DIABETES MELLITUS: NEW TESTING AND TREATMENT FOR RETINOPATHY AND MACULAR EDEMA

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Disclosures

- Aerie Pharmaceuticals
- Biotissue
- Diopsys
- Ellex
- EyePromise
- Ivantis
- Maculogix
- Nidek
- Nova Ocular
- Novartis
- Optovue
- Quantel
- Reichert
- RevolutionEHR
- Sight Sciences
- Shire

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ELECTRORETINOGRAPHY AND DIABETIC RETINOPATHY

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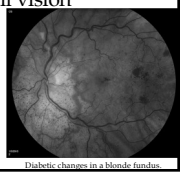
Diabetes and Diabetic Retinopathy

- In the US, 1,500,000 new cases every year
- 285,000,000 in the world (100,000,000 in the US)
  - Glaucoma : 2,700,00 in the US
- In the US, 40% will develop **diabetic retinopathy**
  - Half of them don't know about it until vision problems



Diabetic changes in a blonde fundus.

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Diabetes and Diabetic Retinopathy

- In 2015, 30.3 million Americans had diabetes
  - 9.4% of the population
  - 7.2 million are undiagnosed
  - Between 2015 and 2030 that number will increase to 55 million
- Over the age of 65:
  - 25.2% prevalence of DM
- Pre-diabetes:
  - 84.1 million Americans
- 7th leading cause of death
  - Probably underreported

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Diabetes and Diabetic Retinopathy

- Most frequent cause of new cases of blindness among adults 20-74 in developed countries
- Rate of diabetic retinopathy:
  - 35.4%
    - Type 1 after 5 years – 25%
    - Type 1 after 10 years – 60%
    - Type 1 after 15 years – 80%
    - Type 2 after 5 years – 40% taking insulin, 24% not taking insulin
    - Type 2 after 10 years – 84% taking insulin, 53% not taking insulin
- Proliferative diabetic retinopathy:
  - 7.5%
- Glaucoma, cataracts and other disorders of the eye occur earlier and more frequently in people with diabetes

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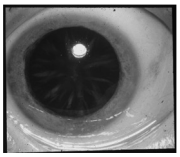
Ophthalmic Consequences of Diabetes

- Increased risk of cataracts
- Increased risk of glaucoma
- Diabetic retinopathy
- Stroke



Middle-aged female with diabetic cataracts and mild diabetic retinopathy. Noteworthy was the spoke-like character of the cataracts.

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Severity of diseases

- Mild Nonproliferative
- Moderate Nonproliferative
- Severe Nonproliferative
- Proliferative
- Diabetic Macular Edema (can happen in any of the above)

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Flicker Electroretinogram (Flicker ERG)

Stimulus Mini-ganzfeld

Retinal signal recorded at the lower lid in response to flash stimuli of high frequency

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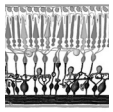
Flicker Electroretinogram (Flicker ERG)

Stimulus Mini-ganzfeld

Photoreceptors & Bipolar



Retinal signal recorded at the lower lid in response to flash stimuli of high frequency

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Full-field ERG (ffERG)

- Tests the outer retina
  - Photoreceptors (rod & cones)
  - Bipolar cells
- Test of overall retinal functioning
  - May not pick up small retinal issues
- Flash flicker stimulus

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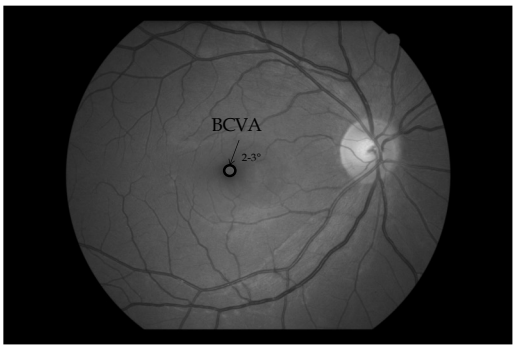

