Ushering in a New Era

More than a decade ago, Olav Bergheim contacted Richard Hill, MD, to discuss the treatment options for a close family member who had been diagnosed with glaucoma at a young age. At the time, trabeculectomy was the recommended therapy and the only viable surgical option available. In their discussions, Dr. Hill presented the concept of a trabecular microbypass stent that could be implanted into Schlemm canal to restore physiologic outflow while avoiding the major drawbacks of more invasive glaucoma surgeries. These two men collaborated with Mory Gharib, PhD, to develop the first prototypes of the device and ultimately founded Glaukos Corporation in 2001.

A year after building the initial prototypes, the first trabecular microbypass stent was placed in a human eye. The design was customized to optimize conventional aqueous humor outflow using an ab interno surgical approach. The implant was made of surgical-grade nonferromagnetic titanium, measured 1 mm in length, and was coated with heparin to promote its proper function. To validate the concept behind this novel technology, the company launched a prospective investigational device exemption clinical trial of the iStent's safety and efficacy.

On June 25, the FDA approved the iStent for use in combination with cataract surgery for the reduction of IOP in adults with a cataract and mild or moderate open-angle glaucoma who are currently using IOP-lowering medical therapy. If the iStent fully delivers in terms of efficacy and safety, this decision has the potential to change the glaucoma treatment paradigm in which surgery is currently a last resort for glaucoma therapy. The new device offers physicians the hope of intervening earlier in the course of glaucomatous disease while reducing the complications often associated with long-term medical therapy (including noncompliance and ocular surface disease) and standard incisional surgery.

As this technology becomes available to surgeons throughout the United States, I look forward to seeing how its place in glaucoma therapy evolves. Certainly, its use should lead to further technological and technical improvements. Even now, Glaukos' iStent Inject and iStent Supra are in FDA premarket approval trials, and several other companies are developing devices for microinvasive glaucoma surgery (MIGS).

Although the exact role of MIGS in glaucoma therapy has yet to be completely defined, patients certainly stand to benefit tremendously from collective efforts to advance these technologies. As a consultant to and clinical investigator for Glaukos and several other companies in the MIGS space, I am extremely grateful to and draw inspiration from the individuals devoted to finding a better way to care for glaucoma patients around the world. ■

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