Journal Pre-proof

Incidence and Outcomes of Hypertensive Phase Following Aurolab Aqueous Drainage Implant Surgery in Adults with Refractory Glaucoma

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Abstract

Purpose: To report the incidence and outcomes of hypertensive phase (HP) following Aurolab Aqueous Drainage Implant (AADI) (Aurolab, Madurai, India) surgery in adults with refractory glaucoma.

Design: Retrospective, noncomparative, interventional case series.

Methods: All eyes that received the AADI and had a minimum of 2-year follow-up were identified, and data of patients who had intraocular pressure (IOP) ≤ 21 mmHg at 6 weeks (i.e. the time at which the tube-ligature suture dissolves) were used for statistical analysis. The HP was defined as IOP > 21 mmHg during the first 3 months after the release of the tube ligating suture (with or without medications) in the absence of tube obstruction.

Results: A total of 200 eyes were included in the study, and the HP was seen in 64 eyes (32%) with a peak IOP (mean ± SD) of 29.6 ± 7.8 mmHg and peak incidence at 2–3 months after surgery. The HP resolved within 3 months of its onset in 60 out of the 64 eyes (94%) with additional IOP lowering medications. The cumulative success rates were 71.8% (95% CI = 59.3%-81.2%) in HP eyes and 76.4% (95% CI = 68.7%-82.7%) in non-HP eyes (p = 0.23). Unadjusted Cox proportional hazards analysis showed that eyes experiencing the HP had a marginally higher risk of failure (HR = 1.16, 95% CI = 0.6-2.1) but this relationship was not statistically significant (p = 0.61).

Conclusions: A third of eyes that underwent AADI placement experienced a HP. The HP was successfully managed with additional IOP lowering medications in a majority of cases and did not have a significant influence on long term success rate.

Title Page

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Incidence and Outcomes of Hypertensive Phase Following Aurolab Aqueous Drainage Implant Surgery in Adults with Refractory Glaucoma

Short title: Hypertensive Phase Following AADI Surgery

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Conclusions: A third of eyes that underwent AADI placement experienced a HP. The HP was successfully managed with additional IOP lowering medications in a majority of cases and did not have a significant influence on long term success rate.

Introduction

The popularity of glaucoma drainage devices (GDDs) for surgically managing glaucoma has grown in recent years. (1) The number of trabeculectomies performed in the Medicare population decreased by 72% between 1994 and 2012, but GDD surgery increased by 510% during the same time period. (2) Surveys of the American Glaucoma Society membership show that GDDs are being selected with increasing frequency as an alternative to trabeculectomy. (3) These devices have been traditionally reserved for refractory glaucomas, but they are now being used in eyes at lower risk for filtration failure. (3)

All GDDs share a common design consisting of a silicone tube that is inserted through a scleral fistula and shunts aqueous humor to an end plate located in the equatorial region of the globe. Fibrous encapsulation of the end plate produces a reservoir into which aqueous pools. The major resistance to aqueous outflow occurs across the capsule surrounding the end plate. (4) The final intraocular pressure (IOP) achieved after GDD surgery is determined by capsular surface area and permeability. A hypertensive phase (HP) may develop if the end plate capsule has reduced permeability, and this is felt to be analogous to bleb encapsulation commonly seen after trabeculectomy.

The occurrence of a HP can result in significant spikes in intraocular pressure (IOP) between 1 and 3 months after surgery.(5) This phase can be detrimental and worsen damage in an already compromised optic nerve head. The HP is much more common with the Ahmed glaucoma valve (AGV; New World Medical, Cucamonga, CA) with an incidence ranging from 50-70%(6,7) compared to lower incidences with the non-valved implants such as the Molteno GDD (Molteno Ophthalmic Limited, Dunedin, New Zealand) and Baerveldt glaucoma implant (BGI; Abbott Medical Optics, Abbott Park, IL). (8,9) In addition to the immediate damage, many eyes experiencing the HP after AGV implantation are at increased risk of long-term failure. (6) The HP after the use of non-valved implants has not been studied extensively.

