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A Method Paper for Earplug-Fitting Augmentative Procedures Tested in Groups of More Experienced and Less Experienced Users of Hearing Protection

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**A Method Paper for Earplug-Fitting Augmentative Procedures Tested in Groups of More
Experienced and Less Experienced Users of Hearing Protection**

Capstone Document

Presented in Partial Fulfillment of the Requirements for the Degree Doctor of Audiology (Au.D.)
in the Graduate School of Illinois State University

By

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ABSTRACT

Although a long history of research has led to extensive knowledge about hearing protection devices (HPDs), there has been limited research about procedures that provide aid and verification during HPD insertion, although several studies have reported about HPD training. No standard methods have been established for training of earplug use (Takahashi, 2011). A review of the literature revealed a need for tools that might be used to improve user ability to properly insert HPDs consistently, even in the absence of training, because training is rarely provided in the workplace. The prevailing research question was "Does the use of simple fitting procedures improve attenuation performance?" The research methodology for such an investigation was described, including standardized measurement procedures, attenuation benchmarks, and considerations for study design.

In order to assess whether various intervention strategies might effectively improve worker ability to use HPDs, methods used to measure attenuation, including fit-test instruments, normal-hearing subjects, ANSI standards, and analytical procedures should be aligned. For example, attenuation data may be collected binaurally using HPD Well-Fit™ (a Center for Disease Control [CDC]/National Institutes for Occupational Safety and Health [NIOSH] fit-testing system) prior to and following an intervention. Alternatively, monaural fit-test measurements might be collected for comparison and analysis. Binaural fit-test measurements may be compared to monaural measurements. The data collected may be analyzed to examine which intervention ascertains improvement of attenuation or some other desired outcome. Use of a control group (e.g., subjects that receive no intervention) should reflect the outcome expected in the typical workforce, because, besides a lack of hearing protection training, workers generally do not use earplug fit improvement procedures. Likewise, controls should allow investigators to

describe the expected degree of variability in the measurement.

Exploration of simple methods that might be implemented in the noise-exposed workforce is critical for reversal of occupational noise-induced hearing loss. It is important to consider noise-induced hearing loss a public health problem. Further, providers should encourage all patients to practice *healthy hearing* through the avoidance of hazardous noise despite the lack of evidence-based guidelines (Rabinowitz, 2010).

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CHAPTER 1

Introduction

Noise-induced hearing loss (NIHL) is one of the most common reportable occupational injuries (Smith, 2010) and produces thirty percent of hearing losses in the adult population (Nodoushan, 2014). Fortunately, NIHL is preventable, especially when appropriate hearing loss prevention (HLP) training and hearing protection education is provided for workers exposed to hazardous noise. According to Rabinowitz (2010), over-exposure to hazardous noise is the leading cause of acquired sensorineural hearing loss. Between 5 and 30 million American workers are thought to be exposed to hazardous noise through their occupation (Murphy, 2011). There are several associated physiological effects associated with NIHL. These include psychophysiological effects, such as depression and frustration, as well as cardiovascular effects, such as high blood pressure (Ismail, 2013). Perhaps the most important factor to consider is that NIHL is 100% avoidable when total exposure levels are safe, less than 80 dBA. This can be done in most noise-exposure settings with the proper use of hearing protection devices (HPDs).

The HPD market generates roughly 300 million dollars in annual sales. Approximately 62% of those sales account for 1,014.6 million earplug units and 35% of sales, accounting for 3.8 million earmuff units sold annually. The effectiveness of HPDs may be impacted by their measured attenuation, fit, and frequency of use when exposed to noise (Themann et al., 2013). Attenuation is represented by the noise reduction rating (NRR); however, this may not be equivalent to the user's personal attenuation rating (PAR). Many HPD users compromise the effectiveness of an HPD because of their inability to correctly fit the protector. In these cases, education and training about the protector should be offered by the worker's hearing

conservation program (HCP) department (Murphy, 2011). In order to preserve hearing, it is necessary that HPDs are donned properly in all situations when employees are exposed to hazardous levels of workplace noise.

Employers are required to provide a variety of HPDs for their workers (Schultz, 2008; Huttunen et al., 2011; Schultz, 2013). These commonly include a variety of commercial off-the-shelf (COTS) inserted HPDs such as the disposable-foam, reusable (multi-use), push-in foam, custom-molded, and banded earplugs (Huttunen et al., 2011; Schultz, 2013). The wide variety of earplug styles create advantages and disadvantages for HPD users. For example, earplugs may be corded or uncorded, which allows the wear to maintain access when the HPDs are not in use. This is an advantage for users who are intermittently exposed to noise.

Disposable (e.g., foam) earplugs may be comfortable when extended use is required. They generally produce the highest levels of attenuation, are available in a variety of materials, and are manufactured in multiple shapes and sizes. The effectiveness of a foam-disposable hearing protector is primarily dictated by correct use of that product. Most importantly, the product must be rolled down properly, according to the earplug manufacturer's specifications, and then inserted directly into the ear canal before it expands. Creases and crevices must be avoided during the insertion of a foam earplug. If used in dirty environments, disposable-foam earplugs may introduce an ear-canal hygiene problem for the wearer; so, to avoid these issues, alternative HPDs should be offered.

Reusable (multi-use) earplugs are an alternative to disposable HPDs that offer benefits like the foam protector. They are available in various sizes and manufactured from different materials. Multi-use earplugs are especially dependent on proper insertion and fitting, are more expensive than foam earplugs, and should be cleaned after use. They are commonly referred to

as pre-molded earplugs.

Push-in foam earplugs are simpler to insert because there is no roll down procedure required. Push-in plugs still require careful insertion. They are more expensive than disposable-foam earplugs. Custom-molded HPDs can be solid, filtered, or have active sound processing. Some models allow radios and other communication headsets to be attached. Custom-molded HPDs typically have higher and less variable attenuation but are the most expensive of the HPD products. They are typically used for workers who are exposed to excessive noise or cannot wear COTS earplugs due to difficulty with ear canal size, earplug insertion, or comfort. Finally, banded earplugs provide convenience for intermittent-noise conditions because they may be worn around the user's neck. Banded earplugs have lower attenuation, a risk of noise traveling through the band itself, and may create an *occlusion effect* (Schulz, 2013).

Although 85% of workers use earplugs, some employees are more comfortable with an over-the-ear product, such as earmuffs. To obtain adequate attenuation, earmuffs require less training than earplugs (Suter, 1984). They tend to have a lower NRR during laboratory testing. Most importantly, earmuffs generally perform better in the field when compared to inserted devices (Murphy, 2011).

Three American National Standard Institute (ANSI) standards that describe real-ear attenuation at threshold (REAT) protocols are ANSI Z24.22, ANSI S3.19 and ANSI S12.6. These standards specify the protocols for measuring, analyzing, and reporting the passive noise-attenuation performance of HPDs. The ANSI Z24.22 (1957) standard describes a measurement procedure for obtaining hearing protector attenuation values at nine one-third octave band center frequencies presented to ten different test subjects, using pure tone stimuli in an anechoic sound environment. This standard was revised in 1974 (ANSI S3.19-1974) with the same procedure as

ANSI Z24.22-1957 but was conducted in a diffuse (reverberant) acoustic field setting. The ANSI S12.6-1997 introduced two alternative procedures that can be used to establish earplug attenuation: Method A (device fitted by trained and motivated subjects) and Method B (devices fitted by inexperienced subjects). None of the aforementioned standards specify a minimum performance requirement for HPDs.

By utilizing the REAT protocol, examiners can determine attenuation for each HPD by measuring unoccluded and occluded thresholds of the subject. The ANSI S12.6-1997 standard may not be appropriate for estimating real world attenuation since the goal of this standard was to produce ideal attenuation performance data. Furthermore, REAT data do not accurately measure the attenuation of non-linear HPDs. The ANSI S12.6-1997 standard eliminated the subject fit and experimenter fit categories in previous standards, creating one category titled experimenter supervised fit. Ultimately, it was determined that the ANSI S12.6-1997 standard would provide more precise data than preceding measurement standards, yet it still is not a reliable estimate of real-world HPD data (Berger, 1985). The ANSI-compliant measurement data may be used to calculate the NRR for a given HPD (EPA, 1979).

The NRR is an attenuation index that represents the overall average noise reduction of an HPD in decibels (Joseph, 2007). It receives frequent criticism as the NRR is rarely correlated with “real-world,” performance. More frequently, an NRR will be far greater than the real protection obtained in the workplace. Schultz (2011) and Themann et al. (2013) suggested moving towards NRR-subject fit metrics to more accurately label the attenuation users might obtain from a protector.

Attenuation can be determined through several measurement methods. An acoustic test fixture (ATF), the Real-Ear-Attenuation at Threshold (REAT) measurement, and the

Microphone-in-the-Ear (MIRE) method may be used to estimate attenuation. An ATF is used in laboratory settings without a need for human subjects. Limitations of this method include differences in bone conduction, occlusion effect, and physiological masking in the ear canal when data from the ATF is contrasted with data obtained from human subjects (Huttunen et al., 2011). This may be the simplest and quickest assessment of an earplug and may be used when use of human subjects is inappropriate (Bockstael, 2010). However, the ATF has been criticized because the attenuation measures may be unduly influenced by the artificial skin lining. Utilizing a silicone earplug, research was conducted that demonstrated the unwanted contribution of the artificial skin of the ATF (Viallet, 2014a). Alternatively, the REAT and MIRE measurements use a loudspeaker and human subjects to present stimuli in the sound field.

The REAT technique is a binaural measurement; whereas, the MIRE approach permits analysis of attenuation one ear at a time, thus resulting in more ear-specific information. Conversely, the MIRE technique may not incorporate the most adequate depth and seal of an HPD due to the necessity of a microphone in the ear canal. The REAT method is susceptible to physiological noises like breathing, heartbeat, blood flow, and stomach rumble. It also accounts for bone-conducted transmission of sound, but the MIRE approach cannot. The absence of bone-conduction factors with the MIRE technique can result in an overestimation of noise reduction when examining HPDs with good attenuation. Altogether, investigators have determined that the REAT measurements are more accurate than the MIRE measurements (Huttunen et al., 2011). As such, REAT measurements have been considered the *gold standard* for earplug performance measurement (Schultz, 2011; Bockstael, 2010; Themann et al., 2013).

Most workers receive little or no training on HPD use, (Gehler et al., 2011; Ismail, 2013), although OSHA mandates worker education on the use and placement of the HPDs (Suter,

1984). It is common for the employers that do train employees to rely on the instructions printed on the product packaging; however, these instructions are typically in small print with vague illustrations, which does not satisfy the OSHA-training requirement (Joseph, 2004). In the workplace, comprehensive training is essential in order to achieve successful HPD use, (Tsekrekos and Lamontagne, 2011). It has been suggested that hearing conservation training programs should motivate workers to be more aware of hazardous noise and its potential for causing hearing loss. Programs should also stress the importance of healthy hearing and hearing loss prevention (Stephenson, 2009; Bockstael, 2010). Some reports identify one-on-one training as the best approach, or, at a minimum, an effective method of training (Schultz, 2008; Gehler et al., 2011). A successful training program not only benefits each worker individually, but also reduces the collective monetary burden of NIHL on the employer. By decreasing or eliminating NIHL compensation cases, employers can avoid large pay outs for hearing disability. One study associated employees without NIHL with higher morale and work-place efficiency, reporting that employees without NIHL are in better health (Ismail, 2013). Thus, hearing protection training is critical in order to sustain hearing loss prevention, worker morale, efficiency, and health.

Three steps for proper insertion an earplug include preparing the earplug, opening the ear canal, and inserting the earplug (Schultz, 2008; Schultz 2013). These steps should be followed up by a check of the device fitting, which is done by visualizing the fit and performing an acoustic verification. An appropriate seal can be verified by cupping yours ears with your hands and comparing this with your ears not cupped. Fir a properly fitted earplug, you should not perceive an appreciable difference of sound between cupped and not cupped. Subject-fit earplug effectiveness measures should be conducted (Schultz, 2008). Recognize that there may be a few

months of acclimation for new HPDs; this is extremely relevant for musicians (Huttunen et al., 2011).

Byrne (2013) reported that a poor hearing protector seal is a major concern and Viallet et al. (2014b) examined the impact of depth and seal on a fitted earplug. It was determined that low frequencies (those below 1kHz) are more impacted by inappropriate earplug depth, which can worsen attenuation by 20-25 dB. Mid-frequencies (1kHz through 5kHz) were generally affected by about 5 dB. A poor seal can impact the low frequencies, but this is dependent on the size of the slit or leak. Viallet et al. (2014b) reported that spaces of 2 mm decreased attenuation by approximately 10 dB and leaks of 5 mm reduced the attenuation by approximately 20 dB. Thus, it is important to complete the aforementioned training and REAT measurements to obtain personal attenuation levels.

Stephenson (2009) reported five factors for non-use of hearing protectors: comfort, convenience, cost, communication, and climate. Some factors are the result of absent or poor training. Huttunen et al. (2011) studied a group of musicians and established outcomes due to reluctance to use HPDs: loss of monitoring ability, alteration of timbre, uncomfortable fit, ear pressure, and deteriorated localization ability (Huttunen et al., 2011). The occlusion effect may be a contributing factor of poor outcomes. It effectively changes how a person perceives the sound of their own voice. Some workers may experience the occlusion effect and improperly insert their earplugs to reduce this problem. Workers should be counseled that deep earplug insertion will reduce the occlusion effect (Byrne, 2013), which should contribute to increased HPD compliance. Hearing conservationists share a common understanding that the best HPD is one that is used properly and consistently (Lutz et al., 2015; Bockstael, 2010; Tsekrekos and Lamontagne, 2011).

Literature Review

Intervention Programs

Takahashi et al. (2011) analyzed 10 university students (5 males, 5 females). Eligibility for this study required thresholds of 15 dBHL or less for frequencies below 2 kHz and 25 dBHL or less for frequencies equal to and above 2 kHz. Intra-aural differences could not exceed 10 dB. Participants were disqualified if they received training in earplug use, used earplugs within the month, or used earplugs on a regular basis. Semi-insert earplugs were reportedly used to improve ease of use for inexperienced participants. Takahashi et al. (2011) permitted workers to position the HPD prior to the intervention by reading only the printed instructions. Their intervention included a five-minute individual training with oral and written instructions, followed by a ten-minute self-practice session every day for seven days. During the self-practice session, participants were asked to complete a daily checklist which included three yes or no questions:

- (1) I wore earplugs by the correct method
- (2) I practice while listening to white noise or music
- (3) I practiced for ten minutes

Takahashi et al. (2011) reported that their intervention increased group-mean attenuation levels by 16 dB, which was technically remarkable; however, as described above, the semi-insert device generally demonstrates the lowest attenuation in hearing protection users.

Tsukada et al. (2008) targeted a group of 76 male workers exposed to hazardous noise in an electrical equipment manufacturing plant. The authors used a two-part training exercise followed by a two-month follow up of 68 male workers. The first sequence of the training began with a pre-education questionnaire on earplug use, followed by group instruction on NIHL

prevention that lasted about two hours. The second sequence occurred one month later and included individual instruction about proper earplug use using an instrument that measured attenuation. Before and after this session, headphone-attenuation measurements were administered. Participants were instructed to press the response button continuously as they heard the stimuli, releasing the button when the sound was no longer heard. Then, two months later, the HPD usage rate was assessed through a post-education questionnaire, including HPD performance attenuation measurements. Following this training, the prevalence of HPD use reportedly increased from 46% to 66% and non-compliance decreased from 19% to 9%. The percentage of those who obtained satisfactory noise attenuation increased from 46% to 72%. Outcomes for this investigation support the importance of multifaceted hearing protection education programs.

Joseph (2004) and Joseph et al. (2007) utilized four groups of 25 participants to examine the effects of group versus individual training using disposable-foam (formable) and reusable (pre-molded) earplugs. Hearing protection attenuation was recorded using Fit-Check™ (Kevin Michael and Associates, State College, PA) and these measurements were conducted before and after training. During pre-intervention testing, no assistance was provided when the subjects were instructed to insert the HPDs. After the intervention, participants were provided with instructions found on the product package. During individualized training, the examiner inserted the earplugs for subjects in order to demonstrate proper fit. Conversely, during group training, the examiner observed subjects during the practice-training session. Joseph (2004) and Joseph et al. (2007) reported that the difference between the training modalities (group versus individual) was not statistically significant, but the data established that earplug-insertion training and practice significantly improves attenuation in both modalities. Joseph (2004) and Joseph et al.

(2007) participants completed the NIOSH Hearing Loss Prevention Attitude-Belief survey about perceptions of susceptibility to hearing loss, severity of the consequences of hearing loss, benefits of preventive action, and the barriers to preventive action. Group scores were compared pre-intervention and post-intervention and, although the post-intervention results improved attitude, group differences were not statistically significant. The authors concluded that a subject's ability to properly insert an earplug and their attitude about hearing loss prevention were uncorrelated.

Nodoushan et al. (2014) compared the effect of face-to-face HPD training and no training with the manufacturer's NRR. Randomly selected workers (n=150) from an occupational medicine clinic formed three groups:

(Group 1) untrained, wearing earplugs with an NRR of 25

(Group 2) trained, wearing earplugs with an NRR of 25

(Group 3) untrained, wearing earplugs with an NRR of 30

Participants were excluded if they had participated in a training program in the past two years, had a history of using earplugs more than six times in the past two years, or had a hearing loss. Hearing loss was defined as any threshold greater than 25 dBHL. Subjects could not have more than a 10-dB difference between two adjacent test frequencies. The same earplug was used for all groups. Training for Group 2 was a 15-minute session under direct supervision on the correct methods for wearing earplugs. When the correct technique was demonstrated, REAT measures were conducted. The authors concluded that training played a significant role in correct earplug use based on higher attenuation values observed for the trained participants.

Two studies were performed by Huttunen et al. (2011) using 15 symphony orchestra musicians and 10 subjects who were musicians, students and people who listened to music or

played a musical instrument recreationally. The aim of the first study was to understand whether HPD usage time was associated with perceived HPD discomfort. The second study highlighted continuous sweep Bekésy audiometry and whether it provided greater information about the relationship between frequency and attenuation. Otoscopy and pure-tone air and bone conduction thresholds were recorded from 125 Hz through 8000 Hz.

