Straylight measurements in patients wearing several types of contact lenses

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To determine straylight values in patients with several types of contact lenses and a differing lenght of wear of contact lenses. This study will lead to objective documentation of loss of function among contact lens wearers and and will lead to...

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

Summary

ID

NL-OMON31163

Source ToetsingOnline

Brief title Straylight measurements in contact lens wear

Condition

• Vision disorders

Synonym Glare, intraocular light scatter

Research involving Human

Sponsors and support

Primary sponsor: Netherlands Institute for Neurosciences **Source(s) of monetary or material Support:** Ministerie van OC&W

Intervention

Keyword: Contact lens, Cornea, Quality of vision, Straylight

Outcome measures

Primary outcome

1. Comparison of stray light values between patients wearing soft and rigid gas

permeable contact lenses; comparing the straylight values with and without

lenses in each group and between groups

2. Comparison of stray light values with corneal pachymetry, results of the

stray light questionnaire and slit lamp examination

Secondary outcome

not applicable

Study description

Background summary

Glare disability can be a problem among contact lens wearers. It is caused by a reduction in contrast of the retinal image due to a veiling luminance caused by forward light scatter within the eye. This causes halo's around bright light sources and difficulty with against the light face recognition. These complaints can be very distressing and invalidating to the patient, while standard examinations are relatively normal. Until now, loss of function was qualified only by visual acuity measurements. However, straylight measurements may offer a significant contribution. Patients with many subjective complaints may still have a good visual acuity. Their complaints may be explained by an increased straylight value.

A new version of the straylightmeter, the Oculus C-Quant, is available since June 2005. This straylight meter is able to objectively measure the amount of straylight and to express this as a number. In the present study we are planning to use the Oculus C-Quant to measure the amount of straylight in contact lens wearers without other ocular pathology who are wearing several different kinds of contact lenses. We are planning to relate the amount of straylight to subjective complaints, the types of contact lenses and the length of contact lens wear.

Null Hypotheses:

1) Patients with soft contact lenses have the same straylight values as patients with rigid gas permeable contact lenses and oxygen permeable silicone contact lenses; there will be no difference in straylight values whether or not the contact lenses are in situ

2) Longer duration of contact lens wear (more hours during the day) will not lead to more hypoxic corneal stromal swelling and to higher straylight values3) More years of contact lens wear will not lead to more hypoxic corneal stromal swelling and to higher straylight values

Study objective

To determine straylight values in patients with several types of contact lenses and a differing lenght of wear of contact lenses. This study will lead to objective documentation of loss of function among contact lens wearers and and will lead to more insight in the etiology of straylight among these groups. In this way we can contribute to the determination of the place of the several types of contact lenses among the scale of refractive possibilities.

Study design

Comparative case series.

Intervention

One eye of each of 5 volunteers will be patched for one hour, while wearing a soft contact lens.

Study burden and risks

All study visits will take place during part of one day. Patients will pay 3 study visits. The first visit will take approximately one hour, the following visits will take place one and 3 hours later, respectively. Both these visits will last approximately 20 minutes.

The subjects will undergo the following measurements:

They will fill in a questionnaire. Questions will pertain to types of contact lenses, length of wear, contact lens hygiene and any visual complaints. After this they will undergo:

- 1) Visual acuity measurement wearing their contact lenses
- 2) Straylight measurement wearing their contact lenses
- 3) Slitlamp examination wearing their contact lenses

After contact lens removal:

- 1) Autorefractor measurement
- 3) Best corrected visual acuity measurement wearing spectacles
- 4) Best corrected straylight measurement
- 5) Orbscan measurement
- 6) Slitlamp examination

The straylight measurement will be repeated one and three hours after contact lens removal.

These measurements will not lead to an increased risk for the subjects.

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

Comparative case-series:

1) All subjects will at least have a corrected visual acuity of 6/7.5

2) No ocular (or systemic) pathology

3) All subjects will be established contact lens wearers of at least 6 months and wear their lenses on a daily wear basis.

4) Subjects will be able to understand and sign the Informed Consent Form and participate in the investigations

5) All subjects will be 18 years or older

Exclusion criteria

Comparative case-series:

1) Presence of ocular (or systemic) pathology

2) Patient is not able to understand and sign the Informed Consent Form or to participate in the investigations

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Basic science	

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2007
Enrollment:	45
Туре:	Anticipated

Ethics review

Approved WMO

5 - Straylight measurements in patients wearing several types of contact lenses 25-05-2025

Application type: Review commission:

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
 NL16953.018.07