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Article

Comparison of PRESERFLO Implantation Techniques Using a New Small Posterior Incision Versus a Standard Anterior Peritomy

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Key Messages:

What is known:

- Poly(styrene-block-isobutylene-block-styrene) (SIBS), a material from interventional cardiology, has allowed creating subconjunctivally draining microshunts with reduced immunogenicity and revision rate.
- The PRESERFLO, a SIBS-based implant, is normally implanted through an anterior, 6-8 mm peritomy from ab externo.

What we found:

- A comparison of the large standard peritomy with minimal posterior snip incision shows that both are equally effective, reducing the IOP to 10 mmHg at 270 days.
- The posterior, small incision approach considerably simplifies the implantation resulting in a 2.6 times faster surgery.

Abstract:

Purpose: To compare the standard implantation technique of a new ab externo microshunt (PRESERFLO) to a posterior technique with a small incision. The standard anterior approach (A) requires a relatively large, 6-8 mm perilimbal peritomy. In contrast, the posterior approach (P) involves only a 2-3 mm snip incision 2 mm posterior to the limbus.

Methods: Charts of 126 PRESERFLO patients (54 A and 72 P) were retrospectively analyzed. Follow-up was 270 days. We compared the surgical time, intraocular pressure (IOP), number of medications, and complications.

Results: The preoperative IOP in A was 21.8±8.5 mmHg and 23.9±8.1 mmHg in P (p=0.08). The surgical time for A was 26±0.8 minutes and 10±0.4 minutes for B (p<0.001). Following a low-pressure phase during the first week, A and P had an IOP value of 10.8±5.9 mmHg and 10.6±4.5 mmHg at 30 days, respectively (p=0.62). IOPs remained at this level throughout the study (all intra-group p> 0.08). There were no inter-group differences in IOP at any visit (all p-values > 0.3). Patients in A and P took 3.2 ± 1.3 and 3.3 ± 1.0 pressure-lowering medications at baseline, respectively (p=0.4). These values declined to 0.2 ± 0.6 in A and 0.3 ± 0.7 in P at 270 days. Both groups had a similar number of revisions (13 (10.3%) versus 10 (7.9%, p=0.14)) and complications (26 (20.8%) versus 31 (24.6%, all p>0.25).

Conclusion: The posterior PRESERFLO insertion technique was 2.6 times faster than the standard anterior technique and yielded similar results with a large reduction in IOP and medications and a safety profile favorable over traditional filtering surgery.

Keywords: glaucoma surgery; PRESERFLO; microshunt; surgical technique

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1. Introduction

The longer the operative time, the greater the risk of complications [1, 2]. Because complications have adverse consequences, decreasing surgical time should be a universal goal for surgeons, hospitals, and policymakers. Traditional filtering glaucoma surgery drains aqueous humor into the subconjunctival space. It effectively lowers the intraocular pressure (IOP) but is rather complication-prone. In trabeculectomy, 10% of patients suffer intraoperative complications and 57% experience postoperative complications during the first year [3]. Different implants have been devised to drain aqueous humor into the subconjunctival or sub-tenon space but with reduced surgery time, increased safety, and comfort. Currently, there are several tube-plate implants (tube shunts) [4] that were not the subject of our study. There are also several plateless implants that are bleb forming: the EX-PRESS (Alcon Laboratories, Inc., Texas, United States) is a trabeculectomy modifying, medical-grade stainless steel (316LVM) device [5]. The Xen gel stent (Allergan Inc., California, United States) is a hydrophilic tube made of porcine gelatin cross-linked with glutaraldehyde [6] implanted via an ab-interno approach. The PRESERFLO microshunt (Santen, Osaka, Japan) used in our study comprises a novel synthetic, thermoplastic, elastomeric biomaterial (polystyrene-block-isobutyleneblock-styrene; SIBS) [7]. It is implanted from ab externo in an approach similar to traditional trabeculectomy, where a bleb is created using a peritomy and a fornix-based conjunctival flap. The challenge with all these devices is to balance IOP-lowering efficacy with an increasing risk of overfiltration the more outflow the implant permits. Additionally, most implant materials will cause a foreign body reaction with varying degrees of encapsidation and fibrosis. In contrast to the silicone of tube shunts or the glutaraldehyde fixated gelatin of the Xen, SIBS appears to avoid a foreign body reaction [8, 9] and to provide a low revision and needling rate [10].

