

Ab Interno XEN Gel Stent Implantation in Eyes with Previous Tube Shunt Surgery

Lily Kai Man Xu¹, Toby Yiu Bong Chan^{2,3}

¹Faculty of Medicine, McMaster University, Hamilton, Ontario, Canada; ²Division of Ophthalmology, Department of Surgery, McMaster University, Waterloo Regional Campus, Kitchener-Waterloo, Ontario, Canada; ³Ocular Health Centre, Kitchener, Ontario, Canada

Correspondence: Toby Yiu Bong Chan, McMaster University, Waterloo Regional Campus, Kitchener-Waterloo, Ontario, Canada, Tel +1 519 208 8104, Fax +1 519 208 8101, Email toby.yb.chan@gmail.com

Purpose: After tube shunt surgery, many factors may contribute to insufficient filtration over time, prompting further intervention to achieve optimal intraocular pressure (IOP) control. This study explores whether ab interno XEN gel stent implantation could be a viable approach in eyes that need further IOP reduction after tube shunt surgery.

Methods: This is a retrospective, single-surgeon case series on ab interno XEN45 gel stent implantation in eyes that had previous tube shunt surgery. Main outcome measures were IOP and number of glaucoma medications at the pre-operative visit, post-operative week (POW) 1, and post-operative month (POM) 1, 3, 6, and 12. Adverse events and further interventions were noted. Surgery outcome was qualified as absolute success (IOP \leq 18mmHg or \geq 20% IOP reduction without glaucoma medications), qualified success (IOP \leq 18mmHg or \geq 20% IOP reduction with glaucoma medications), or failure (IOP $>$ 18mmHg and $<$ 20% IOP reduction with maximum tolerated glaucoma medications).

Results: 7 eyes from 6 patients were included in this study. IOP was reduced from 23.9 ± 5.3 mmHg (mean \pm standard deviation) pre-operatively to 14.0 ± 5.3 mmHg at POM12 ($p < 0.05$). Number of glaucoma medications was reduced from 4.3 ± 1.3 pre-operatively to 1.6 ± 1.6 at POM12 ($p < 0.05$). Hypotony and choroidal effusion were noted in one case which resolved before POM1. Bleb needling was required in 3 of the 7 eyes (43%), with one eye requiring needling twice. By POM12, 2 of 7 eyes (29%) achieved absolute success, 4 eyes (57%) qualified success, and 1 eye (14%) was qualified as failure.

Conclusion: Ab interno XEN gel stent can effectively reduce IOP and number of glaucoma medications after failed tube shunt surgery. Nonetheless, further interventions such as bleb needling may still be required to optimize IOP control.

Keywords: glaucoma, MIGS, tube shunt, Ahmed glaucoma valve, Baerveldt glaucoma device, ab interno XEN implant

Introduction

As one of the leading causes of blindness, glaucoma most commonly results from impaired drainage of aqueous fluid from the anterior chamber, leading to intraocular pressure (IOP) elevation and subsequent optic nerve damage and vision loss. Therefore, mainstay of glaucoma therapy involves lowering IOP to halt the disease progression using medications, laser, or surgery, with many patients needing a combination of treatment modalities to reach target pressures.¹

The implantation of a glaucoma drainage device (GDD), also known as a tube shunt, is generally a treatment option for those eyes considered to have higher risk of surgical failure following standard trabeculectomy alone. This includes eyes with pre-existing tendency to have ocular inflammation that may promote fibroblast proliferation and episcleral scarring, such as neovascular glaucoma and uveitic glaucoma. However, subconjunctival fibrosis over time may still result in underfiltration of tube shunts, resulting in suboptimal IOP control which requires further intervention.²

The XEN45 Gel Stent (Allergan, Dublin, Ireland, an AbbVie Company) is a bleb-forming device for the surgical management of glaucoma refractory to maximum tolerated medical therapy.³ It is one of the many novel options in micro-invasive glaucoma surgery (MIGS) that allows minimal trauma, rapid recovery and reduced complications compared to traditional glaucoma surgeries.⁴

