An Alternative To Trabeculectomy: A 2 Year Retrospective Study Comparing the Efficacy and Safety of the Preserflo™ Microshunt to Trabeculectomy in a Tertiary Centre

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Abstract

Purpose: Over recent years, there has been a rapid increase in development and use of Microinvasive Glaucoma Surgery devices (MIGS). This study was conducted to compare the long term efficacy and safety of the Preserflo™ microshunt as a surgical alternative to Trabeculectomy in patients with moderate to advanced glaucoma at Cambridge University Hospitals, UK.

Methods: Single centre retrospective case series of the first 46 patients who underwent Preserflo™ microshunt surgery (with 0.4mg/mL mitomycin C, MMC) alongside 27 patients who underwent trabeculectomy (with 0.2 mg/mL MMC) during the same time period (1/3/2021 – 10/12/2021). Visual acuity; intraocular pressure (IOP); number of glaucoma medications; incidence of complications and post-operative interventions were recorded with a follow up of 2 years.

Results: The mean (±SD) follow up period was 23±3.4 months for Preserflo™ and 23.1±3.2 months for trabeculectomy patients. For Preserflo™, the mean IOP reduced from 21.6±6.5mmHg pre-operatively to 12.8±5.2mmHg (p<0.0001) at 2 years and the mean number of medications reduced from 2.7±1 to 0.5±0.8 (p<0.0001). Two patients required minimal post-operative intervention and one required a further procedure. For the Trabeculectomy patients, the mean IOP reduced from 26.5±12mmHg pre-operatively to 11.7±5.9mmHg (p<0.0001) at 2 years and the mean number of medications reduced from 3.8±1 to 0.4±0.9 (p<0.0001). Six patients required a post-operative intervention or further procedure. The difference in average percentage IOP reduction between Preserflo™ and trabeculectomy was found to be non-significant (42.6% vs 53.1%, p=0.10).

Conclusions: The Preserflo™ microshunt causes a significant reduction in IOP and medications comparable to trabeculectomy. Preserflo™ patients were less likely to require a post-operative intervention. Whilst we acknowledge potential surgical bias at pre-selection, the Preserflo™ microshunt seems to offer an effective and safe surgical alternative for glaucoma patients.

Background

Glaucoma is an optic neuropathy and major cause of loss of vision and blindness. The mainstay of treatment for glaucoma is reduction of intraocular pressure (IOP), which is the major risk factor for the development and progression of the neuropathy.

Trabeculectomy remains the most commonly performed surgical procedure for glaucoma, the aim of which is to create a guarded fistula to drain aqueous humour from the anterior chamber into the subconjunctival space, usually with the development of a bleb.[1]

There have been many Microinvasive Glaucoma Surgery devices (MIGS) developed and used to manage glaucoma in recent years.

One such device is the Ab Externo Preserflo™ Microshunt which is inserted by creating a fornix-based conjunctival peritomy, followed by creation of a scleral tunnel before entering the anterior chamber anterior to the iris plane. This filters aqueous into the subconjunctival and subtenon's space[2,3] (See Figure 3 and 4).

The Preserflo™ microshunt may represent a useful and less invasive alternative to trabeculectomy which is the current gold standard surgical treatment for glaucoma.

The aim of this study was to directly compare the outcomes of patients who had undergone Preserflo™ microshunt surgery to patients who had undergone trabeculectomy surgery during the same time period in a large tertiary centre.

Methods

This was a single centre, retrospective case series of the first 46 patients who underwent Preserflo™ microshunt surgery alongside 27 patients who underwent trabeculectomy over the same 9 month period from 1/3/2021 to 10/12/2021. All these patients had had maximum tolerated medical therapy requiring surgical intervention. Relevant patients were found using an electronic smartphrase.

A standardised operative technique was followed for both procedures involving mitomycin C 0.4mg/ml for the Preserflo™ microshunt and 0.2mg/ml for trabeculectomy surgery.

Data collected included visual acuity; intraocular pressure (IOP); number of glaucoma medications; incidence of complications and any post-operative interventions with a follow up period of 2 years.

Data was analysed using Microsoft Excel 2018, version 16.16.27 (Microsoft® corporation).

Results

The mean (±SD) follow up period was 23±3.4 months for Preserflo™ and 23.1±3.2 months for trabeculectomy patients.

