Sutureless Amniotic Membrane Workshop: How to Properly Insert and Remove Them





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Disclosure

- Allergan/AbbVie
- BioTissue
- Katena/Corza
- Dompé
- Oyster Point / Viatris
- 🧕 Kala
- Merakris Therapeutics
- Bausch+Lomb
- ImmunoGen
 Zeiss
- Zeiss
- There are no conflicts of interest in this program as all conflicts have been mitigated

Experience

- Have given hundreds of lectures discussing amniotic membranes
- Gave first wetlab on AM November 2014
- Have conducted over 50 wetlabs and workshops around the country
 - AAO, AOA, SECO, ICO, PCO, MCO, OSU, CCO, state associations
 - Instructed 1200+ doctors and students on proper application techniques



What is the amniotic membrane

- Amnion is avascular and a translucent membrane composed of an inner layer of epithelial cells which are planted on a basement membrane
- Amnion is made of Collagen I, III, IV, V and VII, laminin and fibronectin of which IV, VII, laminin and fibronectin are also found in conjunctiva and cornea

Mechanisms of Action

- Promotes Epithelialization
- Suppresses Inflammation
- Inhibits Scarring
- Inhibits Angiogenesis
- Neurotrophic Factors
- Anti-Microbial Agent
- All without the harmful side effects found in topical and oral medications

Indications

- Acute Chemical/Thermal Burns
- Recurrent Corneal Erosions
- Neurotrophic Defects / Persistent Corneal Epithelial Defects
- Filamentary Keratitis
- Vernal Keratoconjunctivitis
- Recalcitrant Dry Eye
- Microbial Keratitis
- Nodular Degeneration
- PRK

Indications

- Acute Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis
- ۵ Post-infectious Recalcitrant Corneal Inflammation (e.g. herpetic, vernal, and bacterial)
- In conjunction with:
 - Superficial Keratectomy
 - High-Risk Corneal Transplantation Corneal ulcers, descemetocele or perforations
 - Scleral melts
 - Limbal graft for partial or total limbal stem cell deficiency
 - Oculoplastic procedures including lid, fornix, and socket reconstruction

 - Glaucoma Surgery Conjunctivochalasis and conjunctival reconstruction
 - Pterygium surgery
 - **Bullous keratopathy**
 - Band keratopathy





Prokera

- Approved by FDA Dec 2003 as a Class II medical device comprised of cryopreserved amniotic membrane graft fastened to thermoplastic ring-set
 - Launched in April 2005
 - Over 300,000 ProKera products placed
- Dual action promotes healing of ocular surface and controls inflammation
- Stored in medium made of Dulbecco's Modified Eagle Medium / Glycerol containing Ciprofloxacin and Amphotericin B
 - Do not use on patients with a history of drug reaction to Cipro or amphotericin B

Prokera

- Cryopreserved
- Store in freezer
 - 1 year bet -49 deg C to 0 deg C (-56.2 F to 32 F)
 - 2 years bet -85 C to -50 C (-121 F to -58 F)- shelf life is 2 years from date of manufacturer
- Allow to thaw to room temperature unopened for 5-10 minutes
- Rinse with saline to reduce stinging sensation
- Do not leave in eye longer than 30 days

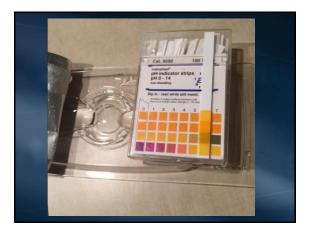










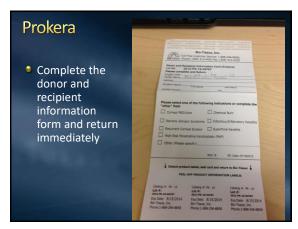














NeoxFlo

- BioTissue
- Sterile, particulate human placental tissue product
- Aseptically processed from Amniotic Membrane and Umbilical Cord tissues
- Processing retains key biological characteristics of the tissue



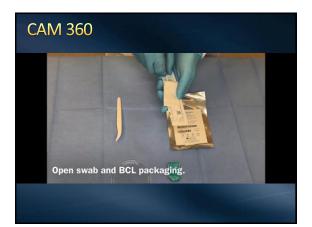
NeoxFlo

- Powder mixed in CL with saline to create gel
- Applied directly to affected eye
- Limited blur
- Generally left for 1-3 days
- New application regimen







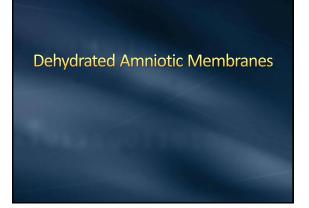




CAM 360







AmbioDisk (Corza) BioDOptix (BioDLogics/IntegraLife) AcellFx (Akorn/Blythe Medical) VisiDisc (Skye Biologics) ReNovaAT (RegenMed) AmnioTek-C (ISP Surgical LLC) Eclipse (Ophthalogix) Xcellereyes (Oculus Biologics) SurSight (Surgenex) Atlas(Atlas Ocular) OptiCyte (Merakris Therapeutics) BioVance 3L Ocular (Versea) iPatch (C5 Biomedical)

