# Advances in Glaucoma Drainage Implants

*a report by*
**Karen M Joos, MD, PhD** *and* **Jeffrey A Kammer, MD**

*Vanderbilt Eye Institute, Nashville* *DOI: 10.17925/USOR.2007.03.00.21*

The first reported attempt to reduce intraocular pressure (IOP) with a device was with a horse hair placed through the cornea to connect the anterior chamber to the external surface.[1] Subsequently, various solid and tubular materials were tried with poor results, concisely reviewed by Lim et al.[2] Successful reduction of IOP with a device was achieved when Molteno added a plate to the end of a tube, with the hypothesis that previous failures were due to continued subconjunctival fibrosis.[3] The reservoir would maintain a space for continued filtration. Various modifications have subsequently been developed and, more recently, devices have been developed or are under development to divert aqueous fluid in conjunction with a trabeculectomy,[4] through Schlemm's canal,[5] or through the suprachoroidal space (personal communication). Several of these alternatives have progressed to the point at which 2008 Current Procedural Terminology (CPT) codes have been assigned, which include 0192T for the Ex-PRESS shunt (Optonol, Israel) and 0191T for the iStent (Glaukos Corp, Laguna Hill, California).

## Indications

Historically, shunts to extraocular reservoirs have been reserved for complicated glaucomas, including uveitic glaucoma, neovascular glaucoma, complicated pediatric glaucomas,[6] and glaucomas after multiple failed trabeculectomy procedures.[7] In these instances, a trabeculectomy with an antimetabolite was less likely to succeed. The Tube Versus Trabeculectomy (TVT) Study sought to determine whether earlier placement of glaucoma drainage implants would be a viable option in patients with uncomplicated glaucomas.[8] After one year of follow-up, the cumulative probability of failure was less for the non-valved 350mm$^2$ Baerveldt shunt group (3.9%) than for the trabeculectomy group (13.5%; p=0.017).[9] However, there was a greater need for supplemental medical therapy in the shunt group than in the trabeculectomy group to maintain similar IOP reductions at one year.[9]

## Non-valved Shunts to Extraocular Reservoirs

The original non-valved shunt was developed by Molteno in 1969 with a round plate.[3] The prototype evolved into the multiple variations that are currently available (see *Figure 1*). To further reduce IOP, a double-plate version was developed.[10] It also comes in a ridge version with division of the top of the plate into two areas in an effort to reduce hypotony.[11] A smaller plate model is also available. Recently, a Molteno3 modification with a thinner plate has been developed in 175 and 230mm$^2$ versions. These shunts are produced by Molteno Ophthalmic Ltd, New Zealand, and distributed in the US by IOP, Inc., Costa Mesa, California. Baerveldt shunts were developed in 1990[12] and evolved to include holes within the 350mm$^2$ plate to greatly reduce the height of the fibrous capsular bleb. A small 250mm$^2$ model is also available.[13] These shunts are produced by Advanced Medical Optics, Inc., Santa Ana, California. The Krupin-style valved shunt is now manufactured in a 194mm$^2$ non-valved choice. This shunt and another 365mm$^2$ non-valved shunt are produced by Eagle Vision, Inc., Memphis, Tennessee. Temporary ligation of the non-valved shunts is performed with either a temporary polyglactin ligature,[14] an intraluminal temporary stent,[15] prolene around the tip in the anterior chamber for later laser suturelysis,[16] or a combination of techniques.[17] The 2008 CPT code for insertion of these shunts is 66180 with revision of these shunts being 66185.

## Valved Shunts to Extraocular Reservoirs

The first valved shunts were developed by Krupin in 1976 in an attempt to reduce immediate post-operative hypotony.[18] Subsequently, White,[19] Joseph,[20] and Ahmed[21] developed other valved versions. The Ahmed valved shunts are produced by New World Medical, Inc., Rancho Cucamonga, California (see *Figure 2*). The original model has expanded into multiple sizes and an optional second plate. The material has evolved from the polypropylene plate to a thinner, tapered silicone plate.[22] Valved aqueous shunts do not require temporary ligatures, but hypotony has been reported in case series.[23,24] Consequently, the 2008 American Academy of Ophthalmology (AAO) Ophthalmic Technology Assessment reports that there are insufficient published data to make conclusions regarding post-operative hypotony following valved versus non-valved shunts.[7] The 2008 CPT code for insertion of valved shunts is 66180, with revision of these shunts being 66185.

