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ALMA MATER STUDIORUM
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ENDOART: IL FUTURO?

Antonio Moramarco, MD

Associate Professor

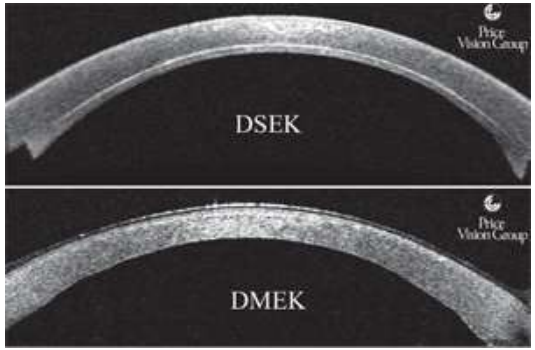
Cornea and Ocular Surface Diseases Service

Ophthalmology Unit, Santa Maria delle Croci Hospital, Ravenna, Italy

University of Bologna, Ravenna Campus, Italy

Background

Endothelial keratoplasty (**EK**) is the preferred treatment for various forms of corneal endothelial dysfunction



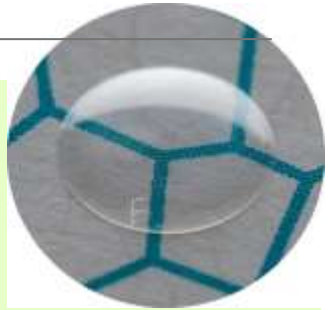
- 82.4%–96% survival for DMEK and 79.4%–95% for DSAEK at five years

Concerns persist regarding **long-term graft survival** in specific groups of patients

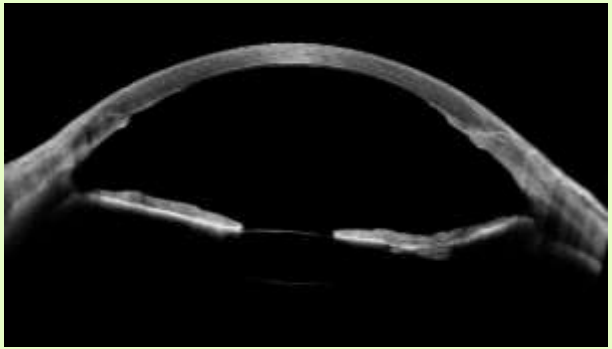
- Repeat keratoplasty accounted for 15.2% of graft surgeries in the US and 14% in Europe in 2022

Background

EndoArt has emerged as a potential solution



- **Contact lens-shaped acrylic hydrophilic implant**, made of flexible material measuring 50 mm in thickness and 6.5 mm in diameter
- Acts as an **artificial fluid barrier** upon adherence to the inner corneal surface
- Due to its **water impermeability**, the device stops aqueous penetration into the central corneal stroma



Cornea 2024

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

Luigi Fontana, MD, PhD,† Natalie di Geronimo, MD,*† Michela Cennamo, MD,‡ Rita Mencucci, MD,‡ Piera Versura, BSD,*† and Antonio Moramarco, MD*†*

Cornea 2026

Long-Term Clinical Outcomes and Anterior Segment Optical Coherence Tomography Findings After Artificial Endothelial Replacement Membrane Implantation

Luigi Fontana, MD, PhD,† Natalie di Geronimo, MD,*† Piera Versura, BSD,*† and Antonio Moramarco, MD*†*

Materials and Methods

7 EYES WITH ENDOTHELIAL DISFUNCTION UNDERWENT ENDOART IMPLANTATION

Corrected distance visual acuity (**CDVA**) (logMAR)

