

TAILORED EYES

4140 Woodmere Park Blvd, Ste 3
Venice, Florida 34293
Phone: 941-499-1570
Web: Tailoredeyes.com



STEVEN KANE, MD

Cornea, Cataract, and Refractive Specialist

Descemet's Stripping Only (DSO) Informed Consent

I have been informed by my physician that I am a candidate for a Descemet's Stripping Only procedure. This consent form is designed to educate me about the various options available to me. It is intended to make me better informed about the risks, benefits, and alternatives of a DSO.

TO THE PATIENT: You have the right, as a patient, to be informed about your cornea condition and the recommended surgical procedure to be used, so that you may make the decision whether or not to undergo the cornea surgery, after knowing the risks, possible complications, and alternatives involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so that you may give or withhold your consent to cornea surgery and should reflect the information provided by your eye surgeon. If you have any questions or do not understand the information, please discuss the procedure with your eye surgeon prior to signing.

DESCEMET'S STRIPPING ONLY (DSO) SURGERY INDICATIONS

The human cornea has three layers, the outer or epithelial layer, the middle or stromal layer, and the inner or endothelial layer. The inner or endothelial layer is made of thousands of small pump cells. These special pump cells are responsible for pumping fluid out of the cornea so it can remain clear and compact and provide good vision for the eye. If the pump cells stop working or become damaged or destroyed then the cornea swells causing it to turn cloudy. A swollen, cloudy cornea can make the vision blurry.

The endothelial pump cells can be lost for many reasons including aging, genetic diseases (like Fuchs' Corneal Dystrophy), trauma, and previous eye surgery. If enough pump cells are lost, then medical therapy is usually not helpful anymore and a corneal transplant is indicated. Often, the other layers of the cornea (the stroma and the outer epithelium) are usually still healthy and can be preserved.

ALTERNATIVE TREATMENTS:

I understand that I may decide not to have a Descemet's stripping procedure, at all. However, if I do not have the cornea surgery, I understand my vision loss from the cornea usually will continue to get worse. Corrective lenses, eyeglasses, or contact lenses will not improve my vision or reverse the worsening of the cornea condition. I understand that worsening of the cornea condition may lead to development of eye pain, increased risk of infection, blindness, and in rare cases even loss of the eye.

FUCHS' DYSTROPHY

In Fuchs' dystrophy, the specialized endothelial pump cells quit working and patients experience a gradual decline in vision and worsening of glare. There are two main changes that cause the vision to decline in Fuchs' dystrophy. Cornea edema, where the cornea becomes hazy and cloudy, is one reason for poor vision. The second is the formation of guttae (pronounced Goo-Tay). Guttae are "water droplet-like" changes that form on the back side of the cornea on the inner-most layer and can cause significant light scatter.

Early in the disease, the vision may clear after an hour or two after waking. In later stages, the vision will remain blurry all day. Often these symptoms progress so gradually that the patient may not notice the vision change until it is quite advanced. Fuchs' dystrophy patients typically start to show symptoms between age 40-60 and typically progress to needing cornea transplant surgery within the following 10 years.

Nonsurgical treatments of corneal edema

Initial treatment of corneal swelling includes topical medications like salt ointments or salt drops. These treatments do not correct the guttae changes or the damage to the endothelium but they can help with low levels of corneal swelling or edema. Often the corneal edema will progress to needing surgical intervention over time.

DESCRIPTIONS, ADVANTAGES, AND DISADVANTAGES OF DSO SURGERY

Descemet's stripping only (DSO) is a minimally invasive procedure used to rejuvenate a cornea when it becomes swollen, cloudy, or develops internal droplet-like changes. DSO surgery is typically done at the same time as cataract surgery. Unlike the other surgical treatments for Fuchs' dystrophy, DSO does not use donor human corneal tissue. Currently, DSO can be used to treat mild to moderate cases of Fuchs' dystrophy that involve primarily the center of the cornea.

The procedure is performed at the time of cataract surgery and uses the same wounds made during the cataract surgery. During DSO, the diseased endothelial layer and the guttae are carefully removed from inside the eye. No donor graft is inserted to replace the layer that was removed.

