Addressing Structural Puzzles in Diabetic Eye Disease

Management and Treatment Decisions Based on Structural and Functional Testing

COPE# 93352-SD (2025)

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Alcon Vision Care, Notal Vision, MacuHealth, LKC Technologies, Maculogix (previous), Tarsus, and Lumithera

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What is Diabetes?

- -Metabolic Disease characterized by hyperglycemia
- -Result from a defect in insulin secretion, insulin action, or both
- -Leads to damage and eventual failure of multiple organs (eyes, kidneys, nerves, vessels)
- -Typically divided into Type 1 and Type 2 – Type 2 much more common
- -It is the 7th leading cause of death in the U.S. (CDC 2017)
- -Economic burden of the disease is estimated at $404B (2017)
- -Estimates place Diabetes as affecting 12-14% of adults in U.S. – could be as high as 1 in 3 adults by 2050!

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Prevalence and Incidence of DM

(2015 data)

- An Estimated 415 million (8.8%) adults worldwide have diabetes
- Number expected to grow to 642 million by 2040 (increase in obesity, lifespan and detection)
- In the U.S. - 30.2 million (12.2%) of all adults over age 18 have diabetes
- Men (12.7%) are more at risk than women (11.7%)
- Diabetes is of increasing concern in children and adolescents; nearly a quarter of a million people under age 20 have the disease and the rate of diagnosis is increasing
- 33.9% of U.S. adults had prediabetes based on FBG or A1c in a 2015 study

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Sugar…The Root of All Evil???

HHS Public Access

Author manuscript

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The Dose Makes the Poison: Sugar and Obesity in the United States – a Review

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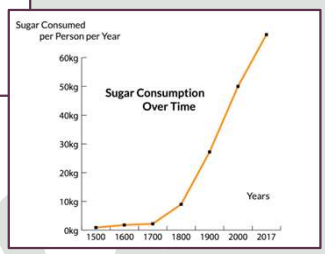
In 1700, people consumed about 4 pounds of sugar per year. By 1800, people consumed about 22 pounds per year.



By 1900, people consumed about 90 pounds per year. By 2012, over 50% of Americans consumed a half pound of sugar per day – over 180 pounds of sugar per year!!!

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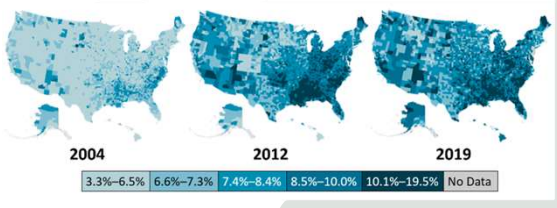
Diabetes Prevalence Among US Adults Aged 20 Years or Older, 2004, 2012, and 2019



United States Diabetes Surveillance System and Behavioral Risk Factor Surveillance System, Centers for Disease Control and Prevention

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Type 1 Diabetes

- Body's immune system attacks and destroys insulin-producing beta-cells in pancreas
- About 6% of patients with diabetes in the U.S. have Type 1
- Although often diagnosed in children/young adults, Type 1 can occur at any age
- **Two Subtypes:**
- -autoimmune markers present (Islet Cell Abs)
- -idiopathic; no ICAs and likely inherited

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Type 2 Diabetes

- *** Also referred to as adult-onset/non-insulin dependent**
- *** Body makes too little insulin or is unable to effectively use the insulin it produces**
- *** Autoimmune destruction of beta cells does not occur**
- *** Most common, is increasing, and represents about 91% of DM cases in the U.S.**
- *** Risk increases with age, BMI, obesity and lack of physical activity**

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Some Additional Subtypes of Diabetes

Gestational:

- Refers to a form of glucose intolerance with onset during 2nd or 3rd trimester
- Caused by hormones secreted during pregnancy
- Glucose tolerance typically returns withing 6 weeks of delivery
- Increases risk for developing Type 2 (35-60 percent within the subsequent 10-20 years)

Prediabetes:

- Blood Glucose levels below the criteria for Diabetes
- Increased risk for developing Type 2
- Age, race, hypertension, obesity and dyslipidemia increase risk of progressing to Type 2
- A1c between 5.7 and 6.4 percent is considered Prediabetes

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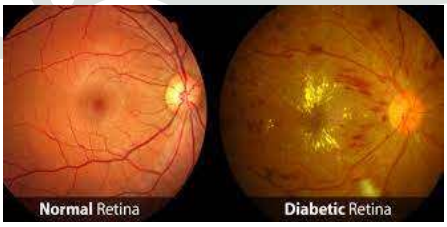
Optometry: On the Front Lines of Diabetes Diagnosis!



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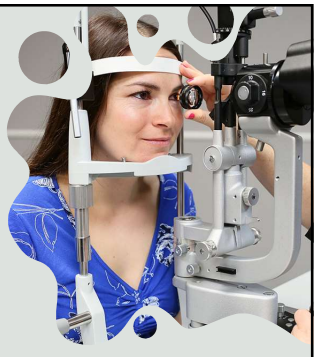
Structural Testing for Diabetes

- Slit Lamp Biomicroscopy
- Fundus Photography
- Ultra-Widefield Fundus Imaging
- OCT (primarily for DME)
- Angio OCT



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Using the Greatest Tools/Technology to Grade Diabetic Retinopathy

Nonproliferative DR

- Does not present a threat to vision
- Mild NPDR: at least one microaneurysm
- Moderate: hemes/MA is 1-3 quadrants or mild soft exudate, venous beeding/IRMA
- Severe: "4-2-1"Rule (H/MA in 4, VB in >/=2, prominent IRMA in at least one)
- Very Severe: 2 or more severe criteria are met – 75% risk of PDR in one year

Proliferative DR

PDR characterized by NVD or NVE

High-Risk PDR: characterized by presence of 3 of the 4 risk factors for severe visual loss:

- Pre-retinal or vitreous hemorrhage
- Presence of new vessels
- New vessels on or near the disc (NVD)
- Presence of moderate or severe new vessels

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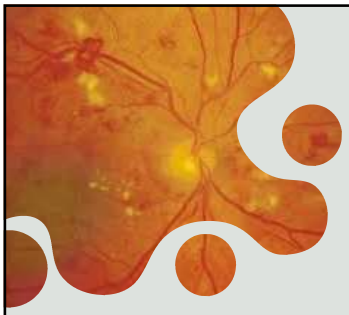

The Grading of DM is Based on Structural Findings, However…

The level of DR seen does not always correlate with visual functioning

DME may be present at any level of retinopathy (non-proliferative or proliferative)

Neuronal degeneration and damage often occurs in the inner retina before the onset of DR

Is Structural Testing Alone Enough?

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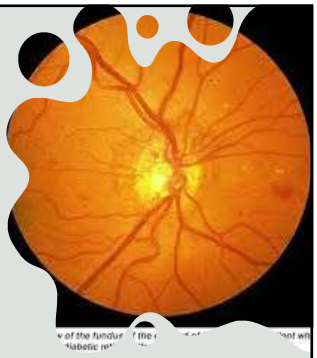
Is Structural Testing Enough?

There are some Limitations to Structural Testing:

- Often hemoglobin A1c and structural findings don't match (earlier in the disease state)
- We may be seeing patient at a "good time" when tissue/structure looks its best
- Structural changes do not provide the clinician insight as to how the retina is functioning
- Chronic diseases tend to wax and wane (with diet, stress, exercise, etc.)



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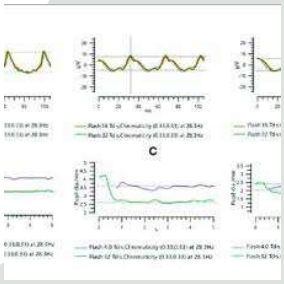
Functional Testing in Diabetes Management



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Traditional Functional Tests for DM

Visual Acuity

Contrast Sensitivity

Visual Field (?)

Amsler Grid (DME)

Preferential Hyperacuity Perimetry (PHP) – used primarily for AMD

Rapin Cone Test

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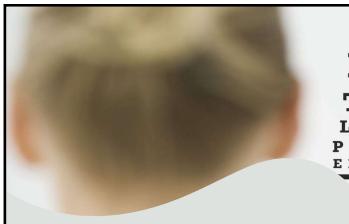

Limitations of Traditional Functional Tests

Often show changes in visual functioning late in the disease process

Tend to focus on the functioning of a small area of the retina

Subjective and patient dependent – patient response is required

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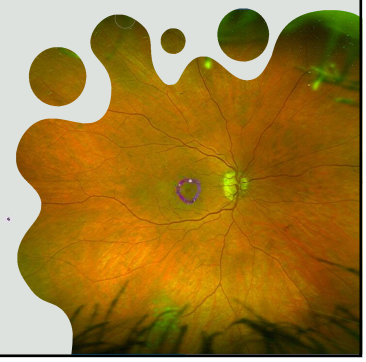
Visual Acuity:

Only gives clinician an idea of the functioning of the fovea and perifoveal area



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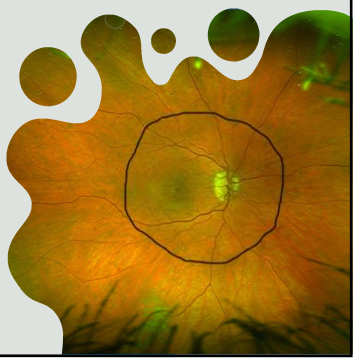
24-2 VF or Pattern ERG:

Gives clinician an idea of the functioning of the posterior pole, but does not provide any useful data on the functioning of the mid-peripheral and peripheral retinal cells



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Is There a Better Way to Assess Retinal Functioning?

Can clinicians capture clinically useful data on the functioning of the entire retina in an objective test?

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YES!...And the Key is Full Field ERG!

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Electroretinography (ERG)

Test measures the electrical response of the eye's photosensitive cells (rods and cones)

Full Field ERG (ffERG) stimulates nearly the entire retina, thereby allowing a functional test of potentially damaged cells in the mid and far periphery

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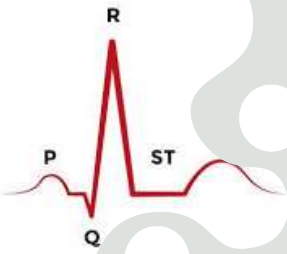

ERG is to Eye what EKG is to Heart

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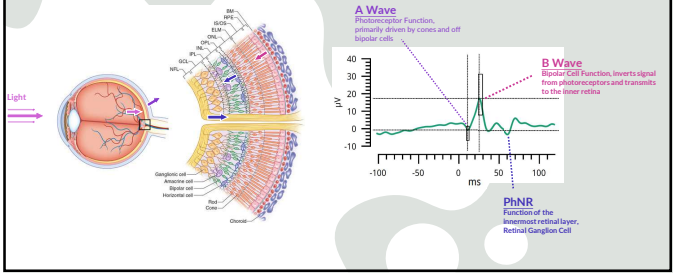
The ERG Waveform



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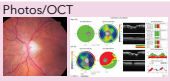
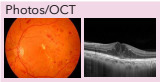
Two Disease States We Often See...

	Glaucoma	Diabetic Retinopathy
Structure	Photos/OCT 	Photos/OCT 
Function	Visual Fields 	?
Next Level Manegement	ERG 	ERG 

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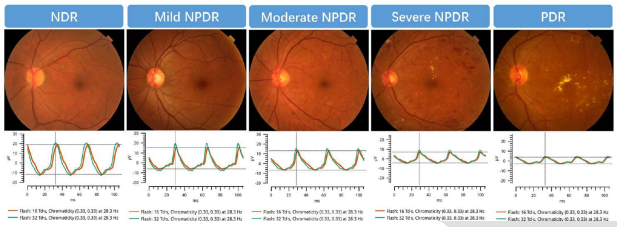

ERG is an effective, objective functional test at all levels of DR

- Zeng Y, Cao D, Yang D, Zhuang X, Yu H, Hu Y, Zhang Y, Yang C, He M, Zhang L. Screening for diabetic retinopathy in diabetic patients with a mydriasis-free, full-field flicker electroretinogram recording device. Documenta Ophthalmologica. 2019 Nov 12:1-0.

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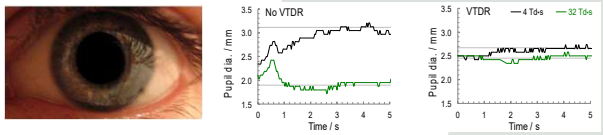
DIABETIC RETINOPATHY

Pupillary response is also impacted by DR

Pupil responses are attenuated as diabetic retinopathy gets worse



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Handheld ERG Produces a Diabetic Retinopathy (DR) Score

Score is based on the pupil's response to light (it is negatively affected by chronic damage to the retina in DM)

Score is also based on the amplitude (strength) and the implicit time (speed) of the signal sent by the retina

Damaged cells/sick cells can be identified by a reduced signal even before there are clinical signs

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Remember the Number 23.5!

