CORNEAL REGENERATION
AMNIOTIC MEMBRANE TRANSPLANTATION IN CLINICAL PRACTICE

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DISCLOSURES

• Bio-Tissue, Inc. – Consultant/Speaker

CORNEA

• Five (or six) layer tissue
• Epithelium regenerates every seven days
• New cells move centripetally from the limbus
• Stromal insult leads to scarring
• Endothelial function critical to maintain dehydration & clarity

CORNEAL DISEASE

• Superficial Keratitis
• Abrasion
• Ulcer
• Streak Infiltrate
• Herpetic Keratitis
• Recurrent Corneal Erosion
• EBMD
• Exposure Keratitis
• Intracorneal Foreign Body
• Radiation Keratitis
• Thermal Keratitis
• Filamentary Keratitis
• Chemical Burn
• Limbal Stem Cell Loss
• Radiation Keratitis
• Corneal Scarring
• Granular Dystrophy

CURRENT METHODS OF TREATMENT

• Topical Medications:
  • Artificial Lubricants
  • Antibiotics
  • Antivirals
  • Steroids
  • Antihistamines
  • Mucolytics

• Surgery/Procedures:
  • Bandage Contact Lenses
  • Anterior/Posterior Keratotomy
  • Lenticule Excision
  • Stromal Desecking
  • Limbal Stem Cell Transplant
  • Keratoplasty
  • PBK, DALK, DSEK, DMEK

NEW METHODS OF TREATMENT

• Amniotic Membrane Transplantation
  • Harvested from pre-planned C-section births
  • Tested and retested for any contagion
  • Sterilized and prepared in cornea-sized patches
  • Frozen for dehydration for long-term storage
  • Prepared and transplanted patient's eye in-office
  • Remains in place for duration of treatment
  • Removed in office and repeated as necessary
AMNIOTIC MEMBRANE PRODUCTS

Wet

- ProKera
- BioTissue proprietary CryoTek process
- Membrane stored in glycerin and foam
- Preserves the HC-HA/PTX3 complex
- "Critical component for establishing fetal wound healing environment & no scarring!"
- Placed on the eye as standalone treatment
- Must be kept in cold storage prior to use
- Shelf life of three to twelve months

Dry

- BioDOptix
- AmbioDisk
- Aril
- Visidisc
- OculoMatrix

WHAT'S THE DIFFERENCE?

Cryopreservation (ProKera)
- Bio-Tissue's proprietary CryoTek process
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Dehydration (everyone else)
- Each company has its own process
- Membrane stored in dry, air-tight packaging
- Dehydration degrades the HC-HA/PTX3 complex
- Debate over importance of complex, potency of dehydrated treatment
- Must be placed behind a bandage contact lens
- Can be kept at room temperature
- Shelf life ranges from two to five years

PREPARATION OF PROKERA FOR PLACEMENT

- Prepare and thoroughly rinse PROKERA
- Anesthetize cornea
- Have patient in down gaze
- Lift upper eyelid
- Place/push graft into upper sulcus
- May pull down lower eyelid during placement
- Allow graft to settle into position
- Evaluate positioning
- Create temporary tarsorrhaphy as needed

PLACEMENT OF PROKERA

- Prepare and thoroughly rinse PROKERA
- Anesthetize cornea
- Place lid speculum
- Optional: dry corneal surface
- Remove amniotic membrane from pouch
- Place amniotic membrane on cornea
- With blunt instrument, flatten to cornea
- Place bandage contact lens over membrane
- Remove speculum

TEMPORARY TARSORRHAPHY

- Patient-dependent
- Indications:
  - If graft is dislocated
  - If graft is at risk for ejection
  - If patient is overly uncomfortable
  - If patient cannot be trusted

PLACEMENT OF DEHYDRATED AMNIOTIC MEMBRANE

- Anesthetize corneas
- Place lid speculum
- Optional: dry corneal surface
- Remove amniotic membrane from pouch
- Place amniotic membrane on cornea
- With blunt instrument, flatten to cornea
- Place bandage contact lens over membrane
- Remove speculum
**POST-OPERATIVE CARE & FOLLOW UP**

- **During wear:**
  - Do not touch or rub eye
  - Do not attempt to remove
  - No water on the eye
  - Continue any/all medications
  - May use artificial tear to comfort

