

A Prospective Multicenter FDA Clinical Trial to Evaluate the Safety and Effectiveness of an Implantable Contact Lens (ICL) for the Correction of Moderate to High Myopia

Five Year Follow-up

STUDY DESIGN

- Prospective, multicenter study of patients with myopia from $-3.0D$ to $-20.0D$
- Assessment of ICL outcomes based on comparison to baseline and to FDA guidance
- Schedule of study visits
 - Preoperative
 - Days 1 and 7
 - Months 1, 3, 6, 12, 24, 36, 48 & 60

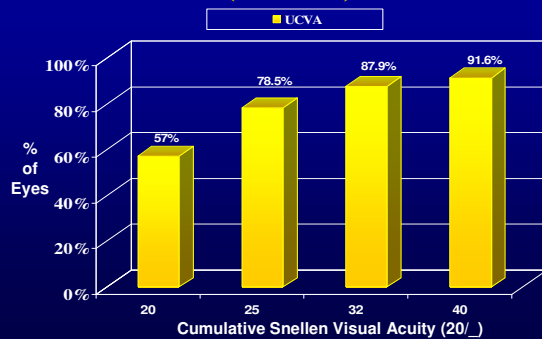
ELIGIBILITY CRITERIA

- 21 to 45 years of age
- BSCVA 20/100 or better
- $\leq 2.5D$ of refractive cylinder
- Stable refraction (change in MRSE of $\leq 0.5D$)
- No previous refractive surgery (except for astigmatic keratotomy)
- No visually significant lens opacities

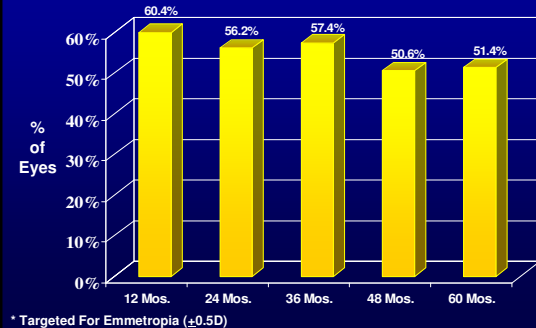
UNCORRECTED DISTANCE VISUAL ACUITY

- UCVA at 5 years
 - Eyes with preoperative BSCVA 20/20 or better
 - Postop UCVA equal to or better than preop BSCVA

UCVA IF PRE-OP BSCVA 20/20* (N = 141)



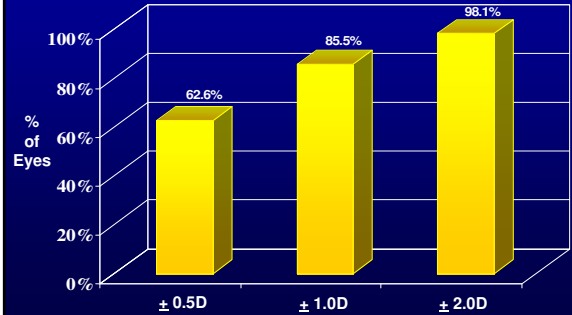
CASES WITH POST-OP UCVA EQUAL TO OR BETTER THAN PRE-OP BSCVA *



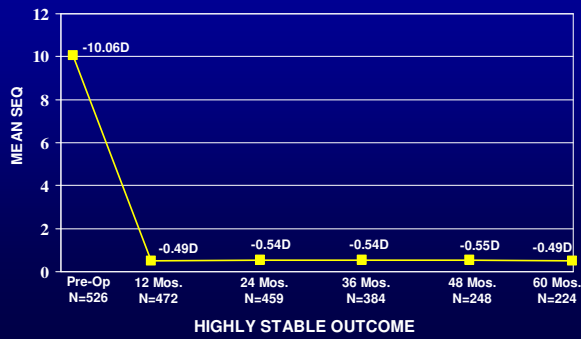
REFRACTIVE PREDICTABILITY

- Attempted vs achieved MRSE
 - Within $\pm 0.50D$ of target MRSE at 5 years
 - Within $\pm 1.00D$ of target MRSE at 5 years
- Mean MRSE over time

