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Comparison of Clinical Outcomes with Open Versus Closed Conjunctiva Implantation of the XEN45 Gel Stent

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Abstract

Purpose: To describe the efficacy and safety of open versus closed conjunctival implantation of the XEN45 Gel Stent (Allergan Inc).

Design: Retrospective, multicenter study.

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Obtained funding: Craven, Panarelli, Schuman; Study was performed as part of regular employment duties at both NYU and JHU.

Overall responsibility: Do, McGlumphy, Shukla, Dangda, Boland, Panarelli, Craven

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HUMAN SUBJECTS: Human subjects were included in this study. The Institutional Review Board at Johns Hopkins and NYU Langone approved this study. The study was compliant with the Declaration of Helsinki and Health Insurance Portability and Accountability Act regulations. It was listed at ClinicalTrials.gov (NCT04406467). Informed consent was not required for this study because all data were de-identified.

No animal subjects were used in this study.

Participants: A total of 137 patients with glaucoma who underwent XEN45 implantation via open or closed conjunctival methods. The XEN45 was implanted as a stand-alone procedure or at the time of cataract surgery by 5 surgeons.

Methods: Patient demographics, diagnoses, preoperative and postoperative clinical data, outcome measures including intraocular pressure (IOP), use of glaucoma medications, visual acuity, and complications were collected. Statistical analyses were performed with $P < 0.05$ as significant.

Main Outcome Measures: Failure was defined as less than 20% reduction of IOP from medicated baseline or IOP >21 mmHg at 2 consecutive visits at postoperative month 1 and beyond, the need for subsequent operative intervention or additional glaucoma surgery, or a catastrophic event such as loss of light perception. Eyes that had not failed by these criteria and were not on glaucoma medications were considered complete successes. Eyes that had not failed but required glaucoma medications were defined as qualified successes.

Results: Complete success was achieved in 31% and 56% of the closed and open groups, respectively ($P = 0.01$). Qualified success was achieved in 53% and 71% of the closed and open groups, respectively ($P = 0.06$). At postoperative month 12, the open conjunctiva group was using fewer glaucoma medications than the closed group (0.9 vs. 1.8, respectively; $P = 0.02$). At postoperative month 12, the open group had a significantly greater percentage of IOP reduction compared with the closed group (43.1% vs. 24.8%, respectively; P = 0.02). Postoperative needling rates were higher in the closed group compared with the open group (36.1% vs. 11.8%, $P = 0.001$).

Conclusions: Implantation of the XEN45 with opening of the conjunctiva is a safe and efficacious procedure to lower IOP with comparable success rate and lower needling rate compared with the closed conjunctiva technique. Prospective evaluation of the various methods for XEN45 implantation will allow for further comparison.

Keywords

Gel stent; Glaucoma; MIGS; Minimally invasive glaucoma surgery; XEN

The XEN45 Gel Stent (Allergan Inc.) shunts fluid from the anterior chamber (AC) to the subconjunctival space. The microshunt is a 6-mm hydrophilic tube made from porcine gelatin (a nonsilicone biocompatible material derived from collagen) cross-linked with glutaraldehyde, a material that is known to induce little inflammation when used elsewhere in the body.[1] The XEN45, which has a luminal diameter of 45 μm, has been shown to achieve a steady-state pressure of 7.56 mmHg at 2.5 μl/min.[2] The length of the device and its luminal diameter help restrict flow and thereby theoretically limit hypotony-related complications.

At 1 year postimplantation, the XEN45 has demonstrated success rates of 27% to 80% when combined with cataract surgery and 15% to 66% as a stand-alone procedure in prospective studies.[1–7] The rate of postoperative bleb interventions, such as needling and injection of antifibrotics, has been reported to vary widely (0%–43.2%).[5,7–10] Encapsulation within Tenon's, both early and late in the postoperative course, has been identified as the primary reason for failure.[10,11] Revision of the XEN45 or subsequent bleb revision requires additional invasive interventions imposing additional risk and is not associated with high

success (19%–61%).[10–13] Various approaches to XEN45 implantation have been evaluated to help improve long-term success and reduce the need for postoperative revisions/needling. The device can be delivered via an ab interno or ab externo approach and be placed in the sub-Tenon's or subconjunctival space. To date, no study has evaluated the benefits of an open versus closed conjunctival approach. In this study, we evaluated open (sub-Tenon's) versus closed (subconjunctival) implantation of the XEN45 at 3 academic centers.

