



ADVANCED HEARING PROTECTOR STUDY

**Conducted at:
General Motors Metal Fabricating Division
Flint Metal Center - Flint, MI**

January 2004 - February 2005

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health



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Executive Summary

National Institute for Occupational Safety and Health (NIOSH) investigators were requested to evaluate the use of customized hearing protection devices for comfort, acceptance, and noise reduction performance. This request came from the UAW-GM Center for Human Resources (UAW-GM CHR). The plant selected for the study was the Flint Metal Center in Flint, Michigan. With the assistance of the United Auto Workers Local 659, a total of 228 workers were recruited for a study to evaluate an advanced technology semi-custom earplug made by Sonomax Hearing Healthcare, Inc.

NIOSH developed a protocol for an investigation which tested three groups of employees:

- Group A was fit with the custom-molded earplug;
- Group B was fit with hearing protectors already available in the plant, and was counseled on proper fitting and selection of hearing protection; and
- Group C used protectors available in the plant but was not directly counseled regarding selection or fitting of hearing protection.

NIOSH investigators made four visits to the facility in February 2004, March 2004, June 2004, and January/February 2005. Objective measurements of hearing protector performance along with the subjective evaluation of employees' beliefs, attitudes, and hearing protector comfort was assessed during each visit. Individual hearing tests were administered during the first and last visits.

Ideally, an employee's protected exposure level should be between 70 and 85 dBA. Based on fit-testing results, employees tended to prefer overprotection (more attenuation than was necessary according to the GM-provided noise exposure data). This may be related to the unique impulsive noise environment of the stamping plant. The custom hearing protectors provided approximately 50-62% of the workers with an appropriate amount of noise reduction. Other protectors used in this study generally provided 30% of wearers with an ideal amount of protection.

The acceptance rate of the Sonomax earplug was approximately 25% based upon the Group A dropout rate and the monthly walk-through assessments conducted during the course of the year-long investigation. Factors influencing acceptance included dislike of the feel of wet lubrication in the ear, difficulty in quickly donning hearing protection, comfort and sanitation issues.

If the plant were to adopt the custom plug, generic hearing protectors must still be stocked. There are days when workers forget their custom plugs or when custom plugs are damaged and the worker must wait for a re-fit. Less than 1% (in the present study) of workers have extremely small or large ear canals and cannot be fit with current Sonomax earplugs.

A major concern is employees "loaned" to different plant departments where noise levels may be significantly different from the home department. Hearing protector attenuation may have to be adjusted to accommodate different levels of noise to adequately protect the worker.

We found the Sonomax earplug to be safe and effective for use in an industrial environment. The high initial cost and low worker acceptance may make it a poor choice in this application. A constant noise environment or a worker pool inexperienced in hearing protector use may make this option more attractive.

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The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health. Mention of company names or products does not constitute endorsement by NIOSH.

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Introduction

Noise-induced hearing loss is an irreversible condition that progresses with continued exposure. Although hearing ability tends to decline with age (referred to as presbycusis), exposure to noise produces hearing loss greater than that resulting from the natural aging process. This noise-induced loss is caused by damage to nerve cells of the inner ear (cochlea) and, unlike some other common hearing disorders, it cannot be treated medically.¹ While loss of hearing may result from a single exposure to a very brief impulse noise or explosion, such traumatic losses are rare. In most cases, noise-induced hearing loss is insidious. Typically, it begins to develop at 4000 or 6000 Hz and then spreads to lower and higher frequencies. Often, material impairment has occurred before the condition is clearly recognized. Such impairment can be severe enough to permanently affect a person's ability to hear and understand speech under everyday listening conditions. Although the primary frequencies of human speech range from 200 Hz to 2000 Hz, research has shown that the consonant sounds, which enable people to distinguish words such as "fish" from "fist," have higher frequency components which may not be audible for persons with a high frequency noise-induced hearing loss.²

Workers exposed to daily noise exposures in excess of 85 dBA must be enrolled in a hearing conservation program (HCP). Exposure to work environments in excess of 90 dBA must be lowered through engineering/administrative noise controls. In cases where noise cannot be economically or practically controlled, the Occupational Safety and Health Administration (OSHA) regulations allow for workers' hearing to be protected by earmuff or earplug hearing protection devices.

The "Four C's" of hearing protection are cost, convenience, comfort, and communication. By far, the biggest complaints of workers are the inability to communicate while wearing hearing protectors, and the lack of comfortable hearing protection. This study was undertaken to determine if a new hearing protector would be more widely accepted over traditional earplugs. The new hearing protector used a molded-in-place technology to conform to the worker's outer ear, and employed acoustic filters to reduce noise. The acoustic filters were selected according to the worker's exposure so as to provide enough reduction to be safe, but not too much to produce isolation and communication problems.

Background

In May 2003, the National Institute for Occupational Safety and Health (NIOSH) was contacted by James, Anderson and Associates, Inc. (JAA), the noise control and exposure monitoring subject matter expert for General Motors (GM) at the Flint Metal Center, about the possibility of providing technical support for a study of hearing protectors. The purpose of this study was to determine if a new, advanced technology semi-custom molded earplug would be better accepted by the workers in the plant than the current selection of five commercially available (non-custom) earplugs. The semi-custom molded protector manufacturer, Sonomax Hearing Healthcare, Inc., advertised that their earplugs were more comfortable and would allow better communication than conventional premolded earplugs.

The Hearing Loss Prevention Team within the Division of Applied Research and Technology (DART) at NIOSH in conjunction with support from the NIOSH Pittsburgh Research Laboratory Hearing Loss Prevention Branch agreed to conduct the study. The United Automobile Workers (UAW), GM, and JAA agreed to request technical assistance from NIOSH through the health hazard evaluation program. JAA served as the administrative interface among all of the parties participating in the study. It was agreed that NIOSH investigators would retain and analyze all data and prepare project reports. The results would be provided to all involved parties, and portions subsequently submitted for publication in the peer-reviewed scientific literature.

Methods

The study was designed to assess the hearing protection acceptance and effectiveness for 300 workers evenly distributed among three groups. The first group would be fit with the semi-custom molded protector; the second group would continue to use their current hearing protector but would receive counseling regarding correct usage and fitting of the protector (or assistance would be provided to select a different protector if necessary); and the third group would also continue to use the protector that they normally used on a daily basis, without receiving any additional counseling. Subjects would be randomly assigned to one of the groups and would be permitted to withdraw from the study at any time. The research protocol was presented to the NIOSH Human Subjects Review Board to ensure it was ethical and safe for the volunteer worker, and it was approved in February, 2004.

Four testing sessions were held at the Flint Metal Center: February 2004 (four days), March 2004 (four days), June 2004 (eight days), and a final session in February 2005 (eight days). Although the initial goal was to enroll 300 workers, due to time constraints and plant production requirements, only 228 were enrolled in the study. At the first session, volunteer subjects signed an informed consent agreement and were assigned to Group A, B, or C by a random card draw. Subjects in Group A received the custom-molded hearing protector, and subjects in Group B or Group C used one of the five standard earplugs routinely provided by the plant: Howard Leight AirSoft™, North Safety Products DeciDamp™, Howard Leight Max-Lite™, Moldex Pura-Fit®, and the Howard Leight Quiet® Earplug.



Questionnaires and Hearing Tests

At the beginning of the first session all subjects filled out a hearing health history questionnaire, and at each of the four sessions they completed a “beliefs and attitudes” questionnaire about working around noise and wearing hearing protectors,³ and were also given a Comfort Survey. (Examples of the Comfort Survey and Beliefs & Attitudes Survey are located in Appendix A.)

The Comfort Survey is a modification of a questionnaire previously published by other hearing loss researchers.⁴ Workers were asked to identify their perceived comfort of the protector based upon a five-point evaluation scale for fourteen different word pairs. The word pairs consisted of adjectives such as painless and painful, or comfortable and uncomfortable. The survey is scored by assigning a “1” to the most comfortable end of the spectrum and a “5” to the most uncomfortable response. Total scores can vary between 14 (most comfortable) to 70 (least comfortable).

During the first and fourth visits, the workers’ pure-tone audiometric thresholds at frequencies of 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz were tested using a Benson CCA-200 audiometer. This testing was conducted inside NIOSH’s mobile Hearing Loss Prevention Unit (Photo 1), which is a self-contained laboratory trailer that houses a four-person sound-treated audiometric booth. The mobile unit was parked inside the plant in the Stamping Ground area. Ambient noise levels were continuously monitored by a Benson SLM-200 sound level meter, which temporarily suspended the audiometric testing if background noise inside the booth exceeded the ANSI maximum permissible levels.



Photo 1: NIOSH Self-contained Hearing Loss Prevention Unit. Used for hearing testing and protector testing.

Hearing Protector Attenuation Testing

Hearing protector attenuation was assessed during each of the four site visits, using the commercially available FitCheck system (Michael and Associates, State College, PA). FitCheck is a computer-controlled version of a system originally developed in the 1970’s by NIOSH.⁵ This system is used to conduct measurements of earplug attenuation on an individual, and was installed along with the audiometric test instrumentation in the NIOSH mobile testing unit. For this test, subjects wear a headset consisting of large circum-aural earcups, each with a small loudspeaker mounted inside. The FitCheck software program uses a soundcard to produce the test stimuli while the computer controls four independent patient response boxes/attenuators. Pulsed one-third octave-bands of noise were used for the fit-testing test stimuli. A Bekesy tracking paradigm was used, which changed the level of the signal at a rate of 3 dB/sec.

Hearing protector attenuation values were obtained by determining the real-ear attenuation measured at the individual's hearing threshold. Real-ear attenuation at threshold (REAT) is defined as the mean value (in decibels) of the occluded threshold of hearing minus the open threshold of hearing. Simply stated, a subject took two hearing tests – one without a hearing protector and one with the hearing protector – the difference between his/her thresholds on the two tests indicated how much sound attenuation was provided by the device being tested. During the test, the subject depresses the response switch until the stimulus becomes inaudible. Once the stimulus was no longer heard, the patient was instructed to release the switch, which caused the loudness to increase again. This procedure was repeatedly performed for 30 seconds at each frequency, and then the test automatically switched to the next stimulus. Unlike the audiometer testing software, which permitted each subject to progress through the test at a different rate, the FitCheck software simultaneously presented the same frequency stimulus to all subjects.

The attenuation for each earplug was tested separately for each subject, i.e., separate tests were conducted for the left and right ears. Each test trial consisted of an un-occluded (ears open) test and an occluded (earplug worn) test. Hearing threshold levels for the un-occluded and occluded conditions were stored in a Microsoft Access™ database for later analysis. The attenuations for the trial, the subject name, left/right ear, and protector were all stored in a single database record. The attenuations were used to estimate the protection the subject achieved and to calculate the noise exposure the subject might receive. The fit-testing that was conducted during the first session used an abbreviated set of 1/3rd octave band noise test stimuli consisting of center frequencies of 125, 500, and 2000 Hz. Subsequent fit-testing during the second, third, and fourth visits was conducted at center frequencies of 125, 250, 500, 1000, 2000, and 4000 Hz.

Experimental Groups and Test Sessions

During the first session, NIOSH administered the questionnaires, conducted hearing tests, performed hearing protector fit-testing, and counseled the workers depending upon the group in which they were placed. The expected examination time for each subject was 45 minutes. However, this estimate proved to be grossly inaccurate due to the time required to complete all paperwork and conduct the hearing testing and earplug fit-testing. Additionally, some subjects required as much as two hours to complete the entire process if they were in the group receiving the custom-molded earplug. The total time away from work was significantly less for the three subsequent test sessions.

Subjects in Group A were issued the custom-molded earplugs. These were made on-site by a visiting manufacturer's representative. Based on the worker's noise exposure estimate from company survey data and the amount of sound recorded by an internal microphone inside the custom molded plug, the representative fitted each hearing protector with one of four acoustic filters or a complete acoustic block. The four acoustic filters provide a variable amount of attenuation and are inserted into a specifically designed channel of the earplug. If maximum attenuation is required due to high noise exposures, the channel can be fully blocked with a removable plug.

One of the unique features of the particular custom-molded protector used in this study is the ability to predict its attenuation from an insertion loss measurement made during the molding

process. During the manufacture of the custom earplugs, the technician selects a “bladder” sized to the subject’s ear canal and concha. The bladder is injected with silicon material that hardens while in the subject’s ear. The bladder has two ports: one for the silicon material injection and the other is a sound bore. The sound bore provides a place for the acoustic filter, but before selecting an acoustic filter, the insertion loss of the device is measured by inserting a probe microphone into the sound bore. The manufacturer has developed a software package, SonoPass™, which analyzes the results. One of the parameters produced by the analysis is the Personal Protection Attenuation Rating (PPAR), which is an estimate of the amount of attenuation that the protector provides for the particular subject. One PPAR measurement was made immediately after the protector was made, and a second measurement was taken after the subject removed the protector, lubricated it, and re-inserted it him/herself. The manufacturer’s representative checked the first measurement against the second one, which is normally used to predict the performance of the protector.

Immediately after the custom earplug fitting, the worker received a hearing protector attenuation test using the FitCheck system. The subject had to remove and re-insert the protector for the fit-testing, which was conducted in a separate location. If the FitCheck attenuation was less than that determined to be protective by the NIOSH investigators (i.e., a protected exposure level of 85 dBA or less), the worker was sent back to the manufacturer’s representative for re-fitting. This re-fitting could consist simply of a filter change or possibly a complete remake of the protector.

During the second, third, and fourth sessions, Group A members were asked to fill out a “wearability” questionnaire developed by JAA. This questionnaire asked the workers to provide feedback about their experiences with the custom-molded hearing protector. During the fourth session, Group A members filled out all four questionnaires and received both a hearing test and a FitCheck hearing protector attenuation test. Between NIOSH site visits, a monthly visual check of Group A participants was made by a JAA consultant. If a Group A participant was seen without the custom-molded earplugs, he or she was further questioned about why the custom earplugs were not being used that day.

Subjects assigned to Group B continued to use their choice of the five hearing protectors provided by the plant, but received counseling regarding correct usage and fitting of the chosen protector. If the NIOSH researchers determined that a particular protector did not provide an adequate fit, assistance was provided to select a more suitable protector for that individual. Workers in this group were told they could return to their original hearing protector at any time if the protector had been changed at the initial session. Group B participants filled out the hearing health history questionnaire, the “beliefs and attitudes” questionnaire, and the Comfort Survey, and were administered a hearing test and earplug fit-test at the first session. Along with earplug fit-testing, they completed the “beliefs and attitudes” questionnaire and the Comfort Survey at the second, third, and fourth test sessions, and also received another hearing test during the final session.

