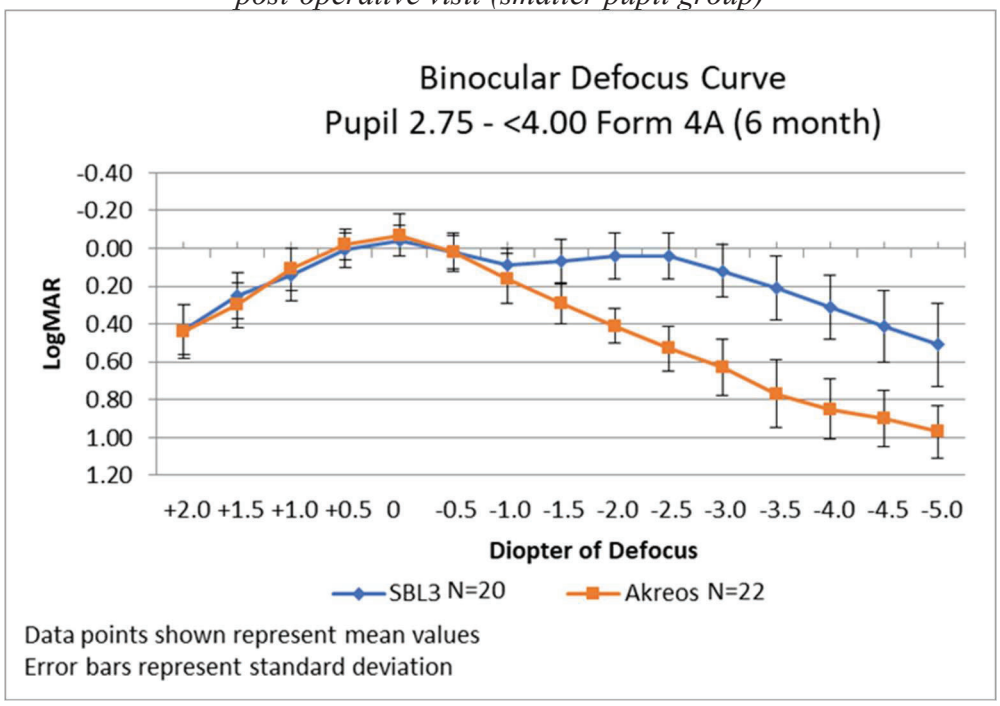
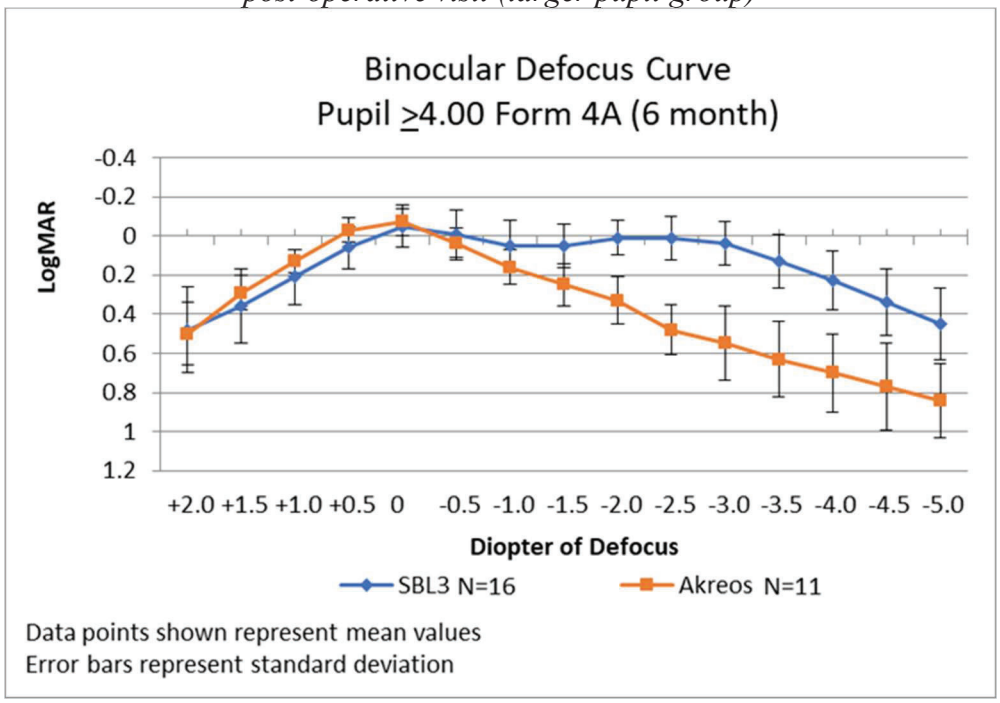


Figure 18: Defocus curve outcomes, binocular, stratified by pupil size at the 6-month post-operative visit (larger pupil group)



Defocus evaluation showed that both IOLs performed well around the 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. The viewing distance used for low contrast testing was 4 meters. The test performed was 10% low contrast best-corrected distance visual acuity.

