ADVANCEMENTS IN SAFETY AND EFFICACY OF PHAKIC INTRAOCULAR COLLAMER LENSES

BRYAN K MONSON MD|MBA

Braden Ashcraft | Cameron Miller | Lauren Broadhead

Advancements in Safety and Efficacy of Phakic Intraocular Collamer Lenses

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Financial Disclosure

- No potential conflicts of interest with respect to the research, authorship, and/or preparation of this presentation.

Course Objectives

Following this course, the practitioner will:

- Understand recent scientific advancements in safety, efficacy, and vision outcomes in the new FDA approved ICL V4c with full thickness 0.360 mm central opening
- Understand the etiology and rates of frequency of the historic risks of ICL surgery for patient education
- Understand novel advancements in ICL surgery techniques
- Understand the effect of 360 micrometer central hole ICL V4c, on the mesopic visual performance, including glare conditions
- Understand recent published advancements in predictive lens sizing, vault and refractive outcomes utilizing swept source Very-High Frequency Ultrasound (VHF-US)
- Understand patient selection criteria in myopia, hyperopia, and astigmatism, including topography, biometry, Scheimpflug, and sulcus ultrasound
- Understand how to assess and manage ICL patients in the post-operative patient, including lens vault, lens position, vision, and co-management considerations
- Understand how to effectively address the most frequently asked questions about ICL vision correction
- Understand the relationship of ICLs to other modern vision restoration procedures including topography guided LASIK, PRK, RELEX SMILE, ICRS and Refractive Lens Exchange
- Understand recent novel healthcare delivery models in eye surgery improving guest patient experience, efficiency, cost savings, and optimized optometry co-management of ICL patients

INTRODUCTION

Objectives:

Understand recent scientific advancements in safety, efficacy, and vision outcomes in the new FDA approved ICL V4c with full thickness 0.360 mm central opening.

Large Global Myopia Impact

- Myopia is projected to affect almost half of the world's population by 2050 — a sevenfold increase
- 5 billion with myopia
- 1 billion with high myopia (>-6D)
- United States and Canada increase to 260 million, or close to half of the population, up from 89 million in 2000
- High myopia cases increase by five times to 66 million[2]

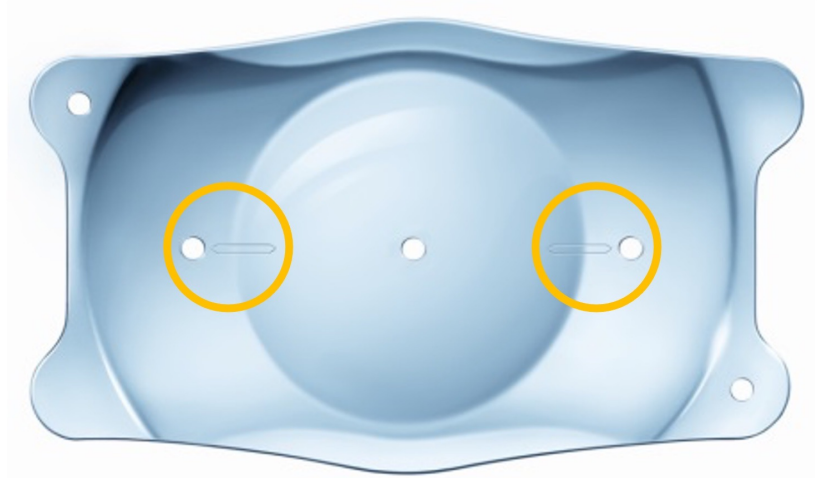
2. Holden BA, et al. Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 through 2050. Ophthalmology. 2016 May;123(5):1036-42.

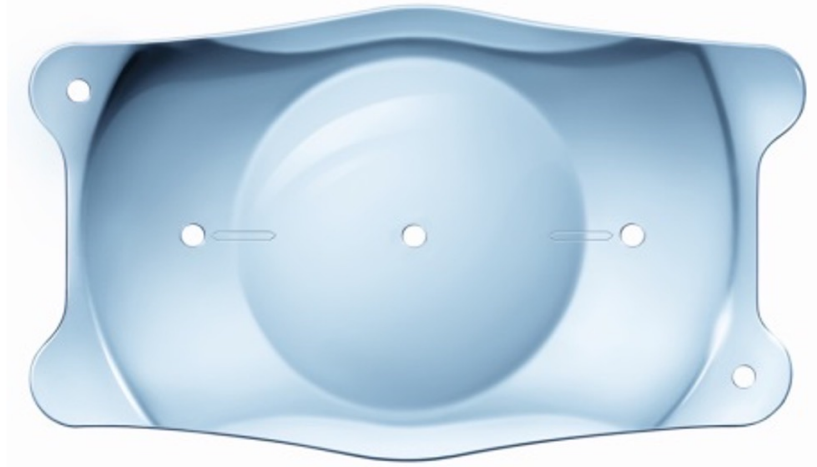
A Brief History

- 2005 US FDA Approval of V4 MICL (Spherical Myopia)
- 2018 US FDA Approval of TORIC MICL (Myopic Astigmatism)
- May 2022 US FDA Approved V4c with a central .360mm opening Sph and Toric
- 20+ years of experience in eyes globally
- Over 1,000,000 V4c lenses implanted worldwide

Lens Anatomy

- Biocompatable: a proprietary hydroxyethyl methacrylate (HEMA)/porcine collagen containing biocompatible polymer
- Plate-haptic design with a central convex/concave optical zone
- 360 µ diameter central port;
- Lens incorporates a forward vault to minimize contact of the lens with the central anterior capsule of the crystalline lens
- Optic Diameter: 5.0 mm to 6.1 mm (depends on the diopteric power)





FDA Trials

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CLINICAL TRIAL REPORT

Evaluation of the EVO/EVO+ Sphere and Toric Visian ICL: Six Month Results from the United States Food and Drug Administration Clinical Trial

Mark Packer

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Purpose: To evaluate the safety and effectiveness of Collamer posterior chamber phakic refractive lenses with a central port design (EVO and EVO+ Sphere and Toric Visian ICLs) for correction of moderate-to-high myopia with or without astigmatism.

Patients and Methods: Six-month results of a multicenter clinical trial performed under United States FDA Investigational Device Exemption. Subjects 21 through 45 years of age with myopia ranging from −3.00 D to −20.00 D and astigmatism up to 4.00 D underwent implantation of EVO or EVO+ Sphere or Toric Visian ICLs. Uncorrected (UDVA) and corrected (CDVA) distance visual acuities, manifest refraction, intraocular pressure (IOP), endothelial cell density, and adverse events were evaluated over 6 months.

Results: This clinical trial enrolled 629 eyes of 327 subjects with mean age 35.6 ± 5.09 years. Mean preoperative spherical equivalent (SE) measured −7.62 ± 2.75 D (range: −3.00 to −15.62 D). At 6 months, mean SE was −0.079 ± 0.33 D, with 90.5% within ± 0.50 D of target and 98.9% within ±1.00 D of target. Mean postoperative UDVA and CDVA were −0.059 ± 0.10 logMAR and −0.13 ± 0.08 logMAR, respectively. 52.3% of eyes gained lines of CDVA. Efficacy and safety indices were 1.06 and 1.24, respectively. No eye experienced pupillary block, required peripheral iridotomy or iridectomy, developed anterior subcapsular cataract or had elevated IOP due to angle narrowing or pigment dispersion. Mean endothelial cell density declined by 2.3%.

Conclusion: EVO ICL lenses demonstrated accuracy of refractive correction and achievement of high levels of UDVA. This clinical trial confirmed that the central port design of EVO and EVO+ Sphere and Toric Visian ICL lenses functions effectively to allow physiologic flow of aqueous humor, thus eliminating the requirement for preoperative peripheral iridotomies. The results of this clinical trial resulted in FDA approval on March 25, 2022.

Keywords: phakic refractive lens, myopia, astigmatism, Implantable Collamer Lens

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Features

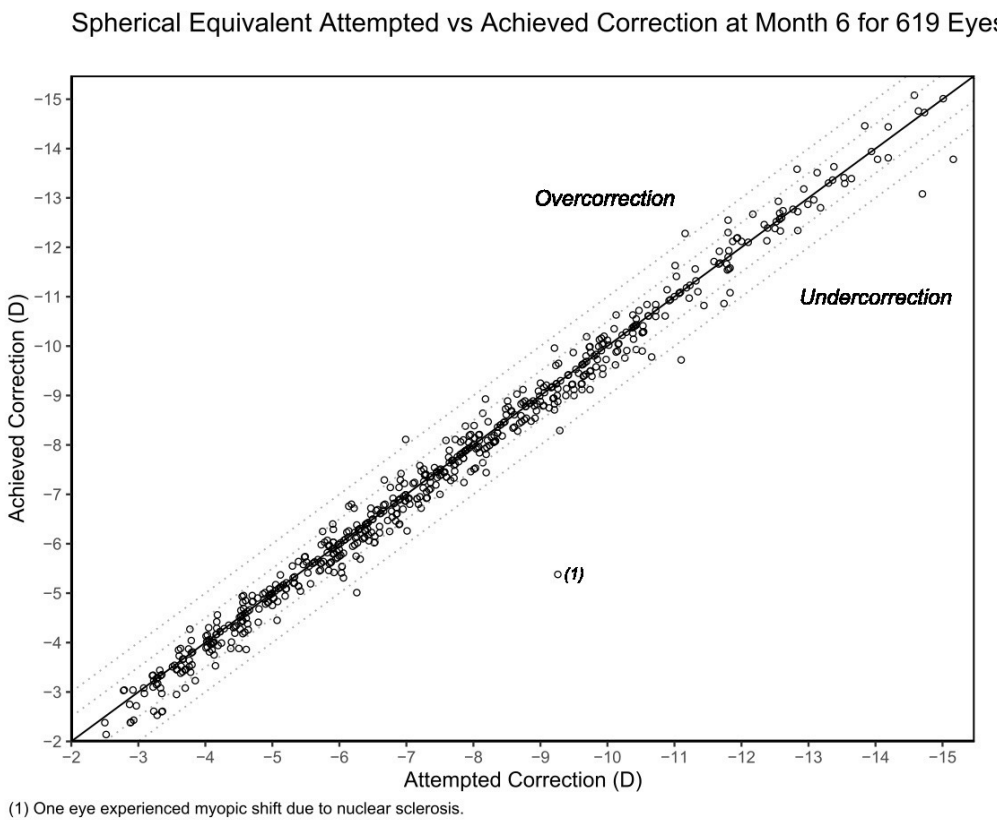
- Sharp, clear vision[5]
- Excellent night vision[6]
- Does not cause dry eye syndrome[7]
- Quick procedure and recovery
- No removal of corneal tissue
- Removable by the surgeon
- Protection from UV rays

Compared with other refractive surgeries, ICL implantation has advantages, including:

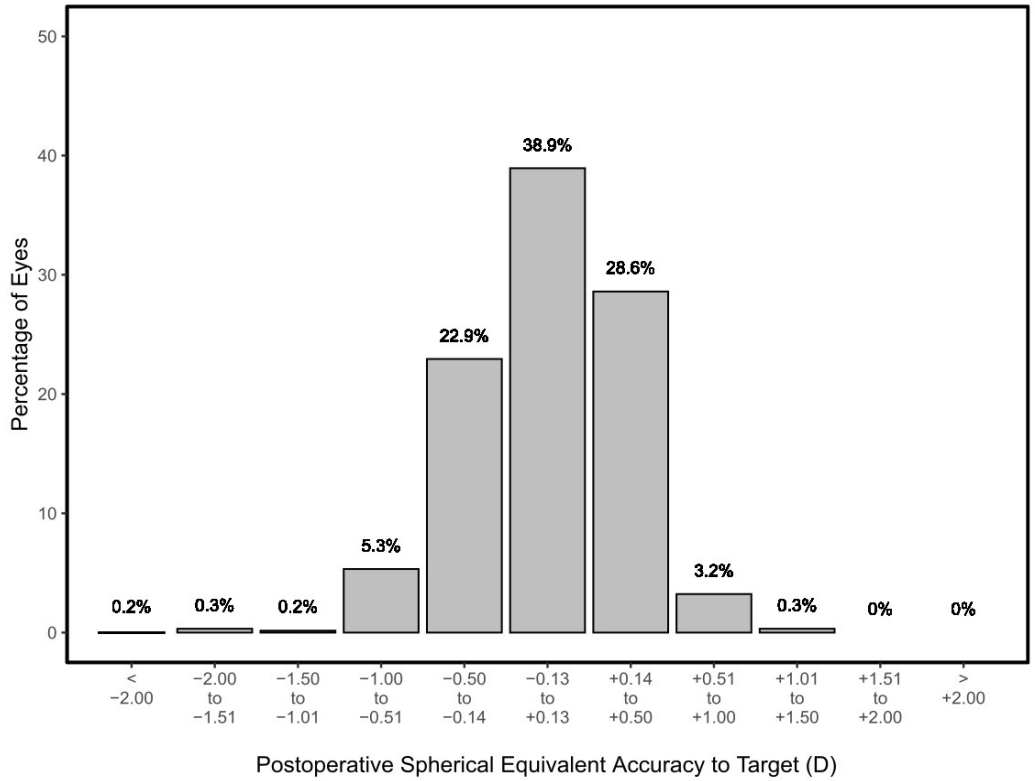
- More satisfactory visual quality
- Retaining the ability to accommodate the crystalline lens

5. Igarashi A, Kamiya K, Shimizu K, Komatsu M. Visual Performance after implantable Collamer lens implantation and wavefront-guided laser in situ keratomileusis for high myopia. Am J Opthalmol. 2009.
6. Martinez-Plazs E, Lopez-Miguel A, Lopez-De La Rosa A, et al. Effect of the EVO+ Visian Phakic Implantable Collamer Lens on Visual Performance and Quality of Vision and Life, Am J Ophthalmol 2021;226: 117–125.
7. Ganesh S, Brar S, Pawar A. Matched population comparison of visual outcomes and patient satisfaction between 3 modalities for the correction of low to moderate myopic astigmatism. Clin Ophthalmol. 2017 Jul 3;11:1253-1263.

Predictability



Attempted versus achieved spherical equivalent (SE) correction (R2 = 98.6%)

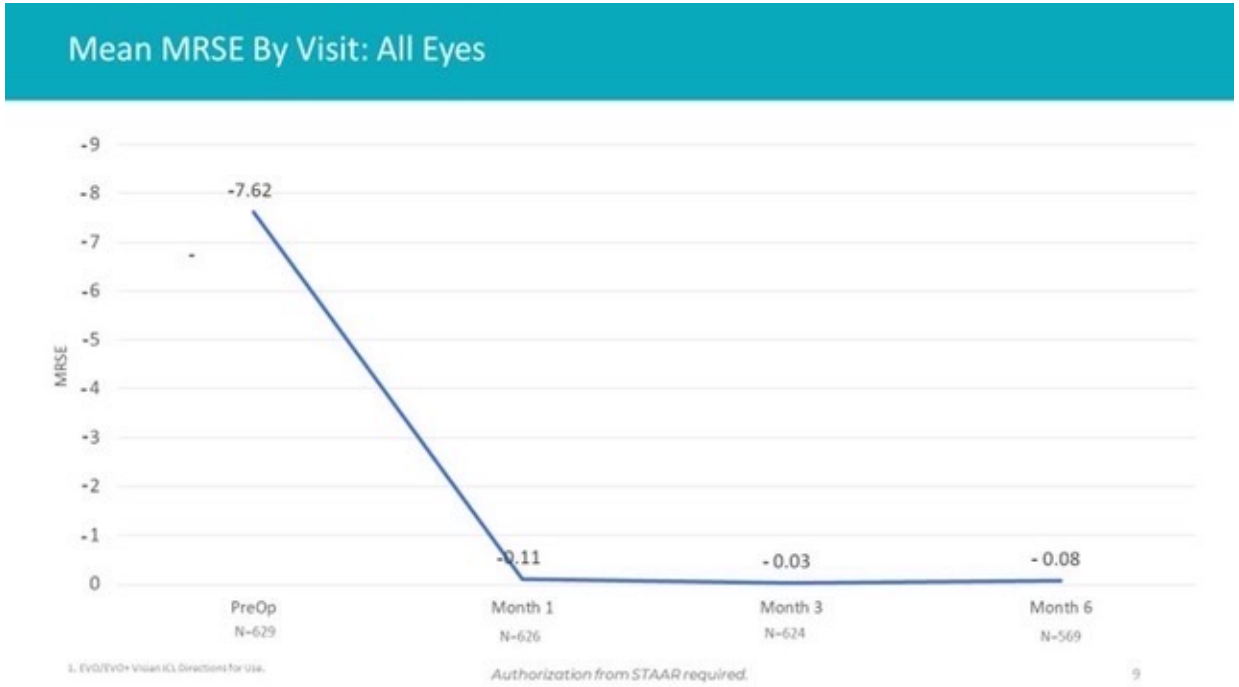


90.5% of eyes were within ± 0.50 D of the targeted SE refraction, and 98.9% of eyes were within ± 1.00 D

Stability

Mean MRSE by visit:

- −7.62 ± 2.76 D preoperatively
- −0.11 ± 0.30 D at 1 month
- −0.03 ± 0.31 D at 3 months
- −0.08 ± 0.34 D at 6 months



26. Packer M. Evaluation of the EVO/EVO+ Sphere and Toric Visian ICL: Six Month Results from the United States Food and Drug Administration Clinical Trial. *Clin Ophthalmol*. 2022;16:1541-1553. doi:10.2147/OPTH.S369467

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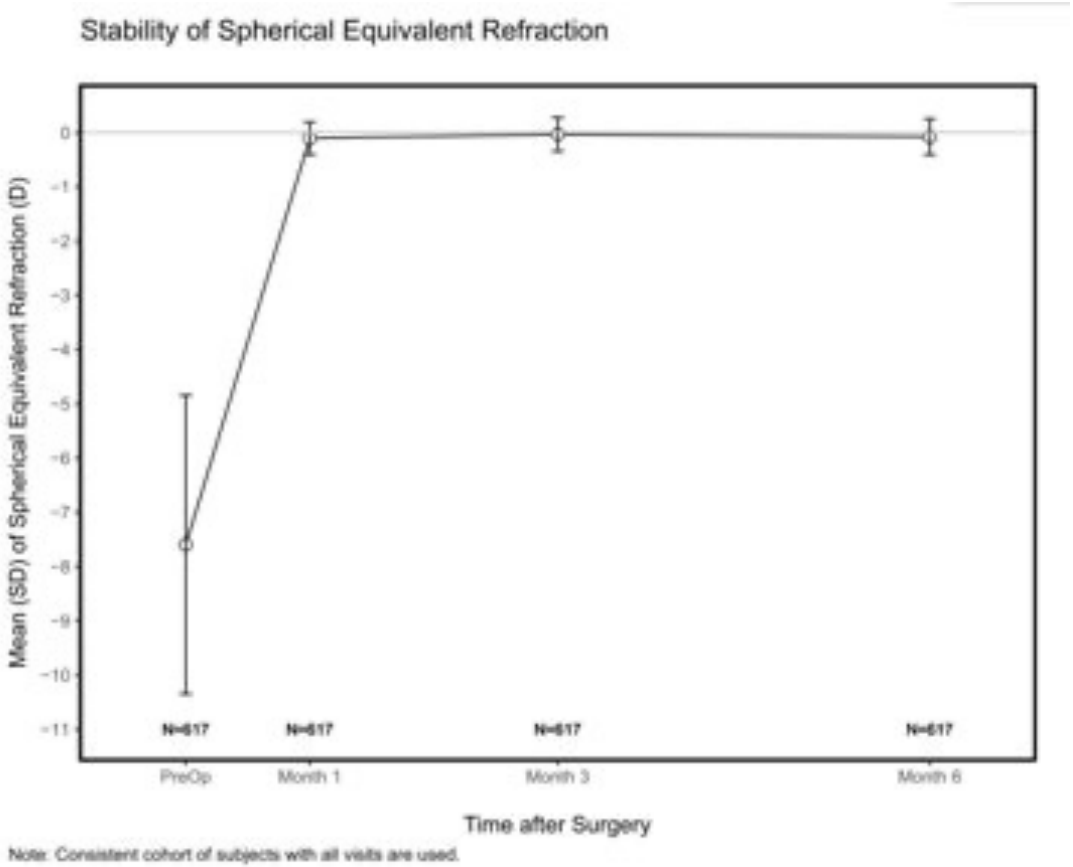

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Safety

Established Safety Profile: Adverse Events (N=629)*

Ocular Adverse Events[1]	Number of Eyes	Percent
Increased IOP	162	25.8%
Anterior Sub-Capsular Cataract	0	0%
Glare/Halo	1	0.2%
ICL Removal	1	0.2%

- Increased IOP commonly occurred either at postop same day visit 0 (125/629; 19.9%) due to retained OVD or 6 to 31 days postoperative due to steroid response.
- ICL removal was due to halo/glare

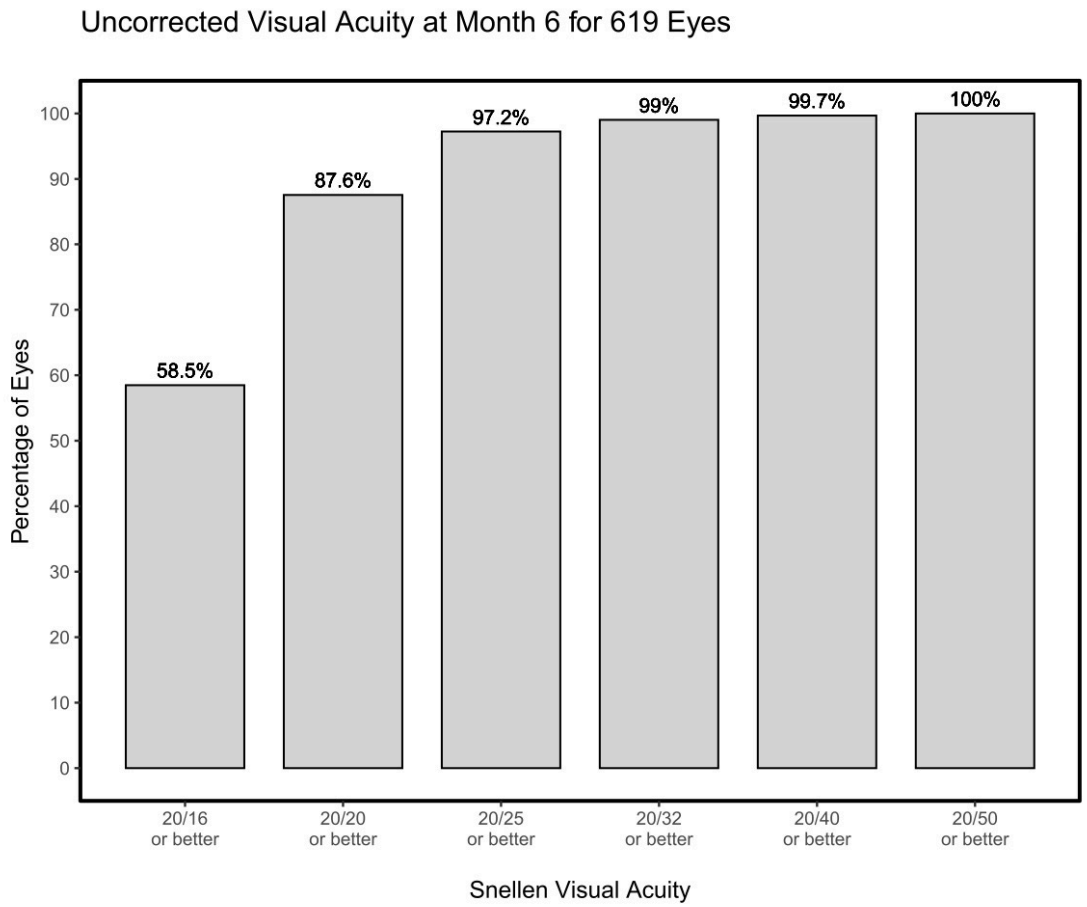
1. EVO/EVO+ Visian ICL Directions for Use.

Authorization from STAAR required.

10

26. Packer M. Evaluation of the EVO/EVO+ Sphere and Toric Visian ICL: Six Month Results from the United States Food and Drug Administration Clinical Trial. *Clin Ophthalmol*. 2022;16:1541-1553. doi:10.2147/OPTH.S369467

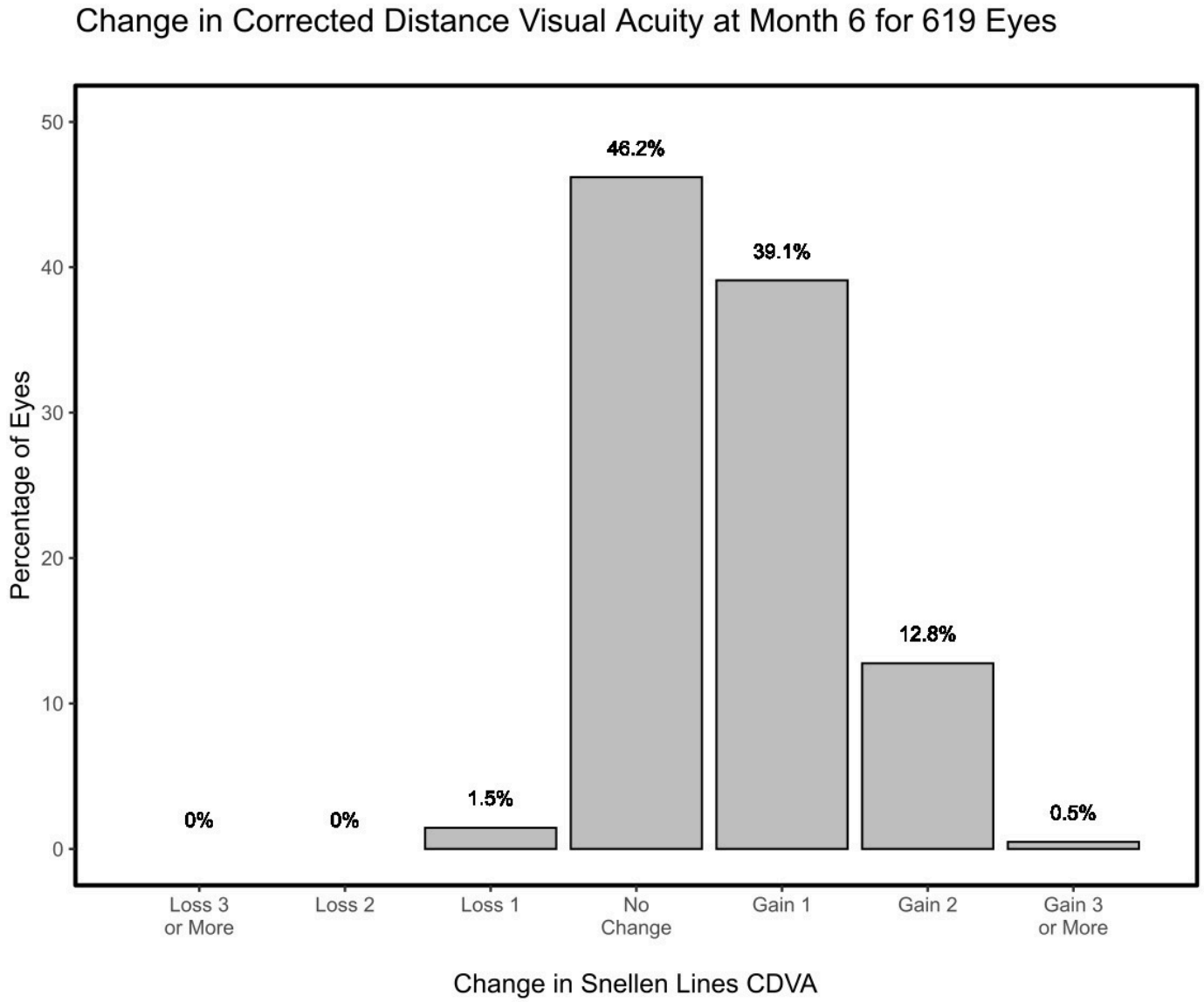
Efficacy



87.6% of eyes achieved 20/20 or better and 99.7% of eyes achieved 20/40 or better postoperative UDVA. Only 2 of 619 eyes (0.3%) reported UDVA less than 20/40 at 6 months.[26]

26. Packer M. Evaluation of the EVO/EVO+ Sphere and Toric Visian ICL: Six Month Results from the United States Food and Drug Administration Clinical Trial. *Clin Ophthalmol*. 2022;16:1541-1553. doi:10.2147/OPTH.S369467

Efficacy



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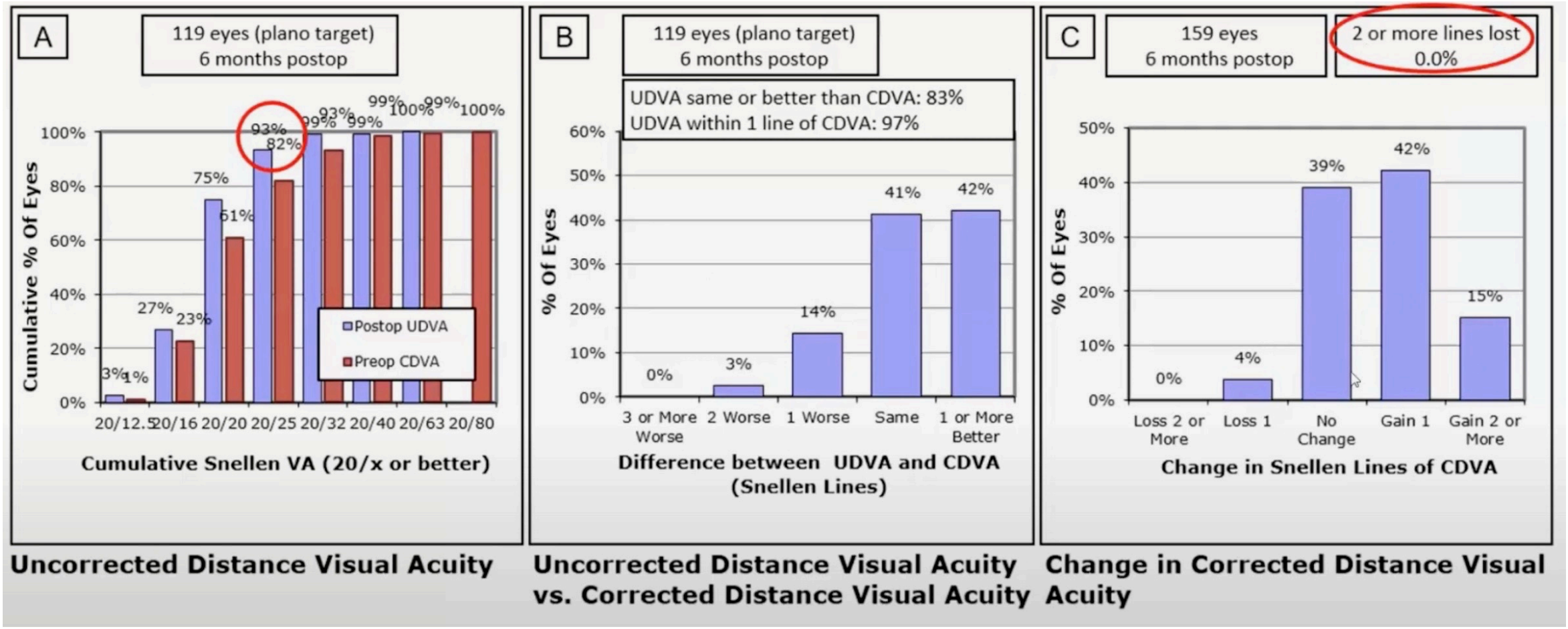
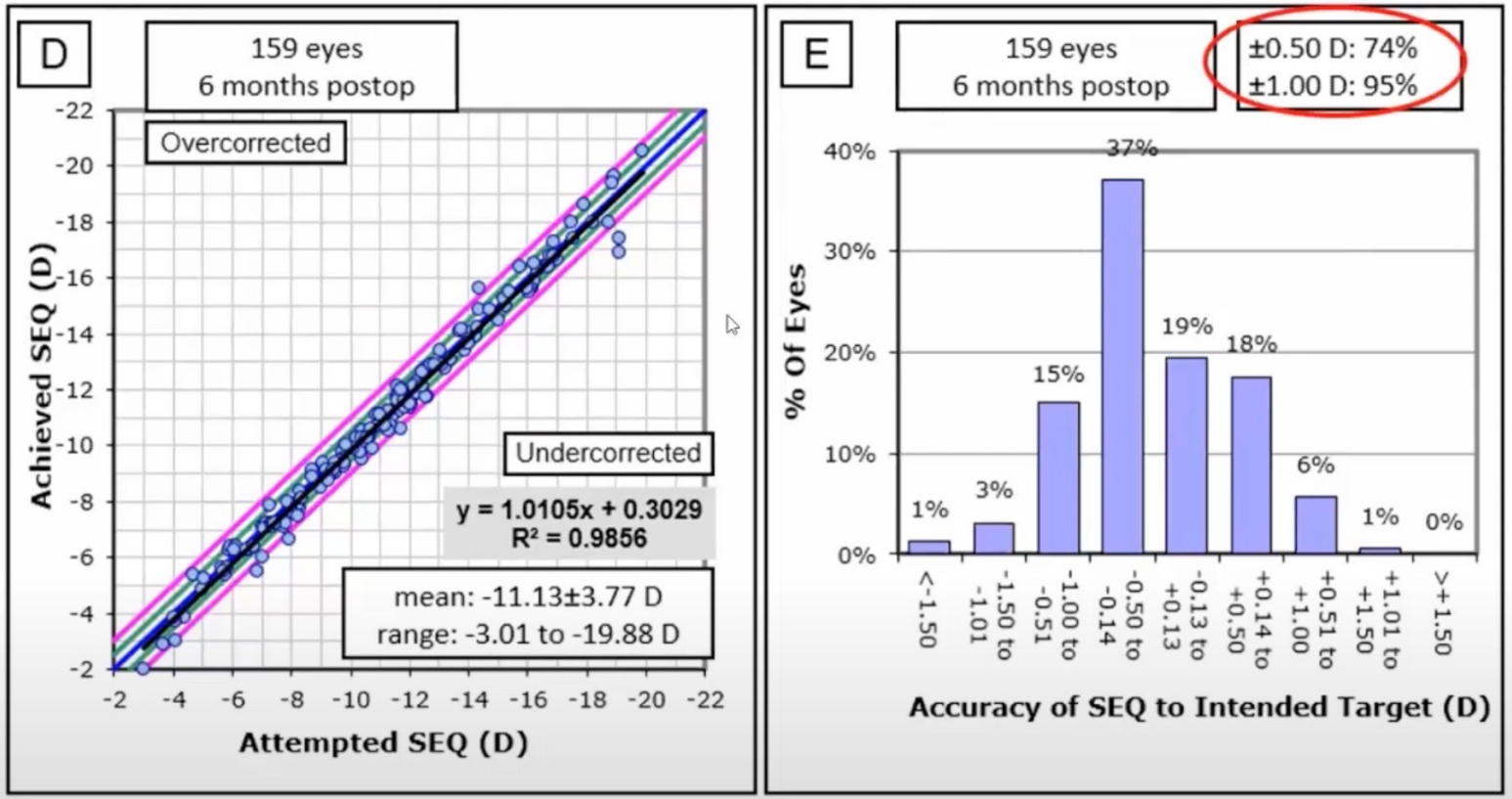
Efficacy


