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CLINICAL TRIAL REPORT

The Duke Baerveldt 350 Versus Ahmed ClearPath 350 Study (DBACS): A Randomized Control Trial In Adults With Medically Refractory Glaucoma

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Purpose: To compare the efficacy and safety profile of two non-valved glaucoma drainage devices (GDDs).

Patients & Methods: In this randomized control trial, patients with medically refractory glaucoma needing surgical intervention were randomized for placement of a Baerveldt 350 (BVT) or an Ahmed ClearPath 350 (ACP). Baseline testing included measures of visual acuity, intraocular pressure (IOP), medication, visual fields, and optical coherence tomography. IOP, medication use, and complications were assessed at post-operative day one, week one, week four, week six, month three, month six, and year one.

Results: A total of 76 subjects were enrolled, 37 randomized to BVT and 39 to ACP. A total of 70 subjects underwent surgery and 61 subjects were seen to one year of follow-up. No significant differences were observed in age, sex, race, eye laterality, glaucoma type, glaucoma severity, prior surgeries, and baseline IOP ($p = 0.66$, 0.10, 0.70, 0.48, 0.06, 0.65, 0.50, 0.56 respectively), between the groups. At one year, both groups showed significant reductions in IOP, though the ACP group showed lower mean IOP at 12 months (11.4 vs 14.1 mmHg, $p = 0.010$) as well as a larger IOP decrease compared to baseline (−44.1 vs −30.7%, $p = 0.038$). Medication usage remained similar in both groups. Complications were infrequent and comparable between the devices. This study did not reach the number of subjects thought to be needed to power the study appropriately; despite the enrollment numbers, statistically significant differences were noted, and no type II occurred for the primary endpoint of mean IOP.

Conclusion: While both GDDs demonstrated efficacy over a 1-year period, ACP showed a lower mean IOP and greater IOP percentage decrease from baseline compared to BVT. Both exhibited low complication rates. Further research over a longer follow-up is warranted to explore the IOP differences.

Keywords: glaucoma surgery, tube shunt, glaucoma drainage device

Introduction

Glaucoma is a group of eye diseases that causes damage to the optic nerve. It represents the leading cause of irreversible blindness and affects roughly 60.5 million people worldwide, with this number expected to increase to 111.8 million by 2040.[1] Given that increased intraocular pressure (IOP) is the only modifiable risk factor for glaucoma progression, treatment is aimed at controlling IOP via medical or surgical intervention.[2] While minimally invasive glaucoma surgeries (MIGS) have risen in popularity due to their relative ease and safety profile, trabeculectomy and glaucoma drainage device (GDD) implantation have remained staple procedures due to their greater IOP lowering capability. Because of this, traditional trabeculectomy or GDD surgery is often utilized in patients with more advanced or rapidly progressive disease, where other treatments may have been insufficient.[3]

The Tube Versus Trabeculectomy (TVT) study was a randomized, multicenter trial that aimed to compare the efficacy and complication rates of trabeculectomy versus GDD implantation (with the Baerveldt 350 implant) in patients with prior trabeculectomy or cataract surgery. While trabeculectomy was shown to have greater IOP lowering capability compared to GDD implantation after one year of follow-up, GDD surgery had fewer complications during this period.[4]

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Subsequent analyses at five years showed greater surgical success and fewer complications among the GDD group.[5] Results of the TVT study have led many clinicians to consider GDD implantation ahead of trabeculectomy for post-surgical eyes with moderate to severe glaucoma.[6]

One commonly implanted GDD in North America is the Baerveldt implant (Johnson & Johnson Vision Inc., Santa Ana, CA). The Baerveldt (BVT) is a non-valved device that was FDA-approved in 1991. The BVT is available in two sizes: a 250 mm^2 model and a 350 mm^2 model (with the 350 mm^2 model also having a pars plana variant with a shorter tube length). Because it is non-valved, the device requires early restriction of aqueous flow to reduce the chance of hypotony in the early postoperative period.[7] One common way of restricting fluid flow is by ligating or tying off the BVT tube with an absorbable suture that dissolves by postoperative week 4 to 6, allowing for a mature fibrous capsule or "bleb" to form. For greater control of tube opening and IOP reduction, many surgeons place a non-absorbable suture within the tube lumen, often referred to as a "ripcord" in practice. This ripcord suture is accessible at the slit lamp in the clinic and can be pulled to achieve greater IOP lowering early in the postoperative course.[8]

The Ahmed ClearPath (New World Medical Inc., Rancho Cucamonga, CA) is a valveless device which was approved in 2019. Similar to the Baerveldt, the Ahmed ClearPath (ACP) device is also available in two sizes: a 250 mm^2 model and a 350 mm^2 model. The plate itself is more flexible in nature and has a lower plate profile. Unique design features include anterior suture fixation points for ease of implantation, a posterior plate to avoid muscle insertions, and a pre-loaded 4–0 polypropylene ripcord. As it is a non-valved implant, it also requires early restriction for the same reasons mentioned for the Baerveldt. Early studies of the ACP have shown favorable outcomes in terms of IOP control and glaucoma medication reduction, with common complications including anterior chamber inflammation, hyphema, and hypotony.[9,10]

The Duke Baerveldt 350 versus Ahmed ClearPath 350 Study (DBACS) is a single institution randomized prospective trial which aims to compare the safety and efficacy of these two valveless devices, the Baerveldt 350 mm^2 and the Ahmed ClearPath 350 mm^2. Given the similarities in design, in particular the equal sizes of the implant plate, we hypothesized that there would be no difference in the efficacy of IOP reduction or complication rates in patients who undergo BVT implantation versus those who undergo ACP implantation. To our knowledge, this is the first prospective, randomized clinical trial comparing these two non-valved glaucoma drainage devices. Like other head-to-head trials in the literature such as the TVT, Ahmed versus Baerveldt (AVB), and Ahmed Baerveldt Comparison (ABC) studies, results of the DBACS study have the potential to significantly impact the practice patterns of glaucoma care providers.

