Five-year Treatment Outcomes in the Ahmed Baerveldt Comparison (ABC)Study

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Disclosure

- No financial interest in any of the two devices

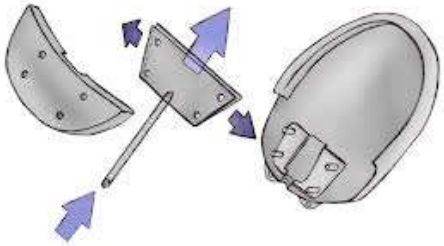
Background

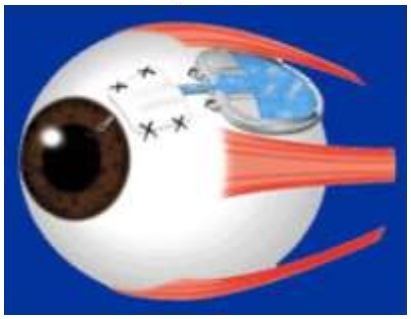
- Glaucoma drainage implants (GDI) have been used with increasing frequency in the management of glaucoma refractive to trabeculectomy, even in the era of antimetabolite use. Medicare data reveals a marked increase in the use of GDIs, from just over 2,000 in 1994 to almost 12,000 in 2012.
- In addition, surveys of the membership of the American Glaucoma Society performed in 1996, 2002, and 2008 show a significant increase in the use of GDIs in patients who had undergone prior surgery This shift in practice pattern has been validated by the results of the Tube Versus Trabeculetomy (TVT) Study, which found that patients with prior trabeculectomy and/or prior cataract surgery had a higher success rate with GDI surgery compared with trabeculectomy with mitomycin-C.

Purpose:

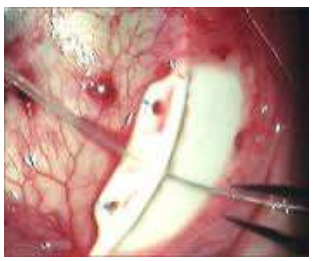
- To compare the five year outcomes of the Ahmed FP7 Glaucoma Valve (AGV) and the Baerveldt 101-350 Glaucoma Implant (BGI) for the treatment of refractory glaucoma.

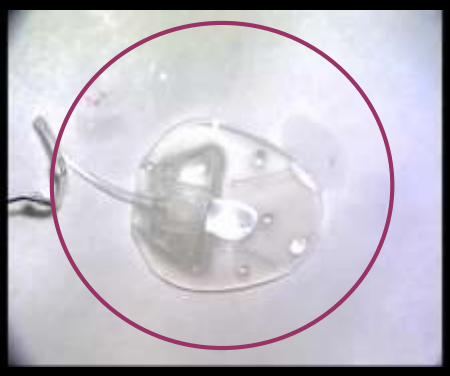
Ahmed Valve AGV FP7





Baervaldt tube BGI 101-350



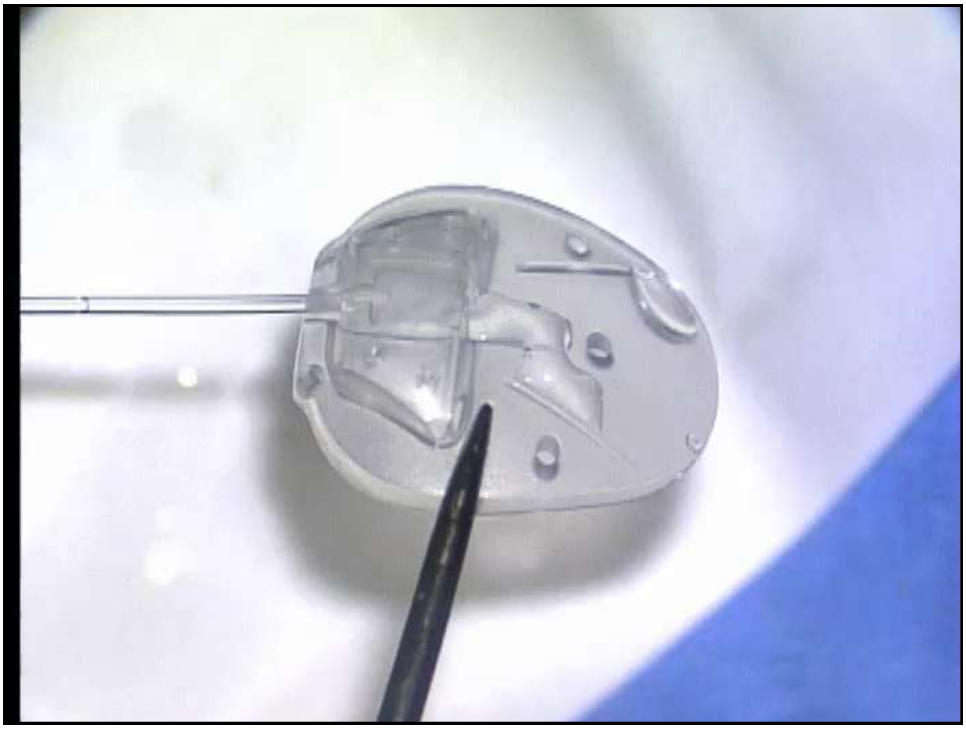


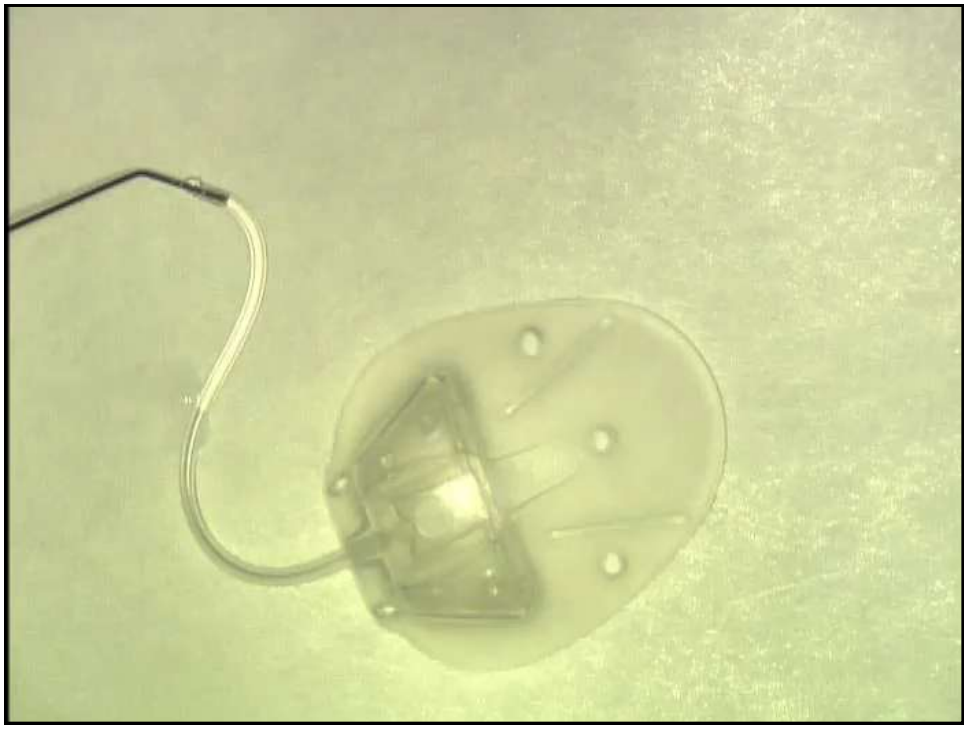
Ahmed FP7
Medium surface area
Flow restrictor

Vs

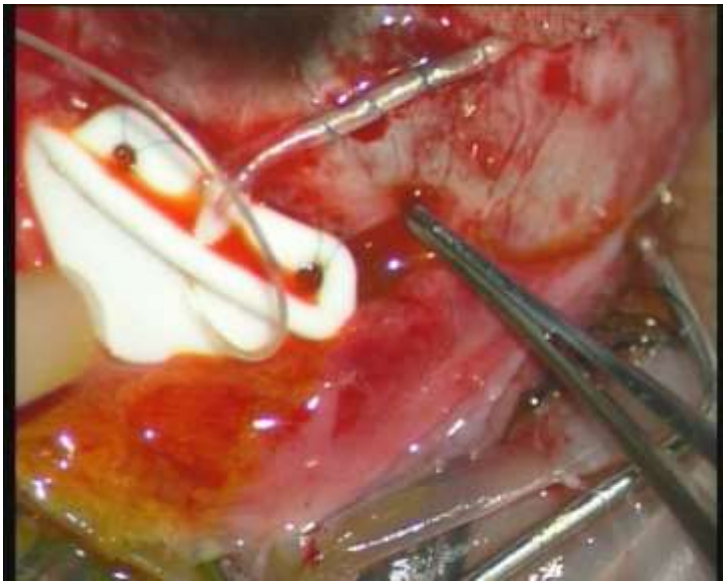
Baerveldt 350
Large surface area and thin
No flow restrictor

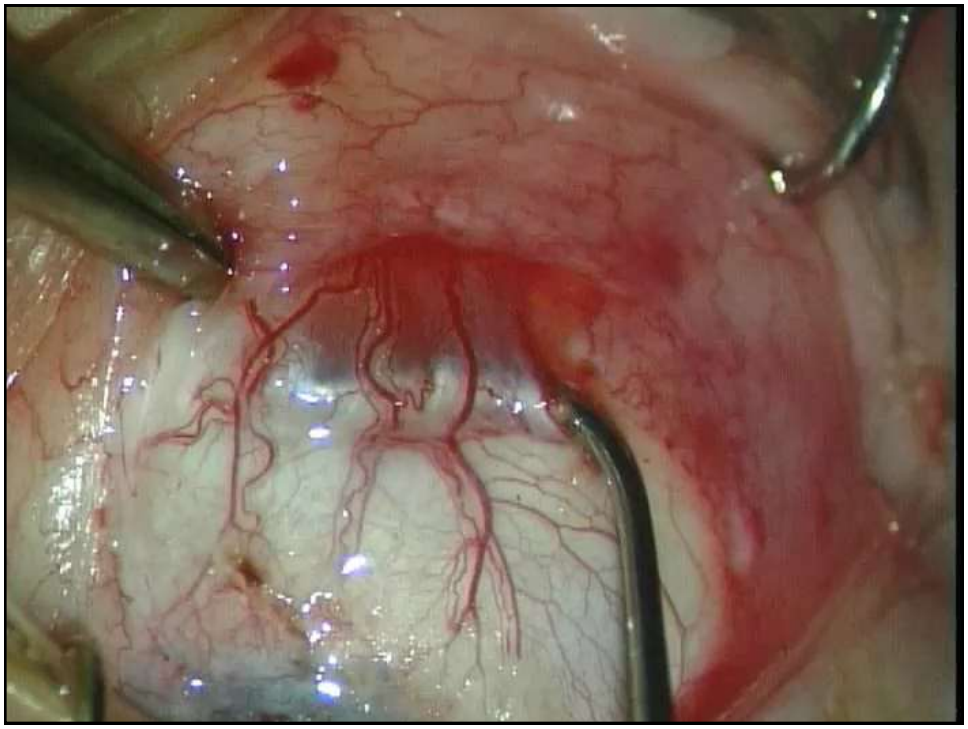
Both silicone and flexible





Stenting of BVT





Design:

- Multicenter (16) randomized controlled clinical trial (prospective).
- Participants: 276 patients, including 143 in the AGV group and 133 in the BGI group.

Demographic Characteristics

	Ahmed Group (n = 143)	BGI Group (n = 133)	P-value
Age (years)			
Mean ± SD	65.4 ± 12.8	62.2 ± 14.2	0.053
Range	24–85	24–85	
Gender (n, %)			
Male	73 (51%)	70 (52%)	0.91
Female	70 (49%)	63 (48%)	
Ethnicity (n, %)			
White	66 (46%)	68 (51%)	0.12
Black	43 (30%)	25 (19%)	
Hispanic	12 (8%)	21 (16%)	
Asian	17 (12%)	16 (12%)	
Other	5 (4%)	3 (2%)	

Methods:

- Patients aged 18-85 years with refractory glaucoma, and IOPs greater than or equal to 18 mmHg in whom GDI surgery was planned were enrolled in the study.
- Patients with primary glaucomas with a previous failed trabeculectomy or other intraocular surgery were included.
- Also, patients without previous intraocular surgery were eligible if they had secondary glaucomas known to have a higher risk of trabeculectomy failure such as neovascular glaucoma (NVG), uveitic glaucoma, or glaucoma associated with iridocorneal endothelialization syndrome.

	Overall (n = 276)	AGV (n = 143)	BGI (n = 133)
Primary glaucoma with previous surgery (Stratum 1)	141 (51%)	72 (50%)	69 (52%)
Secondary glaucomas (excluding neovascular and uveitic glaucomas) (Stratum 2)	37 (13%)	19 (13%)	18 (14%)
Neovascular glaucoma (Stratum 3)	80 (29%)	41 (29%)	39 (29%)
Uveitic glaucoma (Stratum 4)	18 (6.5%)	11 (8%)	7 (5%)

Patient Visits

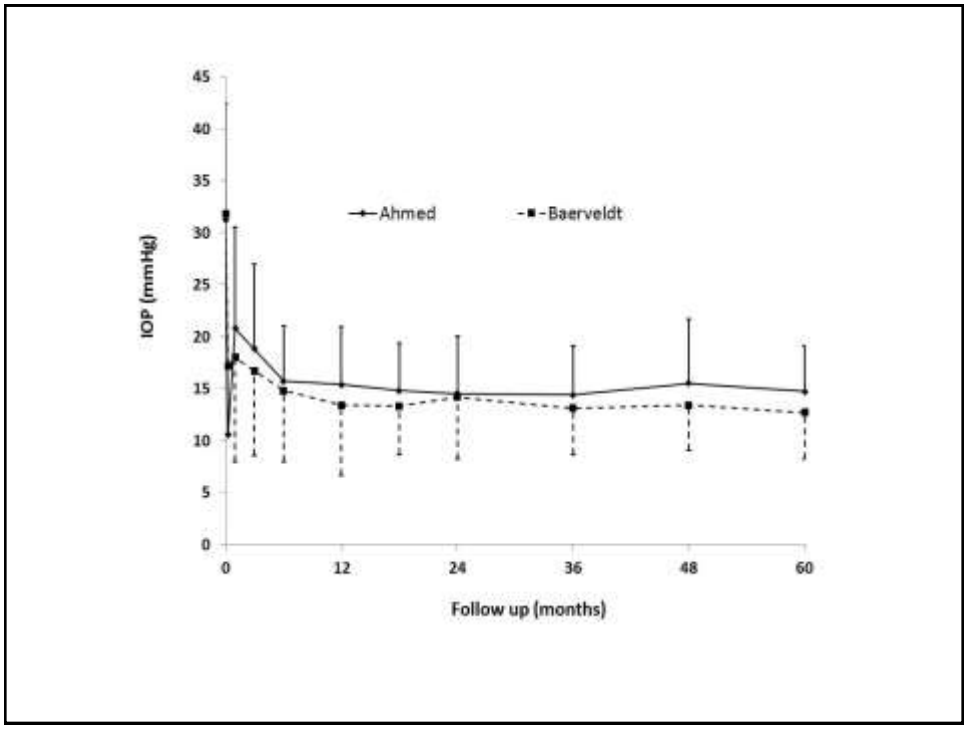
- Follow-up visits were scheduled one day, one week, one month, three months, six months, one year, 18 months, two years, three years, four years, and five years postoperatively.

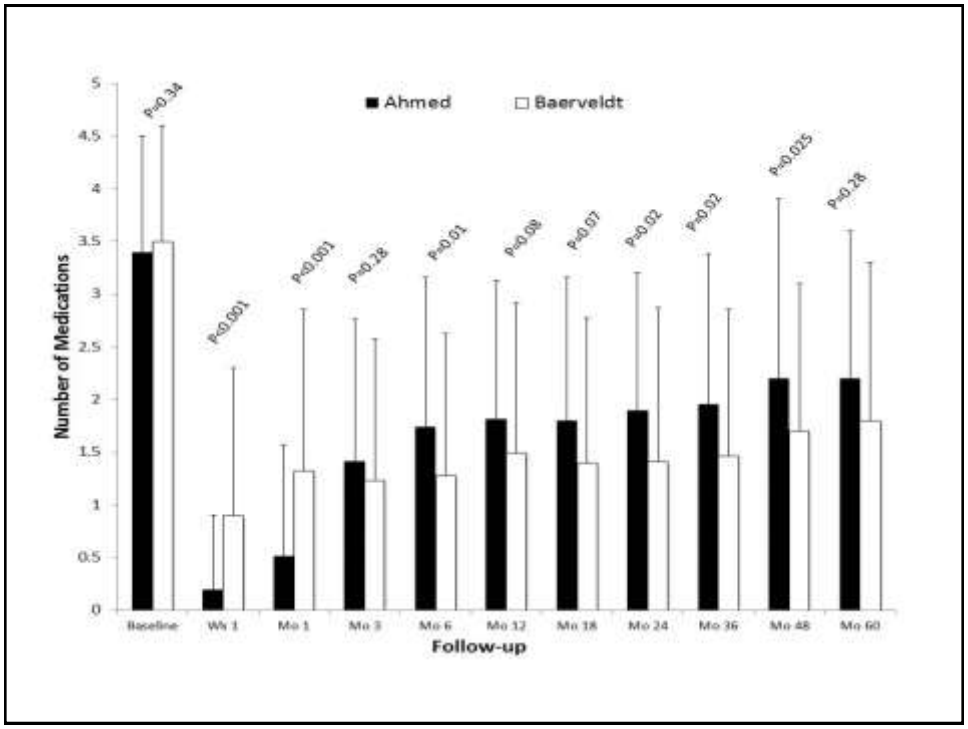
Main Outcome Measures:

- Failure i.e. IOP > 21 mmHg or not reduced by 20% from baseline, IOP ≤ 5 mmHg, reoperation for glaucoma (Interventions performed at the slit lamp, such as needling procedures, removal of occluding stents, or laser suture lysis, were not considered glaucoma reoperations.), removal of implant, or loss of light perception vision.
- Intraocular pressure (IOP), visual acuity, use of glaucoma medications, complications.

Intraocular Pressure and Medical Therapy at Baseline and Follow-up in the Ahmed Baerveldt Comparison Study

	Ahmed Group	Baerveldt Group	P-value
Baseline IOP (mm Hg) Glaucoma med N	29.6 ± 10.1 3.4 ±1.1 143	28.3 ± 9.3 3.5 ± 1.1 133	0.71 0.34
1 year IOP (mm Hg) Glaucoma med N followed (%)	15.4 ± 5.5 1.8 ± 1.3 133 (93%)	13.4 ± 6.9 1.5 ± 1.4 117 (88%)	0.018 0.078
3 years IOP (mm Hg) Glaucoma med N followed (%)	14.5 ± 5.5 1.9 ± 1.3 106 (74%)	14.2 ± 6.0 1.4 ± 1.5 100 (75%)	0.078 0.018
5 years IOP (mm Hg) Glaucoma med N followed (%)	14.7 ± 4.4 2.2 ± 1.4 87 (61%)	12.7 ± 4.5 1.8 ± 1.5 87 (65%)	0.012 0.28


45
40
35
30
25
20
15
10
5
0
IOP (mmHg)
Ahmed
Baerveldt
0
12
24
36
48
60
Follow up (months)


5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
Number of Medications
Ahmed
Baerveldt
P=0.34
P<0.001
P<0.001
P=0.28
P=0.01
P=0.08
P=0.07
P=0.02
P=0.02
P=0.025
P=0.28
Baseline
Wk 1
Mo 1
Mo 3
Mo 6
Mo 12
Mo 18
Mo 24
Mo 36
Mo 48
Mo 60
Follow-up

Reasons for Treatment Failure in the Ahmed Baerveldt Comparison Study

	Ahmed Group	Baerveldt Group
Inadequate IOP control without additional glaucoma surgery	23 (40%)	17 (36%)
Reoperation to lower IOP	23 (40%)	8 (17%)
Explantation for complication	3 (5%)	4 (8%)
Persistent hypotony	1 (2%)	6 (13%)
Loss of light perception	7 (12%)	12 (26%)
Total	57	47

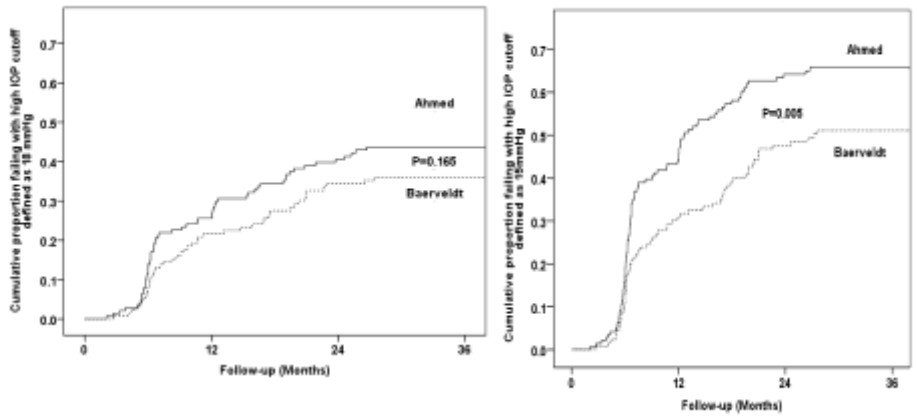
Reoperations for Glaucoma in the Ahmed Versus Baerveldt Study

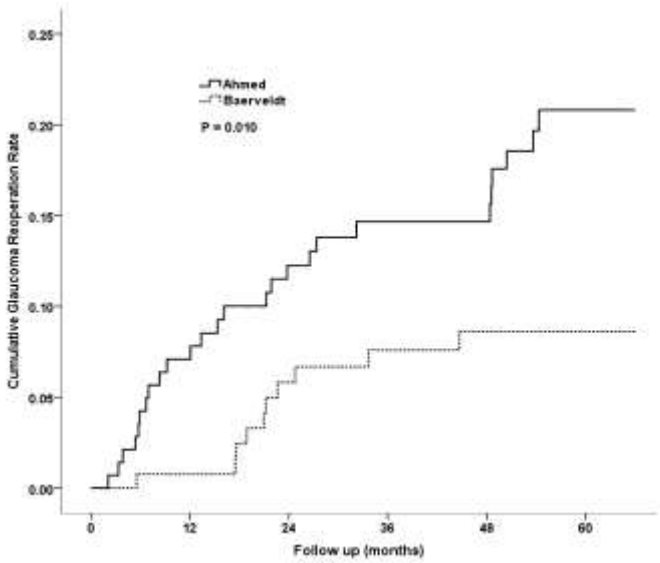
	Ahmed Group (n = 143)	Baerveldt Group (n = 133)
Additional tube shunt	13	8
Cyclodestructive procedure	12	2
Tube revision followed by cyclodestructive procedure	1	0
Total (5 year cumulative Kaplan-Meier percentage ± SE) with reoperation for glaucoma	26 (20.8±3.7%)	10 (8.6±2.6%)

Vision loss

Loss of > 2 Snellen lines at 5 years, n (%)*	Ahmed Group 36 (42%)	Baerveldt Group 38 (44%)	P-value
Glaucoma Retinal disease Corneal opacity, edema, graft failure Cataract Other‡‡ Unknown	14 (39%) 10 (28%) 3 (8%) 3 (8%) 1 (3%) 5 (14%)	17 (45%) 5 (13%) 10 (26%) 3 (8%) 5 (13%) 2 (5%)	0.88

Alternate Outcome Criteria





Discussion

- The lower IOPs in the BGI group were achieved with fewer glaucoma medications compared with the AGV group at most time intervals.
- There are two reasons that may be offered to explain the superior IOP control observed with the BGI relative to the AGV. First, studies have shown that glaucoma drainage devices with larger end plates result in lower IOPs.

Discussion (cont)

- The second possible explanation for lower long term IOPs with the BGI relates to exposure of the filtering bleb to postoperative inflammatory material. In the valved AGV, there is immediate flow of aqueous to the bleb, exposing it to inflammatory cells and protein resulting from the surgery, which may produce more vigorous scarring of the fibrous capsule surrounding the end plate. In the non-valved BGI, complete occlusion of the tube for the first four to six weeks is critical to prevent early hypotony and hypotony-related complications such as flat anterior chambers, choroidal effusions, and suprachoroidal hemorrhages.

Discussion (cont)

- By occluding the BGI for a period of several weeks, the bleb is exposed to much less inflammatory material. Whatever the explanation, the larger, non-valved BGI tends to produce better long-term IOP control, which may make it the preferred implant in patients in whom one is trying to achieve the lowest possible IOP postoperatively

Discussion (cont)

- There are several limitations to the ABC Study. Neither the patient nor the surgeon was masked to the implant used.
- The study only evaluated the AGV and BGI, and the results cannot be extrapolated to other GDIs or different models of the AVG or BGI.
- Patients were excluded if other ocular procedures were required in conjunction with glaucoma surgery, so the study does not provide information about the preferred implant when concurrent ocular surgery is needed.

Conclusion

- The NVG group has the highest failure rates of the four strata in our study.
- NVG accounts for 17 (89%) of the 19 losses of light perception in the study.
- BGI implantation produced greater IOP reduction and a lower rate of glaucoma reoperation than AGI implantation during 5 years of follow-up.
- Similar rates of surgical success were observed with both implants at 5 years.

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Thank You