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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

Registration date
28/04/2022

Overall study status
Completed

Last Edited
04/01/2023

Condition category
Eye Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Case series

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not applicable (retrospective study)

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 measure
Collected by retrospective chart review between 3 and 9 months postoperatively:
1. Uncorrected monocular and binocular distance
2. Near visual acuities
3. Safety

Secondary outcome measures
Collected by retrospective chart review between 3 and 9 months postoperatively:
1. Manifest refraction

Overall study start date
01/07/2021

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

Age group
Adult

Sex
Both

Target number of participants
32

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

Sponsor details
3777 Coon Rapids Blvd NW Suite 100
Coon Rapids
United States of America
55443
+1 763-421-7420
ahalabi@nseyespecialists.com

Sponsor type
Industry

Website
http://www.nseyespecialists.com

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/07/2022

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?
Protocol file			27/04/2022	No	No
Results article		04/08/2022	04/01/2023	Yes	No