1984

Normalization of electroretinograph

Francis K. Iwamoto
Pacific University

David C. Neill

Normalization of electroretinograph

Abstract

Normalization of electroretinograph

Degree Type

Thesis

Degree Name

Master of Science in Vision Science

Committee Chair

Carole Timpone

Subject Categories

Optometry

NORMALIZATION OF ELECTRORETINOGRAPH

Authors:
Francis K. Iwamoto
David C. Neill

Advisors:
Carole Timpone, O.D.
Robert Yolton, Ph.D., O.D.

Pacific University
College of Optometry,
1984

INTRODUCTION

The electroretinogram (ERG) is the measurement of the transient change in the standing potential across the globe in response to a light stimulus.[1] Measurements are generally taken using a contact lens electrode which carries the signal from the cornea, a reference electrode, and a ground. The latter two electrodes can be placed in a variety of locations, although a few standards exist.[2]

1. A bipolar contact lens electrode can be used, in which case the contact lens itself carries the signal and reference wires, and an ear lobe is used as ground.
2. A unipolar contact lens electrode can be used, in which the contact lens carries only the signal, with the reference electrode placed on the forehead and the ground placed on an ear lobe.
3. A unipolar contact lens electrode can be used, in which one ear lobe is used as reference and the other ear lobe is used as ground.

Electroretinography is used to determine both the diagnosis

and prognosis of many retinal disorders, and as such, it has a worthwhile place in the eye-care professions.[3] The ERG is a measure of the total retinal patency, so diseases in which larger areas of retina are involved will show more significant deviations from normal. Since the ERG is sensitive to subtle changes in retinal standing potential, the more insidious or visually unobservable forms of pathology are the target diseases (eg: early Retinitis Pigmentosa, Rod/Cone Dystrophies). It is also an objective method of examination, giving information about retinal function without being dependent on the patient's statements about his vision. Furthermore, it is largely independent of opacities in the ocular media.[4]

OBJECTIVES

1. Establish a standard testing procedure for validity.
    - Establish target age group over which ERG's are most useful.
    - Establish appropriate stimuli for pathology detection.
2. Establish normative data for the equipment in its new set-up and location.
3. Produce adequate documentation to allow future interns to use the electroretinograph quickly and easily.

Since its original installation, the electroretinograph had fallen into disuse. Through testing, repair and reorganization of the equipment, the ERG has been reestablished as a viable part of the Special Procedures Clinic.

The original set-up required the sharing of equipment between the ERG and the EOG. Because of this arrangement, interns needed to be able to re-wire the equipment before collecting data. Since few interns had previous exposure to sophisticated electrodiagnostic wiring, the ERG was increasingly ignored as a diagnostic tool. Careful analysis showed that sharing of equipment was not necessary, and a room could be permenantly prepared for each procedure.

" ... selection of stimuli ... can vary the relative amount of contribution toward the total response of the photopic or scotopic components of the retinal melange."[5] Gouras has stated that "... the rod and cone signals are not only separate but completely independent in the b-wave of the ERG."[6] Comparison of ERG's using certain stimuli can therefore aid in isolating various diseases or dystrophies.

The following four conditions were adopted as the standard test format, and are detailed in **Appendix A:**

1. A high intensity single flash without dark adaptation (photopic 16 W).
2. A mid intensity 30 Hz flicker without dark adaptation (photopic 30 Hz 8 W).
3. A low intensity single flash after 15 minutes of dark adaptation (scotopic 1 W).
4. A high intensity single flash after 15 minutes of dark adaptation (scotopic 16 W).

The photopic 16 white condition produces an ERG from the light adapted retina. Although both rods and cones contribute to the formation of the ERG response, under the light adapted condition, the cone mediated response becomes the principle contributor. It is a check for gross malformations of the full

complement of waveforms.

