INTERNATIONAL CONGRESS OF THE

EGYPTIAN

OPHTHALMOLOGICAL SOCIETY

In collaboration with: MEACO

Additive Procedures for keratoconus in 2025

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EOS

Team of ACED study

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ACKNOWLEDGEMENT

Shaimaa Elbassiouny

Consultant Ministry of Health

Ahmed Sharaby

Consultant ministry of health

What is XENIA Implant

Intrastromal decellularized Porcin Corneal Lenticular Implantation

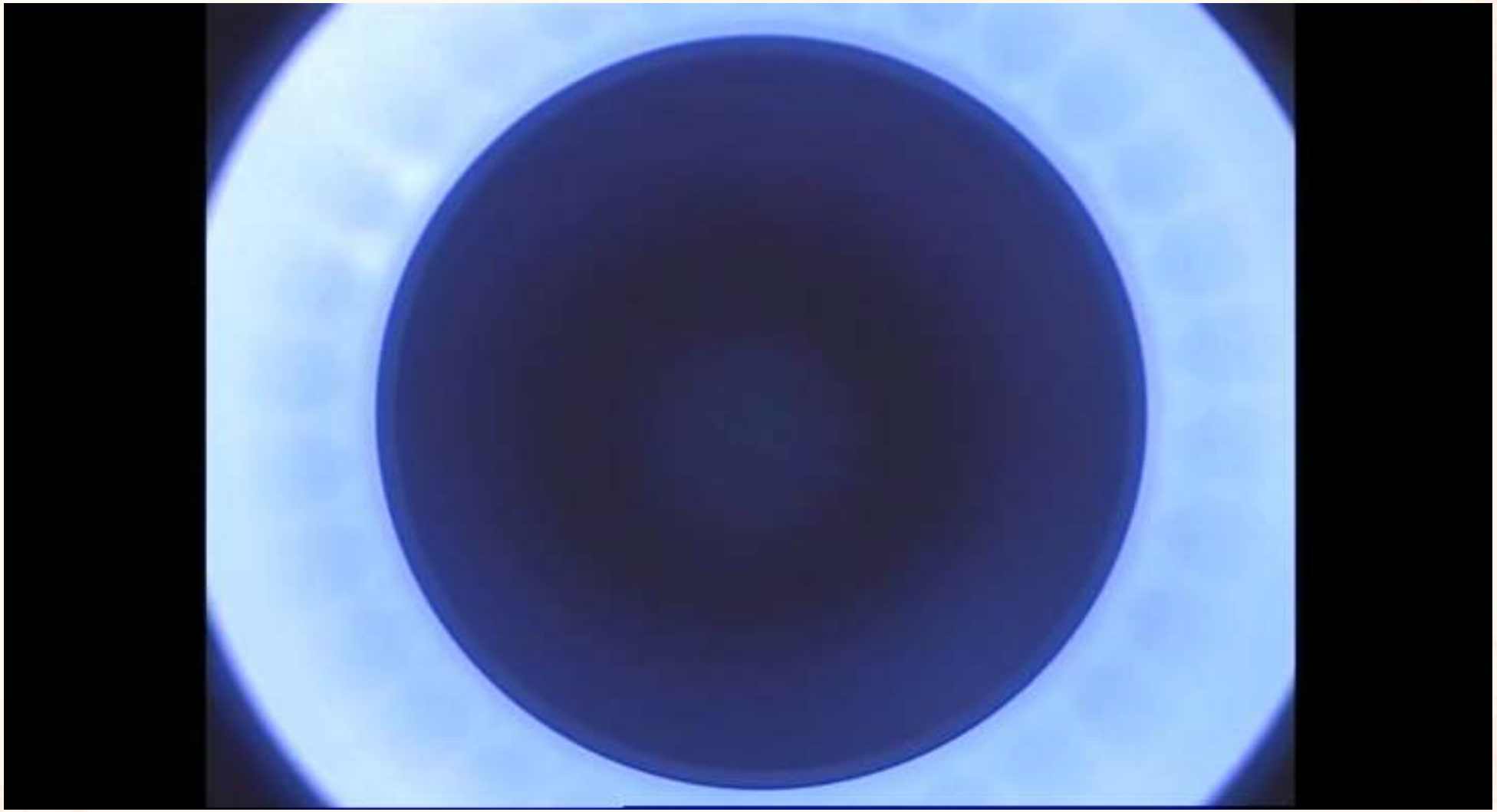
De-cellularization to remove foreign cells including antige then it is crosslinked 500 times.

What is XENIA Implant

The implant is significantly stronger than the patient's own stroma:

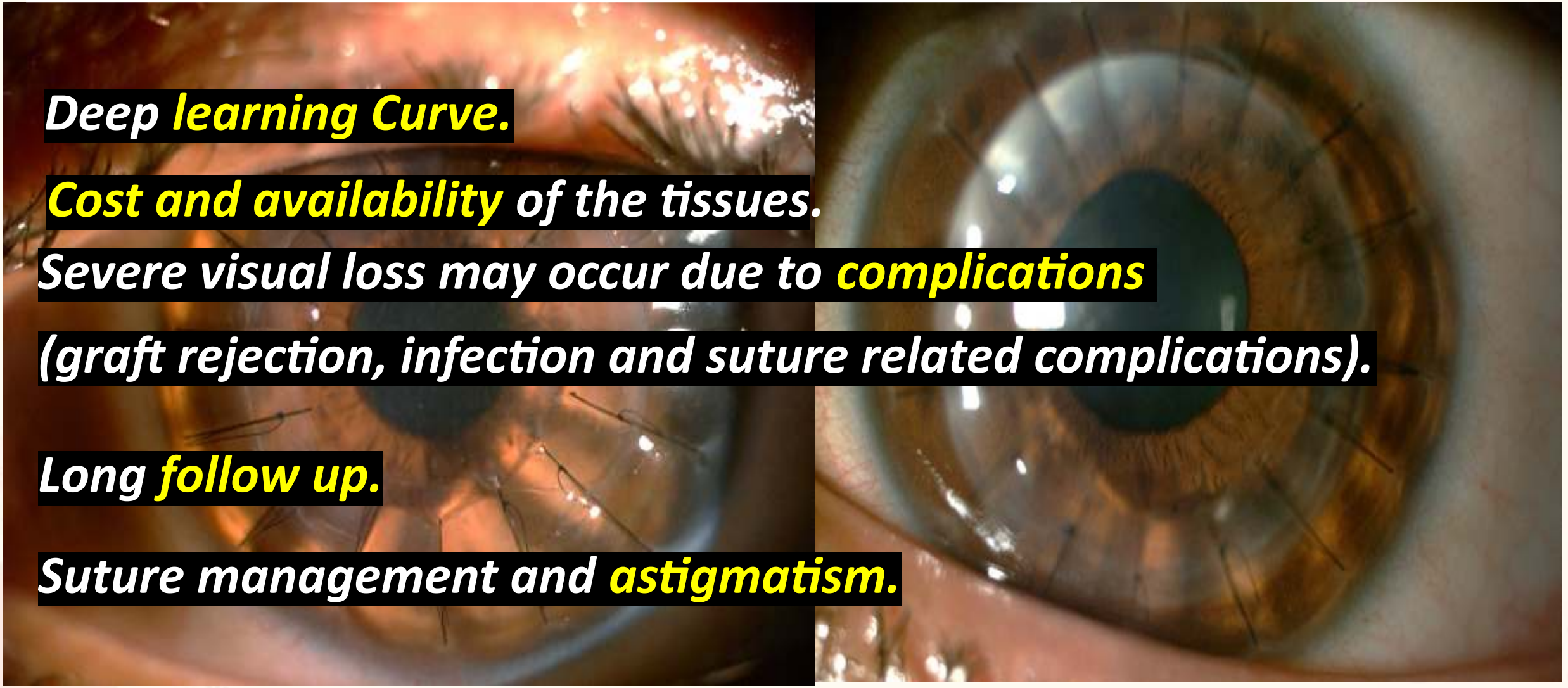
- **XENIA stabilizes the patient's cornea.**
- **Flattening the corneal topography.**
- **Regularizes the patient cornea.**
- **Reducing higher order aberrations.**

XENIA Implantation



DALK & PKP

Cornerstones for treatment of advanced KC , yet:



Deep learning Curve.

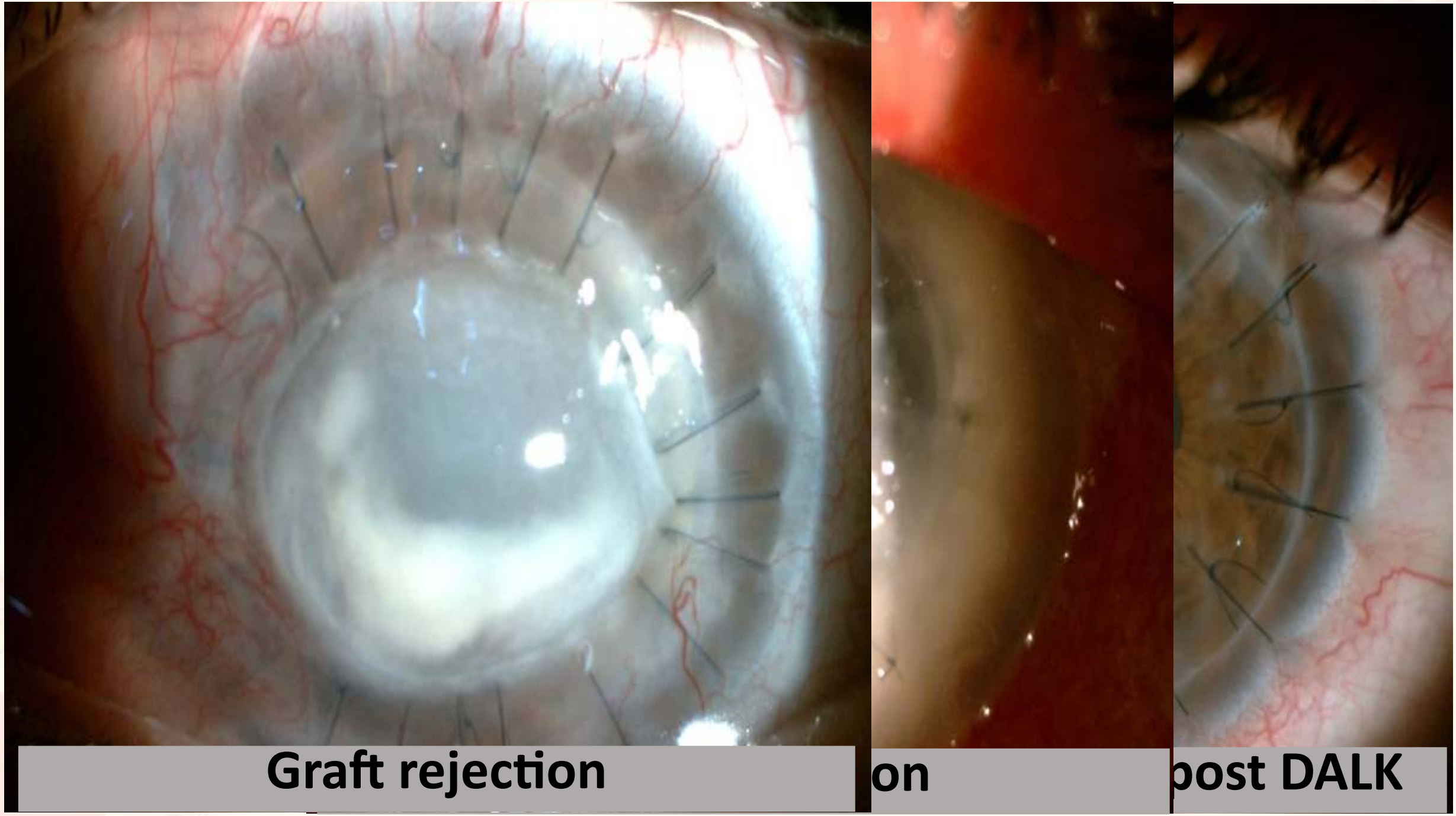
Cost and availability of the tissues.

