ORIGINAL RESEARCH

One-year Outcomes Following Internal Ligation Suture Removal in 350 mm^2 Baerveldt Tube Implant Surgery

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Abstract

Aim: Long-term data of the postoperative management following Baerveldt tube surgery (BVT) is currently limited. This study aims to evaluate the outcome and the safety profile of internal ligation suture removal after BVT surgery for refractory glaucoma.

Materials and methods: A prospective, consecutive, non-comparative case series of patients previously undergoing BVT 350 mm^2 surgery with 0.4 mg/mL mitomycin C (MMC), 3/0 intraluminal suture (Supramid) insertion, and 10/0 nylon external ligation suture(s). For each patient, data was collected over 12 months after internal ligation suture removal. Follow-up assessments looked at intraocular pressure (IOP), complication rate, and postoperative number of glaucoma medications. Definition of success was adopted as per the World Glaucoma Association recommendations.

Results: Twenty-four patients were included. On average, Supramid was removed at 22 ± 18.2 weeks following BVT surgery. Preoperatively, the mean IOP was 30.9 ± 12.6 mm Hg and the average antiglaucoma medications were 1.95 ± 1.13. At 12 months, the mean IOP was 15.2 ± 5.3 mm Hg and the mean number of glaucoma medications was 1.3 ± 0.2. Qualified success with IOP ≤ 21 mm Hg and IOP ≤ 15 mm Hg was achieved in 62.5% and 33.3%, respectively. Only two patients developed hypotony following Supramid removal; both resolved spontaneously within 1 month.

Conclusion: Our results show a good IOP reduction and safety profile at 1 year from internal ligation suture removal following BVT. A drop in IOP of approximately 50% from the preoperative IOP can be expected.

Keywords: Baerveldt implant, Glaucoma surgery, Glaucoma drainage devices.

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Introduction

Glaucoma drainage devices (GDD) are becoming an increasingly popular surgical intervention among glaucoma specialists in the management of refractory glaucoma.[1] With a growing body of long-term evidence for their use, increasing surgical experience as well concerns over the potential complications associated with augmented trabeculectomy surgery, GDDs have been used as a primary surgical intervention.[2]

Glaucoma drainage devices are subdivided into either "valved" or "non-valved" depending on whether an internal flow restriction mechanism is present to limit aqueous humor flow. The Baerveldt implant (Abbott Medical Optics, Santa Ana, CA) consists of a silicone tube connected to a flexible barium impregnated 250 mm^2 or 350 mm^2 silicone end-plate.[3] These non-valved implants require a temporary restriction of aqueous flow by internal and/or external tube ligation until encapsulation around the end plate has occurred. This maneuver reduces the risk of early postoperative hypotony. The internal ligation suture can then be removed in order to achieve target intraocular pressure (IOP).

The use of a 3-0 or 5-0 nylon braided Supramid (S. Jackson Inc., Alexandria, VA, USA) inserted in the tube's lumen with or without external ligation has been described to effectively control the IOP.[4] There is a lack of knowledge regarding the time to internal ligation suture removal following Baerveldt tube (BVT) implantation and the postoperative effect on IOP.

This paper presents the 12-months outcomes following the removal of 3-0 Supramid internal ligation suture from a series of patients following 350 mm^2 BVT surgery.

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Materials and Methods

This study was a prospective, consecutive, non-comparative case series. Data was collected at the Queen's Medical Centre, Nottingham University Hospitals NHS Trust. Formal ethics approval was not needed, although this study adheres to the tenets of the Declaration of Helsinki and local clinical governance approval for data collection was obtained.

The series included 24 eyes of 24 consecutive glaucoma patients in whom a 350 mm^2 BVT (Abbott Medical Optics, Santa Ana, CA) had been implanted over a period of 4 years between March 2014 and July 2018.

