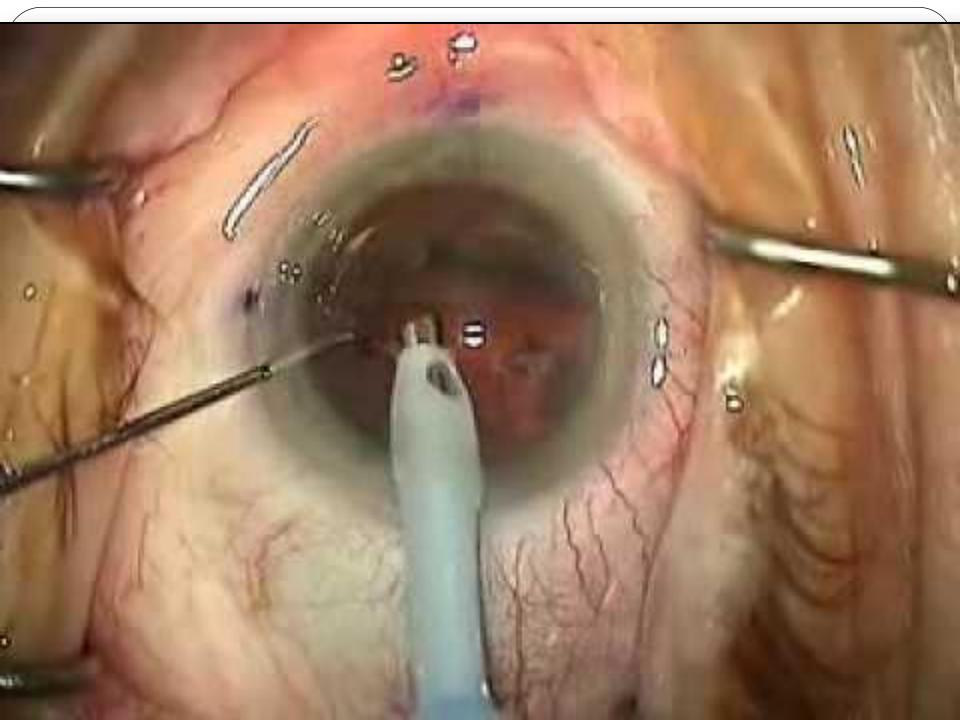
Ten New Innovations In Eye Care

Jim Owen, OD, MBA, FAAO









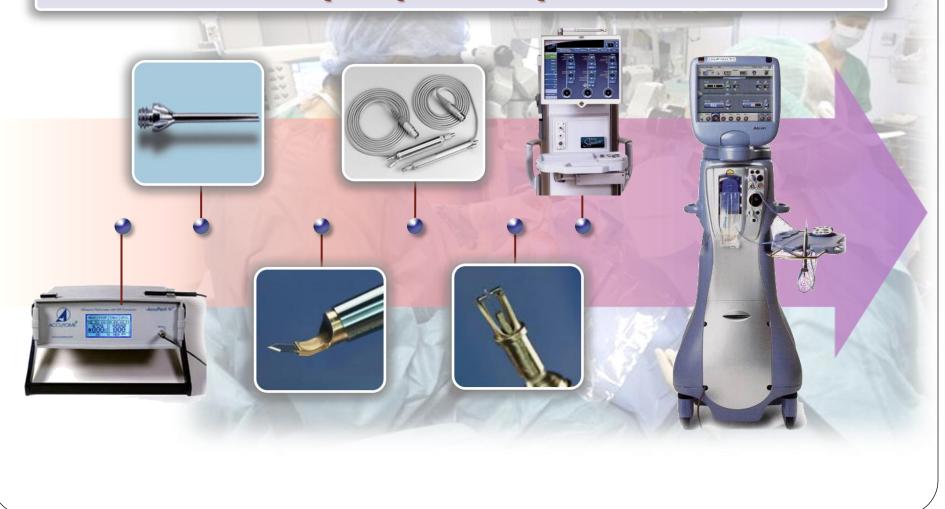
First Innovation

Automating Cataract Surgery



Current Manual Cataract Surgery

Multiple steps and multiple devices



Limitations of Manual Cataract Surgery • Visual Outcomes

- Distance Correction Predictability Far less than that of LASIK
 - Astigmatism Correction
 - Effective Power of IOL
 - Limits Presbyopia Correction
- Safety 0
 - Complications > LASIK
- **Surgeon Confidence** 0
 - Critical for Widespread Adoption



Common	Incidence	Vision Threatening	Incidence
Posterior Capsular Opacification	10-30%	Retinal Detachment 0.6-1.7 %	
Cystoid Macular Edema (transient)	2-10%	Cystoid Macular Edema (persistent) 1-2%	
Vitreous Loss	1-5%	IOL Malposition 0.3%	
Corneal Endothelial Cell Loss	4-10%	Need for Corneal Transplant 0.3%	
		Endopthalmitis	0.1%

Manual Cataract Surgery

- Corneal Incisions
- Capsulotomy
- Lens Removal
- IOL Implantation

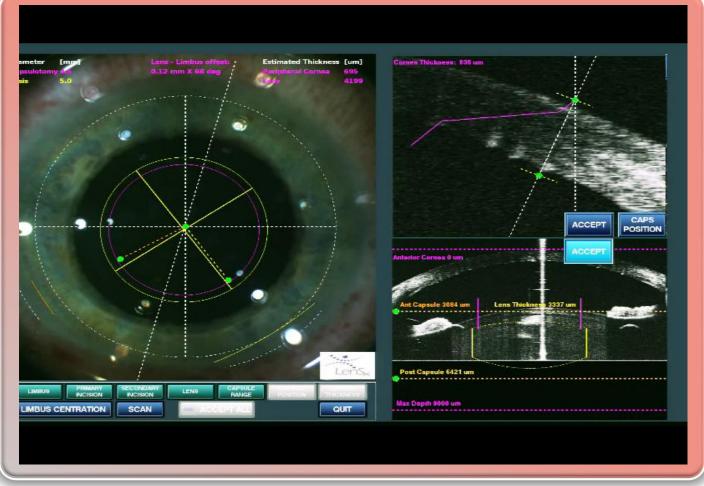


01/04/2013

Pre-Production Model Complete & In Clinical Use



Intuitive Software Control Delivers Image-Guided Surgery



Procedure Precision & Integration

Technology Summary

- 2 systems in clinical use
 - Europe and USA
- >500 cases, fully sighted eyes, lens, capsule and cornea





Image-Guided Laser Cataract Surgery

- Micron Level Precision and Reproducibility
- Key Steps Performed in Low Stress "Closed Eye"
- Unparalleled Procedure
 Flexibility and Innovation

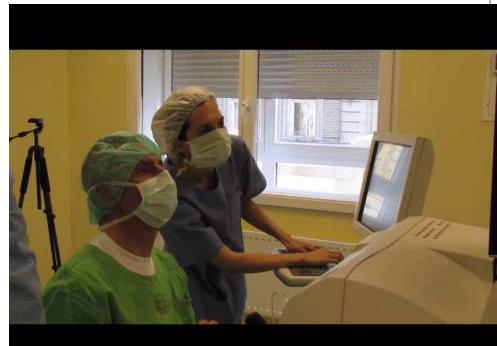


01/04/2013

Image-Guided Laser Cataract Surgery



The lens liquefaction and fragmentation is not available for sale in the United States



LenSx Lasers, Inc.

01/04/2013

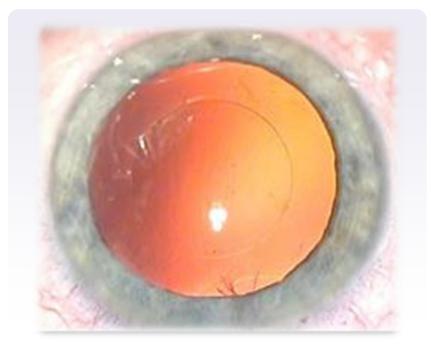
Goals of Laser Cataract Surgery

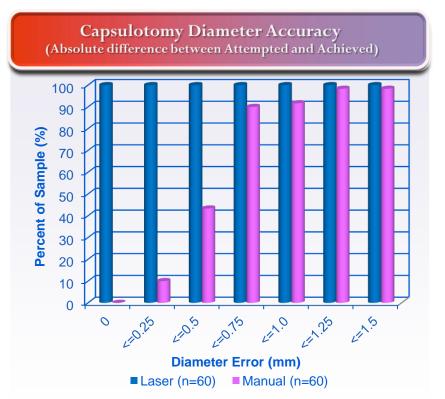
• Improve Every Procedure, Technology and Surgeon

- Presbyopia, Astigmatism & Monofocal
- Refractive Precision and Integration

Key Step	Current Surgery	Refractive Impact	Safety Impact
Corneal Incision	Underutilized	Astigmatism	Infection
	Not Optimized		
Capsulorhexis	Variable Sized,	Variable IOL Position &	Capsular Tears,
	Not Centered	Effective Lens Power	Posterior Capsule Opacification
Lens Fragmentation	Excessive Ultrasound Power	Delayed visual recovery	Loss of endothelial cells,
			Capsule Rupture

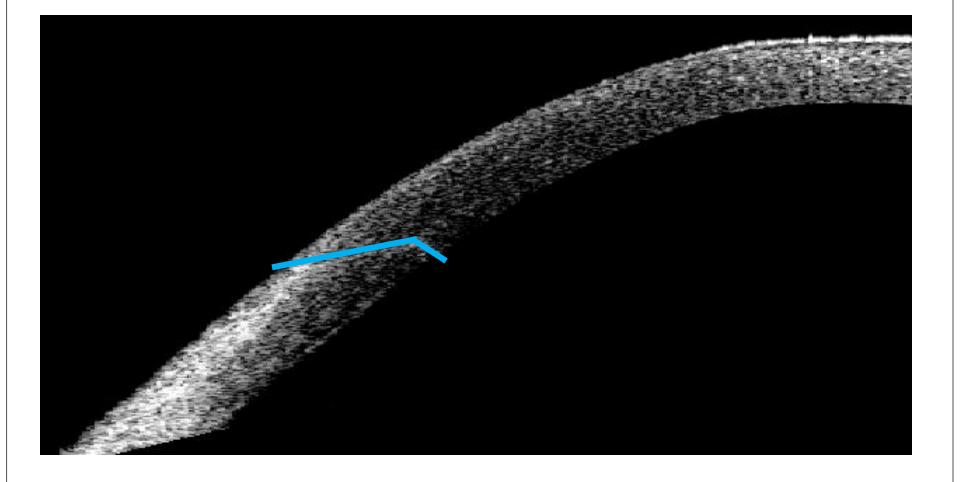
Visibility to Better Medicine





- Two fold reduction in IOL position
- Major opportunity for improvement in retractive correction

2 Weeks PostOp OCT



Conclusions

- Femtosecond laser applications in liquefaction was safe, effective and efficient
- Capsulotomy size, shape and reproducibility was statistically improved over manual techniques
- Corneal incisions were reproducible and had precise dimensions and geometry
- A refractive capsulotomy (perfect shape, size, centration), liquefied lens removal with simple I/A, plus the precision of laser-created corneal incisions may enable surgeons to design and deliver an entirely new level of refractive cataract surgery.

Second Innovation

Replacing Our Natural Lens

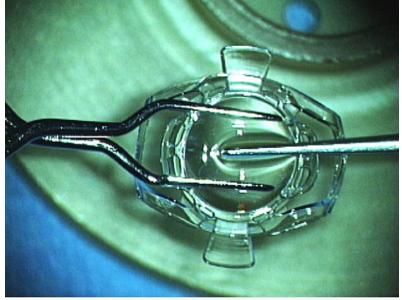


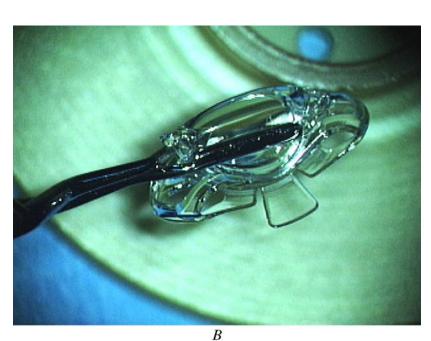
Synchrony Dual Optic IOL

- Single-piece, silicone IOL
- 5.5 mm high plus anterior optic (+32 D)
- 6.0 mm variable negative posterior optic
- Optics connected by spring haptics
- Size 9.5 mm x 9.8 mm

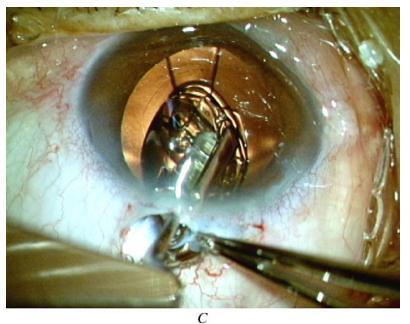


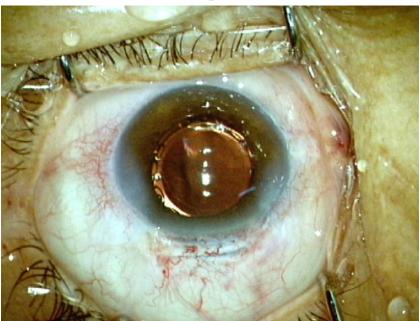
• Theoretical accommodation 3.5 D with 1.5 mm of anterior lens movement





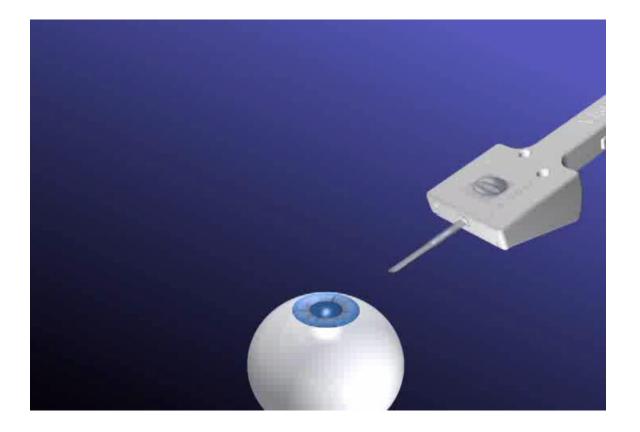
A





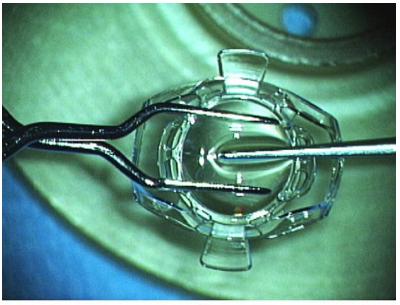


Synchrony Video



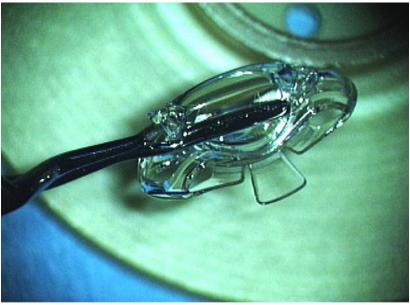
Synchrony dual-optic accommodating intraocular lens Part 2: Pilot clinical evaluation

- Enrolled patients older than 40 with visual significant cataracts and less than 2.00 D of corneal cylinder
- 26 Eyes of 21 Patients
- 67% Female
- All Hispanic



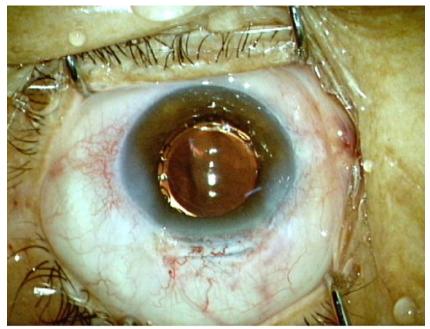
Results - Distance

- No loss of BCVA in all eyes
- Mean SE -0.52 (+/- 0.77D)
- 50 % within +/- (0.50)
- 79.4% 20/40 or better



Results - Near

- 95.8 % J3 or Better
- Minimal add to J1 +0.75
- All stable at 1 and 2 years

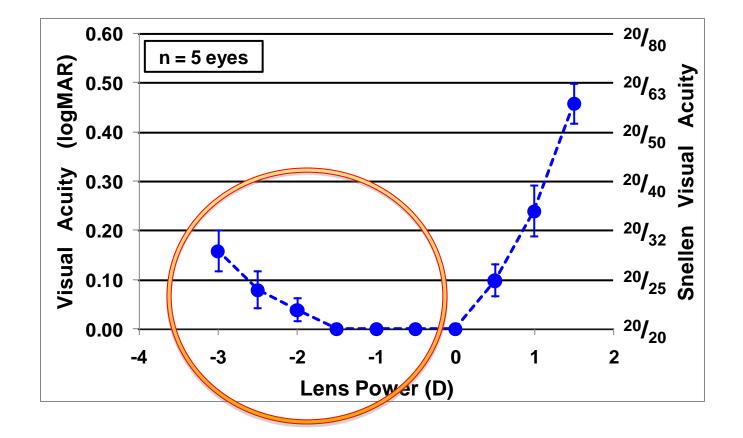


Methods: Subjective Testing

- Subjective tests performed at the 2 year visit
 - Distance-corrected near VA
 - Push Down accommodative amplitude
 - Defocus curve (-3.0 D to +1.5D in 0.5 D steps)
- Tests repeated at the 3 year visit
 - Distance-corrected near VA
 - Push Down accommodative amplitude
- All subjective tests performed with distance correction in place.

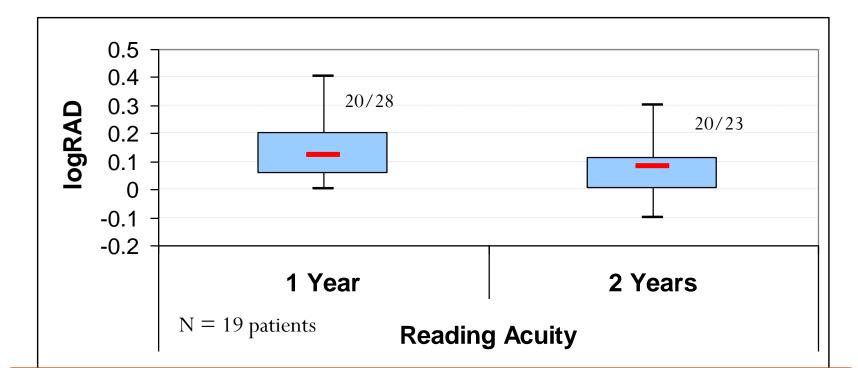
Results: Subjective Testing

• Defocus curve confirms Push Down amplitude of accommodation



Bilateral Synchrony

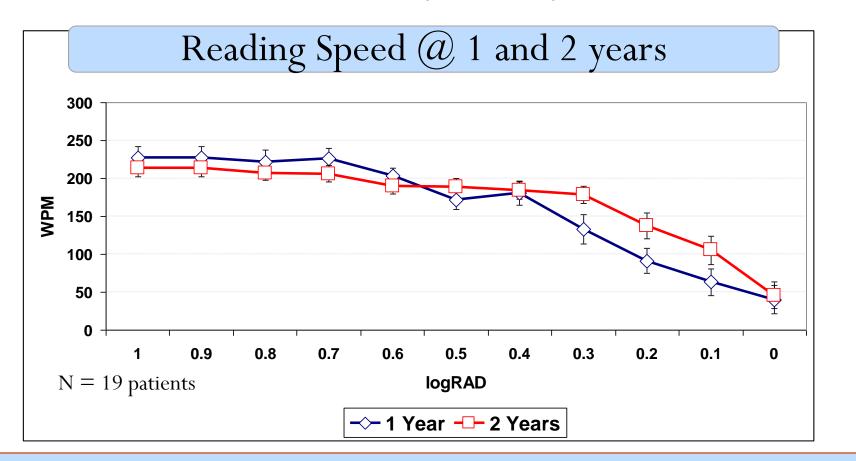
BCDVA Reading Acuity @ 1 and 2 years



Mean Reading Acuity at 1 year was 0.15 logRAD (SD 0.13), and at the 2 year follow-up improved to 0.07 logRAD (SD 0.11). This difference was found to be statistically significant (p< 0.01).

VICTOR BOHORQUEZ, MD., ASCRS 2009

Bilateral Synchrony



Higher (better) scores were seen at smaller font sizes (0.3 and below) at the 2 year follow-up. This difference was statistically significant (p<0.001)

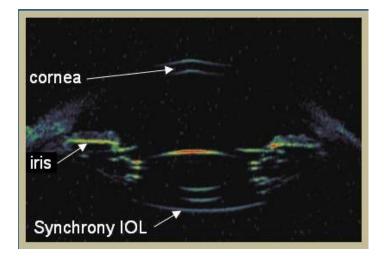
VICTOR BOHORQUEZ, MD, ASCRS 2009

Long Term Objective Evidence of Accommodation of the Synchrony Dual Optic IOL

David Chang, M.D., Ricardo Alarcon, M.D., Victor Bohorquez, M.D, ASCRS 2010

Methods: Objective Testing

• 5 eyes with demonstrated UBM accommodation at 1 year were evaluated at 2 and 3 years with iTrace wavefront aberrometer



UBM @ 1 year



iTrace @ 2 & 3 years

Methods: Objective Testing

• UBM

 Front and back optic position were compared between cycloplegic and near states

• iTrace

- Measurements were performed for a 3 mm pupil
- Average of 3 measurements at cycloplegic and near states were obtained for each patient
- Refractive maps of the average measurements were created

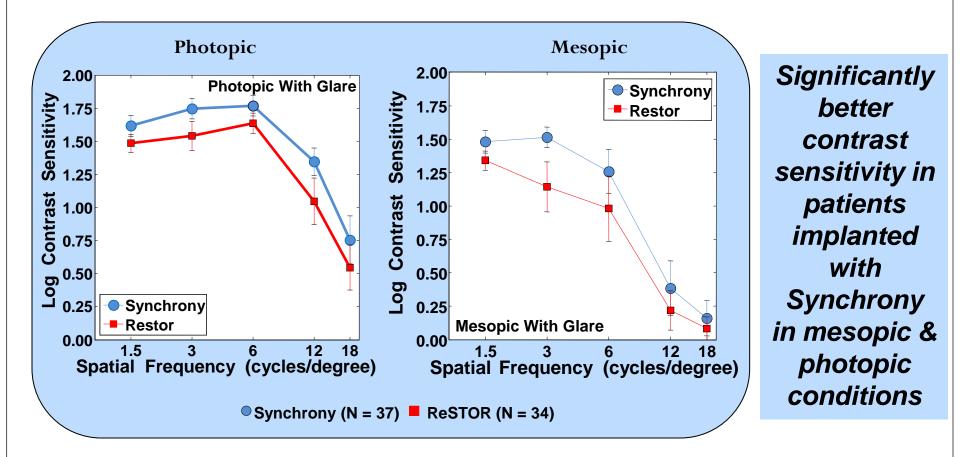
Synchrony vs. ReSTOR Randomized Double-masked Multicenter Clinical Study

- Study Design
 - Randomly assigned to receive binocular Synchrony or ReSTOR
 - 50 subjects (100 eyes) in each arm
 - Patient and technician are masked

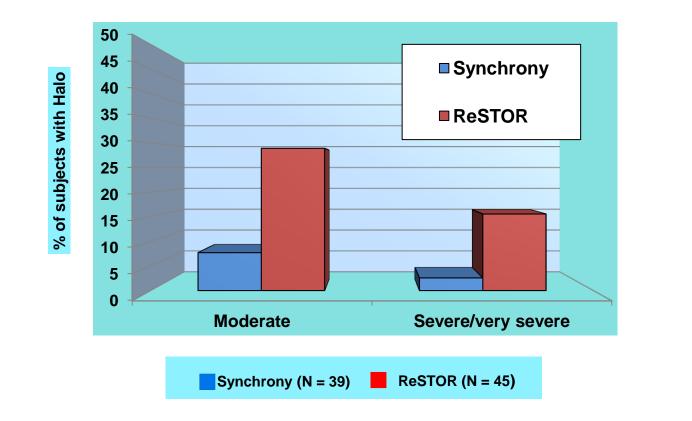
Ivan Ossma, MD, MPH, Victor Bohorquez, MD, Ricardo Alarcon, MD, Andrea Galvis, MD, ASCRS 2009

Contrast Sensitivity

1 Year Results

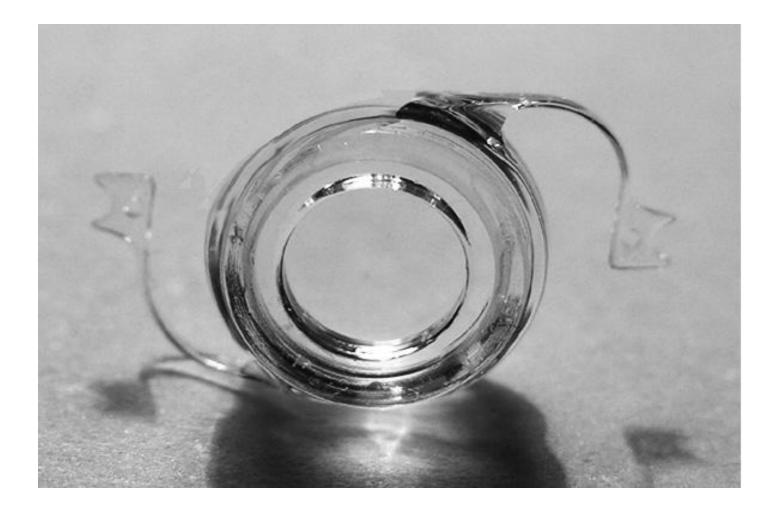


Synchrony vs. ReSTOR Halos at 1 Year



Significantly lower rates of Halos with Synchrony vs. ReSTOR at 1 year

Nu Lens



Purpose

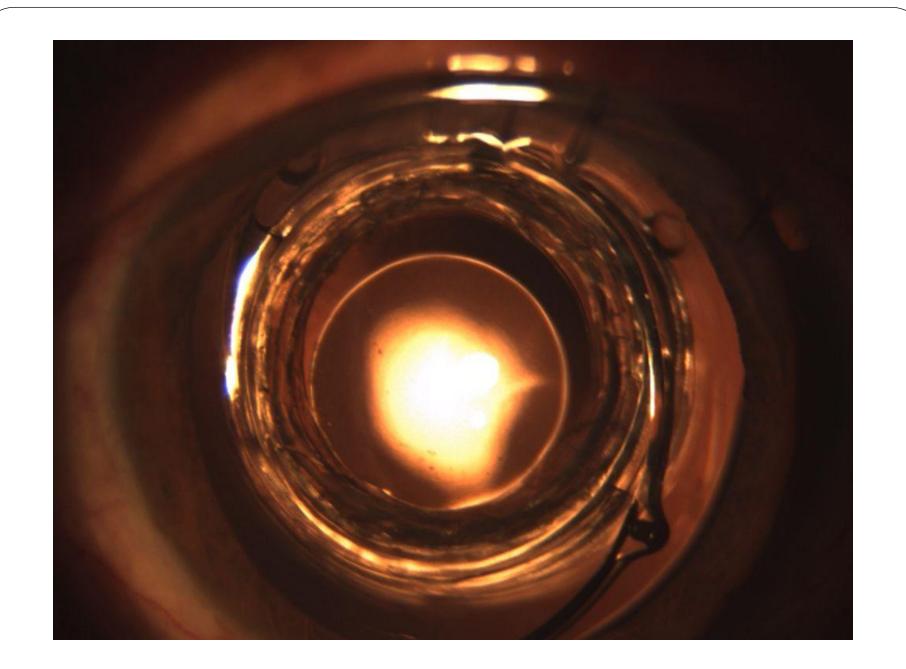
- To evaluate the accommodative range of the NuLens AIOL in
 5 patients and to study its behavior and biomechanics in 5 eyes
- Implanted by one experience surgeon (L. Izquierdo) at Oftalmosalud Eye Institute Lima-Peru.

Material and Methods

- Material and Methods: 5 eyes of patients range between 27 and 65 years old,
- 4 women and 1 men,
- No corneal pathology who had impaired vision in one eye due to amblyopia (4 high myops and 1 cataract patient).

Results

- Pre-Implantation values:
 - sphere -5.60 cylinder -2.55,
 - LogMar BCVA (media 0.6520)
 - Near VA at 40cm (media 12.25).
- Post-Implantation values:
 - sphere -0.45 cylinder -2.50
 - LogMar BCVA (0.7380)
 - near VA at 40cm (media 14.50).
- Accommodative range: 6.00 Diopters. p=0.0000 (See Table).



Zonule implatation of the haptic of the NULENS AIOL

Conclusions

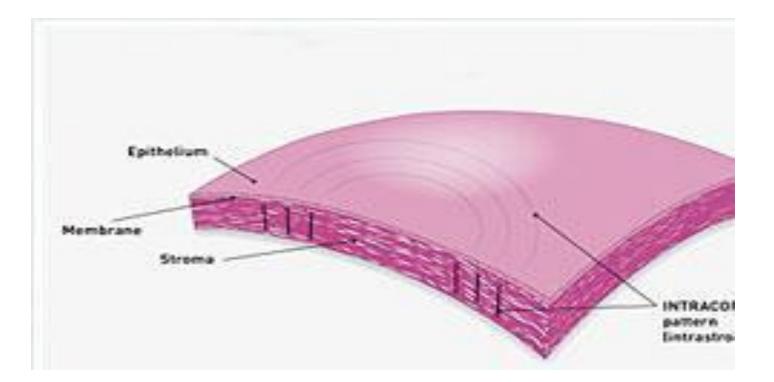
- This is a new technology which seems to be an alternative in the future to achieve more accommodative range and therefore a better quality of vision. We are still working in adjusting the power of the AIOL and its size to improve its biomechanics inside of the eye.
- NuLens demonstrated to have an accommodative range of 6 Diopters in all patients studied so far and a central positioning without damaging any anterior and posterior chamber structures of the eye.

Third Innovation

Can You Do That on the Cornea



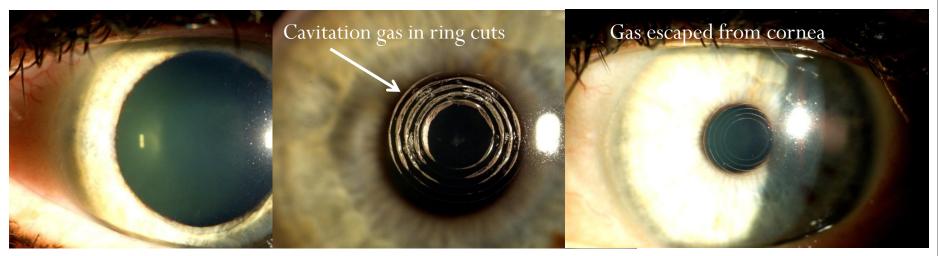
Intracor Procedure



Video



INTRACOR Presbyopia



4 days preop

1 hour postop

1 day postop



4 days preop Mike P. Holzer, MD

Evaluation Study Design

- 132 eyes 6 months follow up
- Average age 52.8 (44-67)
- Bilateral Procedure



Results

- Distance Corrected Near Vision
 - Pre-op average J8
 - 3 months average J2
- Uncorrected Near Vision
 - 97.6% J3 or better
- Uncorrected Distance and Near
 - 93.75% J3 and 20/25

Results

- Wavefront Data
 - Pre-op HO RMS 0.24
 - Post-op HO RMS 0.21
- Spherical Abberation
 - Pre-op 0.080
 - Post-op -0.065

• No change in Pachymetry, Hysteresis, Endothelial Cell Count

Summary: INTRACOR

- High potential for correction of presbyopia
- Non invasive \rightarrow very low risk for infections
 - Stable refractive outcome during follow up period
 - Significant gain in uncorrected near visual acuity
 - Slight central steepening and negative q-value
- No weakening of cornea
- Future treatments: low myopia / hyperopia / astigmatism, retreatments of remaining refractive errors following IOL- or Excimer Laser Surgery

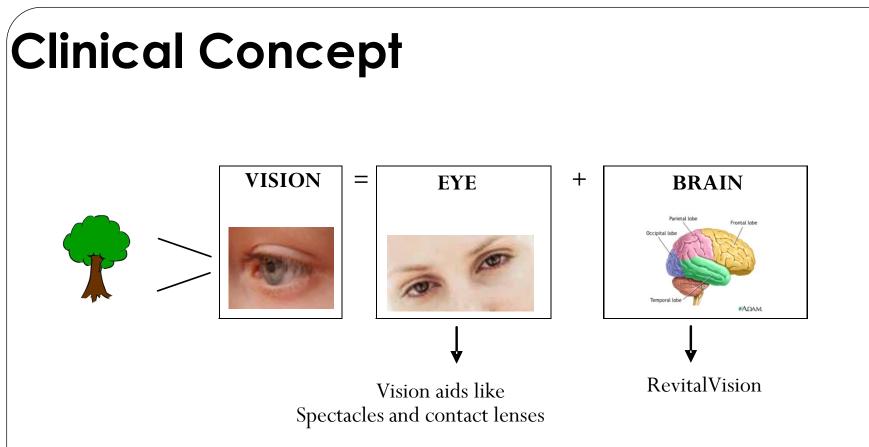
FORTH INNOVATION

Computer Based Cortical Vision Training



Company History

- Originally developed in Israel in 1999.
- US FDA 510(K) approval given in August 2001 for the treatment of amblyopia.
- Relocated to Singapore in 2004 under the company name NeuroVision, Inc.
 - due to government interest in the treatment of pediatric myopia in the Asian Pacific Region.
- Purchased by RevitalVision LLC in 2009 and operations were relocated to Lawrence, Kansas.

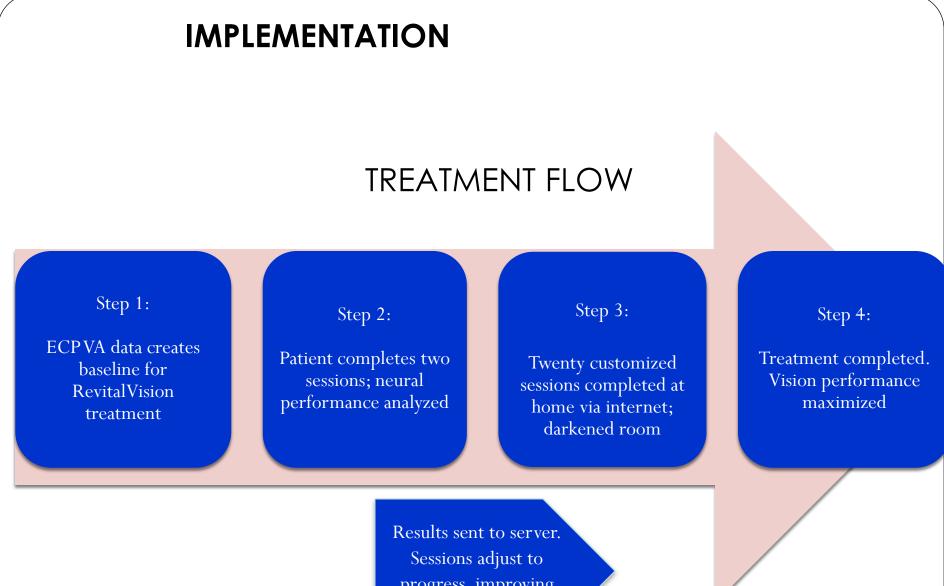


- RevitalVision optimizes cortical visual processing
- Neurologically trains the brain to see better

PRESENT PRODUCT OFFERINGS



OTHER PRODUCTS ON THE MARKET: Sports Vision, Night Driving, Low Myopia, Amblyopia

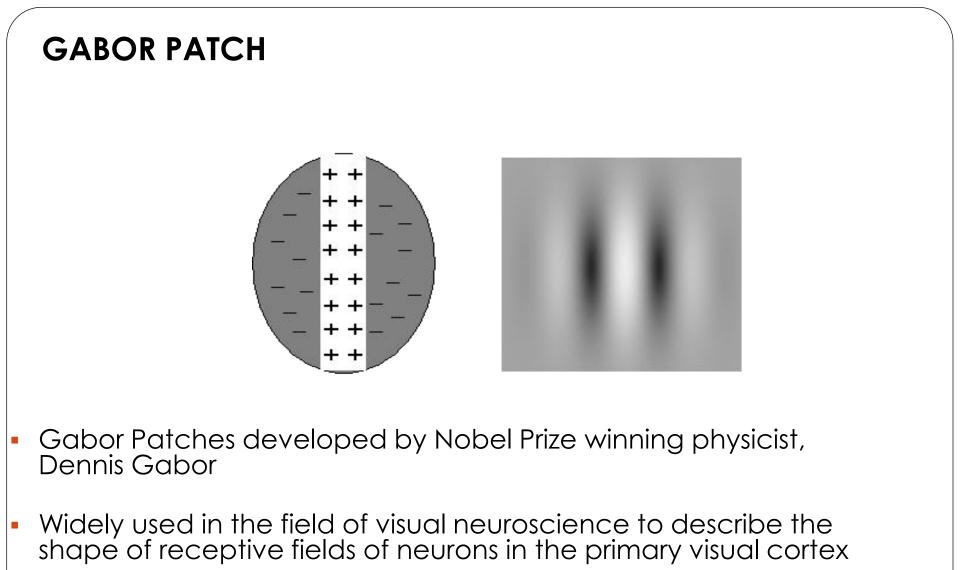


progress, improving neural performance

SCIENTIFIC BUILDING BLOCKS

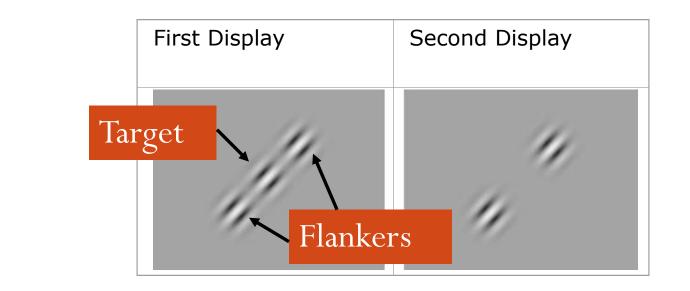
- Neuronal lateral interactions
- Gabor patch visual stimulus
- Use of flankers
- Perceptual learning
- Brain plasticity





