



Efficacy and Safety of PreserFlo® MicroShunt After a Failed Filtering Surgery: A Retrospective Study

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ABSTRACT

This is a retrospective study conducted on patients who have undergone PreserFlo® MicroShunt surgery to manage their glaucoma after previously failed filtering surgery. PreserFlo® MicroShunt is a minimally invasive aqueous fluid delivery system that has shown promising results in managing glaucoma by improving the outflow of aqueous humor from the eye. The aim of the study is to evaluate the effectiveness and safety of PreserFlo® MicroShunt surgery in a challenging patient population, after another failed filtering surgery. The primary focus of the study is to evaluate the effectiveness of the treatment in reducing intraocular pressure (IOP), the need for medication and the survival rate of this device in patients that have had a failure of their previous filtering surgery. The results should determine that PreserFlo® MicroShunt can provide a viable and safer treatment option for this population, as long as it can achieve a good post-operative IOP around mid-tens, with reduction of the use of topical treatment and a good survival rate after the first 20 weeks of follow-up.

INTRODUCTION

PreserFlo® MicroShunt is a novel aqueous fluid delivery system that has shown promising results in the management of glaucoma. It is a simple microshunt device that aims to improve the outflow of aqueous humor from the eye with a flow resistance designed using Poiseuille's formula to prevent over drainage. Since its introduction and Conformité Européenne (CE) approval, it has been used widely as a primary glaucoma surgery in eyes that have failed medical treatment. The success of this device in this group of patients has extensively studied¹⁻³.

In eyes with failed filtering surgery the current standard practice in most glaucoma units will be a glaucoma day age device such as Baerveldt or Ahmed tube⁴. However, it might come with significant and risk of complications such as hypotony, corneal endothelial damage and ocular motility problems, amongst others.

Although the indications and licence for current Preserflo use is as a primary glaucoma surgery without

previous failed filtering surgery, in this St Thomas glaucoma unit, we have been using Preserflo with high dose mitomycin (MMC) (0.4 mg per ml for 5 minutes), for all patients that require filtering surgery including those with previous failed glaucoma filtering surgery.

Our thinking is that higher dose MMC can ensure better success in this group of patients without high complications.

Trabeculectomy is a commonly performed surgery for glaucoma, but it has a high failure rate, particularly in cases of advanced disease or in patients with multiple risk factors. Repeat trabeculectomy can be challenging and may carry a higher risk of complications. Therefore, alternative treatment options are needed for this population.

The results of this study may have important implications for the management of glaucoma in patients with previous failed trabeculectomy. If Preserflo is found to be effective and safe in this population, it could provide a viable and safer treatment option. This study may also help guide clinical decision-making and improve patient outcomes in this challenging patient population.

METHODS

We have created a retrospective study, selecting patients from the database of glaucoma section of

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a tertiary hospital such as St Thomas hospital. In this case, we have identified patients who have been diagnosed with glaucoma and have been treated with a trabeculectomy that have failed previously, and then have undergone a PreserFlo surgery to manage their IOP. We have extracted the relevant data from the patient records, including the patient's age, sex, medical history, and any relevant diagnostic and treatment information.

The main focus of the study was to evaluate the effectiveness of the treatment in reducing IOP and the need for medication. We have collected the data on the patient's baseline IOP and medication use before treatment and then follow up with them over time to see how their IOP and medication use have changed. We have also collected data on any side effects or complications related to the treatment.

Once collected the data, we have analyzed it using SPSS statistics and to create the figures.

SURGICAL TECHNIQUE

PreserFlo surgery, also known as the PreserFlo MicroShunt procedure, is a minimally invasive surgical procedure used to treat glaucoma. The surgery typically takes about 30 minutes to an hour and is performed under local anesthesia. The procedure involves creating a conjunctival flap avoiding bleeding if possible; preparing the shunt to be implanted, through the creation of a tunnel with a needle to open the anterior chamber before the iris and avoiding the cornea. Then the device is inserted and secured if needed with a suture to the sclera. Finally conjunctiva is closed with Nylon.

STUDY MEASURES

A retrospective review was conducted on consecutive patients who have had PreserFlo® MicroShunt with MMC 0.4 mg/ml for 5 minutes and has had previous glaucoma filtering series (trabeculectomy). The surgeries were performed by trained surgeons and some fellowship under surveillance at St. Thomas' Hospital, London, United Kingdom between August 2019 to February 2023. We have approval from the hospital audit committee.

INCLUSION CRITERIA

We have selected patients from age of 18. We have checked that they have had a previous failed filtering surgery before (trabeculectomy) and that it was

possible to record a minimum 6 months of follow-up data.

