

Influence of Cataract on Straylight and Optical Coherence Tomography

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Primary1. Influence of cataract on the image quality of the new generation OCT device, the SD-OCT, and to evaluate the difference with TD-OCT.2. Interrelationship of straylightvalues and the affect of cataract on OCT image quality:a. To evaluate the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Vision disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31276

Source

ToetsingOnline

Brief title

CatStrayOCT

Condition

- Vision disorders

Synonym

Cataract (lens opacity)

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cataract, OCT, Straylight

Outcome measures

Primary outcome

LOCS III score (0-6)

Straylightvalues (log(s))

SS (Signal Strenght) / SNR (Signal to Noise ratio)

Retinal thickness, OCT-measured (micron)

Retinal Nerve Fiber Layer thickness, OCT-measured (micron)

VFQ-25 (0-100%)

Secondary outcome

visual acuity

Study description

Background summary

Optical Coherence Tomography (OCT) is a relatively new imaging technique, similar to ultrasonography, which uses near-infrared light waves, instead of ultrasound, to obtain a reflectivity profile of the retina. OCT is widely used for imaging the vitreoretinal interface, for monitoring macular edema and retinal thickness, retinal nerve fiber layer (RNFL) thickness and optic nerve head parameters in a wide variety of patients. The OCT technique currently available in clinical practice is also referred to as time-domain OCT (TDOCT), because the depth information of the retina is acquired as a sequence of samples, over time. Several efforts have been made to improve TD-OCT imaging quality. Only recently, major advances in imaging speed, sensitivity and image resolution have been achieved with the introduction of spectral-domain OCT (SDOCT). In the elderly population, cataract is a common cause of media opacity that can affect diagnostic imaging quality.

Cataract is likely to cause light scattering and is one of the commonest cause of loss of useful vision. The presence of cataract alone does not determine the indication of a cataract extraction. The ophthalmologist rests his therapy

choice on the patients complaints, physical and additional examination. Despite these examinations it can be difficult to predict the outcome and value of a cataract extraction because of the interference of other unknown factors. The effect of straylight caused by a cataractous lens is one of the possible factors. Patients complaints may, among other things, include problems of difficulty with against-the light face recognition and halos around bright lights. Function loss is now qualified by visus alone, but this has little importance. In June 2005 a device that assesses retinal straylight came on the market, the so-called C-quant.

Study objective

Primary

1. Influence of cataract on the image quality of the new generation OCT device, the SD-OCT, and to evaluate the difference with TD-OCT.
2. Interrelationship of straylight values and the effect of cataract on OCT image quality:
 - a. To evaluate the correlation between straylight values and the effect of cataract on OCT image quality.
 - b. To evaluate if the OCT image quality is a prognostic factor for the amount of straylight?

Secondary

- Which gain in straylight value is achieved by performing a cataract extraction?
- Correlates the alteration in straylight value with the alteration of complaints?
- Correlates the alteration in straylight value with the alteration in visus-related quality of life, irrespective of alteration in visus.
- What is the relationship of the type of cataract with the image quality of the OCT and straylight values?

Study design

a Study design

prospective observational cohort study

b summary (outlined in appendix B)

- * standard ophthalmologic examination
- * classification: LOCS III score 9
- * straylight measurement
- * OCT measurements
- * VFQ-25 questionnaire

c. sample size: 60.

d. duration: 12 months

e. participating departments:

Ophthalmology AMC; dr. F.D. Verbraak
mw. drs. I. van der Meulen
mw. drs. P.H.B. Kok
mw. drs. L.A. Engelbrecht
N.I.N.; dr. T.J.T.P van den Berg

Study burden and risks

Straylight measurement:
CE quality mark, non-invasive, non-contact, no risks

OCT measurements:
CE quality mark, non-invasive, non-contact, no risks

The ophthalmic examination is standard procedure.

The patients needs to fill in the questionnaire twice.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. Indication for cataract removal
2. Able and willing to sign the study agreement after reading the patient information

Exclusion criteria

1. Hypermetropia $>S+5D$ or myopia $>S-8D$
2. other ocular diseases influencing OCT measurements (cornea and media opacities / DR/ AMD (wet) / glaucoma / vascular occlusions, etc.)

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-07-2007

Enrollment: 60

Type: Anticipated

Ethics review

Approved WMO
Application type: First submission
Review commission: METC Amsterdam UMC

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	NL18235.018.07