Represent the most effective stimulus target for the primary visual cortex

FLANKERS



The software measures the contrast threshold of a Gabor target with the presence of flankers

 The patient is exposed to two short displays in succession and the patient identifies which display contains three Gabors

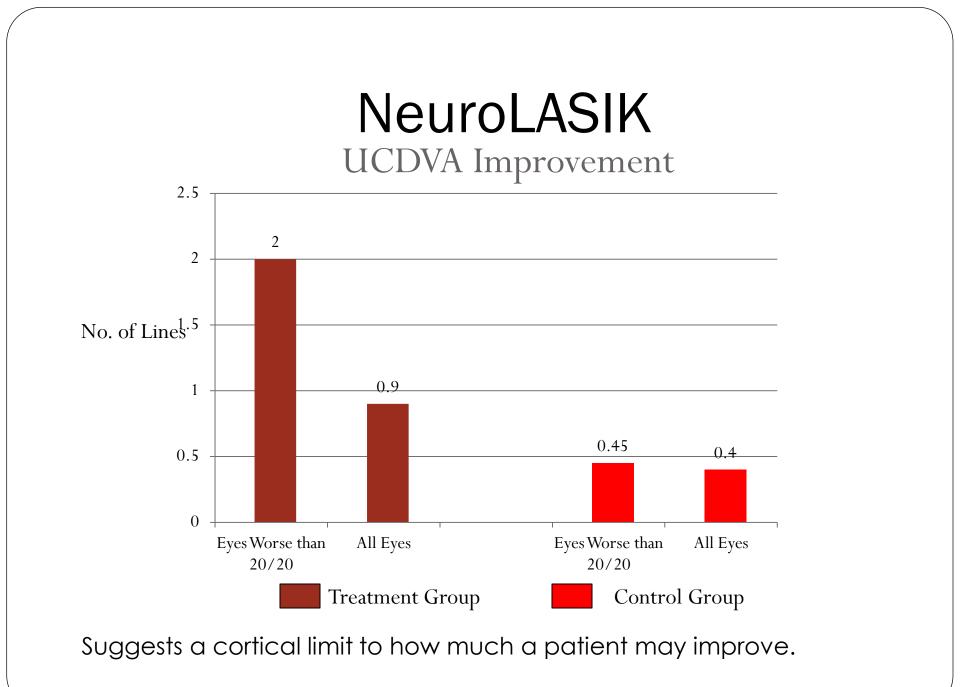
Clinical Research Summary

Polat U, Naim TM, Belkin M, Sagi D. PSNA 2004;101:17:6692-6697.

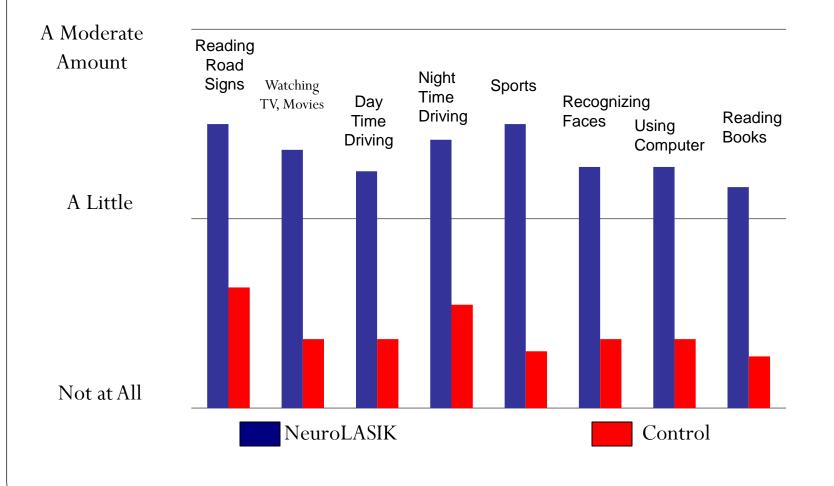
- Studied 54 adult amblyopic patients who were randomized to amblyopic cortical vision training or a placebo vision-training program.
- Pretreatment visual acuity improved by 2.5 lines to 20/30 in the cortical training treatment group, with no improvement in the control group.
- The cortical vision training group experienced a commensurate increase in CSF to within the normal range.
- These improvements in acuity and CSF were sustained after 12 months.

Durrie, D. Slade, S. Waring IV, G. 2008 Unpublished data Prospective, controlled comparison of cortical training after LASIK to sham treatment after LASIK

Postoperative 3 Months	All Patients		Worse than 20/20 postoperative	
N=98	NeuroLASIK	Control Video Game	NeuroLASIK	Control Video Game
UCDVA Improvement	0.80 lines	0.28 lines	1.56 lines	0.34 lines
Contrast Sensitivity Improvement	79%	52%	90%	47%



NeuroLASIK Subjective Improvement after NeuroLASIK



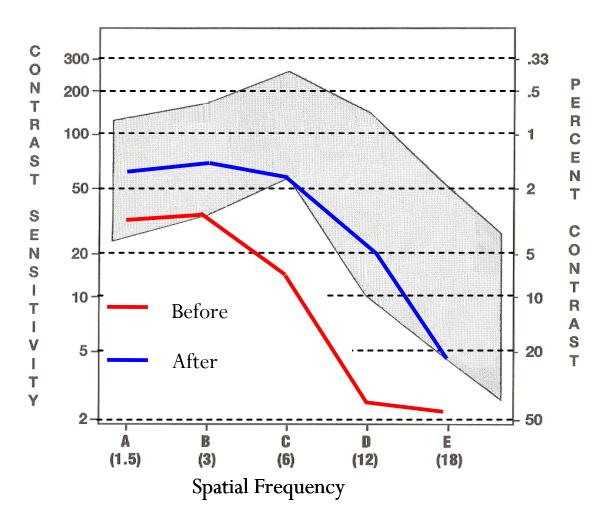
Hunkeler J, Lindstrom D. Unpublished Data 2009

- Prospectively evaluated cortical training after IOL implantation in 60 eyes.
- IOLs included aspheric monofocal, multifocal and accommodative (5 IOL styles total)
- Improvement in UCDVA and UCNVA for the entire group was 1.3 and 1.0 lines respectively
- Mean improvement in distance and near CSF were 223% and 197% respectively.

	No. of Eyes	Distance VA Improvement	Near VA Improvement	Distance CSF Improvement	Near CSF Improvement
Rezoom	24	1.5 Lines	0.6 Lines	157%	160%
Restor	6	1.6 Lines	1.2 Lines	135%	143%
Crystalens	6	0 Lines**	1.8 Lines	370%	227%
Alcon Monofocal	10	1.3 Lines	0.6 Lines	250%	238%
AMO Monofocal	10	1.3 Lines	1.7 Lines	354%	263%
Total	56	1.3 Lines	0.9 Lines	223%	197%

*Standard and premium lenses ** Patients Baseline VA 20/15 – No room to improve

Average Age - 70 years old



- Novel approach to improvement in visual function
 - "Physical therapy for vision"
 - Computer based primary cortex vision training
- Founded on proprietary cortical visual science therapeutic strategies
- Average improvement of 2 lines visual acuity and 100% in contrast sensitivity
- Non-invasive and safe
- Multiple product offerings including post IOL implant therapy, post refractive surgery, presbyopia
- Future product offerings in development

FIFTH INNOVATION

Quantifying Dry Eye



Osmolarity in the Diagnosis of Dry Eye Disease

Clinical Test	PPV
Osmolarity	87%
Schirmers	31%
TBUT	25%
Staining	31%
Meniscus Height	33%

• Osmolarity is the "gold standard" test for Dry Eye Disease

- 45 years peer reviewed research
- Osmolarity has been added to definition of Dry Eye
- Global marker of Dry Eye, indicating a concentrated tear film

Clinical Evaluation of Osmolarity

- Standard osmometers require 10 µL
 - Dry eye patients have less than 1/200th of that volume available
- Traditionally rely on glass capillaries to collect tears
 - Collection can cause reflex tearing
 - Fluid can evaporate during transfer
- Older instruments require half an hour to get one reading
- As a result, tear film osmometry was confined to the laboratory

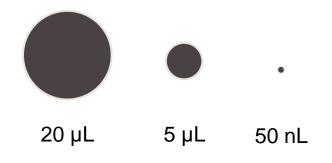


Advanced Instruments Tear Osmometer



TearLab Precision @ 50 nL

- < 2% coefficient of variation @ 50 nanoliters
 - Glucose ≥ 5.0% CV @ 5 microliters (5,000 nL)
 - Cholesterol > 4.0% CV @ 20 microliters

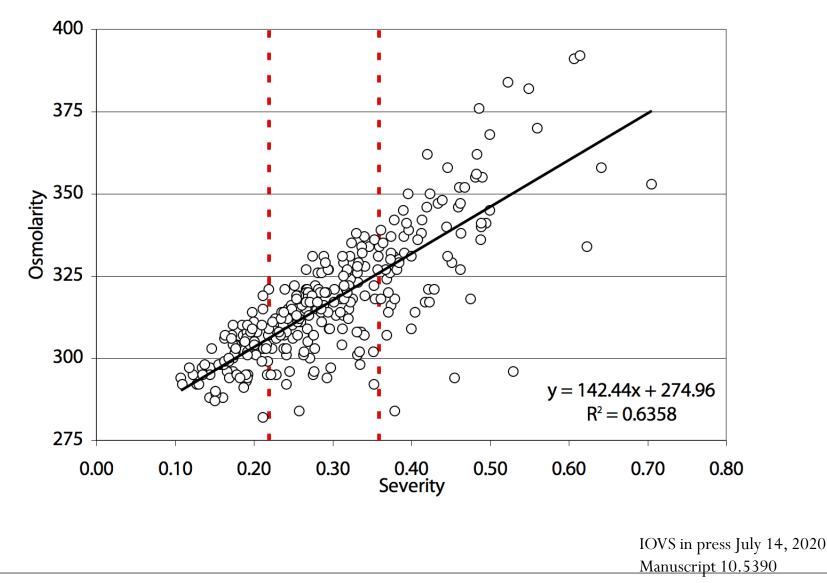


- Safe, simple collection
 - No reports of corneal or conjunctival trauma in 468 eyes [TearLab[™] FDA 510(k) submission]
- Winner 2009 MDEA for In Vitro Diagnostics





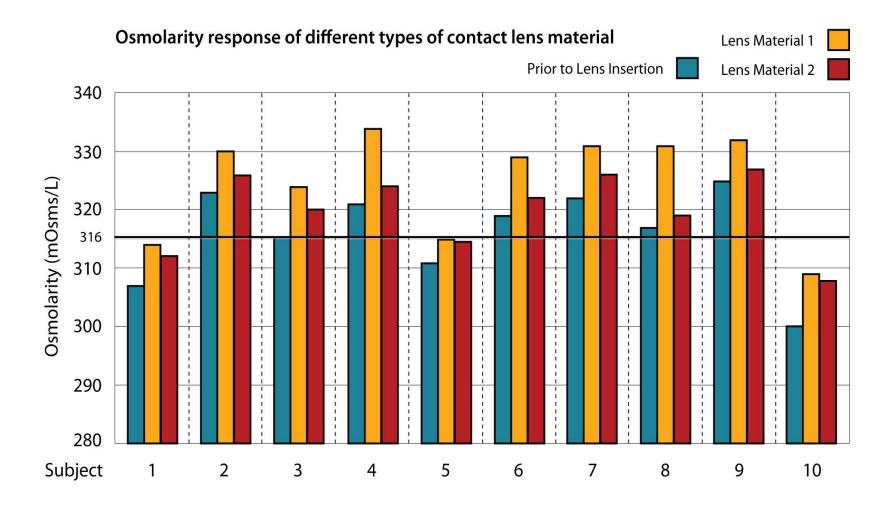
Osmolarity Severity Analysis



Osmolarity Provides Improved Standard of Care

- Tear osmolarity is the most accurate diagnostic test for dry eye disease
- Elevated osmolarity is the central mechanism causing ocular surface damage
- Allows a physician to rapidly diagnose & classify patients with a global assessment
 - In combination with a slit lamp exam, physicians can select therapies based on mechanism of disease and severity
- Modulate therapy using a quantitative endpoint

