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Preserflo™-Baerveldt Hybrid Implant: A Novel Approach for Glaucoma Drainage Surgery

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Abstract

Purpose: To investigate the efficacy and safety of a new technique connecting a Baerveldt glaucoma implant to a Preserflo™ micro-shunt.

Design: Retrospective non-comparative consecutive case series.

Methods: A retrospective consecutive case series analysing data collected from Electronic Patient Records at St Thomas' Hospital. All procedures were performed by a single surgeon (KSL) between November 2021 and February 2023. The following data were collected: demographic variables, IOP, number of glaucoma medications, complications and glaucoma subtype.

Results: Ten eyes underwent connection of the Baerveldt glaucoma plate to a Preserflo™ implant either as a primary combined procedure or as a secondary staged procedure. The mean age of our patients was 68.4 ± 10.9. The mean preoperative IOP was 25.6 ± 7.5 mmHg. The mean number of topical glaucoma medication preoperatively was 3.4 ± 0.7 with 4 patients also being on acetazolamide. All complications resolved without sequalae. One patient needed injection of viscoelastic at the slit lamp. At 6 months, the mean IOP was 11.7 ± 3.7 mmHg with a mean number of topical glaucoma medication of 0.7 ± 1.2, with 70% being off glaucoma medication. At 1 year, the mean IOP at 1 year was 11.7 ± 4.2 mmHg with a mean number of topical glaucoma medication of 1.1 ± 1.2, with 44% being on no glaucoma medications.

Conclusions: This novel technique is a safe and effective way to use as a primary combined procedure in high-risk eyes where Preserflo™ is likely to fail. It can also be used as a secondary procedure to salvage a failed Preserflo™.

Keywords: Glaucoma; Preserflo™; Corneal Endothelium; Hypotony; Glaucoma Drainage Device;

Introduction

Preserflo™ (Santen, Miami, USA) has gained popularity for glaucoma management in the United Kingdom (UK) due to its similar efficacy to trabeculectomy. Due to its flow restriction properties, it offers a lower risk of postoperative complications, such as hypotony. Additionally, it results in overall cost savings driven by a reduction in postoperative visits. [1].

However, the 20-30% failure rates for Preserflo™ necessitates the development of effective alternatives. This study introduces a novel approach which combines Baerveldt Glaucoma Implant (BGI) (Iovision, Inc, Irvine, California, USA) to Preserflo™ micro shunt as a primary combined

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procedure in high-risk eyes or as a secondary procedure when Preserflo™ fails. The Preserflo™ can be inserted into the BGI establishing a secure connection between the two devices. By incorporating the flow-limiting properties of Preserflo™ and the advantage of the large posterior plate of BGI, along with the use of Mitomycin C (MMC), this technique serves as the next step in glaucoma surgery.

Methods

Patient selection

This was a retrospective consecutive case series of ten eyes that underwent a surgical procedure involving the attachment of a BGI plate to a Preserflo™ micro shunt between November 2021 and February 2023. This retrospective case series analysis utilised data collected from Electronic Patient Records at St Thomas' Hospital.

The procedure was conducted either as a primary combined intervention or as a staged procedure following a failed Preserflo™ operation based on clinical judgment. Detailed clinical information and follow-up data were obtained to assess the outcomes of the combined approach. The following postoperative data points were chosen as recommended by the Consensus document by the World Glaucoma Association [2].

Glaucoma drainage device implantation

All surgical procedures were performed by KSL. Surgical technique was standard and similar in all studied cases with the procedures performed under general anaesthesia or local anaesthesia. Appropriate consent was obtained from the patients prior to performing the procedure as per hospital guidelines.

Primary Combined Procedure

Following placement of a corneal traction suture, a large peritomy was performed supero-temporally exposing adequate sclera for placing the BGI. Tenon's layer was identified, and blunt dissection beneath Tenon's Layer was extended posteriorly as far as possible. A sub-tenon application of Mitomycin-C (0.4mg/ml) was administered for 5 minutes via sponge after adequate haemostasis was achieved. The sponge was then removed, and the area washed with 20mls of balanced salt solution. The superior and lateral recti were then identified, and muscle hooks were used to allow appropriate positioning of the wings of the BGI under the recti. The BGI plate was then secured to the sclera, 8-9mm from the limbus, by non-absorbable 7.0 Prolene™ (Ethicon® USA, Johnson & Johnson, Germany,) sutures. A 23G (Blue) needle was then used to make a scleral tunnel through which the BGI tube was passed if there was excess proximal tube length. This helps to reduce micromotions and potentially reduce the risk of tube erosion.

The next step was to insert the Preserflo™ into the anterior chamber (AC). A 3 mm mark was made from the surgical limbus in the same quadrant supero-temporally. The 1mm blade was used to make a scleral pocket and the final entry into the AC was performed with a 25G needle. A paracentesis should be performed prior to entry into the AC. The Preserflo™ was then inserted into the AC. Priming of the Preserflo™ was performed to establish flow.

Once flow has been confirmed from the Preserflo™, both tubes should lie in proximity. The BGI tube was then shortened to the length required to allow Preserflo™ to sit inside it without causing any distortion or kinks in both tubes. The external diameter of Preserflo™ is 350 microns, whilst the Internal lumen of the BGI is 309 microns. To establish the connection between the Preserflo™ device and the BGI, the distal end of the BGI may need to be widened slightly by one or two lateral incisions. (See: Figure 1, 'Side cuts being made to allow the Preserflo™ to fit into the Baerveldt tube'), allowing for the proximal end of the Preserflo™ to enter the lumen of the BVT without excessive constriction. The connection was then secured using a cross/box suture Ethilon™ (Ethicon® USA, Johnson & Johnson Germany,) suture (See Figure 2, 'Preserflo™ inside the Baerveldt tube, tied down onto the sclera with a box tie suture.').

A double layer of processed pericardium graft was used to cover the tubes (Tutoplast®, Innovative Ophthalmic Products, Inc., Costa Mesa, CA, USA) to reduce the risk of erosion and this was secured using 10.0 Ethilon™. The Conjunctiva and tenons layer were then brought forward and the peritomy was closed using two purse string sutures at the sides and mattress sutures along the limbal edge also using 10.0 Ethilon™. Intracameral cefuroxime and dexamethasone were administered.

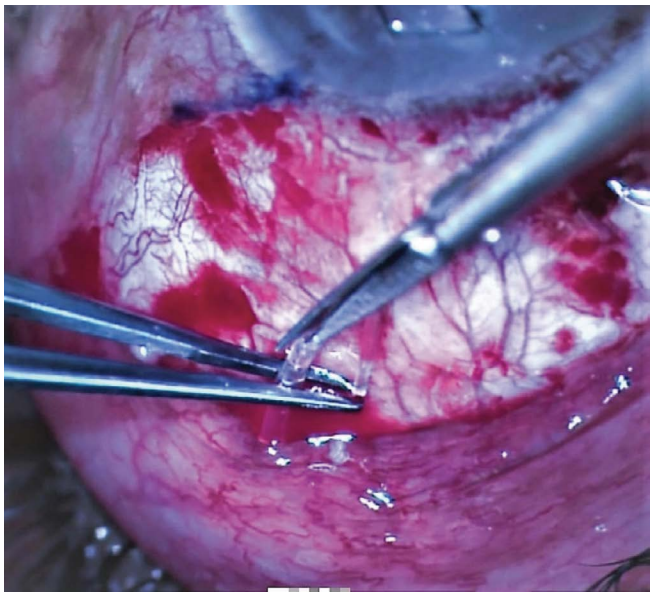

Figure 1: Side cuts being made to allow the PreserfloTM to fit into the Baerveldt tube.

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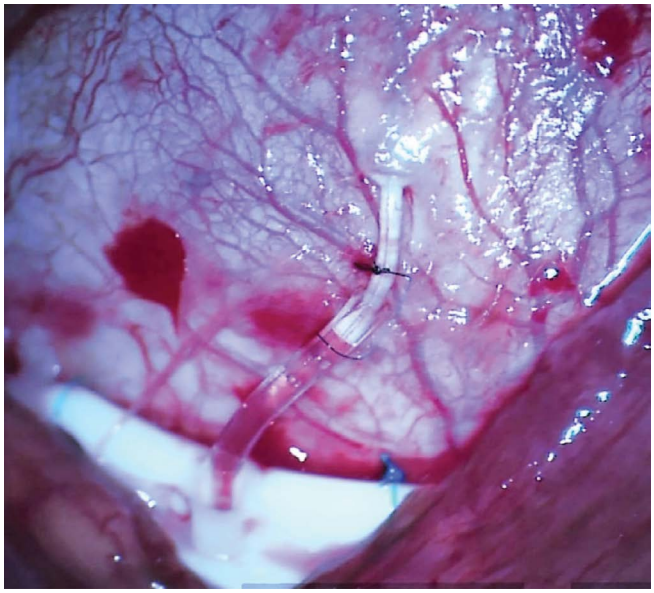

Figure 2: PreserfloTM inside the Baerveldt tube, tied down onto the sclera with a box tie suture

Postoperatively, all glaucoma medications were stopped in the operated eye and given a standard regimen of topical antibiotic and steroid. We used chloramphenicol 0.5% drops four times a day for 2 weeks, followed by dexamethasone 0.1% 2 hourly for at least 1 month. The dose of dexamethasone is then tapered down gradually over follow-up visits, based on clinical judgment.

Baerveldt to failed Preserflo™ connection.

Step 1 was repeated as above, but care was taken to avoid dissection of the Preserflo™ from its encapsulating fibrotic capsule. Flow must be avoided at this stage. If the capsule is disturbed and flow is confirmed, we advise the use of intracameral viscoelastic to avoid influx of MMC into the AC.

After successfully performing step 1, the failed Preserflo™ was released from any surrounding scarred tissue. If the Preserflo™ lies in an inaccessible or inadequate position for connection with the BGI, it must be repositioned closer using the standard technique described in step 2 above. The previous scleral tunnel must be plugged, and this can be achieved using 9.0 Ethilon™ and some tenon's tissue. Continue from step 3 onwards as described in the previous technique and remove any viscoelastic if used.

Results

The results are summarised in Table 1. Ten eyes from nine patients were included in this study. Seven patients were Afro-Caribbean (8 eyes, 80%) and 7 of the patients were Male (7 out of 9). The mean age of our patients was 68.4 ± 10.9. Two different glaucoma subtypes were found among the group, with eight of them being primary open angle glaucoma (POAG), the other being Secondary Glaucoma due to mixed mechanism with aphakia, pigment dispersion syndrome and anterior uveitis in one patient and the other patient developing glaucoma secondary to vitreoretinal surgery.

Table 1: Results A-C = Afro-Caribbean , POAG = Primary Open Angle Glaucoma, SOAG = Secondary Open Angle Glaucoma, N/A = Not Available

	Sex	Glaucoma type	Race	Age	Preoperative	Day 1	Week 1	Month 1	Month 6	1 Year
Eye 1 ²	F	POAG	A-C	76						
IOP (mmHg)					26	12	5	7	11	9
Glaucoma drops					3	0	0	0	2	2
Eye 2	F	POAG	A-C	73						
IOP (mmHg)					22	5	3	8	10	11
Glaucoma drops					4	0	0	0	0	1
Acetazolamide					Yes					
Eye 3	F	POAG	A-C	73						
IOP (mmHg)					28	12	15	23	18	16
Glaucoma drops					4	0	0	0	3	3
Eye 4	M	POAG	A-C	83						
IOP (mmHg)					30	6	7	13	18	7
Glaucoma drops					3	0	0	0	0	2

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Acetazolamide					Yes					
Eye 5[7]	M	POAG	A-C	65						
IOP (mmHg)					30	8	5	6	11	19
Glaucoma drops					4	0	0	0	0	0
Eye 6	M	POAG	A-C	84						
IOP(mmHg)					18	*3	*4	5	12	12
Glaucoma drops					4	*4	*4	0	0	0
Eye 7	M	SOAG	A-C	58						
IOP (mmHg)					42	5	6	5	8	8
Glaucoma drops					4	0	0	0	0	0
Eye 8	M	POAG	Arabic	53						
IOP (mmHg)					18	12	7	6	10	N/A
Glaucoma drops					3	0	3	3	2	N/A
Eye 9	M	SOAG	Caucasian	61						
IOP(mmHg)					18	6	7	15	12	15
Glaucoma drops					3	0	0	0	0	2
Acetazolamide					Yes					
Eye 10	M	POAG	A-C	58						
IOP (mmHg)					24	3	5	6	7	8
Glaucoma drops					2	0	0	0	0	0
Acetazolamide					Yes					
Average Age / SD				68.4 ± 10.9						
Average IOP (mmHg)/ SD					25.6 ± 7.5	7.7 ± 3.5	6.7 ± 3.4	9.4 ± 5.9	11.7 ± 3.7	◊11.7 ± 4.2
Average Glaucoma drops / SD					3.4 ± 0.7	0	0.3 ± 1.0	0.3 ± 0.9	0.7 ± 1.2	◊1.1 ± 1.2
Number of patients on No glaucoma drops					0	*9	*9	9	7	◊4

*- data from eye 6 excluded since patient incorrectly using drops when not required
◊-data from 9 patients since no data at 1 year for eye 8

The mean preoperative IOP was 25.6 ± 7.5 mmHg with the mean number of topical glaucoma medications (TGM) preoperatively being 3.4 ± 0.7 and with 4 patients being on acetazolamide. Eight out of ten eyes had a primary combined procedure in view of high risk of predicted failure for standalone Preserflo™. (Previous failed trabeculectomy or other glaucoma device surgery). Two out of ten eyes had a secondary procedure with connection of BGI to a failed Preserflo™.