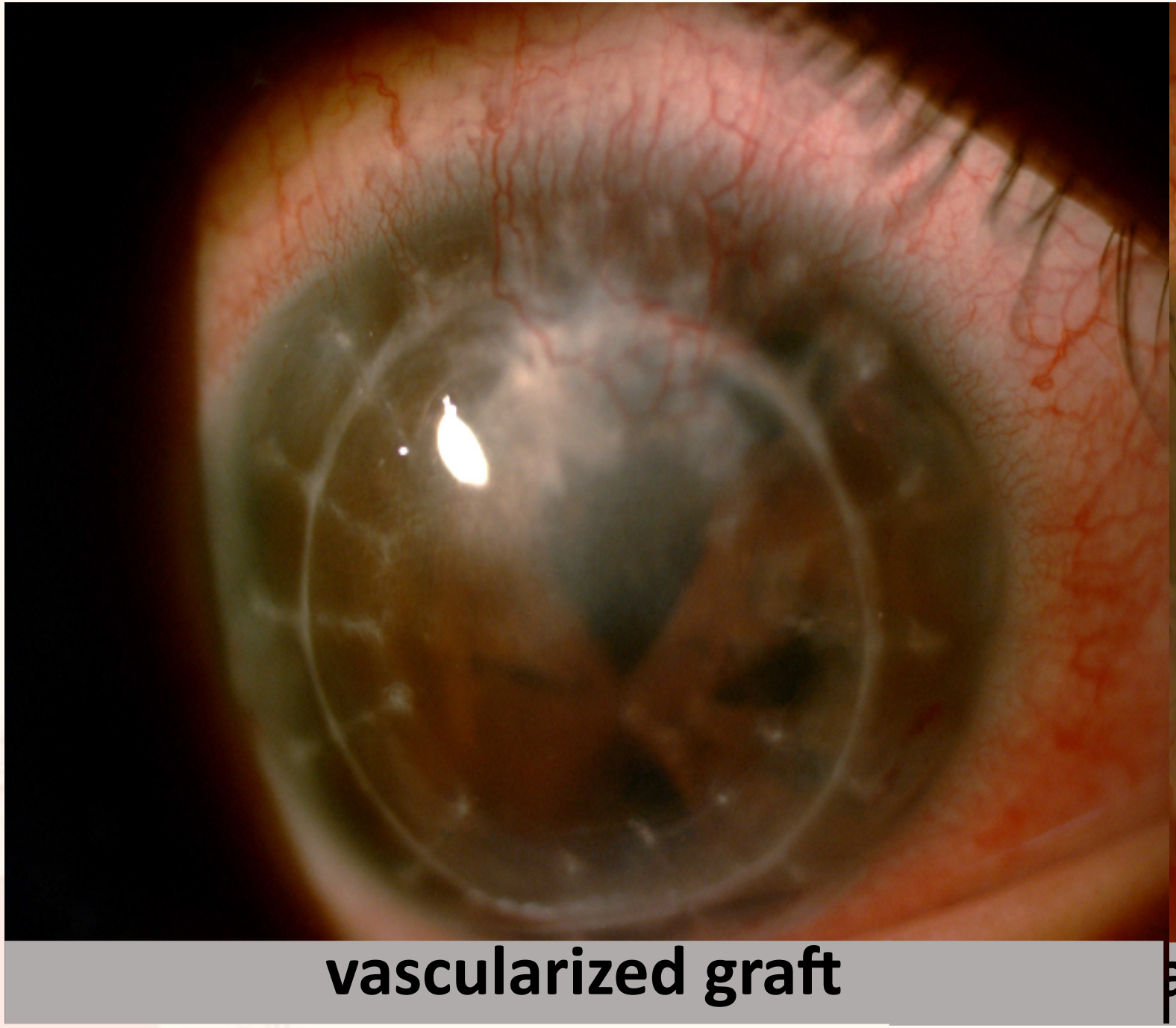
Severe visual loss may occur due to complications

(graft rejection, infection and suture related complications).

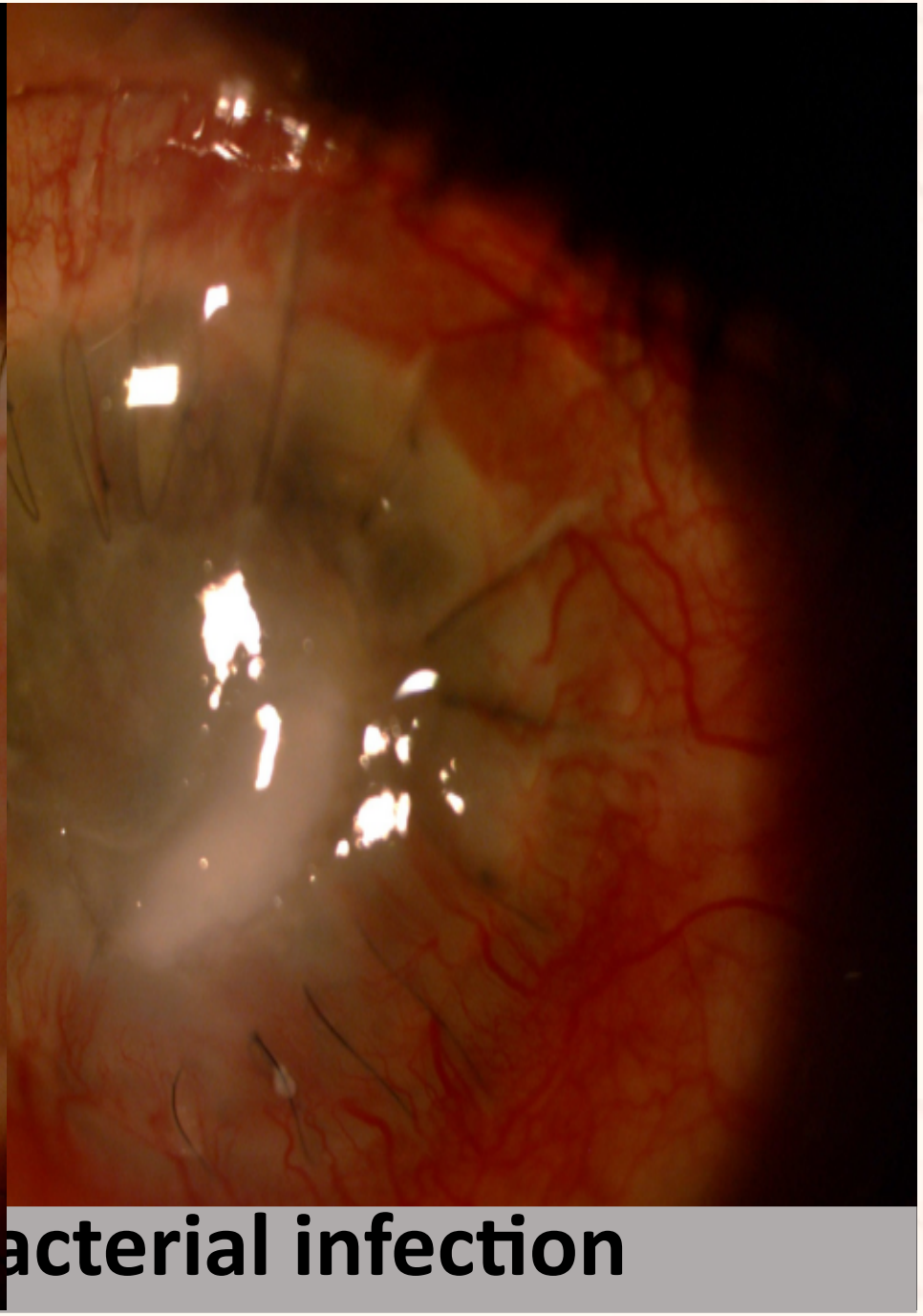
Long follow up.

Suture management and astigmatism.


Graft rejection
on
post DALK



vascularized graft



acterial infection

Why Additive Procedures (Xenia) are safer than DALK in KC

1) Superior Biocompatibility.
2) Minimizing Surgical Complications.
3) Clinical Trials and Real-World Evidence.
4) Regulatory Approvals and Certifications.
5) Cost-Effectiveness.
6) Conclusions.

Why XENIA implant is safer than DALK

1) Superior Biocompatibility

- XENIA implants **integrate easily** with the human body.

- NO **rejection** rates compared to other implants.

- **Reduced** risk of **infection and inflammation**.

Why XENIA implant is safer than DALK

2) Minimizing Surgical Complications:

- XENIA's design reduces **surgical risks** .

- **Easier implantation** process, leading to shorter surgery times.

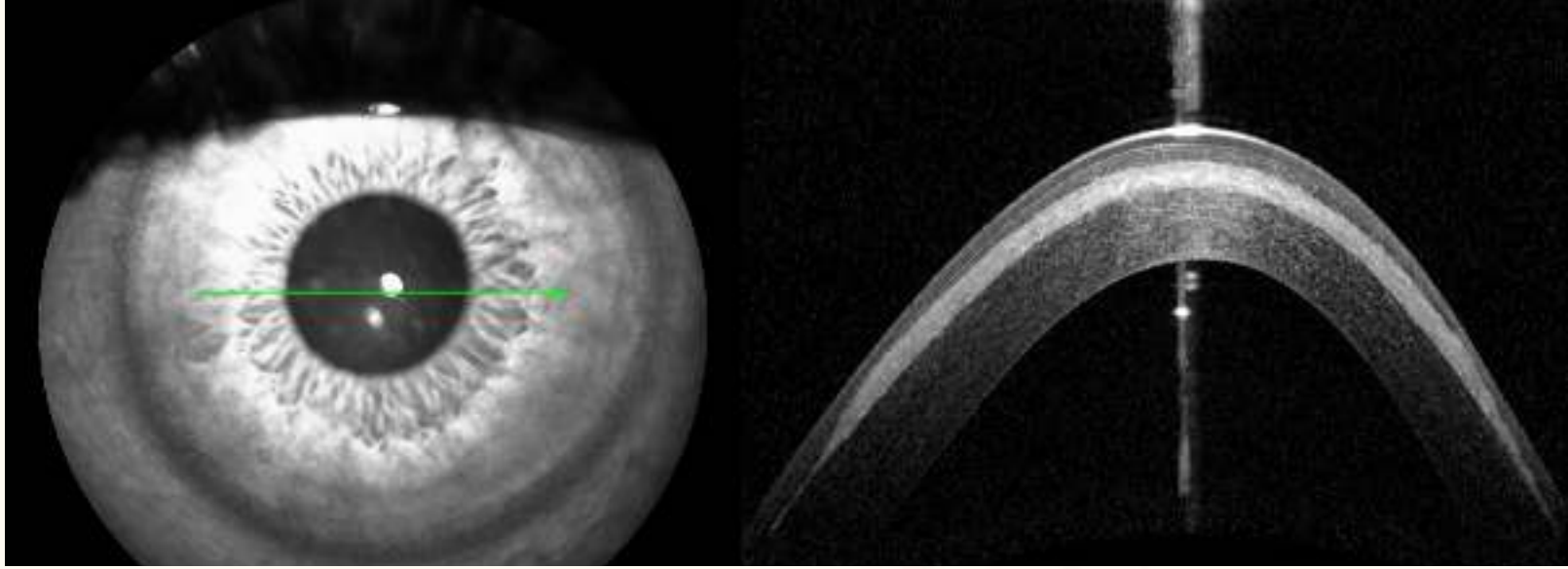
- **Faster recovery** periods for patients.

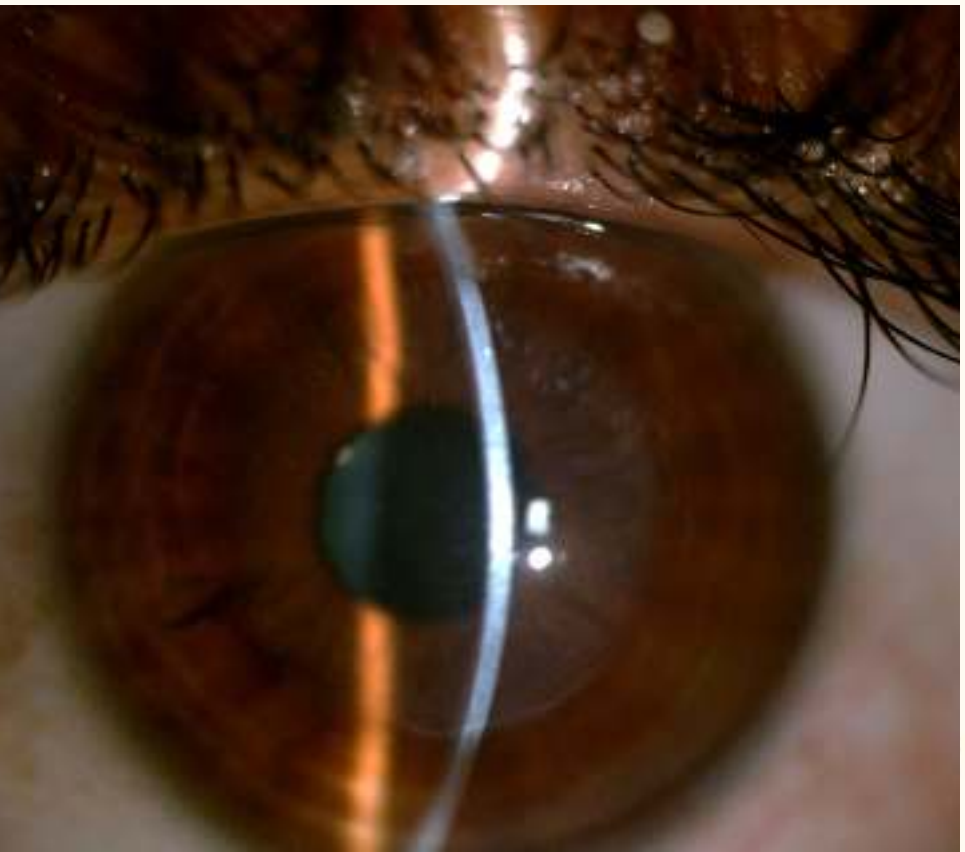
- Comparison with traditional implants **(fewer complications, better results).**

3) Clinical Trials and Real-World Evidence

successful clinical trials and studies on XENIA implants.

