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REVIEW

The Evolving Surgical Paradigm of Scleral Allograft Bio-Tissue Use in Ophthalmic Surgery: Techniques and Clinical Indications for Ab-Externo and Ab-Interno Scleral Reinforcement

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Abstract: To review the latest surgical advances and evolving clinical use of scleral bio-tissue for reinforcement in the eye and review the published literature on novel surgical applications of scleral allograft bio-tissue. Conventional surgical procedures for scleral reinforcement using homologous scleral allograft have been traditionally ab-externo interventions comprising of anterior or posterior reinforcement of the sclera for clinical indications such as trauma, scleromalacia, glaucoma drainage device coverage, scleral perforation, buckle repair as well as posterior reinforcement for pathologic myopia and staphyloma. There have been a few novel ab-interno uses of scleral bio-tissue for reinforcement in both retina and glaucoma. Over the last decade, there has been an increase in peer-reviewed publications on scleral reinforcement, reflecting more interest in its clinical applications. With favorable biological and biomechanical properties, scleral allograft may be an ideal substrate for an array of new applications and surgical uses.

Keywords: sclera, allograft, biotissue, glaucoma

Background

The history of donor scleral allograft tissue use goes back over half a century as a durable biocompatible material widely used in ophthalmic surgery.[1] Scleral tissue has been used for multiple purposes in ophthalmology, predominantly in glaucoma surgery, such as glaucoma drainage devices (GDDs) implantation, where a scleral patch is used to cover the tube reducing the rates of erosion.[2–4] Providing structural integrity is also an important indication for scleral graft use, as in conditions where scleral thinning is present with an imminent risk of perforation.[5–7] Unlike donor cornea, scleral allograft tissue is readily available, representing 4–5% of total eye bank tissue allocations, and the use of sectional donor tissue allows the eye banks to maximize the sclera tissue obtained from a single donor.[8] Furthermore, the tissue is immunologically safe and easy to process and transport, with a shelf life exceeding 1year when stored in optimal conditions.[9,10]

Scleral Anatomy

The sclera is a dense connective tissue that corresponds to more than 80% of the outer surface area of the globe, with the main function of providing a firm substrate to protect the intraocular structures.[11] It comprises three layers: episclera, stroma and inner sclera (lamina fusca). The episclera is more of an envelope not inherent to the scleral biomatrix and corresponds to a layer of connective tissue that is highly vascularized. The stroma is the major scleral tissue layer, essentially avascular and acellular. It is composed of a dense collagenous structure, mainly type I and III collagen and proteoglycans.[12] The dense connective tissue provides the sclera the biomechanics properties of being flexible yet durable. The lamina fusca represents

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a thin, avascular, brown layer on the inner surface of the sclera. The sclera thickness varies across the surface from 0.3 mm at its thinnest at the attachment of the rectus muscles to more than 1.2 mm posteriorly.[11,12] There are significant variations in scleral thickness and rigidity between individuals.[13] Previous studies have shown that the sclera composition and elasticity are variable in normal patients and are altered with aging.[13,14] The sclera tissue is hydrophilic, porous, and has a relatively high permeability, which is why transscleral drug delivery is under increasing interest.[15,16]

Scleral Allograft Properties

Scleral allograft tissue has important properties, making it useful and desirable as a bio-tissue substrate for structural reinforcement and reconstruction. Many of the advantages of the use of sclera tissue are being readily available from donor eyes, easy to manipulate, and well tolerated with minimal inflammatory reaction.[6,12] The essential acellular nature is important as it has limited risk of having antigen-presenting cells and has a low immunogenic profile, further enhanced by the sterilization process.[17,18] Scleral allograft (Figure 1) is non-biodegradable and has high structural integrity, a high tensile strength and non-brittle, leathery physical properties, making it resilient and an ideal substrate for structural reinforcement.[12,19] Its flexibility and conformability enable a wide range of surface applications when used to patch graft a scleral wall defect. In addition, the sclera is highly permeable and hydrophilic, with important properties regarding aqueous conductivity for bio-stenting and outflow maintenance and scaffolding.[15,16] It is homologous and native to the surrounding tissue when used for endo- or epi-scleral reinforcement. This happens to be of further importance regarding implant fibrosis as homologous scleral tissue has one of the lowest index of material stiffness mismatch when implanted adjacent to the scleral surface, thereby reducing the potential for fibrosis and macrophage activation as compared to synthetic implants composed of rigid materials like metal or plastic.[20,21]

Sterilization and Storage of Scleral Allograft

The donor selection and screening process follows U.S Food and Drug Administration (FDA) regulations and the Eye Bank Association of America (EBBA) standards. A serum sample from the donor is tested for HIV, Hepatitis B and C and Syphilis.

