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DSAEK: Does increasing the storage time from the pre-cutting of donors to the date of transplantation cause higher complication rates or cell loss?

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Disclosures

- The speaker has no financial interests relevant to the topic of this talk.
- Non-relevant disclosures:
  - Consultant for Merck, Biotissue, Johnson & Johnson

Devers Eye Institute Prospective IRB Approved Study March 2000 to May 2014

Developed and performed the first EK procedure in the U.S.:

- 275 cases of DLEK (9mm and 5 mm inc)
- 37 cases of DSEK
- Over 1,400 cases of DSAEK
- 200+ cases DMEK, 1 case DMAEK

What Donor Tissue Characteristics are Important in DSAEK?

- Terry MA, Shamie N, Chen ES, Hoar KL, Phillips PM, Friend DJ. Endothelial keratoplasty: the influence of pre-operative donor endothelial densities on dislocations, primary graft failure, and one year cell counts. Cornea 2008; 27:1131-7

- Terry MA, Shamie N, Straiko MD, Friend DJ, Davis-Boozer D. Endothelial keratoplasty: The relationship between donor tissue storage time and donor endothelial survival. Ophthalmology 2011;118:36-40

- Terry MA, Li J, Goshe J, Davis-Boozer D. Endothelial Keratoplasty: The relationship between donor tissue size and donor endothelial survival. Ophthalmology 2011; 118(10);1944-1949

- Chen ES, Terry MA, Shamie N, Hoar KL, Friend DJ. Pre-cut tissue in Descemet's Stripping Automated Endothelial Keratoplasty: Donor characteristics and early post-operative complications. Ophthalmology 2008; 115: 497-502

- Terry MA, Straiko 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; Feb (Epub)

DSAEK Donor Tissue Characteristics: What Doesn't Matter?