Methods

This was a retrospective chart review of consecutive patients who underwent surgery with the XEN45 at Wilmer Eye Institute, New York University, and New York Eye and Ear Infirmary of Mount Sinai between July 2017 and February 2020. The Institutional Review Board at Johns Hopkins and NYU Langone approved this study. The study was compliant with the Declaration of Helsinki and Health Insurance Portability and Accountability Act regulations. Informed consent was not required for this study because all data were de-identified.

Technique

Each surgery was performed by 1 of 5 surgeons under monitored anesthesia care with or without retrobulbar block. The patient was prepped and draped according to standard procedures. Mitomycin-C (MMC) was prepared using the Mitosol kit for injection (0.4 mg/ml concentration) and 20 to 80 μg was injected subconjunctivally before XEN45 insertion. Variations in technique are described next.

Closed Conjunctiva Technique

Ab interno approach (as done by J.S.S. and J.Y.): A clear corneal incision and paracentesis were made, and the AC was filled with 1% sodium hyaluronate. A mirrored gonioprism was used to visualize the superonasal quadrant, and the XEN45 injector was placed into the angle and advanced until it exited the sclera approximately 2 mm posterior to the limbus. After exiting the sclera, the bevel was rotated to ensure that it was free of Tenon's and beneath the conjunctiva. The stent was then deployed into the subconjunctival space. The 1% sodium hyaluronate was removed, and the AC pressurized with balanced salt solution.

Ab externo approach (as done by MB): A traction suture was placed superiorly, and the eye was infraducted. The needle of the inserter entered the subconjunctival space approximately 7 mm posterior to the limbus and tunneled to a point approximately 2 mm from the limbus where it was then redirected to make a tunneled track into the AC. Once the tip of the inserter was visualized in the AC, the XEN45 was deployed and the inserter was removed.

Open Conjunctiva Technique

Ab interno approach (as used by J.F.P. and E.R.C.): A traction suture was placed superiorly, and the eye was infraducted. A 3 to 4 clock-hour superonasal conjunctival limbal peritomy was created followed by blunt dissection down to bare sclera. A clear corneal incision and paracentesis were created, and the AC was filled with 1% sodium hyaluronate. The XEN45 injector was placed into the angle in the superonasal quadrant and advanced until it exited

the sclera 2 to 3 mm posterior to the limbus. The XEN45 was deployed and gently manipulated using tying forceps to ensure proper positioning. The conjunctiva/Tenon's was reapproximated using polyglactin or nylon sutures. The 1% sodium hyaluronate was removed, and the AC was pressurized with balanced salt solution.

Ab externo approach (as used by J.F.P., E.R.C., and J.Y.): The conjunctiva was opened in the same fashion as described earlier. The XEN45 injector was then placed superiorly 2 to 3 mm posterior to the limbus and flush to the sclera, advanced anteriorly, and redirected downward until the tip was visible in the AC. The XEN45 was deployed and gently manipulated using tying forceps to ensure proper positioning. The conjunctiva/Tenon's was reapproximated using polyglactin or nylon sutures.

Postoperative regimen included 4 to 12 weeks of postoperative steroids with a tapering regimen frequency and 7 to 10 days of fluoroquinolone antibiotic eye drops. Postoperative steroid formulation and tapering schedule varied among surgeons.

