

# Influence of the donor-host interface on results of keratoplastic procedures currently in use in corneal surgery. A structured follow-up.

Published: 04-12-2006

Last updated: 09-05-2024

The main objective is to establish whether a relationship can be demonstrated between the amount of light scattered at the post-operative corneal interface on the one hand and visual acuity and contrast sensitivity on the other. In addition, changes...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Ocular structural change, deposit and degeneration NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON30230

### Source

ToetsingOnline

### Brief title

Structured follow-up of keratoplasty.

### Condition

- Ocular structural change, deposit and degeneration NEC

### Synonym

corneal transplant

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Oogziekenhuis Rotterdam

**Source(s) of monetary or material Support:** Stichting Wetenschappelijk Onderzoek Oogziekenhuis - Prol. Dr. H. J. Flieringa.

## Intervention

**Keyword:** cornea, in vivo confocal microscope, lamellar keratoplasty

## Outcome measures

### Primary outcome

Quantification of possible relationship between corneal reflectivity (confocal microscopy) and:

- visual acuity (logMAR)
- contrast sensitivity (Pelli Robson chart)
- keratoplastic technique

### Secondary outcome

Quantification of possible relationship between corneal reflectivity and:

- scatter measured by Oculus C-quant
- pachymetry (3 methods)

Quantification of:

- endothelial cell density
- quality of life

## Study description

### Background summary

The outcome of recently developed lamellar techniques of keratoplasty strongly depends on the optical properties of the donor-host interface. Thus far, no criteria are set for the optical quality of the post-operative cornea. Preferably, such an evaluation should be accurate, reliable and user-friendly at the same time. In vivo confocal microscopy appears to be meet these

requirements as a tool for inspection of the scatter properties of the corneal donor-host interface.

### **Study objective**

The main objective is to establish whether a relationship can be demonstrated between the amount of light scattered at the post-operative corneal interface on the one hand and visual acuity and contrast sensitivity on the other. In addition, changes over time will be explored for the parameters under examination.

### **Study design**

Prospective, non-randomized.

### **Study burden and risks**

Patients due for keratoplasty are standardly scheduled for one pre-op and six post-op visits. Study-related measurements will be performed during these visits and will take approximately 50 minutes extra time per session. Participants of this study do not benefit from the results of this study. Risks are negligible.

## **Contacts**

### **Public**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

Group 1, PKP:

- BCVA  $\geq$  0.4 (logMAR)
- not eligible for ALTK, DALK, PLK; Group 2, ALTK:
- BCVA  $\geq$  0.4 (logMAR); Group 3, DALK:
- BCVA  $\geq$  0.4 (logMAR)
- keratoconus without hydrops or Descemet's rupture
- stromal opacities not reaching Descemet's membrane
- no concomitant endothelial disease; Group 4, PLK:
- BCVA  $\geq$  0.4 (logMAR)
- endothelial dysfunction caused by pseudophakic or aphakic edema
- (Fuch's) endothelial dystrophy

## Exclusion criteria

Group 1, PKP:

- mental retardation
- previous corneal surgery ; Group 2, ALTK:
- mental retardation
- history of (penetrating) keratoplasty
- HLA-typed keratoplasty; Group 3, DALK:
- mental retardation
- history of (penetrating) keratoplasty
- HLA-typed keratoplasty; Group 4, PLK:
- mental retardation
- history of (penetrating) keratoplasty
- HLA-typed keratoplasty
- severe scarring of anterior stroma

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 19-03-2007

Enrollment: 210

Type: Actual

## Ethics review

Approved WMO

Date: 04-12-2006

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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

NL14835.078.06