Pilot study to compare straylight perception in pseudophakic subjects with different intraocular lenses

Published: 18-02-2011
Last updated: 03-05-2024

The purpose of this pilot study is to compare the perception of straylight in patients with CE marked multifocal intraocular lenses, measured with 4 different straylight measuring devices..

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vision disorders
Study type	Interventional

Summary

ID

NL-OMON35080

Source
ToetsingOnline

Brief title
Clear Multifocal Vision (CMV)

Condition

- Vision disorders

Synonym
straylight adverse optical effect

Research involving
Human

Sponsors and support

Primary sponsor: AMO Groningen BV
Source(s) of monetary or material Support: AMO Groningen BV;SenterNovem

Intervention

Keyword: Multifocal Intraocular Lens, Straylight

Outcome measures

Primary outcome

PRIMARY CLINICAL STUDY ENDPOINTS:

Pre- and postoperative stray light perception measured with the C-Quant (standard and with modified tube), Rostock Glare Perimeter, Double Pass System and a subject questionnaire.

Secondary outcome

Uncorrected and best corrected distance visual acuities (ETDRS 100% and 25% charts) • Capsular bag striae ratings • IOL Decentration/Tilt • Posterior capsule opacification (PCO) • Optical visual symptom incidence • Complication rates • Adverse event rates • Subjective subject questionnaire

Study description

Background summary

This pilot study encompasses only commonly used CE approved and marketed multifocal intraocular lens types, the Tecnis® ZMA00 and the newly marketed Tecnis® ZMB00 (both manufactured by AMO Groningen BV) to compare the patients perception of straylight. Acrylic IOLs were selected to ensure small incision cataract surgery where the preoperative parameters of the corneal curvatures and the topography remain manageable. The control lens ZMA00 is a multi-piece IOL where the optic is produced of hydrophobic acrylic material and the haptic is made of extruded PMMA. The ZMB00 is a single-piece IOL made of the same hydrophobic acrylic material like the control lens. The optic design of all multifocal lenses is 6.0 mm, the overall diameter is 13.0 mm. The posterior edge geometry of all lenses is designed for inhibition of posterior capsular opacification. The diffractive pattern which makes the lens a multifocal lens

is modified in the ZMB00 and is intended to cause a reduction in the amount of scattered light.
It is known that bright light sources like the sun or headlights of a car in the night are perceived as glare causing discomfort especially in critical situations like bad weather conditions. This discomfort glare is described by patients in combination with starbursts and/or halos or just scattered light perception. The degree of discomfort produced by a bright light source can be rated from acceptable to not acceptable and up to even threatening. The degree of discomfort may also depend on the size of the glare source, the illumination level as well as the projection area on the retina. These complaints are more frequent in patients with multifocal intraocular lenses than in patients with monofocal intraocular lenses. Recently AMO Groningen BV has introduced a new design into a multifocal IOL (ZMB00). In the optical bench there was a significant reduction of the amount of straylight. To test whether this reduction is also observed with implanted IOLs is the aim of this study. Due to their nature, the complaints of discomfort glare are difficult to quantify. However, in recent years several measuring devices have become available. This study is designed to compare the perception of straylight in patients with two CE marked multifocal intraocular lenses as measured with a marketed medical device called C-Quant (Oculus, CE marked, class I). In addition, a C-Quant is modified having an extended tube (no CE mark). The straylight measuring device, C-Quant with regular and extended tubes, used in this pilot study is the outcome of more than 20 years of investigations with a variety of straylightmeters and mesopic glare testers to ease the examination, especially for the patients and to receive more reliable data on visual capabilities under glare conditions. Using former devices, patients have had difficulties to adjust to different light levels under glare conditions. The C-Quant uses the forced choice method in which the patient has to watch a test field which is split into a left and right half circle to allow simultaneous comparison of the observed flicker strength. The patient has to choose the half circle which flickers most. A special algorithm allows a 0 or 1 response (Yes or No). The consistency of the responses gives information on the reliability of the measurement outcomes. As the device is measuring forward scattering (what the patient sees). A variety of optical tube lengths will be used to change the visual angle of the glare source. Two other investigational devices without CE mark (Rostock Glare Perimeter and Double Pass System) will be used for the evaluation of straylight. These devices are not CE marked.
The Rostock Glare Perimeter is an investigational device consisting of a central light source in a projection screen. This device was developed by Prof. Dr. Rudolf Guthoff, University of Rostock. The light source induces scattering pattern in the patient*s eyes. A beamer projects light dots in various distances from the central light source. The patient have to focus on the central light source and give responses on whether or not he/she is able to see the peripheral light spot projections. The objective straylight measuring device, the Double Pass System, used in this study is an investigational device, developed by Prof. Dr. Pablo Artal, University of Murcia, Spain. The Double Pass method has been used in vision research for more than 10 years,

