Session 6: Paper Session—Methods: 1

6.01 Reference range values for 19 photopic stimulus conditions using the RETeval device

Q. Davis[1], O. Kraszewska[1], R. Feig[2], R. Levy[3], C. Manning[4]

[1]LKC Technologies, Inc., Gaithersburg, MD, USA; [2]Brooklyn Eye Center (3 locations), Brooklyn, NY, USA; [3]Dr's Eyecare Center, Burlington, NJ, USA; [4]Wedgwood Optometry Associates, Fort Worth, TX, USA

Purpose: To determine reference ranges for normal subjects for a variety of stimulus conditions using the RETeval device with Sensor Strip skin electrodes.

Methods: In three ophthalmology and two optometry practices in the US, all patients coming for a normally-scheduled visit were asked to participate. Subjects were tested with dilated or natural pupils based on what was required for their normal examination. Depending on age and dilation status, a subset of 19 photopic stimuli conditions were tested. Subjects with dilated eyes had one randomly-selected eye tested, while subjects with natural pupils had both eyes tested. Dilated subjects were tested with eight constant luminance protocols and two Troland-based (ISCEV-equivalent) protocols that compensate for pupil size, while natural-pupil subjects were tested with 11 Troland-based protocols. Pediatric subjects younger than 8 years of age used a shorter test set; 8–12 years olds were given a choice as to the testing length.

Eyes were classified as normal if the following criteria were met: BCVA of 20/25 (0.1 logMAR) or better, optic nerve cupping <50%, no glaucoma or retinal diseases, no prior intraocular surgery (excepting non-complicated cataract or refractive surgery performed more than 1 year before), IOP ≤ 20 mmHg, no diabetes, and no diabetic retinopathy as determined by the ophthalmologist or optometrist.

Outliers (defined as 2 interquartile ranges away from the 25th and 75th percentiles) were removed after age correction that used a robust (bisquare) linear least squares fit. Replicates were averaged and then the eyes averaged (if both eyes were tested

Stimulus	N	a-wave (ms)	a-wave (μV)	b-wave (ms)	b-wave (μV)
3 cd s/m² **flash**	62	12.2 ± 1.0	−6.9 ± 2.6	29.4 ± 1.2	32.1 ± 9.9
		10–14.7	−12.6 to −2.3	27.1–32	10.7–54
30 cd/m² background		(0.000 ms/year)	(0.032 μV/year)	(0.024 ms/year)	(−0.15 μV/year)
85 Td s **flash**	154	11.7 ± 0.9	−7.1 ± 2.6	29.1 ± 1.3	31.6 ± 9.5
		9.74–13.6	−13.4 to −2.2	26.7–32	14.7–52.4
848 Td background		(0.018 ms/year)	(0.014 μV/year)	(0.032 ms/year)	(−0.12 μV/year)

	N	Fundamental/ms	Fundamental/μV	Waveform/ms	Waveform/μV
3 cd s/m² **flicker**	63	27.6 ± 1.4	21.8 ± 5.8	26.5 ± 1.6	30.8 ± 8.6
		25.3–31.1	11.8–33.7	24.1–31.2	15.2–49
30 cd/m² background		(0.051 ms/year)	(−0.087 μV/year)	(0.041 ms/year)	(−0.18 μV/year)
85 Td s **flicker**	144	26.2 ± 1.0	18.6 ± 5.3	25.5 ± 1.0	29.2 ± 7.3
		24.2–28	9.36–31.2	23.7–27.8	16.1–48.7
848 Td background		(0.044 ms/year)	(−0.06 μV/year)	(0.033 ms/year)	(−0.19 μV/year)

and normal). Percentiles were computed from their rank; (i.e., no underlying distribution was assumed).

Results: To date, 162 subjects have at least one normal eye (out of 415 total subjects), with mean ± standard deviation (range) age 41 ± 19 (4–85) years. The gender distribution was 28.4% male, 70.4% female, and 1.2% no-response. Self-reported race was primarily Caucasian (54%) and African American (34%), with the remainder being Asian, Native American, multiple races, or no response. About 12% self-reported as Hispanic. At the time of testing, 33% of subjects were artificially dilated.

Of the 1587 tests completed on the 162 subjects, 46 (3%) were rejected as outliers. No stimulus had more than three outliers and no subject produced more than two outliers.

The table shows the mean ± standard deviation, 95% reference intervals, and age dependence for the ISCEV photopic tests and their Troland equivalent. Results are adjusted for a subject age of 41 (the mean from this study).

Conclusions: Reference ranges for a variety of photopic tests were determined, although only the ISCEV photopic tests are described in this abstract. The reference ranges for the constant luminance and constant retinal illuminance equivalent are similar. We are continuing to test subjects to increase the confidence in the reference range measurements.

6.02 Evaluation of a soft, disposable ERG electrode prototype

J. R. Hetling[1,2,3], S. Patangay[1], J. C. Park[2], S. Rahmani[3,4], T. Ban[4], J. J. McAnany[1,2]

[1]Department of Bioengineering, University of Illinois at Chicago, Chicago, IL, USA; [2]Department of Ophthalmology and Visual Sciences, University of Illinois at Chicago, Chicago, IL, USA; [3]RetMap, Inc., Grayslake, IL, USA; [4]Department of Ophthalmology, Massachusetts Eye and Ear Infirmary, Boston, MA, USA

Purpose: ERG is the most informative and direct measure of retinal function available, yet is underutilized in the clinic. Barriers to clinical application include those related to the recording electrode: expense, risk of irritation/abrasion, patient apprehension, difficult installation, and inconsistent responses (leading to wide normal ranges and low test sensitivity). The most frequently used ERG electrodes (Burian-Allen, DTL fiber, ERG Jet) all share one or more of these limitations. Here we describe a new electrode prototype (RM Electrode) designed to improve performance with respect to signal amplitude and quality, patient comfort and safety, ease of installation/removal, and cost.

