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Effect of incision on visual outcomes after implantation of a trifocal diffractive intraocular lens

Submission date
22/06/2018

Recruitment status
No longer recruiting

Registration date
23/06/2018

Overall study status
Completed

Last Edited
16/07/2018

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Intraocular lenses (IOLs) are implanted inside the eye to replace the eye's natural lens when it is removed during cataract surgery. Trifocal diffractive IOLs have been demonstrated to restore intermediate vision without damaging distance or near vision. This new concept of IOL has confirmed good performance for visual outcomes, patient satisfaction and spectacle independence. However, patients' corneal astigmatism (imperfection in the curvature of the cornea) is critical to the choice of trifocal diffractive IOL, which is a key factor influencing the visual acuity and refractive outcomes after the operation. Many studies have shown that the location of the corneal incision (cut) has an impact on postoperative corneal astigmatism and higher-order aberrations (HOAs), such as degradation of vision at night, halos and glare. However, there is no research on the effect of incisions on visual outcomes after implantation of trifocal diffractive IOLs. This study aims to evaluate visual acuity, corneal astigmatism and corneal HOAs after implantation of a trifocal diffractive IOL operated with either a corneal steep-axis incision or a 135° incision.

Who can participate?
Patients with cataract or presbyopia suitable for refractive lens exchange, who have pre-existing corneal astigmatism of less than 1.00 D, and who are seeking spectacle independence

What does the study involve?
Participants are randomly allocated to one of two groups: group A are treated with a 2.8 mm clear corneal incision at the steep-axis and group B are treated with a 2.8 mm clear corneal incision at 135°. According to their preoperative corneal astigmatism, groups A and B are separated into two subgroups: A1 (0 ~ 0.50 D), A2 (0.51 ~ 1.00 D), B1 (0 ~ 0.50 D), and B2 (0.51 ~ 1.00 D). Visual acuity, corneal astigmatism and corneal HOAs are followed up for 3 months. Visual outcomes are assessed between group A1 and group B1 and between group A2 and group B2 to evaluate the usability of the intervention.

What are the possible benefits and risks of participating?
After the end of the study the participants are expected to gain high-quality refractive outcomes and spectacle independence. There are no risks associated with the intervention.

Where is the study run from?
The Affiliated Hospital of Qingdao University (China)

When is the study starting and how long is it expected to run for?
December 2015 to March 2018

Who is funding the study?
1. National Natural Science Foundation of China
2. National Natural Science Foundation of Shandong

Who is the main contact?
Dr Shasha Xue
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Effect of incision on visual outcomes after implantation of a trifocal diffractive intraocular lens

Study objectives
Visual outcomes with corneal steep-axis incision are better than 135° incision after implantation of trifocal diffractive intraocular lens (IOL).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Affiliated Hospital of Qingdao University, 30/12/2015, ref: qddxfsyy2614

Study design
interventional randomised controlled study

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
Patients undergoing cataract surgery with implantation of a trifocal diffractive IOL

Interventions
This prospective study enrolled patients randomly assigned to different groups. According to preoperative corneal astigmatism, patients were assigned into group A1 (0 ~ 0.50 D) or A2 (0.51 ~ 1.00 D) with a corneal steep-axis incision or group B1 (0 ~ 0.50 D) or B2 (0.51 ~ 1.00 D) with a 135° incision. Visual acuity, corneal astigmatism and corneal higher-order aberrations (HOAs) were followed up for 3 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Corneal astigmatism measured with a Galilei device (Galilei G2, Ziemer ophthalmic systems AG, Port, Switzerland) at 1 day, 2 weeks, 1 month, or 3 months postoperatively
2. Uncorrected distance visual acuity (UDVA), uncorrected intermediate visual acuity (UIVA) and uncorrected near visual acuity (UNVA) obtained by the standard logarithmic chart at 1 day, 2 weeks, 1 month, or 3 months postoperatively
3. Total corneal wavefront aberration, root mean square value of corneal higher-order

aberrations (RMS HOAs), spherical aberration (SA), coma, or trefoil measured with a Galilei device (Galilei G2, Ziemer ophthalmic systems AG, Port, Switzerland) at 1 day, 2 weeks, 1 month, or 3 months postoperatively

Secondary outcome measures
1. The proportion of astigmatic axial length with the rule (WTR) (90°± 30°), against the rule (ATR) (0°to 30°or 150°to 180°), and oblique (30°to 60°or 120°to 150°) at pre operation and 3 months post operation
2. Surgically induced astigmatism (SIA) calculated using Jaffe/Clayman vector analysis at 3 months post operation
3. UDVA and CDVA between the subgroups obtained by the standard logarithmic chart pre operation

Overall study start date
01/12/2015

Completion date
31/03/2018

Eligibility

Key inclusion criteria
Patients with cataract or presbyopia suitable for refractive lens exchange seeking spectacle independence who had preexisting corneal astigmatism of less than 1.00 D

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
101 eyes of 77 patients undergoing cataract surgery with implantation of a trifocal diffractive IOL (AT LISA tri 839MP, Carl Zeiss Meditec, Germany) were divided into two groups: group A including 49 eyes of 37 patients with a 2.8 mm clear corneal incision at the steep-axis and group B including 52 eyes of 40 patients with a 2.8mm clear corneal incision at 135°. According to the preoperative corneal astigmatism, groups A and B were separated into two subgroups: A1 (0 ~ 0.50 D with 22 eyes), A2 (0.51 ~ 1.00 D with 27 eyes), B1 (0 ~ 0.50 D with 23 eyes), and B2 (0.51 ~ 1.00 D with 29 eyes).

Key exclusion criteria
Patients with a history of glaucoma, retinal detachment, corneal disease, irregular corneal astigmatism, abnormal iris, macular degeneration or retinopathy, neuro-ophthalmic disease, ocular inflammation, or previous ocular surgery

Date of first enrolment
01/01/2016

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
China

Study participating centre
The Affiliated Hospital of Qingdao University
No.16 Jiangsu Road
Shinan District
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266000

Sponsor information

Organisation
The Affiliated Hospital of Qingdao University

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/026e9yy16

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China (81470609, 81300730)

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
National Natural Science Foundation of Shandong (ZR2017BH025)

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal.

Intention to publish date
15/07/2018

Individual participant data (IPD) sharing plan
Data will be available indefinitely at the Data Repository of the Affiliated Hospital of Qingdao University. All of the individual participant data collected during the trial will be shared after deidentification. Participant Information sheet, Study Protocol, Statistical Analysis Plan, Informed Consent Form, and Clinical Study Report will also be available. Data will be available immediately following publication with no end date for anyone who wishes to access the data for any purpose. Anyone who intends to access the datasets could contact Dr Shasha Xue (xueshasha1104@126.com).

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/07/2018		Yes	No