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Ahmed Glaucoma Valve Implantation: Graft-Free Short Tunnel Small Flap versus Scleral Patch Graft After 1 Year Follow-Up: A Randomised Clinical Trial

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Abstract:

Purpose: To compare the efficacy and safety of graft-free short tunnel small flap (STSF) technique with that of scleral patch graft (SPG) in Ahmed glaucoma valve (AGV) implantation.

Design: Randomized clinical trial.

Participants: Eighty-eyes of eighty patients with medically uncontrolled glaucoma including 41 in STSF and 39 eyes in SPG.

Methods: Patients were enrolled and assigned randomly to STSF or SPG.

Main Outcome Measures: tube exposure, Intraocular pressure (IOP), number of glaucoma medications, best corrected visual acuity (BCVA), surgical complications, and success rate (defined as intraocular pressure (IOP) >5 mmHg, ≤21 mmHg, and IOP reduction ≥20% from baseline at two consecutive visits after three months, no reoperation for glaucoma).

Results: only one case in SPG developed tube exposure at 1-year follow-up. The cumulative probability of success during the first year of follow-up was 70% in the STSF and 65% in SPG (P = 0.36). IOP decreased significantly from 29.6 ± 8.6 mmHg at baseline to 16.4 ± 3.6 mmHg at the final follow-up in STSF (p = 0.001). The corresponding numbers for SPG were 30.9 ± 11.2 and 15.8 ± 4.7, respectively (p = 0.001). The final IOP was comparable between both groups (p = 0.65). Mean ± standard deviation of the number of glaucoma medications was 1.8 ± 0.9 in STSF and 1.6 ± 0.9 in SPG at final follow-up (P = 0.32). Postoperative complications developed in 8 patients (19%) in STSF and 9 patients (23%) in SPG (P = 0.81).

Conclusions: STSF and SPG techniques had comparable complication rate at one-year follow-up. Both techniques were comparable in terms of success rate, postoperative IOP, and glaucoma medications.

Keywords: short tunnel small flap; glaucoma drainage device implantation; tube exposure; STSF; Ahmed glaucoma valve; AGV.

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Introduction

Since the tube versus trabeculectomy study,[1] more tube shunts are being implanted even as primary surgeries[2] although the pendulum has started to swing again slightly toward trabeculectomies.[3] While bleb-related complications of trabeculectomy are not seen after glaucoma drainage device (GDD) implantations, [4]these devices predispose patients to certain adverse events related to the implantation of a foreign body on the surface of the eye. One unique complication is the exposure of the glaucoma drainage device. Conjunctival erosion and device exposure occur in the late postoperative period in 1% to 8% of eyes. [5–9] The consequences of tube exposure could be sight threatening such as hypotonia, ocular inflammation, phthisis, and endophthalmitis.[10] Despite uniformity in technique to fix the devices to the sclera and use of free patch graft to cover the drainage seton, tube erosion is an established complication of GDDs. Mechanisms of exposure are patch graft melting due to immunologic reactions, conjunctival rubbing over the tube, the repeated mechanical force caused by the eyelid blinking, and outward pressure onto the tube from eye globe. [11,12] Moreover, viral transmission, Dellen formation at the limbal area, ocular surface symptoms, and cosmetic appeal are concerns of using patch graft in shunt procedure.[13–15]

Alternatives to patch graft are either a large scleral flap or scleral tunnel techniques. [16–19] We proposed a graft-free GDD implantation method that combines advantages of both scleral flap and tunnel techniques while faster, simpler, and with better tube position in the anterior chamber. [12]

This study is a randomized clinical trial comparing the safety and efficacy of graft free short tunnel small flap technique and patch graft method in Ahmed glaucoma valve (AGV, New World Medical Inc, Rancho Cucamonga, California, USA) implantation.

