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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).

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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 to inform 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 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?

Task 1: Determine the prevalence of acoustic reflexes 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 this task was completed during a previous project period, and dissemination is underway.

Significant results

Additional work was completed under this objective, assessing the proportion of clinical acoustic reflexes observed among participants tested at Western Michigan University as part of aims two and three of this project. Analysis were conducted and disseminated as a podium presentation and an invited manuscript in the *International Journal of Audiology* (published in December 2017). Results of this study, which used a diagnostic middle ear analyzer, were consistent with the previously reported results, i.e., that clinical acoustic reflexes are not pervasive.

Other achievements:

Nothing to report.

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

AND

Task 3: Determine whether MEMC can be classically conditioned with 95 % certainty in 95 % of people, either in laboratory or field settings, and if so, identify any differences between reflexive and conditioned MEMC.

Major activities

The major activities during this period included the completion of minimum-risk data collection from the shooter-spotter (SHSP) simulation study, quality review and initial analyses of data from the shooter-spotter simulation study, analysis and dissemination of lab-based data, and preparation for the greater than minimum-risk live fire study.

As noted in prior reports, the overall study design included the detection of reflexive MEMC to brief tones, recorded gunshots, and two non-acoustic elicitor tasks (voluntary eye closure and a puff to various locations on the face). These tasks were collectively grouped as reflexive tasks (RT). A total of 9 conditioned tasks (CT) were also included. Attended Light (AL), Attended Auditory (AA), Unattended Auditory (UA), Simulated Trigger (ST), and Dry Fire (DF) tasks were completed by civilian participants at the Western Michigan University (WMU) data collection site. The remaining four conditioned tasks were intended to be conducted primarily with a military population, and involved the detection of MEMC during simulated shooting (SH) and simulated spotting (SP) of targets, and while the participant holds rifle with live ammunition and actively fires on a target (LA), and is exposed to the gunshot noise from another member of the fire team while waiting for the instruction to fire (LW). The SH and SP tasks were grouped together into one data collection series, as were the LA and LW tasks grouped into a separate data collection series. Each of these task groupings (AL, AA, UA, ST, DF, SHSP, LALW) represent mutually-exclusive participant groups.

Prevalence of reflexive MEMC (RT)

The preceding annual report described the proportions of reflexive MEMC detected visually by three raters on a subset of 120 participants. The final results for all participants in the laboratory study (N > 190 for all stimuli) have been completed (Figure 1). The final results lead to the same conclusions regarding reflexive MEMC prevalence as presented in the prior annual report, which are that:

- only the task involving maximal effort eye closure was observed to elicit MEMC that approached frequency levels consistent with a pervasive response;
- the non-acoustic tasks tended to be more likely to elicit a reflexive MEMC than the acoustic tasks;
- the white noise and 1 kHz elicitor were the most likely acoustic elicitors of a reflexive MEMC; and
- a reflexive MEMC to one acoustic signal did not provide a meaningful indication of whether a reflexive MEMC would be observed for another acoustic signal.

Binary logistic regression models were used to determine whether a predictive model could be used to identify participants most likely to exhibit a reflexive MEMC based on clinical examination variables, demographic characteristics, and procedural factors, controlling for the acoustic elicitor type. A few significant predictors emerged in the final multivariable model (Figure 2).

Equivalent ear canal volume in the probe ear, as measured during clinical tympanometry, was inversely related to the odds of observing a reflexive MEMC. Reflexive MEMC were less likely to be observed among participants in the greatest three quintiles of ear canal volume.

Two descriptors of clinically-measured acoustic reflexes were predictive of a reflexive MEMC to brief stimuli. Participants in the upper two quintiles of contralateral reflex magnitude for a 2 kHz tonal stimulus were more likely to exhibit a reflexive MEMC. Additionally, participants with the longest latency (i.e., quintile 5) for a contralateral reflex to a 1 kHz tonal stimulus were less likely to exhibit a reflexive MEMC.

One procedural variable, stimulus presentation order, was significantly related to the odds of exhibiting an MEMC. Nine acoustic elicitors were presented in these data, and the presentation order was permuted randomly across participants. Twelve trials of each acoustic elicitor were presented with a fixed 5-second interstimulus interval, producing a 60-second recording duration for each elicitor. After including quality checks and computer/disk access time, responses to the entire set of acoustic elicitors were collected over an approximate 12-minute period. To assess the possibility of changes in the MEMC response within that period, we divided the nine elicitors into three groups (i.e., first three, middle three, and last three) based on the timestamps contained within the raw data files. The presentation order variable was significant in the final multivariable logistic regression model. The odds of exhibiting a reflexive MEMC were unaffected through the first six elicitors presented, which corresponded to approximately the first 8 minutes of the acoustic reflex series. However, these odds declined significantly for the last group of three elicitors. It is not clear whether the decline in the likelihood of exhibiting an MEMC is a function of the number of elicitors or the amount of time, but the practical implications of a time-varying probability of an MEMC are that a damage-risk criterion including MEMC as a protective factor for people known to have reflexive MEMC could have declining validity over increasing numbers or durations of exposure.

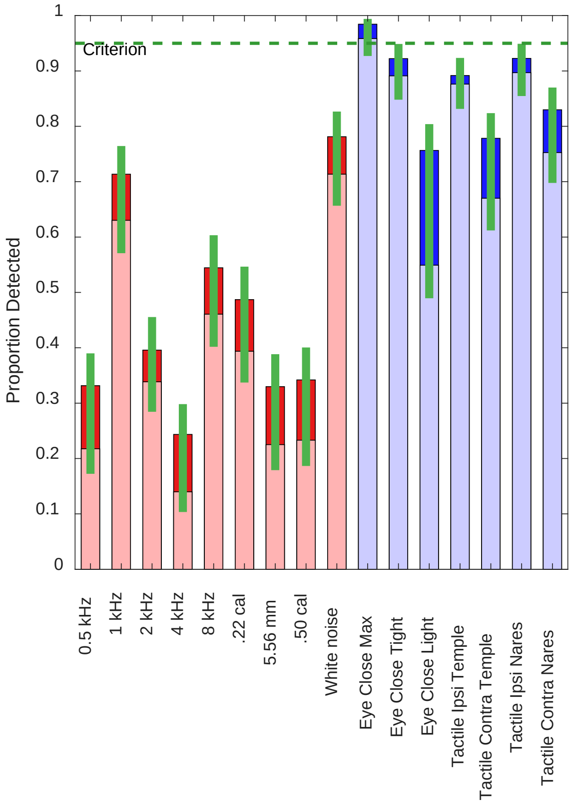


Figure 1. Final observed proportions of a stimulus linked change in impedance for brief acoustic (pink= 3/3 rater agreement, red=2/3 rater agreement) and non-acoustic (light blue= 3/3 rater agreement, dark blue=2/3 rater agreement) reflexive stimulus, including 90% confidence intervals (green). The lower end of the error bar must be above the red horizontal line to declare pervasiveness, and only the non-acoustic maximum eye close task approaches this criterion.

In summary, the analyses of the acoustic RT tasks provide no support for the widespread application of damage-risk criteria including reflexive MEMC as a protective phenomenon. A manuscript describing the RT results for brief acoustic elicitors has been drafted and is currently in circulation among the investigators for final comments prior to submission.

