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**Calibration of an In-Ear Dosimeter for a Single
Hearing Protection Device**

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14. ABSTRACT Military personnel working in high noise environments could be exposed to noise levels up to 150 dB. Daily noise exposure limits are based on both ambient noise levels and the duration of time spent in that noise environment. NAVAIR led ATI in the development of a ship-suitable in-ear dosimeter integrated into a single hearing protector, and co-sponsored an effort executed by AFRL to validate the effective noise dose measured by in-ear dosimetry. This was accomplished by conducting human noise exposure experiments that calculated noise dose from temporary threshold shifts (TTS) in hearing with and without ATI's in-ear dosimeter. Twenty subjects participated in the study. The data describe the subjects' open and occluded (protected with ATI's in-ear dosimeter) TTS response to noise exposure. Results from this study demonstrated that the ATI in-ear dosimeter integrated into a single hearing protective device overestimated the effective noise dose received by subjects by an average of 11 dB.					
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EXECUTIVE SUMMARY

Military personnel working in high noise environments could be exposed to noise levels up to 150 dB. United States (US) Department of Defense (DoD) Hearing Conservation Programs (HCPs) [1-3] set safe noise exposure limits to reduce the risk for noise induced hearing loss. These daily noise exposure limits were based on both ambient noise levels and the duration of time spent in that noise environment. Noise dosimeters, worn on the lapel of personnel and at least one system worn under a hearing protector, were designed to measure noise levels and calculate noise dose, but did not provide a validated measure of effective noise dose external to or under a hearing protector. Noise dose under hearing protectors are commonly predicted using the Octave Band Method described in the American National Standards Institute (ANSI) S12.68 [5]. This method subtracts the Real Ear Attenuation at Threshold (REAT) data, collected in accordance with ANSI S12.6 [4], at each octave band from the ambient octave band noise. However, while ANSI S12.6 procedures provide adequate results for group data, they do not account for individual variations in effective attenuation due to the fit of hearing protective devices. To address this issue, the US Naval Air Systems Command (NAVAIR) led Adaptive Technologies, Inc. (ATI) in the development of ship-suitable in-ear dosimetry integrated into a hearing protector. NAVAIR co-sponsored this effort, which was executed by the Air Force Research Laboratory (AFRL), to calibrate the effective noise dose measured by ATI's in-ear dosimeter. This was accomplished by conducting human noise exposure experiments that calculated noise dose from temporary threshold shifts (TTS) in hearing with and without ATI's in-ear dosimeter. Twenty subjects participated in the study. Exposure levels throughout the experiment were within US DoD safe noise exposure guidelines (DoD HCP) [1-3]. The data presented describe the subjects' open and occluded (protected with ATI's in-ear dosimeter) TTS response to noise exposure. Results from this study demonstrated that the ATI in-ear dosimeter integrated into a single hearing protective device overestimated the effective noise dose received by subjects by an average of 11 dB. These results yielded a calibration factor that, when integrated into the dosimetry software for single hearing protection, would improve the accuracy of the noise dose calculations. However, a follow-on study conducted with additional human subjects to validate the new calibration factor is recommended.

1.0 INTRODUCTION

US national and many international hearing conservation programs (HCPs) have adopted a noise exposure criterion of 85 dBA for a time-weighted average of 8 hours with a 3 dB per doubling exchange rate (safe exposure duration was cut in half for each 3 dB increase in noise level) [1-3]. Military personnel who worked in extreme noise environments, such as those generated by jet aircraft, required high attenuation from hearing protection in order to complete a normal duty day without risk of permanent hearing loss. Improvements to both hearing protection and noise dose monitoring have been consistently recommended and pursued as a means to reduce risk for noise induced hearing loss [6-8].

In order to address this need for improved noise dose monitoring, NAVAIR led Adaptive Technologies, Inc (ATI) in the development of ship-suitable in-ear dosimetry integrated into a single hearing protector. The objective of this study was to measure TTS as the direct indication of the effect of noise on the auditory system, and to use this information to calibrate ATI's in-ear dosimeter integrated into a single hearing protector.

