

Award Number: W81XWH-14-2-0140

TITLE: Effects of Acoustic Impulses on the Middle Ear

PRINCIPAL INVESTIGATOR: Dr. William Ahroon

CONTRACTING ORGANIZATION: The Geneva Foundation
Tacoma, WA 98402

REPORT DATE: October 2015

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick,
Maryland 21702-5012

DISTRIBUTION STATEMENT:

X Approved for public release; distribution unlimited

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

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202- 4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) October 2015		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 22 Sep 2014 - 21 Sep 2015	
4. TITLE AND SUBTITLE "Effects of Acoustic Impulses on the Middle Ear"				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-14-2-0140	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Dr. William Ahroon				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) The Geneva Foundation 917 Pacific Ave., Ste. 600 Tacoma, WA 98402				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) US Army MPMC Ft Detrick, MD 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The objective of this project is to fully document the effects of acoustic impulses on the middle ear and on middle-ear muscle contractions (MEMC). This project will provide critical information on the middle ear musculature states during warned and unwarned exposures to acoustic impulses. This information necessary in the development of new (or revising existing) damage risk criteria and health hazard assessment methods for exposure to high-level acoustic impulses such as experienced by users of military and civilian law enforcement weapon systems, civilian recreational hunting and shooting, and industrial high-level impulsive noises (impacts and impulses).					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Unclassified	18. NUMBER OF PAGES 22	19a. NAME OF RESPONSIBLE PERSON USAMPMC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (include area code)

<u>Table of Contents</u>	<u>Page</u>
Table of Contents	3
Introduction	4
Keywords	4
Accomplishments	4
Impact.....	18
Changes/Problems	19
Products.....	19
Participants & Other Collaborating Organizations	20
Special Reporting Requirements	21
Appendices	21

Introduction:

The objective of this project is to fully document the effects of acoustic impulses on the middle ear and on middle-ear muscle contractions (MEMC). This project will provide critical information on the middle ear musculature states during warned and unwarned exposures to acoustic impulses. This information is necessary for the development of new (or revision of existing) damage risk criteria and health hazard assessment methods for exposure to high-level acoustic impulses such as experienced by users of military and civilian law enforcement weapon systems, civilian recreational hunting and shooting, and industrial high-level impulsive noises (impacts and impulses).

Keywords:

Noise exposure; hearing loss, noise-induced; impulsive noise; reflex; conditioned response; middle ear; damage-risk criteria; health hazard evaluation

ACCOMPLISHMENTS:

What were the major goals of the project?

The major goals of the project as stated in the approved SOW are:

1. Determine the prevalence of acoustic reflexes to among young people with H-1 hearing status as per Army Regulation 40-501, Table 7-1.
2. Determine whether reflexive MEMC are pervasive for multiple acoustic and non-acoustic stimuli.
3. Determine whether conditioned MEMC are pervasive, in either laboratory or field settings, and if so, identify differences between reflexive and conditioned MEMC.

What was accomplished under these goals?

1. Determine the prevalence of acoustic reflexes to among young people with H-1 hearing status as per Army Regulation 40-501, Table 7-1.

Major activities

The majority of the work associated with task was completed during this project period, and the only remaining element of this task is to complete dissemination. Presentations of this work at scientific meetings are scheduled, and the manuscript draft is in preparation.

Specific objectives

The first specific objective involved the development of a MEMC detection algorithm for use with the National Health and Nutrition Examination Survey (NHANES) impedance traces. In accordance with our original proposal, two approaches were developed. One proposal utilized a Frequentist strategy and identified the MEMC based on an improbable sustained departure from the impedance trace baseline. The criterion departure was approximately a 50 millisecond observation exceeding the upper limit of the 95 % confidence interval of the post-stimulus impedance trace. The other proposal utilized a Bayesian strategy wherein Kalman filtering was used to reduce the noise in the impedance traces. The filtered impedance traces were then correlated with prototypical traces and a reflexive MEMC was deemed present when the correlation exceeded a criterion of 0.85.

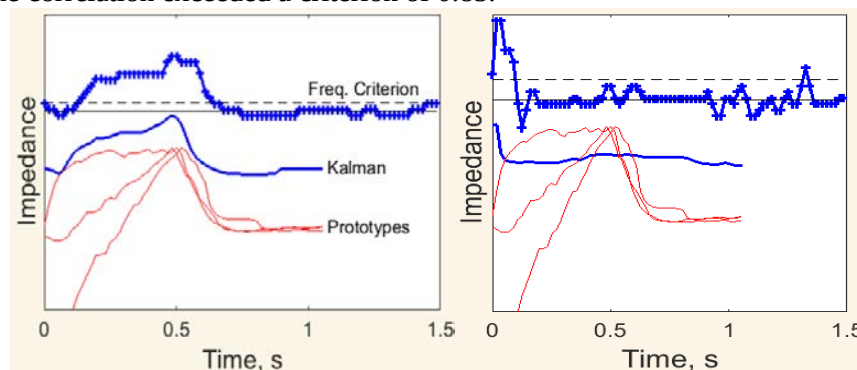


Figure 1. Example of the application of Frequentist and Bayesian approaches to NHANES reflex detection. Three consecutive sample values greater than the dashed line were required by the Frequentist criterion. A correlation coefficient greater than 0.85 between the Kalman filtered trace and at least one prototype was required by the Bayesian criterion. The figure on the left of the panel shows an example of a trace in which

an acoustic reflex was present according to both approaches. The figure in the right of the panel shows an example of a trace in which no acoustic reflex was present.

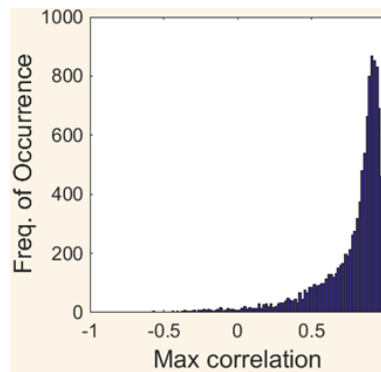


Figure 2: Frequency histogram of maximum correlations between Kalman-filtered reflex traces and prototypes. Note the high rate of large correlation coefficients.

The second specific objective was to determine the prevalence of MEMC, conditioned on demographic, middle ear status, and hearing sensitivity factors and disseminate those findings. This objective was accomplished via the application of conventional techniques for assessing prevalence in complex survey data. This included appending detection algorithm outcomes for each of the four conditions assessed in NHANES (i.e., ipsilateral responses in each ear for elicitor frequencies of 1 and 2 kHz at approximately 105 dB HL). In order to provide a best-case estimate of reflexive MEMC prevalence, a highly sensitive definition was used. A participant was judged to have a reflexive MEMC if a response was detected on any one of the four conditions. Prevalence estimates were then obtained using crosstabulations and via multivariable logistic regression analyses designed to control for the predictive factors. Analyses were adjusted for sample weights, sampling strata, and pseudo-sampling units, following the recommendations from the National Center for Health Statistics.

Significant results

The prevalence of reflexive MEMC to acoustic stimuli was generally high (92 % met both methods, 95 % confidence interval [90, 94]) among listeners with H-1 hearing profiles. However, the probabilities of reflexive MEMC were not uniform across audiometric configurations that fit within the limits of the H-1 hearing profile. Audiometric configurations fitting within the H-1 hearing profile are shown in Figure 3, and the corresponding prevalence estimates (and 95 % confidence intervals for the prevalence estimates are shown in Figure 4.

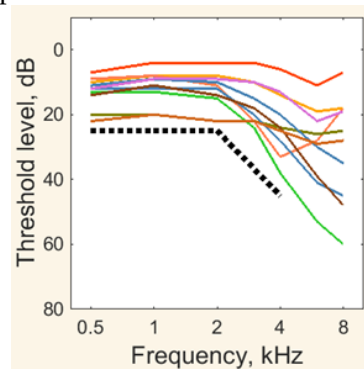


Figure 3. Audiometric configurations meeting the H-1 profile. The dashed line represents the limit of the H-1 hearing profile.

