Comparison Between the eyeWatch Device and the Ahmed Valve in Refractory Glaucoma

Sylvain Roy, MD, PhD,† Adan Villamarin, PhD,**
Constantinos Stergiopulos, MSE, Stéphane Bigler, MSE,**
Nikolaos Stergiopulos, PhD, Josephine Wachtl, MD,‡*
André Mermoud, MD,† and Christoph Kniestedt, MD‡

Purpose: To assess the efficacy and safety of a glaucoma procedure to control intraocular pressure (IOP) using the adjustable eyeWatch glaucoma drainage device compared with Ahmed glaucoma valve (AGV) in refractory glaucoma.

Patients and Methods: Monocentric, retrospective, comparative clinical trial. Patients suffering from refractory glaucoma after failed surgeries and requiring a further glaucoma procedure including an aqueous shunt were enrolled in this study. The first group AGV included patients with an AGV. The second group eW-B included patients receiving an eyeWatch used in connection with a Baerveldt glaucoma implant. The primary outcome was the success rate, defined as an IOP $\leq$ 16 mm Hg and reduction of $>$ 20% from baseline, and IOP $\geq$ 5 mm Hg. Secondary outcomes were mean IOP, number of antiglaucoma medications, visual acuity, number and type of complications.

Results: Twenty-one patients were included. The mean follow-up time was 13.2 $\pm$ 3.4 months. Mean IOP decreased from 24.8 $\pm$ 9.0 mm Hg before surgery to 13.8 $\pm$ 3.6 mm Hg at 12 months for group AGV, and 27.3 $\pm$ 7.0 to 12.8 $\pm$ 2.4 mm Hg for group eW-B, respectively ($P < 0.05$). Mean number of glaucoma medications decreased from 3.0 $\pm$ 0.7 before surgery to 0.3 $\pm$ 0.7 at last control for group AGV, and 2.9 $\pm$ 0.8 before surgery to 0.2 $\pm$ 0.4 for group eW-B, respectively ($P < 0.05$). The complete and overall success rates were 50% and 58% for group AGV, and 67% and 89% for group eW-B, respectively.

Conclusions: The postoperative adjustability of the eyeWatch is believed to help with getting fewer complications and better IOP management whereas AGV cannot be adjusted postoperatively.

Key Words: glaucoma drainage device, Ahmed implant, Baerveldt implant, refractory glaucoma, glaucoma surgery

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Glaucoma is a leading cause of irreversible blindness worldwide.[1,2] Elevated intraocular pressure (IOP) is a significant risk factor for the onset and development and progression of glaucoma. The aim of filtering surgery is to lower IOP to protect retinal ganglion cells. When initial conventional glaucoma treatment fails to control IOP, further surgical procedures should be proposed to prevent further optic nerve damages and visual field loss. Seton tubes have been developed to treat refractory glaucoma. The postoperative phase after implantation of a seton tube is characterized by the mandatory management of the postoperative hypotony that inevitably occurs if no preventive measures, such as placing a stent into the lumen, are taken. Use of such a restrictor during this critical period is essential to minimize the occurrence of postoperative hypotony and its complications, for example, shallow to flat anterior chamber, choroidal detachment/effusion, and suprachoroidal hemorrhage.[3–5] A main drawback to these measures is the lack of precision and predictability in efficiently controlling IOP in the early postoperative phase.[3] The need for further surgical steps to set free the tube from the restricting elements could be another burden in terms of increased costs and risks related to the management of these steps.[6,7] The Ahmed glaucoma valve (AGV) (New World Medical, Inc., Rancho Cucamonga, CA) is a marketed device that has a 184-mm^2 plate and features a flow restrictive system designed to minimize postoperative hypotony and its complications.[5] Thus IOP should be controlled by the flow restrictive system, stabilizing aqueous outflow, and preventing large fluctuations in IOP.

In a previous publication, initial clinical results of the novel adjustable glaucoma drainage device eyeWatch (eW) (Rheon Medical, Lausanne, Switzerland) were presented.[8] The eyeWatch was designed to better control IOP in the early postoperative phase using an adjustable resistance to control aqueous egress from the anterior chamber to the end plate.[9] The efficacy and safety of the eW combined with a Baerveldt were shown in 15 patients.[8] Postoperative IOP was well controlled and adjusted noninvasively by changing the fluidic resistance using an external control unit (eyeWatch Pen).

In this retrospective study, we assessed the efficacy and safety of glaucoma surgery with an eyeWatch device while using the Ahmed valve as a reference group in refractory glaucoma patients after previously failed filtering surgery.

