Methods of fit testing hearing protectors, with representative field test data

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INTRODUCTION

Numerous published studies in the past 20 years clearly demonstrate that use of laboratory measurements to predict real-world attenuation for groups of workers, or even more problematically for individual workers, is fraught with inaccuracies. Thus, the ability to properly assign hearing protectors in critical high-noise environments or even for lower noise levels when one wishes to closely match attenuation to actual exposure, is questionable. Even if the laboratory data were representative of the actual group using the device, the individual variability is large enough that attempts at predicting one person's performance from group data can easily err by up to 20 dB (Gauger & Berger 2004).

One approach to solving these problems is the development of systems to allow individual fit testing in the field, and indeed such systems have been garnering increasing visibility in recent years. In fact, fit-test technology has been available in the laboratory in many forms for nearly 30 years (Berger 1984, 1986, 1988, 1989), but only in the past decade has the hearing conservation community started to look more closely at this issue. Recently, Berger (2006) discussed seven important applications for field-test methods, as listed below.

1) Train and motivate employees to properly and consistently wear their HPDs
2) Train the trainer on how to train employees
3) Assign HPDs based upon noise exposures and expected protection levels
4) Provide useful standard-threshold-shift (STS) follow up to see if the problem may be HPD related
5) Present data that may be accepted by OSHA improved alternative to determine HPD adequacy
6) Audit departments to assess overall HPD effectiveness and suitability
7) Provide potentially useful documentation to defend against workers' compensation claims regarding HPD adequacy and provision of sufficient training

Today there are a number of systems that provide field-test capabilities. Herein we explore various options, especially with respect to their advantages and disadvantages. We will then focus on one of those methods, microphone-in-real-ear (MIRE) and its implementation as a quick and portable field method, termed field-MIRE, abbreviated F-MIRE (Hager & Voix 2006). Representative outputs from the system will be examined to understand how variability may be accounted for in practice, and actual data from industrial plants will be summarized to indicate the types of performance that are currently being achieved.

METHODS OF FIELD TESTING HEARING PROTECTOR ATTENUATION

Field test methods exist in three basic "flavors," consisting of subjective (psycho-acoustic), objective, and non-acoustic methods, as outlined below:

- Subjective (psychoacoustic)
    - REAT (real-ear attenuation at threshold)
        - Sound field (in a small booth or chamber)
        - Circumaural (with earphones in large noise-excluding cups)
        - Supra-aural (using supra-aural audiometric earphones)
    - Loudness balance
- Objective [microphone-in-real-ear (MIRE)]
    - Probe microphone passed through or around an earplug
    - Microphones mounted inside and outside of earmuff cups
- Non-acoustic: static pressure / pneumatic seal measurements

With the exception of the loudness-balance method, all of the subjective procedures are variants of the "gold standard," real-ear attenuation at threshold (REAT) procedure that is well documented in current and prior ANSI standards (ANSI S12.6). In the field, the intention is to replicate laboratory-based REAT. REAT requires listeners to track their hearing threshold levels to measure their hearing sensitivity. The sounds are normally presented from loudspeakers in a test chamber and the procedure is repeated, both with and without HPDs. The difference in the two thresholds is the attenuation of the device. This procedure is called real-ear attenuation at threshold since the attenuation of the HPD is measured on real ears of human subjects, and since it is computed from differences in the threshold of hearing, with and without the hearing protector in place (Berger 2000).

When taking REAT into the field the loudspeakers are normally replaced with headphones, i.e. speakers in large circumaural cups (or as noted above, sometimes mounted in standard audiometer earphone cushions). This enables only the testing of earplugs. However, earplugs are the type of HPD that is most problematic and variable in fit and therefore most in need of fit testing. When the field procedure is accomplished using a small noise enclosure or sound booth, both earmuffs and earplugs can be evaluated, but with the additional cost and difficulty associated with potentially transporting and then positioning a booth near the workplace.

