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# A prospective randomised controlled trial comparing bilateral multifocal intraocular lens implantation with monovision following cataract surgery

**Submission date**
12/12/2006

**Recruitment status**
No longer recruiting

**Registration date**
29/01/2007

**Overall study status**
Completed

**Last Edited**
08/04/2015

**Condition category**
Eye Diseases

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
WILM1007

# Study information

### Scientific Title
A prospective randomised controlled trial comparing bilateral multifocal intraocular lens implantation with monovision following cataract surgery

### Study objectives
Null hypothesis:
There is no difference in the percentage of patients that report that they never wear spectacles after bilateral implantation with either TECNIS ZM000 multifocal IntraOcular Lenses (IOLs) or Bausch and Lomb Akreos AO monofocal IOLs with the powers of the monofocal IOLs adjusted to give 1.5 dioptres of monovision.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Moorfields and Whittington Local Research Ethics Committee, 18/10/2006, ref: 06/Q0504/82

### Study design
Prospective randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Cataract

### Interventions
Bilateral intraocular lens implant with either TECNIS ZM000 multifocal or Bausch and Lomb Akreos AO monofocal intraocular lenses.

### Intervention Type
Device

### Primary outcome measure

Percentage of patients with total spectacle independence

### Secondary outcome measures
1. Visual Function 14-question (VF14) questionnaire
2. Near visual acuity
3. Reading speed
4. Binolcular Logarithm of the Minimum Angle of Resolution (LogMAR) acuity
5. Binocular Pelli Robson contrast sensitivity - photopic and dark adapted
6. Procyon pupillometry
7. Forward light scatter - van den Berg forward light scatter test
8. Wavefront aberrations - Shack Hartmann aberrometry

### Overall study start date
01/02/2007

### Completion date
01/02/2009

## Eligibility

### Key inclusion criteria
1. Patients requiring bilateral cataract surgery with good visual potential and a full visual field in each eye
2. Age range 30 to 90 years
3. Biometry indicating IOL power requirement within the range +10 to +30D for emmetropia (0.00 to -0.50D spherical equivalent) in both eyes

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
212

### Key exclusion criteria
1. Patients aiming for a refractive result other than bilateral emmetropia (0.00 to -0.50D spherical equivalant) or emmetropia in one eye and low myopia in the other, i.e., the intended monovision outcome
2. Significant co-pathology (including macular pathology, glaucoma, uveitis, corneal disease, diabetic retinopathy, previous retinal detachment surgery)
3. Keratometric astigmatism 1.5D in either eye
4. Amblyopia
5. Congenital or traumatic cataracts

6. Poor comprehension of written or spoken English
7. Inability to give informed consent
8. Mobility, tremor or postural problems causing discomfort during slit lamp examination

### Date of first enrolment
01/02/2007

### Date of final enrolment
01/02/2009

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Moorfields Eye Hospital NHS Foundation Trust**
London
United Kingdom
EC1V 2PD

## Sponsor information

### Organisation
Moorfields Eye Hospital NHS Foundation Trust (UK)

### Sponsor details
162 City Road
London
England
United Kingdom
EC1V 2PD

### Sponsor type
Hospital/treatment centre

### Website
http://www.moorfields.nhs.uk/Home

### ROR
https://ror.org/03zaddr67

# Funder(s)

**Funder type**
Industry

**Funder Name**
Advanced Medical Optics (AMO) United Kingdom Ltd (UK)

**Funder Name**
Bausch & Lomb UK Ltd (UK)

# 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

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/12/2013 | | Yes | No |