• Clinical Research •

Assessing XEN microstent's one-year efficacy: independent of site variability

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Abstract

● **AIM:** To evaluate the short-term efficacy of XEN45 Gel Stent (XEN) implantation for primary open angle glaucoma (POAG) and pseudoexfoliation (PEX) glaucoma across two university eye clinics, aiming to assess the impact of varying center-specific protocols during the first postoperative year.

● **METHODS:** We retrospectively examined 282 patients (183 in center 1, 99 in center 2), who underwent XEN microstent implantation for uncontrolled POAG or PEX glaucoma. Parameters including intraocular pressure (IOP), IOP-lowering medication count, best corrected visual acuity (BCVA), and postoperative complications were evaluated over 12mo.

● **RESULTS:** Post-implantation, center 1 reported a mean IOP reduction from 25.3±7.4 to 14.1±4.7 mm Hg (P<0.01) and a decrease in IOP-lowering medications from 3.2±1.2 to 1.0±1.3 (P<0.01). Center 2 observed a similar reduction from 24.4±6.5 to 15.1±5.5 mm Hg (P<0.01) and medication decrease from 3.0±1.1 to 1.2±1.0 (P<0.01). BCVA remained stable in both cohorts. The most common complications were hypotony (center 1: 32; center 2: 20) and choroidal detachment (center 1: 22, center 2: 15), with nearly identical needling rates (40% in center 1, 41% in center 2).

● **CONCLUSION:** XEN implantation yields consistent reductions in IOP and medication use across different centers using comparable surgical and postoperative treatment regime. These findings underscore XEN's short-term effectiveness and suggest standardizable outcomes regardless of exact surgical procedure or treatment differences.

● **KEYWORDS:** glaucoma; XEN45 Gel Stent; minimally invasive glaucoma surgery
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INTRODUCTION

Glaucoma, a progressive disease damaging the retinal ganglion cells and optic nerve head, is one of the most common causes of irreversible blindness worldwide with an estimated prevalence of up to 111.8 million in 2040[1-2]. This mostly asymptomatic chronic disease leads to visual field defects and loss of visual acuity and eventually complete blindness in the final disease stages, if left insufficiently treated or not treated at all[3].

Besides age, myopia, positive family history and ethnic background, the most important risk factor for the development and progression of glaucoma is intraocular pressure (IOP), which can be influenced therapeutically by laser treatment, medication in form of eye drops or surgery[4-5].

Trabeculectomy (TE), with or without intraoperative application of mitomycin C (MMC), is considered the gold standard for surgical glaucoma treatment and is effective in many different glaucoma entities[6]. In recent years, minimally invasive glaucoma surgery (MIGS) techniques were developed to reduce surgical trauma and complications in order to minimize patients' convalescence time and reduce variability of treatment success[7]. The XEN microstent (XEN 45 Gel Stent, Allergan, Irvine, California, USA) was approved in 2016 in the USA by the FDA and is one of the aforementioned MIGS procedures. The XEN microstent consists of a highly flexible gelatin tube of 6 mm length with an internal lumen of 45 μm diameter and connects the anterior chamber with the

subconjunctival/subtenonal space. The effectivity seems to be independent of patient age, glaucoma type, surgical technique (ab interno or ab externo) and whether the procedure was combined with cataract surgery[8]. The few studies comparing TE and XEN did not find significant differences for the risk of failure or the safety profiles[9-10]. However, it must be taken into account that for newer implants often only shorter follow-up periods are surveyed and unfortunately it is not uncommon for very heterogeneous reports on the follow-up[11].

The aim of this study was to compare the efficacy of XEN implantation in primary open angle glaucoma (POAG) and pseudoexfoliation (PEX) glaucoma at two tertiary centers, namely in Bern and Leipzig over a 12-months follow-up.

PARTICIPANTS AND METHODS

Ethical Approval The study was approved by the ethic committee of the University of Leipzig (209/18-ek) and Bern (BASEC-ID: 2022-01046) and complied with the Declaration of Helsinki and its later amendments at all times. The informed consent from each patient was documented in written form.

This study was designed as a retrospective comparative cohort study in 2 different eye hospitals (center 1: Bern, Switzerland; center 2: Leipzig, Germany). All eyes were treated with XEN microstent implantation between July 2016 and December 2020 in the University Eye Hospital Bern, Switzerland or Leipzig, Germany.

Requirements for inclusion were the presence of uncontrolled POAG or PEX glaucoma with a repeatedly measured IOP above target pressure. The diagnosis of POAG or PEX glaucoma was based on the following criteria: presence of typical glaucomatous optic disc changes (pathologically increased cup-to-disc ratio depending on the papillary area and significant thinning of the nerve fiber tissue), IOP of 21 mm Hg or above without therapy and the absence of clinical signs raising suspicion towards any other glaucoma entity (increased iris transillumination, uveitis, *etc*.) or optic neuropathies of non-glaucomatous origin. In eyes with concomitant lens opacification XEN microstent implantation was combined with phacoemulsification and IOL placement. Cases with a clear lens in place without clinically significant opacification and no need for cataract extraction were referred to other kinds of glaucoma surgery sparing the lens (mostly TE). Exclusion criteria were the presence of any other glaucoma entities (other than POAG or PEX glaucoma) and an age <18y. In cases of patients needing glaucoma surgery on both eyes, only data originating from the first operated eye was included in this analysis.

The indication to perform XEN microstent implantation was usually set at an outpatient clinic examination and based on a progressive POAG or PEX glaucoma in form of increasing glaucomatous visual field scotomas or an increase of standard automated perimetry (SAP) mean defect (2 dB/y) despite maximum tolerable IOP-lowering medication. Progression was verified by three repeated visual field tests in static automatic perimetry (Leipzig: Twinfield 2, Oculus, Wetzlar, Germany; 24-2 test strategy, 55 target points; Bern: Octopus 900, Haag-Streit, Köniz Switzerland, G2 test program) during the last 12mo before surgery. Further, a full ophthalmologic examination was performed including demographic data, best-corrected visual acuity (BCVA) using Snellen charts (transformed to logMAR for statistical analysis), examination of anterior and posterior eye segments including a gonioscopic examination of the anterior chamber angle using a contact lens (usually Sussmann-type). IOP was determined by Goldmann applanation tonometry and was defined as the preoperative IOP.

On the day before surgery all patients underwent a full ophthalmic examination again to confirm the indication for surgery and to decide about the surgical procedure (XEN implantation alone or XEN+phacoemulsification+posterior chamber IOL implantation). The IOP-lowering medication was applied in almost all cases till surgery, only in a few patients the local therapy was changed to a systemic therapy to lower the preoperative IOP and reduce conjunctival inflammation if present.

Surgical Procedures Following technique was used for XEN microstent implantation (identical in both treatment centers)[8]: When only an XEN was implanted, the anterior chamber was filled with a dispersive viscoelastic agent and the conjunctiva was prepared with injection of up to 0.1 mL MMC (concentration 0.1 mg/mL). The XEN was then inserted into the eyes anterior chamber *via* a side port incision opposite to the planned implantation site. After implantation the outer orifice was freed from adherent Tenon's capsule using a 30-G needle. When XEN microstent implantation was combined with simultaneous cataract surgery, phacoemulsification and posterior chamber lens implantation were performed *via* a 2.2 mm clear cornea incision at the 12 o'clock position, before the XEN microstent implantation was conducted in the above-described technique.

Postoperative treatment was identical in both centers and included locally applied antibiotics (gentamicin; QID for 1wk), cycloplegics (atropine 1%; BID for 1wk) and steroid eye drops (prednisolone acetate 1%; QID for 4wk, titrated thereafter depending on clinical assessment). Depending on the IOP and the morphology of the bleb a secondary needling procedure with 0.1 mL of fluorouracil (50 mg/mL; 5-FU) was indicated.