Materials and Methods

Study Organization

The DBACS study is a randomized, prospective trial that took place at the Duke Eye Center (Durham, NC, USA) and its satellite locations from December 2020 to June 2023. All Duke-affiliated glaucoma surgeons were invited to participate. Seven Duke-affiliated glaucoma surgeons chose to participate in the study. The study was approved by the Duke University institutional review board and adhered to the principles of the Declaration of Helsinki. Subjects were voluntarily recruited and consented at the time of preoperative evaluation by the participating surgeon. Once enrolled, patients were assigned a study identification number and randomized by random number generator to receive either a Baerveldt 350 mm^2 or Ahmed ClearPath 350 mm^2. Since the surgeons were responsible for implanting the device, masking was not possible. Subjects' data were stored in protected study databases in accordance with the Health Insurance Portability and Accountability Act (HIPAA). The participants of this study did not give written consent for their data to be shared publicly, so due to the sensitive nature of the research, data will not be available publicly. This study was registered through ClinicalTrials.gov (NCT04468633).

Power Calculations

A target of 152 subjects in each treatment group for a total of approximately 304 subjects was calculated. This sample size was based on a power analysis aimed at detecting a 2 mmHg difference in IOP between the Baerveldt and ClearPath groups with 80% power, using the mean post-op year 1 BVT IOP of 13.6±5.9 mmHg from the pooled AVB and ABC

data. Data from these studies were utilized because at the time this study was initiated, there was limited data on ClearPath outcomes as it had just recently been approved. The results were then adjusted for an expected 10% drop out rate at 1 year, making the power calculations quite stringent. As both arms of this study are consistent with current standard-of-care practices, we did not anticipate any increase in rates of complications compared to the reported rates in published literature.

Eligibility Criteria

Inclusion Criteria – All the following criteria must have been met to be eligible for the study.

- Men or women with age at screening ≥18 years and ≤90 years
- Inadequately controlled glaucoma
- Valve-less aqueous shunt as the planned surgical procedure
- Patients with primary glaucomas, pseudoexfoliation glaucoma, pigmentary glaucoma or traumatic glaucoma with or without previous surgical glaucoma treatment (previous failed trabeculectomy or other intraocular surgeries included)
- Superotemporal or inferonasal placement of the tube
- Patient was capable and willing to provide consent

Exclusion Criteria – Any of the following criteria resulted in exclusion of a patient from study eligibility.

- No Light Perception (NLP) vision
- Unable/unwilling to provide informed consent
- Unavailable for regular follow-up
- Previous cyclodestructive procedure
- Prior scleral buckling procedure or other external impediment to superotemporal or inferonasal drainage device implantation
- Presence of silicone oil in the eye
- Vitreous in the anterior chamber sufficient to require a vitrectomy
- Uveitic glaucoma
- Neovascular glaucoma
- Nanophthalmos
- Sturge-Weber syndrome or other conditions associated with elevated episcleral venous pressure
- Procedure combined with other surgery
- Any abnormality other than glaucoma in the study eye that could affect tonometry

Enrollment and Treatment Assignment

After ensuring eligibility for the study and informed consent was obtained from participants, subjects were randomized to receive either the BVT or ACP according to a computer-generated randomization code (random number generator). The randomization was completed by the study coordinator who was not involved in clinical care. Study subjects were not masked as to which implant they would receive. After surgery, the patients received a card detailing which implant they received, as per standard of care. In the patient chart, the device was noted as well.

Surgical Procedure

Subjects underwent implantation of either a BVT or ACP per the randomization protocol. The decision for superotemporal or inferonasal placement was left to the surgeon's discretion. As both devices are non-valved in nature, both required tube occlusion via ligature, before implantation. A limbus based or fornix-based approach for the conjunctival flap could be utilized based on surgeon preference. The wings of each type of implant required placement underneath each adjacent extraocular muscle using muscle hooks, followed by suturing of the implants to the sclera. Tubes were

trimmed to length, beveled, and a shelved scleral tract was used for tube insertion, with the length of the tract and tube per surgeon preference. The tube could be placed in the anterior chamber, sulcus space, or pars plana depending on the patient's anatomy and surgeon preference. A patch graft was placed over the tube, with the choice of the graft material at the surgeon's discretion. Specific techniques such as the use of a ripcord, venting slits, or nylon wicks were left to surgeon preference.[11] The implants were covered with the conjunctival flaps and all wounds were ensured to be water tight at the end of the procedure. Per study protocol, operative notes included GDD type and location, duration of surgery from cut to close, type of patch graft material used, presence of a ripcord, and number of venting slits with or without nylon wicks. If a ripcord was placed, timing of postoperative removal of the ripcord was left to the surgeon's discretion. Use of intra-operative medications and post operative medications, such as antibiotics, steroids, and cycloplegics, were left to the discretion of the surgeon.

Study Measurements and Outcome Measures

The initial evaluation for glaucoma and need for surgical intervention included a standard-of care ophthalmic examination that was performed by a licensed ophthalmologist, as well as questionnaires addressing dysesthesia and quality of life. Collection of all data was under the supervision of a participating ophthalmologist. This included visual acuity, IOP measurement via applanation tonometry, medication inventory, slit lamp examination, fundus examination, and motility/stereoscopic examination, including 9-gaze photography. Subjects were required to have recent retinal nerve fiber layer ocular coherence tomography (OCT) within 6 months and Humphrey visual field (HVF) tests within 3 months of baseline. The questionnaires could be completed in person or by phone by key study personnel. These included the Glaucoma Quality of Life-15 (GQL-15), Glaucoma Utility Index (GUI), and the Glaucoma Symptom Scale (GSS).

Surgical data included randomized tube group, total procedure time, the quadrant in which the surgery was performed, the type of patch graft used, the tube positioning within the eye, and use of ripcords, venting slits, or wicks.

The subjects were seen on post-operative day 1 (±1 day), week 1 (±5 days), week 4 (±1 week), week 6 (±1 week), month 3 (±1 week), month 6 (±2 weeks) and year 1(±1 month) as per the standard-of-care post-operative schedule. At each of these post operative visits, ophthalmic exams were conducted, collecting data for the study. At each postoperative visit, visual acuity, IOP via applanation tonometry, number of glaucoma medications, and notable complications and interventions are recorded. Tonometry was performed using Goldmann applanation tonometry in a masked fashion. The Goldmann dial was randomly set and the observer then aligned the applanation mires without viewing the dial. After final alignment, the dial was read without further adjustment. The measured IOP was documented and the process was repeated. If the two measurements differed by >2 mmHg, a 3rd measurement was performed. The average of these measurements was utilized. Additionally, at each postoperative visit, surgical complications were documented including hyphema, choroidals, AC shallowing, hypotony, wound leak, dehiscence, tube retraction, tube migration, premature tube opening, tube fibrin, footplate exposure, ripcord exposure, patch-graft exposure, wick exposure, iritis, subconjunctival heme, corneal edema, and diplopia. Clinic interventions included ripcord pulling, wick removal, anterior chamber paracentesis with viscoelastic deepening, and bleb needling. Surgical interventions included revisional surgery, additional surgery, and device removal.

OCT, HVF, motility, and stereoscopic examinations, including 9-gaze photography and glaucoma symptom questionnaires, were repeated at post-operative year 1. Glaucoma medications and additional interventions for IOP control were prescribed during postoperative visits at the surgeon's discretion and documented for study purposes.

Criteria for device failure included: IOP >18 mmHg or not reduced by 20% less than baseline on two consecutive visits after three months, IOP < 6 mmHg on two consecutive visits after three months, need for additional glaucoma surgery or device removal, and/or the loss of light perception vision.

At or after the post operative year 1 visit, the patient received a phone call from key study personnel to complete repeat questionnaires addressing dysesthesia and quality of life.

Data Analysis

An Intent-To-Treat (ITT) population includes all randomized subjects who had at least one post-op assessment. The primary efficacy analysis was performed on the ITT population for each post-operative visit that had measured and

quantifiable clinical data, including visits for patients that required rescue procedures. Data was excluded for patients after device removal in either arm. If a patient was not present at a post-operative visit, they were not included in analysis at that time point.

Statistical Analysis

Descriptive statistical analysis of patient characteristics across treatment groups were performed. Student's t-tests for differences between means, Fisher's exact and the $\chi 2$ test, or exact permutation $\chi 2$ test for categorical variables were tested for differences between proportions, and Wilcoxon rank sum test for differences between medians were utilized for between-group analyses. Paired t-tests of mean differences were utilized for within-group analyses. All tests were 2-sided in nature. A p-value of 0.05 was considered statistically significant. All analyses were performed using SAS/STAT software (Version 9.4, SAS Institute Inc).

Results

Recruitment

A total of 76 subjects were enrolled in the DBACS study, with 37 randomized into the BVT arm and 39 in the ACP arm. Subject progression through the study up to 1 year follow-up can be seen in Figure 1. A total of 4 subjects dropped out of the BVT arm before baseline testing. One subject from each arm dropped out (cancelled surgery) after baseline testing. All remaining subjects received their assigned treatment. A total of 70 subjects underwent surgery and 61 subjects were seen to one year of follow-up. Of note, difficulty in enrollment was encountered during the trial, resulting in only 76 total enrolled patients as opposed to the original goal. See limitations for further discussion.

Demographics and Baseline Characteristics

Table 1 summarizes the demographics and the baseline ocular characteristics of those who underwent baseline testing in the DBACS trial. Participants from both BVT (N = 33) and ACP (N = 39) groups were well-matched in terms of age,

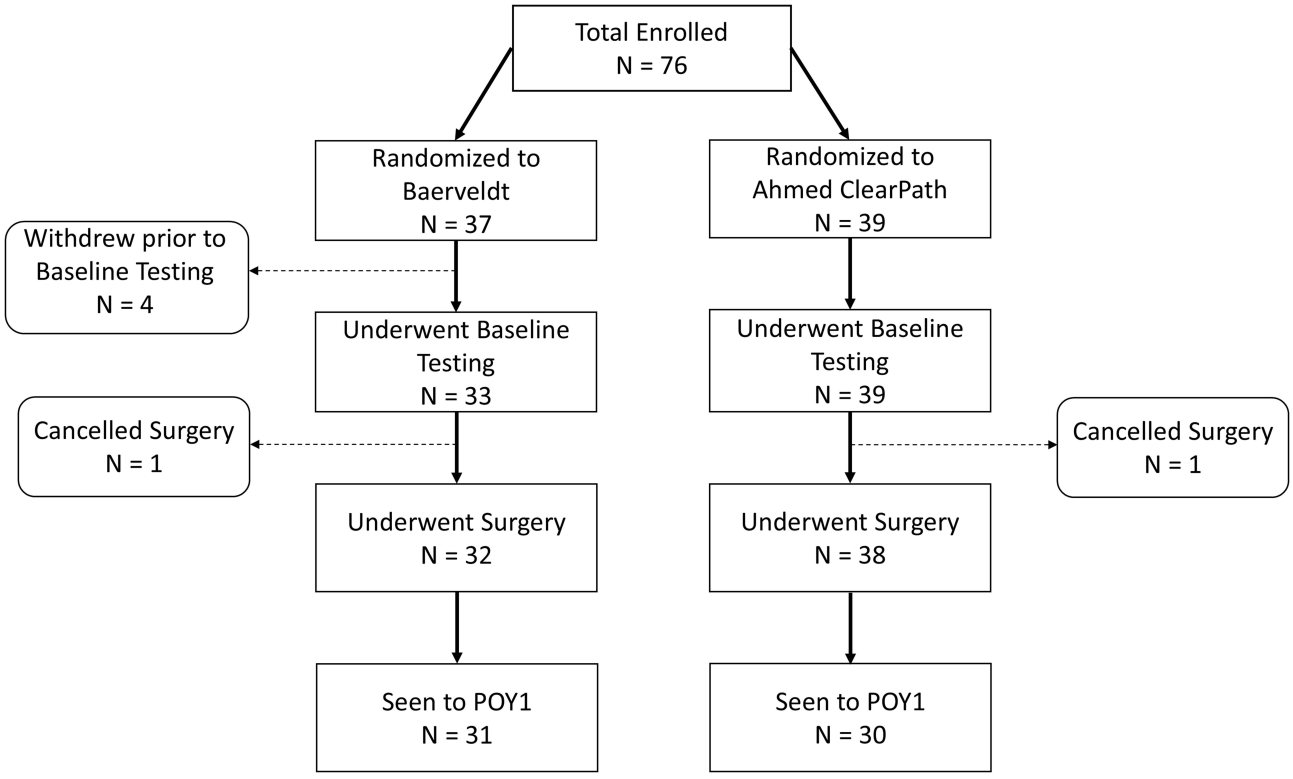

Figure 1 Study Flow Diagram.

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Table 1 Demographics and Baseline Characteristics

Variable	Statistic	Baerveldt N = 33	ClearPath N = 39	P-value*
Age	N	33	39	
	Mean (SD)	70.9 (10.3)	69.6 (11.8)	0.663
	Min, Med, Max	42, 72, 87	23, 72, 86	
Sex	N (%)			0.097
Male		13 (39.4)	24 (61.5)	
Female		20 (60.6)	15 (38.5)	
Race	N (%)			0.700
White		12 (36.4)	11 (28.2)	
Black		21 (63.6)	27 (69.2)	
Other		0	1 (2.6)	
Eye	N (%)			0.481
Right		20 (60.6)	20 (51.3)	
Left		13 (39.4)	19 (48.7)	
Diagnosis	N (%)			0.056
POAG		26 (78.8)	38 (97.4)	
PXG		2 (6.1)	0	
JOAG		3 (9.1)	1 (2.6)	
Angle closure		2 (6.1)	0	
Severity	N (%)			0.651
Mild		1 (3.0)	0 (0)	
Moderate		7 (21.2)	7 (17.9)	
Severe		25 (75.8)	32 (82.0)	
Prior Surgery	N (%)	33 (100.0)	37 (94.9)	0.496
Cataract		25 (75.8)	31 (79.5)	0.780
Valved GDD		3 (9.1)	1 (2.6)	0.327
Non-Valved GDD		1 (3.0)	3 (7.7)	0.620
Trabeculectomy		24 (72.7)	26 (66.7)	0.617
MIGS		6 (18.2)	3 (7.7)	0.285
SLT		11 (33.3)	10 (25.6)	0.604
Other		10 (30.3)	19 (48.7)	0.149
IOP	N	33	39	
	Mean (SD)	21.7 (7.1)	22.4 (6.7)	0.561
LogMAR BCVA	N	33	39	
	Mean (SD)	0.4 (0.5)	0.6 (0.7)	0.380
Medications	N	33	39	
	Mean (SD)	2.7 (1.1)	2.7 (1.5)	0.650
Pachymetry	N	32	39	
	Mean (SD)	531 (31)	532 (46)	0.768
RNFL	N	32	37	
	Mean (SD)	51.6 (13.8)	55.2 (17.5)	0.500

(*Continued*)

Table 1 (Continued).

Variable	Statistic	Baerveldt N = 33	ClearPath N = 39	P-value*
HVF MD	N Mean (SD)	28 −14.2 (9.2)	33 −15.9 (9.5)	0.548

Notes: The demographics, baseline IOP, logMAR BCVA, medications, and other glaucoma baseline clinical characteristics are demonstrated for each arm in Table 1. *P-value for age based on *t*-test of difference between means. P-values for categorical variables based on Fisher's exact test of difference between proportions.

Abbreviations: BCVA, Best corrected visual acuity; GDD, Glaucoma drainage device; HVF, Humphrey visual field; IOP, Intraocular pressure; JOAG, Juvenile open angle glaucoma; LogMAR, logarithm of the minimum angle of resolution; MD, Mean deviation; MIGS, Minimally Invasive Glaucoma Surgery; POAG, Primary open angle glaucoma; PXG, Pseudoexfoliation glaucoma; RNFL, Retinal nerve fiber layer; SLT, Selective Laser Trabeculoplasty.

with mean ages of 70.9 ± 10.3 and 69.6 ± 11.8 years, respectively (p = 0.663). The racial distribution indicated no significant differences between the groups, with the majority being Black in both groups. No significant differences were observed in the distribution of eyes, glaucoma diagnosis type, glaucoma severity, and prior surgery (in general and by prior surgery type) between the two groups. Notably, however, the differences in the distribution of glaucoma diagnosis type approached significance, with primary open angle glaucoma comprising a larger portion of the ACP group (97.4% in ACP vs 78.8% in BVT, p = 0.056).

Intraoperative Surgical Parameters

Table 2 demonstrates intraoperative parameters and characteristic comparisons between each group. No difference was seen in procedure length between the BVT and ACP arms (43.5 ± 11.2 vs 46.9 ± 18.4 mins, p = 0.802). The other surgical parameters, including number of venting slits, number of wicks, surgery quadrant (superotemporal or inferonasal placement), type of surgery graft, and positioning of tube, also showed no statistical difference. A majority of surgeries in both arms were performed in the supertemporal quadrant, used a scleral patch graft, and were positioned into the anterior chamber. Ripcords were placed in all of the surgeries.

Table 2 Intraoperative Surgical Parameters

Variable	Statistic	Baerveldt N = 32	ClearPath N = 38	P-value*
Procedure Length	N Mean (SD)	31 43.48 (11.20)	36 46.89 (18.40)	0.802
Number of Venting Slits	N Mean (SD)	32 2.38 (1.24)	38 2.58 (1.15)	0.221
Number of Wicks	N Mean (SD)	32 1.50 (0.84)	38 1.39 (0.86)	0.533
Surgery Quadrant Supertemporal Inferonasal	N (%)	 24 (75.0) 8 (25.0)	 33 (86.8) 5 (13.2)	0.232
Surgery Graft Sclera Cornea Pericardium	N (%)	 23 (71.9) 6 (18.7) 3 (9.4)	 23 (60.6) 8 (21.0) 7 (18.4)	0.501

(*Continued*)

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Table 2 (Continued).

Variable	Statistic	Baerveldt N = 32	ClearPath N = 38	P-value*
Tube Position	N (%)			0.616
Anterior chamber		26 (81.2)	29 (76.3)	
Sulcus		6 (18.8)	9 (23.7)	
Ripcord Placed	N (%)	32 (100.0)	38 (100.0)	–

Notes: Table 2 demonstrates the intraoperative surgical parameters of each arm.
32 out of 37 enrolled patients underwent surgery in the BVT group after accounting for patients who dropped out. 38 out of 39 enrolled patients underwent surgery in the ACP group after accounting for patients who dropped out.*P-value for continuous based on Wilcoxon rank sum test. P-value for categorical variables based on chi-square test.

IOP Reduction

Figure 2 and Table 3 demonstrate baseline IOP and changes throughout the course of the study. At baseline, no statistical difference in pressure was seen between BVT and ACP (21.7 ± 7.1 vs 22.4 ± 6.7 mmHg, p = 0.687). Each time point after the surgery for both groups showed a statistically lower IOP compared to their respective baselines. No significant differences were found between the BVT and ACP groups at day 1, week 1, week 4, and month 6. However, the ACP group showed a significantly lower IOP compared to the BVT group at week 6 (12.1 ± 5.4 vs 16.3 ± 9.7 mmHg, p = 0.032), month 3 (12.8 ± 6.5 vs 16.5 ± 6.6 mmHg, p = 0.026), and month 12 (11.4 ± 3.9 vs 14.1 ± 4.3 mmHg, p = 0.010 respectively). Similarly, a statistically significant percentage decrease in IOP compared to their baselines was seen in the ACP compared to the BVT group: week 6 (−43.3% vs −24.4%, p = 0.021), month 3 (−38.8% vs −18.3%, p = 0.033), and month 12 (−44.1% vs −30.7%, p = 0.038).

Medical Therapy

Table 3 demonstrates the number of IOP lowering medication classes used by each group at baseline and at each post-operative visit up to one year. At baseline, no difference was seen in number of medications a subject was receiving between BVT and ACP groups (2.7 ± 1.1 vs 2.7 ± 1.5, p = 0.647). No statistical difference in medications was seen at

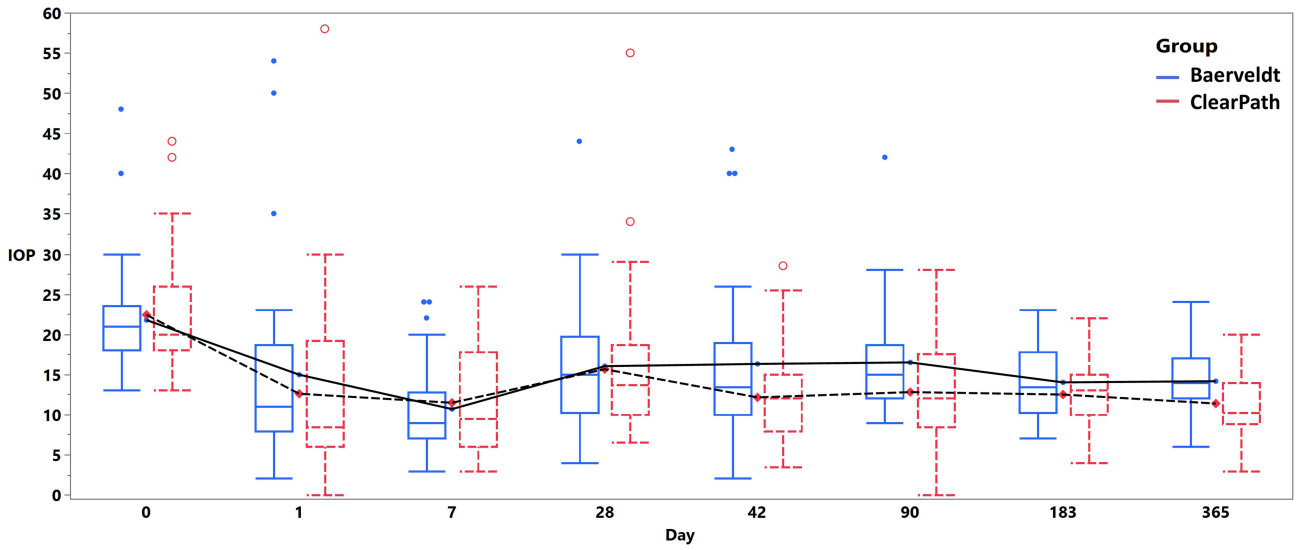

Figure 2 Mean Intraocular Pressure during the post-operative period.
Abbreviations: IOP, Intraocular pressure.

Table 3 Intraocular Pressure and Medications

Time Point	Statistic	Baerveldt	ClearPath	P-value*
Baseline	N	33	39	
	Mean IOP mmHg	21.7 ± 7.1	22.4 ± 6.7	0.687
	% IOP change	(N/A)	(N/A)	–
	Mean Medications	2.7 ± 1.1	2.7 ± 1.5	0.647
Day 1	N	32	38	
	Mean IOP mmHg	14.9 ± 12.1	12.6 ± 10.5	0.384
	% IOP change	–28.1%	–42.2%	0.266
	Mean Medications	0.6 ± 0.8	0.7 ± 1.2	0.807
Week 1	N	32	37	
	Mean IOP mmHg	10.7 ± 5.8	11.5 ± 6.5	0.597
	% IOP change	–47.8%	–47.5%	0.960
	Mean Medications	0.8 ± 1.2	0.9 ± 1.4	0.897
Week 4	N	32	36	
	Mean IOP mmHg	16.0 ± 8.1	15.6 ± 9.2	0.860
	% IOP change	–24.4%	–28.6%	0.613
	Mean Medications	1.1 ± 1.3	1.2 ± 1.5	0.745
Week 6	N	32	35	
	Mean IOP mmHg	16.3 ± 9.7	12.1 ± 5.4	**0.032**
	% IOP change	–24.4%	–43.3%	**0.021**
	Mean Medications	1.4 ± 1.3	1.1 ± 1.3	0.282
Month 3	N	32	33	
	Mean IOP mmHg	16.5 ± 6.6	12.8 ± 6.5	**0.026**
	% IOP change	–18.3%	–38.8%	**0.033**
	Mean Medications	1.5 ± 1.2	1.4 ± 1.3	0.715
Month 6	N	32	31	
	Mean IOP mmHg	14.0 ± 4.3	12.5 ± 4.5	0.172
	% IOP change	–31.8%	–37.9%	0.343
	Mean Medications	2.0 ± 1.3	1.7 ± 1.4	0.334
Month 12	N	31	30	
	Mean IOP mmHg	14.1 ± 4.3	11.4 ± 3.9	**0.010**
	% IOP change	–30.7%	–44.1%	**0.038**
	Mean Medications	2.3 ± 1.2	1.6 ± 1.5	0.079

Notes: Table 3 shows the mean intraocular pressure, the percentage change from baseline of intraocular pressure, and number of medications being utilized at various time points. *P-value based on *t*-test. Bolded values are statistically significant.
Abbreviation: IOP, Intraocular pressure.

each time point afterwards; however, month 12 was approaching significance in favor of less medications for ACP group (2.3 ± 1.2 vs 1.6 ± 1.5, p = 0.079).

Treatment Outcomes, Complications, and Reoperations

Table 4 compares the failure rates and reason for failures between the two groups at post-operative year 1. Figure 3 demonstrates a Kaplan–Meier survival analysis up to post-operative year 1. The BVT group showed a statistically higher failure rate compared to the ACP group (42.94% vs 12.9%, p = 0.021). The majority of failures in both arms were due to failure of meeting IOP goals. 3 subjects in the BVT group needed additional glaucoma surgery for IOP lowering, while no additional surgery was required in the ACP arm. One ACP subject required device removal.

Table 4 Outcome and Failure Reason

Variable	Statistic	Baerveldt	ClearPath	P-value*
Outcome	N (%)			**0.021**
Failure		13 (41.9)	4 (12.9)	
Success		18 (58.1)	27 (87.1)	
Lost to follow-up		1	7	
Withdrew prior to surgery		5	1	
Failure Reason	N (%)			1.00
IOP >18 mmHg / Not reduced by 20% (on 2 consecutive visits)		10 (76.9)	3 (75.0)	
IOP <6 mmHg (on 2 consecutive visits)		0 (0.0)	0 (0.0)	
Needed additional surgery (excluding device removal)		3 (23.1)	0 (0.0)	
Device Removal		0 (0.0)	1 (25.0)	
Loss of light perception vision		0 (0.0)	0 (0.0)	

Notes: Failure rates per the study's protocol for each arm is shown in Table 4. *P-value based on Fisher's exact test. Bolded values are statistically significant.
Abbreviation: IOP, Intraocular pressure.

Figure 4 demonstrates the most common complications seen in both groups at each post-operative time point. Complication rates were commensurate between the two treatment arms at all time points for each complication and when totaled together. However, on day one, the difference in the number of complications neared significance when comparing BVT to ACP (0.47 ± 0.72 vs 0.16 ± 0.37, p = 0.054). Notably, the ACP group required five surgical revisions, with two of them being due to footplate exposure.

Clinical Parameters Through Treatment

Table 5 demonstrates the other baseline and post-operative clinical parameters. LogMAR BCVA was similar at baseline among BVT and ACP, respectively (0.4 ± 0.5 vs 0.6 ± 0.7, p = 0.374). Notably, the logMAR BCVA was better in the BVT group on day 1 (0.7 ± 0.7 vs 1.1 ± 0.9, p = 0.023), week 1 (0.7 ± 0.7 vs 1.0 ± 0.9, p = 0.036), and month 12 (0.4 ± 0.6 vs 0.7 ± 0.8, p = 0.019). However, when comparing the change between the two groups at year 1 compared to baseline, the difference between arms was not found to be statistically significant (−0.03 ± 0.26 vs 0.09 ± 0.46, p = 0.103). Furthermore, each arm

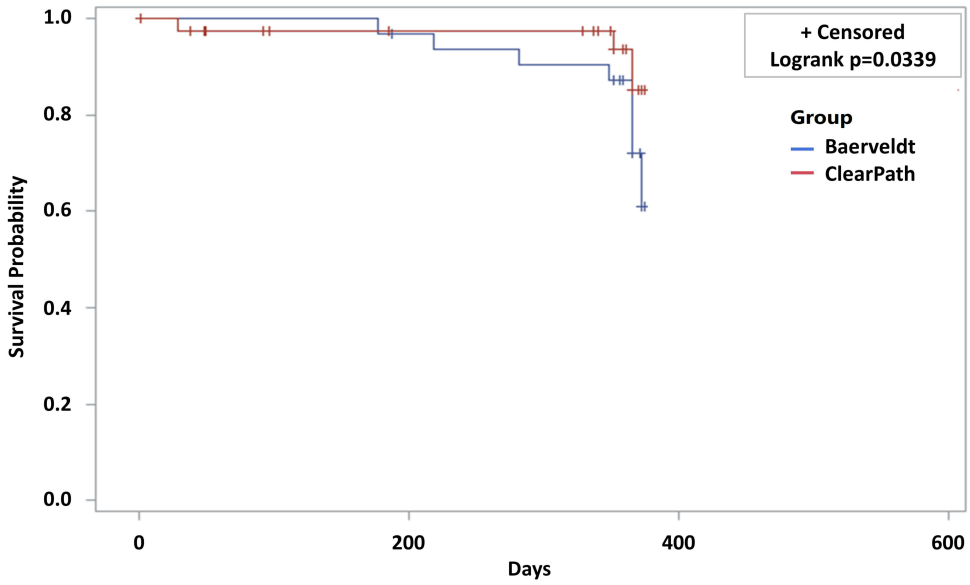

Figure 3 Kaplan-Meier Survival Analysis.
Abbreviations: +, censored data.

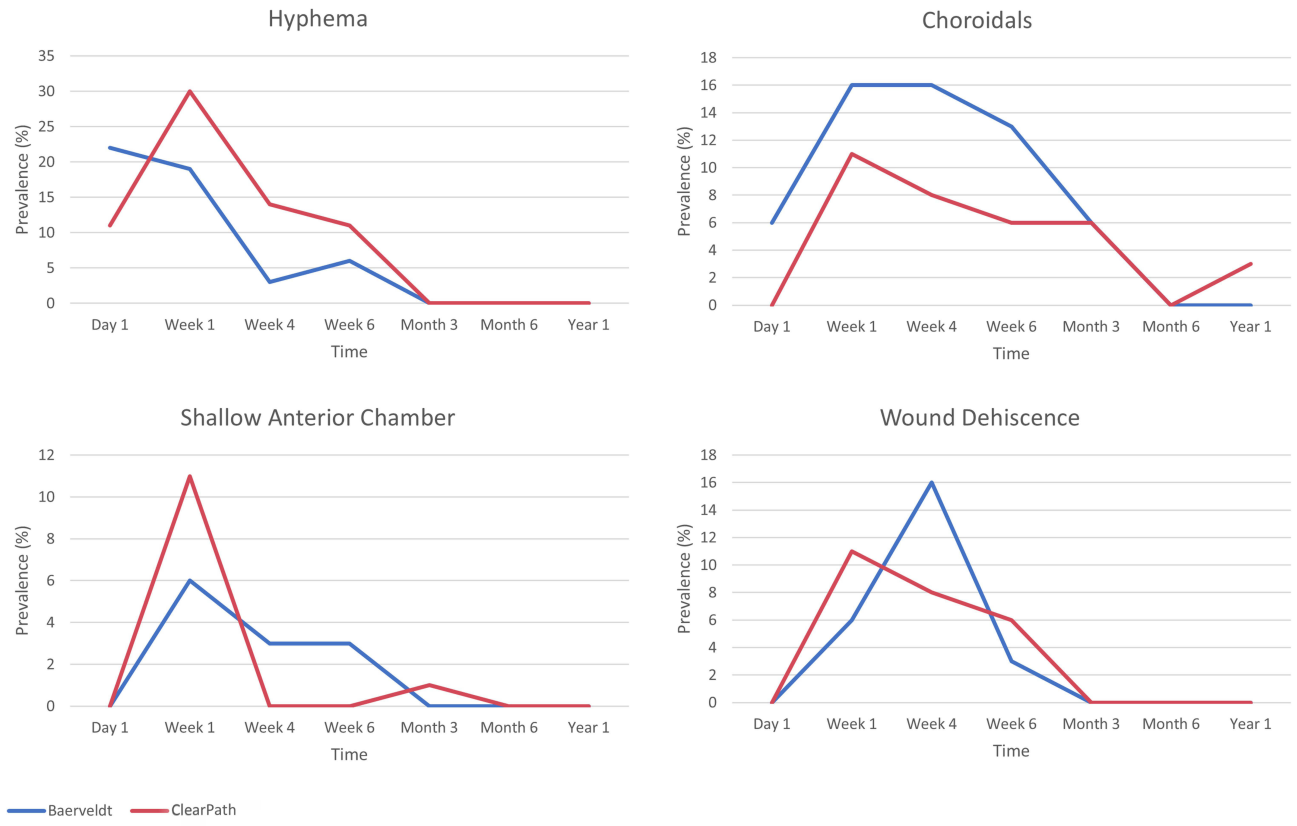

Figure 4 Prevalence of Common Complications.

at year 1 compared to its own baseline was also not significantly changed (p = 0.992 and p = 0.152, respectively). Pachymetry was similar before surgery and during post-operative year 1. For the BVT versus ACP arm, the retina nerve fiber layer OCT (51.6 ± 13.8 vs 55.2 ± 17.6 µm, p = 0.500) and the HVF mean deviation (−14.2 ± 9.2 vs –15.9 ± 9.5 dB, p = 0.548) showed no

Table 5 Clinical Parameters

A. LogMAR Visual Acuity				
Time Point	**Statistic**	**Baerveldt**	**ClearPath**	**P-value***
Baseline	N Mean (SD)	33 0.40 (0.53)	39 0.56 (0.71)	0.374
Day 1		32 0.71 (0.66)	38 1.09 (0.86)	**0.023**
Week 1		32 0.65 (0.68)	36 1.03 (0.87)	**0.036**
Week 4		32 0.45 (0.50)	36 0.71 (0.84)	0.289
Week 6		32 0.49 (0.68)	35 0.71 (0.86)	0.245

(*Continued*)

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Table 5 (Continued).

Month 3		31 0.44 (0.68)	33 0.77 (0.88)	0.067
Month 6		32 0.46 (0.68)	31 0.71 (0.80)	0.146
Year 1		31 0.36 (0.55)	30 0.72 (0.76)	**0.019**
Change		31 −0.031 (0.257)	30 0.088 (0.462)	0.103
B. Pachymetry (μM)				
Baseline		32 530.5 (31.12)	39 531.9 (45.69)	0.768
Year 1		28 544.8 (30.62)	26 559.3 (78.01)	0.890
Change		28 12.18 (25.86)	26 25.96 (57.79)	0.603
C. Retinal Nerve Fiber Layer (μM)				
Baseline		32 51.59 (13.78)	37 55.19 (17.53)	0.500
Year 1		27 56.30 (11.62)	25 61.12 (20.21)	0.264
Change		27 2.81 (9.58)	25 4.72 (13.55)	0.833
D. Humphrey Visual Field Mean Deviation (dB)				
Baseline		28 -14.2 (9.22)	33 -15.9 (9.54)	0.548
Year 1		25 -13.8 (8.87)	20 -14.0 (9.69)	0.945
Change		24 0.36 (6.64)	20 -1.16 (4.44)	0.759

Notes: Table 5 shows changes in non-pressure related clinical parameters compared to baseline. *P-value based on Wilcoxon rank sum test. Bolded values are statistically significant.
Abbreviation: LogMAR, logarithm of the minimum angle of resolution.

significant difference at baseline. Similarly, post-operative year one measurements showed no difference between the groups nor was there a significant change when comparing the baseline to year 1 within each group.

Further information examining quality of life was gathered pre-operatively and post-operatively, using the GQL-15, GUI, and GSS surveys, as well as motility and stereopsis testing in order to quantitively assess possible diplopia. These measures will be assessed in a separate paper.

Limitations

The findings presented must be assessed in the context of the limitations of this study. Firstly, this was a single site study; as such, the cohort of subjects enrolled within the study might have presented a regional bias in terms of patient mix and

types of glaucoma in comparison to other parts of the country or world. Additionally, by design, this study only assessed the 350 mm^2 versions of each type of implant and the results can not necessarily be generalized to the 250 mm^2 variants of each implant. Furthermore, though multiple surgeons at the site participated in the study, there was not complete standardization of the operative and post-operative techniques; several options were left to the discretion of the surgeon, including the decision as to when and how to restart IOP lowering medications. However, having a mix of surgeon preferences better reflects real-world operations and does make the results more generalizable.

As the bulk of this study took place during the COVID-19 pandemic shutdown, enrollment numbers, scheduled surgeries, and follow-up visits were likely negatively affected, impacting data collection. The aforementioned power calculations took into account the AVB and ABC studies given the limited outcomes data on the ClearPath at the time the study was initiated; the calculations also accounted for an expected 10% drop out rate at 1 year. This study did not reach the predetermined number of subjects we thought would be needed to power the study per the aforementioned power calculations. However, despite the low enrollment numbers, given that statistically significant differences were noted, no type II error (false-negative) occurred for the primary endpoint of mean IOP. Because the power calculations were for detecting a 2 mmHg IOP difference, it is possible that a type II error occurred for other values, making it possible that other findings which were not statistically significant in this study, may have been otherwise significant with greater enrollment numbers. Complication rates and other rare events were likely impacted by this the most.

Masking was not possible during the implantation of the surgical device from a practical standpoint, so this could have introduced some bias. Furthermore, as the ACP was a newer device, there might have been less familiarity and a greater learning curve for a number of participating surgeons.

Only 1 year of data available was collected during this study. As such, we cannot confirm that the noted differences in IOP reduction would persist past these time points. Further studies will be required to assess longer term outcomes.

Discussion and Conclusion

The Duke Baerveldt 350 versus Ahmed ClearPath 350 Study (DBACS) presented in this paper is a single-site clinical trial, which prospectively enrolled patients with medically uncontrolled glaucoma; the enrolled patients went on to have glaucoma drainage device placement with either the Baerveldt 350 or Ahmed ClearPath 350 implants. To our knowledge, this is the first randomized prospective clinical study of its kind examining the differences in efficacy and complication rates between non-valved implants. While we initially hypothesized that due to similar plate sizes and other design similarities, there would be no difference in outcomes between the two study arms, our study demonstrated significantly more IOP reduction with the ACP implant compared to the BVT implant at 1 year follow-up.

At 1 year follow-up, the ACP group had an average of 2.7 mmHg lower IOP. While this was statistically significant, we believe that this finding is also clinically significant given the findings of many other landmark studies in glaucoma. The Early Manifest Glaucoma Trial (EMGT) showed that the risk of glaucomatous progression decreased 10% with each additional 1 mmHg reduction compared to baseline.[12,13] Of note, a recent retrospective comparative study by Shalaby et al compared the ClearPath and Baerveldt implants; in their study, they included both the 250 mm^2 and 350 mm^2 variants, unlike this study which only included the 350 mm^2. They assessed 6 months of follow-up and found no difference in surgical failure rates, final IOP, BCVA, and complication rates; however, they did find that the ClearPath group had a significantly lower number of medications at the end of the study.[14] Though their study was retrospective, had shorter follow-up, and included a mix of different models, it seems to follow a similar trend to the results found in this study.

The exact reasons for the difference in IOP reduction noted in this study remain unclear. Possible reasons include differences in plate material, plate shape, resultant capsule morphology, tube material and compliance, and/or tube lumen size. Notably, the base plate of the ACP is narrower when comparing widths (30.47 mm vs 32.00 mm) but is longer and extends further anterior than the BVT (16.48 mm vs 15 mm).[15,16] As such, less of the ACP baseplate is seated under the muscle. Though unclear, these differences may lead to differences in capsular morphology. In fact, a study by Barão et al evaluated bleb morphology by MRI imaging after glaucoma drainage device implantation with either the Ahmed FP7 valved implant, Paul glaucoma implant, Baerveldt, or Ahmed ClearPath devices; the study showed several differences in bleb morphology between the BVT and ACP including a trend towards larger total bleb volume in the ClearPath group

(533 ± 346 mm^2 vs 390 ± 337 mm^2).[16] It is possible that differences in bleb size or capsular morphology may play a role in the IOP differences presented in our study. However, there are varying views and conflicting information on the correlation between bleb size and IOP, and debate as to whether there is any correlation at all.[17–20] Both base plates are made from medical grade silicone, but with the ACP being notably more flexible. The reason for this is that the ACP eliminated the front plate ridge present in the BVT, resulting in a uniform plate thickness of 0.86 mm. Comparatively, the BVT ranges in thickness from 0.5 to 2.0 mm when accounting for the ridge. Difference in internal tube diameter appears to be minimal with the ACP measuring at 305 µm, while the BVT measured at 300 µm.[21] Additionally, a prior laboratory study by Langenberg et al demonstrated that the flow resistance is comparable between the two devices.[22] Therefore, it is unlikely that the differences in tube lumen would be responsible for the differences noted in IOP control.

Additional findings from the study showed that there was no statistically significant difference noted in complication rates between the 2 study groups. The complication rates in the study, in both arms, were similar to that reported in literature for valveless tube shunts.[23–25] Demonstratively, Nguyen et al reported rates of choroidal effusions of 21%, while both the BVT and ACP arms of our study showed peak effusion rates of 16% and 11% at week 1. Finally, two reoperations in the ACP group were due to footplate exposure. This was likely due to the more anterior suture fixation points on the ACP, one of its main design features that separates it from the BVT. It is possible that the footplate is more likely to erode through the conjunctiva given the thinner nature of the conjunctiva anteriorly. For this reason, it is imperative that surgeons ensure that the footplates are completely covered by the patch graft material even if that necessitates the use of a larger patch graft.

Despite the aforementioned limitations, the study still provides highly valuable information for clinicians. Given the similar complication rates, techniques, and surgical times, the ACP seems to provide a safe and more effective option for IOP lowering compared to the BVT. Additional studies are needed to further elucidate these findings. Future papers will compare the quality of life and motility data between the two implant groups.

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Disclosure

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