**Corneal Transplantation**

**Ultra-Thin Descemet’s Stripping Automated Endothelial Keratoplasty (UT-DSAEK)**

This information leaflet is designed to educate about the various options available to you. It is intended to make you better informed about the risks, benefits, and alternatives of traditional corneal transplant surgery (Penetrating Keratoplasty), versus Ultra-Thin Descemet’s Stripping Automated Endothelial Keratoplasty (UT-DSAEK).

**Introduction**

You have a condition that has affected your cornea (the front part of your eye) that may benefit from a corneal transplant. This surgery involves replacing your cornea with a cornea that has been donated by someone who has died (the donor cornea). The donor cornea to be used for your transplant will be provided by a certified Eye Bank in the UK.

More than one type of corneal transplant procedure is available for your condition. This material is designed to help you decide if you would like to have a full thickness corneal transplant (Penetrating Keratoplasty) verses a partial thickness corneal transplant (UT-DSAEK). Please take as much time as you need to ask questions and to discuss the surgery with your doctor and the medical staff, or with family, friends or your general practitioner. You may also decide that you do not wish to have surgery at this time.

You are a candidate for UT-DSAEK because only one part of your cornea is not working properly. The cornea is composed of three layers, the outer or epithelial layer, the middle or stromal layer (which comprises about 90% of the total corneal thickness), and the inner or endothelial layer. The endothelial layer is composed of a single layer of thousands of small pump cells. These endothelial pump cells are responsible for pumping fluid out of the cornea so it can remain clear and thin and provide good vision for the eye. If the pump cells should become dysfunctional, damaged, or destroyed, the cornea fills up with fluid and becomes swollen and cloudy, and causes blurry vision.

The endothelial cells can be lost due to aging, from inherited diseases (such as Fuchs’ Endothelial Dystrophy), from trauma, or from previous intraocular surgery. If a critical number of endothelial cells are lost, and the cornea becomes swollen and cloudy, medical therapy is usually not helpful and a corneal transplant operation is indicated. The remainder of the corneal layers, the stroma and the outer epithelium, are usually healthy. A large number of patients requiring corneal transplant surgery have these sorts of problems where only the endothelial cells have been injured or lost.

The endothelial layer of your cornea is failing and is causing your cornea to become swollen. It is this layer that needs to be replaced. Until recently, the only way to replace that layer of cells was with a full thickness corneal transplant (Penetrating Keratoplasty). Over the last several years, a technique has been developed to replace only the inner layer of the cornea (UT-DSAEK) instead of replacing the entire full thickness cornea. This cornea transplant technique has been shown to provide good vision and to have a number of potential advantages over full thickness transplants, including earlier return of vision, less refractive errors, fewer serious complications, and a more stable eye.

**Procedure**

If you choose to have UT-DSAEK, the surgery will be scheduled in coordination with the Eye Bank and hospital operating schedule. It is usually performed as an inpatient procedure under local anaesthesia, with one night post-operative hospital stay.

On the day of your procedure, an eye examination will be performed to make sure that clinical findings have not changed and that it is safe to proceed with the planned operation. Very rarely, the surgical plan may have to be altered, and if so, your surgeon will discuss alternative options. Consent to proceed with the operation will be confirmed and the appropriate eye for surgery will be marked. Nursing staff will instil drops in to the eye prior to your transfer to the operating room in preparation of the surgery. Depending on the type of anaesthesia you have requested for surgery, you may be reviewed by an anaesthetist.

Before you are escorted to the operating room, the healthy back portion of the donor cornea will be prepared by your doctor. This takes about 30 minutes. Your doctor will only proceed with the operation once he has ascertained a good dissection of the donor cornea.

During the surgery a small incision with a length of only 4 mm is made in the sclera (the white part of the eye), and the diseased back portion of your cornea (Descemet’s membrane and endothelium) will be removed. The back portion of the donor cornea is then inserted through the incision and positioned on the back surface of your cornea to replace the diseased tissue which was removed. The donor cornea is held in place with an air bubble for 24-48 hours. The small incision is then closed with two small sutures and the procedure is completed.

The surgical procedure takes about one hour to perform. You will then be transferred to the inpatient ward with a patch on your eye and will be asked to lie flat on your back with your face towards the ceiling for 24 hours. This helps the air bubble keep the donor cornea floated in the correct position. The patch will be removed and your eye will be examined 1-2 hours after the procedure, after which you will be asked to posture on your back again. You will be placed on antibiotic and steroid drops to prevent infection and to help with healing. Your doctor will review you again the following day prior to your discharge from hospital.

You will generally have additional visits with your doctor at one week, one month, three months, six months, and 12 months after surgery. We will of course see you at any time that you have concerns, questions or problems after your surgery.

