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TITLE: Effects of Acoustic Impulses on the Middle Ear

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The objective of this project is to fully document the effects of acoustic impulses on the middle ear and on middle-ear muscle contractions (MEMCs). This project will provide critical information on the middle ear musculature states during warned and unwarned exposures to acoustic impulses. This information is necessary in the development of new (or revising existing) damage risk criteria (DRCs) 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 (MEMCs). 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 (DRCs) 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 MEMCs are pervasive for multiple acoustic and non-acoustic stimuli.
3. Determine whether conditioned MEMCs are pervasive, in either laboratory or field settings, and if so, identify differences between reflexive and conditioned MEMCs.

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 complete.

Significant results
No new results to report.

Other achievements:
Nothing to report.

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

AND

Task 3: Determine whether MEMCs 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 MEMCs.

Major activities
The major activities during this reporting period included:

- Dissemination of the results from the acoustic reflexive MEMCs (rMEMCs) and early/conditioned MEMCs (eMEMCs);
- Analysis and characterization of rMEMCs and eMEMCs, controlling for concomitant muscle activity;
- Analyses and interpretation of the Simulated Shooter-Spotter (SHSP) eMEMC tasks;
- Completion of the live fire active (LA) and live fire waiting (LW) eMEMC tasks.

Dissemination
Dissemination activities during this project period yielded one accepted manuscript in a peer-reviewed publication and six presentations at scientific meetings. The manuscript on acoustic rMEMCs (Deiters et al., 2019) was submitted in 2019 JAN and accepted for publication in the Journal of the Acoustical Society of America in 2019 OCT. Presentations were made at the annual meetings of the National Hearing Conservation Association and Association for Research in Otolaryngology, and at an international symposium on complex noise.

Control for concomitant muscle activity

Results provided in prior annual reports indicated that muscle activity picked up on the EMG channels used in this study (i.e., orbicularis oculi, masseter, suprathyroid complex, bicep, and flexor digitorum superficialis) can be correlated to MEMCs. This activity could either increase or decrease the probability of detecting MEMCs. In order to more accurately represent the response to the stimuli in the rMEMC and eMEMC tasks, EMG signals were transformed into root-mean-square (RMS) amplitudes that were synchronous with the individual (50 ms) acoustical probe click windows used to detect MEMCs. Individual multivariable linear regression equations were fitted to each combination of participant and task, totaling 2101 regression models. The residuals of these regression models permitted the examination of the proportion of variance in the MEMC ear canal trace that was associated with concomitant muscle activity, and also facilitated visualization of EMG-adjusted MEMC traces at the trial level. A support vector machine (SVM) was trained to match investigator consensus judgements regarding the presence or absence of an MEMC, demonstrating good performance (98% sensitivity; 97% specificity; 84% positive predictive value; 98% negative predictive value). The SVM was then applied to the 18,868 EMG-adjusted MEMC traces at the level of individual elicitor presentations to provide estimates of the likelihood of MEMCs at the level of individual trials – the unit at which DRCs operate.

These analyses revealed that the participant-level analyses used in this project are likely to overestimate rather than underestimate the likelihood that a participant will exhibit an MEMC on a given elicitor presentation (see example in Figure 1 for the white noise rMEMC elicitor). Across acoustic rMEMC stimuli in this study, median proportions of MEMCs for participants ranged between approximately 0.1 and 0.2, indicating that an MEMC could be expected in less than 10 or 20% of exposures for the average person.

Figure 1. Histogram of proportions of trials with EMG-adjusted rMEMCs for the white noise stimulus. The horizontal axis represents the proportion of trials an rMEMC was observed within a participant. The vertical axis represents the number of participants. The light blue vertical line represents the median proportion of trials exhibiting an MEMC. The red vertical line represents the 0.95 criterion required for inclusion in a
DRC. The numerical value in the upper right corner represents the proportion of participants identified as having a tendency toward exhibiting an rMEMC for this stimulus in participant-level analyses. Although there was a 0.71 probability that a participant would exhibit a tendency toward rMEMC for the white noise when examining the 25th percentile RMS difference across all trials for the participant, 50% of participants had less than a 0.2 probability of exhibiting a response on any given trial.

Simulated Shooter-Spotter (SHSP) tasks
A total of 74 participants enrolled in the SHSP component of this study (Figure 2). Of these, 15 participants were dismissed from the study, and the primary reasons for dismissal were insufficient hearing sensitivity. The remaining 59 participants either met strict criteria for eligibility (N=17) or met relaxed criteria (N=42) such as less recent firearm use, or an audiometric threshold falling one audiometric step below the strict criteria limit.

