Evaluating Earplug Performance over a 2-Hour Work Period with a Fit-Test System

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ABSTRACT

Workers rely on hearing protection devices to prevent occupational noise-induced hearing loss. This study aimed to evaluate changes in attenuation over time for properly fit devices when worn by workers exposed to hazardous noise. Earplug fit testing was accomplished on 30 workers at a brewery facility with three types of foam and three types of premolded earplugs. The personal attenuation ratings (PARs) were measured before and after a 2-hour work period while exposed to hazardous noise levels. The minimum acceptable initial PAR was 15 dB. Average decreases in PAR ranged from −0.7 to −2.6 dB across all six earplug types. Significant changes in PAR were observed for the Foam-1 ($p = 0.009$) and Premold-3 ($p = 0.004$) earplugs. A linear mixed regression model using HPD type and study year as fixed effects and subject as random effect was not significant for either fixed effect ($\alpha = 0.05$). Ninety-five percent of the final PAR measurements maintained the target attenuation of 15 dB. Properly fitting earplugs can be effective at reducing worker's noise exposures over time. The potential for a decrease in attenuation during the work shift should be considered when training workers and establishing the adequacy of protection from hazardous noise exposures.

KEYWORDS: hearing protection, fit testing, personal attenuation rating, duration, noise exposure, occupational hearing loss

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Globally, occupational hearing loss is a significant problem for noise-exposed workers. The World Health Organization (WHO) estimates that 6.1% of the world's population have disabling hearing loss.[1,2] Twenty-five percent of U.S. workers self-reported that they had a history of occupational noise exposure.[3] Approximately 22 million Americans are occupationally exposed to hazardous noise levels 85 A-weighted decibels or above.[4] For many workers, using hearing protection devices (HPDs) is the only available option for preventing noise-induced hearing loss (NIHL) due to the lack of engineering noise controls.[5,6]

Numerous studies have suggested that many workers do not wear their hearing protectors correctly or consistently, and, as a result, are not fully protected.[4,6,7] One-on-one training combined with HPD fit testing can effectively teach workers to properly fit/use HPDs and achieve sufficient attenuation.[8–10] However, HPD fit testing provides only an estimate of the attenuation measured at a given point in time while the test subject sits without any movements.[11] In contrast, workers in many jobs are physically active and engaged in physical movements such as walking, head and neck motion, bending, lifting heavy items, talking, yawning, and sometimes even drinking, eating, or chewing gum while wearing HPDs on the job. Some of these activities may cause movement of the temporomandibular joint and anatomical changes in the shape of the ear canal. These fit-testing measurements may not reflect the attenuation provided during work activity or when worn for extended periods.

Several laboratory studies have examined whether extensive jaw movement reduced hearing protector attenuation. Depending on the type of HPD worn, the attenuation can be reduced.[12–14] Casali and Park simulated highly kinematic, strenuous work activity in a laboratory setting to estimate the influence of movement activity during the HPD wearing period on the achieved attenuation of four different HPDs.[15] They found that movement activity significantly reduced frequency-specific attenuation up to 6 dB. In a subsequent study, Casali and Park extended the laboratory research to the field by measuring the noise attenuation obtained over two consecutive 3-week periods of HPD use in the workplace.[16] On average, laboratory attenuation measurements were found to overestimate the field performance by 5.7 to 10 dB depending on the type of earplug (foam or premolded) and fitting method (subject-fit or trained-fit).

Those studies generally pointed out that jaw movements and work-related activity may reduce the attenuation provided by HPDs over time in both the laboratory and field-test settings. However, none of the studies were conducted with workers who properly fit their earplugs to a targeted minimum personal attenuation rating (PAR) reference value sufficient to afford adequate noise protection in the workplace prior to engaging in mobile work activity. Furthermore, it is unknown whether potential changes in attenuation differ as a function of earplug type (e.g., foam vs. premolded earplugs) when measured on workers in a field setting. With these questions in mind, this study was designed to measure PARs of foam and premolded earplugs, fit to a minimum PAR value of 15 dB, and determine if attenuation changes over the course of a 2-hour wear period while engaged in physically active work duties.

MATERIALS AND METHODS

Overview

This study was approved by the NIOSH Institutional Review Board (IRB). Workers volunteering for the study were consented according to the IRB protocol (HSRB 13-DART-01XP) and completed informed consent forms in the presence of the researcher and/or research assistant. All workers were enrolled in a hearing conservation program as mandated by the Occupational Safety and Health Administration (OSHA).[17] A total of 30 workers were enrolled from a Colorado brewery facility during the years 2013 to 2015. During each year, the attenuation of a premolded and foam earplug was evaluated with about 20 workers (see Table 1 and Fig. 1). The PARs were evaluated at the beginning and end of a 2-hour work period for each participant and earplug type. The equivalent continuous A-weighted sound pressure levels (L_{Aeq}) were

Table 1 Study year, number of subjects, number of fit-testing sessions, subject retention, age, and sex

Study year	Subjects (*n*)	Study sessions	Subject retention from 2013 *n* (%)	Age (years)	Sex
2013	20	40	NA	37.1 ± 9.0	95% male 5% female
2014	21	42	14 (70%)	38.0 ± 6.9	90% male 10% female
2015	19	37[a]	9 (47%)	37.6 ± 6.8	95% male 5% female
All years	30	119	–	36.9 ± 7.1	90% male 5% female

[a]One subject was dismissed for the Premold-3 earplug.

measured with personal noise dosimeters over the same 2-hour work period. Each of these methods is described in detail later.

