CORNEAL REGENERATION
AMNIOEIC MEMBRANE TRANSPLANTATION IN CLINICAL PRACTICE

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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
• Uveitis
• Sterile Infiltrate
• Herpetic Keratitis
• Recurrent Corneal Erosion
• EBMD
• Exposure Keratopathy
• Intracorneal Foreign Body
• Radiation Keratitis
• Thermal Keratitis
• Inflammatory Keratitis
• Chemical Burn
• Limbal Stem Cell Loss
• Basal Keratopathy
• Corneal Scarring
• Salzmann’s Dystrophy

CURRENT METHODS OF TREATMENT

• Topical Medications
  • Artificial Lubricants
  • Antibiotics
  • Antivirals
  • Steroids
  • Intrinsically Reparative
  • Hyperosmotic
  • Mucolytic

• Surgery/Procedures
  • Bandsage Contact Lens
  • Punch/High-Cone Excision
  • Epithelial Debridement
  • Limbal Stem Cell Transplant
  • Keroplasty
  • PKP, ALK, DALK, DSEK, DMEK

NEW METHODS OF TREATMENT

• Amniotic Membrane Transplantation
  • Harvested from pre-planned C-section births
  • Tested (and tested again!) for any contagion
  • Treated and prepared in cornea-sized pieces
  • Frozen (or dehydrated) for long-term storage
  • Prepared and placed onto patient’s eye-in-office
  • Remains in place for duration of treatment
  • Removed in office and repeated as necessary

DISCLOSURES

• Bio-Tissue, Inc. – Consultant/Speaker
**AMNIOTIC MEMBRANE PRODUCTS**

**Wet**
- PROKERA

**Dry**
- AmbioDisk
- BioDOptix
- Eclipse/Tetra
- Aril
- Visidisc/OculoMatrix

**WHAT’S THE DIFFERENCE?**

**Cryopreservation (ProKera)**
- Bio-Tissue’s proprietary CryoTek process
- Membrane stored in glycerin and frozen
- 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 two years

**Dehydration (everyone else)**
- Each company has its own process
- Membrane stored 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 downgaze
- 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

**TEMPORARY TARSORRHAPY**

- 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 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
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 tears to wash

Follow-up:
- Schedule removal in two to seven days
- Depends on severity of condition
- Return earlier if increase in symptoms or abnormal discoloration detected
- Consider consistent, mid-week scheduling

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

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

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

THE ALMIGHTY DOLLAR

Cost of Goods
- PROKERA: $699 each (varies 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 $400 - $700
- Further sick and anterior photographs

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 OF THE SMILING EYES
- 62-yr MF, 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-yr 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-yr 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
- 66-yr 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, VAsc 20/30

CASE OF THE WIDE-EYED RECEIVER
- 45-yr WM, poor eye-hand coordination
- Hit in 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
- Kept on PROKERA placed over three weeks with antibiotic coverage
- After 11 days, 20/20 vision uncorrected
- Residual conjunctival inflammation treated with subconjunctival Kenalog

CASE STUDIES
IN CASE YOU ARE NOT CONVINCED

ANY QUESTIONS?

THANK YOU!