The 30 Hz 8 white flicker condition was chosen as the optimum stimulus to isolate cone mediated activity.[7] It has been found that the photopic B-wave response (cone mediated) could follow stimuli at rates in excess of 15 Hz, whereas scotopic B-wave response (rod mediated) tend to drop out at rates of only 3 Hz.[8] [9] Further investigation reports that "peak to peak height of the response (ERG) is augmented between 20 to 30 flashes per second, and a single apparently simple waveform results."[10]

The scotopic 1 white condition generates a rod-mediated ERG. Following dark adaptation, scotopic (rod) function may be accentuated and thus provide the major contribution toward the response.[11]

The scotopic 16 white conditon provides an overall view of retinal patency with rod mediated functioning still dominant. With this stimulus setting, information involving rod/cone recovery and stimulus intensity may be investigated.

METHOD

The population of normal subjects was selected from optometric students that met two criteria:

1. No known history of neural or retinal disease.
2. Met the target age range of 18 to 35 years, which was determined to be the most clinically useful.

Each subject was given a standard consent form to read and sign (example found in **Appendix E**). Pretest subject examinations were provided including: case history, pre-test visual acuity and biomicroscopy. The test procedure followed the format detailed in **Appendix A**. Post-test visual acuity was taken prior to dismissing the subjects.

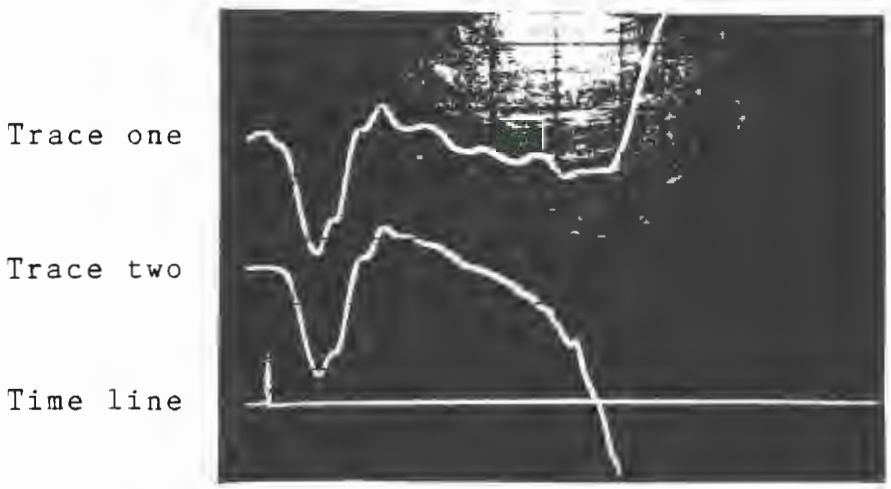
The participants were then given a comprehensive overview of the equipment and its diagnostic importance. Each participant was shown the operation of the apparatus when they were not being the actual subject.

RESULTS

A standard testing format has been developed so that clinically useful data will be recorded. Furthermore, a pool of normal subjects has been tested to establish ranges of normal for each of the 4 stimulus conditions.

Below is a sample recording of one stimulus condition. A diagramatic representation of data measurement is located in **Appendix B.**

Condition 4 Scotopic 16 W



The data pool, as seen in **Appendix C**, is limited to the measurement of B-wave amplitude, measured in microvolts, and the B-wave implicit time, measured in milliseconds.[12] Some subjects have incomplete data files. They were run during the process of developing the standardized format, and subsequent additions to

and deletions from the sequence left gaps.

The data for each condition was then averaged and a range of normal was designated as the mean plus or minus two standard deviations. The statistical analysis appears in **Appendix D**, and is summarized below:

Condition	N	Amp. (microvolts)	Imp. Time (msecs)
1--Photopic 16W	31	122.84 - 265.87	18.61 - 31.33
2--Photopic 30Hz 8W	28	124.10 - 291.98	25.80 - 30.63
3--Scotopic 1W	29	279.43 - 560.23	40.45 - 47.21
4--Scotopic 16W	33	401.42 - 772.78	27.39 - 45.03

CONCLUSIONS

There are many variables that directly or indirectly effect the recording of an ERG. A partial list would include: age and sex of the patient, adaptive state of the patient (amount of dark adaptation, etc.), wavelength of light used as stimulus, test sequence, electrode design and placement, and environmental conditions, such as background 60 cycle noise or stray light.[13] [14] Because of these variables, comparison of results on one device to those of another is difficult and not clinically valid. However, comparison of ranges developed during this study to those developed by others can give a rough idea about whether or not the ranges found here are reasonable. Since researchers are all aware of the variables that influence results in ERG recording, few give general ranges for their data, and those that do are often unclear about the conditions under which their recordings were made. Below are some examples: [15] [16] [17]

Condition	Amp. (microV)	Imp. Time (msec)
1. White light-no intensity, adaptation state noted	115 - 440	40 - 70
2. White 16-no adaptation state noted		35.18+/-1.28
3. No condition stated	75 - 600	
4. Photopic-max intensity	75 - 200	25 - 33
5. Scotopic-max intensity	250 - 400	38 - 58

Through the work done in this study, patients can be determined to be normal or abnormal, which is of significant clinical value. For research purposes, however, normative data could be collected on groups of subjects using red light, using blue light, comparing male to female subjects, and on subjects of other ages. Data of this type may be used in differential diagnosis of various retinal disorders.

The red stimulus has been shown to isolate cone responses very effectively, however, the 30 Hz flicker has been shown to be equally effective. In establishing the standard testing format, the authors initially included a blue stimulus condition. Its amplitude was found to be insufficient for this study, however, the blue stimulus is known to isolate rod activity, and further research could be pursued in this area.[18]

Peterson demonstrated in 1968 that with adequate sample sizes, statistically significant differences are present between male and female subjects.[19] Further data collection at our facility could be used to develop normative ranges for men and women. Finally, expanding the ages for which normal ranges have been generated would open the facility to greater segments of the clinical population.

Appendix A

Standard ERG Testing Format

Equipment Settings

Oscilloscope

5 volts/division on center amplifier (stimulus marker)

0.5 volts/division on both channels of left amplifier

20 milliseconds/division on dial on right (time scale)

External trigger should be pushed in

All 4 storage/erase buttons should be pushed in

Photostimulator

30 Hz frequency (frequency scale must be set to **HI**)

Delayed flash **OFF**

Intensity: initial setting 16 (will be changed for each ERG)

Amplifiers

Full Scale: **OFF** until patient is hooked up

mV/V switch set in **mV** position

Zero Suppression **OFF**

Frequency Cut-off set to **.3** and **100** Hz

Both Amplifiers, for OD and OS, should have identical settings.

Testing Procedure

1. Drop patient's eye(s).
   - 1 drop 0.5% proparacaine.
   - 1 drop 1.0% tropicamide.
2. Check settings on oscilloscope, photo stimulator, and amplifiers.
3. Turn main power bar **ON** (amplifiers should still be OFF).
4. Electrode placement:
   - Clean patient's ears with alcohol--thoroughly.
   - Rub a small amount of electrode paste into ear lobes.
   - Place a small amount of electrode paste onto ear-clip electrodes and place them onto patient's ears.
5. Once the pupillary light reflex is gone, place a further drop of 0.5% proparacaine into eye(s) and moisten the electrode with **ULTRATEARS** solution. Place electrode onto patient's cornea as follows:
   - Direct patient to look down.

- Lift upper lid solidly so that the electrode can be slipped under it.
- Direct patient to look straight ahead.
- Lift electrode and pull down lower lid to allow the electrode to rest securely against the sclera.
- Tape the electrode wire to the patient's collar allowing enough slack so that no tension is placed on the electrode as the head is moved into the ganzfeld.

6. Connect electrodes to the box by the ganzfeld.
7. Turn **AMPLIFIERS** to the **2.5** setting on the full-scale dial.
8. Direct patient to put his head into the ganzfeld.
9. **PHOTOPIC FULL INTENSITY ERG:**

    - Room lights **ON.**
    - Flash intensity **16.**
    - Press stimulus button **DOWN** for single flash.

10. Take a photograph of the oscilloscope screen by exposing the black and white polaroid camera **3** times using maximum flash intensity. Pull the white strip of paper--then pull the exposed film out of the camera and let it rest **1** minute before peeling the developed print from its backing.
11. Erase oscilloscope screen using the button on upper right.

