The Efficacy of Earplugs at a Major Hazard Facility

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Abstract

Introduction:

At a major hazard facility, sporadic cases of occupational noise-induced hearing loss have occurred despite the use of hearing protection devices. Preliminary testing with a system for measuring personal attenuation ratings (PAR) suggested that earplugs may not achieve the attenuation implied by their Australian Class designation in field-use conditions. We believe that ours to be a world-first study at the time it was conducted to check the relationship between Personal Attenuation Rating (PAR) and the Australian SLC80 classification for hearing protection devices, and the findings can be used to complement studies based on the American Noise Reduction Ratio (NRR).

Methods:

A cross-sectional study was performed with 65 volunteers. Participants were recruited from Operations and Maintenance Technicians at the major hazard facility. The participants had their PARs checked with different earplug types using the 3M™ E-A-Rfit™ system. An earplug is deemed to have achieved a 'pass' if it achieved 22 dB attenuation for 80% of users (the definition for Australian Class 4 hearing protection)

Results:

None of the earplug types achieved the attenuation implied by their class rating when tested in field-use conditions. There were statistically significant differences in the frequency of achieving a 'Pass', and in PAR, depending on earplug type. Roll-down foam earplugs may provide superior attenuation compared to pre-moulded earplugs.

Conclusion:

Earplugs are unlikely to achieve the attenuation found in laboratory conditions during field-use. Personalised selection of hearing protection devices based on fit-testing results should be encouraged.

Key Messages

The relationship between PAR and Australian SLC80 Class rating is consistent with what has been observed in the rest of the world when comparing PAR with other hearing protection device classifications such as the American Noise Reduction Rating (NRR). HPDs underperform in field-use conditions compared to laboratory ratings.

Introduction

Occupational noise-induced hearing loss is a significant health problem both in Australia, and globally. Between July 2002 and June 2007, there were approximately 16 500 approved worker's compensation claims for permanent impairment from occupational noise-induced hearing loss in Australia [1]. A survey

by Safe Work Australia in 2010 found that 28–32% of workers were exposed to noise over 85 dB at work, that only 41% of exposed workers reported receiving training on hearing protection, and that there appeared to be a reliance on hearing protection devices (HPDs) to reduce noise exposure [2]. A 2017 parliament inquiry on hearing health in Australia reported that 3.6 million people are affected by hearing impairment, and that this will increase to 7.8 million by the year 2060. It also reported on an estimate that hearing loss costs the Australian economy \$15.9 billion in financial costs and \$17.4 billion in lost wellbeing for individuals [3].

A 2005 study found that globally, 16% of disabling hearing loss in adults is due to occupational noise, ranging from 7–21% by region. This represented a burden of over 4 million disability-adjusted life years (DALYs) [4]. In 2018, hearing loss as a whole is the fourth highest cause of disability worldwide, and has an estimated annual cost of \$750 billion [5]. There are an estimated 466 million people with disabling hearing loss globally, and this figure is expected to rise to 630 million by 2030 and 900 million by 2050 [5].

Hearing protection devices, which include earplugs and earmuffs, represent a mature technology that has been widely used since the 1950s [6]. It is well understood that correct insertion technique is vital to the efficacy of earplugs in noise attenuation [7, 8]. Earplug attenuation is also affected by a number of other factors including the shape and size of the user's ear canal [9, 10], the user's dexterity, and the shape of the earplug [11]. Despite our knowledge of these factors, multiple studies have found that earplugs rarely achieve their laboratory-assigned attenuation ratings [12–15]. A good understanding of the attenuation provided by earplugs under normal field-use conditions, rather than in laboratory settings, is vital to their effective use as a control measure for noise exposure.

Our study examined the objective attenuation achieved by 65 users with four structurally different types of earplugs, which are then compared with the class rating of the earplugs. At the time of writing, the authors were unable to find any prior published studies examining the relationship between personal attenuation rating (PAR) and the Australian SLC80 Class ratings, and believe we may be the first to do so.

Methods

We aimed to examine four structurally different types of Class 4 earplugs and check their attenuation in field-use conditions using a commercially-available microphone-in-real-ear (MIRE) system that produces objective test results. As per AS/NZS 1270:2002 (Table 1), Class 4 earplugs should provide at least 22 dB attenuation to 80% of users [16], and we calculated whether this was met in field-use conditions.

We also aimed to calculate and compare the proportions of each earplug type that achieved the minimum attenuation for their class rating. We compared the PAR of the different types of earplugs using logistic and linear regression models which handle clustered or repeated measurements (each participant received all four types of earplug).

This cross-sectional study was approved by the Monash University Human Research Ethics Committee under Project ID number 21527.

Sixty-five volunteers were recruited by email, telephone call, in person at their worksites, and opportunistically at clinic visits from the Operations Technicians and Maintenance Technicians workgroups at the facility in question. The equipment for the study was supplied by the facility. The researchers were not paid for their time. There were no other costs to account for.

The inclusion criteria were age 18 years or older, and employment as an Operations Technician or Maintenance Technician. The study was open to workers of both genders, but due to the overwhelming majority of the study population being male, there were no female participants.

Exclusion criteria included anatomic or medical conditions that prevented insertion of earplugs (e.g.: severe otitis externa, congenital deformity preventing earplug insertion). Individuals with conditions that affected the ear canal but did not prevent insertion of earplugs, such as mild to moderate exostoses, were not excluded from the study. Participants were given a consent form and the test procedure was explained. An explanatory statement was available if participants desired more information.

Participants had their personal attenuation rating (PAR) measured using the commercially available 3M™ (The 3M Company, Maplewood, Minnesota) E-A-RFit™ system (Figure 1) [18] and a selection of four structurally different probed earplugs. The E-A-RFit™ system is a device with a speaker as the source of a standardised broadband noise. It has been found to be a satisfactory alternative to Real Ear Attenuation at Threshold (REAT) testing methods [17].

The earplugs selected were the following:

1. Bullet-shaped roll-down foam (3M™ Yellow Neons™, Class 4, SLC80 rating 23 dB) (Figure 2) [19]
2. Cone-shaped, rigid-core, pre-moulded earplugs (3M™ Push-Ins™ with Grip Rings™, Class 4, SLC80 rating 22 dB) (Figure 3)[19]
3. Triple-flanged, pre-moulded, reusable earplugs (3M™ Ultrafit™, Class 4, SLC80 rating 22 dB) (Figure 4) [19]
4. Cylindrical roll-down foam earplugs (3M™ Classic™, Class 4, SLC80 rating 23 dB) (Figure 5) [19]

The research participants were seated approximately 30 cm front of the E-A-RFit™ system, wearing probed earplugs that were connected to microphones. The microphones were used to detect the intensity of sound reaching the inside of the ear canal past the earplugs, and just outside the earplugs close to the auricles. The microphones were clipped to either the participant's own eyewear, or to a pair of safety glasses provided for the test. The difference in intensities between the sounds detected by the microphones for outside and inside the earplugs is a measure of the attenuation provided. The system uses a Microphone in Real Ear (MIRE) objective measurement approach, which does not depend on the

participant's subjective sense of hearing [14]. After measuring the attenuation provided, the E-A-RFit™ tool calculates a Personal Attenuation Rating (PAR), a summary measure which can be directly subtracted from the measurements of A-weighted noise sources when calculating a user's protected noise exposure [20]. The system was calibrated every time it was turned on, before testing commenced.

Each participant was examined once in a single session, using the four different types of test earplugs. The sessions were conducted in quiet office environments. Participants were given instructions on how to correctly roll down or grip the relevant earplugs, reach over with the other hand to open the ear canal, and insert the earplugs. The researcher physically demonstrated the correct insertion technique to reinforce the instructions. Where roll-down earplugs were used, approximately 1 minute was allowed to pass for the earplugs to expand. After insertion, the earplugs were visually examined by the researcher to see that they appeared to sit within the ear canal correctly without crumpling or creasing. If the earplugs were incorrectly inserted, or if they protruded past the tragus, the participant was encouraged to attempt a better or deeper insertion of the earplug. Participants were allowed up to three attempts at achieving an optimal insertion. They were not disqualified if the earplugs were visible past the tragus despite their best efforts. They would have been disqualified if the earplugs appeared to otherwise be incorrectly inserted despite three attempts, or unable to be correctly inserted. However, this scenario did not occur with any participant. The participant was then asked to face the speaker, and the broadband sound was then played and the system calculated the worker's binaural PAR. The results were automatically recorded by the system software. The participants were tested with the 3M™ Yellow Neons™, Push-Ins™, Ultrafit™, and Classic™ single-use probed earplugs, in that order. This order was chosen to help avoid the occurrence of a practice effect from one type of foam roll-down earplug being tested immediately following another. Due to logistical constraints, randomised ordering was not able to be employed.