Our study compared the standard PRESERFLO implantation technique, which requires a large, 6 to 8 mm-long peritomy, to a simplified implantation technique through a 2-3 mm snip incision 2 mm posterior to the limbus. We found this approach easier and more reliable; it created a more posterior bleb and could also be performed in eyes with anterior conjunctival scarring from prior surgery. Our main hypothesis was that the implantation through a posterior, small incision provided a shorter surgical time and that results were not inferior to the standard approach using a large incision.

2. Methods

Due to its retrospective nature, this study was granted an exemption from a formal review by the Institutional Review Board (IRB) of the University Hospital of Würzburg. We abided by the principles stated in the Declaration of Helsinki. One hundred twenty-six charts of glaucoma patients who had undergone a PRESERFLO implantation between September 2020 and July 2021 were analyzed. Patients were categorized according to the implantation site of the PRESERFLO microshunt and divided into an anterior (A) and a posterior group (P). The surgical indication was either uncontrolled IOP, an intolerance to glaucoma drops, or a clinically significant glaucomatous progression. Progression was defined as a statistically significant decline of the retinal nerve fiber layer (Heidelberg OCT). Individuals younger than 20 and those with neovascular and trauma-induced glaucoma were excluded. Demographic parameters recorded included age, gender, glaucoma type, implantation site, baseline mean deviation of the visual field as criteria for glaucoma severity, whether a concomitant cataract surgery took place, and the availability of systemic diseases (ex. diabetes). We recorded the IOP, visual acuity, and medication number at every follow-up visit. The total number of revisions, postoperative injections of subconjunctival 5-fluorouracil, and other postoperative complications were also noted.

2.1. Surgical Technique

Two different surgical approaches were used (Figure 1). All interventions were performed by a surgeon experienced with the ab externo implantation of other microshunts and small incision trabeculectomy (NAL).

