



REVIEW ARTICLE

# Review of Patch Graft Uses in Ophthalmology

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## ABSTRACT

The use of patch grafts in the field of ophthalmology has continued to evolve over the last century. Patch grafts are invaluable to reinforce ocular structures, protect implants, facilitate healing, and more. Corneal and scleral tissues, pericardium, dura mater, and amniotic membrane have historically been used as materials for patch grafts. Each material provides its own variation in tensile strength, immunogenicity, resorption, and cosmesis. These variations are important to consider when selecting a graft for a wide variety of conditions, including corneal perforation and melt, scleral melt, and the covering of glaucoma drainage device tubes. The selection of a graft material is also often influenced by the clinical scenario, cost, availability and surgeon preference.

Corneal and scleral grafts have remained a common choice due to their low rejection rates and known structural integrity. Amniotic membrane grafts are notable due to their anti-inflammatory properties and are commonly used in an adjunctive fashion. Tenon's patch graft is a relatively new option that has gained popularity due to accessibility, affordability, success rates, and lack of rejection due to its autologous nature. Multiple comparative studies have shown no significant difference in exposure rates for donor sclera, cornea, and pericardium when used in glaucoma drainage device surgery.

Biodegradable materials like Ologen (Aeon Astron Leiden, The Netherlands) and synthetic grafts, such as polytetrafluoroethylene, may represent innovative alternatives to traditional tissue grafts. There is now a newer alternative option, CorNeat EverPatch (CorNeat Vision, Ra'anana, Israel). Ongoing evaluations and research are needed to continue evaluating efficacy, accessibility, cosmetic outcomes, complications, and healthcare costs as surgical techniques and material sciences advance over time.

## Introduction

The origin of patch grafts can be traced back to what was considered the first successful corneal transplant in a case performed by Eduard Zirm, which opened the door to the development and use of patch grafts in the field of ophthalmology such as the corneal graft which is still used to this day <sup>1</sup>. Zirm's landmark case demonstrated the potential use of corneal grafts. Patch grafts have continued to evolve over time as far as uses and types of graft material. The mid-twentieth century saw a lot of this exploration of different uses and materials, such as the use of autologous sclera for corneal perforation in 1946 <sup>2</sup>. Historical materials as reviewed above also include pericardium, fascia lata, dura mater and amniotic membrane.

Amniotic membrane was tried early for transplantation. In the 1940s, de Roth demonstrated the use of amniotic membrane transplantation (AMT) for ophthalmic applications in conjunctival defects <sup>3</sup>. His work demonstrated good outcomes when compared to the widely used alternative, rabbit peritoneum, but fell out of favor over time as fresh amniotic material was difficult to obtain, preserve, and carried a risk of infection. Corneal and scleral grafts also faced issues with preservation, so they were only used autologously or as immediate allografts. The latter part of the 20<sup>th</sup> century saw the increased capability of preservation and distribution of tissues, as tissue banks emerged increasing accessibility and use of AMT, corneal, and scleral grafts <sup>4,5</sup>. Some other tissue grafts had emerged such as lyophilized cadaveric dura mater in the 1970s, but this fell out of favor due to the realization of the increased risk of graft-associated Creutzfeldt-Jakob disease in the 1980s <sup>6</sup>. During the late 1990s, the use of cadaveric pericardium began to gain prominence in the field as studies showed the grafts appeared to be well-tolerated <sup>7</sup>.

Since the late 1990s, research into the use of synthetic materials such as polycaprolactone and polytetrafluoroethylene nanofibers as an alternative to biological tissues for patch grafts has been performed. Continued research into 2010 has also led to the development of biodegradable materials to be used as an option for patch grafts such as a collagen matrix called Ologen <sup>11</sup>. In 2023, the U.S. Food and Drug Administration approved the CorNeat EverPatch as the first synthetic non-degradable tissue substitute simulating cornea for ophthalmologic surgeries <sup>8,9,10</sup>. Grafts can be acquired from tissue banks and from eye supply companies and often now have longer shelf life due to processing improvements. The indications for the use of patch grafts have continued to expand overtime. Common indications involve multiple eye conditions where tectonic grafts or partial thickness grafts are used and sewn in.

As far as current trends in the field, many factors will influence the choice of material such as the indication, surgeon preference, patch thickness, availability, cosmesis, and cost. There are many indications as alluded to above for patch graft use in ophthalmology, but the same general principles remain throughout regardless of

the choice of material: restoring the integrity of the structure, preventing subsequent damage, promoting healing, and protecting underlying structures or devices with Tenon's being the newest tissue used <sup>2,19,20</sup>.

