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RELIABILITY OF BRAINSTEM AUDITORY EVOKED POTENTIALS (BAEP) USING THE NICOLET PATHFINDER II

U S ARMY RESEARCH INSTITUTE
OF
ENVIRONMENTAL MEDICINE
Natick, Massachusetts

JUNE 1989



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UNITED STATES ARMY
MEDICAL RESEARCH & DEVELOPMENT COMMAND

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In order to establish the ability of the system to replicate results and to create a database of normal values, 22 male and 13 female subjects were tested twice on each of two days. Conditions were identical for all trials. Using the International Electrode Placement System, surface electrodes were placed at Cz, Al, A2 and Fpz. Two sets of 2000 rarefaction clicks were presented at the rate of 11.1/sec at 75 dB. White noise was presented simultaneously to the contralateral ear at 45 dB.

The absolute latency of the five major peaks of the BAEP were assessed for replicability, as were the interpeak latencies for Waves I - III, III - V, and I - V. Differences due to Gender were also analyzed. Means were calculated to use as norms for the new laboratory.

A repeated measures analysis of variance (ANOVA) for Gender x Day x Trial determined there was a significant main effect for Gender. All remaining analyses were then conducted separately for male and female subjects. Repeated measures ANOVA (Day x Trial) revealed no significant differences for either stimulated ear (left or right) on Trial or Day on both absolute peak latencies and interpeak latencies. Significant differences were found for nonstimulated ears. These differences occurred primarily on Waves II and IV. It is well documented, however, that Waves II and IV and waves from unstimulated ears are unreliable for analysis and diagnosis.

The results from this study are comparable to other laboratories engaged in EP research. The Nicolet Pathfinder II is considered to be a reliable system for collecting EP data in the USARIEM Health and Performance laboratory location.

1. The views, opinions, and/or findings contained in this report are those of of the authors and should not be construed as an official Department of the Army position, policy, or decision, unless so designated by other official documentation.

2. Human subjects participated in this study after giving their free and informed voluntary consent. Investigators adhered to AR 70-25 and USAMRDC Regulation 70-25 on Use of Volunteers in Research.

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RELIABILITY OF BRAINSTEM AUDITORY EVOKED POTENTIALS (BAEP)
USING THE NICOLET PATHFINDER II

Donna J. McMenemy, William J. Tharion and Terry M. Rauch

June 1989

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Natick, Massachusetts 01760-5007

FOREWORD

The following project was conducted under the guidance of the Tri-Service Joint Working Group on Drug Dependent Degradation in Military Performance (JWGD3 MILPERF) as part of the Task Area Group (TAG) Level I. The main purpose of the TAG Level I is to identify adverse drug effects on neurological functions in order to provide guidance to other performance related TAG Levels. One goal of TAG Level I is the development of an automated, standardized and clinically relevant assessment of the nervous system integrity. This will be achieved through the creation of the Neurophysiological Performance Assessment Battery (NP-PAB), consisting of a set of eight evoked potential protocols. Before the NP-PAB can be fully implemented, standardization of the test procedures must be accomplished. Then validation of the NP-PAB with two classes of antihistamines will proceed, using the standardized procedures, by a network of laboratories. This will result in a common archive for JWGD3 MILPERF related data.

Several different evoked potential assessment systems are in use by the laboratories in the network. Standardization of the procedures will insure that similar results can be produced by different systems in different laboratory settings. The Health and Performance Division at US Army Research Institute of Environmental Medicine was requested to participate in this validation effort by assessing three of the standardized procedures on the Nicolet Pathfinder II. Testing the ability of this system and laboratory setting to replicate previous findings is the first step in the effort towards the standardization of the NP-PAB. A database of normal values for the Health and Performance evoked potential laboratory will also be established. The second step, validation of the NP-PAB with two classes of antihistamines, may then proceed.

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ABSTRACT

Evoked potentials (EP) are emerging as a useful diagnostic tool to determine the functional integrity of the central and peripheral nervous systems. The Brainstem Auditory Evoked Potential (BAEP) provides a rapid assessment of the functioning of the brainstem. The individual components, or waves, represent the conduction time, and hence state of conduction in, various structures of the auditory pathway.

