ISRCTN14145737 https://doi.org/10.1186/ISRCTN14145737

Comparison of visual outcomes, spectacles dependence and patient satisfaction after implantation of SN6AD1, SN6AD3, FIL611PV and FIL618 intraocular lenses for cataract surgery

Submission date
23/01/2017

Recruitment status
No longer recruiting

Registration date
02/02/2017

Overall study status
Completed

Last Edited
16/02/2017

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Cataracts is a type of eye disease that clouds the lens of the eye causing poor vision or blindness. The most common treatment is a surgical correction with phacoemulsification technique (in which the eye's internal lens is broken down, removed from the eye and replaced with artificial lens called an intraocular lens (IOL)). Monofocal IOLs are normally used to replace the lens of the eye. This kind of lens is only able to help people see long distances, therefore they still need glasses to see things that are close. Recently, there have been other types of IOLs called multifocal and accommodative lenses, which have been developed to try to improve vision but they are not as widely used yet. Multifocal IOLs allow people to see both near and far. Accommodative IOLs try to help the eye keep a clear image on objects as it gets closer using the muscle activity in the eye. The aim of this study is to compare how well the new types of multifocal and accommodative IOLs help vision for different distances and their dependence on glasses and vision quality in patients undergoing phacoemulsification in both eyes (bilateral).

Who can participate?
Adults over the age of 50 who have cataracts in both eyes.

What does the study involve?
Participants are randomly allocated to one of four groups for phacoemulsification with implantation, in both eyes, of one of the multifocal (SN6AD1, SN6AD3, FIL611PV) or accommodative IOLs (FIL618). All participants receive a complete eye evaluation before being enrolled for surgery. The procedure is performed in one eye at a time, for each patient. After the procedure, patients are asked to attend to follow-up visits at one day, seven days, one month, three and six months and to follow the prescribed therapy (eyedrops, to prevent infection, for

15 days following the procedure). Vision outcomes will be evaluated at one day, seven days, one month, three and six months after surgery. Patients' satisfaction and need for glasses is be evaluated at the six months follow-up.

What are the possible benefits and risks of participating?
Participants may experience an increase in vision (due to removal of the cataracts) and reduce their need to wear glasses in order to carry out tasks at near and intermediate distances (which is not possible in case of monofocal IOL implantation). There is a risk of complications due to the surgical procedure (which, although rare, can be severe, such as retinal detachment, ocular internal hemorrhage and infection, or less serious like corneal and/or retinal edema) causing the risk of loss of vision and vision issues like halos, blurs and glows.

Where is the study run from?
S. Luigi University Hospital of Orbassano University of Turin (Italy)

When is the study starting and how long is it expected to run for?
January 2013 to December 2015

Who is funding the study?
University of Turin (Italy)

Who is the main contact?
Professor Raffaele Nuzzi

Contact information

Type(s)
Scientific

Contact name
Prof Raffaele Nuzzi

ORCID ID
https://orcid.org/0000-0002-9213-2718

Contact details
Institute of Ophthalmology
Department of Surgical Sciences
University of Turin
Via Juvarra 19
Turin
Italy
10100

Additional identifiers

Protocol serial number
39/13

Study information

Scientific Title
Visual acuity, additional correction reduction (for close-up and intermediate distances), visual disturbances rate, spectacles dependence, quality of life and personal satisfaction after phacoemulsification and implantation of SN6AD1, SN6AD3, FIL611PV and FIL618 intraocular lenses in patients affected by bilateral cataract

Study objectives
The aim of this study is to evaluate visual outcomes for different working distances (far, 60 cm and 33 cm) and impact on vision quality of multifocal intraocular lens (IOLs), made by AcrySof ResTOR, SN6AD1 and SN6AD3 (Alcon, Inc., Fort Worth, Texas, USA) as well as REVIEW FIL611PV multifocal and OPTOFLEX FIL618 accomodative IOLs (Soleko, Ltd., Rome, Italy) in patients undergoing bilateral phacoemulsification for cataract treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of San Luigi Gonzaga University Hospital University of Turin, 27/02/2013, ref: 39/2013

Primary study design
Interventional

Study design
Single-centre randomised controlled trial

Study type(s)
Quality of life

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

Interventions
Participants are allocated to one of four different arms (SN6AD1 group, SN6AD3 group, FIL611PV group and FIL618 group) by block randomization. All participants receive a complete ophthalmological preoperative evaluation which includes: slit-lamp examination, visual acuity evaluation, manifest refraction measurement, javal ophthalmometry, ocular tonometry, optical coherence tomography, corneal topography, optical and ultrasound ocular biometry).