2.0 BACKGROUND

The goal of adequately protecting the hearing of military personnel in high noise environments could not be achieved without considering the bone/tissue conduction flanking pathways of noise in addition to the air-conducted pathways through the ear canals. It was important to understand the combined effect of sound energy transmission pathways when attempting to calculate an individual's true noise dose. Since TTS is an auditory response to noise dose, it was used in this study to account for the total (air and flanking pathways) effect of noise exposure on the auditory system.

Human subjects, as opposed to animal subjects, were used in this study because of the limitations on information that can be gained about human response to noise from animal models due to differences in sound sensitivities of animal and human auditory systems. TTS studies in humans represent the only ethical means to accurately investigate the effects of noise on human hearing [9,10]. While the risk of permanent hearing damage cannot be said to be nonexistent, data from previous human studies at the same noise levels and exposure times used in this study indicated a less than 1% risk for permanent hearing loss [9-12]. Important safeguards such as initial sensitivity testing, distortion product otoacoustic emissions (DPOAE) testing, and a conservative "walk-up" noise exposure procedure were included in this experiment to keep the risks as low as possible and are discussed in detail in the methods section. A potential benefit from this study was the improvement of hearing protection, thereby lowering risk of permanent hearing loss for personnel who work in hazardous noise. This benefit was deemed to outweigh the nominal risks posed to human subject volunteers by the noise exposures in the study, approved by the AFRL Wright Site Institutional Review Board for human use studies [13].

3.0 METHODS

3.1 Subjects

All human subjects were compensated volunteers. Subjects were recruited primarily from flyers placed on local college campuses and online advertisement. All subjects were required to have a computer administered screening audiogram via Hughson-Westlake method, and were required to have behavioral hearing thresholds inside the normal hearing range, and thresholds of 15 dB hearing level (HL) or lower in the target frequencies that were investigated in this study: 3150, 4000, 6300 Hz. Ear canal size was

verified to be sufficient to accommodate the ATI earplug tested in this study. A self-report questionnaire was administered to all potential subjects and exclusion criteria included current occupational noise exposure, use of nicotine products, any history of ototoxic medication use, audiological history of tinnitus, etc. A total of 54 subjects were screened to participate in this study. 1 subject was excluded from this study based on a history of seizures. 18 subjects were excluded based on hearing threshold results. 15 subjects were qualified to participate, but did not complete the study for personal reasons (schedule conflicts, unforeseen events, etc.) and therefore could not be included in the final analysis due to incomplete data. Subjects were scheduled no more than two sessions per week with at least 24 hours between sessions. 20 subjects (10 male and 10 female) completed the study with a range in age from 21 to 34 years.

Test subjects were introduced to a brief duration of noise (5 minutes at 97 dB overall sound pressure level (OASPL), 10.5% of daily allowable noise dose) after signing the informed consent document and meeting qualification requirements. The purpose of this short exposure was both to ensure that subjects were comfortable with simply being in the noise environment, as well as to eliminate any subject with an unusually susceptible auditory system from the study. A subject was excluded if they experienced a TTS greater than 10 dB at any of the target frequencies from this short noise exposure. This 10 dB limit was based on the acceptable test/retest of thresholds for ANSI S12.6 Real Ear Attenuation at Threshold (REAT) procedures which is 6 dB [4], and the assumption that no subject should sustain a measurable TTS from such a short exposure. Four subjects were excluded from participation based on exceeding the 10 dB limit for this short exposure.

Subjects were trained for the procedure using the paradigm required for REAT qualification. This involved the ability to reliably track thresholds for narrow band stimuli presented via a diffuse sound field within 6 dB for repeated measures in the same session.

3.2 Facilities

AFRL's Battlespace Acoustics Branch at Wright-Patterson Air Force Base, Ohio has been a leader in research and technology development for over 60 years. AFRL facilities and personnel were instrumental in the development of noise exposure criteria used today by DoD HCPs. The facilities and equipment in this laboratory represent a unique test environment that was crucial for the ability to carry out this study [14].

