

Evaluation of the Efficacy and Safety of the New Susanna Glaucoma Drainage Device in Refractory Glaucomas: Short-term Results

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Purpose: To assess the efficacy and safety of the new Susanna glaucoma drainage device (SGDD) in patients with neovascular and refractory glaucomas.

Materials and Methods: In this prospective study, patients with neovascular glaucoma or refractory glaucomas (defined as eyes with previous trabeculectomy failure) were enrolled. All eyes had to have intraocular pressure (IOP) above 21 mm Hg despite maximum tolerated topical medication, or recent documentation of anatomic and/or functional progression. Patients underwent glaucoma surgery with the new SGDD in a standardized manner. Postoperative visits were performed at days 1 and 7; months 1, 3, and 6; and every 6 months thereafter. Preoperative and postoperative IOP, number of antiglaucoma medications, surgical complications, and any subsequent related events were recorded. Success criteria were: (I) IOP ≥ 6 and ≤ 21 mm Hg; (II) IOP ≥ 6 and ≤ 18 mm Hg. Each criterion was classified as complete (without medication) or qualified (with medication).

Results: A total of 58 patients with a mean age of 64.3 ± 11.5 years were included [19 with neovascular glaucoma (group 1) and 39 with failure of first trabeculectomy (group 2)]. Overall, mean follow-up was 7.1 ± 3.8 months, and mean IOP was reduced from 31.5 ± 1.6 (range, 18 to 68) mm Hg to 12.6 ± 0.7 (range, 2 to 28) mm Hg at the last follow-up visit ($P < 0.01$). The mean number of antiglaucoma medications used was reduced from 3.4 ± 0.9 to 1.4 ± 1.5 ($P < 0.01$). At 6 months postoperatively, qualified success rates for groups 1 and 2 were 73% and 86%, respectively (considering the stricter criterion). Main complications were 2 cases of conjunctival erosion and 2 cases of late hypotony.

Conclusions: Our initial findings suggest that the new SGDD is an effective alternative for managing neovascular and refractory glaucomas, with minor postoperative complications in the short-term.

Key Words: refractory glaucomas, drainage device, glaucoma surgery, intraocular pressure

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The second leading cause of blindness in the world is glaucoma¹ and the most important known risk factor for the onset and progression is the intraocular pressure (IOP). Furthermore, the only evidence-based intervention that has shown to slow or halt disease progression is the IOP reduction, which can be successfully achieved in most cases by medical or laser therapies. Surgical therapy is usually indicated when clinical or laser therapies fail to provide an adequate IOP to slow progressive nerve damage.

Trabeculectomy is the most commonly performed glaucoma surgery. Although it is effective in most cases, this procedure may be associated with various complications. In addition, this surgical technique is not best option for all the patients. In refractory glaucoma, for example, when the trabeculectomy was performed without success or is not feasible due to lack of viable surgical site, or even when the etiology of the disease involves cases of neovascular glaucoma and certain types of inflammatory or development glaucoma, the drainage implant is the most suitable option.^{2–4}

Success rates of drainage implants for glaucoma vary from 22% to 97%, depending on the etiology of glaucoma and type of implant.^{5–7} There are several types of implants for glaucoma (valved or nonvalved, rigid, or flexible). We currently have only 2 devices registered in Brazil: the Ahmed valve (silicone and polypropylene) and the silicone implant of Baerveldt.⁸ Costs of these implants in Brazil are in the order of US\$1500.00 to US\$1800.00 each unit, which makes the use of these devices practically prohibitive, especially in the public health system. Consequently, some of the patients with surgical indication for drainage implants become blind (especially those with refractory glaucomas). A national silicone implant (Susanna implant) that is not manufactured anymore in Brazil had been available for some years and was used in the public health system at that time. The results of 2 previous studies using this implant in cases of development glaucoma and adults with refractory glaucomas were comparable with those reported in the literature with other already established implants.^{9,10}

In face of the need for an effective drainage implant with lower cost in Brazil, a new model of the Susanna implant has been recently developed. The aim of this study was to evaluate the efficacy and safety of the new Susanna glaucoma drainage device (SGDD) in patients with neovascular and refractory glaucomas.

