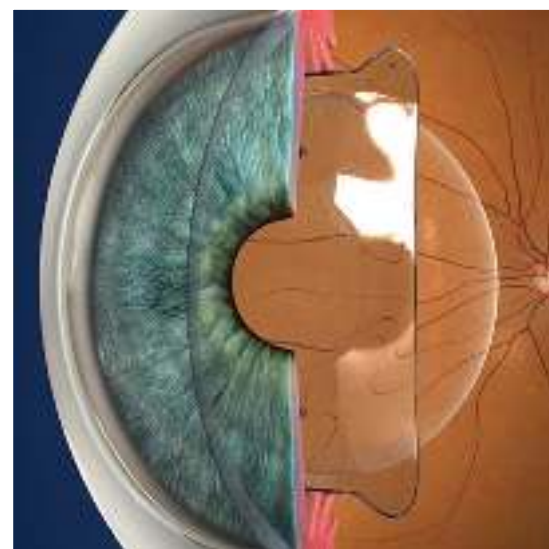


ICL: Planning, Surgery, Follow-up

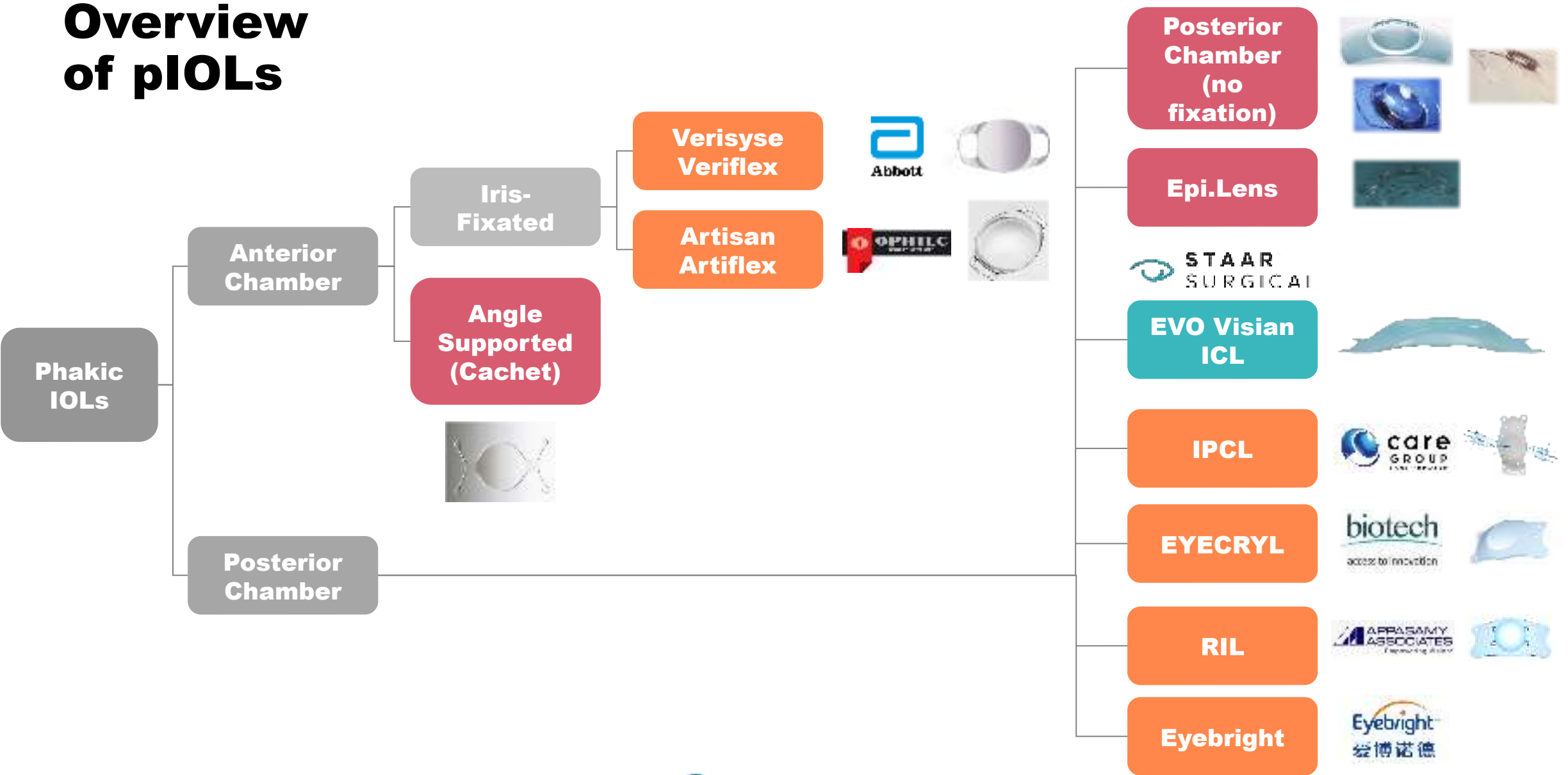
Andrea Russo, MD, PhD, P-CEO, FWCRS



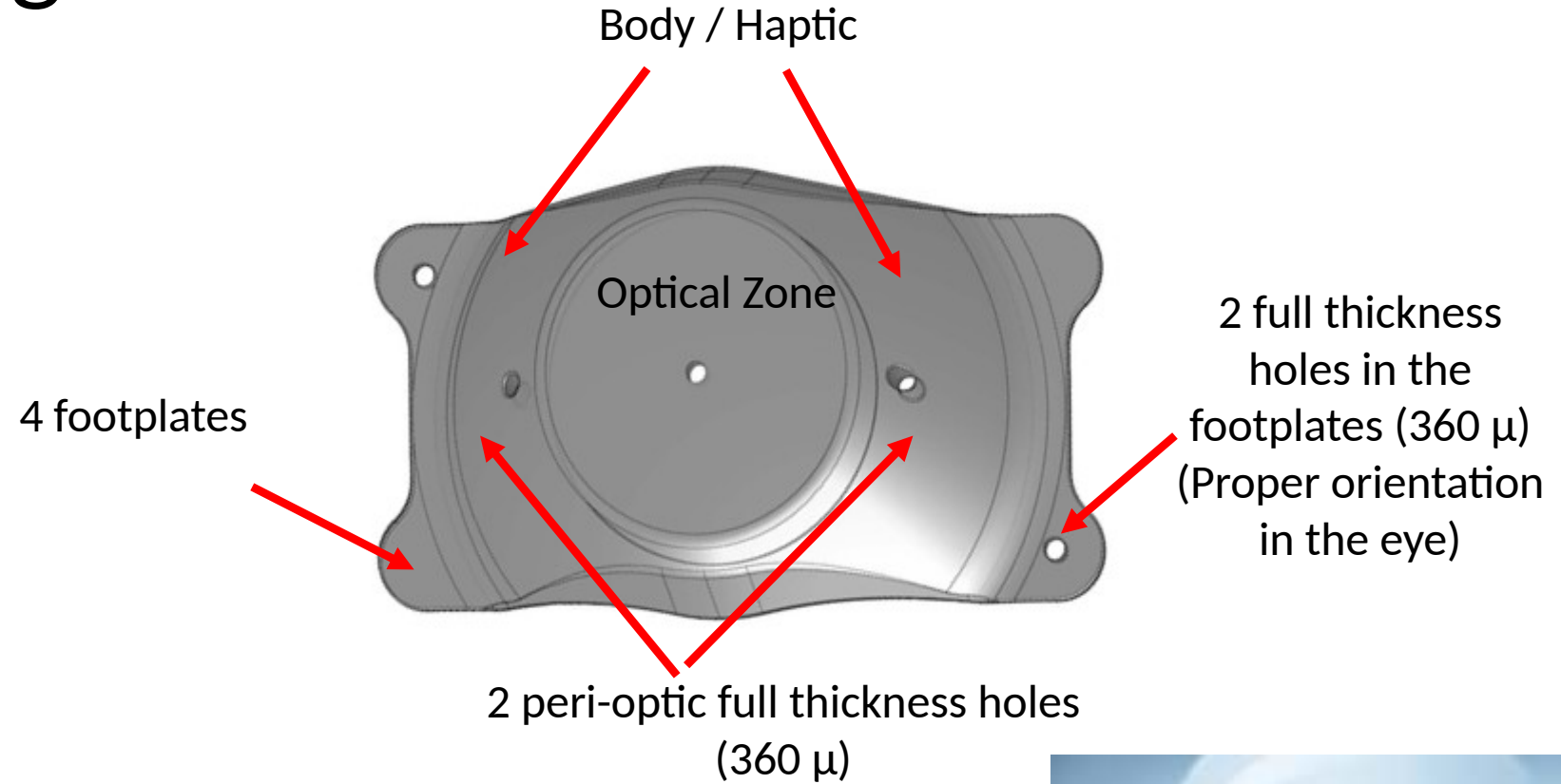
gruppo
refrattivo
italiano



Overview of pIOLs



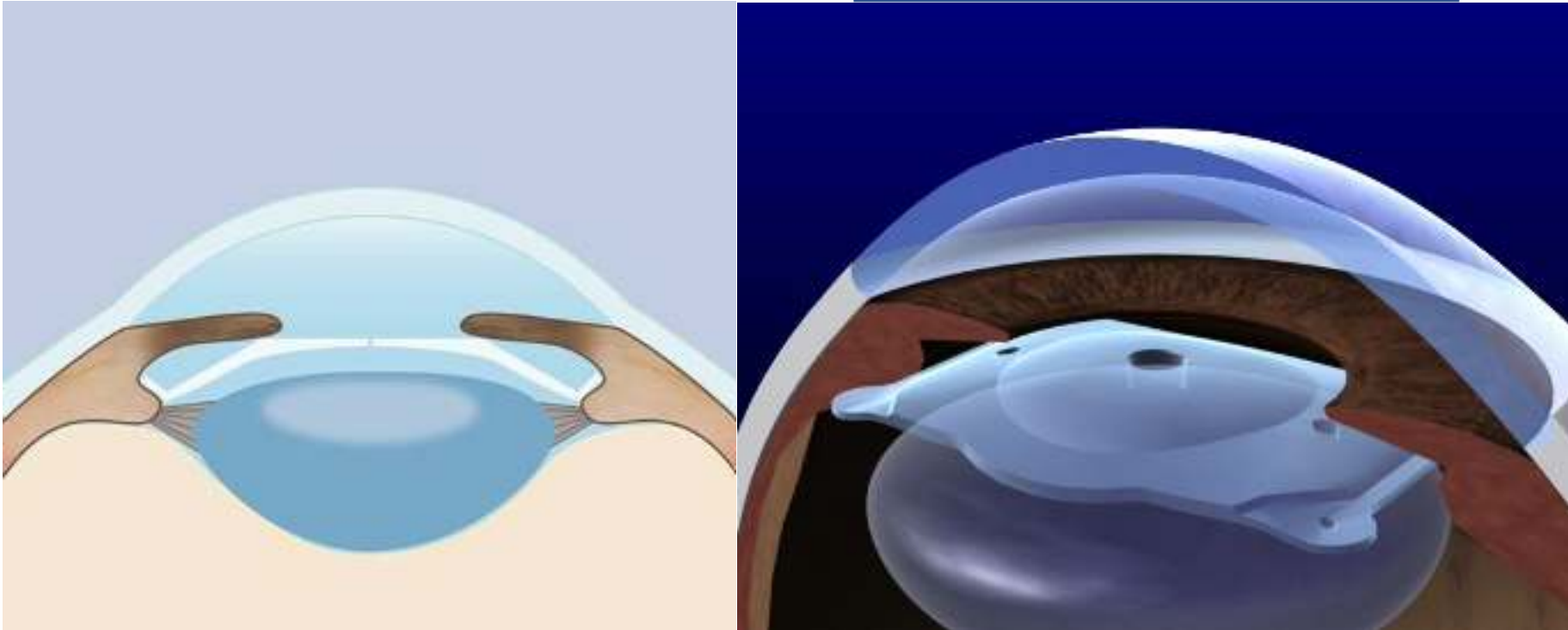
Lens design



VICMO, VTICMO, VICM5, VTICM5



Source: K Shimizu. MD.



- Important step forward in ICL design development.
- Eliminates the need of iridotomies¹
- Restores a more natural aqueous flow¹

1. Alfonso JF, Lisa C, Fernández-Vega Cueto L, Beido-Satnerón L, Madrid-Costa D, Montes-Mico R. Clinical outcomes after implantation of a posterior chamber collagen copolymer phakic intraocular lens with a central hole for myopic correction. J Cataract Refract Surg. 2013 Jun;39(6):915-21



$$M = \frac{1}{1 - d \times P}$$

M = minification effect

d = vertex distance

P = power of the lens

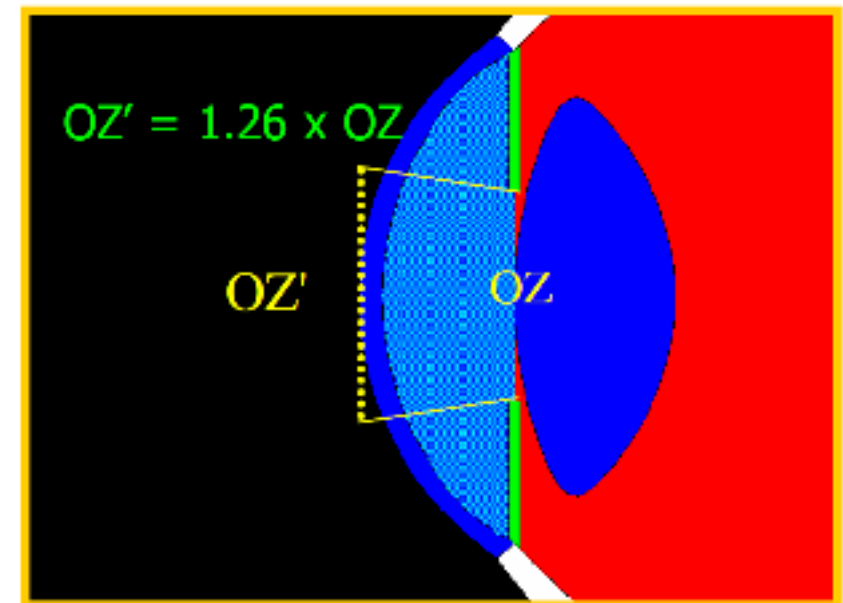
To remember:

- The magnification/minification effect changes with the vertex distance.
- The closer the lens is to the eye, the weaker the effect is.
- Effect on visual acuity: VA is lower with eyeglasses than with contact lenses for someone with high myopia.

Minification effect for a lens power -10.00 D	Vertex distance (mm)	Minification effect for a lens power -20.00 D
0.909/-9.3%	10 mm	0.833/-16.7%
0.893/-10.7%	12 mm	0.806/-19.4%
0.877/-12.3%	14 mm	0.781/-21.9%
0.762/-13.8%	16 mm	0.757/-24.3%

Posterior Chamber Concept

- A PIOL placed in the posterior chamber (before the crystalline lens and behind the iris), **the Collamer lens comes closer to the nodal point of the ocular refractive system and contributes to the optimal retinal image formation in highly myopic eyes.** *Clin Exp Optom 2014; 97: 516–522.*
- **Retro-irideal or pre-lenticular position is ideal for a gain of 23% in optical efficacy.** *Lovisol. Posterior phakic chamber lenses. Chapter 3.*
- Amplification factor of the visual angle (1.26). **The ICL Optical Zone corresponds to an optical zone at the corneal plane which is larger by a factor of 1.26.** *Lovisol. Posterior phakic chamber lenses. Chapter 8.*
- *Jack Holladay rule of thumb: “for each diopter of correction there is 2% mag for Plus and 2% min for minus. So, 12.5 D aphakic spectacles are 25% larger than emmetropia. Each line of visual acuity is 25% larger than the line below, so if a person were -12.5 D of myopia and saw 20/20 with glasses, they should be 20/16 after refractive surgery to be comparable.”*





Ten-year prevalence of rhegmatogenous retinal detachment in myopic eyes after posterior chamber phakic implantable collamer lens

Luis Arrevola-Velasco, MD, PhD, Jaime Beltrán, MD, Ana Rumbo, OD, Raquel Nieto, OD, Vasyi Druchkiv, MSc, José María Martínez de la Casa, MD, PhD, José María Ruiz-Moreno, MD, PhD

Purpose: To determine and compare the prevalence of rhegmatogenous retinal detachment (RRD) in myopic eyes operated of posterior chamber phakic implantable collamer lens (ICL) with a control group of nonoperated myopic eyes over 10 years of follow-up.

Setting: Clínica Baviera, Madrid, Spain.

Design: Retrospective cohort study.

Methods: There were 2 study cohorts: one with patients operated with ICL and a control group of nonoperated patients. The primary outcome of RRD was measured retrospectively, first through chart review of ICL-operated patients with at least 10 years of follow-up, then secondarily through telephone questionnaires and specialist verification for those with incomplete follow-up. Prevalence and incidence were calculated and compared, as well as their possible association with other risk factors.

Results: 58 operated patients completed follow-up in our clinic. A survey of 3849 more patients was conducted for a total of 252 operated with a mean spherical equivalent (SEQ) of -12.6 diopters (D) and 221 nonoperated with a mean SEQ of -10.5 D. 7 eyes developed an RRD in the operated vs 5 eyes among the non-operated (prevalence 1.71% vs 1.25%, respectively, $P = .773$). The equivalence tests, the two one-sided test and the null hypothesis test between groups, were within the 0.02 limits, confirming the null hypothesis, and compared survival curves did not show significant differences ($P = .59$).

Conclusions: ICL implantation surgery for high myopia did not affect the prevalence of RRD in operated eyes compared with similar nonoperated eyes in this long-term study.

J Cataract Refract Surg 2023; 49:272–277 Copyright © 2022 Published by Wolters Kluwer on behalf of ASCRS and ESCRS

Myopia is the most frequent refractive defect, with a prevalence ranging from 30.6% on average among European countries to 47.2% in some Southeast

Refractive surgery in myopic eyes with a phakic posterior chamber implantable collamer lens implant (ICL; STAAR Surgical Co.) which is currently the most used posterior

Posterior Chamber pIOLs Characteristics

Treatment options for the future

- A pIOL is an additive procedure (a lens is implanted inside the eye) that can be removed.
- IOL power calculation in eyes after previous phakic IOL implantation in comparison with eyes after previously performed corneal refractive procedure is more precise and predictable¹.
- Corneal based refractive procedures can be done after phakic intraocular surgery².