Signal averaging systems, such as the Nicolet Pathfinder II, extract the EP from the background electroencephalogram. Because different labs may differ slightly in technique, location, lighting and sound levels, norms must first be established when beginning work with a new system or in a new laboratory.

In order to establish the ability of the system to replicate results and to create a database of normal values, 22 male and 13 female subjects were tested twice on each of two days. Conditions were identical for all trials. Using the International Electrode Placement System, surface electrodes were placed at Cz, Al, A2 and Fpz. Two sets of 2000 rarefaction clicks were presented at the rate of 11.1/sec at 75 dB. White noise was presented simultaneously to the contralateral ear at 45 dB.

The absolute latency of the five major peaks of the BAEP were assessed for replicability, as were the interpeak latencies for Waves I - III, III - V, and I - V. Differences due to Gender were also analyzed. Means were calculated to use as norms for the new laboratory.

A repeated measures analysis of variance (ANOVA) for Gender x Day x Trial determined there was a significant main effect for Gender. All remaining analyses were then conducted separately for male and female subjects. Repeated measures ANOVA (Day x Trial) revealed no significant differences for either stimulated ear (left or right) on Trial or Day on both absolute peak latencies and interpeak latencies. Significant differences were found for nonstimulated ears. These differences occurred primarily on Waves II and IV. It is well documented, however, that Waves II and IV and waves from unstimulated ears are unreliable for analysis and diagnosis.

The results from this study are comparable to other laboratories engaged in EP research. The Nicolet Pathfinder II is considered to be a reliable system for collecting EP data in the USARIEM Health and Performance laboratory location.

INTRODUCTION

Rhythmic variations in the electrical activity of the brain have long been recorded using the technique of electroencephalography. Electrodes are placed on the scalp and differences in electrical potential (resulting from the ionic current flow across cell membranes) between two sites are recorded. This recording is known as the electroencephalogram (EEG). The EEG is generally recorded in the absence of a specific stimulus and is often considered to be spontaneous or background activity.

Another type of electrical activity, the evoked potential (EP), has recently begun to play a large role in neurophysiological and neuropsychological research. The evoked potential is a low voltage (0.5 - 10 microvolts) response of the brain to a specific, externally delivered sensory stimulus. In an evoked potential, the electrical response of the brain to the stimulus always occurs during the same interval of time after the stimulus presentation. Evoked potentials are primarily used to assess the functional integrity of the central and peripheral nervous systems. Specifically, EPs can be used to assess the visual and auditory pathways, peripheral sensory function, and cognitive functioning.

The focus of the present paper is the Brainstem Auditory Evoked Potential (BAEP). The BAEP is a central nervous system electrical response to auditory "click" stimuli delivered to the ear. This stimulation elicits a sequence of five to seven waves generated by the acoustic nerve (eighth cranial nerve) and subsequent brainstem structures in the auditory pathway. The first five of these seven waves are generally consistently present in all subjects, whereas the sixth and seventh wave are more variable. For this reason, at most only

the first five waves are used in analysis, and more often only waves I, III, and V are used. In addition, the interpeak latencies of these three waves are used for diagnostic purposes (American Electroencephalographic Society (AEEGS), 1984; Rowe, 1978). Figure 1 illustrates the location of these first five peaks on a typical BAEP waveform.

Interpeak latencies of the BAEP represent the conduction time of, and hence the state of conduction in, various structures in the auditory pathway. Specifically, since Wave I is generated primarily by the acoustic nerve, close to the cochlea, it provides a good reference point for latency measurements (Chiappa, 1983). The exact origin of the other peaks is still under study, but there is general agreement that the interpeak latency (IPL) of Waves I and III (IPL I-III) represents conduction from the acoustic nerve to the lower brainstem (medulla and pons), IPL II-V from the lower brainstem through the upper brainstem (upper pons and upper midbrain) and IPL I-V conduction from the acoustic nerve to the upper midbrain (Chiappa, 1983; Jewett & Williston, 1971; Owens & Davis, 1985; and Spehlman, 1985).

