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Surgery of Xen45 Gel Micro-Implant and Phacoemulsification: Cross-Sectional Research

Xen45 Jel Mikroimplant ve Fakoemülsikasyon Cerrahisi: Kesitsel Araştırma

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ABSTRACT Objective: To investigate the safety and effectiveness of XEN45 gel micro-implant and phacoemulsification combined surgery in primary open-angle glaucoma (POAG) patients. **Material and Methods:** It is a prospective, single-center, clinical study. 30 patients (30 eyes) who were followed up by Marmara University Glaucoma outpatient clinic due to POAG and cataract were included in the study. Moreover, all patients underwent XEN45 gel micro-implant- phacoemulsification combined surgery. Best corrected visual acuity, slit-lamb biomicroscopic examination, intraocular pressure measurement with applanation, Retinal Nerve Fiber Layer and Ganglion Cell Complex scanning were followed up to the 1st post-operative year. **Results:** Of the participants diagnosed with POAG and cataract, 50% were female, 50% were male, and the average age was 62.63±7.05. A statistically significant decrease was detected in the number of pre-operative antiglaucomatous molecules used by the patients (3.24±0.95) at the end of 1 year (0.66±0.72) (p=0.001). A significant difference was detected between pre and post-operative month 12 intraocular pressure values (22.53±3.81, 14.53±2.86 mmHg, respectively) (p<0.001). At the end of 1 year, the full success rate was 40% and the partial success rate was 36.67%. **Conclusion:** It was concluded that in addition to being a micro-invasive, effective and reliable surgery, the XEN45 gel micro-implant has been observed to reduce POAG progression and the use of anti-glaucomatous drops.

Keywords: Open angle glaucoma; minimally invasive surgical procedures; phacoemulsification; surgery; safety

ÖZET Amaç: Primer açık açılı glokom [Primary open-angle glaucoma (POAG)] hastalarında XEN45 jel mikro-implant ve fakoemülsifikasyon kombine cerrahisinin güvenilirlik ve etkililiğinin araştırılması. **Gereç ve Yöntemler:** Prospektif, tek merkezli, klinik çalışmaya Marmara Üniversitesi Glokom polikliniği tarafından POAG ve katarakt nedeniyle takip edilen 30 hasta (30 göz) dâhil edildi. Dahası tüm hastalara XEN45 jel mikroimplant-fakoemülsifikasyon kombine cerrahi uygulandı. En iyi düzeltilmiş görme keskinliği, slit-lamb biyomikroskopik muayene, aplanasyon ile göz içi basıncı ölçümü, Retinal Sinir Lifi Tabakası ve Gangliyon Hücre Kompleksi taraması ile postoperatif 1 sene boyunca takip edildi. **Bulgular:** POAG ve katarakt tanılı katılımcıların %50'si kadın, %50'si erkek ve yaş ortalaması 62,63±7,05'tir. Hastaların kullandıkları preoperatif antiglokomatöz molekül sayısında (3,24±0,95), 1 yılın sonunda (0,66±0,72) istatistiksel olarak anlamlı düşüş saptandı (p=0,001). Pre ve post-operatif 12. ay göz içi basıncı değerleri (sırasıyla 22,53±3,81, 14,53±2,86 mmHg) arasında anlamlı fark saptandı (p<0,001). Bir senenin sonunda cerrahi tam başarı oranı %40, kısmi başarı oranı ise %36,67'dir. **Sonuç:** XEN45 jel mikro-implantın mikroinvaziv, etkili ve güvenilir bir cerrahi yöntem olmasının yanı sıra POAG progresyonunu ve antiglokomatöz damla kullanımını azalttığı sonucuna varılmıştır.