12. **PHOTOPIC FLICKER ERG:**

    - Room lights **ON.**
    - Flash intensity **8.**
    - Lift stimulus button **UP** for repeated flashes. **NOTE:** To generate a sweep of the oscilloscope, **PARTIALLY** depress the **SINGLE SWEEP** button on the right-hand amplifier of the oscilloscope. Full depression of the button will lock it down and result in repeated sweeps on top of one another.

13. Take photograph as above and erase screen.
14. Dark adapt for **15** minutes.
15. **SCOTOPIC LOW INTENSITY FLASH ERG**

    - Room lights **OFF.**
    - Flash intensity **1.**
    - Push stimulus button **DOWN.**

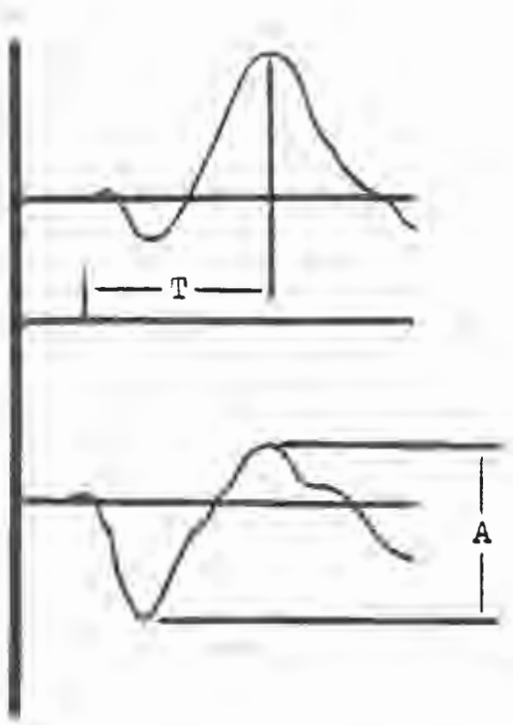
16. Take photograph as above and erase screen.
17. **SCOTOPIC FULL INTENSITY FLASH ERG**

    - Room lights **OFF.**
    - Flash intensity **16.**
    - Push stimulus button **DOWN.**

18. Take photograph as above and erase screen.

Appendix B

Sample Recordings



T = The measure of Implicit Time. It is measured from the stimulus presentation mark to the peak of the B-wave.

A = The measure of Amplitude. It is measured from the trough of the A-wave to the peak of the B-wave.

Scale measurements on the oscilloscope of 20 milliseconds/div. or 0.5 volts/div, refer to the large dashed line increments, not to the smaller hash marks.

Appendix C

Patient Data

NAME: A DATE: 09/20/83
AGE: 24 TESTED EYE: OD [ ] OS [x]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	100			500
	2				500
	AVE.	100			500
B-Wave Implicit Time (msecs.):	1	28			40
	2				35
	AVE.	28			37.5

NAME: B DATE: 09/21/83
AGE: 24 TESTED EYE: OD [ ] OS [x]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	175	250		400
	2	150			500
	AVE.	162.5	250		450
B-Wave Implicit Time (msecs.):	1	30	28		30
	2	30			35
	AVE.	30	28		32.5

NAME: C DATE: 09/22/83
AGE: 26 TESTED EYE: OD [x] OS [ ]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	175	150	425	600
	2	200	175	450	575
	AVE.	187.5	162.5	437.5	587.5
B-Wave Implicit Time (msecs.):	1	25	26	43	37
	2	22	27	43	32
	AVE.	23.5	26.5	43	34.5

NAME: D DATE: 09/26/83
AGE: 26 TESTED EYE: OD [x] OS [ ]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	275	250	375	600
	2	250	250	375	575
	AVE.	262.5	250	375	587.5
B-Wave Implicit Time (msecs.):	1	25	28	45	40
	2	25	28	42	35
	AVE.	25	28	43.5	37.5