After testing, the participants' personal results were shown to them and they were given advice about the type of earplug that had worked best for them. Participants who did not achieve a 'pass' with any type of earplug were encouraged to use earmuffs in future.

Results

The study involved repeated measures, in that all four types of earplug were tested on each participant. Repeated measurements were analysed using logistic regression for protection pass/fail and linear regression for PAR, as initial descriptive analyses suggested that the PAR values for each earplug were normally distributed. Regression was undertaken with the clustered (i.e. repeated measures) version of the robust Huber/White sandwich estimator [21–23].

All 95% confidence intervals took repeated measurements into account (i.e., there were 260 measurements from 65 participants, each participant being tested with four types of earplug).

Following on from a 2018 study [11], foam roll-down plugs (Yellow Neons™ and Classic™) overall, were compared with pre-moulded plugs (Push-ins™ and Ultrafit™) overall, using a planned comparison. Two

other planned comparisons compared:

1. Yellow Neons™ and Classic™ and
2. Push-ins™ and Ultrafit™.

All statistical analyses were undertaken using Stata® version 16 (Stata Corporation, College Station, Texas, 2019).

All participants produced relevant data, and none were rejected for any reason. As discussed earlier, both males and females were invited to participate, but only males did so.

None of the four types of earplugs achieved the attenuation implied by their class rating when tested in field-use conditions; i.e. at least 22 dB PAR for 80% of users. Overall, all earplugs considered together achieved 22 dB PAR for only 62, or 23.85% (95% CI (confidence interval) = 17.19% to 30.51%) of the 260 measurements.

Table 2 below shows the breakdown of the results by earplug type.

There was a statistically significant overall difference in the frequency of achieving a 'Pass' between different earplug types (Wald likelihood chi-square = 27.22, df=3, $p < .001$). Performance of overall earplug category, foam roll-down and pre-moulded, is given in Table 3.

The foam earplugs overall performed significantly better than pre-moulded earplugs (odds ratio (OR) = 5.44, 95% CI = 2.64 to 11.21 $p < 0.001$). Within the foam category, Classic™ performed significantly better than Yellow Neons™ (OR = 1.81, 95% CI = 1.04 to 3.17, $p = 0.037$), whereas within the pre-moulded category there was no statistically significant difference between Push-Ins™ and UltraFit™ earplugs (OR = 1.68, 95% CI = 0.78 to 3.62, $p = 0.182$).

Table 4 shows the mean and 95% confidence interval by earplug type for PAR, measured in decibels.

Table 5 shows the mean and 95% confidence interval for broad earplug category for PAR, measured in decibels.

Overall, foam earplugs overall exhibited significantly higher performance than pre-moulded earplugs (difference between means = 6.10, 95% CI = 3.89 to 8.32, $p < 0.001$). Within the foam category, Classic™ did not significantly differ from Yellow Neons™ (difference = 1.8, 95% CI = -0.83 to 4.43, $p = 0.176$), whereas within the pre-moulded category, UltraFit™ earplugs performed significantly better than Push-Ins™ (difference = 5.74, 95% CI = 3.69 to 7.78, $p < 0.001$).

Discussion

The earplugs we tested did not achieve the attenuation implied by their class ratings. Foam roll-down plugs (Yellow Neons™ and Classic™) appeared to be superior overall to pre-moulded plugs (Push-ins™ and Ultrafit™), which is consistent with the findings of a 2018 study [11]. Within the broad categories, differences were less clear. Classic™ had significantly higher ‘pass’ results than Yellow Neons™, but the two types of earplug did not differ significantly on mean PAR. The opposite pattern was observed in the case of pre-moulded earplugs. Ultrafit™ did not differ from Push-ins™ on passes, whereas Ultrafit™ exhibited significantly higher mean PAR than Push-ins™.

The percentages of earplugs achieving the minimum attenuation for their class were low, which is consistent with the findings of previous studies demonstrating that laboratory measurements are not reliable for predicting the attenuation provided to users in field conditions [12–15]. One of the reasons for this might be that laboratory testing may involve training that differs from what end-users typically undergo in field conditions. Training and fitting technique is crucial to the attenuation provided by earplugs and it has been found to have a larger effect than the laboratory rating for the earplug [8].

In Australia, subjects selected for the SLC80 rating process for HPDs must have had no prior experience or training with HPDs [16]. This is likely to be in contrast to the majority of HPD-users in field conditions. In our study, for example, the participants used HPDs every day at work. While this observation might at first suggest that participants should have performed better than rating subjects, it could also mean that HPD-naïve rating subjects pay closer attention to the training they receive as they are hearing it for the first time, and are more careful in following instructions as closely as possible. Typical HPD-users, on the other hand, may instead default to pre-conceived notions or habits, which may have a negative effect on the earplug fitting.

Rating subjects may also differ from end-users in other meaningful ways. The gender ratio of subjects for SLC80 rating must be 50/50±10% [16], whereas the participants of our study were 100% male due to the vast majority of the study population being male, and the gender ratios of rating subjects may likewise be different to the population of HPD-users. The education level and socioeconomic status may also differ between rating subjects and HPD-users, as the latter may possibly be more likely to be blue-collar workers. Unpredictable physiological differences such as differences in manual dexterity could also be at play. Future studies should take such factors into account.

An advantage of our study design is the objectivity of the MIRE method. Because the earplug attenuation is measured by a microphone with no input from the person being tested, issues like temporary threshold shifts, hearing loss, and concentration did not play a role in the measurements. Our study is also likely to be highly relevant to the majority of frequent users of HPDs, as the participants were drawn from a population that uses HPDs daily. The population was fairly homogenous, being made up of mostly Caucasian males aged from their 20s to late 60s, and our sample was reflective of this. This helps to reduce the effect of confounders such as age, gender, and ethnicity. Recruiting only Operations and Maintenance Technicians also helps to standardise the education level of the participants.

Limitations of our study include the fact that the MIRE method does not account for bone conduction [24], unlike the REAT method. There may have been an order effect as one order of earplugs was used throughout testing, and future studies may instead employ order randomisation. Our study may also be less generalisable to the public, which may be of importance when considering the attenuation of HPD-naïve users, visitors to facilities where HPDs are required, infrequent users of HPDs, and so on. It may be hard to predict how their PARs may differ from our sample, and they may be less protected or even overprotected by comparison. Indeed, the highest measured PAR in our study was 35 dB, which is well above the maximum attenuation of 25 dB for a Class 4 earplug. This could easily have produced attenuated exposures below 70 dB, resulting in overprotection [25]. We also limited our study to Class 4 earplugs manufactured by 3M™. This was due to the selection of probed earplugs available for testing with the E-A-Rfit™ system. It is compatible only with 3M probed earplugs, and Class 4 offered a good variety of different earplug structures. It is uncertain how findings may differ in earplugs of different Class ratings or manufacturers.

Further work could expand on our study by incorporating different Classes of HPDs, including the consideration of overprotection, and relating PAR measurements to ear canal structures and/or hearing threshold shifts.

Conclusion

Earplugs are unlikely to achieve the attenuation found in laboratory conditions during field-use. Roll-down foam earplugs may provide superior attenuation overall compared to pre-moulded earplugs. However, our raw data revealed that for a minority of individuals, their personal best PAR was achieved with pre-moulded earplugs. The range of PAR measurements was also high; from 0 dB to 35 dB. The attenuation offered by earplugs to individuals is thus highly variable, and future studies, with large samples, need to examine what characteristics are associated with responses. Individual fit-testing of HPDs in conjunction with training has been shown to improve PAR results [26]. Fit-testing is a valuable addition to hearing protection programs [27], and personalised selection of hearing protection devices based on fit-testing results should be encouraged.

Declarations

Funding:

The major hazard facility in question loaned their E-A-Rfit device for the study and provided the consumables (test plugs). There was no other funding required or received.