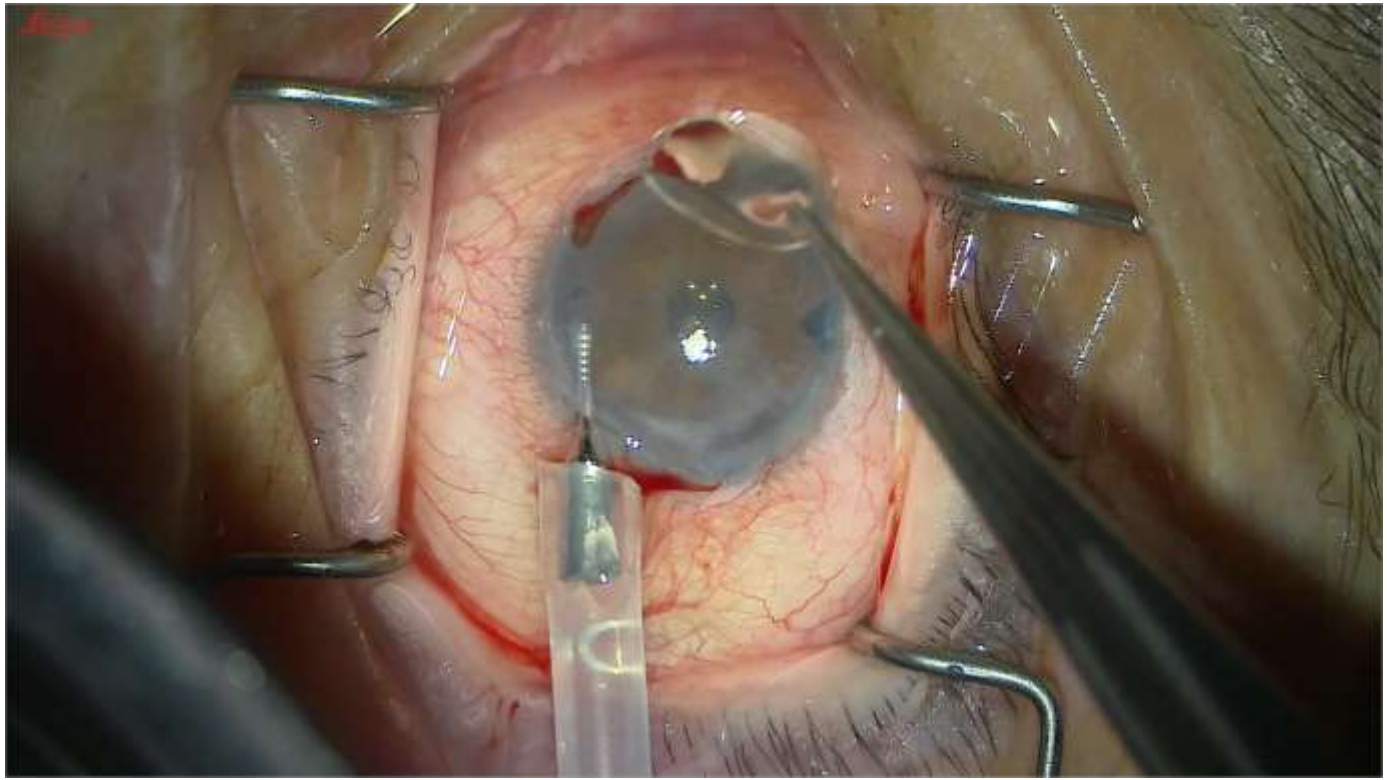
High-resolution AS-OCT images

Central corneal thickness (**CCT**)