These latencies are nearly constant not only within the same subject across time but also between different subjects (Amadeo & Shagass, 1973; Chiappa, Gladstone & Young, 1979; Edwards, Buchwald, Tanguay & Schwafel, 1982; and Jewett & Williston, 1971). The reliability of latencies, both within and between subjects, makes the BAEP a useful diagnostic and research tool. Variations in these latencies indicate a disturbance in the state of conduction in these segments of the auditory pathway, and thus in the functional integrity of the brainstem. Disturbances could be the result of a structural anomaly, a centrally active drug or perhaps an environmental

factor. The BAEP can thus be used to evaluate the degree to which a drug (or other factor) affects this specific area of the central nervous system.

Since the EP is the only aspect of the EEG which is stimulus dependent, the evoked potential can be extracted from the random background activity using a signal averaging system. Successive evoked responses are digitized and added to the previous responses. After each addition, the sums are divided by the number of responses collected to produce a running average until the desired number of responses have been collected. Successive averages are used to obtain a clean, well defined signal.

Several signal-averaging systems have been designed specifically for the collection of evoked potentials. Although technical specifications reasonably assure that each system is reliable to a certain extent, slight variations exist between different types of systems, and even between different units of the same type of system. Further variation in EP data can occur due to different test conditions, variations in procedure or locations. It is therefore strongly recommended by many researchers (Chiappa, 1983; Colon, Visser, deWeerd & Zonnerveldt, 1983; Owens and Davis, 1985; and Spehlman, 1985) that a new EP laboratory establish a normative database for each procedure to be used in the laboratory setting. Evoked potential data from other laboratories may be used initially as a reference standard. However, if the new laboratory cannot replicate these reference standards, only the results obtained in the new laboratory should be used as a future reference standard for that laboratory. Spehlman (1985) recommends that 95 percent of the subjects tested in the new laboratory fall within the limits derived from the reference laboratory before the results should be considered replicated.

In summary, the purpose of this study is twofold. First, the ability of a newly acquired Nicolet Pathfinder II (Nicolet Biomedical Instruments: Madison, WI) to replicate data in the US Army Research Institute of Environmental Medicine's (USARIEM) Health and Performance (H & P) Evoked Potential Laboratory environment will be determined. A normative BAEP database for the H & P laboratory will also be established.

METHOD

Subjects:

The subject population consisted of 35 individuals, 22 males and 13 females, between the ages of 20 and 38 years. Subjects were recruited from within USARIEM and included both civilian and military personnel. Only subjects with normal uncompensated hearing participated in the study. The absolute latencies for individual subjects were required to fall within 2.5 units of standard deviation of the normative values determined by two reference laboratories (Colon, et al, 1983; and Chiappa, 1983). Having met this criterion, the subject was included in the H & P database of normal values.

Procedure:

Total test involvement occurred over two days. The same procedure was followed on each test day. Since the BAEP does not vary significantly over a few hours, days or even several months, stringent scheduling of the two test days was not necessary. However, subjects were tested with several days (2-7) in between test sessions. Each test session took approximately 30 minutes to complete.

The procedure used to collect BAEP data in the H & P laboratory is drawn directly from the procedure protocol published by Nicolet Biomedical Instruments (1987) and is also the procedure standardized by the JWGD3 MILPERF Level I TAG (Reeves, et al, 1989). Evoked potentials were collected using the Nicolet Pathfinder II, a self-contained neurodiagnostic system designed for the collection and assessment of evoked potentials.

Surface electrodes were applied to the scalp at 4 sites: The vertex, the medial surface of each earlobe, and the forehead (sites Cz A1, A2, and Fpz of the 10-20 International Electrode Placement System, respectively). Cz is the reference electrode, A1 and A2 are active electrodes, and Fpz serves as the ground electrode. Two different researchers alternated applying the electrodes; the 10-20 International Electrode Placement System was utilized to insure that electrodes were placed in the same locations over repeated trials (Jasper, 1958).

To minimize interference in the recorded signal, the electrode site was prepared with Omni Prep (D.O. Weaver & Co.; Aurora, CO), an abrasive skin-preparation solution to remove oils and dead skin. Medi-Trace EEG Sol (Graphic Controls Corp.; Buffalo, NY) electrode cream was then used to adhere the electrode to the prepared site.