MATERIALS AND METHODS

This prospective study followed the tenets of the Declaration of Helsinki and was approved by the institutional review board of each study center. Written informed consent was obtained from all patients.

Patients

We conducted a noncomparative, multicenter interventional case series. Patients with neovascular and refractory glaucomas, and above 18 years of age were consecutively enrolled in 2 groups: (1) neovascular glaucoma; (2) refractory glaucomas (patients with at least 2 mo of previous trabeculectomy failure).

Exclusion criteria for both groups were presence of staphyloma or significant scleral thinning; history of scleritis; psychiatric disorder that has required hospitalization, previous retinal detachment surgery with buckle placement, presence of severe corneal opacity, or shallow anterior chamber that does not allow the procedure, and cases of secondary glaucomas (except neovascular glaucoma). Inclusion criteria for both groups are listed below.

- (A) IOP above 21 mm Hg in at least 3 different consecutive visits despite maximum tolerated topical medication, or recent documentation of anatomic and/or functional progression (at least 6 mo apart from the trabeculectomy procedure for patients in group 2), or impossibility to afford with the costs of medical treatment (social surgical indication).
- (B) Visual acuity better than hand motion in the study eye.
- (C) Permanent residence in the health district where the surgery would be performed.
- (D) Clear understanding of the term of consent.

Device Description

The new SGDD is a nonvalved silicone device (as shown in Fig. 1). The plate has 2 extensions measuring only 4×1 mm, which allows easy fixation to the sclera. The anterior portion is fixed at 6 mm from limbus, allowing the plate to be located at 10 mm, decreasing the possibility of extrusion. The presence of fenestrations induces fibrosis that transfixes the plate and makes it more fixed and less susceptible to micro-movements. These fenestrations are also present in other silicone implants, such as Ahmed and Baerveldt.

The area of the new Susanna plate is 200 mm^2 and its silicone is soft enough to allow adjustments to its size in specific situations (the older version had 350 mm^2 and an elliptical form). Total thickness of Susanna drainage device is 0.5 mm, thinner than Ahmed (1.9 mm), and Baerveldt (0.84 mm). The tube (which penetrates the anterior chamber) has an internal diameter of $230 \mu\text{m}$ and an external of $530 \mu\text{m}$. This was designed to minimize the risk of hypotony. When compared with Ahmed, Baerveldt, and the previous model of Susanna device, the new SGDD has a significant smaller diameter, as that all the 3 have an internal diameter of $300 \mu\text{m}$ and the first 2 an external of $600 \mu\text{m}$ (vs. $630 \mu\text{m}$ in the previous Susanna).

Baseline Examination, Procedure, and Postsurgical Assessments

At baseline, all consenting patients underwent assessment of Snellen best-corrected visual acuity (BCVA), Goldmann applanation tonometry, slit-lamp biomicroscopy, gonioscopy using the Zeiss 4-mirror lens, and fundoscopic examination (whenever feasible).

All surgeries were performed by 1 of the 5 authors ahead (L.G.B.; T.S.P.; F.N.K.; F.V.B.; M.H.) using a standardized technique (a full detailed video with the standard procedure was provided for every surgeon). The surgical procedure was performed under peribulbar anesthesia. The conjunctival incision was made just behind and parallel to the corneal