- **Follow-up:**
  - Schedule removal in two to seven days
  - Depends on candidacy of condition
  - Return earlier if increases in symptoms or vision continues to worsen
  - Consider consistent, mid-week scheduling

**REMOVAL OF PROKERA**

- Anesthetize cornea
- Have patient in downgaze
- Lift upper eyelid
- Use upper eyelid margin to find edge of ring
- With mild pressure, separate edge from globe
- Grab free edge with forceps
- Gently lift PROKERA off of cornea and dispose
- Evaluate cornea for improvement

**CHOICES, CHOICES, CHOICES**

**PROKERA Candidates**
- More severe conditions
- Peripheral pathology
- Disabled patients
- Small apertures

**Dehydrated Candidates**
- Mild to moderate conditions
- Central pathology
- High-maintenance patients
- Proptotic patients

**PROKERA CLEAR NOW AVAILABLE**

- Released in March 2016
- Center 6 mm aperture preserves vision
- Coverage of regenerative limbal stem cells maintained
- No dehydrated equivalent at this time

- **Good Candidates**
  - Amblyopia patients
  - Patients with contraindicating exam demands
  - Oily/mucky patients

**THE ALMIGHTY DOLLAR**

**Reimbursement**
- CPT 65778 - Placement of amniotic membrane on the ocular surface; without sutures.
- Medicare reimbursement (2016): $1,568.91
  - Average: $1,100 - $1,200
- Commercial reimbursement: $500 - $1,500
- Med-Care reimbursement (2016): $63.29

**Cost of Goods**
- PROKERA: $699 (each with volume)
- AmbioDisk: $420 (each 12.0 mm disc)
- BioDOptix: $436 (each 9.0 mm disc)
- Aril: $250 (each 8.0 mm disc)

**Profit to Practice**
- Product-dependent, but average of $430 - $710
  - Macrophotographs and anterior photographs

**CASE STUDIES**

**CASE OF THE STICKY CONTACT LENS**
- 55 yo WF, accidentally fell asleep in contact lenses
- Felt intense pain upon removal of lens OS this AM
- Dual abrasions, in and around visual axis
- PROKERA placed with topical antibiotic coverage
- After five days, 100% resolution without scar formation
CASE STUDIES

CASE OF THE SMILING EYES
- 62 yo WF, h/o DES and poor blink function
- Presents with dramatic “smile” keratitis inferiorly OU
- Received PROKERA OD, AmbioDisk OS
- After three days, 100% resolution of keratitis

CASE OF THE PORKED EYE
- 72 yo WF, spattered bacon grease into OD this AM
- Presents with severe pain, watering and vision decrease
- PROKERA placed with topical antibiotic coverage
- Our office’s first amniotic membrane transplant!
- After five days, 100% resolution without scar formation

CASE OF THE LIMBAL LURKER
- 76 yo WF, h/o left esotropia
- Complains of FBS OS
- Staining reveals limbal abrasion OS
- PROKERA placed OS
- Four days later, 100% resolution

CASE OF THE THUMBS UP
- 66yo BM, h/o Bell’s palsy R-side, advanced GLC OD
- Presents for A-Scan, admits he “may have rubbed eye”
- Significant limbus-to-limbus abrasion noted OD
- PROKERA placed with topical antibiotic coverage
- Patient to continue GLC medication
- After five days, 100% resolution without scar formation
- Underwent successful cataract surgery, VA 20/30

CASE OF THE WIDE-EYED RECEIVER
- 45 yo WM, poor eye-hand coordination
- Hit OD with football
- Seen at Urgent Care, admits “may have rubbed eye”
- Significant, irregular corneal abrasion involving visual axis
- PROKERA placed with topical antibiotic coverage
- After six days, 100% resolution without scar formation

CASE OF THE SICK BURN
- Patient splashed sulfuric acid into eyes at work yesterday
- Near complete epithelial loss with conjunctival damage OD>OS
- Two PROKERA placed over three weeks with antibiotic coverage
- After 11 days, multilayering without scarring
- After 17 days, 20/20 vision uncorrected
- Residual conjunctival inflammation treated with sub-conjunctival Kenalog
IN CASE YOU ARE NOT CONVINCED

ANY QUESTIONS?

THANK YOU!