

# A Case of Refractory Open-angle Glaucoma with Failed Baerveldt Glaucoma Implant and Trabeculectomy Treated with Ab Externo XEN Gel Stent Placement

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## ABSTRACT

**Aim:** We report a case of successful intraocular pressure (IOP) management in a patient with refractory primary open-angle glaucoma (POAG) following implantation of XEN gel implant in the same hemisphere as prior failed filtering surgeries [i.e., Baerveldt glaucoma implant (BGI) and trabeculectomy bleb].

**Background:** Glaucoma is a major cause of blindness worldwide and is typically associated with elevated IOP and retinal ganglion cell loss. Treatment centers around decreasing IOP with eye drops and surgical interventions. The advent of minimally invasive glaucoma surgeries (MIGS) has expanded therapeutic options for patients who have failed traditional treatments. The XEN gel implant creates a shunt between the anterior chamber and the subconjunctival or sub-tenon's space, allowing for drainage of aqueous humor without significant tissue disruption. Given that the XEN gel implant also results in bleb formation, it is generally recommended to avoid placement in the same quadrant of prior filtering surgeries.

**Case description:** A 77-year-old man with a 15-year history of severe POAG of OU presents with persistently elevated IOP despite multiple filtering surgeries and maximal eye drop regimen. The patient had a superotemporal BGI in OU and a scarred trabeculectomy bleb superiorly in the right eye (OD). He underwent an open conjunctiva ab externo XEN gel implant placement in the OD in the same hemisphere as previous filtering surgeries. At 12 months postoperatively, the IOP range continues to be maintained within goal without complications.

**Conclusion:** The XEN gel implant can be successfully placed in the same hemisphere as prior filtering surgeries and can achieve goal IOP without any surgical complications at 12 months postoperatively.

**Clinical significance:** A XEN gel implant can effectively lower patients' IOP and can be a unique surgical option in refractory cases of POAG with multiple failed filtering surgeries, even when inserted in close proximity to prior filtering surgeries.

**Keywords:** Gel stent, Glaucoma, Surgery, Tube shunt, XEN.

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## BACKGROUND

Glaucoma, a prevalent disease of the eyes predicted to affect 111.8 million people by 2040, is the primary cause of irreversible blindness worldwide.<sup>1</sup> Treatments for glaucoma revolve around reducing IOP. They include various medications, laser treatments, and surgical interventions, with trabeculectomy being the most commonly performed surgery despite having major side effects of hypotony and infection.<sup>2,3</sup> In recent years, less invasive surgical devices have been developed to allow for the practice of MIGS. The XEN gel implant, an example of such a device, is a gelatin-based tube cross-linked with glycerinaldehyde. It creates a shunt between the anterior chamber and the subconjunctival or sub-tenon's space, allowing for drainage of aqueous humor and consequent reduction of IOP. Like trabeculectomy, XEN is a bleb-forming procedure and relies on the presence of healthy conjunctiva and Tenons. However, with an internal diameter of 40 microns, the XEN gel implant takes advantage of Poiseuille's law to provide a pressure floor of 6–7 mm Hg to minimize the risk of postoperative hypotony. This case report describes a case of refractory open-angle glaucoma with failed trabeculectomy and BGI that was successfully treated with a XEN gel implant placed in the superonasal quadrant.

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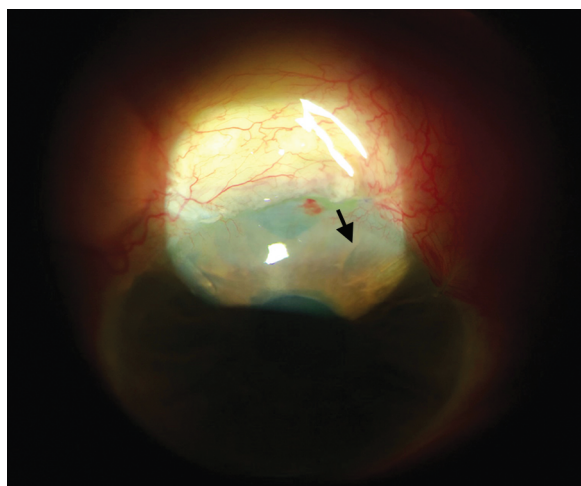
## CASE DESCRIPTION

A 77-year-old man with POAG of both eyes (OU), severe stage, presented to our glaucoma clinic to transfer care after his glaucoma specialist, who had been seeing him for 15 years, retired. His past ocular history was remarkable for failed trabeculectomy in the OD, BGI OU, cataract surgery OU, and central retinal vein occlusion of the OD. Notable medical history included diabetes, hyperlipidemia,

and hypertension. His IOP at the previous glaucoma specialist was 26 OD and 14 OS a month prior to presentation to our clinic. Latanoprost 0.005% (Xalatan; Pfizer Inc., New York, NY) one drop in OD, one time nightly, and brimonidine tartrate 0.2% (Alphagan; Bausch & Lomb Inc., Rochester, NY) one drop in OD, three times daily was added at that visit.