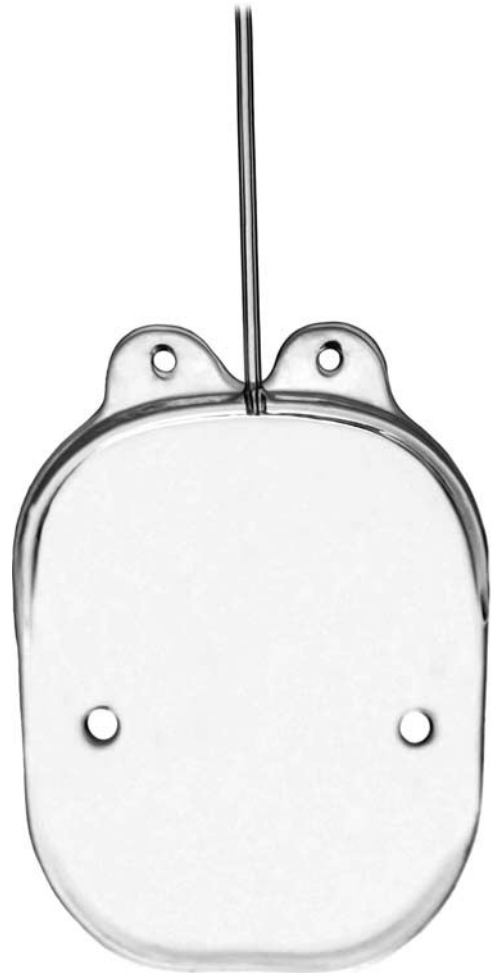


FIGURE 1. The new Susanna glaucoma drainage device.

limbus, preferentially in the superotemporal quadrant. A careful dissection was done anteroposteriorly in the subtenon plane. The plate of the SGDD was placed at 10 mm behind the corneal limbus and secured to the sclera with 7-0 silk sutures at the 2 feet. The silicone tube was shortened to the desired length before insertion and then the tube was ligated with a 7-0 polyglactin suture near the tube-plate junction. Two fenestrations were placed anterior to the ligature using a 10-0 nylon suture needle. This was followed by placement of the silicone tube into the anterior chamber through a 25-G needle track. The anterior part of the tube was covered with previously prepared human donor scleral patch graft. The conjunctiva and the Tenon capsule were closed with 8-0 polyglactin sutures. The eye was inspected for any leaks as the anterior chamber was inflated to a proper pressure using balanced salt solution. All patients were treated with topical corticosteroid (prednisolone eye drops) every 2 hours and antibiotics (moxifloxacin) 4 times daily during the first week. Topical Atropine 1% was also administered 2 times daily for 2 weeks. Prednisolone was then tapered off slowly over 6 to 8 weeks.

The postoperative visits were performed after 1 day, 1 week, 1 month, 3 months, 6 months, and every 6 months thereafter. During the course of follow-up, patients were allowed to complete additional panretinal photocoagulation if required. Postoperative IOP, number of antiglaucoma

medications, surgical complications, and any subsequent related event were recorded.

Statistical Analysis

Descriptive analysis was used to present demographic and clinical data. Preoperative and postoperative means for IOP and number of antiglaucoma medications were calculated and compared in each group. D’Agostino-Pearson test was performed to determine whether the data had a normal distribution. These continuous data were compared using the paired *t* test or the Wilcoxon signed rank test, depending on the data distribution. Kaplan-Meier survival analysis was used to estimate success rates at specific postoperative timepoints. Success was defined according to 2 different criteria based on postoperative IOP values: criterion I = IOP ≥ 6 and ≤ 21 mm Hg; criterion II = IOP ≥ 6 and ≤ 18 mm Hg. Success was also characterized according to whether or not this had been achieved without (complete success) and both with or without antiglaucoma medications (qualified success). Failure was defined as an IOP level measured above the upper limit or below the lower limit on 2 consecutive visits or whenever additional glaucoma surgery was required. Computerized analysis was performed using MedCalc software (MedCalc Inc., Mariakerke, Belgium) and statistical significance was set at *P* < 0.05.

