

Xen® Gel Stent versus PreserFlo™ MicroShunt as a subconjunctival shunt devices in glaucoma: a systematic review

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ABSTRACT

BACKGROUND Glaucoma is the leading cause of irreversible blindness and is primarily managed by reducing intraocular pressure (IOP). Minimally invasive glaucoma surgeries, particularly subconjunctival shunt devices such as Xen® Gel Stent and PreserFlo™ MicroShunt, have emerged as alternatives to traditional trabeculectomy. This study aimed to evaluate their effectiveness in lowering IOP, reducing medication use, and assessing reinterventions and safety.

METHODS A systematic review was conducted in accordance with Cochrane and PRISMA guidelines. Comprehensive literature searches were conducted across PubMed, Cochrane, EBSCOhost, and Google Scholar databases from the earliest available date to September 2023. Studies comparing Xen® Gel Stent and PreserFlo™ MicroShunt in adult patients with glaucoma were included. Data were extracted on study design, sample size, IOP outcomes, antiglaucoma medication use, reinterventions, and safety outcomes. Quality assessment was performed using the Newcastle-Ottawa Scale.

RESULTS Of 5 European studies (2020–2023; 329 patients, 6–18 months of follow-up), 3 studies reported lower postoperative IOP with PreserFlo™ MicroShunt (11.8 [3.7] versus 13.6 [3.5] mmHg, $p = 0.02$; 10.3 [2.1] versus 14.2 [2.1] mmHg, $p = 0.0005$; 10.3 [3.2] versus 13.1 [6.4] mmHg, $p = 0.019$). Only one study noted fewer antiglaucoma medications with PreserFlo™ MicroShunt (0.2 [0.6] versus 1.1 [2.4], $p = 0.04$). Reinterventions including needling and bleb revisions were higher with Xen® Gel Stent (35.4% versus 11.5%; 20% versus 5%). Complication profiles varied, with hypotony more common in Xen® Gel Stent (6.5% versus 0%), hyphema more common with PreserFlo™ MicroShunt (7.7% versus 3.2%), and stent curling and migration more common with Xen® Gel Stent (15% versus 0%; 2% versus 0%), respectively.

CONCLUSIONS Both Xen® Gel Stent and PreserFlo™ MicroShunt effectively lowered IOP and reduced medication burden in patients with glaucoma. PreserFlo™ MicroShunt may provide superior IOP control and fewer postoperative interventions. Further prospective studies in diverse populations are warranted.

KEYWORDS filtering surgery, glaucoma, glaucoma drainage implants, intraocular pressure, minimally invasive surgical procedures

Glaucoma is a group of eye disorders characterized by progressive optic neuropathy resulting from damage to the retinal ganglion cells and nerve fibers. It is the second leading cause of blindness globally after cataracts, affecting an estimated 57.5 million individuals with primary open-angle glaucoma and is

projected to reach 111.8 million by 2040.¹ Despite diverse treatment options, the socioeconomic burden remains substantial, with annual costs in the United States alone estimated at approximately USD 2.9 billion.²

The only modifiable risk factor in glaucoma management is lowering the intraocular pressure (IOP),

which can be achieved through medication, lasers, or surgery. For patients whose disease progression persists despite conservative treatment, surgical intervention is essential.^{3,4} Trabeculectomy (TE) has long been the traditional gold standard for facilitating the outflow of the aqueous humor and maintaining a lower IOP. Minimally invasive glaucoma surgery (MIGS), particularly minimally invasive bleb surgery, is a potential alternative that offers effective results and improved safety.^{5,6}

Among MIGS techniques designed for subconjunctival drainage, the Xen® Gel Stent (Allergan Inc., USA) and PreserFlo™ MicroShunt (Santen Pharmaceutical Co., Ltd., Japan) are two notable options. These implants are the most extensively studied subconjunctival MIGS devices, with numerous peer-reviewed studies evaluating their long-term efficacy and safety. Although they employ different surgical approaches (*ab interno versus ab externo*), both aim to divert the aqueous humor from the anterior chamber to the subconjunctival space. No comprehensive systematic review has directly compared these two types of implants. This study aimed to evaluate their effectiveness in reducing IOP, reducing the need for antiglaucoma medications, and assessing postoperative reintervention and safety outcomes.

METHODS

Search strategy

Two reviewers (MKH and ANS) independently searched PubMed, Cochrane, EBSCOhost, and Google Scholar, covering the literature until September 5, 2023, and identified studies that compared the Xen® Gel Stent with PreserFlo™ MicroShunt in patients with glaucoma. The search strategy incorporated various combinations of the following terms: “Glaucoma,” “Xen® Gel Stent,” “PreserFlo™,” “Efficacy,” and “Effectiveness.” Manual searches were not performed. Discrepancies during screening and data extraction were resolved through discussions between the two reviewers. This review followed the Cochrane Handbook for Systematic Reviews of Interventions version 6.2 and Preferred Reporting Items for Systematic reviews and Meta-Analyses guidelines.

