# Initial Clinical Results of the eyeWatch: a New Adjustable Glaucoma Drainage Device Used in Refractory Glaucoma Surgery

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**Précis:** In this study, we report clinical results after implantation of an adjustable glaucoma drainage device. The intraocular pressure (IOP) profile was efficiently controlled postoperatively as the resistance to aqueous humor outflow was finely adjusted.

**Purpose:** The main purpose of this study was to evaluate the safety and efficacy of the new adjustable glaucoma drainage device eyeWatch used in conjunction with a Baerveldt glaucoma implant in refractory glaucoma.

**Patients and Methods:** This was a multicentric, prospective, noncomparative clinical trial. Patients older than 18 years of age suffering from refractory glaucoma after failed surgeries, with IOP of $\geq 20$ mm Hg, in whom a further glaucoma procedure using an aqueous shunt was planned, were enrolled in this study. The primary outcome was the success rate, defined as an IOP $\leq 18$ mm Hg and reduction of $> 20\%$ from baseline, IOP $\geq 6$ mm Hg. Secondary outcomes were mean IOP, visual acuity, number of antiglaucoma medications, number, and type of complications.

**Results:** Fifteen patients were included. The mean follow-up time was $15.6 \pm 3.5$ months. The mean baseline IOP decreased from $26.2 \pm 6.8$ mm Hg before surgery to $11.9 \pm 2.8$ mm Hg at 12 months ($P < 0.001$). The mean number of glaucoma medications decreased from $3.0 \pm 0.7$ before surgery to $0.8 \pm 0.9$ at last visit ($P < 0.001$). The success rate was 40% for complete success and 93% for overall success at last follow-up. Complication rate was 7%.

**Conclusions:** The novel glaucoma device allows for perioperative and postoperative noninvasive adjustments of the resistance to aqueous humor outflow. This leads to better management of IOP during the early postoperative period, preventing ocular hypotony and eliminating the need for obstructive elements and reinterventions. The rate of complications was low, IOP was adequately controlled and lowered, with a substantial reduction in the number of antiglaucoma medication.

**Key Words:** glaucoma drainage device, Ahmed implant, Baerveldt implant, refractory glaucoma, ocular hypotony

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Intraocular pressure (IOP) management in refractory glaucoma can be challenging. Failure to efficiently control IOP after initial glaucoma surgery may result from excessive scarring of the filtering bleb, extensive closure of the scleral flap after tissue remodeling, or the inability to maintain patent the drainage pathways generated during the filtering surgery.[1–5] Glaucoma drainage devices (GDD) have been designed to address the lack of efficiency of conventional filtering surgeries, that is, trabeculectomy or nonpenetrating filtering surgery.[6] These devices drain the aqueous humor from the anterior chamber via a small bore tube to an end plate located at the equatorial region of the globe.[7] The 2 most commonly used devices are the Baerveldt glaucoma implant (BGI) (Abbott Medical Optics Inc., Santa Ana, CA) and the Ahmed glaucoma valve (AGV) (New World Medical Inc., Rancho Cucamonga, CA). The BGI is available in 2 different end plate sizes, that is, 250 and 350 $mm^2$.[8,9] The Baerveldt implant is a nonvalved device that requires early restriction of flow to allow adequate time for formation of a mature bleb.[2] The adult AGV is a GDD that has a 184-$mm^2$ plate and features a flow-restrictive system designed to minimize postoperative hypotony and its complications, for example, shallow to flat anterior chamber, choroidal detachment/effusion, and suprachoroidal hemorrhage.[2,10,11]

Comparative studies have demonstrated that Baerveldt implants are more effective than the Ahmed to lower the IOP over time.[12,13] Conversely the lack of a built-in flow-restriction mechanism in the BGI and a larger filtration area may result in greater risks of hypotony-related complications.[2,8,14,15] Different techniques have been advocated to circumvent the risk of hypotony using the BGI, such as, for instance, placing a stent into the lumen of the tube shunting the aqueous humor from the anterior chamber to the end plate. A temporary tube ligature restricting the egress of aqueous is another possibility to limit the extent of hypotony before formation of a flow-resisting filtering bleb.[3,16] The drawbacks of such techniques are the lack of precision and predictability in efficiently controlling IOP in the early postoperative phase, that may result in volatile IOP with initial hypertensive and subsequent hypotensive phase.[2] During the flow restriction, resistance to flow through the shunt is high, often leading to IOP above the desired range and necessitating the use of antiglaucoma medication, even if bleb resistance is still at low levels. In addition, further surgical steps are necessary to set free the tube from the restricting element, increasing costs and the risks related to the treatment.

