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## GLAUCOMA

OCULAR SURGERY NEWS EUROPE EDITION June 1, 2009

### Glaucoma surgery heading toward a less invasive, more effective approach

For years trabeculectomy has remained the gold standard for surgical management of glaucoma. Although a few variations in the technique and in the use of antimetabolites have occurred over the years, the procedure has remained substantially the same since its introduction in the late 1970s.

"If we compare it with the techniques that are used in other branches of ophthalmology, like cataract or vitreoretinal surgery, where revolutionary changes have dramatically improved results and minimized complications, we can't avoid feeling some degree of frustration," Roberto Carassa, MD, director of the Italian Glaucoma Center in Milan, said.

Trabeculectomy has a congenital defect, Dr. Carassa said. It does not get to the root of the problem but "makes a hole in the eye" through which the aqueous humor can flow. The principle works, but bleb failure — due to fibrosis and encapsulation — and bleb-related risks such as leaks and endophthalmitis make results unpredictable and dependent on the individual response of each eye.



Roberto Carassa, MD, director of the Italian Glaucoma Center in Milan, said that new glaucoma surgical approaches are going to the root of what causes outflow resistance and, consequently, the IOP increase.

Image: Carassa R

Story continues below ↓

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In the early 1990s, new procedures such as viscocanalostomy and deep sclerectomy aimed to redirect the aqueous into its natural collector channels, principally Schlemm's canal. Of the two, deep sclerectomy also maintained some degree of external filtration and bleb formation.

Nonpenetrating procedures are now well-established in the armamentarium of glaucoma surgery. If some doubts remain about their efficacy compared with trabeculectomy, this is because published results are dishomogeneous.

In a 1999 *Journal of Cataract and Refractive Surgery* editorial, "Nonpenetrating trabecular surgery: it's worth the change," Philippe Sourdille, MD, a pioneer of nonpenetrating surgery and the inventor of the SKGel (Corneal) resorbable crosslinked hyaluronic acid implant, highlighted this change from penetrating to nonpenetrating as a demanding step.

"I share with Robert Stegmann, MD, the concept of surgeon-related results. However, the lower rates of complications and new technical options with lasers for the pre-Descemet approach are positive arguments in favor of nonpenetrating surgery today," Dr. Sourdille said.

Drainage devices such as the Molteno implant (Molteno Ophthalmic), the Baerveldt glaucoma shunt (Abbott Medical Optics) and the Ahmed glaucoma valve (New World Medical), also in use for many years, work by bypassing the trabecular meshwork and redirecting the aqueous humor into a subconjunctival bleb. They were intended for high-risk eyes in which standard trabeculectomy was expected to fail.

Recently, there has been an increased interest in the development of novel approaches.

"Some of them are in addition to previous techniques aimed at optimizing results. Some other approaches are attempting new ways of addressing the problem by going at the root of what causes the outflow resistance and, consequently, the IOP increase," Dr. Carassa said.

#### iTrack microcatheter

Canaloplasty is, conceptually, a new development of viscocanalostomy. Via a scleral flap, a special cannula with a lighted tip, the iTrack microcatheter (iScience Interventional), is inserted through the entire circumference of Schlemm's canal and used to inject viscoelastic. While the catheter is slowly withdrawn, the substance is released sequentially, filling — and therefore dilating — the entire 360° length of the canal. The iTrack is used at the same time as a guide for placing an intracanalicular suture to stretch and hold open Schlemm's canal.

According to Manfred Tetz, MD, director of the Spreebogen private surgical center in Berlin, canaloplasty is

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used by a relatively closed group of surgeons, the same who used viscocanalostomy after it was introduced by Dr. Stegmann.

"Both techniques require a sensitive hand and a great deal of precision. However, those of us who were used to viscocanalostomy have welcomed this new development," Prof. Tetz said.

The results of an international, multicenter, prospective study showed a high rate of success in terms of stable IOP lowering (from mean preop 24.7 mm Hg to mean 15.5 mm Hg at 1 year) and reduction of medications (from mean 1.9 to mean 0.6 per eye) in patients in whom suture tension and, therefore, effective trabecular meshwork distension was achieved. A combination of canaloplasty with cataract surgery was shown in a later study to lower and stabilize IOP even further.

"Results are also significantly better compared to those of viscocanalostomy. In my own series of patients, I've obtained a stable pressure of 13.5 mm Hg to 14 mm Hg, around 3 mm Hg lower than in my previous viscocanalostomy patients," Prof. Tetz said.

### Trabectome bypass device

The Trabectome (NeoMedix) is a surgical device that allows electro-ablation of an arc of trabecular meshwork and inner wall of Schlemm's canal via gonioscopic microsurgery.

