



 AmnioGraft®

 AmnioGuard®

Rapid Recovery.
Lasting Benefit.

Biologic ocular
transplantation tissue grafts
help restore your patients'
eyes to normal and improve
their quality of life.

AmnioGraft® and AmnioGuard® have changed the way eyes heal.

As an eyecare industry partner, we understand you have many options when choosing products and techniques to optimize patient outcomes. Knowing their benefits and limitations are key in determining the best option. BioTissue strives to manufacture biologic tissue products that give you functional and therapeutic benefits that lead to better outcomes and happier patients.



The Challenge with the Conventional Treatments

Autografts



- Requirement for donor site excision¹
- Donor-site hypersensitivity or morbidity^{2,3}
- Time consuming⁴⁻⁶
- Limited quantity
- Limited graft size⁶
- Requirement for retrobulbar anesthesia in some cases⁶

Dehydrated AM



- Reduced structural integrity⁷
- Compromised properties^{8,9}
- No or limited presence of HC-HA/PTX3^{7,10}
- Lack of supporting ophthalmic clinical studies

Gamma-Irradiated Sterile Cornea



- Irradiation alters biomechanical and structural properties of the corneal surface¹¹⁻¹³
- Transplantation procedure is complex¹⁴
- May not retain integrity after aqueous drainage device surgery¹⁵

Human Pericardium Patch Graft



- Significant tube exposure due to graft thinning and melt¹⁶
- Opaque patch graft makes it difficult to diagnose any tube migration, retraction, kinking and twisting¹⁷
- May be too thin for desired application¹⁸

Bioengineered Spacer Graft



- Minor complications including cyst formation, infection, chemosis, pyogenic granuloma, and corneal abrasion contributing to reoperation in 5% of cases¹⁹
- Unsightly and palpable to the patient²⁰
- Possible immunogenic rejection²¹
- Prone to shrinkage²²⁻²⁵
- Takes longer to vascularize compared to mucosal graft^{22,25}

Regenerative Healing with Amniotic Membrane

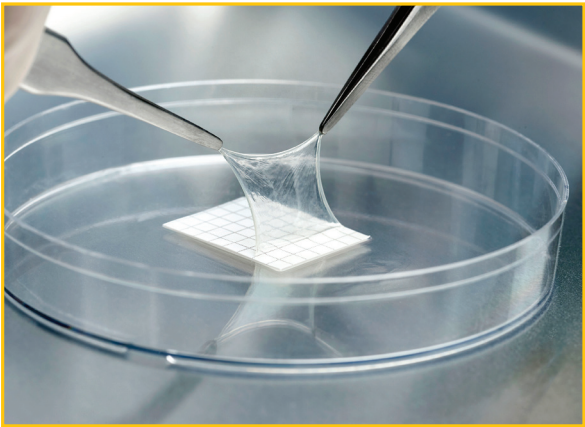


AmnioGraft and AmnioGuard are the only ocular transplantation grafts offering CryoTek® cryopreserved amniotic membrane tissue to help speed post-op recovery, prevent disease recurrence, and optimize long-term patient outcomes.^{3,27-29,31}

Our CryoTek process preserves naturally occurring biological components, including HC/HA-PTX3 complex, which are essential for quality healing. HC/HA-PTX3 suppresses scarring, inflammation and angiogenesis while creating an environment that stimulates regenerative healing.^{7,9,26}

Our biologic ocular transplantation tissue grafts help your patient heal better and faster.

BioTissue's cryopreserved amniotic membrane products are the only amniotic membrane products cleared by the FDA for its therapeutic properties in repairing and healing ocular surface wounds.¹⁰



Comparing AmnioGraft with Conj. Auto and Dehydrated AM

		AmnioGraft	Conj. Auto	Dehydrated
General Properties	Superior Physical Integrity ²⁰	✓	✓	✗
	High Tensile Strength/Elasticity/Durability	✓	✓	✗
	Easy Intra-operative Surgical Manipulation	✓	✗	✗
	Accommodates Any Ocular Defect Size	✓	Limited	✓
Clinical Properties	Facilitate Healing	✓	✗	✗
	Anti-Inflammatory	✓	✗	✗
	Anti-Angiogenic	✓	✗	✗
	Anti-Scarring	✓	✗	✗
Surgical Outcome	Single Surgical Site	✓	✗	✓
	Minimal Surgical Trauma	✓	✗	✓
	Less than 1% Recurrence Rate ²⁷	✓	✗	?
	Faster & Shorter Surgical Procedure	✓	✗	?
	Minimal Post-operative Discomfort	✓	✗	?
	Time for Cosmetic Recovery	2 weeks	30-60 days	Variables
	Superior Cosmetic Outcome	✓	✗	?
Value Added Services	Reimbursement Support	✓	✗	?
	Clinical Implementation Support	✓	✗	?
	Live Surgical Technique Training Support	✓	✗	?
	Account Services	✓	✗	?