NAME: E DATE: 09/26/83
AGE: 26 TESTED EYE: OD [x] OS [ ]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	175	175	300	500
	2	175	175	300	475
	AVE.	175	175	300	487.5
B-Wave Implicit Time (msecs.):	1	25	28	42	38
	2	22	28	45	35
	AVE.	23.5	28	43.5	36.5

NAME: F DATE: 09/27/83
AGE: 24 TESTED EYE: OD [x] OS [ ]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	225	175	500	700
	2	225	175	500	750
	AVE.	225	175	500	725
B-Wave Implicit Time (msecs.):	1	25	28	42	30
	2	25	28	42	30
	AVE.	25	28	42	30

NAME: G DATE: 09/28/83
AGE: 35 TESTED EYE: OD [x] OS [ ]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	175	200	375	500
	2	175	200	400	500
	AVE.	175	200	387.5	500
B-Wave Implicit Time (msecs.):	1	25	28	45	32
	2	25	27	42	35
	AVE.	25	27.5	42	33.5

NAME: H DATE: 09/28/83
AGE: 25 TESTED EYE: OD [ ] OS [x]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	175	250	425	575
	2	175	250	375	525
	AVE.	175	250	400	550
B-Wave Implicit Time (msecs.):	1	22	32	45	42
	2	20	32	45	40
	AVE.	21	32	45	41

NAME: I DATE: 09/29/83
AGE: 23 TESTED EYE: OD [ ] OS [x]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	125	200	375	575
	2	150		425	600
	AVE.	137.5	200	400	587.5
B-Wave Implicit Time (msecs.):	1	23	28	45	34
	2	23		46	34
	AVE.	23	28	45.5	34

NAME: J DATE: 09/29/83
AGE: 26 TESTED EYE: OD [x] OS [ ]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	225	250	550	750
	2	225	250	500	675
	AVE.	225	250	525	737.5
B-Wave Implicit Time (msecs.):	1	25	28	47	30
	2	25	28	47	30
	AVE.	25	28	47	30

NAME: K DATE: 09/29/83
AGE: 24 TESTED EYE: OD [x] OS [ ]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	175	200	325	550
	2	175	200	325	550
	AVE.	175	200	325	550
B-Wave Implicit Time (msecs.):	1	30	28	42	34
	2	28	28	43	35
	AVE.	29	28	42.5	34.5

NAME: L DATE: 09/30/83
AGE: 30 TESTED EYE: OD [ ] OS [x]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	200	275	500	650
	2	200	275	500	675
	AVE.	200	275	500	662.5
B-Wave Implicit Time (msecs.):	1	25	28	42	40
	2	25	28	42	40
	AVE.	25	28	42	40

NAME: M DATE: 10/03/83
AGE: 23 TESTED EYE: OD [x] OS [ ]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	200	175	425	500
	2	175	175	325	500
	AVE.	187.5	175	375	500
B-Wave Implicit Time (msecs.):	1	25	28	42	32
	2	28	28	42	32
	AVE.	26.5	28	42	32

NAME: N DATE: 10/03/83
AGE: 22 TESTED EYE: OD [ ] OS [x]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	225	250	450	725
	2	200		450	700
	AVE.	212.5	250	450	700
B-Wave Implicit Time (msecs.):	1	25	30	45	45
	2	25		45	42
	AVE.	25	30	45	43.5

NAME: O DATE: 10/03/83
AGE: 25 TESTED EYE: OD [x] OS [ ]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	250	200	475	650
	2	250	200	500	750
	AVE.	250	200	487.5	700
B-Wave Implicit Time (msecs.):	1	30	28	45	40
	2	30	28	45	45
	AVE.	30	28	45	42.5

NAME: P DATE: 10/17/83
AGE: 27 TESTED EYE: OD [ ] OS [x]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	125	175	500	600
	2				
	AVE.	125	175	500	600
B-Wave Implicit Time (msecs.):	1	19	28	45	39
	2				
	AVE.	19	28	45	39

NAME: Q DATE: 10/18/83
AGE: 23 TESTED EYE: OD [x] OS [ ]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	175		375	625
	2				
	AVE.	175		375	625
B-Wave Implicit Time (msecs.):	1	17		42	35
	2				
	AVE.	17		42	35