Table 50: 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 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 $\geq 93.3\%$ ($\geq 292/313$) of subjects opting to not use vision correction in all 4 populations listed below and at all three distances compared to $\geq 25.5\%$ ($\geq 41/161$) (for near vision), 45.3% ($\geq 73/161$) (for intermediate vision) and 85.1% ($\geq 137/161$) (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

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.

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Patient Information Brochure

SBL-3™ Multifocal Intraocular Lens

Lenstec Inc

1765 Commerce Avenue North

St. Petersburg, FL 33716 USA

Toll free: 1-866-536-7832

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner

Table of Contents

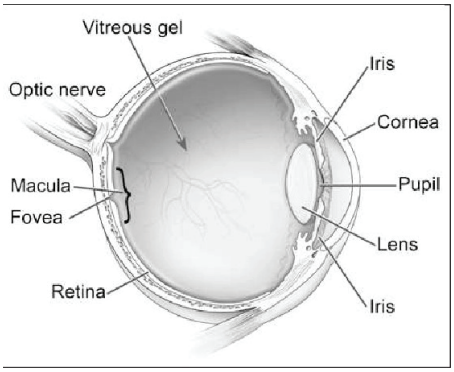
Introduction

Every year, about 4 million Americans have cataract surgery. It is a common procedure which is performed by eye surgeons daily. This brochure will help you understand your cataract, your available options to correct it, and the risks and benefits of choosing the SBL-3™ multifocal intraocular lens.

What is a Cataract?

Inside your eye, there is a natural lens that helps focus light onto on to a structure called the retina). At birth, the natural lens is clear. Over time, the natural lens becomes "cloudy", and that makes vision less clear. This natural process happens slowly over years in most cases. It can get to a point where everything is too blurry to see clearly. The only way to treat this is to have an eye surgeon remove the cataract and replace it with an intraocular lens (IOL).

Figure 1: The eye



What is an Intraocular Lens?

An intraocular lens, or IOL, is a plastic replacement lens for your cataract. It works the same as your natural lens. Once your eye surgeon replaces the cataract with the IOL, vision is usually restored within days of surgery.

Figure 2: The Lenstec Softec HD Intraocular Lens

What is Cataract Surgery?

Cataract surgery is the surgery performed by an eye surgeon to replace the cataract with an IOL. Before surgery, the eye doctor or clinic staff will measure your eye to see what "prescription" of IOL you will need (which is referred to as biometry), just like would be required if you were getting eyeglasses.

On the day of surgery, you will be asked to arrive at the surgical facility early enough to have numbing drops placed on to the eye, so that you don't feel discomfort during surgery. Once the eye is numb, the doctor will view your eye under a microscope and then make a small incision on the outside layer of the eye. He or she will then remove a small part of the front of the lens capsule, which is like a clear bag that holds the cataract. In the next step, the surgeon will remove the cataract by vacuuming the cloudy lens proteins carefully using a very small ultrasound instrument. The surgeon will then insert the rolled, or folded, IOL through the same small incision that was made before. It unrolls inside the eye. Once the IOL is in place, the surgeon will seal the incision site and the surgery is done. The surgeon will probably cover your eye with a shield, to protect it. You will need to have someone available to drive you home after surgery.

The surgeon will likely prescribe some eye drops that you will be asked to place in your eye over several days. This is to help with the healing process and to prevent infection. Some patients are able to see well between 1-2 days after surgery. Others take a little longer, because healing is different for everyone. By 4-6 weeks after surgery, you can expect to be well healed. Just to make sure healing is going as expected, the eye doctor will schedule several visits after surgery for you to come back to the clinic to have your eye examined. Call your eye doctor if you have any concerns after surgery.

What are the potential risks associated with cataract surgery?

As with any surgery, there are risks of side effects or complications. Some of the most common are a reaction to medicines used during surgery, infection, increased eye pressure and pain. There is also a small chance that your vision can get worse after surgery. Your eye doctor can help you understand these risks better. This is not an all-inclusive list. Details for all potential risks should be discussed with your physician.

What types of IOLs are available for my surgery?

There are many different types of IOLs available for your surgery and these choices should be discussed with your eye doctor carefully.