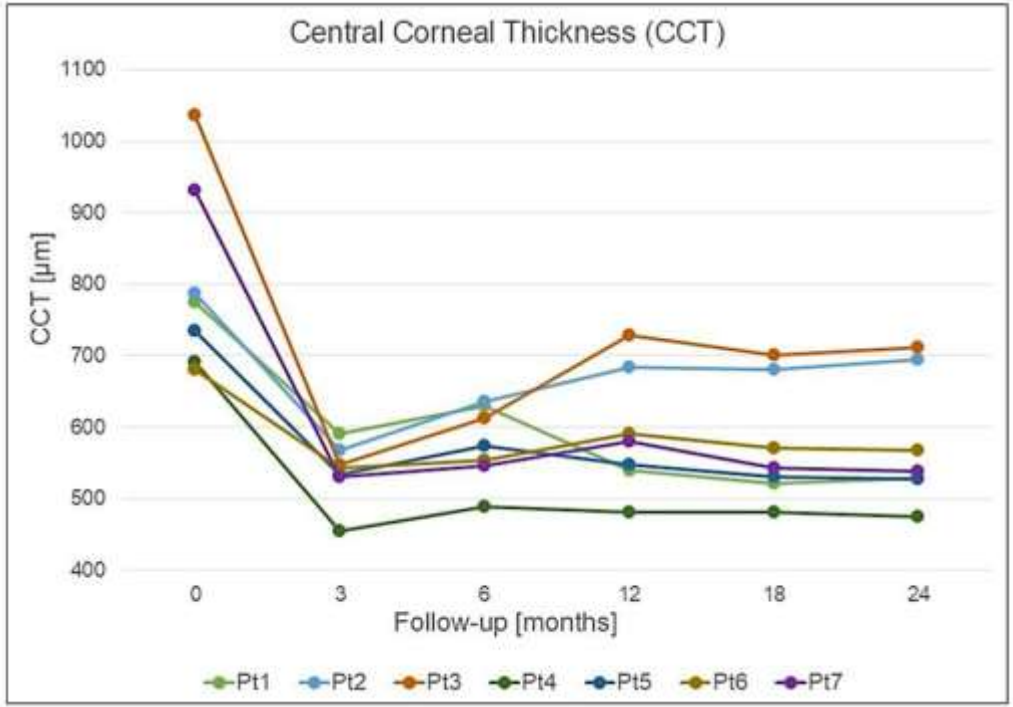
Features of the implant: **adhesion** and **detachment**