Since the central damaged pump cells were removed from inside the eye, the cornea will swell significantly after surgery. This will cause significant decline in vision that will slowly improve over the following 8 weeks. Vision recovery after DSO is very slow, though there are no positioning requirements as there are for the cornea transplant surgeries. Patients may have to wait 8-12 weeks before achieving their best vision after surgery.

Roughly 90% of patients heal well with restoration of corneal clarity and vision. For the patients who do not heal well and are left with persistent corneal edema or haze, a traditional DMEK or DSAEK surgery can be performed to finish rehabilitating the cornea and vision. Normally, one eye is done at a time and only after the first eye is recovered and vision restored will surgery be recommended for the second eye.

IMPORTANT NOTICE OF NON-FDA APPROVED MEDICATION

A class of eye drop medications called a Rho Kinase inhibitor can be used to help your body heal by triggering your endothelial stem cells to make new cells. The current understanding is that using a Rho Kinase inhibitor from Japan called Ripasudil can improve the chances of your eye healing. Please note, **Ripasudil is NOT currently FDA approved for use in the United States**, though it is currently under review in trials. Ripasudil has been used for many years as a glaucoma treatment in Japan. There is a different Rho Kinase inhibitor called netarsudil that is FDA approved however studies are needed to evaluate if netarsudil has a similar impact on healing in DSO surgery.

RISKS AND COMPLICATIONS OF DSO CORNEAL SURGERY

The general risks of DSO are similar to that of cataract surgery and include the risk of hemorrhage in or around the eye, infection, swelling of the retina causing temporary or permanent blurring of vision, a retinal detachment, glaucoma or high pressure in the eye, chronic inflammation, double vision, a droopy eyelid, loss of corneal clarity, poor vision, total loss of vision, or even loss of the eye.

Due to the complex nature of cornea surgery, it is important to follow your eye doctor's instructions. Failure to follow instructions may increase the risk the need for additional surgery.

OTHER RISKS

Depending on the type of anesthesia used, other risks are possible. Local (eye block) anesthesia, if used, may damage the retina, damage the optic nerve or may lead to: bleeding in or behind the eye, double vision, permanent vision loss, perforation of the eye, a droopy eyelid, interference with the circulation of the blood vessels in the retina, respiratory depression, and hypotension. Useful vision can be permanently lost and in rare cases complications may include cardiopulmonary complications, coma, and death.

If you have other known medical conditions, such as heart disease, history of heart failure, or lung disease such as Asthma or Chronic Obstructive Pulmonary Disease, or if you are taking medications such as Coumadin (a blood thinner) or other supplements or vitamins, tell your ophthalmologist so that you can minimize the risk of additional complications during and after surgery.

I understand that there may be other unexpected risks or complications that can occur that were not listed in the consent form or discussed by the doctor. I also understand that during the course of the proposed operation unforeseen conditions may be revealed that require the performance of additional procedures, and I authorize such procedures to be performed. I further acknowledge that no guarantees or promises have been made to me concerning the results of any procedure or treatment. I understand that there is no guarantee that cornea transplant surgery will improve my vision and that in some cases complications may occur weeks, months, or even years later.

PATIENT CONSENT AND ACCEPTANCE OF RISKS

I have had ample opportunity to read this consent form (or it has been read to me), ask questions of my surgeon, and have been offered a copy of this consent form to take home. I voluntarily give my authorization and consent to the performance of the procedure(s) described above by my physician and/or his associates, assisted by hospital or surgery center personnel and other trained persons.

In signing this informed consent for DSO surgery, I am stating that:

_____ I have been offered a copy of this consent to take home.

_____ I have filled in all the blank spaces.

_____ My ophthalmologist has answered all of my questions and this form has been fully explained to me.

_____ I fully understand the possible risks, benefits, and complications of DSO surgery.

_____ I have read this informed consent or this consent was read to me by

_____ (name).

On the basis of the above statements, I voluntarily consent and authorize Steven Kane, MD, (my ophthalmologist) to perform a Descemet's Stripping Only (DSO) surgery on my

_____ RIGHT eye or _____ LEFT eye.

Patient's signature (or person authorized to sign for patient)

Date

Print patient's name