ORİJİNAL ARAŞTIRMA ORIGINAL RESEARCH

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Early Experience Results with Minimally Invasive Glaucoma Surgery with XEN® Gel Stent

XEN® Jel Stent ile Minimal İnvaziv Glokom Cerrahisi Erken Deneyim Sonuçları

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ABSTRACT Objective: To evaluate the results of XEN® gel stent implantation. **Material and Methods:** Thirty-five eyes of 33 patients who underwent XEN gel stent implantation were retrospectively evaluated. The primary outcome measure was target intraocular pressure (IOP). Complete therapeutic success was defined as postoperative IOP≤21 mmHg without antiglaucomatous medication; partial success was defined as postoperative IOP≤21 mmHg with antiglaucomatous medication. The secondary outcome measure was ≥20% reduction in IOP from baseline. Failure was defined as postoperative IOP>21 mmHg, explantation and the need for additional glaucoma surgery. **Results:** The mean preoperative IOP was 25.7±5.8 mmHg and the mean antiglaucomatous medication was 2.7±1.5. After 12 months follow-up, mean IOP was 16.5±4.2 mmHg with a decrease of 33.7%, mean antiglaucomatous medication was 1.8±1.6 with a decrease of 43.9% (p<0.05). When the cases who completed the 12-month follow-up were evaluated, the complete success rate was 23.1% (n=6), the partial success rate was 42.3% (n=11) and the failure rate was 34.6% (n=9) at month 12. In 61.5% of eyes achieved an IOP decrease of 20% or more. Needling was required for 51.4% of eyes. Most of the complications were resolved without any permanent damage in the early period. Serious complications included malignant glaucoma in one eye and endophthalmitis in one eye. XEN gel stent explantation was performed in 22.8% (n=8) of the cases. **Conclusion:** Although XEN gel stent implantation is a minimally invasive method, some postoperative interventions were required. Success rates may increase with the effective management of complications. It may provide a significant decrease in IOP in selected patients.

Keywords: Glaucoma; glaucoma drainage implants; minimally invasive surgical procedures; XEN® gel stent

ÖZET Amaç: XEN® jel stent implantasyonu sonuçlarını değerlendirmektir. **Gereç ve Yöntemler:** XEN jel stent implantasyonu yapılan 33 hastanın 35 gözü retrospektif olarak incelendi. Birincil sonuç ölçütü hedef göz içi basıncı (GİB) idi. Tam terapötik başarı, antiglokomatöz ilaçsız postoperatif GİB≤21 mmHg; kısmi başarı ise antiglokomatöz ilaçla postoprtatif GİB≤21 mmHg olarak tanımlandı. İkincil sonuç ölçütü, başlangıçtaki GİB değerinden %20 ve daha fazla azalma olarak değerlendirildi. Başarısızlık GİB>21 mmHg, eksplantasyon ve ek glokom cerrahisine ihtiyaç olarak tanımlandı. **Bulgular:** Ameliyat öncesi ortalama GİB 25,7±5,8 mmHg ve ortalama antiglokomatöz ilaç sayısı 2,7±1,5 idi. On iki aylık takipten sonra ortalama GİB %33,7 azalmayla 16,5±4,2 mmHg, ortalama antiglokomatöz ilaç sayısı %43,9 azalmayla 1,8±1,6 (p<0,05) idi. Bir yıllık takibini tamamlayan hastalar değerlendirildiğinde, tam başarı oranı %23,1 (n=6), kısmi başarı oranı %42,3 (n=11) ve başarısızlık oranı %34,6 (n=9) idi. Gözlerin %61,5'inde %20 veya daha fazla GİB azalması elde edildi. Gözlerin %51,4'ünde bleb iğnelemeye ihtiyaç duyuldu. Komplikasyonların çoğu erken dönemde kalıcı bir hasar bırakmadan düzeldi. Ciddi komplikasyonlardan bir gözde malign glokom ve bir gözde endoftalmi vardı. Olguların %22,8 (n=8)'inde XEN jel stent explantasyonu yapıldı. **Sonuç:** XEN jel stent implantasyonu minimal invaziv bir yöntem olmasına rağmen, bazı postoperatif müdahaleler gerekli olmuştur. Komplikasyonların etkin yönetimi ile başarı oranları artabilir. Seçilmiş hastalarda GİB'de anlamlı bir düşüş sağlayabilir.