The first component of the experiment was conducted in a reverberant chamber; a specialized hearing test facility in which a subject's behavioral hearing thresholds were assessed using Békésy tracking in a diffuse sound field (Figure 1a). The facility was in compliance with ANSI S12.6 [4]. The second part of the experiment was conducted in an adjacent reverberation chamber (Figure 1b). This facility was capable of generating a high-noise diffuse sound field environment up to levels of 140 dB OASPL, and is one of only a few facilities in the US that is capable of generating these levels. The extremely

close proximity of these two specialized test chambers enabled the collection of hearing threshold measurements following noise exposure (Figure 2).

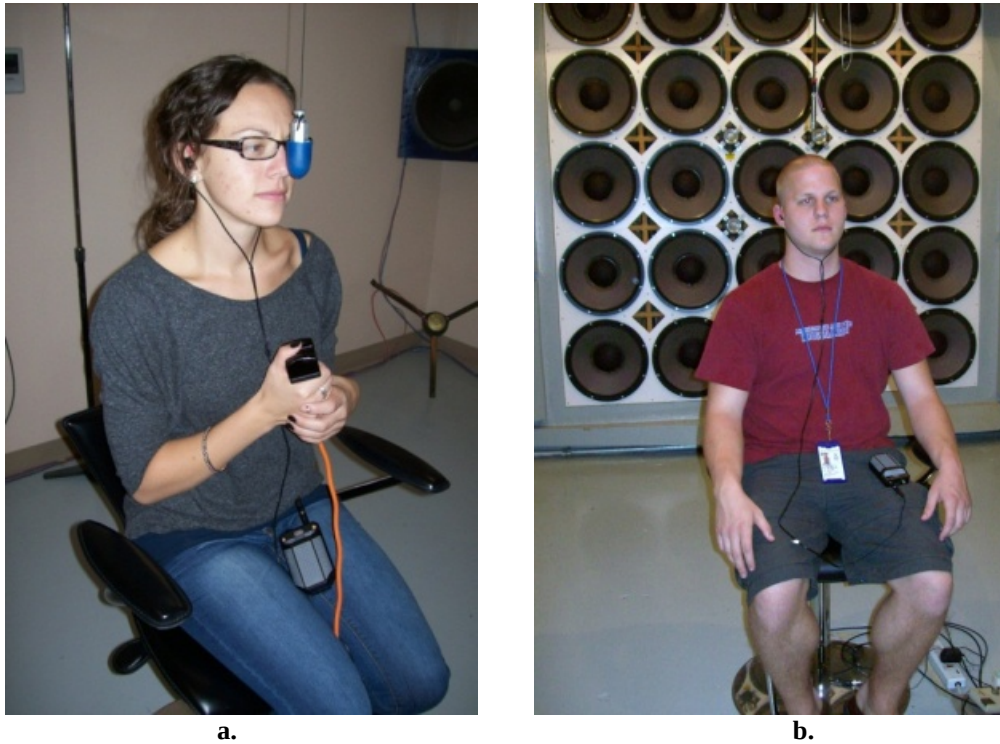


Figure 1. a. Female subject seated in REAT facility b. Male subject during noise exposure



Figure 2. Subject walking between test facilities

3.3 Experimental Procedures

For open ear sessions, every subject participated in a 31% noise dose session calculated using the DoD HCP guidelines. If ≥ 10 dB TTS was achieved at any of the target frequencies at 31% exposure, presentation time was decreased; otherwise, presentation time was increased (Table 1). Two separate open ear measurements were required per subject in order to develop an open ear TTS response curve.