Postoperative follow-up examinations were usually planed 1, 3, 6 and 12mo after XEN implantation and the following data have been collected at any time: age, gender, laterality of surgery (left or right eye), IOP, BCVA and number of IOP-

Table 1 Summary of demographic data and surgical details for the study cohort

Parameters	Center 1	Center 2	*P* (Mann-Whitney *U* test)
Eyes (*n*)	183	99	N/A
Operation side	Right: 101; left: 82	Right: 45; left: 54	0.19
Age at the time of XEN implantation (y)	76.2±12.5	71.2±11.2	0.02
Sex (*n*)	Female: 108; male: 75	Female: 52; male: 47	0.21
IOP baseline (mm Hg)	25.3±7.4	24.4±6.5	0.35
IOP-lowering medication (*n*)	3.2±1.2	3.0±1.1	0.17
Mean BCVA (logMAR)	0.36±0.40	0.46±0.57	0.54
Mean MD (dB)	11.1±7.8	10.2±4.2	0.66
Surgical procedure			<0.01
XEN alone	170	48	
XEN+Phacoemulsification	13	51	

XEN: XEN45 Gel microstent; IOP: Intraocular pressure; BVCA: Best-corrected visual acuity, MD: Mean deviation; N/A: Not applicable.

lowering medication. Additionally, the anterior and posterior segments were examined using slit lamp biomicroscopy. To summarize, the postoperative treatment regimen and follow-up examinations were nearly similar in center 1 and 2. The only differences were postoperative follow-up regimen. In center 1 follow-up during the first month after surgery was scheduled once a week and every second week after the first week in center 2. This might have led to earlier minor post-surgical intervention like 5-FU injection or needling procedures.

Clinical success was evaluated following the recommendations published by the World Glaucoma Association (Guidelines on Design and Reporting of Glaucoma Surgical Trials). For complete success, IOP had to be decreased >20% compared to baseline without the additional use of any IOP-lowering drugs and the resulting IOP had to be <21 mm Hg (A), <18 mm Hg (B), <15 mm Hg (C) or <12 mm Hg (D). For qualified success, IOP had to be reduced >20% compared to baseline with the additional use of IOP-lowering medication, if the preoperative number of drugs was not exceeded. To meet the success criteria, no additional surgical intervention was allowed during the 12-month follow-up after XEN implantation, except needling procedures with 5-FU or sole subconjunctival 5-FU injection. All cases not meeting these criteria were considered as failures. All needling procedures were conducted in the operating room under local anesthesia (eye drops) and in combination with a 5-FU injection in a supine position. For sole 5-FU injection we applied 0.1 mL 5-FU subconjunctivally near the filtering bleb with the patient sitting in a chin up gaze downward position.

Data acquisition and statistical analysis were performed using Excel (Version 2007, Microsoft; Redmond, USA) and SPSS (IBM Version 22.0; Chicago, Illinois, USA). For patient age, IOP, number of taken IOP-lowering drugs, BCVA, mean defect of standard automated perimetry and retinal nerve fiber layer (RNFL) thickness the mean and standard deviation were calculated. The Wilcoxon-test was used for within-group comparisons and the Mann-Whitney *U* test for between-group comparisons. In both cases, $P<0.05$ was set to indicate statistical significance.

RESULTS

During the period from July 2016 to December 2020, 282 eyes from 282 patients who received an XEN microstent were included in this study (center 1: 183 eyes; center 2: 99 eyes). In center 1, the average age at the time of XEN implantation was 76.2±12.5y and the group included 108 female and 75 male patients. The center 2 patient group included 52 female and 47 male patients with an average patient age of 71.2±11.2y. The difference in the average patient age was statistically significant. In center 2 the patients were on average 5y younger than the patients treated in center 1 ($P=0.02$). In both centers only one eye per patient was included. A sole XEN implantation was performed in 96% in center 1 ($n=170$) *vs* 48% of patients in center 2 ($n=48$). A summary of all the demographic and surgical data is set out in Table 1.