All tubes were checked for patency by injecting basic saline solution (BSS) through a Rycroft cannula at the plate's insertion of the tube. Patency was confirmed when BSS was observed at the other end of the tube. All tubes were internally ligated using a 3-0 Supramid (S. Jackson Inc., Alexandria, VA, USA) suture. The internal ligation occupied approximately 50% of the tube's length and the portion outside the tube's end plate was appropriately trimmed and sutured to the sclera approximately 1 cm away from the silicone tube using 10-0 nylon suture. Additionally, an external 10-0 nylon ligation suture was placed around the tube, 1–2 mm from the end plate to temporarily stop aqueous outflow onto the endplate. A 2 mm relieving or venting incision (Sherwood slit) was performed with a 20G corneal/scleral knife 1.3 mm V-Lance® (Alcon Laboratories Inc., Geneva, Switzerland) 1 mm anterior to external ligation suture to control the initial postoperative IOP. All the tubes were then covered with a human sclera donor patch graft.

Postoperatively, if the IOP was deemed clinically suboptimal the argon-laser suture lysis of the external ligation suture was performed at week 3 or 4, when the Sherwood slit had closed. This was performed with Pascal 532nm photocoagulator green argon laser (Topcon Corp., Tokyo 174-8580, Japan) and Blumenthal® suture lysis lens (Volk Optical Inc., 7893 Enterprise Drive, Mentor, United States). The setting used were 200 mW ×0.1 seconds and 100 µm laser spot's diameter.

The internal 3-0 Supramid suture was removed in the operating theater when the IOP was considered clinically suboptimal, but not for at least 4 weeks following BVT surgery in order to allow end-plate encapsulation. All procedures were performed by either the consultant ophthalmic surgeon (PA) or the senior glaucoma fellow. After topical anesthesia with tetracaine hydrochloride 1% and local antisepsis with povidone iodine 5%, the conjunctiva was dissected down to sclera besides the Supramid and the suture exposed. The suture was then pulled out of the tube while checking for any signs of intraoperative hypotony (i.e., anterior chamber shallowing and/or eyeball softening) or extrusion of the tip of the silicone tube from the anterior chamber. The conjunctival wound was then sutured with a 10-0 nylon suture. Postoperative G. Chloramphenicol 1% minims QDS was administered for 7 days and all glaucoma medication was stopped. At each postoperative clinic visit, glaucoma medications were potentially reintroduced according to the IOP.

Table 1: Patients' characteristics and glaucoma etiologies

Demographics	*Mean (%)±SD*
Males	11 (45.8%)
Females	13 (54.2%)
Age	62.2 ± 13.5
Caucasian	17 (70.8%)
Afro-Caribbean	5 (20.8%)
Asian	2 (8.3%)
Glaucoma etiology	
POAG	7 (29.2%)
Secondary to corneal graft	7 (29.2%)
Uveitic glaucoma	5 (20.8%)
NVG	3 (12.5%)
Secondary to retina surgery	2 (8.3%)
Secondary to aphakia	1 (4.2%)
JOAG	1 (4.2%)

SD, standard deviation; POAG, primary open angle glaucoma; NVG, neovascular glaucoma; JOAG, juvenile open angle glaucoma

Data collection included patient age, gender, glaucoma diagnosis and IOP, and number of glaucoma medications before 3-0 Supramid removal. Following stent removal, the IOP and number of medications were collected at each follow-up visit including day 1 and months 1, 3, 6, and 12. Patients who failed to attend follow-up visit in the reporting windows proposed by the World Glaucoma Association (WGA) Guidelines were excluded from this study.[5]

The primary outcome measures were IOP reduction and the number of glaucoma medications at 12 months postoperatively. The secondary outcomes were complications owing to the suture stent removal, timing of stent removal (i.e., number of weeks following Baerveldt tube implantation), and the success rate. We defined success in accordance to WGA guidelines as below.