The advantage of field REAT is that it can yield valid data with only one known measurement artifact - it produces values of attenuation that are spuriously high by typically up to a few decibels in the frequencies at and below 250 Hz. This is due to physiological noise masking in the occluded ear (Berger & Kerivan 1983). The three field-REAT variants that are listed above have all been successfully implemented according to the literature, but the use of supra-aural earphones can be problematic due to potential artifacts (Berger 1984, 1986).

A principal disadvantage of field REAT is its time-consuming nature. Each frequency tested takes at least 30 seconds, requiring a minimum of at least one minute to test the fit in each ear since both an open and an occluded threshold is required, much longer if multiple frequencies are to be tested. Furthermore there is an inherent variability since the data rely on the listener's ability to track his or her own threshold. The process itself has a substantial imprecision of approximately ± 5 dB for typical subjects. Finally accurate REAT measurements require low background noise so that the open-ear thresholds are not masked and contaminated. Even when field REAT is conducted under large noise-excluding earmuff cups, or in a sound booth near the workplace, care must be exercised to be sure that the environment is adequately quiet.

The remaining subjective field procedure is loudness balance, recently updated with a new paradigm (Soli et al. 2005). In this method, applicable to only earplugs, instead of comparing open and occluded thresholds, the subject is asked to establish a balance in the loudness between signals presented to occluded and unoccluded ears. Like a threshold procedure this requires a listener's subjective response and the attendant time and potential variability, especially for the untrained workers in industry. Also, though the balance is probably not inherently any more difficult to track than a threshold, employees generally have familiarity with threshold tracking because of the annual audiograms they receive as enrollees in a hearing conservation program. Another potential problem is that it may not be possible to generate sufficiently intense test signals for a worker with high-frequency hearing loss to detect the stimuli and effect a loudness balance while wearing a hearing protector. An advantage of loudness balance is that it is less susceptible to contamination than REAT from background noise since the testing is conducted at sound levels that are normally at least 30 to 40 dB greater than in the REAT protocol.

An alternative to the subjective procedures is to make objective measurements with microphones, termed a microphone-in-real-ear (MIRE) technique (Berger 1986). When applied in occupational settings this becomes a field-MIRE (F-MIRE) methodology (Hager & Voix 2006; Voix 2006). With F-MIRE the sound pressure levels in the earcanal under the hearing protector and those outside the HPD, are simultaneously measured. Using suitable correction factors to account for known and quantifiable acoustic differences between the F-MIRE and REAT, the values can be used to accurately estimate the hearing protector's attenuation.

MIRE can be conducted with probe measurement devices that consist of thin flexible tubes connected to microphones, with the tubes either placed in the earcanal or through the earplugs or between the earplugs and the canal walls. Working with the tubing can be problematic and can substantially affect the performance of the earplugs unless the tubing is sealed through the body of the plugs. The tubing itself can also leak sound through its wall (i.e., a flanking pathway) if the material of the tube does not possess a sufficiently high insertion loss.

The F-MIRE system in this report incorporates a single small dual-element microphone and associated proprietary technology (Voix & Laville 2002, 2004; Voix 2006). One section of the dual-element microphone couples through the earplug to pickup the sound pressure levels in the earcanal, and the other section measures the external sound field. Broadband steady-state sound is presented via a small speaker in front of the subject. The actual measurement takes about 10 seconds for one fit in one ear for the standard 7 test frequencies from 125 Hz to 8 kHz, from which is calculated an overall noise reduction rating called the Personal Attenuation Rating (PAR[1]). The PAR, though it appears to be an exact number, also contains its own variability, albeit much less than in the classical approach of using mean laboratory data to make individual field predictions. The extent of variability in PAR is defined and explicitly provided with the measurement (Berger 2007).

