2-Year Follow-up Results in XEN Glaucoma Implant Patients

Yusuf AYAZ[1], Elif Betul TURKOGLU[2], Berkay Oner KARACA[3], Iclal YUCEL[4], Mustafa UNAL[4]

ABSTRACT

Purpose: The aim of this study is to evaluate the effect of XEN implant surgery on postoperative intraocular pressure (IOP) reduction and complications related with the surgery 2-year follow-up results in our clinic.

Materials and Methods: A total of 11 eyes of 10 patients with primary open angle glaucoma who underwent XEN implant (Allergan, Dublin, Ireland) surgery were retrospectively analyzed. Patients who included in the study; 5 were female and 5 were male. The mean follow-up time was 29±2.1 months. IOP values were examined at the postoperative 1st day, 1st month, 6th month, 12th month and 24th month controls. Complete success criterion defined as IOP values between 6-21 mmHg without using topical antiglaucomatous medication while qualified success criterion was using topical antiglaucomatous agents and having the same IOP values.

Results: Seven eyes (63,6%) met the complete success criteria and In 10 eyes, it was seen that qualified success criteria were met in the first year. While 7 eyes (63.6%) achieved complete success in the second year controls; the number of eyes that meet the qualified success criteria was again determined as 10 (90.9%). Intraoperative hemorrhage and postoperative hyphema were observed in two eyes. Anterior chamber lavage was applied to one of the eyes with hyphema.

Conclusion: XEN implant surgery is a safe and effective surgery in terms of IOP reduction and reduction in topical drug use up to 2 years postoperatively.

Key Words: Glaucoma, Minimally invasive glaucoma surgery, XEN implant, Topical antiglaucomatous.

INTRODUCTION

Treatment protocols vary in glaucoma patients who are refractory to medical therapy. Besides topical and systemic anti-glaucomatous agents, treatment options include selective laser trabeculoplasty and argon laser trabeculoplasty.[1] Surgical procedures are considered if intraocular pressure, only modifiable factor in glaucoma progression, can not be controlled despite above-mentioned treatments.

Although trabeculectomy is accepted as gold standard approach in the surgical treatment of glaucoma, presence of vision-threatening complications has promoted to seek novel surgical techniques. Today, minimal invasive glaucoma surgeries (MIGSs), commonly used in cases with mild and moderate glaucoma, include techniques aiming IOP reduction with less scleral dissection and conjunctival trauma.[2] In these procedures, it is aimed to ensure rapid recovery and lower complication rates. In a meta-analysis by Lavia et al., it was reported that MIGSs provide acceptable reduction in IOP with less anti-glaucomatous treatment need, lower complication rates and rapid recovery.[3]

The XEN gel stent (6 mm in length) is a micro-implant (Allergan, Dublin, Ireland) that is composed of glutaraldehyde and toughened collagen, and allows humor aqueous flow at a rate of 2-2.5 ml/min.[4] The XEN implant ensures humor aqueous flow to subconjunctival area from anterior chamber when inserted to angle by corneal micro-incision. Although it is not opened in conjunctiva, there is a bleb formation as similar to trabeculectomy and anti-metabolit is recommended to promote external tissue healing.[5] It has advantages against trabeculectomy including shorter duration of procedure, less tissue injury and lower hypotonia incidence.

1- Specialist, MD, Ophthalmology Department, Akdeniz University Hospital, Antalya, Turkey

2- Associate Professor, MD, Ophthalmology Department, Akdeniz University Hospital, Antalya, Turkey

3- MD, Ophthalmology Department, Akdeniz University Hospital, Antalya, Turkey

4- Professor MD, Ophthalmology Department, Akdeniz University Hospital, Antalya, Turkey

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Correspondence Adress:
Yusuf AYAZ
Ophthalmology Department, Akdeniz University Hospital, Antalya, Turkey
Phone: +90 242 249 6640
E-mail: yusufayaz_01@hotmail.com

In a retrospective, multicenter study, Schlender et al. compared 169 cases underwent trabeculectomy and 185 cases underwent XEN implantation and reported that there was no marked difference in efficacy, safety and adverse events between groups, emphasizing that micro-implant can be an alternative to trabeculectomy.[6]

In this study, it was aimed to address effectiveness of XEN implant surgery in lowering postoperative IOP and surgery-related complications at 2-year follow-up.