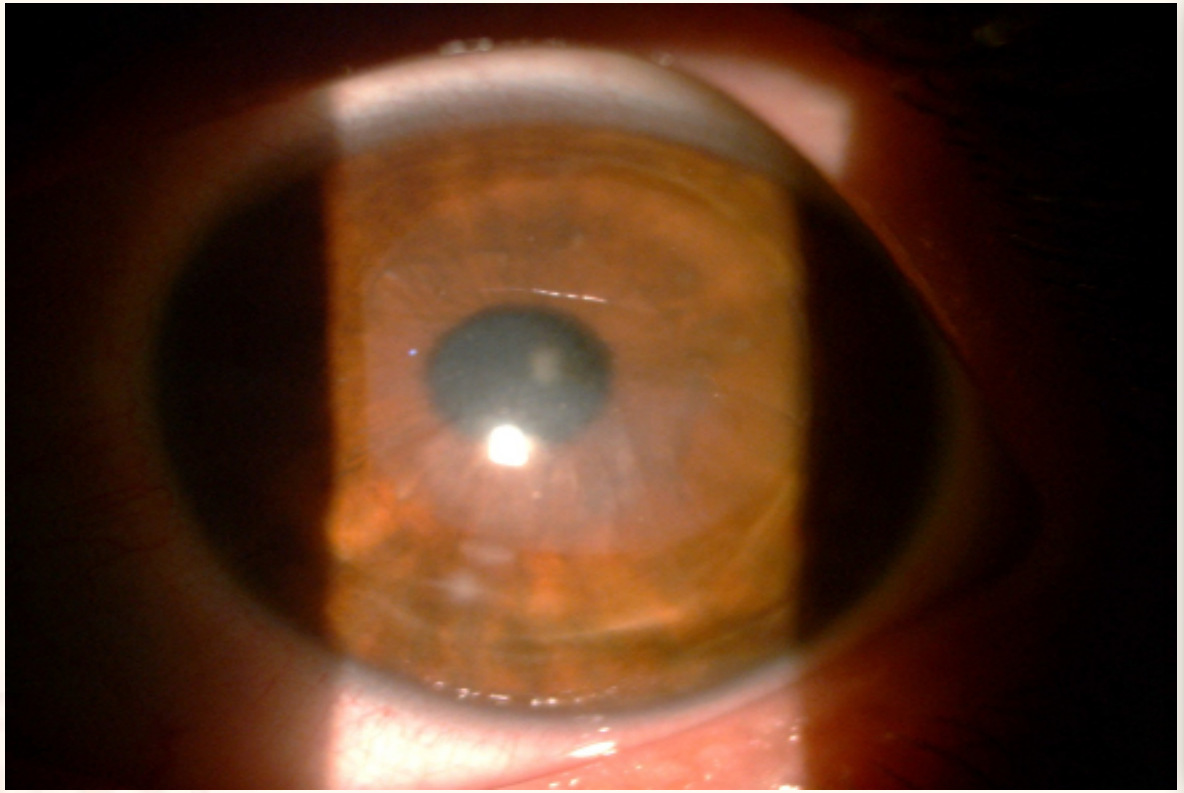
Xenia

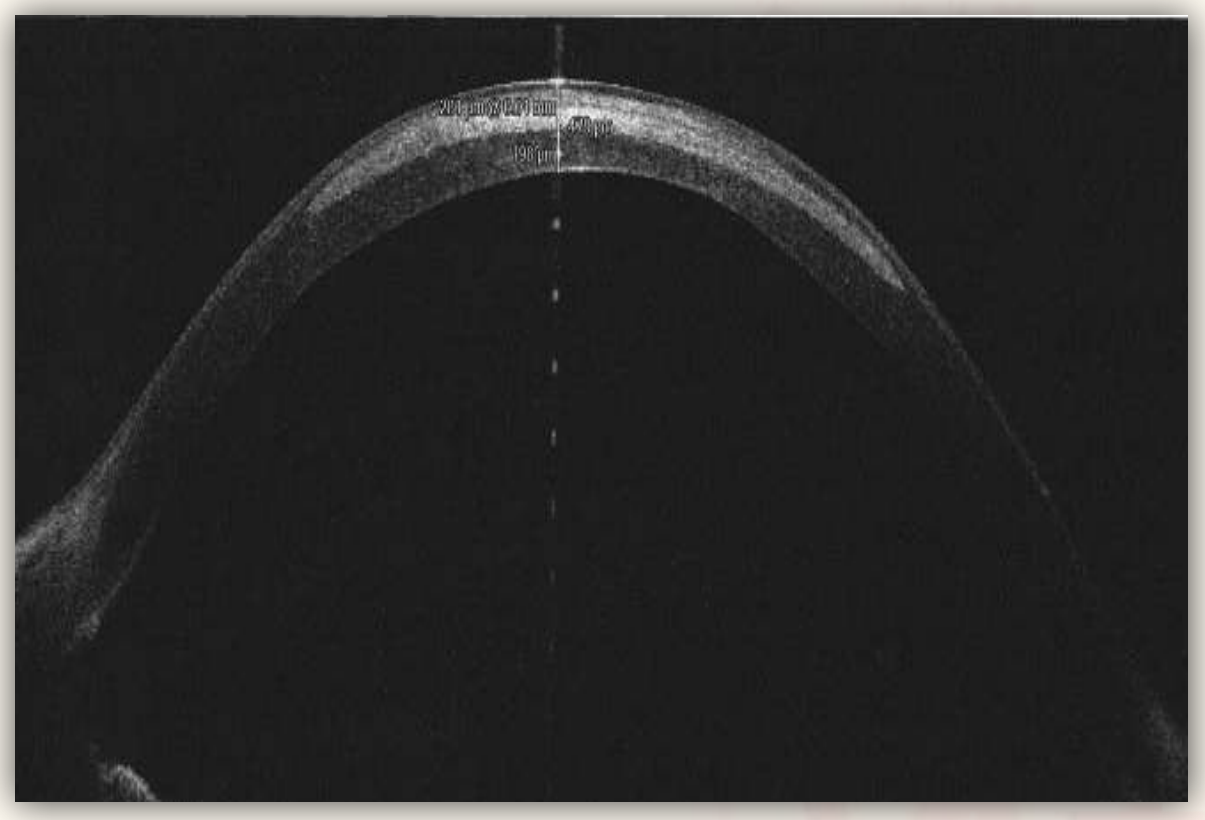




- The first published study was done in July 2019, Roayah Eye Center ,Alexandria, Egypt .
- Follow up on these patients demonstrates a long-term safety of the material.

Three years follow up (Slit lamp & Anterior segment OCT)





3 years follow up

Five years follow up (Slit lamp& Anterior segment OCT)

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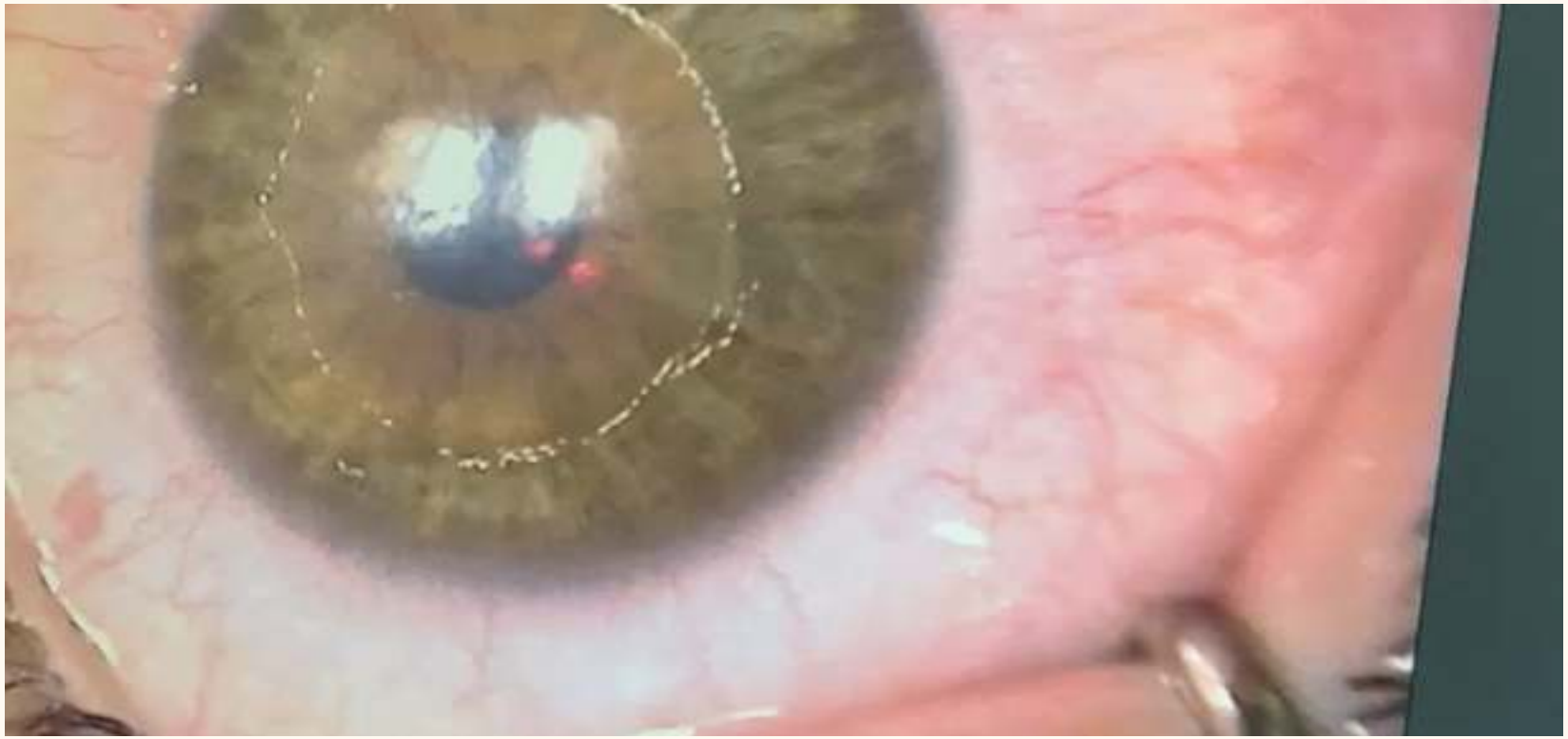
- All cases were **Cross linked** three months Post corneal implant except the post lasik Ectasia.
- Epi-Off CXL.