Worker Recruitment and Eligibility Screening

Workers whose job tasks included bodily motion and not sedentary work activity were identified through health and safety personnel at the brewery. Workers were recruited at the brewery over a 1-week period to maximize efficiency. The brewery operated four rotating 12-hour work shifts and workers were recruited from all four work shifts. Researchers attended the weekly safety meetings held for each of the work shifts to describe the research study and answer questions. Consented workers were

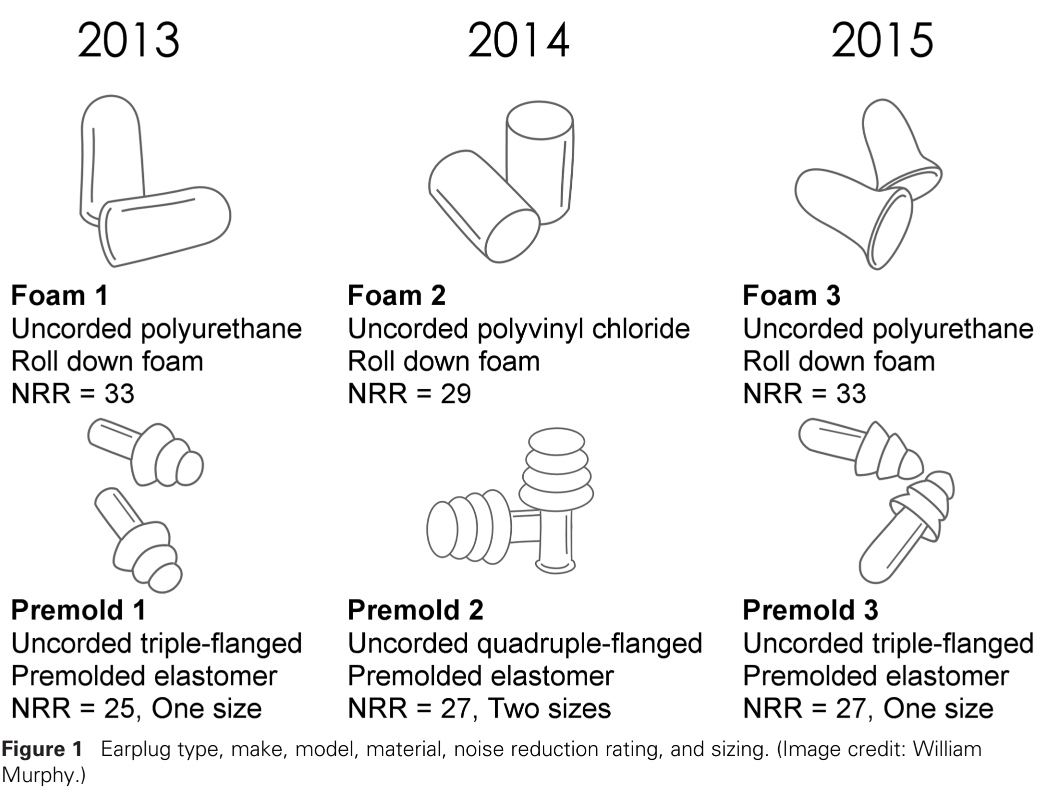

Figure 1 Earplug type, make, model, material, noise reduction rating, and sizing. (Image credit: William Murphy.)

scheduled for preliminary screening for study eligibility prior to study testing.

The study inclusion criteria were (1) English language speaking, (2) sufficient manual dexterity to insert hearing protection properly, (3) clear ear canals upon otoscopy (tympanic membrane was clearly visible), (4) normal tympanogram peak pressure (-150 to $+50$ da Pa) and normal ear canal volume (< 2.5 mL), and (5) pure-tone thresholds ≤ 35 decibels hearing level (dB HL) at 500, 1,000, and 2,000 Hz, and no more than a 15-dB asymmetry between thresholds in each ear. Otoscopy, audiometry, and tympanometry were performed by experienced audiology graduate student researchers under the supervision of a licensed audiologist.

The tympanometry and air-conducted pure-tone audiometry were conducted in a sound-treated booth located in the mobile trailer parked at the facility. The maximum permissible ambient noise levels (MPANLs) inside the booth met ANSI S3.1-1999 (R2018) guidelines for ears-covered testing from 500 to 8,000 Hz. Annual calibrations for the Benson Medical CCA-200mini audiometers were available and daily calibrations were performed using a Benson Medical bioacoustic simulator BAS-200slm. Ambient noise levels were measured continuously during audiometry using the BAS-200slm and testing was temporarily paused when MPANLs exceeded ANSI standards, such as passing truck traffic or other ambient noise.

Participant Enrollment

A total of 30 workers experienced with using hearing protectors participated in this study. The study was not designed to be longitudinal, but data were collected over the course of 3 years to minimize the impact on the employer. Nine workers (30%) participated in all three study years and were tested with different hearing protectors. If workers were unavailable in years 2 and 3, they were replaced with new participants. Participants' age ranged from 25 to 56 years and 95% of participants were male, consistent with the worksite demographics (see Table 1). During each study year, approximately 20 recruited workers participated in one session wearing foam earplugs and another session wearing premolded earplugs. While the workers were wearing the earplugs being evaluated, they were observed by one of the research personnel to ensure that they did not manipulate the protectors. All workers were compensated $100 for each earplug test session. In the first year, all workers received an additional $50 completion incentive for completing both types of earplug fit-testing sessions. In second and third years, no additional completion incentive was provided.

Work Activity

The study participants worked in the filling and packing area of the brewery facility. Their daily tasks included filling, drying, labeling, packing, and loading of bottles, cans, and kegs. Maintenance and utility workers were also recruited. Worker movements included walking around for equipment checks, bending and squatting, and moving their head from side to side or up and down. Packaging/loaders engaged in lifting, twisting, and jumping on and off forklifts when moving pallets and loading trucks. No food or chewing gum was allowed in the brewery production areas. The workers occasionally spoke to each other when working, but were not interrupted by phone calls during the work period.

