

MIGS Seen as the ‘New Sexy’ in the Glaucoma Device World

By LARRY HAIMOVITCH, Medical Device Daily Contributing Writer

SAN FRANCISCO — The second annual “Glaucoma 360 New Horizons Forum,” sponsored by the non-profit organization Glaucoma Research Foundation (GRF; San Francisco) was held here on Friday, February 1st. GRF, which was founded in 1978 by three glaucoma specialists, is a national non-profit organization that funds glaucoma research worldwide. GRF’s major collaborative study, “Catalyst for a Cure,” has redefined how glaucoma research is conducted and fostered a tremendous surge in the understanding of this extremely complex disease.

The New Horizons Forum was designed as a means to bring together worldwide leaders in medicine, science, business, venture capital and philanthropy. It is a forum to share the latest thinking and ideas for dealing with glaucoma, which because of its symptom-less nature, has often been described as a “silent thief of sight.”

Louis Cantor, MD, director of the Glaucoma Service at the Glick Eye Institute, Indiana University School of Medicine (Indianapolis), delivered a keynote address titled “State of Glaucoma Therapy 2013: Is 13 our Lucky Number?”

He noted two key conclusions from the myriad National Eye Institute (Bethesda, Maryland) glaucoma clinical trials: one, that early treatment and the lowering of intraocular pressure (IOP) is critical to minimizing the risk of disease progression and two, that it is vital to maintain a steady level of IOP over time.

Glaucoma researchers now hypothesize that the loss of visual input to the brain may result in early changes to the central nervous system. Indeed, Cantor said that “glaucoma is really a central nervous system disease.”

He further opined that the central nervous system changes resulting from an elevated IOP are currently irreversible and that this strongly supports the need for earlier and more aggressive glaucoma therapy. Further, retinal ganglion cell loss, which occurs in glaucomatous eyes, firmly confirms the need for “neuroprotection,” or a means to protect these precious cells from injury.

Cantor expressed considerable enthusiasm for the various minimally invasive glaucoma surgery (MIGS) devices that are either commercialized or well along in their clinical trials.

“These are very exciting new products and allow for safer and more effective procedures,” he said.

Medical management, which is virtually always the first line of defense in treating glaucoma, has resulted in an annual market of more than \$5 billion worldwide. Despite being relatively safe and efficacious, the physicians treating these patients are very frustrated by a dismal compliance rate that

has been estimated in several studies to be in the 40% to 50% range. As a result, many patients do not attain or maintain the desired level in their IOP and their glaucoma progresses.

There appear to be three solutions to this dilemma: (1) Better delivery of existing drugs. An entire section of the program here was devoted to presentations from a clutch of private companies who have developed creative solutions; (2) New drugs that improve compliance through either a reduced dosing regimen or are more powerful and safer. Another section of the program featured excellent presentations on this topic; (3) Better surgical and device alternatives, such as MIGS.

In a talk titled “The Future of Glaucoma Surgery,” renown glaucoma expert Ike Ahmed, MD, from the University of Toronto said that MIGS is ushering in an exciting new field which he dubbed “interventional glaucoma.” Moreover, their availability is making glaucoma surgery “the new sexy.”

He indicated that these new human hair-sized, implantable stent-like devices will target patients and their surgeons whose needs are not being well served by the current treatment options. He predicted that MIGS would find a role primarily in patients with mild to moderate glaucoma patients (approximately 60% of the total patients) whose IOP was not fully controlled with medications. He suggested that MIGS would be slotted after medications and either before or after laser trabeculoplasty.

The excitement for MIGS in the glaucoma community is tangible. To wit, the cover story for the November/December 2012 issue of Glaucoma Today was devoted to MIGS and the lead author John Berdahl, MD, from Vance Thompson Vision and Sanford Health (both Sioux Falls, South Dakota) wrote that “. . . the MIGS category represents the first step towards an array of new devices for glaucoma surgery.” The article also said that “. . . MIGS has the potential to be offered as an alternative to medications for first-line therapy.”

MIGS devices were a prominent part of this year’s program, as several privately-funded, venture capital backed companies presented on the clinical or commercial status of their devices. A clear indication of how “hot” MIGS is in the venture capital community was amply shown last week when one of the presenters here, Ivantis (Irvine, California) reported that it has closed on a \$27 million funding in the first closing of its Series B round. Its press release stated that these funds will be used to support four randomized, prospective, controlled multi-center trials at various stages around the world, including an ongoing U.S. trial. The company had previously raised \$36 million in 2008 and 2010.

Other MIGS firms have raised substantial funds as well. For example AqueSys (Aliso Viejo, California) CEO Ron Bache noted in his presentation that his company has raised \$47 million to date. Industry leader Glaukos (Laguna Hills, California), which is the only company with an FDA approval thus far, indicated in a September 2012 press release that it had raised \$126 million. Informed industry sources believe that it has raised an additional \$25 million to \$50 million in the past few months.

Transcend Medical (Menlo Park, California) has also raised substantial sums, with \$10 million in its Series A round and \$51 million in its Series B. The company announced at this meeting that it expects to

complete enrolment of its COMPASS domestic pivotal trial in the next couple of months. The trial, which will have enrolled 505 patients in total, utilizes the company's CyPass Micro-Stent. A PMA will be filed in 2015, after an FDA mandated two-year follow-up.

Although not a newcomer to the MIGS space, with more than 100 implants done globally to date, InnFocus (Miami) has been in "stealth mode" until recently. Its CEO Len Pinchuk discussed the company's stent technology, which is unique in the MIGS space since it employs a fundamentally different approach to the reduction of IOP.

The InnFocus MicroShunt, which is made from a proprietary ultra-stable biocompatible material that will not provoke scar tissue in the eye, does not shunt aqueous fluid from the same areas where the other companies devices drain from (i.e., Schlemm's Canal or the supra-choroidal space). Rather, it is inserted where it can bypass both the trabecular meshwork and the venous resistance, which may well be the most important culprit in elevated IOP.

The table outlines what the InnFocus believes are the key attributes of the ideal MIGS procedure.

Table: The Ideal Minimally Invasive Glaucoma Surgical Device

- Long-term IOPs \leq 14 mm Hg
- Less than 15 minute procedure
- Safe
- Minimal patient follow-up
- Procedure that anterior segment surgeons can perform
- Procedure that can be performed with and without cataract surgery
- Greater medication reduction

Source: InnFocus Presentation, New Horizons Glaucoma Meeting, February 2013

Its goal is to drop intraocular pressure to at or below 14 mmHg. Numerous clinical trials have consistently shown that there is little chance of progression of vision loss if IOP is maintained at 14 or below.

This unique approach mimics a trabeculectomy, the most widely-used glaucoma surgical procedure that has been practiced for over 50 years. Trabeculectomy is still regarded as the gold standard in glaucoma surgery as it is by far the most effective surgical approach to lowering IOP to 14 mmHg or less. However, it is fraught with many nasty adverse events and is highly dependent on surgical skill.

InnFocus has raised a total of \$15 million to date and is actively seeking further funding to accelerate its clinical efforts.

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