Light Adjustable Lens (LAL)
John Kung, MD

Financial Interests

Presenter (John S. Kung, MD) has no financial interest in the devices shown in the presentation.

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Video Overview

LAL overview.mp4

Light Adjustable IOL

- FDA approved 2017
- Commercial rollout in June, 2019
- 24 surgical sites in the US
- First surgeon in NJ and NY to implant it. First 10 nationwide.

- Correction of 2D post-op sphere
- Correction of -0.75D to -2D cylinder
- Patients achieved 20/20 vision 2X better than compared to standard patients at 6 months

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Light Adjustable IOL

- Less concern about posterior cornea, effective lens position, surgical induced astigmatism
- Patients to be brought back after 2 weeks to be adjusted, adjusted 3 days-1 week later, and locked in 3 days-1 week later
- Prefer LAL over toric IOL as up to 2-3D astigmatism can be corrected with multiple treatments.

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Ideal Candidates

- Patients that want the best possible post-operative outcome
- Patients with that had surgical vision correction such as RK, LASIK, and PRK
- Patients with irregular corneas
- Patients that want a true Monovision outcome

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Light Adjustable IOL

- Following surgery, patients are provided with UV protective glasses to wear at all waking hours to help protect the Light Adjustable Lens from indoor and outdoor sources of UV light
- May discontinue wear of the UV protective glasses 24 hours after the final light treatment

Contraindications

- Photosenitizing medications ie: tetracycline, doxycycline, amiodarone, phenothiazines, chloroquine, hydrochlorothiazide
- Small pupil (<6.5mm)
- Tamoxifen use (may be at increased risk of retinal damage)
- History of ocular herpes simplex virus due to the potential for reactivation from exposure to UV light
- Nystagmus
- Unwilling to comply with the postoperative regimen and wearing of UV protective eyewear

Slow Growth in Premium IOLs

Barriers include:

Visual side-effects

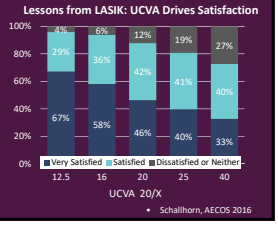
Low surgeon confidence

Low patient satisfaction

Technology hard to explain

Cost/Reimbursement

Inability to deliver LASIK-like outcomes

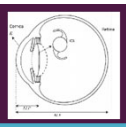


- Schallhorn, AECOS 2016

Cataract Surgery Outcomes

Challenge to consistently achieve great results

- 2016 toric meta-analysis[1]: ~65% of eyes achieve 20/25 or better
- Limited by ability to predict the post-operative eye



Error Source	Contribution*
Post-op IOL Position	35%
Post-Op Corneal Power	15%
Axial Length	17%

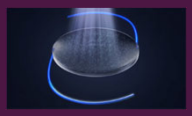
1. Line Kessel, MD, PhD, Et Al. Toric Intraocular Lenses in the Correction of Astigmatism During Cataract Surgery – A Systematic Review and Meta-Analysis Ophthalmology 2016 Feb;123(2):275-86

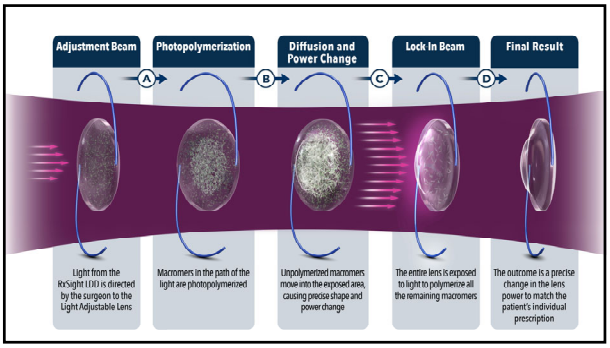
* Norrby, S. Sources of error in intraocular lens power calculation. JCRS 2008: 368-76

Post-Op is the New Pre-Op!

