EyeWatch Rescue of Refractory Hypotony After Baerveldt Drainage Device Implantation: Description of a New Technique

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Abstract: The most effective way to control glaucoma is by lowering intraocular pressure (IOP) in order to prevent the progression of the disease. Glaucoma drainage devices (GDDs) are surgical option reserved for refractory cases and have been designed to address known complications of conventional filtering surgery. They are, however, associated with a higher rate of complications related to early hypotony and late corneal decompensation. In the case of the commonly used Baerveldt Glaucoma Implant (BGI), techniques exist in an attempt to prevent early postoperative hypotony but can be highly variable and surgeon dependent. Moreover, the additional steps required can result in unstable IOP in the immediate postoperative period. In 2014, Villamarin and colleagues described for the first time an adjustable GDD, called the eyeWatch implant, designed to better control IOP fluctuations and avoid hypotony during the early postoperative period via magnetic control of the device tube lumen. This innovation provides the possibility to adjust the amount of aqueous humor outflow after device implantation in a noninvasive manner. We report the case of an 83-year-old patient with advanced pseudoexfoliative glaucoma, referred to our tertiary center because of disease progression despite topical therapy and having undergone deep sclerectomy. First, a BGI was implanted but was unfortunately complicated by a 3-month chronic refractory hypotony from day 8, and choroidal detachment despite medical management, choroidal drainage, and viscoelastic injections. After 3 months, the decision was made to rescue the situation with an eyeWatch adjunction to the BGI. Postoperatively, the IOP was successfully controlled through fine adjustments of the eyeWatch opening position, until the last visit 8 months after the rescue, with complete resolution of the choroidal detachment and without any medications. This demonstrates that the eyeWatch may offer an answer not only to the immediate postoperative hypotonic phase of the GDD surgery but also to the later cystic bleb hypertonic phase.

Key Words: glaucoma, glaucoma surgery, BGI, Baerveldt glaucoma implant, GDD, glaucoma drainage device, chronic hypotony, choroidal detachment, revision, eyeWatch

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The most effective way to control glaucoma is by lowering the intraocular pressure (IOP) in order to prevent the progressive degeneration of retinal ganglion cells of the optic nerve.[1,2] Despite recent innovations, IOP management in refractory glaucoma remains challenging.[3,4] Filtering surgery is generally offered to patients with moderate to advanced glaucoma, while glaucoma drainage devices (GDDs) are reserved for refractory types.[5] The latter have been designed to address known complications of conventional filtering surgery, such as excessive scarring of the filtering bleb, extensive closure of the scleral flap after tissue remodeling, or the inability to maintain the drainage pathways patent.[6–10] The Baerveldt glaucoma implant (BGI) (Abbot Medical Optics Inc., Santa Ana, CA) and the Ahmed glaucoma valve (New World Medical Inc., Rancho Cucamonga, CA), are 2 commercially available GDDs sharing common physiological principles and technical design by diverting the excess of aqueous humor from the anterior chamber (AC) to the retro-orbital space. Compared with traditional mitomycin-augmented trabeculectomy, Gedde et al[11] have reported GDD's success rates to be higher in high-risk patients, including those with a history of failed filtering surgery. Despite their proven efficacy, GDDs are associated with a higher complication rate, primarily early hypotony, and late corneal decompensation. These were attributed to the fluidic characteristics of the devices and their external diameter.[8]

According to Christakis and colleagues the BGI is the most effective GDD in terms of IOP-lowering effect, number of antiglaucoma medications reduction, and surgical success rates compared with Ahmed glaucoma valve. However, it is associated with a higher risk of postoperative hypotony, presumably due to the lack of a built-in flow-restriction mechanism and to a larger filtration area.[7] Similar results were also found in the Ahmed versus Baerveldt Comparison study.[10] Because the Baerveldt implant is a nonvalved tube, after the placement of the plate, the tube is conventionally tied using an absorbable suture to obstruct aqueous humor flow in an attempt to prevent early postoperative hypotony, until encapsulation around the plate occurs. Nevertheless, hypotony may still occur in the early postoperative period and lead to serious complications, such as shallowed to flattened AC, choroidal detachments, and suprachoroidal hemorrhages. Furthermore, flow resistance through these tubes depends on the tightness of the suture or the completeness of the occlusion, which is surgeon dependent. Consequently, while these solutions may be effective, they require additional steps resulting in volatile

