The feasibility of including Distortion Product Otoacoustic Emissions
(DPOAEs) in the annual medical surveillance test battery for the
identification of noise-induced hearing loss in a group of workers in a
beverage manufacturing industry

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DECLARATION

I, Tarryn Marisca Reddy, declare that this dissertation represents my own work in conception

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Day of	2013		

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LIST OF ABBREVIATIONS

dB decibels

dBA A-weighted decibels

dB HL decibels hearing level

dB SPL decibels sound pressure level

NIHL noise-induced hearing loss

OHC outer hair cells

PTS permanent threshold shift

SANS South African national standards

TTS temporary threshold shift

WHO World health organization

DEFINITION OF TERMS

Noise Zone:

An area within which the noise equals or exceeds the noise rating limit for hearing conservation (SANS, 2004).

Feasibility:

In the current study, feasibility referred to the sensitivity, specificity and predictive efficiency of DPOAEs, the ability of DPOAEs to detect subtle noise-induced cochlea changes, the test-retest reliability of DPOAEs and lastly, the duration of time taken to conduct the DPOAE test bilaterally.

Noise-Induced Hearing Loss:

A sensorineural hearing loss which is usually bilateral with a characteristic frequency response known as the 4000Hz dip, following exposure to continuous noise, in which the earliest damage occurs between 3000 and 6000Hz (Sataloff, Hawkshaw & Sataloff, 2011).

Noise-Rating Limit:

The value of the 8-hour rating level, 85dB(A) at and above which hearing impairment is likely to result (SANS, 2004).

Distortion Product Otoacoustic Emission: A two-tone complex that results in the production of distortion products arising from specific regions of the cochlea and disappear with hearing loss of 55dBHL or more (Prieve & Fitzgerald, 2002).

Sensitivity: The ability of the screening procedure to identify

the target population accurately, in terms of the number of individuals screened who actually have

hearing loss (Johnson, 2002).

Specificity: The ability of the screening procedure to not

identify those who truly do not have the disorder that the screening program is designed to identify

(Johnson, 2002).

Predictive Value: The number of false-negative and false-positive

results achieved on a test (Roeser, 1996)

South African National Standard: A document that covers the measurement and rating

of a working environment for hearing conservation

purposes, the physical demarcation of an area where

hearing conservation measures have to be applied

and medical surveillance (SANS, 2004)

ABSTRACT

The study investigated the feasibility of including DPOAEs in the annual medical surveillance test battery for the identification of NIHL in a group of employees in a manufacturing industry in KwaZulu-Natal. Feasibility was investigated by exploring the sensitivity, specificity and predictive efficiency of DPOAEs, the ability of DPOAEs to detect subtle noise-induced cochlea changes, the test-retest reliability of DPOAEs and lastly, the duration of time taken to conduct the DPOAE test bilaterally. A cross-sectional and repeated measures within-in participant design was utilized in the study. A purposive convenience sampling technique was used, as well as a stratified sampling approach in order to realize objective two of the study. The study consisted of 60 participants, which were further stratified into four test groups, i.e. 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. A high sensitivity and negative predictive value was reported in the current study, suggesting that DPOAEs may be able to identify those who present with subtle cochlea changes as a result of exposure to occupational noise. The sensitivity of DPOAEs was 100% at 1, 2, 4, 6 and 8kHz in the right ear and at 4 and 6kHz in the left ear. 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. A negative predictive value of 100% was obtained bilaterally across the frequency range, except at 8kHz in the left ear. Visual inspection of the DPgram in the current study revealed a bilateral reduction in DPOAE amplitudes for all test groups in the high frequency region of the DP-Gram, namely, 5477Hz and 7303Hz, in the absence of a statistically significant difference (p>0.05). A greater frequency range appears to be affected in this group of workers, indicating that the type of noise, namely, impulse noise, may result in cochlea changes. Corresponding changes on the pure tone audiogram were not observed, however, noise notch configurations were observed for the groups with a longer history of noise exposure. This was not seen bilaterally as is typically expected with NIHL. Good test-retest reliability across the frequency range obtained in the current study further indicates the feasibility of including DPOAEs in the annual medical surveillance test battery. Additionally, the current study calculated an average of 86 seconds (1 minute 26 seconds) to conduct the DPOAE test bilaterally, confirming that DPOAEs are a quick test to administer. The findings of this study suggest that DPOAEs may be used to monitor early subtle noise-induced cochlea changes for workers exposed to noise in the beverage manufacturing industry as part of the annual medical surveillance test battery.

Key words: Noise-induced hearing loss, distortion product otoacoustic emissions, subtle cochlea changes, sensitivity, specificity, pure tone audiometry, test-retest reliability

CHAPTER ONE: OVERVIEW AND RATIONALE

1.1 INTRODUCTION

The focus of this study was to determine the feasibility of including Distortion Product Otoacoustic Emissions (DPOAEs) in the annual medical surveillance test battery for the identification of noise-induced hearing loss in a group of workers in a beverage manufacturing industry. This chapter provides the rationale for the study and provides a summary of each of the chapters. The chapter also provides an overview of occupational health, noise-induced hearing loss and the non-auditory effects of occupational noise on employees. The beverage manufacturing industry and the South African standards and guidelines regarding the annual medical surveillance test battery approach to the prevention and minimization of noise-induced hearing loss is also discussed.

1.2 RATIONALE FOR THE STUDY

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 3-6kHz range (Schmuziger, Patscheke & Probst, 2007). 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 (World Health Organization [WHO], 2009). 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 (Nelson, Nelson, Concha-Barrientos & Fingerhut, 2005).

Occupational health refers to the identification and control of these risks arising from physical, chemical and other workplace hazards in order to establish and maintain a safe and healthy working environment (National Institute of Environmental Health Sciences, 2009). Employees represent half the world's population and are the major contributors to economic and social development (World Health Organization [WHO], 2007). Therefore, the occupational health of

employees is determined not only by workplace hazards but also by social and individual factors as well as access to health services (WHO, 2007). These social and individual factors may include social status, geographic location and financial position which directly impacts on an employee's standard of living as well as access to treatment and services (Mega Essays, 2010).

Taking these factors into consideration, the Occupational Safety and Health Administration defines an occupational injury or illness to be work-related if an event or exposure in the work environment either caused or contributed to the resulting condition or significantly aggravated a pre-existing condition (United States Department of Labour, 2009). Occupational illnesses may include skin diseases or disorders, respiratory conditions, poisoning, hearing loss and musculoskeletal disorders (United States Department of Labour, 2009). Furthermore, occupational injuries may result in employees presenting with cuts, broken bones, sprains and strains, amputations, repetitive motion disorders, vision disorders to the extent of blindness, illnesses caused by breathing or ingesting unsafe substances or illnesses caused by exposure to radiation (Medline Plus, 2009). In addition, WHO (2009) states that the results of studies in industrialized countries revealed that psychosocial hazards and work-related stress affect one fifth of the working population. It is, therefore, evident that employees in any occupational setting may be exposed to a myriad of occupational hazards and, therefore, intervention to protect these employees is essential.

However, despite the availability of effective interventions to prevent occupational hazards and to protect and promote health in the workplace, large gaps exist in terms of the health status of employees and their exposure to occupational risks (WHO, 2007). Each year 160 million new cases of work-related illnesses occur, of which 1.7 million lives are lost (WHO, 2009). WHO (2009) provide statistics of occupational risks which are responsible worldwide for 37% of back pain, 16% of hearing loss, 13% of chronic obstructive pulmonary diseases, 11% of asthma, 8% of injuries, 9% of lung cancer, and 2% of leukemia.

According to these statistics, hearing loss is ranked as the second most prevalent occupational injury. Further statistics reveal that the global numbers of individuals with disabling hearing impairment have increased significantly since 1985. Smith (2004) states that 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, and increased to 120 million in 1995, and 250 million in 2001, comprising of 42% of the world's working population. 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 (Smith, 2004). More specifically, high-frequency hearing loss caused by excessive noise is one of the most prevalent occupational injuries (Rabinowitz et al., 2006).

It is evident that employees exposed to occupational noise are at risk of NIHL as well as other psychosocial factors. Consequently, occupational noise is regarded as a major hazard to public health in the industrialized world (Tambs, Hoffman, Borchgrevink, Holmen & Engdahl, 2006). Such an industrialized setting is the beverage manufacturing industry.

The beverage manufacturing industry consists of carbonated soft drinks, bottled and flavoured water, single serve dairy products and nutritional drinks (Market Solutions South Africa, 2012). This industry produces 500 brands over 200 countries and all brands are produced, packed and distributed by manufacturers that are deeply rooted in the countries in which they operate (Coca-Cola South Africa, 2012). In South Africa, there are four major beverage manufacturing bottlers (Coca-Cola South Africa, 2012). These include one of the largest manufacturers and distributors of beverages in the southern hemisphere and with five state of the art manufacturing plants, it accounts for 60% of beverage sales in South Africa by reaching approximately 50 000 customers on a weekly basis, making it part of the top five bottlers in the world (Coca-Cola South Africa, 2012). The second largest beverage manufacturing company in South Africa has 22 sales centres and 3600 employees, serving 80% of the country's land mass and establishing itself in the rural and emerging markets with annual sales exceeding 90 million unit cases (Coca-Cola South Africa, 2012). Beverage manufacturing bottlers in South Africa sell an average of 235 servings to each person in the country every year, with an estimated total of 10 billion units (Coca-Cola South Africa, 2012).

A large sample survey of the manufacturing industry was conducted in 2008 (Statistics South Africa, 2010). This survey is conducted every three years and measures the economic activity in

the South African manufacturing industry. The total income for the manufacturing industry in South Africa in 2008 was R1 526 502 million, with the largest contributors to the total income being Coke, petroleum, chemical products, rubber and plastic (R494 429 million 0r 30%). Hence, the beverage manufacturing industry is one of the leading manufacturing industries within South Africa. The profit margin for all manufacturing in 2008 was 8.0%. This was closely resembled by the food and beverage manufacturing industry with a profit margin of 7.7% and a turnover of R209 818 million in 2008. The profit margin for beverages alone was reported to be 11.8% with a turnover of R56 633 million. The value of beverage goods exported at the end of 2008 was reported to be R 3540 million, as compared to the R854 million beverage goods imported into South Africa.

It is thus evident that the South African beverage industry can be considered as a large contributor to overall manufacturing within the country. Furthermore, the total number of people employed in the manufacturing industry 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. Interestingly enough, of the 191 609 people employed in this industry 38% were reported to be female and the remaining 62% were male. There appears to be an increase in female infiltration into traditionally male dominated fields of work, such as construction and heavy manufacturing (Kurmis & Apps, 2007). It is evident that females play a large role in this industry and need to be included when investigating noise-induced hearing loss in employees in the beverage manufacturing industry.

It is apparent that the beverage manufacturing industry within South Africa contributes substantially to the South African economy and employment rate. As a result of the enormous scale of the beverage manufacturing industry, manufacturers have become better equipped to manufacture beverages at a high speed and at a low cost (Coca-Cola South Africa, 2012) and this results in the need for the use of heavy machinery. Thus, there are several noisy processes involved in the manufacturing of beverages. These include truck offloading and the use of forklifts, angle grinders, pneumatic wrenches, cut-off saws and grinders, can cutters and bench grinders. Other noise sources revealed in a noise survey report conducted at a beverage manufacturing company included general process noise from electrical and circulation pumps,

the compressor motors and pressure releases of equipment, frictional noise generated as bottles traverse the conveyors at high speeds, and general noise from filling and labelling machines. As a result of these noisy processes, hearing conservation programs are essential for workers in the beverage manufacturing industry.

The aim of a hearing conservation program is to conserve the hearing of workers, prevent NIHL, and subsequently, prevent workers from the non-auditory effects of noise on hearing. Traditionally, industrial hearing conservation programs sought to preserve the hearing of workers already exposed to noise (Clark, 2005). However, current emphasis is placed on the importance of the prevention of NIHL and the early detection of noise-induced cochlea changes. According to the South African National Standard (SANS): 10083 (2004) a hearing conservation program consists of a risk assessment, followed by attempts to reduce the noise levels, education and training of the workers, personal hearing protection and annual medical surveillance for workers where noise exposure is equal to or exceeds the noise rating limit of 85dB(A).

Reddy, Welch, Thorne & Ameratunga (2012) state that education and training needs to be effective to facilitate an increase in knowledge and raise worker's awareness regarding the importance of hearing protection devices (HPDs) and the proper use of HPDs. Furthermore, education and training needs to go beyond the basic fact that HPDs protect hearing, as it should stimulate thinking about the importance of hearing and the impact NIHL could have on other aspects of workers lives (Reddy et al., 2012). This suggests a role for an educational approach to increase the awareness of workers regarding the prevention of NIHL, the importance of hearing protection devices and compliance with the South African guidelines and standards. This suggests that these guidelines and standards alone cannot influence the behaviour and attitude of workers. Therefore, a combination of education and training and an appropriate, adequate and feasible test battery used for annual medical surveillance within a hearing conservation program is required.

In considering the feasibility of the tests used for annual medical surveillance for a group of workers exposed to noise within the beverage manufacturing industry, it is essential to consider several aspects. These include sensitivity, specificity and predictive efficiency to determine if a

test is accurately able to identify those who do or do not present with noise-induced cochlea changes and the ability of a test to detect early subtle noise-induced cochlea changes. Furthermore, a high test-retest reliability of a test is essential in determining feasibility as it has implications for monitoring noise-induced cochlea changes over time; and lastly, the duration of time taken to conduct a test by personnel under severe time constraints within the beverage manufacturing industry.

Currently, SANS: 10083 (2004) recommends an annual medical surveillance test battery, which consists of a pure tone air conduction audiogram and an otoscopic examination. The SANS: 10083 (2004) relies primarily on the use of pure tone audiometry in the monitoring of noise-induced cochlea changes. Furthermore, pure tone audiometry is considered to be the gold standard in the identification of NIHL. However, this method is subjective, time consuming and not quite sensitive to small changes in cochlea function (Korres et al., 2009; Attias, Horovitz, El-Hatib & Nageris, 2001; Clark & Bohl, 2005). Therefore, the feasibility of pure tone air conduction audiometry alone in the identification and monitoring of NIHL has been questioned. Additionally, several studies have demonstrated the inadequacy of pure tone audiometry in the early identification of NIHL (Attias et al., 2001; Schmuziger et al., 2007; Edwards, van Coller & Badenhorst, 2010). This is possibly due to the fact that NIHL progresses 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 (Rosen, Vrabec & Quin, 2001). This means that pure tone audiometry may 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 (Daniel, 2007).

This damage to the cochlea caused by the exposure to excessive noise has been shown to affect the ear's dynamic range and frequency selectivity, tone distortions, difficulty understanding speech in noisy environments, recruitment and intolerance to high level sounds (Duvdevany & Furst, 2007). If noise-induced cochlea changes are detected early enough, these effects may be controlled or even prevented, before hearing threshold changes are seen on the pure tone audiogram. It is evident that there is a need for a further sensitive, specific and objective test of cochlea function to be included in the annual medical surveillance test battery, i.e. Distortion

Product Otoacoustic Emissions (DPOAEs) (Swanepoel & Hall, 2010; Edwards et al., 2010; Sampaio, Boger, & Oliveira, 2012).

DPOAEs are most useful in the detection of noise-induced cochlea changes, due to their better performance in the high frequency range (Balatsouras et al., 2005; Bockstael et al., 2008). Reduced DPOAE amplitudes for the frequencies 3, 4 and 6kHz have been found in subjects with normal pure tone audiograms and audiograms depicting NIHL (Attias et al., 2001). It was also found that DPOAEs display a greater sensitivity in detecting early cochlea changes as a result of noise exposure, as compared to pure tone audiometry (Kim, Paparello, Jung, Smurzynski & Sun, 1996; Attias et al., 2001). This has implications for workers exposed to occupational noise in the beverage manufacturing industry as DPOAEs may be able to detect subtle cochlea changes possibly years before hearing threshold changes become evident on the pure tone audiogram.

Vinck, van Cauwenberge, Leroy, & Corthals (1999) proposed that OAE testing be used as an alternative to pure tone audiometry in monitoring cochlea changes for workers exposed to occupational noise. More than a decade later, there is more evidence to show that DPOAEs should be used in conjunction with pure tone audiometry in the monitoring of cochlea changes as a result of noise exposure (Korres et al., 2009; Edwards et al., 2010, Swanepoel & Hall, 2010) as it is a sensitive measure of cochlea function, with the potential for pre-clinical detection of damage (Engdahl & Tambs, 2002). However, DPOAEs are still not accepted by SANS: 10083 (2004) as a feasible test for the early identification of noise-induced cochlea changes.

Therefore, the current study aimed to investigate the feasibility of including DPOAEs in the annual medical surveillance test battery for the identification of NIHL in a group of employees in the beverage manufacturing industry in KwaZulu-Natal. Feasibility was investigated by determining the sensitivity, specificity and predictive efficiency of DPOAEs, the ability of DPOAEs to detect subtle noise-induced cochlea changes, the test-retest reliability of DPOAEs and lastly, the duration of time taken to conduct the DPOAE test bilaterally. The possible inclusion of DPOAEs in the annual medical surveillance test battery may be viewed as a supplement to, rather than a replacement of pure tone audiometry in the early detection of noise-induced cochlea changes (Edwards et al., 2010). Furthermore, the possible inclusion of this

model in the SANS: 10083 (2004) annual medical surveillance test battery would ensure that the reliable and accurate pure tone audiometric thresholds are utilized in the calculation of permanent hearing loss, but, the identification and prevention of NIHL would be enhanced by the use of DPOAEs in an effective annual medical surveillance test battery. The current study, therefore, investigated the possibility of the inclusion of DPOAEs in the annual medical surveillance test battery put forth by SANS 10083: (2004) by considering the feasibility of DPOAEs.

In order to achieve this, the following aims and objectives were generated.

1.3 AIM AND OBJECTIVES

The aim of the present study was to determine the feasibility of including 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 the beverage manufacturing industry in KwaZulu-Natal.

In order to realize the aim of the study, the following objectives were generated:

- 1.3.1 To determine the sensitivity and specificity of distortion product otoacoustic emissions in the identification of noise-induced hearing loss.
- 1.3.2 To determine whether distortion product otoacoustic emissions are able to detect subtle cochlear changes in the early identification of noise-induced hearing loss as compared to pure tone audiometry.
- 1.3.3 To determine the test-retest reliability of distortion product otoacoustic emissions in identifying early noise associated hearing loss for a group of employees in the beverage manufacturing industry.

1.4 SUMMARY OF CHAPTERS

The dissertation consists of six chapters. The following is a summary of each chapter.

1.4.1 Chapter One: Introduction and rationale for the study

The chapter provides the rationale for the study and provides a summary of each of the chapters. This chapter also provides an overview of occupational health, noise-induced hearing loss, the non-auditory effects of occupational noise on employees, the beverage manufacturing industry and the South African standards and guidelines regarding the annual medical surveillance test battery approach to the prevention and minimization of noise-induced hearing loss.

1.4.2 Chapter Two: Theoretical overview of noise, noise-induced hearing loss and regulations for noise control

This chapter provides a theoretical overview of noise, noise-induced hearing loss and regulations for noise control with regards to the annual medical surveillance test battery approach for the prevention and minimization of noise-induced hearing loss.

1.4.3 Chapter Three: Distortion Product Otoacoustic Emissions and a review of the literature

This chapter provides a description of DPOAEs. The measurement of DPOAEs, normative data and the advantages and disadvantages of the test are discussed. The feasibility of DPOAEs in the identification of noise-induced cochlea changes is further explored. In addition, an in-depth review of the literature related to the study is presented and discussed.

1.4.4 Chapter Four: Methodology

This chapter includes the aims and objectives of the study, the study design, a description of the sample and sampling method utilized, data collection instruments and the procedure used to collect the data. A description of how the data was analyzed, the factors considered relating to

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validity and reliability of the study, as well as the ethical and legal considerations is also discussed.

1.4.5 Chapter Five: Results and Discussion

This chapter provides the results and discussion of the study. The results and discussion are presented according to the objectives of the study. In order to determine possible explanations for the results of the study, the relevant literature associated with any significant findings is discussed in detail.

1.4.6 Chapter Six: Conclusion

The final chapter presents a conclusion of the significant findings of the study. Limitations of the study and implications for future research are also discussed.

1.5 CONCLUSION

It is evident that employees in any occupational setting may be exposed to numerous occupational hazards and, therefore, intervention to protect these employees is essential. Occupational noise is regarded as a major hazard to public health in the industrialized world (Tambs et al., 2006). Such an industrialized setting is the beverage manufacturing industry. The South African beverage manufacturing industry is a large contributor to overall manufacturing within the country as well as to the South African economy and employment rate. As a result of the heavy machinery and noisy processes in the beverage manufacturing industry, hearing conservation programs are essential for workers in this setting. The SANS: 10083 (2004) relies primarily on the use of pure tone audiometry in the monitoring of NIHL for workers exposed to occupational noise. However, several studies have demonstrated the inadequacy of pure tone audiometry in the early identification of NIHL, suggesting the need for another sensitive, specific and objective test of cochlea function, i.e. DPOAEs, to be included in the annual medical surveillance test battery. The current study, therefore, focused on the possibility of the

inclusion of DPOAEs in the annual medical surveillance test battery put forth by SANS 10083: (2004) by considering the feasibility of DPOAEs.

The following chapters include a theoretical overview of noise and noise-induced hearing loss, a detailed literature review, a description of the methodology utilized in the study, a display of the results obtained in the study and a discussion of relevant findings.

CHAPTER TWO: THEORETICAL OVERVIEW OF NOISE, NOISE-INDUCED HEARING LOSS AND REGULATIONS FOR NOISE CONTROL

2.1 INTRODUCTION

This chapter provides a theoretical overview of noise, noise-induced hearing loss and regulations for noise control with regards to the annual medical surveillance test battery approach for the prevention and minimization of noise-induced hearing loss.

2.2 NOISE-INDUCED HEARING LOSS

Noise-induced hearing loss is sensorineural in nature and is usually bilateral with a characteristic frequency response known as the 4000Hz dip (Sataloff, Hawkshaw & Sataloff, 2011) which gets wider as the damage increases (Duvdevany & Furst, 2007). This pattern is seen following exposure to continuous noise, in which the earliest damage occurs between 3000 and 6000Hz (Sataloff et al., 2011). While exposure to continuous loud noise exacerbates the risk of hearing loss, single exposures to impulse noise also results in auditory changes (Daniel, 2007). Exposure to excessive noise may cause damage at 2000Hz before affecting the higher frequencies. However, in general, frequencies less than 3000Hz are almost never damaged by occupational noise without greater damage to the higher frequencies (Sataloff et al., 2011). The mechanism of NIHL involves the destruction of outer hair cells in the Organ of Corti within the cochlea of the inner ear (Daniel, 2007). 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 (Daniel, 2007). The damage to the hair cells occurs over time and, therefore, NIHL may develop slowly over a period as long as 15 to 20 years (Atchariyasathian, Chayarpham, & Saekhow, 2008).

This insidious nature of NIHL is as a result of temporary and permanent changes in hearing over time (Feuerstein, 2002). These temporary and permanent changes are classified as either a noise-induced temporary threshold shift (NITTS) or noise-induced permanent threshold shifts (NIPTS) (Melnick, 1978, as cited in Feuerstein, 2002). A NITTS is a temporary change in hearing

sensitivity that occurs following an exposure to high sound levels (Gelfand, 2001). According to the SANS: 10083 (2004), this high sound level refers to exposure to noise at or above the noise rating limit of 85dB(A). NITTS is characterized by a reduction in hearing sensitivity, possible feelings of fullness and tinnitus (Feuerstein, 2002). Feuerstein (2002) states that these characteristics occur as metabolic changes result from the hair cells being unable to maintain proper cell function. This metabolic process includes swelling of the hair cells. As swelling occurs, the hair cells may rotate, changing the orientation of the steriocilia to the tectorial membrane. Recovery of hearing occurs as the swelling of the hair cells diminish and they return to their normal orientation (Feuerstein, 2002). Jordan & Roland (2000) states that NITTS tends to disappear following 24 hours of relative quiet. The SANS: 10083 (2004) controls for the influence of NITTS by ensuring that medical surveillance is immediately preceded by a period of at least 16 hours for audiological screening and 24 hours for diagnostic testing, during which the employee was not exposed to the noise rating limit of 85dB(A). It is, therefore, important that all audiometric testing conducted in industry is preceded by rest periods of 16 hours to ensure the accuracy of the results and to ensure the employees full recovery from NITTS.