The RxLAL is the world's first adjustable intraocular lens that allows office-based optimization of vision after lens implantation and healing

- Delivers world's best clinical outcomes for cataract patients
- Overcomes limitations of both pre-operative and intra-operative prediction processes
- Premium channel driver
- Private pay





How It Works

Standard Cataract Implant Procedure	Residual Refractive Error is Determined Using Standard Phoropter	Refractive Error is Entered into Light Delivery Device
• **Low Stress Cataract Surgery** • Not dependent on prediction of SIA, ELP, Individual Healing, Surgical Technique, Sophisticated Equipment	• **Interactive Post-Op Process** • Refraction optimized with patient after healing is complete and ocular media clear	• **Office Based Refractive Treatment on IOL** • Unparalleled flexibility and accuracy • Bifurcated cataract and refractive procedure

Technology Components

RxLAL

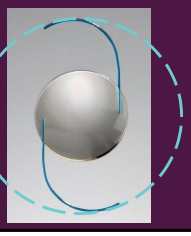
RxSight Insertion Device

RxSight Light Delivery Device (LDD)

RxLAL

OPTIC BODY

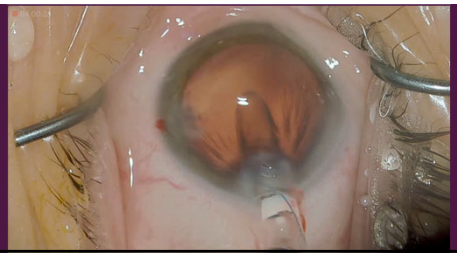
- Photo-reactive UV absorbing Silicone
- Biconvex
- Anterior surface – rounded edge
- Posterior surface – squared edge
- 6mm diameter



HAPTICS

- Blue core polymethylmethacrylate (PMMA) Monofilament
- Modified 'C'
- Haptic angle – 10°
- 13mm - RxLAL Total Diameter

RxLAL Implantation



Light Delivery Device (LDD)

The RxSight LDD consists of the following components:

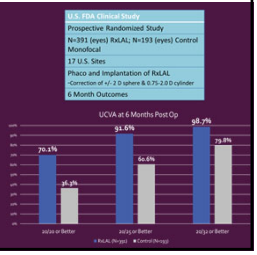
- Anterior segment biomicroscope
- Patient Chin and headrest
- Computer system for planning and performing light treatments
- Ultraviolet (UV) light projection system

Interactive Post-Op Process

- First Ever "Patient Trial' of final outcome
- Patient previews different refractions
- Refraction optimized after healing is complete and ocular media clear
- Increase Optometric (OD) engagement

US FDA Study Results

- RxLAL eyes achieved UCVA of **20/20 or better** at 6 months postoperatively at approximately **2x the rate** of patients receiving a monofocal lens
- **91.8% of RxLAL eyes achieved result within 0.50 D** of target MRSE (similar to LASIK results)
- **Superior Quality of Vision** at all measures compared to control lens:
  - Including BCVA, Vision Rating, Driving Difficulty, Dim Light Conditions, Glare, Halos, and all measures of Contrast Sensitivity



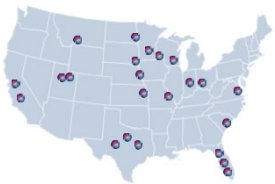
U.S. Approval

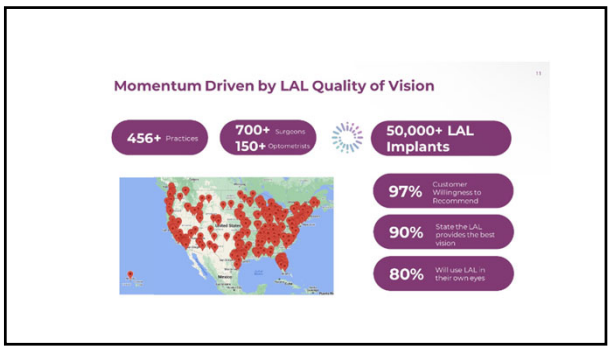
- **November 2017**
  - The U.S. Food and Drug Administration approved the Light Adjustable Lens and Light Delivery Device for patients with pre-existing astigmatism of 0.75 diopters or more who are undergoing cataract surgery

Commercial Launch began in June 2019

Initial Observations:

- Approved by FDA and designated as premium IOL by CMS
- Simple message of adjustability and best quality of vision resonating with patients
- 24 sites offering the LAL positioned along their top premium packages
- Excellent patient acceptance
- Adjustability lead messaging
- Monovision lead approach





Who are they selling to?