For the first study, participants were given a questionnaire about HPD usage rates at home and work, their experience with HPDs, experience with cleaning the HPDs, and reasons for non-use. To determine the attenuation of the ER-15 custom-molded earplugs, REATs were administered. Subjects were asked to insert their earplugs, and testing was conducted after being checked by the experimenter. If there were difficulties with insertion, subjects were given assistance. Pure tone audiometry revealed a pure tone average (PTA), using 500, 1000, 2000 and 4000 Hz, of 5.25 dBHL in the right ear and 7 dBHL in the left ear using earphones. The sound-field PTA revealed an average of 8.5 dBHL. Only 1 of 15 musicians reported using their earplugs *always* or *nearly always*.

For the second study, HPD performance was assessed using Bekésy audiometry to improve frequency specificity. The investigators wanted to discover if there were peaks or troughs that a REAT measurement might not uncover. Due to standing waves and reflected sounds, it is advised that these measurements be obtained using calibrated headphones. The standard ascending-descending 5-dB Bekésy audiometry excursion pattern was used for quality control purposes. Audiometric testing revealed a pure tone average (PTA) of 4.4 dBHL in the right and 4.1 dBHL in the left ear. For Bekésy audiometric measurements, circumaural, open-back headphones were utilized. Subjects were asked to press and hold a button when they heard the stimulus and release it when no longer audible. For counterbalancing, half of the subjects

were examined with, and half without, HPDs. Attenuation measurements of the ER-9 and ER-15 were counterbalanced, as well as the order of the test ear (right or left). Thresholds were tested monaurally utilizing the Bekésy continuous sweep method, which takes approximately seven minutes per trial. A questionnaire about HPD duration of use, musical instruments played, frequency of HPD use, and reasons for non-use, was administered. Earplug use was not significantly different when compared to participants from the first study. The Bekésy data were similar to the low frequency and at 8000 Hz manufacturer data, and the REAT measures resembled high frequency manufacturer specifications (up to 6000 Hz). Given that thresholds were obtained in 5-dB steps, the REAT measurements may not have been as precise as the Bekésy audiometry swept measures.

Employing eight groups of 20 subjects, recruited from the general population to evaluate four earplugs across three training modalities, Murphy et al. (2011) reported four project aims:

- (1) to confirm the results presented in Joseph et al. (2007)
- (2) to investigate the success of using video instructions versus the manufacturer's printed instructions versus individual instruction
- (3) to evaluate whether multiple groups of subjects under the same test conditions would demonstrate agreement with the ANSI REAT standard
- (4) to evaluate if the ANSI HPD standard was valid when comparing various earplugs and participant groups.

Participants underwent a one-hour screening process to ensure their hearing thresholds were not poorer than 25 dBHL at all test frequencies. Subjects were excluded if they had individual video or group training on HPDs or if they had used HPDs within the previous year. Thresholds were obtained in the sound field using a modified Bekésy procedure. Subjects recorded their responses

by pressing and releasing a response switch. The first two responses were rejected, and thresholds were determined from the six ensuing responses, provided that they were within 20 dB of each another and consecutive responses were no more than 3 dB apart. The four earplugs selected were the Moldex Pura-Fit, E-A-R Classic, Howard Leight Fusion, and AirSoft pre-molded earplugs to directly compare results to similar studies. Training modalities were conducted in three methods. The video instruction modality was a modified version of a video developed by Mark and Carol Stephenson for use with construction workers. Murphy and his team added a training video specific to each HPD, instructions for selection of the correct HPD, and information on how to perform a fit-verification check using their own voice. The written instruction modality provided participants with written instructions from the manufacturer. Subjects were given five minutes to review the instructions and practice HPD insertion. Finally, for the experimenter-trained portion of the study, each subject was given five to ten minutes of individualized instruction until they could demonstrate acceptable fit. For all HPDs, the experimenter-trained modality showed significant improvement compared to the video and written instructions. Inexperienced participants did not show significant improvement between using the written instructions and video training. Hence, it appears that individualized training makes the most difference in terms of adequate HPD use.

To examine the prevalence of hearing loss in industrial personnel, Rabinowitz et al. (2006) reviewed the baseline audiograms of 2,526 individuals age 17 to 25 in the early stages of employment. Audiometric employee data were acquired from Alcoa Incorporated from 1985 to 2004. Baseline hearing tests were conducted for all new employees after a noise-free interval of at least 14 hours. The exam protocol included a questionnaire about noisy recreational activities, previous noisy employment, and use of firearms. Nearly 50% of new hires reported exposure to

leisure noise and one third had a history of hunting and shooting. The authors determined that the prevalence of high-frequency hearing loss had not increased significantly between 1985 and 2004, a possible outcome of the hearing protection education program.

Costa Marques et al. (2015) conducted a meta-analysis of social noise exposure and hearing loss prevalence. Their investigation revealed 438 articles with 17 meeting inclusion criteria. Several reports included the World Health Organization's Ear and Hearing Disorders Survey Protocol. This assessment uses measurements or environmental noise, a questionnaire, otoscopic examination, pure-tone audiometry, and impedance testing. Another investigation assessed worker noise exposure, HPD use, heat stress, and whole-body vibration through interviews (Brueck et al., 2016). The authors reported that most exposures were above permissible exposure levels. A retrospective analysis of the company audiometric database was administered. Sound level measurements of the operating equipment and a sample of employee interviews on workplace health were recorded. Dosimetry, whole-body and hand-arm vibration, HPD attenuation, and heat stress measurements were collected. HPD attenuation was assessed using an acoustic mannequin head. The audiometric database (7,908 audiograms) contained 618 current or former employees. Following close examination, 82% exhibited a threshold shift (per National Institute for Occupational Safety and Health criteria) and 63% had documented evidence of an Occupational Safety and Health Administration hearing-threshold shift. Per OSHA, engineering controls should be the first line of prevention (Themann et al., 2013). The company in the Brueck et al. (2016) was ordered to implement engineering controls and improve hearing protection selection options for its workers.

Lutz et al. (2015) assessed the use of engineering controls and hearing protection for miners. The authors recorded sound level meter and in-ear dosimetry for workers classified by

job task, work shift and earplug type. Twenty-two miners were sampled across a 2-week period. Individuals were instructed to select earplugs that resembled the products they typically used. Prior to data collection, HPD use was assessed in the field before training. Education on appropriate use of HPDs was conducted and, using the VeriPRO™ (by Honeywell), attenuation measurements were obtained. The authors reported that sound level meter and in-ear dosimetry measures were correlated, which suggests that measurements were generally stable across miners. Limitations included small sample size and the inability to assess real-time HPD attenuation (examiners were not allowed to enter the mines). The authors neglected to describe their training program.

By comparison, Kelly et al. (2015) assembled five focus groups with 32 participants from three different night clubs to examine barriers to HPD use. Susceptibility, severity, benefits, and barriers were explored using a Health Belief Model (HBM) paradigm. To assess HPD self-efficacy, interpersonal influences and situational influences the Health Promotion Model was used. These data were used to develop an HPD training program. Participants identified that one of the benefits of HPD use was tinnitus prevention. Barriers of HPD use included fears that HPDs might cause infection or injury, and that they take too much time to insert. Communication was reported as a benefit and barrier of HPD use. The focus group described clear or skin-toned, easy to insert, and reusable HPDs as acceptable. Recommended training topics included hazardous noise, tinnitus, and permanent hearing loss. The best way to deliver the training was not discussed.

Stephenson (2009) associated five factors with non-use of HPDs: comfort, convenience, cost, communication, and climate. He suggested that training programs should motivate workers to avoid hazardous noise and potential occupational hearing loss. Most importantly, good hearing

and the activities necessary to encourage good hearing must be included in occupational training programs.

Gehler et al. (2011) administered a simple one-on-one training session that resulted in significant improvement of attenuation. The study included 43 subjects and less than half reported having received training on HPDs. Most received training from a co-worker. Prior to receiving formal study-based training, subjects were asked to insert their hearing protectors as they would routinely. The investigators observed that approximately one third of the subjects rolled the earplugs and one fifth took the time to straighten their ear canal prior to insertion. As a result, the group-mean attenuation was 15 dB with some less than 10 dB and no attenuation. A one-on-one six-step training regimen about proper earplug insertion, including a 30-second video clip from the manufacture, was administered for each subject. After the training, the group-mean attenuation improved to 25 dB, which was evidence of a 10-dB increase of noise reduction attributable to the intervention (Gehler et al., 2011).

Verbeek et al. (2009) conducted a review of the literature, specifically about interventions to prevent noise exposure and occupational NIHL. In total, 25 studies were identified, and all included participants exposed to intensity levels that exceeded 80 dBA. Interventions ranged from improving engineering or administrative controls, hearing protection, and monitoring worker audiometric thresholds. No studies were found that directly addressed engineering controls, but many assessed hearing protectors and the effects of hearing conservation programs. Ultimately, the study identified that strict legislation would likely not reduce the noise-intensity levels. The effectiveness of methods to reduce occupational-noise exposure was found to be absent and proper use of hearing protectors relied heavily on training (Verbeek et al., 2009). Perhaps the most striking finding was that evidence of an association between improved hearing

protector use and hearing loss reduction was not found.