Noise-induced permanent threshold shifts occur when there is less than a full recovery from the NITTS (Feuerstein, 2002). NIPTS is common, with small amounts of permanent damage taking place following each of many NITTS experiences, resulting in a permanent hearing loss. NIPTS is as a result of either a rupture of swollen hair cells (Feuerstein, 2002), fused steriocilia (Durrant, 1978, as cited in Feuerstein, 2002) or degeneration of the auditory nerve fibres (Feuerstein, 2002). Feuerstein (2002) states that if a small number of hair cells are damaged, there may be no perceptual change in hearing following early noise exposure. This means that the effects of these small changes appear to be cumulative in nature, resulting in the insidious nature of NIHL. Many employees incur their hearing losses during the first 5 to 10 years (Morata et al., 2005). Thus, it is essential to identify noise-induced cochlea changes before a perceptual change in hearing is experienced.

This perceptual change in hearing is characterized as the amount of damage sustained as a function of the intensity of the signal, the duration of the noise exposure and the nature of the noise (Feuerstein, 2002). In terms of the duration and intensity of the noise exposure, the

duration of an 8 hour noise rating limit at an intensity of 85dB(A) or greater is considered sufficient to result in NIHL (SANS: 10083, 2004). In terms of the nature of the noise, Feuerstein (2002) outlines four types of noise, i.e. steady state noise, fluctuating noise, intermittent noise and impulse noise. Steady state noise is continuous noise that does not vary by more than 5dB and does not contain impulse signals. Fluctuating noise is described as continuous noise that varies by more than 5dB over time either gradually or rapidly. Intermittent noise is hazardous noise exposure mixed with periods of non-hazardous levels. Impulse noise is of quick rise and duration time.

In addition to the damaging effects of these various types of noise on hearing, the time pattern by which steady-state and impulse noise can be distinguished may also result in noise-induced cochlea changes (Bockstael et al., 2008). This high level impact or impulse noise on the cochlea is different than the effects of continuous exposure to lower levels (Tambs et al., 2006). The critical level for impulse noise is likely to be related to the duration of the impact and the spectral components, which results in the most damaging effects at 3000Hz (Tambs et al., 2006). Swanepoel & Hall (2010) conducted a pretest-post-test study to investigate football match spectator's sound exposure and the effect of impulse noise on hearing during the Soccer World Cup in South Africa. During the event, spectators blew a horn-like instrument called a vuvuzela, which produces a characteristically loud, reverberant sound, averaging 131dB(A). The results of the study revealed that more than 50% of pure tone hearing thresholds demonstrated a postmatch deterioration, with a statistically significant deterioration at 2000Hz. Due to the nature of the beverage manufacturing industry, employees are exposed to impulse noise on a daily basis and therefore the findings of the Swanepoel & Hall (2010) study may have implications for the current study. Additionally, these employees in the current study are exposed to more than one type of noise through the use of power tools and heavy machinery. Bockstael et al. (2008) stated that employees exposed to varying properties of each type of noise must be treated and managed differently in terms of the prevention of NIHL.

Additional impairments as a result of varying types of occupational noise may include a decrease in the ear's dynamic range and frequency selectivity, tone distortions, difficulty understanding speech in noisy environments, recruitment and intolerance to high level sounds (Duvdevany &

Furst, 2007). Hearing loss as a result of excessive noise exposure results in irreversible damage to the hearing mechanism in the inner ear, specifically involving the frequency range of human voices and this interferes with spoken communication (Nelson et al., 2005). Spoken communication involves the reception and transmission of information (Bench, 1992) and therefore relies on the normal functioning of the hearing mechanism. It is thus evident that NIHL may prove disabling to the employee within the workplace and during activities of daily living.

2.3 NON-AUDITORY EFFECTS OF NOISE

Excessive noise is a pervasive occupational hazard with several adverse effects. Adult-onset hearing loss has been described as the fifteenth most serious health problem in the world with profound effects ranging from social isolation and stigmatization of individuals to serious national economic burdens (Smith, 2004). There is increasing evidence that noise pollution is not merely an annoyance, but similarly to other types of pollution, it has wide-ranging adverse health, social and economic effects (Goines & Hagler, 2007). In addition to hearing loss, other effects may be seen, such as elevated blood pressure, reduced performance, sleeping difficulties, annoyance and stress, tinnitus, and temporary threshold shifts (Nelson et al., 2005) as well as dysfunctions to the immune system, heart, blood circulation, respiration and abnormal foetal development (Kujala et al., 2004). Research has also shown that noise exposed individuals are more susceptible to fatigue, irritability, dysfunctions in short-term verbal memory and they are more prone to make errors and encounter accidents (Kujala et al., 2004).

Goines & Hagler (2007) state that noise has also been linked to the acceleration of the development of latent mental disorders as it may contribute to anxiety, stress, nervousness, nausea, headaches, emotional instability, argumentativeness, changes in mood, increase in social conflicts, and psychosis. Noise levels above 80dB are associated with an increase in aggressive behaviour and a decrease in behaviour to help others (Goines & Hagler, 2007). There is a limited amount of available research regarding the long-term effects of noise on neural activity and functioning (Kujala et al., 2004). Kujala et al. (2004) evaluated the effects of long-term noise on task performance and to sound stimuli during this task performance. The researchers concluded

that individuals exposed to long-term noise presented with impaired brain dynamics which affected their ability to conduct tasks normally.

Morata et al. (2005) conducted interviews with focus groups from the manufacturing, mining and construction industries to investigate the impact of working in noise on job performance, ability to monitor equipment, interference with communication, stress and fatigue, communication difficulties caused by hearing protector use and ability to monitor the environment as a result of hearing protector use. In addition to hearing loss, more than half of the 31 participants reported tinnitus, at least periodically and often at the end of the work day. All the participants in the study believed that working in noise had little impact on their job performance due to the repetitive nature of their tasks. However, many of the participants felt that working in noise posed a safety risk and that stress, fatigue and communication difficulties were exacerbated by noise

It is evident that employees exposed to occupational noise are at risk for NIHL as well as other psychosocial factors. Consequently, occupational noise is regarded as a major hazard to public health in the industrialized world (Tambs et al., 2006). This highlights the need for effective hearing conservation programs and an annual medical surveillance test battery that is able to detect early noise-induced cochlea changes for the prevention and minimization of NIHL. In order for this to occur, appropriate guidelines and standards in South Africa and internationally need to be implemented to aid in the prevention or alleviation of NIHL.

2.4 GUIDELINES AND STANDARDS FOR THE PREVENTION OF NOISE-INDUCED HEARING LOSS

The South African National Standard (SANS): 10083 (2004) refers to the 'critical level' as the noise rating limit for hearing conservation, that is, 85dB(A), at and above which hearing impairment is likely to occur, for those who are exposed to noise for a minimum of 8 hours in industrial or occupational settings. South Africa is on par with the legislature of most first world countries with regards to the noise rating limit of 85dB(A) over an 8 hour rating level. However, a degree of variability does exist internationally with regard to noise exposure standards. Though

specific regulatory values have now been incorporated into most national and state workplace safety guidelines (Kurmis & Apps, 2007). As a result of this variability that exists with regards to noise exposure standards internationally, Kurmis & Apps (2007) provided a synopsis of the present understanding of occupational NIHL and explored the international workplace safety guidelines. The authors reported that in the United States, the formal Washington Industrial Safety and Health Act defines the maximum permissible exposure limit as being an eight-hour, full shift average exposure of 85dB. According to Kurmis & Apps (2007), this is a sentiment mostly reflected by the legislature of the majority of Northern America and most other first world countries. This is also observed in the Australian National Occupational Health and Safety Commission (2004), where the National Code of Practice for Noise Management and Protection of Hearing at Work (2004) states that the national standard for exposure to noise in the occupational environment is an 8-hour equivalent continuous A-weighted sound pressure level of 85dB(A). In 2006 the European Parliament and the Council of the European Union further reduced the maximum permissible exposure limit to 80dB(A) (Kurmis & Apps, 2007). Despite this, several of the other developing countries still widely accept a higher permissible exposure level of up to 90dB(A) (Kurmis & Apps, 2007).

With regards to legislation in South Africa, the South African National Standard (SANS): 10083 (2004) is the guideline that attempts to take all the significant factors into consideration in the prevention of NIHL. The SANS is defined as "a normative document, established by consensus within a technical committee or subcommittee, subjected to public enquiry and comment, ratified by the Standards Approval Committee and published by Standards South Africa, that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context" (Standards South Africa, 2003, pp. 5). The normative data for the measurement and assessment of occupational noise for hearing conservation purposes is put forward by SANS: 10083 (2004).

According to SANS: 10083 (2004) hearing conservation is defined as the prevention or minimization of noise-induced hearing impairment by the control of noise through engineering methods and by the implementation of hearing conservation procedures. This includes the assessment and prediction of noise exposure in all workplaces; the reduction of the 8 hour rating

level; the introduction of a prohibition of persons entering a noise zone without adequate hearing protection devices and medical surveillance. Within this context, annual medical surveillance consists of a baseline audiogram, periodic pure tone audiogram and an exit audiogram for every employee exposed to noise at or above the noise rating limit of 85dB(A) (South African Occupational Health and Safety Act, 2003).

The annual medical surveillance test battery put forth by SANS: 10083 (2004) is the focus of the present study. According to the SANS: 10083 (2004) employees who are exposed to noise at and above the noise rating limit for hearing conservation purposes and/or are required to enter noise zones, should undergo audiometric evaluation, in view of the fact that hearing protection devices do not provide adequate protection under all circumstances. A baseline audiogram is required from all new and existing employees before, or within 30 days of commencement of working in a noise zone. The baseline audiogram serves as a reference for all future decisions regarding the hearing status of an employee (SANS: 10083, 2004). Hence, the annual medical surveillance test battery can then be used to monitor the hearing status of employees, allowing for early identification and prevention of NIHL. Furthermore, the result of the baseline audiogram applies to the total working career of an employee and can be used to determine future compensable hearing loss. This is done following the completion of two diagnostic audiological evaluations by calculating the permanent disablement resulting from hearing loss caused by exposure to excessive noise (Compensation for Occupational Injuries and Diseases Act, 1993). The results of the baseline audiogram are compared to the results of the annual medical surveillance audiogram in order to determine if there is a referral threshold shift and indicate the need for further diagnostic testing (Compensation for Occupational Injuries and Diseases Act, 1993). Hence, the annual medical surveillance program serves to detect and identify possible referral threshold shifts and the subsequent diagnostic audiological evaluation is used to identify compensable hearing loss.

Thus, the annual medical surveillance test battery consists of a pure tone air conduction audiogram and an otoscopic examination, obtained on a periodic basis to determine if an employee presents with a referral threshold shift in their hearing level. Furthermore, the medical history of the employee should be obtained, with relevance to previous traumatic injuries,

medical treatment, ototoxic medication and other non-auditory events which could have an effect on the hearing status of an employee. In terms of the frequency of conducting medical surveillance, a period of 12 months is recommended when the 8 hour rating level does not exceed 105dB(A), whereas, a period of 6 months is recommended when the noise exposure is in excess of 105dB(A). In addition, in order to exclude the influence of NITTS during the testing procedure, the annual medical surveillance test battery is preceded by a period of at least 16 hours during which the employee is not exposed to a rating level equal to or in excess of the rating limit for hearing conservation. This has implications for the selection of participants in a study such as this, where testing of participants would form part of the annual medical surveillance program.

If the intensity of noise increases beyond this rating limit for hearing conservation, it may cause damage to the internal structures of the cochlea resulting in a permanent hearing loss, and may even damage structures of the peripheral mechanism such as the tympanic membrane and the ossicular chain within the middle ear (Melnick, 1978, as cited in Feuerstein, 2002). A variety of underlying physiological changes occur following temporary or permanent changes in hearing thresholds (Balatsouras et al., 2005). In terms of the annual medical surveillance protocol put forth by the SANS: 10083 (2004), an otoscopic examination should be conducted on the external ear canals of an employee. It should be ensured that there are no visible abnormalities such as otitis media, perforation of the tympanic membrane or other ear pathology that could result in a hearing loss. Furthermore, where required, successful treatment should be completed before testing is resumed. Otoscopy identifies congenital and pathological conditions of the pinna, ear canal, tympanic membrane, and surrounding areas (Gelfand, 2001).

The normal tympanic membrane should be semi-translucent, pearly-grey and slightly concave (Rappaport & Provencal, 2002). Furthermore, one should search for fluid behind the eardrum or the suggestion of negative pressure within the middle ear that is causing retraction of the membrane, suggesting eustachian tube dysfunction (Rappaport & Provencal, 2002). The majority of health care providers learn otoscopy by trial and error and they may not be properly trained to identify these pathological conditions of the tympanic membrane and middle ear (Rosenfeld & Bluestone, 2003). In view of otoscopy being a subjective measure of the tympanic membrane

and the middle ear, it may be important to conduct other objective measurements to confirm the presence or absence of middle ear disease (Rosenfeld & Bluestone, 2003).

Tympanometry is an objective measure of middle ear function that has been an integral part of the audiologic evaluation for nearly three decades (Fowler & Shanks, 2002). In addition to its objective nature, it is a quantitative method of assessing tympanic membrane mobility and middle ear function (Rosenfeld & Bluestone, 2003). Tympanometry is defined as the dynamic measure of acoustic immittance in the external ear canal as a function of changes in air pressure in the ear canal (ANSI, S3.39, 1987, as cited in Fowler & Shanks, 2002). This refers to measures of acoustic admittance that are taken at various pressure points to obtain values that are graphed to form a tympanogram, which is classified into several types, indicating normal and pathological.

Fowler & Shanks (2002) state that tympanometry is uniquely suited to identifying the physical changes associated with middle ear pathology, and therefore, it is typically used to screen for middle ear disorders and to determine the nature of a conductive lesion. The SANS: 10083 (2004) does not include tympanometry in the annual medical surveillance test battery. Therefore, it is possible that the influences of middle ear disorders are negatively impacting on the audiometric results of employees in various industries and settings. This has implications for the early identification of employees presenting with middle ear disorders and referrals to the appropriate medical practitioners for suitable treatment. In order to form part of the annual medical surveillance test battery in the identification of NIHL, tympanometry is required to be efficient and properly evaluated in order to demonstrate acceptable performance (Johnson, 2002). It is also required to be sensitive and specific, that is, it should identify the target population accurately and not identify those who truly do not have the disorder (Johnson, 2002). Furthermore, tympanometry is required to be quick and easy to administer and above all inexpensive (Weinstein, 2000). It is, therefore, evident that tympanometry meets the requirements of an effective and efficient screening tool, but is excluded from the annual medical surveillance test battery. The SANS: 10083 (2004) does, however, recommend the use of another, easily administered, inexpensive and generally reliable procedure, namely, pure tone audiometry (Johnson, 2002).

2.5 PURE TONE AUDIOMETRY

Pure tone audiometry is unequivocally the gold standard of every audiological evaluation (Roeser & Clark, 2007). An important aspect in the diagnosis of NIHL is a review of the pure tone audiogram pattern (Rabinowitz et al., 2006). Pure tone audiometry forms part of the basic audiological test battery, which includes obtaining audiometric thresholds across a specified frequency range (Gelfand, 1997). The audiometric threshold is defined as the lowest intensity at which the listener can identify the presence of the pure tone signal at least 50% of the time (Harrel, 2002).

Pure tone audiometric thresholds are used to make the initial diagnosis of normal or abnormal hearing sensitivity, thereby developing the breadth and depth of audiological diagnostic and rehabilitation procedures required for each patient (Roeser & Clark, 2007). In addition, pure tone audiometry is used to quantify the degree of hearing loss, and to gain information concerning the site of lesion and, in some cases, the nature of the cause (Harrel, 2002). Pure tone threshold shifts as a result of occupational noise exposure is highly specific to the frequency area within the cochlea (Tambs et al., 2006). This is due to most industrial noise being broadband with the major frequencies well below 3000Hz (Tambs et al., 2006). Hearing loss caused by noise exposure has a characteristic pure tone audiometric pattern with a notch in the 3-6 kHz range, which has been related to the primary resonant frequency of the external auditory canal (Rodriguez & Gerhardt, 1991, Sataloff et al., 2011).

A noise notch typically means thresholds at 3, 4, and/or 6 kHz that are substantially worse than hearing thresholds at lower frequencies (0.5 and 1 kHz) and at 8 kHz, where a recovery is said to take place (Rabinowitz et al., 2006). Various studies have shown thresholds shifts to be strongest at the frequency region around 4000Hz, with little or no damage at or below 2000Hz (Attias et al., 2001; Tambs et al., 2006; Korres et al., 2009). This indicates significantly more damage to the basal end of the cochlea in the inner ear. There is also more recent research to show that the effects of impulse noise on hearing thresholds may affect a greater frequency range, between 1-8kHz, in the absence of a noise notch (Tambs et al., 2006; Balatsouras et al., 2005; Edwards et al., 2010). These patterns are clearly displayed on a pure tone audiogram, where the

configuration of the hearing loss is symmetrical, and rarely asymmetrical (Attias et al., 2001). Noise exposed workers in the beverage manufacturing industry are exposed to both continuous and impulse noise and these findings may be of significance as a noise notch may be present or a greater frequency range may be affected on the pure tone audiogram.

Clark & Bohl (2005) conducted a longitudinal and a cross-sectional study to determine if fire-fighters are an occupational class at risk for acquiring a NIHL. The study included fire-fighters who worked two or three 24 hour shifts per week and were exposed to high levels of noise exceeding 90dB(A). The results of 12 609 annual pure tone audiometric test results which were conducted over an eleven year period were collected and evaluated. Fire-fighters with at least seven consecutive annual audiometric test results were selected for analysis. Furthermore, these participants were divided into age groups based on the age at the time of the final test (25 to 64 years old). For each individual included in the analysis, the hearing threshold value obtained at the first audiometric test was subtracted from the hearing threshold value at the seventh audiometric test to obtain a 'difference' value. The results of the experimental group were then compared to a control group, who had no previous history of noise exposure.

The results of the study revealed minimal changes in hearing sensitivity, particularly for younger fire-fighters. The average decrement was over 3, 4 and 6kHz, and ranged from 0.9dB for the 30 year olds and 7.5dB for the 60 years olds. Furthermore, it was noted that the participants with longer service records in the occupational setting presented with lower audiometric thresholds in comparison to those with a shorter service record. This has implications for the present study as pure tone audiometry may be able to detect NIHL in employees with longer service records, whereas, pure tone audiometry may be inadequate in the detection of NIHL following shorter service records. This is in accordance with Rosen et al. (2001) who state that NIHL progresses 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. Apart from this, little longitudinal research has been conducted to investigate the effects of noise on hearing as seen on the pure tone audiogram (Duvdevany & Furst, 2007).

Additionally, Clark and Bohl (2005) also highlight the significance of the effect of age on hearing in their study. This ageing effect on hearing is referred to as presbycusis (Weinstein, 2002). The cochlea, and in particular, the basal end of the cochlea, is also vulnerable to the effects of ageing (Weinstein, 2002). In contrast to the notch that occupational noise creates on the pure tone audiogram, the audiogram in pure age-related hearing loss is typically downsloping with progressively worsening thresholds in the higher frequencies (Rabinowitz et al., 2006). This is due to the loss of outer hair cells in the basal turn of the cochlea which is, therefore, responsible for the decline in pure tone hearing with age (Weinstein, 2002). In middle-aged and older people who have had noise exposure, the effects of presbycusis and noise may overlap (Rabinowitz et al., 2006). The onset of presbycusis may occur at any time from the third to sixth decade of life (Timiras, 2007). Therefore, in order to exclude the effects of age on hearing in the investigation of the early identification of noise-induced cochlea changes of employees in the beverage manufacturing industry, the present study included participants up to the age of 45 years.

Furthermore, in order to effectively reduce and prevent the likelihood of noise-induced cochlea changes, test procedures are required to detect these cochlea changes as early as possible. The question asked by several researchers is whether or not pure tone audiometry in the conventional frequency range is a sensitive method for this purpose (Schmuziger, Patscheke & Probst, 2007; Rabinowitz et al., 2006; Attias et al., 2001). This suggests that the use of conventional pure tone audiometry alone may not accurately identify the target population. Therefore, extended high frequency audiometry (>8kHz) has been suggested as an additional or alternative method for monitoring the effects of noise exposure on hearing (Harrel, 2002).

This is due to the fact that the higher frequencies are more susceptible to the effects of noise than the middle and low frequencies (Harrel, 2002). Schmuziger et al. (2007) state that several hydrodynamic effects have been proposed as possible contributors of the vulnerability of the base of the cochlea to noise. These effects are said to include the greater travelling wave amplitude at the base of the cochlea; the greater acoustic load at the base as well as a possible basal locus for shock from impulse energy abnormally conducted to the cochlea (Fausti, Erickson, Frey et al., 1981, as cited in Schmuziger et al., 2007). Therefore, it would appear that

extended high frequency audiometry (>8kHz) is the ideal audiological procedure in the assessment of noise-induced damage to the basil end of the cochlea.

However, in reality, the limitations surrounding this audiological procedure appear to far outweigh the clinical value it may have to offer. Extended high frequency audiometry measures hearing thresholds for pure tones from 8 to 16 kHz, resulting in technological limitations (Schmuziger et al., 2007). These researchers explain that the limitations are as a result of complex physical interactions of pure tones in the ear canal forming standing waves that increase intra- and inter-subject variability of hearing thresholds in the affected frequency range.

Furthermore, researchers have proposed several other limitations, including the fact that the standard deviations for high frequency thresholds within groups of normal listeners are larger than those for the 250–8000Hz range (Harrel, 2002) resulting in a difficulty obtaining normative data for high frequency audiometry. Hallmo, Sundby & Mair (1994) stated that this variability is most evident in older age groups seeing that, as age increases, the sensitivity for high frequency tones decreases. It was discovered that high frequency audiometry thresholds increased with both age and frequency in the 8000Hz to 16000Hz range, and there was a large non-significant tendency for the thresholds to be higher in males (Hallmo et al., 1994). Finally, high frequency audiometry requires special headphones not readily available in audiological practice (Harrel, 2002). These factors present as a serious limitation in the use of high frequency audiometry in the identification of NIHL in the adult population (Hallmo et al., 1994).

Schmuziger et al. (2007) conducted an assessment of threshold shifts in non-professional pop/rock musicians using conventional and extended high frequency audiometry. The results of this study were in agreement with previous studies, indicating that normative thresholds in the extended high frequency range cannot be recommended for clinical use due to the large intersubject threshold variability. Therefore, it was concluded by Schmuziger et al. (2007) that the clinical potential of extended high frequency audiometry for the early detection of NIHL is unreliable, which is in agreement with the conflicting findings of other studies (Hallmo et al., 1994). It is evident that there are significant limitations in the reliability and validity of extended high frequency audiometry in the monitoring of noise exposed employees.

Thus, it is essential to consider other reliable, accurate and valid audiological test procedures as these characteristics are critical in the diagnosis of NIHL. If the results are not accurately recorded they can be misinterpreted resulting in an incorrect diagnosis of the patient (Roeser, Valente & Hosford-Dunn, 2000). Factors that can affect the results and should be considered as part of every pure tone test include case history information, test environment, listener position, instructions to the patient, ear examination, earphone placement, threshold procedure, as well as false-negative and false-positive responses (Roeser & Clark, 2007). Pure tone testing is therefore subjective in that it requires complete patient cooperation and is influenced by learning effects (Attias et al., 2001). In medico-legal situations, such cooperation is not always forthcoming. As a result, several researchers (Attias et al., 2001; Schmuziger et al., 2007; Edwards et al., 2010) have questioned the efficiency of pure tone audiometry in the early identification of NIHL.

2.6 CONCLUSION

Hearing loss is ranked as the second most prevalent occupational injury, with adult-onset hearing loss being the fifteenth most serious health problem in the world with profound effects ranging from social isolation and stigmatization of individuals to serious national economic burdens (Smith, 2004). The effects of noise on hearing therefore need to be assessed and legislation in South Africa and internationally need to prevent or alleviate these effects. The South African National Standard (SANS) is the guideline that attempts to take all the significant factors into consideration in the prevention of NIHL. This guideline must be applied to the beverage manufacturing industry. As a result of the enormous scale beverage manufacturers have become better equipped to manufacture at high speeds and low cost. This results in the need for the use of heavy machinery, which often exceeds the acceptable noise rating limit of 85dB(A) and consequently hearing conservation programs are required for the prevention of noise-induced hearing loss in this industry.

Annual medical surveillance consists of otoscopy and a pure tone audiogram on an annual basis. Several studies (Attias et al., 2001; Schmuziger et al., 2007; Edwards et al., 2010) have reported on the inefficiency of pure tone audiometry in the early identification of NIHL. It is evident that a test, addressing the limitations of pure tone audiometry, is required to be included in the annual

medical surveillance test battery outlined by the SANS: 10083 (2004). The test needs to be efficient and extensively evaluated to demonstrate acceptable performance and feasibility. The test is required to be sensitive, i.e. possess the ability to accurately identify the target population, and specific, i.e. to identify those individuals who truly do not present with referral thresholds shifts as a result of noise exposure (Johnson, 2002). In addition, the test is required to specifically assess the site of lesion caused by NIHL. Recent literature suggests the use of DPOAEs to alleviate the limitations of previous test procedures (Bockstael, et al., 2008; Duvdevany & Furst, 2007). The forthcoming chapter will focus on DPOAEs, its advantages and disadvantages and a review of the literature for this study.

CHAPTER THREE: DISTORTION PRODUCT OTOACOUSTIC EMISSIONS AND A REVIEW OF THE LITERATURE

3.1 INTRODUCTION

This chapter provides a description of DPOAEs. The measurement of DPOAEs, normative data and the advantages and disadvantages of the test are discussed. The feasibility of DPOAEs in the identification of noise-induced cochlea changes is further explored. In addition, an in-depth review of the literature related to the study is presented and discussed.

3.2 OTOACOUSTIC EMISSIONS

Otoacoustic emissions (OAEs) are low sounds that are generated in the cochlea and measured in the outer ear canal (Wagner et al., 2008; Robinette & Glattke, 2002). Kemp (1997) explains that the sounds that originate within the cochlea are as a result of physiological, vital and vulnerable activity that occurs inside the cochlea. OAEs are representative of an active cochlea amplification process that is linked to the integrity of the actively motile outer hair cells (OHCs) (Wagner et al., 2008, Engdahl & Tambs, 2002). The low level emissions produced are detected in the external canal following a record of the pattern of ossicle and tympanic membrane motion in response to motion that originates within the cochlea (Robinette & Glattke, 2002). Therefore, OAEs are considered to be a by-product of the OHCs active contribution to vibrations in the cochlea (Engdahl & Tambs, 2002).

Following the discovery of OAEs by Kemp in 1978 (Hall, 2000), confidence in the basic significance and reliability of OAEs as a sensitive indicator of cochlea function has gradually grown, and entered the mainstream of hearing screening and diagnostic audiology as a useful clinical tool (Kemp, 1997; Feuerstein, 2002). In addition to becoming an established screening tool in the examination of newborn and infant hearing, OAEs demonstrate high sensitivity and specificity if used in screening for cochlea dysfunction in adult patients, as well as in individuals with an increased risk of exposure to noise and in epidemiological studies on industrial and

environmental noise effects (Kim et al., 1996; Sliwinska-Kowalska & Kotylo, 2001; Clark, 2005; Job et al., 2009).

OAEs are classified into two types, i.e. spontaneous OAEs are emitted from the ear in the absence of stimulation and evoked OAEs are observed in response to a stimulus presented to the ear (Prieve & Fitzgerald, 2002). There are two ways of eliciting evoked OAE responses, i.e. transiently evoked otoacoustic emission (TEOAE) and the distortion product otoacoustic emission (DPOAE) (Johnson, 2002). DPOAEs involve the simultaneous presentation of two primary tones of different frequencies into the ear canal to elicit a response that is a distorted copy of the original sound presented (Dunkley & Dreisbach, 2004; Johnson, 2002; Prieve & Fitzgerald, 2002). TEOAE uses a brief pulse of sound and measures the resulting response during the quiet period and between each presentation (Johnson, 2002). A click or toneburst is presented to the ear and the response occurs after a brief time-delay (Prieve & Fitzgerald, 2002).

A study conducted by Vinck et al. (1999), investigated the sensitivity and applicability of TEOAEs and DPOAEs as quantitative indices for the functional integrity of the OHCs during temporary threshold shifts (TTS) in order to establish the direct relationship of OAE to human cochlea functioning more firmly. The study consisted of two experiments. Experiment 1 investigated the pre- and post-stimulatory effects following one hour of exposure to broad-band noise (BBN), whereas, experiment 2 examined the effects of a five hour exposure to loud discotheque music. The resulting TTS was measured immediately after the exposures, and changes in audiometric hearing and OAEs were documented during the recovery period. The results of experiment 1 revealed clear TEOAEs and DPOAEs in response to 70dB SPL click stimuli, before exposure. However, after exposure to 90dB SPL BBN, TEOAEs elicited at 70dB SPL clicks decreased in amplitude when compared to the pre-exposure reference, despite the absence of any demonstrable effect on pure tone hearing levels.

Furthermore, both reproducibility scores and signal to noise ratio values were unaffected at 1-3kHz, but showed the greatest sensitivity to the noise exposure at 4kHz. Reduced amplitudes were also observed for post-exposure DPOAEs. However, the noise exposure appeared to affect a greater frequency band than the TEOAEs. The DPOAE results showed a significantly (p<0.05)

reduced amplitude in the frequency region from 2973 to 5582Hz, while the lower frequencies were unchanged. Compared to the behaviourally measured TTS in experiment 1, DPOAEs were more sensitive to TTS in describing the time course of recovery. Although both TEOAEs and DPOAEs provide instruments for the early identification of subtle, dynamic changes of OHC function after noise exposure, DPOAEs were more sensitive to cochlea changes. This indicates that DPOAEs may be more sensitive to cochlea changes when conducted in a group of employees in the beverage manufacturing industry. Furthermore, these workers may also present with decreased amplitudes in the high frequency region of the DP-gram.

Additionally, according to Shaffer et al. (2003) there is no direct correspondence between TEOAEs and the behavioural pure tone threshold test frequencies. Furthermore, TEOAEs arise from stimulation of a broad region of the cochlea partition, indicating that any given TEOAE frequency measured in the ear canal may, in fact, represent energy from multiple cochlea locations (Shaffer et al., 2003). This explains why TEOAE amplitudes have not held much predictive power for determining auditory sensitivity (Avan et al., 1991, 1993, as cited in Shaffer et al., 2003). Although both TEOAEs and DPOAEs have been used to study the effect of noise on the cochlea because they both provide frequency specific information, DPOAEs are probably most useful, due to their better performance in the high frequency range (Balatsouras et al., 2005; Bockstael et al., 2008). DPOAEs are also able to cater to the non-linear features of a healthy cochlea by assessing the output of energy at frequencies other than those contained in the input stimulus (Prieve & Fitzgerald, 2002). As a result, DPOAE testing was investigated in the current study for the identification of subtle cochlea changes in a group of employees in the beverage manufacturing industry.

3.3 DISTORTION PRODUCT OTOACOUSTIC EMISSIONS

DPOAEs are generated by a two-tone complex that results in the production of distortion products arising from specific regions of the cochlea (Shaffer et al., 2003; Wagner et al., 2008). As previously mentioned, DPOAEs are measured simultaneously by the presentation of two pure tone stimuli or primaries (Prieve & Fitzgerald, 2002). When these two continuous acoustic pure tones close in frequency, are presented simultaneously, acoustic distortion products at

frequencies not present in the acoustic stimuli are produced (Dreisbach, Long & Lees, 2006). The frequencies of the primaries are referred to as f1 and f2 (Prieve & Fitzgerald, 2002). In every DPOAE measurement multiple distortion products occur simultaneously at multiple frequencies, according to defined algebraic relationships of f1 and f2, e.g. f1-f2 or 2f1-f2 (Wagner et al., 2008). Research has indicated that the most successful algebraic relationship in clinical use is 2f1-f2 (Prieve & Fitzgerald, 2002; Wagner et al., 2008). The corresponding levels or intensities of the primaries are referred to as L1 and L2 (Prieve & Fitzgerald, 2002). Research has shown that lowering L2 by 6dB below L1 improves DPOAE repeatability (Wagner et al., 2008). When exploring short term DPOAE repeatability the differences between two DPOAE frequency sweeps at frequencies between 0.5 to 4kHz, i.e. geometric mean of f1 and f2; L1=L2 at 35, 45 and 55dB SPL, must exceed approximately 6dB to be statistically significant when tested in the same trial, using immediate test-retest methods (Dreisbach et al., 2006). This has implications for the current study as the primary tone levels of L1=65dB SPL and L2=55dB SPL was used when conducting immediate test-retest methods for DPOAE testing, which may result in improved DPOAE repeatability for noise exposed workers in the beverage manufacturing industry.

These DPOAE results are recorded automatically on a DP-gram. The DP-gram is a graph of the DPOAE level as a function of frequency (Prieve & Fitzgerald, 2002). It is obtained by presenting the stimulus tones at a fixed level across a range of geometric mean frequencies (Gelfand, 2009). A positive feature of the DP-gram is the detailed frequency configuration that can be obtained, which specifies the pattern of remaining OHC function (Burkard, Don & Eggermont, 2007). A representative DP-gram stimulus protocol should include a frequency range of 0.5 to 8kHz with respect to the geometric mean frequency, along with an f2/f1 ratio of 1.22, a level difference of 10dB and absolute levels of L1=65dB SPL and L2=55dB SPL (Burkard et al., 2007). This protocol was utilized in the current study.

Once a representative and appropriate DPOAE protocol has been selected, the DPOAE measurement system will generate a DP-gram. The presence or absence of DPOAEs is commonly determined by comparing the level of the signal in the DPOAE frequency fast Fourier transform bin to the level of closely adjacent frequency bins, which contain only background noise (Burkard et al., 2007). A DPOAE is present if the level of the DPOAE frequency bin is

greater than that of the noise level estimate derived from nearby frequency bins by 6dB or greater (Bukard et al., 2007). DPOAEs are present in 96 percent of audiometrically normal ears and disappear with hearing loss of 55dBHL or more (Shaffer et al., 2003; Gelfand, 2009).

These qualities make DPOAEs a promising clinical tool. The established clinical indications for the use of DPOAEs include the screening of hearing in infants, objective estimation of hearing status in the paediatric and difficult-to-test population, for the distinction between cochlea and retro-cochlea origin of sensorineural hearing loss, monitoring of cochlea function during the administration of ototoxic drugs and for observation of therapeutic success for the treatment of acute sensorineural hearing loss (Wagner et al., 2008). In order to achieve this, normal middle ear functioning is essential prior to DPOAE testing as OAEs are low sounds that are generated in the cochlea and measured in the outer ear canal (Wagner et al., 2008). Several studies have also documented the effects of age on DPOAE results (Clark & Bohl, 2005; Yasue et al., 2008)

Yasue et al. (2008) investigated the effects of aging on DPOAEs in adults with normal hearing. 331 participants (136 men and 195 women) aged 40 to 82 years were evaluated. Pure tone and DPOAE testing was conducted separately for groups of men and women at 22 test frequencies. A stringent audiometric criterion was set as acceptable hearing thresholds could not exceed 15dBHL. A statistically significant difference was found in DPOAE amplitudes among age groups at four test frequencies in men, ranging from 4761 to 6165Hz, and at all but the 3088Hz test frequency in women. Despite the strict audiometric inclusion criterion, statistically significant differences in the mean pure tone thresholds were observed at 4000Hz in men and at all test frequencies for women. The results of this study indicate that DPOAEs deteriorate with age independently of hearing sensitivity, and is evident more in females. Moreover, DPOAE measurements in audiometrically normal hearing elderly people may provide early indications of cochlea damage because of aging. The results of this study have implications for the selection criteria of the present study. In order to investigate the effects of noise on DPOAEs for workers in the beverage manufacturing industry, it was essential to exclude participants who may have presented with age related cochlea damage.

The features of DPOAEs make it an attractive clinical tool as the frequency at which the response occurs is predicted exactly by the frequencies of the primary tones (Robinette & Glattke, 2002). Thus, the frequencies representing the classic noise-induced notch in pure tone audiometry hearing thresholds (3-6 kHz) can be clearly identified and defined (Hall, 2000). As a result, DPOAEs are especially well-suited as a monitoring tool for noise-induced OHC damage within the cochlea, because the frequency range extends up to and beyond the region affected by exposure to occupational noise (Hall, 2000). Due to the structure, function and location of the OHCs within the cochlea, they present with a greater sensitivity to noise exposure as compared to the inner hair cells (Harrel, 2002). Thus, inclusion of DPOAEs in an annual medical surveillance test battery may be able to identify cochlea changes as a result of OHC damage. This suggests that it may be feasible to include DPOAEs in such a test battery as a monitoring tool for the identification of noise-induced cochlea changes for a group of employees in the beverage manufacturing industry.

Additionally, DPOAEs are non-invasive, objective and frequency-specific audiometric tests for evaluating OHC function (Konopka et al., 2005, Engdahl & Tambs, 2002). They are quick, simple to conduct and do not require a sound booth (Johnson, 2002). Additionally, Johnson (2002) explains that although costs remain high, they are decreasing as more equipment options become available. This includes the development of automated DPOAEs which indicates whether the response reached the pass/fail criteria. This has implications for the training of other practitioners conducting annual medical surveillance, as minimal training would be required in the administration and interpretation of DPOAEs. However, although DPOAEs present with these significant advantages in the evaluation of cochlea changes as a result of occupational noise exposure, there are some doubts regarding their utility in hearing conservation programs.

Sliwinska-Kowalska & Kotylo (2001) state that this is possibly due to the fact that legislation and financial compensation associated with the diagnosis of occupational illness is based on the "gold standard", pure tone audiometry. Despite the lack of scientific evidence regarding the replacement of pure tone audiometry by OAEs in industrial settings, various health and safety departments in the Netherlands have replaced conventional audiometry with OAEs and when there appears to be a deterioration in OAE levels, workers are referred for pure tone audiometry

to confirm the diagnosis (Helleman, Jansen & Dreschler, 2010). Within the South African setting, it is quite possible that DPOAEs will assume an important role for the early identification of NIHL in various industries and settings as an objective cross-check to the pure tone audiogram (Hall, 2000) and as part of an annual medical surveillance test battery. Several studies have documented the sensitivity and clinical efficacy of DPOAEs as a tool for the identification of noise-induced cochlea changes (Hall, 2000; Attias et al., 2001; Balatsouras et al., 2005).

A local study conducted by Jhetam, Reddy & Vahed (2008) investigated the use of DPOAEs in the early identification of NIHL in a sample of hairdressers, using pure tone audiometry and DPOAEs. The study involved hairdressers with different durational noise exposure in the professional salon setting. The sample was divided according to the number of years that participants were exposed to noise in the professional salon setting (<11 years and >11years). The results obtained from the experimental groups were compared to a control group, who had no history of previous noise exposure. The results of the study indicated that DPOAEs revealed significant noise-induced cochlea changes.

This significant effect was evident on visual inspection of the DPOAE results, with significant notch configurations observed between 4000-6000Hz bilaterally in the experimental group. DPOAE results proved to be statistically significant (p<0.05). Visual inspection of the pure tone audiograms of the experimental groups revealed notch configurations in the presence of the normal hearing and a statistical significance was not observed. The results of this study suggest that DPOAEs are better suited for the early identification of NIHL than pure tone audiometry. This has implications for the present study, whereby the possible notch configurations between 3 and 6kHz may be present in the DPOAE results of noise exposed workers in the beverage manufacturing industry. It is therefore expected that upon visual inspection of the pure tone audiogram in the present study noise notch configurations may also be present in the presence of normal hearing. Furthermore, DPOAEs may prove to be a suitable method of predicting early noise-induced cochlea changes which may not be depicted on the pure tone audiogram.

Internationally, Attias et al. (2001) further investigated the relationship between the pure tone audiogram and the DP-gram following noise exposure. The aim was to test the application of

DPOAEs in the diagnosis and screening of NIHL and to compare its characteristics to pure tone audiometry. The results revealed reduced DPOAE amplitudes for the frequencies 3, 4 and 6 kHz in participants with normal pure tone audiograms and audiograms depicting NIHL. This confirms that DPOAE amplitudes may indicate cochlea damage without corresponding changes to the pure tone audiogram. Therefore, decreased DPOAE amplitudes may suggest early noise-induced cochlea changes in the presence of normal pure tone audiograms for the groups under investigation in the current study.

Additionally, Attias et al. (2001) discovered that repeated exposure to continuous and impulse noise resulted in bilateral symmetrical high frequency hearing loss depicted on both the pure tone audiogram and DP-gram. Therefore, the pure tone audiogram closely resembled the DP-gram. This has implications for the current study as repeated and prolonged exposure to noise within the beverage manufacturing setting may result in high frequency hearing loss depicted in both pure tone audiometry and DPOAE results. Attias et al. (2001) also found a greater sensitivity of DPOAEs in detecting early cochlea changes as a result of noise exposure, as compared to pure tone audiometry. In the current study, DPOAEs may demonstrate a greater sensitivity in the detection of subtle noise-induced cochlea changes in employees working within the beverage manufacturing setting. Several other studies have investigated the application and repeatability of DPOAEs in occupational health surveillance programs as a monitoring tool for cochlea changes. A summary of the relevant studies is depicted in Table 3.1 overleaf.

Table 3.1 Summary of relevant literature

Authors	Participants	Aims	Findings
Atias et al. (2001)	310 participants	To test the application of DPOAEs in the diagnosis and screening of NIHL and to compare its characteristics to pure tone audiometry in noise exposed workers	-Reduced DPOAE amplitudes for the frequencies 3, 4 and 6 kHz in participants with normal pure tone audiograms and audiograms depicting NIHL. -The pure tone audiogram closely resembled the DP-gram following repeated, prolonged exposure to continuous and impulsive noise, -A greater sensitivity of DPOAEs in detecting early cochlea changes as a result of noise exposure, as compared to pure tone audiometry
Kim et al. (1996)	74 participants	Evaluated DPOAEs as a test of sensori-neural hearing loss by investigating DPOAE performance with regards to sensitivity, specificity and receiver operating characteristics.	- The sensitivity, specificity and predictive efficiency of the test was 85-89% at 6000 and 4000Hz, 82-83% at 2000Hz, and 78-79% at 1000Hz, respectively DPOAEs are more effective at higher frequencies (4000 and 6000Hz).
Chan et al. (2004)	36 participants	To develop DPOAE screening criteria to identify participants likely to meet the Hong Kong requirements for occupational hearing loss compensation.	 A significant correlation was evident at 1000 and 2000Hz (p<0.05), however, a significant difference was not detected at 3000Hz. DPOAE SNR criteria, >0 and 3dB SNR yielded relatively high sensitivity and specificity, while the >6dB SNR criterion yielded lower specificity throughout all DPOAE test frequencies. All DPOAE SNR resulted in 100% test sensitivity for all three criterion.
Clark (2005)	107 South African mine workers	The prevalence and characteristics of DPOAEs and TEOAEs in a population of mineworkers exposed to noise with normal audiometric thresholds.	 - A lower prevalence of DPOAE amplitudes for the noise-exposed group (92%) as compared to a control group (97%). - Visual inspection of the DPOAE results revealed notch configurations in the region of 3640Hz in the noise-exposed group, in the presence of audiometrically normal hearing. - Inter-test reliability - Machine one obtained a 94% pass rate as compared to that of a 90% pass rate obtained by machine two
Dreisbach et al. (2006)	25 participants	Repeatability of high frequency DPOAEs in normal hearing participants.	- A greater variability in the higher frequencies (>8kHz)At the frequencies <8kHz, repeated DPOAE level variations were within +/-10dB for 98.4 and 96% of young adult participants for the 70/55 and 60/50 dB SPL stimulus level conditions.
Wagner et al. (2008)	40 participants	To determine the test-retest repeatability of DPOAEs The participants were randomly assigned to two groups of 20 participants.	-The widely used minimum SNR of 6dB is a recommended criterion when considering measurement quality in a clinic settingThere was decreased DPOAE repeatability at frequencies below 1kHz and above 6kHz - Repeatability of DPOAEs was independent of the time intervals between testing

Kim et al. (1996) evaluated DPOAEs as a frequency specific test of sensorineural hearing loss by investigating DPOAE performance with regards to sensitivity, specificity and receiver operating characteristics (Refer to Table 3.1, p. 35). The study included 71 ears with normal hearing thresholds and 71 ears with abnormal thresholds at one or more frequencies. DPOAE data was collected using the "DPOAE-versus-frequency" paradigm with the stimulus levels of the two tones, L1 and L2, equal to 65dB SPL, across the frequency range of 500-8000Hz. Data at 1000-6000Hz only were analyzed in this study, as, data at 500-750Hz was affected by high background noise and those at 8000Hz had a greater variability. This has implications for the current study as data was analyzed for 1000-8000Hz for pure tone audiometry and 913-7303Hz for DPOAEs. Furthermore, Kim et al. (1996) highlights the importance of measuring ambient noise levels to ensure that the test results are not affected by high background noise. This suggests the need to measure ambient noise levels within the test environment in the beverage manufacturing setting to ensure that accurate test results are obtained.

Kim et al. (1996) found the sensitivity, specificity and predictive efficiency of the test to be 85-89% at 6000 and 4000Hz, 82-83% at 2000Hz, and 78-79% at 1000Hz, respectively. It is evident that DPOAEs have a high sensitivity, specificity and predictive value at 4000 and 6000Hz. However, at 1000 and 2000Hz, there appears to be a discrepancy in the data collected. The authors attribute this to the fact that most of the participants in the study did not present with elevated hearing thresholds at these levels. The study conducted by Kim et al. (1996) supports previous findings stating that DPOAEs are more effective at higher frequencies (4000 and 6000Hz). These authors deduced that DPOAE information about cochlea function at high frequencies may be particularly useful as an early indicator of cochlea impairment since the high frequency (basal) region of the cochlea is more vulnerable than the middle and low frequency (apical) regions in many pathological conditions such as in effects of ototoxic drugs and noise exposure (Kim et al., 1996).

A more recent study investigating sensitivity, specificity and predictive value was conducted by Chan, Wong & McPherson (2004), who aimed to develop DPOAE screening criteria to identify participants likely to meet the Hong Kong requirements for occupational hearing loss compensation, namely, a bilateral sensorineural hearing loss >40dB HL using a pure tone

average at 1000, 2000 and 3000Hz (Refer to Table 3.1, p. 35). The rationale for the study was to reduce the time consuming process of occupational hearing loss compensation. Therefore, Chan et al. (2004) were interested in an accurate testing procedure that would be sensitive to occupational noise exposure, similarly to the rationale of the present study.

The results of 36 randomly selected participants from the Occupational Deafness Compensation Board for the period of 1995 to 1999 were examined. The participants were divided into two groups. Group Y (Yes, compensated) was comprised of 18 participants who presented with bilateral hearing loss >40dB HL. Group N (No, not compensated) was comprised of 18 participants who did not present with hearing loss. Similarly to the present study, all participants underwent pure tone audiometry, DPOAEs and tympanometry. DPOAE results were recorded using two primary tones with the f1/f2 ratio fixed at 1.22 and stimulus levels for the two tones, L1 and L2, set at intensities of 65 and 55dB SPL, respectively. These parameters were also utilized in the current study. Chan et al. (2004) aimed at calculating the sensitivity, specificity, positive and predictive values of three different DPOAE screening criteria, i.e. >0, 3, or 6dB above the noise floor. DPOAE levels at 1000, 2000 and 3000Hz of the normal hearing subgroup (group N) conformed to normative data, whereas, few DPOAEs were present for group Y, with only one or two participants exhibiting measurable responses at each stimulus frequency.

Chan et al. (2004) found that measurable DPOAE levels decreased with increasing hearing loss. A significant correlation (p<0.05) was found between DPOAE levels and corresponding pure tone audiometry thresholds at 2000Hz. However, correlations did not meet statistical significance at 1000 and 3000Hz. Thereafter, the relationship between DPOAE levels and pure tone average thresholds were investigated at 1000, 2000 and 3000Hz. Chan et al. (2004) discovered that a significant correlation was evident at 1000 and 2000Hz (p<0.05), however, a significant difference was not detected at 3000Hz. This has implications for the current study, as these frequencies were also under investigation. With regard to DPOAE SNR criteria in the Chan et al. (2004) study, >0 and 3dB SNR yielded relatively high sensitivity and specificity, while the >6dB SNR criterion yielded lower specificity throughout all DPOAE test frequencies. All DPOAE SNR resulted in 100% test sensitivity for all three criterion, which is in contrast to previous studies of this nature, possibly due to the limited sample size. This study, therefore, has

implications for the present study as sensitivity and specificity was under investigation at a SNR criteria of >6dB SPL at a similar frequency and intensity range. This suggests that similar findings may be obtained for workers exposed to occupational noise within the beverage manufacturing setting.

