Adhesive/Sealant Products and Applications in Anterior Segment Surgery:
Sutureless Conjunctival and Amniotic Membrane Transplantation

Sadeer B. Hannush, MD
Attending Surgeon, Cornea Service, Wills Eye Hospital
Department of Ophthalmology, Sidney Kimmel Medical College,
Thomas Jefferson University
Medical Director, Lions Eye Bank of Delaware Valley
Philadelphia, Pennsylvania

Author has no financial interest in the subject matter of this presentation

I  History

Multiple surgical techniques for removal of pterygium

A. Simple excision (high recurrence rate)

B. Excision
  • with conjuntival autograft
  • with amniotic membrane graft
  • with MMC

Preferred technique by cornea specialists:
excision with conjunctival graft +/- MMC
★ Decreases rate of recurrence !!

II  Disadvantages with current suturing techniques

• Increased OR time
• 10-0 nylon or Vicryl (absorbable, coated and braided) suture cause irritation
• Vicryl may be inflammatory and possibly associated with increased recurrence rate
  (may be less so with other absorbable 9-0 or 10-0 monofilament)
• 10-0 nylon maybe less inflammatory, but requires removal
★ Patient discomfort leading to unplanned visits !

III  Tisseel VH fibrin sealant in conjunctival and amniotic membrane transplantation

A. Components:
  • Sealer protein (Human fibrinogen from pooled plasma)
  • Fibrinolysis inhibitor solution, previously bovine aprotinin, now genetically engineered
  • Thrombin (Human from pooled plasma)
  • Calcium chloride
  • Forms solid coagulum within 3–5 min of delivery
• 70% of ultimate strength attained in the first 10 minutes; full strength reached in about 2 hours
• Dilution of CaCl2 extends period or coagulum formation and allows more time for surgical manipulation (please see attachment)

B. Advantages

Biocompatible, with minimal inflammation or FB reaction, and no tissue necrosis

C. Safety

1. Screening and product preparation
   • Initial evaluation: comprehensive physical exam, tests for viral markers and ALT
   • Within 3 months, must have a second negative test for viral markers and ALT in order for initial plasma harvest to be used
   • Donor tested q 4 months for syphilis and total protein (serum protein electrophoresis)
   • Plasma mini-pools tested with PCR for HIV 1, 2; Hep. A, B, C; Human Parvovirus B19
   • Product undergoes vapor heat viral inactivation (inactivates lipid, and non-lipid enveloped viruses)
   • Generation of hot vapor in a homogeneously moistened lyophilisate
   • Vapor heat: 10 hours, 60°C, 1190 mbar pressure, then one hour at 80°C 1375 mbar

2. Worldwide experience
   • In over 20 million applications of Tisseel VH over 27 years (since 1984), no documented transmission of HIV, Hepatitis A, B, or C, Creutzfeldt-Jakob, or BSE (“mad cow”)
   • Two cases of HPV B19 transmission were reported prior to institution of PCR screening in late 1990’s
   • 2 reports of anaphylaxis in bovine-allergic recipients (non ophthalmologic use)

D. Uses

1. Surgery
   • Cardiovascular, thoracic, gynecologic
   • Repair of splenic and liver injuries
   • Colostomy closure

2. Ophthalmology
   • Adjunct in closure of macular holes
   • Strabismus
   • Glaucoma
   • Cataract
• Blepharoplasty
• Cornea
  • Seal corneal perforations in conjunction with amniotic membrane grafts
  • Enhance wound healing in RK wounds
  • Sutureless lamellar keratoplasty
  • Scleral patch adhesion
  • Prevention of epithelial migration under LASIK flaps
• Conjunctiva (Cut and Paste)
  • Sutureless fixation of conjunctival autografts with an organic tissue adhesive
  • Sutureless fixation of amniotic membrane grafts

IV Experience
217 eyes with primary or recurrent pterygium underwent lamellar keratectomy for excision of the corneal lesion, followed by autologous conjunctival or amniotic membrane transplantation using Tisseel VH fibrin sealant instead of suture (between January 2003 and March 2016)

V Results
• 211 conjunctival grafts remained secure in place throughout the follow-up period (1-150 months)
• 4 partial graft retractions
• 2 lost grafts
• 5 recurrences around grafts (superior or inferior)

VI Discussion

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\begin{array}{ll}
\text{Suture} & \text{Tisseel VH} \\
\hline
\text{Advantages} & \text{Advantages} \\
- No risk of viral transmission & - Less inflammatory \\
- Faster surface rehabilitation & \star Patient comfort \\
- May require removal & - Hypothetical risk of transmission \\
\star Irritation, unscheduled visits & - Risk of anaphylaxis \\
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VII Conclusion
• Tisseel VH is effective in autologous conjunctival and amniotic membrane transplantation as an alternative to suture during pterygium surgery and other ocular surface reconstruction procedures
• It shortens surgical time, may be less inflammatory than suture, allows rapid healing, and improves patient comfort

Dilution Procedure

1. Inject 2 ml 10% CaCl₂ solution into 100 ml Water for Injection and swirl vial.
2. Reconstitute Thrombin + CaCl₂ in the Tisseel Kit.
3. Inject 1 ml of this Thrombin 500 IU/ml into the prepared 20 mM CaCl₂ vial (100 ml vial), swirl vial, flush 3 times. Scrub nurse should draw up desired volume and clip 5 IU/ml Thrombin syringe into syringe holding device.