Anahtar Kelimeler: Açık açılı glokom; minimal invaziv cerrahi prosedürler; fakoemülsifikasyon; ameliyat; güvenilirlik

Primary open-angle glaucoma (POAG) is a chronic and neurodegenerative disease which causes progressive damage to retinal cells and ganglia and visual field loss. Although it is a chronic, multi-factorial disease, the main goal of treatment is to prevent the progression of the disease as the only modifiable

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risk factor is to lower intraocular pressure (IOP).[1,2] The first neurons to be stimulated in the visual pathway are the retinal ganglion cells (RGC). Moreover, a 3rd group of photoreceptors has recently been identified. RGC axons are unmyelinated until they cross the lamina cribrosa and merge to form the optic nerve.[3] Previous studies have observed a decrease in the number of RGCs and significant RGC apoptosis after glaucomatous damage in glaucoma models.[4,5] In some studies, elevated IOP has also been associated with RGC axon degeneration.[6,7]

In the modern ophthalmology, topical anti-glaucomatous medical treatment and laser trabeculoplasty (argon, diode, or selective laser energy) are the 1st-line treatment methods in the management of POAG.[1,2,8] Surgical treatment is applied to patients with POAG who cannot be controlled with conservative methods, and the classic surgical procedure in this field is trabeculectomy.[1]

Although trabeculectomy, which has been performed since the 1960s, is effective and safe in the long term, it carries the risk of serious complications (exposure keratopathy, infection, malignant glaucoma, choroidal hemorrhage.[9] With the new devices called Minimally Invasive Glaucoma Surgery (MIGS) that have become popular in recent years, there is a possibility of less invasive, shorter surgery time and faster recovery.[10]

XEN45 (Allergan Inc., Irvine) contains a 6 mm long micro-implant with an inner diameter of 45 µm and an outer diameter of 120 µm inside a 27 gauge, 437 µm diameter syringe.[11] With XEN45 gel micro-implantation, which is the most frequently applied under the title of MIGS, Ab interno is applied through a clean corneal incision without conjunctival dissection. Since the XEN gel stent is an implant that works in accordance with the Hagen-Poiseuille equation laminated flow law, the risk of early hypotonia is quite low.[1,11]

In this study, XEN45 gel micro-implant and phacoemulsification combined surgery was performed in POAG and cataract patients for whom conservative treatment was not sufficient. In the recent years, as an efficient and effective glaucoma surgical method applied has come forward. In this way, it is aimed to investigate the reliability and effectiveness of the XEN45 gel micro-implant, one of the popular glaucoma surgeries of recent years throughout a year. It was thought that this study may contribute to the literature by monitoring the surgical success and reliability of the XEN45 gel micro-implant, which has been applied since 2016.

MATERIAL AND METHODS

In the prospective, single-center, clinical study, there were 30 patients treated by Faculty of Medicine Glaucoma clinic Marmara University due to primary open-angle glaucoma were included. This study was conducted between March 2019 and September 2020, adhering to the principles of the Declaration of Helsinki, with the approval of Marmara University Local Ethics Committee numbered 09.2019.252. Informed consent was obtained from all participants. Phacoemulsification and XEN45 gel micro-implant combined surgery was performed in 30 patients. Patients who were over 18, diagnosed with primary open-angle glaucoma, had nuclear, cortical and/or posterior subcapsular cataracts between stages 2-5 according to the LOCS III classification and IOP>21 mmHg were included in the study. Considering the exclusion criteria, patients who had ocular surgery, had ocular diseases other than POAG with cataract and took any medication that had an effect on IOP were not included in the study.

All the patients were medicated at least one of the topically administered molecules prostaglandin analog, beta-adrenergic blocker and adrenergic agonist. The patients' anti-glaucomatous treatments stopped one week prior to the surgery. Under intracameral local anesthesia through 1% lidocaine, after phacoemulsification and intraocular lens implantation, subconjunctival 0.2 mg/ml mitomycin-C (MISINTU 20 mg flakon, Onko&Kocsel, Tuŕkiye) was applied. Then, it was checked that the anterior chamber angle was open with the goniolens. The XEN injector was advanced from the anterior chamber towards the angle. The syringe tip entered the angle, it was advanced into the sclera by making a continuous and gentle rotation. The gel micro-implant was implanted in the superonasal region >1.0 mm above

the limbus. After that, the surgery was completed by placing the XEN45 gel micro-implant. During the post-operative period, topical moxifloxacin (Vigamox 0.5%, Novartis, Basel, Switzerland) and topical prednisolone acetate (Pred Forte 1%, Allergan INC, Dublin, Ireland) were applied to the patients 4 times a day.