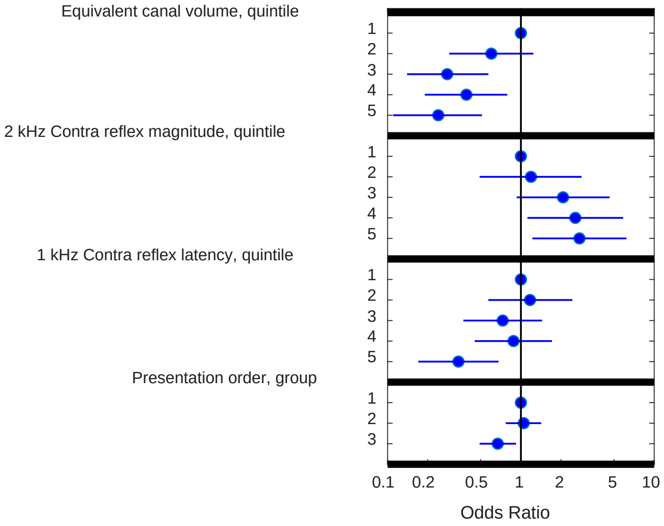


Figure 2. Significant predictors of brief reflexive MEMC and odds ratios associated with each quintile or group. Briefly, higher equivalent canal volume, longer clinically elicited 1 kHz contralateral reflex latencies, and the last group of three reflexive stimulus presented were associated with decreased odds ratios, whereas increased clinically elicited 2 kHz contralateral reflex magnitude was associated with a higher likelihood of exhibiting a response to reflexive MEMC.

Prevalence of conditioned MEMC (CT: AL, AA, UA, ST, DF)

Analyses of the CT from the laboratory environment indicated that the probability of observing an early MEMC (i.e., evidence of a change in the impedance of the ear after the conditioned stimulus and prior to the arrival of the unconditioned stimulus) depended heavily on the sensory modality of the conditioning stimulus and the participant’s attention to or distraction from the conditioning stimulus (Figure 3). In addition, the likelihood of an early response appears to vary with hearing sensitivity and/or sequential exposures to multiple conditioning stimuli (based on the results of the present study combined with the results of a similar study including people who had been exposed to all conditioned tasks and also had slight hearing impairment at one or more stimulus frequency, but still met the hearing criteria suitable for unrestricted duty (H-I profile)).

Early MEMC were observed most frequently for the AA task. The rates of early MEMC were approximately 60 % (consensus judgments) to almost 80 % (majority judgments) in this condition, and the upper limit of the 90 % confidence interval for the majority judgement was about 85 %. Together, these results indicate a pervasive early MEMC was not observed in this study, nor is it likely to approach the pervasiveness criterion in follow-up studies. Note also that the rates of early MEMC for the AA conditioning stimulus were considerably lower in the companion study (between 10 and 40 %), suggesting that exposure to multiple conditioning stimuli, as might happen during military operations involving teams, might compromise the salience of any one conditioning stimulus. This finding could also suggest that slightly reduced hearing sensitivity that does not disqualify a soldier from unrestricted duty may also decrease the rates of early MEMC.

The AL task produced much lower rates of early MEMC, suggesting that conditioned responses are less likely when the conditioning and unconditioned stimuli do not share a sensory modality. Relatively few regular shooters were identified in the laboratory study (hence the large confidence interval range), but the proportions of early MEMC for the ST and DF tasks (consensus judgments on the order of 40% and majority judgements below 70%) indicate that early MEMC are not pervasive in this group and are unlikely to approach the criterion level in another sampling of the same population.

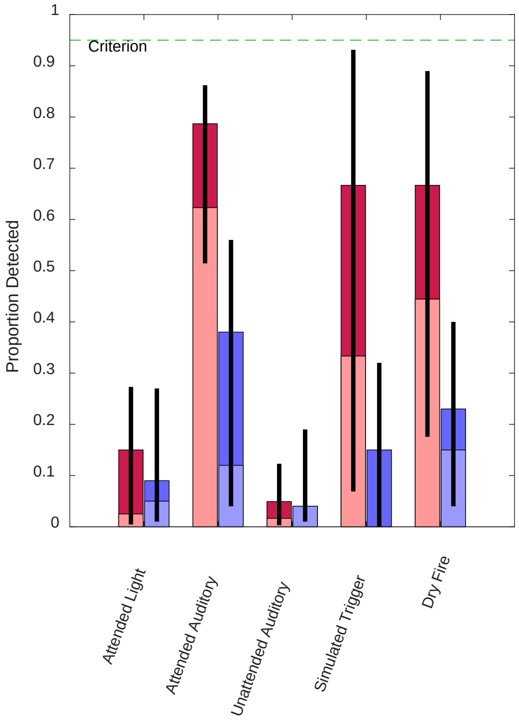


Figure 3. Conditioned task results from the laboratory setting. Light colored bars represent the proportions of early MEMC detected by consensus across three raters. Dark colored bars represent the proportions of early MEMC detected by a majority of three raters. Black bars represent the range from the low bound of the 90 % confidence interval for consensus ratings to the upper bound of the 90 % confidence interval for majority ratings. Red bars are used to illustrate data from the current study. Blue bars represent results from a companion study in which participants were exposed to all conditioned tasks and also had poorer hearing sensitivity than required in the current study.

Perhaps the most surprising aspect of the lab-based CT results comes in the contrast between the AA and UA tasks. The proportions of early MEMC for the UA task were 5% or less, regardless of consensus or majority rater judgments, while early MEMC were observed in 60 to 80% of participants in the AA task as administered in the current study. These tasks had the same conditioning and unconditioned stimuli and differed only in the degree of attention available. In the AA task, participants were instructed to press a response button as soon as they heard the conditioning stimulus. In the UA task, participants were distracted by using a toy gun with an inertial measurement unit to follow the random movements of a target across a display screen. The vast difference in rates in early MEMC across these tasks suggests that the early MEMC depends heavily on attention for encoding the association between the conditioning stimulus and unconditioned stimulus, recognition of the conditioning stimulus and producing a conditioned response, or both. The reduced rates between the AA and UA conditions observed in the companion study suggests that attention is involved in producing the conditioned response because the companion study involved a within-subjects design wherein the conditioned task order was randomized. Therefore, the UA task followed the AA task in many cases. Less of a decline would have been observed in the companion study if the degradation in the proportion of early MEMC was solely associated with encoding the association between the conditioning and unconditioned stimuli.

Taken together, the analyses of the laboratory CT tasks provide no support for an assumption of conditioned MEMC as a protective phenomenon.

Role of concomitant motor activity and activity during baseline intervals on MEMC

In the real-world environment of the warfighter, impulsive noise exposure is part of a rich, sensory motor experience. For example, voluntary eye closure is a strong MEMC elicitor, suggesting that concomitant motor activity during impulsive noise exposure could have a modulating influence on MEMC. As a result, efforts are underway to assess and, if necessary, control for the effects of concomitant motor activity on MEMC. Based on judgments made by the investigative team during data review, over 40 % of 15,384 elicitor periods were judged to contain concomitant motor activity during the elicitor window (i.e., between -0.5 and 2.5 seconds relative to onset of the MEMC elicitor stimulus). Motor activity was assessed via examination of electromyographic (EMG) recordings of selected muscles of the head, neck and upper extremities. Most activity was limited to the EMG electrodes on the head, and over 25 % of the elicitor windows were judged to contain activity in the electrode monitoring the orbicularis oculi (OO) muscle (Figure 4). These results indicate that, even during a highly controlled laboratory environment, concomitant motor activity is common and should be controlled.