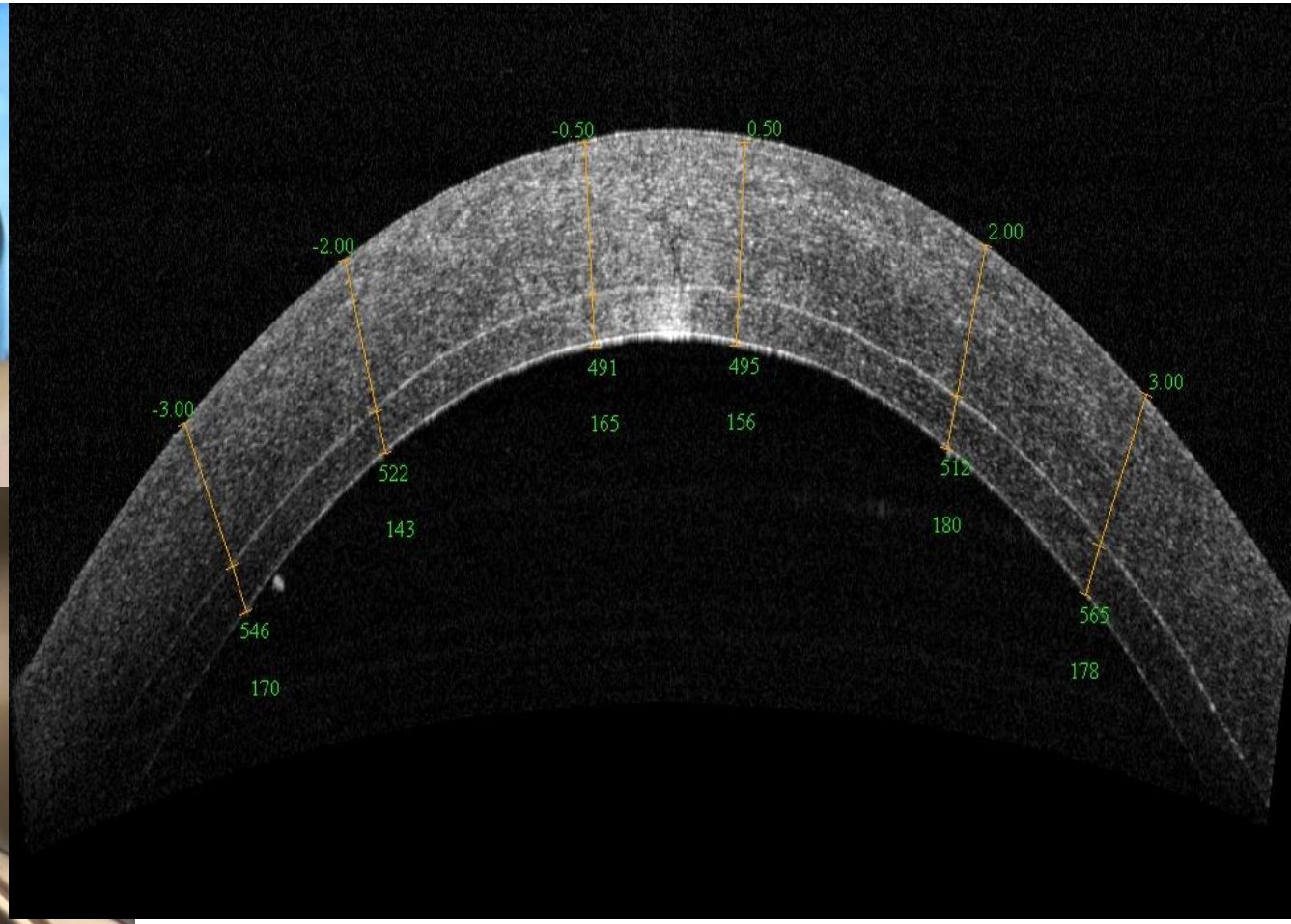
- **Storage time**
  - 7 days is as good as one day (CPTS will look at 7+ days)
- **Cell count**
  - 2100 cell count is as good as 3,000 cell count
- **Age**
  - 70 y/o tissue is as good as 21 y/o tissue
- **Size**
  - 8.0 mm graft is as good as 9.0 mm graft for long term cell counts
- **Thickness**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

Donor Storage Time AFTER Pre-cutting: Does it affect complication rates or endothelial survival?

Relevance to Clinical Practice?

- Tissue use can be delayed after pre-cutting by eye bank, sometimes by days
- Tissue pre-cut in the U.S. is often used overseas, delaying the time of transplantation by days
- Surgeons may be concerned about tissue “swelling” if tissue is pre-cut days before use and worry about how that affects endothelium
- Tissue placement logistics
  - easier if time from pre-cutting to use is not important

Pre-Cut Tissue for DSAEK Surgery



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Method

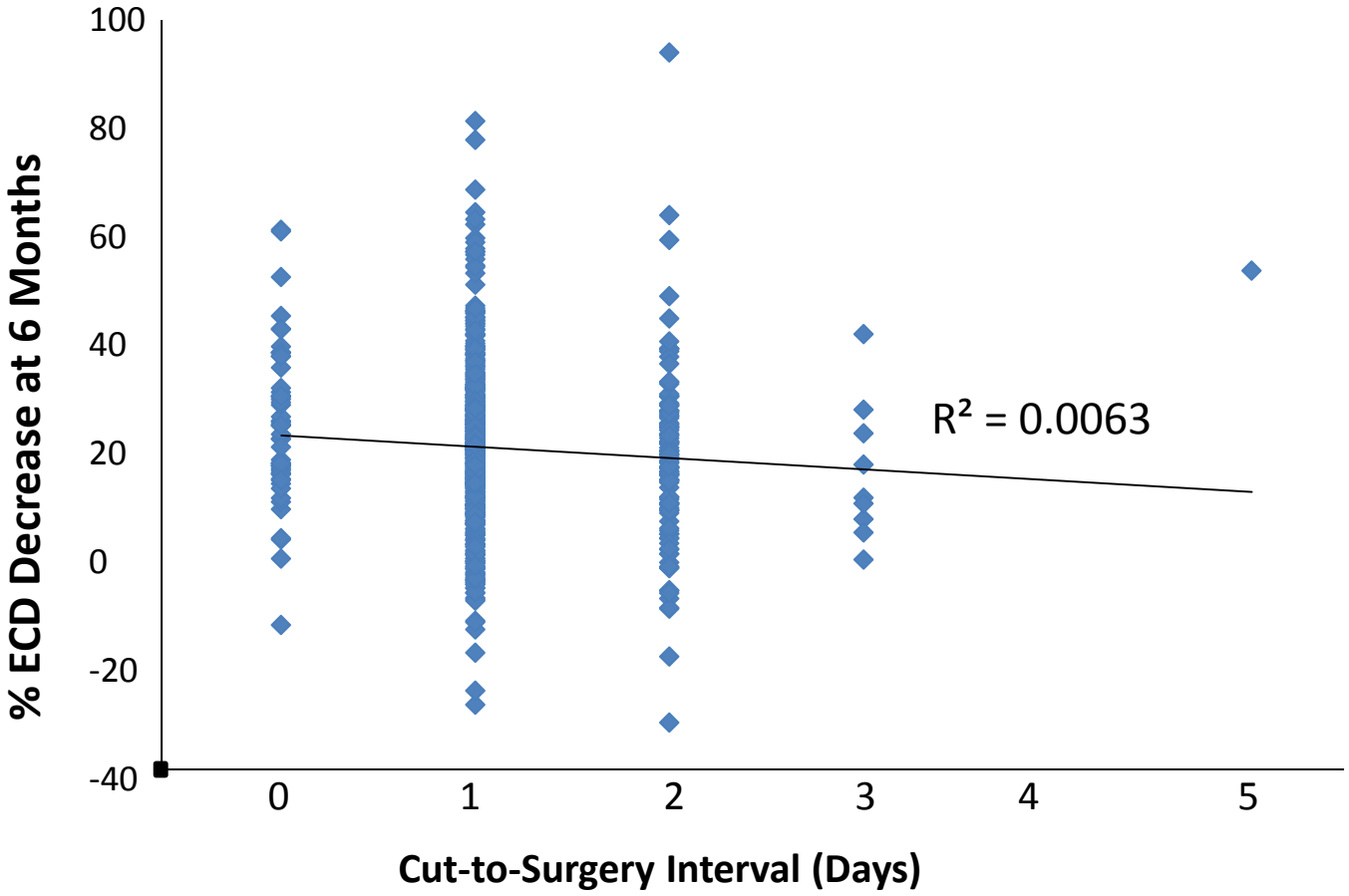
- 566 DSAEK Eyes for Fuchs' dystrophy at Devers
- 129 DSAEK Eyes for Fuchs' dystrophy at Sightline Ophthalmic Associates

  No prior glaucoma surgery, ACIOL, or confounding variable for endothelial cell loss

	Storage Time in Optisol after pre-cutting by eye bank:	
Day 0-1	Transplantation SAME day as pre-cutting	63
Day 1	Transplantation 1 day AFTER pre-cutting	470
Day 2	Transplantation 2 days AFTER pre-cutting	150
Day > 2	Transplantation More than 2 days AFTER pre-cutting	12

- Correlation of Storage Time to:
  - Endothelial Cell Count at 6 months
  - Complication rate (PGF/Dislocations)

Endothelial Cell Loss Over Time – No Correlation with Storage Time after Pre-Cutting



(Pearson Corr. Coeff = -0.079, p = .037)

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Comparison of Storage Time Sub-Groups Endothelial Cell Loss at 6 Months

