

Baerveldt glaucoma implant with Supramid[®] ripcord stent in neovascular glaucoma: a case series

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Abstract

• **AIM:** To report the outcome of Baerveldt glaucoma implant (BGI) with Supramid[®] ripcord use in neovascular glaucoma (NVG).

• **METHODS:** We retrospectively evaluated the surgical outcome of the BGI with Supramid[®] 3/0 ripcord stent in patients with NVG. No tube ligation or venting slits were performed. Supramid was removed after 3mo if the target intraocular pressure (IOP) was not achieved. Surgical success was defined as IOP \leq 21 mm Hg with (qualified success) or without IOP-lowering medications (complete success).

• **RESULTS:** Twenty-six eyes from 24 patients were included in the study. The median duration of follow-up was 4 [interquartile range (IQR)=1-5]y, ranging from 0.5 to 5y. IOP decreased by a mean of 24.2 mm Hg (59.7%); from a mean of 40.5 \pm 12.6 mm Hg at baseline to 16.3 \pm 11.9 mm Hg, $P\leq$ 0.001. The number of glaucoma medications reduced from a median of 5 (IQR=5-6) to 1 (IQR=0-2, $P\leq$ 0.001) at the final follow-up. Overall success rates were 88.0% at 1y, 34.8% at 3y, 66.7% at 4y, and 50% at 5y. Hypertensive phase (HP) in the first 3mo occurred in 15/26 eyes (57.7%) with a mean IOP of 31.1 mm Hg.

• **CONCLUSION:** BGI with Supramid[®] ripcord stent gives close to 90% of the overall survival rate at the final follow-up without significant early hypotony. However, early HP is still a challenge.

• **KEYWORDS:** neovascular glaucoma; Supramid ripcord stent; Baerveldt glaucoma implant

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INTRODUCTION

Neovascular glaucoma (NVG) is commonly the end result of any vaso-occlusive disease causing severe recalcitrant intraocular pressure (IOP) elevation^[1]. It accounts for approximately 0.7%-5.1% of glaucoma in an Asian population^[2]. The visual outcome was poor in the past, especially when disc cupping is advanced and visual loss is irreversible. However, with recent therapeutic advances, the prognosis has improved^[3-4].

There is a myriad of causes for NVG; among the commonest are proliferative diabetic retinopathy, ischemic central retinal vein occlusion, and ocular ischemic syndrome^[5]. The pathogenesis hinges upon a common mediator of retinal ischemia and hypoxia. A proangiogenic milieu of cytokines and proteins promotes the development of a network of new fragile and leaky vessels associated with connective tissue scaffolding on the iris surface and anterior-chamber angle^[1]. IOP elevation, once significant secondary angle closure is established, tends to be refractory to medical treatment and warrants surgery.

Surgical options are often either trabeculectomy or glaucoma drainage device implantation. Un-valved glaucoma devices such as the Baerveldt glaucoma implant (BGI) are commonly preferred as it provides good long-term IOP control^[6]. However, early postoperative hypotony and the hypertensive phase (HP) are challenges with these devices. Tube ligation with venting slits alongside ripcord stents is often performed to prevent early postoperative hypotony.

The 3-0 Supramid or Supramid Extra (S. Jackson, Inc, Virginia, USA) is a cable-type multi-filament suture co-extruded from nylon 6 and 6.6^[7]. The fine inner fibres are nylon 6.6 and the smooth outer shell is nylon 6. This construction results in

the benefits of both monofilament and multifilament threads. When used as a ripcord stent, it allows peri-fibrillar aqueous flow in the early postoperative period resulting in significant IOP control while preventing hypotony, even when the tube is not ligated and venting slits are not made. We retrospectively reviewed the treatment outcome of BGI implantation with Supramid 3/0 ripcord stents in our NVG patients to assess the surgical success rate and complications.

SUBJECTS AND METHODS

Ethical Approval The study was approved by the UKM Ethics Committee (ref No. UKM PPI/111/8/JEP-2022-400). As de-identified data were collected retrospectively, informed consent was not required. BGI implantations were performed by a glaucoma specialist and/or glaucoma fellows from 2016 to 2021.

