

eyeWatch™ System Combined with Non-plated Intraorbital Tube Insertion for the Management of Refractory Glaucoma: A Case Series

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ABSTRACT

Introduction: The eyeWatch™ is a novel device in glaucoma surgery aiming at the control of aqueous flow through the use of an external magnetic control unit. We propose the modification of this approach through the use of an injectable perforated tube rather than a plated valve.

Materials and methods: Procedures were performed at the Department of Ophthalmology of the University of Crete. Three blind painful eyes of three patients were included. All patients were operated under topical anesthesia. A purpose designed blunt-ended injector was used to insert intraorbitally a perforated 4 cm-long silicone tube. The tube was then connected to an eyeWatch™ device which was placed in a standard fashion along the superior-temporal quadrant of the eyeball. The procedure was uneventful in cases I and II, whereas in case III the tube had to be trimmed by 1.5 cm because of cicatricial changes in the orbit. The eyeWatch™ was left closed (position VI) at the conclusion of surgeries. Patients were examined on the 1-day, 1-week, 2-week, 1-month, 3-month, and 6-month intervals and in one case on the 12-month interval.

Results: No major complications were observed. The intraocular pressure (IOP) remained under 15 mm Hg without anti-glaucomatous medications in all postoperative intervals in cases I and 2 with readjustment of eyeWatch™ at position IV. In case III, despite the change of the eyeWatch™ to the open position, the IOP remained high (40 mm Hg).

Discussion: The combination of the eyeWatch™ with an insertable perforated tube instead of a standard non-valved plate may prove a valid minimally invasive option. Modifications of the technique, such as an increased number and diameter of tube perforations, increased inserted tube length, perhaps aided by a sharp-ended injector, and selection of the insertion quadrant, may increase the effectiveness of the method.

Clinical significance: eyeWatch™ combined with a single tube instead of a plated valve is a feasible, quick, and minimally invasive technique that can be used in glaucoma surgery.

Keywords: Anti-glaucomatous implant, Anti-glaucomatous tube, Anti-glaucomatous valve, eyeWatch™, Glaucoma.

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INTRODUCTION

The eyeWatch™ system (Rheon Medical, Switzerland)¹ is a novel device designed to control the outflow of aqueous following aqueous shunt procedures. The device includes a rotating magnetic plate, which can compress or decompress a silicone tube thus enabling controlled increase or decrease resistance in aqueous outflow.¹ According to its original concept, the eyeWatch™ device is connected to a non-valved aqueous shunt plate (eyePlate) positioned intraorbitally as a standard seton system and the amount of tube compression can be adjusted both intraoperatively and postoperatively through a purpose-designed magnet.¹ Through the combined function of the eyeWatch™ and a non-valved plate, aqueous outflow can be adjusted so that the conditions, such as postoperative hypotony or hypertony, may be adequately addressed without the need for commonly required measures, such as anti-glaucomatous medications (for the management of hypertony) or, more importantly, ligating or tube-obstructing sutures for the management of hypotony.² However, such a surgical approach includes both the preparation and intraorbital implantation of the non-valved plate as well as the insertion of the eyeWatch™ device, thus increasing the complexity and duration of the procedure.

Taking into account that in such a system the element controlling aqueous outflow is the eyeWatch™ device, the whole

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procedure could be modified so that the element of non-valved plate (i.e., the direction of the aqueous in the intraorbital space) becomes quicker and easier to perform. Accordingly, we propose a modification of the procedure in which, instead of implanting a non-valved plate, a single perforated tube is inserted into the orbital space through a purpose-designed injector. In this case series, we present results from this approach in three cases as a quicker and less invasive option to the standard eyeWatch™ implantation surgery.

MATERIALS AND METHODS

This study was conducted at the University Hospital of Heraklion, Crete, Greece as part of a multicentric study on the effectiveness of the eyeWatch™ system. The study was in accordance with the Tenets of Helsinki Declaration and informed consent was obtained from all patients before enrollment to the study, following a detailed explanation on the nature, features, and risks of the protocol. Adult patients suffering from primary open angle glaucoma resulting in complete vision loss in the affected eyes (absolute glaucoma) were included. Moreover, all included patients had an elevated IOP of >20 mm Hg under maximally tolerated medications associated with pain in the study eye (blind painful eye) and had previous failed filtering surgery in the study eye. Exclusion criteria were multiple and included neovascular glaucoma, congenital glaucoma, traumatic glaucoma, history of previous intraocular surgery in the study eye referring to extraocular muscles (strabismus), corneal transplant, retinal surgery, aphakia, retinopathy, optic neuropathy other than glaucoma, retinal vein or artery occlusion in the study eye, corneal opacifications or irregularities that may interfere with the optic nerve evaluation or the IOP measurements in the study eye, a history of severe eye trauma in the study eye, microphthalmia in the study eye, concurrent inflammatory/infective eye disorder in the study eye, severe systemic disease or disabling conditions, such as chronic renal failure, post organ transplants as well as pregnancy, breastfeeding, or mental handicap. Overall, three eyes of three patients were included in this series.