- IOP ≤ 21 mm Hg and ≥ 6 mm Hg and ≥ 20% reduction from baseline with no additional glaucoma procedures
- IOP ≤ 18 mm Hg and ≥ 6 mm Hg and ≥ 20% reduction from baseline with no additional glaucoma procedures
- IOP ≤ 15 mm Hg and ≥ 6 mm Hg and ≥ 20% reduction from baseline with no additional glaucoma procedures

Complete success was defined as achieving the above outcomes without the need for glaucoma medications, while a qualified success was achieving the outcomes with or without medications. Numerical hypotony was defined as IOP < 6 mm Hg on two consecutive follow-ups.

The data was recorded with Microsoft Excel (Microsoft Corporation) and the statistical analysis was executed with GraphPad Prism Version 8.2.0 (GraphPad Software Inc.). D'Agostino–Pearson test was used to test for the presence or absence of a normal distribution in the data. Comparison between preoperative and postoperative data was carried out with the Wilcoxon matched-pairs signed-rank test, with a *p*-value of 0.05 or less considered to be statistically significant.

Results

Twenty-four eyes from 24 patients were included in this study. There were 10 females and 14 males, and the mean age was 62.2 ± 13.5 years (range from 82-years). Table 1 shows the preoperative characteristics. The mean time to Supramid removal

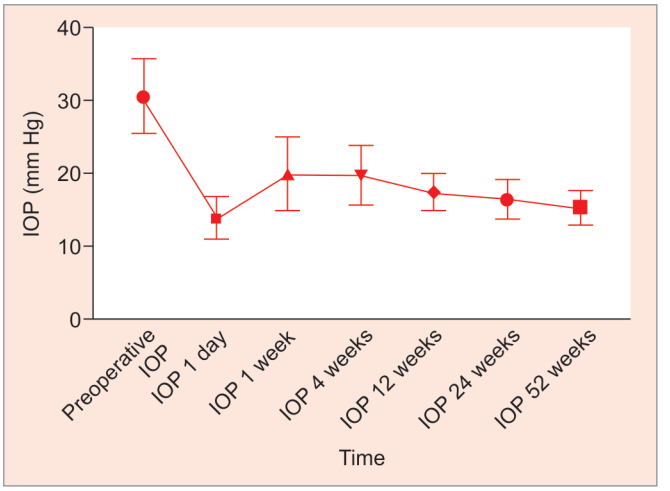


Fig. 1: Mean IOP (mm Hg) over time with 95% confidence intervals. IOP, intraocular pressure

was 22 ± 18.2 weeks (range 4–68 weeks) from Baerveldt tube implantation. The mean IOP reduced from 30.4 ± 12.3 mm Hg preoperatively to 15.2 ± 5.3 mm Hg at 52 weeks follow-up ($p < 0.001$), representing a reduction of 46.1 ± 4.3% (Fig. 1). The mean number of antiglaucoma medications dropped from 1.9 ± 1.1 preoperatively to 1.3 ± 0.2 at 52 weeks ($p = 0.078$).

The complete and qualified success rates are summarized in Table 2. The qualified success rate for an IOP ≤ 21 mm Hg at 12 months was 62.5% (15/24 eyes). For a more stringent IOP of ≤ 15 mm Hg, the qualified success rate was 33.3% (8/24 eyes).

Pearson's Chi-square test showed no statistical correlation ($p = 0.382$) between the timing of stenting suture removal and IOP reduction at 12 months. However, there was a strong statistical correlation between preoperative IOP and the percentage of IOP reduction at 52 weeks ($p = 0.007$, Fig. 2).

There were no cases of postoperative leak or corneal endothelium-tube touch. Hypotony was reported in two patients (8.3%). In both cases, this was noted at day one postoperatively and persisted for 2 weeks in one case and 3 weeks in the other case. The latter was treated with atropine 1% eye drops once a day, in addition to standard postoperative treatment, until the hypotony had resolved. Both of them were managed conservatively through observation and medical management. No clinically significant signs of hypotony were observed, such as choroidal effusion, hypotony maculopathy, striae of Descemet's membrane, or shallowing of anterior chamber.