TearLab Reveals Biocompatibility of Contact Lenses



Montani Giancarlo Optometrist FIACLE, Dept di Optometria, Università del Salento

• 30 subjects were recruited for the study

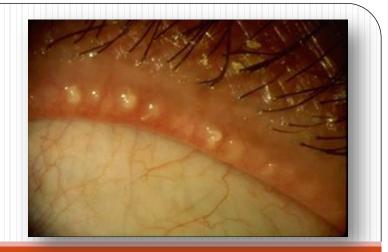
- n = 24 dry eye, n = 6 normal
- Classified as dry eye if the maximum preoperative osmolarity was greater than 308 mOsms/L
- LASIK vision correction with the LADARVision 4000 or the WaveLight ALLEGRETTO WAVE™ Excimer Laser System
- Vitamin, Prednisolone 1% and lubricant drops prescribed post-op
- Bilateral osmolarity measurements were performed in triplicate at each visit using the TearLab Osmolarity System
 - Measurements were made preoperatively, 14 days, and 1 month postoperatively

Osmolarity in Refractive Surgery

- Maximum osmolarity of both Normal and DED subjects increased by 10 mOsms/L following surgery (p = 0.067)
 - Normal: $304.0 \pm 3.5 314.5 \pm 13.1 \text{ mOsms/L}$
 - DED: 329.8 ± 13.7 339.5 ± 24.0 mOsms/L
- Normal subjects had significantly lower post operative osmolarity than DED subjects (*p* = 0.021)
- Very large increases >10 mOsms/L were observed in 13 of the 30 subjects (average increase = 29.1).

Tear Osmolarity in the Diagnosis of Dry Eye Disease

- If > 308 mOsms/L or larger than a 8 mOsms/L difference between eyes
- Normal subjects have a tight band of variability
- Patients with mild/moderate DED show variability
 - Variability is the hallmark of this stage in which compensatory mechanisms are still operative in response to environmental stress
- Patients with moderate to severe DED have tear osmolarity which varies between eyes and over time but generally remains within the abnormal range



Sixth Innovation

The Lid Hygienist



Challenges of Current MGD Therapies

Therapy¹

- Warm compresses
- Eyelid scrubs
- Manual gland expression

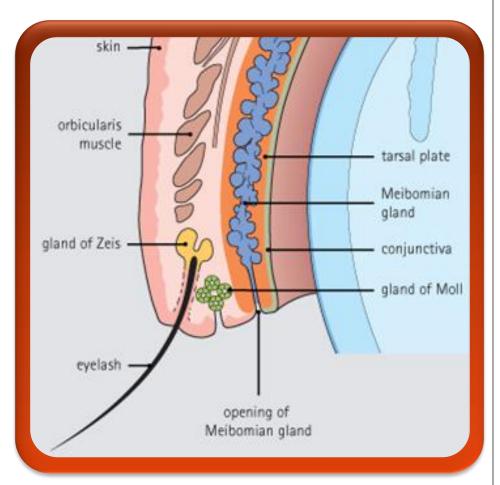


Challenges

- External heat application is inadequate^{2,3}
- Compliance¹
- · Only the upper portion of the glands is treated or expressed

Warm Compresses Are Ineffective

- Anterior lid is highly vascular; therefore, difficult for heat application to reach gland contents
- Adequate temperatures cannot be achieved by the use of external warm compresses



Intense Pulsed Light Therapy

- Flash lamp emits energy from 400 1300 nm
- Filter narrows the range to around 500 nm
- Hemoglobin absorbs the light energy and eliminates the blood vessels
- Closed vessels no longer send inflammatory mediators to the meibomian glands
- Liquifies "plugged" meibomian gland secreations

Treatment

- 8-12 J/cm at 20-30 milliseconds pulse width
- Treat directly below the lid margin
- Apply sunblock
- Non-steroidal bid 4 days
- 4-6 Treatments within 30 days



Results

- Decrease in telagiectasic vessels
- Increase in TBUT
- Improvement in quality of meibomian secretions
- Decrease in patient symptoms

LipiFlow[®] Thermal Pulsation System



LipiFlow safely and effectively treats Meibomian gland obstruction in both upper and lower eyelids simultaneously, in an in-office procedure, taking only 12 minutes per eye

LipiFlow® Offers a Solution for Patients With MGD

In both upper and lower eyelids simultaneously Lid warmer Applies directional heat to inner eyelid

Insulated lid warmer shields eye from heat and vaults above the cornea to prevent corneal contact

> Heats comfortably to liquefy the Meibomian gland contents

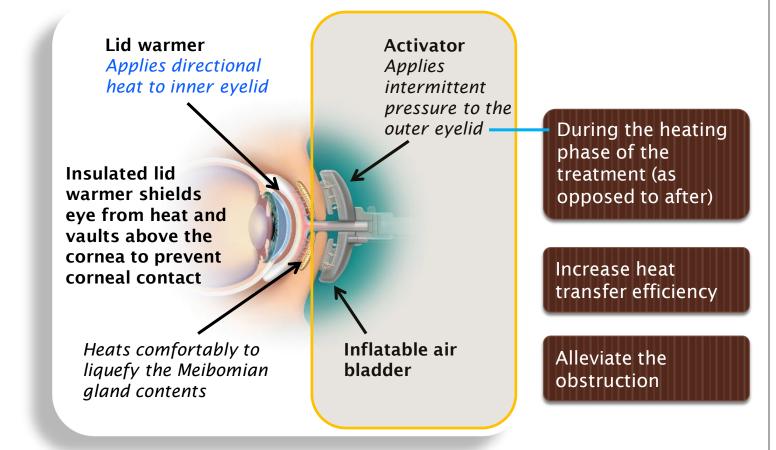
Activator Applies intermittent pressure to the outer eyelid

Inflatable air

bladder

Facilitates release of secretions from the Meibomian glands

Therapeutic Goal of Pulsation



Enable patient to experience little to no discomfort during treatment

LipiFlow[®] Provides Heat and Pressure to Liquefy and Evacuate Obstructed Glands

Lid warmer

Heat is applied to the palpebral surfaces of the upper and lower eyelids directly over the Meibomian glands

Activator

Graded pulsatile pressure is delivered to the outer eyelid



Complete Gland Expression

- Obstructed glands should be monitored for gland atrophy
- LipiFlow® offers relief through evacuation of gland contents

The LipiFlow treatment provides improved quality and quantity of gland secretions

Safety

The globe is insulated/protected from heat during treatment¹

 Massaging pressure is not transferred directly onto the eyeball¹

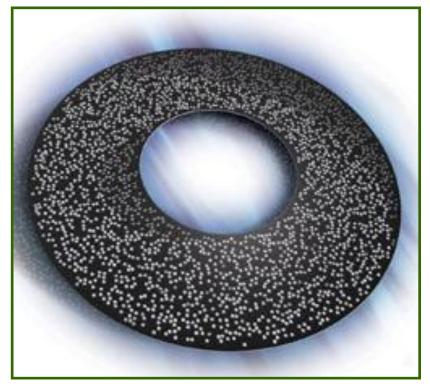
 Pressure required is significantly less compared with unheated manual expression²

1. Friedland BR, Fleming CP, Blackie CA, Korb DR. A novel thermodynamic treatment for meibomian gland dysfunction. *Curr Eye Res.* 2011;36(2):79-87.

2. Korb DR, Blackie CA. Meibomian gland therapeutic expression: quantifying the applied pressure and the limitation of resulting pain. *Eye Contact Lens.* 2011;37(5):298-301.

AcuFocus[™] KAMRA Corneal Inlay

Overall diameter: 3.8 mm



Central aperture: 1.6 mm

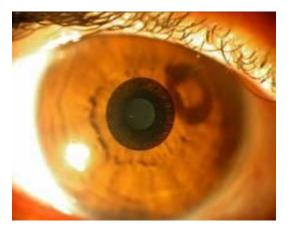
- Designed to improve near vision in patients with Presbyopia
 - Easily implanted
 - Minimal impact on distance vision
 - Removable

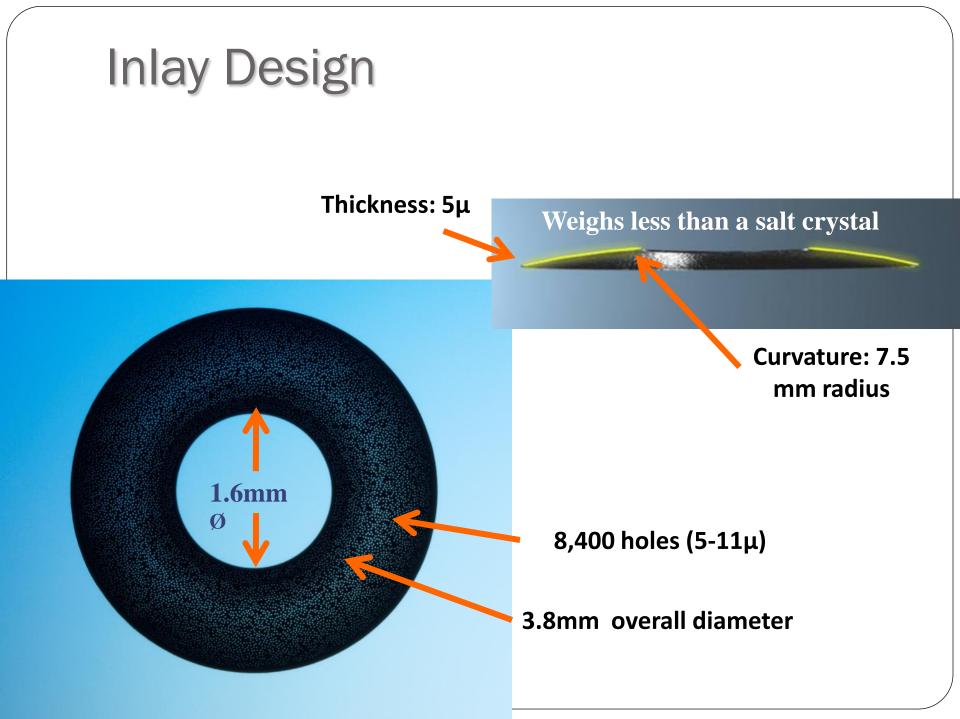
AcuFocus[™] KAMRA How it Works

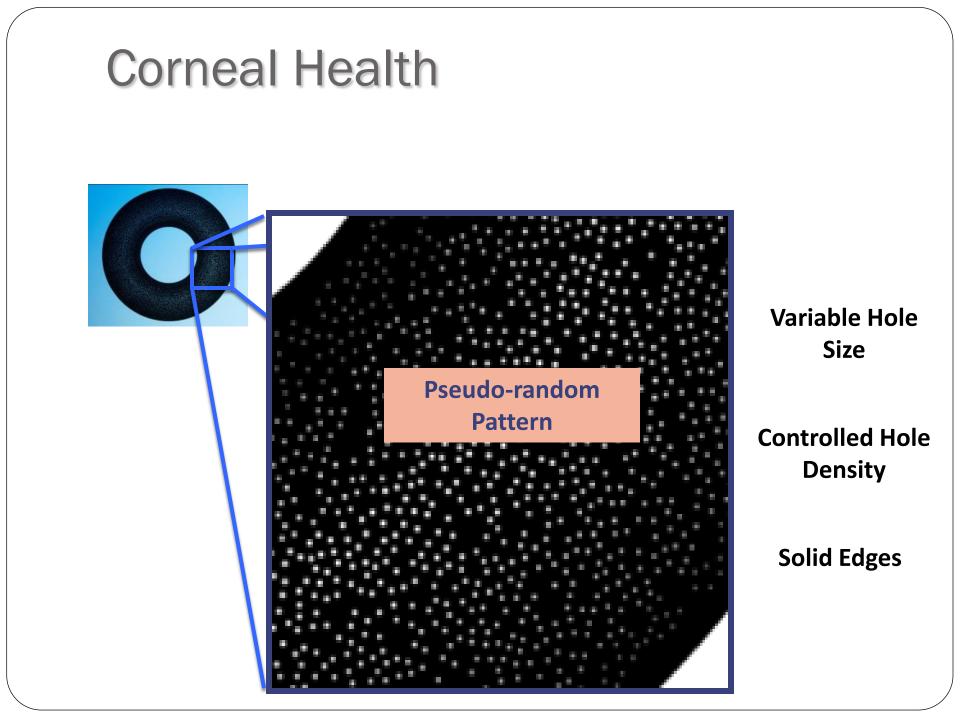
 The small aperture created by the AcuFocusTM ACI 7000 blocks the unfocused light on the retina