The adjustable GDD eyeWatch (eW) (Rheon Medical, Lausanne, Switzerland) was designed to better control IOP

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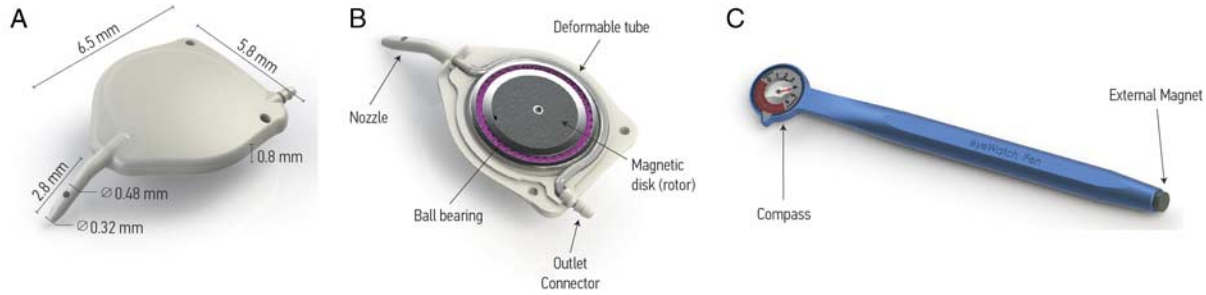


**FIGURE 1.** The eyeWatch system: dimensions of the eyeWatch device (A), internal mechanism of the eyeWatch device (B), and the external control unit (C), the eyeWatch Pen.

in the early postoperative phase by making adjustable the resistance to aqueous egress from the anterior chamber to the end plate (Fig. 1A).[17,18] The details of the design and construction have been reported elsewhere.[17] Briefly, eW is composed of a deformable silicone tube, which drains AH from the anterior chamber into a Baerveldt tube (or any seton tube). The implant contains a mechanism that allows for a variable compression of the tube, altering its cross-sectional area accordingly and thus changing the fluidic resistance. The various levels of compression in the tube are achieved by rotating a magnetic disk around a shaft, which is eccentric to its axis of symmetry. The resistance to aqueous egress depends on the degree of compression of the drainage tube (Fig. 1B). After surgery and during the postoperative follow-up, the IOP can be modified non-invasively by changing the position of the rotor using an external control unit (eyeWatch Pen) (Fig. 1C).

In this prospective study, we evaluated the clinical outcomes of the eW adjustable GDD 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 boards of the Universities of Lausanne and Zurich, Switzerland. Eligible patients were voluntarily recruited by the site investigator (A.M. or C.K.) and each patient gave written informed consent after proper education. The study is registered at clinicaltrial.gov (NCT02554214).

### Eligibility Criteria

Patients aged 18 years or older suffering from refractory glaucoma after previous failed surgeries, with an IOP at 20 mm Hg or higher despite maximally tolerated anti-glaucoma medications, who were planned to receive a seton tube were included. Patients with the diagnosis of neovascular glaucoma, congenital glaucoma or anomaly of the anterior chamber angle, microphthalmia, eye 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) or corneal transplant or retinal surgery, history of severe eye trauma, were excluded. Patients unwilling to sign the written informed consent before participation in the study or unable to complete the postoperative follow-up requirements were also excluded.

### Surgical Procedure

For this study, the eW was connected to a BGI plate with a surface area of 250 or 350 $mm^2$. The choice of the size of the implant was decided by the surgeons (A.M. and C.K.) based on the size of the eye. Surgeries were performed under local anesthesia (retrobulbar, or peribulbar) unless there was an indication for general anesthesia. A fornix-based opening of the conjunctiva was made at the superior limbus and the Tenon's capsule dissected to expose the sclera. Hemostasis was performed using gentle wet-field cautery. The end plate 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 used to prevent hypotony if necessary. A scleral canal was then created using a 25-G needle to allow the insertion of the device's nozzle into the anterior chamber at the level of Schlemm's canal. The body of the eW was finally anchored onto the sclera using 2 single Nylon 10-0 sutures. The proximal end of the Baerveldt tube was trimmed to an appropriate length and connected to the eW (Fig. 2). A pericardium patch (Tutoplast; IOP Ophthalmics, Costa Mesa, CA) of about 7 mm×7 mm was finally placed on the eW 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. Postoperative treatment consisted of topical antibiotics and corticosteroids (TobraDex; Alcon, Fort Worth, TX) that tapered over the first month after surgery and replaced by nonsteroid anti-inflammatory drugs for 2 months.

