The evolution of glaucoma surgery has yielded a variety of new minimally invasive surgical options to better control IOP, the disease’s only modifiable risk factor. The Preserflo MicroShunt (Santen) has several innovative features that allow the creation of a filtering bleb through an ab externo approach. This, in turn, enables controlled subconjunctival drainage of aqueous humor and a reduction of IOP.

The Preserflo MicroShunt received the CE Mark in 2012 and is awaiting FDA approval. Over time, a variety of modifications have been made to the device’s name and design, from the Minimally Invasive Drainage Implant iterations (MIDI-Tube, MIDI-Ray, and MIDI-Arrow) to the InnFocus MicroShunt. This article reviews the design and implantation of the Preserflo MicroShunt and highlights the current evidence on the device.

**DEVICE SPECIFICATIONS**

The Preserflo MicroShunt is composed of poly(styrene-block-isobutylene-block-styrene), a biocompatible, synthetic polymer also known as SIBS. This material was first used in coronary stents and has shown excellent biocompatibility in animal studies.

The Preserflo device has an overall length of 8.5 mm and a beveled tip. A 1-mm fin positioned 4.5 mm from the tip allows fixation and prevents peritubular leakage (Figure 1). Whereas traditional tube shunts have an outer diameter of 630 µm and a lumen size of 300 µm, the Preserflo has an outer diameter of 350 µm and a lumen size of 70 µm. This unique feature allows the device to self-regulate flow based on the Hagen-Poiseuille equation, which was confirmed in animal models. In an ideal system, a steady-state IOP of 6.5 mm Hg should be achieved, assuming normal aqueous production (2.5 µL/min).

Glaucoma surgeons strive for a posterior, diffuse filtering bleb and cringe at the sight of an anterior, avascular bleb due to the long-standing risk of blebitis and bleb leaks. The design of the Preserflo MicroShunt promotes a more posterior flow of aqueous, approximately 6 mm from the limbus, and increases the odds of achieving ideal bleb morphology (Figure 2).

**SURGICAL TECHNIQUE**

The Preserflo MicroShunt is implanted via an ab externo approach, performed under topical anesthesia. Using a traction suture, a small 2–clock hour conjunctival peritomy is performed in either the superonasal or superotemporal quadrant. The Tenon capsule is then disinserted at the limbus and grasped. A deep sub-Tenon pocket is created by removing all adhesions between the Tenon layer and the underlying episclera. Three sponges soaked with mitomycin C (MMC) 0.2 to 0.5 mg/mL are applied for a total of 2 minutes, while care is taken to avoid the limbus. Careful application of MMC is important to avoid anterior avascularity.

Once the MMC sponges are removed, the area is irrigated with copious amounts of balanced salt solution. A 1-mm microknife is used to create a scleral tunnel, starting 3 mm from the limbus and entering just above the trabecular meshwork (Figure 3). Alternatively, the surgeon can use a 25-gauge needle to enter the anterior chamber and advance the microknife up only to the scleral spur, or use a double-step knife to create the tunnel and enter the anterior chamber. The Preserflo device is then inserted into the scleral tunnel, parallel to the iris plane. Balanced salt solution is injected into the anterior chamber to ensure proper flow from the device. The conjunctiva is then sutured using two wing sutures. At the end of the case, a bleb will start to form, and no leaks should be present.

**CURRENT EVIDENCE**

In 2016, Batlle et al reported 3-year outcomes of Preserflo implantation in 23 eyes (14 standalone and nine combined with phacoemulsification). Among standalone cases, mean IOP decreased from 22.1 ±4.9 to 11.1 mm Hg, and the mean number of...
glaucoma medications decreased from 2.6 ±0.9 to 0.8 ±1.2 (62% of patients were medication-free). In combined cases, mean IOP decreased from 26.4 ±5.2 to 10.2 mm Hg, and the mean number of glaucoma medications decreased from 2.0 ±0.9 to 0.4 ±0.1 (67% of patients were medication-free). Complete success was defined as an IOP of 6 to 21 mm Hg, with at least a 20% IOP reduction without medication. This outcome was achieved in 91%, 87%, and 86% of patients at 1, 2, and 3 years, respectively. Qualified success, defined as an IOP of 6 to 21 mm Hg and at least a 20% IOP reduction with or without medication, was achieved by 100% of patients. Minimal complications were observed in this small sample, and only one patient developed bleb fibrosis requiring a second Preserflo implant.

More recently, our group published a large, retrospective, single-surgeon series of 164 consecutive patients who underwent standalone implantation of the Preserflo MicroShunt with 1 year of follow-up. Patients with a history of bleb surgery were excluded. A variety of glaucoma diagnoses were represented, including primary open-angle glaucoma (n = 110), pseudoexfoliative glaucoma (n = 11), and other forms of open-angle glaucoma (n = 43). Varying concentrations of MMC were used: 31% of patients received 0.2 mg/mL, 56% received 0.4 mg/mL, and 13% received 0.5 mg/mL as we grew more comfortable with bleb morphology and the posterior appearance of the blebs.

In our study, median IOP decreased from 20 mm Hg (range, 16.5–26) to 12 mm Hg (range, 10–15), and the median number of glaucoma medication decreased from four to zero. Our primary outcome was complete success, which was defined as an IOP of 6 to 17 mm Hg and at least a 20% IOP reduction. This outcome was achieved in 76.9% of cases. Qualified success, which had the same criteria as complete success but with glaucoma medication, was attained in 92.5% of cases. Secondary outcomes of complete success at 6 to 21 mm Hg and 6 to 14 mm Hg were achieved in 76.9% and 75.6% of cases, respectively. Qualified success for IOPs of 6 to 21 mm Hg and 6 to 14 mm Hg was achieved in 92.5% and 91.9% of cases, respectively. Cox regression analysis showed that lower concentrations of MMC (0.2 mg/mL) were associated with a higher risk of failure (hazard ratio, 2.51; 95% CI, 1.12–5.65). There were no cases of persistent hypotony or bleb leaks. Two patients required bleb revisions, and one patient required a secondary tube shunt surgery.

**CONCLUSION**

The Preserflo MicroShunt offers a novel approach to bleb surgery by combining a minimally invasive device with significant IOP lowering and requiring careful tissue dissection and placement. As with any novel surgery, more time and comfort with the procedure will allow surgeons to optimize their surgical outcomes and enhance their success. The early study results are promising and suggest that another potential game-changing procedure for glaucoma has entered—or will soon be entering—our treatment arsenal.


**GEORGES M. DURR, MD, FRCSC**
- Centre Hospitalier de l’Université de Montréal (CHUM)
- Assistant Professor and Director of the Glaucoma Fellowship, University of Montreal, Montreal
- georges.durr@gmail.com
- Financial disclosure: Consultant/Advisor (Alcon, Allergan, Bausch + Lomb, Glaukos, Santen); Lecture fees (Alcon, Allergan, Glaukos, Labtician Ophthalmics, MicroSurgical Technology, Novartis, Santen, Sight Sciences)