Workers in Group C followed essentially the same procedures as for Group B; however, they did not receive any counseling or recommendations regarding hearing protection at the first test

session. At the final session, Group C participants received counseling on hearing protector best practices similar to what Group B received during the initial session.

Secondary Study

At the request of the UAW to increase numbers of workers wearing the custom-molded earplug to as close as 100 as possible, a secondary “nested” study was implemented during the June 2004 session. The purpose of the nested study was to increase the number of participants in the study and to determine if the technology needed for in-house fittings could be transferred from the advanced hearing protector vendor to GM medical staff. The initial nested study design called for 60 workers (designated as Group S1) to be fitted by the custom-molded hearing protector representative and another 60 workers (designated as Group S2) to be fitted by a GM plant nurse. A total of 62 additional workers (36 fitted by Sonomax, 26 fitted by GM) were able to be recruited and were fitted with the custom-molded hearing protector in the nested study. Both groups filled out informed consent documents, hearing health history questionnaires, the “attitudes and beliefs” questionnaire, and the comfort survey. Also, all subjects had their hearing tested and were given an earplug fit-test. In February 2005 both groups again filled out the “attitudes and beliefs” questionnaire, the comfort survey, and received a second hearing test and hearing protector attenuation fit-test. It should be noted that the GM nurse never reached the level of proficiency required by Sonomax to independently dispense the custom molded hearing protector.

Evaluation Criteria

As a guide to the evaluation of the hazards posed by workplace exposures, NIOSH field staff employs environmental evaluation criteria for the assessment of a number of chemical and physical agents. These criteria are intended to suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. It is, however, important to note that not all workers will be protected from adverse health effects even though their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility or a pre-existing medical condition. In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the criterion. These combined effects are often not considered in the evaluation criteria. Also, some substances are absorbed by direct contact with the skin and mucous membranes, and thus potentially increasing the overall exposure. Finally, evaluation criteria may change over the years as new information on the toxic effects of an agent become available.

The primary sources of environmental evaluation criteria for the workplace are: (1) NIOSH Recommended Exposure Limits (RELs),⁶ (2) the American Conference of Governmental Industrial Hygienists’ (ACGIH[®]) Threshold Limit Values (TLVs[®]),⁷ and (3) the U.S.

Department of Labor, Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs).⁸ Employers are encouraged to follow the OSHA limits, the NIOSH RELs, the ACGIH TLVs, or whichever are the more protective criteria.

OSHA requires an employer to furnish employees a place of employment free from recognized hazards that are causing or are likely to cause death or serious physical harm.⁹ The OSHA standard for occupational noise exposure (29 CFR 1910.95)¹⁰ specifies a maximum PEL of 90 dBA for a duration of 8 hours per day. When discussing noise exposure, the expression time-weighted average (TWA) is used to refer to the average sound level experienced during an 8-hour workday. The OSHA regulation uses a 5 dB time/intensity trading relationship (exchange rate) to calculate the PEL. This means that a person may be exposed to noise levels of 95 dBA for no more than 4 hours, to 100 dBA for 2 hours, etc. Conversely, up to 16 hours exposure to 85 dBA is allowed by this exchange rate. The duration and sound level intensities can be combined in order to calculate a worker's daily noise dose according to the formula:

$$\text{Dose} = 100 \times (C_1 / T_1 + C_2 / T_2 + \dots + C_n / T_n)$$

where CRR_n indicates the total time of exposure at a specific noise level and T_n indicates the reference duration for that level as given in Table G-16a of the OSHA noise regulation. During any 24-hour period, a worker is allowed up to 100% of his daily noise dose. Doses greater than 100% exceed the OSHA PEL, and should be reduced through engineering or administrative controls.

The OSHA noise regulation has an action level (AL) of 85 dBA, which means that an employer shall administer a continuing, effective hearing conservation program when the 8-hour TWA value exceeds the AL. The hearing conservation program must include noise exposure monitoring, employee notification, observation, audiometric testing, hearing protectors, training, and recordkeeping. All of these requirements are included in 29 CFR 1910.95, paragraphs (c) through (o).

NIOSH, in its Criteria for a Recommended Standard,¹¹ and the ACGIH⁷ propose exposure criteria of 85 dBA as a TWA for 8 hours, which is 5 dB less than the OSHA standard. The NIOSH and ACGIH criteria also use a more conservative 3 dB time/intensity trading relationship when calculating exposure limits. Thus, a worker can be exposed to 85 dBA for 8 hours, but to no more than 88 dBA for 4 hours or 91 dBA for 2 hours. Twelve-hour exposures have to be 83.2 dBA or less (which is equivalent to an 8-hour TWA of 85 dBA) according to the NIOSH REL.

Criteria for an adequate earplug fit is that the worker achieves enough attenuation to reduce his or her noise exposure below the NIOSH recommended level of 85 dBA as measured by individual fit-testing.¹¹ Even at an 85 dBA daily exposure, the most vulnerable members of the population will still incur a noise-induced hearing loss over a working lifetime; however, this level will protect about 90% of the population from obtaining a material hearing impairment.

Overprotection is a condition in which the worker receives more attenuation than necessary, and the worker's exposure is reduced to less than 70 dBA. Overprotection results in the reduction in verbal communication with other workers, the potential to miss safety signals, and reduced

acoustic feedback from their machine or work process. Overprotected workers report being “out of touch” with their environment or feeling isolated.

Results

Estimating Noise Exposure under Hearing Protection

The use of hearing protection was mandatory within the plant’s production areas since previous noise surveys indicated most areas to be above 85 dBA. When workers were recruited for the study, JAA provided NIOSH and Sonomax Hearing Healthcare, Inc., with the job description, department number, and representative noise exposure for each employee. These exposures were used in the estimation of the protected noise exposure for each of the hearing protectors in the study.

The fit-testing method used in this study has advantages and disadvantages. The main advantage was the test was quickly completed; approximately 7-8 minutes for the reduced set of noise bands (125, 500, and 2000 Hz) and about 15-16 minutes for the complete set of noise bands (125, 250, 500, 1000, 2000, 4000, and 8000 Hz). The disadvantages were two-fold: (1) due to the experimental nature of the four-person test system (it is the only multi-station system currently in existence) the software did not provide any error checking to ensure that the subject had adequately identified his or her thresholds, and (2) the software had limited database capabilities. Running this system required considerable operator intervention to monitor the testing and manage the data collection/storage. One of the potentially most problematic effects was the extreme attenuation values (in excess of 50 dB) that were sometimes reported by the fit-testing software. Therefore, the professional judgment of the NIOSH researchers was relied upon and some subjectivity was involved when conducting and interpreting the fit-test results.

Measurements from the fit-testing and the subject’s noise exposure were manually entered into a spreadsheet to estimate the protected noise exposures. In essence, the calculation was a reduced Noise Reduction Rating (NRR) calculation based upon the particular frequencies tested. The subject’s estimated protected level (EPL) was calculated for each ear as follows:

$$EPL = L_A - \left(\sum_f 10^{0.1L_C(f)} - \sum_f 10^{0.1(L_A(f) - REAT(f))} \right)$$

where L_A is the subject’s exposure level obtained from earlier plant noise surveys; f is the one-third octave-band center frequencies at which the $REAT(f)$ attenuations are measured; and $L_A(f)$ and $L_C(f)$ are the A-weighted and C-weighted octave band levels of a flat-spectrum noise, respectively. The difference between the C-weighted noise and the A-weighted attenuation is the nominal performance for the protector, which can be thought of as a Personal Noise Reduction Rating (PNRR). In the above equation, the PNRR value (i.e., the mathematical expression contained within the larger parenthesis) is subtracted from the exposure identified for the subject to estimate the protected exposure level. Fit-testing was performed with three 1/3rd octave band noise center frequencies ($f = 125, 500, \text{ and } 2000 \text{ Hz}$) at the first test session. During the second, third, and fourth sessions, the fit-test was performed with seven 1/3rd octave band noise center frequencies ($f = 125, 250, 500, 1000, 2000, 4000, \text{ and } 8000 \text{ Hz}$).

In Figures 1, 2, 3, and 4, the EPL is plotted against the nominal exposure level provided for each employee, with the results for each earplug depicted in a separate panel. No distinction is made between Groups B and C in these graphs. The horizontal lines at 70 and 85 dBA indicate the lower and upper limits of what would be considered an ideal amount of protection. Red symbols represent the right ear and blue symbols represent the left ear data. The data in these plots were screened to discard anomalous results (e.g., attenuations below -5 dB and above 50 dB, and all no-response results). Results such as these were considered to be invalid, and likely were indicative of subject testing difficulties, or the output limitations of the fit-test system may have been reached (in the case of no-response results).

February 2004: First Visit

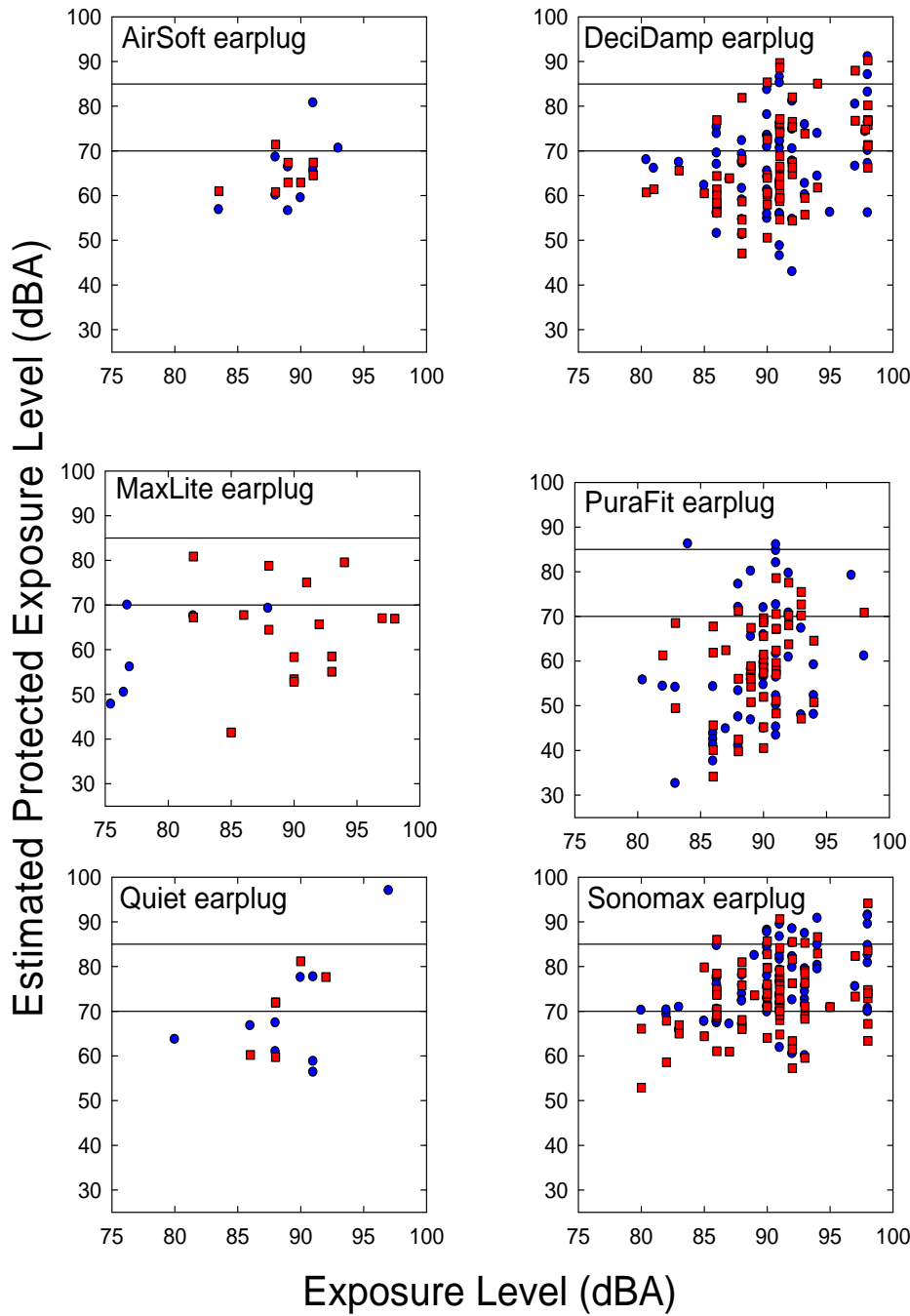


Figure 1. Comparison of the estimated protected exposure level and the nominal exposure level for the initial session in February 2004. The fit of the protector was evaluated at 125, 500, and 2000 Hz using FitCheck. Red symbols depict the results for the right ear and blue symbols depict the left ear. The reference lines at 70 and 85 dBA indicate the ideal range between which a worker's protected exposure level should lie.

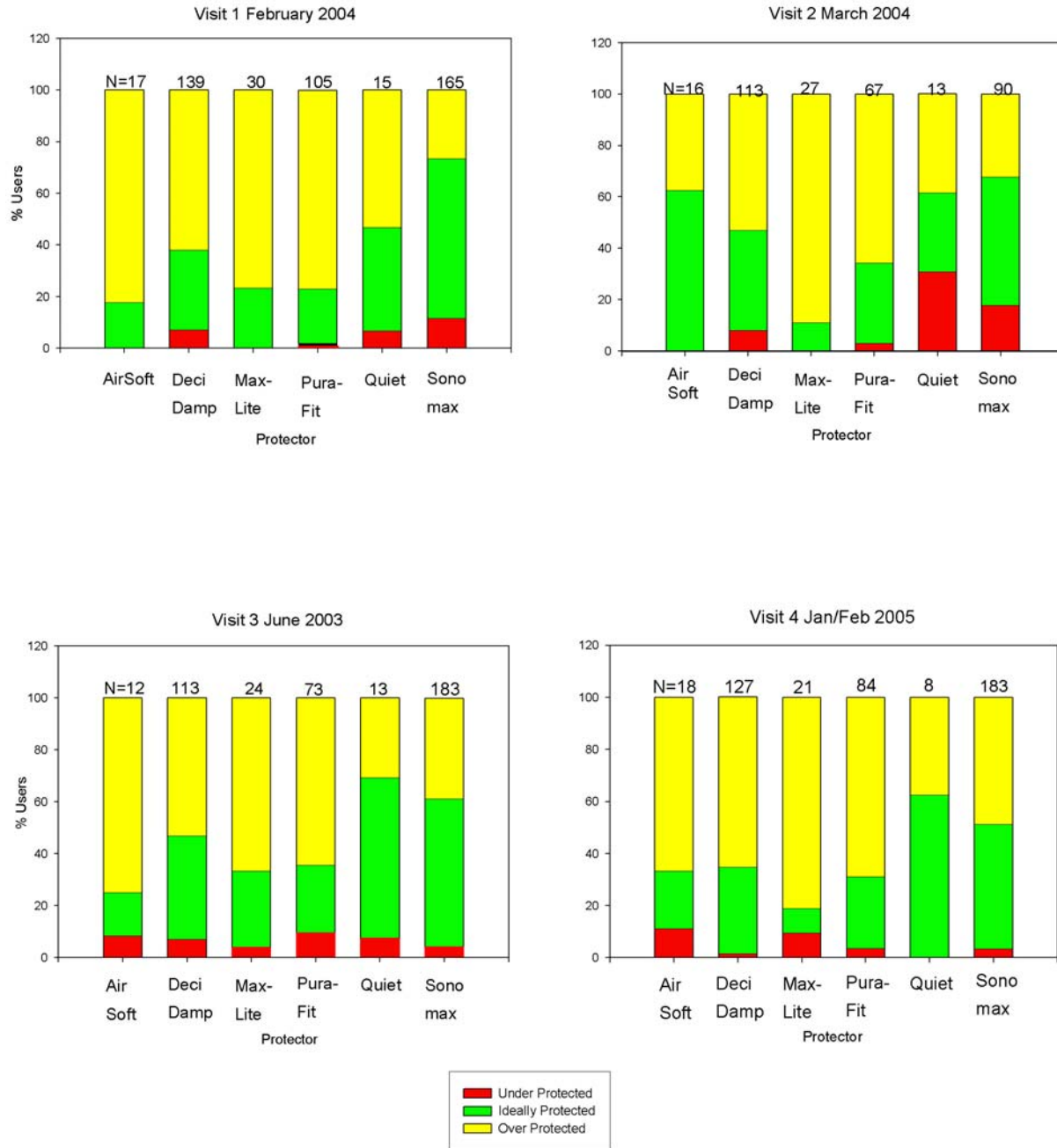


Figure 2 Protection performance of earplugs for visits 1, 2, 3 and 4. Percent of workers under-, ideally- and over-protected. Visit 3 and 4 includes ears from the nested study.

Figure 1 presents the data from the first (February 2004) session. Summary statistics for this series of plots are presented in Figure 2 Visit 1. Overall, about 7% of the subjects' ears were under-protected. Most of the under-protected subjects were wearing the Sonomax, DeciDamp or Quiet earplugs. The majority (53% to 82%) of the non-custom earplug users were over-protected, while those wearing the Sonomax earplug had the least percentage (27%) of ears being over-protected. Subjects wearing the Sonomax earplug had the largest percentage (62%) of ears falling in the ideally protected category.

March 2004: Second Visit

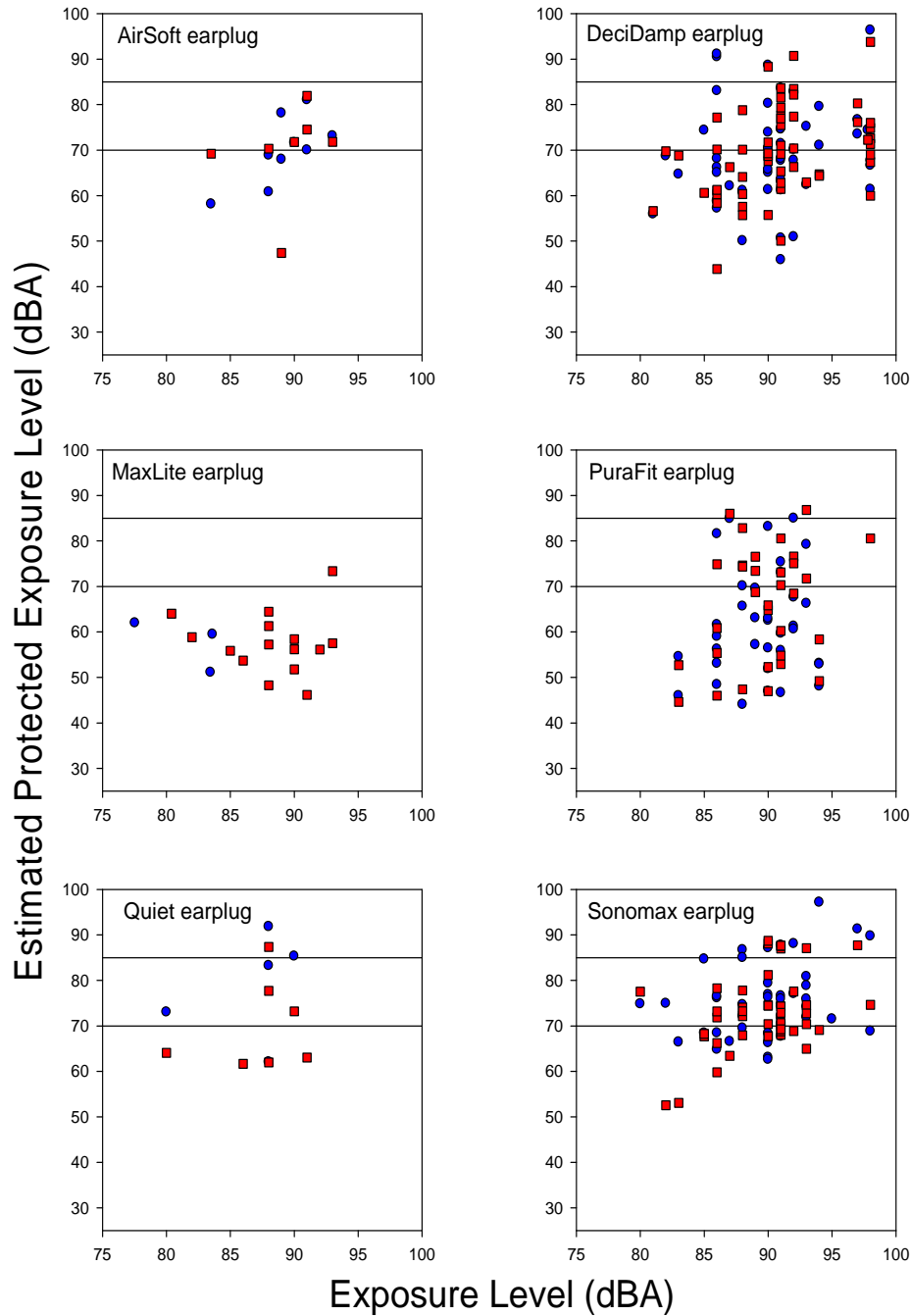


Figure 3. Comparison of the estimated protected exposure level and the nominal exposure level for the March 2004 session. The fit of the protector was evaluated at 125, 250, 500, 1000, 2000, 4000, and 8000 Hz using FitCheck. Red symbols depict the results for the right ear and blue symbols depict the left ear. The reference lines at 70 and 85 dBA indicate the ideal range between which a worker's protected exposure level should lie.

Figure 3 presents the data collected during the second (March 2004) test session. Summary statistics are presented in Figure 2 Second Visit. The Quiet earplug had the greatest percentage

(31%) of subject ears that were under-protected, and the Sonomax earplug had 18% of the subject ears under-protected. Both of these findings represent an increased percentage of under-protection since the initial test session. The Max-Lite, Pura-Fit, and DeciDamp foam earplugs again had high percentages of ears that were overprotected (89%, 66%, and 53%, respectively). The Sonomax earplug had 50% of the subjects' ears achieve an ideal fit, which represented a slight decrease from the first test session. The AirSoft premolded earplug had the highest percentage (63%) of ideally protected ears.

June 2004 Follow-up Visit

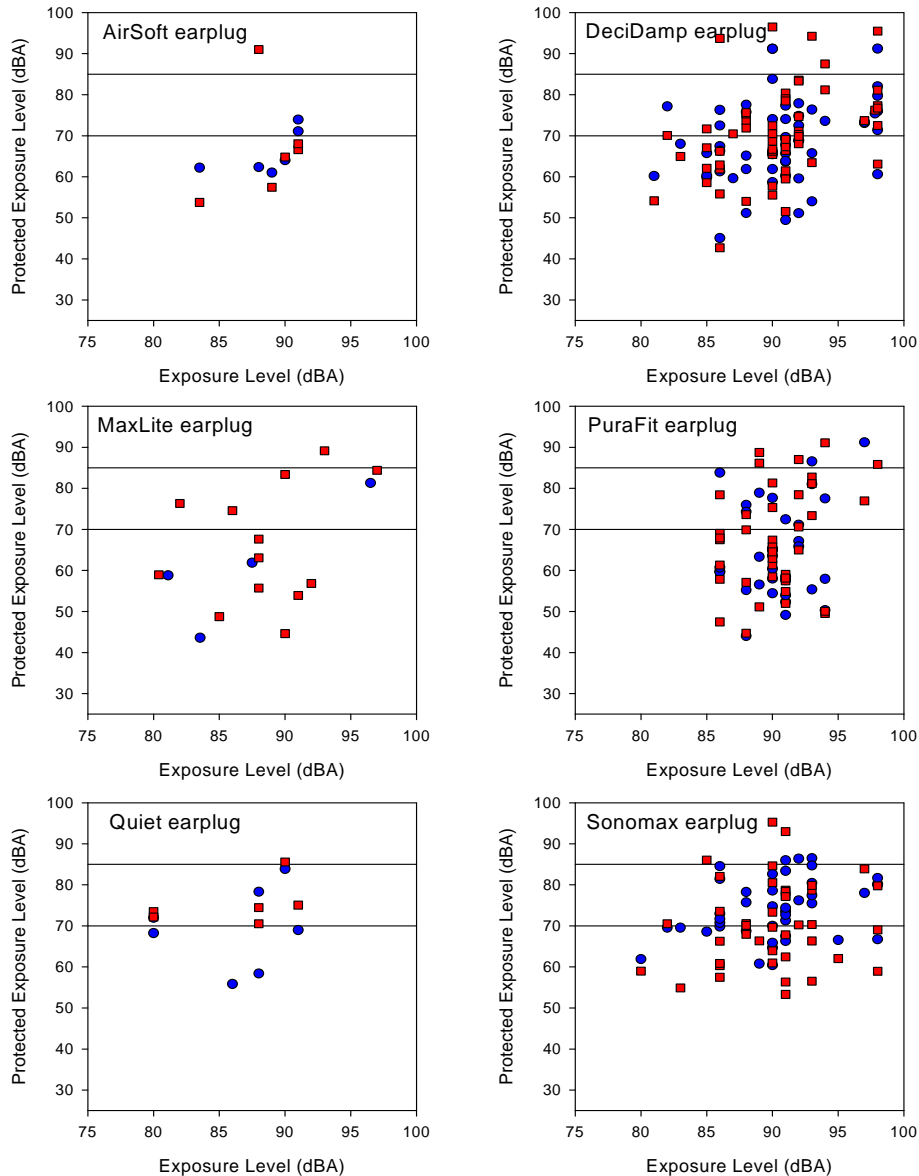


Figure 4. Comparison of the estimated protected exposure level and the nominal exposure level for the June 2004 session. The fit of the protector was evaluated at 125, 250, 500, 1000, 2000, 4000, and 8000 Hz using FitCheck. Red symbols depict the results for the right ear and blue symbols depict the left ear. The reference lines at 70 and 85 dBA indicate the ideal range between which a worker's protected exposure level should lie.

Figure 4 presents the data collected during the third (June 2004) session. Summary statistics are presented in Figure 2 Visit 3. Additional subjects were tested for the secondary study during this site visit, those additional measurements are included in either Figure 3. During this session, all protectors yielded comparable percentages of subject ears that were under-protected (4-10%). Similar to the findings from the first two site visits, the foam earplugs had high percentages of over-protected ears, as did the AirSoft premolded earplug. The Quiet premolded earplug had 62% ideally protected, while the Sonomax earplug again had 50% ideally protected. The largest percentage (42%) of over-protected Sonomax earplug users were found during this test session.

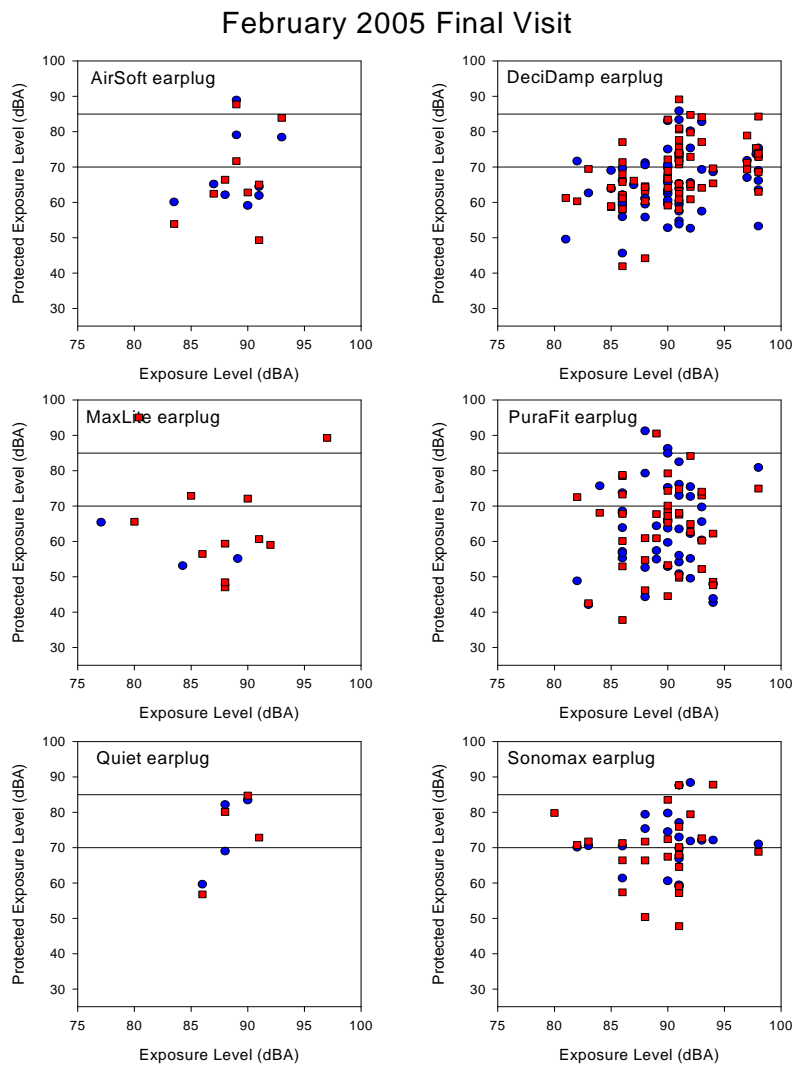


Figure 5. Comparison of the estimated protected exposure level and the nominal exposure level for the January/February 2005 session. The fit of the protector was evaluated at 125, 250, 500, 1000, 2000, 4000, and 8000 Hz using FitCheck. Red symbols depict the results for the right ear and blue symbols depict the left ear. The reference lines at 70 and 85 dBA indicate the ideal range between which a worker's protected exposure level should lie.

Figure 5 presents the data collected during the fourth session (January-February 2005), and the corresponding summary statistics are presented in Figure 2 Visit 4. The data from the secondary study are included in this analysis. Similar trends were observed as in Figure 4, with an exception being that a few subjects wearing the Max-Lite foam earplug shifted from the ideally protected category and increased the percentage in the over-protected column during the final test session. The three foam earplugs and the AirSoft premolded earplug continued to have the greatest percentages of ears that were over-protected. The number of under-protected ears varied from 0% to 11%. The Sonomax device remained consistent with 52% of the subjects' ears falling in the ideally protected range.

Longitudinal Performance

Although the overall number of subjects in each group (A, B, or C) was approximately equal, the numbers of subjects wearing either the DeciDamp or Pura-Fit earplugs were larger than those subjects using the AirSoft, Max-Lite, or Quiet earplugs. After examining the results of the subjects that were seen during all four sessions, only the Pura-Fit and DeciDamp earplugs had enough subjects to merit closer examination for the purpose of comparing the fit-testing with the Sonomax earplug users.

Means and standard deviations are typically reported for noise reduction rating data. Particularly, the Noise Reduction Rating is a metric that was originally meant to estimate what 98% of users might achieve when wearing a hearing protection device. Shortly after the EPA promulgated the regulation for labeling hearing protection devices (40 CFR 211 subpart B¹²) the research community began noting that it overestimated what real-world workers achieved when using protectors. Several excellent review articles on this topic have been written.^{13,14,15,16} Recently, a report on the measurement and rating of hearing protection devices was drafted for the EPA.¹⁷ This report followed the convention of examining the attenuation ratings where the lower ratings represent what a certain percentage of users would achieve. Relating this methodology to the box-and-whisker plots in Figures 6 through 11, several features of the Personal Noise Reduction Rating (PNRR) data are shown. In these plots, the upper and lower boundaries of the box represent the 25th and 75th percentiles of PNRRs for all subjects in a group and session. The line inside the box represents the 50th percentile or median. The lower error bar (whisker) indicates the 90th percentile and the upper error bar indicates the 10th percentile. The open circles indicate the outliers, which are subject(s) either below the 90th or above the 10th percentiles.

Longitudinal Matched for Subjects DeciDamp Group

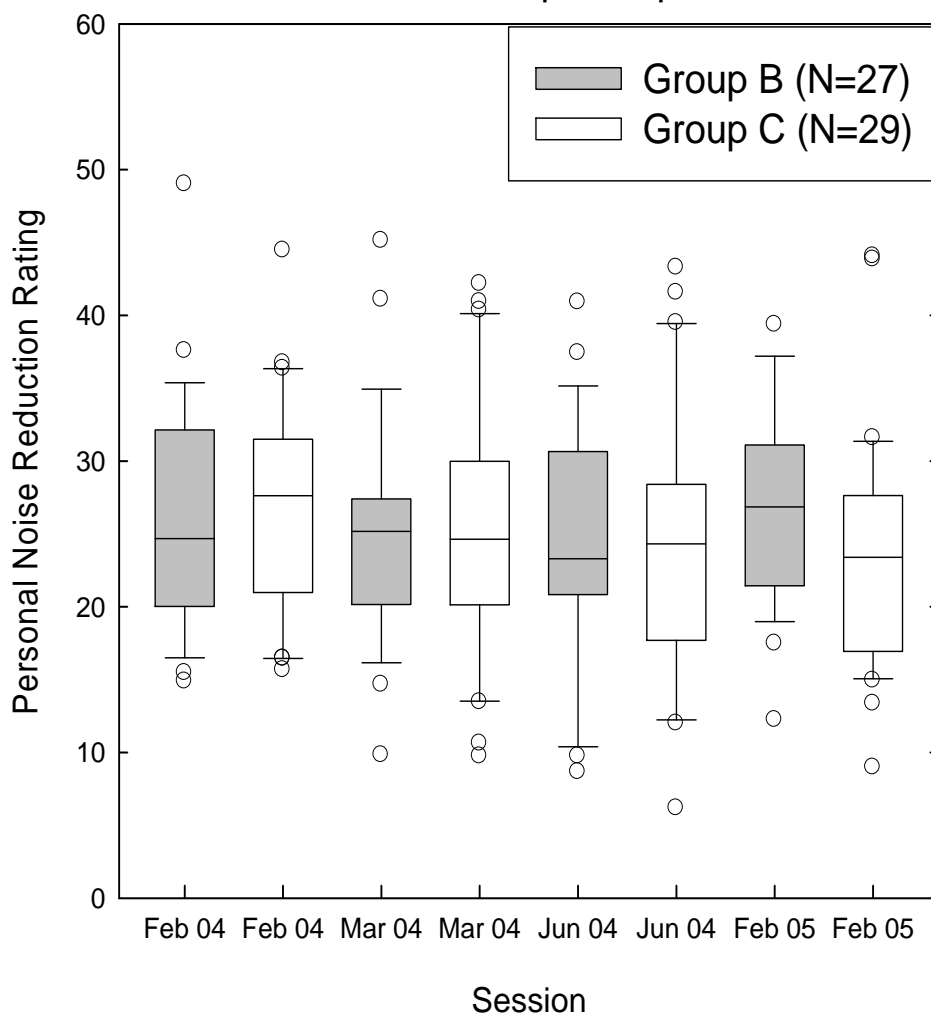


Figure 6. Personal noise reduction ratings (PNRRs) for the workers using the DeciDamp hearing protector. The 10th, 25th, 50th, 75th, and 90th percentiles for workers whose attenuations measured for all four sessions are plotted. The data which fall outside the 10th and 90th percentiles are shown as open circles. Subjects in Group B (N=27) which received counseling regarding protector selection and fitting are shown in gray boxes. Subjects in Group C (N=29) which received no counseling are shown in white boxes.

Figure 6 presents the personal noise reduction ratings (PNRR) for the longitudinally matched subjects measured wearing the DeciDamp earplug at each of the four test sessions. The Group B data are in light gray boxes and the Group C results are shown with white boxes. Both groups tended to achieve a 75th percentile near 20 dB of reduction. The 90th percentile varied from 10 to 19 dB. The 25th percentile varied from 27 to 32 dB, and the 10th percentile varied from 32 to 40 dB of noise reduction. The DeciDamp product has an EPA Noise Reduction Rating of 29 dB, which is meant to indicate the protection that 98% of users will achieve if worn according to the manner in which the manufacturer tested the product. The median value (50th percentile) varied from 23 to 27 dB, clearly below the NRR target of 98%.

Longitudinal Matched for Subjects PuraFit Group

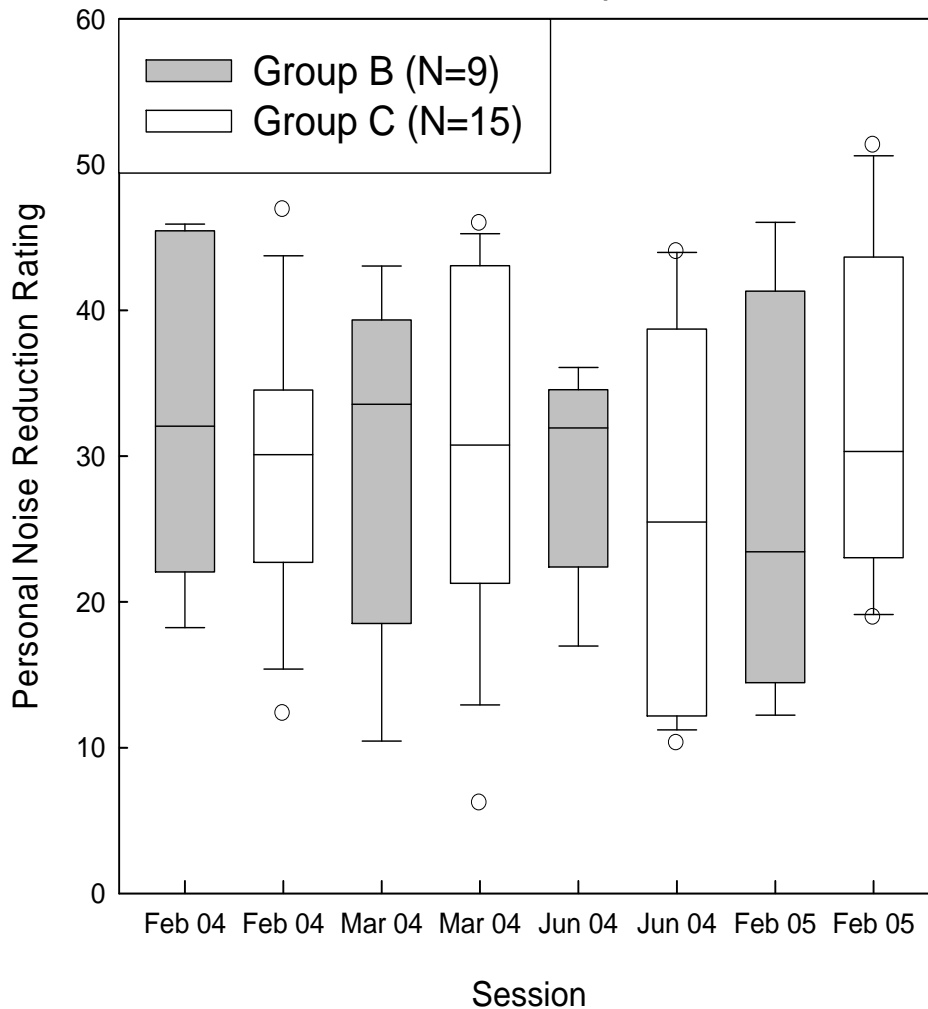


Figure 7. Personal noise reduction ratings (PNRRs) for the workers using the Pura-Fit hearing protector. The 10th, 25th, 50th, 75th, and 90th percentiles for workers whose attenuations measured for all four sessions are plotted. The data which fall outside the 10th and 90th percentiles are shown as open circles. Subjects in Group B (N=9) which received counseling regarding protector selection and fitting are shown in gray boxes. Subjects in Group C (N=15) which received no counseling are shown in white boxes.

Figure 7 presents the PNRR estimates for the longitudinally matched subjects measured wearing the Pura-Fit earplug at each of the four sessions. Results for the 75th percentiles ranged from a low of about 12 dB to high of about 24 dB. These results were more variable than the DeciDamp results, and the overall ranges of the boxes were greater than those for the DeciDamp earplug. The 25th percentiles varied from about 34 dB to 45 dB. It is important to note that the group sizes were smaller and thus the 90th and 10th percentiles represent nominally one subject for groups B and C. The median PNRR values ranged from about 23 dB to about 33 dB. The Pura-Fit earplug has an NRR of 31 dB, and the median performance was mostly below this target level.

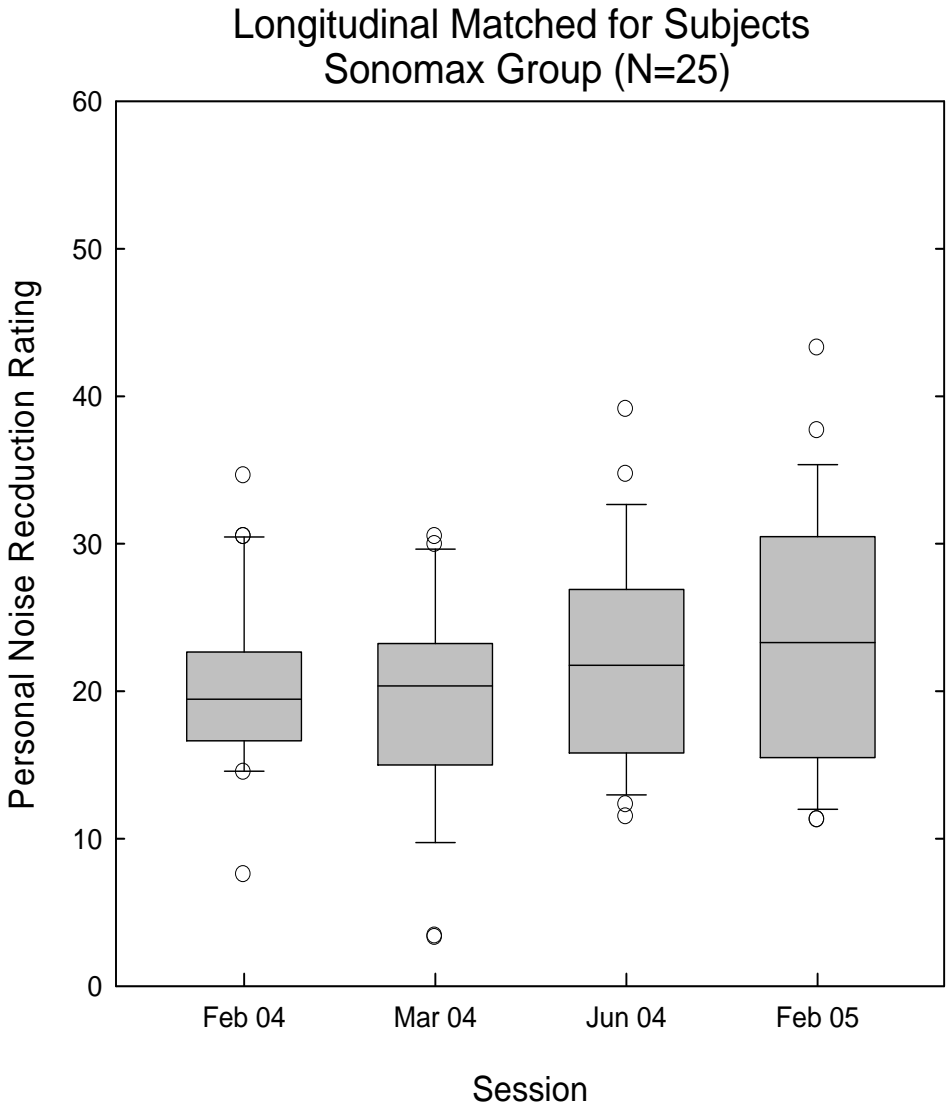


Figure 8. Personal noise reduction ratings (PNRRs) for the workers using the Sonomax hearing protector (Group A). The 10th, 25th, 50th, 75th, and 90th percentiles for workers whose attenuations measured for all four sessions are plotted. The data which fall outside the 10th and 90th percentiles are shown as open circles.

