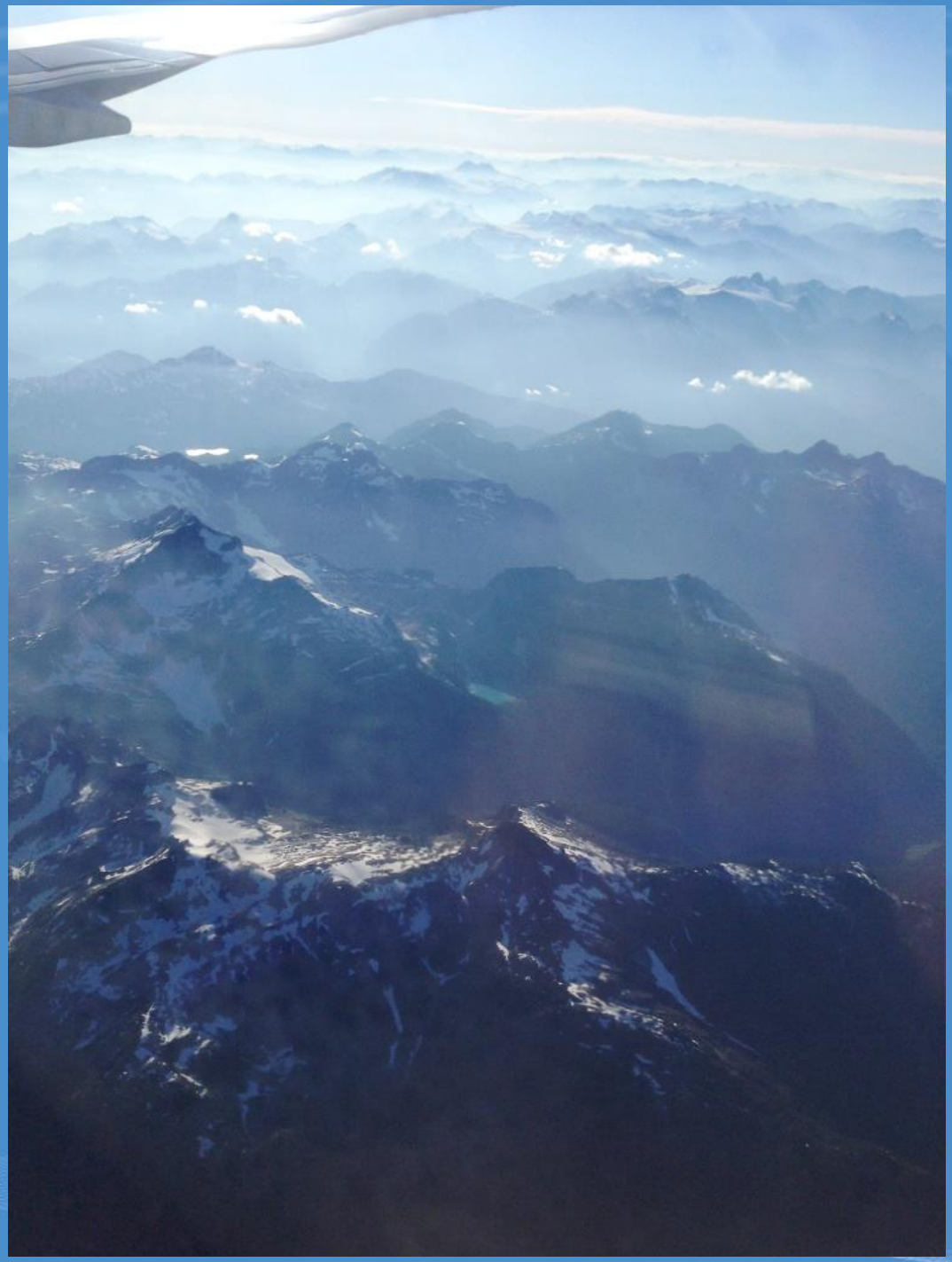
SCHWIND eye-tech-solutions

# ViTAL Keratoconus Classification,

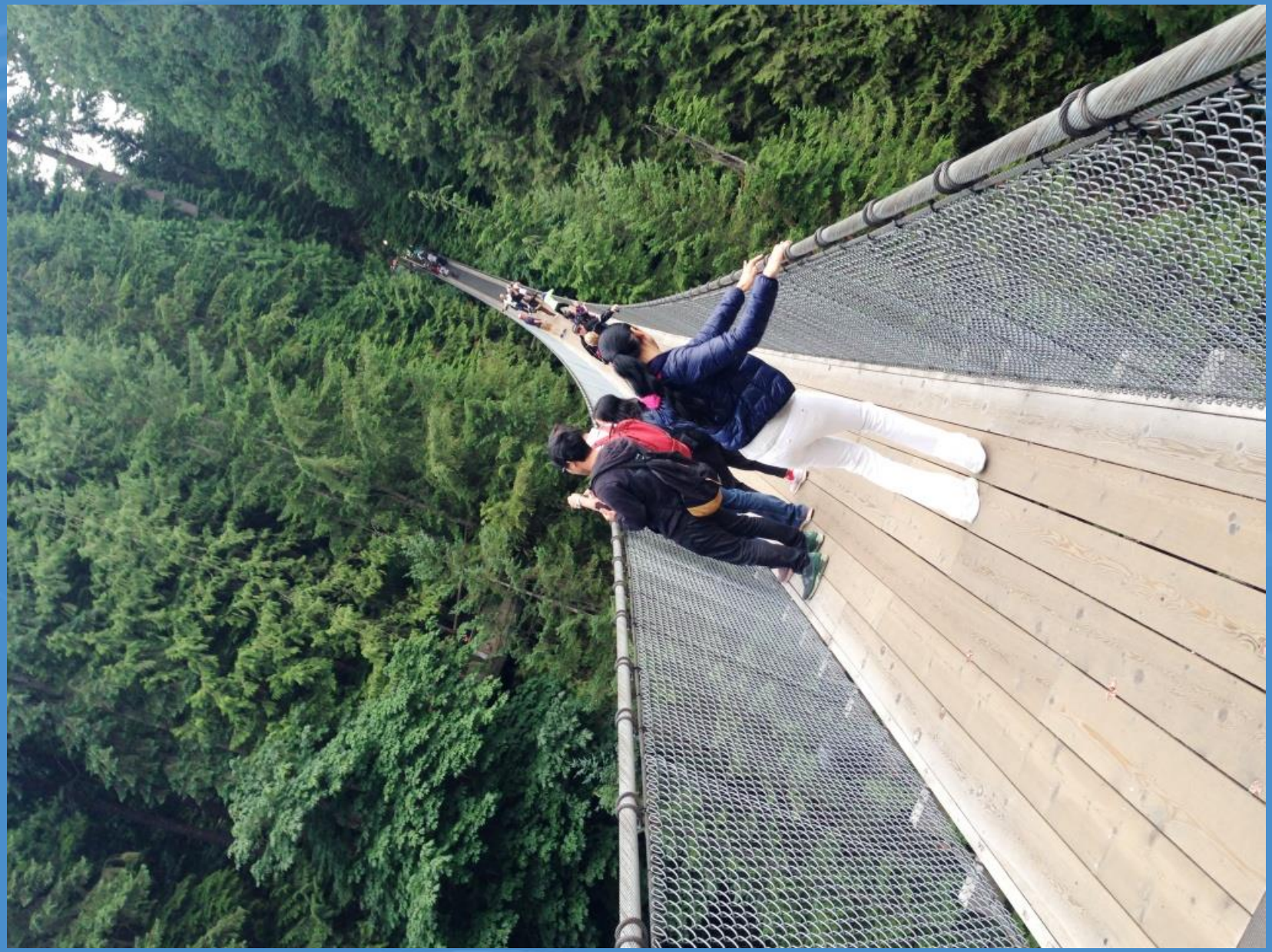
## The AMART (or SECRET) & Gregory Lens Projects


**Anastasios Charonis MD PhD**
**Medical Director, AthensVision Eye Institute**
anastasioscharonis@athensvision.com


Athens Vision



Athens Vision



**Purpose**:

- ✓ To describe a classification system for keratoconus designed to address present and future therapeutic options for the individual keratoconus patient

  **ViTAL Classification**

- ✓ To present an Excimer Laser based technique to treat early, moderate and advanced keratoconus

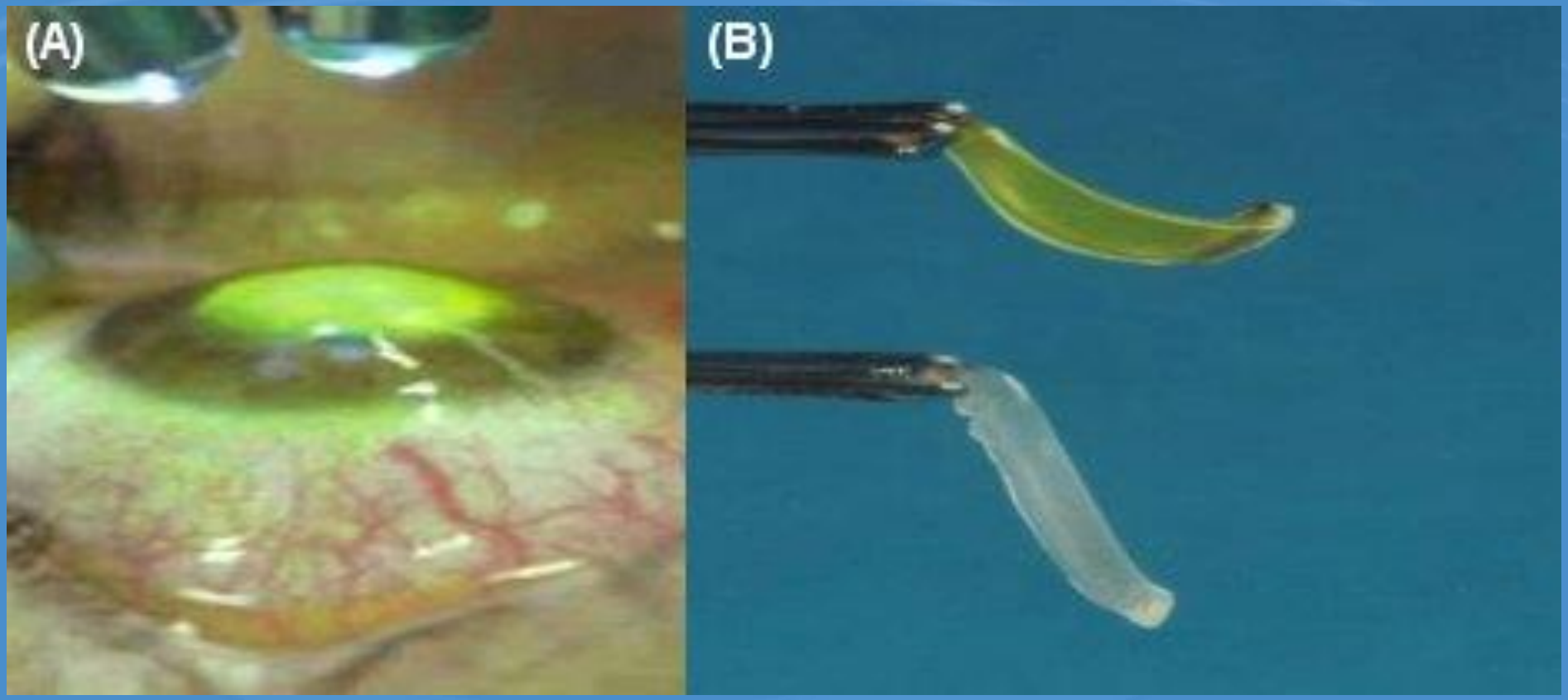
  **The AMART (SECRET) Project**

- ✓ To present an idea for a novel iris supported phakic IOL

  **The Gregory lens Project**

# Wikipedia search for LATERAL THINKING

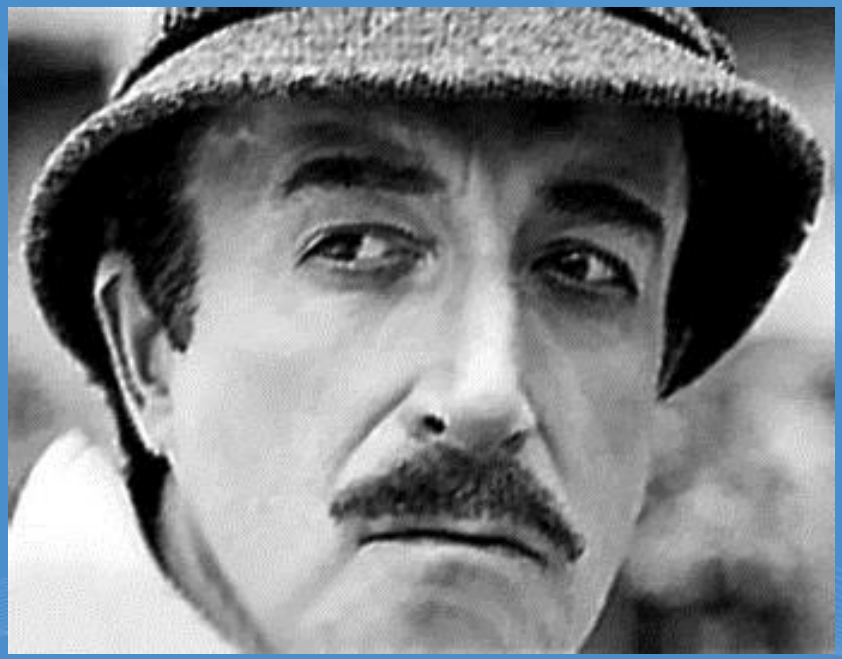
- **Lateral thinking** is solving problems through an indirect and creative approach, using reasoning that is not immediately obvious and involving ideas that may not be obtainable by using only traditional step-by-step logic. The term was coined in 1967 byEdward de Bono. [1]




CXL –Dresden protocol, C3R, TransCXL, Triple CXL,Reverse Bioptics CXL,  Athens Protocol, accelerated CXL, KXL, KXL II, PRK-xtra, Lasik-xtra PACK-CXL, PiXL…….

# Greek Tabloid 1/2014
# “Myopia Terminated with Drops”

“ This revolutionary application …invented in Greece…..is approved for clinical use in Europe (CE Mark) “



# Avedro's PiXL

- **Novel myopic refractive correction with transepithelial very high-fluence collagen cross-linking applied in a customized pattern: early clinical results of a feasibility study**

Clin Ophthalmol. 2014; 8: 697–702.

Published online Apr 7, 2014. doi: 10.2147/OPTH.S59934

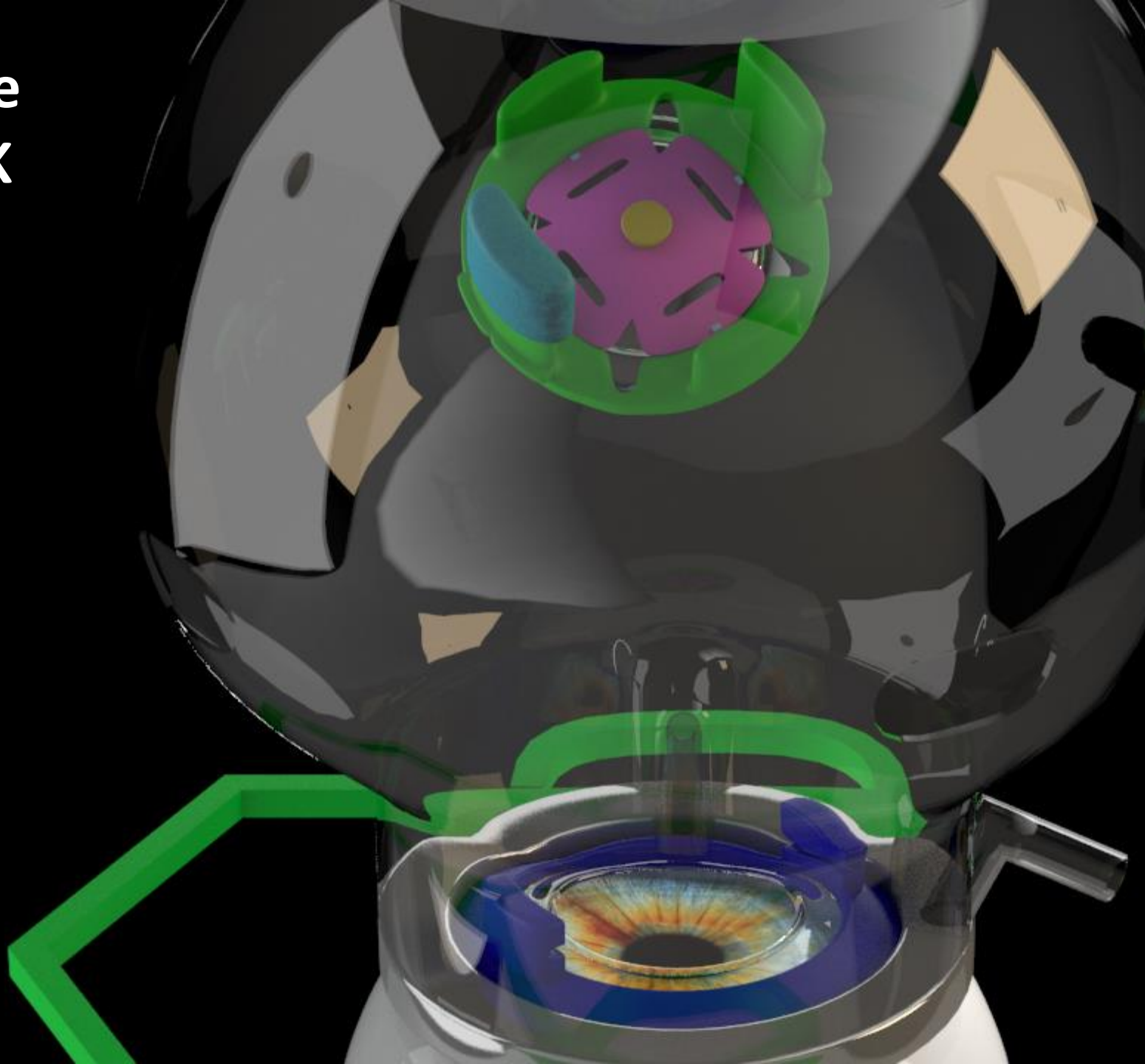
PMCID: PMC3984063

# Personal Lateral thinking in Corneal Surgery

**It is possible to perform PKP/Open Sky Surgery without ever losing the IOP >>the Eyelock KP system**

**It is possible to perform PKP surgery without sutures and without glues and still have the strongest attachment ever >> the T- Kplasty system**

# 2014:The EyeLOCK V.03 Device



Athens Vision

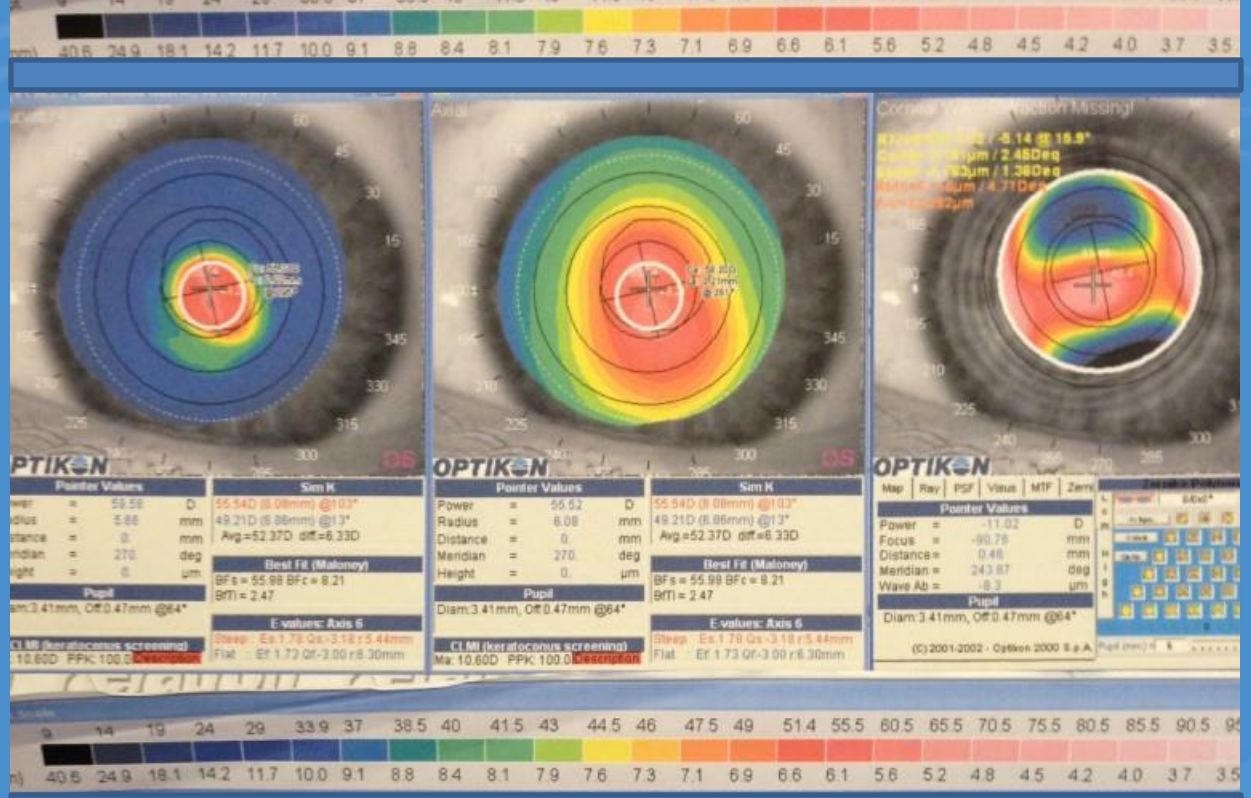
- It is theoretically possible from a simple classification system to predict which keratoconic patient needs which specific (surgical) treatment option

- It is theoretically possible to perform up to -9.00 dpt of ablative excimer laser surgery in a “stable” patient with keratoconus without jeopardizing his recently crosslinked cornea

- It is theoretically possible to manufacture and and place a phakic iris enclavated lens
  - with micron 3D Accuracy in order to safely correct all higher order aberrations.
    - 100% LOS and XY alignment
  - <2mm incision size
  - Procedure accessible to the average surgeon

# *background*

- Not long ago surgical options for keratoconus were limited to PKP or DALK
  - Curvature based classification systems for keratoconus were adequate
- With introduction of new techniques like corneal inlays, wavefront ablation/CXL & phakic IOL's current curvature classification systems do not predict success/failure




**BSCVA**
20/80
**RGP** VA
20/20
**AbVol**
2400nl


**BSCVA**
20/32
**RGP** VA
20/20
**AbVol**
4400nl

ision

# Stage III Keratoconus

**FOSTERING: (<<Insert Area Office>>)**
**Specialist Children's Services**

<<Insert Office Address
<<Address Line 1>>
<<Address Line 2>>
<<Address Line 3>>
<<Post Code>>

Direct Dial/Ext: <<Insert>>
Ask for: <<Insert>>
Your ref: <<Insert>>
Our ref: <<Insert>>
Date: <<Insert>>

Dear <<Insert>>

The above named * applied to foster for Kent County Council. The Fostering Services (England) Regulations 2011 require us to obtain a full medical report before we can give final approval to this application.

