Comparison of subconjunctival microinvasive glaucoma surgery and trabeculectomy

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ABSTRACT.

Purpose: **To assess surgical success and the post-operative development of intraocular pressure between XEN45® gelstent, Preserflo® MicroShunt and trabeculectomy with mitomycin C.**

Methods: **Data from 105 eyes from 105 patients of matched cases with refractory open-angle glaucoma, who underwent surgery between January 2019, and August 2020, were evaluated. Patients underwent either stand-alone XEN gelstent insertion with Mitomycin C, stand-alone Preserflo with Mitomycin C or trabeculectomy with Mitomycin C. The primary outcome was the proportion of complete surgical success at 6 months post-operatively (i.e. intraocular pressure between 5mmHg and 18mmHg, no revision surgery, no loss of light perception and no post-operative pharmaceutical antiglaucomatous treatment). The reduction of intraocular pressure after 6 months, the classes of antiglaucomatous medication used post-operatively, best-corrected visual acuity, spherical refractive errors and astigmatism were assessed as secondary outcomes.**

Results: **We included 35 eyes in each group. After 6-month follow-up, complete success was 73.5% [95%-CI: 57.9%–89.2%] in the trabeculectomy group, 51.4% [95%-CI: 34.0%–68.8%] in the XEN group and 74.2% [95%-CI: 57.9%–90.5%] in the Preserflo group ($p = 0.08$). Regarding secondary outcomes, the reduction of intraocular pressure was 12.1 ± 7.9 mmHg in the trabeculectomy group and was thereby 5.8 [95%-CI: 2.2–9.6] mmHg greater compared with the XEN group ($p < 0.001$) and 4.8 [95%-CI: 0.9–8.7] mmHg higher than the Preserflo group ($p = 0.01$).**

Conclusions: **No statistically significant differences were found between trabeculectomy, XEN45® gelstent implantation and Preserflo® MicroShunt implantation regarding surgical success after 6 months. Yet reduction in intraocular pressure was significantly higher in the trabeculectomy group. However, all three interventions resulted in sufficiently low post-operative intraocular pressure and may therefore be considered individually for glaucoma treatment.**

Key words: glaucoma – MIGS – trabeculectomy – surgical glaucoma treatment – filtration surgery

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Introduction

Globally, glaucoma is a disease affecting about 60.5 million people worldwide (Quigley & Broman 2006). It accounts for 8% of all cases of blindness and is the second leading cause of irreversible blindness worldwide. (Pascolini & Mariotti 2012). Initial therapy for glaucoma typically consists of topical eye drops or laser trabeculoplasty, both of which aim to lower intraocular pressure and have similar efficacy. (Samples et al. 2011) When pharmacologic and/or laser treatment fails to control intraocular pressure (IOP), pressure-lowering surgery is required. Due to its effective reduction of the intraocular pressure and its cost efficiency, trabeculectomy is considered the reference standard in surgical treatment of glaucoma (Kirwan et al. 2013).

However, recent developments have led to an expansion of the therapeutic options. For instance, a new group of procedures is pursuing a less invasive approach, aiming to reduce possible complications. Minimal Invasive Glaucoma Surgery (MIGS) includes a variety of interventions, extending from miniaturized versions of trabeculectomy to minimally invasive shunt or bypass operations, differing from traditional tube shunt procedures through limited surgical manipulation of the sclera and the conjunctiva (Burr et al. 2005).

Amongst these alternative procedures, the XEN45® gelstent (Allergan, Dublin, Ireland) was introduced in 2016 – a 6 mm porcine gelatin implant with a 45 µm lumen. The stent is implanted into the anterior chamber

angle and creates a drainage fistula to the subconjunctival space (Grover et al. 2017), similar to traditional trabeculectomy. However, the stent is implanted ab interno and avoids directly incising and disrupting the conjunctiva.

