

# Patients with Fuchs endothelial dystrophy: evaluation of preoperative quality of vision and postoperative follow-up after posterior lamellar keratoplasty

Published: 10-09-2008

Last updated: 06-05-2024

To evaluate long term results of DSEK and to compare pre- and postoperative quality of vision in patients with Fuchs' endothelial dystrophy.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Vision disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON31840

### Source

ToetsingOnline

### Brief title

Fuchs dystrophy: pre- and postoperative evaluation after PLK

### Condition

- Vision disorders

### Synonym

corneal dystrophy, partial corneal transplantation

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Nederlands Instituut voor Neurowetenschappen

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Fuchs endothelial dystrophy, Posterior lamellar keratoplasty, Postoperative follow-up, Quality of vision

## Outcome measures

### Primary outcome

- 1) Evaluation of the long term clinical results of DSEK: what is the improvement in quality of vision as compared to the pre-operative situation?
- 2) Correlation of the endothelial cell count, keratometry and corneal and posterior transplant thickness with the improvement in quality of vision.

### Secondary outcome

not applicable

## Study description

### Background summary

Descemet-stripping endothelial keratoplasty (DSEK) is a relatively new surgical treatment for Fuchs' endothelial dystrophy. Fuchs' endothelial dystrophy is a common inheritable disorder leading to a slow loss of corneal endothelial cells. As these cells can't divide, the lost cells will not be replaced.

Patients with advanced Fuchs' endothelial dystrophy often complain of deterioration of visual acuity, glare and haloes. They can also suffer from irritation and even pain. There are not many options for medical treatment. Till a few years ago, corneal transplantation was the only available therapeutic option for this group of patients.

DSEK was first described in 1998 and is performed in the AMC since 2001.

Currently, it is a universally accepted surgical technique. The main difference with penetrating keratoplasty is that only the diseased posterior lamella of the cornea is replaced (consisting of the posterior stroma, Descemet's membrane and the endothelium). Major advantages of replacing only the posterior part of

the cornea are: less intraoperative complications, no suture related problems (as no sutures are used), no irregular astigmatism, a less vulnerable wound and less risk of rejection. However, long term results of DSEK are not known yet.

## **Study objective**

To evaluate long term results of DSEK and to compare pre- and postoperative quality of vision in patients with Fuchs' endothelial dystrophy.

## **Study design**

It is an observational cohort study.

Pre- and postoperatively quality of vision will be evaluated by:

- documentation of subjective complaints with a validated questionnaire, the VFQ-25
- measurement of best corrected visual acuity
- straylight measurement
- orbscan measurement to determine thickness and keratometry of the cornea
- endothelial cell count
- anterior segment OCT measurement

All examinations are non-invasive and non-contact and without any risk for the patients.

## **Study burden and risks**

The patients will make one to two study visit to the Department of Ophthalmology, lasting between 2 and 3 hours. The measurements will pose no extra risk for the patients.

## **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

- 1) Fuchs' endothelial dystrophy; either unoperated patients or after PLK
- 2) Able and willing to participate in the study and to understand and sign the informed consent form

### Exclusion criteria

- 1) Patients with Fuchs' endothelial dystrophy and other ophthalmological conditions which can influence quality of vision
- 2) Not able or unwilling to participate in the study or to understand and sign the informed consent form

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2008
Enrollment:	100
Type:	Anticipated

## Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

## 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	NL23685.018.08