The gift of donor cornea: how picky can we afford to be?

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DISCLOSURE

- Consultant for Allergan, B&L, and AMO
- As medical director of TBI Los Angeles, my travel and meeting registration are sponsored by TBI

OUR RESPONSIBILITY AS TRANSPLANT SURGEONS

- Fulfill our responsibility to our patients by offering cutting edge, EVIDENCE BASED medicine
- Fulfill the promise of transplantation to the donor families
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CURRENT STATE OF EYE BANKING

- Surplus of Corneal Tissue but....
- Higher demands on eye banking
  - Tissue wastage with precutting
  - FDA regulations
  - Tissue wastage due to higher rates of PGF
  - Surgeon demands with arbitrary tissue restrictions

TISSUE SELECTION BIAS: SURGEON MISPERCEPTIONS

- Higher ECD leads to less graft failure
- Younger donors are better!
- Fresh tissue is best!
- Thinner EK grafts offer better vision!
- Quote from Donate Life
  - "Corneas are evaluated for cell count and clarity of the tissue. Whenever possible, eye banks try to place the cornea with a recipient that is close in age to the donor to help ensure that the cornea will last throughout the patient’s lifetime."
THE FACTS

Longer preservation time is not associated with graft failure!!


• Retrospective review, PKPs using donor tissue stored in optisol-GS for more than 168 hours (7 days), range 7-14.5 days

• Donor ECD, DT preservation and DT surgery time were not associated with long term graft failure

THE FACTS: CORTES STUDY GROUP

• CORTES Study Group: Cornea 2006
  • Established to describe epidemiology of corneal transplantation and to evaluate the outcome of PK in terms of long-term graft survival and risk factors for graft failure
  • Sample of 1000 patients who underwent PK from October 2001 to October 2004
  • Organ culture storage and ECD of >2200
  • Ectasia the main indication for PKP (50%) followed by regraft (15%)
  • Graft failure occurred in 10% of cases within 5 years, with 50% as a result of endothelial decompensation

THE FACTS: CORTES STUDY GROUP

Surgeon case load associated w/ graft survival!!

• Factors influencing graft survival:
  • Univariate regression analysis showed that the following variables were not associated with an increased risk for graft failure
    • Donor age, sex and cause of death
    • Tissue processing (i.e. postmortem interval, length of storage and endothelial density)
  • The following variables appeared to be significantly associated with graft failure
    • Recipient's indication for graft (highest with regraft)
    • Corneal condition at surgery
    • Concomitant interventions (i.e. vitrectomy)
    • Surgeon's case load

CORNEA DONOR STUDY

• The purpose: to evaluate the effect of donor age (>65 vs ≤65 yo) on cornea graft survival over a 5 year followup.
• Donor Criteria:
  • Age of donor at time of death: 10-75 years
  • DTP: ≤12 hours if body refrigerated or eyes iced and ≤8 hours if not
  • Death to surgery time: ≤5 days!
  • ECD: 2300-3300 cells/mm²
THE FACTS: CDS
Donor age up to 75 does not impact graft survival

- 5 year cumulative probability of success was 86% in <66 yo donor group and 86% in the ≥ 66 yo donor group!!!!
- With donor age as a continuous variable, there was NOT a significant relationship between donor age and outcome
- Conclusion: the donor age pool should be expanded to 75 years and surgeons should feel reassured that use of older donor corneas are suitable for transplantation

THE FACTS: CDS
Donor ECD does not impact graft survival!!!!

- Purpose: central donor ECD and its rate of decline as a predictor of corneal graft failure from endothelial decompensation during 5 years of followup
- Preoperative ECD was not predictive of graft failure from endothelial decompensation

THE FACTS: CORNEA DONOR STUDY

- Preoperative ECD is not predictive of graft failure caused by endothelial decompensation at 5 years following PKP
- Donor age up to 75 years did not impact PKP outcomes at 5 years.
- Graft rejection not associated with donor age
- Death to preservation or to surgery is not associated with changes in ECD over time.

Knowledge leads to change… or does it???