### 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

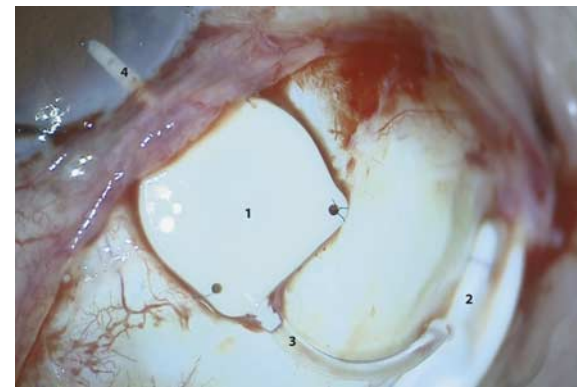


**FIGURE 2.** Clinical photograph of an eye implanted with an eyeWatch device combined with a Baerveldt plate. (1) eyeWatch device, (2) Baerveldt plate, (3) Baerveldt-eyeWatch connection tube, and (4) nozzle of the eyeWatch in the anterior chamber.

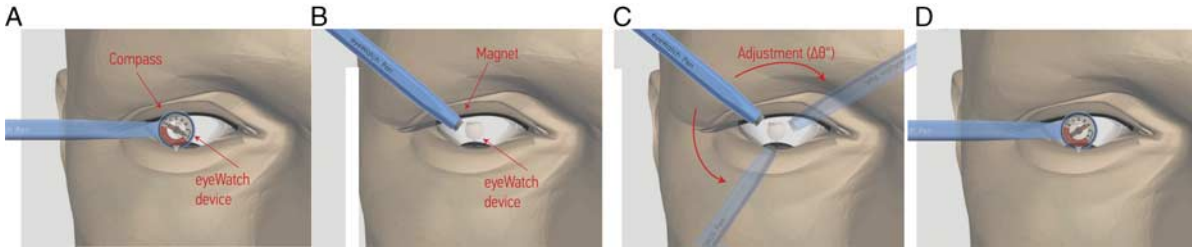


**FIGURE 3.** Sequence of steps necessary to adjust the eyeWatch device. A, Measure the angular position of the implant using the compass of the eyeWatch Pen. B, Flip 180 degrees the eyeWatch Pen to expose the external magnet. C, Turn the pen to the direction and angular position wished. D, Measure the new angular position of the eyeWatch implant using the compass of the eyeWatch Pen.

surgery. Additional interim appointments were made as deemed necessary by the treating ophthalmologists (A.M., J.G., C.K.). IOP was measured using Goldmann applanation tonometer under local anesthesia. Reading of the eW position was performed by the same person performing Goldmann applanation tonometer measurements. Best-corrected distance visual acuity (BCVA) was measured using Snellen charts. Pachymetry was performed using a noncontact pachymeter (Pachmate 2; DGH Technology, PA), and endothelial cell count using XY (SP-1P; Topcon, Tokyo, Japan).

After IOP was measured, adjustments of the eW implant might have been necessary to achieve the target IOP value. For instance, when the IOP was higher than the desired value, the rotor was moved in a direction that resulted in a reduction in outflow resistance. Conversely, if the IOP was initially <6 mm Hg, the rotor was actuated to increase the resistance to outflow to raise IOP to the target value. To adjust the rotor of the implant, an external control unit (eyeWatch Pen) was used:

(1) The compass of the eyeWatch Pen was set coaxially over the implant, at a distance of 1 to 2 mm from the eye, while the patient was looking down (Fig. 3A). The position of the rotor was read on the scale of the compass and measurements around 6 meant the eW was maximally restricting outflow, whereas measurements around 0 indicated the eW was set wide open and not restricting outflow, while measurements in-between left the eW in a partially open position.
(2) The physician then flipped the eyeWatch Pen by 180 degree to couple the magnet of the eyeWatch Pen with the magnetic rotor of the implant (Fig. 3B).
(3) The eyeWatch Pen was moved along a circular movement around the eW to bring the magnetic rotor to a new position [ie, counterclockwise to decrease the position number (6 toward 0) or clockwise to increase the position number (0 toward 6)] (Fig. 3C).
(4) To check whether the adjustment was effective or not, the compass of the eyeWatch Pen was placed over the implant again and the newly achieved position was read again to confirm the proper positioning of the rotor (Fig. 3D).
(5) The IOP was measured 15 minutes later and, if necessary, the adjustment was repeated until the IOP reached the intended target value. All readings and adjustment of the rotor position were recorded.