Monofocal IOLs

A monofocal IOL is the most commonly used IOL for cataract surgery. With monofocal IOLs, a single distance is in focus without vision correction options (like eye glasses or contact lenses). Objects outside this distance are blurry unless bifocal glasses or contact lenses are worn.

Accommodating IOL

An accommodating IOL can also be used for cataract surgery. They are inserted in the same way as monofocal IOLs. These IOLs have one prescription power that changes locations as it "flexes" inside your eye to help you see distance, intermediate and near. That can mean you need vision correction options (like eye glasses or contact lenses) less than you would with a monofocal IOL.

Multifocal IOLs

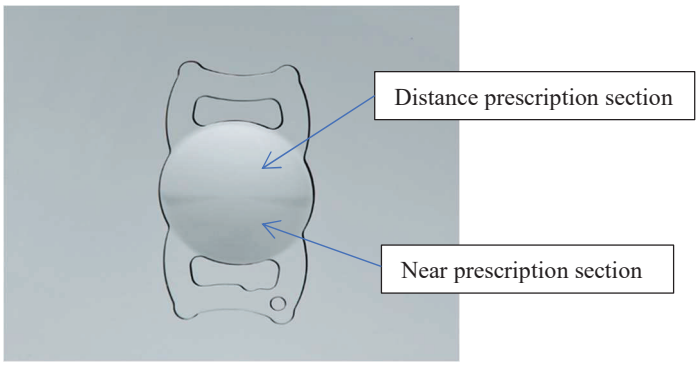
Multifocal IOLs provide focus for distance and near (and some for intermediate as well) so you should not have to wear vision correction options for many tasks in your life. These lenses have different prescriptions built into the lens so there is no need for the IOL to flex inside the eye. The prescription

zones help you see things nearby or up to far away. Traditional multifocal IOLs are made with circular rings that have different zones to help you see well at all distances.

SBL-3™ Multifocal IOL

The SBL-3™ is a multifocal IOL that is used to replace the cataract in your eye. The SBL-3™ lens includes two distinct zones for focusing light, one for distance vision and one for near vision. It is designed differently than most multifocal IOLs. The SBL-3™ does not have these circular rings but rather has these two separate prescription sections that give both images in the eye at the same time (one blurred and one clearer).

Figure 3: Lenstec SBL-3 ™ multifocal IOL



When compared to patients receiving a monofocal IOL, the clinical study for approval demonstrated that the SBL-3™ patients had about equal visual acuity for far and intermediate distances, and had better visual acuity for near (unless the monofocal patients wore reading glasses). Patients who received the SBL-3 ™ did have a higher rate of vision distortions, however, vision distortion occurs with all multifocal IOLs.

Purpose of the device (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.

When the device should not be used (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.

Risks vs benefits

There are some risks that are associated with cataract surgery itself and some that are associated with the SBL-3 IOL.

All surgery has potential risks. Cataract surgery is no different. Vision can be worse after cataract surgery if there are complications during surgery or if infection sets in after surgery. This is rare but it is possible.

The SBL-3 also has risks associated with it. More patients that had the SBL-3 IOL reported that they saw severe symptoms of "halos," "glare," "streaks of light," or "double images" compared to the monofocal IOL. These types of events are commonly referred to as "visual distortions" or "visual disturbances." That made seeing things more difficult for them. This issue is greatly reduced if you select a monofocal IOL in place of a multifocal IOL. The SBL-3 group also had a larger percentage of patients which needed to have secondary surgical intervention, or additional surgery, to correct something because of the SBL-3 itself. This is something that should be discussed with your eye surgeon in more detail.

The benefit of cataract surgery with a monofocal IOL in general is that, by removing the cataract, distance vision is clear. If the SBL-3 is used instead of a monofocal IOL, most patients are less reliant on glasses.