A
119 eyes (plano target)
6 months postop
Cumulative % Of Eyes
100%
80%
60%
40%
20%
0%
3%
1%
27%
23%
75%
61%
93%
82%
99%
93%
99%
99%
100%
99%
100%
Postop UDVA
Preop CDVA
20/12.5 20/16 20/20 20/25 20/32 20/40 20/63 20/80
Cumulative Snellen VA (20/x or better)
Uncorrected Distance Visual Acuity
B
119 eyes (plano target)
6 months postop
UDVA same or better than CDVA: 83%
UDVA within 1 line of CDVA: 97%
% Of Eyes
60%
50%
40%
30%
20%
10%
0%
0%
3%
14%
41%
42%
3 or More Worse
2 Worse
1 Worse
Same
1 or More Better
Difference between UDVA and CDVA (Snellen Lines)
Uncorrected Distance Visual Acuity vs. Corrected Distance Visual Acuity
C
159 eyes
6 months postop
2 or more lines lost
0.0%
% Of Eyes
50%
40%
30%
20%
10%
0%
0%
4%
39%
42%
15%
Loss 2 or More
Loss 1
No Change
Gain 1
Gain 2 or More
Change in Snellen Lines of CDVA
Change in Corrected Distance Visual Acuity

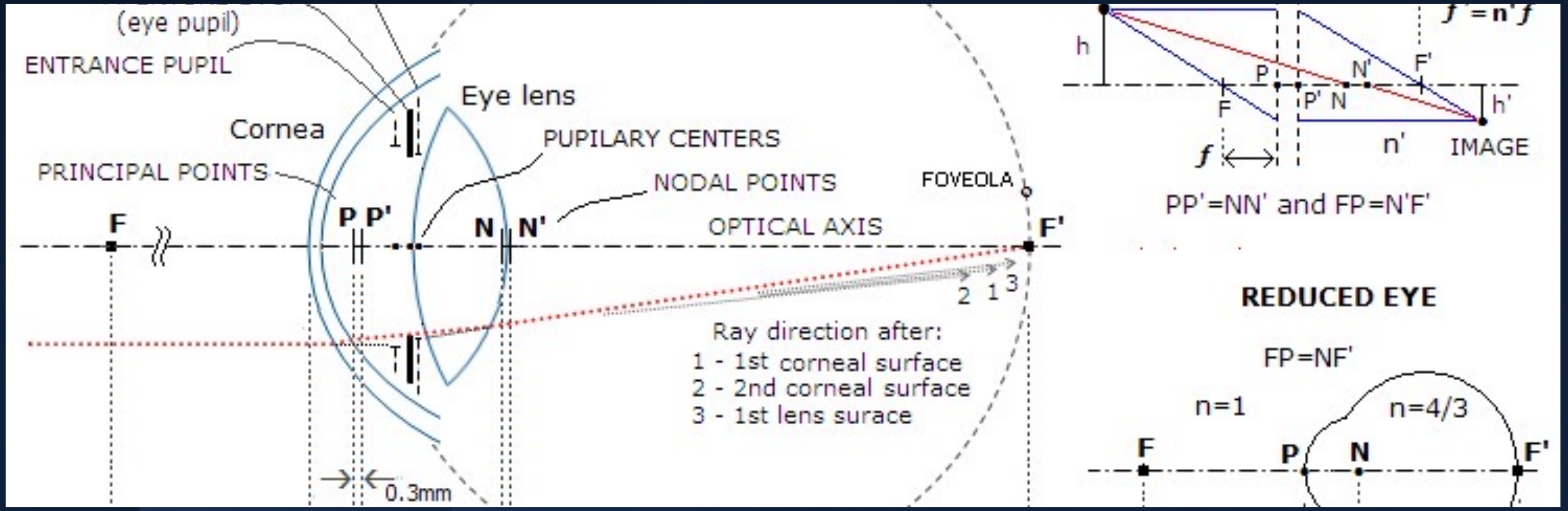
Efficacy



Spherical Equivalent Refraction Attempted vs Achieved

Spherical Equivalent Refraction Accuracy

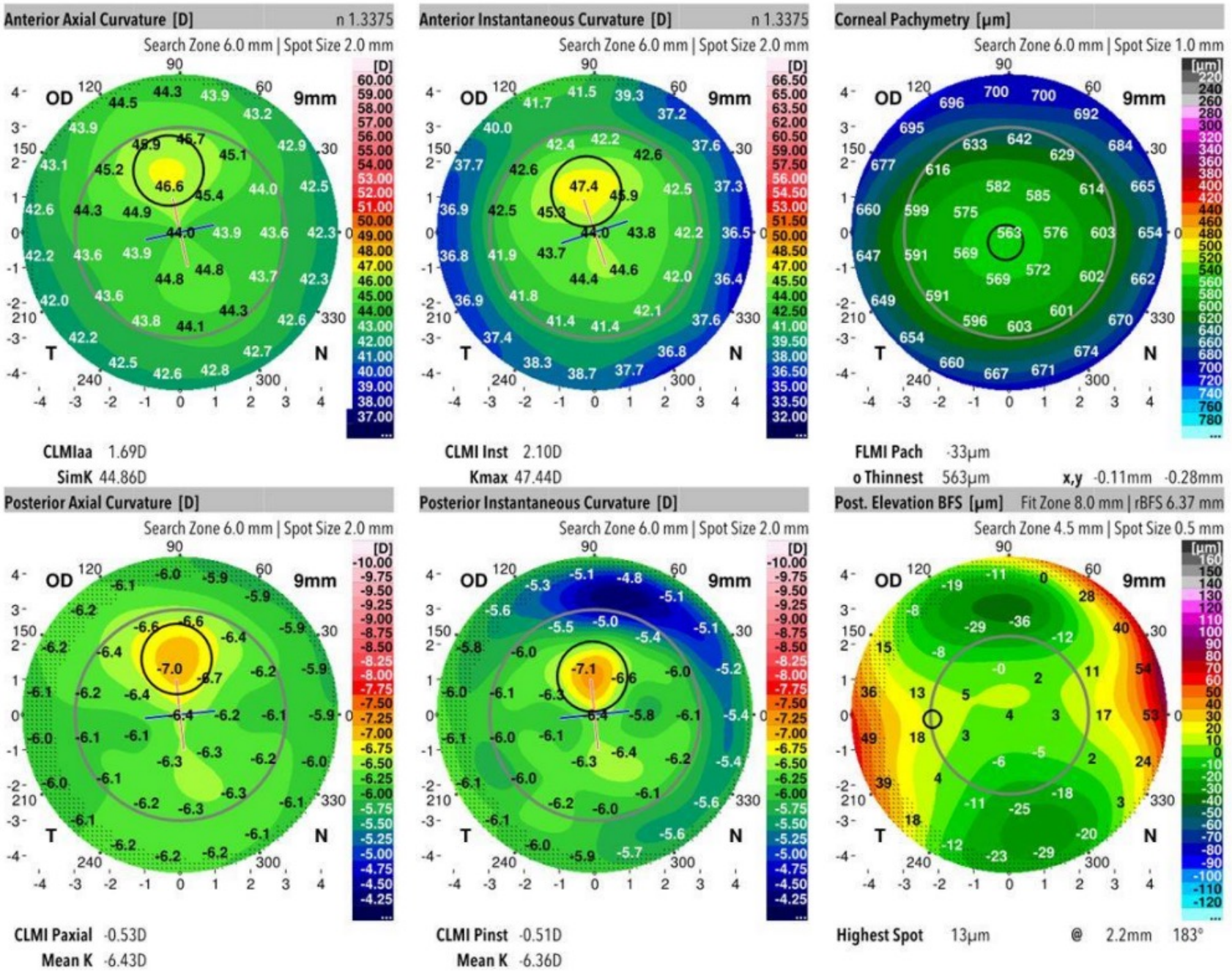
LVC *over* ICL



Nodal Point

- Excellent subjective quality of vision in high myopes
- 99.4% patients say they would do this lens again[2]
- Image quality of near-nodal point correction[3]

2. Holden BA, Fricke TR, Wilson DA, et al. Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 through 2050. *Ophthalmology*. May 2016;123(5):1036-42. doi:10.1016/j.ophtha.2016.01.006
3. Staar ICL Surgical Data Registry 2018



Case Study: Non-LVC Candidates

- 26 yo M
- Same-day Sequential ICL
- PO Day 1
- UCVA
  - OD 20/20+2
  - OS 20/20
  - OU 20/15-2

OPTOMETRY COLLABORATIVE CARE

Objectives:

Understand patient selection criteria in myopia, hyperopia, and astigmatism, including topography, biometry, Scheimpflug, and sulcus ultrasound.

Understand how to assess and manage ICL patients in the post-operative patient, including lens vault, lens position, vision, and co-management considerations.

Understand how to effectively address the most frequently asked questions about ICL vision correction.

Patient Selection Guide: Optometry Patient Work-up

- A standard full ophthalmic exam should be performed on all patients.
- Measurements needed for performing central port ICL calculations:
  - Manifest & Cycloplegic refraction
  - Back Vertex Distance (BVD) in millimeters
  - AD (“true ACD”) in millimeters (3.0mm or greater from posterior surface of the cornea to the anterior surface of the crystalline lens)
  - Corneal thickness in millimeters
  - White to White (WtW) in millimeters
    - OPDIII, Lenstar, Orbscan, Pentacam, G4, G6
  - K1, K2
  - CL Over-refraction Sphere (optional)
- Measurements recommended for patient assessment and records:
  - Corneal Endothelial Cell Density (ECD) assessment
  - Gonioscopic assessment of the angle, Grade III or higher
  - Axial length

Indications

Models	Indication
EVO/EVO+ Visian ICL	For the correction (spherical equivalent: -3.0 D to ≤ -15.0 D) or reduction (spherical equivalent: >-15.0 D to -20.0 D) of myopia in patients at the spectacle plane with less than or equal to 2.5 D astigmatism
EVO/EVO+ Visian Toric ICL	For the correction (spherical equivalent: -3.0 D to ≤ -15.0 D) or reduction (spherical equivalent: >-15.0 D to -20.0 D) of myopic astigmatism with cylinder of 1.0 D to 4.0 D at the spectacle plane

EVO is intended for posterior placement in the phakic eye of patients:

21 to 45 years of age

ACD (from endo) ≥ 3.00 mm

Stable refractive history (within 0.5 D change for spherical equivalent and cylinder in last 12 months)

Preoperative Peripheral Iridotomies No Longer Required

Contraindications

ICL contraindicated in patients:

- With an anterior chamber depth (true ACD) of <3.00 mm*;
- With anterior chamber angle less than Grade III as determined by gonioscopic examination;
- Who are pregnant or nursing;
- Less than 21 years of age;
- Who do not meet the minimum endothelial cell density (ECD);
- Ocular hypertension or glaucoma
- Pseudo-exfoliation
- Pigment dispersion
- History or signs of uveitis
- Cataract, or progressive, sight-threatening disease

Post-Operative Exam

RECOMMENDED PATIENT POSTOPERATIVE ASSESSMENT[10]

- Intraocular pressure should be initially checked 1 – 6 hours postoperatively
- Postoperative 1 day, 7 day and beyond
- Visual acuity
- Intraocular pressure
- Assess the ICL to crystalline lens vault
- Biomicroscopy to assess:
  - EVO centration
  - Inflammation

10. Ye Y, Zhao J, Zhang Z, et al. Long-term follow-up for monovision surgery by Implantable Collamer Lens V4c implantation for myopia correction in early presbyopia. *Graefes Arch Clin Exp Ophthalmol*. Feb 07 2022;doi:10.1007/s00417-021-05545

ADVANCEMENTS IN SURGICAL TECHNIQUES

Objectives:

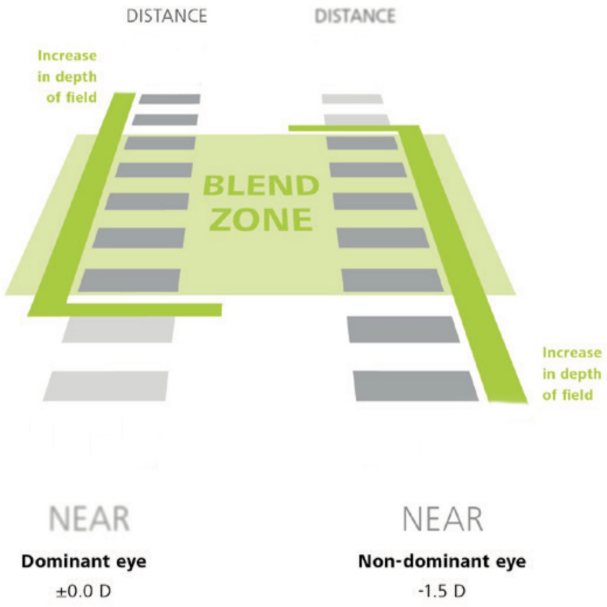
Understand novel advancements in ICL surgery techniques and surgical instrumentation.

Technique Advancements

2nd Generation ICL Vacuum Cannula

Blended Vision Strategy

- 1.7 billion people globally have presbyopia[24]
- 2.1 billion worldwide by 2050
- 84% of 45–60-year-olds suffer from presbyopia[25]
- Blended vision strategy
- Evidence of good binocular vision and long-term safety and efficacy of monovision surgery by ICL implantation in presbyopic myopia.[23]



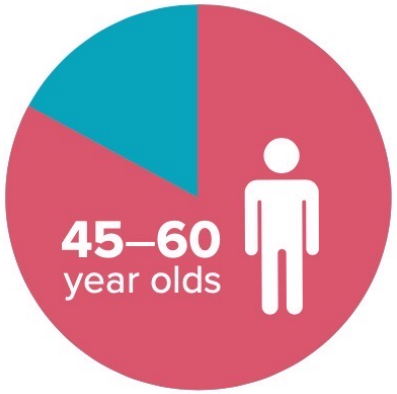
23. Chang DS, Jiang Y, Kim JA, et al. Cataract progression after Nd:YAG laser iridotomy in primary angle-closure suspect eyes. *Br J Ophthalmol*. May 02 2022;doi:10.1136/bjophthalmol-2021-320929

24. Fujisawa K, Shimizu K, Uga S, et al. Changes in the crystalline lens resulting from insertion of a phakic IOL (ICL) into the porcine eye. *Graefes Arch Clin Exp Ophthalmol*. Jan 2007;245(1):114-22. doi:10.1007/s00417-006-0338-y

25. Zeng QY, Xie XL, Chen Q. Prevention and management of collagen copolymer phakic intraocular lens exchange: causes and surgical techniques. *J Cataract Refract Surg*. Mar 2015;41(3):576-84. doi:10.1016/j.jcrs.2014.06.036

Expanded Age Range

- The improved safety has given rise to use in expanded age ranges.
- FDA on-label 21-45yo
- Europe on-label to 60yo



ARTICLE

Posterior chamber phakic intraocular lens with central-port design in 45- to 55-year-old patients: 1-year follow-up

José F. Alfonso, MD, PhD, Carlos Lisa, MD, PhD, Luis Fernández-Vega-Cueto, MD, PhD, Juan Besteiro, MD, Belén Alfonso-Bartolozzi, MD

Purpose: To assess the efficacy, safety, and predictability of the Visian implantable collamer lens with a central port in patients aged between 45 and 55 years.

Setting: Fernández-Vega Ophthalmological Institute, Oviedo, Spain.

Design: Retrospective case series.

Methods: Uncorrected (UDVA) and corrected (CDVA) distance visual acuities, refraction, intraocular pressure (IOP), endothelial cell density (ECD), vault, and adverse events over a 1-year period were evaluated retrospectively.

Results: A total of 87 eyes (49 patients) were evaluated. The mean postoperative UDVA and CDVA were 0.82 ± 0.24 and 0.93 ± 0.12, respectively. Seventy-eight eyes (approximately 90%) achieved a CDVA of 20/25 or greater. No eye lost 1 or more lines, 53 eyes (60.92%) did not change, 15 eyes (17.24%) gained 1 line, and 19 eyes (21.84%) gained 2 lines or more of CDVA. The efficacy and safety indexes were 0.95 and 1.08, respectively. Seventy-eight eyes (89.65%) were within ±0.50 diopter (D) of the desired sphere refraction, and all eyes (100%) were within ±1.00 D. Fifty eyes (57.7%) showed a spherical equivalent within ±0.13 D. The mean postoperative IOP was 13.58 ± 1.79 mm Hg, and no significant rise (>18 mm Hg) occurred during the follow-up. The largest proportion of eyes (35.63%) reported a reduction in IOP by 1 to 2 mm Hg. Postoperative mean ECD was 2574 ± 362 cells/mm^2 (0.41% loss from the preoperative baseline). The mean postoperative vault was 398 ± 187 µm, being the most prevalent range from 201 to 300 µm (22.89% of eyes). No adverse events were reported during the study.

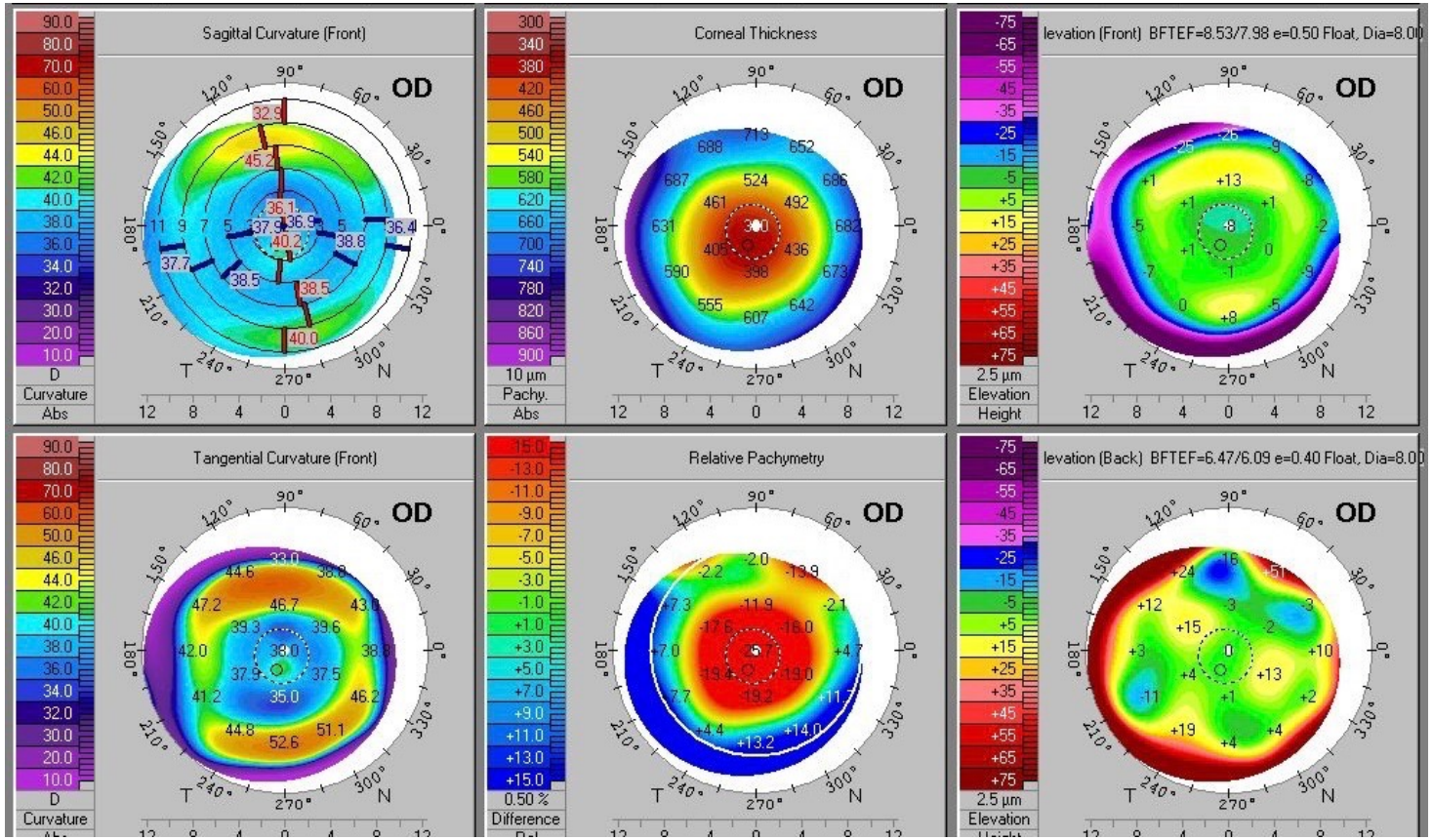
Conclusions: The outcomes reported in this study support the use of this lens in older patients.

J Cataract Refract Surg 2021; 47:459–464 Copyright © 2021 Published by Wolters Kluwer on behalf of ASCRS and ESCRS

Blended Vision Strategy

- Excellent for presbyopic post-LASIK patients (non LVC candidates)

CCT: 300 microns
Normal Topography
S/P LASIK 2002



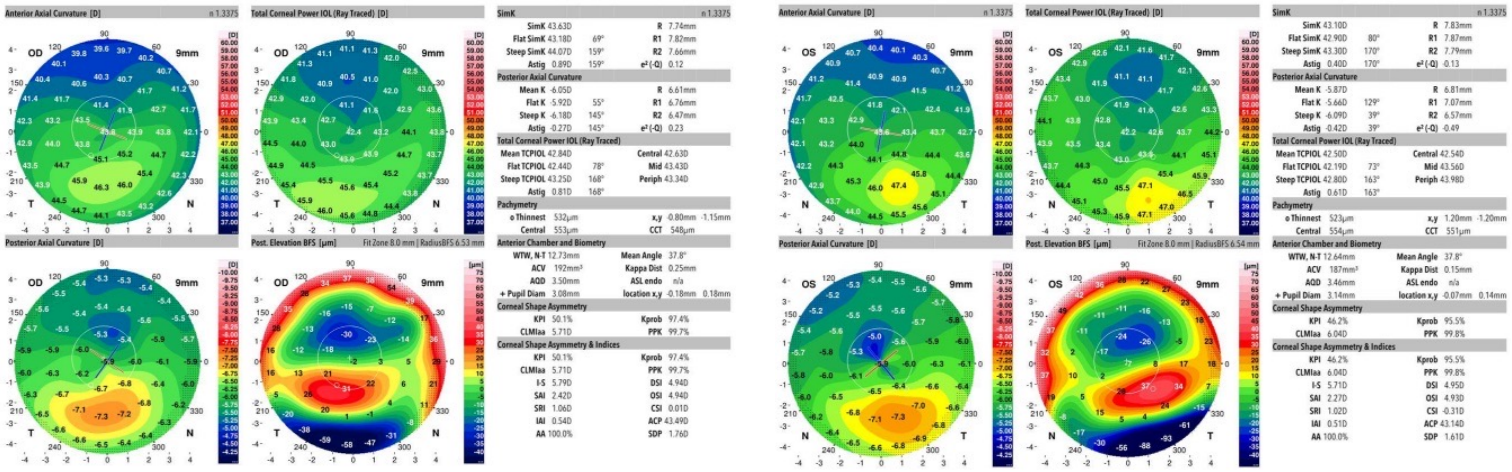
Blended Vision Strategy

- Excellent for early presbyopic, modest KCN (non LVC candidates)

Case Study
45yo Man
Intolerant of CLs

Manifest Refraction
OD: -3.00 -1.50 X 082 +1.25 J1+
-4.50 +1.50X 172

OS: -2.50 -1.75 X 070 +1.25 J1+
-4.25+1.75 X 160



- Self-cross-linked
- Preserve accommodation

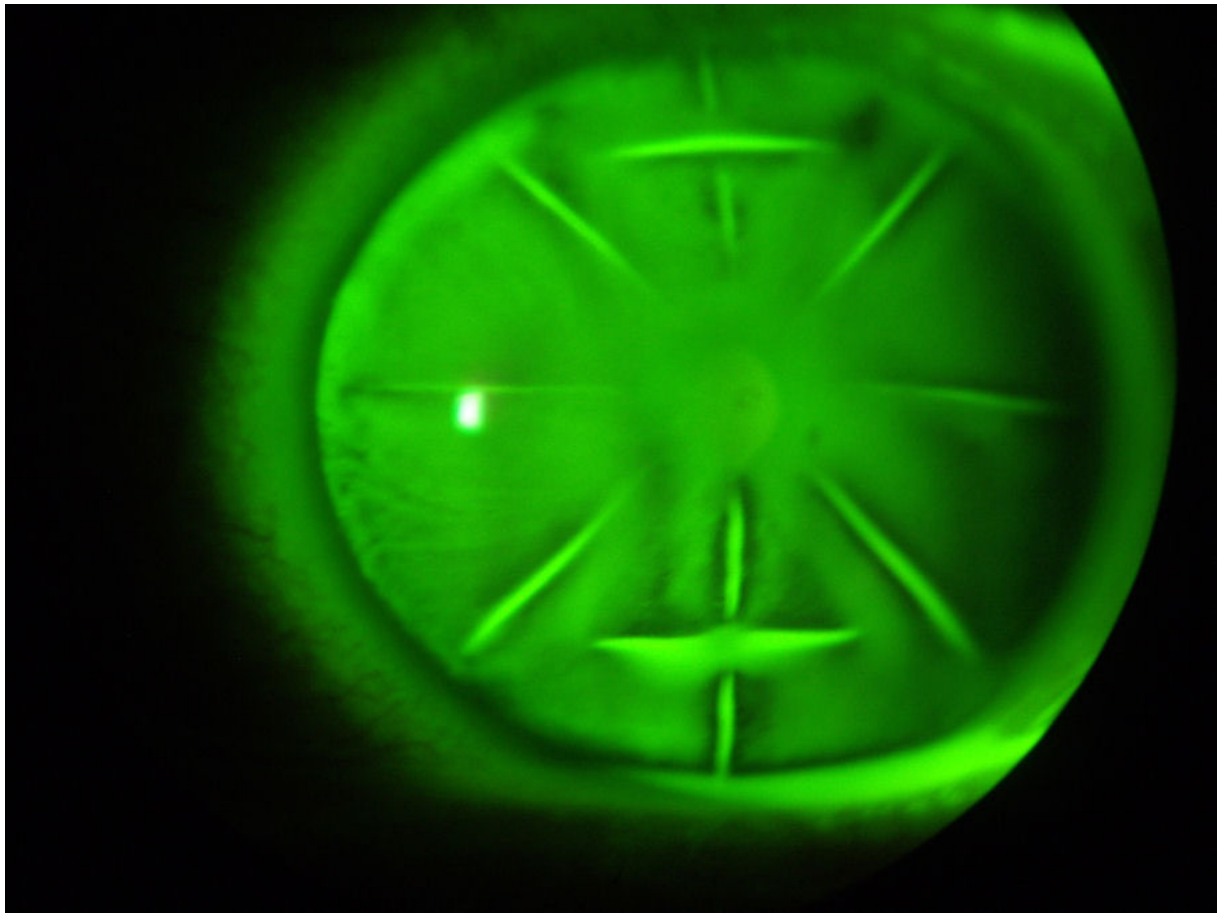
Presbyopic ICL

- ICL with Aspheric (EDOF) Optic
- European approval July 2, 2020
- US FDA Study is going on now

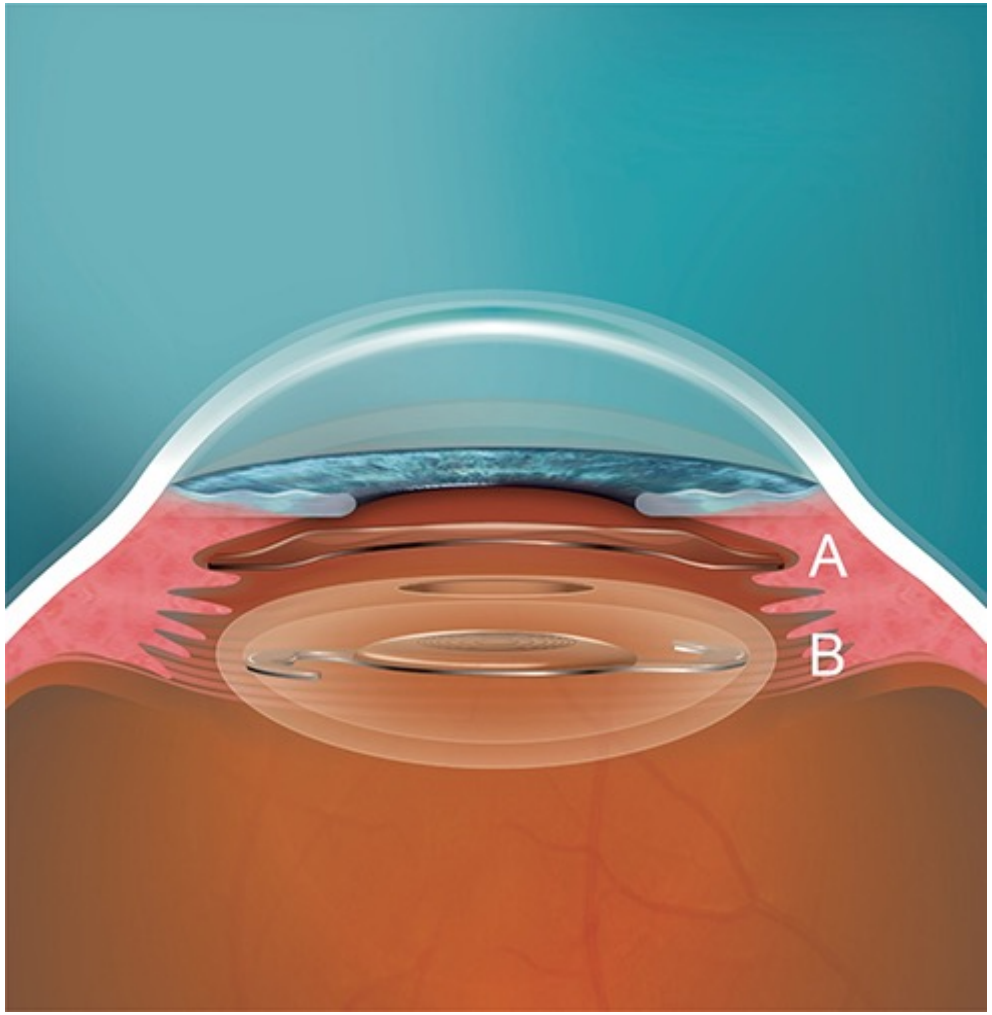
Case Study 2

62 year-old male

- Presented with 8-cut RK OU
- S/P spherical cataract 11 years ago
- UCVA OD -3.50 D +0.75 X 91
- Placed piggyback -3.00 ICL
- 1 month: UCVA 20/20-1



IOL and ICRS



- Safe for IOL Piggyback procedures
- Intrastromal corneal ring segments (ICRS) followed by either TORIC or spherical ICL

FLACS Through ICL

Case Study 1

21-year-old female

- Glasses (for 2 years!)
  - OD −4.5 D sphere 20/20
  - OS plain glass 20/640
- ET OS: 25PD with no variability or incomitance
- BCVA OS: -20.0 D SPH. improved to 20/250
- Exam: myopic degeneration, no staphyloma
- OD amblyopia therapy trial for 3 months
  - No change in VA or ocular deviation

Case Study 1 (continued)

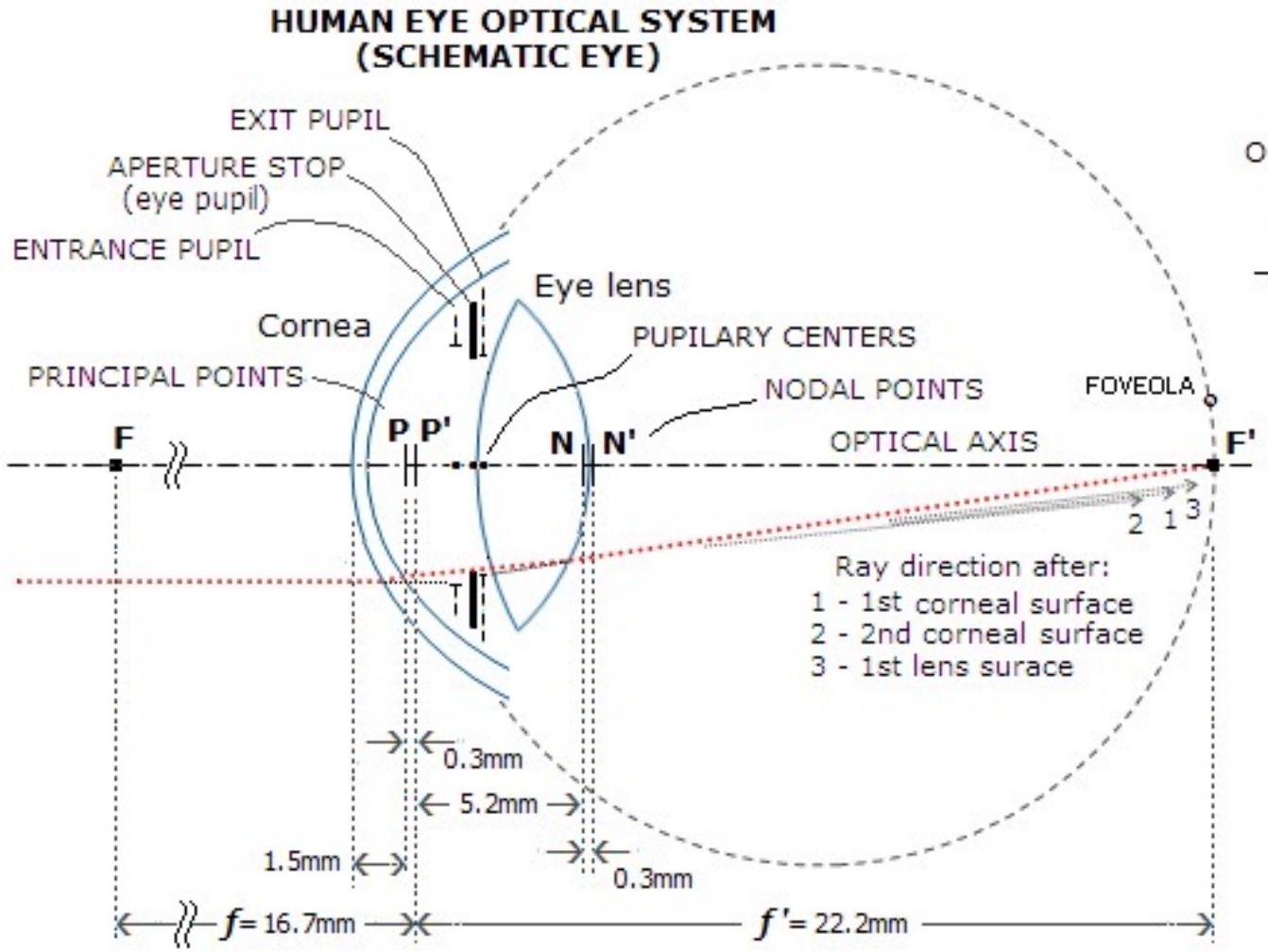
Patient underwent ICL implantation in both eyes (−6.5 D OD, −23.0 D OS).