Figure 8 presents the PNRR estimates for the Sonomax (Group A) subjects that were measured during all test sessions. The 90th percentile ranged from 11 to 15 dB and the 10th percentile ranged from 30 to 35 dB, which are considerably smaller ranges than were observed for the DeciDamp or Pura-Fit earplugs. The 75th percentiles ranged from 15 to 17 dB while the 25th percentiles increased from 23 to about 30 dB over the course of the four sessions. The variability of the 25th percentiles was slightly larger than that observed for the DeciDamp, but less than that for the Pura-Fit earplug. Median values increased from about 19 to 23 dB over the course of the four sessions. It is important to remember that the manufacture of the custom earplugs was conducted by manufacturer’s technicians who installed the appropriate filter for the nominal noise exposure level provided by the plant. Therefore, the NRR of the custom-molded earplug varied as a function of which acoustic filter was inserted into the sound bore of the protector. The NIOSH researchers were not provided this information during the time when the subject was

being tested. During the first several months, a company representative visited the Flint Metal Center to repair, refit, or adjust the filter for the Group A subjects.

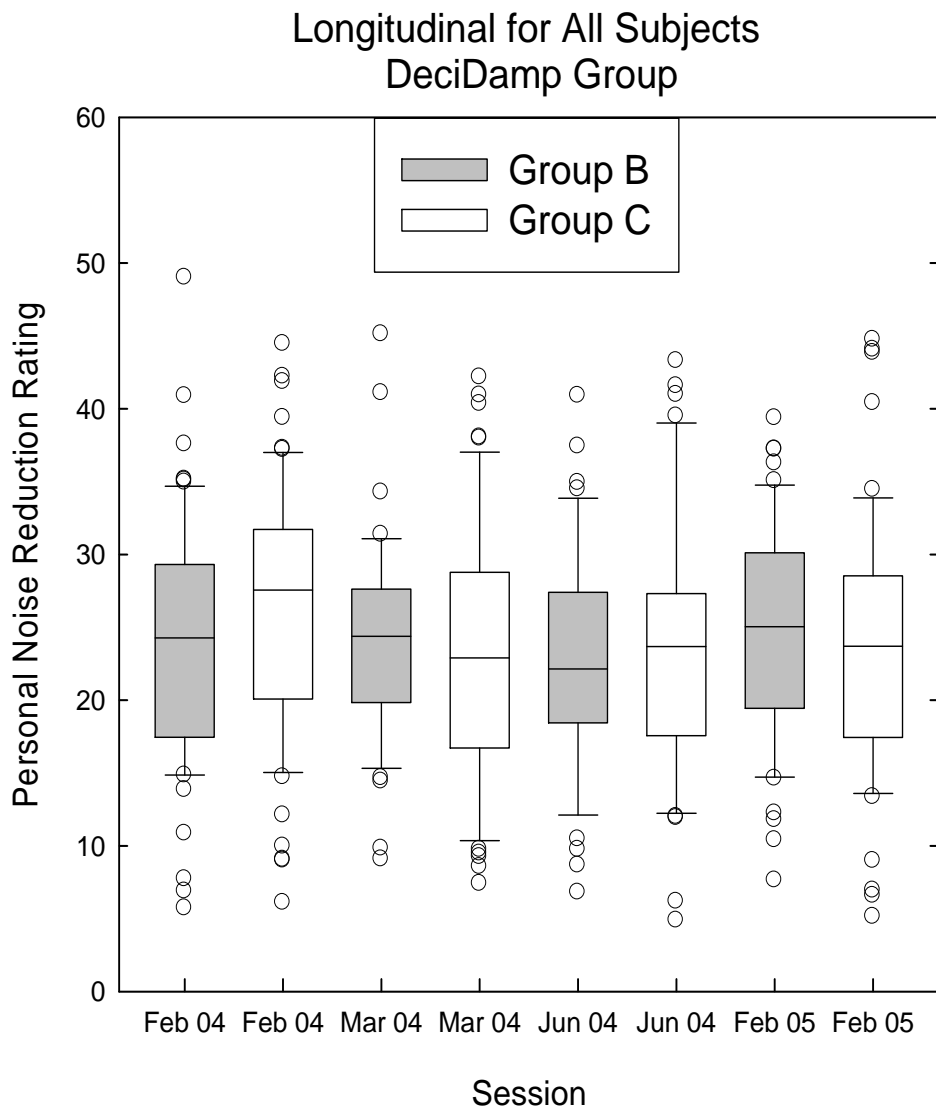


Figure 9. Personal noise reduction ratings (PNRRs) for the workers using the DeciDamp hearing protector. The 10th, 25th, 50th, 75th, and 90th percentiles for workers whose attenuations measured during any of the four sessions are plotted. The data which fall outside the 10th and 90th percentiles are shown as open circles. Subjects in Group B which received counseling regarding protector selection and fitting are show in gray boxes. Subjects in Group C which received no counseling are shown in white. The number of subjects in a group for any given session was not constant.

Figures 9, 10 and 11 are a variation of the previous three figures, except that the data from all subjects are included. The results are largely the same as the previous plots. In Figure 9, the subjects in Groups B and C who wore the DeciDamp earplug consistently achieved attenuations of 10 to 16 decibels at the 90th percentile, 17 to 20 dB at the 75th percentile, 23 to 28 dB for the 50th percentile, 28 to 32 dB for the 25th percentile and 32 to 38 dB for the 10th percentile.

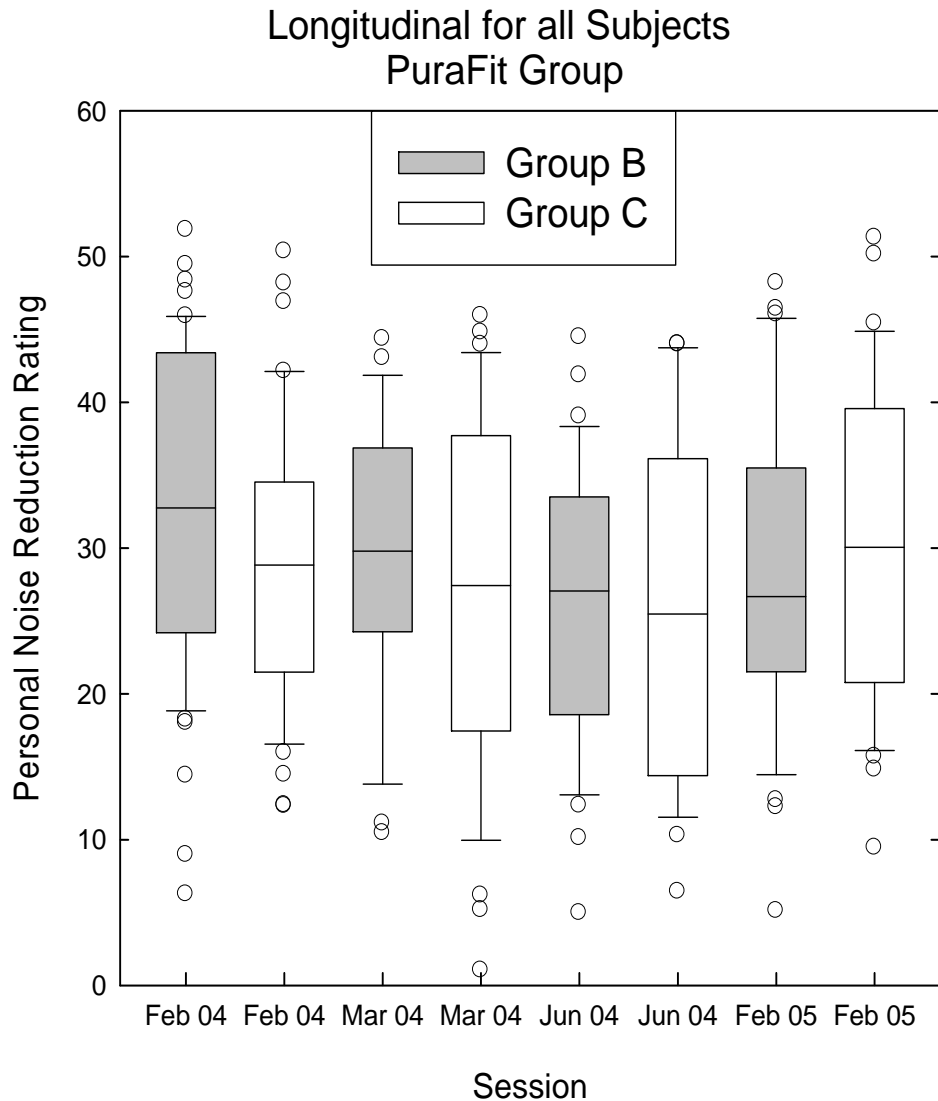


Figure 10. Personal noise reduction ratings (PNRRs) for the workers using the Pura-Fit hearing protector. The 10th, 25th, 50th, 75th, and 90th percentiles for workers whose attenuations measured during any of the four sessions are plotted. The data which fall outside the 10th and 90th percentiles are shown as open circles. Subjects in Group B which received counseling regarding protector selection and fitting are shown in gray. Subjects in Group C which received no counseling are shown in white. The number of subjects in a group for any given session was not constant.

In Figure 10, the subjects in Group B and Group C who wore the Pura-Fit earplug consistently achieved attenuations of 10 to 19 decibels at the 90th percentile, 14 to 24 dB at the 75th percentile, 26 to 33 dB for the 50th percentile, 34 to 44 dB for the 25th percentile and 38 to 46 dB for the 10th percentile.

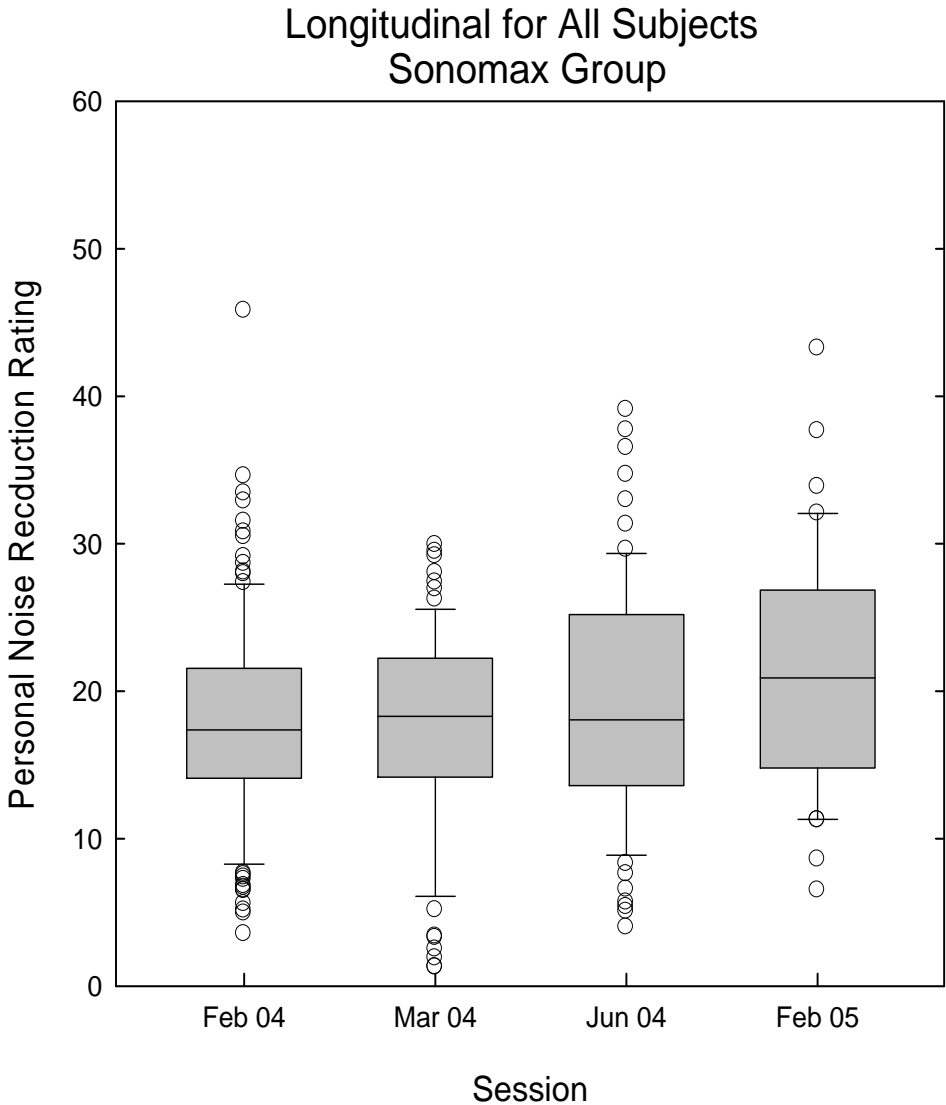


Figure 11. Personal noise reduction ratings (PNRRs) for the workers using the Sonomax hearing protector (Group A). The 10th, 25th, 50th, 75th, and 90th percentiles for workers whose attenuations measured during any of the four sessions are plotted. The data which fall outside the 10th and 90th percentiles are shown as open circles. The number of subjects in a group for any given session was not constant.

In Figure 11, all of the subjects in Group A who were tested with the Sonomax earplug are shown. Ninety percent of the subjects consistently achieved PNRRs of 5 to 11 dB. The 75th percentiles were 13-14 dB. The median (50th percentile) PNRR ranged from 17 to 21 dB. The 25th and 10th percentiles ranged from 22 to 26 dB and 25 to 31 dB, respectively.

