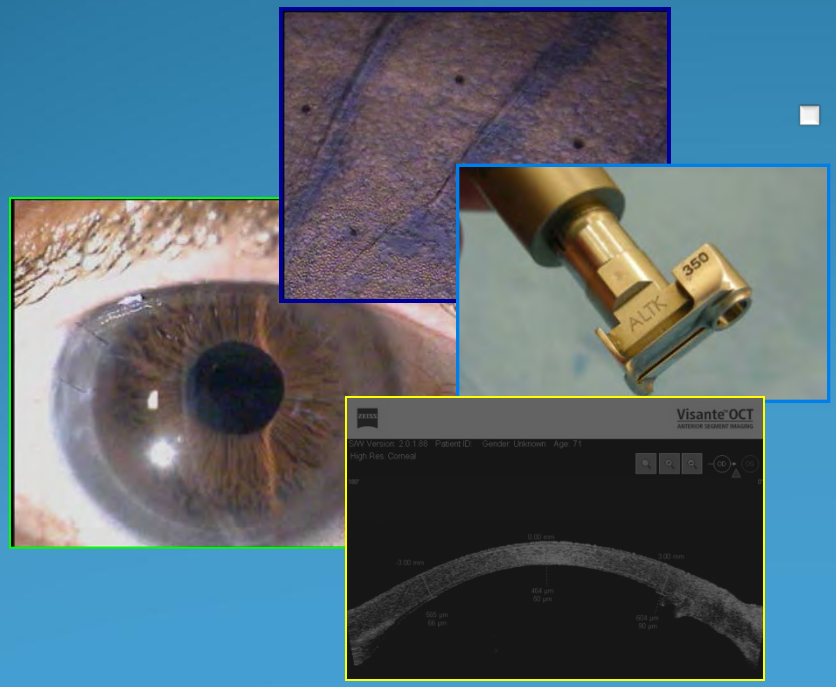
Lenticoli pretagliati per ultra-thin DSAEK

Standardizzazione della procedura di preparazione in Banca e risultati clinici



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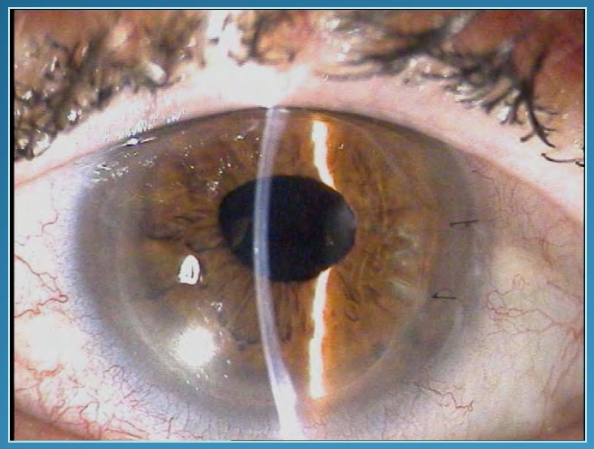
Genova 21 Aprile 2012

Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK) is a stroma-sparing transplant technique that selectively replaces dysfunctional corneal endothelium



Advantages: DSAEK vs PK

- ✓Faster visual recovery
- ✓Minimal refractive change
- ✓Minimal postoperative ocular surface complications
- ✓Better postoperative corneal integrity

The DSAEK technique requires lamellar dissection of the donor graft prior to the implantation of the posterior donor lenticule into the patient's eye

dissection using a microkeratome

Precut Tissue in Descemet's Stripping Automated Endothelial Keratoplasty

Donor Characteristics and Early Postoperative Complications

Edwin S. Chen, MD,[1] Mark A. Terry, MD,[1,2] Neda Shamie, MD,[1] Karen L. Hoar, MD, FRCSC,[1] Daniel J. Friend, MS[2]

Conclusion: The use of precut tissue in DSAEK had a low rate of early postoperative complications such as graft dislocation (1%) and primary graft failure (0%). A wide range of donor characteristics such as donor age, death to transplantation time, precutting to transplantation time, and donor lenticule thickness resulted in excellent adhesion of the tissue and clear grafts. *Ophthalmology 2008;115:497–502 © 2008 by the American Academy of Ophthalmology.*

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The Association for Research in Vision and Ophthalmology
www.arvo.org

Descemet Stripping Automated Endothelial Keratoplasty (DSAEK): The Tenuous Relationship Between Graft Thickness And Visual Results

Mark A. Terry[1,2], *Jennifer Y. Li*[1], *Jeffrey Goshe*[1], *David L. Davis-Boozer*[2]. [1]Corneal Services, Devers Eye Institute, Portland, OR; [2]Vision Research Laboratory, Lions Eye Bank of Oregon, Portland, OR.

The 38 grafts that were thicker than 200 microns had a mean LogMAR vision of 0.245 (20/35), which was significantly worse than the grafts 200 microns or less (Mann-Whitney: p=0.003).

Introduction and working hypothesis

- Main challenges during DSAEK:
  - To minimize endothelial damage of the donor PLD
  - To minimize iatrogenic damage (insertion of the tissue in A.C.)

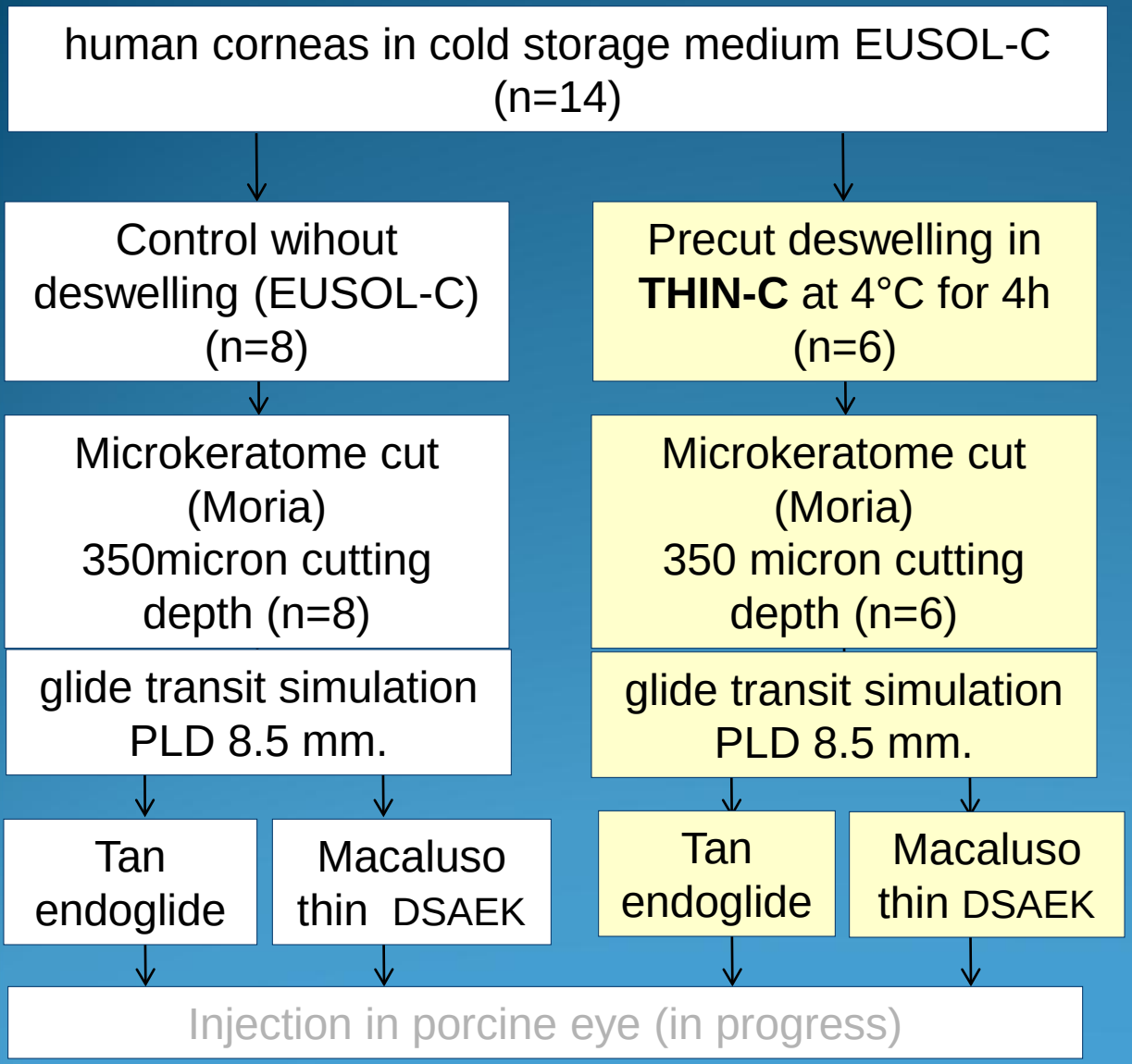
- We have standardized a procedure of Ultra - thin DSAEK using de-swelling medium THIN-C before cut with clinical evidences of better and faster visual recovery.