Conflicts of interest/Competing interests:

Dr Kah Heng Lee provides occupational medical services to the major hazard facility in the study.

Availability of data and material (data transparency):

The de-identified raw data is available on request from the corresponding author.

Code availability (software application or custom code):

Not applicable

Authors' contributions:

Dr Kah Heng Lee - Study design, data collection, article write-up

Dr Geza Benke - Study design, proofreading

Dr Dean McKenzie - Statistical analysis, statistical write-up

Ethics approval:

This cross-sectional study was approved by the Monash University Human Research Ethics Committee under Project ID number 21527.

Consent to participate:

Written informed consent to participate in the study with disclosure that the research could potentially be published was obtained from the study subjects.

Consent for publication:

Written informed consent to participate in the study with disclosure that the research could potentially be published was obtained from the study subjects.

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Tables

Table 1: AS/NZS 1270:2002 determination of HPD class

Specified SLC ₈₀ for Determination of Class	
Class	Specified SLC ₈₀ , dB
1	10 to 13
2	14 to 17
3	18 to 21
4	22 to 25
5	26 or greater

Table 2: Table of earplug ‘pass’ results in order tested

				Protection Sufficiency Binaural based on SLC80 22 dB		
Product				Pass	Fail	Total
3M™ E-A-Rsoft Yellow Neons™			n	29	36	65
			% (95% CI)	44.62 (32.44-56.79)	55.38 (43.21-67.56)	100.0
3M™ E-A-R Push-Ins™			n	8	57	65
			% (95% CI)	12.31 (4.26-20.36)	87.69 (79.64-95.74)	100.0
3M™ E-A-R UltraFit™			n	5	60	65
			% (95% CI)	7.69 (1.16-14.22)	92.31 (85.78-98.84)	100.0
3M™ E-A-R Classic™			n	20	45	65
			% (95% CI)	30.77 (19.46-42.08)	69.23 (57.92-80.54)	100.0
Overall			n	62	198	260
			% (95% CI)	23.85 (17.19-30.51)	76.15 (69.49-82.81)	100

95% CI = 95% confidence interval, proportions/percentages and confidence intervals calculated using linear regression allowing for clustering (repeated measures)

Table 3: ‘Pass’ results by broad earplug type

Product					Pass		Fail		Total
3M™ Earplugs	E-A-R	foam	roll-down	n	49		81		130
				% (95% CI)	37.69	(27.84-	62.31	(52.45-	100
					47.55)		72.16)		
3M™ Earplugs	E-A-R	pre-moulded		n	13		117		130
				% (95% CI)	10.00	(3.48-	90.00	(83.48-	100
					16.52)		96.52)		

95% CI = 95% confidence interval, proportions/percentages and confidence intervals calculated using logistic regression allowing for clustering (repeated measures)

Table 4: Mean PAR by earplug type

	Yellow Neons™ PAR		Push-ins™ PAR		Ultrafit™ PAR		Classic™ Overall PAR	
Mean (95% CI)	20.78	(17.60-23.97)	12.71	(10.24-15.18)	18.45	(16.29 to 20.61)	22.58	(20.48-24.69)
18.63 (16.71-20.55)								

95% CI = 95% confidence interval, means and confidence intervals calculated using linear regression allowing for clustering (repeated measures)

Table 5: Mean PAR by broad earplug type

	Foam roll-down PAR	Pre-moulded PAR
Mean (95% CI)	21.68 (19.33-24.03)	15.58 (13.50-17.65)

95% CI = 95% confidence interval, means and confidence intervals calculated using linear regression allowing for clustering (repeated measures)

Figures

Figure 1

3MTM E-A-RFit™ system showing test subject wearing probed earplugs connected to microphones, which are clipped onto safety glasses. The subject is seated approximately 30 cm in front of a speaker connected to a computer with the system software.

Figure 2

Probed Yellow Neons™ for use with the E-A-RFit™ system.

Figure 3

Probed Push-Ins™ for use with the E-A-RFit™ system.

Figure 4

Probed Ultrafit™ for use with the E-A-RFit™ system.

Figure 5

Probed Classic™ for use with the E-A-RFit™ system.