The resistance to current flow, known as impedance, is a measure of the quality of the electrode-scalp interface. Impedance of the scalp-electrode interface was measured with the impedance meter of the Nicolet Pathfinder II. Before continuing, impedance of each electrode was required to be at least 1 but no more than 5 kilohms. Impedance levels were required to be equal for all electrodes to avoid excessive artifact.

Once electrodes were satisfactorily in place, auditory stimuli were presented in the form of rarefaction clicks of 100 usec duration at a rate of 11.1/sec via electronically shielded headphones. The clicks were presented to the stimulated ear at 75 dB, with white noise presented simultaneously to the contralateral ear at 45 dB to mask cross-stimulation. Two sets of 2000 clicks each were presented to each ear; the left ear was stimulated before the right ear for all subjects. In some cases, additional sets of 2000 clicks were necessary to clarify waveforms that did not appear replicable (usually due to excess artifacts or a problem with the electrode placement). Sensitivity was set to 50 uV in order to reject signals higher in voltage than the evoked potential. This also allowed for the maximum recording gain. Bandpass filters were set at 150 Hz (low bandpass) and 1.5 KHz (high bandpass) to remove all signals except for those occurring in that range. The subject relaxed in a reclined position for the duration of data collection. Since the BAEP has been shown not to differ in the sleeping versus waking state (Amadeo & Shagass, 1973; Edwards, et al, 1982; and Picton & Hillyard, 1974) subjects were encouraged to sleep to reduce artifacts from muscle tension and allow for cleaner, faster data collection.

Upon completion of the data collection, electrodes were removed and warm water used to remove any remaining cream. Electrode sites were dabbed with a sterile alcohol pad as a precaution to skin irritation. The subject was then dismissed.

Analysis:

For BAEP waveform analysis, it has been recommended that only waves I, III, and V, along with the interpeak latencies of these three waves (IPL I-

III, IPL III-V, and IPL I-V), for stimulated ears be used in analysis (AEEGS, 1984; and Rowe, 1978). Waves II and IV have been found to be too variable to be useful for neurodiagnostic purposes, as are the waves from the nonstimulated ear. In accordance with the guidelines of the AEEGS for evoked potential research, the measurements of absolute latency of Wave I, III, and V were made for each recording. From these measurements, IPLs of I-III, III-V and I-V were also calculated. Absolute latencies of Waves II and IV and all waves from the nonstimulated ear were also recorded and analyzed but are not of primary interest.

An analysis of variance (ANOVA) for repeated measures was first conducted to determine if a Gender difference existed. Separate analyses were performed for left and right ears. For this analysis, the two daily grand averages for each ear (left and right, stimulated only) were used. The grand average was obtained by averaging the two daily trials for each stimulated ear via the Nicolet Pathfinder II software. Latencies for Waves I through V were then obtained from these grand averages for each subject and used in the analysis of variance. Interpeak latencies were also calculated from the absolute latencies and analyzed by ANOVA.

After determining any Gender differences, an assessment of the ability to duplicate absolute latencies of Waves I through V from day to day and trial to trial was conducted. Additionally, the ability to duplicate the IPLs of Waves I-III, III-V, and I-V was assessed. Separate analyses were conducted on the right and left ears. The primary focus of the data analysis was on the EPs from stimulated ears, but separate analyses were also conducted for nonstimulated ears. The ability of the waveform latencies to be replicated on

different days and different trials was assessed by means of a repeated measures ANOVA.

In addition, descriptive statistics were applied to absolute latencies and interpeak latencies of both the right and left ear, using individual daily trials, to establish a data base of normal values.

Amplitude data are typically variable, both within and between subjects, and therefore were not analyzed in this study.

Data analyses were performed using BMDP Statistical Software (University of California, 1988). Repeated measures ANOVA were performed using BMDP programs 2V and 8V. Descriptive statistics were performed using the 1D BMDP program.

RESULTS and DISCUSSION

All subjects tested produced waveforms which fell within 2.5 standard deviations of the normative values established by two reference laboratories (Colon et al, 1985; Chiappa, 1985).

