By Magda Rau, MD

An expert's word on the Micro-Stent

170 implants later, this KOL can share her advice.

Full- or partial-thickness filtration procedures, such as trabeculectomy, nonpenetrating glaucoma surgery and shunt implantation, are the most common surgical options for lowering IOP, but they also carry potentially serious complications. More than 35% of these filtration cases could experience these complications, including subconjunctival fibrosis, blebitis, hypotony, endophthalmitis and filtration failure.[1-3]

Because of the challenges associated with these procedures, filtering surgery is often reserved for severe cases of progressive glaucoma. For example, fibrosis can be challenging for both surgeon and patient. For patients with severe glaucoma with IOP greater than 30 mm Hg, trabeculectomy or deep sclerectomy may be necessary. However, postoperative bleb management is demanding, and these procedures require an experienced glaucoma surgeon.

Microstent devices for glaucoma have been generally classified as microinvasive glaucoma surgery (MIGS). They are procedurally efficient, minimally invasive and tissue sparing, and patients recover faster and with fewer complications than traditional procedures.

Although microstents do not lower IOP to the same degree as trabeculectomy, deep sclerectomy or older tube shunts, they should be considered as stand-alone surgical options for patients with mild to moderate open-angle glaucoma or as part of a combined procedure with cataract surgery.

With an added 10 minutes in surgery, a cataract patient with moderate IOP elevation can have an additional microstent procedure that controls IOP in an acceptable fashion. Microstent-based MIGS approaches are also convenient glaucoma procedures for use in outpatient surgery clinics.

One of these microstents is the CyPass Micro-Stent from Alcon. I started CyPass implantation in 2009 and have implanted about 170 of these devices. The first implantations were included in the European multicenter study.

Here, I describe this minimally invasive option along with my experience with implantation.

Overview

CyPass is a 6-mm miniature stent, with a 300-µm inner diameter. Fenestrations along the microstent allow egress of aqueous. CyPass is made from biocompatible, nondegradable, polyimide material, similar to that used in of IOL haptics. The CyPass Micro-Stent's design creates permanent drainage towards the suprachoroidal space.

Suprachoroidal outflow may account about half of the aqueous humor drainage negative pressure gradient of 3-4 mmHg between the suprachoroidal space, and the anterior chamber provides a driving force for aqueous outflow to the suprachoroidal. As a stand-alone procedure, CyPass could be implanted through a 1-, 1.8-, 2-mm incision. As combined procedure after phacoemulsification and IOL implantation, the CyPass implantation follows through the same 1-, 1.8-, 2-mm clear corneal incision.

Surgeons visualize the iridocorneal angle with a goniolens (e.g., Transcend Vold Goniolens, Volk Optical). Then, the CyPass-loaded applier is placed into the anterior chamber and advanced toward the scleral spur. Insertion into the supraciliary space is initiated with a traumatic tip of guide wire, allowing blunt dissection between the ciliary body.

Device placement is minimally invasive because it spares the conjunctiva and avoids formation of a filtering bleb.

Dr. Magda Rau is Chief of Augenklinik Cham, Germany, and Ocni centrum Prague, CZ. She also serves as a member of the editorial board of *CRSJ Europe* and *Ophthalmology Management*.

About the Author

Patient selection

I primarily offer the operation to patients with:

- A diagnosis of open-angle glaucoma
- Iridocorneal angle of Shaffer grade 3 or 4
- Unmedicated or medicated IOP between 21 and 31 mm Hg, or with maximum two to three medication therapies
- Visual field defect outside normal limits, or a pattern standard deviation at more than 5% level
- Vertical cup-to-disc ratio of at least 0.7%; and
- OCT-demonstrated thinness of the RNFL.

Other indications include intolerance of topical medication due to allergy, red eye or pain after application and systemic side effects. Some patients cannot administer medication due to tremor (Parkinson's disease), arthrosis, and so on. I also consider the wish for independence from drops and self-administered therapy.

Because of the noninvasive, safe characteristics of the CyPass implantation procedure, I also offer it to patients who have severe glaucoma progression with only minimal remaining visual field. Performing a trabeculectomy at this advanced stage of glaucomatous disease could result in a loss of the patient's remaining visual field.

Another advantage is that the CyPass procedure spares the sclera and conjunctiva, so a trabeculectomy can be performed without problems if necessary. Glaucoma is a progressive disease, so in some patients, despite CyPass, pressure elevation could occur. For further normalization of IOP, trabeculectomy has to be performed (necessary in only one case for all of my patients).

Advantages of combined procedures: MIGS and cataract surgery

Cataract surgery presents a logical opportunity for adjunct surgical treatment for glaucoma. While cataract surgery may be combined with trabeculectomy this is probably not the best option for patients with mild to moderate glaucoma, for those with substantial vision loss from glaucomatous disease the associated risks with the procedure may have to be accepted. Given the greater number of cataract surgery procedures relative to incisional stand-alone glaucoma surgical procedures performed annually, a safe, minimally invasive, and effective glaucoma surgical adjunct to cataract surgery has the potential to become the most commonly performed glaucoma procedure worldwide.

Glaucoma surgeries — even non-invasive ab interno procedures — carry the risk of inducing cataract development or progression. Combined procedures eliminate this risk. An additional benefit of a combined cataract and glaucoma surgical procedure may be a reduction in cost as the surgeries are performed concurrently.

European study group

Concerning my patients in the European multicenter study group, the higher decrease of IOP could be achieved in the stand-alone group in which the baseline was 26 mm Hg to about 14.6 mm Hg after three months and there was still a IOP depression after one year to 14.6 mm Hg and three years to 14 mm Hg. In the combined group, the baseline mean IOP was 22.3 mm Hg, which could be reduced after three months to 14 to 15 mm Hg after one year and to 15.3 mm Hg after three years. The baseline medication of the stand-alone group was 2.2 mm Hg, which could be reduced to 1.0 mm Hg after one year with a slight elevation to 1.3 mm Hg after three years. The baseline medication of the combined group was 1.8 mm Hg and could be reduced to 0.7 mm Hg after one year and 0.8 mm Hg after three years. These results correlate with groups of the multicenter European study.

I did not observe any intraoperative or postoperative sight-threatening adverse event, including no cases of suprachoroidal hemorrhage or choroidal or retinal detachment.

I have occasionally observed minor intraoperative bleeding, which could be stopped intraoperatively, and only seldom caused hyphema postoperatively, which in all cases resorbed without further surgical intervention within one week. Also, IOP occasionally fluctuates in the first week postoperatively and elevation or hypotony occurs, which could be solved with local therapy.

Personal findings

IOP reduction and number of medications in my patients' group are stable and lasting. I only observed obstruction caused by adherence to the iris in two cases. However, this does not always lead to pressure elevation. All of these obstructions were successfully treated with YAG laser, which caused the atrophy of adhering iris and reopening of the CyPass. **OM**

REFERENCES

1. Francis BA, Singh K, Lin SC, et al. Novel Glaucoma Procedures : A Report by the American Academy of Ophthalmology. Ophthalmology. 2011;118:1466-1480.

2. Borisuth NS, Bryan P. Krupin T. The risk profile of glaucoma filtration surgery. Curr Opin Ophthalmol. 1999;10:112-6.

3. Gedde SJ, Schiffman JC, Feuer WJ, Herdon LW, Brandt JD, Budenz DL; Tube Versus Trabeculectomy Study Group. Three-year follow-up of the tube versus trabeculectomy study. Am J Ophthalmol. 2009;148(5):670-84.