AMNIOGRAFT-G® for Covering Glaucoma Drainage Shunt Tubes

Specifically prepared for covering a wide variety of glaucoma drainage implant/valve tubes:

By Scheffer C.G. Tseng, M.D., Ph.D. and Hosam Sheha, M.D., Ph.D.

Biological Advantages:
- Prevents progressive thinning by encouraging host conjunctival cells to integrate into the graft
- Possesses anti-inflammatory and anti-scarring properties which promote healing

Physical Features:
- Provides strong tectonic support with >300 micron thickness
- Limits mechanical factors of tube exposure by molding easily around the tube eliminating dead space adjacent to the tube
- Facilitates suture lysis with the translucency of AMNIOGRAFT-G®
- Provides a better cosmetic appearance (not opaque)

Easy to Use:
- Easy to suture and handle
- Ready to use without any manipulation

Surgical Technique:
1. Cover the exposed part of the tube with a single AMNIOGRAFT-G®
2. Secure AMNIOGRAFT-G® with four interrupted sutures at each corner with 8-0 Vicryl sutures (or 10-0 nylon sutures depending on surgeon preference)
3. Close the conjunctiva over the graft with either fibrin glue or sutures
4. If there is a conjunctival shortage or buttonhole, apply a piece of AMNIOGRAFT® (Catalog # AG-2015 - F Thickness) to cover the scleral defect then secure the graft with either fibrin glue or sutures

For More Information
Visit www.osref.org for medical education materials and videos on these and many other indications or for more information.

For additional clinical information contact:
Scheffer C.G. Tseng, MD, PhD
Phone: 305-274-1299
E-mail: stseng@ocularsurface.com

Hosam Sheha, MD, PhD
Phone: 305-412-4430 x 219
E-mail: hsheha@biotissue.com

Supplies
- Sutures: 10-0 nylon for bulbar area and 8-0 Vicryl for fornical area, Ethicon BV 130-5, J401G, Somerville, NJ, www.ecatalog.ethicon.com
- Fibrin glue, TISSEEL®, Baxter Bioscience, Deerfield, IL, 888-847-7335, www.tisseel.com

www.osref.org

OSREF Ocular Surface Research & Education Foundation

Postoperative Care

Apply topical antibiotic-steroid eye drops six times a day for 1 week and then taper off within 1 month.

www.osref.org

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AmnioGraft® for Leaking Blebs:

Overview:
Bleb leaks are a serious complication of trabeculectomy with adjunctive use of anti-
metabolites, which may lead to sight-removal complications such as hypotony and endophthalmitis. Amniotic Membrane Transplantation (AMT) is a surgical alternative to mobilize and cover the bleb area with a basement membrane and avascular stroma.

AmnioGraft® as a surgical alternative:
- Conjunctival Integrity: AmnioGraft® is able to support the fragile conjunctival tissue by providing a basement membrane and avascular stroma.
- Suppressed Scarring: AmnioGraft® suppresses exaggerated scarring, resulting in more desirable blebs with lower IOP control.

Surgical Technique:
1. Use a traction suture to expose the bleb area.
2. Cut the AmnioGraft® to size to cover the bleb area.
3. Secure the AmnioGraft® with 9-0 or 10-0 Vicryl or 10-0 nylon sutures to the limbus.
4. Place a single layer of AmnioGraft® under the scleral flap with the stromal side facing posterior to the conjunctival incision and suture it with interrupted 8-0 Vicryl sutures to the limbus.
5. Inspect AmnioGraft® underneath healthy conjunctival posterior to the conjunctival incision and suture it with the underlying Tenon’s capsule using 10-0 nylon.
6. Secure the limbal side of AmnioGraft® with 9-0 Vicryl or 100 nylon sutures to the limbus.
7. Insert AmnioGraft® underneath healthy conjunctival posterior to the conjunctival incision and suture it with the underlying Tenon’s capsule using 10-0 nylon.
8. Pull the conjunctiva over and close with 9-0 Vicryl or 100 nylon using a tapered point needle.

AmnioGraft® for High Risk Trabeculectomy:

Overview:
The success of Trabeculectomy is limited by postoperative fibrosis that leads to bleb failure. Amniotic Membrane Transplantation (AMT) as an adjuvant to conventional techniques prevents wound healing, thereby minimizing scar formation when used with low concentration MMC.

Surgical Technique:
1. Create a limbal-based conjunctival flap.
2. Dissect the scar tissue from the scleral surface.
3. Apply hemostasis using minimal cautery.
4. Create a half-thickness 4x3 mm rectangular scleral flap.
5. Apply MMC (0.02% to 0.04%) under the scleral flap for 2-4 minutes, and rinse the area thoroughly with balanced salt solution for 2 minutes.
6. Perform an internal sclerectomy, followed by peripheral iridectomy.
7. Place a single layer of AmnioGraft® under the scleral flap with the stromal side facing the more posterior portion of the bleb and the wound. Secure the graft using interrupted 8-0 Vicryl sutures at its four corners.
8. Suture the posterior corner of the scleral flap to the sclera under the AmnioGraft® with two interrupted 10-0 Vicryl sutures.
9. Close the Tenon’s capsule with interrupted 8-0 Vicryl sutures.
10. Close the conjunctiva with continuous 10-0 Vicryl suture.

AmnioGraft® for Repair of Conjunctival Buttonholes:

Overview:
Conjunctival buttonholes are unfavorable intraoperative complications of glaucoma surgery. Conventional management includes direct closure with suturing which may include additional multiple buttonholes in the skin and conjunctival surface. AmnioGraft® is able to promote healing and improve immediate and long-term healing properties and is superior to standard closure with fibrin glue.

Surgical Technique:
1. Cut the AmnioGraft graft to the wound and the area of conjunctival deficit plus 2.0 mm surrounding the defect.
2. Secure the graft with glue or sutures.
   a. To suture, place the graft along the wound with the stromal side down covering the more posterior portion of the bleb and the wound. Secure the graft using interrupted or continuous 8-0 Vicryl sutures on a 15 needle using a 15-0 needle to the underlying conjunctiva and Tenon’s capsule to the sclera.
   b. To glue, place the graft onto the conjunctival surface, apply 5-6 drops of 15-0 Vicryl to the stromal side of the graft and 5-6 drops of 0.1% betadine on the conjunctival surface. Flip the graft to the donor planet, stick it out using 0.12 forceps, and smooth it down with a needle hook.

Information
www.osref.org
AmnioGraft® for Leaking Blebs:

Overview:
Bleb leaks are a serious complication of trabeculectomy with adjunctive use of anti-metabolites, which may lead to sight-threatening complications such as hypotony and endophthalmitis. Although leaks can be treated surgically in selected cases with free conjunctival grafts, they show a risk of loss of bleb function. An ideal procedure for repair of a leaking bleb is the one that can both support the fragile conjunctiva and reestablish the bleb function. This can be accomplished with AmnioGraft®.

AmnioGraft® as a surgical alternative:

1. Use a traction suture to expose the bleb area.
2. Cut the AmnioGraft® to size to cover the bleb area.
3. Secure the AmnioGraft® with 9-0 or 10-0 Vicryl or 10-0 nylon using a tapered point needle.
4. Place one layer of AmnioGraft® under the conjunctiva with the stromal side facing posterior to the conjunctival incision and suture it with absorbable material to achieve stability.
5. Apply hemostasis using minimal cautery.
6. Insert AmnioGraft® underneath healthy conjunctive papillae in the posterior part of the conjunctiva with the underlying Tenon’s capsule sutured with 10-0 Vicryl or 10-0 nylon using a tapered point needle.
7. Secure the bleb area with continuous 9-0 Vicryl or 10-0 Vicryl using a tapered point needle.
8. Pull the conjunctiva over and close with 9-0 Vicryl or 10-0 Vicryl using a tapered point needle.
9. Suture the posterior corners of the scleral flap to the sclera through the AmnioGraft® with 9-0 Vicryl or 10-0 Vicryl using a tapered point needle.
10. Close the Tenon’s capsule with interrupted 8-0 Vicryl sutures.

Surgical Technique:

An Amniotic Membrane Transplantation (AMT) without bleb revision for early bleb leaks:
1. Create a limbal-based conjunctival flap.
2. Dissect the scar tissue from the scleral surface.
3. Apply hemostasis using minimal cautery.
4. Insert AmnioGraft® underneath healthy conjunctive papillae in the posterior part of the conjunctiva with the underlying Tenon’s capsule sutured with 10-0 Vicryl or 10-0 nylon using a tapered point needle.
5. Place one layer of AmnioGraft® under the conjunctiva with the stromal side facing posterior to the conjunctival incision and suture it with absorbable material to achieve stability.

AMT-assisted bleb revision for late bleb leaks:
1. Create a traction suture to expose the bleb areas.
2. Cut the AmnioGraft® to size to cover the bleb areas.
3. Secure the AmnioGraft® with 9-0 or 10-0 Vicryl or 10-0 nylon using a tapered point needle.
4. Place one layer of AmnioGraft® under the conjunctiva with the stromal side facing posterior to the conjunctival incision.
5. Apply hemostasis using minimal cautery.
6. Insert AmnioGraft® underneath healthy conjunctive papillae in the posterior part of the conjunctiva with the underlying Tenon’s capsule sutured with 10-0 Vicryl or 10-0 nylon using a tapered point needle.

AmnioGraft® for High Risk Trabeculectomy:

Overview:
The success of trabeculectomy is limited by postoperative fibrosis that leads to bleb failure. Amniotic Membrane Transplantation (AMT) with adjunctive use of anti-metabolites, such as mitomycin C (MMC) or 5-fluorouracil (5FU), achieve limited success in high risk cases and usually are accompanied by complications. AmnioGraft® supersedes the advantages and multiple layers of Amniotic Membrane Transplantation (AMT) in controlling fibrosis while lowering complications such as hypotony and bleb leak at failure.

AmnioGraft® as a superior alternative:

1. Maintenance of a functioning bleb: AmnioGraft® is a natural and anti-angiogenic properties prevents cicatrization and reduces scar formation, thereby maintaining maintenance of the aqueous drainage.
2. Prevention of hypotony: AmnioGraft® placed under the scleral flap acts as a physiological barrier that prevents hypotony that is seen in the early postoperative period.
3. Regression of Rubeosis in Neovascular Glaucoma: AmnioGraft® has anti-fibrotic properties.
4. Suppressed Scarring: AmnioGraft® suppresses exaggerated scar formation, resulting in reduced fibrosis and maintaining a functional bleb.

Surgical Technique:

1. Create a limbal-based conjunctival flap.
2. Dissect the scar tissue from the scleral surface.
3. Apply hemostasis using minimal cautery.
4. Insert AmnioGraft® underneath healthy conjunctive papillae in the posterior part of the conjunctiva with the underlying Tenon’s capsule sutured with 10-0 Vicryl or 10-0 nylon using a tapered point needle.
5. Cut the AmnioGraft® under the conjunctiva 2-3 mm posterior to the incision.
6. Secure the limbal side of AmnioGraft® with 9-0 or 10-0 Vicryl or 10-0 nylon sutures to the limbus.
7. Place AmnioGraft® under the conjunctiva with the area thoroughly with balanced salt solution for 2 minutes.
8. Perform an internal sclerostomy, followed by peribulbar anesthesia.
9. Place a single layer of AmnioGraft® under the scleral flap with the area facing down and suture the membrane to cover the scleral surface around the flap. 2. 10. Suture the AmnioGraft® to the sclera using interrupted 9-0 Vicryl sutures at its four corners.
11. Suture the posterior corners of the scleral flap to the sclera through the AmnioGraft® with two interrupted 10-0 Vicryl sutures.
12. Close the Tenon’s capsule with interrupted 8-0 Vicryl sutures.
13. Close the conjunctiva with continuous 10-0 Vicryl suture.

Pre-Operative Points

1. Evaluate the surrounding problem with the surgical technique shown.
2. If it is not possible to cover the bleb area or if there are increased risks of bleb failure, one may consider using cryopreserved amniotic membrane transplantation.
3. Carefully dissect the scarred tissue underneath the conjunctiva and resume the bleb function. This can be accomplished with AmnioGraft®.

Favorable outcomes can be attributed to a beneficial synergistic effect of AmnioGraft® and antimetabolites, which may lead to sight-threatening complications such as hypotony and endophthalmitis. Although direct closure with conjunctival advancement or surgical revision accompanied with complications. AmnioGraft® suppresses scar formation, resulting in reduced fibrosis and maintaining a functional bleb.

Sealing of Buttonholes:

Overview:
Conjunctival buttonholes are unfavorable intraoperative complications of glaucoma surgery. Currently, the management includes direct closure of surgical incision which may increase additional complications in the area.