PATIENTS AND METHODS

The study protocol conformed to the Declaration of Helsinki and was approved by the institutional review board of the University of Zurich, Switzerland. Eligible patients were recruited voluntarily by the site investigator (C.K.) and each patient gave written informed consent after proper education.

Eligibility Criteria

Patients aged 18 years or older suffering from refractory glaucoma after previous failed surgeries, with an IOP at

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From the *Swiss Federal Institute of Technology; †Glaucoma Center, Montchoisi Clinic, Lausanne; and ‡Augen Zentrum Eyes Center Zurich, Zurich, Switzerland.
S.R. and A.V.: contributed equally to this work.
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Reprints: Sylvain Roy, MD, PhD, Laboratory of Hemodynamics and Cardiovascular Technology, ST1/1B12/LHTC, Swiss Federal Institute of Technology, RED 32526, Station 9, Lausanne 1015, Switzerland (e-mail: sylvain.roy@epfl.ch).

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20 mm Hg or higher despite maximally tolerated antiglaucoma medications were included in this study. One group includes patients that were operated using an AGV between February 2017 and March 2018 (group AGV). A second group received the eyeWatch connected with a Baerveldt implant between June 2017 and April 2018 (group eW-B). Patients with the diagnosis of neovascular glaucoma, congenital glaucoma or anomaly of the anterior chamber angle, microphthalmia, eyes with any sign of past or present uveitis, optic neuropathy other than glaucoma, proliferative or severe nonproliferative retinopathy, previous surgery referring to extraocular muscles (strabismus), corneal transplant or retinal surgery and history of severe eye trauma, were excluded. Furthermore, patients unwilling to sign written informed consent were also excluded.

Surgical Procedure

All surgeries were performed under general anesthesia. For the patients operated with an AGV the conjunctiva was opened at the limbus in the 12-o'clock region and the underlying Tenon capsule was dissected until reaching the sclera. If needed, careful hemostasis was performed using gentle wet-field cautery. The Ahmed valve was prepared and primed according to the recommendations of the manufacturer. The device was inserted between the rectus muscles and secured with 2 single Prolene 8-0 sutures. A paracentesis was made and an anterior chamber maintainer was employed to prevent hypotony. A scleral canal was created using a 23G needle to allow the insertion of the tube of the valve into the anterior chamber. The proximal end of the tube was then trimmed to a proper length and inserted in the anterior chamber, taking care not to touch the cornea, iris, or lens. The conjunctiva was eventually closed using running Vicryl 8-0 resorbable sutures.

For the patients operated with the eyeWatch, the device was connected to a 250-mm^2 Baerveldt glaucoma implant (BGI) (J&J, New Jersey) (Fig. 1). A fornix-based opening of the conjunctiva was made at the superior limbus and the Tenon capsule dissected to expose the sclera. Hemostasis was performed using the same technique. The endplate of the Baerveldt implant was inserted under the rectus muscles and secured with 2 single Prolene 8-0 sutures at 10 to 14 mm from the limbus. A paracentesis was made and an anterior chamber maintainer was employed to prevent hypotony. A scleral canal was then created using a 25G needle to allow the insertion of the device's nozzle into the anterior chamber at the level of Schlemm canal. The body of the device was finally anchored onto the sclera using 2 single Nylon 10-0 sutures. The proximal end of the Baerveldt tube was trimmed to a proper length and connected with the eyeWatch. A pericardium patch (Tutoplast, IOP Ophthalmics, Costa Mesa, CA) of 6 mm×6 mm was finally placed on the eyeWatch to prevent the implant from eroding the conjunctiva. The patch was secured using 4 to 6 single Nylon 10-0 sutures. The conjunctiva was closed using running Vicryl 8-0 resorbable sutures.

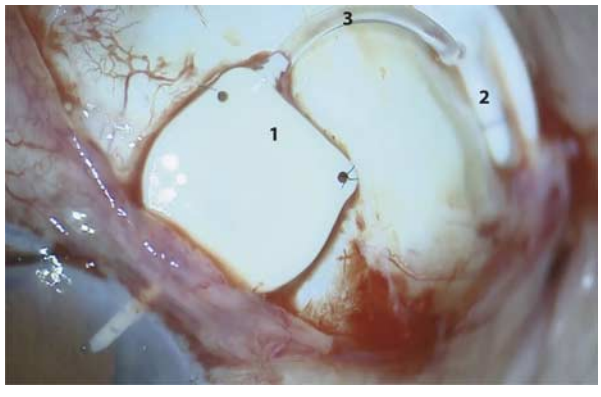

FIGURE 1. Surgical photograph of an eye implanted with an EyeWatch device combined with a Baerveldt plate. (1) eyeWatch device, (2) Baerveldt plate, and (3) Baerveldt-eyeWatch connection tube.