This was a single-centred retrospective case series involving patients diagnosed with NVG from the Ophthalmology Clinic, Universiti Kebangsaan Malaysia Medical Centre. The source of data was the patients' medical and electronic records.

NVG was defined as neovascularization of the iris and/or anterior chamber (AC) angle with elevated IOP of ≥ 21 mm Hg. Glaucomatous optic nerve cupping was not required for diagnosis^[8]. All cases were investigated to determine the cause. Data collected include age, ethnicity, gender, cause of NVG, and co-morbidities. Visual acuity (VA), IOP, and the number of IOP-lowering medications were recorded preoperatively and at set intervals of 1d, 1, 3, and 6mo, and 1, 3, 4, and 5y postoperatively. The use of anti-vascular endothelial growth factor (anti-VEGF) agents, postoperative complications, and additional procedures were also recorded.

Snellen's visual acuity (VA) was converted to the logarithm of the minimal angle of resolution (logMAR) for analysis. An improvement or decrease in VA was defined as a change of two or more lines on the logMAR scale. logMAR values for low vision were defined as follows: counting fingers (CF)=2.3; hand motions (HM)=2.6; light perception (LP)=2.9; and no light perception (NLP)=4^[9]. The number of topical anti-glaucoma medications was counted following its class and systemic anti-glaucoma medication were counted as a fifth and sixth drug.

The BGI (Advanced Medical Optics, Inc., Santa Ana, CA, USA) of either size 250 mm² or 350 mm² was implanted in patients with florid rubeosis iridis and severely elevated IOP, advanced glaucomatous visual field loss which carries a higher risk of wipe-out syndrome, or having logistical difficulty for frequent follow-up. Intravitreal anti-VEGF injections were used on a case-to-case basis and injected a week before surgery to induce temporary resolution of rubeosis and thus prevent intraoperative hyphaema.

The surgical technique for BGI was similar to that described by

Stamper *et al*^[10] except that the lumen of the tubes was stented with a 3/0 Supramid Extra suture (S. Jackson Inc., Alexandria, VA, USA) without tube ligation or venting slits. Intraoperative sponge-soaked mitomycin C 0.02% applied for 3min was used in all cases. Postoperatively topical dexamethasone and ciprofloxacin were used for 4 to 6wk depending on the amount of inflammation. In the event of an early postoperative HP, IOP-lowering medications were resumed while waiting for 3mo at which the Supramid stent will be removed should the IOP remained uncontrolled.

Surgical success was defined as IOP ≤ 21 mm Hg without (complete success) or with (qualified success) IOP-lowering agents and maintenance of VA of LP or better^[11]. IOP were measured with a Goldmann applanation tonometer. Postoperative hypotony was defined as IOP ≤ 5 mm Hg or any IOP with clinical signs of hypotony such as shallow or flat AC, swollen optic disc, choroidal folds, or macular striation occurring within the 1st month after surgery^[12]. HP was defined as IOP > 21 mm Hg during the first 3mo after surgery^[13].

Data analysis was performed using the JMP version 6 statistical package program (Cary, North Carolina, USA). Continuous normally distributed data were presented as mean and standard deviation while non-normally distributed variables were presented as median (interquartile range, IQR). Proportions were used to describe categorical variables. The paired student *t*-test and Wilcoxon signed-rank test were performed to compare the IOP and median number of anti-glaucoma medications at presentation and on the last visit respectively. Kaplan-Meier survival curve analysis was used to summarize the cumulative probability of success, taking 80% of the operative cases as a cut-off point for survival time (censored data made for those lost to follow-up). The survival curve was used to assess factors influencing surgical success by univariate analysis. A *P*-value of ≤ 0.05 was considered statistically significant.

RESULTS

A total of 26 eyes from 24 patients were included in the study. Majority of the cases were due to proliferative diabetic retinopathy ($n=22$, 84.6%); while the remaining eyes had either ocular ischaemic syndrome ($n=3$, 11.3%) or central retinal vein occlusion ($n=1$, 3.9%). The median duration of follow-up was 4 (IQR: 1-5)y, ranging from 0.5 to 5y. There was a slight female preponderance with male to female ratio of 1:1.2. A sizable proportion of them were Malays ($n=17$, 70.8%), while the rest were Chinese ($n=5$, 20.8%), and Indians ($n=2$, 8.3%). The median age was 59.5 (IQR: 42-65)y, ranging from 30 to 75y of age (Table 1).