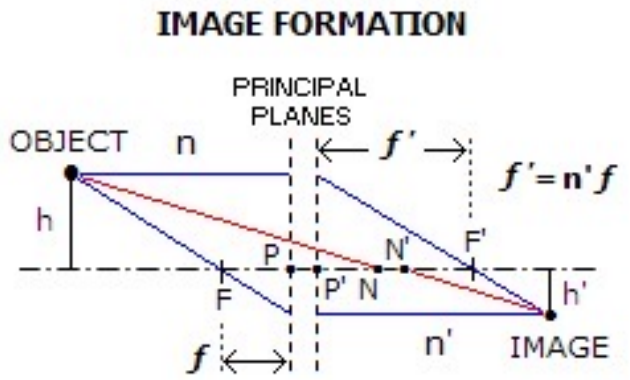
- Postop day :
  - UCVA OD: 20/16 OD
  - BCVA OS: 20/80 (−0.75 D Sph)
- She was orthophoric for distance and near with fusion with a limited range

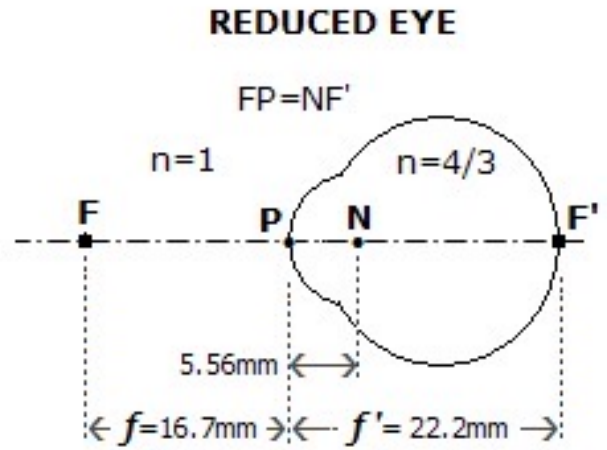
Case Study 1 (continued)

- Exotropia associated with myopia corrected by appropriate refractive correction.[5] However, patients presenting late, high myopia significant anisometropia = limited binocularity and the deviation remains unchanged with glasses.
- Contact lenses are known to increase the accommodative effort in myopes compared to spectacles with the increase being proportional to the refractive error.[6]
- The ICLs have a greater effect on the accommodative effort.[7,8]
- A large portion of the stimulus to fuse is elicited through the peripheral field of vision.
- For highly myopic patients, glasses create significant peripheral distortion. With ICLs, peripheral distortions are eliminated making fusion easier.[9]
- A clearer, lesser minified, and aniseikonia image stimulates and enhances binocularity. Myopic refractive correction closer to the nodal point is well-known to improve VA. [10]

Case Study 1 (continued)







Anisometropic Amblyopia

- 2021
- Non-compliance with occlusion therapy validates the early implantation of ICLs in cases with failed conventional therapy to guard against anisometropic amblyopia
- Watany Eye Hospital, Cairo, Egypt
  - 42 patients
  - Non-compliant children and teenagers: myopic anisometropic amblyopia and unsuccessful conventional therapy
  - Long-term efficacy, safety, and stability of ICLs for correcting myopic anisometropic amblyopia in pediatrics

RISKS OF SURGERY

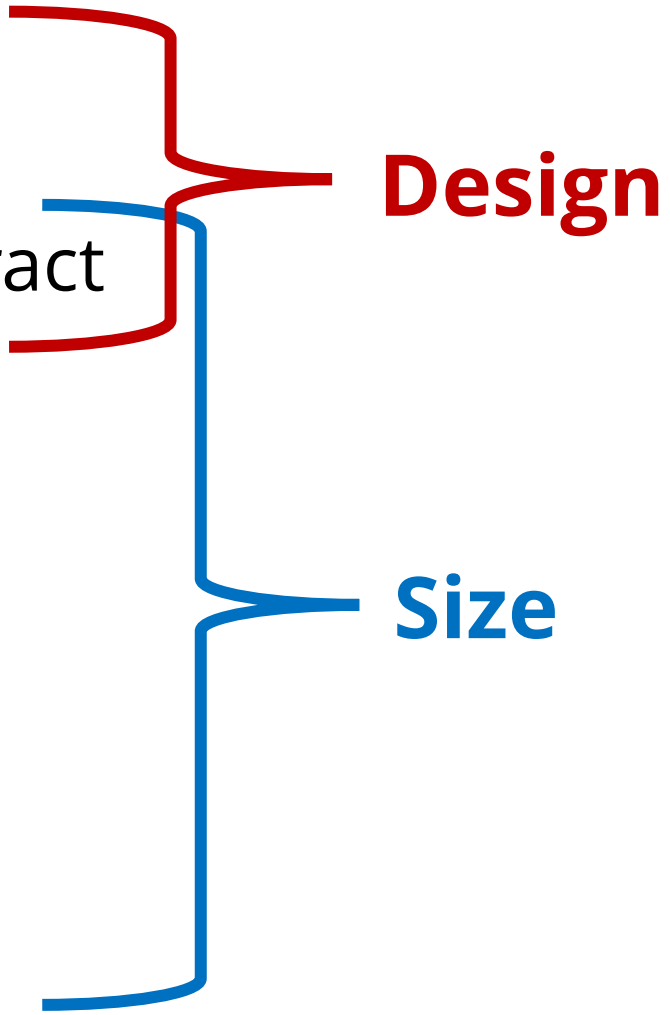
Objectives:

Understand the effect of 360 micrometer central hole ICL V4c, on the mesopic visual performance, including glare conditions.

Understand the etiology and rates of frequency of the historic risks of ICL surgery for patient education.

Risks of Surgery

- Chronic Uveitis
- Iridotomy Glare
- Anterior sub-capsular cataract
- Endothelial cell loss
- TORIC lens rotation
- Lens exchange risk
- Pupil block
- Glaucoma
- Pigment dispersion



Risks: Retinal Detachment?

- Annual risk of retinal detachment among the US population with myopia greater than −3.1 D has been reported to be:
  - 117 in 100,000
  - Lifetime risk of 9.3%[16]
- Phakic intraocular lenses have not been associated with increased risk of retinal detachment compared with other intraocular interventions in highly myopic patients.[17]

> Graefes Arch Clin Exp Ophthalmol. 2012 Dec;250(12):1725-30. doi: 10.1007/s00417-012-2002-z. Epub 2012 Apr 4.

Retinal detachment after phakic intraocular lens implantation in severe myopic eyes

16. Haarman AEG, Enthoven CA, Tideman JWL, Tedja MS, Verhoeven VJM, Klaver CCW. The Complications of Myopia: A Review and Meta-Analysis. *Invest Ophthalmol Vis Sci*. 04 09 2020;61(4):49. doi:10.1167/iovs.61.4.49
17. Flaxel CJ, Adelman RA, Bailey ST, et al. Posterior Vitreous Detachment, Retinal Breaks, and Lattice Degeneration Preferred Practice Pattern®. *Ophthalmology*. 01 2020;127(1):P146-P181. doi:10.1016/j.ophtha.2019.09.027

Risks: Retinal Detachment?

Results: The overall incidence of RD was 1.5 % (eight eyes of seven patients) with a mean time between PIOL implantation and detachment of 23.63 ± 18.12 months (range, 2 days-51 months). Mean spherical equivalent (SE) before PIOL implantation was -17.53 ± 3.86 diopters (D) (range, -11.5D to -23.5D). Six patients underwent bilateral PIOL implantation. Five eyes were implanted with anterior chamber PIOLs and the other three received posterior chamber PIOLs. A traumatic history was presented before RD detection in four cases. Horseshoe tears, atrophic holes, or giant retinal tears were found in four (50 %), two (25 %), and two (25 %) eyes, respectively. Two eyes (25 %) underwent scleral buckling surgery, five eyes (62.5 %) underwent pars plana vitrectomy surgery, and one eye (12.5 %) underwent both procedures. Anatomical retinal attachment was achieved after first RD surgery in seven eyes. Mean BCVA after PIOL implantation and before RD was 20/40 (decimal refraction, 0.51 ± 0.31) compared to that of 20/80 (decimal refraction, 0.26 ± 0.12) after the RD surgery. Mean follow-up after RD surgery was 20.63 ± 12.93 months (range, 8-42 months).

Conclusions: The incidence of RD after PIOLs implantation is low. Its characteristics do not differ significantly from the natural history of RD in high myopic eyes. PIOL implantation for surgical correction of severe myopia does not seem to increase the risk of RD. Good visual prognosis can be obtained with early surgical intervention.

Risks: YAG Iridotomy Glare

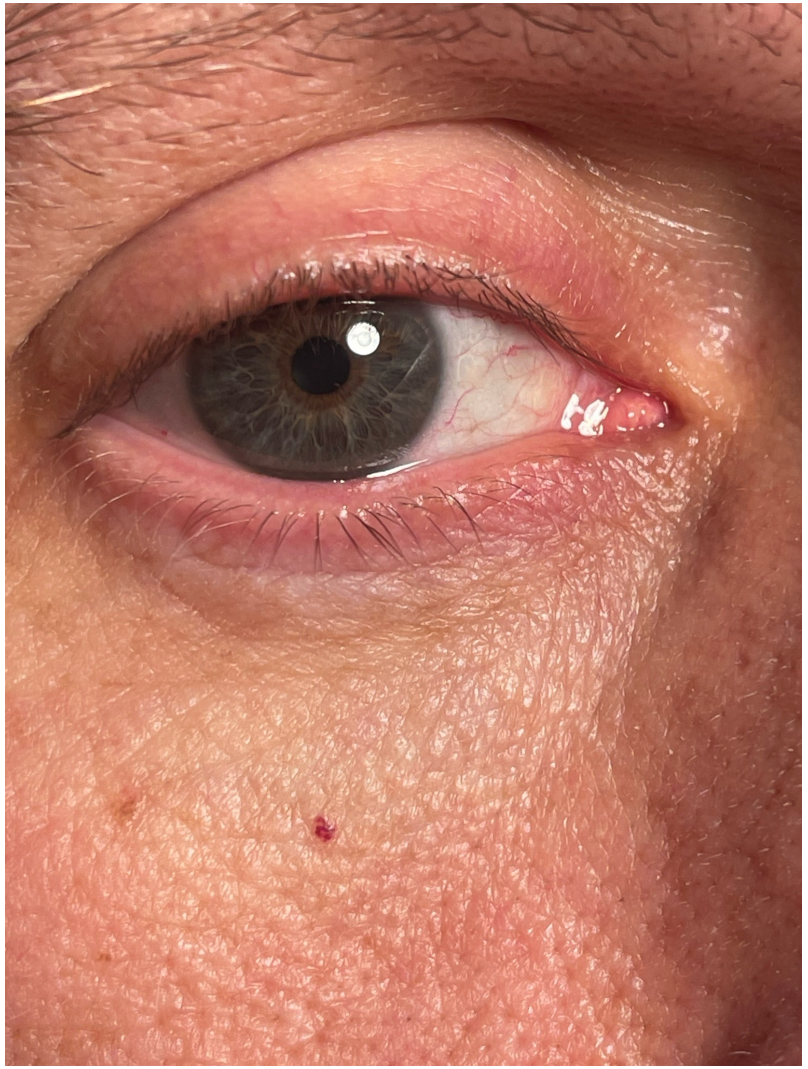
Risks: PI Glare – Case Study

<u>43 year-old male</u>

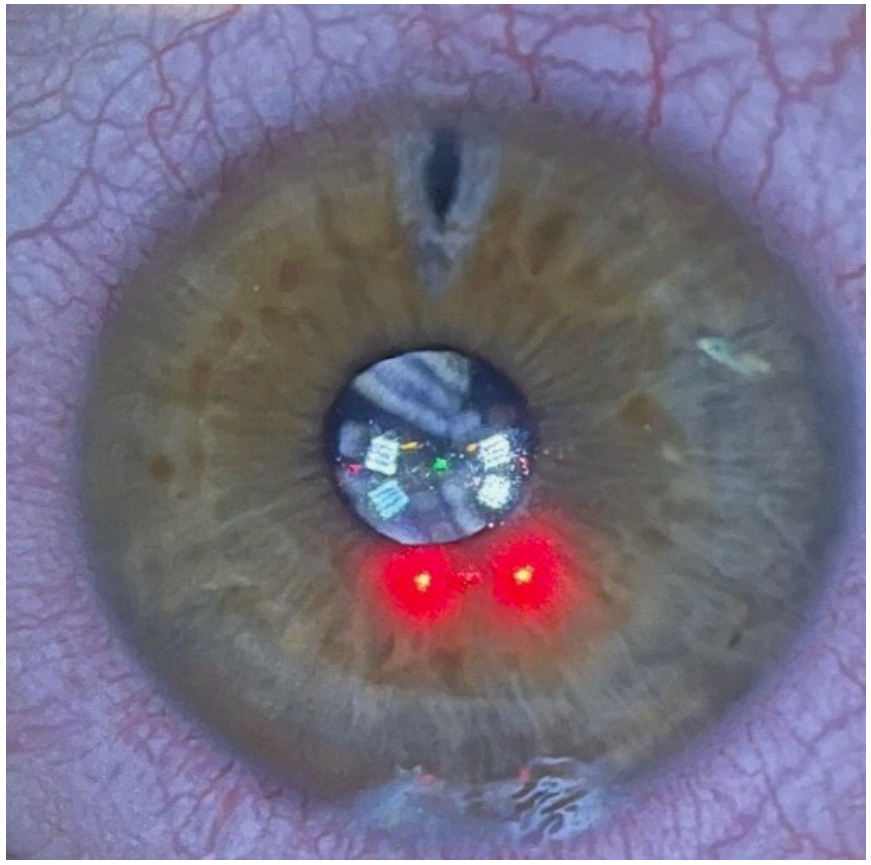
- Post-op 6 months: “Glare down on the floor!”
- Post-op UCVA
  - OD: 20/15
  - OS: 20/15

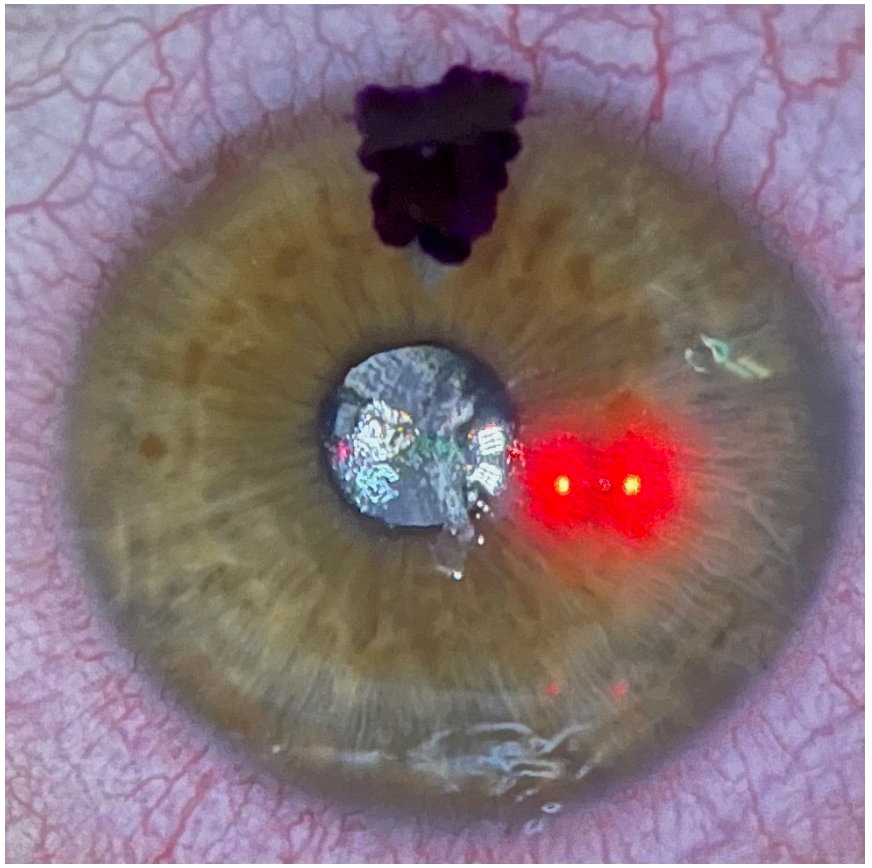
Please provide the following for Peripheral Iridotomy Patient:

- BCVA prior to surgery
- The ICL power used
- Uncomplicated same-day sequential ICL surgery.
- Upper eyelid appears normal.

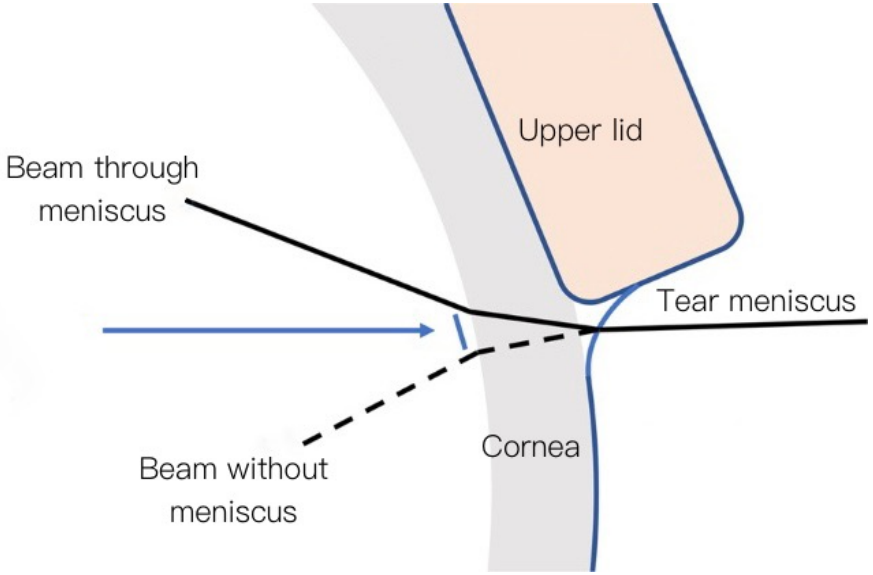


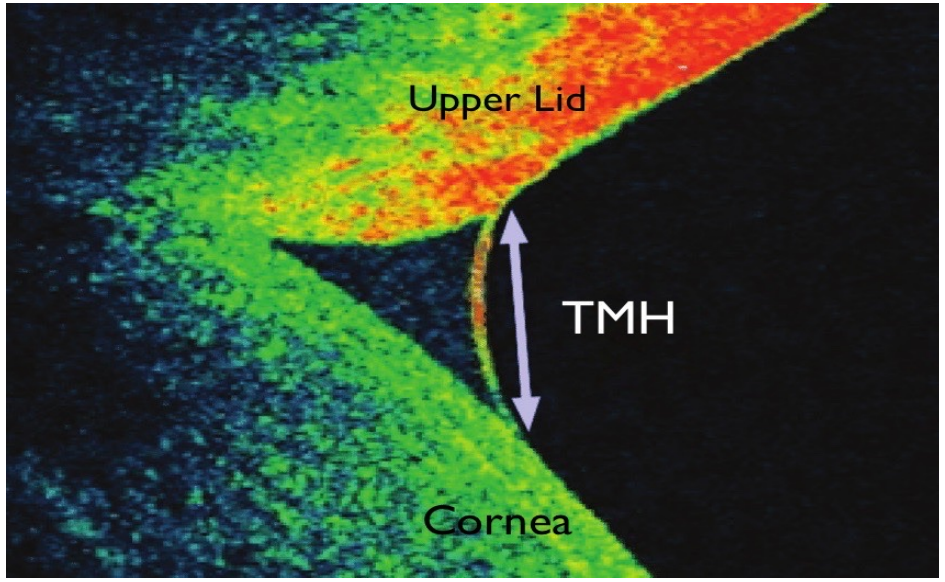
Risks: PI Glare – Case Study (continued)

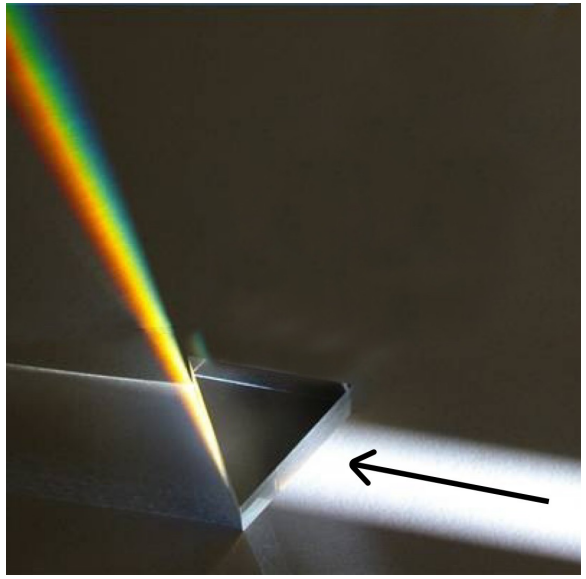




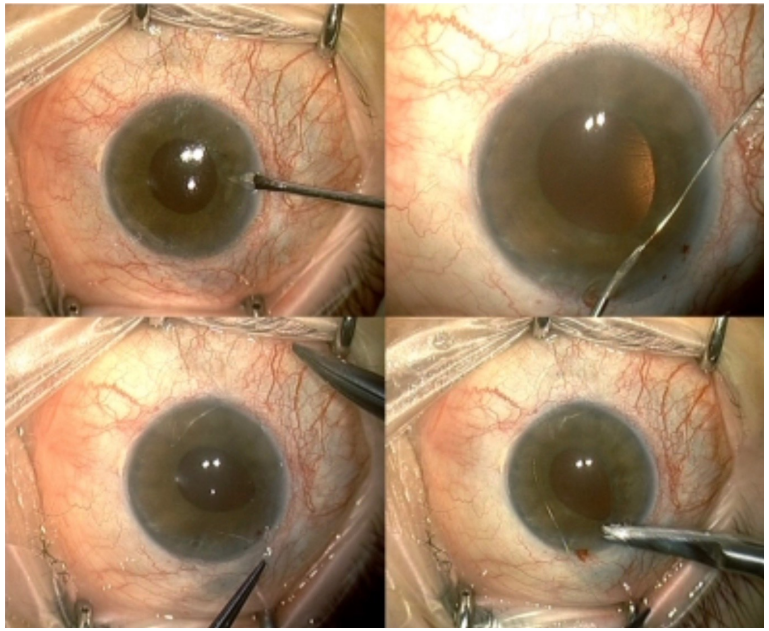
Risks: PI Glare – Case Study (continued)







Risks: PI Glare – Case Study (continued)



- UCVA
  - OD: 20/15
  - OS: 20/15
- Resolution of glare

Risks: Glare Visual Disturbance

- One eye (1/629, 0.02%) underwent ICL explantation due to a subjective report of halo and glare
- Central Port Related
  - Significant improvement. Very few reports.[21]
  - Most completely resolved in weeks to months[22]
- Surgeons are advised to explain to patients the possibility of ring-shaped dysphotopsia after hole ICL implantation.[20]

ICL V4c: Significant improvement

- “In addition, some patients had subjective symptoms in the early postoperative period, such as halo, glare”[21]

20. Eom Y, Kim DW, Ryu D, et al. Ring-shaped dysphotopsia associated with posterior chamber phakic implantable collamer lenses with a central hole. *Acta Ophthalmol*. May 2017;95(3):e170-e178. doi:10.1111/aos.13248
21. Bai Z, Nie D, Zhang J, et al. Visual function assessment of posterior-chamber phakic implantable collamer lenses with a central port. *Ann Transl Med*. Feb 2022;10(4):194. doi:10.21037/atm-22-107

Risks: Lens Design

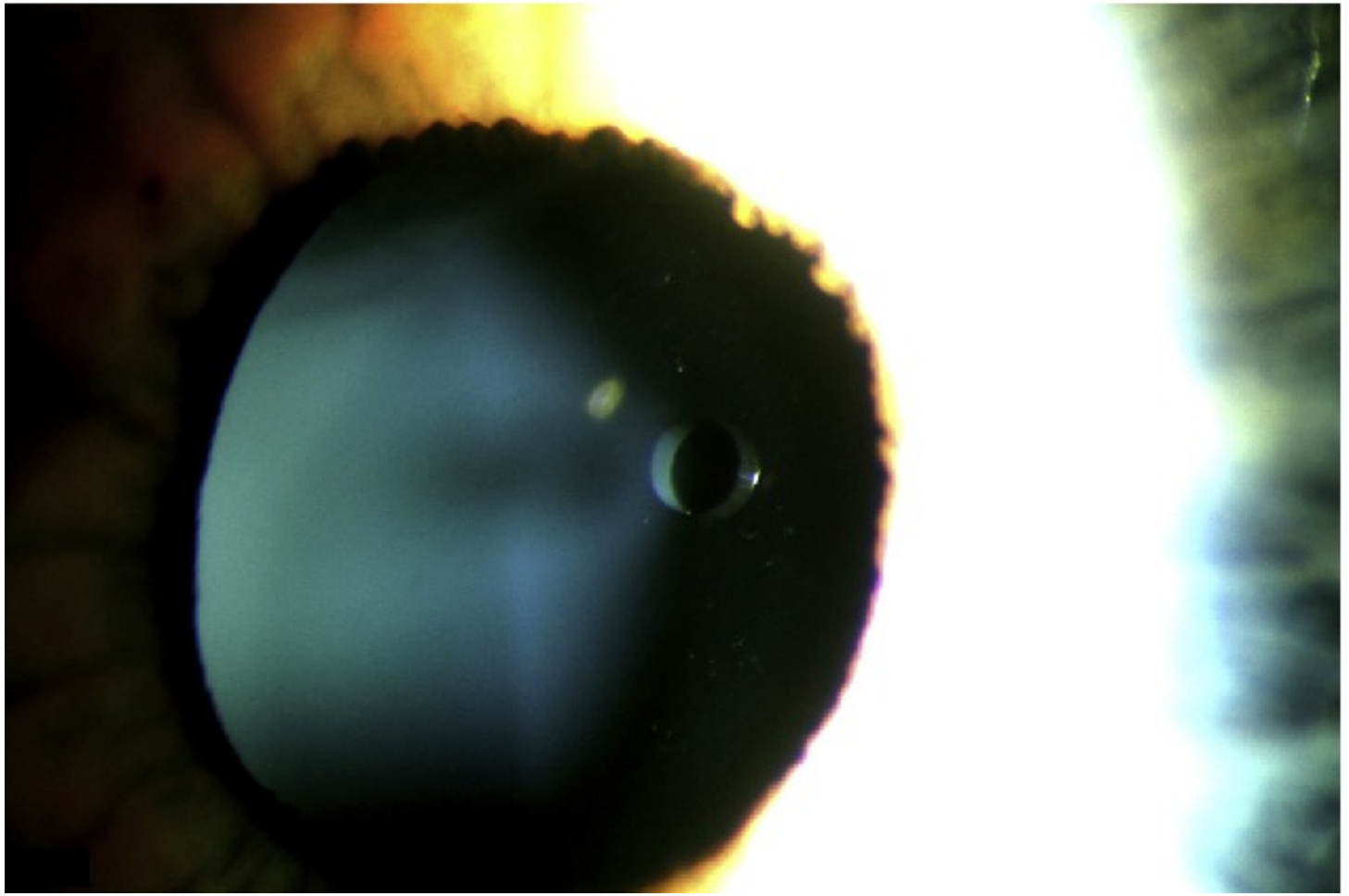
- The addition of the central port to ICL facilitates the flow of aqueous humor through the lens, eliminating the need for peripheral iridotomies (PIs) prior to implantation
- 0.360 mm central hole[1] allow aqueous humor to flow (4 others across the lens)
- Without the requirement for an iridotomy[11]

1. Zhu Y, He T, Zhu H, Chen J, Zhou J. Static and dynamic pupillary characteristics in high myopic eyes with two implantable collamer lenses. *J Cataract Refract Surg*. 07 2019;45(7):946-951. doi:10.1016/j.jcrs.2019.01.027
11. Chuck RS, Jacobs DS, Lee JK, et al. Refractive Errors & Refractive Surgery Preferred Practice Pattern®. *Ophthalmology*. 01 2018;125(1):P1-P104. doi:10.1016/j.ophtha.2017.10.003

Risks: Central Port Dysphotopsia

Safe to administer:

- Brimonidine (Alpha-2-Adreneurgic Agonist)
- 1.25% Pilocarpine



Risks: Endothelial Cell Loss

- ICL endothelial cell density (ECD) loss-rate was no longer statistically significant after 1 year[14]
- Anterior segment biometric parameters: C-lens correlated w less loss
- Specifically, the vault height plays a major role in changes in ECD[15]
- Explantation secondary to vault error

14. Kirwan C, O'Keefe M, O'Mullane GM, Sheehan C. Refractive surgery in patients with accommodative and non-accommodative strabismus: 1-year prospective follow-up. *Br J Ophthalmol*. Jul 2010;94(7):898-902. doi:10.1136/bjo.2009.162420
15. BenEzra D, Cohen E, Karshai I. Phakic posterior chamber intraocular lens for the correction of anisometropia and treatment of amblyopia. *Am J Ophthalmol*. Sep 2000;130(3):292-6. doi:10.1016/s0002-9394(00)00492-x

Risks: Endothelial Cell Loss

Risks: TORICs

- Central Port TORIC ICL follow the same Collamer lens platform and vault design as Central Port ICL but includes a TORIC optic (cylinder correction)
- Cylinder power is in the anterior surface optic
- Has additional linear orientation landmarks to facilitate alignment of the lens in the eye

Risks: Toric Rotation

Clinical Case Report

Medicine®

OPEN

Repeated rotation of a toric implantable collamer lens

A case report

Haorun Zhang, MB, Mengjun Fu, MM*, Jiahao Wang, MB

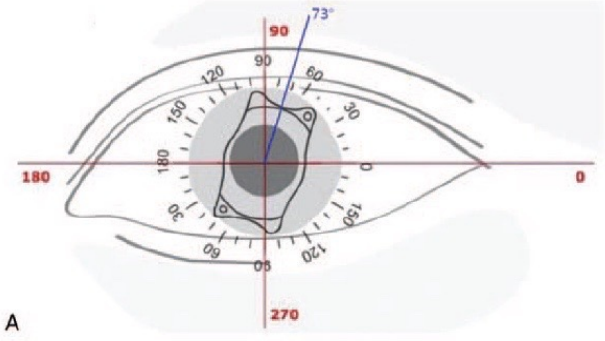
Abstract

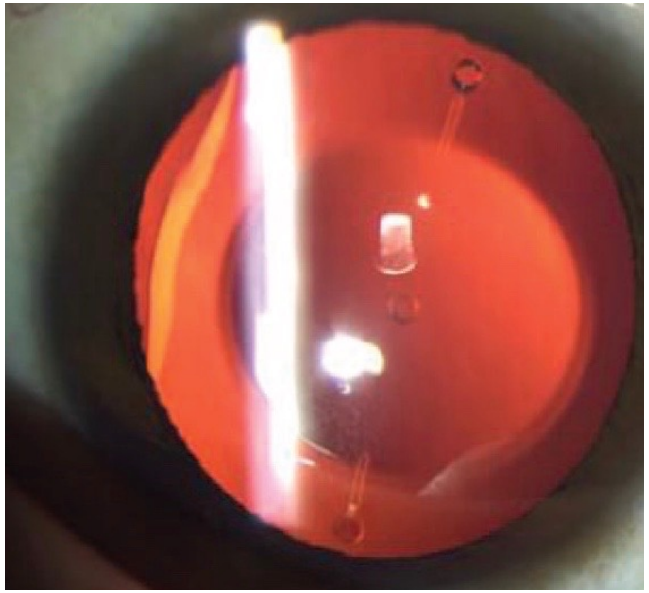
Introduction: Implantable collamer lens have been used widely worldwide, and have been accepted by more and more doctors and patients due to good safety, stability, and effectiveness. However, there is still a problem of crystal rotation. The large angle rotation (over 10°) would weaken the original astigmatism correction effect and even induce irregular astigmatism, seriously affecting the visual quality of patients. Herein, we reported a case who had 2 times of crystal rotations after toric implantable collamer lens (TICL) implantation.

Patient concerns: The patient was a 38-year-old man who underwent TICL implantation for the correction of high myopic astigmatism in eyes. He presented a sudden decrease in the visual acuity (VA) of the left eye 4 months after the TICL implantation. The uncorrected visual acuity (UCVA) was 8/20 (refraction, +2.25 −5.25 × 68).

Diagnosis: Rotation of TICL was diagnosed. The toric marks with a rotation of 75° counter-clockwise from the original position were observed.

Interventions: The TICL was re-set to the original position, leading to the UCVA of 12/20 in the left eye (refraction, −0.00 −0.75 ×
131), with the vaulting of 589 μm. Ten months after the TICL relocation, the patient again presented a sudden decrease in the VA of





Risks: Toric Rotation

- Incidence 0.4 - 3.2%[16-19]
- Under sizing. Morphology of CB & Sulcus[16,20,21]
- At 3 months postoperatively, 96.8% (30/31) eyes had ≤8° and 90.3% (28/31) had ≤5° of axis misalignment.[22]
- Corneal astigmatism changes with age as does crystalline lens size[17]

Chen *et al. BMC Ophthalmology* (2020) 20:350
https://doi.org/10.1186/s12886-020-01597-5

BMC Ophthalmology

CASE REPORT Open Access

Spontaneous rotation of a toric implantable collamer lens related to abnormal ciliary body morphology: a case report

Qian Chen[1,2], Qingyan Zeng[2], Zheng Wang[3], Chao Pan[2], Xiaohua Lei[2] and Weina Tan[1,2*]

Full Thickness Refraction Nomogram

- Spherical ICL only
- On Axis ICL Positioning

Name: Pref: OD OS Allergy: DOB:

DOS: 06/01/2022 **Co-Management Dr: N/A

Prep Revd: 5/27/2022 Reviewed By: _____ & _____

Dr. BKM : _____

MRx	Sph	Cyl	Axis	VA	Astig	Steep	Exam Date
Minus	-1.00	-3.50	10	0	3.50	100	
Plus	-4.50	3.50	100		-3.50	10	
GL							

MRx	Sph	Cyl	Axis	VA	Astig	Steep	Exam Date
Minus	-4.25	-1.00	80	0	1.00	170	
Plus	-5.25	1.00	170		-1.00	80	
GL							

ICL (D):	Ks	FLAT	STEEP	Astig	Meridian	Exam Date
Target: 0.00	L-Star					
Dom: ◄	G4					

ICL (D):	Ks	FLAT	STEEP	Astig	Meridian	Exam Date
Target: 0.00	L-Star					
Dom:	G4					

steep	Main	Opp.
100°	3.8	3.8

ICL SIZE

Exp Vault: HIGH | AVG | LOW

D @ °

- 1.85 D SIA

= 1.65 D @ 100°

	G4 WTW
	LenStar WTW
	Lenstar AD
	Lenstar ACD
	Lenstar CCT

ICL SIZE

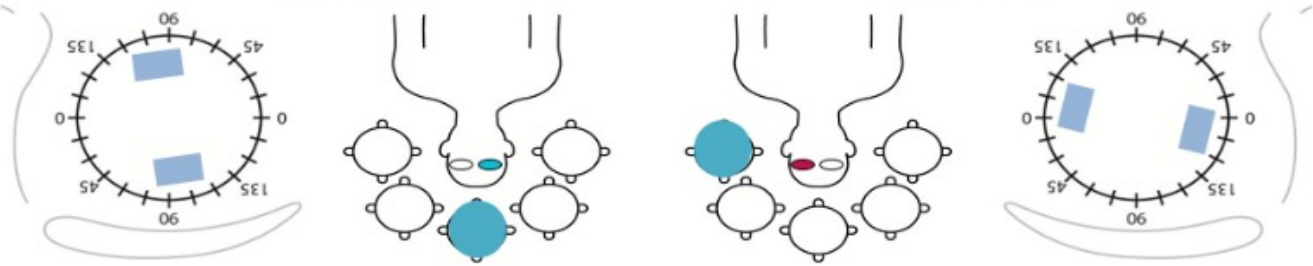
Exp Vault: HIGH | AVG | LOW

D @ °

- 0.96 D SIA

= 0.04 D @ 170°

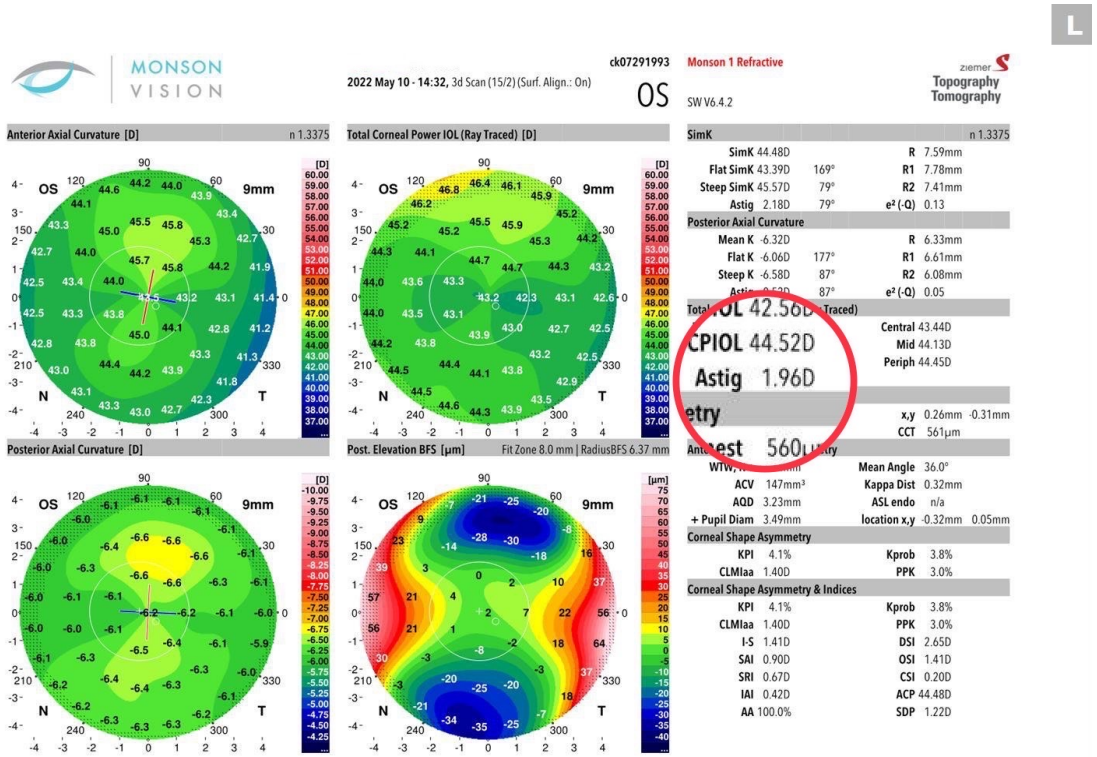
steep	Main	Opp.
170°	3.2	3.2



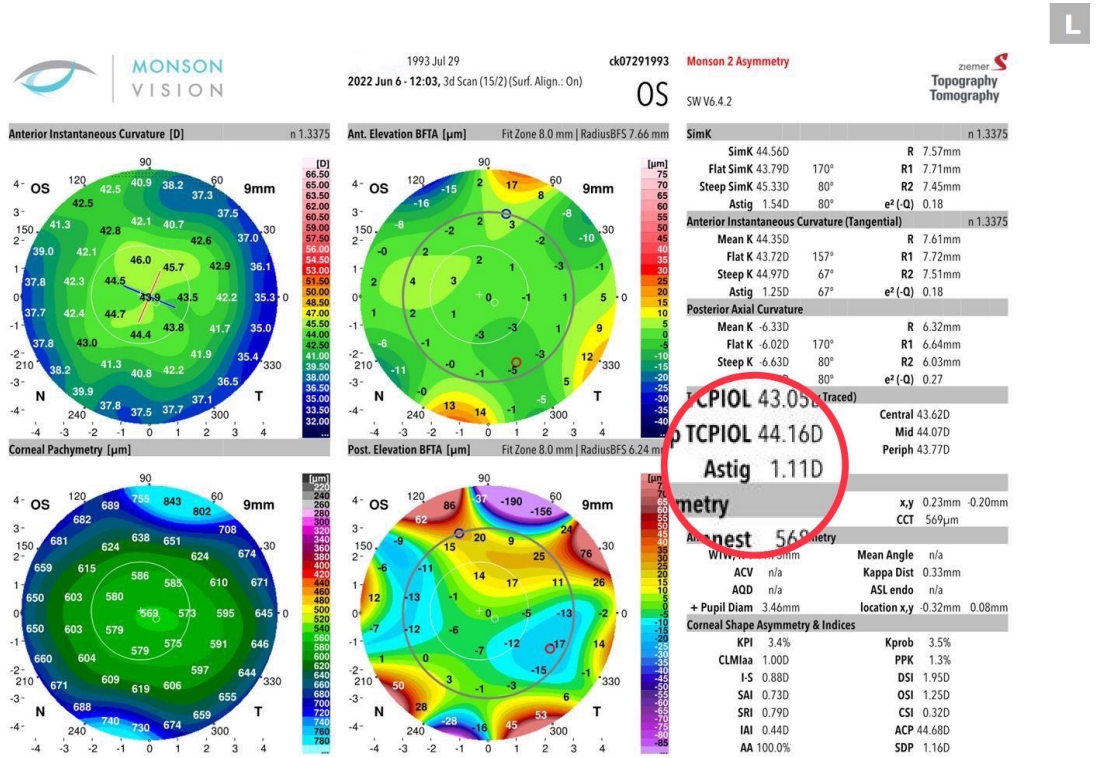
Monson Vision Approach

29 year-old male

Pre-Op
- OD: -10.75 +1.00 x 118
- OS: -11.25 +1.00 x 081



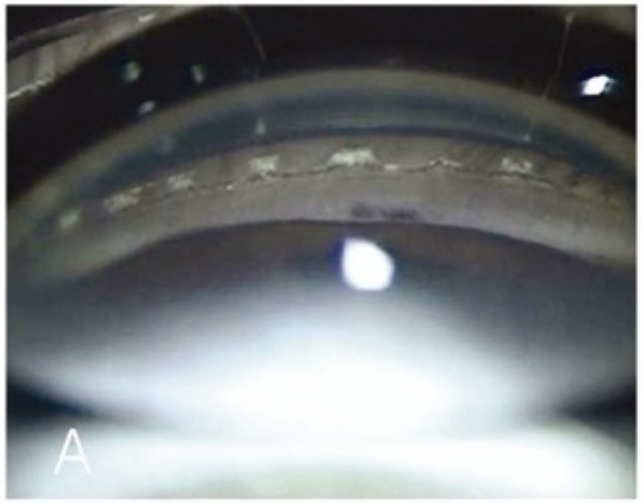
Post-Op 7 Days
- OD: 20/20
- OS: 20/15-1

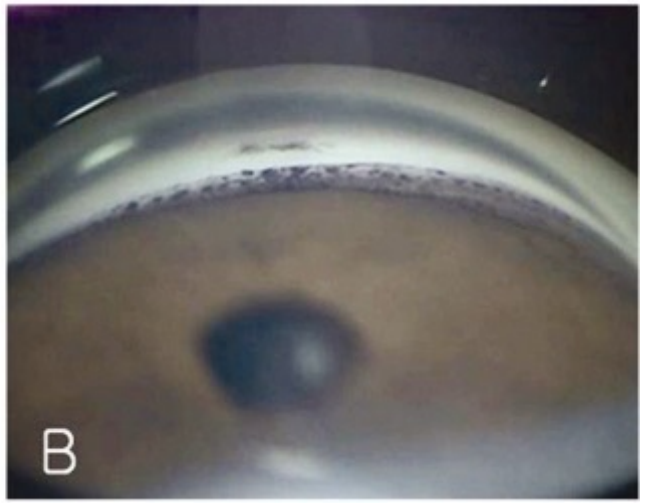


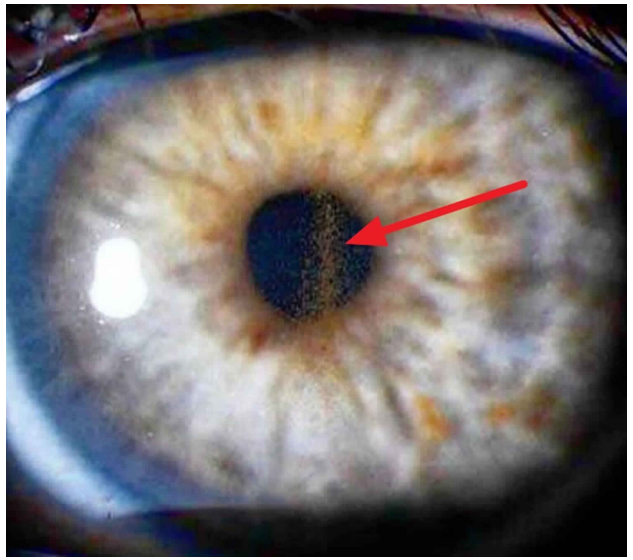
Risks: Pigment Dispersion

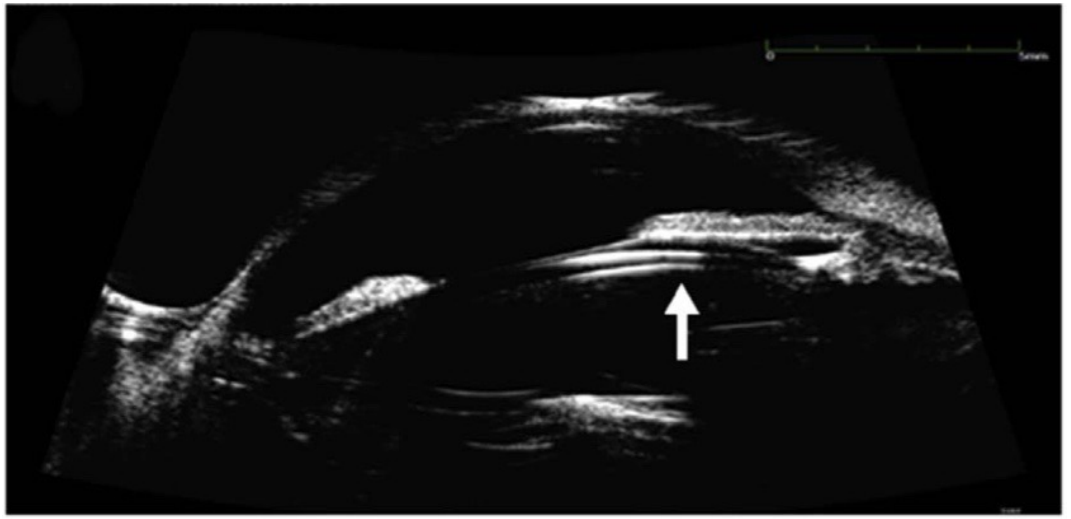
- Oversized ICL Vault
  - Inadequate space in the posterior chamber may precipitate pigment dispersion and chronic uveitis due to iris chaffing from direct implant-iris contact.
  - One report:
    - Pigment Dispersion Syndrome was among the most common late postoperative complications in MICL study with 27 eyes (43.5%)
  - **Very rare** side effect: pigment dispersion glaucoma
    - Severity may require trabeculectomy
- Vigilant long-term monitoring for glaucoma
- Careful slit-lamp examination:
  - Krukenberg spindle
  - Transillumination defect
  - Increased pigmentation of the trabecular meshwork on gonioscopy

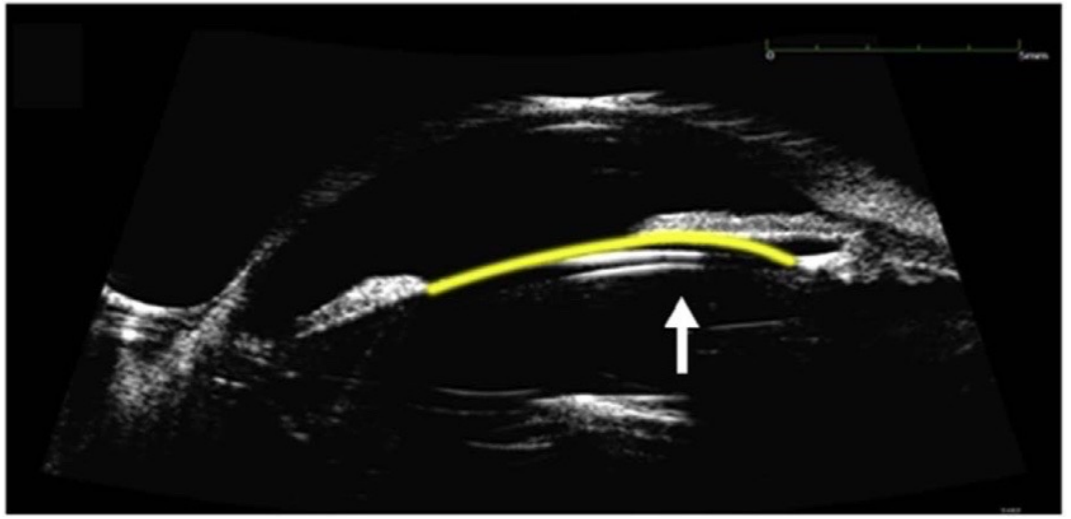
Risks: Pigment Dispersion





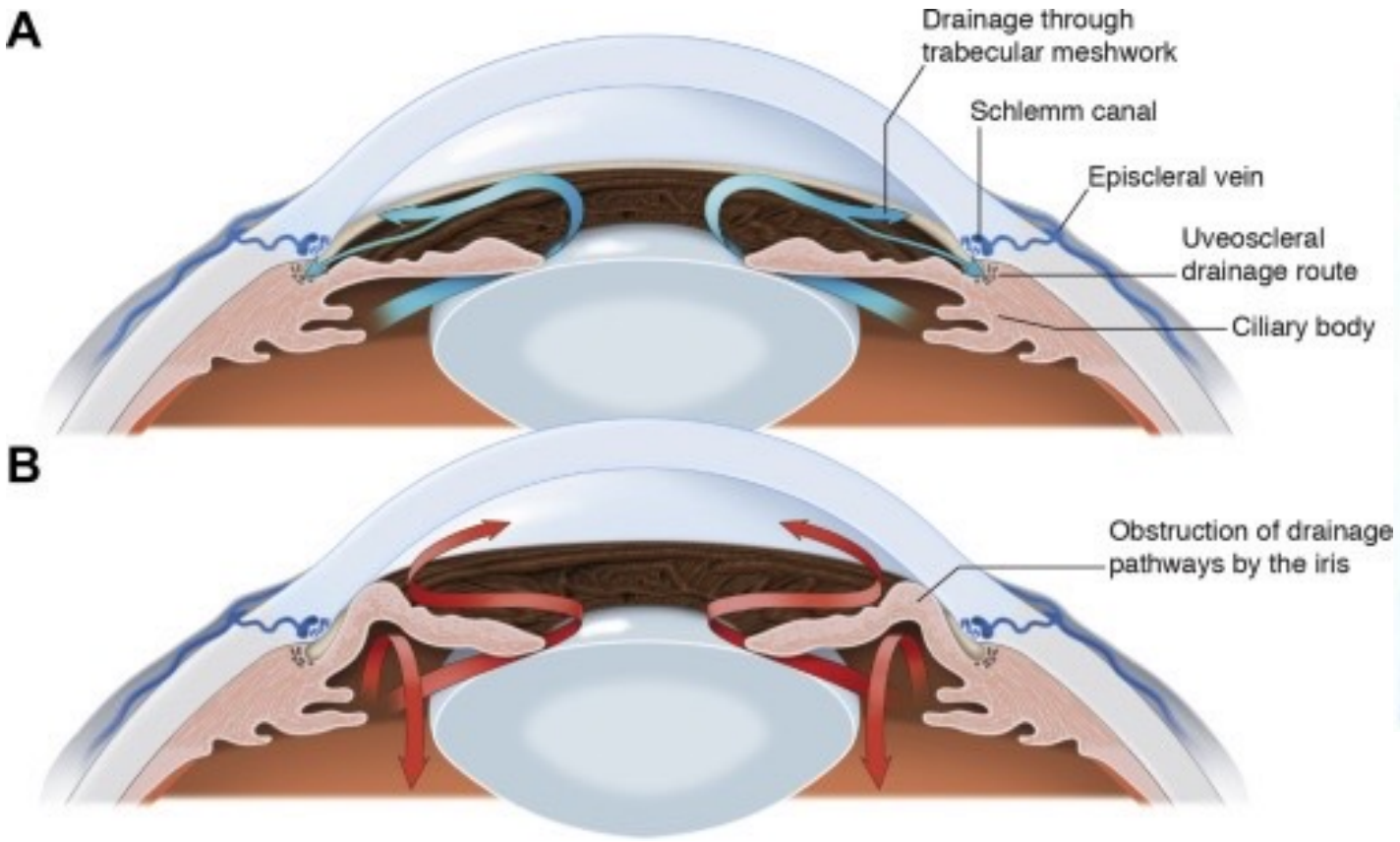


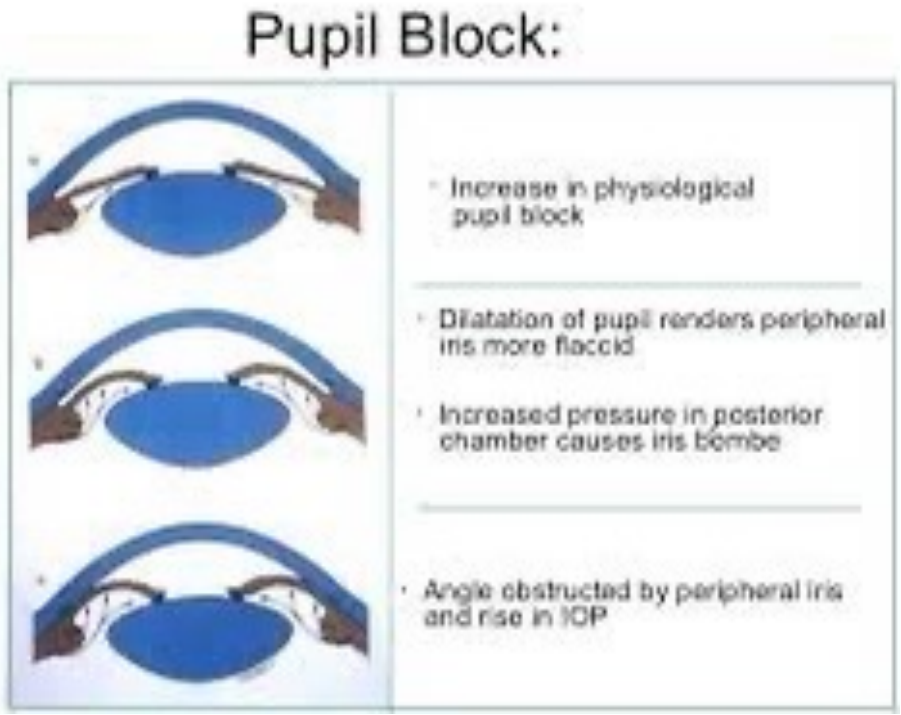




Risks: Pupil Block Glaucoma

- Occurs within first 24 hours





Risks: Anterior Subcapsular Cataract

Sources:

1. **YAG iridotomy** may be a source of anterior subcapsular cataract[20]
2. **Aqueous Flow** in the space between the ICL and the crystalline lens[21]
3. **Undersized Vault**

Figure 1 The EVO Visian ICLs with a central artificial hole.

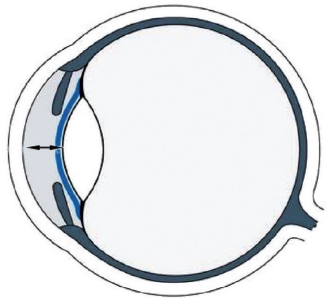
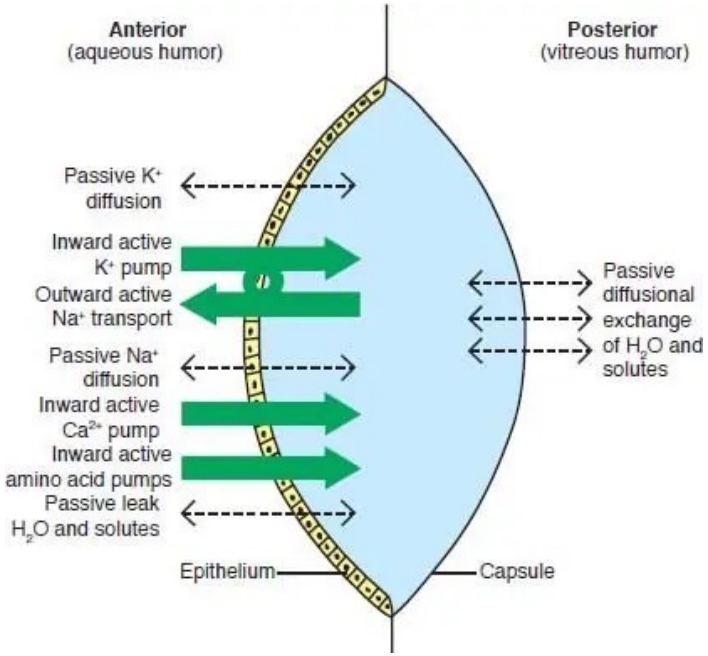
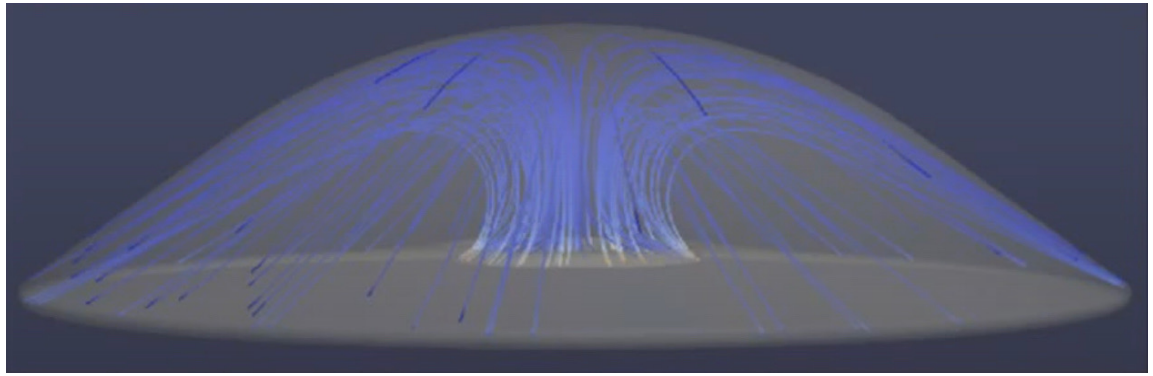


Figure 2 The blue line shows the location of the EVO Visian implantable collamer lens in the posterior chamber The arrow shows the aqueous humour outflow and inflow through the central hole into the anterior chamber.





20. Eom Y, Kim DW, Ryu D, et al. Ring-shaped dysphotopsia associated with posterior chamber phakic implantable collamer lenses with a central hole. *Acta Ophthalmol*. May 2017;95(3):e170-e178. doi:10.1111/aos.13248

21. Bai Z, Nie D, Zhang J, et al. Visual function assessment of posterior-chamber phakic implantable collamer lenses with a central port. *Ann Transl Med*. Feb 2022;10(4):194. doi:10.21037/atm-22-107

Surgical PI Micro-ILM Graspers

Risks: Anterior Subcapsular Cataract

- Traditional MICL
  - The reported incidence of post-ICL cataract is 5.2%[24]
  - Average time of onset 3.4 ± 1.9 years after implantation

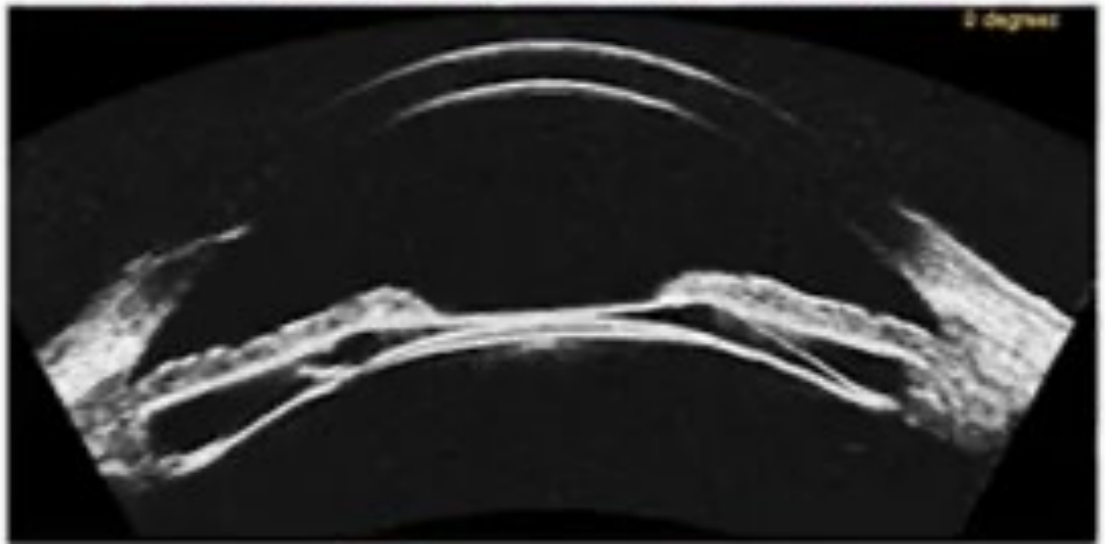
- ICL V4c
  - 2022 US FDA study: 1 cataract (not anterior subcapsular)[23]
  - European Meta-Analysis Data: 0.34%[22]
  - "V4c can potentially **reduce the risk of lens opacification** and may be more tolerant to low vault"[25]

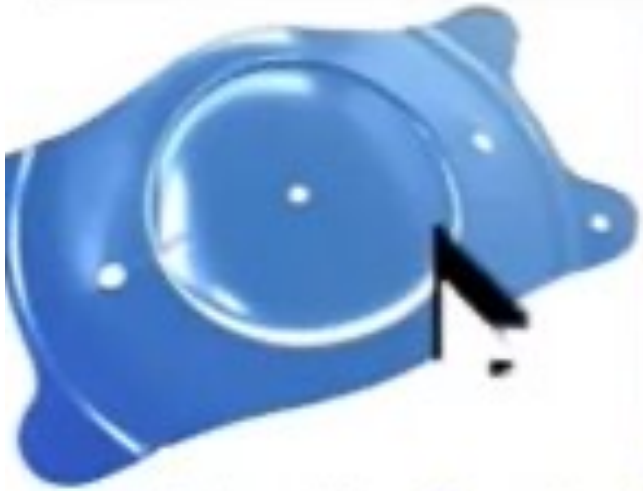
22. Bai H, Li H, Zheng S, Sun L, Wu X. Nd:YAG Capsulotomy Rates with Two Multifocal Intraocular Lenses. *Int J Gen Med*. 2021;14:8975-8980. doi:10.2147/IJGM.S342039
23. Chang DS, Jiang Y, Kim JA, et al. Cataract progression after Nd:YAG laser iridotomy in primary angle-closure suspect eyes. *Br J Ophthalmol*. May 02 2022;doi:10.1136/bjophthalmol-2021-320929
24. Fujisawa K, Shimizu K, Uga S, et al. Changes in the crystalline lens resulting from insertion of a phakic IOL (ICL) into the porcine eye. *Graefes Arch Clin Exp Ophthalmol*. Jan 2007;245(1):114-22. doi:10.1007/s00417-006-0338-y
25. Zeng QY, Xie XL, Chen Q. Prevention and management of collagen copolymer phakic intraocular lens exchange: causes and surgical techniques. *J Cataract Refract Surg*. Mar 2015;41(3):576-84. doi:10.1016/j.jcrs.2014.06.036