- Patients who want the very best vision
- Post-LASIK
- Monovision
- The LAL is positioned as a presbyopic solution

LAL Real World Use & Outcomes

LAL Commercial Outcome and Usage Evaluation

341 subjects received bilateral LAL implants at a total of 45 clinical practices

Patients and doctors customized refractive targets in each eye concurrently during adjustment period

Refractive results collected approximately 1-3 months after final lock-in treatment

Patients were enrolled after all light treatments complete

LAL Commercial Outcome and Usage Evaluation

Prior Corneal Surgery (n = 341)[1]

While a significant percentage of eyes had previous corneal surgery, **more than 70% did not.**

Note that data suggests that 2.7% of all US cataract surgeries are performed on post refractive eyes.[2]

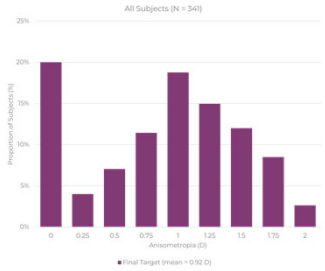
No previous refractive surgery	**71.9%**
Post LASIK, PRK, or SMILE	23.8%
Post Radial Keratotomy	4.3%

1. RxSight Combined PMCS-001 & PMCS-002 Clinical Outcomes of Patients Bilaterally Implanted with LAL.
2. MarketScope 2022.

LAL Commercial Outcome and Usage Evaluation

How Are Doctors Customizing Their Patients' Vision?

Refractive Final Target	
Bilateral Emmetropia	19.7%
Blended Vision	**73.9%**
Bilateral Myopia	6.4%



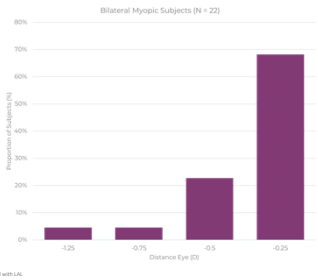
1. RxSight. Combined PMCS-001 & PMCS-002 Clinical Outcomes of Patients Bilaterally Implanted with LAL.

LAL Commercial Outcome and Usage Evaluation

Bilateral Myopia Subjects

After cataract surgery, about 6% of subjects selected myopic targets for BOTH eyes.

Most selected a target of -0.25 D for their most "distance" eye, but 2 subjects selected more than 0.50 D of myopia.



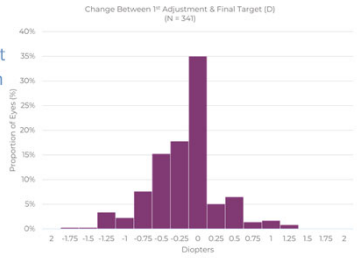
1. RxSight. Combined PMCS-001 & PMCS-002 Clinical Outcomes of Patients Bilaterally Implanted with LAL.

LAL Commercial Outcome and Usage Evaluation

Change in 1st Adjustment & Final Target Refraction

Most subjects will increase the amount of myopia between the first and final adjustment (negative change), but there are many cases of decreasing myopia as well.

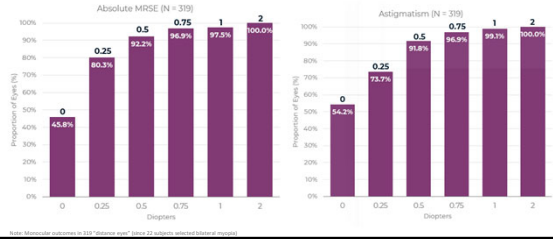
About 66% of myopic eyes see a change in target during adjustments.



LAL Commercial Outcome and Usage Evaluation

Refractive Results

Absolute MRSE and astigmatism were within 0.50 D of emmetropia in **92.2%** and **91.8%** of eyes targeted for emmetropia.

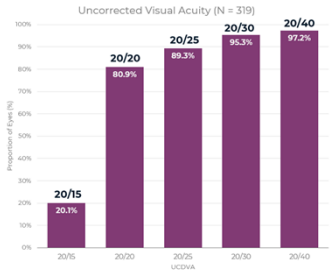


Note: Monocular outcomes in 319 "distance eyes" (since 22 subjects selected bilateral myopia)

LAL Commercial Outcome and Usage Evaluation

Refractive Accuracy Leads To Excellent Visual Acuity

Monocular uncorrected visual acuity of "distance" eyes was 20/20 or better in over 80% of subjects.