On initial exam, IOP was 16 in OU, which did not meet the IOP goal of <13. The best corrected visual acuity with a pinhole was count fingers OD and 20/40 OS. Other notable findings on the exam included superotemporal BGI's OU, scarred trabeculectomy bleb superiorly OD, peripheral iridectomy OD, and cup to disc (C/D) ratio of >0.95 OD and 0.85 OS. Subsequently, netarsudil 0.02% (Rhopressa; Aerie Pharmaceuticals Inc., Irvine, CA) 1 drop in OD, one time nightly, was added. Despite good medication compliance, the patient's IOP continued to remain in the 15–19 range, above the low-teens goal for the OD. In addition, his Humphrey Visual Field (HVF) 24–2 at Stim V showed a progression in his inferior arcuate defect compared to 6 months prior. Of note, the patient's central vision was counting fingers from prior ischemic CRVO, but he was able to perform HVF with a stimulus size V. Initially, an inferonasal BGI was recommended; however, the patient was concerned about the cosmesis and potential discomfort of an inferonasal shunt given his baseline lower eyelid retraction. Fortunately, there was still at least 4 mm of healthy conjunctiva nasal to his superior scarred trabeculectomy. As such, we recommended the patient undergo an open conjunctiva ab externo XEN gel stent placement with mitomycin C (MMC) in the OD. The XEN gel stent (Allergan Inc., Irvine, CA) was placed in the 2 o'clock position adjacent to the nasal border of the scarred trabeculectomy (Fig. 1).

Intraoperatively, the patient was prepped and draped in the usual sterile fashion. After topical anesthesia, a lid speculum was placed, and a 6–0 Vicryl traction suture was placed at the superotemporal cornea to expose the superotemporal quadrant. Paracentesis was made with MVR blade. Mini Westcott scissors and 0.12 forceps were used to create a 3 mm peritomy. Sub-tenon's anesthesia was given. A non-toothed forceps was used to grab both the Tenons and conjunctiva to expose the sub-tenon's space



**Fig. 1:** Slit lamp image of patient's OD status post XEN gel stent implantation. From left to right: BGI with tube in anterior chamber visualized superotemporally at 11 o'clock position. Scarred bleb from trabeculectomy with surgical iridectomy visible at 12 o'clock position. XEN gel stent with bleb visualized superonasally at 2 o'clock position (as indicated by the black arrow)

which was blunt dissected with Westcott scissors. An amount of 0.4 mg/mL of MMC soaked sponges were used on the scleral bed for 120 seconds and subsequently removed and irrigated with BSS for 10 seconds. XEN implant was removed from its packaging and primed. The needle was directed parallel to the iris plane and entered the eye about 2.5 mm behind the limbus in a straight path at the 1 o'clock location. The needle was found to be above the iris plane and away from the cornea. The injector was slowly removed from the eye, leaving the implant in place with 3 mm in the anterior chamber and about 2 mm above the sclera. Two wing sutures were used with 10–0 Vicryl sutures to close the conjunctiva and tenons on either side of the peritomy, and the limbal edge remained Seidel negative. Attention was directed to ensure no tenons were bundled around the XEN implant as the tenons were brought forward at the final closure. All incisions were checked to be watertight and Seidel negative. Subconjunctival injections of cefazolin and methylprednisolone sodium succinate were given inferiorly at the conclusion of the case.

Given the patient's history of failed trabeculectomy, a prophylactic subconjunctival 5-fluorouracil (5-FU) injection was given on postoperative week 2. His IOP remained between 7 and 10 mm Hg for the first 4 weeks after the surgery, with no glaucoma medications. He was kept on prednisolone acetate 1.0% (Pred Forte; Allergan USA Inc., Madison, NJ) 1 drop in the OD, every 2 hours while awake for 3 weeks before being transitioned to four times a day for another month and slowly tapered based on the bleb appearance.

Despite a low diffuse bleb superonasally, his IOP rose to 18 without glaucoma medication at postoperative week 6, and a repeat subconjunctival 5-FU injection was administered on postoperative week 6. From week 8 to week 12, his IOP remained in the 15–18 mm Hg range without glaucoma medication, and at postoperative month 4, we began to add back netarsudil/latanoprost 0.02/0.005% (Rocklatan, Aerie Pharmaceuticals Inc., Athlone, Ireland) 1 drop in OD, one time nightly, followed by dorzolamide hydrochloride–timolol maleate 22.3 mg/6.8 mg per mL (Merck & Co. Inc., Whitehouse Station, NJ) 1 drop in OD, two times daily. Between postoperative month 6 to month 12 after the XEN gel implant, the patient maintained his IOP at 10–12 mm Hg without adverse effects from the medications or surgery.