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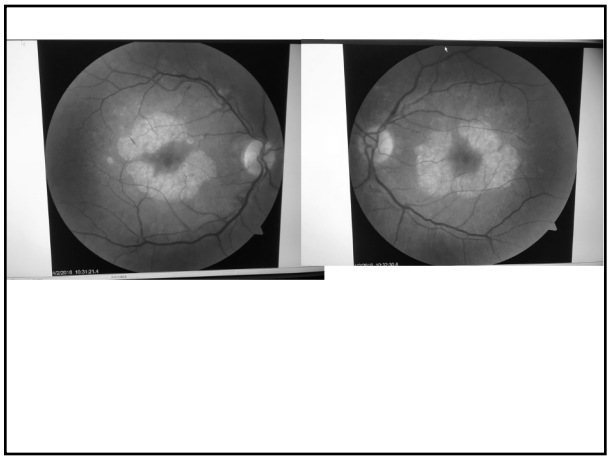

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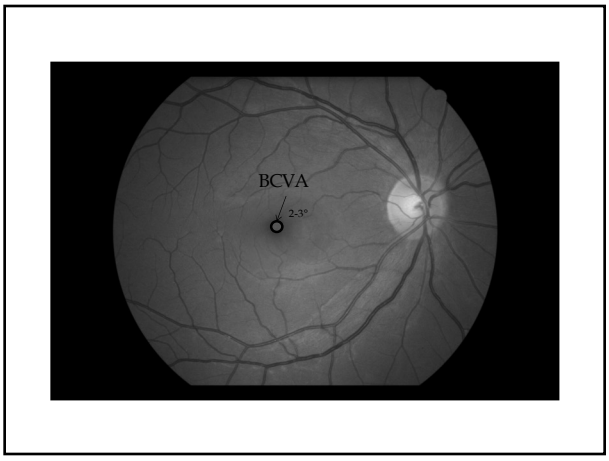

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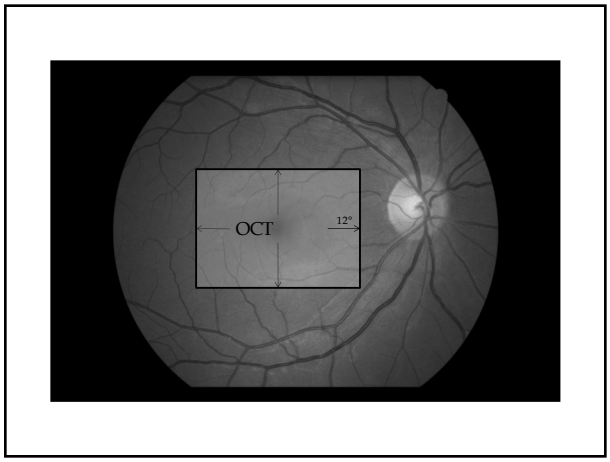

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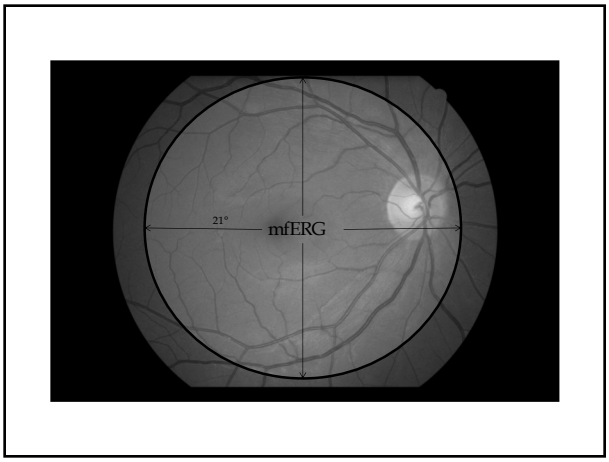

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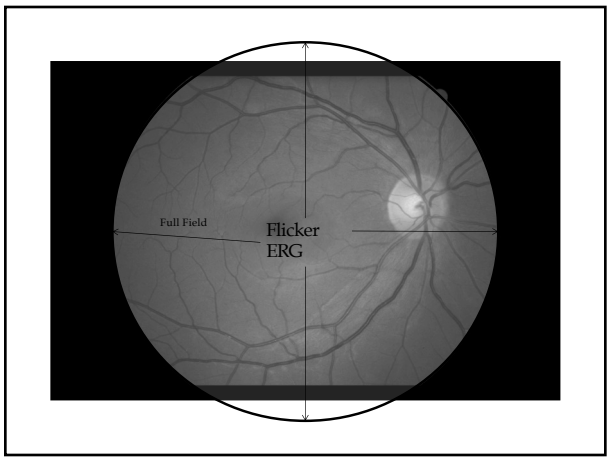

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Full-field ERG (ffERG)

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- Test of overall retinal functioning
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- Flash flicker stimulus

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Full-field ERG (ffERG)

- ffERG indications:
  - DM & diabetic retinopathy
    - Monitoring progression
    - Monitoring improvement with treatment
  - Retinal dystrophies/disease
    - Rod/cone problems
    - RP
  - Pt symptoms:
    - Color vision issues
    - VF defects
    - Decreased vision
    - Unexplained decreased vision
  - Testing retinal function with significant media opacities
  - Indicator for prognosis following cataract surgery
    - Is the retina functioning well or not?

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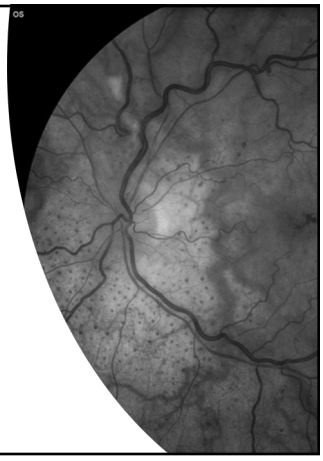
Flicker ERG - Diabetic Retinopathy

- **Evaluation of retinal function**
- **Determining the of level of retinal ischemia**
- **Predicting post-treatment retinal function**
- **Evaluating post-treatment retinal function**



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ERG for Early Detection

Review Article

Role of Electrophysiology in the Early Diagnosis and Follow-Up of Diabetic Retinopathy

Nicola Pescosolido,[1] Andrea Barbato,[2] Alessio Stefanucci,[3] and Giuseppe Buomprisco[4]

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Retinopathy is a severe and common complication of diabetes, representing a leading cause of blindness among working-age people in developed countries. It is estimated that the number of people with diabetic retinopathy (DR) will increase from 126.6 million in 2011 to 191 million by 2030. The pathology seems to be characterized not only by the involvement of retinal microvessels but also by a real neuropathy of central nervous system, similar to what happens to the peripheral nerves, particularly affected by diabetes. The neurophysiological techniques help to assess retinal and nervous (optic tract) function. Electroretinography (ERG) and visual evoked potentials (VEP) allow a more detailed study of the visual function and of the possible effects that diabetes can have on the visual function. These techniques have an important role both in the clinic and in research: the central nervous system, in fact, has received much less attention than the peripheral one in the study of the complications of diabetes. These techniques are safe, repeatable, quick, and objective. In addition, both the ERG (especially the oscillatory potentials and the flicker-ERG) and VEP have proved to be successful tools for the early diagnosis of the disease and, potentially, for the ophthalmologic follow-up of diabetic patients.

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ERG for Evaluating Retinal Dysfunction

The Electroretinogram in Diabetic Retinopathy

R. Tzekov, MD, PhD,[1] and G. B. Arden, MD, PhD, FRCOphth[2]

[1]*Retina Foundation of the Southwest, Dallas, Texas, USA, and* [2]*Center for Applied Vision Research, Department of Optometry and Visual Science, City University, London, United Kingdom*

Abstract. Electroretinography (ERG) is an objective method of evaluating retinal function. Since its introduction to clinical practice in the 1940s, it has become a useful and routine diagnostic clinical tool in ophthalmology. This review summarizes the role of ERG as a clinical technique for evaluating the progression of diabetic retinopathy and as a research tool for increasing our understanding of the pathophysiology of diabetic retinopathy. Most studies show unequivocally that the different types of ERG tests detect local abnormalities or widespread pathology, even in very early stages of the disease. It seems plausible that measurements from ERG recordings, particularly the oscillatory potentials, may be useful for predicting progression from nonproliferative to the more sight-threatening stages—preproliferative or proliferative—of diabetic retinopathy. Some recent work implies that the ERG can also be a useful diagnostic method for discriminating between eyes with diabetic retinopathy and those without the condition. (**Surv Ophthalmol 44**:53–60, 1999. © 1999 by Elsevier Science Inc. All rights reserved.)

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Electrodiagnostics 2.0

It's important to be able to detect diabetes early. Electrodiagnostic testing can make that possible.