George Baerveldt, MD, best known as the inventor of the Baerveldt glaucoma implant, was the first to develop the idea of restoring the eye's physiologic outflow by an ab interno procedure. He said pediatric glaucoma patients often achieved lower IOPs after goniotomy, and he hypothesized that, in adults, the same results could be obtained by removing a strip of the trabecular meshwork. His vision led him to develop the Trabectome.

"To date, some 65 U.S., Mexican, Canadian and Japanese ophthalmologists are actively using the device, and data from more than 1,000 surgeries including Trabectome-only and combined Trabectome-phacoemulsification have been published in peer-reviewed literature. Success defined as an IOP decrease of at least 20%, decrease in adjunctive medications and no repeated surgeries among all cases has been about 70%," said Donald S. Minckler, MD, a professor at the University of California, U.S.A. "Complications have been minimal compared to trabeculectomy. All participating surgeons have undergone pre-use training, including a didactic, a wet lab and live surgery observation."

The procedure takes about 30 minutes. The Trabectome handpiece tip is inserted in the chamber through a small incision and removes a small strip of the diseased tissue with an electro-surgical pulse. The same handpiece provides continuous irrigation and aspiration flow to regulate the temperature and remove tissue debris.

According to Dr. Minckler, the Trabectome is safer and simpler than currently available alternative glaucoma surgical therapies and has the potential to become a new standard in surgery.

"Trabectome has many advantages," he said. "It is minimally invasive surgery via a clear corneal wound, and no external bleb is created. Consequently, as the conjunctiva is not manipulated, it does not preclude subsequent procedures."

### Ex-PRESS mini shunt

According to a number of glaucoma specialists, a new era of glaucoma surgery has been heralded by the introduction of the latest-generation drainage devices.

The Ex-PRESS miniature glaucoma shunt (Optonol) measures less than 3 mm in length and 0.4 mm in diameter and is made of a highly compatible material, the same used worldwide for cardiac stents.

The device works on the same principle as trabeculectomy, lowering IOP by diverting the aqueous humor from the anterior chamber to the subsceral and subconjunctival spaces to form a filtration bleb, but the predetermined restricted lumen (50 µm or 200 µm) makes the aqueous flow in a more controlled, predictable and standardized way, with a lower rate of complications.

"Surgery is also different and can be defined as minimally penetrating because no tissue excision or removal is required. The advantage over classic nonpenetrating surgical procedures, however, is the shorter learning curve. It can be implanted by both a glaucoma specialist and a general ophthalmologist," said Elie Dahan, MD, senior glaucoma consultant at Ein Tal Eye Center in Tel Aviv.



Elie Dahan

For all of these reasons, the Ex-PRESS has a wider range of indications than classic filtering surgery and can be offered as an option also in the earlier stages of the disease, if not as a first-line treatment.

"We all know the advantages of doing surgery on eyes that have never been exposed to medical treatment," Dr. Dahan said.

To date, more than 35,000 Ex-PRESS shunts have been implanted worldwide, with good results and a low rate of complications. Implantation under a scleral rather than a conjunctival flap is now the only recommended technique because it is safer and more effective. Mitomycin C is used at the time of implantation.

In a prospective, randomized study (15 patients, 30 eyes), Dr. Dahan compared the results of trabeculectomy and Ex-PRESS implantation in fellow eyes of the same patient during a 30-month period. Although the mean IOP reduction was similar in both groups at all time points, at 2 years, the complete success rate (IOP less than 18 mm Hg without medications) was higher in the Ex-PRESS group (90%) compared with the trabeculectomy group (60%).

"What's astonishing is the difference in the rate of postoperative complications, which was only 7% in the Ex-PRESS group compared to 40% in the trabeculectomy group," he said.

Similarly, 33% of the trabeculectomy eyes needed postoperative interventions compared with 0% in the Ex-PRESS eyes.

The 3-year results of a large series of 231 eyes treated with Ex-PRESS implantation alone and 114 eyes treated with Ex-PRESS implant combined with phacoemulsification were recently analyzed by Peter Netland, MD, and colleagues. Surgical success was about 95% in both groups. Compared with baseline values, postoperative IOP and number of glaucoma medications were significantly lowered in both groups. Interestingly, the change from baseline IOP was significantly greater after Ex-PRESS implantation alone compared with combined surgery. The most common but rare device-related complication was obstruction of the tube in six eyes, and it was treated successfully with Nd:YAG laser.