*The surgical outcome with AmnioGraft is significantly based on the surgical technique used²⁷

AmnioGraft

Amniotic Membrane Transplantation Graft

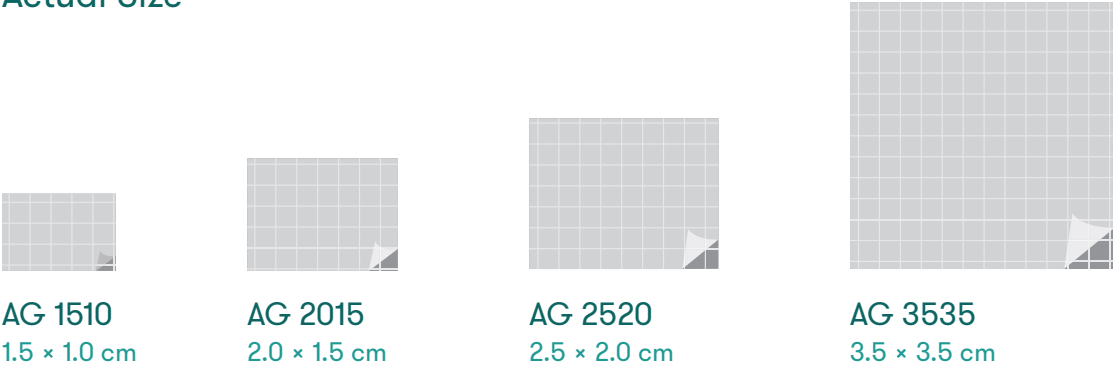
AmnioGraft, an amniotic membrane graft, helps rapidly restore the ocular surface when used during ocular surface reconstruction surgery, especially in indications such as pterygium and Mechanical Dry Eye (MDE), also known as Conjunctivochalasis (CCh).^{3,28,29,31}

AmnioGraft provides greater flexibility amongst a variety of procedures. It’s the only amniotic membrane tissue with high tensile strength that retains intraoperative resilience and workability⁸, ensures reproducible surgical outcomes, and is available in multiple sizes to accommodate different ocular defects—large or small. Its biologic structural integrity is equivalent to fresh tissue.^{7,9}

Post-op recovery time is accelerated, as AmnioGraft reduces inflammation and promotes fast, regenerative healing, typically in 2-3 weeks.^{27-31,33-34}

Long-term, patients treated with AmnioGraft are less likely to have disease recurrence. A recent retrospective study of over 280 patients showed a **recurrence rate of less than 1%** after surgical excision of primary, single-headed pterygium with cryopreserved AM.²⁷

Shown as
Actual Size



Also available in: AG 5050 5.0 × 5.0 cm, AG 10050 10.0 × 5.0 cm
Average thickness: 75-150 µm⁹

AmnioGuard

Ultra-thick Graft Derived from Umbilical Cord

AmnioGuard is the ultra-thick tissue graft that suppresses inflammation, promotes healing, and provides more durable tensile strength to avoid surgical challenges related to conjunctival tumor excisions, glaucoma drainage device implantations, and oculoplastic reconstructions.^{37-39, 42}

Studies have shown AmnioGuard as an excellent alternative to other homologous tissue grafts for ocular surface reconstruction and management of Anophthalmic socket contracture.³⁹
It helps achieve 100% epithelialization, without wound dehiscence and excellent prosthesis fit at final follow-up with no clinically significant complications.³⁹

Shown as
Actual Size



Average thickness: 500-900 µm⁹

AmnioGraft and AmnioGuard are Adjunct Therapies for:

- AminioGraft
- AminioGuard
- Both



Corneal Indications

- Persistent Epithelial Defects
- Ulcers
- Descemetocoele or Perforation
- Neurotrophic
- Bullous Keratopathy
- Band Keratopathy