Although there have been studies investigating XEN stent after previous filtration surgeries, there is limited literature on the performance of ab-interno XEN implants as a second procedure following tube shunt surgery specifically.^{5–8} Compared to tube shunts, which are often made of silicone with a large plate portion that is secured primarily to the superotemporal aspect of the globe, the gelatin XEN stent is much more flexible to implant and is often placed superiorly, superonasally or superotemporally, with less disruption to conjunctiva and Tenon's capsule, especially if the procedure is performed with the ab-interno technique.¹ These characteristics suggest ab-interno XEN can be a potentially safe surgical option after previous primary tube shunt which leaves the superonasal quadrant of conjunctiva untouched. Considering that tube shunt surgery is one of the most commonly performed filtering procedures and that further intervention can still be required if the shunt offers insufficient IOP control,⁹ our study aims to explore the efficacy of ab-interno XEN gel stent as a secondary procedure to previous tube shunt surgery.

Methods

Design

This study adhered to the tenets of the Declaration of Helsinki and Good Clinical Practice guidelines, and received ethics approval (Advarra). Patients signed a waiver for release for videos and photographs taken. An informed consent form was not necessary as this is a retrospective chart review with all patient data locked in a secure EMR and no identifiable personal data recorded in the data collection spreadsheet. A retrospective chart review was conducted of 7 eyes in 6 patients that underwent ab interno XEN implantation after previous tube shunt surgery, all from the Ocular Health Centre, Kitchener, Ontario, Canada. Procedures were performed by a glaucoma subspecialist (T.C.). Visits included in the study were the pre-operative assessment, post-operative week (POW) 1, and post-operative month (POM) 1, 3, 6, and 12. Data collected for each visit include IOP (measured by Goldmann Applanation Tonometry), number of glaucoma medications, complications, and any further procedural interventions required (e.g. bleb needling).

Patients

Various types of glaucoma were included in our study: pseudoexfoliative glaucoma (2 eyes), uveitic open angle glaucoma (2 eyes), mixed mechanism glaucoma (1 eye), primary open angle glaucoma (1 eye), and juvenile open angle glaucoma (1 eye). Six of seven eyes were pseudophakic. Only adult patients aged 18 years or older, who had suboptimal IOP control after previous tube shunt surgery, despite maximum tolerated medical therapy, were included. Suboptimal IOP was considered as IOP above target based on Canadian Ophthalmology Society glaucoma practice guidelines,¹⁰ or if structural and/or functional progression was evident on optical coherence tomography and Humphrey Visual Field, respectively. Five eyes had received an Ahmed valve and two eyes received a Baerveldt glaucoma drainage device. Prior to XEN implantation and after tube shunt surgery, 3 eyes had selective laser trabeculoplasty (SLT) and 2 eyes had micropulse cyclophotocoagulation (MP-CPC). None had previous trabeculectomy. Tube shunt surgeries were performed at least 3 months prior to XEN implantation. As the tube shunts were implanted in the superotemporal quadrant, the superonasal quadrant was untouched prior to XEN implantation.

Surgical Technique

A 7–0 vicryl traction suture is placed at the superior corneal margin to mobilize the globe. Calipers are used to mark the conjunctiva at 2mm posterior to limbus at the superonasal aspect of the globe. A 0.1cc mixture of 0.02% mitomycin C (MMC) and 1% xylocaine in a 2:1 ratio is injected using a 30-gauge needle into the subconjunctival supra-Tenon's space in the superonasal quadrant of the globe, directed away from the plate portion of the tube shunt and any fibrotic bands beside the plate superiorly (Figure 1A). A temporal corneal paracentesis incision is made with a stab blade. The anterior chamber is filled with a cohesive viscoelastic, after xylocaine 1% and acetylcholine are injected into the anterior chamber for local anesthesia and miosis, respectively. The XEN45 injector needle is inserted through the corneal incision, across the anterior chamber, impaling through the angle into the subconjunctival supra-Tenon's space in the superonasal quadrant, to deploy the XEN45 gel stent (Figure 1B). Approximately 1mm of the stent should be visible in the anterior chamber angle with a gonio lens, while aiming at least 3mm of the stent to be in the subconjunctival supra-Tenon's space

