Effect of optical quality on retinal thresholds

Published: 15-03-2018
Last updated: 12-04-2024

(1) To determine the influence of optical quality on peripheral retinal sensitivity (as measured with perimetry) for phakic and pseudophakic healthy eyes, (2) to compare the optical quality between healthy subjects and (phakic and pseudophakic) POAG...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glaucoma and ocular hypertension
Study type	Observational non invasive

Summary

ID

NL-OMON46489

Source
ToetsingOnline

Brief title
Effect of optical quality on retinal thresholds

Condition

- Glaucoma and ocular hypertension

Synonym
Glaucoma; POAG

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Sklodowska-Curie-COFUND grant agreement No 6618830

Intervention

Keyword: Glaucoma, Optical quality

Outcome measures

Primary outcome

Optical aberrations measured using aberrometry and retinal sensitivity

thresholds measured by means of perimetry.

Secondary outcome

Corneal aberrations, ocular biometry, ocular scatter, intraocular pressure,

visual acuity and refraction these parameters are used for descriptive

statistics, to characterize the study population.

Study description

Background summary

Optical aberrations degrade image quality. Optical aberrations are well understood for central (foveal) vision, but not for peripheral vision. In glaucoma, peripheral optical aberrations affect quality of life (as they add to the glaucoma-related loss of peripheral vision) and interfere with the most important diagnostic test in glaucoma, perimetry (visual field testing).

Peripheral optical aberrations may differ between patients with primary open angle glaucoma (POAG), who are most of the time myopic or emmetropic, and patients with a narrow anterior chamber angle (primary angle closure; PAC), who tend to be hyperopic (their lens is relatively large and located closer to the cornea). Also, the aberrations may differ between patients who had a cataract extraction in the past (pseudophakic patients) and those who did not (phakic patients). Especially for peripheral vision, the optical quality of the human lens is better than that of an artificial intraocular lens (IOL).

Therefore, we propose the current study to further understand these factors. The main study parameter of this research is the relation between optical quality and perimetry. We will study this in healthy subjects, POAG patients, and PAC patients. We aim to include both phakic and pseudophakic subjects in each group. This is to cover a wider range of peripheral optical quality

because current IOL technology increases peripheral aberrations. Healthy subjects and POAG patients are only operated if there is a significant cataract. For that reason, we recruit separate groups for phakic and pseudophakic subjects. PAC patients are often operated before their lens becomes cloudy, because the removal of their lens widens the anterior chamber angle and thus improves their situation from the point of view of intraocular pressure. This procedure is called a clear lens extraction (CLE) and is the treatment of choice for narrow angle ocular hypertension or glaucoma. The CLE offers the opportunity to do a within-subject paired comparison between a clear human lens and an IOL.

Study objective

(1) To determine the influence of optical quality on peripheral retinal sensitivity (as measured with perimetry) for phakic and pseudophakic healthy eyes, (2) to compare the optical quality between healthy subjects and (phakic and pseudophakic) POAG patients to check the hypothesis that optics is similar in these two groups, and (3) to determine the effect of a CLE on the optical quality and retinal sensitivity in patients with PAC. For classification purposes, we will also measure retinal sensitivity in the POAG patients. Hence, we will (1) measure foveal and peripheral optical aberrations and (2) perform perimetry in phakic and pseudophakic healthy subjects and POAG patients, and PAC patients before and after a CLE.

Study design

Prospective, observational, study.

Study burden and risks

The healthy volunteers and POAG patients will have one visit to the Laboratory of Experimental Ophthalmology to perform the experiments. Patients with PAC scheduled for CLE will be measured before and after the surgery, following the same protocol and measurements.

Healthy subjects will undergo screening to assess their eye health, which will comprise a questionnaire (see Appendix F1), visual acuity test (letter chart), screening visual field test, OCT test of retina and optic nerve head, IOP measurement, and measurement of the anterior chamber angle. Screening will take around 20 minutes. If abnormal results are obtained in the screening for healthy subjects, they will be referred to their GP. Detection of signs of an eye condition may cause some stress, however, an early diagnosis will allow treatments to be timely initiated and therefore more preservation of visual functioning. POAG patients and patients with PAC will not perform any screening tests, therefore there is no risk of identifying any other eye conditions. Patients will be recruited from a population of patients who visit the

ophthalmology clinic at the UMCG. For the recruitment of healthy subjects, poster adverts (see Appendix E3) will be placed in and around the UMCG. Patients and healthy subjects will not spend more than 2 hours in our lab to complete the required tasks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Phakic and pseudophakic POAG and PACG patients and phakic PAC patients scheduled for CLE, who visit the ophthalmology clinic at University Medical Center Groningen, that have provided the signed informed consent form and meet the inclusion-exclusion criteria. Healthy subjects between ages 50 and 75, who have provided the signed informed consent form and returned the questionnaire with results which do not indicate ophthalmic abnormalities.

Exclusion criteria

POAG patients;Visual acuity less than 0.8
Refractive surgery (LASIK, LASEK, RK, PRK, etc.)
Non-glaucomatous visual field loss
History of closed or blocked angle
Myopia or hyperopia higher than 3D
For pseudophakic patients only: IOL model implanted different than TECNIS Monofocal, Model ZCB00 (default lens in UMCG) and preoperative myopia/hyperopia higher than 3D

Phakic PAC patients scheduled for CLE;Visual acuity less than 0.8
Refractive surgery (LASIK, LASEK, RK, PRK, etc.)
Non-glaucomatous visual field loss
IOL model to be implanted different than TECNIS Monofocal, Model ZCB00 and preoperative myopia higher than 3D;Healthy Subjects;Visual acuity less than 0.8
Refractive surgery (LASIK, LASEK, RK, PRK, contact lenses, etc.)
Any visual field loss
Intraocular pressure above 21 mmHg
Positive family history of glaucoma
Myopia/hyperopia higher than 3D
Angle closure more than 180 degrees
For pseudophakic patients only, IOL model implanted different than TECNIS Monofocal, Model ZCB00 and preoperative myopia/hyperopia higher than 3D

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-10-2018

Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	15-03-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL63159.042.17