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ORIGINAL RESEARCH

Safety and Efficacy of Preserflo Microshunt in Different Subtypes of Glaucoma

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Background: Glaucoma is the leading cause of blindness worldwide. Intraocular pressure is considered the only modifiable risk factor; different modalities have been developed to target this risk factor. Trabeculectomy, a gold standard glaucoma surgery, carries high complication rate, as a result alternative different modalities were developed to mitigate this risk. A newly developed device, Preserflo Microshunt, aims to decrease the complication rate of trabeculectomy with similar efficacy. In this study, we assessed the safety and efficacy of the device in Saudi Arabia, where the patient population has a darker skin color with more intense scarring and a hot climate that can exacerbate ocular surface dryness and compromise conjunctival health.

Purpose: This retrospective study aims to assess the safety and efficacy of Preserflo Microshunt with Mitomycin C 0.5 mg/mL in managing different subtypes of glaucoma.

Methods: Retrospective, interventional single-arm study.

Results: This study included 45 eyes from 45 patients. It included 33 (73.3%) males and 12 (26.7%) females. A median age of 56 years (Interquartile Range 39–63, range 20–77). The Preserflo Microshunt with Mitomycin C 0.5 mg/mL achieved a complete success rate 83.3% at 6 months follow-up and of 80% at 1 year. A significant reduction in both the number of anti-glaucoma medications and intraocular pressure at 1 month, 3 months, 6 months, and 1 year post-operatively was observed ($P<0.001$ for all). The most common early-onset complication was transient hypotony, observed in 12 eyes (26.7%), and the most common late-onset complication was cataract progression, which was observed in 5 (16.67%) patients at 1 year.

Conclusion: Preserflo Microshunt is a viable option for glaucoma patients showing excellent success and low complication rates with good safety profile.

Keywords: glaucoma, intraocular pressure, Preserflo Microshunt, Minimillay Invasive Glaucoma surgery, Minimally Invasive Bleb Surgery

Introduction

Glaucoma remains the leading cause of irreversible blindness worldwide, with an estimated prevalence of 112 million cases projected by 2040.[1] While multiple risk factors contribute to its development and progression, intraocular pressure (IOP) is the only well-established modifiable risk factor.[2,3] First-line management typically involves topical medications to reduce IOP; however, in cases of refractory IOP elevation or when very low target pressures are required, surgical intervention becomes necessary to halt disease progression.[4,5]

Trabeculectomy, first introduced in 1968, remains the gold-standard incisional glaucoma surgery for uncontrolled IOP. However, it necessitates prolonged postoperative recovery, intensive follow-up, and carries significant sight-threatening complications.[6,7] Consequently, the demand for safer, less invasive surgical alternatives has grown, leading to the emergence of minimally invasive glaucoma surgery (MIGS). MIGS techniques aim to achieve IOP reduction with fewer complications than traditional surgeries.[8,9] Nevertheless, while MIGS demonstrates a superior safety profile, its efficacy in achieving very low target IOP remains limited.[10,11]

More recently, minimally invasive bleb surgery (MIBS) has been introduced, bridging the gap between traditional glaucoma surgery and MIGS. The literature suggests, MIBS techniques replicate the mechanisms of conventional

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surgeries while offering greater control over aqueous outflow, reduced complication rates, and superior IOP-lowering efficacy compared to MIGS.[12]

One such MIBS innovation is the Preserflo MicroShunt (Santen, Inc., Osaka, Japan), an ab-externo implant composed of poly(styrene-block-isobutylene-block-styrene), a highly biocompatible material designed to minimize fibrosis and bleb encapsulation.[13,14] The device measures 8.5 mm in length, with a 70 µm lumen diameter and 350 µm outer diameter. Functionally, it diverts aqueous humor from the anterior chamber into the sub-Tenon's space, bypassing the trabecular meshwork and episcleral venous pressure—akin to trabeculectomy—but with enhanced procedural control and reduced invasiveness.[15]

Although several studies have evaluated the safety and efficacy of the Preserflo MicroShunt, further long-term data are needed to validate its outcomes.[16–18] This study investigates the safety and efficacy of the Preserflo MicroShunt with adjunctive Mitomycin C (MMC) 0.5 mg/mL in managing various glaucoma subtypes. Notably, this is the first reported study assessing the device's performance in the Middle East, specifically Saudi Arabia.

Methods

Study Design and Ethical Consideration

This retrospective, interventional, single-arm case series evaluates the safety and efficacy of the Preserflo MicroShunt in various glaucoma subtypes. The study included patients who underwent Preserflo MicroShunt implantation between April 2023 and April 2025, with data collected from three tertiary centers in the Eastern Province of Saudi Arabia. All surgical procedures were performed by a single fellowship trained glaucoma surgeon (A.H) to minimize variability.

The study received Research Ethics Board approval from all three institutions, including King Fahd Hospital of the University, Dhahran Eye Specialist Hospital and Magrabi Health Center, and adhered to the principles of the 1964 Declaration of Helsinki. Given the minimal risk associated and retrospective analysis nature, the Ethics Board waived the requirement for informed consent. Patient data were anonymized and securely maintained, with access restricted to the study investigators to ensure confidentiality.

Inclusion and Exclusion Criteria

This study enrolled adult patients (≥18 years) with inadequately controlled IOP despite maximal tolerated medical therapy or documented glaucoma progression requiring surgical intervention, who underwent Preserflo MicroShunt implantation with standardized intraoperative application of MMC 0.5 mg/mL for 5 minutes. The exclusion criterion was age under 18 years.

