



DAVID D. RICHARDSON, MD, INC.

DAVID RICHARDSON, M.D. • SAN MARINO EYE

2020 Huntington Drive
San Marino, CA 91108

Telephone: (626) 289-7856
Fax: (626) 284-6532

Informed Consent For Canaloplasty Surgery

INDICATIONS, BENEFITS, AND ALTERNATIVES

Your doctor has diagnosed you with glaucoma and informed you that if it is left untreated, it is very likely that you will experience vision loss and eventual blindness. Glaucoma can sometimes be treated successfully with medications to lower the pressure in the eye. If medications are not effective, laser and other surgical procedures may be of value in controlling the pressure and preventing further vision loss. Both medications and surgery are designed to do one of two things: 1) decrease the amount of fluid production in the eye from the cells that make the fluid, or 2) help the fluid flow out of the eye.

Your doctor has informed you that a drainage operation called a canaloplasty is necessary to help control the pressure in your eye(s). If this pressure remains too high, your optic nerve can become damaged, leading to vision loss and eventual blindness. This procedure allows your ophthalmologist to enlarge the natural drainage channel in the eye. Canaloplasty allows fluid from the eye to better flow into the eye's drainage channel (called Schlemm's Canal). When successful, this procedure will lower the pressure in your eye, minimizing the risk of further vision loss from glaucoma. The purpose of the operation is to control the pressure and preserve your vision; **any vision lost to glaucoma cannot be restored.**

COMPLICATIONS

As with any surgical procedure, there are risks associated with canaloplasty surgery. For instance, there is always the possibility that the surgery you have will not help to control your eye pressure. Eye drops or more procedures may be needed. Not every conceivable complication can be covered in this form but the following are examples of risks encountered with glaucoma drainage surgery. These complications can occur days, weeks, months, or years later. They can result in loss of vision or blindness. Careful follow-up is required after surgery. After your eye heals from the surgery, you will still need regular eye exams to monitor your pressure and to watch for other eye problems.

Complication Of The Surgery

- Failure to control eye pressure, with the need for another operation
- Vision could be made worse or, in rare cases, totally lost (soon after or even years after surgery)
- Early or late increase of pressure in eye (ocular hypertension)
- Pressure that is too low (hypotony)
- Infection, early or much later
- Abnormal collection of fluid in eye, with the need for a second operation
- Bleeding in the eye
- Chronic inflammation
- Cataract except in those cases where the cataract has been removed
- Irritation or discomfort in the eye that may persist
- In spite of surgery, vision could become worse from continuing degenerative changes in the eye.

Complications of Anesthesia Injections Around the Eye

- Perforation of eyeball
- Needle damage to the optic nerve, which could destroy vision
- Interference with circulation of the retina
- Possible drooping of eyelid

- Systemic effects that have the potential for life-threatening complications and death

USE OF BIOLOGIC GLUE

Canaloplasty surgery may involve the use of a special glue, TISSEEL. This glue is made from human plasma and its use in canaloplasty is an off label use of this product. When a drug or device is approved for medical use by the Food and Drug Administration (FDA), the manufacturer produces a “label” to explain its use. Once a medication is approved by the FDA, physicians may use it “off label” for other purposes if they base its use on sound scientific method and evidence. TISSEEL has been approved for use in other types of eye surgeries, heart bypass surgeries, colostomies and splenic injuries. Although it is possible to get infectious diseases from the glue, the donor’s blood has been screened by the manufacturer for a variety of diseases, is widely used and is regarded as being safe. If you have any religious or other objections to the use of human products, please let us know. TISSEEL is used to glue the conjunctival flap over the area where the scleral flap was created in order to provide a watertight seal. It is also possible to suture this flap in place if necessary.

PATIENT CONSENT

In spite of the risks noted above, I understand that there is more risk to my vision if I do not have the operation than if I do. I have read and understand the consent form, I have had my questions answered, and I authorize Dr. David Richardson to proceed with the operation on my _____ (indicate “right” or “left” eye).

Patient (or person authorized to sign for the patient)

Date

Witness

Date