ATTEMPTED vs. ACHIEVED CORRECTION



MEAN SPHERICAL EQUIVALENT WITH TIME

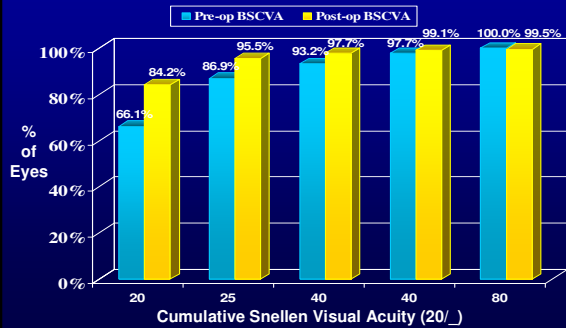


BEST CORRECTED DISTANCE VISUAL ACUITY

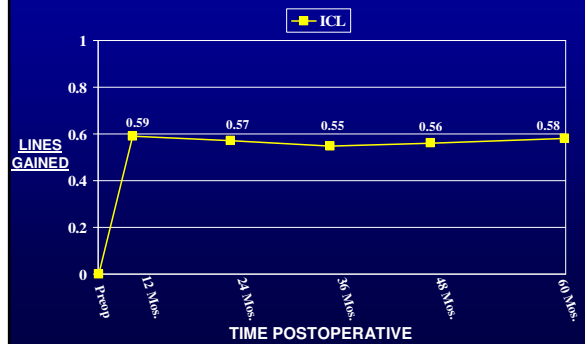
- BSCVA at 5 years
 - Preop BSCVA vs. 5 year postop BSCVA
 - Mean line change in BSCVA from preop over time
 - Line change in BSCVA preop to 5 years postop

PRE-OP BSCVA vs. 5 YEAR POST-OP BSCVA *

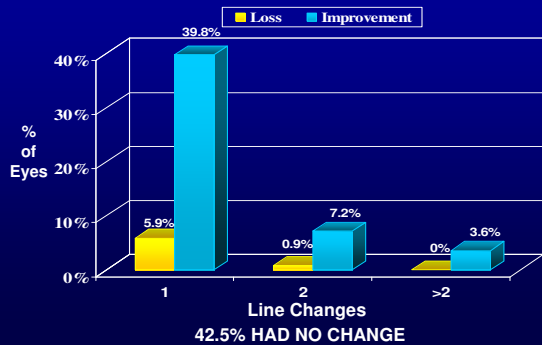
N = 221



CHANGE IN BSCVA FROM PRE-OP MEAN LINE CHANGE

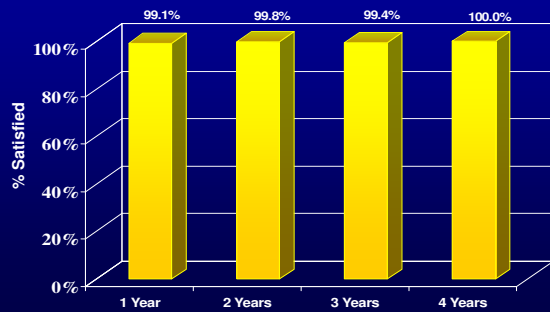


CHANGE IN BSCVA PRE-OP TO 5 YEARS POST-OP



PATIENT SATISFACTION

PATIENT SATISFACTION



COMPLICATIONS

No new complications other than cataract were reported since the 3 year data was submitted to the FDA for approval of the ICL

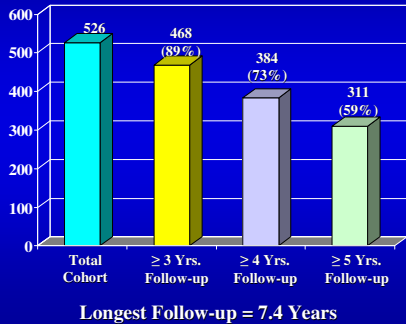
SUMMARY

- The effectiveness data at 5 years postop establishes the effectiveness of the Myopic ICL for the correction of myopia between -3.0 to -20.0 D
- Clinical outcomes also substantiate the overall safety of the Myopic ICL in this moderate to high myopic patient population

ANTERIOR SUBCAPSULAR (AS) LENS OPACITIES AND CLINICALLY SIGNIFICANT CATARACTS IN THE VISION ICL FDA CLINICAL TRIAL AND OPHTHALMIC LITERATURE

Donald Sanders, M.D., Ph.D.