A study conducted by Clark (2005), investigated OAEs in the early identification of noise-induced hearing loss in 107 South African mineworkers. The study investigated the prevalence and characteristics of DPOAEs and TEOAEs, inter-test reliability using two OAE machines to collect data, as well as the sensitivity and specificity of TEOAEs and DPOAEs for the early identification of NIHL (Refer to Table 3.1, p. 35). The results revealed a lower prevalence of DPOAE amplitudes for the noise-exposed group (92%) as compared to a control group (97%). The results obtained for diagnostic DPOAE tests did not prove to be statistically significant (p>0.05), as the results for the noise-exposed group were comparable to that of the control group. However, the correlation for the DPOAE diagnostic test was good (p>0.05 for four out of the five frequencies, i.e. 1797, 2566, 3640, and 5133Hz).

On the other hand, visual inspection of the DPOAE results in the Clark (2005) study revealed notch configurations in the region of 3640Hz in the noise-exposed group, in the presence of audiometrically normal hearing. The study revealed that DPOAE tests appear to be more specific in detecting noise damage in the frequency regions where damage is expected to occur. Frequency specificity appears to be a key advantage of DPOAEs. In addition, DPOAE tests indicated high repeatability and sensitivity to presymptomatic cochlea changes. These findings can be related to the current study as a lower prevalence of DPOAE amplitudes may be expected for the noise exposed workers in the beverage manufacturing industry. In addition, DPOAEs may also present with high repeatability and sensitivity to early subtle cochlea changes in the current study. Clark (2005) also highlighted the importance of visual inspection of DPOAE results in the identification of subtle cochlea changes, indicating that visual inspection of the results obtained for workers in the beverage manufacturing setting may be essential. These findings imply that the use of DPOAEs in conjunction with pure tone audiometry may result in the early identification of subtle cochlea changes, suggesting that DPOAEs are a feasible test to be included in the annual medical surveillance test battery.

With regard to inter-test reliability, Clark (2005) conducted DPOAEs utilizing two machines and two Audiologists. Each Audiologist was assigned to a machine and each had varying levels of experience and exposure to DPOAE testing. The results indicated that machine one obtained a 94 percent pass rate as compared to that of a 90 percent pass rate obtained by machine two. This is in contrast to previous studies, where such discrepancies were not noted. Clark (2005) attributed the discrepancies to a possible difference in tester experience and exposure to DPOAE testing which may have resulted in incorrect probe placement in the participants' ears; extrinsic factors, such as environmental noise, as this was not controlled for; measurement differences, as calibration of the equipment was not carried out prior to testing; and lastly, the probe fit did not remain stable between testing, but was removed and reinserted. Clark (2005) therefore concluded that further research is required to address these issues before DPOAE testing can be applied as a procedure to detect early NIHL in industry. The findings in the Clark (2005) study have implications for the present study as similar parameters were investigated.

It is evident that several factors may influence DPOAE repeatability. Wagner et al. (2008) state that these may include the placement of the probe tip as the probe should be placed adjacent to the isthmus of the outer ear canal to ensure sufficiently stable and firm placement; the sound pressure generated in the ear canal is also greatly influenced by the depth of the probe tip; room noise and biological noise, which may be caused by the patient moving, breathing, swallowing or coughing and ambient noise; and other factors such as middle ear status and SNR. These factors highlighted by Clark (2005) and Wagner et al. (2008) have implications for the repeatability of DPOAEs in the current study. This suggests the need to control for ambient noise, biological noise where possible, middle ear status and probe placement for workers exposed to occupational noise within the beverage manufacturing industry when investigating the repeatability of DPOAEs.

Zhao & Stephens (1999) examined causes of variability in the repeatability of DPOAE frequency sweeps using equal level primary tones of 70dBSPL over the frequency region of 0.6 to 6kHz. Test-retest measures were completed without probe removal (3 times in one trial), with probe removal in the same trial (3 times) and over a 4 week period. The researchers concluded that the probe re-fitting and long term variance were significantly greater than short-term variability with

no removal of the probe. However, the overall variance in the DPOAE measures was reasonably small at most frequencies greater than 1kHz. Although the current study utilized two different primary tone levels, these findings are of significance as it is important to identify the various factors that may contribute to DPOAE variability measured over time.

Another study conducted by Dreisbach et al. (2006) investigated the repeatability of high frequency DPOAEs in normal hearing participants (Refer to Table 3.1, p. 35). Pure tone air conduction audiometry and DPOAE testing was conducting at 2, 4, 6, 8, 10, 12, 14 and 16kHz over a period of four trials, done one week apart. The researchers used four stimulus level conditions, i.e. L1/L2 = 60/45, 60/50, 70/55, 70/60dB SPL). The results of the study revealed a greater variability in the higher frequencies (>8kHz). However, at the frequencies <8kHz, the researchers deduced that repeated DPOAE level variations were within +/-10dB for 98.4% and 96% of young adult participants for the 70/55 and 60/50 dB SPL stimulus level conditions. Although, Dreisbach et al. (2006) utilized a limited sample size, the findings may be significant for the present study as a 65/55 dB SPL stimulus level was used in the collection of the data.

A later study conducted by Wagner et al. (2008), examined 40 participants to determine the test-retest repeatability of DPOAEs (Refer to Table 3.1, p. 35). All participants presented with audiometric hearing thresholds of 20dB HL or better across the frequency range of 0.5 to 8kHz and bilateral recordable DPOAEs between 1 and 6kHz with a minimum SNR of 6dB at stimulus levels L2 = 60, 50, 40, 35, 30, 25 and 20dB SPL. The participants were randomly assigned to two groups of 20 participants. In Group 1, three measurements were made following immediately one after the other on the same day with the acoustic probe left in the ear canal, and one measurement was done on another day, which was on average 5.9 days later. In Group 2, three measurements were performed on three different days. The time intervals varied and were on average 4.8 days between measurements one and two, 5.5 days between measurements two and three, and 10.3 days between measurements one and three.

The results of the Wagner et al. (2008) study revealed that DPOAE repeatability was generally high when compared to previous studies of the same nature. The researchers propose that SNR can be improved by increasing the separation of the primary tone levels with decreasing the

overall primary tone levels, as it is implemented in the 'scissor paradigm.' This paradigm accounts for the non-linear interaction of the two primary tones at the DPOAE generation site at the f2 place. Wagner et al. (2008) therefore agree with previous studies which suggest that lowering L2 by 6dB below L1 improved DPOAE repeatability. Additionally, the study revealed that DPOAE repeatability continuously decreased with decreasing the primary tone level from L2 = 50 to 20dB SPL. The overall findings suggest that a satisfactory level of repeatability can be achieved down to primary tone levels as low as L1/L2 = 47/20dB SPL, under stable measurement conditions and with the use of a common measurement system. Furthermore, the widely used minimum SNR of 6dB is a recommended criterion when considering measurement quality in a clinic setting and this is in agreement with Clark (2005). These findings suggest that a SNR of 6dB and a difference of 6dB between L1 and L2 may result in improved DPOAE repeatability in a clinic setting in the beverage manufacturing industry. This has further implications for the training of personnel within the beverage manufacturing industry. A high test-retest repeatability of DPOAEs in conjunction with appropriate test parameters indicate that an occupational nurse within the beverage manufacturing setting may be trained to conduct and interpret DPOAEs in the annual monitoring of noise-induced cochlea changes, which may eliminate the need for specialized audiologists to conduct the DPOAE test in this setting.

Wagner et al. (2008) further deduced that there was decreased DPOAE repeatability at frequencies below 1kHz, possibly attributed to the high susceptibility of internal noise in the lowest frequencies, and above 6kHz, possibly attributed to reduced DPOAE validity because of interference phenomena in the outer ear canal. This is in accordance with the findings of Kim et al. (1996). Wagner et al. (2008) found that test-retest repeatability values are similar in the frequencies f2 = 1, 2, 3, and 4kHz, with the best values observed at 4kHz. Furthermore, the repeatability of DPOAEs was independent of the time intervals between testing. The results of the Wagner et al. (2008) study indicated a generally good test-retest reliability which is an important pre-requisite for monitoring cochlea function over time. These findings support those of previous studies and may assist clinicians in the correct interpretation of DPOAE level changes in the test-retest situation and increase DPOAE test reliability.

Reliability is an essential part of any clinical procedure as it provides a measure of the degree of confidence that can be placed in an individual DPOAE or between DPOAEs (Beattie, Kenworthy, & Luna, 2003). This is especially important in order to determine how much of a difference in a DPOAE result over time is necessary to be certain that the DPOAE change is attributable to a change in the auditory system, and not simply due to a measurement error (Keppler et al., 2010). Therefore, a good test-retest reliability of DPOAEs in a group of workers in the beverage manufacturing industry will suggest a high level of confidence in the test to monitor noise-induced cochlea changes over time, making it a feasible test to be included in the annual medical surveillance test battery.

An effective annual medical surveillance test battery should successfully separate a large population into two groups, those who have normal hearing (pass) and those who present with abnormal results and require further testing (referral) (Johnson, 2002). Thus, medical surveillance programs are intended to identify those who may have, or those who are likely to have, a hearing disorder. They should strive to be efficient and must be properly evaluated with specific parameters in order demonstrate acceptable performance (Johnson, 2002). These parameters include sensitivity, specificity, efficiency and predictive value (Roeser, 1996).

Sensitivity may be defined as the ability of the screening procedure to identify the target population accurately, in terms of the number of individuals screened who actually have hearing loss (Johnson, 2002). These results are referred to as true-positives, i.e. accurate test results that identify individuals with a condition who actually have the condition (Johnson & Danhauer, 2002). Therefore, the sensitivity of a test is its accuracy to correctly identify participants with a disorder and is calculated by dividing the true-positive results by the total number of individuals with positive test results (Zhu, Zeng & Wang, 2010). Specificity may be defined as the ability of the test procedure to not identify those who truly do not have the disorder that the test is designed to identify (Johnson, 2002). These results are referred to as true-negatives, i.e. accurate test results that dismiss 'normal' individuals as being condition free (Johnson & Danhauer, 2002). Therefore, the specificity of a test is its accuracy in correctly rejecting patients without a particular disorder and is calculated by dividing the true-negative results by the total number of individuals with negative test results (Zhu, Zeng & Wang, 2010). The efficiency of a test procedure

refers to the test's overall accuracy (Roeser, 1996). Roeser (1996) explains that the efficiency of a test procedure can be calculated by dividing the true-positive plus the true-negative findings by the total number of patients.

The final parameter in demonstrating acceptable performance is the predictive value. According to Roeser (1996) the predictive value of a test is related to the number of false-negative and false-positive results. False-negatives are inaccurate test results that dismiss individuals as not having a condition when they actually do have the condition (Johnson & Danhauer, 2002). False-negatives or the negative predictive value is calculated by dividing the true-negative findings by the total number of negative tests (Roeser, 1996). False-positives are inaccurate test results that identify 'normal' individuals as having a condition (Johnson & Danhauer, 2002). False-positives or the positive predictive value is calculated by dividing the true-positive findings by the total number of positive tests (Roeser, 1996). Furthermore, Roeser (1996) states that the predictive value is influenced by the prevalence of a particular disorder. The prevalence of a disorder is defined as the number of individuals having a pathological condition at one point in time per the number of people who may be at risk (Browner, Newman, et al., 1988, as cited in Johnson & Danhauer, 2002).

Considering the above, it is evident that there are several factors and parameters that need to be considered in order for an annual medical surveillance test battery, including DPOAEs, to be effective, efficient and able to demonstrate acceptable performance. Following years of interest in the potential of OAE testing in occupational health, the Health & Safety Executive (HSE) in the United Kingdom decided to take positive action to make a concerted effort to achieve consensus on the way forward for research and practical application of OAE testing (Forshaw, 2011). An international expert symposium on the usefulness of OAE testing in occupational health surveillance was held in Manchester, United Kingdom in February 2011, and attracted the attention of worldwide leading researchers and practitioners in this field (Forshaw, 2011). Participants from the United Kingdom, France, Netherlands, Italy and the United States of America gathered to discuss the potential use of OAEs in occupational health surveillance; to explore the current scientific position; to discuss the barriers involved in advocating this new

method; to identify the gaps in understanding and to decide the future direction for the inclusion of OAEs in annual medical surveillance programs (Forshaw, 2011).

The outcomes of the symposium suggested a three stage approach, i.e. baseline pure tone audiometry and OAE testing, interval OAE monitoring, and pure tone audiometry as and when cochlea changes are identified by OAEs. The limitations for the application of OAEs in occupational health surveillance are in accordance with those found by previous researchers, i.e. the inclusion of tympanometry is required in the annual medical surveillance program to eliminate middle ear pathologies; the need to ensure appropriate probe placement; age may affect the suitability of OAEs; and lastly, OAEs depend on stimulus level and test parameters which need to be controlled and agreed upon to achieve comparable results (Forshaw, 2011). This was the first symposium of its kind and it was hoped that the event would be a catalyst to inspire future research to focus on the usefulness of OAEs in annual medical surveillance programs.

In response, in November 2012, the Council for Scientific and Industrial Research (CSIR) in Pretoria, South Africa, held an international discussion in collaboration with the HSE on the use of OAEs in medical surveillance programs. The aim of the discussion was to share recent research findings on the implementation of OAEs in the early identification of NIHL and the current work on developing standardized terminology and testing methods for OAEs in a health surveillance setting. This discussion was the first of its kind to take place in South Africa and it was found that many of the limitations experienced internationally for the application of OAEs in annual medical surveillance programs are also experienced within the South African context. In view of this current debate and the literature evidence presented, it was essential to consider the feasibility of including DPOAEs in the early identification of noise-induced cochlea changes for a group of employees in the beverage manufacturing industry in South Africa.

3.4 CONCLUSION

It is evident that both local and international studies are in agreement suggesting that pure tone audiometry may have fallen short in the detection of NIHL sufficiently early in order to prevent NIHL from developing further (Clark, 2005). The possible inclusion of DPOAEs in the annual

medical surveillance test battery will require DPOAEs to supplement, rather than replace pure tone audiometry in the early detection of noise-induced cochlea changes. Kemp (1997) states that there is a significant correlation between OAE strength and hearing threshold in a mixed population of normal and impaired ears. OAEs may produce thresholds of 0 – 30 dB SPL. However, it is not possible to accurately translate a person's OAE level into an audiometric threshold (Kemp, 1997). Hall (2000) provides a model for the inclusion of OAEs in hearing conservation programs. The model assumes that pure tone audiometry remains the standard or traditional measure of hearing sensitivity, i.e. calculations of the percentage loss of hearing and decisions regarding possible compensation for hearing impairment are made utilizing audiometric data.

However, OAEs are employed exclusively to monitor the status of the cochlea until changes are observed. The possible inclusion of this model in the SANS: 10083 (2004) annual medical surveillance test battery would ensure that the reliable and accurate pure tone audiometric thresholds are utilized in the calculation of permanent hearing loss, but, the identification and prevention of NIHL would be enhanced by the use of DPOAEs in an effective annual medical surveillance test battery. Due to the sensitivity of OAEs to OHC dysfunction (Konopka et al., 2005), the use of DPOAEs would seem to be of potential value in industrial audiology and hearing conservation programs (Hall, 2000). The fact that DPOAEs are quick, simple to conduct and do not require a sound booth (Johnson, 2002) further augments their use in an occupational setting where testing would be conducted by a trained occupational nurse with severe time constraints. Thus, the current study aims to determine the feasibility of including DPOAEs in the annual medical surveillance test battery for the identification of NIHL in a group of employees in the beverage manufacturing industry. The following chapter is a detailed description of the methodological framework followed in the study.

CHAPTER FOUR: METHODOLOGY

4.1 INTRODUCTION

This chapter includes the aims and objectives of the study, the study design, a description of the sample and sampling method utilized, data collection instruments and the procedure used to collect the data. A description of how the data was analyzed, the factors considered relating to validity and reliability of the study, as well as the ethical and legal considerations is also discussed.

4.2 AIM

The aim of the study was to determine the feasibility of including 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.

In order to realize the aim of the study, the following objectives were generated.

4.3 OBJECTIVES

- 4.3.1 To determine the sensitivity and specificity of distortion product otoacoustic emissions in the identification of noise-induced hearing loss in a group of employees in a manufacturing industry.
- 4.3.2 To determine whether distortion product otoacoustic emissions are able to detect subtle cochlear changes for the early identification of noise-induced hearing loss as compared to pure tone audiometry.
- 4.3.3 To determine the test-retest reliability of distortion product otoacoustic emissions in identifying early noise associated hearing loss for a group of employees in the beverage manufacturing industry.

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4.4 STUDY DESIGN

A cross-sectional design was utilized in this study. A cross-sectional analysis involves observations of a sample, or a cross section of a population or phenomenon, that are made at one point in time (Babbie, 2010). This can be achieved by studying the relationship between different variables at this single point in time (Bailey, 1982 in Leedy and Ormrod, 2005). It allows the researcher to study participants in the same time period but at different stages or levels of involvement (Drummond, 1996, Jackson, 2008). Therefore, for the purposes of this study, the researcher was able to group participants with various years of occupational noise exposure and conduct the annual medical surveillance test battery and DPOAEs at a point in time. For this reason, cross-sectional studies are relatively quick, cheap and easy to carry out, and are straightforward to analyze (Drummond, 1996)

This type of analysis is not without fault. Conclusions are based on observations made at a point in time, however, these studies typically aim at understanding causal processes that occur over time (Drummond, 1996; Babbie, 2010). Babbie (2010) states that conclusions of cross-sectional studies may be limited to one period of time and are subject to further tests based on data collected at other times. Therefore, for the purposes of this study, a review of the literature was done to locate other studies of a similar nature and analyze previous findings in conjunction with the findings of the current study.

In order to realize objective three of the study, i.e. to determine the test-retest reliability of distortion product otoacoustic emissions, a repeated measures within-in participant design was utilized. A repeated measures design is one in which a single sample of individuals is measured more than once using the same dependent variable and the same subjects are used in all the treatment conditions (Gravetter & Vallnau, 2009; Stommel & Wills, 2004). Repeated measures designs involve at least three successive observations on the participants of the study and there are no set criteria regarding the time period between measurements (Stommel & Wills, 2004). Mitchell & Jolley (2010) describe two advantages of the repeated measures design. The first advantage is that this type of design aims to reduce random error by reducing individual differences, thereby, increasing the internal validity of the study. The second advantage is that

the repeated measures design increases the number of observations you get from each participant, thereby, reducing random error and increasing the power of the study.

In addition to the cross-sectional and repeated measures design, quantitative research methods of analysis were utilized in this study. Quantitative methods involve "identifying the characteristics of an observed phenomenon or exploring possible correlations among two or more phenomena" (Leedy and Ormrod, 2005, p. 179). This allowed the researcher to explore the relationship between participants with varying years of occupational noise exposure and their corresponding DPOAE results. Additionally, this type of approach allowed for conclusions to be made regarding the sensitivity and specificity of DPOAEs, by applying the relevant formulae to the data collected. The test-retest reliability of DPOAEs could also be determined using this method as the researcher was able to make inferences by comparing the DPOAE data collected.

4.5 STUDY POPULATION

A review of the company's 2011/2012 noise survey report was done and eight demarcated noise zones were identified. There were approximately 105 employees within the demarcated noise zones. All employees working within the noise zones were approached to participate in the study. Thereafter, participants were selected according to set inclusion and exclusion criteria.

4.5.1 Participant selection criteria

4.5.1.1 The inclusion criteria is recorded in Table 4.1 overleaf:

Table 4.1: Participant inclusion criteria

4.5.1.1.1 Age range	Participants were required to be within the age range of 18-45 years. A			
	minimum of 18 years is stipulated as it is in accordance with the Basic			
	Conditions of Employment Act (Department of Labour, 1997) which states			
	that no person may employ a child, where a 'child' refers to an individual who			
	is under 18 years of age. A maximum of 45 years was stipulated as the onset			
	of presbycusis may occur at any time from the third to sixth decade of life			
	(Timiras, 2007).			
4.5.1.1.2 Occupational	Participants were required to work in the beverage manufacturing setting for			
setting	nine hours a day, for five days a week (Department of Labour, 1997).			
	Furthermore, participants were required to be routinely exposed to			
	occupational noise and working within demarcated noise zones (SANS:			
	10083, 2004), during which hearing protection devices are worn at all times.			
4.5.1.1.3 Noise free period	In accordance with the annual medical surveillance test battery protocol			
	outlined by the SANS: 10083 (2004), each participant was assessed following			
	a period of at least 16 hours during which the participant was not exposed to			
	noise at, or above the noise rating limit of 85dBA, to exclude the possibility of			
	temporary threshold shifts (Jordan & Roland, 2000).			
4.5.1.1.4 Gender	Participants were either male or female and of any ethnicity as these factors			
	were not under investigation in this study.			

4.5.1.2 The exclusion criteria is recorded in Table 4.2 overleaf:

Table 4.2: Participant exclusion criteria

	Participants with a family history of hearing loss were excluded from the study			
4.5.1.2.1 Family history of	as a genetic basis accounts for approximately half of the cases of hearing			
hearing loss	impairment worldwide (Sheth & McHugh, 2007).			
4.5.1.2.2 Medical history	Participants who presented with any of the endogenous or exogenous			
7.0.1.2.2 Modelan Mistory	audiological disorders were excluded from the study. Endogenous auditory			
	disorders are acquired and hereditary, whereas exogenous disorders refer to			
	inflammatory diseases, recreational noise, injury and trauma, ototoxicity, as			
	well as viral and bacterial diseases (Bess & Humes, 2003). The current study			
	was involved in the identification of noise-induced hearing loss and therefore,			
	hearing loss as a result of other endogenous or exogenous audiological			
	disorders may have impacted on the results of the study.			
	Participants with any of the following medical conditions were excluded from			
	the study (Jerger & Jerger, 1988; Bess & Humes, 2003): Acoustic			
	schwannoma/ neuroma, glomus jugular tumors, cholesteatoma, collapsing ear			
	canal, Menier's disease, otosclerosis, history of otitis media, Paget's			
	syndrome, diabetes mellitus, multiple sclerosis, facial nerve disorders, head			
	trauma or skull fractures, infectious diseases, meningitis, sudden idiopathic			
	hearing loss, hereditary familial sensorineural hearing loss. Participants			
	presenting with infectious diseases were excluded from the study if the disease			
	was disclosed, however, this could not be controlled for if a participant did not			
	disclose the presence of an infectious disease (e.g. HIV).			
	Those participants exposed to ototoxic medication, such as, salicylates, non-			
	steroidal anti-inflammatory drugs, aminoglycosides, diuretics, chemo-			
	therapeutic agents, quinine, mucosal protectants and narcotic analgesics, were			
	excluded from the study as these medications may result in a hearing loss			
	(Kaufman, 2000).			
	Participants exposed to noise as a result of recreational activities, such as,			
4.5.1.2.3 Recreational history	target practice, trap shooting, hunting, snowmobile use, motor-cycling, or the			
	use of chain saws or power tools were also excluded from the study (Sataloff,			
	Hawkshaw & Sataloff, 2011).			

4.5.2 Recruitment of Participants

For the purposes of this study, participants were sourced from a beverage manufacturing company in the greater Durban area. This industry consists of carbonated soft drinks, bottled and flavoured water, single serve dairy products and nutritional drinks (Market Solutions South Africa, 2012). The management of a beverage manufacturing company meeting the above mentioned definition was approached to participate in the study.

The participants of the study consisted of employees routinely exposed to occupational noise and working within demarcated noise zones. This was determined by conducting a site survey and reviewing the 2011/2012 noise survey report conducted on site. Thereafter, a list of all the employees within each demarcated noise zone was obtained from the manager of the company. These employees were invited to participate in the study as part of the company's annual medical surveillance program.