AmnioGraft® placed under the conjunctiva of the leaking bleb site while lowering complications such as hypotony and bleb leak at failure.

Surgical Technique:

1. Cut the AmnioGraft® graft to the wound and the area of conjunctival defect plus 2-3 mm surrounding the defect.
2. Secure the graft with glue or sutures:
   a. To glue, place the graft along the wound with the stromal side down covering the conjunctival defect of the bleb and the wound. Secure the graft using a running or interrupted 8-0 Vicryl sutures on a BV needle by the underlying conjunctiva and tenon’s capsule to the sclera.
   b. To glue, place the graft stromal side up on the corneal surface, apply 3-6 drops of fibrin glue to the stromal side of the graft and 2-3 drops of fibrin glue on the conjunctival surface. Flip the graft to the fornix side, peel it using 0.12 forceps, and smoothly it down with a needle hook.
AmnioGraft® for Leaking Blebs:

By Scheffer C.G. Tseng, M.D., Ph.D.

Overview:
Bleb leaks are a serious complication of trabeculectomy with adjunctive use of anti-metabolites, which may lead to sight-threatening complications such as hypotony and bleb leak formation. Although bleb leaks are uncommon in well-maintained blebs, they may lead to loss of bleb function. If more aggressive surgery is indicated in these cases, and there are increased risks of endophthalmitis and sight-threatening hypotony. Although direct closure with conjunctival advancement or surgical revision may resolve bleb leaks, they share the risk of loss of bleb function. An ideal procedure for repairing a leaking bleb is one that can both support the fragile conjunctiva and secure the bleb function. This can be accomplished with AmnioGraft®.

AmnioGraft® as a surgical alternative:
- Conjunctival Integrity: AmnioGraft® is able to support the fragile conjunctival tissue by providing a basement membrane and avascular stroma.
- Suppressed Scarring: AmnioGraft® suppresses exaggerated scarring, resulting in more desirable blebs with better IOP control.
- Halts Bleb Leaks: AmnioGraft® is able to halt bleb leaks and lead to maintenance of a functioning bleb.

Surgical Technique:
Amniotic Membrane Transplantation (AMT) without bleb revision for early bleb leaks:
1. Use a traction suture to expose the bleb area.
2. Cut the AmnioGraft® to size to cover the bleb area.
3. Secure the AmnioGraft® with 9-0 or 10-0 Vicryl or 10-0 nylon using a tapered point needle.

AMT-assisted bleb revision for late bleb leaks:
1. Use a traction suture to expose the bleb area.
2. Create a half-thickness rectangular scleral flap.
3. Carefully dissect the scarred tissue underneath the conjunctiva with the Tenon's capsule using 10-0 nylon.
4. Remove the scleral flap and subconjunctival fluid.
5. Place one layer of AmnioGraft® under the conjunctiva with the stromal side up.
6. Secure the left side of AmnioGraft® with 9-0 Vicryl or 10-0 nylon sutures to the limbus.
7. Insert AmnioGraft® underneath healthy conjunctival tissue near the defect and secure with 10-0 Vicryl sutures.

AmnioGraft® for High Risk Trabeculectomy:

By Hanum Shaha, M.D., Ph.D.

Overview:
The success of trabeculectomy is limited by postoperative failures that leads to bleb failure. Amniotic membrane transplantation (AMT) is used in conjunction with anti-metabolites to seal blebs, thereby reducing the risk of postoperative bleb leak formation. By using low concentrations of MMC, the rate of hypotony and bleb leak or failure can be minimized.

Surgical Technique:
1. Create a limbal-based conjunctival flap.
2. Dissect the flap tissue under the scleral surface.
3. Apply hemostasis using minimal cautery.
4. Create a half-thickness 4×3 mm rectangular scleral flap.
5. Apply MMC (0.5%, 0.2%, 0.5%, or 0.25%) under the scleral flap for 30-60 minutes, and rinse the area thoroughly with balanced salt solution for 1-2 minutes.
6. Perform an internal blebulation, followed by peribulbar injection.
7. Place a single layer of AmnioGraft® under the scleral flap with the stromal side facing the more posterior portion of the bleb and the wound. Secure the graft using a running or interrupted 8-0 Vicryl suture on a 25-gauge needle with the underlying conjunctival 3-4 sutures posterior to the incision.
8. To glue, place the graft stromal side on the corneal surface, apply 3-5 drops of fibrin glue to the graft stromal side and the wound stromal side using a 10-0 Vicryl suture on a 25-gauge needle with the underlying conjunctival 3-4 sutures posterior to the incision.
9. Suture the posterior corners of the scleral flap to the conjunctiva using interrupted 10-0 Vicryl sutures.
10. Close the Tenon's capsule with interrupted 8-0 Vicryl sutures.
11. Close the conjunctiva with continuous 10-0 Vicryl suture.
AMNIOGRAFT-G® for Covering Glaucoma Drainage Shunt Tubes

Specifically prepared for covering a wide variety of glaucoma drainage implant/valve tubes:

By Scheffer C.G. Tseng, M.D., Ph.D. and Hosam Sheha, M.D., Ph.D.

Biological Advantages:

- Prevents progressive thinning by encouraging host conjunctival cells to integrate into the graft
- Possesses anti-inflammatory and anti-scarring properties which promote healing

Physical Features:

- Provides strong tectonic support with >300micron thickness
- Limits mechanical factors of tube exposure by molding easily around the tube eliminating dead space adjacent to the tube
- Facilitatesuture lysis with the translucence of AMNIOGRAFT-G®
- Provides a better cosmetic appearance (not opaque)

Easy to Use:

- Easy to suture and handle
- Ready to use without any manipulation

Surgical Technique:

1. Cover the exposed part of the tube with a single AMNIOGRAFT-G®
2. Secure AMNIOGRAFT-G® with four interrupted sutures at each corner with 8-0 Vicryl sutures (or 10-0 nylon sutures depending on surgeon preference)
3. Close the conjunctiva over the graft with 8-0 Vicryl sutures
4. If there is a conjunctival shortage or buttonhole, apply amniotic sheet over graft (Catalog # AG-2015 - F Thickness) to cover the scleral defect then secure the graft with either fibrin glue or sutures.

www.osref.org

OSREF Ocular Surface Research & Education Foundation

Postoperative Care

Apply topical antibiotic-steroid eye drops six times a day for 1 week and then taper off within 1 month.

For More Information

Visit www.osref.org for medical education materials and videos on these and many other indications or for more information.

For additional clinical information contact:

Scheffer C.G. Tseng, M.D., Ph.D.
Phone: 305-274-1299
E-mail: stseng@ocularsurface.com

Hosam Sheha, M.D., Ph.D.
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3. Close the conjunctiva over the graft with 8-0 Vicryl sutures.
4. If there is a conjunctival shortage or buttonhole, apply another piece of AMNIOGRAFT-G® (Catalog # AG-2015 - F Thickness) to cover the scleral defect then secure the graft with either fibrin glue or sutures.

**Postoperative Care:**
- Apply topical antibiotic-steroid eye drops six times a day for 1 week and then taper off within 1 month.

**Supplies:**

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Ocular Indications for Amniotic Membrane Transplantation (AMT)

According to hundreds of published literature worldwide, ocular surface reconstruction using cryopreserved amniotic membrane transplantation has been shown to be effective in treating the following diseases:

**Corneal Diseases:**
- Persistent Epithelial Defects
- Corneal Ulcers (central or peripheral)
- Descemetocele or Perforation
- Neurotrophic Keratitis
- Bullous Keratopathy
- Band Keratopathy
- Following Removal of Corneal Scar

**Conjunctival Diseases:**
- Primary & Recurrent Pterygia
- Pingueculae
- Tumors & Melanosis
- Conjunctivochalasis
- Superior Limbic Keratoconjunctivitis
- Scars and Symblepharon
- Conjunctival Buttonholes

**Other Applications:**
- Leaking Blebs & Trabeculectomy
- Scleral Melt
- Limbal Stem Cell Deficiency
- Fornix Reconstruction
- Socket Reconstruction
- High-Risk PKP
- Chemical Burns, Stevens Johnson Syndrome and Pemphigoid
- Implant Exposure

Contact Bio-Tissue today at 1-888-296-8858 to learn how our ocular surface tissue therapies can optimize your surgical results.

Bio-Tissue, Inc.
7000 SW 97th Avenue, Suite 211
Miami, FL 33173
Phone: 305-412-4430
Fax: 305-412-4429
E-mail: info@biotissue.com
Website: www.biotissue.com

Customer Service
Toll-Free: 1-888-296-8858

Medical Consultation available through Scheffer C.G. Tseng, M.D., Ph.D.
Phone: 305-274-1299
E-mail: stseng@osref.org
Website: www.osref.org

Surgical instruction available through The Ocular Surface Research & Education Foundation
Website: www.osref.org
E-mail: osref_info@osref.org


Ensuring Superior Surgical Outcomes Through Technological Innovation

The Only Sutureless Amniotic Membrane Graft For Ocular Surface Reconstruction

ProKERA
The Only Amniotic Membrane Graft for Ocular Surface Wound Repair and Healing

The leader in ocular surface tissue therapies

Ophthalmic Indications for Amniotic Membrane Transplantation (AMT)

According to hundreds of published literature worldwide, ocular surface reconstruction using cryopreserved amniotic membrane has been shown effective in treating the following diseases:

**Corneal Diseases:**
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- Limbal Stem Cell Deficiency
- Fornix Reconstruction
- Socket Reconstruction
- High-Risk PKP
- Chemical Burns, Stevens Johnson Syndrome and Pemphigoid
- Implant Exposure
As a dedicated physician, providing innovative treatment to your patients with ocular surface damage is a foremost priority.

With this in mind, Bio-Tissue brings you a new generation of ocular surface tissue therapies designed to accelerate the regeneration of damaged tissue while reducing recipient discomfort associated with ocular surface reconstruction.

Created using our patented cryopreservation method, AMNIOGRAFT® and PROKERA® provide the natural healing properties of amniotic membrane to restore ocular surface function with minimal scarring and inflammation. Our amniotic membrane allografts facilitate the short-term success of surgical procedures as well as the long-term stability of the eye surface when used as indicated.

Bio-Tissue: Advancing the Science of Ocular Surface Reconstruction with Amniotic Membrane.

Amniotic membrane is the innermost lining of the placenta. It contains natural growth factors and cytokines which are integral to the healthy development of the fetus. When implanted on the ocular surface, amniotic membrane promotes faster wound repair and wound healing.

By eliminating the need to harvest your patient’s own tissue, amniotic membrane reduces pain and discomfort, limits complications, reduces surgical time and optimizes surgical outcomes.

Bio-Tissue has contributed over ten years of research and innovation to the ophthalmic community and remains committed to creating ophthalmic products that will advance the treatment of ocular surface diseases.

Ensuring Superior Surgical Outcomes Through Technological Innovation

What Makes Our Amniotic Membrane Different?

Bio-Tissue offers the only commercially available amniotic membrane that preserves the native integrity, activity, and function exhibited by the tissue in utero for ocular surface wound repair and wound healing. Our proprietary processing and preservation method retains vital cytokines and growth factors which facilitate healing mechanisms such as:

- Anti-scarring
- Anti-inflammatory
- Anti-angiogenic
- Pain reduction
- Promotion of epithelial healing

Our products work synergistically with your patient’s own system to enhance and speed tissue repair, resulting in a calm, white eye with minimal discomfort—even immediately following surgery. Although the ophthalmic community has been aware of the healing implications of amniotic membrane allografts since the 1940s, the clinical and biological efficacy of amniotic membrane was not widely accepted until Bio-Tissue introduced its unprecedented technology in 1997. Since then, ophthalmologists worldwide have used AMNIOGRAFT® and PROKERA® to treat a wide array of ocular surface diseases and have enthusiastically endorsed their capabilities in ocular surface wound healing and repair.

A Convenient New Option for Treating Corneal Surface Damage

ProKera® is a Class II medical device created by clipping AmnioGraft® into a dual, concave, polycarbonate ring set. Acting as a biologic bandage, ProKera® effectively treats corneal and limbal surface conditions by reducing scarring, suppressing inflammation, and promoting epithelial healing. Corneal surface healing can be monitored while ProKera® is inserted and the healing is usually visible within 1-2 weeks. The ring set should be removed once the desired healing is complete.

The Benefits of ProKera®:

- Delivers therapeutic actions which aid in corneal wound repair and wound healing
- Conforms snugly to the corneal surface without sutures
- Acts as a symblepharon ring to prevent adhesions and maintain space for tissue re-growth
- Can be inserted easily in an office or surgical setting

Indications for ProKera®:

- Superficial Corneal Erosion
- Neurotrophic Corneal Epithelial Defect or Inflammation
- Recalcitrant Corneal Inflammation (e.g. herpetic or vernal)
- Acute Chemical/Thermal Burns
- Acute Stevens-Johnson Syndrome
- In conjunction with Superficial Keratectomy (to prevent haze)
- In conjunction with Corneal Transplantation (to prevent high-risk corneal complication/rejection)
- In conjunction with Socket, Fornix or Lid Reconstruction (to prevent lid/lash rubbing)

ProKera® sizes:

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>AM-covered Inner Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>PK-15</td>
<td>15 mm</td>
</tr>
<tr>
<td>PK-16</td>
<td>16 mm</td>
</tr>
</tbody>
</table>

Packaged in flat dual pack system for easy handling and long-term storage.
Enhanced Ocular Wound Therapy

**AMNIOGRAFT®** is a cryopreserved amniotic membrane that acts as a tissue replacement and therapeutic treatment for a wide range of ophthalmic indications. Because the membrane is minimally manipulated, **AMNIOGRAFT®** retains natural cytokines and growth factors in its matrix which suppress inflammation, reduce pain and promote ocular surface healing. **AMNIOGRAFT®** is used in a surgical setting and is attached to the ocular surface with sutures or glue.

**The Benefits of AMNIOGRAFT®:**

- Provides natural wound repair and wound healing actions
- Processed with unique patented technology which preserves the original integrity and natural biologic actions of the tissue
- Durable, elastic and easy to handle
- Easily stored in standard refrigeration and freezer devices

**AMNIOGRAFT® sizes:**

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Size</th>
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<tr>
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<td>AG-2520</td>
<td>2.5 x 2.0 cm</td>
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<tr>
<td>AG-2015</td>
<td>2.0 x 1.5 cm</td>
</tr>
<tr>
<td>AG-1510</td>
<td>1.5 x 1.0 cm</td>
</tr>
</tbody>
</table>

Easy to determine **AMNIOGRAFT®** orientation: Stromal side is “sticky,” Epithelial side is not.

“Sticky,” Stromal side (manufactured adhered to the nitrocellulose paper)

“Non-Sticky” Epithelial side
**Tissue Safety and Quality Assurance**

**AMNIOGRAFT® and PROKERA®** are procured and processed according to Good Tissue Practices (GTP) and Good Manufacturing Practices (GMP) regulations established by the United States Food & Drug Administration (FDA). Placental tissues are retrieved from donor mothers after elective cesarean section under full informed consent. The donor mothers are screened at delivery for infectious, malignant, neurological and auto-immune diseases and other exposures or social habits and also undergo a physical exam to determine the suitability for human transplantation. Donors are tested by a CLIA certified independent laboratory using FDA licensed test kits around the time of delivery and found to be serologically negative for, at minimum, the following tests:

- HIV 1 & HIV 2, Antibody
- HIV 1 Virus (NAT)
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B core antibody (HBCAb)
- Hepatitis C Antibody (HCVAb)
- Hepatitis C Virus (NAT)
- HTLV 1 & 2 antibodies
- Syphilis (RPR)
- West Nile Virus, WNV, (NAT)

Amniotic membrane is processed using a validated, proprietary method to produce **AMNIOGRAFT® and PROKERA®**. The final product is released after microbiological testing yields no growth of microorganisms (aerobic, anaerobic, or fungal). **AMNIOGRAFT® and PROKERA®** are preserved in a validated and patented storage medium.

### Storage Instructions:

<table>
<thead>
<tr>
<th>Storage Time</th>
<th>Storage Device</th>
<th>Ideal Temperature Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Until expiration date on packaging</td>
<td>-80°C Freezer</td>
<td>-85°C to -50°C (-121°F to -58°F)</td>
</tr>
<tr>
<td>1 year after receipt or until expiration date on</td>
<td>Standard home freezer (freezer</td>
<td>-49°C to 0°C (-56°F to 32°F)</td>
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<tr>
<td>outer product package, whichever comes first</td>
<td>compartment)</td>
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<td>3 months after receipt or until expiration date</td>
<td>Standard home refrigerator</td>
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<td>Unopened insulated container</td>
<td>2°C to 20°C (35.6°F to 38°F)</td>
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</tbody>
</table>

**References:**


Ophthalmic Indications for Amniotic Membrane Transplantation (AMT)

According to hundreds of published literature worldwide, ocular surface reconstruction using cryopreserved amniotic membrane transplantation has been shown effective in treating the following diseases:

**Corneal Diseases:**
- Persistent Epithelial Defects
- Corneal Ulcers (central or peripheral)
- Descemetocele or Perforation
- Neurotrophic Keratitis
- Bullous Keratopathy
- Band Keratopathy
- Following Removal of Corneal Scar

**Conjunctival Diseases:**
- Primary & Recurrent Pterygia
- Pinguecula
- Tenon’s Cyst
- Conjunctival Melanosis
- Conjunctivochalasis
- Superior Limbic Keratoconjunctivitis
- Scars and Symblephara
- Complicated fistulas

**Other Applications:**
- Leaking Blebs & Trabeculectomy
- Scleral Melt
- Limbal Stem Cell Deficiency
- Fornix Reconstruction
- Socket Reconstruction
- High-Risk PKP
- Chemical Burns, Stevens-Johnson Syndrome and Pemphigoid
- Implant Exposure

Contact Bio-Tissue today at 1-888-296-8858 to learn how our ocular surface tissue therapies can optimize your surgical results.
Overview

The conjunctival tissue starts from the limbus and ends in the lid margin. According to the anatomic location, the conjunctiva can be subdivided into the bulbar and palpebral portions; palpebral conjunctiva can further be subdivided into tarsal and fornical portions. Under normal circumstances, the fornix is deep creating a tear reservoir for the formation of a tear meniscus. A normal, deep fornix also helps provide a full range of ocular motility when there is a natural, smooth contact between the lid and globe during the blink. Collectively, it helps maintain a stable tear film and a healthy ocular surface.

Obliteration or foreshortening of the fornix by a symblepharon due to scar tissue (cicatrix) may result in ocular surface failure. The pathogenic elements include: sicca due to the depletion of the tear flow and spread; blink-related microtrauma due to cicatricial entropion, lid margin/tarsal keratinization/scarring or misdirected lashes; exposure due to inadequate blinking and closure; entropion and ptosis; and restriction of ocular motility.

When symblepharon develops in the superotemporal fornix, severe sicca can develop by the blockage of the lacrimal gland. When symblepharon develops in the inferior fornix, nocturnal corneal exposure may further develop due to the loss of the Bell’s phenomenon during sleep.

Although there are diverse causes for developing symblephara, inflammation is invariably the common denominator. If uncontrolled, inflammation can progressively cause additional scarring worsening the symblepharon and fornix obliteration.

Depending on the location and severity of symblepharon, fornix obliteration can be pathogenic and even give rise to severe visual loss. In moderate to extreme situations, fornix obliteration may cause difficulties for contact/scleral lens insertion and wear; result in ankyloblepharon and socket contraction. All potential pathogenic elements of symblepharon are summarized in the table below.

Table: Pathogenic Elements of Symblepharon

<table>
<thead>
<tr>
<th></th>
<th>Causative Factor</th>
<th>Pathogenic_manifestation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Causing Dry Eye</td>
<td>Obliteration of lacrimal excretory ductules</td>
</tr>
<tr>
<td>2</td>
<td>Contributing to Dry Eye</td>
<td>Obliteration of tear meniscus, interference with lid blinking and closure</td>
</tr>
<tr>
<td>3</td>
<td>Causing Blink-related Microtrauma</td>
<td>Cicatricial entropion together with abnormal lid margins, tarsi and lashes</td>
</tr>
<tr>
<td>4</td>
<td>Causing Diplopia</td>
<td>Restriction of ocular motility</td>
</tr>
<tr>
<td>5</td>
<td>Causing Decreased Vision</td>
<td>Cicatricial ptosis and symblepharon extending to the cornea</td>
</tr>
<tr>
<td>6</td>
<td>Partaking in Ocular Surface Failure</td>
<td>Carrying uncontrolled inflammation</td>
</tr>
<tr>
<td>7</td>
<td>Interfering with Contact (Scleral) Lens Wear</td>
<td>Ankyloblepharon or socket contraction</td>
</tr>
</tbody>
</table>
For each symblepharon, the location is assigned by using “U: upper lid” or “L: lower lid”, and “N: nasal”, “M: middle” or “T: temporal”.

The severity is graded according to the following three parameters:

1. The shortest vertical length of symblepharon measured from the limbus to the lid margin of the foreshortened fornix. It is graded as “Mild” (Fig. 2A) if the length is greater than the palpebral conjunctiva, as “Moderate” (Fig. 2B) if the length is greater than the tarsal conjunctiva but shorter than the palpebral conjunctiva, or as “Severe” (Fig. 2C) if the length is shorter than the normal tarsal conjunctiva.

2. The longest horizontal width of symblepharon as compared to the length of the eyelid. It is graded as “Mild” if the width is less than 1/3 (Fig. 3A), as “Moderate” if the width is greater than 1/3 but less than 2/3 (Fig. 3B), or as “Severe” if the width is greater than 2/3 of the lid (Fig. 3C).

3. The severity and the location of the inflammatory activity of the symblepharon. The inflammatory activity is graded as “0” if absent (Fig. 4A), “1+” if mild (Fig. 4B), “2+” if moderate (Fig. 4C), or “3+” if severe (Fig. 4D) as judged by the vascularity and the presence or absence of whitish scar tissue. The location of most active inflammation is further specified as “L: limbal”, “F: fornical”, or “T: tarsal”.

![Fig. 2](image1)

![Fig. 3](image2)

![Fig. 4](image3)
Management

No treatment is needed if patients are asymptomatic and if clinical staging of symblepharon does not reveal any pathogenic potential. As stated above, a symblepharon can potentially be pathogenic if it obliterates the tear meniscus, the reservoir, or lacrimal secretion (leading to dry eye), induces blink-related microtrauma from the lid margin and misdirected lashes due to cicatricial entropion (inciting mechanical irritation), produces exposure keratopathy due to incomplete blink/closure or loss of Bell’s phenomenon (punctuate/ulcerative keratopathy), restricts ocular motility (causing binocular diplopia) or impedes the comfort of contact/scleral lens wear (Table).

Patients with symptoms caused by pathogenic symblepharon should be treated to avoid potential blindness. The treatments start with conventional therapies including frequent lubrication using artificial tears or ointment, punctal occlusion, bandage contact lens (if not contraindicated), scleral lens, and periodic epilation. Systemic immunosuppressive measures should also be initiated for active inflammation in mucous membrane pemphigoid.

If the above measures fail to achieve the desired effects or cannot be instituted (e.g., lens insertion), even if the inflammatory activity is successfully controlled by systemic immunosuppression in the case of mucous membrane pemphigoid, surgical procedures including symblepharon lysis and fornix reconstruction become necessary. This Guide describes our proposed surgical methods, which include intraoperative application of mitomycin C (MMC) and sutureless transplantation of cryopreserved amnion graft.

Supplies

- Cryopreserved amniotic membrane: AMNIOGRAFT® purchased from Bio-Tissue, Inc. by calling their toll free phone number 1-888-296-8858. For product information, visit www.biotissue.com.

<table>
<thead>
<tr>
<th>Catalog #</th>
<th>AMNIOGRAFT® Sizes</th>
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<tr>
<td>AG-2520</td>
<td>A</td>
<td>2.5 x 2.0 cm</td>
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<tr>
<td>AG-2015</td>
<td>B</td>
<td>2.0 x 1.5 cm</td>
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<tr>
<td>AG-3535</td>
<td>C</td>
<td>3.5 x 3.5 cm</td>
</tr>
<tr>
<td>AG-1510</td>
<td>D</td>
<td>1.5 x 1.0 cm</td>
</tr>
</tbody>
</table>

- For sutureless surgery, use fibrin glue: TISSEEL VH (Vapor Heated) fibrin glue (1.0 mL, part # 921028) purchased from Baxter Biologics by calling their toll free phone number 877-TISSEEL (877-847-7335). For product information, visit www.advancingbiosurgery.com/us/products/tisseel/. We prefer to use the two components separately, each with a special needle provided without dilution, instead of combining them via the provided DUPLOJECT.

NOTE: The ophthalmic use of fibrin glue is considered “off label”.

- 7-O Polyglactin sutures: Vicryl purchased from Ethicon Inc., Johnson & Johnson, Somerville, NJ.
- For severe/moderate cases, 4-O black silk sutures are also needed
Surgical Techniques

In general, the surgical approach is formulated based on the severity of symblepharon according to the grading system described above. In principle, the grading of the vertical length affects the necessity of using anchoring sutures to the lid skin and/or additional transplantation of oral mucosal graft; the grading of the horizontal width affects the size of conjunctival autograft (if possible), oral mucosal graft or cryopreserved amnion graft; and the grading of location and severity of the inflammatory activity affects the site and the duration of intraoperative application of MMC.