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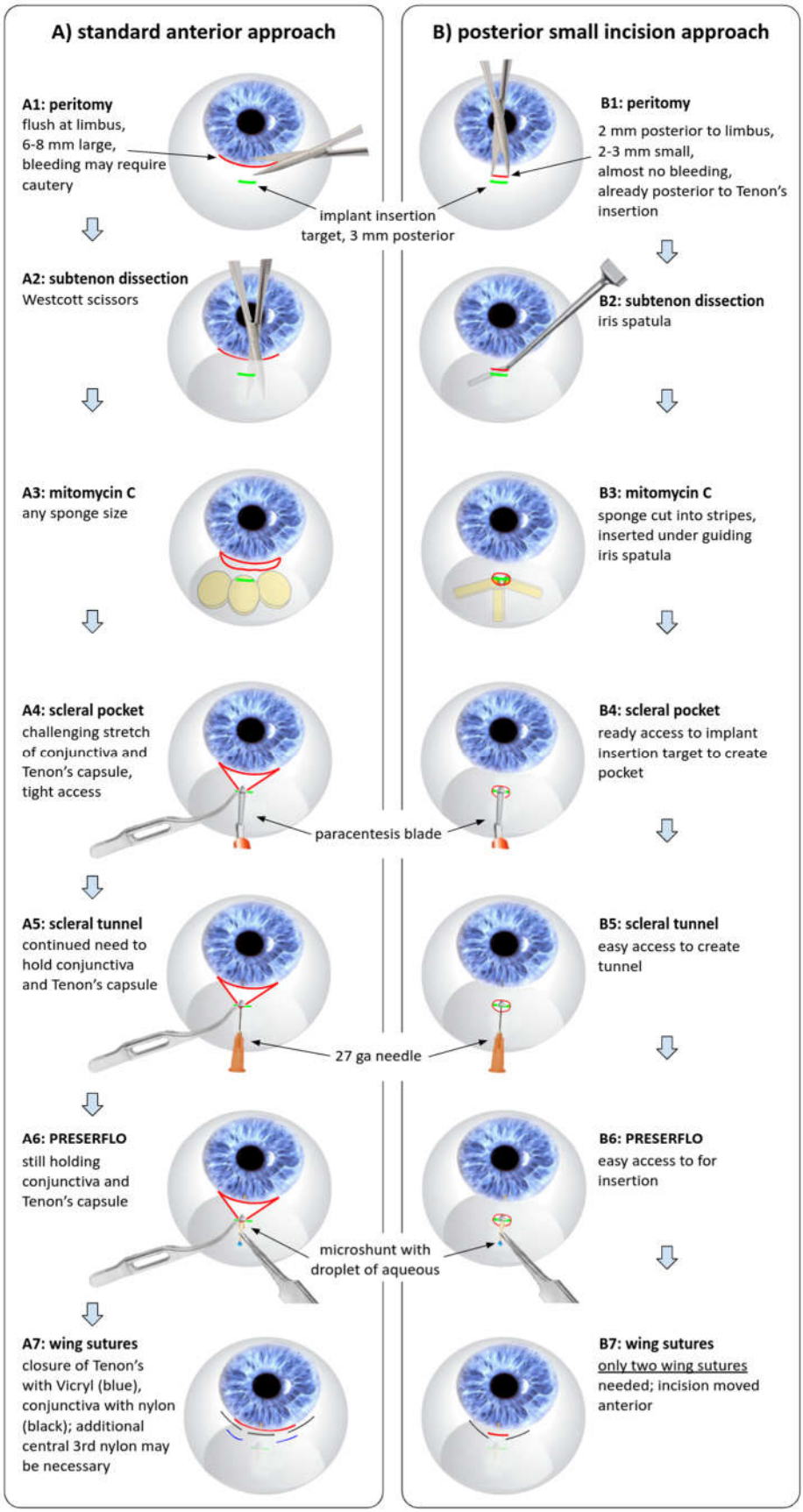

Figure 1. Side-by-side comparison of the standard anterior (left, A) and the posterior small incision approach (right, B). The large anterior peritomy (A1) that was called for by the standard approach and its consequences were the main difference from the posterior snip incision (B1). All steps were

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conducted through a 2-3 mm window in B. An iris spatula allows effective dissection (B2) and insertion of mitomycin C soaked sponges (B3). The incision was in direct proximity to the intended implant insertion site. It provided ready access to create the sclera pocket (B4) and tunnel (B5) to implant the microshunt (B6). Because the incision was so small in B, it could be reliably closed with two wing sutures. The sutures moved the incision towards the limbus and away from the implant (B7).

2.1.1. Standard, anterior approach

A superior corneal traction suture was placed approximately 1 mm anterior to the limbus. Using the standard anterior technique requested by the manufacturer of the microshunt (designated group A), a 6-8 mm peritomy was fashioned flush along the superior cornea using Westcott scissors (Figure 1, A1). The sub-tenon space was also dissected with those (Figure 1, A2). Three sponges soaked with mitomycin C (0.5 mg/ml) were inserted for three minutes (Figure 1, A3), followed by irrigation with buffered saline solution (BSS). Three millimeters posterior to the limbus, the surgeon created a 2 mm long and 1 mm wide pocket with the paracentesis blade included in the kit (Figure 1, A4). A 25 gauge needle was inserted into the pocket with the bevel up and advanced into the anterior chamber to enter halfway between the cornea and the iris (Figure 1, A5). With the bevel pointing up, the microshunt was moved into the tunnel until the wings were secured within the sclera pocket (Figure 1, A6). The microshunt's function was confirmed by visualizing aqueous exiting at the tail. Tenon's capsule and the conjunctiva were advanced to cover the microshunt and reapproximated at the limbus. Tenon's capsule was secured with 7-0 polyglactin 910 (Vicryl, Ethicon, New Jersey, United States) and the conjunctiva with wing sutures using 10-0 nylon (Figure 1, A7). Occasionally, a central loop stitch parallel to the limbus was placed to reduce the chance of leakage. The knots were rotated. The bleb that formed was checked for leakage. The postoperative regimen consisted of dexamethasone drops four times a day for a month and then tapered by one drop per week and ofloxacin drops four times a day for a week.