mainly for measuring the point spread function on the retina. By increasing the sensitivity of the device, the device is now able to quantitatively and objectively measure the amount of straylight on the retina. It measures the forward scattering of light in the eye.

Study objective

The purpose of this pilot study is to compare the perception of straylight in patients with CE marked multifocal intraocular lenses, measured with 4 different straylight measuring devices..

Study design

This study is a single-center, bilateral intra-individual, randomized, double blind pilot study.

Intervention

Implantation of two CE marked Multifocal Intra-ocular lenses after extraction of the natural opacified lens.

Study burden and risks

Patients requiring cataract surgery with lens implantation usually have a monofocal lens implanted. This makes the use of reading glasses necessary. Multifocal intraocular lenses reduce the need for reading glasses but are only obtainable for an additional fee which covers the extra costs of the multifocal intraocular lens. In this study patients are offered the possibility to have multifocal lenses implanted at no additional cost. As a part of the study patients are asked to undergo additional eye measurements during two extra out patient clinic visit. Multifocal lenses can give rise to additional straylight which could result in complaints in some patients. Patients participating in this study will have a small risk of perceiving addiional straylight. In the most severe cases this could result in lens exchange with another type of lensimplant. This would be an additional surgery with risks comparable to those of cataract surgery. (It should also be mentioned that implantation of a monofocal intraocular lens is no absolute garantuee that complaints of unwanted light fenomena will not occur).

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

1. Age 18 or greater
2. Bilateral cataracts for which phacoemulsification cataract extraction and posterior chamber IOL implantation have been planned.
3. Visual potential in each eye of 0.8 (20/25 Snellen) or better as determined by surgeon*s estimation
4. Normal corneal topography with preoperative corneal astigmatism of 1.5 D or less (or the ability to manage astigmatism to 1.0 or less postoperatively by incision placement)
5. Availability, willingness, and sufficient cognitive awareness to comply with examination procedures
6. Signed informed consent

Exclusion criteria

1. Concurrent participation or participation during the last 30 days in any other clinical trial
2. Use of systemic or ocular medications that may affect vision (the use of any miotic agent is specifically contraindicated)
3. Acute or chronic disease or illness that would increase the operative risk or confound the

outcome(s) of the study (e.g., immunocompromised, connective tissue disease, diabetes, etc.)
4. Uncontrolled systemic or ocular disease
5. Irregular astigmatism
6. Requiring an intraocular lens <16.0 or >26.0 diopters
7. History of ocular trauma or prior ocular surgery
8. Corneal abnormalities such as stromal, epithelial or endothelial dystrophies
9 10. Uncontrolled ocular hypertension or glaucomatous changes in the retina
11. Intraocular inflammation or recurrent ocular inflammatory condition
12. Known pathology that may potentially affect vision
13. Pupil abnormalities (non-reactive, tonic pupils, abnormally shaped pupils)
14. Capsule or zonule abnormalities that may lead to IOL decentration, including pseudoexfoliation, trauma, an eccentric anterior capsulorhexis, or posterior capsule defects
15. Retinal changes that may affect vision or that may require surgical intervention during the course of the study (macular degeneration, cystoid macular edema, proliferative diabetic retinopathy, etc.)
16. Planned moving or moving to another home address during the study.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2010
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-02-2011
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	NL31644.042.10