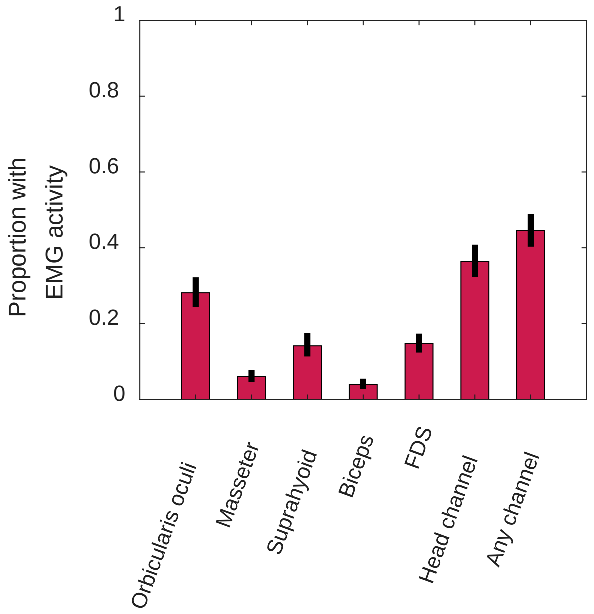


Figure 4. Proportions of MEMC elicitor windows containing EMG activity. FDS: flexor digitorum superficialis.

Careful examination of the role of masseter muscle activity as a potential elicitor of MEMC also was conducted during this reporting period. Masseter muscle activity and changes in acoustic reflectance were observed as participants chewed and swallowed small candies. Figure 5 represents the change in middle ear impedance during masseter muscle activity. Prior to the acoustic interference imposed by bone-conducted sound from the oral cavity, it is reasonable to suspect that changes in impedance during masseter muscle activity are associated with MEMC. Some individuals might contract the masseter muscle to stabilize the jaw prior to an expected physical impact (e.g., recoil or high-level blast wave), and this might be accompanied by an MEMC. However, it is not clear that this behavior would be sufficiently consistent for inclusion in damage-risk criteria.

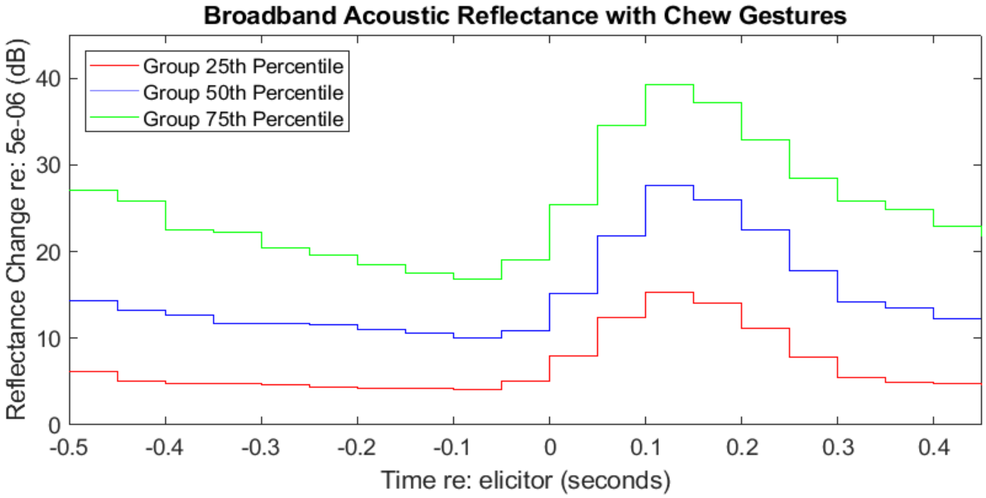


Figure 5. Observed change in broadband acoustic reflectance during masseter EMG control task. Group data is derived from within-subject impedance values calculated at the 25th percentile across elicitor windows. The red line represents the 25th percentile of group change in acoustic reflectance. The blue line represents the group median change in acoustic reflectance. The green line represents the 75th percentile of group change.

The difference in RMS deviation of ear canal recordings for elicitor periods with and without concomitant EMG was determined (Figure 6). Interquartile ranges of concomitant EMG effects were generally equal across the elicitor window and had differing effects on the location of the distribution. For example, the effect of concomitant OO muscle activity was symmetric and centered on a value of zero (upper left panel), while the effect of concomitant masseter muscle activity was skewed in the direction of an apparent MEMC (upper right panel) and did not converge on a mean of zero. The interquartile range of concomitant EMG effects had a similar magnitude to MEMC to intended elicitors. These results suggest that incidental EMG activity occurring in the temporal vicinity of the conditioned or reflexive MEMC elicitor could contribute to an erroneous impression that an MEMC was elicited.

Work is currently underway to develop quantitative procedures for assessing the role of concomitant EMG in both elicitor and baseline periods. Two approaches are under investigation. The first method employs correlation methods to assess for associations between ongoing EMG activity and probe click reflectance during baseline and elicitor periods. The second method quantifies EMG activity within elicitor and baseline periods to assess if EMG activity influences the likelihood of observing MEMC under different conditions. This analysis approach requires a multi-step process. Absolute EMG levels are known to vary across individuals and recording site due to anatomical variation and technical issues related to electrode placement. This necessitates quantification of EMG activity relative to motor activities known to elicit maximal or a consistent submaximal level of contraction. EMG “control” tasks were collected across all five EMG recording channels for all participants. Analysis techniques were developed and successful control trials were collected for 94 percent of all EMG control tasks. Rates were as high as 98 percent for some electrode sites (orbicularis oculi, flexor digitorum superficialis). The lowest rate was for the suprahyoid recording site (86 percent). These lower rates for this site were attributed to the presence of facial hair (men with beards) and/or the effects of subcutaneous fat. This analysis is nearing completion and results will help with interpretation of MEMC in both the laboratory and live fire environments.