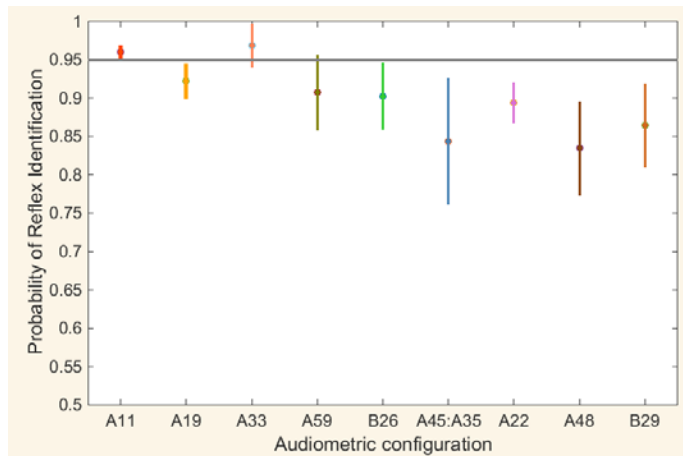


Figure 4. Prevalence of acoustic reflexes by audiometric configuration. Error bars represent the 95 % confidence interval for the proportion. Configurations can be linked by color to those displayed in Figure 3. The horizontal line at the 95 % reflex identification represents the level at which the lower confidence interval must be above to be considered pervasive in the population.

The required certainty of reflexive MEMC was observed only among the participants best described by the A11 audiometric configuration, which represents the best category of hearing sensitivity. The remaining audiometric configurations meeting the H-1 hearing profile either had confidence intervals on the prevalence proportion extending below the criterion (95 %) rate (A33 configuration), had confidence intervals just exceeding the criterion rate (A59 configuration), or had estimates and confidence intervals falling below the criterion rate.

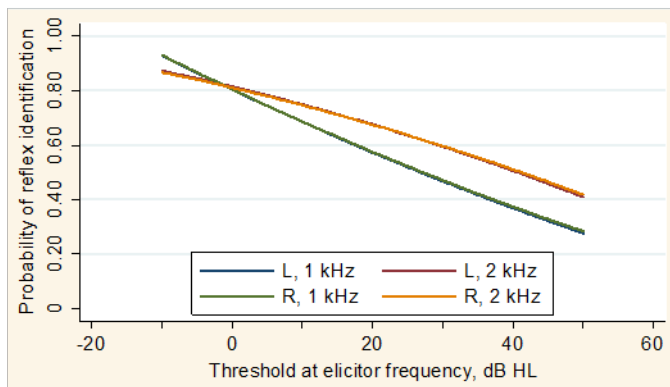


Figure 5. Probability of acoustic reflexes as a function of threshold at the elicitor frequency.

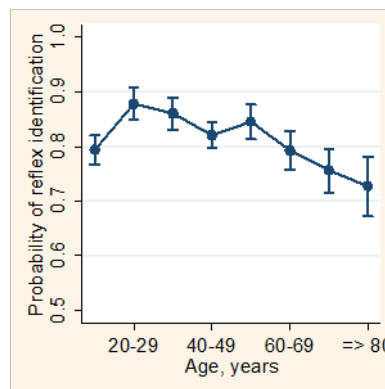


Figure 6. Probability of acoustic reflexes as a function of age.

The probability of observing reflexive MEMC declined as a function of hearing sensitivity at the elicitor frequency and the effect was consistent across ears (see Figure 5). There does not appear to be a clear demarcation point

wherein poorer hearing sensitivity at the elicitor frequency begins to produce a reduction in the probability of observing a reflexive MEMC. Thus, even small reductions in hearing sensitivity were relevant.

The association between age and reflexive MEMC detection was minimal after controlling for hearing sensitivity. A gradual decline was observed above age 59, however, and lower probabilities of detecting reflexive MEMC were observed among participants aged 12-19 years, after controlling other predictive factors.

Other achievements

Nothing to report.

2. Determine whether reflexive MEMC are pervasive for multiple acoustic and non-acoustic stimuli.

Major activities

The major activities during this period followed our proposed timeline. Most efforts were devoted to the development of the elements of the test protocol and receiving approval for conducting research with human subjects in laboratory environments.

Specific objectives

Our first objective associated with this task was to develop a reflexive MEMC study protocol. This protocol included the necessary data acquisition to: determine candidacy; execute the tasks assessing the experimental acoustic MEMC; execute the task assessing tactile (non-acoustic) MEMC; and execute the task assessing MEMC associated with light and tight eye closure. The procedures were embedded in a MATLAB script that reduces data entry errors (e.g., detects incorrect participant ID numbers), executes protocol elements according to a pre-defined sequence, and automatically stores electronic files based on participant identification numbers, visit number, test number, and also codes the level of information contained in the data file (e.g., a code of zero is used to denote raw data, and code values increase with each level of review and validation).

The procedures used to determine candidacy include otoscopy, pure tone thresholds, tympanometry, wideband absorbance, clinical reflexive MEMC measurements, and verification of the integrity of the cranial nerves supplying the stapedius and tensor tympani muscles (c.VII and c.V, respectively). Otoscopy is conducted by means of a video-otoscope operated via custom software in the MATLAB environment and using a footswitch to initiate recording. Video files are saved in the .MAT format to allow future review and analysis.

Pure tone thresholds are obtained using Audiometric Research Tool (ART) software, which presents stimuli via a National Instruments (NI) dynamic signal analyzer module. Threshold is defined as the lowest presentation level producing a 50 % or greater likelihood of response on at least three ascending trials, using a 5-dB step via the modified Hughson-Westlake procedure. In addition to thresholds, the ART software retains the detailed history of stimulus presentations and responses leading to each threshold. These detailed records allow for future review and analysis for the purpose of quality assurance and for evaluation of threshold reliability.