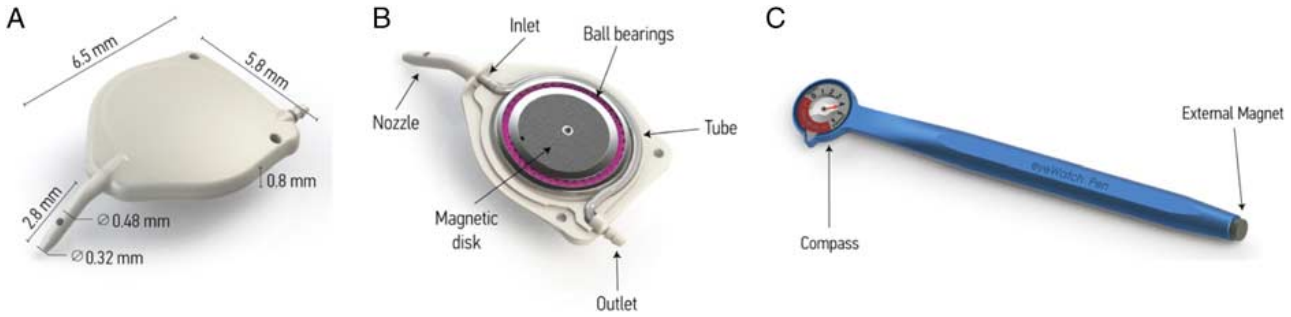

FIGURE 1. EyeWatch device and eyeWatch pen illustration. Aqueous humor flows from the anterior chamber into the nozzle and through the silicon tube of the eyeWatch device, which is variably compressed using a rotating and slightly sliding magnetic disk in order to adjust its outflow through the outlet. A and B, As the magnetic disk is rotated, it slightly slides away from the center of the eyeWatch. Its angular position can, therefore, be measured noninvasively with the use of the eyeWatch Pen, composed with a flat, graded compass (from 0 open to 6 closed) on one side and an external magnet on the other (C) used to adjust the angular position of the disk. Measurements and adjustments can either be done perioperatively or postoperatively through the conjunctiva using local anesthesia. The eyeWatch device itself is then connected to a silicone tube.

IOP with initial hypertensive and subsequent hypotensive phases.[8] During the flow-restriction period, IOP is often above the desired target, as resistance to the flow is high, requiring the reinstatement of antiglaucoma medications despite a low bleb resistance.[12]

In 2014, Villamarin and colleagues described for the first time an adjustable GDD called eyeWatch implant (eW) (Rheon Medical, Lausanne, Switzerland), designed to better control IOP fluctuations and avoid hypotony during the early postoperative period. The innovation of the device lies in the possibility to adjust aqueous humor outflow resistance.[1,2] In brief, the eyeWatch contains a mechanism that allows for a variable compression of a deformable silicone tube, altering its cross-sectional area accordingly and thus changing the fluidic resistance. The various levels of compression and therefore opening of the tube are achieved by rotating a magnetic disk around a shaft, which is eccentric to its axis of symmetry. The external measurement/adjustment device (the eyeWatch Pen) has been designed to perform 2 essential functions: measure the current opening position (from 0 fully opened to 6 fully closed) of the implant, and perform a noninvasive perioperative and postoperative adjustment of the opening in order to optimize fluidic resistance of the implant (Fig. 1). The eyeWatch implant can then be connected to any seton tube, such as the Baerveldt tube.[2]

To the best of our knowledge, this is the first description of a technique in which an eyeWatch has been subsequently attached to a BGI in order to manage refractory postoperative hypotony and severe choroidal detachment after traditional Baerveldt glaucoma surgery.