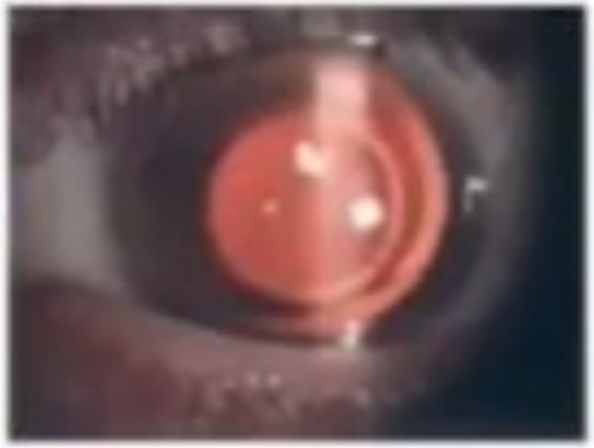
Risks: Anterior Subcapsular Cataract

Undersized Lens

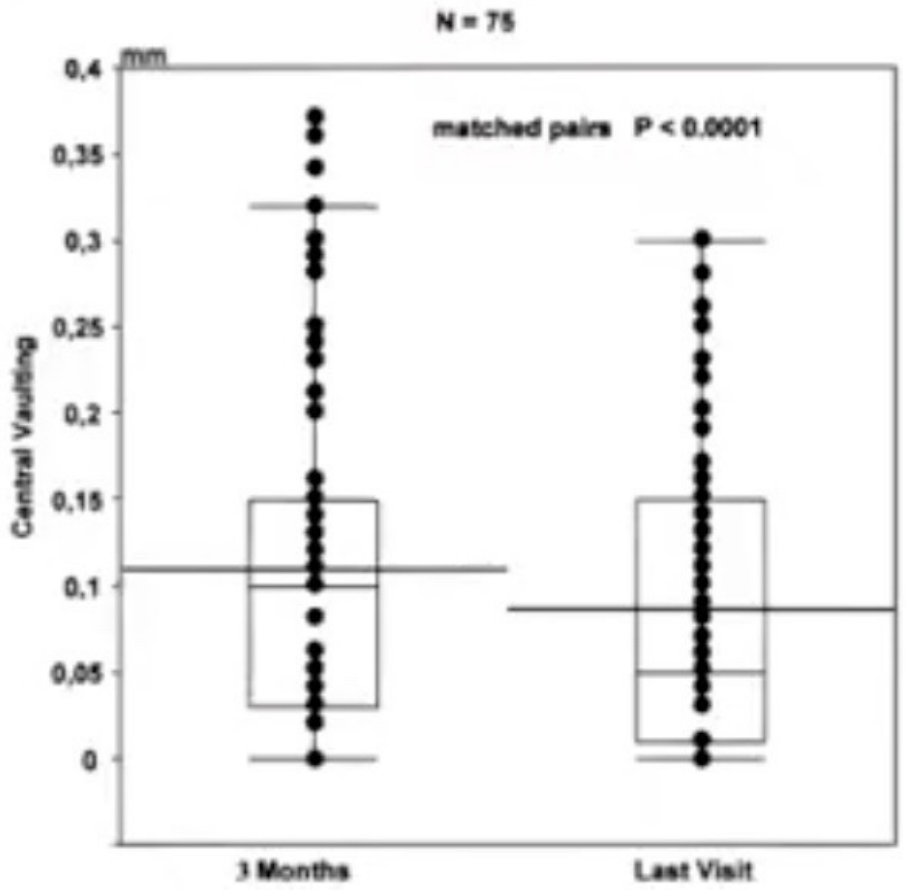
Anterior Capsular Cataract

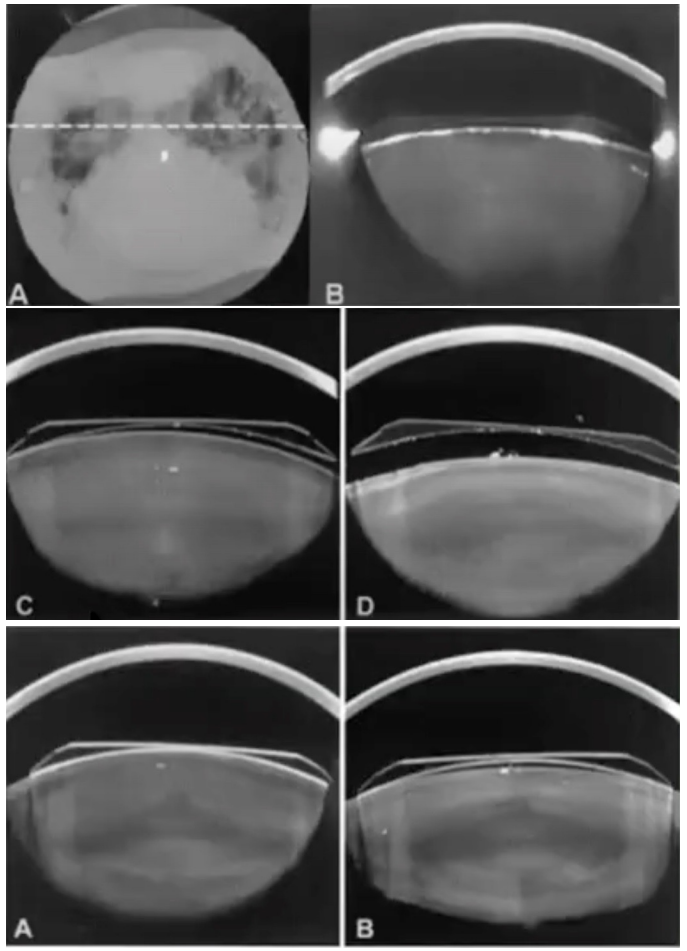






Risks: Anterior Subcapsular Cataract





29. Gonvers M, Othenin-Girard P, Bornet C, Sickenberg M. Implantable contact lens for moderate to high myopia: short-term follow-up of 2 models. *J Cataract Refract Surg*. Mar 2001;27(3):380-8. doi:10.1016/s0886-3350(00)00759-8

VERY HIGH FREQUENCY ULTRASOUND (VHF-US)

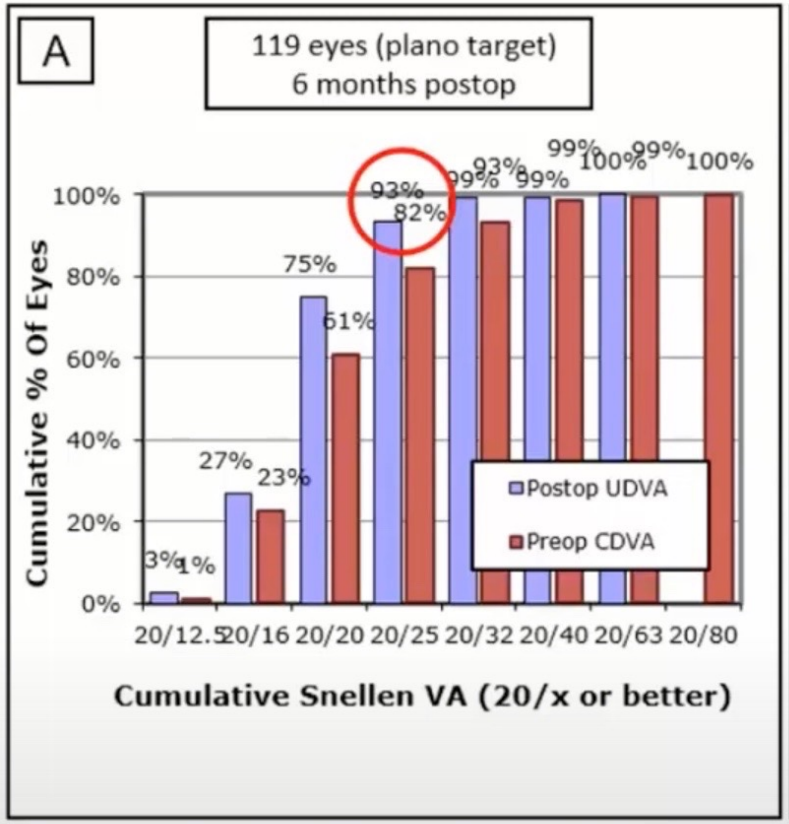
Objectives:

Understand recent published advancements in predictive lens sizing, vault and refractive outcomes utilizing swept source Very-High Frequency Ultrasound (VHF-US).

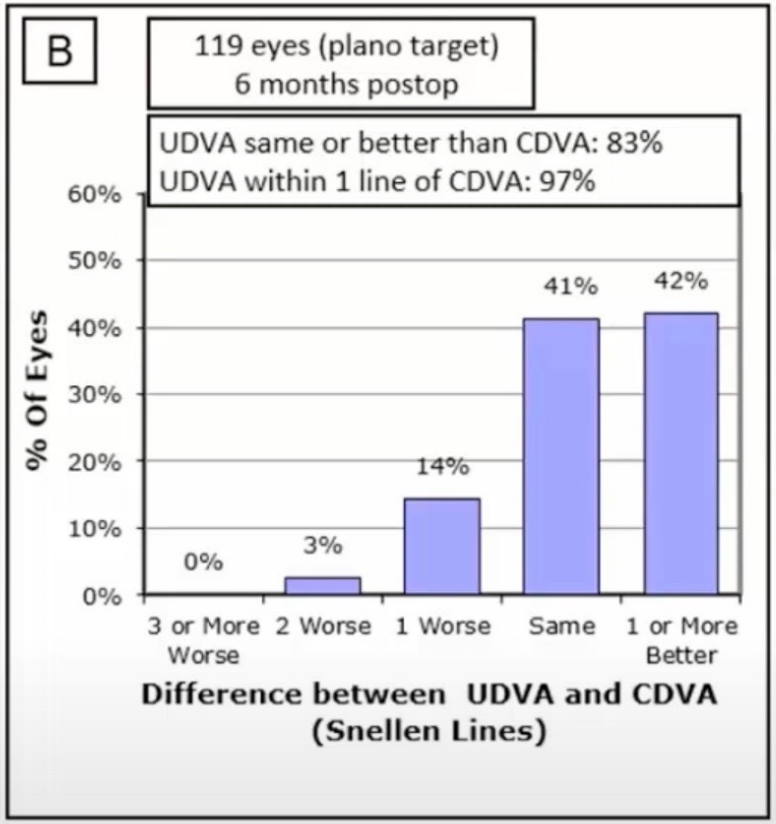
Study Demographics

Population	Number of Eyes	159
	Number of Patients	80
	Min Age at Surgery	19.3 years
	Max Age at Surgery	54.4 years
	Mean Age at Surgery	30.7 years
	SD Age at Surgery	7.7 years
SphEq	Min Attempted Spherical Equivalent	-3.01 D
	Max Attempted Spherical Equivalent	-19.88 D
	Average Attempted Spherical Equivalent	-11.13 D ± 3.77
MaxMer	Min Attempted Maximum Myopic Meridian	-3.24 D
	Max Attempted Maximum Myopic Meridian	-20.06 D
	Average Attempted Maximum Myopic Meridian	-11.87 D ± 3.85
Cyl	Min Attempted Cylinder	0.03 D
	Max Attempted Cylinder	-6.67 D
	Average Attempted Cylinder	-1.49 D ± 1.27

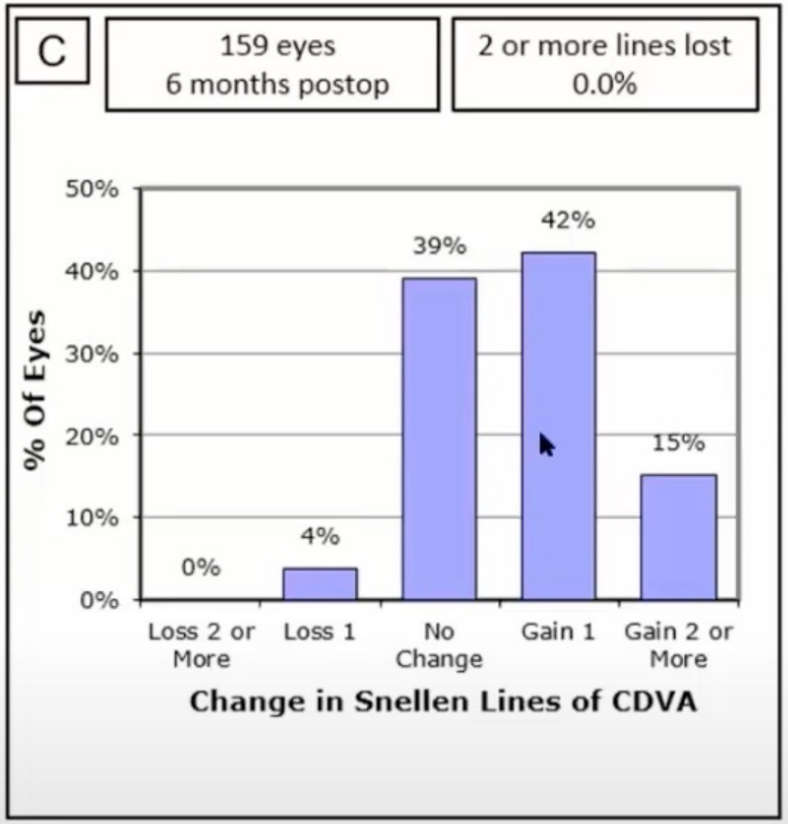
Safety & Efficacy



Uncorrected Distance Visual Acuity

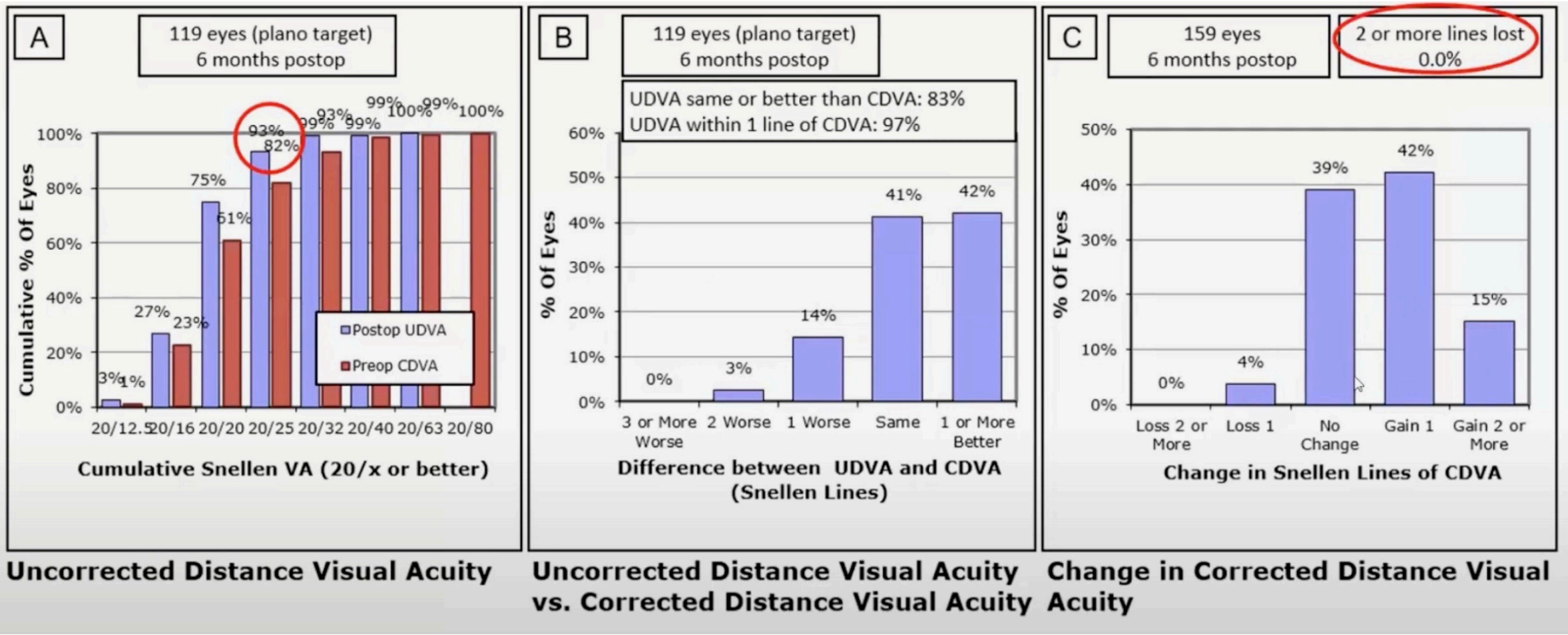


Uncorrected Distance Visual Acuity vs. Corrected Distance Visual Acuity



Change in Corrected Distance Visual Acuity

Safety & Efficacy

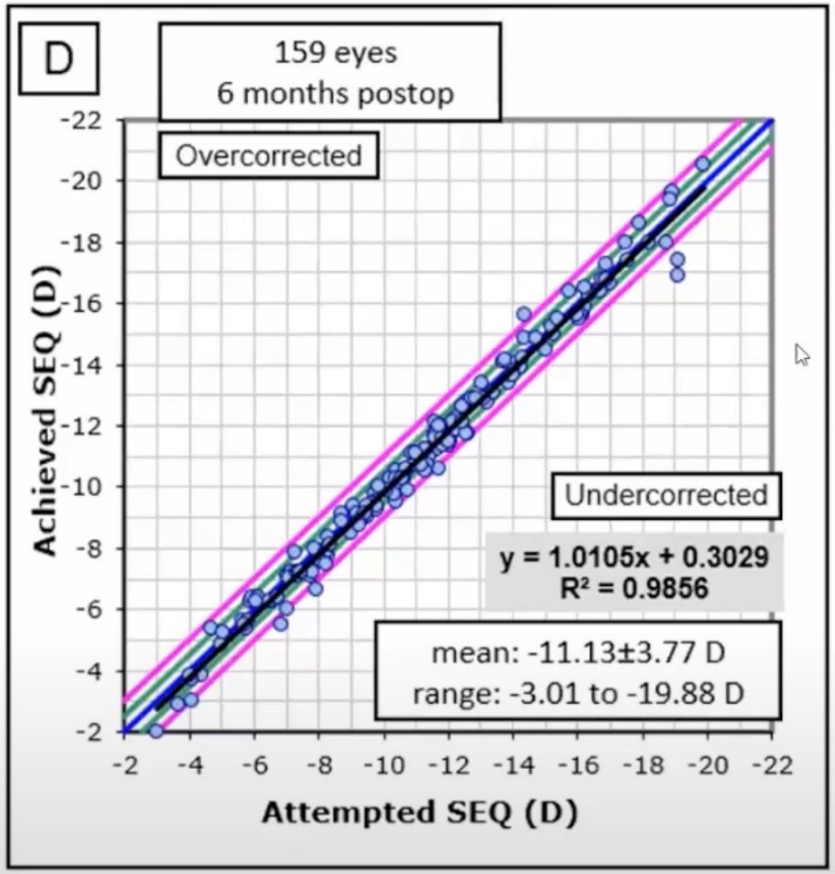


Uncorrected Distance Visual Acuity

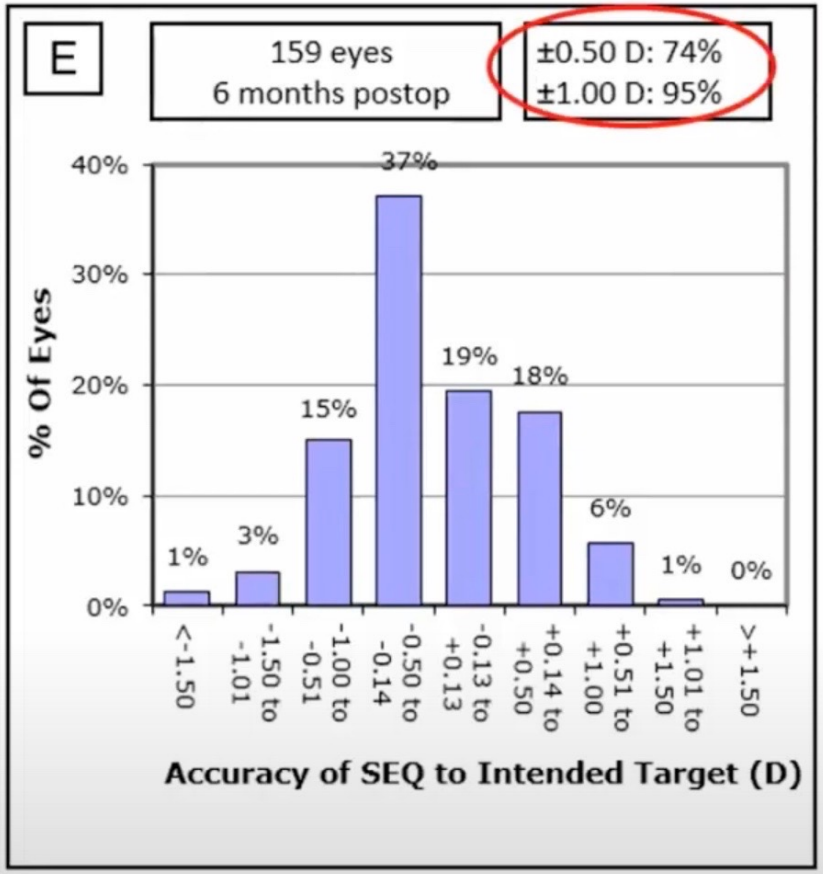
Uncorrected Distance Visual Acuity vs. Corrected Distance Visual Acuity

Change in Corrected Distance Visual Acuity

Accuracy



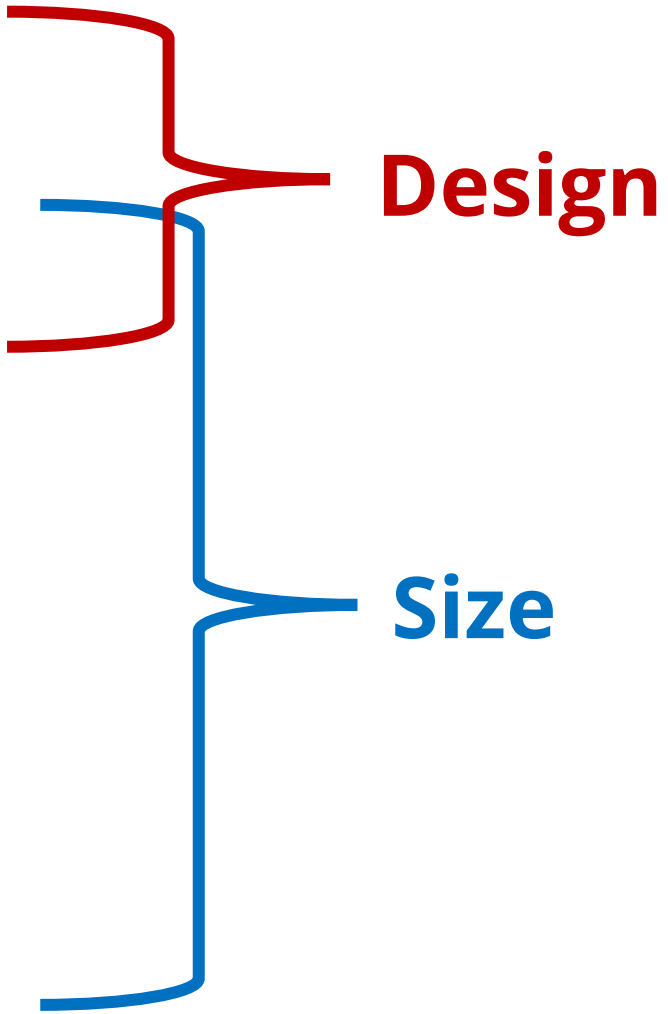
Spherical Equivalent Refraction Attempted vs Achieved



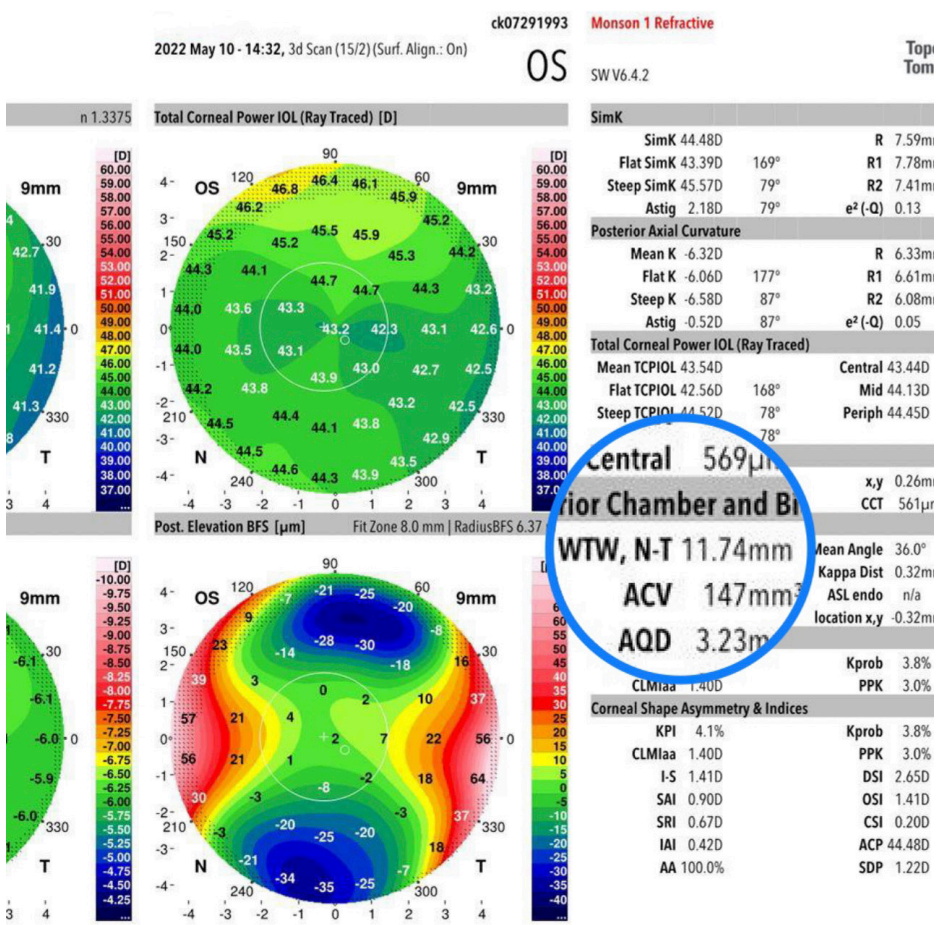
Spherical Equivalent Refraction Accuracy

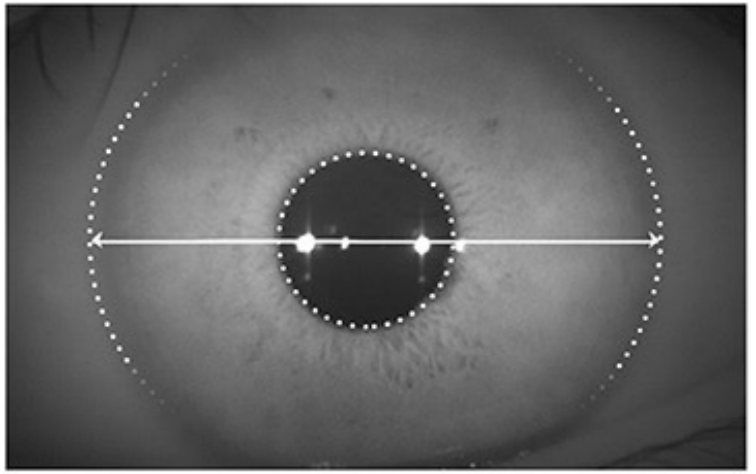
Risks of Surgery

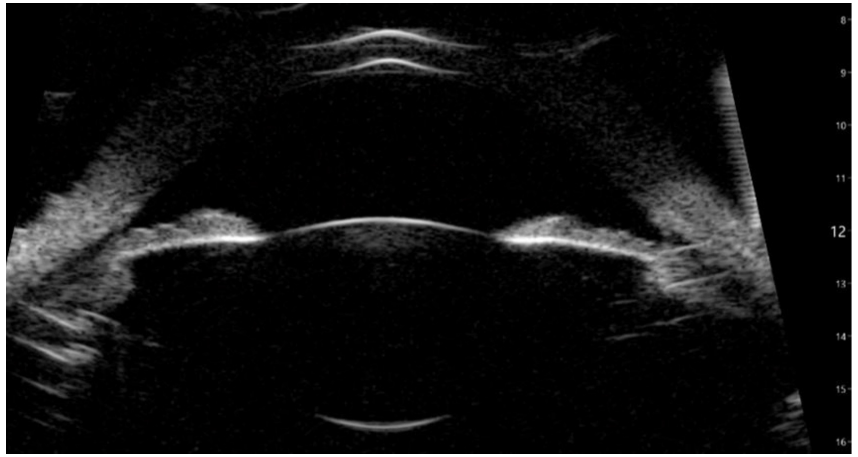
- Chronic Uveitis
- Iridotomy Glare
- Anterior sub-capsular cataract
- Endothelial cell loss
- TORIC lens rotation
- Lens exchange risk
- Pupil block
- Glaucoma
- Pigment dispersion



Sizing Using Horizontal White-to-White

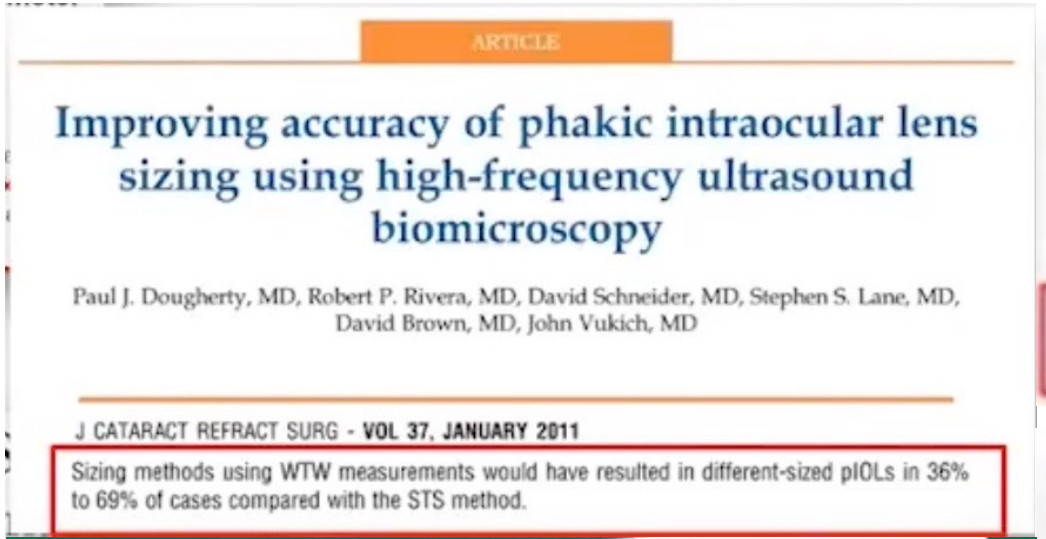






SIZE	DIFFERENCE
12.1	
12.6	0.5mm
13.2	0.6mm
13.7	0.5mm

Sizing Using Horizontal White-to-White



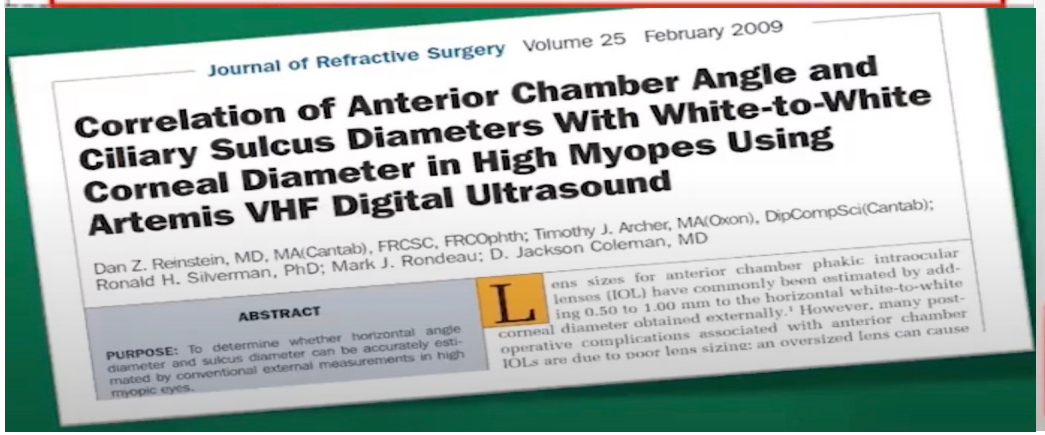
ARTICLE

Improving accuracy of phakic intraocular lens sizing using high-frequency ultrasound biomicroscopy

Paul J. Dougherty, MD, Robert P. Rivera, MD, David Schneider, MD, Stephen S. Lane, MD, David Brown, MD, John Vukich, MD

J CATARACT REFRACT SURG - VOL 37, JANUARY 2011

Sizing methods using WTW measurements would have resulted in different-sized pIOLs in 36% to 69% of cases compared with the STS method.



Journal of Refractive Surgery Volume 25 February 2009

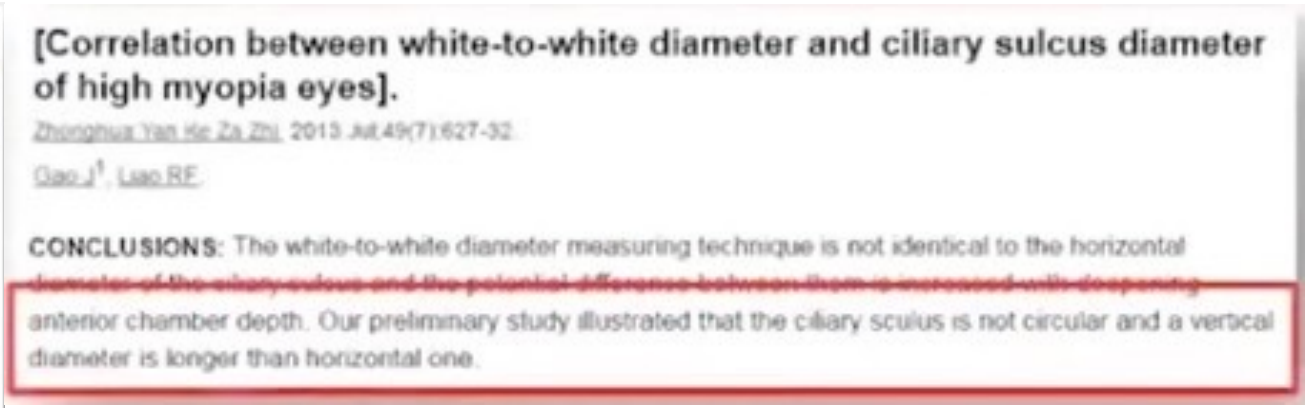
Correlation of Anterior Chamber Angle and Ciliary Sulcus Diameters With White-to-White Corneal Diameter in High Myopes Using Artemis VHF Digital Ultrasound

Dan Z. Reinstein, MD, MA(Cantab), FRCSC, FRCOphth; Timothy J. Archer, MA(Oxon), DipCompSci(Cantab); Ronald H. Silverman, PhD; Mark J. Rondeau; D. Jackson Coleman, MD

ABSTRACT

PURPOSE: To determine whether horizontal angle diameter and sulcus diameter can be accurately estimated by conventional external measurements in high myopic eyes.

