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

Submission date 17/04/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/11/2008	**Overall study status** Completed	
Last Edited 25/11/2008	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Stanislawa Gierek-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 Publicsny 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