2.1.2. Posterior, small incision approach

Compared to the standard implantation technique, the posterior technique created only a 2-3 mm wide peritomy with a direct opening of Tenon's layer 2 mm posterior to the limbus (Figure 1, B1). The sub-tenon space of the bleb was dissected with an iris spatula (Figure 1, B2), and mitomycin C sponges were cut into a thinner but longer shape (Figure 1, B2). The creation of the scleral pocket, tunnel, device insertion, and priming were similar to the standard implantation technique described above but could proceed through the conjunctival incision that readily exposed the implantation site (Figure 1, B4-6). The closure differed from the standard technique in that the 2-3 mm peritomy was pulled over the implant and positioned directly at the limbus instead of at the original position 2 mm posterior to the limbus (Figure 1, B7). This was done to move the incision away from the implant's sclera pocket and prevent the implant from touching Tenon's capsule or conjunctiva. Tenon's layer and conjunctiva were secured at the limbus in a watertight fashion with a single 10-0 nylon wing suture on the left and on the right of the incision. The same postoperative regimen was used as in group A.

2.2. Statistical analysis

SPSS (Version 26, IBM, New York, USA) was used for statistical analysis. Parameters were recorded as dichotomous or continuous variables. Continuous variables were reported as means and standard deviations. We ran the Kolmogorov Smirnov test to check for a normal distribution. Means of normally distributed datasets were compared using t-tests, while those with a non-normal distribution were compared using Mann-Whitney-U tests. We deployed a Chi-square test to check for significant differences between dichotomous variables. A p-value of 0.05 or less was considered statistically significant for all our analyses.

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3. Results

A total of 126 eyes were included in the statistical analysis; 54 eyes in group A and 72 eyes in group P. Table 1 depicts the baseline demographics for A and P. The mean ages in both groups were similar, with an average age of 72.3 ± 12.1 years in A and 70.2 ± 10.7 years in P (p = 0.29). The male-to-female gender ratio was 1:1.7 in A and 1:1.2 in P; these figures did not differ significantly (p = 0.32). Primary glaucomas were the most common glaucoma type in our population, representing 79.6% and 77.8% in A and P, respectively. The mean preoperative IOP value in A was 21.8 ± 8.5 mmHg and 23.9 ± 8.1 in P. Both values were statistically similar (p = 0.08). In both groups, the number of glaucoma eye drops at baseline was comparable (3.2 ± 1.3 and 3.3 ± 1.0 in A and P, respectively, p = 0.63). Visual field tests in A and P showed a mean defect of 12.3 ± 9.4 dB and 10.8 ± 8.1 dB, respectively (p = 0.40).

Table 1. Baseline characteristics.

parameter/technique	anterior (n = 54)	posterior (n = 72)	p-value
age (years) (mean ± SD)	72.3 ± 12.1	70.2 ± 10.7	0.29
gender ratio (M:F)	1 : 1.7	1 : 1.2	0.32
glaucoma type primary (n, %) secondary (n, %)	 43 (79.6%) 11 (20.4%)	 56 (77.8%) 16 (22.2%)	0.77
baseline IOP (mmHg) (mean ± SD)	21.8 ± 8.5	23.9 ± 8.1	0.08
same session phaco (n, %)	7 (13.0%)	14 (19.4%)	0.33
visual field mean defect (dB)	12.3 ± 9.4	10.8 ± 8.1	0.40
number of baseline medications (drops) (mean ± SD)	3.2 ± 1.3	3.3 ± 1.0	0.63

Same session phaco: surgery combined with phacoemulsification.