Anahtar Kelimeler: Glokom; glokom drenaj implantları; minimal invaziv cerrahi işlemler; XEN® jel stent

High intraocular pressure (IOP) is the most important and the only preventable risk factor in the development of glaucomatous damage.[1] The main purpose of medical, laser or surgical treatments in glaucoma is to lower IOP.

Nowadays, trabeculectomy is the most commonly used surgical technique to reduce IOP. In this surgery performed with the ab externo approach, interventions to the conjunctiva and tenon capsule cause fibrosis and bleb failure. Another disadvantage

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of this method is the complications associated with hypotonia such as anterior chamber narrowing, choroidal detachment due to rapid postoperative filtration, and various complications such as bleb-related complications, early and late endophthalmitis can be seen.[2] Recently, minimally invasive methods have been developed to avoid these complications in glaucoma surgery.

Minimally invasive glaucoma surgery (MIGS) is performed ab interno through the clear corneal incision and provides low trauma effect on tissue. These techniques are easy to apply and have high patient comfort after surgery. XEN gel (XEN, Allergan, Dublin, Ireland) stent implantation is one of these techniques. Unlike other MIGSs, the anterior chamber angle is inserted and implant is placed in the subconjunctival area and the drainage of aqueous humor into subconjunctival area is provided.[3]

XEN is a hydrophilic stent made from porcine or bovine gelatin cross-linked with glutaraldehyde. The latest model XEN 45, used in our study, has a 45 mm lumen with a length of 6 mm. The implant is hard and flat when dry, but becomes soft and flexible when implanted and hydrated into the tissue. The flexibility of the implant is important to prevent erosion and migration risk. Hagen-Poiseuille equation was used to determine the implant size. Accordingly, hypotonia is not expected to occur at the average levels of aqueous humor production.[4]

The aim of this study is to evaluate the efficacy, safety, complications, and factors that may affect surgical success of XEN gel stent implantation, a new microinvasive surgical technique in glaucoma surgery.

MATERIAL AND METHODS

In this study; the patients who underwent minimally invasive glaucoma surgery with XEN gel stent between the years of 2016 and 2018 at the Haydarpaşa Numune Training and Research Hospital, Department of Ophthalmology were evaluated retrospectively. The study protocol was approved by Haydarpaşa Numune Training and Research Hospital Clinical Research Ethics Committee (HNEAH-KAEK 2019/7) and this research was consistent with the tenets of the Declaration of Helsinki.

Inclusion criteria was the failure to achieve the target IOP despite the maximum tolerated medical treatment. Primary and secondary open angle glaucoma patients were included. Exclusion criteria were angle closure, neovascular, inflammatory, congenital-juvenile glaucomas and prior glaucoma surgery. Thirty-five eyes of 33 patients were included in the study.

Patient demographics, diagnoses, previous glaucoma treatments, IOP measurements and previous ocular surgeries were evaluated. Slit-lamp biomicroscopy, fundoscopy and gonioscopic examination findings were recorded from the ophthalmological examinations. Surgical notes were reviewed.

SURGICAL TECNIQUE

Surgeries were performed with local anesthesia. In all patients, the superior nasal quadrant selected as the site of implantation was marked 3 mm behind the limbus. Ten minutes before the procedure, 0.1 ml 0.2 mg/ml Mitomycin C (MMC) was injected into the subconjunctival space and spread to the implantation area with the help of a sponge. A corneal lateral incision was constructed from the superior temporal quadrant and myosis was achieved by administering 0.01% carbachol (Miostat®, Alcon, USA) to the anterior chamber. Anterior chamber stability was also provided by cohesive viscoelastic material (Healon GV®, Johnson&Johnson Vision, CA, USA). A corneal main incision was constructed 1 mm from the inferior temporal quadrant for the injector. The preloaded injector was pushed through the trabecular meshwork and the implant was placed in the superior nasal quadrant. The ideal stent placement should be 2 mm of exposed implant in the subconjunctival space, 1 mm in the anterior chamber and 3 mm tunneled through sclera. A gonioscopic lens was used to verify the correct stent placement in the angle. Corneal incisions were closed with hydration after irrigation of viscoelastic material from the anterior chamber. Prophylactic 1 mg 0.1 ml cefuroxime (Aprokam®, Thea Pharma, Italy) was applied to the anterior chamber. In case the implantation was com-

bined with a cataract surgerry, phacoemulsification was done first.

Needling was performed under a surgical microscope. A 27 gauge needle was inserted into the subconjunctival area near the bleb, and fibrotic tissue was dissected by moving the needle. In the needling with antimetabolite, 0.1 ml 0.02 mg/ml MMC solution or 0.1 ml 5 mg/mL fluorouracil (5-FU) solution was injected into the subconjunctival area.

Surgical bleb revision was performed in patients with fibrotic scar tissue around the implant and with bleb failure. In surgical bleb revision, the conjunctiva was opened based on the fornix and the implant area was reached. MMC impregnated sponge was left in the subconjunctival area for 3 minutes and then washed with a saline solution. The fibrotic tissues around the implant were removed with a 27 gauge needle tip to provide aqueous flow through the implant. The conjunctiva was refixated at the limbus with 8-0 vicryl.

Postoperative treatments included moxifloxacin 0.5% (Vigamox®, Novartis, USA) and prednisolone acetate 1% (Pred Forte®, Allergan, USA) administered per hour on the first day with weekly tapering. All antigloucomatous medications were stopped on the first day.

Control examinations were performed on the postoperative day 1, week 1, months 1, 3, 6, 12, 18, and 24. In the follow-up examinations, the IOP, bleb morphology, implant position in the subconjunctival area and iridocorneal angle, additional glaucoma medication, complications and the need for re-surgery were evaluated. The primary outcome measure was evaluated with two different target IOP (18 mmHg-21 mmHg) so that they might be comparable to other studies. Complete therapeutic success was defined as postoperative IOP≤18 mmHg and IOP≤21 mmHg without antiglaucomatous medication; partial success was defined as IOP≤18 mmHg and IOP≤21 mmHg with antiglaucomatous medication. The secondary outcome measure was evaluated ≥20% reduction in IOP from the baseline. Failure was defined as IOP>18 mmHg and IOP>21mmHg, explantation and the need for additional glaucoma surgery.

STATISTICAL ANALYSIS

NCSS (Number Cruncher Statistical System) 2007 (Kaysville, Utah, USA) was used for the statistical analysis. Descriptive statistical methods (mean, standard deviation, median frequency, ratio, minimum, maximum) were used to evaluate the study data. The suitability of the quantitative data for normal distribution was tested with the Shapiro-Wilk test and graphical analyses. In the quantitative data, Student's t-test was used to compare variables showing normal distribution between two groups and Mann Whitney U test was used for the comparison of non-normal distribution variables between two groups. Pearson chi-square test, Fisher-Freeman-Halton test and Fisher's Exact test were used to compare the qualitative data. Wilcoxon Signed Ranks test was used for intragroup comparisons of non-distributed parameters. $p<0.05$ was considered as statistically significant.

RESULTS

Thirty five eyes of 33 patients were evaluated in the study. The mean follow-up period was 12 months. Table 1 shows the baseline patient demographic and characteristics.

TABLE 1: Patient demographic and characteristics.