**TABLE 1.** Baseline Demographics and Ocular Characteristics

| Baseline | |
|---|---|
| Age (mean ± SD) (y) | 72.5 ± 11.1 |
| Gender [n (%)] | |
| Male | 4 (27) |
| Female | 11 (73) |
| Ethnicity [n (%)] | |
| Caucasian | 12 (80) |
| Asian | 3 (20) |
| IOP (mean ± SD) (mm Hg) | 26.2 ± 6.8 |
| Glaucoma medication (mean ± SD) | 3.0 ± 0.7 |
| Diagnosis [n (%)] | |
| POAG | 11 (73.5) |
| PEX | 3 (20) |
| Juvenile glaucoma | 1 (6.5) |
| No. previous filtering surgeries | |
| Mean ± SD | 1.8 ± 0.7 |
| Range | 1-3 |
| Pseudophakia [n (%)] | 5 (33) |
| Snellen VA (mean ± SD) | 0.6 ± 0.3 |
| Endothelial cell count (mean ± SD) (cells/mm$^2$) | 1793 ± 578 |
| Cornea pachymetry (mean ± SD) (μm) | 548 ± 33 |

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

## Outcome Measures

IOP, BCVA, number of antiglaucoma medications, rate of complications, were the outcome measures acquired for the study.

## Complete Success Rate

Complete success was defined as an IOP ≤ 18 and ≥ 6 mm Hg and a reduction by 20% from baseline at the last follow-up visit without glaucoma medications.

## Overall Success Rate

Overall success was defined as an IOP ≤ 18 and ≥ 6 mm Hg and a reduction by 20% from baseline at the last follow-up visit with or without use of glaucoma medications.

## Failure

Additional glaucoma surgery, loss of vision, removal of the implant, IOP > 18 mm Hg or <20% reduction from baseline on 2 visits after 3 months or IOP < 6 mm Hg on 2 consecutive study visits after 3 months, was defined as failure. Additional glaucoma surgery was defined as a surgery requiring a return to the surgical room for further filtering procedure. Interventions performed at the slit-lamp, for example, bleb needling and antimetabolites injections, paracentesis, were not considered as glaucoma reoperations.



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## Statistical Analysis

All statistical analyses were performed using S-Plus. Data were processed using paired Student *t*-test and Mann-Whitney *U* test using 2-sided analysis. A *P*-value of $\leq 0.05$ was considered statistically significant.

## RESULTS

A total of 15 patients were enrolled between November 2016 and September 2017. The mean follow-up time was $15.6 \pm 3.5$ months (mean ± SD). The mean age was $72.5 \pm 11.1$ years. Type of glaucoma were 11 primary open-angle glaucoma (73.5%), 3 pseudoexfoliation glaucoma (20%), 1 juvenile glaucoma (6.5%). The mean number of previous filtering surgeries was $1.8 \pm 0.7$ (Table 1).

The mean baseline IOP was $26.2 \pm 6.8$ mm Hg and went down to $11.9 \pm 2.8$ mm Hg at 12-month visit ($P < 0.001$, paired *t*-test). This represents a 54% IOP reduction from baseline (Table 2, $P < 0.001$). IOP value per patient over time is depicted in the Figure 4.

The positions of the rotor of the eW and the number of adjustments per visit per patient are shown in Table 3.

The mean number of glaucoma medications decreased from $3.0 \pm 0.7$ before surgery to $0.8 \pm 0.9$ at last visit ($P < 0.001$, paired *t*-test). The reduction in medication was 73% (Table 2, $P < 0.001$).

No significant differences have been seen in terms of IOP and number of antiglaucoma medications between the patients with a Baerveldt 250 $mm^2$ and 350 $mm^2$ (Table 2).

The BCVA before surgery was $0.6 \pm 0.3$ and remained fairly stable at $0.6 \pm 0.3$.