Placement is discreet

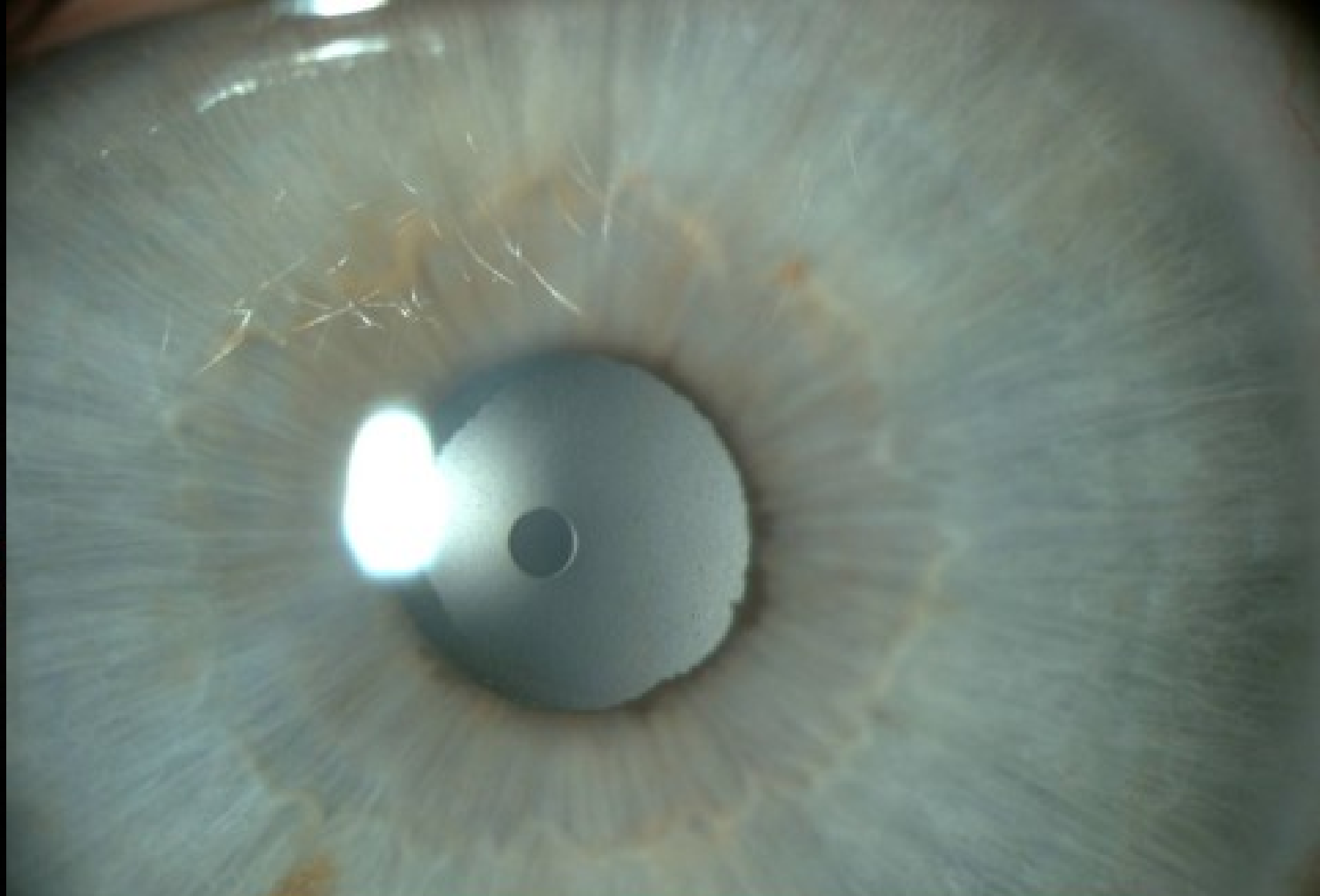
- Because the Visian ICL is implanted in the posterior chamber, behind the iris, unlike other phakic IOLs, the lens is invisible to both the patient and any observer.

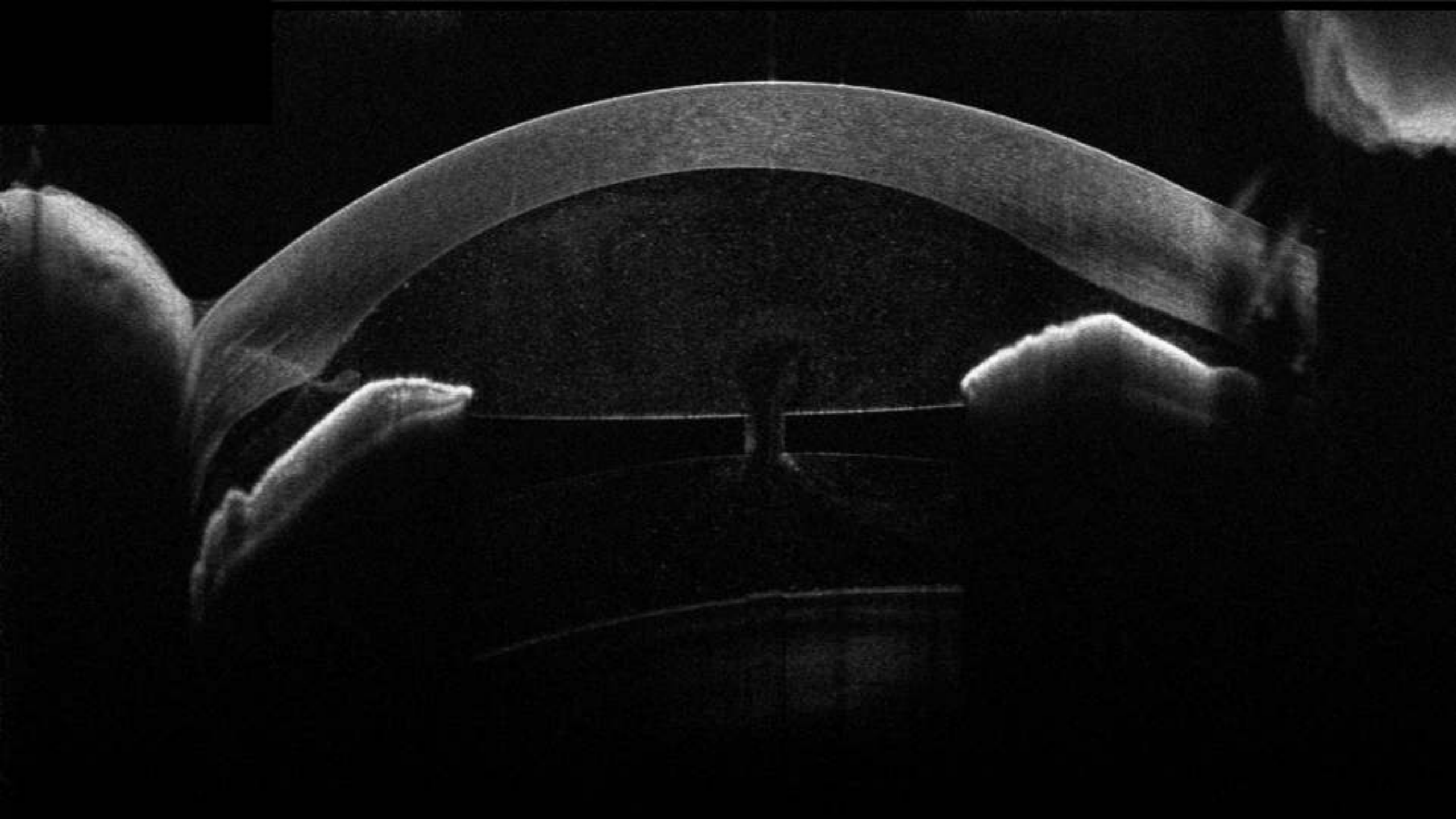
Preserves accommodation³ as crystalline lens is not removed.

1. Lens surgery after previous refractive surgery. Section 4. Chapter 11.

2. Laser in situ Keratomileusis and Photorefractive Keratectomy for Residual Refractive Error After Phakic Intraocular Lens Implantation. César A Sánchez-Galeana, MD; Ronald J Smith, MD; Xavier Rodriguez, MD; Miguel Montes, MD; Arturo S Chayet, MD. Journal of Refractive Surgery. 2001;17(3):299-304.

3. Phakic Intraocular Lenses. Surv Ophthalmol. 50: 549-587, 2005. C. Lovisolo, D. Reinstein.





Approval Ranges

Dioptr	Cylinder	Current Optical Diameter (mm)	EVO+ Optical Diameter (mm)	Approximate Equivalent OZ at Corneal Plane ^{22,23} (mm)
-0.5 to -9.0	+0.5 to +6.0	5.8	6.1	7.6
-9.5 to -10.0	+0.5 to +6.0	5.5	5.9 - 6.1	7.4 - 7.6
-10.5 to -12.5	+0.5 to +6.0	5.3	5.3 - 5.8	6.6 - 7.3
-13.0 to -14.0	+0.5 to +6.0	4.9	5.0 - 5.2	6.3 - 6.5
-14.5 to -18.0	+0.5 to +6.0	4.9	N/A	6.1
+0.0 to 10.0*	+0.5 to +6.0	5.8	N/A	7.3

Available in 0.5 D increments

*The Hyperopic Model is not EVO and has no central port in the optic. Data in this brochure relates to the myopic and toric myopic versions. For information on the hyperopic range, please contact STAAR Surgical

Lens lengths: **11.6 mm / 12.1 mm / 12.6 mm / 13.2 mm / ***13.7 mm

** Available only in the Hyperopic Model

*** Available only in the Myopic Model

Doctor ID **63182** **Andrea Russo** Date: 2021.12.07

Calculate For ☐ ICL ☒ Toric ICL

Patient ID **28052001**

Patient Name **Xxxxxx Yyyyyy**

Operative Eye ☒ OD ☐ OS

Year Month Day
DOB 2001 5 28

Gender ☐ M ☐ F

BVD **16**

Sphere **-8.25**

Cylinder **-2**

Axis **18**

Power Degrees

K1 **42.18**

@ **9**

K2 **43.73**

@ **99**

ACD **3.525**

CT **0.510**

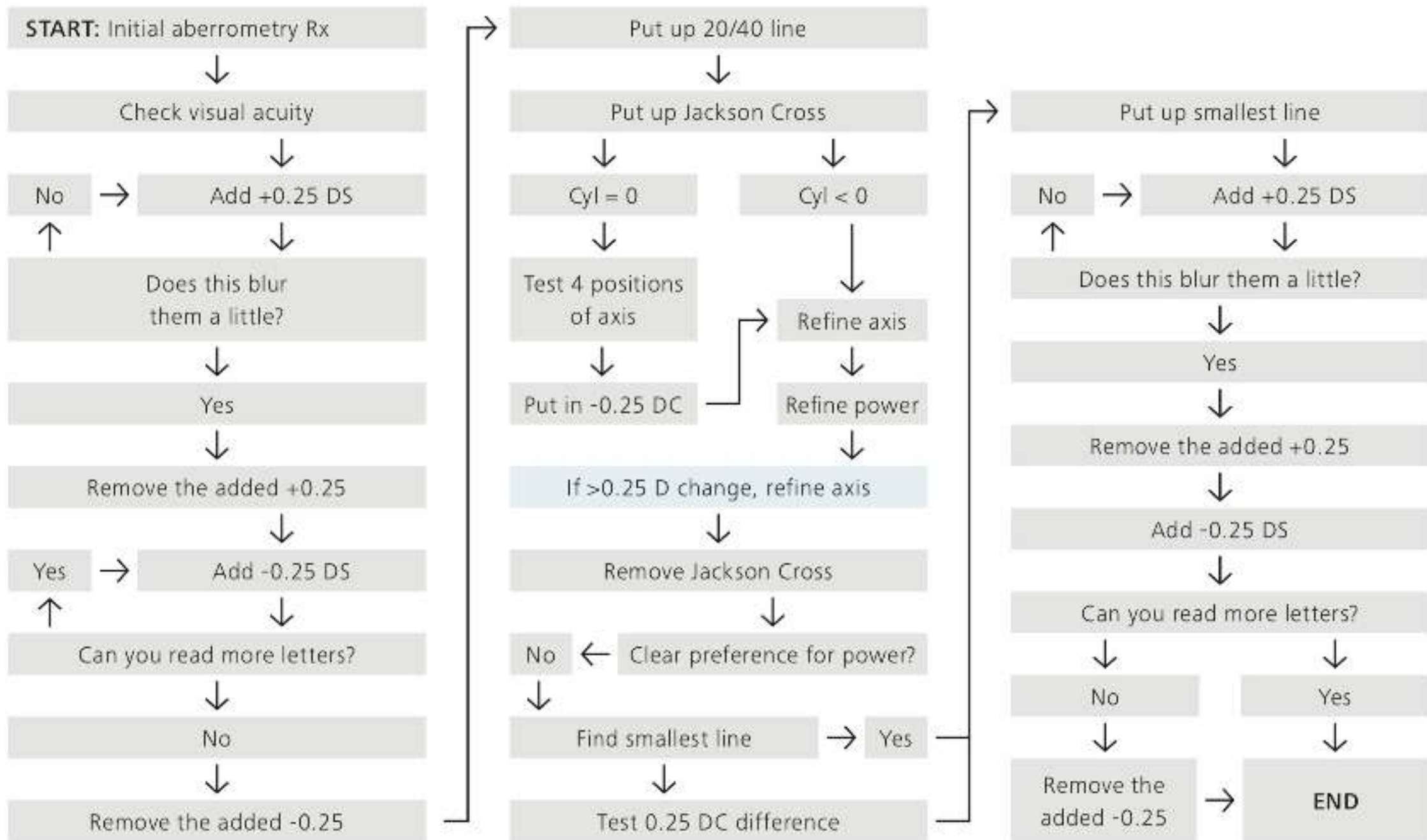
WtW **11.65**

CL Sphere **0**

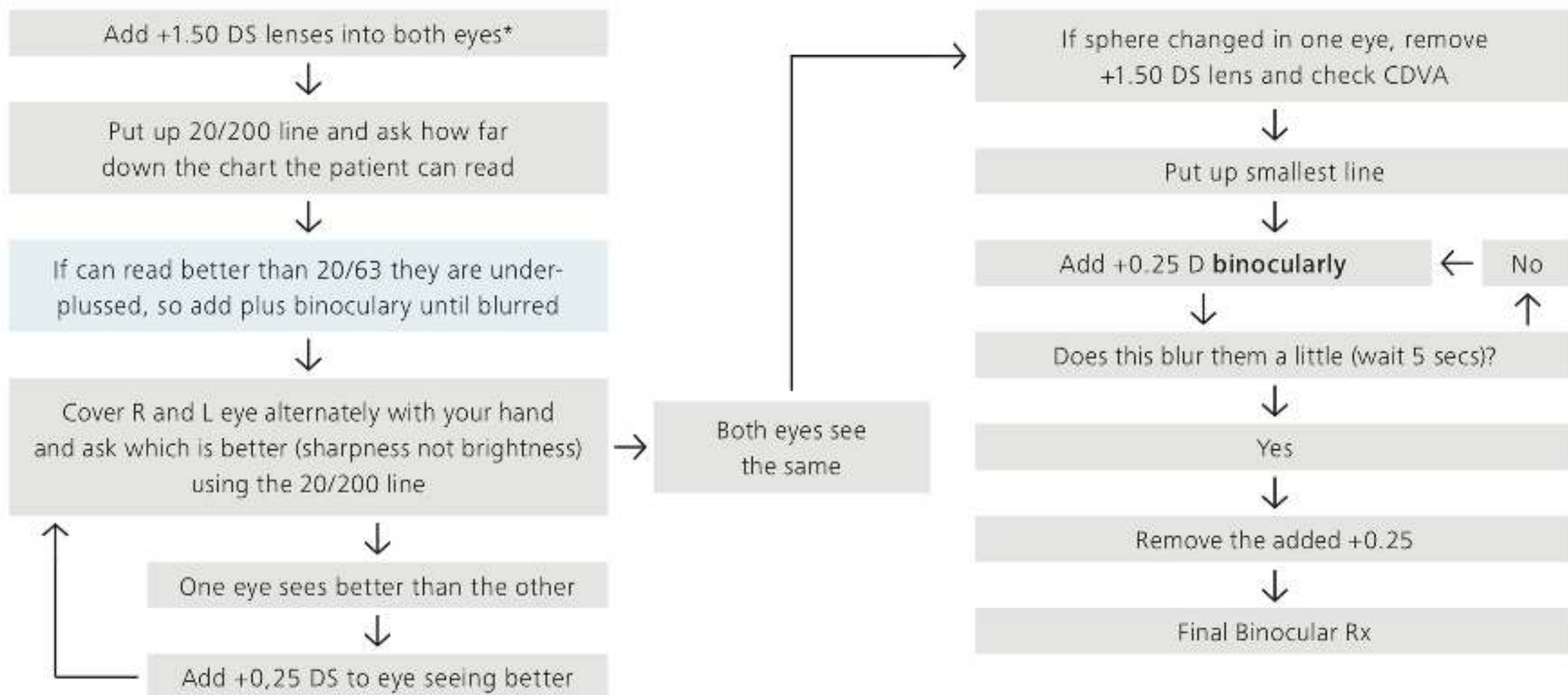
Any previous ☐ No
intervention? ☐ Yes:



Monocular Manifest Refraction Protocol



Binocular Balance Protocol



*N.B. This is for a testing distance of 2.40 m using the CSV-1000 chart – equivalent to +1.08 D

Calculate For ☐ ICL ☒ Toric ICL

Patient ID 28052001

Patient Name [REDACTED]