Surgical Technique

All surgeries were performed by a single surgeon (A.H.) under local anesthesia using a peribulbar block. The anesthetic solution consisted of a 1:1 mixture of 2% lignocaine with 1:200,000 adrenaline and 0.5% bupivacaine. Following inferior positioning of the eye, a superior corneal traction suture was placed using 7–0 Vicryl. A 6 mm fornix-based conjunctival incision was then created in either the superior temporal or superior nasal quadrant, carefully avoiding the superior rectus muscle. Two 2 mm relaxing incisions were added at each edge to improve surgical exposure. Tenon's capsule was dissected, and episcleral vessels were cauterized for hemostasis. MMC was applied using three LASIK sponges soaked in 0.5 mg/mL MMC, which were placed beneath the conjunctival flap for 5 minutes. This was followed by thorough irrigation with balanced saline solution. A 3 mm reference point was marked posterior to the limbus, and a shallow scleral pocket was fashioned. A 25-gauge needle was introduced into the anterior chamber, bisecting the iridocorneal angle. The Preserflo Microshunt was then inserted bevel-up through the scleral track until the distal wedge locked into position. Device patency was confirmed by observing aqueous humor outflow. Finally, the tenon's and conjunctiva were closed using 9–0 Vicryl -VAS- absorbable sutures.

In cases combined with phacoemulsification, the procedure began with conjunctival dissection as previously described. Following this, standard phacoemulsification was performed through a temporal clear corneal incision using 2.2–2.4 mm keratome, the nucleus removal and cortical cleanup were done routinely, followed by in-the-bag

implantation of a posterior chamber intraocular lens and then complete removal of the ophthalmic viscosurgical device. The surgeon then proceeded with Preserflo Microshunt implantation as described above.

Postoperative Management

Following Preserflo Microshunt implantation, all patients received standardized postoperative care consisting of intensive topical corticosteroid therapy (Prednisolone Acetate 1% every 2 hours while awake) with gradual tapering over six months; and Moxifloxacin 0.5% four times daily for two weeks; additionally, phakic patients who underwent Preserflo Microshunt surgery received Cyclopentolate 1% three times daily for two weeks to prevent hypotony complications including anterior chamber shallowing. All preoperative glaucoma medications were discontinued immediately following surgery.

Patient Data and Study Protocol

Baseline demographic data included patient gender, age, nationality, systemic comorbidities, and history of prior ocular surgeries. All enrolled participants received a standardized preoperative ophthalmic evaluation consisting of detailed anterior segment examination with gonioscopy and complete posterior segment assessment.

Goldmann applanation tonometry (GAT; Haag-Streit, Switzerland) served as the reference standard for all IOP measurements throughout the study. Our preoperative assessment protocol evaluated multiple ocular parameters, including; current number of antiglaucoma medications, best-corrected visual acuity (BCVA) measured using Snellen chart at 6 meters, baseline IOP values, and angle status classification (open versus closed angle) determined through standardized gonioscopic examination.

Additionally, we documented the lens status (phakic or pseudophakic) and objectively quantified the cup-to-disc ratio (CDR) using Spectralis optical coherence tomography (Heidelberg Engineering Inc., Heidelberg, Germany). Additional recorded variables comprised the glaucoma subtype and whether the MicroShunt implantation was performed as a standalone procedure or in combination with phacoemulsification.

Postoperative Follow-Up and Outcomes Assessment

All patients were evaluated postoperatively on day 1, week 1, and at 1, 3, 6, and 12 months. Each follow-up visit included recording of BCVA, IOP, number of antiglaucoma medications, and CDR. At each visit postoperative complications were evaluated and documented, these complications include; hypotony (defined as IOP $\leq$5 mmHg), wound leakage, device exposure, IOP spikes (>21 mmHg), new-onset cataract formation; which was assessed subjectively based on patients' complaint of reduction in vision and objectively based on reduction in BCVA not explained by presence of other ocular pathology; and other procedure-related adverse events. All complications were classified according to onset into; early onset < 3 months and late onset > 3 months.

Outcome Measures

Surgical outcomes were evaluated from postoperative month 1 onward and classified into three categories. Complete success (CS) was defined as achieving the target IOP with a reduction of $\geq$20% from preoperative baseline without the need for any antiglaucoma medications. Qualified success (QS) met the same IOP criteria but required the use of antiglaucoma medications to maintain pressure control. Overall success encompassed all cases meeting either complete or qualified success criteria. Cases were deemed failures if they did not achieve target IOP, showed <20% reduction from preoperative IOP, developed persistent hypotony (IOP $\leq$5 mmHg on consecutive visits) with associated vision loss, experienced loss of light perception, or required revision or other glaucoma surgeries.

Three progressively stringent IOP targets were established:

Criterion A: IOP of 6–21 mmHg with a $\geq$20% reduction from preoperative IOP.

Criterion B: IOP of 6–17 mmHg with a $\geq$20% reduction from preoperative IOP.

Criterion C: IOP of 6–14 mmHg with a $\geq$20% reduction from preoperative IOP.

For statistical analysis, the visual acuity was converted into the logarithm of the minimum angle of resolution.

Statistical Analysis

Qualitative data were summarized using counts and percentages. Conversely, quantitative data were summarized with the mean (standard deviation) or medians (interquartile range [IQR]). The normality of data was assessed with Shapiro–Wilk Test. Baird scale data was compared with paired *t*-test. Paired ordinal data were compared with Wilcoxon signed rank test. Statistical analysis was done by using Statistical Package for the Social Sciences (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). A p-value less than 0.05 was considered statistically significant.

