LIGHT ADJUSTABLE LENS AND LIGHT DELIVERY DEVICE FOR THE CORRECTION OF APHAKIA AND REDUCTION OF RESIDUAL ASTIGMATISM

PROFESSIONAL USE INFORMATION

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

Warning: Specific training from RxSight, Inc. or an authorized representative of RxSight is required before anyone is qualified to implant the Light Adjustable Lens, or use the Light Delivery Device.

This document (Professional Use Information) provides information concerning the intended clinical use of the RxSight Light Adjustable Lens (LAL) and must be used in conjunction with the Light Delivery Device (LDD) Operator's Manual that provides general use information concerning system components, safety instructions, installation, maintenance, and troubleshooting for the device.

DEVICE DESCRIPTION

The Light Adjustable Lens (LAL) is a posterior chamber, ultraviolet (UV) absorbing, three-piece, foldable, photoreactive silicone intraocular lens with a squared posterior optic edge intended to be implanted in the capsular bag following phacoemulsification. Selective exposure of the implanted RxSight LAL using the Light Delivery Device (LDD) to deliver spatially profiled UV light produces modifications in the lens curvature resulting in a spherical or spherocylindrical power change post-operatively. A subsequent lock-in exposure is delivered to the implanted LAL to stabilize the lens power.

Lens Optic

- Material: Photo-reactive UV absorbing Silicone
- Light transmission: UV cut-off at 10% T 385 ± 2 nm for all lens powers
- Index of refraction: 1.43
- Diopter power: +10 to +15.0 diopters and +25.0 to +30.0 D in 1.0 diopter increments; +16.0 to +24.0 diopters in 0.5 diopter increments
- Optic type: Biconvex
- Optic edge: Square on posterior surface and round on anterior surface
- Overall diameter: 13.0 mm
- Optic diameter: 6.0 mm

Haptics

- Configuration: Modified C
- Material: Blue core polymethylmethacrylate (PMMA) monofilament
- Haptic angle: 10°

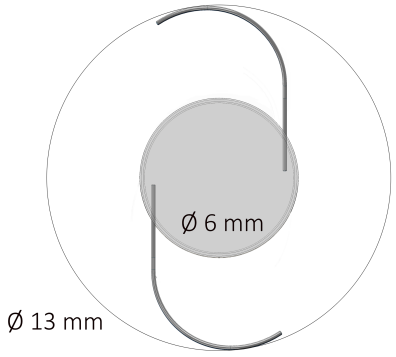


FIGURE 1: LIGHT ADJUSTABLE LENS

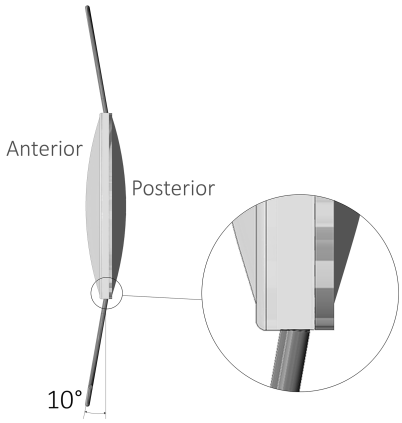


FIGURE 2: LIGHT ADJUSTABLE LENS. INSET DEPICTS BACK LAYER.

The LAL silicone material is designed to respond to a narrowband UV light of a select spatial intensity profile. The silicone material contains photoreactive additive, which is selectively photo-polymerized in targeted areas upon exposure to the near UV light to alter the lens shape thus modifying spherical and sphero-cylindrical power of the LAL.

The Light Delivery Device is a UV light projection system used to induce a predictable change in LAL power after implantation. The LDD consists of an anterior segment biomicroscope with the addition of an optical projection system, electronic control circuitry, and a UV source. The LDD

device can treat postoperative manifest cylinder from -0.75 D to -2.00 D, and manifest sphere (in minus cylinder format) of -2.00 D to +2.00 D.

INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS

Indications for use

The Light Adjustable Lens and Light Delivery Device system is indicated for the reduction of residual astigmatism to improve uncorrected visual acuity after removal of the cataractous natural lens by phacoemulsification and implantation of the intraocular lens in the capsular bag, in adult patients:

- With pre-existing corneal astigmatism of ≥ 0.75 diopters
- Without pre-existing macular disease.

The system also reduces the likelihood of clinically significant residual spherical refractive errors.

Contraindications

Use of the LAL is contraindicated in cases where:

1. The patient is taking systemic medication that may increase sensitivity to UV light such as tetracycline, doxycycline, psoralens, amiodarone, phenothiazines, chloroquine, hydrochlorothiazide, hypercin, ketoprofen, piroxicam, lomefloxacin, and methoxsalen[1]. LDD treatment in patients taking such medications may lead to irreversible phototoxic damage to the eye. **Note:** This is only a partial list of photosensitizing medications. Evaluate all medications that the patient is taking for this effect prior to consideration for implantation.
2. The patient is taking a systemic medication that is considered toxic to the retina such as tamoxifen (e.g., Nolvadex®) as they may be at increased risk of retinal damage during LDD treatment.
3. The patient has a history of ocular herpes simplex virus due to the potential for reactivation from exposure to UV light.
4. The patient has nystagmus as they may not be able to maintain steady fixation during LDD treatment.
5. The patient is unwilling to comply with the postoperative regimen for adjustment and lock-in treatments and wearing of UV protective eyewear.

Warnings

Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio.

1. Patients with any of the following conditions may not be suitable candidates because the intraocular lens may exacerbate an existing condition, interfere with diagnosis or treatment of a condition, or may pose unreasonable risk to the patient's eyesight:
   a. Recurrent severe anterior or posterior segment inflammation or uveitis of unknown origin, or any disease producing an inflammatory reaction in the eye.
   b. Surgical difficulties at the time of cataract surgery before LAL implantation (e.g. persistent bleeding, significant vitreous loss or prolapse, significant iris trauma).

[1] Trade names: Tetracycline (Ala-Tet®, Brodspec®, Panmycin®, Sumycin®, Tetracap®, Tetracon®, Robitet 500®, Emtet-500®); Doxycycline (Acticlate®, Adoxa®, Alodox®, Avidoxy®, Doryx®, Mondoxyne NL®, Monodox®, Morgidox®, Oracea®, Oraxyl®, Targadox®, Vibramycin®); Psoralens (8-MOP®, Oxsoralen-Ultra®, Uvadex®); Amiodarone (Cordarone®, Pacerone®); Phenothiazines (Compro®, Thorazine®, Prolixin®), Chloroquine (Aralen®); Hydrochlorothiazide (Aquazide®, HydroDIURIL®, Microzide®); Hypercin (St. Johns Wart); Ketoprofen (Orudis®), Piroxicam (Feldene®); Lomefloxacin (Maxaquin®); and Methoxsalen (Oxsoralen-Ultra®, 8-MOP®, Uvadex®)

c. A compromised eye due to previous trauma or developmental defects in which appropriate support of the intraocular lens (IOL) is not possible.
d. Circumstances that would result in damage to the endothelium during implantation.
e. Patient in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL.
f. Patient with current vitreoretinal disease or those who are at high risk for future vitreoretinal disease that may require silicone oil as part of therapy.

2. Patients with eyes unable to dilate to a pupil diameter of at least 7 mm to ensure that the edge of the LAL can be visualized during the administration of LDD light treatments.
3. Patients who the doctor believes will be unable to maintain steady fixation that is necessary for centration of the LDD light treatment.
4. Patients with sufficiently dense cataracts that preclude examination of the macula. The device is not indicated for patients with pre-existing macular disease because the effects of UV light exposure during LDD treatment in these patients have not been determined. These patients may be at increased risk for macular disease progression and should be warned of the potential risk.

General LAL and/or LDD Treatment Warnings:

1. Failure to maintain alignment of the target reticle to the implanted LAL could result in significant retinal damage and possibly temporary or permanent loss of vision.
2. An LAL with a noticeable defect (e.g. scratch or physical damage) on the optic should be immediately replaced during the cataract surgery to prevent excessive retina exposure to UV light and potential harm to vision. If a noticeable defect is noted postoperatively, contact RxSight to determine whether to proceed with LDD treatment.
3. The LAL must be implanted in the eye in the correct orientation with the back layer facing posteriorly (see Figure 2). If the lens is implanted in the incorrect orientation, the LAL will not be able to undergo a refractive power change. If the LAL is implanted in the incorrect orientation, then the options the surgeon should pursue are limited to either manipulating the lens into the correct position or explanting the lens and replacing it with another IOL.
4. The LAL is single-use device only. Do not reuse this IOL.

Precautions

1. Prior to surgery, the surgeon must inform prospective patients of the possible risks and benefits associated with the use of this device.
2. The long-term effect on vision due to exposure to ultraviolet light that causes erythropsia (after Light Delivery Device treatment), has not been determined
3. Concurrent light treatments in both eyes after bilateral LAL implantation was not performed in the clinical study. The effect of UV exposure on the primary eye can only be fully assessed after all LDD treatments are completed and should assist with timing of the fellow eye implantation.
4. Do not store the lens in direct sunlight or at a temperature greater than 77°F (25°C).
5. Do not resterilize the lens.
6. Do not soak or rinse the Light Adjustable Lens with any solution other than sterile intraocular irrigating solutions.