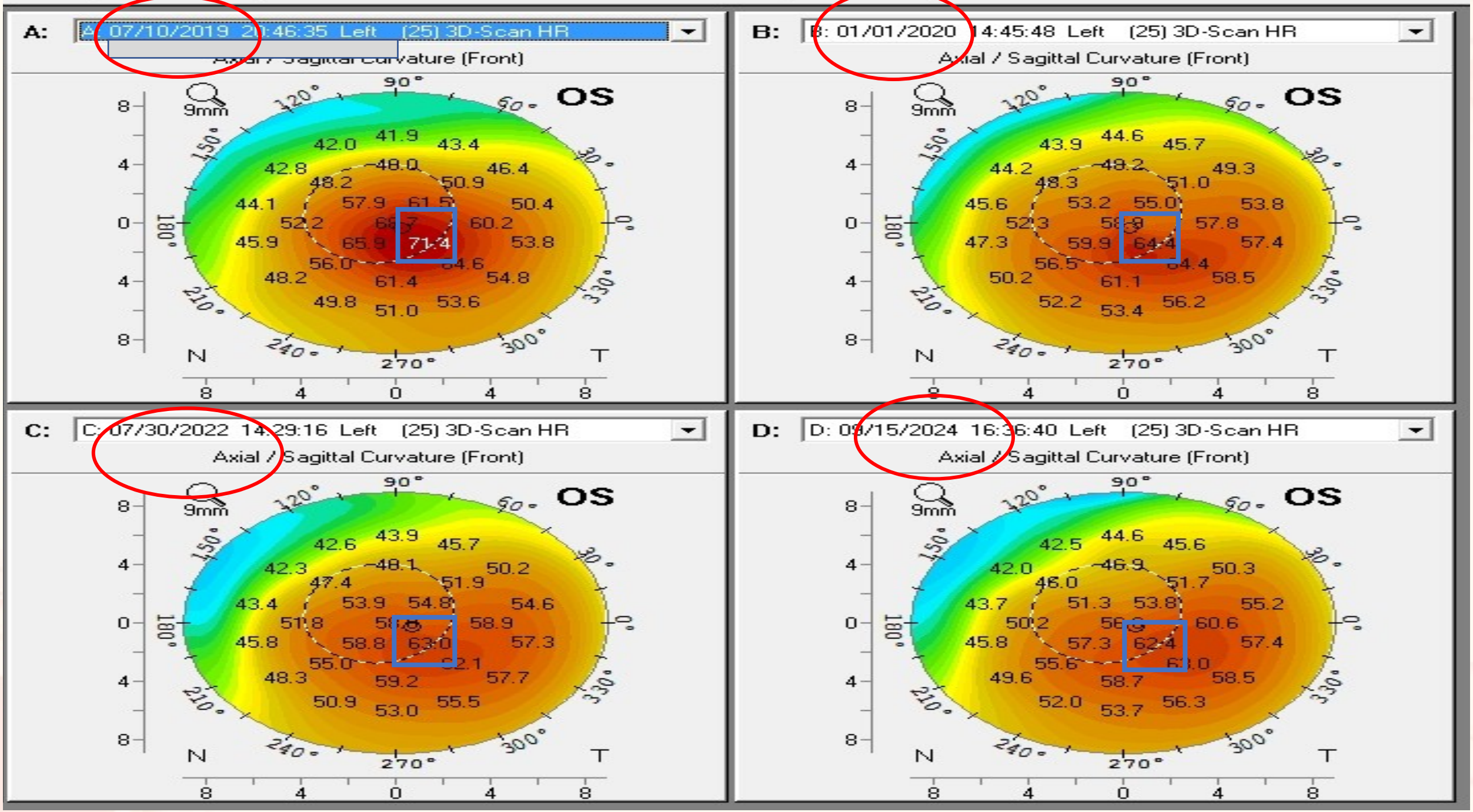


Results

- The mean age of the patients was **27.67 ± 9 years.**
- All the surgical procedures were **uneventful.**
- **One eye** had wrinkles and opacified graft, and it was **exchanged 3 months** postoperatively.
- **All patients (7 eyes)** completed Five years of follow-up.
- **No episodes of rejections** were encountered **up till 5 years.**

Results

- Visual acuity improved in all patients at 6 , 12 months ,3 years and Five years **(Stable from 6 months till 5 years)**
- The mean CCT measured with **Pentacam increased & stable at 1 ,3 and 5 years.**
- **5 years** follow up showed **stability and clear lenticules** all over the follow up period.


A:
07/10/2019 2:46:35 Left (25) 3D-Scan HR
Axial / Sagittal Curvature (Front)
OS
9mm
90°
120°
60°
150°
30°
180°
0°
210°
330°
240°
300°
270°
N
T
8
4
0
4
8
42.0 41.9 43.4
42.8 48.0 46.4
48.2 50.9
44.1 57.9 61.5 50.4
52.2 60.2
45.9 65.9 71.4 53.8
56.0 54.6
48.2 61.4 54.8
49.8 51.0 53.6
B:
01/01/2020 14:45:48 Left (25) 3D-Scan HR
Axial / Sagittal Curvature (Front)
OS
9mm
43.9 44.6 45.7
44.2 48.2 49.3
48.3 51.0
45.6 53.2 55.0 53.8
52.3 57.8
47.3 59.9 64.4 57.4
56.5 54.4
50.2 61.1 58.5
52.2 53.4 56.2
C:
07/30/2022 14:29:16 Left (25) 3D-Scan HR
Axial / Sagittal Curvature (Front)
OS
9mm
42.6 43.9 45.7
42.3 48.1 50.2
47.4 51.9
43.4 53.9 54.8 54.6
58.9
45.8 58.8 63.0 57.3
55.0
48.3 59.2 57.7
50.9 53.0 55.5
D:
09/15/2024 16:36:40 Left (25) 3D-Scan HR
Axial / Sagittal Curvature (Front)
OS
9mm
42.5 44.6 45.6
42.0 46.9 50.3
46.0 51.7
43.7 51.3 53.8 55.2
60.6
45.8 57.3 62.4 57.4
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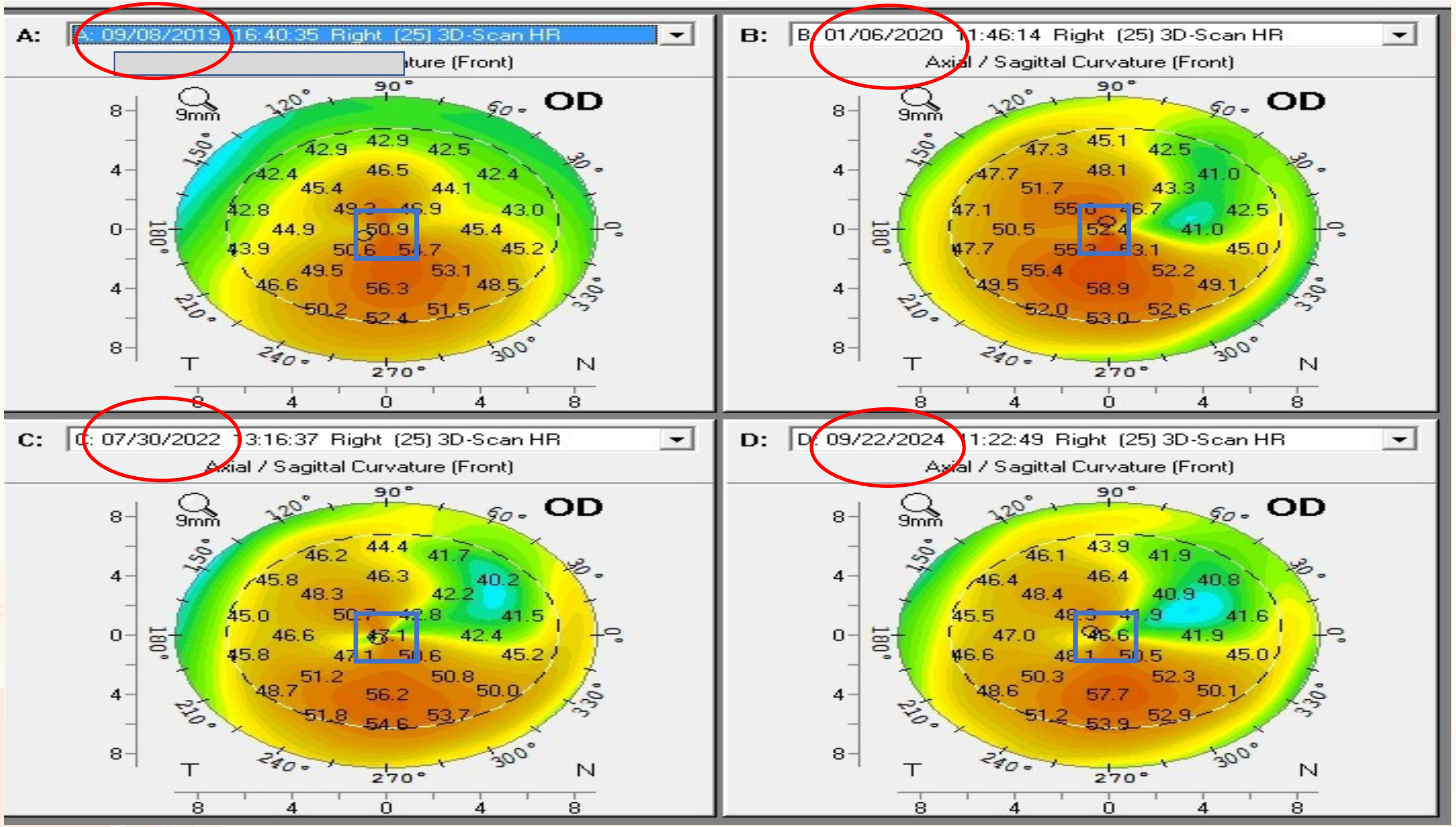
49.6 58.7 58.5
52.0 53.7 56.3


A:
09/08/2019 16:40:35 Right (25) 3D-Scan HR
ture (Front)
OD
9mm
B:
01/06/2020 11:46:14 Right (25) 3D-Scan HR
Axial / Sagittal Curvature (Front)
OD
9mm
C:
07/30/2022 13:16:37 Right (25) 3D-Scan HR
Axial / Sagittal Curvature (Front)
OD
9mm
D:
09/22/2024 11:22:49 Right (25) 3D-Scan HR
Axial / Sagittal Curvature (Front)
OD
9mm

Xenia ACED study

2023 the latest version (version x4) of the XENIA implant:

- **High degree of optical transparency.**
- **Well-balanced material strength to provide optimized corneal stabilization and regularization in KC patients.**

Xenia ACED study

On **November 2024 in Alexandria** and as a **pilot of ACED study** on the new **Xenia version IV :**

- **12 eyes were implanted.**
- **VisuMax 500** femtosecond laser and they are on follow ups.

Xenia ACED study

Patients were of advanced KC but clear corneas:

- Their K max ranged from 55 to 80.
- They are all in the age of KC activity (17~30 years).
- The thinnest pachymetry ranged from (310 ~ 480) using Ms-39.
- Xenia 4 implants of thickness 40 microns were implanted at 210 microns depth from the epithelium.