The mean endothelial cell count was $1793 \pm 578$ cells/$mm^2$ before surgery and $1727 \pm 563$ cells/$mm^2$ at 12 months (loss of 4%) ($P = 0.83$) Central corneal thickness went from a mean $548 \pm 33$ to $560 \pm 37$ μm at 12 months (increase by 2%) ($P = 0.49$, paired *t*-test).

The success rate based on IOP $\leq 18$ and $\geq 6$ mm Hg or a reduction of 20% from baseline was at the level of 40% for complete success and 93% for the overall success. We had 1 case of failure (7%) with IOP $> 18$ mm Hg for 2 visits after 3 months.

At each postoperative visit, all ocular complications and interventions were recorded. There were 4 complications affecting 4 patients. These included 2 cases of conjunctival wound leak (Seidel sign positive) and 2 cases of choroidal detachment. All these complications resolved spontaneously except for 1 case of wound leak that required surgical revision. There were no cases of eyes that lost light

**TABLE 2.** Intraocular Pressure and Number of Antiglaucoma Medications Required in the First Year Follow-up

| Time | eyeWatch+Baerveldt (Mean ± SD) (N = 15) | eyeWatch+Baerveldt 250 (Mean ± SD) (N = 10) | eyeWatch+Baerveldt 350 (Mean ± SD) (N = 5) | *P* (Baerveldt 250 vs. 350) |
|---|---|---|---|---|
| Baseline | | | | |
| IOP (mm Hg) | 26.2 ± 6.8 | 21.6 ± 1.1 | 28.5 ± 7.4 | 0.008 |
| Glaucoma medications | 3.0 ± 0.7 | 2.9 ± 0.7 | 3.2 ± 0.4 | 0.4 |
| Day 1 | | | | |
| IOP (mm Hg) | 12.9 ± 8.7 | 15.4 ± 11.1 | 11.7 ± 7.5 | 0.26 |
| Glaucoma medications | 0.1 ± 0.3 | 0.1 ± 0.3 | 0.0 ± 0.0 | 0.51 |
| Week 1 | | | | |
| IOP (mm Hg) | 9.6 ± 5.0 | 10.4 ± 3.6 | 9.2 ± 5.7 | 0.31 |
| Glaucoma medications | 0.1 ± 0.3 | 0.0 ± 0.0 | 0.2 ± 0.4 | 0.14 |
| Week 2 | | | | |
| IOP (mm Hg) | 11.7 ± 2.7 | 12.2 ± 4.1 | 11.4 ± 1.9 | 0.35 |
| Glaucoma medications | 0.1 ± 0.3 | 0.0 ± 0.0 | 0.2 ± 0.4 | 0.14 |
| Month 1 | | | | |
| IOP (mm Hg) | 12.2 ± 4.6 | 10.8 ± 4.8 | 12.9 ± 4.6 | 0.22 |
| Glaucoma medications | 0.4 ± 0.7 | 0.3 ± 0.6 | 0.6 ± 0.9 | 0.41 |
| Month 2 | | | | |
| IOP (mm Hg) | 14.3 ± 4.6 | 12.8 ± 4.5 | 15.0 ± 4.7 | 0.21 |
| Glaucoma medications | 0.7 ± 0.9 | 0.5 ± 0.8 | 1.0 ± 1.0 | 0.26 |
| Month 3 | | | | |
| IOP (mm Hg) | 15.1 ± 4.1 | 13.0 ± 3.2 | 16.2 ± 4.2 | 0.06 |
| Glaucoma medications | 0.8 ± 0.9 | 0.5 ± 0.8 | 1.2 ± 0.8 | 0.16 |
| Month 6 | | | | |
| IOP (mm Hg) | 13.2 ± 3.4 | 13.4 ± 4.0 | 13.1 ± 3.3 | 0.44 |
| Glaucoma medications | 1.1 ± 1.0 | 1.1 ± 1.1 | 1.0 ± 0.7 | 0.87 |
| Month 12 | | | | |
| IOP (mm Hg) | 11.9 ± 2.8 | 12.0 ± 3.6 | 11.8 ± 2.8 | 0.44 |
| Glaucoma medications | 0.8 ± 0.9 | 0.6 ± 0.9 | 1.0 ± 0.7 | 0.45 |

IOP indicates intraocular pressure.