7. Patients must be supplied with the RxSight specified UV protective eyewear for use after LAL implantation. If the implanted eye is exposed to UV light without the use of UV protective eyewear before 24 hours post final lock-in treatment, the LAL can change unpredictably, causing aberrated optics and blurred vision, which might necessitate explantation of the LAL Patients should be cautioned to wear their UV protective eyewear during all waking hours until 24 hours post final lock-in treatment.
8. The implanted LAL MUST undergo a minimum of three treatments (one adjustment procedure plus two lock-in treatments) with the Light Delivery Device beginning at least 17-21 days post-implantation.
9. Based upon the clinical study results, poorer refractive results may occur with the use of corneal sutures if refractive stability is not achieved prior to LDD treatment.
10. The LAL power for implantation is chosen in a different manner than for most IOLs. Care should be taken to take into account the effect of the LDD lock-in procedure. Please see the section on Lens Power Calculation.
11. The safety and effectiveness of the LAL and LDD have not been substantiated in patients with pre-existing conditions and intraoperative complications listed below.
    - Pseudoexfoliation
    - Retinal degenerative disorder that is expected to cause future vision loss
    - Diabetes with any evidence of retinopathy
    - Eye with evidence of glaucomatous optic neuropathy
    - Significant anterior segment pathology, such as rubeosis iridis, aniridia, or iris coloboma
    - Corneal pathology that is either progressive or sufficient to reduce best spectacle corrected visual acuity (BSCVA) to worse than 20/20
    - Keratoconus or suspected of having keratoconus
    - Any corneal dystrophy including basement membrane dystrophy
    - Undergone previous corneal or intraocular surgery, except eyes with previous pterygium excision were permitted as long as the pterygium did not extend more than 2mm onto the cornea from the limbus
    - Complications during cataract surgery before intraocular lens implantation including posterior capsule rupture, zonular rupture, radial capsulorhexis tear, vitreous loss, iris trauma, corneal complications or any intraoperative abnormality that may affect the postoperative pupillary dilation, or the centration or tilt of the intraocular lens
    - Irregular astigmatism
    - Patients who do not have a projected best-corrected acuity of 20/20 or better (based upon past ocular history and retinal exam).

12. All clinical study outcomes were obtained using LDD power adjustments targeted to emmetropia post LDD treatments (or as close as possible to emmetropia for patients with higher postoperative refractive error). The safety and performance of targeting to myopic or hyperopic outcomes have not been evaluated.
13. Patients should be informed that the average magnitude of manifest refraction spherical equivalent (MRSE) is not significantly different than a standard monofocal IOL. It should be explained that such spherical adjustments reduce the +0.50 D targeted postoperative MRSE and the distribution of residual MRSE, which has clinically significant impact on a minority of patients in conventional cataract surgery.

14. There may be a greater risk of corneal endothelial cell loss associated with LAL implantation than typically seen. (See clinical study results, specular microscopy section). It is recommended that surgeons should perform specular microscopy preoperatively and take endothelial cell density and morphology into consideration.

LENS POWER CALCULATIONS

It is recommended that lens power is selected for post-operative target of + 0.50 D. Therefore, in selecting the appropriate lens power for implantation, the physician should choose the LAL power to try to achieve a target manifest refraction spherical equivalent of +0.50 diopter.

Lens power calculation methods are described in the following references:

- Retzlaff, J.A., Sanders, D.R., and Kraff, M.C. Development of the SRK/T intraocular lens implant power calculation formula. Journal of Cataract and Refractive Surgery. 1990: 16:333-340; ERRATA. 1990; 16:528.
- Haigis W. "The Haigis formula". In: Shammas HJ, ed, Intraocular Lens Power Calculations. Thorofare, NJ, Slack, 2004; 41-57.
- Hoffer K.J., "The Hoffer Q formula: a comparison of theoretic and regression formulas", J Cataract Refract Surg, 19, 700-712 (1993). Erratum in: *J Cataract Refract Surg* 1994;20:677. Erratum in: *J Cataract Refract Surg* 2007;33:2-3.
- Holladay, J.T., Musgrove, K.H., Prager, T.C., Lewis, J.W., Chandler, T.Y., and Ruiz, R.S. "A three-part system for refining intraocular lens power calculations." *J Cataract Refractive Surg*. 1988; 14:17-24.
- Holladay, J.T. "Standardizing constants for ultrasonic biometry, keratometry and intraocular lens power calculations." *J Cataract Refractive Surg*. 1997; 23:1356-1370.

Additional information may be obtained by contacting the local RxSight, Inc. representative.

INSTRUCTIONS FOR USE

Prior to implanting, examine the package for IOL type, power, lens model and expiration date.

Remove the peel pouch from the outer foil pouch, open the peel pouch and transfer the lens case onto the sterile environment.

Once in the sterile environment, hold the lens case with the label face up. Remove the plastic cover on top of the lens by turning the cover in a counter-clockwise direction, carefully, to expose the lens.

Carefully remove the lens by the haptics using forceps, inspect for debris or damage. DO NOT grasp the lens in the optic area. Handle lenses carefully to avoid damage to lens surfaces or haptics. DO NOT attempt to reshape haptics in any way.

DO NOT wet the lens with any solutions prior to grasping with forceps.

Do not use the lens if the package has been damaged. The sterility and/or ability to adjust the lens may have been compromised.

SURGICAL PROCEDURE

The LAL is implanted using standard microsurgical techniques. The recommended surgical procedure is as follows:

1. Prepare and drape the eye for surgery in accordance with standard surgical procedures.
2. Make a clear corneal or scleral incision of approximately 3.5 mm - 3.8 mm using the surgeon's standard instrumentation and techniques.
3. Use viscoelastic to fill the anterior chamber through the incision opening.
4. Perform an anterior circular capsulorhexis of a maximum of 5.5 mm using standard technique.
5. Extract the cataract by phacoemulsification.
6. Introduce the LAL into the eye using the Nichamin III Foldable Lens Inserter (Rhein Medical 05-2349) with the Nichamin II Foldable Lens Insertion Forceps (Rhein Medical 05-2348) and place into the capsular bag.

   Note: If utilizing additional surgical instruments near the incision upon insertion, caution should be taken not to contact the optic of the LAL with the instrument.
7. Aspirate any residual viscoelastic from the eye using a preferred technique.
8. The wound may close without suturing. If the unsutured wound is not watertight, close it with a suture using standard technique.
9. After completion of the surgery, ocular anti-inflammatory and/or antibiotic drops may be applied in accordance with standard clinical practice.

UV PROTECTIVE EYEWEAR

- UV protective spectacles (UVEX Bandit™ #S1600 with clear lens and #S1603 with Espresso tinted lens) are supplied to the patient as a two-pair set, with one having clear lenses for indoor use and the other pair with tinted lenses for outdoor use. Instruct the patient to wear the spectacles at all times indoors and outdoors, keeping the eyes closed when changing spectacles, until 24 hours post the final lock-in treatment.
- Alternatively, an optional patch can be used postoperatively. If used, the patient should be instructed not to remove the patch and keep it in place until the surgeon removes it at the one day post-operative visit. The UV protective eyewear will be provided once the patch is removed at the one day post-operative visit.
- For patients requiring spectacle correction for refractive errors in the fellow eye, "fitover" UV protective spectacles (Cocoons Models C202, C302, C422, C402 or C412 with clear lens or gray lens; manufactured by Live Eyewear) are supplied to the patients as a two-pair set, with one pair having clear lenses for indoor use and the other pair with tinted lenses for outdoor use. Instruct the patient to wear the "fitover" UV protective eyewear over their existing corrective spectacles at all times; keeping the eyes closed when changing spectacles.

LIGHT TREATMENT PROCEDURE

Seventeen (17) to 21 days after surgery, the patient is to return for examination and a 1st adjustment treatment. 3-5 days later, the patient will return and receive a possible 2nd adjustment based on the patient's measured refraction. The patient will receive the 1st of two lock-in treatments 3-5 days after the final adjustment treatment. Lock-in treatments will be separated by 3-5 days.

Special care should be taken to ensure that an accurate refraction is obtained prior to light adjustment treatments. At least two independent refractions were performed in the clinical study to achieve the results described in the clinical study section. While these refractions were within 0.25 D of each other 84% of the time for both MRSE and cylinder, a single refraction may result in poorer results. When performing refraction in patients implanted with the LAL, confirmation of refraction with maximum plus manifest refraction technique is recommended.

Note: If an implanted lens has any evidence of premature photopolymerization as detected by slit lamp examination, a power neutral adjustment should be administered.

Additional Testing and Potential Delay of Light Treatment

The LDD emits ultraviolet radiation which has the potential to cause retinal damage in susceptible eyes. If the retina has been previously stressed by UV exposure it may be more susceptible to UV damage. Therefore, it is recommended that special evaluations be performed, before the initial light treatment to establish a baseline level of performance. These evaluations are to assess changes in performance which might indicate that additional light treatment should be delayed until resolution of these issues.

The following special evaluations should be performed prior to LDD treatments:

- **Evaluation for Erythropsia (reddish/pinkish tinge to vision)**
  - Recommended in-office procedure for erythropsia evaluation:
    - Room illumination should be dark, and the erythropsia test should be done under the same standard white illumination as the described for City University Color Vision Test (CUT) testing.
    - An 8”x11” sheet of white paper should be placed on a black matte surface under the lamp.
    - With the fellow eye covered, ask the subject to rate the amount of redness in the sheet of paper, according to the following 3-point scale:
      - 0 – pure white
      - 1 – pink
      - 2 – red

- **Evaluation of Color Vision (for tritan (blue-yellow) anomalies)**

  We recommend the use of the 3rd edition City University Color Vision Test (CUT). Lighting conditions and administration of the test should be performed per instructions accompanying the test booklet.

- **Evaluation of Best-Corrected Acuity**

  Best-corrected acuity should be evaluated before all LDD treatments.

Physicians may also want to consider an evaluation using spectral domain Optical Coherence Tomography (OCT) prior to the initial LDD treatment.

It is recommended that any LDD treatment should be delayed if any of the following new symptoms or changes in performance are noted;

- Color Vision Testing: Treatment should be delayed if the patient scores worse on Part 2 than the preadjustment test for Tritan evaluation.

- Erythropsia Evaluation: For the in-office assessment: With any score of 2 (red) on the scale above, treatment should be delayed.
- Best-Corrected Acuity: With any loss of best-corrected acuity (unless the cause is known to be non-retinal) of 2 lines or more on a Snellen chart, or any loss of 10 letters or more on an Early Treatment Diabetic Retinopathy Study (ETDRS) (LogMAR) chart, treatment should be delayed.

The physician should consider conducting a spectral domain OCT if any of the above symptoms or changes in performance are observed.

