

Improving *Ab Interno* Trabeculotomy

A combination of advanced technology and insightful design may prompt surgeons to adopt a new technique for lowering IOP.

BY JULIA T. LEWANDOWSKI, SENIOR ASSOCIATE EDITOR

Glaucoma Today's "Innovators" column profiles promising technological developments in glaucoma and the companies bringing them to fruition.

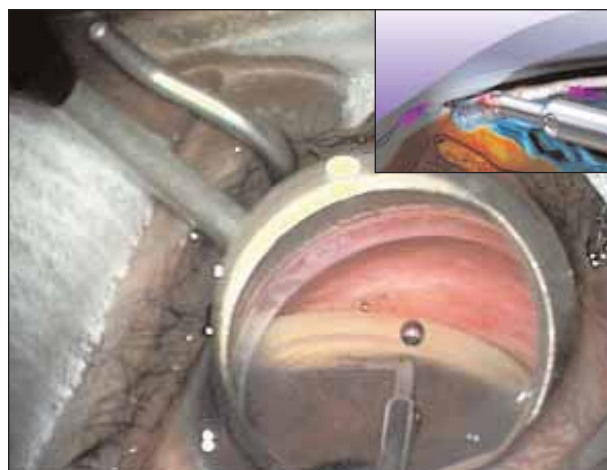
Glaucoma patients who fail to achieve lower IOPs on maximally tolerated medical therapy almost always need surgery to halt the progression of their disease and preserve their remaining vision. Surgical intervention is usually limited to the implantation of an external drainage device or the creation of a filtering bleb. Now, surgeons can choose from several *ab interno* approaches designed to reduce the resistance to outflow through the trabecular meshwork or to bypass it completely.

George Baerveldt, MD, Irving H. Leopold Professor and Chair of the Eye Institute at the University of California, Irvine, is best known as the inventor of the Baerveldt glaucoma implant (Advanced Medical Optics, Inc., Santa Ana, CA). His experience as a young physician in his native South Africa, however, gave him the idea for an *ab interno* procedure that would restore the eye's physiologic outflow. His vision led him to develop the Trabectome (NeoMedix, Inc., Tustin, CA).

TECHNOLOGICAL CHALLENGES

While an ophthalmology resident at the University of the Witwatersrand in Johannesburg, South Africa, Dr. Baerveldt noted that pediatric glaucoma patients often achieved lower IOPs after goniotomy.

"During a goniotomy, the surgeon cuts through the trabecular meshwork into Schlemm's canal," said Dr. Baerveldt in an interview with *Glaucoma Today*. "The elasticity of the trabecular meshwork in children pulls the cut edges of the structure away from each other and maintains a pathway for the aqueous to flow directly into the collector channels." Because the trabecular meshwork in adult eyes lacks this flexibility, the clefts



(Photograph courtesy of Kenneth B. Mitchell, MD. Inset courtesy of NeoMedix, Inc.)

Figure 1. The insulated foot plate on the Trabectome's hand-piece (inset) protects the outer wall of Schlemm's canal as the probe ablates the trabecular meshwork.

created by goniotomy tend to close, thus limiting the procedure's long-term IOP-lowering capabilities.

"For adults to achieve results similar to those seen in children, we would need to completely remove an entire strip of the trabecular meshwork over as much of the angle as possible," Dr. Baerveldt concluded. "The challenge was to design an instrument that was small enough to fit into the anterior chamber and remove the tissue without damaging adjacent structures."

The Trabectome's single-use, 19.5-gauge intraocular probe combines the irrigation and aspiration functions of phacoemulsification technology with an electrode that ablates tissue from the inner wall of Schlemm's canal. To protect the collector channels and the outflow system in the outer wall of Schlemm's canal from the probe's energy, Dr. Baerveldt designed an insulated foot plate (Figure 1). "The addition of the foot plate was a breakthrough that improved the safety of the hand-

piece," he said. "The probe's irrigation and aspiration capabilities help us maintain the anterior chamber while we use the foot plate to guide the removal of the trabecular meshwork."

CLINICAL RESULTS

According to data on file with NeoMedix, Inc., the IOP of 434 patients who underwent the Trabectome procedure decreased on average from 24 to 16 mm Hg (40%) at 52 months postoperatively (Figure 2). The average number of medications used dropped from three to one, and only 22 patients (5.1%) subsequently underwent a trabeculectomy. Even fewer patients required the placement of a tube shunt (seven of 434; 1.6%) or completely failed to achieve lower IOPs (four of 434; 0.9%). (See "Ab Interno Trabeculotomy" in the November/December 2006 issue for a case study of the Trabectome.)