**FOLLOW-UP IN VISIAN ICL
U.S. FDA TRIAL**



**CLINICALLY SIGNIFICANT
CATARACT**

- Loss of ≥ 2 Lines BSCVA
and/or
- Increase In Glare Symptoms
Concurrent with Development
of AS opacity
and/or
- Cataract Extraction

**CLINICALLY SIGNIFICANT AS
CATARACTS**

TO DATE, ONLY 7 (1.3%) CLINICALLY
SIGNIFICANT ANTERIOR
SUBCAPSULAR (AS) CATARACTS
HAVE BEEN OBSERVED IN
U.S. FDA TRIAL

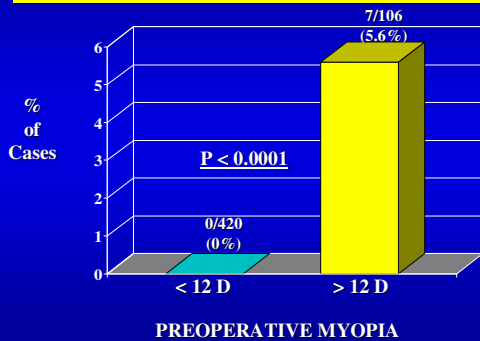
**CLINICALLY SIGNIFICANT AS
CATARACTS**

Average Pre-op Myopia = 16.4D

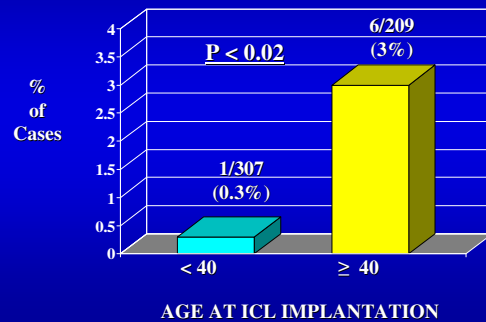
Range = - 12.75D to - 20D

No AS Cataract In Cases With Myopia
Of $< 12.75D$

**CLINICALLY SIGNIFICANT AS
CATARACT VS PREOP MYOPIA**



**CLINICALLY SIGNIFICANT AS
CATARACT VS PATIENT AGE**



ALL 7 AS CATARACTS HAD REMOVAL & IOL IMPLANTATION

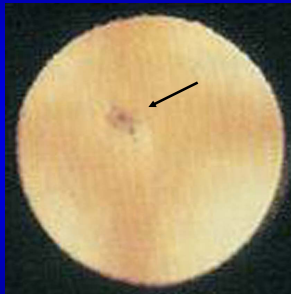
BSCVA Compared To Pre ICL
Implantation:

- 1 (14%) Improved 2 Lines
- 3 (43%) Improved 1 Line
- 3 (43%) Unchanged

SUMMARY – AS CATARACT IN U.S. FDA TRIAL

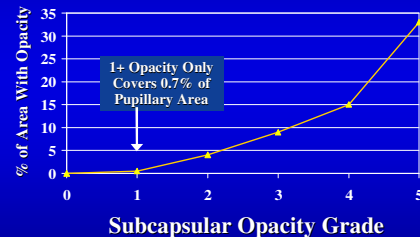
- 7/526 (1.3%) Incidence
- All Had $\geq 12.75D$ Pre-op Myopia
- None Of The 420 Cases With $< 12.75D$ Pre-op Myopia Had AS Cataract
- Cataract Incidence 10 Times Greater For Patients ≥ 40 Years Old (3% Vs. 0.3%)
- None Lost BSCVA After Cataract Extraction, Compared To Pre-ICL

ANTERIOR SUBCAPSULAR OPACITIES GRADE 1 (TRACE) LOCS SCALE



Photograph From Chylack, LT, Wolfe, JK, Singer DM et al. The Lens Opacities Classification System III. 1993, 111: 831-836

RELATIONSHIP BETWEEN AREA OF OPACITY AND LOCS III OPACITY GRADE



*From Chylack et al

ALL AS OPACITIES SYMPTOMATIC & ASYMPTOMATIC

TO DATE, 31 (5.9%) CASES HAD
AS OPACITIES OF TRACE
(1+ OUT OF 5.9+) OR MORE

Two Papers In The Peer-reviewed
Literature Report Significantly Higher
Rates Of “Cataract” With ICL Surgery

Gonvers, et. al. J Cat Ref Surg 2003 29;948
Lackner, et.a. Ophthalmol 110 (11); 2 2153

Gonvers, et. al. - J Cat Ref Surg

Reported:

- 20/75 (27%) Symptomatic and Asymptomatic AS Opacities Which They Called “Cataracts”
- 2/75 (2.7%) Clinically Significant Cataracts Associated With Visual Loss

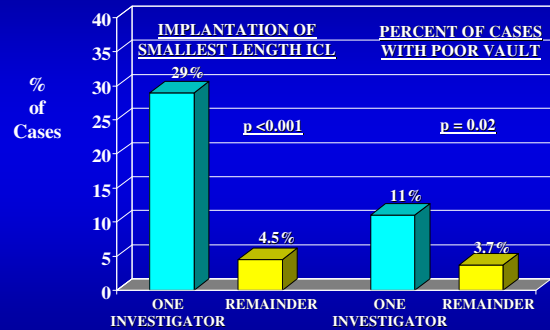
Gonvers, et. al. - J Cat Ref Surg

- Study Combined 24 V3 ICLs and 51 V4 (Visian) ICLs
- Claimed No Difference In Vaulting Between V3 and V4
- Implanted ICLs On Average 0.5mm Smaller Than Recommended By STAAR

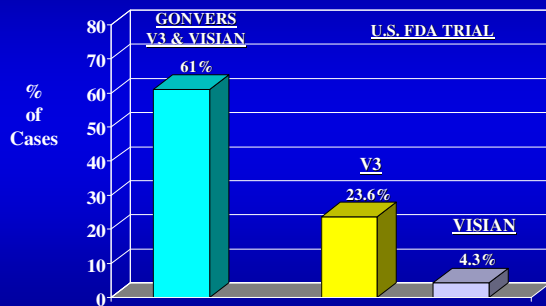
Gonvers, et. al. - J Cat Ref Surg

- All 20 Cases With AS Opacities Had Vault \leq 90 Microns
- In the 20 Cases With AS Opacities, Patients Up to 62 Years Old Were Implanted (Average =42 Years). Patients With Age $>$ 40 Had 3 Times the AS Opacity Rate As Those $<$ 40 Years Old ($p < 0.02$)
- Mean ICL Power Implanted Was 17.6D, So The Group Was Highly Myopic.

U.S. FDA TRIAL



PERCENT OF CASES WITH POOR VAULT



SUMMARY - Gonvers, et. al.

- ICLs Implanted Were Too Small And Had A High Incidence Of Poor Vault.
- Mix Of Current And Discontinued ICL Designs Studied
- Patients Were Very Highly Myopic
- Patients Implanted Up To 62 Years Old
- In Spite Of All This, Clinically Significant Cataract Rate Was Only 2.7%

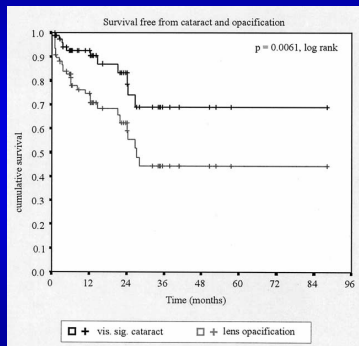
Lackner, et. al. - Ophthalmology

- Studied 75 ICL Patients (65 Myopes – 10 Hyperopes)
- 6 Different ICL Designs Including 4 Discontinued And Prototype Models Were Studied Together (Including V3)
- Although The Authors State That There Was No Significant Difference Between ICL Designs, Type II Statistical Error (a False Negative Outcome) Is Very High With This Sample Size and Number of Groups

Lackner, et. al. - Ophthalmology

- Clinically Significant Cataract = 17.3%
- Patients Up To Age 60 Years Allowed – Age Was Shown To Be A Risk Factor
- Average Myopia In Entire Population Was -16.23D
- While Patients Were Followed For Up To 7 ½ Years, No New Opacities Or Cataracts Occurred After 2 ¼ Years

Lackner, et. al. - Ophthalmology



SUMMARY - Lackner, et. al.

- Visian ICL Data Not Separated From Older Discontinued Designs So Cataract Rate Not Known
- Much Older And More Myopic Patients Than In U.S. FDA Trial Were Studied
- Surgical Trauma Not Ruled Out As Causative Factor

SUMMARY

- 5 Year ICL Outcomes in U.S FDA Study Are Excellent with Low (1.3%) Cataract Rate
- Studies Demonstrating High Cataract Rates Contain Patients With Discontinued ICL Designs, VERY High Myopia, and Much Older Patients Than the U.S FDA Trial