

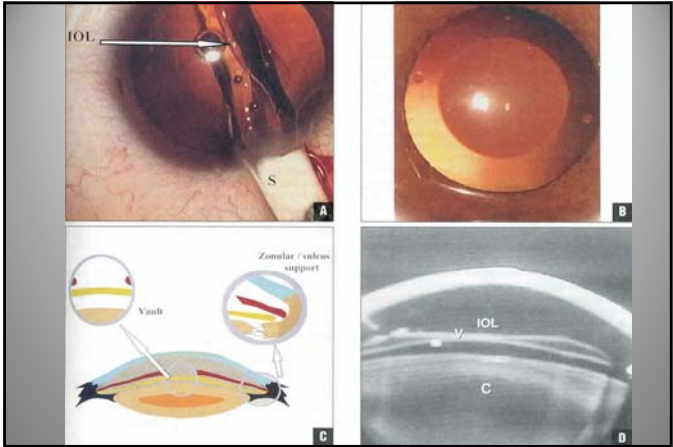
**Refractive Surgery:
Phakic IOL's are the best option
US and Global Experience**

Richard A. Erdey, MD

RAE disclaimer

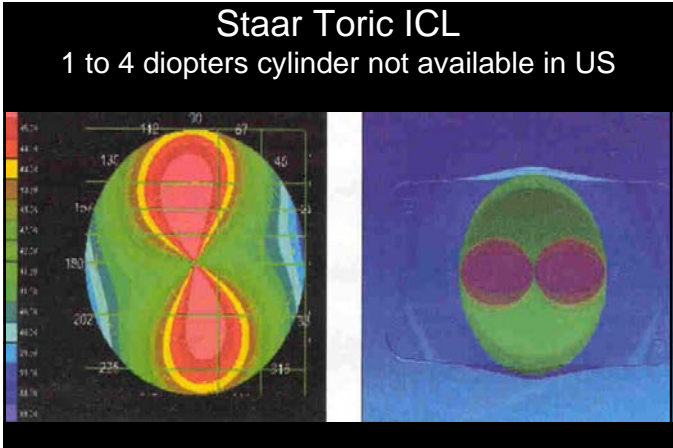
- 1998 Investigator ICL Myopia US FDA study
- 20 yrs experience with the ICL.
- 1990 Investigator Visx PRK FDA study

No financial interest in any products discussed



APPROVED - US FDA ICL MYOPIA - Dec 2005

- -3 to -15D "Correction of Myopia"
- -16 to -20.0 D "Reduction of Myopia" (in higher ranges ICL is not able to correct entire refractive disorder)
- 21 to 45 yrs age with stable myopia



Visian ICL - 2018

- Over 775,000 ICL's implanted worldwide
- > 99% satisfaction

Strong Points...

- reversibility - removability
- predictability - stability
- quality of vision - optical zone size
- cornea and crystalline lens remain untouched
- predictable calculations and high quality of vision for future premium IOL implantations



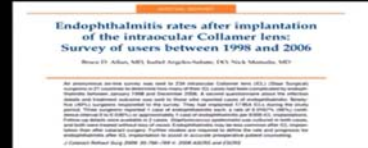
Points of Criticism....

- endophthalmitis
- sizing
- cataract
- IOP

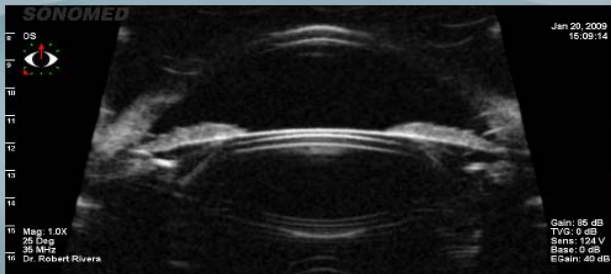


Endophthalmitis

- 0.0167% of cases (#17954)
- 3 reports, 2 with follow-up and full recovery
- Staf. Epidermidis : no vision loss



Ideal Vault – 300-600 microns

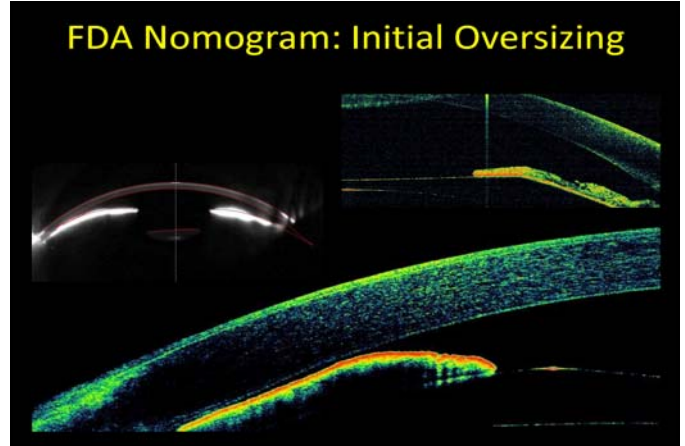
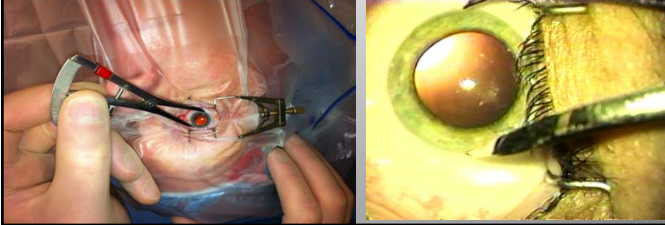


Visian ICL sizes

- 12.1 mm
- 12.6 mm
- 13.2 mm
- 13.7 mm

FDA: ICL Size Determination

- White to White measurement critical
 - use caliper
 - recline patient under microscope
 - IOL master w-w



Meta-analysis and review : effectiveness, safety, and central port design of the intraocular collamer lens
 M. Packer, Clinical Ophthalmology 2016;10 1059-1077

OPHTH-111620-meta-analysis-and-review---effectiveness--safety-an...

Table 2 Studies with objective data on vault also reporting safety outcomes

Study	N (eyes)	Length of follow-up	ICL removal, replacement, reposition % (N eyes)	ASC opacities % (N eyes)	Cataract surgery % (N eyes)	Pupillary block % (N eyes)	Ocular hypertension or glaucoma % (N eyes)
Seo et al ¹⁰	16	19.75 (17.14 months) (range: 6–56 months)	NR	NR	0	NR	NR
Kojima et al ¹¹	36	1 year	0	0	0	0	0
Alfonso et al ¹²	188	5 years	0	1.1 (2)	0.5 (1)	0	0
Sheng et al ¹³	54	8.6 (4.6 months) (range: 3–20 months)	3.7 (2)	0	0	0	0
Kojima et al ¹⁴	81	3 months	0	0	0	0	0
Reinstein et al ¹⁵	50	6.5 (0.7 years) (range: 4.1–7.4 years)	0	4.0 (2)	0	0	NR
Alfonso et al ¹⁶	138	6 months	0	0	0	0	0
Higuera-Esteban et al ¹⁷	35	3 months	NR	NR	NR	0	0
Cao et al ¹⁸	62	3 months	0	NR	0	0	0
Alfonso et al ¹⁹	35	1 year	0	0	0	0	0
Gomez-Bastar et al ²⁰	349	473 (1 months) (range: 3–127 months)	1.2 (4)	0	0	0	0
Kamiya et al ²¹	46	1 year	0	0	0	0	0
Lisa et al ²²	121	1 year	0	0	0	0	0
Lisa et al ²³	147	1 year	0	0	0	0	0
Hedgcock et al ²⁴	29	1 year	0	0	0	0	0
Total N	1387		0.4 (6)	0.3 (4)	0.1 (1)	0	0



Refractive – ICL Sizing - UBM



Ability to measure anatomical distances.... And achieve great postop results....

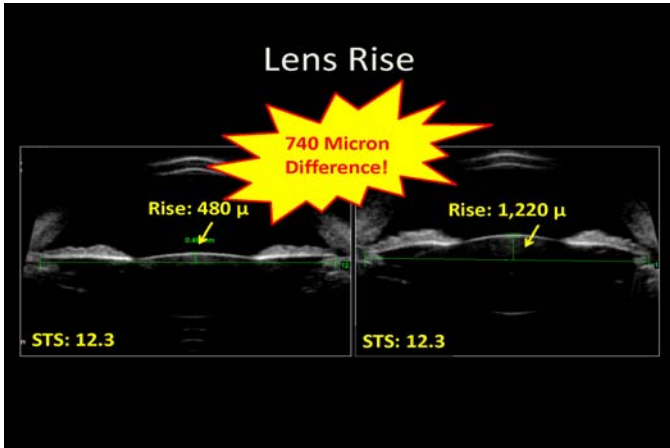
STS Nomogram

J Cataract Refract Surg. 2011 Jan;37(1):134-40. doi: 10.1016/j.jcrs.2010.07.014. Epub 2010 Nov 3.