Assessment and Outcomes

Data obtained from the clinical record included patient demographics, glaucoma diagnosis, number and type of previous ocular surgeries, preoperative ophthalmic imaging and visual field testing, preoperative visual acuity, preoperative IOP, number of preoperative glaucoma medications, and intraoperative complications. Postoperative data collected included IOP, number of glaucoma medications, visual acuity, complications, interventions such as needle revision, AC paracentesis or AC viscoelastic injection, and additional surgery.

Failure was defined as IOP >21 mmHg or less than 20% reduction from medicated preoperative baseline on 2 consecutive follow-up visits at 1 month and beyond, reoperation for complications such as implant exposure, reoperation for glaucoma, or loss of light perception vision. Reoperation for glaucoma was defined as additional glaucoma surgery requiring a return to the operating room, such as for trabeculectomy or tube shunt surgery. Cyclodestruction was also counted as a reoperation for glaucoma. Interventions including needling of the bleb postoperatively were not considered a glaucoma reoperation. Eyes that had not failed by the criteria and were not on glaucoma medications were considered complete successes. Eyes that had not failed but required glaucoma medications were defined as qualified successes.

Statistical Analysis

A P value < 0.05 was considered statistically significant. Postoperative nonparametric continuous variables were compared using Wilcoxon rank-sum tests. Categorical variables were compared using chi-square analyses. A multivariable logistic regression model was used to compare needling between the open and closed conjunctiva groups while controlling for age, gender, ethnicity, preoperative IOP, surgeon, technique of XEN45 implantation for each subtype (open conjunctiva: ab interno vs. ab externo, closed conjunctiva: transconjunctival vs. ab interno), dose of MMC administered, adjunctive surgery at the time of XEN45 implantation (phacoemulsification), history of glaucoma surgeries, number of preoperative glaucoma medications, and glaucoma type.

Results

A total of 137 eyes from 137 patients underwent XEN45 implantation. The closed conjunctiva technique was used in 61 eyes (closed group), and the open conjunctiva technique was used in 76 eyes (open group). Fifty-five percent of patients were male, and the most common diagnosis was primary open-angle glaucoma (58.4%). The baseline IOP was significantly higher in the open group (26.4 ± 0.9 mmHg vs. 23.0 ± 0.9, $P = 0.01$), and patients in this cohort were more likely to have had prior incisional glaucoma surgery (20% vs. 5%, $P = 0.01$). Additional baseline demographics and characteristics are reported in Table 1.

Mean follow-up was 9.6 months (median, 9 months; range, 3–28) for all eyes, with an average of 10.0 months (median, 9 months; range, 3–28) in the closed group and 9.2 months (median, 9 months; range, 3–23) in the open group ($P = 0.69$). XEN45 implantation was performed at the time of phacoemulsification in 31 eyes (22.8%), with a slightly higher percentage in the closed group (n = 17, 28%) compared with the open group (n = 14, 18%), but this difference was not significant ($P = 0.2$). In our multivariable analyses, phacoemulsification at the time of XEN45 implantation had no effect on the rate of needling or failure ($P = 0.3$, $P = 0.3$, respectively).

A reduction in IOP was noted at each time point after XEN45 implantation compared with the preoperative intraocular pressure (IOP) for both the open and closed groups (Fig 1). There was no difference in postoperative IOP between the closed and open groups at any postoperative time point (Table 2). However, at 12 months postoperatively, a significant difference was noted in the percent of IOP reduction from baseline, which was 24.8% in the closed group (n = 26) and 43.1% in the open group (n = 30) (Wilcoxon rank-sum $P = 0.02$).

Complete success was observed in 19 eyes (31%) in the closed group and 40 eyes (53%) in the open group ($P = 0.01$). Qualified success was observed in 34 eyes (56%) in the closed group and 54 eyes (71%) in the open group $P = 0.06$). Time to failure was on average 6.1 (± 4.0) and 6.3 (± 5.4) months for the closed and open conjunctiva groups, respectively. To further characterize the data, we examined the number of eyes achieving IOP <18, ≤15, and ≤12 mmHg with and without medications at the last postoperative examination. A greater number of eyes in the open conjunctiva group compared with the closed conjunctiva were able to achieve an IOP of ≤18 without medications. The percentage of eyes achieving IOP ≤12 mmHg without medication was 38% and 25% in the open and closed groups, respectively. Additional findings are reported in Table 3.