## Patch Graft Materials and Current Grafts

### CORNEA

Since the inception of patch grafts, they continue to be used with corneal conditions. Corneal perforations and severe thinning commonly due to infectious keratitis, immune-mediated conditions, or trauma are among the indications. The use of grafts in these cases is to attempt to restore the strength and integrity of tissue while providing a form of protection as well to prevent further damage <sup>12,13,14</sup>. Scleral melt and necrotizing scleritis which may be seen post-operatively for pterygium surgery, in immunological conditions, and infections also require grafts with the intent to strengthen the thinned sclera and reduce the risk of perforation <sup>2,15,16</sup>. In glaucoma, corneal grafts have been used to reinforce trabeculectomy sites, in the sclera, when there is hypotony due to inadequate remaining scleral tissue to resist aqueous flow from the inside of the eye to the subconjunctival space <sup>48</sup>.

Different materials are often used based on the indication. Management of corneal perforation often depends on the size, location, cause, and severity of the defect. A traditional method for treating corneal perforations includes corneal patch grafts via both lamellar (partial thickness) and tectonic (full thickness) grafts <sup>12,13</sup>. Lamellar corneal patch grafts attempt to restore the structural integrity of the cornea as the graft tissue material is the same as the target <sup>21</sup>. Amniotic membrane grafts (AMG) are often used in combination with others because of its anti-inflammatory nature as it lacks immunogenicity. It is known to reduce scarring and is anti-angiogenic, which aids in reducing vision obscuration and loss. AMG also promotes re-epithelization of the corneal surface, regaining tissue that has been lost <sup>22,23,24</sup>.

More recently, new tissue has gained popularity for corneal perforations, especially in emergent situations where donor tissues are not readily available or where cost is a major factor. Tenon's patch graft (TPG), an autologous method of retrieving graft tissue from Tenon's capsule (fascia bulbi), has been shown to be a safe and cost-effective way to manage corneal perforations. Due to its autologous nature, it provides protection from immune system mediated damage <sup>19,20</sup>. Several options exist in situations of corneal melt and grafts are sometimes used in combination with each other. As with corneal perforation, TPG is a viable option for corneal melts, especially in emergent situations or when donor corneal grafts are not readily available as is with the case of perforations. It has been described for keratoprosthesis, artificial cornea, cases <sup>25</sup>.

### SCLERA

Several materials exist for the treatment of scleral defects. Human donor sclera from an eye bank is naturally used as it is known to provide effective reinforcement and has a low risk of complications, as it is

the same tissue<sup>16,26</sup>. These defects could involve revisions of trabeculectomy scleral flap to treat hypotony as can pericardial tissue<sup>50</sup>. Processed scleral patch grafts with longer shelf life can be used for infectious and noninfectious scleral defects and can be used with or without AMG. This is a viable option when donor scleral grafts are not available<sup>16,27</sup>. CorNeat ever patch is also useful for this and is suggested to never degrade.

#### GLAUCOMA DRAINAGE DEVICE TUBES

Grafts are used to prevent tissue erosion by covering glaucoma drainage device (GDD) implant tubes. This is done prophylactically with the intention to reduce the risk of conjunctival erosion and therefore tube exposure and subsequent complications<sup>2,17</sup>. To be all inclusive, the use of autologous or human donor sclera, bovine and human pericardium, dura mater, donor cornea, autologous fascia lata, acellular dermal graft, buccal mucosa, autologous tragal perichondrium, autologous tenon, amniotic membrane, porcine small intestinal submucosa, and biodegradable implants like Ologen have been reported in the literature for use in glaucoma tube implant surgery<sup>18</sup>. Current common options used include tissue-banked and processed cornea, sclera, and pericardium<sup>17</sup>. Newer biosynthetic material available includes the Ologen collagen matrix and synthetic material like CorNeat ever patch<sup>28</sup>. However, early clinical reviews have shown that the CorNeat EverPatch has significantly increased early conjunctival complications leading to exposure when compared to processed irradiated donor corneal patch grafts<sup>10</sup>.

The author with others reviewed a single surgeon's use of commercial scleral patches (Halo) versus Ologen to cover GDD tubes and found no statistical difference in the rate of erosion over the tube (3.6% for sclera N = 56 and 9.5% for Ologen N = 146) or other difference other than higher cost for Ologen at over 24 months of follow up. *Unpublished data: European Glaucoma Society poster abstract not presented as 2000 meeting cancelled during COVID*. Again, when based on similar efficacies, the choice is often influenced by physician preference, availability, cost, patch thickness, and cosmesis<sup>17</sup>. The concept of covering a GDD tube can be applied to other materials that erode through conjunctiva such as scleral buckles<sup>29</sup>.