**Risks, Side Effects and Discomforts**

**Risks and problems that may occur with both full thickness corneal transplant surgery (Penetrating Keratoplasty) and Ultra-Thin Descemet’s Stripping Automated Endothelial Keratoplasty (UT-DSAEK) include:**

1) There is often mild pain for one week after surgery that may be treated with paracetamol by mouth. Stronger painkillers are generally not needed. Immediately after surgery your eye will be red and irritated. There may be temporary discomfort to you from the eye examination or eye drops. This may include stinging, redness or itching.

2) For many reasons, the vision after any type of corneal transplant is never perfect. Sometimes, strong glasses are needed to correct refractive errors. The glasses may be difficult to tolerate. Sometimes, glare and distortions are noted, or the vision is still somewhat blurred, even with a clear corneal transplant. The goal is to provide the best visual acuity and overall vision quality possible, while minimising the risks.

3) A serious infection or bleeding occurs in 1 in 1000 patients. This could result in a permanent loss of all vision in the operated eye.

4) Anaesthesia is usually with a local injection around the eye. Some anaesthetic complications may include: perforation of the eyeball, damage to the optic nerve, bleeding around the eye, interference with the circulation of the blood vessels in the retina and drooping of the lid. Serious problems caused by anaesthesia occur in 1 in 10000 patients including difficulty awakening from anaesthesia, neurological problems from the anaesthesia, or even death.

5) High pressure (glaucoma) could develop in your eye secondary to surgery or to medications used after surgery. This may require drops, laser treatment or further eye surgery.

6) About 20% of the time the body's immune system produces inflammation that attacks and damages the donor cornea. This is often called a "rejection" reaction. The rejection reaction is usually reversible if treated promptly but it can lead to a failure of the transplant and loss of vision. Symptoms of rejection are sudden onset of redness, sensitivity to light, deterioration of vision or pain. If you experience any of these symptoms, you need to urgently get in touch with the eye casualty (Acute Referral Clinic) or the on-call duty eye doctor at the Royal Bournemouth Hospital.

7) The transplant may become cloudy either because of rejection, as described above, or for other reasons. If this happens it may be necessary for you to have another transplant. However, the risk of further rejection and failure increases each time for second and subsequent regrafts. The risk of the transplant failing varies, depending upon what your current corneal condition is. Your doctor may be able to provide more precise information about your particular risk.

8) The donor cornea is obtained from the NHS Blood and Transplant Special Health Authority (NHSBT) or other accredited Eye Banks. A past medical history is obtained from the donor. The donor is screened carefully for evidence of potentially transmissible infectious or neurological disease. Blood is drawn and tested for hepatitis, AIDS, and other diseases. Every effort is made to exclude donors that could transmit diseases. The risk of getting a serious disease from a donor cornea is felt to be extremely small. Nevertheless, it is still possible that a serious disease could be transmitted from the donor cornea.

9) Other problems that may be encountered include chronic inflammation, swelling of the retina causing temporary or permanent blurring of vision, double vision, a droopy eyelid, cataract formation, total loss of vision, or even loss of the eye.

10) Additional surgery may be needed due to healing problems, retinal detachment, or other problems. Any additional treatments or surgery that may be needed are not included in the fee for this procedure.

**Risks that are unique to Ultra-Thin Descemet’s Stripping Automated Endothelial Keratoplasty (UT-DSAEK) compared with full-thickness corneal transplant surgery (Penetrating Keratoplasty) include:**

1) Dislocation of the partial thickness donor corneal transplant tissue within the eye can occur 5-10% of the time. This requires another surgery to put the tissue back into the proper position. Dislocated tissue is usually noted in the first week after surgery. If the tissue cannot be re-positioned adequately, a repeat DSAEK or a full thickness corneal transplant (Penetrating Keratoplasty) may be necessary.

2) Healing occurs at the interface between your tissue and the new donor tissue. If haze or clouding developed in the central area, your vision could be decreased from its full potential, and a full thickness transplant (Penetrating Keratoplasty) may be necessary.

3) There is the possibility that the endothelial cells of the donor tissue could fail and your cornea becomes cloudy. If the cornea becomes cloudy, the UT-DSAEK may need to be repeated, or a full thickness corneal transplant (Penetrating Keratoplasty) may be required to restore the vision.

4) Although we have tried to list the major possible risks and discomforts with UT-DSAEK surgery, this list is not comprehensive and there may be others that we do not know about at this time.

