Research Square

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Real-World Twelve-Month Outcomes of Open-Conjunctiva XEN45 Gel Stent Implantation Using Trabeculectomy-Style Perioperative Management

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Abstract

Purpose

To analyze 12-month outcomes of XEN open conjunctiva implantation coupled with a “trabeculectomy-style” intraoperative and postoperative management.

Methods

This retrospective cohort study included consecutive eyes that underwent standalone XEN gel stent implantation by a single surgeon between May 2022 and September 2024. Outcomes included intraocular pressure (IOP), glaucoma medication use, adverse events, and surgical success. Comparisons with baseline were analyzed using paired two-tailed t-tests, and overall success was evaluated using Kaplan–Meier survival analysis.

Results

Fifty-three eyes of 42 patients were included. Mean IOP decreased by 40% from 21.45 mmHg to 12.86 mmHg at 12 months ($p < 0.0001$). Mean medication burden decreased by 89%, from 3.17 to 0.34 medications ($p < 0.0001$). Complication rates were low and no postoperative needling procedures were required. Kaplan-Meier analysis demonstrated a surgical success rate of 88% at 12 months.

Conclusions

Open conjunctiva XEN gel stent implantation with trabeculectomy-style perioperative management provides effective IOP and medication reduction with low complication and intervention rates.

Introduction

Elevated intraocular pressure (IOP) is the primary modifiable risk factor for glaucoma, and IOP reduction is the only proven therapy to slow glaucomatous disease progression [1]. This is particularly critical in patients whose IOP remains uncontrolled despite medical and laser therapy; surgical intervention often becomes necessary in such cases [1, 2]. The XEN gel stent procedure is considered a minimally invasive bleb-forming surgery (MIBS) and is designed to lower IOP by creating a path for aqueous humor to drain from the anterior chamber to the subconjunctival or sub-Tenon’s space. The stent is composed of cross-linked porcine gelatin, is 6mm in length, and has an inner diameter of 45 microns [3–5].

Implantation of the XEN gel stent is performed using either an ab interno or ab externo approach and can use either a closed conjunctiva or open conjunctiva technique. When using the ab interno approach, a corneal incision is made and the XEN is inserted through this incision, across the anterior chamber,

and passed through the iridocorneal angle just superior to the trabecular meshwork, and the distal end is placed extrasclerally. The ab externo approach involves guiding the XEN through the sclera and into the anterior chamber through the iridocorneal angle, where the stent is deployed [5]. Neither approach requires opening of the conjunctiva, although the conjunctiva can be opened with either approach.

Compared to traditional filtration surgery such as trabeculectomy, the XEN gel stent can be performed minimally invasively, has a quicker recovery time, and offers a lower risk of hypotony-related complications. While XEN gel stent surgery does provide IOP and medication reduction, it is more difficult to achieve single-digit IOPs with XEN compared to trabeculectomy [2, 4, 6, 7]. Furthermore, the need for postoperative interventions with XEN such as bleb needling remains relatively standard [2, 3].

A key distinction between traditional trabeculectomy and XEN gel stent surgery is the method of mitomycin-C (MMC) application and postoperative corticosteroid management. In trabeculectomy, MMC can be applied via sponges soaked in a 0.02% solution for 2 to 3 minutes, resulting in broad tissue exposure, or MMC can be injected intraoperatively. In contrast, XEN procedures most frequently employ subconjunctival injection of MMC at concentrations ranging from 0.01% to 0.02% [8–11]. Postoperative corticosteroid regimens also differ; trabeculectomy typically requires intensive topical steroid therapy for 3 to 4 months, which has been shown to significantly improve surgical success rates, whereas optimal steroid protocols for XEN have not yet been clearly established [2, 8, 12].

Although open-conjunctiva XEN implantation techniques are increasingly reported, limited data exist evaluating outcomes when perioperative management mirrors that commonly used in trabeculectomy, including sponge-applied mitomycin-C and prolonged and aggressive postoperative corticosteroid therapy. Because postoperative fibrosis remains a major cause of XEN failure, perioperative strategies that optimize antimetabolite delivery and postoperative inflammation control may improve outcomes.

The current study aims to analyze the outcomes of XEN gel stent implantation through postoperative months 12 using an open conjunctiva “trabeculectomy-style” technique using MMC-soaked sponges coupled with an aggressive postoperative steroid regimen, specifically evaluating intraocular pressure reduction, decrease in glaucoma medication use, complication rates, and surgical success rate.

Methods

This study is a single-center retrospective cohort study of 53 consecutive standalone XEN cases on 42 patients performed by a single surgeon at a single institution between May 2022 and August 2024. This study was conducted under approval from the Institutional Review Board at the University of Missouri-Columbia (IRB Project Number 2016641, IRB Review Number 252032).