Warnings

- You might need to use vision correction options (like eye glasses or contact lenses) for some tasks after surgery.
- You should exercise caution when driving at night or in poor visibility conditions. During part of the main clinical study used to approve the SBL-3, there was a simulated driving test. People in the control group were able to recognize signs and road hazards sooner than in the multifocal group. This is consistent with previously approved multifocal IOLs.
- Patients receiving the SBL-3 had poorer contrast sensitivity than those receiving a monofocal IOL. This means that they may have greater problems seeing things that do not have high contrast, and this is often more of a problem in dim lighting. The ability to clearly see might be worse with the SBL-3 than if you get a monofocal IOL. This can cause difficulties in driving, especially under conditions of poor lighting. If you get the SBL-3 multifocal, you should be cautious while driving, especially in dim lighting.
- There are some cases where the SBL-3 IOL should not be implanted and your eye surgeon is aware of those. This could include other uncontrolled eye diseases you may have or problems that could occur during surgery. It is important to speak with him or her before having surgery about any eye issues you have had. For example, dry eye disease, glaucoma, macular degeneration and diabetic retinopathy may be reasons to avoid the SBL-3 IOL.
- After surgery, it is possible that you will see halos, or glare or 'ghost' images around things, or that some things look blurry in general. Squinting or partially closing the eyes may reduce or block distance vision, therefore it may be helpful to open the eyes wider if distance vision is blurry. However, other vision problems will not be helped by this, and will not be helped by anything the patient can do. Patients with larger pupils could be more impacted by these. Your doctor will measure your pupils prior to surgery and let you know if this is a concern.
- In the clinical trial used to approve the SBL-3, the group of people that got the SBL-3 had a higher rate of severe visual disturbances (glare, halos, double images, and streaks of light) than the group that got the approved monofocal IOL. These visual symptoms may contribute to difficulties with driving, under certain conditions. Patients should exercise caution.

- You should wear UV blocking sunglasses after surgery because it is not known how well IOLs protect your eyes from UV light.
- Patients with the largest pupils (7.5 mm or larger) have more chance of more light going around the IOL. This is a generic problem with all IOLs. It could make visual disturbances worse for you.
- People with very small pupils (smaller than 2.75 mm) also could have a problem with their vision.
- The bottom of the SBL-3 optic has a very small part which has less prescription than the rest of the IOL. See the figure below. The green part is the distance prescription. The red part is the near prescription. Just below the red is a white portion, which is the area being discussed here. In eyes that have very large pupils, it is possible that you may see poorly because of that white portion. No patient in the clinical trial used to approve the SBL-3 complained of this problem but it is something that could happen in theory.

Figure 4: SBL-3 optic portion

- You should contact your eye doctor if you have a significant decrease in vision or a significant increase in pain, redness, itching, discharge or sensitivity to light, as any of these could point to one of several complications that need to be treated immediately.
- The SBL-3 was only studied with both eyes implanted (not just a single eye). Your results with just one SBL-3 might vary.
- It is possible that the capsule that holds the IOL will become cloudy over time. This is often referred to as a capsular scar. This is easily treated with a minor laser procedure that occurs more often in patients who received multifocal IOLs than those that get a monofocal IOL. The capsular scar in patients that get an SBL-3 may be more bothersome sooner than those that get a monofocal IOL.
- Patients with the following conditions (Uncontrolled glaucoma, microphthalmia, chronic severe uveitis, retinal detachment, corneal decompensation, diabetic retinopathy, iris atrophy, perioperative complications, previous ocular surgery, non-age related cataract vitreous loss, iris atrophy, severe aniseikonia, ocular hemorrhage, macular degeneration or suspected microbial infection) could be at risk for complication(s) following implantation of the SBL-3. If you are unsure of your eye conditions speak with your eye doctor before surgery.
- The SBL-3 lens has only been studied in adult patients. Children are likely to have special issues with the SBL-3 lenses related to larger pupil size and difficulty in describing problems with visual disturbances. Implantation in children is not recommended.
- In the clinical study for approval, some patients who received the SBL-3 IOL had substantial changes in the strength of glasses needed to see clearly for things far away. These changes happened between doctor visits at least 1 month after surgery. These changes can cause changes in in the sharpness of their vision.
- A higher amount of SBL-3 patients had an increase in near sightedness (the inability to see distant objects) which may increase the chance of IOL replacement surgery.

Precautions

- Only patients who were considered in good general and ocular health (NOT diagnosed with: severe retinal or corneal disorders, swelling of the intraocular anatomy, ocular muscle disorders, abnormal ocular anatomy and not taking medications that could make ocular surgery more troublesome) and who were 22 years of age or older, participated in the study. Therefore, the safety and effectiveness of use of the SBL-3 device in these patients is not known.
- Some eye disorders, like glaucoma, diabetic retinopathy or macular degeneration, may not allow you to get perfectly clear vision even after implanting of an IOL. Also, if you have very droopy eyelids (called Ptosis), you may have trouble seeing either near or far with this IOL. This is something your eye doctor will check for before your surgery.
- It is important that you follow the medication regimen that your eye doctor prescribes, before and after surgery. If you do not, your eyes could become inflamed or infected and your vision may get worse.