For both groups of patients, the postoperative treatment consisted of topical preservative free antibiotics (Floxal) and corticosteroids (Dexafree) tapered during 3 months after surgery.

Follow-up Schedule and Study Measurements

Follow-up visits were scheduled at 1 day, 1 week, 2 weeks, 1 month, 2 months, 3 months, 6 months, and 12 months after surgery. Additional interim appointments were made as deemed necessary by the treating ophthalmologist (C.K.). IOP was measured using Goldmann applanation tonometer under local anesthesia. For the eyeWatch group, reading of the position of the rotor and Goldmann applanation tonometer measurement was performed by the same operator. Best-corrected distance visual acuity (BCVA) was measured using Snellen charts.

The eyeWatch implant was adjusted after IOP measurement as deemed necessary to achieve the target IOP value. Precise details of the adjustment method were given in a previous publication.[9] In brief, when the IOP was >16 mm Hg, the eyeWatch mechanism was moved in a direction that resulted in a reduction in outflow resistance. Conversely, if the IOP was <6 mm Hg, the mechanism was actuated oppositely to increase the outflow resistance and raise IOP to the target value. To adjust and check the functional position of the implant, an external control unit (eyeWatch Pen) was used. The IOP was measured again 15 minutes after adjustment and, if necessary, the process was repeated until the intended target IOP value was reached. All readings and adjustments of the functional position were recorded.

Outcome Measures

These include IOP at different study visits, number of antiglaucoma medications, rate of complications, BCVA and number of adjustments per patient in the eyeWatch group.

Complete Success Rate

Complete success was defined as IOP ≤ 16 and >5 mm Hg plus a reduction of IOP by 20% from baseline at the last follow-up visit without glaucoma medications.

Overall Success Rate

Overall success was defined as IOP ≤ 16 and >5 mm Hg plus a reduction of IOP by 20% from baseline at the last follow-up visit with or without use of glaucoma medications.

Failure

Additional glaucoma surgery, loss of vision due to glaucoma progression, removal of the implant, IOP >16 mm Hg and IOP reduction of $<20\%$ from baseline in 2 consecutive visits 1 month after surgery or IOP ≤ 5 mm Hg in 2 consecutive visits 1 week after surgery, were considered as failure. Additional glaucoma surgery was defined as surgery requiring a return to the operating room for further filtering procedure. Interventions performed at the slit-lamp,

for example, bleb needling, injection of antimetabolites or paracentesis, were not considered as failure.

Statistical Analysis

All statistical analyses were performed using S-Plus 8.1 (TIBCO Software Inc, Palo Alto, CA). Data were processed using paired Student *t* test and Mann-Whitney *U* test using 2-sided analysis. A *P*-value ≤ 0.05 was considered statistically significant.

RESULTS

A total of 21 patients were followed-up between February 2017 and April 2019. For the AGV group, the mean follow-up time was 13.2 ± 3.4 months (mean ± SD). The mean age was 73.8 ± 8.4 years. Type of glaucoma was primary open-angle glaucoma in 6 patients (50%), pseudoexfoliation glaucoma in 5 patients (42%), and 1 secondary glaucoma (8%). The mean number of previous filtering surgeries was 1.2 ± 0.8. For the eW-B group, the mean follow-up time was 11.8 ± 0.8 months. Mean age was 74.0 ± 7.2 years. Type of glaucoma was primary open glaucoma in 5 patients (56%), pseudoexfoliation glaucoma in 3 patients (33%), and 1 secondary glaucoma (11%). The mean number of previous filtering surgeries was 1.2 ± 0.4 in this group (Table 1).

For the AGV group and the eW-B group the mean baseline, IOP was 24.8 ± 9.0 mm Hg and 27.3 ± 7.0 mm Hg, respectively. IOP was reduced to 13.8 ± 3.6 and 12.8 ± 2.4 mm Hg at 12-month visit (Table 2; $P < 0.001$). This represents a 46% and 56% reduction from baseline IOP. IOP profile over time is depicted in Figure 2.