4.6 SAMPLING METHOD

This study involved the use of a purposive convenience sampling technique, whereby the researcher selected a sample of participants from a beverage manufacturing company in the greater Durban area who were available and accessible. Convenience sampling provides the researcher with access to participants who are readily available, whereas, purposive sampling allows the researcher to recruit participants who possess the relevant information required (Newell & Burnard, 2011). The primary goal of purposive sampling is to represent certain participant characteristics relevant to the investigation (Stommel & Wills, 2004). In purposive convenience sampling, the researcher specifies set participant inclusion and exclusion selection criteria, and then recruits as many participants as are required who meet these criteria (Newell & Burnard, 2011). This type of sampling is highly selective and results in a unique group of individuals (Newell & Burnard, 2011).

Thus, for the purposes of this study, the researcher approached the manager of a beverage manufacturing company via written, telephonic and personal communication to participate in the

study (Refer to Appendix A). A review of the company's 2011/2012 noise survey report was done and eight demarcated noise zones were identified. In addition, noisy processes were identified. These included driving of forklift trucks, angle grinding, use of the pneumatic and impact wrenches, as well as use of the cut-off saw and grinder. The researcher obtained a list of employees located in each demarcated noise zone from the manager at the selected company, which allowed for sample selection. In total, there were approximately 105 employees within all the demarcated noise zones. Therefore, due to the limited number of accessible employees a purposive convenience sample was utilized in order to realize objective one of the study. The researcher arranged the list of employees in alphabetical order. A number was assigned to each employee and every employee on the list was approached to participate in the study. Thereafter, participants were selected according to set inclusion and exclusion criteria (Refer to page 49 and 50). Several of the 105 employees were excluded from the study as they exceeded the age limit of 45 years and had been exposed to occupational noise for longer than 10 years. Furthermore, 5 participants were excluded from the study following completion of the case history questionnaire due to a history of Meningitis, previous treatment with ototoxic medication for Tuberculosis, previous ear surgery, history of impacted occluding cerumen which was confirmed on otoscopy and a family history of hearing loss. Hence, the study consisted of 60 participants.

4.6.1 Sample Size

With regards to the number of participants in the study, there are established methods for determining sample size in quantitative research. This involves balancing cost and access against the level of precision required in relation to the variability of the population on the characteristics being measured (Punch, 2006). Additionally, for an accurate estimate of the relationship between variables, a quantitative study method requires a sample of hundreds or even thousands of participants (Hopkins, 2000). A simple sample size calculation was utilized in the study to estimate the required sample size of 55 participants. This was done with the assistance of a trained statistician following the analysis of the pilot study data. Sensitivity and specificity of DPOAEs at each frequency was calculated using the specified formulae. These values were subsequently entered into a sample size calculator utilizing a confidence interval of 95% for each ear to determine an appropriate sample size of 50 participants for objective one of the study.

Thereafter, the mean and standard deviation for pure tone air conduction audiometry and DPOAEs at each frequency was calculated and a paired t-test was done at a confidence interval of 95% to determine an appropriate sample size of 55 participants. Therefore, all the employees within the beverage manufacturing company who were routinely exposed to occupational noise and working within demarcated noise zones were invited to participate in the study.

Thereafter, a stratified sample approach was utilized in order to realize objective two of the study (McBurney & White, 2007). If a population from which a sample is to be drawn does not constitute a homogenous group, stratified sampling is applied in order to obtain a representative sample (Kothari, 2008). This approach identifies subgroups that are likely to differ markedly in their responses. These subgroups are represented according to some predetermined proportion, generally in the same proportion as they exist in the population (McBurney & White, 2007). Hence, the population is divided into several sub-populations that are individually more homogenous than the total population (Kothari, 2008). According to this stratified sample approach, the selected participants were divided into four test groups according to the number of years that they have been exposed to occupational noise within the beverage manufacturing industry. 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 study consisted of 60 participants and each group comprised of 15 participants. This stratified sampling technique results in more reliable and detailed information (Kothari, 2008). In addition, it reduces the number of cases needed to achieve a given degree of accuracy or representativeness (Connaway & Powell, 2010). The stratified sampling method of the test groups is represented visually in Figure 4.1 overleaf.

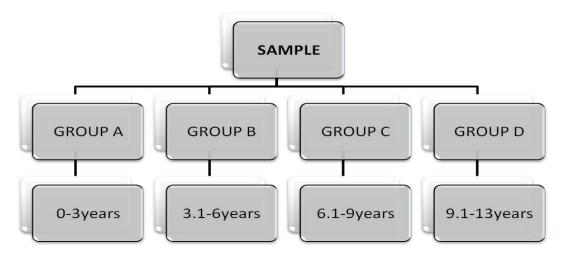


Figure 4.1 Sampling method of the test groups

4.6.2 Description of Participants

The study consisted of 60 participants within various noise zones in a beverage manufacturing company in the greater Durban area. A simple sample calculator estimated a required sample size of 55 participants, however, an additional 5 participants were included to allow for an equal number of participants in each group (i.e. 15 participants) and to account for non-responses, incomplete information and attrition over time. An attrition rate of 10% is common at each occasion on which measurements are made after the initial measurement (Sim & Wright, 2010). The intended sample size of 55 participants was, therefore, increased to 60 participants to allow for these potential loss es, to enable the actual achieved sample size to provide the desired precision or power (Sim & Wright, 2010). The participants were stratified into four test groups depending on the number of years of occupational noise exposure. 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 occupational noise exposure. Each group comprised of 15 participants. 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. Table 4.3 be low indicates a summary of characteristics of each test group.

Table 4.3: Characteristics of Group A, B, C, D

	GROUP A	GROUP B	GROUP C	GROUP D
Years of noise exposure (years)	0-3	3.1-6	6.1-9	9.1-13
Mean age (years)	28.6	29.3	34.5	39.6
Min age (years)	23	24	26	31
Max age (years)	38	40	45	45
Average history of occupational noise exposure (years)	2	4.8	7.3	11.4
Min history of occupational noise exposure (years)	0.2	3.2	6.3	9.2
Max history of occupational noise exposure (years)	3.6	6	8.6	13

4.6.3 Description of Test Environment

All test procedures were conducted in a clinic setting at a beverage manufacturing company. A 1x1 audiometric booth was utilized for pure tone audiometry and DPOAE testing. Sound pressure levels within the audiometric booth were calculated and were in accordance with the recommended limits put forth by SANS 10182-1:2004 (Refer to Appendix B). To determine whether a given room is sufficiently quiet for audiological testing, the ambient noise levels in the room are measured with a sound level meter (Gelfand, 1997). Sound level measurements using broad band filters and a time weighted average of 15 minutes were conducted once daily in the clinic, prior to testing to exclude the influence of ambient noise on audiometric test results. The CEL450 sound level meter was utilized. Average sound pressure levels over a period of nine days were calculated to be 35.1dB(A) (Refer for Appendix C). The A-scale is representative of the frequency response of the human ear, which is less sensitive to low frequency than to high frequency sound (Noise Control Reference, 2012). 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 (Noise Control Reference, 2012). Therefore, the average ambient noise levels within the clinic were acceptable for testing to occur.

4.7 DATA COLLECTION INSTRUMENTS

The following instruments were used to collect the data. All equipment used was calibrated in accordance with the South African National Standards (2004) document. The two phase methodology and data collection instruments are represented visually in Figure 4.2 below.

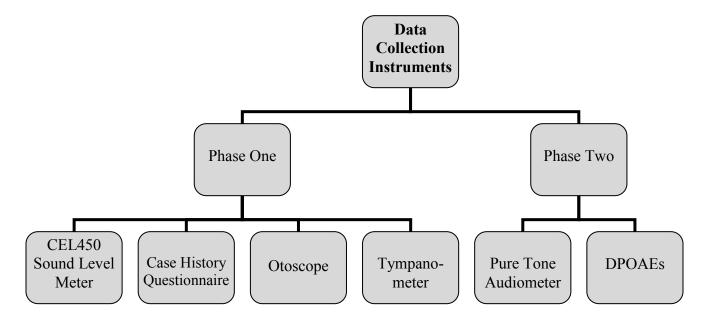


Figure 4.2 The two phase methodology and data collection instruments

Phase One

4.7.1 Noise Measurements

4.7.1.1 Instrument

The Cel450 Sound Level Meter was used to conduct daily noise measurements within the test environment. The Sound Level Meter was calibrated accordingly (Refer to Appendix D). To determine whether a given room is sufficiently quiet for audiological testing, the ambient noise levels in the room are measured with a sound level meter (Gelfand, 1997). 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 (Noise Control Reference, 2012). The

A-scale is representative of the frequency response of the human ear, which is less sensitive to low frequency than to high frequency sound (Noise Control Reference, 2012).

4.7.2 Case History Questionnaire (Pre-selection tool)

4.7.2.1 Instrument

A pre-test Case History Questionnaire was administered to selected employees within the beverage manufacturing company (Refer to Appendix E & F). Case history information plays a critical role in audiologic interpretation (Robinette & Cevette, 2002). The most efficient way to take an audiologic case history is to follow the medical model, whereby direct, highly specific, and briefly stated questions are presented prior to the first test (Robinette & Cevette, 2002). This method provides the maximum amount of information in the minimum amount of time (Rosenberg, 1978, as cited in Robinette & Cevette, 2002). In addition, Robinette & Cevette (2002), state that the use of a questionnaire limits the researcher's influence on the participant's response. Therefore, a properly designed questionnaire forces participants to choose from a list of symptoms that best describe their experiences

The case history questionnaire comprised of both open and close-ended questions regarding the participant's biographical, family, medical, audiological, occupational and recreational history. The purpose of the case history questionnaire was to ensure that all participants met the sample selection criteria of the study. The case history questionnaire was available in both English and isiZulu to ensure that it was linguistically and culturally suitable for each participant and allowed the participant to answer the questions in a language in which they were comfortable. All participants were required to individually complete the pre-test case history questionnaire which reduced the possibility of tester bias. In some cases, the researcher verbally clarified the information received from the case history questionnaire with the participant.

4.7.3 Otoscopy

4.7.3.1 Instrument

A Welch Allyn handheld Otoscope was used to conduct otoscopic examinations on all participants. Otoscopy identifies pathological conditions of the pinna, ear canal, tympanic membrane, and surrounding areas (Gelfand, 2001; Roeser & Wilson, 2008). It must identify malformations of the auricle or the external auditory canal and signs of trauma and infection and must rule out obstruction or collapse of the external auditory canal (Rappaport & Provencal, 2002). Otoscopy identifies conditions that may alter audiological test results or those that may require certain precautions.

4.7.4 Tympanometry

4.7.4.1 Instrument

The GSI Screening Tympanometer was used to conduct tympanometry on all participants. The Tympanometer was calibrated in accordance with the South African National Standards 10154-1: 2004, ISO 389-4, ISO 389-7 and IEC 645-2 (Refer to Appendix G). Tympanometry provides

an objective means for determining the mobility of the tympanic membrane and the ossicular chain (Gelfand, 1997). Used in conjunction with other audiologic test procedures, tympanometry can provide valuable, augmentative information that is not otherwise available (Fowler & Shanks, 2002). Tympanometry is uniquely suited to identify the physical changes associated with middle ear pathology, and therefore, is typically performed to screen for middle ear disorders or to determine the nature of a conductive lesion (Fowler & Shanks, 2002). It is possible that the influences of middle ear disorders are negatively impacting on the audiometric results of employees in various industries and settings. In addition, normal middle ear functioning is essential prior to DPOAE testing as OAEs are low sounds that are generated in the cochlea and measured in the outer ear canal (Wagner et al., 2008). Therefore, this has implications for the early identification of employees presenting with middle ear disorders and referrals to the appropriate medical practitioners for suitable treatment. Tympanometry results were recorded on an Audiometric record form (Refer to Appendix H). The normative data for tympanometry is

displayed in Table 4.4 below.

Table 4.4: Normative data for Tympanometry (Grason-Stadler, 2011)

	Normative values
Ear Canal Volume	0.2 - 2.0ml
Static Compliance	0.2 - 1.8ml
M.E Pressure	+50150daPa

Phase Two

4.7.5 Pure tone air conduction audiometry

4.7.5.1 Instrument

An Interacoustics AS216 Audiometer was used to obtain pure tone air conduction audiograms for all participants. Standard TDH 39P supra-aural headphones were used for pure tone air conduction audiometry. The audiometer was calibrated on 25/10/2011 in accordance with the South African National Standards 10154-1: 2004, ISO 389-4, ISO 389-7 and IEC 645-2 (Refer to Appendix P). The SANS 10083 (2004) defines the audiogram as a chart, graph or table indicating the hearing levels of an individual as a function of frequency. The hearing threshold is the lowest intensity at which a listener can identify the presence of a pure tone signal 50% of the time (Harrel, 2002). Therefore, pure tone audiometry is used to quantify the degree of hearing loss and to gain information concerning the site of lesion and the possible nature of the cause (Harrel, 2002). Pure tone threshold measurement provides a convenient, reliable way to quantify auditory sensitivity (Harrel, 2002).

4.7.6 Distortion product otoacoustic emissions (DPOAE) testing

4.7.6.1 Instrument

BioLogic AuDX SCOUT Otoacoustic Emission Meter was used to collect data. The 750-8000Hz Diagnostic Test was used to measure the DPOAEs (Biologic Systems Corp., 2001). The

BioLogic AuDX SCOUT Otoacoustic Emission Meter was calibrated accordingly in May 2012. DPOAEs assess the functional status of the damaged cochlea in a fast, non-invasive and objective manner (Balatsouras et al., 2005). DPOAEs are especially well-suited as a monitoring tool for the early detection of NIHL due to their better performance in the high frequency range (Hall, 2000). The geometric mean of the frequencies and the values of f1 and f2 are displayed in Table 4.5 below. 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 (Biologic Systems Corp, 2001). The DPOAE results were plotted on a DP-Gram generated by a computer system with SCOUT software. Furthermore, the DPOAE test duration was recorded using a stopwatch and this was documented on an Audiometric record form (Refer to Appendix H). The 65/55 Vanderbilt normative data was utilized in the interpretation of the data and outer hair cell function was considered to be normal if the distortion product minus the noise floor was 6dBnHL or above (Biologic Systems Corp., 2001).

Table 4.5: Primary tones and geometric means of the DPOAE 750-8000Hz Diagnostic Test

750-8000Hz Diagnostic	Primary tone (f1)	Primary Tone (f2)	Geometric Mean
Test			
Hz	625	750	685
Hz	833	1000	913
Hz	1667	2000	1826
Hz	2500	3000	2739
Hz	3333	4000	3651
Hz	5000	6000	5477
Hz	6667	8000	7303

4.8 PILOT STUDY

A pilot study is used to determine if there are insufficiencies in the design of the case history questionnaire, thus allowing the researchers to address those deficiencies before the main study is conducted (Leedy & Ormrod, 2005). In addition, Leon, Davis & Kraemer (2011) state that the purpose of conducting a pilot study is to examine the feasibility of an approach that is intended to be used in a larger scale study. A pilot study can be used to evaluate the feasibility of

recruitment, randomization, retention, assessment procedures, and implementation of the novel intervention and each of these can be quantified, in order that study components that are deemed infeasible or unsatisfactory should be modified in the subsequent trial or removed altogether (Leon et al., 2011). In preparation for the main study, a pilot study can be treated as a test run to enable all procedures to be put in place, including inclusion and exclusion criteria, storage and testing of equipment and materials, training of staff in administration procedures and assessment of the intervention (Lancaster, Dodd & Williamson, 2004).

There are two types of pilot studies, namely, internal and external pilot studies (Lancaster et al., 2004). The authors explain that an internal pilot is carried out on the first pre-specified number of patients entering the trial, whereas, an external pilot is a stand-alone piece of work planned and carried out independently to the main study. Although both types of pilot studies have advantages and disadvantages, the current study utilized an external pilot study.

As pilot studies are exploratory ventures, it is quite reasonable and expected that a pilot study is proposed with no other preliminary pilot data supporting the proposal and that its proposed sample size is based on pragmatics such as patient flow and budgetary constraints (Leon et al., 2011). In general, sample size calculations may not be required for a pilot study (Thabane et al., 2010). If the population is small or if there is limited access to members of a population, then the pilot study may include two or three participants (Carter, 2010). A pilot study should be representative of the target study population and large enough to provide useful information about the aspects that are being assessed for feasibility (Thabane et al., 2010).

Therefore, for the purposes of this study, an external pilot study was conducted on ten employees within the administration building in the beverage manufacturing company, who did not participate in the main study. This allowed the researcher to modify components of the study, where necessary, prior to the actual data collection process. This ensured that all procedures were conducted as efficiently and accurately as possible in the main study.

The results of the pilot study revealed that additional noise in the clinic contributed to overall ambient noise, e.g. the telephone, the cleaner and other employees entering the clinic.

Additionally, truck deliveries made to the beverage manufacturing company outside the clinic contributed to the ambient noise. In order to control for these influences, all calls were directed to the telephone furthest from the room where testing was conducted, the clinic was to be cleaned in the morning prior to the commencement of testing and lastly, testing was not scheduled during the period in which deliveries outside the clinic were expected. Furthermore, this confirmed the need to conduct sound level measurements in the clinic daily prior to the commencement of testing (Refer to Appendix C). No changes to the case history questionnaire or test procedures were required following the pilot study.

The results of the pilot study are also used to determine a more accurate estimation for the sample size of the main study (Carter, 2010). With the assistance of a trained statistician, the pilot study results were analyzed according to objective one and two of the main study. The results revealed that a sample size of 55 participants would be sufficient for the main study.

4.9 DATA COLLECTION PROCEDURE

The following is a detailed description of the data collection procedure:

4.9.1 Ethical Approval

• A research proposal was submitted to the University of KwaZulu-Natal Biomedical Ethics Committee and ethical approval was obtained prior to the commencement of the data collection (Refer to Appendix J).

4.9.2 Recruitment of Participants

• The researcher approached a manager of beverage manufacturing company via written, telephonic and personal communication (Refer to Appendix A). The researcher obtained verbal and written consent from the manager for employees of the company to participate in the study (Refer to Appendix K). The manager was assured that no legal matters may

arise as a result of the participation of their employees in the study as the participants would undergo routine annual medical surveillance.

- A review of the company's 2011/2012 noise survey report was done and eight demarcated noise zones were identified. In addition, noisy processes were identified.
 These included driving of forklift trucks, angle grinding, use of the pneumatic and impact wrenches, as well as use of the cut-off saw and grinder.
- The researcher obtained a list of employees located in each demarcated noise zone from the manager at the selected company, which allowed for sample selection. In order to realize objective one of the study, a purposive convenience sample was utilized. The researcher arranged the list of employees in alphabetical order. A number was assigned to each employee and every employee on the list was approached to participate in the study.
- Informed consent was obtained from all participants who met the sample selection criteria and were included in the study (Refer to Appendix L & M).
- Participants were provided with information documents to further enhance their knowledge of the study (Refer to Appendix N & O).
- A stratified sample approach was utilized. According to this approach, the selected participants were divided into four test groups according to the number of years that they have been exposed to occupational noise within the beverage manufacturing industry. 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. Each group comprised of 15 participants.

4.9.3 Noise Measurements

 Sound level measurements using broad band filters and a time weighted average of 15 minutes were conducted once daily in the clinic, prior to testing to exclude the influence of ambient noise on audiometric test results (Refer to Appendix C). Average sound pressure levels were calculated to be 35.1dB(A), which is within the recommended 43dB(A) (Noise Control Reference, 2012). The CEL450 Sound Level Meter was calibrated accordingly (Refer to Appendix D).

4.9.4 Pilot Study

• Prior to the actual data collection process, an external pilot study was conducted on ten employees within the beverage manufacturing company, who did not participate in the main study. This allowed the researcher to modify components of the study, where necessary. The selected participants for the pilot study were sourced from the administration building within the company. These participants were required to meet the specified sample selection criteria (Refer to Table 4.1, p. 49 and Table 42, p. 50).

4.9.5 Case History Questionnaire (Pre-selection tool)

• Participants were required to complete a case history questionnaire on the day of testing, once informed consent (Refer to Appendix L & M) was obtained. The case history questionnaire comprised of both open and close-ended questions regarding the participant's biographical, family, medical, audiological, occupational and recreational history. The purpose of the case history questionnaire was to ensure that all participants met the sample selection criteria of the study. Therefore, the questionnaire was not analyzed statistically. The case history questionnaire was available in both English and isiZulu to ensure that it was linguistically and culturally suitable for each participant and allowed the participant to answer the questions in a language in which they were comfortable. All participants were required to individually complete the pre-test case history questionnaire which reduced the possibility of tester bias. In some cases, the researcher verbally clarified the information received from the case history questionnaire with the participant.

• Five participants were excluded from the study following completion of the case history questionnaire due to a history of Meningitis, previous treatment with ototoxic medication for Tuberculosis, previous ear surgery, history of impacted occluding cerumen which was confirmed on otoscopy and a family history of hearing loss.

4.9.6 Otoscopy

- Each participant underwent a bilateral otoscopic examination. Participants were instructed appropriately prior to the otoscopic examination (Refer to Appendix O & P). An inspection of the external ear was made in an attempt to identify congenital malformations. The ear canal was then inspected with the use of a handheld Welch Allen otoscope, to provide illumination and magnification of the ear canal and tympanic membrane (Rappaport & Provencal, 2002). The observations made by the researcher were recorded on an Audiometric record form (Refer to Appendix H). The occupational nurse was notified of any significant findings and the participants were thereafter monitored via the company's existing management protocol.
- One participant who presented with impacted occluding cerumen was excluded from the study following otoscopy.

4.9.7 Tympanometry

• All participants underwent Tympanometry. The GSI Screening Tympanometer was used and had been appropriately calibrated (Refer to Appendix G). Participants were instructed appropriately (Refer to Appendix N & O). The classification system modified by Jerger (1970), Jerger et al. (1972) and Liden et al. (1974), as cited in Fowler & Shanks (2002) was used in the interpretation of the tympanometry results. Participants who presented with a Type A tympanogram, characterized by a peak of normal height and representing normal middle ear functioning, were included in the study. These results were recorded on an Audiometric record form (Refer to Appendix H). The occupational nurse was

notified of any significant findings and the participants were thereafter monitored via the company's existing management protocol.

• None of the participants presented with Type Ad, As, B or C tympanograms.

4.9.8 Pure Tone Audiometry

• Each participant underwent pure tone air conduction audiometry. The Interacoustics AS216 Audiometer was utilized to obtain auditory thresholds at 500, 1000, 2000, 3000, 4000 and 6000Hz. The audiometer was calibrated in accordance with the South African National Standards 10154-1: 2004, ISO 389-4, ISO 389-7 and IEC 645-2 (Refer to Appendix I). The participant was seated in a sound treated booth and instructed appropriately (Refer to Appendix N & O). The descending/plateau method was used to obtain hearing thresholds (Carhart & Jerger, 1959). The results were recorded on an Audiometric record form (Refer to Appendix H).

4.9.9 Distortion product otoacoustic emissions (DPOAEs)

• All participants underwent diagnostic DPOAE testing. The BioLogic AuDX SCOUT Otoacoustic Emission Meter was used to collect data. The 750-8000Hz Diagnostic Test was used to measure the DPOAEs. This included the geometric mean frequencies of 750, 984, 1500, 2016, 3000, 3984, 6000 and 7969Hz. Participants were seated in a sound treated booth and instructed appropriately (Refer to Appendix N & O). All tests were completed in one ear before testing the other ear. An appropriately sized probe tip was selected an inserted into each participant's ear. A good probe fit is essential to successful DPOAE testing and the following steps were utilized as recommended by the Biologic Systems Corp. (2001): A probe tip approximately the same diameter or slightly larger than the ear canal was selected; the pinna was pulled outward to open the ear canal; the probe tip was inserted into the ear canal gently but securely, with a slight twisting motion; and lastly the researcher ensured that the probe tip was correctly positioned, before gently letting go of the probe.