CASE REPORT

Initial Presentation

An 83-year-old white male suffering from longstanding pseudoexfoliative glaucoma was referred to our tertiary center following acute right eye visual acuity and visual field deterioration despite in-clinic IOPs consistently in the low-teens after a deep sclerectomy performed 12 years ago. BCVA was then measured at hand movement in the right eye, 0.9 in the left eye, and IOPs of 15 and 13 mm Hg, respectively, under a topical combination of beta-blocker and carbonic anhydrase inhibitor (Cosopt, Santen, Japan), with central corneal thicknesses within average. Right eye anterior segment biomicroscopic examination showed a flat fibrosed filtration bleb and a subluxed intraocular lens (IOL) with cortical proliferation, with no signs of inflammation. Left eye anterior segment examination was unremarkable. Fundus examination showed normal-sized optic discs, with cup/disc ratio measured at 0.8 bilaterally, and an otherwise normal retina. In view of the recent deterioration in the right eye leading to a tubular visual field, a decision was made to implant a BGI in the right eye.

Baerveldt Tube Implantation and Chronic Hypotony

The subluxed IOL was replaced with an iris claw lens and a BGI was implanted into the AC, with a Prolene 4-0 suture within its lumen. A 350 mm^2 Baerveldt plate was placed under the superior and temporal rectus muscles. No antimetabolite was used. Postoperatively, IOP was 16 mm Hg at day 1 and rose to 28 mm Hg on day 5. Topical antiglaucoma medications were resumed with the addition of systemic acetazolamide (Diamox, Vifor, Switzerland). At 1 week postoperatively, the patient presented with a shallow AC with IOL-endothelial contact and a negative Seidel test. IOP was 5 mm Hg and an extensive 180 degrees choroidal detachment was observed. Antiglaucoma medications were stopped and sodium hyaluronate (Provisc) was injected into the AC to reduce overfiltration. IOP transiently rose to 6 mm Hg before decreasing to 4 mm Hg the following week with a 360-degree kissing choroidal detachment. Choroidal drainage was performed and topical scopolamine introduced, leading to a good initial improvement with a day 1 IOP of 10 mm Hg, which subsequently fell to 2 mm Hg and remained under 6 mm Hg for 6 weeks. A second sodium hyaluronate injection was performed, but IOP dropped to 2 mm Hg again (Fig. 2). After 3 months of refractory hypotony, a decision was made to attempt an eyeWatch-rescue to the Baerveldt tube.

eyeWatch Adjunction

Following adequate cleaning and preparation of the right eye, retrobulbar anesthesia was administered. The conjunctiva and Tenon's capsule were dissected at the superior fornix to expose the Baerveldt tube and the sclera. The tube was removed from the AC and its scleral canal was sutured. The eyeWatch was positioned on the sclera, 2 mm away from the limbus, and a superficial sclerectomy was performed following the outline of the device (Fig. 3A). Paracentesis was performed and an AC maintainer was set up. The eyeWatch was initially opened (position 0/6) (Fig. 3C). A scleral canal was created using a 25-G needle and the eyeWatch's nozzle was inserted into the AC at the level of Schlemm's canal, parallel to the iris. Positioning of the nozzle was confirmed by gonioscopy, and viable filtration was assessed by placing a surgical sponge at the distal end of the device (Fig. 3B). The eyeWatch was then closed (position 6/6) (Fig. 3E), and the eyeWatch was positioned within the sclerectomy bed and secured in place using 2 single Prolene 9-0 sutures. The proximal part of the Baerveldt tube was then sectioned at the appropriate length and connected to the eyeWatch's outlet (Fig. 3F), which was covered with a pericardium graft patch (Tutoplast, Innovative Ophthalmic

