SciMedCentral Annals of Otolaryngology and Rhinology

Research Article

The Feasibility of Including Distortion Product Otoacoustic Emissions (Dpoaes) in Annual Medical Surveillance to Identify Noise-Induced Hearing Loss

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Submitted: 09 January 2019

Accepted: 26 January 2019

Published: 28 January 2019

ISSN: 2379-948X

Keywords

- Noise-induced hearing loss; Distortion product otoacoustic emissions; Subtle cochlea changes; Sensitivity; Specificity; Pure tone audiometry; Test-retest reliability

Abstract

Objective: To determine the feasibility of Distortion Product Otoacoustic Emissions in the annual medical surveillance test battery for the identification of noise-induced hearing loss in a group of employees in a beverage manufacturing industry in KwaZulu-Natal, South Africa.

Design: A cross-sectional and repeated measures design with a purposive convenience sampling technique was utilized.

Study Sample: Sixty participants aged 18-45 years, who worked nine hours a day and were not exposed to noise for 16 hours prior to testing.

Results: A high sensitivity and negative predictive value was found. The specificity of Distortion Product Otoacoustic Emissions ranged between 55%-97%. Visual inspection of the DP-gram revealed a reduction in DPOAE amplitudes in the high frequencies, in the absence of a statistically significant difference ($p>0.05$). Corresponding changes on the pure tone audiogram were not observed, however, noise notch configurations were observed for the groups with a longer service history. Good test-retest reliability of DPOAEs was observed with indication that probe removal and reinsertion may have an effect on Distortion Product Otoacoustic Emissions amplitudes. An average of 1 minute 26 seconds was calculated to conduct Distortion Product Otoacoustic Emissions bilaterally.

Conclusion: These findings suggest that Distortion Product Otoacoustic Emissions is a feasible measure to be used to monitor early subtle cochlea changes in workers exposed to noise in the manufacturing industry as part of the annual medical surveillance test battery.

ABBREVIATIONS

DPOAE: Distortion Product Otoacoustic Emissions; dBA: A-weighted decibels; NIHL: Noise-Induced Hearing Loss; OHC: Outer Hair Cells; SANS: 10083 (2004): South African National Standards

INTRODUCTION

Long term exposure to occupational noise results in a noise-induced hearing loss (NIHL), which has a characteristic audiometric pattern of a notch in the 3-6 kHz range [1]. The prevalence of NIHL is substantially high with hearing loss ranked as the second most prevalent occupational injury, despite the recent attempts to raise awareness regarding occupational noise exposure and occupational health and safety [2]. Further statistics reveal that the global numbers of individuals with disabling hearing impairment have increased significantly since 1985. The World Health Assembly Resolution on Prevention of Hearing Impairment revealed that the number of persons with hearing impairment was originally estimated at 42 million in 1985 [3] and increased to 466 million people who currently present with disabling hearing loss worldwide [4].

The increase in the WHO estimates since 1985 is speculated to be due to a combination of improved diagnosis, earlier detection, longer survival rates of elderly people who have the highest prevalence of hearing impairment and an increased incidence due to causes such as NIHL and ototoxic drugs [3]. More specifically, high-frequency hearing loss caused by excessive noise is one of the most prevalent occupational injuries [5]. Along with the detrimental auditory effects of noise, there are several non-auditory effects such as elevated blood pressure, reduced performance, sleeping difficulties, annoyance and stress, tinnitus and temporary threshold shifts [6]. It is, therefore, evident that employees exposed to excessive noise are at risk of a myriad of occupational hazards and, therefore, intervention to protect these employees is essential.

The mechanism of NIHL involves the destruction of outer hair cells in the Organ of Corti within the cochlea of the inner ear [7] specifically in the 3-6 kHz range. The average person is born with approximately 16 000 hair cells in the cochlea, but up to 30-50% can be damaged or destroyed before any measurable level of hearing loss is detected on the pure tone audiogram [7]. While pure tone audiometry is considered to be the gold standard in identifying NIHL, this method is said to be subjective, time consuming and not sensitive enough to small changes in cochlea function [8-10].

The feasibility of pure tone air conduction audiometry alone in identifying and monitoring NIHL has therefore been questioned with several studies having demonstrated its inadequacy in the early identification of NIHL [1, 9, 11]. This is possibly due to NIHL progressing over time, and only after 10 to 15 years of exposure to intense noise, can

the full effects be seen on the pure tone audiogram [12]. Pure tone audiometry may, therefore, be inadequate to detect the early stages of NIHL and by the time a sufficient number of hair cells in the cochlea are destroyed to be noticeable, the damage has been done [7].

However, Distortion Product Otoacoustic Emissions (DPOAEs) have been found to display a greater sensitivity to detecting early cochlea changes as a result of noise exposure than pure tone audiometry (Kim, Paparello, Jung, Smurzynski & Sun, 1996; [9, 13]. Reduced DPOAE amplitudes for the frequencies 3, 4 and 6kHz have been found in subjects with normal pure tone audiograms and audiograms depicting NIHL [9]. DPOAEs are said to be useful to detect these noise-induced cochlea changes as they are representative of an active cochlea amplification process that is linked to the integrity of the actively motile outer hair cells (OHCs) [14, 15].

In 1999, Vinck et al. proposed that Otoacoustic Emission (OAE) testing be used as an alternative to pure tone audiometry in monitoring cochlea changes for workers exposed to occupational noise [16]. More than a decade later, there is more evidence to show that DPOAEs should be used in conjunction with pure tone audiometry to monitor cochlea changes as a result of noise exposure [8, 11, 17] as it is a sensitive measure of cochlea function, with the potential for pre-clinical detection of damage [15]. However, OAEs are still not accepted by the South African National Standard (SANS) as a feasible test for the early identification of noise-induced cochlea changes. Currently, the SANS recommends an annual medical surveillance test battery for workers where noise exposure is equal to or exceeds the noise rating limit of 85dBA [18]. This consists of a pure tone air conduction audiogram and an otoscopic examination to monitor noise-induced cochlea changes in various occupational settings.

Such an occupational setting is the beverage manufacturing industry, which has several noisy processes, including truck offloading and using forklifts, angle grinders, pneumatic wrenches, cut-off saws and grinders, can cutters and bench grinders. As a result of these noisy processes, hearing conservation programs which include an appropriate, adequate and feasible test battery for annual medical surveillance is required in this industry. This will enhance the protection of workers and possibly contribute to the prevention of NIHL.

There is a need for a further sensitive, specific and objective test of cochlea function to be included in the SANS annual medical surveillance test battery, with DPOAEs having been suggested as such a test [11, 17, 19]. In considering the feasibility of including DPOAEs, it is essential to consider several aspects. These include sensitivity, specificity, predictive efficiency to determine if the test is accurately able to identify those who do or do not present with noise-induced cochlea changes, and its ability to detect early subtle noise-induced cochlea changes. Furthermore, a high test-retest reliability of the test is essential in determining feasibility as the results have implications for monitoring noise-induced cochlea changes over time; and lastly, the duration of time taken to conduct the test by personnel under severe time constraints.

METHOD

The study had the following objectives:

1. To determine the test-retest reliability of DPOAEs in identifying early noise associated hearing loss for a group of employees in the beverage manufacturing industry.
2. To determine whether DPOAEs are able to detect subtle cochlear changes for the early identification of noise-induced hearing loss as compared to pure tone audiometry.
3. To determine the sensitivity and specificity of DPOAEs

Participants aged 18-45 years of age who worked in the beverage manufacturing industry for nine hours a day, for five days a week, where hearing protection devices were worn at all times and had no family history of hearing loss, endogenous or exogenous audiological conditions or history of recreational noise exposure were included. Each participant was assessed following a period of at least 16 hours during which they were not exposed to noise at, or above the noise rating limit of 85dBA. A stratified sample approach was utilized in order to realize objective two of the study [20]. The 60 selected participants were divided into four test groups, each consisting of 15 participants, according to the number of years that they had been exposed to occupational noise. The groups were divided as follows: Group A: 0-3 years, Group B: 3.1-6 years and Group C: 6.1-9 years and Group D: 9.1-13 years of working within the beverage manufacturing industry. The average years of noise exposure for Group A was 2 years, Group B was 4.8 years, Group C was 7.3 years and Group D was 11.4 years. The average age of Group A was 28.6 years, Group B was 29.3 years, Group C was 34.5 years and Group D was 39.6 years.

Test environment

All test procedures were conducted in a clinic setting at the beverage manufacturing company, with a 1x1 meter audiometric booth being used for pure tone audiometry and DPOAE testing. Sound level measurements using broad band filters and a time weighted average of 15 minutes were conducted once daily in the clinic before testing to exclude the influence of ambient noise on the audiometric test results. The average sound pressure levels over a period of nine days were calculated to be 35.1dB (A). In many industrial environments, acceptable ambient noise levels for industrial testing can be achieved with noise levels of 43dBA or less inside the audiometric test room [21]. Therefore, the average ambient noise levels within the clinic were acceptable for testing to occur.

Data collection instruments

A pre-test Case History Questionnaire was administered to selected employees, and otoscopy was conducted to identify pathological conditions of the pinna, ear canal, tympanic membrane, and surrounding areas [22, 23]. Tympanometry was conducted on all participants to provide an objective means for determining the mobility of the tympanic membrane and the ossicular chain [24]. Each participant underwent pure tone air conduction audiometry to obtain auditory thresholds at 500, 1000, 2000, 3000, 4000, 6000 and 8000Hz using the descending/plateau method [25] and diagnostic DPOAE testing. The 750-8000Hz Diagnostic Test at geometric mean frequencies of 750, 984, 1500, 2016, 3000, 3984, 6000 and 7969Hz, was conducted using the BioLogic AuDX SCOUT Otoacoustic Emission Meter. The study utilized a fixed *f*2:*f*1 ratio of 1.22 with the f1 equal to 65dB and the f2 equal to 55dB across the geometric mean frequencies [26]. DPOAE measurements of 2f1 – f2 amplitude were plotted as a function of the f2 frequency, which is the higher of the two primary frequency stimuli used in the DP measurement.

Furthermore, the DPOAE test duration was recorded using a stopwatch. The 65/55 Vanderbilt normative data was utilized to interpret the data and outer hair cell function was considered to be normal if the distortion product minus the noise floor was 6dB SPL or above [26]. All tests were completed in one ear before testing the other ear. An appropriately sized probe tip was selected and inserted into each participant's ear, ensuring a good probe fit.

The DPOAE test was conducted three times on each ear for all participants and was repeated immediately with the probe still in the ear. Thereafter, the test was repeated for the second time, after the probe had been removed and reinserted.

Analysis

A quantitative and inferential statistical analysis was used to meet the study objectives.

Objective one: A repeated measures Analysis of Variance (ANOVA) was used to analyse the data using Mauchly's Test of Sphericity.

Objective two: Pure tone air conduction audiometry and DPOAE results of Group A, B, C and D were compared at each frequency for 60 right ears and 60 left ears. The Kolmogorov-Smirnov test was used to determine the normal distribution of the data, allowing for the use of a parametric test of analysis, namely, ANOVA. All calculations were conducted using the Statistical Package for the Social Sciences (SPSS), Version 19 [27]. In addition, visual inspection of the results was conducted through the use of graphs.

Objective three: DPOAEs, were compared to a gold standard, i.e. pure tone audiometry, to determine true positive (TP), false positive (FP), true negative (TN) and false negative (FN) results. Thereafter, sensitivity, specificity, positive and negative predictive values were determined for each frequency by applying the standard formulae to the data collected [28]. A statistical significance level of p<0.05 was used to analyse the data, and the time taken to complete the DPOAE test bilaterally for each participant was recorded. These times were then averaged to provide an estimate of the duration of time it takes to complete DPOAEs as part of the annual medical surveillance test battery.

RESULTS AND DISCUSSION

Objective one

All test groups presented with mean DPOAE amplitudes (DP-NF) for the three tests within the normal limit of >6dB SPL across the frequency range of 913Hz – 7303Hz bilaterally [26]. A comparison of Group C right ear mean DPOAE amplitudes of DP1, DP2 and DP3 resulted in a statistically significant difference at 3651Hz (p=0.021). This statistically significant difference obtained with a repeated measures ANOVA was further investigated using the post hoc Bonferroni adjustment that revealed a statistically significant difference (p<0.05) between DP2 and DP3 (p=0.041) at 3651Hz. A comparison of Group D left ear mean DPOAE amplitudes resulted in a statistically significant difference at 913Hz (p=0.014). The post hoc Bonferroni adjustment revealed a statistically significant difference (p<0.05) between DP2 and DP3 (p=0.048) at 913Hz. The mean DPOAE amplitudes of DP1, DP2 and DP3 did not result in a statistically significant difference for all other comparisons across the frequency range.

A good overall test-retest reliability of DPOAEs was observed for all test groups in the current study across the frequency range. It is therefore, reasonable to suggest that DPOAEs may be a feasible test to consider for inclusion in the annual medical surveillance test battery to monitor noise-induced cochlea changes over time for workers exposed to occupational noise in the beverage manufacturing industry. The results of the current study concur with the findings of previous studies that indicated an overall high test-retest reliability of DPOAEs [14, 29-34]. The results obtained in the current study indicate that probe removal and reinsertion may have had an effect on the DPOAE amplitudes of DP3. These findings concur with the findings of several other studies [14, 30- 34]. Beattie et al. found that standard errors were smaller for immediate test-retest measures than for the DPOAE measurements done 10-20 minutes later [31].

Objective Two

The results for objective two revealed that the mean pure tone air conduction audiometry thresholds were within the normal limit of -10 – 25 dB HL [22] across the frequency range of 1000Hz –108000Hz bilaterally for all test groups. A comparison of pure tone air conduction audiometry thresholds of Group A, B, C and D did not result in a statistically significant difference across the frequency range bilaterally (p>0.05). This indicates that the pure tone audiometry results of participants exposed to noise for 0-3years did not differ from the pure tone audiometry results of those exposed to noise for 9-13years, suggesting that pure tone air conduction audiometry alone may be inadequate for the early identification of NIHL. These results were expected, as NIHL is progressive over time and only after 10-15 years of noise exposure can the full effects be seen on the pure tone audiogram [12]. Visual inspection of the mean pure tone air conduction audiometry thresholds (Figures 1,2) revealed a noise notch configuration for participants with a longer history of noise exposure, however, this was not consistent between the right and left ears, which is atypical, as NIHL is usually bilateral in nature [35]. Furthermore, there appears to be no notable difference in the high frequency pure tone air conduction audiometry thresholds of Group A bilaterally. There also appears to be no indication of decreased pure tone thresholds or a noise notch configuration for Group A bilaterally. This further suggests that pure tone audiometry may be unable to detect any subtle cochlea changes bilaterally in a group of workers exposed to occupational noise for 0-3 years within the beverage manufacturing industry.

A comparison of the left ear mean DPOAE amplitudes of Group A, B, C and D resulted in a statistically significant difference of p<0.05 at 3651Hz (p = 0.021), between the DPOAE amplitude

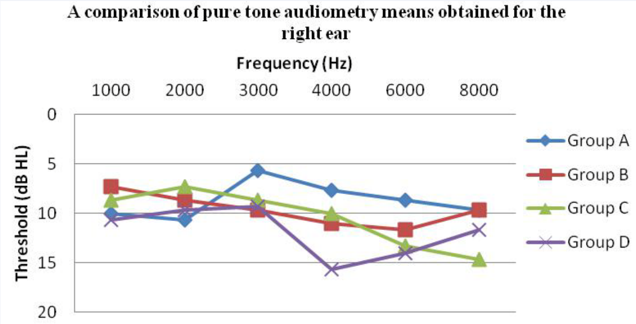

Figure 1 Right Ear: A comparison of the mean pure tone air conduction audiometry thresholds of Group A, B, C and D.

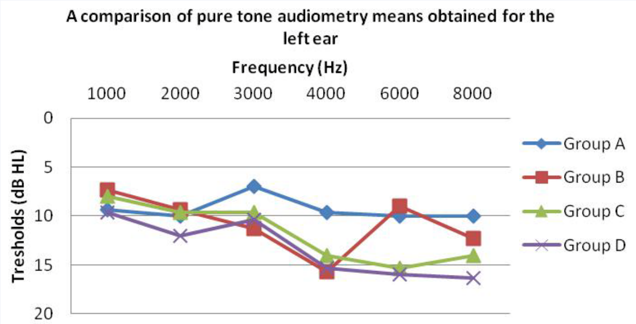

Figure 2 Left Ear: A comparison of the mean pure tone air conduction audiometry thresholds of Group A, B, C and D.

means of Group A and Group D (p = 0.028). This indicates that the mean DPOAE amplitude results of Group D, who had been exposed to noise for 9-13 years, was significantly reduced compared to the DPOAE amplitudes of Group A, who had been exposed to noise for 0-3 years. These results are expected, as many employees incur their hearing losses during the first 5 to 10 years [36]. A statistically significant difference was not observed on pure tone audiometry, but was found when the DPOAE results were compared. DPOAEs may therefore be able to detect subtle noise-induced cochlea changes at 3651Hz for employees in the beverage manufacturing industry before it is evident on the pure tone audiogram. Several studies [8, 9, 11, 17, 19, 37, 38] reported that DPOAEs are able to detect subtle cochlea changes in the absence of corresponding hearing threshold changes seen on the pure tone audiogram.

Upon closer inspection of Figures 3,4, it is evident that there is a reduction in the DPOAE amplitudes in the high frequency region of the DP-Gram, namely, 5477Hz and 7303Hz, in the absence of a typical noise notch. This was evident for all test groups, indicating that the decrease in amplitude may be due to subtle cochlea changes, even for Group A, who were exposed to occupational noise for as little as 0-3 years. This is possibly due to the effects of impulse noise in the beverage manufacturing company which may affect a greater frequency range, between 1-8kHz, in the absence of a noise notch [11, 38, 39].

DPOAE amplitude means of Group D were notably reduced at 3651Hz, 5477Hz and 7303Hz bilaterally compared to Group A, B and C. A reduction in the mean DPOAE amplitudes is apparent as the number of years of occupational noise exposure increases (Figures 3, 4).

It is likely that participants of the current study did not show significant differences in hearing thresholds and DPOAE amplitudes across a wider frequency range due to the stringent hearing protection program present at the beverage manufacturing company. However, visual inspection and closer examination of the mean values still identified reduced DPOAE amplitudes at 5477Hz and 7303Hz bilaterally, without corresponding changes on the pure tone audiogram for workers exposed to occupational noise for 0-23years. This indicates that even when a stringent hearing conservation program is in place, DPOAEs may still be able to detect early subtle noise-induced cochlea changes. In addition, these results suggest that DPOAEs may also be used as a monitoring tool for the evaluation of the effectiveness of hearing conservation programs.

Objective Three

The sensitivity of DPOAEs in the current study was 100% at 913, 1826, 3651, 5477 and 7303Hz in the right ear and at 3651 and 5477Hz in the left ear when compared to the gold standard, pure tone audiometry. A high sensitivity, as seen in the current study, suggests that DPOAEs may be able to identify the target population. Similarly, Kim et al. reported a good sensitivity of 89% at 6000Hz and 86% at 4000Hz when the sensitivity of DPOAEs to detect sensorineural hearing loss was evaluated [13]. Job et al. found the overall sensitivity of DPOAEs to be 72% [43]. Therefore, in view of the high sensitivity found in the current study, DPOAEs may be highly sensitive and suitable for

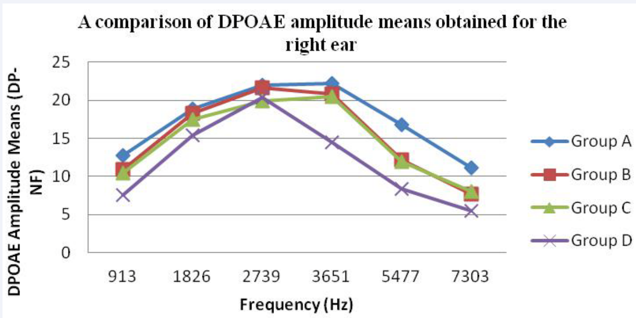

Figure 3 Right Ear: A comparison of DPOAE amplitude means for Group A, B, C and D.

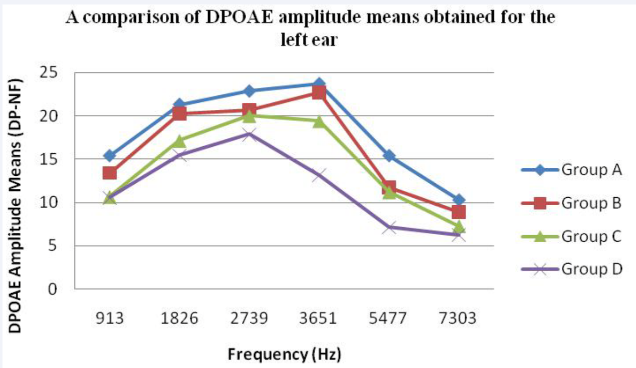

Figure 4 Left Ear: A comparison of DPOAE amplitude means for Group A, B, C and D.

use to identify subtle cochlea changes as a result of exposure to occupational noise.

The specificity of DPOAEs in the current study ranged between 55-97% across the frequency range in the right ear and 49-88% in the left ear when compared to the gold standard, pure tone audiometry. The highest specificity values in the present study were obtained at 1826, 2739, and 3651Hz, ranging from 81-97% bilaterally. Thus, it is plausible to suggest that DPOAEs may be able to efficiently identify those participants with no cochlea changes as a result of occupational noise exposure at these frequencies. Job et al. (2009) found the overall specificity of DPOAEs to be 64%, while, Kim et al. reported a good specificity of 88% at 6000Hz and 85% at 4000Hz. Similar findings were obtained in the current study at 3651Hz with a specificity of 81% bilaterally [13]. Clark found that DPOAEs appear to be more specific in detecting cochlea changes at the frequencies where damage is expected to occur as a result of occupational noise exposure [10].

The final parameter in demonstrating the acceptable performance of DPOAEs is the predictive value. In the present study, a negative predictive value of 100% was obtained bilaterally across the frequency range, except at 7303Hz in the left ear. This high negative predictive value suggests that DPOAEs may be interpreted with confidence when a negative test result is obtained. The negative predictive value obtained in the current study is expected as the more sensitive a test is, the better will be its negative predictive value due to the greater confidence in the test result ruling out the disease [40]. However, a low positive predictive value was obtained in the current study, ranging from 0-15% bilaterally. The low positive predictive value in the current study suggests that DPOAEs may have to be interpreted with caution when a positive test result is obtained.

Finally, several authors have stated that DPOAEs are a rapid and simple test to perform [9, 10, 14, 38, 41]. However, no studies could be found indicating the actual time taken to conduct DPOAE testing bilaterally in an occupational setting. The current study, therefore, recorded the time taken to conduct DPOAE testing to further determine the feasibility of including DPOAEs in the annual medical surveillance test battery. An average of 86 seconds (1 minute, 26 seconds) was calculated to conduct the DPOAE test bilaterally, including the time taken to remove and reinsert the probe.

CONCLUSION

It has been established that chronic exposure to occupational noise at moderately high levels, commonly encountered in the manufacturing setting, brings about damage to the cochlea sensory elements, with the outer hair cells being the most susceptible to this kind of damage [42,43]. Workers in the beverage manufacturing industry are exposed to both continuous and impulse noise due to the use of heavy machinery. Sound level measurements at a beverage manufacturing company ranged between 85-100dBA within the demarcated noise zones. This indicates that hearing conservation programs are required for workers in this industry. The total number of people employed in the manufacturing industry in South Africa at the end of June 2008 was 1 344 170 million, of which 14% (191 609) were employed in the food and beverage manufacturing industry. This emphasizes the need for effective and appropriate hearing conservation measures to ensure that these workers are adequately protected from developing a NIHL.

The South African National Standard (SANS): 10083 relies largely on the use of pure tone air conduction audiometry for the identification and monitoring of NIHL. Pure tone audiometry is considered to be the gold standard in the identification of noise-induced hearing loss, however, this method is subjective, time consuming and not quite sensitive to small changes in cochlea function [8, 9, 10]. Many employees incur their hearing losses during the first 5 to 10 years [36]. However, there is evidence to show that only after 10 to 15 years of exposure to intense noise, can the full effects be seen on the pure tone audiogram [12]. This means that whenever a referral threshold shift is recorded in a hearing conservation program, there is already significant damage to the inner ear [8].

Franklin et al. stated that DPOAEs are not intended to be a test of auditory function in isolation [29], evoked OAEs represent the only objective measures of the dynamic basis of cochlea functioning and should, therefore, be used in combination with other standard tests of audiometric function to determine more precisely the specific anatomic site of dysfunction in the peripheral auditory pathways of individuals with hearing impairment. Two decades later, several more studies have reiterated the thoughts of Franklin et al. and yet DPOAEs are still not accepted as a feasible test for the early identification of noise-induced cochlea changes. Further research is needed in the manufacturing industry to enhance the findings of the current study. Replication of the current study in other manufacturing industries, utilizing a larger sample size may further augment the findings of the study. However, given the limitations of the current study, the findings suggests the need for the South African National Standard to consider the inclusion of DPOAEs in the annual medical surveillance test battery as a feasible test for monitoring and ultimately, preventing noise-induced cochlea changes for workers in the beverage manufacturing industry.

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Cite this article

Reddy TM, Panday S, Govender C (2019) The Feasibility of Including Distortion Product Otoacoustic Emissions (Dpoaes) in Annual Medical Surveillance to Identify Noise-Induced Hearing Loss. Ann Otolaryngol Rhinol 6(1): 1227.