Original Article

PreserFlo™ MicroShunt Combined with Phacoemulsification versus PreserFlo™ MicroShunt as a Standalone Procedure in Patients with Medically Resistant Open-Angle Glaucoma

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Abstract

Purpose: To compare the efficacy and safety of PreserFlo™ MicroShunt (Santen, Osaka, Japan) combined with phacoemulsification to PreserFlo™ MicroShunt as a standalone procedure in eyes with moderate to advanced open-angle glaucoma.

Methods: In an observatory, prospective, clinical study, 30 patients (30 eyes) with moderate to advanced angle glaucoma were allocated to either PreserFlo™ MicroShunt combined with phacoemulsification (15 eyes; Group A) or PreserFlo™ MicroShunt as a standalone procedure (15 eyes; Group B). The follow-up time of the study was 12 months.

Results: Average intraocular pressure (IOP) at 12 months was 11.62 ± 1.6 mmHg in Group A and 13.8 ± 3.6 mmHg in Group B, which was significantly lower than baseline IOP (Group A: 23.47 ± 8.99 mmHg, $P < 0.001$; Group B: 23.4 ± 8.68 mmHg, $P < 0.001$). The absolute reduction of IOP within the 12 postoperative months was not significantly different between the two groups ($P = 0.056$). The number of the topical medications that were administered 12 months after ocular surgery was 0 in Group A and 0.6 ± 0.8 in Group B, compared to 3.13 ± 1.02 in Group A ($P < 0.001$) and 2.4 ± 1.45 in Group B ($P = 0.004$) at baseline. Phacoemulsification combined with PreserFlo™ MicroShunt significantly reduced the number of antiglaucoma agents after 12 months compared to the standalone procedure ($P = 0.026$). One eye in Group A was referred for bleb revision due to bleb fibrosis and a consequent acute postoperative rise in IOP. One eye in Group A required transscleral cyclophotocoagulation with MicroPulse® laser. One bleb revision was also necessary in Group B at the 4th postoperative week. Endothelial cell density did not significantly change over 12 months in either group (Group A: baseline, 2017.3 ± 346.8 cells/mm^2; 12 months, 1968.5 ± 385.6 cells/mm^2; $P = 0.38$; Group B: baseline, 2134.1 ± 382.6 cells/mm^2; 12 months, 2094.4 ± 373.3 cells/mm^2, $P = 0.42$). The PreserFlo™ MicroShunt combined with phacoemulsification produced higher absolute success rates after 12 months in patients with moderate to advanced open-angle glaucoma than the PreserFlo™ MicroShunt as standalone procedure (Group A: 80% and Group B: 60%, $P = 0.022$).

Conclusions: In eyes with moderate to advanced open-angle glaucoma, PreserFlo™ MicroShunt with or without phacoemulsification is effective in reducing IOP and the number of the antiglaucoma agents with a very small incidence of complications and subsequent glaucoma surgeries. However, adding phacoemulsification to PreserFlo™ MicroShunt successfully reduces IOP without the need for ongoing topical medications as are needed after the standalone procedure.

Keywords: Antiglaucoma eye drops, Endothelial cell density, Intraocular pressure, Minimally invasive glaucoma surgery, Moderate to advanced glaucoma

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Submitted: 04-Oct-2021; **Revised:** 19-Mar-2022; **Accepted:** 23-Mar-2022; **Published:** 26-Jul-2022

Access this article online

Quick Response Code:

Website: www.jcurrophthalmol.org

DOI: 10.4103/joco.joco_298_21

How to cite this article: Fili S, Kontopoulou K, Vastardis I, Perdikakis G, Bechrakis N, Kohlhaas M. PreserFlo™ MicroShunt combined with phacoemulsification versus PreserFlo™ MicroShunt as a standalone procedure in patients with medically resistant open-angle glaucoma. J Curr Ophthalmol 2022;34:180-6.