Previous research has reported conflicting findings regarding Gender differences on EPs (Allison, Wood, & Goff, 1983; Colon, et al, 1983). Some results have shown females to exhibit a shorter latency than males. It is speculated that this result is due a smaller head size and thus a small brainstem, corresponding to a shorter latency. This finding, however, has not been universally accepted and each lab is left to determine its own standards. The data obtained in the present study exhibit a significant main effect for Gender on Wave III ($F(1,33) = 13.82$, $p < .001$; male mean = 4.01 ms, female mean = 3.84 ms) and Wave V ($F(1,33) = 10.84$, $p < .002$; male mean = 5.88 ms,

female mean = 5.65 ms) for the stimulated left ear; and a significant Gender effect on Wave II ($F(1,33) = 4.86, p < .04$; male mean = 2.92 ms, female mean = 2.83 ms) Wave III ($F(1,33) = 10.56, p < .003$, male mean = 3.95 ms, female mean = 3.78 ms) and Wave V ($F(1,33) = 19.41, p < .001$, male mean = 5.85 ms, female mean = 5.58 ms) for the stimulated right ear. Accordingly, significant main effects were found for Gender for IPL I-III ($F(1,33) = 14.74, p < .001$; male mean = 2.23 ms, female mean = 2.06 ms) and IPL I-V ($F(1,33) = 11.40, p < .002$; male mean = 4.10 ms, female mean = 3.87 ms) for the stimulated left ear; and for IPL I-III ($F(1,33) = 10.79, p < .002$; male mean = 2.20 ms, female mean = 2.03 ms) and IPL I-V ($F(1,33) = 4.10, p < .0001$; male mean = 4.10 ms, female mean = 3.84 ms) for the stimulated right ear. In all instances the females exhibited a shorter latency than their male counterparts. Since these differences occurred on four of the six important measures for analysis of the BAEP (Waves III and V and IPL I-III and I-V) male and female data were kept separate for the remainder of the data analysis. The H & P laboratory will maintain separate data files for males and females based on these differences in the normative data.

For stimulated ears, both left and right, as well as, male and female, no significant differences were found for test days or for trials for any of the absolute latencies. This held true for interpeak latencies as well. Figures 2 and 3 are actual waveforms recorded in this study and illustrate the typical similarities in waveforms. Both figures represent the same subject (female), Figure 2 being the first test day and Figure 3 being the second test day. Since no differences were found either between trials or days, it was determined that the present method for BAEP collection and Nicolet Pathfinder

II provide a reliable method of collecting BAEP waveforms in the H & P laboratory.

Once it was determined that no differences occurred on the measures for the stimulated ears a database of normal values was created by combining the daily trials. The data consists of two daily trials per ear (left and right, stimulated only) per subject. The latency for each of Waves I through V was obtained from each trial for each subject. Means and standard deviations of absolute peak latencies for Waves I through V and IPL I-III, III-V, and I-V were obtained from the subjects included in the final database and are included in Tables 1 and 2. These values will serve as normative values for the H & P laboratory. The values obtained in this study are comparable to values obtained by two reference laboratories (Colon, et al, 1983; and Chiappa, 1983), indicating that the H & P laboratory is a reliable test site for evoked potential research.

As stated previously, Waves II and IV are not reliable means of measurements for the BAEP, nor are the waveforms from the nonstimulated ear. In this study, Waves II and IV for the stimulated ears were shown to be stable. To assess the ability to replicate waveforms for nonstimulated ears, the same statistical procedures used on the stimulated ear were conducted with the data from the nonstimulated ear trials.

Analysis of the absolute latencies of nonstimulated ears did show a few significant differences. For males, Wave II exhibited a significant difference for Trial for the right ear only ($F(1,21) = 5.71$, $p < .03$; Trial 1 mean = 3.02 ms, Trial 2 mean = 3.00 ms). Females exhibited significant differences for Day on Waves IV ($F(1,12) = 10.88$, $p < .006$; Day 1 mean = 4.89 ms, Day 2 mean = 4.78 ms) and V ($F(1,12) = 4.99$, $p < .05$; Day 1 mean = 5.74 ms,

Day 2 mean = 5.69 ms) on the left ear only. This is not surprising in view of the fact that Waves II and IV are considered unreliable and not useful in diagnosis. Coupled with the fact that waveforms from nonstimulated ears are also considered unreliable this finding is not at all unexpected. Means were obtained from these trials to be used merely as reference points and are included in Tables 3 and 4. In accordance with AEEGS guidelines, future EP research will primarily involve only Waves I, III, and V, and the corresponding interpeak latencies of the stimulated ear.