We hope to place children into families where they will be accepted and find security and affection. It is important that foster parents have a positive attitude to life and to fostering and that they do not suffer from any significant emotional instability or serious physical disorder which might render them unable to care for a child should the child remain with them until the age of independence.

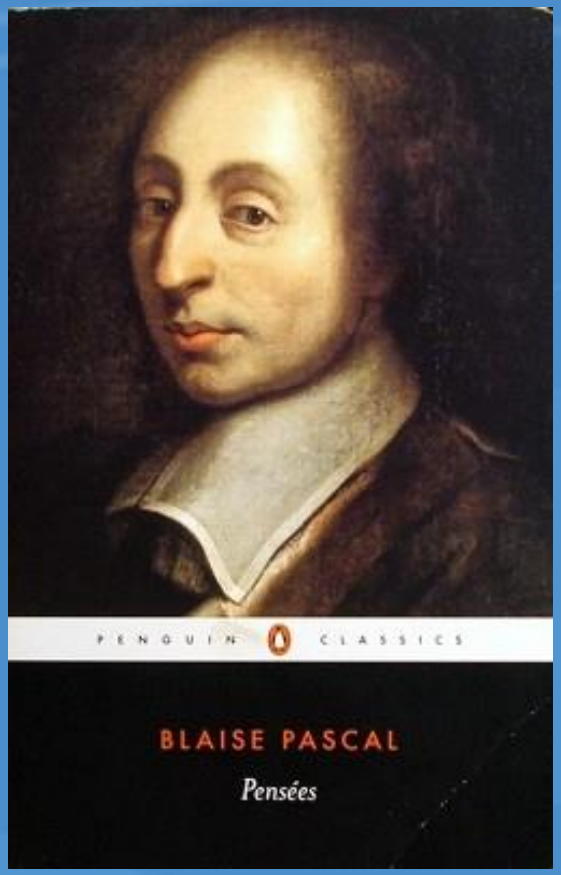
We should be grateful, therefore, if you would arrange for the enclosed questionnaire and medical report to be completed. Kent Area Health Authority has agreed to pay fees on the scale recommended by the Doctor's and Dentist's Review Body applicable throughout the United Kingdom and accepted by the B.M.A. and when we receive your report we will apply to the Kent Area Health Authority on your behalf.

We would ask that a careful review of the applicants mental and psychological health is considered and that any issue that would be significant to their parenting capacity to be recorded on the medical report.

If you have any doubts as to * suitability, it would be helpful if you would discuss with * the difficulties * might encounter if * foster/s a child and/or the reasons why we might not feel able to accept the application.

Should your report indicate certain abnormalities in an otherwise suitable applicant, additional medical information may be required, and if this is so, our Medical Adviser will write to you again. Alternatively, you could discuss any such concerns directly with our Medical Advisor whose contact details can be obtained through this office.

I enclose written consent to a medical examination, dated , indicating that do/do not wish to see the completed medical report, by right of the Access to Medical Reports Act, 1988. *As/When sight of the report is not required, please return the completed report to me as soon as possible. When the patient wishes to see the report the Act requires you to

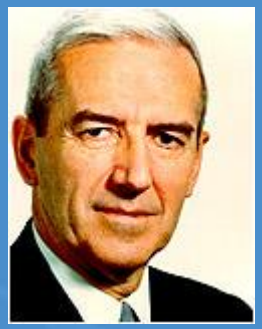



$Vi_2T_{3S}A_2L_1$

“I have only made this letter longer because I have not had the time to make it shorter."
(*Letter 16*, 1657)”
— **Blaise Pascal**, ***The Provincial Letters***

# **ViTAL** Classification for keratoconus

Pierre Denoix (1912-1990)
(1943-52)



GUSTAVE ROUSSY
CANCER CAMPUS
GRAND PARIS

**T umor**
**N odes-(lymph-)**
**M etastasis**

## Ablation Volume

Amount of tissue that needs to be removed in order to regularize keratoconic surface -corneal WF theory!)

Derived from the curvature>elevation topographical disparity from "norm"

incorporates curvature abnormality + Refractive Error of eye of interest

Athens Vision

# ViTAL

| | |
|---|---|
| **Vi** | Vision (BSCVA) |
| **T** | min Thickness |
| **A** | Ablation (ORK-CAM)* |
| **L** | Length (AC Depth) |

- **Extra denominator**

**U /P/ S** **unknown/ progressing /stable** Topography

*ablation volume in nL theoretically needed in CW module to regularize surface **(TAZ 8,30mm)**

Athens Vision

# Vi: BSCVA

- $Vi_1$ 20/20-20/25
- $Vi_2$ 20/32-20/50
- $Vi_3$ 20/63-20/100
- $Vi_4$ <20/125

# Thickness NOT topography (min pachymetry)

- T1 >500min
- T2 >450min
- T3 >400min
- T4 <400min

- Extra denominator

U: unknown stability

P: progressing topography

S: Stable topography

O: opaque –centrally scarred cornea

Eg $T_{4SO}$ = thin & centrally scarred but stable topography

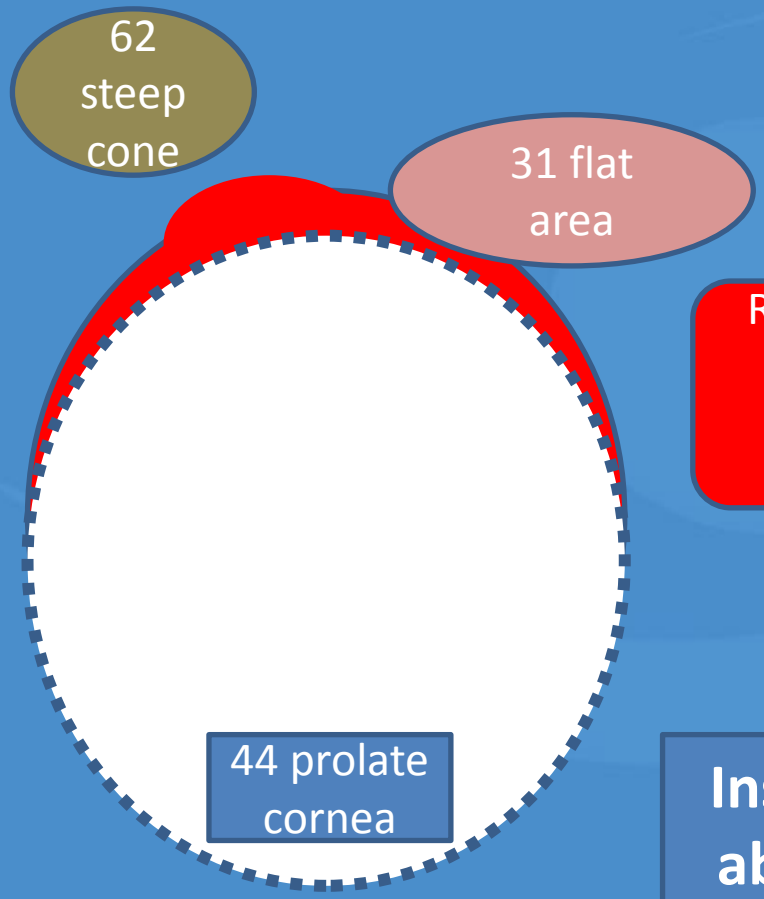
# Length (AC Depth)

- *L1 >3,4mm*
- *L2 >3,1mm*
- *L3 <3,1mm*

# “Ablation”

- Derived from the predicted Volume to be **theoretically** ablated (in nL) from the CornealWF module of the Schwind-Amaris CAM in order to regularize the particular cornea towards EMMETROPIA
  - Total Ablation Zone (TAZ) limited to 8.3mm
  - Full Zernicke Fitting and max allowed refractive correction (eg A -8.00 cyl will be reduced to -6.00 or -5.00)

# KC cornea with steep and flat areas
# Principle of Ablation topography of the KC eye



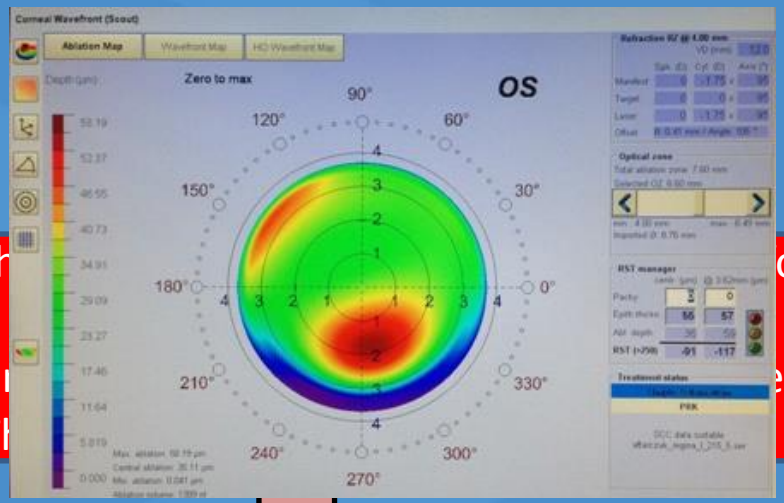

RED : th

Targeti

Th

or

e)



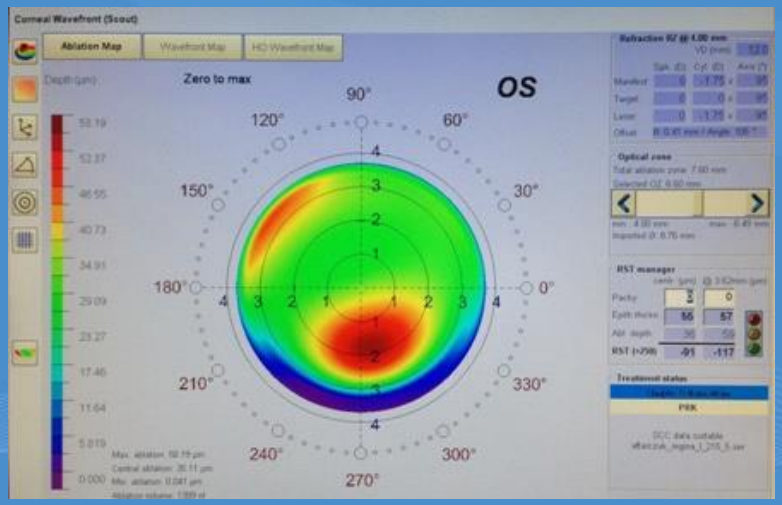

**Instead, we reduce the steep areas by ablating on the cone and steepen the flat areas by ablating distant To the flat areas according to the OZ**

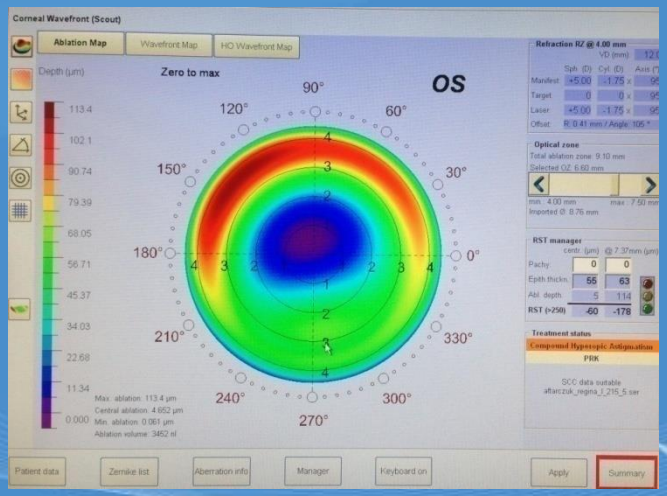
# Why “Ablation” is the single most valuable metric in our system :

- Ablation Volume for the irregularly shaped keratoconic cornea is an excellent metric of the topographic abnormality AND refractive status
- Ablation volume is a function of the P-V (Peak to Valley) value on the Schwind-Keratron Topographical unit.

# An example…….

- The same Keratoconic Cornea requires a totally different excimer laser treatment ablation profile if it belongs in a 20 or a 25mm (or 30mm)Eye and therefore in the ViTAL System they are classified differently!!

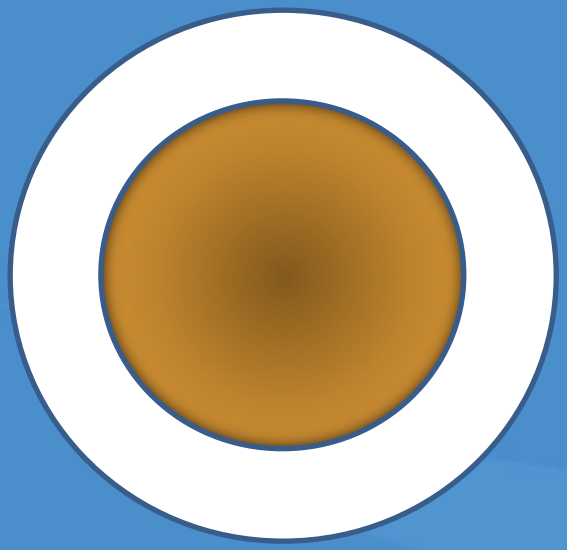


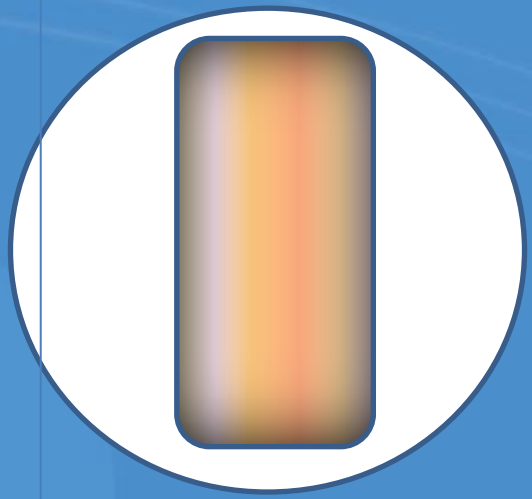



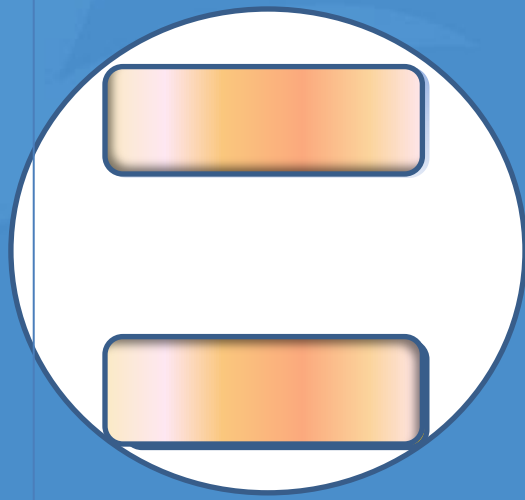
- In fact, Ablation Volume may be a better metric then refractive error dioptric values when it comes to considering Excimer Laser Candidancy for ALL refractive Errors TOGETHER (like in case of KC eyes)

Myopia

Hyperopia







# ORK-CW Ablation Volume in KC
## is a metric of topography+refraction!

| 12,0 vertex | Nominal OZ | Max Depth | Overall Ablation | Abl Volume |
|---|---|---|---|---|
| -10.00 sph PRK | 6. 50 | 148 | 9.00 | **3360-90nl** |
| -10.00sph Lasik | 6,50 | 154 | 8,47 | **3242-65nl** |
| Plano -5,50x90 (lasik) | 6,50 | 99 (centr 88) | 8.71 | **3291nl** |
| Plano+5.50x90 (lasik) | 6,50 | 105 | 8,82 | **1885nl** |
| +5,50 sphere | 6,50 (6,75) | 107 (115) | 9.00 (9,25) | **3913 (4367)** |

Ablation volumes are easier appreciated and are more clinically relevant then pure numbers in orthogonic (routine) refractive Errors for the refractive surgeon

In Higher order Refractive Errors the Ablation Volume describes the topographical abnormality for a given refraction (axial length etc..) therefore is much more suitable then topography staging or refraction alone for excimer laser prediction

# (ViTAL) Ablation (nL Volumes)

- Ablation volume < 550nl $A_1$
- Ablation volume < 2500nl $A_2$
- Ablaion volume < 3500nl $A_3$
- Ablation volume > 3500nl $A_4$

**75% of Stage III KC is classified as $A_3$ or less**

# (ViTAL) Ablation (nL Volumes)

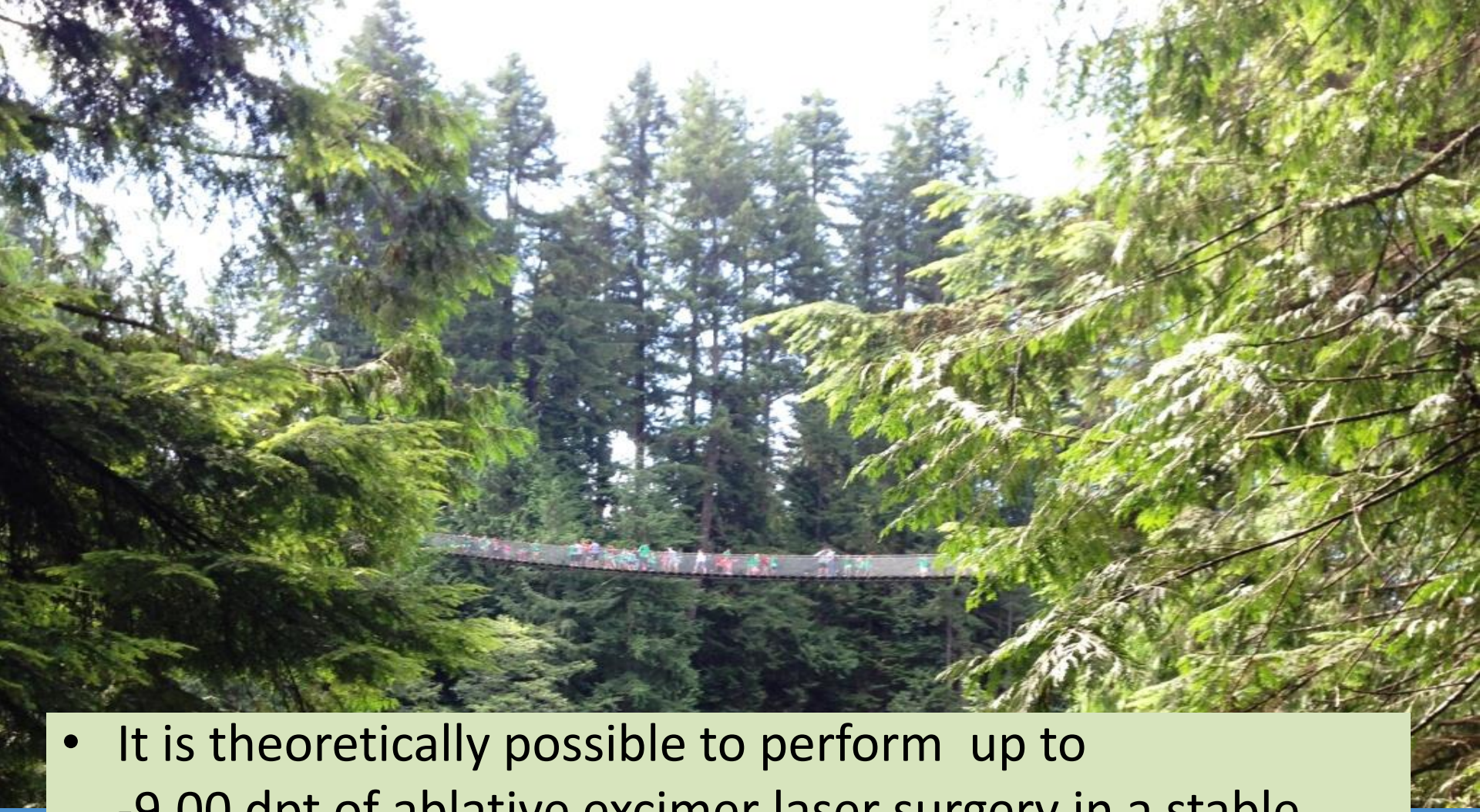
| | | |
|---|---|---|
| • Ablation volume < 550nl | $A_1$ | CW PRK |
| • Ablation volume < 2500nl | $A_2$ | AMART |
| • Ablaion volume < 3500nl | $A_3$ | T-AMART xtra |
| • Ablation volume > 3500nl | $A_4$ | PALK |

# Definition of $A_1$ Keratoconus

## A1 keratoconus Keratoconus amenable to CW Ablation

Keratoconus amenable to CW Ablation with the Amaris Schwind laser is classified as A1 Keratoconus

Currently we define A1 as ablation of less or equal to 550nl. This is roughly the equivalent AblVol of 2 dpt of myopia with a 6,50mm OZ



- It is theoretically possible to perform up to -9.00 dpt of ablative excimer laser surgery in a stable patient with keratoconus without jeopardizing his recently crosslinked cornea

  **We achieve this by (preferentially!)thickening out the "healthy" parts of the cornea**

- **CAN WE ABLATE MORE TISSUE…let's say the equivalent to -9 dpt of myopia in keratoconic eyes ??**
- **Can we ablate more then 5 dpt in the plus direction?**

Athens Minimal Additive Refractive Treatment (AMART)

miniEpikeratophakia-mini EPI

Ablatable Epikeratophakia –A

Micrograft

Customized Collage

Subepithelial Coll

Sub Epithelial Coll ET)

Schwind's Minimal A ment (SMART)

# There are over 30.000 DS(A)EK cases performed in the US/Europe yearly


**Nano/ Femto LaserFabrication of Refractive Neutral Lenticles with Planar Configuration**

Athens Vision

# The AMART PROJECTS

Athens

Minimal

Additive

Refractive

Treatment

Addition of 7500nL of tissue
To thicken the cornea by 120µ
(lamellar 9,25mm planar graft)

# Epikeratophakia

**Werblin/Kaufman**

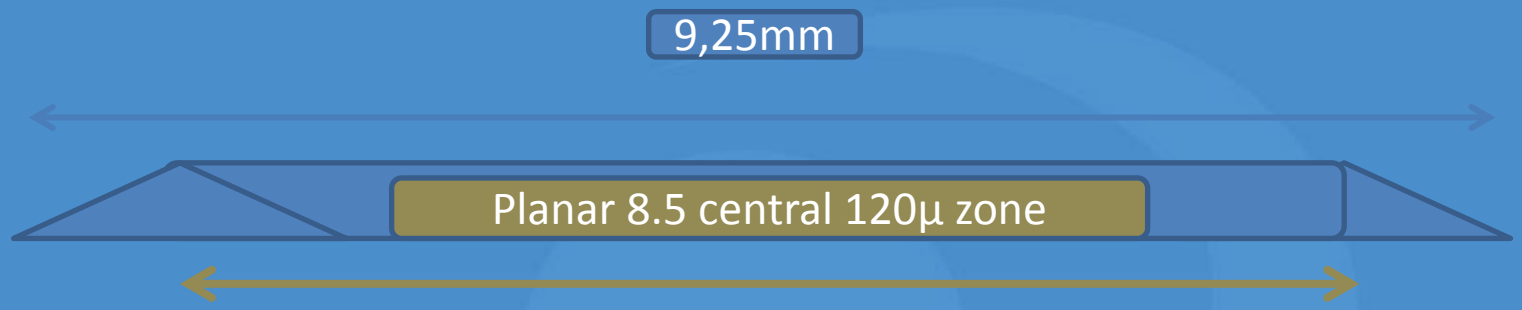
- Thick
-Sutures
-Designed to change the curvature of the cornea

`

**AMART/ micrograft**

- Thin
- No sutures
- Designed to leave the - cornea's curvature (almost) unchanged
- Useless without corneal wavefront Excimer ablation

# The AMART 7500nl Project




## Classic

EpiK lens
Is ablated
30min after
placed on the
cornea

## Tucked in

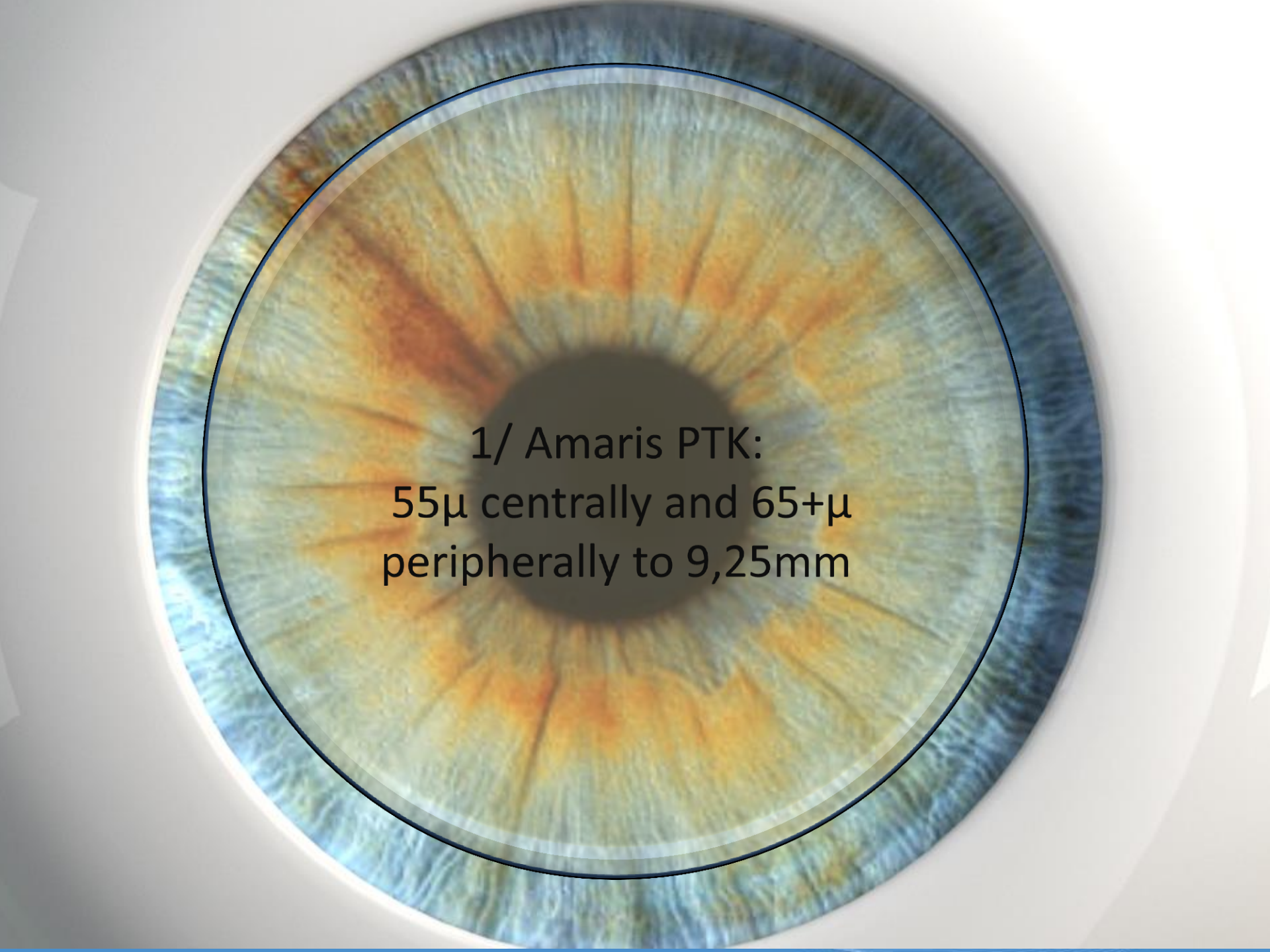
Epi K lens is tucked in a previously prepared groove in order to secure lens on the surface

## Lasik-like

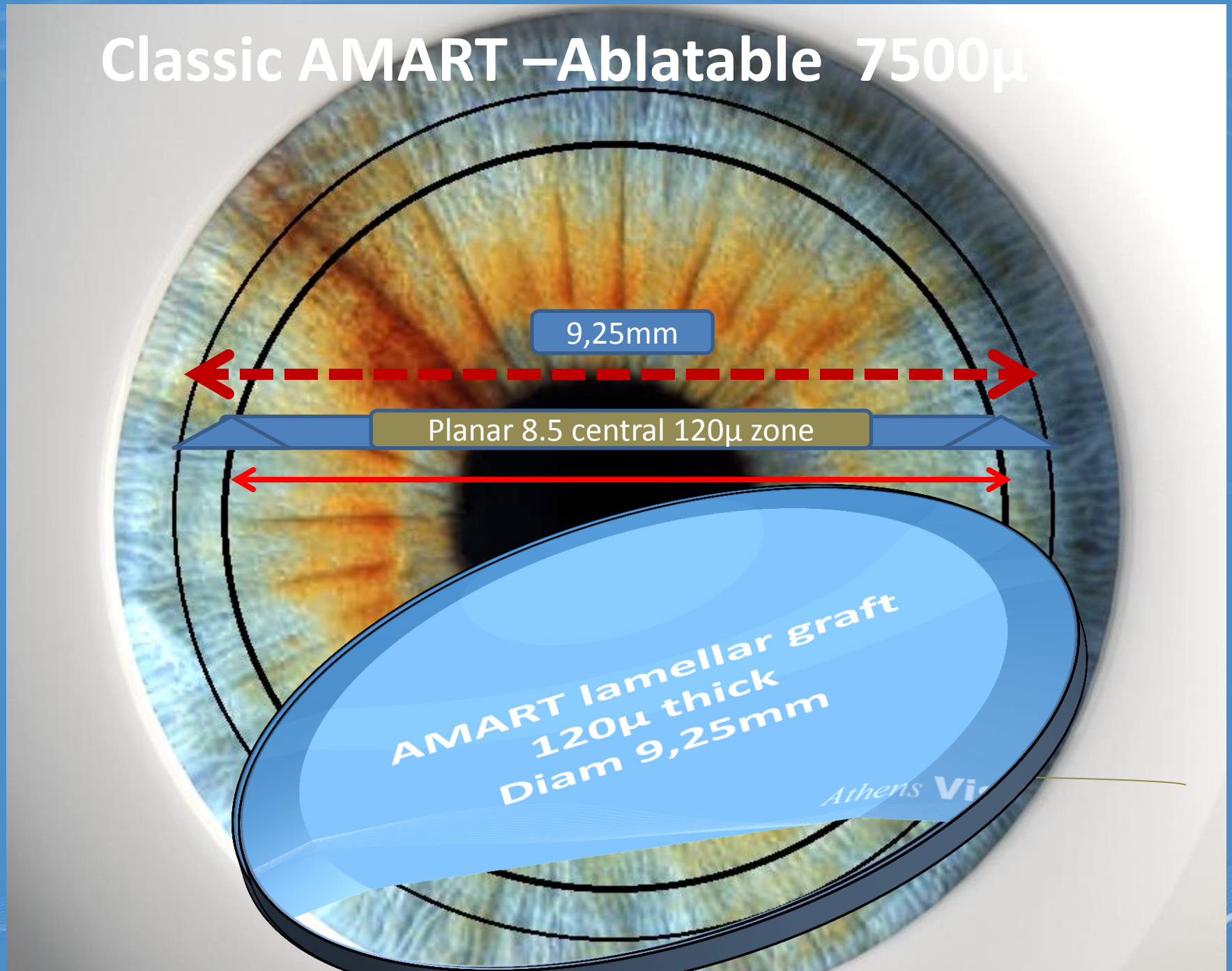
Epi lens is secured in an artificial Hinge, is then lasered on the flip side preserving the graft's Bowman

## Xtra

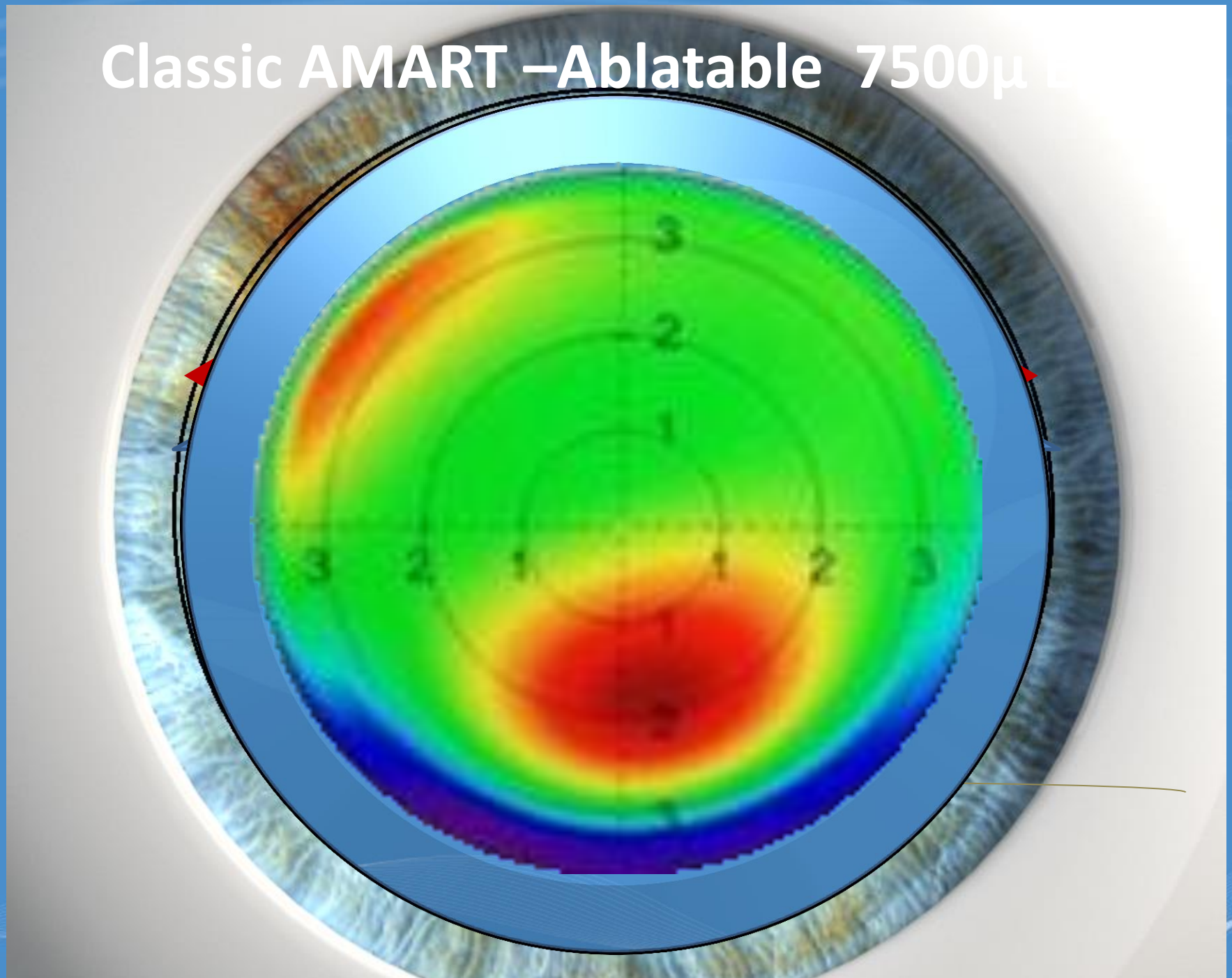
Epi lens is placed and not lasered. It is lasered s/p 3 months transepithelially Allows deeper ablation


1/ Amaris PTK:
55µ centrally and 65+µ
peripherally to 9,25mm

# Classic AMART –Ablatable 7500µ

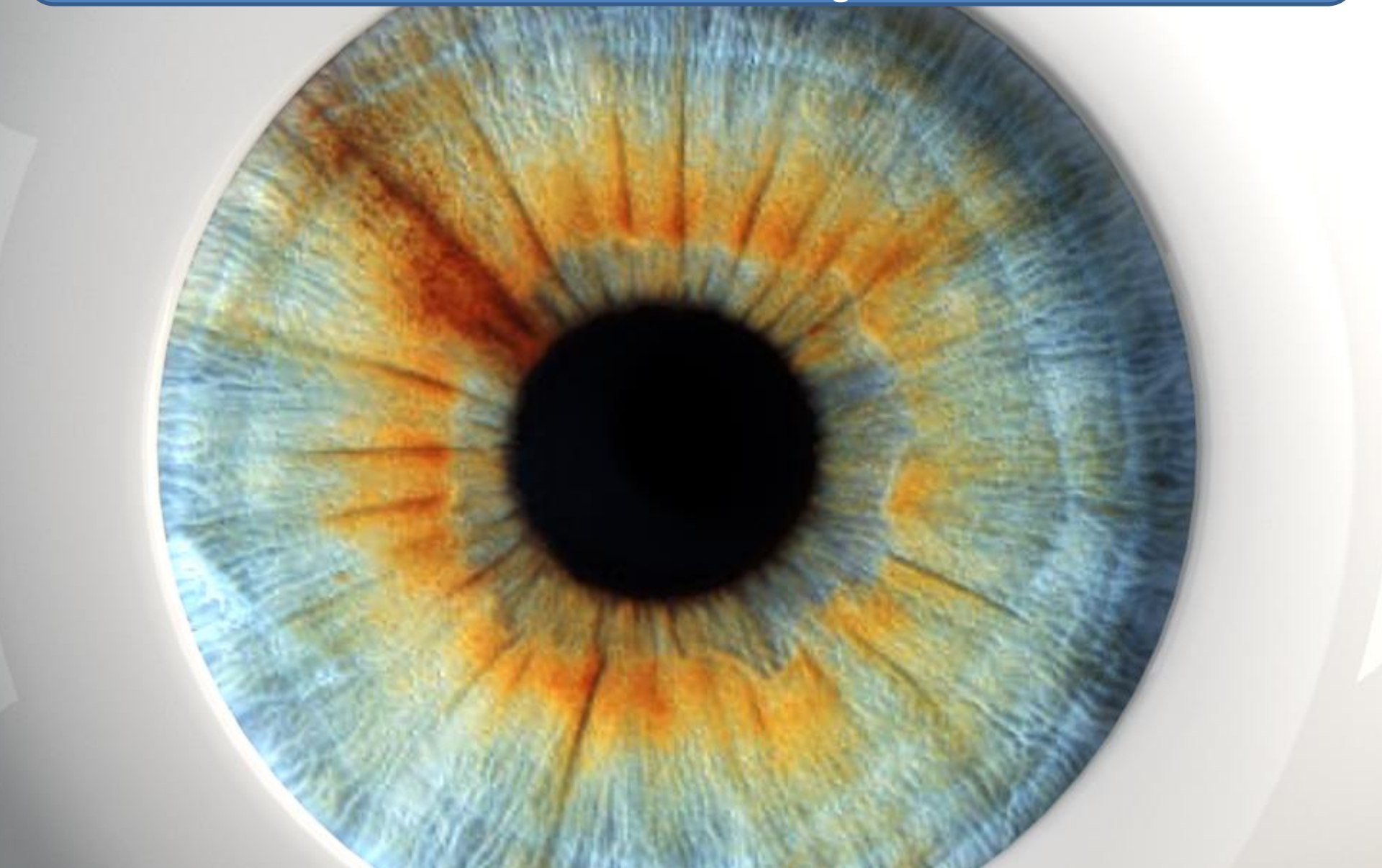


# Classic AMART –Ablatable 7500µ



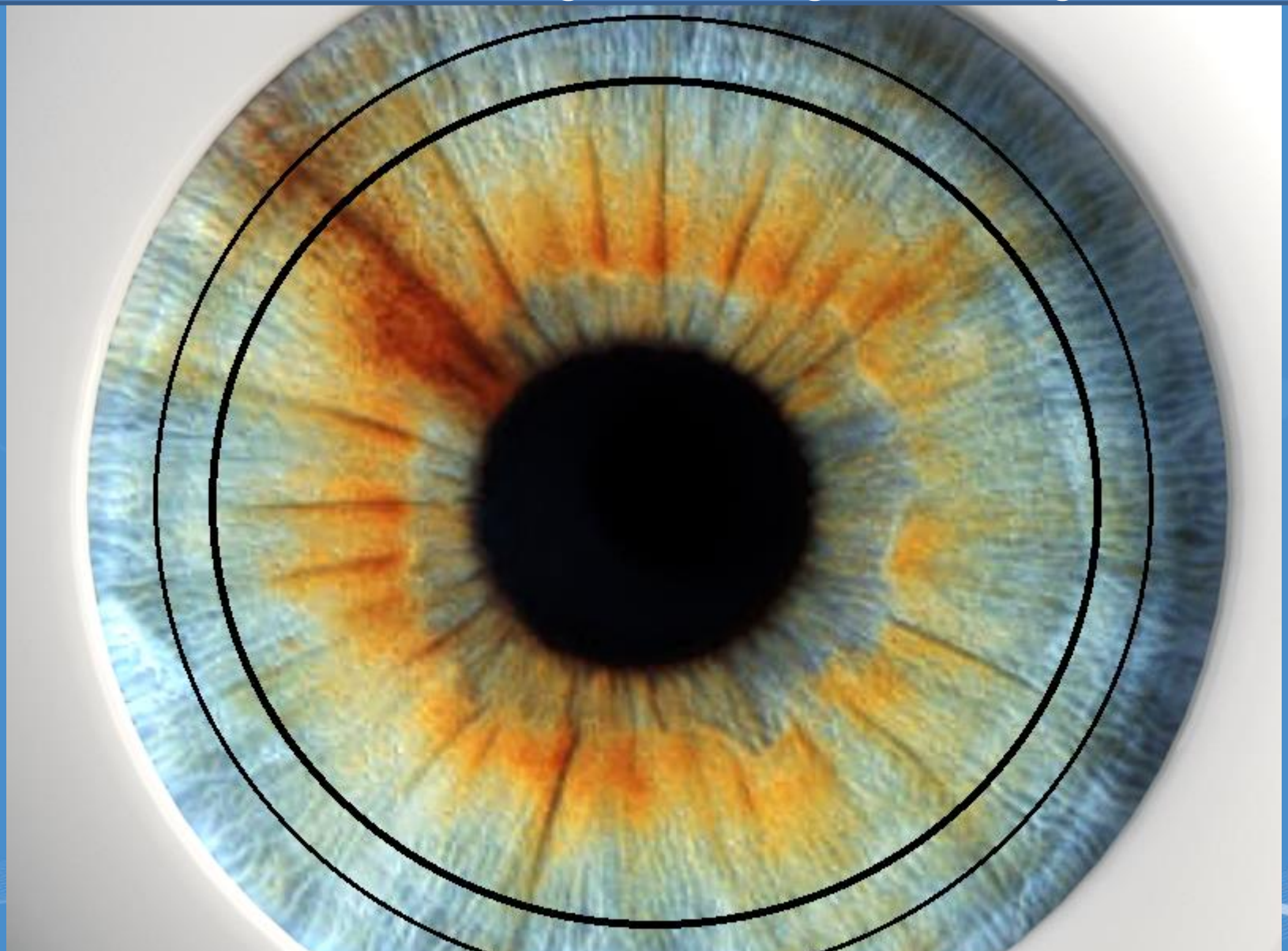
# T-AMART

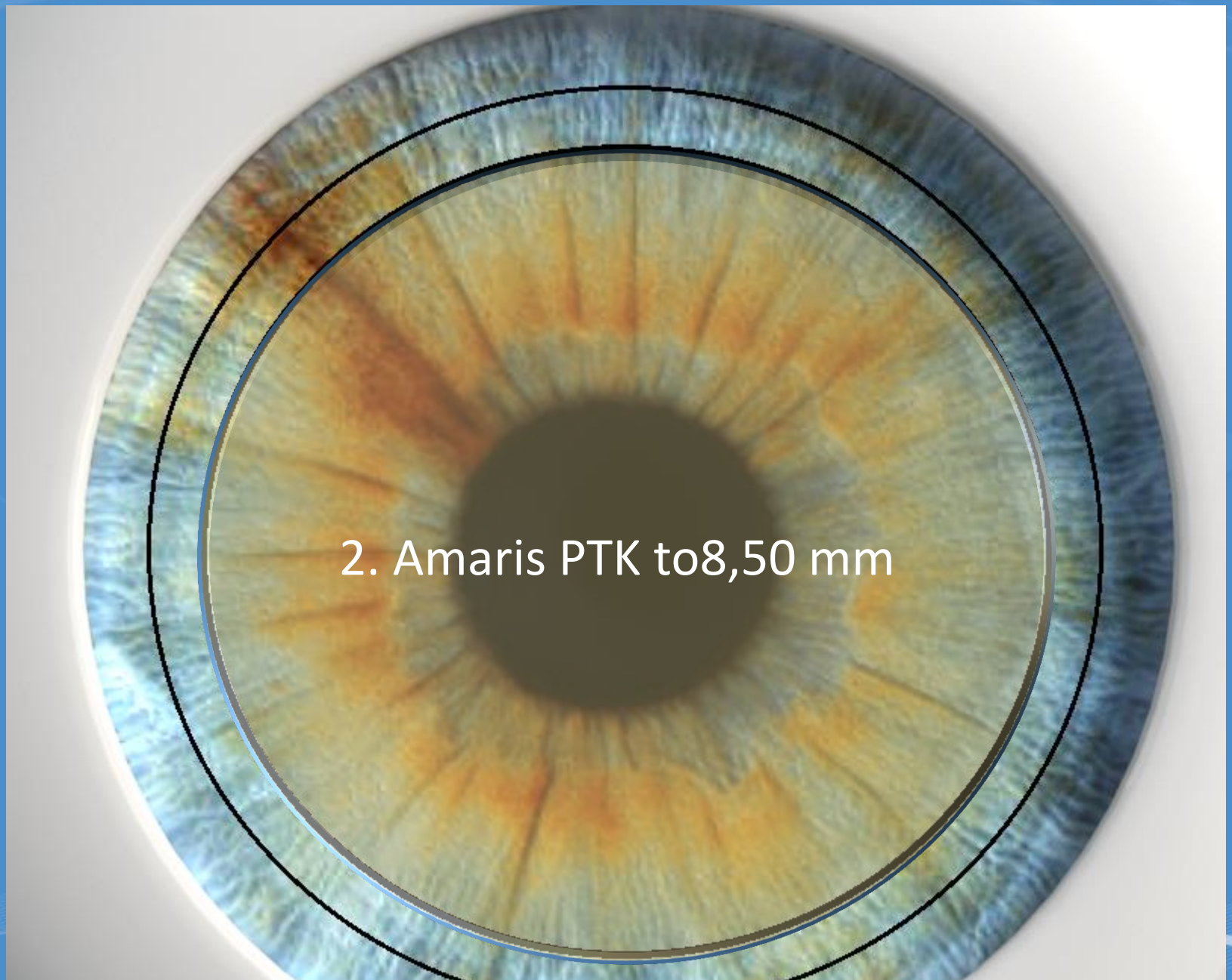
## 1/ Femto/nano lamellar preparation of the Recipient eye to tuck in the AMART graft

