Applying Innovative Technologies in Clinical Practice

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1

Point-of-Care Diagnostics

RPS Adeno Detector™

Components

Unit Package: 1 Box
Case Package: 20 Boxes (Minimum order quantity)

Each unit package, 1 box provides all the needed components to perform one test, except gloves and timer.

RPS Adeno Detector™

Test Procedure

Collecting the Sample

4. Dab the sampling pad inside the lower eyelid (palpebral conjunctiva) 4 – 6 times. Allow the sampling pad to rest against the conjunctiva (membrane on inside of the eyelid) for an additional 3 seconds to ensure saturation of the sampling pad with eye fluid.

RPS Adeno Detector™

Test Procedure

Assembling the Detector

1. Locate the Test Cassette
2. Assemble the detector by gently placing the sampling pad of the Sample Collector into the sample transfer window of the Test Cassette body.
3. Press firmly where indicated until the detector is secure.

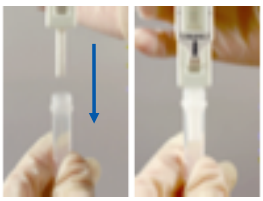
Note: A double auditable click means the detector is properly assembled, transferring the sample to the test strip.

RPS Adeno Detector™

Test Procedure

Running the Test

1. Open the buffer vial. Remove the Protective Cap from the Test Cassette. Do not allow any portion of the detector besides the absorbent tip to touch the buffer vial.
- Immerse the Assembled Detector' s Absorbent Tip into the buffer vial for 15 seconds.

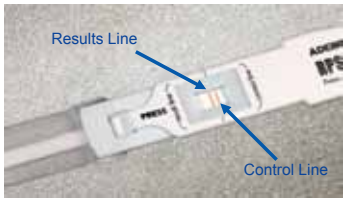


RPS Adeno Detector™

Reading & Interpreting the Results

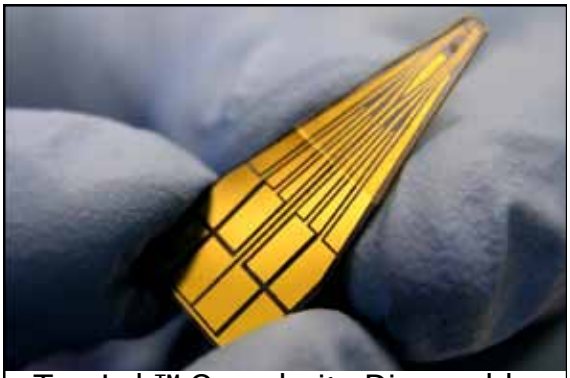
Positive Results:

The Results Line and Control Line are RED in the result window, indicating that Adenovirus antigen is present.



TearLab

TearLab™ Osmolarity Reader & Pens



TearLab™ Osmolarity Disposable Chip

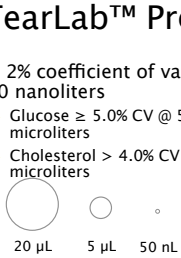
Osmolarity in the Diagnosis of Dry Eye Disease

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

- Osmolarity is the "gold standard" test for Dry Eye
  - 45 years peer reviewed research
  - Osmolarity has been added to definition of Dry Eye

TearLab™ Precision @ 50 nL

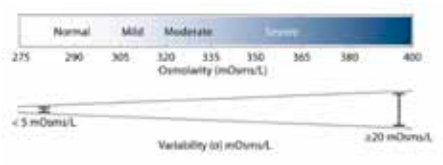
- < 2% coefficient of variation @ 50 nanoliters
  - Glucose ≥ 5.0% CV @ 5 microliters
  - Cholesterol > 4.0% CV @ 20 microliters



- Safe, simple collection
  - No reports of corneal or conjunctival trauma in 468 eyes [TearLab™ FDA 510(k) submission]

Kimberly MM et. al., Clinica Chimica Acta 364 (2006), Volles DF et. al. Pharmacotherapy 18:1 (1998).

Osmolarity in Diagnosis & Grading of Dry Eye



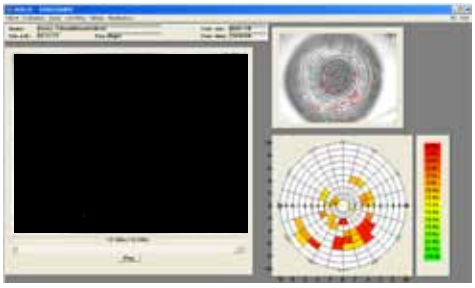
Tear Osmolarity Variability

- Normals
  - Tight range (± 5 mOsms/L) both in individuals and as a group
- Early/Mild cases
  - Variation from one eye to the other and in response to normal environmental stress
- DED Subjects
  - Consistently high osmolarity values

Tear film height in the Keratograph

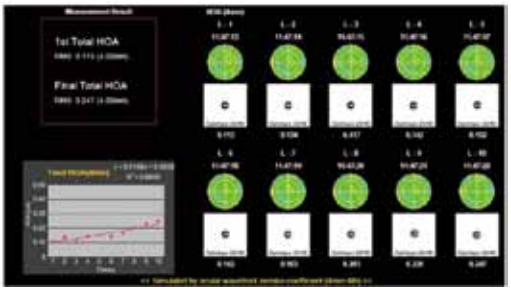
- Keratograph takes a photo
- non invasive
- objective measurement
- repeatable
- documentation

Tear film Non Invasive Break Up Time (NIBUT) with Keratograph



Topcon KR-1W

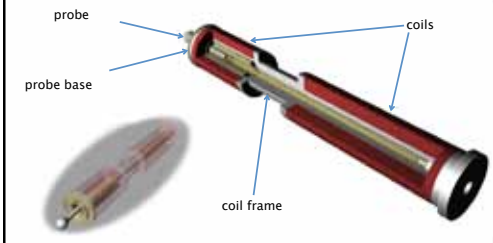
Tear film Non Invasive Break Up Time (NIBUT) with the Topcon KR-1W



Key facts

- Probe
  - weight 26.5 mg ±0.2 mg (TonoLab probes ~12.5 mg)
  - low speed during impact 0.25–0.30 m/s
  - plastic material: PBT Valox 312C (approved for medical use)
  - steel wire with suitable magnetic propertis
  - wire is gold plated for protection against oxidation
  - wire thickness 0.3 mm (TonoLab probes 0.2 mm)
- Two coils
  - two coils for moving the probe and measuring the probe speed
  - front coil moves the probe towards the eye
  - rear coil measures the probe speed (and pulls the probe back after the measurement)

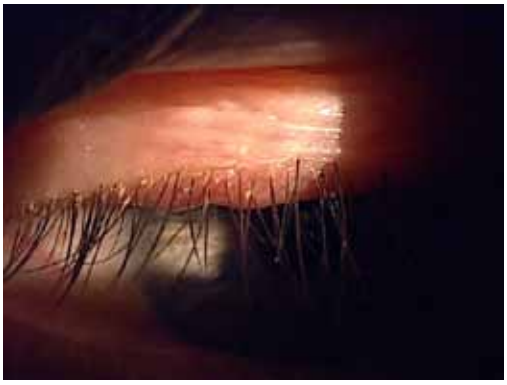
FOR FUTURE VISION



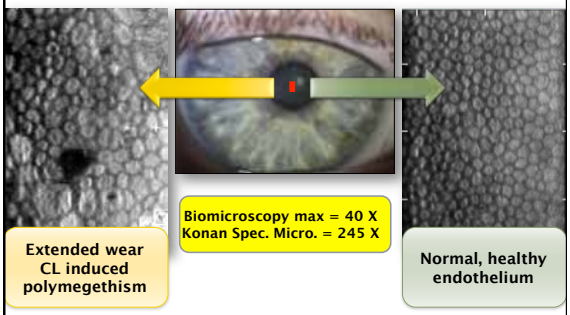
FOR FUTURE VISION

FOR FUTURE VISION

Patient Education: TelScreen



Specular Microscopy

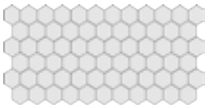


Attribute	Abnormal Condition
Cell Density	• Reduced ECD, but must be age corrected
Cell Size	• Polymegethism
Cell Shape	• Pleomorphism
Cornea Features	• Guttata or Edema

Detailed endothelial cell features are only seen with specular microscopy under high-magnification, high-definition and cannot be seen by standard biomicroscopy.

Normal ECD

- Normal Endothelial Cell density declines with age

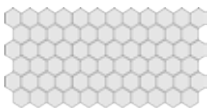


Low ECD

- Low ECD is a risk factor for corneal surgery

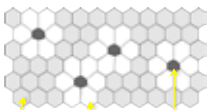
Normal ECD

- Normal Endothelial Cell density declines with age

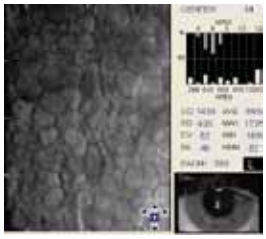


Polymegethism

- Change from uniform cell sizes to variability of cell sizes



Rate of Polymegethism



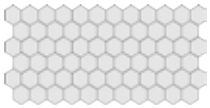
- Repair of the endothelial mosaic relies on cell migration and fusion
- The movement of the cells creates variations in cell size known as polymegethism
- Abnormal rate indicates an overactive wound repair mechanism

CV values from 22 to 31 are normal
CV values from 32 to 40 are elevated
CV values above 40 are abnormal

Phillips C, Laing R, Yee R. Specular Microscopy. In: Krachmer JH, Mannis M Holland EJ (eds) Cornea, 2nd ed. Philadelphia: Elsivier Mosby, 2005: 261-2

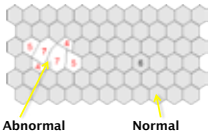
Normal ECD

- Normal Endothelial Cell density declines with age



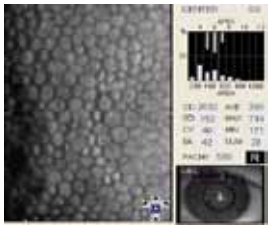
Pleomorphism

- Change from uniform hexagonal cell geometry to variability in cell shape



Presence of Pleomorphism

Six-Sided Cells = 42%



- In the normal corneal endothelium, more than 60% of the cells are six-sided
- Hexagonal shape is best for maintenance of the barrier function
- An endothelium with less than 50% six-sided cells is considered to be pleomorphic

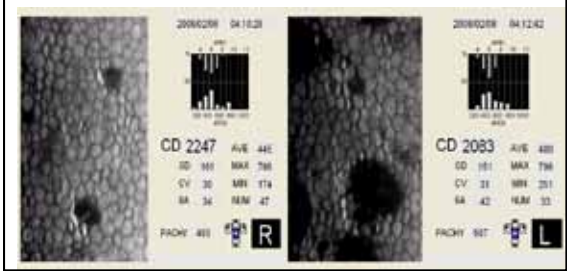
Contact Lens-Induced Endotheliopathy

Lisegang TJ. Physiologic changes of the cornea with contact lens wear. CLAO Journal 2002 Jan;28(1): 12-22

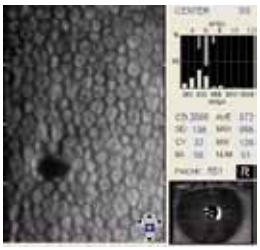
Corneal Guttata

Discrete Guttata

Moderate Guttata



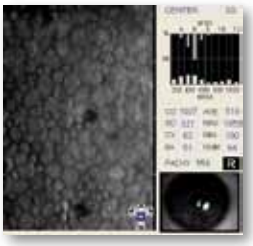
Corneal Guttata



- 70% of population over 40-years-old
- Focal accumulations of extracellular collagen secreted by "stressed" endothelial cells
- Natural history includes five stages of severity
- Increased incidence with previous eye disease

Isolated Corneal Gutta

Glasson CJ, Solomon LD, Polse KA. Morphology of Corneal Endothelium in Patients with Corneal Guttata. Ophthalmology. 2007;114:1469-1475.

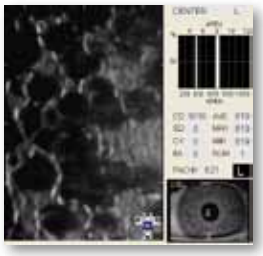


- Abnormal endothelium 35 YO female with 20 years of SCL wear
- Polymegethism (CV=62)
- Pleomorphism (Hex=51)
- Stage 1 guttata

Courtesy:
Craig Thomas, OD

Clinical Evaluation

Stage 3 Fuchs' Endothelial Dystrophy Unmistakable with SM



Courtesy:
Craig Thomas, OD

Anterior Segment Imaging: OCT & Scheimpflug

Visante OCT Applications
Refractive Surgery and Anterior Segment

- Refractive Surgery
  - Corneal laser refractive surgery
  - Phakic IOLs
  - Corneal refractive implants
- Anterior Segment Imaging and Surgery
  - Corneal Imaging and Measurement
  - Iris Imaging and Evaluation
  - Trauma Assessment
  - Crystalline Lens Imaging and Evaluation

Visante OCT Applications
Post Op – Enhancement request denied!

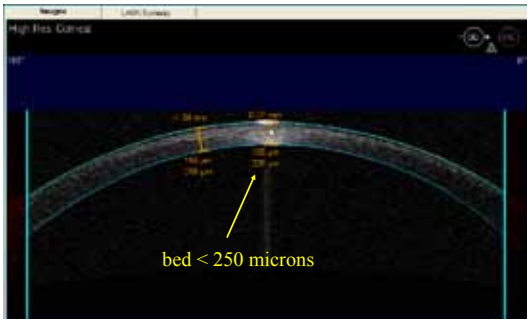


image courtesy of Dr. J. Vukich

Visante OCT Applications
Lamellar Keratoplasty

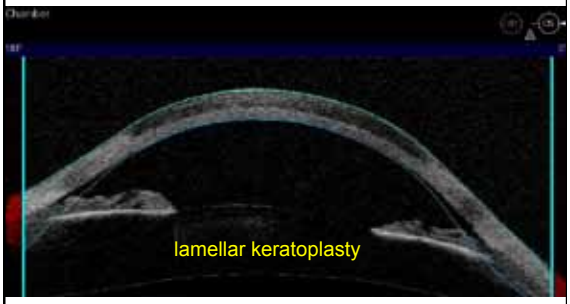


image courtesy of Dr. L. Buratto

Visante OCT Applications
Iris Lesions

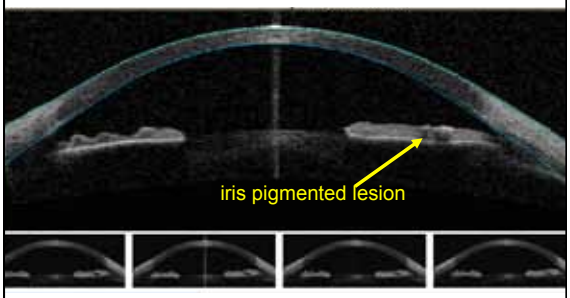


image courtesy of Dr. J. Vukich

Iris Cyst (High Resolution)

image courtesy of Dr. I. Ahmed

Patient JER

- 60 y.o. very active Caucasian female
- Observed in clinic 12 months earlier
- Is an avid target and skeet shooter
- Noticing blur in eyes and wanted to improve vision but also having difficulty with soft contact lenses

Patient JER

- UCVA: 20/25-2 OD, 20/20-2 OS
- Rx:
  - +1.25 – 0.75 X 100 OD 20/20-
  - +1.00 – 0.50 X 85 OS 20/20-

Patient JER

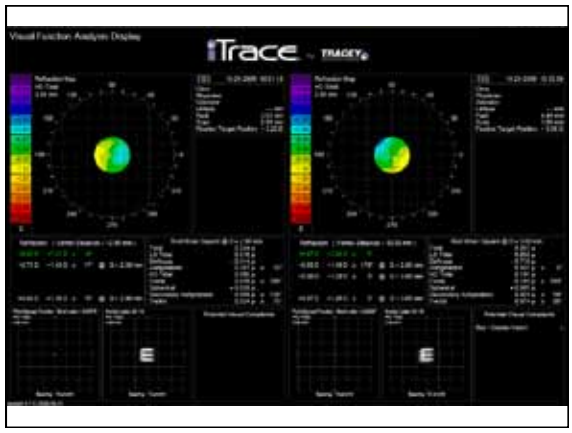
- Did not like how contact lenses would move and affect vision during the day
- Did not want to wear spectacles for potential fogging etc.
- Recommended overnight CRT rather than LASIK
- Patient tried CRT for ~2 months
- Complained of blurred vision OU

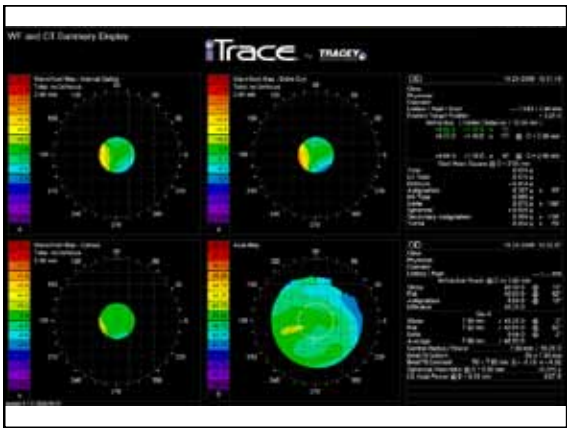
Patient JER 12 mo later

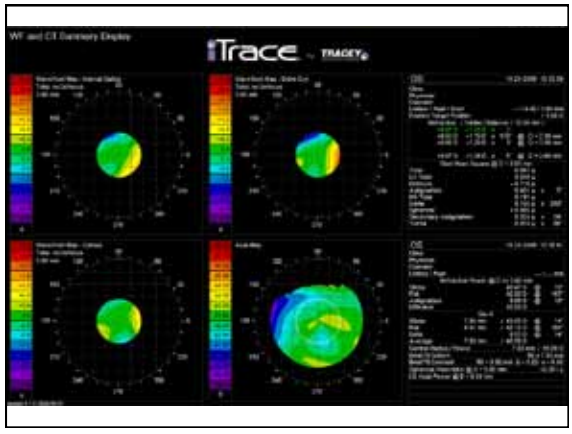
- Believed that the CRT "warped" her eye and vision has never been the same even with current SCL's
- iTrace was performed prior to examination

Patient JER

- CC "Diplopia and difficulty with target shooting"
- "CRT warped my eyes"
- UCVA: 20/30-2 OD, 20/25-2 OS
- Rx:
  - +1.50 – 1.00 X 100 OD 20/20-
  - +1.50 – 0.50 X 100 OS 20/20-







Patient JER – SLEx

Patient JER – SLEx

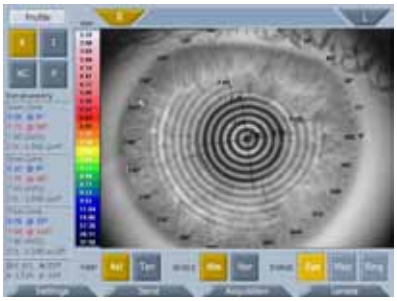
CA-200 Basic module

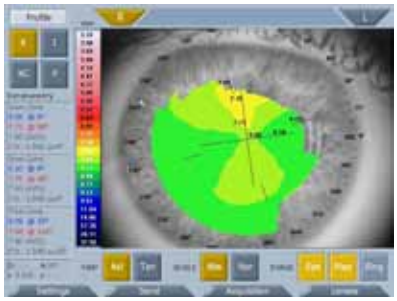
Fast and comfortable image acquisition

High quality of
oscopic images

Press the joystick button to start the aquisition

Out of focus To far (go forward) To near (go back)





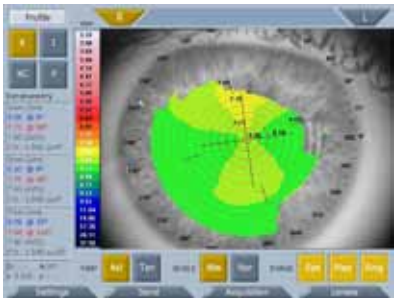
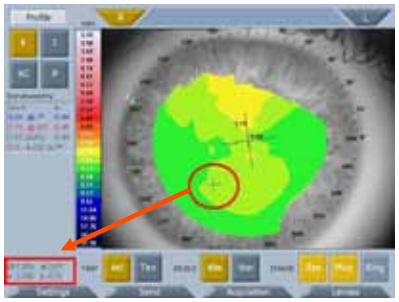


Image selections:

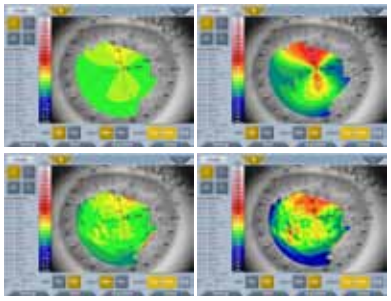
Eye, Map & Ring

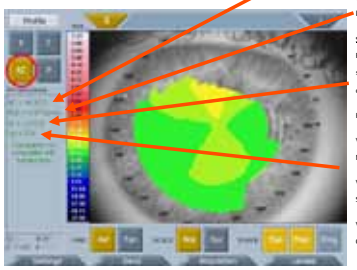


Navigation:

every point can be analized by touching the screen.

- Radius in DPT
- Distance from apex
- Meridian
- Elevation





Apical Curvature. This index repre-
sents the power of the apical cornea.

Apical Curvature Gradient. AGC
higher kerato values than 2 D/mm
show´s possible compatability with
keratoconus.

SI is a vertical asymmetric index.
Positive values means top hemi-
sphere more curved than the bottom
one, and vice versa.

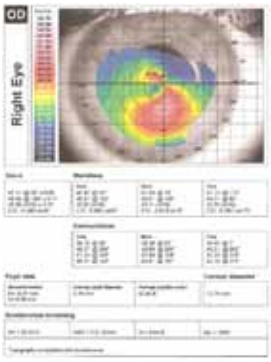
KPI: Keratoconus Probability Index.

Value in Green:
Not compatible with Keratoconus.

Value in Yellow
Suspected keratoconus.

Value in red:
Compatible with keratoconus.

CA-200 Topography of a patient with Keratoconus

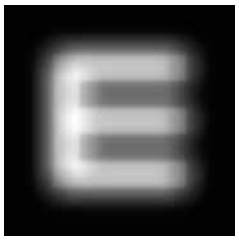


Indicators of potential early keratoconus

1. Topography– inferior steepening
2. Wavefront RMS elevated
   – Especially peripheral aberrations
3. Irregularity index (e.g. IS or Rabinowitz)
4. Peripheral thickness changes (pachymetry)
5. Astigmatism variance between eyes
6. Steep K's (>47D)

63

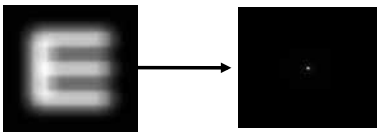
VMax PSF Technology



Snellen is identification: Need more sensitive testing: Point Spread Function (PSF)

VMax Technology

- Based on point spread function (PSF) rather than Snellen recognition



VMax Technology

- Objective and Subjective features
- Measures down to 0.05D
- Statistical increase in VA in pilot study
- Spectacles developed to match the technology

VMax Technology

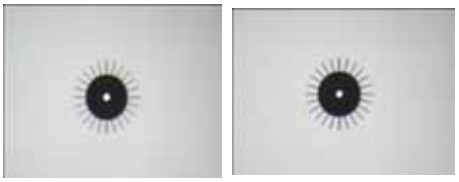
VMax PSF Refraction is subjective

VMax PSF refraction shows clinical reliability at 95% equal or better compared to doctors refraction

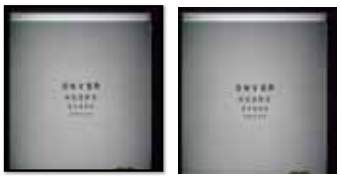
Many show significant improvement in lines of vision

Corrects for all orders of aberration

PSF Refraction is More Sensitive



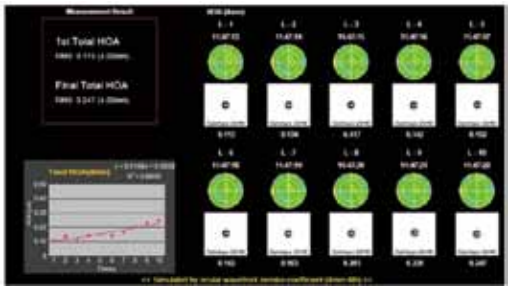
Easier than Snellen Letter Chart



Topcon KR-1W

71

Topcon KR-1W



72

TRS-5100 Autophoropter

- Thinner Profile with faster micro processors
- Color Touch Screen
- Improved Test and Target design

EPIC

- All the same features as the TRS
- Refractions in Half the Space
- Delegation
- Adjustable Motorized Table
- Counterbalanced arm
- Prints hard copies to an external printer or EMR

74

EPIC

- EPIC refraction in 6 min as compared to a traditional manual refraction in 15 min.
- Increase of 50-75% patient throughput
- Staff more efficient
- Profits increase

75

Dry Eye Symptoms

- **Stinging, burning sensation in your eyes**
- **Foreign body sensation**
- Stringy mucus in eye
- Increased irritation from smoke
- **Fatigue after short periods of reading**
- **Sensitivity to light**
- Difficulty wearing contacts lenses
- **Blurred vision, often worsening at the end of the day or after visually focusing for a prolonged period on a nearby task.**

(Mayo Clinic.com)

Eyestrain Symptoms

- Aching/ Pain in eye
- Dry eyes
- Red eyes
- Burning and tearing
- Visual fatigue with near work
- Pulling on eyes with near work
- Headaches

Computer Vision Syndrome

- Sore Eyes
- Tired Eyes
- Burning or Itching Eyes
- Dry Eyes
- Headaches
- Increased Sensitivity to Light

(Mayoclinic.com)

Convergence Insufficiency

- Headaches
- Aching/ Pain in eye
- Dry eyes
- Burning and tearing
- Visual fatigue
- Pulling on eyes
- Diplopia

(Wikipedia)

Mechanism of Eyestrain

- Murry... "found 76% of the 3,585 cases of reported eyestrain were due to poor functioning of **automatic convergence**"
- ICO Study

Proprioceptive Impairment

- "Impaired spontaneously…especially when one is tired"
- "Unnoticed sense… because it has been found we adapt (regress)to continuously-present stimulus"
  - **Computer screen**

Borish

- "Only a **small amount** of **Base-In prism** will produce a **noticeable change** in the relation of fusional demand and reserve so that the average patient may require very limited amounts to restore comfort."