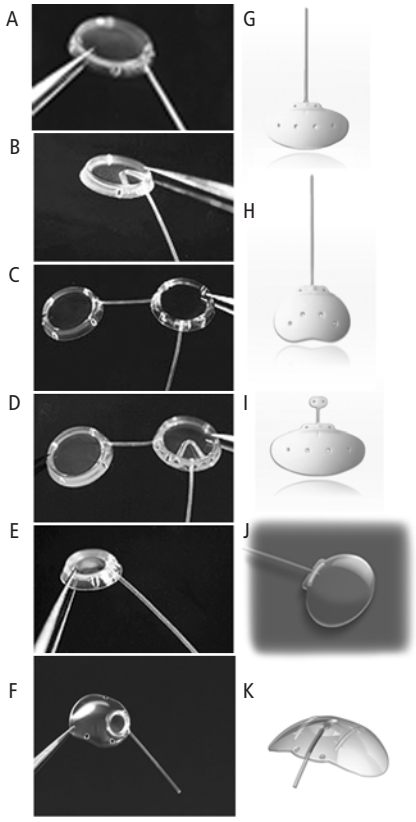
## Alternative Locations for Shunt Placement

The standard placement of shunts is in the superior temporal quadrant with the tube inserted into the anterior chamber at the limbus. An alternative location is often chosen if the anterior chamber is shallow, the cornea is compromised, a penetrating keratoplasty is present, the conjunctiva is prohibitively scarred, or the tube has eroded through the conjunctiva. When the anterior chamber is not an option for

Karen M Joos, MD, PhD, is an Associate Professor of Ophthalmology and Glaucoma Division Chief in the Department of Ophthalmology and Visual Sciences at the Vanderbilt Eye Institute in Nashville. Her clinical interests include treating complicated glaucoma in adults and children, and she is actively involved in a glaucoma model and Department of Defense-sponsored ophthalmic laser research. Dr Joos completed her glaucoma clinical and research fellowship training at the Bascom Palmer Eye Institute in Miami.

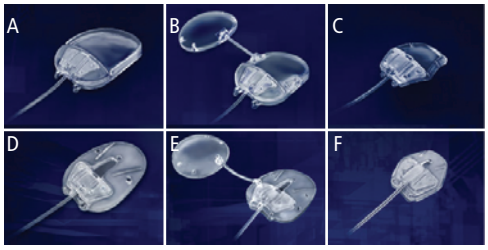
E: Karen.joos@vanderbilt.edu

**Figure 1: Examples of Non-valved Shunts to Extraocular Reservoirs**




*Currently, several non-valved shunts to extraocular reservoirs are available. They include the Molteno-style supplied by IOP, Inc. with single (A), ridged single (B), double (C), ridged double (D), pediatric (E), and Molteno3 plates (F). The Baerveldt-style shunts supplied by Advanced Medical Optics, Inc. include 350mm$^2$ (G), 250mm$^2$ (H), and 350mm$^2$ pars plana plates (I). Eagle Vision, Inc. supplies the 194mm$^2$ Krupin-style plate (J) and a 365mm$^2$ shunt (K).*