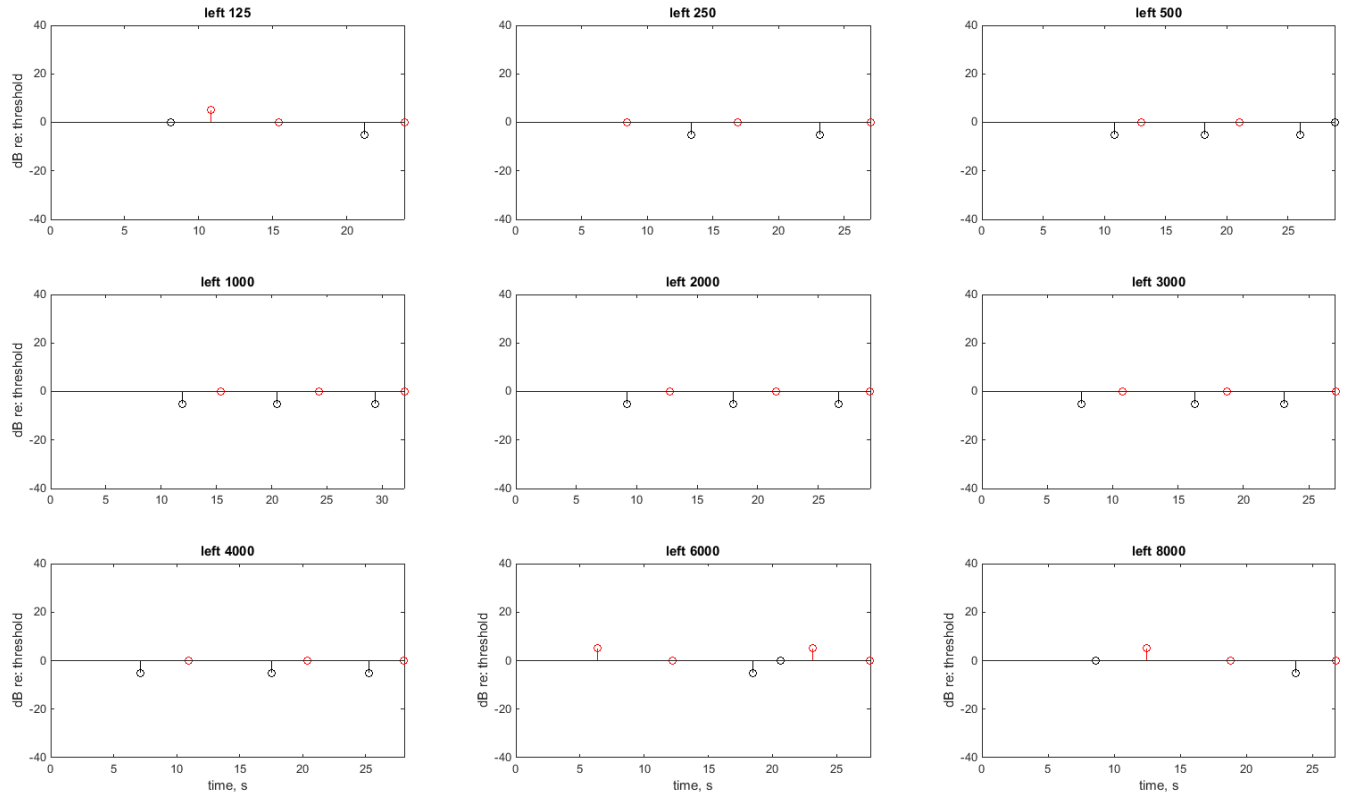


Figure 7. Example of ART presentation history review. Each plot represents ascending presentations as a function of time since the start of testing that frequency. The vertical axis is normalized to the reported threshold to facilitate comparison. Black symbols represent ascending stimulus presentations with no response from the participant. Red symbols represent ascending stimulus presentations that produced a response from the participant. Note that descending presentations are not included in these plots because they are not used for threshold determination.

Tympanograms, wideband absorbance at ambient pressure and as a function of static ear canal pressure, and clinical reflexive MEMC measurements are obtained bilaterally using the Interacoustics Titan system. The manufacturer's software is opened automatically by the MATLAB shell script, and the tests within this device are presented via a protocol that determines the test order and stimulus parameters. Raw data returned by the protocol are stored to the .XML file format and then imported into MATLAB using custom software. Tympanograms are obtained using a 0.226 Hz probe tone at static pressures ranging from +200 to -300 daPa. Wideband absorbance measures for filtered click stimuli (at ambient and tympanometric pressures) are obtained and return proportions of incident energy absorbance as a function of frequency and, in the case of the wideband tympanogram, also as a function of static pressure. An example record is represented in Figure 8.

Clinical reflexive MEMC measurements are obtained for both ears under both ipsilateral and contralateral conditions. Elicitor stimuli are presented in 5-dB increments from 80 to 100 dB HL. Example results are represented in Figure 9. Clinical measurements of decay in reflexive MEMC responses can be indicative of retrocochlear lesion, so positive decay (defined as a 50 % reduction in response within 5 seconds) is an exclusion criterion in this study. An example of the decay measurement is represented in Figure 10.

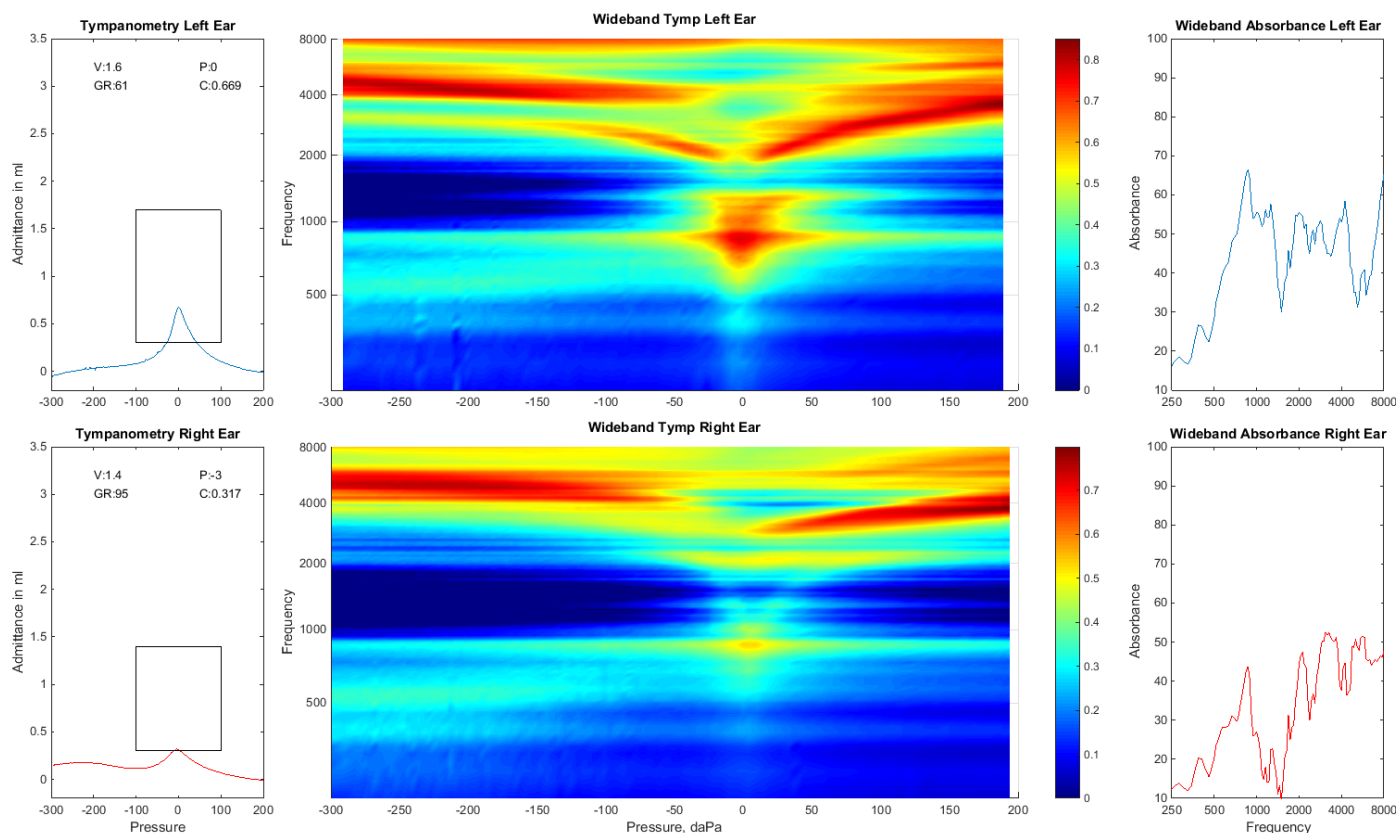


Figure 8. Examples of initial review of tympanograms, wideband tympanograms, and ambient pressure wideband absorbance. Tympanograms are reviewed on the basis of summary values and morphology, wideband tympanograms are reviewed on the basis of increased absorbance below 2 kHz between +/- 50 daPa and high absorbance above 2 kHz, and wideband absorbance at ambient pressure is reviewed on the basis of low absorbance in low frequencies and mean absorbance above 1 kHz greater than 40 %.