MATERIALS AND METHODS

In this study, we retrospectively reviewed 11 eyes of 10 patients underwent XEN implant surgery for primary open-angle glaucoma without pseudoexfoliation and pigment dispersion at Ophthalmology Department of Akdeniz University, Medicine School between December, 2016 and June, 2017.There was no history of preoperative surgery. The study was approved by Ethics Committee on Clinical Research of Akdeniz University.

Patients aged>40 years, those could not tolerate topical anti-glaucomatous agents, those with hyperemic conjunctiva due to drug allergy, those with incompliance to topical treatment, patients with IOP between 15 and 26 mmHg despite 2 or 3 agents, and those with mild (MD<-6dB) and moderate (MD<-12dB; losses up to arcuate scotoma) glaucoma findings were included to the study.

Patients with angle-closure glaucoma, pseudoexfoliation, congenital glaucoma, neovascular glaucoma or uveitic glaucoma, aphakic patients, patients with advanced glaucoma, one-eyed patients and patients with history of glaucoma were excluded.

In all patients, preoperative visual acuity, IOP measurement by Goldmann applanation tonometry, anterior segment examination, optical coherence tomography (OCT) analysis (macula and optic nerve), gonioscopy, corneal pachymetry, visual field examination and fundus examination were performed.

Minimum follow-up was 2 years in all cases. Mean follow-up time was 29.0±2.1 months. The IOP values were measured using Goldmann applanation tonometry on day 1 and at months 1, 6, 12 and 24. The complications were documented by anterior segment imaging. All surgical procedures were performed by a single surgeon (I.Y.). After administration of subconjunctival mitomycin C injection (0.2 mg/ml, 0.1 cc) to superior nasal quadrant at 4-5 mm posterior to limbus under topical anesthesia, the area 3 mm posterior to limbus was marked. At contralateral site, a clear corneal incision was performed using MVR knife (Bausch & Lomb, Tampa, FL, USA) at inferior temporal quadrant. After injection of cohesive viscoelastic, the syringe was moved to palm; the injector was passed to anterior chamber and advanced with an angle. Using gonioscopy, injector was anchored to angle through posterior margin of pigmented trabeculum and advanced. When tip of syringe was observed completely under conjunctiva at area marked on 3 mm, angled needle tip was rotated and implant was injected. Viscoelastic substance was removed. Access sites were closed using stromal hydration.

All topical anti-glaucomatous agents used previously were withdrawn after surgery. During postoperative week 2, topical antibiotic moxifloxacin (Vigamox, 05%, ophthalmic solution, 5 ml, Alcon Laboratories) were given 5 times per day. Topical dexamethasone (Maxidex, 0.1 mg/5 ml, ophthalmic solution, Alcon Laboratories) was given for 2 months after surgery with gradual decrements (12x 1 in first day; 6x1 in first week; 4x1 up to first month; 2x1 up to month 2).

The criteria for complete success included IOP values of 6-21 mmHg without postoperative topical anti-glaucomatous agent while qualified success criteria included IOP values of 6-21 mmHg with topical anti-glaucomatous agent use.

Statistical analysis

Data were analyzed using SPSS version 25.0. Categorical measurements are summarized as count and percent while continuous measurements as mean and standard deviation or median and minimum-maximum if needed. Numeric variables were compared using Wilcoxon signed rank test, Friedman's two-way analysis of variance and Kaplan-Meier survival. A p value<0.05 was considered as statistically significant.

RESULTS

Of 10 patients included, 5 were women while 5 were men. Mean age was 66.1±8.1 years (53-76 years). All cases were phakic. Mean duration of preoperative drug use was 10.5 years.

Table 1 presents change in preoperative and postoperative IOP values and decrease in number of anti-glaucomatous drugs. Table 2 summarizes percent decrease in postoperative IOP values.

Mean preoperative IOP value was 21.5±4.3 mmHg (15-26 mmHg) while mean number of drugs was 2.7±0.4 at preoperative period. Mean IOP value was13.7±4.8 mmHg

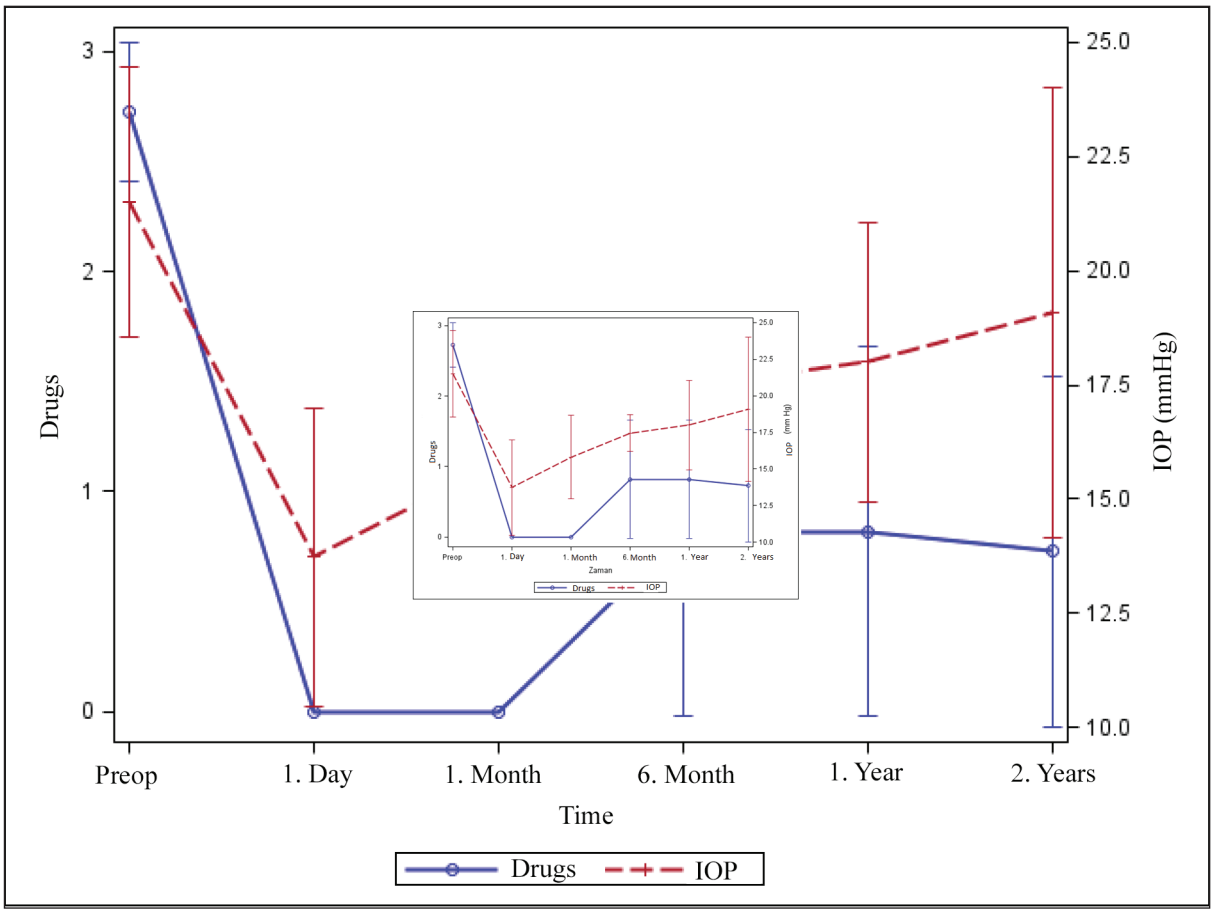
Table 1. *Change in intraocular pressure and antiglaucomatous use over time.*

	Number of drugs			Pressure			Change		
	N	Mean	SD	N	Mean	SD	N	Mean	Ss
Time									
Preop[1]	11	2.73	0.47	11	21.51	4.37	11	0.34	0.23
Day[2]	11	0.00	0.00	11	13.73	4.86	11	0.22	0.28
Month 1[3]	11	0.00	0.00	11	15.82	4.24	11	0.16	0.17
Month[4]	11	0.82	1.25	11	17.45	1.86	11	0.14	0.24
Year 1[5]	11	0.82	1.25	11	18.00	4.56	11	0.09	0.32
Year 2[6]	11	0.73	1.19	11	19.09	7.34			
Z / p	13.82		0.0001	3.41		0.0089	1.64		0.1783
Comparison	1>4,5,6>2,3			1,6>5,4>3,2					

Table 2. *Percentage decrease as intraocular pressure over time*

Percent IOP reduction	%
Postoperative day 1, percent IOP reduction	34.2
Postoperative month 1, percent IOP reduction	22.3
Postoperative month 6, percent IOP reduction	16.1
Postoperative year 1, percent IOP reduction	13.6
Postoperative year 2, percent IOP reduction	9.2

on day 1 and 15.8±4.2 mmHg on month 1 after surgery. None of the patients required topical anti-glaucomatous treatment in control visits on day 1 and at month 1. On control visit on month 6, mean IOP was 17.4±1.8 mmHg and 4 patients required topical anti-glaucomatous agent (mean number of drug. 0.8±1.2). On control visit on month 12, mean IOP was 18.0±4.5 mmHg and 4 patients required topical anti-glaucomatous agent (mean number of drug 0.8±1.2). In control visits during first year, mean IOP



Graphic. *Intraocular pressure and antiglaucoma usage change over time.*

was measured as 19.1±7.3 mmHg and 4 patients required topical anti-glaucomatous agent (mean number of drug 0.7±1.1). No patient required additional glaucoma surgery up to postoperative year one while one eye required trabeculectomy surgery at the end of year one since IOP was measured as 30 mmHg despite use of 3 anti-glaucomatous agents. In the control visits during second year, IOP was measured as 40 mmHg in the same patient despite use of 3 anti-glaucomatous agents and a second trabeculectomy was offered to the patient; however, the patient declined second trabeculectomy. It was found that complete success criteria (IOP: 6-21 mmHg without anti-glaucomatous agent use) were fulfilled in 7 eyes (63.6%) while qualified success criteria (IOP: 6-21 mmHg with anti-glaucomatous agent use) were fulfilled in 10 eyes (90.9%) at year one. Again, it was found that complete success criteria were fulfilled in 7 eyes (63.6%) while qualified success criteria were fulfilled in 10 eyes (90.9%) at year two.

During 2-year follow-up, cataract surgery was performed in 3 eyes (approximately one year after XEN implant surgery in 2 eyes and 1.5 years after XEN implant surgery in one eye). No change was detected in postoperative visual acuity in 8 eyes while postoperative visual acuity was improved in 3 eyes due to cataract surgery. In all patients, diffuse bleb appearance was present at postoperative period.

Hemorrhage was developed in two eyes. Postoperative hyphema was observed in these eyes. No intervention was required in one eye while anterior chamber lavage was performed at postoperative week 1 in the other eye. No needling was required in the patients. In one patient, chronic ocular surface problem and conjunctival irritation were developed in one patients, presumably due to mitomycin C use (Fig. 1).

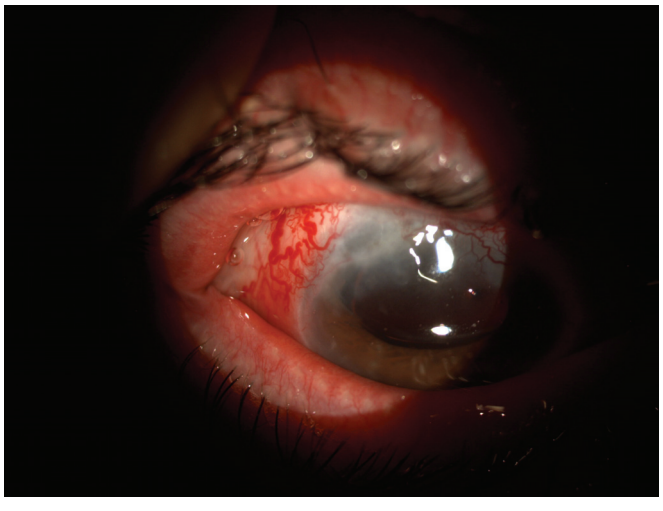


Figure 1: *Chronic ocular surface problem and conjunctival irritation.*

DISCUSSION

The duration of XEN gel implantation is short and it is defined as micro-invasive glaucoma surgery. Preliminary results have been considered as promising in these surgeries. In the literature, it was shown that XEN implant can reduce IOP effectively and decrease need for anti-glaucomatous therapy in the patients.[7-9] Sheybani et al. performed XEN implantation plus phacoemulsification in 37 eyes with mean IOP level of 22.4 mmHg who were using 2.5 topical anti-glaucomatous agents in average and had no history of previous surgery and found that mean IOP level was decreased to 15.4 mmHg while mean number of topical anti-glaucomatous agent was decreased to 0.9 at the end of 12-months follow-up.[7] In another study investigating IOP reduction and anti-glaucomatous agent use after XEN implant in cases with uveitic glaucoma, it was shown that there was IOP reduction by 60.4% and that mean number of topical anti-glaucomatous agent was decreased by 2.7 in average.[8] In a study, it was reported that mean IOP level of 20.8 mmHg at baseline was decreased to 13.1 mmHg while mean number of drugs used was decreased from 2.7 to 0.9 at the end of year one after phacoemulsification plus XEN implantation. In a study by Galal et al., XEN implant surgery was associated with IOP reduction by 23% at the end of year one while mean number of topical anti-glaucomatous agents used was decreased from 1.9 to 0.3. In addition, authors reported complete success rate as 42% and qualified success rate as 66% in the study.[9] In a study by Sheybani et al., XEN 140 was implanted to 49 eyes. Authors reported complete success rate as 40% and qualified success rate as 89% at the end of year one.[10] In a study including 41 eyes of 33 patients, De Gregoria et al. reported that IOP was decreased by 41.8% with complete success rate of 80.4% and qualified success rate of 97.5% at the end of year one.[11] In a study on 30 eyes underwent phacoemulsification plus XEN implant, PerezTorregrosa et al. found a decrease in mean IOP by 29.3% and a decrease in mean number of drugs used by 94.5% at the end of year one.[12] In our case series, significant decreases were observed in mean IOP level and mean number of topical anti-glaucomatous agents used in agreement with literature.

Bleb-related problems and fibrosis may be observed after surgery. Other problems include occlusion of implant secondary to hemorrhage, narrow anterior chamber, bleb leakage, choroid detachment, implant dislocation, exposure due to conjunctival thinning at early postoperative period and cystoid macular edema and endophthalmitis at late postoperative period.[13-15] In a study by Galal et al., it was reported that there was choroidal detachment in 2 eyes and implant exposure in one eye while trabeculectomy surgery was required in 2 eyes due to failure to achieve sufficient

IOP reduction.[9] In the study by De Gregoria et al, it was reported that temporary hyphema was developed in 10 eyes and bleb needling was needed in one eye while there was implant dislocation in one eye, implant occlusion in one eye, hypotonia in one eye and choroidal detachment in one eye.[11] In a study on 30 uveitic eyes, it was found that there was temporary hyphema in 2 eyes, hypotonia in 5 eyes, cataract progression in 3 eyes, endophthalmitis in one eye and need for secondary glaucoma surgery in 4 eyes.[8] In our study, hyphema was developed on postoperative day 1 in 2 eyes while chronic ocular surface problem and chronic conjunctival irritation were developed due to mitomycin C use in one patient.