One patient with aphakic glaucoma underwent an anterior vitrectomy at 1 week following Supramid removal due to vitreous occlusion of the tube causing an IOP spike of 55 mm Hg; the IOP settled to 18 mm Hg with two glaucoma medications at 12 months.

Discussion

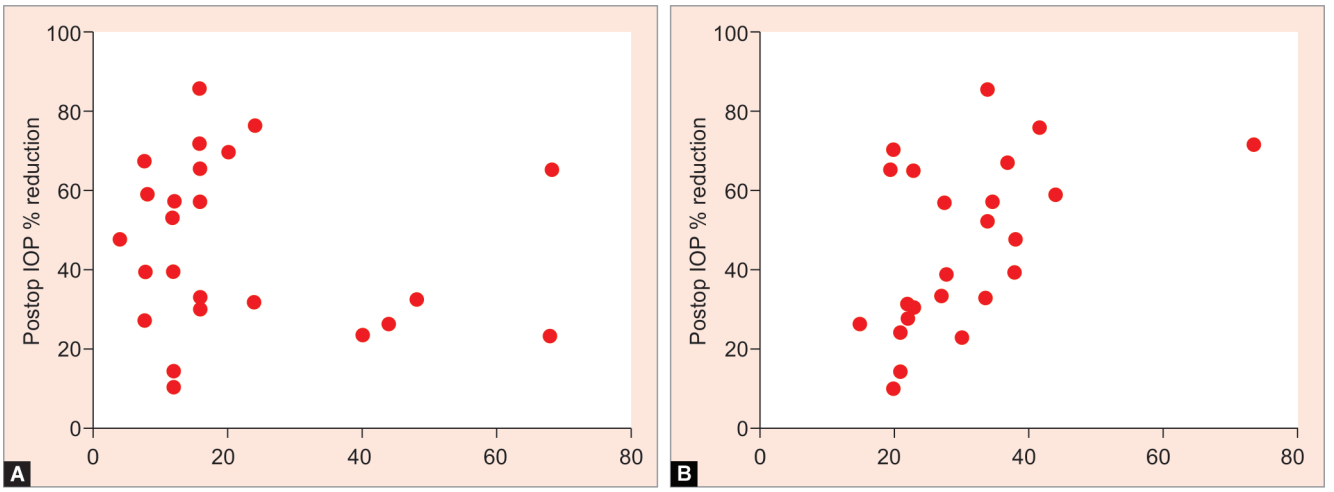
Over the last quarter of a century, there has been great research and evolution in the size, shape, and biomaterials of GDDs, as well as the surgical technique in a quest to reduce complications and improve their surgical success.

The regulation of aqueous outflow onto the end plate is critical in preventing early onset hypotony. Valved GDDs, such as the Ahmed glaucoma valve (AGV), have a theoretical advantage of restricting aqueous outflow thus minimizing hypotony. It consists of two silicone membranes that close below an IOP of 8–10 mm Hg, thus regulating aqueous outflow. However, non-valved GDDs, and in particular the BVT, have been shown to be more effective in lowering IOP compared to the AGV but with a higher rate of postoperative hypotony.[6-9] These non-valved GDDs rely on fibrovascular encapsulation of the end plate to provide enough resistance to aqueous outflow in order to prevent hypotony. Encapsulation can take 4–6 weeks to develop and hence in the interim, flow restriction with either an internal ligation suture or external ligation suture, or both is required.[10,11]

On the contrary, ensuring an early postoperative outflow rate in the normal intraocular pressure range can be achieved by performing venting slits, following insertion of 3-0 Supramid®. This could prevent too high IOP in the early postoperative period while allowing for encapsulation at the tube's plate.[12]

In our case series, all tubes were flow tested before insertion and they all resulted in patent. Given the variation in manufacturing conditions, flow testing all glaucoma drainage devices before insertion is of paramount importance in order to avoid the risk of intraoperative complications.[13] All 350 mm^2 BVTs were internally ligated with a 3-0 Supramid suture as well as externally ligated with a 10-0 nylon suture, which was then suture lysed after 3–4 weeks if the IOP was suboptimal. The Supramid internal ligation suture was then fully removed after a minimum of 4 weeks for further IOP lowering if clinically indicated.