STUDY ENROLLMENT

The collected data included patient demographics, the patient's baseline readings which included intraocular pressure (IOP), number of IOP controlling medications (including topical IOP medications and Diamox), visual acuity (VA) and prior surgeries for IOP control. Post-operative data was collected from 1 day, 1 week, 1 month, 3 months, 6 months, 12 months, 18 months and 24 months after the PreserFlo® MicroShunt implantation. The post-operative data recorded included the complications, use of 5 Fluorouracil (5FU) and further procedures for IOP control in addition to IOP, number of topical IOP medications and VA. Complications post-operatively included choroidal effusion, hypotonous maculopathy, shallow anterior chamber, SCH, hyphema, SPK, bleb encapsulation, MicroShunt obstruction, Fibrin AC, HighIOP>30, AC inflammation, VF Progression, Cataract, Aqueous misdirection, Tube exposure and Macular oedema.

The different outcomes for the study included complete success, qualified success and failure. Complete success was has all four inclusion criteria:

- IOP $\leq$ 21 mmHg.
- Decrease of $\geq$ 20% decrease from baseline.
- Without IOP controlling medications.
- No follow-up procedures or surgeries.

Qualified success included patients that required IOP control medications or required follow-up procedures other than new glaucoma surgeries.

Failure was determine if a patient had any of the following criteria:

- IOP $\geq$ 21 mmHg.
- IOP decreases less than 20% from baseline.
- Follow up glaucoma surgery.
- VA drop of 2 lines and choroidals 3 months after surgery.
- VA drop of 2 lines AND IOP $\leq$ 5 mmHg 3 months after surgery.

With regards to the survival criteria, that would require a patient to have either complete or qualified success 1 year after the surgery. Patients that have yet to have a fail criteria and have not reached their 1 year follow up appointment are considered censored data. Patients that are considered to have failed are those who have had a fail criteria at any point during their follow up appointments post-surgery.

TABLE I.

No. of eyes	32
Mean age at point of surgery (SD)/years	66.8
Race	
White, n (%)	8 (25%)
AfroCaribbean, n (%)	15 (46,88%)
Asian, n (%)	5 (15,625%)
Indian, n (%)	2 (6,25%)
Arab, n (%)	2 (6,25%)
Sex	
Male, n (%)	22 (68.75%)
Female, n (%)	10 (31.5%)
Eye	
Left, n (%)	19 (59,375%)
Right, n (%)	13 (40,625%)
Type of previous filtration surgery, n (%)	
Previous trabeculectomy	28 (87,5%)
Previous PreserFlo® MicroShunt	4 (12,5%)
Mean baseline IOP (SD)/mmHg	27.4 (8.9)
Mean baseline IOP (SD)/mmHg	27.4 (8.9)

RESULTS

This study included 32 eyes of 32 patients: 28 with POAG treated previously with a trabeculectomy that had failed and 4 after another failed Preserflo.

Demographic and baseline characteristics are shown in table I.

Mean age was 66.7 and we could appreciate a majority of afro-caribbean population in our study (that can be assumed to have worse control of their glaucoma and more progression and tendency to inflammation⁵). Most of the previous surgeries failed before were trabeculectomy (28) and we have also followed 4 patients with failed previous Preserflo. The mean IOP baseline was 27,4 and the number of medications used 3,71.

After the surgery, we can appreciate in Figure 1 a drop on the baseline IOP that reduces it to a level between 7-10. It will rise gradually until month 6 staying globally in the mid-tens. The introduction of topical medications and further procedures as 5FU injections or needlings help to stabilize the IOP in those mid-tens until 24 months.

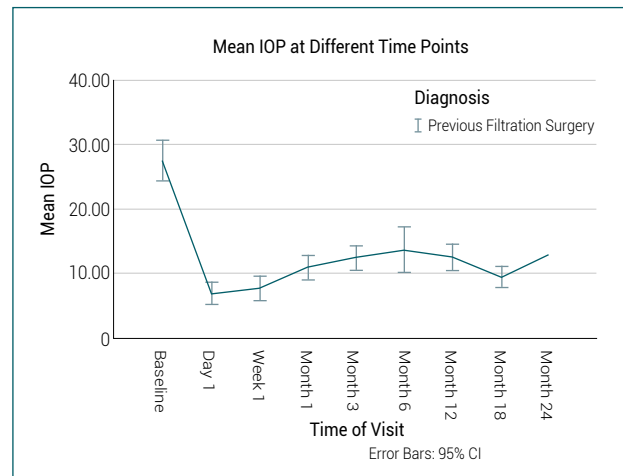


FIGURE 1.

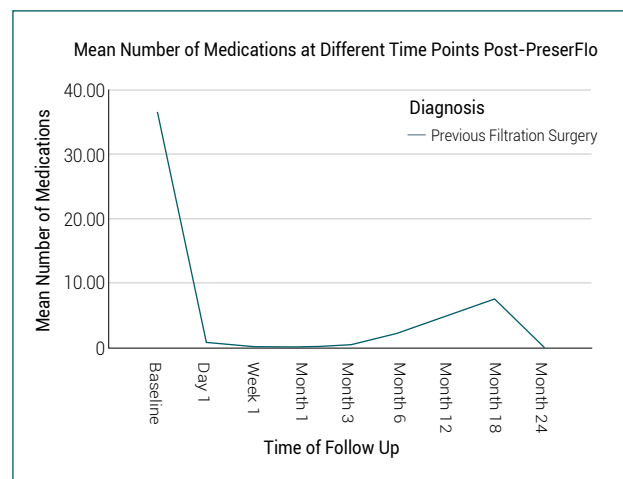


FIGURE 2.