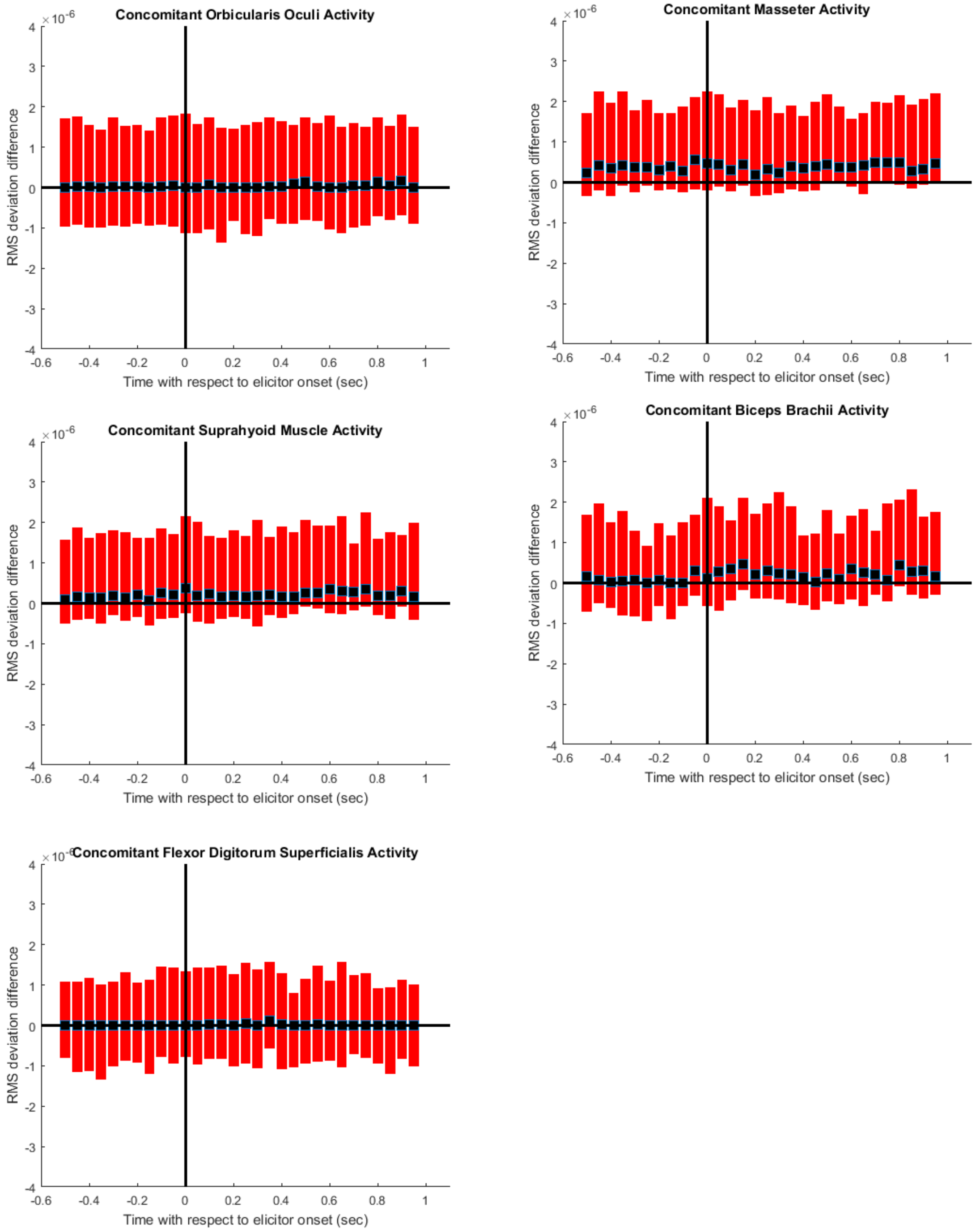


Figure 6. Concomitant EMG effect size by muscle. Each plot represents a muscle monitored using EMG. The horizontal axis represents time relative to elicitor onset. The vertical axis represents the change in RMS deviations from ear canal baseline recordings associated with concomitant EMG. Red bars represent the interquartile range of responses across elicitor periods and blue squares represent median differences. Median differences tend toward a value of zero and do not appear strongly related to the time course of the elicitor. However, the interquartile range suggests that concomitant muscle activity occurring during the elicitor time course could be mistaken for an MEMC.

Baseline periods referenced during routine MEMC analysis immediately precede the elicitor interval under analysis. However, a baseline's temporal proximity to the elicitor window is not necessarily important. The load impedance seen by the probe should be constant unless the probe location is disturbed significantly. It is therefore plausible that the same MEMC would be observed whether using the baseline interval immediately preceding the elicitor periods or if using intervals more remote in time. To test this assertion, we referenced a single elicitor window to multiple baseline periods. The selected baseline periods occurred immediately before, immediately after, and remotely from (i.e. separated by one or more elicitor windows) the elicitor window of interest. The impact of different baseline intervals on the difference waveform (i.e., the underlying basis of MEMC detection) was many orders of magnitude smaller than the MEMC. Therefore, baseline intervals contaminated by nuisance noise sources or that follow prior stimuli too closely can be replaced by other baseline intervals. This strategy can be employed for controlling concomitant muscle activity during baseline intervals and with other tasks having short (e.g., ST) or coordinated muscle activity (e.g., SHSP and LALW).

Simulated Shooter-Spotter (SHSP)

Data collection for the SHSP tasks was completed on November 28, 2017 (see Figure 7 for cumulative enrollment), when the number of participants completing the visit 2 (V2) of the protocol reached 59.

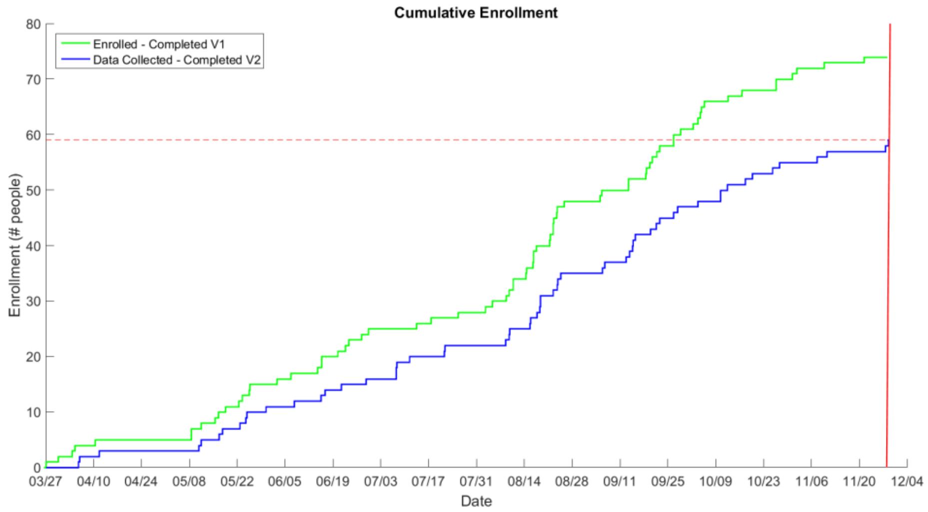


Figure 7. SHSP cumulative enrollment function. All data collection was completed in calendar year2017.

The review and analysis of the SHSP data has taken a lower priority than the completion of the live fire (LALW) data collection and dissemination of lab-based results. Multiple levels of SHSP data review and analysis were completed using custom MATLAB functions and Stata v.15.

Video otoscopy

Otoscopic video recordings were reviewed in .avi format. Each video was examined for a variety of possible conditions including occlusive cerumen, exostoses, abnormal landmarks (scarring, irritation, opaque or perforated tympanic membrane) and the ability to visualize the tympanic membrane and manubrium. Otoscopic results were unremarkable with the exception of four participants exhibiting cerumen allowing only a partial view of the tympanic membrane. All of these participants exhibited immittance values (described in greater detail below) within the normative range for both ears, indicating that the cerumen was non-occlusive.

Pure tone thresholds

Pure tone threshold results, obtained during the enrollment visit (V1), were analyzed for participants who completed the study (Table 1) and for participants who did not take part in the study (Table 2).

In general, participants who completed the study exhibited excellent hearing sensitivity, with the 50th percentile thresholds at or better than 10 dB HL in both ears and at all frequencies. Physiologically unrealistic thresholds were obtained from two participants (right ear, 1000 Hz and 4000 Hz). A review of the time histories leading to these thresholds were suggestive of participant response habituation and a failure on the part of the tester to detect and resolve the error. Pure tone thresholds for participants who did not take part in the study (N=15) were also very good (Table 2).