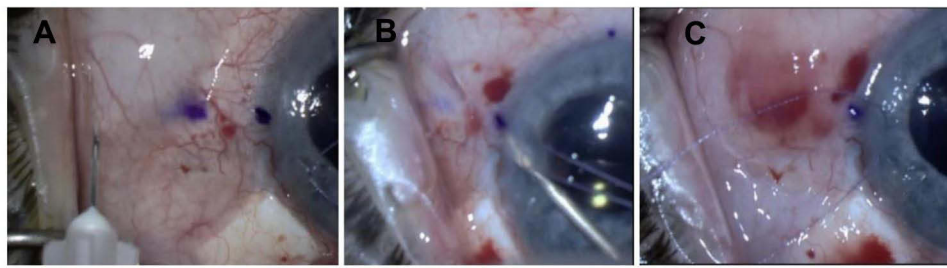


Figure 1 (A) Mixture of mitomycin C and xylocaine 1% is injected into subconjunctival space, directed away from tube shunt. (B) XEN45 gel stent is implanted into subconjunctival space using the injector needle. (C) Bleb forms after flushing viscoelastic out of the anterior chamber using balanced saline solution.

so aqueous flow can be directed posteriorly. Viscoelastic is then flushed out of the anterior chamber using balanced saline solution (BSS), thereby priming flow through the XEN stent to form a bleb (Figure 1C). The traction suture is then removed and the corneal incision is hydrated with BSS to ensure watertight closure.

Postoperative Management

Antibiotic (Moxifloxacin, QID for 1 week) and steroid (Prednisolone 1% q2H when awake for 1 week, then taper weekly to stop) topical drops were applied to the eye after each procedure. IOP-lowering medications were added based on the indication if IOP target was not met during visits (e.g. aqueous suppressant for hyper-encapsulation).

Bleb Needling Technique

Bleb needling with subconjunctival MMC was performed on under-filtrating blebs at the slit lamp as needed during follow-up. Topical tetracaine and topical iodine were applied, then a lid speculum was placed. At the slit lamp, 0.1cc of 0.02% MMC was injected into subconjunctival space just superior to the XEN, with Q-tip rolling the MMC away from limbus (Video 1). Topical xylocaine jelly was applied. Then 10–15 min later topical tetracaine and topical iodine were applied again with lid speculum placed. At the slit lamp, a 30-gauge needle was inserted into conjunctiva at superior aspect of globe, pointed away from shunt plate but toward XEN (Video 2). The needle tip lysed fibrotic tissue between conjunctiva and XEN, then between XEN and sclera in a sweeping motion. If no increase in bleb was seen immediately, then the needle was turned sideways in the space between conjunctiva and XEN, and the side of the needle was used to slice and truncate the tip of the XEN over sclera to restore flow into bleb.

Statistical Analysis

Analysis was performed with Microsoft Excel Professional Plus 2013 Software (Microsoft Corp., Edmond, WA, USA). The mean and standard deviation were plotted for the changes in IOP and number of glaucoma medications for each visit. A one-tailed paired *t*-test was conducted to compare data in post-operative visits with pre-operative baseline. Categorization into absolute success (IOP \leq 18mmHg or \geq 20% IOP reduction without glaucoma medications), qualified success (IOP \leq 18mmHg or \geq 20% IOP reduction with glaucoma medications), and failure (additional glaucoma surgery, or IOP >18mmHg or <20% IOP reduction with maximum tolerated glaucoma medications) was also performed for each post-operative visit.

Results

Intraocular Pressures (Figure 2)

Mean IOP was 23.9 ± 5.3 mmHg preoperatively, 10.0 ± 3.9 mmHg at POW 1 ($p < 0.001$ compared to pre-operative baseline), 15.9 ± 4.6 mmHg at POM1 ($p < 0.001$), 18.2 ± 5.7 mmHg at POM3 ($p < 0.05$), 17.0 ± 5.4 mmHg at POM6 ($p < 0.05$), and 14.0 ± 5.3 mmHg at POM12 ($p < 0.05$). From pre-operative baseline to POM12, there was a 9.9mmHg or 41% decrease in mean IOP.

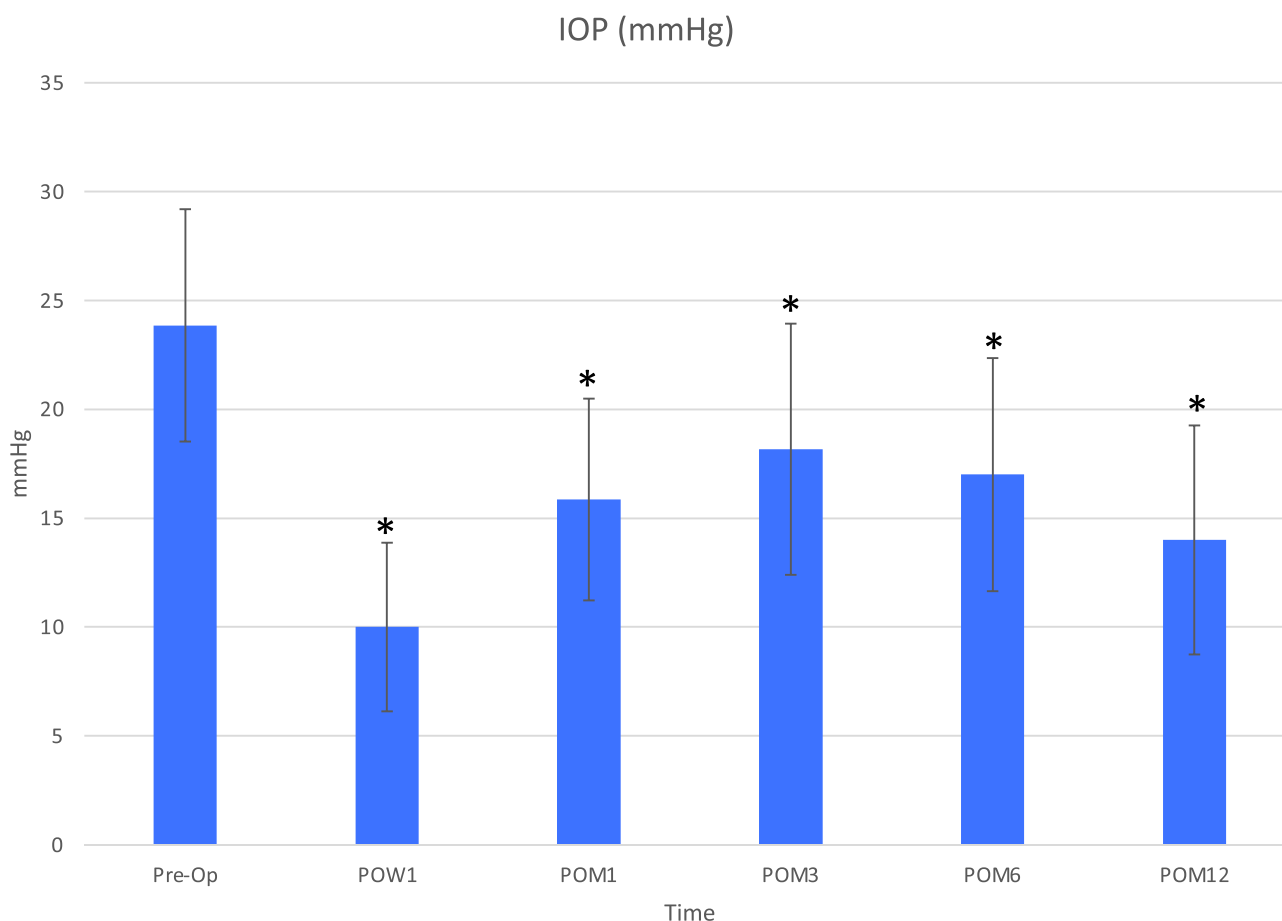


Figure 2 Mean IOP at pre-operative (Pre-op) and post-operative visits for eyes that had XEN45 gel stent after previous tube shunt surgery. * = $p < 0.05$ compared to pre-operative visit by *t*-test. Error bars indicate standard deviation.

Abbreviation: POM, post-operative month; POW, post-operative week.

Glaucoma Medications (Figure 3)

Mean number of medications was 4.3 ± 1.3 pre-operatively, 0.1 ± 0.4 at POW1 ($p < 0.001$), 0.9 ± 1.2 at POM1 ($p < 0.001$), 2.0 ± 2.1 at POM3 ($p < 0.05$), 2.8 ± 2.1 at POM6 ($p < 0.05$), and 1.6 ± 1.6 at POM12 ($p < 0.05$). From pre-operative baseline to POM12, there was a 2.7 or 63% decrease in the mean number of medications.

Complications and Post-Operative Interventions (Table 1)

One eye had choroidal effusion from hypotony at POW1 which resolved after a week. Bleb needling was performed in 3 eyes: one eye at POM3 and POM6, and the other two eyes at POM12. Two eyes also underwent laser therapy (one had selective laser trabeculoplasty, the other had micropulse cyclophotocoagulation) by POM12.

Surgical Success (Figure 4)

By the end of POM12, 2 of the 7 eyes (29%) was considered as absolute successes, 4 eyes (57%) as qualified successes, and 1 eye (14%) as a failure.

Discussion

Our study explores the potential of ab-interno XEN45 gel stent as a solution to failed tube shunt surgeries for IOP control. By 1 year, we see a statistically significant 41% reduction of IOP from pre-operative baseline. In comparison, literature reports mean IOP reductions of $>20\%$ by 12 months, generally ranging from 25–47% in XEN stents implanted both with and without concurrent phacoemulsification.^{1,11–14} Karimi et al found an IOP reduction of 36.7% with ab-interno XEN after

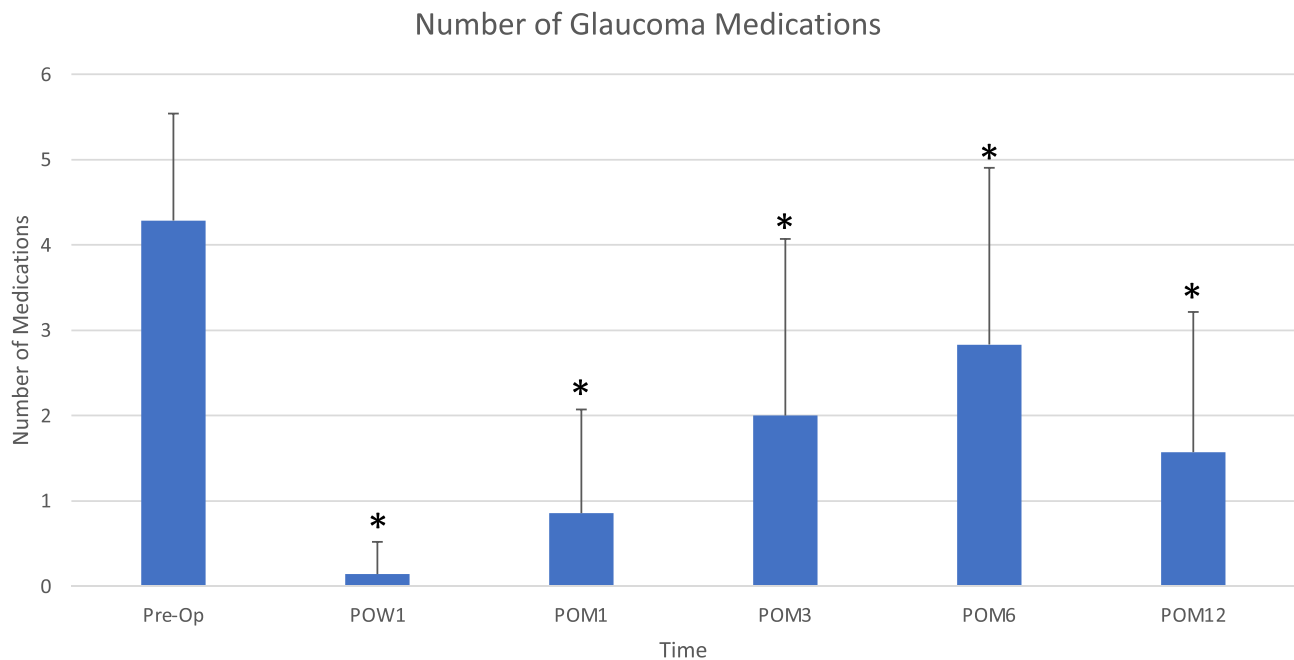


Figure 3 Mean number of glaucoma medications for eyes that had XEN45 gel stent after previous tube shunt surgery, at pre-operative (Pre-op) and post-operative visits. * = $p < 0.05$ compared to pre-operative visit by t-test. Error bars indicate standard deviation.

Abbreviations: POM, post-operative month; POW, post-operative week.

previous trabeculectomy.⁵ Similarly, Zhang et al reported IOP reduction of about 37%, though with ab-externo XEN after previous surgery.¹⁵ Sandhu and Dorey described a case where an ab interno XEN implant was able to reduce IOP by 29% by 1 year in a patient with multiple unsuccessful filtration surgeries.¹⁶ A large series on XEN implantation with or without combined cataract surgery reported approximately 30% IOP reduction by 18 months in eyes with or without previous glaucoma surgery; however, no subgroup analysis was carried out for XEN without phacoemulsification in eyes with previous tube shunt.¹² The efficacy from our results is comparable to the range reported in the aforementioned studies.

Reduction in number of glaucoma medications was also significant at every visit. Our reported 63% medication reduction falls within the 51–95% reduction range seen in the literature for XEN gel stent.^{11,17–22} This suggests that post-tube XEN may lessen the impact of medication burden on patients, with potential benefits to their ocular surface and quality of life. For instance, greater number of medications is associated with increased severity of dry eye and risk of ocular surface disease.^{23,24} Increasing drops may also lead to lower patient-reported outcome and experience measures, such as interference with daily function and perception of worsening glaucoma.²⁵

XEN gel stent and other MIGS procedures are known to have better safety profiles than traditional filtration surgery, with relatively few severe complications.²⁶ Early hypotony is noted to be the most common adverse event after XEN implantation, though it is usually self-limited.^{11,18,20,21} In our study, 1 eye experienced transient hypotony and associated choroidal effusion that resolved within a few weeks using a bandage contact lens to reduce overfiltration.

Table 1 Number of Complications and Interventions in the Post-Operative Visits

	Complications	Bleb Needling	Lasers
POW1	1 (hypotony and choroidal effusion)	0	0
POM1	0	0	0
POM3	0	1	0
POM6	0	1	0
POM12	0	2	2

Notes: Subconjunctival mitomycin-C injection was done at the time of bleb needling. For the two eyes that required laser, one had selective laser trabeculoplasty and the other had micropulse cyclophotocoagulation.