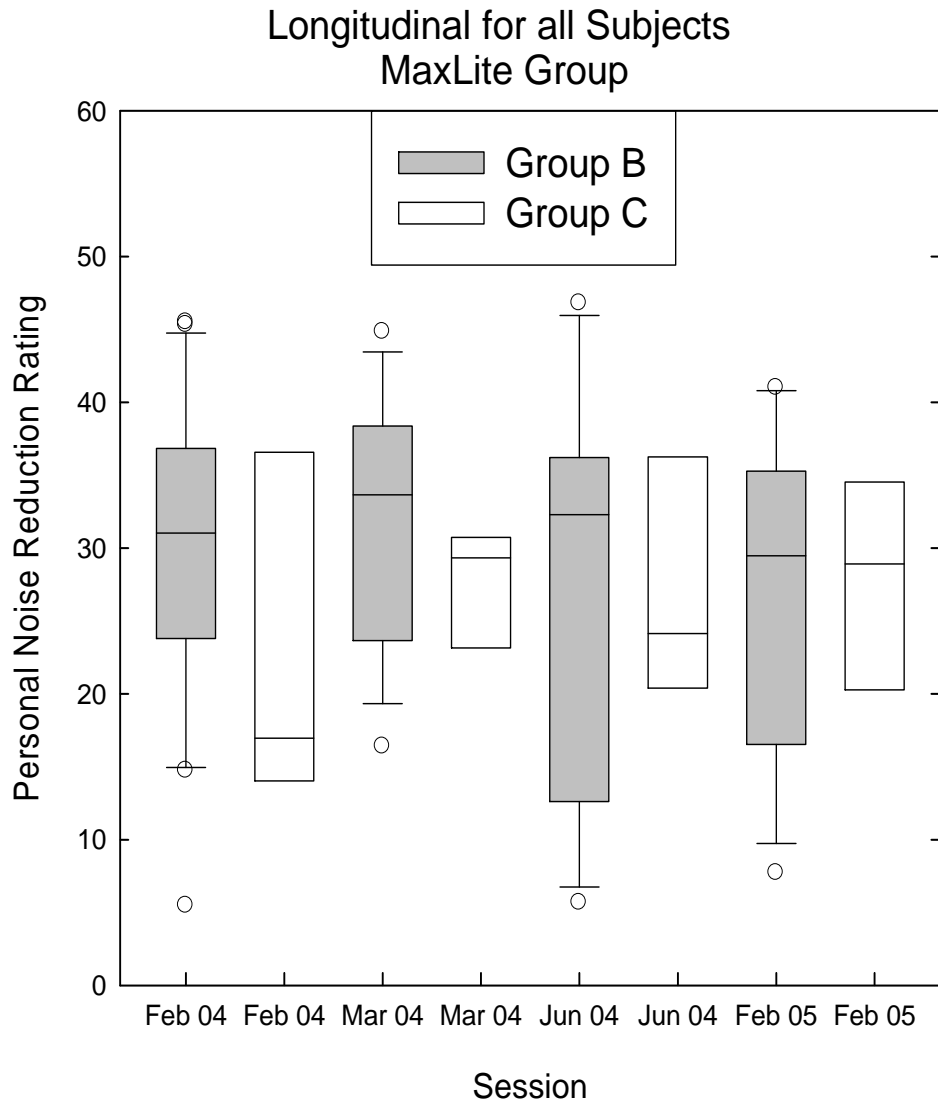


Figure 12. Personal noise reduction ratings (PNRRs) for the workers using the Max-Lite hearing protector. The 10th, 25th, 50th, 75th, and 90th percentiles for workers whose attenuations measured during any of the four sessions are plotted. The data which fall outside the 10th and 90th percentiles are shown as open circles. Subjects in Group B which received counseling regarding protector selection and fitting are show in gray boxes. Subjects in Group C which received no counseling are shown in white. The number of subjects in a group for any given session was not constant.

Longitudinal for all Subjects
AirSoft Group

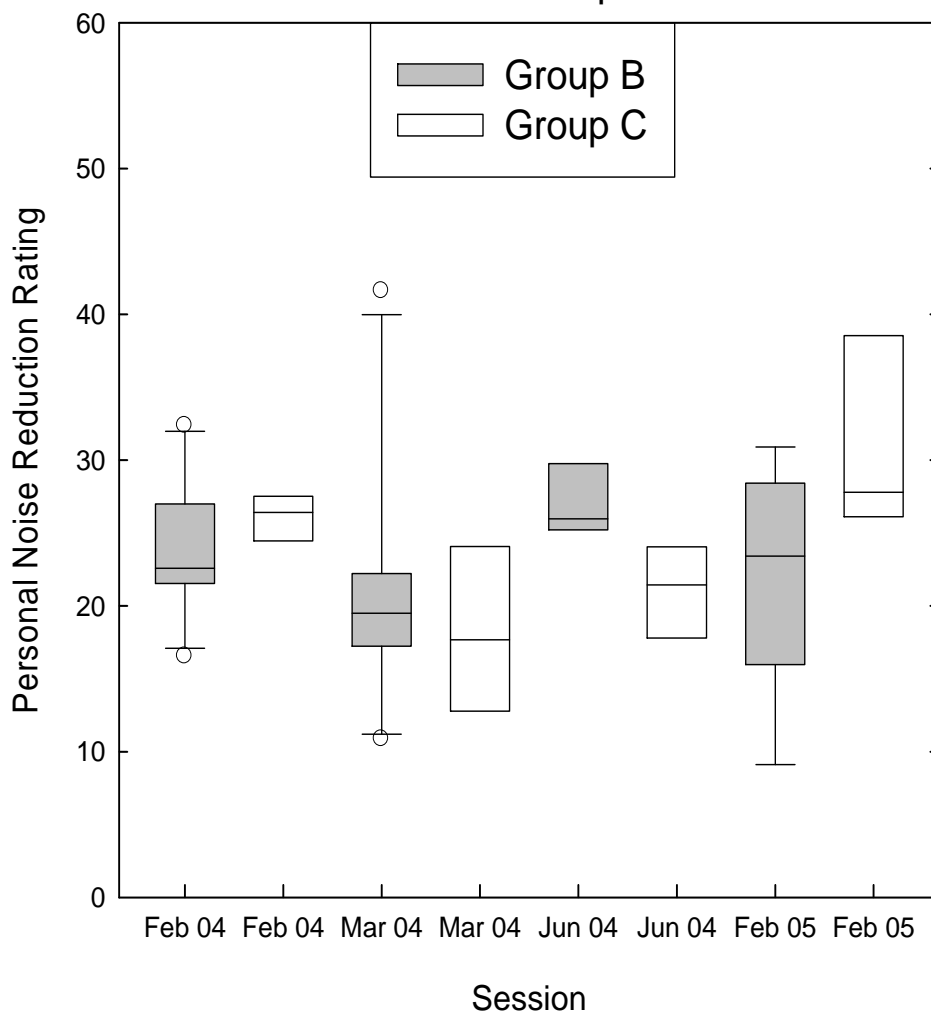


Figure 13. Personal noise reduction ratings (PNRRs) for the workers using the AirSoft hearing protector. The 10th, 25th, 50th, 75th, and 90th percentiles for workers whose attenuations measured during any of the four sessions are plotted. The data which fall outside the 10th and 90th percentiles are shown as open circles. Subjects in Group B which received counseling regarding protector selection and fitting are shown in gray boxes. Subjects in Group C which received no counseling are shown in white. The number of subjects in a group for any given session was not constant.

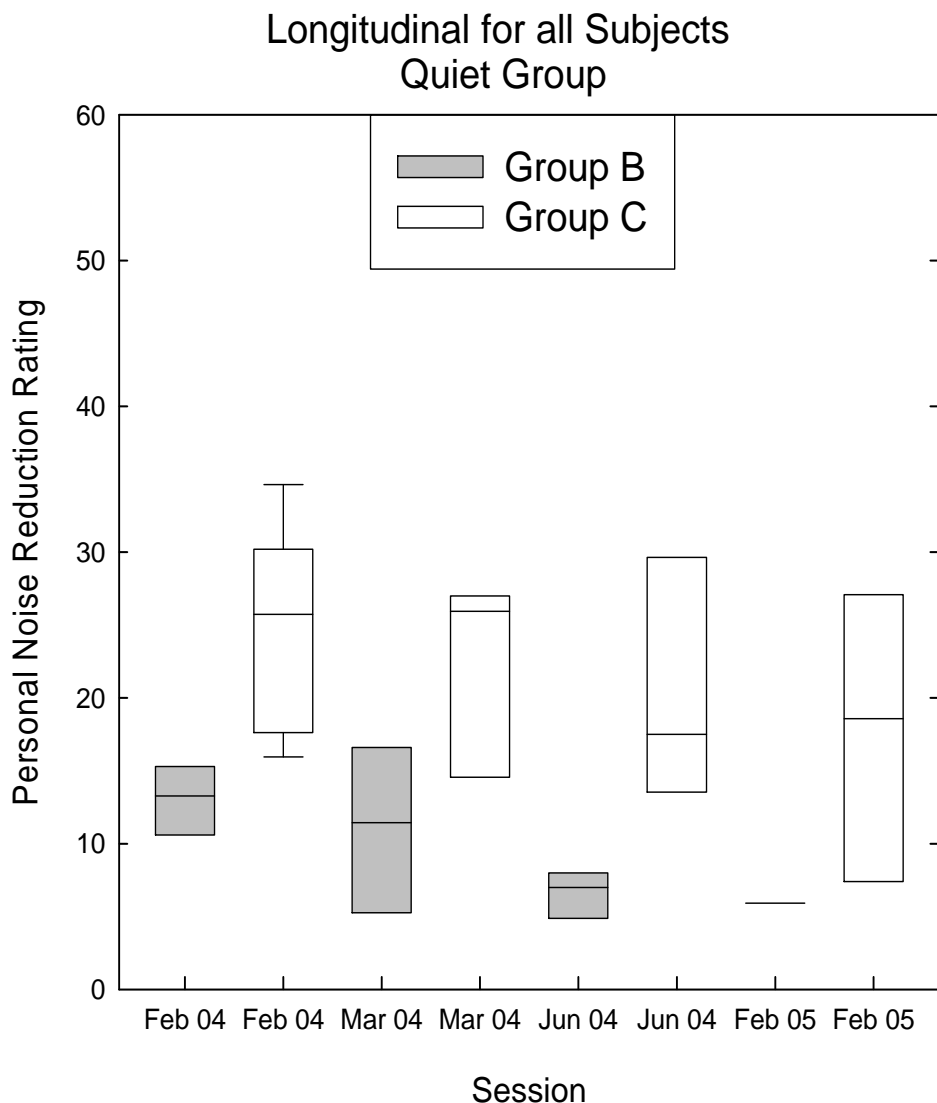


Figure 14. Personal noise reduction ratings (PNRRs) for the workers using the Quiet hearing protector. The 10th, 25th, 50th, 75th, and 90th percentiles for workers whose attenuations measured during any of the four sessions are plotted. The data which fall outside the 10th and 90th percentiles are shown as open circles. Subjects in Group B which received counseling regarding protector selection and fitting are shown in gray boxes. Subjects in Group C which received no counseling are shown in white. The number of subjects in a group for any given session was not constant and was less than five for each group.

In Figures 12, 13, and 14, the PNRR data for all subjects using the Max-Lite, AirSoft, and Quiet protectors are shown. In large part, the results exhibit a wide range of attenuations. Without more subjects, the discussion of the results has limited utility. Most of the subjects achieved at least 10 dB of noise reduction. Many were able to achieve 20 to 30 dB of noise reduction. For the Quiet earplug, the few subjects in Group B consistently achieved lower noise reductions than those subjects in Group C. During the final session, only one subject was tested in Group B for the Quiet protector.

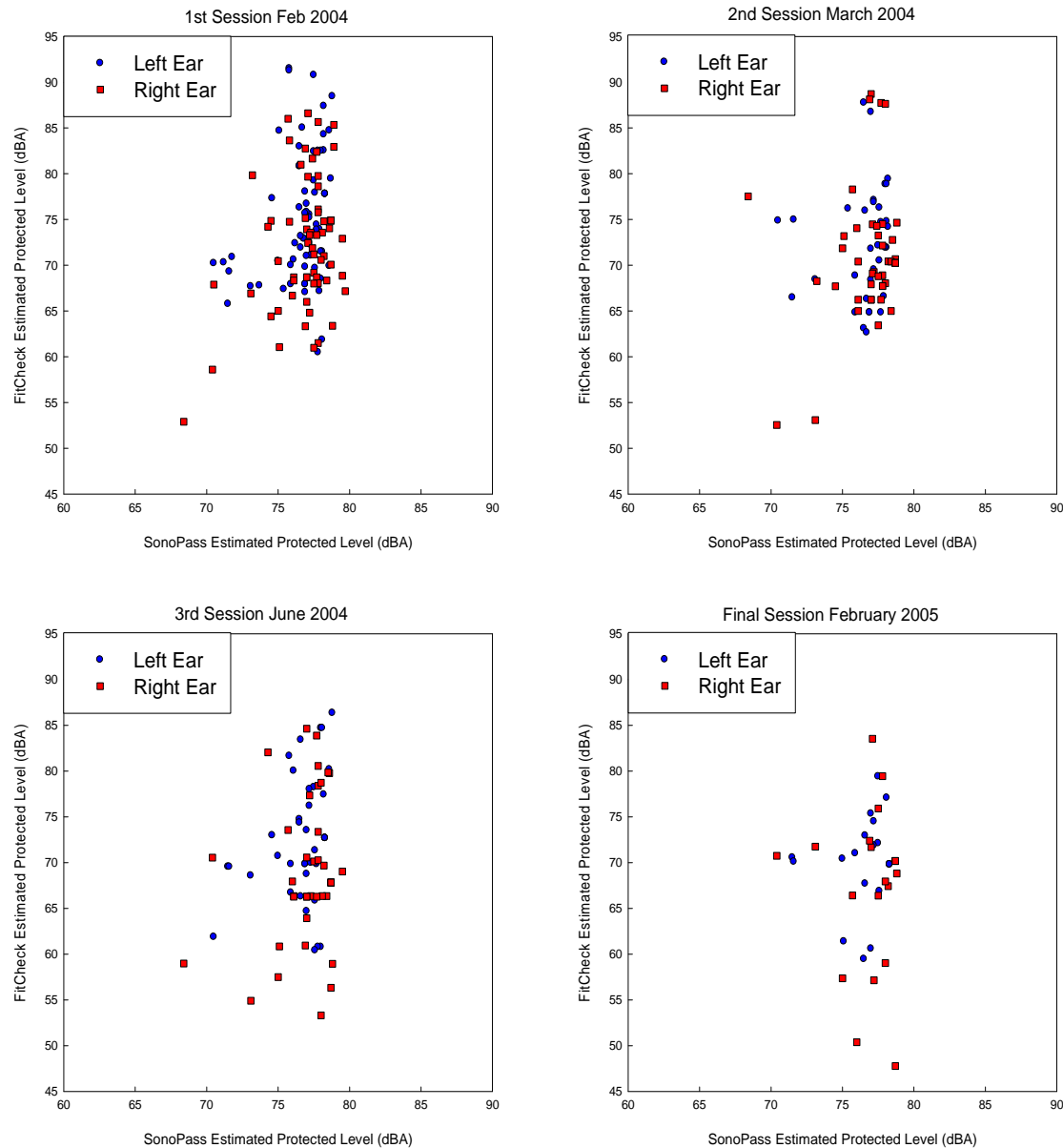


Figure 15. Comparison of the Estimated Protected Level derived from the FitCheck assessment and from the SonoPass™ attenuation measurement. The results from the right and left ears are shown in red and blue symbols, respectively. The SonoPass value shown in these graphs was measured once at the initial fitting of the custom earplug during February 2004 -- any changes to the filter selection are not reflected in subsequent sessions.