A thorough clinical ophthalmic examination was completed in all cases and all examinations were repeated on the 1st postoperative day, the 1st and 2nd postoperative weeks, and the 1st, 3rd, 6th, and 12th postoperative months. On each postoperative interval, the position of the eyeWatch™ tube into the anterior chamber, the integrity of conjunctiva overlying the eyeWatch™ mechanism and covering pericardium, and any aqueous leakage from the incision sites were also examined. The position of the valve in the eyeWatch™ mechanism was checked both at the conclusion of surgeries and on all postoperative intervals. In case the IOP was above 20 mm Hg or under 5 mm Hg, opening or closing (respectively) of the mechanism was attempted as per the manufacturer's instructions. Moreover, one patient (patient no. 1) underwent a CT scan of the orbits (GE Healthcare, Waukesha, WI, USA) to confirm the position of the eyeWatch™ mechanism and intraorbital tube.

A standard eyeWatch™ system was used in all cases. However, instead of a plated non-valved implant, a silicone tube was connected to the eyeWatch™ implant. The tube, manufactured by Rheon Medical, is a 4 cm-long silicone tube, which features 24 lateral microholes of 40 µm of diameter allowing multiple drainage exit sites for aqueous humor. The tube is provided within its injector, which features a sliding mechanism allowing placement of the tube at the target position chosen by the surgeon (Fig. 1).

All surgeries were performed under topical anesthesia (Ropivacaine Hydrochloride, Naropeine, AstraZeneca, Cambridge, UK), administered by both subconjunctival and sub-Tenon's injections by the same surgeon (ETD). Following the placement of a corneal traction suture for adequate infraduction of the eyeball, a conjunctival peritomy was performed at the superior-temporal quadrant. Entrance into the anterior chamber was achieved with a 25G needle and a side port was also prepared with 19G blade. The eyeWatch™ mechanism was sutured on the sclera with 8.0 prolene sutures and its tube inserted into the anterior chamber

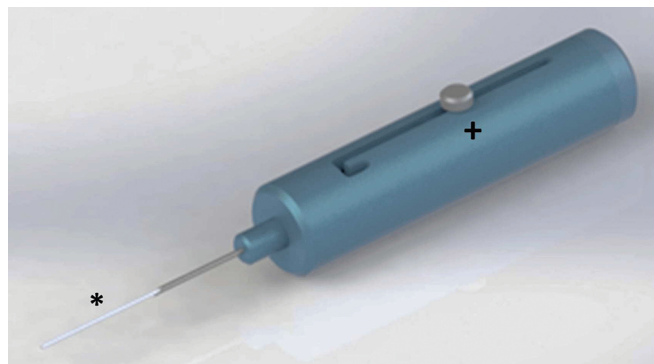


Fig. 1: eyeWatch™ blunt-ended silicone tube injector (Courtesy: Rheon Medical, Switzerland). The injector contains a knob (+) which can be pushed forward and turned sideways to insert and release the silicone tube (*)