If the decision is made to delay treatment, then the patient should return weekly and the testing repeated, until resolution of the changes including any signs suggesting phototoxic damage on OCT. If, after three weeks there is no resolution, continue routine monitoring of the patient, at the physician's discretion, to evaluate improvement until resolution. If there is no resolution of symptoms, explantation should be considered.

Patient Preparation for Adjustment or Lock-In Procedures

The patient will undergo a standard eye examination including refraction prior to all light treatments.

Dilate the patient's eye to be treated completely to ensure that the edge of the LAL optic can be visualized. Examine the eye using the LDD microscope and ensure visualization of the LAL edge. If some part of the LAL is obscured by the pupil, administer additional dilation drops and repeat the examination. If adequate pupil dilation is not achieved, it is recommended that the treatment be rescheduled and that the dilation is attempted at another visit or another dilation method is used.

Patch the patient's fellow eye and position the patient comfortably in front of the LDD with chin in the chinrest and forehead against the support bar. Ask the patient to grasp the handles on the LDD table for support. Inform the patient to concentrate on the green fixation light presented in front of them and to try and minimize eye movement.

Adjustment Procedure(s)

Refer to LDD Operator's Manual for instructions on LDD start up and alignment procedure.

To adjust the lens power, the physician should follow the LDD touchscreen prompts to enter the patient identification, eye to be treated, i.e. OD or OS, and manifest refraction (sphere, cylinder and axis), target refraction, LAL serial number, and LAL base power.

Review all information and press the "Confirm" button.

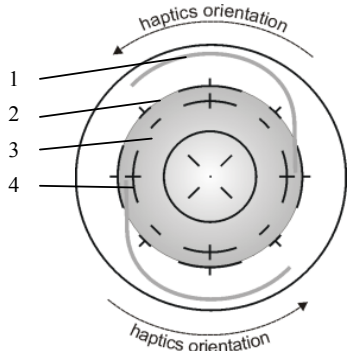
A topical anesthetic such as proparacaine HCL or tetracaine HCL (Alcaine, Ophthaine, Ophthetic or equivalent) will be applied to the cornea in order to facilitate insertion of a contact lens required to focus the LDD on the eye.

Position the RxSight supplied contact lens (0.835X ADJUSTMENT) on the cornea using hydroxypropyl methylcellulose as the coupling media.

Note: The RxSight contact lens is similar to those used in other ophthalmic procedures in which customized magnification is required. To ensure correct magnification for treatment, use only the

RxSight designated contact lens (0.835X for adjustment procedures or 0.766X for Lock-in procedures).

Using the microscope, focus on the LAL with the contact lens in place on the cornea and activate the LDD alignment reticle image and fixation light. Instruct the patient to focus on the LDD fixation light with the treatment eye and align the irradiation reticle with the periphery of the LAL.



1. LAL haptics
2. LAL edge
3. LAL
4. Target reticle

FIGURE 3: TARGET RETICLE

Initiate the UV light treatment as prompted by the LDD display using the joystick to keep the LAL centered in the alignment reticle. In the case of patient movement, loss of alignment or loss of focus, pause the treatment, quickly refocus, realign the lens with respect to the reticle beam, and immediately resume treatment to limit the duration of any pauses once the light treatment has been initiated.

Note: In the event of an aborted or incomplete Adjustment Treatment, do not initiate a new treatment sequence; instead, instruct the patient to return 3-5 days later for refractive evaluation to assess whether an adjustment treatment is required or to proceed directly to a lock-in treatment. Following the light adjustment, instruct the patient to continue wearing the UV protective eyewear provided at all times.

All patients will return at 3 to 5 days following the final Adjustment Treatment for lock-in treatments using the LDD.

Lock-in Irradiation Procedure

Refer to LDD Operator's Manual for instructions on LDD start up and alignment procedure.

Select "LOCK IN" on the LDD screen.

Enter the patient ID, eye to be treated i.e. OD or OS, LAL Serial Number and Base Power as directed on the touchscreen of the Light Delivery Device.

Review all information and press the "Confirm" button.

The physician will be asked to confirm all information prior the initiation of treatment.

A topical anesthetic such as proparacaine HCL or tetracaine HCL (Alcaine, Ophthaine, Ophthetic or equivalent) should be applied to the cornea in order to facilitate insertion of a contact lens required to focus the LDD on the eye.

Position the RxSight supplied contact lens (0.766X LOCK-IN) on the cornea using hydroxypropyl methylcellulose as the coupling media.

Note: The RxSight contact lenses are similar to those used in other ophthalmic procedures in which customized magnification is required. To ensure correct magnification for adjustment and lock in treatments, use only the corresponding RxSight designated contact lens (0.835X for adjustment procedures or 0.766X for Lock-in procedures).

Using the LDD microscope, focus on the LAL with the contact lens in place on the cornea and activate the alignment reticle image and fixation light. Instruct the patient to focus the treatment eye on the fixation light and align the irradiation reticle with the periphery of the LAL.

Perform the UV light treatment as prompted by the LDD display using the joystick to keep the LAL centered in the alignment reticle. In the case of patient movement, loss of alignment or loss of focus, the investigator should pause the treatment, quickly refocus and realign the lens with respect to the reticle, and immediately resume treatment to limit the duration of any pauses once the irradiation delivery has been initiated.

Note: In the event of an aborted or incomplete Lock-in treatment, contact RxSight for technical assistance.

Instruct the patient to continue to wear the UV protective eyewear provided at all times and to return for the second lock-in treatment at 3 to 5 days after the first lock-in treatment.

Note: UV protective eyewear can be discontinued one day after the second lock-in treatment.

ADVERSE EVENTS

Specific risks of the Light Adjustable Lens and Light Delivery Device:

Adverse events related to the ultraviolet light from the LDD could induce damage to the retina, which may potentially cause loss of vision, transient or long-term erythropsia (reddish tinge to vision), and transient or long-term color vision anomalies.

If the eye is exposed to bright lighting without the use of UV protective eyewear before 24 hours after the final lock-in treatment, the LAL can change unpredictably, causing aberrated optics and blurred vision which might necessitate explantation of the LAL.

Since a special contact lens is used for adjustment and lock-in procedures, some patients may experience corneal abrasion.

Potential adverse events for all cataract or implant surgery may include but are not limited to: infection (endophthalmitis), hypopyon, corneal endothelial damage, IOL dislocation out of the posterior chamber, cystoid macular edema, corneal edema, pupillary block, iritis, retinal detachment, transient or persistent glaucoma, vitritis, iris prolapse, rupture of the capsule, and secondary surgical intervention. Increased visual symptoms related to the optical characteristics of the IOL including: halos, glare and/or double vision.

Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspirations or iridectomy for pupillary block, lysing of synechiae, wound leak repair, retinal detachment repair and corneal transplant.

CLINICAL TRIAL

A prospective, randomized, controlled, multi-center clinical trial of the LAL and LDD designed to evaluate safety and effectiveness over a 12-month period was conducted at 17 sites. In addition to the visual correction of aphakia, reduction in residual spherocylindrical refractive error and improvement in uncorrected visual acuity were evaluated following LAL implantation and subsequent refractive adjustment of the LAL by the LDD.

Eyes with ≥0.75 diopters (D) of keratometric cylinder were randomly assigned to receive either the LAL or a commercially available, posterior chamber, non-accommodating, control monofocal IOL of the investigator's choice. Six hundred eyes were implanted monocularly with 403 eyes randomized to the LAL group and 197 eyes to the Control group. Control eyes were matched to the LAL group by the amount of preoperative keratometric cylinder. Control eyes were targeted to emmetropia and LAL eyes targeted for +0.50 D due to the assumed myopic shift from the lock-in treatment.

All subjects underwent standard small incision, phacoemulsification surgery and implantation of the LAL or the control lens. While the LAL initially could be implanted with either the Navijet Injector or the Nichamin inserter and forceps, the former was discontinued due to delivery failures, with the final one third of LAL cases using only the Nichamin inserter and forceps.

At 17 to 21 days post-implantation, the study eye was refracted and visual acuity testing performed by two unmasked independent examiners. LAL eyes received power adjustment using the LDD based on the manifest refraction and within the allowed range. LAL subjects returned 3 to 5 days after the first adjustment for a possible second adjustment. The first of the two lock-in treatments was performed 3 to 5 days after the final adjustment, with the second lock-in treatment performed 3 to 5 days later.

Postoperatively, all subjects underwent full ophthalmic examinations for 12 months and a masked observer performed manifest refraction, BSCVA and uncorrected visual acuity (UCVA) at key follow-up examinations. Subjects were not masked to the lens type implanted.

The gender, age and race demographic characteristics, as well as the baseline visual acuity and ocular history were well-matched between LAL and Control groups. The population in the clinical trial consisted of 40% male and 60% female in the LAL group with 48% and 52% respectively for the Control group. Race and mean age for both study groups were the same where 95% were Caucasian and mean age was approximately 66 in both groups (range: 41-80 in LAL group and 42-80 in Control group).

Accountability in this study was very good with examinations performed in 98% of eyes in the LAL group and 99% of eyes in the Control group at the 6-month time point, at which time the effectiveness endpoints were evaluated.

STUDY OUTCOMES - SAFETY

The safety endpoints were analyzed using the population that includes any subject who had signed the informed consent and had the procedure attempted. This population consisted of 600 eyes with 403 eyes randomized to the LAL and 197 eyes randomized to the control IOL.

BSCVA Safety Endpoint

The primary BSCVA safety endpoint was a comparison of the rates of BSCVA of 20/40 or better at 6 months postoperatively compared between the LAL group and the Control group and the LAL rate compared to the historic control for intraocular lenses (ISO 11979-7). As shown in Table 1, at 6 and 12 months postoperatively, 100% of eyes in both the LAL and Control groups had BSCVA of 20/40 or better, exceeding the historic control rate of 92.5% (ISO 11979-7). Refer to the Adverse Event section for a complete description of cases with significant losses of BSCVA.

