The Use of Fixation Suture to Treat Inferonasal Hypertrophic Bleb after Xen Gel Stent Implant: A Case Report

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Abstract
We report a case of an inferonasal hypertrophic bleb complication which formed 5 months after Xen Gel Stent implantation for intraocular pressure (IOP) control in a primary open-angle glaucoma patient and its management using a fixation suture. The patient underwent an uneventful right-eye phacoemulsification and intraocular lens implantation combined with Xen Gel Stent ab interno implantation surgery. A month after the surgery, a second needling was performed due to a flat bleb and increased IOP. Post-needling slit-lamp examination showed a well-formed diffuse bleb in the superonasal quadrant. Two months after the needling, the patient presented with redness and irritation medially. Upon examination, a large inferonasal bleb was observed together with scarring of a previously formed superior bleb above the Xen Gel Stent implant. Fornix-based conjunctival incision technique was used to release the conjunctival scarring, and a fixation suture was used for the Xen implant in order to change the filtration direction. A Palmberg compression mattress suture was used to stop the inferior filtration. Despite an open conjunctiva surgical revision in the superior quadrant, no additional scaring was formed in the follow-up period of 20 months. There was good post-operative IOP control and formation of superiorly positioned bleb. To our knowledge, this is the first report to describe the use of a fixation suture for treating inferonasal hypertrophic bleb as a late complication of Xen Gel Stent implantation surgery.
Introduction

The past decade has witnessed a revolution in glaucoma surgery, fuelled largely by the rapid advancements in technologies for microinvasive glaucoma surgery (MIGS) [1]. MIGS has been shown to achieve the modest intraocular pressure (IOP), lowering the effect in glaucomatous eyes with shorter surgical time compared to trabeculectomy [2]. In addition, MIGS is intended to achieve a medication sparing effect and to avoid the post-operative complications associated with trabeculectomy [3]. As MIGS is a relatively new surgical procedure, there is scarcity of published data with regard to its complications, especially the management of long-term post-operative complications.

The Xen Gel Stent (Allergan, Dublin, Ireland), a bleb-forming minimally invasive glaucoma surgery device, reduces IOP by creating a subconjunctival drainage pathway [4]. Recently, García-Feijóo and colleagues have proposed the term "minimally penetrating glaucoma surgery" to describe the implantation of devices which employ the subconjunctival outflow pathway [5]. Xen is a delicate 6-mm device made of collagen, and as such, care should be taken when handling the implant [6]. In addition, the Xen implant has been previously described as a "modified trabeculectomy" and may share some of the potential risks of trabeculectomy [3]. Therefore, correct positioning of the Xen implant is critical to prevent post-operative complications.

To date, there is little evidence on the complications associated with Xen implants. The present report is a description of a case of late post-operative secondary bleb formation in the inferonasal quadrant with an increased risk of bleb infection. In addition, we describe the use of fixation suture as a preferred surgical management method for repositioning the implant and for managing the post-operative inferior bleb.

Case Report/Case Presentation

A 70-year-old Caucasian female patient with a history of bilateral open-angle glaucoma presented with glaucoma progression in both eyes. The patient reported a history of intolerance to many topical IOP-lowering medications. At the initial visit, the patient was on topical therapy with Cosopt eyedrops (fixed combination of dorzolamide hydrochloride 2% and timolol maleate 0.5%; Santen UK Ltd, Shenley, UK). Initial examination revealed a Snellen best-corrected visual acuity (BCVA) of 20/25 and 20/20 in the right and left eyes, respectively. IOPs measured with the iCare rebound tonometer were 23.0 mm Hg (IOP fluctuation range of 15–23 mm Hg over time) and 19.0 mm Hg (IOP fluctuation range of 14–18 mm Hg over time) for the right and left eyes, respectively. The pachymetry readings were 515 μm and 520 μm for the right and left eyes, respectively. Slit-lamp examination of the anterior segment revealed a corticonuclear cataract in the right eye and pseudophakia in the left eye. A 24-2 Humphrey visual field test showed a mean deviation of −2.108 dB in both eyes but more predominant in the right eye.