Working hypothesis was to combine:

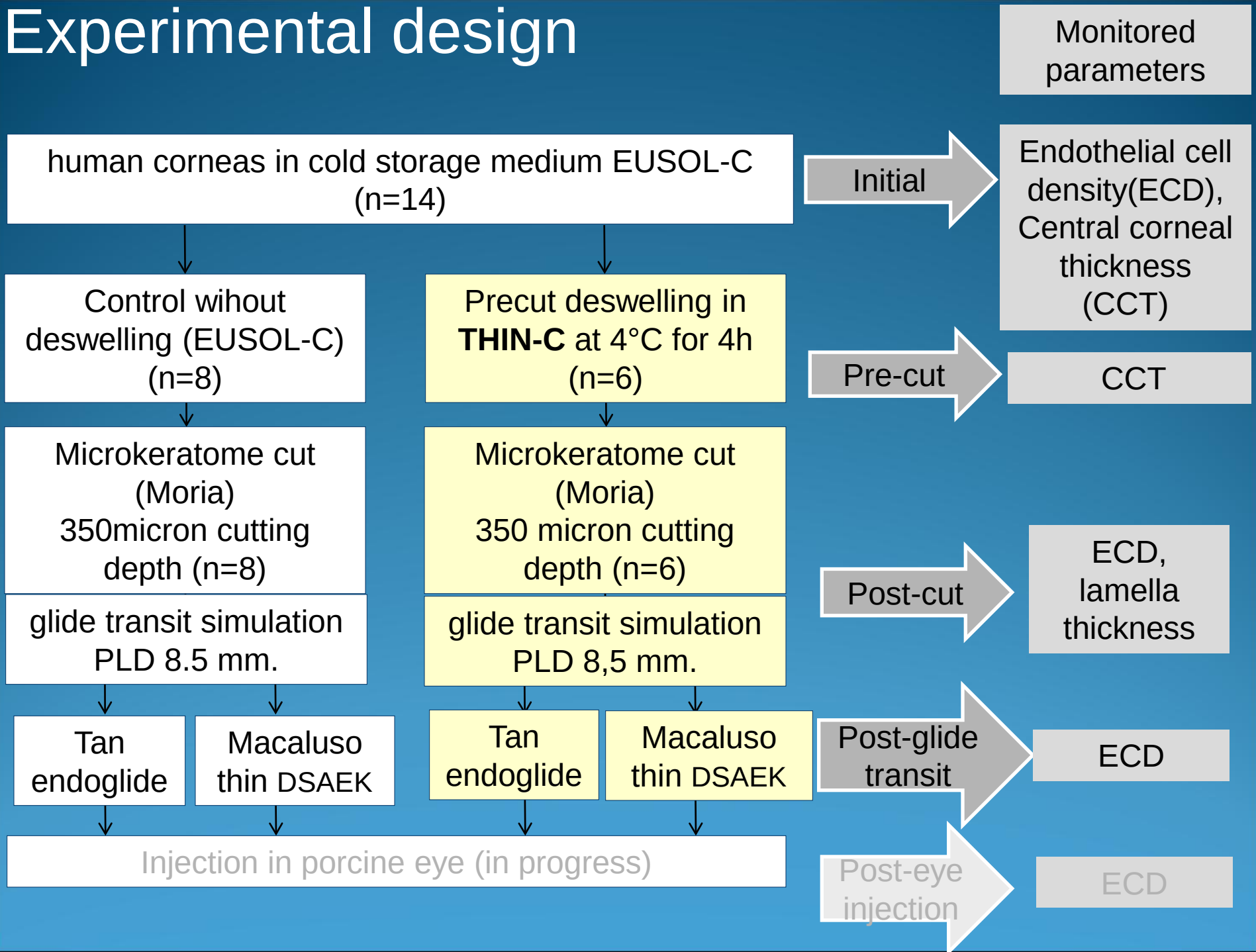
- ultra-thin tissue
- with microinjector compatible with minimal incision of the cornea (3,5 mm)

preservation of endothelial cells has to be evaluated

Experimental design



Experimental design



Materials

Media

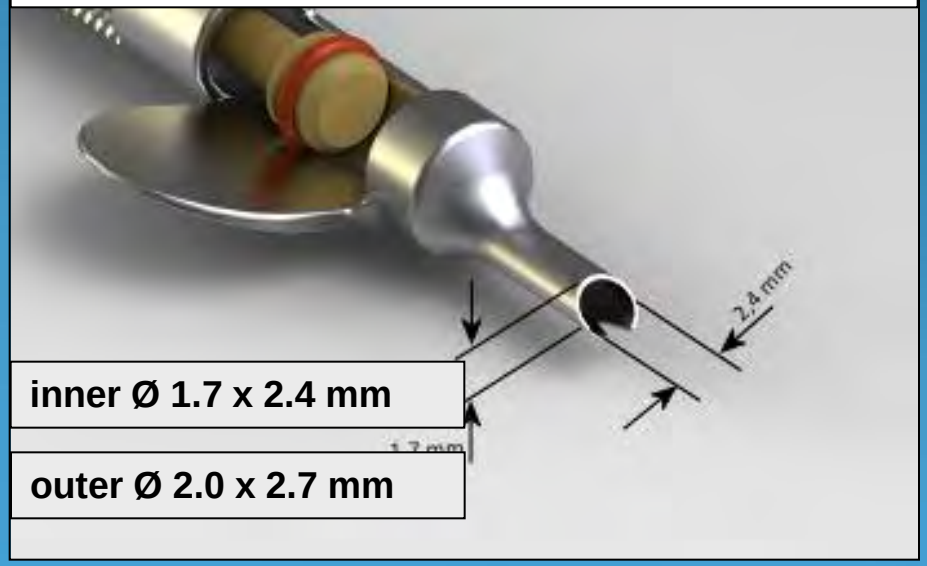
- EUSOL-C (ALCHIMIA) cold storage medium
- THIN-C (ALCHIMIA) pre-cut deswelling medium

Glides

Tan endoglide

outer horiz Ø 3.85mm

Macaluso THIN-DSAEK inserter (Janach)



inner Ø 1.7 x 2.4 mm

outer Ø 2.0 x 2.7 mm

Methods

Tissue evaluation

- **Corneal Central Thickness and lamella thickness**
  - OCT VISANTE (ZEISS) equipped with adaptor for in-vial measurement

Evaluation of a new method for the measurement of corneal thickness in eye bank posterior corneal lenticules using Anterior Segment Optical Coherence Tomography

Domenico Amato,[1] Marco Lombardo,[1] Francesco Oddone,[1] Mario Nubile,[2] Rossella A M Colabelli Gisoldi,[3] Carlo M Villani,[3] Sonia Yoo,[4] Jean-Marie Parel,[4] Augusto Pocobelli[3]