Lens sizes for anterior chamber phakic intraocular lenses (IOL) have commonly been estimated by adding 0.50 to 1.00 mm to the horizontal white-to-white corneal diameter obtained externally.[1] However, many postoperative complications associated with anterior chamber IOLs are due to poor lens sizing; an oversized lens can cause

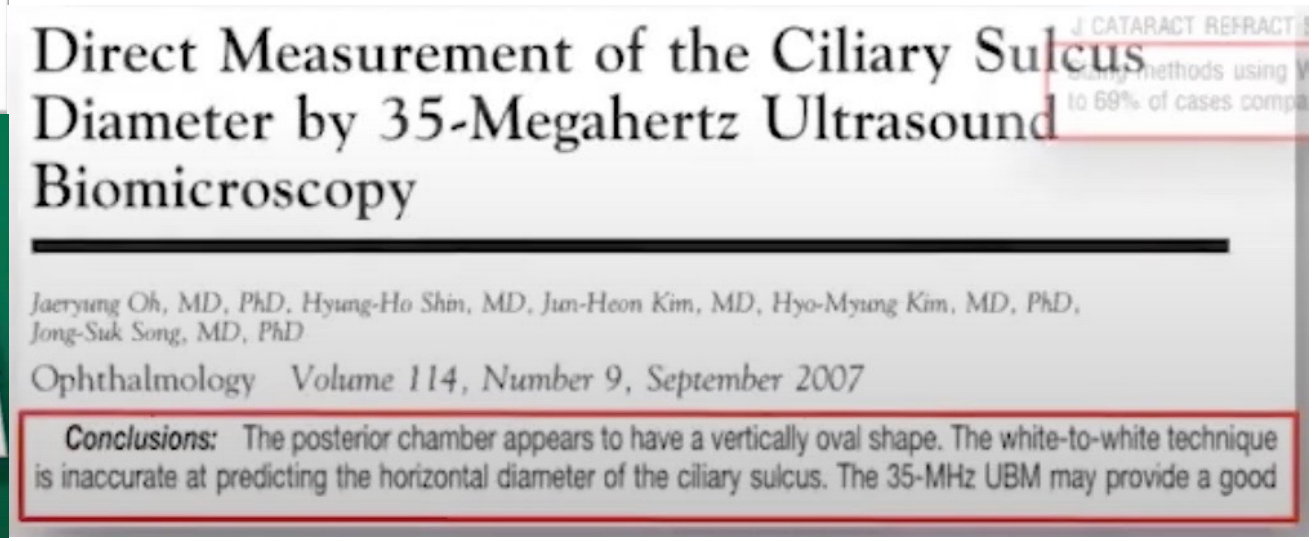


[Correlation between white-to-white diameter and ciliary sulcus diameter of high myopia eyes].

Zhonghua Yan Ke Za Zhi. 2013 Jul;49(7):627-32.

Qiao J[1], Liao RF.

CONCLUSIONS: The white-to-white diameter measuring technique is not identical to the horizontal diameter of the ciliary sulcus and the potential difference between them is increased with deepening anterior chamber depth. Our preliminary study illustrated that the ciliary sulcus is not circular and a vertical diameter is longer than horizontal one.



Direct Measurement of the Ciliary Sulcus Diameter by 35-Megahertz Ultrasound Biomicroscopy

Jaeryung Oh, MD, PhD, Hyung-Ho Shin, MD, Jun-Heon Kim, MD, Hyo-Myung Kim, MD, PhD, Jong-Suk Song, MD, PhD

Ophthalmology Volume 114, Number 9, September 2007

Conclusions: The posterior chamber appears to have a vertically oval shape. The white-to-white technique is inaccurate at predicting the horizontal diameter of the ciliary sulcus. The 35-MHz UBM may provide a good

29. Gonvers M, Othenin-Girard P, Bornet C, Sickenberg M. Implantable contact lens for moderate to high myopia: short-term follow-up of 2 models. *J Cataract Refract Surg*. Mar 2001;27(3):380-8. doi:10.1016/s0886-3350(00)00759-8

Lens Sizing: History to Present

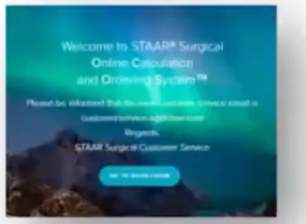
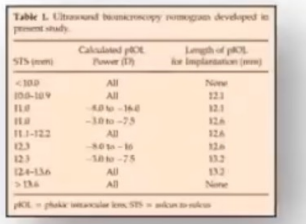
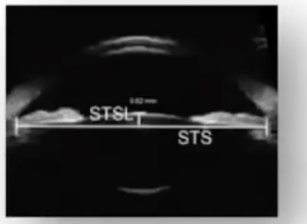
STAAR (v1.5)	Dougherty (v2.0)	Kojima (v2.5)
		
WTW		
Refraction	ICL Power	
Keratometry		
ACD		ACD
	STS	STS
		STSL

Table 1. Ultrasound biomicroscopy nomogram developed in present study.

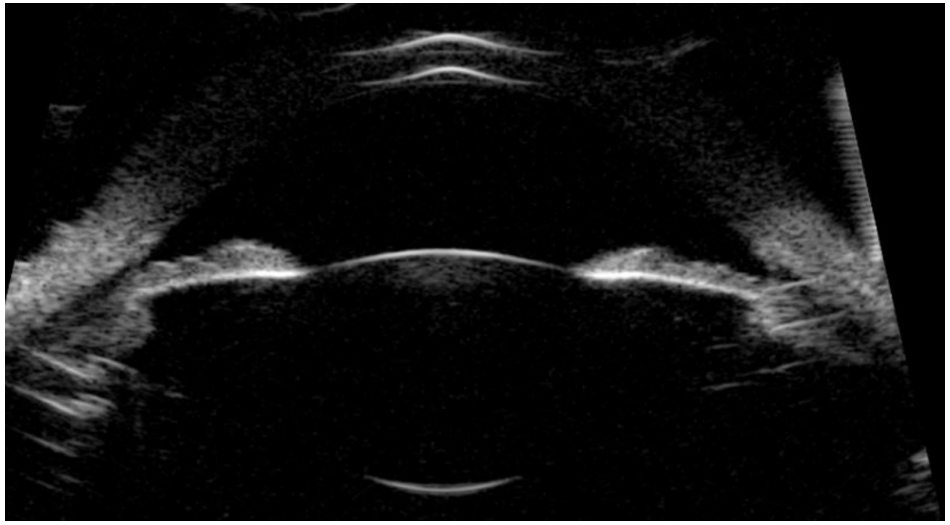
STS (mm)	Calculated pIOL Power (D)	Length of pIOL for Implantation (mm)
<10.0	All	None
10.0–10.9	All	12.1
11.0	−8.0 to −16.0	12.1
11.0	−3.0 to −7.5	12.6
11.1–12.2	All	12.6
12.3	−8.0 to −16	12.6
12.3	−3.0 to −7.5	13.2
12.4–13.6	All	13.2
>13.6	All	None

pIOL = phakic intraocular lens; STS = sulcus-to-sulcus

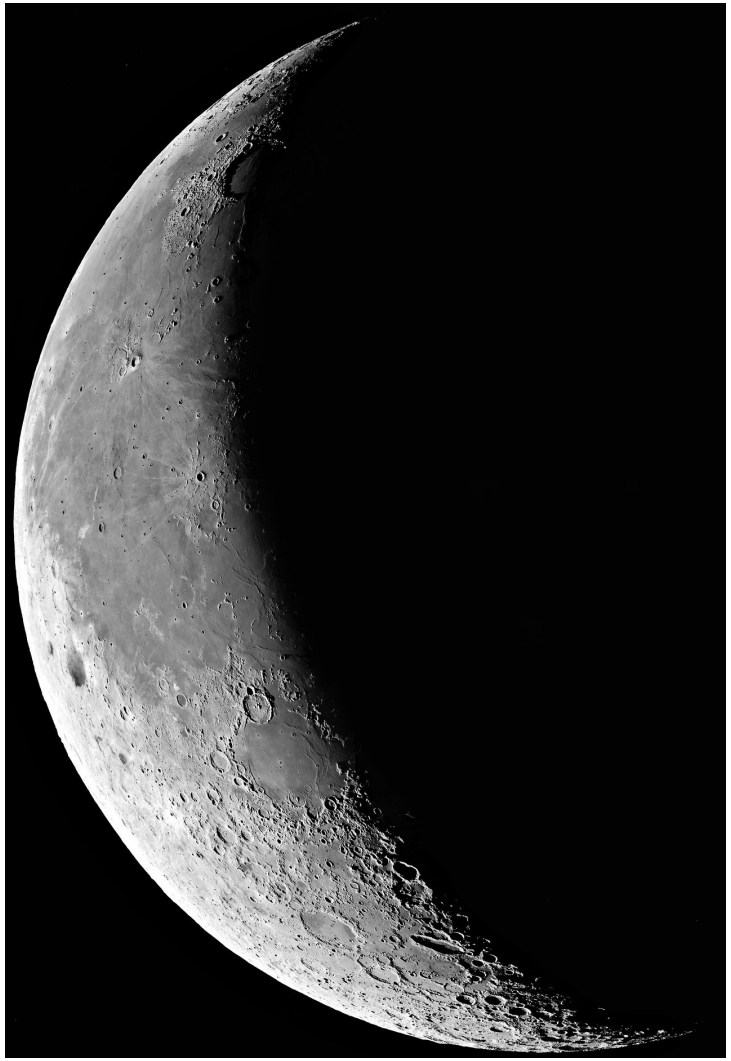
LoVC

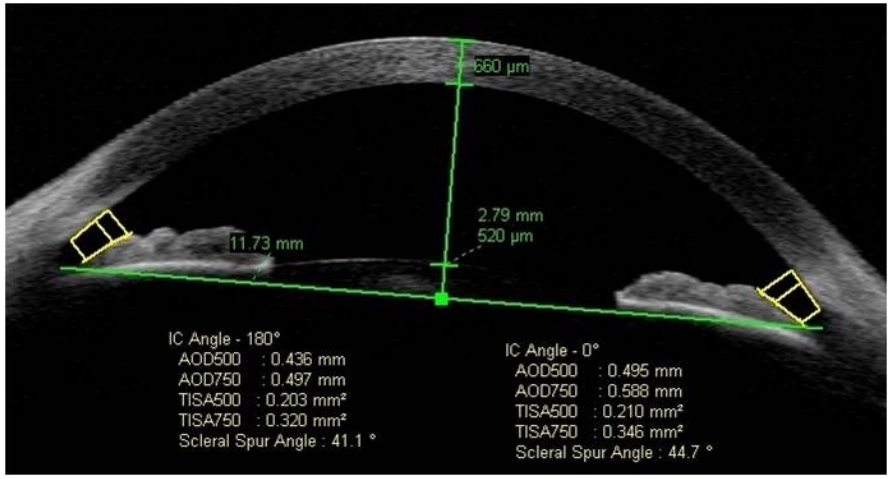
Dougherty (**Insight** STS)
+
Kojima (**Insight** ACD, STS, STSL)

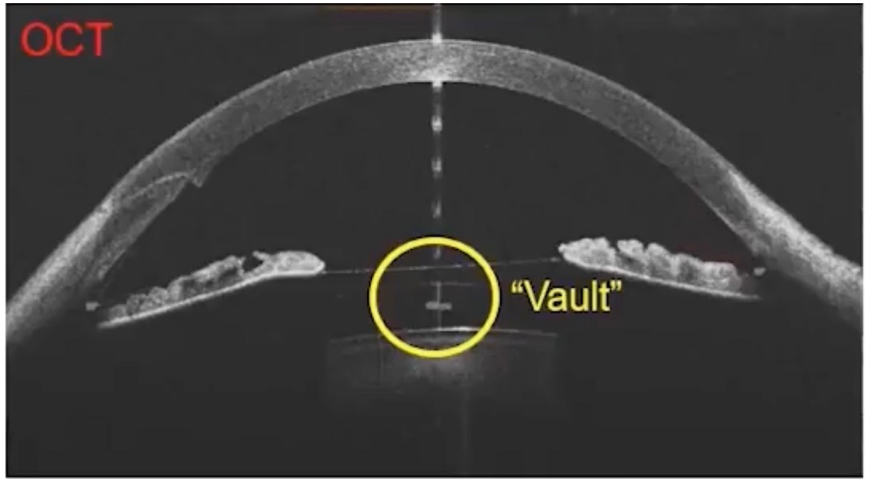
Handheld UBM 25M-Hz: Correlation with the Sulcus

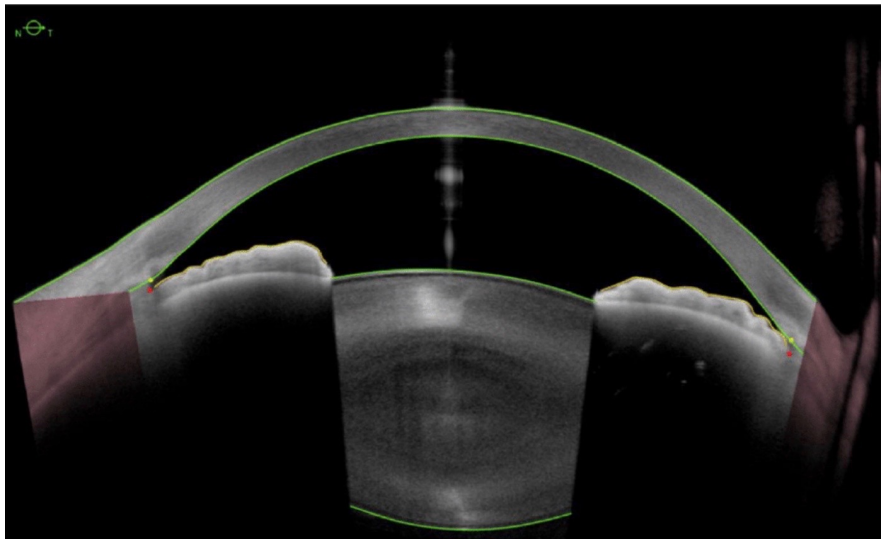


Anterior Seg OCT: Dark Side of the Moon





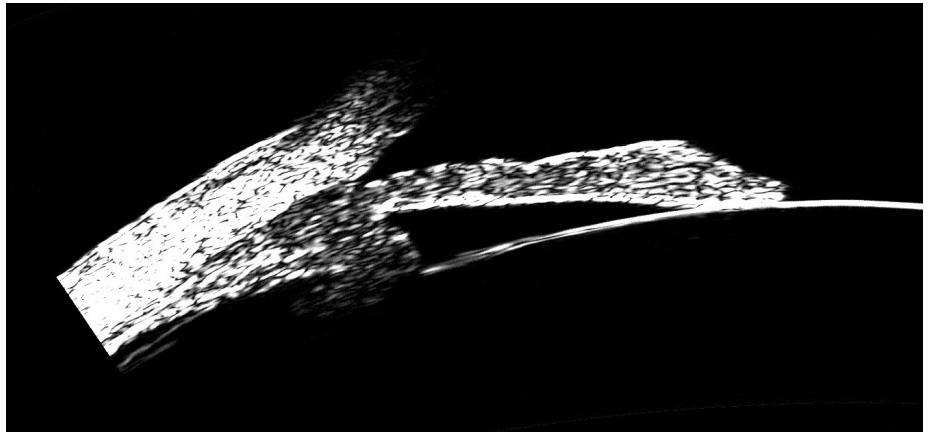




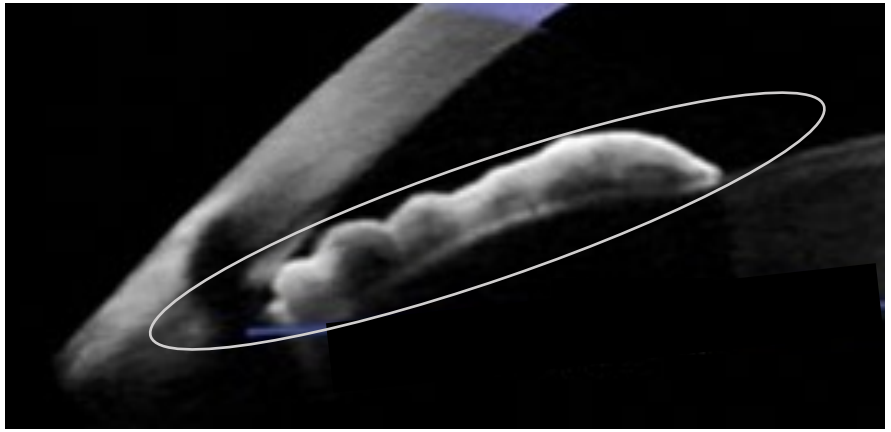
SIZE	DIFFERENCE
12.1	
12.6	0.5mm
13.2	0.6mm
13.7	0.5mm

Very High Frequency Ultrasound Quality

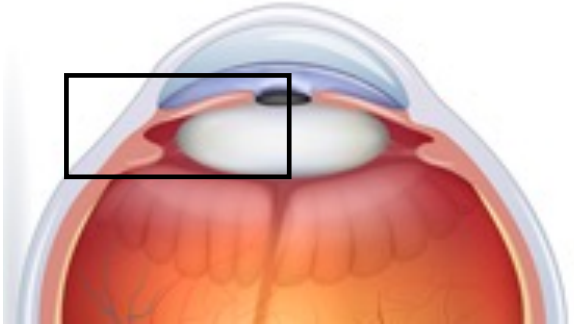
Very High Frequency-Ultrasound

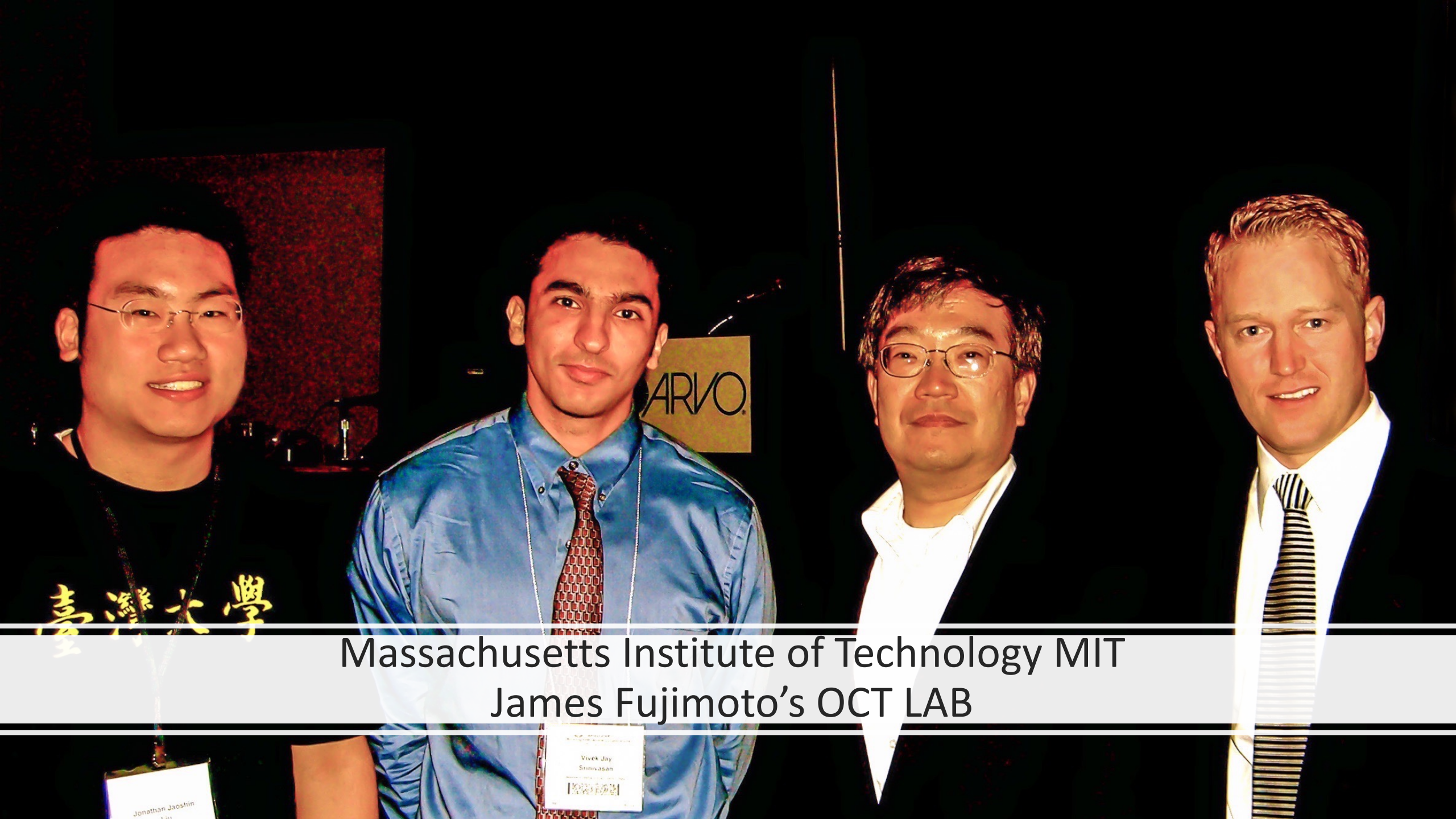


Current High Def (HD) OCT



Note: no image detail behind the iris



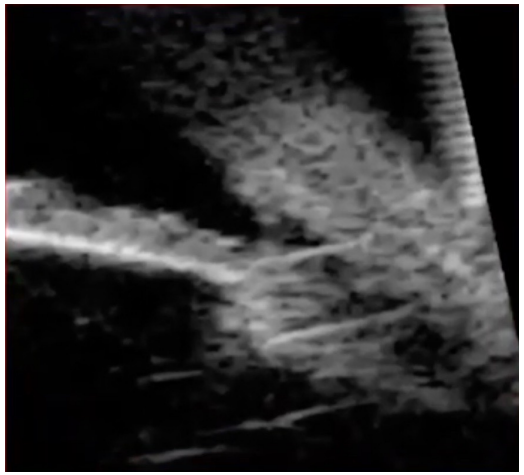


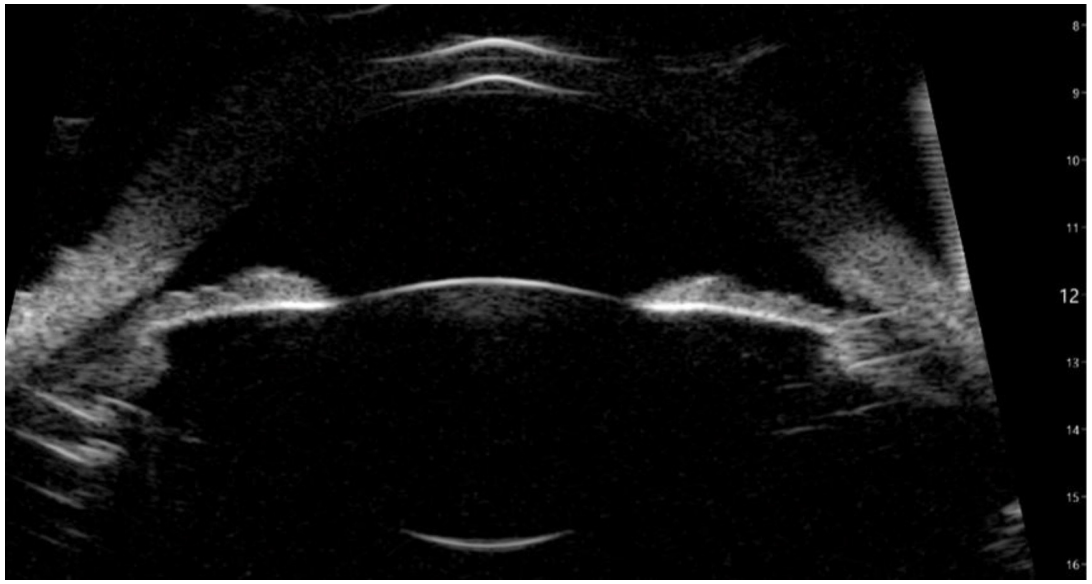
Massachusetts Institute of Technology MIT
James Fujimoto’s OCT LAB

Very High Frequency Ultrasound (VHF-US)

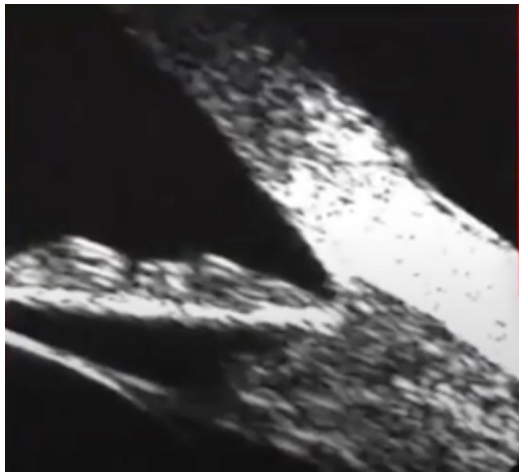
UBM vs Very-high Frequency Ultrasound (VHF-US)

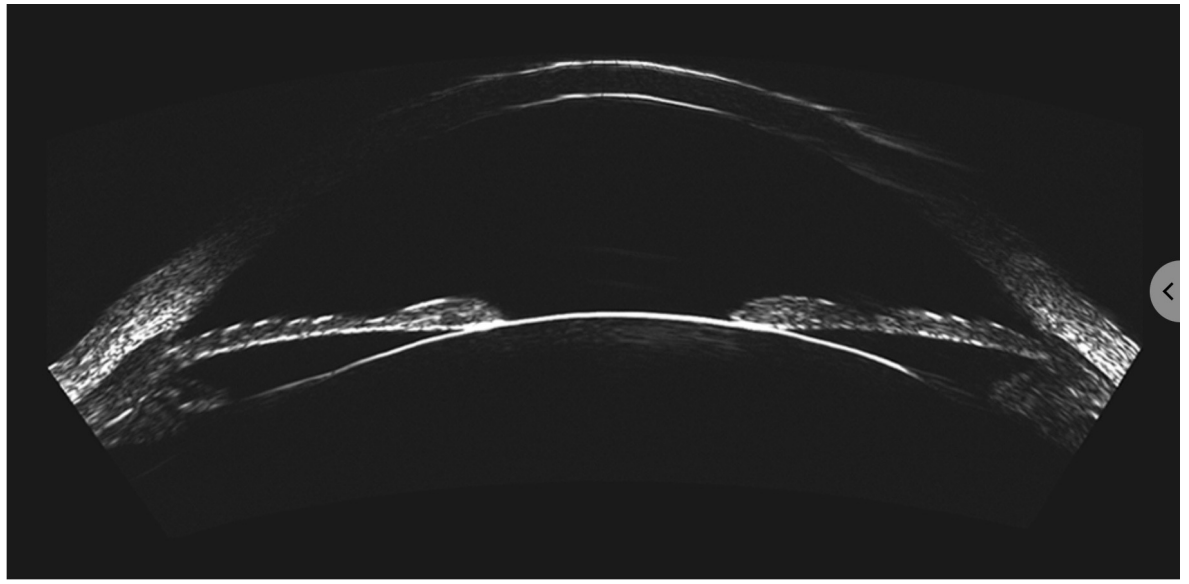
UBM



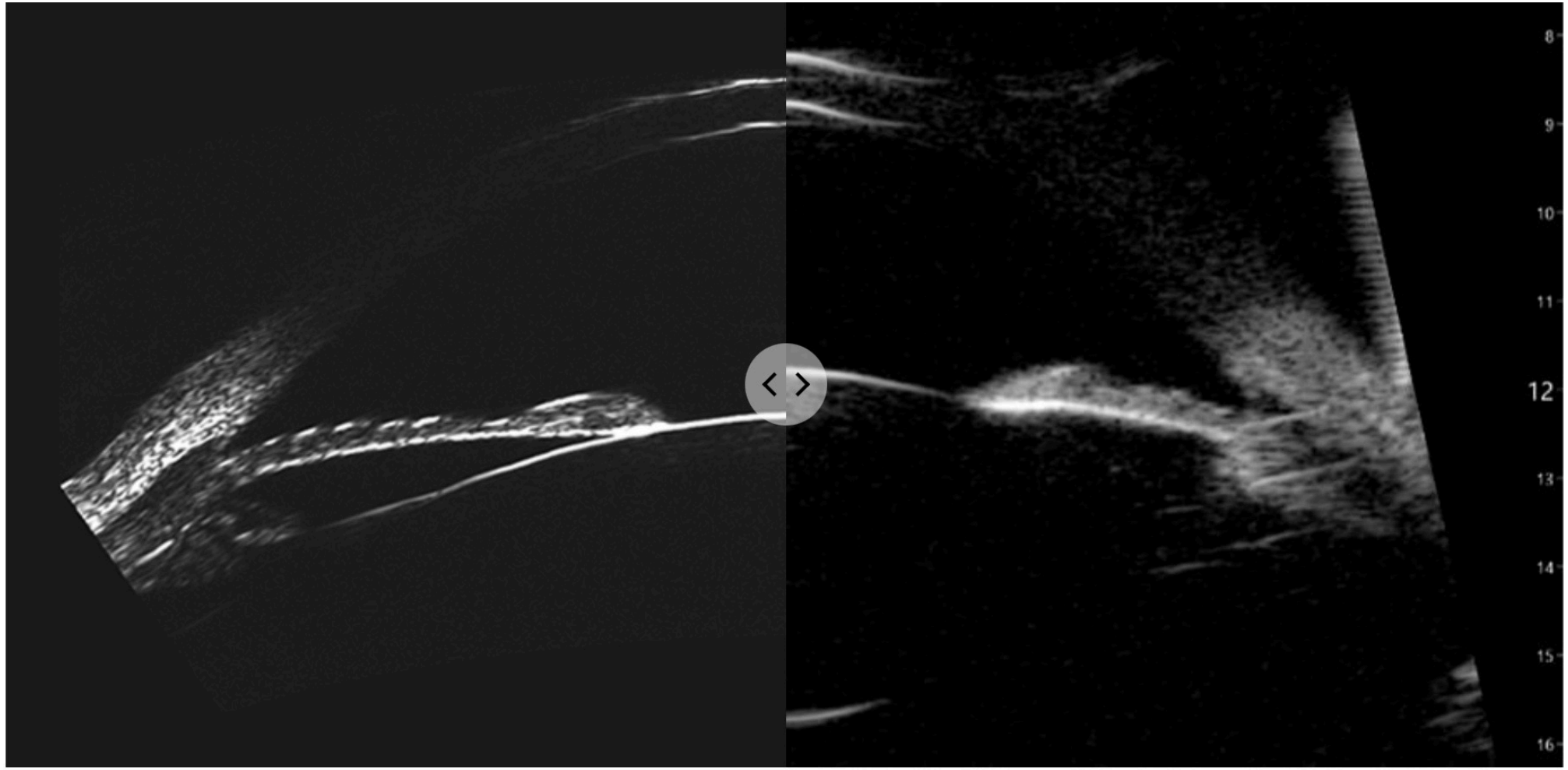


VHF-US

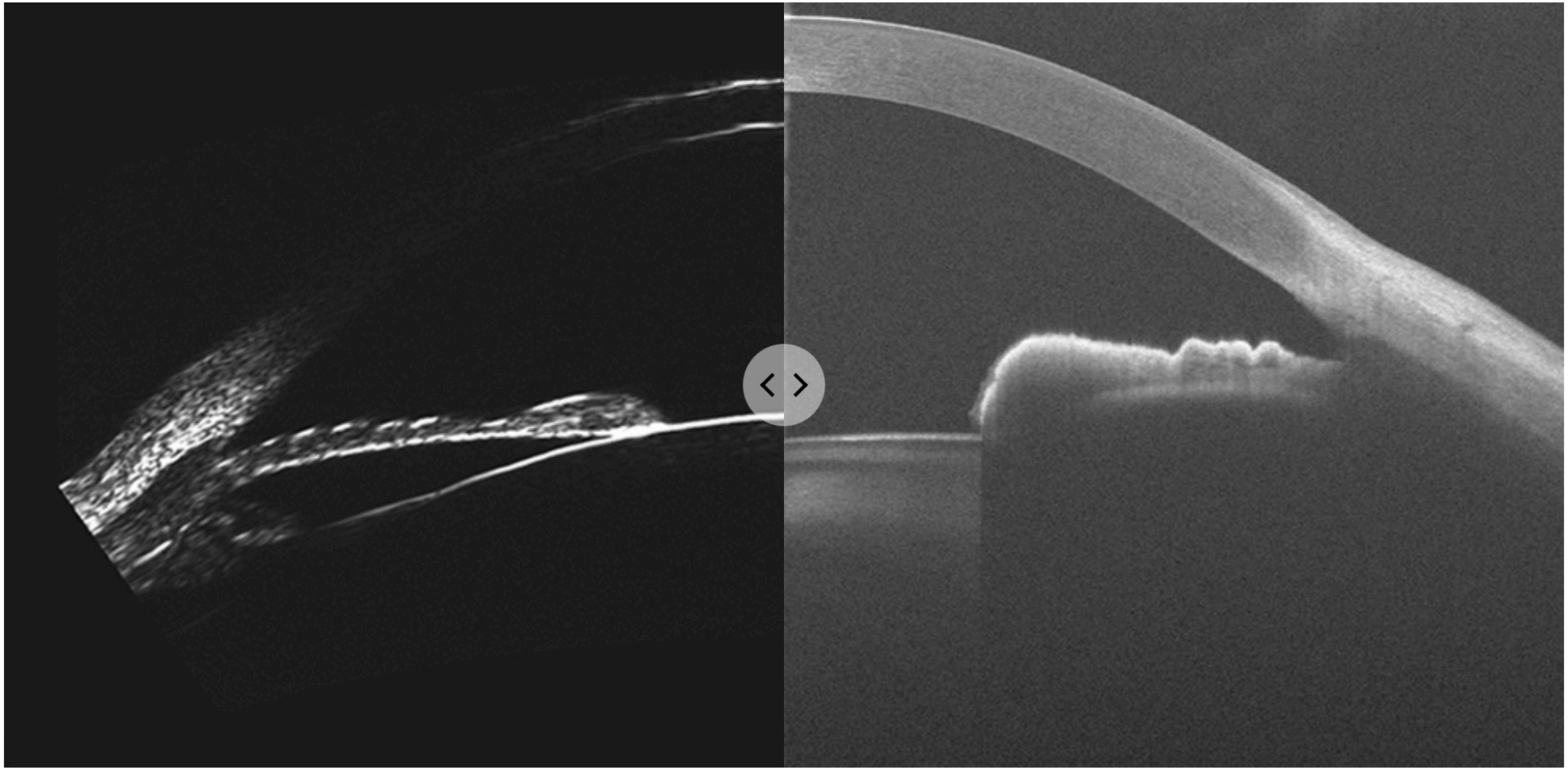




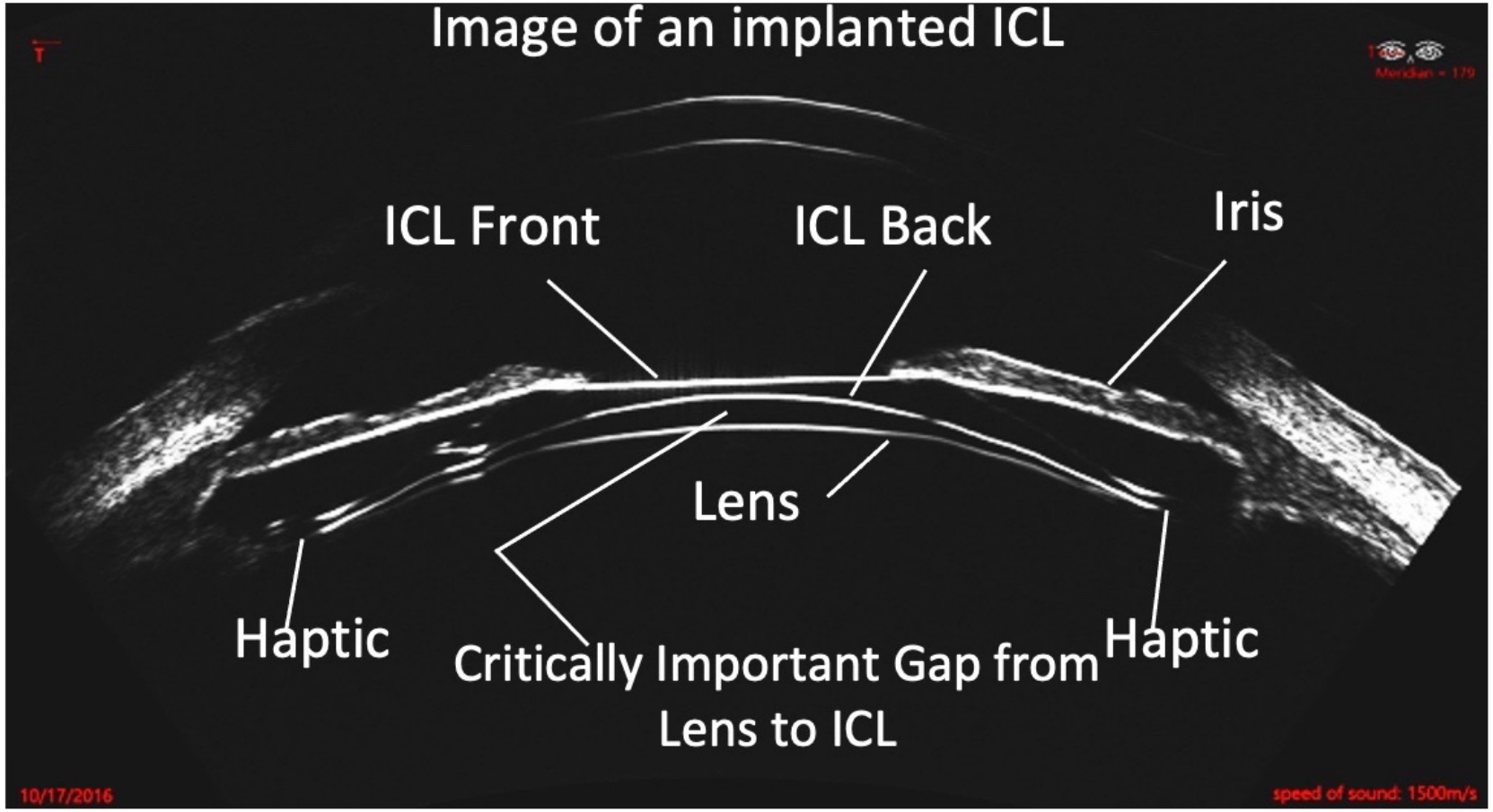
Very-high Frequency Ultrasound (VHF-US) vs. UBM



