

CORNEAL REGENERATION

AMNIOTIC MEMBRANE TRANSPLANTATION IN CLINICAL PRACTICE

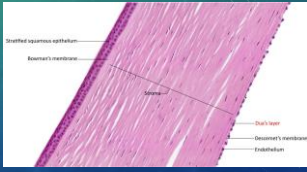
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DISCLOSURES

- 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
- Sterile Infiltrate
- Herpetic Keratitis
- Recurrent Corneal Erosion
- EBMD
- Exposure Keratopathy
- Intracorneal Foreign Body
- Radiation Keratitis
- Thermal Keratitis
- Filamentary Keratitis
- Chemical Burn
- Limbal Stem Cell Loss
- Bullous Keratopathy
- Corneal Scarring
- Salzmann's Dystrophy

CURRENT METHODS OF TREATMENT

- Topical Medications
 - Artificial Lubricants
 - Antibiotics
 - Antivirals
 - Steroids
 - Immunosuppressants
 - Hyperosmotics
 - Mucolytics
- Surgery/Procedures
 - Bandage Contact Lenses
 - Punctal Plugs/Cautery
 - Epithelial Debridement
 - Limbal Stem Cell Transplants
 - Keratoplasty
 - 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



AMNIOTIC MEMBRANE PRODUCTS

Wet



Dry



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 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



PLACEMENT OF PROKERA

- 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 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 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 add artificial tear for comfort
- Follow-up:
 - Schedule removal in two to seven days
 - Depends on severity of condition
 - Return earlier if increase in symptoms or excessive discomfort occurs
 - 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:

- Monocular patients
- Patients with contraindicating vision demands
- Wishy-washy 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
- Medi-Cal reimbursement (2016): ~~\$475~~

Cost of Goods

- PROKERA: \$699 each (varies with volume)
- AmbioDisk: \$420 each (12.0 mm disc)
- BioDOptix: \$436 each (9.0 mm disc)
- Anil: \$250 each (8.0 mm disc)

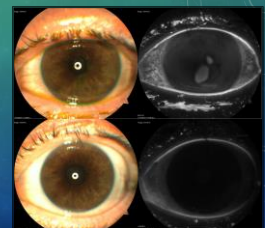
Profit to Practice

- Product-dependent, but average of \$400 - \$700
 - Plus office visits and anterior photographs

CASE STUDIES

CASE OF THE STICKY CONTACT LENS

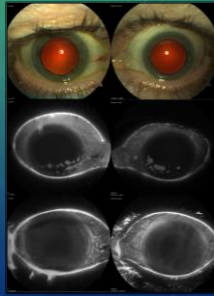
- 55 yo WF, accidentally fell asleep in contact lenses
- Felt intense pain upon removal of lens OS this AM
- Dual abrasions, in and around visual axis
- PROKERA placed with topical antibiotic coverage
- After five days, 100% resolution without scar formation



CASE STUDIES

CASE OF THE SMILING EYES

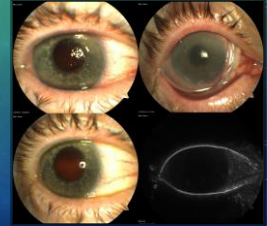
- 62 yo WF, h/o DES and poor blink function
- Presents with dramatic "smile" keratitis inferiorly OU
- Received PROKERA OD, AmbioDisk OS
- After three days, 100% resolution of keratitis



CASE STUDIES

CASE OF THE PORKED EYE

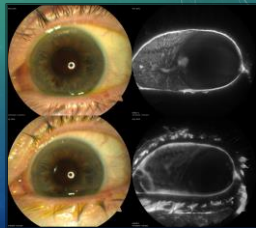
- 72 yo WF, spattered bacon grease into OD this AM
- Presents with severe pain, watering and vision decrease
- PROKERA placed with topical antibiotic coverage
 - Our office's first amniotic membrane transplant!
- After five days, 100% resolution without scar formation



CASE STUDIES

CASE OF THE LIMBAL LURKER

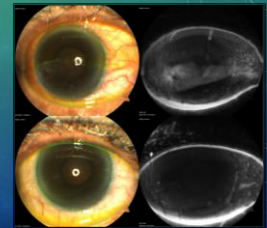
- 76 yo WF, h/o left esotropia
- Complaints of FBS OS
- Staining reveals limbal abrasion OS
- PROKERA placed OS
- Four days later, 100% resolution



CASE STUDIES

CASE OF THE THUMBS UP

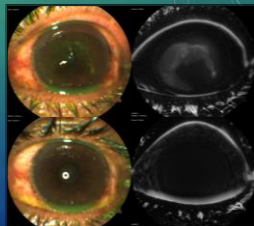
- 66yo BM, h/o Bell's palsy R-side, advanced GLC OD
- Presents for A-Scan, admits he "may have rubbed eye"
- Significant limbus-to-limbus abrasion noted OD
- PROKERA placed with topical antibiotic coverage
 - Reverts to normal OD appearance
- After five days, 100% resolution without scar formation
 - Underwent successful cataract surgery, 10/11/2016



CASE STUDIES

CASE OF THE WIDE-EYED RECEIVER

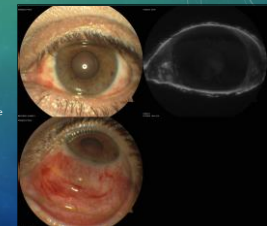
- 45 yo WM, poor eye-hand coordination
- HR in OD with football
- Seen at Urgent Care, admits "may have rubbed eye"
- Significant, irregular corneal abrasion involving visual axis
- PROKERA placed with topical antibiotic coverage
- After six days, 100% resolution without scar formation



CASE STUDIES

CASE OF THE SICK BURN

- Patient splashed sulfuric acid into eyes at work yesterday
- Near-complete epithelial loss with conjunctival damage OD-OS
- Multiple PROKERA placed over three weeks with antibiotic coverage
- After 11 days, epithelial regrowth 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!