Comparison of Early Results of Stand-alone XEN Gel Stent Implantation to Treat Pseudoexfoliative Glaucoma and Primary Open-angle Glaucoma

Ali OLGUN[1], Eyup DUZGUN[2], Fatih ATMACA[3], Hakan KACAR[4], Murat KARAPAPAK[5], Melih USTAOGLU[6], Selam Yekta SENDUL[7], Dilek GUVEN[8]

ABSTRACT

Purpose: To compare the postoperative outcomes of stand-alone XEN45® Gel Stent implantation in patients with pseudoexfoliative glaucoma (PEXG) and primary open-angle glaucoma (POAG).

Materials and Methods: This study included 69 eyes of 46 patients with POAG and 26 eyes of 17 patients with PEXG who had undergone XEN45® stent implantation. The inter- and intra-group changes in mean intraocular pressure (IOP), glaucoma medication requirements, needling rate, incidence of adverse effects, and success rate were analyzed.

Results: There was no significant intergroup difference in the mean IOP (p=0.326) or number of antiglaucoma medications (p=0.450) preoperatively. Both groups showed a significant decrease in IOP and antiglaucoma medication usage at all postoperative time points, relative to the preoperative values. However, there was no significant intergroup difference in the mean IOP or number of medications at any postoperative endpoint. In the POAG group (n=37) the mean preoperative IOP was 23.10±3.90 mmHg, with an average of 3.32±0.47 medications being used; these values decreased to 13.27±1.74 mmHg (42.5% decrease) and 0.70±1.24 (78.9% decrease) after 12 months of postoperative follow-up, respectively. Similarly, the mean IOP and number of medications used in the PEXG group (n=11) decreased from 22.63±3.23 mmHg and 3.18±0.60 preoperatively to 13.00±2.61 mmHg (42.5% decrease) and 1.27±1.49 (60% decrease) at 12 months postoperatively, respectively.

Conclusion: In our study, stand-alone XEN® Gel Stent implantation produced no significant difference in change in IOP or antiglaucoma medication usage between overall patients with POAG and PEXG, However, complete success rate was lower in the PEXG group.

Keywords: Intraocular pressure, Open-angle glaucoma, Outcome assessment, Pseudoexfoliative glaucoma, XEN® gel stent.

INTRODUCTION

Implantation of the XEN45 Gel Stent (Allergan, Dublin, CA, USA), an *ab interno* gelatin stent, is a minimally invasive glaucoma surgery (MIGS) procedure. It allows a safe and efficient reduction of intraocular pressure (IOP) by creating a diffuse outflow of aqueous humor from the anterior chamber into the non-dissected tissue of the subconjunctival space. The XEN45 Gel Stent, in particular, was designed with sufficient length, tube rigidity, and lumen diameter to reduce or eliminate hypotony by providing precisely enough outflow resistance.[1]

The XEN® Gel Stent is indicated for surgical management of refractory glaucoma in patients with primary open-angle glaucoma (POAG) or pseudoexfoliative glaucoma (PEXG) or pigmentary glaucoma with open angles who are unresponsive to the maximum tolerated medical therapy. XEN® Gel Stent implantation is a highly effective and safe option for open-angle glaucoma (OAG) patients with unregulated IOP despite prior medical or surgical intervention.[2-8] It can be performed as a stand-alone procedure or in combination with cataract surgery[5-8]

POAG and PEXG, the most common types of OAG

1- Uz. Dr., Ophthalmology Department of Altunzade Dunya Goz Hospital, İstanbul, Turkey
2- Uz. Dr., Ophthalmology Department of Sisli Hamidiye Eftal Training and Research Hospital, İstanbul, Turkey
3- Uz. Dr., Ophthalmology Department of Altınbas University Hospital Medical Park Bahcelievler, İstanbul, Turkey
4- Uz. Dr., Ophthalmology Department of Viranşehir City Hospital, Sanliurfa, Turkey
5- Uz. Dr., Ophthalmology Department of Basaksehir Cam and Sakura Hospital, Istanbul, Turkey
6- Uz. Dr. Ophthalmology Department of Bursa Training and Research Hospital, Bursa, Turkey
7- Doç. Dr Ophthalmology Department of Sisli Hamidiye Eftal Training and Research Hospital, İstanbul, Turkey
8- Prof. Dr., Ophthalmology Department of Sisli Hamidiye Eftal Training and Research Hospital, İstanbul, Turkey