One of the patients incorrectly continued using all his preoperative TGM for day 1- and 1-week postoperative visits. Excluding his data for this period, the mean IOP at day 1 was 7.7 ± 3.5 mmHg without any glaucoma medication. The mean IOP at week 1 was 6.7 ± 3.4 mmHg with the mean number of TGM being 0.3 ± 1.0, with one patient using glaucoma medications. The mean IOP at month 1 was 9.4 ± 5.9 mmHg with the mean number of TGM being 0.3 ± 0.9, with one patient using glaucoma medications. The mean IOP at month 6 was 11.7 ± 3.7 mmHg with the mean number of TGM being 0.7 ± 1.2, with three patients using glaucoma medications. At

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1 year, the mean IOP was 11.7 ± 4.2 mmHg with the mean number of TGM being 1.1 ± 1.2, with five patients out of nine using glaucoma medications.

Six eyes developed transient shallow choroidal effusions in the early post operative period which resolved spontaneously. Two eyes developed shallow AC with one eye requiring injection of viscoelastic into AC in view of tube cornea touch. All the complications occurred within the first month post-surgery and all cases recovered with no significant sequalae.

Discussion

Preserflo™ use is increasing in the United Kingdom (UK) instead of trabeculectomy as a first-line glaucoma filtering surgery. However, when Preserflo™ has a high risk of failure or has failed, the next procedure of choice can be uncertain. We describe a new technique which can be used in cases deemed at high risk of failure as a primary combined procedure, or as a secondary procedure in cases of Preserflo™ failure.

The technique presented here combines the advantage of the BGI (large plate maintaining a minimum size bleb, which increases the chances of long-term success) with those of the Preserflo™, designed based on Poiseuille's formula which has innate flow resistance and therefore reduces the risk of hypotony. Additionally, it has a smaller external lumen that can potentially reduce the risk of endothelial cell attrition with proper placement.

Preserflo™ micro shunt has been reported for use in patients who require effective reduction in IOP (12-17mmHg), as a bridge between minimally invasive glaucoma surgery and filtering surgery [3]. In recently published reports, Preserflo™ delivers a mean IOP of 14 mmHg at 1 year and it has fewer reported cases of postoperative hypotony vs. traditional trabeculectomy (28.9% vs 49.6%) [4]. Results so far have been promising for this device with safe and effective clinical results at 2 years [5].

In the case of Preserflo™ failure, where the IOP remained too high, a tube shunt, such as a BGI, is traditionally recommended. The main concerns of BGI surgery are twofold; firstly, the problem of having a large tube in the AC has been shown to cause significant endothelial cell loss at 5 years quoted as 36.8% for central corneal endothelial cell loss and 50.1% for peripheral corneal endothelial cell loss [6,7]. Secondly, BGIs do not have a flow restrictor, and to prevent early hypotony, a tying suture or intraluminal stent must be employed which leads to high initial IOP, with a latent risk of subsequent hypotony when these flow restrictors are eventually removed.

Preserflo™ has an external diameter of 350 microns which is almost half the size of the external diameter of a BGI (630 microns) and is also associated with low endothelial cell loss (7.4%) at 1 year, but for micro-shunt tubes that are located >600 microns from the endothelium the endothelial cell loss becomes close to zero [8]. Therefore, with the correct placement of the device, the risk of endothelial failure is reduced significantly.

By combining the two tubes we hope to take advantage of both the flow-limiting properties achieved by Preserflo™, combined with the long-term success rate of the BVT. This combined with a high dose of MMC, will achieve early flow control, whilst significantly reducing the risks of hypotony (both long and short-term), and corneal endothelial failure. The use of Preserflo™ as a flow restrictor device with glaucoma drainage devices has been previously reported but Preserflo™ was added onto the GDD only after the occurrence of late hypotony [9]. Our technique would also avoid the need to put a second tube in the AC with all its associated risks.

Conclusion

Our technique is a novel way, which can improve outcomes in high-risk failure cases or give a second life to a failed Preserflo™, extending the use of a device which is already in a good position in the AC, has immediate flow control which also enables the use of high dose of MMC. The BGI also serves to divert aqueous to a more posterior area whilst maintaining a minimum bleb size. Based on our initial experience, we think this technique provides an effective way to treat these complex cases safely. However, a long-term study is needed to ascertain the efficacy and safety of this technique.

Acknowledements

The authors declare that Ethical Committee approval was not required for this retrospective consecutive case series analysis. The authors declare that guidelines on patient consent were met and these are indicated in the manuscript.

Conflicts of Interests

The authors declare that they have no conflict of interest and that no funding was involved for this publication.

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