Operational steps

1. Xenia preparation
2. Femto-pocket creation
3. Xenia implantation

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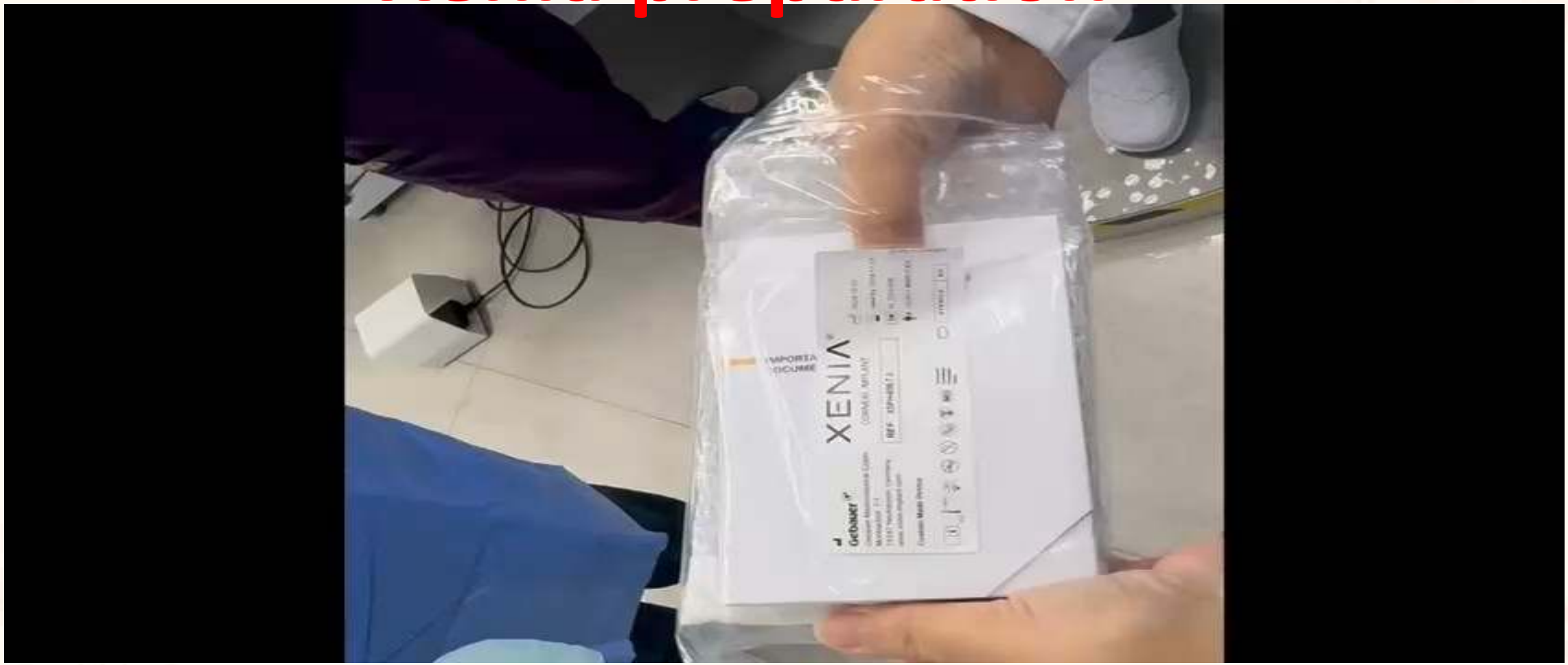
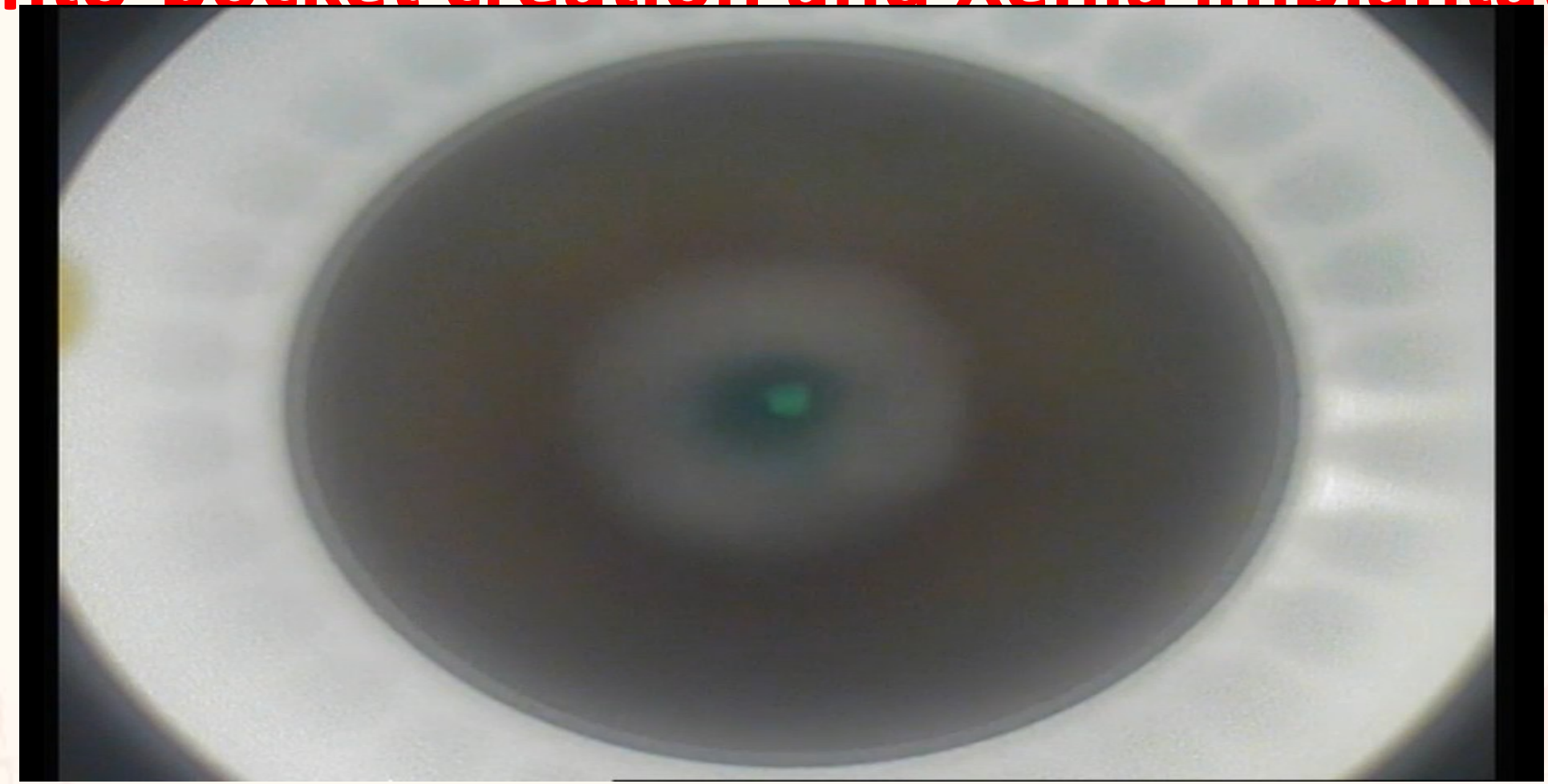
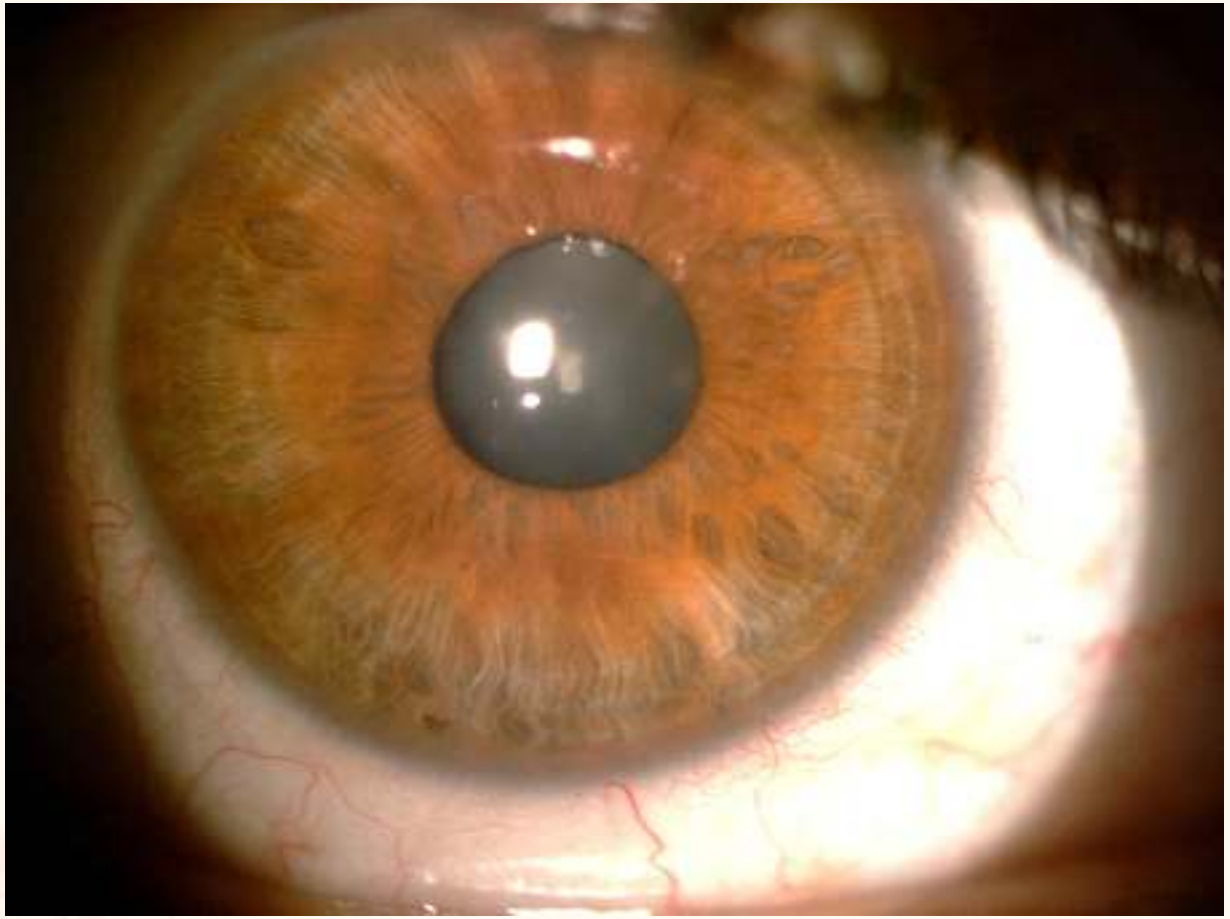
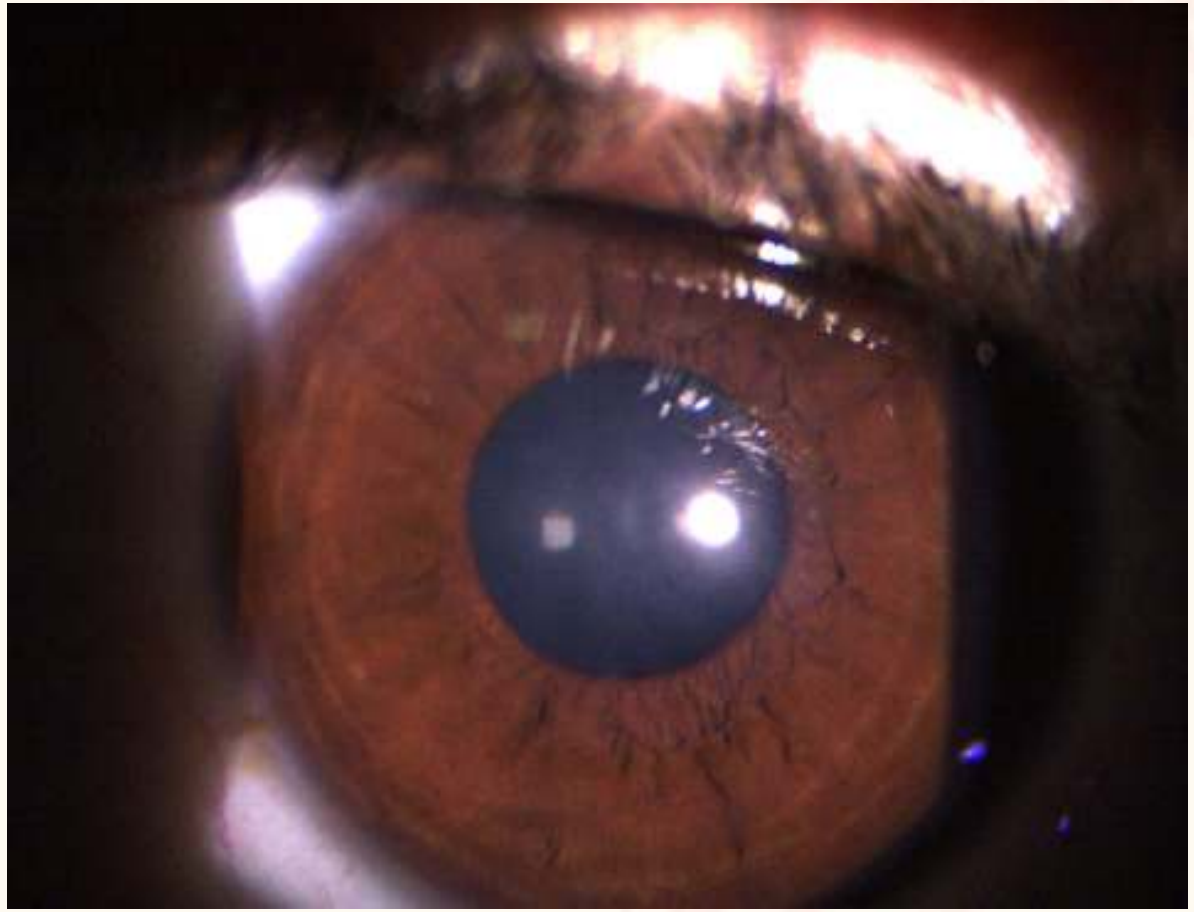
Xenia preparation