Key Surgical Steps

Anesthesia: Topical anesthesia with 2% lidocaine gel under intravenous sedation is preferred for mild cases. General anesthesia is preferred for moderate to severe cases in which traction sutures to open the eyelids without a speculum, more extensive excision, an oral mucosal graft, or anchoring sutures are required.

Preparation of the Eye: After standard prep and drape of the eye, a speculum is inserted for mild cases. In moderate to severe cases, one 4-O black silk suture is placed at each lid margin as a traction suture to open the eye if the speculum cannot be inserted (Fig. 5). Several drops of non-preserved 1:1000 epinephrine (Hospira, Inc., Lakes Forest, IL) are applied on the entire ocular surface to achieve vasoconstriction for subsequent hemostasis.

Incision, Traction Suture and Excision of Cicatrix: Circumlunar incision (like peritomy) starts from the perilimbal region between the normal conjunctiva and the beginning of the symblepharon (Fig. 6). Relaxing incisions are made extending toward the fornix along the border of symblepharon (Fig. 7). A traction suture made of double-armed 7-O polyglactin (Vicryl, Ethicon Inc., Johnson & Johnson, Somerville, NJ) is placed near the exposed bulbar sclera, and the eye is rotated opposite to the vertical axis of symblepharon, allowing better exposure of symblepharon and subsequent excision of cicatrix (Fig. 8).

With the assistant grabbing the tip of the symblepharon, the cicatrix, which consists of scar and thickened fibrovascular tissue included in the Tenons capsule, is dissected away from the epithelial tissue of the symblepharon and amputated at the base using scissors near either the fornix or the tarsus (Fig. 9A-9C). This step invariably results in further recession of the symblepharon epithelial tissue to the fornix, leaving a larger bare bulbar sclera. The epithelial lining tissue is intentionally saved for reconstructing the palpebral conjunctiva. The thoroughness of cicatrix removal can be judged by the free motility of the globe under the traction suture.
**Key Surgical Steps**

**Intraoperative Application of Mitomycin C:** With the exception of cases without inflammation, nearly all symblephara need intraoperative application of 0.04% MMC delivered via soaked sponges. The MMC sponges are inserted at the base where cicatrix is amputated (Fig. 10, arrow marks the inserted sponge). The duration of MMC application depends on the severity of inflammatory activity. For those graded as 3+, MMC is applied for 5 min; for those graded as 2+, MMC is applied for 4 min; and for those graded as 1+, MMC is applied for 3 min. During incubation, the inserted sponge is covered by the recessed symblepharon tissue. The traction suture helps pull the bulbar sclera away from being exposed to the MMC sponges. Periodically dry the bulbar sclera with a dry Weckcell sponge. After incubation, the sponges are removed and counted, and the contact area is thoroughly rinsed with BSS (half a bottle).

**For Mild Symblepharon-Transplantation of Cryopreserved Amnion Graft Alone:**

For mild cases (judged by the vertical length measured from the limbus to the lid margin of the foreshortened fornix), the recessed symblepharon conjunctiva is large enough to be used to cover the entire palpebral conjunctiva (Fig. 11, after removing the cicatrix in gray, the original host conjunctiva in green in the preoperative scheme (Fig. 11A) is recessed in the postoperative scheme (Fig. 11B) and contiguous with cryopreserved amnion graft denoted in black). First, attach the recessed conjunctiva to the palpebral area using fibrin glue with the two components applied separately. The remaining bare bulbar sclera is covered with cryopreserved amnion graft also using fibrin glue as follows.

Peel the amnion graft from the nitrocellulose filter paper and lay it down on the defect with the sticky, stromal surface down to cover the entire bare sclera. Use 0.12 forceps to flip half of amnion graft onto the other half to allow half of the stromal surface to face upwards (Fig. 12A). Apply the thrombin (watery, colorless) solution to the bare sclera adjacent to the folded graft (Fig. 12B). Then apply the fibrinogen (viscous, tawny) solution on the stromal surface of folded graft (Fig. 12C). Flip the graft back on the sclera and a muscle hook is used to spread the fibrin glue into an even and thin layer under the amnion graft (Fig. 12D). These steps are repeated for the other half of the amnion graft to cover the entire sclera. Check the graft edges using 0.12 forceps to make sure they are secure. If not, apply small drops of both components to secure any loose areas. Trim off any excess membrane graft and fibrin gel to make the graft flush with the conjunctival edge.

If sutures are used instead, 10-O nylon sutures are placed interruptedly to secure the amnion graft to the limbal and bulbar sclera, while 8-O Vicryl sutures are placed interruptedly to secure the recessed conjunctival tissue over the amnion graft with episcleral bites parallel to (but not perpendicular to) the forniceal line.
Key Surgical Steps

For Moderate Symblepharon-Transplantation of Cryopreserved Amnion Graft and Anchoring Sutures:

For moderate cases (judged by the vertical length measured from the limbus to the lid margin of the foreshortened fornix), there is enough recessed symblepharon conjunctiva to cover the tarsal area but not large enough to cover the entire palpebral area. (Fig. 13, after removing the cicatrix in gray, the original host conjunctiva in green in the preoperative scheme (Fig. 13A) is recessed in the postoperative scheme (Fig. 13B) and contiguous with cryopreserved amnion graft denoted in black, and is secured to the tarsus by an anchoring suture in red). The recessed conjunctiva is attached to the palpebral area by anchoring a double armed 4-O black silk suture to the edge and securing it to the skin with a bolster made of 25 gauge butterfly tubing (Fig. 14A-C). One such anchoring suture is needed per quadrant. The remaining bare sclera and bare palpebral area is covered by cryopreserved amnion graft using the following steps.

After it is removed from the filter paper, the amnion graft is laid down to cover the entire bare area with reflection made at the fornix. The portion of the membrane laid on the bulbar sclera is first attached with fibrin glue using the steps described in the mild symblepharon section. The portion of the graft supposed to be attached to the palpebral area is first flipped on the graft attached onto the bulbar sclera with the stromal surface facing up (Fig. 15A). After the two components of fibrin glue are applied on the flipped surface, a muscle hook is used to glide this flipped membrane toward the fornix and continuously upward to reach the recessed symblepharon conjunctiva which is now anchored by 4-O black silk (Fig. 15B). Use 0.12 forceps to check the edges to make sure the graft is not detachable. If it is, an additional touch up by applying drops of both components of the fibrin glue is needed. The excessive graft and fibrin gel are trimmed off to make the membrane flush with the conjunctival edge.

For Severe Symblepharon-Transplantation of Cryopreserved Amnion Graft, Anchoring Sutures, and Oral Mucosal Graft/Conjunctival Graft:

For severe cases (judged by the vertical length measured from the limbus to the lid margin of the foreshortened fornix), there is not enough of the recessed symblepharon conjunctiva to cover the tarsal area (Fig. 16, after removing the cicatrix in gray, the original host conjunctiva is recessed and contiguous with an oral mucosal graft in brown and with cryopreserved amnion graft denoted in black.)
and secured by an anchoring suture in red as shown in the postoperative scheme (Fig. 16B). Therefore, it is necessary to obtain a free cell-containing graft to substitute the tarsal conjunctiva. A conjunctival autograft is the natural choice if it is available from the same eye or the fellow eye. However, if it is not available, an oral mucosal graft from the mouth is the alternative. The size of conjunctival autograft or oral mucosal graft depends on the width of symblepharon.

To obtain an oral mucosal graft, the oral cavity is opened with two towel clamps and the oral mucosa is prepared with beta-iodine. Submucosal injections of 2% lidocaine with epinephrine are given using a 30 gauge needle. An incision is made into the oral mucosa with a superblade (Fig. 17A) and the free graft is dissected off with scissors (Fig. 17B), and soaked in gentamicin solution. After trimming off the stromal fat, the oral mucosal graft is sutured to the recessed conjunctiva with interrupted 8-O Vicryl sutures at each corner. The graft is attached to the tarsal plate with fibrin glue (Fig. 18A) and then further secured to the palpebral area by anchoring a double armed 4-O black silk suture to the edge of the mucosal graft and secured to the skin with a bolster made of 25 gauge butterfly tubing (Fig. 18B). One anchoring suture is needed per quadrant. The remaining bare sclera and bare palpebral area is covered with cryopreserved amnion graft in the same manner as described for moderate cases.

Tarsorrhaphy: To minimize the eye exposure for severe cases where a large bulbar sclera is covered by cryopreserved amnion graft, it is advised that the eye is closed with 4-O black silk suture passing through the bolster (Fig. 19).

**Key Surgical Steps**

**Literature Summary**

Traditionally, fornix reconstruction involves symblepharon lysis and cicatrix removal followed by measures taken to prevent readhesion (reformation of symblepharon). The efforts toward latter include insertion of conformers, silicone rubber sheets, or plastic. It is also believed that these measures can postpone but not prevent regrowth of symblepharon. To augment the success, transplantation of such tissues as a pedicle graft from skin, and full-thickness mucous membrane graft have been attempted to prevent symblepharon reformation.

A conjunctival autograft is the best free graft option for reconstruction when there is enough healthy conjunctival tissue available. Tseng et al first showed that cryopreserved amnion grafts can be considered as an alternative substrate for conjunctival surface reconstruction during the removal of large conjunctival lesions, scars or symblepharon. Using sutures to anchor cryopreserved amnion graft, 5 of 16 eyes (31%) showed partial success or failure due to persistent host conjunctival inflammation.

Prabhasawat and Tesavibul noted a success rate of 54% in 13 eyes with symblepharon. Katircioglu et al reported that 1 of 6 eyes (17%) with chemical burns failed because there was no healthy host conjunctiva before surgery. Oberhansli and Spahn reported that 8 of 48 eyes (17%) failed to achieve a deep fornix due to progressive retraction.

Solomon et al introduced anchoring sutures to achieve 12 of 17 eyes (71%) success in fornix reconstruction. The remaining failed cases had underlying causes such as autoimmune disorders or recurrent pterygium.

Barabino et al used the same approach together with systemic immunosuppression and reported 100% success rate in 9 eyes with mucous membrane pemphigoid for the first 16 weeks of follow up. A small area of symblepharon returned in 4 eyes (44%) in 28 weeks.

Recently, Tseng et al added the intraoperative application of MMC to the subconjunctival space in the fornix to the above procedure and reported that all 18 eyes (100%) regained a deep fornix and continuous tear meniscus, but 3 of 12 eyes (25%) with motility restriction showed recurrence of partial motility restriction. Most notable was a combination of transplantation of cryopreserved amnion graft, anchoring sutures and intraoperative application of MMC which achieved a deep fornix in all 6 eyes with prior mucous membrane graft. Nava-Castaneda et al also confirmed that additional use of intraoperative MMC significantly enhanced the success of transplantation of cryopreserved amnion graft.


· When is the best time to perform symblepharon lysis and fornix reconstruction?

In general, the surgery is best performed when the eye is quiet. Taking chemical burns as an example, symblepharon lysis and fornix reconstruction are already at the chronic stage when there is no ongoing active inflammation. For the same reason, it is better to wait for 6 months if the eye has failed from the first attempt of fornix reconstruction.

· Why is it necessary to use intraoperative MMC?

If the preoperative evaluation does not reveal any inflammatory activity in the area of symblepharon and the patient’s underlying disease is not active, it is not necessary to use MMC at all. Unlike conjunctival autograft, cryopreserved amnion graft does not contain any live cells. Therefore, the healing depends on the migration of host cells into the membrane. The chronic inflammation in the host tissue surrounding the symblepharon, if not treated with MMC, may still retain its “malignant and abnormal” phenotype, and upon invasion into the membrane may continue to develop a cicatrix. That is why it is necessary to use MMC to suppress this abnormal phenotype and active inflammation in order to enhance the aesthetic outcome. It should be noted that MMC is applied subconjunctivally, but not onto the bare sclera, to avoid any side effects.

· Why is it necessary to use conjunctival autograft or oral mucosal graft in severe cases?

In severe cases, there is a significant shortage of epithelial tissue between the lid margin and the limbus. The remaining conjunctival tissue is not sufficient to cover the tarsal conjunctiva, let alone to regenerate the entire fornix. For this reason, a small epithelium-containing tissue such as conjunctival autograft or oral mucosal graft is needed to provide the epithelial source. This free graft can help recover the entire region with the help of an amnion graft. The oral mucosal graft is more ideal to resurface the tarsal conjunctiva while the amnion graft is more ideal to resurface the bulbar conjunctiva.

· Why is it necessary to place any anchoring sutures during fornix reconstruction?