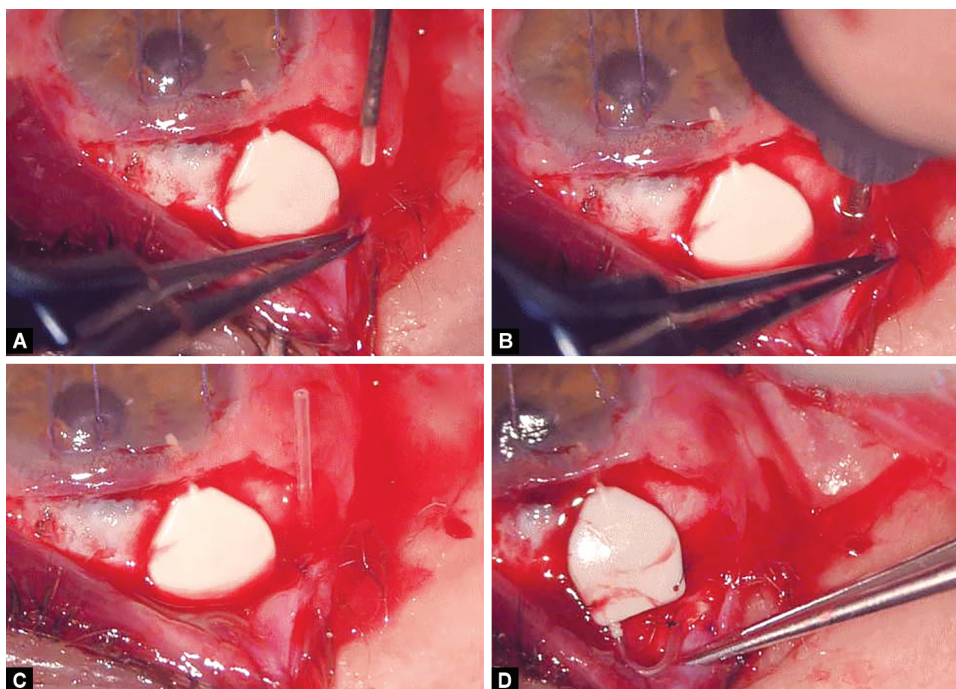
through the prefashioned 25G tract. The retro-orbital space at the ipsilateral (superior-temporal) quadrant was then prepared with blunt dissection at the sub-Tenon's space. The tube was then inserted into the prepared sub-Tenon's space of the superior-temporal quadrant using a purpose-designed blunt-ended injector (the product is still investigational), which allows for the release of the tube once the tip of the injector has reached the area of the orbital apex (4 cm). Once the tube was in place, it was released from its injector and the tip of the tube connected to the connector of the eyeWatch™ implant after securing it with transscleral 8.0 nylon suture (Fig. 1). The position of the magnetic disc in the eyeWatch™ mechanism was then examined and closed (position V or VI) using the specially designed external control unit. The area of the eyeWatch™ was then covered with a graft of bovine pericardium and the overlying conjunctiva sutured with interrupted 8.0 Vicryl sutures.

Postoperatively, patients were hospitalized for 2 days and then examined on regular intervals. They received a standard postoperative regimen of tobramycin-dexamethasone eye drops in a tapering fashion for 1 month. One patient completed a 12-month follow-up period, and two patients a 6-month follow-up period. On all postoperative intervals, the eyeWatch™ system was adjusted as required in an attempt to achieve acceptable IOP values.

RESULTS

Patient 1

A 75-year-old Caucasian woman with a history of high myopia (corrected in the past by uneventful clear lens extraction) and absolute open-angle glaucoma in both eyes. Preoperatively, the IOP was 45 mmHg in oculus dextrus (OD) and 42 mmHg in oculus sinister (OS) under maximal topical medications and she complained of bilateral painful eyes. The eyeWatch™-tube implantation procedure (OD) was uneventful and at the conclusion of surgery the magnet position was left closed (positions V–VI). On the 1st postoperative day, the operated eye presented with 2 mm of hyphema and a small amount of vitreous hemorrhage. The IOP was 12 mm Hg (operated eye) and 45 mm Hg (fellow eye). All anti-glaucomatous medications had been discontinued to the operated eye but continued to the fellow eye, which was also scheduled for a standard (non-eyeWatch™) anti-glaucomatous procedure. The position of the eyeWatch™ mechanism magnet position was left unchanged (closed, position V).



Figs 2A to D: Procedure of tube insertion at the superior–temporal quadrant following the placement of eyeWatch™: (A) Tip of the injector with silicone sleeve in place; (B) Insertion of tip into the prefashioned space in the superior–temporal quadrant; (C) Appearance of the silicone tube following its release from the tip; (D) Connection of the silicone tube to the eyeWatch™ mechanism

Further postoperative examinations on the 1st and 2nd weeks and until the 12th postoperative month revealed progressive resolution of hyphema and vitreous hemorrhage with IOP readings below 15 mm Hg without medications to the operated eye. A change of the eyeWatch™ mechanism magnet position to position IV was attempted on the third postoperative visit and it remained at that position thereafter. CT scanning of the orbits performed on the 3-month postoperative interval confirmed the position of eyeWatch™ and tube (Fig. 2).

Patient 2

A 70-year-old Caucasian woman with open-angle glaucoma OU. Preoperative IOP was 14 mm Hg (OD) and 36 mm Hg (OS), under maximal medications, with associated pain to the OS. The eyeWatch™-tube implantation procedure (OS) was uneventful at the conclusion of surgery the magnet position was left closed (positions V–VI). On the 1st postoperative day, the operated eye was quiet, the eyeWatch™ tube was in place and the anterior chamber deep. The IOP to the OS was 14 mm Hg (no medications) and the position of the eyeWatch™ mechanism magnet position was left unchanged (closed, position V). On the 1st postoperative week, the operated was quiet, the anterior chamber deep and the tube in place. The IOP to the OS was 18 mm Hg (no treatment). The eyeWatch™ mechanism magnet was opened (to position III) with subsequent immediate drop of the IOP to 16 mm Hg. On subsequent postoperative examinations until the 6th postoperative month, the operated eye remained quiet and the IOP under 15 mm Hg without medications. No further changes in the eyeWatch™ mechanism position were required (it remained to position III).