Table 1. Noise Doses Used to Assess TTS in Hearing Without Hearing Protection

	Open Ear Noise Dose (%)		
	15	31	62
Noise Level (dB OASPL)	Duration (min)		
97	7.5	15	30
94	15	30	60
91	30	60	120

Subject's wore the ATI in-ear dosimetry earplugs, Figure 3, (developed under NAVAIR contract N00421-08-D-0022) for occluded ear sessions. Each in-ear dosimetry earplug had an integrated microphone for use in determining noise dose. Daily microphone calibrations were conducted during experimentation. Each subject's predicted dose level was calculated to ensure subject safety using the DoD HCP program guidelines and the subject's prior response to the noise exposures. Prior to noise exposure, baseline behavioral sound-field thresholds were measured from 125 to 8000 Hz for open ear and then occluded ear. The subject's passive noise attenuation was calculated for that day's fit across all seven octave band frequencies. The subject's fit remained unaltered between the measurements and the noise exposure. The noise level in the room was determined using the octave band method described in ANSI S12.68. The method added the subject's octave band attenuation values for the earplugs to the test noise spectrum on a band-by-band basis to achieve the desired SPL (91, 94, and 97 dBA). An example calculation is shown in Table 2. Based on the subject's auditory responses to open ear sessions, it was determined if the subject should be exposed at 25%, 50%, or 100% noise dose from the individual susceptibility to threshold changes. Table 3 lists the presentation noise level and duration for each occluded ear noise dose.

Table 2. Example calculation for ambient noise spectrum for occluded noise presentations

	Frequency (Hz)							
	125	250	500	1000	2000	4000	8000	
Noise Spectrum/Level, under HPD	85	85	85	85	85	85	85	94
A-weighted Correction	-16	-8.6	-3.2	0	1.2	1	-1.1	
Measured REAT Attenuation	22.5	28.5	31.8	41.5	34.2	40.7	45.0	
Noise Spectrum/Level, Ambient	124	123	121	127	119	125	132	135

Table 3. Noise Doses Used to Assess TTS in Hearing With Hearing Protection

	Occluded Ear Noise Dose (%)		
	25	50	100
Noise Level (dBA)	Duration (min)		
97	7.5	15	30
94	15	30	60
91	30	60	120



Figure 3. a. ATI non-custom earplugs b. In-ear dosimeter, calibration device, and analysis equipment

Pre and post-noise exposure DPOAE measurements were collected for left and right ears at 3000, 3250, 4000, and 6000 Hz. Since DPOAE's have been demonstrated to be highly sensitive to transient effects of noise, they were used as an additional line of defense to protect subjects from overexposure. The subjects were verbally warned that for 24 hours before and after each session they should refrain from participating in recreational noise exposure such as rock concerts, woodworking, shooting, listening to personal audio devices, and any other noise environments where voice elevation is necessary for communication. In order to prevent testing an individual who had already been exposed to hazardous noise, a pass criteria of +6 signal-to-noise ratio for DPOAE's from 3000-6000 Hz was established that was used prior to beginning any noise exposure session as well as verbal confirmation. A baseline behavioral sound-field threshold was measured for 3150, 4000, and 6300 Hz prior to all noise exposures. Threshold measurements were collected again for the same three frequencies 1 minute post-noise exposure. The TTS was calculated at this time for each of the target frequencies by subtracting the baseline threshold from the post-noise exposure threshold. If a TTS occurred (> 6 dB from baseline), threshold measurements were collected 7.5 minutes post-noise exposure and every 15 minutes following until the subject returned to baseline thresholds obtained prior to noise exposure.

4.0 RESULTS

The subjects were required to consistently track their pre-noise exposure hearing threshold levels. On average, the standard deviation for all of our subjects was 3 dB, significantly less than the 6 dB test/retest variability commonly reported in human subjects [4].

Initially data were collected at 91 dB as well as 97 dB; however, it was determined that 94 dB would be the only level used for determining the calibration factor due to the following: (1) Many subjects achieved such high attenuation values with the earplugs that the equipment limitations made it impossible to test them in an occluded condition of 97 dB under ATI's in-ear dosimetry earplug. (2) 91 dB presentations required the longest amount of time for subject sessions, and there was a significant amount of attrition with this study due to the duration of these sessions and the duration of the overall study. (3) Analysis of the data that we were able to collect at all three levels did not yield any significant differences in the results obtained from each level.