Improving accuracy of phakic intraocular lens sizing using high-frequency ultrasound biomicroscopy.
 Dougherty PJ¹, Flores RP, Subrasiel D, Lane SB, Brown D, Vitek J.

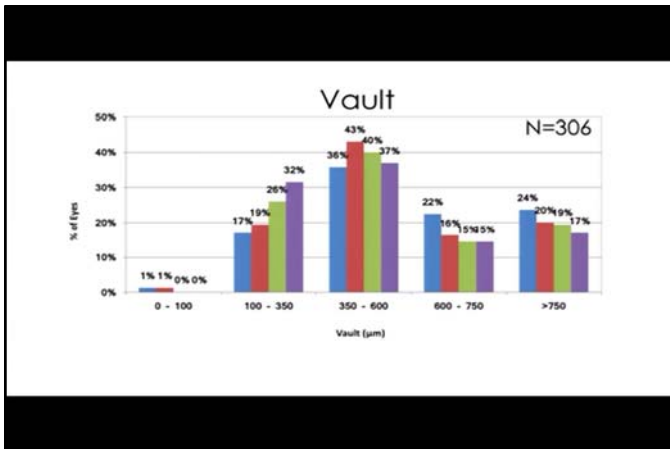
¹ Author information
¹ Dougherty Laser Vision, Camarillo, California, USA. fpex@jcrs.com

Abstract
PURPOSE: To assess the efficacy of high-frequency ultrasound biomicroscopy (UBM) in improving the accuracy of phakic lens (pIOL) sizing by increasing the incidence of acceptable postoperative vault.
SETTING: Multiple private practices, United States.
DESIGN: Evaluation of diagnostic test or technology.
METHODS: This prospective multicenter clinical study evaluated eyes having pIOL (Visian Implantable Collamer Lens) and retrospective data analysis was performed using UBM measurements (OrMaX-1) of preoperative sulcus-to-sulcus (STS) or postoperative vault. The regression data and clinical input from investigators were then used to develop a pIOL sizing nomogram used only STS and pIOL power as variables to determine length. Inadequate vault ($<+90 \mu\text{m}$) and excessive vault (μm) were defined based on peer-reviewed literature. Sizing recommendations using the nomogram were studied prospectively compared with 2 sizing methods used in the United States that are based on white-to-white (WTW) measurements.
RESULTS: One eye was excluded from the analysis because the wrong length pIOL was placed (12.6 mm instead of none recommended 13.2 mm), resulting in 0.1 μm of vault. The mean postoperative vault in the remaining 72 cases was 340 μm (range 90 to 952 μm); there were no cases of inadequate or excessive vault with the newly developed UBM nomogram. Six methods using WTW measurements would have resulted in different-sized pIOLs in 36% to 69% of cases compared with 5 methods.



New Nomogram

Current STS Nomogram	My Current Nomogram
STS	STS:
<11.0 use 12.1	<10.8 use 12.1
11.1 to 12.2 use 12.6	10.8 to 11.7 use 12.6
12.3 to 12.9 use 13.2	11.8 to 12.9 use 13.2
>13.0 use 13.7	>13.0 use 13.7
If power of ICL is -3 to -7.5, go larger at threshold; if power -8 to -16, go smaller at threshold	If Lens Rise <650 or >900, go to respective larger/smaller size when within 0.2 of the STS threshold***
	*Account For Special Anatomy



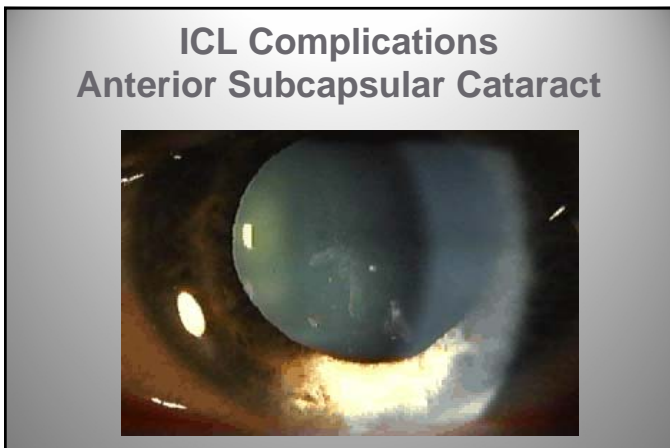
ICL Complications

Cataract

Incidence US FDA study:

1.7% after 7 yrs

All eyes that developed cataracts > -12D




POST-OPERATIVE FOLLOW UP

- Reviewed on day 1 & 7, 6 weeks
- Thorough ocular examination
- Check Manifest refractive error
- ASSESSMENT OF VAULT**
- Central distance between anterior surface of the crystalline lens and posterior surface of the ICL
- Ideal sized ICL will provide a vault of 0.250 to 0.750 mm (1/2 CT to 1 1/2 CT)

Safety Evolution


Data combined with Dr. Alfonso

	V4	V4B	V4c
N	2406	1976	1888
Cases of Cataract	21	12	0
% of cases with cataracts	0.88%	0.61%	0
Years of follow-up	Up to 14 y	Up to 8 y	Up to 4 y



Literature Review V4c Visian ICL

Publications	Follow-Up	N cases	Cataract	Pigment Dispersion	Posterior Blebs	GLT
Shimizu, Br J Ophthalmology 2012 Mar	6 months	20	0	0	0	
Alfonso, J Cataract Refract Surg 2013 Jun	6 months	138	0	0	0	
Gonzalez-Lopez, J Cataract Refract Surg 2013 Dec	1 month	100			0	
Kamiya, J Cataract Refract Surg 2015 Jan	1 year	23	0	0	0	
Alfonso, J Cataract Refract Surg 2015 Apr	6 months	781	0			
Lisa, J Cataract Refract Surg 2015 Jun	1 year	147	0	0	0	
Fernandez-Vigo, AJO 2016	3 months	50	0		0	
Shimizu, Medicine 2016 Apr	5 years	32	0	0	0	
Total		1291				



IOP

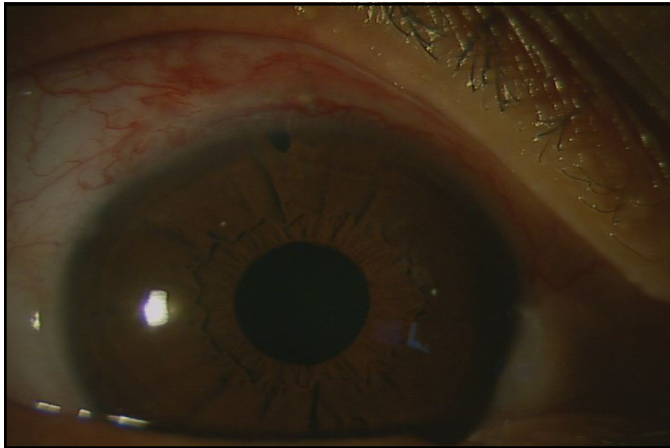
Implantable Collamer Posterior Chamber Intraocular Lenses: A Review of Potential Complications

Paulo Parronchi, PhD; José M. González-Mérida, PhD; David Muñoz-Corcuera, PhD; Teresa Ferrer-Badillo, PhD; Jorge Jorjón, PhD; Roberto Méndez-Medina, PhD

Journal of Refractive Surgery • Vol. 27, No. 10, 2011

Study	No. of Eyes	No. (%)	Potential Cause	Management
Alfonso et al ¹¹	1000	0 (0%)	High angle	Medical treatment
Chou et al ¹²	40	0 (0%)	Shallow	Medical treatment
Chung & Lee ¹³	44	1 (2.3%)	Shallow	Medical treatment
Lawton et al ¹⁴	70	1 (1.4%)	Shallow angle	Medical treatment

Yag Peripheral Iridotomy • Surgical Iridectomy




V4C: Aquaport available internationally

- 0.360mm central hole – no iridotomy required

Strong Points...

- reversibility - removability
- predictability - stability
- quality of vision - optical zone size
- cornea and crystalline lens remain untouched
- predictable calculations and high quality of vision for future premium IOL implantations



Lens Surgery

Better IOL calculations

No changes in corneal quality

The Visian Myopic Implantable Collamer Lens Does Not Significantly Affect Axial Length Measurement With the IOLMaster

Donald R. Sanders, MD, PhD; David A. Bernitsky, MD; Paul J. Hanton, Jr, MD; Robert R. Rivera, MD


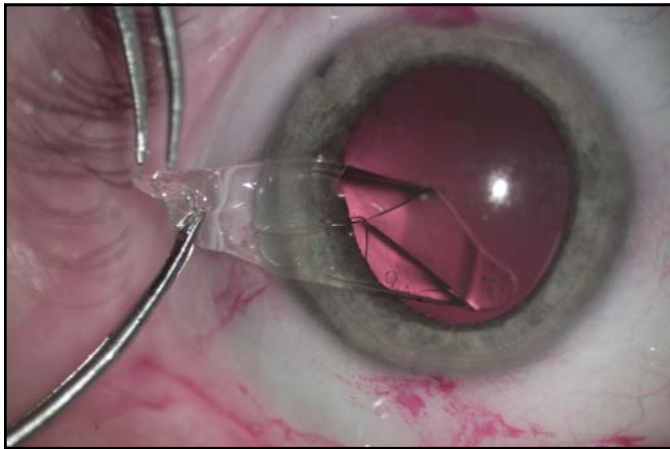
ABSTRACT

PURPOSE: To compare pre- to postoperative axial length measurements with the IOLMaster (Ziemer Ophthalmics Systems) to determine whether a correction factor for laser intraocular lens (IOL) power calculation is necessary with an Implantable Collamer Lens (ICL, STAAR Surgical) in place.

METHODS: The commercially approved Visian ICL was implanted in 60 eyes from 3 separate sites (20 eyes each). Pre- and postoperative axial length measurements were obtained using partial coherence interferometry.


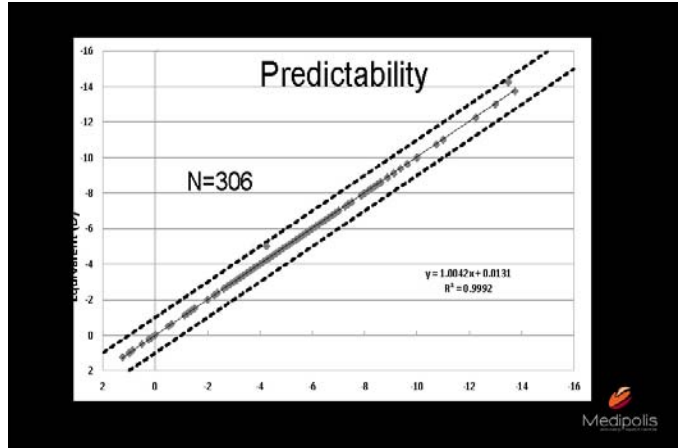
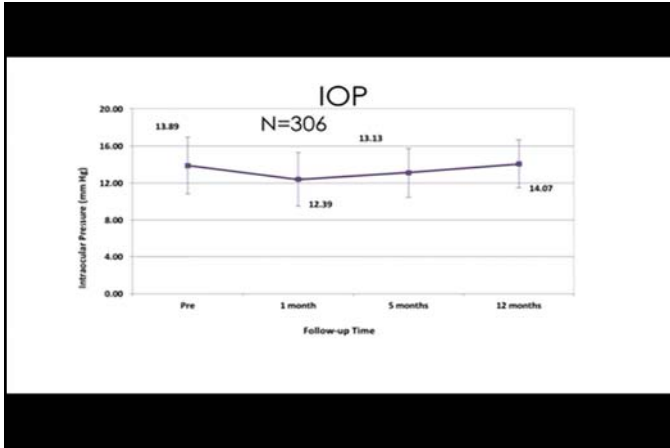
RESULTS: The pre- and postoperative axial lengths were highly correlated with an R² value of 0.9963. For all ranges of axial lengths tested, the use of postoperative axial length instead of preoperative axial length resulted in a ± 0.1-mm error in axial length measurements.