Received: 06.06.2020
Accepted: 07.01.2021
Glo-Kat 2021; 16:18-25
DOİ: 10.37844/glauc.cat.2021.16.4

Correspondence Adress:
Hakan KACAR
Ophthalmology Department of Viranşehir City Hospital, Sanliurfa, Turkey
Phone: +90 538 450 1001
E-mail: hakankacar@yahoo.com

worldwide, might cause vision loss, especially in cases of late diagnosis and improper treatment.[9] Exfoliation glaucoma is the most common identifiable form of secondary OAG, characterized by the progressive accumulation of pseudoexfoliative fibrillar material on anterior segment tissues, causing both OAG and angle-closure glaucoma.[10] PEXG represents a relatively severe and progressive glaucoma with a generally poor prognosis because of high IOP, fluctuation in the diurnal IOP curve, and a greater resistance to medical therapy than POAG.[11] PEXG has a more serious clinical course than POAG and is associated with common surgical complications, making it one of the more difficult glaucomas to manage.[12]

This study aimed to compare the postoperative outcomes of stand-alone XEN45 Gel Stent implantation in PEXG and POAG patients.

MATERIALS AND METHODS

This prospective comparative cohort outcome study included 69 eyes of 46 patients with POAG and 26 eyes of 17 patients with PEXG who had undergone XEN45 stent implantation between November 2016 and March 2018. The study followed the tenets of the Declaration of Helsinki and was approved by the Sisli Hamidiye Etfal Training and Research Hospital Ethical Committee. All patients provided informed consent for the procedure.

The baseline characteristics included age, sex, best corrected visual acuity (BCVA), IOP (measured by Goldmann applanation tonometry), slit-lamp examination findings of the anterior segment, gonioscopy findings, optic disc and fundus examination findings, lens status, glaucoma type, and history of laser and surgical treatment. Optic nerve status was evaluated by using a 78D lens. Gonioscopy of undilated pupils was performed by using a goniolens in a darkroom. The presence or absence of exfoliation was recorded in dilated pupils. For counting the number of medications, each unique antiglaucoma medication was recorded as one agent. Preoperative IOP was measured on the day the surgeon recommended surgery.

The inclusion criteria for this study were: presence of POAG/PEXG without cataract, already diagnosed and being followed up in our clinic, and failure to reach target IOP despite maximum medication. The exclusion criteria were: shallow anterior chamber; angle-closure glaucoma; ocular inflammatory diseases; pigment disruption; previous ocular trauma resulting in conjunctival scarring or angle recession; and previous incisional procedures (trabeculectomy, tube shunts, and vitrectomy

Complete surgical success was defined by postoperative IOP <18 mmHg achieved without antiglaucoma medication or further surgical intervention except needling within 12 months of follow-up. Qualified success was defined by postoperative IOP <18 mmHg achieved with/without medication and without any secondary intervention except needling.

Surgery

All operations were performed under intracameral anesthesia by the same experienced surgeon (AO) by using a standard technique. After regular preparation and sterile draping of the eyes, the eyelids were opened with an eyelid speculum. The target sector was marked in the upper nasal quadrant with a 3-mm limbal distance. Then, 0.1 mL Mitomycin C (MMC) (0.2 mg/mL) was subconjunctivally injected into the superonasal quadrant, 6 mm from the limbus. A 19G clear corneal incision was made from the temporal limbus, and intracameral anesthesia (1% preservative-free lidocaine) was administered. A 1.6% cohesive viscoelastic (Healon GV®, Advanced Medical Optics, Inc, Santa Ana, CA) was then injected into the anterior chamber.

