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Visual outcomes using the light adjustable lens in patients with previous LASIK and/or PRK (laser eye surgery)

Submission date
21/02/2023

Recruitment status
No longer recruiting

Registration date
21/02/2023

Overall study status
Completed

Last Edited
20/11/2023

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The Light Adjustable Lens (LAL) from RxSight, Inc. (Aliso Viejo, CA) is an intraocular lens (IOL) used in cataract surgery that enables vision customization after implantation and ocular healing has occurred.
A second-generation IOL from RxSight (LAL 2.0) incorporates an enhanced UV absorber (ActivShield) that may increase the stability of the IOL and refractive outcomes.
Patients with a history of previous refractive surgery pose problems with postoperative refractive error following cataract surgery. This population of patients is particularly well-suited for LAL technology.
Previous studies have reported good outcomes of the LAL in post refractive patients, but a large-sample clinical study has yet to be published on post LASIK or PRK patients electing for the second-generation ActivShield LAL (LAL 2.0) in the peer reviewed literature. The aim of this study is to report on the safety and visual acuity (VA) outcomes using the second generation, ActivShield LAL (LAL 2.0) in patients with previous history of LASIK or PRK. To our knowledge, this retrospective study will be the first report of visual outcomes using the ActiShieldTM (LAL 2.0) in post LASIK or PRK patients in the peer-reviewed literature.

Who can participate?
Patients with previous history of LASIK and/or PRK undergoing cataract surgery with use of the ActivShield LAL (LAL 2.0) and adequate pupil dilation of 6.5 mm or more.

What does the study involve?
Having cataract surgery and using the ActivShield 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 is “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 centers where cataract surgeries are performed and Praxis Vision where the post-op light treatments are performed (USA)

When is the study starting and how long is it expected to run for?
This retrospective chart review will look at patients from approximately July, 2021, through December, 2022.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
David V. Folden, MD, dfolden@nseyespecialists.com

Contact information

Type(s)
Principal Investigator

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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
Visual outcomes using an enhanced UV protected light adjustable lens in patients with previous LASIK and/or PRK

Acronym
VOwLAL for PO-LASIK & PRK

Study objectives
The second-generation, ActivShield LAL (LAL 2.0), used in patients undergoing cataract surgery and with previous history of LASIK or PRK should provide excellent refractive outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/02/2023, SALUS IRB (2111 W. Braker Lane, Ste 300, Austin, TX 78758, USA; +1 888-834-6632; clientservices@salusirb.com), ref: 2023.02.15 Exempt Determination

Study design
Observational retrospective chart review

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Medical and other records

Study type(s)
Other

Participant information sheet
Not applicable (retrospective study)

Health condition(s) or problem(s) studied
Use of the Light Adjustable Lens in Post-LASIK and PRK patients

Interventions
This retrospective observational case series assessed the VA and safety outcomes of a consecutive series of post LASIK or PRK patients after cataract extraction and IOL implantation with the ActivShieldTM LAL 2.0 in a private practice setting between July 2021 and December 2022.
The primary outcome measures for this study were monocular uncorrected distance visual acuity (UDVA), monocular mean spherical equivalent (SE), and monocular mean residual cylinder for emmetropic-goal eyes at the 3+ month post surgical follow-up. Safety outcomes reported include serious adverse events (AEs) occurring at the time of surgery extending out to the final postoperative examination.
All final postoperative exams included slit lamp biomicroscopy, intraocular pressure, MRx with

corrected distance visual acuity (CDVA), and uncorrected distance visual acuity (UDVA). Distance VA testing was achieved using a computer calibrated Snellen chart under photopic conditions. 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.

Intervention Type
Procedure/Surgery

Primary outcome measure
Measured using patient records:
1. Monocular uncorrected distance visual acuity (UDVA)
2. Monocular mean spherical equivalent (SE)
3. Monocular mean residual cylinder for emmetropic-goal eyes at the 3+ month post surgical follow-up.
4. Safety outcomes reported include serious adverse events (AEs) occurring at the time of surgery extending out to the final postoperative examination.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/07/2021

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Patients who receive the ActivShield LAL with their cataract surgery
2. Have previous history of LASIK and/or PRK
3. Have pupil dilation of 6.5 mm or greater
4. Age between 40-90 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Upper age limit
90 Years

Sex
Both

Target number of participants

Approximately 40 patients and 50 eyes.

Total final enrolment
40

Key exclusion criteria
Patients with retinal or macular disease, clinically significant corneal abnormalities, corneal scarring, or ectasia were excluded from the study.

Date of first enrolment
01/07/2021

Date of final enrolment
31/12/2022

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
Praxis Vision
3601 76th Street W, Suite #150
Edina
United States of America
55435

Study participating centre
Edina Specialty Surgery Center
4100 Minnesota Drive, #200
Edina
United States of America
55435

Sponsor information

Organisation
North Suburban Eye Specialists

Sponsor details
3777 Coon Rapids Blvd NW, Suite 100
Coon Rapids
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55433
+1 7630-421-7420
dfolden@nseyespecialists.com

Sponsor type
Hospital/treatment centre

Website
https://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
31/08/2023

Individual participant data (IPD) sharing plan
Existing medical records are kept at the Twin Cities Eye Consultants' clinic locations and LDD treatment records at Praxis Vision. Patients will be de-identified in the analysis and be assigned a Subject ID number.
Electronic charts are stored in a computer which is password protected. The database used for analysis will also be password protected. The Principal Investigator and the LDD Specialist will perform the analysis.
The data used for analysis will be stored according to Clinic guidelines which is generally seven years. The outcomes analysis database would be stored for 7 years, and deleted electronically.
Consents from participants will not be obtained because of the retrospective design of the study and all PHI will be de-identified. It has already received "Exempt" status approval from

Salus IRB.
Data will be available through attempted publication.
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

Stored in non-publicly available repository, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/11/2023	20/11/2023	Yes	No