The cases were performed using either an ab interno or ab externo approach based on surgeon preference, and all cases were performed with an open conjunctiva technique. Baseline characteristics and demographic information for these patients was collected. Outcomes included IOP, number of

glaucoma medications, and surgical success rates. The IOP, number of medications, and adverse events were recorded at postoperative day (POD)1, POD7, and postoperative month (POM)1, 3, 6, and 12.

Patient baseline characteristics were analyzed using unpaired two-tailed t-tests for continuous variables and Fisher's exact test for categorical variables. Comparative analyses for IOP and glaucoma medications at POM1, 3, 6, and 12 compared to preoperative baselines were assessed with paired two-tailed t-tests. The success rate was assessed with a Kaplan-Meier curve through POM12. Surgical success was defined as the absence of reoperation for glaucoma and either (1) a ≥ 20% reduction in IOP from baseline on the same or fewer medications or (2) an IOP not exceeding baseline IOP + 1 mmHg on fewer medications, with an additional requirement that postoperative IOP remain ≤ 15 mmHg or ≤ 21 mmHg depending on the success threshold applied. Failure by the IOP criterion required two consecutive visits at an uncontrolled IOP.

Of the 53 eyes included in the study, eyes which failed due to secondary surgical intervention (SSI) during follow-up were excluded from subsequent IOP and medication burden analyses at later time points, but these failures are reflected in the Kaplan–Meier survival analyses. Patients who were lost to follow-up due to leaving the hospital system, death, etc. were included in IOP and medication analyses only until the time of their censoring.

Surgical Technique

In both approaches, a 2–3 clock-hour peritomy was made at the limbus, Tenon's capsule was identified, and blunt dissection was performed broadly to delineate the sub-Tenon's space in the quadrant of planned XEN implantation. Cellulose sponges soaked in MMC 0.04% were applied to the sclera with the conjunctiva and Tenon's capsule draped over the sponges for 2–3 minutes, achieving a wide diffuse application. All sponges were then removed and copious irrigation with 30-45cc of balanced salt solution (BSS) was performed. Calipers were used to mark for planned XEN entrance/exit 2mm posterior to the limbus. After XEN insertion, the Tenon's was anchored to the sclera with two 8 – 0 vicryl wing sutures anterior to the XEN scleral exit point, and the conjunctiva was closed at the limbus with 8 – 0 vicryl sutures. Postoperative steroid management included frequent topical steroids for one month (typically prednisolone acetate 8x daily or difluprednate QID), followed by a very slow taper of topical steroids for at least 3 months.

Ab Interno Approach

After MMC application and BSS rinse, a paracentesis was made with a 1.8mm keratome inferotemporally and a cohesive viscoelastic was instilled into the anterior chamber. The XEN needle was placed through the corneal incision and inserted into the superior angle just anterior to the trabecular meshwork using a gonioscopic mirror. The XEN needle was then advanced until the needle tip exited at the 2mm scleral mark where the XEN was deployed. The XEN was adjusted leaving approximately 3mm of the XEN extrascleral. The cohesive viscoelastic was then flushed from the anterior chamber with BSS on a cannula and flow through the XEN was confirmed.

Ab Externo Approach

After MMC application and MMC rinse, the XEN was introduced into the eye through the sclera at the 2mm scleral mark and advanced into the anterior chamber parallel to the iris. The tip was confirmed to be in a good position in the anterior chamber and the XEN was deployed. The XEN was adjusted leaving approximately 3mm of the XEN extrascleral, and flow through the XEN was confirmed.

Results

Overall, 53 eyes were included in the study and 38 eyes were available for analysis at one year. The majority of cases were comprised of Caucasian patients (98%), and most eyes had primary open-angle glaucoma (POAG) (66%). The average age was 80.6 years, the average preoperative IOP was 21.45 mmHg, and the average preoperative number of glaucoma medications was 3.17 (Table 1).

Table 1
Baseline Characteristics of XEN Gel Stent Cases

Characteristics	**Total (n = 53)**
Age (y), Mean (SD)	80.6 (6.7)
Sex, n (%)	
Male	22 (41.5%)
Female	31 (58.5%)
Ethnicity, n (%)	
White	52 (98.1%)
Black	0.0%
Other	1 (1.9%)
Preoperative lens status, n (%)	
Pseudophakic	50 (94.3%)
Phakic	3 (5.7%)
Laterality, n (%)	
Right Eye	28 (52.8%)
Left Eye	25 (47.2%)
Average Preoperative IOP (mmHg)	21.45
Average Number of Pre-operative Medications	3.17
Glaucoma Type, n (%)	
Primary Open-Angle Glaucoma	35 (66.0%)
Normal Tension Glaucoma	11 (20.8%)
Pseudoexfoliative Glaucoma	2 (3.8%)
Secondary Open-Angle Glaucoma	3 (5.7%)
Uveitic Glaucoma	1 (1.9%)
Mixed Mechanism Glaucoma	1 (1.9%)
Glaucoma Severity, n (%)	
Mild	6 (11.3%)
Moderate	8 (15.1%)
Severe/Endstage	35 (66.0%)