Research on HPD Fit-testing

Hearing protection fit testing is becoming more prevalent in hearing conservation programs. It is being used for training and selection of earplugs, verification of adequate protection (versus under-protection or over-protection), medico-legal documentation, employer compliance and effectiveness of the hearing conservation program. Fit testing also contributes to interpretation of clinical data, appropriate allocation of resources for retraining for individuals such as new employees and threshold shift, and the cost of hearing protectors. Earplug fit testing helps employers determine which hearing protection products are most beneficial for their workers (Schultz, 2011). Appropriate selection of a hearing protector is critical because over-protection, or excessive attenuation, could decrease user audibility of warning signals which could increase risk of injury and even death (Byrne, 2013).

Byrne et al. (2016) compared three fit-test systems: the NIOSH HPD Well-Fit, Michael and Associates Fit-Check, and Honeywell Safety Products VeriPRO. In this multi-site study, 20 normal-hearing listeners were recruited at each location. Experience level with HPDs was not a requirement for inclusion. Individuals were trained on fit test procedures and required to record thresholds within 6 dB at each frequency. Different protocols were associated with each fit-test system. For example, the VeriPRO required listeners to match the loudness of tonal stimuli from 250 Hz through 4,000 Hz inter-aurally when (1) unoccluded, then (2) one ear occluded and (3) with both ears occluded. By comparison, Fit-Check records the unoccluded and occluded thresholds from 125 Hz through 8,000 Hz using the Bekésy approach. Although the system can perform monaural measurements, only binaural measurements were obtained for this study. Finally, HPD Well-Fit operates like the Fit-Check system, however HPD Well-Fit uses a method

of adjustment. For HPD Well-Fit, the listener uses a mouse scroll wheel to adjust the presentation intensity to a barely audible level. Howard Leight Airsoft pre-molded earplugs were used for the Byrne et al. (2016) study. Data from two of three systems was in good agreement with ANSI/ASA S12.6 (2008) and measurements from the VeriPRO were not and were below the other fit-test instruments.

Murphy et al. (2016) discussed the use of HPD Well-Fit with 126 off-shore oil-rig inspectors. Having designated a target PAR of 25 dB, they discovered that less than 50% of the group achieved that goal. After refitting and retraining, more than 85% of the group met the 25-dB PAR. During the refitting and retaining processes, various styles and sizes of earplugs were used by workers. If unable to achieve the PAR goal, custom HPDs were ordered for workers. Testing, including retraining, was done in less than 35 minutes and typically lasted 6-8 minutes. Based on group performance, investigators suggested more frequent retraining.

Joseph (2013) stated that employers commonly use a *one size fits most* approach; however, this approach may be risky for some workers due to the highly variable size and shape of the human ear canal. Workers should be afforded a variety of earplug shapes and sizes. It is common for employers to select protectors using the NRR, even though is not a good estimate of real-world attenuation. Another common practice is to use the NRR derating approach, although this produces poor individual-level estimates of attenuation. Joseph (2013) reported a more efficient and accurate method to estimate real ear attenuation at threshold (REAT), revealing that 500 Hz was highly correlated REAT threshold. His screening method stipulated that 500 Hz attenuation measurements below 25 dB are a *bad fit* and 25 dB and above are a *good fit* for 100 dBA exposures. Notably, 500 Hz is a plausible frequency for estimation of REAT because it provides useful information about the depth and seal of the earplug (Joseph, 2013). His protocol,

the Sound Attenuation Fit Estimator (SAFE-500), has a few advantages including ease of administration, test-time efficiency, and reasonable cost of test equipment.

CHAPTER 2

Methodology

Subjects

Eighty normal-hearing students and campus personnel, 18 to 64 years old, will be recruited from Illinois State University (ISU). We will recruit 40 less experienced and 40 more experienced HPD users. They will be qualified if the following is evident:

- (1) able to pass a hearing screening at 25 dBHL for 250 through 4000 Hz
- (2) demonstrates unremarkable cerumen verified by an otoscopic inspection
- (3) has proficiency in English.

Once qualified, hearing protection experience level will be determined with the Hearing Protection Use Questionnaire (HPU-Q), an internally developed, unvalidated survey tool. Four groups of 20 subjects will be formed to examine the augmentation procedures (use of a mirror only, use of a speaker only, or use of a mirror and speaker simultaneously) and a sham condition. Subjects will be randomly assigned to one of the four study groups. Within each group of 20 randomly-assigned subjects, 10 will be from the HPU-Q classified *More Experienced* and 10 will be from the *Less Experienced* pool (see **Figure 1**). All subjects will be consented in the laboratory, brought into an Eckel Industries 8-by-8-foot acoustic enclosure for audiometric and fit-testing, and taken outside the enclosure for the experimental intervention. Qualified participants will be reimbursed \$10 upon completion of the 60-minute research session.

Instrumentation

Mirror

A mirror will be provided for use by Group 2 and Group 4. The hypothesis is that use of the mirror will improve HPD insertion. The mirror 18-by-18-inch mirror will be positioned

approximately 4.5 feet off the ground (**Figure 2**) for the subject to easily visualize their face, specifically their ears. Participants will be instructed to stand no further than two feet from the mirror. A plastic cover will be placed on the mirror for procedures that do not require its use.

Fitting Noise

A speaker will be provided for use by Group 3 and Group 4. The hypothesis is that use of the speaker will improve HPD insertion. The speaker, which is beneath the mirror (**Figure 2**), will be positioned approximately 4.5 feet off the ground for the subject to consistently hear the calibrated fitting noise. Participants will be instructed to stand no further than two feet from the speaker. An intensity level of 80 dBA was chosen for the fitting noise because it is considered safe for an unoccluded ear. This allows for a Minimal Risk classification for a total exposure of two minutes. At 80 dBA, the fitting noise should be loud enough for the subject to perceive an appreciable level of attenuation during the earplug fitting.

The USB hard-wired multimedia speaker routed to a computer will be used to generate the fitting signal. The speaker has a self-contained volume control. The signal used for this experiment will be a relatively flat broadband pink noise (**Figure 3**). It was a continuous pink noise that was ramped up and down to improve stimulus presentation onset and offset during the fitting process. A copy of the looped wave file was saved on the computer and will be presented using Windows Media®. The speaker was placed on a shelf immediately beneath the mirror

HPD Well-Fit

The HPD Well-Fit system by NIOSH is a computer-based earplug fit-test package that uses circumaural headphones (Murphy, 2010). During the time this report was being written, HPD Well-Fit was procured by Kevin Michael and Associates (State College PA) and the commercial product is named Fit-Check Solo®. It was designed to address the need for cost

effective, adaptable, and timely earplug fit-test capabilities using a standard computer. Testing can be administered in two to three minutes. Reliable unoccluded and occluded thresholds may be obtained for three frequencies in this short time (Murphy, 2016). A high-definition audio output board allows HPD Well-Fit (Fit-Check Solo®) to introduce noise-band stimuli while the subject responds with the computer-mouse scroll wheel. The PAR is calculated from an algorithm that was developed by NIOSH developers. This allows the subjects earplug attenuation to be accurately quantified (Murphy, 2013; Murphy 2016). The HPD Well-Fit system can measure a wide range of stimulus frequencies using three modalities: Method of Adjustment, Modified Bekésy, and the Hughson-Westlake. Capable of binaural and monaural measures, HPD Well-Fit provides a dynamic display of the test data during and after the procedure that culminates in a comprehensive test report, including an estimation of A-weighted (dBA) attenuation. Although circumaural headphones are used with the system, ambient noise levels must be compliant with ANSI S3.1-1999 (R-2017), *Ears Covered*, as shown in **Table 1** (from Murphy, 2010).

Acoustic Calibration

Calibration will be conducted weekly to ensure accurate data precision for the length of this study. The HPD Well-Fit stimuli will be transmitted by computer through a sound card via a PreSonus HP-4 4-channel compact headphone amplifier. This amplifier is a stereo AC-powered device, which amplifies the signal from HPD Well-fit. From the PreSonus HP-4 4-channel compact headphone amplifier, the HPD Well-Fit signal will be transmitted through the patch panel in the sound booth, then to a set of Sennheiser HDA-200 headphones that will be retrofitted with well extenders. Of note, the Fit-Check Solo® system no longer uses these headphones. The Sennheiser HDA-200 headphones will be used with an AEC-201 coupler, plate,

and quarter-inch microphone for calibration. Calibration signals will be measured by a Larson Davis 831, AC powered, Type 1 sound level meter (SLM) through a LEMO cable. The Larson Davis 831 sound level meter will be set to its Z-weighted filter (dBZ), which provides the flattest, most linear, response. The SLM will be configured to fast response mode and 1:1 octave band measurement. Measurements will be made at “L,” which reflects the actual intensity level (in dB) for each frequency and will also be measured using “LZ,” which is the actual level in dB according to the dBZ level. Calibration measurements must be within 1 dB of the original (baseline) measurement from week to week, per laboratory policy (personal communication with Joseph, 2017).