In the pre-operative and post-operative periods (day-1, month-1, month-3, month-6, month-12), best-corrected visual acuity (BCVA), detailed slit-lamb biomicroscopic examination, and IOP measurement with applanation were performed. Retinal Nerve Fiber Layer (RNFL) and Ganglion Cell Complex (GCC) scanning (RTVue - 100 5.1 fourier-domain OCT - Optovue Inc., Fremont, CA, USA) was performed during pre-operative month, 3, 6 and 12 post-operative visits. 24-2 Automated Computerization Visual Field Test (CVFT) was performed preoperatively and during post-operative month 12.

Complete success for the XEN45 gel micro-implant was defined as a >20% reduction in IOP values compared to pre-operative IOP values during 12 months without the need for any anti-glaucomatous medication. Partial success was defined as a >20% reduction in IOP values for 12 months compared to pre-operative IOP values with anti-glaucomatous drugs. Additionally, it was decided to perform bleb needling in patients if IOP>21 mmHg with bleb fibrosis.

The data obtained in the study were analyzed through the SPSS (version 26.0; SPSS, Inc., Chicago, IL, USA) program and a p value of <0.05 was found to be statistically significant. After the suitability of the data for normal distribution was evaluated with the Kolmogorov-Smirnov test, the nonparametric Wilcoxon Signed Ranks test was applied for dependent variables analysis.

RESULTS

The ages of the patients ranged from 51 to 75 years (62.63±7.05 years) and 50% were female and 50% were male. 33.3% of the patients were operated on the right eye and 66.7% were operated on the left eye.

The mean pre-post-operative month the central corneal thickness of the patients was 533.97±24.69 mm and cup/disc ratio (c/d) was 0.63±0.30. The difference between the number of pre-operative anti-glaucomatous molecules used by the patients due to POAG (3.24±0.95) and the number of molecules used at the end of 1 year (0.66±0.72) was statistically significant (p=0.001). In the case of clinical data, the difference between the pre-operative BCVA (0.77±0.93 LogMAR) and month 12 post-operative BCVA (0.62±0.93 LogMAR) values was not statistically significant (p=0.72).

While no intra-operative complications were observed in any patient, a 20% rate of complications developed within 6 months. 13.33% of the complications were hyphemia, all of which resolved with medical treatment in less than a week. Choroidal detachment developed in 3.33%; it improved with medical treatment. Inclusion cysts developed in 3.33%; local intervention was applied. Additionally, moderate IOP elevation (21 and 22 mmHg) was detected in 2 patients in the 1st post-operative week (6.66%).

The pre-operative IOP value of the patients was 22.53±3.81 mmHg. Pre-operative IOP value and post-operative day 1 (10.68±6.64 mmHg), month 1 (11.42±6.40), month 3 (13.00±3.82), month 6 (15.68±5.53) and month 12 (14.53±2.86). The difference between IOP values was found to be statistically significant (p<0.001). It is given in Figure 1. At the end of 1 year, the full success rate was 40% and the partial success rate was 36.67%.

33.3 % of the patients (10 patients) were utilized bleb needling, yet 6.67% of the patients were utilized twice. Although the first bleb needling time of the pa-

