

ABC Study highlights improved safety with the Ahmed Glaucoma Valve

The ABC study is the largest and longest prospective clinical trial comparing two aqueous shunts, with an enrollment of 276 subjects followed over 5 years.

“Conclusions: Similar rates of surgical success were observed with the both implants at 5 years. The Baerveldt Group Implant produced greater IOP reduction and a lower rate of glaucoma reoperation than the Ahmed Glaucoma Valve, but the **Baerveldt Glaucoma Implant was associated with twice as many failures because of safety issues.**”¹

Serious Complication Associated with Reoperation and/or Vision Loss in the ABC Study

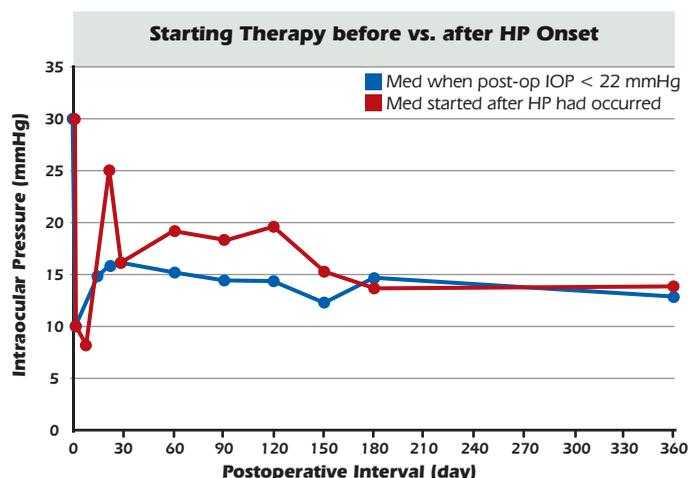
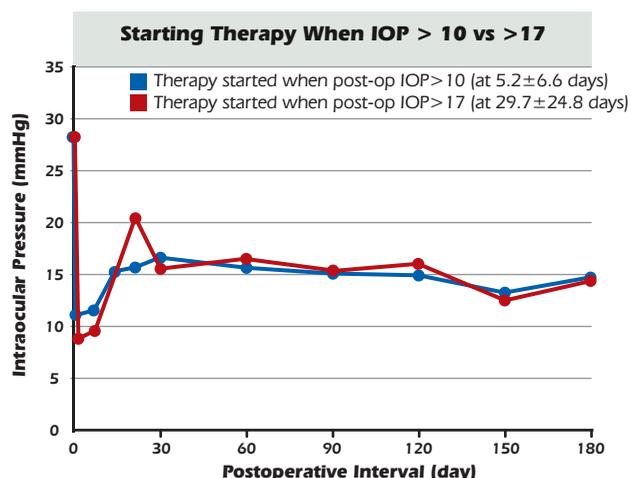
	Ahmed Group (n = 143)	Baerveldt Group (n = 133)
Reoperation for complications	16 (14.3%)	24 (19.5%)
Vision loss of ≥ 2 Snellen lines		
Persistent corneal edema	1	1
Persistent corneal edema + hypotony maculopathy	0	1
Persistent corneal edema + tube-corneal touch	0	2
Cystoid macular edema	0	1
Total number of subjects with serious complications	17 (15.9%)	29 (24.7%)

“In addition, there were more cases of phthisis bulbi in the Baerveldt Glaucoma Implant BG 101-350 group than the Ahmed Glaucoma Valve FP7 group, perhaps due to the fact the Baerveldt Glaucoma Implant BG 101-350 group has a similar proportion of subjects experiencing failures due to persistent hypotony. It may be that the larger end plate of the Baerveldt Glaucoma Implant BG 101-350, which is generally considered to provide lower long-term IOPs, appears to put patients at increased risk of persistent hypotony and phthisis bulbi as well.”²

Aqueous Suppressant Therapy³

“Hypertensive Phase: After tube implantation, an initial reduction of IOP is frequently followed by a rebound IOP increase called the hypertensive phase (HP).” This typically occurs from 1 week to 3 months after surgery.

“In summary, we demonstrated that early initiation of aqueous suppressant treatment after Ahmed Glaucoma Valve implantation improves the success rate of the procedure, provides better IOP control, and reduces the likelihood of a hypertensive phase.” One main benefit of this technique is the reduction in the IOP spike associated with the HP.



It is best to start aqueous suppressant therapy as soon as IOP rises above 10mmHg post-op. This does not increase complication rate.

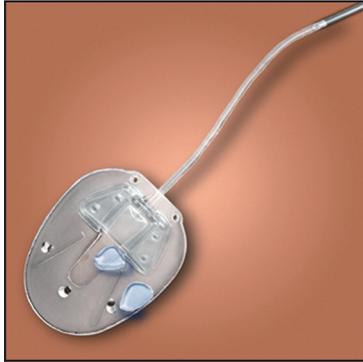
¹Budenz, Donald L, et al. “Five-Year Treatment Outcomes in the Ahmed Baerveldt Comparison Study.” *Ophthalmology* (2014): 1-9.

²Budenz, Donald L, et al. “Postoperative Complications in the Ahmed Baerveldt Comparison Study during 5-Years of Follow-up.” *AJO* (2015).

³Law, Simon K, et al. “Early Aqueous Suppressant Therapy on Hypertensive Phase Following Glaucoma Drainage Device Procedure.” *Journal of Glaucoma* (2014).

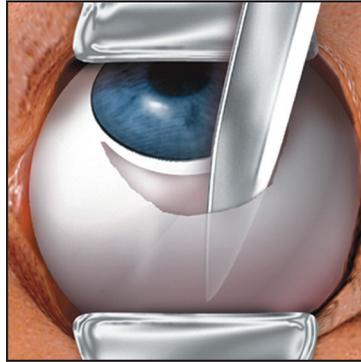
The Ahmed® Glaucoma Valve Surgical Procedure

Step 1



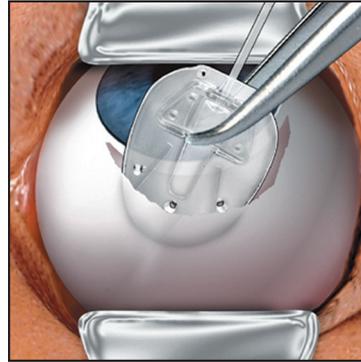
The implant should be examined and primed prior to implantation. Priming is accomplished by injecting 1cc balanced salt solution or sterile water through the drainage tube and valve, using a blunt **26 gauge cannula**.

Step 2



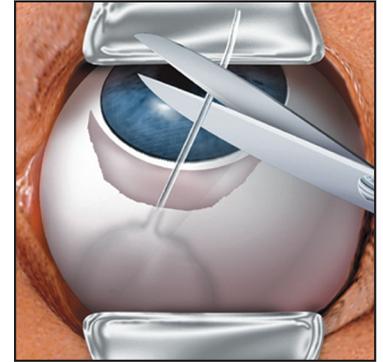
A fornix-based incision is made through the conjunctiva and Tenon's capsule. A pocket is formed at the superior quadrant between the medial or lateral rectus muscles by blunt dissection of Tenon's capsule from the episclera.

Step 3



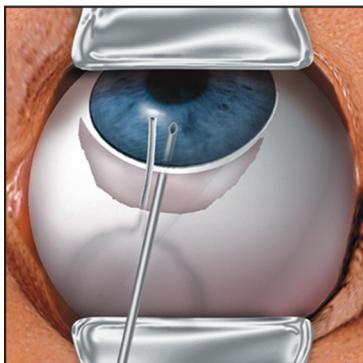
The valve body is inserted into the pocket between the rectus muscles and sutured to the episclera. The leading edge of the plate should be at least **8-10mm from the limbus**.

Step 4



The drainage tube is trimmed to permit a **2-3 mm** insertion of the tube into the anterior chamber (AC). The tube should be bevel cut to an anterior angle of **30°** to facilitate insertion.

Step 5

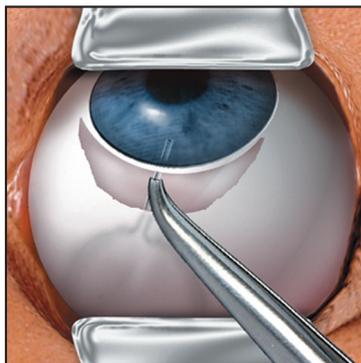


A paracentesis is performed, and the AC is entered at 1-2 mm way from the limbus with a sharp 23 gauge needle to create a needle track, parallel to the iris.

Caution: Care must be taken to ensure that the drainage tube does not contact the iris or corneal endothelium after insertion.

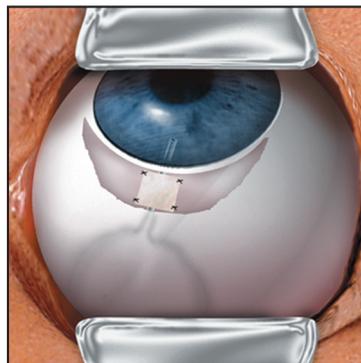
Note: Some surgeons prefer to enter the AC from at least 3mm away from the limbus.

Step 6

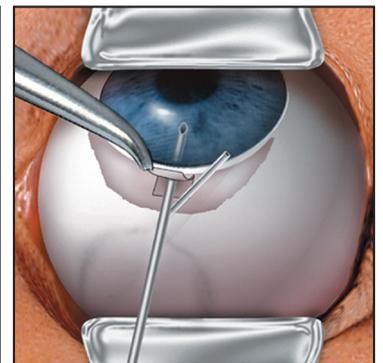


The drainage tube is inserted approximately **2-3 mm** into the AC through the needle track created in step 5.

Step 7



The exposed drainage tube is covered with a piece of preserved, donor sclera, pericardium, cornea, or other suitable patch graft material which is sutured into place and the conjunctiva is closed.



NOTE: As an alternative to Step 7, a **2/3 thickness limbal-based scleral flap** may be made. The tube is inserted into the AC through a 23 gauge needle puncture made under the flap. The flap is sutured closed.

The steps illustrated here are intended as a **guideline only**, and do not represent recommended treatment for any particular patient. The use of any specific surgical technique or maneuver is at the sole discretion of the surgeon. Surgeons should be familiar with the use of glaucoma drainage devices and post-operative care considerations before implanting any drainage device. Reference papers and surgical video tapes are available upon request.



**NEW WORLD
MEDICAL**

Humanity's Vision Is Our Focus

www.newworldmedical.com

+1.909.466.4304

10763 Edison Court
Rancho Cucamonga, CA 91730