TABLE 1
BSCVA BY VISIT
(SUBJECTS WITH DATA AT RELEVANT TIMEPOINTS)

	Pre-Operative		1-week Post-Op		Pre-Adjustment (LAL) or 17-21 days post-op (control)		Pre-Adjustment #2
BSCVA	**LAL (N=403)**	**Control (N=197)**	**LAL (N=401)**	**Control (N=195)**	**LAL (N=400)**	**Control (N=197)**	**LAL (N=262)**
	n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
20/12.5 or better	0 (0.0%)	0 (0.0%)	13 (3.3%)	5 (2.6%)	42 (10.5%)	14 (7.1%)	37 (14.1%)
20/16 or better	3 (0.7%)	0 (0.0%)	138 (34.5%)	64 (32.8%)	229 (57.3%)	95 (48.2%)	162 (61.8%)
20/20 or better	35 (8.7%)	14 (7.1%)	320 (80.0%)	161 (82.6%)	367 (91.8%)	176 (89.3%)	250 (95.4%)
20/25 or better	140 (34.7%)	59 (29.9%)	375 (93.8%)	189 (96.9%)	394 (98.5%)	193 (98.0%)	261 (99.6%)
20/32 or better	221 (54.8%)	105 (53.3%)	392 (98.0%)	192 (98.5%)	399 (99.8%)	196 (99.5%)	262 (100.0%)
20/40 or better	300 (74.4%)	141 (71.6%)	398 (99.5%)	195 (100.0%)	399 (99.8%)	196 (99.5%)	262 (100.0%)
20/80 or better	386 (95.8%)	189 (95.9%)	399 (99.8%)	195 (100.0%)	399 (99.8%)	197 (100.0%)	262 (100.0%)
20/200 or better	394 (97.8%)	197 (100.0%)	399 (99.8%)	195 (100.0%)	399 (99.8%)	197 (100.0%)	262 (100.0%)
Not Reported	0	0	1	0	0	0	0
Mean ± standard deviation (SD)[1] (n)	0.274 (20/37.6) 0.240 (403)	0.268 (20/37.1) 0.172 (197)	-0.002 (20/19.9) 0.124 (400)	-0.009 (20/19.6) 0.082 (195)	-0.051 (20/17.8) 0.113 (400)	-0.038 (20/18.3) 0.082 (197)	-0.068 (20/17.1) 0.072 (262)

	Pre-Lock-in #1	Pre-Lock-in #2	1 week post Lock-in #2	6 months		9 months		12 months	
BSCVA	**LAL (N=399)**	**LAL (N=398)**	**LAL (N=396)**	**LAL (N=391)**	**Control (N=193)**	**LAL (N=388)**	**Control (N=193)**	**LAL (N=391)**	**Control (N=188)**
	n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
20/12.5 or better	63 (15.8%)	61 (15.3%)	51 (12.9%)	77 (19.7%)	15 (7.8%)	67 (17.3%)	21 (10.9%)	57 (14.6%)	20 (10.6%)
20/16 or better	252 (63.2%)	260 (65.3%)	252 (63.6%)	223 (57.0%)	84 (43.5%)	236 (60.8%)	94 (48.7%)	227 (58.1%)	89 (47.3%)
20/20 or better	385 (96.5%)	381 (95.7%)	374 (94.4%)	369 (94.4%)	160 (82.9%)	364 (93.8%)	170 (88.1%)	365 (93.4%)	155 (82.4%)
20/25 or better	398 (99.7%)	395 (99.2%)	392 (99.0%)	386 (98.7%)	188 (97.4%)	385 (99.2%)	188 (97.4%)	390 (99.7%)	184 (97.9%)
20/32 or better	399 (100.0%)	398 (100.0%)	396 (100.0%)	389 (99.5%)	192 (99.5%)	388 (100.0%)	192 (99.5%)	390 (99.7%)	188 (100.0%)
20/40 or better	399 (100.0%)	398 (100.0%)	396 (100.0%)	391 (100.0%)	193 (100.0%)	388 (100.0%)	193 (100.0%)	391 (100.0%)	188 (100.0%)
20/80 or better	399 (100.0%)	398 (100.0%)	396 (100.0%)	391 (100.0%)	193 (100.0%)	388 (100.0%)	193 (100.0%)	391 (100.0%)	188 (100.0%)
20/200 or better	399 (100.0%)	398 (100.0%)	396 (100.0%)	391 (100.0%)	193 (100.0%)	388 (100.0%)	193 (100.0%)	391 (100.0%)	188 (100.0%)
Not Reported	0	0	0	0	0	0	0	0	0
Mean ± SD[1] (n)	-0.071 (20/17.0) 0.075 (399)	-0.072 (20/16.9) 0.078 (398)	-0.068 (20/17.1) 0.077 (396)	-0.066 (20/17.2) 0.084 (391)	-0.028 (20/18.8) 0.091 (193)	-0.069 (20/17.1) 0.083 (388)	-0.041 (20/18.2) 0.090 (193)	-0.063 (20/17.3) 0.079 (391)	-0.039 (20/18.3) 0.090 (188)

%=n/N(100)
[1]LogMAR (Snellen)

Adverse Events and Complications

The second safety endpoint was incidence of sight-threatening complications and adverse events for the LAL group and the Control group. For the many specific categories of adverse events, the LAL incidence rates are compared to the 1-year historical control for intraocular lenses (ISO 11979-7 (Ophthalmic implants – Intraocular lenses – Part 7: Clinical investigations). This endpoint was analyzed based on the methods described in Annex B of the ISO 11979-7 standard.

Table 2 presents cumulative and persistent (to 12 months) adverse events as defined in ISO 11979-7. The numbers of observed cumulative and persistent safety events did not exceed the rates in the ISO historical control except for the category of Secondary Surgical Interventions (SSI), which was significantly higher than the historical rate ($p<.05$).

Because of the unique nature of the LAL/LDD device system (which includes a UV light emitting device), some additional categories of types of adverse events were evaluated, including phototoxic retinal damage causing reduction in best spectacle corrected visual acuity, induction of tritan color vision anomalies, induction of erythropsia, and distortion of the LAL optic due to premature polymerization. Rates for these and other categories of adverse events that are not in the historical control are also shown in Table 2. Additionally, information concerning device-related adverse events concerning erythropsia and color vison anomalies are provided in Tables 4 and 5.

TABLE 2
KEY ADVERSE EVENTS – STUDY EYE

Adverse Events - Cumulative	**Safety and Performance Endpoint %**	**LAL (N=403)**	**Control (N=197)**
		n (%)	**n (%)**
Cystoid Macular Edema (CME)[6]	3.0%	3 (0.7%)	3 (1.5%)
Hypopyon	0.3%	1 (0.2%)	0 (0.0%)
Pupillary Block	0.1%	0 (0.0%)	0 (0.0%)
Retinal Detachment	0.3%	0 (0.0%)	0 (0.0%)
Endophthalmitis	0.1%	1 (0.2%)	0 (0.0%)
Lens Dislocated From Posterior Chamber	0.1%	0 (0.0%)	0 (0.0%)
Secondary Surgical Intervention (excluding Posterior Capsulotomy)[1]	0.8%	7 (1.7%)	1 (0.5%)
Adverse Events – Persistent[2]	**Safety and Performance Endpoint %**	**LAL (N=391)**	**Control (N=188)**
		n (%)	**n (%)**
Corneal Edema	0.3%	0 (0.0%)	0 (0.0%)
Cystoid Macular Edema	0.5%	0 (0.0%)	0 (0.0%)
Iritis	0.3%	0 (0.0%)	0 (0.0%)
Elevated Intraocular Pressure (IOP) Requiring Treatment	0.4%	0 (0.0%)	0 (0.0%)

Adverse Events – Key Non-Standard Categories of Events[3]		LAL (N=391)	Control (N=188)
		n (%)	n (%)
Phototoxic Retinal Damage causing temporary loss of BSCVA[1]		1 (0.2%)	N/A
Persistent Induced Tritan Color Vision Anomaly[1]		2 (0.5%)	N/A
Persistent Induced Erythropsia		1 (0.3%)[4]	N/A
Reactivation of Ocular Herpes Simplex Infection after LDD UV treatment		1 (0.3%)[5]	N/A
Persistent Unanticipated Significant Increase in Manifest Refraction Error (≥1.0 D cylinder or MRSE)		5 (1.3%)	N/A
Premature Polymerization of the LAL Causing Visible Distortion of LAL Optic		0 (0.0%)	N/A
Intraoperative Iris Prolapse		1 (0.3%)	0 (0.0%)
Intraoperative Capsular tear during primary IOL implantation after unremarkable phacoemulsification		1 (0.3%)	0 (0.0%)
Horseshoe Retinal Tear		1 (0.3%)[7]	1 (0.5%)

%=n/N(100)

[1] One subject experienced a retinal phototoxic injury that was determined to be caused by a faulty filter within the UV source of the LDD. Corrective action was taken to ensure that defective filters were not released to the market. The retinal phototoxicity was associated with loss of BSCVA to 20/150, which recovered to 20/22 approximately 5 months after surgery. This subject also experienced a tritan color vision defect that was persistent to 4 years postoperatively. The patient underwent an explant with a replacement with a monofocal IOL.

[2] The rates of persistent adverse events were calculated based on the observed population at 12 months.

[3] The rates of Key Non-Standard Categories of Events were calculated based on the observed population at any time during the clinical study.

[4] Resolved at 14 months postoperatively.

[5] Following the initial light treatment, one subject experienced a reactivation of previously undiagnosed herpes simplex virus (HSV). Following anti-HSV therapy, the subject's condition improved and remaining light treatments were administered. At the 12-month postoperative exam, BSCVA was 20/20.

[6] One case of CME required sub-Tenons kenalog injection; this caused delay of light treatment.

[7] One case included a vitreous detachment with sub-retinal fluid.

As shown in Table 2, 7 eyes (1.7%) in the LAL group had a secondary surgical intervention (SSI); 3 explants, a Descemet's Stripping Endothelial Keratoplasty (DSEK) procedure, two treatments to dissolve iris adhesions to permit full pupil dilation, and a barrier retinal laser procedure as described in the table below.

