

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

<b>Submission date</b> 31/10/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/11/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/11/2024	<b>Condition category</b> 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

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

### 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 Vivity™ 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 Vivity™ 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**

All

**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

Santiago

Chile

7600830

## **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](mailto:msrur@centrodelavision.cl))

**IPD sharing plan summary**

Available on request