Chuck Aldridge, OD

At a Glance

- Flicker electroretinography (ERG) can detect whether patients with diabetic retinopathy are at risk for developing neovascular changes.
- Flicker electroretinography is objective, gathers many responses in a short period of time, samples the entire retina, and is accurate in its assessment of the retina. It is reimbursed only when used on patients with retinal vascular changes.
- The Diopsys Chromatic Flash Vision Screener allows clinicians to identify patients who are at risk.

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Original Article

CONCLUSION The periodic global flashes produce a greater multifocal response reduction in diabetics than in normals, indicating impairment in the rate or magnitude of recovery from the bright preceding stimulus. The new stimulation protocol reveals early changes in retinal function of diabetics.

Yoshiaki Shimada[a], Yong Li[b], Marcus A Bearse, Jr[b], Erich E Sutter[b], Wayne Fung[c]

Author affiliations +

Abstract

AIMS To assess early functional retinal changes in diabetics without retinopathy, a new multifocal stimulus paradigm was used that emphasises fast adaptive response contributions.

METHODS 25 normal control subjects (25 eyes) and 11 diabetics without retinopathy (22 eyes) served as subjects. Stimulation and analysis were performed with Veris Science 4.0. A stimulation protocol was used that combines regular multifocal flicker stimulation with a periodic "global" flash inserted between the multifocal stimuli. The multifocal stimuli were presented four video frames apart. The global flash covered the entire screen in the third frame of the four frame interval. The remaining two frames were dark. The periodic global flashes could only contribute to the focal responses if they were affected by the multifocal stimulation. A non-linear component induced by the interaction of the focal and global flashes was observed. The differences between control subjects and diabetics were assessed in both the multifocal responses and their induced effect on the following global flashes.

RESULTS The responses to focal flashes were reduced significantly in diabetics matched in age to the control subjects. The induced components showed large intersubject variability in controls and patients, and did not differ significantly between the two groups.

CONCLUSION The periodic global flashes produce a greater multifocal response reduction in diabetics than in normals, indicating impairment in the rate or magnitude of recovery from the bright preceding stimulus. The new stimulation protocol reveals early changes in retinal function of diabetics.

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ERG vs FA : Predictive value of Vascularization

FA:82%
ERG:94%

Acta Ophthalmologica Scandinavica 1998

Fluorescein angiography versus ERG for predicting the prognosis in Central Retinal Vein Occlusion

Jörgen Larsson, Birgitta Bauer, Ulla Cavallin-Sjöberg and Sten Andréasson

Department of Ophthalmology, Lund University Hospital, Sweden

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Flicker ERG is a good predictor of ischemia

Flicker ERG can be used to evaluate DR

Flicker ERG can be used to monitor patients and evaluate referals

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Full-field ERG (ffERG)

- ffERG indications:
  - DM & diabetic retinopathy
    - Monitoring progression
    - Monitoring improvement with treatment
  - Retinal dystrophies/disease
    - Rod/cone problems
    - RP
  - Pt symptoms:
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    - Decreased vision
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  - Testing retinal function with significant media opacities
  - Indicator for prognosis following cataract surgery
    - Is the retina functioning well or not?

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ffERG Testing

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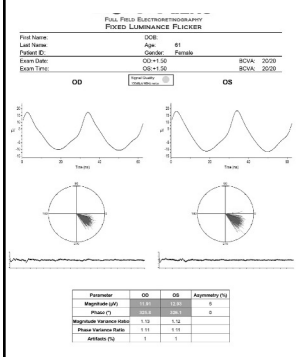
Healthy

Dysfunction



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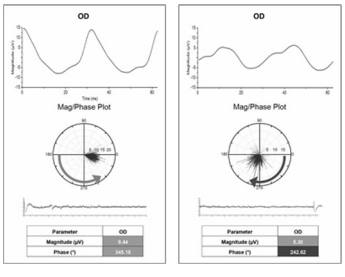