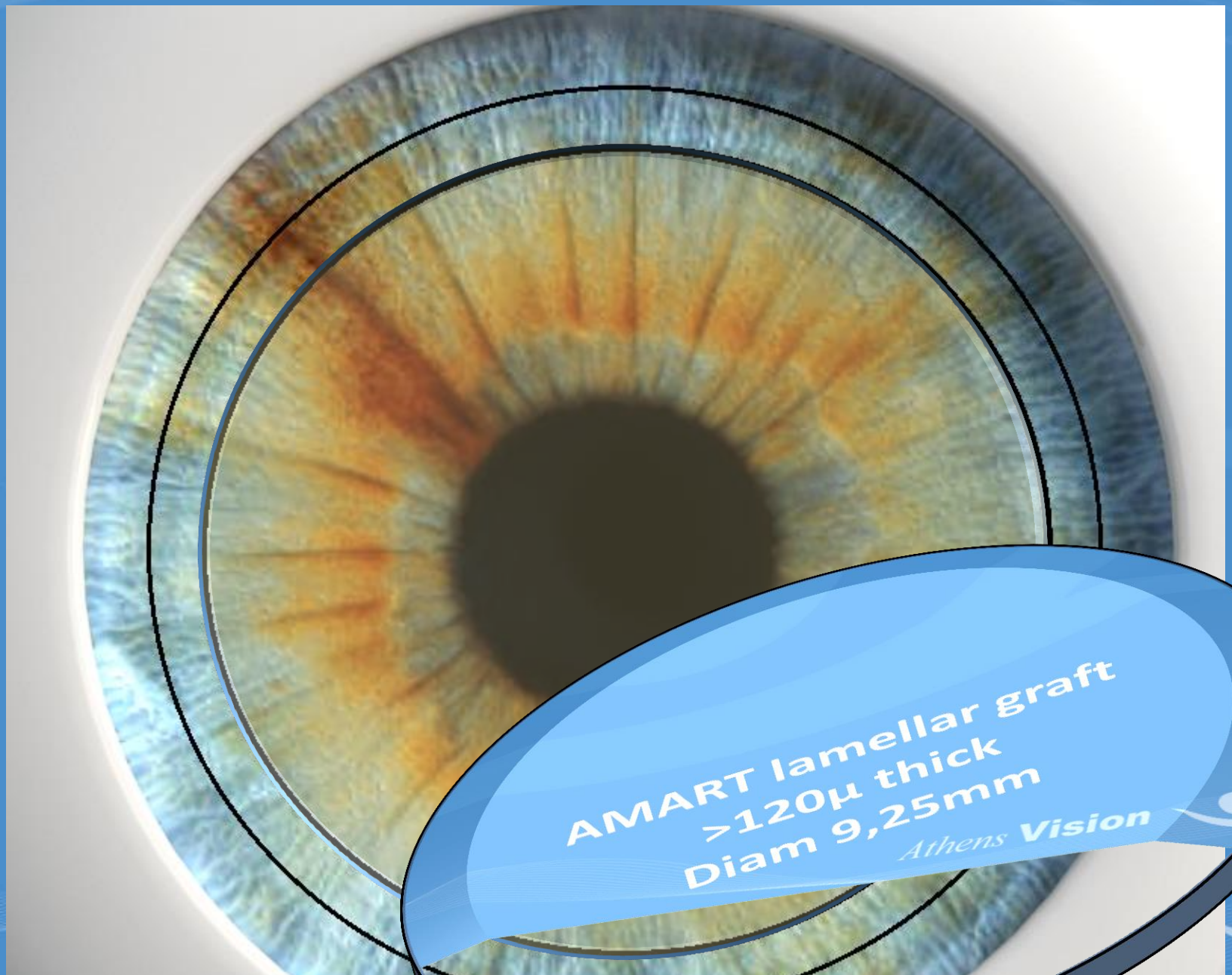


# T-AMART

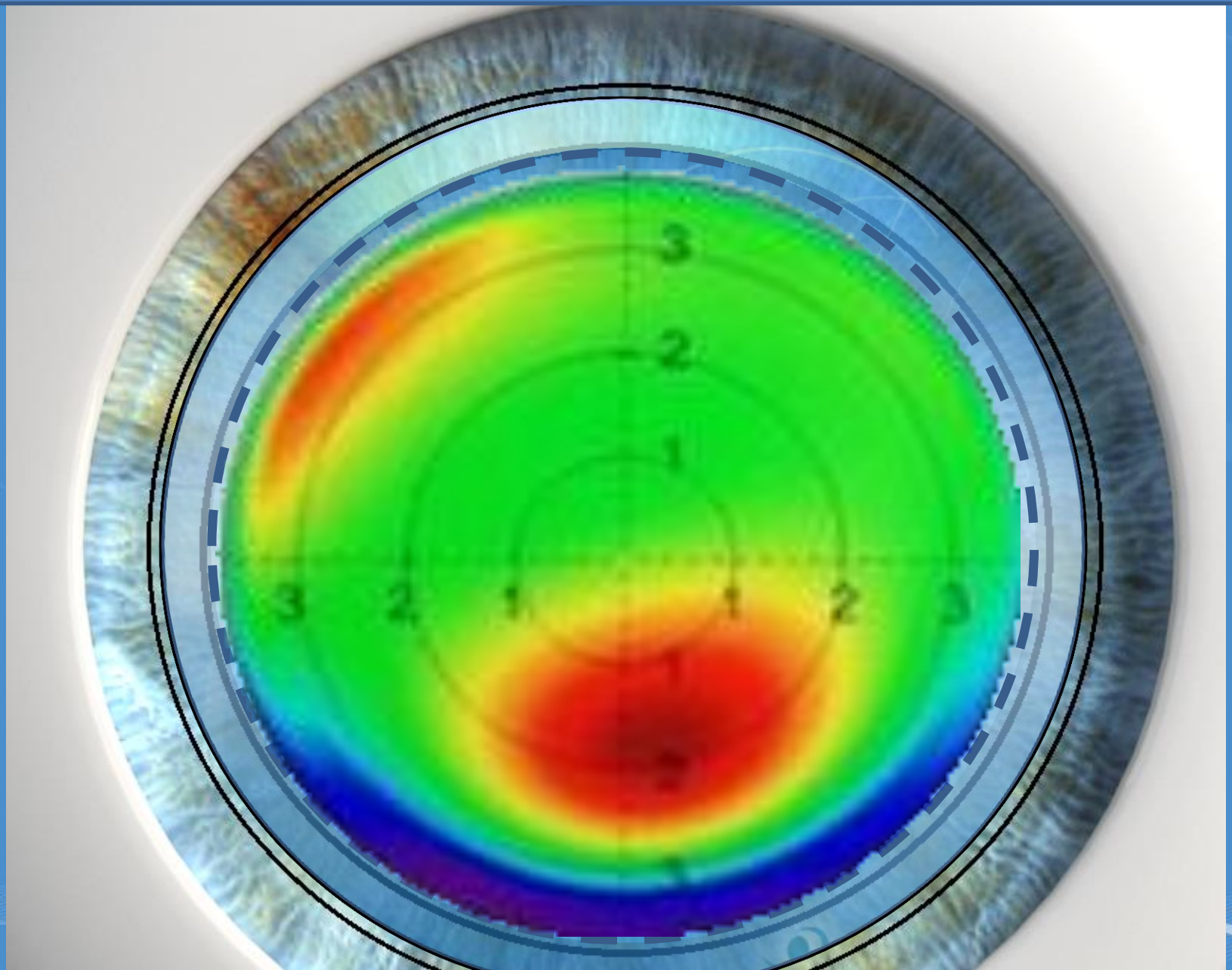
**1/ Femto/nano lamellar preparation of the Recipient eye to tuck in the AMART graft: Pull the graft into the groove**



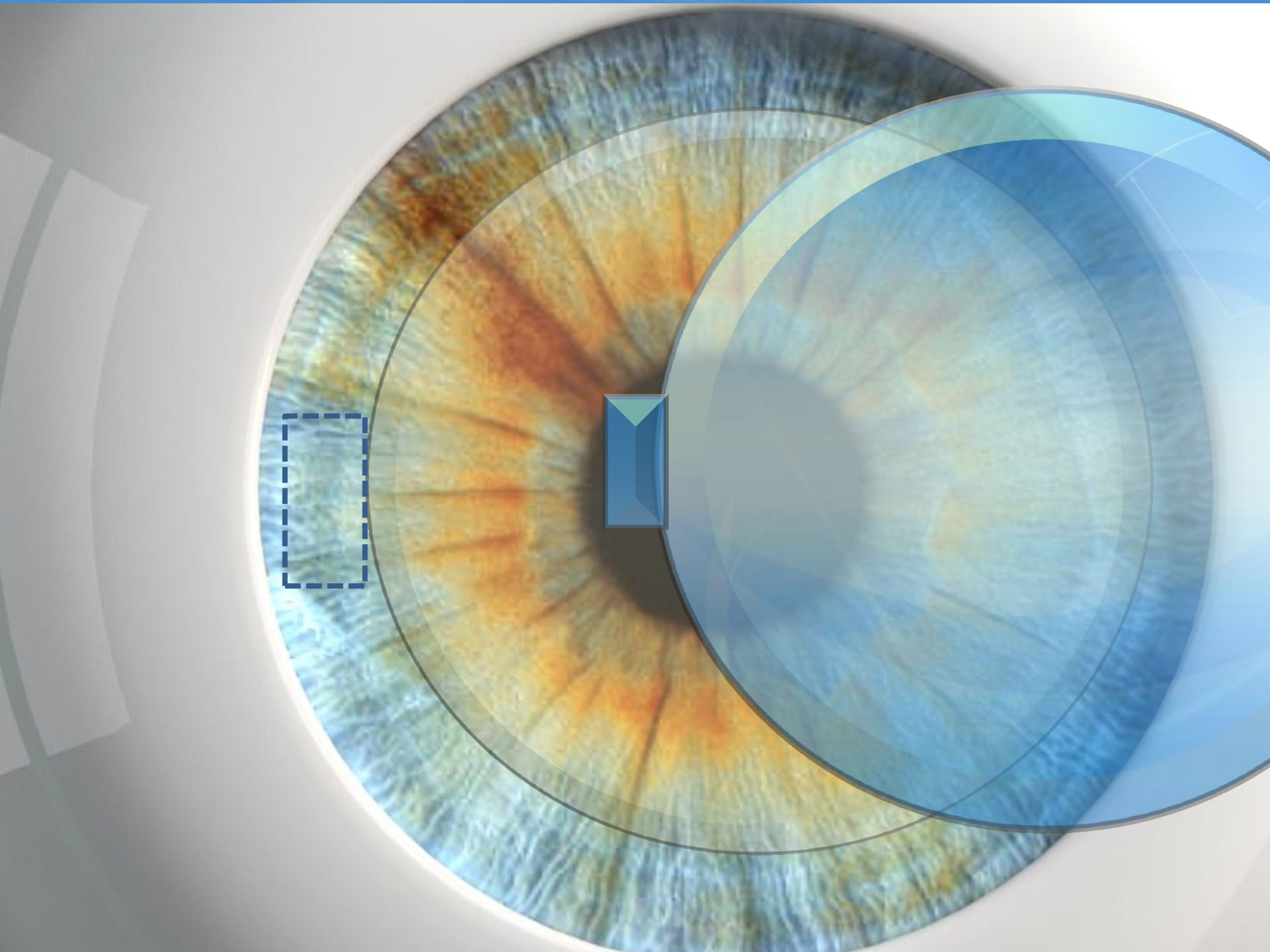

2. Amaris PTK to8,50 mm

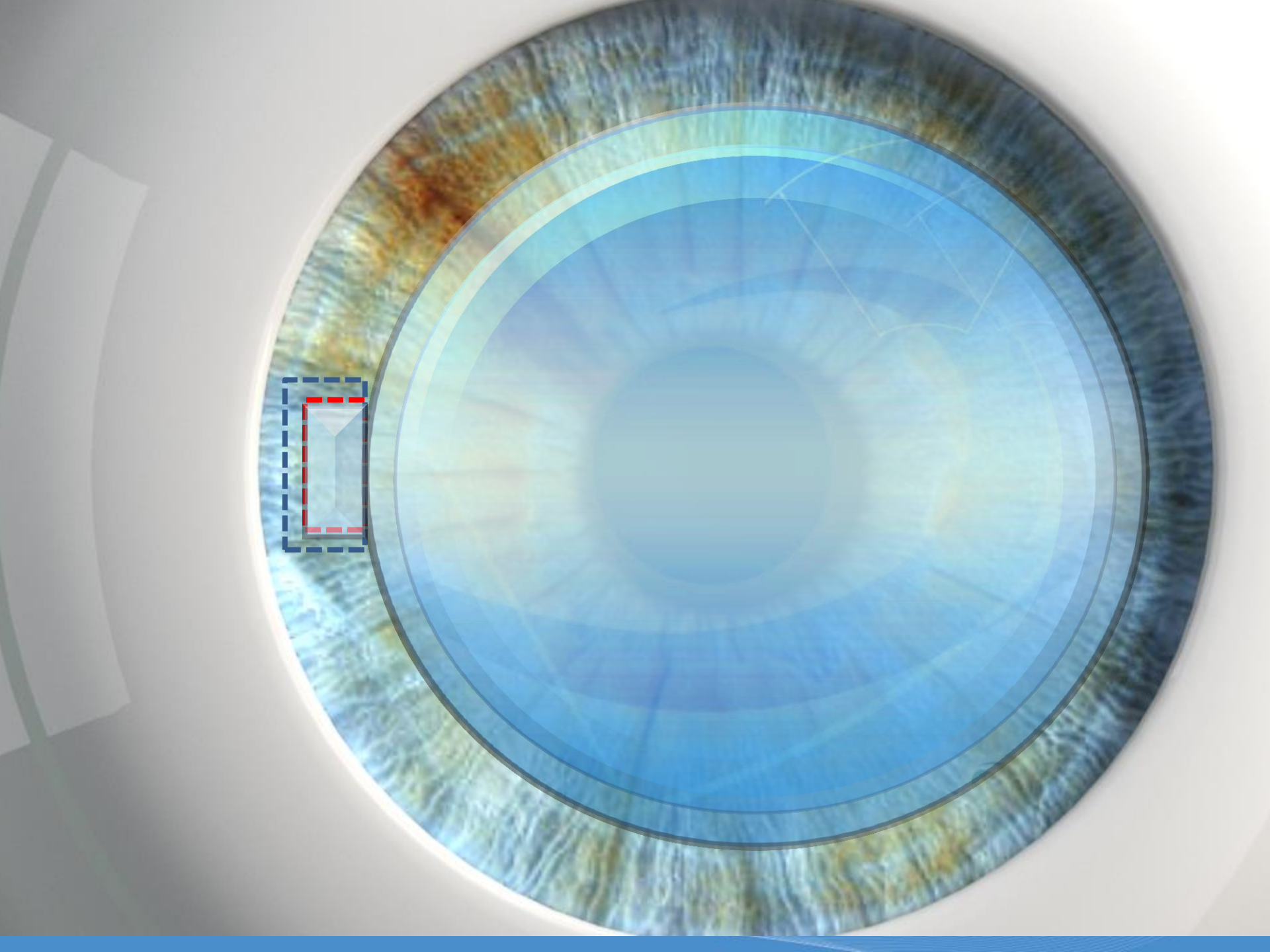

AMART lamellar graft
>120μ thick
Diam 9,25mm
Athens Vision

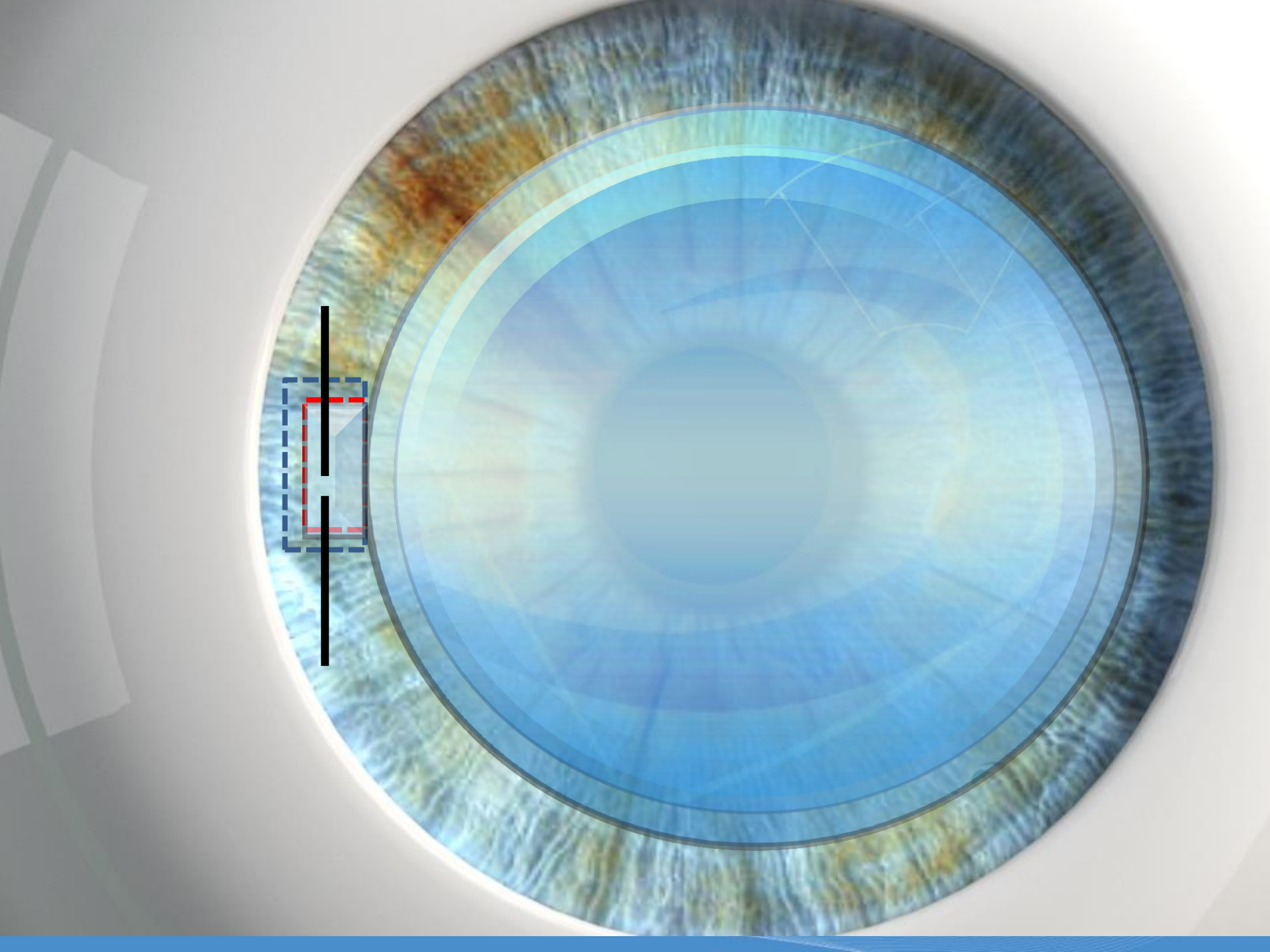
# The 7500nano graft is tucked in the peripheral groove without sutures

