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ORIGINAL ARTICLE

Treatment results of standalone XEN-45 implantation in patients with primary and secondary open-angle glaucoma

Meryem Erbey, Mine Esen Baris, Halil Ates, Suzan Guven Yilmaz

Department of Ophthalmology, Ege University Faculty of Medicine, Izmir, Türkiye

Abstract

Purpose: The purpose of this study was to evaluate the treatment results and complications of XEN-45 microstent implantation in open-angle glaucoma.

Methods: In this study, 17 eyes of 17 patients who underwent XEN-45 implantation with 0.2 mg/cc mitomycin-c between June 2016 and February 2018 were retrospectively examined. Pre- and post-operative best-corrected visual acuity (BCVA), intraocular pressure (IOP), number of antiglaucomatous drugs, endothelial cell count (ECC), retinal nerve fiber layer (RNFL) thickness, number of post-operative needlings, and post-operative complications were evaluated.

Results: The mean age of the patients (11 M, 6 F) was 62.6±19.8 (29–94) years and mean follow-up period was 16.8±3.5 (12–21) months. The mean IOP which was 27.6±6.0 (21–40) mmHg before glaucoma surgery decreased significantly to 14.1±3.3 3.4 (8–20) mmHg at the last visit ($p<0.001$). The number of antiglaucomatous drugs was 3.9±0.8 (2–5) preoperatively and 1.7±1.3 (0–3) at the final examination ($p=0.001$). Pre-operative BCVA was 0.78±0.99 LogMAR and 0.8±0.99 LogMAR at the last visit (Wilcoxon test, $p=0.99$). The ECC was 2356.8±533.3 (1635–3275) cells/mm^2 preoperatively and 2338.7±472.7 (1712–3178) cells/mm^2 at the last visit and did not show statistically significant difference ($p=0.470$). The pre- and post-operative RNFL thickness measurements were 61.4±11.8 (43–82) µm and 61.3±11.5 (45–82) µm at the last visit, respectively ($p=0.764$). Needling was required in 4 (23.5%) eyes. Post-operative complications were observed in four eyes (23.5%). In the early post-operative period (≤1 month), shallow anterior chamber and hypotony were detected in 1 eye and were treated medically. As late complications (>1 month), Tenon's cyst in two eyes and fibrotic bleb in one eye were observed.

Conclusion: XEN-45 implant surgery in open-angle glaucoma patients is an effective surgical procedure for IOP control. With preserved visual acuity and ECC, causing no devastating complications, it can also be considered as a very safe option in open-angle glaucoma cases.

Keywords: Glaucoma surgery surgical outcome; open-angle glaucoma; XEN-45 implant.

Glaucoma is the most common cause of irreversible blindness according to the World Health Organization (WHO).[1] It is estimated that 64 million people have glaucoma and half of the patients remain undiagnosed until the advanced stages.[2] The only known modifiable risk factor is elevated intraocular pressure (IOP) and the goal of treatment is to reduce this pressure in various ways.[3] Glaucoma treatment modalities include medical, laser, and surgical treatments.[4]

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Correspondence: Suzan Guven Yilmaz, M.D. Department of Ophthalmology, Ege University Faculty of Medicine, Izmir, Türkiye
Phone: +90 232 390 37 88 **E-mail:** drsuzan2003@yahoo.com
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Trabeculectomy is the most commonly performed glaucoma surgery world-wide. It is cheap and effective for a long time and allows modifications during the surgery. Therefore trabeculectomy is accepted as the gold standard for most glaucoma types. However, its potentially devastating short and long-term complications, including hypotony and bleb-related endophthalmitis, lead to a search for less invasive techniques. Minimally invasive glaucoma surgery (MIGS) offers safer and less invasive ways to reduce IOP compared to conventional surgeries and can often be combined with cataract surgery. MIGS procedures are currently targeted at patients with mild-to-moderate glaucoma.[4]

In general, MIGS procedures are ab interno, micro-incisional and conjunctival-mediated to create minimal tissue trauma, and minimal disruption of normal anatomy and physiology.[5] MIGS provides rapid visual rehabilitation and less dependence on topical treatment, with a decreased risk of complications.