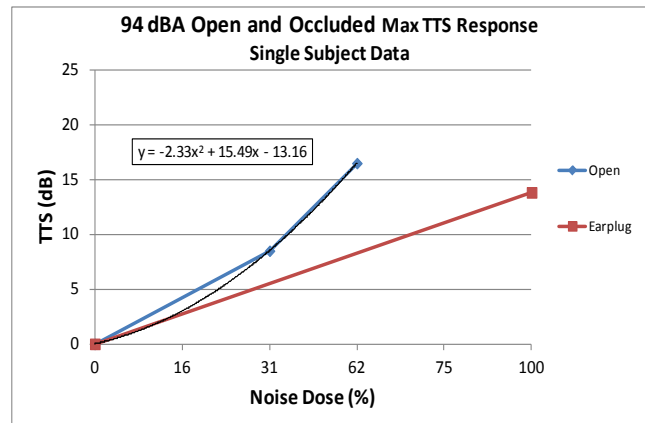
Maximum TTS was chosen for data analysis because in previous work on TTS studies in humans it has been the most commonly presented measure [15]. TTS was the only method available to assess the true effects of noise exposure on the auditory system, and therefore this paper contends that it should be used to calibrate in-ear dosimetry to improve the accuracy of noise dose monitoring for personnel.

The maximum open ear TTS data at 94 dB OASPL for each subject were used to calculate a second-order polynomial function to display the individual TTS growth. The maximum occluded TTS was entered into the polynomial function to determine the effective noise dose for each individual subject (Table 4). The calculated effective dose, the measured dose using the ATI in-ear dosimeter, the A-weighted sound levels recorded by the microphone integrated in the earplug in the ear canal, and a ratio of the ATI measured dose and the calculated effective dose are listed in Table 4 for each subject. The predicted level in the ear canal was 94 dBA; however, the average ATI measured level for all subjects was 97 dBA.

Table 4. Individual Subject TTS Results

Subject ID	Effective Dose (%)	ATI Measured Dose (%)	ATI Measured Sound Level (dBA)	Ratio ATI/Effective Dose (dB)
1382	11%	68%	92	8
1436	51%	419%	103	9
1451	13%	162%	95	11
1481	13%	193%	97	12
1500	1%	480%	105	27
1507	6%	224%	101	16
1510	8%	82%	93	10
1524	0.50%	99%	97	23
1526	52%	108%	94	3
1532	19%	290%	100	12
1540	16%	580%	108	16
1542	13%	151%	95	11
1547	13%	96%	94	9
1550	10%	77%	93	9
1553	14%	147%	95	10
1555	18%	70%	92	6
1561	11%	73%	95	8
1564	16%	33%	89	3
1566	4%	206%	100	17
1567	10%	317%	100	15

In-ear dosimetry, in its current form, overestimated the effective noise dose the subjects received on average by 11 dB with a standard deviation of 6 dB. Figures 4-6 are representative individual subject data. Each figure displays maximum open ear TTS response as well as the second-order polynomial curve and equation and the maximum TTS response while wearing the ATI in-ear dosimetry earplugs.