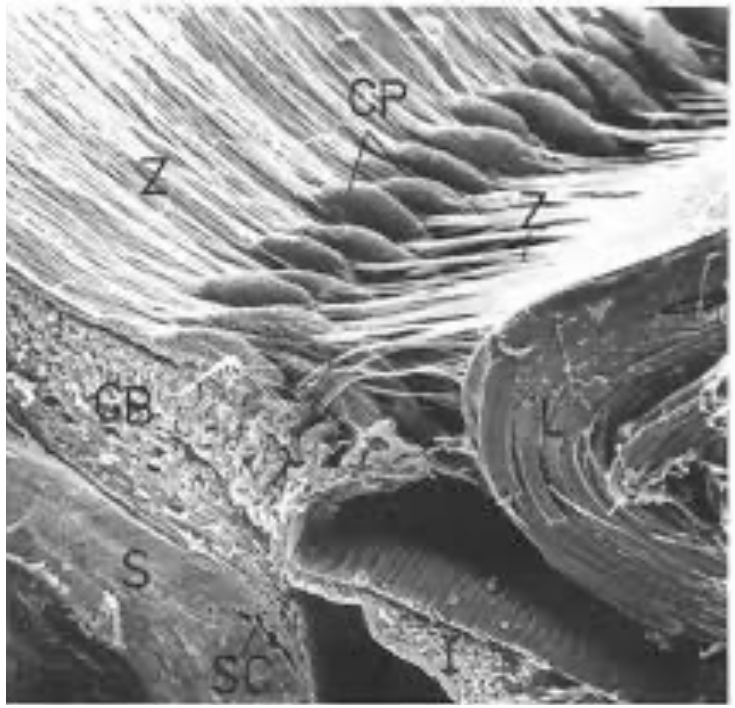
Very-high Frequency Ultrasound (VHF-US) vs. OCT

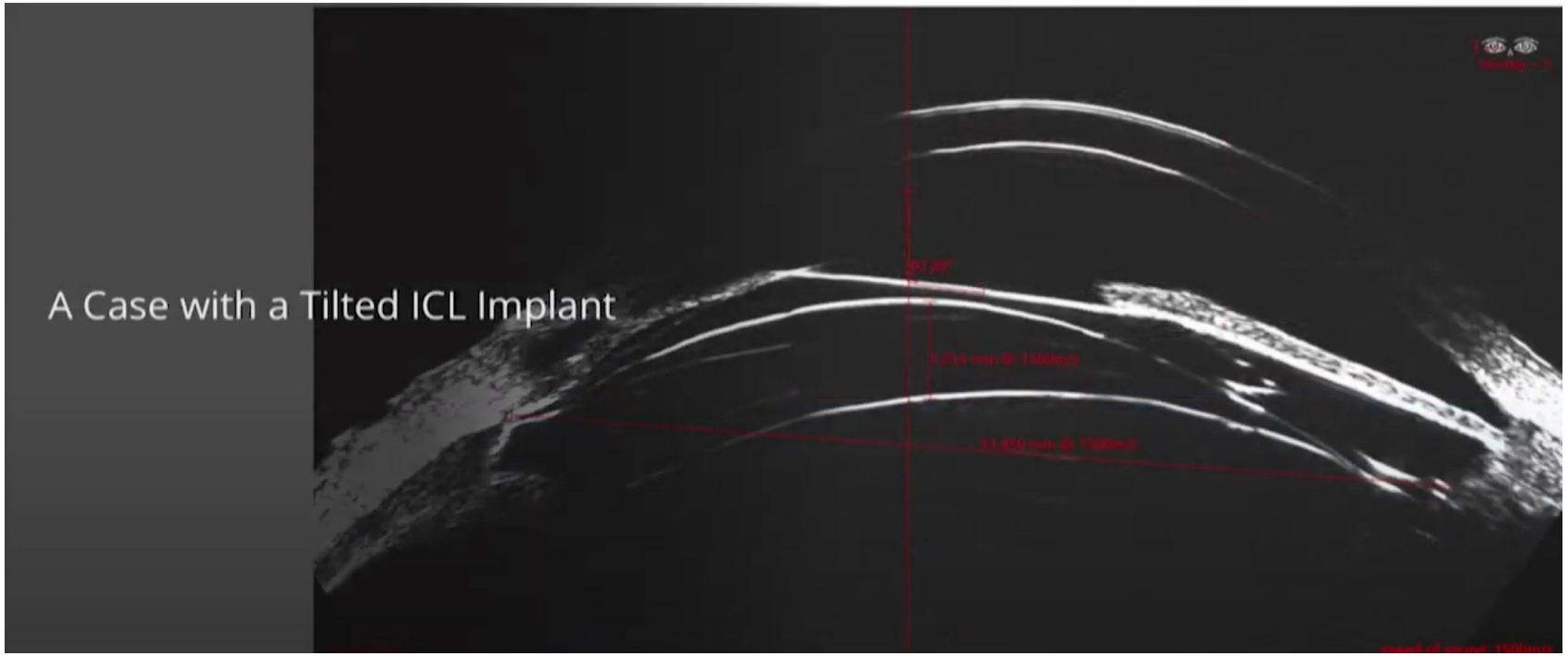


Quality of Very-High Frequency Ultrasound

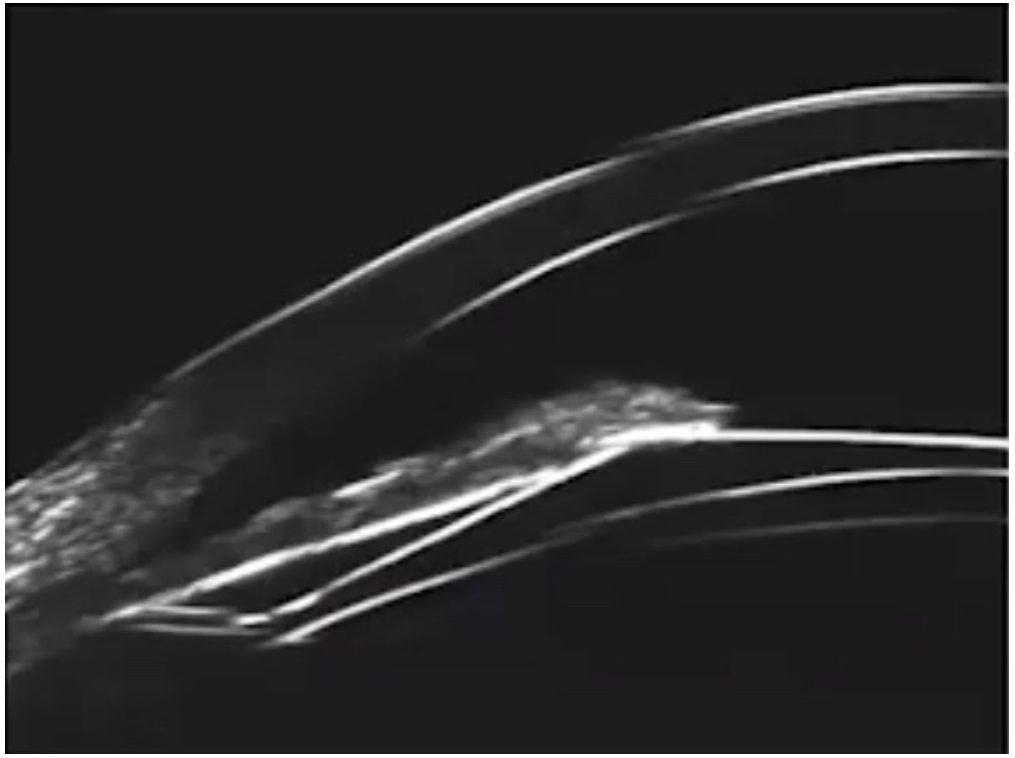


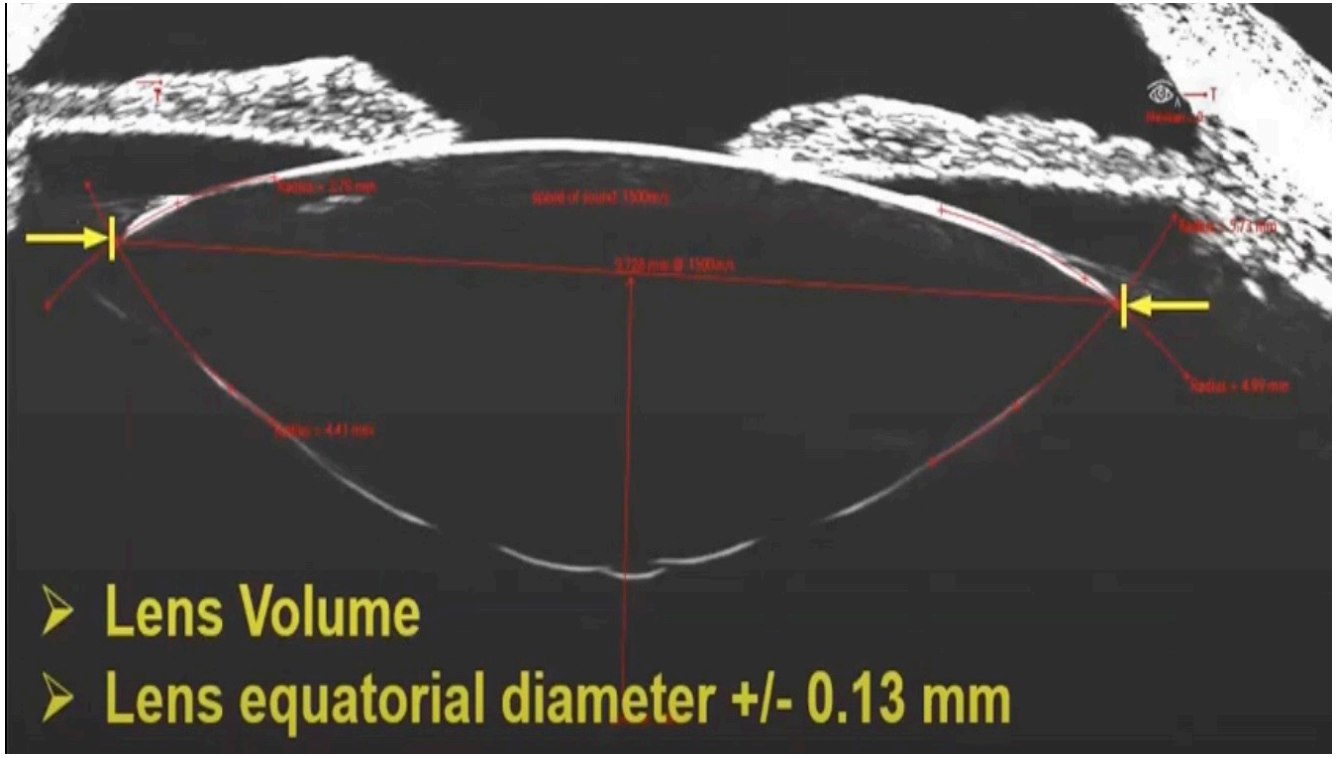
Difficult Cases





Comparing High Frequency to Very High Frequency Ultrasound





Very High Frequency Ultrasound (VHF-US)

Very-High Frequency Ultrasound (50-MHz) Correlation

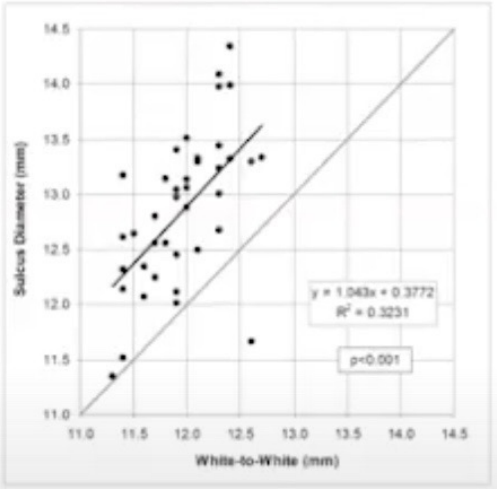
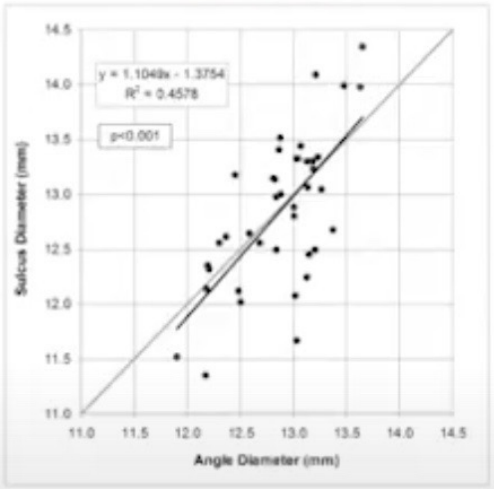
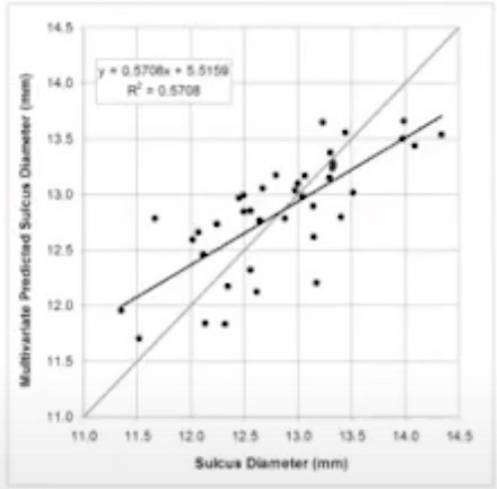
Correlation of Anterior Chamber Angle and Ciliary Sulcus Diameters With White-to-White Corneal Diameter in High Myopes Using Artemis VHF Digital Ultrasound

Dan Z. Reinstein, MD, MA(Cantab), FRCSC, FRCOphth; Timothy J. Archer, MA(Oxon), DipCompSci(Cantab); Ronald H. Silverman, PhD; Mark J. Rondeau; D. Jackson Coleman, MD

Journal of Refractive Surgery Volume 25 February 2009

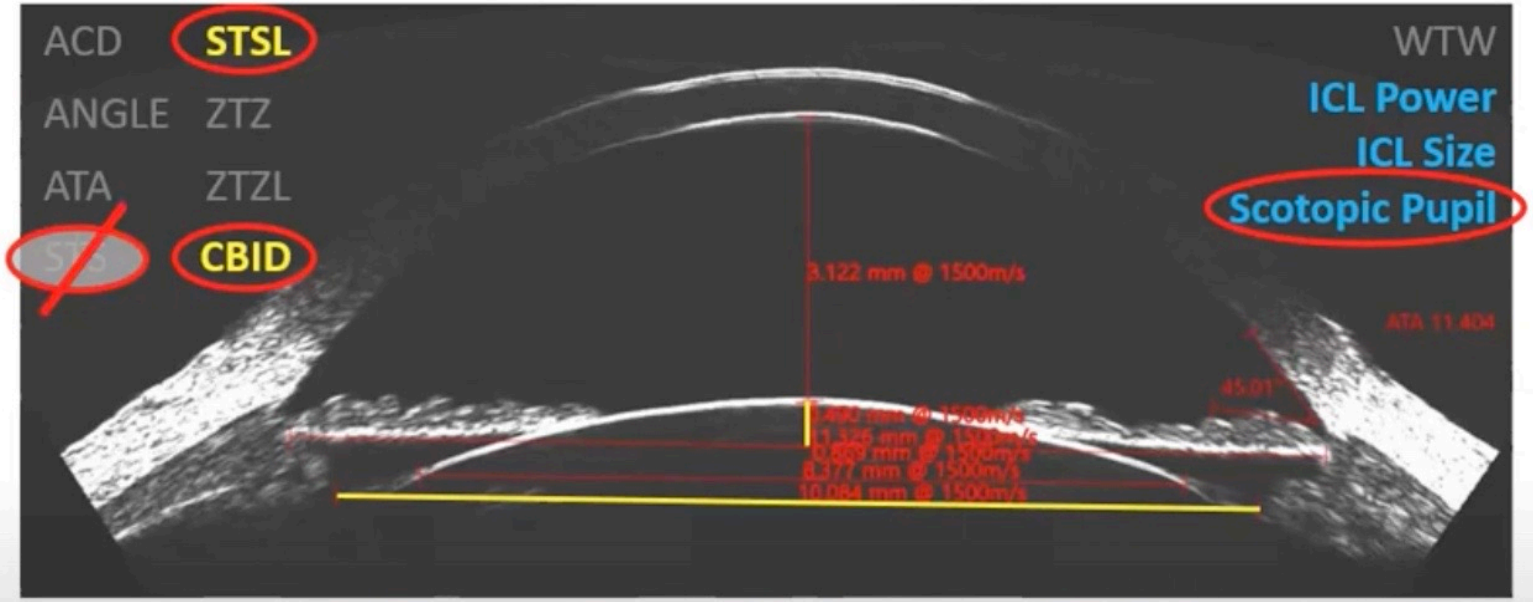
Age, sphere, cylinder, SEQ, WTW, ACD, SimK, CCT, angle diameter

Sulcus Diameter

White-to-White	Angle Diameter	Multivariate
		
Error >0.50 mm	38.0%	32.7%	26.7%

Next Generation ICL Sizing Model

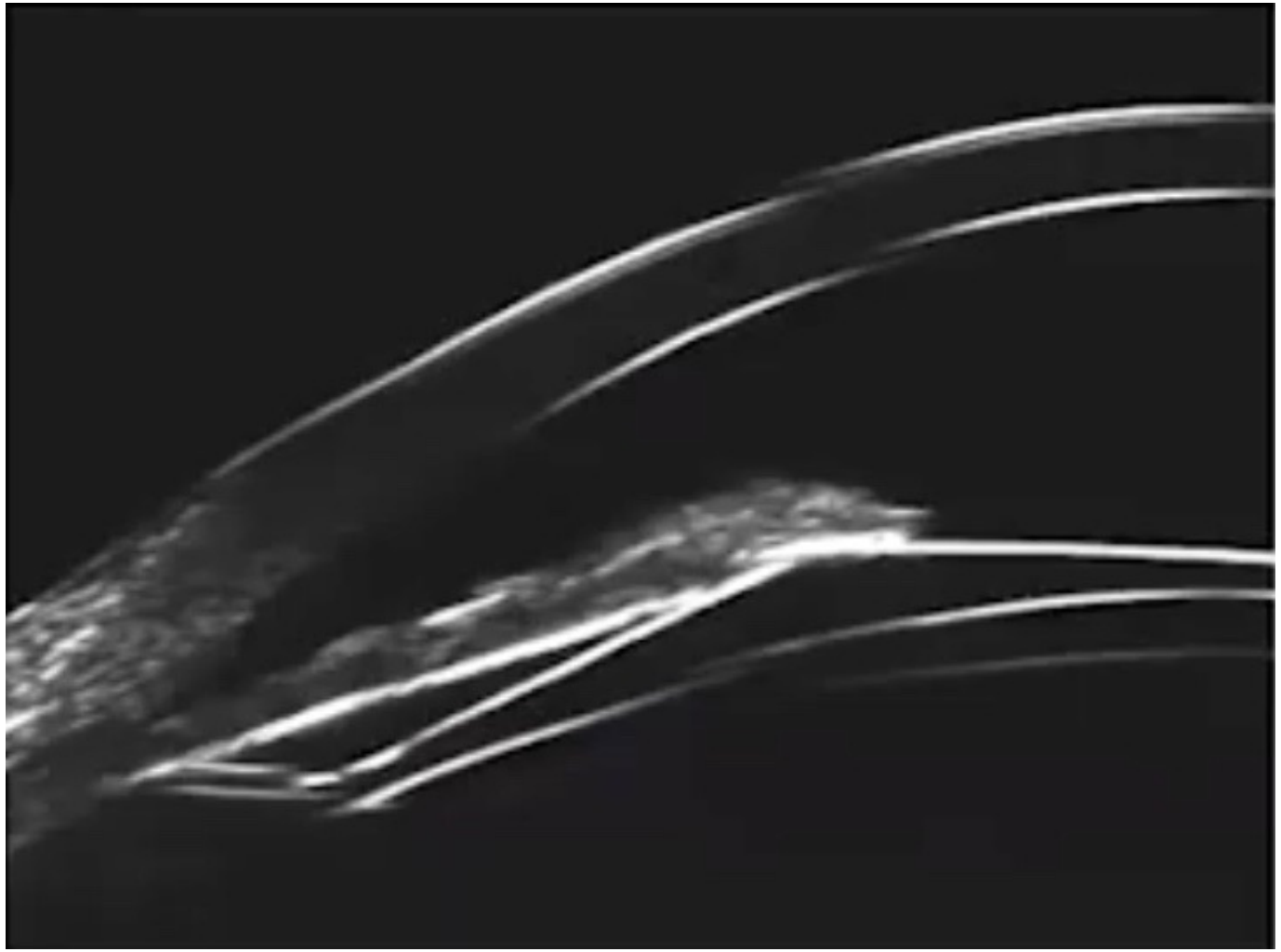
Regression Variables

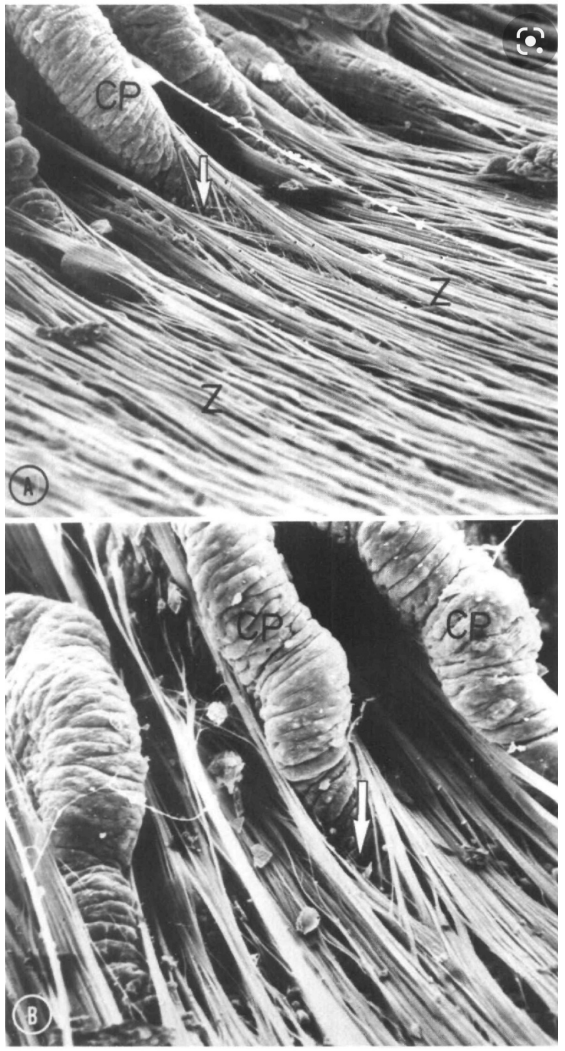


Vault = a*CBID + b*STSL + c*ICL Power + d*ICL Size + e*SPD

Reinstein, et al 2021: utilized the first-time posterior iris view for all new Regression Variables

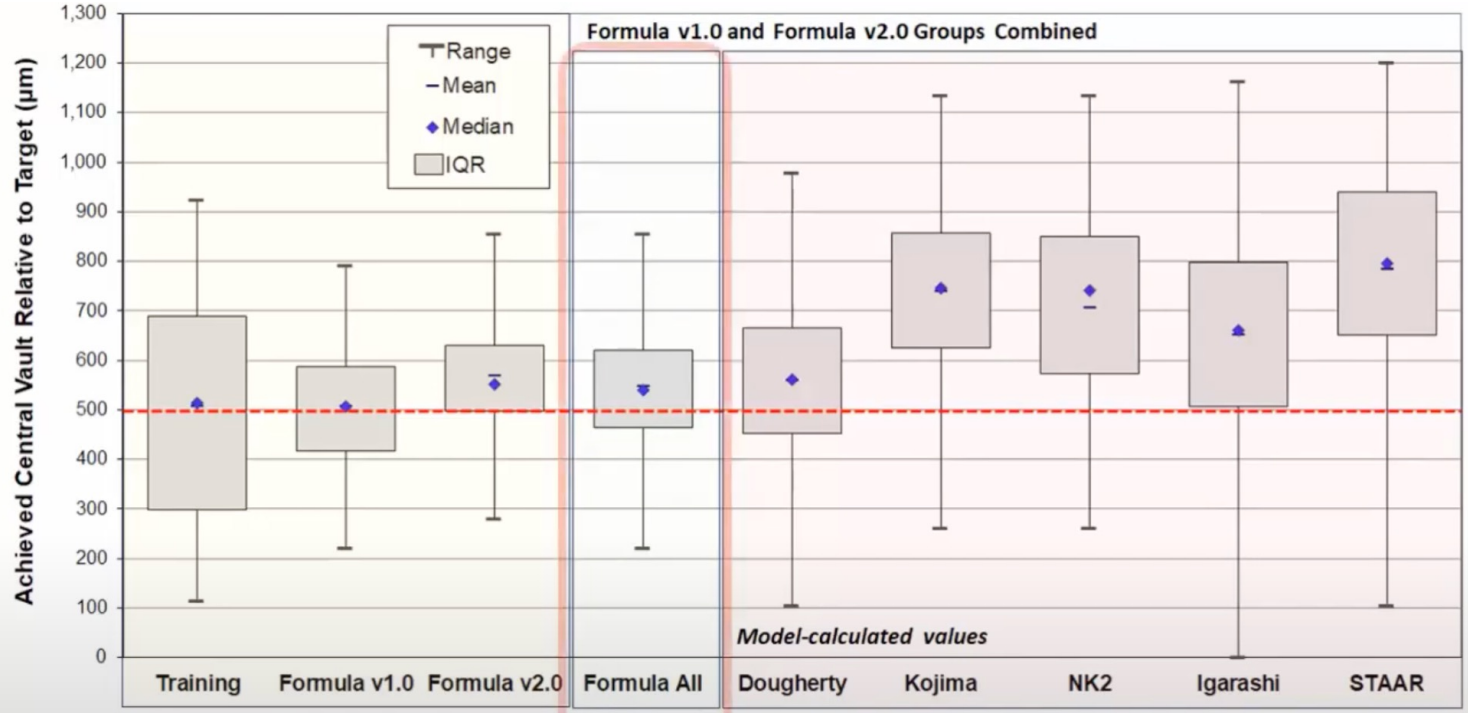
Next Generation ICL Sizing Model





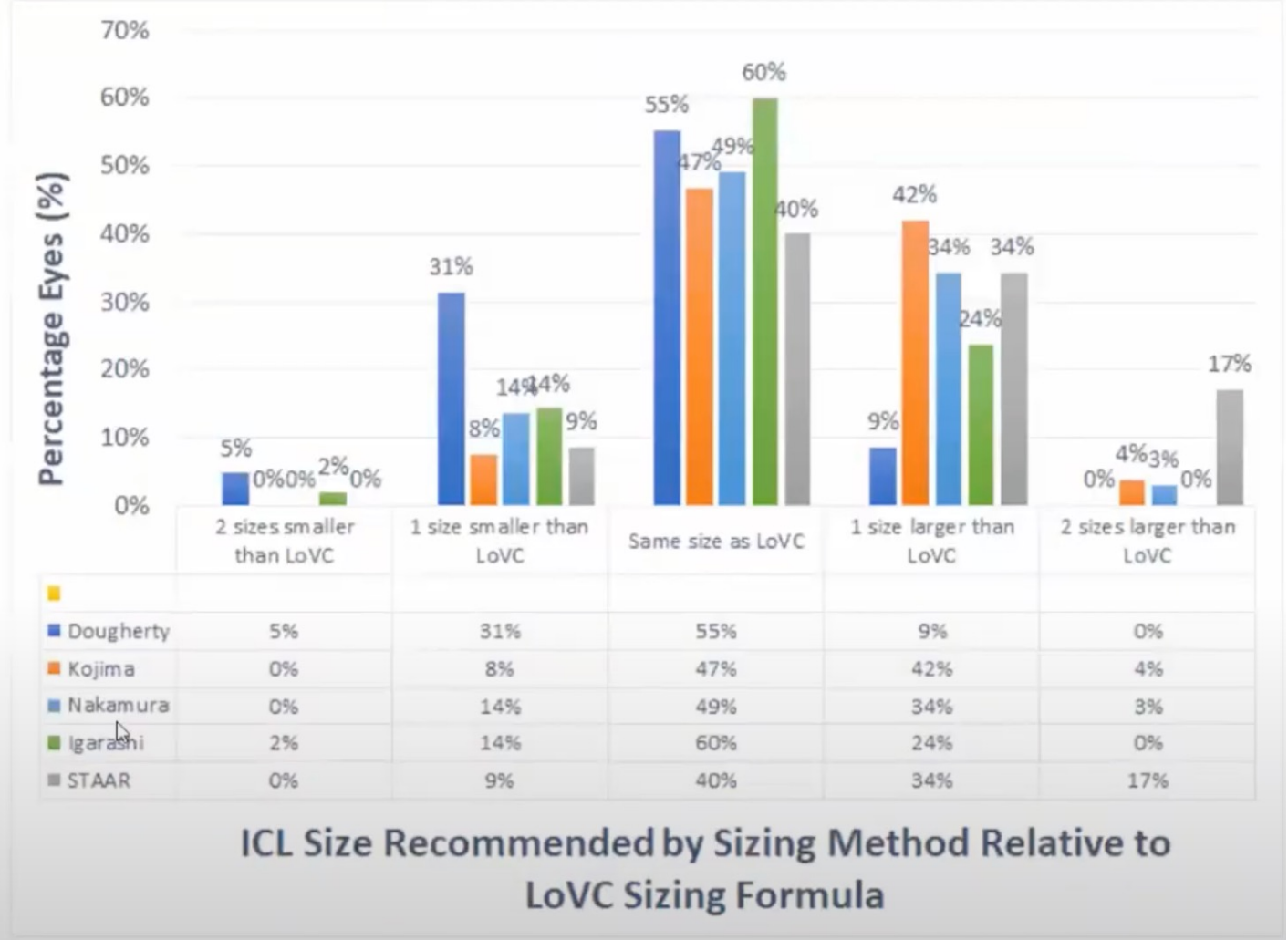
Direct Sulcus-Based Model vs All Other Formulas