#### **Comparative properties** thickness, tensile strength, resorption, immunogenicity

Scleral tissue is considered a high-tensile strength, flexible material that is easy to mold for the purposes of scleral defects due to its dense collagen structure. This makes scleral grafts useful for providing strong tectonic support and maintaining the integrity of the eye<sup>2,16</sup>. The thickness of the sclera varies from 0.3 mm to 1.2 mm throughout the eye<sup>30,31</sup>. The thickness of donor sclera can vary based on donor and location the scleral tissue was extracted from, but the average thickness of the whole sclera has been reported to be  $670 \pm 80 \mu\text{m}$ <sup>32,33</sup>. When compared to corneal tissue, it is considered more readily available and more accessible. It is also known to be immunologically safe due to its low immunologic profile with minimal inflammatory reaction<sup>30</sup>. It can be too thick causing cosmetic issues.

#### Corneal tissues for the center

Corneal tissue is often used to patch areas of perforation or severe thinning. The thickness of the graft will vary depending on whether it is intended to be full-thickness or lamellar. Full-thickness grafts often match the patient's corneal thickness, while lamellar grafts are thinner and will involve less of the donor corneal stroma. The total thickness of each graft will also depend on the donor as this will vary biologically. Some surgeons like the increased clarity of this tissue versus sclera. The average central thickness of donor corneas is  $550 \pm 63$  when measured by optical coherence tomography. Due to the cornea's collagen lamellae structure, it tends to have high tensile strength which provides durability and support. Because the cornea is considered immune-privileged, since it is avascular, corneal tissue grafts have low immunogenicity, reducing the risk of rejection compared to other materials<sup>34,35</sup>.

#### Pericardium

The use of this patch was likely adopted from its use in vascular surgery. Tissue bank supplied tissue and some commercially supplied can be too thin but can be doubled<sup>36</sup>. Processed commercial grafts can be whiter appearing than sclera which can affect cosmesis.

#### **Outcomes and Complications**

##### Tenon's patch

Tenon's patch graft has been shown to have a high rate of success in cases of corneal perforation and descemetocoele. TPG has demonstrated a high success rate ranging from 74-87%<sup>37, 38</sup>. Complications can include graft dehiscence with a flat anterior chamber, graft ectasia, scarring, delayed epithelialization, and wound leaks which can also affect the chamber depth<sup>36,39</sup>. One disadvantage of the use of TPG is when the graft is centrally located in the cornea. It may provide a tectonic solution, but the cornea will require a future keratoplasty for visual rehabilitation due to its opaqueness versus a corneal tissue patch.

##### Cornea

For corneal patch grafts, anatomic/tectonic success was achieved in 63.2-74.6% of eyes where no further surgical intervention was required based on studies. Sharma study found that 59.5% of eyes had functional success due to visual gain. Absolute graft failure was reported in 24.5-26.8% of eyes based on the same two studies<sup>12,40</sup>. Noted complications in these studies include recurrence of primary pathology, graft failure, cataract formation, intraocular pressure rise, recurrent perforations, infectious keratitis, recurrence of herpes simplex keratitis, and graft dehiscence<sup>12, 40</sup>. Tectonic grafts have been noted to have major complications of peripheral anterior synechiae and graft melting<sup>41</sup>.

Erosion rates for corneal patch grafts used for glaucoma drainage devices vary based on processing of the tissue. For corneal tissue that is sterilized by  $\gamma$ -irradiation, a low erosion rate of 2% has been noted<sup>42</sup>. However, for partial thickness corneal grafts, a study found a 6.7% rate for graft melting and a rate of 2.2% for tube exposure. Another study found corneal grafts that were preserved with glycerol were found to have an erosion rate of 1.9%<sup>44</sup>.

### Sclera

Scleral tissue has long been used as patch grafts following GDD surgery. The erosion rate for scleral patch grafts is relatively low and varies by study with a range of erosion rate from 0-3.1% which is comparable to some scleral studies<sup>45,46</sup>.

### Amniotic membrane

The use of amniotic membrane as a patch graft for GDD has a reported success rate of 93% with a rate of tube exposure of 2.27% based on one study. However, it is not frequently used due to concern about its thinness.