> Blocks unfocused light

Allows focused light into the eye

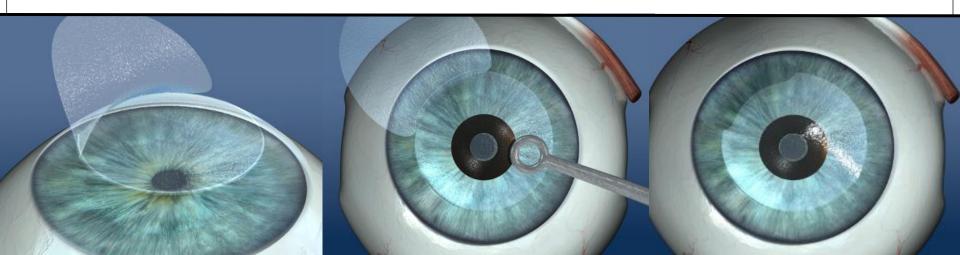


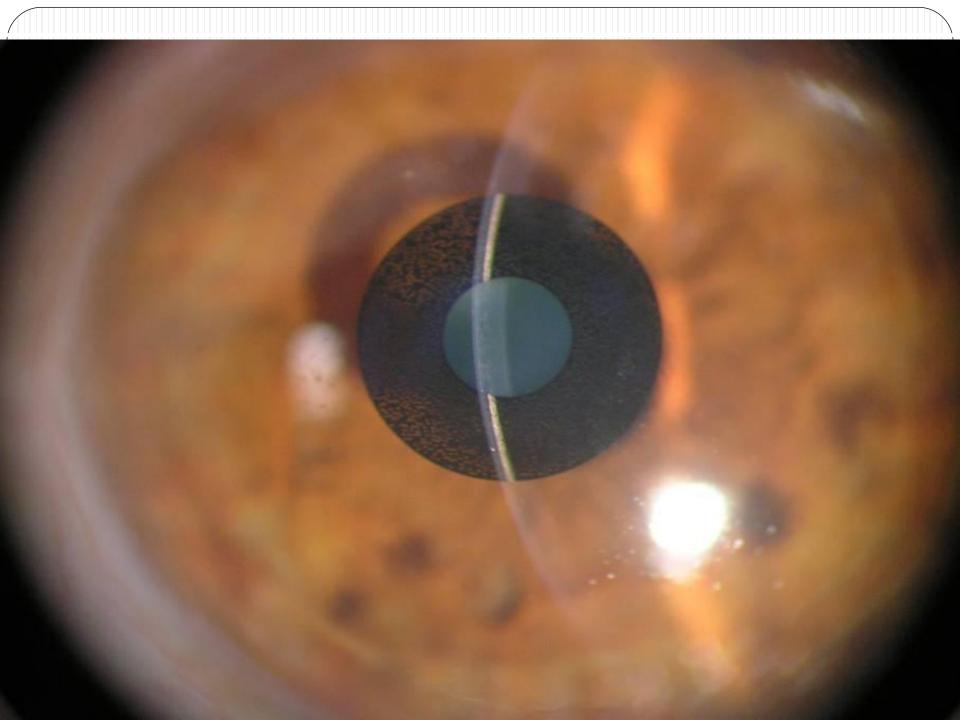


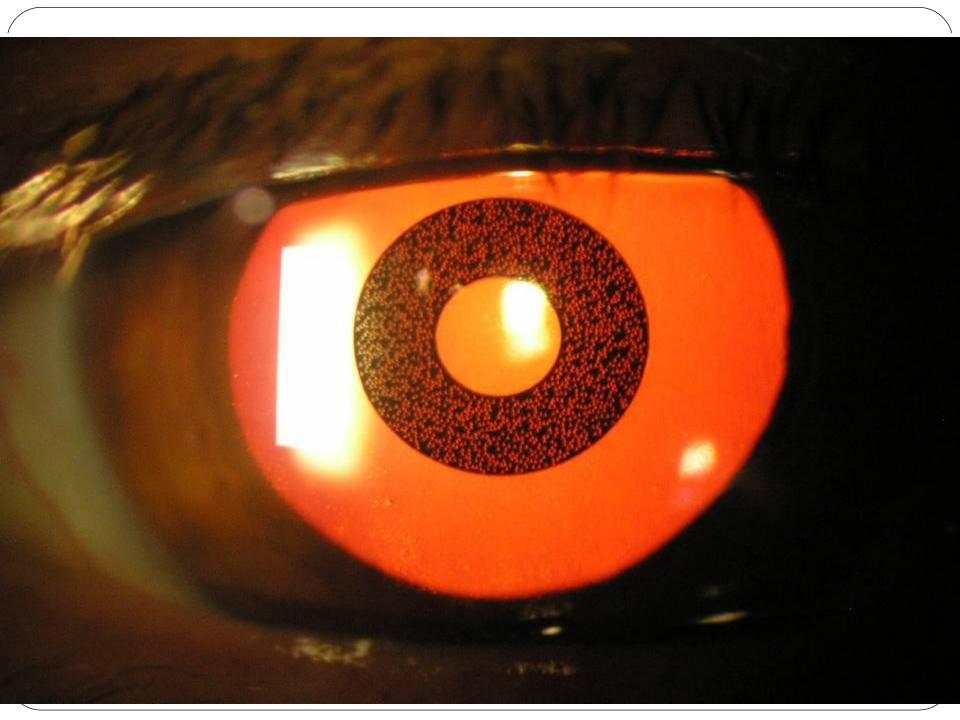


The AcuFocus[™] KAMRA Procedure

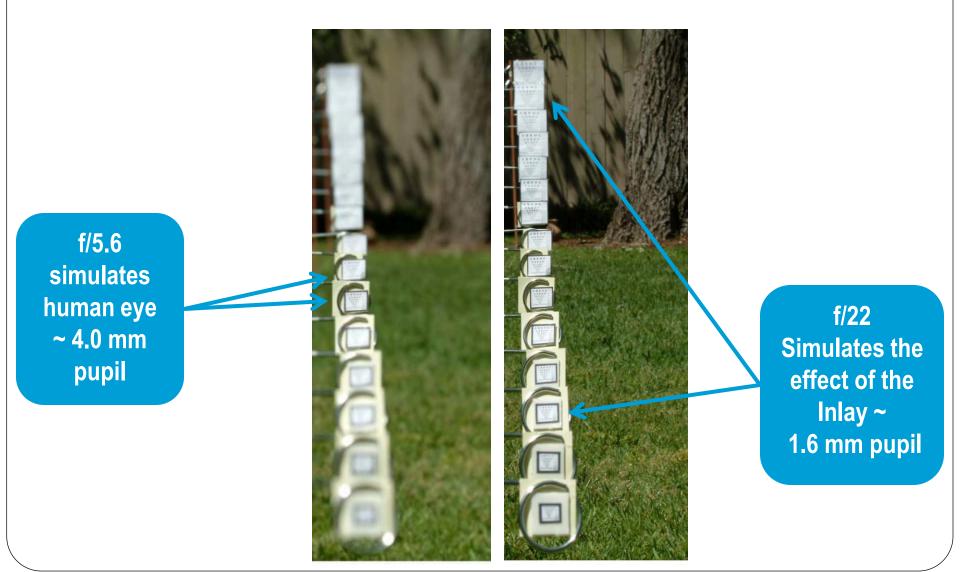
- Topical anesthetic eye drops
- Flap created
- The AcuFocusTM ACI 7000 is inserted and centered
- The flap is closed
- Takes less than 30 minutes start to finish