Given the patient’s good BCVA in the right eye (albeit slightly lower than the left BCVA), concerns regarding trabeculectomy, as well as her desire for fast visual recovery, an implant of the ab interno Xen collagen device combined with cataract surgery was proposed for her right eye. Phacoemulsification with implantation of +22.0D intraocular lens was performed with a clear corneal incision.
lens and Xen Gel Stent implantation using the ab interno approach were therefore performed. The procedure was done together with a subconjunctival injection of 0.1 mL of mitomycin c (MMC) 0.04% under sub-tenon anaesthesia with 3 mL of 0.5% bupivacaine. The procedure was uneventful.

The patient reported the next day for IOP and BCVA assessments, which were recorded as 9 mmhg and 20/20, respectively. At the 2 weeks post-operative visit, slit-lamp examination revealed the Xen implant positioned in the superonasal quadrant (2 o’clock position) with newly formed pigment deposits around the implant’s external orifice as well as a flat bleb. Presenting IOP was 23.0 mm Hg. Bleb needling was carried out under topical anaesthesia using the slit-lamp. This was followed by an injection of dexamethasone 0.1% in the subconjunctival area since there is evidence to show that direct injection of steroids into the bleb following bleb-forming filtration procedures can represent a sustained mode of steroid delivery to modulate wound healing [7]. Post-needling IOP was 14.0 mm Hg, and the patient was advised to continue with hourly use of Maxitrol drops (1 mg dexamethasone, 6000 iu polymyxin b sulphate, 3500 iu neomycin sulphate per mL suspension; Novartis Pharmaceuticals UK Ltd, Shenley, UK). Two weeks after the first needling, the formed bleb was undesirable. IOP was 30 mm Hg, and the Xen implant was immobile. A second needling with dexamethasone injection in the subconjunctival area decreased the IOP to 13.0 mm Hg. Post-needling slit-lamp examination showed a well-formed diffuse bleb in the superonasal quadrant.

Two months after the second needling, IOP was well controlled. The patient however complained of discomfort, redness, and irritation in the nasal half of the right conjunctiva. Slit-lamp examination revealed a large hypertrophic inferonasal bleb as well as scarring of a previously formed superior bleb above the Xen Gel Stent implant (Fig. 1). A week treatment with thrice daily dosing of Maxitrol drops resolved the conjunctival inflammation. Since there was a potential risk of conjunctival erosion and infection remained, surgical revision of the bleb was considered as the better option to yield a more permanent outcome.

Under local anaesthesia, fluid was aspirated from the inferior bleb with a 30-gauge needle (Fig. 2a). The conjunctiva and Tenon’s layer were widely dissected above the Xen implant in the superior quadrant. The conjunctiva and Tenon’s layer were then separated to facilitate a two-layer closure. The implant was found to be functional after it had been released from the surrounding fibrosis (Fig. 2b). A Palmberg compression mattress suture was placed in the nasal quadrant to treat an inferior overfiltering bleb. As the Xen implant was undesirably angled towards the inferior quadrant, a nylon 10-0 fixation suture was used to redirect the drainage of aqueous humour more superiorly (Fig. 2c). To avoid any unnecessary manipulation that could damage the implant, the suture was first placed at the desired position on the sclera before it was gently wrapped around the implant. The Tenon’s layer was placed over the implant and sutured. The conjunctiva was partially dissected and released beneath the superior fornix to allow for the possibility of closure.

Fig. 1. Exposed inferior nasal bleb (white arrow).
No complications were noted post-operatively following the surgical revision. Three weeks after the surgery, a superior bleb was formed, and the IOP was well controlled. A month later, the right eye had full visual recovery (BCVA was 20/20 and the IOP was 13.0 mm Hg) and a superior diffuse bleb under the upper lid. Twenty months after the Xen revision surgery, the bleb was still functional, diffuse, and posteriorly directed (Fig. 2d). Further, the IOP was well controlled (13.0 mm Hg) without the need for any additional glaucoma drops. Structural and functional tests showed no further progression of glaucoma.