Introduction

Glaucoma is one of the leading causes of irreversible blindness worldwide and is estimated to affect 111.8 million people by 2040.[1,2] The global ophthalmological community still considers trabeculectomy to be the gold standard surgical treatment for glaucoma.[3] However, substantial progress has been made over the last decade to develop innovative glaucoma surgical procedures with similar efficacy to trabeculectomy but with a better safety profile. Some minimally invasive glaucoma surgical procedures succeed in providing an artificial outflow pathway for the aqueous humor from the anterior chamber to the subconjunctival space by mimicking trabeculectomy while avoiding its severe complications.[4] Consequently, micro-invasive glaucoma surgery is increasingly performed as the number of trabeculectomies is gradually decreasing.[5]

An innovative subconjunctival draining, minimally-invasive glaucoma device is the PreserFlo™ MicroShunt (Santen, Osaka, Japan), which results in the formation of a posterior bleb in the upper subconjunctival space and provokes minimal inflammation.[6-10] The most important innovation of the PreserFlo™ MicroShunt is the self-regulated outflow based on the Hagen–Poiseuille equation through a smaller lumen (70 μm vs. 300 μm of typical tube shunts).[7,11]

Although several studies have shown PreserFlo™ MicroShunt is effective in moderate to advanced open-angle glaucoma, the efficacy of PreserFlo™ MicroShunt with or without phacoemulsification in these patients has not yet been reported.[5,12,13]

The objective of this prospective clinical study was to compare the efficacy of PreserFlo™ MicroShunt combined with phacoemulsification versus PreserFlo™ MicroShunt as a standalone procedure. We assessed the intraocular pressure (IOP), the number of topical antiglaucoma medications needed postoperatively, the influence of the procedures on endothelial cell density (ECD), and the occurrence of postoperative complications in the primary and subsequent surgical procedures.

Methods

This prospective observational study was conducted in the Department of Ophthalmology of St. Johannes Hospital between September 2019 and December 2020. A total of 30 patients with advanced open-angle glaucoma underwent either PreserFlo™ MicroShunt combined with phacoemulsification or PreserFlo™ MicroShunt as a standalone procedure. All patients provided their written consent to the surgery. The tenets of the Declaration of Helsinki were fully respected. This study was an institutional prospective comparison case series study, which was approved by the local institutional review board committee (February 13, 2021/Preserflo).

The participating patients were divided in two groups depending upon the presence of cataract or pseudophakia before surgery:

- Group A: PreserFlo™ MicroShunt combined with phacoemulsification
- Group B: PreserFlo™ MicroShunt as a standalone procedure.

The key inclusion criteria were the diagnosis of moderate to advanced open-angle glaucoma and IOP above 18 mmHg. Using the Hodapp-Parrish-Anderson classification system, moderate to advanced glaucoma cases were defined by visual fields with a mean deviation (MD) of the Humphrey visual fields worse than −6 dB. The secondary inclusion criteria were: cup-to-disc ratio 0.7–1.0, not meeting target IOP with either maximal tolerated topical antiglaucoma medications (2–4 antiglaucoma agents) or systemic therapy (acetazolamide). All the patients of Group A were phakic, and all the participants of Group B were pseudophakic. Patients with previous intraocular surgeries, secondary open-angle glaucoma including pseudoexfoliative glaucoma and pigmentary glaucoma, uveitis or oculus ultimus or unicus were not excluded. No pregnant women were included in the study because of the teratogenic effect of mitomycin C (MMC).

Baseline examinations included best-corrected visual acuity (BCVA), slit-lamp biomicroscopy of the anterior and posterior segment, gonioscopy with angle grading, IOP measurement using Goldmann applanation tonometry (Haag Streit, Essex, UK), visual field perimetry with Zeiss Humphrey Analyzer 3 (Zeiss, Jena, Germany) using Swedish Interactive Testing Algorithm Fast, and ECD using the Topcon specular microscope (Topcon Healthcare, Oakland, USA). The postoperative follow-up visits were conducted at 2 weeks and 1, 3, 6, and 12 months after the surgical intervention.

Target IOP was set in this study according to the Canadian target IOP Workshop.[14] If this target IOP was not achieved at any time postoperatively, and then we reinstituted topical antiglaucoma medications or revised the filtering bleb. We considered persistently high IOP above target IOP that was resistant to the above interventions as an indication for additional glaucoma procedures.

Our criteria of absolute success were a postoperative IOP between 6 mmHg and 15 mmHg and at least a 30% reduction of IOP from baseline without any postoperative antiglaucoma agents or additional glaucoma surgeries. A qualified success was defined as a postoperative IOP between 6 mmHg and 18 mmHg and at least a 20% reduction of the IOP from baseline under fewer or the same number of preoperative antiglaucoma agents without additional glaucoma surgeries. If an eye required subsequent glaucoma surgery or showed a significant reduction in ECD, it was considered a failure.