This study has some limitations including retrospective nature and relatively smaller sample size.

In conclusion, XEN implant was developed as a less invasive and easy to use alternative to trabeculectomy in patients with glaucoma. In the literature, it was demonstrated that this minimal invasive procedure provided IOP reduction and decreased number of topical anti-glaucomatous agents needed. However, there is a scarcity in studies and long-term follow-up outcomes in XEN implant. Further clinical trials can allow more effective use of XEN implant by establishing eligible patient profile. There is a need for randomized studies comparing with other surgical options in order to clearly establish clinical efficacy.

REFERENCES

1. Kennedy JB, SooHoo JR, Kahook MY, et al. Selective laser trabeculoplasty: an update. Asia Pac J Ophthalmol. 2016;5:63-9.
2. Sarıcaoğlu MS. Glokomda yeni cerrahi yaklaşımlar: mikroinvaziv (minimal invaziv) Glokom Cerrahisi. Glo-Kat Dergisi 2015;10:2.
3. Lavia C, Dallorto L, Maule M, et al. Minimally-invasive glaucoma surgeries (MIGS) for open angle glaucoma: a systematic review and meta-analysis. PLoS One. 2017;12:e0183142.
4. R. A. Lewis, "Ab interno approach to the subconjunctival space using a collagen glaucoma stent," Journal of Cataract and Refractive Surgery, 2014, 40, 8, 1301-6.
5. Kerr NM, Wang J, Barton K. Minimally invasive glaucoma surgery as primary stand-alone surgery for glaucoma. Clin Exp Ophthalmol. 2017;45:393-400.
6. Schlenker MB, Gulamhusein H, Conrad-Hengerer I, et al. Efficacy, safety, and risk factors for failure of standalone Ab interno gelatin microstent implantation versus standalone trabeculectomy. Ophthalmology. 2017;124:1579-88.
7. Sheybani A, Lenzhofer M, Hohensinn M, et al. Phacoemulsification combined with a new ab interno gel stent to treat open-angle glaucoma: pilot study. J Cataract Refract Surg. 2015;41:1905-1909.
8. Sng, C. C., Wang, J., Hau, S., et al. XEN-45 collagen implant for the treatment of uveitic glaucoma. Clin Exp Ophthalmol. 2018;46:339-345.
9. Galal, A., Bilgic, A., Eltanamly, et al. XEN Glaucoma implant with mitomycin C 1-year follow-up: result and complications. Journal of Ophthalmology, 2017, 1-5.
10. Sheybani A, Dick B, Ahmed II K. Early clinical results of a novel ab interno gel stent for the surgical treatment of open-angle glaucoma. J Glaucoma. 2016;25
11. De Gregorio A1, Pedrotti E2, 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.
12. Pérez-Torregrosa VT, Olate-Pérez Á, Cerdà-Ibáñez M et al. Combined phacoemulsification and XEN 45 surgery from temporal approach and 2 incision. Arch Soc Esp Oftalmol. 2016;91:415-21.
13. Salinas L, Chaudhary A, Guidotti J, et al. Revision of a leaking bleb with XEN gel stent replacement. J Glaucoma. 2018;27:11-3.
14. Dervenis N, Mikropoulou AM, Dervenis P, et al. Dislocation of a previously successful XEN glaucoma implant into the anterior chamber: a case report. BMC Ophthalmol. 2017;17:148.
15. Lim R, Lim KS. XEN implant-related endophthalmitis. Ophthalmology. 2018;125:209.