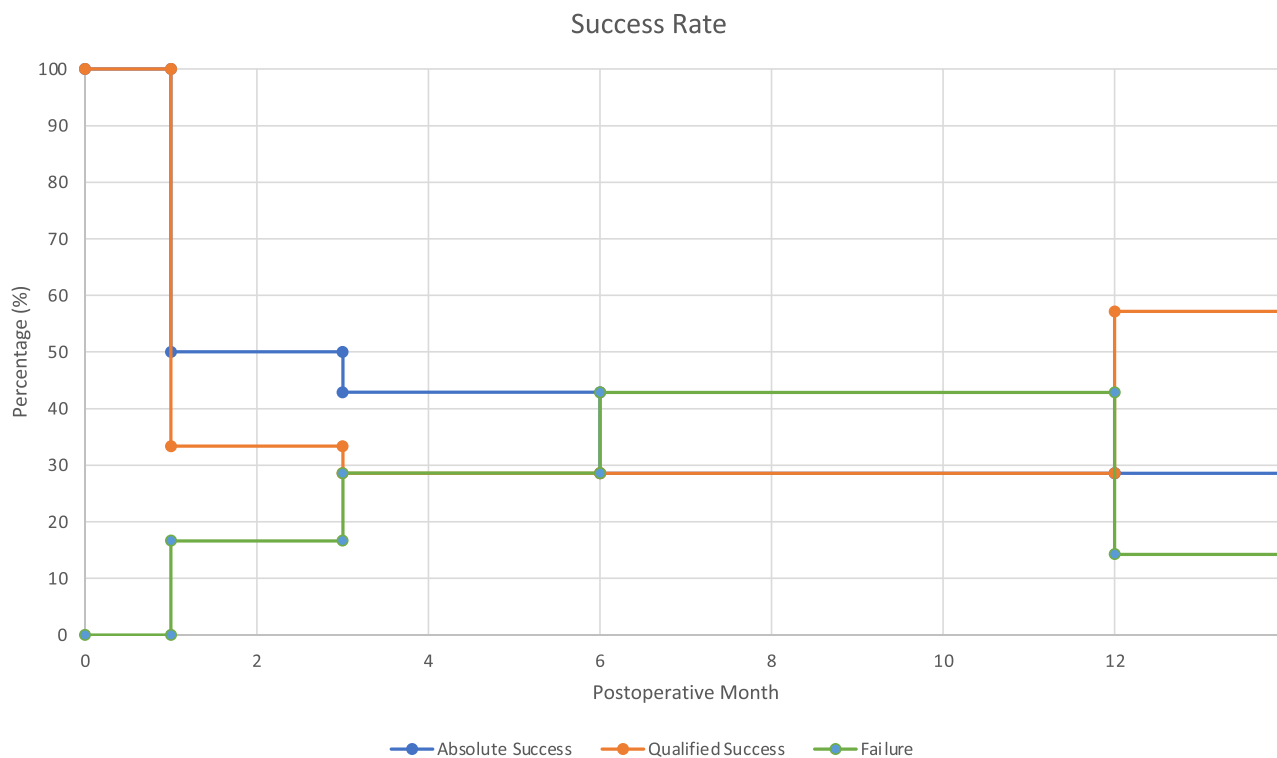


Figure 4 Kaplan-Meier survival curve for eyes that had XEN45 gel stent after previous tube shunt surgery. Absolute success = IOP \leq 18mmHg or \geq 20% IOP reduction without glaucoma medications. Qualified success = IOP \leq 18mmHg or \geq 20% IOP reduction with glaucoma medications. Failure = additional glaucoma surgery, or IOP $>$ 18mmHg or $<$ 20% IOP reduction with maximum tolerated glaucoma medications.

Post-operatively, bleb needling is often needed as rates of bleb fibrosis may reach 45%, especially within the first year of XEN implantation.^{13,27–29} Literature reports needling rates ranging from 21% to 52.3%, which may vary according to how and how much mitomycin C was administered at the time of surgery.^{11,18,19,21,22,27,30–32} In our study, needling was necessary in 3 of 7 eyes (43%), one of which received needling twice within first year after XEN implantation. Nonetheless, needling led to some complications prompting further interventions. One eye had positive Seidel test at the needle entry site which resolved with a bandage contact lens. Another eye had choroidal effusion, which resolved with a short course of topical steroid drops. Despite these complications, needling was able to achieve further IOP reduction in these eyes.

Lasers were performed on 2 eyes that had post-tube XEN implantation: selective laser trabeculoplasty at POM7 for one and micropulse cyclophotocoagulation at POM9 for the other. However, number of medications and IOP did not decrease notably after laser for either eye. The first eye eventually improved to 8mmHg with bleb needling at POM12 and the outcome for the second eye was qualified as surgical failure.

At 12 months, the cumulative success of post-tube XEN gel stent was 83% with medications and 33% without medications. This is comparable to the surgical success rate of approximately 60–80% reported by other XEN studies.^{11,21,22,31}

Limitations of the study include its uncontrolled and non-randomized retrospective nature, of which selection and observation biases are inherent. As our study only included 7 eyes, the demographics of our population was limited and was predominantly Caucasian. Our results therefore may not necessarily reflect the efficacy of XEN after tube shunt in patient populations known to have lower rates of success after filtering surgeries, such as patients of African or Latino descent.³³ Future research can elucidate the relationship between factors such as age, ethnicity, specific glaucoma diagnosis, medication burden, and previous procedures that may have an impact on XEN gel stent efficacy in eyes with previous tube shunt.

Conclusion

The XEN45 gel stent can be considered as an option to further reduce IOP and number of glaucoma medications in patients with previous tube shunt surgery. It has a substantial rate of success which is comparable to those reported for eyes without

prior surgery. The gel stent has a relatively safe profile with mild complications and can be implanted with minimal trauma to ocular tissue, allowing further procedures if necessary. Nonetheless, further modifications or interventions such as bleb needling may still be required within the first year to optimize IOP control.

Disclosure

Dr Toby Yiu Bong Chan reports personal fees from Aequus Pharmaceuticals, Alcon, Allergan (an AbbVie Company), Bausch & Lomb, Iridex, Ivantis, Johnson & Johnson, Latician Thea, and Novartis; grants from Novartis and Alcon, outside the submitted work. The authors report no other conflicts of interest in this work.

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