Preserflo MicroShunt – A Modern Microinvasive Approach in the Surgical Treatment of Glaucoma. A Review

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I declare that I have not forwarded the study "Preserflo MicroShunt – A Modern Micrionvasive Approach in the Surgical Treatment of Glaucoma" for publication in any other journal, and that this study has been read by all the co-authors, who agree with its content. At the same time I declare that no conflict of interests exists in the compilation, subject and subsequent publication of this professional article, and that it is not supported by any pharmaceuticals company.



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SUMMARY

Preserflo MicroShunt (Santen Pharmaceutical, Osaka, Japan) is a new drainage implant designed for controlling intraocular pressure (IOP) in patients with open-angle glaucoma in cases where conservative therapy has failed. The implant, made of biocompatible SIBS material, drains aqueous humor from the anterior chamber to the sub-Tenon's space, ensuring the long-term reduction of IOP. This review article summarizes the available clinical and experimental data on the Preserflo MicroShunt, compares its efficacy and safety to traditional trabeculectomy, and defines its role within the current glaucoma surgery algorithm.
Key words: glaucoma, microinvasive glaucoma surgery, Preserflo MicroShunt, intraocular pressure, drainage implant

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INTRODUCTION

Glaucoma is a chronic progressive disease of the optic nerve, which ranks among the chief causes of irreversible blindness worldwide [1]. Despite the broad range of options of pharmacological treatment, a significant proportion of patients are still unable to attain adequate control of intraocular pressure (IOP), which results in the need for surgical intervention [2].

For several decades the gold standard remained trabeculectomy, although due to its invasiveness, technical demand factor and higher risk of complications, professionals in the field have searched for lower-risk alternatives. In recent years the concept of microinvasive glaucoma surgery (MIGS) has established itself as an option, the aim of which is to achieve effective reduction of IOP while preserving the anatomical integrity of the eye and minimizing perioperative and postoperative complications [2,3].

Preserflo MicroShunt is one of the most innovative drainage implants, which combines simplicity of implantation with long-term effectiveness, comparable with traditional filtration surgery [4].

MATERIAL AND TECHNICAL CHARACTERISTICS

Preserflo MicroShunt is a thin, flexible tube with a length of 8.5 mm and an internal diameter of 70 µm. It is manufactured from copolymer poly(styrene-block-isobutylene-block-styrene) (SIBS) – material with excellent biocompatibility, resistance to biodegradation and minimal inflammatory reaction [4–6] (Figure 1).

The implant drains chamber fluid from the anterior ocular chamber into the sub-tenon's space, where a filter cushion is formed. Unlike in the case of trabeculectomy, no scleral flap or fistula is formed, thereby reducing the risk of postoperative hypotonia [3,5,7].

SURGICAL TECHNIQUE

The procedure is mostly performed in local retrobulbar anesthesia. Following peritomy of the conjunctiva in the superotemporal or superonasal region, the te-

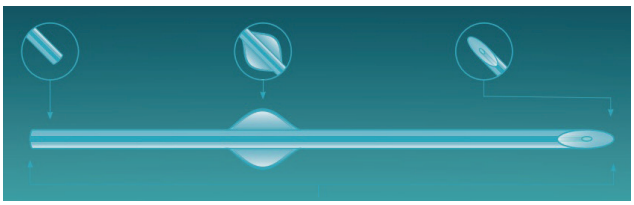


Figure 1. PRESERFLO™ MicroShunt
Source: https://glaucoma.org.nz/wp-content/uploads/2023/03/2023AU-0182-Preserflo-patient-brochure_NZ.pdf

non's capsule is removed by dissection. Subsequently a tunnel is created in the sclera, 3 mm from the limbus, leading into the anterior ocular chamber, with the aid of a 25G needle. The implant is inserted so that the proximal end lies in the anterior ocular chamber and the distal end beneath the conjunctiva [8,9] (Figure 2). Upon implantation of the Preserflo MicroShunt, mitomycin C (MMC) is used as standard in order to inhibit fibroblast proliferation and prevent scarring in the sub-tenon's space. MMC is traditionally applied with the aid of a moistened sponge, which is inserted beneath the conjunctiva for 2–3 minutes before implantation [3,9].

