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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- The speaker has no financial interests relevant to the topic of this talk.

- Non-relevant disclosures:
  - Consultant for Merck, Biotissue, Johnson & Johnson
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, 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
- 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

<table>
<thead>
<tr>
<th>Storage Time in Optisol after pre-cutting by eye bank:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 0-1 Transplantation SAME day as pre-cutting</td>
<td>63</td>
</tr>
<tr>
<td>Day 1 Transplantation 1 day AFTER pre-cutting</td>
<td>470</td>
</tr>
<tr>
<td>Day 2 Transplantation 2 days AFTER pre-cutting</td>
<td>150</td>
</tr>
<tr>
<td>Day &gt; 2 Transplantation More than 2 days AFTER pre-cutting</td>
<td>12</td>
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</tbody>
</table>

- 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

R² = 0.0063

(Pearson Corr. Coeff = -0.079, p = .037)
## Comparison of Storage Time Sub-Groups

### Endothelial Cell Loss at 6 Months

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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**

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

<table>
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What About Longer Times From Tissue Preparation to Implantation?
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)
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
Processing to Transplantation

Oregon/Penn
Mean: 1.2
Range: 0-11

Germany
Mean: 4.9
Range: 3-9
Death to Transplantation

Oregon/Penn
Mean: 4.8
Range: 2-9

Germany
Mean: 9.7
Range: 5-13
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
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.
Additional Thanks

Andrea Gareis-Lok for data provided by Hornhautbank – Muenchen