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Evaluation of visual acuity in patients with previous corneal surgery and AcrySof® IQ VivityTM IOL implantation

Submission date 31/10/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 06/11/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 05/11/2024	**Condition category** Eye Diseases	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study, conducted from May 2023 to March 2024, aimed to evaluate a new type of lens called the AcrySof® IQ Vivity™ IOL. The focus was on patients who had LASIK surgery for nearsightedness and later needed cataract surgery. The goal was to see how well these patients could see and how accurate their vision correction was after getting the new lens.

Who can participate?
Participants were over 50 years old, needed cataract surgery in both eyes, and met specific eye measurement requirements.

What does the study involve?
Participants underwent comprehensive eye exams before and after surgery. Follow-ups were done at 1 month and 3 months to track vision changes. These exams measured vision clarity at different distances, checked prescriptions, eye pressure, and any visual issues using a questionnaire.

What are the possible benefits and risks of participating?
The benefits include potentially improved vision after cataract surgery with the new lens. The risks are similar to any cataract surgery, such as infection, inflammation, and possible errors in lens power calculation, but these are very rare.

Where is the study run from?
Centro de la Visión (Chile)

When is the study starting and how long is it expected to run for?
September 2022 to March 2024

Who is funding the study?
Alcon Laboratories (Switzerland)

Who is the main contact?
Dr Miguel Srur, msrur@centrodelavision.cl

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluation of visual acuity, postoperative refractive error and optical aberrations, in patients with previous corneal surgery and AcrySof® IQ VivityTM IOL implantation

Study objectives
Vivity Intraocular Lens improves visual acuity in patients in patients with prior history of myopic LASIK.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/10/2022, Centro de la Vision Ethical Committee (Camino el Alba 9500, Santiago, 7600830, Chile; +56 23303000; hborel@centrodelavision.cl), ref: 102023

Study design
Prospective interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Cataract surgery in patients with prior history of myopic LASIK

Interventions
This single-center prospective interventional study assessed eyes with a prior history of corneal refractive laser surgery for myopia that underwent intraocular lens implantation (AcrySof®IQ Vivity TM IOL Alcon) for cataract.

Patient assessments included comprehensive ophthalmic examinations before and after Vivity intraocular lens implantation. After the surgery, patients were instructed to use gatifloxacin 0.3%/ prednisolone 1% eye drops four times a day for 1 month. Follow-up was done at 1 and 3 months to assess the visual outcomes.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase IV

Drug/device/biological/vaccine name(s)
AcrySof® IQ VivityTM intraocular lens

Primary outcome measure
Binocular uncorrected and corrected visual acuity for far distance, measured using LogMAR scale at baseline, 1 and 3 months

Secondary outcome measures
1. Binocular uncorrected and corrected visual acuity of patients for intermediate and near distance (66 and 40 cm respectively) measured using LogMAR scale at baseline, 1 and 3 months

2. Manifest refraction with spherical equivalent (SE) measured using subjective refraction at baseline, 1 and 3 months
3. Intraocular pressure measured using tonometry (mmHg) at baseline, 1 and 3 months
4. Dysphotopsies evaluated using the McAlinden Quality of Vision (QoV) questionnaire at baseline and 3 months

Overall study start date
01/09/2022

Completion date
31/03/2024

Eligibility

Key inclusion criteria
1. Patients older than 50 years old
2. Undergoing bilateral phacoemulsification
3. Preoperative corneal higher order aberrations (HOA) less than 0.6
4. Coma less than 0.4

Participant type(s)
Patient

Age group
Adult

Lower age limit
50 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
13

Total final enrolment
13

Key exclusion criteria
1. Glaucoma
2. Macular disease
3. History of retinal detachment
4. Any previous corneal diseases

Date of first enrolment
01/05/2023

Date of final enrolment
01/03/2024

Locations

Countries of recruitment
Chile

Study participating centre
Centro de la Vision
Camino el Alba 9500
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Sponsor information

Organisation
Centro de la Vision

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Sponsor type
Hospital/treatment centre

Website
https://www.cev.cl

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 peer-reviewed journal

Intention to publish date
01/03/2025

Individual participant data (IPD) sharing plan
The dataset generated from this study will be available from Dr Miguel Srur upon reasonable request (msrur@centrodelavision.cl)

IPD sharing plan summary
Available on request