Influence of neutral density filters on RNFL thickness as assessed with OCT

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To determine the influence of signal-to-noise ratio (SNR) and layer thickness assessment software on the RNFL thickness as assessed with OCT.

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

Summary

ID

NL-OMON45633

Source
ToetsingOnline

Brief title
Influence of neutral density filters on RNFL thickness as assessed with OCT

Condition

- Glaucoma and ocular hypertension

Synonym
Glaucoma; POAG

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,European committee

Intervention

Keyword: Glaucoma, OCT, RNFL

Outcome measures

Primary outcome

Retinal Nerve Fiber Layer (RNFL) thickness as derived from OCT data.

Secondary outcome

N/A

Study description

Background summary

Glaucoma causes thinning of the retinal nerve fiber layer due to loss of retinal ganglion cells. Currently, retinal nerve fiber layer (RNFL) thickness measurements are used as a measurement of glaucomatous damage, both for detecting glaucoma (screening) and for progression detection (monitoring), once glaucoma has been diagnosed. Optical coherence tomography (OCT) has become the most important instrument for the assessment of the RNFL thickness. In the beginning, OCT was cheered because of its presumed objectivity (test result independent of patient performance) and reproducibility. However, much like other imaging techniques, OCT is subject to artifacts and variability.

Media opacities like cataract are a common cause of error in the measurement of RNFL thickness, causing an underestimation of layer thickness. Cataract is often present in patients with glaucoma, especially in the eyes of older patients. It can act as a confounding factor and lead to an incorrect diagnosis of glaucoma or give inaccurate results on glaucoma progression. Because the RNFL thickness measurement with OCT is important for early detection of glaucoma and detecting glaucoma progression, it is of interest to know what the exact influence of media opacities is on RNFL thickness measurements and how the analysis of OCT images can be improved in order to overcome the influence of media opacities.

In this study, we assess the effect of media opacities by employing neutral density (ND) filters (*sunglasses*) in OCT imaging in healthy subjects. These ND filters cause the light to be attenuated and therefore degrades the signal to noise ratio (SNR) in the same way as changed media opacity in cataract. The degrading effect of ND filters on OCT layer thickness measurements has been shown before (Darma 2015). We aim (1) to reproduce their findings and (2) to analyse the data in a different way, in order to avoid this image quality bias. For the reproduction (aim #1), we use the proprietary software of the OCT machine and freely available segmentation software, being the Iowa Reference

Algorithm (Garvin et al. 2009), which was also used by Darma (2015), and the DOCTRAP software (Chiu et al 2010). For the alternative analysis (aim #2), we follow the theoretical framework as recently developed in our department (Jansonius 2016). Two different OCT machines will be used: the machine (*Topcon*) used by Darma (2015) and a more recent machine (*Canon*), the current state of the art.

Study objective

To determine the influence of signal-to-noise ratio (SNR) and layer thickness assessment software on the RNFL thickness as assessed with OCT.

Study design

Cross-sectional study

Study burden and risks

Healthy subjects will have one visit to the Laboratory of Experimental Ophthalmology to perform OCT measurement. Subjects will undergo screening to confirm their eye health, which will comprise a questionnaire (see Appendix F1), visual acuity (letter chart) testing, a screening visual field test, and an intraocular pressure (IOP) measurement. Screening will take around 15 minutes. The eye will not be touched during the screening.
For the OCT measurement, the pupil is dilated with a mydriatic drug, 1% tropicamide. After 20 minutes of waiting the OCT measurements will be taken, with and without a ND filter in front of the eye. An OCT measurement takes approximately six minutes (this includes three images per condition of which the median value of each analysis will be used for the final comparison and includes also time to change filters, saving data, explanation, and rest: an actual OCT scan is like taking a picture: seconds rather than minutes); with and without ND filters (optical density 0, 0.3, 0.6, and 0.9) and two different devices (Topcon and Canon) it will thus take 48 minutes.

If abnormal screening results are obtained for healthy subjects, they will be referred to their GP. Detection of signs of an eye condition may cause psychological stress. However, an early diagnosis will allow treatments to be initiated earlier and therefore more preservation of visual functioning. For the recruitment of healthy subjects, poster adverts (see Appendix E3) will be placed in and around the UMCG. Healthy subjects will spend 1.5 hour (15 min screening, 20 min waiting (pupil dilation), and 48 min OCT scanning) in our lab to complete the required measurements.

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

Healthy subjects between ages 18 and 50, who have provided informed consent form and returned the questionnaire with results which do not indicate ophthalmic abnormalities

Exclusion criteria

Glasses with lens power < -4 or > +1 D
Visual acuity less than 1.0
Any visual field loss
Intraocular pressure above 21 mmHg

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	03-05-2017
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	NL60973.042.17
Other	UMCG register and NTR