

# Study of toric intraocular lens (IOL) versus limbal relaxing incisions in the management of cataract astigmatism

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| <b>Submission date</b><br>12/04/2013   | <b>Recruitment status</b><br>Stopped      | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>15/05/2013 | <b>Overall study status</b><br>Stopped    | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>18/05/2017       | <b>Condition category</b><br>Eye Diseases | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

The quality of vision following cataract surgery is affected by the clarity of the ocular media (transparent substances of the eye, i.e the cornea, intraocular lens [IOL], lens capsule and vitreous gel), focus (corneal curvature and IOL) and co-morbidity, e.g. retinal or optic nerve disease. One aspect of focussing is astigmatism, where the vision is blurred due to the inability of the optics of the eye to focus a point object into a sharp focused image on the retina, and is caused in cataract post-surgical patients by asymmetry of corneal curvature. This study aims to assess the effect of two alternative means of correcting astigmatism to optimise focus. The first is the placement of additional corneal incisions to directly reduce corneal astigmatism and second is the use of toric IOLs which may alternatively be used to compensate for corneal astigmatism.

### Who can participate?

Males and females aged over 18 years listed for cataract surgery.

### What does the study involve?

The participants are randomly allocated to one of two groups:

Group 1: Corneal Limbal Relaxing Incisions (LRIs). These are paired partial-thickness incisions placed just within the cornea immediately prior to small incision cataract surgery. This technique corrects up to 3D of cylinder, which is the maximum level correctable on the inclusion criteria.

Group 2: IOL. The Tecnis toric IOL is implanted during cataract surgery to correct astigmatism. The study will be conducted in compliance with the protocol, Good Clinical Practice, and all applicable regulatory requirements.

### What are the possible benefits and risks of participating?

The study intervention is a choice between two alternative means of reducing post-operative astigmatism. Additional surgical incisions carry a risk of infection, reduced by the routine use of post-operative antibiotic eyedrops. The corneal incisions may also in the immediate post-operative period give a foreign body sensation in the eye. Toric IOLs may rotate in the eye; if rotation is excessive then surgical repositioning may be required. Both techniques carry the risk

of over- or under-correcting astigmatism, such that spectacle correction of vision remains necessary.

Where is the study run from?

Royal Berkshire NHS Foundation Trust (UK).

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

May 2013 to January 2014

Who is funding the study?

Abbott Medical Optics Inc. (USA)

Who is the main contact?

Mr Martin Leyland

## Contact information

### Type(s)

Scientific

### Contact name

Mr Martin Leyland

### Contact details

Royal Berkshire NHS Foundation Trust

London Road

Reading

United Kingdom

RG1 5AN

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

13/SC/0050

## Study information

### Scientific Title

Randomised controlled trial of Tecnis 1-piece toric intraocular lens (IOL) versus limbal relaxing incisions in the management of cataract astigmatism

### Study objectives

Toric IOLs may be an effective alternative to limbal relaxing incisions (LRIs) for the treatment of astigmatism post cataract surgery.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Berkshire South Central NRES Committee, 05/03/2013, ref: 13/SC/0050

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

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

Cataract surgery

**Interventions**

Reducing astigmatism by comparing toric IOLs vs limbal relaxing incisions (LRIs). This study is a randomised controlled trial of two techniques to control post-operative astigmatism.

Group 1: Corneal Limbal Relaxing Incisions (LRIs). These are paired partial thickness incisions placed just within the cornea immediately prior to small incision cataract surgery. This technique corrects up to 3D of cylinder, which is the maximum level correctable on the inclusion criteria.

Group 2: IOL. The Tecnis toric IOL is can be implanted during cataract surgery to correct astigmatism, and is available in cylindrical powers of 1.00, 1.5, 2.25, 3.00 and 4.00 with a spherical diopter range of 5-34 dioptries. Toric IOL biometry calculations using a proprietary algorithm (AMO Abbott Medical Optical), cross-referenced with standard biometry calculation.

The study will be conducted in compliance with the protocol, Good Clinical Practice, and all applicable regulatory requirements.

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

1. Visual acuity
2. Corneal astigmatism

Unaided vision will be measured 2 weeks after the operation  
Optician sight test will be carried out 6 weeks after the operation

### **Secondary outcome measures**

Visual satisfaction score will be measured 6 weeks after the operation

### **Overall study start date**

01/05/2013

### **Completion date**

01/01/2014

### **Reason abandoned (if study stopped)**

Participant recruitment issue

## **Eligibility**

### **Key inclusion criteria**

1. Symptomatic cataract
2. Vision 6/12 or worse
3. Corneal astigmatism  $>0.75D$  horizontal or  $>1.25D$  vertical and (maximum 3.0D)
4. Males and females aged over 18 years

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

40

### **Key exclusion criteria**

1.  $<18$  years of age
2. Astigmatism  $>3.0D$  or irregular
3. Dry eye severe enough to affect keratometry despite topical lubricant treatment
4. Ocular co-morbidity

### **Date of first enrolment**

01/05/2013

### **Date of final enrolment**

01/01/2014

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

**Royal Berkshire NHS Foundation Trust**

Reading

United Kingdom

RG1 5AN

# Sponsor information

## Organisation

Royal Berkshire NHS Foundation Trust (UK)

## Sponsor details

London Road

Reading

England

United Kingdom

RG1 5AN

## Sponsor type

Hospital/treatment centre

## Website

<http://www.royalberkshire.nhs.uk>

## ROR

<https://ror.org/034nvrd87>

# Funder(s)

## Funder type

Industry

## Funder Name

Abbott Medical Optics Inc. (USA) will provide the toric IOL at the same price as the non-toric IOL

# 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="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |