Spectrum of Glaucoma Technologies and Standard of Care Implications

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Spectrum of Glaucoma Technologies

A. OCT
1.RNFL measurements (also with GDx)
2.Ganglion cell complex aka ganglion cell analysis
3. Screening OCTs – iWellness or Wellness
4. Anterior segment OCT for angle assessment
5. OCTA (angiography)

B. Visual fields- advantages and disadvantages of each:

1. 10-2 vs 24-2 vs 30-60 vs new modified programs- 24-2C
2. Micro-perimetry and virtualfield and

C. Electrophysiology-objective ganglion cell assessment
1. pERG
2. PhNR
3. mf VEPs

D. Corneal hysteresis measured with **O**cular **R**esponse **A**nalyzer

E. Endothelial cell count measured with Specular Microscopy

F. . Others: Pachymetry , Gonioscopy, UBM, Simultaneous color and contrast testing, Diurnal IOPs

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- Objective visual fields- measuring pupillary contraction to visual stimuli in different locations and different intensities

Sherman's education circa 1970

- In order to diagnose glaucoma, you need:
- High Pressures
- Characteristic Optic Nerve Head Cupping
- Field Loss Predictable from the Cupping

"We see only what we look for.
We look for only what we know."

-Merrill Sosman, MD
(after Goethe) circa 1955

Examples:
Normal tension glaucoma
Normal field glaucoma

Normal cup glaucoma

If you "know" that glaucoma only exists with high pressure, field loss and cupping, you will never look for the above & hence never see it.

A Most Revealing Case dating back 2 decades!

- A 40 year-old female optometrist requested to learn how to evaluate her patients on the new GDx VCC that recently had become available. As part of the learning experience, we typically have the doctor experience the test from the patients' point of view.

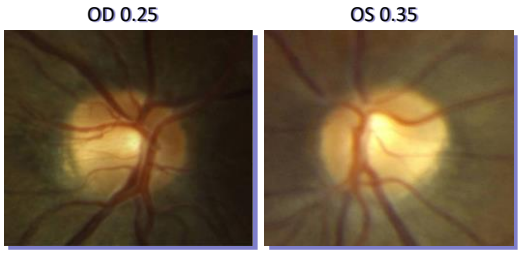
Examination following Failed GDx Screening

- Family history revealed a paternal aunt with glaucoma
- The health history was unremarkable
- No history of trauma
- Corrected visual acuity was 20/20 OU
- Goldmann IOPs were then measured at 13 mm Hg OU
- Angles were judged as open with biomicroscopy and gonioscopy

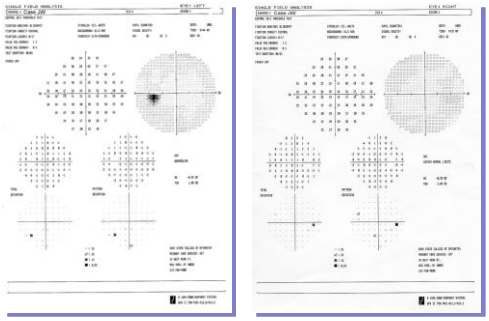
Examination (con't)

- Ophthalmoscopy revealed normal discs and normal cups
- Cup to disc ratio:
  - 0.25 OD
  - 0.35 OS
- Pachymetry was normal (550 OD, 555 OS)

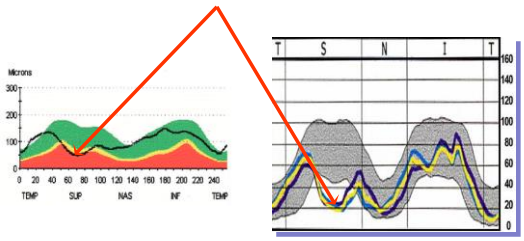
Fundus: Think ISNT Rule - J Jonas



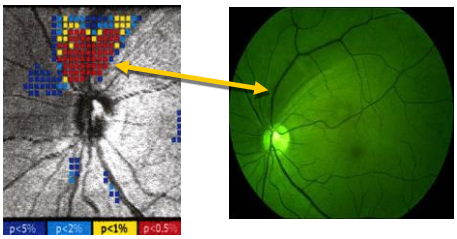
Humphrey VF 30-2



GDx VCC & OCT III
Demonstrate Superior RNFL Loss OS



Synergy of Red Free Fundus and GDx VCC OS



Note the correspondence between the digital, enhanced red-free photo and the GDx deviation map in the left eye.

Casptomap® **Fundus ImageSsuch**

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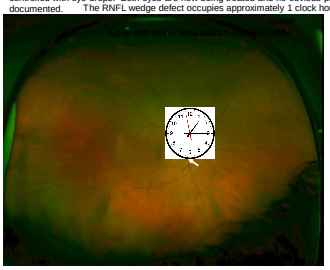
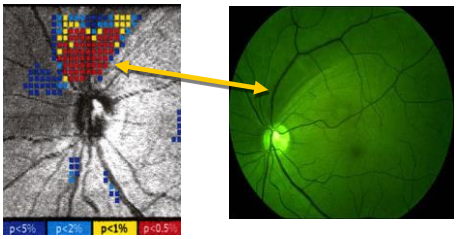
Corresponding RNFL defects were also obtained with the GDx VCC and OCT. IOPs have been controlled with eye drops. Both eyes are now being treated and no obvious progression has been documented. The RNFL wedge defect occupies approximately 1 clock hour



Note the RNFL wedge defect inferior temporal

Synergy of Red Free Fundus
and GDx VCC OS



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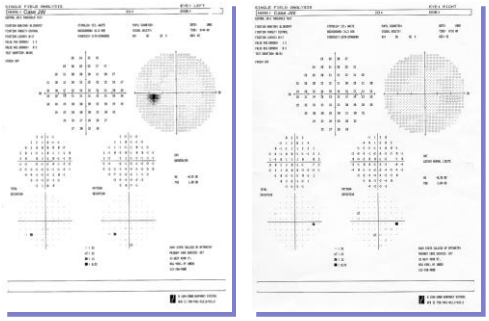
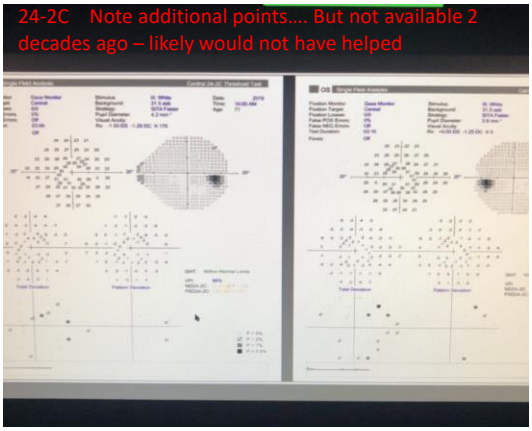
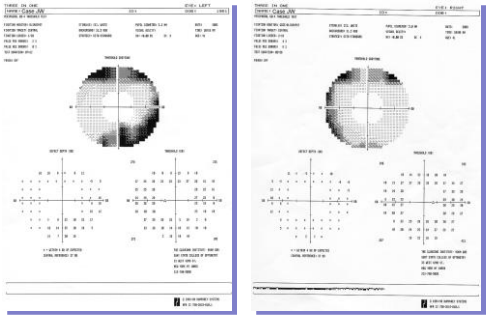
Humphrey VF 30-2



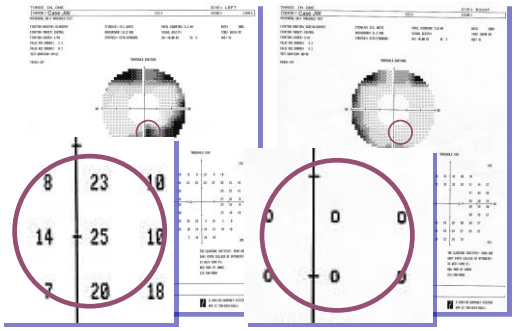
24-2C Note additional points…. But not available 2 decades ago – likely would not have helped



Humphrey VF 60-4

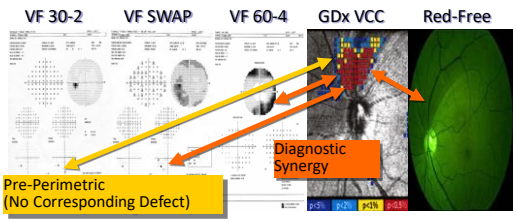


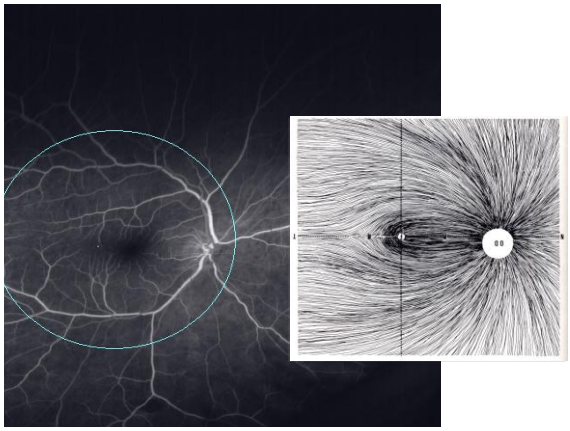
Humphrey VF 60-4



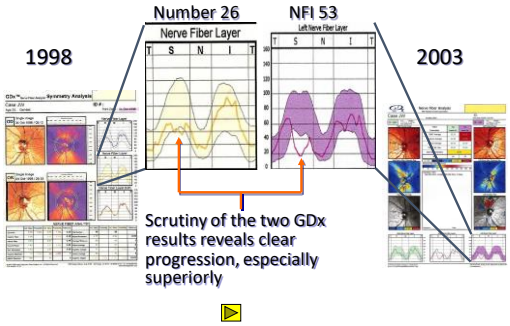
GDx VCC , 30-2 , SWAP , 60-4 ,
Red Free Fundus Photography OS

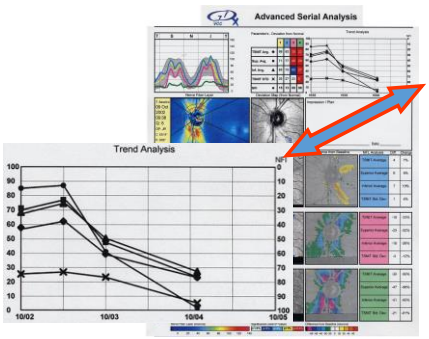
Note the diagnostic synergy of the GDx VCC Deviation Map, 60-4 Peripheral visual field, SWAP visual field, and red free fundus photo. Central 30-2 visual field is pre-perimetric.





Progression in OS





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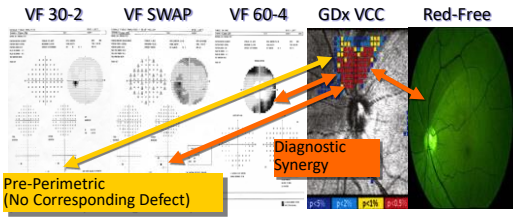
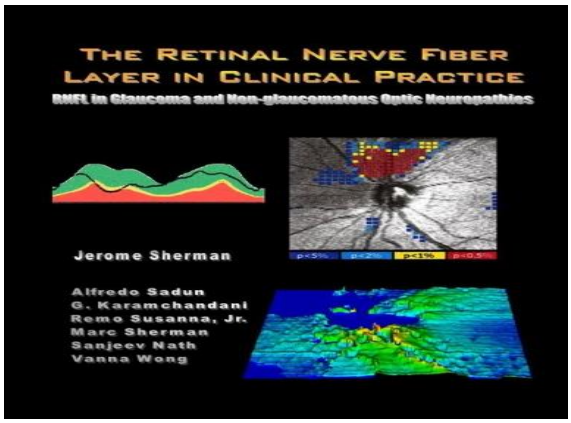
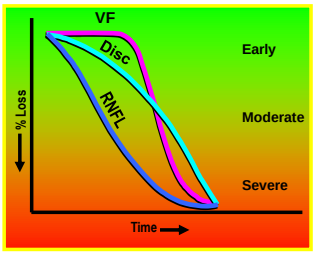




Weinreb's Structural/ Functional Relationship in Glaucoma as the Disease Progresses

- Visual Field changes occur late in the disease
  - The Optic disc often changes before visual fields
  - The RNFL usually changes before both the visual fields and optic disc



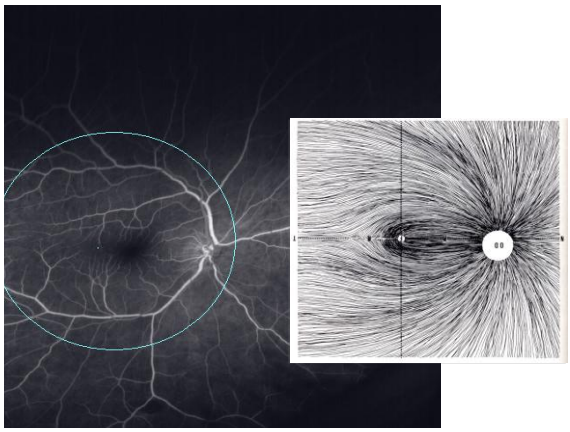
Adapted from Professor Robert N. Weinreb
Hamilton Glaucoma Center, University
California San Diego

What do ***all*** Glaucoma patients have?

- Symptoms
- Family history
- High IOPs
- Thin corneas
- Narrow angles
- Cupping
- Field defects
- RNFL/ganglion cell loss
-

Glaucoma screening on everyone?
Recommended 20 yrs ago

- Yes! GDxVCC screening takes one minute
- Several malpractice cases are presently running through the court system.
- "The GDx VCC is one malpractice case away from becoming the standard of care"
- NFL defects occur years earlier than field defects in over 90% of cases.
- The GDx will grow your practice, earn money, allow you to provide better care and help prevent malpractice allegations.
- Glaucoma care is the single largest income producer
- It is a NO-BRAINER!

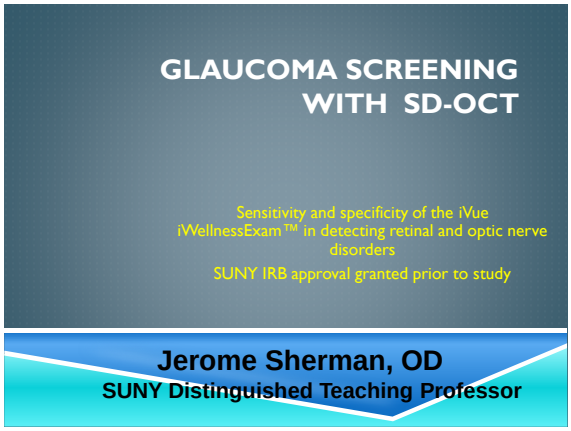


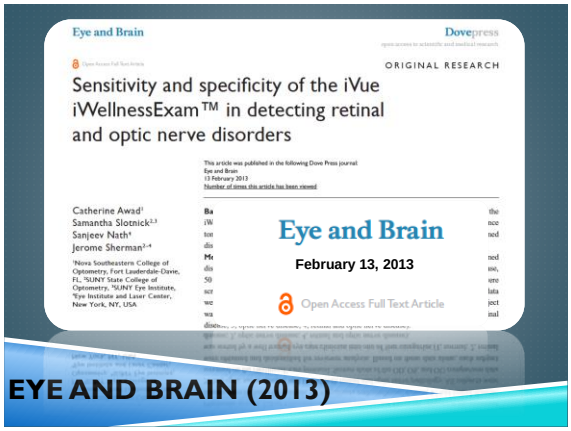
Fields ARE Fundamental

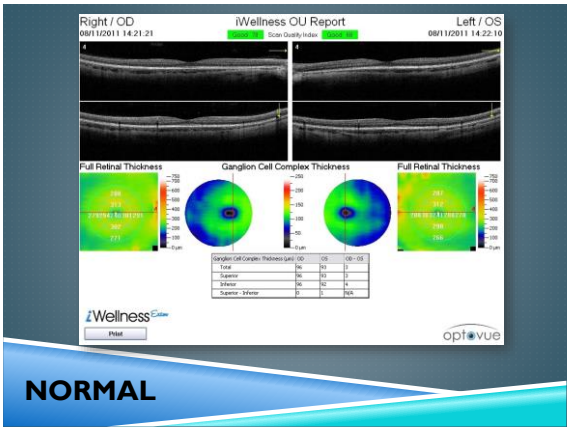
- The single most important test for retinal, optic nerve and visual pathway disorders
- Three cases of chiasmal tumors with normal confrontations but no automated visual fields

Case 1	Dx Amblyopia	NLP	$9.2 Mil
Case 2	Dx Hyperopia	NLP	$3 Mil
Case 3	Dx Cats	Death	?

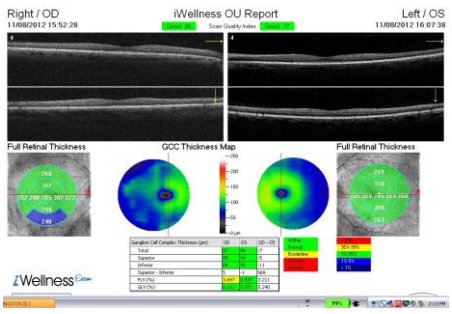
Screen Everyone:
MATRIX makes sense.

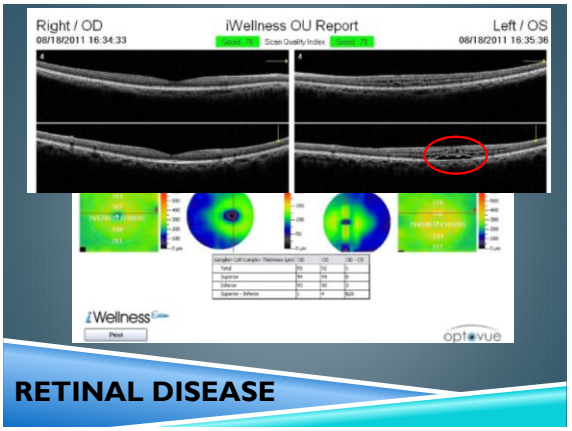


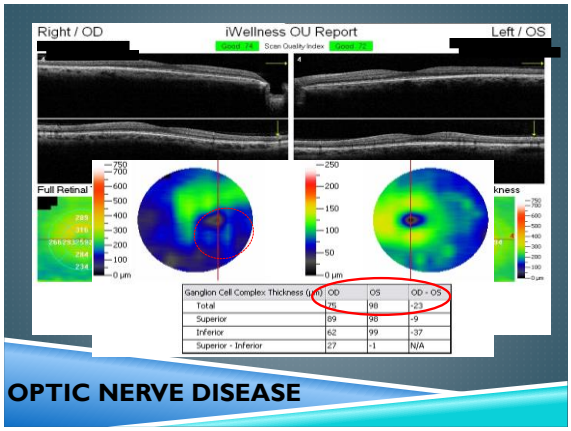


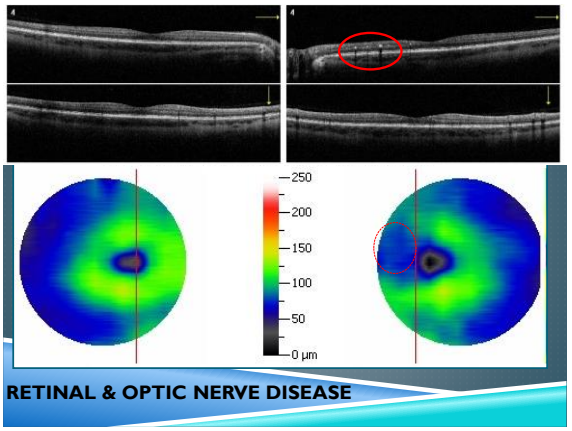


iWellness OU









- Normal Subjects: 125 of 126 correctly identified as normal.
- Retinal and/or optic nerve disease: 97 of 101 patients correctly identified as having the disease.
- Retinal Pathology: 64 of 67 patients correctly identified as having a retinal disease.
- Optic Nerve Pathology: 45 of 50 patients correctly identified as having an optic nerve disease.

Table 2 iWellnessExam sensitivity and specificity, on expert review

	Sensitivity			Specificity
	Any disease	Retinal disease	Optic nerve disease	Normal
Test (+)	97	64	45	1
Test (–)	4	3	5	125
	96.0%	95.5%	90.0%	99.2%

RESULTS

- Sensitivity: the proportion of actual positives which are correctly identified as such.
  - e.g. the percentage of sick people who are correctly identified as having the condition
- Specificity: the proportion of negatives which are correctly identified as such
  - e.g. the percentage of healthy people who are correctly identified as not having the condition

- Normal Subjects: Specificity 99%
- Retinal and/or optic nerve disease: Sensitivity 96%
- Retinal Pathology: Sensitivity 95.5%
- Optic Nerve Pathology: Sensitivity 90%

SPECIFICITY & SENSITIVITY

VEP/ERG for the Office:

How New Technology Can Impact Your Practice

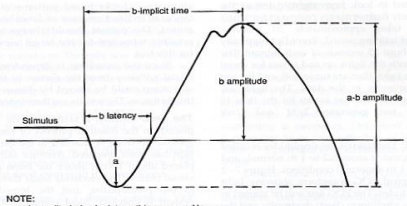
Jerome Sherman, OD
SUNY Distinguished Teaching Professor

BEYOND OPHTHALMOSCOPY

COPE

ERGs

Traditional flash ERG does not record the PhNR which is very helpful in glaucoma



NOTE:
- a-b amplitude (major interest) is measured in uv.
- Average 80-150 uv photopic 300-500 uv scotopic with high intensity flash (photopic is usually 30% of scotopic).
- Average b implicit is 30 ms photopic and 50 ms scotopic.

WAVEFORM	RETINAL COMPONENT	ALTERED IN
Photopic A	Cones	Cone dystrophies
Scotopic A	Rods	Congenital stationary night blindness
Photopic B	Inner nuclear layer (cones)	
Scotopic B	Inner nuclear layer (rods)	
Flicker ERG	Macular cones	Cone dystrophies (macular degeneration)

Components of the photopic clinical ERG.

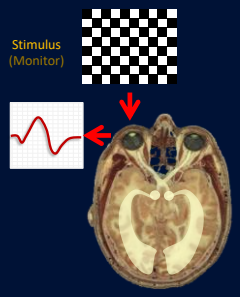
ASSESSMENT OF NEURO-VISUAL FUNCTION

pERG

Eye stimulation by a checkerboard pattern elicits a ganglion cell response known as PERG.

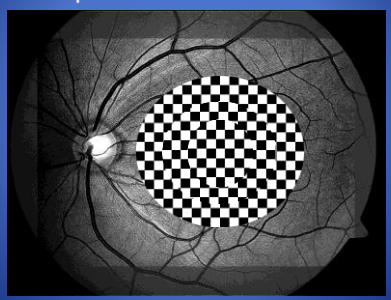
PERG is an accurate and objective indicator of ganglion cell and macular function. (ISCEV)

PERG can detect retinal dysfunction (OHT) before structural tests. (Parisi et al.)



ASSESSMENT OF NEURO-VISUAL FUNCTION

pERG AMD Stimulus



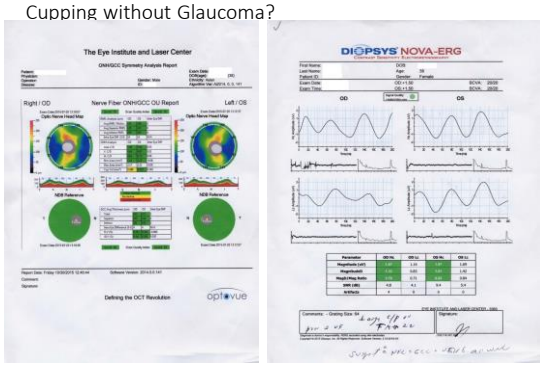
Cupping without Glaucoma

Case Review Physiological or Pathological cupping?

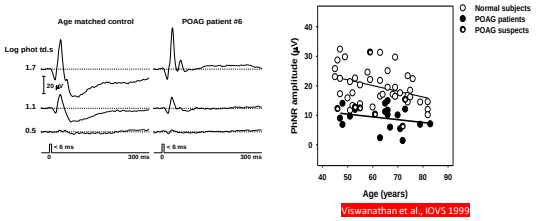
Reason for test:
C/D .8 OU
T max = 22 OU

Patient Work-Up			
Gender	Female		
Age	38		
Ethnicity	Asian		
Complaints/Symptoms	Referral : Large cups , high IOPs		
Family History	Mom reported to have Glaucoma		
Pachymetry	530 OD 535 OS		
Date of Exam	Exam 1	Exam 2	Exam 3
IOP (mmHg) OD	23	22	23
IOP (mmHg) OS	20	23	22
BCVA OD	20/20	20/20	20/20
BCVA OS	20/20	20/20	20/20
Refraction OD and OS	--1.50 OU		
Visual Fields :	Minor reduction but no consistent loss OU		
Preliminary Diagnosis	Glaucoma suspect		

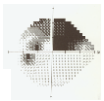
Cupping without Glaucoma?

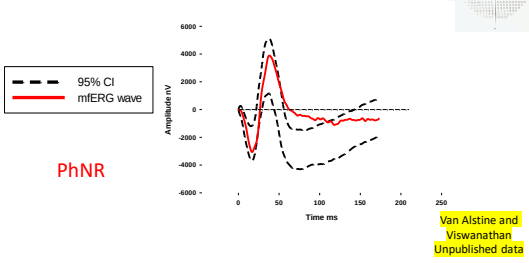


Photopic Negative Response PhNR



Example slow sequence mfERG from a 71 year old open angle glaucoma patient

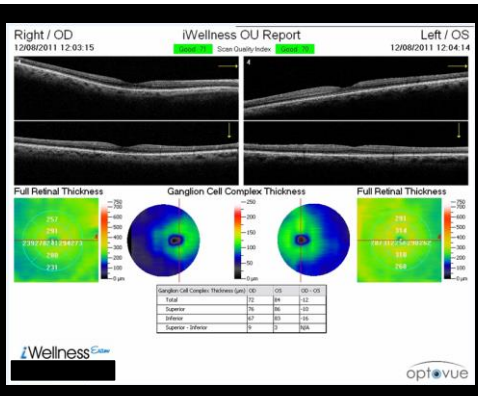




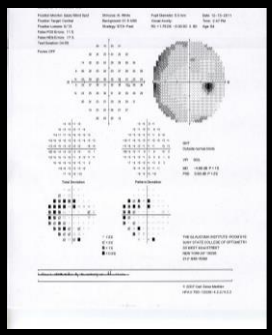
SUNY ORS

- 64 year-old WM seen by a local optometrist in NYC on July 19, 2011.
- Pt. BC VA OU was 20/20- and his IOPs @ 4pm on July 19, 2011 were 24 in OD and 16 in OS.
- IOPs were taken on another day, July 25, 2011 @ 10am OD was 18 and OS 13.
- O.D. did several VF on the OD and noted that Pt. had VF defects superiorly and inferiorly. OS was WNL.
- Pt. then referred to University Eye Center at SUNY College of Optometry where Dr. has requested further testing.
- Procedures done at SUNY: GDx, OCT, HRT, Pachymetry, VEP, Humphrey Visual Field, and ORA., B-scan ultrasonography

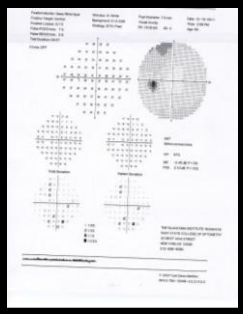
IOPs done on December 15, 2011 @ 6pm OD was 34 and OS was 22.

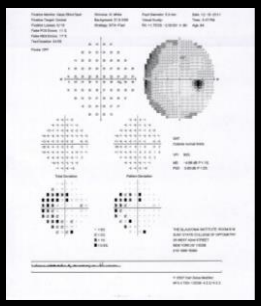


Visual Field Results: OD



Visual Field comparing OU





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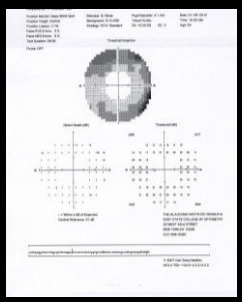
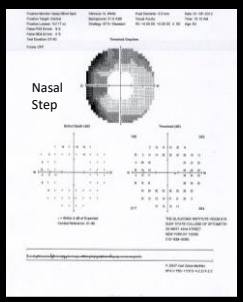


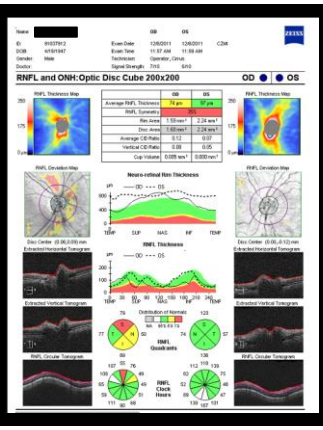
Nasal Step

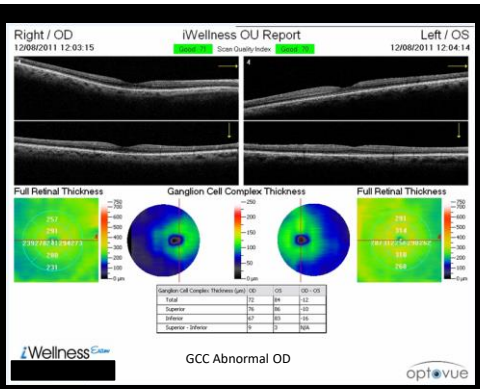


OS

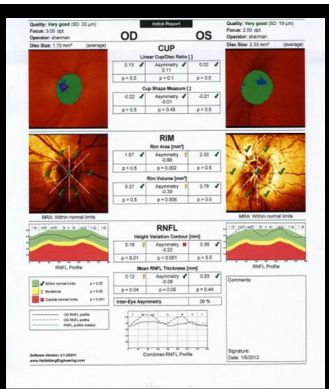
OD

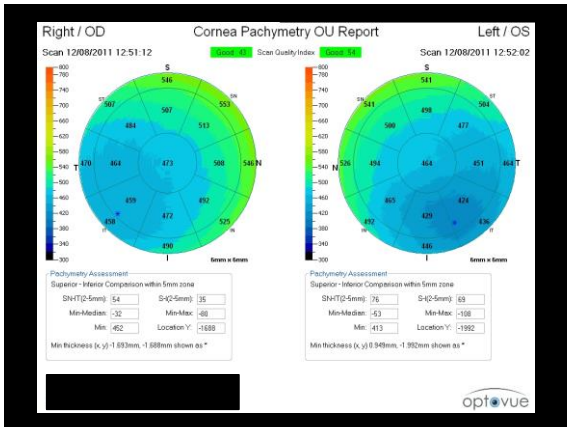
OCT Abnormal RNFL OD C/D .12 OD

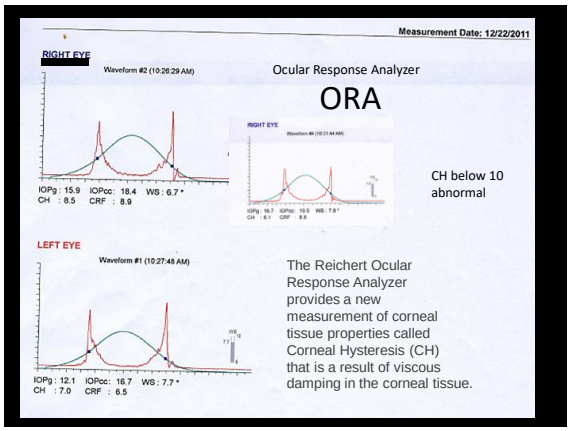




GCC Abnormal OD







ORA G3 / Corneal Hysteresis (CH)

- **A corneal property measured by rapidly deforming the cornea under a gentle puff of air** *(This is not your father's NCT!)*
- **CH is a tissue property that reflects the ability of the cornea to *absorb and dissipate energy***
  - *How good of a shock absorber is the eye?*
- Reimbursement possible under CPT code 92145
- Device also provides IOPcc – proven to be closer to true IOP than GAT

The Changing Face of Malpractice

- "Standard of Care"
- New Technology and new knowledge
- Hence, the standard of care is evolving

BEYOND OPHTHALMOSCOPY

Three Factors Must Exist for Malpractice

- The doctor failed to meet the existing standard of care at the time of the incident
- The patient (plaintiff) suffered a loss
- The loss was causally linked to the failure to meet the standard
  - issue of causation

BEYOND OPHTHALMOSCOPY

Standard of Care

- Defined standards of care such as the AOA practice guideline documents
- When defined standards are nonexistent, consider "like practitioner under like circumstance"
- Minimal standards apply, not the Distinguished Professor at Harvard

BEYOND OPHTHALMOSCOPY

Cover Your Bases…

- *1st base:* Is the best correctable VA 20/20 in each eye? If not, a clinically supportable explanation needs to be found. This may involve hi-tech diagnostic testing
- *2nd Base*: All patients deserve IOP measurements
- *3rd Base*: All patients deserve a fundus exam, preferably dilated.
- *Home Plate:* All patients deserve visual fields, preferably automated.

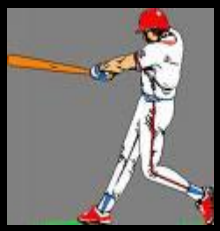
BEYOND OPHTHALMOSCOPY

And to Hit a "Home Run"….

- Requires:

"Follow-Through"

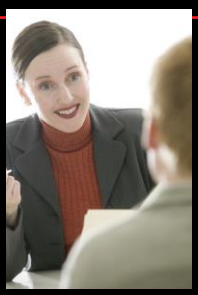
1. Patient
2. Other health personnel



BEYOND OPHTHALMOSCOPY

Cover your Bases

- Over 90% of malpractice allegations disappear
  - when you cover the four bases
  - When you communicate



BEYOND OPHTHALMOSCOPY

What conditions have resulted in the big dollar malpractice awards?

- Glaucoma
- Retinal detachments and precursors to RD
- Eye and brain tumors
- Diabetic blindness
- Choroidal neovascularization

BEYOND OPHTHALMOSCOPY

A Bottle of Nyquil for a Bad Cold Induces Bilateral Angle Closure in a Hyperopic Malpractice Attorney

- A 40 yo hyperopic malpractice attorney presented to an ER with a self diagnosed angle closure glaucoma in both eyes simultaneously
- The history revealed a bad cold that was self -treated by ingesting an entire bottle of Nyquil over a period of several hrs. He reported that his last eye exam was about 3 years earlier and his glasses dated back to that evaluation.
- VA 20/60 OU, believed to be due to edematous corneas. IOPs around 70 mm OU.
- Gonioscopy confirmed bilateral angle

BEYOND OPHTHALMOSCOPY

DIAGNOSIS and FOLLOW-UP

- Bilateral, simultaneous angle closure in a hyperopic attorney secondary to Nyquil induced pupillary dilation.
  - Nyquil has 3 sympathomimetic agents
- Laser PIs were successfully performed following the immediate treatment with Osmoglyn, Diamox and various eye drops. Even with patent PIs, pupillary dilation on one occasion resulted in IOP spikes into the 50's.
- Pt. now appears to have normal discs but visual fields & NFL measurements with GDx and OCT reveal damage.
- After cat ext, IOPs normal w/o gtts OU.

BEYOND OPHTHALMOSCOPY

ALLEGED MALPRACTICE

- Although the previous doctor who prescribed the glasses for the hyperopia did not do gonioscopy and did not warn about possible pharmacologically induced angle closure, the most recent exam took place nearly 3 years earlier.
- In NYS, the statue of limitations in malpractice cases is 30 months from the last doctor patient contact.

BEYOND OPHTHALMOSCOPY

COMMENT

- Careful slit lamp exam for angle assessment as well as gonioscopy should be considered in all hyperopes, since these small eyes have a much higher risk of angle closure.
- Prophylactic LPI is recommended in such cases to prevent angle closure.
- Patients who are anatomically prone to angle closure should be told that many over-the -counter medicines contain (sympathomimetic) ingredients that can induce angle closure.

BEYOND OPHTHALMOSCOPY

Visit # 1

- 32 y.o. diabetic presented with c.c. of right eye irritation for 3 days RE also watery and red but not stuck down in A.M.
- VA: 20/20- - 20/20-
- S.L.: 2+ cells + 2+ flare +2+ hyperemia OD and 2+ SPK (corneal defect drawn slightly temporal to visual axis)
- Dx: Kerato-uveitis OD
- Rx: PF q 2h OD
- HA QID OD
- Occuflox QID OD
- RTC: 1 day

BEYOND OPHTHALMOSCOPY

Visit #2

- Patient returns in 1 day - feels a little better
- VA: 20/20 - 20/20
- S.L.: trace cells and flare, 1+ corneal edema,small abrasion - same location as before
- Doctor noted patient diabetic: slow healer
- Rx: patch with occumycin ung
- RTC: 1 day

BEYOND OPHTHALMOSCOPY

Visit #3

- Next day seen by different doctor in same office
- S.L.: abrasion resolving 80% OD
- 2+ corneal and conjunctival edema
- + 1+ hyperemia, 1+ cells and 1+ flare OD
- Rx: resume previous meds
- PF 1% q 2H, Occuflox QID, HA QID OD
- RTC: 1 day

BEYOND OPHTHALMOSCOPY

Visit #4

- Next day seen by 2nd doctor
- c.c.: patient feels a lot better
- VA: 20/20-3 20/20
- drawing of cornea labeled as clear
- minimal edema, good VA
- Rx: DC Homatropine
- Occuflox to BID
- taper PF q 4H, QID, TID BID OD
- No RTC unless symptoms persist or worsen

BEYOND OPHTHALMOSCOPY

Cover Your Bases…

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- *2nd Base*: All patients deserve IOP measurements
- *3rd Base:* All patients deserve a fundus exam, preferably dilated.
- *Home Plate:* All patients deserve visual fields, preferably automated.

BEYOND OPHTHALMOSCOPY

Visit #5

- 10 wks later
- c.c. eye irritation rt eye - also blurry 2 wks
- "tried drops from before"
- 1+ corneal edema, trace cells and flare
- doctor draws "healing abrasion in same location as previously"
- Dx: RCE (recurrent corneal erosion)
- Rx: dilate homatropine
- Muro 128q ung HS OD
- Refresh Plus 6x day OD
- RTC: 5 days

BEYOND OPHTHALMOSCOPY

Visit #6

- VA worsens, now has pain OD; presents to different doctor in different office
- c.c. rt eye red 2 wks, vision reduced 1 wk
- IDDM 20 yrs
- VA: RE LP only and LE 20/25
- TA: 70 OD, 21 OS
- S.L.: corneal bullae with drawing shown later

to match location as previously

- GONIO: opened angle with reddish tint-NVA
- DFE: Proliferative diabetic retinopathy

OU Rx: IOPs reduction with 6 meds

BEYOND OPHTHALMOSCOPY

Visit #6 *(continued…)*

- PRP within 1 wk OD then OS
- Final VA: NLP OD, 20/40 OS
- Did care deviate?
- Problem with problem specific vs problem-oriented exam
- "Tip of the iceberg"

Actual chain of events

- Long-standing diabetic retinopathy which progressed to proliferative stage without macula involvement followed by rubeosis, neovascular glaucoma, sky high IOPs, corneal edema, corneal bullae

BEYOND OPHTHALMOSCOPY

Why an iritis in a diabetic patient?

- The new blood vessels on the iris are fragile and prone to leak.
- Hence the "inflammation" is not a true iritis and the treatment must be directed to the cause.
- Because of the corneal bullae, present from the first visit on but misdiagnosed, the IOP must have been elevated for months.

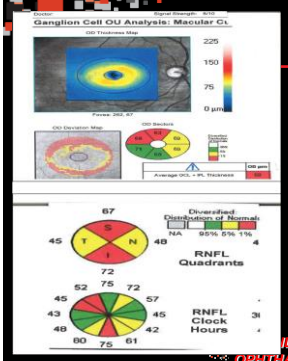
BEYOND OPHTHALMOSCOPY

A Tale of Two Sisters

- 1- Both sisters were myopic, in their mid 40s and since mom had glaucoma, both were followed as glaucoma suspects with IOPs in the low 20's but on ***different coasts***
- 2- Both had subtle but not consistent field errors and both had .6 C/D ratios. The older sister's doc obtained an OCT which then revealed substantial loss of GCC and RNFL OU and was hence treated both with drops & SLT
- 3-The younger sister had stable "basic" findings and was not tested with an OCT until about 5 years later and similar to her sib, she had very substantial GCC and RNFL loss even though her fields were essentially normal
- 4-The premise of the lawsuit related to a 5 year delay in diagnosis and treatment but the question becomes, what is the standard of care?
- 5-At the time, only about a quarter of ODs had OCTs, and hence it was not the standard of care as per the concept of "like practitioner under like circumstance"
- 6- When 51% of ODs have OCTs, the standard changes and such a case would perhaps result in a large jury award

BEYOND OPHTHALMOSCOPY

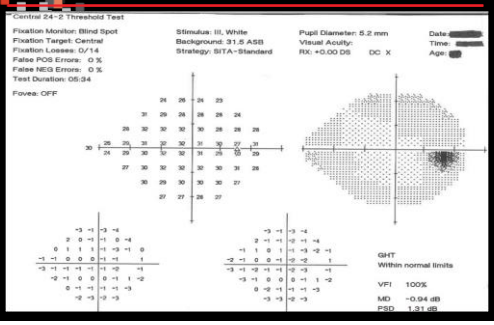
Exemplary Real Case



- High IOPs OD
- .8 C/D ratio
- Normal fields OD
- Abnormal OCT
  - GCC
  - RNFL

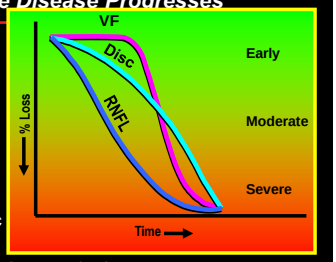
BEYOND OPHTHALMOSCOPY

Normal 24-2 Visual Fields



Weinreb's Structural/ Functional Relationship in Glaucoma as the Disease Progresses

- Visual Field changes occur late in the disease
- The Optic disc often changes before visual fields
- The RNFL usually changes before both the visual fields and optic disc



Adapted from Professor Robert N. Weinreb
Hamilton Glaucoma Center, University
California San Diego

BEYOND OPHTHALMOSCOPY

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- *2nd Base*: All patients deserve IOP measurements
- *3rd Base*: All patients deserve a fundus exam, preferably dilated.
- *Home Plate:* All patients deserve visual fields, preferably automated.
- In glaucoma cases, we need to go beyond the 4 bases and we recommend OCT and to consider other technologies

BEYOND OPHTHALMOSCOPY

Introducing Compass:

Fundus Perimetry in the management of glaucoma

Fundus Perimetry *is a technique that images the retina during Visual Field testing, enabling accurate correlation between visual function and retinal structure*

BEYOND OPHTHALMOSCOPY

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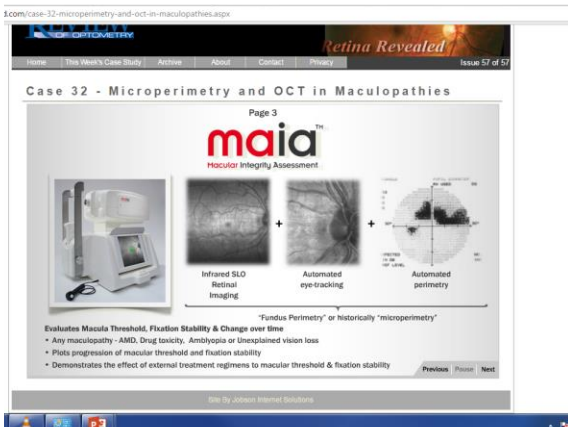
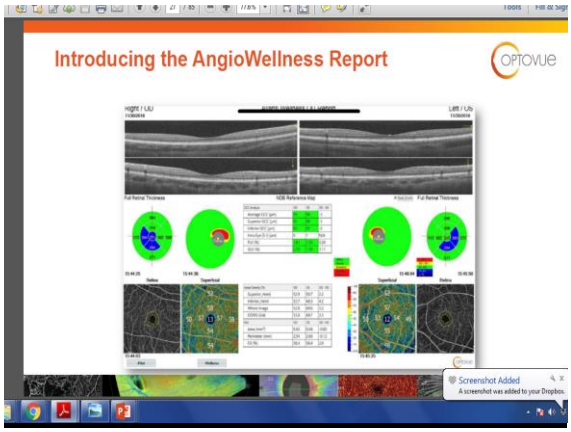
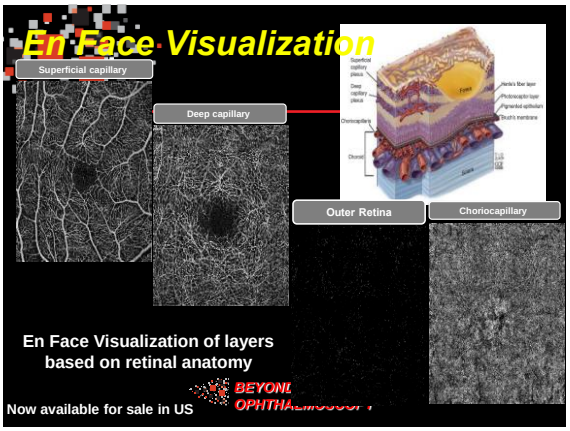
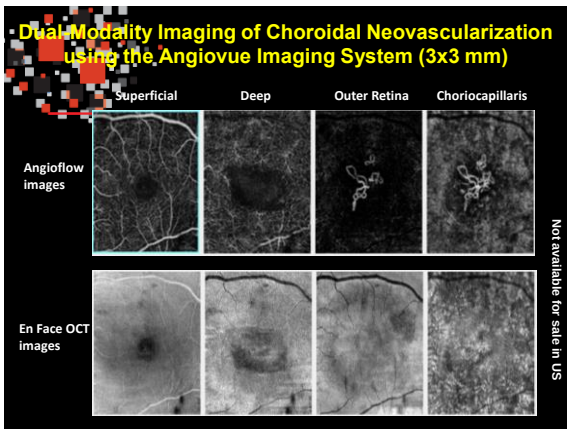
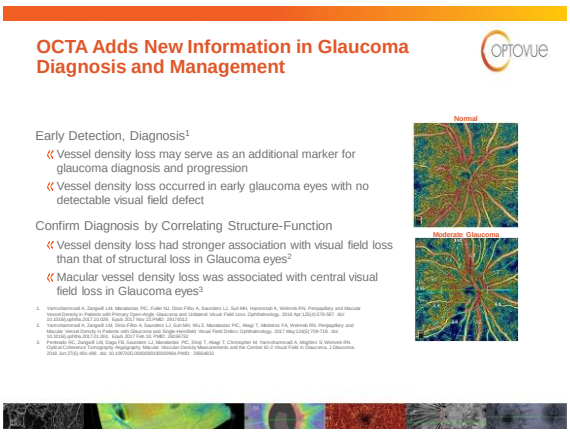

Retina Revealed
Case 32 - Microperimetry and OCT in Maculopathies
Page 3
maia
Macular Integrity Assessment
Infrared SLO Retinal Imaging
Automated eye-tracking
Automated perimetry
"Fundus Perimetry" or historically "microperimetry"
Evaluates Macula Threshold, Fixation Stability & Change over time
• Any maculopathy - AMD, Drug toxicity, Amblyopia or Unexplained vision loss
• Plots progression of macular threshold and fixation stability
• Demonstrates the effect of external treatment regimens to macular threshold & fixation stability


Commercially available OCTs:
Cirrus HD-OCT (Zeiss)
3D-OCT-2000 (Topcon)
RTVue-100 (Optovue)
Spectral OCT/SLO
iVue (Optovue)
Spectralis (Heidelberg)


Introducing the AngioWellness Report
OPTOVUE
Screenshot Added
A screenshot was added to your Dropbox.


En Face Visualization
Superficial capillary
Deep capillary
Outer Retina
Choriocapillary
En Face Visualization of layers based on retinal anatomy
Now available for sale in US
BEYOND OPHTHALMOSCOPY

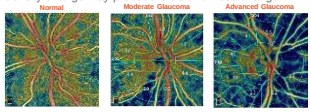

Dual Modality Imaging of Choroidal Neovascularization using the Angiovue Imaging System (3x3 mm)
Superficial
Deep
Outer Retina
Choriocapillaris
Angioflow images
En Face OCT images
Not available for sale in US


OCTA Adds New Information in Glaucoma Diagnosis and Management
OPTOVUE
Early Detection, Diagnosis[1]
Vessel density loss may serve as an additional marker for glaucoma diagnosis and progression
Vessel density loss occurred in early glaucoma eyes with no detectable visual field defect
Confirm Diagnosis by Correlating Structure-Function
Vessel density loss had stronger association with visual field loss than that of structural loss in Glaucoma eyes[2]
Macular vessel density loss was associated with central visual field loss in Glaucoma eyes[3]
Normal
Moderate Glaucoma

OCTA Adds New Information in Glaucoma Diagnosis and Management

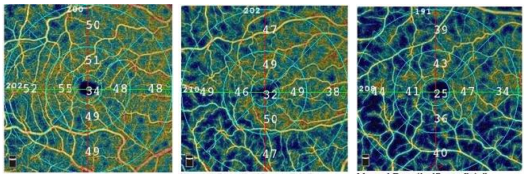
Progression Detection

- Baseline OCTA measurements may serve as an additional marker in the assessment of the risk of progression in POAG patients[4]
- Macular vessel density loss occurs faster in eyes with POAG than either glaucoma-suspect or healthy eyes[5]
- Macula vessel density change may precede GCC thickness change[5]



4. Moghimi S, Zangwill LM, Penteado RC, Hasenstab K, Ghahari E, Hou H, Christopher M, Yarmohammadi A, Manalastas PIC, Shoji T, Bowd C, Weinreb RN. Macular and Optic Nerve Head Vessel Density and Progressive Retinal Nerve Fiber Layer Loss in Glaucoma. Ophthalmology. 2018 Jun 12. doi: 10.1016/j.ophtha.2018.05.006. [Epub ahead of print]
5. Shoji T, Zangwill LM, Akagi T, Saunders LJ, Yarmohammadi A, Manalastas PIC, Penteado RC, Weinreb RN. Progressive Macula Vessel Density Loss in Primary Open-Angle Glaucoma: A Longitudinal Study. Am J Ophthalmol. 2017 Oct;182:107-117. Epub 2017 Jul 20.

Glaucoma Also Affects Vasculature of the Macula

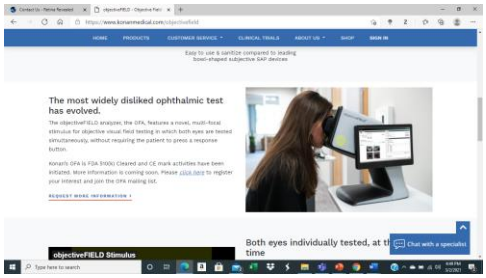


Normal Eye | Moderate Glaucoma | Advanced Glaucoma

Images courtesy of Drs. Weinreb, Nudleman, Goldbaum, Zangwill, San Diego, California

Virtual Fields

Objective Visual Fields –based upon pupils reacting to light stimuli



objectiveFIELD analyzer by KONAN

Worth Exploring OCULUS Easyfield C ? I have not as yet