Results

The study cohort comprised 45 eyes from 45 patients, with a male predominance (33 patients, 73.3%) and a median age of 56 years (IQR 39–63, range 20–77). Follow-up compliance was excellent in the early postoperative period, with all patients completing day 1, week 1, and month 1 visits. Follow-up compliance remained high at 3 months (84.4%, n=38) and 6 months (80%, n=36), with 30 patients (66.7%) completing the 1-year follow-up.

The study population consisted predominantly of Saudi patients, with 41 individuals (91.1%) identifying as such. Systemic comorbidities included diabetes mellitus (22.2%, n=10), hypertension (17.7%, n=8), and cardiac disease (8.8%, n=4). Ocular characteristics showed most eyes were phakic at the time of Preserflo MicroShunt implantation (82.2%, n=37). Previous ocular surgeries included phacoemulsification (11.1%, n=5), penetrating keratoplasty (6.7%, n=3), and refractive procedures (6.7%, n=3). Gonioscopic evaluation demonstrated open angles in 91.1% of eyes (n=41). Glaucoma subtype distribution was as follows: primary open-angle glaucoma (53.3%, n=24), juvenile open-angle glaucoma (20.0%, n=9), pseudoexofliative glaucoma (8.9%, n=4), steroid-induced glaucoma (8.9%, n=4), chronic angle closure glaucoma (6.7%, n=3), and uveitic glaucoma (2.2%, n=1). Complete demographic and clinical characteristics are presented in Table 1.

Table 1 Demographic and Clinical Characteristics

Age	**Median** **Interquartile Range** **Minimum-Maximum**	**56** **39–63** **20-77**	
Categorical variables		**Number**	**Percentage**
Gender	Male	33	73.3
	Female	12	26.7
Nationality	Saudi	41	91.1
	Non-Saudi	4	8.9
Systemic comorbidities	Diabetes mellitus	10	22.2
	Hypertension	8	26.72.2
	Cardiac disease	3	2.2
	Sickle cell trait	1	2.2
	Rheumatoid arthritis	1	2.2
	Osteoporosis	1	2.2
	Peptic ulcer disease	1	2.2
	Psychiatric disorder	1	2.2
	Chronic Kidney Disease	1	2.2
	Medically free	18	40
Type of glaucoma	Primary Open Angle Glaucoma	24	53.3
	Chronic Angle Closure Glaucoma	3	6.7
	Juvenile Open-Angle Glaucoma	9	20.0
	Pseudo-exfoliative Glaucoma	4	8.9
	Uveitic Glaucoma	1	2.2
	Steroid-Induced Glaucoma	4	8.9

(*Continued*)

Table 1 (Continued).

Age	**Median** **Interquartile Range** **Minimum-Maximum**	**56** **39–63** **20-77**	
Categorical variables		**Number**	**Percentage**
Angle status by gonioscopy	Open	41	91.1
	Closed	4	8.9
Lens status	Phakic	37	82.2
	Pseudophakic	8	17.8
Past surgeries	None	27	60.0
	Phacoemulsification	5	11.11
	Refractive surgery	3	6.7
	Full-thickness keratoplasty	3	6.7
	Micropulse CPC	2	4.4
	Phacoemulsification + Endocyclphotocoagulation	2	4.4
	Phacoemulsification + iStent	1	2.2
	Squint surgery	1	2.2
	Selective laser trabeculoplasty	1	2.2
	Intravitreal injections	1	2.2
	YAG laser peripheral iridotomy	1	2.2
	Ozurdex implant	1	2.2

Tables 2 and 3 show the details of the preoperative and postoperative outcomes of IOP and number of medications, demonstrating a significant reduction in both at 1 month, 3 months, 6 months, and 1 year post-operatively (P<0.001 for all). Visual acuity remained stable throughout the follow-up period, with no significant changes observed at 1 month (p=0.818) or 1 year (p=0.337) postoperatively (Figure 1). Similarly, serial evaluation of the cup-to-disc ratio showed no significant progression at any measured timepoint (1 month: p=0.323; 3 months: p=1.0; 6 months: p=0.325; 1 year: p=1.0).

Postoperative complications included early postoperative hyphema occurred in 3 eyes (6.7%), all of which resolved spontaneously within the first week. Transient hypotony (IOP ≤5 mmHg) was observed in 12 eyes (26.7%), these cases were not associated with reduced BCVA, choroidal effusion, hypotony maculopathy or shallow anterior chamber, all cases resolved by the 3-month follow-up without intervention. IOP spikes (>21 mmHg) occurred sporadically in 5 eyes (11.1%) at various timepoints during follow-up. Surgical revisions or other glaucoma surgeries were required in 5 cases (11.1%): 3 eyes (6.7%) within the first postoperative month had Preserflo Microshunt revision, 1 eye (3.3%) at 3 months

Table 2 Intraocular Pressure Before and at Different Follow-Ups in Eyes Treated with PRESERFLO® MicroShunt Surgery

	Number of eyes	**Median**	**Interquartile range**	**Minimum- Maximum**
Before surgery	45	26	23.0–33	14 - 47
Day1 postoperative	45	8	7.0–10	3 - 22
Week 1 postoperative	45	9	7.0–10	1 - 24
Month 1 postoperative	45	10	8.0–14	5 - 27
Month 3 postoperative	38	10	8.3–14	6 - 26
Month 6 postoperative	36	10	8.0–14	7 - 25
Month 12 postoperative	30	10	9.0–14	7 - 28