The phacoemulsification procedure is done to the standard level of care.
SN6AD1 group: Participants undergo phacoemulsification and then receive intraocular lens implantation SN6AD1 in both eyes. SN6AD1 is a single-piece diffractive multifocal IOL (produced by Alcon, Inc, Fort Worth, Texas, USA) with an additional power of +3.0 D, 9 diffractive steps and a central optic zone for intermediate distance vision.
SN6AD3 group: Participants undergo phacoemulsification and then receive intraocular lens implantation SN6AD3 in both eyes. SN6AD3 is a single-piece diffractive multifocal IOL IOL (produced by Alcon, Inc, Fort Worth, Texas, USA) with additional power of +4.0 D, 12 diffractive steps and central optic zone for intermediate distance vision.
FIL611PV group: Participants undergo phacoemulsification and then receive intraocular lens implantation FIL611PV in both eyes. FIL611PV a single-piece refractive multifocal IOL (produced

by Soleko Ltd, Rome, Italy) with four haptics, an additional power of +3.75 D and a central optic zone suited for near distance vision.
FIL618 group: Participants undergo phacoemulsification and then receive intraocular lens implantation FIL618 in both eyes. FIL618 is a single-piece accommodative IOL (produced by Soleko Ltd, Rome, Italy) provided with an annular peripheral haptic and three helical loops, which are conceived to allow movements of its optical zone in accordance with capsular and vitreal modifications, providing an estimated accommodative potential of +2 D

After the procedure, patients are requested to attend to follow-up visits at 1 day, 7 days, 1 month, 3 and 6 months and observe the prescribed therapy (eyedrops, containing an antibiotic association with a steroidal anti-inflammatory drug, for the 15 days following the procedure) and investigators' recommendations. Visual outcomes are evaluated at day 1, day 7, month 1, month 3 and month 6. Participants satisfaction and spectacle independence are evaluated at 6 months follow-up.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Postoperative uncorrected and best-corrected visual acuity for far distances is assessed with LogMar and ETDRS charts for each eye at 1 day, 7 days, 1 month, 3 months and 6 months
2. Postoperative uncorrected and best-corrected visual acuity for intermediate distances (60 cm) is assessed using the Jeager eye chart for each eye at 1 day, 7 days, 1 month, 3 months and 6 months
3. Postoperative uncorrected and best-corrected visual acuity for near distances (33cm) is assessed using the Jaeger eye chart for each eye at 1 day, 7 days, 1 month, 3 months and 6 months
4. Additional correction (diopters), in order to achieve best-corrected binocular visual acuity at intermediate and near distances, assessed with trial lenses during visual acuity examination with Jaeger eye chart for both eyes at the preoperative time and 6 months after surgery

Key secondary outcome(s)
1. Rate of visual disturbances (glare, difficulties in night vision, difficulties in colour perception, difficulties in depth perception, halos, distorted close-up vision, distorted vision for far distances, obscured close-up vision, obscured vision for far distances, doubled vision) is assessed by patient questionnaires with scores from 0 (for absence of disturbances) to 5 (for maximal difficulty) designed for the purpose of this study at six months after surgery (follow-up visit)
2. Spectacle dependence rate at intermediate and close-up distances is assessed by a patient questionnaire with scores from 0 (total independence) to 5 (for maximal dependence) designed for the purpose of this study at six months after surgery (follow-up visit)
3. Global visual satisfaction is assessed by a patient questionnaire with scores from 0 (totally unsatisfied) to 5 (totally satisfied) designed for the purpose of this study at six months after surgery (follow-up visit)
4. Difficulties in everyday activities is assessed using a patient questionnaire with scores from 0 (no difficulties) to 5 (for maximal difficulty) designed for the purpose of this study at six months after surgery (follow-up visit)

FIL618 IOL Group only (measured in each eye):
1. Surgical capsulorhexis diameter is measured using a mm caliper applied on the excised portion of the capsular bag at the end of the capsulorhexis procedure (in course of surgical intervention)
2. Ocular axial length is measured using IOL Master and/or Ultrasound contact biometry at pre-

surgical evaluation
3. Preoperative visual defect measured with Automatic refractometry at pre-surgical evaluation

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Aged over 50 years
2. Bilateral cataract
3. Maximum regular corneal astigmatism of 1.0 D

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Optical means opacities different from cataract
2. Age-related macular degeneration
3. Previous history of ocular surgery
4. Irregular corneal astigmatism
5. Amblyopy
6. Concurrent neuro-muscular diseases (i.e. cerebral ictus, myasthenia)
7. Uncontrolled open/close-angle glaucoma
8. Severe ocular complications related to diabetes (i.e. retinopathy, macular edema, vitreal hemorrhage)
9. Intra/postoperative complications
10. Pupil diameter ≤ 5,2 mm in mesopic lighting conditions measured with a slit lamp-based cobalt blue light method

Date of first enrolment
01/04/2013

Date of final enrolment
01/02/2015

Locations

Countries of recruitment
Italy

Study participating centre
A.O.U. S. Luigi Gonzaga di Orbassano - University of Turin
Regione Gonzole, 10
Orbassano
Italy
10043

Study participating centre
Eye Clinic Section fo the University of Turin
Institute of Ophthalmology, Department of Surgical Sciences, University of Turin, Via Juvarra 19
Turin
Italy
10100

Sponsor information

Organisation
Institute of Ophthalmology

Organisation
San Luigi Gonzaga University Hospital

Organisation
University of Turin

ROR
https://ror.org/048tbm396

Funder(s)

Funder type
Not defined

Funder Name
Università degli Studi di Torino

Alternative Name(s)

University of Turin in Italy, University of Turin, Italy, Università di Torino, , University of Turin, UNITO

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are intended to be available upon reasonable request forwarded to the Institute of Ophthalmology of University of Turin (segreteria.oculistica@unito.it)

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/02/2017		Yes	No
Basic results		31/01/2017	14/02/2017	No	No