Noise Measurements

Before the fit testing, workers were instructed on how to wear the noise dosimeter during a 2-hour HPD wear period. The 3M Edge 5 personal noise dosimeter (3M, United States) was positioned on the worker's shoulder after the hearing protector fit testing was completed. Workers were advised that they should not tamper with or remove the dosimeter. Researchers stopped the noise dosimeter after 2 hours to prevent accumulating additional noise measurements while walking to the mobile trailer. The noise measurement protocol was consistent with NIOSH recommendations for workplace noise exposure sampling,[1] except that in the first year the setup used a threshold level of 90 dBA sound pressure level (SPL) rather than 80 dBA SPL as specified and used in subsequent years. Before the noise measurement, each

Table 2 Summary of the mean noise exposures, $L_{Aeq,2h}$, and the mean run time for the dosimeter measurements for each study year and model earplug

Study year	Earplug type	Run time HH:MM:SS	NIOSH $L_{Aeq,2h}$ (dBA)
2013	Foam-1	2:05:40	86.6 ± 3.6
	Premold-1	2:05:47	87.0 ± 3.4
2014	Foam-2	2:04:09	86.7 ± 3.8
	Premold-2	2:04:03	87.7 ± 3.3
2015	Foam-3	2:01:58	86.9 ± 2.1
	Premold-3	2:03:23	88.0 ± 3.1

Notes: The dosimeter was configured with a 3-dB exchange rate, A-weighting, and SLOW time constant. The threshold settings are described in the "Materials and Methods" section.

dosimeter was calibrated using a 3M Quest QC-10 calibrator (TSI, United States). At the end of the 2-hour noise sampling time, the worker returned to the mobile test van. The noise dosimeter was removed before the final earplug fit-testing measurement. The L_{Aeq} sampled over the 2-hour earplug wearing time ($L_{Aeq,2h}$) was downloaded from the dosimeters using 3M Detection Management Software.

Hearing Protection Devices and Fit Testing

The field attenuation estimation system used in this study was HPD Well-Fit™, which is a product marketed as FitCheck Solo by Michael and Associates, developed by and licensed from NIOSH. HPD Well-Fit uses a real ear attenuation at threshold (REAT) under headphones approach.[10] The system determines the hearing threshold difference measured with HPDs (occluded) and without HPDs (unoccluded) worn by the workers. The system calculates PAR as an A-weighted attenuation value in units of dB. HPD Well-Fit can be used to test any type of earplug and provides a quantitative measure of noise attenuation. For this study, fit testing was sequentially performed at 500, 1,000, and 2,000 Hz using the method of adjustment paradigm. The paradigm used a 2-dB step when descending and a 1-dB step when ascending. The subject was required to identify three consecutive thresholds with a range of no more than 6 dB. Following each threshold identification, the stimulus was increased a random amount between 10 and 20 dB.[10] The fit testing was conducted in the same sound-treated booth as audiometry.

Each worker participated in two fit-testing sessions with a pair of foam and a pair of premolded earplugs during each study year, respectively. A total of three foam and three premolded earplugs were tested with noise reduction ratings (NRRs) between 25 and 33 dB (see Fig. 1). The Premold-2 earplug was available in regular and small sizes. The research assistant would select the earplug size based on visual inspection and otoscopy of the ear. If the minimum PAR was not achieved, a refit or alternative size was attempted to obtain the minimum PAR. Each worker was issued a new package of earplugs for each test session. The testing order of earplug type was randomized during each study year to eliminate any order effect between sessions. Earplugs were fit tested before each session to ensure that they achieved at least 15 dB PAR. The fit-testing measurement sessions were conducted according to the following procedure during each study year.

Session 1: Initial fit testing was conducted with the first type of earplug. Unoccluded testing (without earplugs) was done first, followed by the occluded condition (with earplugs). When foam earplugs were tested, a 2-minute waiting period preceded the occluded test to ensure that the earplugs had fully expanded. Workers with a PAR of at least 15 dB in each ear were immediately enrolled in the study, and the PAR score was recorded as the initial PAR. Workers with a PAR less than 15 dB were individually trained by the researcher or research assistant, refit and retested. If a satisfactory PAR (≥15 dB) was obtained on the second trial, the worker was enrolled in the study and the second PAR was recorded as the initial PAR score. Workers who were unable to achieve a satisfactory PAR after retraining and refitting were dismissed from the study and partially compensated. Only one subject was dismissed during this study (Year 3 cohort).

Prior to the initial fit testing, workers were instructed regarding the upcoming 2-hour HPD wear period and the subsequent repeat HPD fit testing. It was emphasized that once the hearing protector fit testing was completed and an acceptable minimum PAR achieved ($\geq$15 dB), the worker should not manipulate or remove the HPDs in any way until they were instructed that the 2-hour wear period had ended. Once the initial hearing protector fit testing was completed, the researcher carefully placed large-volume electronic sound restoration earmuffs over the ears of the worker without disturbing the earplug fittings or contacting the stem of the earplugs. Because the protectors were fitted properly, the potential for contact with the interior of the large-volume sound restoration earmuffs was minimized. The earmuffs ensured that workers would not inadvertently adjust their earplugs during the work period and allowed for communication and audibility while performing their job duties and participating in the study. The volume setting on the earmuffs were adjusted by the worker. Additionally, the worker would also be adequately protected from hazardous noise exposure if an earplug fitting failed while working during the wear-period. The workers were advised that their compliance with HPD wear and work activity would be visually monitored by a researcher or research assistant throughout the 2-hour work period. The workers were also instructed to notify the observer if a subjective change in hearing protector attenuation was noticed.