Characteristics	Total (n = 53)
Indeterminate	4 (7.6%)

51 eyes were available for IOP and medication analysis at POM1 as one eye had been lost to follow-up and another underwent SSI prior to this visit. At POM3, 47 eyes were included in the analysis as two additional patients had SSI performed, another was lost to follow-up, and one missed their appointment before returning for their next follow-up. 45 eyes were available for IOP and medication analyses at POM6, as one eye had undergone SSI, and two more eyes had been lost to follow-up. At POM12, 35 eyes were analyzed for IOP and medication burden, as one additional eye required an SSI, and nine additional eyes had been lost to follow-up between months 6 and 12.

XEN implantation using trabeculectomy-style perioperative management demonstrated a statistically significant reduction in IOP at 1, 3, 6, and 12 months compared to their respective preoperative values. Mean IOP decreased from 21.45 mmHg preoperatively to 12.16 mmHg at POM1, 11.77 mmHg at POM3, 12.60 mmHg at POM6, and 12.86 mmHg at POM12 (all $p < 0.0001$). Similarly, the procedure yielded a statistically significant reduction in the average number of glaucoma medications over the course of 12 months. From a starting point of 3.17, the average number of glaucoma medications was reduced to 0.08 at POM1, 0.19 at POM3, 0.13 at POM6, and 0.34 at POM12 (all $p < 0.001$) (Fig. 1).

The surgical success rate was determined by a Kaplan-Meier survival curve. The more stringent definition of surgical success with a target IOP ≤ 15 mmHg showed a success rate of 86% while the more lenient target IOP ≤ 21 mmHg yielded a success rate of 88% at month 12. (Fig. 2)

Five eyes failed due to bleb encapsulation/XEN failure, and five eyes underwent secondary surgical intervention (SSI), yielding an SSI rate of 9.4%. Other complications, including XEN occlusion, suprachoroidal hemorrhage, choroidal effusion, and cystoid macular edema each occurred once in separate eyes in this cohort (Table 2). There were no postoperative needling procedures performed.

Table 2
Postoperative Adverse Events and Procedures after XEN Gel Stent Implantation

Postoperative Complications/Procedures	Timepoint						
	POD1	POD7	POM1	POM3	POM6	POM12	Total
Encapsulation & Bleb/XEN Failure	0.0%	1 (1.9%)	1 (1.9%)	1 (1.9%)	1 (1.9%)	1 (1.9%)	5 (9.4%)
Suprachoroidal Hemorrhage	1 (1.9%)	0.0%	0.0%	0.0%	0.0%	0.0%	1 (1.9%)
Choroidal Effusion	0.0%	0.0%	1 (1.9%)	0.0%	0.0%	0.0%	1 (1.9%)
Cystoid Macular Edema	0.0%	0.0%	1 (1.9%)	0.0%	0.0%	0.0%	1 (1.9%)
XEN Occlusion	0.0%	0.0%	1 (1.9%)	0.0%	0.0%	0.0%	1 (1.9%)
All Secondary Surgical Interventions	0.0%	1 (1.9%)	2 (3.8%)	1 (1.9%)	0.0%	1 (1.9%)	5 (9.4%)
XEN Revision/Explant	0.0%	1 (1.9%)	1 (1.9%)	0.0%	0.0%	1 (1.9%)	3 (5.7%)
Ahmed ClearPath	0.0%	0.0%	1 (1.9%)	0.0%	0.0%	0.0%	1 (1.9%)
Ahmed Glaucoma Valve	0.0%	0.0%	0.0%	1 (1.9%)	0.0%	0.0%	1 (1.9%)
Needling	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

There were no significant differences in outcomes between the ab interno and ab externo approaches. Both approaches resulted in similar reductions in intraocular pressure and glaucoma medication use over 12 months. Furthermore, no significant differences were identified between the two approaches regarding complication rates, needling rates, or the need for SSI.

Discussion

Based on this study's results, standalone XEN gel stent implantation utilizing an open conjunctiva “trabeculectomy-style” perioperative management effectively reduces IOP and glaucoma medication use through 12 months. The absence of postoperative needling procedures in this cohort is particularly notable, as needling remains one of the most common postoperative interventions following XEN implantation.

Potential limitations of this study are its small sample size and retrospective cohort nature. Additionally, the homogeneity of the study population (predominantly Caucasian, mostly POAG, relatively older age, mostly severe/endstage glaucoma, and all standalone cases) limits generalizability to the broader

glaucoma population. Given this study's single-center and single-surgeon design, the results reflect this institution's protocols and a single surgeon's technique and patient selection. However, the results still offer valuable insights into surgical outcomes using a standardized open conjunctiva surgical technique and postoperative management.