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Table 3 Number of Glaucoma Medications Before & at Different Follow-Up Visits After PRESERFLO® MicroShunt Surgery

	None		1 to 2		3 to 4		More than 4	
	Number	Percentage	Number	Percentage	Number	Percentage	Number	Percentage
Before surgery	2	4.4	3	6.7	28	62.2	12	26.7
Day1	45	100.0	0	0.0	0	0.0	0	0.0
Week1	45	100.0	0	0.0	0	0.0	0	0.0
Month 1	42	93.3	3	6.7	0	0.0	0	0.0
Month 3	32	71.1	6	13.3	0	0.0	0	0.0
Month 6	30	75.0	4	6.7	2	4.4	0	0.0
Month 12	24	53.3	4	8.9	2	4.4	0	0.0

had other glaucoma surgery, and 1 eye (3.3%) at 1 year had Preserflo Microshunt revision. Iridodialysis was documented in 2 eyes (4.4%). Cataract progression was observed in 1 eye (2.2%) at 1 month, an additional eye (3.3%) by 6 months, and 5 eyes (16.7% of those completing 1-year follow-up) at 12 months postoperatively. All complications were systematically documented and categorized by onset time, Table 4.

Table 5 demonstrates excellent IOP control following Preserflo MicroShunt implantation at 1-year follow-up (n=30). When evaluating outcomes using an IOP threshold of ≤21 mmHg with ≥20% reduction from baseline, the procedure achieved complete success in 80.0% of cases (24/30 patients), with an additional 13.3% (4/30) achieving qualified success. This resulted in an overall success rate of 93.3% for this target pressure range. Applying more stringent criteria revealed consistent surgical efficacy. For the intermediate target of IOP ≤17 mmHg with ≥20% reduction, complete success rates remained at 80.0%, while qualified success was maintained at 13.3%. The most strict criterion (IOP ≤14 mmHg with ≥20% reduction) showed slightly reduced but still favorable outcomes, with 76.7% (23/30) achieving complete success and 6.7% (2/30) reaching qualified success, culminating in an 83.4% overall success rate.

At the 6-month postoperative evaluation (n=36), the Preserflo MicroShunt demonstrated excellent efficacy in intraocular pressure (IOP) reduction across multiple success criteria. When assessing outcomes using an IOP threshold of ≤21 mmHg with ≥20% reduction from baseline, complete success was observed in 83.3% of cases (30/36 patients), while qualified success was noted in an additional 13.9% (5/36), yielding overall success rate of 97.2%. More strict

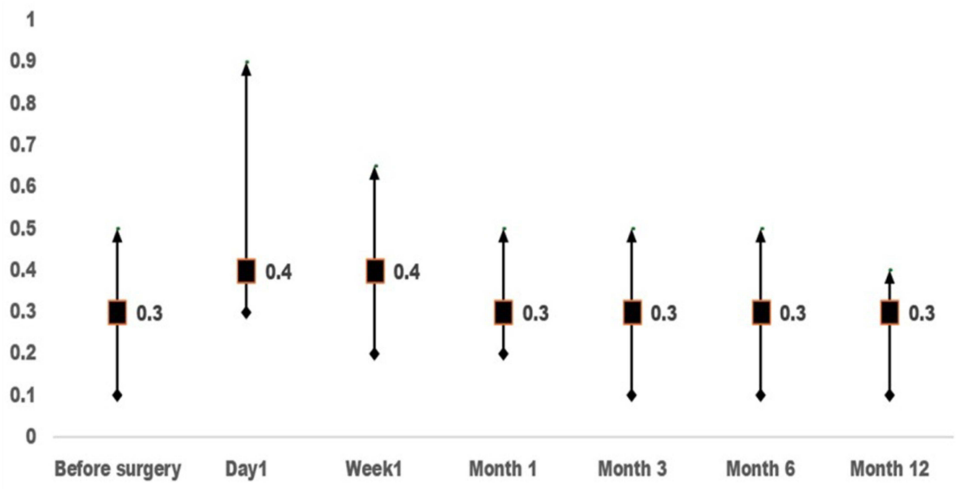

Figure 1 Changes in the best visual acuity in the eyes of glaucoma patients before and after Preserflo MicroShunt surgery.

Table 4 Complications at Different Follow-Ups

Number of Patients	Complications							
	Hyphema	High IOP	Booked for Revision or Other Glaucoma Surgery	Iridodialysis	Cataract	Hypotony	None	Total
45	3 (6.67%)	1 (2.23%)	0	1 (2.23%)	0	7 (15.53%)	33 (73.34%)	45 (100%)
45	0	1 (2.23%)	0	1 (2.23%)	0	7 (15.53%)	36 (80.01%)	45 (100%)
45	0	0	3 (6.67%)	0	1 (2.23%)	2 (4.43%)	39 (86.67%)	45 (100%)
38	0	1 (2.63%)	1 (2.63%)	0	0	0	36 (94.73%)	38 (100%)
36	0	3 (8.33%)	0	0	1 (2.77%)	0	32 (88.90%)	36 (100%)
30	0	1 (3.33%)	1 (3.33%)	0	5 (16.67%)	0	23 (76.67%)	30 (100%)

Table 5 Surgical Outcome

Surgical outcome	Postoperative Time	
	6 Months (n=36)	1 Year (n=30)
Complete success, n (%)		
Criterion A	30 (83.3%)	24 (80%)
Criterion B	28 (77.8%)	24 (80%)
Criterion C	27 (75%)	23 (76.7%)
Qualified success, n (%)		
Criterion A	5 (13.9%)	4 (13.3%)
Criterion B	4 (11.1%)	4 (13.3%)
Criterion C	2 (5.6%)	2 (6.67)
Failure, n (%)		
Criterion A	1 (2.8%)	2 (6.67%)
Criterion B	4 (11.1%)	2 (6.67%)
Criterion C	7 (19.4%)	5 (16.67)

pressure targets revealed similarly favorable outcomes. For an IOP goal of ≤17 mmHg with ≥20% reduction, complete success was maintained in 77.8% of patients (28/36), with qualified success achieved in 11.1% (4/36). The most strict criterion (IOP ≤14 mmHg with ≥20% reduction) showed sustained performance, with complete success in 75.0% of cases (27/36) and qualified success in 5.6% (2/36), resulting in an 80.6% overall success rate.