The closed and open groups required on average 3.6 ± 0.14 and 3.6 ± 0.11 medications before surgery, respectively ($P – 0.9$). This was significantly reduced at all time points after XEN 45 implantation (Table 4). The open group required less medications than the closed group at months 3 and 12 (1.2 vs. 0.6, $P = 0.02$, and 1.8 vs. 0.9, $P = 0.02$, respectively).

Intraoperative details are shown in Table 5, and postoperative complications are noted in Table 6. The postoperative needle revision rate was higher in the closed group (22 of 61 eyes, 36.1%) compared with the open group (9 of 76 eyes, 11.8%) ($P = 0.001$). Postoperative needling was performed on average 3.3 months and 5.1 months after initial XEN45

implantation in the closed and open groups, respectively. A multivariable logistic regression model, accounting for previously stated variables, showed the closed conjunctiva technique significantly increased the likelihood of postoperative needling compared with the open conjunctiva technique (odds ratio, 7.38, $P = 0.002$). Operative bleb revision was performed in 4 eyes in the closed group compared with 0 in the open group ($P = 0.02$). The closed group also demonstrated a higher rate of conjunctival erosion (3 eyes, 4.9% vs. 0 eyes, $P = 0.05$) and iris plugging of the internal lumen (8 eyes, 13.1% vs. 1 eye, 1.3% $P = 0.005$) compared with the open group.

Discussion

XEN45 implantation has been shown to effectively lower IOP as a primary surgical intervention across various glaucoma subtypes and in eyes with failed filtration surgery. The success rate and safety profile of the XEN45 implantation with MMC have been shown to be similar compared with trabeculectomy with MMC.[14] The XEN45 design for implantation in the eye closely follows the bleb-forming principles of filtering surgery, thus mimicking trabeculectomy while not requiring a scleral flap, ostium, iridectomy, or releasable sutures.[15] In bleb-dependent glaucoma surgery, long-term IOP control is curbed by subconjunctival scarring, and the role of antifibrotic agents has been well established in failed or failing blebs. The most common complication with the XEN45 is the high rate of failure requiring postoperative bleb needling with MMC or 5-fluorouracil, reportedly with rates varying from 32% to 53%.[1,16]

In this study, 76 eyes underwent the open conjunctival approach and 61 eyes underwent the closed conjunctival approach. The open group had a higher mean preoperative IOP (26.4 mmHg vs. 23.0 mmHg, $P = 0.01$), and a greater number of patients had refractory glaucoma (15 eyes underwent prior incision glaucoma surgery in the open group vs. 3 eyes in the closed group). Despite this, the open group achieved a higher rate of complete success compared with the closed group, and at postoperative month 12, the percentage of IOP reduction was significantly higher in the open group (43.1% vs. 24.8%, $P = 0.02$). We believe that opening the conjunctiva and Tenon's capsule allows for more consistent placement of the XEN45, thereby reducing the risk of intraoperative or postoperative occlusion of the distal end of the device and improving outcomes. In addition, the extensive dissection of Tenon's and creation of a broad posterior pocket may contribute to higher rates of surgical success in this group.

Single-center studies have reported needling rates up to 51%, with the median time to first needling being 59.5 days and median number of interventions being 2.[7,8] Considering the high needling rates, various alternate ways of implanting the XEN45 are now being explored, including variations in the amount and mode of MMC use, depth of placement of the implant, preimplantation subconjunctival injection of viscoelastic or air, and postimplantation conjunctival manipulation with blunt instruments or even "on-table" needling. Midha et al[11] hypothesize that the minimally invasive "closed" conjunctiva technique of implantation has a high rate of needling due to its minimal dissection of subconjunctival and episcleral tissues. They note a significant direct association between day 1 IOP and number of postoperative needling procedures. A high chance of blockage of the