- The DPOAE test was conducted three times on each ear, per participant. The three measurements were made following immediately one after the other on the same day. The researcher repeated the test 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. This allowed the researcher to investigate test-retest reliability using a repeated measures study design, in order to realize objective three of the study.
- The results were recorded automatically on a DP-Gram as well as on the Audiometric record form (Refer to Appendix H). A representative DP-Gram stimulus protocol should include a frequency range of 0.5 to 8kHz with respect to the geometric mean frequency, along with an f^2/f^1 ratio of 1.22, a level difference of 10dB and absolute levels of L1=65dB SPL and L2=55dB SPL (Burkard et al., 2007). Therefore the current study utilized a fixed f2:f1 ratio of 1.22 with the f1 equal to 65dB and the f2 equal to 55dB across the geometric mean frequencies (Biologic Systems Corp., 2001). A f2:f1 ratio of 1.22 results in the largest distortion products (Biologic Systems Corp, 2001). When exploring short term DPOAE repeatability the differences between two DPOAE frequency sweeps at frequencies between 0.5 to 4kHz, i.e. geometric mean of f1 and f2; L1=L2 at 35, 45 and 55dB SPL, must exceed approximately 6dB to be statistically significant when tested in the same trial, using immediate test-retest methods (Dreisbach et al., 2006). 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 (Biologic Systems Corp, 2001). The DPOAE results were plotted on a DP-Gram generated by a computer system with SCOUT software. Furthermore, the DPOAE test duration was recorded using a stopwatch and this was documented on an Audiometric record form (Refer to Appendix H). The 65/55 Vanderbilt normative data was utilized in the interpretation of 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 (Biologic Systems Corp., 2001).

4.9.10. Time Taken to Conduct Annual Medical Surveillance

• The time taken to conduct the case history questionnaire, otoscopy, tympanometry, pure tone audiometry and DPOAEs in the current study was approximately 20-25 minutes per participant

4.9.11. Audiological Management of Participants

- Results of all test findings and recommendations were presented and explained to all participants. This was done verbally and through the use of posters and pamphlets (Refer to Appendix R).
- Participants who presented with any endogenous or exogenous hearing disorders or pathological conditions of the ear were referred for a diagnostic audiological evaluation and/or referred to the appropriate professional for further management (i.e. General Practitioner or Ear, nose and throat specialist). Additionally, the occupational nurse was notified of the findings and the participants were thereafter monitored via the company's existing hearing conservation program.

4.9.10 Analysis of the data collected

• All the raw data was captured in the form of excel spreadsheets. The data was analyzed with the assistance of a trained statistician according to each objective of the study.

4.10 ANALYSIS

A quantitative and inferential statistical analysis was used in this study. Frequencies and cumulative frequencies were primarily presented as descriptive statistics. Furthermore, graphical representations of findings aided in the comparison of the results and allowed for visual inspection of the results.

In order to realize objective one of the study, the data collected was compared to normative information available for each test, i.e. air conduction pure tone audiometry and DPOAEs. In order to obtain this graphical representation, the statistical software used was the Statistical Package for the Social Sciences (SPSS), Version 19 (Polit & Beck, 2004). The data was then coded and transferred from the original collection form, into a format that lends itself to data analysis (Polit & Beck, 2004). This enabled the researcher to calculate sensitivity, specificity and predictive value from the data collected. Data for estimating sensitivity and specificity are typically displayed in a 2 x 2 contingency table that classifies individuals according to their disease status and test result (Schoebach, 2002). Outcomes of the test, i.e. DPOAEs, are 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. This is displayed in Table 4.6 below.

Table 4.6: Terms used to define sensitivity, specificity and accuracy (Zhu, Zeng & Wang, 2010)

Outcome of the Test	Condition (e.g. Disease) as determined by the Standard of Truth Pure Tone Testing									
DPOAEs	CASES									
	Positive	Negative	Row Total							
Positive	True Positive (TP)	False Positive (FP)	TP + FP							
			(Total number of subjects with							
			positive test)							
Negative	False Negative (FN)	True Negative (TN)	FN + TN							
			(Total number of subjects with							
			negative test)							
Column Total	TP + FN	FP + TN	N = TP + TN + FP + FN							
	(Total number of subjects	(Total number of subjects	(Total number of subjects in							
	with given condition)	without given condition)	the study)							

Thereafter, sensitivity, specificity, positive and negative predictive values were subsequently determined for each frequency by applying the following formulae to the data collected from the Table 4.6 above:

Sensitivity =
$$\frac{\text{True Positives}}{\text{All Cases}}$$
 = $\frac{\text{T P}}{\text{TP + FN}}$

Specificity =
$$\frac{\text{True Negatives}}{\text{All Non-Cases}} = \frac{\text{T N}}{\text{TN + FP}}$$

Positive Predictive Value =
$$\frac{\text{True Positives}}{\text{All Positives}} = \frac{\text{TP}}{\text{TP} + \text{FP}}$$

Negative Predictive Value =
$$\frac{\text{True Negatives}}{\text{All Negatives}} = \frac{\text{TN}}{\text{TN} + \text{FN}}$$

Objective two of the study was to determine whether DPOAEs are able to detect subtle cochlear changes in the early identification of NIHL as compared to pure tone audiometry. This involved a comparison of DPOAE results obtained for each test group, as well as a comparison of pure tone air conduction audiometry results obtained for each test group. Prior to the data analysis, the Kolmogorov-Smirnov test was used to determine the distribution of the data. This is a one-sample test that examines the 'goodness of fit' between sample values and theoretical distribution (Jones, 2002). The null hypothesis defines the nature of the population and the test statistically compares the sample data to theoretical data (Jones, 2002). The results of Kolmogorov-Smirnov test retained the null hypothesis for each frequency, indicating normal distribution of the data and allowing for the use of a parametric test of analysis, namely, Analysis of Variance (ANOVA).

ANOVA is recommended for the simultaneous comparison of more than two sets of data (Jones, 2002). This is a parametric statistical technique, therefore, it is used whenever the conditions of the experimental design conform to the assumptions of the test (Jones, 2002). According to Jones (2002) these assumptions consist of normally distributed data, homogeneity of variance in the population from which the sample was derived and all observations must be independent of each other. All calculations were conducted using SPSS and a statistical significance level of p<0.05 in the analysis of the data. A level of significance determines how likely a given result could have occurred by chance alone (Turner & Thayer, 2001). A significance level of p<0.05 indicates that the probability of getting the obtained result by chance alone is less than 5%, therefore suggesting good confidence that the results obtained are a true reflection of an actual difference in the data (Turner & Thayer, 2001).

In order to realize objective three of the study, i.e. to determine the test-retest reliability of DPOAEs, a repeated measures ANOVA was used in the analysis of the data. This method of analysis is used when the researcher repeatedly takes measurements from the same participants (Jackson, 2008). The repeated measures ANOVA relies on four assumptions, namely, independence, normality, homogeneity of variance and sphericity (Turner & Thayer, 2001). Sphericity suggests that the variances of the differences between the repeated measurements should be about the same and any violations of the sphericity assumption may lead to a biased p-value and therefore needs to be adjusted for appropriately (Li & Baron, 2012). In the current study, Mauchly's Test of Sphericity was used. This test was used to determine whether the correlations between the within-subjects variable were comparable (Meyers, Gamst, & Guarino, 2006). During the analysis of the data, results that were not statistically significant suggested that the sphericity assumption had been met and the p-value was accepted (Meyers et al., 2006). A statistically significant difference on Mauchly's test of sphericity indicated heterogeneity of covariance and SPSS generated three correction options (Meyers et al., 2006).

For the purposes of this study, the Greenhouse-Geisser correction was selected and utilized. Furthermore, a statistical significance level of p<0.05 was used in the analysis of the data. A statistically significant difference obtained with ANOVA was further investigated using a post hoc pairwise significance test, also known as a pairwise comparison, to determine which groups were responsible for the significant difference obtained (Cohen & Lea, 2004). For the purposes of the current study, the post hoc Bonferroni adjustment was utilized as it is one of the more powerful post hoc adjustments with better performances in the presence of fewer tests (Cohen & Lea, 2004).

Furthermore, to determine the duration of time taken to administer DPOAEs as part of the annual medical surveillance test battery in the identification of noise-induced hearing loss, 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. The results of these comparisons will be discussed in the results section of the study (Refer to page 78).

4.11 VALIDITY AND RELIABILITY

Validity of a research study is the extent to which it measures what it is supposed to measure whereas, reliability is the consistency with which a research study yields a certain result when the entire entity being measured hasn't changed (Leedy & Ormrod, 2005). Validity and reliability influences the extent to which one can draw meaningful conclusions from the data and the probability that one will obtain statistical significance from the analysis of the data (Leedy & Ormrod, 2005). Validity is measured in terms of two separate but related dimensions, i.e. internal and external validity (Bess, Higson-Smith & Kagee, 2006). Internal validity investigates the extent to which a research design is able to exclude all other possible hypotheses which may explain the variation of the dependent variable (Bess et al., 2006). This means that there must be one, and only one, explanation for the research results (Gravetter & Forzano, 2010). External validity refers to the extent to which the findings of the study can be generalized and the study is said to have external validity when the research findings can be generalized outside the confines of the specific study (Bess et al., 2006; Gravetter & Forzano, 2010). Table 4.6 and 4.7 overleaf display a description of possible factors that may threaten external and internal validity and the implications for the present study in terms of how these factors were controlled for.

4.11.1 Factors affecting the external validity of the study are described in Table 4.7 below:

Table 4.7: Factors affecting the external validity of the study

		Description	Implications in the present study
1.	Participants	Characteristics that are unique to a specific group of participants in a study may limit the ability of the findings to be generalized to other populations (Gravetter & Forzano, 2010)	Findings of the current study may not be generalized to employees in other industries, outside the beverage manufacturing industry due to the specific types of noise and machinery in this industry.
2.	Features of the study	Characteristics that are unique methods used in a study may limit the ability to generalize the results to other situations in which other procedures are used (Gravetter & Forzano, 2010)	There was a consistent procedure for each step of the standard audiological evaluation. Therefore, this standard method may be reproduced in other similar settings.
3.	Measurement	Characteristics that are unique to a specific measurement procedure may limit the ability to generalize the results to situations in which different measurement procedures are used (Gravetter & Forzano, 2010)	Standard audiological test procedures were conducted in the present study and may be administered by other trained personnel in similar settings.

4.11.2 Factors affecting the internal validity of the study are described in Table 4.8 below:

Table 4.8: Factors affecting the internal validity of the study

		Description	Implications in the present study
1.	Environment	If two or more treatments are administered in	All test procedures were conducted in a clinic setting by a single researcher.
		noticeably different environments, internal	Pure tone air conduction audiometry and DPOAEs were conducted in a sound
		validity may be affected (Gravetter &	treated booth to ensure that the environment was controlled.
		Forzano, 2010)	
			Allocation of the audiological evaluation to a single researcher prevented
			tester differences and bias in the results obtained.
			Noise measurements were conducted prior to pure tone and DPOAE testing
			to ensure that ambient noise in the environment did not affect the test results.
2.	Assignment bias/	If participants in one treatment have	All participants were selected from a beverage manufacturing company
	Participant related	characteristics that are noticeably different	according to set inclusion and exclusion criteria to avoid the influence of
	threats to validity	from participants in another treatment	assignment bias and to prevent confounding contributions to the results
		(Gravetter & Forzano, 2010)	obtained (Refer to Table 4.1, p. 49 and Table 42, p. 50)
			Each participant was provided with written and verbal instructions regarding
			each test procedure (Refer to Appendix N & O). This was to ensure that all
			participants understood the test procedures of the audiological evaluation.
			The instructions were available in two languages, namely, English (Appendix
			N) and Zulu (Appendix O) so as to be linguistically and culturally suitable for
			each participant. The instructions ensured that the participant was able to
			understand the instructions in a language in which they were comfortable.
3.	History	If outside events influence the participants	All test procedures were conducted immediately after each other in a clinic
		differently in one treatment than in another	setting by a single researcher to exclude the effects of outside influences.

	(Gravetter & Forzano, 2010)					
4. Maturation	If participants experience physiological or psychological changes between treatments	A standard annual medical surveillance test battery was conducted and did not result in the possibility of physiological or psychological changes				
	(Gravetter & Forzano, 2010)					
5. Instrumentation	If the measurement instruments change from	There was consistent use of the audiological equipment for each test				
	one treatment to another (Gravetter &	procedure. This was maintained by the researcher to prevent technical				
	Forzano, 2010)	discrepancies in the results obtained.				
		Calibration of audiological equipment ensured accurate results of the testing				
		procedure (Refer to Appendix B, D, G & I).				
6. Testing effects	If the experience of being in one treatment	The study utilized a repeated measures design, whereby participants				
	influences the participants scores in another	underwent DPOAE testing three times by a single researcher in order to				
	treatment (Gravetter & Forzano, 2010)	assess the test-retest reliability of DPOAEs. This is a standard audiologic test				
		and the participant's results were not influenced by the repetition of the				
		DPOAE test procedure. Therefore, the researcher was able to reduce random				
		error due to individual differences, increasing the internal validity of the				
		study (Mitchell & Jolley, 2010).				

4.12 ETHICAL AND LEGAL CONSIDERATIONS

The following clinical considerations were made during the course of this study:

- a. The participation of employees in this study was voluntary and no employee was obligated to participate.
- b. Confidentiality was maintained at all times. The personal details and annual medical surveillance audiometric results of all participants remained anonymous for the duration of the research study and thereafter. This was achieved by assigning a numerical value to each participant.
- c. The manager was assured that no legal matters may arise as a result of the participation of their employees in the study as the participants would undergo routine annual medical surveillance.
- d. Furthermore, the personal details and annual medical surveillance audiometric results of all participants were stored in a locked cupboard on the University of KwaZulu-Natal (Westville campus) premises. Only the researcher and two supervisors had access to the data.
- e. Each participant was informed of their rights as a participant, i.e. voluntary participation and the right to confidentiality. Subsequently, informed consent was obtained from all participants (Refer to Appendix L & M).
- f. The researcher verbally explained each audiological test procedure to all participants. Prior to each audiological test procedure, the participant was appropriately instructed (Refer to Appendix N & O). Furthermore, all participants were provided with written information documents to further enhance their knowledge of the study (Refer to Appendix P & Q).
- g. In order to prevent the spread of infection, the researcher ensured that universal precautions were maintained. This involved the use of gloves during otoscopy and tympanometry and the sterilization of all equipment used during the audiological evaluation.
- h. The results of all audiological test procedures were carefully explained to each participant, with the use of visual aids, i.e. a diagram of the ear (Refer to Appendix R), the pure tone audiogram (Refer to Appendix H) and the DPOAE results.

- i. If any of the participants required further audiological management, the occupational hygienist/ nurse was notified of the findings and the participants were thereafter monitored via the company's existing management protocol.
- j. If any pathological conditions were detected by evaluation procedures, participants were referred to the appropriate professional for further management (i.e. General Practitioner or Ear, nose and throat specialist). Furthermore, the occupational nurse was notified of the findings and the participants were thereafter monitored via the company's existing management protocol.

4.13 CONCLUSION

The study utilized a cross-sectional and repeated measures design. In addition, quantitative research methods were used. The study involved the use of a purposive convenience sampling technique, whereby, 60 participants were selected from a beverage manufacturing company, according to specified sample selection criteria. Phase one of the study consisted of sound level measurements on a daily basis prior to testing, completion of a pre-test case history questionnaire, otoscopy and tympanometry. Phase two of the study consisted of the administration of pure tone air conduction audiometry and DPOAEs. In order to realize objective one of the study, the sensitivity, specificity, and positive and negative predictive value of DPOAEs was calculated with the use of specific formulae. A stratified sample approach was used in order to realize objective two of the study, whereby, the selected participants were divided into four test groups according to the number of years that they have been exposed to occupational noise within the beverage manufacturing industry, i.e. 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. Each group comprised of 15 participants. In order to realize objective three of the study, the researcher repeated the DPOAE test immediately with the probe still in the ear. Thereafter, the test was repeated for the second time, after the probe had been readjusted. Furthermore, the researcher recorded the time taken to conduct DPOAEs bilaterally. Thereafter, all raw data was captured in the form of excel spreadsheets and statistical analysis was done with the assistance of a trained statistician. The following chapter illustrates the results and discussion obtained for each objective of the study.

CHAPTER FIVE: RESULTS AND DISCUSSION

The ultimate criterion for the usefulness of a test is whether it adds information beyond that

otherwise available, and whether this information leads to a change in management that is

ultimately beneficial to the patient (Lang & Secic, 2006).

5.1 INTRODUCTION

This chapter provides the results and discussion of the study. The results and discussion are

presented according to the objectives of the study. In order to determine possible explanations

for the results of the study, the relevant literature associated with any significant findings is

discussed in detail.

5.2 OBJECTIVE ONE

For objective one of the study, the pure tone air conduction audiometry and DPOAE results

obtained for 60 ears were analyzed per frequency and corresponding geometric means. Pure tone

air conduction audiometric thresholds at 1000, 2000, 3000, 4000, 6000 and 8000Hz and the

corresponding geometric mean frequencies at 913, 1826, 2739, 3651, 5477 and 7303Hz were

utilized and considered for statistical analysis.

Table 5.1 overleaf indicates the results obtained for this objective.

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Table 5.1 Sensitivity, specificity and predictive values for the right and left ear

	PT_1	1000	PT_2	2000	PT_3	3000	PT_4	1000	PT_6	5000	PT_8	000
Frequency (Hz)	DP 913		DP_1826		DP_2739		DP_3651		DP_5477		DP_7303	
Ear	Right Ear	Left Ear										
Total number of ears	60	60	60	60	60	60	60	60	60	60	60	60
True Positives (ears)	1	0	1	0	0	0	1	2	2	3	2	2
True Negatives (ears)	37	38	49	48	58	53	48	47	32	28	32	29
False Positives (ears)	22	22	10	12	2	7	11	11	26	29	26	28
False Negatives (ears)	0	0	0	0	0	0	0	0	0	0	0	1
Sensitivity (%)	100	#	100	#	#	#	100	100	100	100	100	67
Specificity (%)	63	63	83	80	97	88	81	81	55	49	55	51
Positive Predictive	4	0	9	0	0	0	8	15	7	9	7	7
Value (%)												
Negative Predictive	100	100	100	100	100	100	100	100	100	100	100	97
Value (%)					1 . 41	4. 1						

Note: # - the formula resulted in zero as the denominator which is a mathematical error

As evident in Table 5.1 (Refer to page 79), the DPOAE test was under investigation as compared to the gold standard, pure tone audiometry. The total number of ears presenting with true positive, true negative, false positive and false negative results were recorded in order to calculate sensitivity, specificity and positive and negative predictive value of the DPOAE test. The results revealed 100% sensitivity across the frequency range, except at 2739Hz where a mathematical error prevented further analysis bilaterally. Sensitivity was calculated by the use of a specific formula, which resulted in zero as the denominator in the calculation. This is a mathematical error and hence, sensitivity could not be calculated at certain frequencies as evident in Table 5.1 (S. Van der Linde, personal communication, October 17, 2012). The results revealed 100% sensitivity at 3651 and 5477Hz and 67% sensitivity at 7303Hz in the left ear. A mathematical error prevented the analysis of the data at 913, 1826 and 2739Hz in the left ear.

Specificity ranged from 51-97% across the frequency range bilaterally. For the right ear, a high specificity score of 83%, 97% and 81% was observed at 1826, 2739 and 3651Hz, respectively, whereas, a low specificity score of 55% was obtained at 5477 and 7303Hz. For the left ear, a high specificity score of 80%, 88% and 81% was observed at 1826, 2739 and 3651Hz, respectively, whereas, a low specificity score of 49% and 51% was obtained at 5477 and 7303Hz, respectively. A low positive predictive value ranging from 0-15% was also observed across the frequency range bilaterally. The negative predictive value of DPOAEs was calculated to be 100% across the frequency range bilaterally, except at 7303Hz in the left ear, where it was observed to be 97%.

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. The sensitivity of a test is its accuracy to correctly identify participants with a disorder (Roeser, 1996), i.e. the number of participants tested who may actually present with a hearing impairment (Johnson, 2002). A high sensitivity, as seen in the current study, suggests that DPOAEs may be able to identify the target population. Similarly, Kim et al. (1996) reported

a good sensitivity of 89% at 6kHz and 86% at 4kHz when the sensitivity of DPOAEs to detect sensorineural hearing loss was evaluated. Job et al. (2009) also assessed the sensitivity and specificity of DPOAEs in a group of pilots exposed to continuous noise. An overall sensitivity of 72% was obtained in this study. The results of the current study, therefore, concur with Kim et al. (1996) and Job et al. (2009). Therefore, in view of the high sensitivity found in the current study, it may be plausible to suggest that DPOAEs may be highly sensitive and can be used to identify those individuals who present with subtle cochlea changes as a result of exposure to occupational noise. In order to determine if DPOAEs may be able to identify those who truly do not present with subtle noise-induced cochlea changes, the specificity of DPOAEs was calculated.

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 specificity of a test is its accuracy in correctly rejecting participants without a hearing impairment (Johnson & Danhauer, 2002). It is the ability of a test to not identify those who truly do not have the disorder (Johnson, 2002). 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 1826, 2739, and 3651Hz. Job et al. (2009) found the overall specificity of DPOAEs to be 64%. Whereas, Kim et al. (1996) reported a good specificity of 88% at 6kHz and 85% at 4kHz. Similar findings were obtained in the current study at 3651Hz with a specificity of 81% bilaterally. However, the specificity at 5477Hz was calculated to be 55% and 49% for the right and left ear, respectively. Chan et al. (2004) found that a >6dB SNR criterion yielded lower specificity throughout all DPOAE test frequencies, while DPOAE test sensitivity was calculated to be 100% across the frequency range. Clark (2005) found that DPOAEs appear to be more specific in the detection of cochlea changes at the frequencies where damage is expected to occur as a result of occupational noise exposure.

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 possibly be interpreted with confidence when a negative test result is obtained. Negative predictive value is the probability of not having the disease when the test result is negative (Fletcher & Fletcher, 2005). 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 as there is more confidence in the fact that the negative test result rules out the disease (Fletcher & Fletcher, 2005). However, a low positive predictive value was obtained in the current study, ranging from 0-15% bilaterally. Positive predictive value is the probability of disease in a patient with a positive (abnormal) test result (Fletcher & Fletcher, 2005). The low positive predictive value in the current study suggests that DPOAEs may possibly have to be interpreted with caution when a positive test result is obtained.

A possible reason for a low positive predictive value obtained in the current study may be due to the fact that the predictive value of a test is largely influenced by the prevalence of the disorder under investigation. Many employees only present with a hearing loss on the pure tone audiogram following 10 to 15 years of occupational noise exposure (Rosen et al., 2001) and the current study investigated participants who have been exposed to occupational noise for a period of 0-13 years. Therefore, many of the employees in the present study did not present with NIHL on the pure tone audiogram. Therefore, the low prevalence of NIHL detected by pure tone audiometry may have influenced the positive predictive efficiency of DPOAEs. According to Roeser (1996) the predictive value of a test is related to the number of false-negative and false-positive results. Kim et al. (1996) reported an overall predictive efficiency of 89% at 6kHz and 85% at 4kHz. Furthermore, Clark (2005) found fewer false positives with the use of DPOAEs. This was also found in the current study, with only 1 false positive result recorded at 8000Hz in the left ear.

Several authors have stated that DPOAEs are more sensitive than pure tone audiometry in detecting subtle changes in outer hair cell function (Kim et al., 1996; Attias et al., 2001, Balatsouras et al., 2005; Jhetam et al., 2008; Edwards et al., 2010; Swanepoel & Hall, 2010; Baradarnfar et al., 2012). The findings of the current study concurs with previous findings, suggesting that in view of DPOAEs being highly sensitive and specific, it may be a feasible test to consider for inclusion in the annual medical surveillance test battery for the identification of noise-induced cochlea changes for workers in the beverage manufacturing industry. However, in order to further investigate its feasibility, it is essential to consider the DPOAE test's ability to identify early subtle cochlea changes as a result of occupational noise exposure. This was explored in objective two of the study.

5.3 OBJECTIVE TWO

In order to realize this objective the 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 current study consisted of three DPOAE measurements (DP1, DP2 and DP3) that were conducted immediately one after the other on the same day. A repeated measures ANOVA revealed a statistically significant difference between the DPOAE amplitude means of DP2 and DP3 at two frequencies, namely, 913Hz in the left ear and 3651Hz in the right ear. Hence, DP1 was chosen in the analysis of objective two of the study. Table 5.2 overleaf indicates the mean pure tone air conduction audiometry results obtained, whereas, Table 5.3 (Refer to page 90) indicates the mean DPOAE amplitudes obtained for each test group. Thereafter, visual inspection of the results was done with the use of graphs.

Table 5.2 Means, standard deviations and level of significance of pure tone air conduction audiometry thresholds obtained bilaterally across the frequency range for Group A, B, C and D

Frequency (Hz)	Group	Mean Thresh	old (dp UI)	Std Deviation	on (dD HI)	Signif	icance
(112)	Group		1 `		1 ` ′		
1000		Right Ear	Left Ear 9.33	Right Ear 7.319	Left Ear 9.037	Right Ear	Left Ear
1000	A					1	
	В	7.33	7.33	5.936	5.3	p = 0.529	p = 0.730
	С	8.67	8	6.114	5.606		
	D	10.67	9.67	7.037	5.164		
2000	A	10.67	10	9.037	8.238		
	В	8.67	9.33	7.432	5.627	p = 0.649	p = 0.733
	С	7.33	9.67	7.037	7.432]	
	D	9.67	12	5.815	6.761]	
3000	A	5.67	7	7.287	8.824		
	В	9.67	11.33	8.756	8.121	p = 0.389	p = 0.454
	С	8.67	9.67	5.499	7.669	1	1
	D	9.33	10.33	5.936	5.499		
4000	A	7.67	9.67	7.761	9.348		
	В	11	15.67	6.601	7.528	p = 0.106	p = 0.298
	С	10	14	6.814	10.385		
	D	15.67	15.33	12.938	10.601		
6000	A	8.67	10	8.121	8.864		
	В	11.67	9	8.591	7.368	p = 0.489	p = 0.120
	С	13.33	15.33	11.127	10.768		
	D	14	16	12.277	11.526		
8000	A	9.67	10	6.935	8.018		
	В	9.67	12.33	9.537	9.424	p = 0.568	p = 0.370
	С	14.67	14	13.689	10.724]	
	D	11.67	16.33	12.91	11.568		

The results displayed in Table 5.2 above revealed that the mean pure tone air conduction audiometry thresholds were within the normal limit of -10 – 25 dB HL across the frequency range of 1000Hz – 8000Hz bilaterally (Gelfand, 2001). 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 0-3 years did not differ from the pure tone audiometry results of participants exposed to noise for 9-13 years. These results are 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 (Rosen et al., 2001). Figure 5.1 and Figure 5.2 below further illustrates the comparison of the mean pure tone air conduction audiometry thresholds obtained for Group A, B, C and D at the frequencies earliest affected by exposure to occupational noise for the right and left ear, respectively.

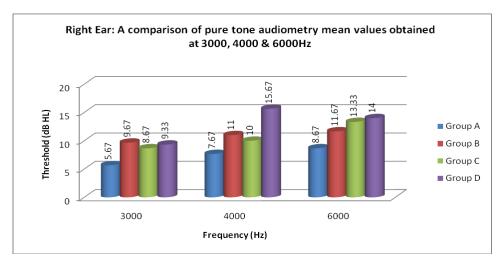


Figure 5.1 Right ear: A comparison of the mean pure tone air conduction audiometry thresholds obtained for Group A, B, C and D at 3000, 4000 and 6000Hz

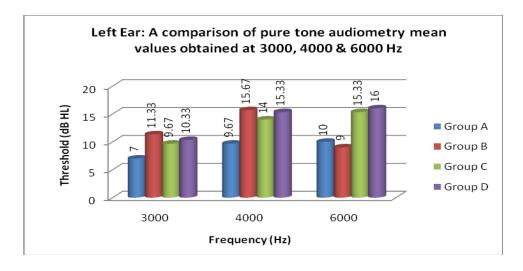


Figure 5.2 Left ear: A comparison of the mean pure tone air conduction audiometry thresholds obtained for Group A, B, C and D at 3000, 4000 and 6000Hz

Figure 5.1 (Refer to page 85) illustrates the right ear comparison of the mean pure tone air conduction audiometry thresholds obtained for Group A, B, C and D at 3000, 4000 and 6000Hz. On visual inspection, the mean pure tone air conduction audiometry thresholds of Group A (5.67dB) appear to be slightly better compared to that of Group B (9.67dB), C (8.67dB) and D (9.33dB) at 3000Hz. At 4000Hz, the mean pure tone air conduction audiometry thresholds of Group D (15.67dB) appear to be decreased as compared to that of Group A (7.67dB), Group B (11dB) and Group C (10dB). At 6000Hz, it is apparent that the mean pure tone air conduction thresholds deteriorate with an increase in the number of years of occupational noise exposure. Figure 5.2 (Refer to page 85) illustrates the left ear comparison of the mean pure tone air conduction audiometry thresholds obtained for Group A, B, C and D at 3000, 4000 and 6000Hz. On visual inspection of the left ear mean pure tone air conduction audiometry thresholds at 3000Hz and 4000Hz, the results of Group B, C and D appear to be slightly decreased as compared to that of Group A. At 6000Hz, it is evident that the results of Group A (10dB) and Group B (9dB) are slightly better than that of Group C (15.33dB) and Group D (16dB).

The absence of a statistically significant difference (p>0.05) in the comparison of the mean pure tone air conduction thresholds of the test groups, as well as visual inspection of Figure 5.1 and Figure 5.2 (Refer to page 85) suggests that pure tone air conduction audiometry may be inadequate for the early identification of NIHL as the results of Group A (0-3 years of occupational noise exposure) and Group B (3-6years of occupational noise exposure) at 3000, 4000 and 6000Hz are well within the normal limits of -10 – 25dB (Gelfand, 2001). Furthermore, there is no indication of NIHL at any of these frequencies when compared to normative data (-10–25dB), even for the test group who presented with occupational noise exposure of 9-13 years (Group D). Additionally, there appears to be little difference in the mean pure tone thresholds of Group A at 3000, 4000 and 6000Hz, and this is also evident for the other test groups, indicating that the typical pattern of NIHL has not been detected by pure tone air conduction audiometry at any one of these frequencies. A graphical representation of the mean pure tone air conduction audiometry thresholds of Group A, B, C and D is displayed overleaf for the right ear in Figure 5.3 and for the left ear in Figure 5.4.

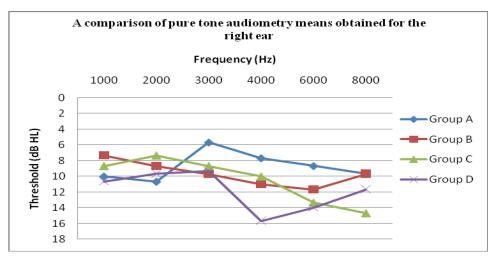


Figure 5.3 Right Ear: A comparison of the mean pure tone air conduction audiometry thresholds of Group A, B, C and D

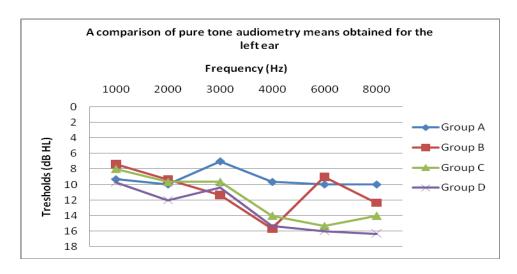


Figure 5.4 Left Ear: A comparison of the mean pure tone air conduction audiometry thresholds of Group A, B, C and D

Visual inspection of the mean pure tone air conduction audiometry thresholds indicate hearing within the normal limit of -10 - 25 dB HL across the frequency range of 1000Hz - 8000Hz bilaterally (Gelfand, 2001). However, upon closer inspection of Figure 5.3 and Figure 5.4 above, a notch configuration is observed at 4000Hz for Group D and Group B, respectively. A noise notch typically means thresholds at 3, 4, and/or 6 kHz that are substantially worse than hearing thresholds at lower frequencies (0.5 and 1 kHz) and at 8 kHz, where a recovery is said to take place (Rabinowitz et al., 2006). Hearing loss caused by noise exposure has a characteristic pure

tone audiometric pattern with a notch in the 3-6 kHz range (Rodriguez & Gerhardt, 1991; Sataloff et al., 2011). Considering this definition, it is evident that a noise notch is also present in the right ear at 6000Hz for Group B and a recovery is seen at 8000Hz (Refer to Figure 5.3, p. 87). There also appears to be a noise notch in the left ear at 6000Hz for Group C, with a recovery at 8000Hz (Refer to Figure 5.4, p. 87). However, the right ear mean pure tone air conduction thresholds of Group C decrease at 6000Hz and 8000Hz in the absence of a noise notch (Refer to Figure 5.3, p. 87). Decreased high frequency pure tone air conduction audiometry thresholds are also evident for Group C and Group D in the left ear in the absence of a noise notch (Refer to Figure 5.4, p. 87).

It is evident that visual inspection of the mean pure tone air conduction audiometry thresholds 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. This is atypical as NIHL is usually bilateral in nature (Sataloff et al., 2011). Therefore, to determine if a statistically significant difference existed between the results of the right and left ears, a paired t-test was done. A paired t-test compares the means for two groups of cases and involves matched samples drawn from a population with a normal distribution (Singh, 2007). The results of the paired t-test revealed a significant difference between the mean pure tone air conduction audiometry thresholds of the right and left ears at 4000Hz (p=0.002). A significant difference was not observed for all other test frequencies.

Pirila (1991) states that most epidemiological surveys concerning populations exposed to occupational noise have shown that the left ear is slightly but significantly poorer than the right ear, especially at the frequencies most susceptible to noise damage. Pirila (1991) studied the left-right ear asymmetry in response to noise exposure by exposing 28 participants to symmetrical broad band noise for 8 hours. The results of the study revealed that TTS was higher in the left ear than in the right ear at 4000Hz, in the presence of a statistically significant difference. The findings of the current study is in accordance with Pirila (1991). Another study conducted by

Linblad, Rosenhall, Olofsson, & Hagerman (2011) found that intra-individual standard deviations in a control group following noise exposure for the left ear were larger than that of the right ear. Furthermore, a test of equal variances in the Linblad (2011) study showed that the variances on the two ears were significantly different at 3000Hz and 4000Hz. The authors attributed the significant difference to a possible effect on threshold stability of the left ear as a result of noise exposure. This suggests that the left ear may be more susceptible to the effects of occupational noise exposure. Linblad et al. (2011) is in agreement with Pirila (1991) that the left ear is more sensitive to noise than the right ear following noise exposure.

This was observed on visual inspection in the current study as reduced left ear mean pure tone thresholds of Group B and Group C is evident in Figure 5.3 and Figure 5.4 (Refer to page 87). However, there appears to be no notable differences in the high frequency pure tone air conduction audiometry thresholds of Group A bilaterally. In addition, there 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. This has implications for the early detection of NIHL in this particular industry. For this reason, Vinck et al. (1999) proposed that OAE testing be used as an alternative to pure tone audiometry in monitoring cochlea changes for workers exposed to occupational noise. However, several other authors have suggested that DPOAEs should be used in conjunction with pure tone audiometry in the monitoring of cochlea changes as a result of noise exposure (Korres et al., 2009; Edwards et al., 2010, Swanepoel & Hall; 2010). The ensuing tables and graphs illustrate the means, standard deviations and level of significance of DPOAEs obtained across the frequency range for each test group to investigate the ability of DPOAEs to identify early subtle cochlea changes as a result of occupational noise exposure in the beverage manufacturing industry.

Table 5.3 Means, standard deviations and level of significance of DPOAE amplitudes obtained across the frequency range for Group A, B, C and D bilaterally

Frequency (Hz)	Group	Mean Amplitudes (dB SPL)		Std Deviatio	n (dB SPL)	Significance		
Ear	•	Right Ear	Left Ear	Right Ear	Left Ear	Right Ear	Left Ear	
913	A	12.73	15.4	7.176	6.162			
	В	10.93	13.4	7.968	8.305	p = 0.264	p = 0.163	
	С	10.47	10.67	5.167	6.195	1 1	1	
	D	7.6	10.53	7.605	6.357			
1826	A	18.87	21.33	8.593	9.7			
	В	18.33	20.27	8.886	8.916	p = 0.656	p = 0.235	
	С	17.47	17.13	6.255	7.19	1 '	1	
	D	15.4	15.47	8.105	8.855			
2739	A	22	22.87	6.876	7.736	p = 0.790		
	В	21.6	20.73	5.527	10.243		p = 0.513	
	С	19.87	20	6.621	7.483			
	D	20.33	17.87	7.394	10.419			
3651	A	22.2	23.73	9.12	6.1		p = 0.021	
	В	20.8	22.73	9.511	10.166	p = 0.085		
	С	20.47	19.4	6.334	9.664	1 '	•	
	D	14.53	13.13	9.187	12.478			
5477	A	16.8	15.4	5.335	7.179			
	В	12.13	11.73	9.628	10.025	p = 0.056	p = 0.085	
	С	12	11.2	9.173	9.01	1 1	1	
	D	8.4	7.07	7.763	8.198			
7303	A	11.13	10.27	7.891	7.995			
	В	7.73	8.87	9.392	9.913	p = 0.282	p = 0.557	
	С	8.07	7.27	7.723	8.362	1	_	
	D	5.53	6.2	5.842	6.505			

The results displayed in Table 5.3 above revealed that the mean DPOAE amplitudes (DP-NF) were within the normal limit of >6dB SPL across the frequency range of 913Hz – 7303Hz for all test groups bilaterally (Biologic Systems Corp., 2001). However, it was observed that the right ear mean DPOAE amplitude of Group D at 7303Hz was slightly outside the normal limit of >6dB SPL. A comparison of the mean DPOAE amplitudes of Group A, B, C and D did not result in a statistically significant difference across the majority of the frequency range for the right ear (p>0.05). However, a significant level of p = 0.056 was obtained at 5477Hz in the right ear. Although this is not a statistically significant difference, it may be valuable to note the proximity to a significant difference of p<0.05 in the high frequency region of the audiogram. 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). This statistically significant difference obtained with ANOVA was further investigated using the post hoc Bonferroni adjustment which revealed a statistically significant difference (p<0.05) between the DPOAE amplitude means of Group A and Group D (p = 0.028). This indicates that the mean DPOAE amplitude results of Group D, who have been exposed to noise for 9-13 years is significantly reduced as compared to the DPOAE amplitudes of Group A, who have 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 (Morata et al., 2005). A statistically significant difference was not observed on pure tone audiometry but there was a statistically significant difference when the DPOAE results were compared. It may, therefore, be plausible to suggest that DPOAEs may 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. Figure 5.5 and Figure 5.6 below further illustrates the comparison of the mean DPOAE amplitudes obtained for Group A, B, C and D at the frequencies earliest affected by exposure to occupational noise for the right and left ear, respectively.

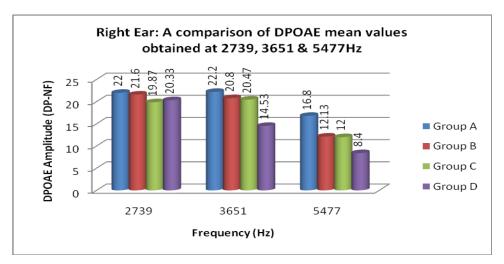


Figure 5.5 Right Ear: A comparison of the mean DPOAE amplitudes obtained for Group A, B, C and D at 2739, 3651 and 5477Hz

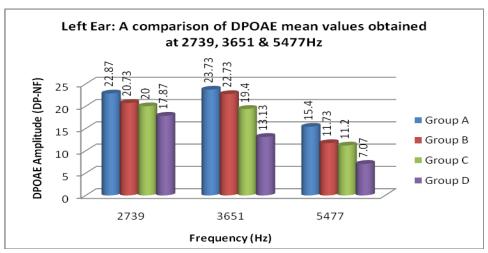


Figure 5.6 Left Ear: A comparison of the mean DPOAE amplitudes obtained for Group A, B, C and D at 2739, 3651 and 5477Hz

At 2739Hz and 3651Hz, DPOAE amplitude means of each test group are well within the normal limit of >6dB SPL and there appears to be little difference between the means for both the right and left ear. However, the mean DPOAE amplitude of Group D at 3651Hz appears to be considerably decreased as compared to the other test groups bilaterally. Furthermore, there is a notable decrease in the mean DPOAE amplitude of Group D at 3651Hz as compared to the mean DPOAE amplitude at 2739Hz bilaterally. At 5477Hz, although the mean DPOAE amplitudes of all the test groups are within the normal limit of >6dB SPL, there is a considerable deterioration in the mean amplitudes of all the test groups as compared to 2739Hz and 3651Hz bilaterally. This again may be suggestive of subtle cochlea changes at 5477Hz for both the right and left ears. Moreover, the mean DPOAE amplitudes of Group A (0-3years of occupational noise exposure) and Group B (3-6years of occupational noise exposure) are notably decreased bilaterally, indicating the possible early identification of subtle cochlea changes at 5477Hz.

A graphical representation of the mean DPOAE amplitudes of Group A, B, C and D is presented to further identify any trends in the data collected. This is displayed in Figure 5.7 and Figure 5.8 overleaf.

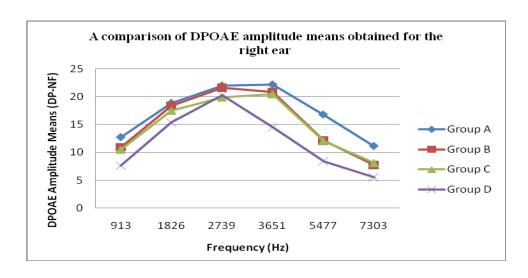


Figure 5.7 Right Ear: A comparison of DPOAE amplitude means for Group A, B, C and D

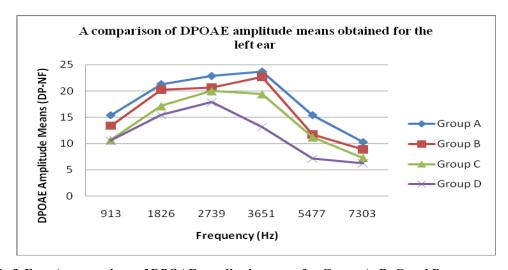


Figure 5.8 Left Ear: A comparison of DPOAE amplitude means for Group A, B, C and D

Visual inspection of the mean DPOAE amplitudes [Distortion product-Noise floor (DP-NF)] were essentially within the normal limit of >6dB SPL across the frequency range of 913Hz – 7303Hz for all test groups bilaterally (Biologic Systems Corp., 2001). However, upon closer inspection of Figure 5.7 and Figure 5.8 above, 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. DPOAE amplitude means of Group D are notably reduced at 3651Hz, 5477Hz and 7303Hz bilaterally, as 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. In addition, the DPOAE amplitude means of all test groups appear to be reduced at 913Hz bilaterally.

In summary, the results of the right and left ear comparisons of the mean DPOAE amplitudes are possibly indicative of subtle cochlea changes at 5477Hz for all test groups. Furthermore, visual inspection revealed decreased DPOAE amplitude means at 7303Hz. There was little indication of subtle cochlea changes at 2739Hz and 3651Hz for Group A, B and C bilaterally. Deterioration of Group D (9-13 years of occupational noise exposure) DPOAE amplitude means were evident at 3651Hz and 5477Hz. Furthermore, the 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), in the absence of corresponding findings on the pure tone audiogram. Attias et al. (2001) reported reduced DPOAE amplitudes at 6kHz for participants with normal pure tone audiograms and audiograms depicting NIHL. Although the current study did not find similar results at this frequency, which may be due to a difference in the type, duration and intensity of the noise in the beverage manufacturing industry. The finding of the current study as described above and that of Attias et al. (2001) suggest that decreased DPOAE amplitudes may be an indicator of cochlea damage without corresponding changes to the pure tone audiogram.

Similarly, a study conducted by Edwards et al. (2010) indicated that 53 of 73 participants with normal hearing on the pure tone audiogram, presented with DPOAE levels below the expected range. These results are indicative of cochlea damage, despite the lack of evidence on the pure tone audiogram. Edwards et al. (2010) investigated the feasibility of using DPOAEs as an adjunct to pure tone audiometry in the annual medical surveillance environment commonly found in the South African platinum mining industry. Correlations between eight audiometric thresholds and eleven DPOAE levels were calculated to reveal statistically significant

differences at most of the frequencies, and in particular the high frequencies (1605Hz-6434Hz). Thus, it is evident that there is a need to identify these noise-induced cochlea changes before a perceptual change in hearing on the pure tone audiogram is experienced.

This perceptual change in hearing is characterized as the amount of damage sustained as a function of the intensity of the signal, the duration of the noise exposure and the type of the noise (Feuerstein, 2002). A review of the 2011/2012 noise survey report conducted at the beverage manufacturing company in the current study revealed that both steady-state and impact noise types were present in the demarcated noise zones. Within the demarcated noise zones, noise levels ranged between 85 and 100dB(A). High level impulse noise on the cochlea is different than the effects of continuous exposure to lower levels (Tambs et al., 2006). The critical level for impulse noise is likely to be related to the duration of the impact and the spectral components, which results in the most damaging effects at 3kHz (Tambs et al., 2006). A maximum threshold shift due to impulse noise should take place half an octave above 3kHz, around 4-5kHz, and this effect would be similar to the effect of continuous industrial noise, but impulse noise may produce more local notches (Tambs et al., 2006). Distinction of impulse and continuous noise may be difficult in an occupational setting as continuous noise may include sources of impact noise, such as riveting and hammering, although generally at lower intensities than the typical impulse noise (Tambs et al., 2006).

Tambs et al. (2006) investigated hearing loss induced by occupational and impulse noise using pure tone audiometry. The results of the study revealed that hearing impairment due to impulse noise was almost as strong at 8kHz as it was at 4 and 6kHz. Impulse noise produced a mean threshold shift of similar values at 3, 4 and 6kHz. Interestingly, even the 8kHz threshold shift induced by impulse noise was only 1-2dB smaller than at 4kHz. Furthermore, this pattern of frequency-specific effects observed for women was consistent with that of the pattern observed for the male participants in the Tambs et al. (2006) study. The findings of Tambs et al. (2006)

suggests that although gender differences were not under investigation in the current study, similar patterns may be expected for both male and female participants.

Balatsouras et al. (2005) also found significant differences in pure tone audiometry thresholds and DPOAE amplitudes at 1-8kHz following exposure to impulse noise. In the current study, visual inspection of the right ear mean pure tone air conduction thresholds of Group C decreased at 6000Hz and 8000Hz in the absence of a noise notch. Furthermore, decreased high frequency pure tone air conduction audiometry thresholds were evident for Group C and Group D in the left ear in the absence of a noise notch. This possibly indicates that workers in the beverage manufacturing industry with a longer history of noise exposure may present with cochlea changes at a greater frequency range on the pure tone audiogram.

Furthermore, Tambs et al. (2006) state that impulse noise may produce more local notches on the pure tone audiogram and this possibly accounts for the notch configuration observed for Group B bilaterally and for Group C in the left ear and Group D in the right ear. Visual inspection of the pure tone air conduction threshold means 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. This is atypical as NIHL is usually bilateral in nature (Sataloff et al., 2011). However, these findings in the current study indicate that pure tone audiometry may still be useful in the annual medical surveillance program for the detection and monitoring of NIHL for those workers with a longer service record in the beverage manufacturing industry.

Clark & Bohl (2005) also found that participants with longer service records in an occupational setting presented with lower pure tone audiometric thresholds in comparison to those with a shorter service record. The results of their longitudinal study to determine if fire-fighters are an occupational class at risk for acquiring a NIHL revealed minimal changes in hearing sensitivity at 3, 4 and 6kHz, particularly for younger fire-fighters with a shorter service record. This is in accordance with Rosen et al. (2001) who state that NIHL progresses 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. The current study included participants who were exposed to occupational noise within the beverage manufacturing industry for a maximum of 13 years. Therefore, it was anticipated that the mean pure tone audiometry thresholds of Group D would result in lower audiometric thresholds as compared to Group A, B and C. This was not observed in the current study as the mean pure tone air conduction audiometry thresholds were within the normal limit of -10 - 25 dB HL across the frequency range and a significant difference was not observed between all test groups. However, reduced thresholds and notch configurations were observed on visual inspection of the pure tone audiogram.

Additionally, Swanepoel & Hall (2010) investigated changes in hearing thresholds by conducting a pre- and post-test study on the effects of impulse noise. The A-weighted sound pressure level of the impulse noise was recorded to be 131dB(A). The results of the study revealed that more than 50% of pure tone hearing thresholds at 250, 2000, 3000, 4000 and 6000Hz demonstrated a post-exposure deterioration, with a statistically significant deterioration at 2000Hz. Another significant finding by Swanepoel & Hall (2010) was a 73% decrease in post-exposure DPOAE amplitudes, which were statistically significant at 1266, 3163 and 5063Hz. However, visual inspection of the mean pure tone audiometry thresholds in the current study revealed that 1-3kHz were unaffected bilaterally by the exposure to occupational noise. Furthermore, visual inspection of the mean DPOAE amplitudes in the current study revealed that 1826, 2739 and 3651Hz were well within the normal limit of >6dB SPL and appear to be unaffected by the exposure to occupational noise for Group A, B and C. The DPOAE amplitude means of all test groups appear to be reduced at 913Hz. This is possibly due to the increased variability of DPOAEs below 1000Hz (Franklin et al., 1992).

