Comparison between six different cornea topography measurement instruments.

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The objective of this study is to make a comparison between six different cornea topography measurement systems.

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

Summary

ID

NL-OMON34898

Source ToetsingOnline

Brief title Comparison between cornea measurement instruments.

Condition

• Vision disorders

Synonym cataract, pearl eye

Research involving Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen **Source(s) of monetary or material Support:** N.V. Nom - Investerings en Ontwikkelingsmaatschappij voor Noord-Nederland

Intervention

Keyword: cornea, optical aberrations, Zernike polynomials

Outcome measures

Primary outcome

The primary parameters are the coefficients of the main Zernike-polynomials for coma-like aberrations C(3/-1) and C(3/1). These represent the objective results of the different cornea topography measurement instruments.

Secondary outcome

Besides comparing the objective results of the instruments, it is also important to study the clinical user friendliness of the instruments. Therefore the time of total measurement of each instrument with each patient will be measured. Furthermore will the operator and the subject judge each instrument using grades from 1 to 10, where 1 is worst and 10 is best, on comfort and patient friendliness.

Study description

Background summary

Cataract extraction is one of the most commonly performed ophthalmologic surgeries, where the crystalline natural lens is replaced by an intraocular lens (IOL). The design of the IOL is nowadays focused on personalizing the lens to the aberrations (optical imperfections) of the individual eye of the patient for an optimal sight.

The aberrations in the human eye are majorly caused by the cornea and the lens. With cataract surgery the lens is removed and thus the aberrations of the cornea remain. To enhance the optical performance of the pseudo-phakic eye (eye after cataract extraction) it should be aimed for to compensate all aberrations of the cornea with the IOL, leaving a perfect sight. The first step in such a novel approach is a reliable and reproducible measurement of the aberrations of the cornea.

The determination of the aberrations in the cornea is performed by looking at the topography of the cornea. There are several instruments which are potentially capable of measuring and imaging the topography of the cornea and therefore it is important to investigate the differences of these systems. The instruments in this study will be judged on both the quality of the results and user and patient friendliness.

Study objective

The objective of this study is to make a comparison between six different cornea topography measurement systems.

Study design

The cornea of both eyes of all the subjects will be measured with six cornea topography imaging systems. These instruments are located at the University Medical Centre Groningen. The order of the instruments and left/right eye will be randomized. The randomized order in which the instruments are used is generated beforehand. The instruments are spread over two locations with three instruments each. These locations are pretty far from each other, thus it would be very inefficient to walk back and forth between these locations. Therefore it is chosen to first randomize the order of the locations that is used and then generate a randomized sequence of the instruments located at each location. The order in which the eyes are measured with each instrument is fixed: the right eye is fixed in all subjects.

Furthermore the subjects are asked to grade the comfort and patient friendliness of each instruent with a grade from 1 to 10, where 1 is worst and 10 is best. All in all it is expected that the whole procedure will not take more than one hour.

The six instrument consist of five commercial instruments and one instrument which was designed for research purposes: the Dubbelman Scheimpflug. This last instrument will serve as a golden standard, since it is not a black box like the commercial ones.

The following cornea topography measuring systems are included in this study:

- 1. Orbscan
- 2. IOL-master
- 3. combined Topcon refracto/keratometer
- 4. Dubbelman Scheimpflug
- 5. Galilei (Zeimer)
- 6. Pentacam (Oculus)

Study burden and risks

It is thought that there is no risk for the subjects and the burden is minimal.

The instruments that are tested use optical techniques and thus the eye will not be touched. Furthermore are five of the instruments commercial available and thus fully tested and licensed for use in the medical setting. Even the Dubbelman Scheimpflug, which is not commercial available, is an adjusted commercial instrument originaly. Non of these adjustments are made on the measurement unit of the instrument however and thus the subject will not run any risk.

Participation in this study requires the subjects to come to the University Medical Centre Groningen for measurements of about one hour.

Contacts

Public Universitair Medisch Centrum Groningen

W.A. Scholtenstraat 12-14 9712KW Groningen Nederland **Scientific** Universitair Medisch Centrum Groningen

W.A. Scholtenstraat 12-14 9712KW Groningen Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Subjects without any history of corneal eye diseases are included in this study.

Exclusion criteria

Subjects that have worn contact lenses for the past two years are excluded from this study. Furthermore subjects that had refractive surgery in the past are also excluded.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	07-06-2010
Enrollment:	30
Туре:	Actual

Ethics review

Approved WMO	
Date:	28-05-2010
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 CCMO **ID** NL31712.042.10