Conjunctival Indications

- Primary & Recurrent Pterygia
- Pinguecula
- Removal of Tumors or Lesions
- Conjunctivochalasis
- Superior Limbic Keratoconjunctivitis
- Symblepharon
- Leaking Blebs
- Shunt Tube Exposure Prevention
- Limbal Stem Cell Deficiency

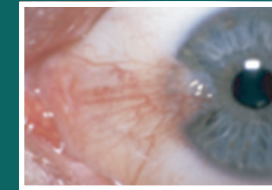


Other Ocular Surface and Oculoplastics Indications

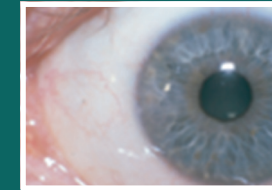
- Chemical and Thermal Burns
- Stevens-Johnson Syndrome / Toxic Epidermal Necrosis
- Pemphigoid
- Marginal Entropion Repair
- Scleral Melt/Ischemia
- Fornix & Socket Reconstruction
- Strabismus Repair
- Medial Canthal Reconstruction



Pterygium: The TissueTuck™ Technique



Pre-Op



1 Year Post-Op

Lower Recurrence, Optimal Healing

- AmnioGraft easily tucks into position to recreate the semi-lunar fold, “sealing the gap” between the conjunctiva and Tenon Capsule to help prevent reinvasion of residual fibrovascular tissue
- Creates only one wound

Optimizes Surgical Outcomes

Long-term recurrence of
<1%²⁷

Superior cosmetic outcomes as early as
7 days

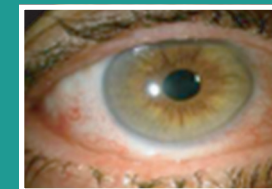
Cuts procedural time by
30 min.

Recurrence rate with conventional pterygium surgery is as high as 88%²⁷

Conjunctivochalasis (CCh): The Reservoir Restoration Technique

Mechanical Dry Eye (MDE), also known as CCh is one of the most commonly underdiagnosed/misdiagnosed ocular surface diseases. Dry eye syndrome patients who are not responding to current interventions should be evaluated for CCh.

Conventional CCh procedures may further diminish the tear reservoir.³⁶



Pre-Op

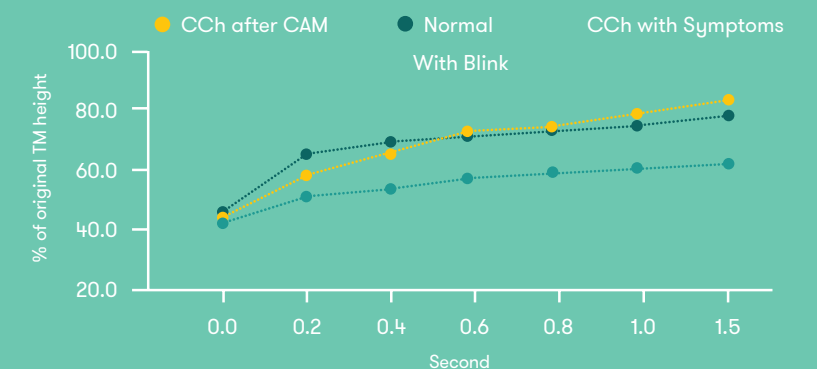


1 Year Post-Op

AmnioGraft Addresses the Underlying Cause of CCh^{28,31,40}

- Efficiently replaces the degenerated Tenon's fascia and excised conjunctiva
- Natural properties support restoration of the tear reservoir to a healthy state
- Restores tear flow from fornix to tear meniscus

Recovery Rates After Reservoir Restoration Procedure^{40*}



“These results suggest a high correlation between symptomatic relief and rapid recovery of the tear meniscus height after maximal depletion in CCh patients as early as the first post operative day.”⁴⁰

Explore Techniques and Results

BioTissue.com/AmnioGraft
BioTissue.com/AmnioGuard

Including:

Lower recurrence and optimal healing in Pterygium:
The TissueTuck Technique

Optimized outcomes in Mechanical Dry Eye:
The Reservoir Restoration Technique

A comparison of cryopreserved amniotic membrane to
conjunctival autograft and dehydrated amniotic membrane

Advanced healing in post-excision of conjunctival tumors

Superior stability in post-glaucoma treatment

Post-oculoplasty optimal healing

Superior alternative to pericardium as a solution for safe
and stable tube shunt coverage

Links to clinical trials and research

Surgical Guides



TissueTuck Procedure for Pterygium



Reservoir Restoration Procedure for
Mechanical Dry Eye (MDE)