SSI	Cause	Final Acuity at Last Visit
Explant	As described in Table 2, footnote 1, a faulty UV filter within the UV source of the LDD prevented completion of light treatments	BSCVA 20/23 with persistent tritan anomaly
Explant	Scratch on the LAL optic acquired at time of lens implant that required lens replacement at 3 weeks postop. Secondary procedure had complications.	BSCVA 20/20
Explant	Subject requested lens replacement prior to light treatment	UCVA 20/15

DSEK	Problems during delivery of LAL which led to corneal edema	BSCVA 20/26.4
Lysing of iris adhesions and sphincterotomy	Following the initial light treatment, posterior synechiae were observed which limited pupil dilation for final light treatment	BSCVA 20/17.4
Lysing of iris adhesions by YAG laser	Following the initial light treatments, posterior synechiae were observed which limited pupil dilation for final light treatment	BSCVA 20/17.4
Barrier laser treatment	Hemorrhagic posterior vitreous detachment and a horseshoe retinal tear with sub-retinal fluid 9 months postoperative.	BSCVA 20/14.5

Additional Safety Analyses

Best Spectacle Corrected Visual Acuity Change

Table 3 presents change in BSCVA at each postoperative visit compared to pre-adjustment #1 (LAL) or 17-21 day visit (Control) BSCVA. At 1 week post lock-in #2, the majority of eyes had an increase or no change in BSCVA. The mean change in BSCVA from pre-adjustment #1 to 1 week post lock-in #2 was +0.7 letters.

Overall, the distribution of eyes with gains and losses of 2 or more lines of BSCVA was similar for the LAL and the Control group at 6 and 12 months. At 6 months, only 2 eyes in the LAL group and 3 eyes in the Control group had a decrease of 2 or more lines of BSCVA. At 12 months, only 1 eye in the LAL group and 4 eyes in the Control group had a decrease of 2 or more lines of BSCVA.

TABLE 3
BSCVA CHANGE COMPARED TO PRE-ADJUSTMENT #1 (LAL)/17-21 DAYS (CONTROL)
(SUBJECTS WITH DATA AT RELEVANT TIMEPOINTS)

	Pre-Lock-in #1	Pre-Lock-in #2	1 week Post Lock-in #2
BSCVA change	**LAL (N=399)**	**LAL (N=398)**	**LAL (N=396)**
	n (%)	**n (%)**	**n (%)**
Increase in 15 letters or more (3 lines or more)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increase in 10-14 letters (2 lines)	2 (0.5%)	3 (0.8%)	2 (0.5%)
Increase in 5-9 letters (1 line)	36 (9.0%)	42 (10.6%)	43 (10.9%)
No Change	347 (87.0%)	339 (85.2%)	330 (83.3%)
Decrease in 5-9 letters (1 line)	13 (3.3%)	13 (3.3%)	19 (4.8%)
Decrease in 10-14 letters (2 lines)	1 (0.3%)	1 (0.3%)	2 (0.5%)
Decrease in 15 letters or more (3 lines or more)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Not reported	0	0	0
Mean change in number of letters	0.8 ± 2.9 (399)	0.9 ± 3.0 (398)	0.7 ± 3.2 (396)

	6 months		9 months		12 months	
BSCVA change	**LAL (N=391)**	**Control (N=193)**	**LAL (N=388)**	**Control (N=193)**	**LAL (N=391)**	**Control (N=188)**
	n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Increase in 15 letters or more (3 lines or more)	1 (0.3%)	1 (0.5%)	1 (0.3%)	1 (0.5%)	1 (0.3%)	2 (1.1%)
Increase in 10-14 letters (2 lines)	5 (1.3%)	1 (0.5%)	4 (1.0%)	6 (3.1%)	2 (0.5%)	3 (1.6%)
Increase in 5-9 letters (1 line)	52 (13.3%)	17 (8.8%)	48 (12.4%)	15 (7.8%)	50 (12.8%)	18 (9.6%)
No Change	312 (79.8%)	150 (77.7%)	307 (79.1%)	150 (77.7%)	306 (78.3%)	142 (75.5%)
Decrease in 5-9 letters (1 line)	19 (4.9%)	21 (10.9%)	25 (6.4%)	20 (10.4%)	31 (7.9%)	19 (10.1%)
Decrease in 10-14 letters (2 lines)	2 (0.5%)	3 (1.6%)	3 (0.8%)	1 (0.5%)	1 (0.3%)	4 (2.1%)
Decrease in 15 letters or more (3 lines or more)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Not reported	0	0	0	0	0	0
Mean change in number of letters	0.7 ± 4.9 (391)	-0.5 ± 3.9 (193)	0.9 ± 5.0 (388)	0.1 ± 4.2 (193)	0.6 ± 5.2 (391)	0.0 ± 4.4 (188)

%=n/N(100)

Erythropsia

Erythropsia is an uncommon abnormality of vision in which objects appear to be tinged with red. It can be caused by exposure to high levels of ultraviolet light. Since the LDD exposes the eye to higher than usual levels of UV light, the study attempted to assess the presence and severity of erythropsia experienced by the subjects (It is assumed that post-light treatment erythropsia is related to use of the LDD). At a number of study visits, subjects were asked (without occlusion of the untreated eye): "At this moment, how would you rate your color vision? Is it normal, pink, red, or dark red?" Erythropsia was graded as none for a normal response, mild for a pink response, moderate for a red response, or severe for a dark red response. (This erythropsia assessment methodology was not determined to be a psychometrically valid assessment of the concept of patient reported erythropsia.)

Table 4 presents results from the erythropsia assessment. After light treatment, 233 (58.3%) eyes in the LAL group had erythropsia of any grade. The highest rate of erythropsia was reported prior to the lock-in #2 treatment when 49.0% (195/398) of LAL subjects reported mild erythropsia. This proportion decreased significantly at 1 week post lock-in #2 (17.7%) and was only 0.5% at 6 months. Only 1 (0.3%) LAL subject continued to report mild erythropsia at the 12-month exam with resolution at 14 months postoperatively. The mean duration for mild erythropsia could not be established because subjects were not required to return for interim visits with "mild" symptoms.

The highest rate of moderate erythropsia also was reported prior to the lock-in #2 treatment when 11 LAL subjects reported this level. Fourteen subjects reported moderate erythropsia at some point in the study, with none reporting severe levels. The average duration of moderate erythropsia was 11.6 days with the minimum duration of 5.0 days and a maximum duration of 22.0 days. No LAL subjects reported moderate erythropsia after the lock-in #2 visit. All but one of the reports of moderate erythropsia occurred prior to the introduction of a safety improvement to the LDD device to reduce UV exposure during the Lock-in procedure. (This device modification was instituted after about half of the subjects had received the earlier version of the LDD treatments.) However, the overall rate of subjects experiencing mild erythropsia was not substantially affected by this modification of the LDD.

TABLE 4
ERYTHROPSIA
(SUBJECTS WITH DATA AT RELEVANT TIMEPOINTS)

Degree of Erythropsia	Adj. #1	Interim	Adj. #2	Interim	Lock-In #1	Interim	Lock-In #2	Interim
LAL								
	N=400	N=9	N=262	N=8	N=399	N=24	N=398	N=9
	n (%)	n	n (%)	n	n (%)	n	n (%)	n
None	394 (98.7%)	3	223 (85.1%)	6	349 (87.5%)	3	203 (51.0%)	-
Mild (pink)	5 (1.3%)	0	38 (14.6%)	0	50 (12.5%)	6	195 (49.0%)	-
Moderate (red)	0 (0.0%)	0	1 (0.4%)	0	0 (0.0%)	11	0 (0.0%)	-
Severe (dark red)	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	-
Not assessed	1	6	0	2	0	4	0	9

Degree of Erythropsia	1 Week Post Lock-In #2	Interim	6 Months	Interim	9 Months	Interim	12 Months
LAL							
	N=396	N=57	N=391	N=18	N=388	N=23	N=391
	n (%)	n	n (%)	n	n (%)	n	n (%)
None	326 (82.3%)	11	389 (99.5%)	1	387 (99.7%)	2	388 (99.7%)
Mild (pink)	70 (17.7%)	1	2 (0.5%)	0	1 (0.3%)	0	1 (0.3%)
Moderate (red)	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Severe (dark red)	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Not assessed	0	45	0	17	0	21	2

Degree of Erythropsia	17-21 Days	Interim	6 Months	Interim	9 Months	Interim	12 Months
Control							
	N=197	N=21	N=193	N=8	N=193	N=13	N=188
	n (%)	n	n (%)	n	n (%)	n	n (%)
None	196 (99.5%)	2	193 (100.0%)	1	193 (100.0%)	1	188 (100.0%)
Mild (pink)	1 (0.5%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Moderate (red)	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Severe (dark red)	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Not assessed	0	19	0	7	0	12	0

%=n/N(100)

Color Vision Testing

Since a high level of exposure to UV light can also affect color vision (especially causing a weakness related to perception of blue color or a tritan anomaly), the study also used color vision testing to look for defects of color vision. (It is assumed that a tritan anomaly that appears only after light treatment is related to use of the LDD.) The City University Color Vision Test (3rd Edition 1998) consists of a series of 11 plates, 4 for Part One and 7 for Part Two. Part One is generally used for screening for color vision defects.

The objective of Part Two is to classify color vision defects. Per the score sheet provided with the test, more than one entry for protan, deutan or tritan is considered abnormal. A protan anomaly is a color vision deficiency that affects the long wavelength sensitive cones and affects a patient's ability to distinguish blue and green colors and also red and green colors. A deutan anomaly is a color vision deficiency that affects the medium wavelength sensitive cones and affects a patient's ability to distinguish red and green colors but others may also be slighted affected. A tritan anomaly is a color vision deficiency that affects the short wavelength sensitive cones and typically affects a patient's ability to distinguish between violet, blue and green colors.