Study selection and data extraction

We applied predetermined inclusion and exclusion criteria based on our search strategies. Literature

searches were conducted using combinations of terms related to glaucoma and devices of interest. For PubMed and Cochrane, the following Medical Subject Headings (MeSH) and keywords were used: “Glaucoma/surgery”[Mesh] OR “Glaucoma/therapy”[Mesh] OR “glaucoma”[MeSH Terms] OR glaucoma[Text Word] AND “Xen® Gel Stent” AND “PreserFlo™” AND (efficacy OR effectiveness). In EBSCOhost and Google Scholar, the following broader terms were used: (glaucoma OR primary glaucoma OR secondary glaucoma OR raised intraocular pressure) AND (Xen® Gel Stent) AND (PreserFlo™). No date, language, or study design filters were applied to any database. Eligible studies were cohort studies or case series involving adult patients with glaucoma of any age group that compared the Xen® Gel Stent (intervention) with PreserFlo™ MicroShunt (comparator). Studies were excluded if the full text could not be retrieved, reported only qualitative outcomes, or the outcomes of interest were not measured. Studies that measured but did not report outcomes of interest were included. If such data were used later in the extraction, we attempted to contact the authors of the report. Only studies published in English were considered eligible for inclusion.

The quality of each included study was assessed using the Newcastle-Ottawa Scale (NOS) for Cohort Studies. This tool evaluates studies across three domains: selection of study groups (four items), comparability of groups (one item), and ascertainment of outcomes (three items). Each item was rated with a star (*) if the criterion was met. Based on the total number and pattern of stars, the overall study quality was categorized using the Agency for Healthcare Research and Quality (AHRQ) standards. Studies with 3–4 stars in selection, 1 in comparability, and 2–3 in outcome were rated good; those with 2 stars in selection, 1 in comparability, and 2–3 in outcome were rated fair; and those with 0–1 stars in selection, 1 in comparability, and 0–1 in outcome were rated poor. Two reviewers (MKH and ANS) independently performed the assessments, and discrepancies were resolved through discussion. In the quality assessment table, each NOS item was labeled according to the subcategories of the original scale (e.g., a and b). A star (*) was awarded to response options that satisfied the NOS criteria; some items allowed more than one acceptable option (e.g., both a and b may receive a star).

Key information extracted from each study included (1) author and year of publication, (2) study design and location, (3) sample size and mean age of participants, (4) intervention details, and (5) study outcomes (the parameters assessed, pre- and postintervention values, and statistical significance). A formal assessment of reporting bias (e.g., funnel plot) was not performed as no meta-analysis was conducted. However, we assessed the risk of selective reporting by verifying whether the outcomes described in the methods section were fully reported in the results section of each included study.

For efficacy, the data included IOP, the number of antiglaucoma medications used, and reinterventions (e.g., reoperations, postoperative bleb management, needling, bleb revisions, or glaucoma filtration surgery). Complications, such as hypotony, hyphema, choroidal detachment, and conjunctival dehiscence, were recorded for safety. Data extraction was performed independently by two reviewers (MKH and ANS) using a standardized form. The extracted data were cross-checked to ensure accuracy and completeness. Discrepancies were resolved through discussion to reach a consensus.

A narrative synthesis was performed to summarize and compare the outcomes of the included studies. Given the small number of included studies (n = 5), a meta-analysis was not conducted. Instead, key findings, including IOP reduction, changes in antiglaucoma medication use, and reported complications, were extracted and compared. The data were compiled and summarized using Microsoft Excel (Microsoft, USA). No additional effect size measures (e.g., odds ratios or mean differences) were calculated. Means, standard deviations, p-values, and complication frequencies were reported, as presented in the original studies.