Dehydrated Membranes

- All stored at room temperature
- Shelf life typically 2-5 years
- Do not need to be rehydrated
- All require the use of BCL
 - Careful with sizing



 Complete the donor and recipient information form and return immediately



Dehydrated Membranes

Ambio Disk
 Ambio 2 (35µ)
 9, 12 or 15 mm
 Ambio 5 (100µ)

BioDOptix

- Three disc sizes
 9mm, 12mm, 15mm
- 40-60um thick membrane



AmbioDisk Basement membrane side (epithelium) noted by correct right-to-left nomenclature orientation of "IOP" Apply to cornea with IOP down, i.e. basement

- Apply to cornea with IOP down, i.e. basement membrane (epithelium) of tissue directly in contact with cornea.
- Processed with Streptomycin Sulfate and Gentamicin Sulfate
 - Caution in patients with allergies to these

AmbioDisk

- In September 2019, Katena switched to next-generation AmbioDisk
- Preserved using the Clearify process
 The graft is packaged with
- The graft is packaged with amnion (epithelial) side facing up (no longer has "IOP" watermark)
- During application, apply the graft amnion (epithelial) side facing down directly in contact with the cornea
- No longer processed with streptomycin sulfate and gentamicin sulfate
- Over 150,000 distributed



Dehydrated Membranes

AcellFx

- 5 mm Disc
- 8 mm disc
- 10.5 mm disc
- 🛯 15 mm disc
- 1 cm x 2 cm ellipse
- Skye Biologics
 - VisiDisc Thin (45μ)
 - VisiDisc Thick (200μ)
 - 10 mm
- 10 mm
 12 mm
- 15 mm

Dehydrated Membranes

- Ophthalogix
 - Eclipse
 5 8 10 12 14 16 m
 - 5,8,10,12,14,16 mm discs
- Surgenex
 - Sursight
 - 5,8,10,11,12,14,15 mm discs
- Merakris Therapeutics
 - OptiCyte
 - 10,12,15 mm discs
 - 1x1, 2x2, 2x3 cm sheets
 - 45u and 200u thickness

- Renovo-AT Oculus
 9, 12, 15 mm discs
- AmnioTek-C
 - 12 mm disc

Dehydrated 4 Step Process

- 1. Speculum Insertion
- 2. Membrane Placement
- 3. Bandage Contact Lens Placement
- 4. Speculum Removal





1. Lid Speculum Insertion

- Insert the upper lid first followed by the lower lid
- Anesthetize the eye
- Recline chair to supine position
- Instruct patient to look down
- Insert upper speculum onto upper lid
- Instruct patient to look up
- Insert lower speculum onto lower lid, while squeezing near opening

1. Lid Speculum Insertion









4. Lid Speculum Removal

- Remove the Lower Lid followed by the upper lid.
- Instruct patient to look up
- Removed the speculum from the lower lid
- Instruct patient to look ****DOWN****
- Remove from the upper lid while pulling down and away from the patient

4. Lid Speculum Removal





Suggestions

- Create a routine for using these
- Consent Form
- Home going instructions help
 - Antibiotic
 - Corticosteroid
 - Cycloplegic
 - Oral narcotic
- Debridement prior
- Follow up call
- Dropbox link to consent form, etc



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Side Effects

- Contact lens slippage or displacement of Prokera Ring
- Blurry vision
- Burn and sting upon instillation
- Too uncomfortable for patient to tolerate
- Membrane dissolves too quickly
- Need thicker membrane
- Membrane doesn't dissolve
 - Typically due to CL being too tight
 Recommend checking K values prior to insertion and find appropriate BSCL
- <u>Created irritation to cornea (almost micro burns)</u>
 - Sensitivities to chemical make up of cryo / dehydration process

Insertion Techniques







Billing

CPT 65778

- Placement of amniotic membrane on the ocular surface; without sutures Bundled code
- Medicare Fee reduction started Jan 1 roughly down \$250 (\$254.32)

- Modifier
 76 Repeat procedure by same physician
 Repeat procedure by same physician: The physician may need to indicate that a service was repeated the same day subsequent to the original service. This modifier indicates the difference between duplicate services and repeated services.
- No global period

Conclusion

- When to use a Sutureless AM?
 - Promote Epithelialization
 - Suppress Inflammation
 - Inhibit Scarring

How to use a Sutureless AM?

- Practice makes perfect
- Don't wait for last resort treatment



Hands On Workshop Please feel free to contact us:

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QR Code Link to DropBox Files