The eyeWatch was adjusted for each patient during the early follow-up period extending up to 6 months postoperatively. Table 3 summarizes the resulting adjusted position performed at each visit for all patients. From the 9 patients, 8 were having the eyeWatch set on a fully open position at the end of the follow-up. The remaining patient had the device set in an intermediate position at around 4 to achieve the target IOP.

TABLE 1. Baseline Demographics and Ocular Characteristics

Baseline	n (%) Ahmed Valve (Group A, n = 12)	n (%) eyeWatch-Baerveldt (Group B, n = 9)	*P*
Age, mean ± SD (y)	73.8 ± 8.4	74 ± 7.2	0.48
Gender			
Male	3 (25)	4 (44)	0.18
Female	9 (75)	5 (56)	
Ethnicity			
Caucasian	11 (91)	7 (78)	
Asian	1 (9)	1 (11)	
African		1 (11)	
IOP, mean ± SD (mm Hg)	24.8 ± 9.0	27.3 ± 7.0	0.24
Glaucoma medication, mean ± SD	3.0 ± 0.7	2.9 ± 0.8	0.37
Diagnosis			
POAG	6 (50)	5 (56)	
PEX	5 (42)	3 (33)	0.44
Secondary glaucoma	1 (8)	1 (11)	
No. previous filtering surgeries			
Mean ± SD	1.2 ± 0.8	1.2 ± 0.4	0.43
Range	0 -3	1-2	
Snellen VA			
Mean ± SD	0.4 ± 0.3	0.5 ± 0.3	0.21

PEX indicates pseudoexfoliation; POAG, primary open-angle glaucoma.

TABLE 2. Intraocular Pressure and Number of Anti-glaucoma Medications Required in the First-year Follow-up

Time	Ahmed Valve (Mean ± SD) (n = 12)	eyeWatch + Baerveldt (Mean ± SD) (n = 9)	*P*
Baseline			
IOP (mm Hg)	24.8 ± 9.0	27.3 ± 7.0	0.24
Glaucoma medications	3.0 ± 0.7	2.9 ± 0.8	0.37
Day 1			
IOP (mm Hg)	7.3 ± 7.6	8.6 ± 6.8	0.35
Glaucoma medications	0.0 ± 0.0	0.0 ± 0.0	
Week 1			
IOP (mm Hg)	6.3 ± 3.2	7.4 ± 3.1	0.21
Glaucoma medications	0.0 ± 0.0	0.0 ± 0.0	
Week 2			
IOP (mm Hg)	10.8 ± 5.5	11.4 ± 2.9	0.38
Glaucoma medications	0.0 ± 0.0	0.0 ± 0.0	
Month 1			
IOP (mm Hg)	14.6 ± 7.7	11.8 ± 3.6	0.16
Glaucoma medications	0.0 ± 0.0	0.0 ± 0.0	
Month 2			
IOP (mmHg)	18.9 ± 7.9	12.2 ± 2.5	0.01
Glaucoma medications	0.2 ± 0.4	0.0 ± 0.0	0.1
Month 3			
IOP (mm Hg)	15.3 ± 5.1	14.7 ± 2.3	0.37
Glaucoma medications	0.2 ± 0.4	0.0 ± 0.0	0.1
Month 6			
IOP (mm Hg)	14.7 ± 4.3	13.4 ± 2.9	0.23
Glaucoma medications	0.4 ± 0.7	0.2 ± 0.4	0.23
Month 12			
IOP (mm Hg)	13.8 ± 3.6	12.1 ± 1.8	0.13
Glaucoma medications	0.3 ± 0.7	0.2 ± 0.4	0.33

IOP indicates intraocular pressure.

Measurements of IOP on week 1 have shown that 3 patients of the AGV group and only 1 patient in the eW-B group had transient low IOP measurement. In the AGV group, only 1 patient did experience persistent low IOP on 3 consecutive visits (Fig. 2).

The mean number of glaucoma medications decreased from 3.0 ± 0.7 before surgery to 0.3 ± 0.7 at last control (group AGV), and 2.9 ± 0.8 before surgery to 0.2 ± 0.4 at last control (group eW-B) ($P < 0.001$). This is a reduction in medication of 90% for group AGV and 93% for group eW-B, respectively (Table 2).

Preoperative BCVA was 0.4 ± 0.3 (group AGV) and 0.5 ± 0.3 (group eW-B), remaining fairly stable at last follow-up with 0.3 ± 0.3 (group AGV) and 0.5 ± 0.3 (group eW-B), respectively.