Operative Eye ☒ OD ☐ OS

DOB 2001.05.28

Gender ☐ M ☒ F

BVD 16

Sphere -8.25

Cylinder -2

Axis 18

	Power	Degrees
K1	42.18	@ 9

K2	43.73	@ 99
----	-------	------

ACD 3.525

CT 0.510

WtW 11.65

CL Sphere 0

Any previous intervention? ☒ No ☐ Yes:

Please select a lens from the list below

Sel SPH	Sel CYL	Exp SPH	Exp CYL	Exp AXIS	Exp SEQ
-12.50	+1.5	+01.05	+00.35	106	+01.22
-12.00	+1.5	+00.68	+00.35	106	+00.85
-11.50	+1.5	+00.30	+00.35	106	+00.47
-11.00	+1.5	-00.09	+00.35	106	+00.09
-10.50	+1.5	-00.48	+00.36	106	-00.30

Target Lens Selected **Toric Myopic 12.6mm -11.50/+1.5/X108**

☒ DIFFERENT LENGTH REQUESTED

☐ 12.1

☒ 12.6

☐ 13.2

☐ 13.7

Cylinder Power

☐ +0.5 ☐ +1.0

☒ +1.5 ☐ +2.0

☐ +2.5 ☐ +3.0

☐ +3.5 ☐ +4.0

☐ +4.5 ☐ +5.0

☐ +5.5 ☐ +6.0

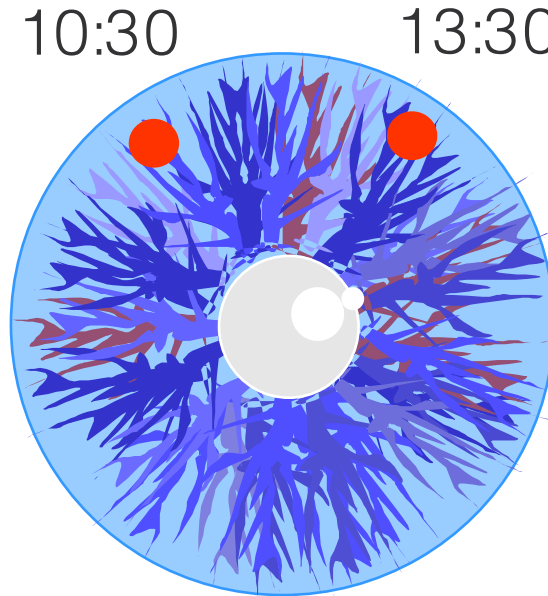
Back

Submit

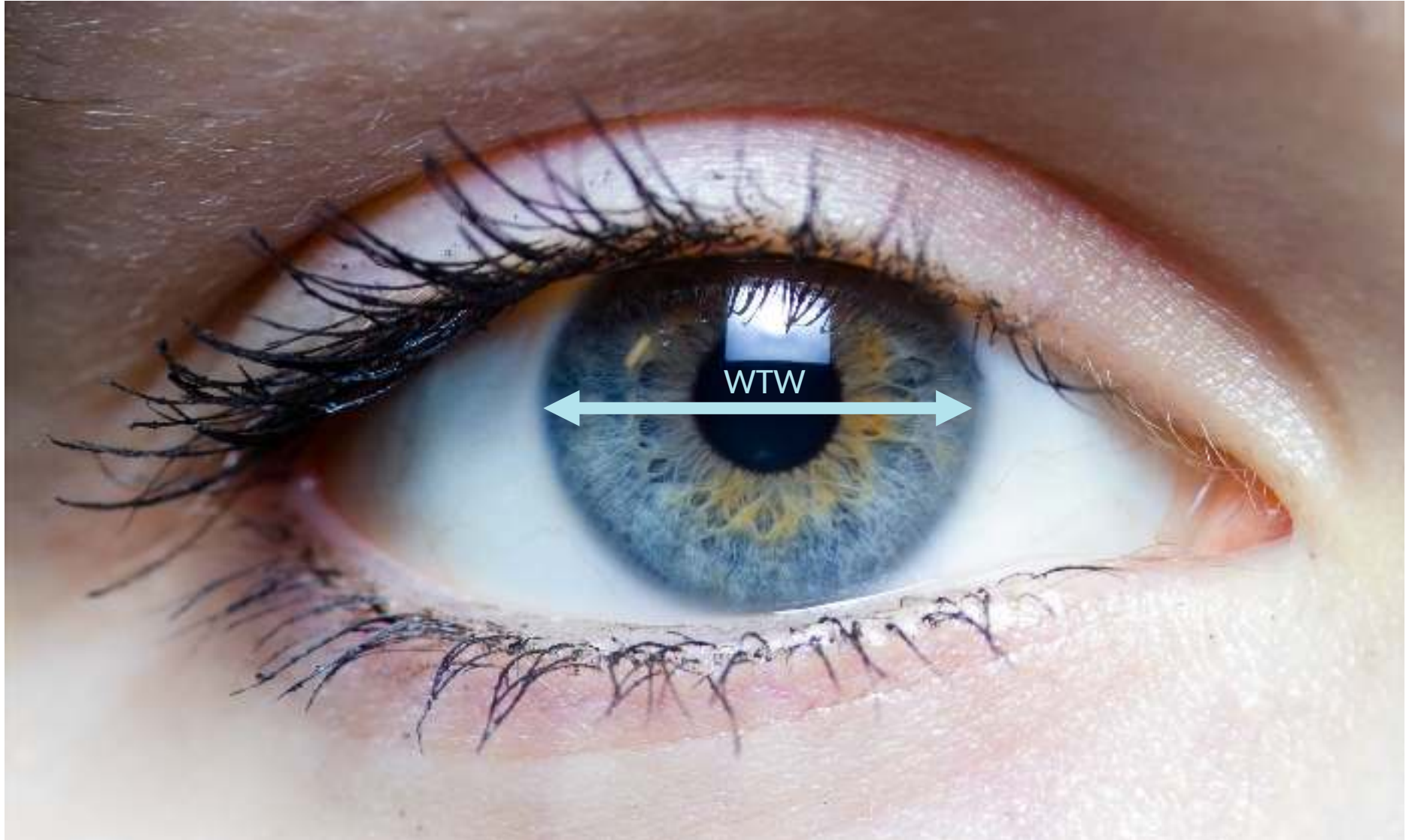
Print

Peripheral Iridotomies (PIs)

- Two YAG Iridotomies (0.5 to 0.8 mm) placed superiorly, 90° apart should be placed 1 to 2 weeks prior to surgery
- Check patency of iridotomies prior to surgery and at the end of surgery
- Prevents pupillary block



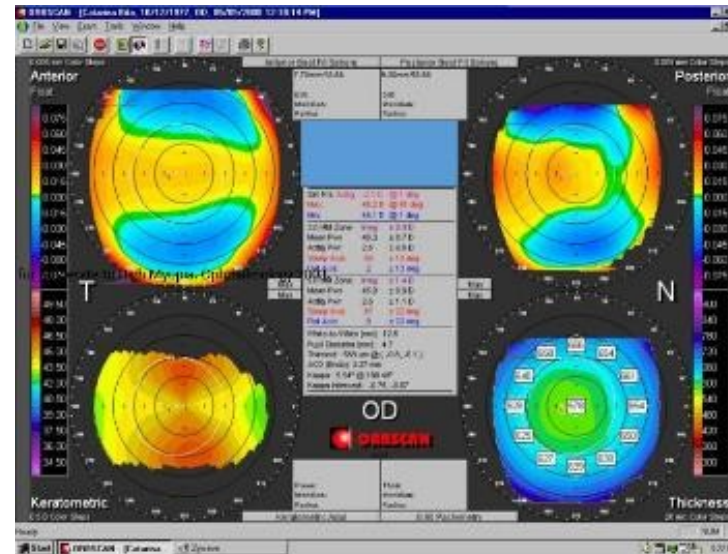
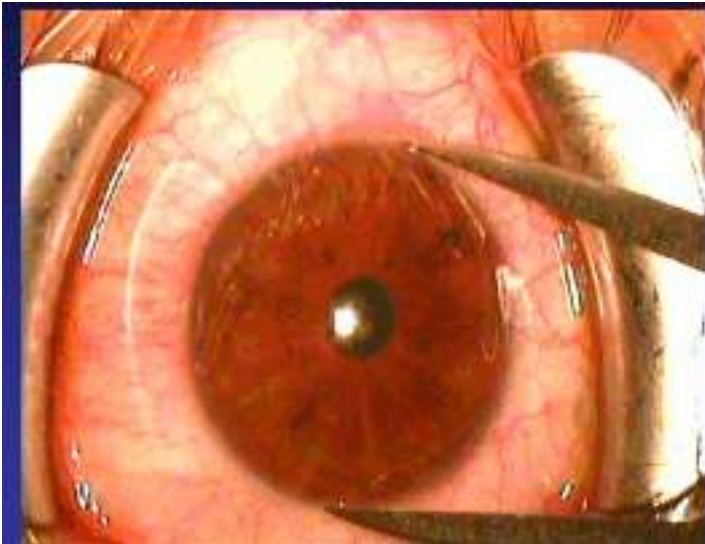
Horizontal White to White (WTW)



Horizontal White-To-White

- During the FDA Clinical Trial for the ICM/TICM, the Horizontal **WTW diameter** and **ACD (endo)** were used to determine the ICL overall diameter (length).
- The WTW values were obtained using Calipers at the slit lamp or using the Orbscan unit.

U.S Food and Drug Administration Clinical Trial of the Implantable Contact Lens for Moderate to High Myopia. Ophthalmology 2003.



BAUSCH + LOMB Orbscan

The Orbscan is a non-contact topography system used for anterior segment evaluation.

It uses the horizontally moving scanning camera to acquire slit images. After image reconstruction, a mathematical three-dimensional model of the cornea and the anterior segment is calculated.¹

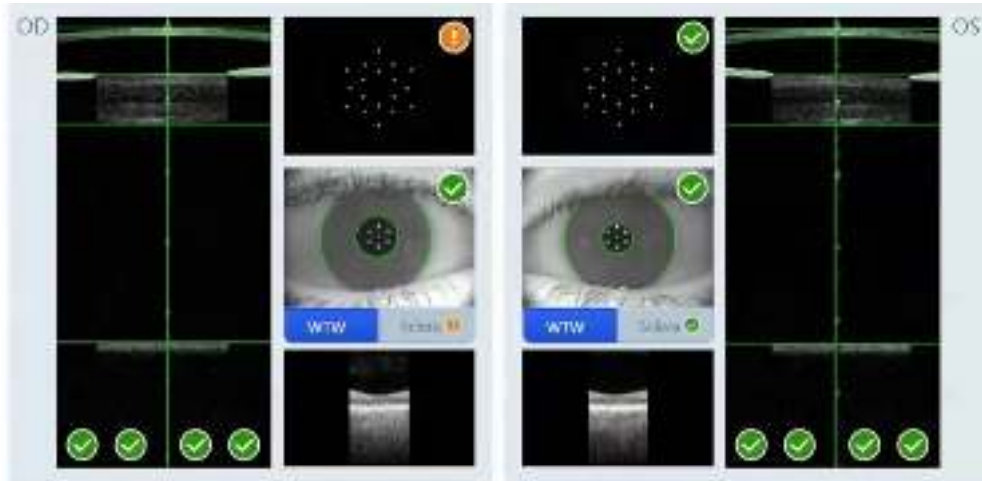
Manufacturer	Bausch & Lomb
Type	Optical
Measurement Principle	Slit-scanning with Placido disk topographer
Models	Orbscan, Orbscan II, Orbscan IIz, Orbscan 3
Measurements	WTW, ACD (epi or endo), Keratometry (K), CT
Comments	Automated vs. Manual (Digital Caliper, Eye Metrics)



1. Domínguez-Vicent A, Pérez-Vives C, Ferrer-Blasco T, García-Lázaro S, Montés-Micó R. Device interchangeability on anterior chamber depth and white-to-white measurements: a thorough literature review. *Int J Ophthalmol.* 2016;9(7):1057-1065. doi:10.18240/ijo.2016.07.20Technologies for anatomical and geometric characterization of the corneal structure and anterior segment: a review. *Semin Ophthalmol.* 2015;30(3):161-170. doi:10.3109/08820538.2013.835844



IOLMaster



Manufacturer	Carl Zeiss Meditec
Type	Optical
Measurement Principle	Swept Source OCT + Partial Coherence Interferometry (PCI)
Models	1, 2, 3, 4, 5.4, 500, 700
Measurements	WTW, K, ACD (epi), LT, Central Corneal Thickness (CCT), Axial Length (AL), PS

Pentacam

- The **Pentacam** rotating Scheimpflug camera (Oculus, Wetzlar, Germany) imaging system is a rapid, non-contact modality that enables the study of the eye's anterior segment using a blue light emitting diode and a rotating Scheimpflug camera. Using the Pentacam rotating Scheimpflug camera, the patient was asked to fixate straight ahead on the blue circular fixation target.
- The rotating camera captured up to 25 slit images of the anterior segment in less than 2 s, whereas the horizontal WTW and the ACD were automatically yielded by the imaging system.¹

Manufacturer	Oculus Optikgeräte GmbH
Type	Optical
Measurement Principle	Scheimpflug Topography System
Models	2002: Pentacam 2007: Pentacam HR 2015: Pentacam AXL 2019: Pentacam AXL Wave
Measurements	WTW, ACD (epi or endo), K, CT
Comments	Pentacam AXL has integrated Axial Length measurement in addition to AS tomography, the original function of Pentacam HR.

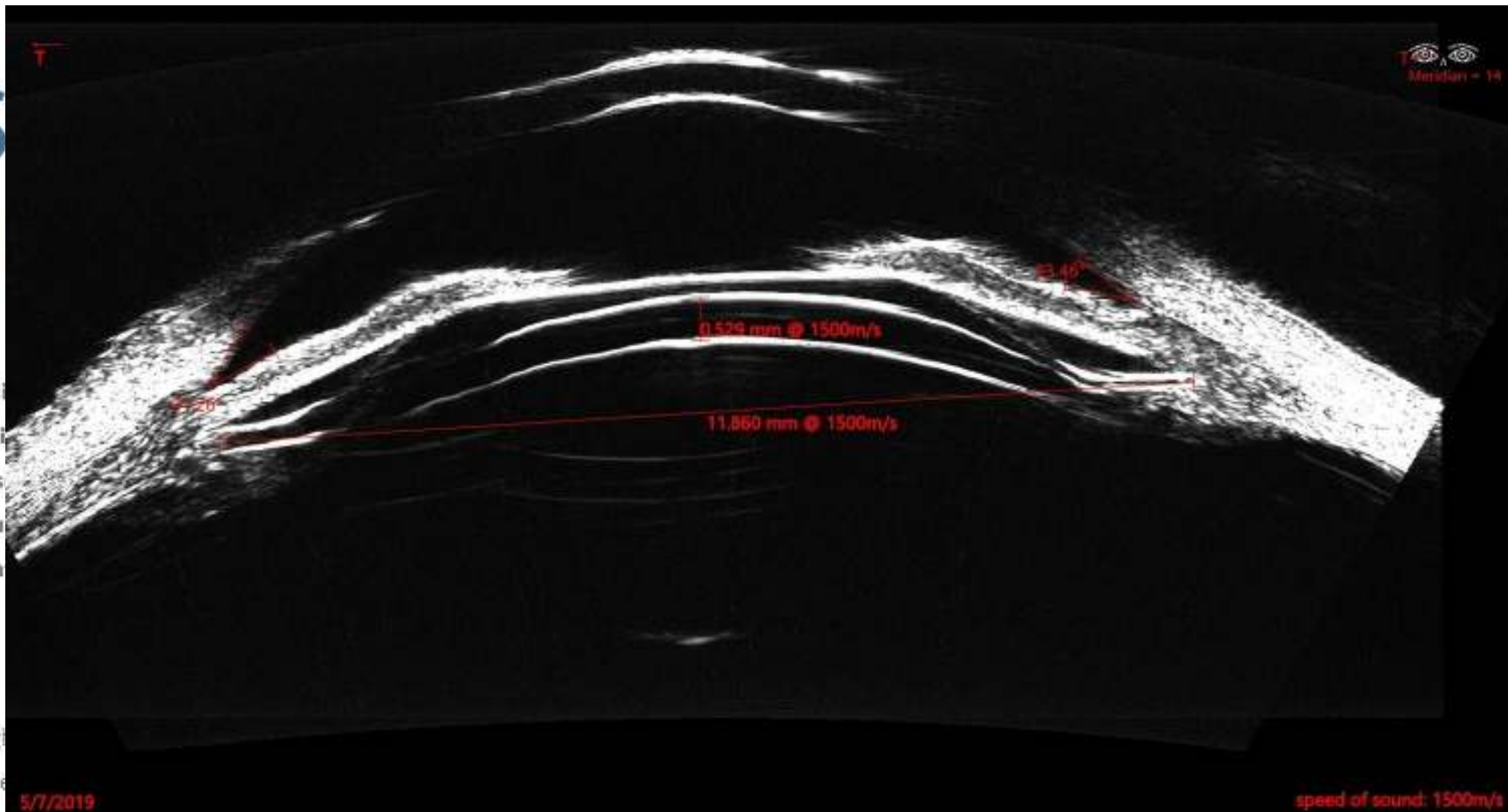


1. Calvo-Sanz JA, Poyales F, Zhou Y, Arias-Puente A, Garzón N. Agreement between the biometric measurements used to calculate the size of the implantable collamer lenses measured with four different technologies. Indian J Ophthalmol. 2022;70(5):1586-1592. doi:10.4103/ijo.IJO_2217_21

ArcScan 100

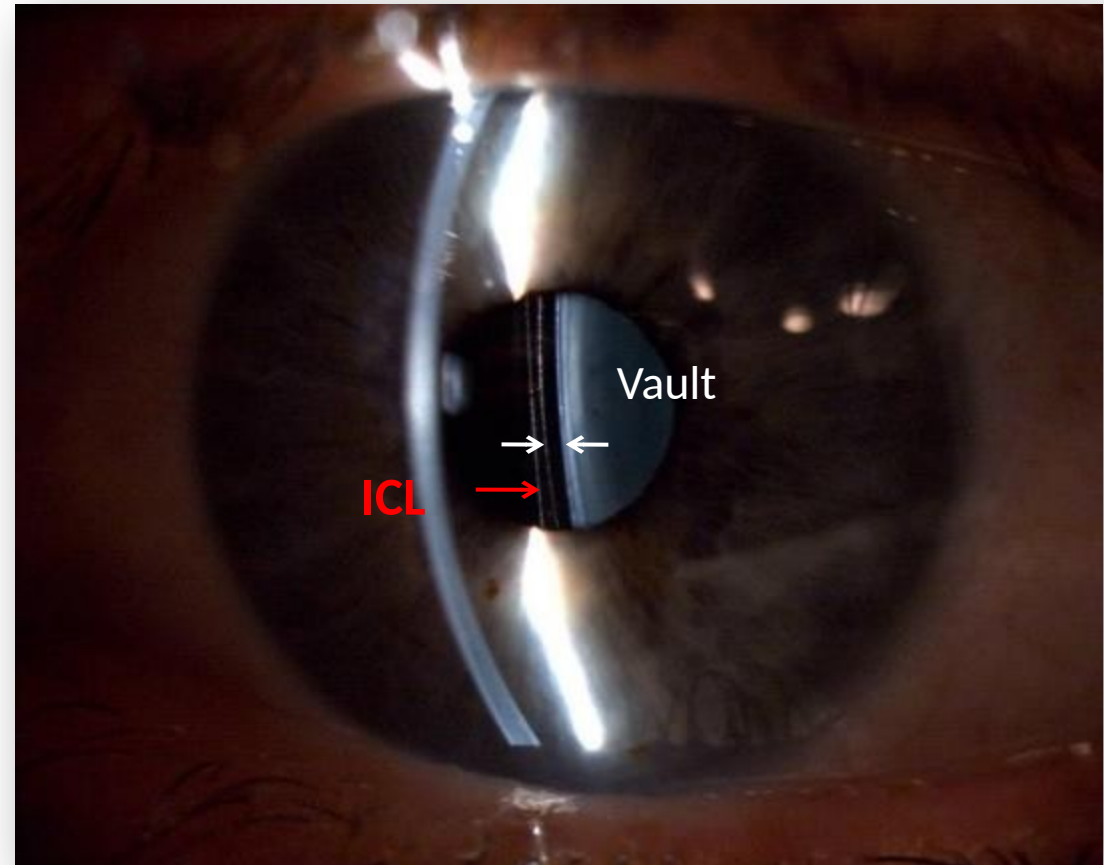
The ArcScan Insight is a device that uses very high speed 100 device and sensors to easily obtain structural data of the anterior segment of the eye. It uses advanced technologies.