At the end of the 2-hour wear time, the research assistant notified the worker and stopped the noise dosimeter, then accompanied the worker back to the mobile test van. The dosimeter was removed, and then repeat fit testing was conducted. Occluded testing was done first, followed by the unoccluded condition. This repeat PAR was recorded as the "final PAR." Workers were then de-briefed regarding the outcomes from the study measurements and scheduled for the second earplug type session (typically after their break or meal-break).

Session 2: Workers who finished session 1 subsequently participated in session 2 with a different type of earplug. Earplug fitting, hearing protector attenuation measurements, earmuff fitting, noise dosimeter measurements, and worker observations were conducted in the same manner as described for session 1.

A total of 119 study sessions were conducted during the 3-year study timeframe (see Table 1). One subject was dismissed on one earplug at study year 3. The majority (97%) of the workers completed both sessions on the same day over the course of 5.5 to 6 hours (not including meal or meeting breaks). The other 3% completed the two sessions across two adjacent workdays. Only one worker was tested at a time during any particular work shift at the plant.

Data Validation and Analysis

The experimental data were maintained and merged into Excel for data analysis on secure laptop computers. All experimental data were de-identified and coded by subject number. To validate the PAR results, the unoccluded thresholds measured before and after each study session were compared. If the changes in unoccluded threshold at each frequency (500, 1,000, and 2,000 Hz) were within a range of less than 6 dB, then the corresponding PARs were considered valid measurements and included for the data analysis.[10] Two subjects (S107 and S111) were categorized as invalid results based on these criteria, which removed data from 10 of the 119 test sessions. Next, the valid attenuation values were adjusted for bone conduction limits,

$$\text{BC Atten} = -10\ \log_{10}\left(10^{\left(\frac{-\text{Atten}(f)}{10}\right)} + 10^{\left(\frac{-\text{BCLimits}(f)}{10}\right)}\right),$$

where the Atten(*f*) are the attenuations measured at frequencies, *f*, 500, 1,000, and 2,000 Hz, and the BCLimits(*f*) are 61, 49, and 41 dB at the same frequencies, respectively.[18,19] In general, the 41-dB bone-conduction limit at 2,000 Hz is the limiting factor for estimating the PAR.

A change in PAR (initial PAR–final PAR) more than 15 dB was considered a "fitting failure" and results were excluded from subsequent analysis. Five persons had a fitting failure and were removed from 5 of the 109 test sessions. Finally, a total of 104 test sessions were valid for the subsequent analysis.

Statistical analyses were performed with SAS (Release 9.4; SAS Institute, Inc., Cary, NC). Descriptive statistics of initial and final PARs were calculated. Paired *t*-tests were used to test the significance of the differences between initial and final PARs since they were normally distributed except for the final PARs of the Premold-1 and Premold-3 earplugs. A linear mixed regression model of the data was generated using hearing protector type and year as fixed effects and subject as a random effect. Since workers were recruited across all shifts, the work shift was not included as a factor in the analysis. Statistical significance alpha levels were set at 0.05.

RESULTS

Noise Exposure

The personal noise exposure obtained during the 2-hour work period ($L_{Aeq,2h}$) ranged from 80 to 93 dBA. The $L_{Aeq,2h}$ was determined using the configuration described in the methods. The mean for all measurements $L_{Aeq,2h}$ was 87.2 dBA and were generally consistent across all study years and job category (Table 2).

Initial and Final PAR Outcomes

The initial PARs without correction for bone conduction limits for all tested earplugs ranged from 15 to 48 dB with a mean PAR of 27.7 dB, and a standard deviation (SD) of 7.0 dB. After 2-hour wearing with normal work activity, the final PARs ranged 0.3 to 41 dB, with a mean PAR of 25.3 dB, and a SD of 7.5 dB.

Five subjects experienced a fitting failure (> 15 dB change in PAR from initial to final). The fitting failures included two subjects wearing the Premold-1 earplug in year 2013, and three subjects wearing the Premold-2 earplug in year 2014 (two subjects wearing the small size, and one wearing the regular size). There were no fitting failures observed for foam earplugs or for the Premold-3 earplug. Table 3 summarizes the mean PAR values with correction for bone conduction limits by earplug type. Note that all the mean PAR changes appear to indicate a slight loss of attenuation (−0.7 to −2.6 dB). Ninety-five percent of the subjects (99 out of 104) maintained the target attenuation of 15 dB for the final PAR measurement.

The trends from the initial PAR (dB) to the final PAR (dB) are shown for each subject without a fitting failure in Fig. 2. Each earplug model is shown in a separate panel of the figure. The lines connect the subjects' initial and final PARs. Circles were used for the plugs in the first year, squares for the second year, and diamonds for the third year.

Change in PAR over 2-Hour Wear Period

The change in PAR (dB) reflects the difference between the final PAR measurement and the initial PAR measurement. Negative changes correspond with a loss of attenuation, while

Table 3 Descriptive statistics and paired *t*-test on initial and 2-hour final PARs

Earplug	*N*	Initial PAR (dB)		Final PAR (dB)		Change in PAR (final–initial) (dB)		*t*	*p*-Value $p < 0.05^a$
		Mean	SD	Mean	SD	Mean	SD		
Foam	55	29.4	6.4	27.9	6.9	−1.5	3.2	3.500	0.001[a]
Foam-1	18	31.5	7.8	29.4	9.2	−2.1	3.0	2.970	0.009[a]
Foam-2	19	29.1	6.3	27.9	5.7	−1.2	3.2	1.690	0.109
Foam-3	18	27.5	4.4	26.4	5.1	−1.1	3.3	1.440	0.168
Premolded	49	25.1	5.8	23.2	4.9	−1.9	4.4	2.940	0.005[a]
Premold-1	16	24.0	3.6	23.2	4.2	−0.7	2.5	1.140	0.272
Premold-2	16	26.6	7.4	24.4	5.3	−2.2	6.6	1.360	0.195
Premold-3	17	24.7	5.6	22.1	5.1	−2.6	3.2	3.360	0.004[a]
Overall	104	27.4	6.5	25.7	6.4	−1.7	3.8	4.480	<0.001[a]

[a]Changes in personal attenuation rating (PAR) were statistically significant at $p < 0.05$.

