LIVING WITH GLAUCOMA
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THE COMBINATION OPERATION
Cataract and I-Stent

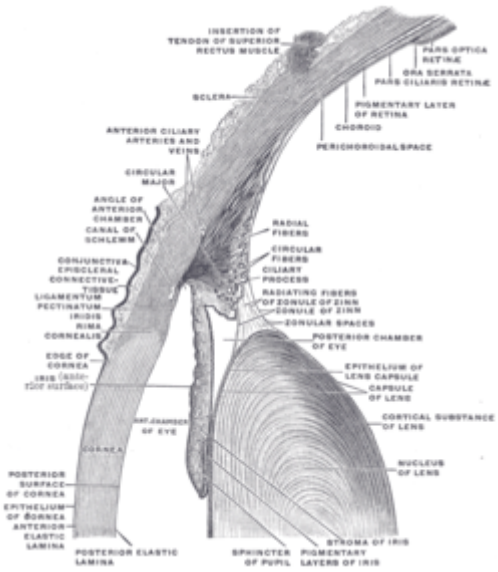
I ponder the word program. You're handed a program at the theater, you develop a college program. Your doctor gives you a medical program to follow. And so it goes. Your life is full of programming activities. But there is a different kind of programming going on all around us now—the programs generated by technology developed and implemented by a host of people called programmers who are responsible for creating algorithms (a program) that tells a machine what to do. Amazingly some of these algorithms are created by young (in their teens) men. Be that as it may, that these machines have entered the lexicon of the surgical theater and eye surgery is no exception. To explain how the latest technological tool for cataract surgery works, the Group welcomed Dr. R.J. Mackool Jr. of the Mackool Institute on March 20. Dr. Mackool Jr. is an expert in femtosecond-laser-assisted cataract surgery and iStent® surgery and teaches the techniques worldwide.

First, a brief description of the Femtosecond laser. This instrument uses ultra short pulses of energy to create incisions. The time duration is on the order of ten to the minus fifteenth power. It's very, very short, which allows very precise and focused application. Ahmed H. Zawail won the 1999 Nobel Prize in Chemistry for this discovery.

Fortunately for patients requiring cataract removal the Femtosecond laser has improved the reproducibility of the process. Because of its speed and accuracy in performance, the machine facilitates extremely accurate procedures. The machine allows visualization of the cataract in cross section using advanced imaging technology, and allows the surgeon to precisely perform the incisions used to enter the eye and to break apart the cataract.

The iStent®: Pairing the operation with iStent® offers mildly to moderately affected

glaucoma patients an option for pressure control. The iStent® was recently approved by the FDA and is also called the Glaucus Trabecular Micro-Bypass Stent. It is a very tiny L-shaped device made of titanium, 1 millimeter long and 0.33 millimeters high. Compare the average thickness of a human hair--.04 and .25 and you realize its infinitesimal size; furthermore, it is pre-loaded rendering it ready for implantation inside the eye. It is designed to increase the flow of fluid out of the eye by creating a direct path for fluid to reach Schlemm's Canal, bypassing the trabecular meshwork.



Schlemm's Canal then removes the fluid through an osmotic process into the veins of the body.

At this point in time the procedure is performed in adults with mild to moderate glaucoma who are being treated with medications to reduce eye pressure.

The i-Stent is primarily for use in open-angle glaucoma. However other glaucoma patients may benefit from the procedure once data on these patients is collected. Conditions that may <u>not</u> be amenable for iStent® or are currently investigational are:

- **Chronic angle-closure glaucoma, where the fluid is prevented from leaving the eye because the angle of the eye, where the fluid normally drains out, gets closed off. Dr. Mackool has used the iStent® in patients with narrow angles and partially closed angles with success. However more data analysis is needed.**
- **The stent is NOT used in patients with any condition that causes high pressure in the veins into which the collector channels of the eye drain the fluid, such as thyroid eye disease, a tumor behind the eye, or a "port-wine stain" birthmark involving the upper eyelid caused by an abnormal**

collection of small vessels near the eye.

- **Pigmentary dispersion syndrome, or exfoliation are potentially iStent® territory and Dr. Mackool has used the stents with success; however more data collection is required.**
- **Neovascular glaucoma due to diabetes or any other cause is a contraindication to iStent® use.**

On average pressure is lowered by three points with iStent®. In studies, however Dr. Mackool has had cases where pressure was reduced by 50% and that success certainly rivals a trabeculectomy. Two iStents® can be introduced into the eye with obviously greater pressure lowering effects, but the FDA has not approved that strategy. Dr. Mackool Sr. has placed two iStents® in many patients; however this must be done out of insurance. In general if you have glaucoma that cannot be controlled with medications, then the iStent® is not the best option and a trabeculectomy or other filtering procedure should be considered. If your glaucoma is controlled by medications, then the iStent® is an attractive option.

When using two iStents®, they are placed in opposite directions like a ring around the eye. Dr. Mackool assured the group that the iStent® was easy to insert and the entire operation, cataract removal, lens and stent could all be performed with the patient awake using topical anesthesia with intravenous sedation.