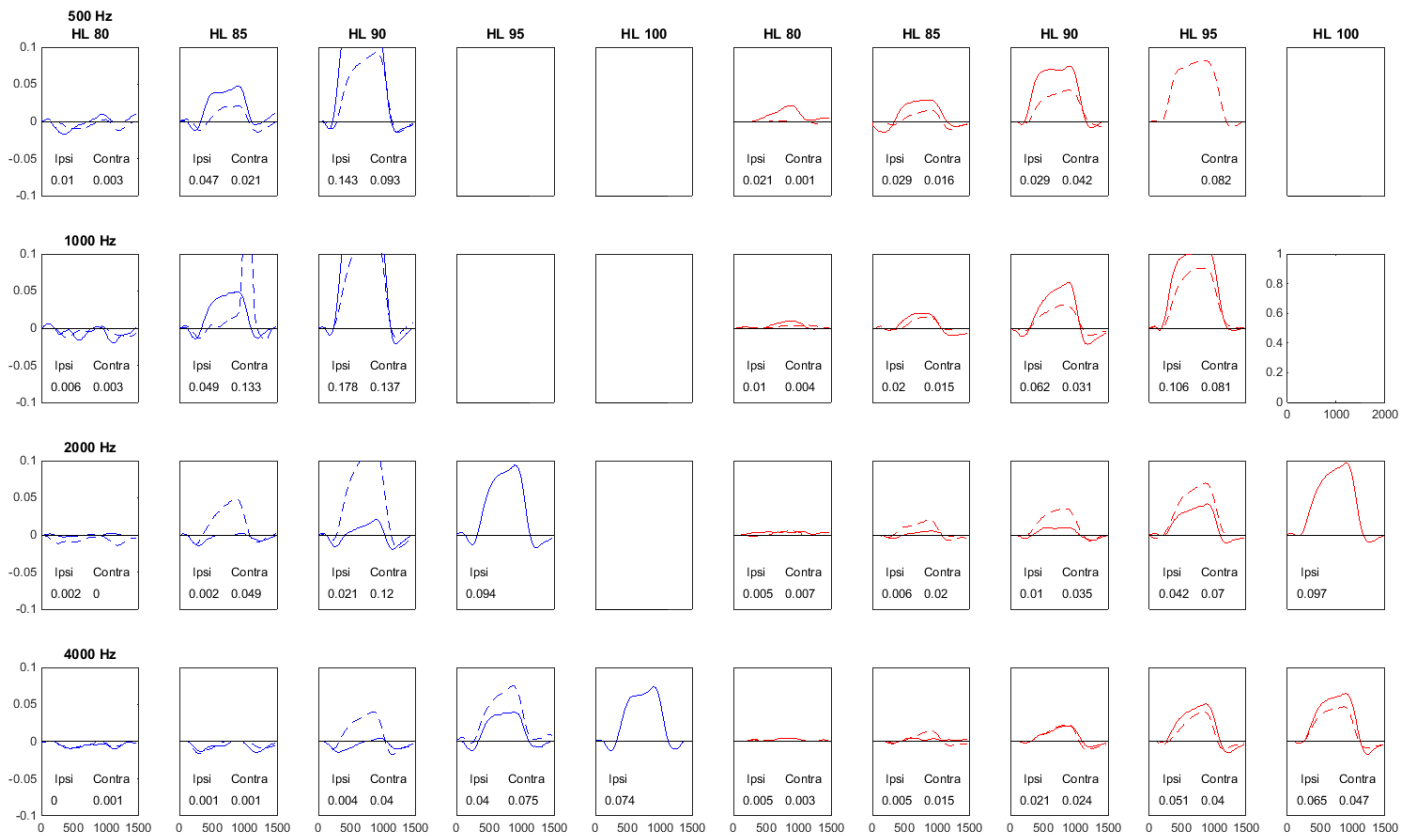


Figure 9. Example of initial review of clinical reflexive MEMC data. Plots represent impedance changes in impedance as a function of time. The eliciting stimulus was presented for 1000 ms. Results from placement of impedance probe on the left side are presented in blue; results from placement of the impedance probe on the right side are presented in red. Ipsilateral (i.e., probe and stimulus on same side) results are represented by a solid line. Contralateral (i.e., probe and stimulus on opposite ear) results are presented with a dashed line. A clinical reflexive MEMC is conventionally indicated by a change greater than 0.02 units. Results are reviewed on the basis of both magnitude and growth with increased stimulation. Empty figures represent conditions wherein additional presentations were not necessary to determine the presence of a clinical reflexive MEMC.

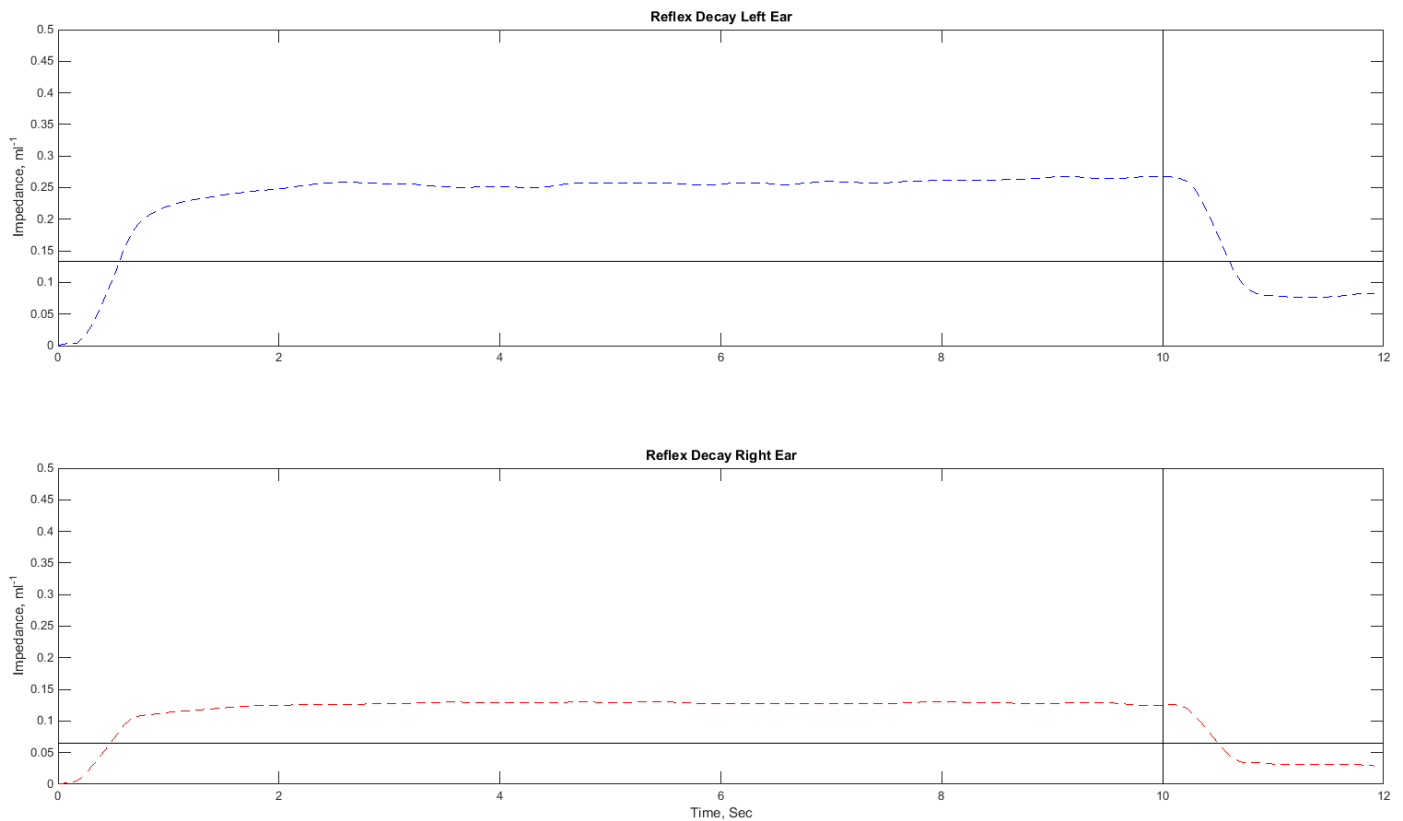


Figure 10. Example of clinical assessment of reflexive MEMC decay. Plots represent impedance as a function of time, and decay is indicated by a rapid decline of impedance during the 10-second duration of the contralateral elicitor tone.

Verification of cranial nerve c.V and c.VII integrity is accomplished by verifying both sensory and motor performance, including sustained lifting of the eyebrows, a sustained grin, retention of air pressure within the oral cavity via voluntary closure of the mouth, ability to resist opening and closure of the jaw, and sensation via each of three branches of the trigeminal (c. V) nerve bilaterally.

The procedures involved in the experimental acoustic reflexive MEMC detection involve both acoustic and electromyographic transducers. The Etymotic ER-10x system is used for both presentation of click-based probe signals and for recording those signals in the ear canal. A commercial insert earphone (Etymotic ER-4PT) is used for contralateral delivery of the elicitor stimulus. It is these recordings that are used for the detection of MEMC. The MEMC is indicated by a change from baseline in the pressure-versus-time function obtained. These changes are integrated across the 50 ms click interval, and the integrated levels are monitored as a function of time relative to the onset of the MEMC elicitor. All signals are presented and acquired at a 44.1 kHz sample rate. An example of this process is illustrated in Figures 11 through 13. These figures demonstrate one example of a reflexive MEMC to an acoustic stimulus, and this method can be applied to any elicitor stimulus for which the onset time is known and shall be applied for the detection of all reflexive and conditioned MEMC in this study.