City University Test results are provided in Table 5. Any new tritan anomaly measured after the initial light treatment was considered related to the LDD UV exposure. A total of 7 (1.8%) LAL eyes had a tritan score >1 any time after light treatment. Five eyes resolved after light treatments were complete and 2 persisted. Of the five eyes that resolved, four of the eyes were seen at consistent follow-up exams to monitor progress. The average duration of the tritan anomaly for these 4 eyes was 16 days with a minimum duration of 10 days and a maximum duration of 30 days. The fifth eye had a large time gap (557 days) from the time the eye was diagnosed with a tritan anomaly to the next clinical visit in which no tritan anomaly was observed. The two eyes with persistent tritan anomalies were measured with a tritan score >1 at the last study visit, and 1 of these eyes previously described as having an adverse device effect due to a faulty UV filter was documented as having the tritan anomaly at 4 years postoperatively. Both of the persistent and all but one of the transient tritan anomalies occurred prior to the introduction of a safety improvement to the LDD device to reduce UV exposure during the Lock-in procedure.

TABLE 5
CITY UNIVERSITY
(SUBJECTS WITH DATA AT RELEVANT TIMEPOINTS)

Part 1	Pre-Adj #1 LAL (N=400)	17-21 Days Control (N=197)	Interim Visit LAL (N=10)	Pre-Lock-in #1 LAL (N=399)	Interim Visit LAL (N=21)	Pre-Lock-in #2 LAL (N=398)	Interim Visit LAL (N=0)	1 week post Lock-in #2 LAL (N=396)	Interim Visit LAL (N=10)	Interim Visit Control (N=0)
	n (%)	n (%)	n	n (%)	n	n (%)	n	n (%)	n	n
Abnormal (<9)	12 (3.0%)	4 (2.0%)	0	8 (2.0%)	11	12 (3.0%)	0	6 (1.5%)	1	0
Not reported	1	0	0	2	0	0	0	0	0	0
Part 2										
Protan >1	2 (0.5%)	0 (0.0%)	0	2 (0.5%)	0	1 (0.3%)	0	0 (0.0%)	0	0
Deutan >1	1 (0.3%)	1 (0.5%)	0	3 (0.8%)	1	2 (0.5%)	0	1 (0.3%)	0	0
Tritan >1	0 (0.0%)	0 (0.0%)	0	1 (0.3%)	5	0 (0.0%)	0	1 (0.3%)	1	0
Not reported	1	0	0	2	0	0	0	0	0	0

	6 months		Interim Visit		9 months		Interim Visit		12 months	
Part 1	LAL (N=391)	Control (N=193)	LAL (N=1)	Control (N=1)	LAL (N=388)	Control (N=193)	LAL (N=1)	Control (N=0)	LAL (N=391)	Control (N=188)
	n (%)	n (%)	n	n	n (%)	n (%)	n	n	n (%)	n (%)
Abnormal (<9)	8 (2.0%)	4 (2.1%)	0	0	5 (1.3%)	2 (1.0%)	0	0	6 (1.5%)	2 (1.1%)
Not reported	0	0	0	0	0	0	0	0	0	0
Part 2										
Protan >1	1 (0.3%)	0 (0.0%)	0	0	2 (0.5%)	0 (0.0%)	0	0	1 (0.3%)	0 (0.0%)
Deutan >1	2 (0.5%)	1 (0.5%)	0	0	3 (0.8%)	1 (0.5%)	0	0	2 (0.5%)	1 (0.5%)
Tritan >1	3 (0.8%)	0 (0.0%)	0	0	0 (0.0%)	0 (0.0%)	0	0	1 (0.3%)	0 (0.0%)
Not reported	1	0	0	0	0	0	0	0	0	0

%=n/N(100)

Contrast Sensitivity

Best spectacle corrected contrast sensitivity testing was performed using the Vector Vision CSV-1000E with glare sources on a subgroup of 272 LAL and 141 Control eyes under photopic and mesopic test conditions, with and without glare, at pre-adjustment #1 (LAL) and 17-21 days (Control) and at 6 months postoperatively.

Photopic results without glare show a mean improvement at each frequency for the LAL group and at each frequency except 12 cycles per degree (cpd) for the Control group. Photopic results with glare show a mean improvement at each frequency for the LAL group and for the Control group. Therefore, in photopic conditions both with and without glare, there was no statistically significant difference noted between the LAL and Control groups.

Mesopic results without glare show a mean improvement at each frequency for the LAL group and at each frequency except 12 cpd for the Control group. Mesopic results with glare show a mean improvement at each frequency for the LAL group and for the Control group. Therefore, in mesopic conditions both with and without glare, there was no statistically significant difference noted between the LAL and Control groups.

Specular Microscopy Sub-Study

As shown in Table 6, at 6 months postop, the mean endothelial cell loss (ECL) for subjects participating in the endothelial cell sub-study was within the range described in literature following phacoemulsification cataract extraction. At this time point, the minimum confirmed postoperative endothelial cell density (ECD) value observed was 814 and the maximum confirmed percent loss from baseline was approximately 66%.

TABLE 6
SPECULAR MICROSCOPY
ALL SPECULAR MICROSCOPY SUB-STUDY SUBJECTS WITH DATA AT RELEVANT TIMEPOINTS

	Preop	6 Months Postop	12 Months Postop
N	104	99	102
ECD			
Mean (SD)	2493.0 (318.7)	2139.8 (516.0)	2120.7 (505.5)
Percent Change in ECD			
Mean (SD)		-14.7% (15.9%)	-15.0% (15.2%)

STUDY OUTCOMES - EFFECTIVENESS

Key Outcomes

All 3 co-primary effectiveness endpoints were met with a p-value of < 0.0001 and are provided in Table 7. All three co-primary effectiveness endpoints were compared using pre-adjustment (LAL) or 17-21 days (Control) to 6 months postoperatively. The first two endpoints were compared between the LAL and Control groups.

- The difference in means for percent reduction in manifest cylinder was 54.7% ($p < 0.0001$ using a two-sample t-test). In the LAL group, the mean percent reduction in manifest cylinder

was 74.6% (95% confidence interval (CI): 71.1%, 78.1%) while in the Control group it was 19.9% (95% CI: 10.9%, 28.9%).

- The difference in means for percent absolute reduction in MRSE was 41.1% ($p < 0.0001$ using a two-sample t-test). In the LAL group, the mean percent absolute reduction in MRSE was 51.5% (95% CI: 43.8%, 59.1%) while in the Control group it was 10.4% (95% CI: -3.8%, 24.7%).

- Axial rotation of the LAL of ≤ 5 degrees (between pre-adjustment and 6 months postop) was observed in 96.1% (344/358) of eyes implanted with the LAL, meeting the endpoint. Both the upper and lower bound of the 95% confidence interval are above 90% (95% CI: 93.5%, 97.8%).

TABLE 7
PRIMARY ANALYSES OF CO-PRIMARY EFFECTIVENESS ENDPOINTS
(SUBJECTS WITH DATA AT PRE-ADJUSTMENT AND 6 MONTHS)
(EXCLUDED SUBJECTS SHOWN IN FOOTNOTES)

Endpoint		LAL (Number Implanted = 391)	Treatment Effect	Control (Number Implanted = 193)
Percent reduction in manifest cylinder from Pre-Adjustment (LAL) or 17-21 days post-op (control) to 6 months postop[1]				
	Number in Analysis	286		126
	Mean ± SD [95% CI]	74.6 ± 30.1) [71.1,78.1]		19.9 ± 51.1 [10.9,28.9]
	Median	83.3		20.0
	(Min, Max)	(-33, 100)		(-200, 100)
	Difference in means		54.7	
	p-value		<0.0001	
Percent absolute reduction in MRSE from Pre-Adjustment (LAL) or 17-21 days post-op (control) to 6 months postop[2]	Number in Analysis	380		166
	Mean ± SD [95% CI]	51.5 ± 76.0 [43.8,59.1]		10.4 ± 93.1 [-3.8,24.7]
	Median	75.0		36.7
	(Min, Max)	(-500, 100)		(-400, 100)
	Difference in means		41.1	
	p-value		<0.0001	
Number (%) of eyes with axial rotation of LAL of ≤ 5 degrees from Pre-Adjustment to 6 months postop[3]	n/N (%)	344 /358 (96.1 %)		N/A
	95% Confidence Interval	[93.5%, 97.8%]		N/A

[1] Excludes subjects with <0.75 D of cylinder at Pre-Adjustment (LAL) or 17-21 days post-op (Control). 105 of LAL and 67 of Control subjects were excluded for this reason. Note that the LDD power adjustment does not treat less than 0.75 D of cylinder

[2] Excludes subjects with MRSE of 0 at Pre-Adjustment (LAL) or 17-21 days post-op (Control) since it is not possible to divide by zero (11 of LAL and 27 of Control subjects were excluded for this reason)

[3] Excludes subjects that do not have readable images at both Pre-Adjustment or 6 months (33 eyes were excluded for this reason).

Subjects not receiving astigmatic treatment (105 LAL subjects with <0.75 D cyl) were not included in the main analysis of "percent reduction" of astigmatism. Subjects with zero MRSE were not included in the "percent reduction" MRSE analysis. Also, when choosing the LAL implantation power, subjects were targeted to +0.50 D MRSE (to compensate for the expected 0.5 D myopic shift of the lock-in), as opposed to the controls who were targeted to zero MRSE.

Table 8 provides key effectiveness results evaluated for all implanted subjects available, at 6 months.

TABLE 8
SUMMARY ADDITIONAL EFFECTIVENESS ANALYSES AT 6 MONTHS
(ALL SUBJECTS WITH DATA AVAILABLE AT 6 MONTHS)

	LAL (N=391)	Treatment Effect	Control (N=193)
Mean absolute MRSE ± SD (D)	0.224 ±0.225	0.089	0.313 ±0.322
Mean manifest cylinder ± SD (D)	0.299 ±0.366	0.450	0.749 ±0.620
Percent of eyes with MRSE within 0.50 D of zero n (%)	360 (92.1%)	8.7%	161 (83.4%)
Percent of eyes with MRSE within 1.00 D of zero n (%)	389 (99.5%)	2.6%	187 (96.9%)
Percent of eyes with manifest cylinder within 0.50 D of zero n (%)	322 (82.4%)	31.1%	99 (51.3%)
Percent of eyes with manifest cylinder within 1.00 D of zero	385 (98.5%)	23.9%	144 (74.6%)
Mean BSCVA LogMAR acuity (Snellen equivalent) ± SD	-0.066 (20/17.2) ± 0.084	-0.038	-0.028 (20/18.8) ± 0.091
Mean UCVA LogMAR acuity (Snellen equivalent) ± SD	0.005 (20/20) ± 0.103	0.127	0.132 (20/27) ± 0.165

%=n/N(100)

Table 9 presents the five secondary effectiveness outcomes. A p-value of <0.01 was required for each outcome to be considered successful. Four of the five secondary effectiveness endpoints were met: percent of eyes having UCVA 20/20 or better, percent reduction in cylinder by cylinder bin (0.75 to 1.25 D and >1.25 D) and mean BSCVA in the "best case" cohort. One secondary endpoint was not met (p-value=0.03), however, additional analyses support a meaningful contribution to effectiveness for this endpoint as well.