XEN-45 (Allergan Inc., CA, USA) is a hydrophilic, non-inflammatory, soft, collagenous, and minimally invasive implant. The XEN-45 works according to the Hagen–Poiseuille equation, which allows to calculate the resistance to the current through the cylindrical tube. It provides drainage of the aqueous into the subconjunctival space. It swells with hydration and adapts to the surrounding tissue. It prevents the passive resistance to the flow and provides standard flow rate. Indications for use include primary open-angle glaucoma (POAG), pseudoexfoliative glaucoma, pigmentary glaucoma, and conditions where the trabecular meshwork is visible and there is a healthy, free, and mobile conjunctiva in the target area.[6]

The aim of this article is to evaluate the efficacy and complications of the XEN-45 Gel Stent implantation in patients with open-angle glaucoma (OAG).

Materials and Methods

A retrospective chart review was carried out in 17 patients with OAG who underwent XEN-45 Gel Stent implantation in Ege University Faculty of Medicine, Department of Ophthalmology between June 2016 and February 2018. The Ethics Committee approval was obtained from Ege University Ethics Committee for Clinical Research (Approval number: 18-2/42).

Patients

Patients with OAG diagnosis and who have an IOP above the target pressure (>21 mmHg) despite treatment with maximum antiglaucomatous medications were included in the study. Eyes with closed or narrow angles, eyes with fibrotic conjunctiva, and the eyes with a history of prior glaucoma surgery were considered as unsuitable and excluded from the study.

The demographic data, diagnosis, and pre- and post-operative ophthalmological examination findings including best-corrected visual acuity (BCVA), IOP values measured with Goldmann Applanation Tonometer, anterior and posterior segment features, gonioscopy findings, pre- and post-operative antiglaucomatous treatment, endothelial cell counts (ECC) with CEM-530 (Nidek Co, Ltd, Gamagori, Japan), pre- and post-operative optic nerve retinal nerve fiber layer thickness (RNFL) as measured with optical coherence tomography (3D OCT, Topcon, GB Ltd, Newbury, Berkshire, UK), additional post-operative procedures including needling, and post-operative complications were noted and analyzed. Anterior segment photographs were also evaluated.

The surgery results were divided into three groups according to the efficacy in controlling IOP as:

- Total Complete success: Post-operative IOP in the range of 5–21 mmHg without medications,
- Partial success: IOP in the range of 5–21 mmHg with post-operative antiglaucomatous eye drops,
- Failure: IOP >21 mmHg despite treatment with post-operative antiglaucomatous drugs.

Surgical Method

XEN-45 Gel Stent was implanted by two surgeons (HA and SGY). Pre-operative preparation and standard ophthalmic care were applied. A subconjunctival injection of 0.2 mg/cc mitomycin C was made into the upper nasal quadrant. After creating a clear corneal incision from the inferior temporal quadrant, anterior chamber was filled with viscoelastic and implantation was performed using the preloaded injector, through the anterior chamber. The stent entered into the subconjunctival space to a distance of 3 mm from the limbus. The viscoelastic was completely cleaned afterward.

All patients were prescribed tobramycine (Tobrex, Alcon, Belgium) and dexamethasone (Maxidex, Alcon, Belgium) eye drops every 2 h for the post-operative 1st week and 4 times daily for the next 3 weeks.

Patients were evaluated on the 1st and 3rd post-operative days for IOP and for the signs of infection. Data of patients' BCVA, IOP, ECC, and RNFL were extracted from patient files at post-operative 1, 3, 6, 9, 12, and the last visits. Needling was considered in cases where when IOP >21 mmHg was detected despite maximum antiglaucomatous drugs.

Statistical Analysis

IBM SPSS Statistics 25.0 (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.) was used for statistical analysis. The Shapiro–Wilk test was used to confirm that the numerical variables were normally distributed. Wilcoxon signed-rank test was used in the analysis of variables that are not distributed normally and Paired samples t-test was used for normally distributed variables. ANOVA was applied in repeated measurements for the variables, in which periodic controls were made. The statistical significance level was defined as $p<0.05$.

Results

The mean age of 17 patients (11 M, 6 F) included in the study was 62.6±19.8 (29–94) years. Mean post-operative follow-up period was 16.8±3.5 (12–21) months. The cases were followed prospectively for 15 months after XEN-45 Implant. The diagnosis was POAG in 13 eyes (76%), keratoplasty glaucoma (KPG) in three eyes (18%), and angle recession glaucoma (ARG) in one eye (6%) (Table 1). Nine (52.9%) of the eyes were pseudophakic (with posterior chamber intraocular lens), whereas 8 (47.1%) eyes were phakic. The mean pre-operative IOP was 27.6±6.0 (21–40) mmHg, whereas mean post-operative IOP was 16.1±7.2 (8–32) mmHg at the 1st month, 17.2±5.9 (10–32) mmHg at the 3rd month, 16.2±4.7 (10–32) mmHg at the 6th month visits, 15.1±3.2 (10–21) mmHg at the 9th month, 14.1±3.1 (10–18) mmHg at the 12th month, and 14.1±3.4 (8–19) mmHg at the 15th last month visit ($p<0.001$, repeated measures ANOVA). While the number of antiglaucomatous drugs was 3.9±0.8 (2–5) preoperatively, it decreased to 1.7±1.3 (0–3) at the last examination ($p=0.001$). The BCVA was 0.78±0.99 LogMAR preoperatively and 0.8±0.99 LogMAR postoperatively with no significant difference ($p=0.99$). Needling was required twice in one eye and once in four eyes, totally in 5 (29.4%) eyes. Mean time between surgery and needling was 2.2±1.4 (range, 1–5) months and mitomycin C was used during needlings. While the target IOP was reached in three of five patients with needling, IOP was still above 21 mmHg in 2 eyes. In one of these eyes, tube damage occurred during revision and in the other filtering surgery was needed. Trabeculectomy was performed 19 months after XEN-45 implantation. The mean pre-operative ECC was 2356.8±533.3 (1635–3275) cells/mm^2 and 2356.8±527.7 (1642–3284) cells/mm^2 at post-operative 1st month visit, 2308.5±473.3 (1562–3242) cells/mm^2 at 3rd month, 2323.5±498.2 (1514–3212) cells/mm^2 at 6th month, 2294.8±476.9 (1519–3148) cells/mm^2 at 9th month, 2318.2±492.5 (1516–3176) cells/mm^2 at 12th month, and 2346.2±437.6 (1518–2874) cells/mm^2 at the last visit. The differences were not statistically significant ($p=0.470$, repeated measures ANOVA) (Fig. 1). While pre-operative RNFL was 61.4±11.8 (43–82) µm, no significant change was observed at the final follow-up with 61.3±11.5 (45–82) µm ($p=0.764$). Pre-operative and post-operative

Table 1. Demographics and clinical characteristics of patients

Patient	Gender	Age (years)	Diagnosis	Pre-op VA (logMAR)	Pre-op IOP	Pre-op ECC (cells/mm^2)	Pre-op RNFL	Pre-op. glaucoma medications
1.	Female	74	POAG	0.30	22	2246	60	3
2.	Male	87	POAG	1.80	26	–	62	4
3.	Male	72	POAG	3.10	28	–	58	4
4.	Female	53	PKG	1.30	21	3208	56	4
5.	Male	35	POAG	3.10	36	2189	49	4
6.	Female	61	POAG	0.00	22	2696	82	2
7.	Female	29	PKG	0.22	30	1635	48	5
8.	Male	71	POAG	0.15	28	1930	53	5
9.	Male	71	POAG	0.30	40	2728	54	5
10.	Male	62	ARG	0.52	36	2234	76	4
11.	Female	78	POAG	0.00	28	2649	77	4
12.	Male	79	POAG	0.30	26	2356	63	4
13.	Male	36	POAG	0.30	25	3275	76	4
14.	Male	53	POAG	0.15	21	1782	43	3
15.	Male	76	POAG	0.15	21	1710	62	3
16.	Female	94	POAG	0.80	30	–	65	4
17.	Male	33	PKG	0.70	32	–	60	5

ARG: Angle recession glaucoma; ECC: Endothelial cell count; IOP: Intraocular pressure; PKG: Postkeratoplasty glaucoma; POAG: Primary open-angle glaucoma; Preop.: Pre-operative; RNFL: Retina nerve fiber layer; VA: Visual acuity.

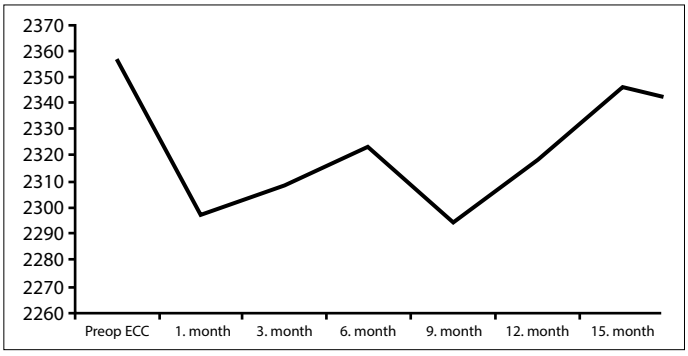

Fig. 1. ECC change of patients with XEN-45 implants.

clinical findings of the study eyes are summarized in Table 2. Post-operative complications were observed in 4 (23.5%) eyes, including shallow anterior chamber and hypotonia hypotony, which improved with medical treatment (topical corticosteroids, dexamethasone eye drops every 2 h) within a week in one eye in the early post-operative period (≤1 month), Tenon's cyst in two eyes, and fibrotic appearance in the bleb in one eye. More serious complications such as choroidal detachment or malignant glaucoma were not observed in any of the eyes.

Total complete success was observed in 5 (29.4%) eyes, partial success in 10 (58.8%) eyes, and failure in 2 (11.8%) eyes.

Functional bleb was observed in 88.2% of the eyes.

Discussion

MIGS aims to provide a safer, less invasive method to decrease IOP, and reduce dependence on drugs, compared to trabeculectomy. The implant uses subconjunctival filtration, which creates a non-physiological route for aqueous outflow, which is the basis of traditional trabeculectomy and drainage tube surgery.[7]

In the study of Sheybani et al.[6] with XEN-140 implant in 49 eyes, IOP decreased from 23±4.1 mmHg to 14±3.7 mmHg at the end of 12 months. In the study of Galal et al.,[7] a statistically significant decrease from 16±4 mmHg to 12±3 mmHg in 13 eyes was reported. In a pilot study published in 2015, IOP decreased from 22.4±4.2 mmHg to 15.4±3.0 mmHg at 12 months postoperatively in cataract surgery combined with XEN-63 or XEN-140 (p<0.001).[8] In the combined XEN-45 with mitomycin C and cataract surgery performed on 31 patients with OAG in 2015, IOP decreased from 20.8±4.6 mmHg to 13.1±3.6 mmHg at the end of 12 months (p<0.001).[9] In the study of Grover et al.[10] with 975 patients, IOP decreased by 31% compared to pre-operative values at 12-month follow-up. In the study of Sng et al.[11] in 24 patients with uveitic glaucoma, IOP decreased from 30.5±9.8 mmHg to 12.2±3.1 mmHg at the end of 12 months (p<0.001). In the combined XEN+cataract or XEN-only implant surgery performed by Mansouri et al.[12] in 149 eyes, IOP decreased from 20.0±7.1 mmHg to 13.9±4.3 mmHg at the end of 12 months (p<0.01) and 31% IOP reduction was achieved. The rate of decrease in IOP was higher in the XEN-only group.[12] In the present study, a statistically significant decrease (p<0.001) in IOP from an average of 27.6±6.0 mmHg to 14.1±3.4 mmHg at the last visit was detected after 15 months of follow-up. In a meta-analysis study that included ten studies, standalone XEN-45 implantation was reported to be superior to combined XEN-45-phacoemulsification surgery in terms of IOP reduction and decrease in number of antiglaucomatous drugs.[13]

While the number of pre-operative antiglaucomatous drugs was 3.9±0.8 (2–5) in the present study, it was 1.7±1.3 (0–3) at the last examination and a statistically significant decrease was observed (p=0.001). Similar to this study, Sheybani et al.[6] reported a significant decrease in the number of antiglaucomatous drugs from 3.0 to 1.3 in their study and from 1.9 to 0.3 in the study by Galal et al.[7] In a pilot study published in 2015, the number of drugs decreased from 2.5±1.4 to 0.9±1.0 in cataract surgery combined with XEN-63 or XEN-140.[8] In another study, the combined XEN-45 with mitomycin C and cataract surgery were performed on 31 patients with OAG and the number of drugs decreased from 2.7±1 to 0.9±1.1 at 12 months (p<0.001).[9] In the study of Grover et al.[10] with 975 patients, a 50% decrease was found in the number of drugs compared to the pre-operative values. In the study of Sng et al.,[11] the number of drugs decreased from 3.3±0.8 to 0.4±0.8 (p<0.001) in patients with uveitic glaucoma. In

Table 2. Comparison of pre-operative and post-operative examination findings of all study eyes

Finding	Operative	Post-operative (last visit)	p-value
IOP (mmHg), mean±SD	27.6±6.0 (21–40)	14.1±3.4 (8–19)	<0.001
ECC (cells/mm^2), mean±SD (range)	2356.8±533.3 (1635–3275)	2346.2±437.6 (1518–2874)	0.47
BCVA (logMAR), mean±SD	0.78±0.99	0.8±0.99	0.99
RNFL (µm), mean±SD	61.4±11.8 (43–82)	61.3±11.5 (45–82)	0.76
Number of glaucoma medications, mean± SD (range)	3.9±0.8 (2–5)	1.7±1.3 (0–3)	0.001

IOP: Intraocular pressure; ECC: Endothelial cell count; BCVA: Best-corrected visual acuity; RNFL: Retinal nerve fiber layer; SD: Standard deviation.

the combined XEN+cataract or XEN implant surgery performed by Mansouri et al.[12] in 149 eyes, the number of drugs decreased from 1.9±1.3 to 0.5±0.8 at the end of 12 months ($p<0.001$).

In the present study, pre-operative diagnosis was POAG in 13 eyes, KPG in 3 eyes, and ARG in 1 eye. In the studies in the literature, it has been reported that although POAG constitutes XEN most of the XEN implant indications, XEN implantation is also performed in other OAG types. In the study of Galal et al.,[7] pre-operative diagnosis was POAG in all 13 eyes, in the study of Sheybani et al.,[6] diagnosis was POAG in 38 eyes, pseudoexfoliative glaucoma in six eyes, juvenile glaucoma in three eyes, and pigmentary glaucoma in two eyes. In the study of Grover et al.,[10] pre-operative diagnosis was POAG 85%, pseudoexfoliative glaucoma 8%, and other glaucoma types 6%.

Herein, the pre-operative BCVA was 0.78±0.99 LogMAR, and it did not show any significant change at the last examination ($p=0.99$). While Galal et al.[7] reported an increase in pre-operative BCVA from 0.33±0.34 LogMAR to 0.13±0.11 LogMAR, Sheybani et al.[6] reported no significant difference, similar to our results.

The most frequently reported side effects in studies with XEN implants are hyphema, stent occlusion, choroidal effusion, shallow anterior chamber, and hypotonia.[6] In the study by Sheybani et al.,[6] shallow anterior chamber was observed in 4 eyes (9%) in the 1st week postoperatively, and viscoelastic was applied to the anterior chamber. No complications were found in combined XEN-45 and cataract surgery with mitomycin C performed on 31 patients with OAG in 2015.[9] In the study of Grover et al.,[10] the most common intraoperative complication was anterior chamber hemorrhage, followed by subconjunctival hemorrhage, while the most common post-operative complication was stent-related secondary surgical requirement followed by hyphema. Complication rates were found to be lower as compared to traditional glaucoma surgeries.[10] In the study of Sng et al.[11] in patients with uveitic glaucoma, permanent hypotonia requiring surgical revision was found in one eye and blebitis in one eye. In the study of Mansouri et al.,[12] choroidal detachment in two eyes, bleb revision in five eyes, and secondary surgical access in nine eyes were detected. In the present study, complications were encountered in 4 (23.5%) eyes which were shallow anterior chamber and hypotonia in one eye as an early complication, Tenon's cysts in two eyes, and fibrotic appearance in the bleb in one eye as late complications (>1 month). Early hypotonia resolved with medical treatment. No medical or surgical intervention was needed for late complications.

Herein, blebs were found to be functional in 88.2% of the eyes. In the study of Olate-Perez et al.,[14] 90% of the blebs were found to be functional, which is similar to our study.[13]

In the present study, complete success was achieved in 5 (29.4%) eyes, partial success in 15 (88.2%) eyes, and failure in 2 (11.8%) eyes. Gillmann et al.[15] reported complete success in 29% of the eyes and qualified success in 31% of the eyes, which included eyes that undergone standalone XEN-45 implantation and XEN-45-phacoemulsification combined. In the study of Sheybani et al.[6] with XEN-140 implant in 49 eyes, 40% complete success, 89% partial success, 11% failure were observed. Partial success and failure rates were found to be similar to our study. In the combined XEN+cataract or XEN implant surgery performed by Mansouri et al.[12] in 149 eyes, 57.7% complete success, 71.1% partial success, and 28.9% failure were observed.

In the study of Sheybani et al.,[6] additional glaucoma surgery was required in 3 (6.6%) eyes. In the present study, additional surgical interventions were required in 2 (11.8%) eyes. This difference might be due to the low number of patients in our study.

The needling rate of 29.4% in the present study was similar to the needling rate of Galal et al.[7] (30.7%). Needling was required at a rate of 47% in the study by Sheybani et al.[6] In the study by Mansouri et al.,[12] needling was required at a rate of 37%. In the study of Eraslan et al.,[16] the needling rate of standalone XEN implantation group was 42.3%, similar with the literature.

In this study, there was no statistically significant decrease in the number of ECC and RNFL. Oddone et al.[17] reported a low decrease in ECC in eyes with XEN implantation,[16] similarly, Olgun et al.[18] reported a 2.1% ECC decrease at 3 months postoperatively.[17] XEN-45 implantation resulted with lower decrease in ECC compared to both combined XEN-45-phacoemulsification, phacoemulsification alone, and trabeculectomy in those studies.[16–18]

The limitations of our study are the low number of patients and the absence of a control group. Studies on XEN implant are few in the literature and more studies with longer follow-up periods are needed.

Conclusion

XEN-45 implant surgery in patients with OAG is an effective surgical procedure for IOP control and requires needling in some patients. Visual acuity and corneal endothelium of the cases were preserved after surgery and no serious complications were detected.

Ethics Committee Approval: This study was approved by Ege University Faculty of Medicine Clinical Research Ethics Committee (date: 08.05.2018; number: 18-5/42).

Peer-review: Externally peer-reviewed.

Authorship Contributions: Concept: H.A.; Design: H.A.; Supervision: H.A., S.G.Y.; Resource: H.A.; Materials: M.E.B., S.G.Y.; Data Collection and/or Processing: M.E.; Analysis and/or Interpretation: M.E.B.; Literature Search: M.E., S.G.Y.; Writing: M.E.; Critical Reviews: M.E.B., H.A., S.G.Y.

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