References

1. Clearfield E, Muthappan V, Wang X and Kuo IC. Conjunctival autograft for pterygium. Cochrane Database of Systematic Reviews. 2016.
2. Prabhasawat P, Barton K, Burkett G and Tseng SCG. Comparison of conjunctival autografts, amniotic membrane grafts and primary closure for pterygium excision. Ophthalmology. 1997; 104: 974-85.
3. Solomon A, Pires RTF and Tseng SCG. Amniotic membrane transplantation after extensive removal of primary and recurrent pterygia. Ophthalmology. 2001; 108: 449-60.
4. Soliman Mahdy MA and Bhatia J. Treatment of primary pterygium: role of limbal stem cells and conjunctival autograft transplantation. European journal of ophthalmology. 2009; 19: 729-32.
5. Al Fagez MF. Limbal versus conjunctival autograft transplantation for advanced and recurrent pterygium. Ophthalmology. 2002; 109: 1752-5.
6. Alpay A, Uğurbaş SH and Erdoğan B. Comparing techniques for pterygium surgery. Clinical ophthalmology (Auckland, NZ). 2009; 3: 69.
7. Cooke M, Tan EK, Mandrycky C, He H, O'Connell J and Tseng SC. Comparison of cryopreserved amniotic membrane and umbilical cord tissue with dehydrated amniotic membrane/chorion tissuuJWoundCare. 2014; 23: 465-76.
8. Thomasen H, Pauklin M, Steuhl KP and Meller D. Comparison of cryopreserved and air-dried human amniotic membrane for ophthalmologic applications. Graefes ArchClinExpOphthalmol. 2009.
9. Tan EK, Cooke M, Mandrycky C, et al. Structural and Biological Comparison of Cryopreserved and Fresh Amniotic Membrane Tissues. Journal of Biomaterials and Tissue Engineering. 2014; 4: 379-88.
10. Tighe S, Mead O, Lee A and Tseng S. Basic Science Review of Birth Tissue Uses in Ophthalmology. Taiwan Journal of Ophthalmology. 2020; 10.
11. Maslennikova A, Kochueva M, Ignatieva N, et al. Effects of gamma irradiation on collagen damage and remodeling. International journal of radiation biology. 2015; 91: 240-7.
12. Bowes J and Moss J. The effect of gamma radiation on collagen. Radiation research. 1962; 16: 211-23.
13. Chae JJ, Choi JS, Lee JD, et al. Physical and biological characterization of the gamma-irradiated human cornea. Cornea. 2015; 34: 1287-94.
14. Chaurasia S, Das S and Roy A. A review of long-term corneal preservation techniques: Relevance and renewed interests in the COVID-19 era. Indian Journal of Ophthalmology. 2020; 68: 1357.
15. De Luna RA, Moledina A, Wang J and Jampel HD. Measurement of gamma-irradiated corneal patch graft thickness after aqueous drainage device surgery. JAMA ophthalmology. 2017; 135: 941-6.
16. Lama PJ and Fechtner RD. Tube erosion following insertion of a glaucoma drainage device with a pericardial patch graft. ArchOphthalmol. 1999; 117: 1243-4.
17. Singh M, Chew PT and Tan D. Corneal patch graft repair of exposed glaucoma drainage implants. Cornea. 2008; 27: 1171-3.
18. Bogaert J and Francone M. Pericardial disease: value of CT and MR imaging. Radiology. 2013; 267: 340-56.
19. Tao JP, Aokalu VK, Wladis EJ, et al. Bioengineered acellular dermal matrix spacer grafts for lower eyelid retraction repair: a report by the American Academy of Ophthalmology. Ophthalmology. 2020; 127: 689-95.
20. Oestreicher J and Mehta S. Complications of blepharoplasty: prevention and management. Plastic surgery international. 2012; 2012.
21. Korn BS, Kikkawa DO, Cohen SR, Hartstein M and Annunziata CC. Treatment of lower eyelid malposition with dermis fat grafting. Ophthalmology. 2008; 115: 744-51. e2.
22. Teo L, Woo YJ, Kim DK, Kim CY and Yoon JS. Surgical outcomes of porcine acellular dermis graft in anophthalmic socket: comparison with oral mucosa graft. Korean Journal of Ophthalmology. 2017; 31: 9-15.
23. Dailey RA, Marx DP and Ahn ES. Porcine dermal collagen in lower eyelid retraction repair. Ophthalmic Plastic & Reconstructive Surgery. 2015; 31: 233-41.
24. Sullivan SA and Dailey RA. Graft contraction: a comparison of acellular dermis versus hard palate mucosa in lower eyelid surgery. Ophthalmic Plastic & Reconstructive Surgery. 2003; 19: 14-24.
25. Karesh JW, Fabrega MA, Rodrigues MM and Glaros DS. Polytetrafluoroethylene as an interpositional graft material for the correction of lower eyelid retraction. Ophthalmology. 1989; 96: 419-23
26. Tseng, S. C. (2016). HC-HA/PTX3 purified from amniotic membrane as novel regenerative matrix: insight into relationship between inflammation and regeneration. Investigative ophthalmology & visual science, 57(5), ORSFh1-ORSFh8.
27. Desai N. Outcomes of Tissuetuck Surgery for Primary Pterygium. Paper. 2022 ASCRS ASOA Annual Meeting
28. Kheirkhah A, Casas V, Esquenazi S, et al. New surgical approach for superior conjunctivochalasis. Cornea. 2007;26(6):685-691.
29. Kheirkhah A, Casas V, Blanco G, Li W, Hayashida Y, Chen YT, Tseng SC. Amniotic membrane transplantation with fibrin glue for conjunctivochalasis. Am J Ophthalmol. 2007;144(2):311-3.
30. Tseng S, Espana E, Kawakita T, et al. How does amniotic membrane work? The Ocular Surface. 2004; 2(3):177-187.
31. Georgiadis NS, Terzidou CD. Epiphora caused by conjunctivochalasis: treatment with transplantation of preserved human amniotic membrane. Cornea. 2001; 20(6):619-621.
32. (8). Shay E, He H, Sakurai S, Tseng SC. Inhibition of angiogenesis by HC-HA, a complex of hyaluronan and the heavy chain of inter-inhibitor, purified from human amniotic membrane. Invest Ophthalmol Vis Sci. 2011; 52(5): 2669-2678.
33. Zhang S, He H, Day AJ, Tseng SC. Constitutive expression of inter--inhibitor (II) family proteins and tumor necrosis factor-stimulated gene-6 (TSG-6) by human amniotic membrane epithelial and stromal cells supporting formation of the heavy chain-hyaluronan (HC-HA) complex. J Biol Chem. 2012;287(15):12433-1244.
34. He H, Zhang S, Tighe S, Son J, Tseng SC. Immobilized HC-HA polarizes LPS-activated macrophages toward M2 phenotype. J Biol Chem. 2013; 288(36): 25792-25803.
35. American International Medical University. Conjunctivochalasis: symptoms, diagnosis and management. <https://www.aimu.us/2016/11/25/conjunctivochalasis-symptoms-diagnosis-and-management>.
36. The Ocular Surface Research & Education Foundation. Reservoir restoration procedure. <https://info.biotissue.com/hubfs/EDU-SG-002.%20Ver%201%20-%20CCH%20Reservoir%20Restoration%20Surgical%20Guide.pdf>.
37. Sheha H, Tello C, Al-Aswad L, Sayed M, Lee R. Outcomes of the Shunt Tube Exposure Prevention Study (STEPS), a randomized clinical trial. Ophthalmol Glaucoma. [Online] August 16, 2019.
38. Finger PT, Jain P, Mukkamala SK. Super-thick amniotic membrane for ocular surface reconstruction. Am J Ophthalmol. 2019;198:45-53.
39. Slentz, D. and Nelson, C. (2019). Novel Use of Cryopreserved Ultra-thick Human Amniotic Membrane for Management of Anophthalmic Socket Contracture. Ophthalmic Plastic and Reconstructive Surgery, 35(2), pp.193-196.
40. Huang, Y., Sheha, H. and Tseng, S. (2013). Conjunctivochalasis Interferes with Tear Flow from Fornix to Tear Meniscus. Ophthalmology, 120(8), pp.1681-1687.
41. Slentz D, Joseph S, Nelson C. The use of umbilical amnion for conjunctival socket, fornix, and eyelid margin reconstruction. Ophthalmic Plast Reconstr Surg. 2019. doi: 10.1097/IOP.0000000000001555.[Epub ahead of print]
42. Johnson, Amy, et al. "Understanding the impact of preservation methods on the integrity and functionality of placental allografts." Annals of plastic surgery 79.2 (2017): 203-213.



The time is now to achieve a new standard of care. Together, we can make a difference in eye care management.