- Debunk myths
- Establish new standards
- Change practice patterns
**THE IMPACT OF CDS**

- From 1998 to 2009: Percentage of donors who were 66 or older increased from 19% before CDS to 21% during CDS and 25% after CDS.
- Slight shift up in the age range of donors of corneas placed within the US
- Study Limitations: retrospective, not clear if trend truly as result of CDS

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**SURGEON DEMANDS: DONOR AGE**

- Informal data on 437 surgeons’ submitted preferences to 19 eye banks
- 58% request tissue from donors <60 years old
- 3.5% request max age <40 yo
- 4.5% request < 40-45 yo
- 10% request < 45-55 yo
- 40% request < 55-60 yo

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**SURGEON DEMANDS: ECD**

- Informal survey of 19 eye banks.
- Of 437 surgeons
  - 10% request >3000 cells/mm²
  - 40% request >2800 cells/mm²
  - 32% request >2500 cells/mm²

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Great information but I’m only picky about my EK tissue!
WHAT DONOR TISSUE CHARACTERISTICS ARE IMPORTANT IN DSAEK?

- Terry MA, Strollo MD, Goshe J, Li JY, Davis-Boozer D. Endothelial Keratoplasty: The absence of a relationship between pre-operative donor thickness and post-operative visual acuity. Ophthalmology 2012; 119 (Epub)

DSAEK donor tissue characteristics: What doesn’t matter?

- **Size**
  - 8.0 mm graft is as good as 9.0 mm graft for long term cell counts
- **Storage time**
  - 7 days is as good as one day (CPTS will look at 7+ days)
- **Cell count**
  - 2100 cell count is as good as 3,000 cell count
- **Age**
  - 70 y/o tissue is as good as 21 y/o tissue
- **Thickness**
  - 180 um graft as good as 100 um graft for visual results at 6 months

IMPACT OF TISSUE SELECTION PRACTICES ON EYE BANKING COSTS AND PROCESSING FEES

Kevin Ross, M.S., M.P.H.
John J. Requard B.S.
Roni M. Shtein, M.D., and
Maria A. Woodward, M.D.

DONOR AGE DISTRIBUTION
EFFECT OF LIMITING DONOR AGE

<table>
<thead>
<tr>
<th>Maximum Age</th>
<th>Minimum Cell Density</th>
<th>Percent of Suitable Tissue</th>
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<tbody>
<tr>
<td>75</td>
<td>2000</td>
<td>100.0%</td>
</tr>
<tr>
<td>70</td>
<td>2000</td>
<td>90.0%</td>
</tr>
<tr>
<td>65</td>
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<tr>
<td>50</td>
<td>2000</td>
<td>29.1%</td>
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Since donor age is known prior to donor recovery, can comment only on decreased availability of restrictions in donor age.

METHOD

- Assumed fixed, hypothetical costs, with a fee of $2,000 needed to operate the eye bank at current activity level (actual eye bank fees differ)
- Donor age between 5 and 75 for surgical use (your eye bank criteria may vary)
- Cell density ≥ 2000 cells/mm² by specular microscopy

EFFECT OF LIMITING CELL DENSITY

<table>
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<th>Minimum Cell Density</th>
<th>Percent of Suitable Tissue</th>
<th>Relative Fee</th>
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<td>2000</td>
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<tr>
<td>75</td>
<td>2300</td>
<td>87.5%</td>
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<tr>
<td>75</td>
<td>2500</td>
<td>71.1%</td>
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<tr>
<td>75</td>
<td>2800</td>
<td>36.9%</td>
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EFFECT OF COMBINED LIMITS

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<th>Maximum Age</th>
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<th>Percent of Suitable Tissue</th>
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<td>100.0%</td>
</tr>
<tr>
<td>70</td>
<td>2300</td>
<td>79.6%</td>
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<tr>
<td>65</td>
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<td>55.3%</td>
</tr>
<tr>
<td>60</td>
<td>2800</td>
<td>23.4%</td>
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Multiple criteria interact to limit availability

THE MISSION OF A CORNEAL SURGEON

- To offer highest level of care in restoring vision for each individual patient using evidence-based medicine, and advanced techniques and technology
- With a responsibility to addressing not only the needs of each individual patient but also of society, to use resources responsibly and to work together with the community of fellow physicians and eyebankers in advocating for the field.

“No single drop of water thinks it is responsible for the flood”
Any suggestions…. radical or not?

- More studies like the CDS and CPTS
- Anonymous surveys directed to medical directors, corneal surgeons, etc. evaluating practice patterns
- Avoid asking for surgeon preferences
- Remove listed variables from the donor profile sheet….why offer information proven NOT to impact outcomes!
- Transfer the increased relative cost of tissue to the surgeon requesting extreme criteria

THANK YOU!

- Acknowledge the help of...
  - Chris Stoeger
  - Mark Terry
  - Kevin Ross
  - Mike Straiko
  - Liliano Barrios