**Figure 2: Valved Shunts for Extraocular Reservoirs**




*Shunts currently available include the Ahmed-style supplied by New World Medical, Inc.: A: 184mm$^2$ polypropylene single; B: total 364mm$^2$ polypropylene double; C: 96mm$^2$ polypropylene pediatric; D: 184mm$^2$ silicone single; E: total 364mm$^2$ silicone double; and F: 96mm$^2$ silicone pediatric plates.*

tube placement, the tube can be inserted into the ciliary sulcus in pseudophakic or aphakic eyes.[25] Another alternative is through the pars plana in conjunction with a complete vitrectomy.[26] Standard shunts have been successfully inserted into the vitreous cavity and, more recently, tube shunts have been modified with a bend for insertion through the sclerostomy into the vitreous cavity (see *Figure 3*).[27] In addition, a pars plana clip is available to assist in guiding the tube through the pars plana.[28] A shunt that was originally inserted into the anterior chamber may be repositioned into the vitreous cavity following a complete vitrectomy if anterior segment problems develop, such as corneal decompensation or recurrent erosions.[29] Another option for revising a shunt is to lengthen the tube with a tube extender, and select an alternative site for insertion. A tube extender is commercially available.[30] The tube has also been lengthened by splicing the tube with a 22-gauge angiocatheter and securing it with a 10-0 prolene suture.[31] Another technique is to use nasolacrimal tubing (inside diameter [ID] 0.020 inches, outer diameter [OD] 0.037 inches) as a sleeve to connect the shunt tube to smaller nasolacrimal tubing (ID 0.012 inches, OD 0.025 inches).

## Innovations in Glaucoma Drainage Implants

While our armamentarium of glaucoma drainage implants to extraocular reservoirs has served us well over the past decades, there is determination among glaucomatologists to improve the current technology. Specifically, the glaucoma surgical paradigm is shifting toward procedures that are more reproducible, with lower blebs and fewer complications. To that end, a variety of new aqueous drainage devices are being developed to facilitate aqueous outflow in a manner that is both safe and efficacious (see *Figure 4*). There are three drainage units that are being actively employed in the US and/or Europe, and these will be discussed below.

The Ex-PRESS Mini Glaucoma Shunt is a small, non-valved stainless steel tube that transports aqueous fluid from the anterior chamber into the subconjunctival space, which has been approved by the US Food and Drug Administration (FDA). There are two options available. The more recent is a 2.64mm-long stent with an internal diameter of 50µm (P-50), an outer discoid flange, and an internal spur that prevents implant extrusion. The shunt was originally designed to be placed through the limbus and directly under the conjunctiva. While this effectively decreased the IOP, the complications of hypotony and conjunctival erosions required surgical intervention in approximately 50% of cases.[4]

To reduce the high complication rate, the technique was modified so that the Ex-PRESS Mini Glaucoma Shunt was inserted through the blue-gray transition zone underneath a scleral flap. This modification resulted in IOP control (41% at 12 months and 45% at 24 months) with fewer complications.[32] This procedure was compared with trabeculectomy in a single-surgeon retrospective study. During the first three months post-operatively, trabeculectomy provided better IOP control than the Ex-Press shunt did. After the three-month point, the percentage decrease in IOP was not statistically different between the two groups. Additionally, both groups were similar in terms of final visual acuity and number of post-operative glaucoma medications. There were significantly fewer post-operative complications in the Ex-PRESS group[15] than in the trabeculectomy group[46] throughout the entire post-operative period ($p<0.05$).[33] While this new procedure is promising, a prospective, randomized study needs to be performed to better define its strengths compared with trabeculectomy.

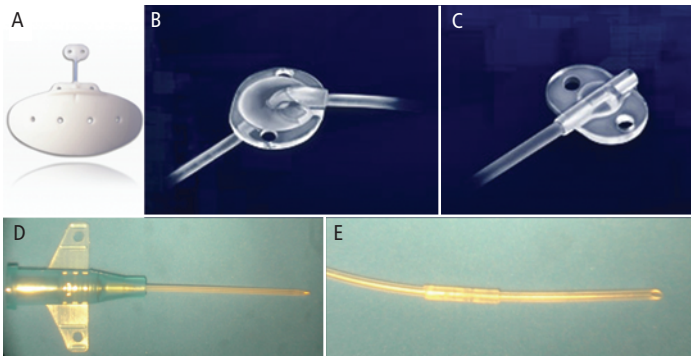
While the traditional approach to glaucoma surgery has been to lower the IOP by diverting aqueous into the subconjunctival space, novel strategies favor a technique that will decrease IOP without creating a bleb. This would enable IOP lowering without the bleb-related complications such as dysesthesia and leaks. To this end, the suprachoroidal space is a potential target into which fluid can be shunted. The theory is to create a shunt that

