New Handheld, Non-Mydriatic ERG Device to Screen for Diabetic Retinopathy and Other Eye Diseases

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Abstract

Purpose: To evaluate the use of the 30 Hz RETeval(TM) handheld ERG device in diabetic and glaucoma patients in the office setting.

Methods: The RETeval(TM) (LKC Gaithersburg, MD) is a small handheld ERG device using adhesive skin electrodes in lieu of contact lens electrodes to assess cone function in patients without mydrasia. The RETeval(TM) is currently in Phase 2 and 3 clinical trials (US FDA, and EC, respectively). RETeval(TM) (REv) was used in patients with diabetes mellitus and glaucoma patients in a retina practice in San Jose, CA. Inclusion criteria: Diabetic pts HbA1c > 6.0 mg/dL or FBS > 100 mg/dL; Glaucoma patients were verified by visual field findings. Visual acuity was 20/15-20/40. The Stata statistical software program was used. For each patient, ERG data from only one eye was used, based on randomization by coin toss. Informed consent was obtained.

Results: A total of 50 patients and controls were enrolled over 3 months: Control (C): n=22: age range 23-75 yrs, avg=47.9, sd=16.3; Diab (DM): n=12: age range 23-77 yrs, avg=55.8,sd=14.6; Glaucoma (G) n=16: age range=37-76 yrs, avg=59.2, sd=11.95. ERG photopic implicit times were prolonged in both diabetic and glaucoma patients: 2 tailed t-test: Control mean 33.2 msec vs DM mean 34.6 msec, implicit time p=0.045; Control mean 33.2 msec vs G mean 35.4 msec, implicit time p=0.0009. No significant differences were noted between implicit times in the diabetic and glaucomatous patients or for difference in response in amplitude: C vs DM: p=0.26.

Conclusions: This small study suggests that prolongation of flicker implicit times in diabetes and glaucoma can be discerned with the RETeval(TM) in a clinical setting. The RETeval(TM) may thus be of value as a screening tool in nursing homes or facilities where ophthalmic exams are not available.

Purpose

To evaluate diabetic patients, glaucoma patients and control patients for electrophysiologic changes using a new, handheld ERG device, RETeval[TM], measuring 30 Hz flicker amplitude and implicit times.

Background

Diabetic retinopathy is the leading causes of blindness in Americans aged 20~65 years old. Screening for diabetic retinopathy has involved the use of non-mydriatic cameras and are expensive to purchase, use and maintain. Retinal function testing for diabetic retinopathy with ERG techniques are available in the academic setting. ERG machines are costly and require trained medical technicians thus making electrophysiologic testing a rarely used test in clinical practice.

Tahara et al (1993) and Holopigan et al (1997) showed that 30 Hz flicker ERG in diabetic patients have longer peak latency than controls. Tahara in their work used an LED light to perform the 30 Hz flicker.

RETeval[TM] uses LED based 30 Hz flicker test in a handheld device, without corneal contact electrodes, or mydriasis. Glaucoma patients have been studied with multifocal ERG using 30 Hz flicker and the results have shown a difference between glaucoma patients from controls. We postulate that this RETeval[TM] device may be useful in screening for glaucoma from controls (Chu, 2009).

Methods

Device
- RETeval[TM] with proprietary software and hardware (LKC Technologies, Gaithersburg, MD). 30 Hz LED based flicker test.
- Noncontact skin electrodes

Testing
- RETeval[TM], new handheld device.
- Non-Mydriasis
- Non contact eletrodes - Sensor strip skin electrodes* are placed on the lateral side of the zygoma of the test eye, on the infraorbital rim.
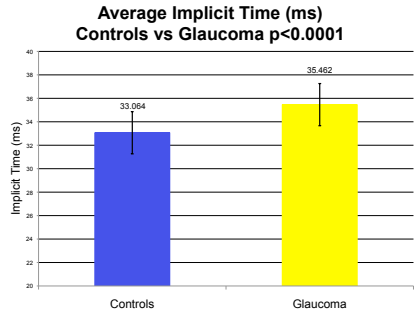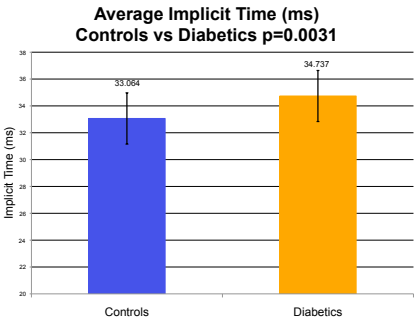- One eye is tested each time. Fellow eye is covered.
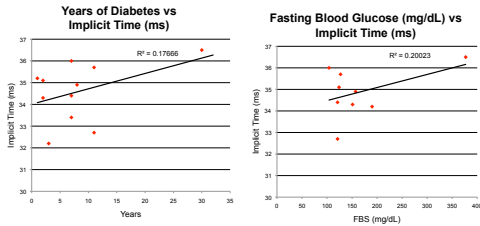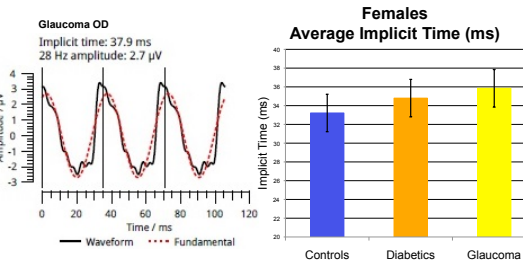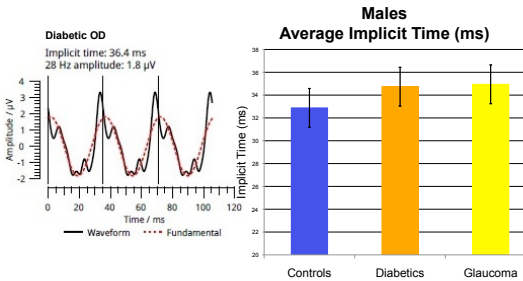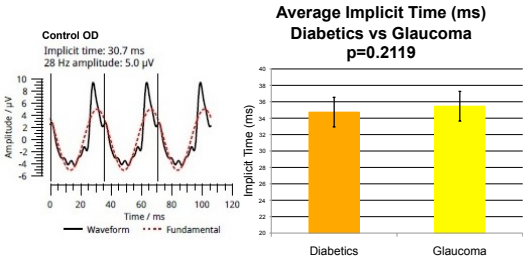
Methods