Figure 15 shows a comparison of the protected exposure levels estimated using the SonoPass™ software and using the FitCheck system. The two measurements involved separate fittings of the Sonomax earplug (i.e., the earplug had been removed and reinserted before NIOSH conducted the fit-test). The SonoPass™ estimated protected exposure level was narrowly confined in the 70 to 80 dBA range for all but one subject. Because the SonoPass™ measurements were not repeated (except for the three subjects who were refit or received different acoustic filters) this range remained consistent throughout the remainder of the sessions. Furthermore, the SonoPass™ estimate incorporates the estimated attenuation of the filter selection designed to bring the protected exposure into the 70 to 80 dBA range. The FitCheck measurements suggest

considerably more variability as has already been discussed for Figures 2, 8 & 11. According to the FitCheck testing, the Sonomax earplug consistently had about 50% of the subjects with protected exposures in the 70 to 85 dBA range, which represents an ideal amount of attenuation.

Changes in Hearing Thresholds

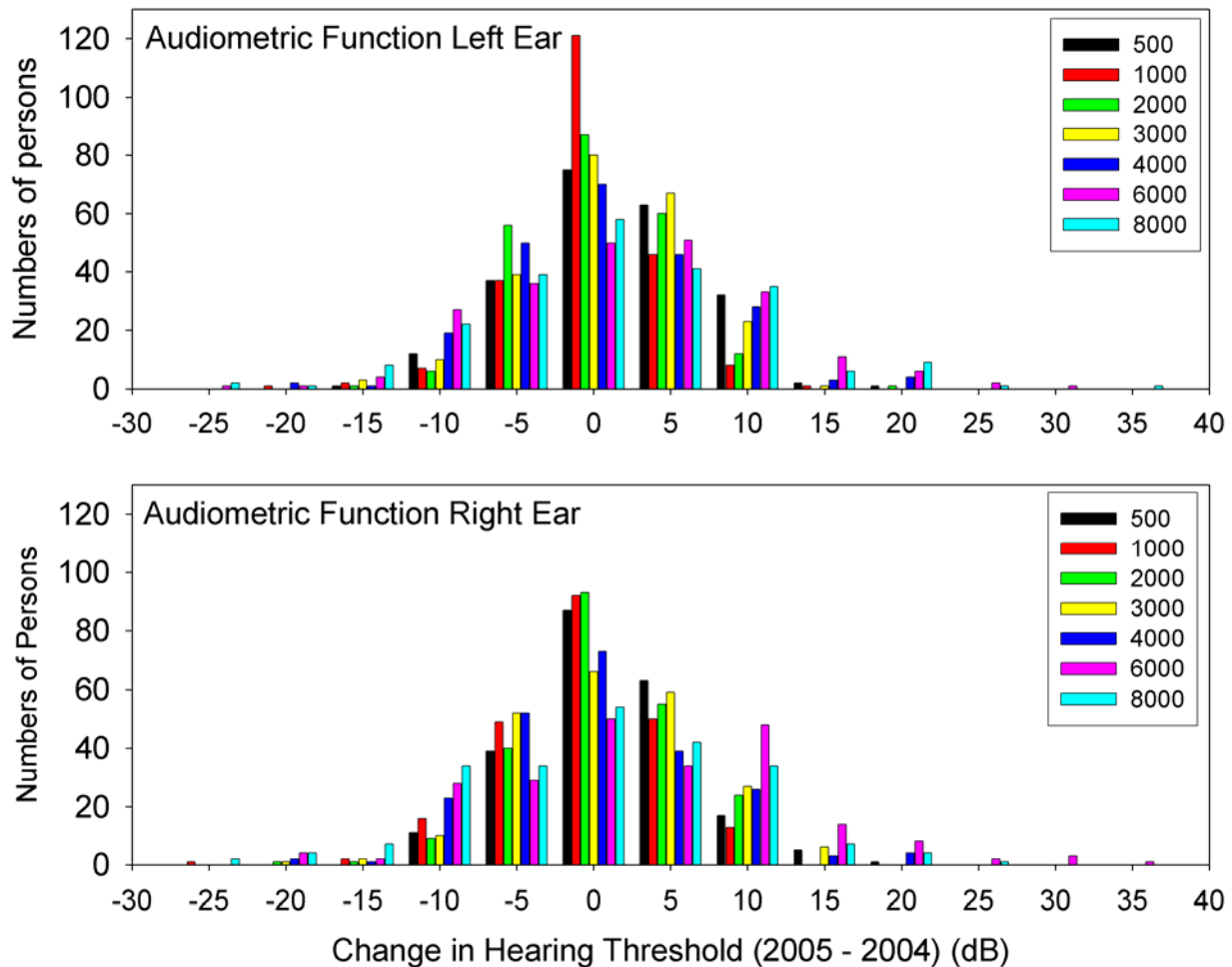


Figure 16. Histogram of the change in hearing threshold (dB) from 2004 to 2005 for all subjects. The NIOSH definition of a significant threshold shift is a 15 dB or more increase in threshold at any frequency (500, 1000, 2000, 3000, 4000, or 6000 Hz) in either ear. Thirty-two subjects experienced a shift in the left ear and 41 shifts occurred in the right ear.

Standard hearing tests were administered to all study participants during the first (January 2004) and last (January/February 2005) test session for Groups A, B, & C, and in June 2004 and again in January/February 2005 for the subjects in the secondary nested study. According to the NIOSH recommendation, the computer-controlled audiometer software was set to automatically flag any shifts of 15 dB or more and conduct an immediate retest at the suspect frequency. Figure 16 contains the threshold shift results (i.e., the hearing level value on the 2004 audiogram subtracted from the 2005 audiogram) that were calculated for each subject having both tests and valid data at all frequencies. The data from three subjects who had audiograms containing a No-Response or a Not-Tested indicator were not included in this analysis. What was not completed

due to the logistics of the study design was a separate confirmation audiogram, which is why these shifts are considered as potential rather than confirmed. Any subject that exhibited a shift was counseled by a NIOSH audiologist. Subjects were given information about the shift in hearing, re-instructed regarding the importance of proper use of hearing protection, and were directed to see the plant occupational health unit for further information.

Table 1. Numbers of subjects exhibiting a significant threshold shift in hearing using the NIOSH recommendation, which is defined as a $\geq +15$ dB shift at any frequency (500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz) in either ear. Results are shown for right/left ears.

Frequency	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz	8000 Hz	Total
Group A	1 / 0	0 / 1	0 / 0	1 / 1	1 / 2	5 / 2	2 / 3	10 / 9
Group B	2 / 2	0 / 0	0 / 1	4 / 0	4 / 2	8 / 5	2 / 5	14 / 13
Group C	0 / 0	0 / 0	0 / 0	0 / 0	2 / 2	8 / 8	2 / 4	12 / 13
Group S	3 / 1	0 / 0	0 / 0	1 / 0	0 / 1	7 / 5	6 / 5	15 / 11

An analysis of hearing threshold changes from the first to the last session was conducted using two different approaches. First, the NIOSH criterion for a significant threshold shift was used, which is a difference of +15 dB (worse hearing) in either ear at any frequency from 500-6000 Hz. Summary statistics separated by groups and frequency are shown in Table 1. Since NIOSH recommends the testing of 8000 Hz,¹¹ this frequency was included in the criterion as well. Subjects in Group A exhibited the least number of potential shifts using the NIOSH criterion; 10 subjects had potential shifts in the right ear and 9 had potential shifts in the left ear. For Group B, potential shifts were identified for 14 right ears and 13 left ears. For Group C, potential shifts were identified for 12 right ears and 13 left ears. For the secondary study (Groups S1/S2) 15 potential shifts were identified for the right ears and 11 were identified for the left ears.

Table 2. Numbers of subjects exhibiting an STS using the OSHA criterion, which is defined as a ≥ 10 dB shift in the pure-tone average of 2000, 3000, and 4000 Hz in either ear.

	STS - Left ear	STS - Right ear	Total STS
Group A	0	0	0
Group B	1	2	3
Group C	1	1	2
Group S	0	0	0

In Table 2, the results for subjects who exhibited an OSHA-defined standard threshold shift (STS) are detailed. An OSHA STS represents an average change of 10 dB or more in the pure-tone hearing threshold levels at 2000, 3000, and 4000 Hz for either ear. Only five subjects exhibited an OSHA STS -- three subjects in Group B and two subjects in Group C. No consideration was given to a 25 dB hearing threshold level “fence,” since recording these shifts on the OSHA Form 300 was not within the scope of this study. Comparing these results to Table 1, the majority of shifts identified with the NIOSH criterion occurred at 6000 and 8000 Hz.

Actual Noise Reduction vs. Labeled NRR

Table 3. Measured noise reduction vs. labeled noise reduction rating (NRR) for the DeciDamp, Pura-Fit, and Sonomax earplugs.

Hearing Protector Brand	Measured Noise Reduction	Labeled NRR
DeciDamp	11 dB	29 dB
Pura-Fit	12 dB	31 dB
Sonomax	6 dB	4 – 17 dB

Table 3 displays the noise reduction delivered by the DeciDamp, Pura-Fit, and Sonomax earplugs along with the labeled Noise Reduction Ratings required by the U.S. EPA.¹² Examination of the data in Figures 6, 7, and 8 shows that some of the test subjects wearing the DeciDamp or Pura-Fit earplugs may have achieved the NRR level of attenuation. Since the Sonomax earplug is an adjustable device, its labeled rating ranges from 4 dB with no filter to 17 dB when completely blocked. Data are not shown for the AirSoft, Max-Lite, and Quiet earplugs, because there were insufficient numbers of users of these protectors within the study group.

Comfort Scores

An analysis of covariance (ANCOVA) model of the Comfort Questionnaire scores indicate that there is a statistically significant difference due to group ($p = 0.0002$) and time ($p = 0.03$). The Sonomax wearers (Group A) reported a slightly higher comfort score (35.27) than Group B (33.06) and Group C (32.19) [scores range from 14 (most comfortable) to 70 (least comfortable)]. Although statistically significant, the 2-3 point difference may not be practically different. When analyzed over the course of one year, the change in time of the slope main effect is not statistically significant for Group A (-0.025, slightly more comfortable over time) nor Group C (-0.019, slightly more comfortable over time). Group B's slope (-0.212, slightly more comfortable over time) is statistically significant over one year ($p < 0.0001$).

Observations

Table 4. Results of observations of use of the Sonomax earplug over the course of the study.

Month	Enrolled	Observed	Wearing	Not wearing	Percent wearing
April 2004	57	46	20	26	43%
May 2004	57	44	11	33	25%
July 2004	114	88	18	70	20%
August 2004	102	90	21	69	23%
Sept 2004	100	75	20	55	27%
Oct 2004	99	76	28	48	37%
Dec 2004	93	75	19	56	25%
Jan 2005	93	64	16	48	25%

About once per month, a JAA consultant would observe as many members of Group A (and later the two secondary groups) as possible and record information regarding usage of the custom-molded hearing protector wearers in their work setting. No effort was made to monitor the study subjects in Group B or Group C. Table 4 shows that for each month for which an observation was reported it was possible to observe between 60% and 80% of the enrolled study population. Generally less than half (20-43%) of the workers fitted with the custom earplugs were wearing them when observed at work on the plant floor. Due to the NIOSH site visit in June 2004, no observations were made although the number of active participants was reported. July 2004 was the first month which included the secondary study so the numbers increased from 52 to 114.

Discussion

According to the data in Figures 1-5, about 90% of the subjects were able to achieve sufficient attenuation to be protected to an 85 dBA exposure level. The custom-molded earplug provided the most consistent results with 50-62% of the subjects reaching the ideal range of protection (i.e., estimated exposure levels of 70 to 85 dBA). As can be seen in Figures 6 and 7, subjects tended to wear their protectors consistently from test to test. Observational data revealed that approximately 25% of the subjects fitted with the custom-molded protectors were wearing them while at work; therefore, the acceptance rate was inferred to be 25%.

One of the more striking outcomes from the data is that the study subjects seemed to prefer being over-protected. In Figure 8, the custom-molded earplug users showed a shift toward increasing attenuation, which, in turn, resulted in estimated exposure levels below 70 dBA. During the first and second sessions several subjects requested to have the partial filters replaced with the full block. This trend may be attributable to the experience the subjects had with using traditional hearing protectors. Since the non-custom formable earplugs have the potential to provide attenuations of greater than 20 dB and nearly 40 dB at several frequencies, perhaps some subjects incorrectly perceived themselves to be under-protected. This would cause some test subjects who had requested a full acoustic block for their custom earplugs to subsequently fall into the over-protected range. Had this study been conducted with new workers inexperienced with both hearing protector use and working in noise, the outcome may have been somewhat different. Subjects might not have requested greater attenuation for their custom-molded earplugs and more readily accepted the prescribed partial block. It is also possible that the impulsive noise environment is not ideal for the Sonomax product.