**Discussion/Conclusion**

There is a paucity of studies addressing the safety profile of Xen Gel Stent implant. Previously reported adverse events associated with Xen implants include transient minimal hyphema, improper implant position, IOP spikes, choroidal effusion, flat anterior chamber, chemosis, post-operative encapsulation of the bleb, vitreous haemorrhage, dellen, malignant glaucoma, 280° subconjunctival haemorrhage, and Xen extrusion during repositioning [2, 8, 9]. In the present report, we describe a post-operative complication of dysaesthesia from a large hypertrophic inferonasal bleb, which occurred after 5 months of Xen implantation and management with bleb revision surgery combined with scleral fixation suture. No post-operative complications had developed, and IOP was well controlled at the 20-month post-operative visit.

A scleral fixation suture is an optional step when performing tube surgery [10]. For MIGS devices which allow for subconjunctival drainage of aqueous humour, a fixation suture is not required. That notwithstanding, a nylon 10-0 suture has been previously employed with ab externo Xen implantation to reduce post-operative rate of erosion after subconjunctival Xen

**Fig. 2.** Intraoperative and post-operative images of a fixation suture for managing inferonasal hypertrophic bleb. **a** Aspiration of bleb during surgical revision. **b** Released conjunctiva and Tenon in the superonasal quadrant above the Xen Gel Stent implant with wrong angulation. **c** Xen Gel Stent fixation suture with Nylon 10-0. **d** Functional, superiorly positioned bleb 20 months after Xen revision surgery.
placement [11]. Also, Yavuzer and Meşen employed the “drainage channel with sutures” to treat a hypertrophic bleb complication which developed after the third month of Xen gel implantation [12]. This is the first report, to our knowledge, to treat an inferonasal hypertrophic bleb complication with fixation suture. At 20-month follow-up, IOP was well controlled, and no complication had occurred. IOP data reported in this study were obtained with the iCare rebound tonometer. We employ both the Goldmann Applanation (GAT) and rebound tonometers in our routine practice because studies have shown that the accuracy of the rebound tonometer in human eyes agrees with the GAT [13]. Indeed, previous studies have revealed that the iCare tonometer shows a relative positive bias ranging from 0.50 mm Hg to 1.50 mm Hg over GAT in normal eyes and a similar bias in ocular hypertensive and glaucomatous eyes [13, 14]. Thus, the iCare tonometer could be considered as a reliable and well-tolerated alternative to GAT for patients in a low to moderate IOP range [13, 15].

In conclusion, the positive outcomes observed in this case suggest that fixation suture is a plausible technique for treating an undesired filtration route associated with a hypertrophic bleb complication. However, larger studies with extended follow-ups are warranted to enhance our understanding of the safety and effectiveness profiles of fixation suture for hypertrophic bleb complications.

Statement of Ethics

Written informed consent was obtained from the patient for publication of this case report and any accompanying images. This study was reviewed and approved by the Research Ethics Committee of the Waterford Institute of Technology, Ireland (WIT2021REC039).

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

Writing (original draft): Jasna Pavičić-Astaloš; writing (review and editing): Jasna Pavičić-Astaloš, Emmanuel Ankamah, John M. Nolan, Eugene Ng, and Julian García-Feijoó; data collection: Emmanuel Ankamah; supervision: Jasna Pavičić-Astaloš. Jasna Pavičić-Astaloš, Emmanuel Ankamah, John M. Nolan, Eugene Ng, and Julian García-Feijoó read and approved the final manuscript.

Data Availability Statement

All data generated or analysed during this study are included in this article. Further enquiries can be directed to the corresponding author.
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