A similar approach is the Preserflo® MicroShunt (Santen, Osaka, Japan) (formerly known as the InnFocus MicroShunt) which is made from an elastomeric biomaterial (poly [styrene-block-isobutylene-block-styrene]; SIBS) that resists biodegradation in the body. The Preserflo® MicroShunt is an 8.5-mm-long (350 μm outer diameter; 70 μm lumen) surgical device that has been designed for implantation under the conjunctiva and Tenon's capsule through the sclera into the anterior chamber (Pinchuk et al. 2016, 2017).

Few studies have yet compared trabeculectomy with either XEN45® gelstent or Preserflo MicroShunt implantation. Most recently, Theilig et al. reported that there was no difference in the reduction of IOP or the use of IOP-lowering topical medication between trabeculectomy and XEN45® gelstent implantation (Theilig et al. 2020). To the best of our knowledge, there are no studies comparing Preserflo® MicroShunt implantation with either trabeculectomy or XEN45® gelstent implantation yet.

This study aims to assess the clinical outcome of alternative pressure-lowering surgery by comparison of surgical success and post-operative IOP development between XEN45® gelstent implantation, Preserflo® MicroShunt implantation and standard trabeculectomy.

Methods

We conducted a retrospective case–control study including patients with refractory open-angle glaucoma (primary open-angle glaucoma, secondary open-angle or normal-tension glaucoma) who underwent either stand-alone XEN45® gelstent insertion with Mitomycin C (MMC), stand-alone Preserflo® with MMC or trabeculectomy (TE) with MMC. We identified 35 consecutive cases of Preserflo implantation and matched each of these with one patient after XEN implantation and one patient after trabeculectomy. We included patients that underwent surgery between January 2019, and August 2020, by 2 experienced and certified surgeons at the University Eye Hospital Mainz, Germany. Identification of eligible patients was achieved by searching an electronic surgical case register and matched them for age and sex between the three groups. Eligible subjects were then confirmed by manual chart review. All data were fully pseudonymized before they were accessed. According to regional laws, the requirement for informed consent was waived by the ethics committee of the medical board of Rhineland-Palatinate.

Collected characteristics included demographics and ocular characteristics, such as preoperative intraocular pressure used for decision for surgery [preoperative IOP], number of different glaucoma medications, glaucoma diagnosis, history of previous cataract surgery, visual acuity and refractive errors. Follow-up data were obtained 6 months after surgery through chart review and correspondence with ophthalmologists engaged in patients' follow-up.

Inclusion and exclusion criteria

Patients above the age of 18 with primary open-angle glaucoma, secondary open-angle glaucoma and normal-tension glaucoma were included. Patients who did not meet these criteria or had prior filtering glaucoma surgery were excluded. Only the first treated eye of subjects within the observed time frame was included in this study.

XEN45® gelstent implantation

After disinfection with povidone iodine, 0.02 mg MMC (0.1 ml) was injected under the conjunctiva posterior to the area of the planned gelstent injection site (at least 9 mm from the limbus). The fluid was then massaged further posterior to avoid contact with the vulnerable limbus. A main and a side-port paracentesis were made, and the anterior chamber was filled with viscoelastic (Healon® or Healon GV®). The injector was inserted through the main incision and the needle guided to the opposite side of the anterior chamber. The correct positioning of the entry side was verified gonioscopically, and the surgeon aimed to puncture the sclera above the trabecular meshwork. The needle was then advanced through the sclera, emerging below the conjunctiva. The injector was rotated 90° and then withdrawn from its implantation area without any shift movement during the manoeuvre. The correct placement of the gelstent in the anterior chamber was confirmed by a second gonioscopy. By moving the conjunctiva with curved blunt forceps, the mobility of the gelstent was tested and checked for its straight, free and mobile position under the tenon. The viscoelastic was removed from the anterior chamber, the paracenteses were hydrated, the anterior chamber was deepened, and the presence of a bleb was confirmed.

