# 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 commenest cause of loss of useful vision. The presents of cataract alone does not determine the indication of a cataractextraction. 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 cataractextraction because of the interference of other unknown factors. The effect of straylight caused by a cataractious lens is one of the possible factors. Patients complaints may, among other things, include problems of difficulty with against-the ligt face recognition and halos around bright lights. Functionloss 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 socalled C-quant.

#### Study objective

Primary

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

a. To evaluate the correlation between straylightvalues and the affect of cataract on OCT image quality.

b. To evaluate if the OCT image quality is a prognostic factor for the amount of straylight?

Secondary

- Wich gain in straylightvalue is achieved by performing a cataractextraction?

- Corelates the alteration in straylightvalue with de alteration of complains?

- Corelates the alteration in straylightvalue 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 straylightvalues?

#### Study design

a Study design

prospective obeservational cohort study

b summary (outlined in appendix B)

- \* standard ophthalmologic examination
- \* classification: LOCSIII score9
- \* straylight measurement
- \* OCT measurements
- \* VFQ-25 guestionnaire

c. sample size: 60.

d. duration: 12 months

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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-ivasive, non-contact, no risks

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

The opthalmic examination is standard procedure.

The patients needs to fill in the questionnaire twice.

# Contacts

**Public** Academisch Medisch Centrum

Meibergdreef 9 1105 AZ Amsterdam Nederland **Scientific** Academisch Medisch Centrum

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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 oclusions, 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
Туре:	Anticipated

# **Ethics review**

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Approved WMO Application type: Review commission:

First submission 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** CCMO **ID** NL18235.018.07