RESULTS

A total of 105 articles were identified across the four databases, and 12 duplicates were removed. After screening the titles and abstracts of the remaining 93 articles, 51 were excluded as they were irrelevant. The full texts of 42 articles were assessed, and five studies met the inclusion criteria for this review (Figure 1). Overall, these five studies were rated as good quality (Table 1). However, some

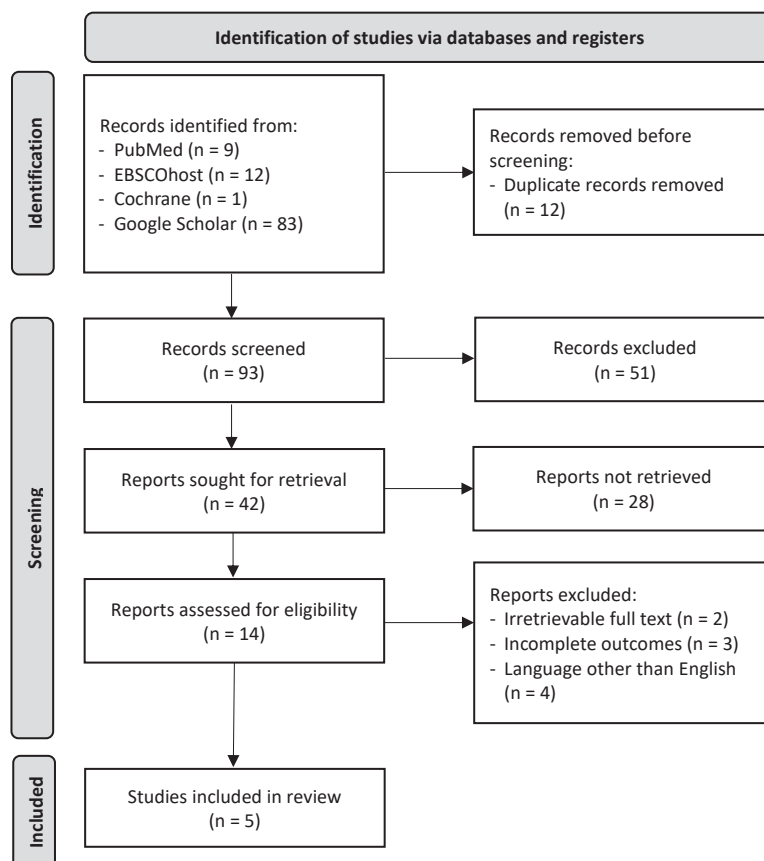


Figure 1. Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) flow diagram of literature search

Table 1. Quality assessment of selected studies based on the NOS and AHRQ standards

First author, year	Selection			Comparability			Outcome			Total quality score	AHRQ standard
	Representativeness of exposed cohort	Selection of nonexposed cohort	Ascertainment of exposure	Demonstration that outcome of interest was not present at start of study	Design or analysis controlled for confounders	Assessment of outcome	Follow-up length	Loss to follow-up rate			
Giansanti, ¹⁰ 2023	a*	a*	a*	a*	b*	b*	a*	a*	a*	8	Good
Hasan, ⁷ 2023	b*	a*	a*	a*	b*	b*	b	a*	a*	7	Good
Theilig, ¹¹ 2023	a*	a*	a*	a*	b*	b*	a*	b*	b*	8	Good
Gambini, ⁹ 2022	a*	a*	a*	a*	b*	b*	a*	a*	b*	8	Good
Scheres, ⁸ 2020	b*	a*	a*	a*	b*	b*	b	a*	a*	7	Good

AHRQ=Agency for Healthcare Research and Quality; NOS=Newcastle-Ottawa scale
 A study is rated good with 3–4 stars in selection, 1 in comparability, and 2–3 in outcome; fair with 2 in selection, 1 in comparability, and 2–3 in outcome; and poor with 0–1 in selection, 1 in comparability, and 0–1 in outcome. NOS item responses are labeled (a, b) according to the original scale
 *Indicates that the criterion was met and awarded a point toward quality scoring

studies, including Hasan et al⁷ and Scheres et al⁸ had shorter follow-up periods, which may limit the significance of the results compared with studies with longer durations.

All studies were conducted in Europe (Italy, Germany, and the Netherlands) between 2020 and 2023 and included a total of 329 patients. Four studies employed retrospective cohort designs, and one was a case series. Follow-up periods ranged 6–18 months, and the outcomes primarily included IOP, number of antiglaucoma medications, and the need for additional procedures (Tables 2 and 3).

Three of the five studies reported significantly lower postoperative IOP in patients treated with PreserFlo™ MicroShunt compared to those treated with Xen® Gel Stent. For instance, Hasan et al,⁷ reported a mean IOP of 13.6 (3.5) mmHg (Xen® Gel Stent) versus 11.8 (3.7) mmHg (PreserFlo™ MicroShunt; *p* = 0.02). Gambini et al⁹ similarly reported mean IOP values of 14.2 (2.1) mmHg (Xen® Gel Stent) versus 11.3 (2.1) mmHg (PreserFlo™ MicroShunt; *p* = 0.0005) at 1 month postsurgery. Scheres et al⁸ found significant differences at 1 and 2 months, although these differences were no longer observed at 24 months. Giansanti et al¹⁰ and Theilig et al¹¹ found no significant differences in IOP between the groups. Only Hasan et al⁷ observed a significantly lower number of antiglaucoma medications in the PreserFlo™ MicroShunt group (0.2 ± 0.6) compared to Xen® Gel Stent (1.1 ± 2.4; *p* = 0.04).