Hearing Protection Devices (HPDs)

Howard Light *Disposable Max Uncorded* HPDs will be used for this study. These earplugs are a bell-shaped, tapered polyurethane foam device with an NRR of 33 dB. They are a *one size fits all* product manufactured in a coral color (by Howard Leight, San Diego CA). Both trials of attenuation measurements (i.e., pre-intervention and post-intervention) will be conducted with a new pair of HPDs.

Environment

Participants will receive all audiometric and fit-tests in an acoustic sound-treated enclosure. Our laboratory contains a single-walled Eckel Industries noise control technologies audiometric booth. Booth performance measures were obtained using a precision Type 1 Larson Davis 831 SLM (see **Figure 4** for sound level measurements of enclosure attenuation performance). Overall, the A-weighted measurements were 54.2 dB externally as compared to an internal measurement of 24.2 dB. A difference of 30 dB was indicative of acceptable sound reduction by the enclosure. C-weighted measurements were 63.4 dB externally compared to of

46.6 dB internally. A difference of 16 dB was also acceptable attenuation for purposes of this experiment. Internal Z-weighted (e.g., linear) measurements were obtained with the Type 1 SLM (**Figures 4 and 5**).

Our Eckel Industries sound-treated test booth will be used for all testing. The booth satisfies ANSI S3.1 (1999, R-2013) and OSHA certification requirements. The examiner will be situated in the control area outside the booth, which faces the participant and permits continuous observation during the experimental session. The mirror and speaker will be positioned adjacent to the control area outside the test booth as well.

Procedures

Qualification Testing and Informed Consent

A pure-tone air conduction test will be conducted for each subject that includes 500, 1000, 2000, 3000, 4000, and 6000 Hz. To qualify for the study, participants must have clinically-normal hearing thresholds, defined as equal to, or less than, 25 dBHL. An otoscopic inspection of the external auditory canal and the outer ear structures will be conducted bilaterally. Qualified subjects must have minimal cerumen accumulation and both tympanic membranes must be visible. There cannot be any other medical abnormalities that inhibit subjects from properly inserting HPDs. After these assessments, subjects will be counseled on their test results and informed about their status of qualification or disqualification. If qualified for the study, subjects will be informed and permitted to ask questions about the experiment prior to providing consent. Voluntary consent will be acknowledged by a signature from the subject, to be written on IRB-approved documentation.

Hearing Protection Use Questionnaire (HPU-Q)

The HPU-Q was developed by the Hearing Loss Prevention Laboratory as a dichotomous 6-item, “yes” or “no” response questionnaire used to determine if participants should be categorized as “less experienced” or “more experienced” hearing protection device users. Questions include HPD experience and training status, and history of enrollment in the campus Hearing Conservation Program (see **Appendix A**).

Study Group Assignments

A blocked design matrix will be used to determine which test protocol will be administered for each participant. The matrix will reflect the two arms of hearing protection device users, less experienced or more experienced (**Figure 1**). Additionally, the blocked design counterbalances which ear should be tested first, right ear versus the left ear.

Pre-intervention attenuation measurements

After the consenting process, testing will begin with pre-intervention attenuation measurements. Circumaural headphones will be placed comfortably on the subject for unoccluded thresholds at 500, 1000, 2000, 3000, 4000, and 6000 Hz. Participants will be provided a pair of Howard Leight HPDs and asked to insert them as they would if entering a noisy setting. They will be given at least two minutes to allow the foam ear plugs to expand in place, and then occluded measurements at 500, 1000, 2000, 3000, 4000, and 6000 Hz will be recorded. Measurements will be obtained for the left ear, right ear, and binaurally. As previously mentioned, the design matrix will determine if the left ear or the right ear will be tested first; binaural testing will always follow monaural testing. To complete threshold measures, subjects will be given a wireless mouse with a scroll wheel. They will be instructed to adjust the pulsing sound to the point where they can just barely hear it. At this point, they will right click the mouse to record the threshold. Participants will complete this process at each frequency until three of

their responses are within 5 dB of each other. When finished with monaural and binaural measurements, subjects will be asked to remove their earplugs and exit the test booth.

Intervention

Subjects will be given a new pair of Howard Leight HPDs and receive their assigned earplug fitting augmentative procedure. Group 1 (Control): will be asked to stand outside the booth and conduct a sham task (“breath through your nose while inserting the HPDs”). Group 2 (Mirror only): will be asked to use the mirror to insert their earplugs. Group 3 (Fitting noise only): will be asked to use the 80-dBA fitting noise to insert their earplugs. Group 4 (Mirror and fitting noise): will be asked to use the mirror and the 80-dBA fitting noise to insert their earplugs. All subjects will be asked to insert the earplugs as they would if entering a noisy setting.

Post-intervention attenuation measurements

Testing will conclude with post-intervention attenuation measurements following the earplug augmentative fitting procedure intervention. Circumaural headphones will be placed comfortably on the subject for occluded thresholds at 500, 1000, 2000, 3000, 4000, and 6000 Hz. Subjects will be given at least two minutes to allow the foam ear plugs to expand in place, and then occluded measurements at 500, 1000, 2000, 3000, 4000, and 6000 Hz will be recorded. Measurements will be obtained for the left ear, right ear, and binaurally, according to the design matrix. To complete threshold measures, subjects will be given a wireless mouse with a scroll wheel. They will be instructed to adjust the pulsing sound to the point where they can just barely hear it. At this point, they will right click the mouse to record the threshold. Subjects will complete this process at each frequency, as done for the pre-intervention measures, until three of their responses are within 5 dB of each other. When finished with monaural and binaural measurements, subjects will be asked to remove their earplugs, exit the test booth, and begin the

debriefing process. Attenuation data will be written on the data collection sheets and saved to a secure folder on a Hearing Loss Prevention Laboratory computer using the HPD Well-Fit software and Microsoft Excel spreadsheet.

Database search

To complete an expanded literature review, a database search was conducted, seeking articles that cited Joseph (2007). At the time this report was written, 16 papers were discovered and as more literature were discovered, additional publications were identified by bibliography jumping (**Table 1**). This resulted in an additional 17 papers. The literature search identified publications from 1985 through 2017, and it became evident that there was heightened interest about this subject in 2011 and 2013, given that there were six articles published during that time.

CHAPTER 4

Discussion

This research was conducted to identify a method for investigating earplug-fitting augmentative procedures. Multiple methodological alternatives have been presented in a Study Design Matrix (**Tables 2A-M**). A compilation of earplug-training and related studies has been catalogued in Tables 2A to 2C (title, general summary, and participants), Tables 2D to 2F (hearing requirements, exclusionary criteria, and HPD used), Tables 2G to 2I (attenuation measures, pre-training, and training), Tables 2J to 2L (post-training, conclusions, and other information), and Table 2M (reported limitations). Considering all of the methodologies covered in Tables 2A to 2M, the following EFAP study procedures are suggested: limit session to approximately one hour to minimize subject fatigue, counter balance right ear first versus left ear first condition to reduce an ear effect based on ordering, utilize an equal number of experienced versus inexperienced earplugs users as a difference in attenuation improvement is noted in Murphy et al. (2011), ensure inclusion of control group to determine the effectiveness of the intervention, and exclude individuals with hearing loss to avoid ceiling of attenuation measurements.

As can be seen in Table 2, if a study limitation was presented, it was often related to small sample size or sampling error (Tsukada et al., 2008; Lutz et al., 2015). For most studies, if training was conducted there was an increase in attenuation, (Nodoushan et al., 2014; Takahashi et al., 2011; Tsukada et al., 2008; Joseph et al., 2004; Joseph et al., 2007; Murphy et al., 2011; Stephenson, 2009; Kelly et al., 2015; Murphy et al., 2016).

Recommendations

Training should be concise, lasting 5-10 minutes or less, and should include some form of self-evaluation method as modeled in Takahashi et al. (2011). It is recommended that Table 2 should be used as a guideline for constructing EFAP studies because it culminates the pitfalls listed by research teams within this scope of audiology.

Study Limitations

Study limitations are anticipated that emerged during the investigation. First, the computer-based REAT fit-testing system, NIOSH HPD WellFit, has a ceiling of 95 dB. Hence, this study should only include normal-hearing listeners. Second, there may be limitations discovered later because this procedure has not been formally implemented. When testing the parameters for the study design, we discovered that the Dell® sound interface introduced a sound enhancement feature that caused the headphones to generate a binaural signal although a monaural signal was selected in the software interface. We elected to disengage this feature which repaired the problem.

Future Research

In summary, data-collection should be administered with the test procedures outlined above. Additional research may include a comparison between binaural and monaural REAT thresholds, foam and pre-molded earplugs, and various configurations of foam and push-in earplugs. Handedness is another variable that may impact earplug insertion, so this should be investigated as well.

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TABLES AND FIGURES

Table 1. Database search

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2008	(1) Schultz, T. (2008). PPE Management: What Trainers Need to Know About Fitting Earplugs. <i>Environmental Health and Safety Today</i> , 18-23. (2) Tsukada, T., Sakakibara, H. (2008). A Trail of Individual Education for Hearing Protection with an Instrument that Measures the Noise Attenuation Effect of Wearing Earplugs. <i>Industrial Health</i> , 46, 393-396.
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2006	(1) Rabinowitz, P., Slade, M., Galusha, D., Dixon-Ernst, C., & Cullen, M. (2006). Trends in the Prevalence of Hearing Loss Among Young Adults Entering An Industrial Workforce 1985 to 2004. <i>Ear and Hearing</i> , 27(4), 369-375.
2004	(1) Joseph, A. (2004). Attenuation of Passive Hearing Protection Devices as a Function of Group Versus Individual Training. (Doctor of Philosophy), Michigan State University.
1985	(1) Berger, E. (1985). A New Hearing Protection Attenuation Standard - ANSI S12.6. EARLOG.