CONCLUSION and SUMMARY

The BAEP is emerging as a useful diagnostic tool to assess the functioning of the various components of the auditory pathway. The Nicolet Pathfinder II is one signal averaging system which can be used to extract the EP from the background EEG. A normative database must first be established for a new EP laboratory. This study assessed the ability of a new Nicolet Pathfinder II and the surroundings to be used in future EP testing to replicate results of other laboratories, as well as to replicate its own results on a day to day basis. No significant differences were found on the measures to be used in future EP research (absolute latencies of Waves I, III and V, and IPL I - III, III - V and I - V of the stimulated ear). Since these measurements did not differ from trial to trial or day to day, it is concluded that the H & P laboratory offers a site where EPs can be collected confidently and accurately. Means and standard deviations were calculated from these measurements and established as the norms for the H & P laboratory.

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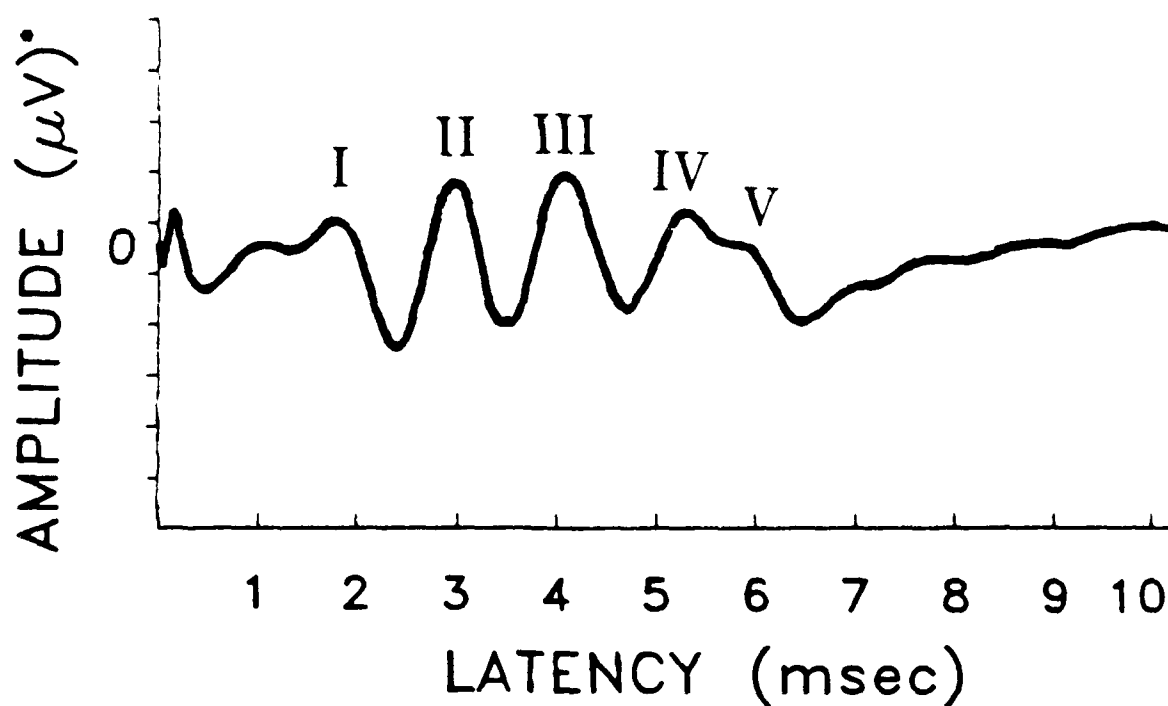
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Spehlman R (1985). Evoked potential primer : visual, auditory and somatosensory evoked potentials in clinical diagnosis. Boston : Butterworth.

