ISRCTN88815601 https://doi.org/10.1186/ISRCTN88815601

Comparison of posterior capsule opacification after two different surgical methods of cataract extraction

Submission date 08/10/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/10/2007	**Overall study status** Completed	
Last Edited 14/04/2008	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jana Nekolová

Contact details
University Hospital in Hradec Králové
Department of Ophthalmology
Sokolská 581
Hradec Králové
Czech Republic
50005
+420 60 410 6256
jani.nekolova@seznam.cz

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives
Posterior capsule opacification (PCO) is the most frequent complication of crystalline lens extracapsular extraction. When PCO reaches the central part of IOL (intraocular lens), it can induce a decrease in visual acuity after cataract surgery. Many preventive factors and many surgical techniques decreasing secondary cataract development exist but there is still no extended procedure of its complete eradication. AquaLase is a new crystalline lens removal technology using the method of liquefaction of lens material by the pulses of warmed balanced salt fluid produced just inside the aspiration port of the tip. As the AquaLase tip is made of smooth rounded-bevel polymer rather than metal, the risk of capsule tears is reduced making this method more capsule friendly. Thus the lens epithelial cells (LECs) removal from the capsule bag is much easier which may be preventive for the PCO occurrence and progress. Subjective EPCO 2000 and objective OSCA are systems for computer PCO assessment.

The study is aimed at comparison of PCO extent after AquaLase and NeoSoniX cataract removal modalities using two types of software for PCO quantification, and at the comparison of these two different methods for PCO measurement. Better results in PCO for AquaLase are expected. While using this device, it is difficult to rupture the posterior capsule. Several studies have shown that the technology may have applications in polishing the capsule through mechanical washing of the lens epithelial cells (LEC) from the capsule bag with the fluid pulses. The reduction of LECs has been shown to help prevent PCO. The OSCA is a newly presented system of PCO computer assessment, evolved from previous systems. It is based on location-sensitive entropy based texture analysis of digital images. It was presented by Aslam in 2006. The OSCA results are compared to EPCO 2000 outcomes in this study. The EPCO 2000 is a computer-assisted system of PCO morphological assessment which incorporates planimetric and grading assessment. No correlation between OSCA and EPCO 2000 outcomes is expected.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee at University Hospital in Hradec Králové, Sokolská 581, 50005 Hradec Králové, Czech republic. Date of approval: 04/10/2007

Study design
Prospective, single-centre, randomised controlled study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Not specified

Study type(s)
Prevention

Participant information sheet

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

Interventions
The AquaLase is used in the right eye and NeoSoniX in the left eye of each patient. The same IOL (Alcon AcrySof® Single Piece Intraocular Lens) is implanted in all eyes.

Examination is carried out at 1, 2, 3 and 5 years after surgery. Digital retroillumination photographs of pseudophakic anterior segments, after attaining maximal pupil dilatation are obtained using a CSO Epsilon Lyrae photo slit lamp. Exact focusing on the IOL and posterior capsule is also carried out. The images are computer analyzed with the EPCO 2000 and OSCA software. Best corrected visual acuity (BCVA) is measured using Snellen optotypes pre- and postoperatively. The "Nd: YAG" laser capsulotomy incidence is evaluated.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The following will be measured at 1, 2, 3 and 5 years after surgery:
1. EPCO index for minimal, mild, moderate and severe opacities and total EPCO index for PCO under entire IOL optic (score 0 = no opacities, 4 = maximal opacities)
2. OSCA score. The possible range is from 0 (no PCO) to approximately 15 (practical expected maximum). Typical OSCA values for images with very little or no PCO is around 0.5. Values for patients that are deemed to warrant laser capsulotomy is typically around 4 - 5.
3. Best corrected visual acuity measured using Snellen optotypes at 6 metres distance

Secondary outcome measures
The "Nd:YAG" laser capsulotomy rate at 1, 2, 3 and 5 years after surgery. This shows how many capsulotomies are needed for treatment of PCO-induced decrease of BCVA.

Overall study start date
11/11/2004

Completion date
20/10/2012

Eligibility

Key inclusion criteria

1. Bilateral non-brunescent cataract (according to the Buratto classification - a cataract grade less than 5)
2. Both eyes with cataract with similar density grade
3. No other severe ocular pathology potentially affecting visual acuity (patients with mild age-related macular degeneration [ARMD] were not excluded)
4. Age 40 or older
5. Both males and females
6. Written informed consent to surgery and willing to participate in the study
7. Good compliance

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
75

Key exclusion criteria
1. Brunescent cataract
2. Severe ocular pathology potentially affecting visual acuity
3. Unable to achieve good artificial mydriasis
4. No informed consent

Date of first enrolment
11/11/2004

Date of final enrolment
20/10/2012

Locations

Countries of recruitment
Czech Republic

Study participating centre
University Hospital in Hradec Králové
Hradec Králové
Czech Republic
50005

Sponsor information

Organisation
University Hospital in Hradec Králové (Czech Republic)

Sponsor details
c/o Dr Jana Nekolová
Department of Ophthalmology
Sokolská 581
Hradec Králové
Czech Republic
50005
+420 49 583 3395
jani.nekolova@seznam.cz

Sponsor type
University/education

Website
http://www.fnhk.cz

ROR
https://ror.org/04wckhb82

Funder(s)

Funder type
University/education

Funder Name
The trial is mainly funded internally by the University Hospital in Hradec Kralove. The trial is also supported by research project grant from the Ministry of Health of Czech Republic (ref: MZO 00179906).

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	01/03/2008		Yes	No