The upper tail of the distribution of thresholds for participants completing the SHSP study suggested poorer hearing sensitivity than was observed in the lab-based data collection. This difference may need to be considered when comparing results across study groups.

Table 1.Pure tone thresholds in dB HL, obtained at the initial visit, for participants who completed the study.

Hz	125	250	500	1k	2k	4k	8k
Left ear							
min	-5	-10	-10	-10	-5	-10	-10
p10	-5	-10	0	-5	0	0	0
p25	0	-5	0	0	0	0	0
p50	0	-5	5	0	5	5	5
p75	5	0	5	5	10	10	10
p90	5	5	10	10	15	15	15
max	10	5	15	15	25	25	30
mean	2	-3	3	1	6	7	5
sd	4	5	5	5	6	7	7
Right ear							
min	-15	0	0	-20	-10	-45	-10
p10	-5	5	5	-5	-5	0	-5
p25	0	5	5	0	0	0	0
p50	0	5	10	0	0	5	5
p75	5	10	10	5	5	10	10
p90	10	15	20	10	10	10	15
max	15	15	30	10	20	20	20
mean	2	7	10	1	1	4	4
sd	5	4	6	5	6	10	7

For the purpose of detecting protocol-associated changes in hearing sensitivity such as temporary threshold shift (TTS), pure tone threshold measurements at the end of the second data collection visit (V2) were compared with those at the beginning of the visit and the thresholds obtained at the enrollment visit. No evidence of TTS was observed.

Tympanometric results

Results of conventional middle ear assessments (226 Hz tonal probe) indicated normal effective volume, static admittance, peak pressures, and tympanometric widths for the participants completing the study (Table 3) with the exception of nine participants, whose results were slightly above the normative values for one measure, and within normative values for the remaining measures. Mean results among those not completing the study were also consistent with normal middle ear function, although outlier results showed considerable variability.

Table 2. Pure tone thresholds in dB HL, obtained at the initial visit, for participants who did not complete the study.

Hz	125	250	500	1k	2k	4k	8k
Left ear							
min	-5	-10	0	-5	0	-5	-5
p10	-5	-5	0	-5	0	0	-5
p25	0	-5	0	0	5	0	0
p50	5	-5	5	5	5	10	5
p75	5	0	5	5	10	15	20
p90	10	5	10	10	15	25	25
max	10	5	15	15	30	30	60
mean	4	-2	5	3	8	11	11
sd	5	4	4	6	7	10	16
Right ear							
min	0	5	0	0	0	-10	-5
p10	0	5	10	0	0	0	-5
p25	0	5	10	0	0	0	0
p50	5	10	10	0	0	5	5
p75	10	10	15	5	10	15	15
p90	10	15	20	5	15	20	25
max	15	20	20	10	15	20	45
mean	5	9	11	3	4	8	9
sd	5	4	5	3	6	8	13

Table 3. Tympanometric results, including ear canal volume, compliance, peak pressure, and tympanometric width, at the enrollment visit (V1) for participants who completed the study, and for those who did not complete the study. Electronic data were not available for one participant completing the study at the time of these analyses.

		Mean	**SD**	**p5**	**P95**	**n**
Participants completing the study, Left ear						
	Volume (cm^3)	1.30	0.36	0.71	1.86	58
	Admittance (mmho)	0.79	0.33	0.40	1.46	58
	Peak Pressure (daPa)	-10	23	-55	12	58
	Tympanic Width (daPa)	88	37	45	152	58
Participants completing the study, Right ear						
	Volume (cm^3)	1.27	0.37	0.73	2.00	58
	Admittance (mmho)	0.76	0.29	0.40	1.52	58
	Peak Pressure (daPa)	-10	27	-41	6	58
	Tympanic Width (daPa)	85	26	46	128	58
Participants not completing the study, Left ear						
	Volume (cm^3)	1.22	0.29	0.80	1.93	14
	Admittance (mmho)	1.35	1.39	0.46	4.99	14
	Peak Pressure (daPa)	-5	56	-145	128	14
	Tympanic Width (daPa)	70	25	19	109	14
Participants not completing the study, Right ear						
	Volume (cm^3)	1.16	0.26	0.73	1.48	14
	Admittance (mmho)	0.83	0.37	0.44	1.64	14
	Peak Pressure (daPa)	-2	44	-103	117	14
	Tympanic Width (daPa)	81	25	41	114	14

Live Fire (LALW)

The final two tasks for assessing the presence of early MEMC involves simultaneous data collection from two volunteer soldiers. Soldiers attend to standard 25-meter targets down range while awaiting simulated tower instructions played into an earphone in their non-test ear. The acoustic probe is placed in the test ear, which is contralateral to the side where the soldier holds the gun. In order to stagger the order of fire, each participant receives firing instructions separately, which permits the assessment of early MEMC for the soldier actively firing their weapon (LA) and the soldier waiting to be instructed to fire their weapon (LW). The LA and LW conditions are roughly parallel to the Warned and Unwarned conditions implemented in the AHAAH damage-risk criterion.

During this project period, we have developed the procedures for obtaining access to the Fort Rucker North Range through USAARL command and Ft. Rucker Range Operations, secured periodic access to weapons (M4 rifles) and ammunition, identified military support personnel on site during data collection (e.g., Officer in Charge, Range Safety Officer, ammunition and weapons handlers, combat life savers), prepared the USAARL audiometric trailer, including both maintenance and study-related modifications, transported the audiometric trailer to the range, developed the procedure for LALW data collection, re-organized the study hardware for simultaneous playback of instructions to participants and 34-channel data acquisition in the field, developed procedures and acquired necessary hardware for simultaneous pre- and post-firing audiometry, developed procedures for rapid stand-up and storage of instrumentation in the event of inclement weather, conducted pilot live fire exercises, and initiated data collection.

At the time of writing, six participants have provided informed consent to participate (none have declined to participate during or after an explanation of the study), four participants (out of the six enrollments) were dismissed due to failure to meet study criteria, and LALW data have been collected from two participants. Data collection periods have been scheduled with Ft. Rucker Range Operations, military support personnel, and investigators every month through the end of calendar year 2018.

Data collection for the LALW tasks are conducted near firing lane 38 at the Ft. Rucker North Range (Figures 8 and 9). Ft. Rucker Range Operations have permitted the investigators to place the audiometric trailer on site for the duration of data collection. Most of the instrumentation required for data collection (e.g., computers, data acquisition chassis and modules) is secured within the audiometric trailer to minimize the probability of damage and shorten the time necessary for daily set up and take down. Some instrumentation (e.g., ER-10X otoacoustic emissions system, electromyography systems, field microphones, monitors and keyboards) are placed under canopies erected daily (Figure 9), and signals are then routed into the data acquisition system using cables routed from the front of the audiometric trailer to the firing stations daily.

Figure 8. The audiometric trailer, generator, and storage box at the unoccupied firing range.

Figure 9. Live fire staging area during trial equipment set up. (Canopies were lowered to increase shade in the work areas.)