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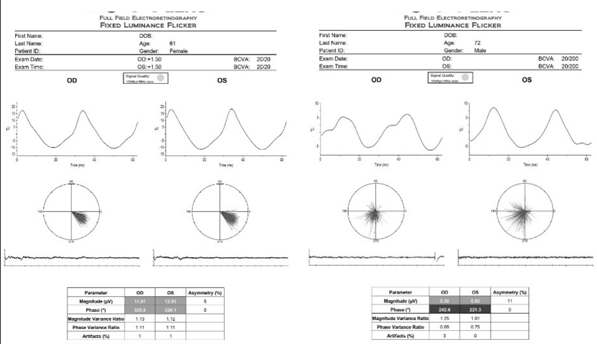
Healthy

Dysfunction



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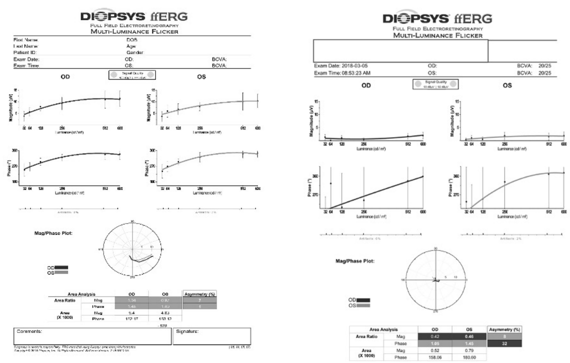
Healthy

Dysfunction



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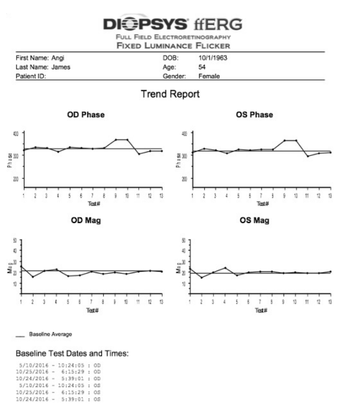

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What else can we do after such an early diagnosis?

- No longer need to wait for structural damage
- Multi-component nutritional supplement can benefit these patients

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The DiVFuSS Formula

(available as EyePromise® DVS)

Supplement Facts

Serving Size: 2 Softgels / Servings per Container: 30

Amount Per Serving		%DV
Vitamin C (Ascorbic Acid)	60 mg	100%
Vitamin D3* (Cholecalciferol)	2,000 IU	500%
Vitamin E* (d-alpha Tocopherol)	60 IU	200%
Vitamin B12 (Cyanocobalamin)	6 mcg	100%
Zinc (Zinc Oxide)	15 mg	100%
Fish Oil EE* 70%	320 mg	†
Total Omega-3 A%	240 mg	†
EPA 40% (Eicosapentaenoic Acid) A%	128 mg	†
DHA 30% (Docosahexaenoic Acid) A%	96 mg	†
Alpha Lipoic Acid	150 mg	†
Coenzyme Q-10 (Ubidecarenone)	20 mg	†
Mixed Tocotrienols/Tocopherols*	20 mg	†
Zeaxanthin*	8 mg	†
Lutein*	4 mg	†
Proprietary Blend*	530 mg	†

Benfotiamine, N-Acetyl Cysteine, Grape Seed Extract, Resveratrol (Polygonum Cuspidatum), Turmeric Root Extract (curcuminoids), Green Tea Leaf, *Pycnogenol®* (French Maritime Pine Bark Extract).

† Daily Value not established * From natural sources

Other Ingredients: Gelatin, glycerin, soybean oil, purified water, beeswax, colors (annatto extract, titanium dioxide), lecithin oil.

DOCTOR RECOMMENDED

Gluten Free

Contains NO Yeast

Contains soy & fish (cod, pollack, whiting)

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Science Based Health DiaVis

DiaVis®

Nutrition Support for Retinal Circulation

DiaVis is a specialized nutritional formulation that offers targeted nutrition for visual and overall health. DiaVis delivers key nutrients that support retinal vessel health, help combat oxidative stress, support kidney health and promotes a balanced cellular environment.