One experienced glaucoma surgeon performed ocular surgery on all patients under general anesthesia. The surgical procedure for the PreserFlo™ MicroShunt is minimally invasive. The device is implanted through an ab externo

approach. A fornix-based subconjunctival and sub-Tenon's flap was dissected at the upper nasal or temporal quadrant over a circumference of 1–2 h, to at least 8–10 mm posterior to the limbus. Three MMC-soaked sponges were placed in the subconjunctival flap for 3 min. Cataract surgery with phacoemulsification was performed on patients in Group A through a clear corneal tunnel that was placed temporally. Subsequently, a marker was used to mark a point 3 mm from the middle border of the surgical limbus at the blue-gray zone. At the distally-marked point on the sclera, a 1.2 mm width diamond blade was used to create a small triangular pocket in the sclera (large enough to seat the fins of the MicroShunt). A 25G needle was then bent and used to create a transscleral tunnel from the apex of the scleral pocket into the anterior chamber. Using forceps, the MicroShunt was threaded, bevel up and fins flat, into the transscleral tunnel. The fins were then wedged into the scleral pocket. Importantly, flow through the MicroShunt was confirmed prior to closure of Tenon's capsule and the conjunctiva. Flow was confirmed visually by wiping the humor drop away with a sponge and visualizing the formation of a small drop. The conjunctiva and the Tenon capsule were anchored to the limbus with continuous cross suture with 10–0 nylon. In patients who had prior antiglaucoma surgeries, we implanted an Ologen implant subconjuctivally.

The postoperative topical medications in both groups consisted of prednisolone acetate 1% six times daily, moxifloxacin three times daily, and cyclopentolate twice daily, which were gradually tapered. No antiglaucoma agents were initially given in either group postoperatively.

Statistical calculations were carried out with IBM SPSS Statistics version 22 (International Business Machines Corporation, Armonk, New York, USA). Independent sample *t*-test was used to determine whether the combined surgery or the implantation of the PreserFlo™ MicroShunt as standalone procedure influenced the efficacy of the intervention. Paired sample *t*-test was used when each observation in each group was paired with a related observation in the other group. Normality of the data was assessed using a histogram as a graphical method. $P < 0.05$ was considered statistically significant. In addition, we performed a Kaplan–Meier survival analysis.

An *a priori* power analysis was conducted using G*Power 3[15] to test the difference between two independent group means using a two-tailed test, a medium effect size ($d = 0.50$), and an alpha of 0.05. The result showed that a total sample of 26 participants were required to achieve a power of 0.80. Therefore, we included in our sample 30 eyes with two equal sized groups of $n = 15$, and the power of our analysis was 0.86.

Results

Our patient population consisted of 8 men and 22 women with a mean age of 67.8 ± 11.4 years. All patients completed the 12-month follow-up as they fulfilled all the inclusion criteria, and no patient was withdrawn in this period. Fourteen eyes in Group A and 12 eyes in Group B had moderate to advanced primary open-angle glaucoma, 1 eye in each group had advanced pigmentary glaucoma, and 2 eyes in Group B had pseudoexfoliative glaucoma [Table 1].

The mean IOP after 1 month was 11.08 ± 6.08 mmHg for Group A ($P < 0.001$) and 10.5 ± 5.37 mmHg for Group B ($P < 0.001$) and at 3 months postoperatively, IOP was 10.77 ± 2.42 mmHg for Group A ($P < 0.001$) and 11.92 ± 2.98 mmHg for Group B ($P < 0.001$), all of which were significantly lower than preoperative IOP (baseline IOP of Group A: 24.13 ± 8.99 mmHg, baseline IOP of Group B: 26.9 ± 8.68 mmHg). Twelve months after surgery, the IOP remained significantly reduced compared to baseline in both groups (Group A: 11.62 ± 1.6 mmHg, $P < 0.001$; Group B: 13.8 ± 3.57, $P = 0.002$). The absolute reduction of IOP within the 12 postoperative months was not significantly different between the two groups ($P = 0.056$) [Figure 1].

