

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/09/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/08/2023	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Athens

Greece

11521

Sponsor information**Organisation**

LaserVision

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

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