It is preferable to combine the iStent® with cataract surgery to avoid additional surgery. Those who have already had trabeculectomies and other surgeries may not be the right candidates for iStent®, but as Dr. Mackool stated, this is unchartered territory and one never knows what new guidelines will develop in the coming years. Right now we are at the very beginning in our use of this technology. It has been available in the United States for only the past several months. Dr. Mackool, however, has seen excellent results. Since he began using the device some patients no longer needed drops; other patients were able to use fewer drops.

In a study that Dr. Mackool cited, the number of drops prescribed pre-operatively was 2.3. This figure decreased to 0.6 within six months after surgery and 66% of patients were drop-free. There are a number of

studies now underway. As with any new procedure or device, researchers evaluate effectiveness by conducting both short- and long-term studies.

Dr. Mackool stated that the stents offer exciting possibilities and they are safer than the traditional operations for glaucoma. With a stent you can be more pro-active. The doctor can assure the patient that the stent will most likely improve pressure and very unlikely create problems deriving from its insertion. The implant itself is stable. It doesn't get displaced. A tiny hole is punctured in Schlemm's Canal, a structure that runs 360 degrees around the eye, allowing for the filtering of fluid out of the eye. The fluid accumulated in the Canal seeps out slowly. It does not flush out immediately, and the eye will not develop too low a pressure.

Determining who will benefit from the implant is decided on a case by case basis. In the future, aiming for a drop-free existence or a reduction in the number of drops after cataract surgery will likely become routine. Once the iStent® is inserted even if you still require medications, it provides a route for avoiding more extensive glaucoma surgery down the road by lowering pressure. For uncontrolled glaucoma patients, Dr. Mackool told the group that it is not the best option. The iStent® takes advantage of the eye's natural drainage system but when glaucoma is uncontrolled the drainage system is compromised. Chances of the iStent® working for uncontrolled glaucoma, are, therefore, unfortunately minimal.

HEALING:

In cataract surgery and iStent® surgery people return to normal activities the day after surgery. Vision is usually good the first week and best by two weeks. The majority of patients are off steroid drops by six weeks. The human body responds to surgery with inflammation and patients are kept on steroid drops as a precaution to counter the inflammatory response.

WHO NEEDS CATARACT SURGERY:

Cataract surgery has become much more prevalent and is performed earlier now due to dramatic improvements in safety and outcomes. Cataracts usually grow slowly although there are cases of rapid progression. There is no need to wait for a cataract to "ripen." When you have symptoms from a cataract it is time to have surgery.

In almost all cases cataract surgery is performed one eye at a

time. It is best to allow the operated eye to recover before the second eye is done. In most cases the iStent® is used for early stages of glaucoma. At present the iStent® is mainly used on eyes that have not had glaucoma or cataract surgery and it is implanted at the same time that cataract surgery is performed. Dr. Mackool Sr. has placed iStent® on patients well after they have had cataract surgery with excellent results; however this must be done out of insurance. While we do know the iStent® works well in these patients, FDA approval is pending. Once the procedure is approved for patients who have already had cataract surgery, the iStent® can be performed under insurance.

SECONDARY CATARACT:
This problem occurs when the capsule holding the lens becomes opacified. It can be corrected by using a YAG Laser that creates an opening, permitting the penetration of light onto the retina.

HYPOTONY:
This condition can follow traditional glaucoma surgery. It does NOT occur with the iStent® because the stent enhances the eye's normal drainage system, bypassing the internal filtering layer of the eye.

RESTOR LENS / MULTIFOCAL IMPLANTS:
Dr. Mackool also performs multifocal lens implants that allow patients to both read and see in the distance without glasses, but he does not recommend this procedure for glaucoma patients. Glaucoma patients are more subject to vision loss and the multifocal implants are not designed for patients with compromised vision. He feels the standard implants allow the patient better sight; however the patient will need to use glasses for reading. Multifocal implants are not covered by insurance. Dr. Mackool also performs laser vision correction. Usually, people in their 20's and 30's opt for laser vision correction, allowing them to see without glasses.

MACULAR DEGENERTION:
There is a new lens invented by Dr. Richard Mackool, Sr. It is presently in the study phase, but it promises to restore reading vision to patients with macular degeneration. Since the study is in its formative stages, those persons with ARMD plus cataracts would be eligible to join in the study. The lens under study is a strong bifocal lens. It allows

patients to hold objects close to their eye(s) to read.

CATARACT AFTER TRABECULECTOMY:

Cataract surgery for patients with previous trabeculectomy is performed without femtosecond laser to avoid injuring the bleb, and the inflammatory process following surgery needs to be controlled to protect the filtering bleb. For patients having cataract surgery who also have a trabeculectomy, a substance called Viscoelastic, a jelly-like substance, is placed in the filter to prevent lens material from entering the bleb. Once cataract surgery is finished, 5-FU, an antimetabolite medication that works on scar tissue, is injected near the bleb to prevent scarring. It's important to do careful follow-up of eye pressure when a cataract operation is performed on an eye that has had a trabeculectomy.

We want to thank Dr. Mackool for bringing this very exciting technology to our attention. Those of us who are newly diagnosed will certainly benefit from learning about these options. What is especially exciting as Dr. Mackool pointed out is that benefit is high and risk is low. At the meeting Dr. Mackool mentioned that you can call the office for a free booklet with information on eye conditions to be sent to you. The number is 718-728-3400. You can visit his website at www.drmackool.com or www.mackoolonline.com.

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