The ArcScan Insight is a device for imaging and biomechanics.

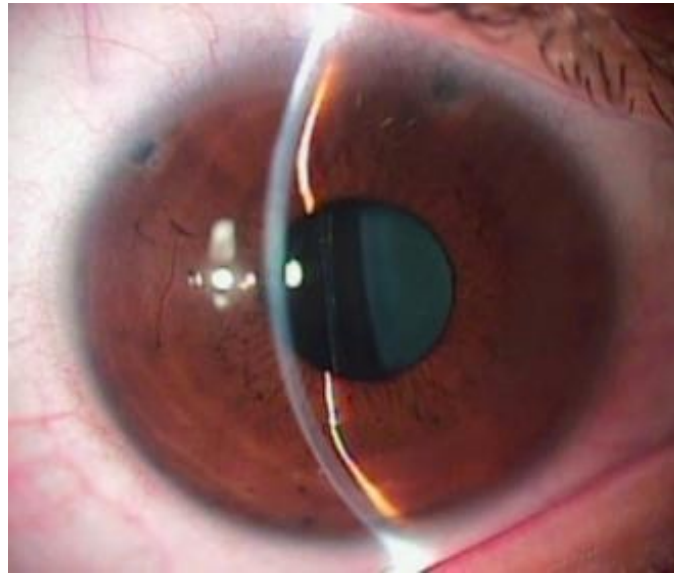
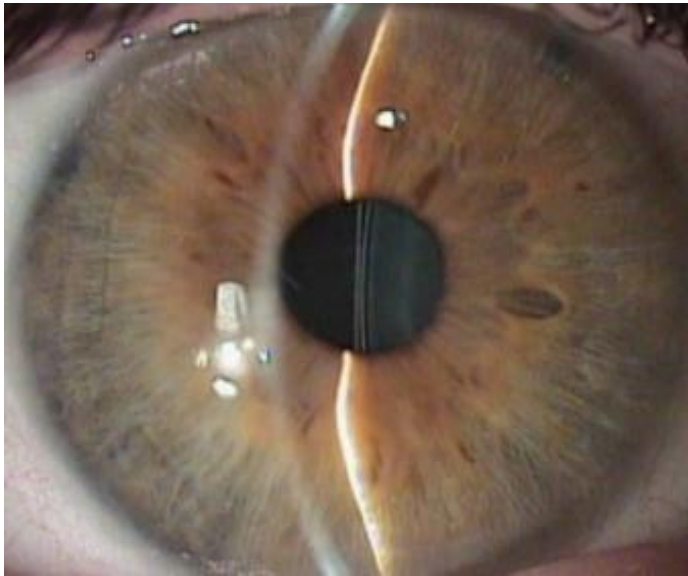
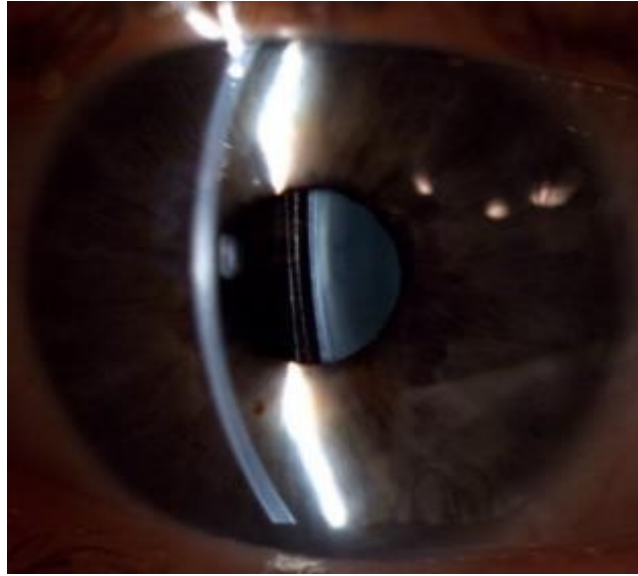


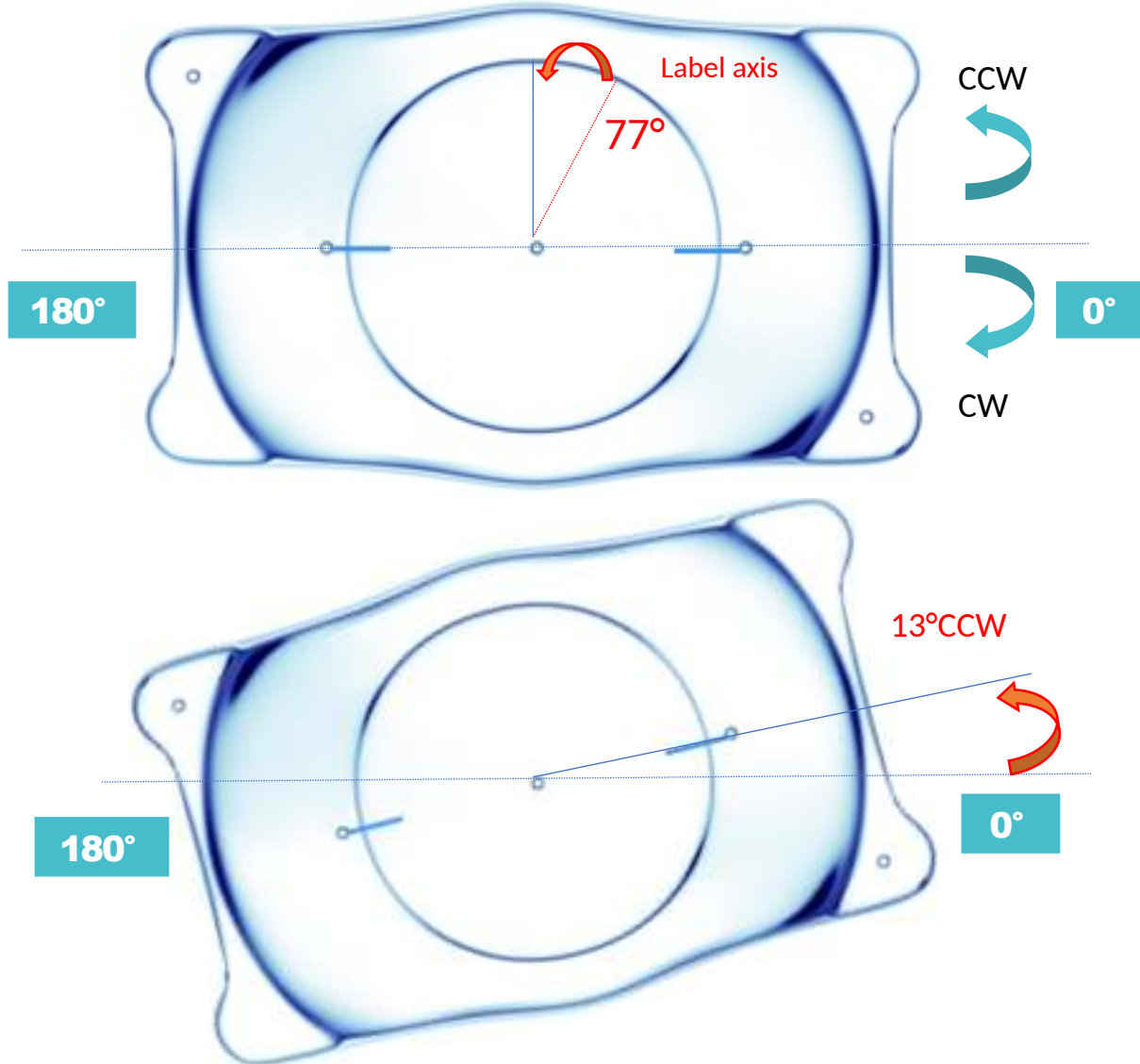
Definition of VAULT

Distance between the posterior surface apex of the ICL and the anterior apex of the crystalline lens



Examples of ICL postop Vault





Rotating Lens 13°CCW moves the positive axis (label) to 90°

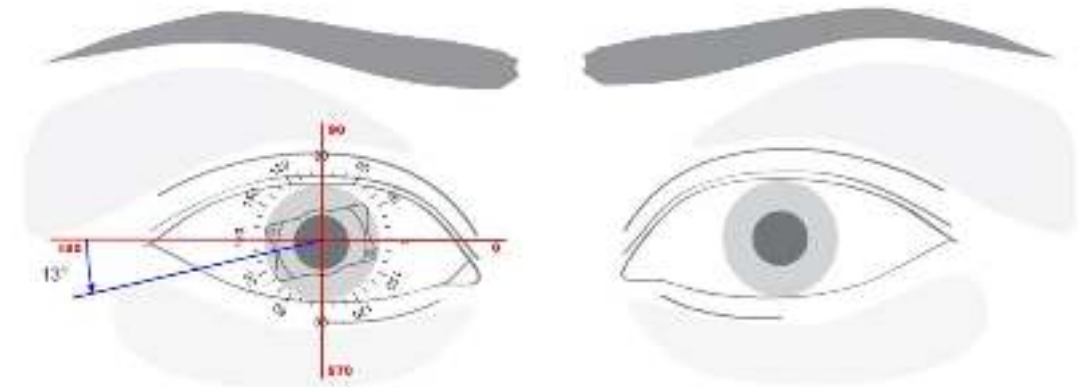
Note: the positive axis (label) is not visible. It's drawn in the picture for explanation.

TARGET LENS

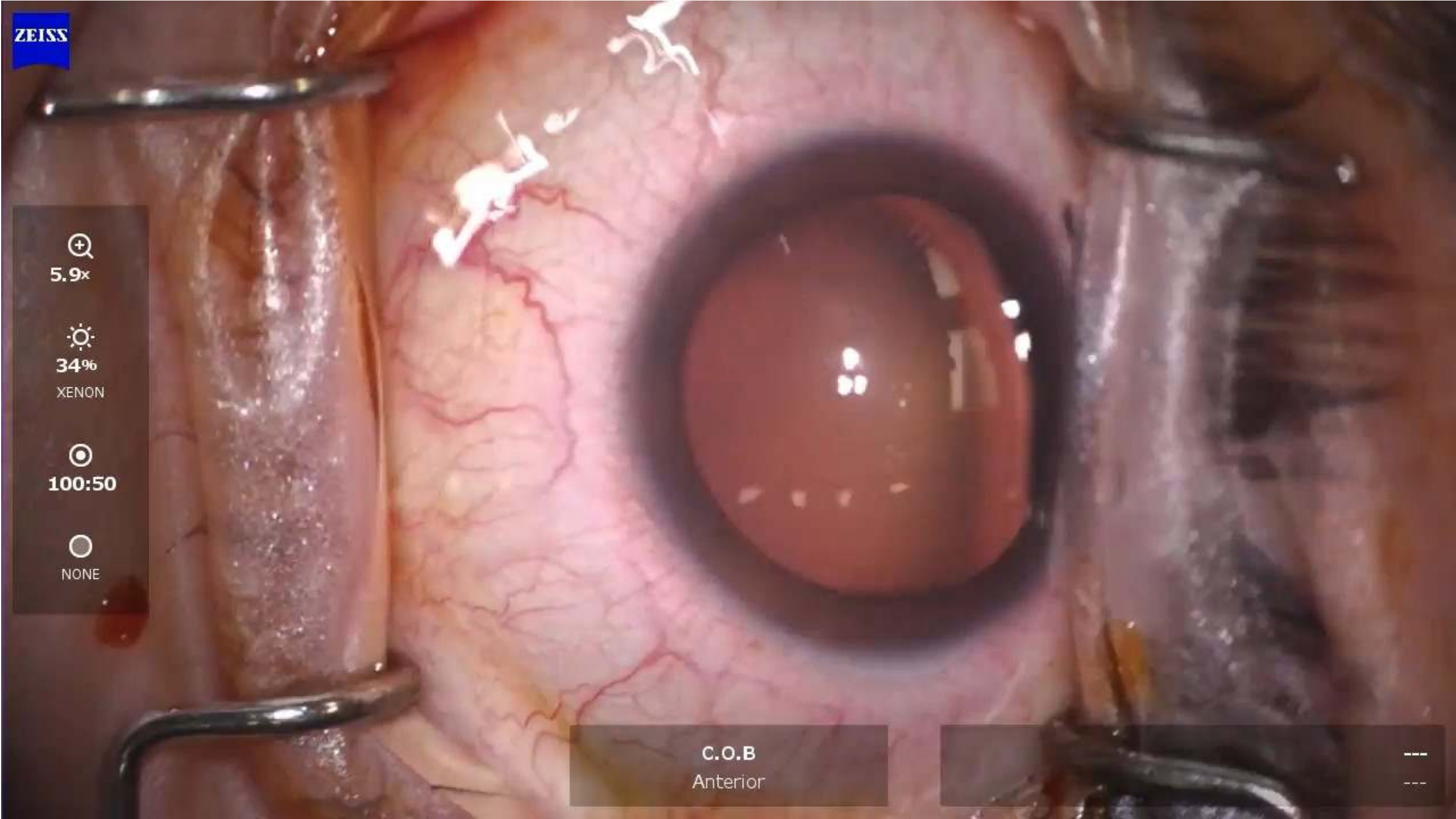
Lens	Model	Sphere	Cylinder	Axis
Toric Nyope 13.2mm	VTICM5_13.2	-8.50	3.0	090

LENS ORDERED

Lens	Model	Sphere	Cylinder	Axis	Serial Number
Toric Nyope 13.2mm	VTICM5_13.2	-8.50	3.0	077	T708811



Rotate lens **counterclockwise 13°** after horizontal implantation to position lens at **13°**



