A Suprachoroidal Device for the Treatment of Open-Angle Glaucoma

The CyPass Micro-Stent System can safely reduce IOP in conjunction with cataract surgery.

BY MAGDA RAU, MD

Medical management of primary open-angle glaucoma, although widely used and effective for many patients, has limitations. Studies have shown that, in 30% of patients, the application of topical antiglaucomatous medications is irregular and insufficient.1 Sometimes, even with good compliance, the maximal tolerated medication is not capable of effectively reducing IOP.2 Additionally, long-term administration can sometimes cause issues that prevent continuation of the treatment.1,3 New diagnostic technologies now make possible the recognition of glaucomatous pathologic changes of the optic nerve much earlier than in the past.

Taken together, these factors have caused an increase in the use of glaucoma surgery in recent years. Surgical interventions for glaucoma are directed almost exclusively at increasing aqueous outflow, often by creating an alternate or improved pathway to Schlemm canal or by directing aqueous outflow externally to the sub-Tenon or subconjunctival space. Aqueous shunts direct aqueous outflow via drainage sites outside the eye, and complications such as hypotony, infection, bleb fibrosis, and erosion can occur with their use.

These factors have generated interest in alternative approaches to increasing aqueous outflow. The CyPass Micro-Stent (Transcend Medical, Inc.) implant increases aqueous outflow through the uveoscleral outflow system of the eye when implanted ab interno into the supraciliary space.4,5

The CyPass Micro-Stent System consists of a custom-designed delivery device for transcorneal placement and a miniature polyimide stent. The Micro-Stent has a 300-µm lumen and is roughly 6 mm in length. Fenestrations along the device allow aqueous to egress throughout its length. The tube is placed into the iridocorneal angle with its distal portion resting in the supraciliary space (Figure 1). The suprachoroidal space has a negative pressure gradient and a high absorptive capacity, which drives aqueous outflow and reduces IOP.

The CyPass Micro-Stent is Conformité Européenne (CE)-Mark approved and continues to be studied in multiple clinical trials throughout the European Union. The device is also being evaluated for US Food and Drug Administration (FDA) approval in one of the largest trials to date of a glaucoma device in the United States, the COMPASS trial (compassclinicalstudy.com).

CLINICAL EXPERIENCE

In the past 2 years, under multiple European studies of the CyPass Micro-Stent, I have implanted 60 of these devices,
either in combination with cataract surgery or as a standalone procedure.

When CyPass implantation is combined with cataract surgery, I first perform coaxial phacoemulsification through a 2.2-mm clear corneal incision. After the IOL is implanted and the ophthalmic vicosurgical device (OVD) is removed, I inject acetylcholine chloride into the anterior chamber to achieve miosis. When miosis is sufficiently attained, I inject Healon (sodium hyaluronate; Abbott Medical Optics Inc.) to obtain a deepening of the anterior chamber, especially in the area of the angle where I intend to implant the CyPass. A video of the procedure can be viewed at eyetube.net/?v=hinig.

Using a goniolens, I carefully visualize the angle, choosing the exact spot to implant the device. Then I insert the delivery device, loaded with the Micro-Stent, through the clear corneal incision into the anterior chamber and across to the angle on the opposite side. The CyPass Micro-Stent is positioned on a small guidewire with an atraumatic tip, which is used to separate the iris from the scleral spur, facilitating insertion. First, I establish contact of the tip with the scleral spur, and once I feel the resistance of this structure, I move the tip below the scleral spur and slowly advance the CyPass device into the small cleft created by the guidewire. I then release the Micro-Stent at the desired depth, leaving only the proximal collar of the device in the anterior chamber.

In some cases, usually with high preoperative IOP, high blood pressure, or hyperemia of the conjunctiva, bleeding around the CyPass device can occur. If so, I use repeated irrigation and aspiration to remove the blood. The bleeding can also be stopped through the tamponade with an OVD, which must later be removed.

In my initial 60 cases, normalization of IOP was achieved. In nearly all cases, reduction of the number of medications and lowered IOP were achieved. In some patients, improvement of the retinal nerve fiber layer contour was observed postoperatively on optical coherence tomography. Specifically, the fibers in the border area can show recovery. The reason for this, in my opinion, is stabilization of IOP during the day and at night, due to the implantation of the drainage device.

After implanting the CyPass Micro-Stent now in more than 70 cases to date, I have begun to place it more anteriorly, resulting in increasingly more stable results.

MULTICENTER TRIAL

Interim results of a multicenter clinical study of the CyPass were presented last year. The data were compiled from CyCLE, a European study of the device. Patients included in the presentation underwent phacoemulsification with implantation of the CyPass. Intraoperative events and short-term postoperative observations at 1 and 7 days were recorded, as well as longer-term postoperative data at 1, 3, and 6 months.

The investigators evaluated 94 patients in this multicenter study. Ninety-three percent were taking IOP-lowering medications preoperatively, and one-third were using three or more of these agents at the time of surgery. The mean number of preoperative medications was 2.2. The average preoperative IOP was 20 mm Hg, and 40% of patients had IOPs greater than 21 mm Hg.

Among patients whose baseline IOP was greater than 21 mm Hg, the mean reduction in IOP was 38% at 1 month, 36% at 3 months, and 35% at 6 months. Simultaneously, the number of medications per patient in this group dropped from 2.2 at baseline to less than 0.4 at 3 months and 0.8 at 6 months. None of the following complications were observed: choroidal detachment or hemorrhage, persistent hyphema, flat anterior chamber, or retinal detachment.

CONCLUSION

The data from European clinical trials of the CyPass Micro-Stent are encouraging and are consistent with my own overall clinical experience with the device. In our clinic, CyPass implantation has almost completely replaced trabeculectomy because of its reduced risk and its faster, less invasive procedure.

Magda Rau, MD, is the Head of the Augenklinik Cham and Refractive Privatklinik-Dr. Rau, Cham, Germany, and Eye Centre Prag, Czech Republic. Dr. Rau states that she has no financial interest in the products or companies mentioned. She may be reached at tel: +49 9971 861076; e-mail: info@augenklinikcham.de.