Table 2A. Study Design Matrix. Compilation of earplug-training and related studies

Author	Title	General summary	Participants
Joseph et al. (2004, 2007)	Attenuations of Passive Hearing Protection Devices as a Function of Group Versus Individual Training (2004), The effects of training format on earplug performance (2007)	Compares the difference between earplug attenuation following group training versus individual training and if formal training is more effective than no training at all	100 adult listeners, recruited from Michigan State University's student body, listeners were assigned to four independent, gender balanced groups of 25 participants each
Tsukada et al. (2008)	A Trail of Individual Education for Hearing Protection with an Instrument that Measures the Noise Attenuation Effect of Wearing Earplugs	Delivered a two-part training program which included prevention of NIHL and proper use of HPDs	68 male workers exposed to hazardous noise in an electrical equipment parts manufacturing plant
Stephenson (2009)	Hearing Protection in the 21st Century: They're Not Your Father's Earplugs Anymore	Discusses barriers to HPD use and promotes self-efficacy towards HPD use	n/a
Smith (2010)	Real-World Attenuation of Foam Earplugs	Recommends utilizing REAT measurements as opposed to derating to estimate real world attenuation of HPDs	n/a
Schulz (2011)	Individual fit-testing of earplugs: A review of uses	Reviews the purpose of fit-testing	Referenced other studies, no participants for this one
Huttunen et al. (2011)	Symphony orchestra musicians' use of hearing protection and attenuation of custom-made hearing protectors as measured with two different real-ear attenuation at threshold methods	Using a questionnaire, reasons for non-use of HPDs in musicians were identified, attenuation measurements were obtained	15 volunteers from the specified orchestra who owned a pair of musician's earplugs

Table 2B. Study Design Matrix. Compilation of earplug-training and related studies

Author	Title	General summary	Participants
Takahashi et al. (2011)	Improvements in sound attenuation performance with earplugs following checklist-based self-practice	Used a basic checklist to improve placement, subsequently improved attenuation of HPD use	10 subjects (5 men and 5 women), from a university school of medicine
Murphy et al., (2011)	Effects of training on hearing protector attenuation	Compared the effects of three different training modalities using inexperienced HPD users and four different earplugs	8 groups of 20 subjects, recruited from the general population
Nodoushan et al. (2014)	Training in Using Earplugs or Using Earplugs with a Higher than Necessary Noise Reduction Rating? A Randomized Clinical Trial	Compared face-to-face training versus no training when utilizing HPDs with the appropriate NRR; comparison of utilizing HPDs with and without the appropriate NRR	150 workers referred to occupational medicine clinic were randomly assigned to 3 arms (G1-wore earplugs with 25dB NRR with training; G2-earplugs with 25dB NRR without training, G3-earplugs with 30dB NRR without training)
Viallet et al. (2014)	Investigation of the variability in earplugs sound attenuation measurements using a finite element model	Examined the precise manner of how depth and seal can be impacted (frequencies, size of space)	None
Lutz et al. (2015)	Effectiveness Evaluation of Existing Noise Controls in a Deep Shaft Underground Mine	Assessed engineering, administrative, and HPDs using traditional and in-ear dosimetry for miners. Groups were based on job task, work shift, and use of five different earplugs	22 miners followed for a 2-week period (n=56 shifts)
Kelly et al. (2015)	Perceived barriers to hearing protection use by employees in amplified music venues, a focus group study	Utilized focus groups to assess the barriers to HPD use in night clubs	32 participants divided into five focus groups from three different night clubs

Table 2C. Study Design Matrix. Compilation of earplug-training and related studies

Author	Title	General summary	Participants
Murphy et al. (2016)	Hearing Protector Fit-testing with Off-Shore Oil-rig Inspectors in Louisiana and Texas	Using Well-Fit, assess the noise reduction of HPDs for workers, understand length of time needed to complete above measurements, analyze training effectiveness	126 (40 in 2012, 51 in 2013, 35 in 2012 and 2013)
Byrne et al. (2016)	Inter-laboratory Comparison of Three Earplug Fit-test Systems	This study examined three earplug fit-test systems (NIOSH HPD Well-Fit, Michael and Associates Fit-Check, and Honeywell Safety Products VeriPRO) using the Howard Leight Airsoft premolded earplug. An additional site (US Army Aeromedical Research Laboratory) provided data for this paper.	20 participants at each location (total of 80 participants)
Brueck et al. (2016)	Health hazard evaluation report: evaluation of impact and continuous noise exposure, hearing loss, heat stress, and whole-body vibration at a hammer forge company.	Employees' noise exposure was assessed in multiple areas of the workplace. Data was collected on and employees were interviewed about noise exposure, hearing loss, heat stress and hearing protection devices	Visit 1: 10 participants selected at random from a list of 89 production employees (interview privately regarding workplace health conditions); Visit 2: 36 production employers representing 15 job titles (dosimetry- impact noise), reviewed hearing conservation program, Visit 3: whole body and hand-arm vibrations, HPD attenuation, heat stress measurements

Table 2D. Study Design Matrix. Compilation of earplug-training and related studies

Author	Hearing requirement	Exclusionary criteria	HPD used
Joseph et al. (2004, 2007)	Normal tympanograms, bilaterally. Pure-tone hearing thresholds at or below 25 dB HL at 500, 1000, 2000, and 4000 Hz	Normal pinnae and ear canals pathology free or cerumen impaction. No health problems. Ability to read English in small print. No prior experience with HPD. Never had instruction on use of earplugs. No experience with HPD testing. No discussion with another study participant about details of project and available for all phases of required testing and intervention	Formable (EAR Classic), premolded (Howard Leight Fusion)
Tsukada et al. (2008)	At the conclusion of the study, zero participants were diagnosed with NIHL		Earplugs
Stephenson (2009)	n/a	n/a	Many discussed
Smith (2010)	n/a	n/a	n/a
Schulz (2011)	n/a	n/a	n/a
Huttunen et al. (2011)	Not used as a qualifier, however, average hearing loss for the participants was within normal limits, those who had hearing loss, did so in the high frequencies, some individuals had up to a moderate-severe HFHL	n/a	Custom-molded musician earplugs (ER-15)

Table 2E. Study Design Matrix. Compilation of earplug-training and related studies

Author	Hearing requirement	Exclusionary criteria	HPD used
Takahashi et al. (2011)	Baseline audiometry was performed for 125 Hz - 8000 Hz, 15 dB or less for 2000 Hz and below, 25 dB or less for 3000 Hz and higher, differences in hearing level between the right and left ears not exceeding 10 dB	Received training in earplug use, have earplugs in the past month, have used earplugs on a regular basis	Semi-insert E-A-R flex 350-1001 (selected because it was easy to use by inexperienced people, causes minimal discomfort, does not require compression of plug portion), should minimize differences between individuals
Murphy et al., (2011)	25 dB or less at all frequencies	Received individual, video or group training regarding the fit and use of HPDs or if they have used HPDs in the past year	Moldex Pura-Fit, E-A-R Classic foam earplugs, Howard Leight Fusion, AirSoft pre-molded earplugs
Nodoushan et al. (2014)	Baseline audiometry was performed for 500, 1000, 2000, 3000, 4000, 6000, and 8000 using air and bone conductions, thresholds must be less than 25 dBA and the difference between two adjacent frequencies must be less than 10 dBA	Those with a history of participating in a training program on proper usage of earplugs during last two years, those with a history of wearing earplugs more than six times during the previous two years, those with conductive or sensorineural hearing loss detected at baseline audiometry	Pre-molded, one-size, Moldex Comets EN 352, one with an NRR of 25 and another with an NRR of 30
Viallet et al. (2014)	None	n/a	n/a
Lutz et al. (2015)	22 miners followed for a 2-week period (n=56 shifts)	None	None
Kelly et al. (2015)	32 participants divided into five focus groups, from three night clubs	None	None

Table 2F. Study Design Matrix. Compilation of earplug-training and related studies

Author	Hearing requirement	Exclusionary criteria	HPD used
Murphy et al. (2016)	126 (40 in 2012, 51 in 2013, 35 in 2012 and 2013)	None	None
Byrne et al. (2016)	20 participants at each location (total of 80 participants)	125 to 8000 Hz less than or equal to 25 dB HL	None
Brueck et al. (2016)	Visit 1: 10 participants selected at random from a list of 89 production employees (interview privately regarding workplace health conditions); Visit 2: 36 production employers representing 15 job titles (dosimetry-impact noise), reviewed hearing conservation program, Visit 3: whole body and hand-arm vibrations, HPD attenuation, heat stress measurements	Retrospective analysis: 7908 audiograms (618 current or former employees) for years 1981-2006; 0.5-6kHz; after quality analysis 4750 audiograms from 483 were included, of these 82% had a NIOSH shift and 63% had an OSHA shift	None