Needling, bleb revisions, and additional glaucoma interventions (e.g., TE, MicroPulse transscleral cyclophotocoagulation, and stent placement) were generally more common with Xen® Gel Stent in most studies. Giansanti et al¹⁰ also noted a needling rate of 35.4% (Xen® Gel Stent) versus 11.5% (PreserFlo™ MicroShunt), whereas Scheres et al⁸ reported similar trends (20% versus 5%). Complications varied among the studies. Giansanti et al¹⁰ found higher hypotony rates in the Xen® Gel Stent group (6.5% versus 0%) but more cases of hyphema in the PreserFlo™ MicroShunt group (7.7% versus 3.2%). Theilig et al¹¹ documented choroidal detachment and conjunctival dehiscence in both groups. Scheres et al⁸ reported more early postoperative complications with PreserFlo™ MicroShunt, whereas late complications—such as stent curling or migration—were more frequently observed with Xen® Gel Stent.

Table 2. Summary of study characteristics and primary outcomes

First author, year	Sample characteristic	Time	Outcomes						
			IOP, mean (SD)		Antiglaucoma medications taken, mean (SD)		Reinterventions		
			Xen® Gel	PreserFlo™	p	Xen® Gel		PreserFlo™	p
Giansanti, ¹⁰ 2023	Sample (n): Xen® Gel: 31; PreserFlo™: 26	Baseline	17.84 (4.48)	17.27 (4.23)	0.626	2.45 (1.26)	2.65 (0.89)	0.496	- Needling: Xen® Gel: 11 (35.4%); PreserFlo™: 3 (11.5%)
	Age, mean (SD): Xen® Gel: 71 (9); PreserFlo™: 72 (7)	Post-op day 1	9.13 (3.019)	8.38 (4.759)	0.477	0	0	0	- Bleb revisions: Xen® Gel: 3 (9.6%); PreserFlo™: 1 (3.8%)
	Follow-up duration (month): Xen® Gel: 12; PreserFlo™: 12	Post-op month 3	15.13 (7.915)	13.58 (4.402)	0.377	0.06 (0.359)	0.23 (0.652)	0.228	- TE/glaucoma valve implantation: Xen® Gel: 4 (12.9%); PreserFlo™: 3 (11.5%)
		Post-op month 6	15.35 (6.626)	13.54 (3.695)	0.235	0.13 (0.499)	0.17 (0.565)	0.795	
		Post-op month 12	13.94 (3.463)	14.67 (5.370)	0.543	0.35 (0.709)	0.52 (0.947)	0.462	
			13.48 (2.55)	13.31 (1.54)	0.76	0.32 (0.653)	0.24 (0.66)	0.642	
Hasan, ⁷ 2023	Sample (n): Xen® Gel: 39; PreserFlo™: 41	Baseline	21.4 (4.6)	11.8 (3.7)	0.26	2.9 (1.0)	3.0 (1.3)	0.8	NA
	Age, mean (SD): Xen® Gel: 67.4 (8.5); PreserFlo™: 67.2 (13.0)	Post-op	13.6 (3.5)	11.8 (3.7)	0.02	1.1 (2.4)	0.2 (0.6)	0.04	
	Follow-up duration (month): Xen® Gel: 10; PreserFlo™: 8								
Theilig, ¹¹ 2023	Sample (n): Xen® Gel: 29; PreserFlo™: 23	Baseline	24.2 (4.7)	27.3 (8.7)	0.109	0.7 (1.3)	1.2 (1.3)	0.178	
	Age, mean (SD): Xen® Gel: 70.5 (6.6); PreserFlo™: 73.3 (6.9)	Post-op month 1	14.3 (3.2)	14.5 (6.0)	0.896	0.4 (0.9)	1.2 (1.3)	0.295	- Re-operations: Xen® Gel: 9; PreserFlo™: 9
	Follow-up duration (month): Xen® Gel: 6; PreserFlo™: 6	Post-op month 3	14.0 (3.9)	18.6 (11.3)	0.082	0.5 (0.9)	0.9 (1.5)	0.227	
		Post-op month 6	13.5 (4.6)	15.9 (5.8)	0.140	0.4 (0.8)	1.0 (1.5)	0.097	
Gambini, ⁹ 2022	Sample (n): Xen® Gel: 29; PreserFlo™: 29	Baseline	22.1 (2.9)	22.0 (3.3)	0.81	2.5 (1.0)	2.7 (0.8)	0.53	- Bleb needling: Xen® Gel: 6 (21%); PreserFlo™: 2 (7%)
	Age, mean (SD): Xen® Gel: 73.2 (4.8); PreserFlo™: 72.2 (5.7)	Post-op month 1	14.2 (2.1)	11.3 (2.1)	0.0005	-	-	-	- Bleb revision: Xen® Gel: 2 (7%); PreserFlo™: 1 (3%)
	Follow-up duration (month): Xen® Gel: 6; PreserFlo™: 6	Post-op month 3	13.8 (2.0)	12.1 (2.2)	NA	-	-	-	
		Post-op month 6	14.2 (2.0)	12.9 (2.1)	NA	0.7 (1.1)	0.4 (1.2)	0.14	