Among this study's results, the 0% needling rate, low SSI rate, and high success rate offer unique clinical insight into XEN best practices. Previously reported needling rates for closed conjunctiva XEN implant surgery are 25–54% [3, 13–18], but a closed conjunctiva technique with an intraoperative posterior sweep of Tenon's (PoST) resulted in a needling rate of 9.2% [19]. Retrospective studies of open conjunctiva XEN techniques have reported needling rates as low as 4–12% at one year [20–23]. Similarly, in this study only five eyes (9%) required an SSI over the 12-month follow-up period, which compares favorably to a PoST SSI rate of 17.2% [19] and to other open conjunctiva XEN techniques with reported rates of SSI ranging from 13–18% at one year [21, 23]. We also report a success rate with an IOP threshold of ≤ 21mmHg of 88% and a success rate of 86% using an IOP criterion of ≤ 15mmHg. Previously reported surgical success rates with open conjunctiva XEN techniques using a similar success definition are 60–71% [21, 23].

We hypothesize that a broad dissection of the sub-Tenon's space with direct application of MMC 0.04% sponges between sclera and Tenon's may have contributed to the low needling rate observed in this cohort. Furthermore, this open conjunctiva technique, while potentially more time intensive than a closed technique, allows for direct visualization of this surgical plane and avoidance of XEN entanglement in Tenon's. Another factor that may have contributed to the low postoperative procedure rate was the aggressive postoperative topical steroid management. Patients were instructed to use frequent topical steroids for one month and these were tapered slowly for a total of 3 months. We hypothesize that liberal corticosteroid use suppresses the inflammatory response after surgery, mitigating the risk of bleb fibrosis and XEN failure. Finally, careful patient selection and the resultant homogenous baseline patient characteristics likely also contributed.

Multiple comparative studies and systematic reviews have shown that the ab interno and ab externo approaches to XEN gel stent surgery exhibit similar intraocular pressure, medication burden outcomes, and complication rates [5, 24–27]. However, the ab interno approach may be beneficial in eyes with a prominent brow or in cases where the surgeon desires to spare the superotemporal quadrant for future glaucoma surgery as ab externo superonasal placement can be more challenging. Alternatively, an ab externo approach may be preferred in eyes with corneal opacities or compromised gonioscopic visualization [24] and may be particularly advantageous in eyes with prior conjunctival surgeries (e.g., trabeculectomy, tube shunt) where conjunctival scarring may limit space for another bleb-forming surgery [24, 25, 28].

The ab externo technique also minimizes intraocular maneuvers and obviates the need for a larger paracentesis and the use of viscoelastic. Furthermore, due to its similarities with traditional tube shunt procedures, the ab externo approach may be more familiar to glaucoma surgeons and therefore

associated with a shorter learning curve [28]. Other studies revealed that the ab externo approach is associated with shorter surgical times and more rapid visual recovery, without an increase in adverse events or need for postoperative interventions compared to ab interno implantation [24, 25, 27].

Similarly, no significant differences in outcomes or complications were observed between the ab interno and ab externo approaches in this cohort.

This study demonstrates that an open conjunctiva trabeculectomy-style intraoperative technique including broad sub-Tenon's dissection and MMC-soaked sponges directly applied to this surgical plane coupled with an aggressive postoperative steroid regimen can achieve a high surgical success rate. The lack of the need for needling procedures and the low secondary surgical intervention rate may be appealing to patients and surgeons alike.

These findings suggest that surgical technique and perioperative management may play a critical role in optimizing outcomes with XEN implantation, potentially narrowing the gap between minimally invasive bleb-forming surgery and traditional filtering procedures. However, these results were achieved in a rather homogeneous patient population and were based on the outcomes of a single surgeon at a single institution. Future studies would include a prospective study design, evaluation of longer-term surgical outcomes, and inclusion of more sites and surgeons.

Declarations

Competing Interests

The authors have no relevant financial or non-financial interests to disclose.

Ethics Approval

This is an observational study. This study was approved by the Institutional Review Board at the University of Missouri–Columbia (IRB Project Number 2016641, IRB Review Number 252032). The study was performed according to the 1964 Declaration of Helsinki and its later amendments. Informed consent was obtained from all patients.

Informed consent

Written Informed consent was obtained from all patients for surgery. This is a retrospective study, and no experimental interventions were performed in relation to the writing of a scientific manuscript. All methods were carried out in accordance with relevant guidelines and regulations. No images of patients or identifying information were published in this study.

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Author Contribution

All authors contributed to the study conception and design. All authors read and approved the final manuscript.

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