The personal noise reduction ratings were also an interesting result from this study. During the initial session, subjects were measured for a reduced set of frequencies: 125, 500, and 2000 Hz. These three frequencies were used effectively to predict the attenuation of the earplugs. The use of fewer test frequencies presents the possibility for wider implementation of fit-testing for hearing protection devices due to the relatively small time commitment required. In respiratory protection programs, many of the same issues are encountered as for hearing protection programs. Manufacturers are required to rate the performance protection factor for a respirator and a noise reduction rating for a hearing protector. Workers that use respirators are required to participate in annual training and fit-testing to demonstrate that an acceptable level of protection can be achieved. If one improperly wears a respirator, death could be an outcome; however, if

one improperly wears hearing protection, hearing loss is the outcome. The gradual nature of noise-induced hearing loss leads to complacency with respect to noise hazards and lack of attention to wearing hearing protection. Prior NIOSH and other research has shown that effective use of training programs within the construction industry leads to greater levels of motivation for correct use of hearing protectors among workers.¹⁸

A more thorough examination of the prediction algorithm employed by SonoPass™ and the measurement algorithm used in FitCheck needs to be completed. Two possible interpretations of the results could be made. First, the SonoPass™ measurement may not adequately describe the attenuation for a particular filter and consequently yields too narrow a range of protected exposure values. A second possibility is that the FitCheck software and hardware could have difficulties accurately estimating the subject's real-ear attenuation at threshold (REAT) as described above. The fixed time for testing and the lack of error checking may not allow subjects sufficient opportunity to establish occluded or unoccluded thresholds. These factors could increase the uncertainty of the attenuation measurements. Sonomax Hearing Healthcare, Inc. has conducted external validation of their algorithm¹⁹ which leads one to suspect that the problems may lie with the FitCheck algorithms.

The audiometric data collected in conjunction with the fit-testing contains a wealth of information. A recent paper by Dobie²⁰ examined a simulation of hearing thresholds for a hypothetical set of subjects that may or may not be noise-exposed. Dobie tested the OSHA criterion for an STS and the NIOSH criterion for a significant threshold shift. His findings demonstrated that the OSHA criterion resulted in less false-positive identification of subjects with a hearing loss. The NIOSH criteria resulted in more false-positives since it identified any frequency which shifted by 15 dB or more. From the data presented in Tables 1 and 2, the types of potential shifts that were flagged represent different parts of the audiogram. The shifts that were flagged by the NIOSH rule captured all of the shifts that were found using the OSHA rule. The subtlety of the NIOSH rule has to do with the frequencies at which noise-induced hearing loss most often occurs. The traditional belief is that a “notch” will occur in the audiogram at 4000 Hz. Recent analyses of the National Health and Nutrition Examination Survey audiometric data from 1999-2004 indicates that the majority of noise-induced hearing losses occurred at 4000 and 6000 Hz.^{21,22,23} Notches that were flagged in this study's data occurred at 4000 Hz, and were at least 15 dB. Several of the subjects had shifts at other frequencies, notably 6000 and 8000 Hz.

Early identification should be the focus of a proactive hearing loss prevention program, and the OSHA criterion for identifying an STS ought to be considered a safety net. Subjects with an OSHA STS will most likely also be identified with the NIOSH criterion. The OSHA STS criterion accounts for more of a material change in hearing, given it is an average over three frequencies. The NIOSH significant threshold shift criteria will capture a subject that may be exhibiting a noise-induced hearing loss that is beginning to become evident at one particular frequency. While more subjects will be flagged using the NIOSH criterion, the purpose of a hearing loss prevention program is to prevent hearing loss before it becomes debilitating. Therefore, hearing loss prevention programs should err on the side of identifying subjects that might be exhibiting shifts at frequencies other than 2000, 3000, and 4000 Hz as included in the OSHA STS definition. When a worker incurs material impairment at 2000, 3000, and 4000 Hz, a significant shift (>10 dB) will likely have occurred at 6000 or 8000 Hz as well.

Comfort scores were statistically different for the three subject groups. However, the differences in the scores were small (within 2-3 points of each other) and, from a practical view point, the comfort scores may be considered similar. This indicates that the custom-molded earplug users did not consider their comfort to be greater than the non-custom earplugs. In fact, it would appear that the custom earplug users judged them to be slightly less comfortable than the workers in Group B and Group C rated their hearing protectors. Overall, this opinion did not change over time. As shown in Table 4, JAA observer data suggests that workers were wearing their custom-fitted earplug between 20-43% of the time.

An issue that also needs to be considered carefully is the cost of fitting workers with a custom earplug. The manufacturer's suggested retail price (MSRP) of a Sonomax protector was about \$95/pair, and the projected life of a pair of these protectors is about three years. Combining these two estimates yields a cost per protector per employee per year of approximately \$31.67. Considering that the cost of 200 pairs of foam earplugs (MSRP) is about \$25 (\$0.125 per pair), and workers are on the job approximately 250 days per year, the annual cost per employee would be \$31.25 assuming that only one pair was used each workday. At face value, these estimates are comparable. However, workers indicated that they wear multiple sets of non-custom earplugs through out the workshift. In fact, as many as four pairs per worker per day could be worn accounting for two scheduled break periods and mealtime. Several additional factors must be considered for the custom-molded protector such as the acceptance rate (i.e., approximately four workers must be fit for every protector actually used). An additional cost is incurred in the process of fitting and adjusting the custom device, and replacement plugs will occasionally need to be made for those employees who are using the custom protector. Further, the wages for the time away from the production floor must be incorporated into the calculation. The Sonomax Hearing Healthcare fitting process required about 15 minutes to complete, and if it were implemented plant-wide, then it should be conducted in conjunction with the annual audiometric screening. The wages of the occupational health worker who performs the fitting must also be accounted for in a comprehensive cost analysis.

Conclusions

Judging from the reported comfort scores and the attenuation measurements collected, workers tended to select protectors that provided more attenuation than was necessary for the noise in which they were working. The current best-practices suggest that a worker's protected exposure level should fall in the 70 to 85 dBA range. The custom-molded protector achieved a better rate of fitting users to the ideal exposure range than the other protectors used in this study. Had workers achieved the labeled attenuations for the other earplugs, many of them would have been over-protected, and their communication ability could have been impaired as well.

It should be noted that the recommendation for a 70 to 85 dBA ideal exposure range is based upon exposure to continuous noise levels -- not impulsive noise. At the Flint Metal Center, the predominant noise exposure is impulsive due to the stamping presses which are operated in the plant. The noise exposures measured for the workers were collected using a slow-scale, A-

weighted sound level measurement, as mandated by OSHA. However, the estimates of protected exposure may underestimate the peak exposures received by these employees.

Some of the workers that were fit with the custom-molded hearing protector complained that noise impulses from the stamping presses startled them or caused them to jump while wearing their new earplugs. Such anecdotal evidence suggests that performing this same study in a more continuous noise environment might yield different outcomes with respect to acceptance rate. The data suggest that the custom earplug users preferred more attenuation, based upon the increase in the PNRR values measured over the course of the study. When using this style of adjustable-attenuation protector, the choice of filter should take into account the peak sound pressure levels of the impulsive noise.

None of the Group A subjects (i.e., custom-molded earplug wearers) in the primary study or any of those in the shorter-duration secondary study exhibited an OSHA STS. Five subjects in Groups B and C exhibited STSs, but the small numbers were not sufficient to achieve statistical significance. As described elsewhere in this report, the hearing threshold shifts for these five employees were not confirmed by a follow-up audiogram. The audiometry performed in this study was not a substitute for the annual audiometric monitoring as required by law for persons enrolled in the plant's hearing conservation program.

Recommendations

Based upon the measurements and observations collected at the Flint Metal Center, custom-molded hearing protectors can be effectively fit and worn by noise-exposed workers. The employee acceptance rate was lower than anticipated; however, this effect may result from several factors not considered in the initial design of the study:

1. The fitting procedure for the custom-molded earplug should be changed to consider the effects of impulsive noise, rather than be based solely upon an exposure estimate derived from a sound level meter reading obtained with a slow-time constant and A-weighting network. If the plant noise environment is largely impulsive, then peak levels should be measured and provided to the earplug fitting technicians. Impulsive measurements can be assessed by collecting several measurements and examining the variability of the noises. If the range of measured levels exceeds 6 dB, then the fluctuations in the noise generated should be considered.
2. The possibility of conducting a follow-up study should be considered. If an area where both impulsive and continuous noises can be identified within the same plant, then acceptance rates might be different for the custom earplug users. As discussed above, the acceptance rate may have been low due to the annoyance of higher peak exposure levels experienced by the custom earplug users during the initial periods of the study. Since the measured attenuations were demonstrably less than those for traditional foam earplugs, the peak levels could contribute to an annoyance for users of the new device.

3. The plant should consider locating a cohort of workers with less experience using hearing protection devices. The majority of the population at the Flint Metal Center had been long-term users of hearing protection. As a result, workers already had significant experience and were probably biased against the lower attenuating custom-molded device. An additional bias could be against the way the custom earplug felt in the ear canal, and the fact that for the first several uses subjects had to lubricate the silicon material to facilitate proper insertion. Thus, if an inexperienced cohort of hearing protection users could be identified, then repeating this study may reveal different outcomes.
4. If a follow-up study is conducted, the workers should be recruited according to the most popular style of protectors routinely provided by the plant. In the present study, Groups A and B only had sufficient subjects for meaningful comparisons for the DeciDamp and Pura-Fit earplugs. Recruiting according to the plug type (so an equal number of subjects were in each group) would enhance the analysis in a future study.
5. Routine earplug fit-testing should be implemented to provide a better indication of the performance of the hearing protectors as they are worn by individual employees. Fit-testing verifies not only that the earplug is capable of providing sufficient protection for the particular noise exposure, but also that the user is capable of fitting the device properly.

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Appendix A

Examples of Questionnaires Completed on Each Visit

This questionnaire asks about the comfort of the protector you are currently wearing on a daily basis. Each line contains a word pair that consists of opposites. You are asked to place a check or x in one of the five boxes that best describes the comfort of your protector along that line.

HOW DOES THE HEARING PROTECTOR FEEL NOW?

Painful	9	9	9	9	9	Painless
Comfortable	9	9	9	9	9	Uncomfortable
Uncomfortable Pressure	9	9	9	9	9	Not Uncomfortable Pressure
Tolerable	9	9	9	9	9	Intolerable
Loose	9	9	9	9	9	Tight
Bothersome	9	9	9	9	9	Not Bothersome
Light	9	9	9	9	9	Heavy
Not Cumbersome	9	9	9	9	9	Cumbersome
Hard	9	9	9	9	9	Soft
Hot	9	9	9	9	9	Cold
Rough	9	9	9	9	9	Smooth
No Feeling of Complete Isolation	9	9	9	9	9	Feeling of Complete Isolation
Ear Blocked	9	9	9	9	9	Ear Open
Ear Full	9	9	9	9	9	Ear Empty

Form B

Name:

Today's Date:

Date of Birth:

Please read each item and circle the number that best describes your opinion about the statement. Remember, there are no right or wrong answers! We are interested in your opinions.

		Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1.	<i>I don't think I have to wear hearing protectors every time I am working in loud noise.</i>	1	2	3	4	5
2.	<i>It would not be harder for people to talk to me if I lost part of my hearing.</i>	1	2	3	4	5
3.	<i>Hearing protectors are not readily available for me to use where I work.</i>	1	2	3	4	5
4.	<i>I know when I should use hearing protectors.</i>	1	2	3	4	5
5.	<i>If I wear hearing protectors I can protect my hearing from loud noise.</i>	1	2	3	4	5
6.	<i>Earplugs are uncomfortable to wear, even when they are fit right.</i>	1	2	3	4	5
7.	<i>Even when I am wearing hearing protectors, I can still hear back-up beeps or other warning signals.</i>	1	2	3	4	5
8.	<i>I can still hear people talking to me while I do my job, even when I am wearing my hearing protectors.</i>	1	2	3	4	5
9.	<i>It is convenient for me to get hearing protectors to use at work.</i>	1	2	3	4	5
10.	<i>I intend to wear hearing protectors when I am around loud tools or equipment.</i>	1	2	3	4	5
11.	<i>My co-workers don't usually wear hearing protectors when they work in hazardous noise.</i>	1	2	3	4	5
12.	<i>I'm not sure I know how to fit and use hearing protectors.</i>	1	2	3	4	5
13.	<i>If I don't protect my ears, loud noise can hurt my hearing.</i>	1	2	3	4	5
14.	<i>It would not bother me if I lost part of my hearing because of the noise I work around.</i>	1	2	3	4	5
15.	<i>I can't always tell when an earplug or muff needs replacing.</i>	1	2	3	4	5
16.	<i>I won't lose my hearing if I wear hearing protectors around loud noise.</i>	1	2	3	4	5

		<i>Strongly Agree</i>	<i>Agree</i>	<i>Neither Agree Nor Disagree</i>	<i>Disagree</i>	<i>Strongly Disagree</i>
17.	I can find an earmuff that is not too hot or heavy for me to use.	1	2	3	4	5
18.	I can't hear problems with my tools or machinery if I wear hearing protectors.	1	2	3	4	5
19.	I can't hear speech well enough to do my job if I am wearing hearing protectors.	1	2	3	4	5
20.	I can't find a hearing protector I like to use, because there's not a big enough variety to choose from where I work.	1	2	3	4	5
21.	I usually <u>don't</u> wear hearing protectors while I'm working around loud noise or equipment.	1	2	3	4	5
22.	My co-workers usually wear hearing protectors when they need to work in noisy areas.	1	2	3	4	5
23.	I don't think I could show a co-worker the right way to fit and wear hearing protectors.	1	2	3	4	5
24.	I need to wear hearing protectors every time I'm around loud noise if I really want to keep my hearing.	1	2	3	4	5
25.	If I need to use an earmuff I can get one that can be adjusted so it won't put too much pressure on my ears.	1	2	3	4	5
26.	Even when it's quiet, sometimes I have trouble hearing what people are saying to me.	1	2	3	4	5
27.	Hearing protectors are too expensive for me to buy.	1	2	3	4	5
28.	Even if I had one with me, I probably wouldn't wear a hearing protector every time I was around noise that was loud enough to hurt my hearing.	1	2	3	4	5
29.	My hearing protector never interferes with my other safety equipment (safety glasses, hard hat, gloves, respirator, etc.)	1	2	3	4	5

COMMENTS:

December 18, 2009