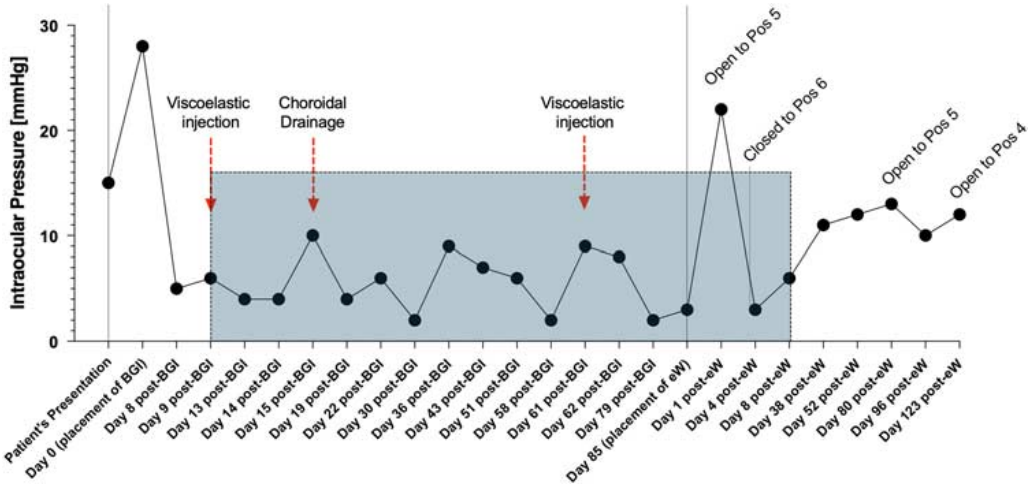

FIGURE 2. Variations of intraocular pressures throughout the patient's follow-up. After the first BGI intervention, the patient suffered from chronic refractory hypotony and related complications (tube-endothelium contact, shallowed chamber, vision loss, choroidal detachment) despite numerous medical and surgical attempts. Once the eyeWatch was used, IOP was reliably controlled postoperatively through fine adjustments of the eyeWatch opening position.

Products, Inc., Costa Mesa, CA) anchored with 10-0 Nylon sutures. The Tenon's capsule and conjunctiva were then closed over the drainage system using Vicryl 8-0 resorbable sutures (Fig. 1). Postoperatively, a regime of topical tobramycin and dexamethasone (TobraDex, Novartis Pharma, Switzerland) was initiated.

On day 1 after surgery, IOP was 22 mm Hg and some cells were noted within the AC. Topical antiglaucoma treatment was resumed temporarily and the eyeWatch was opened to 5/6 using the eyeWatch pen. At day 4, IOP was down to 3 mm Hg, antiglaucoma treatment was stopped, and the eyeWatch was closed to 6/6 again.