Interaction at the **implant's edge** and the **posterior cornea**

Surgical Technique

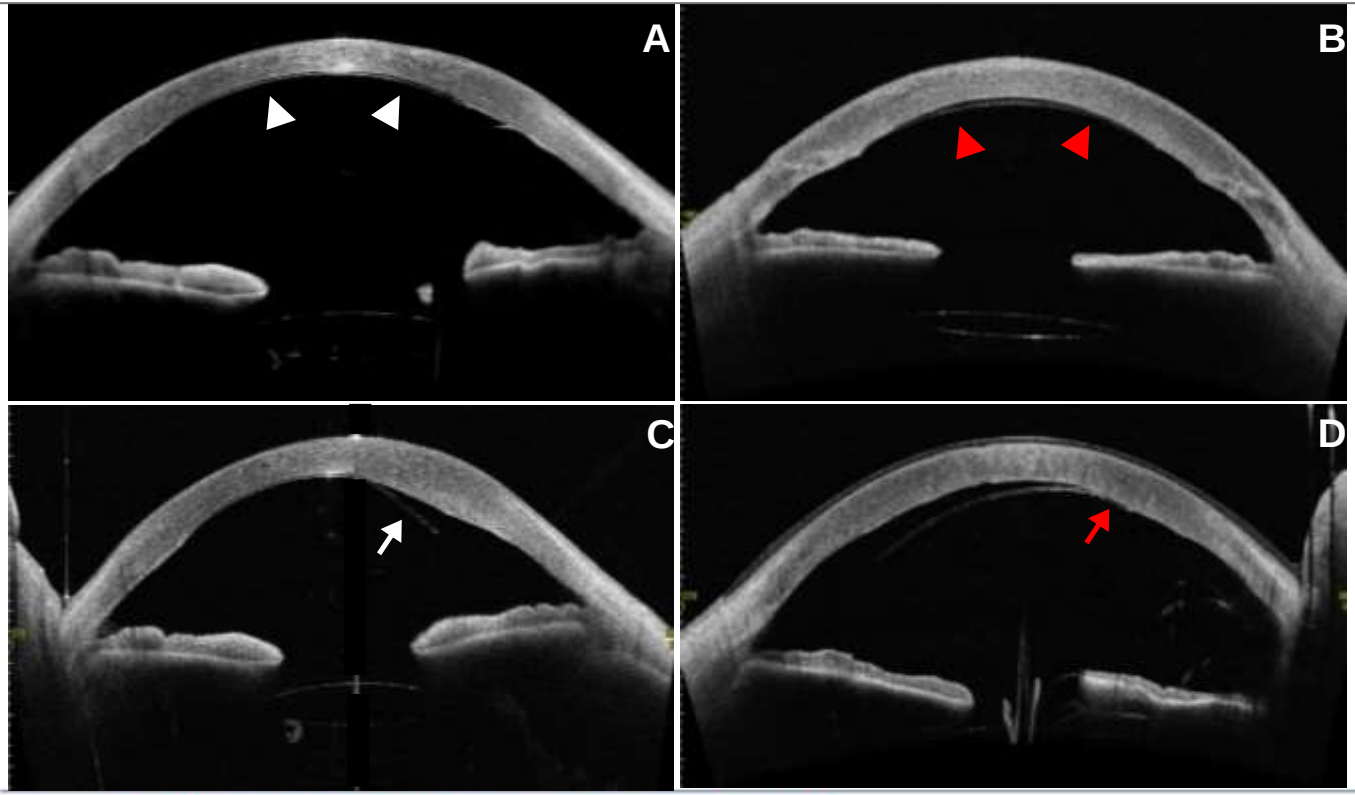


Results



- **CDVA** improved from **1.32 ± 0.23** logMAR to **0.95 ± 0.28** logMAR two years postoperatively (p=0.03)
  - Two patients without relevant comorbidities improved 11 lines
- The mean **CCT** changed from **805 ± 131** mm to **577 ± 90** mm at the last follow up visit (p=0.002)
- **No significant complications** related to the device

Results



Inferior detachments manifested within three months

Removal of the suture was followed by **superior detachments** in some cases

Results

Hyper-reflective circumferential band between the edge of the implant and the posterior stroma

- Five patients exhibited a **complete** circumferential band
- In two patients the band **did not extend fully** around the circumference

Discussion

Impact on V.A. was limited by the selection of patients

More significant CDVA improvements in patients with **few ocular comorbidities**

High compatibility profile

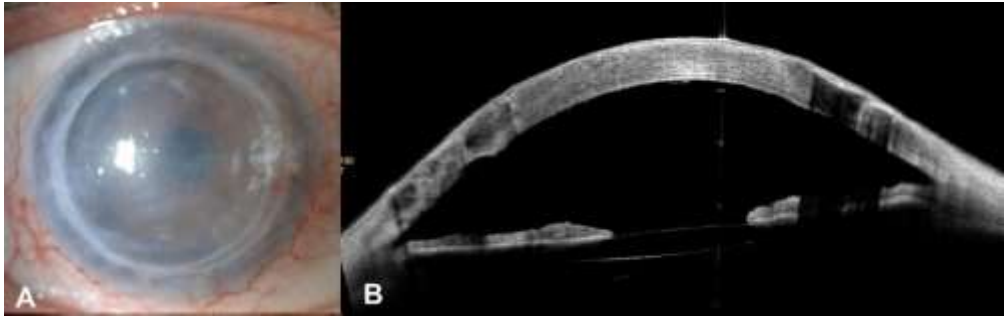
The most frequent complication is **implant detachment**

Primarily localized in **inferior** and **temporal** sectors

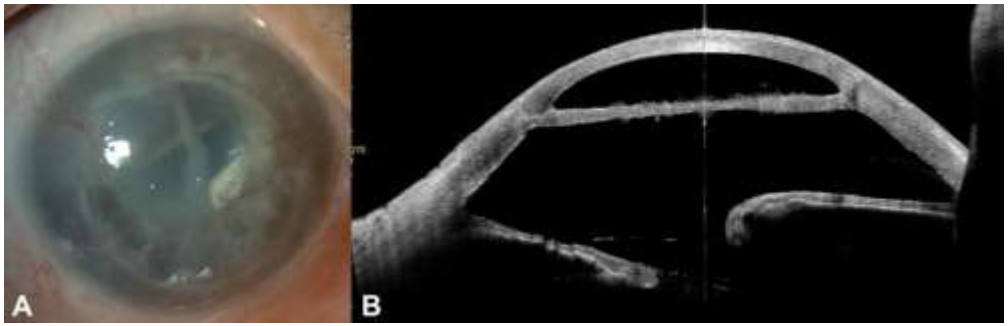
After suture removal most detachments occurred in the **superior** sectors

