CLEAR VIEW
• EYE CONSULTANTS •

iStent Trabecular Micro-Bypass Consent

WHAT IS GLAUCOMA AND HOW IS IT TREATED?

Glaucoma is a chronic disease defined by characteristic optic nerve damage. It is a multifactorial disease with over 300 different anatomic variations and affects over 40,000,000 people worldwide. Glaucoma is a slowly progressive and irreversible disease and in most cases, causes a painless loss of eyesight. It is, in short, "the sneak thief of sight".

The damage to the optic nerve is commonly caused by a fluid imbalance, or pressure, in the eye, as well as possible alterations in the blood flow to the optic nerve. It is well established that lowering the intraocular pressure can slow the process of optic nerve damage. The degree of pressure lowering necessary to prevent optic nerve damage is individualized for each person and each optic nerve. The greater the optic nerve damage, the lower the intraocular pressure is needed to achieve stability and prevent further optic nerve damage and further visual field loss.

Your doctor has diagnosed you with elevated eye pressure and has informed you that if it is left untreated, that you may experience vision loss and eventual blindness. Treatment strategies are individualized to achieve the greatest lowering of the intraocular pressure with the least amount of risk to the individual's eyesight and well being. Commonly, topical medications or laser are used as a first line of treatment. In many situations, multiple medications are tried to achieve the desired pressure level. Unfortunately, there can be difficulties with compliance, cost and side effects with many of these medications. There are many other alternative treatments available, but they have increasing potential risk.

Recently there have been further technologic advances or better control of the intraocular pressure. Minimally invasive glaucoma surgical procedures, so-called MIGS involve alterations of the drainage area that are performed inside the eye. The iStent® trabecular micro-bypass is a surgical therapy for patients who have mild to moderate open angle glaucoma and have been tried possibly on topical medications or laser therapy. It is designed to improve the aqueous outflow to better lower the intraocular pressure and reduce the need for medications. The iStent® is the smallest medical device approved by the FDA to date. It is placed in your eye into the drainage area, so-called Schlemm's Canal through the trabecular meshwork.

The iStent® is an elective procedure. As your surgeon has discussed, the iStent® is potentially beneficial in helping to reduce the number of glaucoma medications with this surgery. If you decide not to have the iStent®, other treatment options may be recommended and should be discussed with your physician to better control your glaucoma.

HOW WILL THE iStent® AFFECT MY CONDITION?

The goal of the procedure is to improve the outflow of fluid from your eyes. The iStent® helps to control the pressure in the eye and reduce the risk of future vision loss to glaucoma. After implantation, many patients are able to better control their eye pressure with fewer medications.

WHAT TYPE OF ANESTHESIA IS USED? WHAT ARE THE MAJOR RISKS FOR ANESTHESIA?

The iStent® is inserted through a small incision generally less than 2mm and can be performed under topical or local regional anesthesia. In most cases, it is performed in conjunction with cataract surgery. Depending on the type of anesthesia, other risks are potentially associated including cardiac and respiratory problems and in rare cases, death. All operations and procedures are risky and can result in complications, injury or even death from both known and unknown causes. The major risk of cataract surgery include, but are not limited to, infection, injury to parts of the eye and nearby structures from anesthesia, the operation itself, or pieces of the lens that cannot be removed, possible fluctuation in intraocular pressure, a detached retina and a droopy eyelid.

WHAT ARE THE MAJOR RISKS OF THE iStent® TRABECULAR MICRO-BYPASS SURGERY?

As mentioned earlier, the iStent® is noted to successfully lower the intraocular pressure in most all cases when it is successfully implanted, but it may not necessarily stabilize your glaucoma. In some cases, it may not function well at all, even though it is properly placed. In addition, sometimes there can be complications that do not appear in the early post operative period but may develop days, months or years later; it is impossible to inform you of every possible complication that could occur. You may need further treatment or surgery to treat those complications. As with any intraocular surgery, there may be loss of vision, blindness, loss of the eye, as well as bleeding, infection and injury to the eye or nearby body parts.

CONTRAINDICATIONS:

The iStent® is contraindicated in eyes with primary or secondary angle closure, including neovascular glaucoma as well as in patients with thyroid eye disease, Sturge-Webber syndrome or retro bulbar tumors and/or any other type of condition that may cause elevated episcleral venous pressure.

Consent. By signing below, you consent (agree) that:

- You read this informed consent form, or someone read it to you.
- You understand the information in this informed consent form, including the risks, benefits and alternatives to surgery.
- The eye surgeon and/or staff offered you a copy of this informed consent form.
- The eye surgeon and/or staff answered your questions about iStent surgery.

I consent to have iStent implantation surgery in my _____ (state "right" or "left") eye.

_____ _____

Patient (or person authorized to sign for the patient) Date

_____

Witness