Table continued on next page

Table 2. (Continued)

First author, year	Sample characteristic	Outcomes							
		Time		IOP, mean (SD)		Antiglaucoma medications taken, mean (SD)		Reinterventions	
		Xen® Gel	PreserFlo™	p	Xen® Gel	PreserFlo™	p	Xen® Gel	PreserFlo™
Scheres, ⁸ 2020	Sample (n): Xen® Gel: 41; PreserFlo™: 41	Baseline	19.2 (4.4)	20.1 (5.0)	0.39	2.5 (1.4)	2.3 (1.5)	NA	- Bleb revision: 2 (5%) - Bleb needling: 8 (20%) - MP-TSCPC: 8 (20%)
	Age, mean (SD): Xen® Gel: 69 (8); PreserFlo™: 66 (9)	Post-op month 1	13.1 (6.4)	10.3 (3.2)	0.019	0.1 (0.3)	0.1 (0.4)	NA	- Trabecular micro-bypass stent: 1 (2%) - Glaucoma filtration device: 2 (5%) - TE: 1 (2%)
	Follow-up duration (month): Xen® Gel: 22.4; PreserFlo™: 18.9	Post-op month 3	13.8 (4.6)	10.9 (2.8)	0.002	0.2 (0.7)	0.0 (0.0)	NA	
		Post-op month 6	14.5 (4.8)	12.5 (4.2)	0.07	0.6 (1.0)	0.2 (0.5)	NA	
		Post-op month 12	13.3 (2.9)	12.1 (3.5)	0.17	0.8 (1.2)	0.6 (1.0)	NA	
		Post-op month 24	13.8 (3.8)	12.1 (3.5)	0.19	0.9 (1.2)	0.7 (1.1)	NA	

IOP=intraocular pressure; MP-TSCPC=MicroPulse transscleral cyclophotocoagulation; NA=not available; SD=standard deviation; TE=trabeculectomy. Studies by Giansanti and Gambini are from Italy, Hasan and Theilig are from Germany, and Scheres is from Netherlands. Studies by Giansanti, Hasan, Theilig, and Gambini are using XEN-Gel-Stent and Scheres is using XEN45 Gel Stent®(Xen) implant. All studies are using PreserFlo™ MicroShunt as comparator.

DISCUSSION

In this study, we compared two microinvasive glaucoma surgeries, namely the Xen® Gel Stent and PreserFlo™ MicroShunt, both of which improve subconjunctival drainage to lower IOP in patients with open-angle glaucoma.⁹ Xen® Gel Stent (6 mm long, 45 µm diameter), made of cross-linked porcine gelatin, is typically inserted via an *ab interno* approach, and is designed to reduce postoperative hypotony using the principles of Hagen–Poiseuille flow.^{12,13} The PreserFlo™ MicroShunt (8.5 mm long, 70 µm diameter) is composed of a synthetic, non-biodegradable elastomer styrene-block-isobutylene-block-styrene (SIBS) and is implanted using an *ab externo* approach with Hagen–Poiseuille resistance to minimize scarring and inflammation.^{14,15} The Xen® Gel Stent is generally indicated for refractory and various types of open-angle glaucoma but is avoided in angle-closure cases due to potential implant obstruction, whereas PreserFlo™ MicroShunt is used in cases of early to advanced open-angle glaucoma inadequately controlled by medication.^{14,16}