Br J Ophthalmol 2011;**95**:580–584. doi:10.1136/bjo.2010.190595

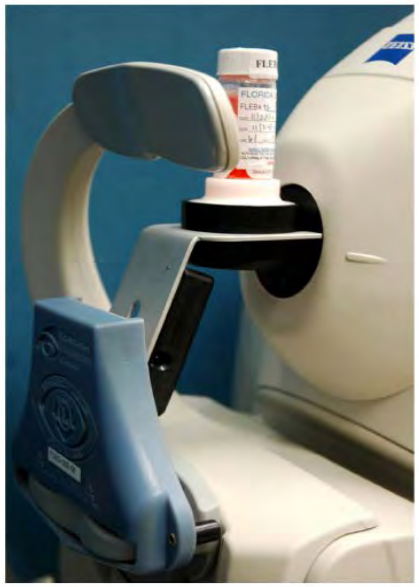


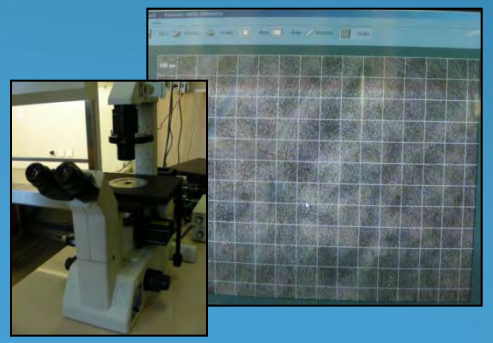
Figure 1. The Florida Eye Bank tissue adaptor does not require modification of optical coherence tomography and can be easily plugged in and out without compromising the sterility of donor corneal tissue.[1,2]

- **Endothelial Cell Density (ECD)**
  - Trypan Blue staining and cell count using digital inverted microscope and software NAVIS (Nidek Technologies)

Precut Donor Tissue for Descemet Stripping Automated Keratoplasty: Anterior Hinged Lamella On versus Off.

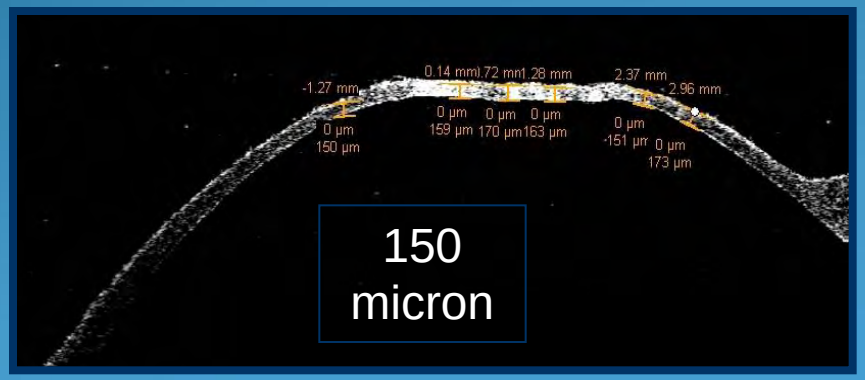
Amato D, Oddone F, Nubile M, Maria Colabelli Gisoldi RA, Villani CM, Pocobelli A.

Br J Ophthalmol. 2010 Apr;94(4):519-22.

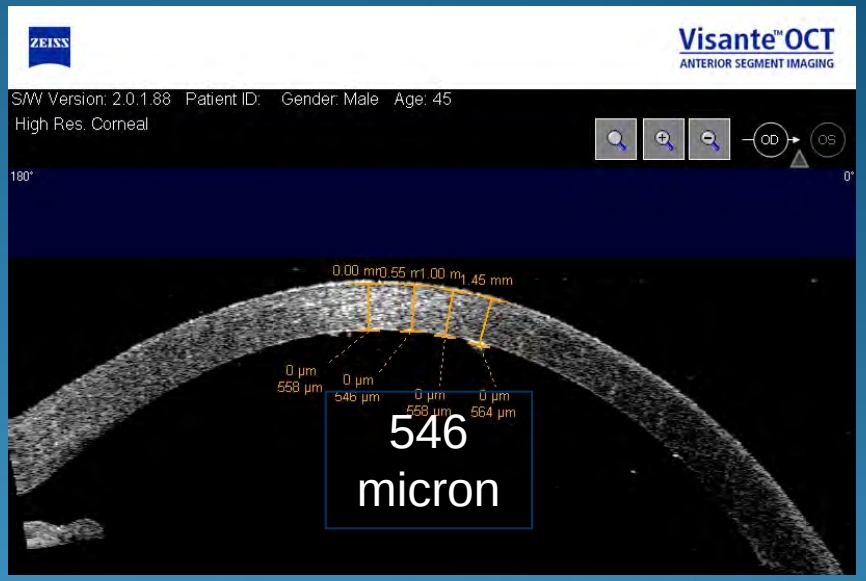


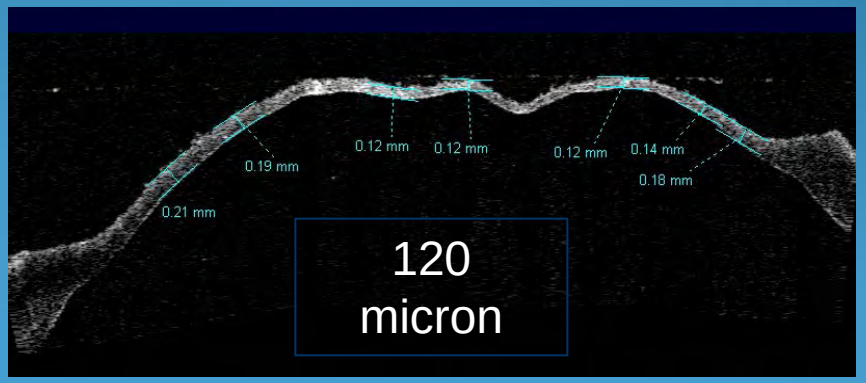
Central corneal thickness

Eusol-C treated cornea

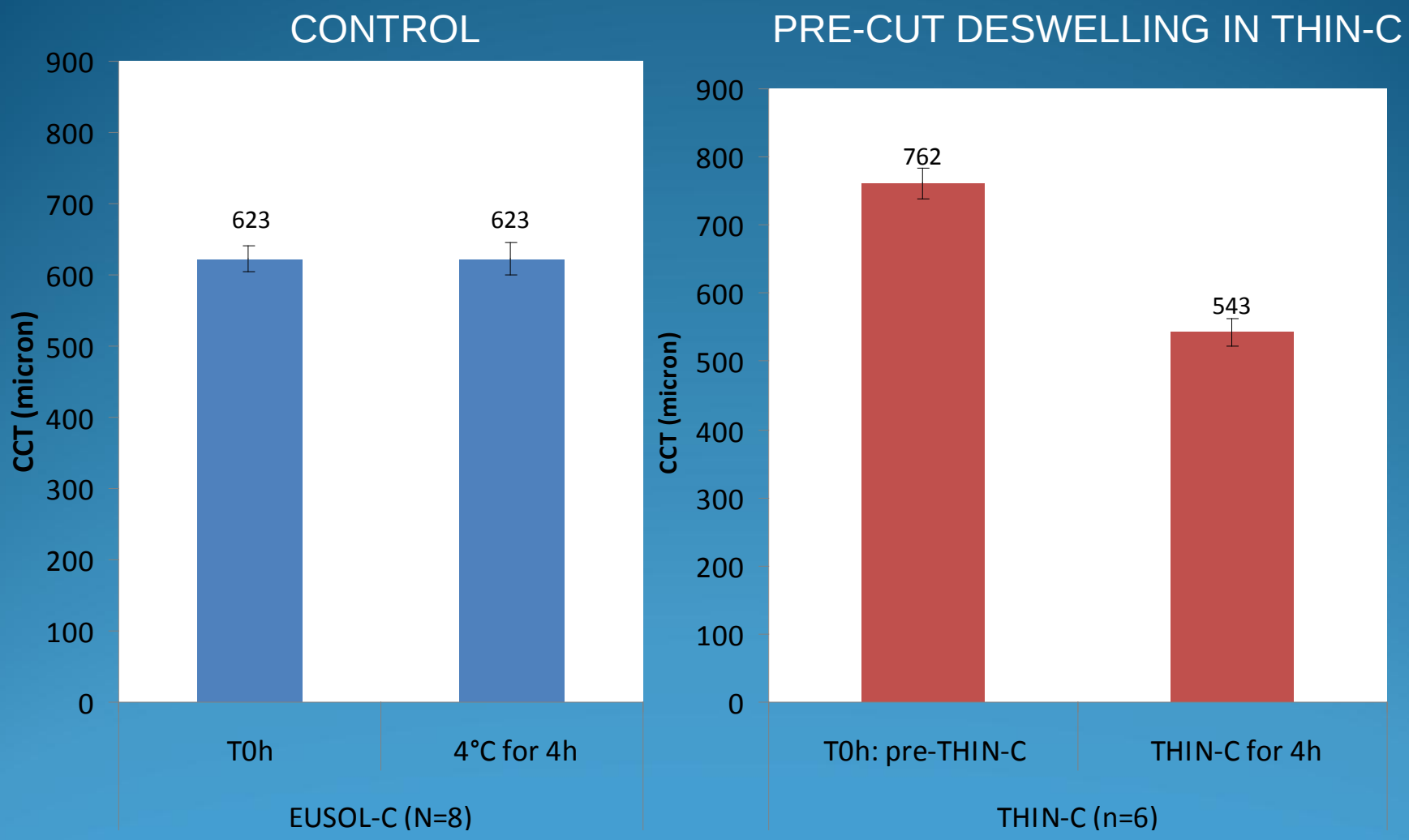


THIN-C treated cornea

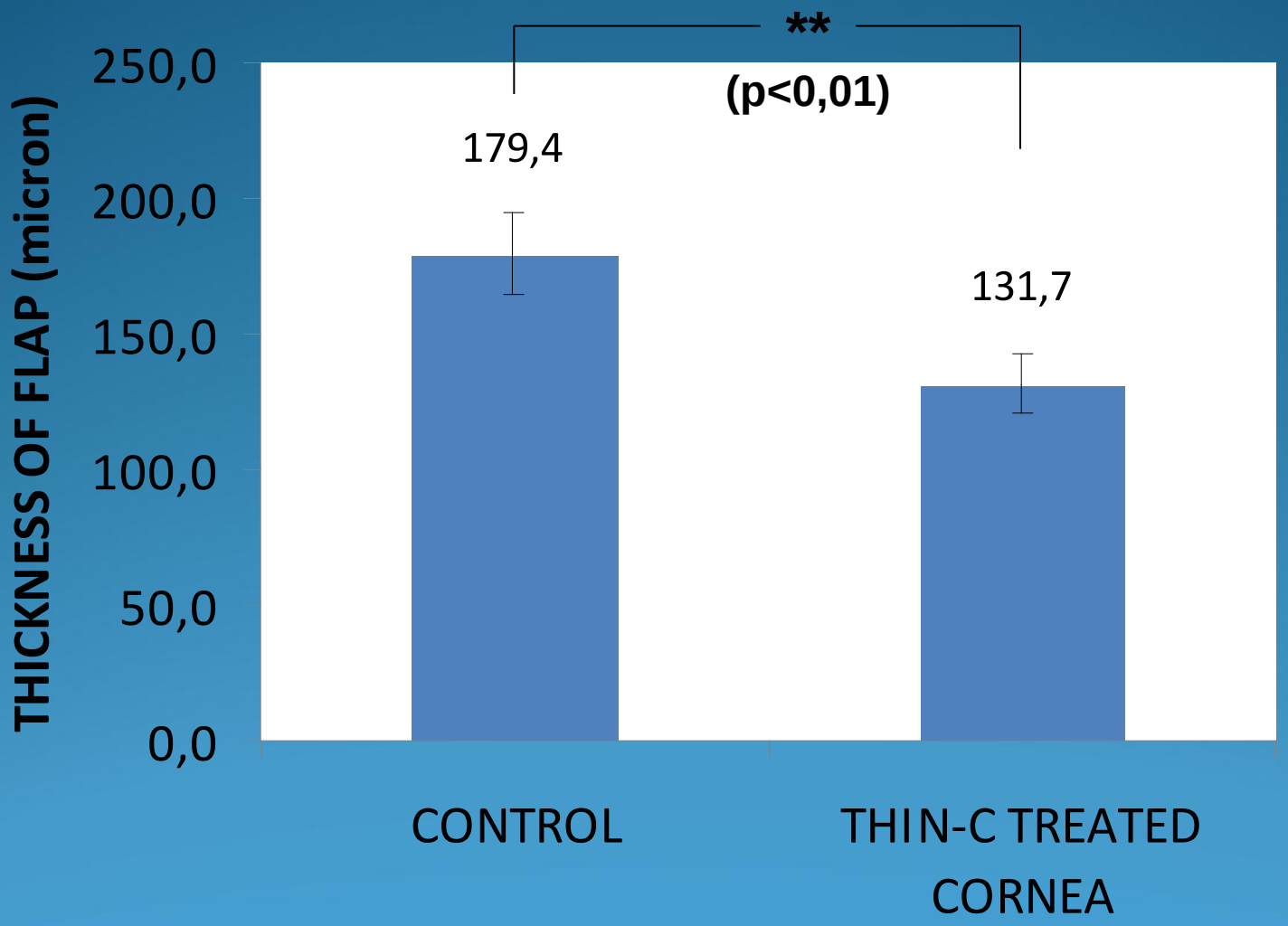




Corneal thickness before cut

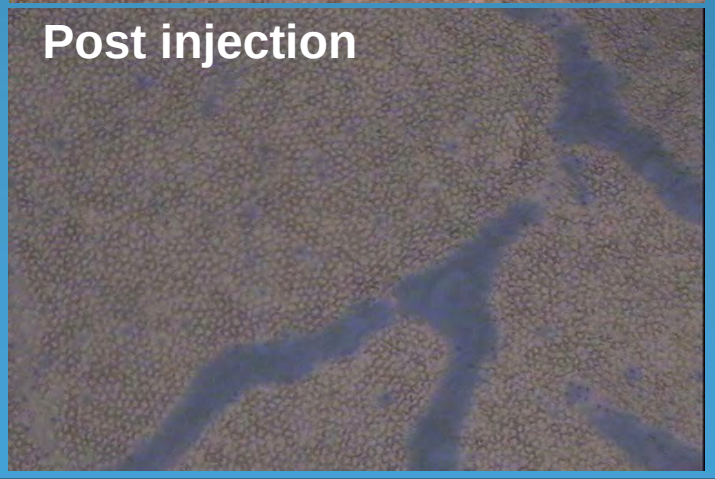


Posterior lamellar disc thickness

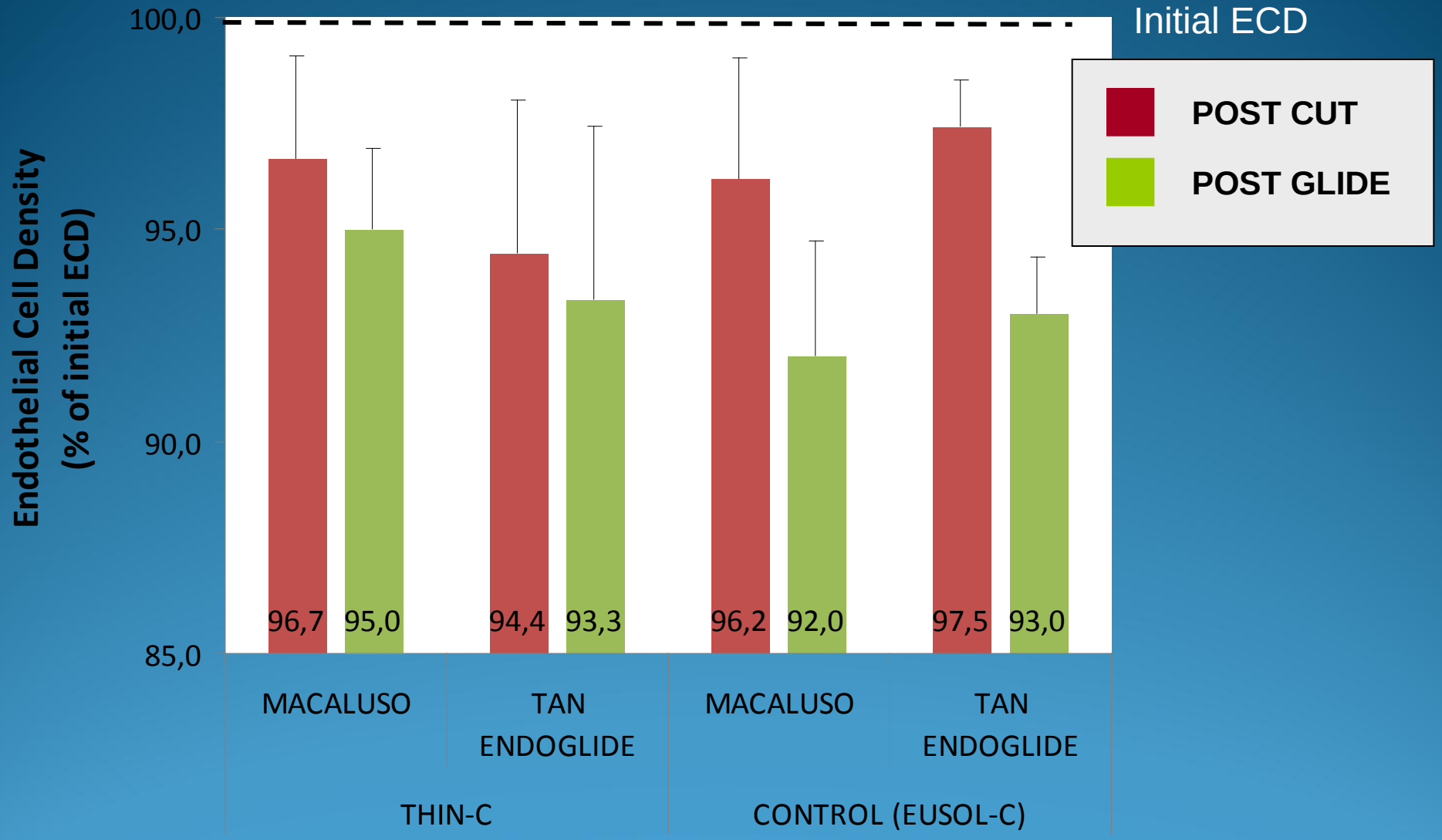


Tan endoglide

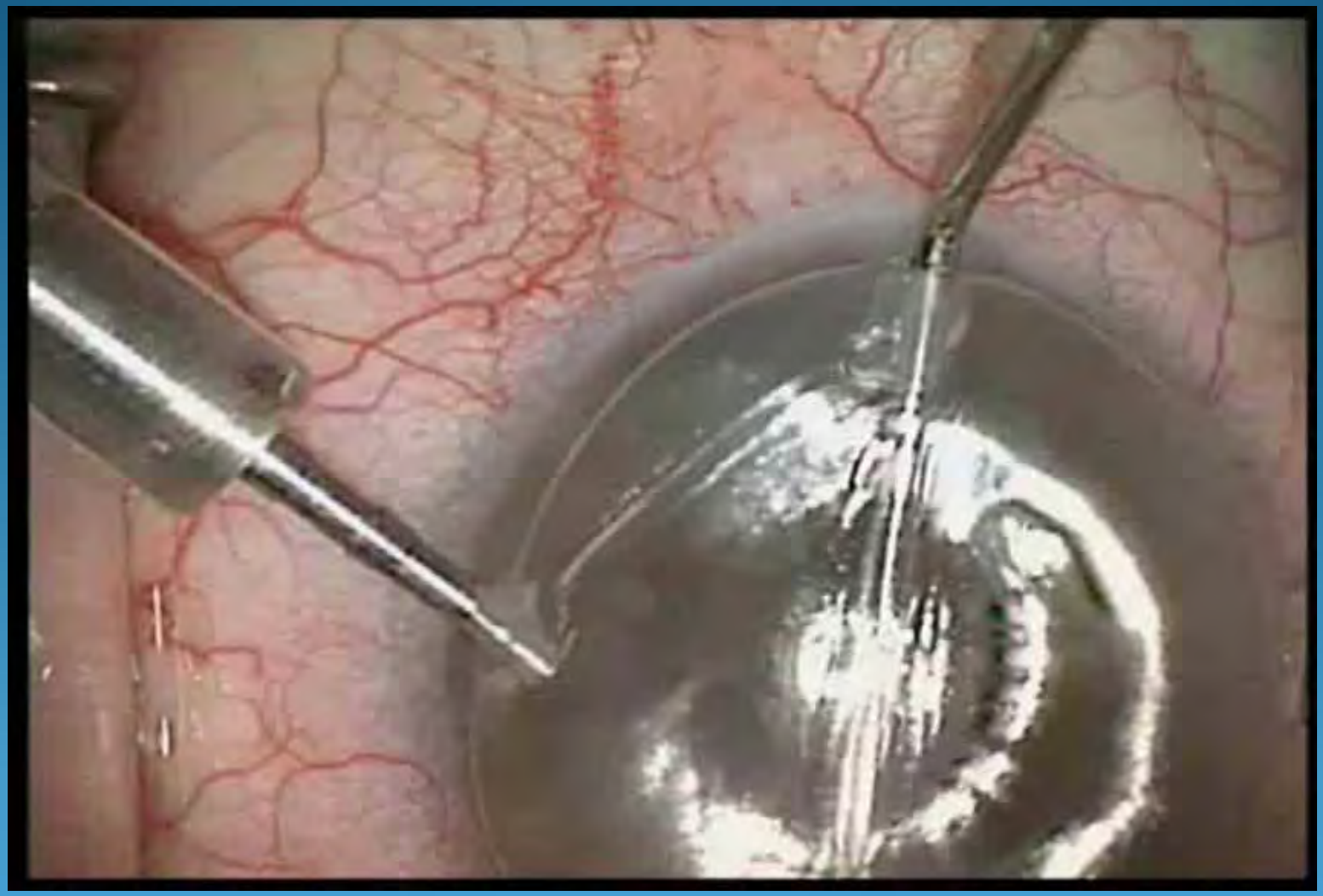
Macaluso endoglide



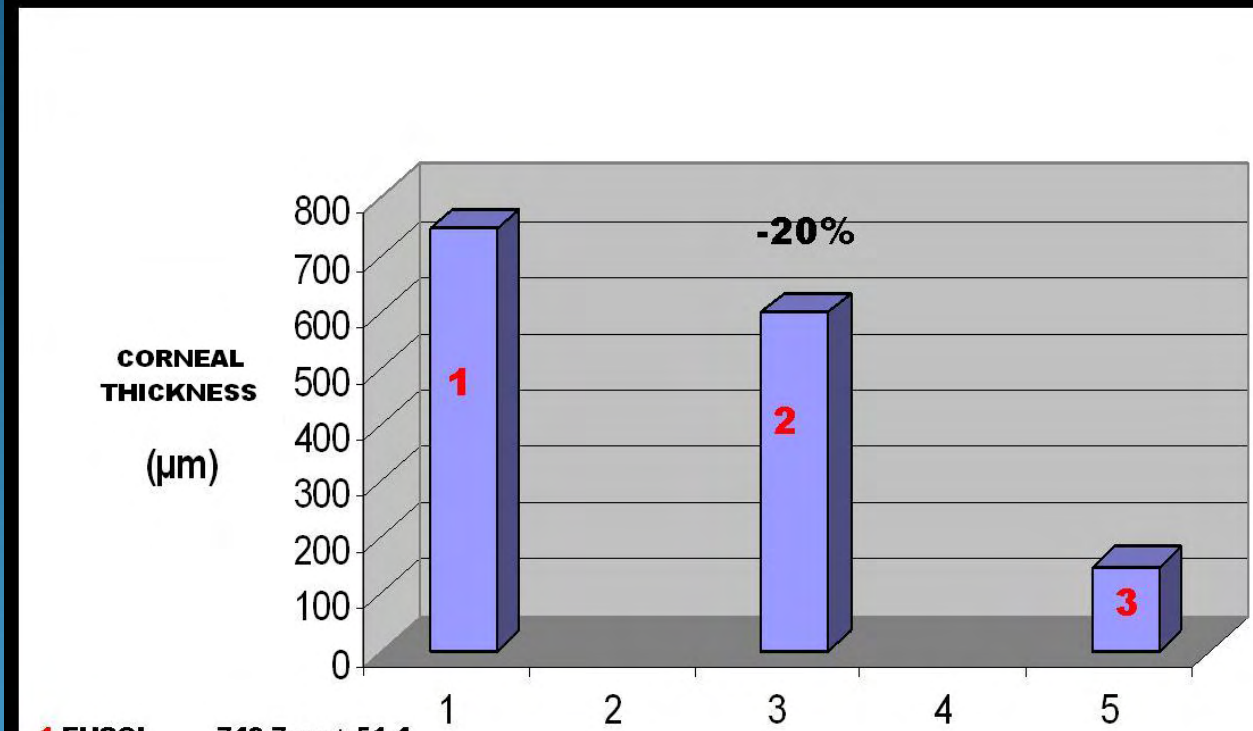
ECD MONITORING

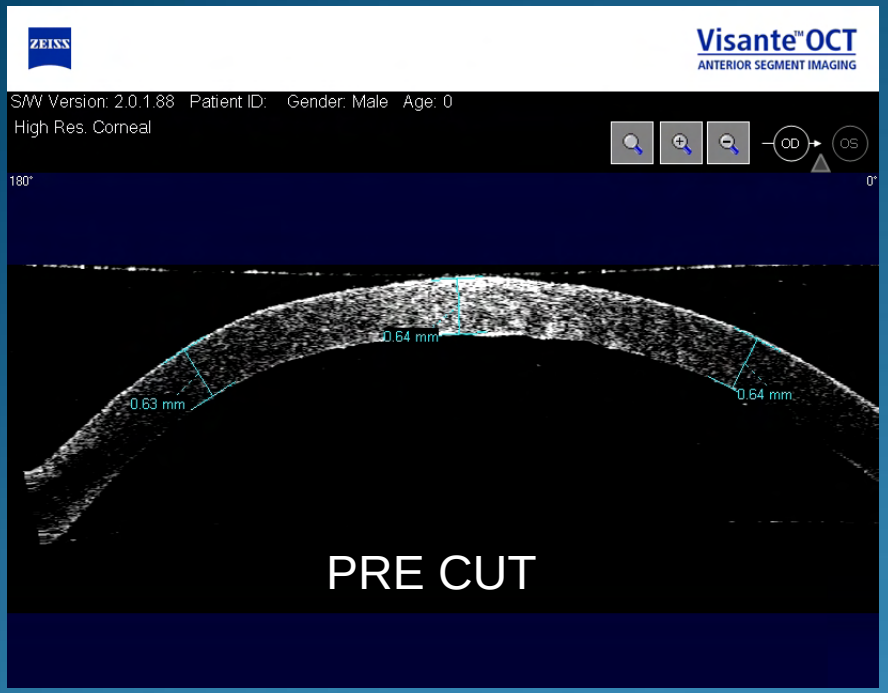


Ultra-thin DSAEK

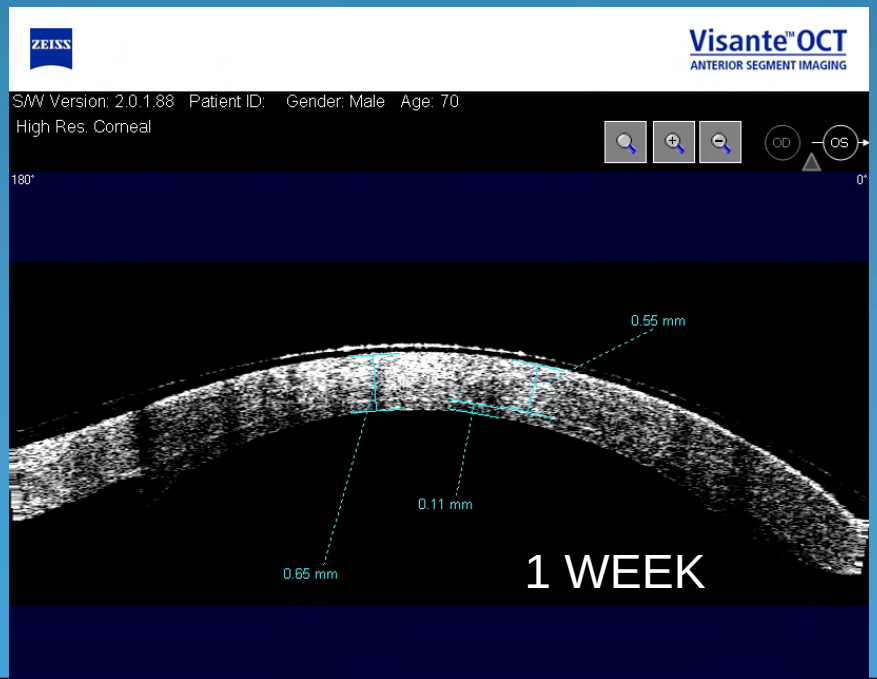


Ultra-thin precut tissues
12 months of follow up

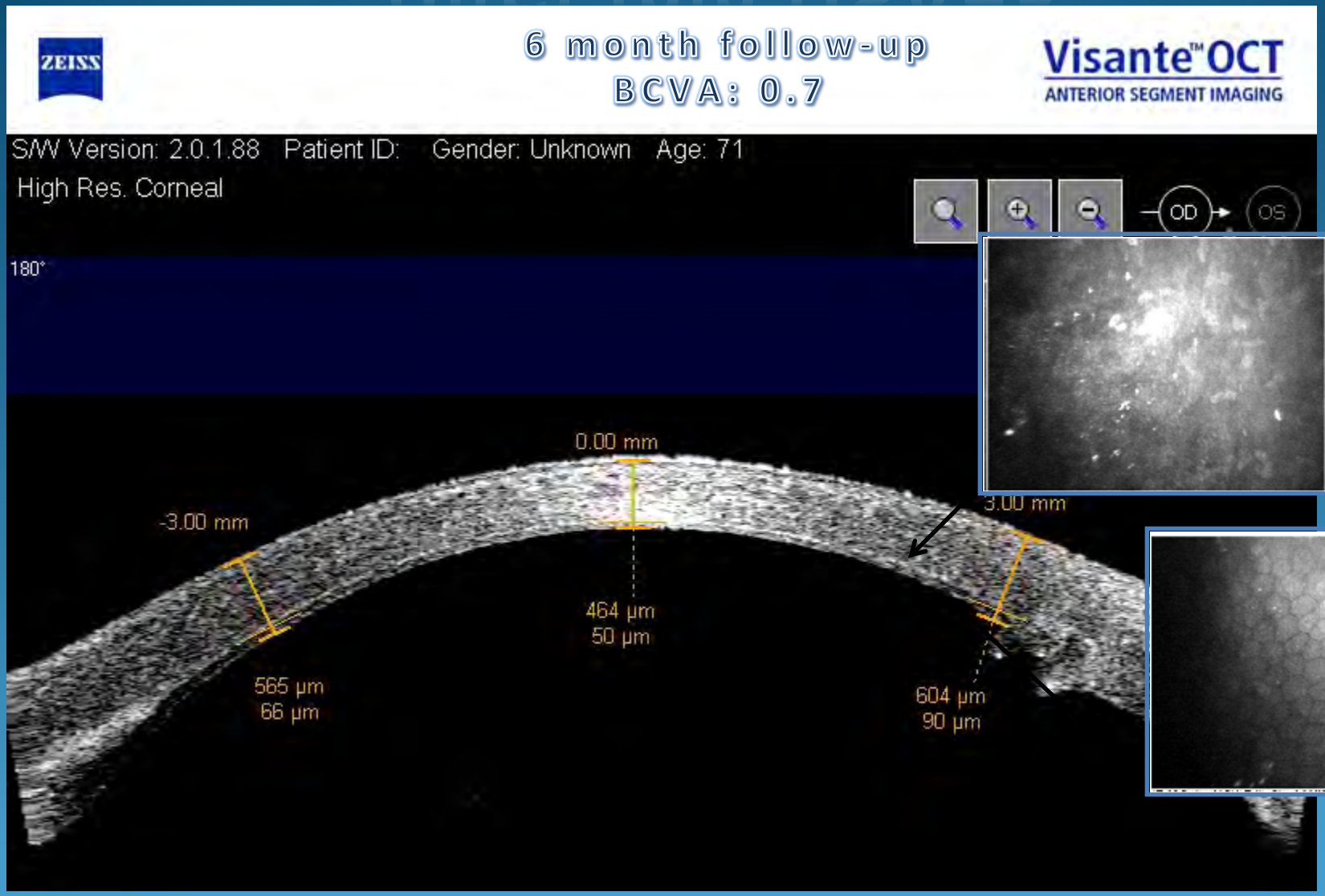



ZEISS
Visante™ OCT
ANTERIOR SEGMENT IMAGING
S/W Version: 2.0.1.88 Patient ID: Gender: Male Age: 0
High Res. Corneal
OD
OS
180°
0°
0.64 mm
0.63 mm
0.64 mm
PRE CUT


ZEISS
Visante™ OCT
ANTERIOR SEGMENT IMAGING
S/W Version: 2.0.1.88 Patient ID: Gender: Male Age: 0
High Res. Corneal
OD
OS
180°
0°
0.14 mm
0.14 mm
POST CUT


ZEISS
Visante™ OCT
ANTERIOR SEGMENT IMAGING
S/W Version: 2.0.1.88 Patient ID: Gender: Male Age: 70
High Res. Corneal
OD
OS
180°
0°
0.55 mm
0.11 mm
0.65 mm
1 WEEK

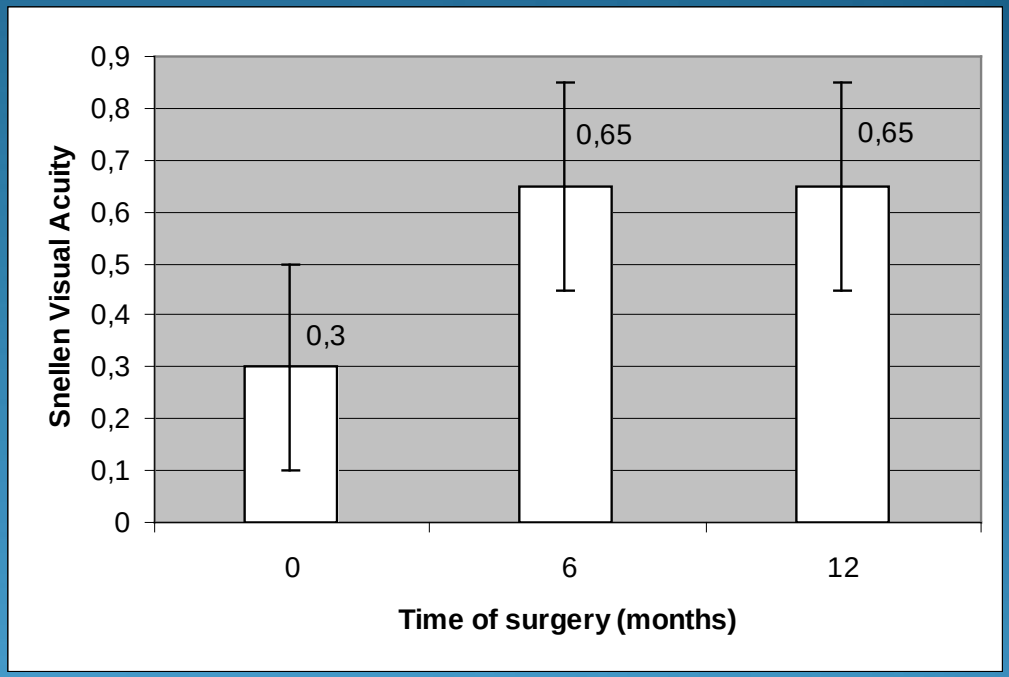
Ultra-thin DSAEK



Results

BCVA (Snellen)

All the patients (31) improved the visual acuity at the end of the follow-up



Pre-op BCVA

Mean BCVA 0,25 ± 0,2

Post- op BCVA

6 months fw 0,65 ± 0,2 (31 cases)

12 months fw 0,65 ± 0,23 (31 cases)

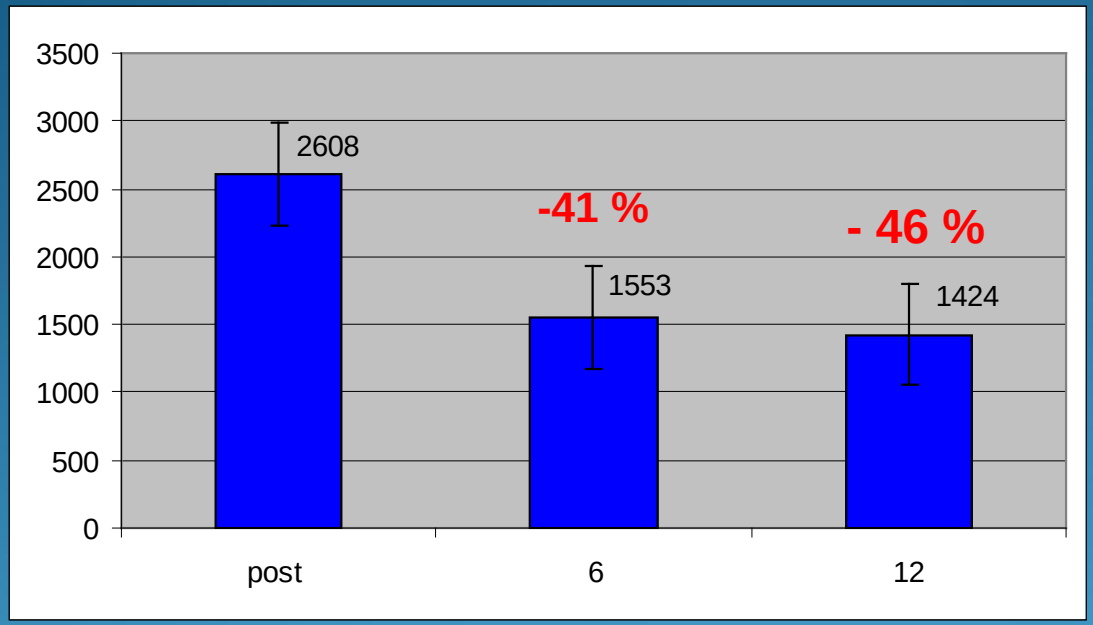
12 months fw excluding comorbidity 0,67 ± 0,22 (25 cases)

At 6 months after surgery, BCVA was improved in all eyes (100%).
At 12 months a further improvement has been recorded excluding comorbidity.
In 7/31 (22,6%) patients 1,0 BCVA was reached at 12 months.

Results

ECD (Specular Microscopy)

The mean pre-operative ECD (post – cut) was 2608,7 cells/ mm2



ECD loss % 12 months

- 46%

At the end of follow-up, the average ECD was 1553,2±329.13 cells/mm2 and 1424,1±438.30 cells/mm2 at 6 and 12 months respectively

Literature Data: ECD loss ranged from 25% to 62% at 6 months after surgery

Terry MA, Shamie N, Chen ES, Phillips PM, Hoar KL, Friend DJ. Pre-cut tissue for Descemet's stripping endothelial keratoplasty: vision,astigmatism, and endothelial survival. Ophthalmology 2009; 116: 248-256.

Ichihashi Y, Tomita M, Shimazaki J; The short-term results of Descemet's Stripping and Automated Endothelial Keratoplasty; Nippon Ganka Gakkai Zasshi. 2009 Jul; 113(7):721-6

Conclusions

An ultra- thin pre-cut tissue for DSAEK (110-190 µm) at the time of surgery may offer better handling characteristics and lead to minimal manipulation of tissue during surgery.

ECD loss in Ultra - Thin DSAEK is comparable with literature's data.
BCVA at 12 months improved in all the patients
22% of the patients reached 1 ,0 BCVA at 12 months follow-up

Larger and longer-term studies are required to evaluate how the graft thickness may influence the outcome of DSAEK surgery.

Ultra- thin pre- cut tissues can be inserted by a new generation of donor delivery sistems (Busin glide or Macaluso glide) suitable with a corneal incision of 3,2 mm or less ECD loss -23%

Thinner is better

Acknowledgments

A. Pocobelli

C. Amici

R. Donati

S. Lorenzetti

Domenico Amato

Jana D'Amato Tothova

THANK YOU

Conclusions

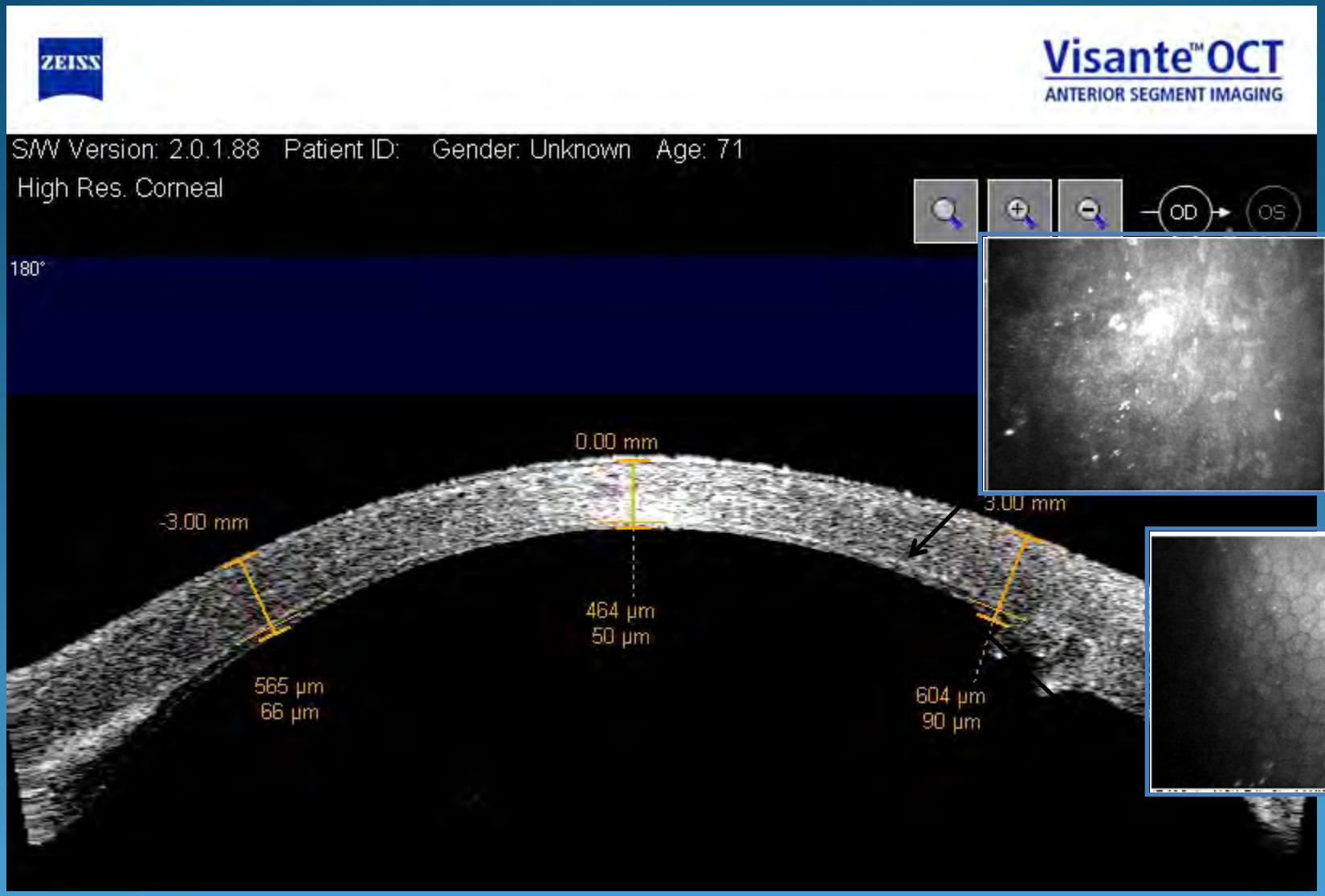
- A de-swelling of the tissue before the cut allows consistent preparation of ultra-thin PLD for DSAEK with a standardized procedure
- Ultra-thin tissues can be utilized with both the Macaluso THIN-DSAEK Inserter and the Tan Endoglide without damaging the endothelium
- The Macaluso THIN-DSAEK Inserter combined with ultra-thin PLD gives the surgical advantage of a smaller incision (3.2-3.5mm)
- More corneas have to be treated to confirm the statistical significance of the present observations

Thinner is better

Purpose

To monitor endothelial cell density (ECD) at different steps of a simulated DSAEK surgery, after use of THIN-C de-swelling medium and two different insertion glides.

6 month follow-up
BCVA: 0.7



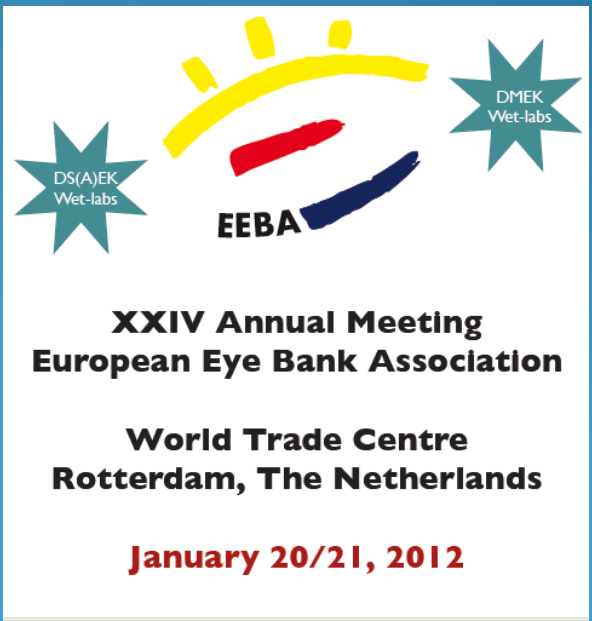
Monitoring of endothelial cell density during simulation of DSAEK phases in vitro using THIN-C de-swelling medium and two different glides for endothelium insertion .

A. Pocobelli (1), C. Amici (1), R. Donati (1), R. Leaci (2), D. Amato (3), J. D'Amato Tothova (3)

(1) Eye Bank of Rome, S. Giovanni Addolorata Hospital, Rome
(2) Dept. of Ophthalmology, University of Parma, Parma
(3) R&D Alchimia.Srl, Ponte San Nicolò, Italy

Dept. of Ophthalmology, University of Parma

ALCHIMIA



FINANCIAL DISCLOSURE

Dr. A. Pocobelli, Dr. C. Amici, Dr. R. Donati and Dr. R. Leaci have no financial interest in any product involved the present study.

Dr. D. Amato and Dr.J. D'Amato Tothova are employed by AlchimiaSrl, company that manufactures corneal media discussed in the present study

Complications

At 12 months a further improvement of BCVA has been recorded in 25 of 31 patients

- **2 patients developed a cataract and they are waiting for a cataract surgery**
- **1 patient had a pre-existing maculopathy that worsened**
- **1 patient had an open – angle glaucoma in progression**
- **1 patient had a corneal decompensation**