PROTOCOL:

Study design and participants

This retrospective observational case series assessed the VA and safety outcomes of a consecutive series of patients after cataract extraction and IOL implantation with the LAL 2.0 in a private practice setting between July 2021 and January 2022. All patients were de-identified with no PHI patient specific data being used in the analysis. The study was registered with the ISRCTN Registry site (number)[in process], approved by an institutional review board (SALUS IRB, Austin, TX) [in process] and performed in accordance with the tenets of the Declaration of Helsinki. Patients with reduced best corrected visual acuity (BCVA) related to retinal or macular pathology and corneal abnormalities including scarring and ectasia were excluded from the study.

Patients undergoing cataract surgery and choosing the LAL with an emmetropic target (+/- 0.25 D) in at least one eye were included in the study. All surgeries were performed in Blaine, Minnesota, by a single surgeon (DVF). Postoperatively, through a co-managed arrangement at an open-access facility, all LDD treatments were performed by a single LDD Specialist (JRW) in Edina, Minnesota, until patients achieved their desired visual outcomes.

All patients had a complete baseline ophthalmic examination prior to surgery. Biometry was achieved using an IOLMaster 500 for all patients. IOL powers were calculated using the Barrett Universal II, SRK/T, and Holladay 2 formulas in non-postrefractive cataract patients. The Post-Refractive IOL Calculator at American Society of Cataract and Refractive Surgery (ASCRS) was

used for eyes that had previous LASIK, PRK, and/or RK with emphasis on the Masket, Modified Masket, and Barrett True K in patients with historical refractive records, and Barrett True K No History in patients with no historical refractive records.

Postimplantation refractive targets were based on patient's estimated preoperative refractive goals. A goal of +0.25 to +0.50 manifest refraction spherical equivalent (MRSE) was targeted for emmetropic-goal eyes, and plano MRSE was targeted in myopic-goal eyes for patients wanting customized monovision. Patients were allowed to adjust their refractive target to fit their lifestyle postoperatively during LDD exams and adjustments, with a wide range of near targets being selected.

The primary outcome measures for this study were monocular uncorrected distance visual acuity (UCDVA), monocular mean spherical equivalent (SE) and mean residual cylinder for emmetropic-goal eyes in patients within their final 3–9-month postoperative visit. Safety outcomes reported include serious adverse events (AEs) occurring at the time of surgery extending out to the final postoperative examination.

Surgical technique and postoperative light adjustments

All cataract surgeries were performed with topical anesthesia using a 2.4 mm clear corneal self-sealing temporal incision, and widening to 2.8-3.0 mm for LAL implantation. The LENSAR^{TM} femtosecond laser was used for capsulotomy and lens fragmentation on all patients except for those with previous history of RK. Capsulotomy diameters ranged from 4.9-5.2 mm with

centration on the optical axis to ensure full 360-degree anterior capsule overlap of the IOL optic. All patients received the LAL 2.0.

After ocular healing and refractive stabilization, the LDD was used to adjust the LAL power by delivering targeted UV light in a precisely programmed pattern to correct spherical and cylindrical refractive error, facilitating optimization of the lens to achieve the patient's desired vision. LDD treatments provided a custom prescription formulated on refractive measurements and lifestyle requirements of the patient. After the desired vision was achieved and the refraction verified, the entire lens was exposed to UV light to "lock in" the IOL power. Patients were instructed to always wear RxSight UV protective eyewear to prevent inadvertent changes to the LAL due to environmental UV light exposure, until 24 hours post final "lock-in" treatment.

Initial LDD treatments typically occurred 17 to 21 days post LAL implantation with final "lock-in" occurring between 25 to 67 days. Patients with a history of previous corneal refractive surgery (history of LASIK, PRK, and/or RK) had longer duration from surgery to final "lock-in" to help ensure refractive stability and good long-term UCVA.

At all postoperative visits, clinical examinations included slit lamp biomicroscopy, intraocular pressure, MRx with BCDVA, and monocular and binocular UCDVA and UCNVA. Distance VA testing was achieved using a computer calibrated Snellen chart under photopic conditions. Near VA testing was assessed using a Jaeger chart under photopic conditions. The near VA goal was a fluid process in all patients and based on functionality with adjustments to the original goal based on patient experience and feedback during LDD treatments. Patients were instructed to

hold the Jaeger card at their preferred reading distance [14-20 inches), MRx was then completed to bring the desired near point into focus, and LDD treatments were performed to adjust accordingly. A standard phoropter was used to determine the subjective MRx rounded to steps of 0.25 D. All testing was “standard of care” and there were no “study specific” tests performed.

STATISTICS:

Table 1. Patient demographics and baseline characteristics

Age (y)	
Mean	XX
Range	XX
Gender	
Female	XX
Male	XX
Eyes with prior corneal refractive surgery	
No	XX
Yes	XX
Number of corneal refractive surgeries (%)	
0	XX
1	XX
2	XX
3	XX
4	XX
5	XX
Eyes with original refractive surgical records available	
No	XX
Yes	XX

Table 2. All emmetropic goal eyes at 3-9 months postoperative exam

	N = XX
UCDVA	
20/15 or better	XX
20/20 or better	XX
20/25 or better	XX
Spherical Equivalent	
Mean (SD)	XX
Within 0.25 D, n (%)	XX
Within 0.50 D, n (%)	XX
Residual Cylinder	
Mean (SD)	XX
Within 0.25 D, n (%)	XX
Within 0.50 D, n (%)	XX

Uncorrected Distance Visual Acuity (UCDVA), Spherical Equivalent (SE), Standard Deviation (SD)

Table 3. Postrefractive emmetropic goal eyes at 3-9 months postoperative exam

	N = XX
UCDVA	
20/15 or better	XX
20/20 or better	XX
20/25 or better	XX
Spherical Equivalent	
Mean (SD)	XX
Within 0.25 D, n (%)	XX
Within 0.50 D, n (%)	XX
Residual Cylinder	
Mean (SD)	XX
Within 0.25D, n (%)	XX
Within 0.50 D, n (%)	XX

Uncorrected Distance Visual Acuity (UCDVA), Spherical Equivalent (SE), Standard Deviation (SD)