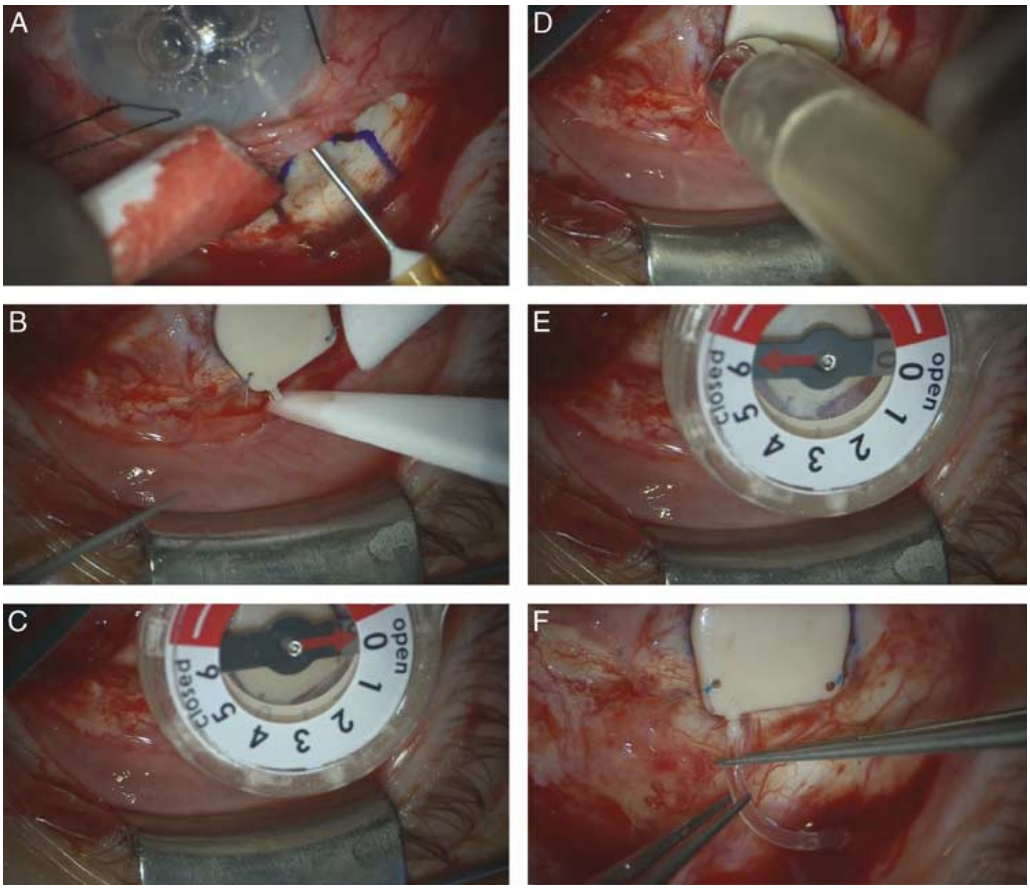

FIGURE 3. A–F, Surgical steps of the eyeWatch-adjunction technique. After carefully positioning the eyeWatch nozzle in the anterior chamber while lying sutured in a scleral bed (A), outflow through the eyeWatch is tested (B) while the device is fully opened (C). Using the magnetic tip of the eyeWatch Pen (D), the eyeWatch is then fully closed (E) and inserted into the proximal part of a silicon tube, in this case, a Baerveldt Tube (F). At a later point postoperatively, the eyeWatch will be slowly opened and finely adjusted until the desired IOP is attained.

Over the following days, AC inflammation subdued and IOP increased to 6 mm Hg at 1 week, 11 mm Hg at 4 weeks, 12 mm Hg at 6 weeks, and 13 mm Hg at 10 weeks. The eyeWatch was subsequently reopened to 5/6 and the unmedicated IOP remained stable between 8 and 12 mm Hg through the next 6 months.

At the last follow-up visit, 6 months after eyeWatch implantation, the patient was unmedicated and presented a BCVA of 0.5 with an IOP of 8 mm Hg in the right eye, on an eyeWatch position of 4/6. The AC of the patient was quiet in presence of mild stromal edema and fundus examination showed a stable cup/disc ratio at 0.8 with a nontractional epiretinal membrane on a flat retina in the right eye. B-mode ultrasound examination of his right eye confirmed complete resorption of the choroidal detachment.

CONCLUSIONS

The eyeWatch was designed to prevent postoperative hypotony and related complications after GDD surgery. This case describes its successful use as a means to manage refractory postoperative hypotony and choroidal detachment, as a secondary rescue procedure, after an initial GDD surgery.

Management of postoperative hypotony often represents a challenge following GDD surgery and can lead to choroidal effusion, choroidal hemorrhage, and hypotony maculopathy, all of which can potentially cause permanent visual loss.[13] Various techniques were developed to manage hypotony after GDD surgery in the form of medication, injections, ligatures, or surgical revision. A recent study reported that 17% of patients undergoing GDD experience hypotony, 29% of which resolve with intracameral viscoelastic injection, 61% needing up to 3 injections, and 11% needing an additional procedure such as a surgical tie.[14] Stein et al[13] reported that 65% of tube ligations were successful but they had to perform up to 3 revisions per eye. Recently, a case series (n = 12) of a novel ab-interno partial tube ligation reported 100% success using surgical ligatures, but with up to 8 revisions.[15] Some investigators have described performing scleral flap revision to resolve refractory hypotony (LIU) or removing the GDD entirely.[13,16] Although these techniques might effectively control postoperative hypotony, they do so often at the prize of multiple revisions and do not offer an adjustable patient-based solution, which consequently results in periods of volatile IOPs.[17–19] The adjustability of the eyeWatch device could potentially remediate these issues as adjustment of aqueous humor filtration could help to achieve optimal IOPs, with immediately visible and reversible results.

In the case presented, attempts were made to manage complicated hypotony after BGI in stand-alone surgery with traditional methods but these have failed or only provided transient results. The eyeWatch-combined technique achieved immediate resolution of the hypotony and sustainable optimal IOPs without medication. Of note, regular short-spaced visits are required initially to fine-tune the settings of the eyeWatch opening, tailored to the patient, and to potential subsequent fibrosis. In this case, moreover, the patient had transient postoperative IOP spikes presumably linked to AC inflammation, which necessitated short-term medication and eyeWatch adjustments. Interestingly, the eyeWatch may offer an answer not only to the immediate postoperative hypotonic phase of the GDD surgery but also to the later cystic bleb hypertonic phase.

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