Table 2 shows the postoperative outcomes of A and P. Both techniques resulted in a significant IOP drop from baseline at every follow-up (all p-values < 0.05). When comparing IOP levels of A and P, both showed similar readings on days 30, 90,180, and 270 (all p-values > 0.05). Figure 2 visualizes the IOP curves for both techniques. The PRESERFLO significantly reduced glaucoma drops in both groups (0.2 ± 0.6 and 0.3 ± 0.7 in A and P, respectively, both p-values < 0.05).

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Table 2. Postoperative outcomes for the anterior and posterior insertion techniques.

	anterior	posterior	p-value
IOP (mmhg) (mean ± SD)			
day 30	10.8 ± 5.9 (n = 51)	10.6 ± 4.5 (n = 69)	0.62
day 90	10.4 ± 3.4 (n = 44)	11.5 ± 4.4 (n = 62)	0.31
day 180	12.0 ± 4.3 (n = 12)	11.8 ± 4.2 (n = 44)	0.95
day 270	10.4 ± 2.1 (n = 7)	10.8 ± 2.5 (n = 12)	0.76
number of medications (mean ± SD)	0.2 ± 0.6 (n=54)	0.3 ± 0.7 (n=72)	0.19
number of 5-fu (mean ± SD)	1.9 ± 1.7	2.7 ± 2.5	0.14
number of revisions (n, %)	13 (10.3%)	10 (7.9%)	0.14
complications (n, %):			
conjunctival scarring	13 (10.3%)	18 (14.3%)	0.90
hyphema	1 (1%)	0 (0%)	0.25
choroidal effusion	9 (7.1%)	11 (8.7%)	0.83
bleb leakage	2 (1.6%)	1 (0.8%)	0.40
tube dislocation	1 (0.8%)	0 (0%)	0.25
conjunctival erosion	0 (0%)	1 (0.8%)	0.39

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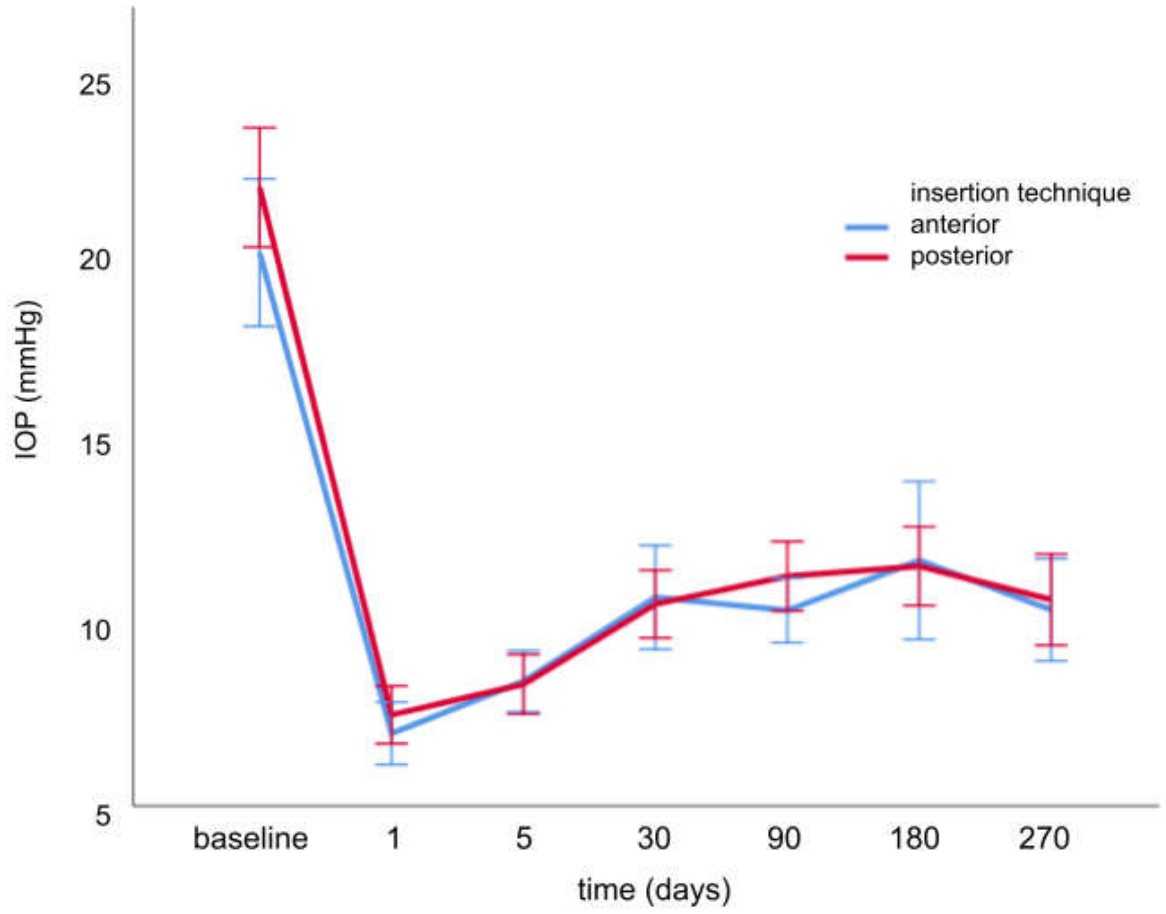