For Preserflo™, the mean IOP reduced from 21.6±6.5mmHg pre-operatively to 12.8±5.2mmHg (p<0.0001) at 2 years and the mean number of medications reduced from 2.7±1 to 0.5±0.8 (p<0.0001). Two patients required minimal post-operative intervention and one required a further procedure (trabeculectomy due to disease progression and poor IOP control).

For the Trabeculectomy patients, the mean IOP reduced from 26.5±12mmHg pre-operatively to 11.7±5.9mmHg (p<0.0001) at 2 years and the mean number of medications reduced from 3.8±1 to 0.4±0.9 (p<0.0001). Six patients required a post-operative intervention or further procedure (this included a bleb revision due to bleb leak and a Baerveldt tube insertion due to iris prolapse and a poorly functioning trabeculectomy).

The difference in average percentage IOP reduction between Preserflo™ and trabeculectomy was found to be non-significant (42.6% vs 53.1%, p=0.10).

Figure 1: Mean Intraocular Pressure vs Time

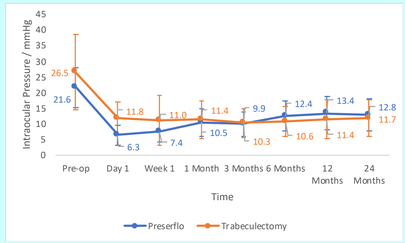


Figure 2: Mean number of anti-glaucoma medications

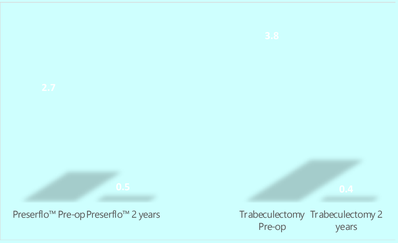
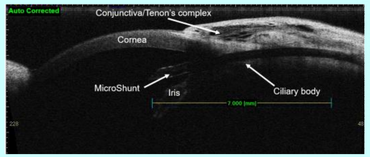
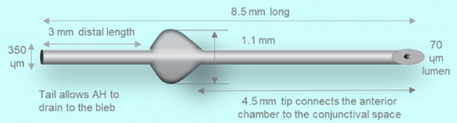


Figure 3. Optical Coherence Tomography image demonstrating adequate postoperative placement of the PreserFlo™ Microshunt in vivo and detailed specs of the PreserFlo™ Microshunt[2]





References

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Figure 4: Preserflo™ bleb of a patient at 6 months.

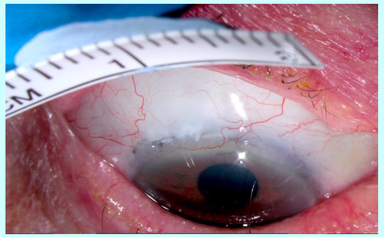


Table 1: Glaucoma Diagnosis

Type of Glaucoma	Preserflo™ (n=46)	Trabeculectomy (n=27)
Primary Open Angle	38	13
Normal Tension	2	1
Ocular hypertension	0	4
Secondary Open Angle	1	6
Primary Angle Closure	4	3
Secondary Angle Closure	1	0

Table 2: Complications and Interventions:

Preserflo™ Complication	Preserflo™ Intervention	Trabeculectomy Complication	Trabeculectomy Intervention
Shallow anterior chamber and over-drainage	Anterior chamber reformation and device ligation	Blocked Sclerostomy	YAG Laser
Shallow anterior chamber and device embedded in iris	Anterior chamber reformation and subsequent revision	Bleb leak	Bleb revision
		Sudden bleb elevation	Anterior chamber reformation
		Bleb leak	Bleb revision
		Bleb leak	Bleb revision
		Poor functioning bleb and iris prolapse	Baerveldt tube

Conclusions

The Preserflo™ microshunt causes a significant reduction in IOP comparable to trabeculectomy. Furthermore, we found the Preserflo™ microshunt also caused a significant reduction in number of topical anti-glaucoma medications required by patients, again, comparable to trabeculectomy. The importance of being on fewer or no medications and its impact on patients' quality of life cannot be underestimated.[4] Preserflo™ patients were less likely to require a post-operative intervention compared to trabeculectomy patients. It is also worth noting that two of the patients who required re-operation following Preserflo™ were angle closure patients, in whom, a trabeculectomy may be preferable. Whilst we acknowledge the limitations of this study, which includes a relatively small sample size in a single centre as well as potential surgical bias at pre-selection, the Preserflo™ microshunt seems to offer an effective and safe surgical alternative for glaucoma patients.



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