All five secondary effectiveness endpoints were compared between the LAL and Control groups using pre-adjustment (LAL) or 17-21 days (Control) to 6 months postoperatively.

- The difference in percent of eyes with UCVA of 20/20 or better was statistically significant ($p < .0001$ using a chi-square test) with 70.1% (274/391) of eyes in the LAL group and 36.3% (70/193) of eyes in the Control group with UCVA 20/20 or better.

- The difference in means for percent reduction in manifest cylinder was 54.8% for the 0.75 to 1.25 D cylinder bin was statistically significant with a $p < 0.0001$ using a two-sided t-test with unequal variances. In the LAL group, the mean percent reduction in manifest cylinder was 73.4% while in the Control group it was 18.6%.

- The difference in means for percent reduction in manifest cylinder was 54.4% for the >1.25 D cylinder bin was statistically significant with a $p < 0.0001$ using a two-sided t-test with unequal variances. In the LAL group, the mean percent reduction in manifest cylinder was 77.5% while in the Control group it was 23.1%.

- For eyes with <0.75 D cylinder at pre-adjustment #1 (LAL) or 17-21 days (Control), the difference in means for percent absolute reduction in MRSE was 28%, with a p-value of 0.0319 using a two-sample t-test with unequal variances. However, this result was non-significant based upon the statistical plan adjustment for testing of multiple hypotheses.

- For the "best case" cohort (with no macular problems causing a decrease in BSCVA to worse than 20/20 at 6 months), the 99% upper bound confidence interval was -0.04 LogMAR, which is well below the 0.10 LogMAR non-inferiority margin. The mean BSCVA for the LAL group was -0.066 and -0.029 for the Control group (i.e. BSCVA in the LAL group is better than the BSCVA in the Control group). Therefore, this secondary endpoint is met.

TABLE 9
SECONDARY EFFECTIVENESS ENDPOINTS AT 6 MONTHS
(SUBJECTS WITH DATA AT RELEVANT TIMEPOINTS
(EXCLUDED SUBJECTS EXPLAINED IN FOOTNOTES)

		LAL (Number implanted=391)	Treatment Effect	Control (Number implanted=193)	p-value
UCVA 20/20 or better at 6 months[1]	n (%)	274 (70.1 %)	33.8%	70 (36.3 %)	< .0001
Percent reduction in manifest cylinder at 6 months in the 0.75 to 1.25 D cylinder treatment group[2]	Mean ± SD (number in analysis)	73.4 ± 33.1 **(n =203)**	54.8	18.6 ± 57.0 **(n =90)**	< .0001
Percent reduction in manifest cylinder at 6 months in the >1.25 D cylinder treatment group[3]	Mean ± SD (number in analysis)	77.5 ± 20.7 **(n=83)**	54.4	23.1 ± 32.3 **(n=36)**	< .0001
Percent absolute reduction in MRSE at 6 months for eyes with < 0.75D of cylinder at Pre-Adjustment (LAL) or 17-21 days post-op (control) [4]	Mean ± SD (number in analysis)	55.2 ± 76.3 **(n=100)**	28.0	27.2 ± 75.2 **(n=53)**	0.0318
Mean BSCVA for 'best case' cohort (no macular problems) at 6 months [5]	Mean ± SD (number in analysis)	-0.066 ± 0.083 **(n=390)**		-0.029 ± 0.090 **(n=191)**	-
	Difference in means [99% Confidence Interval]		-0.04 [-0.06,-0.02]	-	-

%=n/N(100)

[1] All eyes with UCVA data at 6 months

[2] Includes only eyes with 0.75 D to 1.25 D of cylinder at Pre-Adjustment (LAL) or 17-21 days post-op (Control); excludes eyes without data at 6 months

[3] Includes only eyes with > 1.25 D of cylinder at Pre-Adjustment (LAL) or 17-21 days post-op (Control); excludes eyes without data at 6 months

[4] Excludes subjects with MRSE of 0 at Pre-Adjustment (LAL) or 17-21 days post-op (Control) since it is not possible to divide by 0); excludes eyes without data at 6 months

[5] One LAL eye and 2 Control eyes excluded from "best case" cohort, because of macular problems

Additional Effectiveness Analyses

Table 10 shows the percent reduction in cylinder at 6 and 12 months postoperative.

TABLE 10
MANIFEST CYLINDER AT 6 AND 12 MONTHS AND PERCENT REDUCTION IN CYLINDER IN EYES WITH ≥ 0.75 D CYLINDER AT PRE-ADJUSTMENT (LAL) /17-21 DAYS (CONTROL)
(SUBJECTS WITH DATA AT RELEVANT TIME POINTS)

	6 Months		12 Months	
Manifest Cylinder (D)	LAL (N=286)	Control (N=126)	LAL (N=284)	Control (N=122)
Mean ± SD	0.295 ± 0.339	0.962 ± 0.626	0.370 ± 0.420	0.967 ± 0.651
Median	0.250	1.000	0.250	1.000
(Min, Max)	(0.00, 1.50)	(0.00, 2.50)	(0.00, 3.50)	(0.00, 4.50)
% Reduction in Manifest Cylinder				
Mean ± SD	74.6 ± 30.1	19.9 ± 51.1	67.6 ± 36.5	19.9 ± 45.6
Median	83.3	20.0	75.0	20.0
(Min, Max)	(-33, 100)	(-200, 100)	(-133, 100)	(-125, 100)

Table 11presents the accuracy of the cylinder correction at 6 and 12 months for all LAL eyes that had a cylinder correction attempted.

TABLE 11
CYLINDER CORRECTION ACCURACY (LAL)
(SUBJECTS WITH DATA AT RELEVANT TIME POINTS)

	6 months	12 months
Accuracy of Cylinder Correction to Intended Target	**LAL (N=286)**	**LAL (N=284)**
	n (%)	n (%)
Within 0.50 D	237 (82.9 %)	227 (79.9 %)
Within 1.00 D	283 (99.0 %)	271 (95.4 %)

%=n/N(100)

Table 12 presents the accuracy of MRSE correction for eyes in the LAL group at 6 and 12 months.

TABLE 12
ACCURACY OF MRSE CORRECTION TO INTENDED TARGET (LAL)
(SUBJECTS WITH DATA AT RELEVANT TIME POINTS)

	6 months	12 months
Accuracy of MRSE Correction to Intended Target	**LAL (N=391)**	**LAL (N=391)**
	n (%)	n (%)
Within 0.50 D	358 (91.6%)	357 (91.5%)
Within 1.00 D	387 (99.2%)	390 (100.0%)

%=n/N(100)

Refractive stability of the MRSE for the LAL and Control groups for the pairwise cohort is shown in Table 13. All 5 refractive criteria per ANSI Z80.11-2012 were met and/or exceeded at the 6-month visit. The most rigorous of these criteria, i.e., change in MRSE no greater than 0.04D/month and change per year no greater than 0.5 D, were considerably exceeded, as shown in Table 15. The mean rate of change per month for the LAL group was 0.004 D beginning at the 1 week post lock-in #2 through the 6-month visit, and the 95% confidence interval for the mean rate of change includes zero at all intervals for the LAL.

TABLE 13
MRSE REFRACTIVE STABILITY
(SUBJECTS WITH DATA AT RELEVANT TIME POINTS)

	1 week post Lock-in #2 (LAL)/17-21 days (control)to 6M		**6M to 9M**		**9M to 12M**		**1 week post Lock-in #2 (LAL)/ 17-21 days (control)to 12M**	
MRSE	**LAL (N=387)**	**Control (N=193)**	**LAL (N=382)**	**Control (N=191)**	**LAL (N=388)**	**Control (N=188)**	**LAL (N=387)**	**Control (N=188)**
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Eyes with ≤ 1.00 D change	385 (99.5%)	185 (95.9%)	379 (99.2%)	188 (98.4%)	387 (99.7%)	183 (97.3%)	384 (99.2%)	182 (96.8%)
Eyes with ≤ 0.50 D change	363 (93.8%)	156 (80.8%)	366 (95.8%)	170 (89.0%)	371 (95.6%)	171 (91.0%)	356 (92.0%)	157 (83.5%)
Mean Change Between Visits [95% CI]	0.021 ± 0.296 [-0.009,0.050]	0.046 ± 0.520 [-0.028,0.120]	-0.012 ± 0.302 [-0.042, 0.018]	-0.015 ± 0.384 [-0.070,0.040]	0.012 ± 0.277 [-0.016,0.040]	0.041 ± 0.391 [-0.016,0.097]	0.029 ± 0.327 [-0.003,0.062]	0.074 ± 0.458 [0.009,0.140]
Mean Change per Month	0.004	0.009	-0.004	-0.005	0.004	0.014	0.003	0.007
Mean Change per Year (Change per Month x 12)	0.050	0.110	-0.048	-0.060	0.048	0.162	0.032	0.081

%=n/N(100)

UCVA

Table 14 presents UCVA for the LAL and Control groups. At 6 months postoperatively, the mean UCVA was 20/20.0 in the LAL group and 20/27.0 in the Control group. At 6 months, twice as many LAL eyes had UCVA of 20/20 or better compared to the Control.

