

Effect of number and position of haptic on anterior capsule contraction

Submission date 06/02/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/02/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/01/2019	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

In cataract surgery, the lens inside the eye that has become cloudy due to cataracts is removed and replaced with an artificial lens. These lenses are called intraocular lenses (IOL) and they make the vision clear. Sometimes after cataract surgery, people develop a thickening of the back of the lens called opacification. This may lead to complications. For these reasons, preventing opacification is very important and there are many different designs of IOLs worldwide for this purpose. This study aims to investigate the effect of the number and position of IOLs after implantation of three different designs of IOLs.

Who can participate?

Adults aged 55 to 75 years old who have a cataract.

What does the study involve?

Participants are randomly allocated to one of three groups as to which type of intraocular lens (IOL) during cataract surgery. Those in the first group receive the Ophtec Precision. Those in the second group receive the Lucid Korea Microflex. Those in the last group receive the Carl Zeiss Asphina. The same surgeon performs all the cataract surgeries using a standard procedure. At week one, two and six months after the procedure the participants are followed up to assess how their procedures went.

What are the possible benefits and risks of participating?

The three IOLs used in this study are intraocular lenses that have been proven safe and approved by the KFDA in Korea. The products that have already proven the safety of intraocular lenses are unlikely to cause additional risk or benefits to patients.

Where is the study run from?

Seoul St. Mary's Hospital (South Korea)

When is the study starting and how long is it expected to run for?

August 2016 to December 2016

Who is funding the study?
Investigator initiated and funded (South Korea)

Who is the main contact?
Professor Choun-ki Joo (Scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
KC18RESI0081

Study information

Scientific Title
Effect of number and position of intraocular lens haptics on anterior capsule contraction: A randomised, prospective trial

Study objectives
The number and position of IOL haptics might affect anterior capsular contraction. The present study evaluates the capsulorhexis aperture after implantation of three differently designed intraocular lens.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Seoul St. Mary's Hospital Korea, 05/02/2016, ref: KC18RESI0081

Study design

This was a prospective, randomized study of patients who were to undergo cataract surgery at Seoul St. Mary's Hospital, Seoul, South Korea, between August 2016 and December 2016.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Patient who have age related cataract in Seoul St.Mary's hospital.

Interventions

Participants who diagnosed senile cataract are included in this study. One of the following three randomly assigned IOLs was implanted during each patient's cataract surgery: Precizon IOL (OPHTEC; IOL A), Microflex IOL (Lucid Korea Inc.; IOL B), and CT Asphina 509M IOL (Carl Zeiss; IOL C). Before the study began, a simple randomization is done with the Excel software (Version 2010, Microsoft). The randomly assigned three type of IOL was implanted during cataract surgery.

The same experienced surgeon (CKJ) performed all cataract surgeries using a standard procedure. Except intraocular lens, the postoperative protocol was same in all groups. At week one, two and six months postoperatively, the area of the anterior capsule opening in these patients was measured using digital retro-illumination images after dilating the pupil, followed by evaluation using the POComan software.

Intervention Type

Device

Primary outcome(s)

Anterior Capsule Opening Size is measured by analyzing the image of digital retro-illumination using POComan software at 1 week, 2, and 6 months postoperatively.

Key secondary outcome(s)

Posterior Capsule Opacification is measured also by analyzing the image of digital retro-illumination using POComan software at 1 week, 2, and 6 months postoperatively.

Completion date

31/12/2016

Eligibility

Key inclusion criteria

1. Aged over 55 years and under 75
2. Presence of age-related cataract
3. Axial length within the normal range (22–25.5 mm)
4. Dilated pupil larger than 8.0 mm in diameter

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Ocular disease
2. Intraocular surgery
3. Laser treatment
4. Glaucoma
5. Severe retinal pathology

Date of first enrolment

02/08/2016

Date of final enrolment

28/02/2018

Locations

Countries of recruitment

Korea, South

Study participating centre

Seoul St. Mary's Hospital

Department of Ophthalmology

College of Medicine

The Catholic University of Korea, Seoul, Republic of Korea

222, Banpo-daero, Seocho-gu

Republic of Korea

Seoul

Korea, South

06591

Sponsor information

Organisation

Ethics Committee of the Seoul St. Mary's Hospital

ROR

<https://ror.org/056cn0e37>

Funder(s)

Funder type

Not defined

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mihyun Choi, MD at MNyoung23@gmail.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/03/2018	29/01/2019	Yes	No