Comparative analyses yielded mixed results, with some studies showing no significant differences in surgical outcomes, whereas others showed that PreserFlo™ MicroShunt was superior in lowering IOP and the need for antiglaucoma medications. While both devices use the Hagen–Poiseuille equation to calculate flow resistance based on lumen diameter and tube length, PreserFlo™ MicroShunt is predicted to produce a resistance of 2 mmHg/l/min, compared to 8.5 mmHg/l/min for Xen® Gel Stent. This difference in outflow resistance likely explains why the IOP was lower in the PreserFlo™ MicroShunt group, as lower flow resistance produced intermediate drainage that was maintained over time. In addition, the technique used to insert the device may affect the outcome.⁹ PreserFlo™ MicroShunt is normally implanted using an *ab externo* technique, allowing for more controlled positioning of the tube. In contrast, Xen® Gel Stent can be inserted via the *ab interno* or *ab externo* approach. Lenzhofer et al¹⁵ reported that Xen® Gel Stent inserted via the *ab interno* technique can be inserted superficially (intraconjunctival) or deeper near the sclera, with better IOP control and lower flow resistance achieved with deeper insertion of the device.¹⁵ While *ab interno* implantation is less traumatic, implant placement is relatively uncontrolled, leading to uncertainty regarding whether the implant is placed superficially or

Table 3. Summary of secondary outcome

First author, year	Complications	
	Xen® Gel	PreserFlo™
Giansanti, ¹⁰ 2023	- Hypotony: 2 (6.5%) - Hyphema: 1 (3.2%)	- Hypotony: 0 - Hyphema: 2 (7.7%)
Hasan, ⁷ 2023	NA	NA
Theilig, ¹¹ 2023	- Choroidal detachment: 3 - Conjunctival dehiscence: 3 - Exposure of the implant: 0	- Choroidal detachment: 3 - Conjunctival dehiscence: 0 - Exposure of the implant: 1
Gambini, ⁹ 2022	NA	NA
Scheres, ⁸ 2020	<p>Early postoperative complications:</p> <ul style="list-style-type: none"> - Hypotony <5 mmHg at anytime: 10 (24%) - Hypotony requiring reformation of anterior chamber: 2 (5%) - Hyphema: 9 (22%) - Choroidal detachment: 1 (2%) <p>Late postoperative complications:</p> <ul style="list-style-type: none"> - Ptosis: 0 - Hypotony: 3 (8%) - Curling of stent: 6 (15%) - Tube occlusion: 0 - Migration of stent: 1 (2%) 	<p>Early postoperative complications:</p> <ul style="list-style-type: none"> - Hypotony <5 mmHg at anytime: 16 (39%) - Hypotony requiring reformation of anterior chamber: 1 (2%) - Hyphema: 8 (20%) - Choroidal detachment: 1 (2%) <p>Late postoperative complications:</p> <ul style="list-style-type: none"> - Ptosis: 1 (2%) - Hypotony: 0 - Curling of stent: 0 - Tube occlusion: 1 (2%) - Migration of stent: 0

NA=not available

deeper. The *ab externo* technique allows dissection of Tenon's capsule from the sclera, allowing the implant to be placed in the sub-Tenon space.¹¹

The differences in outflow resistance have several implications. Scarring is more likely to develop in areas of higher bleb pressure, typically at the top, but not at the horizontal margins, where the pressure is lower.¹⁶ Subconjunctival fibrosis is the most significant risk factor for bleb failure, as aqueous humor outflow through the bleb directly influences IOP reduction.⁹ PreserFlo™ MicroShunt allows lower pressure flow, thus allowing a higher number of functional blebs and increasing bleb horizontal bounds, explaining the lower rate of surgical bleb revisions needed.^{7,9} Another aspect to consider is the inflammatory response postoperatively. Inflammation is a major contributor to surgical failure in patients with glaucoma. PreserFlo™ MicroShunt is made with SIBS polymer, a material used in cardiac stents, which has been shown to have no biodegradation and little tissue reactivity.⁹ However, a study by Giansanti et al¹⁰ showed that while fibrosis is higher in Xen® Gel Stent (38.7%) compared to PreserFlo™ MicroShunt (23.0%), this difference is not statistically significant ($p = 0.205$).¹⁰ These two devices also used different techniques of mitomycin C (MMC) application to prevent postoperative scarring.

In PreserFlo™ MicroShunt, a cellulose sponge soaked in 0.02 mg/dl of MMC was placed onto the bare sclera for 2.5–3 min. In contrast, an intrableb injection administered at the end of surgery was administered for Xen® Gel Stent, allowing for a more controlled application.^{10,11} Different amounts and methods of MMC administration impact the surgical success of glaucoma filtration surgery.⁸