At the 1-year postoperative evaluation, failure rates demonstrated a graded increase corresponding to the stringency of the success criteria. For Criterion A (IOP ≤21 mmHg with ≥20% reduction), failure occurred in 2 eyes (6.7%). Criterion B (IOP ≤17 mmHg with ≥20% reduction) showed an identical failure rate of 6.7% (2 eyes). Notably, under the strictest Criterion C (IOP ≤14 mmHg with ≥20% reduction), the failure proportion rose to 16.7% (5 eyes). This stepwise escalation in failure rates reflects the challenge of achieving lower target pressures over time, with the most demanding criterion (C) exhibiting a 2.5-fold higher failure rate compared to Criteria A and B.

Analysis for each glaucoma subtype was performed and there was statistically non-significant difference between glaucoma subtypes, the data indicate an excellent overall success rate for individuals with Primary Open-Angle Glaucoma, Juvenile Open-Angle Glaucoma, Pseudoexfoliation Glaucoma, Chronic Angle-Closure Glaucoma, Uveitic glaucoma and steroid-induced glaucoma.

Discussion

In recent years, MIBS has gained increasing prominence as alternative to traditional glaucoma procedures, with the Preserflo Microshunt emerging as a particularly promising option. However, despite this growing adoption, there remains a notable paucity of data regarding outcomes of Preserflo Microshunt implantation in the Middle Eastern population, and specifically in Saudi Arabia. This study aims to address this critical knowledge gap by evaluating the surgical outcomes of Preserflo Microshunt procedures performed in Saudi Arabia. Our findings provide valuable insights into the efficacy and safety profile of this device within this unique demographic context, offering much needed clinical data to inform treatment decisions in the region.

This study evaluated 45 eyes that underwent Preserflo Microshunt implantation with intraoperative application of 0.5 mg/mL mitomycin C for 5 minutes. All procedures were performed by a single surgeon across various glaucoma subtypes. The results demonstrate an excellent safety profile along with statistically and clinically significant IOP reduction throughout the intermediate term follow-up period.

The Preserflo Microshunt drain aqueous into the sub-Tenon's space bypassing the trabecular meshwork, and it offers a more controlled outflow mechanism compared to traditional trabeculectomy. This controlled drainage is governed by the Hagen-Poiseuille equation, which provides good lowering effect of the IOP while minimizing the risk of chronic hypotony. The device's design promotes diffuse and posteriorly located bleb formation, in contrast to the anteriorly located limbal blebs characteristic of trabeculectomy. This anatomical distinction is clinically significant, as anteriorly positioned blebs have been linked to various complications, including fibrosis and subsequent surgical failure.[19,20]

The device demonstrated excellent IOP control, with 6-month follow-up data (n=36) showing a 97.2% overall success rate (83.3% complete success, 13.9% qualified success) for Criterion A (IOP <22 mmHg with ≥20% reduction), achieving a median IOP of 10 mmHg (61.5% reduction from baseline). At 1-year follow-up (n=30), success rates remained consistently high, with 93.3% overall success (80.0% complete, 13.3% qualified) for both Criteria A and B, while the most strict Criterion C (IOP <15 mmHg with ≥20% reduction) showed an 83.4% overall success rate (76.7% complete, 6.7% qualified). At 1 year mean IOP was maintained at 10 mmHg, representing a sustained 61.5% reduction from preoperative values. These results indicate that the MicroShunt provides effective IOP control across multiple therapeutic targets, with success rates remaining stable despite progressively stricter pressure criteria. The stability of complete success rates across different IOP thresholds (76.7–80.0%) suggests consistent device performance regardless of target pressure. The predictable decline in qualified success rates with stricter criteria (from 13.3% to 6.7%) reflects the expected need for supplemental medical therapy when pursuing lower pressure goals.

Among the 45 eyes, four eyes (8.89%) required surgical revision due to uncontrolled IOP despite use of antiglaucoma medications, with three revisions cases occurred after the first month and one case required revision after 1 year follow-up. Intraoperative findings of the revision cases revealed kinking of the microshunt tip with Tenon's capsule obstructing the distal end of the device. One eye required additional glaucoma surgery after 3 months postoperatively, and it was considered as a failure.

The most frequent early postoperative complication (<3 months) was transient hypotony, observed in 12 eyes (26.6%). All cases represented numerical hypotony (IOP ≤5 mmHg) without associated vision loss, and all resolved spontaneously by the 3-month follow-up. The most common late postoperative complication (>3 months) was cataract progression, which developed in 5 eyes (16.7% of 1-year follow-up cases). Sporadic IOP spikes (>21 mmHg) occurred in 5 eyes (11.1%) at various timepoints during follow-up, with no clear pattern. These findings demonstrate an overall favorable safety profile, with most complications being either self-limiting or manageable. The absence of vision-threatening complications and the resolution of all hypotony cases by 3 months demonstrate the safety of the Preserflo MicroShunt implantation.