The most recent prospective randomized trial conducted by Majtanová et al. (2025) compared this method with an alternative sub-tenon injection of MMC (0.2 mg/ml, 0.1 ml) applied before insertion of the implant. The trial incorporated 100 eyes with open-angle glaucoma and observed the patients over the course of 12 months. The results demonstrated that an injected application of MMC was equivalent or slightly more effective than the traditional method using a sponge, in which the following applied:

- complete success of the operation (reduction of IOP to a level of ≤ 21 mmHg, or 18 mmHg without the use of medication, with a decrease of IOP by 20% as against the baseline value) was achieved in 26.4% in the group with injection vs. 19.3% in the group with a sponge,
- partial success (IOP ≤ 21 mmHg) was achieved in 87.4% in the group with injection vs. 59% in the group with a sponge,
- no statistically significant difference was recorded in the incidence of complications or in the amount of postoperatively reduced medication between the two groups [9].

These results confirm that sub-tenon application of MMC is safe, technically simpler and reduces the risk of local damage to the conjunctiva, while maintaining an equal hypotensive effect [9]. Following application of MMC, the tenon's capsule is closed with an absorbable suture and the conjunctiva with a non-absorbable suture. The entire procedure takes approximately 10–20 minutes, and has a relatively short learning curve [8,9]. Topical antibiotic treatment is applied postoperatively for a period of at least 7 days, and local corticosteroid treatment is applied for a period of 4–6 weeks, which reduces the risk of inflammation and fibrosis [6,9].

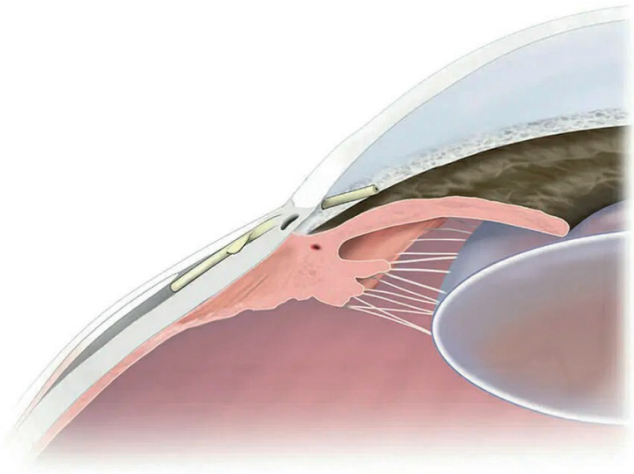


Figure 2. Implantation of the PRESERFLOTM MicroShunt
Source: https://mivision.com.au/2021/08/preserflo-microshunt-for-poag/

CLINICAL RESULTS

Studies published in recent years confirm that patients with a Preserflo implant attain a mean reduction in the level of IOP within the range of 30 to 45%, which is comparable with traditional filtration operations such as trabeculectomy [5,7,10–13].

A multicentric cohort trial conducted by the authors Tanner et al. (2023) observed 104 eyes over a period of 1 year. The mean IOP value was reduced from 23.4 ±0.8 mmHg preoperatively to 14.7 ±0.6 mmHg after 12 months. After implantation of the Preserflo the authors also recorded a reduction of used antiglaucoma drugs, from 3.4 ±0.1 preoperatively to 0.7 ±0.1 preparations after 12 months [13].

In short-term observation (less than 12 months), a high success rate was recorded in terms of reducing pressure, in which fewer than 10% of patients required reoperation or another surgical intervention. Complications during this period are usually of a mild character (hyphema, loss of intraocular fluid), while more severe complications (infection, perforation of filter cushion) are rare [7,9,11].

Batlle et al. (2016) published a 3-year study on 23 eyes, in which a reduction of mean IOP was recorded from 23.8 ±5.3 mmHg to 10.7 ±2.8 mmHg after 12 months, and this hypotensive effect was maintained even after three years (10.7 ±3.5 mmHg). After three years a reduction of the used medication was recorded from 2.4 ±0.9, to 0.7 ±1.1 preparations. [5].

The results of a retrospective 5-year observation of 66 eyes with primary open-angle glaucoma and pigmentary glaucoma following implantation of Preserflo were published by Scheres et al. in 2025. After five years, a reduction of IOP was recorded from the mean baseline value of 21.8 ±1.0 mmHg to the level of 13.2 ±1.4 mmHg. A reduction of used medication was recorded from the baseline value of 2.5 preparations preoperatively to 0.9 preparations after three years, 1.0 preparations after four years and 1.1 preparations after five years. It was necessary to perform surgical revision or needling in 18% of patients [14].