The number of the topical medications that were administered 12 months after the ocular surgery was on average 0 ± 0 in Group A and 0.6 ± 0.8 in Group B, compared to 3.13 ± 1.02 in Group A and 2.4 ± 1.45 in Group B administered prior to the

Table 1: Demographic data of the patients included in the study

	Group A: PreserFlo + Phaco/PCL	Group B: PreserFlo	*P*
Gender (females/males)	12/3	10/5	
Age	62±9.02	73.53±10.52	0.002
Eye (RE/LE)	6/9	4/11	
Baseline MD (dB)	−12.34±10.69	−13.68±8.49	0.36
Baseline IOP (mmHg)	23.47±8.99	23.4±8.68	0.49
Baseline antiglaucoma agents	3.33±1.02	2.4±1.45	0.06
Baseline BCVA (Snellen)	0.7±0.23	0.6±0.24	0.13
Baseline CD	0.89±0.12	0.89±0.14	0.49
Baseline RNFL thickness	60.14±15.35	71±15.87	0.04
Operation			
PreserFlo + MMC	8	12	
PreserFlo + MMC + Ologen	7	3	
Total	15	15	
Diagnose			
POAG	14	12	
Pigmentary glaucoma	1	1	
Pseudoexfoliative glaucoma	0	2	
Total	15	15	
Previous surgeries			
Phaco/PCL	0	0	
Canaloplasty	5	3	
mTS-CPC	3	3	
Trabeculectomy	3	0	
Iridectomy	2	0	

Paired sample t-test was used for the calculation of the P values. BCVA: Best-corrected visual acuity, CD: Cup-disc-ratio, IOP: Intraocular pressure, MD: Mean deviation, mTS-CPC: MicroPulse® transscleral cyclophotocoagulation, Phaco: Phacoemulsification, PCL: Posterior capsular lens, RNFL: Retinal nerve fiber layer, MMC: Mitomycin C, POAG: Primary open-angle glaucoma

surgery [Figure 2]. This represents a significant reduction of topical glaucoma therapy in all patients of Group A ($P < 0.001$) and in 75% of Group B ($P = 0.004$). Phacoemulsification combined with PreserFlo™ MicroShunt significantly reduced the number of antiglaucoma agents after 12 months compared to the standalone procedure ($P = 0.026$).

Concerning BCVA, we observed a stable mean visual acuity of 0.7 in Group A and 0.5 in Group B (decimal values) between 3 and 12 months of the postoperative period. BCVA did not deteriorate in any patient in either group [Figure 3].

The corneal ECD was not statistically significantly reduced at 6 and 12 months postoperatively (Group A: preoperative ECD 2017.25 ± 346.82 cell/mm^2; 6 months postoperative ECD 1923.5 ± 135.4 cell/mm^2, $P = 0.25$; 12 months postoperative ECD 1968.54 ± 385.59 cell/mm^2, $P = 0.37$, Group B: Preoperative ECD 2134.11 ± 382.59 cell/mm^2; 6 months postoperative ECD 1941.9 ± 373.31 cell/mm^2, $P = 0.18$; 12 months postoperative ECD 2094.38 ± 373.31 cell/mm^2, $P = 0.42$) [Figure 4]. The ECD remained stable in both groups for the entire follow-up period (baseline: $P = 0.25$, 6 months: $P = 0.46$, 12 months: $P = 0.25$).

The implantation of the PreserFlo™ MicroShunt stabilized all of the parameters used for glaucoma diagnosis and monitoring progression in both groups, namely visual fields and optical coherence tomography of the optic nerve head, as no significant changes were shown either in Group A or in Group B over 12 months [Table 2]. None of the above parameters was significantly different between the two groups (visual fields: $P = 0.087$, retinal nerve fiber layer [RNFL] thickness: $P = 0.061$, cup-to-disc ratio: $P = 0.25$).