Figure 2. Of the 59 participants completing the experiment visit, 17 were eligible based on strict inclusion and exclusion criteria. Forty-two participants were allowed to complete the experimental visit based on relaxed criteria. TBI=traumatic brain injury, ARs=acoustic reflexes, H-1 hearing level defined as average threshold at 0.5, 1, and 2 kHz not more than 25 dB hearing level (HL), with no individual level greater than 30 dB HL at these frequencies, and threshold at 4 kHz not more than 45 dB HL (Department of the Army, 2008).

Live fire active and live fire waiting (LALW) tasks
A total of 34 participants were recruited into the LALW aspect of the project, and 14 of these participants did not meet study inclusion criteria (Figure 3). A total of three participants were lost to follow-up either prior to the visit for rMEMC measures (V2) or prior to the live fire visit (V3). Interim analyses after the 16th participant revealed that there was no meaningful chance of supporting the hypothesis of a pervasive eMEMC for either task. Continued data collection was futile once the answer to the research question was known, and the study enrollment was closed to further enrollment to reduce risk to participants. As per the a priori interim analysis protocol, participants who had not yet completed the LALW protocol were notified that the primary research question had been answered and that their data would contribute only supplementary information. With this information in mind, participants were asked to make a decision about whether to re-affirm informed consent to complete the LALW task or withdraw from the study. All three participants to whom this situation applied elected to finish the LALW task. A total of 19 participants completed the LALW task.
One the 16 LA participants examined during interim analyses showed a tendency toward an eMEMC when searching for the eMEMC during the 1.5 seconds prior to weapon discharge. An additional participant showing a tendency was observed in the final three participants, leaving an estimate of 10.5% of LALW participants showing a tendency toward eMEMC. Starting with 2 of 19 participants, the next 488 consecutive participants would need to exhibit eMEMCs in order to support an assumption that eMEMCs are pervasive during discharge of an M4 carbine on a military firing range. The probability of that event is below the computational resolution of our statistical software.

The time frame preceding the 1.5 seconds prior to discharge (up to 8 seconds prior to discharge) was also examined for evidence of eMEMCs, as were EMG-adjusted traces. The decision to reject the hypothesis of a pervasive eMEMC during discharge of the M4 carbine was upheld in these analyses. The lack of a pervasive, or even common, eMEMC when discharging the U.S. Army’s service weapon with live ammunition implies major deficiencies in any DRC depending on eMEMCs as a protective factor.

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

Nothing to report.

**How were the results disseminated to communities of interest?**

One manuscript (Deiters, et al., 2019) was accepted for publication in the Journal of the Acoustical Society of America. A total of 6 presentations were made at the annual meetings of the National Hearing Conservation Association and Association for Research in Otolaryngology, and at an international symposium on complex noise.

**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 expanding dissemination of these results, including USAARL technical reports that can be disseminated through the Defense Technical Information Center (DTIC). It is expected that the reports available through DTIC can inform policy, training, and doctrine throughout the U.S. Department of Defense. These will include two reports on clinical acoustic reflexes, one report on acoustic rMEMCs, one report on the association between voluntary eye closure and MEMCs, and one omnibus report describing the methods and results for all 9 eMEMC tasks conducted in this project.

Dissemination will also include two additional manuscripts prepared for publication in peer-reviewed journals (topics: voluntary eye closure and MEMC; eMEMC 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 MEMCs 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 MEMCs are not pervasive in the U.S. population and that people with clinical reflexive MEMCs do not necessarily exhibit MEMCs for brief tones, noises, or recorded gunshots. Non-acoustic elicitors appear more likely to produce an MEMC than acoustic elicitors. These data provide no support for an assumption of eMEMCs as a reliable protective factor. In addition, the refined methods for detecting MEMCs 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 eMEMC via classical conditioning. There is a weak evidentiary basis for a protective role of MEMCs for such brief sounds, and the evidentiary basis for an eMEMC was nearly non-existent prior to this work. This project has found no support for either rMEMC or eMEMC as a form of protection that should be invoked in any damage-risk criterion for impulsive noise. 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**

Nothing to report.

**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.


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

Nothing to report.

Other publications, conference papers, and presentations.


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?

<table>
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<th>Project Role:</th>
<th>Nearest person month worked:</th>
<th>Contribution to Project:</th>
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<tr>
<td>William A. Ahroon, Ph.D.</td>
<td>Principal Investigator (USAARL)</td>
<td>3 (Calendar)</td>
<td>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.</td>
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<td>Gregory A. Flamme, Ph.D.</td>
<td>Principal Investigator (SASRAC)</td>
<td>10</td>
<td>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.</td>
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<td>Stephen M. Tasko, Ph.D.</td>
<td>Co-Investigator (SASRAC)</td>
<td>3</td>
<td>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.</td>
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<td>Kristy K. Deiters, Au.D.</td>
<td>Co-Investigator (SASRAC)</td>
<td>3</td>
<td>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.</td>
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<tr>
<td>Heath Jones, Au.D.</td>
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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