Results of a New Technique for Implantation of Nonrestrictive Glaucoma Devices

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ABSTRACT

Objective: To describe and present results of an original technique for nonvalved glaucoma implants.

Patients and methods: Thirty-five eyes of 34 patients with aggressive and/or advanced glaucomas of different causes were included. A Baerveldt implant was used in all cases, using an absorbable ligature that had been titrated to allow flow from day 1, but avoiding hypotony. Intraocular pressure (IOP) during the first 8 weeks, final IOP, visual acuity and complications were analyzed.

Results: Mean preoperative IOP was 42.8 mm Hg (range: 24-64 mm Hg). IOP was 14.4, 17.2, 18.6, 19 and 16.4 mm Hg during the 1, 2, 4, 6 and 8 postoperative weeks. Mean final IOP was 13.8 ± 4.25 mm Hg, a 67.8% reduction, after a mean follow-up time of 13 months (range: 8-29 months). Twenty-nine eyes (82.9%) had complete success, two had qualified success (5.7%) and four were failures (11.4%). Choroidal detachments and transient tube obstructions were the most frequent complications.

Conclusion: Titrated ligature of Baerveldt tubes was effective for controlling IOP during both the early and late postoperative phases in eyes with severe glaucomas.

Keywords: Glaucoma surgery, Glaucoma implants, Titrated ligature.

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INTRODUCTION

Glaucoma implants are a valuable alternative for controlling intraocular pressure (IOP) in difficult to treat glaucomas that have been in use for the past 30 years. All implants share some common features, although design, materials and size differ. In all a tube is inserted into the anterior chamber that is connected to a main body or plate, located at or behind the equator, around which a fibrous capsule that regulates aqueous outflow is formed. Implants may have restrictive flow (e.g. Ahmed or Krupin) or unrestrictive (e.g. Molteno and Baerveldt).¹

Implants with restrictive flow are designed to permit a more controlled flow from the beginning, while the

tube must be occluded fully or partially during the first postoperative days in unrestricted implants to avoid severe hypotony. Occluding the tube will raise IOP until the ligature is removed or reabsorbed, an event that is usually planned for a time when sufficient fibrosis is formed around the implant, usually after 3 to 6 weeks. During this hypertensive period, eyes with advanced glaucomas or those with very high initial IOP might suffer additional devastating damage. Making venting slits anterior to the ligature, or using a suture inside the tube to permit some limited flow are established techniques that tend to have unpredictable results.^{2,3}

After years of using Baerveldt implants we have devised the 'Ortiz' partial titrated ligature' technique to lower IOP from the first postoperative day with limited flow that lasts until the implant begins functioning fully.

PATIENTS AND METHODS

We report a case series of patients with difficult to control glaucomas, in whom a Baerveldt implant with partial titrated ligature was performed. Eyes in immediate need of an implant, with very high IOP on maximum tolerated therapy and/or advanced glaucoma damage were included. We excluded patients unable to comply with visits and those with less than 6 months of follow-up.

A signed informed consent was obtained from each patient after explaining the nature of the study and of the procedure. Our hospital's surgery investigation department and the ethics committee of the faculty of medicine of the Universidad Nacional de Colombia approved the protocol. Data was collected in a specially designed form that registered age, sex, race, diagnosis, date of the surgery, type of procedure, implant location and tube location, initial and final visual acuity, complications, additional procedures needed and initial IOP, plus IOP at day 1, weeks 1, 2, 4, 6 and 8th, and last recorded IOP.

Complete success was defined as an IOP above 5 and under 22, with an IOP reduction of 30% or better without glaucoma medications, and qualified success if they needed glaucoma medications to reach this goal. Eyes with failure had IOP fewer than 6, above 21, less than 30% reduction, loss of light perception or phthisis bulbi. Reinterventions such as anterior tube revisions, YAG laser to unocclude the tube, or repair of an exposed tube were not considered failures as long as other criteria were still met.

Fig. 1: The height of the irrigation bottle was 50 cm above the level of the eye that needed to be operated, a column that corresponds to approximately 30 mm Hg for doing the ligature titration

Fig. 2: The tubing connects the irrigation bottle to the tube of the implant via a 26G cannula and permeability is checked. The tube is ligated with an absorbable suture (white arrow) and the tension is adjusted until a very slow flow is achieved before the knot is secured (dark arrow)

SURGICAL PROCEDURE

The tube of the implant was connected through a 26G cannula to a BSS bag placed 50 cm above the head of the patient. Every 15 cm of height above the eye represents about 10 mm Hg, so any flow that occurred at this level would mean that pressure would be less than 30 mm Hg (Fig. 1). Once the tube was tested for permeability the tube was ligated with an absorbable suture (7-0 or 8-0 polyglactin, Vicryl® Ethicon Inc.) titrating for a slow, continuous flow of BSS, similar to checking the flow of a trabeculectomy (Fig. 2). Once the desired flow was obtained the suture was locked in place with 5 knots. Then the implant was fixed in place in the conventional manner, in the superotemporal quadrant, using a long-needle tract with a 23G needle bent as a Z without a patch (Dr Felix Gil's Technique).⁴

Postoperative Regimen

Every patient was examined on the first or second day, and at the end of weeks 1, 2, 4, 6 and 8 as per protocol, then every

2 to 3 months depending on IOP behavior or complications behavior. A topical antibiotic was used during the first week and prednisolone 1% every 2 to 4 hours during 8 to 10 weeks. Whenever, hypotony was present prednisolone was replaced with a nonsteroidal anti-inflammatory to promote a greater and faster scarring around the implant.

RESULTS

During the study period (January 2000 to December 2003) 53 eyes (19 were left eyes) of 51 patients received a Baerveldt implant, but 18 had to be excluded due to a short follow-up period.

We included 35 eyes of 34 patients, of which 22 were women; mean age was 59.9 years (range 22-73), including 30 mestizos, 3 Caucasian and 1 black. Demographic and surgical data for each case are included in Table 1. Most cases (25) received a Baerveldt 350 mm² implant and the rest (10) a 425 mm² implant. The tube was inserted into the anterior chamber in most eyes, 6 eyes additionally required an anterior or pars plana vitrectomy to avoid tube blockage.

Visual acuity improved in at least 1 line in 9 eyes, remained the same in 19 and worsened in 7. Initial visual acuity ranged from LP to 20/60 and final visual acuity from NLP to 20/40 (Table 2).

During follow-up the tube got blocked with vitreous in five cases, one could be treated with YAG laser vitreolysis, another also required medications and the other three additional surgical vitrectomy; one of these ultimately failed. One tube retracted out of the anterior chamber and needed to be relocated without loss of IOP control. Seven cases had transient hypotony with no choroidal detachments; only one of them had a mild shallow anterior chamber. Four additional cases had choroidal detachments, three of which were solved spontaneously; the other had to be drained. A patient who initially had light perception only had repeated tube extrusions and after finding calcified material inside the lumen, the tube was trimmed and removed from the anterior chamber. It was considered a failure and eventually needed cyclocryotherapy to further control IOP. In total 13 eyes needed additional procedures to either free the tube or relocate it in a better position (Table 3).

Mean initial IOP was 42.8 mm Hg (range: 24-64), and it was 14.4, 17.2, 18.6, 19 and 16.4 mm Hg during the 1, 2, 4, 6 and 8th postoperative weeks. Mean final IOP was 13.8 ± 4.25 mm Hg, a 67.8% reduction, after a mean follow-up time of 13 months (range: 8-29 months, Table 2, Graph 1).

Mean IOP for 425 mm² implants was 14.7 mm Hg and it was 13.5 mm Hg for the 350 mm² implant, a nonsignificant difference. Twenty-nine eyes (82.9%) had complete success, two had qualified success (5.7%) and four were failures

Table 1: Patients, diagnosis and procedures

No.	Age	Sex	Glaucoma diagnosis	Race	Tube location	Implant	Ligature material
1	54	M	Pseudophakic AC IOL	MES	PC	Baerveldt 425	7-0 Vicryl
2	62	M	Pseudophakic	MES	AC	Baerveldt 350	7-0 Vicryl
3	75	F	PK	MES	AC	Baerveldt 350	7-0 Vicryl
4	76	F	CACG	MES	AC	Baerveldt 350	7-0 Vicryl
5	50	M	PK	MES	AC	Baerveldt 350	7-0 Vicryl
6	72	F	PK	MES	PC	Baerveldt 425	7-0 Vicryl
7	65	F	Uveitic	CAU	AC	Baerveldt 350	7-0 Vicryl
8	65	F	Uveitic	CAU	AC	Baerveldt 350	7-0 Vicryl
9	61	F	Pseudophakic	MES	VC	Baerveldt 350	7-0 Vicryl
10	70	F	Uveitic	MES	AC	Baerveldt 350	7-0 Vicryl
11	69	F	PK	BLA	VC	Baerveldt 350	7-0 Vicryl
12	65	F	Aphakic	MES	VC	Baerveldt 350	8-0 Vicryl
13	49	M	Pseudophakic	MES	AC	Baerveldt 350	7-0 Vicryl
14	43	F	Pseudophakic	MES	AC	Baerveldt 350	7-0 Vicryl
15	49	M	Pseudophakic	MES	AC	Baerveldt 350	7-0 Vicryl
16	38	M	Uveitic	CAU	AC	Baerveldt 350	7-0 Vicryl
17	69	F	PK	MES	PC	Baerveldt 350	7-0 Vicryl
18	35	M	NVG	MES	AC	Baerveldt 350	7-0 Vicryl
19	65	M	Pseudophakic	MES	AC	Baerveldt 350	7-0 Vicryl
20	60	F	GPAA	BLA	AC	Baerveldt 350	7-0 Vicryl
21	60	M	PK	MES	AC	Baerveldt 425	7-0 Vicryl
22	72	F	PK	MES	AC	Baerveldt 425	8-0 Vicryl
23	64	F	Pseudophakic	MES	PC	Baerveldt 425	7-0 Vicryl
24	72	F	Pseudophakic	MES	VC	Baerveldt 350	7-0 Vicryl
25	37	F	PK	MES	PC	Baerveldt 350	7-0 Vicryl
26	67	F	PK	MES	AC	Baerveldt 350	7-0 Vicryl
27	22	F	PK	MES	AC	Baerveldt 425	7-0 Vicryl
28	65	F	PK	MES	PC	Baerveldt 425	7-0 Vicryl
29	38	M	Post-traumatic	MES	AC	Baerveldt 350	7-0 Vicryl
30	62	M	PK	MES	AC	Baerveldt 425	7-0 Vicryl
31	67	F	Pseudophakic	MES	AC	Baerveldt 350	7-0 Vicryl
32	73	F	PK	MES	AC	Baerveldt 425	7-0 Vicryl
33	64	M	PK	MES	AC	Baerveldt 350	7-0 Vicryl
34	70	F	PK	MES	PC	Baerveldt 350	7-0 Vicryl
35	73	F	Pseudophakic	MES	AC	Baerveldt 425	7-0 Vicryl

AC: Anterior chamber; PC: Posterior chamber; VC: Vitreous cavity; MES: Mestizo; BLA: Black; CAU: Caucasian; IOL: Intraocular lens; PK: Penetrating keratoplasty; M: Male; F: Female; CACG: Chronic angle closure glaucoma; POAG: Primary open angle glaucoma; NVG: Neovascular glaucoma

(11.4%, Table 2, Graph 2). Two failures were due to tube obstruction with vitreous, one to repeated tube extrusion and one neovascular glaucoma that went from hand movements to no light perception.

DISCUSSION

We found that modifying Baerveldt implant technique by using ‘Ortiz’ partial titrated ligature’ was useful in our group

of patients to lower IOP significantly during the immediate postoperative period, although not all eyes to normal levels.

Long-term results are also encouraging, since our success rate was 88.6% (84.9% cumulative success rate at 30 months by Kaplan-Meier), while maintaining a low complications rate, many transient and not needing many reinterventions. In fact, the seven cases of transient hypotony and the three cases of transient choroidal detachments are comparable to

Table 2: IOP, visual acuity and final result

No.	Visual acuity		Intraocular pressure (mm Hg)							Result
	Preoperative	Final	Pre	1 day	1 week	2 weeks	4 weeks	6-8 weeks	Final	
1	HM	HM	48	24	30	34	38	26	16	Success
2	20-60	20-40	41	18	19	17	18	12	17	Success
3	HM	HM	32	7	17	23	22	13	13	Success
4	CF 1M	CF 1M	38	9	17	24	3	8	8	Success
5	CF 50 cm	HM	40	4	12	19	20	14	12	Success
6	HM	HM	66	16	24	30	54	9	9	Success
7	20/100	20/70	31	15	8	7	7	8	12	Success
8	CF	CF	28	5	18	17	6	15	15	Success
9	HM	HM	66	16	10	11	12	10	14	Success
10	CF 20 cm	CF 20 cm	30	5	4	4	7	15	9	Success
11	LP	LP	50	35	30	26	17	16	17	Success
12	HM	HM	38	2	2	14	14	13	18	Success
13	CF A 1M	CF 2M	28	19	21	20	25	24	23	Failure
14	HM	HM	39	9	12	14	—	8	13	Success
15	LPP	HM	29	23	9	10	12	10	12	Success
16	20/400	20/400	28	4	7	7	4	16	12	Success
17	HM	CF 2.5M	52	28	24	28	29	22	20	Relative success
18	HM	NLP	60	18	38	30	10	39	15	Failure
19	CF 50 cm	CF 50 cm	44	22	23	20	22	15	17	Success
20	20/60	20/200	24	22	24	—	28	10	14	Success
21	HM	CF 20 cm	46	10	9	11	13	14	16	Success
22	HM	HM	41	5	6	15	10	31	17	Success
23	HM	NLP	60	16	30	22	30	19	24	Failure
24	20/400	20/400	32	2	9	9	6	6	10	Success
25	LP	LP	59	17	16	—	15	15	14	Success
26	HM	HM	32	7	27	34	35	40	12	Success
27	CF 50 cm	CF 50 cm	56	7	12	12	11	12	10	Success
28	HM	CF 1M	46	20	26	22	46	22	8	Success
29	20/100	20/300	40	21	25	24	11	12	11	Success
30	CF 3M	CF 3M	39	17	16	14	18	12	16	Success
31	CF 2M	20/800	28	22	20	23	20	14	13	Success
32	CF 50 cm	CF 2M	55	18	18	15	13	15	13	Success
33	HM	LP	46	32	26	28	29	11	4	Failure
34	CF 20 cm	CF 20 cm	42	8	7	16	59	29	12	Success
35	LPP	LPP	64	2	16	15	12	20	18	Relative success
Mean			42.8	14.429	17.235	18.63	19.6	16.42	13.82	

NLP: No light perception; LP: Light perception; LPP: Light perception and projection; HM: Hand movements; CF: Counts fingers

Table 3: List of complications, some eyes had more than one

Complications	n	Total (%)
Choroidal detachment	4	11.4
Tube occlusion	4	11.4
Tube exposure	4	11.4
Hyphema	2	5.7
Hypotony	1	2.9
Flat anterior chamber	1	2.9
Tube migration	1	2.9
Tube extrusion	1	2.9
Vitreous hemorrhage	1	2.9
Endothelial contact	1	2.9
Uveitis	1	2.9

the rates of the same complications reported for restrictive implants or even for unrestricted implants with full ligature after it has dissolved.⁵⁻⁷

Studies comparing restrictive and unrestricted implants have shown variable results.^{8,9} A previous comparison of Ahmed vs Baerveldt 350 that used similar success criteria as our study, found similar results between them, with final IOP of 12.1 ± 5.3 mm Hg and 13.6 ± 5.6 mm Hg, but

Graph 1: IOP behavior (in mm Hg) from the preoperative IOP, during the first 8 postoperative weeks and at last visit

complete success rates of 15.6 and 18.7%, plus qualified success rates of 50 and 46.8% were not as good as in our series. The rates of hypotony were 34.4% for the Ahmed

Graph 2: Kaplan-Meier survival plot, n indicates the number of remaining successful cases at each time-point

and 37.5% for the Baerveldt implants with venting slits in some eyes.¹⁰ We observed seven cases (20%) of early hypotony with spontaneous resolution during the first 2 weeks in 6, and at week 6 in the other.

Shallow anterior chamber was also present in one eye (2.8%), a better rate than the typical 5 to 44% reported with several other implants.⁶⁻⁹

A hypertensive phase has been reported in up to 60% of Ahmed valves, beginning between weeks 2 and 6, requiring antiglaucoma medications and that will get better in a small percentage of cases after several months.¹¹ A more recent study showed that the hypertensive phase lasted more than a year despite the use of mitomycin C, in 40% of cases if a partial removal of Tenon's was performed and in 46% when it was not done.¹² This prolonged hypertensive period was not present in our series, although a mild IOP elevation did occur in 4 eyes between months 2 and 3 that was spontaneously solved. Another 3 cases had early IOP elevation due to a too tight ligature or tube obstruction with either fibrin or vitreous.

Experimental studies in animals and humans have shown the formation of a fibrous capsule around the plate, which is responsible for primary resistance to aqueous outflow, and is made up of an inner acellular collagen band with spaces among its strands, an intermediate layer with greater organization and an external vascularized layer.¹⁴

There are three different Baerveldt models, with surface areas ranging from 250, 350 and 425 mm². The surface area for the Ahmed valve is 185 mm² (and also of each additional plate), it is 184 mm² for the Krupin and each Molteno plate has an area of 134 mm². Several studies have found that a greater surface area is related with a better long-term aqueous outflow and a lower IOP, supporting a size of around 268 mm² for a Molteno-type implant and 350 mm² for Baerveldt.¹³⁻¹⁵ The role of aqueous in the bleb during the initial postoperative period might decrease fibrosis and be

related to better IOP in the long run, so having some flow of aqueous initially might be desirable.^{14,16} This is an advantage of restricted implants and might explain why IOP reduction might be similar despite their smaller size and lower long-term outflow.

Among the disadvantages of restricted implants a higher risk of obstruction with detritus or inflammatory cells that might predispose them to a higher risk of a hypertensive phase.

An implant that is closer to the ideal should have a larger area for long-term IOP control, a good aqueous outflow that will indefinitely keep those IOP levels without peaks, but with a low risk of hypotony despite having an effective IOP lowering in the early postoperative period.

Our method is in line with all these postulations, but requires experience and is affected by the subjectivity of the surgeon during flow titration, which makes it less reproducible. A more exact and standardized method to restrict early flow during the first weeks that eventually frees full flow is needed.

SUMMARY

The modified surgical technique that we used in this group of patients, allowed us to obtain a success rate that compares favorably with most published studies on glaucoma implants. Further studies to ascertain the reproducibility of the technique, the results and even the design of new implants aiming to improve long-term results and reduce complications are needed.

REFERENCES

1. Nguyen QH. Avoiding and managing complications of glaucoma drainage implants. *Curr Opin Ophthalmol* 2004 Apr;15(2):147-150.
2. Rietveld E, van der Veen AJ. Postoperative pressure regulation in glaucoma shunt surgery: focal tube constriction is not the answer. *J Glaucoma* 2004 Jun;13(3):216-220.
3. Kansal S, Moster MR, Kim D, Schmidt CM Jr, Wilson RP, Katz LJ. Effectiveness of nonocclusive ligature and fenestration used in Baerveldt aqueous shunts for early postoperative intraocular pressure control. *J Glaucoma* 2002 Feb;11(1):65-70.
4. Albis-Donado, O. Atlas of glaucoma surgery. In: Shaarawy T, Mermoud A, editors. New Delhi, India: Jaypee Brothers Medical Publishers Pvt. Ltd; 2006. Chapter 6: the Ahmed Valve. p. 58-76.
5. Krupin T, Podos SM, Becker B, Newkirk JB. Valve implants in filtering surgery. *Am J Ophthalmol* 1976 Feb;81(2):232-235.
6. Krupin eye valve with disk for filtration surgery. The Krupin Eye Valve Filtering Surgery Study Group [editorial]. *Ophthalmology* 1994 Apr;101(4):651-658.
7. Coleman AL, Hill R, Wilson RM, Choplin N, Kotas-Neumann R, Tam M, Bacharach J, Panek WC. Initial clinical experience with the Ahmed Glaucoma Valve Implant. *Am J Ophthalmol* 1995 Jul;120(1):23-31.

8. Rosenberg LF, Krupin T. Implants in glaucoma surgery. In: Ritch R, Shields MB, Krupin T, editors. *The glaucomas*. 2nd ed. St. Louis: CV Mosby; 1996. p 1783-1807.
9. Taglia DP, Perkins TW, Gangnon R, Heatley GA, Kaufman PL. Comparison of the Ahmed Glaucoma Valve, the Krupin Eye Valve with Disk, and the double-plate Molteno implant. *J Glaucoma* 2002 Aug;11(4):347-353.
10. Syed HM, Law SK, Nam SH, Li G, Caprioli J, Coleman A. Baerveldt-350 implant versus Ahmed valve for refractory glaucoma: a case-controlled comparison. *J Glaucoma* 2004 Feb;13(1):38-45.
11. Nouri-Mahdavi K, Caprioli J. Evaluation of the hypertensive phase after insertion of the Ahmed Glaucoma Valve. *Am J Ophthalmol* 2003 Dec;136(6):1001-1008.
12. Susanna R Jr; Latin American Glaucoma Society (SLAG) Investigators. Partial Tenon's capsule resection with adjunctive mitomycin C in Ahmed glaucoma valve implant surgery. *Br J Ophthalmol* 2003 Aug;87(8):994-998.
13. Prata JA Jr, Santos RC, Labree L, Minckler DS. Surface area of glaucoma implants and perfusion flow rates in rabbit eyes. *J Glaucoma* 1995 Aug;4(4):274-280.
14. Wilcox MJ, Minckler DS, Ogden TE. Pathophysiology of artificial aqueous drainage in primate eyes with molteno implants. *J Glaucoma* 1994 Summer;3(2):140-151.
15. Heuer DK, Lloyd MA, Abrams DA, Baerveldt G, Minckler DS, Lee MB, Martone JF. Which is better? One or two? A randomized clinical trial of single-plate versus double-plate Molteno implantation for glaucomas in aphakia and pseudophakia. *Ophthalmology* 1992 Oct;99(10):1512-1519.
16. Francis BA, Cortes A, Chen J, Alvarado JA. Characteristics of glaucoma drainage implants during dynamic and steady-state flow conditions. *Ophthalmology* 1998 Sep;105(9):1708-1714

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