stent lumen by Tenon's, blood, or exudates on day 1 translates into a higher day 1 IOP, thus increasing the needling rate. The probability of needling was 35% in eyes with IOP <10 mmHg compared with 80% in eyes with IOP >20 mmHg on postoperative day 1. A relatively low rate of needling was noted in the open group in our study (11.8%). In the pivotal Food and Drug Administration trial by Grover et al,[1] an open conjunctiva approach was also used, but the needling rate was 32%. Their technique involved making a conjunctival peritomy for placement of sponges soaked in MMC (0.2 mg/ml). Two half-moon pledgets were left on the scleral bed for 2 minutes. We prefer a subconjunctival injection of a fixed amount of MMC instead because the dose of MMC can be more accurately measured and more precisely delivered. The dose of injected MMC in our study ranged from 20 to 80 μg, with the majority of patients in the open group receiving at least 40 μg (97%). This may have improved our outcomes and resulted in a relatively low rate of needling in the open group compared with the needling rate in the aforementioned study. However, it is interesting that despite using similar doses of MMC in both groups (Table 5) in our study, there was a significantly higher rate of needling in the closed group (36.1%). The broad dissection and creation of a fluid lake with the open technique elevate Tenon's from the sclera and create a better separation between this tissue and the distal end of the device. In contrast, the XEN45 device lies on top of the Tenon's layer when it is placed in the subconjunctival space and may be more likely to become encased over time and require needle revision.

Postoperative complications were infrequent in both groups; however, the closed group demonstrated a higher rate of operative bleb revisions, stent exposure, and iris plugging of the internal lumen (Table 6). Bleb revisions and stent exposure may be related to the technical difficulty of consistently and precisely placing the injector needle in the subconjunctival space. The higher rate of proximal occlusion of the shunt with iris may be related to the inability to make micro-adjustments once the stent has been deployed with the closed technique. Also, when placing the stent via a closed approach, the AC needs to be maintained with a cohesive viscoelastic, and there is the possibility that the angle is artificially "widened" if the chamber was overfilled/hyperinflated. This can result in the device being delivered too posteriorly in the angle and later lead to stent obstruction.

Study Limitations

This study is limited by its retrospective nature and limited follow-up time. Additionally, this study reports the outcomes from 5 surgeons and thus may not be representative of surgeons with variable levels of experience. The reason why a particular surgeon chose a certain technique for XEN45 implantation was not recorded. Surgeons varied in their approach, with some surgeons performing only 1 technique and others using multiple techniques during the study period. We surmise that the approach to implantation may have been affected by ease of exposure, whether or not the procedure was combined with phacoemulsification, and surgeon preference. Some surgeons may have changed their technique preference based on their personal experiences or dissatisfaction with their initial outcomes. Morphologic assessment of blebs would have added valuable information to this study. The decision to needle at various postoperative time points was at the surgeon's discretion. Subtle differences in surgical technique and postoperative steroid management

were not standardized among surgeons and have an unknown effect on the outcomes. Furthermore, the minimum length of postoperative follow-up for study inclusion was 3 months, and the average time to needling in the open group was 6 months versus 3 months in the closed group; therefore, it is possible that the rate of needling is artificially lower in the open group because of the longer time to needling.

In conclusion, we advocate an “open” technique of implantation of the XEN45 using a conjunctival peritomy in ab externo or ab interno fashion. The findings of this study suggest that this technique is associated with a trend toward greater complete and qualified surgical success, lower needling rate, and less postoperative complications. Our retrospective analysis of a cohort of patients who underwent XEN45 implantation showed that the open conjunctiva technique was associated with a lower postoperative needling rate; however, prospective, randomized, controlled studies are warranted before the broader application of these findings. It is our hope that these data will serve as the basis for further prospective analyses to study how we can improve postoperative outcomes for patients with glaucoma.