After symblepharon lysis and the removal of any cicatrix, the recessed conjunctival tissue will readily collapse to contact the bare bulbar sclera, leading to recurrent formation of symblepharon. Therefore, it is important to anchor it to the palpebral tissue plane so that the subconjunctival fibrovascular tissue will point toward the orbital space instead. With the close apposition by the amnion graft to the epithelial edge, epithelial tissue, but not fibrovascular tissue, will grow onto the membrane.

· How do you handle Limbal Stem Cell Deficiency (LSCD) in conjunction with symblepharon?

Before tackling the LSCD issue, it is important to control and correct any scarring and inflammation related to the symblepharon. Therefore, in general, it is better to perform symblepharon lysis and fornix reconstruction before treatment for LSCD because there will be a more favorable environment to treat LSCD when the eye is quiet. For some cases, symblepharon is contiguous with the pannus extending onto the corneal surface in the region where there is LSCD. If LSCD is partial, i.e., the other limbal region still contains healthy limbal stem cells, transplantation of cryopreserved amnion graft can be extended to cover the corneal surface after superficial keratectomy to remove the pannus. Frequently, this approach will also result in restoration of the limbus in this region. However, if LSCD is diffuse and total, it is best not to remove the pannus from the corneal surface during the symblepharon lysis and fornix reconstruction. The LSCD is best left to the second stage when transplantation of limbal stem cells by either conjunctival limbal autograft (from the fellow eye) or keratolimbal allograft (from the cadaver) is contemplated.
Cryopreserved Amnion Grafts for Conjunctivochalasis and Superior Limbic Keratoconjunctivitis

By Scheffer C.G. Tseng, M.D., Ph.D. with Hosam Sheha, M.D., Ph.D.

Overview

Conjunctivochalasis (CCh) represents one of the most common age-related eye diseases and is characterized by the presence of redundant folds of the conjunctiva that typically are detected between the eyeball and the eyelids. It is commonly found along the lower lid margin and mechanically interferes with the normal distribution of tears giving rise to unstable tear film (dry eye) and delayed tear clearance (epiphora). The differences between CCh-induced dry eye and aqueous tear deficiency (ATD) are summarized in Table 1. For asymptomatic CCh, no treatment is needed, and patients may be given tear substitutes, lubricants, corticosteroids or antihistamine drops. Persistent symptomatic CCh despite maximal medical treatments to dry eye can be treated using amniotic membrane (AM) transplantation.

Diagnosis of Conjunctivochalasis

Slit Lamp Examination

The loose conjunctiva can be demonstrated as follows:

- Ask the patient to blink vigorously.
- Press the eyelid against the conjunctiva with an upward motion (Fig. 1).
- Fluorescein staining will help visualize the wrinkles as well as obliterate tear meniscus by the redundant conjunctival folds (Fig. 2).
- Rose Bengal staining may show punctate staining on the bulbar conjunctiva adjacent to the lid margin (Fig. 3).

<table>
<thead>
<tr>
<th>Distinguishing Feature</th>
<th>ATD Dry Eye</th>
<th>CCh Dry Eye</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diurnal variation</td>
<td>Worse in PM</td>
<td>Same throughout the day</td>
</tr>
<tr>
<td>Worst gaze</td>
<td>Up gaze</td>
<td>Down gaze</td>
</tr>
<tr>
<td>Effect of vigorous blinking</td>
<td>Symptom improved</td>
<td>Symptom worsened</td>
</tr>
<tr>
<td>Recurrent subconjunctival hemorrhage</td>
<td>Infrequent</td>
<td>Frequent</td>
</tr>
<tr>
<td>Fluorescein Staining Pattern</td>
<td>Low tear meniscus without interruption</td>
<td>Tear meniscus interruption or obliteration</td>
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<tr>
<td>Tear Clearance</td>
<td>Normal/Delayed</td>
<td>Frequently delayed</td>
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<tr>
<td>Rose Bengal Staining</td>
<td>Exposure zone</td>
<td>Non-exposure zone</td>
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<tr>
<td>Effect of Punctal Occlusion</td>
<td>Symptom improved</td>
<td>Symptom worsened</td>
</tr>
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</table>
**Key Surgical Steps:** Estimated surgery time: 15 min.

**Surgical Techniques for Inferior CCh:**

- **Insert** a 15 mm solid blade **Speculum** (K1-5014 Katena), apply **Epinephrine** (1:1000) for hemostasis and 2% lidocaine gel (Astra Zeneca) for **Topical Anesthesia**.

- **Identify** the location of CCh by grabbing the conjunctiva with 0.12 forceps (Fig. 4).

- Create an arc like conjunctival **peritomy** from 4 to 8 o’clock positions 1-2 mm posterior to the limbus (Fig. 5).

- Place 7-0 Vicryl **Traction Suture** 1-2 mm posterior to the limbus at the 6 o’clock position. Rotate the eye upward to allow the conjunctiva posterior to the peritomy to retract and expose the bare sclera.

- **Excise** a strip of fragile and wrinkled conjunctival tissue along with any underlying movable Tenon’s capsule (Fig. 6).

- **Transplant Cryopreserved Amnion Graft with Fibrin Glue:** Place the cryopreserved AmnioGraft on the bare sclera with the sticky/stromal surface facing down. Secure the membrane using fibrin glue while tucking the graft underneath the conjunctival edge and sealing the conjunctiva over the graft (Fig. 7).

**Supplies:**

- AmnioGraft® from Bio-Tissue (1-888-296-8858):
  - AG-2015 if CCh involves the inferior temporal bulbar conjunctiva.
  - AG-2520 if CCh involves the entire inferior bulbar conjunctiva.
  - AG-3535 if CCh involves the entire inferior and superior bulbar conjunctiva.

- Traction Sutures: use 7-0 Vicryl sutures.

- For sutureless surgery: use fibrin glue; TISSEEL from Baxter Biologics (1-877-TISSEEL) 2.0 mL (Catalog # 1501236) or Evicel from Ethicon from Johnson & Johnson (1-800-255-2500) 1 mL (NDC # 63713-390-11).

- For surgery with sutures, 10-0 nylon and 7-0 Vicryl sutures are recommended.
If Associated with Pinguecula:

- Remove any pinguecula during the surgery to avoid progression into a pseudopterygium. AM should cover the entire denuded area (Figure 8).

If Associated with Fat Prolapse extending from the fornix (Fig. 9A):

- Anchor the recessed remaining conjunctival tissue to the fornix using 7-0 Vicryl mattress sutures to the sclera (Fig. 9B).

If Associated with SLK:

- Create a limbal based conjunctival flap about 5 mm posterior to the superior limbus. Rotate the eye down using a 7-0 traction suture 1-2 mm posterior to limbus at the 12 o'clock position. Remove all mobile Tenon’s capsule (Fig. 10A) prior to laying down and adhering AM on the bare sclera with fibrin glue (Fig. 10B). Remove the traction suture and secure the conjunctival flap on top of AM with bipolar cautery.

Post Operative Care

Begin topical Prednisolone four times and Ocuflox three times a day for 4 weeks. Epithelialization will be completed in 2 to 3 weeks. If the surrounding conjunctiva is not inflamed, stop Ocuflox and taper off PF on a weekly schedule from four times a day. If, however, the surrounding conjunctiva is inflamed, give subconjunctival injection of 0.1 cc Kenalog (40 mg/ml) per site in the office. Symptoms related to CCh will be quickly resolved. The residual symptoms due to aqueous tear deficiency, meibomian gland dysfunction (MGD), or excessive blinking can be managed accordingly.
• Why not just remove the excess conjunctiva? Why use an amnion graft?
CCh is not caused by excessive or redundant conjunctiva. Instead it is caused by poor adhesion between the Tenon’s capsule and the sclera. Simple excision may not prevent fat prolapse and may aggravate a pingoecula, if present. Covering the bare sclera with cryopreserved amniotic membrane reinforces such adhesion without stirring up unnecessary inflammation or scarring based on the important biologic actions preserved in cryopreserved amnion grafts. These include anti-inflammation, anti-scarring, anti-angiogenesis and the promotion of healing while reducing patient pain.

• Why are cryopreserved amnion grafts recommended over other amniotic membrane products?
AmnioGraft® is the only cryopreserved amnion graft available and approved by the FDA for commercial use in the United States. The cryopreserved method of preserving amniotic membrane is the only method for use in ocular surface wound repair and wound healing because this method retains the biologic actions of the tissue in utero (anti-scarring, anti-inflammation, anti-angiogenesis, and promotion of healing).

• What happens if ocular irritation persists after CCh surgery?
If the conjunctivochalasis has been corrected, the remaining irritation might come from aqueous tear deficiency dry eye, MGD blepharitis, or delayed tear clearance, which can then be successfully treated by punctal occlusion, lid scrub, or non-preserved steroid drops.

• Should CCh correction surgery be performed before blepharoplasty?
Yes. If an eye had CCh and the lid is tightened through blepharoplasty, then the symptoms will get worse.

• If the patient has entropion with CCh, should both corrective surgeries be performed at the same time?
Operate on the entropion first to see if CCh persists. If so, then CCh will be managed accordingly.

• Can this procedure be performed on both eyes in the same surgical session?
Yes, because topical anesthesia makes it possible.
**Overview**

ProKera™ consists of a piece of cryopreserved human amniotic membrane clipped into a dual PMMA symblepharon ring system (see sketch left). Thus, ProKera™ can be used as a temporary amnion graft for suppressing inflammation and promoting corneal surface healing without sutures.

ProKera™ is assembled so that the stromal (sticky) side of the tissue is in contact with the corneal surface and fits snugly between the cornea and the eyelids by conforming to the corneal surface like a contact lens. ProKera™ also functions like a symblepharon ring while delivering the therapeutic benefits a cryopreserved amnion graft including anti-inflammatory, anti-scarring, anti-angiogenic, promotion of healing and reduction of patient pain without sutures.

ProKera™ is intended for the use in eyes where the ocular surface cells have been damaged, or the underlying stroma is inflamed and scarred. The most common indications for use are:

- Epithelial defects, erosion, or ulceration
- Chemical/thermal burns (acute stage)
- Following the removal of corneal lesions, e.g., band keratopathy
- Chronic Recalcitrant Keratitis from HZO, HSV, or Vernal Keratitis
- Stevens Johnson Syndrome (acute stage)
- In conjunction with Socket or Fornix Reconstruction (to prevent lid/lash rubbing)

**Supplies for Procedure**

1. Sterile lid speculum
2. Sterile gloves
3. Anesthetic drops
4. Antibiotic drops
5. Sterile scissors (provided with the ProKera™ device)
6. Sterile forceps (provided with the ProKera™ device)
7. ProKera™ (by Bio-Tissue™) call for info: 1-888-296-8858

**ProKera Usage by Application**

*Data provided by Bio-Tissue, Inc. from returned donor recipient information forms from transplanted devices (April 2005 - December 2005).*

<table>
<thead>
<tr>
<th>ProKera™ sizes:</th>
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<td>PK-16</td>
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Pre-Insertion Tips:

• Verify Eye Closure: If there is an eye closure problem, ProKera™ should not be used. Exposure problems will diminish the effects of the membrane and should be treated prior to ProKera™ insertion or at the time of ProKera™ insertion with additional tarsorrhaphy.

• Consider Eye Opening for Sizing: There are two different diameters of ProKera™ available: 15 mm and 16 mm. Most adult patients will tolerate a 16 mm ProKera™ device. ProKera™ should not be used for patients with unusually tight eyelids close to the eyeball making it difficult and/or painful to insert anything between the lid and the globe.

• Handle Aseptically: ProKera™ can be inserted in an office setting using aseptic technique; the supplies listed below assist with handling the device. ProKera™ is packaged in a dual pouch system. The outer aluminum foil pouch should not be placed in the sterile field, but the inner, clear pouch may be placed in a sterile field. The membrane in the device is slippery. Thus, grab the ring with fingers using a sterile glove or with the sterile (blunt) instruments to avoid tearing the membrane. Do not trim off the extra membrane hanging over the sides of the ring.

Key Insertion Steps:

• Use a lid speculum to open the eye
• Administer anesthetic drops
• Insert ProKera™ into the upper lid, and then tuck it under the lower lid
• Administer prophylactic antibiotic drops after removing the speculum

Using a tarsorrhaphy with ProKera™:

After insertion, if there is no complaint of a foreign body sensation, and the patient seems to have reasonable blink and closure, then there is no need for a tarsorrhaphy. However, if the ProKera™ is a little too small for the eye, or the device does not center well on the corneal surface (e.g. with floppy lids or exophthalmos) or the eye does not blink/closure well (e.g. neurotrophic), then add a temporary tarsorrhaphy (see illustration and photo below).
Key Surgical Steps (continued)

Post-Insertion Care:

• **Patient Instructions:** Patients should be instructed not to rub their eyes, excessively blink or move the ProKera™ insert with their fingers. Patients should not swim or soak their face in water without protective eyewear. The eye should be closed tightly during showering. As vision will be blurred by the opacity of the tissue, patients should not drive, operate heavy machinery or do any other task that requires unobstructed vision or good depth perception.

• **Topical Medications:** Artificial tears or other eye drops should be used 3-4 times daily, especially if there is a concern about dry eye exposure. The cryopreserved amniotic membrane in ProKera™ does not interfere with antibiotics’ penetration. ProKera™ can be soaked in antibiotic solution before placing it in the eye.

• **Routine Examination with ProKera™:** Without removing ProKera™, healing can be assessed using fluorescein staining (see photo to the right) and the IOP can be measured with a Tonopen. If temporary removal is required then handle the ProKera™ device aseptically and store it in a sterile container with BSS before re-insertion.

• **Length of Wear:** The FDA approved ProKera™ can remain in the eye until the ocular surface has healed or the membrane has dissolved for up to 8 weeks after insertion. However most healing is complete within 1-2 weeks. For cases with severe inflammation (e.g. acute chemical burns), it is beneficial to insert a new ProKera™ device every 5 days to avoid PMN cells becoming trapped on the membrane which may lessen its therapeutic effect.

• **Membrane Dislodgment and Dissolution:** As the ocular surface heals, the membrane will thin and dissolve. However the membrane should not dissolve in less than one week. If the membrane dissolves after adequate healing has taken place, then remove the device. If the membrane dissolves before healing, then this is most likely due to an exposure problem which should be corrected before the insertion of another ProKera™.

Removal Tips:

ProKera™ can be removed using blunt, sterile forceps with or without the help of a lid speculum. The application of an eye ointment can facilitate the removal.

Testimonials (from ProKera™ Users)

**Neurotrophic Persistent and Non-healing Corneal Epithelial Defects/Ulcers**

Dr. Michael Ehrenhaus of NY, NY has used ProKera™ in patients with non-healing epithelial defects due to bacterial keratitis. The ProKera™ device stabilized their corneas and helped stop progression of the defects, some of which were deep, almost like a descemetocele. He can be reached for further comments or questions by phone at 718-780-2600.

Dr. Lisa Chriss of Orlando, FL was very impressed after using ProKera™ for a patient with a non-healing epithelial defect and scar due to HZO (under control) which failed to heal after using a bandage contact lens for 3 months. The defect healed 3 days after ProKera™ insertion. She can be reached for comments or questions by phone at 407-629-6646.

Dr. George Rosenwasser of Hershey, PA used ProKera™ after EDTA chelation in a one-eyed neurotrophic child with band keratopathy and vascularization. He noted a rapid and impressive improvement. He observed that “This device has fast-tracked the relief of damage from alkali burns to the ocular surface. I recommend it to anyone who sees a serious alkali injury, and the faster it is placed, the better.” He can be reached by phone at 717-533-5200.

Reimbursement:

ProKera™ is a new device and no procedure or supply reimbursement codes are available at this time. However, because ProKera™ is assembled using the same amniotic membrane tissue as AmnioGraft®, some physicians and facilities have asked if they can apply the AmnioGraft® codes. (Please see Bio-Tissue’s Billing Guidelines for details about the use of CPT code 65780 -Ocular Surface Reconstruction; Amniotic Membrane Transplantation and HCPCS Level II code V2790 -Preserved Human Amniotic Membrane.) Also consult your coding specialists for more details preferably prior to surgery. As a safeguard, always get the patient to sign an Advance Beneficiary Notice (ABN) form.
1. How often does ProKera™ fall out?
Due to the device construction and the placement of ProKera™ under the eyelids, ProKera™ will not fall out with normal wear or blink. However, the device may not be secured well in exophthalmos or severe floppy lid. A tarsorrhaphy can help to limit this.

2. If the sticky stromal side is down, when ProKera™ is removed, what keeps it from taking the epithelium with it?
ProKera™ acts as a temporary graft and the epithelial healing takes place under the covering of the amniotic membrane. Once the corneal surface inflammation reduces and the defect heals (visible by fluorescein staining), the amniotic membrane clipped into the PMMA rings will thin out or dissolve completely. The remaining PMMA ring will need to be removed after this has happened. No epithelium will be removed with the ring.

3. What happens if the graft is sloughing off even with a tarsorrhaphy?
It is likely that there is an exposure problem if this happens. For example, in a recent case a patient suffering from the lack of Bell’s phenomenon (after HZO) the eye was not rotating during sleep. This created a severe exposure of the lower portion of the cornea as it is never covered by tear film. Amniotic membrane healed the defect, but broke down again for the very same reason. To overcome this issue, blood vessels will have to be brought to the peripheral cornea using a conjunctival flap and then covering it with ProKera™.

4. What if the membrane slips out of the ProKera™ ring? Should I try to clip it back in?
The amnion graft inserted in the ProKera™ ring will thin out as the healing of the corneal surface progresses. Occasionally this will cause the membrane to detach from the ring. If this occurs, remove the device. Do not try to reassemble it. Provided the healing is complete, another ProKera™ is unnecessary.

5. Why is there mucous debris with ProKera™ inserted?
The membrane may show some degradation during wear and thus generate some mucous debris. If this occurs simply rinse with non-preserved saline.
The sclera serves as a protective coat and a stable support for the intraocular tissues (Fig. 1). Its thickness is not uniform, being the thickest at the posterior pole (1.1-1.35 mm), gradually decreasing to be the thinnest immediately posterior to the rectus muscle insertion (0.3 mm), and increasing again towards the limbus (0.8 mm). The scleral matrix is compact and made of collagen fibers and interfibrillar proteoglycans. In a normal healthy eye, the scleral stroma is avascular, receiving its nutrition from choroidal blood vessels and the vascular plexus in the Tenon’s capsule and on the episcleral surface.

Scleral melt is a serious and challenging clinical problem as it threatens the integrity of the eye. Clinically, scleral melt is almost always the result of ischemia which interrupts the blood flow of episcleral blood vessels. Therefore, scleral ischemia and melt can be caused by a number of diseases that interrupt the blood circulation. Acutely, scleral ischemia can occur in chemical or thermal burns. When such ischemia extends near the limbus, it further compromises the limbal epithelial stem cells. Chronically, scleral ischemia can happen when excessive beta irradiation or mitomycin C are used to treat pterygia or develop after systemic vasculitis and connective tissue disorders.

This Guide demonstrates how Tenonplasty can be used to restore the blood supply. Once the blood supply is established on the ischemic sclera, lamellar corneal graft and/or amniotic membrane transplantation can be used as a tectonic substitute for the missing scleral tissue depending on the depth of the scleral defect. Furthermore, the overlying conjunctival surface healing is facilitated by the transplantation of a cryopreserved amnion graft. As illustrated in this Guide, lamellar corneal tissue and amniotic membrane transplantation can be accomplished without sutures by using fibrin glue. As a result, the surgical time is shortened (allowing topical anesthesia), the patient’s recovery time is reduced, and the postoperative care is simplified.

Key Pre-operative Points:

• If the patient does not have a clear underlying etiology such as acute chemical burn or use of beta irradiation or MMC for pterygium, known to cause scleral ischemia, and if the scleral melt is limited to the limbal and peripheral corneal regions (like peripheral ulcerative corneal diseases), it is advised to rule out whether there is a systemic collagen vascular disease caused by autoimmune dysregulation. An appropriate diagnostic work-up and consultation are needed. If verified, systemic immunosuppression should also be initiated. Mooren’s ulcer is a disease diagnosed after exclusion of these diseases.
• Dellen formation due to insufficient tear flow or spread can cause scleral thinning or aggravate a scleral melt. Therefore, it is also important to determine whether there is neurotrophic keratopathy, aqueous tear deficiency (dry eye) or surface exposure due to infrequent blink and incomplete closure by checking corneal sensitivity, performing Schirmer test without anesthetics, and checking the blink rate. If noted, these problems should be managed first by punctal occlusion (to both upper and lower) with punctal plugs or even with permanent cauterization, followed by large scleral lens protection, pressure patch (temporarily), or tarsorrhaphy.

**Supplies:**

• Donor corneal tissue from any eye bank: Both epithelial and endothelial qualities do not matter as the main purpose is tectonic but not optical.

• Cryopreserved amniotic membrane: AMNIOGRAFT® purchased from Bio-Tissue, Inc. by calling their toll free phone number, 1-888-296-8858. Four sizes are available as shown. The graft size is chosen according to the area that needs to be covered. For more information visit www.biotissue.com

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<th>Catalog #</th>
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<tr>
<td>AG-1510</td>
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</tr>
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</table>

• Traction Sutures: Use 7-O Vicryl sutures

• For sutureless surgery, use fibrin glue: TISSEEL VH (Vapor Heated) fibrin glue (1.0 mL, part # 921028) purchased from Baxter Biologics by calling their toll free phone number, 877-TISSEEL (877-847-7335). For product information, visit www.advancingbiosurgery.com/us/products/tisseel/. We prefer to use the two components separately, each with a special needle provided without dilution, instead of combining them via the provided DUPLOJECT.

NOTE: The ophthalmic use of Fibrin Glue is considered “off label”.

• For surgery with sutures, 10-O nylon is used for the bulbar area and 8-O Vicryl is used for the fornical area.
It is recommended that you view OSREF DVD Vol. 11 “Scleral Ischemia and Melt” and call Dr. Tseng at 305-274-1299 for any questions BEFORE your first procedure.

**Anesthesia:** Topical anesthesia is preferred. After prep and drape of the eye and insertion of a lid speculum, drops of non-preserved epinephrine 1/1000 (Hospira, Inc., Lakes Forest, IL) are instilled on the ocular surface to achieve vasoconstriction for hemostasis, and 2% lidocaine gel (AstraZeneca LP, Wilmington, DE) is applied for anesthesia.

**Traction Suture and Exposure:** A 7-O double armed Vicryl suture is placed as a traction suture at 2 to 3 mm from the superior and inferior limbus with episcleral bites (Fig. 2). The eye is rotated by hanging a locking needle holder to allow adequate exposure of the bulbar sclera where the ischemia and melt is most pronounced.

**Incision:** Sharp Wescott scissors are used to release the healthy conjunctiva along the border of the scleral melt (Fig. 3A) and to create relaxing incisions radially from the edge of the scleral melt toward the healthy fornix. This allows for subsequent isolation of the Tenon’s capsule located posterior to the melt and creates a pedicle graft (Fig. 3B).

**Removal of Necrotic Tissue and Calcium Plaque:** The scleral melt area is further debrided to remove all unhealthy necrotic tissue (Fig. 4A). If there is calcified plaque (e.g., in chronic scleral melt) it can simply be removed by superficial lamellar dissection using a #64 blade (Fig. 4B). The goal is to restore a clean host bed that may reveal the underlying uveal tissue.

**For Repair of Scleral Ischemia in Acute Chemical/Thermal Burns:** After removal of necrotic tissue (Fig. 5A, 5B, 5C), the ischemic zone is first covered by a layer of cryopreserved amnion graft to protect the remaining sclera using 10-O nylon interrupted sutures (Fig. 5D) or fibrin glue (see below).
**Key Surgical Steps**

**For Repair of Scleral Tissue Loss using a Lamellar Corneal Graft:** For eyes showing scleral melt, a notable loss of scleral tissue can be supplanted by lamellar corneal tissue. After measuring the dimension of the scleral defect, the corneal graft is stripped off the endothelium and the epithelium using a Q-tip. A free-hand lamellar graft is created by using scissors and a super blade to match the scleral defect size (Fig. 6A). This lamellar corneal graft can be secured to the scleral bed without sutures using fibrin glue; it is hard to place sutures if the melt extends to the equator. This gluing is achieved by drying the scleral bed with a Weckcel, applying the thrombin (watery, colorless) solution to the bare sclera (Fig. 6B), and then by applying the fibrinogen (viscous, tawny) solution to the concave stromal surface of the lamellar corneal graft (Fig. 6C). The lamellar corneal graft is then flipped to cover the scleral defect, and attached to the sclera using a muscle hook to smooth and spread the fibrin glue evenly underneath (Fig. 6D).