MMC at higher doses and for longer durations carries a well-documented risk of complications such as bleb leaks, thin cystic blebs, chronic hypotony, choroidal detachment, and corneal epithelial toxicity, these adverse events were not observed in our cohort, likely attributable to the posterior placement of the bleb and the careful avoidance of the conjunctival edge during application.[21]

Schlenker et al, 2020, published an article in which they evaluated 164 eyes undergoing Preserflo MicroShunt implantation. Their cohort demonstrated a 76.9% complete success rate (IOP <22 mmHg without medications) and 15.6% qualified success rate (with medications) at 1 year, yielding a combined 92.5% overall success rate for this criterion. For stricter pressure targets (IOP <15 mmHg), success rates remained similar at 75.6% (complete) and 16.3% (qualified), with a median IOP reduction from 20 mmHg to 12 mmHg postoperatively. These outcomes closely parallel our findings, though our series showed marginally higher complete success rates (80% for IOP <22 mmHg; 76.7% for IOP <15 mmHg), potentially attributable to our standardized use of 0.5 mg/mL MMC compared to their variable concentrations (0.2–0.5 mg/mL). Notably, Schlenker et al identified choroidal detachment as the most frequent early complication (6.7% vs none in our cohort), while transient hypotony dominated our complications (26.6%); these cases were numerical hypotony cases without vision loss or choroidal detachment. Their multivariable analysis revealed that lower MMC concentration (0.2 mg/mL) significantly increased failure risk (HR 2.51; 95% CI 1.12–5.65), underscoring the importance of antimetabolite dosing in surgical success. This evidence collectively suggests that while the Preserflo Microshunt achieves consistent IOP reduction across diverse populations, outcomes may be optimized with MMC concentrations ≥0.4 mg/mL.[17]

On 2023, a comparative study by Panarelli et al reported 2-year outcomes of Preserflo Microshunt versus trabeculectomy, revealing several clinically significant findings. Their protocol utilized a lower antimetabolite concentration (0.2 mg/mL MMC for 2 minutes) compared to our standardized approach (0.5 mg/mL for 5 minutes), which may substantially explain the observed differences in outcomes. The study demonstrated superior success rates with trabeculectomy (64.4%) relative to Microshunt (50.6%), along with corresponding mean postoperative IOP values of 10.7 ± 3.7 mmHg versus 13.9 ± 3.9 mmHg, respectively.[22] These results contrast markedly with our findings of 93.3% success rate (IOP <22 mmHg with ≥20% reduction) at 1 year, suggesting that both MMC concentration and application duration may be critical determinants of surgical success. This interpretation is supported by Schlenker et al identification of 0.2 mg/mL as an independent risk factor for failure (HR 2.51).[17]

Notably, Panarelli's study confirmed the MicroShunt's superior safety profile, demonstrating significantly lower hypotony rates (IOP <6 mmHg) compared to trabeculectomy (30.9% vs 51.1%; $p<0.05$). Our results further reinforce this safety advantage, with only 26.6% incidence of transient hypotony (all cases resolving by 3 months). This collective evidence suggests that while MicroShunt outcomes are protocol dependent, the procedure consistently offers a safer alternative to trabeculectomy regarding hypotony risk, particularly when using optimized MMC parameters. The disparity in success rates between studies highlights the importance of antimetabolite use in achieving optimal IOP control while maintaining the procedure's safety advantages.

Another study published by Baker et al, 2021, provides further evidence comparing Preserflo MicroShunt and trabeculectomy outcomes, reporting a 53.9% success rate for MicroShunt versus 72.7% for trabeculectomy. While these results appear less favorable than our demonstrated 1-year success rates (complete success: 80%; qualified success: 13.3%), the studies show remarkable consistency regarding safety outcomes. Baker et al documented significantly higher hypotony rates with trabeculectomy (49.6%) compared to MicroShunt (28.9%), aligning closely with our observed hypotony incidence of 26.6%. Notably, all hypotony cases in our cohort resolved spontaneously within three months, reinforcing the transient nature of this complication.[23]

The performance disparity between studies likely stems from critical differences in surgical protocol. Our study employed a more intensive antimetabolite regimen (0.5 mg/mL MMC for 5 minutes) compared to Baker et al's protocol (0.2 mg/mL for 2 minutes). This interpretation is supported by accumulating evidence that MMC parameters significantly influence outcomes, as demonstrated by Schlenker et al's finding that 0.2 mg/mL concentration increased failure risk by 2.5-fold.[17] These collective results suggest that while the MicroShunt consistently offers superior safety compared to trabeculectomy, optimal IOP control requires careful attention to MMC dosing and application duration.