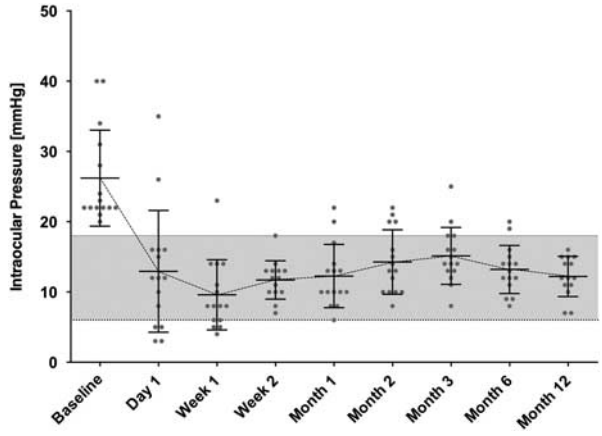


**FIGURE 4.** Intraocular pressure (IOP) per patient for each visit during the first year of follow-up. Bars represent mean and SD. The gray area represents the targeted physiological range where $18 \leq IOP \leq 6$ mm Hg. The dashed line connects the mean IOP. For all postoperative visits, the *P*-value was significant compared with baseline ($P < 0.001$).

perception, and no interventions at the slit-lamp including bleb needling, antimetabolites injections, and paracentesis were performed.

## DISCUSSION

This pilot study reports on the initial results on 15 patients of a new adjustable GDD, eW, in conjunction with a Baerveldt seton tube, intended to be used in refractory glaucoma after failed filtering surgeries. The goal of the eW is to provide a variable, postoperatively adjustable resistance to the egress of aqueous humor after glaucoma surgery and minimize the complications related to the lack of IOP control over time (eg, hypotony). The IOP profile over time during the early postoperative period shows that the pressure was efficiently controlled to prevent postoperative hypotony. Similarly, IOP spikes during that period were prevented. Contrary to a BGI used alone, where a stent needs to be inserted to restrict flow of aqueous humor, the adjustable resistance of the eW was providing the limitation of aqueous humor flow to the end plate of the BGI, hence allowing for a totally atraumatic avoidance of hypotony and eliminating the need of an additional intervention to remove the stent. The adjustment of the eW was performed noninvasively by the treating physician. It resulted in a quick and simple gesture, while for the patients, the adjustment was atraumatic and with no discomfort.

Treatment success was subdivided into complete and qualified success on the basis of whether there was IOP volatility at last follow-up visit, glaucoma medications used, significant loss of vision, or additional surgical procedures required. With 40% of complete success, the eW device has demonstrated to be efficient in the treatment and safe for the patients. The rate of complete success is higher than the values reported in other studies using the BGI tube,[2,19,20] where the rate of complete success treatment at 1-year follow-up is comprised between 17% and 36%.

The failure rate (7%) remained low compared with previous studies, where the reported failure rates ranged between 13% and 28%.[2,19,20] No failures were associated with hypotony. The resistance of the implant, initially set to high values to avoid hypotony, was gradually reduced as the fibrotic capsule around the Baerveldt plate formed to control the IOP in the 10 to 15 mm Hg range (Table 3). The slow onset of fibrosis on the filtering capsule changes the overall resistance to aqueous humour outflow and progressive reduction of filtration was managed by adjusting the implant. In the initial few days after surgery, the readings were close to 6, indicating a highly resistive tube. Conversely in later stages, when the filtering bleb had build-up enough resistance of its own from the development of a capsule, the implant was set to open position (readings close to 0-1) to freely allow aqueous flowing through the device.

The importance of early flow control after filtering surgery is a key component for the surgical success. Many methods have been extensively used in order to restrict flow in the early period postoperatively and thus reduce the risk of hypotony. When implanting a nonvalved Baerveldt shunt, the tube is often restricted with a suture to prevent early hypotony. To avoid hypotony and shallow chambers, great care needs to be taken to make sure that the suture indeed causes a full restriction to the fluid flow. The addition of temporary tube occlusions in the BGI group has demonstrated its efficacy.[21] However, preventing hypotony by means of ligations, plugs or sutures often leads to IOPs above the targeted range ($IOP > 21$ mm Hg) during the first postoperative weeks, which is partly managed by substantial augmentation of pressure-lowering medications.[21,22] Moreover, these techniques bring additional complications and risks related to the extrasurgical steps necessary for the maintenance and removal of these occlusions. On the basis of the results obtained in this study, the eW implant allows for a more accurate and predictive management of the IOP, especially in the first 4 weeks following surgery. The eW seems to prevent IOP spikes usually present in the AGV and BGI groups.[2,23] With this device there is likely to be a smooth transition, thus avoiding hypotony and reoperation for hypotony-related complications.