Femto-pocket creation and Xenia implantation







One week post operative

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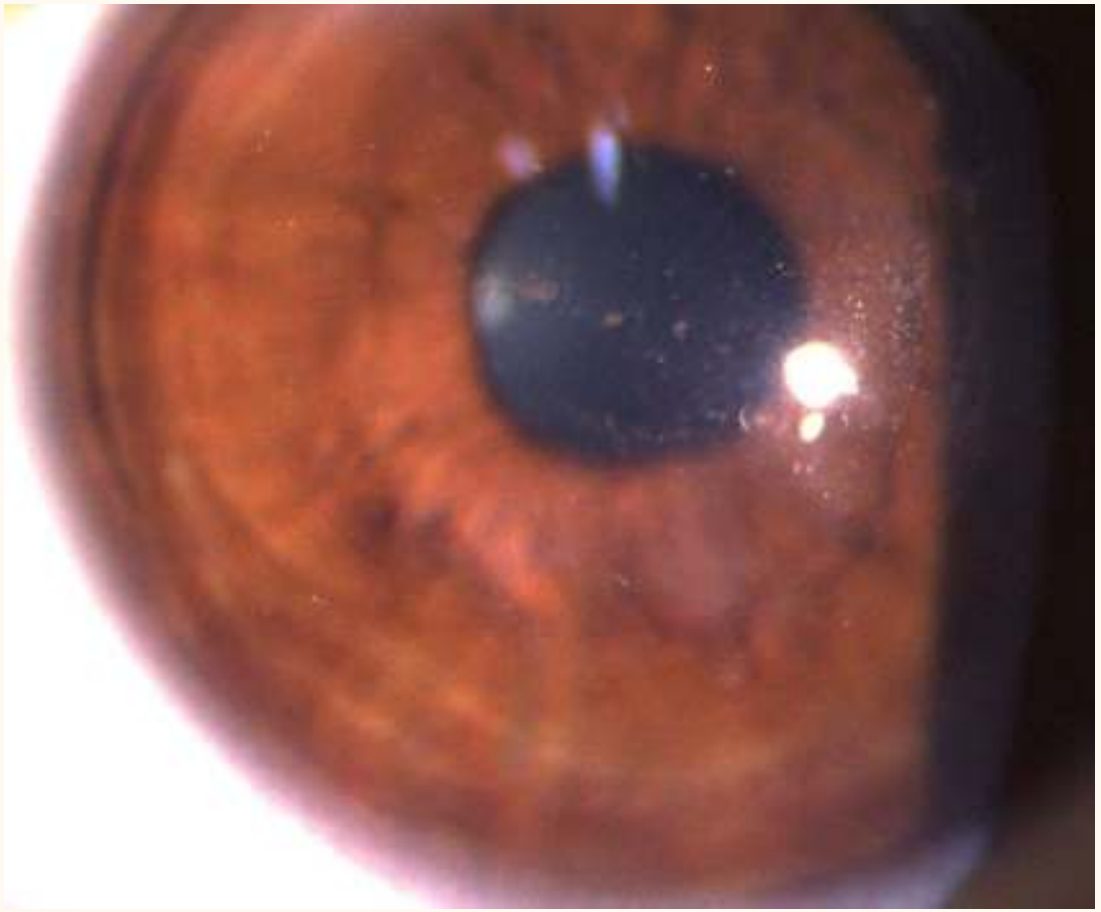
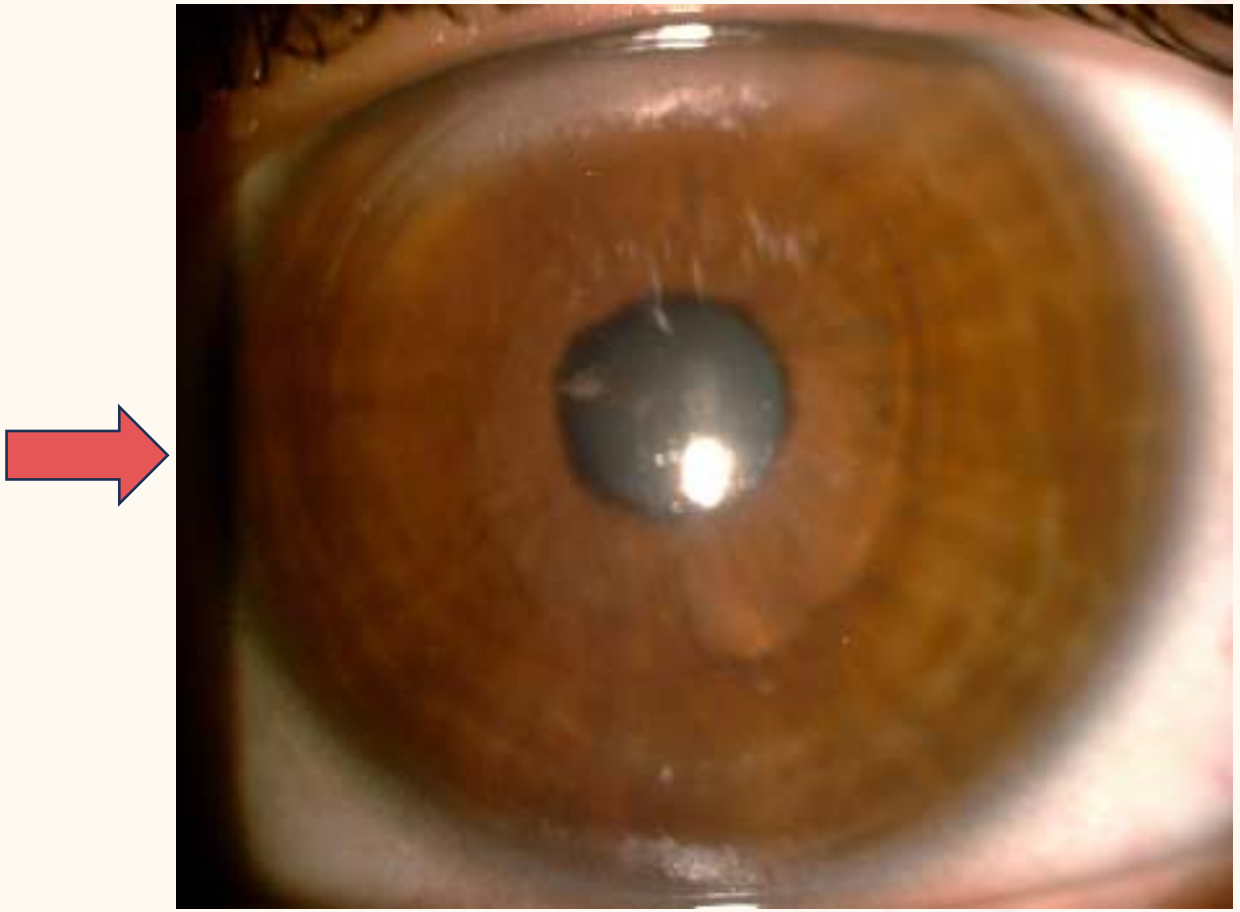
Difficulties of xenia

Difficult dissection of the





Corneal edema at D1 due to difficult dissection of femto pocket

D7 after resolution of edema

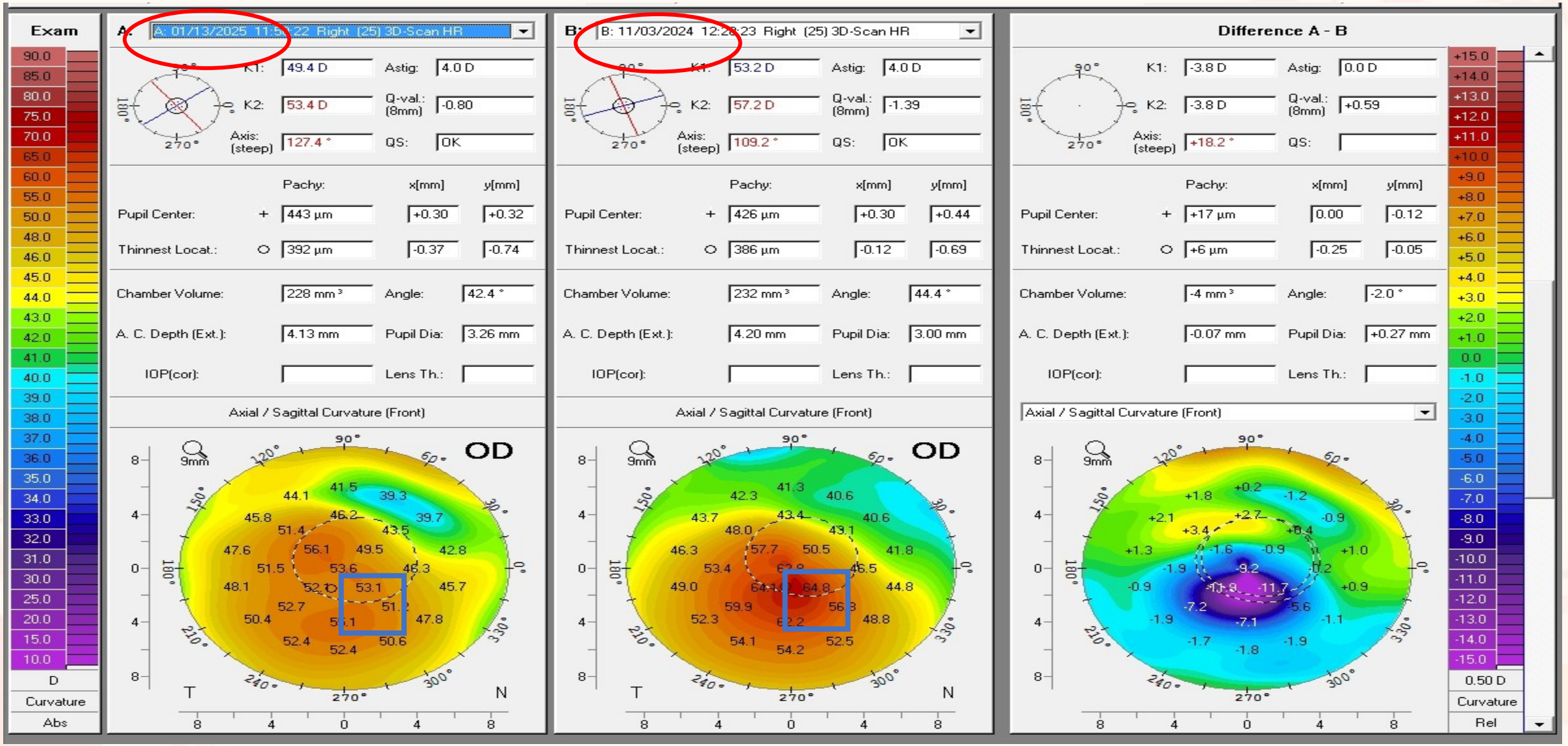
Difficult implantation of xenia

The Wow Effect of xenia !