Although the need for additional postoperative procedures was higher in the Xen® Gel Stent group, the difference was not significant. Scheres et al⁸ reported no significant differences in the number of bleb needling procedures or additional glaucoma surgery rates between the two groups. Because Xen® Gel Stent and PreserFlo™ MicroShunt placement depend on functional blebs for efficacy, bleb needling is a common postoperative procedure. Giansanti et al¹⁰ and Scheres et al⁸ noted higher needling in the Xen® Gel Stent group than in the PreserFlo™ MicroShunt group. The need for reoperation or bleb revision was generally lower in the Preser Flo group, with revisions being 9.6% in the Xen® Gel Stent group and 3.8% in the PreserFlo™ MicroShunt group. The lower rate of fibrosis in PreserFlo™ MicroShunt can also explain the lower rate of complications, bleb revisions, and bleb manipulation. Despite the techniques, bleb fibrosis

remains the most common cause of surgical failure, despite the use of MMC.¹⁷

For MIGS devices that rely on subconjunctival filtration, bleb-related complications are the most common issues. These problems often require postoperative needling to restore bleb function.¹⁶ Early needling is usually triggered by elevated IOP on the first postoperative day. This rise in pressure may result from blockage of the Xen® Gel Stent by tenon's tissue, blood, or exudates, although this mechanism has not been well studied.¹⁸

Hypotony frequently occurred within the first month in both groups, but rarely persisted for >30 days. Giansanti et al¹⁰ reported a 6.5% hypotony rate in the Xen® Gel Stent group, with none in the PreserFlo™ MicroShunt group. Gambini et al⁹ reported higher hypotony rates (20% at Xen® Gel Stent and 28% at PreserFlo™ MicroShunt group), which resolved spontaneously within 30 days. Hyphema was also observed in 3.2% of the Xen® Gel Stent group, while 7.7% were in the PreserFlo™ MicroShunt group.¹⁰

Ocular hypotony is often defined by a specific numerical threshold, typically ≤ 6 mmHg. One identified risk factor for hypotony after Xen® Gel Stent implantation is eyes with longer axial lengths, likely due to a thinner scleral wall that potentially leaks aqueous humor near the implant.¹⁹ Postoperative hypotony can reverse the normal pressure gradient between the episcleral venous pressure and IOP, potentially leading to hyphema. In MIGS procedures, where the natural outflow system is restored, hyphema may indicate regurgitation of blood from the episcleral venous system through the Xen® Gel Stent. Most self-limiting hyphae occur during or shortly after surgery, with the bleeding source often located at the base of the iris.²⁰

Choroidal detachment is a complication of ocular hypotony. Although some patients required anterior chamber reformation, most resolved spontaneously. This condition is thought to be caused by reduced IOP and inflammation. Prolonged medication use can harm the ciliary body. During surgery, it can lead to decreased aqueous production, resulting in significant hypotony. Conversely, prostaglandins may lead to permanent changes in collagen levels within the uveoscleral outflow pathway, increasing the risk of postsurgical hypotony and altering capillary permeability, which can promote uveal exudation.²¹

This study has several limitations. The included studies were retrospective observational studies.

Therefore, prospective studies are required to provide stronger evidence. Furthermore, all studies were conducted in Europe with Caucasian patients, limiting their generalizability to different ethnic populations. Postoperative treatment with MMC also differed between the two groups, which may have influenced the surgical outcomes outside the implanted device. In addition, the review process was subject to certain limitations, such as language bias owing to the exclusion of non-English studies. Future research should address these gaps to better inform clinical decision-making across a broader population.

This systematic review summarizes studies that compared two microinvasive glaucoma surgical approaches: the Xen® Gel Stent and the PreserFlo™ MicroShunt. Both interventions significantly lower IOP from baseline, with comparison in preoperative and postoperative values, with reductions maintained for up to 24 months. However, notable variations emerged at approximately Days 300 and 239. Postoperatively, the patients in both groups required fewer antiglaucoma medications. Some individuals required additional interventions, such as bleb needling, bleb revision, cyclophotocoagulation, TE, or glaucoma valve implantation, within 6 months to 2 years of the initial procedure. The Xen® Gel Stent was linked to a higher number of reinterventions compared with the PreserFlo™ MicroShunt. Hypotony was the most frequently observed complication, although the incidence was low. In some cases, anterior chamber reformation was necessary.

Conflict of Interest

The authors affirm no conflict of interest in this study.