It is important to ensure that the tissue sterilization and storage method does not change the structural properties of sclera, which could compromise its performance. The ideal method should combine the maximum capacity to eliminate pathogens while keeping the scleral integrity as much as possible. Sterilization with gamma radiation allows for reliable long-term storage and has become the standard method for sclera storage.[22] The use of gamma-irradiated tissue has the advantage of inactivating most pathogens, decreasing the risk of disease transmission, and is a highly standardized process consistent with the sterilization of most medical devices.[23] Several methods have been described for scleral tissue storage, including short-term storage (up to 30 days) using sterile saline with gentamicin and longer storage, allowing the tissue to be easily stored for up to 2 years.[9,10,24,25] The last can be achieved using glycerin, 95% ethanol or freeze-drying. Glycerin has traditionally been used for scleral storage, having a great ability to maintain structural integrity compared to other storage methods.[17] However, it can be ineffective for the inactivation of some organisms, like specific viruses and prions. Alcohol preservation (ethanol 70–95%) offers robust tissue sterilization and is a simple, cost-effective

Figure 1 Scleral patch graft.

methodology. Soaking the tissue for 40 minutes in basic saline solution before clinical use is recommended, effectively removing all traces of ethanol.[10]

Clinical Applications of Scleral Allograft for Ab-Externo Reinforcement

Several alternatives exist, but sclera tissue remains popular due to its strength, availability, ease of use, and storage. Conventional use over the last several decades has been mostly through an ab-externo approach to reinforce the ocular surface and the integrity of the scleral interface/wall and protect the ocular tissues from the erosive effects of implantable hardware such as glaucoma drainage devices.[1,2,5]

Use for Scleral Reinforcement of Glaucoma Drainage Devices

For a few decades, glaucoma drainage devices (GDD) have been used to surgically control IOP in patients with glaucoma. Amongst the complications associated with these devices, tube exposure is potentially vision-threatening and poses a risk for the development of endophthalmitis.[23] Rates of tube exposure in the literature range from 3–9% in the first 5 years,[1–4] with younger age and preoperative inflammation considered as risk factors for an erosion.[26] The rates of exposure between different GDDs appear to be similar.[27]

Using a biotissue, like sclera, to cover the tube can potentially decrease conjunctiva erosion.[28] Other tissues, such as the cornea, pericardium, fascia lata and dura mater, are also available.[29] Choosing the ideal tissue for tube coverage is critical, and sclera seems to provide a firm and durable coverage for GDD. A study comparing the pericardium and sclera graft for tube cover showed that patch thinning occurred faster in the pericardium group (33 months) compared to sclera (66 months).[2] Scleral graft has also been used during scleral fistula closure at the time of tube repositioning during surgical revision.[30] One specific disadvantage of the scleral graft is the thickness and color, which may be a cosmetic issue.

Use for Scleral Reinforcement in Post-Trabeculectomy Revision Procedures

Scleral allograft can also be helpful in trabeculectomy revision procedures. Chronic thinning and disintegration of the scleral flap and conjunctival tissues after trabeculectomy can result in late bleb leakage, and antifibrotic adjuvants can increase the risk of those complications.[31] Managing hyperfiltration or bleb leakage is always a challenge, and using a scleral patch graft in trabeculectomy revisions can offer a long-term solution for hypotony. Previous studies have shown good outcomes when using a scleral patch associated with conjunctiva advancement for managing late bleb leaks and hypotony for overfiltration.[32,33]