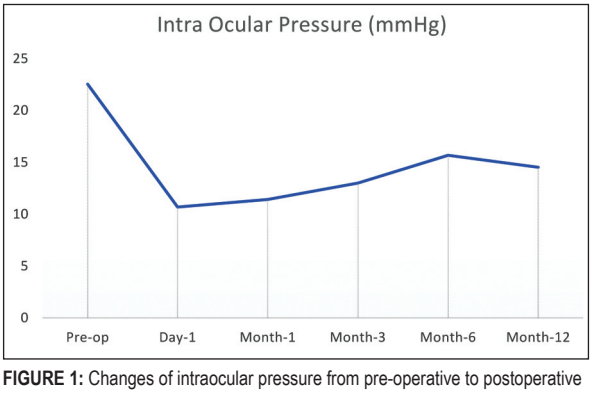

FIGURE 1: Changes of intraocular pressure from pre-operative to postoperative

TABLE 1: Pre-post-operative RNFL changes

All participants			p value
RNFL average (µm)	Pre-op	88.00±18.48	0.5
	Post-op month-12	84.00±18.48	
RNFL superior (µm)	Pre-op	113.50±17.90	0.47
	Post-op month-12	113.00±16.17	
RNFL inferior (µm)	Pre-op	109.50±25.98	0.9
	Post-op month-12	105.50±22.52	

Wilcoxon test. RNFL: Retinal nerve fiber layer; Pre-op: Preoperative; Post-op: Postoperative

TABLE 2: Pre-post-operative GCC changes

All participants			p value
GCC average (µm)	Pre-op	78.43±11.67	0.54
	Post-op month-12	84.51±5.89	
GCC superior (µm)	Pre-op	77.23±11.76	0.79
	Post-op month-12	85.95±3.64	
GCC inferior (µm)	Pre-op	79.89±11.29	0.18
	Post-op month-12	83.06±8.15	
GCC FLV (%)	Pre-op	8.94±8.89	0.55
	Post-op month-12	7.67±7.78	
GCC GLV (%)	Pre-op	22.14±13.36	0.42
	Post-op month-12	15.10±6.47	

Wilcoxon test. GCC: Ganglion cell complex; FLV: Focal loss volume; GLV: Global loss volume; Pre-op: Preoperative; Post-op: Postoperative

TABLE 3: Pre-post-operative CVFT changes

All participants			p value
CVFT MD	Pre-op	-14.58±2.70	0.75
	Post-op month-12	-15.28±14.23	
CVFT PSD	Pre-op	9.33±1.43	**0.01**
	Post-op month-12	6.46±2.64	
CVFT VFI (%)	Pre-op	67.00±9.24	0.26
	Post-op month-12	54.50±47.92	

Wilcoxon Signed Ranks Test. CVFT: Computerised visual field test; MD: Mean deviation; PSD: Pattern standard deviation; VFI: Visual field index; Pre-op: Preoperatif; Post-op: Postoperatif

tients was 4.30±2.75 months, the 2nd bleb needling time was 10.50±0.50 months.

The changes in RNFL and GCC values until the end of post-operative month 12 were examined with the Wilcoxon test (Table 1, Table 2).

CVFT values of the patients were compared pre- and postoperatively at month 12. As a result, the change between the CVFT PSD value in the pre-operative and post-operative month 12 was found to be statistically significant ($p<0.01$). The change in CVFT values until the end of post-operative month 12 was examined with the Wilcoxon test (Table 3).

DISCUSSION

Phacoemulsification combined with trabeculectomy and phacoemulsification combined with MIGS represent 2 distinct approaches for managing cataract and glaucoma simultaneously. Trabeculectomy has been the gold standard for patients with moderate to severe glaucoma, as it provides significant and long-term IOP reduction. However, it comes with a higher risk of complications, such as infection, hypotony, and filtration bleb failure, and requires close postoperative monitoring. It is particularly useful for patients with advanced glaucoma who need aggressive IOP control alongside cataract surgery.[12,13]

On the other hand, phacoemulsification combined with MIGS offers a safer and less invasive alternative, particularly for patients with mild to moderate glaucoma. However, they may provide less IOP reduction, which might not be sufficient for patients with more severe glaucoma.[14,15] MIGS is a good choice for patients who require moderate IOP control and want to minimize surgical risks, but it may not be adequate in cases where more extensive glaucoma management is needed. Thus, the choice between these approaches depends largely on the severity of the glaucoma and the desired balance between efficacy and safety.[15]