A comparative study done by Wagner et al, 2022, of 105 eyes provides valuable insights into the relative efficacy of trabeculectomy versus minimally invasive bleb surgeries, including Preserflo Microshunt. Their results demonstrated comparable 6 month complete success rates between procedures (trabeculectomy: 73.5% vs Microshunt: 74.2%), suggesting equivalent short-term efficacy. However, the study revealed significantly greater IOP reduction in the

trabeculectomy group (mean reduction of 12.1 mmHg) compared to the Preserflo Microshunt cohort (7.3 mmHg reduction, $p<0.05$). This differential efficacy must be weighed against the well-documented safety advantages of Microshunt procedures across studies, including our series which showed low hypotony incidence. The evidence suggests that while trabeculectomy may offer superior IOP lowering magnitude; however, the overall success rate between the groups is similar.[24]

The Preserflo Microshunt represents a valuable advancement in glaucoma surgical management, offering a safe and effective option for patients with medically uncontrolled disease. Compared to traditional glaucoma surgeries, the procedure demonstrates several distinct advantages; a shorter learning curve, significantly lower complication rates (particularly regarding hypotony), and reproducible efficacy when using optimized surgical protocols.[23,24] While other less invasive glaucoma surgeries like deep sclerectomy have shown favorable long-term outcomes, their technical complexity and steep learning curve have limited widespread adoption.[25,26] The Microshunt's relative technical simplicity and favorable risk profile position it as a practical alternative to trabeculectomy, particularly in cases where maximal IOP reduction is not required or when safety considerations are paramount. Current evidence suggests that outcomes may be further optimized through protocol standardization, particularly regarding MMC concentration and duration, making the Microshunt an increasingly important tool in the field of glaucoma.

Limitations and Clinical Significance

While this article provides valuable insights into Preserflo Microshunt outcomes, several limitations must be acknowledged. The retrospective design, single-arm nature, relatively small sample size (n=45), and intermediate-term follow-up period constrain the generalizability of our findings.

Despite these limitations, this study represents a significant contribution to the literature as the first report of Preserflo Microshunt outcomes using 0.5 mg/mL MMC application for 5 minutes from the Middle Eastern region, specifically Saudi Arabia. Our results demonstrate excellent safety and efficacy profiles with this protocol, achieving 97.2% success at 6 months and 93.3% at 1 year follow-up. These findings provide compelling evidence for surgeons adopting this technique and support the use of optimized MMC parameters to enhance surgical outcomes. The study serves as a foundation for future prospective, controlled trials with longer follow-up periods to further validate these observations in Middle Eastern populations.

Conclusion

The Preserflo Microshunt demonstrates the potential as a surgical treatment for glaucoma, offering a favorable balance of efficacy and safety. Our findings support its use as a viable alternative to traditional glaucoma surgeries, with high success rates, significant IOP reduction, and minimal complications. The procedure's advantages include a simplified surgical technique with a shorter learning curve, reduced postoperative medication burden, and lower rates of vision threatening complications compared to trabeculectomy. While these intermediate term results are promising, further prospective studies with longer follow-up periods are needed to establish standardized protocols for MMC application (particularly regarding optimal concentration and duration) and to refine patient selection criteria.

Abbreviations

IOP, intraocular pressure; MIGS, minimally invasive glaucoma surgery; MIBS, minimally invasive bleb surgery; MMC, Mitomycin C; BCVA, best-corrected visual acuity; CDR, cup-to-disc ratio; CS, complete success; QS, qualified success; IQR, interquartile range; SD, standard deviation; P, p-value.

Data Sharing Statement

The data that support the findings of this study are available through the corresponding author. Restrictions apply to the sharing of these data requiring the approval of the research center and the institutions.

Ethics Approval and Patient Consent to Participate

Ethical approval was obtained through the IRB committee in all centers in the study (located at eastern province of kingdom of Saudi Arabia), which include King Fahd Hospital of the University, Dhahran Eye Specialist Hospital, and Magrabi Health Center.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