FIGURE 1

BAEP

LOCATION OF INDIVIDUAL PEAKS

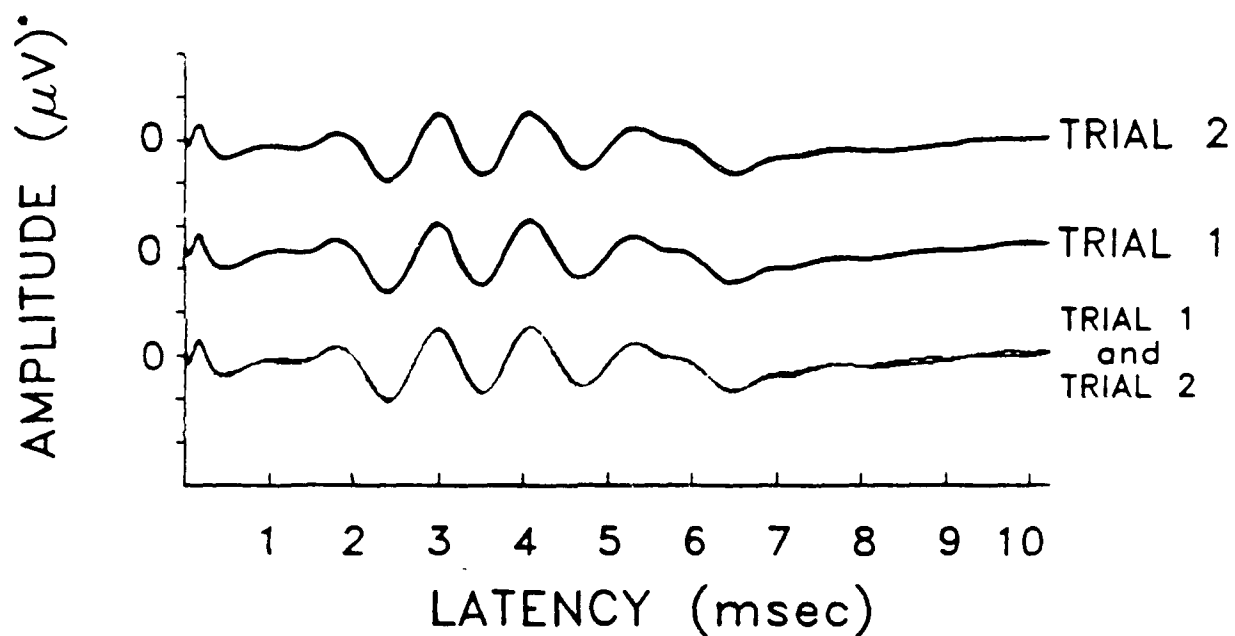


* 1 DIVISION = 0.31 μV

FIGURE 2

BAEP

STIMULATED EAR
DAY 1

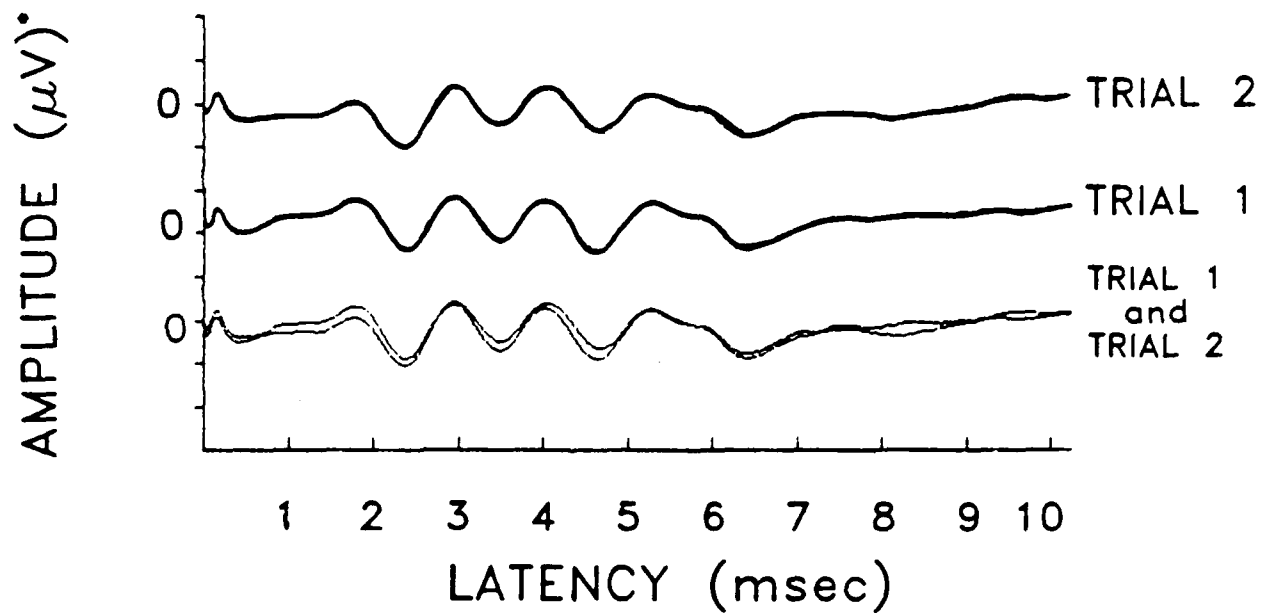


* 1 DIVISION = 0.62 μV

FIGURE 3

BAEP

STIMULATED EAR
DAY 2



• 1 DIVISION = 0.62 μV

TABLE 1

MEANS (in ms) CALCULATED FROM DAILY TRIALS
STIMULATED EAR

	<u>MALES</u>				<u>FEMALES</u>			
	LEFT EAR		RIGHT EAR		LEFT EAR		RIGHT EAR	
	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD
WAVE I	1.77	.10	1.75	.09	1.79	.15	1.74	.10
WAVE II	2.93	.15	2.93	.15	2.89	.15	2.84	.12
WAVE III	4.01	.14	3.96	.14	3.84	.12	3.77	.16
WAVE IV	5.10	.21	5.08	.17	4.99	.19	4.98	.20
WAVE V	5.88	.22	5.87	.16	5.64	.20	5.59	.20

TABLE 2

MEAN INTERPEAK LATENCIES (in ms) CALCULATED FROM DAILY TRIALS
STIMULATED EAR

	<u>MALES</u>				<u>FEMALES</u>			
	LEFT EAR		RIGHT EAR		LEFT EAR		RIGHT EAR	
	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD
WAVE I - III	2.23	.12	2.21	.11	2.06	.15	2.03	.14