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Methods:

The institutional review board of the Shahid Beheshti University of Medical Sciences approved the study protocol before recruitment began. Written informed consent was obtained from all subjects. The study adhered to the tenets of the Declaration of Helsinki and the provisions of the Health Insurance Portability and Accountability Act. This study is registered at www.clinicaltrials.gov (identifier,NCT03551834).

Eligibility Criteria

Eligible subjects were Iranian patients with Caucasian ethnicity at least 25 years of age who had inadequately controlled glaucoma. Exclusion criteria included no light perception vision, history of AGV implantation in the same eye, pregnant or nursing women, iridocorneal endothelial syndrome, epithelial or fibrous down growth, and unwillingness to participate in the study.

At baseline, all patients underwent a comprehensive ophthalmic examination including determination of best corrected visual acuity (BCVA), slit-lamp examination, Goldmann applanation tonometry, gonioscopy, fundus examination and perimetry (Humphrey visual field analyzer; model 750; Carl Zeiss Meditec, Dublin, California, USA).

Randomization and Treatment

Subjects enrolled in the study were randomized to the placement of an AGV with short tunnel small flap technique (STSF) or AGV and scleral patch graft (SPG). Randomisation was performed on the day of surgery. Assignments were generated by a computer programme employing a random permuted block algorithm with block sizes of 2, 4 and 6. Neither the patient nor the clinician was masked to the randomization assignment during follow-up.

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Surgical technique:

After administration of intravenous sedation, local peribulbar anesthesia was achieved using 2 mL of lidocaine 2% (Lignidic 2%, Caspian Tamin Pharmaceutical Co., Rasht, Iran). Following lid speculum insertion and cul-de-sacs irrigation with povidone/ iodine and normal saline solution, a 7-0 silk traction suture was placed through the superior clear cornea. An eight millimeter long, limbus-parallel incision through the conjunctiva and Tenon's capsule, four millimeters posterior to the limbus was created in the supratemporal quadrant, and Tenon's capsule was dissected away from the sclera with Westcott scissors to provide space for the plate insertion. The device (Ahmed glaucoma drainage implant, model FP7, New World Medical, Rancho Cucamonga, California) was primed with two ml of buffered saline solution (BSS) and gently pushed through the incision into the subtenon space. The plate was secured to the sclera 10 mm posterior to the limbus using a 7-0 silk suture. The tube was trimmed bevel up with an estimated intracameral length of 2 mm.

In STSF group, A 2.5mm×2.5mm trapezoidal half thickness scleral flap was fashioned using a crescent knife followed by lamellar dissection of the scleral flap at 11 or 1 o'clock in the right eye and the left eye, respectively. A 23-gauge needle was bent bevel up and inserted into sclera just anterior to the plate and directed to the superior border of the scleral flap bed to be retrieved from the depth of the flap margin. The needle was then redirected toward the anterior chamber parallel to iris plane. The scleral flap was then secured using two 10-0 nylon sutures with knots buried into the sclera.

In SPG, the needle was inserted into the anterior chamber bevel up, parallel to the iris and 1 mm posterior to the limbus. The tube was passed through the tunnel into the anterior chamber and secured to the sclera with a 10-0 nylon suture. A 5x8 mm scleral patch graft was placed over the tube.

Tenon's capsule and the conjunctiva were closed using a running 10-0 nylon mattress suture. The postoperative regimen consisted of chloramphenicol 0.5% eye drops (Sina Darou Lab, Tehran, Iran) four times a day for 1 week and betamethasone 0.1% eye drops (Sina Darou Lab, Tehran, Iran) four times per day for one week followed by a gradual taper.

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Postoperatively patients were visited on a weekly basis for 1 month and then at 3,6, and 12 months. At each postoperative visit, BCVA, IOP, antiglaucoma medications, and complications were noted.