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REFERENCES

- Allison K, Patel D, Alabi O. Epidemiology of glaucoma: the past, present, and predictions for the future. *Cureus*. 2020;12(11):e11686.
- Rif'Ati L, Halim A, Lestari YD, Moeloek NF, Limburg H. Blindness and visual impairment situation in Indonesia based on rapid assessment of avoidable blindness surveys in 15 provinces. *Ophthalmic Epidemiol*. 2021;28(5):408–19.
- Goel M, Picciani RG, Lee RK, Bhattacharya SK. Aqueous humor dynamics: a review. *Ophthalmol J*. 2010;4:52–9.
- Sihota R, Angmo D, Ramaswamy D, Dada T. Simplifying “target” intraocular pressure for different stages of primary open-angle glaucoma and primary angle-closure glaucoma. *Indian J*

- Ophthalmol. 2018;66(4):495–505.
5. Cairns JE. Trabeculectomy. Preliminary report of a new method. *Am J Ophthalmol.* 1968;66(4):673–9.
 6. Agrawal P, Bradshaw SE. Systematic literature review of clinical and economic outcomes of micro-invasive glaucoma surgery (MIGS) in primary open-angle glaucoma. *Ophthalmol Ther.* 2018;7(1):49–73.
 7. Hasan SM, Theilig T, Papadimitriou M, Meller D. A comparative analysis of morphology and dimensions of functional blebs following PRESERFLO-Microshunt and XEN-Gel-Stent, a study using anterior segment OCT. *Diagnostics (Basel).* 2023;13(14):2318.
 8. Scheres LM, Kujovic-Aleksov S, Ramdas WD, De Crom RM, Roelofs LC, Berendschot TT, et al. XEN® Gel Stent compared to PRESERFLO™ MicroShunt implantation for primary open-angle glaucoma: two-year results. *Acta Ophthalmol.* 2021;99(3):e433–40.
 9. Gambini G, Carlà MM, Giannuzzi F, Boselli F, Grieco G, Caporossi T, et al. Anterior segment-optical coherence tomography bleb morphology comparison in minimally invasive glaucoma surgery: XEN Gel Stent vs. PreserFlo MicroShunt. *Diagnostics (Basel).* 2022;12(5):1250.
 10. Giansanti F, Quaranta G, Serino F, Vicini G, Franco F. Comparison of clinical outcomes between XEN gel stent and PreserFlo microshunt: a monocentric experience. *J Clin Exp Ophthalmol.* 2023;14(4):953.
 11. Theilig T, Papadimitriou M, Albaba G, Meller D, Hasan SM. Results of open bleb revision as management of primary bleb failure following XEN 45 gel stent and Preserflo™ Microshunt. *Graefes Arch Clin Exp Ophthalmol.* 2023;261(11):3249–55.
 12. Panarelli JF, Yan DB, Francis B, Craven ER. XEN gel stent open conjunctiva technique: a practical approach paper. *Adv Ther.* 2020;37(5):2538–49.
 13. Fea AM, Durr GM, Marolo P, Malinverni L, Economou MA, Ahmed I. XEN® Gel Stent: a comprehensive review on its use as a treatment option for refractory glaucoma. *Clin Ophthalmol.* 2020;14:1805–32.
 14. Saeed E, Gołaszewska K, Dmuchowska DA, Zalewska R, Konopińska J. The PreserFlo MicroShunt in the context of minimally invasive glaucoma surgery: a narrative review. *Int J Environ Res Public Health.* 2023;20(4):2904.
 15. Lenzofer M, Strohmaier C, Sperl P, Hohensinn M, Hitzl W, Steiner V, et al. Effect of the outer stent position on efficacy after minimally invasive transscleral glaucoma gel stent implantation. *Acta Ophthalmol.* 2019;97(8):e1105–11.
 16. De Gregorio A, Pedrotti E, Stevan G, Bertocello A, Morselli S. XEN glaucoma treatment system in the management of refractory glaucomas: a short review on trial data and potential role in clinical practice. *Clin Ophthalmol.* 2018;12:773–82.
 17. Teus MA, Paz Moreno-Arrones J, Castaño B, Castejon MA, Bolivar G. Optical coherence tomography analysis of filtering blebs after long-term, functioning trabeculectomy and XEN® stent implant. *Graefes Arch Clin Exp Ophthalmol.* 2019;257(5):1005–11.
 18. Midha N, Rao HL, Mermoud A, Mansouri K. Identifying the predictors of needling after XEN gel implant. *Eye (Lond).* 2019;33(3):353–7.
 19. Galimi ME, Weller JM, Kruse FE, Laemmer R. Risk factors for ocular hypotony after XEN Gel Stent implantation. *Graefes Arch Clin Exp Ophthalmol.* 2023;261(3):769–78.
 20. Rezkallah A, Mathis T, Denis P, Kodjikian L. XEN gel stent: a total delayed-onset postoperative hyphema. *Int J Ophthalmol.* 2019;12(7):1224–6.
 21. Cutolo CA, Negri L, Olivari S, Cappelli F, Traverso CE, Lester M. Choroidal detachment after XEN Gel Stent implantation. *J Ophthalmol.* 2021;2021:6674505.