## DISCUSSION

The XEN gel stent is a device that allows for minimally invasive treatment of glaucoma by creating a shunt between the anterior chamber and the subconjunctival space, through which aqueous humor is drained, resulting in the reduction of IOP. Its valveless design regulates the flow of aqueous humor by virtue of the stent's dimensions *via* Poiseuille's law, thereby reducing the risk of hypotony. Indications include POAG, cases of refractory glaucoma, including those unresponsive to previous surgical interventions, and open-angle pseudoxfoliative or pigmentary glaucoma unresponsive to maximal medical treatment. Most importantly, implantation of the XEN gel stent does not preclude the patient from undergoing other filtering surgeries in the future.<sup>4</sup>

The stent can be inserted *via* an ab interno or ab externo method and is meant to remain in the eye permanently. Although no clinical study has officially compared the effectiveness of the two methods, the ab externo method is believed to result in better bleb morphologies which consequently yield lower IOPs.<sup>5</sup>

At the time of writing, the XEN gel stents' long-term effects have yet to be studied; however, based on current data, the efficacy and safety profile of this device appear promising.<sup>6</sup> A study performed on patients with refractory glaucoma, defined as previously failed filtering or cycloablative procedure and/or uncontrolled IOP on maximal medical therapy, found that at 12 months after implantation, the XEN gel stent improved IOP and reduced the number of medications the patients needed to be on without causing any safety issues.<sup>7</sup> Another nonrandomized, prospective study on 33 eyes with open-angle glaucoma undergoing XEN gel stent implant alongside cataract surgery found a 41.8% decrease in mean IOP in treated eyes, in addition to a complete success rate (defined as postoperative IOP of  $\geq 6$  and  $\leq 17$  mm Hg without glaucoma medications) of 80.4%, and a qualified success rate (defined as postoperative IOP  $\geq 6$  and  $\leq 17$  mm Hg, with glaucoma medications) of 97.5%.<sup>8</sup> Very few complications caused by this device are reported in the literature. A prospective, interventional study by Galal et al., performed XEN gel stent placement with MMC on 13 eyes with POAG. The authors reported choroidal detachment in two eyes, implant extrusion in one eye, and the need for trabeculectomy in two eyes.<sup>9</sup> In a case of a failed XEN in a patient with refractory glaucoma, a novel technique has also been described in which a BGI was attached to the failed XEN, which worked together to successfully lower the patient's IOP. This procedure is a potential option for failed XEN implants due to subconjunctival fibrosis or obstruction.<sup>10</sup>

The XEN gel stent is not recommended to be placed in a target quadrant of an eye where prior filtering surgeries have been performed.<sup>11</sup> However, in our case, the XEN gel stent was placed next to a failed trabeculectomy in the superonasal quadrant. To our knowledge, only one case report exists in the literature describing a similar scenario,<sup>4</sup> with the exception that the tube shunt used in the case report is an Ahmed Glaucoma Implant (AGI) inserted inferonasally and not a BGI. The BGI is known to have a slightly lower long-term failure rate than the AGI.<sup>12</sup> The fact that our patient's eye had previously failed a superotemporal BGI and a trabeculectomy highly suggests that this patient is prone to aggressive fibrosis and encapsulation. Despite this propensity to scar, our patient is now on one fewer glaucoma medication, and his IOP is at target 1 year after the XEN gel implant. Future studies are needed to assess the long-term safety and efficacy of XEN gel implant placement, especially in refractory eyes that had failed multiple filtering surgeries. The seminal finding, in this case, is that in refractory cases of POAG with multiple failed filtering surgeries, a XEN gel stent can effectively lower patients' IOP, even when it is inserted in close proximity to previous filtering surgeries.

## CONCLUSION

This manuscript presents a case of refractory POAG, with previously failed BGI and trabeculectomy, where a XEN gel stent was successfully implanted ab externo in the same quadrant. The XEN gel stent was eventually able to reduce the patient's IOP within goal without any surgical complications. Further research regarding the safety and efficacy of this surgical technique is still required.

## CLINICAL SIGNIFICANCE

This case demonstrates that a XEN gel stent can be successfully placed next to other filter surgeries without any complications—offering a unique surgical solution to refractory glaucoma patients.

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## Manufacturer Name

XEN gel stent (Allergan Inc., Irvine, CA).

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