Data collection for the LALW task is divided into four series with six shots each. The sensors are checked prior to the first series using an abbreviated administration of the EMG tasks described above (Figure 10) and through swept-sine measurements of the ER-10X transducers. Data are monitored during acquisition and swept-sine measurements of the ER-10X transducers are conducted before and after each shot series.

Figure 10. An investigator conducting the test of each microphone channel prior to ammunition distribution and the first shot series.

The Officer in Charge has range authority at all times when weapons and ammunition are present. The Range Safety Officer monitors the participants, simulated tower instructions to the participants, and responds according to standard procedures in the event of a jammed weapon or other malfunctions. Each shot series is initiated by command of the Range Safety Officer.

Figure 11. Soldiers in left and right shooter positions, supervised by the Range Safety Officer.

At the time of writing, we have begun data review with an initial scan of the recordings (Figures 12 through 14). These recordings indicate that:

- the ear canal signals obtained in the LALW task have similar morphology to those obtained in the laboratory tasks (Figures 12 and 13),
- the force-sensing resistors attached to the triggers of the M4 rifles used in the study provide a good indication of the increased trigger force prior to firing, as well as the trigger release during firing (Figure 14),
- activation of the orbicularis oculi muscle can accompany the firing gesture, and this activation can precede the onset of applying force to the trigger (Figure 14), and
- the EMG signals are sensitive to within- and between-subject differences in facial activity associated with weapon discharge events.

The LALW task poses greater than minimal risk to volunteer participants. These risks have been minimized by limiting the number of impulsive events, the use of double hearing protection (i.e., the earphone and probe provide attenuation and are covered by large-volume earmuffs), adherence to standard operating procedures for range and weapon safety, and monitoring for protocol-related temporary threshold shift and other adverse events. In addition, software for rapid analysis of observations is under development and will be used to periodically examine outcomes. In the event that there is less than a 5 % chance that 95 % of the population will exhibit early MEMC, data collection will be postponed until a determination is made regarding the potential futility of collecting additional data designed to inform a rejected hypothesis (re: pervasiveness of conditioned MEMC).

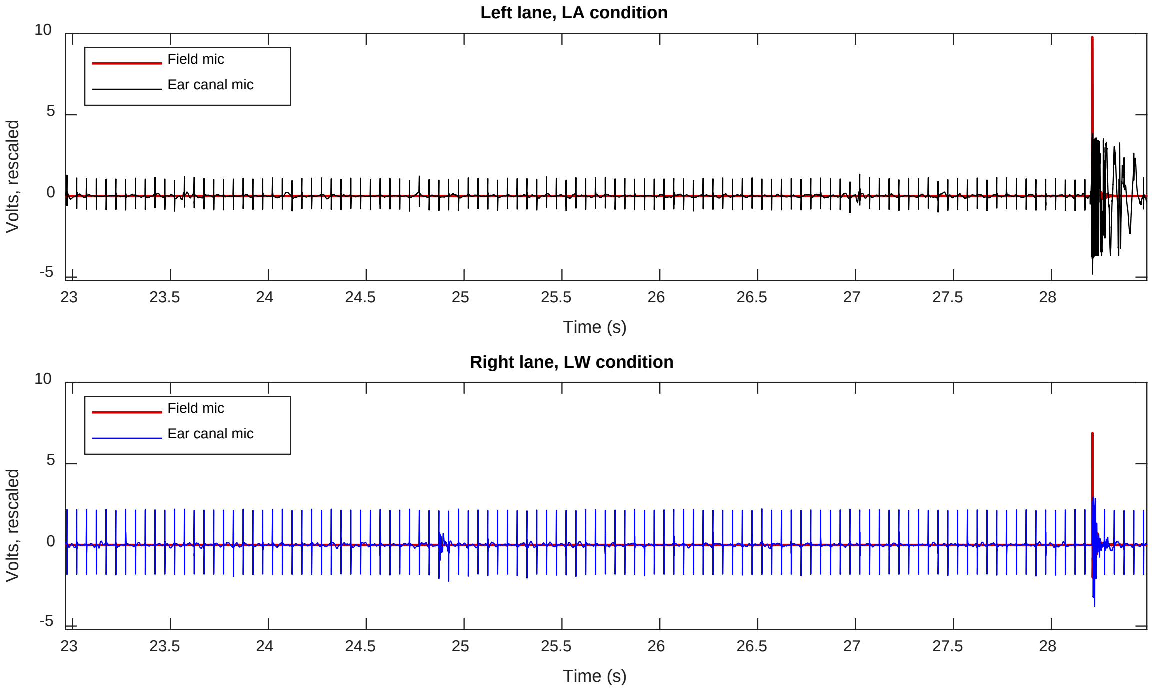


Figure 12. Example of field microphone and ear canal recordings. Participant in left lane active (LA); right lane waiting (LW). The red trace represents the field microphone signal nearest the selected firing lane. The black trace represents the recording taken from the participant in the left firing lane. The blue trace represents the recording taken from the participant in the right firing lane. Click signals (repeated every 50 ms) appear as vertical bars in the black and blue traces. The gunshot noise appears as the spike in the red traces (Time approximately 28.5 s). The disturbance in ear canal recordings following the arrival of the gunshot indicates overload of the ER-10X system and reflection of the gunshot in the ear canal.

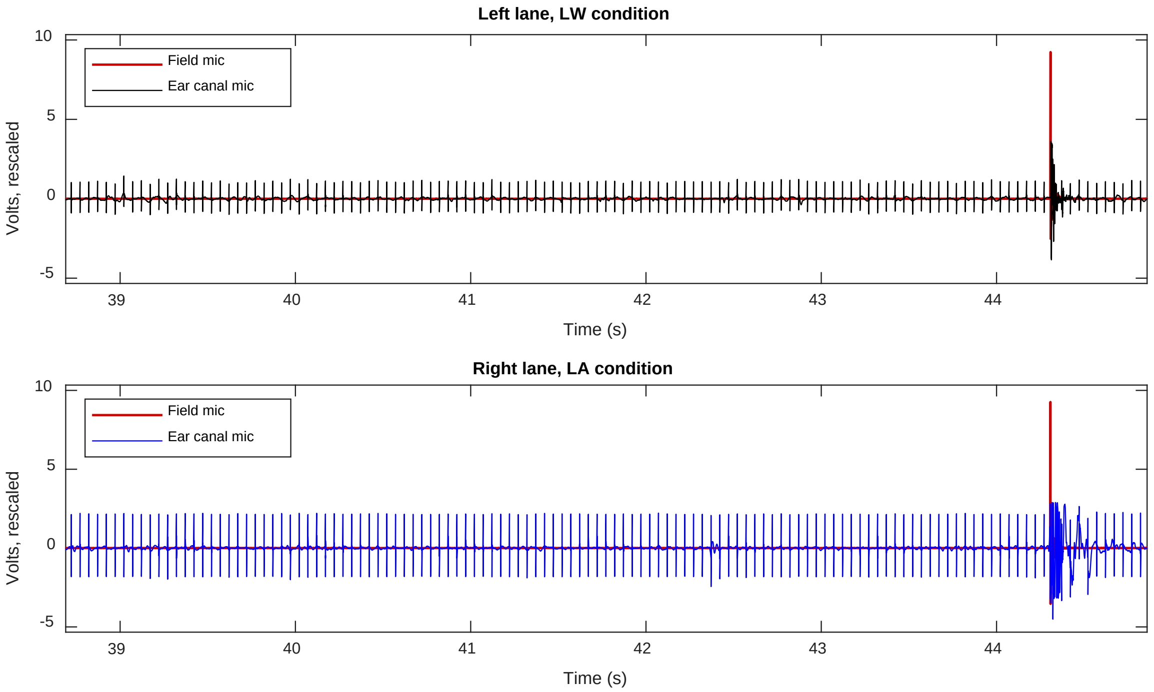


Figure 13. Example of field microphone and ear canal recordings. Participant in left lane waiting (LW); right lane active (LA). Details similar to preceding figure.

