

THE GLOBAL EMERGENCE OF A SUBCONJUNCTIVAL MICROSHUNT



Widespread adoption of the Preserflo MicroShunt is transforming glaucoma surgery in countries outside the United States.

BY KIN SHENG LIM, MBCHB, MD, FRCOPHTH

The Preserflo MicroShunt (Glaukos/Santen) has emerged as a promising alternative to trabeculectomy for managing primary open-angle glaucoma (POAG). Although adoption of this minimally invasive bleb-based surgical device has been widespread internationally, regulatory and procedural challenges have delayed its routine use in the United States. This article explores the evolution of the Preserflo, its advantages and limitations, and the adjustments to surgical technique that have improved outcomes.

ABOUT THE DEVICE

The Preserflo MicroShunt is 8.5 mm long and made from poly(styrene-block-isobutylene-block-styrene), also known as SIBS. The device's small lumen tube restricts flow, thereby preventing hypotony. The implant is designed to create a new and more posterior drainage pathway for aqueous humor compared with trabeculectomy. A trabeculectomy involves the manual creation of a scleral flap and conjunctival bleb, whereas the standardized Preserflo procedure involves less tissue manipulation. The device is implanted ab externo, with one end placed in the anterior chamber and the other under the conjunctiva, to minimize anatomic disruption.

LIMITATIONS OF THE FDA PIVOTAL TRIAL

Significant limitations of the pivotal FDA trial for the Preserflo MicroShunt¹

affected outcomes and ultimately delayed the device's approval for use in the United States.

Low Concentration of Mitomycin C

The FDA trial used a mitomycin C (MMC) concentration of 0.2 mg/mL (the only dose approved by the FDA) applied for 2 minutes. However, international studies have shown that higher concentrations of MMC (typically 0.4 mg/mL) applied for at least 3 minutes significantly improved outcomes by reducing postoperative fibrosis.^{2,3}

Device Placement

The trial protocol stipulated placing the device over the superior

quadrant, meaning nearly 60% of the Preserflo was placed over the superior rectus muscle. Muscle fiber movement and contraction over the device in this area likely contributed to excessive fibrosis at the tube's exit point. A post hoc analysis of the pivotal study demonstrated that superior placement of the device was associated with a lower success rate.⁴

Suboptimal Tenon Tissue Management

The trial protocol did not emphasize proper dissection of the sub-Tenon space, which could lead to suboptimal MMC application, scarring, and surgical failure. It is likely that these factors contributed to the trial's

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“THE LACK OF FDA APPROVAL FOR THE PRESERFLO MICROSHUNT HAS RESULTED IN A DIVERGENCE IN SURGICAL APPROACHES TO GLAUCOMA MANAGEMENT BETWEEN THE UNITED STATES AND OTHER COUNTRIES.”

failure to meet its primary endpoint, thereby delaying FDA approval for the Preserflo's routine use for the management of POAG.⁵

INTERNATIONAL ADOPTION: A PARADIGM SHIFT

Although the FDA has not approved the Preserflo MicroShunt, the device has gained widespread acceptance globally as an alternative to trabeculectomy. Three modifications to the surgical technique have been instrumental in improving outcomes.

No. 1: Employ Higher Concentrations of MMC

International surgeons routinely use MMC at concentrations of 0.4 mg/mL or higher applied for at least 3 minutes during surgery. This potent antifibrotic agent minimizes scarring at the conjunctival bleb site, encouraging long-term patency of the drainage pathway. Studies have shown that higher doses of MMC resulted in a lower postoperative IOP and fewer complications compared with lower doses.³

No. 2: Avoid Superior Device Placement

Avoiding device placement over the superior rectus muscle may result in higher surgical success.⁴ In my experience revising early Preserflo cases, most of the failed implants were placed on or near the superior rectus. Avoiding this placement will

likely reduce mechanical stress on the device's exit point. This adjustment should minimize fibrosis caused by muscle contraction and improve long-term bleb function.

No. 3: Improve Tenon Tissue Management

Proper dissection under the sub-Tenon layer before the broad posterior application of MMC with a sponge promotes uniform drug distribution in this space. During closure, careful suturing of Tenon tissue helps prevent retraction and scarring, which can compromise surgical success.

These modifications have achieved similar postoperative IOP control and success rates compared with trabeculectomy but with fewer complications.⁶

FUTURE DIRECTIONS

The lack of FDA approval for the Preserflo MicroShunt has resulted in a divergence in surgical approaches to glaucoma management between the United States and other countries. The FDA's insistence on the use of only approved concentrations of MMC limits the ability of US surgeons to replicate international success rates with the Preserflo.

To bridge this gap and facilitate US adoption of the device, new clinical trials are required. Future studies should incorporate higher concentrations of MMC and optimize

surgical techniques to better evaluate the implant's efficacy compared to trabeculectomy.

In addition, comprehensive training programs that cover these modified techniques could help US surgeons achieve better outcomes with the Preserflo.

CONCLUSION

The Preserflo MicroShunt has become a preferred option in many countries for managing POAG, and international experience with the device has shown that optimizing surgical techniques is central to achieving superior outcomes. However, regulatory challenges and limitations in pivotal trial protocols have delayed its approval in the United States. As research continues and regulatory barriers are addressed, there is hope that the Preserflo will gain FDA clearance and US patients will have access to this innovative treatment option. ■

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