In addition to the brevity of the test, another advantage is that it can be conducted in substantially higher noise levels than can a field-REAT measurement, and it reduces

[1] The PAR is computed like the Noise Level Reduction Statistic (NRS_A as defined in ANSI S12.68) except it is calculated individually for each subject and reported as a median PAR instead of at the 80^{th} and 20^{th} percentiles.

the inherent variability by replacing the variance of the subject's open and occluded thresholds, or loudness balances, with the smaller variance of the measurement system. The system is useful for training, monitoring, and other applications (Berger 2006), but it does rely on surrogate HPDs that consist of earplugs modified by passing probe tubes through them. Thus the plug that the subject fits is not identical to the plug that will be worn on a day-to-day basis. This is discussed further in the following section.

Another implementation of MIRE approach is to instrument earmuff cups with internal and external microphones as has been done for research purposes, as well as in a commercially available product intended for regular use in industry to monitor hearing protector effectiveness (Berger 1986; Burks & Michael 2003).

The last type of field test method listed above is one based on static pressure measurements to determine the presence of a pneumatic seal. This method has been primarily used to validate that a custom earmold is well made and fits the ear properly, and indeed it is suitable for such a purpose. However, translation of that seal to assurance of a particular degree of sound attenuation has sufficient uncertainty that this is not a viable method for field protection, except for possibly a pass/fail determination for selected types of products. This would not be a suitable way to test most foam earplugs since although they provide a strong acoustic barrier to sound, one of their positive attributes is that they leak at very low frequencies and hence do not create a pneumatic seal.

COMPONENTS OF A FIELD MICROPHONE-IN-REAL-EAR (F-MIRE) SYSTEM

Of the preceding methods, in our estimation, F-MIRE provides the best balance between speed, accuracy, repeatability, and correspondence with actual practice. The F-MIRE method investigated in this study was adapted from one developed by Sonomax Hearing Healthcare Inc. (Voix & Laville 2002; Voix 2006) for use with their custom earmold technology. Certain features of the system required modification for use with a wide range of earplugs such as non-custom foam and premolded earplugs that provide higher-levels of attenuation than the earplugs for which the system was initially designed. The particular F-MIRE implementation evaluated in this study is the E•A•RFit™ system from Aearo Technologies.

Figure 1 illustrates the components of the system and Figure 2 provides an expanded view of the microphone and probed earplug tips. The F-MIRE system consists of a sound source that generates high-levels of broadband random (pink) noise at the listener's ear, a dual-element microphone that simultaneously measures in a repeatable location the sound present at the outside of the earplug and in the earcanal after having passed through the earplug, a probed earplug to act as a surrogate for the actual earplug that subjects will wear, and an analysis system installed on a desktop or laptop PC that can rapidly record accurate and repeatable measurements. The sound levels used, depending upon the amount of attenuation