Success was defined as IOP ≤21 mmHg, > 5 mmHg, and a >20% reduction from baseline with no need for further glaucoma surgery. The hypertensive phase (HP) was defined as an IOP above 21 mmHg during the first 3 months after surgery (with or without medications) after reduction of IOP to less than 22 mmHg was achieved within the first week postoperatively [20]

Statistical analysis:

Normal distribution of data was assessed by Kolmogorov-Smirnov test and Q-Q plot. To present data, we used mean, SD, median and range, frequency and percentage values. To evaluate differences between the study groups, we used $\chi 2$, t-test and Mann-Whitney tests. To assess changes within the study groups, we used Wilcoxon signed-rank test and the linear mixed model. The latter test was followed by Bonferroni correction to consider multiple comparisons. To compare the groups adjusted for baseline values, we used analysis of covariance and Poisson regression (based on the type of response). All statistical analyses were performed using SPSS software (IBM SPSS Statistics for Windows, V.23.0, Released 2014, IBM, Armonk, New York, USA.). All tests are two-sided and p values less than 0.05 are considered statistically significant.

Results:

A total of 84 eyes of 84 patients were enrolled and underwent AGV implantation between September 2015 and January 2017, including 41 patients in the STSF and 39 patients in the SPG group. There were 4 patients who were randomized but did not receive surgical treatment in the study, and they were not included in the analysis of outcomes. The reasons for exiting the

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study before undergoing operation was patient refusal at the operation room, and transfer to another location in two cases, and unknown in the fourth patient.

The baseline characteristics of the study population are provided in Table 1. No significant differences in any of the demographic or ocular features were observed between STSF and SPG at enrollment. The mean ±standard deviation (SD) age of the study population at enrollment was 53.2 ± 17.3 years, and 53 patients (66%) were men. The mean baseline visual acuity was 0.49 ± 0.74 logMAR. The mean IOP ±SD of the overall study group was 30.2 ± 9.9 mmHg, and the mean SD number of glaucoma medications was 3.5 ± 0.8. The most common diagnosis was neovascular glaucoma in 23 eyes (29%).

At 1-year treatment failure had occurred in 8 (20%) patients in the STSF and 7 (18%) patients in the SPG. (P=0.62). In the STSF, 18 (44%) and 13 (32%) patients were classified as a complete and qualified success, respectively. In the SPG, the respective values were 16 (41%) and 15 (38%). The rate of complete and qualified success rate was comparable between STSF and SPG. (P= 0.47)

The most common cause of failure was high IOP (Table 2)

Kaplan-Meier survival analysis was also used to compare cumulative probability of success at 1-year follow-up. (Figure 1) The cumulative percent of success was 70% in STSF and 65% in SPG group (log Rank= 1.02 P = 0.36)

Both techniques produced a significant reduction in IOP at 1-year follow up. The mean final IOP was 16.4 ± 3.6 in STSF and 15.8 ± 4.7 in SPG. (P=0.65) (Table 3) Nine eyes in STSF (22%) and 8 eyes in A (21%) experienced a hypertensive phase within three months of operation (p=0.85)

Table 4 shows the number of glaucoma medications in both groups at 1-year follow-up. Significant reduction in the medication usage was observed in both groups. It decreased from 3.6 ± 0.8 to 1.8 ± 0.9 in STSF. (P<0.001) Corresponding values for SPG were 3.5 ± 0.8 and 1.6 ± 0.9. (P<0.001) The mean number of medications between both treatment groups was comparable at final follow-up (P=0.32).

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Glaucoma reoperation was done in cases in whom IOP could not be controlled within target range or there was evidence of disease progression. Additional glaucoma surgeries included 1 secondary AGV implantation and 1 cyclophotocoagulation (CPC) in STSF and one case of CPC in SPG group.

The mean BCVA at the baseline was 0.46 ± 0.56 logMAR in STSF and 0.51 ± 0.88 logMAR in SPG (p=0.122). Corresponding numbers for final follow-up visit were 0.42±1.07 logMAR and 0.43±0.97 logMAR, respectively (p= 0.41).