Figure 2. Pre- and postoperative mean IOPs for anterior and posterior insertion techniques. Both methods had similar IOP levels at all time points ($p > 0.05$).

Differences in surgical techniques were most apparent in the time required for each: 26 ± 0.8 minutes were needed for A and 10 ± 0.4 minutes for B ($p<0.001$). The larger, anterior incision through the vessel-rich perilimbal conjunctiva resulted in more bleeding and a more challenging visualization of the intended target site where the implant was to be inserted (Supplementary Material 1). Removing mitomycin C soaked sponges was difficult using the standard anterior technique (Supplementary Material 1, A3), so we threaded them on a vicryl suture for easier retrieval. Because of a relatively posterior scleral tunnel required for the implant, the conjunctiva and Tenon's layer had to be pulled back and held under tension to create the scleral pocket and tunnel. The tension required to achieve a triangular stretch of Tenon's and the conjunctiva would often cause the edges of the peritomy to tear, resulting in further bleeding (Supplementary Material 1, A3-6). Distorting the conjunctiva in this fashion required a second instrument (Colibri forceps (Figure 1, A4-6) or stable swab (Supplementary Material 1, A4-6.2)) to hold it in place firmly.

These issues were contrasted with the relative ease of operating through the posterior 2-3 mm snip incision (B1). An iris spatula allowed effective dissection (B2) and insertion of mitomycin C soaked sponges (B3). The incision was in direct proximity to the intended implant insertion site. It provided ready access to create the sclera pocket (B4) and tunnel (B5) to implant the microshunt (B6). Because the incision was so small in B, it could be reliably closed with two wing sutures. The sutures moved the incision towards the limbus away from the implant (B7).

During the first postoperative weeks, individuals received a similar average number of 1.9 ± 1.7 subconjunctival 5-FU injections (50 mg/ml, 0.2 ml) in A and 2.7 ± 2.5 in P ($p =$

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0.14). In A, 13 patients (10.3%) needed a revision and 10 (7.9%) in P (p = 0.14). Bleb failure from fibrosis and choroidal effusion were the most common postoperative complications. The number of complications for both groups was similar (all p-values > 0.05).