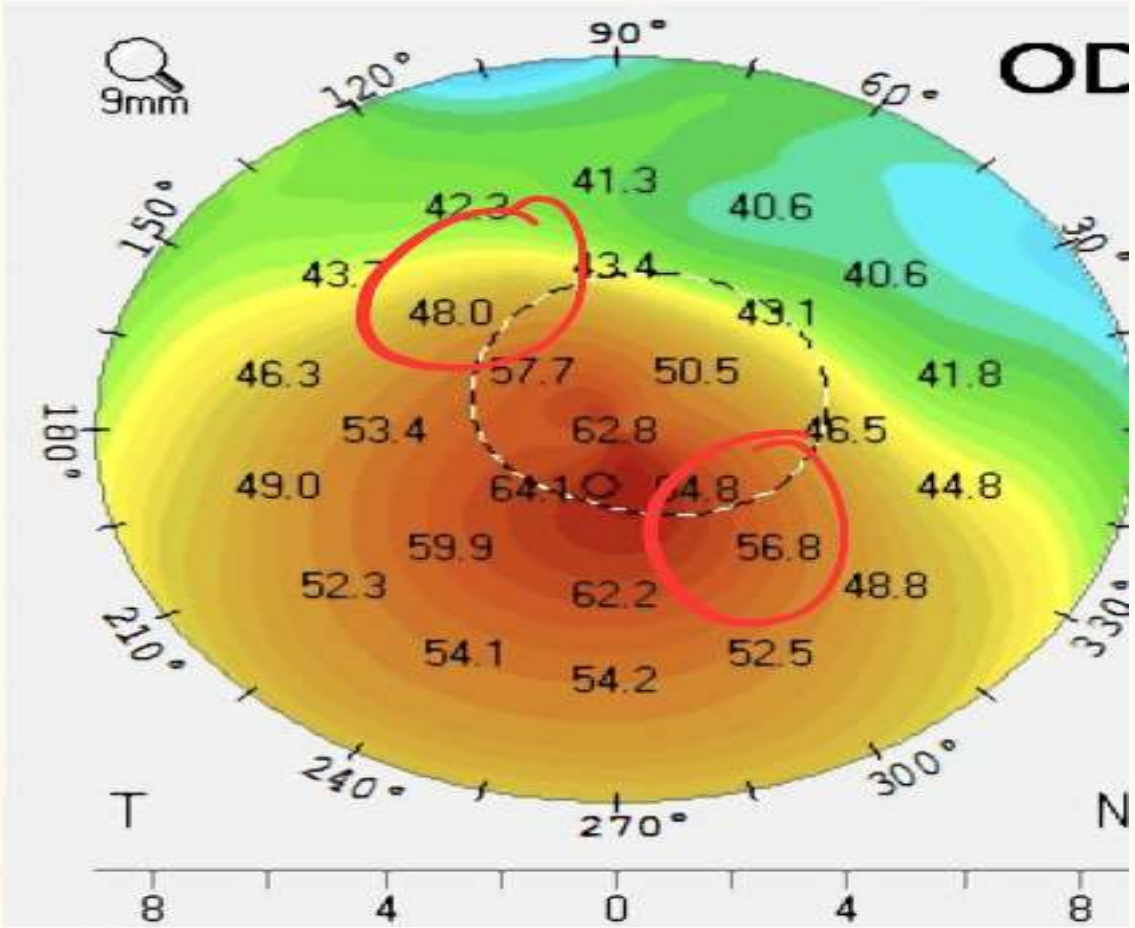
Case 1

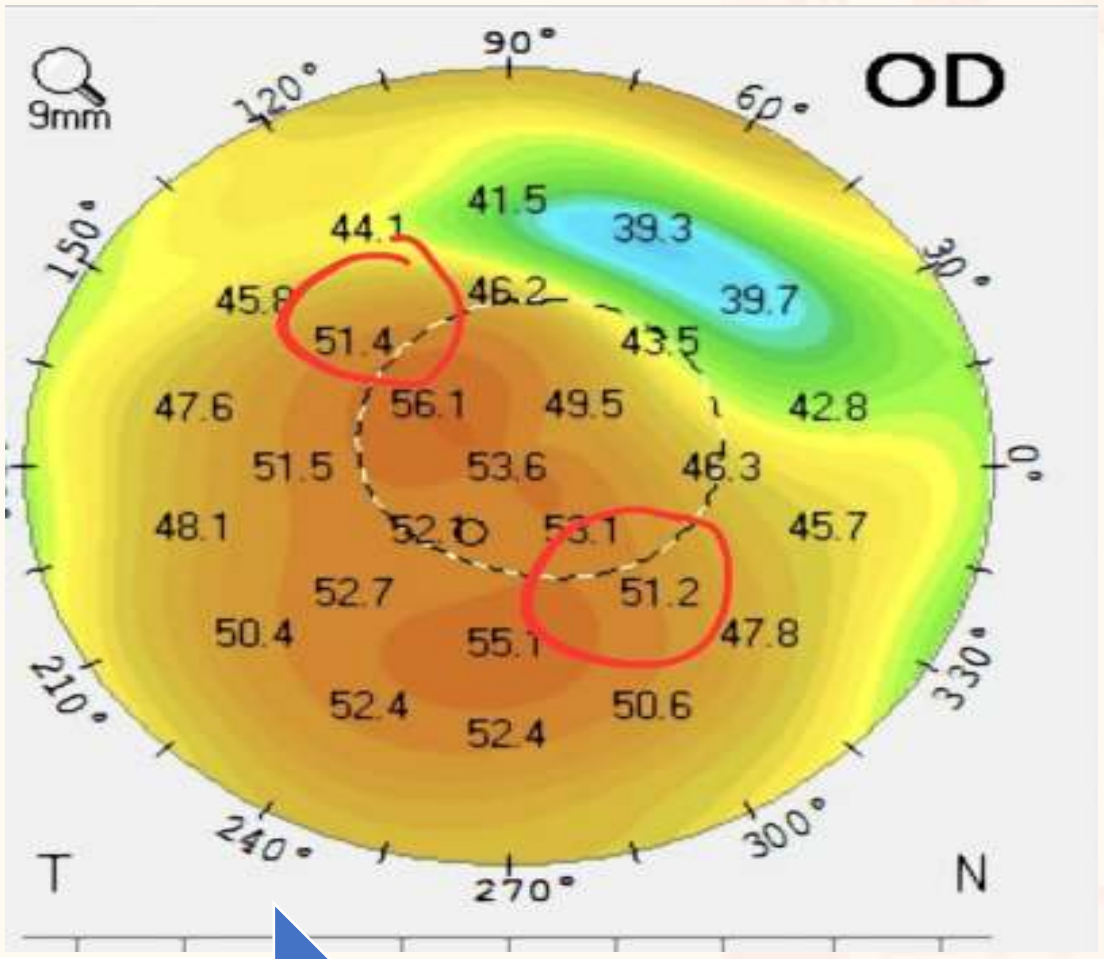
	PRE-OP	1 WEEK	2 MONTHS
UCVA	0.2	0.9	0.9
BCVA	0.3	NOT NEEDED	NOT NEEDED
COMA	-3.373	-1.930	-2.433
Sph.Aberr	-2.088	0.118	-0.801

2 months difference map



Case 2





2 months

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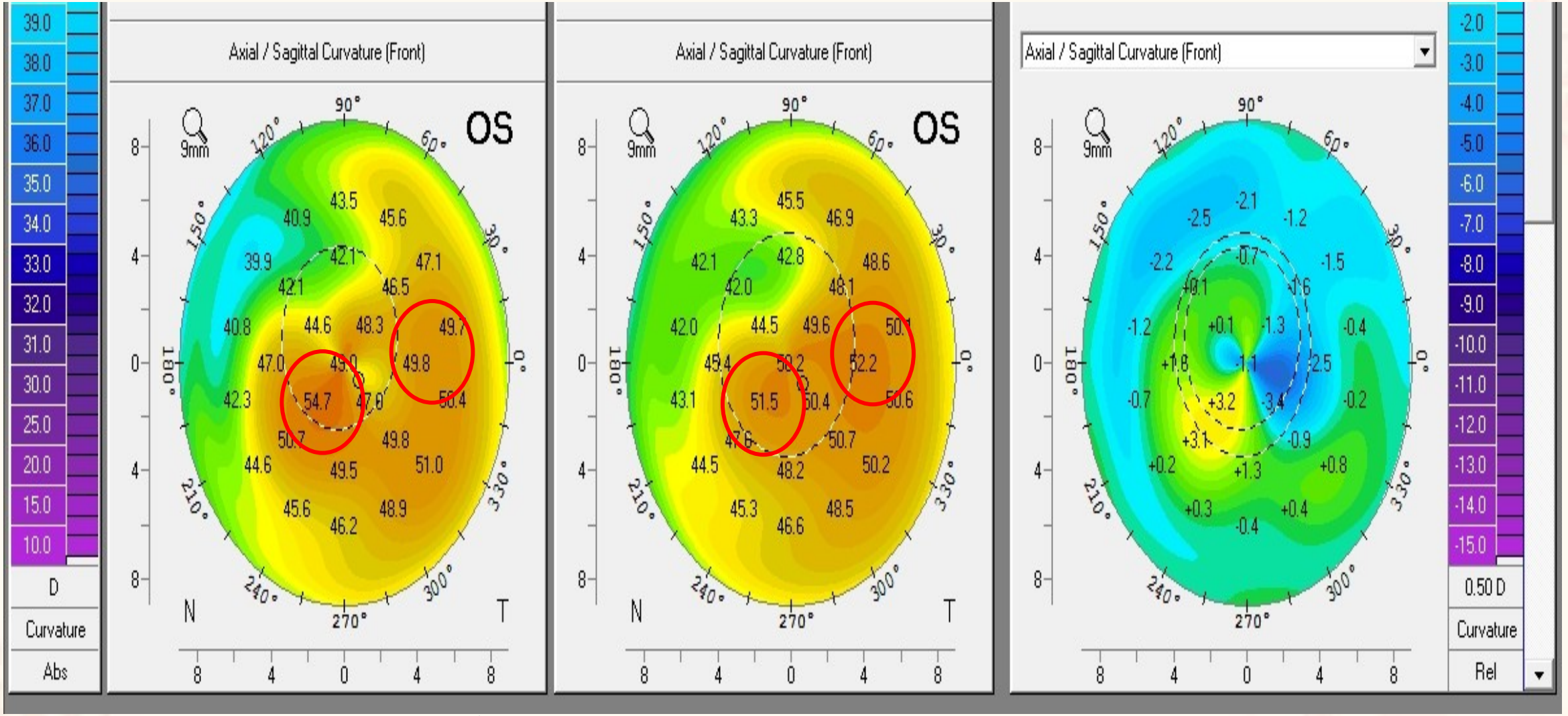
Case 3

	PRE-OP	1 WEEK	1 MONTHS
UCVA	0.05	1.0	1.0
BCVA	0.3	NOT NEEDED	NOT NEEDED
COMA	2.202	0.655	0.545
SPH.ABARR	-0.411	- 0.016	-0.091



1 MONTH

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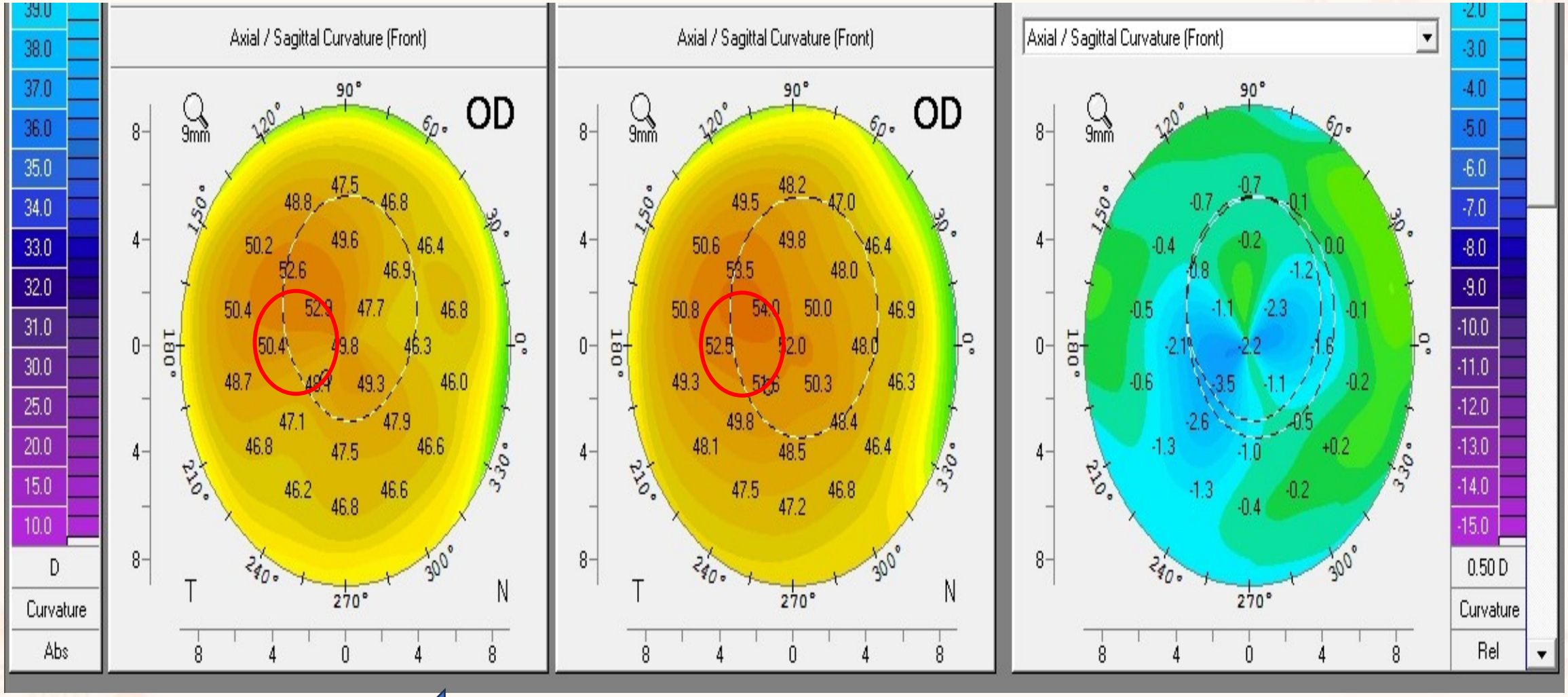
Case 4

	PRE-OP	1 MONTH
UCVA	Cf 3m	0.6
BCVA	0.3	0.8
COMA	-2.797	-0.373
SPH.ABARR	-2.10	-0.373

Case 5



1 MONTH

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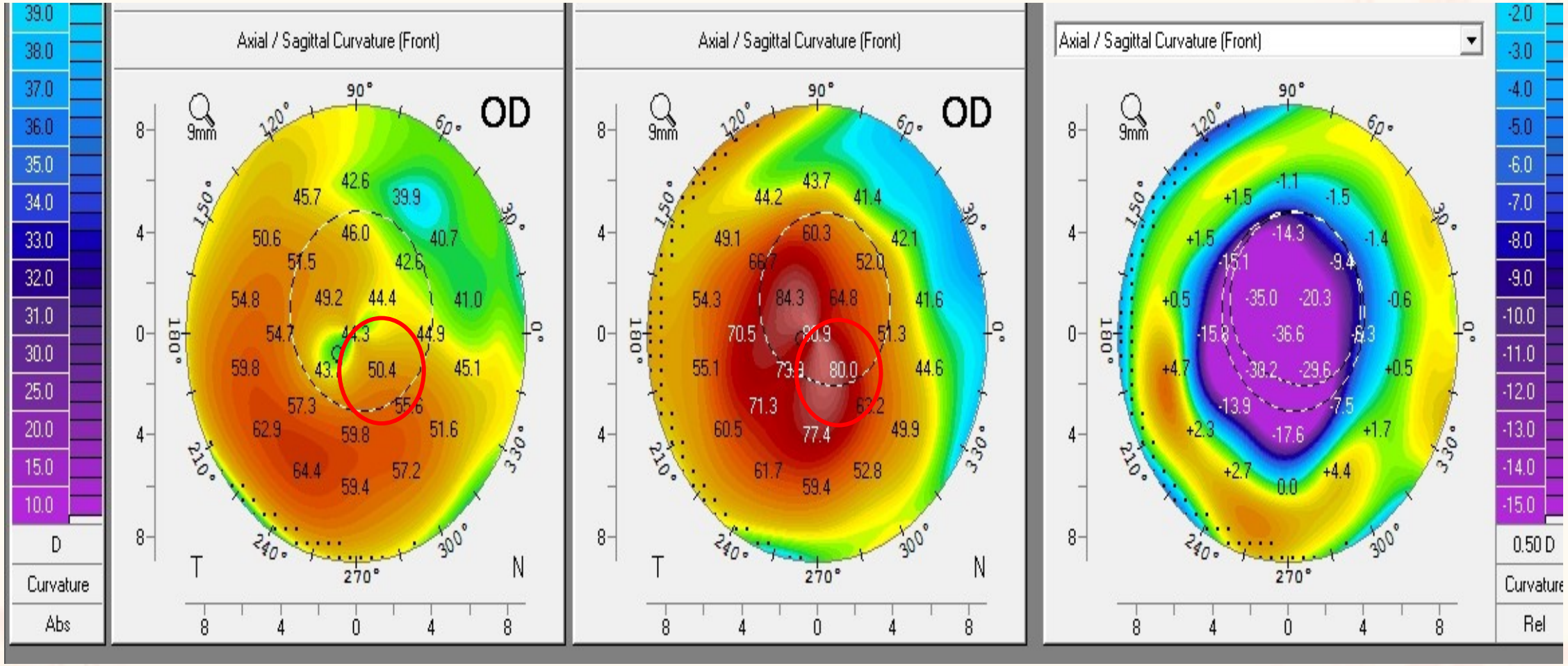
Case 5