Table 2G. Study Design Matrix. Compilation of earplug-training and related studies

Author	Attenuation measures	Pre-training	Training
Joseph et al. (2004, 2007)	REAT	No assistance provided to subjects, however, they were provided with the instructions found on the packaging. Completed the NIOSH Hearing Loss Prevention Attitude Belief (HLPAB) survey.	Individual training: examiner inserted the earplugs for the participants to demonstrate appropriate fit. Group Training: Examiner observed the practice part of the training session. Completed the HLPAB survey
Tsukada et al. (2008)	REAT	Pre-education questionnaire asking about earplug use	Two-part training exercise followed by a two month follow up. (1) Group instruction regarding the prevention of noise induced hearing loss (2) Individual instruction of the proper use of earplugs (3) Usage rate and proper use of HPDs were examined. First sequence: Group instruction prevention of NIHL for about 2 hours. Second sequence: Individual instruction of the proper use of earplugs.
Stephenson (2009)	n/a	n/a	n/a
Smith (2010)	n/a	n/a	n/a
Schulz (2011)	n/a	n/a	n/a
Huttunen et al. (2011)	REAT, sweeping signal (Bekésy audiometry)	n/a	n/a

Table 2H. Study Design Matrix. Compilation of earplug-training and related studies

Author	Attenuation measures	Pre-training	Training
Takahashi et al. (2011)	REAT	Allowed workers to place the HPDs prior to intervention by reading only the printed instructions	(1) Individual five-minute training with oral and written instructions and a 10-minute self-practice each day for 7 days with a daily check list. Checklist included three Y/N questions on wore earplug use and practice compliance.
Murphy et al., (2011)	REAT	n/a	Three training methods: (1) Video instruction. Added video training specific to each earplug, instructions to select the correct HPD, and performing a self-check of the fit using their voice. (2) Written instructions: participants given written instructions from manufacturer posted on package. (3) Individualized five to 10-minute, one-on-one training session.
Nodoushan et al. (2014)	REAT	n/a	Group 2 only: 15-minute session on correct methods of wearing the earplugs and placing the earplugs correctly under direct supervision
Viallet et al. (2014)	Test figure	None	None
Lutz et al. (2015)	REAT	Assessed	Complete, unknown extent
Kelly et al. (2015)	n/a	n/a	n/a

Table 2I. Study Design Matrix. Compilation of earplug-training and related studies

Author	Attenuation measures	Pre-training	Training
Murphy et al. (2016)	Well-Fit, goal to achieve 25 dB PAR	None, less than 50% obtained the goal PAR	Refit and retraining (not specified)
Byrne et al. (2016)	REAT, VeriPro (loudness matching), Fit-Check (Bekésy), HPD WellFit (method of adjustment)	Trained in the psychophysical test method used in the laboratory REAT system (previous three test responses must be within 6 dB for each frequency)	None
Brueck et al. (2016)	Acoustic mannequin head, research fit devices	None	None

Table 2J. Study Design Matrix. Compilation of earplug-training and related studies

Author	Post-training	Conclusions	Other
Joseph et al. (2004, 2007)	n/a	HPD use improved with training, but there was no statistically significant difference between the training methods (individual versus group)	n/a
Tsukada et al. (2008)	Post-education questionnaire and proper use of HPDs via attenuation measurements were examined	Improved usage rate (56% to 63%), non-use rate (19% to 9%), attenuation (46% pre-training, 72% directly following training, and 62% two months post-training).	n/a
Stephenson (2009)	n/a	Appropriate selection and training of HPDs can increase HPD use.	n/a
Smith (2010)	n/a	VeriPro and Fit-Check allow for adequate attenuation measures to improve worker protection.	n/a
Schulz (2011)	n/a	n/a	n/a
Huttunen et al. (2011)	n/a	Bekésy audiometry was more accurate through 1kHz and at 8kHz whereas REAT measurements were more accurate 1kHz through 6kHz, individuals need to adapt to the auditory changes that occur due to HPD use	n/a

Table 2K. Study Design Matrix. Compilation of earplug-training and related studies

Author	Post-training	Conclusions	Other
Takahashi et al. (2011)	n/a	NRR was increased by 16 dB following intervention	n/a
Murphy et al., (2011)	n/a	Inexperienced subjects did not improve from use of the manufacturer (written) instructions compared to the video training method. Individualized training makes the difference in adequate HPD use.	n/a
Nodoushan et al. (2014)	n/a	Higher attenuation for trained individuals	n/a
Viallet et al. (2014)	None	Frequencies below 1kHz are most impacted by depth and can worsen the attenuation by 20-25 dB. Mid-frequencies (1kHz through 5kHz) were impacted about 5 dB. A poor seal can impact the low frequencies and is dependent on the size of the leak.	Spaces such as creases of 2mm cause decreases in attenuation by about 10 dB and leaks of 5mm reduce the attenuation by about 20 dB
Lutz et al. (2015)	None	Author challenged engineering and administrative controls, regular training and fit-testing of HPDs.	n/a
Kelly et al. (2015)	n/a	Recommended topics of training included hazardous noise, tinnitus, and hearing loss (authors did not recommend the best way to deliver this training).	n/a

Table 2L. Study Design Matrix. Compilation of earplug-training and related studies

Author	Post-training	Conclusions	Other
Murphy et al. (2016)	Over 85% obtained goal PAR	Suggested retraining more frequently than annually.	Well-Fit is the fastest fit testing program on the market
Byrne et al. (2016)	None	The data from two of three systems was in good agreement with ANSI/ASA S12.6-2008. Attenuation from the VeriPRO were reduced when compared to results obtained from the Fit-Check and HPD Well-Fit systems.	N/a
Brueck et al. (2016)	None	Company was advised to increase engineering and administrative controls and to improve personal protective equipment.	n/a

Table 2M. Study Design Matrix. Compilation of earplug-training and related studies

Author	Reported limitations
Takahashi et al. (2011)	Small sample size
Lutz et al., (2015)	Limitations of this work suggested by the research team, include a small sample size, inability to assess proper HPD fit during data collection (researched were not permitted in the mine shafts), and the exclusion of assessment for HPD training.
Kelly et al. (2015)	Focus group data cannot be overly generalized

Figure 1. Experimental study groups

Group 1e: Control Group 10 Experienced Male	Group 2e: Mirror Only 10 Experienced Male
Group 1i: Control Group 10 Inexperienced Male	Group 2i: Mirror Only 10 Inexperienced Male
Group 3e: Fitting Noise Only 10 Experienced Male	Group 4e: Fitting Noise + Mirror 10 Experienced Male
Group 3i: Fitting Noise Only 10 Inexperienced Male	Group 4i: Fitting Noise + Mirror 10 Inexperienced Male

Figure 2. Mirror and speaker configuration



Figure 3. Fitting noise 80-dBA broadband pink noise generated by sound bar (1ft, 2ft)