Preserflo® MicroShunt implantation

A fornix-based flap of the conjunctiva was dissected at the nasal or temporal quadrant over a distance of 6-8 mm, depending on conjunctival laxity. To allow adequate implantation of the 8.5 mm long MicroShunt, a deep sub tenon socket is created. Following placement of 0.02 mg of MMC in 0.1 ml under the conjunctiva for 3 min using a 7×7 mm soaked sponge followed by intensive rinsing with saline solution, a 3 mm marker was used to mark a point 3 mm from the middle border of the surgical limbus in the blue–grey zone. At the distally marked point on the sclera, a 1-mm width knife was used to incise a shallow pocket in the sclera. A needle was then used to create a transscleral tunnel from the apex of the scleral pocket into the anterior chamber. Using forceps, the MicroShunt was threaded, bevel up and fins flat, into the transscleral tunnel. The fins were then wedged into the scleral pocket. Flow was confirmed visually at the end of the tip. Additionally, the anterior chamber was inflated with balanced salt solution. The distal end of the MicroShunt was tucked underneath Tenon's capsule and the conjunctiva, ensuring that it is straight and free of tissue; sutures were then used to reposition Tenon's capsule and the conjunctiva over the device and to the limbus.

Trabeculectomy

A fornix-based flap of the conjunctiva was dissected and Tenon's capsule was

mobilized. Then, a shallow groove was created directly behind the former conjunctival insertion to anchor conjunctiva later on. A 7 × 7 mm sponge soaked with 0.02 mg MMC in 0.1 ml was placed posteriorly under the conjunctiva for 3 min, followed by intensive rinsing with saline solution. A 4 × 4 mm scleral flap of partial thickness was prepared, and a temporal paracentesis was made. A rectangular corneo-trabeculectomy was created, and a peripheral iridectomy was performed. The scleral flap was closed with four 10-0 nylon sutures, two edge sutures and two side sutures stitched tangentially through the scleral flap and the adjacent sclera to allow aqueous humour to flow posteriorly whereby side sutures were pulled tighter than edge sutures (10). The conjunctiva was closed with improved sutures in a meander-like fashion for fornix-based conjunctival flaps as described by Pfeiffer and Grehn (11). The presence of a bleb and tightness of the sutures was confirmed by anterior chamber inflation with balanced salt solution.

Perioperative management

According to the University Eye Hospital Mainz protocol, all patients were instructed to stop the use of antiglaucomatous eye drops on the treated eye 2-4 weeks preoperatively. In order to reduce conjunctival inflammation, patients were advised to use unpreserved topical steroids for 5 days 4 times daily preoperatively. In case of an IOP increase, patients and treating ophthalmologists were instructed to treat IOP spikes with oral acetazolamide. Patients were hospitalized for surgery and were seen daily in the post-operative course. The post-operative topical regimen was the same for each of the three procedures: topical antibiotic prophylaxis for 1 week and unpreserved prednisolone eye drops 6 times daily, tapering off over a period of 3-6 weeks. Subconjunctival 5 FU injections were given at the discretion of the treating surgeon. Any necessary interventions (including laser suture lysis, and digital ocular compression posterior to the scleral flap increasing the scleral outflow) were performed on site during the inpatient stay, which lasted 2 nights by default.

Outcome measures

The primary outcome was the proportion of surgical success at 6 months post-operatively; we distinguished complete success and qualified success.

Failure

The procedure was considered as failure if one of the following criteria was met: IOP >18 mmHg, hypotony (IOP at 5 mmHg or less), revision surgery or loss of light perception.

Revision surgery was defined as additional surgery required, including needling procedures. Post-operative in-clinic manoeuvres or interventions, including laser suture lyses, were not considered failures.

Complete success

The procedure was considered a complete success if it did not fail by these criteria and did not require supplemental medical therapy to lower the IOP.

Qualified success

If post-operative pharmaceutical treatment was necessary to achieve adequate IOP-lowering (IOP ≤18 mmHg) but no surgery was necessary in the meanwhile, these cases were considered a qualified success.

In order to enable comparability with studies using different success definitions, success was also measured in a stricter manner.

Strict success

In addition to the aforementioned criteria, the IOP had to be reduced at least 20% compared with the preoperative IOP. Patients who met the stricter criteria are referred to as strict success.

We assessed the IOP reduction after 6 months, the classes of antiglaucomatous medication used post-operatively, best-corrected visual acuity (VA), spherical refractive errors and astigmatism as secondary outcomes.

Statistical analysis

Subjects' demographic and ocular characteristics, including age, sex, intraocular pressure, intraocular pressure-lowering medication, type of glaucoma, objective refraction and visual acuity, were described with mean and standard deviation for approximately normally distributed continuous data, otherwise with median and interquartile range for continuous variables, and with absolute and relative frequencies for categorical variables.

Comparisons between the three treatment groups were performed with a Kruskal–Wallis test for continuous parameters, with pairwise comparisons using Dunn's test with Bonferroni adjustment for non-normally distributed variables and one-way Analysis of Variance with pairwise comparisons using Tukey post hoc tests for normally distributed variables. Categorical data were compared using the χ^2 test. Continuous data of paired samples were compared by Wilcoxon signed-rank test. Multivariable logistic regression analysis was applied to evaluate associated factors with IOP reduction including age, sex and preoperative IOP as independent variables.

This is an explorative study, and a p value of 0.05 or less was considered as statistically significant. Statistical analyses were carried out with R (version 4.0.3, the packages ggplot2, dplyr and rstatix) (Kassambara, 2020; R Core Team, 2020; Wickham, 2016; Wickham et al., 2020).

Results

A total of 105 eyes of 105 patients were included and underwent surgery between January 2019, and August 2020, including 35 eyes in the trabeculectomy group, 35 eyes in the XEN group and 35 eyes in the Preserflo group.

The baseline characteristics and glaucoma characteristics were similar between the 3 patient groups but differed in the number of medication classes used and in the preoperative IOP (Table 1).

The study population consisted of 59 women (56%) and 46 men (44%) between the age of 54 and 87 years. The median age was 70 years. Preoperatively, the trabeculectomy group used 3 classes of medication. In the XEN group and in the Preserflo group, 2 classes of medication were used in median, statistical analysis indicated that there are slight differences between the proportions among the three groups (p = 0.02). Also, preoperative IOP was slightly higher in the trabeculectomy group (21.0 mmHg), compared with the XEN group

Table 1. Baseline characteristics

Characteristic	Total (n = 105)	Trabeculectomy (n = 35)	XEN (n = 35)	Preserflo (n = 35)	p value
Demographic					
Age, Median (IQR), yrs	70.0 (63.0–76.0)	68.0 (61.5–76.0)	70.0 (63.0–75.5)	73.0 (66.0–78.5)	0.31
Female sex % (no.)	56 (59)	51 (18)	57 (20)	60 (21)	0.76
Preop. IOP Median (IQR), mmHg*	20.0 (17.0–24.0)	21.0 (20.0–26.0)	20.0 (16.0–23.5)	18.0 (16.0–22.5)	0.03
Medication classes, median (IQR)†	2.0 (2.0–3.0)	3.0 (2.0–3.0)	2.0 (1.0–3.5)	2.0 (2.0–3.0)	0.02
Glaucoma type % (no.) and severity					0.21
Primary open-angle	64 (67)	63 (22)	71 (25)	57 (20)	
Pseudoexfoliation	24 (25)	20 (7)	26 (9)	26 (9)	
Pigment dispersion	2 (2)	6 (2)	0 (0)	0 (0)	
Normal tension	10 (11)	11 (4)	3 (1)	17 (6)	
Visual field (MD in dB (SD))	9.3 (6.7)	10.6 (6.2)	7.9 (7.4)	9.3 (6.5)	0.29

Abbreviations: IOP, intraocular pressure; IQR, interquartile range; MD, mean deviation; SD, standard deviation.
*At which, the decision was made to proceed with surgery.
†Number of medication classes to lower IOP when indication for surgery was made.

(20.0 mmHg) and the Preserflo group (18.0 mmHg) (p = 0.03). Patients scheduled for surgery had similar visual field defects. We did not find statistical differences for any of the other study characteristics.

Primary outcome: Surgical success

After 6-month follow-up, complete success was descriptively higher in the trabeculectomy group (73.5% [95%-CI: 57.9%–89.2%]), then with 51.4% [95%-CI: 34.0%–68.8%] in the XEN group, while the Preserflo group showed comparable proportion of complete success (74.2% [95%-CI: 57.9%–90.5%]). Nevertheless, the difference between the three groups was not statistically significant (p = 0.08).

Qualified success

The proportion of qualified success after 6 months was also descriptively higher in the trabeculectomy group (94.1% [95%-CI: 85.8%–100%]) compared with the XEN group (77.1% [95%-CI: 62.5%–91.58]) and the Preserflo group (90.6% [95%-CI: 79.9%–100%]) (p = 0.08).

Strict success

The rate of strict success (i.e. 5 mmHg < IOP ≤18 mmHg, no revision surgery, no loss of light perception, no postoperative pharmaceutical treatment *and* reduction of IOP by at least 20% compared to the preoperative IOP) was 64.7% [95%-CI: 47.8%–81.6%] in the trabeculectomy group, 31.4% [95%-CI: 15.2%–47.6%] in the XEN group, and 54.8% [95%-CI: 36.3%–73.4%] in the Preserflo group 6 months after surgery (p = 0.02), showing a statistical significant difference between the three groups for strict success. Compared separately with each other, the trabeculectomy group showed a statistically higher strict success rate compared with the XEN group (p = 0.006), whereas there was no statistically difference between the trabeculectomy and the Preserflo group (p = 0.42), while the XEN group had a tendency towards lower strict success compared with the Preserflo group (p = 0.06) (Fig. 1). Further comparisons are shown in Figure S1.

Secondary outcomes

The IOP reduction after 6 months compared with the preoperative IOP was statistically different between the three groups (p < 0.001), as shown in fig. 2. IOP including 1st postoperative day IOP are shown in figure S2. IOP reduction for trabeculectomy was 12.1 ± 7.9 mmHg and was thereby 5.8 [95%-CI: 2.2–9.6] mmHg higher than in the XEN group (p < 0.001) and 4.8 [95%-CI: 0.9–8.7] mmHg higher than in the Preserflo IOP group (p = 0.01). IOP reduction was not statistically different between the XEN and the Preserflo group (p = 0.81).

After adjusting for preoperative IOP, the IOP reduction in the trabeculectomy group was 2.8 ± 0.9 mmHg higher compared with the XEN group (p = 0.002) and 2.2 ± 0.94 mmHg higher than the reduction in the Preserflo group (p = 0.02). After 6 months, two patients from the trabeculectomy group showed hypotony – as defined with an IOP ≤ 5 mmHg – but without vision reduction or clinical signs, such as corneal oedema, hypotony maculopathy or choroidal effusion. There was no patient with hypotony in the XEN or Preserflo group after 6 months.

Medication use was comparable between the three study groups after 6 months: the trabeculectomy group used 0.5 ± 1.0 classes of medication, vs. 0.7 ± 1.0 classes in the XEN group and 0.4 ± 0.8 classes in the Preserflo group (p = 0.50).

Best-corrected visual acuity (VA) was similar between all groups at baseline, as shown in Table 1. VA deteriorated post-operatively in all groups but reached preoperative levels in all groups after 6 months (Table 2).

Spherical refractive errors did not change in the trabeculectomy (p = 0.67) or the XEN group (p = 0.40) 6 months post-operatively, while at the same time, a moderate myopic shift occurred from −0.5 [IQR: 1.6–0.6] dpt to −1.1 [IQR: −2.9–0.6] dpt (p = 0.02) in the Preserflo group. Regarding astigmatism, cylindrical power (p > 0.2–for all groups) did not change significantly in any of the groups.

Discussion

This retrospective case–control study of consecutive patients with refractory open-angle glaucoma compared the surgical success of trabeculectomy combined with MMC to the implantation of XEN45® gelstent and the

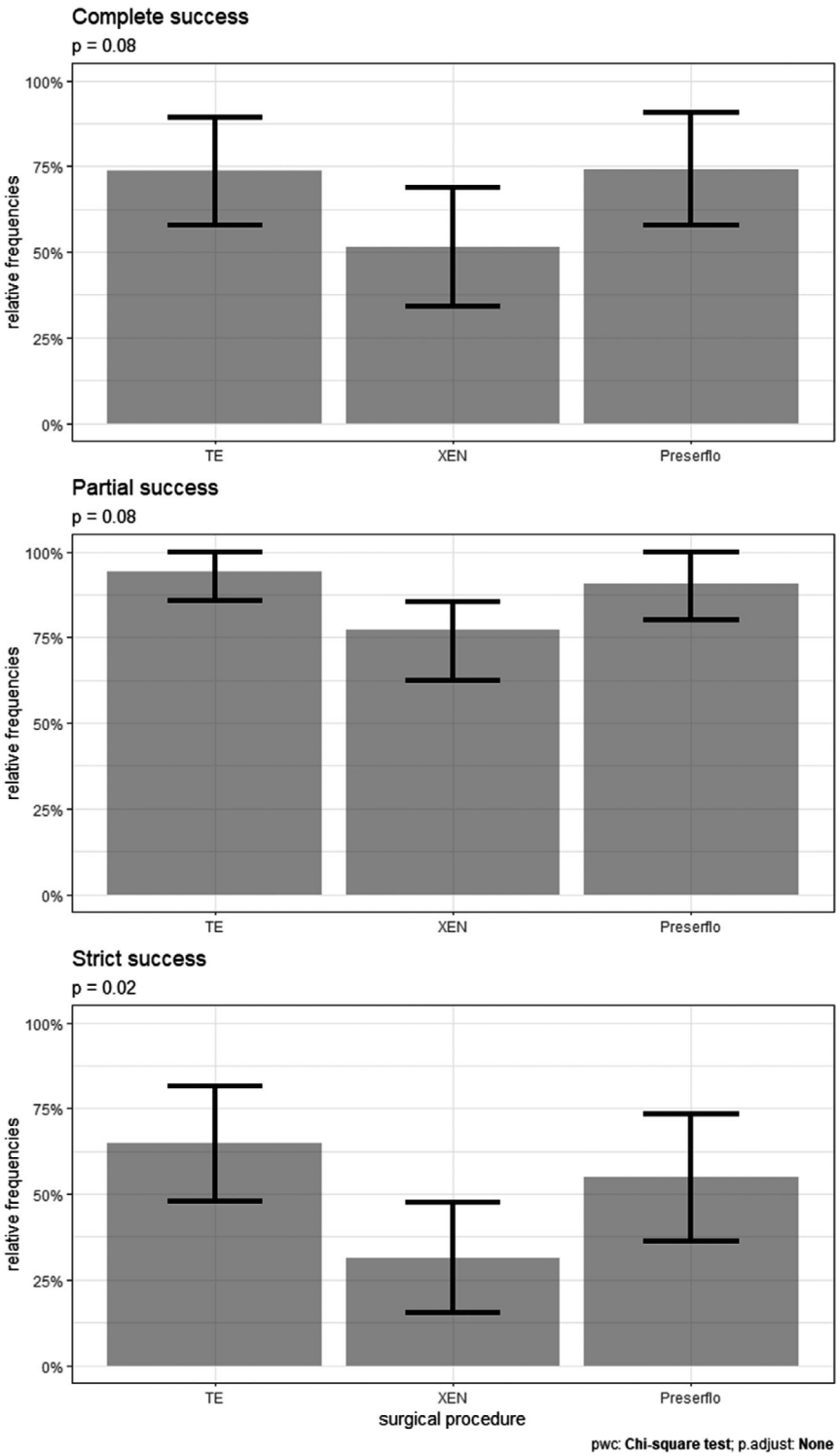

Figure 1. Complete Success proportion, partial success proportion and strict success proportion for the three study groups: trabeculectomy, XEN and Preserflo

implantation Preserflo® MicroShunt. We did not find evidence for a difference in the primary outcome of complete surgical success between the three groups 6 months post-operatively, although the proportion of strict success was significantly higher in the trabeculectomy group. With respect to qualified surgical success, we also found similar results between the three groups after 6 months.

Until today, few studies exist comparing the surgical outcome of trabeculectomy combined with MMC and the implantation of a XEN gelstent (Schlenker et al. 2017; Basílio et al. 2018; Marcos Parra et al. 2019; Teus et al. 2019; Theilig et al. 2020). Schlenker et al. compared the rate of surgical failure after trabeculectomy and XEN gelstent implantation, which directly corresponds to surgical success. Recently, Wagner et al. compared success rates of trabeculectomy and

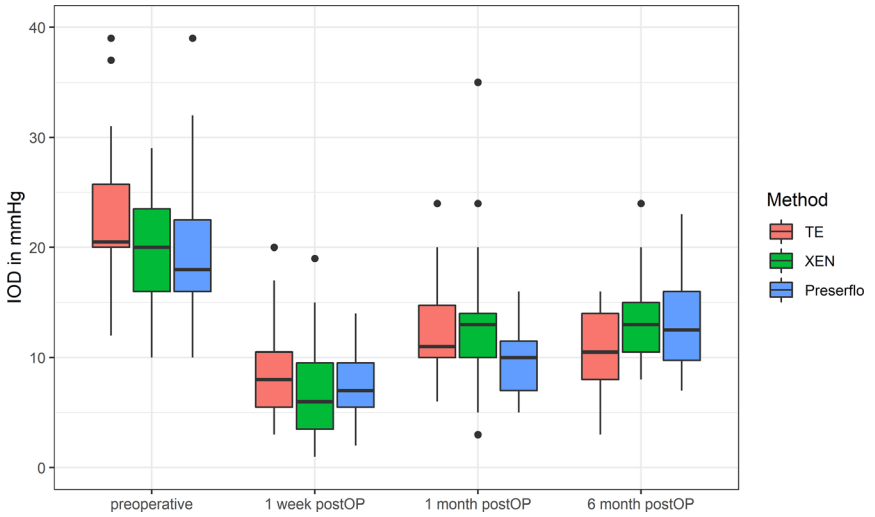

Figure 2. IOD preoperative, 1 week post-operative, 1 month post-operative and 6 months post-operative grouped by surgical method

Table 2. Development of visual acuity (in logMAR)

Visual acuity in logMAR, mean (SD)	Trabeculectomy (n = 35)	XEN (n = 35)	Preserflo (n = 35)	p value
logMAR preoperatively	0.22 (0.25)	0.22 (0.41)	0.23 (0.27)	0.97
logMAR at 1 week	0.48 (0.31)	0.32 (0.33)	0.51 (0.37)	0.06
logMAR at 1 month	0.45 (0.31)	0.34 (0.49)	0.28 (0.32)	0.41
logMAR at 6 months	0.22 (0.24)	0.23 (0.40)	0.23 (0.25)	0.93

