

BEST Cornea study

The Belgian Endothelial Surgical Transplant of the Cornea

Information brochure patients



Participating partners



Dear patient,

Welcome to the Ophthalmology Department!

As already explained by your doctor, you suffer from an endothelial disease of the cornea and a corneal transplant is the only way to treat this disease.

There are 2 types of corneal transplants that are commonly applied and belong to the standard treatment.

The UZA's ophthalmology department, together with 10 other Belgian hospitals, has set up a study, the BEST Cornea study, to compare which corneal transplant technique is best for patients.

This brochure serves as a general supplement to the explanations given by the ophthalmologist and the nurse during your consultation.

Your ophthalmologist

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1. What is the cornea?

The cornea is made up of 5 layers (see figure 1), all of which work to provide a clear image on the retina. The innermost layer of cells, the endothelium, is responsible for pumping fluid out of the cornea and keeping it transparent: a normal endothelium is essential to keeping the cornea clear. The endothelium lies on a membrane called the Descemet membrane. The thickest layer of the cornea is called the stroma and this provides rigidity and strength to the cornea. When the corneal endothelium fails, it cannot regrow and the best treatment is to replace the cells with healthy donor cells. This is called a corneal endothelial transplantation or endothelial keratoplasty.

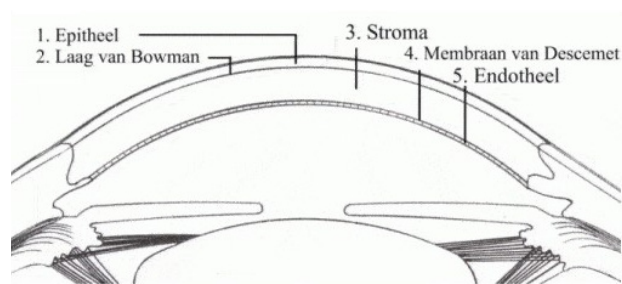


Figure 1: the cornea (hoornvlies patiënten vereniging, oogvoor.nl)

2. What is a cornea transplant?

Only the inner part of the cornea is replaced in patients with endothelial problems. There are currently two types of transplantation method:

- **the DSAEK technique** (Descemet Stripping Automated Endothelial Keratoplasty);
- **the DMEK technique** (Descemet Membrane Endothelial Keratoplasty).

In the DSAEK technique, a piece of the donor's endothelium is transplanted with a supporting layer of donor stroma, whereas in the DMEK technique only a piece of donor endothelium layer, together with its supporting membrane (the Descemet membrane), is transplanted.

Both treatment techniques (DSAEK and DMEK) are effective, have been proven, and belong to the standard treatment. A DSAEK transplant is thicker than a DMEK transplant because there is a layer of stroma attached to it (figure 2). This stroma allows

the cornea to attach very well with fewer postoperative problems.

DMEK does not have any stroma but the thinner layer may give slightly better vision. To date, there is little evidence which is the best corneal technique from a vision, complication and most importantly from the patient's perspective. This is the purpose of the BEST Cornea Study.

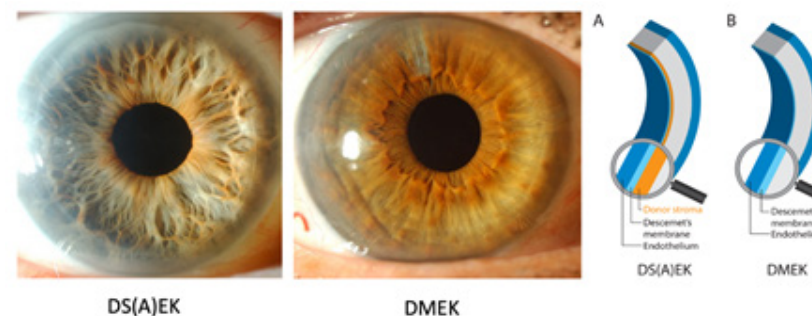


Figure 2: Images of the corneal transplants to be examined

3. The BEST Cornea study

Both corneal transplants (DSAEK and DMEK technique) are suitable for the eye disease with which you are suffering and belong to the standard treatment. Which corneal transplant (DSAEK or DMEK technique) is best is still hotly debated and there is a lack of data upon which to base a judgement about which method is the superior method.

However, studies comparing both corneal transplants are still needed. This is why your hospital, together with 10 other Belgian hospitals, has set up the BEST Cornea study.

This study was approved by the Ethic committee of your hospital.

The aim of this study is to determine the best cornea transplant technique (DSAEK or DMEK) for the patient.

Should one cornea transplant (DSAEK or DMEK technique) yield a better outcome, then ophthalmologists can focus on one and the same cornea transplant.

4. What additional measures will your involvement in the study require?

Your participation in this study is entirely voluntary and you will have sufficient time to decide whether or not you wish to participate.

You are perfectly free at any time to indicate that you no longer wish to participate in the study, without having to give a reason for your decision.

Withdrawal from the study will not affect your further treatment or your relationship with either your treating physician or the hospital staff.

Only the data registered up to the point at which you decide to withdraw will be kept for research and analysis.

If you want to participate in the BEST Cornea study, we will first give you some more detailed information about the study.

You will then have to sign an informed consent form to allow us to use your data for the study. You will never be identified in publications resulting from this study.

During corneal transplantation, you will be followed up in several consultations, up to at least one year after the operation. The only additional thing that you will be asked to do is to fill in 2 questionnaires during 4 consultations (before the cornea transplant and 3-6-12 months after the transplant).

It takes about 15 minutes to fill in the two questionnaires and the questionnaires are about your quality of life.

With regard to the patient, your ophthalmologist will always speak of a corneal transplant, not about which technique (DSAEK or DMEK) that was applied. This non-disclosure will allow for the questionnaires to be completed in a more objective fashion.

5. Are there benefits to my participation in the study?

You will not benefit directly from this study. With this study, we expect to gain more insight into the treatment of corneal endothelial diseases and to compare the two most commonly practiced corneal transplant methods.

For your full participation in the study (4 times completing the 2 questionnaires), you will receive a gift voucher worth 60 euros after the 12-month consultation (after the intervention). This voucher is not exchangeable for money or for any other compensation.

Contact details for people at participating hospitals

In case of problems or questions, your ophthalmologist will be happy to provide further information. He or she can be contacted:

Participating Hospital	Principal Investigator	Contact
Universitair Ziekenhuis Antwerpen (UZA)	Prof Dr. Sorchia Ni Dhubhghaill Prof. Dr. Carina Koppen	03/821 44 28
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