5.9x



34%

XENON



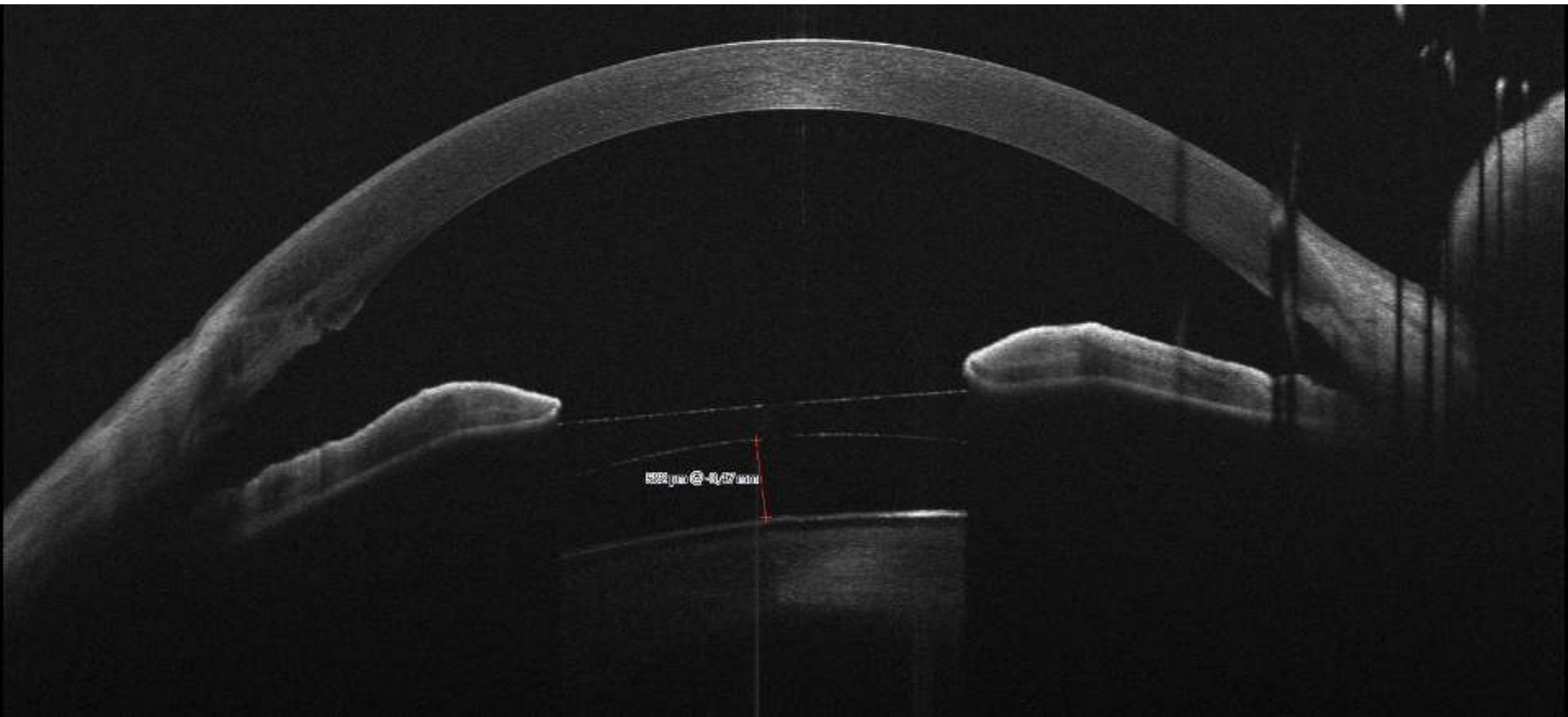
100:50

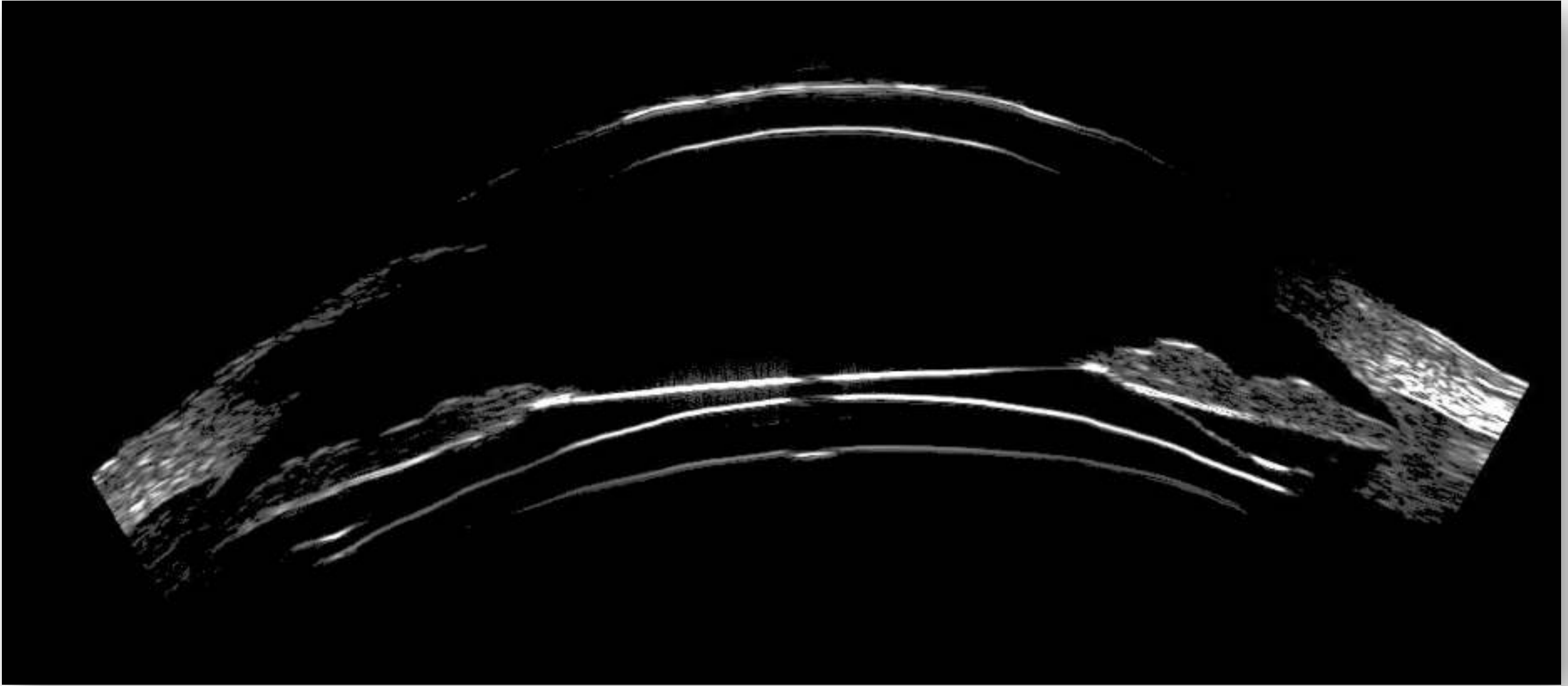


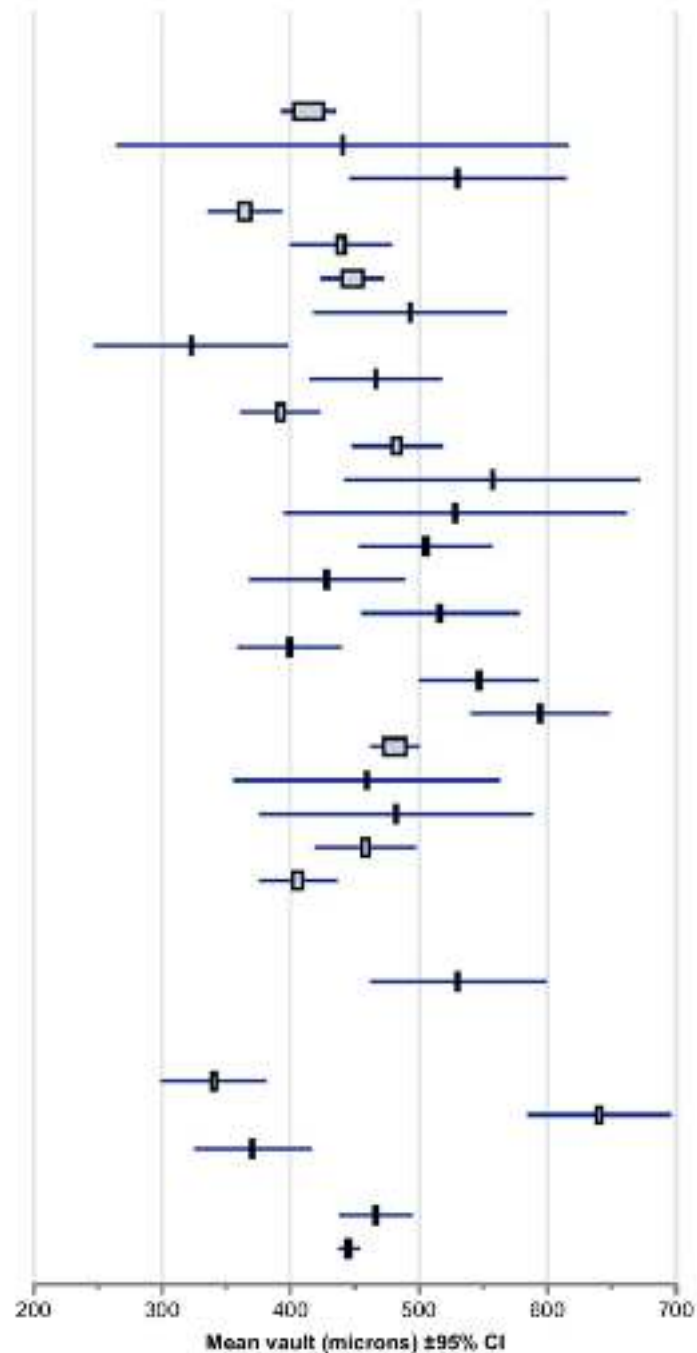
NONE

C.O.B
Anterior



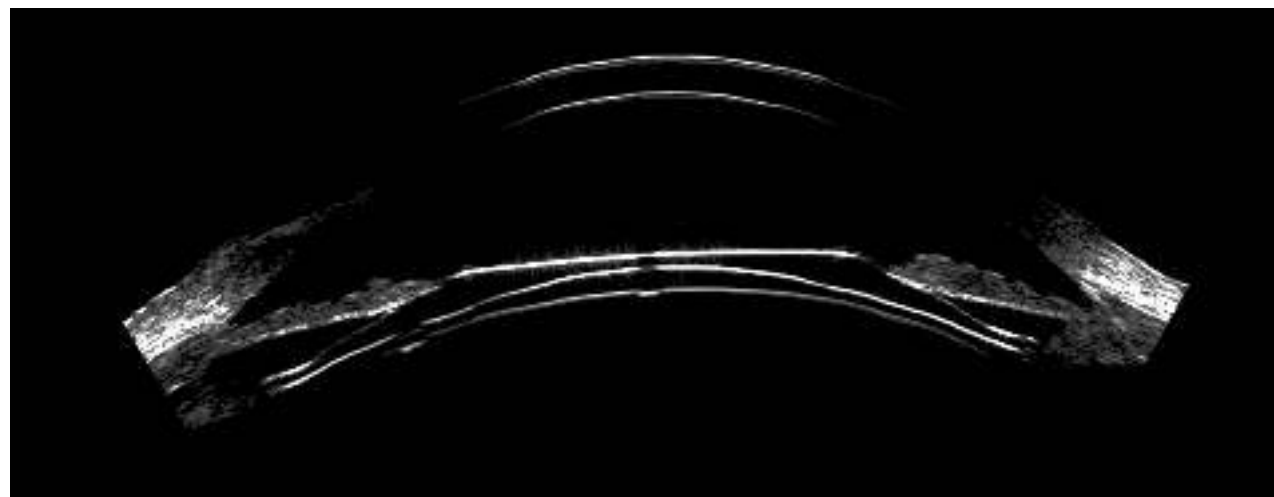
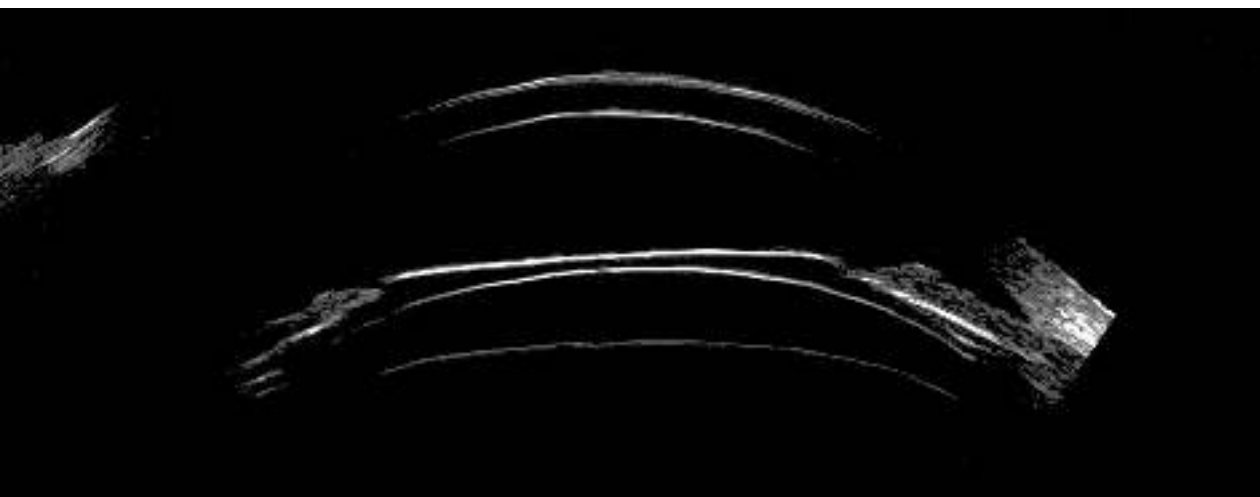
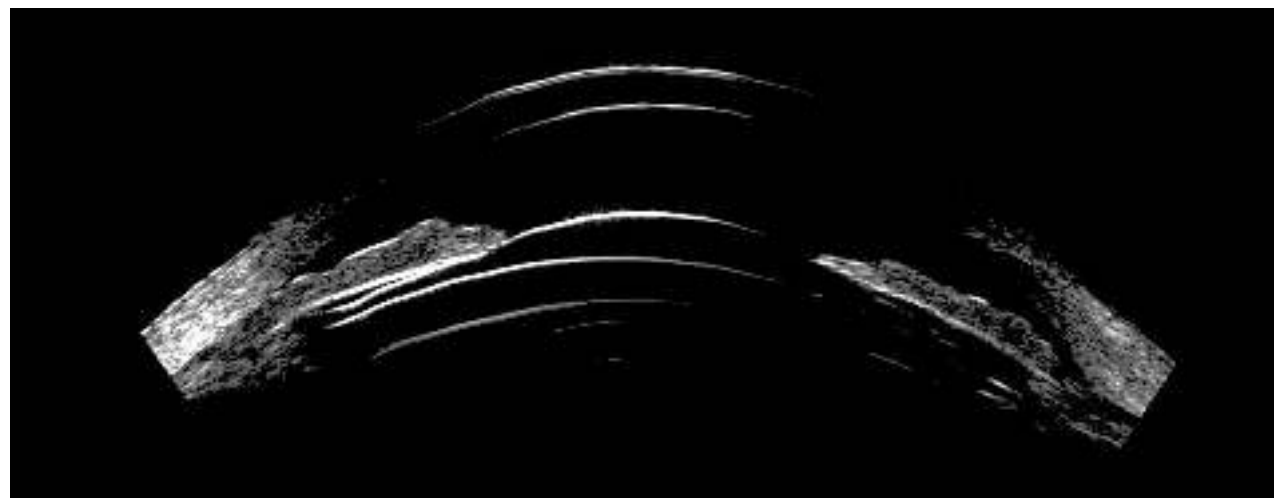
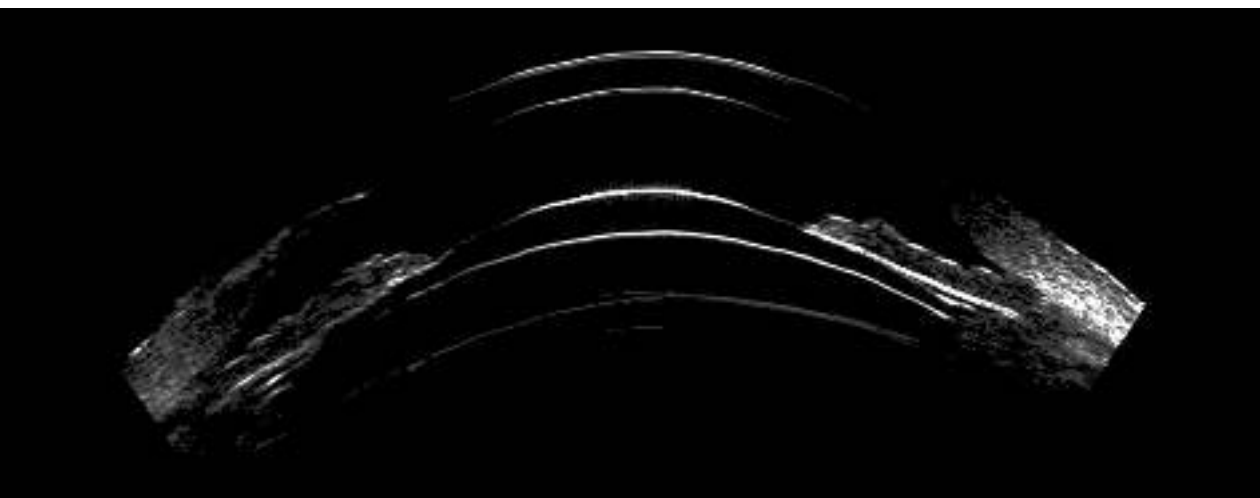




WTW/ACDAlfonso et al⁸Seo et al⁷Kojima et al²¹Alfonso et al¹⁴Alfonso et al²⁵Alfonso et al¹²Alfonso et al¹⁷Sheng et al²⁴Sheng et al²⁴Du et al⁶Alfonso et al⁴³Higuera-Esteban et al⁶⁷Higuera-Esteban et al⁶⁷Cap et al⁷³Lee et al²⁴Lee et al²⁴Lee et al²⁶Lee et al²⁶Alfonso et al¹⁹Gomez-Bastar et al²⁹Kamiya et al¹⁷Kamiya et al¹⁷Lisa et al⁸Lisa et al²¹**PTP**Malyugin et al²⁸**STS**Dougherty et al⁶Kojima et al²⁶Reinstein et al¹⁷**All STS****All WTW/ACD**

Why a correct prediction is so difficult?

- Only four sizes
- A number of parameters
- Many formulas use linear regression models
- Significant Noise: postoperative lens position





FULL LENGTH ARTICLE: REFRACTIVE

Predictability of the Vault after Implantable Collamer Lens Implantation Using OCT and Artificial Intelligence in Caucasian Eyes

Russo, Andrea MD, PhD^{1,2,3}; Filini, Ottavia¹; Savini, DMath; Giacomo MD²; Festa, Giulia MD¹; Morescalchi, Francesco MD²; Boldini, Alessandro MD²; Semeraro, Francesco MD²

[Author Information](#)

Journal of Cataract & Refractive Surgery (JCRS):10.1097/j.jcrs.0000000000001182, March 13, 2023. | DOI: 10.1097/j.jcrs.0000000000001182

OPEN

PDF

[Metrics](#)

Abstract

Purpose:

To compare the predicted vault using machine learning with the achieved vault using the online manufacturer's nomogram in patients undergoing posterior chamber implantation with an implantable collamer lens (ICL).

