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

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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.[1] 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

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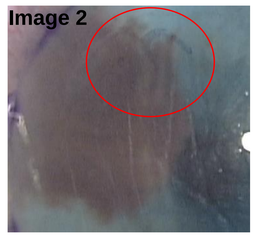
Pre-Stripped S-Stamped DMEK Tissue Prepared at Lions VIsionGift

Image 1. A stromal sided S-stamp is added during pre-stripping of the DMEK tissue. While the tissue is folded over in the SCUBA technique, a 2mm punch is used to create an access through the corneal stroma. After using cellulose sponges to draw the tissue back into its original position, the corneal cap is then turned endothelial side down and an S-stamp is applied, through the stromal access, to the stromal side of Descemet's using a dry stamping technique.[2] The plug is then replaced and the cornea is returned to the carrier.

S-Stamped Tissue Allows Absolute DMEK Graft Orientation Prior to Graft Elevation



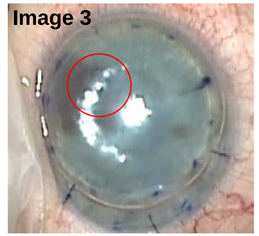


Image 2. A properly oriented S-stamp is clearly visible through an edematous cornea following unscrolling and prior to gas injection, confirming graft orientation. **Image 3**. The S-stamp is seen after SF6 elevation.

The S-Stamp Induces Limited Relative Endothelial Cell Damage

Figure 1

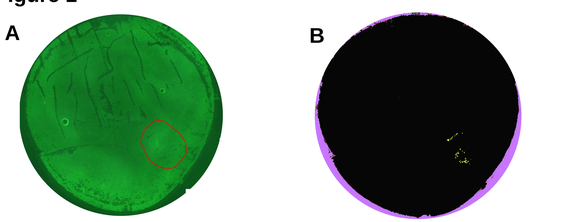


Figure 1. A. DMEK preparation (Tissue 5) stained with calcein AM, allowing assessment of overall preparation related cell loss. **B.** Endothelial cell damage attributed to S-stamp application. **C.** Close up of endothelial cell loss over S-stamp. **D.** High magnification image of S-stamp with overlying endothelial cells.

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

Tissue ID	Total ECL Damage Induced from Graft Preperation	ECL Attributed to S-Stamp
Tissue 1	14.22%	1.74%
Tissue 2	17.37%	2.56%
Tissue 3	17.43%	1.41%
Tissue 4	13.25%	0.64%
Tissue 5	12.47%	0.28%
Tissue 6	12.07%	1.51%

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.[3]

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Results

In the initial 30 DMEK transplantations 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.

References

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