### Pericardium

Pericardial tissue is often used as a patch graft for GDD surgery. Preserved human cadaveric pericardium can be sourced either commercially such as Tutoplast (Kateena, Corza Medical, Parsippany, NJ, USA) or can be sourced locally from a tissue bank, rather than an eye bank, as for example LifeNet (Virginia Beach, VA, USA)<sup>17</sup>. Thinning has been shown to be at a rate of 11.3%, but the same study also demonstrated that there was no infection, tube erosion, graft rejection, or inflammation to be noted and considered the thinning to be asymptomatic<sup>7</sup>.

### Polytetrafluoroethylene

Polytetrafluoroethylene (PTFE) is a synthetic material option for patch grafts. It is considered inert and non-antigenic. Originally designed to be used as a pericardial membrane substitute in vascular surgery, it has since been shown to be an effective material for expanding the surface area of GDD. One study demonstrated that the use of PTFE to expand the surface area of Ahmed glaucoma valves resulted in a lower mean IOP, fewer postoperative glaucoma medications required and had a higher complete success rate when compared to a non-expanded group<sup>50</sup>.<sup>51</sup> It remains unknown if it is effective as a patch material. A similar study was done for Ologen over the plate to improve results and it was ineffective<sup>51</sup>.

### **Cost, Access, and Healthcare Considerations: Cosmetic outcomes and patient satisfaction**

When it comes to cosmetic outcomes of patch grafts, corneal patch grafts, specifically those that are derived from small incision lenticule extraction (SMILE), are considered superior to scleral patch grafts. One study demonstrated that the corneal grafts resulted in a thinner appearance in 2.2% of cases when compared to the scleral grafts that had a thinner appearance in 5.5% of cases. The corneal grafts were noted to be less visible under the conjunctiva. Scleral patch grafts are known to be effective but may result in a less esthetically pleasing appearance when compared to corneal patch grafts<sup>52</sup>. Amniotic membrane grafts should also be considered as an option cosmetically due to the clear nature of the tissue.

### Cost

Centers for Medicare in the United States of America bundle the billing of the patch graft with the implantation of the GDD to encourage surgery sites and surgeons to choose lower cost grafts. This is what prompted the author

to investigate the locally source pericardial patch material and make a comparison with the other patches being used locally. The cost was lower and yet the efficacy remained competitive<sup>17</sup>. Several studies have looked to compare which graft is better as far as current conventional materials. Muir et al. looked at the rate of tube exposure between eye bank sclera, and Tutoplast sclera pericardium (Kateena, USA) and found no significant difference. Smith et al. compared eye bank sclera, dura, and pericardium and found no significant difference. A study from Zalta compared the erosion rates in donor dura and sclera and found no significant difference<sup>45,53,54</sup>. Multiple sources note that the choice of patch graft material should consider cost, especially since it has been demonstrated that there is not a significant difference in efficacy, although more research is needed. Autologous grafts such as TPG are a strong choice when considering affordability along with locally sourced patches<sup>18</sup>. Many sites in the world do not have tissue banks or commercially available grafts.

### **Future Directions**

Research and development are ongoing in the field to develop new synthetic materials as options for patch grafts, many of which look to reduce the cost of patch grafts as they eliminate processing to eradicate possible germs, increase accessibility, improve cosmetic results, and possibly increase shelf life and availability. One example is the CorNeat EverPatch. <https://www.biospace.com/corneat-everpatch-hits-the-us-market-farewell-to-traditional-ocular-tissue-grafts> This graft is still under clinical investigation to find where it may be of best use. Polycaprolactone (PCL) nanofibers are also currently being researched as an alternative to biologic tissue grafts. With the intent of repair for melting, thinning, and perforation, research in rabbit eyes have demonstrated merging between the host tissue and PCL fibers. However, clinical data in humans are limited<sup>8</sup>. Synthetic materials may indeed be longer lasting than biological patches which retain no blood supply and may more slowly degrade.

### **Conclusion**

The purpose of patch grafts in ophthalmology is to provide tectonic support, protection of intraocular structures, and facilitate healing. They are used for corneal and scleral conditions and in glaucoma drainage devices surgery. The selection of a graft material is influenced by the indication, availability, cost, and in some cases, cosmetic outcome. Comparative studies have found no significant difference in tube exposure among common graft materials for glaucoma drainage device (GDD) coverings. Tenon's patch grafts have gained attention as data has shown them to be an effective, affordable, and accessible autologous option, especially in emergencies and resource deficient settings. The emergence of synthetic materials may provide increased accessibility but has raised concerns due to complication and cost.

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