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Abbreviations and Acronyms:

AC	anterior chamber
IOP	intraocular pressure
MMC	mitomycin-C

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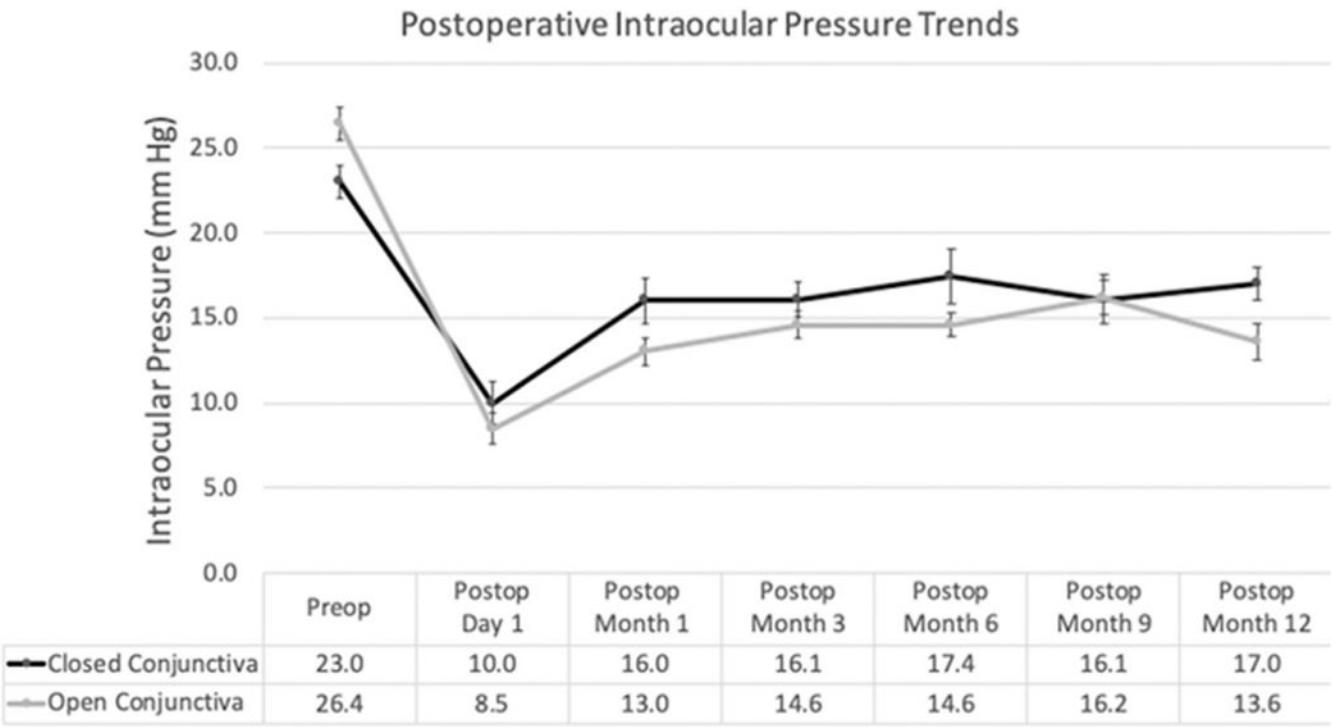

	Preop	Postop Day 1	Postop Month 1	Postop Month 3	Postop Month 6	Postop Month 9	Postop Month 12
Closed Conjunctiva	23.0	10.0	16.0	16.1	17.4	16.1	17.0
Open Conjunctiva	26.4	8.5	13.0	14.6	14.6	16.2	13.6

Figure 1.

A reduction in IOP was noted at each time point post XEN45 implantation compared with the preoperative intraocular pressure for both the open and closed groups.

