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

Submission date	Recruitment status	Prospectively registered
31/10/2024	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
06/11/2024	Completed	Results
Last Edited	Condition category Eye Diseases	☐ Individual participant data
05/11/2024		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

Contact name

Dr Miguel Srur

Contact details

Camino el Alba 9500 Santiago Chile 7500956 +56 23303000 msrur@centrodelavision.cl

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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

Phase

Phase IV

Drug/device/biological/vaccine name(s)

AcrySof® IQ VivityTM intraocular lens

Primary outcome(s)

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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

50 years

Upper age limit

100 years

Sex

Αll

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

Sponsor information

Organisation

Centro de la Vision

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 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

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet

Participant information sheet 11/11/2025 11/11/2025 No