Methods: A soft, transparent silicone substrate was designed with two base curves, similar to a scleral contact lens, to minimize relative motion between the substrate and the eye. A ring-shaped stainless-steel electrode is recessed within a channel in the substrate and makes electrical contact via the tear film; the electrode lies outside the margin of a dilated pupil. The substrate extends beneath the eyelids and is shaped to prevent blinking. Two versions of the RM Electrode were fabricated and tested: a water-clear version and a version with a light-diffusing layer incorporated into the substrate. Comparison was made with Burian-Allen, DTL fiber, and ERG Jet

electrodes using full-field flash stimuli in dark-adapted healthy subjects. All corneal electrodes were referenced to a skin electrode on the ipsilateral temple, except the Burian-Allen, which was used in bipolar configuration (referenced to eye lids). Subjective qualities were noted (ease of installation/ removal, subject comfort), and relative motion between eye and electrode was quantified. Responses were evaluated for pre-stimulus noise, a- and b-wave amplitudes, effect of fixation error, and repeated-measure variability.

Results: Mean a-wave amplitudes (3.0 ph cd s m^{-2} flash) were consistently largest with the RM electrode; normalized amplitudes for the RM electrode-clear, RM electrode-diffusing, ERG Jet, Burian-Allen and DTL electrodes were 100, 98, 90, 81, 60%, respectively. The ERG potential sensed by the Burian-Allen reference electrode was approximately 20% of that sensed by the corneal electrode, which was then subtracted by the differential amplifier. A-wave amplitudes for repeated stimuli were most consistent with the B-A electrode and least consistent with the DTL electrode. Both DTL and B-A electrodes had significant baseline drift (±200 μV) compared to the RM design (±50 μV). Extreme fixation error (approximately 40° off axis) resulted in significantly reduced a-wave amplitudes for all electrode designs except the RM Electrode with integral light-diffusing layer. The RM electrode design was more comfortable and less imposing during installation than the B-A but comparable to the DTL.

Conclusions: The greater signal to noise ratio and lower baseline drift observed with the RM electrode design are attributed to the increased stability on the eye and the reference electrode location. Incorporation of a light-diffusing layer within the electrode substrate can substantially eliminate response amplitude variation due to fixation error. These advantages are obtained in a soft, disposable design, increasing patient comfort and safety.

6.03 Factors affecting mydriasis-free flicker ERGs recorded with real-time correction for retinal illuminance: Study of 150 young normal subjects

M. Kondo[1], K. Kato[1], R. Nagashima[1], A. Sugawara[1], M. Sugimoto[1], H. Matsubara[1], D. L. McCulloch[2], K. Ikesugi[1]

[1]Department of Ophthalmology, Mie University Graduate School of Medicine, Tsu, Japan; [2]School of Optometry and Vision Sciences, University of Waterloo, Waterloo, Canada

Purpose: A small, full-field flicker ERG recording system was recently developed to record flicker ERGs without mydriasis (RET*eval*®). The device delivers a stimulus with constant retinal illuminance by adjusting the luminance to compensate for changes in the pupillary area. The purpose of this study was to determine what factors affect the fundamental components of the flicker ERGs recorded by RET*eval* in young normal subjects.

Methods: Flicker ERGs were recorded with the RET*eval* system from 150 eyes of 150 young normal subjects (age, 20–29 years). Univariate and multivariate linear regression analyses were performed to identify the factors that affected the implicit times and amplitudes of the fundamental component of the flicker ERGs. The independent variables included age, sex, refractive error, axial length, and pupillary area.

Results: Multivariate regression analyses indicated that a longer axial length ($p = 0.03$) and larger pupillary area ($p = 0.008$) were independent factors that were significantly associated with longer implicit times of the fundamental component of the flicker ERGs. Multivariate regression analyses also showed that the female sex ($p = 0.03$) was an independent factor that was significantly associated with larger amplitude fundamental component of the flicker ERGs.

Conclusions: These results indicate that the fundamental components of the RET*eval* flicker ERGs are significantly affected by the axial length, pupillary area, and gender of young normal subjects. The results also suggest that the Stiles-Crawford effect should be compensated for when flicker ERGs are recorded with natural pupils.

6.04 - New method to provide dark adaptation in the operating room for ERG recording

BL Lam, A Gonzalez, C Rowaan, J Martin, M Liu, P DiStefano, D Miller, J-M Parel

Bascom Palmer Eye Institute, University of Miami, Florida, USA

Purpose: Sedated ERG is a useful diagnostic tool in infants and young children with visual loss. With increasing anesthesia monitoring equipment and electronic medical record, performing scotopic ERG in the operating room (OR) is challenging because of difficulties to have a dark adapted environment. Light from equipment indicators and display monitors cannot be eliminated by covering them with black tape or cloth. The purpose of this project is to develop a practical, feasible method to provide dark adaptation in the OR for scotopic ERG recording.

Methods: We developed procedures to test and modify a commercially available compact, collapsible, and portable dark room (SCIENTEX Inc, Japan, Model B-LP1-X, 120 x 120 x 208 cm width, length, height) to conform to OR requirements (Fig 1). Modification included adding a small covered rectangular portal to allow the wires of the ERG recording electrodes and the hand-held full-field stimulus dome to enter the dark room (Figs. 2 and 3). Infection control/cleaning/microbiology testing were performed on the fabric by applying a hospital grade disinfectant

Figure 1