**Possible direct benefits unique to Ultra-Thin Descemet’s Stripping Automated Endothelial Keratoplasty (UT-DSAEK) compared with full thickness corneal transplant surgery (Penetrating Keratoplasty) include:**

1) Patients who undergo full thickness corneal transplants usually must wait 12 months or more before their vision is restored and stable enough to obtain new glasses. With UT-DSAEK, a smoother surface for focusing usually results in improved vision much sooner – generally about 3 months.

2) Full thickness corneal transplant surgery results in a change in the corneal curvature. Since the power of one’s glasses is partially related to this curvature, strong glasses are often required to correct large amounts of near-sightedness, far-sightedness and astigmatism. Sometimes, a rigid contact lens or even surgery is required to correct the astigmatism. In contrast, after UT-DSAEK, the corneal surface remains smooth and relatively unchanged from the curvature before transplant surgery. Therefore, there is much less chance of requiring strong or thick glasses after UT-DSAEK compared to full thickness corneal transplant surgery.

3) Patients who undergo full thickness transplant surgery often have problems with glare and distortions due to surface irregularity from the large corneal wound and many corneal sutures. Patients who have UT-DSAEK have been shown to have a much smoother corneal surface. This occurs because the natural surface of the cornea is not replaced so the focusing power of the cornea remains more natural than with a full thickness cornea transplant. This smoother surface would be expected to result in better quality of vision, less distortions and less glare.

4) Patients who have full thickness transplant surgery require 16 sutures or more, some of which may be left in for several years. These sutures can lead to problems such as surface irregularity, discomfort, blood vessel formation, infection, and corneal wound problems. In contrast, the 2-4 tiny sutures that are used in UT-DSAEK are not irritating and usually do not cause problems.

5) Patients who undergo full thickness transplant surgery are much more susceptible to wound rupture and serious injury from trauma, since the full thickness corneal wound never regains full strength. With UT-DSAEK, because there is a much smaller wound, the eye should be stronger and less susceptible to serious injury from trauma.

6) In full thickness transplant surgery, all the corneal nerves are cut. While the nerves eventually grow back, this sometimes leads to healing problems on the surface of the cornea which can result in irritation, blurred vision, erosions, infection, and scarring. In UT-DSAEK, only a very small peripheral incision is made. Therefore, the corneal nerves remain largely intact, and surface problems are not expected to occur.

**Pregnancy Warning**

Pregnant patients should NOT undergo elective corneal transplant surgery. This applies to full thickness transplant surgery and UT-DSAEK. It is possible that the medications used during anaesthesia and the eye medications used after the surgery could have adverse effects on a foetus. Women of child bearing potential should be certain they are not pregnant prior to corneal transplant surgery. For women at risk for pregnancy, a blood or urine pregnancy test must be obtained prior to the surgery.

**Alternative Options or Treatment**

You do not have to have UT-DSAEK surgery. You may still choose to have a full thickness corneal transplant (Penetrating Keratoplasty), or you may choose to not have any surgery at all.

**Consenting for Information Sharing**

To comply with the law and to ensure high quality transplant material, we are required to share your information with the NHSBT. However, we require your consent to share this information. If you do not give consent for your information to be shared with or held by the NHSBT, this may affect availability of donor cornea for the transplant or create problems with contacting you should any issues be identified later on with the corneal transplant you received. For further details, please read the leaflet ‘NHS Blood and Transplant: Giving consent for use of your information’ which can be found here:

 <https://www.organdonation.nhs.uk/newsroom/publications/living_donor_consent.pdf>

**Statement of Consent to Investigation or Treatment**

You will be asked by your doctor to provide a signed statement of consent to proceed with your treatment.

You agree that UT-DSAEK corneal transplant surgery, its advantages and disadvantages, risks and possible complications, as well as the treatment alternatives have been explained to you by your doctor.

You recognise that it is impossible for your doctor to inform you of all complications and that no guarantees or promises have been made to you concerning the results of any procedure or treatment.

You have been explained the need for follow up as frequently as advised by your doctor and that it may span several years, with multiple investigations at each visit.

You have been explained that using medications properly is essential for the success of the corneal transplant.

You understand that there may be other unexpected risks or complications that can occur that were not listed in the information factsheet or discussed by your doctor. You also understand that during the course of the proposed operation unforeseen conditions may be revealed that require the performance of additional procedures, and you authorise such procedures to be performed.

You understand that post-operative follow-up appointments for ninety (90) days after surgery are included in the original surgery billing. After ninety (90) days, or if a consultation during that 90 day period is unrelated to the surgery, you and/or your insurance company will be billed and responsible for all charges.

You have had ample opportunity to read this consent form, ask questions of your surgeon to your satisfaction, and have been offered a copy of the information factsheet to take home. You voluntarily give your authorisation and consent to carry out the procedure(s) described above by your doctor and/or his associates, assisted by hospital or surgery centre personnel and other trained persons.