The clinical data confirm that Preserflo MicroShunt is an effective and safe means of reducing IOP, with a minimal risk profile, making it an attractive option especially for patients in whom rapid and reliable reduction of IOP is required.

COMPLICATIONS AND SAFETY PROFILE

The most common complication is fibrosis of the filter cushion, which can lead to insufficient drainage and is the main cause of failure of the operation. In such cases needling with MMC is indicated, or repeated application of MMC [9,15].

Less frequent complications include hypotonia, serous

ablation of the choroid, loss of chamber fluid and temporary hyphema, which in most cases require conservative therapy [9,13].

A significant advantage of Preserflo MicroShuntu is the low incidence of infectious complications (endophthalmitis < 0.5%), which differentiates it from trabeculectomy and tubular implants of the Ahmed or Baerveldt type [3,10].

POSITION OF PRESERFLO MICROSHUNT IN GLAUCOMA TREATMENT

Preserflo MicroShunt is currently ranked among microinvasive drainage implants with external filtration, which represent a bridge between minimally invasive procedures of the MIGS type (e.g. iStent, Hydrus, Kahook Dual Blade) and classical filtration operations such as trabeculectomy or implantation of tubular drainage systems (Ahmed, Baerveldt) [1,2,14,16].

Its main advantage is the possibility of predictable drainage of the chamber fluid outside the eyeball, while retaining the natural anatomical structure of the eye. By contrast with intracanalicular or trabecular MIGS systems, which are limited by the functionality of the trabecular meshwork and the Schlemm's canal, Preserflo creates a new drainage channel outside of these structures [6].

From the perspective of the therapeutic algorithm, Preserflo is suitable for the following patients:

- with primary open-angle glaucoma, who do not attain the target value of IOP even with the application of maximum pharmacotherapy,
- in whom there is a higher risk of complications following trabeculectomy (e.g. thin conjunctiva, high risk of hypotonia),
- as an alternative to trabeculectomy or drainage implants for patients requiring a medium-pronounced reduction of IOP,
- who have undergone another operation without attaining an adequate effect [2].

In patients with neovascular glaucoma, uveitic glaucoma, angle-closure glaucoma, or in patients in whom an excessive fibrotic reaction of the conjunctiva is expected (e.g. younger patients with aphakia), the results of implantation of Preserflo are less favorable [2,6].

In some trials Preserflo achieved a reduction of IOP comparable with trabeculectomy in 1-year observation, while at the same time achieving a lower degree of complications and shorter period of convalescence, although the long-term results so far remain limited [3,7,11,16]. It is suitable especially for patients with a medium to high risk of progression of glaucoma, who are not suitable patients for a classical filtration operation [3,16]. A further advantage is the possibility of repeating the procedure or subsequent implantation of another drainage system if drainage fails. This factor increases the flexibility of long-term treatment, and enables an individualized approach to each patient [6]. From an economic perspective, although the implant is more expensive than traditional trabeculectomy, several analyses indicate that thanks to the lower incidence of complications and the smaller number of monitoring procedures, in the medium-term perspective Preserflo may be potentially cost-effective [3,16].

Preserflo MicroShunt thus occupies a unique position as a "low-bleb risk" drainage implant – i.e. an implant with a low probability of the occurrence of a non-functional or ischemic filter cushion, thereby reducing the risk of later infections [6,15].

DISCUSSION

The introduction of Preserflo MicroShunt means a fundamental advance in the surgical treatment of glaucoma. While trabeculectomy was considered the standard with the highest degree of effectiveness for decades, the development of microinvasive implants has demonstrated that effective and long-term reduction of IOP can be achieved also with a lower risk of complications and better postoperative stability [3,13,16].

The main principle of Preserflo is controlled laminar flow of chamber fluid via the lumen with a precise diameter of 70 µm, which is calculated in order to prevent excessively rapid drainage of the fluid, leading to postoperative hypotonia. This procedure differentiates Preserflo from older implants with a larger diameter or uncontrolled flow [5].

From a physiological perspective, drainage into the sub-tenon's space is enabled by the formation of a filter cushion, which functions as a reservoir of chamber fluid and ensures long-term stability of IOP. The quality and height of the filter cushion correlates with the success rate of the procedure, which is also confirmed b the results of OCT studies, where the height and homogeneous reflex structure of the cushion signal better drainage function [4,6].

