From shape to wavefront: retrieving optical aberrations from corneal anatomy

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To determine the aberration pattern of the cornea from its shape.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anterior eye structural change, deposit and degeneration
Study type	Observational non invasive

Summary

ID

NL-OMON36829

Source
ToetsingOnline

Brief title
From shape to wavefront

Condition

- Anterior eye structural change, deposit and degeneration

Synonym
cataract, pearl eye

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: SNN (Stichting Noord-Nederland)

Intervention

Keyword: aberrations, anatomy, cornea, topography

Outcome measures

Primary outcome

The main study parameters are the following Zernike polynomials for defocus

(z20), astigmatism (z2-2 and z22), coma (z3-1 and z31) and spherical aberration

(z40) for both the description of corneal shape and corneal wavefront.

Secondary outcome

None

Study description

Background summary

The optical quality of the human eye is pivotal for the quality of vision of the subject - and thus for quality of life. Imperfections in the eye optics are called aberrations and are measured with wavefront analysis. The optics of the eye consists of the cornea and the crystalline lens. During a cataract extraction, the crystalline lens is replaced by an intraocular lens (IOL). The aberrations of the cornea can - theoretically - be compensated by the IOL. This IOL should then be custom made. When measuring the aberrations of a subject, one always measures the aberrations of the complete system (i.e. cornea + lens). However, for predicting the aberrations after a cataract extraction it is necessary to know the aberrations of the cornea alone. This requires a thorough understanding of the relationship between the shape of the cornea and the corresponding aberration pattern. We will determine this relationship by measuring the shape of the cornea and the aberration pattern of the whole eye in patients who already had a cataract extraction in the past. In these patients, we know the optical properties of the lens (IOL). This relation can then be used to predict the aberration pattern of future cataract-extraction patients pre-surgery.

Study objective

To determine the aberration pattern of the cornea from its shape.

Study design

Cross-sectional study.

Study burden and risks

The measurements of both the corneal shape (by the Pentacam HR) and the aberration pattern (by the WASCA) are harmless procedures that do not contain any risk for the subject. Both instruments are already used for regular ocular examinations and validated for use in the clinic.
The risks of the eye-drops of tropicamide are none, due to the fact that subjects are pseudo-phakics; there is no risk of acute glaucoma. The mydriasis of the eyedrops will cause a mild photophobia in one eye, which can be minimised by wearing sunglasses.
In total the subjects will extent a regular visit to the UMCG by 30 minutes.
The subjects do not have a benefit to participating in the study, however the results of the study will benefit future patients because the final aim of the project is individualized IOL design aiming to reduce optical aberrations after the cataract extraction. There is no risk of finding previously undiscovered ocular diseases because all patients were thoroughly checked for other eye diseases as part of the cataract extraction procedure.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The inclusion criteria are that subjects are 18 years or above and underwent a successful cataract extraction and got an IOL implanted.

Exclusion criteria

Exclusion criteria are subjects with any history of ocular disease, other than the cataract extraction, and refractive surgery. Also the cataract extraction should have been successful without any complications.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2012
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	28-08-2012
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	NL40670.042.12