Evaluation of an eye donor diabetes mellitus (DM) rating scale for prediction of DMEK preparation failure

EBAA Scientific Session
June 6, 2015

Ryan S. Williams, CEBT, Christopher G. Stoeger, MBA, CEBT, Zachary Mayko, MS, Michael D. Straiko, MD, Ryan Clay, MD
Financial Disclosures

Relevant to this talk: None
Increased DMEK demand and unique tissue criteria has made it difficult to fill all surgeries with current supply of tissue.
DM - Risk to Peel

- DMEK donor pool was shrinking as we try to only peel tissue that we predict will be successful.
- DM in donor history shown to increase risk of preparation failure by 7x.

**TABLE 3. DMEK Graft Preparation Outcomes in Diabetic Versus Nondiabetic Tissues**

<table>
<thead>
<tr>
<th></th>
<th>Diabetes</th>
<th>No Diabetes</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Graft preparation failure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Successful preparations</td>
<td>99 (86.84)</td>
<td>241 (98.37)</td>
<td>—</td>
</tr>
<tr>
<td>failed preparations</td>
<td>15 (13.16)</td>
<td>4 (1.63)</td>
<td>—</td>
</tr>
<tr>
<td>Site-adjusted preparation failure rate, % (95% CI)</td>
<td>15.3 (9.0–25.0)</td>
<td>1.9 (0.8–4.8)</td>
<td>0.001</td>
</tr>
<tr>
<td>Graft preparation difficulty</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean processing time, min (SEM)</td>
<td>25:36 (0:48)</td>
<td>22:42 (0:36)</td>
<td>0.009</td>
</tr>
</tbody>
</table>

Impact on Tissue Pool

Transplant Donors > 50 years old - 2014

All donors

Donors w/ DM

39%
LVG DMEK Tissue Pool 2014

Total Released for TxP 2044
- Tissues

>50 Years Old
- 1670 Tissues

ECD>2300
- 1270 Tissues

Phakic or IOL outside the graft zone
- 1024 Tissues

No Diabetes
- 658 Tissues

32% of total available tissue
Basis of Rating System

**TABLE 1. Past Medical History and Past Ocular History among Descemet Membrane Endothelial Keratoplasty Donor Preparation Failure and Success Groups**

<table>
<thead>
<tr>
<th>Outcome Group</th>
<th>Diabetes Duration (y)</th>
<th>Hypertension</th>
<th>Hyperlipidemia, Obesity, or Both</th>
<th>Tobacco</th>
<th>Cancer</th>
<th>Alcohol</th>
<th>Intraocular Surgery</th>
<th>Superficial Surgery</th>
<th>Other Ocular Disorders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure (n = 26)</td>
<td>18 (69)</td>
<td>13.9 ± 15.5</td>
<td>22 (85)</td>
<td>22 (85)</td>
<td>5 (19)</td>
<td>11 (42)</td>
<td>3 (12)</td>
<td>1 (4)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Success (n = 462)</td>
<td>110 (24)</td>
<td>6.5 ± 8.4</td>
<td>287 (62)</td>
<td>224 (48)</td>
<td>46 (10)</td>
<td>181 (39)</td>
<td>75 (16)</td>
<td>24 (5)</td>
<td>28 (6)</td>
</tr>
</tbody>
</table>

*P value* .000028 .023 .021 .0004

SD = standard deviation.

Data are no. (%) or mean ± standard deviation, unless otherwise indicated.


- DM, DM duration, HLD/BMI>30, and related comorbidities (e.g. neuropathy, nephropathy, retinopathy) all were thought to contribute to increased failure rate.
Creating a System

- The system needed to be:
  - simple
  - generated from available medical information without adding unreasonable burden
  - A clear communication tool between departments reviewing records, and choosing tissue to offer for DMEK preparation
Methods of the System

- A system was created to categorize the severity of diabetes from 1-5, five indicating the most severe case, and 0 indicating the absence of any DM in the donor history.

- This rating would be displayed on our main tissue board where both departments would have access.
Example of Rating System I

COD: Myocardial Infarction

Current Hx: Pt presented to hospital w/ weakness increasing over last 2 months. Admitted for observation & testing after all preliminary tests negative. Labs suggest non-Q wave MI. Heart cath. revealed diffuse cardiac Dz. Pt. declined Sx (CABG) Pt. not able to care ADL’s & noncompliant. Pt. requests no Tx. & moved to comfort care.


DM Duration: 3-4 yrs, was on Metformin

BMI: 24.6

DM Severity Rating = 2
Example of Rating System II

**COD:** Respiratory Failure 2/2 Obesity Hypoventilation Syndrome

**Current Hx:** Admitted w acute on chronic resp failure w hypercapnia and hypoxia. Course complicated by BiPAP dependence, UTI, on abx, possible PE that was unable to be evaluated d/t body habitus motion and inability to lie flat. Decision was made to de-escalate care for comfort measures. BiPAP was withdrawn and pt expired.

**PMH:** CAD, HTN, HLD, CHF, morbid obesity w obesity hypoventilation syndrome, on home O2 2L NC, OSA, DM2, PVD, CKD stage 3, anemia, OA, spinal stenosis, IBS, gastric ulcer, former smoker (1 ppd x 30 yrs). SurgHx: tonsillectomy, tubal ligation, CABG, abdominal wall sx, elbow sx.

**DM Duration:** >10 yrs, treated w insulin

**BMI:** 50.4

**DM Severity Rating = 5**
Application of Rating System

• This system was retrospectively applied to 125 consecutive DMEK preparations of diabetic tissue done at LVG between Sep 2012 and Feb 2015

• The second tissue prepared of mated pairs was not included in the study

• Blinded to success or failure of specific preparation
Results of Application

LVG DMEK Preparation by DM Severity Rating

<table>
<thead>
<tr>
<th>DM Severity Rating</th>
<th>Pass</th>
<th>Fail</th>
<th>Failure %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8</td>
<td>1</td>
<td>11.1%</td>
</tr>
<tr>
<td>2</td>
<td>25</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>3</td>
<td>29</td>
<td>2</td>
<td>6.5%</td>
</tr>
<tr>
<td>4</td>
<td>20</td>
<td>4</td>
<td>16.7%</td>
</tr>
<tr>
<td>5</td>
<td>25</td>
<td>11</td>
<td>30.6%</td>
</tr>
</tbody>
</table>

\( p = 0.009 \)
Tissue Supply with Scale Applied

Total Released for TxP
2044 Tissues

>50 Years Old
1670 Tissues

ECD>2300
1270 Tissues

Phakic or IOL outside the graft zone
1024 Tissues

No Severe Diabetes
844 Tissues

Including DM Severity Rating 1,2,3

28% increase in available tissue.
Conclusions

• Employing a DM rating system may be helpful in expanding the pool of available tissue for DMEK preparation
• A DM rating scale may reduce wasted tissue due to failed DMEK preparation

Thank You!
Questions?

Ryan@visiongift.org