Studies concerning straylight, image magnification and phakic IOL implantation

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What is the effect of image magnification on straylight values and is there a correlation between change in straylight values and change in visual acuity after pIOL (Artisan/Artiflex) implantation.

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

Summary

ID

NL-OMON39712

Source
ToetsingOnline

Brief title
Studies concerning straylight

Condition

- Vision disorders

Synonym
glare, straylight

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: AIOSKO;ANVVB;Opthec,OPHTEC BV

Intervention

Keyword: Artisan, Image magnification, Phakic IOL, Straylight

Outcome measures

Primary outcome

Straylight values

Visual acuity

Secondary outcome

Pupil diameter

Axial length

Study description

Background summary

The importance of assessing the role of glare and contrast sensitivity as part of the quality of vision has increased since cataract and refractive surgery is increasingly performed worldwide. A safe and effective way to optically correct high refractive errors is by implanting a phakic intraocular lens (pIOL). But restoration of excellent visual acuity may not necessarily lead to complete patient satisfaction if the vision is tinged by troublesome glare. Patients who have undergone a pIOL implantation may complain about glare and halos. Tahzib et al. found that 44.1% of patients implanted with an Artisan pIOL complained about bothersome glare during driving at night. Performing the usual clinical examinations like visual acuity, contrast sensitivity and slitlamp examination rarely gives an indication of the cause of the complaints. Most probably, the patient*s complaints are caused by increased light scattering, which cannot be detected by the common tests. In 2010 the CEI has defined disability glare as *the effect of stray light in the eye whereby visibility and visual performance are reduced*. (CEI Recodification-Ordainmen, Chapter 16, 07/26/2010) Disability glare is the result of forward intraocular light scatter. Typical straylight dependent symptoms are against the light facial recognition problems, glare while driving at night, color and contrast loss.

After pIOL implantation in high myopic patients, visual acuity may increase 1 or 2 lines due to image magnification effects. Furthermore, Paarlberg et al. found significantly lower (better) straylight values after Artiflex pIOL

implantation compared to pre-operative. In literature, a partial explanation for better straylight values after refractive surgery is given by the discontinuation of contact lens wear. Our hypothesis is that image magnification is a possible (additional) explanation for better straylight values after pIOL implantation in myopic patients. With this study we want to investigate possible effects on retinal straylight values caused by image magnification.

Study objective

What is the effect of image magnification on straylight values and is there a correlation between change in straylight values and change in visual acuity after pIOL (Artisan/Artiflex) implantation.

Study design

Cross-sectional study

Study burden and risks

There are no risks for participating in this study.

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

study population 1. *Emmetropic* participants
• Between 18-30 years of age
• No ocular pathology
• Refractive error between -2 and +2 diopters (spherical)
• Cylindrical refractive error < 2 diopters
• Visual acuity > 0,2 ;Studypopulation 2. Myopic participants
• Minimum 18 years of age
• No ocular pathology other than high refractive error
• Refractive error at least S-6 diopters
• Satisfied contact lens wearers
• Glasses
• Visual acuity > 0,2;Studypopulation 3. Myopic patients who will undergo an Artisan/Artiflex pIOL implantation
• Minimum 18 years of age
• No ocular pathology other than high refractive error
• Will undergo Artisan implantation for the correction of myopia >S-6 diopters

Exclusion criteria

Ocular pathology

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):	19-04-2012
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	18-04-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	22-01-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL39885.058.12