Early postoperative complications included a transient ocular hypotony with choroidal detachment in one eye in both groups (first 2 postoperative weeks). Persistent ocular hypotony did not occur in any eye in either group over 12 months. Two eyes in Group A and one eye in Group B developed subconjunctival fibrosis that completely compromised function of the filtering bleb leading to IOP decompensation

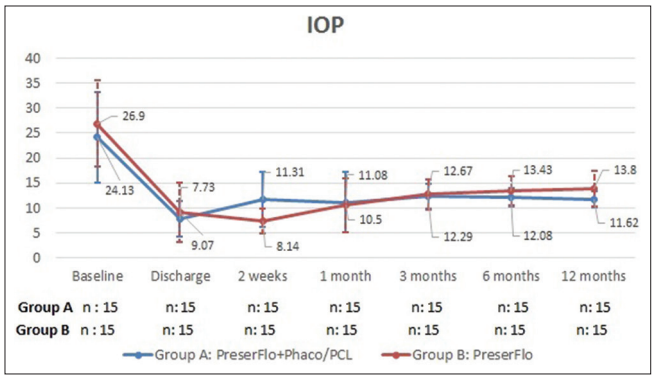

Figure 1: Mean intraocular pressure (mmHg) with standard deviation up to 12 months. Phaco: Phacoemulsification, PCL: Posterior capsular lens, IOP: Intraocular pressure

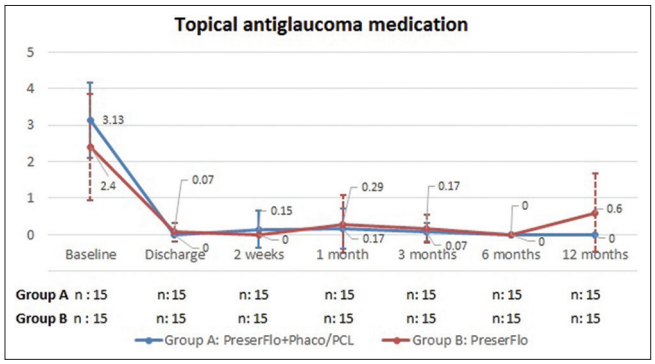

Figure 3: Mean best corrected visual acuity with standard deviation up to 12 months. Phaco: Phacoemulsification, PCL: Posterior capsular lens

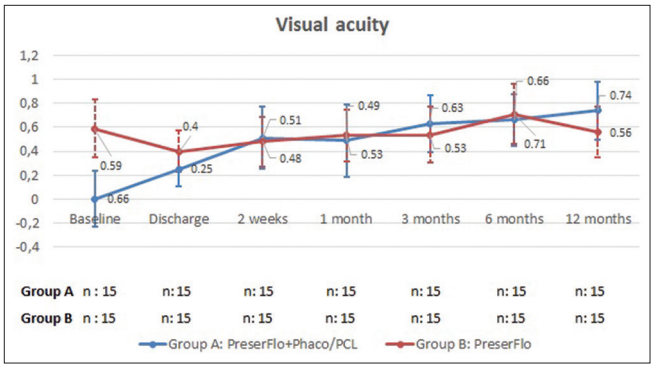

Figure 2: Number of topical antiglaucoma medications with standard deviation up to 12 months. Phaco: Phacoemulsification, PCL: Posterior capsular lens

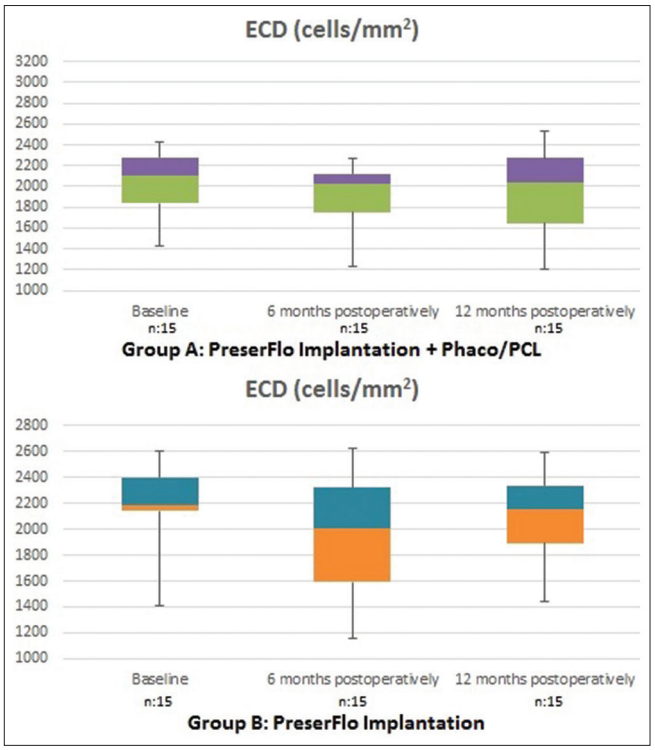

Figure 4: Endothelial cell density up to 12 months. Phaco: Phacoemulsification, PCL: Posterior capsular lens, ECD: Endothelial cell density

and early failure of the procedure during the 1st postoperative month. One eye in Group B developed partially compromised function of the filtering bleb and a consequent rise in IOP during the 1st postoperative month. The IOP was regulated with antiglaucoma eye drops [Table 3].