Age (years)	Mean+SD	70.4 ±10.2
	Min-Max (median)	46-87 (72)
Follow-up period (months)	Mean+SD	12.0 ±7.7
	Min-Max (median)	2-28 (9)
Sex, n (%)	Women	13 (39.4)
	Men	20 (60.6)
Glaucoma diagnosis, n (%)	POAG	15 (42.9)
	PXF	17 (48.5)
	Steroid induced	2 (5.7)
	Angle recession	1 (2.9)
Glaucoma stage, n (%)	Early	15 (42.9)
	Moderate	13 (37.1)
	Severe	10 (28.6)
Lens status, n (%)	Pseudophakic	13 (37.1)
	Phakic	22 (62.9)
Surgery type, n (%)	XEN	18 (51.4)
	XEN+Phaco	17 (48.6)

POAG: Primary open angle glaucoma, PXF: Pseudoexfoliation syndrome.
XEN+phaco: Combined Phacoemulsification -XEN gel implant surgery.

The mean preoperative IOP was 25.7±5.8 mmHg (range=19-40) which reduced significantly to 16.5±4.2 at 12 months of follow-up with a decrease of 33.7% ($p<0.05$). Figure 1 shows mean IOP through the follow up period.

The mean number of medications was 2.7±1.5 (range=0-4) which reduced significantly to 1.81±1.5 at 12 months of follow-up with a decrease of 43.9% ($p<0.05$). Figure 2 shows the mean number of medications through the follow up period.

There was no difference in the mean IOP or the number of medications preoperatively in XEN and XEN+Phaco groups ($p>0.05$) and no statistically significant difference was found in the IOP and the number of medications between the two groups in all control examinations postoperatively ($p>0.05$). There was no difference in the mean IOP or the number of medications preoperatively in primary and secondary open-angle glaucoma groups and no statistically significant difference was found in the IOP and the num-

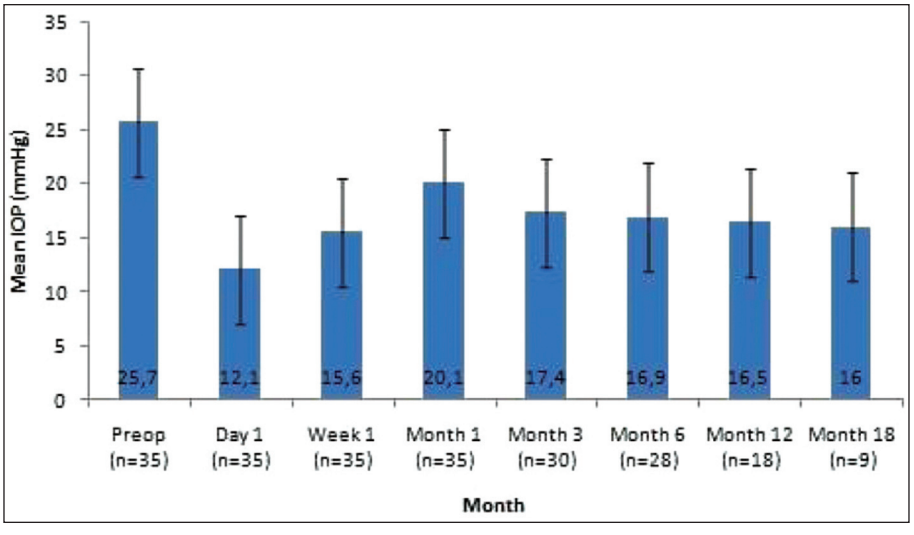

FIGURE 1: Mean IOP over time (Error bars represent standart deviation in mean IOP).