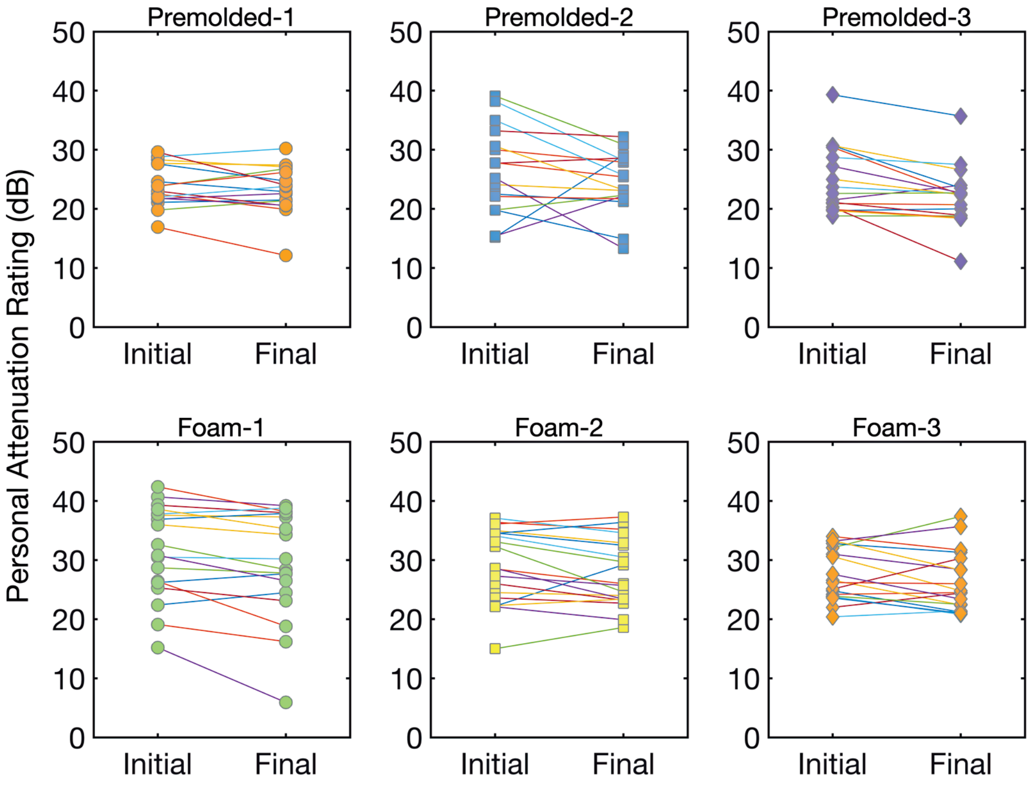

Figure 2 Initial and final personal attenuation rating (PAR) outcomes (dB) for individual subjects meeting the minimum 15 dB PAR for each earplug before the 2-hour work-shift. Circles were used for the earplugs evaluated in the first year, squares for the second year, and diamonds for the third year. A color code for symbols (orange, blue, purple, green, yellow, orange) are matched in Figs. 2 and 3. Colors for lines are for clear visualization only.

positive changes reflect an increase in attenuation. The change in PAR values for each subject are illustrated in Fig. 3. Each subject is indicated on a vertical gray line. The foam earplugs are displayed in the upper panel and the premolded earplugs are in the lower panel. The symbols, shapes, and colors are the same as in Fig. 2. Open white symbols are used for those subjects whose test results were removed from the study.

Fig. 4 presents box plots of the medians and percentiles of initial PARs, final PARs, and the difference in PARs between final and initial tests by earplug type. Foam earplugs provided generally higher attenuation than premolded earplugs. Visual inspection of the plots suggests that changes in PAR over a 2-hour work period for foam earplugs were slightly smaller with less variability than changes for premolded earplugs. The loss of attenuation of 26 sessions (12 of the foam earplug and 14 of the premolded earplug measurements) was more than the 4-dB, test–retest variability observed for repeated REAT tests.[20,21]

Table 3 also contains the Student's *t*-test results comparing initial and final PARs for each earplug, earplug type (foam, premolded), and all HPDs. A statistically significant change in PARs was observed for the Foam-1 ($p = 0.009$) and the Premold-3 ($p = 0.004$) earplugs. When examining the type of earplug, both the foam ($p = 0.001$) and premolded ($p < 0.01$) types had significant changes between the initial and final PARs. When combining all of the data, there is a significant difference ($p < 0.001$) between initial and final measurements. This statistical analysis should be considered in the context of the actual magnitude of change in PARs. The change in attenuation for foam earplugs was -1.5 ± 3.2 dB and for premolded was -1.9 ± 4.4 dB. Across all earplugs, the