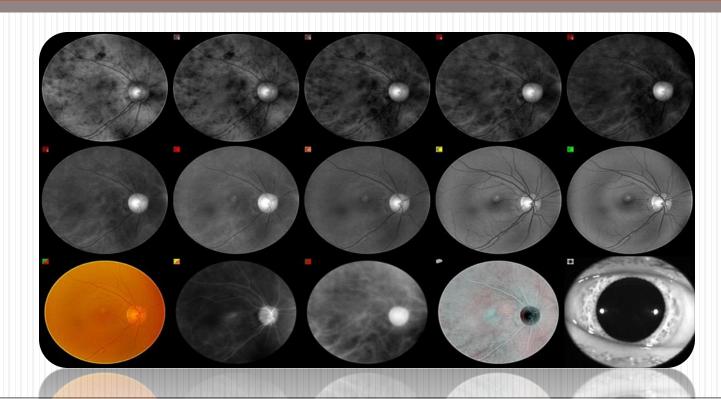


Depth of Focus Simulation



8th Innovation

Annidis - Multi-spectral Digital Ophthalmoscope

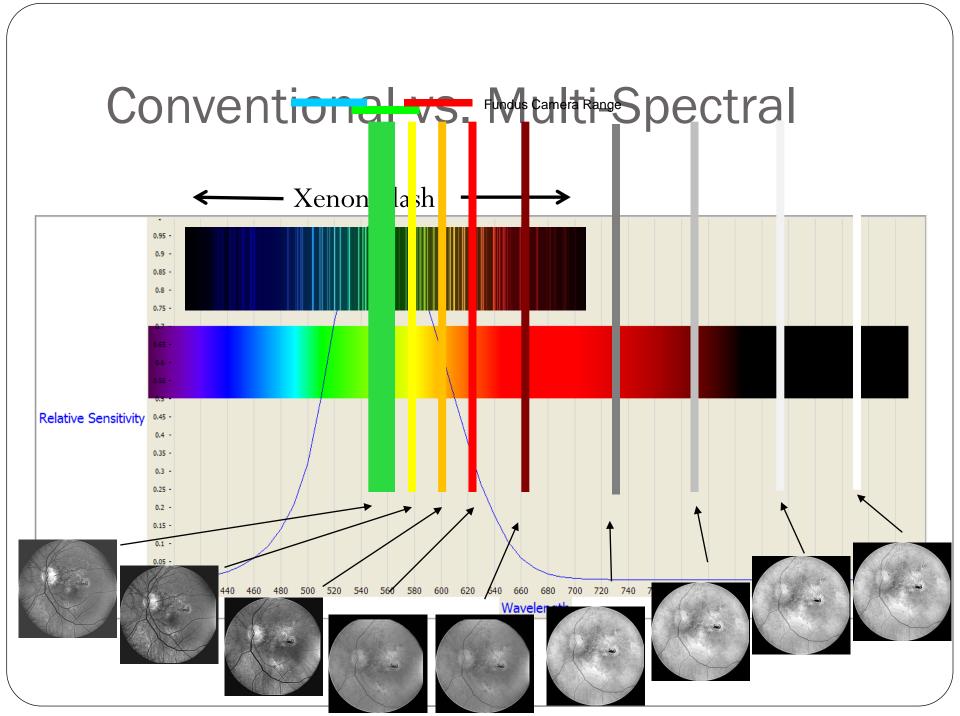


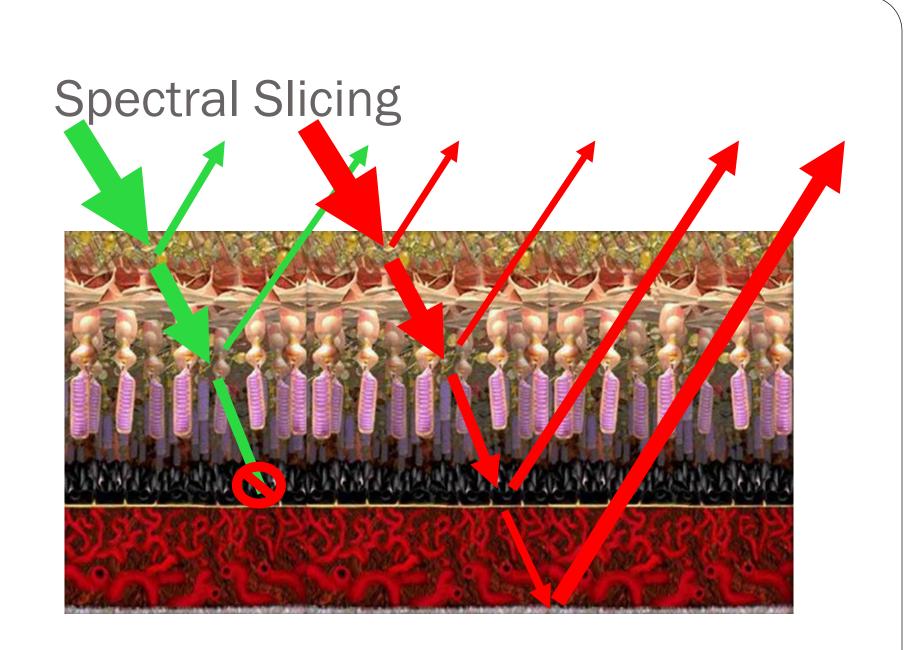


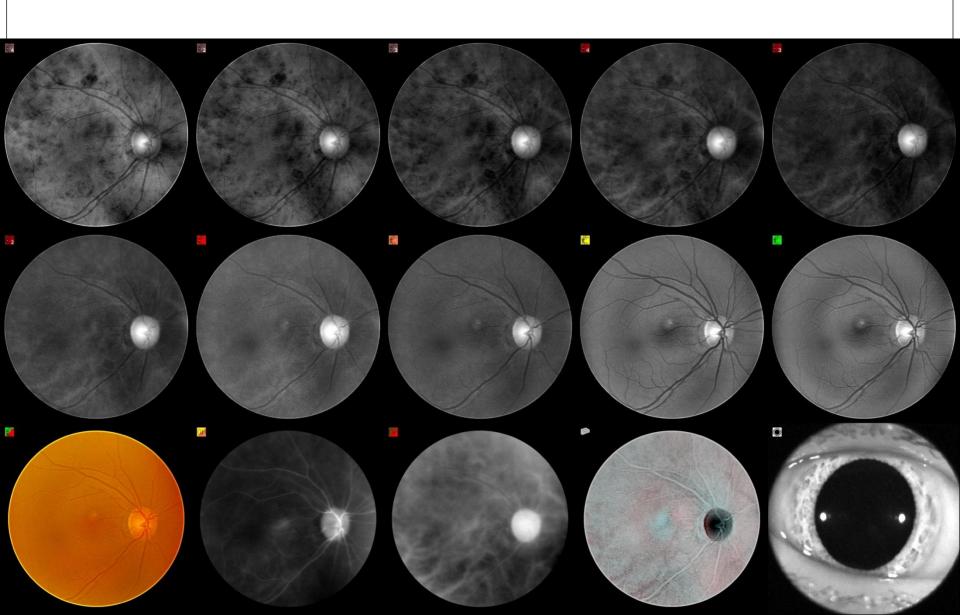
RHATM

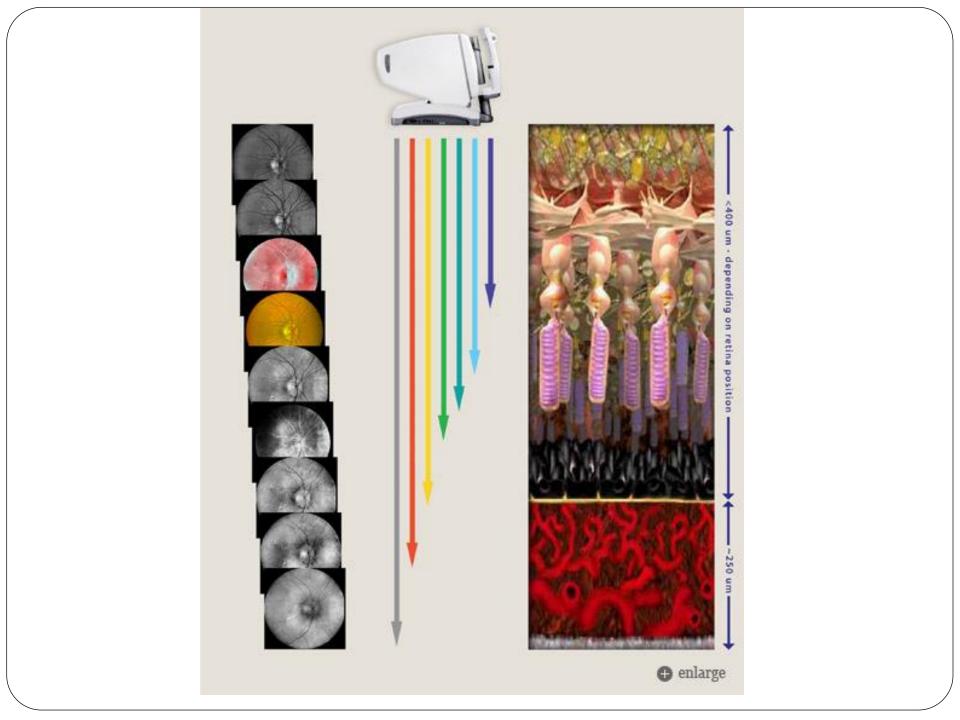
Optometrist's Gateway to the RPE

FDA approved Health Canada approved European CE Mark obtained





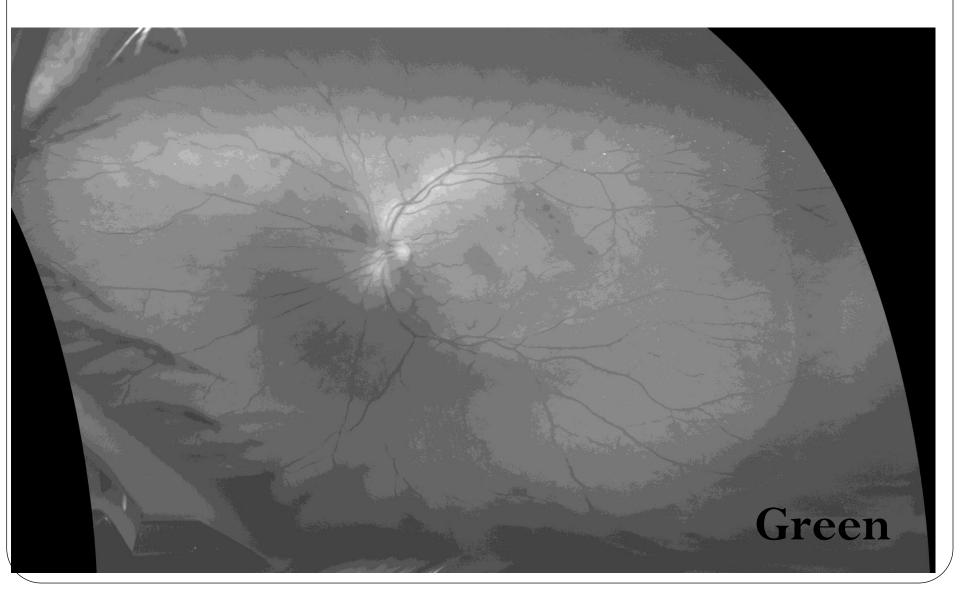




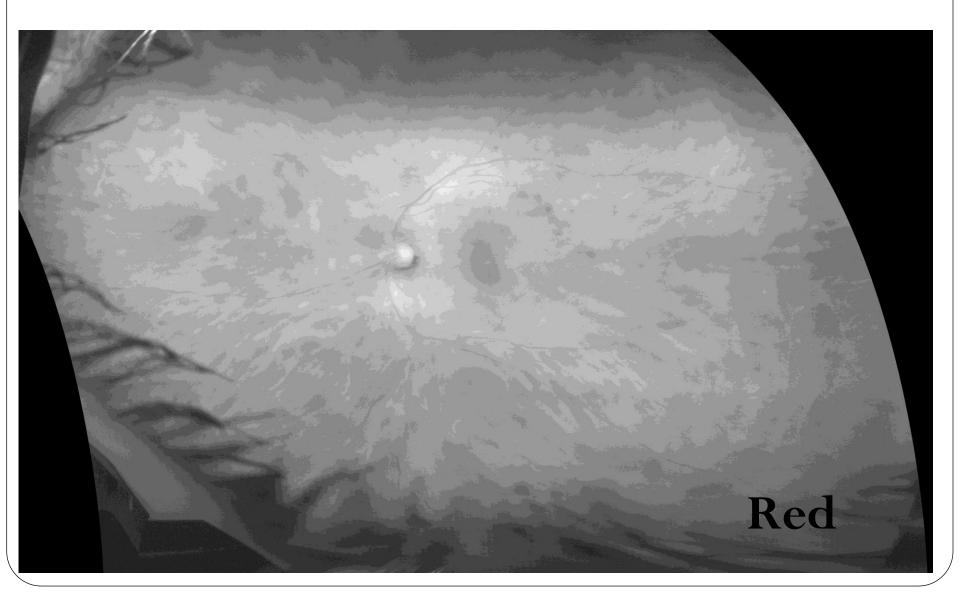
PID 79 - Optos



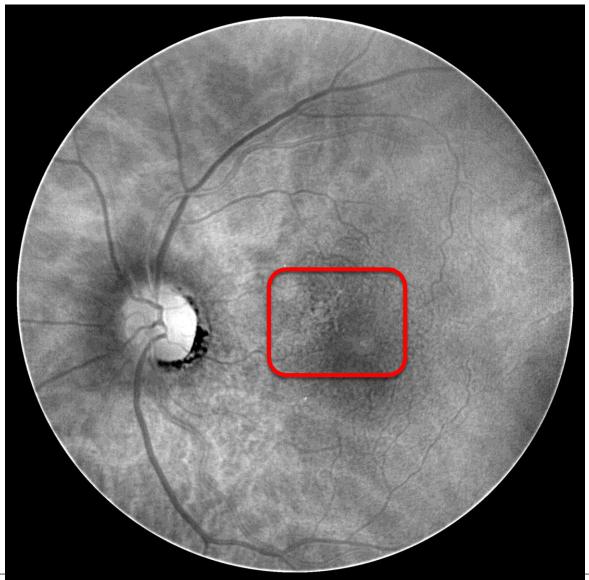
PID 79 - Optos



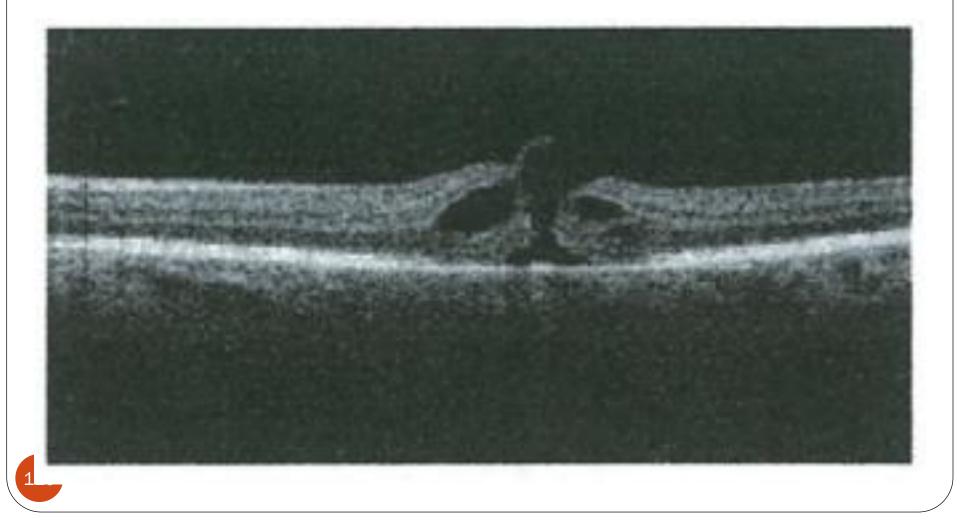
PID 79 - Optos



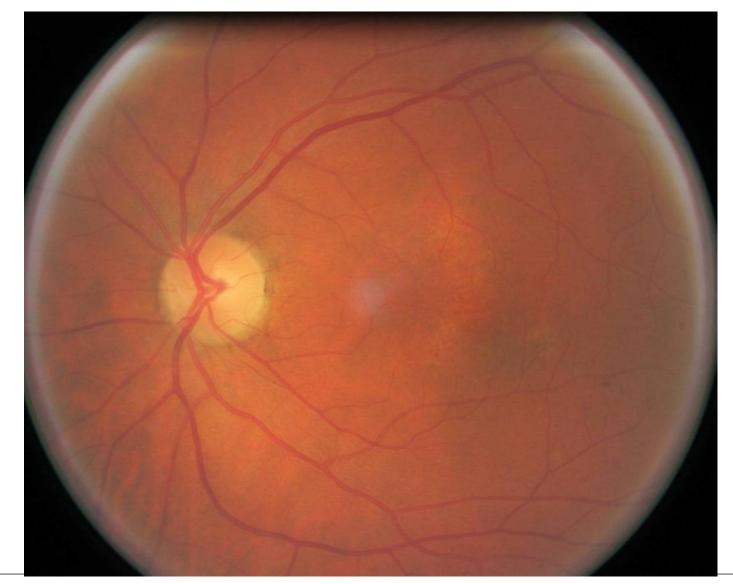
PID 79 - RHA,



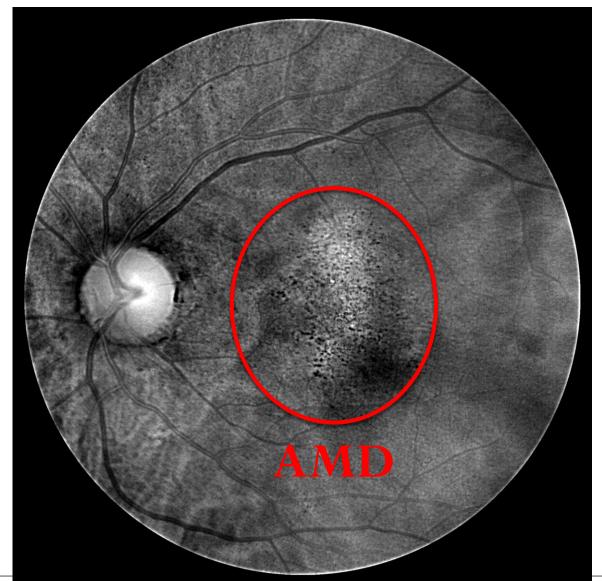
PID 79 – OCT, Macular Hole



PID 144 – Fundus Photo



PID 144 - RHA,



Ninth Innovation

A New Age in Refraction

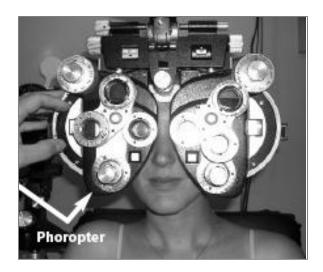


Surpassing Yester-decade's Refraction Technology

PSF Refractor



Classical Phoropter

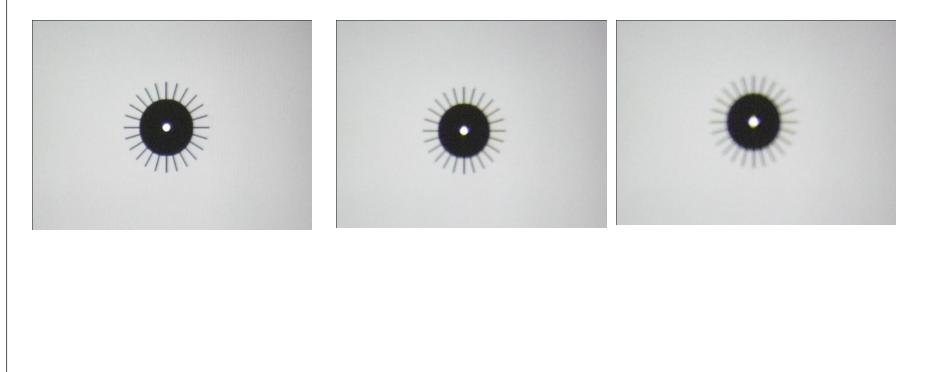


Subjectivity is the Key to Reliability

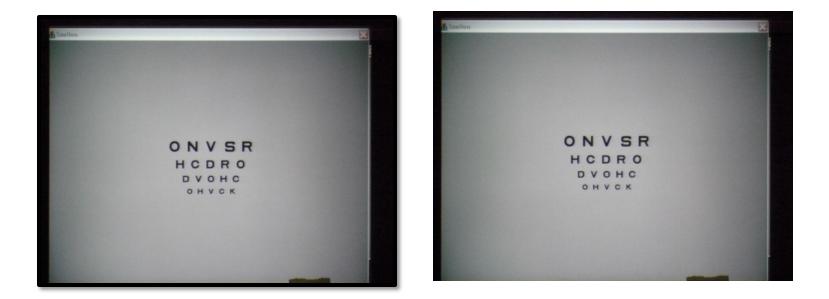
- Vmax PSF refraction reliability is maximized where the optics of the eye, retina and the brain are working together
- Since it is refracting using PSF, higher order aberrations are eliminated as well.
- Patient Vision is thereby, maximized

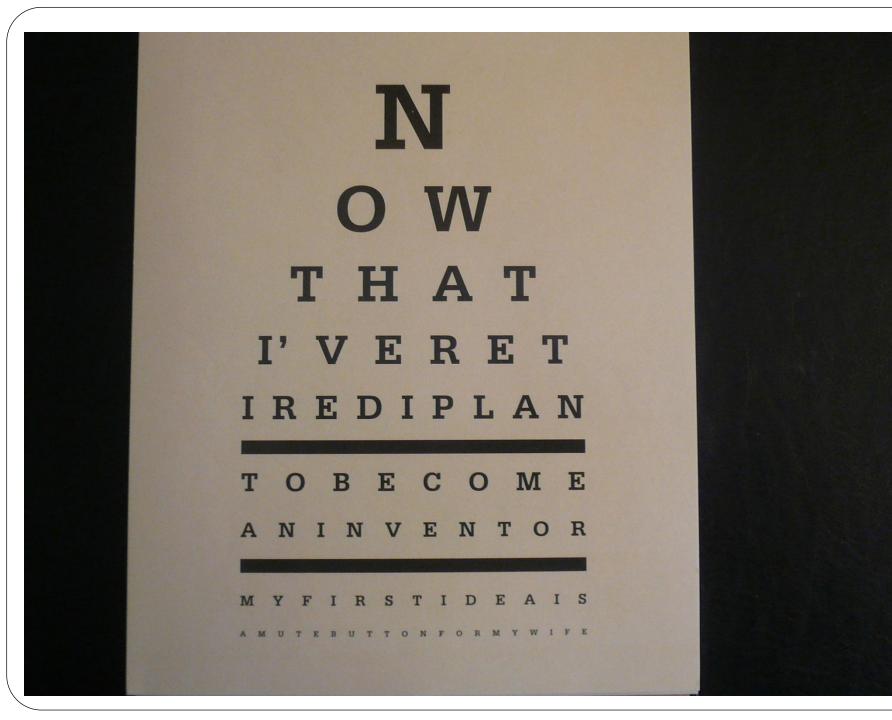
PSF Refraction is More Sensitive

• Changes in 0.05D are now noticeable



Easier than Snellen Letter Chart





