

Comparative clinical study of visual results between three types of multifocal lenses

Submission date 17/04/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/11/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/11/2008	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Stanislaw Gierak-Ciaciura

Contact details
University Hospital No. 5 of the Medical University of Silesia
Ceglana 35
Katowice
Poland
40-952

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives

To compare the patients visual results after bilateral implantation of ReZoom™ multifocal intraocular lens (IOL) (NXG1, Advanced Medical Optics), AcrySof® ReSTOR® IOL (SA60D3, Alcon Laboratories) and Tecnis® multifocal IOL (ZM900, Advanced Medical Optics).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Standard procedure of cataract removal with implantation of intraocular lenses being in common usage means that no ethics board approval was required.

Study design

Single-centre, interventional, non-randomised, non-masked study

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Cataract

Interventions

Phacoemulsification and aspiration of lens mass were carried out with the Infiniti® Vision System (Alcon Laboratories, Inc.) or Sovereign® Compact (Advanced Medical Optics, Inc.) through 2.8 - 3.0 mm in upper temporal quadrant of transparent cornea with no sutures used and consequent artificial lens implantation to native lens capsule with a single-use injector.

The candidates were provided detailed information concerning the structure and action of each tested multifocal implant and they expressed which type of intraocular lens they would like to have implanted. The doctor also tried to assess the best option for each involved individual based on performing job and lifestyle. Definite reply depended on patient. Follow-up was 6 month in all eyes (from 6 to 13 months).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Evaluation of anterior and posterior segments of the eyeball with slit lamp biomicroscope
2. Examination of uncorrected distance visual acuity (UCDVA) and best distance corrected visual acuity (BDCVA) (logarithm of the minimum angle of resolution [LogMAR] and Snellen's chart)
3. Examination of uncorrected near visual acuity (UNVA) and best distance corrected near visual acuity (BDCNA) (Jaeger reading chart)
4. Axial length
5. Intraocular pressure
6. Measurement of corneal endothelial cell density
7. Contrast sensitivity measurement with CSV-1000 test (Vector Vision)
8. Evaluation of pupil size
9. Measurement of eye aberration with aberrometer WASCA (Carl Zeiss, Inc.)

The primary outcomes were measured 1 day, 1 week, 1, 3 and 6 months after surgery.

Secondary outcome measures

1. Spectacle dependency
2. Subjective satisfaction with vision using the 14-item Visual Function (VF-14) survey

The secondary outcomes were measured 3 and 6 months after procedure.

Overall study start date

05/10/2005

Completion date

29/05/2007

Eligibility

Key inclusion criteria

1. Aged 40 - 75 years, either sex
2. Visual acuity equal to or less than 0.7 according to Snellens chart
3. Cataract in both eyes classified according to the Lens Opacities Classification System III (LOCS III)
4. Astigmatism less than 1.5 D
5. Mesopic pupil larger than 3.0 mm
6. Lack of other ophthalmological illnesses, such as:
 - 6.1. Post-transplant cornea
 - 6.2. Irregular astigmatism
 - 6.3. Chronic uveoscleritis
 - 6.4. Damage to ciliary/zonular system of lens
 - 6.5. Pseudoexfoliation syndrome
 - 6.6. Glaucoma
 - 6.7. Previous refractive and anti-glaucomatous operations
 - 6.8. Diabetic retinopathy
 - 6.9. Macular degeneration

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Thirty patients

Key exclusion criteria

1. Age below 45 and more than 75 years
2. Any other diseases besides cataract
3. Unrealistic expectations concerning vision
4. Patients practising professions which required night-time driving

Date of first enrolment

05/10/2005

Date of final enrolment

29/05/2007

Locations**Countries of recruitment**

Poland

Study participating centre

University Hospital No. 5 of the Medical University of Silesia

Katowice

Poland

40-952

Sponsor information**Organisation**

University Hospital No. 5 of the Medical University of Silesia, Katowice (Poland)

Sponsor details

Ul. Ceglana 35

Katowice

Poland

40-952

Sponsor type

Hospital/treatment centre

Website

<http://www.kli-okul.katowice.pl>

ROR

<https://ror.org/005k7hp45>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital No. 5 of the Medical University of Silesia, Katowice (Samodzielny Publiczny Szpital Kliniczny Nr 5 Śląski Uniwersytet Medyczny w Katowicach) (Poland)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration