



DMEK

Massimo Busin

Forlì



Financial Disclosure

**Massimo Busin Has Received
Royalties (2006-2015) and
Reimbursement of Travel Expenses
from Moria (Antony France)**

Disclosure of Off-Label Use

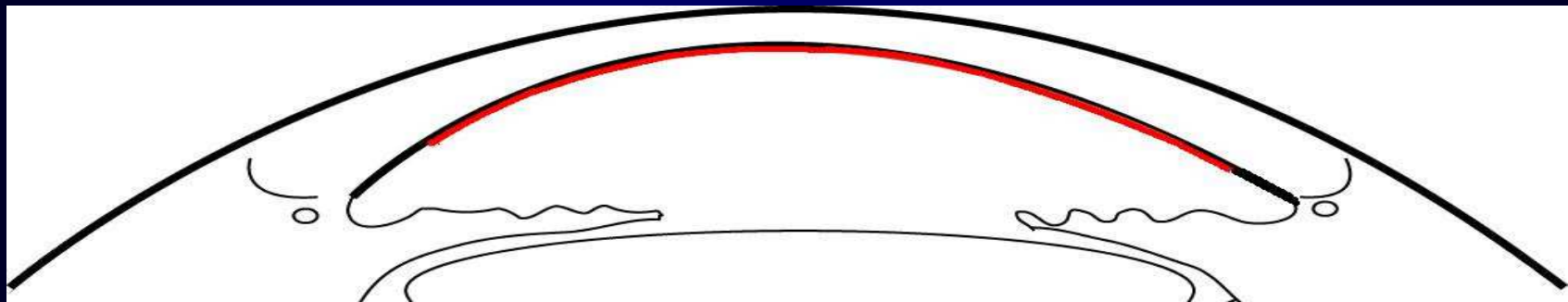
**IOL Cartridges Used for Graft Delivery
(MDJ, La Monnerie Le Montel, France)**

**Soft CLs Used for Graft Loading
(SOOFT, Montegiorgio, Italy)**

POSTERIOR INLAY LK

(D)escemet (M)embrane
(E)ndothelial (K)eratoplasty

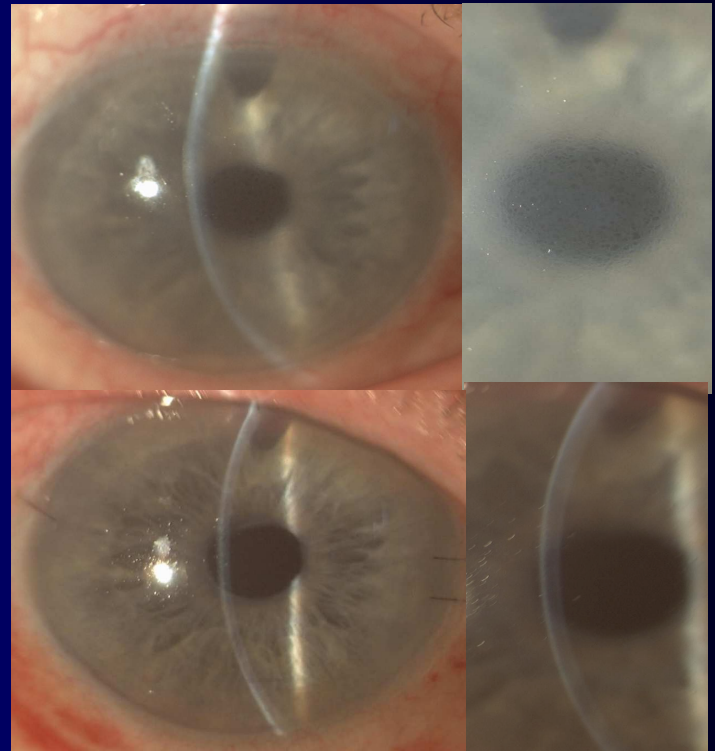
DMEK (Melles 2002 in vitro)



DMEK

SURGICAL CHALLENGES

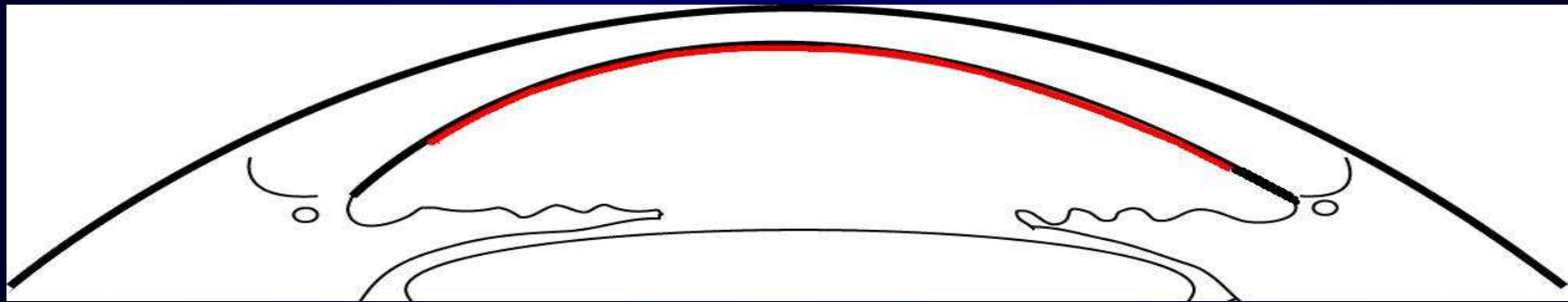
- Preparation
- Delivery into AC
- Positioning
- Attachment



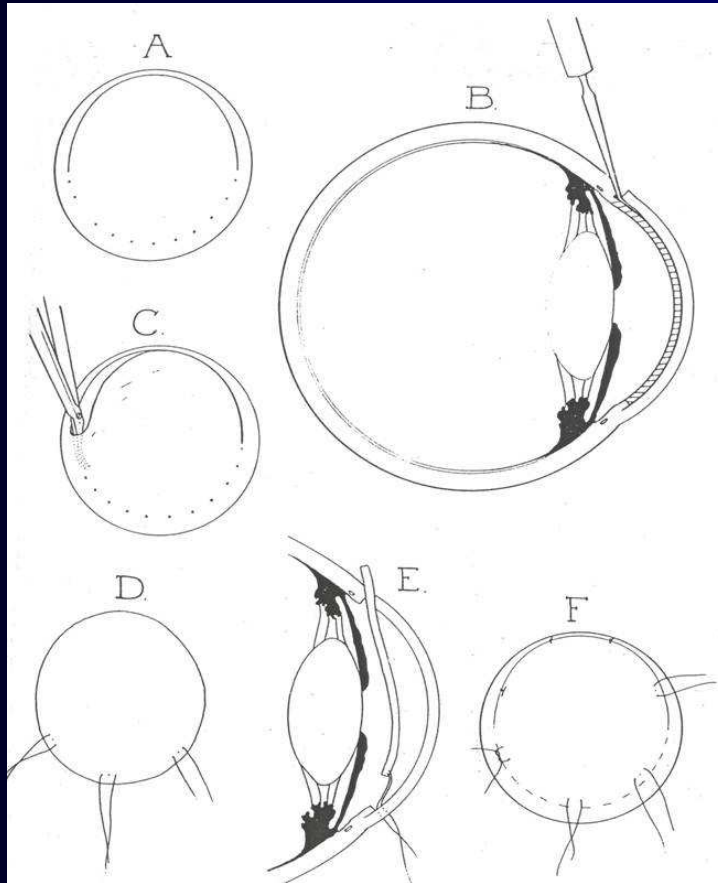
POSTERIOR ONLAY LK

(D)escemet (M)embrane
(E)ndothelial (K)eratoplasty

DMIEK (Melles 2006 in vivo)



POSTERIOR LK



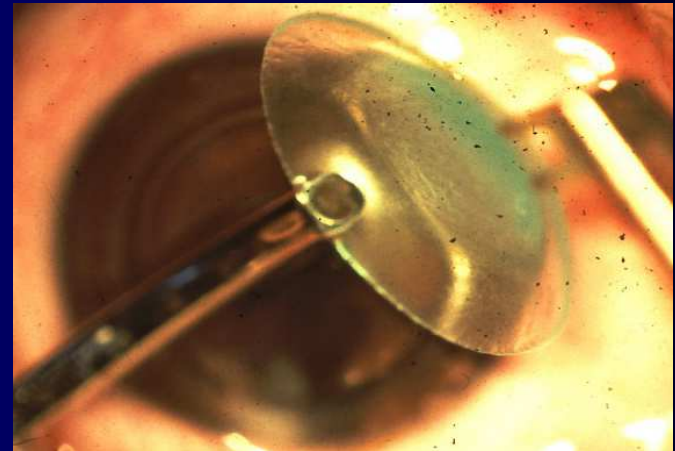
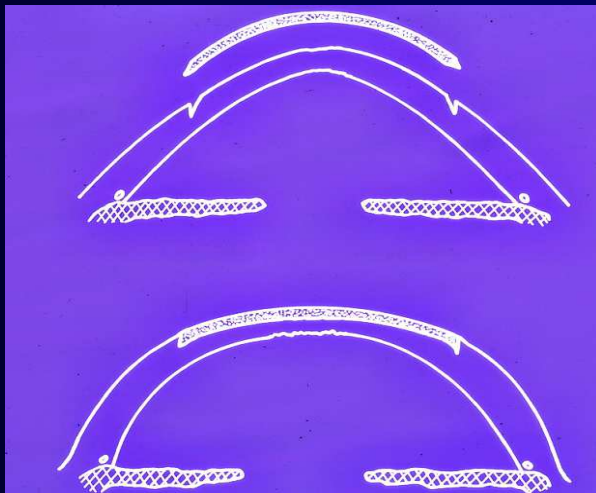
Tillet ('50s)
Barraquer ('60s)



Ko (1993)

ANTERIOR “ONLAY” LK Kaufman 1980

Epikeratophakia for Aphakia
“THE LIVING CONTACT LENS”



POSTERIOR "ONLAY" LK (ENDOKERATOPLASTY)

ENDOKERATOPLASTY: A NEW SURGICAL TECHNIQUE FOR THE REPLACEMENT OF DISEASED CORNEAL ENDOTHELIUM

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INTRODUCTION

To date, penetrating keratoplasty (PK) is the only available surgical treatment for endothelial decompensation. Although epithelium and stroma are not primarily affected, this procedure involves full-thickness transplantation, leading to unsatisfactory refractive results in a relatively high number of patients. A new surgical technique aimed at replacing exclusively the diseased endothelium is presented by means of a rabbit model.

RESULTS

Despite the technical difficulty of handling very thin corneas like the rabbit ones, it was possible in all animals used in this experiment study to perform endokeratoplasty as theoretically designed. By two weeks all of the corneas with endokeratoplasty-lenticles demonstrated substantial clearing, while the scraped cornea did not. On histology only a small proportion of the endothelial cells were present on the donor lenticles.

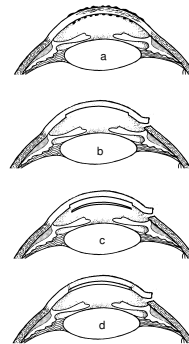
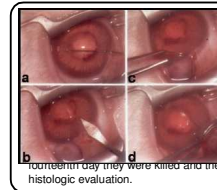


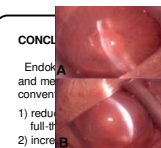
Fig. 1: Schematic representation of endokeratoplasty surgery: a) Edematous cornea; b) Removal of Endothelium from the center of the recipient cornea (arrows); c) Insertion of the endokeratoplasty lenticle through a scleral tunnel; d) Suturing in place of the endokeratoplasty lenticle.

Fig. 2: Endokeratoplasty surgery in a rabbit model: A) Removal of Descemet's membrane and endothelium from the recipient central cornea; B) Entering the anterior chamber with a 4mm keratome; C) Preparation of a 10-0 prolene mattress suture to fixate the endokeratoplasty lenticle; D) Mattress suture led through the recipient cornea at the 6 o'clock position.

Fig. 3: Postoperative results: A) Rabbit cornea with endokeratoplasty lenticle fixated with four 10-0 prolene mattress sutures. The slit lamp examination reveals tight contact between donor lenticle and recipient cornea as well as only moderate corneal edema; B) Control cornea exhibiting marked edema in the central area denuded of the endothelium.



vs: Approximately 80% of the removed with a microkeratome button was trephined. In five of the central endothelium and four eyes a donor lenticle was placed in the central cornea, using four to six 10-0 prolene mattress sutures. In five eyes did not receive any sutures. All eyes were examined 1, 3, 5, 7, and 14 days postoperatively. On the 14th day they were killed and the excised corneas submitted for histologic evaluation.



CONCLUSIONS

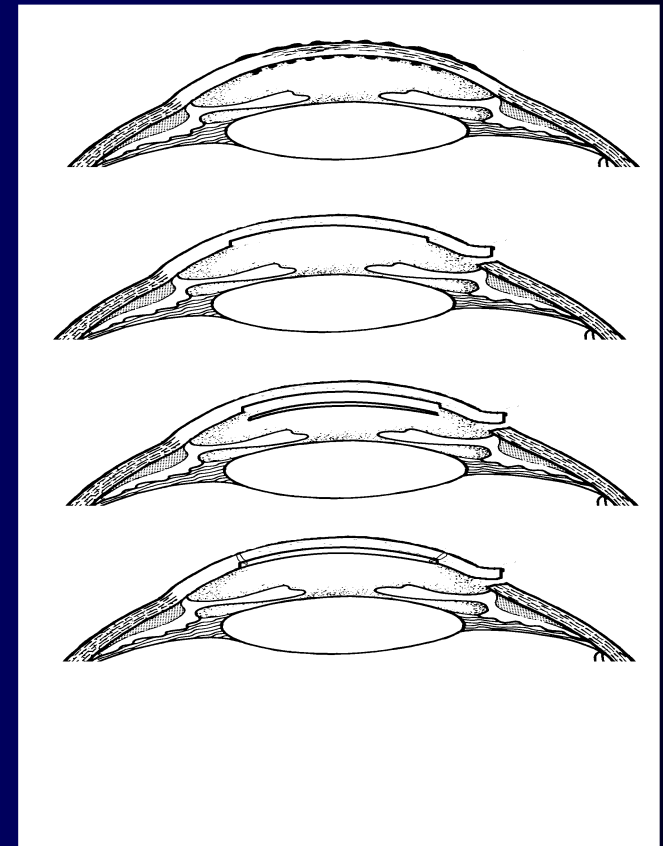
Endokeratoplasty is a potential for endothelial transplantation and may have several advantages of this procedure over conventional PK: 1) reduced surgical trauma; 2) increased endothelial cell survival due to the use of a short tunnel approach; 3) reduced immunogenicity (no epithelium is transplanted). Improved handling of the donor lenticle and use of an alternate animal model, e.g. primates, may improve endothelial cell transfer.

This study was supported in part by a grant from the Medical Eye Bank of Western Pennsylvania, Pittsburgh, Pennsylvania.

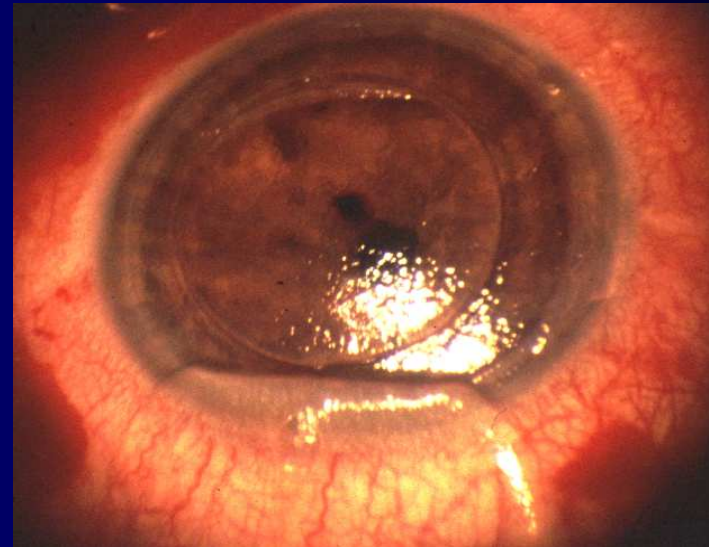
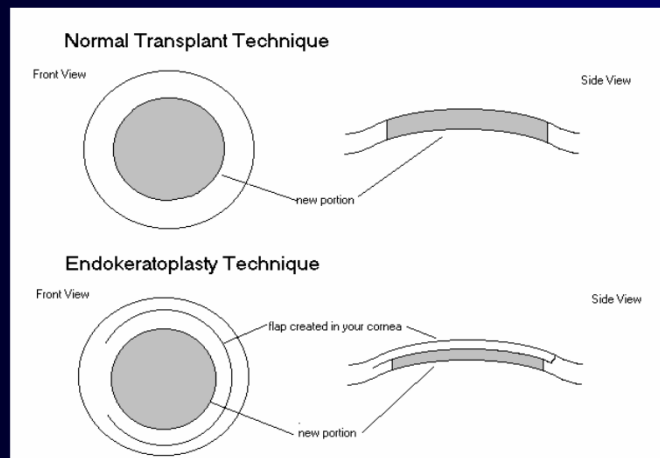
Busin et al. OPTHALMOLOGY, 1996 (Suppl.)

POSTERIOR “ONLAY” LK CONCEPT

1. **Peeling of endothelium and Descemet**
2. **Tunnel approach**
3. **Preparation of posterior donor lamella (endothelium and deep stroma)**
4. **Suturing to the bare posterior corneal surface**



ENDOKERATOPLASTY



Busin et al.

OPHTHALMOLOGY, 2000

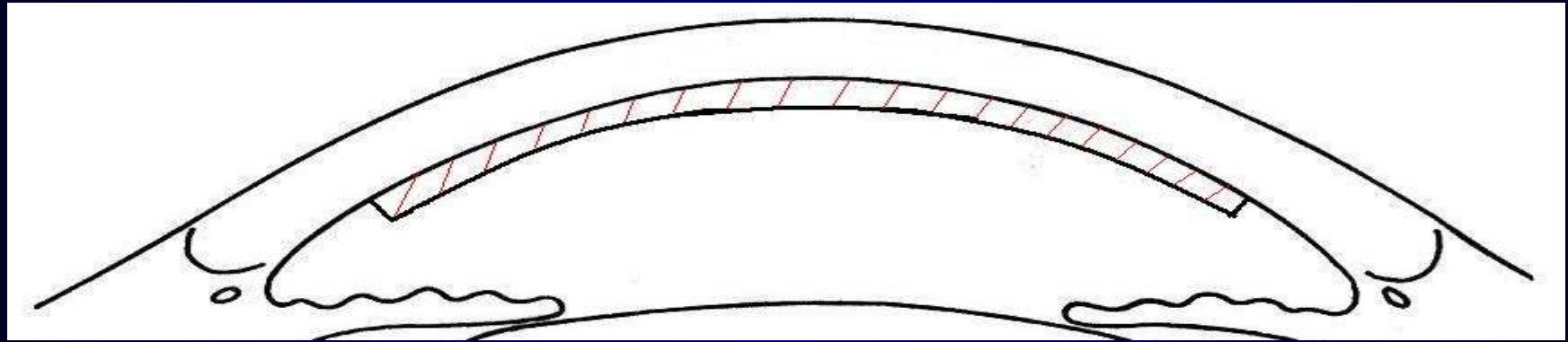
ENDOKERATOPLASTY CONS

- Lower Quality of **CORNEAL OPTICS** (flap fibrosis)
- Recovery of **VISUAL ACUITY** Delayed in Comparison to Wound Healing
- **INTRAOPERATIVE INCREASE** of IOP (60-80 mm Hg)
- Limited Amount of **ENDOTHELIUM!!**



DSEK

(Price 2002)

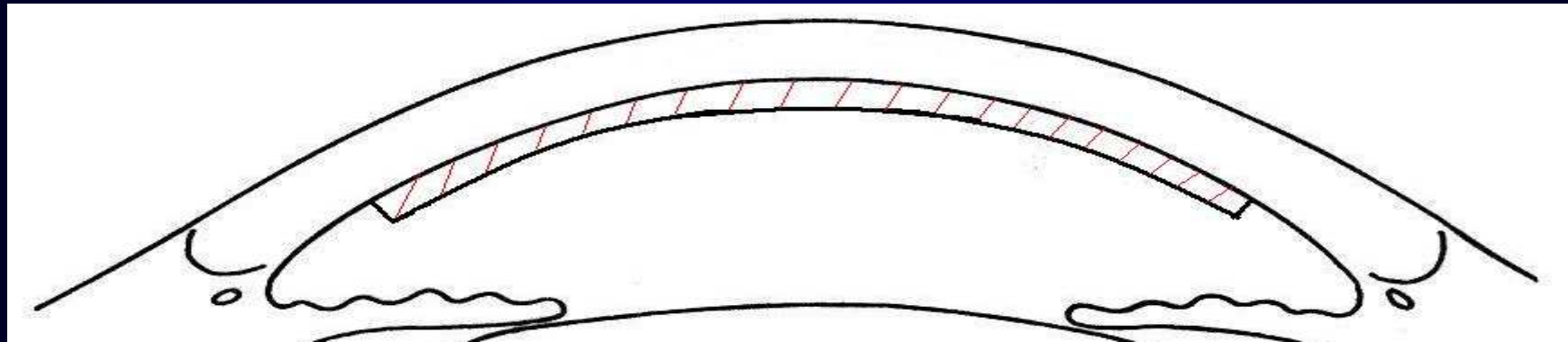


TISSUE REMOVAL = Endothelium

NEW LAMELLA = 100-300 μm

DSAEK

(Gorovoy 2004)

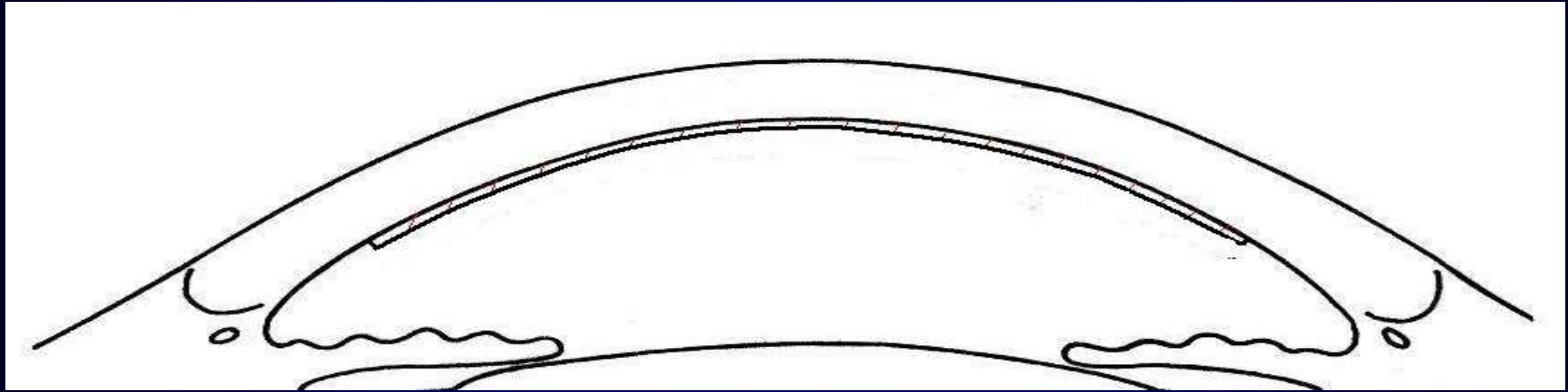


TISSUE REMOVAL = Endothelium

NEW LAMELLA = 100-300 μm

ULTRATHIN (UT) DSAEK

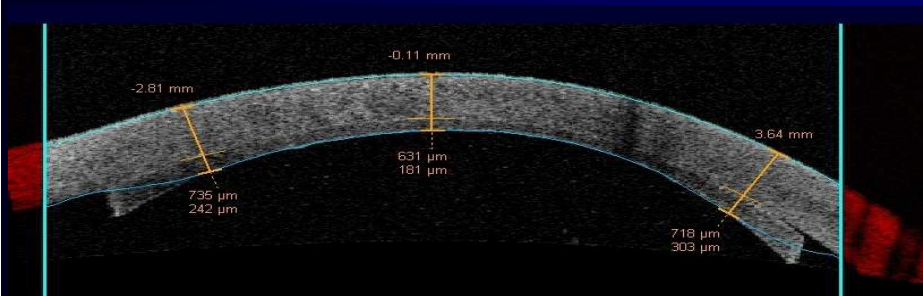
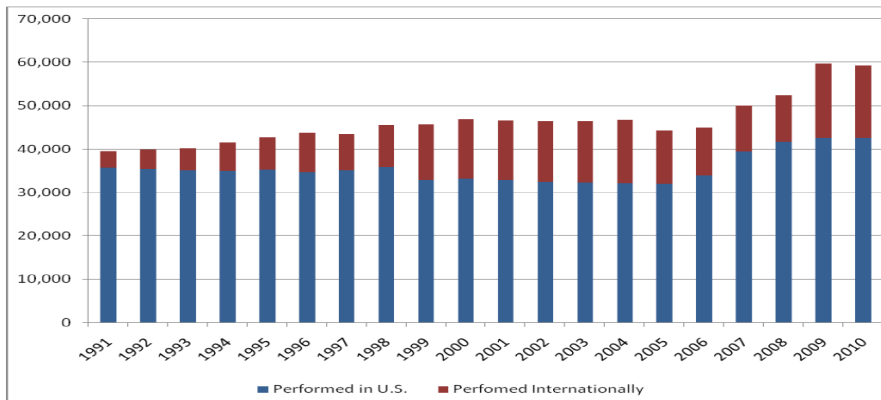
(Busin 2009)



TISSUE REMOVAL = Endothelium
NEW LAMELLA = 30-100 μm

(UT)DSAEK TODAY
GOLD STANDARD
FOR SURGICAL
TREATMENT OF
ENDOTHELIAL
DECOMPENSATION

**2010 U.S. Eye Banking Statistics Reported by U.S. Banks:
Annual Number of Corneal Transplants Supplied by U.S. Banks
79 U.S. Eye Banks Reporting**



USA

■ 1.429 2005
 ■ 6.122 2006
 ■ 14.159 2007

- 17.468 2008
- 18.221 2009
- 19.159 2010

ITALY

- 1000/5.300 (2010)

EK IN THE USA

In 2011 (5 Years after DMEK 1):

DSAEK $n = \underline{21,100}$

DMEK $n = \underline{343}$

EK IN THE USA

In 2014:

DSAEK $n = \underline{23,100}$

DMEK $n = \underline{2,865}$

EK IN THE USA

In 2015:

DSAEK $n = \underline{22,514}$

DMEK $n = \underline{4,694}$

DSAEK vs DMIEK

Patients with BSCVA \geq 20/20

DSAEK = 0% to 33%*

DMIEK = 20% to 50%

*DSAEK Personal Data

DSAEK vs DMIEK

Graft Rejection Rate in Fuchs

DSAEK = 2% - 18%

DMIEK = < 1%

DSAEK/UT-DSAEK/DMEK

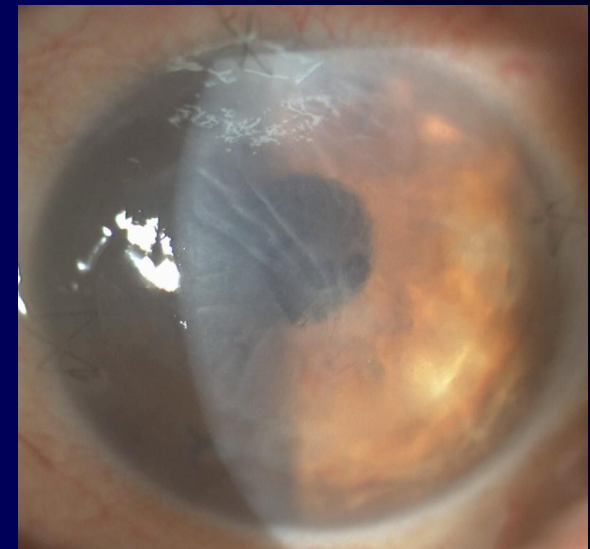
Cumulative Probability (K-M)

	DSAEK*	UT	DMEK
1 Year	2-8%	2.5%	<1%
2 Years	12%	2.5%	1.2%

*Fuchs Indications Only

DMEK CONS

- **Waste of Tissue up to 16%**
- **Detachment Rate up to 77%**
- **Primary Graft Failure up to 8%**



DMEK

TISSUE PREPARATION

- **STRIPPING**
(Melles, Kruse, Price, Terry, etc.)
- **AIR/FLUID INJECTION**
(Busin, Dua/Agarwal)

Pneumatic Dissection and Storage of Donor Endothelial Tissue for Descemet's Membrane Endothelial Keratoplasty

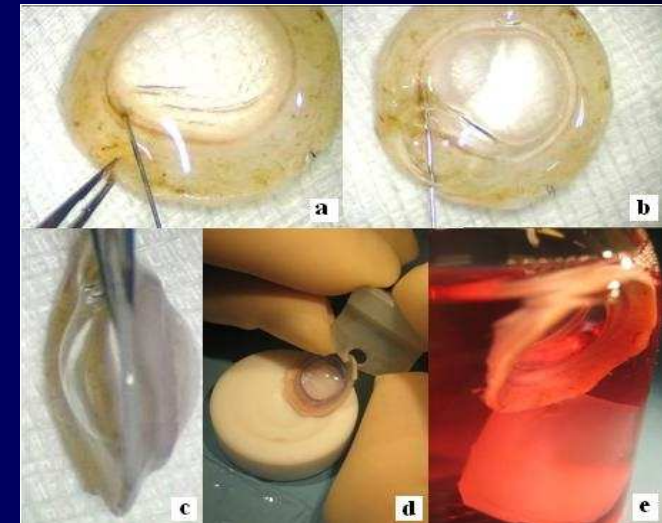
A Novel Technique

Massimo Busin, MD,^{1,2,3} Vincenzo Scorcia, MD,^{1,2} Amit K. Patel, FRCOphth,^{1,3} Gianni Salvalaio,³
Diego Ponzin, MD³

¹ "Villa Serena" Hospital, Department of Ophthalmology, Forlì, Italy.

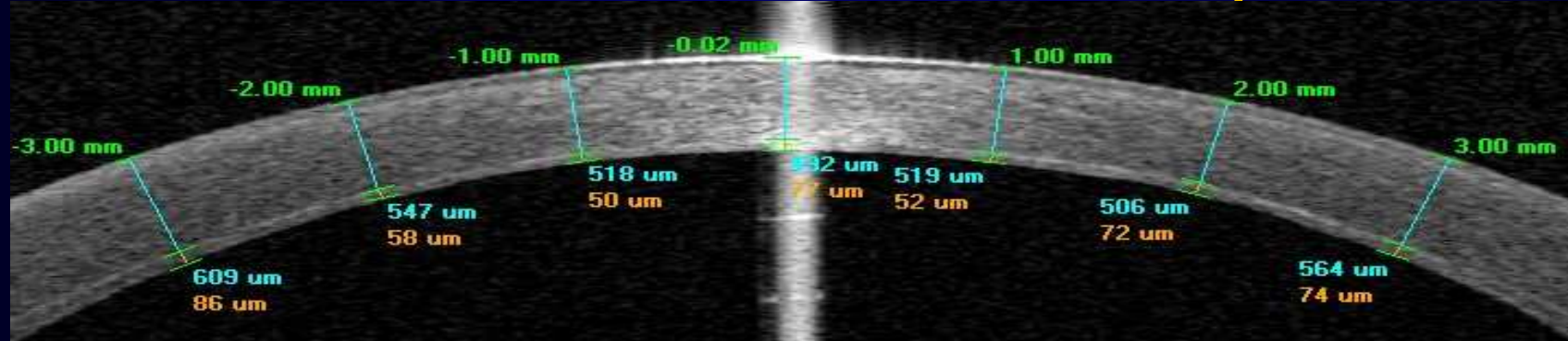
² University of Magna Graecia, Department of Ophthalmology, Catanzaro, Italy.

³ Fondazione Banca degli Occhi del Veneto, Venice, Italy.

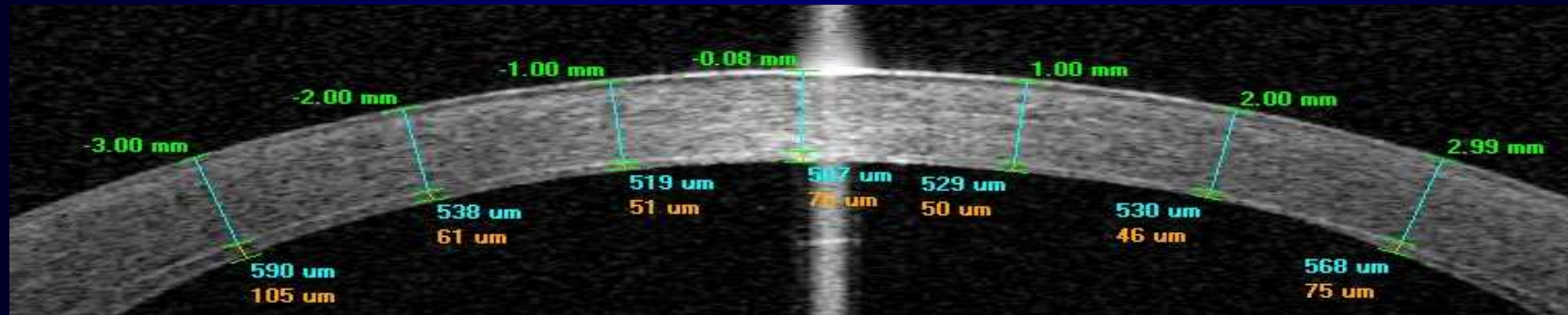


2008-2010

UT-DSAEK vs DMEK(PDEK)



UT-DSAEK



DMEK??? → (PDEK) UT-DSAEK

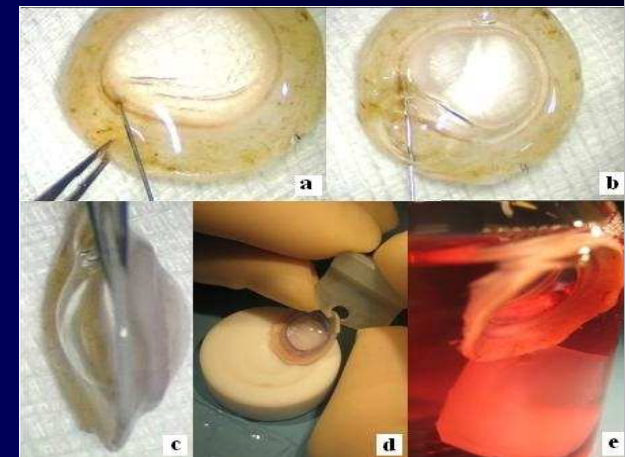
UT-DSAEK/DMIEK

DMIEK-PDEK-UT-DSAEK

Pneumatic Dissection and Storage of Donor Endothelial Tissue for Descemet's Membrane Endothelial Keratoplasty

A Novel Technique

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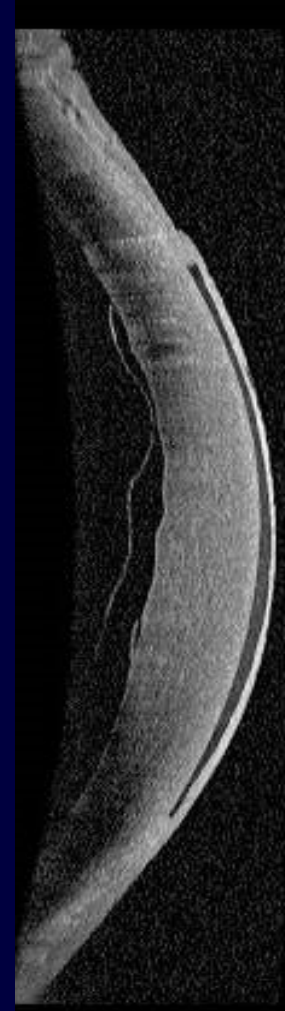


(2008-2010) ECL ↑↑↑

DMEK

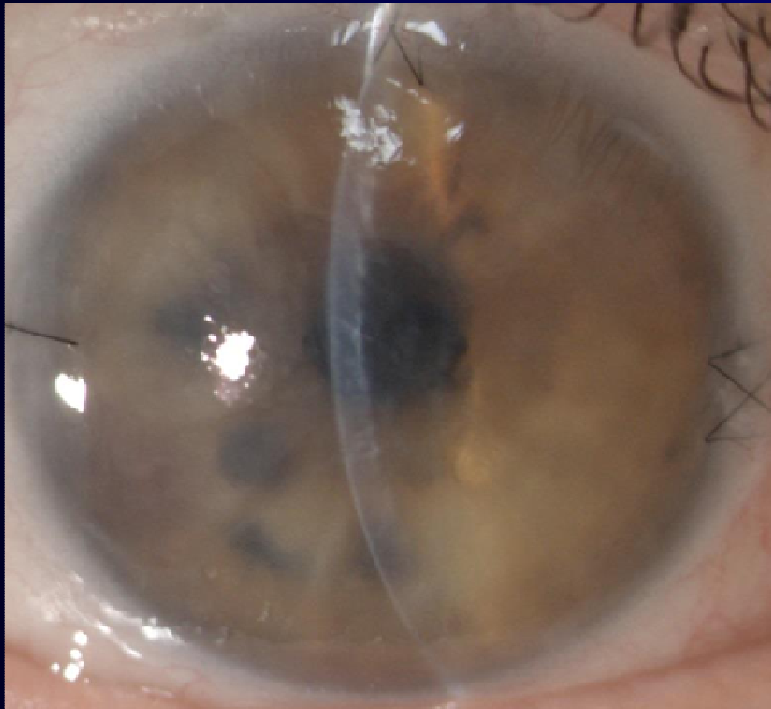
<u>RELEVANT ISSUES</u>	PREPARATION	
	EYE BANK	SURGEON
COSTS	-	+
TISSUE WASTE	+	-
QUALITY CONTROL	+	-
SURGICAL TIME	+	-

DMIEK

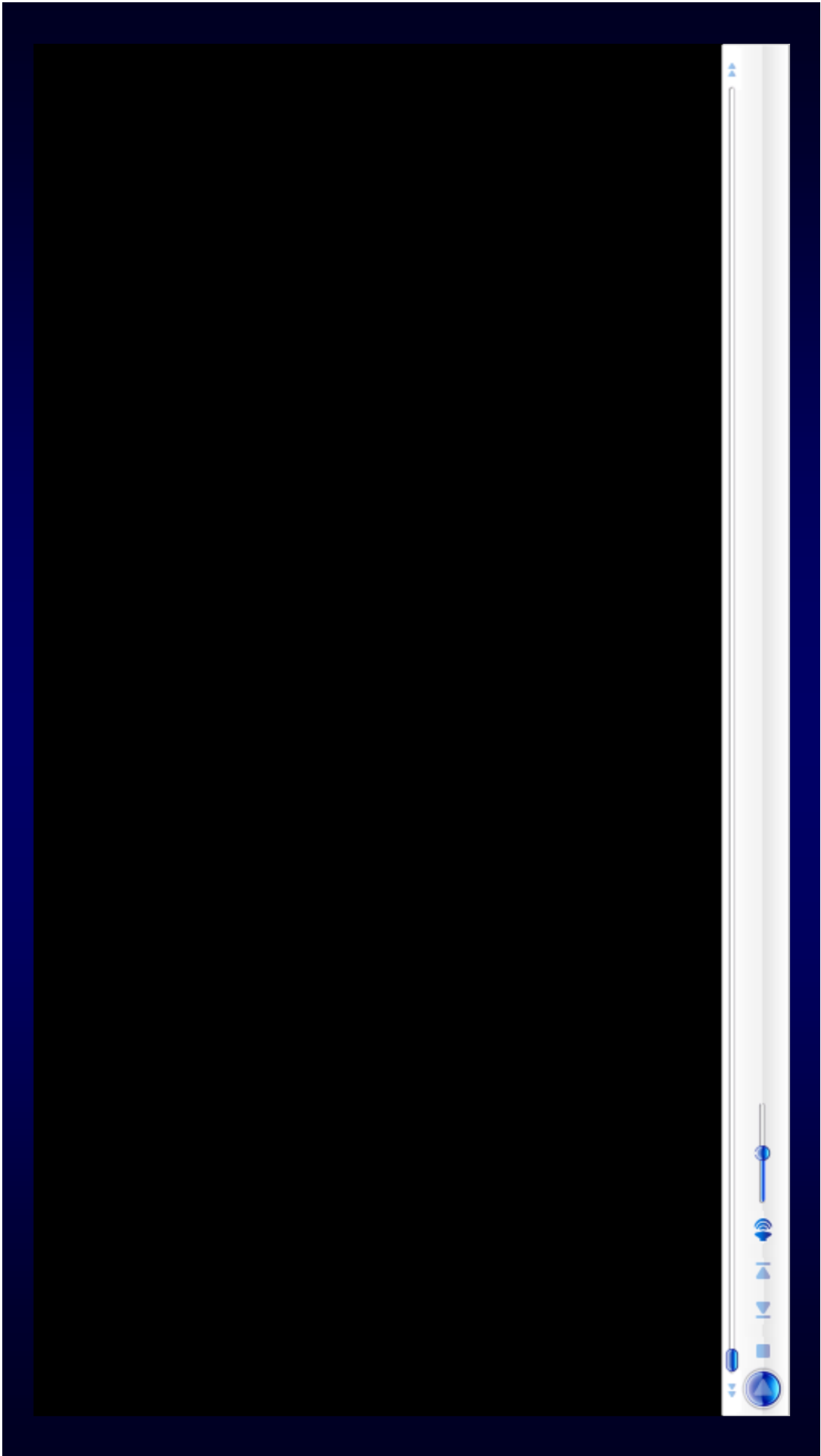


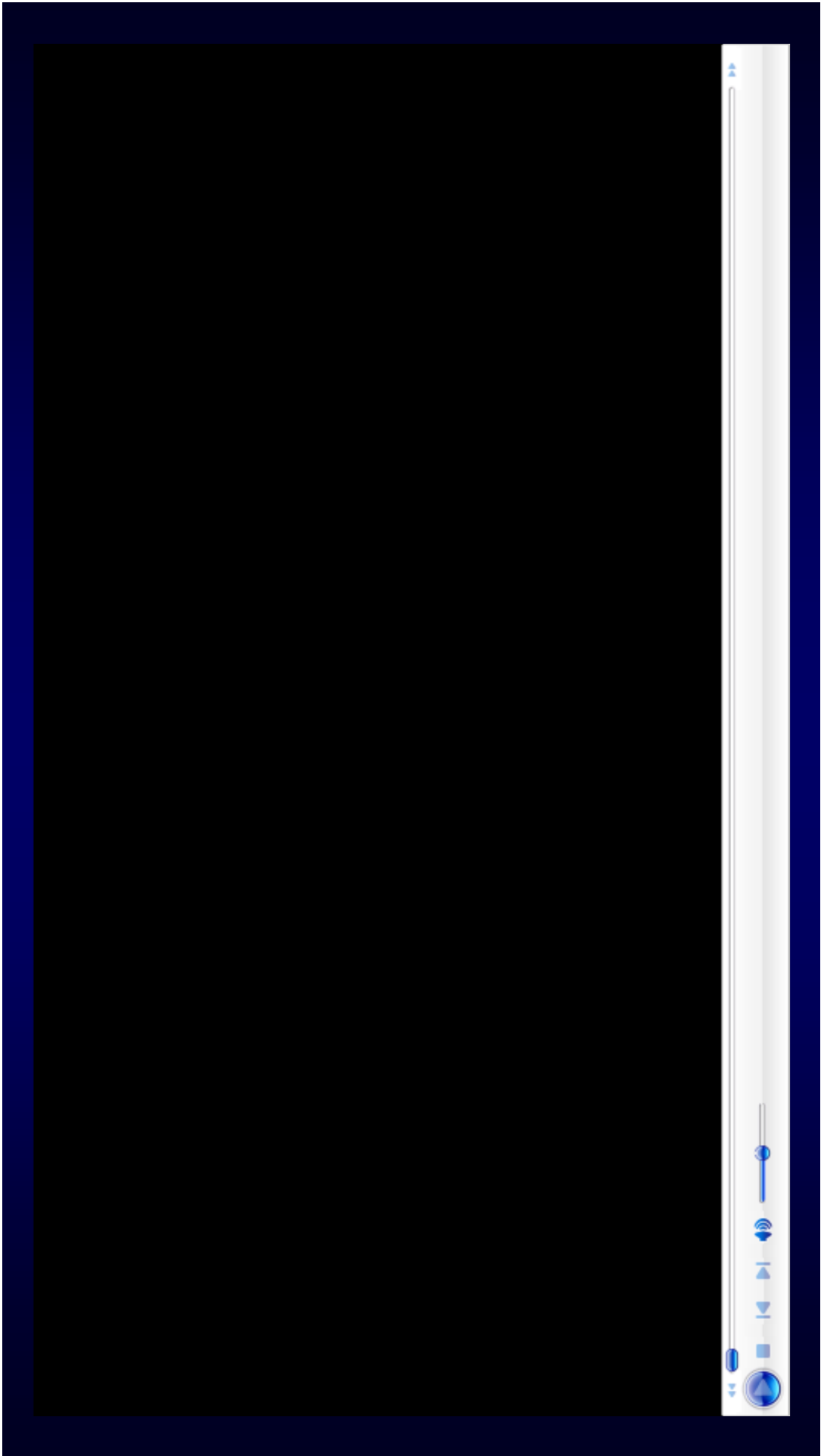
4 DAYS POSTOP

DMIEK



1 MONTH POSTOP





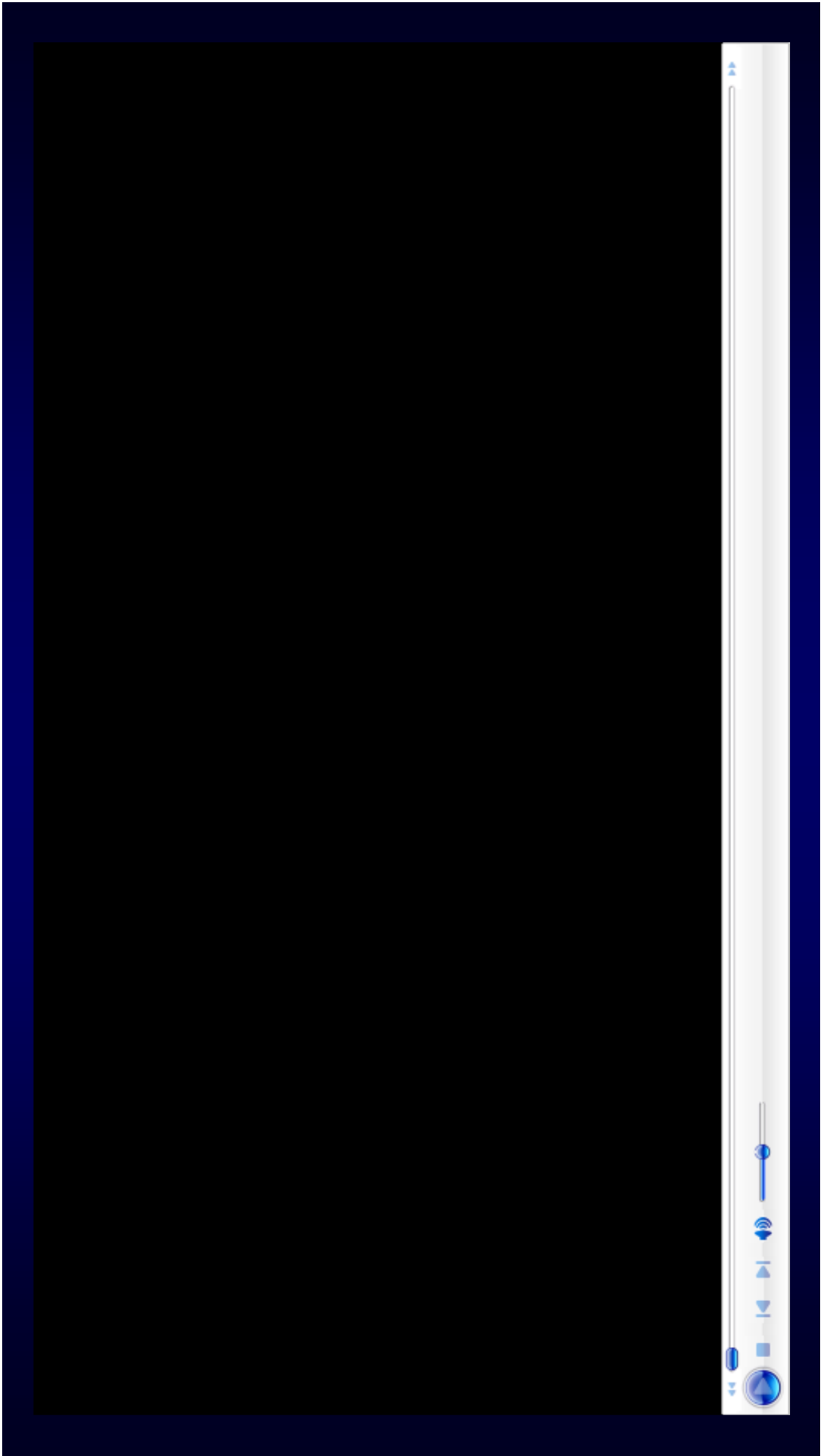
DMEK CHALLENGES

- **Simplify (STANDARDIZE)**
- **Minimize Rebubbling/ECL**
- **Eliminate Primary Failure**
(Upside Down !!!)
- **SUBSTANTIAL ADVANTAGES**

DMIEK 2.0

IMPROVED CONTROL

!!!

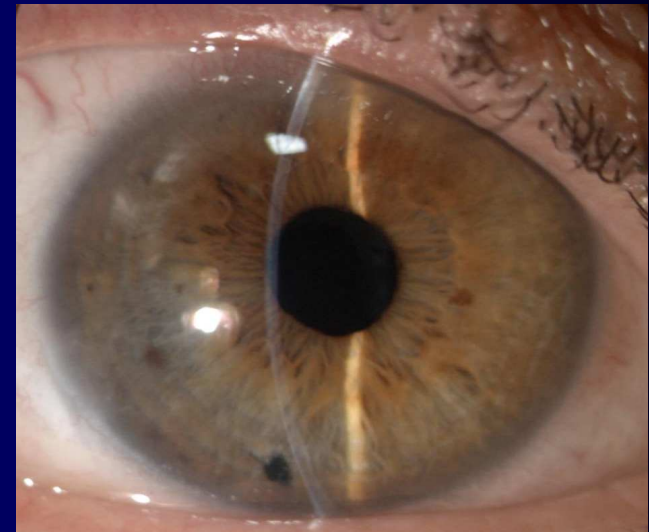


DMIEK 2.0

Results 6 Mos Post-DMIEK

- 46 Consecutive Uneventful
DMIEK

- Surgical Time
≤ 20 Minutes

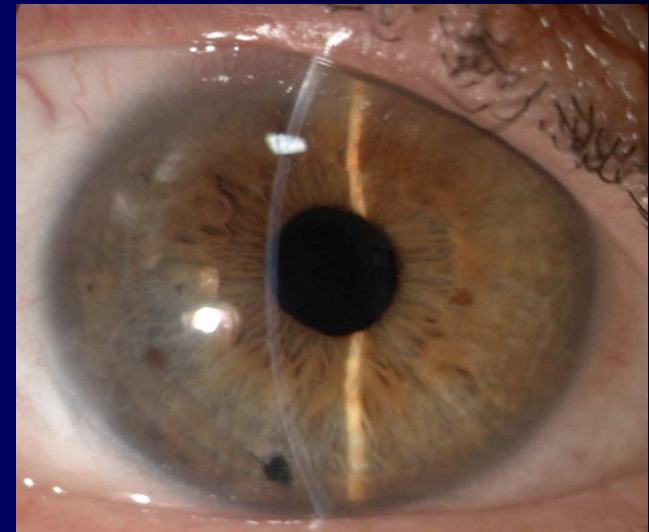


DMIEK 2.0

Results 6 Mos Post-DMIEK

- 46 Consecutive Uneventful
DMIEK

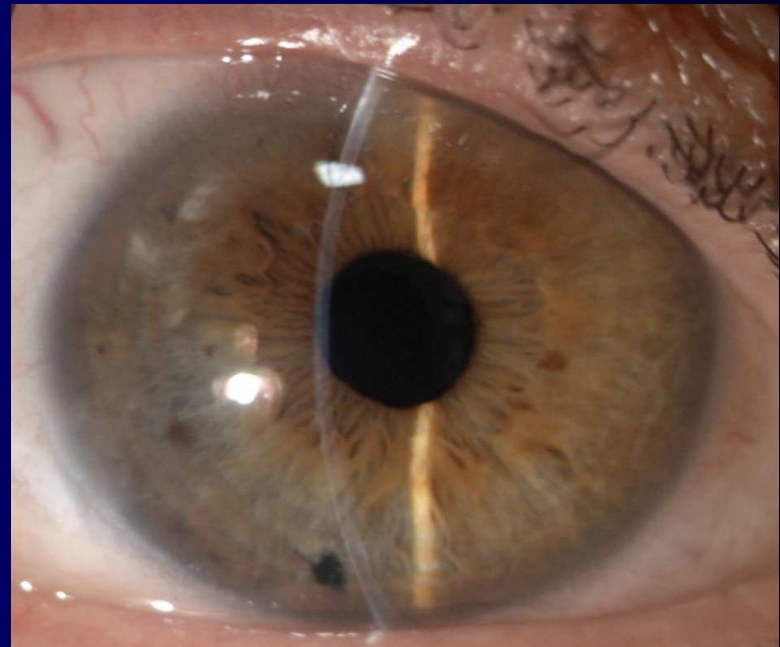
- VA \geq 20/25 in
38/46 Eyes



DMEK 2.0

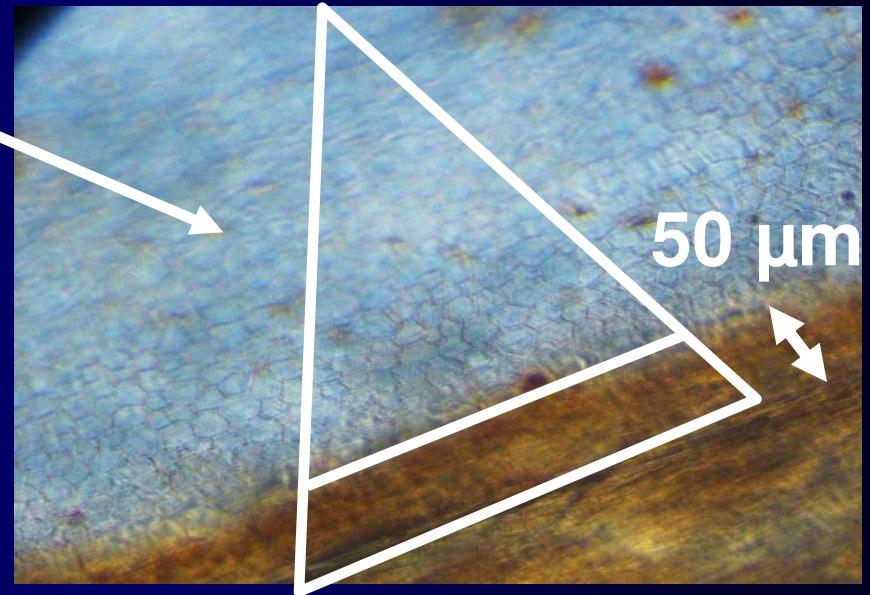
Possible Sources of ECL

- **Stripping**
- **Loading**
- **Preservation**
- **Delivery**
- **Manipulation**



DMEK 2.0

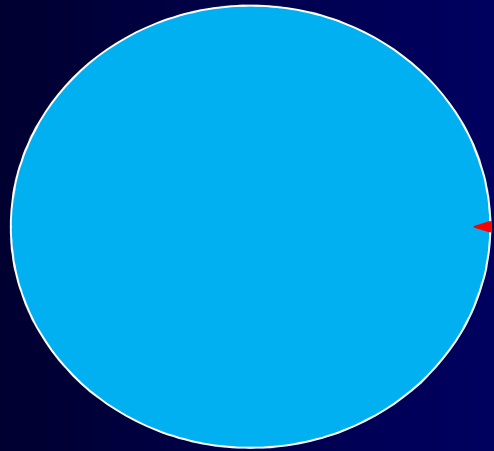
Forceps Trauma



EACH BITE = 0.03mm^2 = 50-75 Cells

DMEK 2.0

Forceps Trauma



$$r = 4.125 \text{ mm}$$

$$S = 4.125^2 \pi$$
$$= 53,43 \text{ mm}^2$$

← EACH BITE

$$53.43/0.03 \text{ mm}^2$$

0,00056 of Total

18 Bites = 1%

DMIEK 2.0

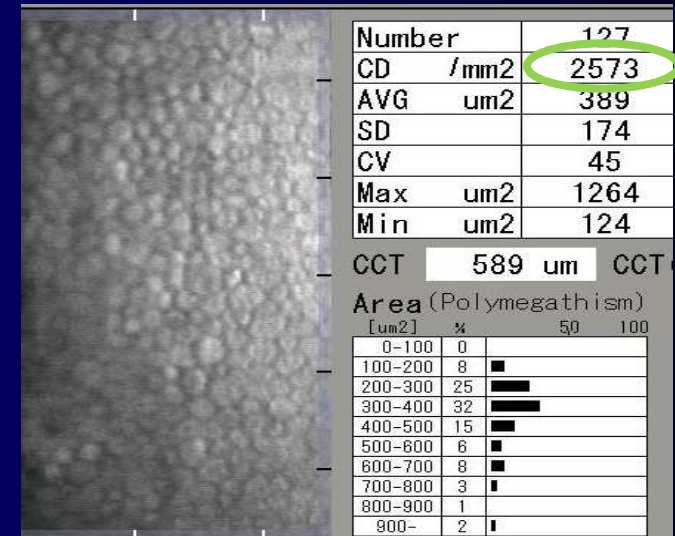
ECL 6 Mos Post-DMIEK

• $< 20\%$ = 46/46

• $< 16\%$ = 45/46

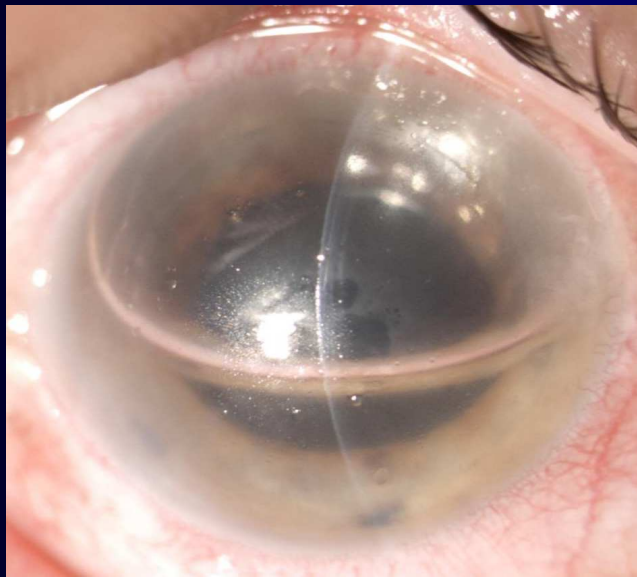
• $< 12\%$ = 38/46

• $< 8\%$ = 5/46

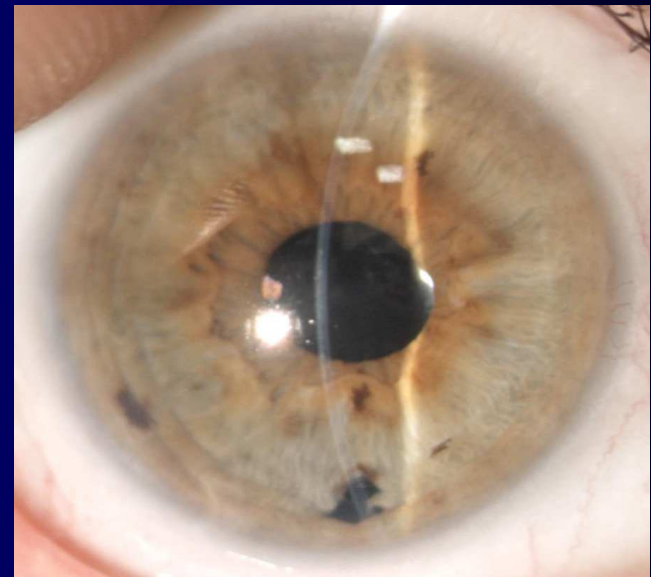


DMIEK 2.0

SUTURELESS



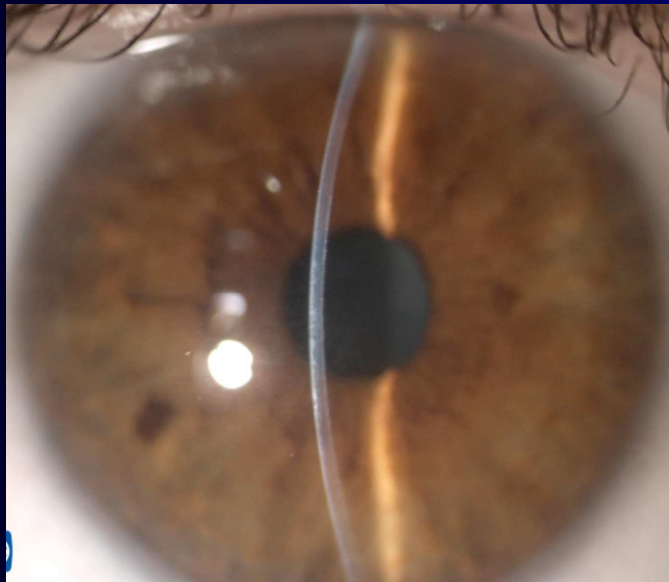
1d Postop



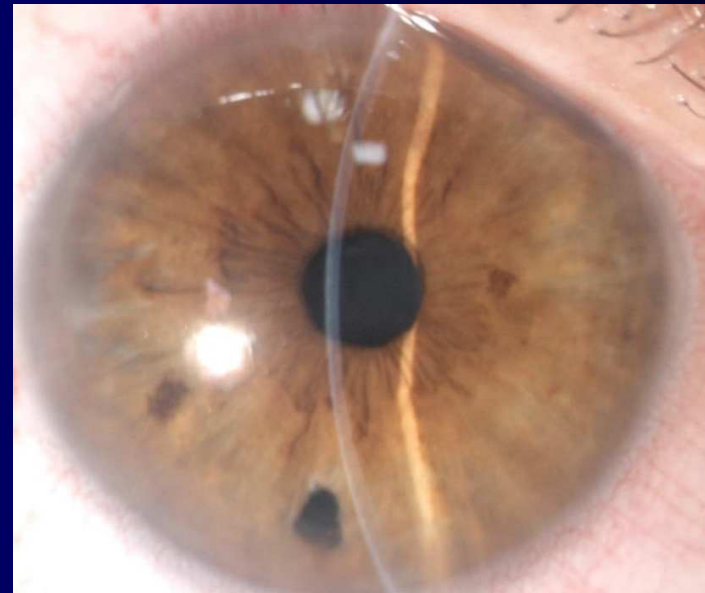
2w Postop VA = 20/20

DMEK 2.0

SUTURELESS (PHAKIC)



Preop



2w Postop VA = 20/20

DMEK

DMEK 2.0

- **Preparation** → **Eye Bank**
- **Incision** → **Suturless**
- **Delivery** → **Pull-through**
- **Positioning** → **Direct**
- **Attachment** → **Air/Gas**

DMEK 2.0

NEW!!!

Detachment Rate

Sutured = 17/60 = 28%

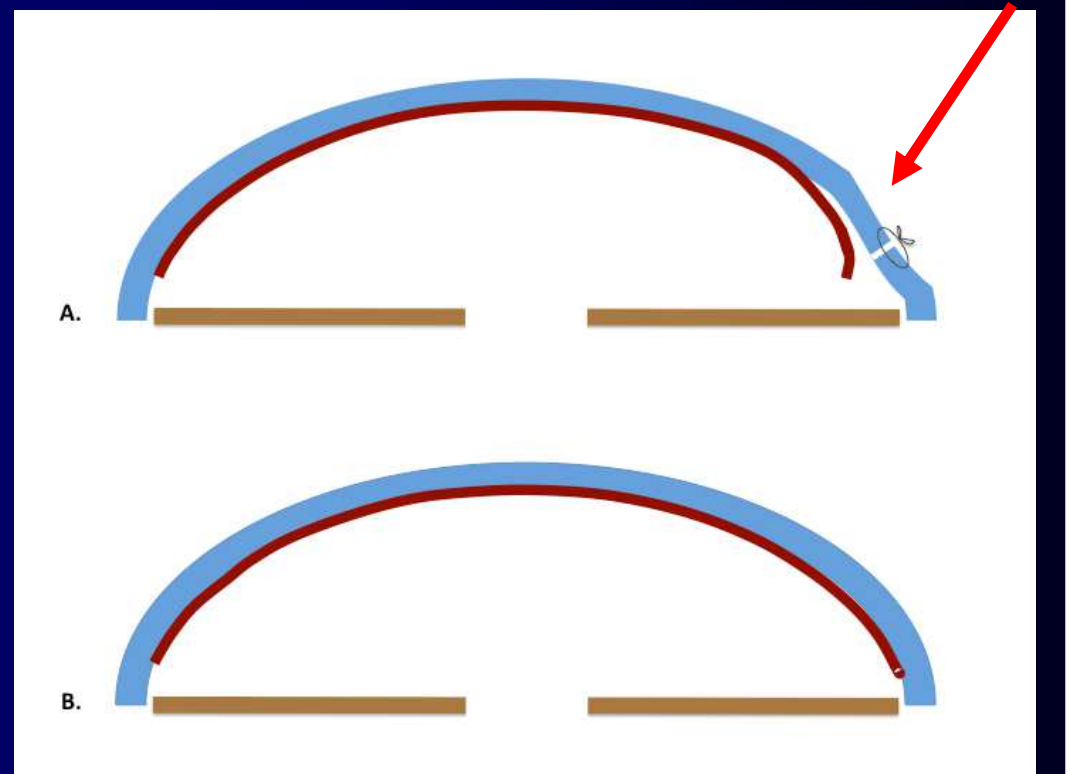
Sutureless = 4/30 = 13%

P = 0.06 (Fischer's Exact Test)

DMEK 2.0

**DMEK Sutures
Causes Indentation of
the Cornea and
Detachment (A)**

**Sutureless DMEK
Does Not Change
Corneal Shape (B)**



DMEK

DMEK 2.1 (Sutureless)

- Preparation** → **Eye Bank**
- Incision** → **Suturless**
- Delivery** → **Pull-through**
- Positioning** → **Direct**
- Attachment** → **Air/Gas**

DMIEK 2.0

THANK YOU !!!

