# Comparison of two techniques for toric intraocular lens implantation: hydroimplantation versus ophthalmic viscosurgical devices

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
08/12/2017		☐ Protocol		
Registration date 25/03/2018	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
23/11/2020	Eye Diseases			

#### Plain English summary of protocol

Background and study aims

A cataract is a clouding of the lens in the eye which decreases vision. It is estimated that 25% to 40% of cataract patients have astigmatism, a focusing disorder of the eye that distorts vision. During cataract surgery toric intraocular lenses (IOLs) can be implanted inside the eye to replace the eye's natural lens and correct astigmatism. In the standard procedure, ophthalmic viscosurgical devices (OVD) are solutions used during implantation of IOLs to create and maintain space in the eye. Hydroimplantation is a technique for implantation of a foldable IOL without an OVD. The aim of this study is to compare the OVD and hydroimplantation techniques for the implantation of a toric IOL.

#### Who can participate?

Patients with cataract and regular astigmatism between 1.0 and 3.0 diopters (D)

#### What does the study involve?

Participants undergo phacoemulsification (cataract removal) and are randomly allocated to undergo implantation of toric IOLs with either the OVD technique or the hydroimplantation technique. In the OVD group, the toric IOLs are implanted with OVD. In the hydroimplantation group, balanced salt solution (BSS) is used instead of OVD during implantation of toric IOLs. The eyes are examined at 2 hours, 1 day, 1 week, 1 month, and 3 months after surgery.

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

The hydroimplantation technique provides similar visual outcomes to the conventional technique using OVDs for the implantation of toric IOLs, but it has the advantage of increased efficiency, reduced surgical time and cost, and does not cause high intraocular pressure. The hydroimplantation technique is also useful for the alignment of the toric IOLs during the surgery. However, this technique is only recommended for experienced surgeons, and may cause complications for novice ophthalmologists.

Where is the study run from? Jinling Hospital (China)

When is study starting and how long is it expected to run for? January 2012 to December 2014

Who is funding the study? Jinling Hospital (China)

Who is the main contact? Dr Zhenping Huang hzpjlyy@hotmail.com

#### Contact information

#### Type(s)

**Public** 

#### Contact name

Dr Yueqin Chen

#### Contact details

Jinling Hospital 305 East Zhongshan Road Nanjing China 210002

### Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers 2016007

# Study information

#### Scientific Title

Comparison of two techniques for toric intraocular lens implantation: hydroimplantation versus ophthalmic viscosurgical devices

#### Study objectives

In this study, patients with cataract and preexisting regular corneal astigmatism between 1.0 and 3.0 diopters (D) underwent phacoemulcification and implantation of toric IOLs with the ophthalmic viscosurgical device (OVD) technique or hydroimplantation technique.

The aim of this study was to evaluate and compare the clinical results between the OVD group and the hydroimplantation group for the implantation of a single-piece, acrylic foldable toric IOL. In the OVD group, the toric IOLs were implanted with OVD. In the hydroimplantation group, balanced salt solution (BSS) was used instead of OVD during implantation of toric IOLs.

It is hypothesized that the hydroimplantation technique will provides comparable visual outcomes to the OVD technique for the implantation of toric IOLs but with increased efficiency, reduced surgical time and cost, and no concerns of OVD-induced elevated IOP.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethical Committee of Jinling Hospital, 25/08/2011, ref: 2011NLY-027

#### Study design

Prospective interventional single-center study

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

No participant information sheet available

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

Eyes with cataract and preexisting regular corneal astigmatism between 1.0 and 3.0 diopters (D)

#### **Interventions**

60 eyes with cataract and preexisting regular corneal astigmatism underwent phacoemulsification and AcrySof toric IOLs implantation, and the eyes were randomized to undergo either the OVD technique or the hydroimplantation technique.

#### Intervention Type

Procedure/Surgery

#### Primary outcome measure

- 1. Postoperative IOP is measured using the Computerized Tonometer at 2 hours, 1 day, 1 week, 1 month, and 3 months after surgery
- 2. Postoperative UDVA is measured using Snellen or "E" chart 3 months after surgery
- 3. ECD is measured using SP-3000P, Topcon Corp. Tokyo, Japan at 3 months after surgery

- 4. Refractive astigmatism is measured using keratometry: IOLMaster at 3 months after surgery
- 5. IOL rotation is measured using a slit lamp at 3 months after surgery
- 6. Time taken for IOL implantation is measured using records at time of surgery

#### Secondary outcome measures

Astigmatism vector analysis is measured using Thibos and Horner's power vector notation at 3 months after surgery

#### Overall study start date

01/01/2012

#### Completion date

31/12/2014

## **Eligibility**

#### Key inclusion criteria

- 1. Age-related cataract with preoperative corneal astigmatism between 1.0 and 3.0 D and nucleus sclerosis up to grade 3
- 2. 40-90 years old

#### Participant type(s)

Patient

#### Age group

Mixed

#### Sex

Both

#### Target number of participants

60

#### Total final enrolment

60

#### Key exclusion criteria

- 1. Patients with history of previous ocular surgery
- 2. Pupil size less than 7.5 mm after dilatation
- 3. Anterior chamber less than 2.25 mm
- 4. Compromised endothelial cell functio
- 5. Corneal disorder
- 6. Complicated cataract
- 7. Glaucoma
- 8. Pseudoexfoliation
- 9. Severe myopia
- 10. Diabetic retinopathy

#### Date of first enrolment

10/01/2012

# Date of final enrolment 29/05/2014

#### Locations

# **Countries of recruitment**China

Study participating centre Jinling Hospital 305 East Zhongshan Road Nanjing China 210002

# Sponsor information

#### Organisation

Jinling Hospital

#### Sponsor details

305 East Zhongshan Road Nanjing China 210002

#### Sponsor type

Hospital/treatment centre

#### **ROR**

https://ror.org/04kmpyd03

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

Jinling Hospital

## **Results and Publications**

#### Publication and dissemination plan

The manuscript is under minor revision with BMC Ophthalmology.

#### Intention to publish date

23/06/2018

#### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Yueqin Chen.

#### IPD sharing plan summary

Available on request

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/04/2018	23/11/2020	Yes	No