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Optimum test conditions and variability of otoacoustic emission testing in individuals with normal hearing

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Optimum test conditions and variability of otoacoustic emission testing in individuals with normal hearing

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This study investigates issues important for the potential usefulness and practical application of OAE testing within an occupational health surveillance programme. Before this technique can be used within health surveillance, it is important to understand how reliable the measurements are and the level of change that could be detected over time within individuals. As any test of hearing function is potentially susceptible to background noise levels, it was also important to establish whether a soundproof room or audio booth would be required if this were to be used within health surveillance. We also wished to compare the reliability of OAE to that of standard puretone audiometry.

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KEY MESSAGES

1. Otoacoustic emission testing (OAE) has good reliability and repeatability in individuals with normal hearing. It should be borne in mind that this study did not investigate the impact of noise exposure or hearing difficulties on OAE, both of which would be important factors in occupational health surveillance.

2. The smallest difference that can be detected using the technique appears to be small enough to be able to pickup changes that may be expected with noise-induced hearing loss over time, but this would need to be verified by future research work.

3. The room in which the measurements are performed (quiet room versus audio booth) has little influence on the reliability of the technique. Thus, a soundproof room may not be necessary to obtain good quality information.

EXECUTIVE SUMMARY

The hearing loss that can occur in response to excessive exposure to noise in the workplace is permanent. Therefore, health surveillance has an important role in trying to prevent this. The standard technique for monitoring hearing as part of health surveillance, puretone audiometry, only detects changes once hearing loss has occurred. However, the measurement of otoacoustic emissions (OAE) from the ear is a simple, quick technique that may be useful in picking up early changes in hearing function before hearing loss occurs. Detection of early markers of hearing damage may be more useful in preventing permanent irreversible effects. There are two main ways of stimulating OAEs by delivering sounds in the form of clicks (transient-evoked or TEOAE) or tones (distortion-product or DPOAE) to the ear.

This study investigates issues important for the potential usefulness and practical application of OAE testing within an occupational health surveillance programme. Before this technique can be used within health surveillance, it is important to understand how reliable the measurements are and the level of change that could be detected over time within individuals. As any test of hearing function is potentially susceptible to background noise levels, it was also important to establish whether a soundproof room or audio booth would be required if this were to be used within health surveillance. We also wished to compare the reliability of OAE to that of standard puretone audiometry.

Individuals who had normal hearing and were not exposed to noise within their work were asked to attend for measurements of OAE and standard audiometry on three separate occasions; each occasion was separated by around one week. On each testing occasion three measures of OAE were obtained in both a quiet room and an audio booth. In this way the reliability of OAE could be established over a period of around two weeks and the effect of the room used for testing investigated.

Objectives

To establish the reliability of OAE testing (both transient-evoked and distortion-product methods) in individuals not exposed to noise.

To investigate the influence of the environment in which the testing is performed (quiet room versus audio booth) on the measurement of OAE.

To establish the smallest change in OAE that could be detected over time.

To compare the two methods of OAE measurement and the current recommended scheme of puretone audiometry.

Main Findings

1. A total of 33 individuals (61% male) with an average age of 43 years were involved in this study. All ears tested were clear of wax, undamaged and had normal hearing (as defined by using a standard audiogram and HSE's guidance on health surveillance for noise exposure [1]).

2. A total of 2,350 tests of OAE were performed, 1,174 for TEOAE and 1,176 for DPOAE.

3. Overall, the proportion of tests that gave a measurable OAE response varied from 96% to 68% for TEOAE and 99% to 82% for DPOAE, depending upon the frequency (Hz) measured. The lowest number of acceptable tests was seen at the higher frequency of 4000Hz, and this was particularly so for TEOAE.

4. The test-retest reliability, as measured by the intra-class correlation coefficient (ICC), for the absolute emission levels for both TEOAE and DPOAE were good. However, they were generally slightly better for TEOAE when compared to DPOAE.

5. There was no clear effect of the environment in which the measurements were taken on the reliability of TEOAE. However, the use of an audio booth may improve the reliability of DPOAE when measured at frequencies of 2000 and 3150 Hz.

6. The signal to noise ratio (SNR) was not as reliable as the absolute emission level as an outcome measure.

7. The smallest detectable difference (SDD) for the absolute emission level for TEOAE was established as between 3.4 and 5.6 dB SPL (sound pressure level), depending upon the frequency and environment used. The SDD for DPOAE was established as between 5.8 and 9.6 dB SPL.

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1 INTRODUCTION

Health surveillance is an integral tool in the overall risk management of noise exposure in the workplace, acting as an essential feedback on the effectiveness of any controls in place and highlighting individuals at increased risk. The current method used in health surveillance for noise [1], pure tone audiometry, only detects changes once hearing loss has taken place and relies on an individual giving an accurate indication of when they can hear a sound. To help to prevent the hearing loss related to noise exposure at work it would be more desirable to have a method which could provide an earlier warning of health damage, rather than waiting until permanent hearing loss has taken place. The measurement of otoacoustic emissions from the ear may be such a technique.

Otoacoustic emissions (OAE) are very low amplitude sounds emitted from the cochlea of the ear in response to outer hair cell stimulation, and are sometimes described as echos. They can be spontaneous but can also be evoked by sounds being passed into the ear. The two main ways of stimulating OAEs is by delivering sounds in the form of clicks (transient-evoked or TE) or tones (distortion-product or DP) to the ear. The technique is simple and quick to use and does not require the patient to respond to the sound, and is thus completely objective. It is widely used as a screening tool in newborns in the United Kingdom.

There is published evidence that otoacoustic emissions can be used to distinguish between those with normal hearing and those with hearing impairment [2, 3]. There have also been several studies published suggesting that otoacoustic emissions could be used to detect early changes to hearing in response to noise exposure, prior to any detectable changes taking place on standard audiometry [4-9]. In one longitudinal study investigating noise exposure in sailors, the measurement of very small or absent OAE emissions prior to exposure to noise was shown to predict those who developed permanent hearing loss following the exposure [7]. In addition, many more individuals who had been exposed to noise developed significant changes in their OAE, which were not reflected in their standard audiometry measurement; the authors of this work suggested that this could imply that OAE changes could indicate subclinical noise-induced hearing loss [7]. These authors also suggested that transient evoked OAEs appear to be better predictors of permanent thresholds shifts in audiometric measurements than distortion product OAE [6, 7]. More recently, Job et al [5] have reported that the use of an index based upon distortion-product OAE could be used to measure the ear's vulnerability to noise and the risk of early hearing loss in those with normal audiometry results.

For otoacoustic emission testing to be useful as a monitoring tool within a health surveillance programme for noise exposure, it needs to be reliable (good test-retest reliability), measurable (measurable OAE obtained in a high proportion of tests), and the change in OAE that could be detected on each re-test over time needs to be defined. There should also be equipment available commercially that is easy to use and relatively affordable, such as it might be used by occupational health professionals. Some work has been published investigating the repeatability of both transient-evoked OAEs [10-13] and distortion-product OAEs [10-12, 14, 15]. Overall, these publications would suggest that both of the methods of measurement give good repeatability, and may be more repeatable than puretone audiometry. However, the equipment and test protocols used in these studies varied. Factors such as the population used, the OAE equipment used, the measurement parameters used for the OAE tests and the environment the tests are conducted in will affect the measurability and reliability of the test. The background noise level within the testing environment will affect the measurability (i.e. the proportion of the tests that are above the noise floor) of the OAE tests but the influence of different testing environments (e.g. the use of an audio booth) has not been investigated.

2 IMPLICATIONS

1. This study provides evidence for the potential usefulness and practical application of OAE testing. It develops our understanding of the measurement conditions required and the smallest detectable difference that can be achieved. These issues are important if this technique is to be used within occupational health surveillance.

2. This study demonstrates the validity and reliability of otoacoustic emission testing and also shows that it compares favourably with the current test method recommended for noise health surveillance (namely puretone audiometry).

3. This study has moved us closer to being able to provide more detailed evidence based advice to those interested in undertaking OAE testing as part of health surveillance for noise-induced hearing loss. We are not aware of other research that has looked specifically at the nature of the OAE test method in this detail, particularly in relation to its application as an occupational health surveillance tool.

4. This research was conducted on individuals with normal hearing and the results should be considered in this respect. In practice if this technique were to be used within occupational health surveillance then individuals would be exposed to noise and be likely to have hearing difficulties. The implications of these factors were not assessed in the current study.

3 METHODOLOGY

3.1 STUDY DESIGN

This study followed a repeated measures design with each volunteer acting as their own control (Figure 1). Each volunteer attended the laboratory for two hours on three separate days. On each day individuals underwent three repeated tests of both transient-evoked otoacoustic emission (TEOAE) and distortion-product otoacoustic emission (DPOAE) tests in both a quiet room (QR) and an audio booth (Audio). These three repeated tests within a testing environment allowed the within-day variability of measures of TEOAE and DPOAE to be examined. The testing on three separate days allowed the between-day variability in TEOAE and DPOAE to be established. Measurements conducted in the same individual in the QR and Audio could be compared to investigate the influence of the external environment on the measurements of TEOAE and DPOAE. On each day of testing in the audio booth standard puretone audiometry (AM) was performed. The randomisation strategy was used to randomise the order of TEOAE and DPOAE tests, the QR and Audio and whether the standard audiometry was performed at the beginning or end of the OAE testing in the audio booth.

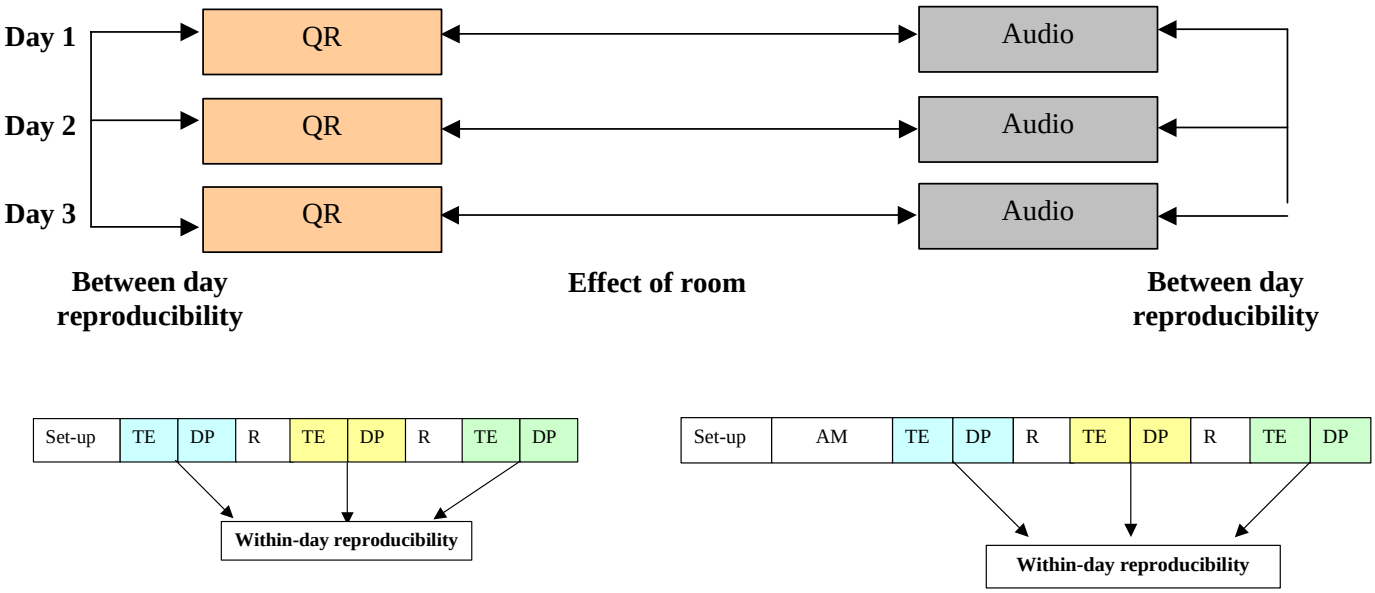

Figure 1 Testing strategy and design of study

In Figure 1 above QR refers to testing strategy for quiet room and Audio refers to testing strategy for audio booth. In each testing environment repeated OAE measurements were conducted: TE refers to TEOAE test, DP refers to DPOAE test, R refers to a 5 minute rest period and AM refers to standard puretone audiometry measurement. The order of QR versus Audio, TE versus DP and AM was randomised.

3.2 SUBJECTS AND RECRUITMENT

An invitation to take part in this research study was sent out to all staff at the Health and Safety Laboratory via an electronic calling notice (Appendix 1a). Those who responded to the calling notice were asked to attend a short interview with the Occupational Health Nurse involved in the study to establish if they were eligible to take part. Those who reported that they had had an injury, operation, recurrent infections, or perforated ear drum in either ear, or had ever taken ototoxic medication, were excluded from the study. The ears were then examined using an otoscope to identify if individuals had excessive wax in the ear canal or damage to the ear drum. If an individual was identified as having excessive wax in their ear they were informed of this and asked to consult their GP if they wished to have the wax removed. If this was successful then the individual was recruited into the study. In addition, if individuals were found to have current perforation of the ear drum, or scarring associated with previous perforation, then they were excluded from the study.

Those individuals who had passed the screening process were then recruited into the study and asked to sign a consent form. A background questionnaire (Appendix 1b) asking about previous noise exposure and difficulties in hearing was then completed. Individuals were asked to refrain from significant noise exposure for at least 16 hours before visiting the laboratory for testing.

The study was given ethics committee approval by the HSE research ethics committee (ETHCOM/REG/09/03).

3.3 MEASUREMENT OF BACKGROUND NOISE LEVELS

Two locations were used for this study, the audio booth located in the mobile laboratory and a quiet office room. Background noise levels were monitored before testing of volunteers commenced in these two locations using a Bruel and Kjaer sound analyzer (type 2260) and analysed in third-octaves.

3.4 PROCEDURE FOR TESTING

On each of three occasions (separated by at least a week) each volunteer visited the laboratory for testing. They visited either the quiet room or the mobile testing laboratory (where the audio booth is housed) first, depending upon the randomisation strategy. On arrival to each testing session a pre-test questionnaire was completed (Appendix 1c) to establish if there had been any exposure to significant noise over the last 16 hours, and whether any other changes had occurred (e.g. development of viral infection). Ears were then checked using an otoscope to ensure that they were free of wax and debris prior to testing.

In the first location (quiet room or audio booth) three sets (one set consists of one TEOAE and one DPOAE) of OAE tests were then performed, with a 5minute rest period between each set (see Figure 1). The individual then went to the second location and had a further three sets of OAE tests performed. Standard pure tone audiometry (AM) was also performed when the measurements were performed in the audio booth.

3.4.1 Otoacoustic emission (OAE) testing

The IL0292 Echoport USB-II (Otodynamics Ltd, Hertfordshire, UK) coupled with a laptop using the ILOv6 software was used for all of the OAE testing. Standard ear probes that could be used for both the TEOAE and DPOAE tests were used (Otodynamics Ltd, Hertfordshire, UK).

3.4.1.1 Calibration check of equipment prior to testing

Visual inspection of the equipment and probes was made prior to each testing session. Additionally, three procedures were performed to ensure that the test probes were functioning correctly. Firstly, a probe test was carried out which involved placing a known signal (70-80 dB) through the probe and checking that the value registered was within the manufacturer's acceptability criteria (Otodynamics Ltd, Hertfordshire). The second procedure is termed a probe cavity test and involved securing the probe in a 1cc calibration cavity, providing a stimulus of 85 dB and recording the signal. This was only deemed acceptable if no otoacoustic emissions were measured in the cavity. Thirdly, an occlusion test was performed to ensure that when the probe was covered that no signal was detected. Only if the probe passed all three of these procedures was it used for subsequent testing.

3.4.1.2 Checking the fit of the OAE probe in the ear canal

Appropriate sized tips were selected for each individual to ensure that the probe was fitted as securely as possible within the ear canal. A trained operator then inserted the probe into the ear canal. Once satisfied visually with the fit of the probe, click stimuli were delivered to the ear canal so that the stimulus waveform could be inspected. If this was acceptable then the OAE tests described below were performed. If this was unacceptable then probe re-fit was attempted until a satisfactory fit could be obtained.

3.4.1.3 Transient-evoked OAE (TEOAE)

Transient evoked OAE involves delivering a sound stimulus as a series of clicks to the ear canal. The stimuli were rectangular pulses of 80 μs presented as a rate of 50 clicks per second. The clicks had a stimulus intensity of 84 dB and 260 sweeps were performed. The background noise rejection level used was 6mPa. The emission, or absolute threshold, and background noise levels were analysed over half-octave frequency bands centred at 1000, 1500, 2000, 3000 and 4000 Hz. An example of a recording is shown in Figure 2. For each frequency band the difference between the absolute threshold and noise levels was calculated, this is called the signal to noise ratio or SNR. If a value of zero or below was calculated then that measure at that frequency was excluded from the analysis as this meant that a measurable OAE had not been recorded.

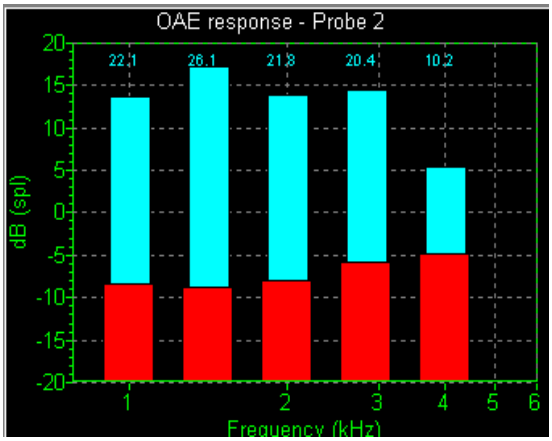

Figure 2 Example of a recording of a transient-evoked OAE (TEOAE) test

In the bar chart above, the red bars represent the background noise level and the blue bars the OAE emission. The figure above the blue bar is the difference between the absolute threshold and the noise level, the SNR.

3.4.1.4 Distortion-product OAE (DPOAE)

Distortion-product OAE testing involves delivering a sound to the ear canal made up of two harmonious tones at different frequencies and different levels. Two primary frequencies of stimulation, F1 and F2, were used in the ratio of F2/F1=1.22. The amplitudes of the two stimuli (L1 and L2) were fixed throughout the test with L1 = 65 dB SPL and L2=55 dB SPL. The resolution of 3 points per octave was used and the test lasted three minutes. The background noise rejection level used was 6mPa. The absolute threshold and background noise levels were analysed over one third-octave frequency bands centred at 1000, 1250, 1600, 2000, 2500, 3150, 4000, 5000 and 6300 Hz. An example of a recording is shown in Figure 3. For each frequency band the difference between the absolute threshold and noise levels (SNR) was calculated. If a value of zero or below was calculated, that measure at that frequency was excluded from the analysis as this meant that a measurable OAE had not been recorded.

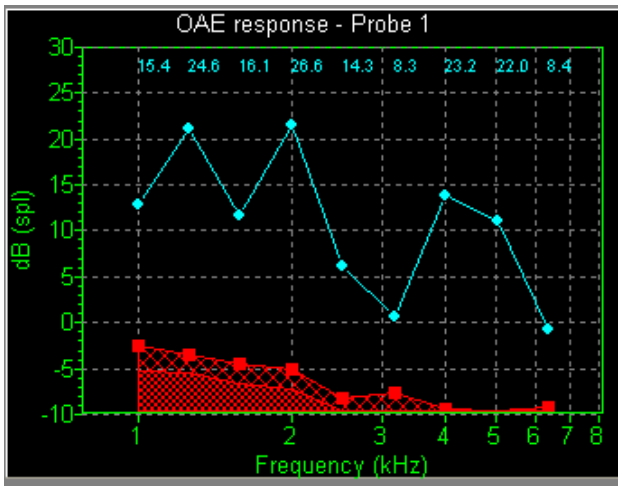

Figure 3 Example of a recording of distortion-product OAE (DPOAE) test

In the chart above, the red lines represent the background noise level and the blue line represents the OAE emission. The number above the blue line is the difference between the absolute threshold and the noise level; the SNR.

3.4.2 Puretone audiometry

Air conduction puretone audiometry is a subjective measurement of hearing threshold, and relies on the patient response to pure tone stimuli. Air conduction means that the sound is delivered to the ear via earphones. Pure tones are sounds of a fixed frequency that have no audible distortion components and are presented at varying intensities to the ears.

All audiometric tests were carried out on both ears in an audio booth using an ASRA audiometer (GM instruments, Kilwinning, Scotland), ear phones and cups. The test frequency range was between 500 and 8 kHz and the sound was presented following the Hughson and Westlake method and was in accordance with EN 26189. [16, 17]

The sum of the hearing levels at 1000, 2000, 3000, 4000 and 6000 Hz were calculated for each individual's audiogram. These were compared to the age and gender related values for warning and referral levels published in HSE's guidance on health surveillance for noise exposure [1]. Any individual who obtained a classification of category 2 (mild hearing impairment) or worse, based upon HSE's criteria, were deemed to have an abnormal audiogram. Those who obtained a classification of 1 (acceptable hearing ability) were deemed to have a normal audiogram and were included in the present study.

3.5 STATISTICAL ANALYSIS

The outcome measures of interest for both the TEOAE and DPOAE tests were the absolute threshold level and the SNR at each frequency band. As there were a large number of potential outcome variables, particularly in terms of frequency, it was necessary to reduce the number of frequencies investigated in terms of statistical analysis. Frequencies of 1000, 2000, 3000 and 4000 Hz were chosen for TEOAE and standard audiometry. For comparison, frequencies of 1000, 2000, 3150 and 4000 Hz were chosen for DPOAE.

A linear mixed model containing both 'fixed effects' and 'random effects' was constructed for both the TEOAE and DPOAE tests in the two measurement conditions (quiet room and audio booth), for each frequency and for each of the outcome measures (absolute threshold and SNR). This random effect structure provides estimates of the between-subject, between-ear, between-day and within-day variabilities.

Other factors that may influence the results were included as fixed effects in the model; these were the day of the test (one, two or three), the order of the test within each day (first, second, or third), ear (left or right) and the order of the TEOAE/DPOAE tests. The individual characteristics of age, whether previously occupationally exposed to noise, sex, and time from first test, were included as fixed effects in a stepwise procedure (significance, $p<0.05$).

For standard audiometry similar models were created.

The models created were then used to estimate the following parameters:

Test-retest reliability

This measures the consistency of a test, and can be quantified using intra-class correlation coefficients (ICCs). In this instance, the ICC estimated the correlation between measurements on the same subject and ear, which was calculated as

$$\text{ICC} = \frac{\text{between subject variance} + \text{between ear variance}}{\text{total variance}}.$$

A value of zero indicates no correlation/reliability, and a value of 1 indicates perfect correlation/reliability.

Standard Error of Measurement (SEM)

This gives an indication of the precision of individual measurements, and is calculated from the known sample standard deviation (SD) and the test-retest reliability:

$$\text{SEM} = \text{SD}\sqrt{(1-\text{ICC})}.$$

The SEM can be used to construct a 95% confidence interval for a subject's true result as

$$S \pm 1.96 \times \text{SEM},$$

where S is the subject's observed result.

Smallest Detectable Difference (SDD)

This is the difference needed between separate measurements on an individual subject for the difference in the measurements to be considered real, and is estimated using the SEM:

$$\text{SDD} = 1.96 \times \sqrt{2} \times \text{SEM}\,.$$

That is, for a statistically significant change between two separate observations to be detected (on the same individual, on the same ear), this change must be at least the SDD.

4 RESULTS

4.1 BACKGROUND NOISE LEVELS MEASURED IN THE TWO ENVIRONMENTS

The main difference between the noise levels in the two environments was that noise levels over the 250 Hz to 2500 Hz range were lower in the audio booth, when compared to the measurements made in the quiet room (see Appendix 2).

4.2 CHARACTERISTICS OF THE STUDY PARTICIPANTS

A total of 33 individuals with normal audiograms were recruited into the study and their characteristics are shown in Table 1.

Table 1 Characteristics of those participating in the study

Characteristic	
Number of participants	33
Age in years, mean (SD)	43 (11)
Gender, number (%) Male Female	 20 (61%) 13 (39%)
Ever previously exposed to noise at work, number (%) No Yes	 22 (67%) 11 (33%)
Days after first test, median (range) Second test (Day 2) Third test (Day 3)	 7 (7-28) 17 (14-48)

4.3 DATA COLLECTED AND INCLUDED IN ANALYSIS

In each of the environmental conditions (quiet room and audio booth) for each type of test (TEOAE or DPOAE), the total number of tests possible were 594. As a result of technical failures, and one subject not attending for their final test session, it was not possible to collect complete data. A total of 589 and 585 tests were recorded for TEOAE in the QR and Audio respectively. For the DPOAE, a total of 588 were achieved in both conditions. From this data tests that achieved measurable OAE responses (i.e. an OAE response was measured over and above the background noise level) were selected for analysis (see sections 3.4.1.3 and 3.4.1.4). The relative proportions of tests that gave measurable responses at the different frequencies for each condition are shown in Tables 2 and 3.

Table 2 The number of measurable tests achieved for TEOAE

	Audio		***QR***	
Frequency (Hz)	Tests measurable (n)	% measurable tests (out of 585)	Tests measurable (n)	% measurable tests (out of 589)
1000	525	90	541	92
2000	546	93	568	96
3000	475	81	515	87
4000	396	68	437	74

Table 3 The number of measurable tests achieved for DPOAE

	Audio		***QR***	
Frequency (Hz)	Tests measurable (n)	% measurable tests (out of 588)	Tests measurable (n)	% measurable tests (out of 588)
1000	554	94	547	93
2000	584	99	578	98
3150	519	88	529	90
4000	500	85	482	82

4.4 RELIABILITY OF TEOAE MEASUREMENTS

The test-retest reliability was investigated for both the absolute thresholds and the SNR values (Table 4). Overall, TEOAE absolute thresholds gave good reliability in both the QR and Audio conditions with the intra-class correlation coefficient varying between 0.88 and 0.94. There was no clear effect of the room in which the test was performed, or the frequency of the measurement on the reliability of the absolute thresholds. The smallest detectable difference (SDD) in absolute threshold varied between 3.4 and 5.6 dB SPL. The SDD tended to fall with increasing frequency (up to 4000 Hz), and tended to be slightly smaller in the audio booth.

The test-retest reliability of the SNR values was poorer than that for the absolute thresholds and the intra-class correlation coefficient varied between 0.72 and 0.90. The reliability was related to the frequency of the measurement with the lower frequencies (1000 and 2000 Hz) having the lowest reliability. There was no evidence that the room in which the measurements were performed affected this. The smallest detectable difference varied between 4.4 and 10.2 dB SPL and there was little evidence that the room had any effect on this, other than at 1000 Hz where the audio booth gave a smaller SDD of 9.4 as compared to 10.2 in the quiet room.

Table 4 Test-retest reliability for TEOAE measurements

Frequency	***Audio***				***QR***			
	Test-retest reliability	***(95% CI)***	***SEM***	***SDD***	***Test-retest reliability***	***(95% CI)***	***SEM***	***SDD***
Absolute threshold								
1000Hz	0.88	(0.83-0.93)	2.0	5.4	0.89	(0.84-0.94)	2.0	5.6
2000Hz	0.90	(0.86-0.94)	1.6	4.4	0.88	(0.83-0.93)	1.9	5.2
3000Hz	0.93	(0.91-0.96)	1.2	3.4	0.92	(0.88-0.95)	1.5	4.3
4000Hz	0.93	(0.90-0.96)	1.3	3.5	0.94	(0.91-0.97)	1.4	3.8
SNR								
1000Hz	0.72	(0.62-0.81)	3.4	9.4	0.74	(0.64-0.83)	3.7	10.2
2000Hz	0.76	(0.67-0.84)	2.7	7.5	0.77	(0.69-0.85)	2.7	7.4
3000Hz	0.84	(0.77-0.90)	1.9	5.4	0.87	(0.81-0.92)	2.0	5.5
4000Hz	0.89	(0.85-0.94)	1.6	4.4	0.90	(0.86-0.95)	1.8	4.9

CI, confidence interval; SEM, standard error of measurement; SDD, smallest detectable difference

The variability between measurements due to differences between subjects (between-subject SD), differences between the right and left ear (between-ear SD), differences between repeated measurements when tested on the same day (within-day SD) or differences between repeated measurements when tested on three separate days (between-day SD) were explored (Table 5). The greatest source of variability between measurements was due to differences between subjects, followed by differences between the right and left ears. In general, the within-day variability was slightly higher than the between-day variability. There were no clear differences in the variability related to whether the measurements were performed in the audio or quiet room environments.

Table 5 Sources of variability (SD) in repeated measurements of TEOAE

Frequency	***Audio***				***QR***			
	Between subject	***Between ear***	***Between day***	***Within day***	***Between subject***	***Between ear***	***Between day***	***Within day***
Absolute threshold								
1000Hz	4.5	3.0	1.4	1.4	5.1	2.9	1.6	1.3
2000Hz	3.2	3.1	1.1	1.1	3.4	3.3	1.5	1.0
3000Hz	3.6	2.7	0.7	1.0	4.0	2.8	1.2	0.8
4000Hz	4.3	2.4	0.9	1.0	4.5	2.5	0.9	0.9
SNR								
1000Hz	4.3	3.1	1.5	3.0	5.3	3.1	2.2	3.0
2000Hz	3.4	2.7	1.1	2.1	3.6	3.3	1.5	2.2
3000Hz	3.2	2.6	0.9	1.6	4.3	2.5	1.0	1.6
4000Hz	3.9	2.4	0.7	1.4	4.7	2.3	1.0	1.4

All figures above present the SD from the mixed effects models for each source of variability.

4.5 RELIABILITY OF DPOAE MEASUREMENTS

The test-retest reliability was investigated for both the absolute thresholds and the SNR values (Table 6). Overall, DPOAE absolute thresholds gave reasonable reliability (varying between 0.72 and 0.86) in both the QR and Audio, but the intra-class correlation coefficient was generally lower than that for the equivalent frequency with TEOAE. There was no systematic effect of the room in which the test was performed on measurements at all frequencies, although the audio booth did seem to improve the reliability at 2000 and 3150 Hz. The smallest detectable difference in absolute threshold varied between 5.8 and 9.6 dB SPL. There was no systematic effect of using the audio booth on the SDD across the frequencies, however the lowest SDD of 5.8 was observed at 3150 Hz in the audio booth.

The test-retest reliability of the SNR values was poorer than that for the absolute thresholds and the intra-class correlation coefficient varied between 0.58 and 0.82. Here the use of the audio booth did tend to improve the reliability and reduce the SDD, apart from at the lowest frequency of 1000 Hz. The smallest detectable difference varied between 7.6 and 13.0 dB SPL.

Table 6 Test-retest reliability for DPOAE measurements

Frequency	*Audio*				*QR*			
	Test-retest reliability	*(95% CI)*	*SEM*	*SDD*	*Test-retest reliability*	*(95% CI)*	*SEM*	*SDD*
Absolute threshold								
1000Hz	0.72	(0.61-0.82)	3.5	9.6	0.78	(0.69-0.87)	2.9	8.1
2000Hz	0.84	(0.79-0.90)	2.7	7.5	0.80	(0.72-0.88)	2.8	7.7
3150Hz	0.87	(0.82-0.93)	2.1	5.8	0.79	(0.70-0.87)	2.8	7.8
4000Hz	0.82	(0.74-0.89)	3.1	8.6	0.86	(0.80-0.92)	2.7	7.5
SNR								
1000Hz	0.58	(0.45-0.71)	4.7	13.0	0.64	(0.51-0.76)	4.6	12.6
2000Hz	0.75	(0.67-0.83)	3.6	10.1	0.63	(0.51-0.75)	4.4	12.1
3150Hz	0.82	(0.74-0.89)	2.8	7.6	0.68	(0.57-0.80)	3.6	10.0
4000Hz	0.80	(0.73-0.88)	3.4	9.5	0.73	(0.63-0.84)	3.9	10.9

CI, confidence interval; SEM, standard error of measurement; SDD, smallest detectable difference

As with the TEOAE measurements the greatest source of variability between DPOAE measurements was due to differences between subjects, followed by differences between the right and left ears (Table 7). There were no clear systematic differences between the between-day and within-day variability. The room in which the measurements were performed did not affect the variability of the measurements of absolute threshold, however there was a suggestion that the use of the audio booth reduced the variability of the SNR measurements.

Table 7 Sources of variability in repeated measurements of DPOAE

Frequency	*Audio*				*QR*			
	Between subject	*Between ear*	*Between day*	*Within day*	*Between subject*	*Between ear*	*Between day*	*Within day*
Absolute threshold								
1000Hz	4.5	2.5	2.5	2.1	4.5	2.3	2.2	1.5
2000Hz	4.5	4.2	1.6	2.2	4.5	3.0	2.0	1.8
3150Hz	5.0	3.0	1.7	1.5	5.1	2.1	2.3	1.8
4000Hz	5.2	3.3	2.5	1.6	5.6	3.8	2.2	1.6
SNR								
1000Hz	4.2	2.6	2.9	3.1	5.5	2.9	3.5	3.2
2000Hz	4.5	4.1	1.9	2.9	5.0	2.7	2.8	3.3
3150Hz	4.9	3.2	1.6	2.3	5.0	1.8	2.3	2.8
4000Hz	5.7	3.7	2.3	2.4	5.7	3.0	2.7	2.8

All figures above present the SD from the mixed effects models for each source of variability.

4.6 OTHERS FACTORS AFFECTING TEOAE AND DPOAE MEASUREMENTS

The influence of age of the volunteer (<40 or 40+ years of age), gender and differences between the right and left ears was investigated. For the absolute thresholds for TEOAE it was found that females had significantly higher thresholds than males for the measurements at 2000, 3000, and 4000 Hz ($p<0.05$). In addition, those over 40 years of age had lower thresholds measured at 3000 and 4000 Hz ($p<0.05$).

For the absolute thresholds for DPOAE there was no systematic effect of gender or ear on the measurement. However, age (being greater than 40 years of age) significantly lowered the threshold at 1000 and 4000Hz ($p<0.05$).

4.7 RELIABILITY OF AUDIOMETRY

The reliability of audiometry was good with the intra-class correlation coefficient varying between 0.80 and 0.89 between frequencies (Table 8). The reliability increased slightly with increasing frequency of measurement, with the measurement at 4000 Hz having the greatest ICC.

Table 8 Reliability of standard audiometry measurements

Frequency	*Test-retest reliability*	*(95% CI)*	*SEM*	*SDD*
1000Hz	0.80	(0.71-0.89)	3.2	9.0
2000Hz	0.82	(0.75-0.90)	3.3	9.1
3000Hz	0.88	(0.82-0.93)	3.4	9.4
4000Hz	0.89	(0.84-0.94)	4.4	12.1

4.8 OTHER FACTORS AFFECTING THE MEASUREMENTS OF AUDIOMETRY

The influence of age of the volunteer (<40 or 40+ years of age), gender, differences between the right and left ears and the influence of performing audiometry before or after the measurement of OAE was investigated. There was no evidence that systematic differences existed between the ears, or that gender influenced the results. There was also no evidence that whether audiometry was performed before or after OAE testing was important. However, there was a statistically significant influence of age on the results at 1000 ($p<0.05$), 3000 ($p<0.05$) and 4000 Hz ($p<0.01$), with the older group having higher thresholds.

A full discussion of the results in this section can be found at Appendix 3.

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APPENDICES

APPENDIX 1A – CALLING NOTICE

Calling notice for Volunteers
CAN YOU HELP?

Health surveillance for noise exposure currently involves the use of hearing tests (audiometry) to detect if an individual has lost any of their hearing. However, this only picks up changes if an individual has already lost some of their hearing. Another technique that is available (otoacoustic emission testing) may pick up changes before hearing loss takes place, and may be able to detect those at risk of loosing their hearing. This would be a great benefit in health surveillance and would help in preventing permanent damage to hearing.

We are now recruiting volunteers to establish the best test conditions and reproducibility of this simple hearing test (otoacoustic emission testing). This test has been used in adults before and is used nationally as a screening test for newborn babies. Before we can use this technique in health surveillance for workers, we need to investigate how repeatable the test is, and the best way to carry it out. We would also like to compare the results of this technique with a standard hearing test (audiometry).

If you agree to participate in the study you will be asked to attend our laboratory on three occasions, each lasting about 2 hours. On each occasion we will measure your hearing using a technique that involves playing sounds into the ears (either clicks or tones) and recording the sounds that come back. We will also perform a standard hearing test (audiometry) on you at each of the laboratory visits.

These tests are **non-invasive** and **painless**.

Prior to taking part in the study we will ask you to complete a short screening questionnaire with one of the doctors or nurses in the Centre for Workplace Health. They will also have a look inside your ears to see if you have any problems with your ear canal or ear drum.

Participation in this study is completely voluntary and you are free to withdraw from the study at any time.

All time spent on the study will be charged to the project at the volunteer rate.

If you feel you may be able to help or require further information please contact:

Dr Kerry Poole Tel: 8420 E-mail: kerry.poole@hsl.gov.uk

APPENDIX 1B – BACKGROUND QUESTIONNAIRE

A study to establish the reproducibility and test conditions required for optimum measurement of otoacoustic emissions (OAE).

BACKGROUND QUESTIONNAIRE (to be completed at time of recruitment)

Surname _____ Age _____

Forenames _____

Date of interview _____

1. Do you have any difficulty with your hearing? Yes / No

   If yes, please give details _____

2. Do you have a family history of deafness? Yes / No

   If yes, please give details _____

3. Have you ever had whistling or ringing in your ear(s)? Yes / No

4. Have you ever worked in any jobs where you have had to shout to make yourself heard because of the background noise level? Yes / No
   If yes, please give details _____

5. Have you ever regularly fired a firearm such as a rifle, pistol or shotgun? Yes / No
   If yes, please give details _____

6. Do you have any of the following hobbies?
   DIY/home improvements Yes / No
   Motor sport (competing or watching) Yes / No
   Playing in a brass band/orchestra/pop group Yes / No
   Going to night clubs / pop concerts Yes / No
   Gardening (using motorised equipment) Yes / No
   Shooting Yes / No

APPENDIX 1C – PRE-TEST QUESTIONNAIRE

A study to establish the reproducibility and test conditions required for optimum measurement of otoacoustic emissions (OAE).

PRE-TEST QUESTIONNAIRE

Surname _____ Forename _____

Subject ID number: _____

1. Have you been anywhere in the last 16 hours where you had to shout to make yourself heard? Yes / No

   If yes, for how long? _____

2. Have you been exposed to any loud noise within the last 16 hours (e.g. riding a motorbike, using gardening or power tools, listening to music through earphones/headphones, shooting)? Yes / No

   If yes, please give details _____

3. Are you suffering from a cold or viral infection at the moment? Yes / No

4. Are you suffering from whistling or ringing in your ears at the moment? Yes / No

OTOSCOPY

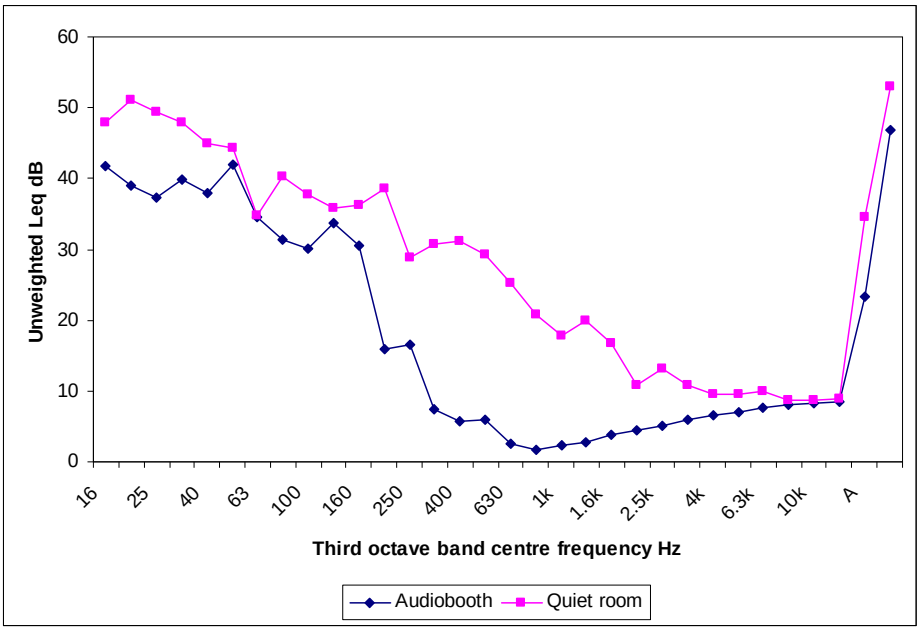
(Please answer Y/N to each of the following):	**RIGHT**	**LEFT**
Wax in auditory canal? (i.e <50% of tympanic membrane visible)		
Exudate in auditory canal?		
Tympanic membrane- scarred/perforated		

Signed: _____

Dated: _____

APPENDIX 2 - BACKGROUND NOISE MEASUREMENTS IN THE TWO ENVIRONMENTS

The figure below presents the data for the measured background noise levels in both the audio booth and quiet room.



APPENDIX 3 – FULL DISCUSSION OF RESULTS IN RELATION TO PUBLISHED LITERATURE

For a test to be useful in monitoring changes in health status over time, such as would be required within occupational health surveillance, the reliability and measurability of the test must be established. In the case of otoacoustic emission testing the reliability and measurability may be dependent upon a range of factors including the type of individuals studied, the type of test applied, the parameters used and the testing environment. In addition, to be able to detect changes between repeated otoacoustic emission tests over time the smallest change that could be detected over and above the repeatability of the test, the smallest detectable difference, needs to be established in a population that has not been recently exposed to noise or suffering noise induced hearing loss.

The current study was designed to assess the reliability and measurability of otoacoustic emission testing (TEOAE and DPOAE) using commercially available equipment, such as could be used within an occupational health surveillance programme. As part of this the smallest detectable difference for both TEOAE and DPOAE was established at a range of test frequencies. In addition, the effect of the testing environment (quiet room or audio booth) on the reliability of both tests was investigated. Clearly, if an audio booth is not required to obtain optimum reliability from OAE testing, this would be an advantage for its application and ease of use within a health surveillance environment. To our knowledge no work has been published comparing OAE testing done in these two environments.

A small number of studies have been published investigating the reliability of OAE testing [10-15] and an even smaller number have measured both TEOAE and DPOAE on the same individuals [10-12], thus allowing comparison of the reliability of these methods. These studies vary in terms of the subjects used, with some studies only involving those with normal hearing [11, 14, 15], and others involving a range of hearing abilities [10, 12, 13]. They also vary in terms of the parameters used within the software to run the test and analyse the data, and the period over which the repeated testing is done. Some of these studies have performed their testing in a soundproofed room [10, 12-14] and others have used the equivalent of a quiet room [15]. Furthermore, the way in which a measurable OAE result is defined varies between studies. The difference between the measured emission level and the background noise level is referred to as the signal to noise ratio or SNR. Not all studies have reported if they have selected data for analysis, but in those that have some report only using tests where the SNR is above the value of 6 dB SPL [14, 15], and others where the emission amplitude is above the noise level (i.e. SNR > 0) [11]. All of these factors are likely to contribute to the reliability and measurability of OAE testing and thus this makes direct comparison between studies reporting reliability difficult.

In the present study, in order to optimise the data collected from the study we chose to include all data that had an SNR greater than 0 (i.e. that an OAE was measurable over the background noise level), rather than exclude data that had a measurable response but did not meet the criteria of an SNR of 6 dB SPL. Nevertheless, this still meant that a number of tests were lost from the analysis, with the proportion of tests being acceptable ranging between 99% and 68% depending upon the test used and the frequency. There was no clear difference in the proportion of tests reaching the acceptability criteria in the two testing environments, however DPOAE tended to have a slightly higher proportion of acceptable tests compared to TEOAE, and the proportion of acceptable tests tended to reduce with increasing frequency, similar results have been reported in recent publication by Helleman [18]. For example, when TEOAE was measured at 4000 Hz in the quiet room 74% of the tests were acceptable as compared to 82% for DPOAE.

If different selection criteria had been used, such as having to achieve an SNR of 6 dB, then it is likely that more data would have been unacceptable. It should also be borne in mind that individuals who experience hearing loss will have lower emission values thereby making it more likely that these tests may not meet the acceptability criteria. These selection criteria are important to consider if these tests are likely to be used in occupational health surveillance for noise exposure, as a test for such monitoring is unlikely to be useful if it is not possible to obtain acceptable measurements in a large proportion of individuals, particularly over the frequency range most susceptible to noise damage 3-4000 Hz [12]. A recent study has shown that the number of acceptable tests that can be obtained falls with abnormality in hearing as detected using audiometry [18]. In addition, Keppler et al showed that the reliability of DPOAE tests with an SNR above or below 12 dB SPL was different, with those below 12 dB SPL having the poorest reliability, particularly at lower frequencies [11].

The current study has shown that the absolute emission thresholds for both TEOAE and DPOAE tests give good reliability over a median duration of 17 days. This was dependent upon the frequency measured, with the poorest reliability being seen at the lowest frequency of 1000 Hz. Overall, the reliability of the TEOAE was slightly better than that for DPOAE and this has also been seen in other studies [10, 12]. Studies published to date report that the reliability of both TEOAE and DPOAE are good [10, 11, 13-15], but the follow-up times used in these studies varies from immediate repeat testing or up to 9 months later [12]. In addition, the statistic used to measure reliability has also varied across studies, making it difficult to compare the reliability obtained in the present study to other published studies. However, one published study assessed reliability in a similar way to our study [11] by reporting intra-class correlation coefficients and minimal detectable differences for both TEOAE and DPOAE at a range of frequencies. In Keppler's study they reported intra-class correlation coefficients of 0.94 and above for measurement of TEOAE across the frequencies; this was slightly better than that found in the present study which ranged between 0.88 and 0.94. Consequently, the minimal detectable differences reported by Keppler for TEOAE were between 1.85 and 2.81 dB, compared to 3.4 to 5.6 dB in the present study. For DPOAE testing the intra-class correlation coefficients reported by Keppler were between 0.92 and 0.98, with minimal detectable differences between 1.97 and 4.43 dB. In the present study these were 0.72 to 0.87 and 5.8 to 9.6 dB respectively. Possible explanations for these differences between the two studies could be the length of the follow-up period, with Keppler having a follow-up period of 7 days as compared to a median of 17 days in our study, or differences in the test parameters used for data collection. For example, the two studies used different noise rejection levels for the TEOAE tests.

Background noise levels could potentially have a big influence on the acceptability of measurements of OAE, as high noise levels could mask any OAEs present. Indeed, a study by Rhoades et al has shown that changes in the background noise level can affect the reproducibility of click-evoked otoacoustic emissions [19]. This may be more critical in individuals who have low OAE emissions, such as may be expected in those with hearing damage. In the present study we did not find any convincing evidence that the use of an audio booth, which acts to reduce the background noise levels (particularly between 250 Hz and 2500 Hz), affected either the measurability or the reliability of the two different tests of OAE. Therefore, the results of the present study would suggest that using an audio booth does not give any additional benefit for OAE testing in those with normal hearing.

When reviewing the literature on OAE testing it was not always clear whether the emission level or the SNR had been used as the outcome measure. To this end, we not only investigated the use of absolute emission thresholds but also the SNR as outcome measures. Overall, the reliability of the SNR was lower than the corresponding absolute threshold for both the TEOAE and DPOAE methods. For example, for TEOAE at 3000 Hz the reliability of the absolute threshold in the quiet room was 0.92 compared to 0.87 for the SNR. It is likely that the SNR is

less reliable as it is influenced by changes in the background noise levels, which are likely to vary from testtotest and daytoday.

If these otoacoustic test techniques are to be used within occupational health surveillance in the future, it is important to establish whether the reliability of the technique is sufficient to allow the expected changes in the test that would occur with hearing loss to be detected. In a small number of publications it has been suggested that otoacoustic emission testing can detect sub-clinical changes prior to changes in the audiogram [5, 7-9]. In the present study we have been able to establish the smallest differences that could be detected at the various frequencies for both techniques. However, there is little information available in the literature that reports the level of differences in DPOAE or TEOAE that may occur with hearing loss, particularly measured overtime in the same individuals. In a longitudinal study conducted by Lapsley-Miller et al (2004) [6] an example of an individual who developed a permanent threshold shift in the study was presented. At a frequency of 2000 Hz the fall in TEOAE was approximately 8 dB SPL and the fall in DPOAE was 6 dB SPL. In the present study the smallest detectable differences for TEOAE and DPOAE at 2000 Hz in a quiet room were 5.2 and 7.7 dB respectively. Therefore, if these changes were typical of the changes to be expected with permanent thresholds shifts, this could be detected using TEOAE but would not be picked up by DPOAE. A difference in DPOAE level at 2000 Hz of around 4 dB SPL has been reported between a group with normal audiograms and those with mild hearing loss (threshold ≤20 dB at all frequencies with > 10 dB at least one frequency) and a difference of around 12 dB SPL between those with normal audiograms and those with high hearing loss (threshold > 20 dB at least at one frequency)[20]. A recently published study investigating changes in audiometry and OAE over a 17-month period in individuals working in a printing press office has reported statistically significant changes in both TEOAE and DPOAE over this timeframe [18]. The largest changes in TEOAE and DPOAE were a fall of 2 dB SPL at 4 kHz and 3.8 dB SPL at 5657 Hz respectively. Correlation between changes in OAE and audiometric measurements were generally weak. However, any changes in OAE measurements were seen across a wider frequency range compared to changes in the audiometric measurements. The authors proposed that OAE had a greater sensitivity to changes than audiometry. Further work is required to better understand the level of change in these tests that could be measured over time in noise-exposed individuals and how this relates to hearing loss.

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Optimum test conditions and variability of otoacoustic emission testing in individuals with normal hearing

This study investigates issues important for the potential usefulness and practical application of OAE testing within an occupational health surveillance programme. Before this technique can be used within health surveillance, it is important to understand how reliable the measurements are and the level of change that could be detected over time within individuals. As any test of hearing function is potentially susceptible to background noise levels, it was also important to establish whether a soundproof room or audio booth would be required if this were to be used within health surveillance. We also wished to compare the reliability of OAE to that of standard puretone audiometry.

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