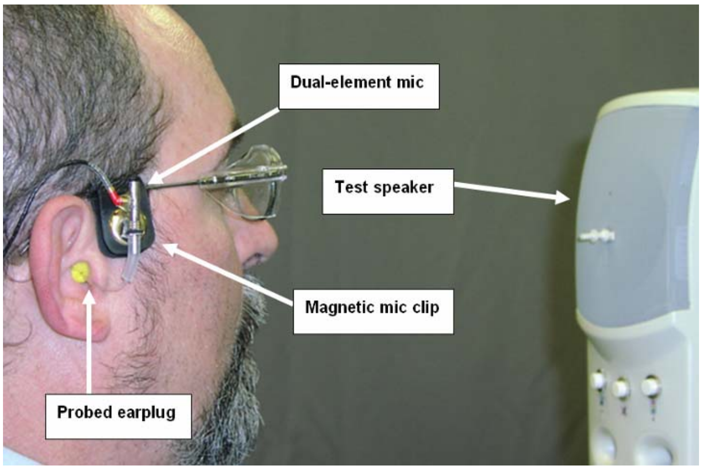

Figure 1: Key components of the F-MIRE system

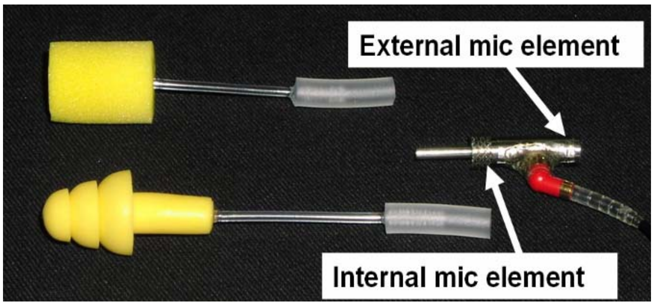

Figure 2: The dual-microphone element and representative probed tips for foam and premolded earplugs

provided by the earplug, are up to 90 dBA with a duration of approximately 10 seconds. The listener's nose is positioned 30 cm from the front of the loudspeaker at a preset elevation.

A key feature of the development of this F-MIRE system was the design of the probed test tips. The tubing through the plug needed to allow measurement via the dual-element mic of the sound pressure levels in the earcanal, but at the same time provide high levels of self-insertion loss (i.e., sound transmission through the walls of the tubing) so as not to affect the attenuation properties of the earplug. The tubing was selected to minimize its effect on use of the HPD, being of sufficiently small diameter and suitable softness so as not to materially affect the listener's ability to insert the earplugs. In the case of the foam tips the tubing also could not affect the ability to roll the plug into a tiny crease-free cylinder for insertion into the earcanal.

F-MIRE can provide a close approximation of REAT, but F-MIRE measurements yield a noise reduction (NR) value which is the difference between the levels outside and inside the earcanal. REAT, however, is an insertion loss (IL) measurement that is the difference in the sound pressure levels at one point in space (such as the eardrum) with and without the HPD in place. NR and IL are directly related, but they are not the same; thus a mathematical adjustment is required that uses the transfer function of the open ear (TFOE). TFOE is the difference between the sound pressure levels in the sound field and at the eardrum (Berger 1986). In addition to a TFOE correction, the variation of sound conduction with frequency through the probe tips and other correction factors are also needed utilize F-MIRE to predict REAT (Voix 2006).

The most direct way to account for all of the above factors is to make a simultaneous measurement of REAT and NR, for a given fitting of probed earplugs on a group of subjects. One can then directly compare the two measured values of attenuation and determine the correction factors (also called compensation) to bring them into the closest possible agreement (Voix & Laville 2002). This approach is commonly accepted and has previously been used for other types of field-test systems (Michael et al. 1976).

The compensation factors noted above only describe the differences due to system bias, factors that are stable from measure to measure. There is also an inherent variability of the REAT and F-MIRE procedures. Accounting for this multiplicity of factors required the development of a complex test paradigm that has been described by Berger et al. (2006). An example of the correspondence between REAT and F-MIRE values is shown in Figure 3.

VARIABILITY

Berger et al. (2006) found that on the average, their F-MIRE predictions were reliable indicators of REAT values. However, review of the data indicated that REAT vs. F-MIRE differences for a single measurement on a given subject could exceed 10 dB for individual 1/3-octave bands.