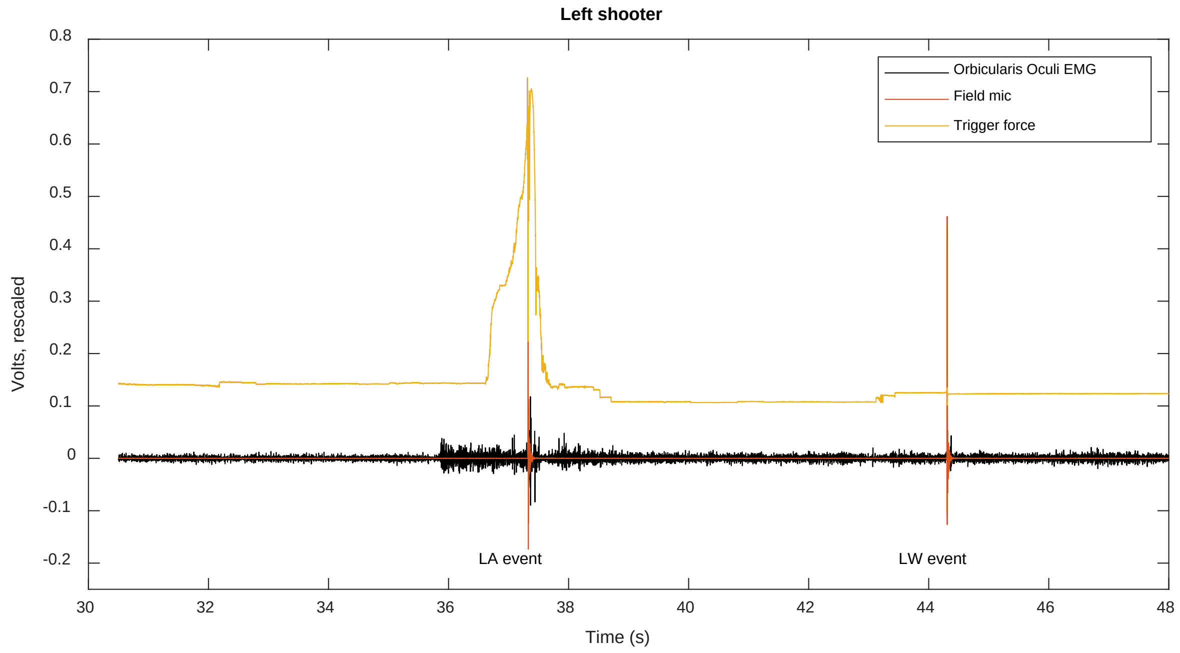


Figure 14. Example of consecutive LA and LW events from the same participant. The black trace represents the EMG signal from the orbicularis oculi (OO) muscle. The red trace represents the waveform recorded at the field microphone. The yellow trace represents the force applied to the gun trigger by the participant. The LA event region begins with activation of the OO muscle, followed by increasing trigger force leading to discharge, which is detected using the field microphone. The LW event region shows only the discharge of the weapon operated by the right shooter, with no significant change in OO EMG or trigger force during the event period, except a small startle response on the OO muscle immediately following blast arrival.

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

Nothing to report.

How were the results disseminated to communities of interest?

Presentations were made at the: 2018 National Hearing Conservation Association (NHCA) Annual Meeting; 2018 American Auditory Society (AAS) Annual Conference; Association for Research in Otolaryngology (ARO) 41st Annual Mid-Winter Meeting; 2018 Annual Collaborative Auditory/Vestibular Research Network (CAVRN); 2018 annual meeting of the Michigan Speech and Hearing Association; 3rd Japan-US Technical Information Exchange Forum on Blast Injury (JUFBI); 2018 Acoustical Society of America Spring Meeting; 2018 USAMRMC In-Progress Review meeting; and the 2018 U.S. Office of Naval Research Noise-Induced Hearing Loss Program Review.

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 completing the live fire data collection at USAARL, analyzing the SHSP data, and publishing study results.

Impact

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

The methods developed for this study enable the assessment of MEMC for a wide range of stimuli, and ultimately this project will inform the development of damage-risk criteria for impulsive noises.

To date, the results of this work suggest that clinical reflexive MEMC are not pervasive in the U.S. population and that people with clinical reflexive MEMC do not necessarily exhibit MEMC for brief tones, noises, or recorded gunshots.

Non-acoustic elicitors appear more likely to produce an MEMC than acoustic elicitors. In addition, the refined methods for detecting MEMC that were developed for this study provide a means for future studies of these phenomena.

What was the impact on other disciplines?

The results of the laboratory-based components of this study demonstrate that assessments of middle ear function could be compromised if concomitant muscle activity is not also monitored. This finding has implications for medical diagnostic evaluations and among investigators interested in motor control.

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 multiple 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. In addition, these criteria could inform the evaluation of the hazard of impulsive noise for firearm users.

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

The primary delays for the project (i.e., Dr. Greene’s departure) were anticipated and described in annual report for year 3 of the project. The actions designed to mitigate those delays (e.g., shifting duties to Dr. Jones and Ms. Milam at USAARL and the SASRAC team), along with the one-year no-cost extension have been implemented. Some unexpected delays with the maintenance and modification of the USAARL audiometric trailer were introduced during this reporting period and have been resolved.

Changes that had a significant impact on expenditures

Nothing to report.

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

Nothing to report.

PRODUCTS:

Publications, conference papers, and presentations

Journal publications.

McGregor, K.D., Flamme, G.A., Tasko, S.M., Deiters, K.K., Ahroon, W.A., Themann, C.L., Murphy, W.J. (2017). Acoustic reflexes are common but not pervasive: Evidence using a diagnostic middle ear analyzer. *Int J Audiol.*, Early online: 1-9. *https://doi.org/10.1080/14992027.2017.1416189*
(Published, federal support acknowledged)

Deiters, KK, Flamme, GA, Tasko, SM, Murphy, WJ, Greene, NT, Jones, HG, Ahroon, WA (under internal review). Generalizability of clinically-measured acoustic reflexes to brief sounds. *Journal of the Acoustical Society of America.*
(Under review, federal support acknowledged)

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

Nothing to report.

Other publications, conference papers, and presentations.

1. Greene, NT, Jones, HG, Ahroon, WA, Deiters, KD, Tasko, SM, Flamme, GA. U.S.Army Medical Research and Materiel Command (USAMRMC): U.S. Army Aeromedical Research Laboratory (USAARL) (2018). *Assessment of middle ear function during the acoustic reflex using wideband acoustic reflectance* (USAARL Report No. 2018-22). Washington, DC.
(Technical report, published, federal support acknowledged)

2. Flamme GA, Tasko SM, Deiters KK, Smith MV, Murphy WJ, Jones HG, Ahroon WA (2018). Dependability of conditioned middle ear muscle contractions. Presented at the U.S. Office of Naval Research Noise-Induced Hearing Loss Program Review. Portland, OR, August 2018.