WAVE III - V	1.87	.14	1.91	.14	1.80	.12	1.82	.09
WAVE I - V	4.09	.20	4.12	.15	3.86	.20	3.85	.19

TABLE 3

MEANS (in ms) CALCULATED FROM DAILY TRIALS
NONSTIMULATED EARS

	<u>MALES</u>				<u>FEMALES</u>			
	LEFT EAR		RIGHT EAR		LEFT EAR		RIGHT EAR	
	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD
WAVE I	1.80	.10	1.81	.14	1.80	.06	1.80	.12
WAVE II	3.02	.14	3.01	.15	2.89	.10	2.91	.14
WAVE III	3.95	.14	3.96	.16	3.75	.17	3.79	.17
WAVE IV	5.03	.17	5.07	.20	4.84	.18	4.89	.16
WAVE V	5.96	.17	5.99	.19	5.72	.20	5.76	.18

TABLE 4

MEAN INTERPEAK LATENCIES (in ms) CALCULATED FROM DAILY TRIALS
NONSTIMULATED EAR

	<u>MALES</u>				<u>FEMALES</u>			
	LEFT EAR		RIGHT EAR		LEFT EAR		RIGHT EAR	
	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD
WAVE I - III	2.15	.13	2.15	.15	1.95	.17	1.98	.20
WAVE III - V	2.01	.17	2.04	.17	1.97	.12	1.98	.14
WAVE I - V	4.16	.13	4.19	.17	3.92	.19	3.96	.18

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