4. Discussion

Primary open angle glaucoma (POAG) can be treated effectively with eye drops, but even the latest prostaglandin analogs offer continuous-treatment success rates of only 10% at one year [11]. 59% of patients lose vision during initial medical treatment [12], and 32% [13] need surgery within one year. This makes the search for standardized, reliable, and safe glaucoma surgery pertinent. We developed a new surgical technique for a recently introduced glaucoma implant to address this unmet need. We compared two different PRESERFLO implantation techniques. The standard technique involves a relatively large 6 to 8 mm peritomy, while the posterior approach uses a 2-3 mm snip incision. We developed the posterior implantation to make the surgery easier and faster and the conjunctival closure more standardized. One problem with the standard approach we encountered was the need to pull the conjunctiva back hard to gain access to the sclera 3 mm posterior to the limbus where the sclera pocket is fashioned. The separate closure with suturing of both Tenon's layer and the conjunctiva was cumbersome. Another problem was an unreliably watertight closure of the large peritomy, which sometimes required a loop stitch in the center of the incision directly on top of the PRESERFLO implantation site. These issues did not appear to do the potential of the PRESERFLO justice that its minimal design and small size promises.

We found no statistically significant difference in the clinical outcome between the two surgical techniques nine months postoperatively. Both approaches were equally safe and effective. There were no differences in conjunctival scarring, number of bleb revisions or 5 FU injections. The clinical outcomes are so similar because the implantation of the microshunt itself was not altered. The main difference was improved ease and speed with 2.6 times shorter surgical time using the posterior approach (10 versus 26 minutes). This much difference may be surprising but can be explained by how little the conjunctiva or Tenon's capsule had to be manipulated. Because of the small size of the incision, two wing sutures could pull the opening of the snip incision towards the limbus and close it reliably. Seidel positive leaks never occurred.

There are still few PRESERFLO studies due to its relatively recent introduction and different market approval times [7, 14–18]. Pinchuk et al. reported a case series of 23 successful microshunt implantations in 23 consecutive cases [9]. The authors observed a large reduction in IOP postoperatively and minor complications such as minimal hypotony and bleb encapsulation, concluding that this procedure provided an alternative to primary trabeculectomy. Riss et al. reported similar results in a retrospective study with a one-year follow-up period [19]. The authors reported an IOP and medication reduction ranging from 38 to 55% and 72 to 85%, respectively. Other studies reflected this experience [7, 15–18]. Batlle et al. published 3-year results in 23 eyes [15]. At 1, 2, and 3 years of follow-up, the success rate for an IOP of equal to or less than 14 mmHg and an IOP reduction of more than 20% was 100%, 91%, and 95%, respectively. The mean IOP was reduced from 23.8±5.3 to 10.7±2.8, 11.9±3.7, and 10.7±3.5 mmHg, and the mean number of glaucoma medications per patient was reduced from 2.4±0.9 to 0.3±0.8, 0.4±1.0, and 0.7±1.1, respectively. The most common complications were transient hypotony (13%) and transient choroidal effusion (8.7%), which resolved spontaneously. There were no leaks, infections, migrations, erosions, persistent corneal edema, or other serious long-term adverse events [15]. Our observation time was shorter, but we had similar results.

Our study was limited by its retrospective nature. The follow-up duration of 9 months was shorter than others, and the number of patients participating was lower. The number of patients was sufficient to detect differences in surgical time and major differences in IOPs and complications. However, more subtle IOP differences of 1 mmHg may require a larger number of patients. When soliciting feedback for the new technique

presented here, we were reminded by material researchers and other surgeons to point out that it is important to make sure the implant is covered by both Tenon's capsule and the conjunctiva. The wing sutures need to move the incision toward the limbus. This allows for sufficient space between the scleral pocket of the implant and the overlying conjunctiva to avoid erosion.

In conclusion, we found the PRESERFLO microshunt to be highly effective in lowering IOP and medications. The posterior insertion technique was 2.6 times faster than the standard approach. Both showed similar results in IOP and medication reduction as well as postoperative complications. There were no significant differences at the nine months follow-up.

Funding: This research received no external funding.

Data Availability Statement: Data is available from the corresponding author on request.

Ethics Approval: Approval was obtained from the Institutional Review Board (IRB) of the University of Würzburg.

Conflicts of Interest: The authors declare no conflict of interest.