Setting:

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Email or username

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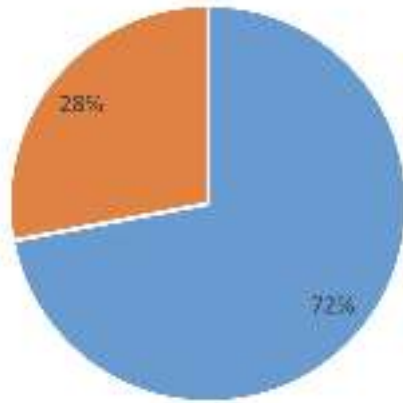
[Cite](#)

[Share](#)

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[Permissions](#)

Attempted result: Vaulting = $500 \pm 250 \mu\text{m}$

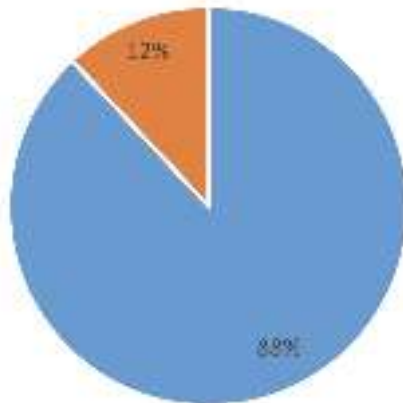


■ Correct prediction ■ Out of range

Manufacturer's Nomogram

- 72% of predictions are within the range of $250 \mu\text{m}$ of accuracy

Attempted result: Vaulting = ET prediction $\pm 250 \mu\text{m}$

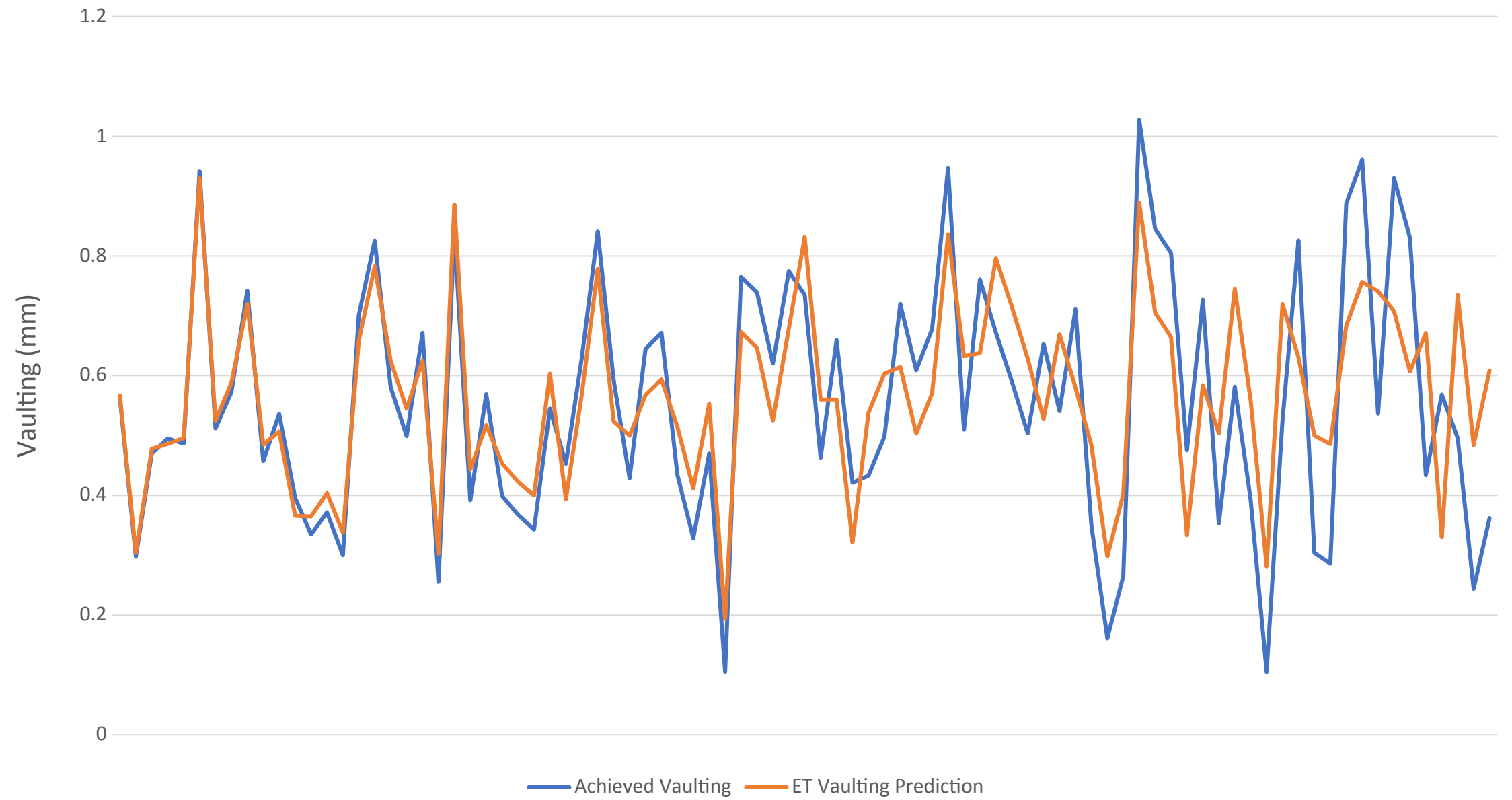


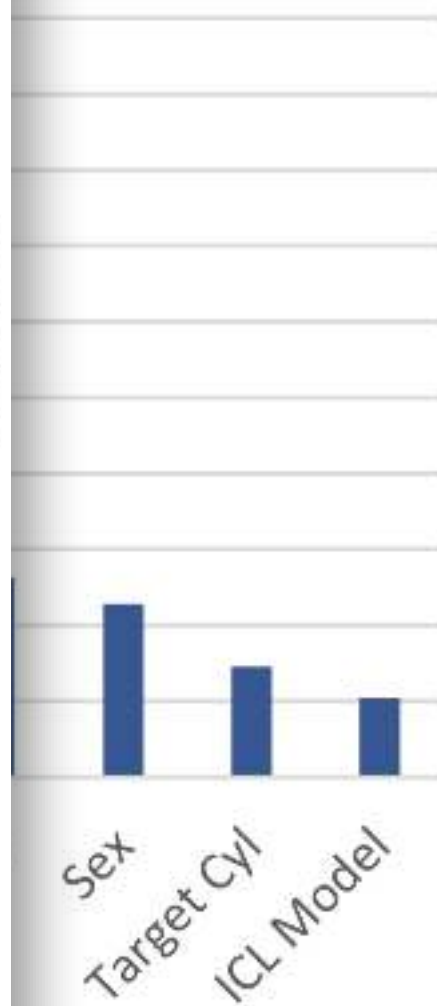
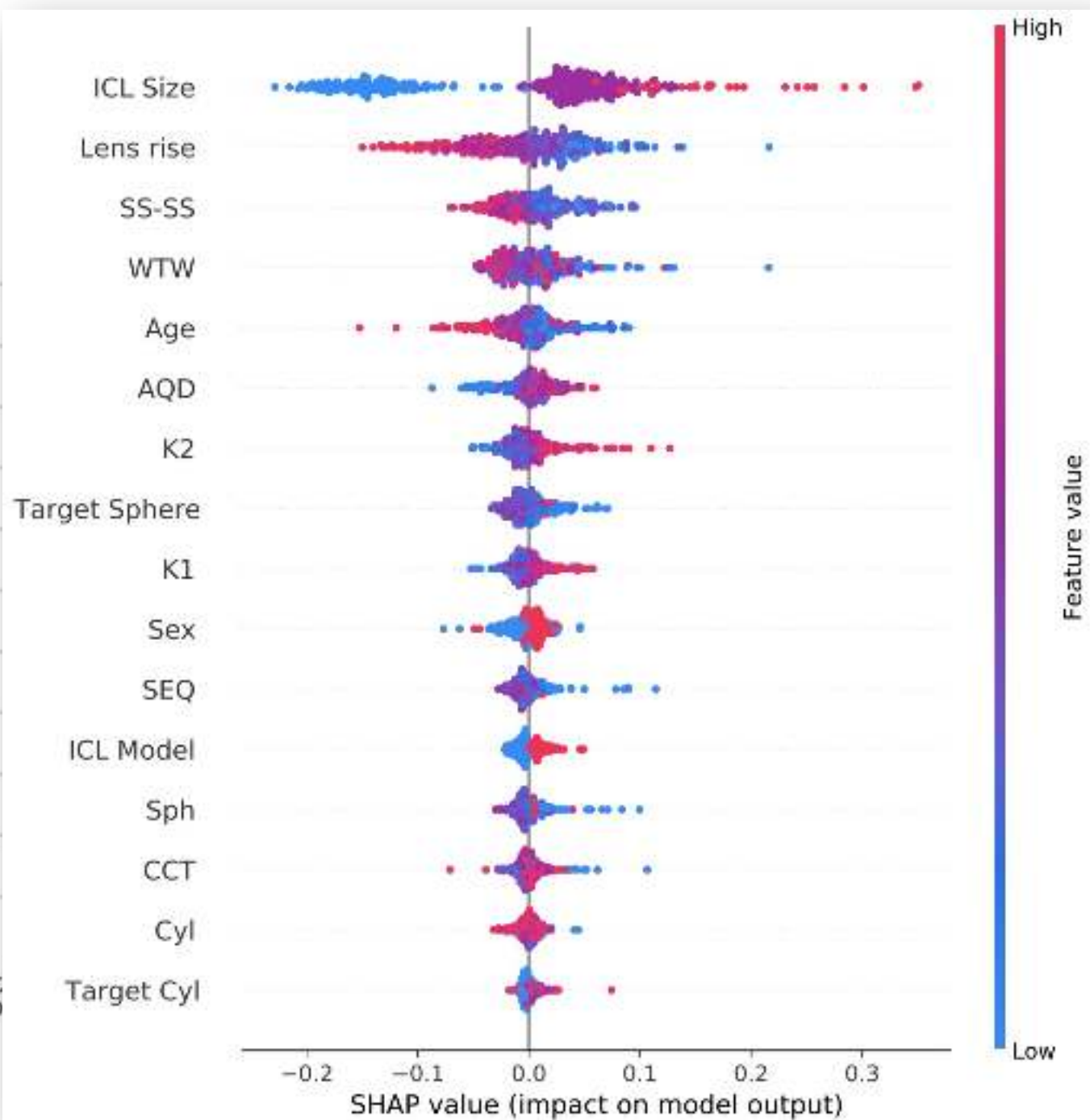
■ Correct prediction ■ Out of range

Machine Learning

- 88% of predictions are within the range of $250 \mu\text{m}$ of accuracy
- accuracy improvement of 16%

High accuracy across the entire range of vaulting values





Phakic IOLs – Surgical Technique

Immediate Pre-Op

- The patient should be prepared for surgery according to standard operating procedure.
- Ensure sufficient pupil dilation to allow for easy and effective manipulation of the ICL behind the iris.
- Typical pre-surgical dilation ophthalmic drops: Tropicamide, Phenylephrine or per surgeon's operating procedure.

Well dilated pupil



Surgical Technique

- Two Paracentesis (help with manipulation of the lens without crossing the center of the pupil)
- **Anesthetic injection**
- Viscoelastic injection
- Temporal, clear corneal incision (less than 3.5 mm) typically 3 to 3.2 mm
- Injection of ICL into the AC
- (Injection of viscoelastic on top of the ICL)
- Positioning of ICL posterior to iris
- Check for proper centration and alignment
- Irrigation (and aspiration) of viscoelastic
- (Constriction of pupil (miotic))
- Confirm patency of the iridotomies- in non-central port Visian ICL models
- Immediate post-op check (typically 1 to 4h postop)