utilizes the natural pressure differential between the anterior chamber (IOP) and the suprachoroidal space (hydrostatic pressure) to reduce IOP. This resulted in a biocompatible 24-carat Gold Shunt (SOLX, Waltham, Massachusetts), which is 5.2mm long, 3.2mm wide, and 60µm thick. This ultra-thin device is designed to be inserted into a deep 4mm-wide incision, 2.5mm from the limbus that connects the suprachoroidal space to the anterior chamber. The aqueous enters the ingress holes within the shunt, percolates through the internal micro-channels, and exits the shunt into the suprachoroidal space.

The Gold Shunt received European CE approval for clinical use in 2005. The clinical trial results are available online, but have not yet been presented in peer-reviewed publications. In one study, 76 eyes with a mean pre-operative IOP of 27.5mmHg were implanted with the Gold Shunt and followed for two years. The mean post-operative IOP at both the 12- and 24-month time-points was 19.7mmHg without formation of a bleb. The most common reported complication was transient hyphema, with no cases of long-term hypotony or post-operative infections.[34] While the results are encouraging, the FDA is awaiting further clinical studies.

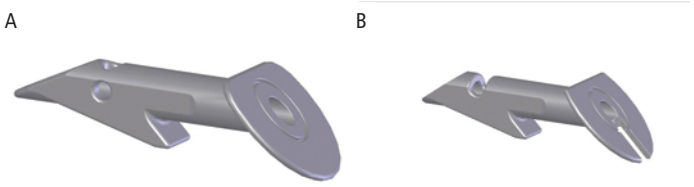
Another strategy that has gained significant attention is 'trabecular bypass.' It is based on the observation that half of the outflow resistance in the normal eye is secondary to the trabecular meshwork and inner wall of Schlemm's canal.[35,36] Thus, any mechanism that is employed to bypass this source of outflow resistance and shunt aqueous to Schlemm's canal will presumably lower IOP. This idea is the basis for the development of the iStent, a small titanium implant that is inserted by way of an *ab interno* transcameral approach, through the trabecular meshwork and into Schlemm's canal, while leaving the conjunctiva entirely intact. In a recent prospective, non-randomized, uncontrolled, multicenter clinical study, 47 patients underwent a clear cornea phacoemulsification cataract extraction with *ab interno* placement of an iStent trabecular Micro-Bypass Stent and were then followed for at least six months. The six-month data demonstrated a statistically significant mean IOP reduction of 5.7±2.8mmHg ($p<.001$) and a mean decrease of 1±0.8 glaucoma medications ($p<0.001$).[5] This represents a greater IOP drop compared with the 1.9–4.4mmHg IOP reduction reported after cataract surgery alone.[37–40] No instances of infection, hypotony, flat anterior chamber, or choroidal detachments have been reported. In the US, there is an active clinical trial that is prospectively comparing clear corneal phacoemulsification alone versus clear corneal phacoemulsification with iStent placement.

**Figure 3: Components Available for the Modification of Placement of Shunts in Extraocular Reservoirs**




*A: Baerveldt 350mm$^2$ model with the pars plana elbow; B: New World Medical, Inc. pars plana clip permitting a bend in the tubing of shunts for insertion. Components to lengthen a shunt tube include the New World Medical, Inc. tube extender (C), angiocatheters (D), and nasolacrimal tubing (E).*

**Figure 4: The Ex-PRESS Mini Glaucoma Shunt**




*This small, non-valved stainless steel tube (Optonol, Israel) transports aqueous from the anterior chamber into the subconjunctival space. Options available include the: R-50 (A) and P-50, P-200 (B). The tube is inserted through the blue-gray transition zone underneath a scleral flap.*

In summary, standard shunts to extraocular reservoirs continue to be an effective method to treat glaucoma. They continue to be modified to improve outcomes and minimize complications. In addition, new devices are in various stages of development and show considerable potential for the future. ■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