Intraocular Pressure The mean IOP at the time of indication was 25.3±7.4 mm Hg in the patient group undergoing surgery in center 1 and 24.4±6.5 mm Hg in the eyes treated in center 2. This difference between both groups did not show a difference of statistical significance ($P=0.35$). In both groups the mean IOP dropped strongly 1, 3, 6, and 12mo after XEN implantation compared to the initial measurements prior to surgery ($P<0.01$). The mean IOP 12mo after surgery was 14.1±4.7 mm Hg in the eyes treated in center 1 and 15.1±5.5 mm Hg in center 2, without a statistically significant difference between the two groups ($P=0.17$). The exact postoperative IOP course is shown in Table 2 and Figure 1. Follow-up values of IOP, IOP-lowering medication and BCVA were compared intra-group wise to baseline values before surgery using Wilcoxon-test. Inter-group comparisons were conducted using Mann-Whitney *U* tests for each follow-up examination.

Table 2 Baseline and follow-up results for IOP, IOP-lowering medication and BCVA during the 12mo follow-up after XEN microstent implantation

Parameters	Center 1 (*n*=183)	*P* (Wilcoxon test)	Center 2 (*n*=99)	*P* (Wilcoxon test)	*P* (Mann-Whitney *U* test)
IOP (mm Hg)					
Baseline	25.3±7.4	N/A	24.4±6.5	N/A	0.35
1mo	12.4±6.0	<0.01	14.6±8.0	<0.01	0.02
3mo	14.4±5.5	<0.01	15.1±6.7	<0.01	0.58
6mo	14.8±5.7	<0.01	15.5±7.7	<0.01	0.93
12mo	14.1±4.7	<0.01	15.1±5.5	<0.01	0.17
IOP-lowering medication (*n*)					
Baseline	3.2±1.2	N/A	3.0±1.1	N/A	0.17
1mo	0.1±0.4	<0.01	0.8±1.4	<0.01	<0.01
3mo	0.5±1.0	<0.01	1.0±1.4	<0.01	<0.01
6mo	0.8±1.2	<0.01	0.9±1.4	<0.01	0.78
12mo	1.0±1.3	<0.01	1.2±1.5	<0.01	0.38
BCVA (logMAR)					
Baseline	0.36±0.40	N/A	0.46±0.57	N/A	0.54
1mo	0.52±0.56	<0.01	0.46±0.55	0.59	0.17
3mo	0.43±0.52	0.24	0.41±0.55	0.11	0.29
6mo	0.41±0.50	0.48	0.43±0.56	0.91	0.85
12mo	0.45±0.55	0.19	0.44±0.55	0.33	0.73

IOP: Intraocular pressure, BCVA: Best-corrected visual acuity; N/A: Not applicable.

IOP-Lowering Medication The mean number of IOP-lowering medication before XEN microstent implantation was 3.2±1.2 and 3.0±1.1 without a statistically significant difference between the two cohorts (*P*=0.17). The mean number of glaucoma eye drops decreased during the postoperative course 1, 3, 6 and 12mo after XEN implantation in both treatment groups (Figure 2 and Table 2). The 3mo after XEN implantation the mean number of IOP-lowering medication decreased to 0.5±1.0 and 1.0±1.4 in center 1 *vs* center 2, respectively. There was also a statistically significant difference between the two groups (*P*<0.01) at this point in time. However, 6 and 12mo after surgery there was no longer a significant difference between the two groups (center 1: 0.8±1.2 and 1.0±1.3 at 6 and 12mo after XEN; center 2: 0.9±1.4 and 1.2±1.5 at 6 and 12mo after XEN).

Mean BCVA The mean BCVA was 0.36±0.40 logMAR and 0.46±0.57 logMAR in the eyes treated in centers 1 and 2 respectively. The difference at baseline was not statistically significant (*P*=0.54). In center 1, only one month after surgery the mean BCVA decreased to 0.52±0.56. However, there was no significant difference 3, 6 and 12mo after XEN implantation (Table 2) anymore compared to baseline values in both treatment groups. In the center 2 patient group, the mean BCVA remained almost stable during the postoperative follow-up and did not show any significant differences compared with the results prior to the XEN microstent implantation. (Table 2). The difference between the two groups was also not statistically significant during the examined postoperative course (6mo: *P*=0.85; 12mo: *P*=0.73).