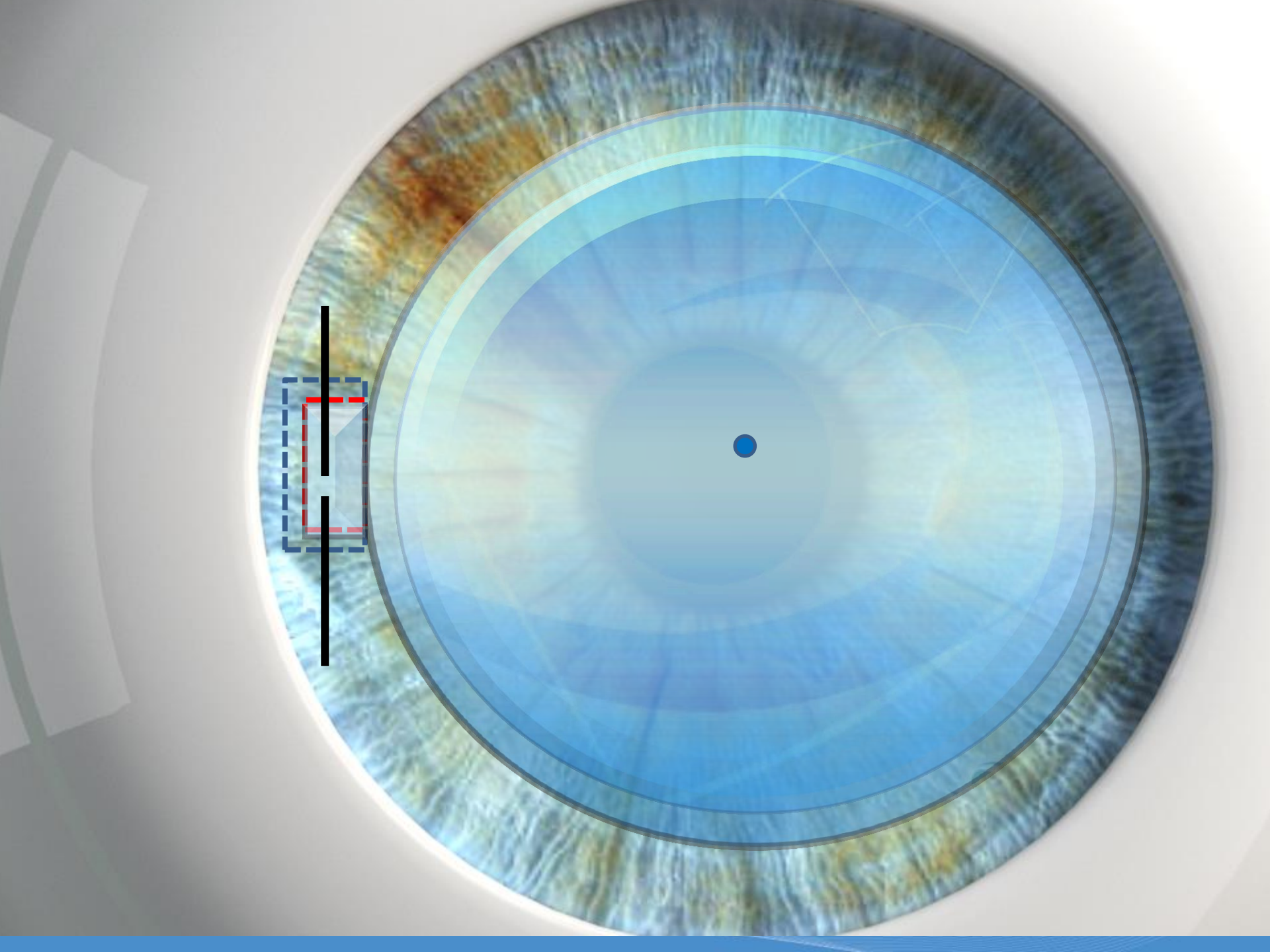


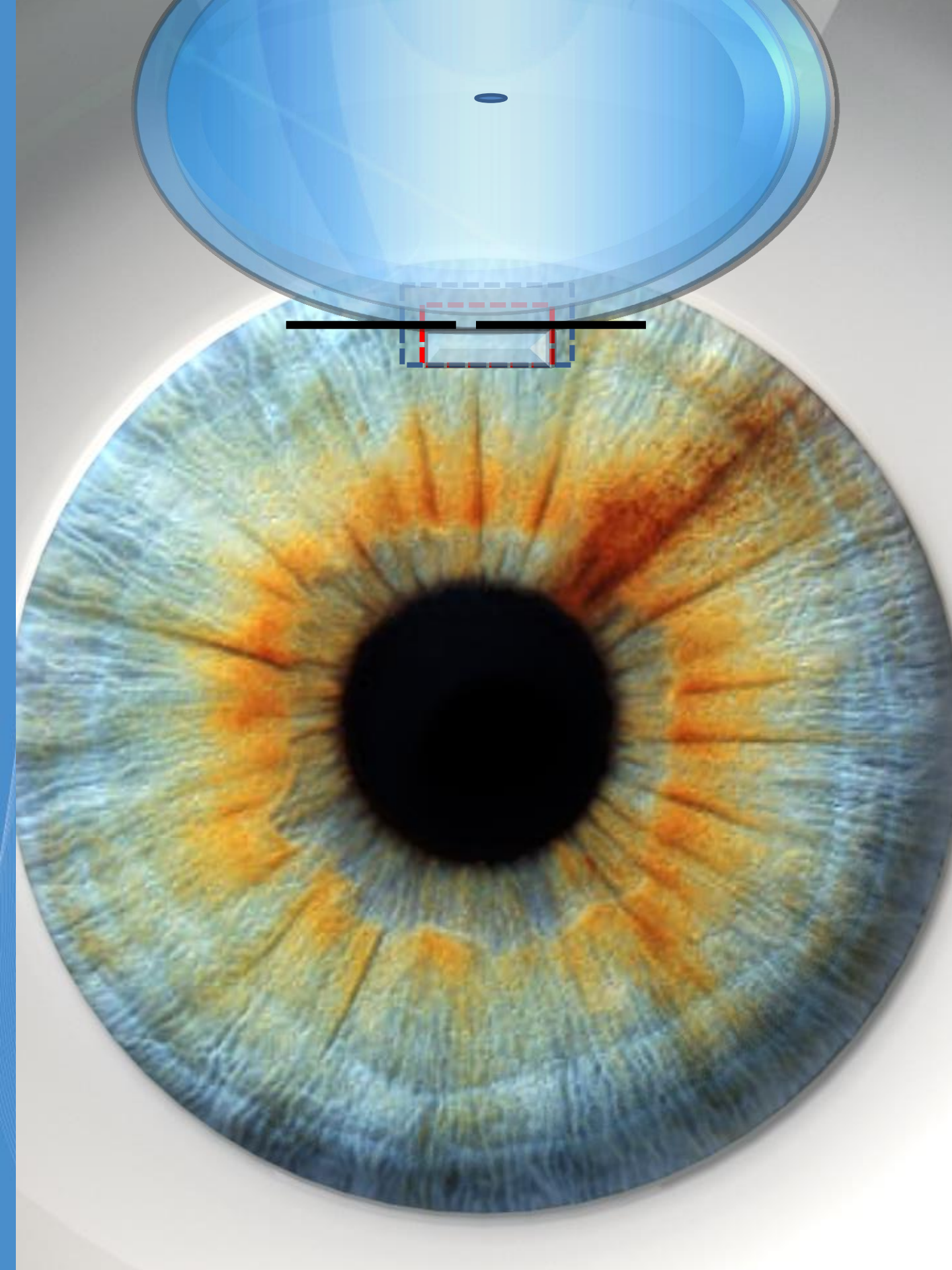
# The lasik-like AMART

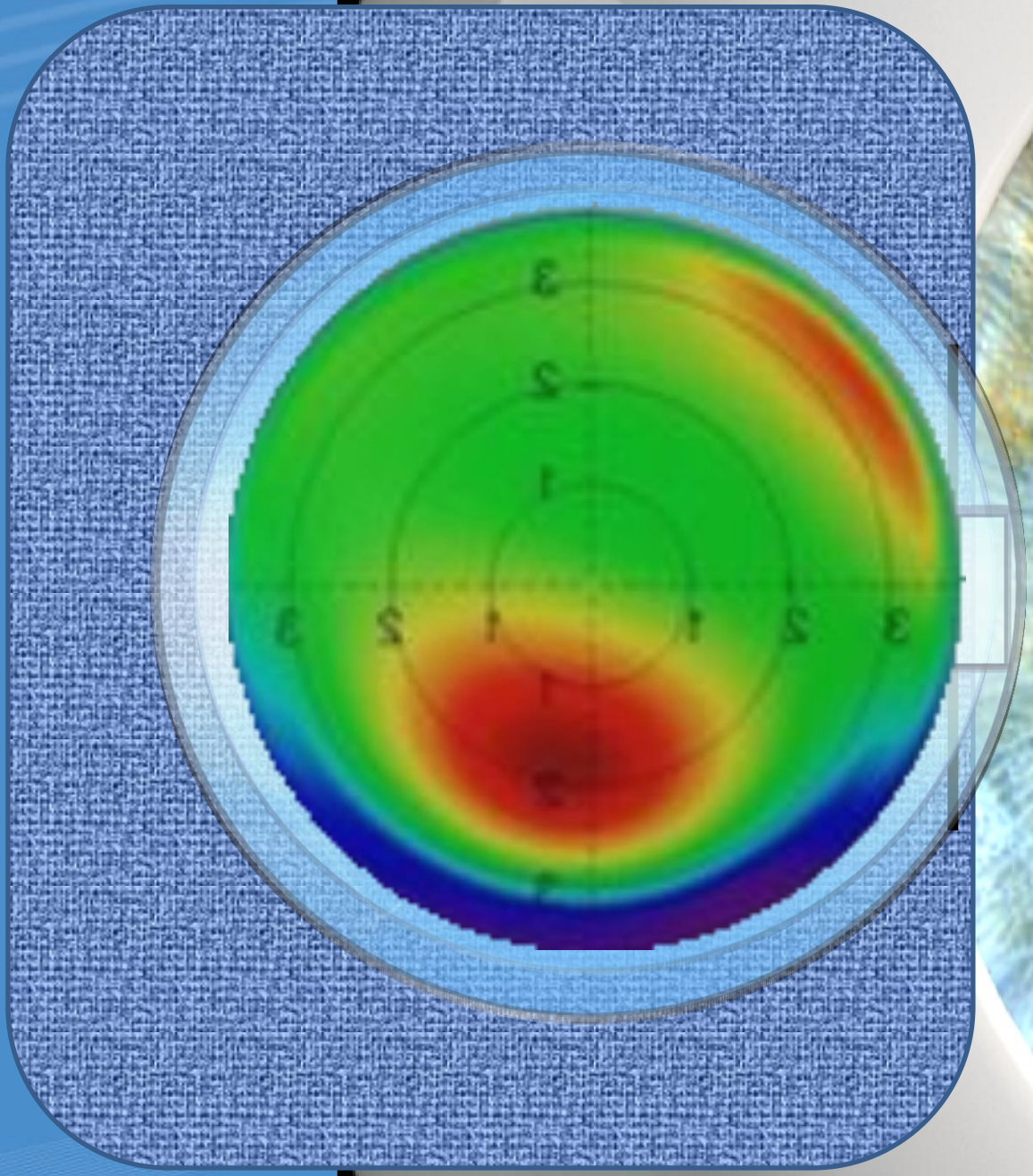


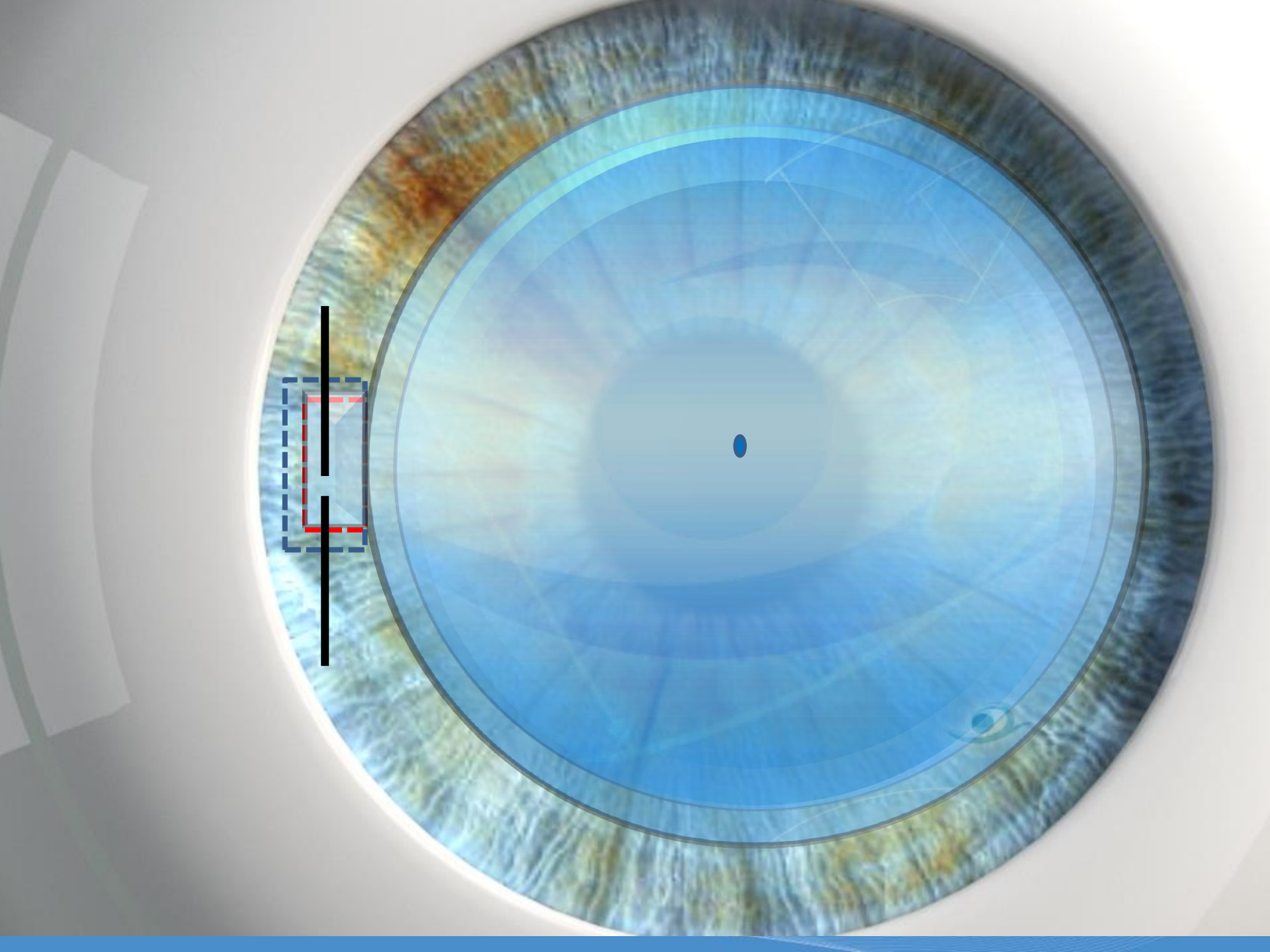












| | Ablation Volume | Added Tissue |
|---|---|---|
| A1 | <550nL | n.a. |
| A2 | <2500nL | >5000nL |
| A3 | <3500nL | >3500nL |
| A4 | >>3500nL | >25000nL |

# $Vi_1T_{3s}A_2L_3$

- This eye has excellent BSCVA, has a corneal minimum Thickness of  more then 400µ (but less then 450µ)with a stable topography and the ablation volume needed to regularize the surface is less then 2500nl for a total ablation zone of 8.30mm and OZ >6mm. The AC length (depth) is short and no phakic lens may be implanted!
- This Eye is probably amenable to Ti-AMART since the graft will add over 7500nl of tissue and no ablation is going to take place on the patient's own cornea

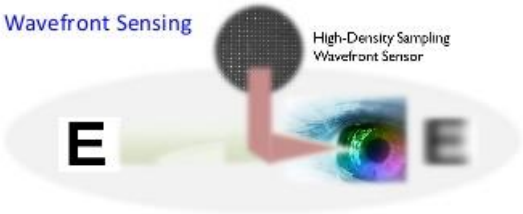
# ViTAL /AMART Weakpoints

- BSCVA is a poor metric for Visual function in keratoconics
- Lower order refraction is unreliable in keratoconics but important in CW corrections
- CAM software limits for astigmatism/sphere
- A1 definition is arbitrary
- New ablation algorithm is necessary
- Optical index diversity between air/cornea vs aqueous/cornea

# AONeye

*Seeing is believing*

## Wavefront Sensing

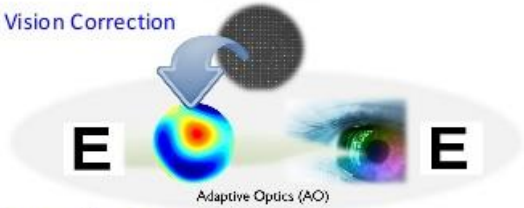



HD Wavefront Sensor provides an Objective Characterization of the Eye's Optics

## Vision Testing


OLED micro-display projects a variety of Vision Tests in one finger touch

## Vision Correction




Adaptive Optics Proprietary Technology gives Full Control of the Ocular Wavefront

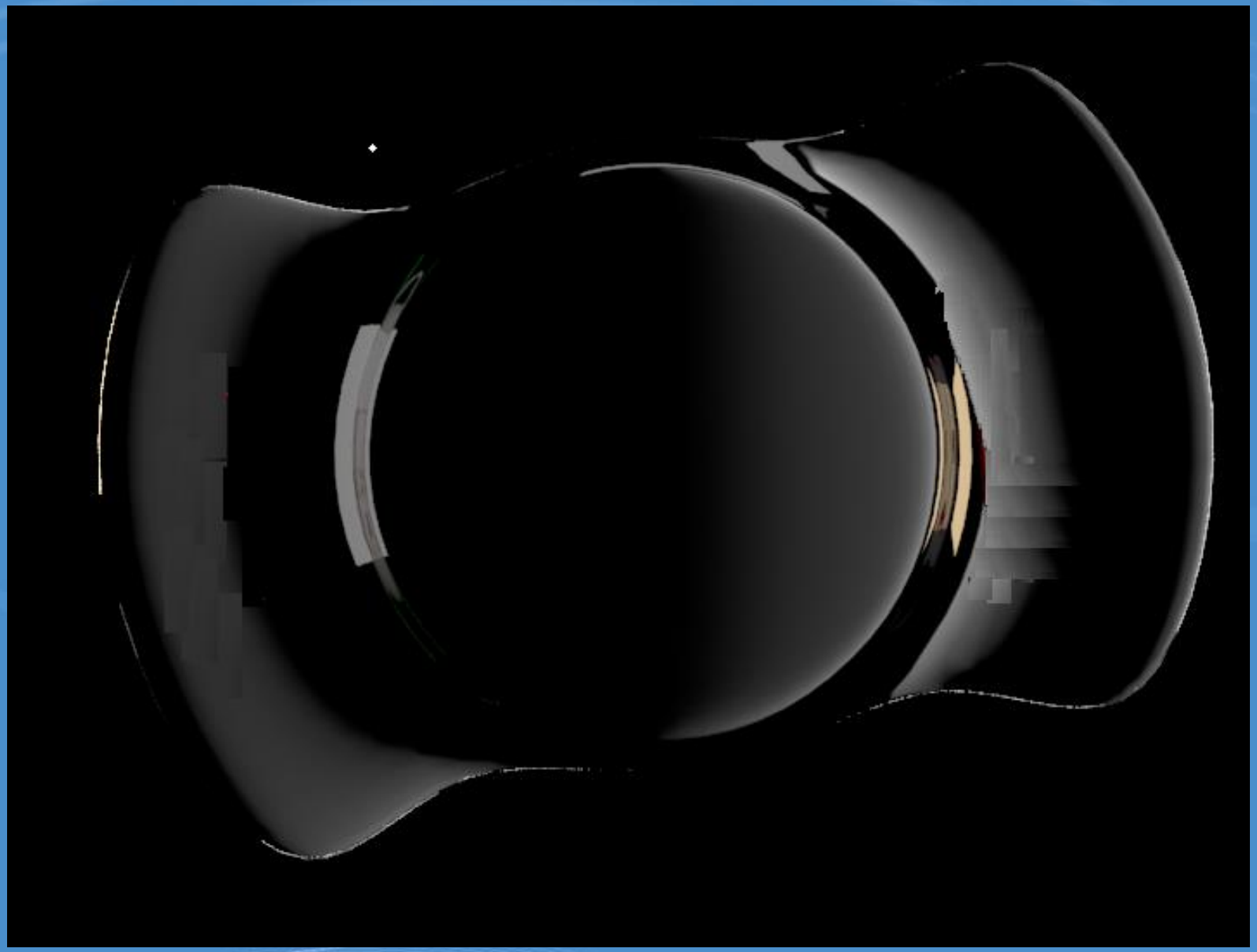
## Personalization


Adaptive Optics to replicate & customize optical designs prior the implementation as Personalized Solutions for Vision

voptica
smart visual optics

# $Vi_3T_{3s}A_4L_1$

- This eye has decreased BSCVA (less then 20/50), has a corneal minimum Thickness of more then 400μ (but less then 450μ)with a stable topography and the ablation volume needed to regularize the surface is more then 3500nl for a total ablation zone of 8.30mm. The AC length (depth) is actually very long and would certainly accommodate a phakic implant.
- **CAN WE IMPLANT A PHAKIC IMLANT IN AN EYE WITH A BSCVA of less then 20/50???**



**YES if we could fabricate the lens we designed!**

**The Gregory Lens System !!**

## The Gregory Lens

It consists of

**Element 1**: A frame (same for every patient)

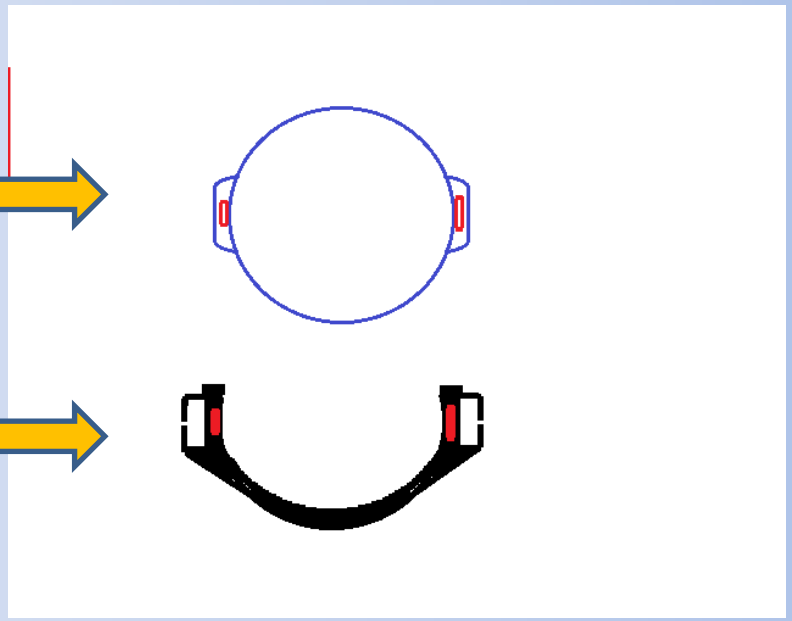
**Element 2**: An individualized Optic (Constructed after the exact ELP is known )

Downside: It needs two surgical procedures (Wound <2mm and most likely <1,5mm possible in both)

# Element 1:frame same for every patient
# Element 2: individualized optic

Element 2

Element 1

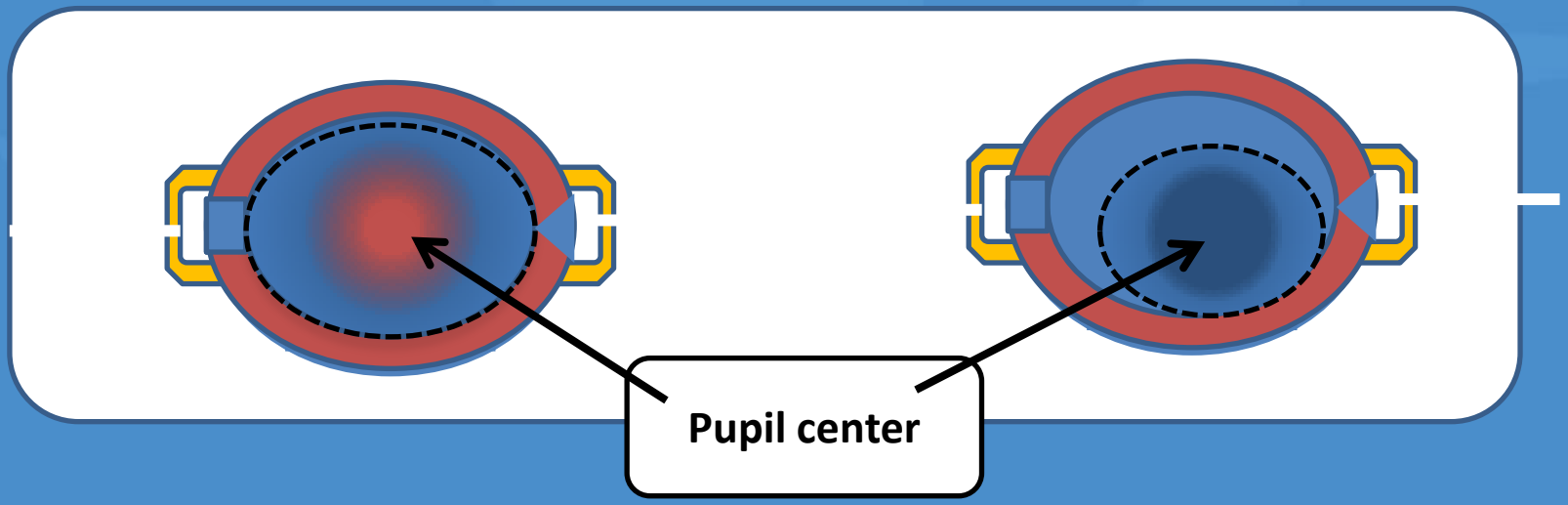


# Initial Version of the Gregory Lens

– V01.1-3

Versions had to have off centered OZ's which is a real burden to produce!