TABLE 14
UCVA BY VISIT
(SUBJECTS WITH DATA AT RELEVANT TIME POINTS)

	Pre-Adjustment (LAL) or 17-21 days post-op (control)		6 months		12 months	
UCVA	**LAL (N=400)**	**Control (N=197)**	**LAL (N=391)**	**Control (N=193)**	**LAL (N=391)**	**Control (N=188)**
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
20/12.5 or better	1 (0.3%)	2 (1.0%)	25 (6.4%)	3 (1.6%)	23 (5.9%)	5 (2.7%)
20/16 or better	12 (3.0%)	14 (7.1%)	118 (30.2%)	18 (9.3%)	104 (26.6%)	23 (12.2%)
20/20 or better	63 (15.8%)	59 (29.9%)	274 (70.1%)	70 (36.3%)	260 (66.5%)	71 (37.8%)
20/25 or better	176 (44.0%)	112 (56.9%)	358 (91.6%)	117 (60.6%)	358 (91.6%)	115 (61.2%)
20/32 or better	285 (71.3%)	149 (75.6%)	386 (98.7%)	154 (79.8%)	383 (98.0%)	144 (76.6%)
20/40 or better	352 (88.0%)	178 (90.4%)	390 (99.7%)	174 (90.2%)	391 (100.0%)	172 (91.5%)
20/80 or better	398 (99.5%)	195 (99.0%)	391 (100.0%)	192 (99.5%)	391 (100.0%)	188 (100.0%)
20/200 or better	399 (99.8%)	197 (100.0%)	391 (100.0%)	193 (100.0%)	391 (100.0%)	188 (100.0%)
Not Reported	0	0	0	0	0	0
Mean[1] ± SD (n)	0.186 (20/31.0) ± 0.154 (400)	0.150 (20/28.3) ± 0.152 (197)	0.005 (20/20.0) ± 0.103 (391)	0.132 (20/27.0) ± 0.165 (193)	0.011 (20/20.5) ± 0.101 (391)	0.122 (20/26.4) ± 0.158 (188)

%=n/N(100)
[1]LogMAR (Snellen)

Table 15 presents UCVA at 6 months stratified by pre-adjustment #1 (LAL) and 17-21 days (Control) cylinder bin. The difference in mean UCVA between the LAL and Control groups is largest in the >1.25 D cylinder bin with a mean UCVA of 20/22.1 in the LAL group versus 20/40.0 in the Control group, a difference of almost 3 lines. Similarly the LAL group had approximately 45% higher rate of UCVA 20/20 or better for the > 1.25 D cylinder group compared to the control.

TABLE 15
UCVA AT 6 MONTHS STRATIFIED BY CYLINDER TREATMENT GROUP
(SUBJECTS WITH DATA AT 6 MONTHS)

	<0.75 D cylinder at Pre-Adjustment #1 (LAL)/ 17-21 days Post-op (control)		0.75 to 1.25 D of cylinder at Pre-Adjustment #1 (LAL)/17-21 days Post-op (control)		>1.25D of cylinder at Pre-Adjustment #1 (LAL)/17-21 days Post-op (control)	
UCVA	**LAL (N=105)**	**Control (N=67)**	**LAL (N=203)**	**Control (N=90)**	**LAL (N=83)**	**Control (N=36)**
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
20/20 or better	71 (67.6%)	37 (55.2%)	156 (76.8%)	29 (32.2%)	47 (56.6%)	4 (11.1%)
20/40 or better	104 (99.0%)	65 (97.0%)	203 (100.0%)	87 (96.7%)	83 (100.0%)	22 (61.1%)
Mean UCVA ± SD (n) at 6 months[1]	0.003 (20/20.1) ± 0.113 (105)	0.050 (20/22.4) ± 0.118 (67)	-0.011 (20/19.5) ± 0.089 (203)	0.126 (20/26.7) ± 0.136 (90)	0.044 (20/22.1) ± 0.113 (83)	0.301 (20/40.0) ± 0.184 (36)

%=n/N(100)
[1]LogMAR (Snellen)

Table 16 presents mean manifest refraction cylinder results at 6 months postop based on preoperative keratometric astigmatism to allow estimation of the astigmatic effect of treatment based on preoperative levels of astigmatism.

TABLE 16
MANIFEST REFRACTION CYLINDER AT 6 MONTHS
STRATIFIED BY PREOPERATIVE KERATOMETRIC CYLINDER
(SUBJECTS WITH DATA AT 6 MONTHS)

	Preoperative Keratometric Cylinder								
	0.75-1.24D			1.25 - 1.74D			≥1.75D		
	LAL (N=213)	Control (N=118)	Difference	LAL (N=110)	Control (N=41)	Difference	LAL (N=68)	Control (N=34)	Difference
Manifest Refraction Cylinder at 6 Months									
Mean	0.255	0.572	-0.317	0.298	0.835	-0.537	0.441	1.257	-0.816
SD	0.362	0.460	-	0.322	0.665	-	0.415	0.750	-

Table 17 presents the percent of LAL eyes that did not receive an astigmatic treatment by preoperative keratometric astigmatism. Eyes with lower preoperative keratometric cylinder are less likely to receive an astigmatism treatment.

TABLE 17
PERCENT OF LAL EYES THAT DID NOT RECEIVE ASTIGMATISM TREATMENT BY PREOPERATIVE KERATOMETRIC CYLINDER

	Preoperative Keratometric Cylinder (LAL only)						
	0.75-0.99 (N=111)	1.00-1.24 (N=108)	1.25-1.49 (N=62)	1.50-1.74 (N=50)	1.75-1.99 (N=32)	≥2.0 (N=37)	Total (N=400)
Proportion of eyes that received NO astigmatic treatment	53 (47.7%)	34 (31.5%)	12 (19.4%)	6 (12.0%)	4 (12.5%)	1 (2.7%)	110 (27.5%)

%=n/N(100)

Figure 4 illustrates mean absolute MRSE at 6 months stratified by the pre-adjustment (LAL)/17-21 days (Control) signed MRSE. The figure shows that outcomes for the LAL are essentially independent of the initial refractive error through the 2 D treatment range while the Control eyes had a significant degradation of results with increased signed (myopic or hyperopic) MRSE at 17-21 days. In addition, subjects with an MRSE outside the range of correction are indicated by the blue dotted line.

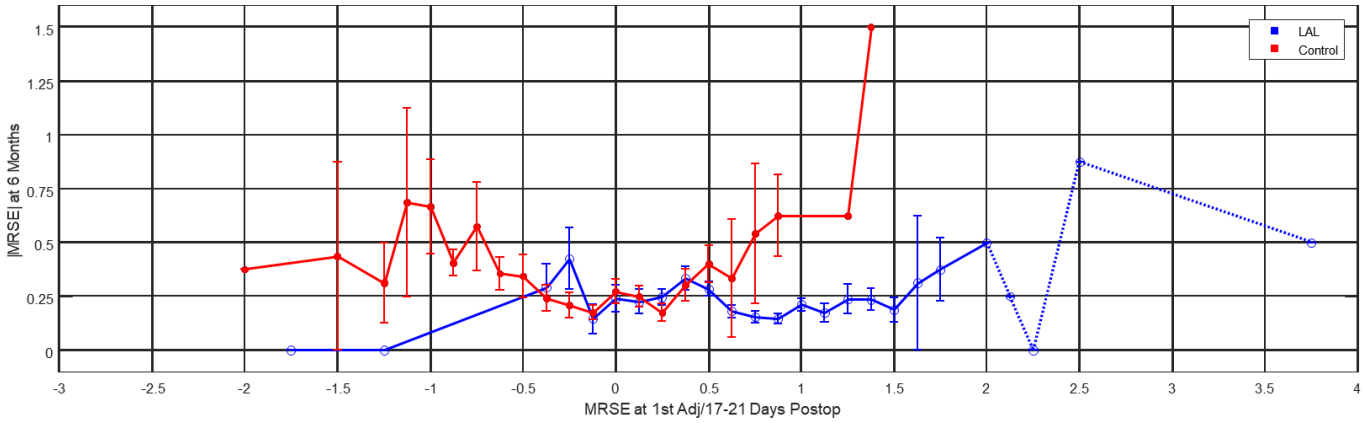


Figure 4. Absolute MRSE at 6 Months Postop Versus Pre-Adjustment/17-21 days Postop Signed

Note that the LAL and Control had different distributions of subjects with the LAL having a 25th, 50th and 75th percentile of +0.375, +0.625, and +1.00 diopter respectively, while the control had a 25th , 50th and 75th percentile of -0.50, -0.125, and +0.125 respectively.

PATIENT CARD

Each patient who receives the Light Adjustable Lens must be registered with RxSight at the time of lens implantation. Two Implant Identification cards are enclosed in the package.

Registration is accomplished by completing the Implant Identification Card and mailing it to RxSight. Patient registration will assist RxSight in responding to Adverse Reaction Reports and/or potentially sight-threatening complications.

A second Implant Identification Card should be given to the patient with instructions to keep the card as a permanent record of his/her implant and to show the card to any eye care practitioner seen in the future.

REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as related to the LAL and LDD and that were not previously expected in nature, severity or rate of occurrence should be reported to RxSight at 1-949-521-7955.

HOW SUPPLIED

The Light Adjustable Lens supplied sterile in a lens tray within a peel pouch. The peel pouch is sterilized with ethylene oxide and should be only opened under sterile conditions. The peel pouch is contained within a secondary foil pouch which is NOT a sterile barrier.

EXPIRATION DATE

The expiration date of the lens package is the sterility expiration date shown on the outside box. The lens should not be implanted after the indicated expiration date.

RETURN / EXCHANGE POLICY

Please contact the local RxSight representative for the lens return or exchange. Return the lens with proper identification and the reason for return. Label the return as a biohazard. Do not attempt to resterilize the lens.

Symbols

Symbols	English
	See Instructions for Use
	Do not reuse
	Sterilized by Ethylene Oxide
	Catalogue Number
	Lot/Batch Number
	Use by (YYYY-MM Year-Month)
	Store at 5-30° C (41-86°)
	Keep away from sunlight
	Keep Dry
	Do Not use if package is damaged
	Caution
	Manufacturer
EC REP	European Representative

MANUFACTURER

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