In the AGV group complete success rate, as defined above, was 50% and overall success rate was 58%. In the eW-B group, 67% reached the criteria for complete success and 89% reached overall success. Failure was reported in 5 AGV cases (42%) while 1 case of failure (11%) occurred in the eW-B group (IOP > 16 mm Hg in 2 consecutive visits 1 month after surgery) (Table 4).

At each postoperative visit, all ocular complications and interventions were recorded. There were no cases of eyes that lost light perception. In the AGV group there were 2 cases of choroidal effusion, 1 case of retinal hemorrhage, and 1 case of

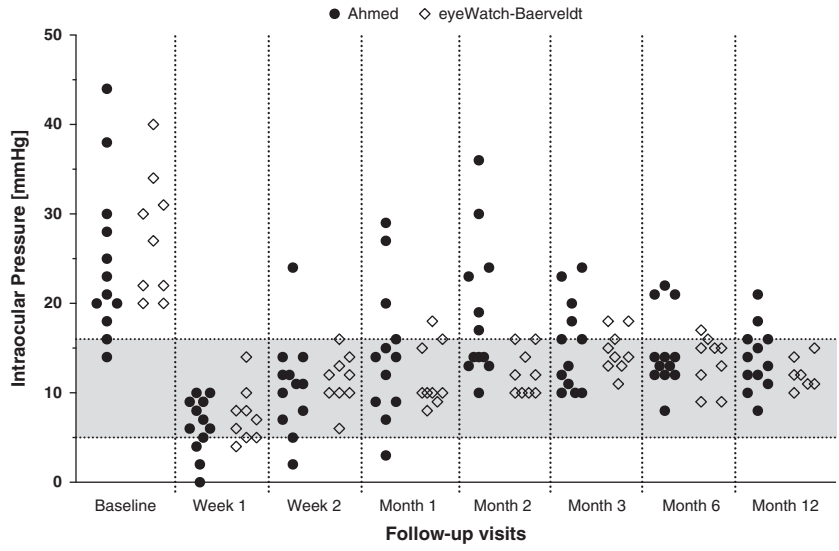

FIGURE 2. Intraocular pressure (IOP) per patient for each visit during the first year of follow-up. Circle-shapes represent individual results for the Ahmed group and diamond-shapes represent individual results for the eyeWatch-Baerveldt group. The gray area represents the targeted physiological range where 16 ≤IOP ≤5 mm Hg. For all postoperative visits, the *P*-value was significant compared with baseline ($P < 0.001$).

diplopia with all complications resolving spontaneously. No complications were observed in the eW-B group (Table 5). Injection of 5-Fluorouracil (5-FU) was performed twice in one AGV patient 1 month after implantation of the Ahmed device; no patients from the eW-B group needed bleb needling and/or injection of antimetabolites.

DISCUSSION

This study reports on the clinical results of 21 patients operated with either an AGV or a new adjustable glaucoma drainage device, the eyeWatch in conjunction with a Baerveldt seton tube, to control IOP in refractory glaucoma after failed surgeries. The aim of this study was to examine whether the eyeWatch can manage IOP during the postoperative period in reference to the AGV.

Management of the IOP during the early postoperative period is essential for limiting the potential IOP-related complications and to increase the success rates. Different techniques have been implemented to avoid hypotony and its related complications. The Ahmed device has been developed with this objective and contains a passive valve that closes for low IOP values and opens when the IOP increases. However, experience has shown that despite the presence of the valve, hypotony can still occur.[5] In contrast, the eyeWatch device works like a "faucet," where the ophthalmologist can precisely and actively adjust the resistance to the aqueous humor outflow to achieve the desired IOP.

During the early postoperative phase, we have reported that some patients had lower pressure in the AGV group compared with the eW-B group. In addition, complications related to low pressures were observed only in the AGV group (n = 4), demonstrating that the valve might not be sufficient to effectively prevent hypotony-related complications from happening. Such hypotony-induced complications were not seen in the eW-B group.

Budenz et al[10] have described a number of complications occurring during the early postoperative phase (≤3 mo). Most of these complications could be attributed to low IOP. Moreover, the frequency and type of complications described in the study of Budenz and colleagues. were more prevalent in the Baerveldt group and less in the Ahmed group. In the present study, we have shown that the use of the eyeWatch device combined to a Baerveldt tube resulted in a significant reduction of early complications.

TABLE 3. eyeWatch Functional Positions and Adjustments During the Follow-up

Follow-up (d)	1	7	14	30	60	90	180	360
Mean position*	5.1	4.1	3.8	3.1	2.8	2.2	1.7	1.8
Total no. adjustments performed	2	5	6	4	1	3	2	0
No. patients with an eyeWatch open/partially open	0	1	2	4	4	6	8	8

*Position 0 corresponds to the fully open position (no resistance to outflow), positions 1-3 partially open, position 4-5 partially closed and position 6 is fully closed (maximal resistance to outflow).

