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AHMED CLEARPATH: IMPROVING THE TUBE SHUNT

By Davinder S. Grover, MD, MPH



Medical research and emerging technology have fueled exciting and tremendous innovation in the glaucoma space in recent years. The advent of multiple microinvasive glaucoma surgery (MIGS) options has greatly benefited patients, as have advances in hypotensive drug molecules and delivery modalities. However, there remains a need for the traditional filtration devices that has been largely ignored for the last decade. Fortunately, New World Medical has recognized the need for improvement to the traditional filtration shunt, and with the needs of surgeons and patients in mind, has developed the Ahmed ClearPath (Figure 1).

Support for Surgeons

For many ophthalmologic equipment manufacturers, the tube shunt is a niche device that sells itself but lacks explosive market potential. Thus, companies have not invested much in terms of marketing and development of updated devices. However, the tube shunt remains an important tool in the armamentarium of glaucoma surgeons, who desired adjustments to the current tube shunt options to create an option that would be more convenient and efficient to implant. New World Medical answered the call and worked jointly with a cohort of surgeons to develop the Ahmed ClearPath non-valved glaucoma drainage device intended to shunt aqueous humor in eyes suffering from refractory glaucoma.

The collaboration started by truly engaging the surgeons currently using non-valved drainage devices and soliciting their ideas. Requested areas of improvement included creating a device that comes with a pre-placed ripcord and a 23-gauge needle. The device needed to have flexible material, a low-lying design, and fixation eyelets placed more anteriorly so they are easier to access. The desire was to make the surgery more convenient and efficient, potentially avoiding complications from the procedure itself. Design changes developed together with surgeons and prototypes were tested in a wet lab. The entire process focused on helping surgeons and improving efficiency in the operating room.

Thoughtful Design

The result of this process is a design that is hopefully a major step forward in the evolution of the non-valved tube shunt.

The ClearPath Model 250 is a smaller device that allows for a

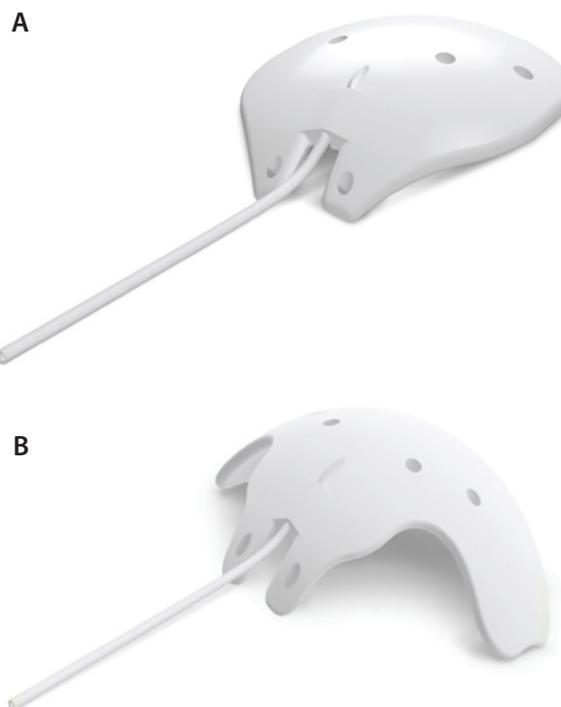


Figure 1. The Ahmed ClearPath Model 250 (A) and Model 350 (B) from New World Medical.

true single-quadrant implantation that sits between the rectus muscles, allowing us to completely skip the steps of muscle isolation and disruption when circumstances allow. The ClearPath Model 350 is suited for patients who need the largest implant possible. While it is still necessary to tuck the implant behind the rectus muscles, the winged design avoids the rectus muscle attachment points, offering more stability when placed under the rectus muscles. This design also results in a more efficient implantation procedure and less trauma to the eye.