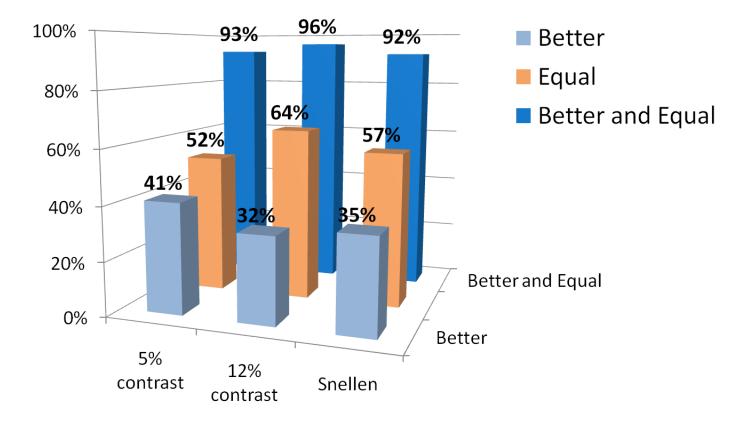
Vmax PSF Refractor- a Phoropter "Extreme Makeover"

- Increase sensitivity of measurement- 5x
- Easier for Patient, moves quicker to the end point
- Ergonomic, no strains and no aches
- Connectivity to EMR, error-free operation
- Positioning- Differentiate your practice!!

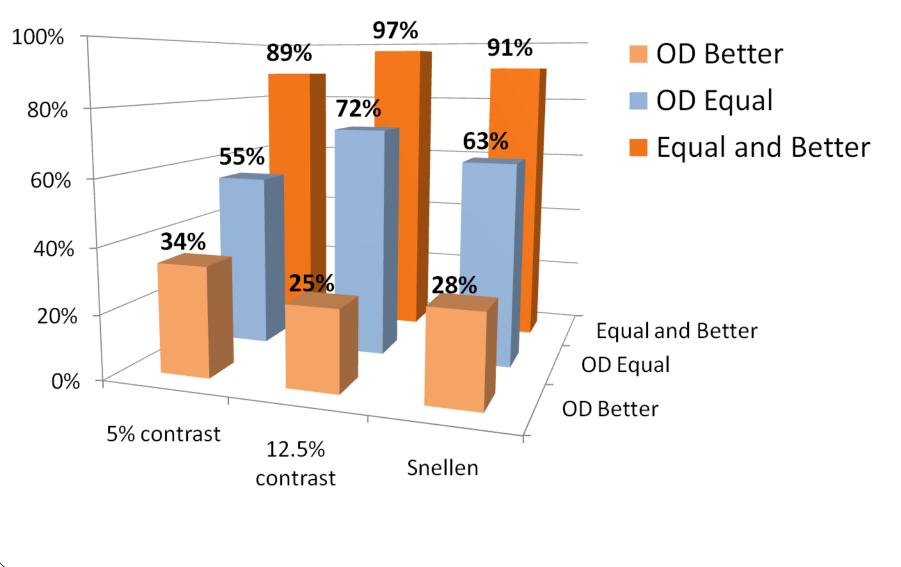
Clinical Test Results

- Eight clinical test sites in the US
- Over 800 patient data points
- Male/ female: 49% : 51%
- Age range: 5 to 92
- Tested over 9 months

OS Results of Clinical Trials

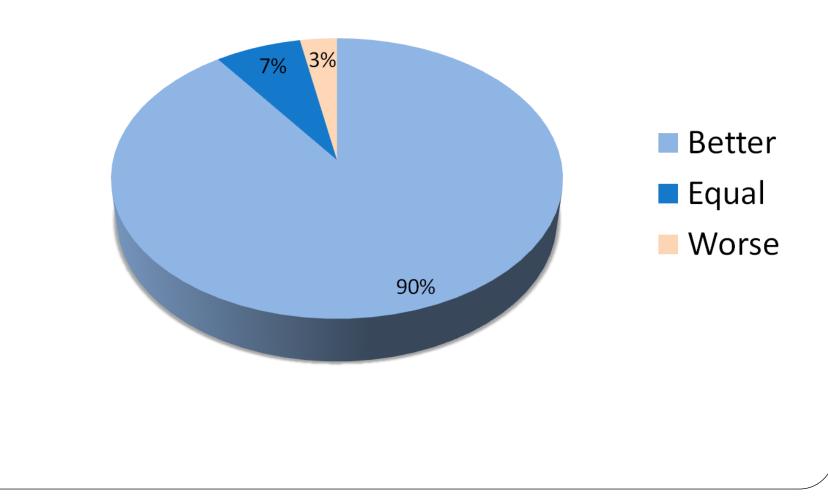


OD Results of Clinical Trials



Overall Patient Response

Responses from Patients



Encepsion Lenses Options

- Designs: Hard, Intermediate, and Soft
- Corridor: from 11mm to 18mm
- Pantoscopic, Vertex Distance, Seg Height, PD
- Materials: All Standard, 1.60, 1.67, 1.74, Trivex
- Transition, Polarized
- Lens Coating: Premium Only with 2Yr warranty (Reflection Free, AR, Super Hydrophobic, Extra Tough Thermal Cure)
- Sport, Sun

Tenth Innovation

There is an "App" for That



IPad

- <u>www.ipadfordoctors.com</u>
- <u>www.mobilehealthnews.com</u>
- Fits in a white coat
- Allows point of care display
- Battery last a full clinic day



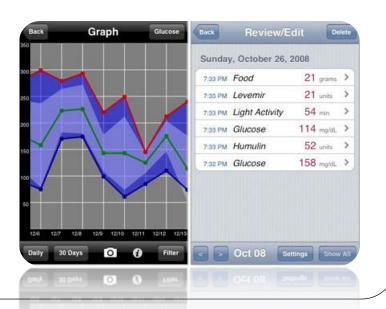
Current Trends

- 46 % of physicians plan on purchasing an ipad in 2012
- 32% of physicians currently use an ipad
- 58% of those with ipads use them in their clinic



Cool Apps

- EyeXM
- Eye Exam Pro
- Islet for Diabetes
- Pollen Count



Questions