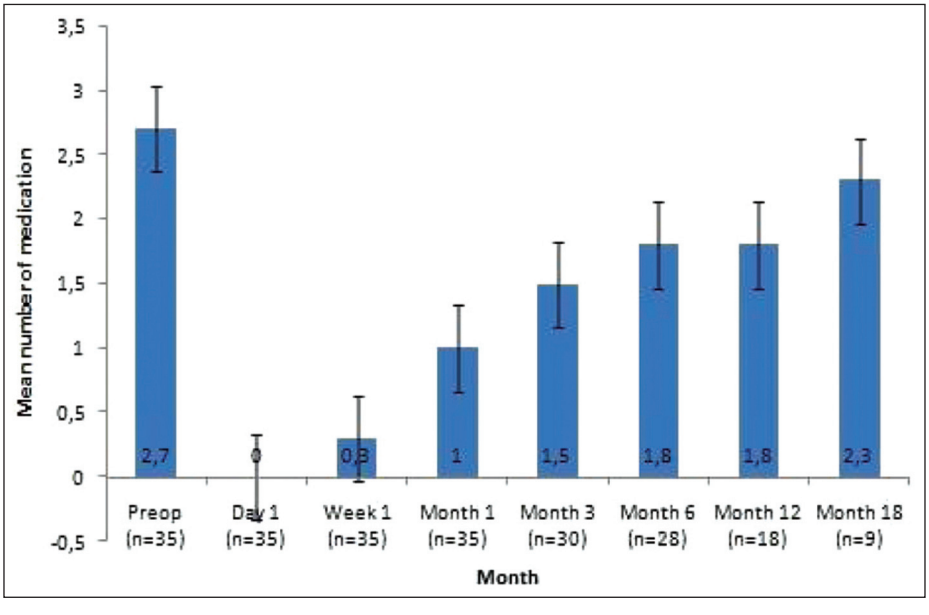

FIGURE 2: Mean number of medicationsover time (Error bars represent standart deviation in mean number of medication).

ber of medications between the two groups in all control examinations postoperatively (p>0.05).

Needling was performed in 51.4% (18) of all cases. The total number of needling performed was 29; 4 of them were with MMC, 22 with 5-FU and 3 without drug. The mean number of needling was 1.6. Needling times range from 1 to 8 months. Twelve were needled in the first month postoperatively, 13 in months 1 to 3, 3 in months 4 to 6, and 1 in months 6 to 9.

Surgical bleb revision was performed in 17.1% (n=6) of all cases. Revision was performed in one case in the first month, in 3 cases in the second month, in one case in the 4th month, and in one case in the 20th month. In these patients with fibrotic scar tissue around the implant and with bleb failure, the conjunctiva was opened and the fibrotic tissues around the implant were removed. The conjunctiva was sutured (Figure 3).

XEN gel stent explantation was performed in 22.8% (n=8) of the cases. The reasons for explantation are implant migration in 3 cases, conjunctival erosion and exposure in 3 cases, exposure and endophthalmitis in one case and fracture of the implant in one case. A second glaucoma surgery was recommended in these patients and additional glaucoma surgery for those who accept surgery; trabeculectomy in one patient and Ahmed Glaucoma Valve (AGV) implantation in 3 patients.

When 26 patients who completed the 12-month follow-up were evaluated, according to the IOP≤18 criteria; complete success rate was 23.1% (n=6), partial success rate was 34.6% (n=9) and failure rate was 42.3% (n=11). According to the IOP≤21 criteria; the complete success rate was 23.1% (n=6), the partial success rate was 42.3% (n=11) and the failure rate was 34.6% (n=9) in month 12. In 61.5% of eyes achived 20% or more IOP decrease.

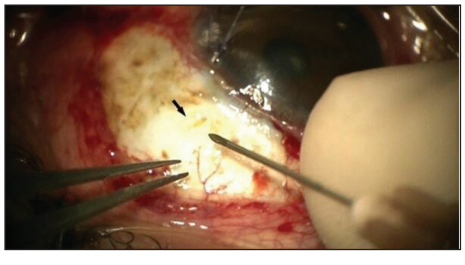

FIGURE 3: Surgical bleb revision.

TABLE 2: Postoperative ocular complications.

