

Innovations in Glaucoma: Sterile Cornea Improves Coverage of Glaucoma Valves

Glaucoma patients who are non-responsive to standard and maximal medical therapy are an increasing challenge for healthcare providers today. It is estimated that several thousand glaucoma drainage devices are implanted in the U.S. every year to manage these patients.ⁱ Traditionally treatment for patients with “complicated glaucoma” requires a surgically-implanted glaucoma drainage device. These devices include the Molteno implant (IOP Inc., Costa Mesa, CA), the Baerveldt tube shunt (Abbott Medical Optics, AMO, Santa Ana, CA), and the valved implants, such as the Ahmed glaucoma valve (New World Medical, Rancho Cucamonga, CA), the Krupin (Hood Laboratories, Pembroke, MA), and the pressure ridge Molteno implants (IOP Inc., Costa Mesa, CA). To prevent tube erosion and associated complications, most drainage devices are covered with sclera or pericardium.ⁱⁱ

There are many potential complications that can be seen after insertion of a glaucoma drainage device such as hypotony, choroidal complications, hyphema, and choroidal hemorrhage and effusion.ⁱⁱⁱ One of the

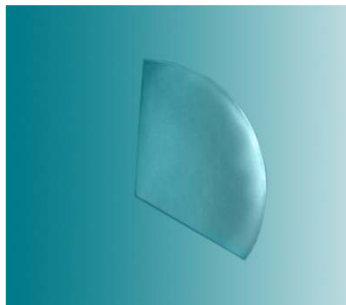


Figure 1: VisionGraft GC patch graft

most serious complications is exposure of the drainage device that can lead to intraocular infection if not detected in a timely manner and surgically corrected.^{iv} While

tissue erosion can be addressed surgically via the use of additional overlay tissue (if residual

healthy tissue is available in the eye), in many cases, terminal erosion requires removal of the device and a new implantation at a different surgical site.

The inability to peer through certain tissue coverings can be a problem for both surgeon and patient. The clarity of the VisionGraft® provides the option of laser suture lysis to increase drainage post-operatively without the risk of releasable sutures or instrumentation within the eye.^v This is particularly important for non-valved devices such as the Baerveldt tube shunt or the Molteno implant, as the

SYNOPSIS

Indications for glaucoma drainage devices

- Prior failed glaucoma filtration surgery
- Need for better intraocular pressure control
- Refractory glaucomas, such as neovascular glaucoma, uveitic glaucoma, pediatric glaucoma, or traumatic glaucoma

VisionGraft Characteristics:

- Gamma-irradiated corneal tissue
- Shelf-stable at room temperature for two years
- Transparent tissue graft
- Durable, easy to manipulate and suture

Surgeon Perspective of VisionGraft

- Reduces or eliminates erosion
- Reduces re-operations
- Good re-epithelialization
- Provides a diagnostic window to the valve

Patient Perspective

- Clarity provides a good cosmetic outcome
- Reduces or eliminates the need for repeated surgeries to replace eroded tissue

Alternative Solutions:

- Sclera
- Pericardium
- Glycerine-preserved cornea

VisionGraft allows visualization of the tube for selected suture removal depending on the IOP level in the eye.^{vi} In some extreme cases, the surgeon may be required to remove the tissue for diagnostic or interventional purposes. This can also be problematic as pericardium, in many cases, “grows” into the sclera making revisions more difficult; whereas, the VisionGraft patch grafts peel back in a plane leaving all surrounding tissue intact. The VisionGraft can also potentially be utilized in cases of scleral staphyloma, trabeculectomy, and inadvertent blebs.^{vii}

Patients also complain about the aesthetics of some overlying tissue such as pericardium or sclera – stating that the discoloration is noticeable and unpleasant in appearance. The VisionGraft offers

superior clarity and cosmesis for the patient with the graft providing a natural appearance and no trace of a foreign material.^{viii}

In a recent study, ten patients with complicated glaucoma were treated with VisionGraft coverage for primary/ revised glaucoma tube shunt coverage and other tectonic support procedures. Ten eyes of ten patients were treated with the VisionGraft. There were zero cases of required revision of the allograft with a mean follow-up of 10 months. The VisionGraft was found to be safe and effective in glaucoma and anterior segment surgical procedures as evidenced by maintained clarity of the tissue, zero clinical signs of immunologic rejection or inflammation, and integrity of the tissue and the conjunctiva over the graft. Cosmetic results were excellent, and there were no complications during the follow-up period. The results suggested definite advantages of the VisionGraft for tissue coverage of glaucoma implant tubes, including tissue transparency, resilience, and ease of surgical use.^{ix} Additional surgeon experience has demonstrated that the VisionGraft is easier to work with than other patch graft materials, provides better durability (does not melt over time), better tensile strength, and reduces or eliminates erosions.^x The

learning curve for incorporation of the VisionGraft is relatively simple. Suture material and surgical technique required for this tissue is similar as compared to other patch graft material.



Figure 2: Implanted VisionGraft GC patch graft

Today, physicians are finding high utility with this new tissue graft from TBI/Tissue Banks International. The VisionGraft is a sterile cornea that combines the clarity and durability of corneal tissue with a shelf life of two years at room temperature and a reduced rate of erosion. It has been demonstrated to be safe and effective. To date, the new graft has been utilized in over 1,500 glaucoma cases since its release with no reports of erosions or other tissue-related complications.

ⁱ Shen, C, Salim, S, Du, H, Netland, P. Trabeculectomy versus Ahmed Glaucoma Valve Implantation in Neovascular Glaucoma. *Clin Ophthalmology* 2011; 5: 281-286.

ⁱⁱ Smith, M, Doyle, J, Ticney, J. A comparison of glaucoma drainage implant tube coverage. *J of Glaucoma* 2002; 11(2): 143-7

ⁱⁱⁱ Maris, P, Ishida, K, Netland, P. Comparison of Trabeculectomy with EX-PRESS Miniature Glaucoma Device Implanted Under Scleral Flap. *J Glaucoma* 2007; 16: 14-19.

^{iv} S. Salim (personal communication, November 16, 2011)

^v Rojanaponpun, P, Ritch, R. Clear corneal graft overlying the seton tube to facilitate laser suture lysis. *Am J Ophthalmol* 1996; 122(3): 424-5

^{vi} S. Salim (personal communication, November 16, 2011)

^{vii} Schwartz, G. (2011, October). Corneal Patch Grafts for Glaucoma Drainage Devices [PowerPoint slides]. Presentation given at the TBI annual glaucoma conference at the American Academy of Ophthalmology, Orlando, FL.

^{viii} D. Cute (personal communication, August 25, 2011)

^{ix} Netland, P, Lawrence, S. (2010). Clinical Outcomes of Sterile Cornea Allograft in Glaucoma Surgery. Proceedings of the Association for Research in Vision and Ophthalmology, USA.

^x F. Cotter (personal communication, Sept. 6, 2011)

VisionGraft™ is a registered trademark of TBI/Tissue Banks International, Baltimore, MD.