TABLE 4. Success Rates and Reasons for Failure

	n (%)	
	AGV Group (n = 12)	eW-B Group (n = 9)
Complete success	6 (50)	6 (67)
Overall success	7 (58)	8 (89)
Failure*	5 (42)	1 (11)
High IOP* (>16 mm Hg)	5 (42)	1 (11)
Low IOP* (≤5 mm Hg)	—	—

*IOP-related failures require 2 consecutive visits at or after 1 month in which the criterion is not met.

IOP indicates intraocular pressure.

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TABLE 5. Postoperative Complications

	n (%)	
	AGV Group (n = 12)	**eW-B Group (n = 9)**
Choroidal effusion	2 (18)	—
Retinal hemorraghe	1 (9)	—
Diplopia	1 (9)	—
Total no. complications	4	—
Patients with complications	3 (25)	—

AGV indicates Ahmed glaucoma valve.

The eyeWatch device allows for a patient-specific adjustment of the resistance to aqueous humor egress. In long term, the eyeWatch implant can durably be set in a fully open position, whereas the resistance to outflow of aqueous humor depends mainly on the bleb resistance of the BGI. On the basis of this assertion, the long-term results are expected to rely solely on BGI performance. Difference in performance between the Ahmed and the Baerveldt have been discussed in several studies.[3,10] Considering results from the AGV, the ABC study reported an IOP change from 31.2 ± 11.2 to 15.4 ± 5.5 mm Hg at 1 year, and the AVB study showed a reduction from 31.1 ± 10.5 to 16.5 ± 5.3 mm Hg at 12 months.[3,10] These studies have demonstrated that the AGV is able to reduce IOP by 52% on average (58% to 46%). In the present study, the baseline IOP was 24.8 ± 9.0 in the AGV group, reaching even lower IOP results at 12 months compared with these previous studies (mean IOP, 13.8 ± 3.6 mmHg) and a reduction of 44%.

In contrast, the BGI is more effective in lowering the IOP than the AGV.[3,10] For instance, in the ABC study, the IOP went from a mean of 31.8 ± 12.5 mm Hg baseline to 13.2 ± 6.8 mm Hg at 1 year (−58%), and the AVB study reported a change from 31.7 ± 11.1 to 13.6 ± 4.8 mm Hg at 12 months (−57%). In the present study, the eW-B group reached a mean IOP of 12.8 ± 2.4 mmHg at the 12-month visit (reduction of 53%). Recently, a comparable mean IOP and reduction were achieved in a recently published study using the same combination of eyeWatch and Baerveldt.[8] It was reported that the mean baseline IOP decreased from 26.2 ± 6.8 to 11.9 ± 2.8 mm Hg at 12 months (−54% reduction).

The number of postoperative interventions was low consisting essentially in injecting antimetabolites in the eye of 1 single patient from group AGV. All patients from group eW-B who received an eyeWatch-Baerveldt were free from postoperative intervention to manage complications on the filtering bleb or the filtering device. This should be considered as major progress in the postoperative management of glaucoma filtering surgery using modern seton devices. The cost and burden of postoperative interventions should not be underestimated and the use of any technique and device that reduce these cost and burden should be encouraged in the frame of modern glaucoma surgery.

However, differences reported for these comparisons need to be taken with caution as demographics and number of patients were different and could create bias. The small number of patients in each group (n = 12 for group AGV and n = 9 for group eW-B) and the relatively short follow-up time (12 mo) could limit the significance of the results. The nonmasked aspect of the study design might be another limitation of this study. In contrast, the monocentric and comparative aspect of this study with 1 surgeon operating patients of both groups coming from the same demographics should be considered as an asset for the analysis of these results.

In summary, this clinical study reports on the initial results of a filtering surgery using either an AGV or an eyeWatch device connected to a Baerveldt implant. The novelty brought by the eyeWatch device to the management of glaucoma surgery lies in the capability to alter the resistance of aqueous outflow during the critical postoperative period. We hypothesized that this feature, performed postoperatively without further surgical management, and the precision achieved in controlling the IOP, might be playing a beneficial role in clinical success. A larger set of data should be used to continue to substantiate and support the safety, efficacy and clinical relevance of the eyeWatch device in comparison with other seton drainage devices.

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