CUSTOM-MOULDED EARPLUGS

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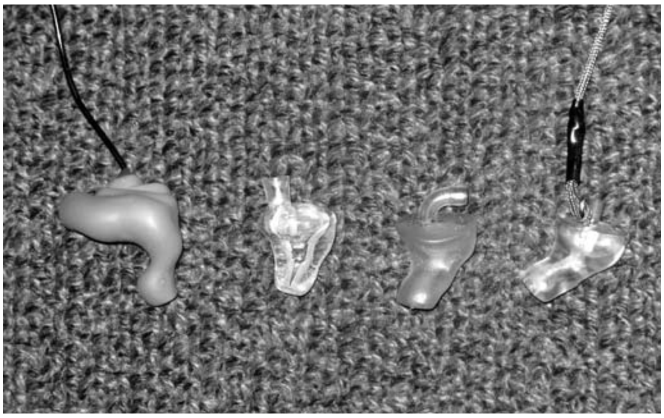
Custom-moulded earplugs are often presented as the ultimate in hearing protector technology and attenuation ability. This analysis compared the performance of custom-moulded devices to off-the-shelf earplugs and earmuffs and found that, while custom devices performed better than the 'average' earplug, they were not as good as the 'average' earmuff. The suggestion is made that the standard hearing protector rating specification of SLC80 may not be applicable to custom-moulded devices and perhaps a more individual rating should be used.



INTRODUCTION

For better or worse hearing protectors are a well recognised tool in the management of noise exposure in the workplace [1, 2, 3]. Quite appropriately these same sources clearly emphasise that the use of hearing protectors is seen as the last step in the occupational noise exposure management process – elimination of the hazard is always preferable to the use of personal protective equipment. This said, hearing protectors do have a legitimate role in the reduction of noise exposure in those workplaces where long term solutions are in the process of being implemented or there are no other practicable solutions.

The main attenuation parameter for hearing protectors in Australia is the well recognised SLC80 (Sound Level Conversion) or attenuation that is applicable to approximately 80% of the users at any one time. This has been further simplified through the use of the Classification System for selecting hearing protectors [4, 5]. Employing the SLC_{80} method for the determination of appropriate hearing protectors involves two noise exposure measurements, both A- and C-weighted, and some minor calculation while the Classification Method requires only the A-weighted noise exposure – a simplification for the end user.

When selecting hearing protectors for use, the main parameters to be considered are the required attenuation, comfort and the ability to communicate and/or hear warning signals. The attenuation performance and communication ability are self-explanatory but comfort is critical because no matter how well a device performs, if individuals will not wear it, it is ineffective. Comfort is a very difficult parameter to define [6]. An important consideration often not considered is the consistency of attenuation. This consistency should be expected by the wearers and be independent of the actual attenuation specification. Consistency in this case is interpreted in terms of the variation in attenuation obtained between different test subjects. In practice it is represented by the variance of the attenuation results of a specific protector or, similarly, the standard deviation of the results.

Thus if individuals are being supplied with hearing protectors as their main tool against noise exposure, consistent performance of the hearing protector is extremely important. If the performance of the device varies significantly individuals may have a tendency to not wear them. This can particularly be the case in lower noise environments [7].

When considering the range of different hearing protectors available, any that offered some form of personal fitting procedure would seem to be preferable as they would tend to minimise fitting variability. This view would be enhanced when endorsing statements are made such as:

"Custom moulded earplugs ... are made-to-measure to the individual's auditory ear canal. The [resulting] plug provides the sealing, while an additional acoustic filter determines the actual attenuation required" [8];

and

"Custom moulded HPDs [Hearing Protection Devices] are comfortable and cannot be worn incorrectly" [9] (p 18).

In general the advertising around custom-moulded hearing protectors emphasises better performance because of the personalised aspect. It is intended in this work to look closely at the performance of custom-moulded earplugs and the suitability of the traditional single figure rating system.

Custom made devices are made by either one of two processes. The first are made on site in a single process where by some manner a moulding material is injected into the ear and ear canal. This mould is then turned into a permanent earplug. The second process is one where an ear impression is taken and sent off site to a manufacturing facility where a permanent earplug is produced, using the impression, from a more durable material than that used for taking the original impression.

As well as having a personalised physical fit many devices also have a personalised acoustic fit. This is where an acoustic filter is inserted into the plug with the intention of matching the attenuation characteristics of the plug to the noise spectrum experienced by the individual. The emphasis at all times is that the devices are personally tailored and individually fitted by an experienced operator in order to better fit the device to the user's ear and to match the attenuation of the device to the users noise exposure.

METHOD

The data used for the analysis was taken from hearing protector testing that had been carried out in accordance with the requirements of combined Australian/New Zealand Standard AS/NZS 1270:2002 Acoustics – Hearing protectors [10]by laboratories accredited by the National Association of Testing Authorities, Australia. In fact most of the basic data can be gathered from the information that is required to be supplied with the sale of the devices as described in AS/NZS 1270. Devices tested before the introduction of the 1999 and 2002 versions of the Standard have not been included in this analysis as they were tested with a smaller number of subjects (minimum 15). The number of test subjects in the later versions of the standard is set at a minimum of 20 for earplugs. (The difference between the 1999 and 2002 versions of the Standard was only in the mechanical testing procedure)

The attenuation of a hearing protector is determined by exposing individual test subjects to one-third octave bands of pink filtered noise at seven octave band centre frequencies from 125 to 8k Hz and determining the subjects occluded (wearing the protector) and unoccluded (not wearing the protector) hearing threshold level difference. This threshold difference is the attenuation of the device. With the test procedure as used in Australia, the tester is not permitted to assist the test subject to fit the protector. The test subject may only use the instructions as provided by the supplier of the devices thus it is termed an inexperienced subject-fit test.

The SLC is calculated as described by Waugh [11]; the SLC_{80} as described in *AS/NZS 1270, Appendix A* [10]; and the mean standard deviation of the device by taking the average of the standard deviations of the attenuations for the seven octave bands. The mean individual SLC (*mi*SLC), mean individual SLC_{80} ($miSLC_{80}$) and individual standard deviation (*i*SD) are a proposed new procedure and are calculated as detailed by Williams [12]. The *mi*SLC is, as suggested by the name, the mean of the individual overall attenuation calculated from the octave band attenuation experienced by the test wearer. The *i*SD is simply the standard deviation of the *i*SLC values while the *mi*SLC80 is the *mi*SLC minus the *i*SD (ie $miSLC_{80} = miSLC - iSD$).

The main difference between the SLC_{80} and the $miSCL_{80}$ is essentially that the SLC_{80} uses the mean and standard deviations of the octave band results for the final calculation while the $miSLC_{80}$ uses the mean individual performance and the standard deviation of the mean.

The devices chosen for this analysis are current and commercially available on the Australian market.

RESULTS

Table 1 summarises all of the calculated parameters for ten custom-moulded ear plugs. Several of the devices were produced by the same manufacturer but were fitted with different filters to provide a specific attenuation. For example, one particular plug may be produced with three filters in order to provide a range of protectors with Classification ratings of 3, 4 and 5 respectively. Each of these plugs would be indicated as being a separate device. For commercial reasons the name and/or manufacturers of the respective devices have not been supplied.

Device	SLC	SLC_{80}	Mean SD	*mi*SLC	iSD	$miSLC_{80}$	Min	Max	Range
A	19.0	15.0	4.2	18.3	3.1	15.2	14.1	25.1	11.0
B	21.5	17.5	4.4	20.9	3.1	17.8	17.1	26.8	9.7
C	22.9	18.8	4.8	22.5	3.6	18.9	17.7	30.0	12.3
D	24.6	20.3	4.8	24.1	3.7	20.3	16.0	30.7	14.7
E	29.0	23.6	5.8	28.4	4.9	23.6	21.2	36.5	15.3
F	30.6	25.0	5.7	29.7	4.2	25.5	22.6	38.1	15.5
G	30.5	22.1	8.0	29.2	7.3	21.9	12.7	45.5	32.8
H	29.6	23.0	6.9	29.0	6.3	22.8	12.8	37.5	24.7
I	27.7	20.4	7.7	26.9	6.8	20.1	14.5	36.6	22.1
J	27.9	23.2	4.7	27.3	4.1	23.3	18.6	32.7	14.1
Average			5.7		4.7				
Average for all plugs			7.8		(4.2)				
(Average for all muffs)			6.2		(3.3)				

Note: All figures are expressed in dB

Table 1: A summary of the parameters calculated from the available test data for custom-moulded earplugs. 'Min' is the minimum individual attenuation (iSLC) measured for a particular device while 'Max' is the maximum and 'Range' is the difference between the Max and Min. All figures expressed in dB. ($miSLC_{80} = miSLC - iSD$)

The *"Average for all plugs"* figures is the average *'Mean SD'* and *iSD* respectively for earplugs (including two custom-moulded pairs) that were tested in accordance with AS/NZS 1270:2002 [10] by National Acoustic Laboratories over the years 2002 to 2004 [7]. Thus they present standard deviation values that could be considered typical for earplugs in general. A similar situation also applies to the "*Average for all muffs*" figures.

DISCUSSION

If it is accepted that consistency of performance can be adequately represented by standard deviation, then the overall performances of the custom-moulded devices are more consistent compared to the general results obtained for tests of many earplugs. This is shown by the average 'Mean SD' for custom-moulded plugs being 5.7 dB while for all plugs it is 7.8 dB and the average iSD being 4.7 dB compared to 6.2 dB for all plugs. However, the custom-moulded plugs do not perform as well as the average for all ear muffs, which have average values for mean SD and iSD of 4.2 dB and 3.3 dB respectively. The best earplugs have an iSD of 3.1 dB while for the best earmuffs it is as low as 1.4 dB.

While most devices performed with standard deviations around the average value some performed very poorly. This is reflected in the range of *i*SLC attenuations provided, which varied by 9.7 dB, from 17.1 to 26.8 dB, for the most consistent performer to a variation of 32.8 dB, from 12.7 to 45.5 dB, for the worst. Even for the best result a range of attenuation of 9.7 dB around the mean of 20.9 represents a variation in performance of around 46%.

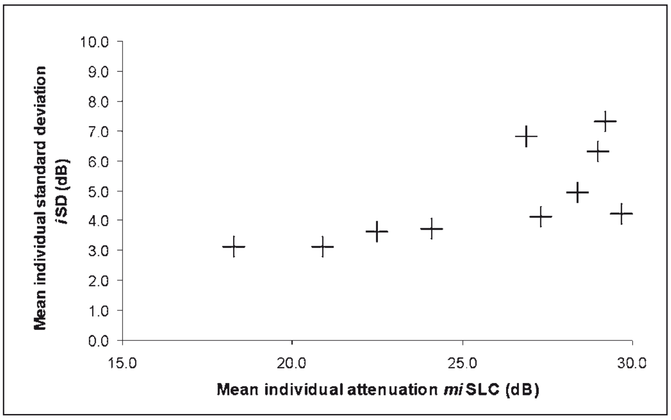


Figure 1: Individual standard deviation (iSD) (dB) versus the mean individual attenuation (miSLC) (dB) for ten, commercially available custom-moulded earplugs.

Figure 1 graphs the distribution of the individual standard deviations (iSD) (dB) versus the mean attenuation (miSLC) (dB). The majority of the devices behave as would reasonably be expected in that they have very similar standard deviations. This is reasonable because it could be presumed that the variations for each device tested would come from similar sources and hence yield a consistent value. Three devices obviously fell well away from range exhibited by the majority of the plugs tested. It should be noted that these are three devices produced by the same company but with different 'filters' to better personalise their performance to the clients requirements. It can only be speculated that the cause of these larger than average standard deviations may be due to a particular production technique or fitting procedure.

One question to pose is that rather than produce an overall attenuation performance figure for custom-moulded earplugs should we be paying more attention to the 'personalised' feature of these devices and somehow look more at a personal performance measure more related to the individual and their personalised device? It may be possible that currently by mixing two processes, ie personalising the fit but including a 'standardised' filter, there is a degree of uncertainty introduced into the process. Perhaps it would be better to fit a personalised device to an individual and more accurately measure the insertion loss they experience when the device is in use. This would then be more accurately described as a personally fitted earplug.

This now leads to an important point. Is there a real need for a parameter such as SLC80 for a personalised hearing protector? And, if for some persuasive argument the SLC80 is retained, does it have any relevant meaning?

Some occupational health and safety jurisdictions require that for a hearing protector to be legitimately applied as part of an occupational noise management programme it must have been tested in accordance with AS/NZS 1270. This implies the rating to have been measured as the result of a statistical performance amongst a specified minimum number of suitable test subjects. Since the SLC80 measure is a population statistic strictly it does not apply to the individual even though this is frequently conventionally done.

If we are using a personally specific device perhaps the implementation of a standardised personal 'insertion loss' test would be of more value than trying to fit the characteristics of personalised devices to an unsuitable 'population' measure. A better rating may simply be the iSLC, calculated from the individual's measured attenuation at each octave band for overall attenuation as demonstrated here by the use of miSLC, iSD and miSLC80 [12]. If the octave band method of specification must be used then the same octave band attenuations can be employed.

CONCLUSION

An overall analysis indicates that overall custom-moulded earplugs do perform more consistently than earplugs in general, with the average individual standard deviation for custom-moulded devices being 4.7 dB while it is 6.2 dB for earplugs in general. However, they still are not as consistent as the general performance for earmuffs that have an average individual standard deviation of 3.3 dB.

This analysis also suggests that the current method of specification of custom-moulded earplug performance using the SLC80 figure may not be entirely satisfactory and perhaps another more individualised rating is required.

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