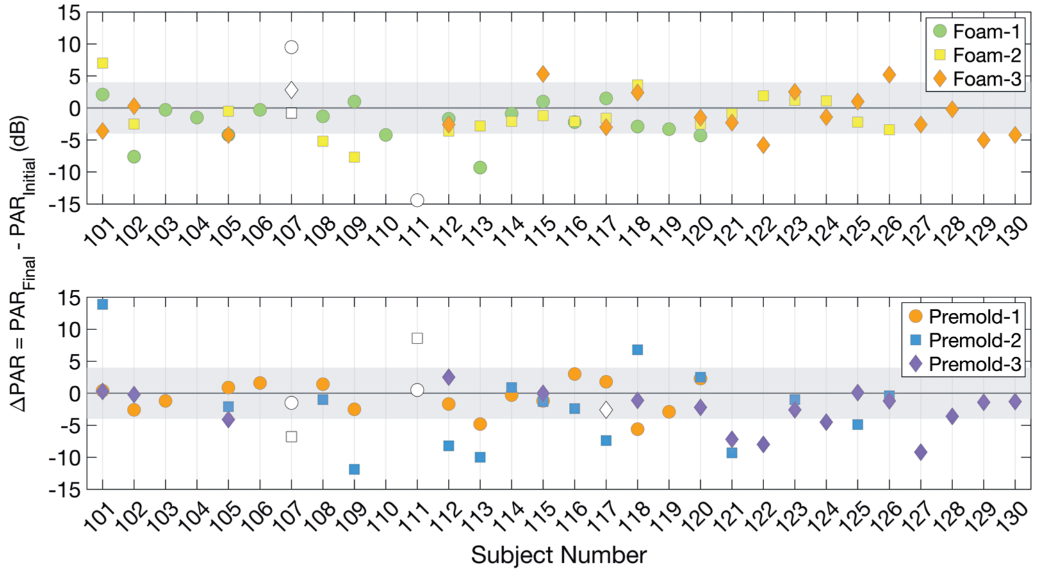

Figure 3 Change in personal attenuation rating (dB) for each subject and hearing protector worn for a 2-hour work period. Open symbols represent subjects who had inconsistent responses and were not included in the analysis. Circles were used for the earplugs evaluated in the first year, squares for the second year, and diamonds for the third year.

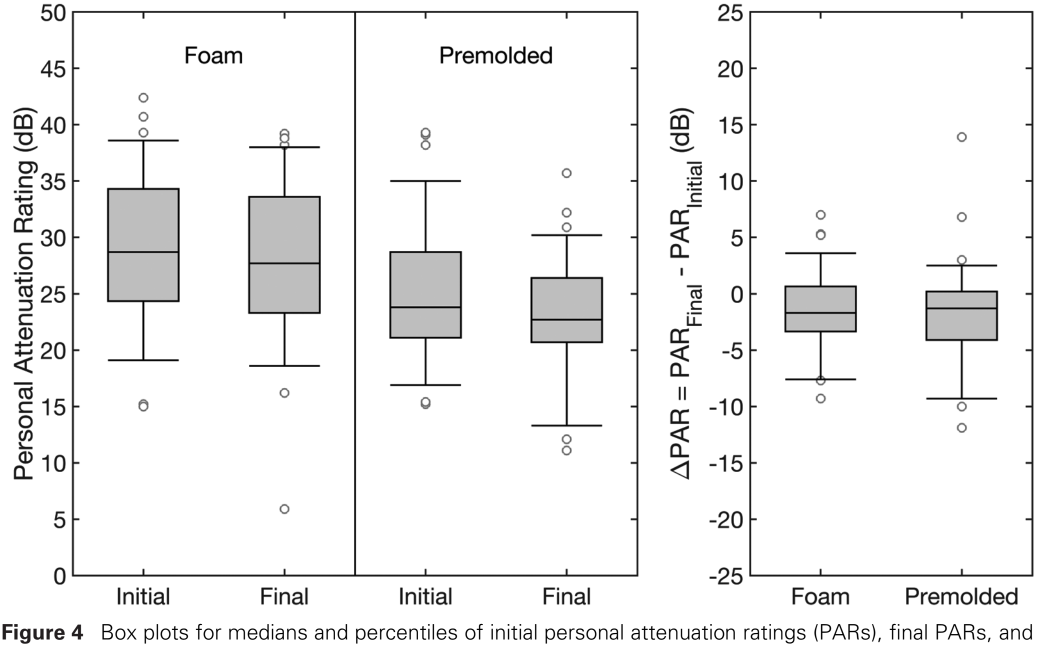

Figure 4 Box plots for medians and percentiles of initial personal attenuation ratings (PARs), final PARs, and the difference between final and initial attenuation measurements by earplug type. The median (–), 25th and 75th quartiles are depicted with the box. The vertical lines extend from the ends of the box to the 5th and 95th percentile values. A circle (○) represents outlier that is more than the upper quartile plus 1.5 × interquartile range or less than the lower quartile minus 1.5 × interquartile range.

mean loss of attenuation was less than 2 dB (-1.7 ± 3.8 dB).

The linear mixed regression model of all the attenuation data did not correspond to the earplug type/earplug model ($F = 0.34$, $p = 0.5594$) or study year ($F = 0.10$, $p = 0.9071$).

DISCUSSION

The results for the change in PAR over the 2-hour work shifts were statistically significant when considering the aggregate of protectors and years. However, the changes observed for specific models exhibited mixed results. The Foam-1 and Premold-3 earplugs both had statistically significant decreases of at least 2 dB. The majority of workers maintained the target attenuation and a complete fit-failure was observed only in workers wearing premolded earplugs. Factors such as earplug type or study year were not found to be related to the loss in PAR. A general discussion and considerations for application follow.

Attenuation Changes and Movement Activities Considerations

Ninety-five percent of the final PAR measurements maintained the target attenuation of 15 dB. This finding suggested that even though a statistically significant ($<$ 2 dB) loss in PAR was found for two earplug models (Foam-1 and Premold-3), the majority of the workers still received sufficient attenuation while performing active work duties during a 2-hour period. These results agreed with the findings of Casali and Park that once an HPD is properly fit, it remains stable during vigorous movement over an extended wearing period.[16] In the current study, the average magnitude of attenuation loss ranged between 0.7 and 2.6 dB across earplug models. This helps support the generalization of these findings to other types of hearing protectors as long as the initial fit is adequate for the noise exposure.

