

# Axial IntraOcular Lens position and posterior capsule opacification with a microincisional single-piece open-loop hydrophilic IntraOcular Lens: a randomised trial (XCelens Idea versus single-piece Acrysof IntraOcular Lens)

<b>Submission date</b> 12/12/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/11/2012	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

FINO1001

## **Study information**

**Scientific Title**

**Study objectives**

To assess the axial stability and the Posterior Capsule Opacification (PCO) inhibiting efficacy of a 360° sharp edge hydrophilic IntraOcular Lens (IOL) (Idea, XCelens) and compare it to that of a standard hydrophobic acrylic IOL (Acrysof SA60AT, Alcon) both single-piece open-loop in design with sharp optic edges.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved by Moorfields and Whittington LREC on the 15th November 2006 (ref: 06/Q0504/96).

**Study design**

Randomised, bilateral, double-masked clinical trial with intra-individual comparison

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

**Health condition(s) or problem(s) studied**

Cataract; posterior capsular opacification

**Interventions**

Intraocular lens implant (XCelens Idea or Acrysof)

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Posterior Capsule Opacification (PCO), measured with an image analysis system Automated QUantification of After-cataract (AQUA), scale zero to ten, from digital retroillumination photographs of the posterior capsule at two years.

**Secondary outcome measures**

1. Anterior chamber depth (mm) with ACMaster
2. Decentration (mm)
3. Refraction
4. Rhexis size (mm<sup>2</sup>)
5. Slitlamp biomicroscopy (descriptive)

**Overall study start date**

28/11/2006

**Completion date**

28/05/2009

**Eligibility****Key inclusion criteria**

1. Bilateral age-related cataract
2. Age 40 and older
3. Visual Acuity more than 0.05
4. Normal findings in the medical history and physical examination unless the investigator considers an abnormality to be clinically irrelevant
5. Written informed consent to surgery and participation in the study

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

35 (70 eyes)

**Key exclusion criteria**

Relevant other ophthalmic diseases (such as pseudoexfoliation, glaucoma, retinal degenerations, ocular trauma, etc.)

**Date of first enrolment**

28/11/2006

**Date of final enrolment**

28/05/2009

# Locations

## Countries of recruitment

Austria

England

United Kingdom

## Study participating centre

**Moorfields Eye Hospital NHS Foundation Trust**

London

United Kingdom

EC1V 2PD

# Sponsor information

## Organisation

Moorfields Eye Hospital NHS Foundation Trust (UK)

## Sponsor details

162 City Road

London

England

United Kingdom

EC1V 2PD

## Sponsor type

Hospital/treatment centre

## Website

<http://www.moorfields.nhs.uk/Home>

## ROR

<https://ror.org/03zaddr67>

# Funder(s)

## Funder type

Industry

## Funder Name

XCelens SA (Switzerland)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/11/2011		Yes	No