Several physicians interviewed by *GToday* reported similar results among their Trabectome patients.

Kenneth B. Mitchell, MD, Chief of Glaucoma Service at the University of South Carolina School of Medicine in Columbia, has treated 13 patients with the Trabectome in the past 3 months. "Their IOPs dropped a minimum of 30% after the procedure," he noted. "One patient needed extra care and the reinstitution of medical therapy. It may be too soon to tell if the effect will persist in some of these patients, but I am encouraged by the early results."

Approximately 70% of the patients treated with the Trabectome by Douglas J. Rhee, MD, Assistant Professor of Ophthalmology at Harvard Medical School in Boston, have achieved clinical success (defined as lower IOPs not requiring additional surgery at last follow-up), and 12 of the 17 patients treated by Quang H. Nguyen, MD, Director of the Glaucoma Service at Scripps Clinic Torrey Pines in La Jolla, California, no longer use IOP-lowering drugs. "Three of the patients who still need medication were able to reduce the number of drugs they use from four to one, however," commented Dr. Nguyen.

John R. Tribble, MD, a private practitioner from Des Moines, Iowa, emphasized the advantages of the Trabectome versus incisional surgical procedures. "Because *ab interno* trabeculotomy with the Trabectome does not produce a bleb, it eliminates many of the complications associated with traditional filtration surgery such as hypotony and late infection," he wrote in an email to *GToday*. "The procedure does not require the implanta-



Figure 2. This graph shows the mean IOPs $\pm$ SD of 434 patients treated with the Trabectome through 52 months postoperatively (data on file with NeoMedix, Inc.).

tion of a permanent device, which reduces the risk of chronic inflammation, erosion with infection or damage to adjacent structures, and accelerated corneal endothelial cell loss."

The results of the Trabectome procedure vary among individual patients. "Some of the 20 patients I have treated showed a modest drop in IOP from 24 to 15 mm Hg, whereas others' IOPs decreased from 48 to 11 mm Hg," noted Dr. Tribble.

Dr. Baerveldt considers *ab interno* trabeculotomy with the Trabectome a failure if a patient's IOP does not decrease by 30% or if he does not achieve postoperative IOPs of 18 mm Hg or lower. "I do not know why the procedure does not work for everyone, but we suspect that it may be because the collector channels are not functioning properly or are blocked by some type of debris," he said. "We are trying to identify the physiologic factors that may contribute to the procedure's failure in some patients."

Dr. Nguyen stated that his familiarity with the Trabectome did not influence its success or failure: "The patients who did not respond to the surgery were not the first ones I treated, so I do not attribute the results to a learning curve."

ADVERSE EVENTS

Data on file with NeoMedix, Inc., show a low incidence of adverse effects with the Trabectome. According to Dr. Rhee, potentially significant postoperative complications include peripheral corneal damage and aqueous misdirection, but the 52-month follow-up data show that the former is not evident and the latter has occurred in only one (0.2%) of 434 cases.

The most common adverse event associated with the Trabectome is transient hyphema. "Because Schlemm's

canal is connected to the eye's venous outflow system, the presence of blood in the anterior chamber indicates that we successfully removed the trabecular meshwork," said Dr. Baerveldt. "The hyphema usually resolves spontaneously by 1 week postoperatively."

To minimize the accumulation of blood in the anterior chamber, Martha M. Leen, MD, a glaucoma specialist from Bremerton, Washington, asks patients to discontinue the use of anticoagulants such as coumadin, aspirin, or clopidogrel bisulfate (Plavix; Sanofi Aventis, Bridgewater, NJ) prior to surgery. She also instills apraclonidine preoperatively to constrict the blood vessels in the eye.

In addition to using apraclonidine, Dr. Baerveldt has patients sit upright immediately after the surgery to increase the pressure gradient between their heads and hearts. "We have also found that the placement of a suture over the clear corneal incision at the conclusion of surgery reduced leaking from the wound and dramatically decreased the size of postoperative hyphemas," he said.