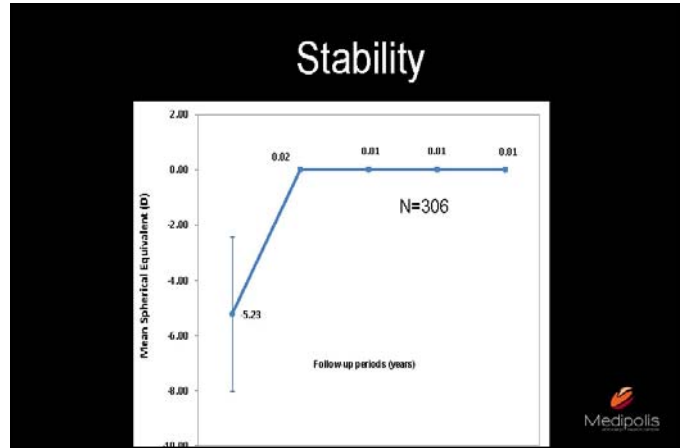
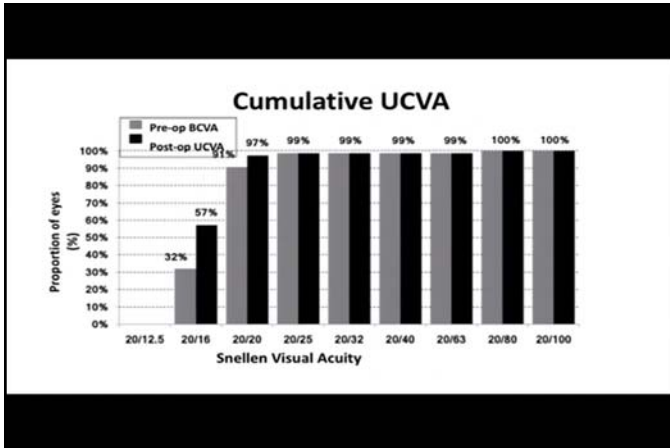
CONCLUSIONS: Based on the SRK formula, a 0.1-mm axial length difference would result in a 0.23-diopter (D) change in calculated IOL power; possibly a 0.20-D change in manifest refraction. These differences are so small as to make any correction to IOL power calculation formula based on the presence of an ICL unnecessary. (J Refract Surg. 2008;24:657-658.)

1469 EVO implants 306 with F-U > 4 years

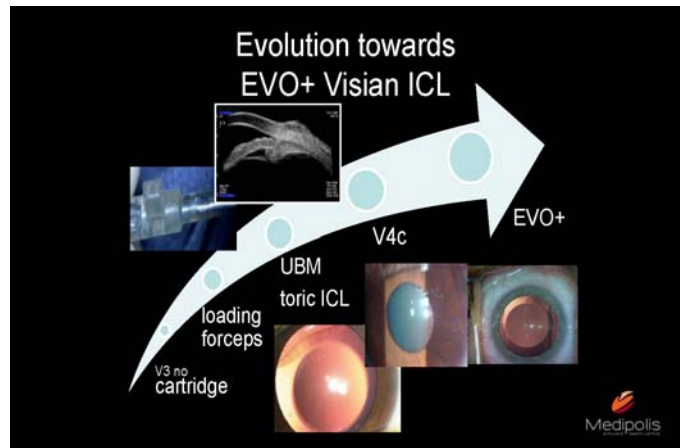
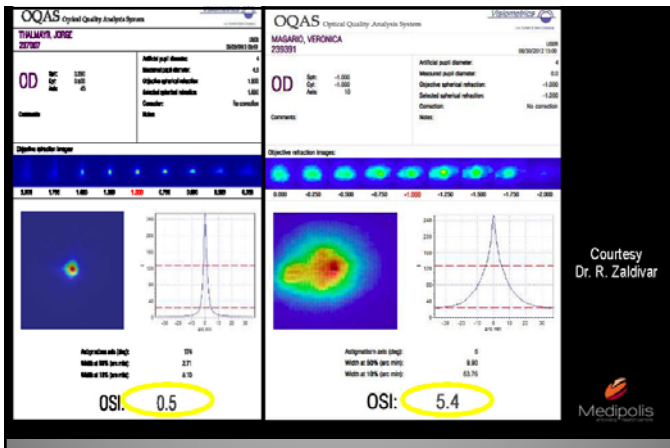
Parameter	Mean±SD (range)
Age (yrs)	31.8±7.6 (19 to 45)
Sphere (D)	-6.97±2.83 (-0.75 to -14.75)
Cylinder (D)	-0.94±0.87 (0 to -4.25)
ACD (mm)	3.24±0.20 (2.80 to 3.71)
WTW (mm)	11.83±0.36 (11.00 to 12.70)
Corneal Pupil (mm)	6.30±0.66 (4.5 to 7.75)
ECC (µm/km ²)	2021.2±771.3 (2295 to 2688)
IOP (mmHg)	13.84±1.38 (8 to 22)

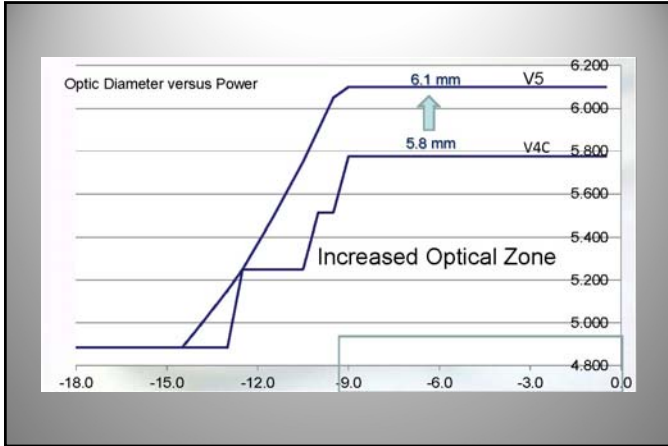





Cornea and crystalline lens remain untouched

- Related issues only for LVC
 - Dry eye
 - Ectasia
 - IOL calculation
 - HOA and premium IOL implantation





US FDA ICL MYOPIA

SAFETY – Cornea Endothelial cell loss

- Consistent with expected loss associated with all intraocular procedures
- Initial acceptable very small loss 0.6% with subsequent remodeling
- Endothelial cell cts stable long term.
- Consistent with healthy, stable cornea endothelium

Long-term Effects of LASIK on Cornea Innervation and Tear Neuropeptides as Associations With Dry Eye

Structural and functional changes in corneal innervation after laser in situ keratomileus and their relationship with dry eye

Journal of Refractive Surgery

August 2016 • Volume 32 • Issue 8 • 518-524

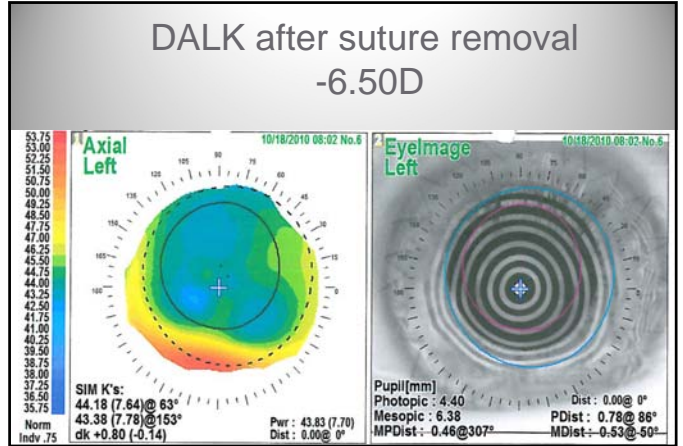
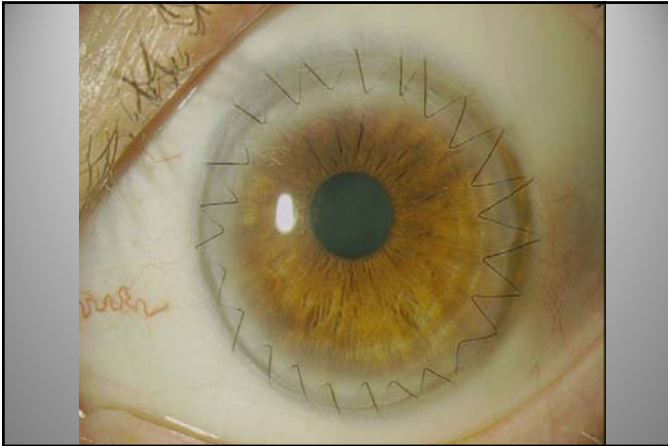
Medipolis logo is in the bottom right.