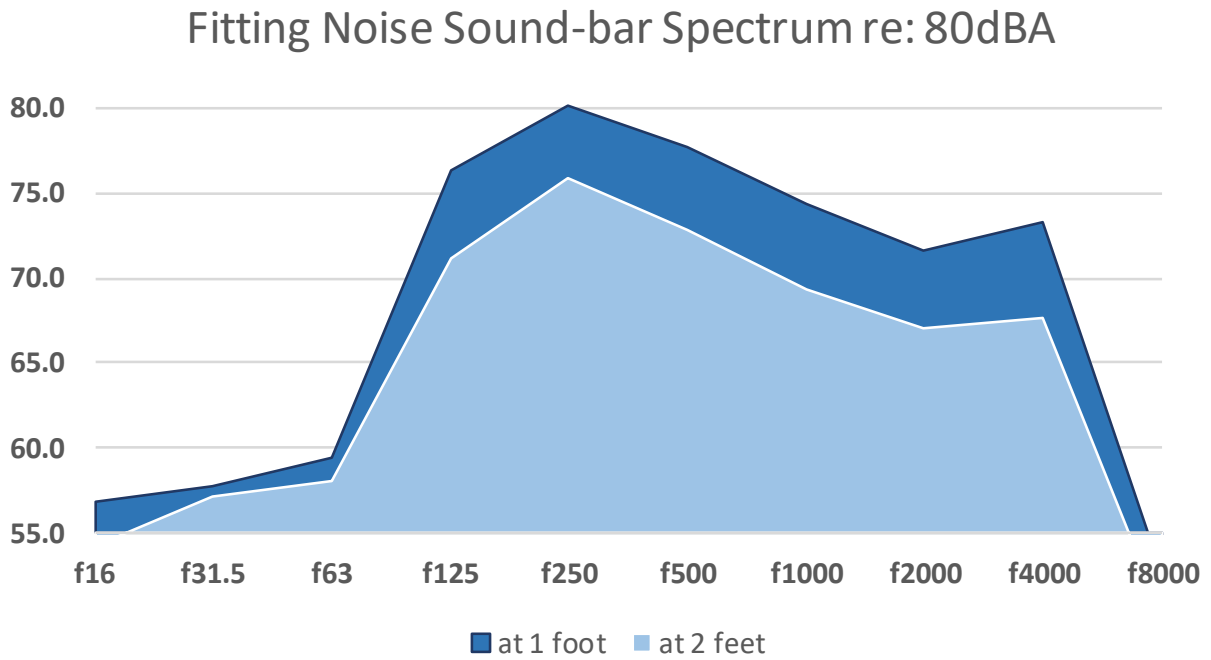


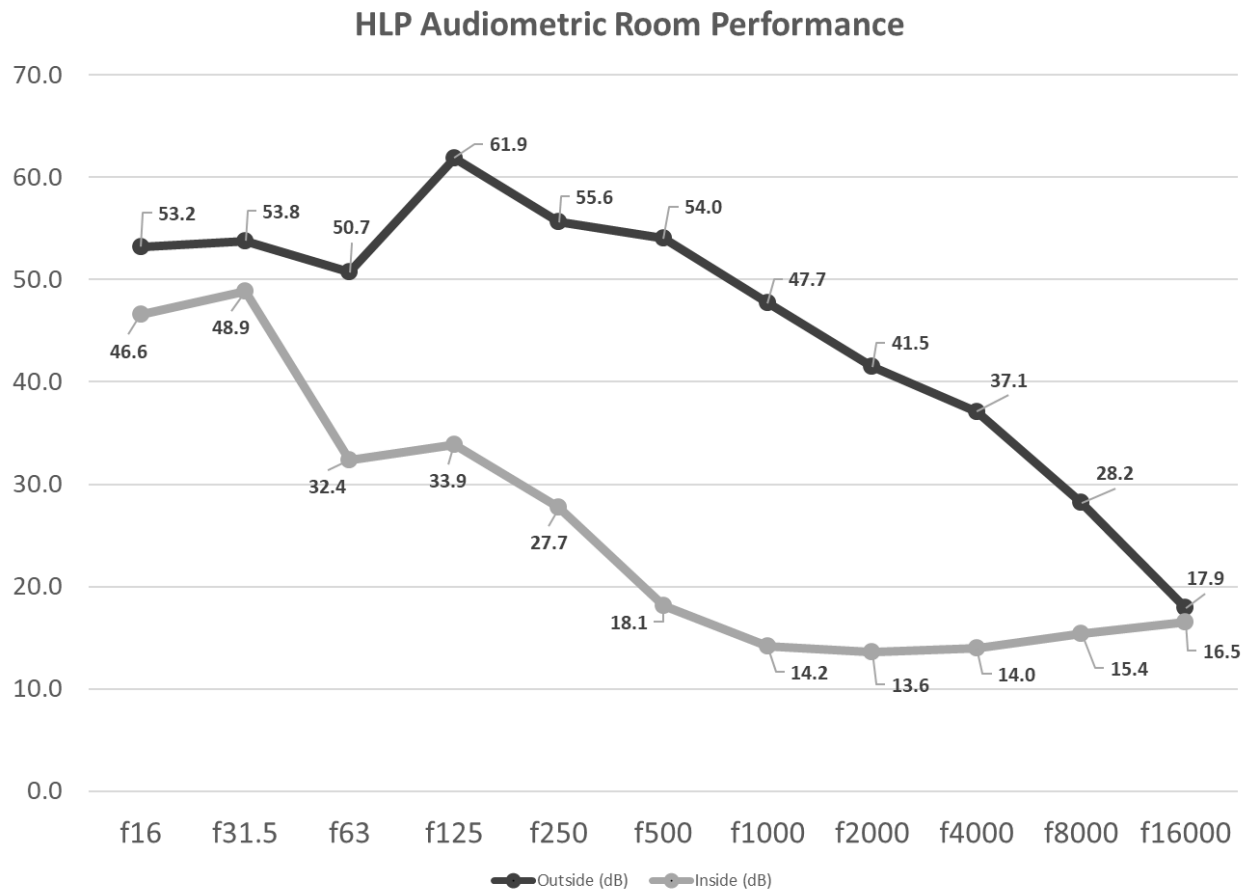
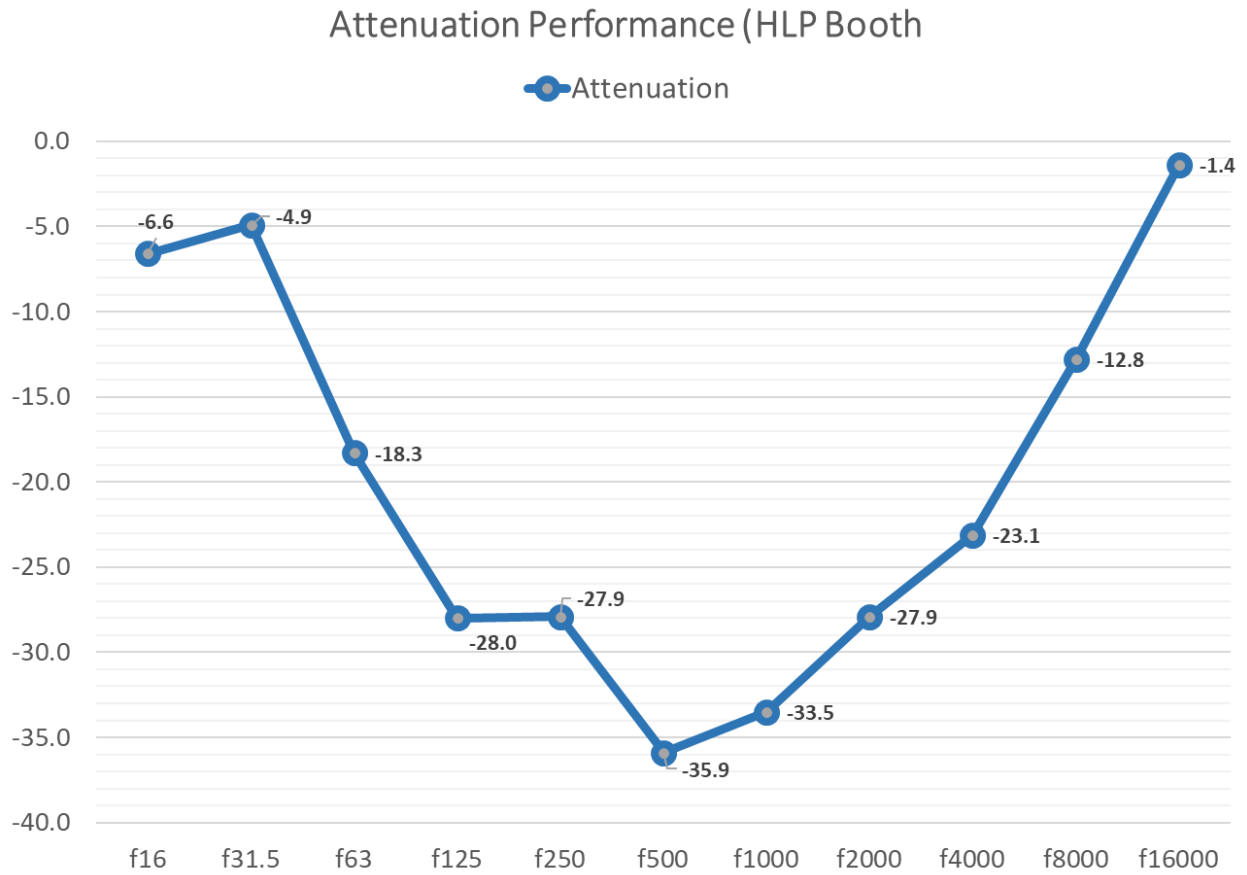
Figure 4. Test booth sound level measurements for enclosure internal-external measures

Figure 5. Test booth sound level measurements for enclosure attenuation performance

Appendix A

Hearing Protection Use Questionnaire (HPU-Q)

Subject IDN: _____ Date: _____ P/AI: _____

The Hearing Protection Use Questionnaire (HPU-Q) is designed to be used with individuals who are interested in study participation. This tool should crudely classify participants as “less experienced” or “more experienced” hearing protection users.

Instructions: Please do your best to answer “Yes” or “No” to the following questions:

- | | | |
|---|----------|---------|
| 1. Have you used swim plugs in the past 12 months? | [YES] +1 | [NO] +0 |
| | _____ | |
| 2. Have you received instruction on the use of earplugs within the past 6 months? | [YES] +1 | [NO] +0 |
| | _____ | |
| 3. Are you required to use hearing protection because of your job responsibilities? | [YES] +1 | [NO] +0 |
| | _____ | |
| 4. Are you enrolled in a Hearing Conservation Program at Illinois State University or somewhere else? | [YES] +1 | [NO] +0 |
| | _____ | |
| 5. Have you used a foam earplug in one or both ears within the past year? | [YES] +1 | [NO] +0 |
| | _____ | |
| 6. Have you used a foam earplug in one or both ears at least once per month for the past 6 months? | [YES] +1 | [NO] +0 |
| | _____ | |
| 7. Have you used a foam earplug in one or both ears at least once per week for the past 6 months? | [YES] +1 | [NO] +0 |
| | _____ | |
| <hr style="border: 0.5px solid black;"/> | | |
| Have you had discussions with another study participant who revealed details about this project? | [YES] +1 | [NO] +0 |
| | _____ | |

Classification: ___ **More Experienced** (score: 3 points or greater)

 ___ **Less Experienced** (score: less than 3 points)