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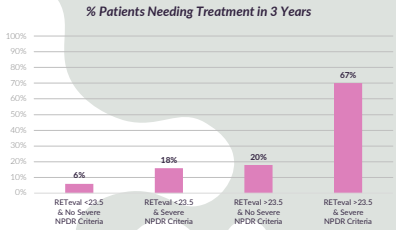
DIABETIC RETINOPATHY

Longitudinal study shows ability of the ERG to predict progression

- Longitudinal study with 279 patients
- Conducted in USA
- Primary outcome: treatment conducted in follow-up period
- Structure & ERG function were measured to predict progression
- In general: 17% of DR progresses to treatment



Brigell MG, Chiang B, Mao AY, Davis CQ. Enhancing Risk Assessment in Patients with Diabetic Retinopathy by Combining Measures of Retinal Function and Structure. Trans Vis Sci Tech. 2020;9(9):40.

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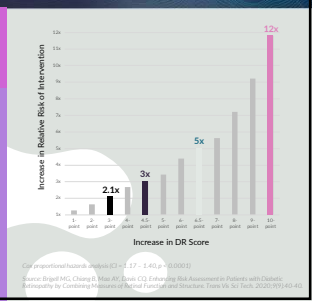
DIABETIC RETINOPATHY

Why the DR Score matters

Each 1-point change in the DR Score increases the probability of ocular intervention over 3 years by 28%

Higher DR Score & change over time dramatically increases risk:

- Risk of intervention more than doubles with a 3-point increase in DR Score (e.g. 20 to 23)
- Risk of intervention triples with a 4.5-point increase in DR Score (e.g. 20 to 24.5)
- Risk of intervention increases 5x with a 6.5-point increase in DR Score (e.g. 20 to 26.5)
- Risk of intervention increases 12x with a 10-point increase in DR Score (e.g. 16 to 26)



Cox proportional hazards analysis (CI = 1.17 – 1.40, p < 0.0001)

Source: Brigell MG, Chiang B, Mao AY, Davis CQ. Enhancing Risk Assessment in Patients with Diabetic Retinopathy by Combining Measures of Retinal Function and Structure. Trans Vis Sci Tech. 2020;9(9):40.

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My Handheld ERG in Action!

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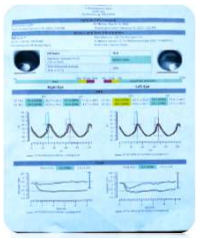
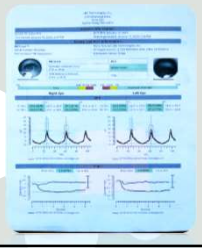
A Couple of Cases from my Practice:

One of our doctors (my control!)



Patient with background DM, OU



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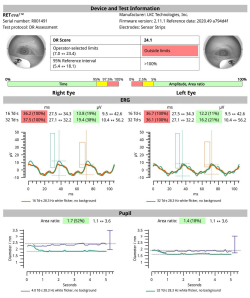
Adding the DR Score to the Clinical Picture Allows for an Informed Management Plan

A DR Score over 23.5 must be monitored more closely!



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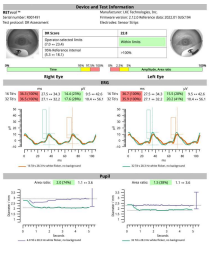
Working with GP and Lifestyle Conversation

- Increased Metformin
- Increased Exercise/Reduced Soda consumption
- Began a Fish Oil Supplement (Omega-3; EPA and DHA)
- Seeing improvements in A1c and in the health of the retinal cells!
- DR Score lowered to 22.8!



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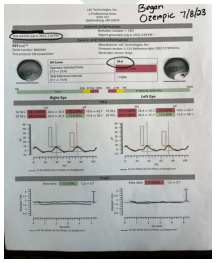
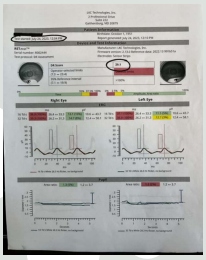
Improvement in DR Score after consult with GP:





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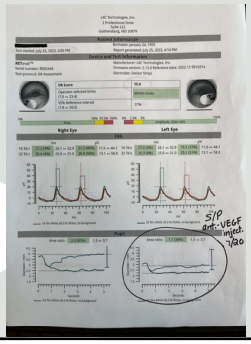
Another Patient:



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Summary

Incorporating objective functional testing means intervening at the earliest and most appropriate time points

Interventional management leads to enhanced patient outcomes

Enhanced patient outcomes increases satisfaction of both patient and doctor

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Thank You!

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Addressing Structural Puzzles in Diabetic Eye Disease

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