ISRCTN35593439 https://doi.org/10.1186/ISRCTN35593439

# Cataract surgery with combined Primary Posterior Continuous Curvilinear Capsulorhexis (PPCCC) and Posterior Buttonholing (POBH) in comparison to conventional in the bag Intraocular Lens (IOL) implantation

**Submission date**
17/08/2007

**Recruitment status**
No longer recruiting

**Registration date**
26/10/2007

**Overall study status**
Completed

**Last Edited**
31/12/2020

**Condition category**
Surgery

[_] 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
N/A

# Study information

### Scientific Title
Cataract surgery with combined Primary Posterior Continuous Curvilinear Capsulorhexis (PPCCC) and Posterior Buttonholing (POBH) in comparison to conventional in the bag Intraocular Lens (IOL) implantation

### Study objectives
A Primary Posterior Continuous Curvilinear Capsulorhexis (PPCCC) is the method of removing the central part or the posterior capsule during cataract surgery to prevent the formation of Posterior Capsule Opacification (PCO). One way to prevent lens epithelial cell growing on an intact vitreous face is using a buttonhole technique (Posterior Buttonholing [POBH]) to place the optic of the Intraocular Lens (IOL) posteriorly through the PCCC.

These recent improvements in surgical technique have reduced or delayed the incidence of PCO formation in adults. These new techniques could be a welcome addition to other attempts of preventing PCO. Therefore it is the aim of the present studies to compare the influence of PCCC, POBH and conventional in-the-bag implantation of IOL on PCO, visual acuity, and the axial IOL shift.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
The Ethics Committee of the Medical University of Vienna (Borschkegasse 8b/E 06, A-1090 Vienna, Austria) approved this study on the 13th March 2007 (ref: 067/2007).

### Study design
Prospective, randomised, single-masked clinical trial with within-patient comparison.

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

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

Cataract surgery innovation

### Interventions
Cataract surgery will be performed under topical anaesthesia through a 3.0 mm temporal self-sealing sclero-corneal tunnel incision. In all techniques, the Anterior Continuous Curvilinear Capsulorhexis (ACCC) with appropriate overlap of the IOL optic will be created using a needle. Thereafter hydrodissection, phacoemulsification and irrigation/aspiration of the lens will be performed.

In randomised order, cataract surgery with combined PPCCC and POBH will be performed in one eye; in the fellow eye cataract surgery will be performed conventionally with in-the-bag IOL implantation keeping the posterior lens capsule intact (standard procedure).

### Intervention Type
Procedure/Surgery

### Phase
Not Specified

### Primary outcome measure
The following measurements will be performed preoperatively, at 1 day, 1 week, 1 month, and 8 - 12 months postoperatively:
1. Anterior and posterior capsule opacification
2. Intraocular lens position
3. Best corrected visual acuity
4. Contrast sensitivity
5. Optical Coherence Tomography (OCT) central retinal thickness
6. Postoperative vitreous detachment

### Secondary outcome measures
No secondary outcome measures

### Overall study start date
20/08/2007

### Completion date
01/12/2007

## Eligibility

### Key inclusion criteria
1. Patients with age-related cataract on both eyes awaiting bilateral same-day cataract surgery
2. Age range: 55 - 88 years, both male and female

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
60 patients (120 eyes)

### Total final enrolment
50

### Key exclusion criteria
1. Anamnesis or clinical signs of uveitis
2. Glaucoma
3. Proliferative diabetic retinopathy
4. Trauma
5. Small pupil
6. Previous ophthalmic operation

### Date of first enrolment
20/08/2007

### Date of final enrolment
01/12/2007

## Locations

### Countries of recruitment
Austria

### Study participating centre
**Department of Ophthalmology**
Vienna
Austria
A -1090

## Sponsor information

### Organisation
The Medical University of Vienna (Austria)

### Sponsor details
Waehringer Guertel 18-20
Vienna
Austria
A -1090

**Sponsor type**
University/education

**Website**
http://www.meduniwien.ac.at/index.php?id=372&language=2

**ROR**
https://ror.org/05n3x4p02

# Funder(s)

**Funder type**
University/education

**Funder Name**
The Medical University of Vienna (Austria) - internally funded

# 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 | intraocular pressure results | 01/11/2010 | 31/12/2020 | Yes | No |
| Results article | macular morphology results | 01/07/2008 | 31/12/2020 | Yes | No |