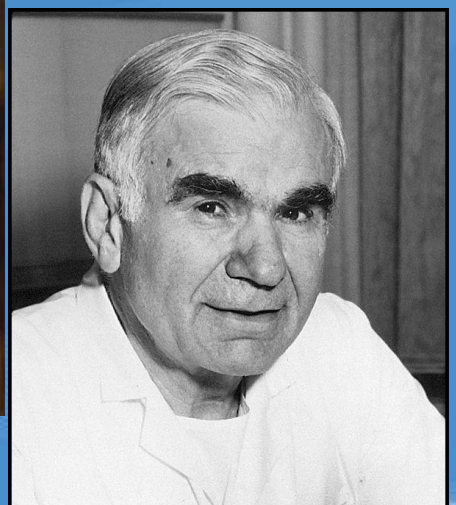
The OZ size had be substantially decreased as well



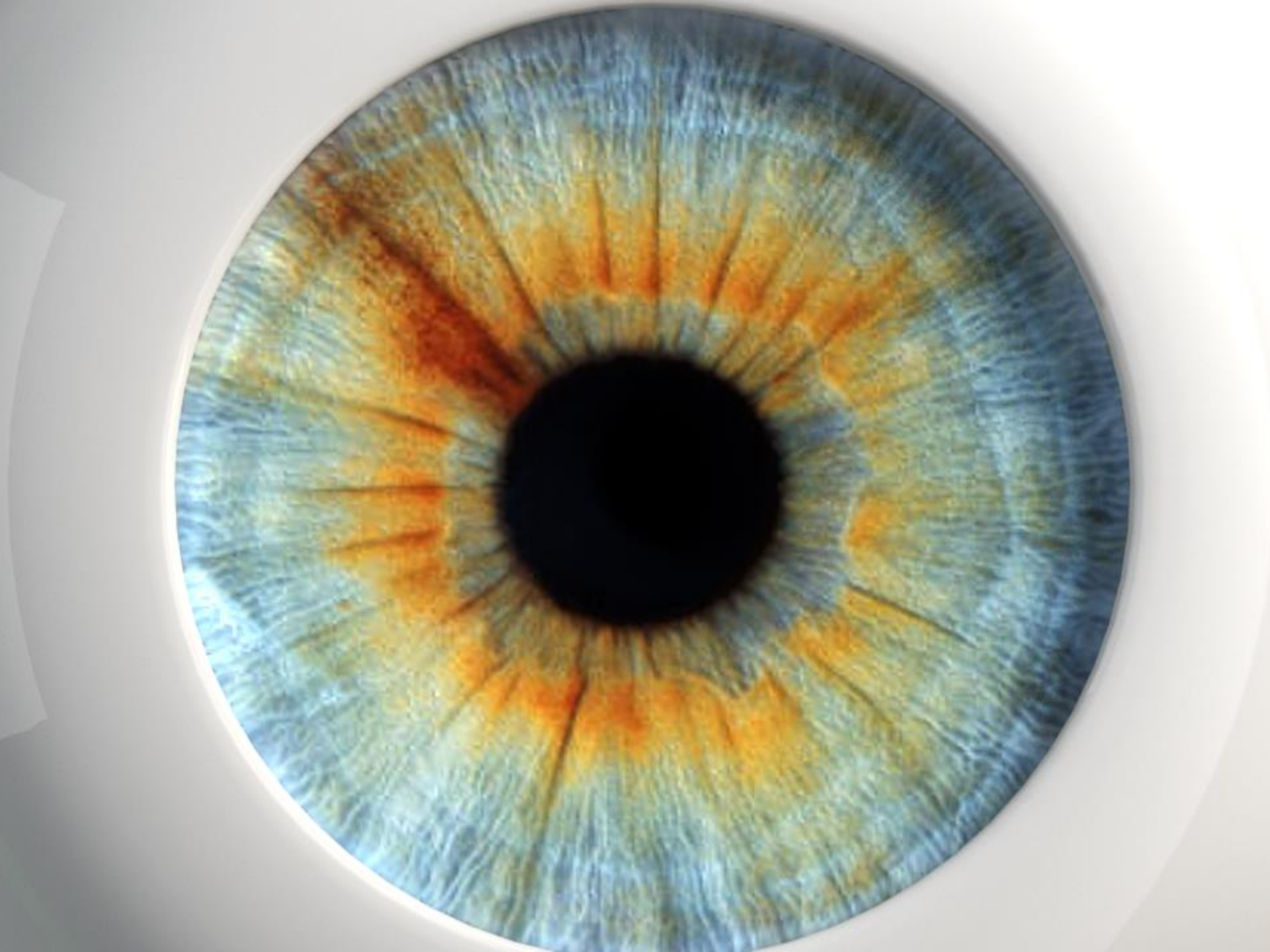

## V2 fixes all these issues

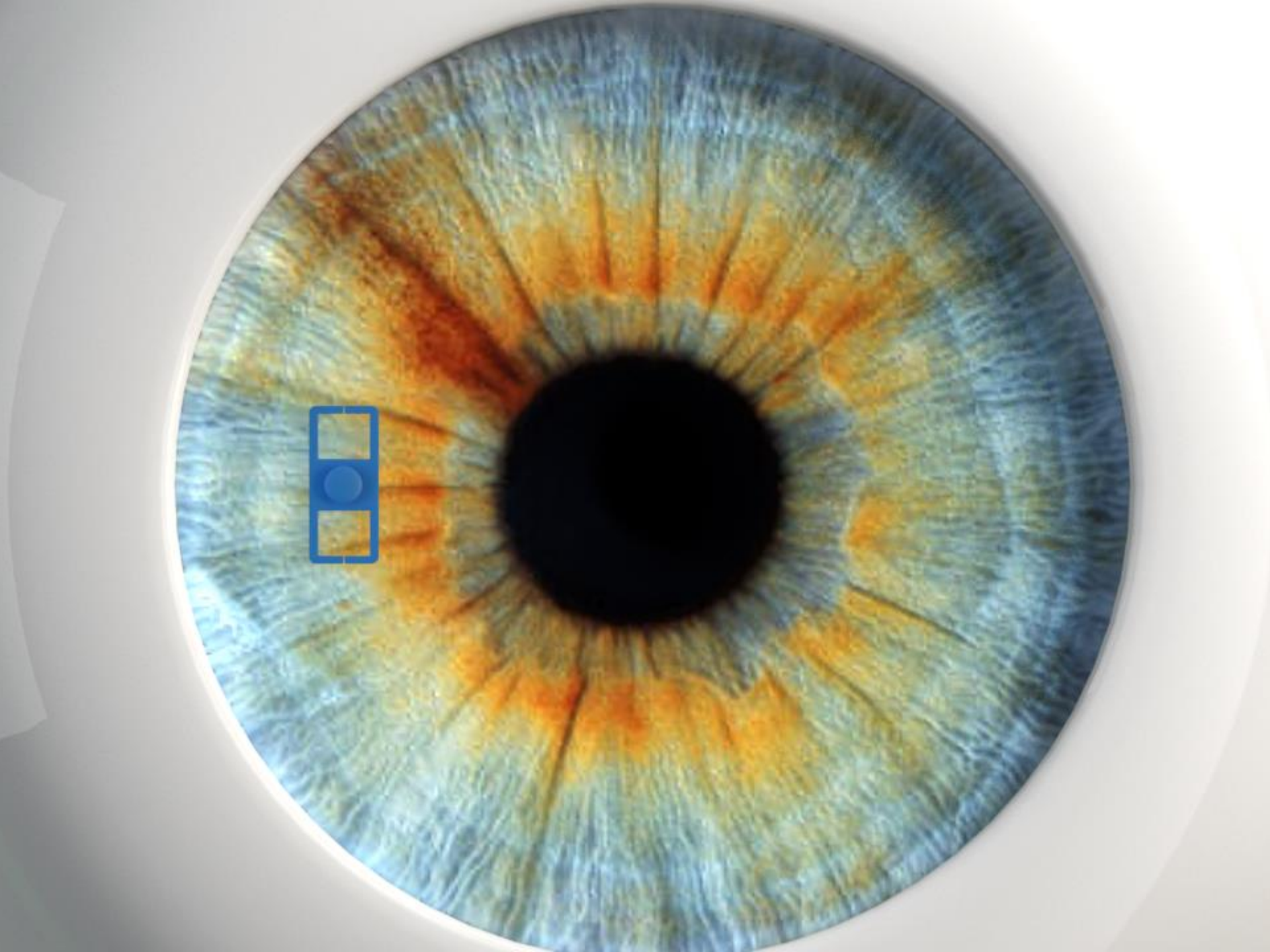
Athens Vision

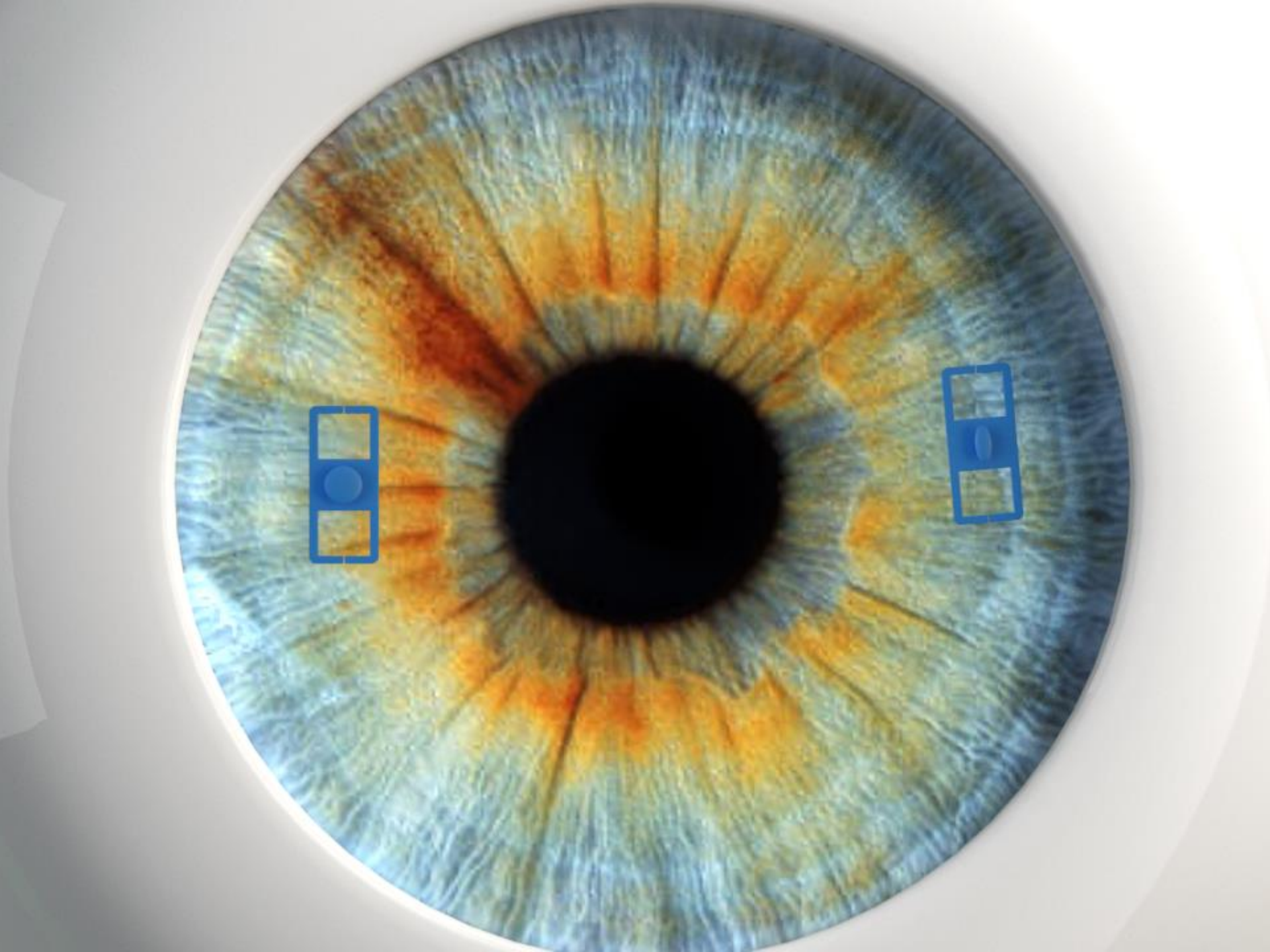
- March 23, 1937 First silver clip for aneurysm in the neck – (Walter Dandy)
- There are over 1.500.000 Yasargil clips that have been implanted since 1968
- Why can’t we use “double” Yasargil-like clips, for the Gregory lens project?