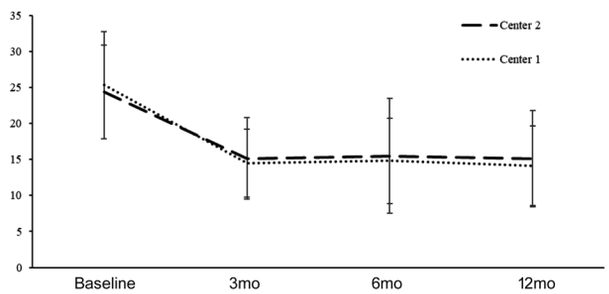

Figure 1 Mean IOP results for eyes undergoing surgery in center 1 and center 2 during the first 12mo follow-up after XEN microstent implantation IOP: Intraocular pressure; XEN: XEN45 Gel microstent.

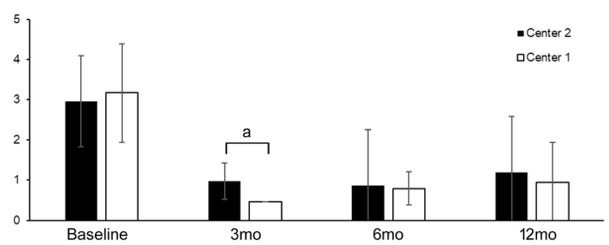

Figure 2 Number of taken IOP-lowering medication and standard deviation in the center 1 and center 2 groups during the 12mo follow up after XEN microstent implantation IOP: Intraocular pressure; XEN: XEN45 Gel microstent. [a]*P*<0.01.

Needling Procedure and Postoperative Complications During the first 12mo after surgery, at least one needling with 5-FU was necessary in 43 eyes (41%) in center 2 with 57 needling procedures in total. Only one needling was necessary in 32 eyes, whereas 2 needling procedures were performed on 8 eyes and three needling procedures on 3 eyes. During the

postoperative course, needling with 5-FU was performed in 75 eyes in center 1 (40%). A total of 96 needling procedures were carried out; in 60 eyes only one needling procedure, in 11 eyes 2 needling procedures, in 3 eyes 3 needling procedures and 1 eye with 5 needling procedures during the 12mo follow-up after XEN microstent implantation (Table 3). The duration between XEN implantation and the first 5-FU injection (2.4 and 2.8wk in center 1 and 2 respectively) or performance of the first needling procedures (4.5 and 5.0wk in centers 1 and 2 respectively) was not different between eyes undergoing surgery in the two centers.

During the first 12mo after XEN implantation, 20 eyes treated in center 2 showed postoperative numerical hypotony (<5 mm Hg) with accompanying choroidal detachment in 15 eyes. In center 1, 32 eyes developed hypotony and in 22 of these a choroidal detachment was observable. All of these eyes were treated conservatively, without further necessity for surgical intervention and hypotony and choroidal detachment resolved without further sequelae. Numerical hypotony was due to over filtration and larger conjunctival filtration zones in all cases and was only treated when choroidal detachment developed. Hypotony with choroidal detachment were treated by placement of a large bandage contact lens with a diameter of 22 mm. Compression and thereby minimizing the conjunctival filtration zone, letting scarification set in and reducing hyperfiltration was the reasoning behind this treatment. Additional treatment with eye drops containing atropine were utilized to paralyze the ciliary muscle to prevent further shallowing of the anterior chamber. Other occurring complications like anterior chamber hemorrhage and hyposphagma were followed-up. In cases of anterior chamber hemorrhages steroid containing eyedrops were given with an increased frequency (every 1-2h during waking hours) until resolution. No case needed a surgical anterior chamber washout. Apart from this, there occurred no other serious complications at both sites. In particular, there was no case of expulsive choroidal hemorrhage and no case of endophthalmitis in both observed patient groups during follow-up (Table 4).

Success Levels In both observed centers reached success levels were nearly similar over 12mo follow-up after XEN microstent implantation. A complete success with postoperative IOP <21 mm Hg (success level A) was found in 64% (center 1) and 65% (center 2) Leipzig. In 42% (center 1) and in 43% (center 2) a complete success with a postoperative IOP <12 mm Hg (success level D) was observed. Failure rates were 7% in center 1 and 18% in center 2. The differences between the two groups were not statistically significant during the whole examined postoperative course. An overview of all success levels is shown in Table 5.