**Tenonplasty:** The subconjuctival Tenon tissue is carefully dissected from the episcleral space and from the overlying conjunctiva tissue, and prepared as a pedicle graft (Fig. 7A). Such a Tenon graft is easily stretched to cover a large area. The size of such a Tenon graft is contingent upon the size of the ischemic area to be covered. It is advisable to cover at least a part, if not all, of the defect by either using 10-0 nylon sutures with solid episcleral bites to the healthy sclera (Fig. 7B) or fibrin glue. The thrombin (watery, clear) solution is applied on the top of the corneal graft (Fig. 7C) and the fibrinogen (viscous, tawny) solution is applied to the inner surface of Tenon's capsule. Using two 0.12 forceps, the Tenon is stretched to cover the scleral defect area, and held for at least 5 seconds (Fig. 7D). A muscle hook is then used to spread and smooth the fibrin glue underneath.
Transplantation of Amnion Graft: The cryopreserved amnion graft is peeled from the nitrocellulose filter paper using two 0.12 forceps and laid down onto the scleral melt area with the sticky, stromal surface facing down to cover the entire defect (Fig. 8A). The membrane is flipped in half so one half of the stromal surface will be facing up (Fig. 8B). The thrombin (watery, clear) solution is applied to the surgical bed/defect (now covered by Tenon's capsule) (Fig. 8C) and fibrinogen (viscous, tawny) solution is applied to the stromal side of folded membrane (Fig. 8D). Next the membrane is flipped back on the bed/defect and a muscle hook is used to spread the fibrin glue into an even and thin layer underneath the amnion graft (Fig. 8E). The above steps are repeated to secure the other half of the membrane. After a short time (less than 30 sec) of polymerization, check the strength of the adhesion by lifting each corner of the membrane with 0.12 forceps. If easily detached, apply the two fibrin glue components directly onto the bed/defect and spread the glue and smooth the membrane again using a muscle hook. Trim the excess membrane and fibrin glue from the edges (Fig. 8F).

About Sutures:
If fibrin glue is not used, both lamellar corneal graft and Tenon's pedicle graft can be secured by interrupted 10-O nylon sutures. The cryopreserved amnion graft can be secured using several interrupted 10-O nylon sutures on peri-limbal bulbar conjunctiva and by 8-O Vicryl sutures in a mattress fashion, parallel to the fornix, with solid episcleral bites to seal the fornix border.

Key Post-operative Points:
It is advised to see the patient POP 1 day, 1 week, 3 to 4 weeks and thereafter depending on the clinical outcomes. At POP day 1, instructions such as avoiding dirty water into the eye are given and medications such as Prednisolone acetate 1% (Pred Forte®) four times a day and Ofloxacin 0.3% (Ocufox®) three times a day are started. At the 3 to 4 week visit, complete epithelialization over the cryopreserved amnion graft and restoration of the scleral integrity are expected. During this visit, Ocufox® is stopped and PF is tapered off at a weekly schedule from four times a day. Additionally, if fibrin glue is not used, remove all sutures at this time. (Fig. 9A and 9B for acute chemical burn: Fig. 9C and 9D following pterygium surgery).
Scleral ischemia, thinning and melt can occur in acute severe chemical or thermal burns and following ocular surgeries such as pterygium excision with a bare sclera technique, especially if such adjuvant therapies as beta-irradiation and mitomycin C are used. In addition, scleral melt has also been described after retinal detachment repair, glaucoma surgery, systemic vasculitis and connective tissue disorders.

Reim et al first described the use of Tenonplasty as an excellent alternative to treat limbal and scleral ischemia in patients with severe chemical and thermal eye burns in 1989 to facilitate conjunctival healing and to halt progressive scleral melt. Since then, several reports have been published reassuring the effectiveness of this surgical approach. Lin et al in 2002 reported the use of Tenonplasty and amniotic membrane transplantation in 6 patients with scleral perforation after pterygium surgery. There were no recurrences during a follow-up period of 12 to 24 months.

On the other hand, when severe scleral thinning or melt with impending globe perforation is evident, sclera reinforcement is necessary. Different types of tissue grafts have been proposed and/or actually used to fulfill this purpose. They include preserved sclera, cornea, pericardium, fascia lata, dura, conjunctiva, amniotic membrane, etc. None of the proposed grafts have been universally accepted. Lin et al in 1996 described a method for scleral grafting using preserved sclera and tissue adhesive with an overlying conjunctival flap, and noted good results in 5/6 cases with infectious scleral ulcers. Rodriguez-Ares et al successfully used scleral graft and amniotic membrane transplant to repair a large scleral perforation in a patient with Marfan's syndrome and a past history of various surgeries in both eyes. Hanada et al used multilayered amniotic membrane transplantation for the treatment of 11 patients (11 eyes) with deep corneal ulcers (n=5), corneal perforations (n=4) and scleral ulcers (n=2). After surgery 8/11 eyes, including 2 cases with scleral defects did properly heal. Ma et al used cryopreserved amniotic membrane as a patch graft to reduce stromal melting and promote reepithelialization in four cases of infectious scleral ulcers with persistent scleral melting and three cases with corneoscleral ulcers with perforation. They noted that melting and inflammation at the lesion site decreased after the amniotic membrane grafting. It should be noted that in all their cases the causative microorganisms were identified and the appropriate topical and systemic antibiotics were given to all patients before the surgery. Oh et al performed a prospective study in 8 eyes (8 patients) using preserved sclera and amniotic membrane transplantation for the surgical repair of scleromalacia with impending perforation. All patients experienced loss of ocular pain and inflammation and rapid epithelialization. Ti et al reported the successful use of tectonic corneal lamellar grafting with overlying conjunctival flap in 95% of their cases (19/20 patients) with severe scleral melts after pterygium surgery with mitomycin C or beta irradiation. Golchin et al reported lamellar keratoplasty as an effective treatment option for scleral necrosis induced by beta irradiation, achieving tectonic restoration in all of their patients (30 eyes). Most recently Sangwan et al retrospectively evaluated the outcome of alcohol preserved scleral patch grafts in conjunction with overlying conjunctival flaps or amniotic membrane, in patients (n=13) with scleral defects of varying etiologies, and noted this approach was effective in preserving the globe integrity in 77% of these cases.


• Is it safe to use retrobulbar or peribulbar anesthesia?
Both peribulbar and retrobulbar anesthesia, if not done properly, can induce orbital congestion and hemorrhage that will distort the tissue planes and make isolation of the Tenon’s capsule difficult.

• Could I retrieve the Tenon from the caruncle area?
No. It is better not to do so because Tenon’s capsule retrieved from the caruncle area might result in contracture, leading to motility restriction. Therefore, it is better to take Tenon from the superior or the inferior fornix.

• Do I always need to perform lamellar corneal graft?
No. If the scleral melt is not full thickness and large, multiple layers of cryopreserved amnion graft are sufficiently strong to restore the scleral integrity. That is why lamellar corneal graft is not used in acute chemical burns when there is scleral ischemia without melt. However, when the scleral melt is near full-thickness and large in size, it is necessary to reinforce the tectonic support. In addition to lamellar corneal graft, one can also consider scleral graft or pericardium graft (also see Literature Summary).

• Should the amnion graft be trimmed while still on the paper or after being laid on the defect?
As a personal preference, the entire amnion graft is best laid on the defect without trimming. The excessive graft and fibrin gel can be trimmed after the glue has set. This avoids the graft being cut too small to cover the defect.

• What is the real value of using fibrin glue?
The use of fibrin glue eliminates sutures, which can be very difficult to do especially if the melt is close to the equator. Due to the lack of sutures, the surgical time is shortened to the point topical anesthesia is feasible in most cases.

• Should I perform tarsorrhaphy at the end of the surgery?
For most cases, it is not necessary to do so. However, for severe chemical burn, especially if the lid margin is also involved and if there is a thermal component (e.g., firework injury), it is a good idea to bring the lid margin together with tarsorrhaphy, which will prevent exposure (due to lack of effective blink and closure) and wound contracture to the lid tissue.

• Should I perform transplantation of limbal stem cells at the same time in acute chemical burns?
No. It is better to wait until the limbal tissue has been fully vascularized by the aforementioned procedures before transplantation of autologous or allogeneic stem cells. Therefore, it is better not to do it at the same time.

• Why is cryopreserved amnion graft (AMNIOGRAFT®) recommended?
AMNIOGRAFT® is the only commercially available cryopreserved amnion graft in the U.S. The method of cryopreservation retains the biologic actions of the tissue in utero (anti-scarring, anti-inflammation, anti-angiogenesis, and promotion of healing).

• What if the patient experiences pain after surgery?
This complaint is infrequently observed using the surgical methods detailed above. If it is, use analgesics.

• Is it necessary to use ointment and patch at the end of surgery?
Application of an antibiotic/steroid ointment such as TobraDex® and a patch at the end of surgery maintained overnight, stabilizes and secures the graft.

FAQs:
The Ocular Surface Research & Education Foundation Presents:

**Cryopreserved Amnion Grafts for Pterygium**

By Scheffer C.G. Tseng, MD, PhD & Hosam Sheha, MD, PhD

**Overview**

Multiple procedures have been advocated in the treatment of pterygium ranging from simple excision with bare sclera to the use of grafts to cover the sclera. Simple excision carries a high recurrence rate ranging from 24%-89%. The addition of mitomycin C (MMC) or the use of grafts has been reported to be effective in preventing recurrence.

Cryopreserved amniotic membrane with fibrin glue and intraoperative application of MMC can improve the surgical aesthetic outcome with a recurrence rate similar to that of conjunctival autograft. Limbal conjunctival autografts provide less recurrence, but the procedure of harvesting the graft is time consuming, technically difficult and inapplicable in cases with limbal disturbances. Therefore, cryopreserved amniotic membrane with MMC and fibrin glue is the preferred treatment for pterygium.

**Pterygium Key Pre-operative Points:**

- The aggressiveness of a pterygium can be judged by looking at the lesion's morphology through a slit lamp. In a more aggressive pterygium the episcleral vessels are obscured by dense fibrovascular growth.

- Other diseases that may cause surface inflammation such as dry eye, allergy/atopy or demodex blepharitis should be eliminated or controlled prior to surgery.

**Surgical Supplies for Pterygium Surgery:**

- Cryopreserved Amniotic Membrane Allograft: AMNIOGRAFT® from Bio-Tissue (1-888-296-8858). For primary pterygium use the 2.0 x 1.5 cm size (Catalog # AG-2015). For double headed pterygium use the 2.5 x 2.0 cm size (Catalog # AG-2520) or 3.5 x 3.5 cm size (Catalog # AG-3535).

- Mitomycin C (MMC): Prepared by diluting lyophilized powder with Balanced Salt Solution (BSS). Make sure the concentration is correct. 0.02% - 0.04% MMC is equal to 0.2 - 0.4 mg/ml.

- Traction Sutures: Use 7-0 Vicryl sutures

- For sutureless surgery, use fibrin glue: TISSEEL from Baxter Biologics (1-877-TISSEEL) 2.0 mL (Catalog # 1501236) or Evicel from Ethicon from Johnson & Johnson (1-800-255-2500) 1 mL (NDC # 63713-390-11).

- For surgery with sutures, 10-0 nylon and 8-0 Vicryl sutures are recommended.

**References:**


Surgical Technique for Primary Pterygium

• Insert a 15 mm solid blades Speculum (K1-5014 Katena), apply Epinephrine (1:1000) for hemostasis and 2% lidocaine gel (Astra Zeneca) for Topical Anesthesia

P.S. Avoid peribulbar anesthesia which may distort the tissue plane

• Place 7-0 Vicryl Traction Suture at the superior and inferior limbal sclera for adequate exposure and fixation of the globe

• Excise pterygium head and body by using 0.12 forceps to pick up the conjunctiva in front of the semilunar fold (Fig. 1), and use scissors to make a conjunctival peritomy up and down. Then pick up the fibrovascular pterygium tissue toward the surgeon while using scissors to truncate it from the fornix without damaging the muscle or the Tenon (Fig. 2).

• Apply MMC (0.02% to 0.04%): Cut strips from a Weckcel’s slant edges, soak them in the MMC solution, and apply approximately 3 sponges to subconjunctival fibrovascular tissue at the fornix edge (Fig. 3) of the conjunctiva above the Tenon for 2 min for mild, for 3 min for moderate, and 4 min for severe pterygium while using a Q-tip to dry the bare sclera (Fig. 4). Irrigate the contact surface with half a bottle of BSS after the incubation.