A XEN® Gel Stent was inserted through the corneal incision by using a preloaded injector with a small 27G needle designed specifically for stent implantation. The injector needle was introduced into the anterior chamber through the inferior temporal incision. The eye was stabilized with a Vera hook placed through the superior temporal incision. The injector needle was then directed across the anterior chamber and inserted through the trabecular angle, after which it was directed in a 3-mm intrascleral route. When the entire bezel was seen under the conjunctiva, the needle was rotated 90°. The implantation sleeve was then removed, and the XEN® Gel Stent was injected and the injector system was removed. The exact internal and external location of the stent was verified, and the anterior chamber was irrigated to ensure flow and bleb formation. Approximately 1 mm of the implant was left in the anterior chamber. Correct stent placement in the angle was verified by using a mirrored gonioscopic lens. After extracting the viscoelastic by using a bimanual irrigation–aspiration system, the anterior chamber was pressurized by injecting balanced salt solution through the sideport while hydrating both incisions. No sutures were needed to seal the wound. A pre-prepared cefuroxime axetil solution (1 mg/0.1 cc) was injected into the anterior chamber. Intraoperative and postoperative adverse events were recorded.

Postoperative protocol

After surgery, the patients were instructed to discontinue all glaucoma medications. They were treated with topical 0.3% ofloxacin for 10 days and 1% prednisolone acetate eyedrops 4 times a day for a month. Postoperative follow-

up was performed at 24 h, 1 week, and 1, 3, 6, and 12 months for assessing the Snellen BCVA, IOP, glaucoma medication usage, anterior segment stent location (Figure 1) and postoperative complications. Additional antiglaucoma medication or needling were administered at the discretion of the surgeon. Bleb needling was performed if a subconjunctival filtering bleb was absent and the IOP exceeded the target IOP. Needling or surgical revision was performed in the operation room and under topical anesthesia, by using a surgical microscope. Bleb revision with Tenon dissection was performed in case of extensive subconjunctival scarring around the implant, presence of a flat bleb with no microcysts, or bleb failure (as determined by the investigator). Neither MMC nor anti-vascular endothelial growth factors were administered during needling or revision surgery.

Statistical analysis

Descriptive statistics are presented as numbers and percentages for categorical variables and as mean, standard deviation, and minimum and maximum values for numerical variables (SPSS 15.0 for Windows). Independent groups were compared by the Student t-test or Mann–Whitney U test when the numerical variables did or did not meet the distribution requirements. Dependent groups were compared by the paired t-test or Wilcoxon test when the differences of the numerical variables did or did not meet the normal distribution requirements. Rates within groups were compared using the chi-square test. The statistical significance level was set at $p<0.05$.

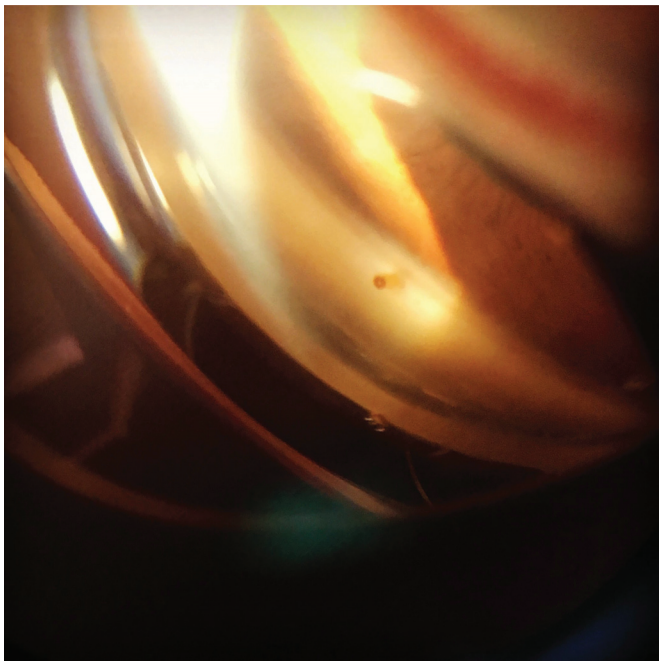

Figure 1: *Anterior segment photography of XEN® Gel Stent.*

RESULTS

This study included 95 eyes of 63 patients. The mean patient ages were 64.0±11.4 (44–82 years) and 68.2±10.0 (50–84 years) years in the POAG and PEXG groups, respectively. Demographic data and baseline characteristics of the study subjects are shown in Table 1. There was no statistically significant intergroup difference in age, sex, lens status, preoperative BCVA, or number of eyes with advanced glaucoma (p=0.220, 0.191, 0.053, 0.802, and 0.680, respectively).