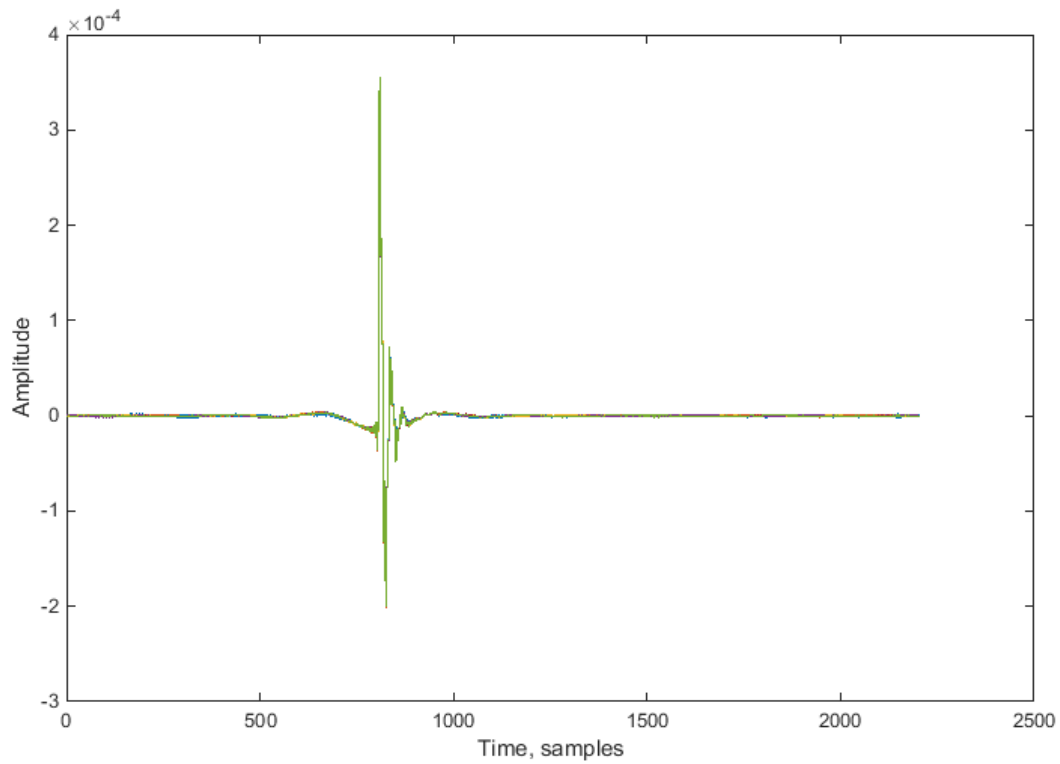


Figure 11. Superimposed baseline recordings of click signals in the ear canal. The horizontal axis represents time in samples (range = 2205 samples, which equals 50 ms). All signals are preserved for review, which includes disturbances in the baseline recordings. Such disturbances could represent disturbance of the ER-10x probe in the ear canal, external noise, or self-generated noise from the participant.

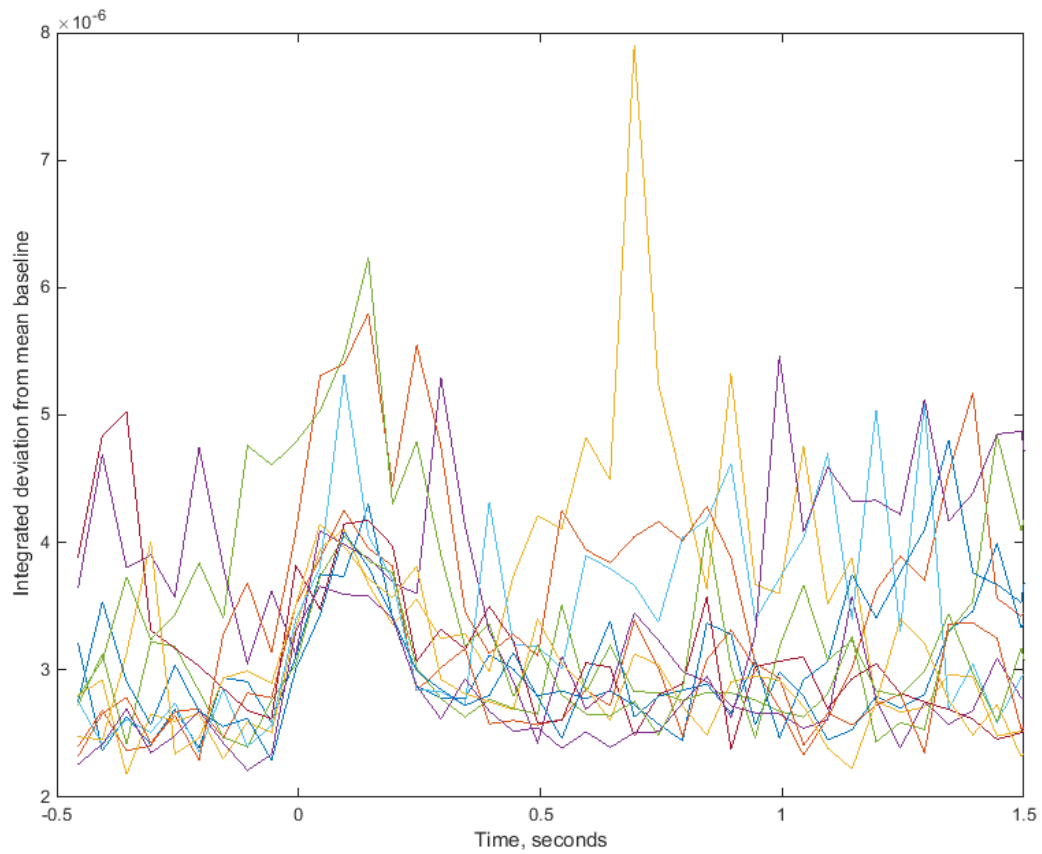


Figure 12. Integrated deviations from baseline clicks. Each parameter in the figure represents one trial of an MEMC elicitor stimulus. Note the systematic increase in the integrated deviation during the 0 to 0.3 second time interval. This systematic increase represents a change in the amount of energy reflected from the eardrum that is linked to MEMC elicitor onset. This is evidence of an MEMC.