3. Flamme GA, Tasko SM, Deiters KK, Smith MV, Murphy WJ, Jones HG, Ahroon WA (2018). Dependability of reflexive middle ear muscle contractions. Presented at the U.S. Office of Naval Research Noise-Induced Hearing Loss Program Review. Portland, OR, August 2018.

4. Flamme GA, Ahroon WA, Tasko SM, Deiters KK, Murphy WJ, Jones HG, Greene NT (2018). Effects of acoustic impulses on the Middle Ear. Presentation at the USAMRMC In-Progress Review meeting. Ft. Detrick, MD, July 2018.

5. Flamme, GA, Tasko, SM, Deiters, KK, Murphy, WJ, Jones, HG, Ahroon, WA, Greene, NT (2018). Anticipatory middle ear muscle contractions in damage-risk criteria. Presented at the Acoustical Society of America Spring Meeting, Minneapolis, MN, May 2018.

6. Tasko, ST, Flamme, GA, Deiters, KK, Ahroon, WA, McGregor, KD, Smith, MV, Murphy, WJ, Greene, NT, Jones, HG, (2018). Can middle ear muscle contractions provide dependable protection from impulse noise? Presented at the 3rd Japan-US Technical Information Exchange Forum on Blast Injury, May 2018.

7. Flamme, GA, Tasko, SM, Deiters, KK, Greene, NT, Murphy, WJ, Jones, HG, Ahroon, WA, (2018). Middle ear muscle contractions as hearing protection? Presented at the Annual Collaborative Auditory/Vestibular Research Network (CAVRN), April 2018.

8. Smith MV, Tasko SM, Flamme GA, Deiters KK (2018). Middle ear muscle activity associated with mastication. Presentation at the 2018 annual meeting of the Michigan Speech and Hearing Association. East Lansing, MI, March 2018.

9. Green, NT, Jones, HG, Flamme, GA, Tasko, SM, Deiters, KK, Ahroon, WA, (2018). A method of detecting frequency dependence in middle ear muscle contractions during task engagement. Poster

presented at the Association for Research in Otolaryngology (ARO) 41st Annual MidWinter Meeting, San Diego, CA, February, 2018.

10. Flamme, GA, Tasko, SM, Deiters, KK, Greene, NT, Murphy, WJ, Jones, HG, Ahroon, WA, (2018). Middle ear muscle contractions are not dependable hearing protection. Presentation at the American Auditory Society (AAS) Annual Conference, February, 2018.

11. Flamme, GA, Tasko, SM, Deiters, KK, Greene, NT, Murphy, WJ, Jones, HG, Ahroon, WA, (2018). Laboratory conditioning of middle ear muscle contractions. Presented at the National Hearing Conservation Association (NHCA) Annual Meeting, Orlando, FL, February, 2018.

12. *Deiters, KK, Flamme, GA, Tasko, SM, Murphy, WJ, Greene, NT, Jones, HG, Ahroon, WA, (2018). Generalizability of clinically-measured acoustic reflexes to brief sounds. Presented at the National Hearing Conservation Association (NHCA) Annual Meeting, Orlando, FL, February, 2018.

13. Smith, MV, Tasko, SM, Flamme, GA, Deiters, KK, Murphy, WJ, Jones, HG, Greene, NT, Ahroon, WA, (2018). Middle ear muscle activity associated with mastication. Poster presented at the National Hearing Conservation Association (NHCA) Annual Meeting, Orlando, FL, February, 2018.

14. Tasko, SM, Flamme, GA, Deiters, KK, Smith, MV, Murphy, WJ, Jones, HG, Greene, NT, Ahroon, WA, (2018). Concomitant head/neck muscle activity and middle ear muscle contractions. Poster presented at the National Hearing Conservation Association (NHCA) Annual Meeting, Orlando, FL, February, 2018.

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 (SASRAC)
Nearest person month worked: 10
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 (SASRAC)
Nearest person month worked: 3
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: Kristy K. Deiters, Au.D.
Project Role: Co-Investigator (SASRAC)
Nearest person month worked: 3
Contribution to Project: 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.

Name: Heath Jones, Au.D.
Project Role: Co-Investigator (USAARL)
Nearest person month worked: 3
Contribution to Project: Dr. Jones will be involved with participant recruitment and scheduling as the on-site contact for the field testing being conducted at USAARL. He will also be assisting with IRB protocol management, data collection, quality assurance, 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:

Attached.

Appendices

None

“Effects of Acoustic Impulses on the Middle Ear”

Log Number: 13063028

Award Number: W81XWH-14-2-0140

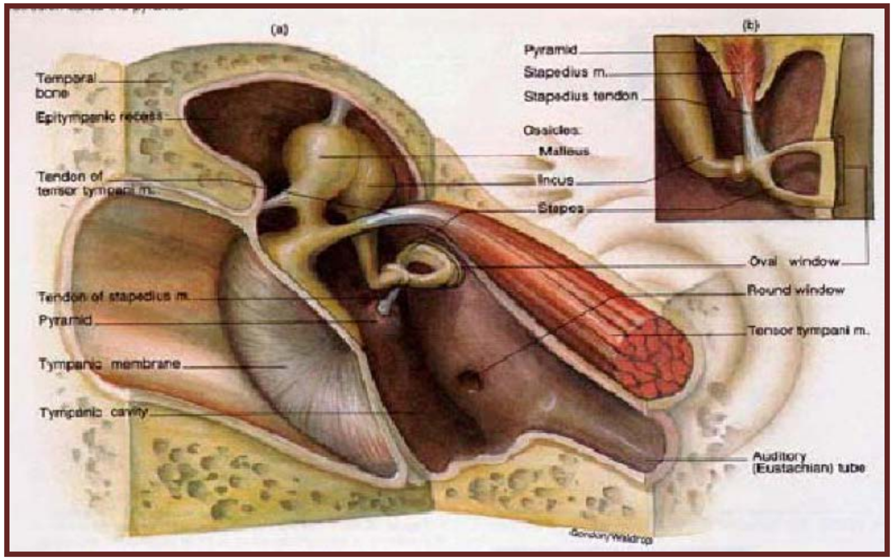
PI: Dr. William Ahroon **Org:** The Geneva Foundation/U.S. Army Aeromedical Research Laboratory **Award Amount:** $3,081,623

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 (AHAAH)

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	19
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**	

Updated: 02 Nov 2018

Goals/Milestones

FY15 Goal – MEMC Prevalence

✓ Develop MEMC detection algorithm on NHNES impedance traces

☐ Determine the prevalence of the acoustic reflex from the NHANES data base

FY16 Goals – Wide-band Absorbance Methods

☐ Validate MEMCs using Wide-Band Absorbance

FY17 Goal – MEMC Classical Conditioning

☐ Determine form and prevalence of MEMC conditioned response

FY18 Goal – Operational Demonstration

☐ Sniper-spotter lab & field test of AHAAH middle-ear assumptions

FY19 Goals

Comments/Challenges/Issues/Concerns

- None

Budget Expenditure to Date

Projected Expenditure:	$3,081,623
Actual Expenditure:	$2,222,865