### iStent trabecular micro-bypass implant

The iStent trabecular micro-bypass implant (Glaukos) offers potential benefits similar to those of viscocanalostomy. It lowers IOP without the formation of a filtering bleb and, therefore, without affecting the conjunctiva. It is delivered ab interno through a clear corneal incision, advanced through the trabecular meshwork and implanted through a pre-loaded applicator into Schlemm's canal.

"Since 50% to 90% of resistance to aqueous outflow is in the trabecular meshwork, it makes a lot of sense to have a bypass device that creates a pathway for the aqueous to drain directly from the anterior chamber to the Schlemm's canal," said Ike K. Ahmed, MD, FRCS, assistant professor at Toronto University, Canada.

The first studies were carried out in Europe, basically looking at the results of one stent implantation in combination with cataract surgery. A 22% mean IOP reduction was obtained, and the mean number of medications dropped from 1.7 to 0.5 per eye.

Dr. Ahmed and colleagues found that better results can be obtained with more than one stent because multiple bypasses further reduce outflow resistance.

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"In a consecutive series of 25 patients with [primary open-angle glaucoma] or [pseudoexfoliation glaucoma], we evaluated the results of the implantation of two or three eye stents in combination with cataract surgery. The follow-up ranged from 6 months to 1 year," he said.

Mean IOP decreased from 20.5 mm Hg preoperatively to 14.2 mm Hg with two stents and to 12.7 mm Hg with three stents. Three stents appear to be more effective also in reducing medication use, which dropped from three to 1.5 with two stents and to zero with three stents. Results remain stable beyond the 1-year endpoint of the study.

The biggest advantage compared with trabeculectomy is the near absence of any serious sight-threatening complication, with results that are reasonable in terms of efficacy, Dr. Ahmed said.

"We are trying to overcome the biggest drawback of non-traditional surgery, which is the limitation in IOP-lowering capability. This study shows that we may be able to obtain results beyond our own expectations with trabecular bypass surgery," he said. "In addition, we are able to titrate the number of stents required for a given patient, from one to three or, theoretically, even more, depending on the target pressure and disease severity."

The concept of creating multiple bypasses over a larger area of the canal to provide a further reduction in outflow resistance will be tested further, with longer follow-up and more controlled studies.

### Gold Micro-Shunt

The "third way" pursued by drainage devices is the suprachoroidal way, "a very natural pathway of aqueous filtration, exploited by the Gold Micro-Shunt (Solx)," according to Gabriel Simón, MD, PhD inventor of the device and director of the Gabriel Simón Institute in Madrid and Barcelona.

Rather than a tube, this implant is a tiny, 24-karat gold flat plate, containing multiple microchannels.

Inserted through a 2.8-mm incision at the limbus, the shunt creates a bridge between the anterior chamber and the supraciliary space. The difference in pressure gradient between these two areas draws the aqueous from the anterior chamber through the microtubules of the implant, lowering IOP without creating a bleb.

"The Gold Micro-Shunt can be used in conjunction with a special titanium-sapphire 790-nm laser (Solx), which is used to open the drainage channels," Dr. Simón said.

At the time of implantation, not all of the channels are activated. Some are held in reserve and can be titrated at a later stage to increase outflow if needed.

This new technology has numerous advantages.

"First of all, it recuperates a natural outflow pathway. So you basically are dumping fluid to a place where it is supposed to go, like a cyclodialysis. There is no bleb, which is a reservoir created in an unnatural place, leading to a great deal of complications. Second, you can modulate the flow. Profiting from the fact that you are working on a transparent tissue as the cornea, you can visualize the front of the shunt that is exposed to the anterior chamber and then, with the laser, you can open new channels," Dr. Simón said.

These postoperative adjustments allow a modulation of the target pressure according to the individual response of the patient and to the stage of disease progression.

"Treating glaucoma is not just a matter of lowering the pressure. It's lowering the pressure to the point you need. This technology gives us this new possibility," he said.

Another considerable advantage of the Gold Micro-Shunt is that it is an easy surgical procedure, which can be performed in about 10 minutes under topical anesthesia.

From the clinical point of view, results are "astounding," according to Dr. Simón, who has personally implanted more than 300 Gold Micro-Shunt devices.

"I'm not saying that we have achieved the perfect product, but I think we are heading to perfection. Although there are some cases in which the shunt doesn't work as well as we would like, we have some idea of why this happens," he said. "On the other hand, we have a big number of cases, more than 70%, in which we achieve the pressure we want, and we are talking about very aggressive glaucoma, where all other ways of lowering pressure have been tried and failed." – by *Michela Cimberle*

### POINT / COUNTER

Could modern surgery become a primary option in glaucoma treatment?

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