30 day supply: 60 capsules

PRICE: $44.95

Save up to 20% Learn more »

Quantity: 1 ADD TO CART

DOCTOR recommended

Supplement Facts

Serving Size 2 capsules	Servings per Container 30	
	Amount per Serving	% Daily Value
Vitamin C (as ascorbic acid)	550 mg	611%
Vitamin D (as cholecalciferol)	25 mcg	125%
Benfotiamine (Pro-Vitamin B1, thiamin)	200 mg	†
Polyphenol Blend	670 mg	†
VinCare® Whole Grape Extract (*Vitis Vinifera*) (80% polyphenols; 60% proanthocyanidins)	350 mg	†
Longvida® Optimized Curcumin Extract (from turmeric rhizome, 23% curcuminoids)	200 mg	†
Quercetin	50 mg	†
Bilberry Fruit Extract (25% anthocyanins)	25 mg	†
Pycnogenol® French Maritime Pine (*Pinus pinaster*) Bark Extract (65-75% procyanidins)	20 mg	†
Myricetin (from *Morella rubra* bark extract)	15 mg	†
Trans-resveratrol (from *Polygonum cuspidatum* root extract)	10 mg	†
Alpha Lipoic Acid	300 mg	†
Lutein (FloraGLO®)	2 mg	†
Zeaxanthin (FloraGLO®)	120 mcg	†

† Daily Value not established.

Other Ingredients: Bovine Gelatin, Water, Rice Flour, Magnesium Stearate, and Silica.

Contains soy.

FloraGLO® is a registered trademark of Kemin Industries, Inc. **LONGVIDA®** is patented protected under EP 1993365, other patents pending and a registered trademark of Verdure Sciences Inc. **Pycnogenol** is a registered trademark of Horphag Research Ltd. Use of this product is protected by one or more of U.S. patents #5,720,956 / #6,372,266 and other international patents. **VinCare** is a trademark of Ethical Naturals, Inc.

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BJO Online First, published on June 18, 2015 as 10.1136/bjophthalmol-2014-306534

Clinical science

OPEN ACCESS

The Diabetes Visual Function Supplement Study (*DiVFuSS*)

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[3]Private Practice, Olathe, Kansas, USA
[4]Kresge Eye Institute, Wayne State University, Detroit, Michigan, USA

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ABSTRACT

Background Diabetes is known to affect visual function before onset of retinopathy (diabetic retinopathy (DR)). Protection of visual function may signal disruption of mechanisms underlying DR.

Methods This was a 6-month randomised, controlled clinical trial of patients with type 1 and type 2 diabetes with no retinopathy or mild to moderate non-proliferative retinopathy assigned to twice daily consumption of placebo or a novel, multi-component formula containing xanthophyll pigments, antioxidants and selected botanical extracts. Measurement of contrast sensitivity, macular pigment optical density, colour discrimination, 5-2 macular threshold perimetry, Diabetic Peripheral Neuropathy Symptoms, foveal and retinal nerve fibre layer thickness, glycohaemoglobin (HbA1c), serum lipids, 25-OH-vitamin D, tumour necrosis factor α (TNF-a) and high-sensitivity C reactive protein (hsCRP) were taken at baseline and 6 months. Outcomes were assessed by differences between and within groups at baseline and at study conclusion using mean± SDs and t tests (p<0.05) for continuous variables.

Results There were no significant intergroup differences at baseline. At 6 months, subjects on active supplement compared with placebo had significantly better visual function on all measures (p values ranging from 0.008 to <0.0001), significant improvements in most serum lipids (p values ranging from 0.01 to 0.0004), hsCRP (p=0.01) and diabetic peripheral neuropathy (Fisher's exact test, p=0.0024) No significant changes in retinal thickness, HbA1c, total cholesterol or TNF-α were found between the groups.

Conclusions This study provides strong evidence of clinically meaningful improvements in visual function, hsCRP and peripheral neuropathy in patients with the risk of DR and its progression, evidence shows that there is no level of average blood glucose (as reflected by glycosylated haemoglobin) that is totally protective against DR. The current clinical algorithm for delaying DR and preventing STR is earlier diagnosis of diabetes, tighter metabolic control, routine dilated retinal examinations and treatment (laser photocoagulation, intravitreal injections of anti-vascular endothelial growth factor (VEGF) agents and corticosteroids) if/when DR progresses to a level that threatens vision.