Use for Scleral Reinforcement Due to Scleral Thinning and Necrosis

Scleral thinning is a well-reported complication following pterygium excision, retinal detachment repair, systemic vasculitis, scleritis, high myopia, or trauma. In rare cases, it results in staphyloma formation, scleral perforation, and uveal exposure.[5,7,8] Reinforcement of thin or perforated sclera is necessary and is considered an ophthalmic emergency. Scleral allograft has been successfully used to treat corneoscleral pathology such as scleral perforations, corneoscleral melts, scleromalacia, as well as in the repair of intercalary staphyloma, which forms between the ciliary body and the limbus in patients with Marfan's syndrome.[6,34,35]

Use of Donor Sclera to Coat Orbital Implants

The sclera is also widely used in oculoplastics for wrapping orbital implants after enucleation.[36] Coating orbital implants with scleral graft reduces the risk of implant exposure and rejection.[37]

Use of Donor Sclera in Oculoplastic Applications

Scleral allograft has been used in the treatment of cicatricial entropion. While not a common application today, surgical splicing of the graft to the tarsoconjunctival layer of the entropic eyelid allows spontaneous epithelialization and anatomic recovery of the eyelid architecture[38,39] Scleral allograft has proven to be excellent substrate as a spacer for eyelid reconstruction surgery in cases of upper and lower lid retraction.[40] A retrospective review by Feldman et al[41] on

the use of donor sclera as a spacer graft in eyelid retraction surgery is informative of the long term outcomes with scleral allograft as well as the evolution of the surgical technique over time.

Novel Applications of Scleral Allograft for Ab-Interno Reinforcement

More recently, ab-interno surgical applications are opening new possibilities for advanced surgical techniques allowing intraocular use of scleral tissue. When minimally modified to precise geometries and delivered with ab-interno micro-interventional instrumentation, the scleral bio-tissue can provide durable and non-resorbable structural reinforcement for glaucoma and retina surgical applications. The biomaterial properties of the scleral graft can enable a new frontier of clinical utility for both conductive and/or occlusive scaffolding with intraocular implantation.

Retinal Applications

In the surgical retinal field, scleral patch can be used to manage optic disc pit maculopathy.[42] In a case series, the use of autologous scleral patch has shown to be well tolerated in the posterior segment when implanted into the optic disc pit (ODP) to occlude ("plug") subretinal cerebrospinal fluid leakage and resolve the fluid accumulation.[42,43] Better resolution of the maculopathy was seen when vitrectomy with internal limiting membrane (ILM) peeling was combined with ODP plug compared to the procedure without the plug.[43] Another example is an ab-interno endoscleral patch graft for a leaking sclerotomy that could not be sutured closed because of necrosis of the surrounding tissue.[44]

Glaucoma Applications

In glaucoma, the uveoscleral outflow can be enhanced by creating a cyclodialysis cleft to surgically control intraocular pressure, first described by Heine in 1905.[45] While effective in lowering the IOP, durability was limited due to spontaneous closure of the cyclodialysis cleft.[46] Devices targeting the suprachoroidal space were developed to prevent cleft closure and may offer more predictable and sustained outcomes.[47–49] Synthetic suprachoroidal devices such as polyimide stents showed long-term outflow enhancement and sustained IOP reduction but were associated with accelerated endothelial cell loss in the cases where the implantable hardware was anteriorized and close to the cornea.[50] Further challenges with synthetic implants in the suprachoroidal space may be in part due to the significant stiffness mismatch between synthetic materials such as metal and plastic and the surrounding ocular tissue.[51,52]

Using scleral allograft to enhance uveo-scleral outflow is another promising clinical application of ab-interno scleral tissue reinforcement (Figure 2). Homologous conforming bio-tissue has potential advantages over rigid implantable hardware devices because of its porosity, hydrophilic aqueous permeability and structural stability without the fibrosis-inducing bio-mechanical mismatch to the surrounding native tissues. Intraocular implantation of a scleral allograft in the supraciliary space has been shown to structurally enhance and maintain the suprachoroidal outflow because of the conductive and reinforcing properties of the allograft acellular matrix (Figure 3).[53] Early results are encouraging in that respect - in a study with 12 months of follow-up, flexible conforming bio-tissue was well tolerated without anterior

