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Lens replacement planning in patients with cataracts and corneal astigmatism using the iTrace program

Submission date
05/02/2020

Recruitment status
No longer recruiting

Registration date
11/02/2020

Overall study status
Completed

Last Edited
22/01/2021

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
An estimated 40 to 50% of the population aged over 60 years has significant astigmatism (change in the curve of the eye resulting in blurred and distorted vision). The same proportion of patients with cataracts (clouding of the lens in the eye which leads to a decrease in vision) also have astigmatism. Cataracts are treated through lens replacement surgery of the cloudy lens with a clear artificial lens. Managing astigmatism faced by a large number of patients has become crucial in modern cataract surgery. If there is significant astigmatism after surgery this will have an effect on vision quality and spectacle independence, which can leave patients dissatisfied. Toric intraocular lenses, which are the type of artificial lenses used in this study, have become an increasingly common replacement due to their advantage of predictably, stably, and safely correcting preexisting astigmatism. Currently, there is no standard technique for measuring astigmatism.

The factors influencing whether an astigmatism is successfully corrected following surgery include accurate pre-surgical measurements, the size and direction of surgical incision, correct calculation of the dimensions of the toric lens needed, the stability of the lens, and lens tilt. The aim of this study is to investigate the outcomes of planning lens replacement surgery with iTrace toric calculator and whether this has better outcomes than the current standard calculation and planning tools.

This study will evaluate the visual outcomes for cataracts and astigmatism, lens stability after surgical planning using iTrace, and the safety and effectiveness of iTrace as a planning device.

Who can participate?
Participants who have cataracts and have regular corneal astigmatism, with no other current or previous eye disease, who require lens replacement and would like the implantation of a toric lens which can correct the visual issues experienced due to astigmatism, will be recruited to the trial.

What does the study involve?
All recruited participants will receive a full eye examination and testing and an eye scan with the iTrace system. This information will be used to calculate and plan their lens replacement surgery with the aim to restore perfect vision. They will receive their lens implantation, which follows the same procedure as the current standard. Over the following 3 months, participants will be assessed for the success of the lens implantation through various eye examinations and tests the same as those undertaken before surgery.

What are the possible benefits and risks of participating?
Through the planning and evaluation of the surgical process in the study, it is anticipated that participants will receive even more satisfactory visual improvements than if they were to receive the standard surgical procedure.

The surgical operation follows the standard surgical procedure, the only change is that more accurate measurement equipment is used in the surgical planning, therefore there is no increase in the risk of the surgery. The study aims to improve the effect on vision of the surgery

Where is the study run from?
Shanxi Eye Hospital (China)

When is the study starting and how long is it expected to run for?
May 2017 to July 2019

Who is funding the study?
Shanxi Science and Technology Department (China0

Who is the main contact?
Dr Zhe Zhang

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
201601D021142

Study information

Scientific Title
Clinical evaluation of the safety and effectiveness of toric intraocular lens implantation planning based on iTrace wavefront keratometric astigmatism calculation

Study objectives
Using iTrace built-in toric calculator with wavefront keratometric astigmatism values for toric IOL planning is safe and effective

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/01/2017, Medical Ethics Committee of Shanxi Eye Hospital (100 Fudong St, Liu Xiang Shang Quan, Xinghualing, Taiyuan, Shanxi, 030001 China; +863518286882; eye8286500@163.com), ref: N20170309

Study design
Prospective interventional single-center study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cataracts with corneal astigmatism

Interventions
All patients with cataract and preexisting corneal astigmatism underwent phacoemulsification and toric IOL implantation. The IOL power and cylinders were chosen with the help of the iTrace toric planning program using wavefront keratometric astigmatism.

All patients had a full ophthalmologic examination at baseline including subjective refraction, uncorrected distance and best-corrected visual acuity measurements, a slit-lamp examination, Goldmann applanation tonometry, and fundoscopy in mydriasis. Ocular biometry was performed using a partial coherence interferometry device (IOL Master 500, Carl Zeiss Meditec AG). Corneal

topography was measured using the Oculus Pentacam (Optikgeräte GmbH, Wetzlar, Germany) and iTrace Surgical Workstation. All measurements were acquired in automatic release mode for each eye before using any eye drops or performing other contact-based examinations. Eye alignment evaluations and measurements with good quality (graded as “ok”) obtained via Pentacam, were used in the final analysis. The participant was placed in front of the iTrace and his or her head was carefully aligned with the chin and forehead fixed with the help of an assistant.

All measurements were performed in a semidark room with undilated pupils.

Postoperative examinations were performed at 1 week, 1 month, 3 months, 6 months and 1 year following surgery and included uncorrected and corrected distance visual acuity, intraocular pressure, subjective and objective (autorefractometry) refractions, slit-lamp evaluation, and corneal topography (Pentacam HR and iTrace).

The IOL axis was assessed with toriCAM (Graham Barrett, AppStore, USA) at the slit-lamp following mydriasis. The toriCAM is a newly developed smartphone application, invented by Professor Graham Barrett, based on the accelerometer and gyroscope built into modern smartphones that can provide a photographic analysis to identify the actual IOL axis postoperatively.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Astigmatic changes assessed by vector analysis using the Alpins method at baseline and 3 months
2. Postoperative refractive error assessed by the display of the postoperative refractive cylinder at 3 months

Key secondary outcome(s))
1. Visual acuity assessed using a Snellen E chart at baseline and 3 months
2. IOL axial position is measured with toriCAM when participants underwent mydriasis at 3 months
3. Corneal astigmatism measured with different devices are compared

Completion date
22/07/2019

Eligibility

Key inclusion criteria
1. Cataracts with preexisting regular corneal astigmatism and requested toric IOL implantation
2. Cylindric values between 0.75 D and 5.0 D.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
63

Key exclusion criteria
1. Pregnancy and/or lactation
2. Irregular corneal astigmatism
3. Diabetic retinopathy
4. Iris neovascularization
5. Congenital eye abnormalities
6. Severe unstable tear film
7. Retinal detachment
8. Glaucoma
9. Pseudoexfoliation syndrome
10. Uveitis
11. Long-term anti-inflammatory treatment
12. Amblyopia
13. Advanced age-related macular degeneration
14. Previous ocular surgery
15. Severe corneal and/or retinal disease
16. History of eye trauma

Date of first enrolment
02/01/2018

Date of final enrolment
01/06/2019

Locations

Countries of recruitment
China

Study participating centre
Shanxi Eye Hospital
No. 100 Fudong Street
Liu Xiang Shang Quan
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Sponsor information

Organisation
Shanxi Eye Hospital

Funder(s)

Funder type
Government

Funder Name
ShanXi Science and Technology Department

Alternative Name(s)
, Shanxi Provincial Department of Science and Technology, Department of Science and Technology of Shanxi Province, Science and Technology Department of ShanXi Province, Shanxi Science and Technology Department

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/11/2020	22/01/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes