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Research Article

Comparison of Clinical Outcomes between XEN Gel Stent and PreserFlo Microshunt: A Monocentric Experience

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ABSTRACT

Purpose: To compare the clinical efficacy and safety outcomes in patients with Primary Open Angle Glaucoma (POAG) who underwent PreserFlo microshunt implantation and XEN-45 gel stent implantation at a single center.

Materials and methods: This is a monocentric retrospective study on patients with POAG treated with XEN-45 gel stent implantation or PreserFlo minishunt implantation at our centre in Florence. We included 31 eyes in 24 patients with XEN-45 and 26 eyes treated with twenty-six eyes in 25 patients with PreserFlo microshunt. All patients underwent a complete preoperative assessment, which included Intraocular Pressure (IOP) measurement with Goldmann Applanation Tonometry (GAT). Follow-up lasted for 12 months.

Results: We included 31 eyes treated with XEN-45 gel stent and 26 eyes treated with PreserFlo microshunt. The probability of complete success, meant as IOP ≤ 18 mmHg at month 12 without the need for surgically revising the bleb or reoperation, was of 51.6% in group 1 (XEN45) and 65.3% in group 2 (PreserFlo), without statistically significant difference (P=0.294). IOP dropped from 17.84 ± 4.48 to 13.48 ± 2.55 at month 12 in group XEN45, and from 17.27 ± 4.23 to 13.31 ± 1.54 at month 12 in group PreserFlo (P=0.760). The number of IOP-lowering medications dropped from 2.45 ± 1.26 to 0.24 ± 0.66 (month 12) in the XEN45 group and from 2.65 ± 0.89 to 0.24 ± 0.66 (month 12) in the PreserFlo group, without statically significant differences (P=0.642). Needling rate was 35.4% in group 1 and 11.5% in group 2 (P=0.036).

Conclusion: In our experience, both XEN45 gel stent and PreserFlo microshunt demonstrated to be effective and safety with similar results in terms of IOP-lowering and surgical success.

Keywords: Micro-invasive filtering surgery; Glaucoma; Preserflo microshunt

INTRODUCTION

Glaucoma is the second leading cause of blindness in Europe according to the European Glaucoma Society (EGS) [1]. Intraocular Pressure (IOP) represents a primary and modifiable risk factor for the onset and progression of disease [2]. Despite medical and laser treatment are universally accepted as the first line of therapy, surgery becomes necessary when other treatment modality prove to be ineffective or are not suitable and in patients with severe visual field loss at presentation [3].

Minimally Invasive Glaucoma Surgery (MIGS) includes a heterogeneous group of devices and procedures aimed to reduce IOP which have gained popularity over the last years. MIGS have a moderate Intraocular Pressure (IOP) lowering effect compared to conventional filtering surgery such as trabeculectomy, but with a better safety profile, a more rapid recovery, less surgical time, and a quick learning curve [4]. Currently, there are different commercially available MIGS; they can be classified according to their site of action such as enhancing aqueous outflow through the trabecular meshwork (Schlemm's canal devices), enhancing aqueous outflow through the suprachoroidal space and shunting the aqueous outflow into the subconjunctival space [5].

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The aim of this study is to compare the efficacy, rate of success and rate of complications in patients with Primary Open Angle Glaucoma (POAG) who underwent PreserFlo microshunt (Santen Pharmaceutical Co. Ltd., Osaka, Japan) implantation or XEN45 gel stent (Abbvie, USA) implantation. Both act on the same anatomical site, the subconjunctival space, creating a filtering bleb; despite the subconjunctival space is not part of the physiological pathway, is the most common drainage pathway as it is used in conventional filtering surgery (trabeculectomy) [6].

MATERIALS AND METHODS

This is a monocentric retrospective study on patients with POAG, who's IOP was uncontrolled with medications or laser, treated with subconjunctival MIGS devices at Careggi University Hospital Eye Clinic, University of Florence, from May 2020 to June 2021. All surgeries were performed by two certified surgeons with standardized procedures.

Patients were divided into two groups such as group 1 (XEN group) was implanted with XEN45 gel stent (Abbvie, USA) and group 2 (PreserFlo group) was implanted with PreserFlo microshunt (Santen, Osaka, Japan).

We included patients with primary open-angle glaucoma. Hodapp, Parish and Anderson criteria were used to stage glaucoma. It is clinically useful method that considers the overall extent of damage, using both Mean Deviation (MD) value and the number of defective points in the Humphrey Statpac-2 pattern deviation probability map of the 24-2, Swedish Interactive Thresholding Algorithm (SITA) standard test, and the proximity of defect(s) to fixation. The HPA classification system includes three groups such as early, moderate and severe defects [7,8]. The exclusion criteria were angle closure presence, prior glaucoma surgery, history of other ocular disorders (e.g., corneal lesions, retinal diseases, uveitis) and non-glaucomatous optic neuropathy, secondary glaucoma (e.g., pigmentary, pseudoesfoliative, uveitic, neovascular glaucoma) and incomplete follow-up (less than 12 months).

At baseline each patient underwent a complete ophthalmic examination, including Best Corrected Visual Acuity (BCVA) evaluation, intraocular pressure measurement with Goldmann Applanation Tonometry (GAT), ocular eye examination with biomicroscopy of the anterior segment, including examination of the iridocorneal angle through a gonio lens, and dilated fundus examination.

XEN gel stent

XEN45 gel stent has a total length of 6 mm and a lumen diameter of 45 µm, and it is made of porcine cross-linked glutaraldehyde. All implantations were performed with an ab-interno approach. After appropriate disinfection of periocular skin and conjunctival fornix with povidone iodine 10% and 5% respectively, a topical anesthesia with 2.5 ml of lidocaine was done. The surgeon identifies the area of the future bleb, usually in the supero-nasal quadrant, and marks the area at 3.0 mm from the limbus where the XEN gel stent will come out. Then he proceeds to create the conjunctival dissection with 0.1 mL of air and then 0.1 mL of a dispersive viscoelastic (we use ViscoAT, Alcon). The disposable injector enters the Anterior Chamber (AC), filled with a cohesive viscoelastic (Healon GV Pro, Johnson and Johnson), through a main corneal incision in the infero-temporal sector, upon coloring the stent with a blue dye (Trypan blue) and is directed toward the supero-nasal angle. An indirect gonio lens is used to watch the angle (a direct view gonio lens can also be used); the correct placement is just anterior to the pigmented trabecular meshwork. Once the needle tip is in the correct place, it's pushed forward through the sclera coming out in the subconjunctival space 3.0 mm away from the limbus. The injector is actioned, and the needle retracts into the sleeve. The device correctly positioned is 1 mm in the AC, 2 mm in the scleral tunnel and 3 mm in the subconjunctival space; the stent is well visible under the conjunctiva since it has been previously colored, it must be linear and with the tip mobile. The right placement in the angle is verified using a gonio mirror. The viscoelastic is removed from the anterior chamber with Balanced Salt Solutions (BSS). Finally, the surgeon performs a subconjunctival injection of 0.1 mL of Mitomycin C (MMC), 0.02% in the bleb. In the end, 0.1 mL of Cefuroxime is injected in the anterior chamber for prophylaxis. If a combined surgery was necessary, the phacoemulsification was performed at the beginning of the procedure.

PreserFlo microshunt

PreserFlo microshunt is composed of a synthetic polymer (polystyrene-block-isobutylene-block-styrene), has an overall length of 8.5 mm and a lumen size of 70 µm. After appropriate disinfection as before, a sub-tenon anesthesia with 2 ml of lidocaine was performed.

A fornix-based conjunctival peritomy is created, typically in the supero-nasal or supero-temporal quadrants. The Tenon capsule is gently but completely disinserted at the limbus removing all adhesions with the underlying episcleral. Mitomycin-C 0.02% soaked sponges are then applied to the scleral bed for 2.5 to 3 minutes considering the condition of the conjunctive (grade of inflammation, previous surgical failed procedures). The MMC sponges are removed, and the area is irrigated with copious amounts of balanced salt solution. The sclera is then marked 3 mm posterior the limbus. A scleral tunnel is created from this point following the curvature of the globe; then a 25-gauge needle is inserted in the tunnel previously created and enters the anterior chamber parallel to the iris plane. The device, previously primed using BSS, is then inserted through this tract. The surgeon tests the device patency *via* injection of balanced salt solution. At this point, the conjunctiva and the tenon capsule are sutured to the limbus with Vicryl 7/0 taking care to avoid distal obstruction of implant. Finally, a bleb will start to form; the surgeon makes sure there are no leaks using a fluorescein strip. 0.1 mL of Cefuroxime is injected in the anterior chamber for prophylaxis. If a combined surgery was necessary, the phacoemulsification was performed at the beginning of the procedure.

Post-operative management

Patients were instructed to discontinue all glaucoma medications on the day of the surgery. Post-operative therapy includes antibiotic prophylaxis for 1 week and steroids tapered in 6 months.

After the surgery, follow-up lasted for 12 months, with intermediate visits at week 1, month 1, month 3 and month 6. Every visit includes evaluation of Best Corrected Visual Acuity (BCVA), a slit lamp examination of anterior and posterior segment of the eye, IOP tonometry with GAT, and assessment for post-operative complications. Each patient with IOP rise underwent Anterior Segment Optical Coherence Tomography (AS-OCT) (MS39, CSO, Italy) to study the bleb morphology.

Whenever bleb needling was performed, 0.1 mL of 5-fluorouracil was used as anti-fibrotic agent. In case of another bleb failure or severe scar formation, surgically revising the bleb with the addition of MMC 0.02%, repeating trabeculectomy, or implanting a tube shunt was done. Patients were excluded at the time of reoperation.

Statistical analysis was performed using SPSS software version 26 (SPSS Inc., Chicago, Illinois, USA). Visual acuity was converted to a logarithm of the Minimum Angle of Resolution (logMAR) for analysis. Continuous variables were analyzed using the paired t-test, whereas categorical variables with the Chi-squared test. The probability of success was estimated with Kaplan-Meier method. A P value of less than 0.05 was considered statistically significant.

RESULTS

We evaluated 31 eyes in 24 patients treated with XEN45 (XEN group) and 26 eyes in 25 patients treated with PreserFlo microshunt (PreserFlo group). Demographic and clinical characteristics of patients included in the study are summarized in Table 1. The mean age of patients at time of treatment was 71 ± 9 years in XEN group, and 72 ± 7 years in PreserFlo group. XEN group was composed of 20 males (64.5%) and 11 females (35.5%), while Preserflo group was composed of 12 males (46.15%) and 14 females (53.8%). Baseline intraocular pressure was similar in the two groups: 17.84 ± 4.48 mmHg in group XEN group and 17.27 ± 4.23 mmHg in PreseFlo, without statically significant differences (p=0.626). The number of IOP-lowering medications at baseline, meant as number of active principles, was 2.45 ± 1.26 in the XEN group and 2.65 ± 0.89 in PreserFlo group, without statically significant differences (p=0.496). Distribution of patients according to severity classification didn't show statistically significant difference too, as well as the other baseline characteristics (Table 1).

Table 1: Demographic and clinical characteristics of patients included in the study.

Characteristics	XEN group (N=31)	PreserFlo group (N=26)	p-value
Age, Mean ± SD	71 ± 9	72 ± 7	0.831
Gender, male, n(%)	20(64.5%)	12(46.2%)	0.164
IOP Mean ± SD, mmHg	17.84 ± 4.48	17.27 ± 4.23	0.626
Anti-glaucomatous medications (No. of active ingredients), Mean ± SD	2.45 ± 1.26	2.65 ± 0.89	0.496
Anti-glaucomatous medications (No.of active ingredients), n of patients			
0	2(6.5%)	0(0%)	-
1	6(19%)	2(7.7%)	
2	7(22.6%)	10(38.5%)	
3	8(25.8%)	9(34.5%)	
4	8(25.8%)	5(19.2%)	
Oral acetazolamide, n(%)	6(19.4%)	3(11.5%)	0.42
Stage of glaucomatous damage, MD mean ± SD	-10.14 ± 8.01	-12.94 ± 7.67	0.186
Mild (MD<-6.00 dB)	11(35.5%)	8(30.8%)	0.399
Moderate (MD -6.01<>-12.00 dB)	12(38.7%)	7(26.9%)	
Severe (MD>-12.01 dB)	8(25.8%)	11(42.3%)	
Preoperative BCVA, Mean ± SD (range)	0.614 ± 0.32	0.484 ± 0.26	0.105
Previous surgery: Phaco+IOL, n(%)	19(61.3%)	12(46.2%)	0.253
Previous SLT, n(%)	3(9.7%)	5(19.2%)	0.301

Note: SD: Standard Deviation; IOP: Intraocular Pressure; MD: Mean Deviation; BCVA: Best Corrected Visual Acuity; Phaco: Phacoemulsification; IOL: Intraocular Lens; SLT: Selective Laser Trabeculoplasty

The probability of complete success, meant as IOP ≤ 18 mmHg at month 12 without the need for surgically revising the bleb or reoperation, was of 51.6% (16 about 31 cases) in XEN group and 65.3% (17 about 26 cases) in PreserFlo group, without statistically significant difference (P=0.294). The probability of qualified success (IOP ≤ 18 mmHg at month 12 with the use of medications or following bleb revision) or unsuccess (IOP>18 mmHg with the need for reoperation) are listed (Table 2).

Table 2: Post-operative procedures of XEN group and PreserFlo group.

Post-operative procedures	XEN group (N=31)	PreserFlo group (N=26)	p-value
Needling	11(35.4%)	3(11.5%)	0.036**
Bleb revisions	3(9.6%)	1(3.8%)	0.390**
Reinterventions (Trabeculectomy/glaucoma valve implantation)	4(12.9%)	3(11.5%)	0.875**
Transscleral cyclophotocoagulation	0	0	0

Note: **: Chi-square test

Regarding the need of postoperative procedures, needling was performed in 11 cases (35.4%) in XEN group and in 3 cases (11.5%) in PreserFlo group, with a statistically significant difference (p=0.036). In XEN group, 3 eyes (9.6%) underwent bleb revision (9.6%), and 4 eyes (12.9%) required reoperation; in PreserFlo group, 1 eye (3.8%) needed bleb revision, and 3 eyes (11.5%) required reoperation, without significant differences between the two groups. Postoperative procedures are reported (Table 3).

Table 3: Intraocular pressure and medications of XEN group and PreserFlo group.

Categories	XEN group (N=31)	PreserFlo group (N=26)	p-value
Baseline			
IOP(mmHg): Mean ± SD	17.84 ± 4.480	17.27 ± 4.229	0.626

No. of medications: Mean ± SD	2.45 ± 1.26	2.65 ± 0.89	0.496
Postoperative day 1			
IOP(mmHg): Mean ± SD	9.13 ± 3.019	8.38 ± 4.759	0.477
No. of medications: Mean ± SD	0	0	0
Postoperative week 1			
IOP(mmHg): Mean ± SD	10.77 ± 3.613	10.65 ± 7.037	0.934
No. of medications: Mean ± SD	0	0	0
Postoperative month 1			
IOP(mmHg): Mean ± SD	15.13 ± 7.915	13.58 ± 4.402	0.377
No. of medications: Mean ± SD	0.06 ± 0.359	0.23 ± 0.652	0.228
Postoperative month 3			
IOP(mmHg): Mean ± SD	15.35 ± 6.626	13.54 ± 3.695	0.235
No. of medications: Mean ± SD	0.13 ± 0.499	0.17 ± 0.565	0.795
Postoperative month 6			
IOP(mmHg): Mean ± SD	13.94 ± 3.463	14.67 ± 5.370	0.543
No. of medications: Mean ± SD	0.35 ± 0.709	0.52 ± 0.947	0.462
Postoperative month 12			
IOP(mmHg): Mean ± SD	13.48 ± 2.55	13.31 ± 1.54	0.76
No. of medications: Mean ± SD	0.32 ± 0.653	0.24 ± 0.66	0.642

Note: SD: Standard Deviation; IOP: Intraocular Pressure

At month 12, IOP was 13.90 ± 3.46 in XEN group with a reduction of 22.1% as compared to preoperative value. At the same time, patients implanted with PreserFlo had a mean IOP value of 14.62 ± 4.5, with a reduction of 15.3% as compared to preoperative value. Postoperative IOP at different time points did not show statistical significance between the two groups ($p>0.05$). Postoperative IOP values at different time points are listed.

We considered early complications (occurred within the first 30 days) and late complications (occurred after the first 30 days). Among the first, we registered two eyes with hypotony (IOP<6 mmHg) in XEN group (6.5%), while no cases were observed in PreserFlo group. We also observed one case of hyphemia in group XEN45 (3.2%), and two cases in group PreserFlo (7.7%). All cases spontaneously resolved without the need of surgical intervening. No cases of athalamia or choroidal detachment were noticed in the short-term postoperative period. In the late postoperative period, we didn't register any case of hypotony (IOP<6 mmHg), hypotony maculopathy and choroidal detachment. Filtering bleb fibrosis occurred in 12 eyes (38.7%) in XEN group and 6 eyes (23.0%) in PreserFlo ($p=0.205$); the lack of filtration required needling procedures, bleb revision or reoperation (as reported above).

DISCUSSION

Minimally Invasive Glaucoma Surgeries (MIGS) for primary open angle glaucoma are efficient in the reduction of the IOP and have good safety profile, so that they became a valid surgical alternative for glaucomatous patients. A recent meta-analysis has proven that the subconjunctival drainage pathway is the approach with a greater percentage of IOP reduction as compared to the other class of MIGS [9].

Our study compared two different devices shunting the aqueous in the subconjunctival space; XEN45 gel stent and PreserFlo microshunt. The results show that IOP decreased of 22.1% as compared to preoperative value in patients implanted with XEN45, and of 15.3% in patients implanted with PreserFlo. At the same time, the number of IOP-lowering medications dropped from 2.45 ± 1.26 to 0.32 ± 0.653 in the XEN45 group, and 2.65 ± 0.89 to 0.24 ± 0.66 in the PreserFlo group. While the reduction of IOP and number of medications over the preoperative period was statistically significant in both groups, the comparison of these values in the post-operative period in the two groups did never show statistically significant differences. Thus, our results show that both procedures are effective and similar in lowering IOP and reducing the number of postoperative IOP-lowering medications. The probability of complete success, qualified success and failure was similar in both groups, without statistically significant differences. More specifically, the probability of complete success was 51.6% and 65.3% at 12 months of follow-up for XEN45 and PreserFlo implantations, respectively ($P=0.294$). If we include the qualified successes, the probability of success rises to 87.1% and 88.5% respectively, without statistically significant differences ($p=0.876$). Our results are certainly limited by the small cohort and the retrospective design with the lack of randomization; but despite this, our results are compatible with what reported in literature. Scheres et al. [10] compared these two devices, showing similar data. Wagner et al. [11] likewise reported no statistically significant differences between trabeculectomy, XEN45 gel stent implantation and PreserFlo microshunt implantation regarding surgical success after 6 months and IOP reduction, as well as reported by Gambini et al. [12].

Focusing on complications, we didn't register any case with intraoperative problems. Early postoperative complications that occurred in the first 30 days were all mild and self-limiting. We registered two eyes with hypotony (IOP<6 mmHg) in group XEN45 (6.5%), while no cases in group PreserFlo. We also observed one case of hyphemia in group XEN45 (3.2%), and two cases in group PreserFlo (7.7%). No cases of athalamia or choroidal detachment were noticed in the short-term postoperative period.

In the late postoperative period, fibrosis in the filtering bleb occurred in 12 eyes in group XEN45 (38.7%) and 6 eyes in group PreserFlo (23.0%), without statistically significant differences ($p=0.205$). The lack of filtration required needling procedures, bleb revision or reoperation (as above). During both type of implantations, 0.02 mg/dl of Mitomycin C (MMC) was used to prevent excessive post-operative scarring and thus reduce the risk of failure. Despite the MMC concentration was the same, the application of this was different. An intra-bleb injection in the end of the surgery in the case of XEN45 implantation and placing cellulose sponges soaked in MMC onto bare sclera for 2.5-3 minutes in the case of PreserFLo implantation. Previous studies determined the safety and efficacy of MMC injection versus sponge during trabeculectomy, showing that both methods are safe and equally effective with comparable estimated

complete treatment success [13,14]. However, we must consider that a similar comparison has not been done during MIGS implantations especially since the sponge application doesn't fit the ab-interno surgery for XEN implantation. Consequently, the different types of administration may have caused a bias and should be further investigated.

Speaking of needling procedures, our results show that these have been performed more in the XEN group (35.4%) than in the PreserFlo group (11.5%) with statistically significant difference (p=0.036). This is compatible with previous study [15]. We explained these data saying that a correct visualization of the device is mandatory to perform the needling. Lysing the scars around a scarred bleb is more difficult in the case of PreserFlo because of the deeper and posterior localization of the distal end of the tube compared to XEN45; an in-the-office procedure could be less easy and safe. This could have affected these results.

CONCLUSION

XEN45 gel stent and PreserFlo microshunt demonstrated to be effective in lowering IOP and reducing the number of medications, with a similar and good safety profile. All variables examined didn't show statistically significant differences, except for needling rate. We believe that the two devices are similar, and the surgeon can liberally choose the one to which he/she is more confident or depending on availability. Further investigations are required, preferably with a prospective design.

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