There was no significant intergroup difference in the mean IOP (p=0.326) or number of antiglaucoma medications (p=0.450; Table 2) preoperatively. Both groups showed a significant decrease in IOP and antiglaucoma medication usage at all postoperative time points, relative to the preoperative values. However, there was no significant intergroup difference in the mean IOP or number of medications at any postoperative endpoint (Table 2).

In the POAG group (n=37) the mean preoperative IOP was 23.10±3.90 mmHg, with an average of 3.32±0.47 medications being used; these values decreased to 13.27±1.74 mmHg (42.5% decrease) and 0.70±1.24 (78.9% decrease) after 12 months of postoperative follow-up, respectively. Similarly, the mean IOP and number of medications used in the PEXG group (n=11) decreased from 22.63±3.23 mmHg and 3.18±0.60 preoperatively to 13.00±2.61 mmHg (42.5% decrease) and 1.27±1.49 (60% decrease) at 12 months postoperatively, respectively. At 12 months postoperatively, 31 (64.5%) patients did not require any medication. Among POAG patients, complete success was achieved in 70.2% of the cases and qualified success in 86.4%; the corresponding values in the PEXG group were 45.4% and 81.8%, respectively, within the available 12-month data.

The most common complications overall were slight transient intracameral hemorrhage (25.5%) and conjunctival bleeding (10.5%). On postoperative day 1, 21 eyes (POAG, 13; PEXG, 8) showed small hyphemas, which resolved spontaneously during the early postoperative period, with no long-term consequences. One patient in each group required stent repositioning during surgery for optimizing device positioning. Postoperatively, 21 (30.4%) and 7 (26.9%) eyes in the POAG and PEXG groups, respectively, required bleb needling for further IOP reduction in eyes with bleb failure. There was no significant intergroup difference in needling number (both groups: 1 time per eye; p=0.738) or time (POAG: 1.71±0.96 [1–3 months] months; PEXG: 1 month; p=0.059). There was no significant association between needling and preoperative IOP (p=0.176) or antiglaucoma medication usage (p=0.442).

Table 1: *Demographics and Baseline Ocular Parameters of the Study Population.*

	POAG group	PEXG group	p
Number of eyes / patients (n)	69/46	26/17	
Sex (n,%)			0,191
Male	16 (34,8)	9 (52,9)	
Female	30 (65,2)	8 (47,1)	
Age (yrs, Mean ± SD)	64,0±11,4	68,2±10,0	0,220
Range	44-82	50-84	
Lens status (n,%)			0,053
Phakic	62 (90)	19 (73)	
Pseudophakic	7 (10)	7 (27)	
Preoperative BCVA (LogMAR, Mean±SD)	0,62±0,37	0,68±0,29	0,802
Range	0,05-1	0,05-1	
Preoperative IOP (mmHg, Mean±SD)	23,68±3,60	24,85±4,44	0,326
Range	18-35	20-35	
Preoperative medications (n,Mean±SD)	3,28±0,45	3,35±0,56	0,450
Range	3-4	2-4	
Cup-to-disc ratio(Mean± SD)	0,64±0,18	0,69±0,22	0,198
Advanced glaucoma (n,%)	26 (37,7)	11 (42,3)	0,680

POAG: primary open-angle glaucoma; PEXG: pseudoexfoliative glaucoma, **logMAR:** logarithm of the minimum angle of resolution, **SD:** standard deviation, **IOP:** Intraocular pressure

Table 2: *Comparison of the IOP and the number of glaucoma medications between POAG group and PEXG group.*