Mansouri K. et al. followed the patients who underwent combined surgery with XEN gel micro-implant and phacoemulsification throughout 1 year. A 31% decrease in IOP and a significant decrease in the number of anti-glaucomatous medications were detected. On the other hand, bleb needling was needed in 37% of the patients.[16] Wu et al., POAG followed patients who received XEN45 gel stents for primary angle closure and secondary glaucoma for 3-12 months. While complications (shallow anterior chamber, hypotony, stent occlusion) were observed in 25%, bleb needling was required in 53%.[17] Arnould L. et al., in their meta-analysis, a 21.7% decrease in

IOP and a significant decrease in the number of anti-glaucomatous medications were found in patients followed for 2 years after XEN45 gel micro-implantation. On the other hand, bleb needling was applied once in 28.4% of the cases, and bleb needling was applied a second time in 18%.[18]

In the prospective, single-center clinical study, 30 patients diagnosed with POAG and cataract between the ages of 51 and 75 were included. All the patients underwent XEN45 gel micro-implant and phacoemulsification combined surgery and they were followed throughout 12 months. In this study, the IOP reduction after 1 year was 35.5%. Moreover, while no intra-operative complications were observed in any patient, complications developed at a rate of 20% in the post-operative period. These complications resolved completely with medication within a maximum of 2 weeks.

At the end of 1 year, the full success rate was 40% and the partial success rate was 36.67%. On the other hand, bleb needling was applied once to 33.3% of the patients, and bleb needling was applied to 6.67% twice.

However, a 2-4 mmHg decrease in IOP after cataract surgery is reported in the literature.[19-21] In this current study, the IOP decrease occurred with the synergistic effect of XEN implant and phacoemulsification surgeries.

In this study, the significant decrease in the CVFT PSD value compared to the pre-operative value indicates that the focal scotoma has decreased. This study shows that the XEN45 gel stent is an effective and reliable method. In addition, it made a positive contribution to the visual field damage caused by POAG.

CONCLUSION

The XEN45 gel micro-implant appears to be a minimally invasive, safe and effective method that can be applied to POAG patients who do not benefit from conservative treatment. In addition, it provides effective IOP control in the medium term and significantly reduces the number of anti-glaucomatous drop uses. Moreover, this study demonstrates that it has a positive effect on early visual field damage. As a result, it has been determined that the XEN45 gel micro-implant stands out as a very reliable and effective method in the treatment of POAG.

Although there was an increase in the visual acuity of the patients, there was no statistically significant result. Therefore, it can be considered that this is due to the glaucomatous damage and insufficient number of patients.

Other limitations of the study are that the sample size was not large and the follow-up period was limited to 1 year. As for the recommendations, further studies can demonstrate the effectiveness and reliability of the XEN45 gel micro-implant with a longer follow-up period.

Source of Finance

The ethics committee approval was obtained from the Clinical Research Ethics Committee of Marmara University, İstanbul, Türkiye on March 1, 2019 with registration number 09.2019.252. It was financed by Marmara University Scientific Research Project Unit and University Clinical Research Ethics Committee.

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

Idea/Concept: *Ceren Türkoğlu, Muhsin Eraslan;* ***Design:*** *Ceren Türkoğlu, Muhsin Eraslan;* ***Control/Supervision:*** *Ceren Türkoğlu, Muhsin Eraslan;* ***Data Collection and/or Processing:*** *Ceren Türkoğlu, Muhsin Eraslan;* ***Analysis and/or Interpretation:*** *Ceren Türkoğlu, Muhsin Eraslan;* ***Literature Review:*** *Ceren Türkoğlu, Muhsin Eraslan;* ***Writing the Article:*** *Ceren Türkoğlu;* ***Critical Review:*** *Ceren Türkoğlu, Muhsin Eraslan;* ***References and Fundings:*** *Ceren Türkoğlu, Muhsin Eraslan;* ***Materials:*** *Ceren Türkoğlu, Muhsin Eraslan;* ***Other:*** *Ceren Türkoğlu, Muhsin Eraslan.*

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