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Comparing standard myopic LASIK to contralateral eye LASIK customised with a novel software already EU approved

Submission date 03/05/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 14/09/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 29/08/2023	**Condition category** Eye Diseases	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
LASIK is a type of eye surgery that can fix nearsightedness. It has been used a lot in the past and is considered safe and effective. This study is trying to see if a new way of doing the surgery, called automated ray-tracing optimization, is as safe and effective as another way called Custom Q excimer profile ablation.

Who can participate?
Adults undergoing femtosecond laser-assisted LASIK in the LaserVision Ambulatory Eye Surgery Unit.

What does the study involve?
In this study, 25 people will have LASIK surgery done with the help of a femtosecond laser. The surgery will be done on both eyes of each person, but one eye will be treated with a new technique called raytracing customization, and the other eye will be treated with a technique called asphericity-adjusted (custom) excimer profile ablation. The patients will be carefully watched to see how well the different treatments work and to make sure they are safe.

What are the possible benefits and risks of participating?
Participants will correct their refractive error. The known risks for refractive surgery apply, such as infection, dry eyes, glare, halos or need for additional correction at a later date.

Where is this study run from?
It is run by the LaserVision Ambulatory Eye Surgery Unit in Greece

When is the study starting and how long is it expected to run for?
April 2023 to December 2023

Who is funding the study?
Alcon LLC (USA)

Who is the main contact?
Anastasios John Kanellopoulos
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
LV002

Study information

Scientific Title
Contralateral Eye myopic LASIK customization comparison Custom Q vs Ray Tracing (Wavelight Plus)

Acronym
CustomVsRay

Study objectives
Visual performance can be superior in Ray-tracing compared to custom Q

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 15/03/2023, LaserVision Ethics Committee (Tsocha 17, Athina, 115 21, Greece; +30 2107472777; info@laservision.gr), ref: 49/4/213

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Treatment of myopic refractive error with LASIK

Interventions
For each patient undergoing LASIK treatment correction, one eye is randomly assigned to be treated with raytracing customization and the other with asphericity adjusted (custom Q) excimer profile ablation, both CE approved options on the same device (EX500 excimer laser). This study will evaluate the visual function outcomes.

Randomisation of the treatment allocation will be made by flipping a coin. Both eyes will be evaluated pre-operatively for both modalities and treatment allocation will be made at the time of surgery. All measurements, procedures and post care are estimated to take 3-6 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Pre- and Post- operation mean refractive error is measured with an autorefractor
2. Topographic astigmatism is measured using keratometry at Pre- and Post- operation

Secondary outcome measures
Visual Acuity is measured using the Snellen chart at Pre- and Post- operation

Overall study start date
01/04/2023

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Adults undergoing refractive error laser correction with no other corneal/ocular pathology (ie. Keratoconus, Pterygium) other than refractive error

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
25

Key exclusion criteria
Corneal/Ocular pathology other than refractive error

Date of first enrolment
15/04/2023

Date of final enrolment
01/10/2023

Locations

Countries of recruitment
Greece

Study participating centre
LaserVision Ambulatory Eye Surgery Unit
Tsocha 17
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Sponsor information

Organisation
LaserVision

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.kanellopouloseyecenter.net/US/indexus.htm

ROR
https://ror.org/02xm4cz36

Funder(s)

Funder type
Industry

Funder Name
Alcon

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request
ajkmd@mac.com, Anastasios John Kanellopoulos

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		28/08/2023	29/08/2023	No	No