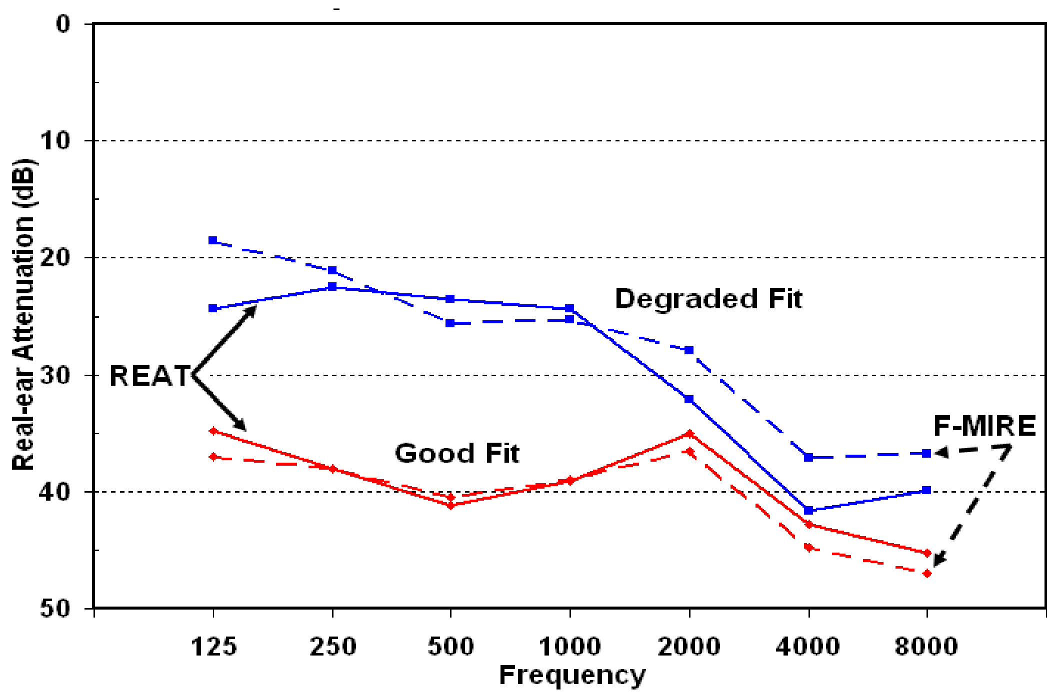

Figure 3: Comparison of corrected F-MIRE predictions, using compensation factors determined by Berger et al. (2006), to REAT data for the same fit for 20 subjects

To further examine this phenomenon they compared the variability for 10 repeat measurements for a single fitting of a foam earplug (i.e., nothing was touched; experimenters just pressed the "run" button and took the measurement 10 times) to the variability for five separate measurements for both ears in which the mic was removed from the plug, the plug removed from the ear, and the subject refitted the plug and the experimenter refitted the mic. They concluded that the largest part of the measurement problem was the precision with which the subject could fit and refit the plug. Furthermore when a similar experiment was conducted with repeat REAT measurements it was found that the variability due to the subjective determination of the thresholds in a REAT paradigm caused the REAT variability to exceed F-MIRE variability at all frequencies. Thus the divergence between a single REAT and F-MIRE measurement does not necessarily indicate an F-MIRE error, but can simply be due to measurement uncertainty. This type of variability is taken into account in the E•A•Rfit software with suitable uncertainty factors provided to the operator.

REPRESENTATIVE FIELD TEST DATA FROM AN F-MIRE SYSTEM

As an example of the measurements that are available with field test systems, distribution bar charts are presented in Figure 4 for 196 employees who were F-MIRE tested with a cylindrical polyvinyl chloride (PVC) foam earplug (E•A•R Classic® plug) and 155 using a tapered polyurethane (PU) foam earplug (E•A•Rsoft® Yellow Neons® plug). The data are from five different plants over seven studies, including military, research, manufacturing, and petrochemical facilities. Employees were asked to fit the plugs as they normally would for daily use and were tested for one fit, each ear.

The data for the PVC plug are approximately unimodal but highly skewed to higher attenuation values, whereas the PU plug's distribution is bimodal in appearance with the upper mode similar to that found for the vinyl plug but with the lower mode showing more low-attenuation values. The range of PAR data is 14 to 43 dB (mean = 29 dB) for the vinyl plug and 6 to 42 dB (mean = 26 dB for the urethane). Such broad ranges of values are not unusual when field measurements are recorded and highlight the difficulty of predicting individual performance from group data measured in the laboratory.