Eligibility Criteria
- Inclusion criteria: Snellen visual acuity: 20/15-20/40; Diagnosis of Open Angle Glaucoma, Diabetic Retinopathy, Diabetic patients: HbA1c ≥ 6.0% or fasting blood glucose ≥ 100 mg/dL
- Exclusion criteria: optic neuritis or unspecified optic neuropathy, multiple sclerosis, macular disease,
- Controls were normal volunteers, patients with no ocular pathology affecting the macula, such as peripheral retinal holes, headache
- Informed consent
- Data from only one eye was used (randomization by coin toss).
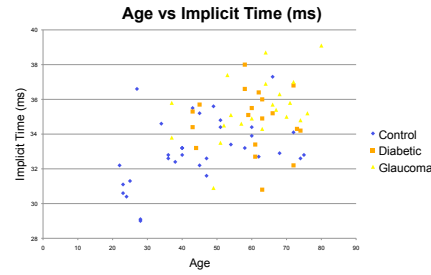- STAT statistical software was used to analyze the data.

Results

	Males	Females	Age Mean (yrs)	Age SD (yrs)	Age Range (yrs)
Total patients: 73	32	41	53.64	15.41	22-80
Controls: 33	15	18	45.18	15.98	22-75
Diabetics: 19	8	11	60	9.97	44-74
Glaucoma: 21	9	12	61.19	11.82	37-80

Average Implicit Time (ms) Controls vs Diabetics p=0.0031

Average Implicit Time (ms) Controls vs Glaucoma p<0.0001

Results

Control OD
Implicit time: 30.7 ms
28 Hz amplitude: 5.0 µV

Diabetic OD
Implicit time: 36.4 ms
28 Hz amplitude: 1.8 µV

Glaucoma OD
Implicit time: 37.9 ms
28 Hz amplitude: 2.7 µV

Average Implicit Time (ms) Diabetics vs Glaucoma p=0.2119

Males Average Implicit Time (ms)

Females Average Implicit Time (ms)

Years of Diabetes vs Implicit Time (ms)

Fasting Blood Glucose (mg/dL) vs Implicit Time (ms)

Results

Age vs Implicit Time (ms)

Sensitivity and Specificity of Control vs Diabetes

	Diabetic	Control
IT ≥ 33.5 ms	14	11
IT < 33.5 ms	5	22
	Sensitivity = 73.7%	Specificity = 66.6%

Sensitivity and Specificity of Control vs Glaucoma

	Glaucoma	Control
IT ≥ 33.5 ms	19	11
IT < 33.5 ms	2	22
	Sensitivity = 90.4%	Specificity = 66.6%

Age Groups

Control vs Diabetics	P values
41~50: C(7) vs D(4)	0.4272
51~60: C(6) vs D(4)	0.0054
61~70: C(3) vs D(7)	0.9483
71~80: C(3) vs D(4)	0.3535
41~80: C(18) vs D(19)	0.0452

Control vs Glaucoma	P values
31~40: C(7) vs G(2)	0.042
41~50: C(6) vs G(1)	N/A
51~60: C(6) vs G(6)	0.126
61~70: C(3) vs G(7)	0.1991
71~80: C(3) vs G(5)	0.0256
31~80: C(25) vs G(21)	0.0003

Profile on Diabetics

	Mean	SD	Range
Hemoglobin A1C (%)	7.3	1.3	6.0 - 11.0
Cholesterol (mg/dL)	167.7	76.5	106 - 377
Triglycerides (mg/dL)	68.1	19.7	62 - 249
Years of Diabetes	8.1	8.1	1 - 30

Conclusions

1. Implicit times were significantly different between diabetics and controls, glaucoma patients and controls in patients with good visual acuity.

2. The RETeval test takes 5-7 seconds to administer thus providing a quick quantitative, screening evaluation of diabetes and glaucoma.

3. Further studies with more patients and controls will be needed to further delineate the capabilities of RETeval device.

References

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