NAME: R DATE: 10/18/83
AGE: 30 TESTED EYE: OD [x] OS [ ]

ELECTRODE: Burian-Allen unipolar

CONDITION:
1. Photopic flash Intensity 16 W
2. 30 Hz photopic flash Intensity 8 W
3. Scotopic low intensity Intensity 1 W
4. Scotopic high intensity Intensity 16 W

	TRIAL	CONDITION 1	2	3	4
B-Wave Amplitude (microvolts):	1	225	225	375	575
	2				
	AVE.	225	225	375	575
B-Wave Implicit Time (msecs.):	1	25	28	45	42
	2				
	AVE.	25	28	45	42

Appendix D

Statistical Analysis

****

Condiiton 1 - Photopic 16 W

****

ENTRY	Amplitude (microvolts)	Implicit Time (msecs)
1	175.00	30.00
2	150.00	30.00
3	175.00	25.00
4	200.00	22.00
5	275.00	25.00
6	250.00	25.00
7	175.00	25.00
8	175.00	22.00
9	225.00	25.00
10	225.00	25.00
11	175.00	25.00
12	175.00	25.00
13	175.00	22.00
14	175.00	20.00
15	125.00	23.00
16	150.00	23.00
17	225.00	25.00
18	225.00	25.00
19	175.00	30.00
20	175.00	28.00
21	200.00	25.00
22	200.00	25.00
23	200.00	25.00
24	175.00	28.00
25	225.00	25.00
26	200.00	25.00
27	250.00	30.00
28	250.00	30.00
29	125.00	19.00
30	175.00	17.00
31	225.00	25.00
	MEAN 194.35	MEAN 24.97
	STD DEV 35.76	STD DEV 3.18
	NORMAL RANGE MEAN (+/- 2 STD DEV) 122.84 TO 265.87	NORMAL RANGE MEAN (+/-2 STD DEV) 18.61 TO 31.33

****

Condition 2 - 30 Hertz 8 W

****

ENTRY	Amplitude (microvolts)	Implicit Time (msecs)
1	100.00	28.00
2	250.00	28.00
3	150.00	26.00
4	175.00	27.00
5	250.00	28.00
6	250.00	28.00
7	175.00	28.00
8	175.00	28.00
9	175.00	28.00
10	175.00	28.00
11	200.00	28.00
12	200.00	27.00
13	250.00	32.00
14	250.00	32.00
15	200.00	28.00
16	250.00	28.00
17	250.00	28.00
18	200.00	28.00
19	200.00	28.00
20	275.00	28.00
21	275.00	28.00
22	175.00	28.00
23	175.00	28.00
24	250.00	30.00
25	200.00	28.00
26	200.00	28.00
27	175.00	28.00
28	225.00	28.00
	MEAN 208.04	MEAN 28.21
	STD DEV 41.97	STD DEV 1.21
	NORMAL RANGE MEAN (+/- 2 STD DEV) 124.10 TO 291.98	NORMAL RANGE MEAN (+/- 2 STD DEV) 25.80 TO 30.63

****

Condition 3 - Scotopic 1 W

****

ENTRY	Amplitude (microvolts)	Implicit Time (msecs)
1	425.00	43.00
2	450.00	43.00
3	375.00	45.00
4	375.00	42.00
5	300.00	42.00
6	300.00	45.00
7	500.00	42.00
8	500.00	42.00
9	375.00	45.00
10	400.00	42.00
11	425.00	45.00
12	375.00	45.00
13	375.00	45.00
14	425.00	46.00
15	550.00	47.00
16	500.00	47.00
17	325.00	42.00
18	325.00	43.00
19	500.00	42.00
20	500.00	42.00
21	425.00	42.00
22	325.00	42.00
23	450.00	45.00
24	450.00	45.00
25	475.00	45.00
26	500.00	45.00
27	500.00	45.00
28	375.00	42.00
29	375.00	45.00
	MEAN 419.83	MEAN 43.83
	STD DEV 70.20	STD DEV 1.69
	NORMAL RANGE MEAN (+/-2 STD DEV) 279.43 TO 560.23	NORMAL RANGE MEAN (+/- 2 STD DEV) 40.45 TO 47.21