Table 1

Baseline Characteristics of All Included Eyes and the Open and Closed Conjunctiva Groups

		All Eyes	Closed Group	Open Group	
Eyes	**n**	***137***	***61***	***76***	***P* Value**
Age (yrs)	Mean (SD)	72 (13.2)	72.5 (14.9)	71.5 (13.2)	0.4 *
	IQR	64–81	65–81	62–81	
Gender	Female n (%)	61 (45%)	24 (39%)	37 (49%)	0.3 †
	Male n (%)	76 (55%)	37 (61%)	39 (51%)	-
Laterality	Right n (%)	66 (48%)	26 (43%)	40 (53%)	0.2 †
	Left n (%)	71 (52%)	35 (57%)	36 (47%)	-
Ethnicity	White (%)	95 (69%)	43 (70%)	52 (68%)	0.1 †
	Hispanic (%)	10 (16%)	1 (2%)	9 (12%)	-
	Black (%)	22 (16%)	13 (21%)	9 (12%)	-
	Asian (%)	6 (4%)	3 (5%)	3 (4%)	-
	Other (%)	4 (3%)	1 (2%)	3 (4%)	-=
Glaucoma Type	Primary open-angle (%)	80 (58%)	38 (62%)	42 (55%)	0.5 †
	Pseudoexfoliation (%)	31 (23%)	11 (18%)	20 (26%)	-
	Chronic angle-closure (%)	8 (6%)	3 (5%)	5 (7%)	-
	Secondary (%)	18 (13%)	9 (15%)	9 (12%)	-
Visual Field Characteristics	Baseline MD, Mean (SD)	−13.9 (8.2)	−14.8 (8.3)	−12.9 (8.1)	0.2 *
	Mild (MD >–6 dB) (%)	28 (20%)	12 (20%)	16 (31%)	0.4 †
	Moderate (MD −12 to −6 dB) (%)	25 (18%)	14 (23%)	11 (22%)	-
	Advanced (MD <–12 dB) (%)	58 (42%)	34 (57%)	24 (47%)	-
Prior Surgeries	Laser trabeculoplasty (%)	52 (38%)	20 (33%)	32 (42%)	0.3 †
	Trabeculectomy or tube shunt (%)	18 (13%)	3 (5%)	15 (20%)	0.01 †
Lens Status	Phakic (%)	67 (49%)	33 (54%)	34 (45%)	0.3 †
	Pseudophakic (%)	70 (51%)	28 (46%)	42 (55%)	-
CCT µm	Mean (SD)	554.2 (82.4)	568.1 (97.5)	544.0 (68.2)	0.1 *

Eyes	n	All Eyes 137	Closed Group 61	Open Group 76	P Value
Preoperative IOP mmHg	Mean (SD)	24.9 (8.4)	23.0 (7.8)	26.4 (8.6)	0.01 *
	IQR	18–29	17–27	21–31	
Preoperative Medications	Mean (SD)	3.6 (1.0)	3.6 (1.1)	3.6 (0.9)	0.9 *

CCT = central corneal thickness; dB = decibels; IOP = intraocular pressure; IQR = interquartile range; MD = mean deviation; SD = standard deviation. Baseline characteristics and preoperative clinical data are shown for all eyes included, eyes in the closed group, and eyes in the open group.

* Wilcoxon rank-sum test for nonparametric variables used for comparison of means between closed and open conjunctiva groups.

† Chi-square test for comparing closed versus open conjunctiva groups.

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Table 2.

Mean Intraocular Pressure Over Time in Open and Closed Groups

	Closed Group		Open Group		
	N	***Mean (SD)***	***n***	***Mean (SD)***	**P Value**
Preoperative	61	23.0 (7.8)	76	26.4 (8.6)	0.01
Postoperative Day 1	60	10 (9.6)	76	8.5 (7.7)	0.3
Postoperative Month 1	61	16.0 (9.9)	76	13.0 (7.1)	0.07
Postoperative Month 3	61	16.1 (7.8)	72	14.6 (6.9)	0.3
Postoperative Month 6	50	17.4 (11.0)	57	14.6 (5.3)	0.4
Postoperative Month 9	36	16.1 (8.6)	44	16.2 (6.9)	0.4
Postoperative Month 12	26	17.0 (9.5)	29	13.6 (6.3)	0.2

SD = standard deviation.

