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A six month clinical evaluation of the Toric Multifocal Intraocular Implant after cataract or lens replacement surgery

Submission date 01/01/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 09/01/2017	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 12/01/2017	**Condition category** Eye Diseases	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

Cataracts are a condition in which the natural lens inside the eye can become cloudy and hard. Cataracts can develop from normal aging, from an eye injury, or after taking certain types of medications. Cataracts may cause blurred vision, dulled vision, sensitivity to light and glare and /or ghost images. Presbyopia is a condition associated with aging of the eye (typically after age 40) that leads to a progressively worsening ability to focus clearly on close objects. Symptoms include a hard time reading small print, having to hold reading material farther away, headaches, and eyestrain. These two conditions are often accompanied by astigmatism, an eye condition distorts or blurs the ability to see both near and distant objects, as the cornea (the clear front window of the eye) is not round and smooth (like a basketball), but instead is curved (like a football). For some patients, corrective eye surgery is the only truly effective treatment if they are suffering from these conditions. These procedures often involve replacing the damaged natural lens with a clear, artificial one (intraocular lens). Normally the correction of astigmatism if present requires additional surgery in the form of laser surgery as a secondary procedure a few months later. As more sophisticated intraocular lens are being developed, such as the toric lens, full correction can be done in the one procedure without the need for additional laser surgery. The aim of this study is to look the long-term improvement patients receiving lens replacement surgery with the toric lens.

Who can participate?

Patients with cataracts, presbyopia or astigmatism who are undergoing corrective eye surgery aged between 21 and 80 years.

What does the study involve?

All patients undergo their corrective eye surgery and have the toric lens implanted in one or both of their eyes after removal of the damaged natural lens. The intra ocular lens implant will be inserted according to standard procedure and manufacturers recommendations. Before they have surgery and then again after one week, and one, three and six months, participants undergo standard eye examinations to see If the procedure has improved their vision and if there is a need for later laser eye surgery.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating as patients will undergo the procedure whether or not they take part in the study.

Where is the study run from?
Viewpoint Vision services Ltd (UK)

When is the study starting and how long is it expected to run for?
September 2016 to January 2018

Who is funding the study?
Viewpoint Vision services Ltd (UK)

Who is the main contact?
Mr Deepak Chitkara
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Contact information

Type(s)
Public

Contact name
Mr Deepak Chitkara

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
216627

Study information

Scientific Title

Safety and efficacy of a Toric Multifocal Intraocular Implant after routine Bilateral implantation following Cataract or Lens Refractive surgery

Study objectives
The principal aim of this study is to evaluate the visual performance after bilateral implantation of a toric multifocal Intraocular(tMIOL) implant ('Torica Diff-aA" IOL; Humanoptics AG, Erlangen, Germany) in patients with preexisting corneal astigmatism and eligible for MIOL implantation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre prospective case series observational study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Presbyopia and astigmatism

Interventions
Any patient presenting for Corrective eye surgery with Refractive lens exchange will undergo the standard pre operative assessment for suitability for this procedure. The pre operative assessment consist of a full history and examination of the eyes. The examination consists of slit lamp examination of the eyes with dilation of pupils, assessment of visual acuity,refraction topographic assessment of corneal, Biometry, iTrace aberrometry and pupil size after dilation. If the patient is found to have pre existing corneal astigmatism and is suitable for toric multifocal Implantation, the patient will be offered Refractive lens exchange or cataract surgery with toric multifocal Lens implant to both eyes under local anaesthetic. The surgical procedure will be fully explained including the surgery to both eyes and post operative follow up schedule. After the patient has accepted to undergo the surgical procedure the surgeon will introduce the option of taking part in this multifocal study. If the patient agrees he/she will be given the Patient Information and Consent Form (see Attached) to study at leisure at home. The patients will be under no obligation to take part in the study and will able to change their mind at anytime without any consequence.

The patient will be advised to post the signed consent form before the day of surgery to the Viewpoint Vision clinic as per normal routine.

On the day of surgery, the patient will undergo standard surgical procedure for Refractive lens Exchange to both eyes under topical anaesthetic with insertion of the toric multifocal Implant. The procedure is carried out as a day case procedure. After the procedure the patient is allowed to go home after standard recovery in the day case ward of St Helens hospital.

The patient is given an appointment for follow up the next day in the clinic. At this appointment a slit lamp exam is carried out as well as a digital retro illuminated photographs of the eyes.

Further follow up appointments are scheduled for 1 week, 1 month, 3 month and 6 months post operative. At each follow up appointment a schedule of assessments are carried out to assess the refractive outcome, Stability of Implant in the eye with measurement of position and photographs of implant and patient questionnaire to determine the satisfaction with the surgical procedure and results

Intervention Type

Primary outcome measure
The rotational stability of the implant within the eye at 6 months compared with the axial position of the implant within 24 hours after surgery will be assessed by assessing the position of the implant on the slit lamp and by using digital retroillumination photographs at baseline (24 hours post-operatively), 1 week, 1 month, 3 month and 6 month post-operatively.

Secondary outcome measures
1. Subjective refraction is measured using subjective testing with lenses in a trial frame as at the opticians at baseline (pre-operatively), and 3 and 6 months post-operatively
2. Visual acuity at distance and for near at 40 cm both uncorrected and fully corrected and binocular acuity is measured using a Snellen chart in LogMAR units at basline, 1, 3 and 6 months post-operatively
3. Use of spectacles for distance or reading, presence of photic phenomenon and overall satisfaction with the procedure is measured using a questionnaire designed for the purpose of this study 3 and 6 months post-operatively

Overall study start date
01/09/2016

Completion date
01/01/2018

Eligibility

Key inclusion criteria
1. Male or female adults
2. Aged 21 to 80 years
3. Patient's who wish to be free of spectacles
4. Best distance corrected visual acuity projected to be better than 0.2 logMAR postoperatively (= 20/32 Snellen or 0.63 decimal)
5. Axial Length (AL) </= 25mm
6. Angle kappa<0.55mm (central optical zone of 1.11mm/2) measured with the wavefront iTrace

aberrometer
7. Pupil size large enough to visualise the toric axis markings
8. Availability, willingness and sufficient cognitive awareness to comply with examination procedures
9. Signed informed consent
10. Patients suitable for Refractive lens exchange as a procedure to correct their refractive error

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Twenty

Key exclusion criteria
1. Previous corneal or intraocular surgery
2. Corneal Pathology
3. uncontrolled glaucoma
4. Pseudoexfoliation syndrome
5. Retinal Detachment
6. Macular degeneration
7. Retinopathy
8. Evidence of previous uveitis
9. Amblyopia
10. Any pupil abnormalities
11. Previous ocular trauma
12. Patients with insufficient cognitive ability to undergo pre operative and post operative tests and assessments or unable to sign consent form themselves
13. Any per operative complications or deviation from the standard procedure

Date of first enrolment
01/03/2017

Date of final enrolment
01/08/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Viewpoint Vision services Ltd
Allen Day Unit
St Helens Hospital
Marshalls Cross Road
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United Kingdom
WA9 3DA

Sponsor information

Organisation
Viewpoint Vision Services Ltd

Sponsor details
Allen Day Unit
St Helens Hospital
Allen Day Unit
St Helens
England
United Kingdom
WA9 3DA

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/026xgbm91

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Viewpoint Vision Services Ltd

Results and Publications

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

Intention to publish date

01/01/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Deepak Chitkara (deepak@viewpointvision.com)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		01/09/2016	12/01/2017	No	Yes