Innovations in Cornea Surgery: The VisionGraft® Gamma-Irradiated Cornea

One of the many challenges to the ophthalmic surgeon are impending or frank perforations that require emergency intervention as is typically the case with sterile corneal necrosis or more frequently with infectious keratitis.[i] These cases frequently require emergency tectonic surgery to restore integrity due to potential complications such as endophthalmitis, hypotony with choroidals, and iris cornea touch.[ii] Other indications for emergency patch graft surgery include limbal mass lesions, pterygium, and perforating trauma.[iii] Traditionally, treatment of corneal defects has been managed with utilization of tissue adhesives,[iii] conjunctival flaps,[iv] amniotic membrane grafting,[v] patching with scleral tissue,[vi] or patching with fresh corneal tissue[vii] versus glycerin-preserved corneal tissue.[viii]

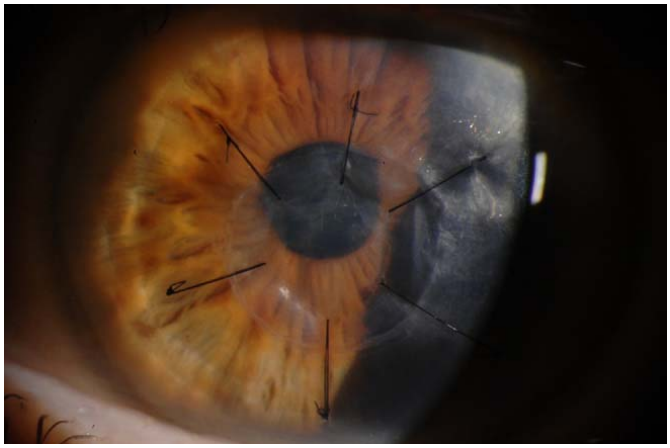

Figure 1: Central corneal patch using VisionGraft

Glycerin–cryopreserved corneas have long been used for tectonic procedures. There are several disadvantages in utilizing the glycerin corneas in surgery. One difficulty is that the glycerin-cryopreserved corneas need to be rehydrated and rinsed of residual glycerin repeatedly prior to any procedure. Additionally, surgeon manipulation and handling of the glycerin corneas is problematic due to the considerably increased thickness and haze. Once implanted, the glycerin corneas tend to take several weeks before complete stromal clearing, potentially leading to more complications and medical management.[ix]

VisionGraft® is a patent-pending, sterile, gamma-irradiated corneal tissue that can be used in lamellar corneal procedures not requiring a viable endothelium. The tissues are available in several iterations including whole cornea with or without scleral rim, laser pre-cut full thickness donut-shaped cornea for utilization with the Boston Keratoprosthesis Type I device, and split thickness lamellar grafts for both cornea and glaucoma surgical applications. The tissues are stored at room temperature for up to two years, thus convenient to stock in case of trauma/emergency scenarios. Pre-release testing on the VisionGrafts included suture pull-through testing which demonstrated comparable strength with that of fresh corneal tissue, histopathology studies that demonstrated normal collagen structure

SYNOPSIS

Indications for patch graft surgery

- Corneal ulcer with microperforation
- Keratoprosthesis-associated corneal melt
- Limbal mass lesion
- Chemical burns
- Chronic ulcerative keratitis
- Central ulcers

VisionGraft Characteristics:

- Gamma-irradiated sterile corneal tissue
- Shelf-stable at room temperature for two years
- No pre-op soak required
- Transparent tissue graft
- Durable, easy to manipulate and suture

Surgeon Perspective of VisionGraft

- Same handling as fresh corneas
- Gamma-irradiation reduces the likelihood of graft rejection
- Gamma-irradiation eliminates the risk of bacterial, or fungal disease

Alternative Solutions:

- Fresh donor corneas
- Cryopreserved whole globes
- Glycerin preserved corneal tissues
- Tissue adhesives
- Conjunctival flaps
- Amniotic membrane grafting
- Sclera lamellae

and electron microscopy testing which demonstrated similar mean interfibrillar distance and fibril diameter to that of non-irradiated fresh corneas.[x]

VisionGrafts are similar in thickness and handling as compared to fresh corneas.[ii] The tissue does not require rehydration prior to surgery and is clear when implanted. The gamma irradiation offers additional patient safety compared to fresh corneas and virtually eliminates the risk of bacterial, or fungal disease.[xi] A key benefit of the VisionGraft gamma-irradiated corneas are the lack of antigen-presenting cells that are transferred within the donor tissue. Gamma irradiation has demonstrated the ability to deplete antigen-presenting cells; this reduces the likelihood of graft rejection by "preventing the direct sensitization."[xii]

In a recent study reporting on the clinical outcomes of lamellar keratoplasty utilizing VisionGraft sterile corneas, 10 patients with partial thickness corneal defects were reviewed. Primary indications for surgical procedures included corneal melt with microperforation, keratoprosthesis-associated corneal melt, and non-inflammatory limbal lesions. VisionGraft full or split thickness grafts were fashioned using disposable trephines based on the depth, shape, and size of the defect. The allograft tissues were secured with multiple interrupted 10/0 nylon sutures. All but one graft became epithelialized between post-op day 1 and 13. The one problematic graft was assumed by the researcher to be attributable to the progression of underlying Sjögren's syndrome as fresh donor corneal graft also melted in this case. All other VisionGraft corneas completely epithelialized within 10 days, and remained clear over a period of 7 to 15 months. There was no incidence of immune rejection, infection, significant opacification, or neovascularization of the donor tissues during the follow-up period.[ii]

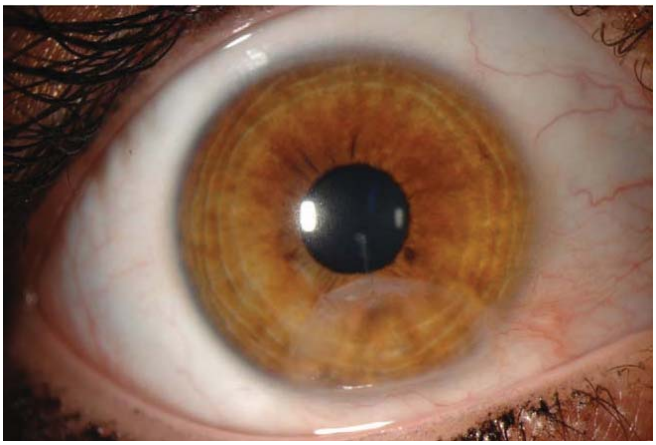

Figure 2: Peripheral lamellar patch using VisionGraft

Today, physicians are finding high utility with this new tissue graft from TBI/Tissue Banks International. The VisionGraft is a sterile gamma-irradiated cornea that combines the clarity and durability of corneal tissue with a shelf life of two years at room temperature. It has been demonstrated to be safe and effective in lieu of fresh corneas for lamellar corneal patch grafts due to its availability, easy handling, and lack of immunogenicity.

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