**Figure 4. Maximum Open and Occluded TTS Results for Subject 1436**

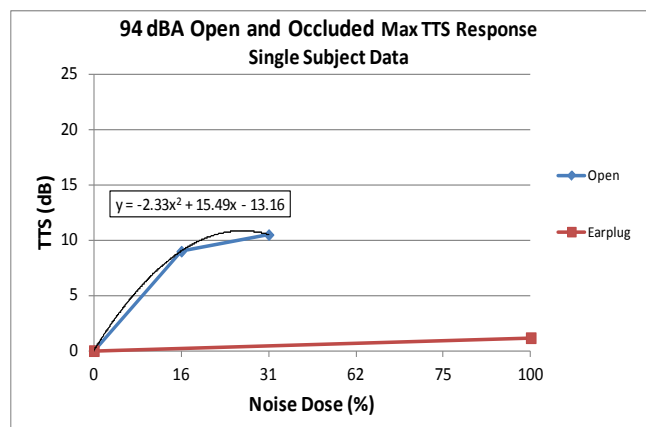


Figure 5. Open and Occluded TTS Results for Subject 1500

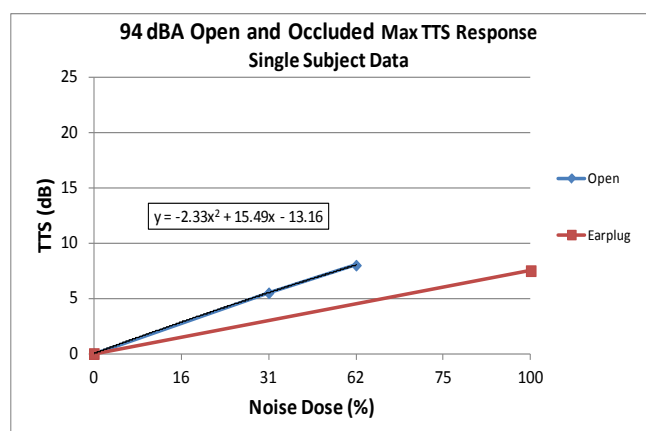


Figure 6. Open and Occluded TTS Results for Subject 1526

5.0 DISCUSSION

In-ear dosimetry in its current form utilizes the free-field to in-ear transfer function as a calibration factor. This method appears to accurately estimate the sound pressure level inside the ear canal. However, results from this experiment clearly indicate that accurate predictions of the in-ear microphone sound pressure level measurement alone does not take into account the actual human auditory response to noise. 94 dB SPL inside the ear under a hearing protection device does not produce an equivalent auditory response to 94 dB in the free-field.

One criticism for the use of TTS to determine a calibration factor for in-ear dosimetry is a high level of variability. Individual variation for both magnitudes of TTS, as well as the pattern of TTS growth curves, has been well documented in previously published human TTS experiments [9-12]. One explanation for the high variability in individual TTS data could be related to individual differences in the peak of the sound transfer function from free-field to the eardrum. Factors cited as contributing to these differences were ear canal

length, cross-sectional area, acoustic impedance of the eardrum, and shape of the canal entrance [9,15]. While some have argued that the high level of variation in TTS responses may lead to inaccurate results with limited usability, it is important to note that the level of variation between individual threshold measurements collected to determine hearing protection attenuation (ANSI S12.6) was typically equal to or greater than that of the variability in TTS. If ANSI S12.6 values are accepted and used as the gold standard in measuring hearing protection performance, then the level of variation in TTS should not be used as evidence against its utility. With appropriately large sample sizes in carefully controlled experimental sessions, it is reasonable to use TTS results as a method to prevent noise induced hearing loss by improving noise dose calculations for individual users.

There are many potential explanations for the results of this study, which indicated a large disparity between expected TTS responses and actual TTS responses to an equivalent noise presentation in open versus protected ear canals. One possibility could be changes in the acoustic impedance of the tympanic membrane due to the occlusion of the ear canal from a hearing protector. Additionally, there could be differences in the acoustic reflex and ossicular chain dynamics when the ear canal is occluded. Another factor could be an increase in the perceived safety of the noise by the individual when wearing a hearing protector, which could lead to a reduction in stress reaction. Likely all of these things, as well as other unknown factors, are combined to create more effective attenuation for individuals than the available ANSI S12.6 and ANSI S12.68 methods. Future studies are needed to come to a better understanding of the mechanisms that are involved in sound transmission and the overall effects of high noise on the auditory system.

6.0 CONCLUSIONS

In-ear dosimetry is a promising advancement in hearing protection technology with the potential to be a new tool in the efforts to reduce the risk of noise induced hearing loss. Based on the subjects' maximum TTS results from this study, exposed at 94 dBA in the single hearing protective device condition, the in-ear noise dosimeter evaluated in this study substantially overestimated the noise dose by an average of 11 dB. Preliminary findings indicate that human subject data are extremely important in developing and calibrating the effective noise dose for any type of noise dosimeter, but particularly so for in-ear dosimetry. Additional studies should include investigating the dosimeter calibration under double hearing protection, investigating middle ear impedance using laser Doppler vibrometry, evaluating subjective and objective measures of stress during noise exposures, and examining TTS responses from noise generated inside the ear canal as opposed to outside the hearing protector.

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