After initial treatment, two eyes (13.3%) in Group A were referred for additional treatment due to an acute postoperative increase in IOP. Therefore, an eye of Group A underwent a needling of the bleb followed by a bleb revision 2 weeks later. One eye showed recurrently elevated IOP due to persistent fibrosis of the filtering bleb in the first 4 postoperative weeks. The patient refused a bleb revision or other incisional ocular surgery and instead underwent a double treatment with Micropulse Transscleral Cyclophotocoagulation. The additional glaucoma intervention satisfactorily reduced IOP by >20%, and both eyes reached the target IOP. Furthermore, one eye in Group B underwent a bleb revision due to primary bleb fibrosis [Table 4].

Summarizing the above results, the cumulative probability of absolute success was 86.7%, 80%, 80%, 80%, and 80% in Group A and 100%, 93.3%, 86.7%, 80%, and 60% in Group B at 2 weeks and 1, 3, 6, and 12 postoperative months, respectively. In the Kaplan–Meier survival analysis, 80% of eyes in Group A reached the absolute success rate goal by the end of 12 months compared to 60% of eyes in Group B [$P = 0.022$; Figure 5]. Moreover, we observed a cumulative probability of qualified success in 86.7%, 86.7%, 86.7%, 86.7%, and 86.7% in Group A and 100%, 93.3%, 93.3%, 93.3%, and 93.3% in Group B at 2 weeks and 1, 3, 6, and 12 postoperative months, respectively. The qualified success rate was not statistically different between the two groups ($P = 0.061$).

While RNFL thickness differed between the two groups at baseline ($P = 0.04$), MD of the visual fields was not significantly different between the two groups at baseline ($P = 0.36$).

Table 2: Parameters of monitoring glaucoma progression after PreserFlo™ implant + Phaco/posterior capsular lens in Group A and PreserFlo™ implant in Group B

Parameters of monitoring glaucoma progression			
	Baseline	**12 months**	***P***
Group A			
Visual fields	−12.33±10.69	−10.83±11.2	0.36
RNFL thickness	60.14±15.35	58.2±14.84	0.37
Cup-disc ratio	0.89±0.12	0.87±0.13	0.34
Group B			
Visual fields	−13.68±8.5	−15.4±9.0	0.33
RNFL thickness	71±15.87	67.6±11.9	0.29
Cup-disc ratio	0.89±0.14	0.93±0.1	0.25

Independent sample *t*-test was used for the calculation of the *P* values.
RNFL: Retinal nerve fiber layer,

Table 3: Postoperative complications after PreserFlo™ implant + Phaco/posterior capsular lens in Group A and PreserFlo™ implant in Group B

Complications					
	2 weeks	**1 month**	**3 months**	**6 months**	**12 months**
Group A: PreserFlo + Phaco/PCL					
Bulbus hypotony	1	0	1	0	0
Positive Seidel Test	0	0	0	0	0
Choroidal detachment	1	0	0	0	0
IOP decompensation	1	3	0	0	0
Irvine gas syndrome	0	1	0	0	0
Group B: PreserFlo					
Bulbushypotony	1	0	0	0	0
Positive Seidel test	0	0	0	0	0
Choroidal detachment	1	1	0	0	0
IOP decompensation	0	1	0	0	0
Irvine gas syndrome	1	1	2	0	0

IOP: Intraocular pressure, Phaco: Phacoemulsification, PCL: Posterior capsular lens

Discussion

In this cohort of patients with moderate to advanced glaucoma, the absolute success rates were high and remained stable in Group A for the period of 12 months while absolute success

