ISRCTN55696872 https://doi.org/10.1186/ISRCTN55696872

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

Submission date
08/12/2017

Recruitment status
No longer recruiting

Registration date
25/03/2018

Overall study status
Completed

Last Edited
23/11/2020

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
Astigmatism vector analysis is measured using Thibos and Horner’s power vector notation at 3 months after surgery

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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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

ROR
https://ror.org/04kmpyd03

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Jinling Hospital

Results and Publications

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