However, five subjects had an earplug fitting failure ($>$ 15 dB attenuation loss) when wearing premolded earplugs only. These were five different subjects, and each was able to obtain and maintain attenuation with other premolded devices. Only one subject reported noticing the change in attenuation because he had to turn the volume down on the sound restoration earmuffs part-way through the wear session. The other four workers did not notice a change in sound level (likely because of wearing double hearing protection). The level of the electronic sound restoration earmuff worn over the earplug being tested was adjusted by the workers. We did not measure the output of the earmuff system. Earmuffs were used to comply with IRB and regulatory requirements to ensure the employees were adequately protected at all times. None of the five workers reported "feeling" a shift in earplug fitting. One subject reported that the earplugs were uncomfortable at the end of the wear period, and two subjects were visually observed by the researchers that the earplugs moved out of the ear canal at the end of the study session. A change in sound level ($>$ 15 dB) should be noticed by the wearers immediately if the wearers did not wear double hearing protection, and then the earplugs should be refitted. However, this study design did not allow the subjects to manipulate the earplugs during the study session. Because of that, we excluded the "failure fitting" data for further analysis. These observations demonstrated that "failure fitting" happens even though the wearers had proper initial fit, and it is highly recommended that wearers should re-fit the earplugs as soon as they notice the change in sound level.

Although the mean reduction of attenuation (-1.7 dB) for the validated 104 study sessions was within the range of the test–retest variability ($\pm$4 dB), 12 of the foam earplug and 14 of the premolded earplug measurements exhibited a loss of more than 4 dB (Fig. 3). The variability has different components related to the HPD fit-testing paradigm, the ability for an individual to achieve the same threshold, and the uncertainty of the acoustic output of the fit-test system. The reduction of attenuation clearly indicated that although there is a tendency toward a very small loss of mean attenuation for earplugs worn while performing active work, individual workers may experience greater losses on the order of 10 dB or more. The fitting failures should also be considered as having significant loss of attenuation, more than 15 dB.

Jaw motion was not excessive during this study, and workers were not allowed to have snacks or a meal during the 2-hour work period, although they did drink water occasionally and spoke to each other on occasion. Body and head motion was continuous during the work period. The results of this study are consistent with findings from Casali and Park who evaluated the effects of head movements on four hearing protectors: two models of earmuff, one foam earplug, and one premolded earplug.[16] Noise attenuations were obtained prior to use, following 1 hour of use, and following 2 hours of use with highly kinematic work activity. They found that the rapid head acceleration/deceleration could induce HPD slippage. The hearing protector attenuations were influenced by the activity and were larger for premolded earplug than earmuffs and foam earplugs,[16] which were consistent with the "failure fitting" observation in this study were premolded earplugs only. The foam earplugs were largely resistant to movements and did not show any clinically significant reduction of noise attenuation. Additionally, a lab study showed that body movement had inconsistent, minimal effects ($\leq$ 2 dB) on noise attenuation.[22] In this study, the mean change in PAR was also less than 2 dB and slightly less for foam earplugs as compared to premolded earplugs (foam -1.5 ± 3.2 dB; premolded -1.9 ± 4.4 dB).

HPD fit-testing technology has been recognized as an effective tool for training workers to properly fit/use HPDs and achieve efficient attenuation.[8–10] Sayler et al evaluated the association between hearing conservation program cost and NIHL outcomes in 14 U.S. metal manufacturing facilities.[23] They found that higher expenditures for training and HPD fit testing were significantly associated with reduced prevalence of standard threshold shift. This study applies HPD fit-testing technology as a means of monitoring attenuation over time and potentially further reducing the prevalence of occupational NIHL.

Attenuation Changes and Fit-Testing Protocol Considerations

Although the accuracy of attenuation measurement improves as the number of test frequencies increases, the test time also increases. Murphy et al suggested that fit testing at 500, 1,000, and 2,000 Hz was sufficient for accurately estimating worker PARs and decreased test time by at least half.[10] Federman and Duhon considered the effect of the change in PAR when subjects were given an experiential fit followed by a self-refit of a foam earplug that was essentially the same as the Foam-1 earplug.[24] They varied the number of frequencies in the testing protocol from 1, 3, 5, and 7 and did not find a statistically significant effect related to the number of frequencies. They concluded that there was little rationale to support additional test frequencies beyond 500, 1,000, and 2,000 Hz. Testing the HPDs twice (before and after work periods) increases the test time. The poor performance of an earplug can be more readily identified when lower frequencies ($<$ 1,000 Hz) are assessed.[25–27] Consequently, a fit-testing protocol should include 500 Hz to better identify the poor fits. The higher frequencies, 1,000 and 2,000 Hz, provide a stronger correlation to the estimate of attenuation when measured with the frequencies specified by ANSI to determine an HPD's rating.[28] More importantly, the target attenuation should be determined from the noise exposure in combination with an allowance for minor attenuation changes over wear time. More research is needed to determine the allowance for minor attenuation changes over wear time.

