Introduction

At Devers Eye Institute, we have incorporated a novel stromal sided S-stamp on our pre-stripped DMEK grafts. Prior to incorporating the S-stamp into our standardized “Gas and Glass” technique we placed three upside down grafts, an inherent risk of the DMEK surgery, despite using other commonly available graft orientation techniques. At that point upside-down graft placement represented 75% of our iatrogenic primary graft failure events. The subsequent incorporation of the S-stamp has allowed complete graft orientation prior to gas bubble elevation and eliminated upside down grafts in our practice. We are now reporting a direct comparison of outcomes between our initial 30 S-stamped DMEK transplants and the 32 consecutive unstamped DMEK transplants immediately preceding this addition to our standardized DMEK technique.

Methods

Thirty consecutive patients underwent DMEK surgery utilizing a previously validated and reported stromal sided S-stamp technique between August and October of 2013. Data was collected prospectively, including anterior segment OCT, tomography and 6 month endothelial cell density. Additionally, the clinical course was documented including need for re-bubbling, graft failure, graft rejection or other post-operative complications. Comparison was made to similar 6 month data from the preceding 32 consecutive unstamped DMEK procedures completed utilizing our otherwise identical DMEK surgical technique.

Disclosures - None

Six-Month Clinical Outcomes of Our Initial 30 Stromal Sided S-Stamped Descemet Membrane Endothelial Keratoplasty (DMEK) Cases

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Results

In the initial 30 DMEK transplantsations utilizing the S-stamp there were 2 re-bubbles (2/30), compared to one re-bubble in the 32 preceding unstamped DMEK cases (1/32), demonstrating no statistically significant difference (p=0.6). There have been no primary graft failure in the initial 30 cases in the S-stamp group (0/30) compared to four in the unstamped cases (4/32), all of which were due to iatrogenic causes (3 upside down grafts, 1 break in technique). This difference in graft failure approaches statistical significance (p=0.11). There was a single rejection event in the unstamped group and no rejection events in cases with an S-stamp. Average six month endothelial cell loss was 27.6% (+/- 12.7%) for 32 control cases and 28.5% (+/- 19%) in the 19 S-stamped cases for which data was available (as of 4/29/14). There was no statistically significant difference in 6 month ECL between the two groups (p=0.854).

Conclusion

Early clinical data suggests that a stromal sided S-stamp can be utilized to safely and effectively orient DMEK grafts and thus prevent upside down graft placement, a known cause of iatrogenic primary graft failure. Comparison of 6 month endothelial cell loss between 19 S-stamped and the preceding 32 consecutive unstamped tissues demonstrates no statistically significant difference in cell loss between the two groups. Further experience with S-stamped DMEK tissue will continue to clarify its role in minimizing the risk of iatrogenic primary graft failure in the performance of DMEK.

Pre-Striped S-Stamped DMEK Tissue Prepared at Lions VisionGift

Endothelial Cell Loss at 6 Months

- Non S-Stamped: 27.6% (n=23)
- S-Stamped: 28.5% (n=19)
  p = 0.864 Not Statistically Significant

Mean Best Corrected Vision

- Non S-Stamped: 20/26 (n=23)
- S-Stamped: 20/30 (n=19)
  p = 0.198 Not Statistically Significant

Primary Graft Failure

- Non S-Stamped: 4/32
- S-Stamped: 0/30
  p = 0.11 Approaching Statistical Significance

Rejection Events

- Non S-Stamped: 1/32
- S-Stamped: 0/30
  p = 0.99 Not Statistically Significant

Validation Study of ECL Attributable to S-stamp

<table>
<thead>
<tr>
<th>Tissue ID</th>
<th>Total ECL Damage Induced from Graft Preparation</th>
<th>ECL Attributable to S-stamp</th>
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</thead>
<tbody>
<tr>
<td>Tissue 1</td>
<td>14.22%</td>
<td>1.74%</td>
</tr>
<tr>
<td>Tissue 2</td>
<td>17.33%</td>
<td>2.05%</td>
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<tr>
<td>Tissue 3</td>
<td>19.44%</td>
<td>2.15%</td>
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<tr>
<td>Tissue 4</td>
<td>17.44%</td>
<td>1.75%</td>
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<tr>
<td>Tissue 5</td>
<td>12.45%</td>
<td>0.28%</td>
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<tr>
<td>Tissue 6</td>
<td>13.77%</td>
<td>1.52%</td>
</tr>
</tbody>
</table>

Legend: Six 8mm DMEK tissues were prepared, mounted and vital dye staining was performed. The tissue was analyzed with software to determine the absolute and percentage cell loss, overall and attributable to the S-stamp.

References