Mean observed IOP and SD at baseline and subsequent postoperative visits in the closed and open groups.

Table 3.

Postoperative Intraocular Pressure at Last Documented Follow-Up, Expressed as n (%)

IOP		Closed Group	Open Group	P Value
≤18 mmHg	± Medications	35 (57%)	55 (72%)	0.07
≤18 mmHg	No Medications	22 (36%)	42 (55%)	0.03
≤15 mmHg	± Medications	31 (51%)	41 (54%)	0.7
≤15 mmHg	No Medications	19 (31%)	35 (46%)	0.07
≤12 mmHg	± Medications	23 (38%)	31 (41%)	0.7
≤12 mmHg	No Medications	15 (25%)	29 (38%)	0.09

IOP = intraocular pressure.

Number of eyes and (%) in the closed and open groups that met the IOP criteria of ≤18, 15, and 12 mmHg, with or without glaucoma medications.

Table 4.

Mean Glaucoma Medications Over Time in Open and Closed Groups

	Closed Group		Open Group		
	n	***Mean (SD)***	***n***	***Mean (SD)***	***P* Value**
Preoperative	61	3.6 (1.1)	76	3.6 (0.94)	0.9
Postoperative Month 1	61	0.51 (1.1)	76	0.29 (0.92)	0.1
Postoperative Month 3	61	1.2 (1.5)	72	0.57 (1.0)	0.02
Postoperative Month 6	50	1.2 (1.4)	57	0.98 (1.5)	0.3
Postoperative Month 9	36	1.1 (1.5)	44	1.3 (1.6)	0.8
Postoperative Month 12	26	1.8 (1.6)	29	0.90 (1.4)	0.02

SD = standard deviation.

Mean number of glaucoma medications in the closed and open group at preoperative and subsequent postoperative visits. Wilcoxon rank-sum tests used for comparison of means between closed and open conjunctiva groups.

Table 5.

Intraoperative Features between Closed and Open Groups

	Closed Group	Open Group	*P* Value
MMC Dose Mean (SD)	54.0 μg (19.9)	49.1 μg (14.6)	0.1*
20–39 μg	1 (2%)	2 (3%)	-
40–60 μg	36 (61%)	60 (86%)	-
>60 μg	22 (37%)	8 (11%)	-
Concurrent Phacoemulsification	17 (27%)	15 (19%)	0.2†

MMC = mitomycin-C; SD = standard deviation.

Mean (in μg) and SD of MMC dose administered before XEN45 implantation for the closed and open groups. The number of eyes that underwent concurrent phacoemulsification in each group is also shown.

Table 6.

Postoperative Interventions and Adverse Events

	Closed Group n = 61	Open Group n = 76	*P* Value
Bleb Interventions			
Needling	22 (36.1%)	9 (11.8%)	<0.001
1 needling	21	7	
≥2 needling	2	1	
Subsequent Surgery			
Operative bleb revision	4 (6.6%)	0	0.02
Overall	18 (30%)	14 (18%)	0.1
Trabeculectomy	4 (6.6%)	5 (6.6%)	0.9
Glaucoma tube shunt	6 (9.8%)	4 (5.3%)	0.3
Other glaucoma surgery	6 (9.8%)	3 (3.9%)	0.2
Cataract extraction	2 (3.3%)	2 (2.6%)	0.8
Postoperative Complications			
Transient hyphema	0	5 (6.6%)	0.05
POD 1 IOP spike >10 mmHg	1 (1.6%)	1 (1.3%)	0.9
Choroidal effusion	2 (3.3%)	7 (9.2%)	0.2
Conjunctival Erosion/implant exposure	3 (4.9%)	0	0.05
Iris plugging stent	8 (13.1%)	1 (1.3%)	0.005
Blebitis/endophthalmitis	0	0	-

IOP = intraocular pressure; POD = postoperative day.

The number of eyes that underwent postoperative interventions and had complications in each group are represented.

Chi-square tests used for comparing postoperative events between closed and open conjunctiva groups.