****

Condition 4 - Scotopic 16 W

****

ENTRY	Amplitude (microvolts)	Implicit Time (msecs)
1	500.00	40.00
2	500.00	35.00
3	400.00	30.00
4	500.00	35.00
5	600.00	37.00
6	575.00	32.00
7	600.00	40.00
8	575.00	35.00
9	500.00	38.00
10	475.00	35.00
11	700.00	30.00
12	750.00	30.00
13	500.00	32.00
14	500.00	35.00
15	575.00	42.00
16	525.00	40.00
17	575.00	34.00
18	600.00	34.00
19	750.00	30.00
20	675.00	30.00
21	550.00	34.00
22	550.00	35.00
23	650.00	40.00
24	675.00	40.00
25	500.00	32.00
26	500.00	32.00
27	725.00	45.00
28	675.00	42.00
29	650.00	40.00
30	750.00	45.00
31	600.00	39.00
32	625.00	35.00
33	575.00	42.00
	MEAN 587.10	MEAN 36.21
	STD DEV 92.84	STD DEV 4.41
	NORMAL RANGE MEAN (+/- 2 STD DEV) 401.42 TO 772.78	NORMAL RANGE MEAN (+/- 2 STD DEV) 27.39 TO 45.03

Appendix E

Sample Release Form

Informed Consent Form

I. Institution

a. Title of Project: Clinical Electrical Diagnostic Testing

b. Principal Investigators: Dave Neill, Francis Iwamoto

Advisors: Robert L. Yolton, O.D., Ph.D., John R. Roggenkamp, O.D.

Location: Pacific University College of Optometry
Forest Grove, OR 97116

Date: April 1983 - February 1984

II. Description of project

This project is a research study designed to obtain data from normal patients who undergo electroretinographic and electro-oculographic testing. Electroretinographic testing involves the placement of a contact lens electrode on the surface of the eye and the recording of electrical signals produced by the eye in response to a flash of light. Two different types of electrodes will be used for this recording. They will be shown to you prior to their use.

Electro-oculographic recording involves placing small silver disks near the corners of the eye (not on the eye directly) and the recording of electrical signals produced when you move your eyes back and forth between the electrodes. All procedures and techniques used in this study will be those which are normally used in the clinical measurement of these electrical signals.

Drugs to anesthetize (numb) the front surface of your eye and to dilate your pupil will be used in combination with electroretinographic measurements. These drugs are normally used in optometric testing and are not experimental. The contact lens electrodes which are used to record the electroretinographic and electro-oculographic signals are also commonly used clinically and are not experimental.

III. Description of Risks

Prior to electroretinographic or electro-oculographic testing, your visual acuities will be measured, the pressure within your eye determined, a case history completed, and an evaluation will be conducted of interior and exterior health of your eyes. If these procedures reveal any abnormalities, you will not be continued in the experiment.

The placement of electrodes on the skin involves the use of electrode paste which is sometimes irritating. Care will be taken to remove the paste from your ears and skin following recording; however, you must wash these areas carefully upon returning to your home.

The drugs that are used to anesthetize the front surface of your eye and to dilate the pupil, occasionally produce unwanted reactions. These reactions can include irritation and redness of the eye, increases of the pressure inside of the eye, and the loss of the top cell layer of the front surface of the eye (corneal sloughing).

The electronic equipment that is used in this project is designed specifically for clinical recording from human patients and has isolation circuits to prevent the return of any electrical current to you. Other techniques and procedures are the same as those utilized in normal clinical optometric environments and your risks from them are the same as those that would be encountered in any health care clinic.

IV. Description of benefits

This study will serve to increase our basic understanding of the difference between two standard recording electrodes for electroretinographic recording and will provide normative data against which data from patients with suspected pathologies can be evaluated. Data will be kept confidential and you will not be identified in any way in written publications arising from this project.