XEN gelstent implantation. The applied criteria for surgical failure by Schlenker et al. and Wagner et al. were similar to those reported in this study. Schlenker et al. found no statistical significant difference for surgical failure between the two groups (Schlenker et al. 2017), while Wagner et al. reported a descriptively higher rate of qualified success for trabeculectomy (Wagner et al. 2020). Theilig et al. did not find significant differences in success proportions for TE versus XEN implantation 9 and 12 months post-operatively either (Theilig et al. 2020). Scheres et al. compared XEN gelstent and Preserflo MicroShunt implantation: they did not find a difference in the proportion of qualified success (Scheres et al. 2020). Baker et al. recently published the first prospective randomized multicentre study comparing Preserflo and trabeculectomy. They showed significantly higher surgical success rates for trabeculectomy and significantly higher IOP-lowering after trabeculectomy compared with Preserflo. In comparison with our study, they defined surgical success as an IOP-lowering of at least 20% from baseline without increasing the number of glaucoma medication. This different success definition might explain the notable higher difference in the success rates of Preserflo and trabeculectomy compared with our study. Furthermore, they used MMC 0.2 mg/ml for only 2 min (Baker et al. 2021). To the best of our knowledge, this study is first to compare all three procedures. Varying definitions of success in publications reporting on IOP-lowering surgical interventions are a known problem, which makes comparability of those studies difficult (Rotchford & King 2010). We have therefore decided to evaluate success with and without relative IOP reduction compared with preoperative values in order to enable comparability.

Patients having received trabeculectomy had a significantly higher IOP reduction compared with patients after XEN gelstent or Preserflo implantation. The changes in IOP after all three procedures are similar to reported IOP changes in current literature (Gedde et al. 2007; Jea et al. 2012; Matlach et al. 2015; Batlle et al. 2016, 2021; Song et al. 2016; Karimi et al. 2019; Durr et al. 2020; Scheres et al. 2020; Schlenker et al. 2020; Theilig et al. 2020). Theilig et al. reported a mean IOP reduction of 10.4 mmHg 6 months after trabeculectomy, which is lower than the reduction 12.1 mmHg we observed (Theilig et al. 2020). Scheres et al. found a mean IOP reduction of 5.6 mmHg 6 months after XEN stent implantation, which is slightly lower than our reduction of 6.2 mmHg. Further, they reported an IOP reduction of 7.6 mmHg 6 months after Preserflo implantation, which is similar to the reduction of 7.3 mmHg we reported (Scheres et al. 2020). A 10.8 mmHg reduction of IOP 6 months after Preserflo implantation was reported by Battle et al. (Batlle et al. 2016).

It is therefore justified to state that all three interventions show beneficiary outcomes regarding the IOP.

Nonetheless, our study has several limitations. First, it is a single-centre retrospective study. Due to its retrospective nature, the lack of randomization can lead to a selection bias. However, patients in all groups showed comparable glaucoma damage, based on visual field examinations. Although the number of patients is reasonable high for a single-centre study, the sample size is still small considering the small differences between the investigated methods. This study helps to plan prospective studies with sufficient larger sample size to detect possible differences between trabeculectomy, XEN- and Preserflo implantation. Moreover, the follow-up time was only 6 months and further studies investigating long-term outcome are required.

Intraocular pressure in the trabeculectomy group was higher at the time of inclusion in the study compared with the other two groups. But even after adjusting for preoperative IOP, the reduction of intraocular pressure was still significantly higher in the trabeculectomy group.

In conclusion, trabeculectomy, XEN45® gelstent implantation and Preserflo® MicroShunt implantation showed comparable complete and qualified surgical success after 6 months, although the IOP reduction was significantly higher in the trabeculectomy group. All three interventions resulted in sufficiently low post-operative IOP

values and may therefore be considered adequate treatment options to control intraocular pressure in glaucoma.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Fig S1
Fig S2