ZEISS



9.1x



28%

XENON



100:50



NONE

Centro Oculistico BS
Anterior

Recommended ICL Positioning Instruments

Deitz tucker



Pallikaris olive tip

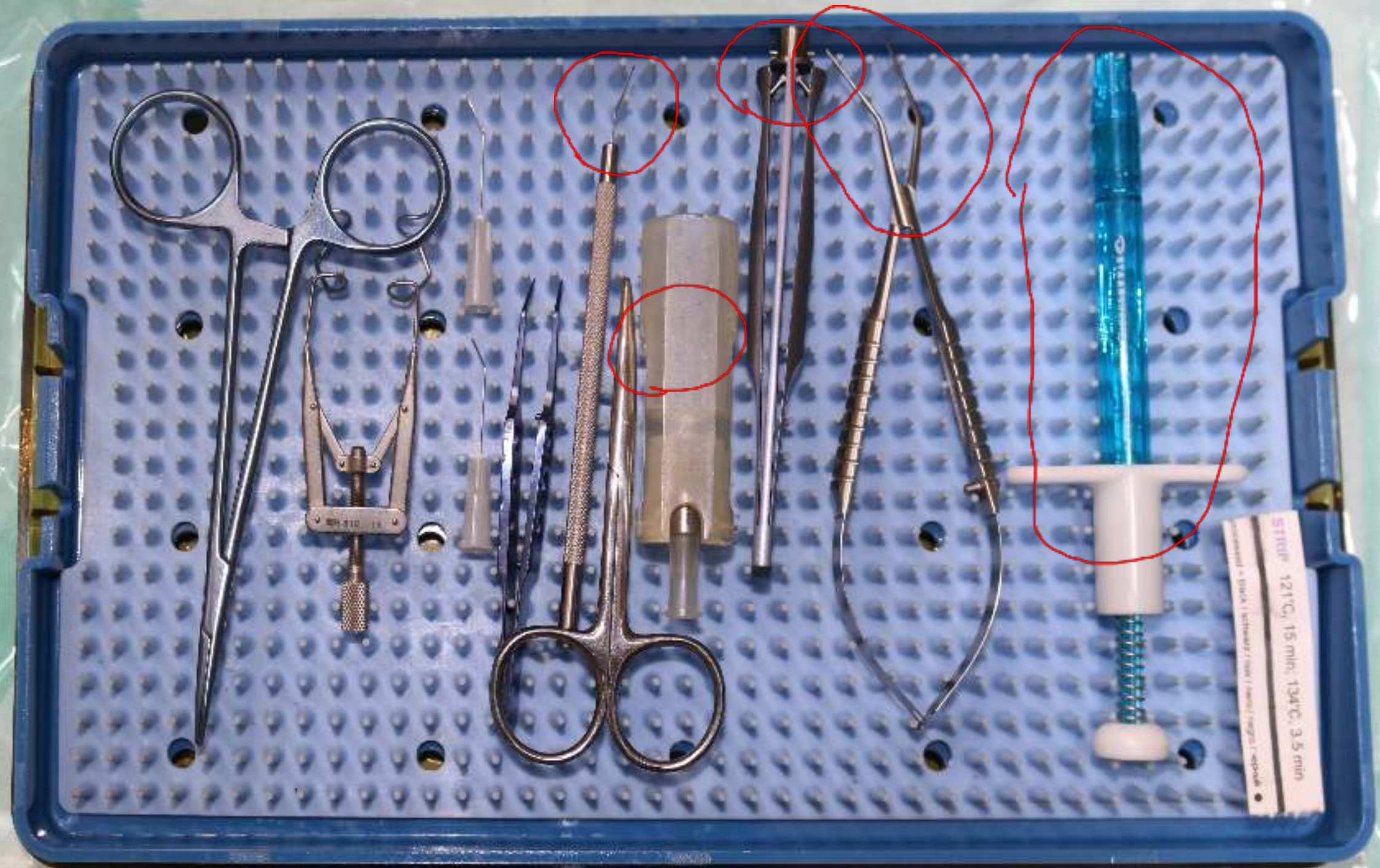


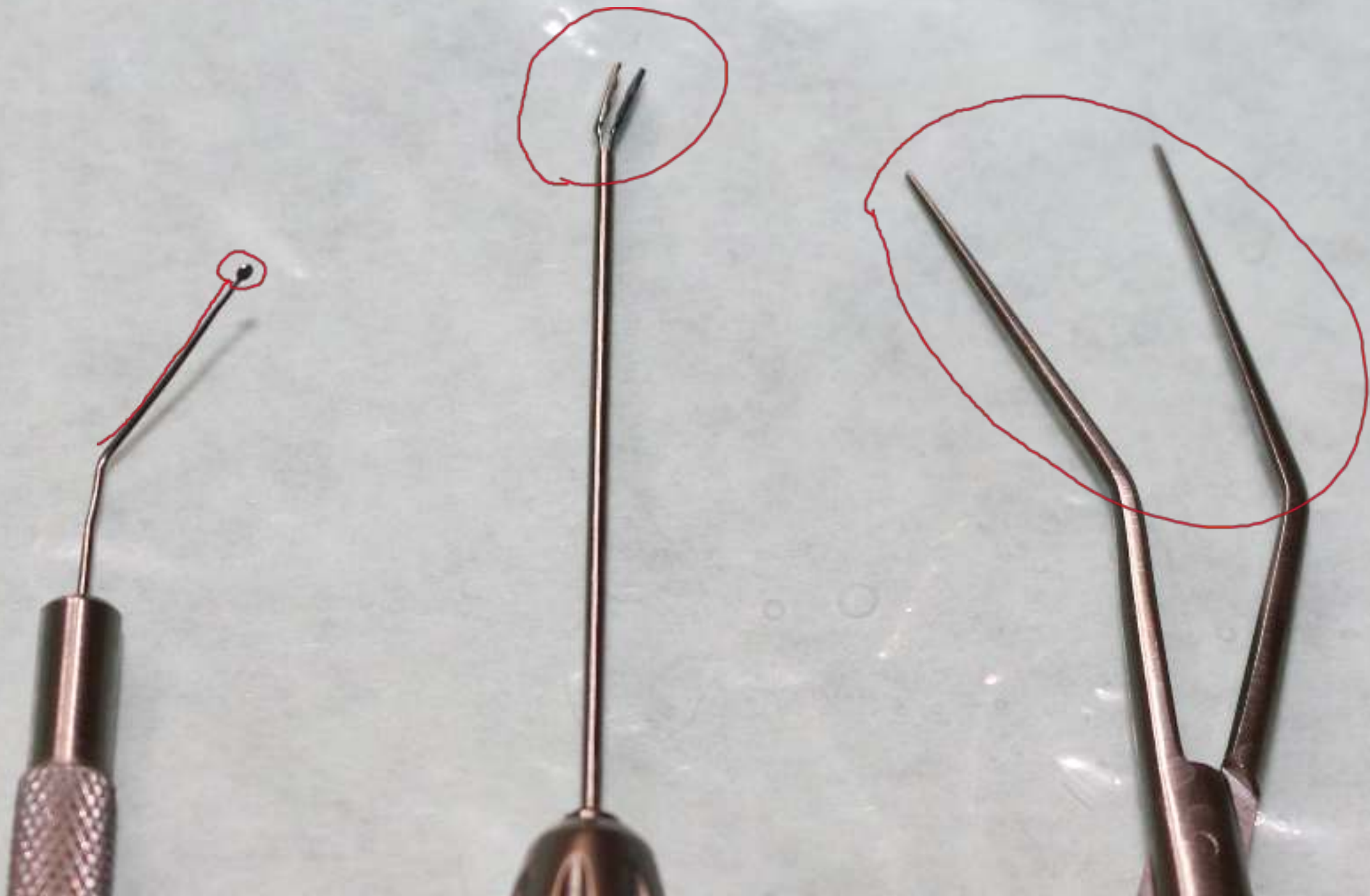
Vukich ICL Manipulator



Batlle ICL Manipulator







Post-op Medication: Surgeon's standard procedure and medical judgement

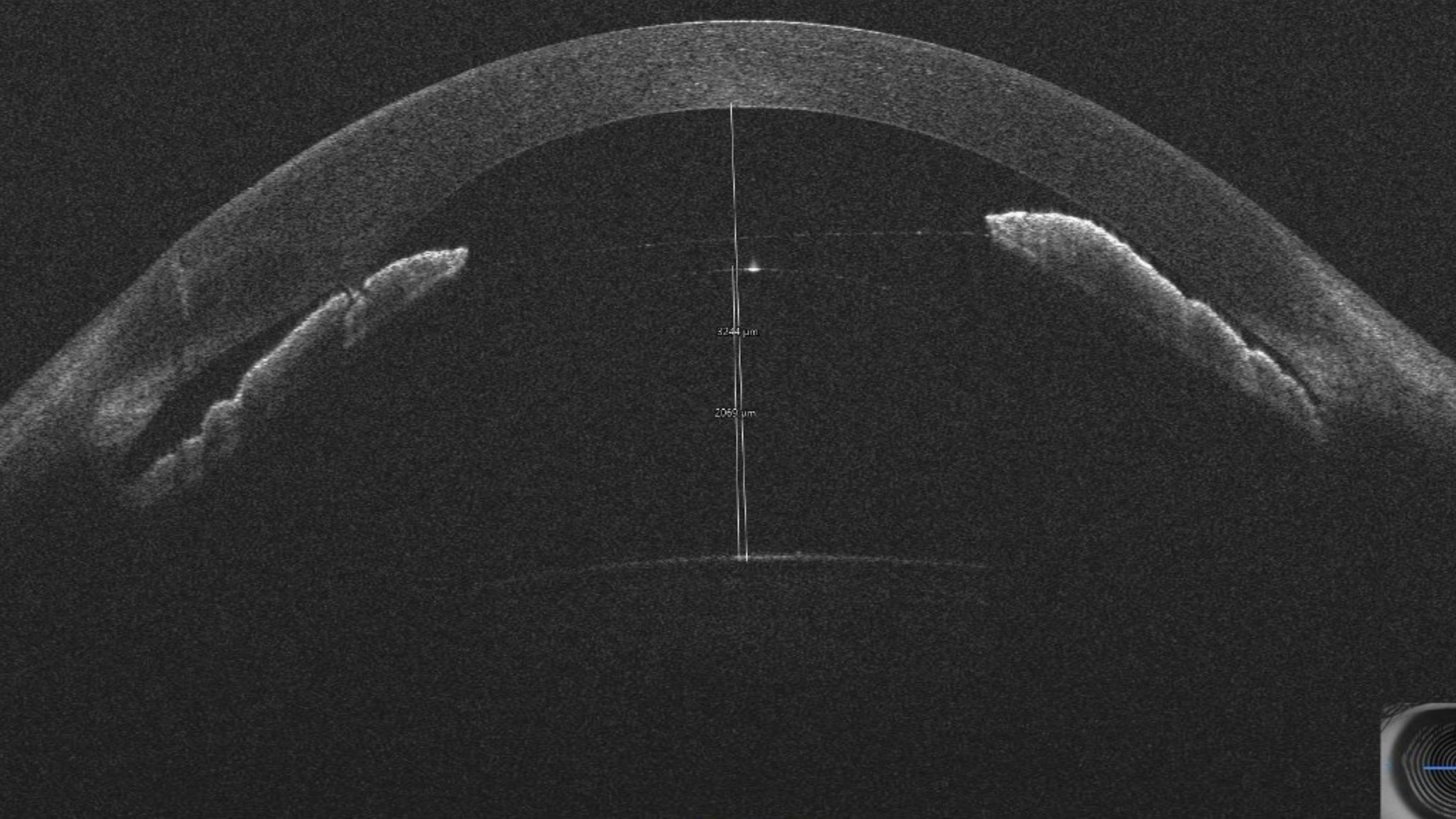
- Follow your standard procedure.
- Medications may include antibiotics and anti-inflammatories.
- **Diamox 1+2 tablets**
- **Patient's accommodation close to the clinic**

M. Packer. Clinical Ophthalmology 2016 June

- “Extremes of vault must be viewed as risk factor for adverse events, not as adverse events in and of themselves”
- Adequate vault range 90 to 1,000 microns^{1,2}
- Ideal vault range 250 – 750 microns³

Therefore, as these authors state, the variability of vault regardless of sizing methodology probably reflects unmeasurable ocular characteristics such as “vertical compression by the iris and dampening effect of the ciliary sulcus structure”. The demonstrated variability of vault regardless of sizing methodology may be due to unmeasurable anatomic and physiologic factors affecting the relationship of the ICL and the posterior chamber.

1. Gonvers M, Bornet C, Othein-Girard P. Implantable Contact Lens for Moderate to High Myopia; relationship of vaulting to cataract formation. J Cataract Refract Surg 2003; 29:918-924
2. Dougherty PJ, Rivera RP, Schnieder D, Lane SS, Brown D, Vukich J. Improving accuracy of phakic intraocular lens sizing using high-frequency ultrasound biomicroscopy. J Cataract Refract Surg 2010; 37: 13-18.
3. Alfonso JF, Fernandez-Vega, L, Lisa C, Fernandes P, Jorge J, Montes-Mico R. Central Vault after phakic intraocular lens implantation: Correlation with anterior chamber depth, white-to-white distance, spherical equivalent, and patient age. J Cataract Refract Surg 2012; 38:46-53