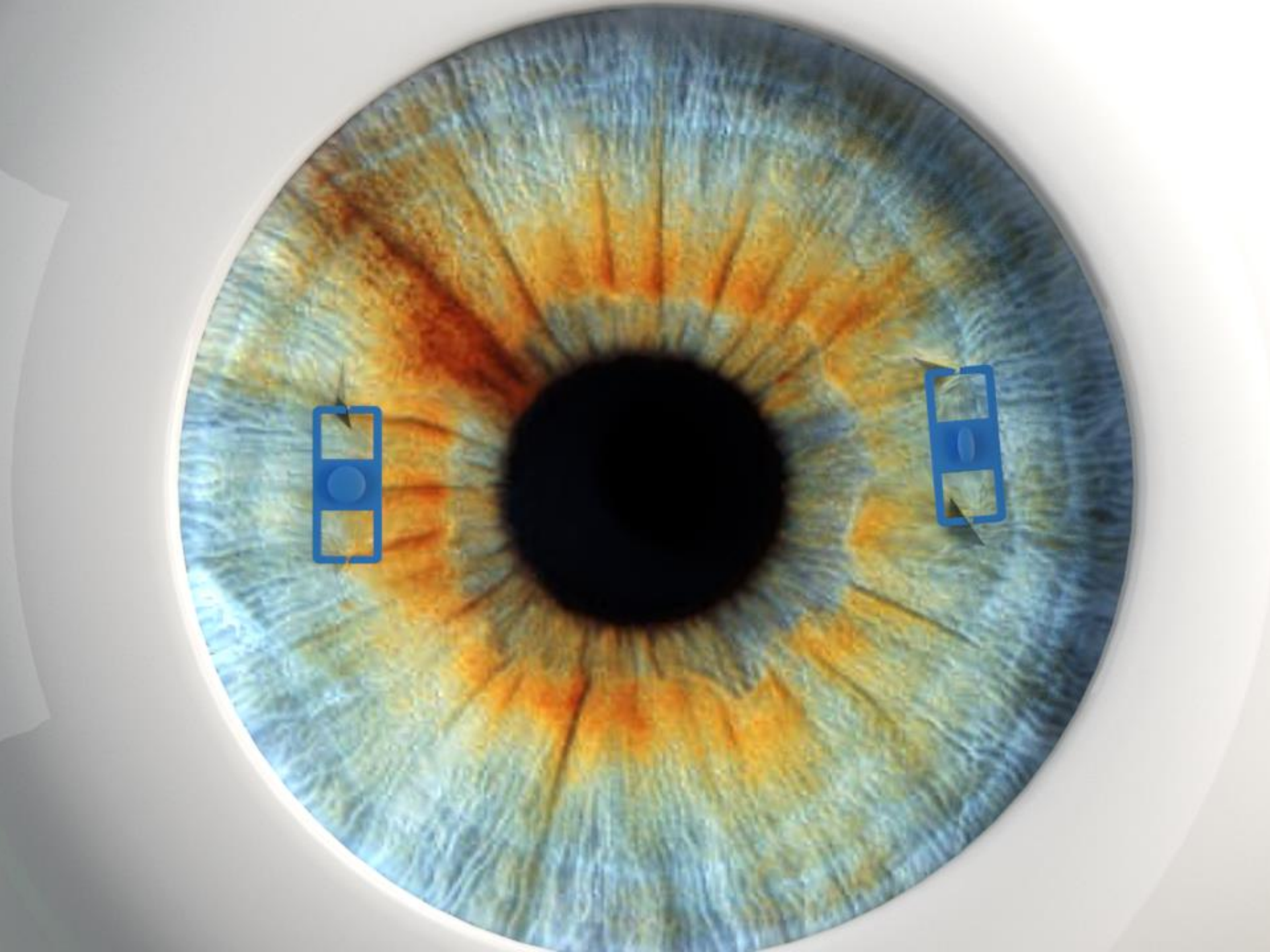


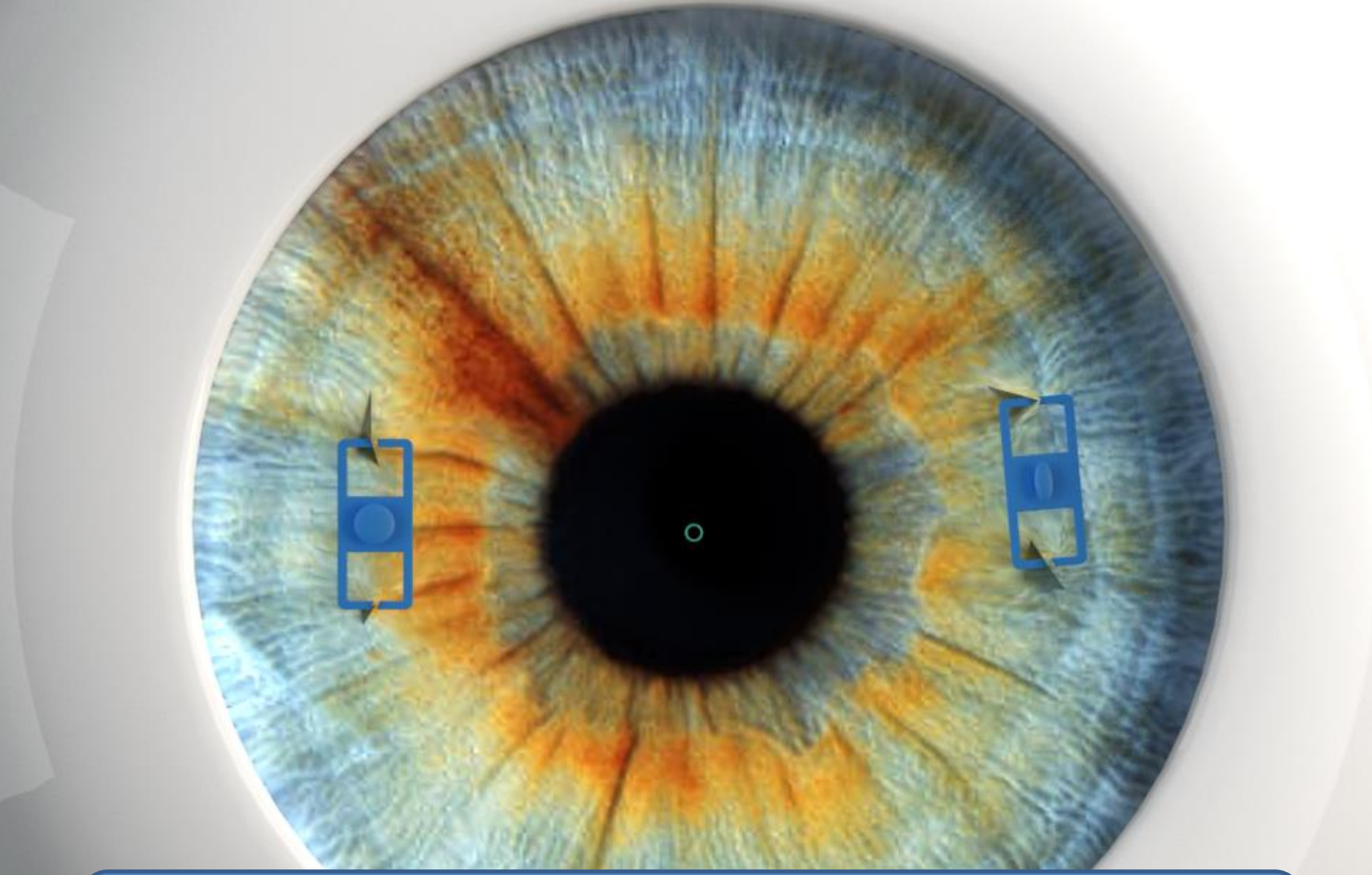
Athens Vision



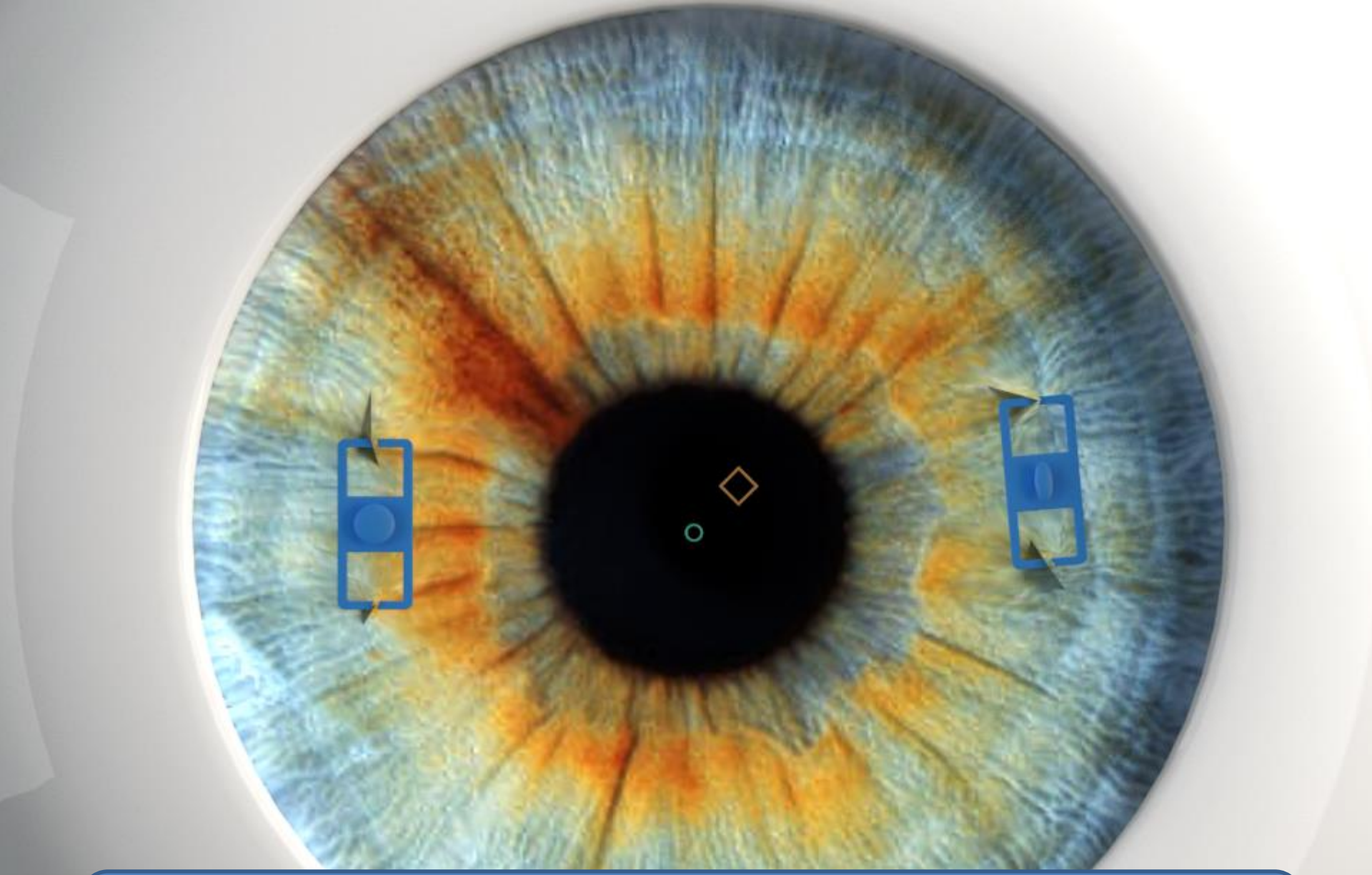




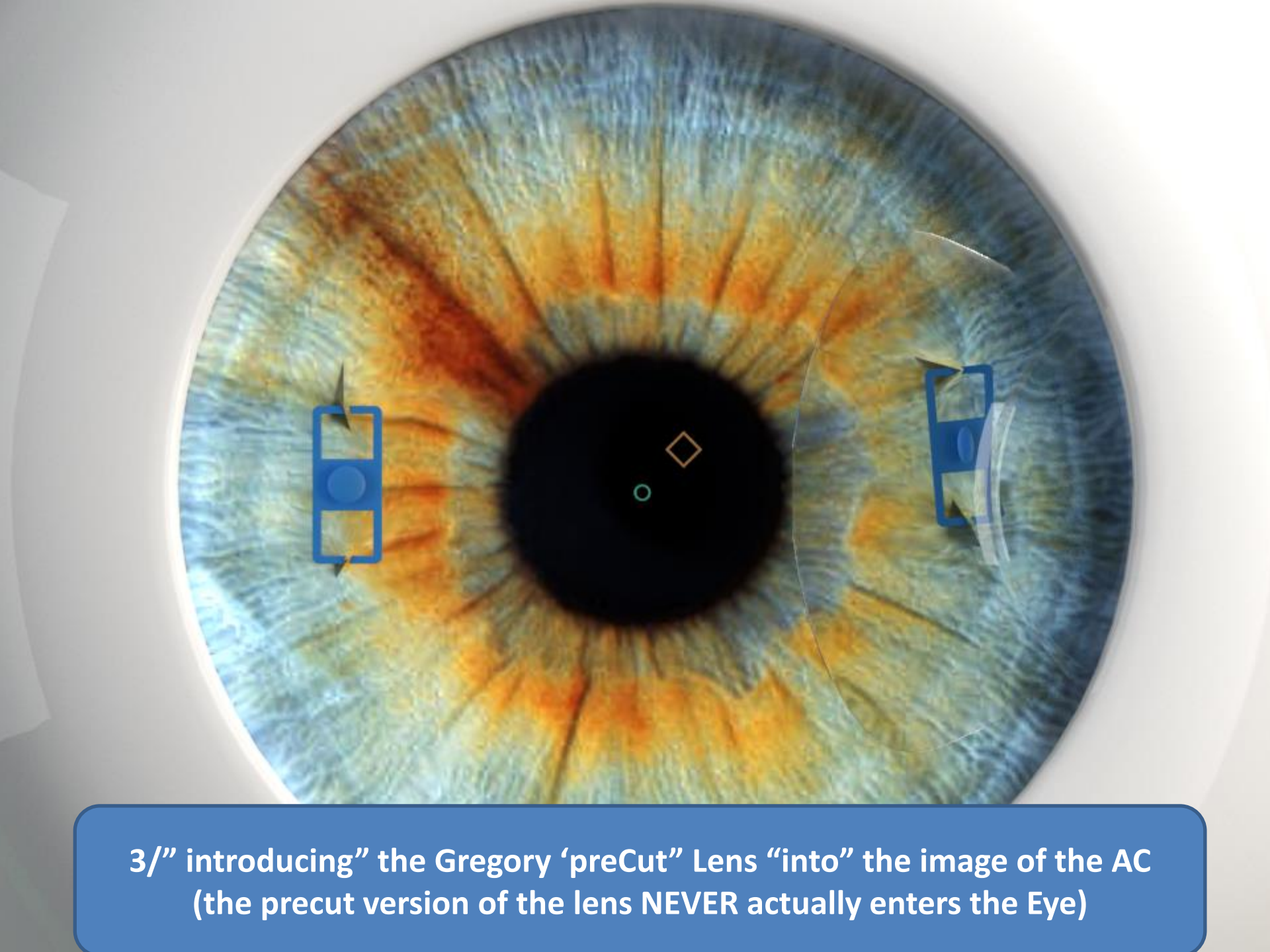




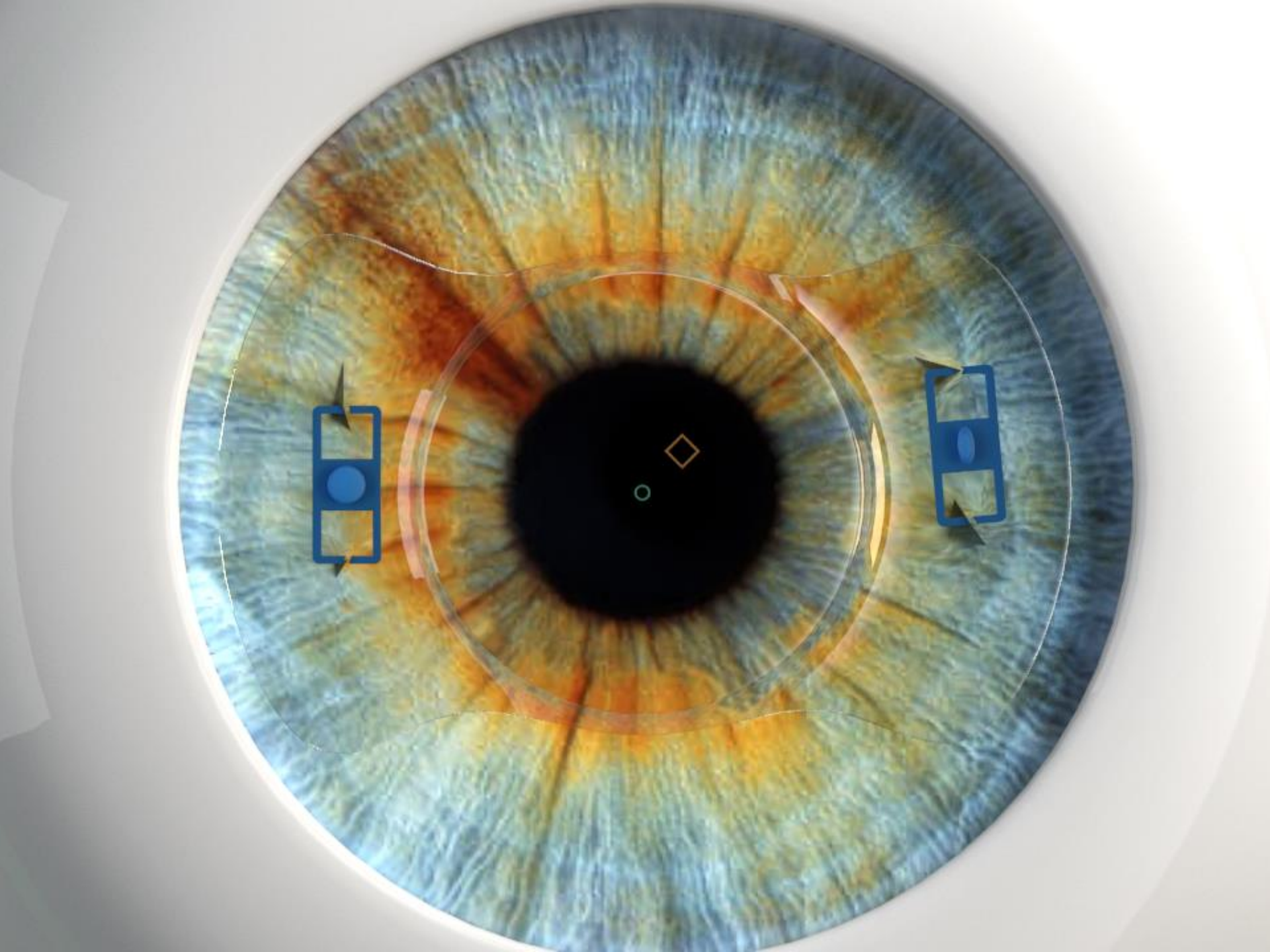
designing the Individualized Optics ex Vivo
Based on the Two Pillars preplaced in the eye

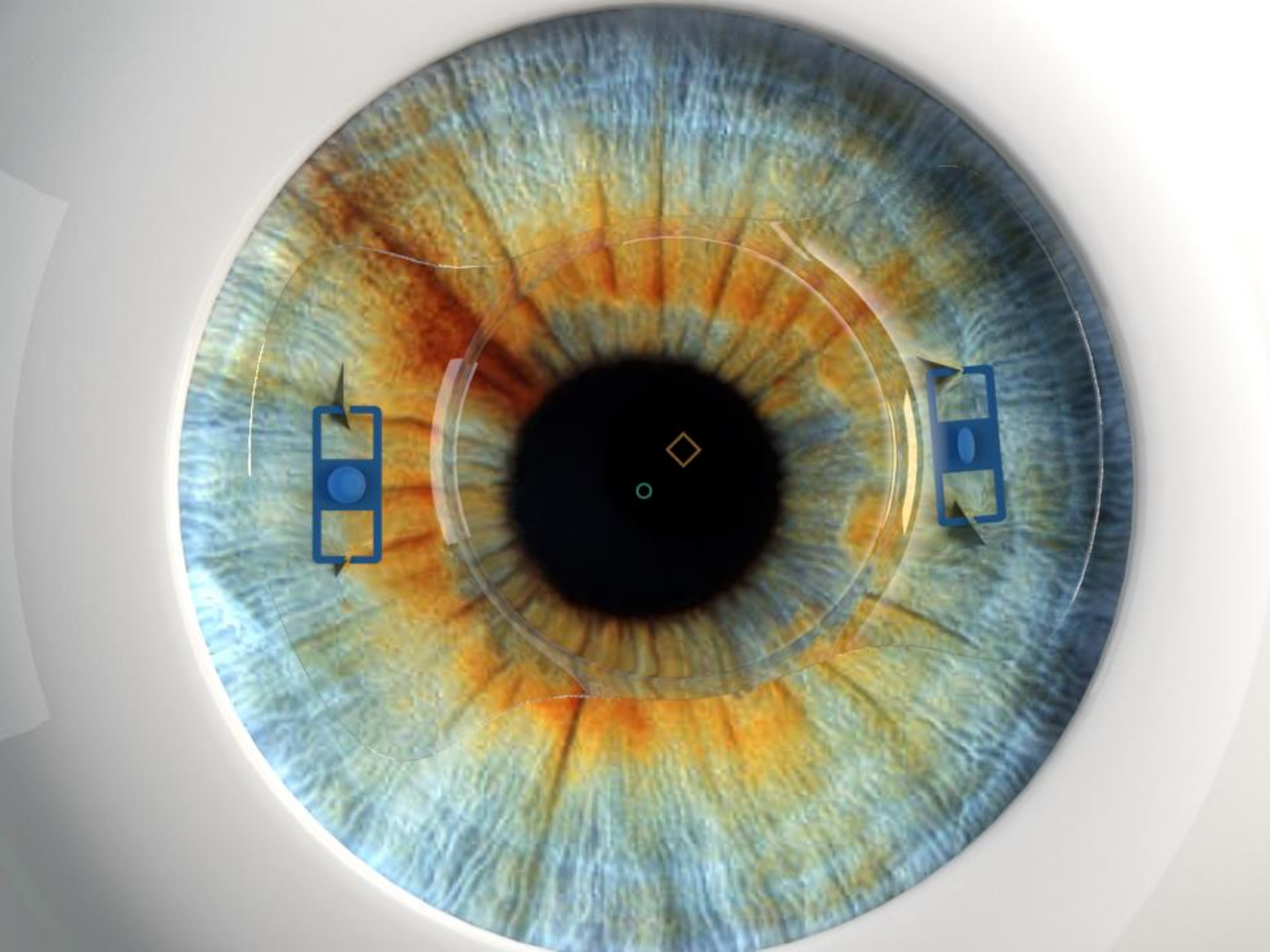


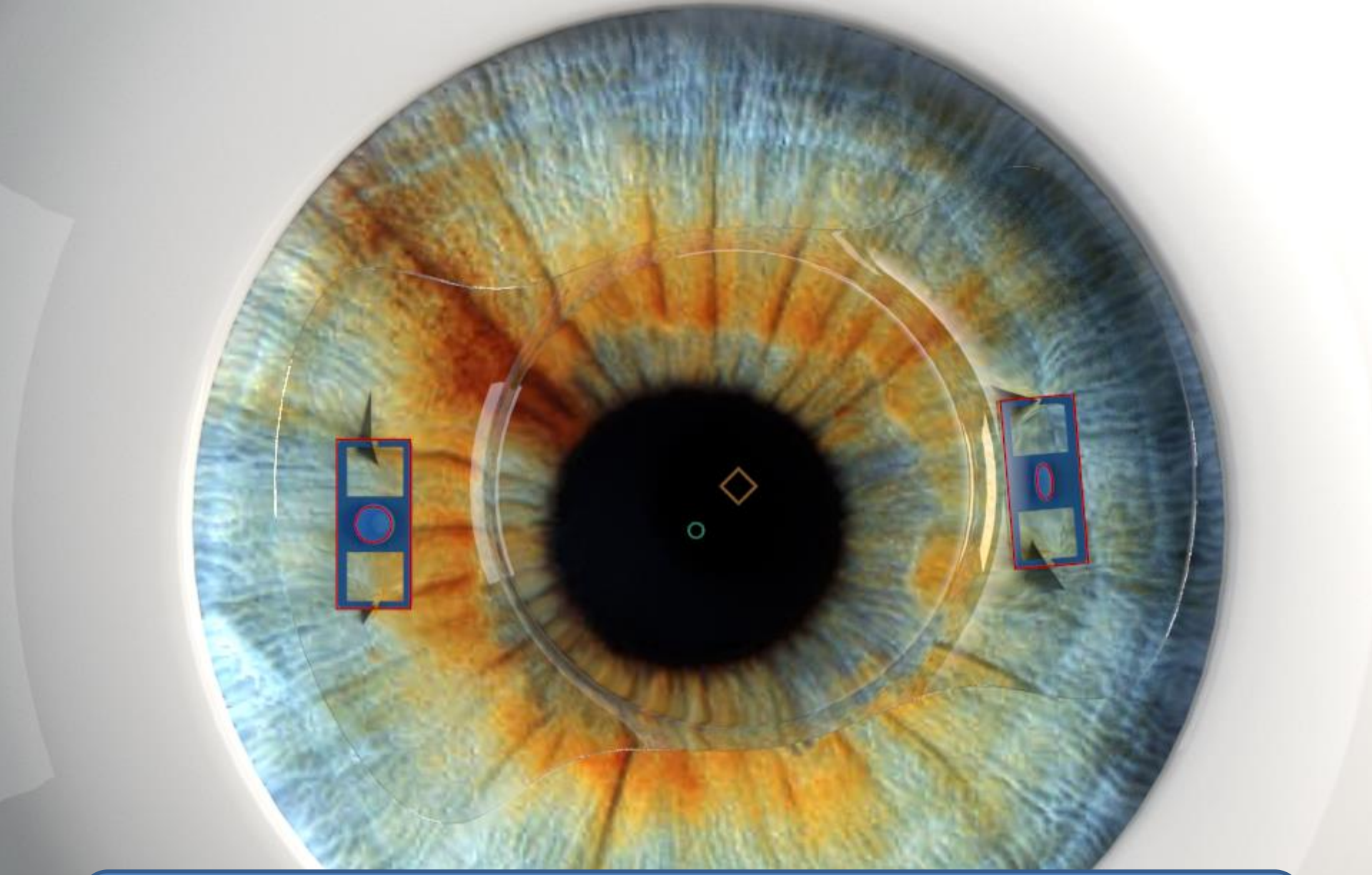
2/ designing of the Individualized Optics ex Vivo
Marking of the Line of Sight
Photo can not be rotated !



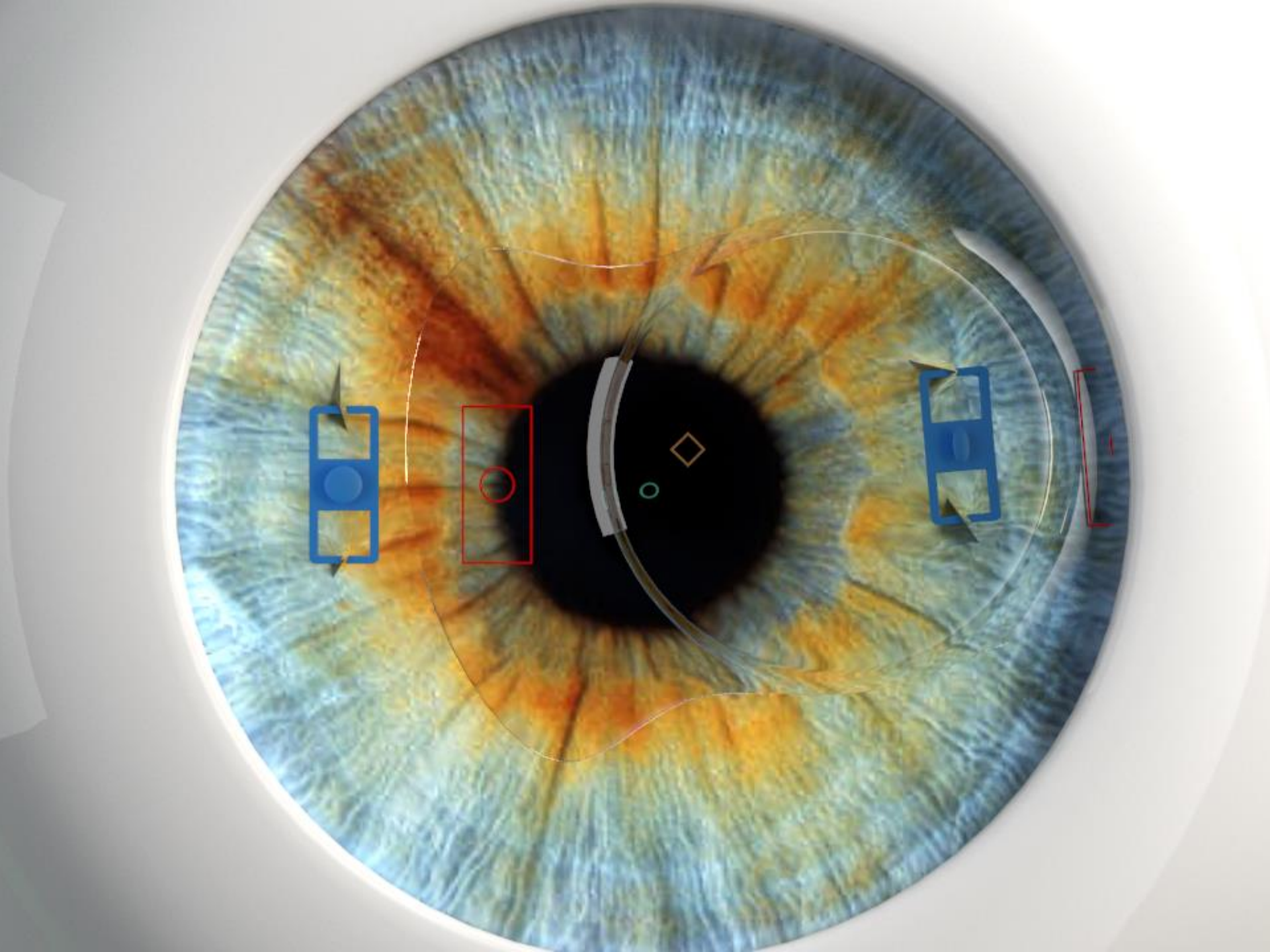
3/" introducing" the Gregory 'preCut" Lens "into" the image of the AC
(the precut version of the lens NEVER actually enters the Eye)