1 WEEK

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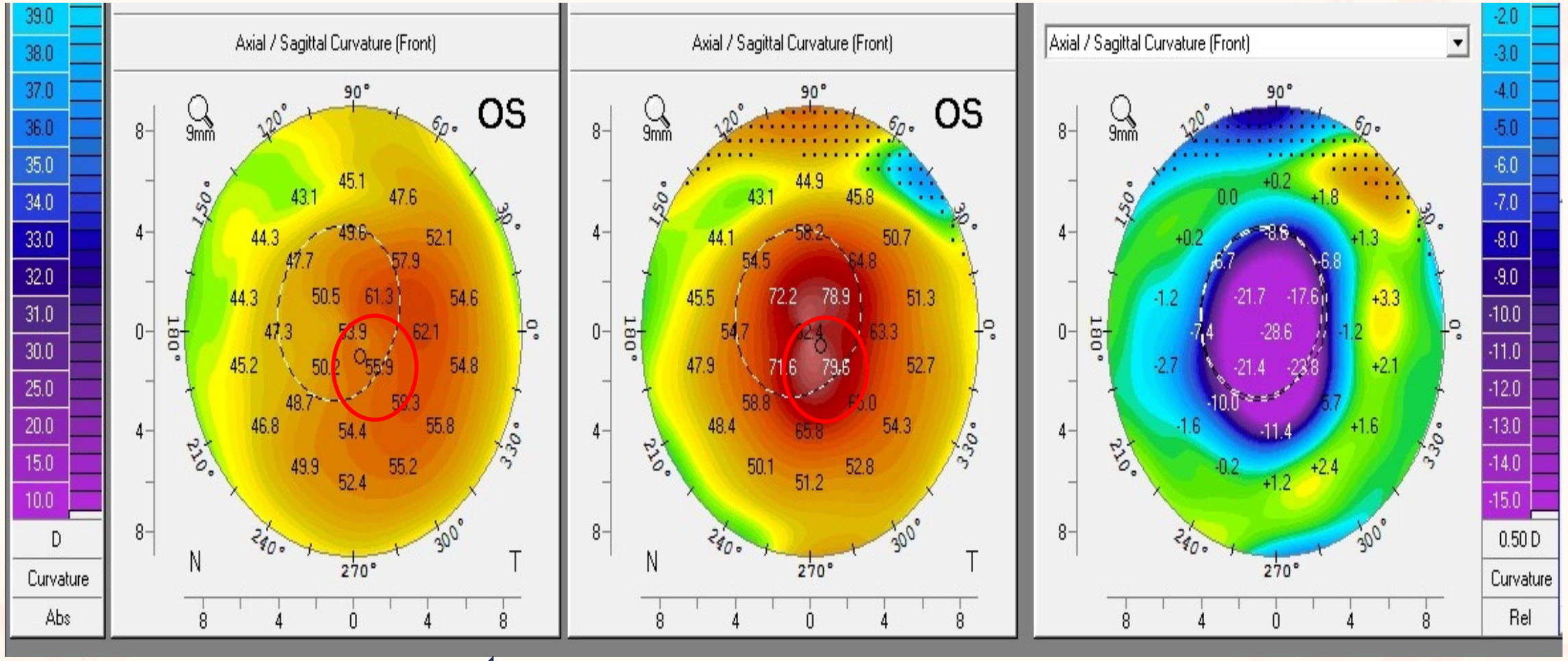
Case 6



1 WEEK

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- Central corneal flattening mean ~ 11D.
- Marked improvement of corneal HOA.
- A refractable eye in 100% of cases.
- Improvement of UCVA to 0.1 ~ 0.9
- BCVA gained more than 4 lines.

Xenia 4

REGULARIZES
Patient's Corneal Topography

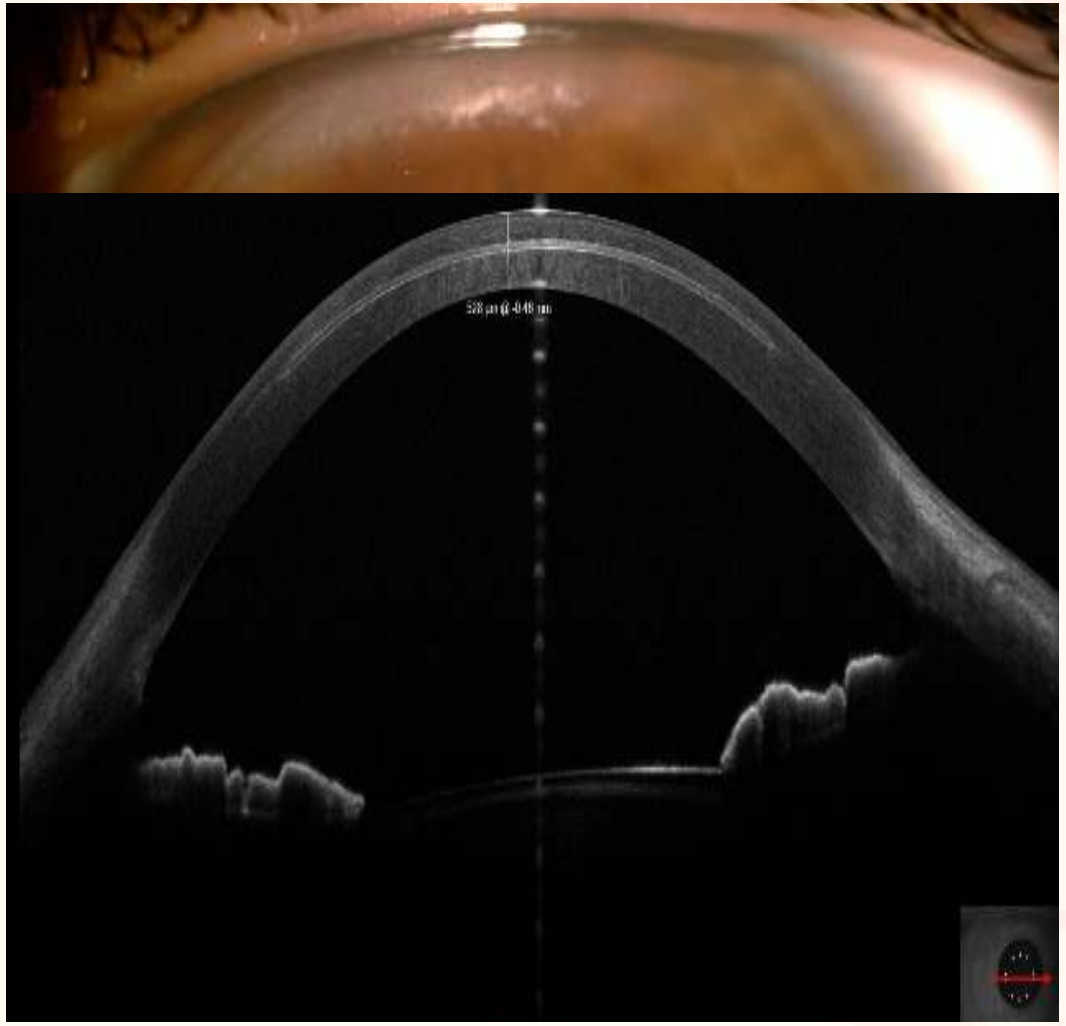
DECREASES
Higher Order Aberrations.

Xenia between past and present

- Implants have been made **more resistant**, and **more stable.**
- The implants used in **Pilot study** were **smaller in diameter** (some of them only **6.5mm**).
- The implants of the **ACED** study were used earlier March2025 was **7.8 mm diameter.**
- If Xenia reduced the diameter as directed to, 7.0mm this may have an effect on outcomes.
- **The improvements are coming from the larger diameter, deeper insertion (220 micron) and harder xenia .**

XENIA VERSION 1

XENIA VERSION 4



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Why XENIA implant is one of your Safest BET

4) Regulatory Approvals and Certifications

- International certifications and approvals.

- XENIA’s adherence to global safety standards.

-Trust from surgeons and healthcare institutions worldwide

4) Regulatory Approvals and Certifications

ORIGINAL RESEARCH

Safety and Indicative Effectiveness of Porcine Corneal Lenticular Implants in Patients with Advanced Keratoconus and Post Lasik Ectasia: A Retrospective Clinical Study

Ahmed El-Massry
Osama Ibrahim
Moones Abdalla
Ihab Osman
Shahira Mahmoud

Department of Ophthalmology, Alexandria Faculty of Medicine, Alexandria, Egypt

Purpose: This study aimed to evaluate the safety and feasibility of implanting decellularized porcine corneal lenticules in a femtosecond laser-created pocket for patients with advanced keratoconus and post-Lasik ectasia.

Methods: This is a retrospective clinical study of implanting a porcine corneal lenticule implant in seven eyes (six with advanced keratoconus and three cases and one with advanced post-Lasik ectasia with a follow-up for 12 months. The lenticules are extracted from porcine tissue, subjected to a decellularization process, intensely cross-linked, sterilized and packed. They are 7 mm in diameter with a 100–140-micron thickness. The femtosecond laser was used to create an intra-stromal pocket, and then the lenticules were implanted inside the pocket. Followed by corneal cross-linking 3 months later for six out of seven eyes.

Results: Five patients had keratoconus (6 eyes) and one patient (one eye) had post-Lasik ectasia. Visual acuity improved in all patients except for one case at 6 and 12 months and this was statistically significant ($P=0.02$ and 0.007). At one-year follow-up, the mean central corneal thickness increased from 389.43 ± 45.41 to 429.33± 63.20 µm, the maximum keratometry decreased from 64.8 ±5.11 to 62.82± 6.16 D, the mean corneal resistance factor (CRF) increased from 5.07 to 8.42, and the total higher-order aberrations decreased from 1.80 to 1.16. Both changes in the CCT and CRF were statistically significant. One eye had wrinkles and opacified graft, and it was exchanged 3 months postoperatively.

Conclusion: Porcine corneal lenticules implantation is immunologically safe and well tolerated in patients with advanced keratoconus and post-Lasik ectasia and may be feasible as an alternative to keratoplasty.

Keywords: keratoconus, keratoplasty, femtosecond, ectasia

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Lenticular Intrastromal Keratoplasty for Keratoconus

Chapter | First Online: 28 October 2022

pp 989–998 | Cite this chapter

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Keratoconus

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5) Cost-Effectiveness

Long-term **cost savings** due to fewer complications and replacements.

-**Lower post-operative** care **costs.**

-**Competitive pricing** without compromising on quality.

Conclusions

Tissue augmentation with decellularized Porcine lenticules (XENIA Implants) and Corneal cross-linking results in *improvement in*

- **Visual acuity.**
- **Corneal Curvature.**
- **Corneal hysteresis.**
- **Decreased Corneal higher order aberrations.***

* Safety and Indicative Effectiveness of Porcine Corneal Lenticular Implants in Patients with Advanced Keratoconus and Post Lasik Ectasia: A Retrospective Clinical Study. Clinical Ophthalmology. 26 July 2021.
Ahmed El-Massry, Moones Abdalla, Ihab Osman, Shahira Mahmoud.
https://www.dovepress.com/getfile.php?fileID=72045

Conclusions

- Five years follow up , confirmed the transparency, and ***Immunologically Stable Implants***, improvement of Pentacam readings, increased thickness by U/S pachymetry.*
- Further studies with a ***larger number and longer follow-ups , new version of the Implants*** are needed to confirm its effectiveness and stability over time.

* Lenticular Intrastromal Keratoplasty for Keratoconus. Keratoconus. Chapter First Online: 28 October 2022 Mirko R. JankovII & Ahmed Elmassry https://link.springer.com/chapter/10.1007/978-3-030-85361-7_86

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