

Visual outcomes using a comanaged and open access method for the Light Adjustable Lens® in cataract surgery

Submission date 20/04/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/04/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/01/2023	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

To assess the safety and effectiveness of cataract surgery using the Light Adjustable Lens (LAL) using two doctors, co-managing for each patient. The surgeon will do the surgery and a medical provider will do light treatments to the LAL to further improve vision after surgery. Surgery and light treatments will be done in different locations. Light treatments will be done in a facility that is open access for patients of other surgeons.

Who can participate?

Patients that have cataracts, wanting the LAL and do not have any diseases of the macula or cornea.

What does the study involve?

Having cataract surgery and using the LAL as the IOL implant at the time of the cataract surgery. It will involve up to 5 follow-up light treatments to adjust the power of the LAL after surgery to further improve the patient's vision.

What are the possible benefits and risks of participating?

The benefits would include improved vision from correction of the cataract and improved vision from correction of refractive error (glasses) through adjustment of the power of the LAL after surgery. All surgery and testing are "standard of care" with no "study specific" surgery or tests performed. Risks are related to those of cataract surgery including vision loss and the need for additional surgery.

Where is the study run from?

It is run from the surgery center where cataract surgery is performed and the TCEC LASIK Center where the post-op light treatments are performed (USA)

When is the study starting and how long is it expected to run for?

July 2021 to January 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
David V. Folden, MD
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Contact information

Type(s)
Principal investigator

Contact name
Dr David Folden

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
7459325

Study information

Scientific Title
Novel care delivery model for the RxSight Light Adjustable Lens®: a co-managed, open-access methodology

Acronym
NCDM LAL CoMOA

Study objectives
Using a comanaged arrangement at an open access facility, use of the Light Adjustable Lens in cataract surgery is safe and efficacious.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval is not required given its retrospective chart review design, confirmed by Salus IRB.

Study design

Observational retrospective case series

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Use of the Light Adjustable Lens in patients with cataracts and receiving cataract surgery

Interventions

Observational retrospective case series chart review of a consecutive series of patients in a private practice setting between July 2021 and January 2022.

The visual acuities, manifest refractions, and adverse events were evaluated in the charts of patients that underwent cataract surgery using the light adjustable lens. Data was extracted from the patient's final postoperative visit sometime between 3 and 9 months postoperatively.

Intervention Type

Other

Primary outcome(s)

Collected by retrospective chart review between 3 and 9 months postoperatively:

1. Uncorrected monocular and binocular distance
2. Near visual acuities
3. Safety

Key secondary outcome(s)

Collected by retrospective chart review between 3 and 9 months postoperatively:

1. Manifest refraction

Completion date

31/01/2022

Eligibility

Key inclusion criteria

Patients who received cataract surgery and management of their Light Adjustable Lens using a comanaged approach at an open access facility.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

32

Key exclusion criteria

1. Retinal or macular disease
2. Clinically significant corneal abnormalities
3. Corneal scarring
4. Ectasia

Date of first enrolment

01/07/2021

Date of final enrolment

31/01/2022

Locations**Countries of recruitment**

United States of America

Study participating centre**North Metro Surgery Center**

11855 Ulysses Street, Suite 270

Blaine

United States of America

55434

Study participating centre**TCEC LASIK Center**

3601 76th Street W, Suite #150

Edina

United States of America

55435

Sponsor information

Organisation

North Suburban Eye Specialists

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets will be de-identified with no PHI patient specific data being used in the analysis. Any raw data generated during the current study are not expected to be made available unless requested by the publication source after the manuscript is submitted.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/08/2022	04/01/2023	Yes	No
Protocol file			27/04/2022	No	No