Posterior Lamellar Surgery: Techniques, complications and clinical results

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DISCLOSURE

The speaker has a financial interest in the EK instruments which he designed.

The author has been a sponsored speaker for Moria

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Endothelial Keratoplasty: Multiple names and acronyms

- **PLK**: Posterior Lamellar Keratoplasty (Melles)
- **DLEK**: Deep Lamellar Endothelial Keratoplasty (Terry)
- **DSEK**: Descemets Stripping Endothelial Keratoplasty (Price)
- **DSAEK**: Descemets Stripping with Automated Endothelial Keratoplasty (Gorovoy)
- **DMEK**: Descemets Membrane Endothelial Keratoplasty (Melles)
- **DMAEK**: Descemets Membrane Automated Endothelial Keratoplasty (Price)
DLEK v DSEK/DSAEK Anatomy

DLEK: Pocket dissected
Stromal fibers exposed

DSEK/DSAEK:
No pocket or dissection
Our Current experience with over 1,100 cases of EK surgery from March 2000 to September 2009 (Prospective IRB Study)

We developed and performed the first EK procedure in the U.S.:

- About 275 cases of DLEK
- About 37 cases of DSEK
- Over 750 cases of DSAEK (this includes over 625 cases using “pre-cut” tissue)

We currently perform 6 to 10 DSAEK surgeries a week with the Fellow doing >70 cases a year
Terry MA: Pre-cut Tissue in DSAEK: Complications are from technique, not tissue. Cornea 2008 (Editorial); 6:627-9


2009 Published Peer-Review EK Papers by Devers Eye Institute

2 year Visual results:
Fuchs’ Dystrophy Eyes

Visual Results (eyes with no retinal disease)

- mean BSCVA 20/28
- 99% with vision 20/40 or better
- 30% with vision 20/20 or better
Major Problems with DSAEK surgery

- Dislocation of Donor from Recipient Bed
- Primary (iatrogenic) Graft Failure
- Pupillary Block Glaucoma immediately post-op from residual air bubble

**DSAEEK**

Current Complication Rates
Devers Eye Institute, Portland, Oregon, USA

*First 725 cases: same surgical technique*

(1 experienced surgeon and 6 novice)

- Dislocation rate: 2.6% (19 out of 725)
- Primary graft failure rate: 0.1% (1 out of 725)
- Pupillary Block rate: 0.1% (1 out of 725)

Why does our surgical technique have such a low rate of complications?
WHY DO OUR DSAEK GRAFTS HAVE SUCH A LOW DISLOCATION RATE??
Clinical Implications of Lab Results

- The smoother surface of DSEK recipient bed can provide better optics for vision but make dislocation rate much higher.

- The rougher surface of DLEK recipient bed allows attachment of the graft with NO air bubble support (ie: better adhesion) but may limit visual acuity by one line worse than DSEK
Do you want to “insure” your DSAEK graft will stick?

*Take a Lesson from the Gecko anatomy*...
Actual studies at Lewis and Clark College in Portland, OR:

The gecko knows how to stick.

“Peripheral scraped stromal fibrils of recipient bed”

“Central smooth recipient bed”

Tokay gecko demonstrating how good peripheral adherence allows a DSAEK graft to stick.
DSAEK Videos
-- (on AAO website; also on website of dlek-dsek.com)

DSAEK: A simplified technique to avoid complications and enhance results

How many of you are scraping the recipient bed in DSAEK surgery?

- If not, WHY not?
  - Not difficult
  - Takes very little time…2 minutes tops
  - Area of scraping is invisible at 6 weeks
  - Does not affect vision
  - Will reduce your dislocation rate…if done properly
  - With obvious band of white fibrils
  - Has no real downside!

What’s Not To Love About Scraping??
Interface Fluid Centrally: Only where the recipient bed edges were scraped are holding the graft on.

Different meridians show the areas of attachment and also the access region for interface fluid.
Note that inferior edge of graft is still allowing entrance of interface fluid
1 month s/p DSAEK
- VA 20/60
- EK graft fully attached
1 year s/p DSAEK
- VA (without glasses!) = 20/25
- Graft interface clear
- Endothelial Specular = 2580 cells/mm²
Interface fluid resolves without intervention

1 day post-DSAEK
UCVA=20/200

1 weeks post-DSAEK
UCVA=20/200

3 weeks post-DSAEK
UCVA=20/100

2 months post-DSAEK
+1.25 + 1.00 x 25 = 20/40
UCVA=20/60
Take Home Points

- Scraping can provide a physical adhesion of tissue to prevent dislocation until the endothelium “wakes up” to solidify adhesion.
- If tissue is attached but interface fluid…do NOT re-bubble…WAIT…tissue will attach without intervention.
- Only re-bubble if detachment is imminent or patient is impatient for vision.
- One exception to the rule…
Full Thickness Edge from Eccentric Trephination
Implanted Tissue Shows “Architectural Separation”
(Which will NOT resolve with observation and
risks epithelial ingrowth of donor epithelium)
Take Home Point

Use the **Microscope** for Trephination of the Donor Tissue to avoid Eccentric Trephination...even if you are a “pre-presbyope” you cannot reliably discern a tolerance of $\frac{1}{4}$ mm with the naked eye! (ie: an 8.5 mm trephination in a 9.0 mm bed)

Summary of practical points regarding pre-cut tissue for DSAEK:

(Experience with COLD STORAGE OPTISOL only)

- My personal experience with it is with over 625 cases and it has worked as well as tissue cut on site.
- Request tissue that is at least 150 microns in thickness…thicker is easier, no detriment to vision.
- Do NOT trust any centering marks made by Eye Bank Technician…made with naked eye and can smudge in transit.
- Care must be taken in not getting an eccentric punch…use the microscope to punch tissue!
- Ink Marks on stromal surface KILL endothelial cells! (and are not necessary)

Terry MA: Pre-cut tissue for Descemet stripping automated endothelial keratoplasty: Complications are from technique, not tissue. Cornea 2008 (Editorial); 6:627-9
Key points to avoiding complications in DSAEK surgery

- My surgery for DSAEK takes 40 minutes to complete every step...faster surgery may cause more damage and complications
- Use 5 mm scleral incision at limbus
- Minimize trauma to donor at EVERY step of the surgery
- Do peripheral scraping of bed – NOT SUBTLE!
- **Modulate** the size of the pupil for what you need:
  --dilate pupil (without NSAIDS) for cataract surgery
  --constrict pupil (with Miochol and stroking iris) for insertion of tissue
  --dilate pupil (with standard drops) at end of case to prevent block
- To remove interface fluid: sweep cornea with elevated IOP of air-
  leave IOP at above 40 for 2 to 3 minutes then lower to normal for 7 to 8 minutes
- Close wound with vicryl sutures: prevent hypotony
- Remove ALL air from eye, then replace with only a 5 or 6 mm air bubble
- Patient SUPINE for 1 hour then as much as possible day of surgery – NO Pressure on Eye!
Update on longer term Endothelial Survival in DSAEK

Devers Eye Institute
ECD After DSAEK

![Graph showing ECD over time post-op]

- **Years 1-2**: p=0.4
- **Years 2-3**: p=0.2
- **Years 1-3**: p=0.07

Endothelial Cell Survival After DSAEK

- **Percent Cell Loss**
  - 1 year: 33%
  - 2 year: 35%
  - 3 year: 39%

N = 40 eyes – Fuchs + PBK (all eyes at all time points)
What else do we know about DSAEK?
Most any case of endo failure can be treated successfully with DSAEK

- EK under an old RK
- EK under PK for old RK
- EK for CHED in a 7 year old
- EK over a Phakic Artisan AC IOL for PBK
What else do we know about DSAEK?
(Peer review data…more than just anecdotal)

- Use of cohesive viscoelastic (Healon) for DSAEK does NOT cause dislocations or cause the dislocation rate to increase.
- DSAEK with Phaco/IOL should be done as a triple, NOT sequentially…no difference in complications rate or endo survival
- Dislocation rates are still low (<3%) in complex cases such as PBK with filters, tubes, and under failed PK grafts…as long as hypotony is avoided
- Donor PRE-OP Endo counts don’t matter…tissue with a cell count of 2,100 is just as good as a cell count of 3,100.
- Storage time doesn’t matter…tissue stored for 1 day is no better than tissue stored for 7 days…no difference in complications or ECD
- Donor tissue with RK scars, LASIK, surface scars can all be used safely for DSAEK…no difference in refractive results, complications or ECD.
- Fellows can do DSAEK during their fellowship just as well as their Attendings …as long as the same surgical technique is followed.
References for Previous Slide


OTHER DSAEK TECHNIQUES
WHAT ABOUT “VENTING INCISIONS” TO REMOVE INTERFACE FLUID AND REDUCE DISLOCATION RATES?
Venting Incisions in DSAEK

- Introduced by Dr Frank Price: reduced his dislocation rate from about 25% to about 6% in his initial 165 cases
- We have not used them at all and with simple sweeping have a dislocation rate of 2.6% in our first 725 cases by 6 different surgeons
- Venting incisions have been documented to cause epithelial downgrowth into the interface and interface infections
- We do NOT recommend using venting incisions in routine cases
What about Ant Ch Maintainers?

Irrigation with a separate metal device in the eye causes:

--risk of damage to the endothelium from the device itself hitting the endo
--risk of expulsing tissue from the eye
--risk of flipping the tissue upside down without the surgeon knowing it

We do not currently recommend using an AC maintainer for DSAEK surgery
What about incision size for insertion of tissue?

Also: Does technique of insertion of tissue matter?

Laboratory Study of DSAEK: Analysis of Insertion and Incision Size

- 5 mm incision v 3 mm incision
- Techniques used in both inc sizes:
  - Forceps
  - Pull through
  - Busin Glide
Video:
Busin’s Glide insertion through 3mm incision
5mm Forceps

3mm Busin’s Glide

3mm Folded Pull-Through

5mm Pull-Through

3mm Forceps

3mm Pull-Through

6
Acute Endothelial Damage from Insertion: Incision size matters, method is less important

![Bar chart showing average endothelial damage across different incision sizes and methods.](chart.png)
Maneuver-Induced Endo. Damage

5mm incision size: 8% +/- 3% Damage

Versus

3mm incision size: 26% +/- 13% Damage

p < .001
Take Home Message

REGARDLESS OF TECHNIQUE
Because the wound compresses the tissue during insertion:
- Small incision – Big Damage
- Larger incision – Small Damage

Ideal insertion technique: Tissue injector

- Entirely avoid wound compression
  - Tube injector that “delivers” tissue into AC
- Entirely avoid folding tissue
  - Tube injector that “rolls” tissue without overlap
  - Minimal incision size = 4 mm for an 8.0 mm graft, otherwise get graft overlap

See: Letter to Editor and Response: by Donald Tan and Mark Terry
Ophthalmology 2008 February Issue
Bill Neusidl

Prototype Tissue Injector for DSAEK

Now available commercially by Fischer Instruments

Dr Terry has NO Financial interest in the NCI device
Neusidl Corneal Injector for DSAEK
Other injectors for DSAEK

- **Endosaver**: similar platform device as NCI but overlaps tissue to go through a smaller incision (3.5 mm)

- **Tan Endoglide**: similar to a “closed system” Busin glide, but with a plastic base to prevent iris prolapse. Requires a “pull through” forceps from opposite limbus. May be well suited for Asian eyes and eyes with shallow AC
What we need to know about injectors

- Is the endothelial trauma truly less than other techniques going through a compressive incision? If so, where is the data?!
- Is the technique using an inserter easier than other techniques?...and therefore easier for the novice surgeon?
- Is the cost of the injectors worth the possible advantages?

We are doing a prospective study to answer these questions and we encourage other EKG members to do prospective studies as well.
What About DMEK?

1. Stripping of recipient Descemets’

2. Implantation of just donor Descemets’ with NO donor stroma
DMEK Advantages

- Represents the pure anatomic replacement of just the diseased part of the cornea
- Visual rehabilitation (on average) appears to be a month or two faster than DSAEK
- A higher proportion of eyes reach the level of 20/25 or 20/20 than with DSAEK

Ham and Melles: 2009 EYE
DMEK

Key questions:

--what is the “learning curve”?
--what is the dislocation rate in the hands of novice v experienced surgeons?
--what is the PGF rate in novice v experienced surgeons?
--what is the tissue wastage rate and endothelial cell damage in DMEK?
--can we ever have “pre-cut” DMEK tissue and is there a way to determine the health of the tissue before it is sent to the surgeon?
--Are the results of DMEK (v DSAEK) worth it?
Current Challenges with DMEK: Melles Initial Series

- N = 50
- Dislocation rate = 25%
- Primary graft failure rate = 20%
- Tissue positioned “Upside down” in several cases
- Endothelial cell damage reported on only handful of cases

Ham and Melles: 2009 EYE
N = 60 (51 Fuchs)

Vision at 3 months: 26% were ≥20/20
63% were ≥20/25

Refractive: mean hyperopic shift of +.49 D

Endothelial cell loss: 30%=/-20 at 3 months

Iatrogenic Primary Graft Failure: 8%

Interface fluid re-bubbling rate: 48% once
8% twice

Upside down grafts: 2 (4%)

Tissue wastage (8%): 72 donors for 60 cases
6 grafts converted to DSAEK
6 grafts totally destroyed (8%)
Practical considerations with DMEK

- “You break it, You buy it!” …monetary cost to surgeon/ASC of destroying tissue at time of DMEK surgery is huge (>U.S.$2800 per tissue) and so “Pre-cut DMEK Tissue by Eye Bank” is essential to general adaptation of DMEK.

- Donor Supply is Limited: DSAEK has already hampered the donor supply. The published “learning curve” of DMEK (8% to 20% donor failure) may overwhelm our donor supply creating severe shortages of tissue for other transplant procedures.

- How about “DMAEK”: Price has shown the complex donor prep technique of DMAEK using combination “big bubble” and “scuba” techniques with high tissue wastage rates….can eye banks do this for us and at what cost of tissue wastage?
DMAEK: A hybrid technique of DMEK and DSAEK

- Descemets’ membrane with a peripheral ring (or crescent) of posterior stroma
- Hope is for better peripheral attachment of the stroma edges (like DSAEK) but better vision with the central area (like DMEK)
- Tissue preparation is complex, involving techniques of Big Bubble and DSAEK
- No data on outcomes currently published, but early work by Busin is encouraging
Pre-Cut DMAEK Preparation and Evaluation by Eye Banks: Is this our future?

DMAEK tissue can be stored in Optisol in standard containers and slit lamp exam and central specular ECD can be obtained... But what will be the tissue wastage rate and damage to the endothelium from technician processing?
The evolution of EK

We’ve come a long way from 9.0 mm incision PLK/DLEK with manual dissections and average vision of 20/50.

DSAEK is well established with minimal tissue wastage, low complications and happy patients.

Can DMEK/DMAEK give us the same high benefit to low complications ratio as DSAEK? Only then will general acceptance of DMEK become reality…
Summary

- The current technique that we use with DSAEK surgery yields a very low dislocation rate in the hands of novice and experienced surgeons alike.

- Central Endothelial cell density (with our technique) appears to be relatively stable over the first 3 years after DSAEK, but longer term data is needed.

- DSAEK surgery should be done with 5mm or larger wounds to prevent endothelial damage – Regardless of what technique of insertion is used.

- Newer insertion devices (such as injectors) which avoid wound compression should help reduce endothelial damage and improve long term cell counts, but data is needed.

- DMEK and DMAEK surgery can offer marginally faster and better visual results, but the failure rate (8-20%), complication rate (25-63%) and tissue wastage rate (>8%) are unacceptable at this time.

- Strict adherence to an established DSAEK technique will yield a near 0% rate of PGF and a dislocation rate of less than 2%.
Thank You

Charlie

Cindy

Charlie

Nicholas