Protection Performance Related to Type of HPD

Foam earplugs are generally considered to be more difficult to insert than premolded earplugs, largely because of the need to roll, compress, and quickly insert it before the earplug expands to its original shape.[16] In the present study, both types of earplugs (foam and premolded) could be fit adequately to afford 15 dB of attenuation. Earplug type did not influence the PAR outcomes. In fact, the change in mean PAR values was not significantly different except for two products (one foam and one premolded type). Although the current study found that both types of earplugs and all six products were able to be properly inserted by the workers, the earplug fitting failures ($n = 5$) all occurred with premolded earplugs. Three of the failures were with the Premold-2 earplugs (two subjects fitted with small size), and two of the failures were with the Premold-1 earplugs. Although the exact reason for the fit failure cannot be ascertained from this study, it is possible that premolded earplug size is important. Currently, there is no standardized sizing for earplugs. The ANSI/ASA S12.6-2016 standard references a plastic tool with five different ball diameters: extra-small (7.26 mm), small (8.48 mm), medium (9.27 mm), large (10.46 mm), and extra-large (11.53 mm) that can be used to measure the ear canal diameter by placing the ball into the aperture of the ear canal.[28] However, even if the earplug size is categorized using this method, there is no provision for direct transformation to the labeled earplug size. There is also no uniform standard for manufacturers to reference when characterizing earplugs as small, medium, or large. Yu et al suggest that more sophisticated ear canal measurements such as computed tomography technology should be utilized to measure the geometric shape of ear canals.[29]

Initial and final PARs for the foam earplugs demonstrated more variability than PARs for premolded earplugs. However, when investigating the loss in attenuation over time, foam earplugs showed less reduction with smaller variability than premolded earplugs. This finding is congruent with the laboratory study conducted by Berger.[13] Berger measured the noise attenuation of one premolded, one fiberglass down, and one foam earplug fit to 10 subjects. Subjects wore the earplugs for 3 hours and engaged in normal activities. Berger reported the average loss in attenuation was 5 dB for the premolded earplug and reported no statistically significant change in attenuation or variability at any test frequency for the foam earplug. Studies consistently demonstrate that attenuations obtained with earplugs, other than foam earplugs, were reduced substantially (up to 8 dB) at some frequencies, while attenuation from foam earplugs was resistant to the effects of wearing time and to head and jaw movements.[14,15] This might be attributed to the cylindrical shape and inherent porous texture which helps develop substantial expansion force and friction with the canal walls, and compliance with canal distortions.[14,15]

The subjects were required to wear the large volume earmuffs over the earplugs as a part of the IRB approval process. In the event that the earplug were to become dislodged, the IRB wanted assurance that the workers would still be adequately protected. While it is possible that the earmuff's interior foam padding could contact the distal edge of the foam earplug or the stem of the premolded earplug, this is unlikely to have occurred. The instances where this is potentially a problem are when the earmuff is shallow. Instead, the larger volume earmuff that we used provides adequate room for a poorly fit earplug to be worn and not contact the interior foam padding. For these subjects, the earplugs were tested, observed, and verified that they were properly inserted. Thus, we do not believe that the earplug failures would have resulted from contact with the interior foam padding.

Additionally, the majority of the tested workers in the study voluntarily expressed less subjective comfort while wearing the premolded earplug in comparison to the foam earplug. The relationship of the PAR to subjective comfort ratings may be of interest since workers may intentionally fit an earplug poorly in order to achieve comfort. Comfort may indirectly influence the likelihood that work activity will result in a loss of attenuation.[30] Requiring a minimum PAR may also impact the comfort rating.

A pair of new earplugs was fitted and evaluated during each session. Earplugs wear out even when properly used in the field. Even though premolded earplugs are advertised as reusable, the flanges may shrink or harden when continuously exposed to cerumen, perspiration, or repeated washing. If the flanges break off, become cracked or hardened, the earplugs should be replaced. Disposable foam earplugs should be replaced with new earplugs if they become dirty due to cerumen or contamination from the hands. Washing or rinsing formable earplugs is not advised because water changes the slow expansion rate of some urethane foams. This study did not evaluate any push-in type earplugs, earplugs with a firm fitting stem and a soft foam tip. Regardless, the foam part of the earplug can become dirty, and workers should be educated about when earplugs should be replaced. Consequently, the findings of this study may be limited to new earplugs only.

Implications for HPD Training

Earplug attenuation can decrease slightly over wear time if the earplugs shift or work loose. If an earplug shifts position or loosens, subtle changes in the attenuated sound occur. Workers should be encouraged to monitor the earplug fit throughout the work period and be advised that repositioning may be necessary over the course of the work shift. For workers wearing double hearing protection, it may be especially difficult for them to identify the loss of attenuation of an earplug and consequently the fit of the earmuff is critical.

Future Research Needs

More studies are needed to investigate the cost–benefit of performing HPD fit testing with regard to the number of test frequencies in the context of changes in attenuation over time. More investigation is needed regarding the selection and fitting of sized earplugs. The Premold-2 earplug was the only earplug in this study with multiple sizes and the SD of the change in PAR value was greater than for the other earplugs. The 2-hour period was selected to reflect the typical amount of time workers wear earplugs before removing them for a work break. There may be a need to evaluate earplug attenuation when worn for longer periods of time to capture potential changes. Multiple fit tests might be needed to investigate the effect of refitting the device during an entire work shift.

CONCLUSION

Overall, properly fit earplugs can be effective at reducing worker's noise exposures over time. In the current study, potential issue of "ear plug failure" was observed. Among the valid study sessions, 95% of the final PAR measurements maintained the target PAR measurement of 15 dB after having been worn in the workplace for 2 hours. However, hearing protectors may lose some attenuation over time. Although this amount is small (on average < 1.5 dB for foam plugs and < 1.9 dB for premolded plugs), this amount varies considerably among individuals. Additionally, the slight change over time was found to be greater for premolded rather than foam earplugs. The potential for a loss of attenuation over time and the variance between HPD types should be taken into consideration when establishing the adequacy of noise protection when based on individuals achieving a minimal PAR score. It should be noted that in order to measure the potential effects of slippage over time, workers in the present study were not allowed to readjust the earplug fit even when they noticed a change. Hearing conservation training content should address the proper fitting of HPDs and potential issue of "ear plug failure" and/or slippage during the work shift.

CONFLICT OF INTEREST

None declared.

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INSTITUTION AND ETHICS APPROVAL AND INFORMED CONSENT

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DISCLAIMER

The findings and conclusions in this paper are those of the authors and do not necessarily represent the official position of the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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