References

1. Tham YC, Li X, Wong TY, Quigley HA, Aung T, Cheng CY. Global prevalence of glaucoma and projections of glaucoma burden through 2040: a systematic review and meta-analysis. *Ophthalmology*. 2014;121(11):2081–2090. PMID: 24974815. doi:10.1016/j.ophtha.2014.05.013
2. Fechtner RD, Weinreb RN. Mechanisms of optic nerve damage in primary open angle glaucoma. *Surv Ophthalmology*. 1994;39(1):23–42. PMID: 7974188. doi:10.1016/s0039-6257(05)80042-6
3. Wg EHM, Farhat RG, Nehme JC, et al. Comparison of efficacy and ocular surface disease index score between bimatoprost, latanoprost, travoprost, and tafluprost in glaucoma patients. *J Ophthalmology*. 2018:1319628. PMID: 29707390; PMCID: PMC5863284. doi:10.1155/2018/1319628
4. Gedde SJ, Herndon LW, Brandt JD, Budenz DL, Feuer WJ, Schiffman JC. Tube Versus Trabeculectomy Study Group. Postoperative complications in the Tube Versus Trabeculectomy (TVT) study during five years of follow-up. *Am J Ophthalmology*. 2012;153(5):804–814.e1. PMID: 22244522; PMCID: PMC3653167. doi:10.1016/j.ajo.2011.10.024
5. Gedde SJ, Feuer WJ, Shi W, et al. Primary Tube Versus Trabeculectomy Study Group. Treatment outcomes in the primary tube versus trabeculectomy study after 1 year of follow-up. *Ophthalmology*. 2018;125(5):650–663. PMID: 29477688. doi:10.1016/j.ophtha.2018.02.003
6. Cairns JE. Trabeculectomy. Preliminary report of a new method. *Am J Ophthalmology*. 1968;66(4):673–679. PMID: 4891876. doi:10.1016/0002-9394(68)91288-9
7. Edmunds B, Thompson JR, Salmon JF, Wormald RP. The national survey of trabeculectomy. iii. early and late complications. *Eye*. 2002;16(3):297–303. PMID: 12032721. doi:10.1038/sj.eye.6700148
8. Francis BA, Singh K, Lin SC, et al. Novel glaucoma procedures: a report by the American Academy of Ophthalmology. *Ophthalmology*. 2011;118(7):1466–1480. PMID: 21724045. doi:10.1016/j.ophtha.2011.03.028
9. Saheb H, Ahmed IIK. Micro-invasive glaucoma surgery: current perspectives and future directions. *Curr Opin Ophthalmology*. 2012;23(2):96–104. PMID: 22249233. doi:10.1097/ICU.0b013e32834ff1e7
10. Baser EF, Seymenoglu G, Mayali H. Trabeculectomy for advanced glaucoma. *Int Ophthalmology*. 2011;31(6):439–446. PMID: 22200860. doi:10.1007/s10792-011-9494-0
11. Salimi A, Kasner O, Schendel S, et al. Outcomes and risk factors for Kahook Dual Blade excisional goniotomy with concomitant phacoemulsification: a multicentre Canadian study. *Can J Ophthalmology*. 2024;59(5):e461–e470. PMID: 37634551. doi:10.1016/j.jcjo.2023.08.004
12. Konopińska J, Gołaszewska K, Saeed E. Minimally invasive bleb surgery versus minimally invasive glaucoma surgery: a 12-month retrospective study. *Sci Rep*. 2024;14(1):12850. PMID: 38834618; PMCID: PMC11150400. doi:10.1038/s41598-024-61811-y
13. Pinchuk L, Riss I, Batlle JF, et al. The development of a micro-shunt made from poly(styrene-block-isobutylene-block-styrene) to treat glaucoma. *J Biomed Mater Res B Appl Biomater*. 2017;105(1):211–221. PMID: 26380916; PMCID: PMC5215625. doi:10.1002/jbm.b.33525
14. Pinchuk L, Riss I, Batlle JF, et al. The use of poly(styrene-block-isobutylene-block-styrene) as a microshunt to treat glaucoma. *Regen Biomater*. 2016;3(2):137–142. PMID: 27047682; PMCID: PMC4817329. doi:10.1093/rb/rbw005
15. Batlle JF, Fantes F, Riss I, et al. Three-year follow-up of a novel aqueous humor microShunt. *J Glaucoma*. 2016;25(2):e58–65. PMID: 26766400. doi:10.1097/IJG.0000000000000368
16. Durr GM, Schlenker MB, Samet S, Ahmed IIK. One-year outcomes of stand-alone ab externo SIBS microshunt implantation in refractory glaucoma. *Br J Ophthalmology*. 2022;106(1):71–79. PMID: 33097520. doi:10.1136/bjophthalmol-2020-317299
17. Schlenker MB, Durr GM, Michaelov E, Ahmed IIK. Intermediate outcomes of a novel standalone ab externo SIBS microshunt with mitomycin C. *Am J Ophthalmology*. 2020;215:141–153. PMID: 32173344. doi:10.1016/j.ajo.2020.02.020
18. Tanner A, Haddad F, Fajardo-Sanchez J, et al. One-year surgical outcomes of the PreserFlo MicroShunt in glaucoma: a multicentre analysis. *Br J Ophthalmology*. 2023;107(8):1104–1111. PMID: 35365491; PMCID: PMC10359526. doi:10.1136/bjophthalmol-2021-320631
19. Batlle JF, Corona A, Albuquerque R. Long-term results of the preserflo microshunt in patients with primary open-angle glaucoma from a single-center Nonrandomized Study. *J Glaucoma*.;30(3):281–286. PMID: 33137019; PMCID: PMC8041565. doi:10.1097/IJG.0000000000001734

20. Pillunat KR, Herber R, Jamke M, et al. Early results of preserflo microshunt for primary open angle glaucoma in white patients. *J Glaucoma*.;34 (2):103–113. PMID: 39401481. doi:10.1097/IJG.0000000000002509
21. Nassiri N, Sheibani K, Kavousnezhad S, Nassiri S, Azemati A, Nassiri N. Use of mitomycin c in ophthalmic surgery. *J Curr Ophthalmology*. 2024;36(3):211–222. PMID: 40557398; PMCID: PMC12184863. doi:10.4103/joco.joco_283_23
22. Panarelli JF, Moster MR, Garcia-Feijoo J, et al. INN005 Study Group. Ab-externo microshunt versus trabeculectomy in primary open-angle glaucoma: two-year results from a randomized, multicenter study. *Ophthalmology*. 2024;131(3):266–276. PMID: 37769852. doi:10.1016/j.ophtha.2023.09.023
23. Baker ND, Barnebey HS, Moster MR, et al. INN005 Study Group. Ab-externo microshunt versus trabeculectomy in primary open-angle glaucoma: one-year results from a 2-year randomized, multicenter study. *Ophthalmology*. 2021;128(12):1710–1721. PMID: 34051211. doi:10.1016/j.ophtha.2021.05.023
24. Wagner FM, Schuster AK, Munder A, et al. Comparison of subconjunctival microinvasive glaucoma surgery and trabeculectomy. *Acta Ophthalmology*. 2022;100(5):e1120–e1126. PMID: 34626093. doi:10.1111/aos.15042
25. Rabiolo A, Leadbetter D, Alaghband P, Anand N. Primary deep sclerectomy in open-angle glaucoma: long-term outcomes and risk factors for failure. *Ophthalmol Glaucoma*. 2021;4(2):149–161. PMID: 32882413. doi:10.1016/j.ogla.2020.08.013
26. Mendrinos E, Mermoud A, Shaarawy T. Nonpenetrating glaucoma surgery. *Surv Ophthalmology*. 2008;53(6):592–630. PMID: 19026321. doi:10.1016/j.survophthal.2008.08.023