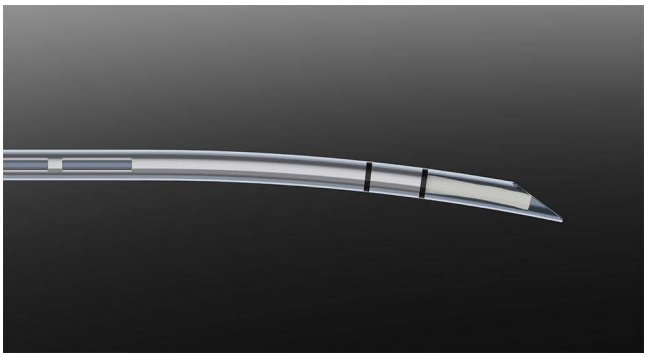

Figure 2 The scleral allograft microtrephined into a minimally-modified, bio-scaffolding implant. Photo courtesy with permission from Iantrek.

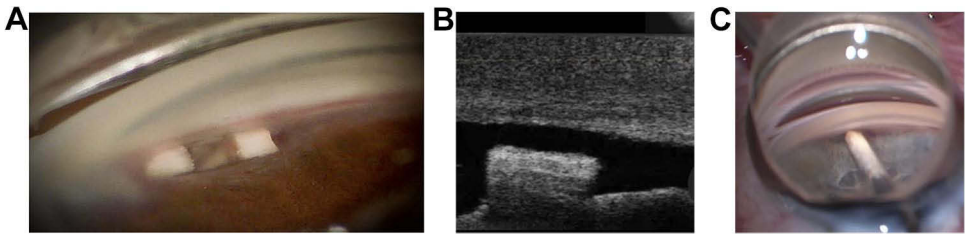

Figure 3 Scleral allograft used for intraocular reinforcement. (**A**) Gonioscopic image of two allograft spacers used for cyclodialysis bio-scaffolding and reinforcement. (**B**) OCT image of an allograft intraocular spacer (**C**) Scleral allograft bio-scaffolding spacer during ab-interno surgical deployment.

chamber inflammation, anterior synechiae or corneal adverse events. The allograft remained well positioned within the cyclodialysis cleft with no evidence of migration.[53]

Different surgical techniques and allograft formulations have been developed in the effort to augment uveo-scleral outflow. In one application, scleral allograft tissue is minimally modified for optimal aqueous permeability which can allow its use as a conductive bio-stent in the supraciliary space.[53] In another formulation, allograft tissue is processed to maximize the structural integrity of the collagen matrix so it can be implanted as a scaffolding and reinforcement material of the cyclodialysis thus creating a durable supraciliary filtration reservoir for sustained aqueous outflow.[53] In the former approach, the primary outflow mechanism is through the porous bio-stent implant while in the latter, the outflow is mainly through the reinforced endogenous cyclodialysis.

Ab-interno scleral reinforcement may have other future applications for structural support, stabilization, stenting and other conductive or occlusive interventions in the management of hypotony, over-filtration or for enhanced aqueous outflow.

Conclusions

Scleral allograft has demonstrated excellent safety as an inert biocompatible and non-biodegradable material that can provide tectonic support and preserve the integrity of the scleral interface, as well as protect the ocular tissues from the erosive effects of implantable hardware such as glaucoma drainage devices. Novel applications of homologous scleral allograft for ab-interno reinforcement and scaffolding allow intraocular use of scleral tissue and have demonstrated promising results in the surgical treatment glaucoma and retina conditions.

Disclosure

Dr Ticiana De Francesco is a consultant to Iantrek, outside the submitted work. Dr Tsontcho Ianchulev reports patents for and is the founder of Iantrek Inc. Dr Douglas Rhee is a consultant to Iantrek, during the conduct of the study; grants from and a consultant to AbbVie / Allergan, Alcon, Ocular Therapeutix, and Avellino, outside the submitted work. Dr Louis Pasquale is a paid consultant to Twenty Twenty. Dr Ike Ahmed is a consultant to Iantrek. The authors report no other conflicts of interest in this work.

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