Comparison of efficacy and safety

MicroShunt achieves a mean reduction of IOP by 40%, with a probability of severe complications of less than 5%. In comparison with trabeculectomy the risk of postoperative hypotonia is statistically lower [3,7,16]. At the same time, a lower risk of blebitis and endophthalmitis has been recorded, which is associated with the fact that the filter cushion in Prserflo is generally located more towards the posterior and is more diffuse, which reduces the risk of its perforation [3,14–16].

Surgical and practical aspects

The surgical procedure of implantation of a Preserflo Microshut has a relatively short learning curve (approx. 10–15 procedures), which facilitates its use in clinical practice [8,9]. Thanks to the standardized procedure, the reproducibility of results is high. The operating time is 10–20 minutes, which is markedly lower than for trabeculectomy (30–45 minutes) [8,9]. However, these values are dependent to a large extent on the experience of the operating surgeon.

From a practical perspective, thorough postoperative observation is required during the course of the first 6–8 weeks, since it is in this period that the majority of complications (fibrosis of the filter cushion, hemorrhage, loss of intraocular fluid) occur. When adequate care is applied, the function of the implant remains stable for several years [6,10].

The results of the study conducted by Majtanová et al. (2025) have expanded our knowledge concerning optimizing surgical procedure of implantation of a Preserflo MicroShunt. It has been demonstrated that the method of application of MMC has a fundamental influence on healing and long-term function of the filter cushion. A sub-tenon injection of MMC simplifies the surgical process, shortens the operating time and eliminates the need for manipulation of the sponge, which could lead to uneven distribution of cytostatics and local damage to tissue. Thanks to the even diffusion of MMC within the sub-tenon's space, more homogeneous inhibition of fibroblasts is achieved, which is manifested in a lower degree of fibrosis and better stability of drainage [9]. The authors point to the fact that injection application of MMC may also contribute to a reduction of postoperative discomfort and more rapid visual rehabilitation. The results thus support the endeavor for standardization of microinvasive procedures in glaucoma surgery, which are effective but with a lower risk than traditional procedures [9]. Within the context of the available data it is therefore possible to state that Preserflo MicroShunt in combination with sub-tenon injection of MMC represents a new, optimal surgical procedure, which combines the effectiveness of trabeculectomy with the safety of microinvasive techniques [9].

Long-term results and perspectives

Long-term studies confirm that the effect of reducing IOP achieved with the aid of Preserflo MicroShunt may persist for five years, in which the results are comparable with traditional tubular implants. In these studies a long-term reduction of IOP by an average of 35–45% was recorded, in which a significant proportion of patients maintained control without the need for reoperation or further procedures even up to three to five years after the procedure [5,10,14]. Long-term observation revealed that the stability of function of the implant depends on the correct implantation technique and on suitable selection of patients. The results show that upon thorough postoperative care and observation it is possible to maintain good control of IOP while minimizing the risk of complications such as fibrosis of the filter cushion [9,14,16].

At present, intensive investigation is under way into the possibility of combining implantation of Preserflo with other procedures, in particular with cataract surgery, which could have the potential to increase the overall effectiveness of the procedure while at the same time improving quality of vision for patients [13].

In future, we can expect the development of modifications of the implant with an adjustable lumen and biocompatible surface treatments (e.g. heparinization), which could further reduce the risk of fibrosis [6].

Clinical significance

Preserflo MicroShunt fulfills the requirements for modern glaucoma surgery – effective reduction of IOP, low risk of complications, reproducible procedure and short convalescence period. Thanks to these factors it represents an optimal choice for patients with insufficiently controlled glaucoma, who are not suitable for trabeculectomy but require a more pronounced reduction of IOP than can be achieved by conventional MIGS techniques [13,16].

CONCLUSION

Preserflo MicroShunt extends the portfolio of surgical possibilities for the treatment of glaucoma. It is distinguished by its simple implantation, stable hypotensive effect and favorable safety profile. Its place within clinical practice is being consolidated as an alternative for patients in whom pharmacological therapy has failed and who are not suitable for classical trabeculectomy.

Long-term prospective studies confirm its effectiveness, while complete determination of its economical viability and long-term safety still requires further research.

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