RESULTS

A total of 58 patients (58 eyes) with a mean age of 64.3 ± 11.5 years were included. Baseline and postoperative data of study patients are described in Table 1. There were 19 patients with neovascular glaucoma (group 1) and 39 with failure of first trabeculectomy (group 2). Overall, after a mean follow-up of 7.1 ± 3.8 months (6.8 ± 3.9 mo for group 1 and 7.6 ± 3.6 mo for group 2), mean IOP was reduced from 31.5 ± 1.6 (range, 18 to 68) mm Hg to 12.8 ± 0.7 (range, 2 to 28) mm Hg at the last follow-up visit (*P* < 0.01). The mean number of antiglaucoma medications used was reduced from 3.4 ± 0.9 to 1.4 ± 1.5 during the same period (*P* < 0.01). In addition, only 1 patient in both groups had an initial IOP < 21 mm Hg. This patient from group 2 had an initial IOP of 18 mm Hg and despite using 4 topical medications, had functional progression. Success in this specific case was evidenced by the reduction of the IOP to 13 mm Hg, with the use of only 2 medications.

Comparing baseline IOP values and number of antiglaucoma medications between groups, we found that although there was no difference in the mean number of antiglaucoma medications [3.6 ± 0.8 (group 1) vs. 3.3 ± 0.9 (group 2); *P* = 0.16], preoperative IOP was significantly higher in group 1 (44.3 ± 11.1 mm Hg) than in group 2 (25.3 ± 6.5 mm Hg; *P* < 0.01). Following surgery, mean baseline IOP was significantly reduced to 13.5 ± 6.5 mm Hg in group 1 and 12.5 ± 5.0 mm Hg in group 2 (*P* < 0.01). The mean number of antiglaucoma medications was also significantly reduced to 0.9 ± 1.3 in group 1 and 1.7 ± 1.5 in group 2 (*P* < 0.01). At 6 months postoperatively, qualified success rates for groups 1 and 2 were 73% and 96%, respectively (based on the less strict criterion; Fig. 2). When considering the stricter criterion, qualified success rates for groups 1 and 2 were 73% and 86%, respectively (Fig. 3). In 1 eye with an initial IOP of 18 mm Hg success was achieved by reducing the number of antiglaucoma medications from 3 to 1, while maintaining an IOP < 18

TABLE 1. Baseline and Postoperative Data of Study Patients

Variables	Group 1 (n = 19 Patients)	Group 2 (n = 39 Patients)	Total (n = 58 Patients)
Age (y)	59.8 ± 12.5	66.5 ± 10.7	64.3 ± 11.5
Sex (male/ female)	12/7	21/18	33/25
Baseline IOP (mm Hg)	44.3 ± 11.1	25.3 ± 6.5	31.5 ± 1.6
Baseline medications	3.6 ± 0.8	3.3 ± 0.9	3.4 ± 0.9
Follow-up (mo)	6.8 ± 3.9	7.6 ± 3.6	7.1 ± 3.8
PO IOP (mm Hg)	13.5 ± 6.5	12.5 ± 5.0	12.8 ± 0.7
PO medications	0.9 ± 1.3	1.7 ± 1.5	1.4 ± 1.5

Data are given as mean ± SD whenever indicated.
Group 1, neovascular glaucoma; group 2, refractory glaucomas (previous trabeculectomy failure).
IOP indicates intraocular pressure; PO, postoperative.

mm Hg. Other results are provided in Table 2, which summarizes the estimates of survival probability for both groups according to each criterion adopted.

Regarding surgical complications, 3 patients had hypotony and shallow anterior chamber in the early postoperative period (within 6 wk), 2 of which showed improvement after early rapprochement (filling the anterior chamber with viscoelastic). The implant was removed in the other patient due to persistent shallow anterior chamber, even after surgical rapprochement. Two patients showed late hypotony (4 mo after surgery in both cases) with shallow anterior chamber. They were successfully treated with topical atropine 1% for ~15 days. There were 2 cases of conjunctival erosion that had required surgical management. Transient changes in the extrinsic ocular motility were observed in 5 patients, in the early postoperative period.

DISCUSSION

Several previous studies have reported success rates of different types of drainage implants available on the market for various types of glaucoma.¹¹⁻²⁵ The comparison of these results is not always easy, due to different populations studied and various methodologies used. In this prospective series, evaluating the efficacy of the SGDD in patients with neovascular glaucoma or failure of previous trabeculectomy, we documented good short-term success rates with a relative small number of surgical complications. As this is the first study to report on the initial results of this new drainage device (efficacy and safety study), a straight comparison with other (well-established) drainage device was not performed at this time. Notwithstanding, the results we found seem to be comparable with previously published data on major implants in cases of refractory glaucomas.

Regarding cases of neovascular glaucoma treated with the implant of Ahmed valve, Netland et al²⁶ found 73.1% of the patients with IOP < 21 mm Hg after 1 year of surgery, whereas Li et al²⁷ and Shen et al²⁸ found a similar qualified success rate of ~70% for the same follow-up

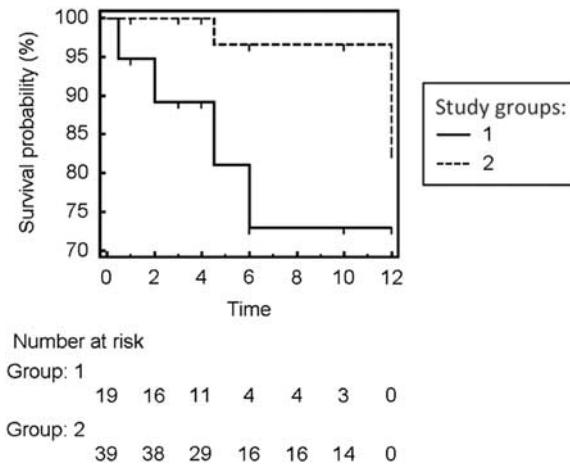


FIGURE 2. Kaplan-Meier survival curves showing qualified success rates for patients with neovascular glaucoma (group 1) and refractory glaucomas (previous trabeculectomy failure; group 2), based on the less strict criterion ($IOP \geq 6$ and ≤ 21 mm Hg). IOP indicates intraocular pressure.

period. Two others studies found similar success rates using the drainage implants of Ahmed (83.8%) and Baerveldt (79%).^{29,30} Taking into consideration the shorter follow-up of our study, its findings were similar to those previously reported in the literature, as we documented qualified success rates of 73% for both criteria. We believe that the identical qualified success rates we found in this group independent of the criterion adopted (upper IOP limit at 18 vs. 21 mm Hg) is likely due to the fact that surgical failure in these eyes with neovascular occurred at very high IOPs, generally far above from 21 mm Hg.

When compared with the Baerveldt implant and Ahmed valve for cases of refractory glaucomas (with a failure of a previous trabeculectomy), the SGDD had comparable success rate after 6 months of surgery (qualified success of 96%) when considering the upper IOP limit of 21 mm Hg. Gedde et al.,³¹ using the Baerveldt implant, reported a similar

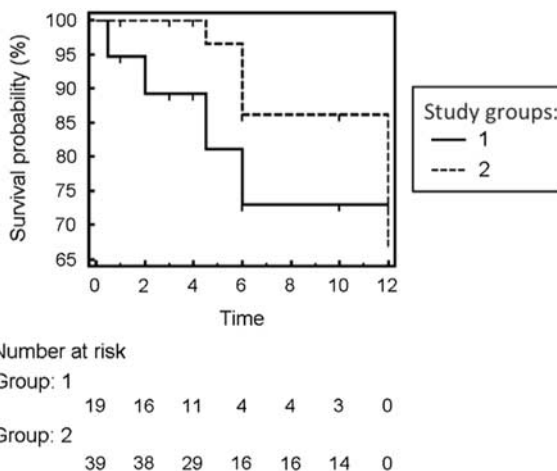


FIGURE 3. Kaplan-Meier survival curves showing qualified success rates for patients with neovascular glaucoma (group 1) and other refractory glaucomas (previous trabeculectomy failure; group 2), based on the stricter criterion ($IOP \geq 6$ and ≤ 18 mm Hg). IOP indicates intraocular pressure.

TABLE 2. Surgery Success Rates at 6 Months Postoperatively

Success Rates Criteria	[n (%)]	
	Group 1 (n = 19 Patients)	Group 2 (n = 39 Patients)
Criterion I ($6 \leq IOP \leq 21$ mm Hg)		
Complete	11 (58)	23 (58)
Qualified	14 (73)	37 (96)
Criterion II ($6 \leq IOP \leq 18$ mm Hg)		
Complete	10 (54)	12 (31)
Qualified	14 (73)	33 (86)

Group 1, neovascular glaucoma; group 2, refractory glaucomas (previous trabeculectomy failure). IOP indicates intraocular pressure.

success rate of 96.1% after a follow-up of 1 year in the Tube versus Trabeculectomy (TVT) study, while the mostly recent reports of TVT with 3 and 5 years of follow-up showed a failure rate of 15.1% and 29.8%, respectively for the tube group.^{32,33} In other previous reports with longer follow-ups, the success rates ranged from 75% to 88% with Baerveldt implants.^{18,25} The mostly recent report from Ahmed Baerveldt comparison study with 5 years of follow-up, the cumulative probability of failure was 44.7% and 39.4%, respectively, in the Ahmed and Baerveldt groups.³⁴ In our study, the rates of complete and qualified success differed significantly in these patients with refractory glaucomas (criterion I: 58% vs. 96%; criterion II: 31% vs. 86%, respectively). Analyzing the cases of failure of complete success in this group, we found that they occurred at much lower pressure levels than group 1 (eyes with neovascular glaucoma), and therefore, many patients could achieve qualified success when using antiglaucoma medications. Considering all patients in our study (regardless the type of glaucoma), we found a short-term failure rate of 12% at 6 months. This result is similar to those reported in the Ahmed Baerveldt Comparison Study for refractory glaucomas, as failure rates at 1 year of follow-up were 16% (Ahmed) and 14% (Baerveldt).³⁵ Interestingly, a previous report comparing 2 models of the Ahmed valve (FP7 vs. S2) for refractory glaucomas found a higher success rate (94.2% vs. 83.2% after 1 year) for the silicone model (FP7),³⁶ which is the same material that is used to manufacture the SGDD.

Regarding postoperative complications, the TVT study reported 7% of surgery-related complications during the first year of follow-up, and mostly were self-limited,³⁷ which is similar to our findings. We believe that our most important complication was shallow anterior chamber due to hypotony, which was observed in ~9% of our patients. Once again, this number is similar to those previously reported with other well-established devices, as shallow anterior chamber was present in 11% of the patients in the tube group of TVT study.³⁷ It is worth mentioning that in 5 years after the Ahmed Baerveldt Comparison Study, 20% of patients with surgery failure in the Ahmed group experienced complications (eg, persistent hypotonia and loss of visual acuity), whereas in the Baerveldt group this rate reached 47%.³⁴ For the TVT study, 43% of the patients during the 5 years of follow-up in the tube group experienced ≥ 1 surgical complications postoperatively.³³

It is important to emphasize the main limitations of the present study. As the first study of efficacy and safety evaluation of this new model of the Susanna implant, it did

not include a control group, which limits its comparison with other drainage devices. Other factors that should be considered while interpreting our results include its short follow-up duration, relative small sample size, and inclusion of multiple surgeons (despite using a standardized technique). Finally, the fact that we excluded some of the high-risk eyes such as those with previous buckle placement, presence of severe corneal opacity, or anterior chamber disorganization may have increase our success rates. However, it should be emphasized that most of the aforementioned studies have not included such type of patients as well.

In summary, our initial findings suggest that the new SGDD is an effective alternative for managing neovascular and refractory glaucomas, with relative minor post-operative complications in the short-term. Its initial results seem to be comparable with those reported in previous studies with other commercially available drainage devices, such as the Baerveldt implant and the Ahmed Glaucoma Valve in cases of neovascular and refractory glaucomas. These results deserve a longer follow-up and likely replication in different studies to be confirmed. With the aim of knowing the long-term results of this new implant, patients involved in this study continue to be monitored.

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