The second most common adverse event associated with the Trabectome procedure is a postoperative spike in IOP, which has occurred in 79 (18.2%) of the 434 patients treated to date (data on file with NeoMedix, Inc.). Drs. Nguyen and Tribble have observed pressure spikes in at least one of their patients, but they noted that the risk of this complication can be minimized by evacuating all of the ophthalmic viscosurgical device from the anterior chamber at the end of surgery. "I recommend performing irrigation and aspiration of the anterior chamber for at least 3 minutes at the conclusion of surgery to remove as much venous blood as possible and to ensure that no viscoelastic remains inside the eye," commented Dr. Nguyen.

PATIENT SELECTION

Like other surgical procedures that utilize the eye's physiologic outflow system, the Trabectome probably will not lower patients' IOP as much as trabeculectomy. Nevertheless, Dr. Rhee believes that the Trabectome can be offered to patients with all stages of glaucoma as an alternative to trabeculectomy, with surgeons always taking into account the factors affecting each individual case. "In my experience, the Trabectome has a decreased chance of success compared with a trabeculectomy, but the risks are lower and the rate of postoperative recovery is faster with the Trabectome," he said. "In addition, because the procedure does not disrupt the conjunctiva, patients can still undergo trabeculectomy if the Trabectome fails."

To date, the Trabectome has been used either during standalone surgery or in conjunction with cataract extraction on patients who have primary open-angle

glaucoma. In addition to focusing on this patient population, Dr. Tribble has offered *ab interno* trabeculotomy with the Trabectome to individuals with pseudoexfoliation and pigmentary dispersion glaucoma, and to patients who have lower IOPs that tend to spike, especially if they have progressive visual field loss. "In my experience, the Trabectome procedure seems particularly well suited to young myopes who do not need exceedingly low IOPs. I offer the Trabectome to these patients as a lower-risk alternative to filtration surgery."

BARRIERS TO ACCEPTANCE

Despite the procedure's reported safety and efficacy for lowering IOP,¹⁻⁴ glaucoma surgeons have been slow to adopt the procedure. One obstacle to the Trabectome's acceptance, wrote Murray A. Johnstone, MD, Consultant in Glaucoma for the Department of Ophthalmology at the Swedish Medical Center in Seattle, in an email to *GToday*, may be surgeons' level of comfort with the *ab interno* technique. "The Trabectome requires the same surgical skills as goniotomy, which are very different from those used during trabeculectomy," he said. "Few surgeons routinely perform goniotomy, and their lack of familiarity with the necessary skills may contribute to their reluctance to try the Trabectome." The skill set is relatively easy to master, he added, stating that the procedure is fairly straightforward once surgeons become familiar with the device.

Reay Brown, MD, a private practitioner from Atlanta, agreed that the Trabectome appears to meet the criteria for successful glaucoma surgery, but he has not asked the ambulatory surgical center at which he works to purchase the equipment, and cited the device's price as a reason for his hesitation. "The procedure is reportedly safe, effective, requires little follow-up, and can be performed in 20 minutes or less," he said in an interview with *GToday*. "If it did not require a large capital investment, I would have started using the Trabectome already. I do not feel right asking my ambulatory surgical center to spend thousands of dollars on the device without good evidence of its long-term efficacy, however. I need to be sure that the surgeons who buy a Trabectome are still enthusiastic about the procedure 6 months or 1 year later. I am nearly convinced."

HUMANITARIAN APPLICATIONS

Dr. Baerveldt envisions the role of the Trabectome differently in first versus third world countries. "In industrialized countries like the US, I would place the Trabectome in my treatment hierarchy between medical therapy and minimally invasive surgical procedures such as selective laser and argon laser trabeculoplasty," he said. "In third world countries, however, the

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Trabectome may be a viable first-line alternative to medical therapy for early glaucoma."

The reason, he explained, is that IOP-lowering medications are expensive in developing countries. Even when patients can afford the drugs, he noted, they may avoid using them because of ocular discomfort or no visible improvement in their condition.

Dr. Nguyen pointed out that the bleb is a liability in glaucoma surgery. "Patients who undergo *ab interno* trabeculotomy with the Trabectome require fewer postoperative visits compared with those who undergo a typical trabeculectomy with an antimetabolite," he commented, based on his experience. "Theoretically, this makes a lot of sense for people who may not have access to dependable healthcare."

Upon the Trabectome's acceptance by glaucoma surgeons in the US, Dr. Baerveldt hopes to introduce the procedure in developing countries as a first-line therapy. "In order to do this, we need to lower the price of the procedure by mass producing the Trabectome instrument and to begin teaching surgeons from other countries to perform the surgery," he said. □

The physicians interviewed for this article acknowledged no financial interest in the products or companies mentioned herein unless otherwise noted.

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