UBM OCT Formulae W-2-W



Mean	506	507	567	547	560	738	706	650	784
Min	114	222	281	222	105	262	262	1	105
Max	924	791	854	854	978	1133	1133	1162	1200
IQR	391	169	131	155	213	230	278	292	288
Range	810	569	573	632	872	871	871	1161	1095

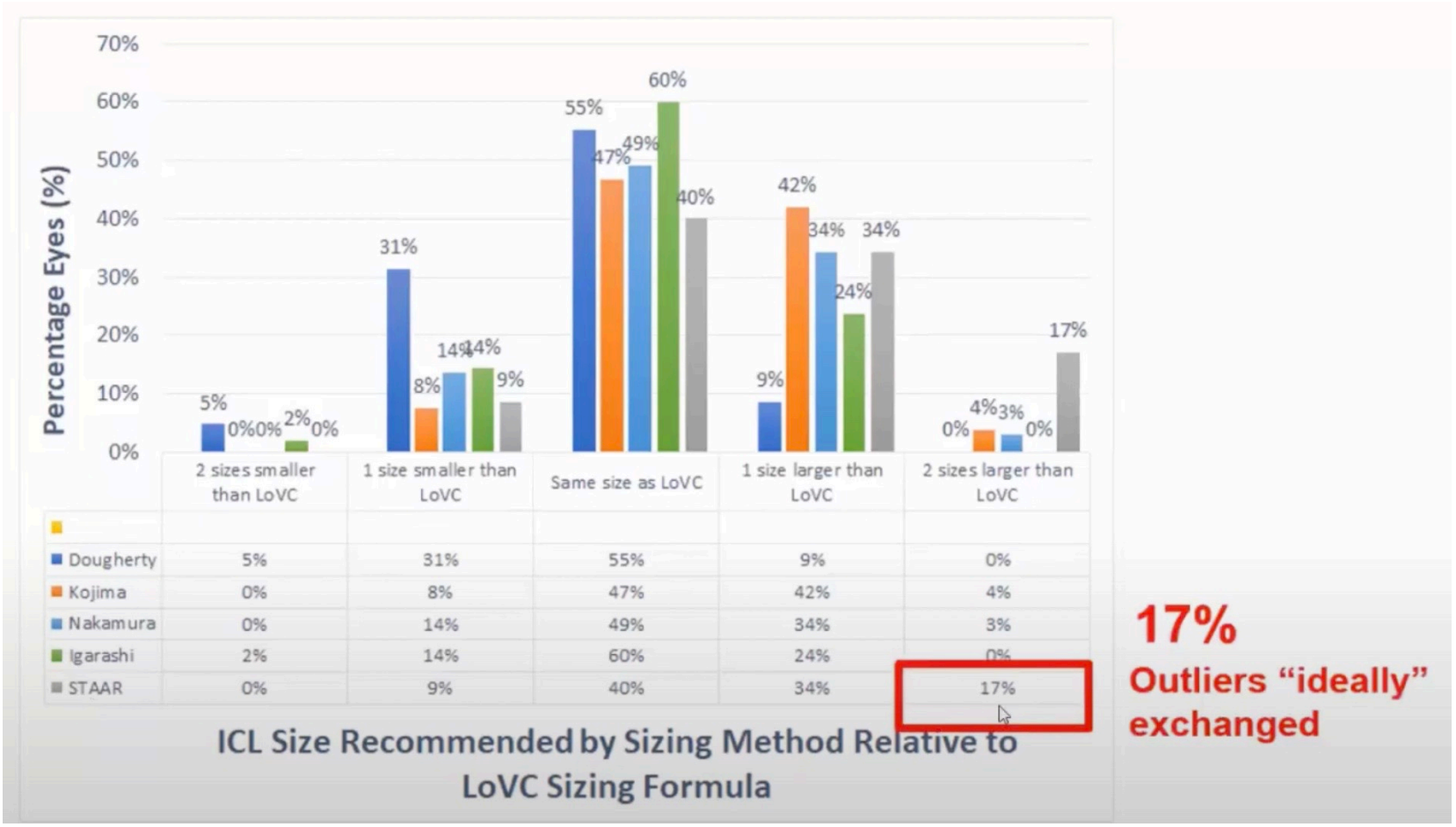
Choosing A Lens Size



	2 sizes smaller than LoVC	1 size smaller than LoVC	Same size as LoVC	1 size larger than LoVC	2 sizes larger than LoVC
Dougherty	5%	31%	55%	9%	0%
Kojima	0%	8%	47%	42%	4%
Nakamura	0%	14%	49%	34%	3%
Igarashi	2%	14%	60%	24%	0%
STAAR	0%	9%	40%	34%	17%

ICL Size Recommended by Sizing Method Relative to LoVC Sizing Formula

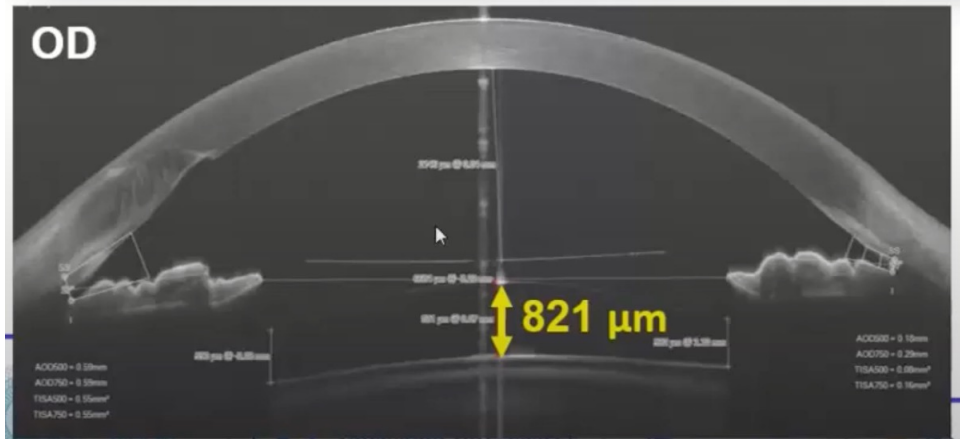
Choosing A Lens Size

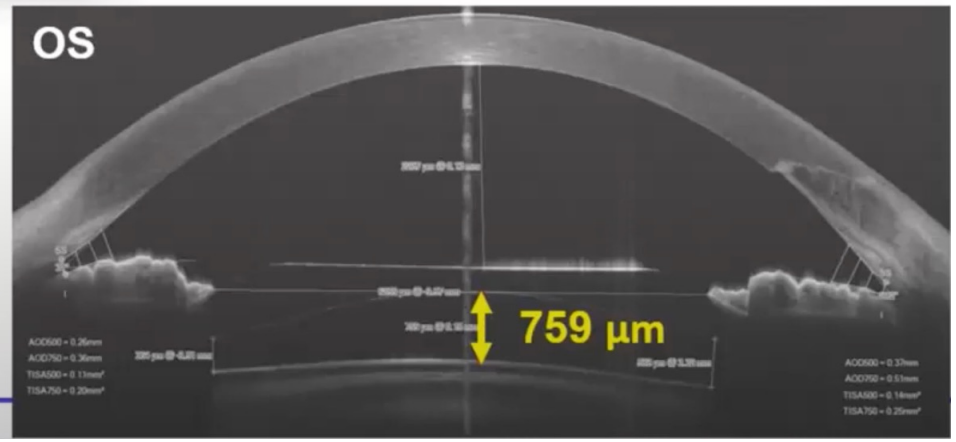


Case Example: 25 Y/O Female

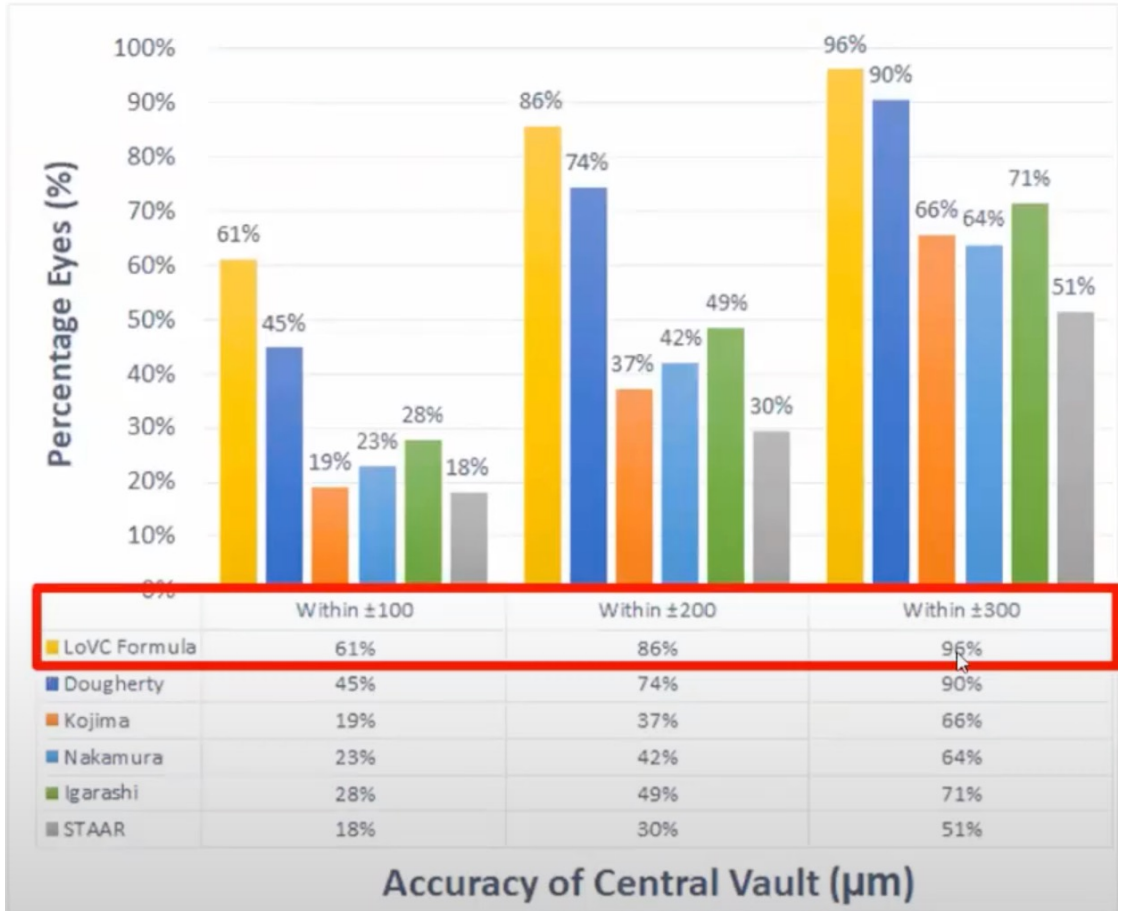
Formula	Recommended lens size		Final	
LoVC	12.6	12.6	12.6	12.6
Dougherty	13.2	13.2		
Kojima	13.12	13.17		
Nakamura	13.09	13.08		
STAAR	13.7	13.7		

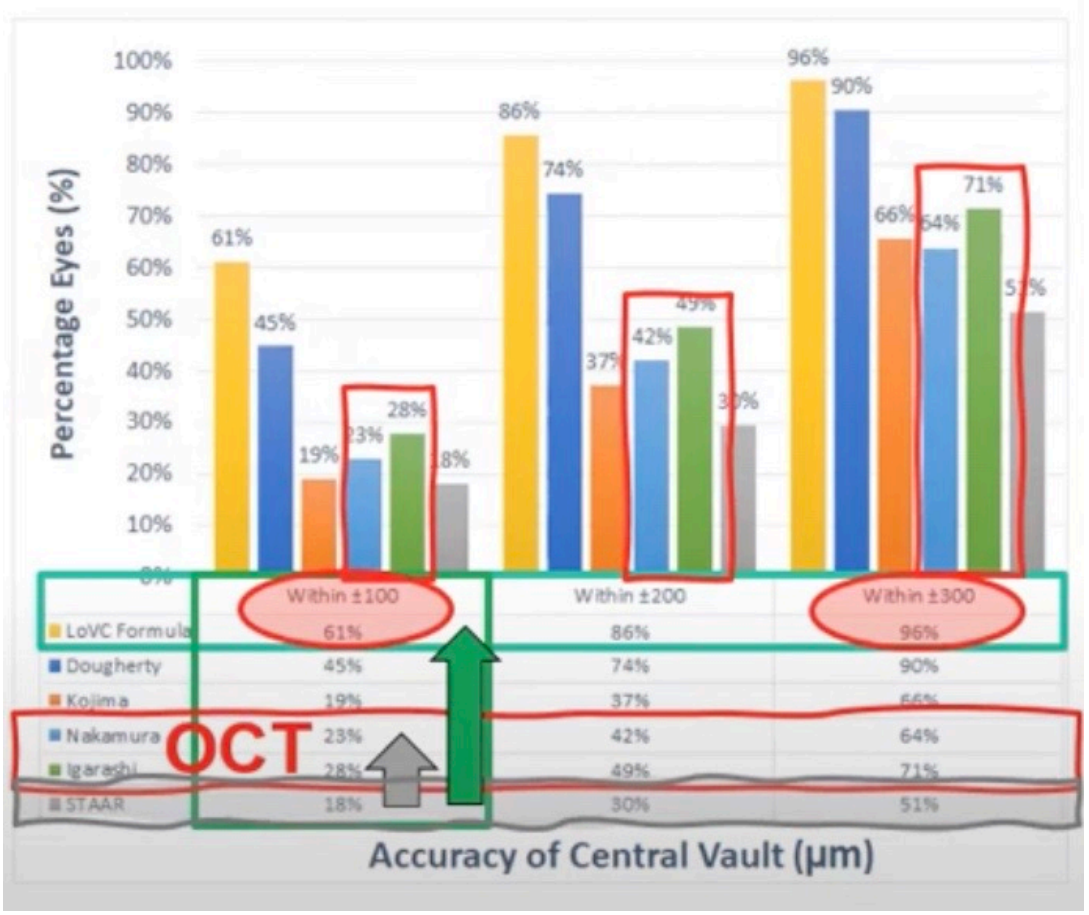
		OD	OS
LoVC formula	Lens size	Predicted vault	
	12.1	351	330
	12.6	568	547
	13.2	828	808
	13.7	1045	1025



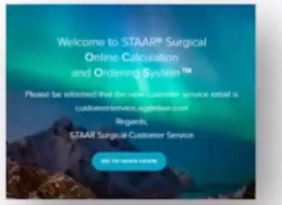
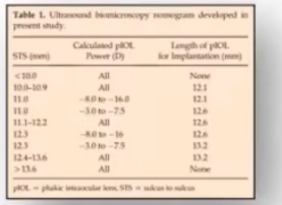
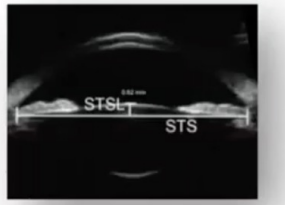


Results: Attempted vs. Achieved Vault





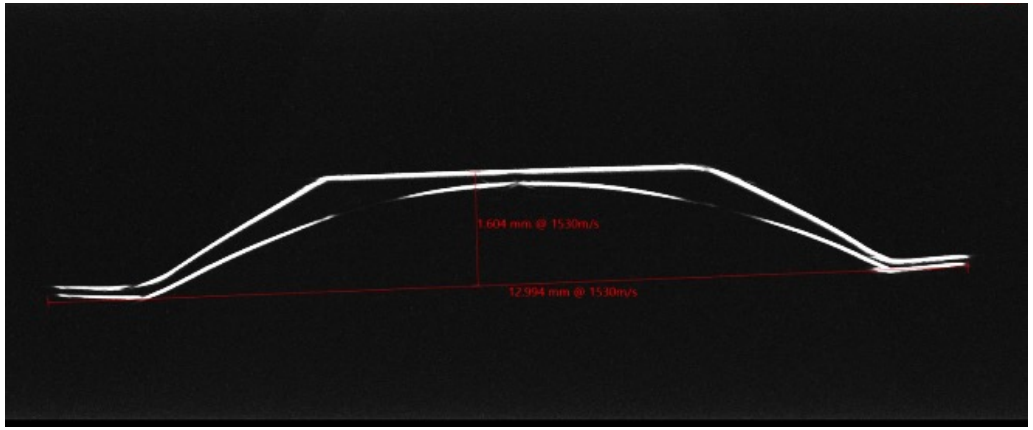
Lens Sizing: v3.0

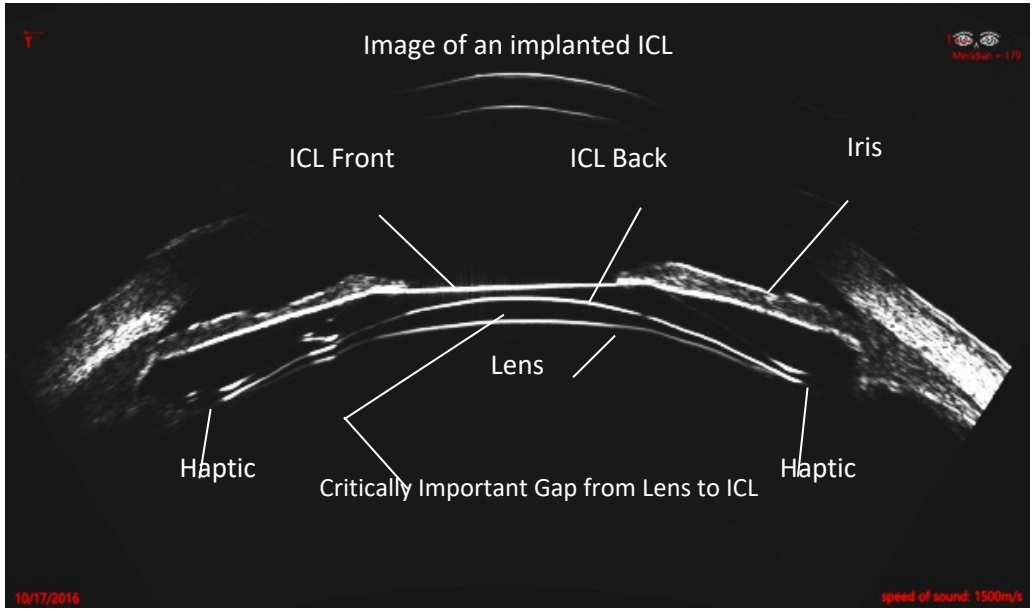
STAAR (v1.5)	Dougherty (v2.0)	Kojima (v2.5)	LoVC (v3.0)
			
WTW			
Refraction	ICL Power		ICL power
Keratometry			
ACD		ACD	
	STS	STS	
		STSL	STSL
			CBID
			Pupil size
			Lens size
Recommended lens size	Recommended lens size	Ideal lens size	Predicted vault for each available lens

ArcScan Imaging: Enabling for Therapeutics

Anterior Segment

- Biometry for surgery including sulcus-to-sulcus distance
- Pathology Assessment
- Biometry for pre-op and post-op IOL, premium IOL, and ICL
- Evaluate accurate lens position, tilt, vault, and volume





ADVANCEMENTS IN HEALTHCARE DELIVERY

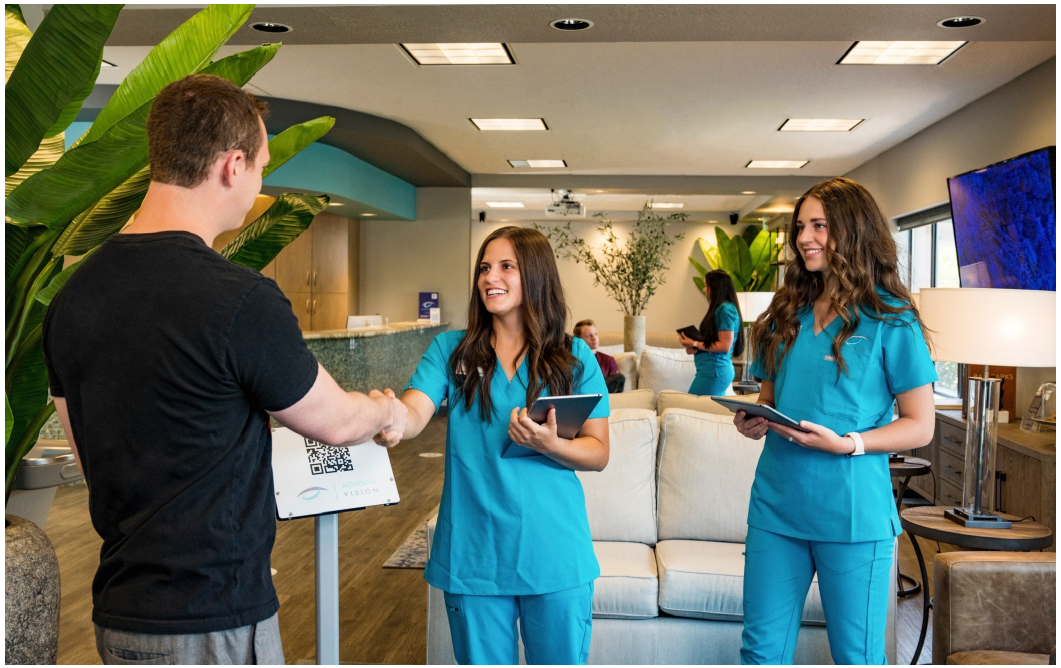
Objectives:

Understand the relationship of ICLs to other modern vision restoration procedures including topography guided LASIK, PRK, RELEX SMILE, ICRS and Refractive Lens Exchange.

Understand recent novel healthcare delivery models in eye surgery improving guest patient experience, efficiency, cost savings, and optimized optometry co-management of ICL patients.

Next-Gen Delivery Model: Same-Day Surgery

- Old Model - Travel
  - 1st visit: Meet your surgeon
  - 2nd visit: Return for b-scan and white-to-white caliper measurements
  - 3rd visit: Procedure
- Advanced Model - Procedure, Same Day
  - World-class integrated operating suites
  - VHF-US: 2 minutes
  - Expert delivery team
  - House a full ICL inventory (2^{nd} location in the country).



Advancements in Surgical Delivery Design

Advancements in Surgical Delivery Design

HOW DOES SAME {NEXT} DAY™ SURGERY WORK?

1

INITIAL CONTACT

The Optometrist will text, call, or QR the Collaborative Care Coordinator. Shortly after, Monson Vision will contact the patient to schedule an online consultation.

2

ONLINE CONSULTATION

Patients will have a phone or zoom consultation with Dr. Monson to review medical information, surgical goals, and sign consents. The patient will then be scheduled for surgery and Monson Vision will arrange accommodations.

3

SURGERY DAY 1

When the patient arrives, a live consultation will take place in the morning, followed by surgery on the first eye. Afterward, the patient will be safely transported to a nearby first rate hotel, arranged by Monson Vision.

4

SURGERY DAY 2 AND DEPARTURE

Surgery on the second eye will take place the following morning. After a brief post-op, the patient will be discharged and on their way home.

5

RETURN TO OPTOMETRIST

The day after surgery, the patient will undergo a post-op appointment with you, their optometrist.

Individual Custom Planning

THANK YOU

References

1. Zhu Y, He T, Zhu H, Chen J, Zhou J. Static and dynamic pupillary characteristics in high myopic eyes with two implantable collamer lenses. *J Cataract Refract Surg*. 07 2019;45(7):946-951. doi:10.1016/j.jcrs.2019.01.027
2. Holden BA, Fricke TR, Wilson DA, et al. Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 through 2050. *Ophthalmology*. May 2016;123(5):1036-42. doi:10.1016/j.ophtha.2016.01.006
3. Staar ICL Surgical Data Registry 2018
4. PASCAL JI. Retinal image in axial and refractive ametropia. *Br J Ophthalmol*. Jun 1955;39(6):380-1. doi:10.1136/bjo.39.6.380
5. Igarashi A, Kamiya K, Ichikawa K, et al. Multicenter clinical outcomes of hole implantable collamer lens implantation in middle-aged patients. *Sci Rep*. 03 10 2022;12(1):4236. doi:10.1038/s41598-022-08298-7
6. Martínez-Plaza E, López-Miguel A, López-de la Rosa A, McAlinden C, Fernández I, Maldonado MJ. Effect of the EVO+ Visian Phakic Implantable Collamer Lens on Visual Performance and Quality of Vision and Life. *Am J Ophthalmol*. 06 2021;226:117-125. doi:10.1016/j.ajo.2021.02.005
7. Ganesh S, Brar S, Pawar A. Matched population comparison of visual outcomes and patient satisfaction between 3 modalities for the correction of low to moderate myopic astigmatism. *Clin Ophthalmol*. 2017;11:1253-1263. doi:10.2147/OPTH.S127101
8. Fricke TR, Tahhan N, Resnikoff S, et al. Global Prevalence of Presbyopia and Vision Impairment from Uncorrected Presbyopia: Systematic Review, Meta-analysis, and Modelling. *Ophthalmology*. 10 2018;125(10):1492-1499. doi:10.1016/j.ophtha.2018.04.013
9. Market Scope, LLC. STAAR Surgical Global Model 2018 to 2024. 2020.
10. Ye Y, Zhao J, Zhang Z, et al. Long-term follow-up for monovision surgery by Implantable Collamer Lens V4c implantation for myopia correction in early presbyopia. *Graefes Arch Clin Exp Ophthalmol*. Feb 07 2022;doi:10.1007/s00417-021-05545-x

References

11. Chuck RS, Jacobs DS, Lee JK, et al. Refractive Errors & Refractive Surgery Preferred Practice Pattern®. *Ophthalmology*. 01 2018;125(1):P1-P104. doi:10.1016/j.ophtha.2017.10.003

12. Noorden E. Exotropia. In: Binocular vision and ocular motility: Theory and Management of Strabismus. CV Mosby; 2010.

13. Hermann JS, Johnson R. The accommodation requirement in myopia. A comparison of contact lenses and spectacles. *Arch Ophthalmol*. Jul 1966;76(1):47-51. doi:10.1001/archopht.1966.03850010049011

14. Kirwan C, O'Keefe M, O'Mullane GM, Sheehan C. Refractive surgery in patients with accommodative and non-accommodative strabismus: 1-year prospective follow-up. *Br J Ophthalmol*. Jul 2010;94(7):898-902. doi:10.1136/bjo.2009.162420

15. BenEzra D, Cohen E, Karshai I. Phakic posterior chamber intraocular lens for the correction of anisometropia and treatment of amblyopia. *Am J Ophthalmol*. Sep 2000;130(3):292-6. doi:10.1016/s0002-9394(00)00492-x

16. *American Academy of Ophthalmology Basic and clinical sciences, Clinical Optics*. 2010

170.

17. Haarman AEG, Enthoven CA, Tideman JWL, Tedja MS, Verhoeven VJM, Klaver CCW. The Complications of Myopia: A Review and Meta-Analysis. *Invest Ophthalmol Vis Sci*. 04 09 2020;61(4):49. doi:10.1167/iovs.61.4.49

18. Flaxel CJ, Adelman RA, Bailey ST, et al. Posterior Vitreous Detachment, Retinal Breaks, and Lattice Degeneration Preferred Practice Pattern®. *Ophthalmology*. 01 2020;127(1):P146-P181. doi:10.1016/j.ophtha.2019.09.027

19. Garcia-De la Rosa G, Olivo-Payne A, Serna-Ojeda JC, et al. Anterior segment optical coherence tomography angle and vault analysis after toric and non-toric implantable collamer lens V4c implantation in patients with high myopia. *Br J Ophthalmol*. 04 2018;102(4):544-548. doi:10.1136/bjophthalmol-2017-310518

20. Eom Y, Kim DW, Ryu D, et al. Ring-shaped dysphotopsia associated with posterior chamber phakic implantable collamer lenses with a central hole. *Acta Ophthalmol*. May 2017;95(3):e170-e178. doi:10.1111/aos.13248

References

21. Bai Z, Nie D, Zhang J, et al. Visual function assessment of posterior-chamber phakic implantable collamer lenses with a central port. *Ann Transl Med*. Feb 2022;10(4):194. doi:10.21037/atm-22-107
22. Bai H, Li H, Zheng S, Sun L, Wu X. Nd:YAG Capsulotomy Rates with Two Multifocal Intraocular Lenses. *Int J Gen Med*. 2021;14:8975-8980. doi:10.2147/IJGM.S342039
23. Chang DS, Jiang Y, Kim JA, et al. Cataract progression after Nd:YAG laser iridotomy in primary angle-closure suspect eyes. *Br J Ophthalmol*. May 02 2022;doi:10.1136/bjophthalmol-2021-320929
24. Fujisawa K, Shimizu K, Uga S, et al. Changes in the crystalline lens resulting from insertion of a phakic IOL (ICL) into the porcine eye. *Graefes Arch Clin Exp Ophthalmol*. Jan 2007;245(1):114-22. doi:10.1007/s00417-006-0338-y
25. Zeng QY, Xie XL, Chen Q. Prevention and management of collagen copolymer phakic intraocular lens exchange: causes and surgical techniques. *J Cataract Refract Surg*. Mar 2015;41(3):576-84. doi:10.1016/j.jcrs.2014.06.036
26. Packer M. Evaluation of the EVO/EVO+ Sphere and Toric Visian ICL: Six Month Results from the United States Food and Drug Administration Clinical Trial. *Clin Ophthalmol*. 2022;16:1541-1553. doi:10.2147/OPTH.S369467
27. Packer M. Meta-analysis and review: effectiveness, safety, and central port design of the intraocular collamer lens. *Clin Ophthalmol*. 2016;10:1059-77. doi:10.2147/OPTH.S111620
28. Chen X, Wang X, Xu Y, Cheng M, Han T, Zhou X. Long-term Comparison of Vault and Complications of Implantable Collamer Lens with and without a Central Hole for High Myopia Correction: 5 Years. *Curr Eye Res*. Apr 2022;47(4):540-546. doi:10.1080/02713683.2021.2012202
29. Gonvers M, Othenin-Girard P, Bornet C, Sickenberg M. Implantable contact lens for moderate to high myopia: short-term follow-up of 2 models. *J Cataract Refract Surg*. Mar 2001;27(3):380-8. doi:10.1016/s0886-3350(00)00759-8
30. Dejaco-Ruhswurm I, Scholz U, Pieh S, et al. Long-term endothelial changes in phakic eyes with posterior chamber intraocular lenses. *J Cataract Refract Surg*. Sep 2002;28(9):1589-93. doi:10.1016/s0886-3350(02)01210-5

References

31. Yang W, Zhao J, Sun L, Niu L, Wang X, Zhou X. Four-year observation of the changes in corneal endothelium cell density and correlated factors after Implantable Collamer Lens V4c implantation. *Br J Ophthalmol*. 05 2021;105(5):625-630. doi:10.1136/bjophthalmol-2020-316144

32. Bohac M, Jagic M, Biscevic A, Shijakova V, Gabric N, Patel S. Changes in Endothelial Cell Count Up to Three Years After Implantation of Toric Implantable Collamer Lenses. *Cornea*. Jul 2019;38(7):873-879. doi:10.1097/ICO.0000000000001914

33. Bohac M, Biscevic A, Gabric I, Gabric K, Shijakova V, Patel S. A critical evaluation of longitudinal changes of astigmatism following implantation of toric implantable collamer lens (TICL): a comparison between treated and untreated cases over 4 years. *Graefes Arch Clin Exp Ophthalmol*. Apr 2022;260(4):1377-1386. doi:10.1007/s00417-021-05449-w

34. Branger GA, Baenninger P. Late-Onset Toric Implantable Collamer Lens Rotation: A Case Report. *Klin Monbl Augenheilkd*. 04 2022;239(4):416-417. doi:10.1055/a-1785-4276

35. Fairaq R, Almutlak M, Almazyad E, Badawi AH, Ahad MA. Outcomes and complications of implantable collamer lens for mild to advance keratoconus. *Int Ophthalmol*. Jul 2021;41(7):2609-2618. doi:10.1007/s10792-021-01820-2

36. Chen Q, Zeng Q, Wang Z, Pan C, Lei X, Tan W. Spontaneous rotation of a toric implantable collamer lens related to abnormal ciliary body morphology: a case report. *BMC Ophthalmol*. Aug 28 2020;20(1):350. doi:10.1186/s12886-020-01597-5

37. Kato S, Shimizu K, Igarashi A. Assessment of low-vault cases with an implantable collamer lens. *PLoS One*. 2020;15(11):e0241814. doi:10.1371/journal.pone.0241814

38. Hashem AN, El Danasoury AM, Anwar HM. Axis alignment and rotational stability after implantation of the toric implantable collamer lens for myopic astigmatism. *J Refract Surg*. Oct 2009;25(10 Suppl):S939-43. doi:10.3928/1081597X-20090915-08

39. Kamiya K, Ando W, Hayakawa H, Gotoda S, Shoji N. Vertically Fixated Posterior Chamber Phakic Intraocular Lens Implantation Through a Superior Corneal Incision. *Ophthalmol Ther*. Apr 2022;11(2):701-710. doi:10.1007/s40123-022-00470-6

References

40. Kaur M, Titiyal JS, Falera R, Sinha R, Sharma N. Indications for explant of implantable collamer lens. *Eye (Lond)*. 04 2018;32(4):838-840. doi:10.1038/eye.2017.307

41. Alhamzah A, Alharbi SS, Alfardan F, Aldebasi T, Almudhaiyan T. Indications for exchange or explantation of phakic implantable collamer lens with central port in patients with and without keratoconus. *Int J Ophthalmol*. 2021;14(11):1714-1720. doi:10.18240/ijo.2021.11.10

42. Reinstein DZ, Archer TJ, Silverman RH, Rondeau MJ, Coleman DJ. Correlation of anterior chamber angle and ciliary sulcus diameters with white-to-white corneal diameter in high myopes using artemis VHF digital ultrasound. *J Refract Surg*. 02 2009;25(2):185-94. doi:10.3928/1081597X-20090201-03