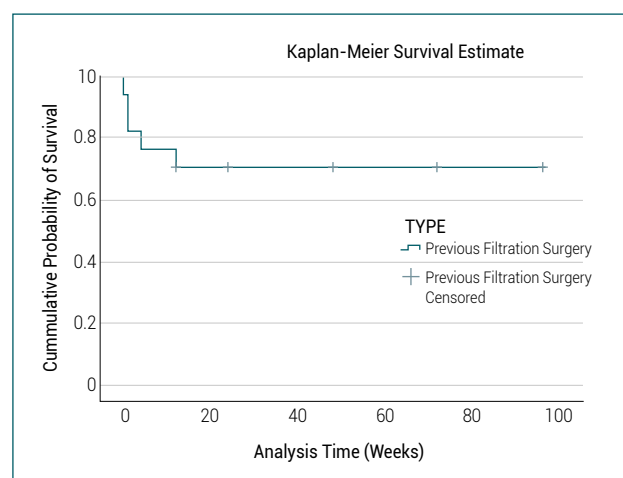


FIGURE 3.

Parallel to the decrease in pressure, it is logical to verify the reduction of glaucoma medications in

these patients in Figure 2 until month 6, when the increase in IOP begins to lead to a use of drugs that is accentuated at 12 months. The fact that we still do not have enough data at 24 months may determine that we do not present a large number of medications in our study in that period, although this condition would be expected.

Regarding implant survival in these patients (Figure 3), its failure, following our aforementioned definitions, leads us to postulate that if it occurs, it will be mostly in the first 20 weeks of follow-up, with survival stabilization later around 70% of survival.

DISCUSSION

Preserflo surgery after a filtering surgery has been found according to our results to be a safe and effective treatment option for patients with glaucoma^(1,2). The procedure involves implanting a small device into the eye that helps to regulate the flow of aqueous humor, which can help to lower intraocular pressure (IOP). These cases usually are the most complex to manage, due to the failing of a previous filtering surgery, maybe because an underlying tendency to inflame or fibrose.

Only one previous study have demonstrated the effectiveness of Preserflo surgery in reducing IOP after a previous filtering surgery and this results remark the good profile of risk-benefit that we can assume taking this surgery in account.

The lowering of IOP remains until month 6, where it may rise a little bit although it is easily manageable due to the introduction of topical medication. Longer-term medication use may reduce as well, potentially due to further procedures, such as needling, 5-FU use or even another surgery, although there is less data available.

One previous study⁶ found that patients who underwent Preserflo surgery after a previous trabeculectomy had a significant reduction from baseline at 12 months post-surgery. The study also reported a low rate of complications, with no cases of serious hypotony or device-related adverse events.

In the other hand, the surveillance of Preserflo surgery is an essential part of the post-operative management for patients with glaucoma. The first six months post-surgery are particularly critical as this is when the majority of complications and adverse events are likely to occur.

During the first six months after Preserflo surgery, patients should be closely monitored to ensure that the

device is functioning correctly and that the intraocular pressure (IOP) is stable. The surgeon will typically schedule regular follow-up appointments during this period, which may involve IOP measurements, visual acuity tests, and slit-lamp examinations.

After the first six months, the frequency of complications decrease, bearing in mind that changes can be more related to chronic changes instead of acute complications.

It is important to note that the duration and frequency of surveillance can be dependent on the fact that patients who have experienced previous surgical failures may require more frequent follow-up appointments, as in our case can happen.

Preserflo surgery after a filtering surgery has been found to be a safe treatment option for patients with glaucoma⁶. The procedure has a low rate of complications, with good management of any adverse events that may occur. Moreover, there have been no significant reports of patients experiencing vision loss as a result of the surgery.

Several studies have reported on the safety of Preserflo surgery in patients with glaucoma⁷. It has been found that the rate of complications following Preserflo surgery was low, with no cases of hypotony or device-related adverse events reported^{2,7}.

Finally, we have to consider that no clear data are available on the likely effect of the Preserflo in the visual acuity. Any study have reported a remarkably loss of it, although we have experienced some cases of loss of more than 2 lines of VA, not being them significant.

Overall, the evidence suggests that Preserflo surgery after a filtering surgery is a safe and effective treatment option for patients with glaucoma. The procedure has a low rate of complications, and patients typically experience a stable reduction in intraocular pressure. Moreover, the device has been shown to have a positive impact on visual acuity and quality of life.

Preserflo surgery can now be considered as an option for patients who have failed previous surgical interventions, including trabeculectomy or tube shunt surgery⁶.

Careful patient selection and close post-operative monitoring remains still essential to ensure optimal outcomes. Patients should be fully informed about the benefits and risks of Preserflo surgery and have a thorough evaluation of their ocular health before the procedure is undertaken.

However, more research is needed to fully understand the long-term outcomes of this procedure, particularly with regards to medication use and the need for additional surgeries.

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