LAL Commercial Outcome and Usage Evaluation

No Differences in Visual Outcomes Between Eyes With and Without Prior Refractive Surgery

Outcome	No Prior Surgery	Prior Corneal Surgery
N	226	93
Mean Monocular UCDVA	20/20	20/20
Mean Absolute MRSE	0.21 D	0.23 D
Mean Astigmatism	0.21 D	0.23 D
Mean Monocular BCDVA	20/20+2	20/20+2

Note: Monocular outcomes in 319 "distance eyes" (since 22 subjects selected bilateral myopia)

LAL Commercial Outcome and Usage Evaluation

Binocular Surgery Outcomes

	Uncorrected binocular distance vision			Uncorrected near vision			
	20/15 or better	20/20 or better	20/25 or better	J1+ or better	J1 or better	J2 or better	J3 or better
All (n=341)	33%	**88%**	96%	49%	**79%**	91%	97%
Blended Vision (n=252)	31%	87%	95%	53%	85%	94%	98%
Bilateral Myopia (n=67)	18%	82%	99%	77%	91%	100%	100%
Bilateral Emmetropia (n=22)	45%	95%	99%	22%	57%	76%	93%

LAL Commercial Outcome and Usage Evaluation

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LAL Commercial Outcome and Usage Evaluation

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LAL Commercial Outcome and Usage Evaluation

Binocular Surgery Outcomes

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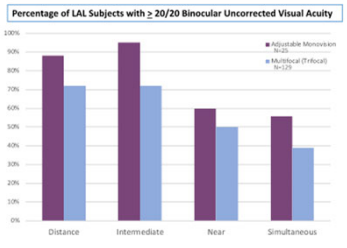
Adjustable Monovision: Single Center Study*

- 25 subjects subjects bilaterally implanted with LAL
- LDD treatments targeting 1 D anisometropia to maintain stereopsis and visual comfort
- No reduction in BCVA due to utilizing 100% of light
- Dysphotopsias and contrast sensitivity similar to monofocal
- Rates of excellent visual acuity at all distances compare favorably to trifocal multi-center data



A. Chayet, A Single Center Exploratory Study To Evaluate The Use Of The RxSight Light Adjustable Lens (LAL) and the Light Delivery Device (LDD) to Improve Visual Outcomes (unpublished data)

Multifocal from PanOptix Summary of Safety and Effectiveness Data

Presbyopia Correction

- Current technology offers trade-off between slightly lower visual side effects and somewhat better uncorrected near vision for EDF and Trifocal IOLs, respectively
- RxSight delivers better uncorrected vision at all distances, with precise targeting of astigmatism, mini-monovision, while maintaining monofocal IOL side effect
- RxSight also enables EDF procedure that delivers even better UCVA at all distances and minimal visual side effects **(IDE Study underway)**

Patient Experience Roadmap

As the LAL is post operatively adjusted to deliver customised vision, there are two major differences in the period after cataract surgery.

1 Required wear of Ultraviolet (UV) Protective Glasses

2 Completion of Light Treatments

UV Protective Glasses

At the end of surgery RxLAL Patients are provided with UV Protective glasses to help protect the RxLAL from sources of UV light

- The patient may discontinue wear of the UV protective glasses 24 hours after the final light treatment has been completed
- Exposure to UV light, such as sunlight, can cause uncontrolled changes to the RxLAL

Light Treatments

Light Treatments are Painless, Non-Invasive and Last Approximately 90 Seconds

Light Treatment Schedule	
Initial Light Treatment	At Least 17 Days After Surgery
Secondary Light Treatment	At Least 3 Days After Initial Light Treatment
Additional Light Treatments (if required)	At Least 3 Days After Each Prior Light Treatment

LDD Treatment

LDD treatment.mp4

Practice Integration Tips

- Prepare office for more visits (post op)
- Ensure patient education/communication postoperatively (compliance and vision optimization)
- Increase internal and co-managed optometric (OD) engagement for refraction and visual outcome planning
- Schedule patients similar to Yag

Co-Management w/ Optometrists

- Shortage of cataract surgeons in coming years
- Never before has refraction been more important
  - Entering refraction/target (after surgery, pre-lock in) is essentially choosing patient vision for lifetime
- RxLAL perfect bridge between surgeon & OD
  - Refractive counseling shifts from preop to postop; where OD is best suited

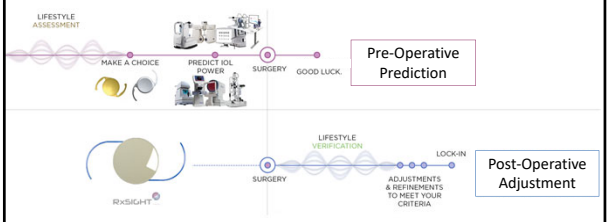
Entry Screen from Light Delivery Device

Key Contraindications

Use of the RxLAL is contraindicated in cases where:

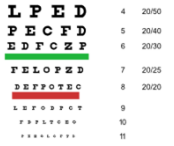
- Patients are unwilling to comply with the postoperative regimen for adjustment and lock-in treatments and wearing of protective eyewear.
- Patients are taking systemic medication that may increase sensitivity to UV light such as tetracycline, doxycycline, psoralens, amiodarone, phenothiazines, chloroquine, hydrochlorothiazide, hypercin, ketoprofen, piroxicam, lomefloxacin, and methoxsalen. LDD treatment in patients taking such medications may lead to irreversible phototoxic damage to the eye.
- Patients have a history of ocular herpes simplex virus

A Better Way to Deliver Premium Cataract Surgery



RxSight Overcomes Current Premium IOL Limitations

2×	More patients get 20/20 or better uncorrected vision
10×	Significant reduction in outliers (20/30 or worse results), from >15% to <1%
	Near and intermediate vision meets or exceeds best multifocals, with minimal glare and halo



[1]Hengerer F, Srinivasan S., Dick B. Visual Outcomes After Cataract Surgery Following Bilateral Implantation of a Postop Adjustable Intraocular IOL. AAO 2019

RxLAL Summary

The RxLAL is the world's first adjustable intraocular lens that allows office-based optimization of vision after lens implantation and healing

- Delivers world's best clinical outcomes for premium cataract patients
- Overcomes limitations of both pre-operative and intra-operative prediction processes
- Simple patient messaging
- Patient pay

LM Interview

- 69 yo WM s/p LASIK 2005
- OS. Distance eye. -0.25-1.50x90, 20/50
- OD. Near eye-2.0-1.0x95, 20/70
- OS. LAL 3/14/20
- OS. LAL 06/09/20
- Video

LM Side Effects, Conclusion

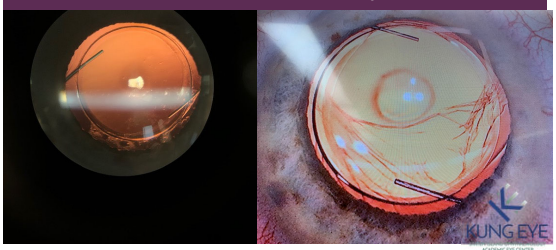
- Video

LMolloy Outcome.MOV

Uncooperative Pt

- 76 yo WM wanted “Best”
- Phaco OD 07/07/20
- Phaco OS 07/21/20
- 08/20/20. Va 20/30,20/40
- 08/20/20 1st LDD. Pl-1.00x90
- 08/27/20 2nd LDD. No effect
- 08/31/20 Emerg. “Blurred Va”
- OD:20/40- M+0.75-2.00x85 20/30
- OS:20/60 M-0.75-0.25x30 20/40-. Blurry
- 10/1/20 20/80- OU, OD:pl-0.75x90,OS -0.75

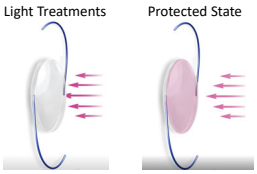
PPP-Premature Photo Polymerization



ActivShield™ UV Protector

How does it work?

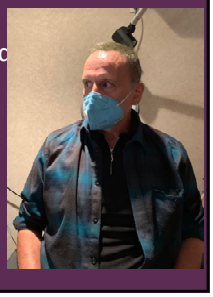
During light treatments, the ActivShield automatically opens to allow delivery of the precise light from the Light Delivery Device to adjust the lens. After the treatment is complete, ActivShield is automatically engaged to once again protect the lens from outside UV rays.



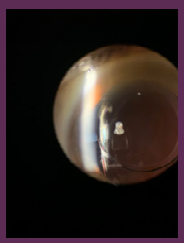
ActivShield Open **ActivShield Engaged**

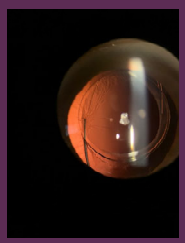
LAL Consult

- 59 yo WM, LAL 08/19,Clevelanc
- 02/20 sudden blurriness OD
- 10/1/20. -1.0-0.50x75 20/25



Photos. How To Fix?





Thank You!

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