Table 5 lists surgical complications encountered during the first year of the Study. Hyphema was the most common intraoperative complication in both treatment groups, occurring in 3 patients (7%) in the STSF and 2 patients (5%) in the SPG. The overall incidence of postoperative complications was similar between both groups. A total of 13 early postoperative complications were reported in 6 patients (15%) in the STSF, and 7 complications were noted in SPG (18%). No early postoperative complications occurred with significantly greater frequency in the STSF than the SPG.

The overall incidence of late postoperative complications occurring more than 1 month after surgery was similar between treatment groups. A total of 4 late postoperative complications were seen in 2 patients (5%) in the STSF, and 2 (5%) complications were observed in SPG group. No late postoperative complication occurred with significantly higher frequency in either treatment group.

Discussion:

Both groups had a comparable success rate during the first year follow-up. At 1 year, the cumulative probability of success was 70% in STSF and 65% in the SPG group. Both techniques produced significant reductions in IOP from baseline averages of 30 to 31 mmHg to final average IOPs of 16.4 mmHg in the STSF and 15.8 mmHg in the SPG group. The total IOP reduction was almost 50% in both treatment groups and settled in mid-teens at final follow-up, which is comparable to previous studies. [5,21,22] The IOP after AGV implantation typically follows

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two phases: 7 to 10 days of relative hypotony that may be followed by the rise of intraocular pressure above 21 mmHg during the hypertensive phase [23]. The rate of a hypertensive phase in our study was almost 20%, lower but not inconsistent with previous studies [20,23,24]. The reason for the lower incidence of HP in the current study could be explained by early administration of aqueous suppressants in our practice. We showed previously that starting aqueous suppressants once postoperative IOP raised to 10 mmHg would decrease the rate of HP following AGV implantation probably due to the reduced concentration of inflammatory cytokines and capsule stretch in bleb area.[24]

The benefit of glaucoma surgery in reducing intraocular pressure should be interpreted in the context of associated complications. In our study, intraoperative complications occurred at a similar rate with STSF and SPG. Hyphema was the most common intraoperative complication while no serious intraoperative complications were observed in our study. Early and late postoperative adverse events were comparable between both groups during the first year of follow-up.

Tube exposure is a common complication of GDDs and has been reported in almost 5% of cases. [6,25] Currently, the most common practice is to cover the tube by a patch graft. [26] The risk of tube erosion is very high in the absence of a patch graft to cover the tube. [27] While the rate of tube exposure has decreased significantly following donor scleral patch, concerns remain about the transmission of infection from donor tissue. [28] Bovine pericardium (Tutopatch) has been used as an alternative to prevent erosion as it is twice as thick. However, with Tutopatch, a severe inflammation of the conjunctiva, as well the risk of Dellen formation in the peripheral cornea is reported in the postoperative period. [5] In contrast, human pericardium (Tutoplast) has a thin configuration and is not associated with postoperative inflammation, which makes it a favorable choice to cover the tube in GDD implantation. [3] The rationale for using patch graft is to protect the tube from direct eyelid repetitive trauma and broaden the elevated area to reduce the risk of tube erosion. In spite of covering the seton with patch graft, tube erosion occurs. It seems that the real mechanism of exposure is not just conjunctival erosion due to constant eyelid rubbing, but curve configuration of the tube that eventually leads to erosion. [12,16] As a result, some surgeons put the tube under the scleral flap or into a tunnel with or

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without patch grafts. The idea is that these methods of insertion provide a flatter configuration and less chance of exposure.[18] The drawbacks of the scleral flap are the need for extensive conjunctival exposure and cautery as well as free patch graft to prevent tube exposure through partial thickness lamellar flap. [29] Another approach is to pass the tube into a tunnel created by 23 gauge needle. Although the risk of exposure with this method is very low, but since the tube follows the contour of the globe, it may be displaced toward the cornea and causes corneal decompensation. Attempt for posterior insertion may result in high risk of hyphema and iris peak. In a case series on 16 eyes, we reported the outcomes of STSF for graft free AGV implantation that combines advantages of both methods. [12] Short tunnel in this technique provides a flat configuration for the tube insertion, which prevents tube exposure, and limbal flap gives space for steeper insertion of the tube into the anterior chamber and prevents corneal decompensation. The results of the current study are in agreement with our previous case series and confirms the role of graft-free STSF technique as an alternative for AGV implantation with a patch graft. Only one case in SPG developed tube exposure in the current study that was patched over by secondary scleral patch graft and conjunctival closure.

There are several limitations to our study. The clinicians and patients were not masked to the randomization and this could be a potential source of bias. The follow-up was relatively short, especially for evaluating late-onset complication such as tube exposure. We plan to report outcomes of this trial at 3 and 5-year follow-up as long-term data are needed to investigate traditional glaucoma surgeries fully.

There are now so many glaucoma surgery options it has become difficult to select the most appropriate one. The demand for microincisional glaucoma surgeries (MIGS) has been steadily increasing as well informed patients demand safer alternatives to traditional filtering procedures. Almost all MIGS have an improved safety profile, a minimal recovery time, and have a good long-term efficacy in several types of glaucoma, but they are generally less effective than conventional procedures. [4,30] Randomized clinical trials such as this one are needed to evaluate safety and efficacy of different surgical approaches to provide surgeons with high-level evidence so that they select the most appropriate procedure for individual patients.

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Table1: Baseline clinical characteristics of participants

		Total	Surgery		
			STSF, N (%)	SPG, N (%)	P-value
Mean Age ± SD		53.2 ± 17.3	51.48 ± 17.22	55.11 ± 17.42	0.35**
Sex	Male	53 (66.3%)	28 (68.3%)	25 (64.1%)	>0.99*
	Female	27 (33.8%)	13 (31.7%)	14 (35.9%)	
Eye	OD	50 (62.5%)	26 (61.9%)	24 (63.2%)	>0.99*
	OS	30 (37.5%)	16 (38.1%)	14 (36.8%)	
Type of glaucoma	NVG	23 (28.7%)	10 (23.8%)	13 (34.2%)	0.91†
	Failed Trabx	14 (17.5%)	9 (21.4%)	5 (13.2%)	
	Uveitic	13 (16.3%)	7 (16.7%)	6 (15.8%)	

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	GFCS	10 (12.5%)	5 (11.9%)	5 (13.2%)
	Post-vitrectomy+SO	9 (11.3%)	6 (14.3%)	3 (7.9%)
	Post-PK	7 (8.8%)	3 (7.1%)	4 (10.5%)
	Others	4 (5.0%)	2 (4.8%)	2 (5.3%)
BCVA (LogMAR)		0.49 ± 0.7	0.46 ± 0.5)	0.51 ± 0.8	0.52**
IOP		30.2 ± 9.9	29.5 ± 8.6	30.8 ± 11.1	0.56**
Medications		3.54 ± 0.81	3.56 ± 0.84	3.53 ± 0.8	0.85

Trabx: trabeculectomy, NVG: neovascular glaucoma, GFCS: glaucoma follwing cataract surgery, SO: silicon oil, PK: penetrating keratoplasty. *p-values are based on Chi-square test, †p-values are based on fisher exact test, **p-values are based on t-test

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Table 2: treatment outcome at final follow-up

	STSF	SPG	P
Complete success	18 (44%)	16 (41%)	0.47*
Qualified success	13 (31.7%)	15 (38.4%)	
Failure			
High IOP > 21 or less than 20% reduction from baseline IOP	8 (19.5%)	7 (18 %)	0.62*
Glaucoma reoperation	2 (4.8%)	1 (2.5%)	

IOP: intraocular pressure. *based on Chi-square. STSF: short tunnel small flap; SPG: scleral patch graft. IOP: Intraocular pressure.

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Table 3: Changes in intraocular pressure during the course of the study in 2 groups.

		Surgery		P-value†
IOP	Total	STSF	SPG	
Baseline	30.22 ± 9.9	29.59 ± 8.6	30.89 ± 11.1	0.56
Month1	12.32 ± 5.9	12.63 ± 5.9	11.97 ± 5.9	0.62
P-Within*		<0.001	<0.001	
Month 3	15.41 ± 2.1	15.81 ± 3.2	15.11 ± 1.2	0.40
P-Within*		<0.001	<0.001	
Month 6	15.51 ± 4.4	15.49 ± 5	15.61 ± 3.64	0.32
P-Within*		<0.001	<0.001	
Month 12	16.12 ± 4.1	16.41 ± 3.5	15.84 ± 4.7	0.65
P-Within*		<0.001	<0.001	

IOP: intraocular pressure. *P-values are based on Paired T-test, †P-values are based on a generalized linear model

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Table4- Changes in the number of glaucoma medication during the course of the study in 2 groups.

		Surgery		P-value†
	Total	STSF	SPG	
Baseline	3.54 ± 0.8	3.56 ± 0.8	3.53 ± 0.8	0.85
Month 1	0.24 ± 0.6	0.24 ± 0.6	0.24 ± 0.6	0.96
Month 3	1.46 ± 0.5	1.51 ± 0.4	1.41 ± 0.7	0.63
Month 6	1.56 ± 0.8	1.61 ± 0.8	1.5 ± 0.8	0.58
Month 12	1.73 ± 0.8	1.83 ± 0.9	1.63 ± 0.8	0.32

†P-values are based on generalized linear model

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Table 5: Postoperative complications

		Total†	STSF	SPG	P value*
Early-onset postoperative complications	Choroidal effusion	5 (6.25)	2 (4.8)	3 (7.6)	0.75
	endophthalmitis	1 (1.25)	0 (0.0%)	1 (2.5)	0.91
	flat AC	1 (1.25)	1 (2.4)	0 (0.0)	0.93
	hyphema	2 (2.5)	1 (2.4)	1 (2.5)	0.99
	leakage	1 (1.25)	0 (0.0)	1 (2.5)	0.91
	Tube closure	2 (2.5)	2 (4.8)	0 (0.0)	0.54
	Tube malposition	1 (1.25)	0 (0.0)	1 (2.5)	0.93
Late-onset postoperative complications	cataract	1 (1.25)	1 (2.4)	0 (0.0)	0.93

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	malignant glaucoma	1 (1.25)	0 (0.0)	1 (2.5)	0.91
	Diplopia	1 (1.25)	1 (2.4)	0 (0.0)	0.93
	Tube exposure	1 (1.25)	0 (0.0)	1 (2.5)	0.91
Total number of patients with postoperative complications			8 (19.5)	9 (23)	0.81

AC: anterior chamber, † numbers (%), *Based on Chi-square test

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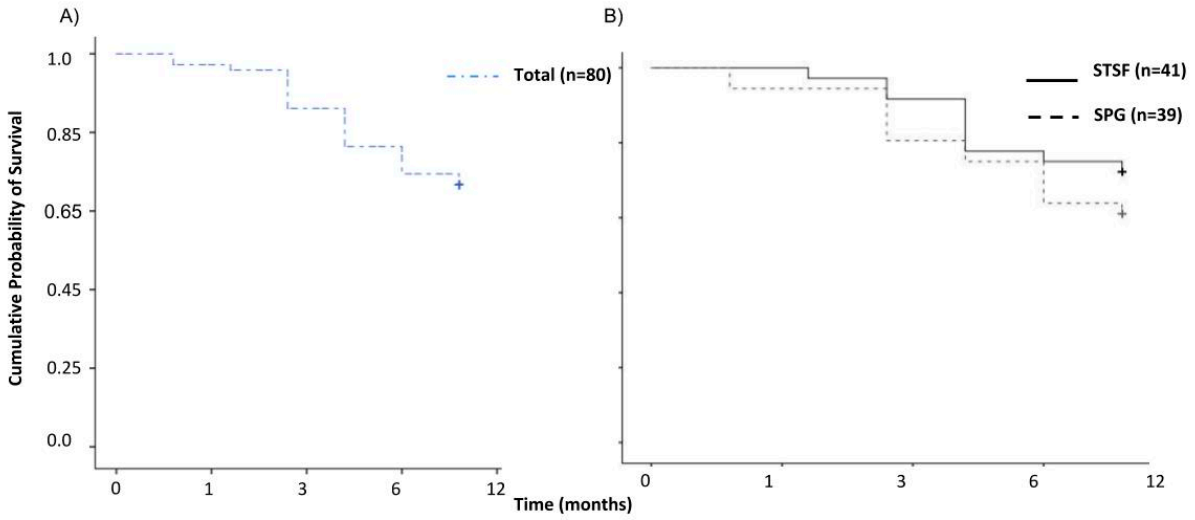

Figure 1: Kaplan-Meier plots of the cumulative probability of success in all cases (left) and in each method (right) defining inadequate intraocular (IOP) reduction as IOP >21 mmHg or <20% reduction below the baseline. These criteria must have been present on 2 consecutive visits after 3 months to qualify as failure.

References:

1. Gedde SJ, Schiffman JC, Feuer WJ, et al. Treatment outcomes in the tube versus trabeculectomy study after one year of follow-up. Am J Ophthalmol 2007;143:9–22.

2. Desai MA, Gedde SJ, Feuer WJ, et al. Practice preferences for glaucoma surgery: a survey of the american glaucoma society in 2008. Ophthalmic Surg Lasers Imaging 2011;42. Available at: http://dx.doi.org/10.3928/15428877-20110224-94.

3. Gedde SJ, Feuer WJ, Shi W, et al. Treatment Outcomes in the Primary Tube Versus Trabeculectomy Study after 1 Year of Follow-up. Ophthalmology 2018;125:650–663.

4. Esfandiari H, Pakravan M, Loewen NA, Yaseri M. Predictive value of early postoperative IOP and bleb morphology in Mitomycin-C augmented trabeculectomy. F1000Res 2017;6. Available at: https://f1000research.com/articles/6-1898/v1/pdf [Accessed November 7, 2017].

5. Wishart PK, Choudhary A, Wong D. Ahmed glaucoma valves in refractory glaucoma: a 7-year audit. Br J Ophthalmol 2010;94:1174–1179.

6. Gedde SJ, Herndon LW, Brandt JD, et al. Postoperative complications in the Tube Versus Trabeculectomy (TVT) study during five years of follow-up. Am J Ophthalmol 2012;153:804–814.e1.

7. Chaku M, Netland PA, Ishida K, Rhee DJ. Risk factors for tube exposure as a late complication of glaucoma drainage implant surgery. Clin Ophthalmol 2016;10:547–553.

8. Christakis PG, Zhang D, Budenz DL, et al. Five-Year Pooled Data Analysis of the Ahmed Baerveldt Comparison Study and the Ahmed Versus Baerveldt Study. Am J Ophthalmol 2017;176:118–126.

9. Pakravan M, Esfandiari H, Yazdani S, et al. Clinical outcomes of Ahmed glaucoma valve implantation in pediatric glaucoma. Eur J Ophthalmol 2018:1120672118761332.

10. Gedde SJ, Scott IU, Tabandeh H, et al. Late endophthalmitis associated with glaucoma drainage implants. Ophthalmology 2001;108:1323–1327.

11. Huddleston SM, Feldman RM, Budenz DL, et al. Aqueous shunt exposure: a retrospective review of repair outcome. J Glaucoma 2013;22:433–438.

12. Pakravan M, Hekmat VR, Pakravan P, et al. Graft-free glaucoma drainage device implantation: Short tunnel small flap technique. Eur J Ophthalmol 2018:1120672118761458.

13. Seiff SR, Chang JS Jr, Hurt MH, Khayam-Bashi H. Polymerase chain reaction identification of human immunodeficiency virus-1 in preserved human sclera. Am J Ophthalmol 1994;118:528–530.

14. Thadani V, Penar PL, Partington J, et al. Creutzfeldt-Jakob disease probably acquired from a cadaveric dura mater graft. Case report. J Neurosurg 1988;69:766–769.

15. Hong C-H, Arosemena A, Zurakowski D, Ayyala RS. Glaucoma drainage devices: a

systematic literature review and current controversies. Surv Ophthalmol 2005;50:48–60.

16. Ozdamar A, Aras C, Ustundag C, et al. Scleral tunnel for the implantation of glaucoma seton devices. Ophthalmic Surg Lasers 2001;32:432–435.

17. Ollila M, Falck A, Airaksinen PJ. Placing the Molteno implant in a long scleral tunnel to prevent postoperative tube exposure. Acta Ophthalmol Scand 2005;83:302–305.

18. Mesa-Gutiérrez JC, Lillo-Sopena J, Monés-Llivina A, et al. Graft-free Ahmed tube insertion: a modified method at 5 mm from limbus. Clin Ophthalmol 2010;4:359–363.

19. Kugu S, Erdogan G, Sevim MS, Ozerturk Y. Efficacy of long scleral tunnel technique in preventing Ahmed glaucoma valve tube exposure through conjunctiva. Semin Ophthalmol 2015;30:1–5.

20. Nouri-Mahdavi K, Caprioli J. Evaluation of the hypertensive phase after insertion of the Ahmed Glaucoma Valve. Am J Ophthalmol 2003;136:1001–1008.

21. Gedde SJ, Panarelli JF, Banitt MR, Lee RK. Evidenced-based comparison of aqueous shunts. Curr Opin Ophthalmol 2013;24:87–95.

22. Riva I, Roberti G, Katsanos A, et al. A Review of the Ahmed Glaucoma Valve Implant and Comparison with Other Surgical Operations. Adv Ther 2017;34:834–847.

23. Won HJ, Sung KR. Hypertensive Phase Following Silicone Plate Ahmed Glaucoma Valve Implantation. J Glaucoma 2016;25:e313–7.

24. Pakravan M, Rad SS, Yazdani S, et al. Effect of early treatment with aqueous suppressants on Ahmed glaucoma valve implantation outcomes. Ophthalmology 2014;121:1693–1698.

25. Gedde SJ, Schiffman JC, Feuer WJ, et al. Treatment outcomes in the Tube Versus Trabeculectomy (TVT) study after five years of follow-up. Am J Ophthalmol 2012;153:789–803.e2.

26. Minckler DS, Francis BA, Hodapp EA, et al. Aqueous shunts in glaucoma: a report by the American Academy of Ophthalmology. Ophthalmology 2008;115:1089–1098.

27. Woodcock MGL, Richards JC, Murray ADN. The last 11 years of Molteno implantation at the University of Cape Town. Refining our indications and surgical technique. Eye 2008;22:18–25.

28. Centers for Disease Control (CDC). Update: Creutzfeldt-Jakob disease in a second patient who received a cadaveric dura mater graft. MMWR Morb Mortal Wkly Rep 1989;38:37–8, 43.

29. Yu JH, Nguyen C, Gallemore E, Gallemore RP. Combined Scleral Flap with Donor Scleral Patch Graft for Anterior Tube Placement in Glaucoma Drainage Device Surgery. Case Rep Ophthalmol Med 2016;2016:2124581.

30. Saheb H, Ahmed IIK. Micro-invasive glaucoma surgery: current perspectives and future directions. Curr Opin Ophthalmol 2012;23:96–104.