Both models of the ClearPath have a low-lying design that is generally easier to place and position and less intrusive to the eye than the traditional drainage implants. The globe-shaped implant provides a more natural fit that is hopefully less likely to cause problems or put unnecessary pressure on the eye. Ideally,

“The tube shunt remains an important tool in the armamentarium of glaucoma surgeons ...”

this new design and natural contour should help when dealing with eyes that have conjunctiva scarring, tight orbits, or difficult anatomy. With two different sizes, surgeons have the flexibility to tailor the implant depending on preference.

The ClearPath also improves access and visibility with anterior suture points. This is particularly beneficial in patients who have a tight or small orbit, limiting visibility. Dissecting in a less posterior position makes securing the implant to the wall easier and more efficient since we do not have to reach back as far and rotate the globe down and retract the conjunctiva.

The ClearPath implant is packaged with a 23-gauge needle to facilitate creation of the track for tube insertion and an optional 4-0 prolene pre-threaded ripcord suture. The ripcord suture can be removed prior to implantation if desired; however, it is a convenient option for those who prefer not to open a separate suture. The all-inclusive packaging minimizes the number of tasks the surgeon or surgical staff need to perform prior to implantation while still allowing for varying surgical styles and techniques.

Indications for Use

Pathology such as uveitis, neovascular glaucoma scarring, conjunctiva scarring, eyelid disease, and severe glaucoma usually indicates a patient who is susceptible to forming excess scar tissue or who may not respond favorably to trabeculectomy or other subconjunctival filtration procedures. A tube shunt is generally a good option in these cases. Multiple studies including the Tube Versus Trabeculectomy study, the Primary Tube Versus Trabeculectomy Study, and the Ahmed Baerveldt Comparison Study have helped us establish which patient profiles are best suited for a certain traditional glaucoma surgery; without question, there remains a need for tube shunts. Now that New World Medical provides both valved and non-valved options for glaucoma drainage implants, surgeons have the full support of the company and can benefit from New World Medical’s surgical support staff, company resources, and, most importantly, their humanitarian-minded business model to allow proper access for all patients.

Surgical Procedure

Once a conjunctival peritomy and sub-tenon’s pocket are created, the ClearPath is secured to the sclera using the surgeon’s preferred suture material. If the Model 350 is selected, the extraocular muscles will need to be isolated. The body of the plate is placed 8 to 10 mm from the limbus in the superior quadrants, resulting in the anterior edge of the suture arms being placed 6 to 8 mm from the limbus. An anterior bevel is cut on the distal end of the silicone tube, and the tube is then inserted into the anterior chamber using forceps to feed the

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INNOVATION THAT DELIVERS EASE OF USE

Tom Samuelson, MD (shown), and Malik Kahook, MD, describe the benefits of two new features—anteriorly-placed suture holes and enhanced curvature.



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tube through a scleral tunnel created by a 23-gauge needle. If the tube is inserted into the sulcus, a posterior facing bevel may be used to prevent occlusion by the posterior iris. The product was designed to be very intuitive and familiar for surgeons who have historically used a Baerveldt Glaucoma implant (Johnson & Johnson Vision), with some additional convenience benefits.

The Right Intentions

The Ahmed ClearPath is a unique product designed with the specific needs of the glaucoma patient and surgeon in mind. New World Medical is a robust company that has continued to honor its core value of providing safe, effective products and delivering them to patients in need. As mentioned above, having valved and non-valved implants allows surgeons to customize treatment depending on the specific patient’s needs and surgeon’s preference. ■

Endnotes

1. Gedde SJ, Schiffman JC, Feuer WJ, et al. Treatment outcomes in the Tube Versus Trabeculectomy (TVT) study after five years of follow-up. *Am J Ophthalmol.* 2012;153(5):789-803.e2.
2. Gedde SJ, Chen PP, Heuer DK, et al. The Primary Tube Versus Trabeculectomy Study: methodology of a multicenter randomized clinical trial comparing tube shunt surgery and trabeculectomy with mitomycin C. *Ophthalmology.* 2018;125(5):774-781.
3. Budenz DL, Barton K, Feuer WJ, et al. Treatment outcomes in the Ahmed Baerveldt Comparison Study after 1 year of follow-up. *Ophthalmology.* 2011;118(3):443-452.

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