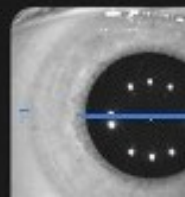
3244 μm

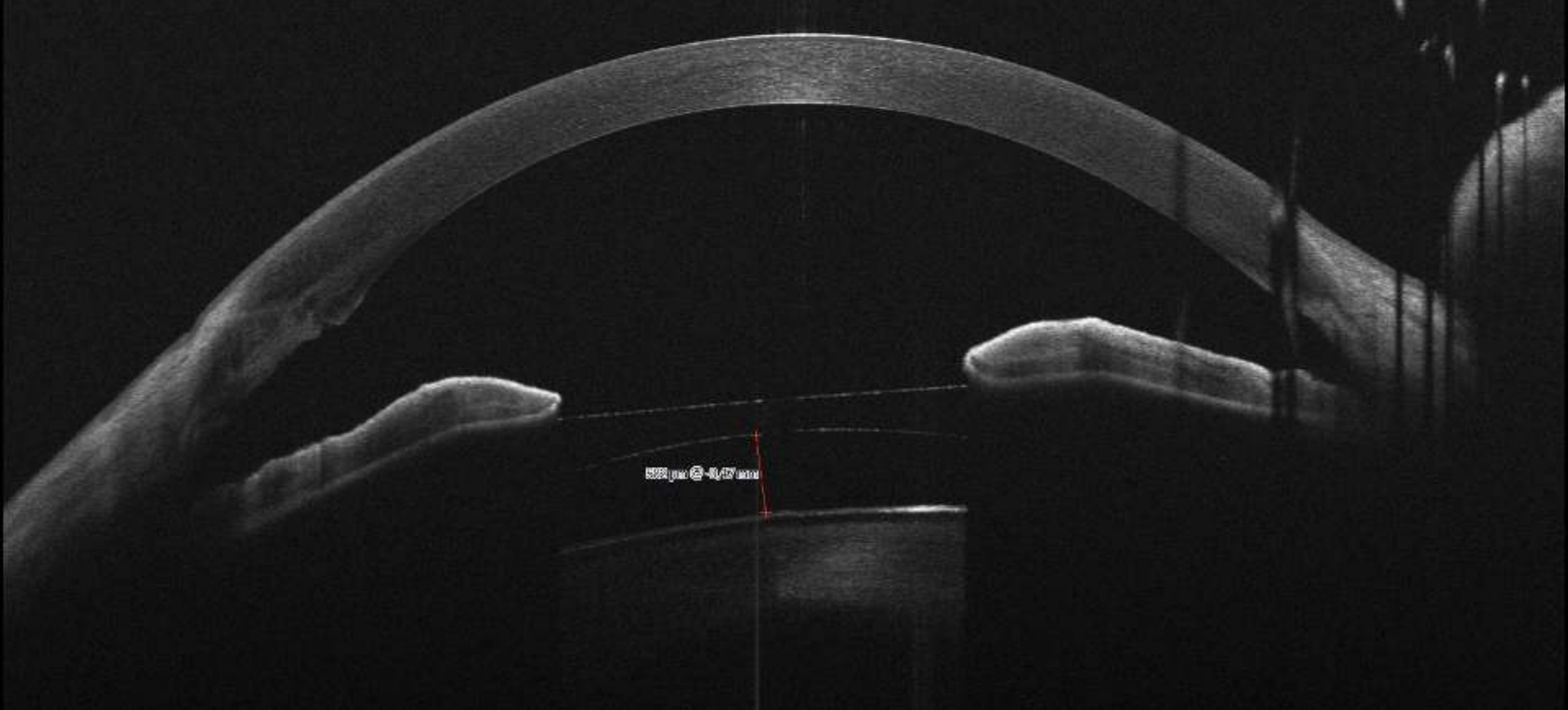
2069 μm

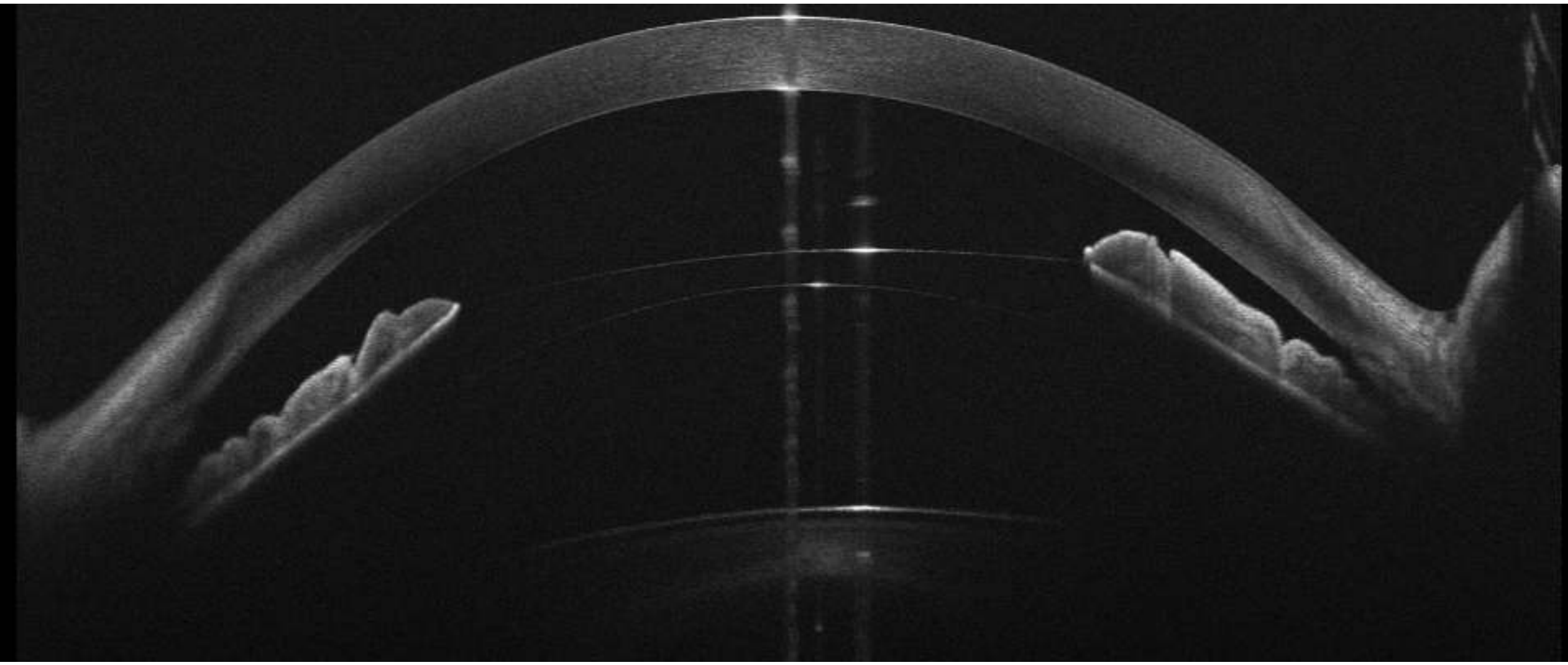


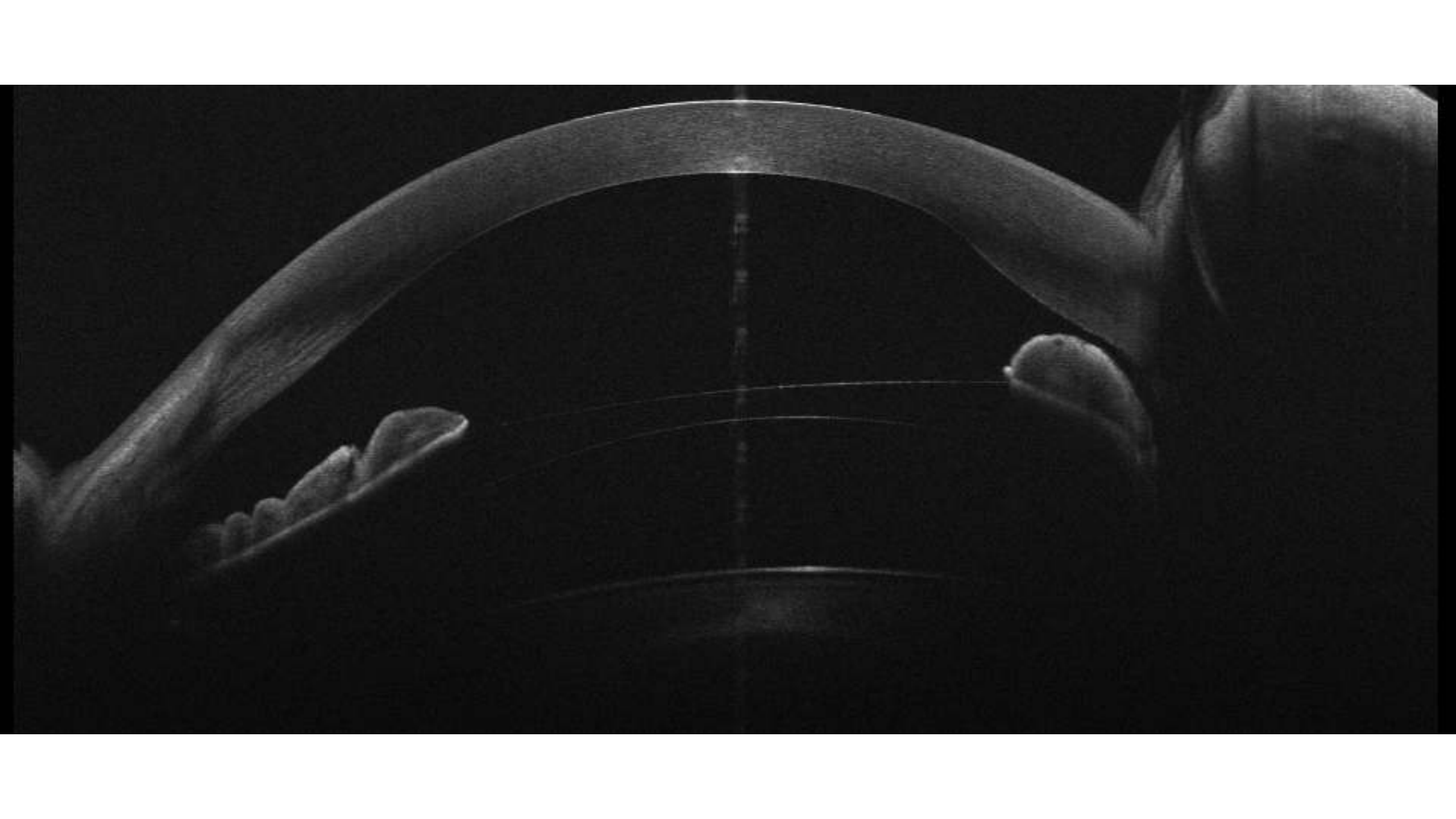


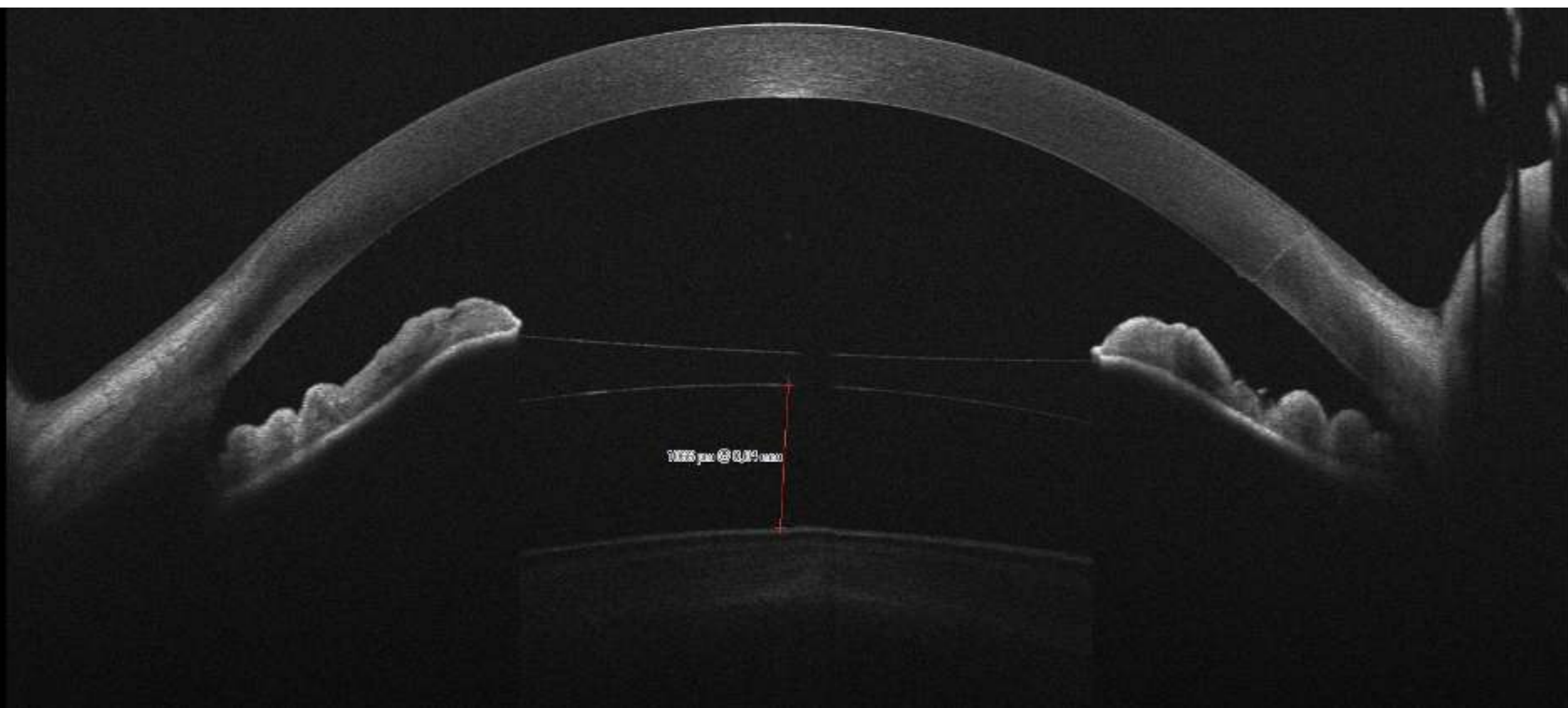
3175 μm

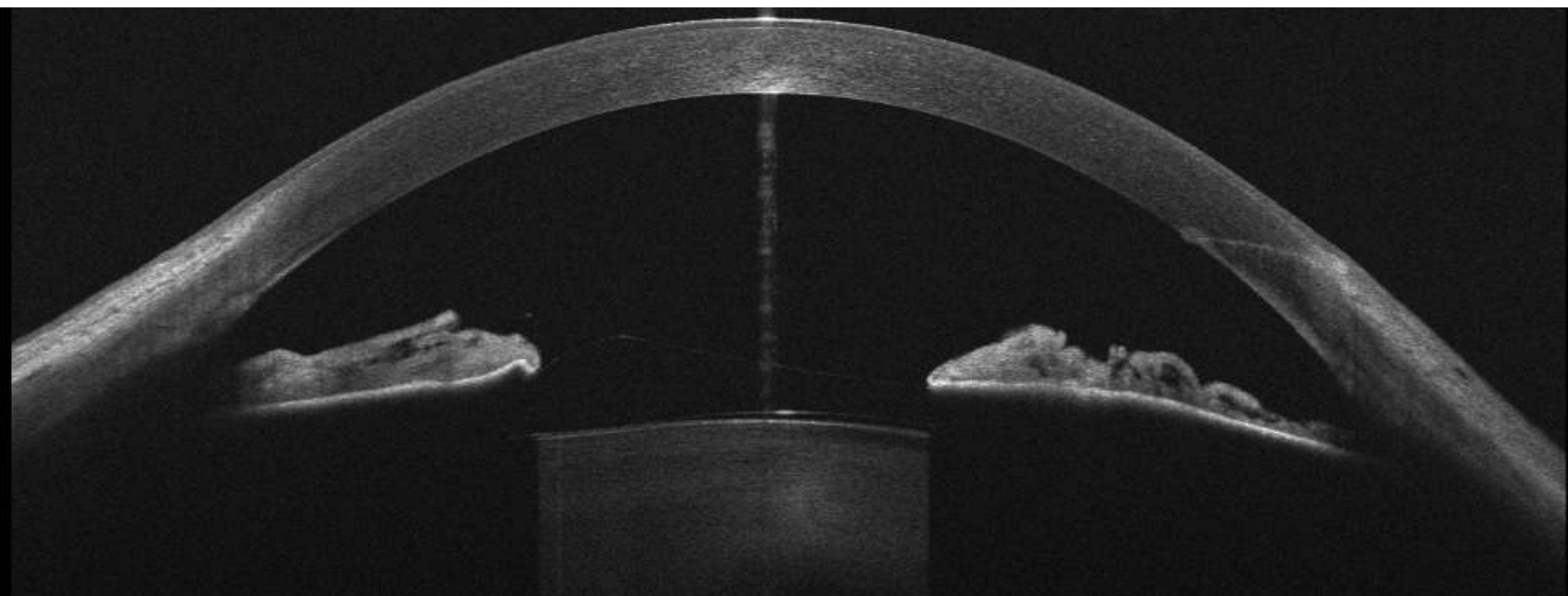














Immediate Sequential Bilateral Implantable Collamer Lens Surgery Is Safe and Effective

Andrea Russo, MD, PhD; Ottavia Filini, DMATH; Erik Mertens, MD; Sheraz M. Daya, MD, FACP, FACS, FRCSEd; Luigi Conti, MD; Francesco Carones, MD; Giulia Festa, MD; Alessandro Boldini, MD, FEBO; Giacomo Savini, MD

ABSTRACT

PURPOSE: To assess the clinical outcomes and safety profiles of patients who underwent immediate sequential bilateral phakic lens surgery.

METHODS: This retrospective multicenter study included 254 consecutive patients (508 eyes) who underwent bilateral same-day implantable Collamer Lens (ICL) (STAAR Surgical) surgery. The authors focused on 1-year postoperative clinical outcomes and adverse events.

RESULTS: In the initial cohort, 176 patients (352 eyes) met inclusion criteria. Of these, 335 eyes underwent myopic ICL placement, and 17 eyes received a hyperopic ICL. Notably, 87% of eyes achieved ± 0.50 diopters (D) and 95% achieved

± 1.00 D of the intended refraction. One year postoperatively, 78% of eyes demonstrated optimal vaulting (250 to 750 μ m), with a significant 19% reduction in vaulting observed over the 12 months ($P < .001$). Only minor adverse events, including early cataract formation (1 case), secondary toric ICL rotation (3 cases), and ICL exchange due to inappropriate vaulting (6 cases), were noted.

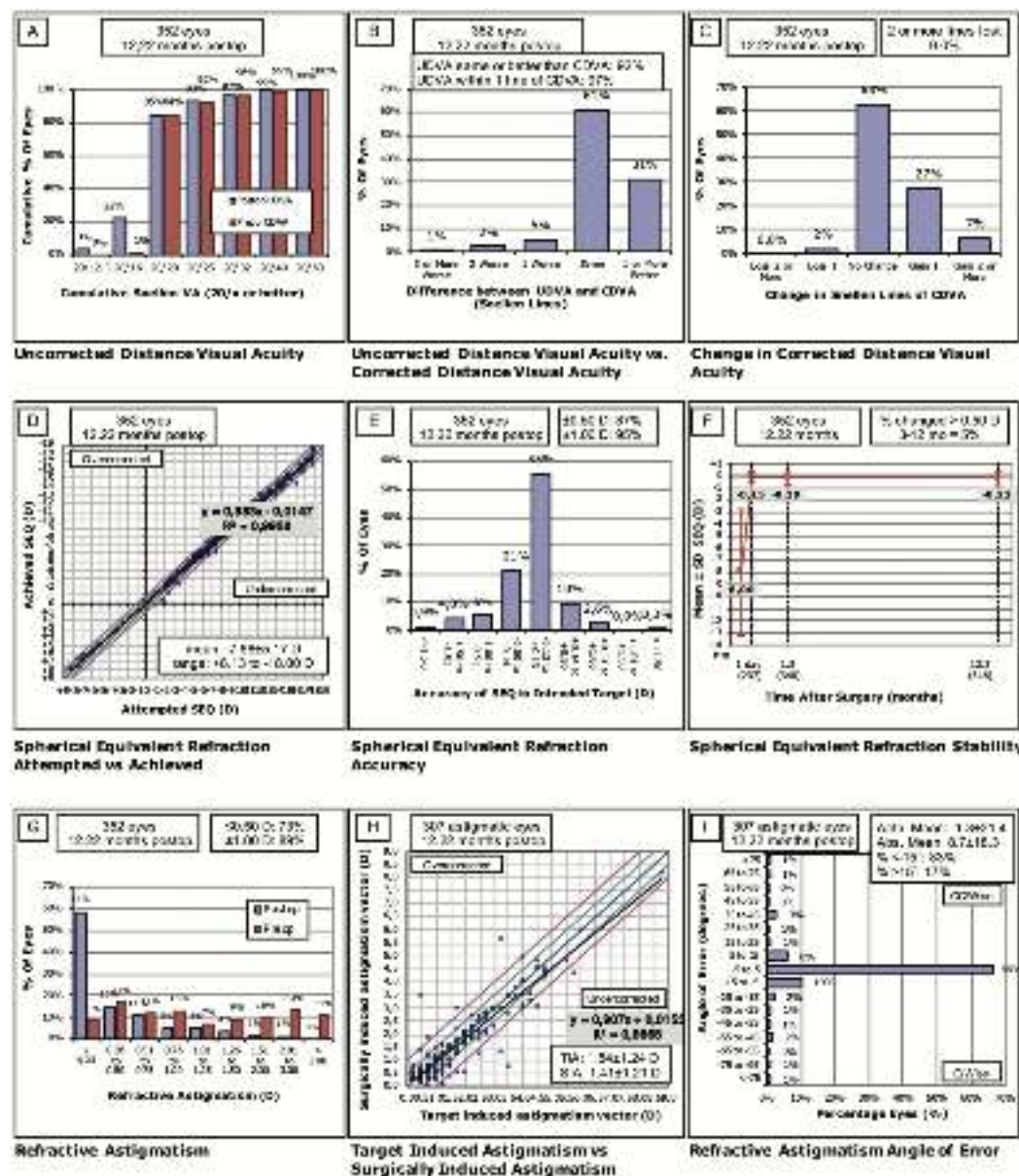
CONCLUSIONS: The findings corroborate the safety and efficacy of immediate sequential bilateral phakic lens surgery and indicate its potential as a treatment option. The low incidence of minor adverse events further reinforces its favorable safety profile.

[J Refract Surg. 2024;40(5):e313–e320.]

Refractive surgery has undergone rapid advancements with substantial market potential, particularly in light of the escalating prevalence of myopia. As of 2010, approximately 28% of the global population was affected by myopia, a figure projected to rise to 50% by 2050.¹ This estimation does not account for the exacerbating impact of coronavirus disease 2019 (COVID-19) restrictions, which have increased indoor time for younger individuals.⁴ The implantable Collamer Lens (ICL; STAAR Surgical)

is the most prevalent phakic intraocular lens globally and has been used in more than 2 million eye procedures for myopia correction, consistently yielding satisfactory results.^{2–5}

Although substantial evidence supports the efficacy of immediate sequential bilateral cataract surgery, including recent meta-analyses,^{6–10} in clinical practice a delayed approach in ICL surgery is sometimes preferred.¹¹ Concerns regarding potential bilateral sight-threatening complications such as endophthalmitis¹²

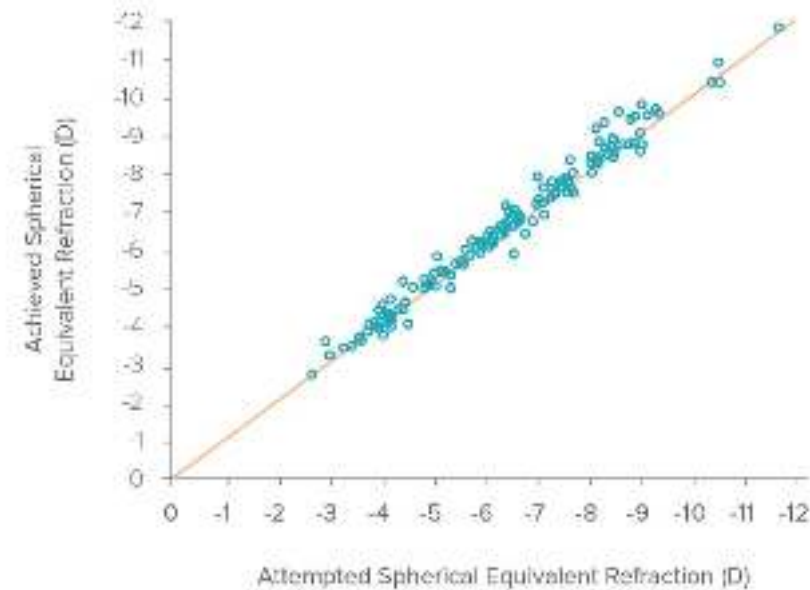


Proven Predictability¹

The EVO Visian ICL product family offers predictable outcomes across a broad range of treatment correction¹

Spherical Equivalent Attempted vs Achieved

No nomograms needed
Refraction!

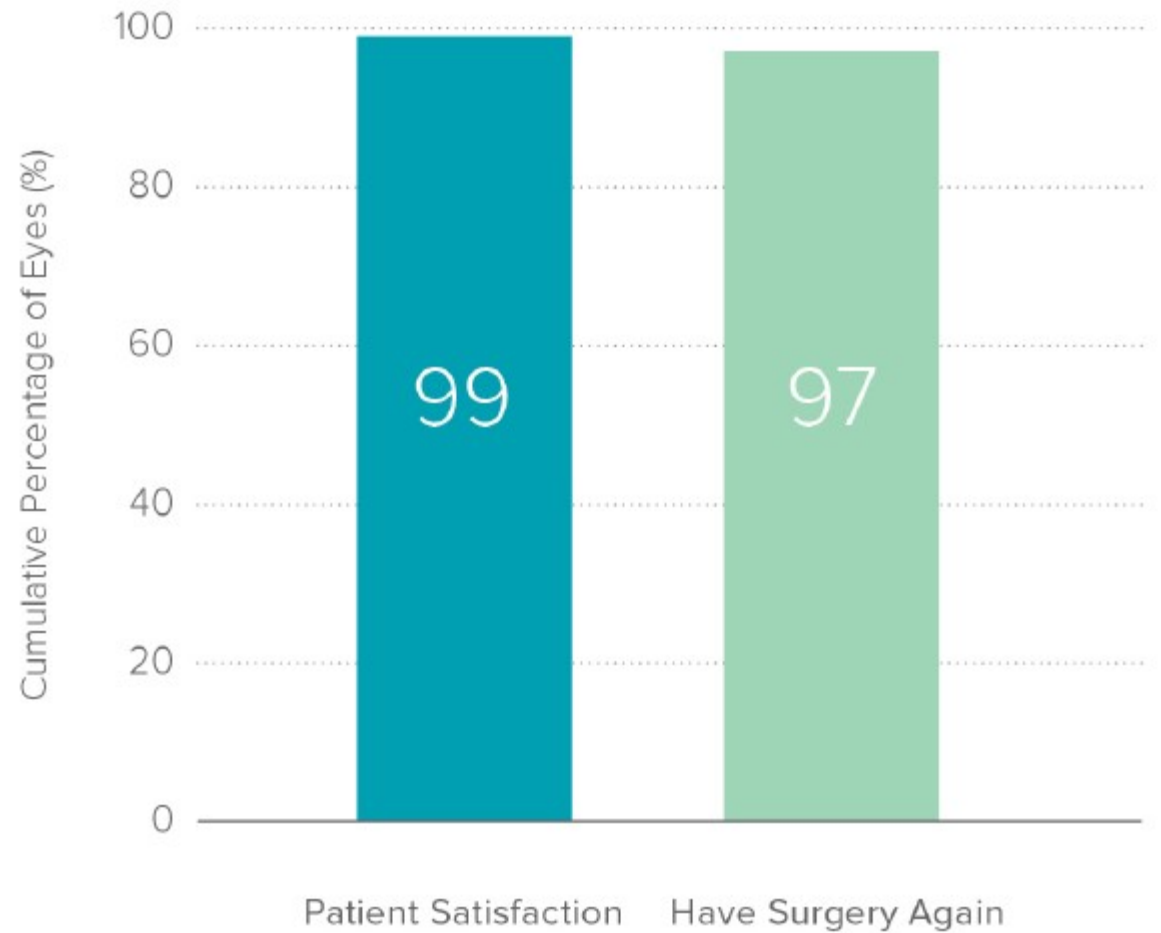


1. Parkhurst G, Psolka M, Kezirian G. Phakic intraocular lens implantation in United States military warfighters: A retrospective analysis of early clinical outcomes of the Visian ICL. J Refract Surg. 2011;27(7):473-481.

Patient Experience

In a pivotal FDA study, the **EVO Visian ICL Product Family** showed **99% patient satisfaction**¹

Patient Satisfaction
Patient Satisfaction at 3 years (n=341)



1. MICL PMA data: P030016.