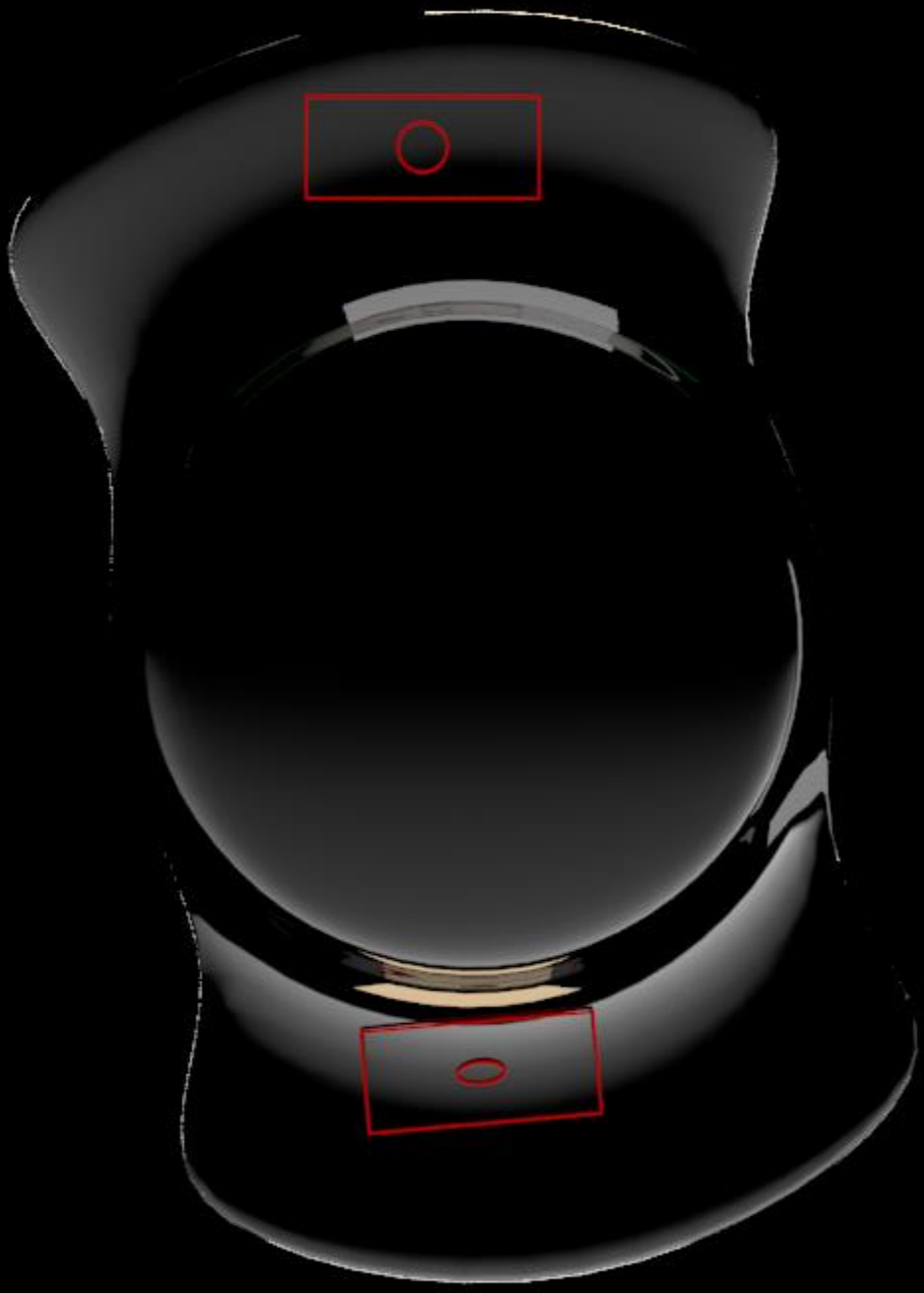


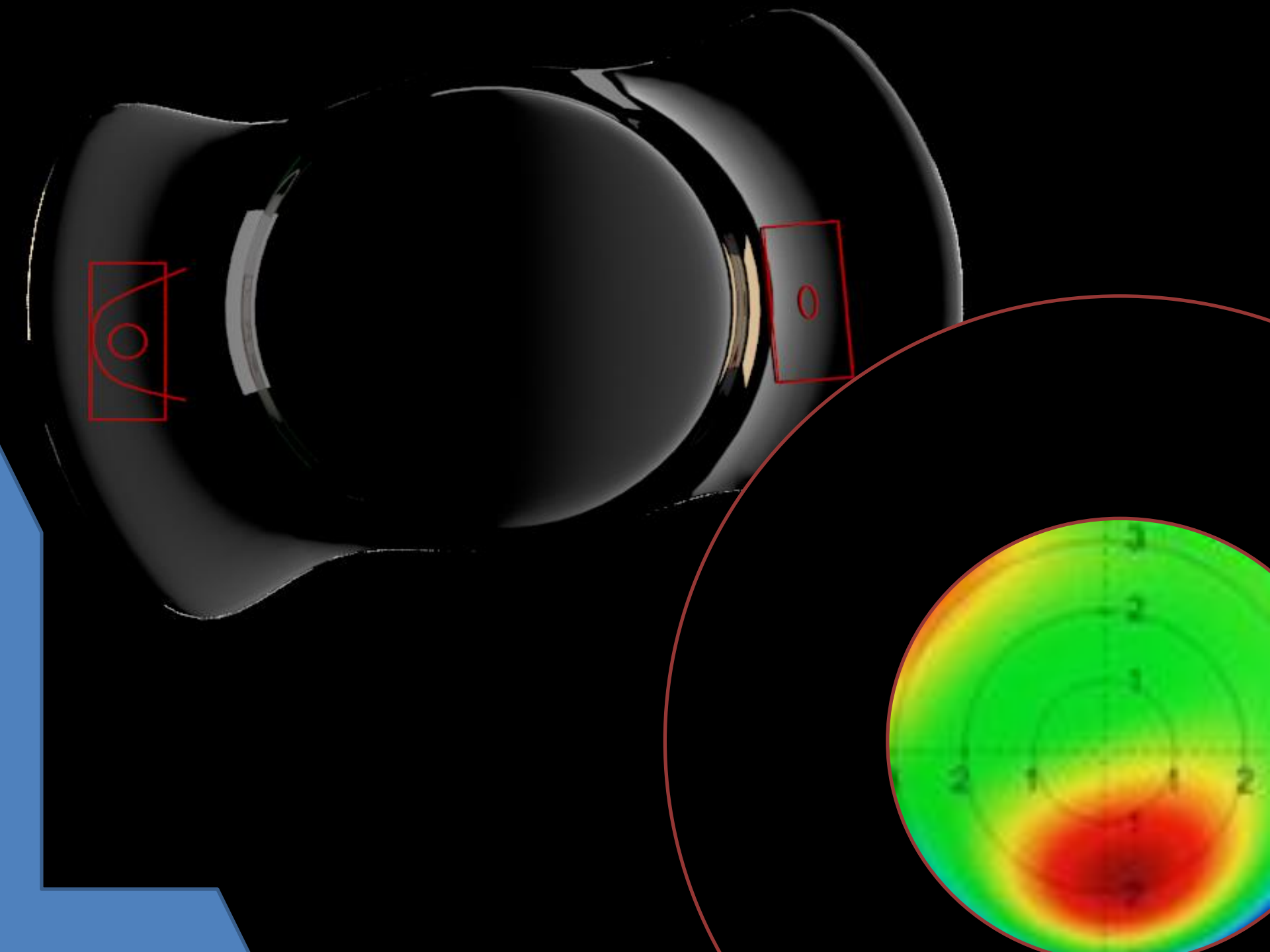


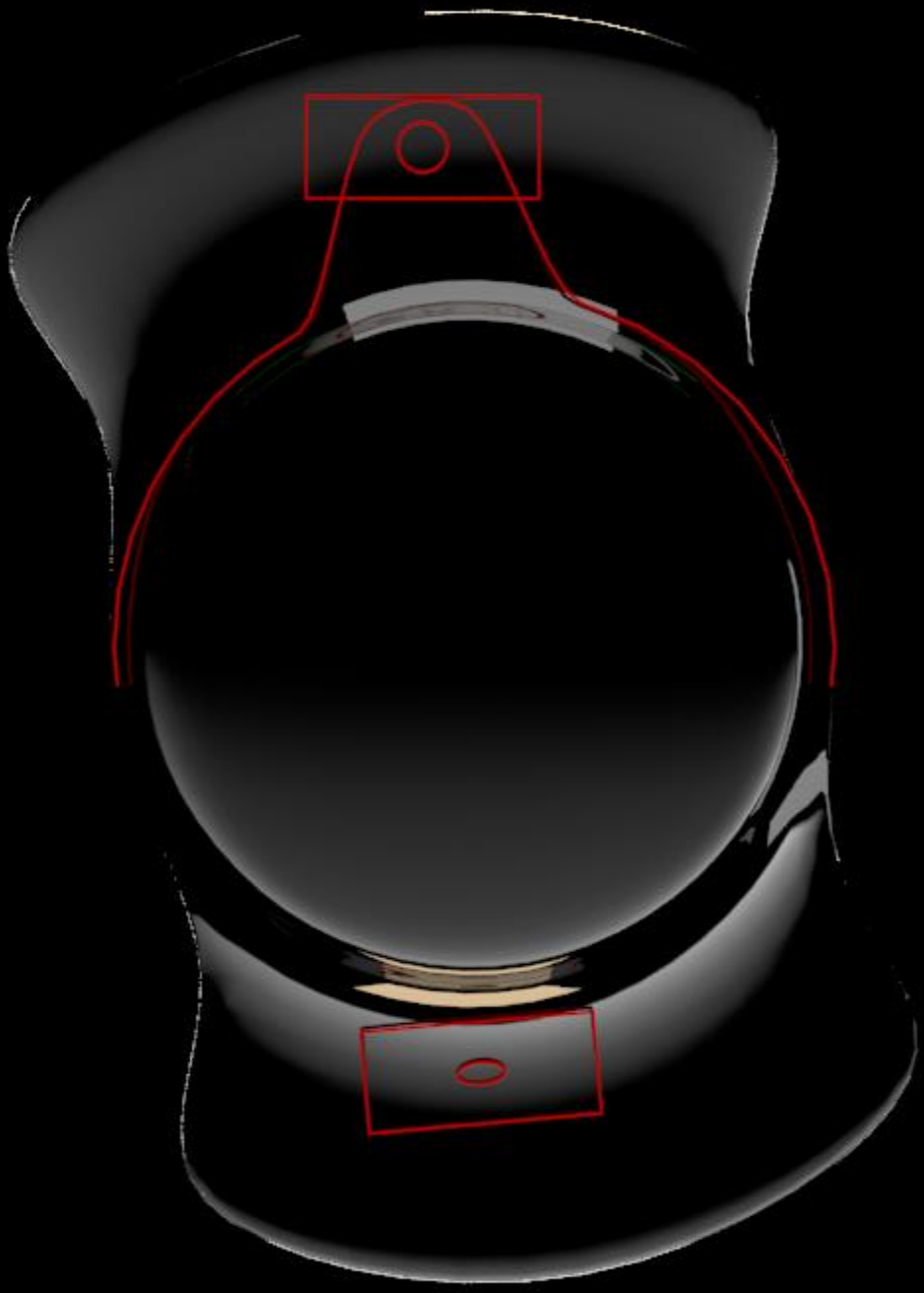


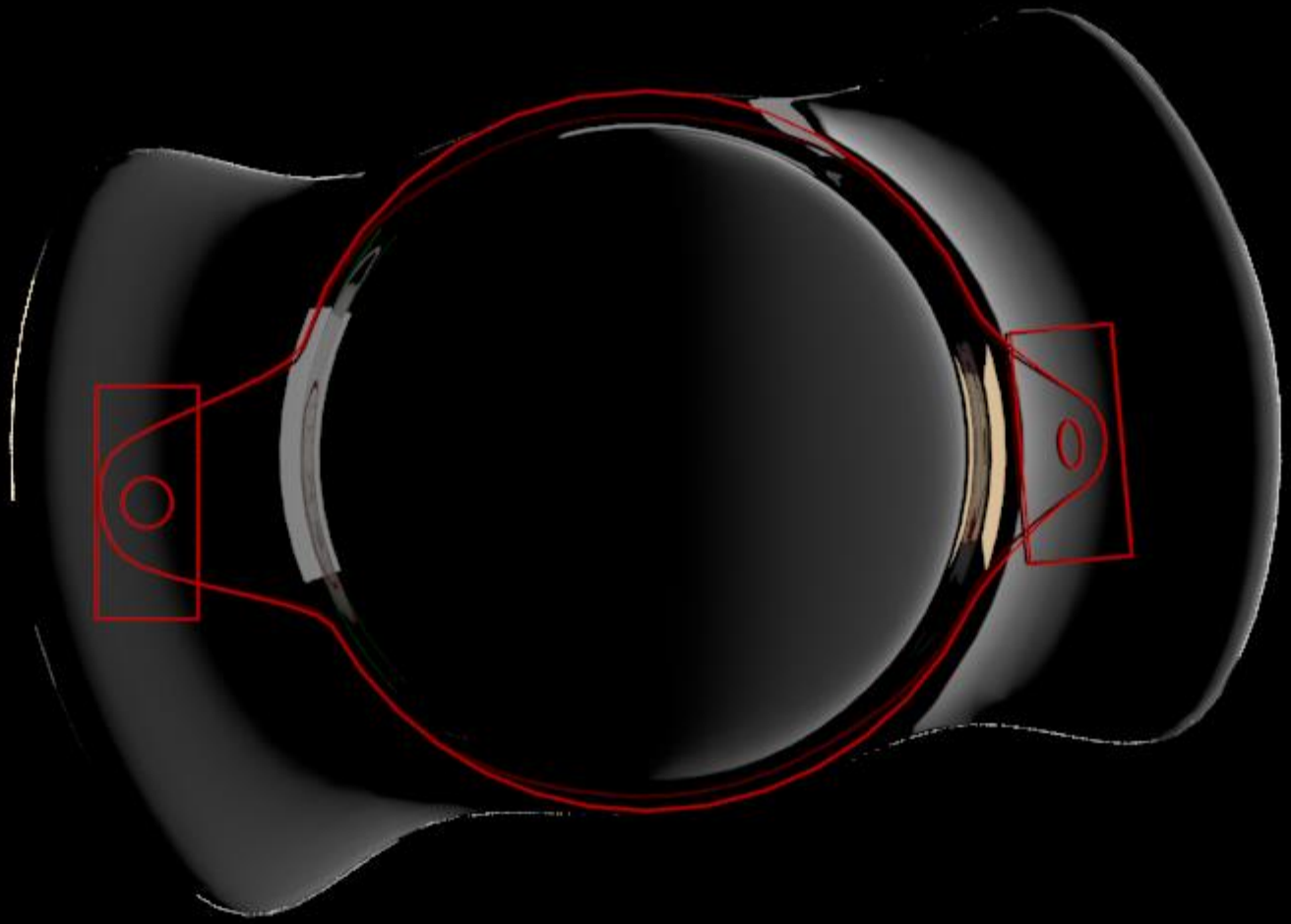
3/" introducing" the Gregory 'preCut" Lens "into" the image of the AC
(the precut version of the lens NEVER actually enters the Eye)

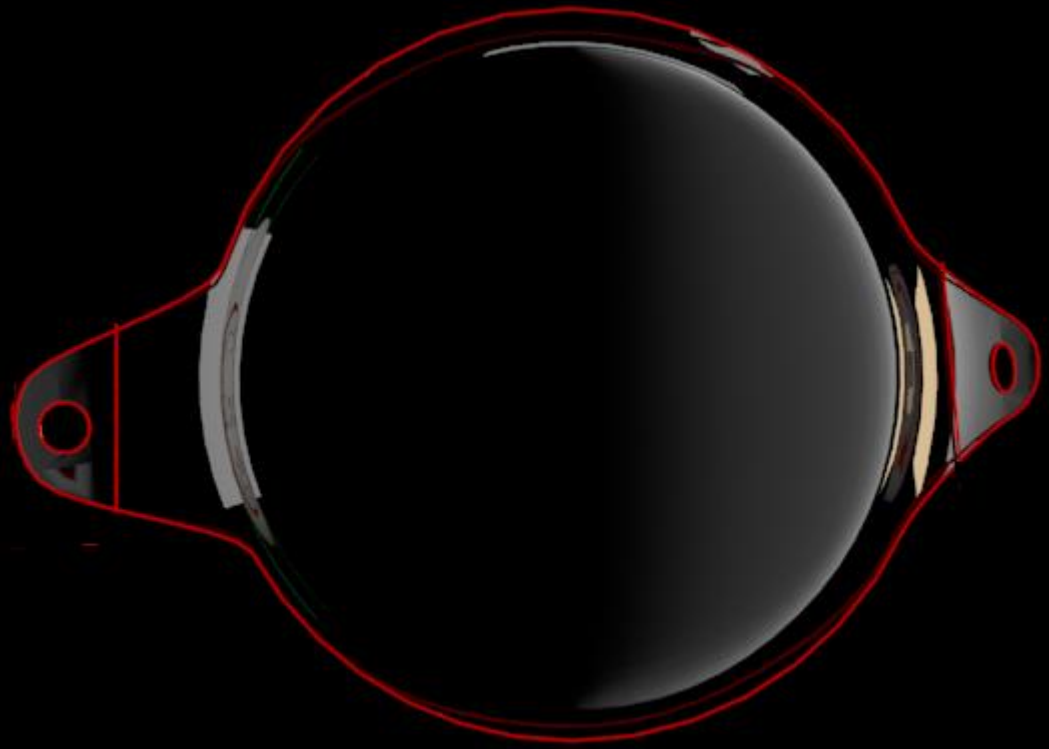


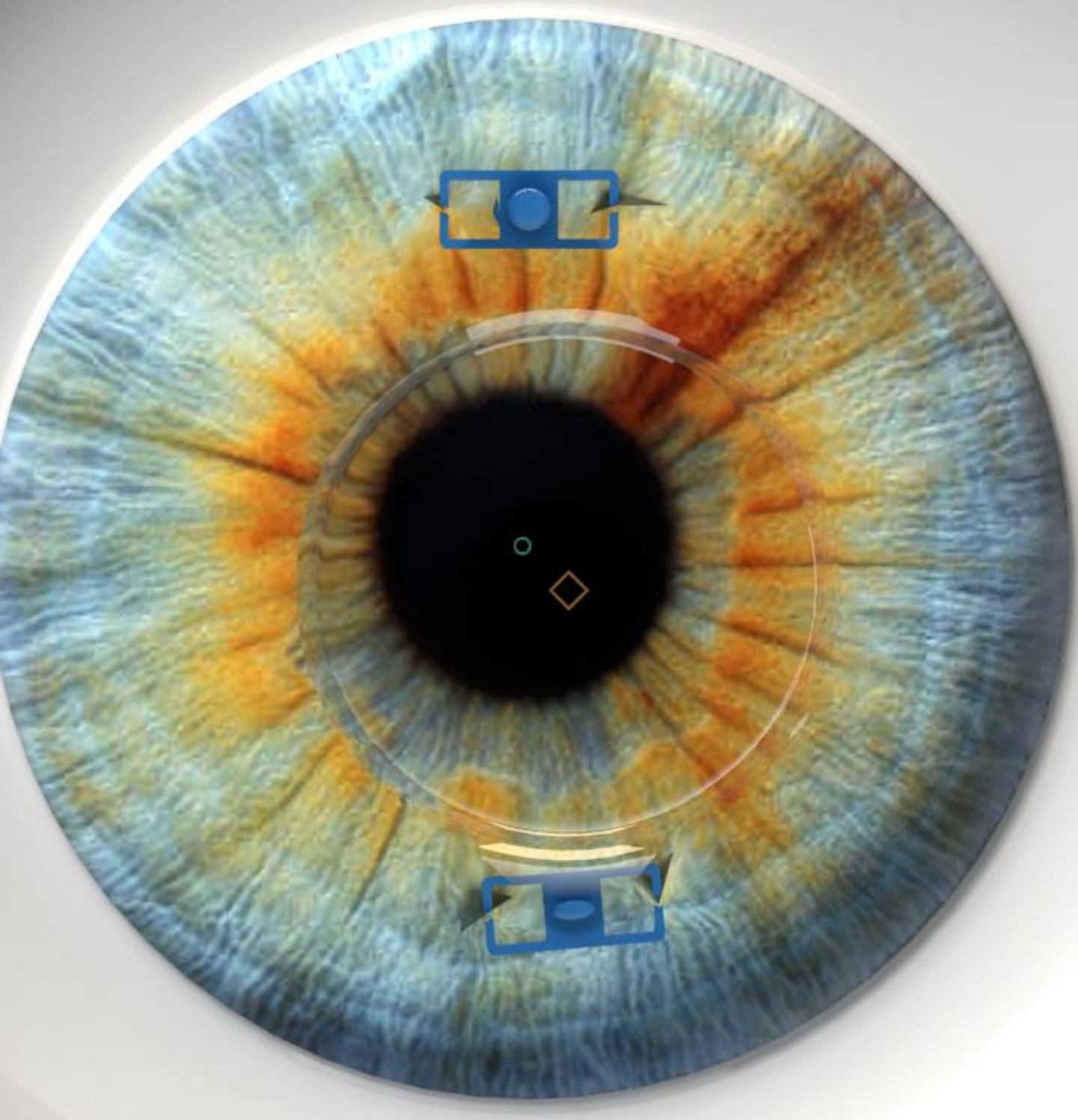












# Conclusions

1. The ViTAL system offers a novel approach in registering important clinical information in KC patients
2. It allows accurate description of four important denominators to guide specific treatment options & enhances communication among care providers
3. Ablation Volume: Is the most important Metric in our system that addresses both topographical abnormality and refraction. The ORK-CAM is a valuable tool in our staging system

# Conclusions

4. The AMART project may allow deep ablations on keratoconic corneas of ~ 3500nl.
5. The design of best possible ablations for keratoconus is still evolving (SCHWIND R/D dept)

# Conclusions

6. Correcting huge higher order aberrations is theoretically possible in the phakic young KC patient with a customized phakic IOL like the Gregory lens system we describe here.

**Thank you for your kind attention !**