



ÖZEL

Anadolu
Hastanesi

Informed Consent for Glaucoma Filtering Surgery (Trabeculectomy) and Use of Anti-Metabolites

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 glaucoma filtering operation ("trabeculectomy") 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 create a new drainage channel for the eye. The trabeculectomy allows fluid from the eye to flow into a filtering area called a bleb. The bleb is mostly hidden under the eyelid. 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 my vision; any vision lost to glaucoma cannot be restored.

USE OF ANTI-METABOLITE MEDICATIONS

Anti-metabolite medications, have been found to be of value with certain types of glaucoma filtration operations. These agents, applied during or after the surgery, reduce the growth of scar tissue, a common cause of failure in glaucoma surgery. The physician's decision to use these agents is based on the evaluation of the advantages and potential disadvantages in each individual case.

Mitomycin-C and 5-Fluorouracil are the most commonly used anti-metabolites in ophthalmology today; these medications are used in conjunction with other preoperative, operative and postoperative medications designed to increase the success rate in glaucoma operations. Mitosol, is the FDA approved ophthalmic formulation of Mitomycin-C.

FDA STATUS OF MTIOMYCIN-C and 5-FLUORACIL

Mitomycin-C and 5-Fluoracil were originally approved by the Food and Drug Administration (FDA) for the treatment of various types of cancer. Upon approval, the drug manufacturer produces a "label" that explains its use. Once a drug is approved by the FDA, physicians can use it for other purposes "off-label" as part of the practice of medicine if they are well-informed about the product, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects.



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COMPLICATIONS

As with any surgical procedure, there are risks associated with glaucoma filtering surgery. For instance, there is always the possibility that the surgery you have will not help to control my 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 risk encountered with glaucoma filtering surgery. These complications can occur days, weeks, months, or years after later. They can result in loss of vision or blindness. Careful follow-up is required after surgery. After your eye heals you will still need regular eye exams to monitor your pressure and to watch for other eye problems.

RISKS OF THE SURGERY AND USE OF ANTI-METABOLITES

- Failure to control eye pressure, with the need for another operation (early or late)
- Vision could be made worse or, in rare cases, totally lost
- Early or late increase of pressure in eye (glaucoma)
- Pressure that is too low (hypotony)
- Unintended corneal and/or scleral damage including thinning or perforation
- 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

RISKS SPECIFIC TO USE OF ANIT-MATABOLITES

- Contraindicated for women who are or may become pregnant during therapy
- Not known whether this drug is excreted in human milk. Physicians should discuss potential for adverse reactions to nursing infants.

RISKS SPECIFIC TO 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

PATIENT'S ACCEPTANCE OF RISKS

I understand that it is impossible for the doctor to inform me of every possible complication that may occur. By signing below, I agree that my doctor has answered all of my questions, and that I understand and accept the risks, benefits, and alternatives of glaucoma filtering surgery.



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I authorize my surgeon to proceed with the operation on my I wish to have AK performed on my

_____ Right eye _____ Left eye

I authorize my ophthalmologist to use anti-metabolite medication (indicate medication)

Mitosol _____

Mitomycin-C _____

5-Fluoracil _____

Patient Signature (or Person Authorized to Sign for Patient)

Date