SINGLE-PASS MICROKERATOME SYSTEM FOR EYE-BANK DSAEK TISSUE PREPARATION: IS STROMAL BED THICKNESS PREDICTABLE AND REPRODUCIBLE?

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Financial disclosure

- No financial interest
Introduction

- 2006: eye banks began supplying DSAEK tissue
- Preparation increases OR efficiency and ensures tissue quality
- Sierra Donor Services uses Med-Logics (Med-Logics Inc, Athens, USA)
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- 2006: eye banks began supplying DSAEK tissue
- Preparation increases OR efficiency and ensures tissue quality
- Sierra Donor Services uses Med-Logics (Med-Logics Inc, Athens, USA)
- Most published data is with Moria (Moria International, Antony, France)
To evaluate the predictability and reproducibility of stromal bed thickness

- Using the ML7 Microkeratome Donor Cornea System manufactured by Med-logics, Inc (TX, USA)

- Single-pass donor DSAEK tissue preparation
The 3 questions:

1. Can this MK system cut tissue reliably?
2. Is this system safe in terms of tissue loss?
3. Is this system safe in terms of ECC?
Material and Methods

- Retrospective chart review
- 256 consecutive corneal tissue preparations
- June 2013 to August 2014
- Sierra Donor Services
Surgeon thickness preference

- **Group A**: <91 μm
- **Group B**: 90 - 120 μm
- **Group C**: 120 - 160 μm
Results
Post-cut Anterior Segment OCT
Electron microscopy
## Graft thickness

<table>
<thead>
<tr>
<th>Average thickness</th>
<th>Total (A+B+C)</th>
<th>A (&lt;91)</th>
<th>B (90-120)</th>
<th>C (120-160)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precut cornea in μm</td>
<td>514±71 (364-648)</td>
<td>515±59 (418-628)</td>
<td>514±80 (364-648)</td>
<td>518±43 (424-612)</td>
</tr>
<tr>
<td>Postcut graft in μm</td>
<td>114±30 (60-183)</td>
<td>97±23 (60-128)</td>
<td>113±21 (77-179)</td>
<td>134±43 (89-183)</td>
</tr>
</tbody>
</table>
Group A – Number of grafts in target range (<91 microns)

42%
Group A – Number of grafts in target range 
(<91 microns)

Graft thickness 
[Range 60-130 μm ]

<table>
<thead>
<tr>
<th>Graft Thickness</th>
<th>Number of Grafts</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;91 μm</td>
<td>20</td>
</tr>
<tr>
<td>91-100 μm</td>
<td>5</td>
</tr>
<tr>
<td>100-105 μm</td>
<td>2</td>
</tr>
<tr>
<td>105-110 μm</td>
<td>1</td>
</tr>
<tr>
<td>110-115 μm</td>
<td>0</td>
</tr>
<tr>
<td>115-120 μm</td>
<td>1</td>
</tr>
<tr>
<td>120-125 μm</td>
<td>1</td>
</tr>
<tr>
<td>125-130 μm</td>
<td>1</td>
</tr>
</tbody>
</table>

Total number of grafts: 33

46% of the grafts are in the target range (<91 microns).
Group B – Number of grafts in target range (90-120 microns)
Group B – Number of grafts in target range (90-120 microns)
Group B – Number of grafts in target range (90-120 microns)
Group C – Number of grafts in target range (120-160 microns)

Graft thickness
[Range 89-183 μm]
Group C – Number of grafts in target range (120-160 microns)

Graft thickness
[Range 89-183 μm]

63%
Group C – Number of grafts in target range (120-160 microns)

Graft thickness
[Range 89-183 μm]

77%
Tissue loss and disqualification
Tissue loss and disqualification

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>A</td>
<td>3</td>
<td>2 in first 11 cuts</td>
</tr>
<tr>
<td>B</td>
<td>4</td>
<td>2 in first 42 cuts</td>
</tr>
<tr>
<td>C</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Tissue disqualification

- Total of 7 failed procedures
  - 2.7% of all attempts
- Of which: 4 in first 53 attempted procedures
- After learning curve adjustment:
  - 1.5% in the last 200 attempts
Endothelial cell count
## Endothelial cell count

<table>
<thead>
<tr>
<th></th>
<th>Average ECC</th>
<th>Total (A+B+C) n = 249</th>
<th>A (&lt;91) n = 48</th>
<th>B (91-120) n = 152</th>
<th>C (121-160) n = 49</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precut ECC</td>
<td>2955±224 (2786-3484)</td>
<td>2945±190 (2825-3413)</td>
<td>2962±241 (2273-3484)</td>
<td>2938±199 (2632-3401)</td>
<td></td>
</tr>
<tr>
<td>Postcut ECC</td>
<td>3013±250 (2252-4053)</td>
<td>3028±262 (2667-4063)</td>
<td>3014±256 (2252-3778)</td>
<td>2981±207 (2646-3460)</td>
<td></td>
</tr>
</tbody>
</table>
Question 1: Can this system cut donor tissue reliably?
Cutting reliability

- Average cut $114 \pm 30 \mu m$
  - Most studies: average varies $145 \mu m$ and $199 \mu m^{1,2,3,4,5,6,7}$
  - UT-DSAEK specific studies:
    - Busin M, et al. (2013)$^8$: 
      - $100\% < 151 \mu m$
      - $95,6\% < 131 \mu m$
      - $78,3\% < 101 \mu m$
      - Discarded tissue rate = 2,1%
    - Woodward MA, et al. (2014)$^9$: 
      - $65\% < 101 \mu m$
      - Perforation tissue rate = 23-29%
Question 2: Is this system safe in terms of Tissue disqualification?
Tissue disqualification

- Overall discarded tissue rate = 2.7%
- Last 200 procedures = 1.5%

- Kanavi MR, et al. (2014): 2.6%
- Kelliher C, et al. (2009): 1.5% (5% → 0.5%)
- Chen ES, et al. (2008): 2.5%
Question 3: Is this system safe in terms of Endothelial Cell Count?
Endothelial cell count

- Average post-cut ECC = 3013±250 cell/mm²
  - 66%: higher ECC after cutting process

- Kelliher C, et al. (2009): 66.8% increase in post-cut ECC
  - Bias before or after cutting
    - Descemet folds
    - Sampling error
Conclusion

- The ML7 Microkeratome Donor Cornea System manufactured by Med-logics, Inc (TX, USA) allows for single-pass donor DSAEK tissue preparation
  - Comparable to other MK systems
Bibliography


Questions?