EBAA Inspector Guide to Eye Bank Cornea Preparation on Femtosecond Laser

EBAA Accreditation Board
Femtosecond Laser Keratoplasty

• First FSLK performed in 2005
• First Eye Bank prepared tissue in 2006
• 4-5 Eye Banks that have prepared tissue on FSL
• 2009 EBAA stats 288 Laser prep tissue
  – 265 PK
  – 25 ALK
Applicable Aseptic Questions
(From EBAA “Technician Practical Performance Test - Femtosecond Laser Processing”)

1. Appropriate, monitored environment for performing open-container processing with femtosecond laser (e.g. records of routine culturing, acceptable CFU levels).

   "1" Yes
   "0" No  
   If no, describe deficiency of environment ______________________________

   • Review records of culturing and results
     – Needs to be <25 CFU per 90mm² settling plate
     – At least annually done
Applicable Surgical Questions

1. Femtosecond Laser warm up and appropriate check(s) run according to manufacturer’s recommendations – Per Eye Bank’s SOP
   - 1 Acceptable
   - 0 Unacceptable If unacceptable, describe: ________________________________
   - 0 Not performed: SOP requires, however technician did not perform

   • Laser warm-up takes about 20min, should be done before room prep

2. Objective(s) for graft configuration established and reviewed. Laser settings programmed accordingly. – Per Eye Bank’s SOP
   - 1 Acceptable
   - 0 Unacceptable If unacceptable, describe: ________________________________
   - 0 Not performed: SOP requires, however technician did not perform

   • Confirm with surgeon request form. This may be done right before laser applanation onto cornea.
Field Set-Up and
Cornea
Mount
Applicable Aseptic Questions

2. Appropriate dress (Was the technician wearing moisture impermeable clothing with sterile sleeves/sterile impermeable gown, cap, mask and protective eye wear?)
   - Yes
   - No
   If no, what was technician wearing?

3. Wrapping of instruments (includes double wrapped, single-wrapped, and visi-peel bag)
   - Acceptable
   - Unacceptable
   If unacceptable, describe:

4. Kit unwrapped so that the sterility of instruments, equipment, and sterile field are not compromised
   - Yes
   - No
   If aseptic technique violated, note how:

5. Placement of non-sterile items around sterile field
   - Acceptable
   - Unacceptable
   If unacceptable, describe:

• All question are same as if viewing EK processing
Applicable Aseptic Questions, cont

5. Placement of non-sterile items around sterile field
   "1 Acceptable
   "0 Unacceptable If unacceptable, describe:______________________________

6. Scrubbing technique, per AORN standards, utilizing aseptic technique
   "1 Appropriate
   "0 Inappropriate technique If not appropriate, describe:____________________

7. Gloving technique
   "1 Acceptable
   "0 Unacceptable If unacceptable, describe:______________________________

8. Transfer of corneoscleral rim or whole globe from container to sterile field
   "1 Acceptable
   "0 Unacceptable If unacceptable, describe:______________________________

• All question are same as if viewing EK processing
3. Conjunctiva removal (360° peritomy) – Per Eye Bank’s SOP
   - 1 Acceptable: complete removal
   - 0 Unacceptable: compromised cornea, incomplete removal or contaminated the tissue
   - 0 Not performed: SOP requires, however technician did not perform
   - 1 N/A: Eye Bank’s SOP does not require

   • Same as EK

4. Cornea placed on Artificial Chamber satisfactorily (ie. centers cornea, does not fold, induce stress lines, or traumatize endothelium) – Per Eye Bank’s SOP
   - 2 Acceptable
   - 1 Acceptable: slight problems
   - 0 Unacceptable: many problems If many problems, describe:___________________________
   - 0 Not performed: SOP requires, however technician did not perform