Table 3 postoperative needling procedures during 12mo follow up after XEN microstent implantation

Parameters	Center 1 (*n*=183)	Center 2 (*n*=99)	*P* (Mann-Whitney *U* test)
Postoperative needlings	96	57	0.609
Eyes with needlings, *n* (%)	75 (40)	43 (41)	0.805
1×needling	60 (33)	32 (32)	0.839
2×needling	11 (6)	8 (8)	0.541
3×needling	3 (2)	3 (3)	0.458
4×needling	0	0	1.000
5×needling	1 (1)	0	0.456

XEN: XEN45 Gel microstent.

Table 4 Overview of all postoperative complications for all eyes treated during the 12mo postoperative follow up after XEN microstent implantation *n* (%)

Parameters	Center 1 (*n*=183)	Center 2 (*n*=99)	*P* (Mann-Whitney *U* test)
Hypotony (<5 mm Hg)	32 (17)	20 (20)	0.77
Choroidal detachment	22 (9)	15 (15)	0.52
Anterior chamber hemorrhage	6 (3)	6 (6)	0.38
Hyposphagma	7 (4)	5 (5)	0.77
Blebitis/endophthalmitis	0	0	1.0
Expulsive choroidal hemorrhage	0	0	1.0

XEN: XEN45 Gel microstent.

Table 5 Summary of success levels for all eyes treated in center 1 and center 2 during the 12mo postoperative follow-up after XEN microstent implantation %

Parameters	Center 1 (*n*=69)	Center 2 (*n*=61)	*P* (Mann-Whitney *U* test)
A (<21 mm Hg)			
Complete	64	65	0.29
Qualified	93	82	0.06
B (<18 mm Hg)			
Complete	64	60	0.25
Qualified	87	74	0.22
C (<15 mm Hg)			
Complete	55	56	0.89
Qualified	70	64	0.12
D (<12 mm Hg)			
Complete	42	43	0.53
Qualified	49	44	0.11
Failures	7	18	0.06

XEN: XEN45 Gel microstent.

DISCUSSION

Our study cohort of 282 patients underwent XEN microstent implantations in two independent ophthalmic centers and received follow-up examinations during the first 12mo after surgery. The results showed no significant difference in IOP, IOP-lowering medication or BCVA between the two centers after 12mo despite different surgeons and follow-up protocols.

Additionally, the number of necessary needling procedures and the rate of postoperative complications did not differ between both sites. This suggests that XEN microstent implantation is an effective method, leading to almost standardized results independent of the ophthalmic surgeon or center.

The efficacy of XEN has been shown in various real-world studies before, which demonstrated a reduction of IOP to an average of 14-15 mm Hg with less IOP-lowering medication[12-15]. Our results showed a mean IOP of 14.1±4.7 mm Hg (center 1) and 15.1±5.5 mm Hg (center 2) and a number of IOP-lowering medication of 1.0±1.3 (center 1) and 1.2±1.0 (center 2) 12mo after XEN microstent implantation, which is consistent with previously published data by other centers. In the APEX study the IOP decreased from 21.4±3.6 mm Hg to 15.2±4.2 mm Hg and the number of applied IOP-lowering medication from 2.7±0.9 to 0.9±1.1 in 202 POAG eyes 12mo after XEN microstent implantation[12]. Mansouri *et al*[13] reported of a postoperative IOP of 14.1±3.7 in 149 eyes with POAG 24mo after XEN microstent implantation. In a large systematic review of about 111 studies reporting outcomes after XEN implantation with follow-up times up to 36mo the postoperative IOP averaged at approximately 14 mm Hg with the use of about 1 glaucoma eyedrop[16].