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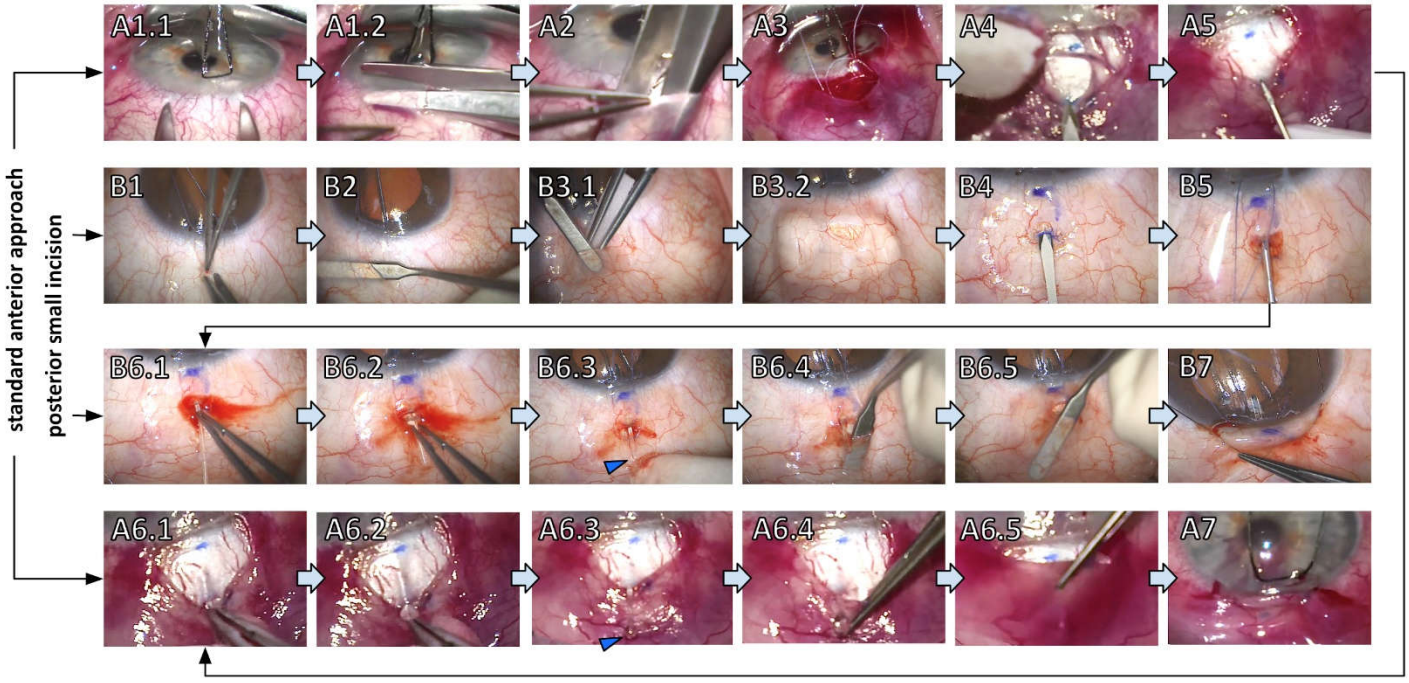
Supplementary Material

Supplementary Material 1



Supplementary material 1: Intraoperative photographs of the standard anterior (A) and the posterior small incision approach (B) with corresponding steps shown side-by-side. The steps shown are peritomy (A1.1-1.2), bleb dissection (A2), mitomycin C sponges on a vicryl suture (A3), scleral pocket (A4) and tunnel (A5) creation, implant insertion (A6.1-6.2), function checking (blue arrowhead in A6.3 shows aqueous exiting tail), positioning of the tail under Tenon's and conjunctiva (A6.4-6.5) and bleb closure (A7). Analogous steps are shown in B where the surgery occurred through a posterior 2-3 mm snip incision (B1) in close proximity to the implantation site. An iris spatula allowed effective dissection (B2) and insertion of mitomycin C soaked sponges (B3).