• Seal the gap between the conjunctiva and Tenon using fibrin glue. Apply one drop of each of the two components to the gap and then seal it by approximating them with two 0.12 forceps (Fig. 5)

• Transplant Cryopreserved Amnion Graft with Fibrin Glue: Peel the cryopreserved AmnioGraft off from the nitrocellulose paper. Lay it on the bare sclera with the sticky/stromal surface
Surgical Technique (continued)

Facing down. Flip one half of the graft up to cover the other half revealing the bare sclera. Apply the fibrinogen oily/cloudy solution to the bare sclera and/or the stromal side of the graft. Next, apply the thrombin/watery/clear solution to the same area. Using two 0.12 forceps to flip back the graft to re-cover the bare sclera. Stretch and flatten the graft with two forceps at different areas for a total of 45 sec before final smoothening by a muscle hook. Repeat the above steps to the other half of the membrane. Trim any excess membrane and fibrin glue from around the defect and then tuck the graft underneath the conjunctival edge and seal the conjunctiva over the graft with fibrin glue placed in between (Fig. 6). Always check the adhesion strength at the edge of the graft by 0.12 forceps. If the graft detaches, do “touch up” by applying fibrin glue to the unsecured areas. (Video)

- **Inject Kenalog (0.2 c.c. of 40 mg/ml)** into the caruncle area at the end of surgery (Fig. 7).

Post Operative Care

Begin topical Prednisolone every 2 hours and Ocuflox three times a day for 4 weeks and see the patient at that time (mandatory). If the surrounding conjunctiva is not inflamed (Fig. 8), stop Ocuflox and taper off PF at a weekly schedule from four times a day. If however the surrounding conjunctiva is inflamed (Fig. 9), give subconjunctival injection of 0.1 cc Kenalog (40 mg/ml) per site in the office at to abort any progression into recurrence and watch for IOP elevation. At time points later than one month, if early recurrence is suspected, you may like to consider subconjunctival injection of 5-FU (5 mg/0.1cc) twice, 2 weeks apart, or holding a sponge soaked with MMC 0.02% at the area of concern for 5 min before rinse.
What should I do if I see a separation in the graft edge at nasal fornix in the early post-operative days?

This happens because of poor fibrin glue adhesion or excessive fibrin glue trapped in between. To avoid this, stretch the membrane with the muscle hook toward the cornea to squeeze excess glue out. If the area of graft shows hyperemia or inflammation, give an injection of Kenalog to avoid granuloma formation in one month.

Why would pyogenic granuloma develop and how do you treat it?

Pyogenic granuloma (Fig. 10) may develop for several reasons including exposed sclera or subconjunctival tissue, suture induced trauma, residual fibrovascular tissue, large mass of fibrin glue left, and/or lack of good contact with the MMC soaked sponge during incubation. One can avoid this complication by fully covering the bare sclera with amniotic membrane using fibrin glue without sutures, by making sure there is full contact between the caruncle tissue and the MMC sponge by pushing caruncle down during MMC incubation time via 0.12 forceps, and by carefully monitoring inflammation of the host conjunctival tissue at one month postop visit. If pyogenic granuloma develops, one can increase PF to q2h for one or two weeks. Once the stalk is not congested, it can simply be excised in the office.

What are the advantages of amniotic membrane transplantation over conjunctival limbal autograft in pterygium surgery?

Although the use of free grafts of conjunctiva and limbal tissue is reported to have better success rates, cryopreserved amniotic membrane has the following advantages:

1. Less pain (as no donor site is injured)
2. Shorter surgical time
3. Faster patient recovery
4. Amenable to cover a larger defect
5. Saves the donor site for other surgeries such as glaucoma
6. Better cosmetic outcome

Amniotic membrane can provide consistently better results than conjunctival autograft. However, to achieve this goal, one will have to use intraoperative MMC.

Can we use MMC in patients who have had previous radiation treatment?

It is advisable to avoid using Mitomycin C in such cases as there is increased risk of scleral melting due to pre-existing ischemia.

How far should the pterygium head and body be removed?

If the semilunar fold can be identified, the truncation is made before the fold. It is important not to excise the fibrovascular tissue/Tenon in the fornix to allow fat to prolapse (herniated).

How is the corneal epithelial defect handled during pterygium surgery?

For primary pterygium, the cryopreserved amnion graft does not need to go beyond the limbus to cover the corneal defect because the corneal healing occurs rapidly without any complications.
The Ocular Surface Research & Education Foundation Presents:

**Stevens - Johnson Syndrome and Toxic Epidermal Necrolysis**

By Hosam Sheha, M.D., Ph.D. and Scheffer C. G. Tseng M.D., Ph.D.

Stevens-Johnson Syndrome (SJS) is an immune-complex–mediated hypersensitivity disorder which typically involves the skin and the mucous membranes.1 SJS is a serious systemic disorder with the potential for severe morbidity and even death. Significant involvement of oral, nasal, eye, vaginal, urethral, GI, and lower respiratory tract mucous membranes may develop in the course of the illness.2 The severe variant of SJS showed extensive skin involvement resulting in toxic epidermal necrolysis (TEN). Although SJS/TEN is considered one of the most devastating ocular surface diseases which causes corneal damage and threatens vision, management of ocular involvement may be compromised because more attention is directed to maintaining the vital functions during the acute stage.

Furthermore, upon eye examination of patients suffering SJS/TEN at the acute stage it is difficult to recognize hidden conjunctival inflammation and ulceration deep in the fornix and tarsus. Inadequate control of ocular surface inflammation and ulceration at the acute stage will set in a vicious cycle, leading to the chronic stage of scarring (cicatrix), which then contributes greatly to subsequent corneal complications.3,4

Although systemic corticosteroids are commonly used and shown to be of some benefit in ameliorating systemic manifestations of the acute phase of SJS and TEN,5 its therapeutic effect has never been demonstrated in a controlled trial. Furthermore, retrospective studies demonstrate no benefit of corticosteroids or higher rates of morbidity and mortality in corticosteroid-treated patients.6,7 Cyclosporin A8 and plasmapheresis9 have been proposed as alternatives. Recently, IV immunoglobulin has also been advocated for both SJS10 and TEN.11 Despite these measures, specific attention to suppress ocular surface inflammation and to promote early epithelialization has not been considered. A recent retrospective study verified that the extent of lid margin keratinization and tarsal scar (as a result of cicatricial complications) is highly correlated with sight-threatening corneal complications.12

Amniotic membrane transplantation has been used as a temporary graft (or patch) during the acute stage, defined as the first two weeks, of chemical and thermal burns. It can suppress inflammation and prevent subsequent scarring in the later stage.13-15 Amniotic membrane has also been used as a temporary graft in patients with acute SJS/TEN with16,17 or without12,18 corneal involvement in the acute stage to suppress inflammation and facilitate wound healing, resulting in restoration of a normal and healthy ocular surface and sight.

A new medical device recently approved by the FDA, PROKERA® (Bio-Tissue, Miami, FL), can facilitate the early delivery of the needed biological effects of cryopreserved amniotic membrane at the bedside or clinic without sutures. This delivery mechanism for cryopreserved amniotic membrane is an important utility in treating this devastating disease at the acute stage.

In conclusion, transplantation cryopreserved amniotic membrane performed in the acute phase of SJS/TEN can be highly effective not only in reducing inflammation and preventing scarring in the conjunctival and corneal surfaces and in restoring corneal epithelial integrity in eyes even when the hidden inflammation and ulceration is not detected. As a result, it prevents sight-threatening cicatricial complications at the chronic stage.17

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**Supplies for Procedure**

1. Sterile lid speculum
2. Sterile gloves
3. Anesthetic drops
4. Antibiotic drops
5. Sterile scissors (provided with the ProKera™ device)
6. Sterile forceps (provided with the ProKera™ device)
7. ProKera™ (by Bio-Tissue™) call for info: 1-888-296-8858

**ProKera™ sizes:**

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What is Stevens-Johnson Syndrome (SJS) and what are the symptoms?
Stevens-Johnson Syndrome is a serious, potentially life-threatening skin disease. With Stevens-Johnson Syndrome the sufferer can first experience non-specific symptoms, such as headaches, aching body, fever, and cough. Then a rash may develop over the face and trunk, which then spreads to other parts of the body. The rash is patchy and spreads. Blistering can then appear, usually in places such as the eyes, mouth, nose and genital areas, and the mucous membrane becomes inflamed. Because some of the above symptoms can be found in many other diseases, it is important to consider SJS in the differential diagnosis due to its severe morbidity.

What is Toxic Epidermal Necrolysis (TEN)?
Toxic Epidermal Necrolysis is another variation of the disease. With this variation the skin also begins to peel away in large amounts. This leaves the sufferer looking as though the patient has burns. There is a significant risk of infection and fluid can profusely leak out in the places where the skin has come away.\cite{19,20}

What are the differences between Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)?
SJS and TEN (Toxic epidermal necrolysis) are characterized by identical clinical signs and symptoms, identical treatment approach, and identical prognosis.

Several classification schemes have been reported, the simplest (French, Allergol Int, 2006) breaks the disease down as follows:

- **SJS** - A "minor form of TEN," with less than 10% body surface area (BSA) detachment
- **Overlapping SJS/TEN** - Detachment of 10-30% BSA
- **TEN** - Detachment of more than 30% BSA

Patients with 90% skin detachment and diagnosed with TEN may have none or only mild ocular involvement with excellent prognosis, and patients with 10% skin detachment may have severe ocular involvement with blinding consequences, and vice versa.\cite{21}

What is the main cause of SJS/TEN?
The most common cause of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis is through an allergic drug reaction. The drugs that are usually responsible for these reactions include: Penicillin family, some non-steroid anti-inflammatory drugs (NSAIDS), Allopurinol, Phenytoin, Carbamazepine, barbiturates, anticonvulsants, and sulfa antibiotics. The onset of symptoms in drug related Stevens-Johnson Syndrome may not appear for one or two weeks after first taking the drug. Reaction to drugs is by far the most common cause of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis.

What causes SJS/TEN in children?
Medication is usually the cause of the disease of Stevens-Johnson Syndrome in children. However, this condition can stem from other unknown causes. Some of the medications that have been linked to SJS in children include children's Motrin, Advil, and other ibuprofen based drugs. These drugs have received highly negative publicity on a number of occasions after being identified as the cause in a range of cases where children have become seriously ill with SJS.\cite{22}
Who can diagnose SJS/TEN?
A dermatologist is the most likely clinician to establish the diagnosis, with or without biopsy. Severe cases may require the involvement of a burn specialist or plastic surgery specialist. Internal medicine, critical care, or pediatrics consultants direct inpatient care.

A consultation with an ophthalmologist is mandatory when there is ocular involvement. Even if the eye is closed, one cannot assume the eye is not involved. Bedside examination is inadequate to assess ocular involvement because hidden inflammation and ulceration in the fornix and tarsus may not be visible when eyelids are not everted. Due to the severe ocular morbidity of this disease at the chronic stage, it is advised to assume all victims of SJS/TENS have ocular involvement until a thorough ocular examination can be performed.

Are there any laboratory tests for diagnosing SJS/TEN?
Skin biopsy is the only diagnostically helpful laboratory study. Serum levels of tumor necrosis factor-a, soluble interleukin 2-receptor, interleukin 6, and C reactive protein typically are elevated in patients with SJS; however, none of these serologic tests is used routinely in diagnosing and managing SJS.

What is the differential diagnosis of ocular SJS?
Although there are other diseases that may present cicatricial complication such as Chemical burns, Conjunctivitis, Keratoconjunctivitis, Atopic Dermatitis, Trichiasis, Entropion, Ocular Rosacea, Sarcoidosis, Scleritis, Sjogren Syndrome, Squamous Cell Carcinoma and Trachoma, SJS/TEN has a characteristic clinical presentation different from these diseases.

How is SJS treated?
Upon diagnosis of SJS, the doctor will first need to identify the cause of the disorder, as this will determine the treatment and steps required. If the disease has occurred as a reaction to medication, the patient should stop taking the medication immediately. Treatment may take place in the burns unit at the hospital depending on the severity of the symptoms. It is important that anyone with this type of disease is treated in the cleanest environment, as this is a disease that leaves both adults and children open to secondary infections. If you have already contracted an infection on top of the SJS, the doctor may also need to administer antibiotics.

The treatment for a patient with SJS can vary depending on the health of the person and the severity of the disease. Fluid replacement and topical steroids may be needed, and the doctor may also administer oral and eye exams and treatments. For eye problems, it is important to consult ophthalmologists to consider early (within the first two weeks) intervention with amniotic membrane transplantation.

What are the complications of SJS/TEN?
Ophthalmologic: Corneal ulceration, anterior uveitis, panophthalmitis, blindness
Gastroenterologic: Esophageal strictures
Genitourinary: Renal tubular necrosis, renal failure, penile scarring, vaginal stenosis
Pulmonary: Tracheobronchial shedding with resultant respiratory failure
Cutaneous: Scarring and cosmetic deformity, recurrences of infection through slow-healing ulcerations

How can SJS/TEN be prevented?
Early recognition and avoidance of possible offending agents may reduce the incidence and/or severity of SJS/TEN.
References


18) Roujeau JC: Stevens-Johnson syndrome and toxic epidermal necrolysis are severity variants of the same disease which differs from erythema multiforme. J Dermatol 1997 Nov; 24(11): 726-9


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