Postoperative care instructions

After surgery, you will need someone to drive you home. The eye doctor will need to see you after surgery, usually the next day, to check your eye and the results of surgery. He or she will likely give you some eye drops to help reduce inflammation and possible infection, which should help the healing process. You will be asked to come back to the doctor's office a few times after surgery, so the doctor can check your eye again. If you have any issues with your vision, discuss them with your eye doctor.

Making the best choice for you

During one clinical trial, the SBL-3 was compared to a standard monofocal IOL at 18 different clinical sites across the US for 1 year after surgery. The study compared distance vision, intermediate vision and near vision between the two groups. It also had the eye doctors involved make note of any and all adverse outcomes that happened in either group. These are things that could happen following any routine cataract surgery. It also had the patients complete a survey asking them how often they used vision correction options (like eye glasses or contact lenses) for distance, intermediate and near. The same survey asked the patients about the presence and the difficulty or disruption of the visual distortion they saw. Finally, the survey also asked them how satisfied they were with their distance, intermediate and near vision without the vision correction options (like eye glasses or contact lenses). The tables below will summarize the results of that study.

Table 1: Results from clinical study in the US

Test performed	Results	Summary
Distance vision measured on a chart in the clinic	The distance vision was comparable between the two groups	Both groups of patients had similar visual acuity
Intermediate vision measured on a chart in the clinic	The intermediate vision was comparable in the SBL-3 group	Both groups of patients had similar visual acuity
Near vision measured on a chart in the clinic	The near vision without glasses was better in the SBL-3 group	SBL-3 patients saw better for near vision than the patients that had the monofocal IOL, when looking at the eye chart
Contrast sensitivity (ability to distinguish different shades of grey or shades of a color) measured on a chart in the clinic	Contrast sensitivity was somewhat poorer in the SBL-3 group than it was in the control group	The control group had better contrast sensitivity results than the SBL-3
Survey results: Distance vision without vision correction	The distance vision without vision correction was comparable between the two groups	Both groups of patients used their vision correction similarly at far distance
Survey results: Intermediate vision without vision correction	The intermediate vision without vision correction was better in the SBL-3 group	Both groups of patients used their vision correction equivalently at intermediate distances
Survey results: Near vision without vision correction	The near vision without vision correction was better in the SBL-3 group	SBL-3 patients reported use of vision correction less for near distances
Survey results: Visual distortions (halos, glare, starbursts, double vision)	The number and amounts of distortion reported was worse in the SBL-3 group	The number and difficulty or disruption due to distortions reported was worse in the SBL-3 group
Survey results: Overall satisfaction with near, intermediate and distance vision	Satisfaction was better in the SBL-3 group for intermediate and near vision, whereas the satisfaction in the monofocal lens group was better for distance	Patients were more satisfied with their distance vision with the monofocal lens, whereas patients with the SBL-3 were more satisfied with their intermediate and near vision.

In the same study, the clinical site staff measured adverse outcomes that occurred in patients. Overall, both groups had similar percentages of these adverse outcomes. The table below will list those specific instances of adverse outcomes that occurred. You will see there was a greater number in the SBL-3 group than there was in the monofocal IOL group. It is worth noting that each of the negative outcomes are known outcomes from cataract surgery in general, and not new to this clinical study.

Table 2: Adverse event from clinical study in the US

Type of negative outcome	Results for the SBL-3	Results for the monofocal IOL	Summary
Key adverse events occurring at any time during the study			
Swelling of the retina (Cystoid macular edema)	2.0 %	2.7%,	This was similar for both groups of patients
Blockage of fluid traveling within the eye caused by the iris (colored part of the eye) (Pupillary block)	0.2%	0%	This was similar for both groups of patients
Detachment of retina from the back of the eye (Retinal detachment)	0.2%	0%	This was similar for both groups of patients
Additional surgery (Total secondary surgical intervention))	1.8%	0.9%	SBL-3 patients experienced more instances of secondary surgical intervention for reasons not related to the IOL optic than the monofocal group
Additional surgery related to the SBL-3 (visual disturbance or decrease in vision) (Secondary surgical intervention reasons <u>related</u> to the IOL optical characteristics)	0.9%	0%	SBL-3 patients experienced more instances of secondary surgical intervention for reasons related to the IOL optic than the monofocal group
Key adverse events existing at the 1 year follow up visit			
Swelling of the cornea (Corneal stromal edema)	0.2%	0%	This was similar for both groups of patients
Swelling of the retina (Cystoid macular edema)	0.2%	0%	This was similar for both groups of patients

As discussed above, the SBL-3 group had patients report more visual disturbances than those of the monofocal group. Visual disturbances are the main negative outcomes most patients who receive multifocal IOLs experience.