In our two groups the BCVA did not change in a significant manner during the follow-up period and was nearly similar in center 1 (0.45±0.55 logMAR) and center 2 (0.44±0.55 logMAR) 12mo after XEN microstent implantation. That suggests, that the BCVA was not influenced by the surgical method utilizing sole XEN implantation or combination of XEN microstent implantation with cataract surgery. A possible explanation for this finding might be the relatively progressed disease stages of the eyes undergoing surgery. In our study population the mean deviation (MD) of eyes undergoing surgery were 11.1 dB in center 1 and 10.2 dB in center 2, so that the lack of postoperative BCVA increase might have been due to advanced glaucomatous optic nerve head atrophy and the resulting visual field scotomas prohibiting further postoperative BCVA increase.

A number of studies noted no significant difference in postoperative results (IOP, IOP-lowering medication and success level) after sole XEN microstent implantation or combined XEN implantation and cataract surgery[12,17-19]. In a large multi-center study 259 eyes were treated with XEN or combined XEN and cataract surgery and found a mean IOP of 14.3 (12.9-15.4) mm Hg after XEN and 13.8 (12.6-15.0) mm Hg after combined surgery 12mo after surgery[17]. Furthermore, Reitsamer *et al*[12] found a clinical success of 67.3% after XEN alone and nearly similar with 67.9% after XEN+cataract surgery 12mo after surgery. In our study we included sole XEN procedures as well as combined cases of XEN microstent implantation with cataract surgery. Almost all patients in center 1 were treated with sole XEN and nearly half of the cohort in center 2 was operated in combination with cataract surgery, which was mostly due to surgeons' preferences. We did not find differences of statistical significance concerning IOP and number of IOP-lowering medication between the two different groups.

The XEN microstent implantation is known as a standardized surgical technique for the treatment of glaucoma with the benefits of less surgical trauma, manageable complications and reduced patients' convalescence times. On the other hand, many outpatient clinic examinations and interventions with 5-FU or needling procedures or revisions are necessary during post-surgical follow-up. Our results showed a needling rate of 40% in center 1 and 42% in center 2 during the first 12mo after XEN microstent implantation, which is in line with observed needling rates of 33%-67% during the first 12mo after XEN implantation[9,20-22]. Most needling interventions were performed in the first 1-3mo after XEN microstent implantation and also repeated needling in the same eye were reported. On the other hand, Wagner *et al*[23] reported a lower needling rate of 16% after XEN or TE during the 12mo follow-up in 171 eyes.

Unfortunately, one observed major disadvantage after XEN implantation is the lower rate of IOP-reduction and the lower clinical success rates compared to TE±MMC[9]. In addition, the efficacy of XEN often decreased after 3-5y because of the tendency for scaring of the bleb. Today TE±MMC is still considered to be the gold standard of glaucoma surgery. Several studies, including multicenter studies, showed a drastic reduction in IOP and IOP-lowering medication in eyes with various forms of glaucoma[24-25]. A large study in the UK demonstrated a reduction in IOP from 23.0±5.5 to 12.4±4.0 mm Hg 24mo after TE in 428 eyes with POAG which did not undergo prior glaucoma surgery[16]. Comparing the two techniques TE and XEN microstent implantation, IOP reduction and higher success levels were more pronounced in eyes undergoing TE compared to XEN-microstent implantation[8-9,26]. On the other hand, TE±MMC needs a longer surgical times, involves a larger surgical trauma and usually longer hospitalization and convalescence times compared to XEN microstent implantation. The high needling rate also revealed the problem of not being able to control the exact positioning in relation to the Tenon/sclera during surgery without opening the conjunctiva. Longer follow-up observations are definitely required to detect late scarring and long-term failure.

Limitations to our study are its retrospective, non-randomized design and the smaller study population in center 2 compared to center 1. Additionally, the study population is heterogenous, there is no control group and the follow-up time was only

12mo. In the future, larger study populations, multicenter studies and longer follow up times are necessary.

To summarize, our results showed no significant difference in IOP, IOP-lowering medication, BCVA between the two centers after 12mo. Therefore, the results seem to be independent of the treating surgeon and the treatment regime. Thus, suggesting that XEN microstent implantations is a rather standardized surgical procedure, not so much depending on the individual skill set of the surgeon in comparison to other glaucoma surgeries.

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