Long-term efficacy in corneal deturgescence

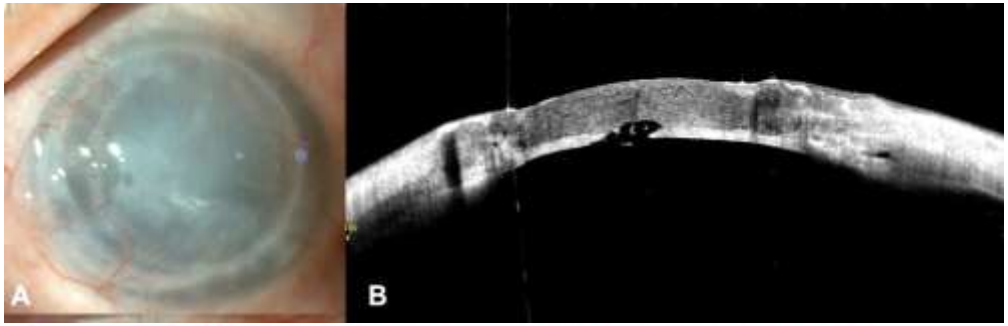
CCT reduced significantly and remained stable



KC, 2 PK failed, stromal opacity



PBK, 1 PK failed, 1 DSAEK failed,
IOL captured

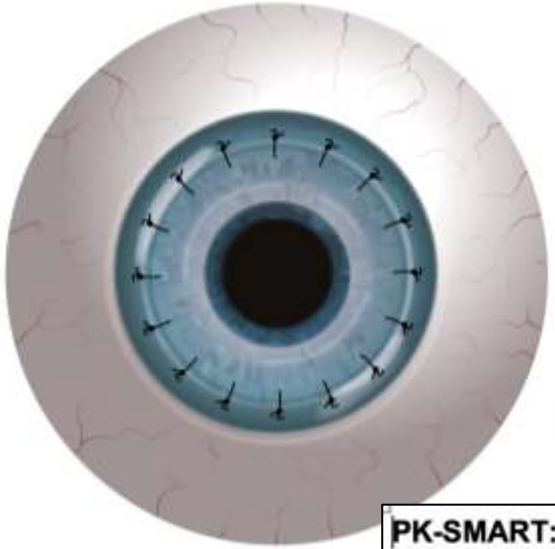


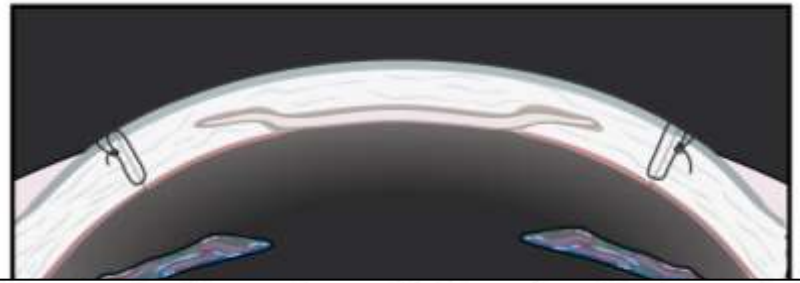
KC, 1 PK failed, VR surgery x2,
2 DSAEK failed, aphakia, partial aniridia,
silicone oil

PK SMART:

Penetrating **K**eratoplasty with
Sutureless **M**embrane **A**rtificial
Endothelial **R**eplacement

A novel surgical approach that combines PK with sutureless implantation of an artificial endothelial membrane (**EndoArt**) in a single procedure.





PK-SMART: Penetrating Keratoplasty with Sutureless Membrane Artificial Endothelial Replacement Technique. Report of the first three clinical cases.

Sub title: PK-SMART Technique

Luigi Fontana MD, PhD[1,2]; Vito Romano MD[3]; Natalie di Geronimo MD[1,2]; Piera Versura BSD[1,2]; Maurizio Mete MD[1,2]; and Antonio Moramarco MD[1,2].

In press. Cornea 2026

PK SMART:

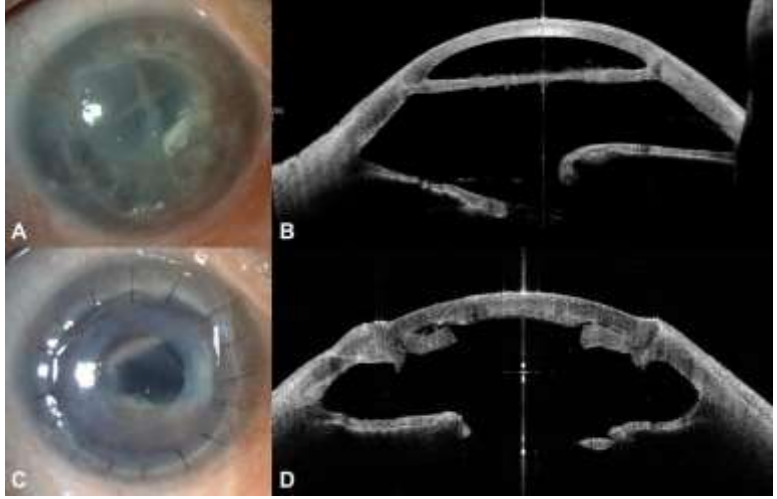
Background **A**nd **R**ationale
Of PK-Smart

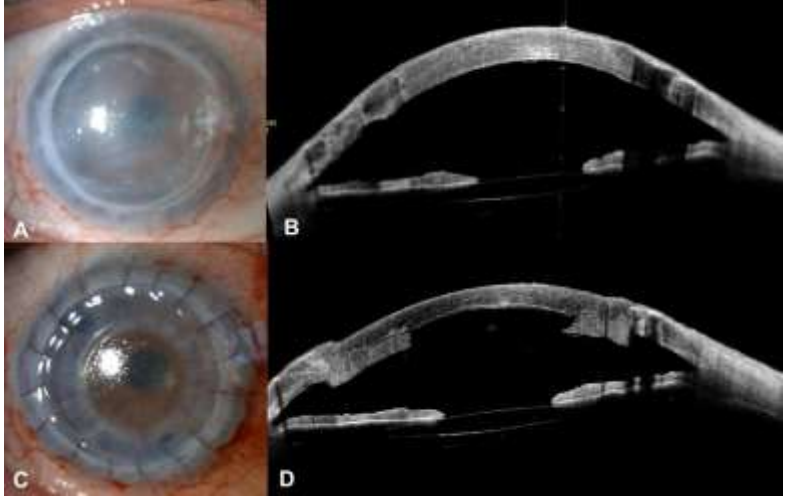
Standalone EndoArt implantation cannot address stromal scarring and **carries a high risk of device detachment** in complex eyes.

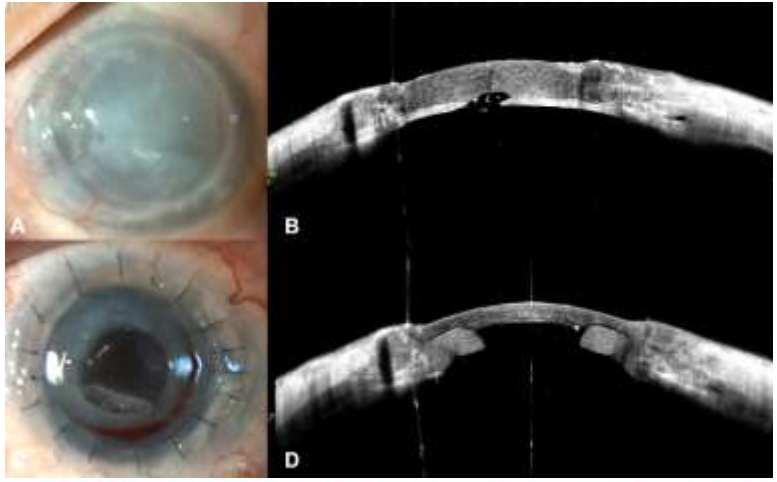
PK-Smart addresses both pathologies simultaneously:

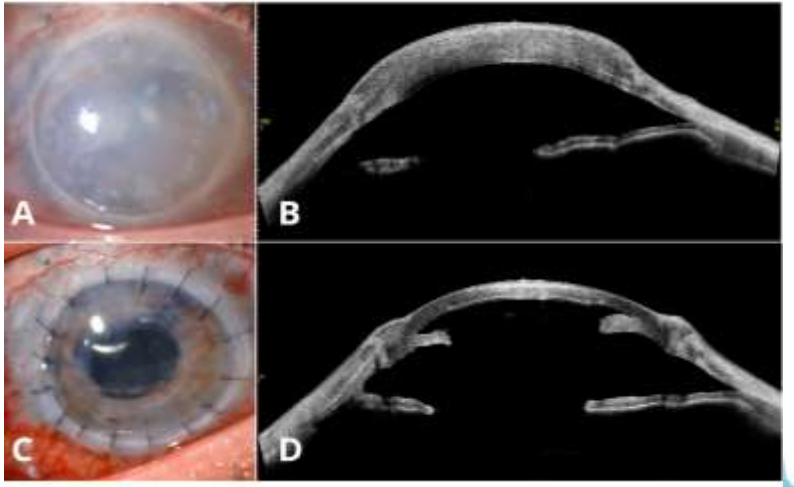
- Stromal replacement through penetrating keratoplasy
- Endothelial dysfunction through artificial endothelial membrane (EndoArt)


Patient, Anonymous
Normal
Unspecified Surgeon









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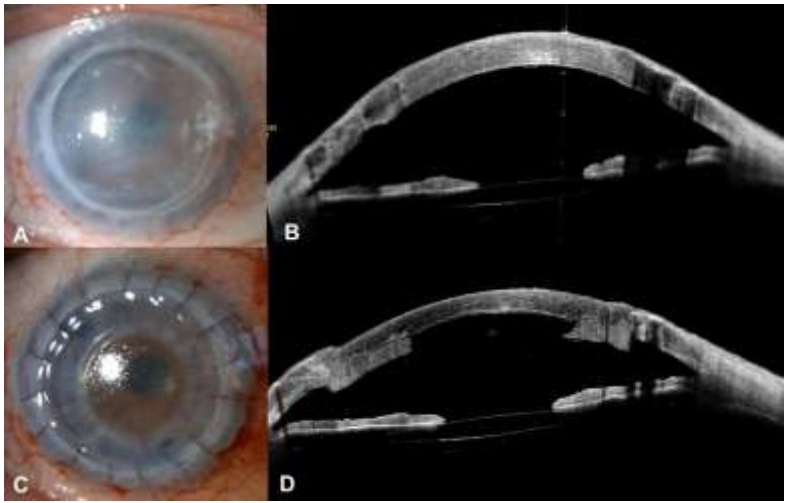
PK SMART:

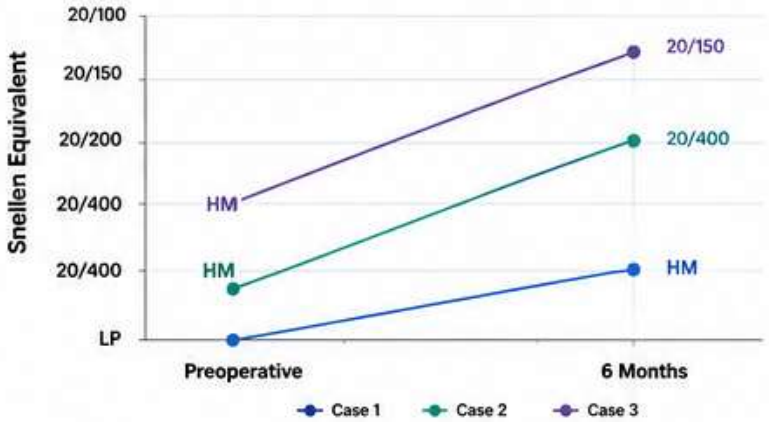
Results:
Short Term Outcomes



HM → 20/150

Visual Acuity (CDVA)

All patients showed functional visual improvement at 6 months



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Conclusions And Take Home Messages

- ✓ Device's biocompatibility could overcome the high failure rate of repeat corneal transplantations
- ✓ Long-term evidence of EndoArt's efficacy in promoting stromal deturgescence and enhancing corneal transparency
- ✓ Good safety profile
- ✓ Refine the implantation technique to reduce the frequency of device detachment
- ✓ PK-SMART may expand surgical options for patients with multiple graft failures and complex AS anatomy, potentially improving graft survival and visual rehabilitation.

Grazie per l'attenzione!

Antonio Moramarco, MD

Cornea and Ocular Surface Diseases Service

Ophthalmology Unit, Santa Maria delle Croci Hospital, Ravenna, Italy

University of Bologna, Ravenna Campus, Italy

moramarco.antoniomd@gmail.com

+39 3283509872


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