Median VA in logMAR at baseline was 1.48. VA improved in 10 (38.5%) eyes; 6 eyes (23.1%) remained unchanged, and 10 eyes (38.5%) worsened. One patient had deterioration in vision

Table 1 Demographic data

Demographics	Value
Ethnicity, n (%)	
Malays	17 (70.8)
Chinese	5 (20.8)
Indian	2 (8.3)
Age (y)	
Median (IQR)	59.5 (42-65)
Range	30 to 75
Gender, n (%)	
Male	13 (54.2)
Female	11 (45.8)
Aetiology of NVG, n (%)	
Diabetic retinopathy	22 (84.6)
Ocular ischemic syndrome	3 (11.3)
Central retinal vein occlusion	1 (3.9)
Follow-up (y)	
Median (IQR)	4 (1-5)
Range	0.5 to 5
Preoperative IOP (mm Hg)	
Mean±SD	40.5±12.6
Range	20 to 66
Presenting vision, n (%)	
Improvement	10 (38.5)
Unchanged	6 (23.1)
Decreased	10 (38.5)
IOP-lowering medications, median (IQR)	
At presentation	5 (5-6)
At the final follow-up	1 (0-2)
Preoperative anti-VEGF intravitreal injection (n)	9

IQR: Interquartile range; NVG: Neovascular glaucoma; SD: Standard deviation; IOP: Intraocular pressure; VEGF: Vascular endothelial growth factor.

from HM to NPL because of severe ocular ischemia despite good IOP control postoperatively.

IOP decreased by a mean of 24.2 mm Hg (59.7% reduction), from a mean of 40.5±12.6 at baseline to 16.3±11.9 mm Hg, $P \leq 0.0001$. The number of IOP-lowering medications also reduced from 5 (IQR=5, 6) to 1 (IQR=0, 2), $P \leq 0.001$ at the final follow-up. Nine eyes received intravitreal anti-VEGF injections about a week prior to surgery, of which four were for pre-existing diabetic macula oedema and the rest as pre-operative prophylaxis for hyphaema. Apart from NVG, two eyes had preexisting primary open angle glaucoma, one had a history of endogenous endophthalmitis, one had herpetic uveitis, and two had previous complicated cataract surgery.

Table 2 shows the complete and qualified success and failure rates at the final follow-up. After a median of 4y, 4 eyes (44.4%) had complete success, 2 eyes (22.2%) qualified success, and 0 eyes failed, giving an overall success of 66.7%. Ten percent

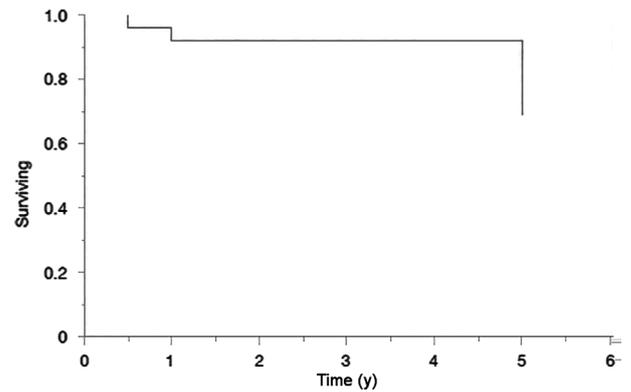


Figure 1 Kaplan Meier survival curve showing the treatment outcome in the NVG patients Censored data related to patients who did not have failure at that time. NVG: Neovascular glaucoma.

of patients were lost to follow-up within one year and this increased to over 60% after 3y.

Almost all patient was on maximum topical and systemic anti-glaucoma preoperatively. Postoperatively, the number of patients who are medication free can be derived from the complete success criteria. The mean number of medications post operatively was 1.2. Seventeen eyes (65%) still required some anti-glaucoma medications in the immediate post-operative period up until 1mo. By 6mo, five patients (19%) required medications.

