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

Staar Toric ICL
1 to 4 diopters cylinder not available in US
**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 part design of the intracocular collamer lens

OPTH-11620-meta-analysis-and-review—effectiveness—safety—an....

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<th>Study</th>
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<th>Length of ICL (mm)</th>
<th>ICL central</th>
<th>IOL central</th>
<th>Central distance</th>
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Refractive – ICL Sizing - UBM

ST-20 Nomogram
Improving accuracy of phakic intracocular lens sizing using high-frequency ultrasound biomicroscopy.

- Improved accuracy of phakic intracocular lens (ICL) sizing by reducing the width of the ultrasound marker.
- Based on the analysis of 100 eyes treated with ICLs, the Su et al. method showed a mean difference of 0.01 mm compared to the manufacturer-recommended size, with a standard deviation of 0.02 mm.
ICL Complications

Anterior Subcapsular Cataract

1.7% after 7 yrs
All eyes that developed cataracts
> -12D

New Nomogram

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 (½ CT to 1 ½ CT)
USA: ICL Surgical Considerations

Preoperative Yag Peripheral Iridotomy vs. 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
After ICL

After LASIK

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

In daily life

- Pupilometry magnifies pupil by 13%
- Corneal OZ = 1.24 x optical EVO+ diameter
- 6.0 D EVO+ ICL with 6.1 mm optic covers 6.9 mm pupil
- 6.1 mm optical diameter = 7.56 mm corneal OZ

LVC: Corneal complications

Case 4: Severe Keratoconus

LASIK Ectasia: 48yo male, CL intoler
-7.0 + 7.0 x 20/80
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

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

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

- 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+?

Visian ICL

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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

- Donor Cornea
- Recipient 1
- Recipient 2
- SPLITTING
- DALK
- DMEK
- Fuchs’ Endothelial Dystrophy
- Edema
- Desquamated Membrane and Endothelium
- Recipient 1 Scar
- Keratoconus
4/8/2018

Case #4

**RIGHT EYE**

- 64 year old with cataract and RK-induced cornea ectasia
- Progressive hyperopia, irregular astigmatism
- OD: +7.25 + 2.25 x 137   20/70   Pre-op

Running suture removed: Right Eye 7 mos after DALK

- 10 yrs after DALK (10mm diameter)
- 9 yrs after cat extraction with Alcon SN6AT5 IOL
- Uncorrected Distance VA remains 20/20- plano !

Demonstrates EXCELLENT long-term refractive stability!

Richard Erdey, MD

Case #4

**LEFT EYE**

- 64 year old with cataract and RK-induced cornea ectasia
- Progressive hyperopia, irregular astigmatism
- OS: +4.50 + 2.25 x 25   20/30   pre-op

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