	Storage Time in Optisol after pre-cutting by eye bank:		Endothelial Cell Loss
Day 0-1	Transplantation SAME day as pre-cutting	63	24%
Day 1	Transplantation 1 day AFTER pre-cutting	470	20%
Day 2	Transplantation 2 days AFTER pre-cutting	150	18%
Day > 2	Transplantation More than 2 days AFTER pre-cutting	12	20%

Storage Time Sub-group Analysis

Shortest

- 10 Eyes from day Zero group
  - Mean = 1.4 hours
- 19 % Cell Loss at 6 months

Longest

- 10 eyes from >2 day group
  - Mean = 71 hours
- 20 % Cell Loss at 6 months

Comparison of Storage Time Sub-Groups Graft Dislocation Rates

	Storage Time in Optisol after pre-cutting by eye bank:		Dislocations
Day 0-1	Transplantation SAME day as pre-cutting	63	0 (0%)
Day 1	Transplantation 1 day AFTER pre-cutting	470	12 (3%)
Day 2	Transplantation 2 days AFTER pre-cutting	150	3 (2%)
Day > 2	Transplantation More than 2 days AFTER pre-cutting	12	1 (8%)

Possible increase in dislocations after longer storage time, but more data needed to examine relationship

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What About Longer Times From Tissue Preparation to Implantation?

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International Data

39 Precut DSAEK tissues shipped from Lions VisionGift in Oregon to Germany

- Death to DSAEK preparation
  - Average 4.7 days (range 2-9)
- DSAEK preparation to implantation
  - Average 4.9 days (range 3-9)
- Death to implantation
  - Average 9.7 days (range 5-13)

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International Data

- ECD data not available
- Complications
  - No primary graft failures
  - One dislocation (2.6%)
  - Successfully re-bubbled on post-operative day 2
    - Tissue was precut 8 days prior to surgery
    - Death to surgery time of 13 days
    - Death to preservation time of 15h 49min
- 38 uneventful DSAEK surgeries