V. Compensation Medical Care

If you are injured in this experiment, it is possible that you will not receive compensation or medical care from Pacific University, the experimenters or any organization associated with the experiment. All reasonable care will be taken to prevent injury. Should you have additional questions regarding compensation, please contact Dr. James Peterson, Pacific University College of Optometry, Forest Grove, Oregon who is chairperson of the Institutional Review Board.

VI. Alternatives advantageous to subjects - not applicable

VII. Additional information

Should you have concerns regarding this project or should you experience discomfort or other adverse reactions following the project, you may contact the researchers at Pacific University College of Optometry, 357-6151 Ext. 217 or you may contact them at home, Dr. Roggenkamp - 640-3310, Dr. Yolton - 357-7998, Mr. Iwamoto - 357-6051, Mr. Neill - 357-6051. If you are unable to reach any of these individuals please contact the College of Optometry Clinic - 640-1731.

II. Questions

Experimenters will be happy to answer any questions that you may have at any time during the course of the study.

IX. Freedom to withdraw

Your participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation any time.

X. Note

You will not be assessed fees for this project, nor will you receive a complete optometric exam. Such an examination is available on a fee basis from the College of Optometry Clinic. No clinic records will be maintained regarding your participation in this project.

I have read and understand the above. I am 18 years of age or over.

_____ _____

Printed Name Signature

Address _____

_____

Date_____ Phone_____

Name and address of person not living with you who will always know your address _____

_____

---

1. Armington, John C., The Electroretinogram, Academic Press (1974), 1.

2. Fisherman, G. A., The Electroretinogram and Electro-Oculogram in Retinal and Choroidal Disease, AAOO (1975), 12-13.

3. Frank, Marco, Alberto Wirth, "A Transistorized Electroretinograph For Clinical Use," Clinical Electroretinography, Pergamon Press (1966), 1.

4. Karpe, G., "Clinical Electroretinography: Its Development and Future," The Clinical Value of Electroretinography, Karger Press (1968), 5.

5. Jacobson, J. H., Clinical Electroretinography, Charles C Thomas Press (1961), 36.

6. Gouras, P., "Relationships of the Electro-Oculogram to the Electroretinogram," The Clinial Valdue of Electroretinography, Karger (1968), 69.

7. Potts, A. M, op. cit., 188.

8. Armington, J. C., op. cit., 321.

9. Jacobson, J. H., op. cit., 36.

10. Armington, J. C., op. cit., 322.

11. Jacobson, J. H., op. cit., 36.

12. Fishman, G. A., op. cit., 16.

13. Jacabson, J. H., op. cit., 389.

14. Babel, Jean, et al., Ocular Electrophysiology, Georg Thieme Publishers (1977), 19.

15. Jacobson, J. H., op. cit., 73.

16. Babel, Jean, et al., op. cit., 19.

17. Fishman, G. A., op. cit., 12.

18. Armington, J. C. and Schwab, G. J., "Electroretinogram in

Nyctalopia," A.M.A. Archives of Ophthalmology, 1954, 52, 725-733.

19. Peterson, H., "The Normal B-Potential in the Single Flash Clinical Electroretinogram," Acta Ophthalmologica Supplement 99, 1968, 1-77.

BIBLIOGRAPHY

Armington, J. C. The Electroretinogram. New York: Academic Press, 1974.

Babel, J., et al. Ocular Electrophysiology. Stuttgart: Georg Thieme Publishers, 1977.

Best, W. "The Importance of ERG in Comparison with Other Visual Function Tests," The Clinical Value of Electroretinography. New York: S. Karger, 1968. 46-50.

Burian, H. M., and J. H. Jacobson. Clinical Electroretinography. New York: Pergamon Press, 1966.

Fishman, G. A. The Electroretinogram and Electro-Oculogram in Retinal and Choroidal Disease. Rochester: AAOO Press, 1975.

Gouras, P. "Relationships of Electro-Oculogram to the Electroretinogram", The Clinical Value of Electroretinography. New York: Karger, 1968. 66-73.

Jacobson, J. H. Clinical Electroretinography. Springfeild: Charles C Thomas Publisher, 1961.