The *Age-Related Eye Disease Study* (AREDS) demonstrated that a nutritional supplement could positively influence progression of a vision-threatening eye disease, age-related macular degeneration.[3] This begs the question as to whether nutritional supplements may benefit other eye diseases, including DR. Vitamins, minerals and other micronutrients have a variety of biological functions potentially beneficial in diabetes, serving as enzymatic cofactors mediating glucose homeostasis, as regulators of cell growth and differentiation, and as building blocks of antioxidant defence. Thus, there has been renewed interest in their potential for preventing or treating a host of diabetes complications.[4]

A number of investigators have shown that diabetes affects visual function prior to the development of DR detectable by ophthalmoscopy. This includes deficits in contrast,[5 6] visual field[7 8] and colour vision sensitivity.[9 10] As such, amelioration of these visual function deficits may serve as an additional, useful biomarker for the onset and progression of retinopathy in patients with diabetes, yet no clinically evident DR, as well as those with

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Diabetes Visual Function Supplement Study (DiVFuSS)

- 6 month double-blind placebo-controlled, randomized, controlled clinical trial of adults with type 1 diabetes or type 2 diabetes > 5 years
- No DR (2:1) and mild-moderate NPDR (1:1)
- Daily use of a multi-component nutritional supplement (zeaxanthin, lutein, vitamins D/C/E including tocotrienols, curcumin, benfotiamine, Pycnogenol™, lipoic acid, NAC, resveratrol, green tea & grapeseed extracts, O-3 FAs, CoQ10, Zn)
- Pre- and post- analysis of CSF, MPOD, color vision, macular perimetry, OCT, A1c, lipids, 25(OH) vitamin D3, hsCRP, TNF-à, NFL thickness and diabetic peripheral neuropathy symptom scores (DPNSS)

***Br J Ophthalmol* 2015 e-published June 18**

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Diabetes Visual Function Supplement Study (DiVFuSS)

- Pre- and post- analysis of:
  - CSF
  - MPOD
  - color vision
  - macular perimetry
  - NFL thickness
  - OCT of macula
  - A1c
  - lipids
  - 25(OH) vitamin D3
  - hsCRP
  - TNF-a
  - diabetic peripheral neuropathy symptom scores (DPNSS)

***Br J Ophthalmol* 2015 e-published June 18**

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Diabetes & DR Affect Visual Function

- Snellen visual acuity is a 150+ yr old test that does not always reflect real world visual function
- DM/DR also impair: color perception, contrast sensitivity, visual field sensitivity

Graefes Arch Clin Exp Ophthalmol. 2012 Dec;250(12):
Diabet Med. 2011 Jul;28(7):865-71
Acta Opthalmol 2005; 82(5):574-80
Graefes Arch Clin Exp Ophthalmol. 2001 Sep;239(9):643-8
BJO 1996;80: 209-13
IOVS 1997; 38(9): 1819-24
Diabetes Care 1992; 15(5):620-25

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Subject Characteristics (n = 67)

- 28-79 yo (mean = 56.1 yrs)
- 30 with NPDR & 37 with no DR
- 27 type 1 diabetes & 40 type 2 diabetes
- HbA1c range 5.85 to 10.3% (mean 7.2%)
- Diabetes duration 5-52 years (mean 16.1 yrs)
- Both Placebo and Supplement Groups showed similar and significant deficits in contrast sensitivity, color vision and visual field at baseline

No statistically significant differences at baseline between Supplemented and Placebo groups

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Mean Change/SD in visual function measures, serum lipids, hsCRP, TNF-α, glycohemoglobin, foveal thickness and symptoms of diabetic peripheral neuropathy with 95% p-Values

Δ from baseline	Suppl	v.	Plac	p-Value
Color Error Score	-20.55±24.37		+7.5±22.01	**<0.0002**
5-2 MD (db)	+2.78±9.83		-0.75±0.98	**<0.0001**
MPOD (du)	+0.09±0.05		-0.01±0.03	**< 0.0001**
LDL-C (mg/dl)	-7.61±16.08		+0.82±10.15	**0.01**
HDL-C (mg/dl)	+3.82±6.24		-1.61±5.31	**0.0004**
TGs (mg/dl)	-10.46±28.48		+2.39 ±11.56	**0.01**
hsCRP (mg/L)	-2.14±3		-0.28±1.83	**0.01**
TNF-a (pg/ml)	+0.78±5.04		+0.56±2.79	**0.88**
HbA1c (%)	-0.1±0.4		+0.1±0.4	**0.06**
Foveal Thickness	2.66±11.25μm		0.34±3.48 μm	**0.35**
DPNSS	-30.7%		+10.7%	**0.0024** Fisher's Exact Test

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Summary of Facts

- The DiVFuSS formula significantly improved visual function, diabetic peripheral neuropathy symptoms, blood lipids and hsCRP in patients with established diabetes - without significantly affecting blood sugar control
- The DiVFuSS formula significantly increased MPOD
- No adverse events occurred during the study

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Who Should Consider Taking DVS Formula?