To the best of our knowledge, this is the first study to report 12-month outcomes of internal 3-0 Supramid suture removal following 350 mm^2 BVT surgery. At 12 months we report a 46% decrease in IOP and 32% reduction in number of antiglaucoma medications. The final mean IOP was 15.2 ± 5.3 mm Hg, similar to the 3 years IOP outcome in the Tube Versus Trabeculectomy (TVT) trial reported as 13.0 ± 4.9 mm Hg.[14] A significant proportion of the patients in this series had moderate to advanced glaucoma and hence required adjunctive antiglaucoma medication following Supramid removal; the mean being 1.3 ± 0.9 at 12 months. This compares similarly to the 12 months outcomes in the TVT study where the mean number of medications in the Baerveldt group was 1.3 ± 1.3, and explains why only 4 eyes of 24 (16.6%) had a complete success for an IOP ≤ 21 mm Hg in our study. We also identified a strong correlation between the IOP before the internal ligation suture being removed and percentage drop in IOP following



Figs 2A and B: Correlations (Pearson's r test) between: (A) number of weeks from Baerveldt implant to suture stent removal and percentage of IOP reduction at 52 weeks; (B) Preoperative IOP (i.e., before suture stent removal) and percentage of IOP reduction at 52 weeks. IOP, intraocular pressure

Table 2: Statistical comparison of outcome measures and success rates

I Outcome measures	*Preop (n = 24) Mean ± SD*	*Postop (n = 24) Mean ± SD*	*p-value*
IOP (mm Hg)	30.4 ± 12.3	15.2 ± 5.31	<0.05
Number of agents	1.9 ± 1.1	1.3 ± 0.9	>0.05
II Outcome measures	*Mean ± SD*	*Max*	*Min*
Removal timing (weeks)	22 ± 18.2	68	4
Complications			*n (%)*
Hypotony			2 (8.3)
Vitreous in the tube			1 (4.1)
Total			3 (12.5)
Definitions of success		*Complete*	*Qualified*
IOP ≤ 21 / ≥ 6 mm Hg; ≥20% drop		62.5%	16.6%
IOP ≤ 18 / ≥6 mm Hg; ≥20% drop		58.3%	12.5%
IOP ≤ 15 / ≥6 mm Hg; ≥20% drop		33.3%	8.3%

IOP, Intraocular pressure

its removal. Patients with high-flow glaucoma in which the IOP was >30 mm Hg before Supramid removal had a greater percentage drop in IOP, as can be seen in Figure 2. The "high-flow" aqueous in these patients can partially overcome the fibrovascular scarring at the end plate and hence earlier Supramid® removal should not be considered in these patients, to mitigate the risk of hypotony. The time to Supramid removal was not correlated with percentage drop in IOP (Fig. 2) and suggests that sufficient fibrovascular resistance has developed at the end plate at 4–6 weeks following BVT surgery, and that any further resistance which may develop after that time point does not hinder the success of Supramid® removal.

The complications rate was relatively low. Two patients had hypotony, although there were no related clinical signs, nor vision loss and there was no need for any surgical reintervention. Only one patient had to be brought back to theater for anterior vitrectomy due to vitreous in the anterior chamber.

The main limitation of this study is the limited sample size. Further subgroup analysis with glaucoma etiology, alternative internal ligation suture removal analysis as well as longer term follow-up will provide further insight into outcome measures.

Conclusion

In conclusion, this study demonstrates that the removal of the internal ligation suture following BVT surgery can significantly reduce the IOP at 12 months with a smaller medication index. Higher preoperative pressures lead to greater percentage reductions in IOP and hence these patients could be at higher risk of hypotony. A proactive postoperative management regime following BVT surgery is needed to ensure the best possible outcome is achieved.

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