LVC : Corneal complications

Case 4: Severe Keratoconus

LASIK Ectasia: 48yo male, CL into

-7.0 + 7.0 x 20/50


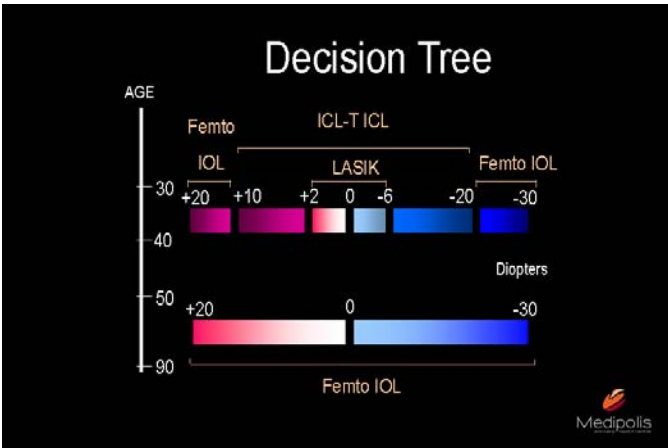


Keratoconus – Dalk - ICL

- DALK: -6.50 + 1.25 x 150 20/40
- ICL : UCVA 20/25

Indications

- every eye suitable for ICL
- unless there is a contra-indication
- LASIK and dry eye = dramatic

Visian ICL

my favorite operation to perform based on the outstanding results.

It is the best vision correction procedure I have ever seen.

Once you chose ICL surgery for your patients, you can look forward to your patients having the best vision that there is.

It will truly change the way your patients see the world!

Toric, Aquaport, EVO+ available internationally

ICL vs LASIK – Patient Selection

- 25 yo - 2.50 OU
- 48 yo - 2.50 OU

ICL vs LASIK – Patient Selection

- 25 yo - 4.00 OU
- 48 yo - 4.00 OU

ICL vs LASIK – Patient Selection

- 25 yo -6.00 OU
- 48 yo -6.00 OU

ICL vs LASIK – Patient Selection

- 25 yo - 7.50 OU
- 45 yo - 7.50 OU

ICL - Case #1

30 yo female

OD -3.75 + 0.25 x 100 20/20
OS - 3.75 + 0.25 x 127 20/20

ICL OU same day sequential

UCVA
OD 20/15-
OS 20/15-
OU 20/15

ICL - Case #2

32 yo male

-5.5 + 0.25 x 100 20/20
-4.0 20/20

ICL OD OS one wk apart

UCVA 1 mo post-op
OD 20/15
OS 20/15

ICL - Case #3

25 yo female

OD -10.5 + 1.25 x 32 20/20
 OS - 11.0 + 0.75 x 169 20/20

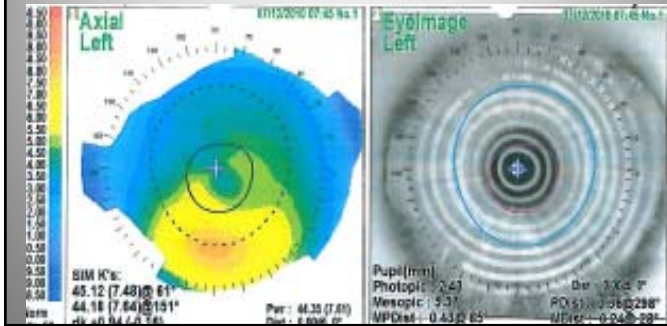
ICL OD OS one wk apart

UCVA 3 mo post-op
 OD 20/15-3
 OS 20/15-3
 OU 20/15-1

ICL + LASIK

- -25.0 D OU 20/50
- ICL OU
- post op – 6.50 OU 20/30!!
- LASIK ?

ICL: keratoconus (irregular astig)
 -8.0 + 0.75 x 80 20/30



keratoconus after ICL combined
 with clear cornea incision

- UCVA: 20/20
- Vs. Pre-op BSCVA 20/30

Mild Keratoconus / Myopia

- Pre-op: -12.50 + 4.50 x 65 20/40
- Post -ICL -0.75 + 0.75 x 90 20/25

-5.00



-7.50 + 3.00 x 90 OU

- K's 40 OU
- LASIK?
- ICL + LASIK?
- Toric ICL EVO+?

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Toric, Aquaport, EVO+ available internationally

Cornea

62 yo cataracts

OD -1.5 + 0.5 x 90 20/50 OS -5.0 + 4.75 x 42 20/70

Keratoconus / LASIK ectasia