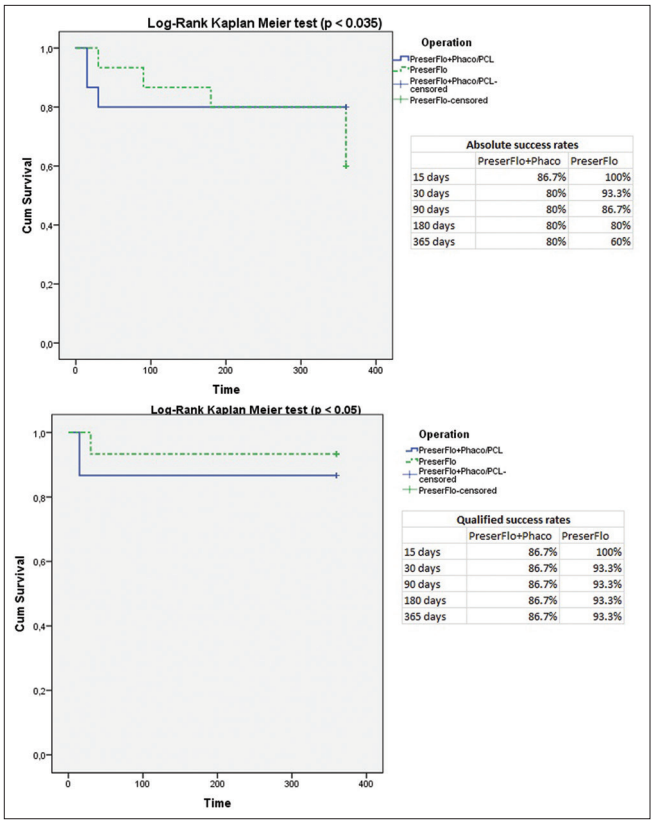

Figure 5: Kaplan–Meier survival curve showing the number of patients that met absolute or qualified success criteria after PreserFlo™ Impl. + Phaco/PCL in Group A and PreserFlo™ Impl. in Group B: Phaco: Phacoemulsification, PCL: Posterior capsular lens

Table 4: Additional eye surgeries after PreserFlo™ implant + Phaco/posterior capsular lens in Group A and PreserFlo™ implant in Group B

	Surgical procedures postoperatively				
	2 weeks	1 month	3 months	6 months	12 months
Group A: PreserFlo + Phaco/PC-IOL					
Suture removal	2	2	2	0	0
Bleb revision	0	1	0	0	0
Needling	1	0	0	0	0
mTS-CPC	1	1	0	0	0
Group B: PreserFlo					
Suture removal	2	4	2	0	0
Bleb revision	0	1	0	0	0
Needling	0	0	0	0	0
mTS-CPC	0	0	0	0	0

mTS-CPC: MicroPulse® transscleral cyclophotocoagulation, PC-IOL: Posterior chamber intraocular lenses

rates in Group B deteriorated somewhat. During the 12-month follow-up, 80% of patients in Group A had an IOP under 15 mmHg and at least a 30% reduction in IOP from baseline without any postoperative antiglaucoma agents. However, the percentage of participants in Group B who achieved the same outcomes deteriorated gradually from 100% at 2 weeks postoperatively to only 60% at 12 months postoperatively.

PreserFlo™ MicroShunt implantation with or without phacoemulsification succeeded in significantly reducing IOP over the entire follow-up period of 12 months (Group A, 50.5%; Group B, 41.03%). Batlle *et al*. reported a similar reduction in IOP of 55.04% 12 months after the filtering surgery employing a microlumen aqueous drainage device (InnFocus MicroShunt), which also remained stable after 24 and 36 months.[16] In addition, a 52% reduction in IOP was described by Riss *et al*. Twelve months after the InnFocus MicroShunt with subconjunctival application of 0.2 mg/mL MMC.[13]

The number of the topical glaucoma medication required after surgery in our study is similar to published results. Target IOP was achieved in both groups without the addition of topical glaucoma medication (Group A: 100%, Group B: 87%) after 12 months follow-up and the average number of topical medications was reduced 100% and 75% from 3.1 and 2.4 at baseline to 0 and 0.6 in each Group A and B, respectively. The number of the topical medications dropped about 88% 1 year after InnFocus MicroShunt implantation with subconjunctival application of 0.2 mg/ml MMC.[13] The InnFocus MicroShunt also reduced the mean number of glaucoma medications by 87.5% at 1 year of follow-up in the study by Batlle *et al*., which remained stable for the following 2 years.[16] Batlle *et al*. reported a 66.7% reduction in eye drops in a 5-year extension study of the same patients.[12]