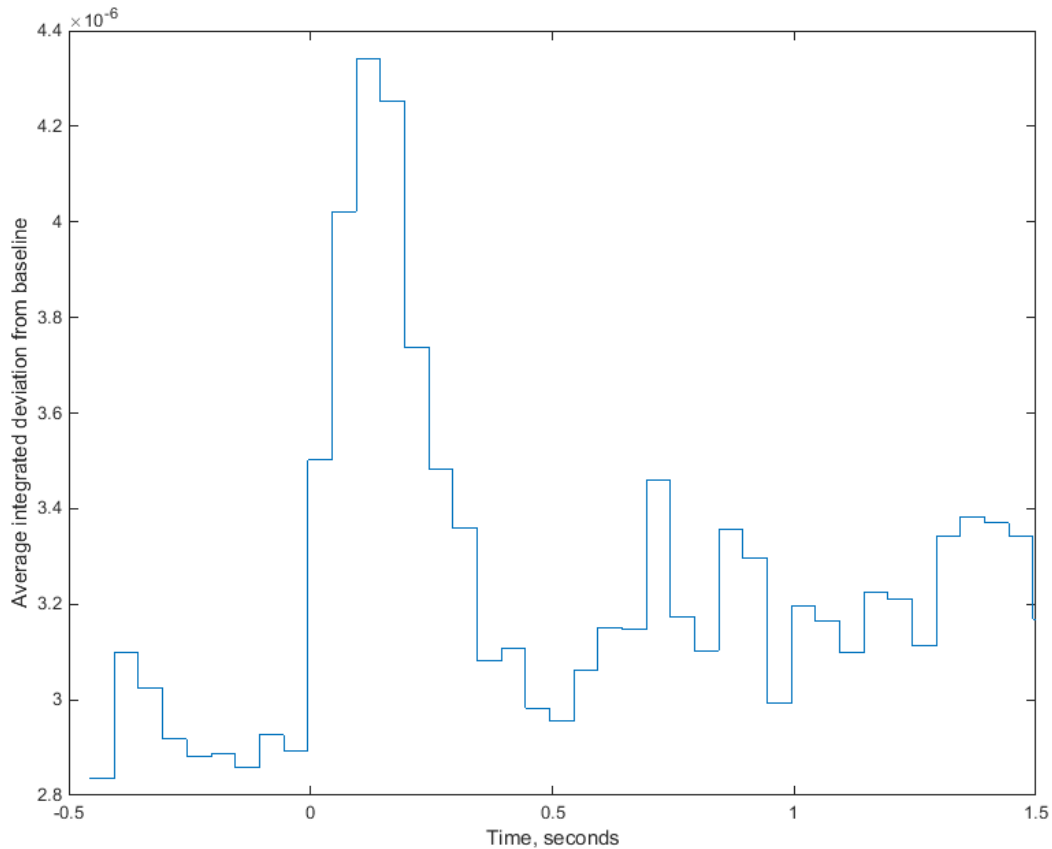


Figure 13. Mean integrated deviations across trials of MEMC elicitor stimuli. The horizontal axis represents time in seconds relative to the onset of the MEMC elicitor, the vertical axis represents the mean integrated deviations. Each step in the plot represents one 50 ms click interval. The systematic deviation that begins immediately following the elicitor onset (i.e., time=0) is evidence of an MEMC.

Surface electromyography (EMG) of multiple muscles sharing the neural supply of the stapedius and tensor tympani muscles is included in the reflexive MEMC protocol to help identify artifacts in the ear canal recordings associated with movement and to differentiate between contractions that are limited to the middle ear versus coordinated contractions across multiple muscles (e.g., a startle response). The muscles monitored include the orbicularis oculi (OO), masseter (MAS), the suprahyoid complex (SH), the biceps (BIC), and the flexor digitorum superficialis (FDS). With the exception of the FDS muscle, the EMG electrodes are placed on the same side as the ER-10x probe. The FDS electrode is placed on the opposite side because the output of that electrode is used for some of the conditioned tasks, described below.

The procedures involved in the non-acoustic reflexive MEMC detection task involve the delivery of short-duration puffs of nitrogen gas to four areas of the face (the temple and just above the nasolabial fold bilaterally). The onset of the puffs is accomplished via fast-acting valves that are controlled by a microprocessor. The puffs are delivered via hose (1/8" lumen) to ports approximately 1 cm above the surface of the selected area. The ports are held at a constant distance from the surface of the selected area by a mounting apparatus attached to a modified helmet. The MEMC detection software requires only a known onset time for the eliciting stimulus. In this task, the onset time is derived from two sources. First, the output of a pressure sensor located between the compressed nitrogen source and the fast-acting valve is monitored to determine the moment that the valve opened (see Figure 14). Second, the delay time between the moment of valve opening and air flow through the port at the end of the tube is a constant value (approximately 20 ms) that was measured using a blast probe transducer.

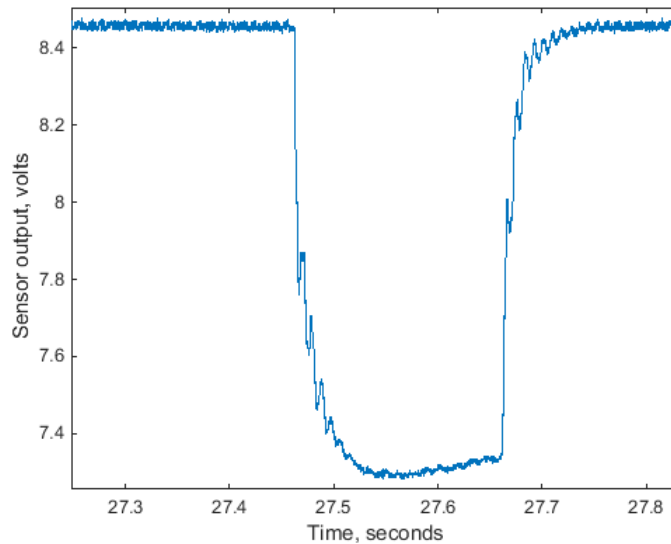


Figure 14. Upstream pressure function associated with air puff. Reduction in pressure sensor output is associated with the opening of the fast-acting valve.

The procedures involved in the detection of MEMC associated with light and tight eye closure, rely on the use of a cross-modality magnitude production task wherein participants are asked to close the eye with the EMG electrode with a level of effort consistent with a vertical bar graph (Figure 15). The EMG responses from the OO muscle via this paradigm can provide easily distinguishable onsets of OO muscle activity and segregation of light and tight eye closure (Figure 16).

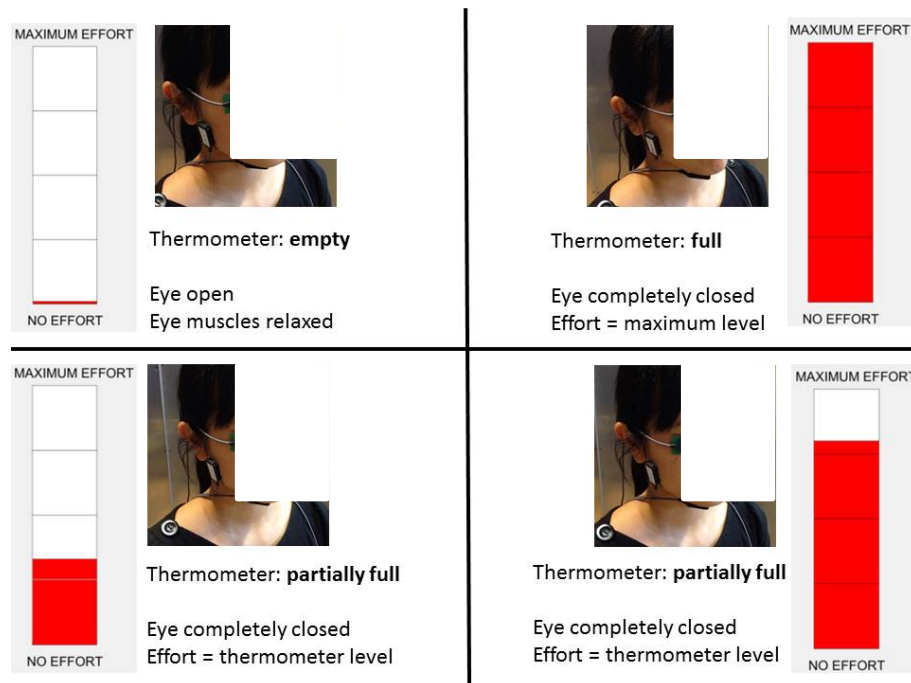


Figure 15. Example of cross-modality magnitude production task for obtaining light and tight eye closure. Note that the example photograph has been partially occluded for this report.

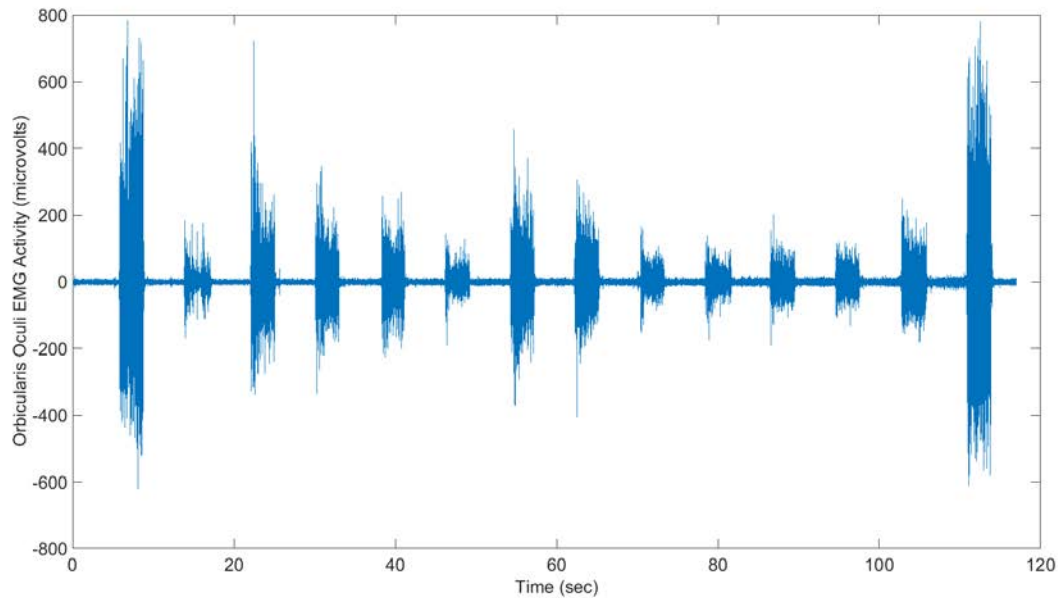


Figure 16. Example of orbicularis oculi EMG responses from maximal, light, and tight eye closure. The horizontal axis represents time, the vertical axis represents the voltage output from the EMG measurement system. In this example, light and tight eye closures can be easily discerned by the magnitude of EMG activity.