The Aurolab aqueous drainage implant (AADI; Aurolab, Madurai, India), is a relatively new non-valved implant based on the design of the BGI, and has been shown to be safe and effective in managing refractory glaucoma in both adult and paediatric eyes.(10,11,12,13) Except for a study

by Senthil et al,(14) which reported a 16% incidence of the HP following AADI in refractory paediatric glaucoma, there are no other studies describing this aspect in detail. In this study, we report on the incidence of HP following AADI surgery, peak IOP during this phase, and its outcomes in a cohort of adult Indian eyes with refractory glaucoma.

Methods

The study was approved by the institutional ethics committee of the Aravind Eye Hospital, Madurai (RET202000254). The study was conducted as per the tenets of the Declaration of Helsinki and all patient identifiers were anonymized. Case records of consecutive adult patients who underwent the AADI surgery by a single surgeon (GVP) between January 2012 and January 2018 were identified from a computerized database, and case files of those patients with a minimum of 2 years follow up were extracted. Detailed indications for the use of the AADI in our settings are described elsewhere. (10) Data of patients who had an IOP < 21 mmHg at 6 weeks (i.e. the time point at which the tube-ligature suture dissolves or is released) was used for statistical analysis.

Patient demographics and clinical characteristics were recorded at baseline, such as the best-corrected visual acuity (BCVA), type of glaucoma, IOP, number of IOP reducing medications, previous ocular surgery, automated visual field parameters (mean deviation and pattern standard deviation), and the date of AADI surgery. The IOP, number of IOP lowering medications, BCVA, complications, and reoperations were also recorded at every available visit for the first 9 months postoperatively, and at 12 months, 18 months, 24 months, and last follow-up. The surgical technique has been described in detail elsewhere. (10) In summary, after fashioning a fornix based conjunctival flap, the AADI implant was sutured to the sclera 9-10mm posterior to the limbus. After ligating the tube with 6-0 polyglactin sutures (braided coated polyglactin 910 violet; Ethicon, Johnson & Johnson Ltd, Mumbai, India) at the tube-plate junction, the tube was cut at an appropriate length and introduced into the anterior chamber via a 23-gauge needle track initiated 2.5mm posterior to the limbus. A piece of donor cornea or sclera was then secured over the limbal portion of the tube, and conjunctiva was re-

approximated to the limbus with 8-0 polyglactin sutures (Aurolab, Madurai, India).

The HP was defined as IOP > 21 mmHg during the first 3 months after the release of the tube ligating suture (with or without medications) in the absence of tube obstruction, and the following reduction of IOP ≤ 21 mm Hg at the 6-week time point. Resolution of the HP was evaluated by comparing the IOP and number of glaucoma medications at the time of diagnosis of the HP and 3 to 6 months later. Resolution of the HP was defined as IOP ≤ 21 mm Hg with (1) reduction of IOP ≥ 3 mmHg with the same number or fewer glaucoma medications or (2) reduction of at least 1 glaucoma medication with a change of IOP < 3 mmHg. Failure was defined as IOP > 21 mmHg or < 20% reduction below baseline on 2 consecutive follow-up visits after 3 months, IOP ≤ 5 mmHg on 2 consecutive follow-up visits after 3 months, reoperation for glaucoma, or loss of light perception vision. Eyes that had not failed by the above criteria and were not on supplemental medical therapy were considered complete successes. Eyes that had not failed but required supplemental medical therapy were categorized as qualified successes.

Outcome measures included the incidence of the HP, timing of its occurrence, peak IOP during this phase, and its outcomes such as resolution rate, time to resolution, and long-term influence on failure rates.

Statistical analysis

Continuous variables were expressed as mean with standard deviation and group differences in continuous variables between those with and without the HP were analysed using student t-test or the Wilcoxon rank-sum test for non-parametric variables. Categorical variables were expressed as proportions (n, %) and group differences were analysed using the chi-square or the Fischer's exact test. Visual acuity was converted to logarithm of minimum angle of resolution (logMAR) for statistical analysis. The comparison of IOP between pre- and post-AADI at different time intervals was carried out using one-way ANOVA with Bonferroni adjustments. The risk of having a HP was assessed using logistic regression analysis and outcomes were expressed as odds ratios with 95% confidence intervals (CI).

Survival analysis was performed and Kaplan-Meier curves were plotted to depict cumulative survival rates at various time points of eyes that experienced the HP versus those that did not. Differences in survival rates between these groups were determined using log-rank test. The risk of failure due to the HP was also assessed using the Cox Proportional Hazards Models and displayed using hazard ratios (HR) with 95% CI. Data was entered into Microsoft Excel and analyzed using STATA (version 12.1, I/C, Forth Worth, Texas, USA) statistical analysis software package and $p < 0.05$ was considered statistically significant.

Results

A total of 280 eyes of 280 adults underwent AADI implantation during the study period of which 200 eyes (70%) were eligible for inclusion and were used for statistical analysis. The 80 eyes were excluded since they had IOP >21mmHg at the 6-week time point. There were no differences in baseline characteristics such as IOP, type of glaucoma or BCVA in those included vs. excluded. The age of participants (mean ± SD) was 45.2 ± 17.3 years, and 131 were women (66%). Among the 200 eyes in the study, 64 (32%) experienced the HP between 2 months and 4 months after surgery. There were no differences in demographic and baseline characteristics between the eyes that experienced the HP and eyes that did not experience the HP (NHP) (Table 1). Eyes in the HP group had a marginally higher proportion of open-angle glaucomas, though this difference was not statistically significant.

A comparison of IOP, visual acuity, and IOP lowering medications at baseline and across follow-up between the HP and NHP groups is shown in Table 2. The IOP was significantly higher at the 1-month time point (figure 1) in the HP group, and these eyes required significantly more IOP lowering medications up to 1 year of follow-up. There were no significant differences in visual acuity between study groups at any time point.

The peak IOP (mean ± SD) during the HP was 29.6 ± 7.8 mmHg. The HP was seen at the 2-month time point in 34 eyes (53%), in another 28 eyes (44%) at the 3-month and in 2 eyes (3%) at the 4-month time point. The HP resolved within 3 months of its onset in 60 out of the 64 eyes (94%) with

additional IOP lowering medications. Of these, 30 (50%) resolved within 4 weeks, 29 (49.5%) resolved over 6 weeks, and 1 resolved at 8 weeks after onset of the HP. Four eyes (6%) did not resolve with persistent raised IOP after 3 months and were considered treatment failures. Univariate logistic regression showed that none of the baseline or demographic factors such as age, gender, type of glaucoma, previous surgery, preoperative visual field severity, preoperative IOP or the number of preoperative IOP lowering medications could accurately predict the occurrence of the HP (Supplementary Table 1- available at AJO.com).

There were no differences in the rates of surgical complications (Table 3) or reoperation rates (Table 4) in eyes with and without the HP. Cataract surgery was the commonest procedure performed during the follow-up period in both, the HP (n=7,11%) and NHP groups (n=8, 6%) (p=0.21). The overall cumulative rate of qualified success was 89.3% (95% CI=85.3 – 92.4%) at 1 year which reduced to 71.8% (95%CI=66.1 – 76.7%) at 2 years follow-up. There were no differences in the absolute and cumulative success rates (figure 2) in eyes with and without the HP at all time points (Table 5). Unadjusted Cox proportional hazards analysis showed that eyes experiencing the HP had a marginally higher risk of failure (HR=1.16, 95%CI=0.6-2.1), but this relationship was not statistically significant (p=0.61).

Discussion

A HP occurred in a third of adult eyes receiving the AADI for refractory glaucoma with a peak IOP of about 30 mmHg and a peak incidence between two and three months after surgery. A majority of the eyes had resolution of the HP with controlled IOP within 4–6 weeks after onset, albeit with a significant increase in the number of IOP lowering medications. The HP did not significantly increase the risk of long-term failure, nor did it lead to higher postoperative complications and reoperations.

We report a slightly higher incidence of the HP compared to Senthil et al,(14) who report its occurrence in 7 out of 36 eyes (19%) that received the AADI. Differences in the study populations and definitions of outcome measures may account for the differences in results between the two studies. Ours was a larger study of adult eyes with the HP, and Senthil et al had a

smaller sample of paediatric eyes and a comparison between IOP outcomes of the AADI and AGV was the main outcome measure. Additionally, Senthil et al did not define the postoperative timepoint up to which they considered an IOP spike to be included in the HP. As we show, an IOP spike can occur up to 4 months after surgery, and hence it is possible that Senthil et al slightly underestimated the incidence. Although Senthil et al do not report on the peak IOP during the HP, both these studies show a very high rate of resolution of the HP and no higher risk of long-term failure, which is encouraging.

The occurrence of the HP has been attributed to the formation of a less permeable capsule around the end plate of these GDDs.(15) In valved implants, aqueous humor is delivered to the end plate in the immediate postoperative period. In view of greater pro-inflammatory cytokines in the aqueous at this time, more fibrovascular reaction may occur leading to a HP in a large proportion of eyes.(5,6,16) In contrast, aqueous flow starts only after the tube ligature suture dissolves or is released in non-valved implants like the BGI and AADI. This occurs at approximately 6 weeks after surgery,(8,17,18) when the inflammatory cytokines have reduced. This could explain the lower incidence, slightly lower peak IOP, and better resolution of the HP with non-valved implants compared with valved implants, without any influence on the long-term failure rates. The larger surface area of the end plates of the BGI and AADI relative to the AGV may also contribute to the difference in surgical outcomes.

The incidence of the HP after Baerveldt implantation has been reported to vary between 27%–52%.(8,9,17,18) While Tasi reported a lower rate of encapsulation (27%) in 70 eyes receiving Baerveldt implant,(9) Ayyala et al found a slightly higher incidence in 13 of 30 eyes (43%) with the Baerveldt compared to 60% eyes receiving the AGV. (8) Similarly, Chansangpetch reported an incidence of 48%, while Pitukcheewanont et al showed a slightly higher incidence of 52% in eyes receiving the Baerveldt.(17,18) All authors have reported excellent resolution rates from the HP within 4–6 weeks. These results are very similar to ours suggesting that the HP is not uncommon in eyes receiving the non-valved implants, but the IOP spike is not severe, can be managed with aqueous suppressants, and have no bearing on the long-term IOP control and overall success.

Our study has several limitations. Data were collected retrospectively rather than prospectively at predetermined time points. Bleb characteristics were not documented in the clinical examination or with ocular imaging. The study was conducted at a single academic center in India, and the results may not be generalizable to other populations.

In summary, we found that a third of eyes that underwent placement of an AADI experienced a HP. A majority of cases had resolution of the HP with the addition of IOP lowering medications. The presence of a HP was not associated with a lower rate of surgical success.

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References

1. Chen J, Gedde SJ. New developments in tube shunt surgery. *Curr Opin Ophthalmol* 2019;30(2):125–131.

2. Arora KS, Robin AL, Corcoran KJ, Corcoran SL, Ramulu PY. Use of Various Glaucoma Surgeries and Procedures in Medicare Beneficiaries from 1994 to 2012. *Ophthalmology* 2015;122(8):1615–1624.

3. Vinod K, Gedde SJ, Feuer WJ, et al. Practice Preferences for Glaucoma Surgery: A Survey of the American Glaucoma Society. *J Glaucoma* 2017;26(8):687–693.

4. Minckler DS, Shammas A, Wilcox M, Ogden TE. Experimental studies of aqueous filtration using the Molteno implant. *Trans Am Ophthalmol Soc* 1987; 85:368-392.

5. Fargione RA, Tansuebchueasai N, Lee R, Tania Tai TY. Etiology and management of the hypertensive phase in glaucoma drainage-device surgery. *Surv Ophthalmol* 2019; 64:217–224.

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

7. Ishida K, Netland PA, Costa VP, Shiroma L, Khan B, Ahmed IIK. Comparison of Polypropylene and Silicone Ahmed Glaucoma Valves. *Ophthalmology* 2006; 113:1320–1326.

8. Ayyala RS, Zurakowski D, Monshizadeh R, et al. Comparison of double-plate Molteno and Ahmed glaucoma valve in patients with advanced uncontrolled glaucoma. *Ophthalmic Surg Lasers* 2002;33(2):94–101.
9. Tsai JC, Johnson CC, Dietrich MS. The Ahmed shunt versus the Baerveldt shunt for refractory glaucoma: a single-surgeon comparison of outcome. *Ophthalmology* 2003;110(9):1814–1821.

10. Puthuran GV, Palmberg P, Wijesinghe HK, Krishnadas SR, Robin A. Intermediate-Term outcomes of an affordable aqueous drainage implant in adults with refractory glaucoma. *Ophthalmol Glaucoma* 2019;2(4):258-266.

11. Pandav SS, Seth NG, Thattaruthody F, et al. Long-term outcome of low-cost glaucoma drainage device (Aurolab aqueous drainage

implant) compared with Ahmed glaucoma valve. *Br J Ophthalmol* 2020;104(4):557-562.

12. Puthuran GV, Palmberg PF, Wijesinghe HK, Pallamparthy S, Krishnadas SR, Robin AL. Intermediate-term outcomes of Aurolab aqueous drainage implant in refractory paediatric glaucoma. *Br J Ophthalmol* 2020;104(7):962-966.

13. Kaushik S, Kataria P, Raj S, Pandav SS, Ram J. Safety and efficacy of a low-cost glaucoma drainage device for refractory childhood glaucoma. *Br J Ophthalmol* 2017;101(12):1623-1627.

14. Senthil S, Gollakota S, Ali MH, et al. Comparison of the New Low-Cost Nonvalved Glaucoma Drainage Device with Ahmed Glaucoma Valve in Refractory Pediatric Glaucoma in Indian Eyes. *Ophthalmol Glaucoma* 2018;1(3):167–174.

15. Lloyd MA, Baerveldt G, Nguyen QH, Minckler DS. Long-term histologic studies of the Baerveldt implant in a rabbit model. *J Glaucoma* 1996;5(5):334–339.

16. Jung KI, Park CK. Risk factors for the hypertensive phase after implantation of a glaucoma drainage device. *Acta Ophthalmol* 2016;94(5):260-226.

17. Chansangpetch S, Surukrattanaskul S, Tapaneeyangkul P, Tantisevi V. Hypertensive phase and its association with surgical outcomes in Baerveldt implantation. *Int Ophthalmol* 2018;38(4):1717–1725.

18. Pitukcheewanont O, Tantisevi V, Chansangpetch S, Rojanapongpun P. Factors related to hypertensive phase after glaucoma drainage device implantation. *Clin Ophthalmol* 2018; 12:1479.

Figure Legends

Figure 1: Median intraocular pressure at various time points along with 95% confidence intervals in eyes with and without the hypertensive phase

Figure 2: Kaplan Meier curves showing cumulative failure rates at various time points in eyes with and without the hypertensive phase.

Table 1. Baseline Characteristics

	No Hypertensive Phase (n = 136)	Hypertensive Phase (n = 64)	P value
Age (years, mean ± SD)	46.3 ± 16.8	46.4 ± 17.7	0.96
Gender (n, % men)	45 (33%)	24 (37%)	0.54
MD (dB, mean ± SD)	-20.3 ± 8.5	-20.8 ± 7.1	0.88
PSD (dB, mean ± SD)	9.16 ± 4.7	8.91 ± 3.9	0.49
Type of glaucoma (n, %)			0.29
POAG	26 (19%)	14 (22%)	
PACG	11 (8%)	6 (9%)	
SOAG	30 (22%)	23 (36%)	
SACG	47 (35%)	13 (20%)	
JOAG	10 (7%)	3 (5%)	
Congenital/Developmental	12 (9%)	5 (8%)	
Prior trabeculectomy (n, %)	82 (60%)	32 (50%)	0.56
Open angle glaucoma (n, %)	66 (49%)	40 (63%)	0.06
Monocular status (n, %)	20 (15%)	10 (16%)	0.86
Total follow up (months, mean ± SD)	38.8 ± 16.4	38.2 ± 17.1	0.81

JOAG = Juvenile open-angle glaucoma; MD= Mean deviation; PACG = Primary angle-closure glaucoma; POAG = Primary open-angle glaucoma; PSD= Pattern standard deviation; SACG = Secondary angle-closure glaucoma; SD= Standard deviation; SOAG = Secondary open-angle glaucoma

Table 2. Intraocular pressure (IOP), IOP Lowering Medications, and Visual Acuity at Baseline and Follow-up

	No Hypertensive Phase (n = 136)	Hypertensive Phase (n = 64)	P value
Baseline			
IOP	32.7 ± 10.4	33.8 ± 9.6	0.35
IOP lowering medications	3.22 ± 0.7	3.25 ± 1.0	0.86
LogMAR VA	0.56 ± 0.56	0.52 ± 0.57	0.53
1 day			
IOP	25.7 ± 11.3	28.6 ± 10.6	0.20
IOP lowering medications	2.1 ± 1.1	2.5 ± 1.1	0.07
LogMAR VA	0.89 ± 0.85	0.80 ± 0.80	0.49
1 month			
IOP	20.1 ± 11.1	25.4 ± 11.8	**0.003**
IOP lowering medications	2.0 ± 0.9	2.33 ± 1.1	**0.03**
LogMAR VA	0.69 ± 0.67	0.62 ± 0.62	0.43
2 months			
IOP	12.8 ± 4.6	22.3 ± 11.6	**<0.001**
IOP lowering medications	1.2 ± 0.9	1.6 ± 1.1	**0.04**
LogMAR VA	0.80 ± 0.7	0.56 ± 0.62	0.06
3 months			
IOP	12.8 ± 4.3	23.8 ± 8.4	**<0.001**
IOP lowering medications	1.2 ± 0.9	2.0 ± 1.1	**0.002**
LogMAR VA	0.76 ± 0.7	0.58 ± 0.6	0.09
6 months			
IOP	14.6 ± 6.2	16.1 ± 6.8	0.18
IOP lowering medications	1.2 ± 1.0	1.6 ± 0.9	**0.03**
LogMAR VA	0.76 ± 0.74	0.58 ± 0.54	0.12
12 months			
IOP	14.7 ± 6.8	16.3 ± 6.4	0.16
IOP lowering medications	1.3 ± 0.9	1.6 ± 0.9	**0.04**
LogMAR VA	0.80 ± 0.8	0.63 ± 0.7	0.18
18 months			
IOP	14.6 ± 6.5	15.8 ± 6.5	0.26
IOP lowering medications	1.2 ± 0.9	1.4 ± 1.0	0.09
LogMAR VA	0.86 ± 0.8	0.63 ± 0.7	0.09
24 months			
IOP	14.5 ± 6.1	15.9 ± 5.6	0.15
IOP lowering medications	1.3 ± 0.9	1.6 ± 1.1	0.07
LogMAR VA	0.87 ± 0.86	0.65 ± 072	0.10

Data are presented as mean ± standard deviation

IOP = Intraocular pressure; LogMAR VA = Logarithm of the minimum angle of resolution visual acuity

Table 3: Surgical Complications

	No Hypertensive Phase (n = 136)	Hypertensive Phase (n = 64)	P value
Tube-related complications			0.46
Tube exposure	1 (0.7%)	0	
Plate exposure	0	0	
Tube retraction	0	0	
Tube obstruction	2 (1.5%)	1 (1.5%)	
(iris/vitreous)	1 (0.7%)	0	
Plate migration			
Other complications			0.22
Choroidal detachment	11 (8%)	2 (3%)	
Retinal detachment post CD	0	1 (1.5%)	
Corneal decompensation	7 (5%)	2 (3%)	
Previous graft failure	1 (0.7%)	0	
Macular edema	5 (3.5%)	1 (1.5%)	
Tube obstruction	4 (3%)	1 (1.5%)	
(fibrin/blood clot)	0	0	
Aqueous misdirection	5 (3.5%)	0	
Severe anterior uveitis	2 (1.5%)	3 (4.6%)	
Hypotony			
Total number of patients with complications	39 (28%)	11(17%)	0.12

Data reported as number (percentage) of patients; CD= choroidal detachment

Table 4: Reoperations for Glaucoma and Complications

	No Hypertensive Phase (n = 136)	Hypertensive Phase (n = 64)	P value
Tube ligation	1 (0.7%)	2 (3%)	0.73
Tube trimming	1 (0.7%)	2 (3%)	
Tube repositioning	2 (1.5%)	0	
PPV ± SOI	4 (3%)	4 (6.3%)	
Choroidal drainage	2 (1.5%)	0	
Scleral patch graft	0	1 (1.5%)	
Repeat AADI	2 (1.5%)	1 (1.5%)	
AADI exchange	0	1 (1.5%)	
AADI explantation	1 (0.7%)	1 (1.5%)	
Iris repositioning	0	1 (1.5%)	
Repeat PK	3 (2.2%)	0	
Cyclophotocoagulation	1 (0.7%)	0	
Total number of reoperations	17 (12.5%)	13 (20%)	0.37

Data reported as number (percentage) of patients

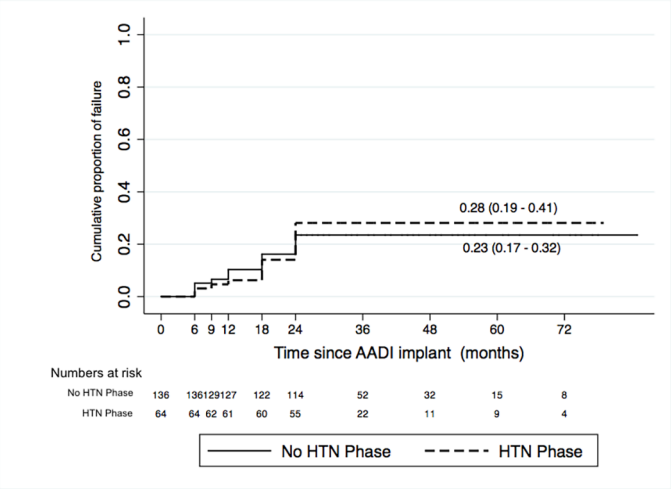
AADI= Aurolab Aqueous Drainage Implant; PK= Penetrating keratoplasty; PPV= Pars plana vitrectomy; SOI= Silicone oil infusion

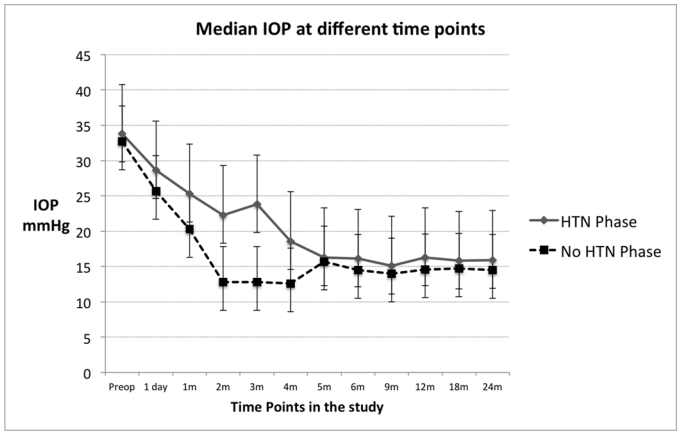
Table 5: Comparison of Success at various time points in eyes with no hypertensive phase and with hypertensive phase.

At time point	No Hypertensive Phase (n=136)	Hypertensive Phase (n=64)	P value
Complete success (Absolute)**	52 (38%)	34 (53%)	0.09
Qualified success (Absolute)**	32 (23%)	18 (28%)	0.48
Cumulative Complete success			
6 months	94% (89.8 – 97.8%)	92.7% (82.5 – 96.9%)	0.35
12 months	88.8% (82.8 – 93.7%)	78.6 (65.0% - 86.8%)	
18 months	80.4% (73.1 – 86.8%)	70.7% (57.1% - 79.4%)	
24 months	62.4% (53.5 – 69.7%)	47.6% (34.4% - 58.9%)	
Cumulative Qualified Success			
6 months	94.8% (89.8 – 97.8%)	96.8% (88.5 – 99.2%)	0.23
12 months	89.7% (83.8 – 93.7%)	93.7 (84.0% - 97.6%)	
18 months	83.8% (76.2 – 89.6%)	85.9% (74.1% - 92.4%)	
24 months	76.4% (68.7 – 82.7%)	71.8% (59.3% - 81.2%)	

Complete success= Achieving intraocular pressure (IOP) control (IOP range 5-21 mmHg or 20% reduction from baseline) without the use of IOP lowering medications, Qualified Success= Achieving IOP control with the use of IOP lowering medications

**Absolute success= Complete/qualified success calculated at 2 years' time point.





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Credit Author Statement

All authors made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work.

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