Transient hypotony, n (%)	6 (17.1)
Transient choroidal detachment, n (%)	2 (5.7)
Malignant glaucoma, n (%)	1 (2.9)
Hyphema, n (%)	1 (2.9)
Implant damage (Fracture), n (%)	1 (2.9)
Malposition (Curl in the implant), n (%)	2 (5.7)
Implant migration, n (%)	3 (8.6)
Implant occlusion with iris, n (%)	1 (2.9)
Implant exposure, n (%)	4 (11.4)
Endophthalmitis, n (%)	1 (2.9)

The relationship between success and glaucoma diagnosis or surgical type was investigated. There was no significant difference between the groups in terms of success rate at month 12 (p>0.05).

Postoperative ocular complications are seen in Table 2.

Although 17.1% (n=6) of the patients had hypotonia (IOP≤6mmHg) in the early period, all of these cases and choroidal detachament resolved at first week without intervention. Malingnant glaucoma occured in one patient on postoperative 3rd day and resolved on the 7th day with medical treatment. Hyphema occured and resolved spontaneously. One patient had a fracture in the subconjunctival area of the implant and bleb failure. AGV implantation was performed after explantation in this patient (2nd month). In two of the patients, there was folding of the implant in the subconjunctival area. In one of these cases in the follow-up the implant eroded conjunctiva and exposure occured. Implant migration occured in 3 patients. The stent without contact to anterior chamber wasn't seen with gonioscopy. Explantation was performed in these three patients (2nd month). Two of these patients underwent AGV implantation. One patient refused second glaucoma surgery. In one case, the implant was obstructed by iris in the anterior chamber and opened with argon laser. Implant exposure occured in 11.4% (n=4) of the patients. One patient underwent explantation and trabeculectomy (6th month). The other two patients were

followed with medical treatment after explantation without additional glaucoma surgery (3rd month and 2nd month). One patient underwent pars plana vitrectomy and XEN gel stent explantation (6th month) after implant exposure and endophthalmitis.

DISCUSSION

In our study, the mean IOP decreased by 33.7% at month 12 ($p<0.05$). IOP reduction rates have been reported between 23% and 41.8% in various studies with XEN gel stent.[5-10]

Success in various studies in the literature has been evaluated with many different criteria. Table 3 shows success criteria and success rates of published reports of the XEN gel implant. Our success rates are lower than most studies in the literature.[6-9,11,12] In our study, patients who underwent explantation and new glaucoma surgery constitute the majority of the unsuccessful group. Six patients who underwent surgery during the initial period underwent explantation due to exposure and implant malposition. In similar studies in the literature, revisions such as repositioning, suturing and reimplantation have been tried primarily in similar complications.[5,7,10-12]

Needling was performed in 51.4% (n=18) of the patients. In other studies with XEN needling rates have been reported betwen 30% and 51.3%.[5,8,11-13] In their study, Widder et al. reported that no patient underwent bleb needling and in cases with bleb failure the conjunctival fornix was opened and fibrotic scar tissue around the implant was removed and the conjunctiva was sutured. In this study, revision surgery rate was reported as 34%.[12] In our study, surgical bleb revision was performed with the same technique in 6 cases (17.1%) with fibrotic scar tissue around the implant and with bleb failure.

XEN gel stent explantation was performed in 22.8% (n=8) of the patients. In other studies, the rates of explantation and additional glaucoma surgery have been reported between 2.5% and 15%.[5,7,10-13] In our study, the rate of explantation and additional glaucoma surgery was found to be higher than other reports. This may be associated with explantation as the first method for complications such as exposure and implant malposition. There were not many publications about these complications at that time. We now see that revisions such as repositioning, suturing and reimplantation have been performed in similar complications in the other studies.[5,7,10-12]

In our study, no statistically significant difference was found in IOP or number of medications between XEN and XEN+Phaco groups at all control examinations postoperatively ($p>0.05$). There was also no significant difference between the groups in terms of success rate ($p>0.05$). Some similar studies have also reported no statistically significant differ-

TABLE 3: Success criteria and success rates of published reports and comparison with this study.