Figure 1 shows the Kaplan-Meier survival analysis. The survival curve was plotted for up to 5y, considering the number of failed events and censored data, which were cases that were lost to follow-up. There was slightly more than half of the data that were censored just after one year. The overall survival rates were 91.97% at 1y and this percentage maintained up until the 4th year. At 5y the survival rate dropped to 68.98%.

We examined factors that might affect the surgical outcome at the last follow-up (Table 3). Younger age, higher presenting IOP, and proliferative diabetic retinopathy were associated with poorer surgical outcome, although all were not statistically significant, possibly because of the small sample size.

Early postoperative hypotony occurred in 2/26 (7.7%) eyes on postoperative day 1 and 1/26 (3.8%) eyes at 1mo, with IOP ranging from 3 to 5 mm Hg. IOP picked up spontaneously in all patients. None of the patients had clinical signs of hypotony or required additional procedures to correct the hypotony. The HP occurred in 15/26 (57.7%) eyes within the first 3mo postoperatively. This was treated with anti-glaucoma medications while waiting for the safe removal of the Supramid ripcord to allow for adequate IOP control.

All patients had Supramid ripcord used to prevent postoperative hypotony. Of these, 20 (76.9%) eyes required removal of the Supramid ripcord at a mean of 23.2wk postoperatively. Three eyes had hypotony with shallow AC after Supramid removal, two of them had Supramid removed

Table 2 Complete and qualified success at the final follow-up

Time	Overall success	Complete success	Qualified success	Failure	Cumulative transfer out/lost to follow-up ^a	Remaining eyes
6mo	22 (84.6)	12 (46.1)	10 (38.4)	0	1 (3.8)	25
1y	22 (88.0)	11 (44.0)	11 (44.0)	1 (4.0)	3 (11.5)	23
3y	8 (34.8)	5 (21.7)	3 (13.0)	1 (4.3)	17 (65.4)	9
4y	6 (66.7)	4 (44.4)	2 (22.2)	0	20 (76.9)	6
5y	3 (50.0)	2 (33.3)	1 (16.7)	1 (16.7)	22 (84.6)	4

^aThe cases were not due for review yet at the time of writing.

Table 3 Logistic regression analysis showing factors affecting success rate at the final follow up

Variable	Regression coefficient	Standard error	P	95% confidence interval
Age	0.037	0.05	0.50	-0.07 to 0.14
Aetiology of NVG	-1.60	1.13	0.16	-3.80 to 0.62
Presenting IOP	-0.02	0.06	0.73	-0.13 to 0.09

NVG: Neovascular glaucoma; IOP: Intraocular pressure.

at 6wk for uncontrolled IOP and both required AC reformation with viscoelastic and reintubation of the tube.

Seven eyes had late post-operative complications. Apart from the three eyes which developed hypotony after Supramid removal, one eye had persistent high IOP because of a blocked tube by iris tissue and required repositioning of the tube. One eye had severe fibrinous AC reaction after supramid removal and was treated with intracameral recombinant tissue plasminogen activator (rTPA) injection, one eye had jutting Supramid from the conjunctiva which was re-sutured, and one eye had vitreous haemorrhage secondary to uncontrolled proliferative diabetic retinopathy which required vitrectomy for retinal stabilization.

Co-existing ocular pathologies which contributed to poorer visual outcomes include diabetic macula oedema in five eyes, significant cataract in four, vitreous haemorrhage in five, herpetic uveitis in one, epiretinal membrane in three, and foveal atrophy in one eye.

DISCUSSION

NVG accounts for approximately 5.8% of all glaucoma cases seen in a tertiary referral center^[2]. The outcome is normally grim and more often requires surgical intervention with either trabeculectomy or more commonly glaucoma drainage devices.

Sidoti *et al*^[9] evaluated the Ahmed glaucoma valve in NVG. Their definitions of success were complete success: final IOP between 6 and 21 mm Hg without medications, qualified success: final IOP between 6 and 21 mm Hg with medications, qualified failure: final IOP>21 mm Hg without further glaucoma procedures (or recommendation thereof). Complete failure were patients who underwent additional glaucoma procedures (or for whom they were recommended), who lost LP, and whose final IOP was >21 mm Hg. With these definitions, they reported success rates of 79% at 1y and 56% at 18mo. No intravitreal anti-VEGF injections were given in any of the eyes.

The long-term outcome of Molteno glaucoma implant in NVG patients was reported by Mermoud *et al*^[14]. Their definitions were complete success: IOP≤21 mm Hg without medication, qualified success: IOP≤21 mm Hg with medication, qualified failure: IOP>21 mm Hg with or without medication, and complete failure as eyes that required further glaucoma drainage surgery, developed phthisis bulbi, or lost LP. The reported success rates were 62.1% at 1y, 52.9% at 2y, 43.1% at 3y, 30.8% at 4y, and 10.3% at 5y. Again, no intravitreal injections were given in any of the eyes.

Shen *et al*^[15] on the other had compared trabeculectomy and the Ahmed glaucoma valve outcomes in NVG patients. Their definition of surgical success was: IOP between 6 and 21 mm Hg with or without medications, without further glaucoma surgery including cyclophotocoagulation or complications that required removal of the Ahmed implant, and without loss of LP. Failure was defined as IOP>21 mm Hg on two consecutive visits. Laser suture lysis and bleb needling to improve bleb function were not considered failure of the procedure. They found that the success rate of Ahmed glaucoma valve was 70% at 1y vs 65% in trabeculectomies and 60% at 2y vs 55% in trabeculectomies. Three eyes received intravitreal anti-VEGF injections but all three cases were ultimately classified as failures based on the criteria in this study, possibly due to advanced disease at the time of presentation.

Other studies reported success rates of 63.2% at 1y, 56.2% at 2y, 43.2% at 3y, 37.8% at 4y, and 25.2% at 5y with Ahmed glaucoma valve compared to 37.0% at 1y, 29.6% at 2y, 29.6% at 3y, 29.6% at 4y, and 29.6% at 5y with Molteno devices^[16-18]. The surgical success for BGI in NVG has been reported to be between 77.4% and 85% at 3y^[19-20]. These reported success rates were much lower than our data which shows more than 90% survival rates up until 3y, and more than 60% at 5y.

We think that this surgical technique of stenting the tube with a Supramid 3/0 suture without any tube ligation, allows

peri-fibrillar drainage in the earlier phases after surgery. This in turn likely allows good IOP control in the early post operative period, and decreasing the need for anti-glaucoma medications. Complete removal of the Supramid stent after approximately 3mo allows further drainage and better IOP control following adequate encapsulation of the plate. We do have patients who developed hypotony after Supramid removal. All our patients had Supramid 3/0 ripcord inserted in the tubes, so we couldn't compare with those who did not use ripcord. However, based on a study by Tao *et al*^[21] there were no statistically significant difference in terms of complication rates between glaucoma drainage implants with or without ripcord use. However, as this is conjectural, further studies *i.e.*, randomised control trials with a control group would be necessary to prove its advantage.

The advent of anti-VEGF as a valuable adjunct to reduce intraoperative and postoperative complications such as hyphaema, and improving postoperative IOP control has been proven^[22-23]. However, successful surgical outcome depends on several other factors too, and not merely the mode of therapy alone^[24-25]. Some poor prognostic factors reported were younger age, previous vitrectomy, and having a fellow eye with NVG due to proliferative diabetic retinopathy^[11]. We used intravitreal anti-VEGF injections in eyes with florid rubeosis to prevent intraoperative hyphaema and to improve the surgical outcomes. All 9 cases injected had successful outcomes, 5 attaining complete success while 4 others achieving qualified success. Our study concurs with previous reports that anti-VEGF is a useful adjunct to NVG cases. The indication for intravitreal anti-VEGF injection here is to prevent intraoperative bleeding from florid iris neovascularization or for treatment of active diabetic macula oedema. Some of the cases had iris neovascularization which was not too florid, and therefore did not require intravitreal anti-VEGF injection. The retina was stabilized with pan-retinal photocoagulation instead. Further postoperative intravitreal anti-VEGF injections were given as and when were needed. This is to ensure judicious use of this expensive drug to only for the indication described above. All patients underwent pan-retinal photocoagulation as a standard protocol as long as the fundal view is permissible.

Proliferative diabetic retinopathy was the commonest aetiology of NVG in our case review. This is consistent with reports from other countries^[2,15]. Some reviews report ischemic retinal vein occlusion to be as frequent^[3], but diabetes is not only rampant in our local community but also on the rise globally. Because of the smaller number of vein occlusions and ocular ischemic syndrome (OIS) in our case series, we were not able to demonstrate any difference in visual outcome from these aetiologies. However, generally, ischaemic vein

occlusion and OIS have poorer visual outcomes because of the profound retinal ischemia compared to proliferative diabetic retinopathy^[26-28].

The post-operative visual outcome perse should not be used as an indicator for success or failure determinant in surgical outcome. Co-existing ocular morbidities such as high myopia, diabetic macular edema, corneal haze or decompensation, vitreous haemorrhage, and cataracts were among the reasons for poorer visual outcomes in our patients. Moreover, despite lowering average IOP by drainage implant surgery to preserve vision, the progression of diabetic retinal ischemia may result in poor visual outcomes if the sugar control remained poor^[8].

The preferred glaucoma device in our centre is the Baerveldt glaucoma device. This makes the number of eyes receiving other forms of surgical modalities small and insufficient to report their outcomes. However, our findings do reflect the reality of management and real-world outcomes in a tertiary care centre in Kuala Lumpur. A large proportion of patients remained under our follow-up for at least up to a year with only about 10.3% lost to follow-up within the first year. Thereafter, a significant proportion of them was "lost to follow up" as they would then continue their follow-ups in their respective hospitals throughout the country.

We used the Kaplan-Meier curve to report the survival rates. Our survival data were truncated markedly at 1y due to data that were censored from lost to follow-up. This was made up largely by cases that were deemed stable enough to be referred back to their respective hospitals for subsequent management. Throughout the postoperative period, the observed failure rate of surgery was around 6.8% by the end of one year. The failure rate increases slightly to 10.3% by the end of 5y.

While the staging of the disease is important to be factored-in to the success rate seen, many of the eyes had poor view of the angle and iris details due to cornea oedema. Further, the fact that these eyes required glaucoma surgery and on maximum anti-glaucoma medications, would indicate that these eyes were at the advanced stage of the disease with severely elevated IOP.

Post-operative complications in our patients include AC collapse and hypotony after Supramid ripcord removal requiring AC reformation and tube re-stenting in 3 eyes, persistent high IOP post-Supramid removal requiring either bleb needling or transscleral cyclophotocoagulation in 3 eyes, and vitreous haemorrhage requiring pars plana vitrectomy and conjunctival wound leakage needing re-suturing in one eye each. Among eyes with persistently high IOP, one eye had a blocked tube by iris tissue. Following failed attempts to retract the iris tissue using Argon and YAG lasers, surgical revision and relocation of the tube were performed. All 3 cases of AC collapse with hypotony after Supramid removal had to be

reformed with viscoelastic device, usually a more thixotropic type if available. Re-suturing was done for the conjunctival wound leakage, and refashioning of the stent jutting out of the conjunctiva was performed.

The number of cases reviewed in this nascent study is small, therefore, limited conjectures and inferences can be made. The number of interventions was too small to conduct further analysis. Although it cannot be compared with other larger similar studies, our data provide some insight into the better outcome of surgical treatment of NVG in our centre, perhaps contributed by the surgical technique of non-ligation of the tube, allowing earlier peri-fibrillar flow through the Supramid ripcord. A prospective study with a bigger sample size will be able to further demonstrate the benefits of this technique. By the third year, our data volume reduced markedly due to the local practice of referring those who were deemed stable enough, back to their respective hospitals throughout the country for subsequent management. This “real-world” data reflects the reality of clinical practice in a tertiary referral centre. Long-term management of these cases is affected by logistics issues, especially for patients staying in other states of the country.

In conclusion, the long-term surgical success rates of NVGs in our patients appear to be better than previously reported studies that were discussed, and could be attributed to improvements in surgical techniques that have evolved over the years.

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