	POAG group				PEXG group				
	n	**Mean.±SD**	**ΔMean±SD**	**p***	**n**	**Mean±SD**	**ΔMean±SD**	**p***	**p ****
Preoperative									
IOP	69	23,68±3,60			26	24,85±4,44			0,326
Medication	69	3,28±0,45			26	3,35±0,56			0,450
1 day									
IOP	69	8,55±3,01	15,13±4,54	<0.001	26	8,77±3,05	16,08±5,22	<0,001	0,746
Medication	69	0,00±0,00	3,28±0,45	<0.001	26	0,00±0,00	3,35±0,56	<0,001	1,000
1 week									
IOP	69	10,93±3,01	12,75±4,66	<0.001	26	12,19±4,32	12,65±6,50	<0,001	0,088
Medication	69	0,10±0,39	3,17±0,64	<0.001	26	0,00±0,00	3,35±0,56	<0,001	0,161
1 month									
IOP	69	14,03±5,10	9,65±5,47	<0.001	26	15,00±5,04	9,85±7,85	<0,001	0,215
Medication	69	0,59±1,09	2,68±1,13	<0.001	26	0,69±1,19	2,65±1,35	<0,001	0,730
3 months									
IOP	69	13,75±4,37	9,93±5,28	<0.001	26	13,31±2,45	11,54±5,01	<0,001	0,550
Medication	69	0,57±1,09	2,71±1,15	<0.001	26	0,58±1,10	2,77±1,21	<0,001	0,982
6 months		23.56±3.72				24.21±3.76			
IOP	58	13,38±4,11	10,19±5,47	<0.001	19	13,63±2,31	10,58±4,41	<0,001	0,328
Medication	58	0,60±1,09	2,69±1,01	<0.001	19	0,89±1,37	2,53±1,47	<0,001	0,432
12 months		23.10±3.90				22.63±3.23			
IOP	37	13,27±1,74	9,84±3,86	<0.001	11	13,00±2,61	9,64±4,06	0,003	0,764
Medication	37	0,70±1,24	2,62±1,16	<0.001	11	1,27±1,49	1,91±1,22	0,007	0,219

*Wilcoxon Test, **Mann Whitney U test, Δ Reduction according to preoperative values, **n:** number of cases remaining after survival accounted for at each endpoint, **IOP:** Interocular pressure, **POAG:** primary open-angle glaucoma, **PEXG:** pseudoexfoliative glaucoma

Table 3: *Ocular Adverse Effects.*

	Total (n)	POAG (n)	PEXG (n)
Transient intracameral hemorrhage	25	15	10
Conjunctival bleeding	10	7	3
Hyphema	21	13	8
Vitreous hemorrhage	0	0	0
Suprachoroidal hemorrhage	0	0	0
Hypotony (IOP <5 mmHg)	4	4	0
Corneal decompensation	0	0	0
Macular edema	0	0	0
Blocked microstent	1	1	0
Stent exposure	1	0	0
Shallow anterior chamber	0	0	0
Leak/dehiscence	0	0	0
Revision surgery for hypertrophic bleb	1	0	1
Trabeculectomy	9	6	3
Retinal detachment	0	0	0
Endophthalmitis	2	2	0

POAG: primary open-angle glaucoma, **PEXG:** pseudoexfoliative glaucoma, **IOP:** Interocular pressure.

Within 5 days postoperatively, 4 eyes in the POAG group showed an IOP of 3–4 mmHg. In the PEXG group, one of the eyes which required revision surgery for a hypertrophic bleb achieved the target IOP; nevertheless, this case was considered unsuccessful. In 6 (8.6%) and 3 (11.5%) cases in the POAG and PEXG groups, respectively, trabeculectomy was performed because the eyes failed to achieve the target IOP despite needling. In a case that was considered unsuccessful, the IOP was brought under control after administering a tissue plasminogen activator to resolve stent-lumen occlusion due to thrombosis. Two eyes in the POAG group required vitrectomy because of endophthalmitis due to stent exposure and blepharitis. There was no incidence of sustained hypotony, choroidal effusion or hemorrhage, corneal alteration, or wound leakage.

DISCUSSION

XEN® Gel Stent implantation uses a quick and minimally invasive procedure to achieve a sustained decrease in IOP without conjunctival tissue disruption and minimize early hypotony as well as the complications of traditional glaucoma surgery.[7] The procedure was initially recommended for treating mild to moderate glaucoma and relatively contraindicated for pigmentary, pseudoexfoliation, or uveitic glaucoma. Pigment granules and pseudoexfoliative material might accumulate in the tube lumen, causing diminished outflow or obstruction. However, subsequent clinical studies have reported successful results in PEXG and pigmentary, uveitic, and neovascular glaucomas as well as in patients with previous glaucoma surgery.[2,13-15] However, there is insufficient information on the outcomes of XEN® implantation in different OAG types and its superiority against other MIGS techniques.

