ISRCTN15458241 https://doi.org/10.1186/ISRCTN15458241

Comparison of ray tracing-guided LASIK versus SMILE Pro for myopic and astigmatic correction

Submission date
06/07/2025

Recruitment status
No longer recruiting

Registration date
11/07/2025

Overall study status
Completed

Last Edited
11/07/2025

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is designed as a contralateral eye comparison of two advanced refractive surgical techniques. Approximately ten years after the original comparison, the investigators repeat the evaluation using updated technologies. One eye undergoes ray tracing–optimised LASIK using the FS200 femtosecond laser and the EX500 excimer laser (Alcon/Wavelight), enhanced by the Sightmap diagnostic device and Wavelight Plus optimisation software. The contralateral eye is treated with SMILE Pro, the latest iteration of small incision lenticule extraction, performed using the Visumax 800 femtosecond laser. Both procedures are well-established, widely used in clinical practice, and supported by robust safety and efficacy data. The study aims to assess potential differences in visual acuity outcomes between these two enhanced surgical approaches.

Who can participate?
Otherwise healthy patients aged between 18 and 45 years with stable myopia or myopic astigmatism for at least 12 months before surgery.

What does the study involve?
This investigation was designed as a prospective, randomly allocated, within-person, contralateral eye clinical trial conducted at the Laservision Clinical and Research Institute in Athens, Greece. The contralateral eye design was deliberately chosen to eliminate inter-subject variability, allowing for a more precise comparison of the two refractive surgical techniques. By treating each patient with both procedures—SMILE Pro in one eye and wavelight plus customized femtosecond laser-assisted LASIK in the other—systemic, anatomical, and environmental factors were inherently controlled, enhancing the internal validity of the outcomes.

The study adhered to the tenets of the Declaration of Helsinki and received approval from the Laservision Ambulatory Surgical Center Institutional Ethics Board. Informed consent was obtained from all participants before enrollment.

What are the possible benefits and risks of participating?
No benefits and risks given at registration

Where is the study run from?
Alcon Greece

When is the study starting and how long is it expected to run for?
January 2025 to June 2025

Who is funding the study?
Alcon Greece

Who is the main contact?
A. John Kanellopoulos, MD, ajkmd@mac.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IIT #90760251

Study information

Scientific Title
Contralateral eye comparison of femto-second laser-assisted, ray tracing-guided LASIK vs small incision lenticule extraction (SMILE Pro) for myopic and astigmatic correction calculated by ray tracing rather than conventional manifest refraction in all eyes

Acronym
wpLASIKvsSMILEpro

Study objectives
Raytracing optimised LASIK will result in more lines of vision gained than Smile Pro in the correction of myopia in a contralateral eye study.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/01/2025, Ethics Committee for the Laservision Ambulatory Surgical Unit EC (15 Tsocha Street, Athens, 11521, Greece; +30 210 7472777; info@laservision.gr), ref: 2527

Study design
Single-centre within-person randomized contralateral eye study

Primary study design
Interventional

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Refractive error correction

Interventions
All participants are treated for correction of myopia with or without astigmatism. The intervention will be either raytracing optimised LASIK or Smile Pro, both laser-assisted lamellar procedures on the cornea. The contralateral eye design was deliberately chosen to eliminate inter-subject variability, allowing for a more precise comparison of the two refractive surgical techniques. By treating each patient with both procedures—SMILE Pro in one eye and Wavelight Plus customized femtosecond laser-assisted LASIK in the other—systemic, anatomical, and environmental factors were inherently controlled, enhancing the internal validity of the outcomes. Randomization of the procedure to either the right or left eye was computer-generated to avoid selection bias.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Lines of vision gained, comparing preoperative best corrected distance acuity, measured using data collected from patient records, measured at baseline and 3 months following each procedure

Key secondary outcome(s))
1. % of eyes with defocus equivalent within ±0.25D, ±0.50D, ±0.75 and ±1.0D measured using subjective manifest refraction at baseline and 3 months
2. % of eyes with absolute MRSE (manifest refraction spherical equivalent) within ±0.25D, ±0.5D, ±0.75 and ±1.0D measured using subjective manifest refraction again at baseline and 3 months
3. % of eyes with UCDVA and BCDVA of 20/10, 20/12.5, 20/16, 20/20, 20/25, 20/32, or better

measured using subjective manifest refraction at baseline and 3 months
4. Lines of vision gained in LogMAR (defined as the change in pre-CDVA to post-op CDVA (1 week and 1 month) and pre-CDVA to post UDVA at all time points), measured using subjective manifest refraction at baseline and 3 months

Completion date
01/06/2025

Eligibility

Key inclusion criteria
1. Age between 18 and 45 years
2. Stable myopia or myopic astigmatism for at least 12 months before surgery, within the following limits: Preoperative myopia from -1 to -8 D (minimum spherical equivalent -2D) and up to -3 D of astigmatism. Stable refraction (within ± 0.50 D) as determined by manifest refraction spherical equivalent for a minimum of 12 months before surgery, verified by consecutive subjective refractions or medical records or prescription history.
3. Preoperative corrected distance visual acuity (CDVA) of 20/20 or better in both eyes
4. Minimum central corneal thickness of 500µm
5. Absence of ocular surface disease or significant dry eye
6. Willingness to comply with the postoperative follow-up schedule

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
All

Total final enrolment
68

Key exclusion criteria
1. Anisometropia >1D in sphere and >0.5D cylinder between the eyes
2. History of ocular surgery or trauma
3. History or clinical evidence of dry eye.
4. Evidence of corneal ectatic disorders such as keratoconus or pellucid marginal degeneration
5. Presence of corneal scars, opacity, or other structural abnormalities
6. Active ocular inflammation or infection

7. Systemic conditions affecting wound healing (e.g., uncontrolled diabetes, autoimmune disorders)

Date of first enrolment
01/01/2025

Date of final enrolment
01/03/2025

Locations

Countries of recruitment
Greece

Study participating centre
Laservision Ambulatory Surgical Unit
15-17 Tsocha Street
athens
Greece
11521

Sponsor information

Organisation
Alcon Greece

Funder(s)

Funder type
Industry

Funder Name
Alcon Greece

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request.
• The name and email address of the investigator/body who should be contacted for access to

the datasets: Anastasios John Kanellopoulos, MD, ajkmd@mac.com
• The type of data that will be shared: all informed consent, preoperative data and postoperative evaluations, along with analysed statistical comparison data on all outcomes measured, along with any adverse effects noted
• Timing for availability: up to 10 years
• Whether consent from participants was required and obtained: it is required and will be obtained from all participants
• Comments on data anonymization: All data will be anonymised and used only identified by number from 1 to 60 allocated at the time of enrolment

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes