EyeYon MEDICAL

EndoArt®

New Approach for Corneal Healing

TRN-E008 Rev.5.0 (December 2024)

EndoArt® Safe & Effective

>5 YEARS OF FOLLOW-UP

>350 IMPLANTATIONS

VISION

60%

Improved in 3 lines or more at 12 mo. FU

EYE PAIN

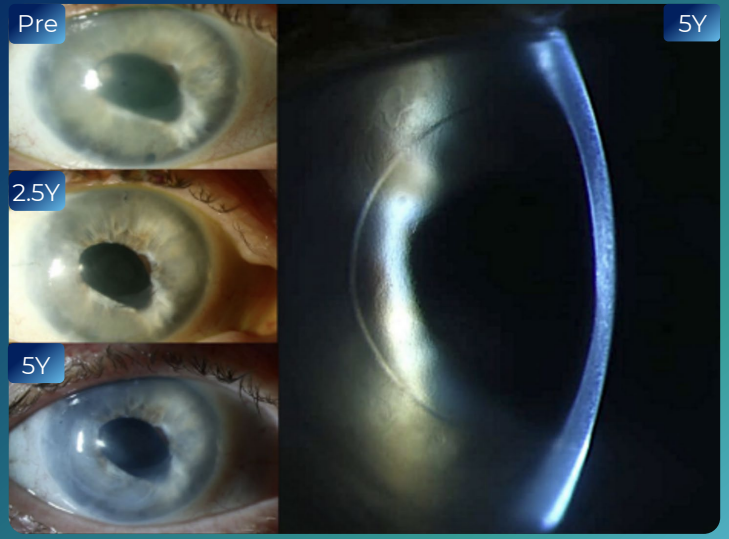
90%

Improved by more than 20 points at 12 mo. FU

Early Outcomes of an Artificial Endothelial Replacement Membrane Implantation After Failed Repeat Endothelial Keratoplasty

Luigi Fontana [1,2], Natalie di Geronimo [1,2], Michela Cennamo [3], Rita Mencucci [3], Piera Versura [1,2],

5Y follow-up



Baseline
6 / 150 787µm

6M
6 / 9 . 5 548µm

EndoArt®

Artificial Endothelial Layer

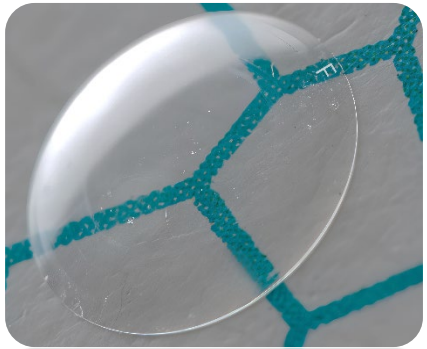
Diameter
6.5 mm

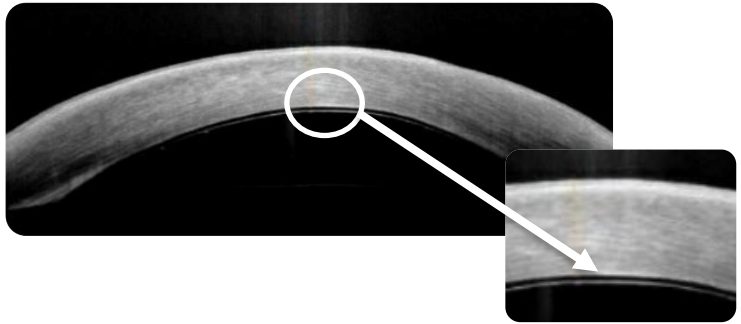
Shape
Dome

Thickness
50 µm

Curvature fits all
6.8 mm –
49 Dioptre –curvature
*Not a refractive power

Optically clear – No refractive power
Biocompatible
Hydrophilic acrylic polymer (as acrylic IOL)
Robust- can be handled





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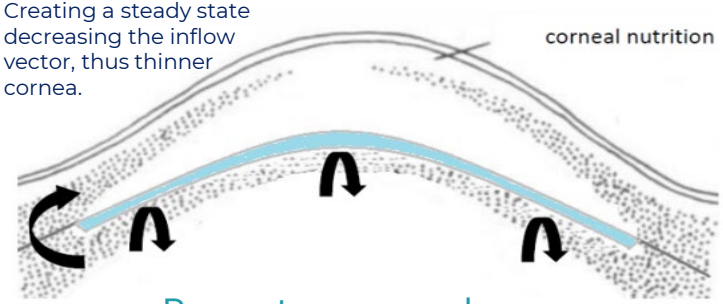
Mechanism of Action

Impermeable barrier to fluid

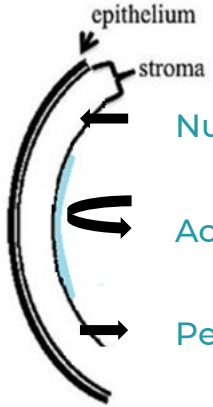
Decrease passive movement of aqueous humor into corneal stroma

Restores fluid homeostatic balance in stroma

Creating a steady state decreasing the inflow vector, thus thinner cornea.



Prevents aqueous humor from entering the cornea

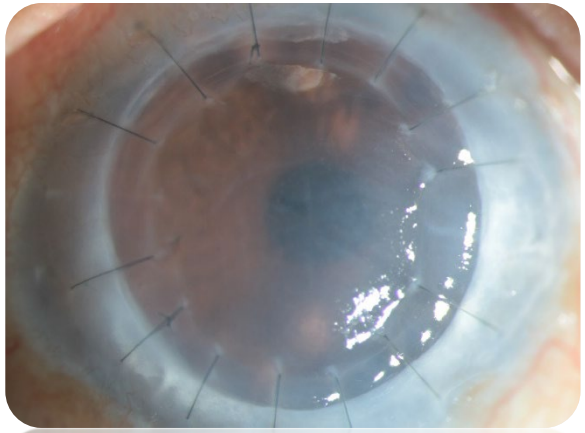


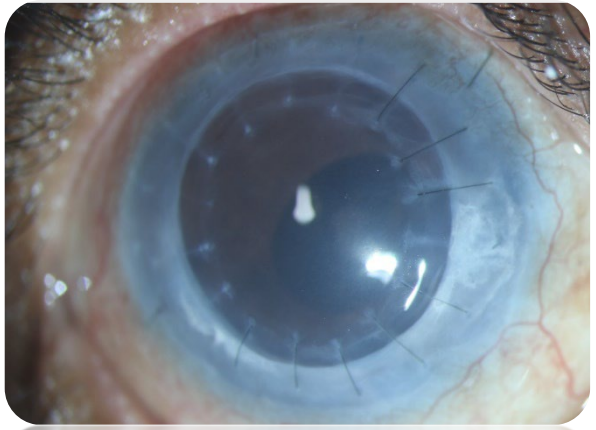
Nutrients enter from periphery

Achieve hydration balance

Peripheral dehydration

EndoArt® Clinical Applications





Indications:

- Failed keratoplasties
- Glaucoma drainage devices
- Where tissue is not available

Contraindication:

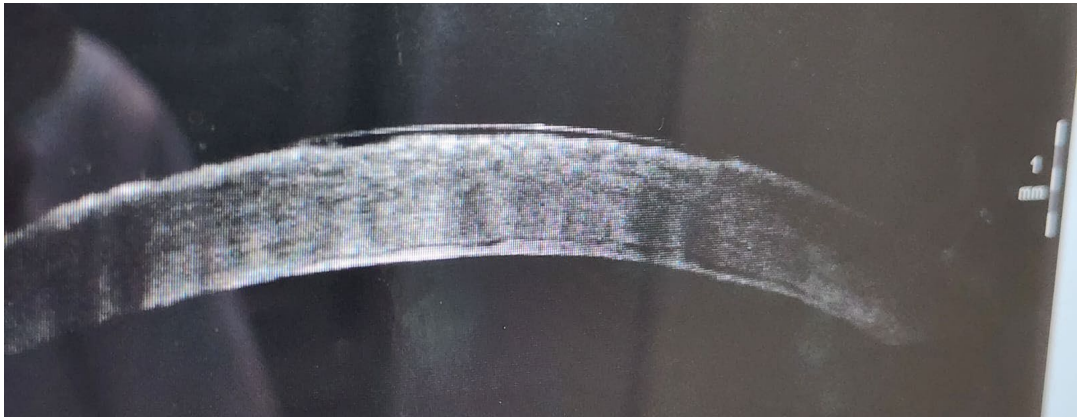
- Post refractive surgery
- Naturally-thin cornea
- Post anterior keratoplasty

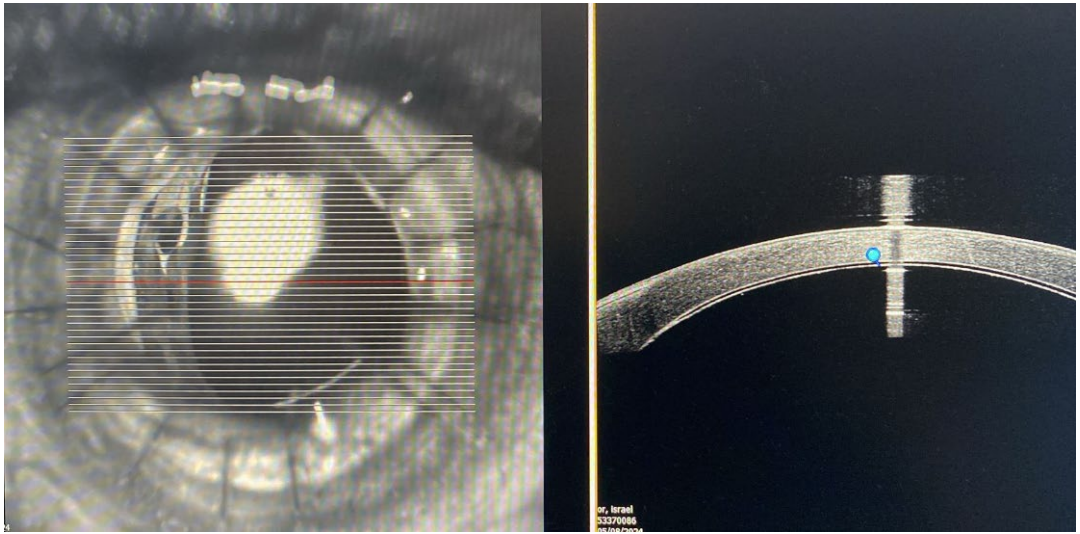
Before surgery key point

- Contra indication
- Patient cooperation post op
- Advance glaucoma cupping re-bubbling
- Oct posterior surface
- Plan Descemetorhexis
- Size of PKP
- Epithelial condition fibrosis
- Instruct the patient
- Set up expectation

Before surgery OCT Assessment of The Cornea

- Naïve patient -remove Descemet's
- Remove old DSAEK
- DMEK & PKP consider not to remove





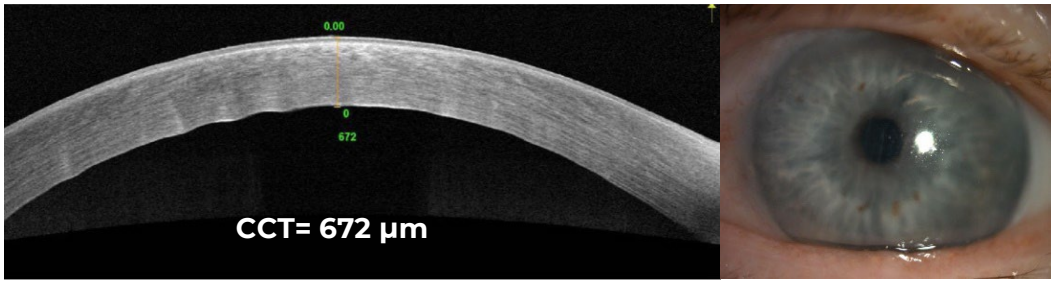
Patient 04-001 Phase II study, France – 2.5 Years FU

Dr. Eric E. Gabison, Deputy Director of the Ophthalmology Department
at Rothschild Ophthalmic Foundation and Bichat Hospital in Paris

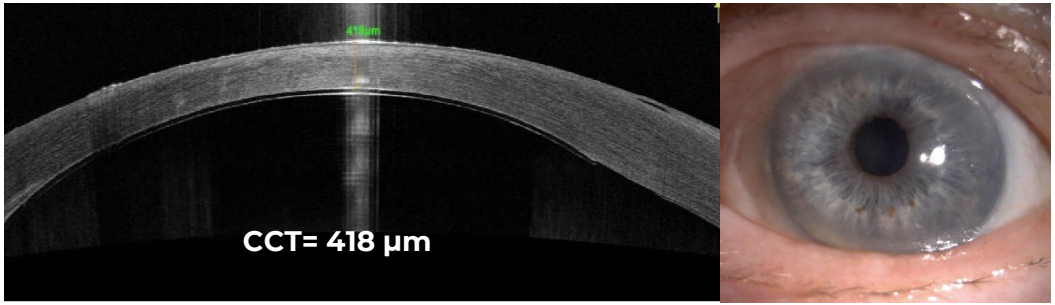
Female, 85y

- Cataract extraction
- Glaucoma filtering
- 2 Failed DMEK
- Low IOP at BSL (5mmHg)

Baseline: BCVA=6/24 | CCT=672 µm

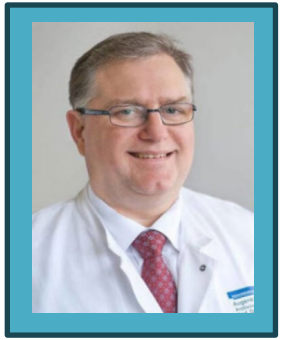


12M: BCVA=6/12 | CCT=418 µm | Re-bubbling: 2



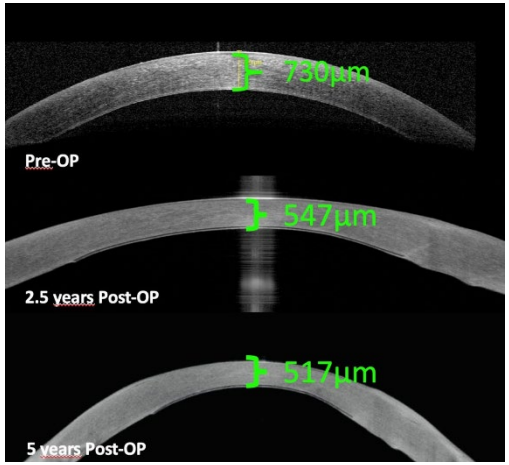
Compassionate Patient: 5.5 years follow-up, Germany

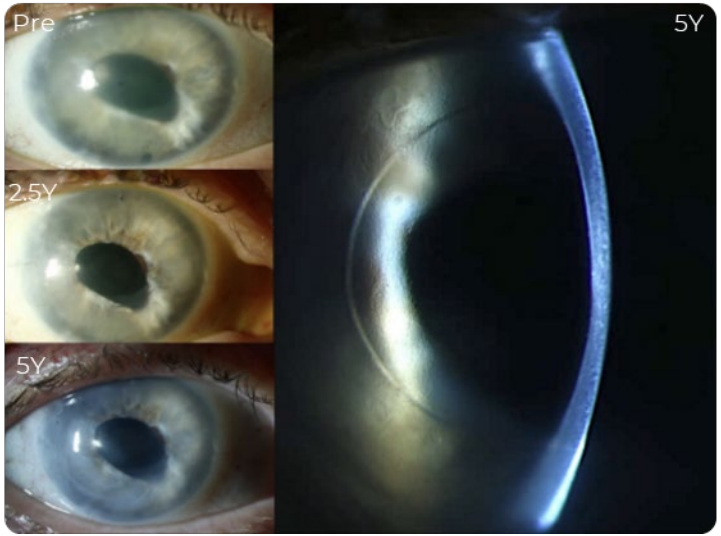
Prof. Dr. Med. Gerd U. Auffarth, Department of Ophthalmology, Ruprecht-Karls University of Heidelberg



Female 58y

- Post Endophthalmitis (Post PPV)
- Optic atrophy
- 3 failed DMEK
- NO visual potential



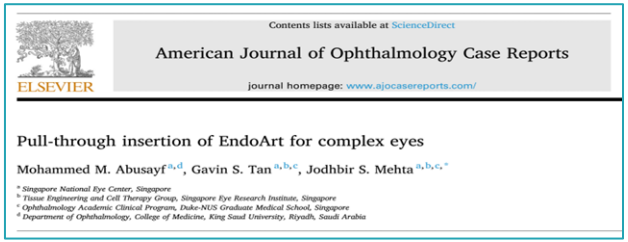


EndoArt® Implantation in “High-Risk” Patients – 2.5 Years FU

Prof Jodhbir Mehta, Professor Singapore National Eye Centre, Senior Consultant Cornea External Disease and Senior Consultant in Refractive Surgery, Singapore

Female, 48y

- Edema on-set: 10/2021
- Cataract extraction in 2017
- Trabeculectomy in 2021
- Previous blebitis (resolved)



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ELSEVIER

Pull-through insertion of EndoArt for complex eyes

Mohammed M. Abusayf [a,d], Gavin S. Tan [a,b,c], Jodhbir S. Mehta [a,b,c,*]

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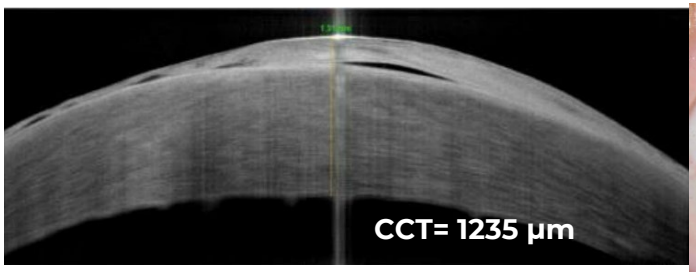
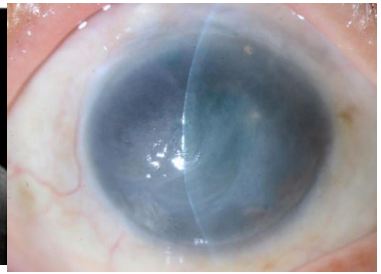
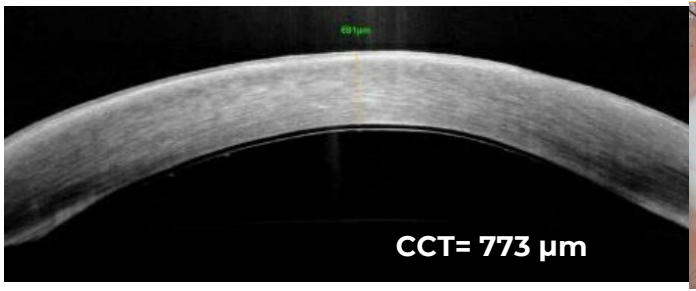
[b] Tissue Engineering and Cell Therapy Group, Singapore Eye Research Institute, Singapore
[c] Ophthalmology Academic Clinical Program, Duke-NUS Graduate Medical School, Singapore
[d] Department of Ophthalmology, College of Medicine, King Saud University, Riyadh, Saudi Arabia

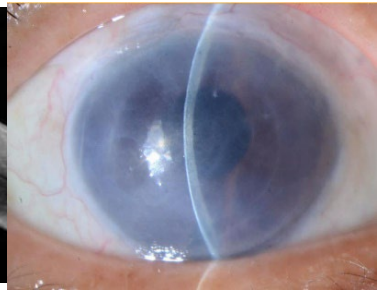
Baseline: BCVA=CF | CCT=1235 µm





12M: BCVA=6/150 | CCT=773 µm





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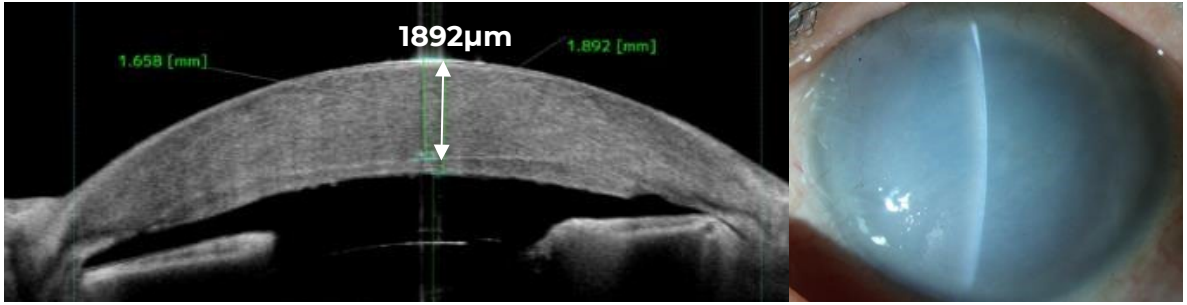
Compassionate Patient in China – 3 years FU

Professor Hong, Director of Ophthalmology, Peking University Third Hospital

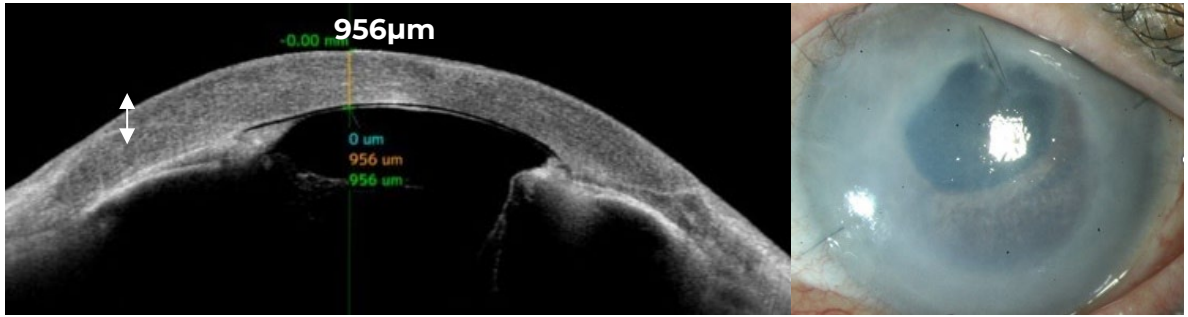
Female, 63y

- Post cataract (2020)
- Corneal edema
- Glaucoma
- Post DSAEK (2020)
- 2 filtering surgeries
- Cyclophotocoagulation

Baseline: VA = LP | CCT = 1892µm



16M: VA = HM | CCT = 956µm | 3 Re-bubbling



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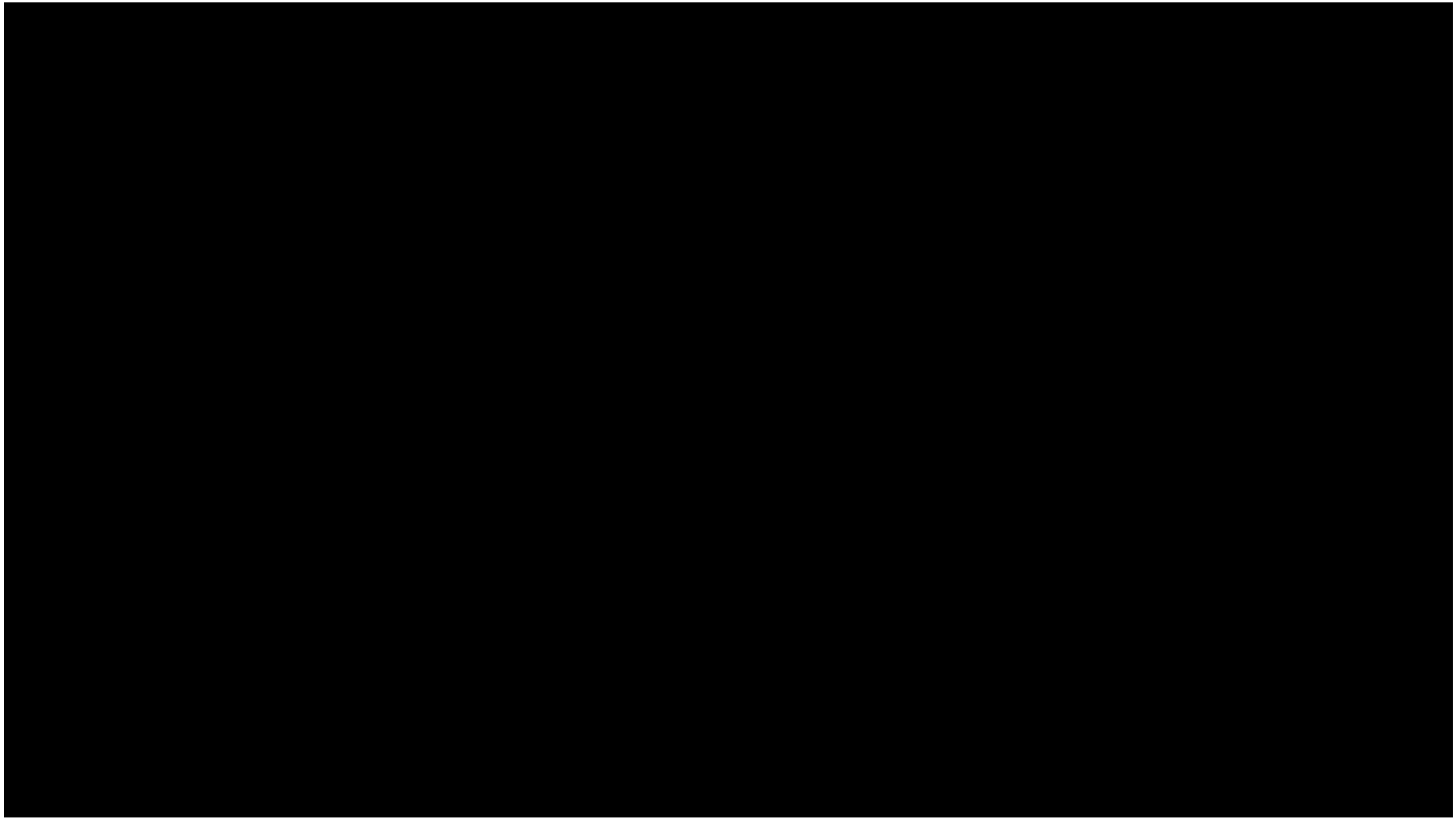
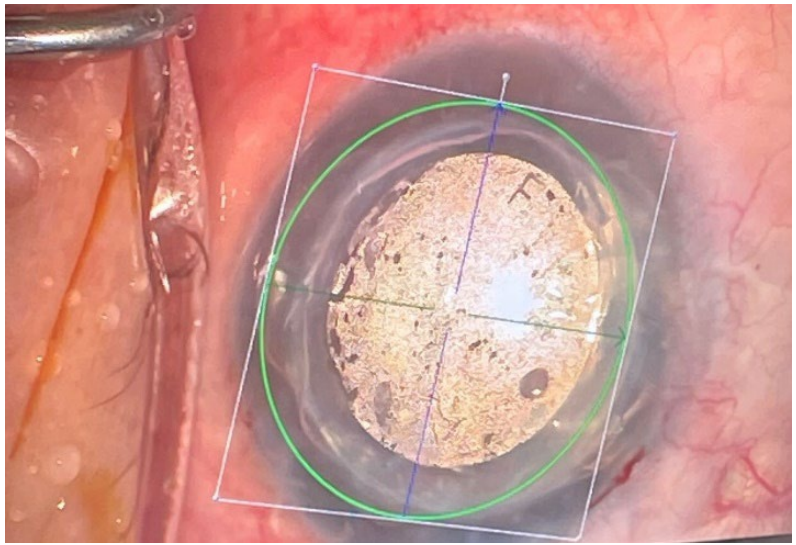
During surgery

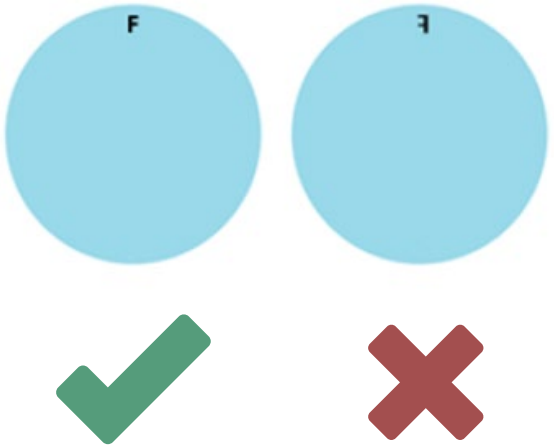
- Plan entrance
- Access need for PI
- Chamber stability
  - Vitrectomy
  - GDD
- Use v blue air for Descemetorhexis
- Gas: 10% C3F8 / 20% SF6
- Air bubble size to avoid post op manipulation
- End surgery on IOP around 20 mmhg



EndoArt® Correct Orientation

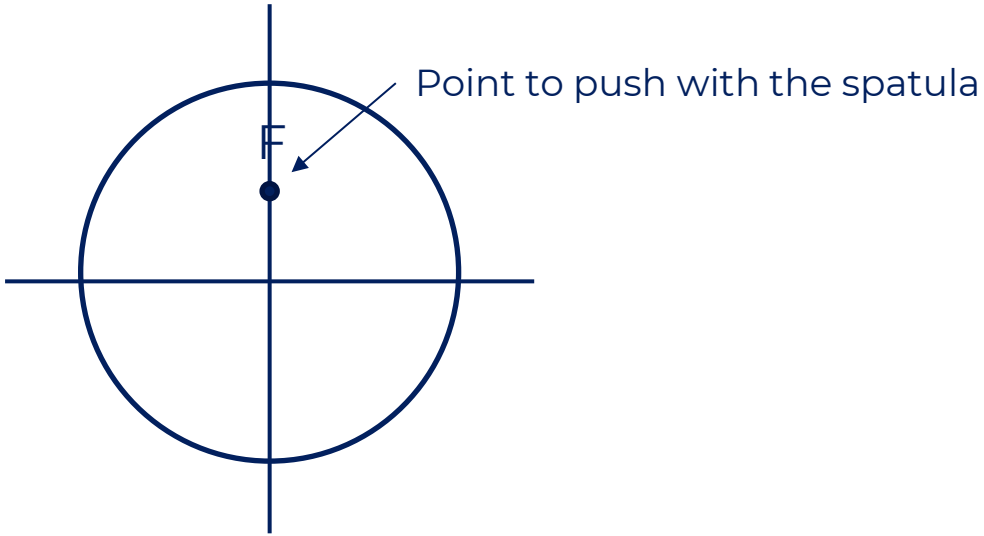
The peripheral surface of the EndoArt® is marked with an “F" letter, which should appear correctly prior to the final attachment with the gas bubble.





EndoArt® Insertion

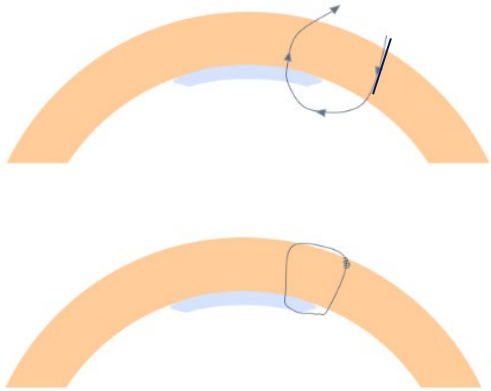
Insert the EndoArt® implant with a spatula preferably when the AC maintainer is running



Most important Procedure Steps

How to increase the chances of EndoArt® success

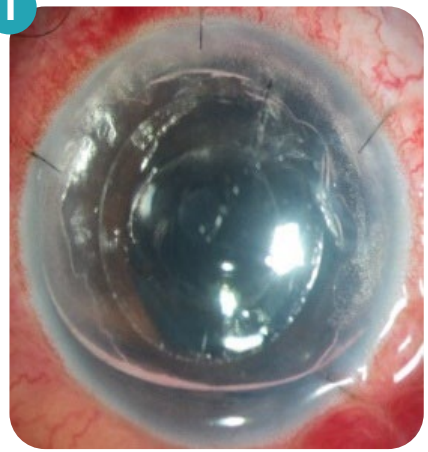
- Ensure there are no Descemet implant **overlaps/ different levels.**
- Both Descemetorhexis and positioning of the implant should be **centered** relative to the corneal apex
- **Consider Suture** all entrances 10-0 Nylon
- Not too tight
- **Supine position** facing up for:
  - 20 minutes in the OR (speculum open)
  - 4 hours after the operation



EndoArt ® Mechanism of Attachment

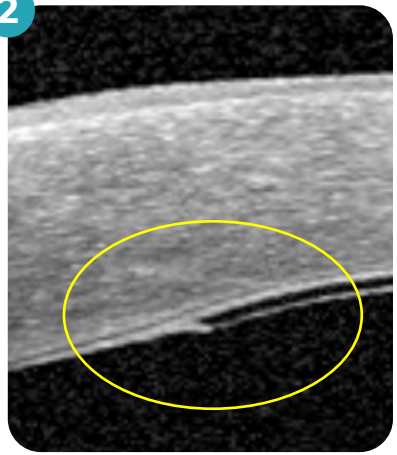
The two-phase adhesion of EndoArt® to the posterior surface of the cornea:

1



Gas bubble (SF6 20%; C3F8 10%) during the first 0-48 hours post-op

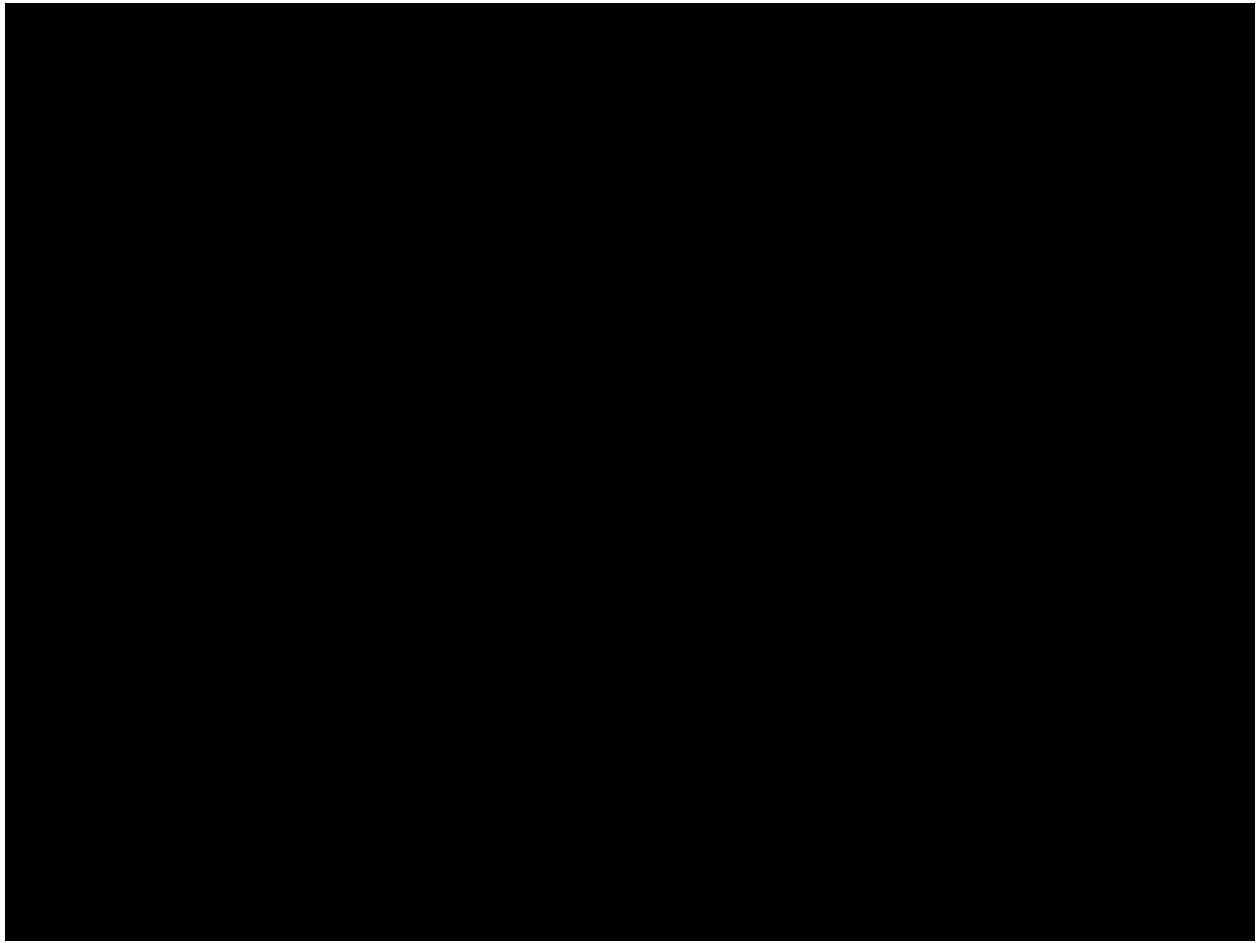
2



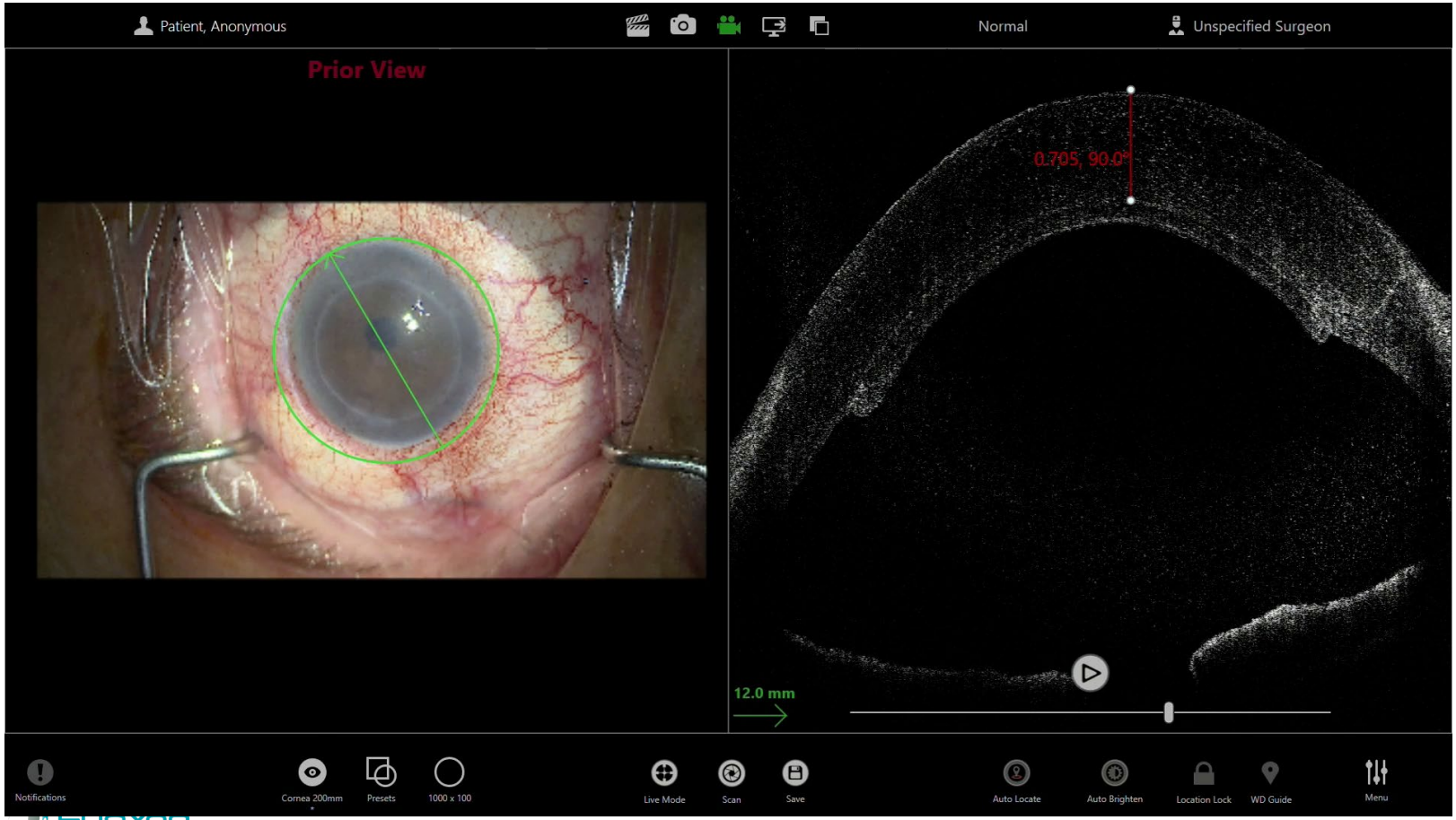
EndoArt's Biological Attachment during the first 3-7 days post-op.

OCT demonstrating Tissue Fixation to the implant edge.

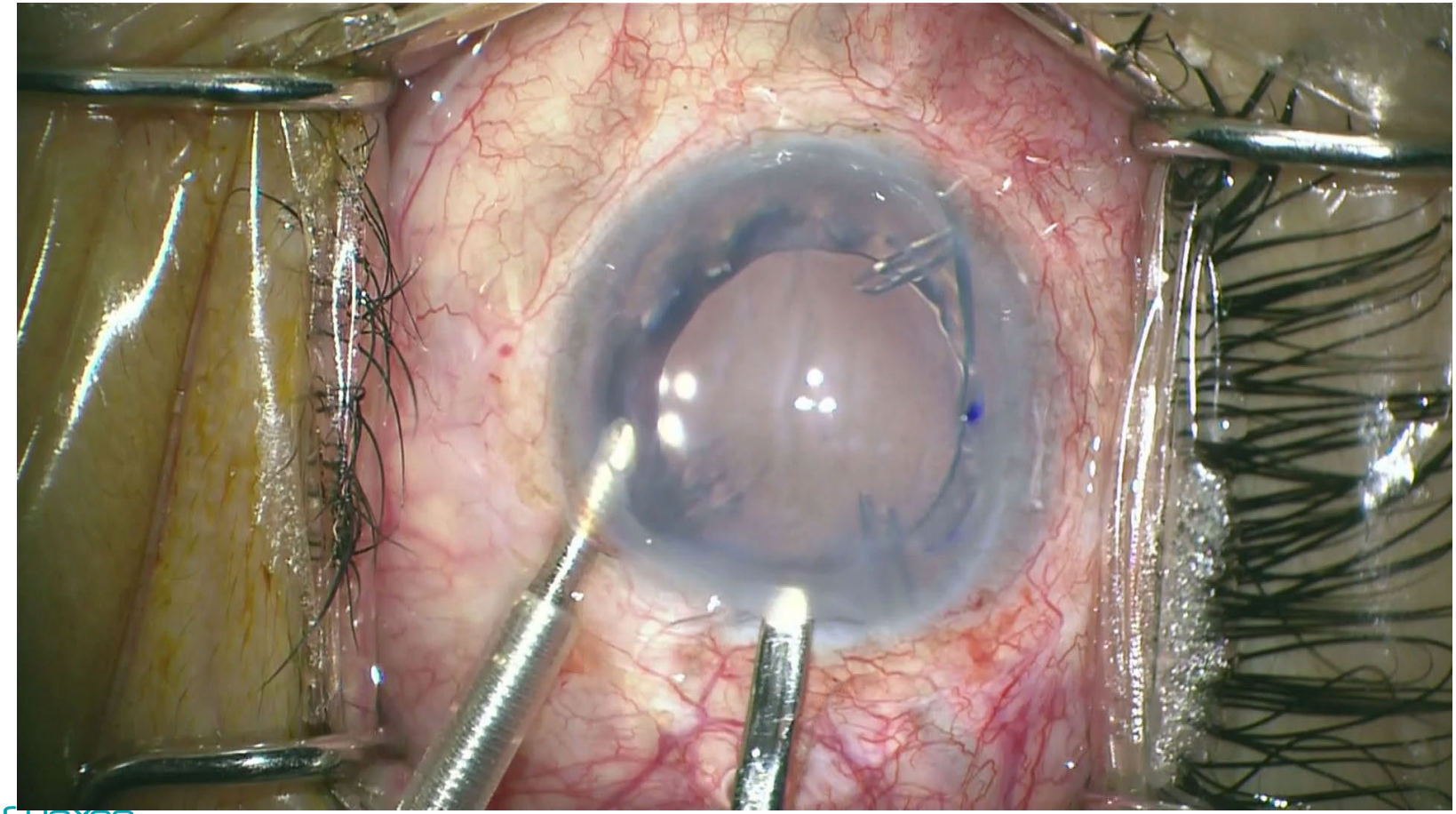
Descemetorhexis On air



Mercedes stiches – Prof. Fontana



Pull Through – Prof. Mahata

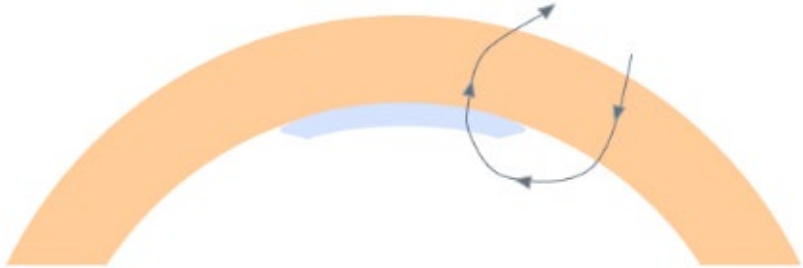


After surgery

- Drops regimen
- Dry eye multiple surgery tendency for infection
- Attachment
- Oct corneal thickness
- Contact lens
- Suture removal

Suture Removal

- The suture will be removed not sooner than 12 weeks from obvious attachment
- Recommended removing before 6 months post good attachment
- May be performed under a slit lamp after application of local anesthesia and povidone-iodine 5%
- Suturing removal direction is presented in the drawing



Instructions For Patient

Crucial for the success of the operation

- Guide the patient to avoid touching/rubbing the eye during the first three months after implantation
- Guide the patient to remain with a **transparent eye shield for 14 days** post-procedure/re-bubbling
- Guide the patient **not to fly** or increase geographical altitude post-air injection if a gas bubble exists in the operated eye. This may lead to increased IOP, pain, and pathological damage to the eye.
- Guide the patient to **lay on his back (face up)** as much as possible **in the first week**
- Guide the patient to **avoid any heavy lifting or sports activities** of any kind for at least 2 weeks after the surgery.
- Guide the patient **not to swim for 4 weeks (or for as long as the contact lens is used)** after surgery.
- Guide the patient to avoid activities that put him/her at **risk for infection** (like gardening, cleaning out stalls, attics, etc.) for the first month after surgery.

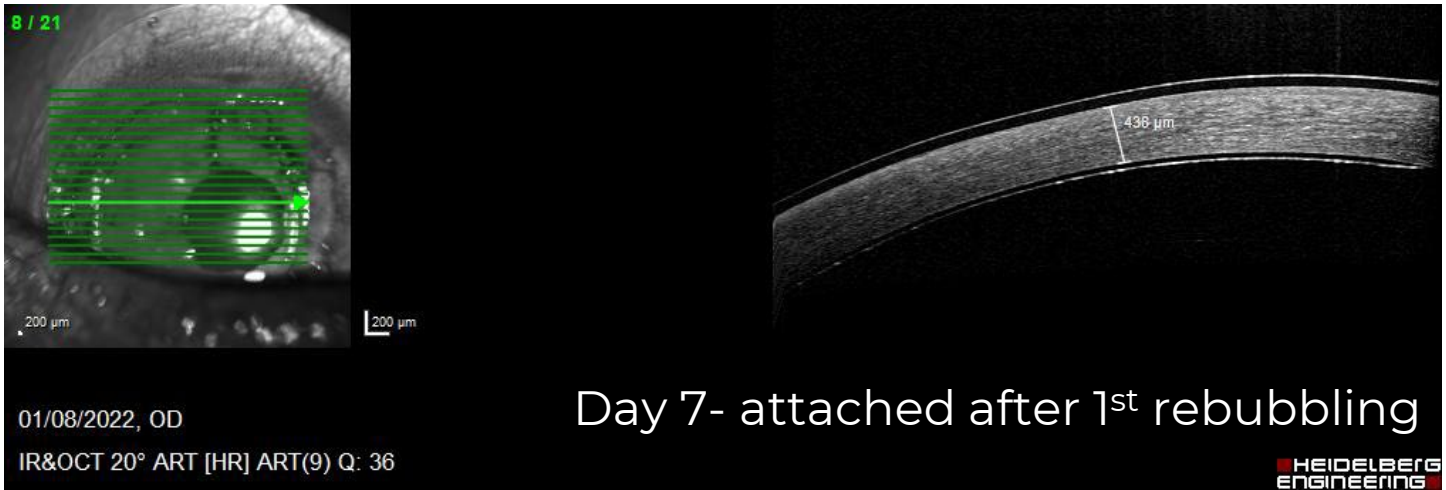
Post-operation Medication

Post-procedure Medication Type* (Eye drops)	**Duration**
Steroid	At least 6 months post-op *6-8 drops per day until the eye is calm then tapering over 6 months. With patients who are steroid respondents should be identified prior to surgery and given appropriate medication for increased IOP.*
Antibiotic	Minimum 4 weeks post implantation

- It is recommended to use a therapeutic soft contact lens between 3 to 6 months, or longer, if necessary, unless a medical condition indicates otherwise, especially whenever there are bullae or severe surface dryness.
- Ensure the consistent application of topical antibiotics as long as the contact lens remains in use.

“Attached” but Not Functioning

The EndoArt effect- Thinning of the stroma



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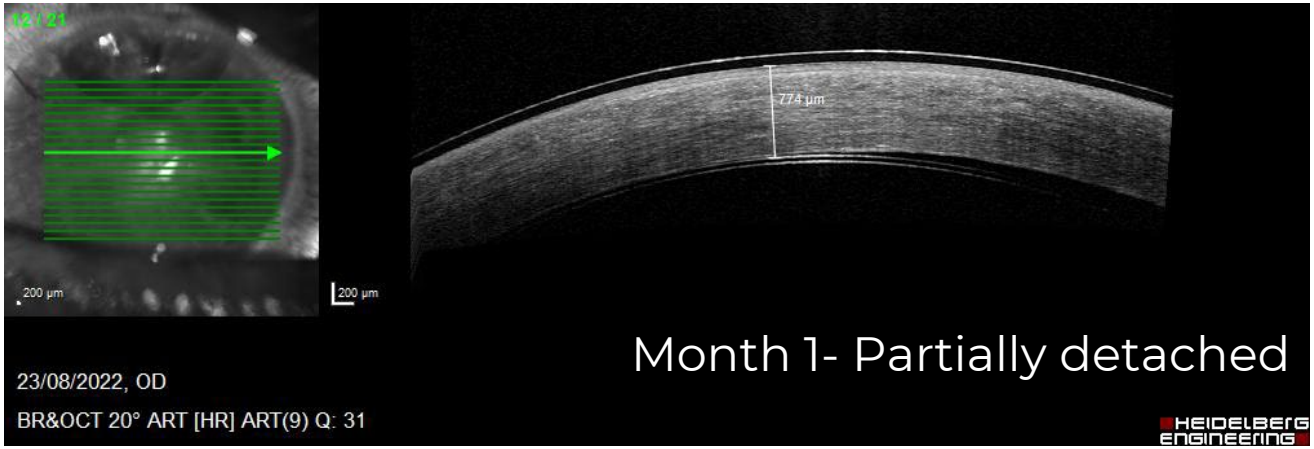
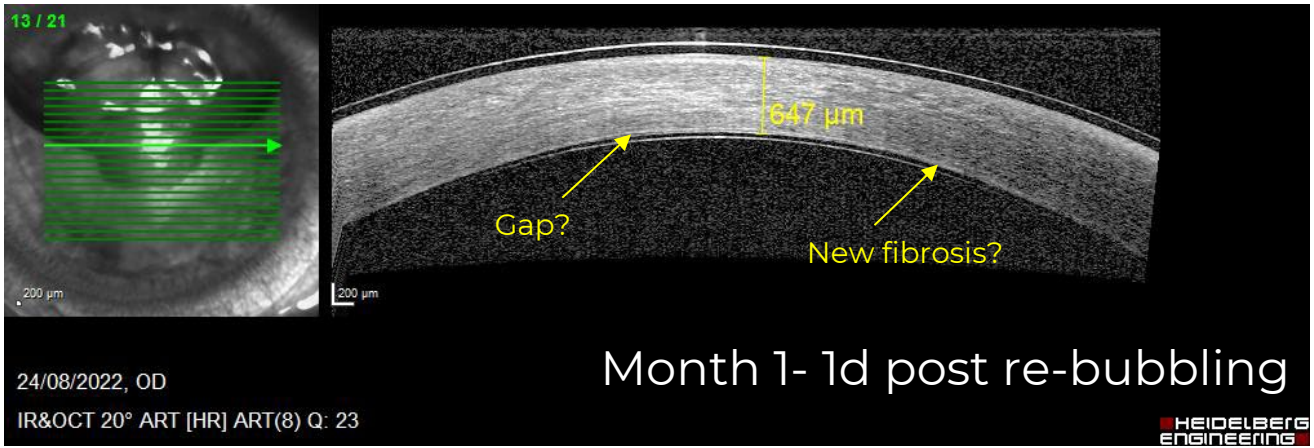
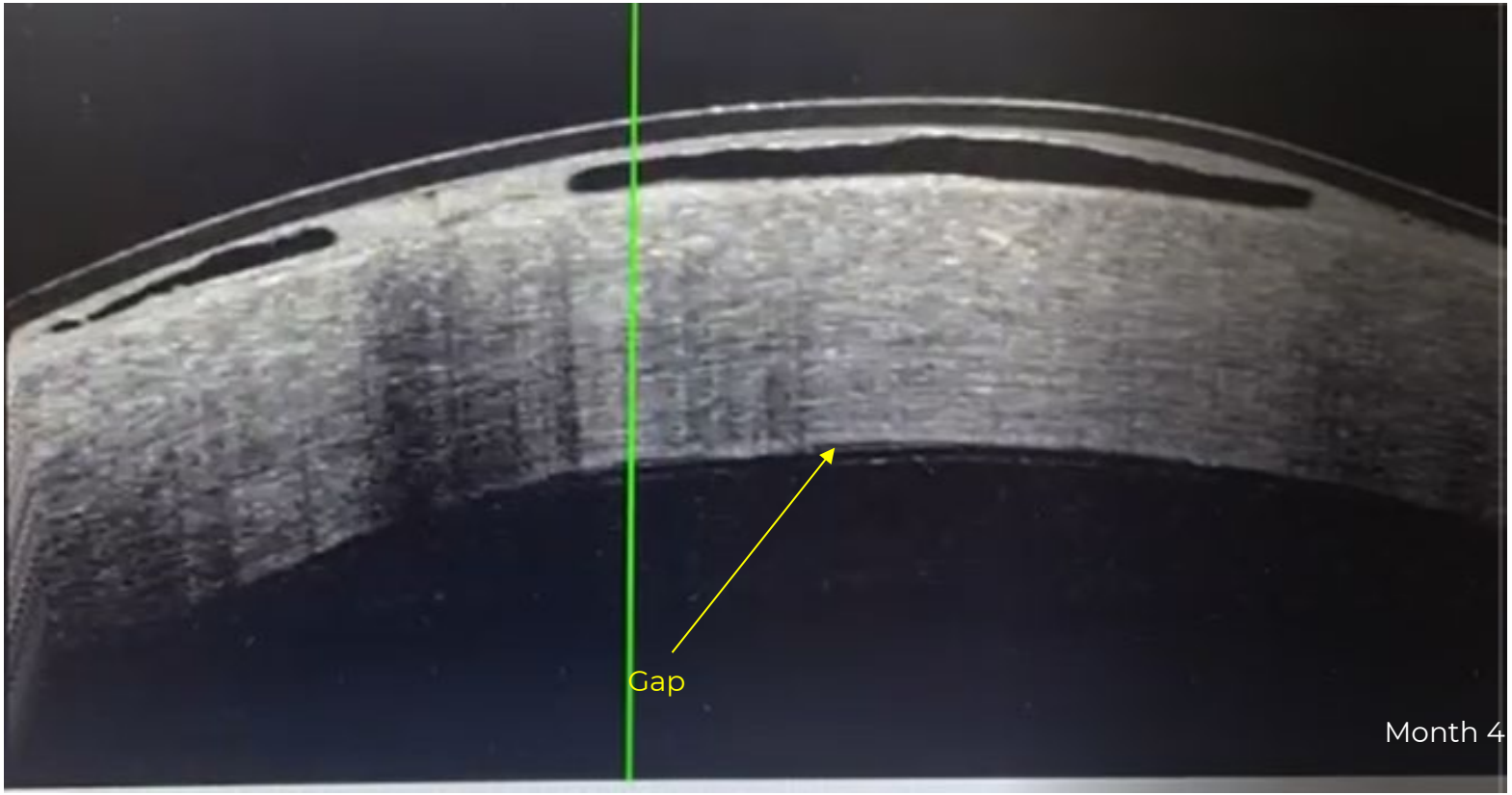
“Attached” but Not Functioning

Only minor decrease in CCT, suggesting unseen detachment





“Attached” but Not Functioning



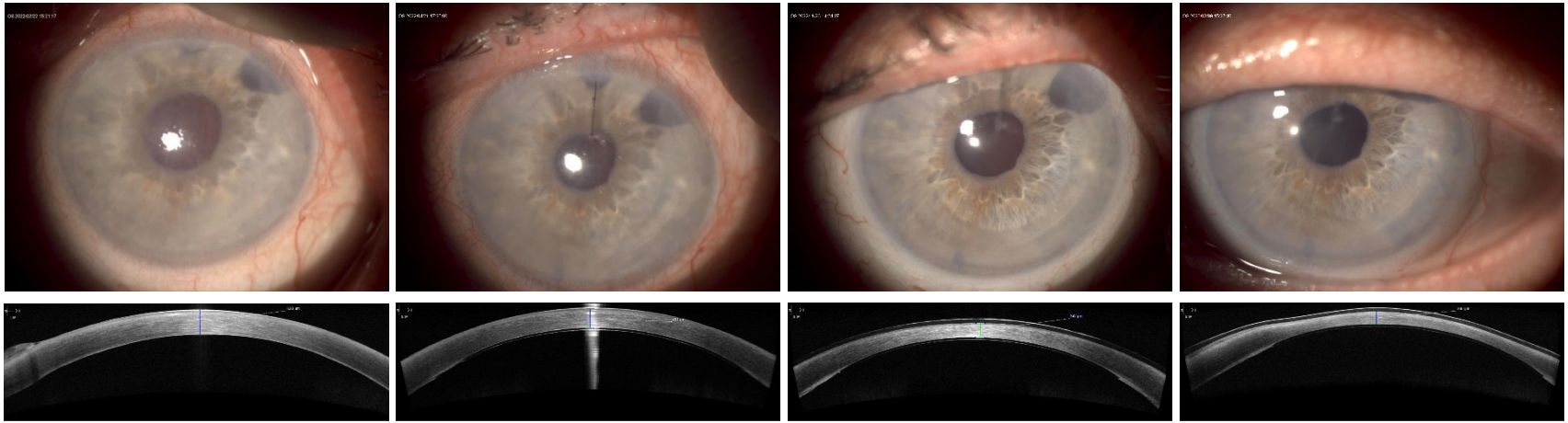
If there is no function → EndoArt is not fully attached

Thinning and Perforation

Georgia, Male, 72y

Post cataract, glaucoma filtering surgery

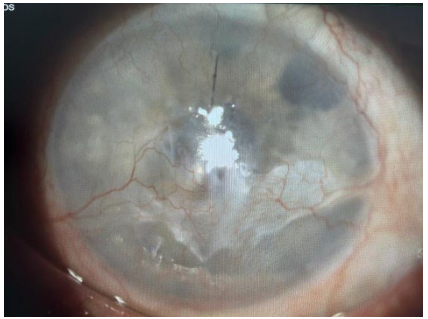
Edema onset: 2019



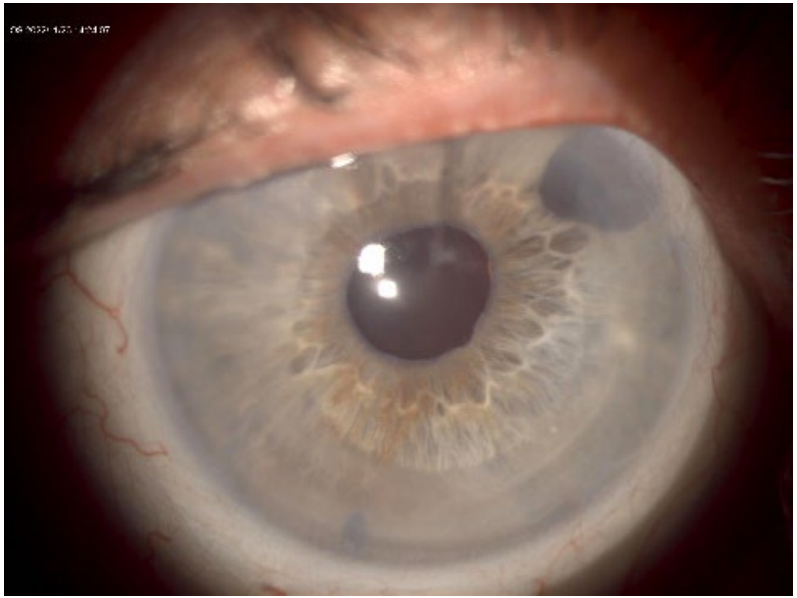
Pre-op	2M	8M	12M
CCT=630µm, VA=HM	CCT=451µm, VA=HM	CCT=385µm, VA=6/190	CCT=305µm, VA=6/190

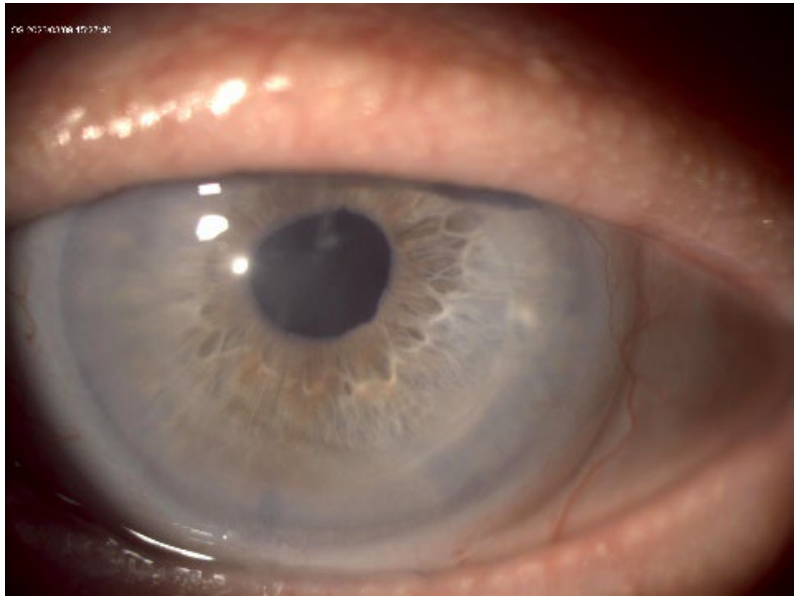
Perforation →

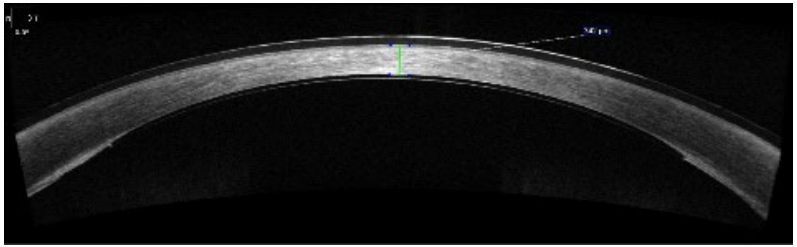
Flap patching →

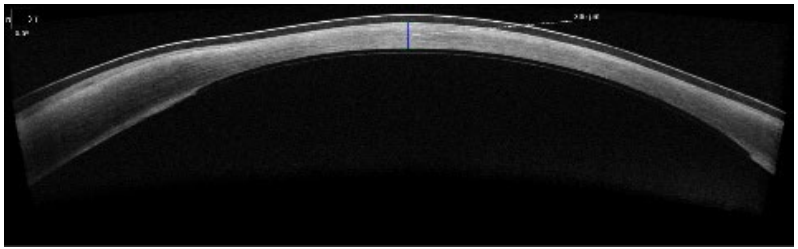


Thinning and Perforation





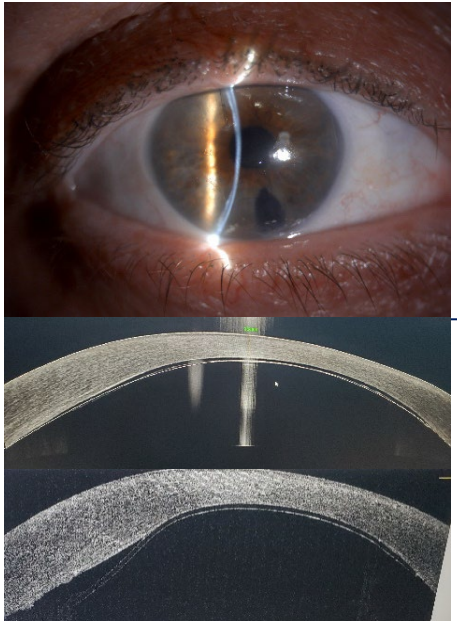




Thinning and Perforation Treatment

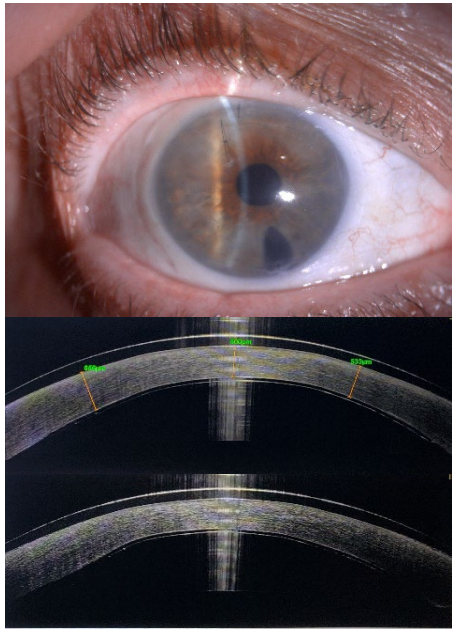
Georgia, Female, 55y

Post cataract, CME
Edema onset: 2020



3M
CCT=354µm

TCL, lubrication, hypotensive medication if required, patching of the eye



5M
CCT=500µm

Follow corneal thickness with OCT regularly until a stable thickness is established.

If corneal thickness does not stabilize and continues to decrease, a close follow-up should be performed.

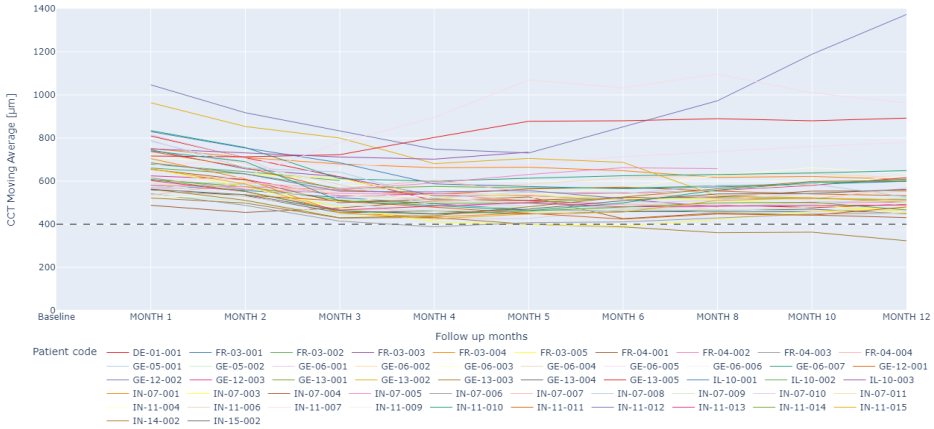
In case of corneal thinning below 300 microns, especially in combination with epithelial melting, consider removing the implant.

Close post-operative follow-up should be performed until stabilization for at least 6 months .

Thinning must be managed and is reversable

Corneal Thinning

Moving average (3 visits timeframe) of CCT over time, Phase II subjects



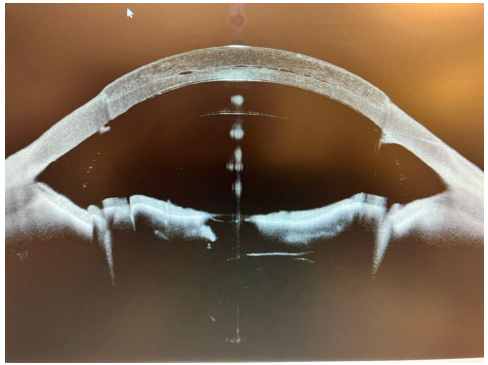
- EndoArt restores corneal transparency by reducing the influx of aqueous humor and decreasing corneal thickness.

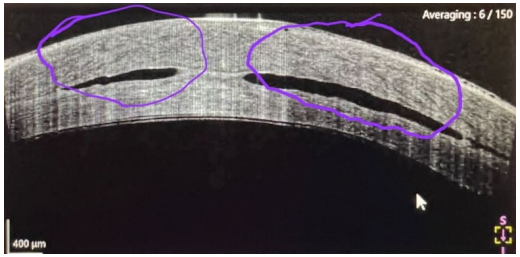
- Corneal thinning occurrence post EndoArt implantation below 400µm (n=52):
  - Overall rate during the study: 17.3%; at 12 month follow-up: 5.8%.
  - Despite instances of CCT reduction below 400µm, their overall trend generally remains **stable**.

CCT Thinning Treatment Table

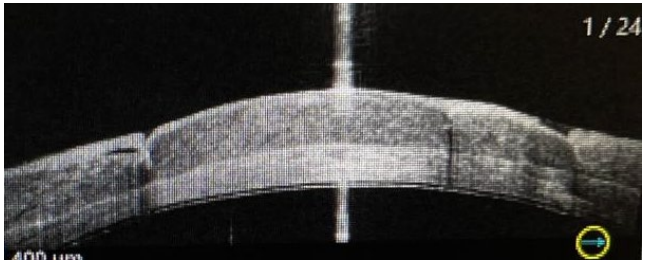
CCT	Treatment
≤ 450µm	• Follow every month until stabilization
	• Lubricants 4 times/day
≤ 400µm	• Follow every 2 weeks until stabilization
	• Lubricants 4 times/day
	• Use of contact lens with antibiotics
≤ 350 µm	• Follow every week until stabilization
	• Lubricants 4 times/day
	• Use of contact lens with antibiotics
	• If stabilization is reached below 350µm, continue to follow the patient every month
≤ 350 µm & corneal shape deformities	• Follow every 2 days until stabilization
	• Use contact lens with antibiotics and lubrication
	• Patch the eye
	• In case steroids are not used, treat with topical steroids 3 times/day
	• Treat IOP if above 16mmHg
	• If stabilization is reached below 350µm, continue to follow the patient every month.
300 ± 10 and below	• Follow every day until stabilization
	• Use contact lens with antibiotics and lubrication
	• Patch the eye
	• In case steroids are not used, treat with topical steroids 3 times/day
	• Treat IOP if above 16mmHg

EndoArt implantation in a patient with Epikeratophakia *Contraindication*

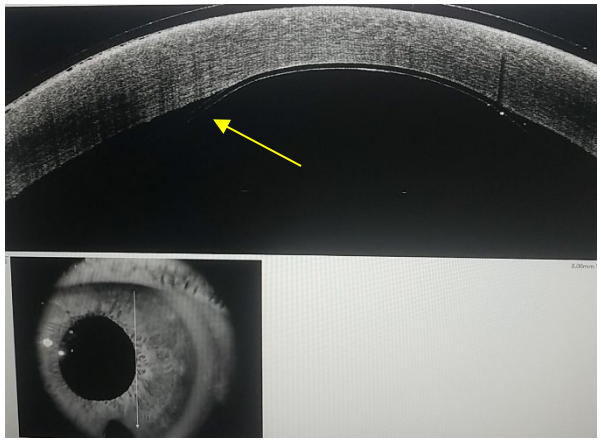


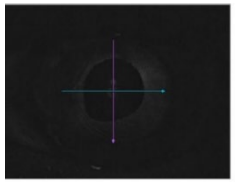


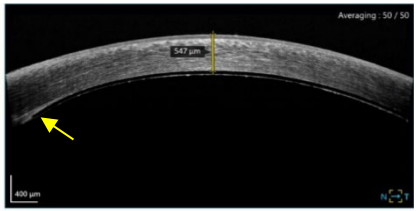
Suturing of the interfacial gap

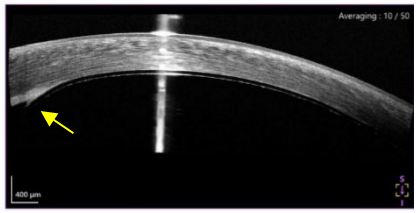


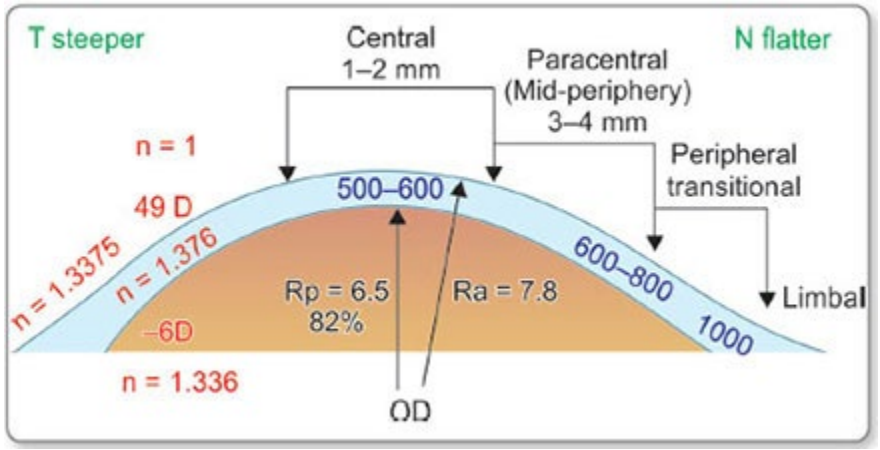
EndoArt Centration











EndoArt centration should be relative to cornea's apex.

Eccentric implant may result in partial detachment and/or asphericity

Thin with bullae

The problem :

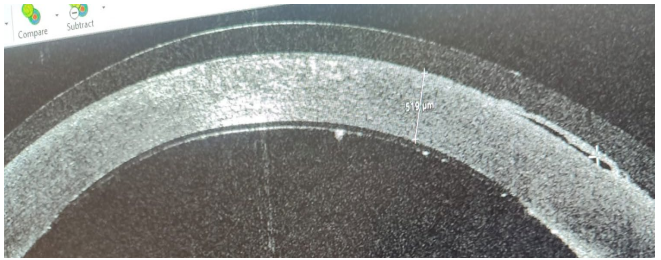
- Potential space b\w Bouman and epithelium

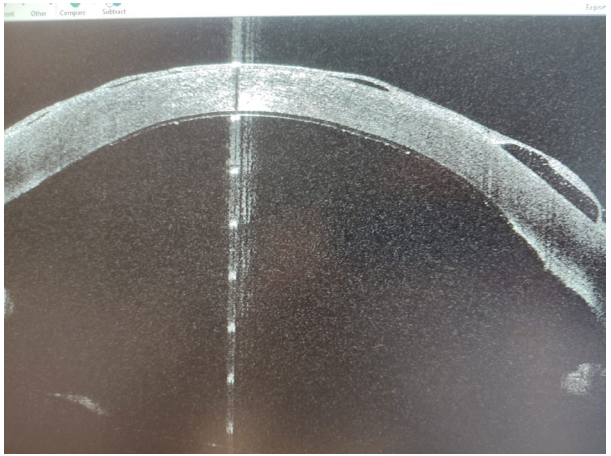
Reason:

- Recurrent corneal erosion like dystrophy situation
- No adhesion
- Bad healing

Solution:

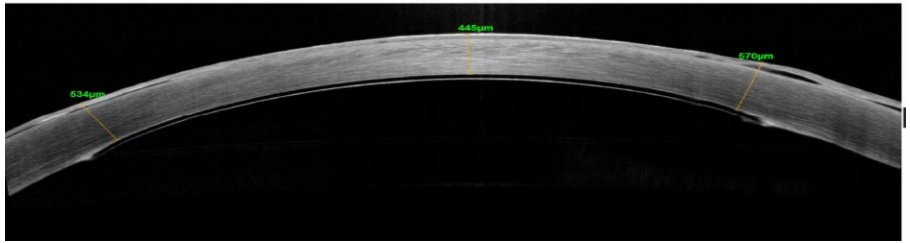
- IOP lowering
- Removal of epithelium
- Contact lens
- Needell Puncturing
- PTK





List of Complication

- Re-bubble (Surgical techniques and learning curve)
- 1 patient perforation
- IOP elevation (as in EK)
- CME
- Infections keratitis (resolved with antibiotics)
- Stromal suspected herpes keratitis 1 patient resolved with treatment
- Persistent peripheral bullae
- Surface- dry eye long contact lens use
- Hyperopic shift

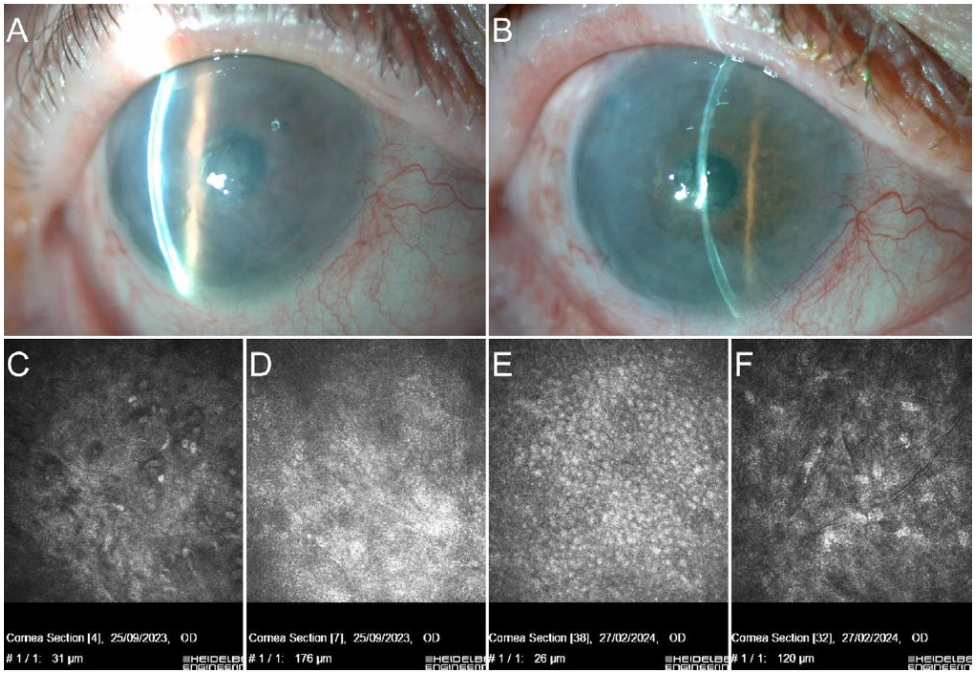


EyeYon MEDICAL

“Short-term clinical and confocal microscopy changes after synthetic endothelial replacement”

L. Fernández-Vega-Cueto, C. Lisa

“IVCM scanning showed a progressive reduction in corneal edema, allowing visualization of cellular structures. The epithelial layer has begun to become visible, with the restoration of its phenotype (Fig. 1E). The keratocytes are becoming recognizable within the corneal stroma (Fig. 1F), correlating with the clinical improvement observed.”

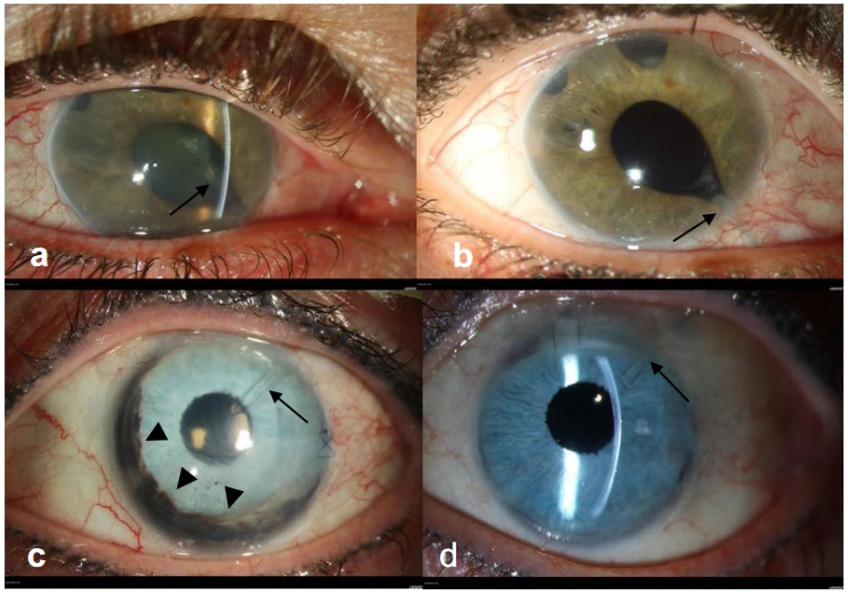


Clinical outcomes after EndoArt® Implantation in High-risk Glaucoma Patients
Wiedemann et al. Cornea accepted

38 glaucoma patients of 44 EndoArt surgeries due to endothelial decompensation

Results:

- CCT decreased in 94% of the patients
- Mean preoperative CCT: 795 µm ± 208
- Mean postoperative CCT 3-4 months after surgery: 494 µm ± 191 (p=0.023)



EndoArt:

- ✓ safe and effective
- ✓ It improves Corneal Thickness and Visual Acuity
- ✓ EndoArt® is a safe option for patients with repeated corneal rejection or who are at high risk
- ✓ EndoArt is not subjected to rejection
  - ✓ EndoArt success rate is the same in high and non-high-risk patient
- ✓ User friendly
- ✓ Expands treatment capabilities

"I' m living at home again by myself"

"This operation allowed me to drive my car"

"I can watch television, I can read a book, and I can even see everything in my phone without glass"

EyeYon MEDICAL

THANK YOU

www.eye-yon.com

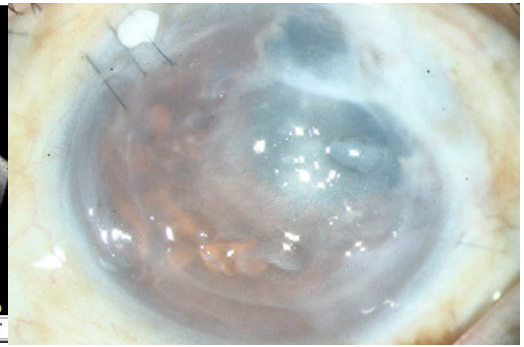
Compassionate Patient in China - 3 years FU

Professor Hong, Director of Ophthalmology, Peking University Third Hospital

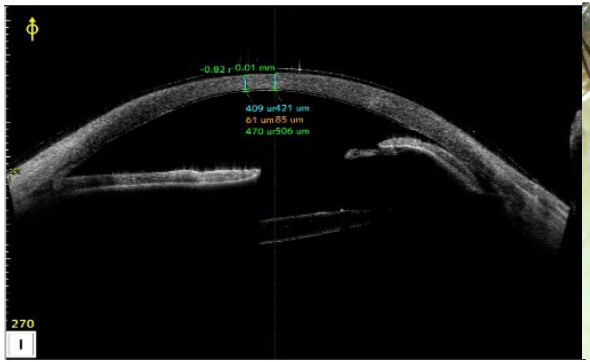
Female, 55y

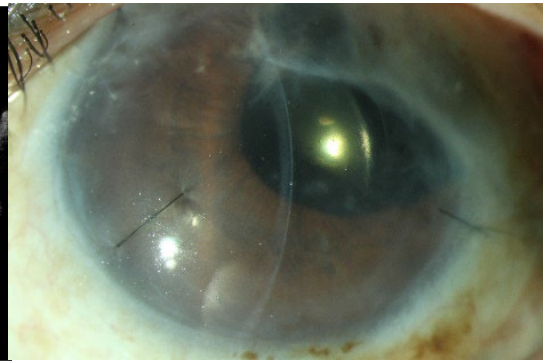
- Eye trauma, corneal laceration suture
- Cataract extraction + intraocular lens implantation (2007)
- Abnormal pupil, synechiae
- DSAEK (2019)

Baseline: VA= HM | CCT= 795µm



14M: VA = 6/19 | CCT= 470µm





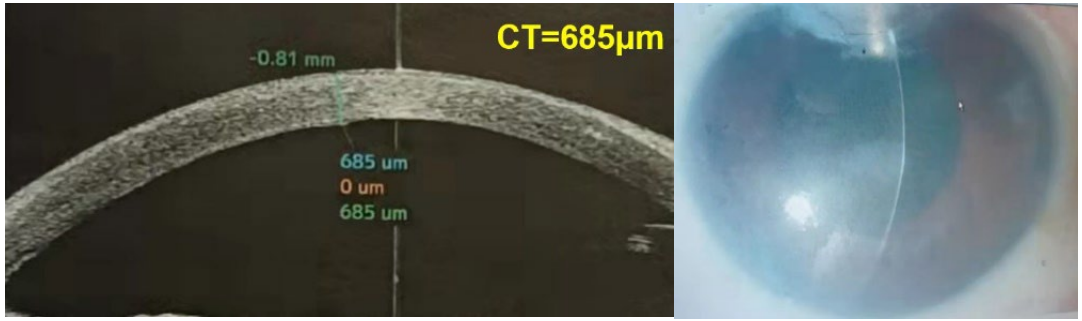
Compassionate Patient in China – >2.5 Years FU

Professor Hong, Director of Ophthalmology, Peking University Third Hospital

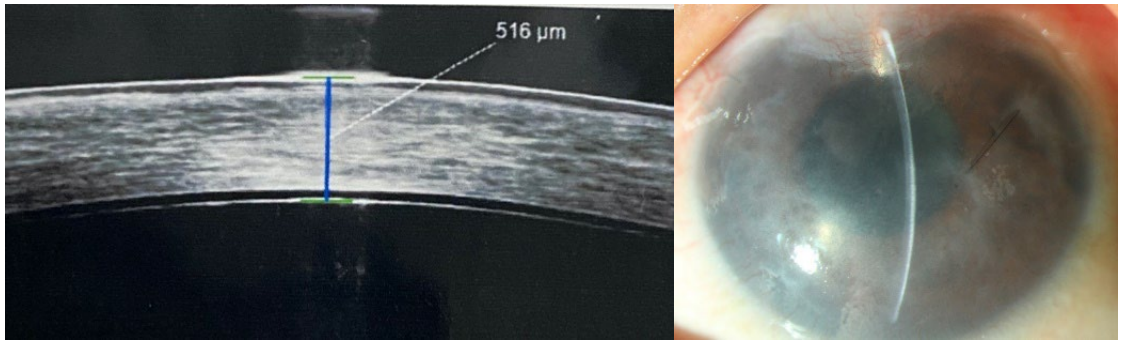
Male, 35y

- Glaucoma filtering surgery
- Cataract extraction + intraocular lens implantation
- Abnormal pupil, synechiae

Baseline: VA= HM | CCT= 685µm



12M: VA = 6/48 | CCT= 516µm



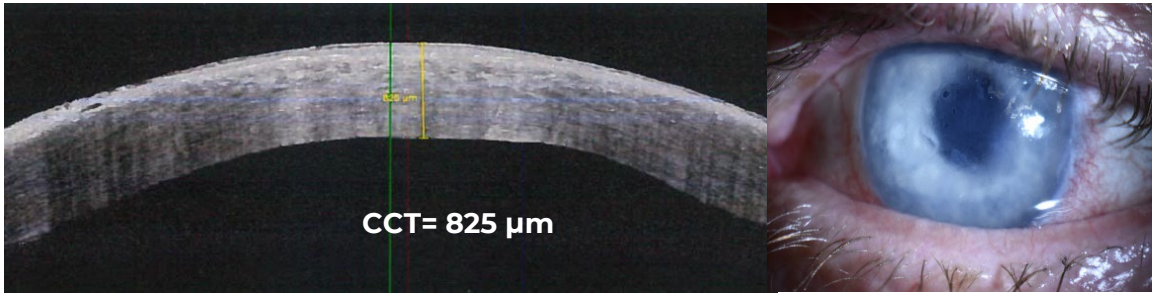
Patient 04-005 FIH study, Netherlands – 4 Years FU

Dr. Lapid-Gortzak Ruth, Head of Ophthalmology Department, Academic Medical Center, University of Amsterdam

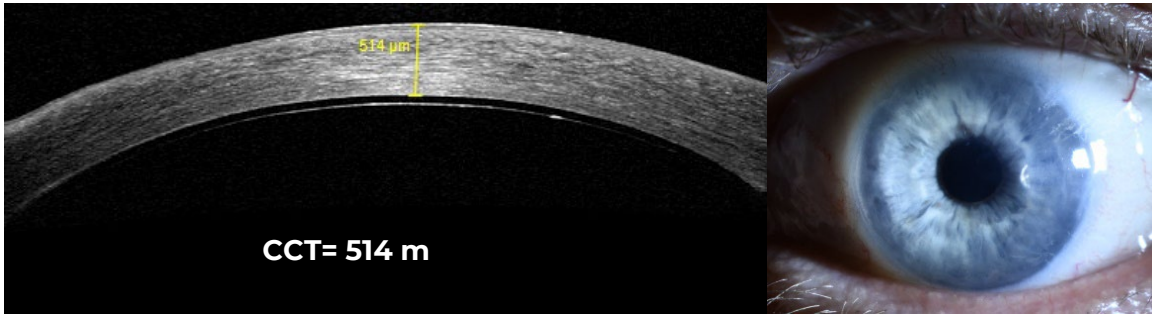
Male, 67y

- Cataract extraction 2009,
- Fuchs Dystrophy
- Macular Degeneration
- Corneal Edema 2013
- DWEK

Baseline: BCVA=LP | CCT=825µm

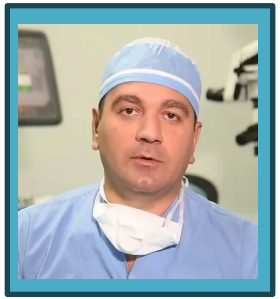


24M: BCVA 6\120 | CCT 514µm



Phase II study, Georgia – 2.5 Years FU

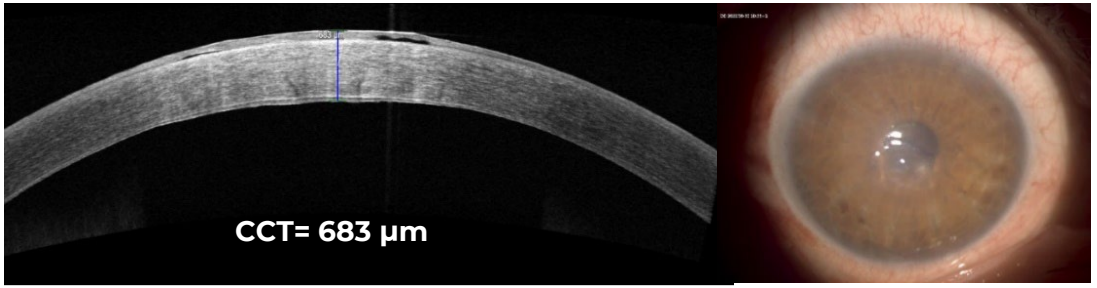
Dr. Nikoloz Labauri, Founder of the Davinci Eye Clinic in Tbilisi



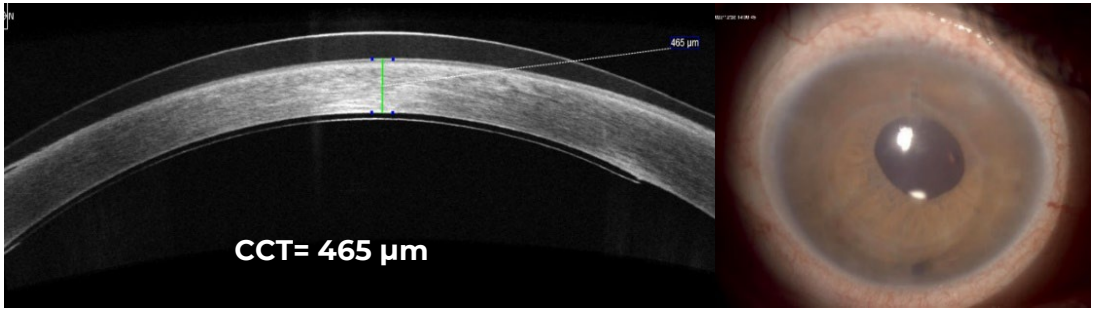
Female, 65y

- Cataract extraction
- FECD
- Corneal Edema

Baseline: VA= 6/150 | CCT=683µm

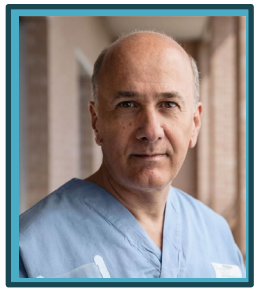


12M: VA=6/12 | CCT=465 µm



Patient 001 CE Post-marketing, Italy – 2.5 Years FU

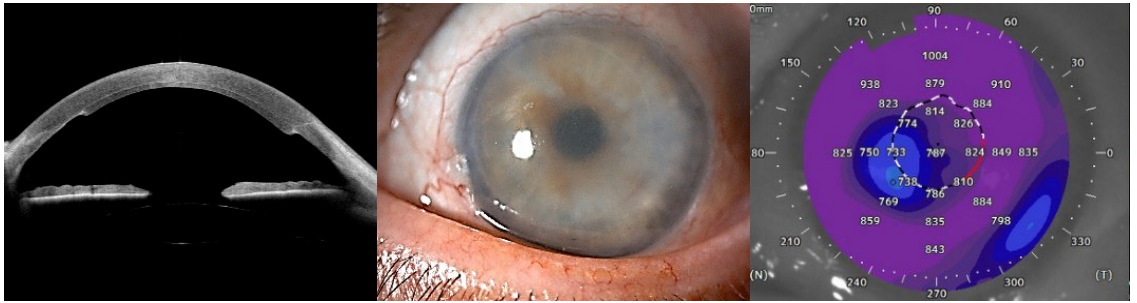
Professor Luigi Fontana, MD, PhD, Director of the Complex Ophthalmology Unit, Sant'Orsola Hospital, Bologna



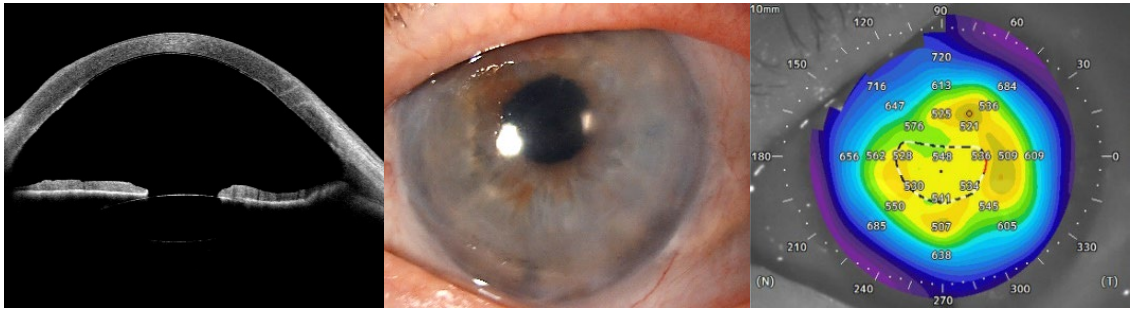
Female, 76y

- IOL
- Bullous keratopathy
- 2016 DSAEK
- 2018 the second DSAEK

Baseline: VA: 20/500 | CCT:787µm



6M: VA: 6/9.5 | CCT: 548µm



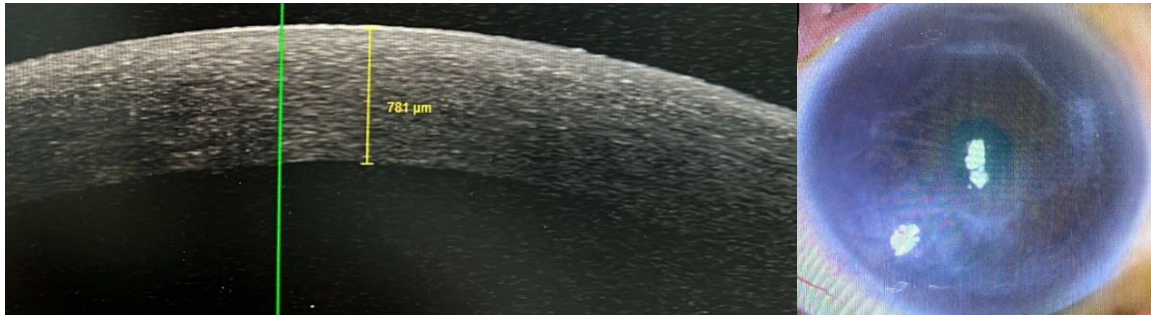
Patient S005 AMAR case, Israel – 2.5 Years FU

Professor Boris Knyazer, Soroka Medical Center, Head of Cornea Unit,
Professor at Ben-Gurion University of the Negev

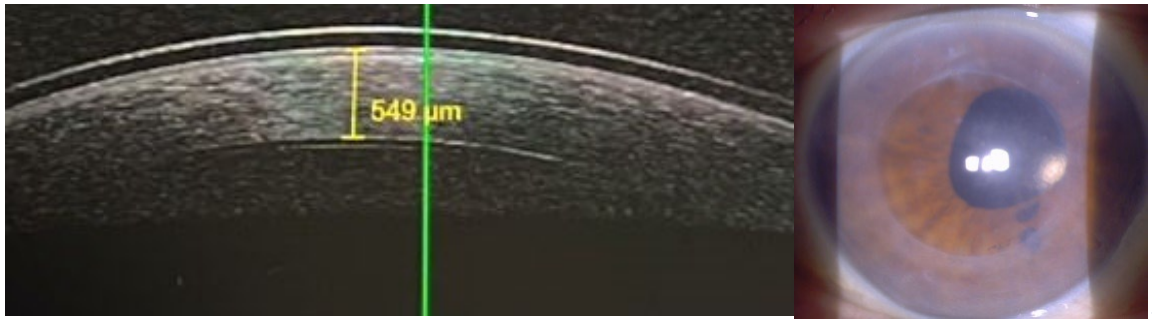
Male, 80y

- FECD

Baseline: BCVA=CF | CCT=781 µm



15M: BCVA=6\19 | CCT=549 µm



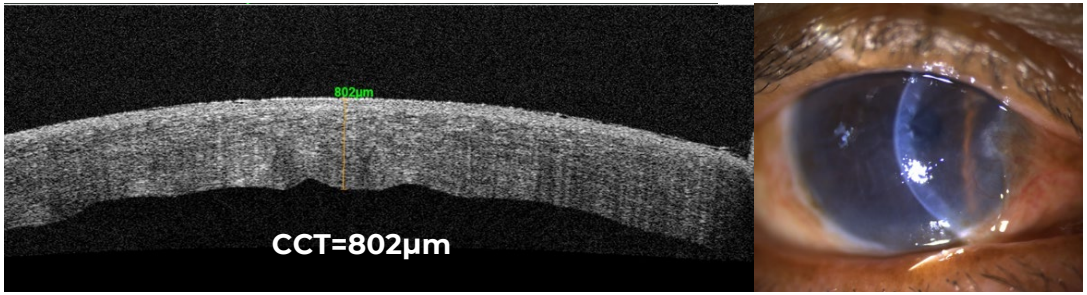
中国首次商业化” 博鳌特许进口, Japan – 1.5 Years FU

Professor Chen, Vice-president of Eye Hospital of Wenzhou Medical University,
Director of the Ophthalmology Center of Boao Super Hospital

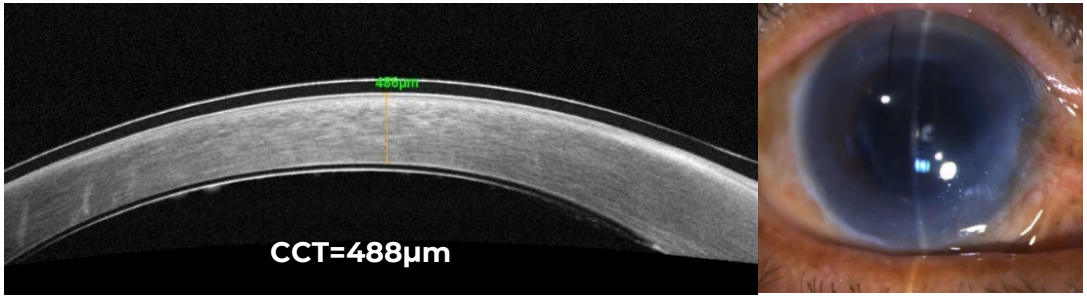
Female, 69y

- Cataract removal + IOL implantation (2022)
- Corneal Edema
- Endothelial dysfunction

Baseline: VA=CF/60cm | CCT=802 µm

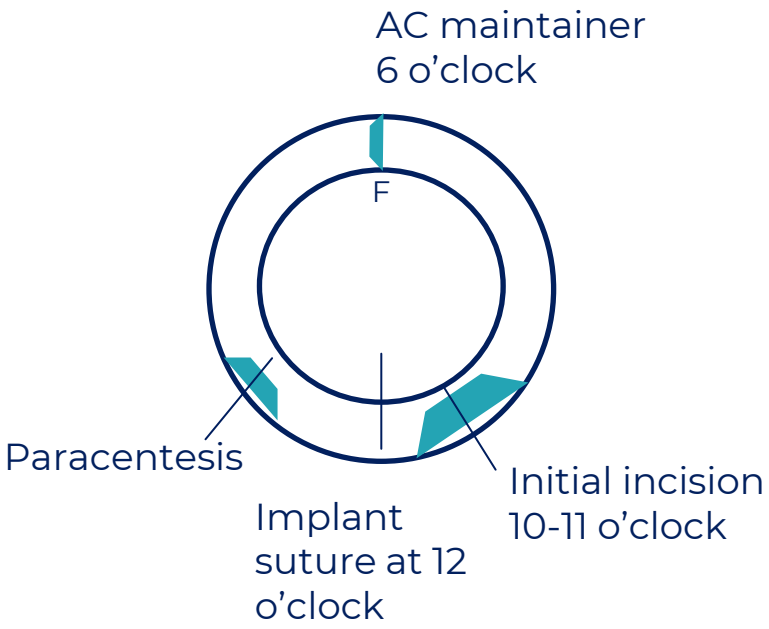


2M: VA=6/30 | CCT=488 µm



Field Experience – Tips and tricks

- **Device Durability:**
  - Restart, reimplant, reposition on interference.
  - Use a flat-tipped cannula for BSS injection.
  - Venting sutures as a last step (avoid unless misshapen cornea).
- **EndoArt Handling:**
  Place in BSS-filled Galipot; keep the lid.
- **Instrument:**
  Round-tipped flat spatula.
- **Gas:**
  SF6 20%; C3F8 10%.
- **Positioning:**
  Ensure proper placement of AC Maintainer, instruments, and sutures.



Combined insertion (IOL) – Prof. Knyazer