A transient ocular hypotony with choroidal detachment occurred in 6.7% (one eye) in each group in our study compared to 13% in the study of Batlle *et al*.[16] No serious complications occurred in our cohort, nor have they been reported in published case series.[12,13,16] A fibrosis of the filtering bleb led either to bleb revision or antiglaucoma intervention in two cases in Group A (13.34%). A bleb revision was also necessary in one case in Group B. Two of the 23 participants in the observational study by Batlle *et al*. (8.6%) underwent similar reoperations.[12,16]

Qualified success rates did not differ significantly between the combined surgical procedure of PreserFlo™ MicroShunt implantation with or without phacoemulsification. Previous studies, which compared the efficacy and safety of the phacotrabeculectomy versus trabeculectomy as a standalone intervention, also revealed no significant differences between groups in the long-term reduction of average IOP and the average number of eye drops.[17-19] However, Tsai *et al*. and Wang *et al*. reported that initial combined surgical procedures also reduced the number of subsequent surgical interventions.[17,18] The absolute success rate of the group treated with PreserFlo™ combined with phacoemulsification (80%) is higher than that after phacotrabeculectomy (56%) after 12 months.[17] Absolute success rates were also comparable between PreserFlo™ MicroShunt as a standalone intervention (60%) and trabeculectomy (54%) after 12 months.[17]

A comparative study showed no statistically significant differences in IOP reduction, eye drop reduction, success rates or number of complications between isolated implantation of XEN® Gel Stent (XEN) with or without cataract surgery.[20] However, the implantation of the PreserFlo™ MicroShunt combined with cataract surgery or as a standalone procedure was superior (absolute success: Group A: 80%, Group B: 60%; qualified success: Group A: 86.7%, Group B: 93.3% in our study) to XEN implantation (complete success: 57.7%; qualified success: 71.1%) at the end of a 12-month follow-up. [21]

Based on previous studies, the mean decrease in ECD after trabeculectomy was between 9.3% and 24.6%, respectively.[22-24] Gillmann *et al*. reported a higher percentage of reduction of ECD after the combined XEN implantation with cataract surgery (14.3%) after 2 years.[25] Although the reduction of the mean ECD after EX-PRESS device implantation of 3.5% is lower than after trabeculectomy or XEN plus cataract surgery, cell density loss remains higher than the ECD values we found after PreserFlo™ implantation in both groups of our study.[22-24] Mean ECD after the PreserFlo™ MicroShunt with or without cataract surgery insignificantly reduced ECD by 2.4% and 1.8%, respectively.

In both groups, PreserFlo™ MicroShunt implantation was combined with subconjunctival placement of Ologen collagen matrix when the preoperative risk for postoperative bleb failure was high [Table 1]. An early subconjunctival fibrosis can be avoided because Ologen modulates conjunctival wound healing and inhibits excessive fibrosis.[26-28]

Despite having adequate cohort numbers based on power analysis, our study may be limited by a relatively small sample size and follow-up duration of only 1 year. Moreover, our results may not be generalizable to many community-based glaucoma practices as the patients participating in this study had moderate to advanced open-angle glaucoma. Therefore, further studies are needed to evaluate the long-term efficacy and safety of PreserFlo™ MicroShunt with or without phacoemulsification in a larger and more clinically diverse patient population.

In conclusion, this prospective study demonstrated that the implantation of PreserFlo™ MicroShunt is an effective approach to reduce IOP and topical antiglaucoma medications in moderate to advanced glaucoma refractory to medical management. PreserFlo™ is satisfactorily safe as evidenced by the absence of serious adverse events such as persistent ocular hypotony with choroidal detachment and by largely avoiding secondary procedures. In addition, success rates of PreserFlo™ MicroShunt combined with phacoemulsification are more stable than success rates achieved with PreserFlo™ MicroShunt as a standalone procedure over 12 months postoperatively.

Acknowledgment

We thank our colleagues from the Department of Ophthalmology, St. Johannes Hospital, Dortmund, Germany, who provided insight and expertise that greatly assisted the research.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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