- Adults with any degree of DR
- Adults with DM and reduced visual function and/or low macular pigment
- Patients with sub-optimal blood glucose control
- Adults with DM > 5 years
- Every patient with diabetes???

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RESEARCH Open Access

Beneficial effects of the nutritional supplements on the development of diabetic retinopathy

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Abstract

Purpose: Increased oxidative stress and inflammatory mediators are implicated in the development of diabetic retinopathy, and in rats, its development can be prevented by antioxidants. Carotenoids are some of the powerful antioxidants, and diabetes decreases lutein and zeaxanthin levels in the serum and retina. The aim of this study is to investigate the effect of carotenoid containing nutritional supplements (Nutr), which is in clinical trials for 'Diabetes Vision Function', on diabetic retinopathy.

Methods: Streptozotocin-induced diabetic rats (Wistar, male) were fed Purina 5001 supplemented with nutritional supplements containing zeaxanthin, lutein, lipoic acid, omega-3 fatty acids and other nutrients, or without any supplementation. Retinal function was analyzed at ~4 months of diabetes by electroretinography. After 11 months of diabetes, capillary cell apoptosis (TUNEL-staining) and histopathology (degenerative capillaries) were quantified in trypsin-digested retinal vasculature. Retina was also analyzed for mitochondrial damage (by quantifying gene expressions of mtDNA-encoded proteins of the electron transport chain), VEGF and inflammatory mediators, interleukin-1β and NF-kB.

Results: Diabetes impaired retinal function decreasing the amplitudes of both a- and b-waves. In the same animals, retinal capillary cell apoptosis and degenerative capillaries were increased by 3–4 fold. Gene expressions of mtDNA encoded proteins were decreased, and VEGF, interleukin-1β and NF-kB levels were elevated. Supplementation with the nutrients prevented increased capillary cell apoptosis and vascular pathology, and ameliorated these diabetes-induced retinal abnormalities.

Conclusions: Nutritional supplementation prevents diabetic retinopathy, and also maintains normal retinal function, mitochondrial homeostasis and inflammatory mediators. Thus, this supplementation could represent an achievable and inexpensive adjunct therapy to also inhibit retinopathy, a slow progressing disease feared most by diabetic patients.

Keywords: Carotenoids, Diabetic retinopathy, Macular pigment, Mitochondria, Nutritional supplements, Zeaxanthin

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Full-field ERG (ffERG)

- ffERG indications:
  - DM & diabetic retinopathy
    - Monitoring progression
    - Monitoring improvement with treatment
  - Retinal dystrophies/disease
    - Rod/cone problems
    - RP
  - Pt symptoms:
    - Color vision issues
    - VF defects
    - Decreased vision
    - Unexplained decreased vision
  - Testing retinal function with significant media opacities
  - Indicator for prognosis following cataract surgery
    - Is the retina functioning well or not?

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Applying to Your Practice

VEP

1. Glaucoma & glaucoma suspects
2. Unexplained vision loss
3. Transient vision loss
4. Unexplained VF defects
5. Unreliable VF
6. Optic neuropathies
7. Optic neuritis/MS
8. Amblyopia
9. TBI

PERG

1. Glaucoma & glaucoma suspects
2. Unexplained VF defects
3. Unreliable VF
4. Optic neuropathies
5. Maculopathies
   1. AMD
   2. Diabetic macular edema
   3. High risk med use (Plaquenil)
   4. Generalized DR

FFERG

1. DM & retinopathy
2. RP & its variants
3. Cone dystrophies & Rod monochromat
4. Symptoms:
   - "Night blindness"
   - Restricted peripheral fields
   - Color vision deficits
   - Unexplained decreased vision
5. To get an idea of retinal functioning in a pt with media opacity

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DIABETES MELLITUS: NEW TESTING AND TREATMENT FOR RETINOPATHY

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