   • Same as EK, disposable AAC often used (Katena)
5. Adequately assesses pressure (ie. does not induce stress lines or traumatize endothelium) – Per Eye Bank’s SOP
   - 2 Acceptable
   - 1 Acceptable: slight problems
   - 0 Unacceptable: many problems If many problems, describe:___________________________
   - 0 Not performed: SOP requires, however technician did not perform

   • IV line should be left ‘open’. Laser applanation presses cornea down, must return to shape

6. Appropriate applanation of femtosecond laser interface onto the cornea.
   - 2 Acceptable
   - 1 Acceptable: slight problems
   - 0 Unacceptable: many problems If many problems, describe:___________________________

   • Centered
   • Complete, not too much applanation
IntraLase IEK™ Settings and Cut
Cornea Dissection
Applicable Aseptic Questions

9. Placement of instrumentation and equipment during procedure
   - 1 Acceptable
   - 0 Unacceptable
     If unacceptable, describe: ________________________________

10. Instruments used for conjunctival resection—Per Eye Bank’s SOP
    - 1 Acceptable
    - 0 Unacceptable
      If unacceptable, describe: ________________________________
    - 0 Not performed: SOP requires removal however technician did not perform
    - 1 N/A: Eye Bank’s SOP does not require

• Same as EK processing
Applicable Aseptic Questions

11. Measurement of the stromal bed while maintaining aseptic technique (ie. using pachymetry during procedure) – Per Eye Bank’s SOP.
   - 1 Acceptable
   - 0 Unacceptable  If unacceptable, describe: ____________________________________________
   - 0 Not performed: SOP requires, however technician did not perform
   - 1 N/A: Procedure does not require (e.g. full thickness graft vs. DSAEK)

   • Pachymetry not usually performed because mostly PK and ALK

12. Transfer of corneoscleral rim to vial or viewing chamber of preservation medium
   - 1 Acceptable
   - 0 Unacceptable  If unacceptable, describe: ____________________________________________

   • May be just the graft into the vial
7. Anterior Chamber Maintained
   "2 Acceptable
   "0 Unacceptable: anterior chamber collapsed or high pressure fluid rupture through laser cut.

   • IV pole should be lower to reduce flow before deapplanation
     — Otherwise graft will rupture (PK)

   • IV flow should be controlled during blunt dissection of PK graft, otherwise graft distortion

8. Thickness and diameter of stromal bed measured - per Eye Bank’s SOP (*Note: The timing of this step may vary between banks, but should occur at the time specified by each Eye Bank’s SOP)
   "1 Acceptable
   "0 Unacceptable
   "0 Not performed: SOP requires, however technician did not perform
   "1 N/A: Procedure does not require (e.g. full thickness graft vs. DSAEK)

   • Only if EK being performed, possible for ALK
9. Cornea removed from Artificial Chamber satisfactorily (ie. does not fold, induce stress lines, or traumatize endothelium) – Per Eye Bank’s SOP
   "2  Acceptable
   "1  Acceptable: slight problems
   "0  Unacceptable: many problems  If many problems, describe:_____________________________

• Just the graft in case of PK
• Corneo-scleral rim for ALK or EK (so same as EK processing)

10. Manual dexterity during procedure
    "2  Acceptable
    "1  Acceptable: slight problems
    "0  Unacceptable: many problems  If many problems, describe:_____________________________

• Often directly handling the graft, much care needed
11. Question: Did the technician perform this procedure as described in the Eye Bank policies and procedures manual?
   "1 Yes
   "0 No

12. Question: Did the technician explain deviations, if any, from the procedure as described in the Eye Bank policies and procedures manual?
   "1 Yes (or not applicable)
   "0 No

• Same as EK
Post-Dissection Evaluation
Common Shapes

ZigZag

Tongue-in-Groove

Mushroom
TopHat Configuration
Poor Dissection
Alignment Marks

• 500-1250μ length
• 75-100μ depth (etch stroma)
• 8 or 50 spot width
• -2 offset, into graft
• Use mostly 8 or 12 marks

• Helps surgeons align graft with host
• Assists with suture placement