Pakravan et al[24] proposed to reduce the IOP spikes with the utilization of aqueous suppressants such as beta-blockers or carbonic anhydrase inhibitors during the early phase in the postoperative period. The eW offers a continuously adjustable resistance, avoiding thus complete tube occlusions in the early postoperative period and therefore, requiring a lower number of antiglaucoma medications during the entire postoperative phase (Table 2). Furthermore, antimetabolites to modulate the fibrosis and encapsulation of the filtering bleb around the BGI plate were not used in this study. Use of such antifibrosis drugs was reported in the clinical trials using AGV with adjunctive mitomycin C in refractory glaucoma.[25–27] Likewise, no long-term slow-release corticosteroids were used as proposed by Hennein et al[28] in their comparative retrospective cohort study. Using the eW along a seton surgery, the postoperative IOP spikes were reduced following the adjustments made on the device (Table 3)

**TABLE 3.** Mean Values of Implant Position During Follow-up

| Day | 1 | 7 | 14 | 30 | 60 | 90 | 180 | 360 |
|---|---|---|---|---|---|---|---|---|
| Mean position | 5.78 | 5.05 | 4.38 | 3.7 | 1.66 | 0.9 | 0.9 | 0.9 |
| No. implants adjusted | 1 | 3 | 6 | 9 | 4 | 0 | 0 | 0 |
| Total number of adjustments | 1 | 3 | 6 | 10 | 5 | 0 | 0 | 0 |

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

and the noninvasively changes of the resistance to the aqueous humor flow, thus minimizing use of antiglaucoma medications and antifibrotic drugs. There were no differences between the 2 Baerveldt plate sizes and we did not expect any difference between these 2 groups at 1-year follow-up. This was previously reported by a comparative study demonstrating there was no significant difference between the Baerveldt 250 and 350 $mm^2$.[29]

Complications were essentially related to incomplete wound closure. There were no clinical complications related to the functioning of the device. Magnetic resonance imaging (MRI) scans might be a concern for patients implanted with eW. In that prospect, 5 patients underwent MRI-scan for nonophthalmic reasons. None of these patients experienced any problems during and after this imaging procedure. There was no pain or discomfort and artifacts did not interfere with the imaging diagnostics. There was a requirement for new reading of the position of the eW rotor and adjustment to the position set before performing the MRI-scan due to exposure to the magnetic field. There were no problems in reading or adjusting the eW for these patients.

One specific and potentially beneficiary feature of the AGDD lies in the very small size of the nozzle inserted into the anterior chamber. Compared with the BGI which has an external diameter of 0.635 mm, the external diameter of the eW nozzle is 0.48 mm (Fig. 1A). This small diameter, its rigidity and the specific fixed angle geometry of the device, is believed to play a favorable role in preserving the inner surface of the cornea. Endothelial cells count showed a small percentage (4%) of cells loss after 12 months of follow-up, a figure much lower than the results reported from the Baerveldt tube study (13.1%).[30] Further support for this argument is provided as the endothelial cell loss is comparable with the value reported for the Ex-PRESS device (range between 3.5% and 5%), which is to be expected, as both the eW and the Ex-PRESS have about the same external diameter, that is, <0.5 mm.[31,32]

Finally, despite the small inner bore, we had no tube obstruction nor iris incarceration. The lateral secondary opening in the nozzle could have also played a positive role in preventing total tube occlusion. Covered by a sheet of Tutoplast no erosion of the device was seen.

The small number of patients (n = 15) and the relatively short follow-up time (12 mo) could limit the significance of the results. Additional studies are underway to extend both the number of patients and the follow-up time.

In summary, this clinical trial reports on the first results of a novel glaucoma device that allows periopeartive and postoperative noninvasive adjustments of the resistance to aqueous humour outflow. These adjustments greatly contribute to prevent ocular hypotony during the early postoperative phases up to 8 weeks after surgery using seton tubes, as well to maintain IOP in the targeted range with reduced medications and without the need of temporary tube obstructions and the required reinterventions. The rate of complications was low, and the IOP was adequately controlled and significantly lowered as compared with preoperative values, with a reduction in the number of antiglaucoma medications.

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