Although POAG and PEXG have many common characteristics, they vary in their responsiveness to medical or surgical treatments. Certain large series studies have reported no difference in the success of trabeculectomy in POAG and PEXG patients, whereas some studies have reported differences.[16-18] Variation in trabeculectomy outcomes may be attributed to differences in patient population, surgical techniques, follow-up times, and success criteria.[16] The current study enrolled POAG and open-angle PEXG patients to comparatively evaluate the effects of XEN® implantation surgery on IOP and medication usage. In the PEXG group, stand-alone XEN® stent implantation produced a significant decrease in mean IOP at all postoperative endpoints. Both groups showed a 42.5% decrease in IOP, and there was a 78.9% and 60% decrease in medication usage in the POAG and PEXG groups at the 12-month follow-up, respectively. At 12 months postoperatively, 70.2% and 45.4% of eyes in the POAG and PEXG groups achieved an IOP <18 mmHg without medication, respectively.

The POAG and PEXG groups showed a significant decrease in glaucoma medication usage (78.9% and 60%, respectively) at 12 months postoperatively, with 64.5% of the eyes requiring no medication; these results are comparable to those of previous studies. Unlike other MIGS, the XEN® stent can avoid the need for IOP-lowering medications.[7,13] Although PEXG patients used a greater number of medications than POAG patients, the difference was not statistically significant (p=0.219). However, the greater medication usage in the PEXG group caused its complete success rate to be lower than that of the POAG group. However, the qualified success rates, in which medication usage was not considered, were similar for both groups.

IOP changes after cataract surgery can vary among different glaucoma types. In POAG and PEXG, uncomplicated phacoemulsification and posterior chamber intraocular lens implantation alone can decrease IOP as well as the need for antiglaucoma drugs.[19-21] Previous studies have reported a greater IOP decrease in PEXG than in POAG after cataract surgery.[22] Therefore, in order to remove the secondary contribution of cataract surgery, this study included only those eyes that had undergone XEN® implantation.

Previous studies involving POAG and/or PEXG treatment with XEN® implantation combined with cataract surgery have reported an IOP decrease of 29.3-41.8%, with success rates of 80-90%. The difference in IOP decrease and success rates between the present and previous studies might be related to the use of combined surgery .[7,8]

In a retrospective case-series study, PEXG patients (n=21) who underwent XEN45 implantation with MMC showed a 27.3% and 41.7% decrease in IOP and antiglaucoma medication usage a year after surgery.[14] Another study. reported an IOP decrease of about 30% in POAG and PEXG patients and showed that XEN® stent implantation (stand-alone or combined) shows similar efficacy and safety in treating POAG and PEXG.[15] However, these two studies evaluated the stand-alone and combined (with cataract surgery) procedures of XEN® implantation together. Their IOP decrease rates were lower than those observed in our study, which might be because of the higher preoperative rates in our study.

A previous study. reported similar success rates for XEN® Gel Stent implantation with or without cataract surgery in OAG patients.[6] However, after subgroup analysis, the authors recommended XEN® stent implantation combined with cataract surgery for increasing therapeutic success in PEXG cases. Another study that observed similar success rates for both surgical methods reported a greater IOP decrease in the stand-alone XEN® group.[5] However, owing to the higher baseline IOP, medication usage, and needling rate in the stand-alone group, this result does not reflect real-life clinical experiences.

The IOP decrease rates in studies involving XEN45 vary between 27% and 53%.[14,23] However, owing to differences in study protocols and populations (including differences in OAG type and preoperative IOP), it is difficult to compare the differences in IOP decrease or success rates among these studies. The greater postoperative decrease in IOP and medication usage in our study might be attributable to the inclusion of advanced glaucoma cases with high preoperative IOP as well as our low rates of target IOP.

Since XEN45 stent implantation does not require conjunctival dissection, the outflow pathway is frequently occluded with Tenon's fascia or subconjunctival fibrosis after surgery. To increase the likelihood of success, the bleb is usually injected with antifibrotic agents or treated with MMC-saturated sponges by opening the conjunctiva in similar manner as in trabeculectomy.[4] To this end, our study most frequently employed subconjunctival injection of MMC. However, a significant proportion of cases require needling or bleb revision with or without MMC to achieve a functioning bleb. Needling of a failed bleb is widely considered as a part of the postoperative management regimen of XEN® surgery and not as an adverse event or secondary glaucoma intervention.[2-5] However, some researchers have suggested that, since needling would not affect the scar tissue, scar-removal revision surgery by opening the conjunctiva would be more effective for obtaining a functioning bleb.[13] In the current study, 30.4% and 26.9% of eyes in the POAG and PEXG groups required bleb needling for further IOP reduction. The present needling rates are comparable to those reported previously.(32–37%).[2-4,13,15] All needling procedures in our study were performed in the early postoperative phase, (between month 1 and 3) in the POAG group; in the PEXG group, 7 patients required needling during postoperative month 1. There was no significant intergroup difference in needling rate (p=0.738) or timing (p=0.059). A previous study.[2)] reported similar a needling rate (27.7%) and time (within month 3 postoperatively) over a 12-month follow-up. However, some studies have also reported needling or revision surgery after 3 months.[5,13]