The second and third objectives were to apply the protocol in laboratory and field settings. Pilot testing of the reflexive protocol in lab settings was initiated near the end of this study period and will be followed by the collection of study data. Application of the protocol in field settings is not scheduled until 2016.

The final objective was the analysis and dissemination of reflexive findings. Preliminary analysis routines have been developed and will be applied once sufficient study data are obtained.

Significant results

We have no significant results to report because we are in an early stage of data collection.

Other achievements

Nothing to report.

3. Determine whether conditioned MEMC are pervasive, in either laboratory or field settings, and if so, identify differences between reflexive and conditioned MEMC.

Major activities

The major activities on this task during this period followed our proposed timeline and were devoted to the development and testing of the conditioned tasks.

Specific objectives

Our first objective associated with this task was to develop a reflexive MEMC study protocol. This protocol included the necessary data acquisition to assess the influence of acoustic conditioning stimuli on pupil contractions, execute each of the five conditioned tasks, and identify MEMC in the data. For all tasks, probe clicks will be presented and ear canal recordings will be obtained throughout testing.

The first conditioned task (Attended Auditory, AA) involves the use of a gap in a series of beeps as the conditioned stimulus. The 1 kHz beeps are presented at approximately 55 dB SPL in an occluded ear simulator, which will be easily audible but not sufficiently high to produce a reflexive MEMC. A white noise unconditioned stimulus follows the gap, and will produce the MEMC. In order to ensure that participants attend to the stimulus, they are instructed to press a response button when they detect the gap. As noted above, the MEMC detection software requires only the

onset of the eliciting event to parse the ear canal recordings and detect an MEMC if one is present. In this task, the onset of the eliciting event will be the moment in the gap where the beep would have been.

The second conditioned task (Attended Light, AL) involves the use of a change in an image on a video monitor as the conditioned stimulus. The same white noise unconditioned stimulus will be used. Participants are asked to watch a video monitor in front of them. The monitor will display one image (e.g., a yellow rectangle). The conditioned stimulus is the change from the yellow rectangle to a blue oval. The white noise unconditioned stimulus will be delivered to the earphone shortly after. In order to ensure that participants attend to the stimulus, they are instructed to press a response button when they detect the change in the image. The blue oval contains the same number of pixels on the monitor as the yellow rectangle, and the two colors have been specified to have equal brightness. The onset time of the elicitor is the moment that the stimulus changes.

The third conditioned task (Unattended Auditory, UA) is identical to the AA task, except that instead of asking the participant to press a response button when they detect the gap, they are asked to track a target on the video monitor using a toy gun mounted on a stand. This toy gun is equipped with an inertial measurement unit (IMU), the output of which is used to change the location of a cursor on the video monitor. The target (see Figure 17) moves randomly around the video monitor, and the difficulty of the task is adaptive. If the participant is able to follow the target closely, the rate of target movement increases.

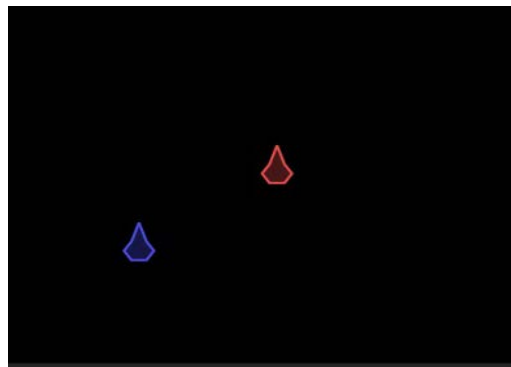


Figure 17. Example of target (red) and cursor (blue) used in the UA, ST, and DF tasks.

The fourth conditioned task (Simulated Trigger, ST) uses the same toy gun as the UA task. However, in this task, only the MEMC probe clicks will be presented. The onset of the conditioned stimulus is the onset of triggering, which is determined by force applied to the trigger on the toy gun (and measured using a force-sensing resistor), EMG activity on the FDS muscle, and the output of a microphone in the test area that can record the impact of the trigger mechanism upon completion of the trigger action. The trigger action is easily identified from the output of the force-sensing resistor (Figure 18). The presumed conditioning in this task is associated with the participant's prior experience as a shooter.

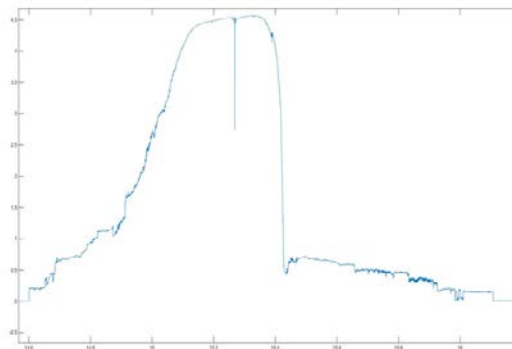


Figure 18. Force-sensing resistor output associated with a trigger pull.

The fifth conditioned task (Dry Fire, DF) is identical to the ST task, with the exception that a disabled gun is used instead of a toy gun. The disabled gun is permanently mounted on a rail and movement centers on rotation around a fulcrum defined by a yoke system (see Figure 19).

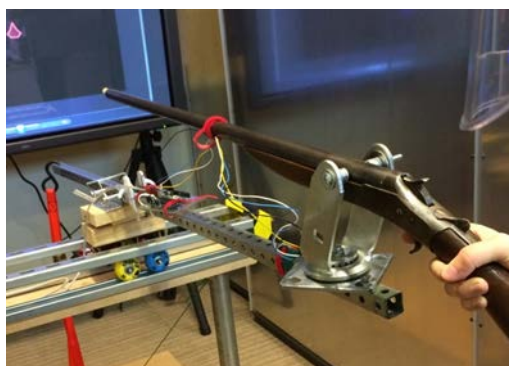


Figure 19. Photograph of the disabled gun used in the DF condition.

The second and third objectives were to apply the protocol in laboratory and field settings. Pilot testing of the reflexive protocol in lab settings was initiated near the end of this study period and will be followed by the collection of study data. Application of the protocol in field settings is not scheduled until 2016.

The final objective was the analysis and dissemination of reflexive findings. Preliminary analysis routines have been developed and will be applied once sufficient study data are obtained.

Significant results

We have no significant results to report because we are in an early stage of data collection.

Other achievements

The principal achievements associated with this objective relate to the development required for all tasks. With the exception of the cursor-target game component – which was mouse-driven MATLAB game modified to accept IMU input instead of mouse input, all aspects of this objective were constructed from scratch for this project.

What opportunities for training and professional development has the project provided?

Nothing to report.

How were the results disseminated to communities of interest?

A presentation on the study was made at the 2015 In-Progress Review meeting (Ft. Detrick, June 2015). No other presentations were made.

What do you plan to do during the next reporting period to accomplish the goals?

During the next reporting period, our efforts will focus on executing the laboratory data collection protocol with human subjects, modifying the protocol for use in field studies, and publishing a manuscript summarizing our results on the prevalence of reflexive MEMC in the general US population.