Author	Study Details	Complate Succes	Complate Succes Rate	Qualified Succes	Qualified Succes Rate
Gregorio[7]	41 eyes, 12 months	IOP≤17 without medication	80.4%	IOP≤17 with medication	97.5%
Tan[8]	39 eyes, 12 months	IOP≤18,21 without medication	56.2% (IOP≤18) 56.4% (IOP≤21)	IOP≤18, 21 with medication	92.0% (IOP≤18) 95.0% (IOP≤21)
Mansouri[9]	149 eyes, 12 months	IOP≤16,18 without medication	57.7% (IOP≤16) 62.4% (IOP≤18)	IOP≤16,18 with medication	71.1% (IOP≤16) 77.9% (IOP≤18)
Karimi[10]	259 eyes, 12 months	IOP≤21 and 20% reduction from preoperative IOP without medication	37.4%	IOP≤21 and 20% reduction from preoperative IOP with medication	61.6%
Widder[12]	261 eyes, 8.6 months	IOP≤21 without medication and revision	66.0%	IOP≤21 with medication and 1 revision	90.0%
Hohberger[14]	111 eyes, 6 months	IOP≤18 without medication	46.9% (XEN) 53.3% (Phaco+XEN)	IOP≤18 with 1-2 medication	49.4 (% XEN) 56.6% (Phaco+XEN)
The study	35 eyes, 12 months	IOP≤18, 21 without medication	23.1% (IOP≤18) 23.1% (IOP≤21)	IOP≤18, 21 with medication	57.7% (IOP≤18) 65.3% (IOP≤21)

IOP: Intraocular pressure, XEN+phaco: Combined Phacoemulsification –XEN gel implant surgery.

ence in patients with combined surgery.[9,10,14] The effect of cataract surgery on IOP reduction has been shown in many studies.[15-17] A higher IOP reduction can be expected in combined surgery. However, studies comparing the results of trabeculectomy and trabeculectomy+Phaco surgery showed higher IOP reduction in the trabeculectomy group. This result has been associated with the proinflammatory effect of phacoemulsification.[18-22]

Although 17.1% (n=6) of the patients had hypotonia (IOP≤6 mmHg) in the early period, all of these cases and choroidal detachament resolved at first week without intervention. Hypotonia rates in similar studies ranged from 2.4% to 34%.[5,7,8,10-12] In our study and other XEN gel stent studies in the literature, complications were not as serious as in trabeculectomy studies and most of them improved without additional intervention.[2,23-26]

Endophthalmitis occured in a case who had undergone uncomplicated XEN gel stent implantation 6 months prior because of POAG. Conjunctival erosion and stent exposure were observed in this patient. Immediate pars plana vitrectomy and stent explantation was performed, with intravitreal antibiotic administration and silicon oil tamponade. Then, the patient was treated with topical antibiotics. There was no positive growth in microbiological culture. At the 5th month after pars plana vitrectomy, best corrected visual acuty was 1/10 and IOP was 15 mmHg with IOP-lowering medication. In the literature, endophthalmitis has been previously reported in cases following XEN stent exposure and a case after bleb needling.[27-29] Kerr et al. reported two cases of bleb-related endophthalmitis.[30]

The study has some shortcomings. This is a retrospective study, a small series with a short follow-up period. The number of patients with one-year follow-up data is very low. Despite experienced surgeons performing the procedures, there was a learning curve associated with this new intervention. This study was performed early in the surgeons' experience with the XEN implant and there were not many publications in terms of management of complications seen in the first cases.

CONCLUSION

Although MIGS techniques are easy to apply and have high patient comfort after surgery, there was a learning curve associated with this new intervention. However, severe adverse events may occur and needling rates are not low in this method. Success rates may increase with the effective management of complications in the postoperative period. Therefore, patients should be informed that additional interventions may be required postoperatively. It may provide a significant reduction in IOP and IOP lowering drugs in selected cases.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

All authors contributed equally while this study preparing.

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