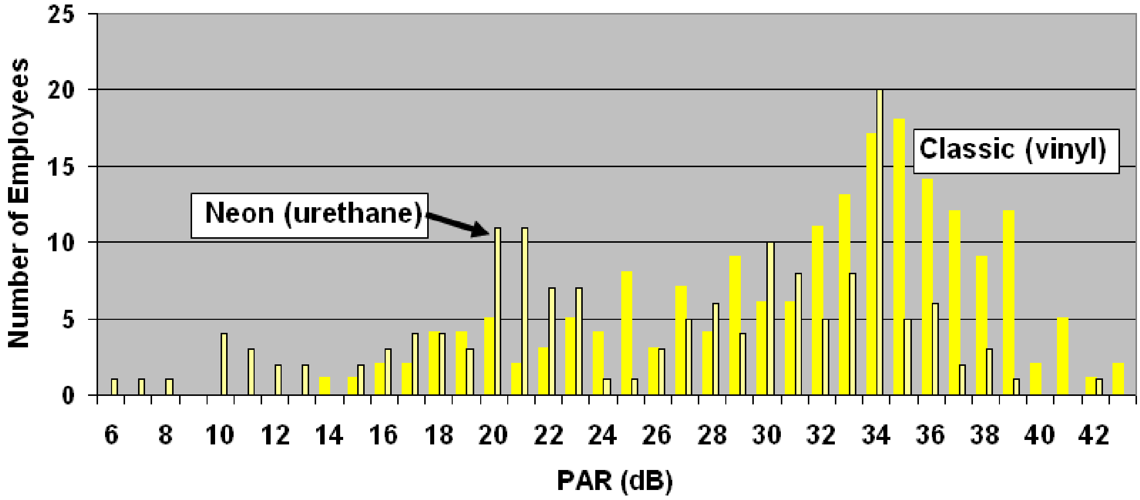

Figure 4: Distribution of PARs for Classic (N=196) and Neon (N=155) users in 7 different industrial plants

Keeping in mind that PAR is intended to be subtracted from A-weighted sound levels while Noise Reduction Ratings (NRRs) per the current labeling requirements (EPA 1979) are to be subtracted from C-weighted sound levels, one must make an adjustment to properly compare NRR to PAR. Based on Gauger and Berger (2004) the mean and median C – A value for industrial noises are 2.5 and 1.9 dB respectively. Thus, a 2-dB C – A correction was subtracted from the NRR to compare to PAR. For a PVC plug with an NRR of 29 dB, 98 % of users fitting the device under the exact conditions of the laboratory REAT test should have obtained approximately 27 dB of protection, but in these plants only about 73 % of users did so; their effective real-world NRR achieved by 98 % of the employees (computed from PARs) was 18 dB. This is better than anticipated for a PVC plug based on prior real-world studies (Berger, 2000). For the PU plug, 98 % of users should have achieved a PAR of 31 dB (based on a labeled NRR of 33) but only 38 % did so, for an effective real-world NRR of 10 dB.

The differences between the PVC and PU earplugs are unexplained at this time, but it is interesting to note that in a prior real-world study that examined the performance of various products including foam earplugs, the PVC plug exceeded a PU plug by approximately 9 dB in terms of a mean less one standard deviation (Scott 1995), and in this study the difference is 8 dB.

CONCLUSIONS

The concept and importance of field fit testing is reviewed and various subjective, objective, and non-acoustic methods are described. Seven important applications for field test methods are highlighted, with the most obvious being for training and motivation. An objective method, F-MIRE is selected as one of the more useful approaches and a system incorporating that technology is presented along with a brief discussion of its development. Uncertainty in laboratory and field test methods is discussed so that users understand that all methods include an inherent degree of variability.

Test data from recent implementations using the F-MIRE system are presented to illustrate the wide variability of earplug performance in practice, the large divergence between laboratory and field-measured performance, and the need for individual fit testing to characterize the performance that will be obtained for workers in practice.

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