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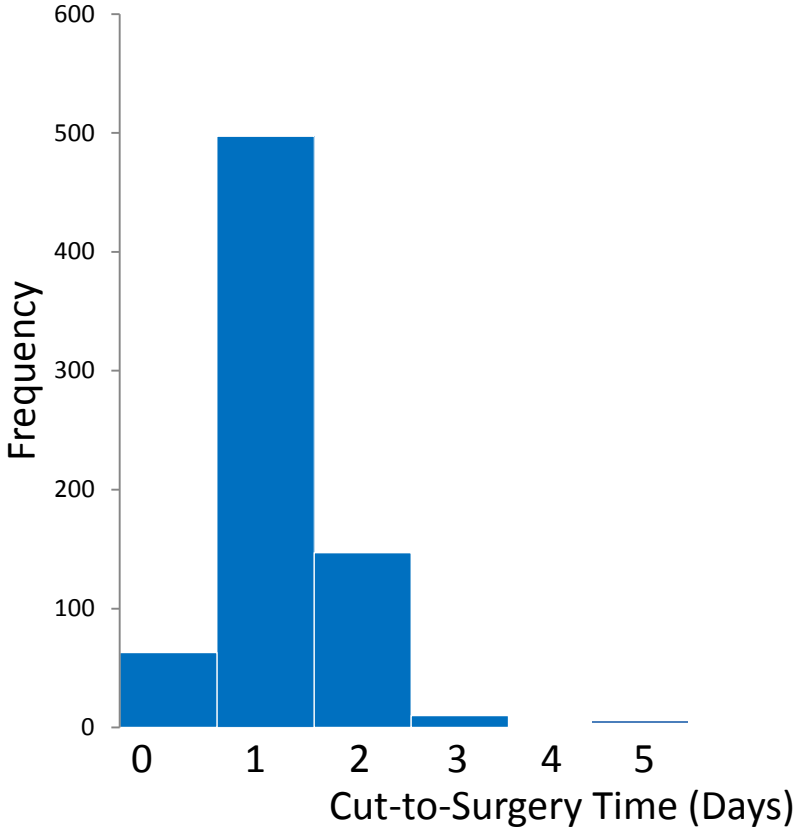
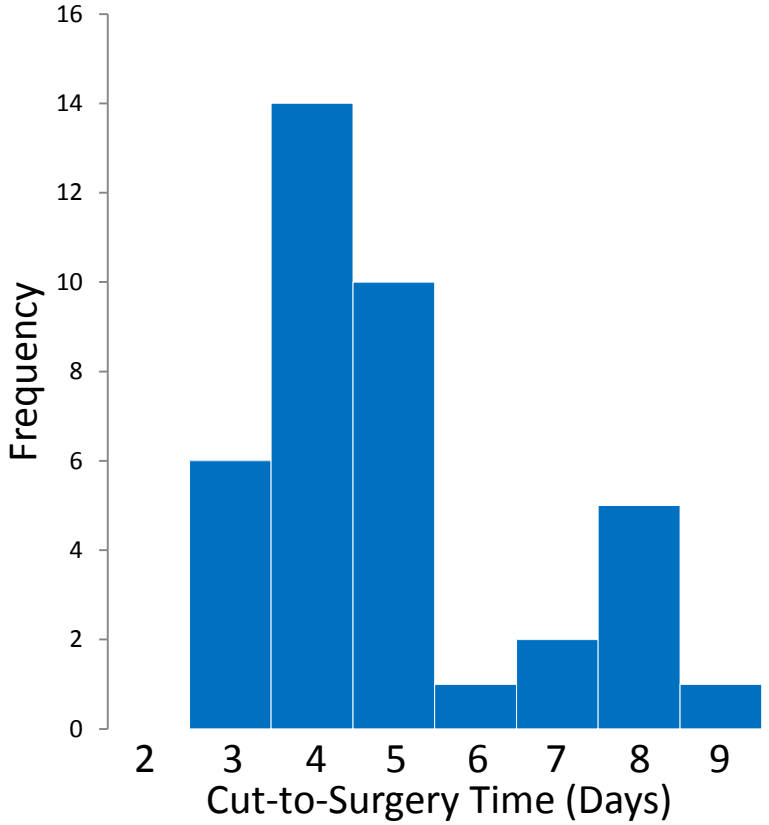
Processing to Transplantation