Impact

What was the impact on the development of the principal discipline(s) of the project?

In the field of hearing science, the methods developed for this study enable the assessment of MEMC for a wide range of stimuli, and ultimately this project can provide information about the best way to account for MEMC in damage-risk criteria for impulsive noises.

What was the impact on other disciplines?

Nothing to report.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

The MEMC has been assumed to have a protective role in many damage-risk criteria for impulsive sounds. Some damage-risk criteria have presumed that a listener who knows of an imminent impulse will produce anticipatory protective MEMC via classical conditioning. There is a weak evidentiary basis for a protective role of MEMC for such brief sounds, and the evidentiary basis for an anticipatory MEMC is nearly non-existent. The current project is likely to inform the development and application of damage-risk criteria and health hazard evaluations by policymakers. The consequent improvements in the accuracy of damage risk criteria will benefit warfighters and other personnel exposed to impulsive sounds in the line of their duty and occupation.

Changes/Problems

Changes in approach and reasons for change

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them

There was a delay in the manufacture of some key hardware (i.e., the ER-10x system) because it is a new system. However, this system has been delivered and is operating well in pilot testing.

Changes that had a significant impact on expenditures

There have been delays in hiring staff. At the Western Michigan University site, the delays were tied to the delay in the manufacture of the ER-10x system. The additional personnel were not needed until all hardware and software were in place. At the USAARL site, the delays with hiring staff have been related to the specialized skills required in that position and the reluctance of applications to move to Alabama.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

There have been no significant deviations, unexpected outcomes, or changes in approved protocols. Our efforts were approved by the Western Michigan University Institutional Review Board on 11 November 2014 for the reflexive MEMC prevalence study and designated as research *not involving human subjects* by the MRMC HRPO on 15 February 2015. The laboratory study was approved by the Western Michigan University Institutional Review Board on 14 April 2015 and approved by the MRMC HRPO on 8 May 2015.

PRODUCTS:

Publications, conference papers, and presentations

Journal publications.

Nothing to report.

Books or other non-periodical, one-time publications.

Nothing to report.

Other publications, conference papers, and presentations.

Nothing to report.

Website(s) or other Internet site(s)

Nothing to report.

Technologies or techniques

Nothing to report.

Inventions, patent applications, and/or licenses

Nothing to report.

Other Products

Nothing to report.

Participants & Other Collaborating Organizations

What individuals have worked on the project?

Name:	William A. Ahroon, Ph.D.
Project Role:	Principal Investigator (USAARL)
Nearest person month worked:	3 (Calendar)
Contribution to Project:	Dr. Ahroon is a Research Psychologist in the Acoustics Branch of the U.S. Army Aeromedical Research Laboratory (USAARL). As the PI for this project, he will be responsible for scientific and programmatic oversight of the project. Specifically, he will guide the protocol through the IRB and other regulatory reviews in implementing the protocol at USAARL, train and supervise research personnel, and facilitate team meetings.

Name:	Gregory A. Flamme, Ph.D.
Project Role:	Principal Investigator (Western Michigan University)
Nearest person month worked:	0.125 (Academic) 0.67 (Summer)
Contribution to Project:	During year 1, Dr. Flamme's duties are to direct the analyses for the reflexive MEMC study, develop, test, and obtain pilot data for the reflexive and lab-based studies of reflexive and conditioned MEMC. During years 2 through 4, he will work on dissemination of prior results, direct the conduct of the lab-based MEMC studies, and coordinate with USAARL to obtain field study data that are maximally comparable across sites.

Name:	Stephen M. Tasko, Ph.D.
Project Role:	Co-Investigator (Western Michigan University)
Nearest person month worked:	0.125 (Academic) 0.67 (Summer)
Contribution to Project:	During year 1, Dr. Tasko's duties are to develop, test, obtain pilot data, and prepare analytic routines for the EMG-based measurements obtained in this study. During years 2 and 3, he will manage the

EMG-based measurements, perform ongoing quality assurance tasks, and conduct analyses on these data. During year 4, he will conduct analyses on the WMU EMG measures and work on dissemination of study data.

Name:
Project Role:
Nearest person month worked:
Contribution to Project:

Kristy K. Deiters, Au.D.
Co-Investigator (Western Michigan University)
2.4 (Calendar)
Dr. Deiters will be the project coordinator during all years of the project, focusing on participant recruitment, day-to-day operations, and coordinating efforts between WMU and USAARL. During years 2 through 4, she will also be responsible for data management, quality assurance, descriptive analyses, preparing data sets for inferential analyses, and dissemination.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report.

What other organizations were involved as partners?

Nothing to report.

Special Reporting Requirements

Quad Chart:

Appendices

None.

"Effects of Acoustic Impulses on the Middle Ear"

Log Number: 13063028

Award Number: W81XWH-14-2-0140



PI: William A. Ahroon, Ph.D.

Org: The Geneva Foundation/U.S. Army Aeromedical Research Laboratory

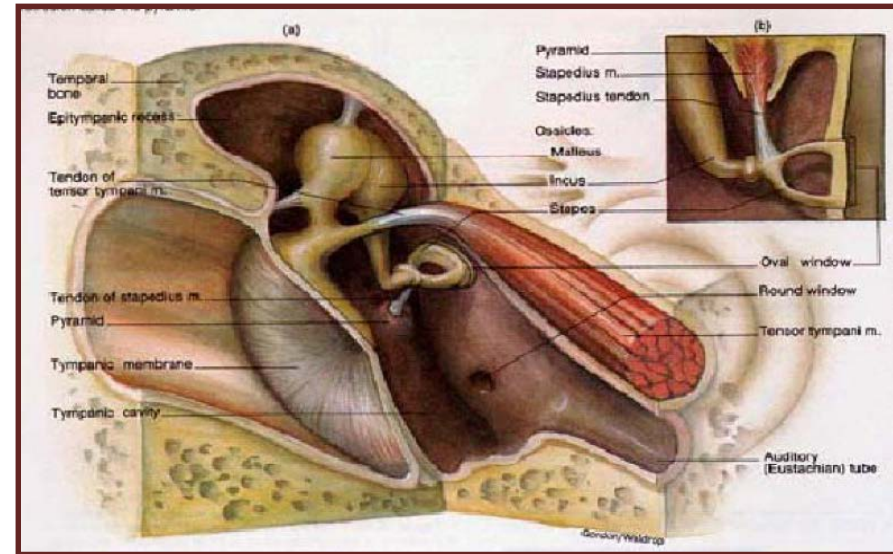
Award Amount: \$3,081,623

Study/Product Aim(s)

- Fully document the effects of acoustic impulses on the middle ear and on middle-ear muscle contractions (MEMC)
- Determine the prevalence of the MEMC as a function of hearing sensitivity and demographic factors.
- Determine whether reflexive MEMC are pervasive among normal-hearing listeners.
- Determine whether classically-conditioned MEMC are pervasive among normal-hearing listeners.
- Determine the validity of the middle-ear assumptions of the Auditory Hazard Assessment Algorithm for the Human Ear (AHAH)

Approach

The response of the middle ear to acoustic impulses will be measured using Wide Band Absorbance (WBA) alone and in classical conditioning paradigms.



Timeline and Cost

Activities	CY	14	15	16	17	18
NHANES prevalence study						
Characterize MEMC using WBA						
MEMC classical conditioning test						
Operational evaluation of MEMC						
Estimated Budget (\$3,081,623)		275.4K	804.6K	776.8K	767.3K	457.5K

Goals/Milestones

CY15 Goal – MEMC Prevalence

- ✓ Develop MEMC detection algorithm on NHNES impedance traces
- ✓ Determine the prevalence of the acoustic reflex from the NHANES data base

CY16 Goals – Wide-band Absorbance Methods

- Validate MEMCs using Wide-Band Absorbance

CY17 Goal – MEMC Classical Conditioning

- Determine form and prevalence of MEMC conditioned response

CY18 Goal – Operational Demonstration

- Sniper-spotter lab & field test of AHAH middle-ear assumptions

Comments/Challenges/Issues/Concerns

- None

Budget Expenditure as of 9/30/2015

Projected Expenditure: \$826,236

Actual Expenditure: \$432,713

Updated: 29 OCT 2015