Proprioception System

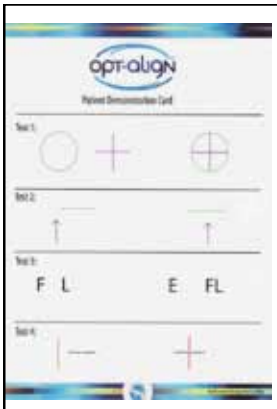
- Research has confirmed that our Proprioceptive system is responsible for the coordinated movements of our muscles in space.
- When there is disparity btw the focal plane and vergence location …cortical supervision is needed to adjust the retinal disparity.

Opt-align

- Distance proprioceptive value
- Near proprioceptive value
- Vertical imbalance

Opt align

- Distance Proprioceptive disparity
  - Combination of 4 test ….Peripheral vision is 1st under monocular condition then binocular stimuli
  - Central vision is under altering monocular/ binocular conditions with & W/O peripheral fusion…
- Near Proprioceptive disparity
  - Combination of 4 test …Peripheral vision is under constant binocularity while central vision is under alternating monocular fixation
- Vertical Imbalance
  - Monocular measurement….
    - Values= BI Prism diopters



Saccadic Eye movements

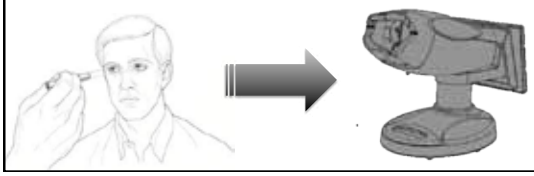
700 /s

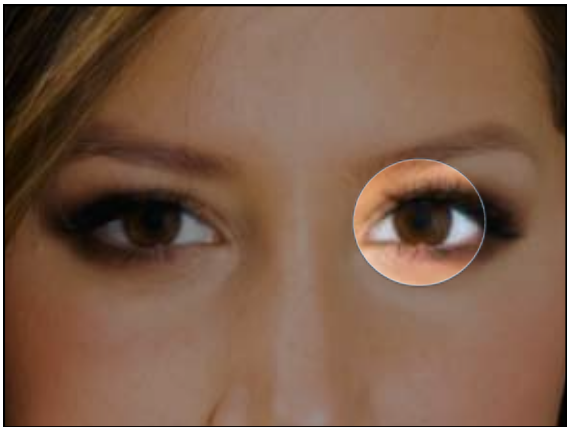
Smooth pursuit

50/ s prevent blurring
100-130 ms

RAPD x

Pupil diagnostics have just been transformed from the dark ages to the 21st Century





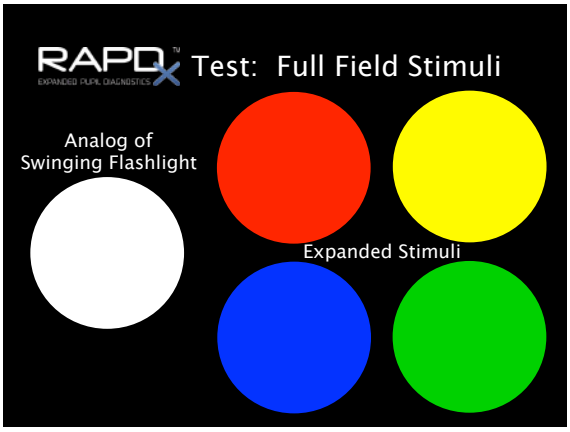
RAPDx™ Technology

- HD, machine-vision
- Automated blink rejection

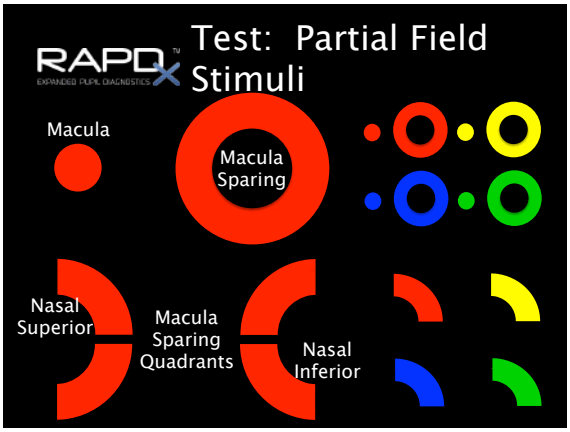
RAPDx Technology

- Optically isolated, monocular stimuli
- Fused, cycloptic view

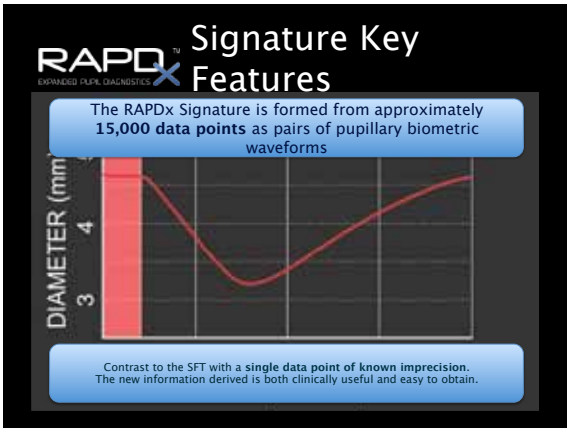
RAPDx Test: Full Field Stimuli



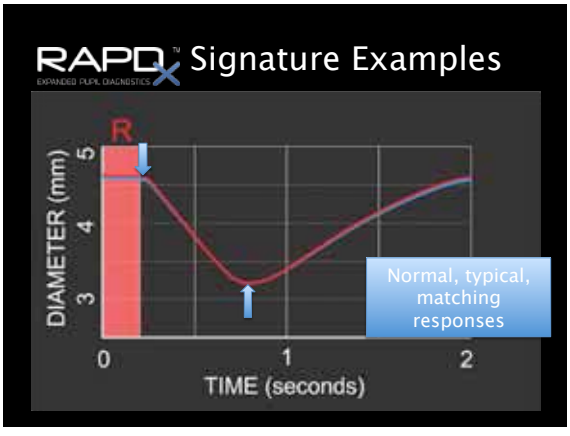
RAPDx Test: Partial Field Stimuli



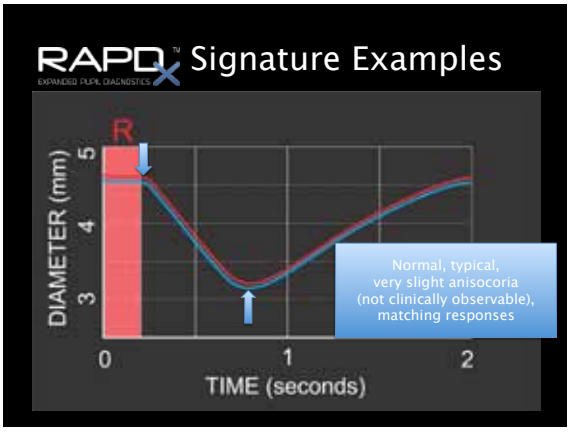
RAPDx Signature Key Features



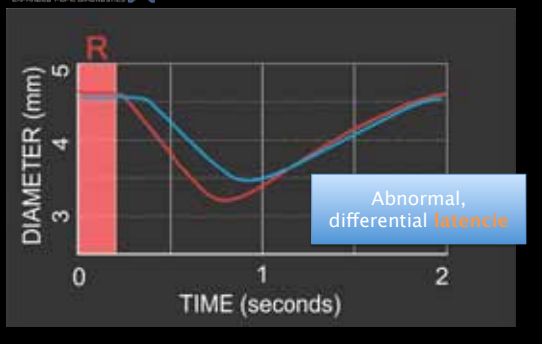
RAPDx Signature Examples



RAPDx Signature Examples



RAPDx Signature Examples



RAPDx Results

- Substantially more detailed than the best human observers
  - Clinicians typically only are reporting gross RAPD defects
  - Clinicians cannot see or judge pupil latency or velocities
  - Simplified assessment of dark iris patients and anisocoria

"The reason that eye doctors don't do RAPD testing is that it is too difficult."

R. Susanna, 2009, President World Glaucoma Association, 2007

RAPDx Report

- For patient record
- For patient handout
- Anterior segment images
- URL (+QR code) to:
  - Patient friendly explanation
  - Enhancement of your practice

Conclusions

- Many exciting advances in technology
- Important as gatekeepers to be aware of the technologies and apply them to uncover disease
- Patients are more educated than in the past and expect to see doctors who know the answers to their eye care questions and can communicate that knowledge

THANK YOU!

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