Patient 3

A 76-year-old Caucasian man with multiple anti-glaucomatous procedures to the OD for open-angle glaucoma (trabeculectomy,

revised trabeculectomy, Express™ valve insertion), resulting in total loss of vision to this eye (“No light perception”) with uncontrollable IOP (42 mm Hg) despite maximal topical medications as well as oral acetazolamide. The eyeWatch™-tube implantation procedure (OD) was associated with difficulty in inserting the full length of the tube to the retro-orbital space, possibly because of increased scarring and the fact that the tube tip was blunt. As a result, the tube had to be trimmed by about 1.5 cm, resulting in an actual inserted tube length of about 2.5 cm. At the conclusion of surgery, the magnet position was left closed (positions V–VI).

On the 1st postoperative day, the IOP was 7 mm Hg and a shallow anterior chamber was noted at the operated eye. Aqueous leak from the wound was absent and the tube was in place. The position of the magnet was left unchanged. On postoperative day 7, the IOP was 6 mm Hg, the anterior chamber remained formed but shallow and a choroidal detachment was noted. Topical atropine was added to the standard postoperative regimen. However, progressively the IOP rose to the operated eye despite opening the magnet position to maximal aperture (position 0) and the addition of topical anti-glaucomatous medications. At the 6th postoperative month, the anterior chamber was deep, the tube in place and the eye remained quiet, despite the fact that IOP had risen to 40 mm Hg under maximal topical medications and with the magnet position at maximal opening, implying retro-orbital scarring.

DISCUSSION

The eyeWatch™ has been described by Villamarin et al. and validated *in vitro* and *in vivo*.^{3,4} Within the mechanism, an eccentrically shaped magnetic disk can be rotated by an externally controlled magnet unit to adjust fluidic resistance. A customized adjustment of aqueous humor outflow can thus be achieved to minimize the risk of hypotony or inadequate lowering of IOP. eyeWatch™ is therefore a continuously adjustable glaucoma drainage device, which allows

the dynamic modification of aqueous outflow.^{1,3,4} According to its original concept, eyeWatch™ is connected to a non-valved aqueous drainage implant placed intraorbitally.¹ Thus, aqueous flow is mediated by this implant but the rate of drainage is controlled by the eyeWatch™ unit. However, this combined implantation of two aqueous drainage units (i.e., the non-valved implant posteriorly and the eyeWatch™ unit anteriorly) increases surgical time and creates a need for extensive tissue preparation to receive both implants.

The current approach represents a minimally invasive alternative to the standard surgical technique of eyeWatch™ system implantation, reducing surgical time and associated tissue trauma. Moreover, the tube design with multiple perforations along its length implies that aqueous may drain along all the orbital anterior-posterior length, increasing the possibility of reaching non-scarred areas. By selecting larger diameters of the perforations, aqueous outflow may be increased in selected cases. Difficulties in tube insertion encountered in the third patient of this series, may be attributed to scar tissue along the insertion path and may perhaps be overcome by the use of a sharp tip in the insertion catheter, rather than the blunt tip used in all three cases of this series. The proposed technique has also other potential advantages including the possibility of multiple tube insertions, which could be connected to a single eyeWatch™ implant and the individualized selection of an optimal drainage quadrant for each patient, depending on the efficacy of the local vascular elements. The latter point is supported by literature reports on sectorial differences in aqueous outflow depending on the presence of adequate vascularity to each area.^{5,6} Moreover, the tube material may be modified by the potential addition of slow-released antimetabolites in an effort to decrease scarring along its length.

Results from the first three cases imply that the proposed technique has potential efficacy, contradicting to some extent the need for a stereotypical larger scale surgical approach.

Complications observed, such as the hyphema and vitreous hemorrhage of the first patient, may not be related with the tube technique but with the clinical features of the case (high myopia, previous lens extraction, pseudophakia). The failure to control the IOP in the third case may be attributed to the extensive scar tissue in the retroorbital area encountered, which resulted in trimming part of the length of the tube inserted. The present report is certainly a mere feasibility study on the technique and large prospective studies would be required, along with adequate modifications of the proposed technique. The end point of this approach would be a less invasive but equally effective alternative to standard plated intraorbital implants.

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