Oregon/Penn
Mean: 1.2
Range: 0-11



Germany
Mean: 4.9
Range: 3-9

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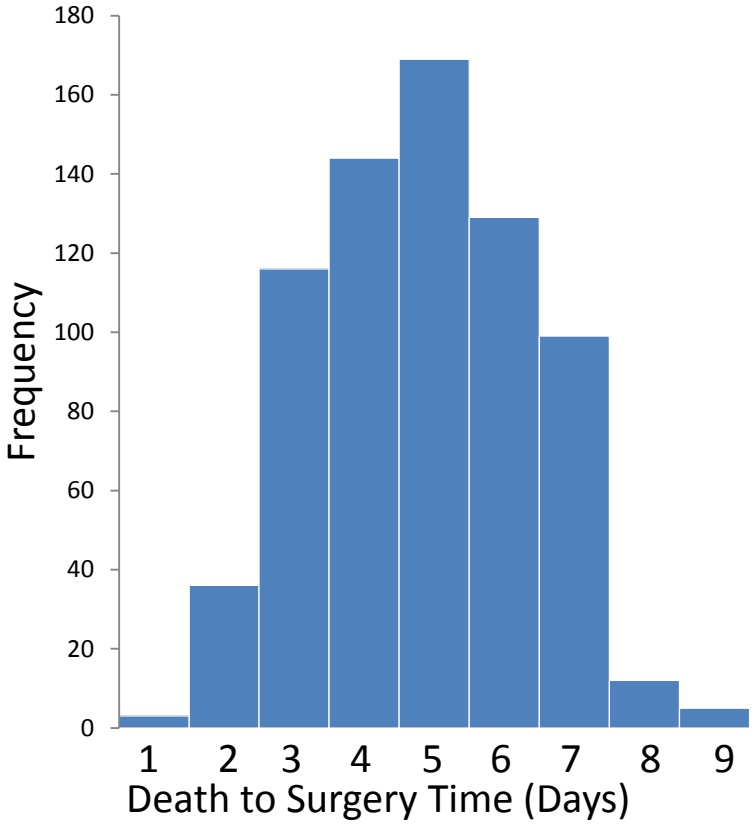
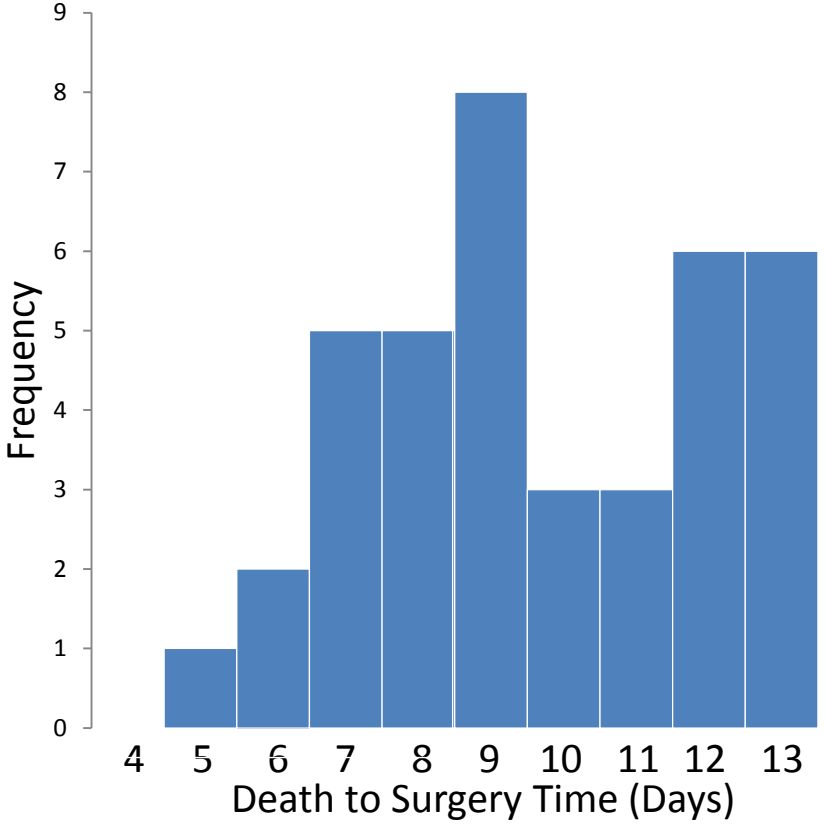
Death to Transplantation



Oregon/Penn
Mean: 4.8
Range: 2-9



Germany
Mean: 9.7
Range: 5-13

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Complication Rates

- Oregon/Penn

- 695 grafts
- Sixteen dislocations (2.3%)
  - Possible increase in dislocations after longer storage time, but more data needed to examine relationship.
- No correlation with cell loss at 6 months.

- Germany

- 39 grafts
- One dislocation (2.6%)
  - Tissue was precut 8 days prior to surgery
  - Death to surgery time of 13 days
  - Death to preservation time of 15h 49min

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Summary and Conclusions

- Storage time after Pre-Cutting DSAEK tissue does not affect the cell loss seen at 6 months

- Tissue stored for at least 2 or 3 days after pre-cutting can safely be used for DSAEK surgery

- Surgeons should not be concerned about using tissue that was pre-cut a few days before transplantation

- The upper limit of storage time is not known and further data collection (especially from our overseas colleagues who receive U.S. pre-cut tissue) is encouraged

- CPTS will provide more data on death to transplantation time


OSHKOSH


The END

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