The XEN® Gel Stent has been more recently introduced into clinical practice than other MIGS procedures. Unlike other MIGS techniques, the XEN® gel implant has shown good results, including postoperative IOP control with the potential to avoid the need for medications and a risk of complications comparable to that of trabeculectomy.[3] Although the XEN45 stent shows promise for glaucoma treatment, it has some limitations and complications.

There was a low incidence of postoperative hypotony (<5 mmHg), which resolved without intervention. However, in the POAG group, 2 eyes experienced severe vision loss because of endophthalmitis.[24] Although XEN® stent implantation is a MIGS technique, it should be borne in mind that it can cause severe complications such as hypotony, suprachoroidal hemorrhage, and endophthalmitis.[24-27]

Our study was limited by the small number of patients in the PEXG group. Because our center is a tertiary hospital, some patients stopped visiting for follow-up after 6 months, which decreased the number of patients with a 12-month follow-up. Although all operations were performed by the same surgeon, decisions on onset of medication, needling, and second surgery were made mutually by the patients and specialist and, therefore, lacked standardization. Additionally, we did not record irrigation volumes. Since we did not include patients with complex cataract surgery or closed-angle/pigmentary glaucoma with PEXG, our results might not be generalizable to all PEXG cases.

In conclusion, XEN® implantation for POAG and PEXG can effectively decrease the IOP and medication usage. MMC-augmented stand-alone XEN® Gel Stent implantation produced no significant difference in change in IOP or antiglaucoma medication usage between patients with POAG and PEXG. However, complete success rate was lower in the PEXG group. The XEN® Gel Stent offers a viable alternative to standard filtration surgery for POAG and PEXG treatment. However, the risk-benefit ratio has to be carefully weighed and discussed with the patient. Patients should be informed about the probable need for antiglaucoma medications, needling, or a second surgical intervention. Well-designed randomized clinical trials with extended follow-up remain necessary for evaluating the long-term efficacy and late complications of XEN® implantation in different types of OAG.

ACKNOWLEDGEMENT

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Informed Consent

All patients provided informed consent for the procedure.

REFERENCES:

1. Lewis RA. Ab interno approach to the subconjunctival space using a collagen glaucoma stent. J Cataract Refract Surg. 2014;40:1301-6.
2. Hengerer FH, Kohnen T, Mueller M, et al. Ab interno gel implant for the treatment of glaucoma patients with or without prior glaucoma surgery: 1-year results. J Glaucoma. 2017;26:1130-36.
3. Schlenker MB, Gulamhusein H, Conrad-Hengerer I, et al. Efficacy, safety, and risk factors for failure of standalone ab interno gelatin micro stent implantation versus standalone trabeculectomy. Ophthalmology. 2017;124:1579-88.
4. Grover DS, Flynn WJ, Bashford KP, et al. Performance and Safety of a New Ab Interno Gelatin Stent in Refractory Glaucoma at 12 Months. Am J Ophthalmol. 2017;183:25-36.
5. Mansouri K, Guidotti J, Rao HL, et al. Prospective Evaluation of Standalone XEN Gel Implant and Combined Phacoemulsification-XEN Gel Implant Surgery: 1-Year Results. J Glaucoma. 2018;27:140-7.
6. Hohberger B, Welge-Lüßen UC, Lämmer R. MIGS: therapeutic success of combined XEN Gel Stent implantation with cataract surgery. Graefes Arch Clin Exp Ophthalmol. 2018;256:621-5.
7. Pérez-Torregrosa VT, Olate-Pérez Á, Cerdà-Ibáñez M, et al. Combined phacoemulsification and XEN45 surgery from a temporal approach and 2 incisions. Arch Soc Esp Oftalmol. 2016;91:415-21.
8. De Gregorio A, Pedrotti E, Russo L, et al. Minimally invasive combined glaucoma and cataract surgery: clinical results of the smallest ab interno gel stent. Int Ophthalmol. 2018;38:1129-34.
9. Anastasopoulos E, Founti P, Topouzis F. Update on pseudoexfoliation syndrome pathogenesis and associations with intraocular pressure, glaucoma and systemic diseases. Curr Opin Ophthalmol. 2015;26:82-9.
10. Ritch R. Exfoliation syndrome-the most common identifiable cause of openangle glaucoma. J Glaucoma 1994; 3:176-7.
11. Ritch R, Schlötzer-Schrehardt U, Konstas AG. Why is glaucoma associated with exfoliation syndrome? Prog Retin Eye Res. 2003;22:253-75.
12. Conway RM, Schl€otzer-Schrehardt U, K€uchle M, et al. Pseudoexfoliation syndrome: pathological manifestations of relevance to intraocular surgery. Clin Exp Ophthalmol 2004; 32:199-210
13. Widder RA, Dietlein TS, Dinslage S, et al. The XEN45 Gel Stent as a minimally invasive procedure in glaucoma surgery: success rates, risk profile, and rates of re-surgery after 261 surgeries. Graefes Arch Clin Exp Ophthalmol. 2018;256:765-71.
14. Ibáñez-Muñoz A, Soto-Biforcos VS, Chacón-González M, et al. One-year follow-up of the XEN® implant with mitomycin-C in pseudoexfoliative glaucoma patients. Eur J Ophthalmol. 2019;29:309-14.
15. Mansouri K, Gillmann K, Rao HL, et al. Prospective evaluation of XEN gel implant in eyes with pseudoexfoliative glaucoma. J Glaucoma. 2018;27:869-73.
16. Ehrnrooth P, Lehto I, Puska P, et al. Long-term outcome of trabeculectomy in terms of intraocular pressure. Acta Ophthalmol Scand 2002; 80:267-71.
17. Pelitli Gürlü V, Güçlü H, Özal A, et al. Comparison of long-term results of trabeculectomy to treat pseudoexfoliative glaucoma and primary open angle glaucoma. Int J Ophthalmol. 2018: 18;11:66-70.

18. Mietz H, Raschka B, Krieglstein GK. Risk factors for failures of trabeculectomies performed without antimetabolites. Br J Ophthalmol 1999;83:814-21.

19. Chen PP, Lin SC, Junk AK, et al. The effect of phacoemulsification on intraocular pressure in glaucoma patients: a report by the American Academy of Ophthalmology. Ophthalmology 2015;122:1294-307.

20. Shrivastava A, Singh K. The effect of cataract extraction on intraocular pressure. Curr Opin Ophthalmol. 2010;21:118-22.

21. Hayashi K, Hayashi H, Nakao F, et al. Effect of cataract surgery on intraocular pressure control in glaucoma patients. J Cataract Refract Surg. 2001;27:1779-86.

22. Damji KF, Konstas AGP, Liebmann JM, et al. Intraocular pressure following phacoemulsification in patients with and without exfoliation syndrome: a 2 year prospective study. Br J Ophthalmol 2006; 90:1014-8.

23. Ozal SA, Kaplaner O, Basar BB, et al. An innovation in glaucoma surgery: XEN45 gel stent implantation. Arq Bras Oftalmol. 2017;80:382-5.

24. Olgun A, Imamoğlu S, Karapapak M, et al. Endophthalmitis After XEN Gel Stent Implantation: 2 Cases. J Glaucoma. 2018; 27:e191-e194.

25. Karri B, Gupta C, Mathews D. Endophthalmitis Following XEN Stent Exposure. J Glaucoma. 2018;27:931-3.

26. Prokosch-Willing V, Vossmerbaeumer U, Hoffmann E, et al. Suprachoroidal Bleeding After XEN Gel Implantation. J Glaucoma. 2017;26:e261-e263.

27. Bruynseels A, Sii F, Masood I, et al. Severe Intraocular Pressure Elevation After Intracameral Healon 5 Viscoelastic Support for Postoperative Hypotony After XEN Gel Stent Insertion. J Glaucoma. 2018 ;27:e75-e76.