Balatsouras et al. (2005) also investigated participants who did not use hearing protection and were not exposed to a hearing conservation program and thus, found significant differences in pure tone audiometry thresholds and DPOAE amplitudes at 1-8kHz following exposure to

impulse noise. In contrast, however, the workers in the beverage manufacturing company under investigation had a systematic hearing conservation program in place. The occupational nurse was responsible for conducting annual medical surveillance as well as informing the employees about the importance of wearing hearing protection in the various noise zones. An occupational health and safety manager was responsible for providing hearing protection devices and ensuring that all employees were wearing these hearing protection devices when working in any of the demarcated noise zones. Moreover, these employees received annual education and training regarding noise-induced hearing loss and the importance of wearing hearing protection devices from final year Audiology students for the last three years. There is evidence to show that attitudes to noise may be influenced by the perspective from which workers perceive it (Reddy et al., 2012). Furthermore, the perceived benefit and self-efficacy of use correlates strongly with the use of hearing protection devices (Kurmis & Apps, 2007). This implies that if workers are educated regarding the type of noise that they are exposed to and, as a result, if they are able to identify noise as a hazard, it will support the idea of the importance of using hearing protection devices to prevent NIHL (Reddy et al., 2012).

Therefore, 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 0-3 years. 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 for workers in the beverage manufacturing industry. 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.

The results obtained by Balatsouras et al. (2005), Tambs et al. (2006) and Swanepoel & Hall (2010) all indicate that hearing thresholds and cochlea changes as a result of exposure to impulse noise may affect a greater frequency range than expected with other types of occupational noise and, hence, the typical noise notch configuration may not be evident on the pure tone audiogram or the DP-Gram. Similar results were obtained for the current study. Pure tone audiometry and DPOAE were within the normal limit of -10-25dB HL and >6dB SPL, respectively, however, visual inspection of the mean thresholds and amplitudes appeared to be decreased in the high frequency region of the audiogram and DP-gram. Noise notch configurations were present on the pure tone audiogram for participants with a longer history of occupational noise exposure, though, these were not observed bilaterally. Whereas, the absence of a typical noise notch was highlighted in the visual inspection of the DPOAE mean amplitudes for all test groups at 5477Hz and 7303Hz bilaterally. This possibly indicates that DPOAEs may be able to detect noiseinduced cochlea changes at a greater frequency range and for those workers exposed to occupational noise for as little to 0-3 years. The 2011/2012 noise survey report conducted at the beverage manufacturing company stated that participants of the current study were exposed to both impact and steady-state noise which were produced both constantly as well as intermittently. Therefore, these participants may have been exposed to varying doses of noise.

A study conducted by Sampaio et al. (2012) evaluated the amplitude of DPOAEs in three groups of normal hearing workers exposed to different noise doses in the metalworking industry. Group 1 was non-exposed, Group 2 was sporadically exposed to noise and Group 3 was often exposed to occupational noise. DPOAE alterations in amplitude and SNR were found in Group 2 and 3 bilaterally (p<0.05). The study also revealed that the greater the exposure to noise dose, the lower the DPOAE amplitude (p<0.05). Significant differences between the DPOAE amplitudes of Group 1 were seen when compared to Group 2 and 3 (p<0.05). These findings are significant as it highlights the importance of investigating undetectable hearing changes in all workers exposed to occupational noise, even sporadically. Furthermore, these findings support the findings of Attias et al. (2001), Edwards et al. (2010) and Swanepoel & Hall (2010) in that

cochlea changes were evident in DPOAEs in the absence of hearing changes on the pure tone audiogram.

Another study conducted by Korres et al. (2009) evaluated NIHL in a group of industrial workers in a pastry producing factory using DPOAEs in conjunction with pure tone air conduction audiometry on 210 ears. The 8-hour averaged A-weighted sound exposure equivalent measurements from the site was 92dB(A), similar to that of the current study. The results of the noise exposed group were compared to a control group. The study found statistically significant lower DPOAE amplitudes in the noise exposed group as compared to that of the control group. Pure tone audiometry results of the noise exposed group showed that 60% of the ears presented with a >10dB HL threshold shift at 4kHz, indicating that pure tone thresholds are mostly affected at 4kHz. In the current study, the mean pure tone air conduction audiometry thresholds were reduced at 4kHz in the right ear for Group D and in the left ear for Group B, C and D. However, the results of Group C and D were equally reduced at 6 and 8kHz in the left ear. This difference may be attributed to the different type of noise found in the beverage manufacturing company as compared to the type of noise that may be found in a pastry producing factory. Furthermore, Korres et al. (2009) used a larger sample size of 210 ears as compared to the 60 right ears and 60 left ears over four test groups used in the current study. A larger sample size in the current study may have allowed for further inferences to be made regarding the feasibility of DPOAEs for inclusion in the annual medical surveillance test battery put forth by SANS (2004).

Korres et al. (2009) also found that a high percentage of ears tested presented with significantly reduced DPOAE amplitudes in the frequency range of 3-6 kHz, with the most affected frequencies being 4kHz (48.1%) and 6kHz (52.8%). DPOAE amplitudes remained robust at 2kHz, similarly to the current study. However, the results of the current study revealed that DPOAE mean amplitudes for Group A, B and C were also robust at 3651Hz, with a deterioration of Group D mean amplitudes evident only on visual inspection. Similarly to Korres et al. (2009) the current study revealed reduced DPOAE amplitude means at 5477Hz, possibly suggesting that

workers exposed to occupational noise in the beverage manufacturing industry are most affected in the higher frequency range of the DP-gram. Korres et al. (2009) did not consider the number of years of occupational noise exposure, therefore, the researchers were unable to comment on early cochlea changes as a result of years of occupational noise exposure in this industry.

Baradarnfar et al. (2012) conducted a study to compare the sensitivity of DPOAEs with pure tone audiometry for the early diagnosis of NIHL in workers exposed to high levels of noise within the tile industry. The study used similar DPOAE test parameters to the current study. An f1/f2 ratio of 1.22, primary combination levels of L1/L2 was L1 = 65dB SPL and L2 = 55dB SPL, and 2f1-f2 frequencies were measured with f2 frequency in half-octave-band frequencies of 1, 2, 3, 4, 6 and 8kHz. Furthermore, these participants were exposed to occupational noise with an average of 92dB(A), similarly to that of the current study where participants were exposed to noise at a level of 85-100dB(A). Baradarnfar et al. (2012) investigated the results of pure tone air conduction audiometry and DPOAEs of two groups as compared to a control group with no history of noise exposure. Group 1 was exposed to occupational noise but presented with normal pure tone audiograms and Group 2 was exposed to noise with evidence of NIHL seen on the pure tone audiogram. The results of the study revealed a significant difference in the DPOAE results between the first and second group as well as the first and third group, in the absence of a significant difference between the pure tone audiometry results of the first and second group.

Similarly to Korres et al. (2009), Baradarnfar et al. (2012) did not take into account the number of years of occupational noise exposure for each test group. However, both studies offer significant value to the argument that states that DPOAEs are able to detect subtle cochlea changes prior to changes seen on the pure tone audiogram. Additionally, both these studies highlight the importance of comparing the results obtained for each test group to that of a control group. The current study did not utilize a control group which may have allowed for enhanced inspection of the mean pure tone audiometry thresholds and the mean DPOAE amplitudes to investigate early noise-induced cochlea changes.

It is evident that several studies (Attias et al., 2001; Balatsouras et al., 2005; Korres et al., 2009; Edwards et al., 2010; Hall & Swanepoel, 2010; Baradarnfar et al., 2012; Sampaio et al., 2012) have reported that DPOAEs are able to detect subtle cochlea changes in the absence of corresponding hearing threshold changes seen on the pure tone audiogram. It is also evident that the type of noise that participants are exposed to needs to be considered as a typical noise notch may not be evident and a greater frequency range may be affected with exposure to impulse noise. This has implications for the protection and monitoring of cochlea changes for workers exposed to occupational noise. Although several studies have reported that DPOAEs are able to detect subtle cochlea changes, in order to be a feasible test, DPOAEs are also required to be repeatable for the monitoring of cochlea changes in noise exposed workers. This was explored in objective three of the study.

5.4 OBJECTIVE THREE

In order to realize this objective, the DPOAE test was conducted three times on each ear, per participant. A repeated measures ANOVA was used to analyze the data and where necessary, the post hoc Bonferroni adjustment was utilized. The ensuing tables and graphs display the means and standard deviations obtained for the right and left ears of each test group, as well as the significance levels obtained as a result of a comparison of the three DPOAE tests.

Table 5.4 Group A: Means, standard deviations and level of significance of DPOAE amplitudes obtained across the frequency range for the right ear

	DP1	DP2	DP3	
Frequency	Mean (Std Deviation)	Mean (Std Deviation)	Mean (Std Deviation)	
(Hz)	(dB SPL)	(dB SPL)	(dB SPL)	p-value
913	13 (7)	14 (7)	13 (7)	p = 0.717
1826	19 (9)	20 (8)	19 (8)	p = 0.402
2739	22 (7)	22 (7)	19 (9)	p=0.126
3651	22 (9)	24 (8)	23 (9)	p = 0.250
5477	17 (5)	17 (7)	17 (6)	p = 0.940
7303	11 (8)	11 (7)	12 (8)	p = 0.790

Table 5.5 Group A: Means, standard deviations and level of significance of DPOAE amplitudes obtained across the frequency range for the left ear

	DP1	DP2	DP3	
Frequency	Mean (Std Deviation)	Mean (Std Deviation)	Mean (Std Deviation)	
(Hz)	(dB SPL)	(dB SPL)	(dB SPL)	p-value
913	15 (6)	15 (6) 14 (6)		p = 0.448
1826	21 (10)	22 (10)	21 (8)	p = 0.635
2739	23 (8)	23 (7)	23 (7)	p = 0.975
3651	24 (6)	24 (7)	24 (7)	p = 0.707
5477	15 (7)	16 (7)	15 (7)	p = 0.229
7303	10 (8)	11 (8)	10 (7)	p = 0.467

The results displayed in Table 5.4 and Table 5.5 above revealed that the Group A mean DPOAE amplitudes (DP-NF) for the three tests were within the normal limit of >6dB SPL across the frequency range of 913Hz – 7303Hz bilaterally (Biologic Systems Corp., 2001). A comparison of the right ear mean DPOAE amplitudes of DP1, DP2 and DP3 and a comparison the left ear mean DPOAE amplitudes of DP1, DP2 and DP3 did not result in a statistically significant difference across the frequency range (p>0.05). A graphical representation of the right and left ear mean DPOAE amplitudes of Group A is displayed below in Figure 5.9 and Figure 5.10, respectively.

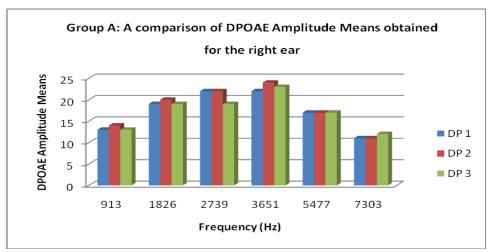


Figure 5.9 Group A: A comparison of DPOAE amplitude means obtained for the right ear

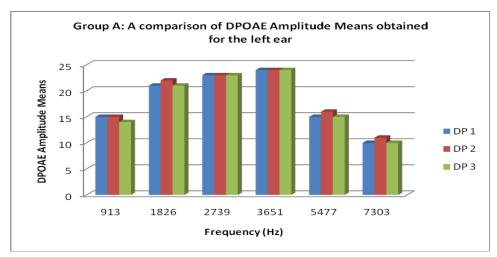


Figure 5.10 Group A: A comparison of DPOAE amplitude means obtained for the left ear

Visual inspection of Figure 5.9 and 5.10 above revealed that the Group A mean DPOAE amplitudes (DP-NF) for the three tests were within the normal limit of >6dB SPL across the frequency range of 913Hz - 7303Hz bilaterally (Biologic Systems Corp., 2001). Reduced DPOAE amplitudes are evident at 913, 5477 and 7303Hz for DP1, DP2 and DP3 bilaterally. These results indicate a good test-retest reliability of DPOAEs across the frequency range in the early identification of noise-induced cochlea changes as Group A consisted of workers exposed to occupational noise for 0-3years. The means, standard deviations and level of significance of DPOAEs obtained for Group B are displayed in Table 5.6 and Table 5.7 below.

Table 5.6 Group B: Means, standard deviations and level of significance of DPOAE amplitudes obtained across the frequency range for the right ear

	DP1	DP2	DP3	
Frequency (Hz)	Mean (Std Deviation) (dB SPL)	Mean (Std Deviation) (dB SPL)	Mean (Std Deviation) (dB SPL)	p-value
913	11 (8)	12 (7)	11 (7)	p = 0.329
1826	18 (9)	17 (9)	17 (9)	p = 0.613
2739	22 (6)	19 (6)	20 (6)	p = 0.319
3651	21 (10)	20 (9)	23 (7)	p = 0.420
5477	12 (10)	13 (10)	12 (9)	p = 0.037
7303	8 (9)	9 (10)	10 (8)	p = 0.159

Table 5.7 Group B: Means, standard deviations and level of significance of DPOAE amplitudes obtained across the frequency range for the left ear

	DP1	DP2	DP3	
Frequency (Hz)	Mean (Std Deviation) (dB SPL)	Mean (Std Deviation) (dB SPL)	Mean (Std Deviation) (dB SPL)	p-value
913	13 (8)	14 (8) 13 (8)		p = 0.897
1826	20 (9)	21 (10)	22 (9)	p = 0.425
2739	21 (10)	21 (10)	21 (11)	p = 0.981
3651	23 (10)	23 (9)	23 (10)	p = 0.732
5477	12 (10)	12 (9)	12 (10)	p = 0.627
7303	9 (10)	10 (10)	10 (10)	p = 0.276

The results displayed in Table 5.6 and Table 5.7 above revealed that Group B mean DPOAE amplitudes (DP-NF) for the three tests were within the normal limit of >6dB SPL across the frequency range of 913Hz – 7303Hz bilaterally (Biologic Systems Corp., 2001). A comparison of the right ear mean DPOAE amplitudes of DP1, DP2 and DP3 resulted in a statistically significant difference at 5477Hz (p=0.037). However, this statistically significant difference obtained with a repeated measures ANOVA was further investigated using the post hoc Bonferroni adjustment which revealed the absence of a statistically significant difference (p>0.05) between DP1 and DP2 (p=0.062), DP1 and DP3 (p=1.00) and DP2 and DP3 (p=0.076). A comparison of the left ear mean DPOAE amplitudes of DP1, DP2 and DP3 did not result in a statistically significant difference across the frequency range (p>0.05). A graphical representation of the right and left ear mean DPOAE amplitudes obtained for Group B is displayed overleaf in Figure 5.11 and Figure 5.12, respectively.

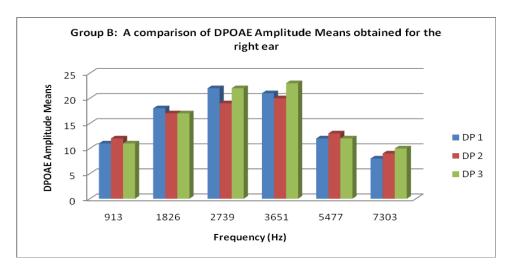


Figure 5.11 Group B: A comparison of DPOAE amplitude means obtained for the right ear

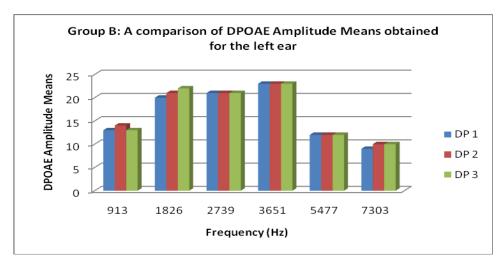


Figure 5.12 Group B: A comparison of DPOAE amplitude means obtained for the left ear

Visual inspection of Figure 5.11 and Figure 5.12 above revealed that the Group B mean DPOAE amplitudes (DP-NF) for the three tests were within the normal limit of >6dB SPL across the frequency range of 913Hz - 7303Hz bilaterally (Biologic Systems Corp., 2001). Reduced DPOAE amplitudes are evident at 913, 5477 and 7303Hz for DP1, DP2 and DP3 bilaterally. At 2739Hz and 3651Hz in the right ear, DP1 and DP3 present with improved mean thresholds as compared to DP2. On visual inspection there appears to be good repeatability of DPOAEs across the frequency range. This is especially evident at 2739, 3651 and 5477Hz. The means, standard

deviations and level of significance of DPOAEs obtained for Group C is displayed in Table 5.8 and Table 5.9 below.

Table 5.8 Group C: Means, standard deviations and level of significance of DPOAE amplitudes obtained across the frequency range for the right ear

	DP1	DP2	DP3	
Frequency	Mean (Std Deviation)	Mean (Std Deviation)	Mean (Std Deviation)	
(Hz)	(dB SPL)	(dB SPL)	(dB SPL)	p-value
913	10 (5)	10 (6) 9 (6)		p = 0.518
1826	17 (6)	18 (6)	17 (5)	p = 0.477
2739	20 (7)	20 (5)	19 (8)	p = 0.744
3651	20 (6)	22 (7)	19 (8)	p = 0.021
5477	12 (9)	13 (9)	12 (9)	p = 0.130
7303	8 (8)	8 (9)	8 (9)	p = 0.889

Table 5.9 Group C: Means, standard deviations and level of significance of DPOAE amplitudes obtained across the frequency range for the left ear

	DP1	DP2	DP3	
Frequency	Mean (Std Deviation)	Mean (Std Deviation)	Mean (Std Deviation)	
(Hz)	(dB SPL)	(dB SPL)	(dB SPL)	p-value
913	11 (6)	11 (6)	10 (7)	p = 0.948
1826	17 (7)	18 (6)	18 (6)	p = 0.665
2739	20 (7)	19 (7)	19 (6)	p = 0.520
3651	19 (10)	20 (9)	20 (10)	p = 0.901
5477	11 (9)	11 (10)	12 (10)	p = 0.371
7303	7 (8)	8 (8)	9 (8)	p = 0.240

The results displayed in Table 5.8 and Table 5.9 above revealed that the Group C mean DPOAE amplitudes (DP-NF) for the three tests were within the normal limit of >6dB SPL across the frequency range of 913Hz – 7303Hz bilaterally (Biologic Systems Corp., 2001). A comparison of the 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 which revealed a statistically significant difference (p<0.05) between DP2 and DP3 (p=0.041) at

3651Hz. A comparison of the left ear mean DPOAE amplitudes of DP1, DP2 and DP3 did not result in a statistically significant difference across the frequency range. A graphical representation of the right and left ear mean DPOAE amplitudes of Group C is displayed below in Figure 5.13 and Figure 5.14, respectively.

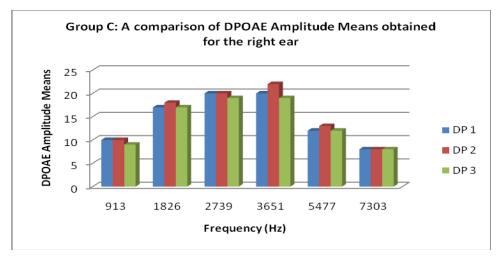


Figure 5.13 Group C: A comparison of DPOAE amplitude means obtained for the right ear

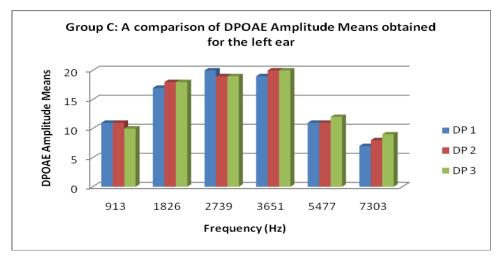


Figure 5.14 Group C: A comparison of DPOAE amplitude means obtained for the left ear

Visual inspection of Figure 5.13 and Figure 5.14 above revealed that the Group C mean DPOAE amplitudes (DP-NF) for the three tests were within the normal limit of >6dB SPL across the frequency range of 913Hz - 7303Hz bilaterally (Biologic Systems Corp., 2001). Reduced

DPOAE amplitudes are evident at 913, 5477 and 7303Hz for DP1, DP2 and DP3 bilaterally. On visual inspection there appears to be good repeatability of DPOAEs across the frequency range in the right ear, except at 3651Hz where DP2 (22dB SPL) presents with a slightly improved mean amplitude as compared to DP1 (20dB SPL) and DP3 (19dB SPL). On visual inspection there appears to be good repeatability of DPOAEs across the frequency range in the left ear, with a minimal difference between the mean DPOAE amplitudes at 7303Hz. The means, standard deviations and level of significance of DPOAEs obtained for Group D is displayed in Table 5.10 and Table 5.11 below.

Table 5.10 Group D: Means, standard deviations and level of significance of DPOAE amplitudes obtained across the frequency range for the right ear

	DP1	DP2	DP3	
Frequency	Mean (Std Deviation)	Mean (Std Deviation)	Mean (Std Deviation)	
(Hz)	(dB SPL)	(dB SPL)	(dB SPL)	p-value
913	10 (5)	10 (6) 9 (6)		p = 0.222
1826	17 (6)	18 (6)	17 (5)	p = 0.428
2739	20 (7)	20 (5) 19 (8)		p = 0.977
3651	20 (6)	22 (7)	19 (8)	p = 0.796
5477	12 (9)	13 (9)	12 (9)	p = 0.297
7303	8 (8)	8 (9)	8 (9)	p = 0.413

Table 5.11 Group D: Means, standard deviations and level of significance of DPOAE amplitudes obtained across the frequency range for the left ear

	DP1	DP2	DP3	
Frequency	Mean (Std Deviation)	Mean (Std Deviation)	Mean (Std Deviation)	
(Hz)	(dB SPL)	(dB SPL)	(dB SPL)	p-value
913	11 (6)	11 (7)	14 (6)	p = 0.014
1826	15 (9)	17 (8)	17 (7)	p = 0.456
2739	18 (10)	18 (9)	20 (9)	p = 0.158
3651	13 (12)	16 (11)	16 (12)	p = 0.062
5477	7 (8)	7 (8)	7 (8)	p = 0.631
7303	6 (7)	6 (7)	6 (7)	p = 0.898

The results displayed in Table 5.10 and Table 5.11 (Refer to page 108) revealed that the Group D mean DPOAE amplitudes (DP-NF) for the three tests were within the normal limit of >6dB SPL across the frequency range of 913Hz – 7303Hz bilaterally (Biologic Systems Corp., 2001). A comparison of the right ear mean DPOAE amplitudes of DP1, DP2 and DP3 did not result in a statistically significant difference across the frequency range. Whereas, a comparison of the left ear mean DPOAE amplitudes of DP1, DP2 and DP3 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. A graphical representation of the right and left ear mean DPOAE amplitudes of Group D is displayed below in Figure 5.15 and Figure 5.16, respectively.

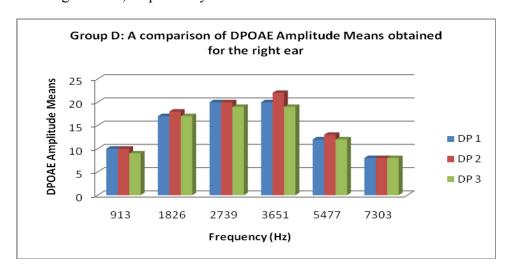


Figure 5.15 Group D: A comparison of DPOAE amplitude means obtained for the right ear

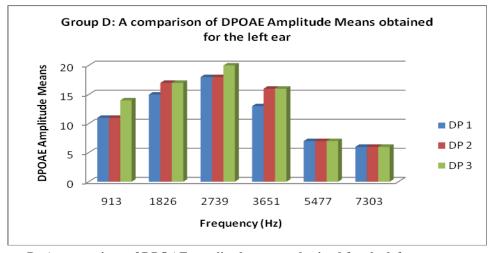


Figure 5.16 Group D: A comparison of DPOAE amplitude means obtained for the left ear

Visual inspection of Figure 5.15 and Figure 5.16 (Refer to page 110) revealed that the Group D mean DPOAE amplitudes (DP-NF) for the three tests were within the normal limit of >6dB SPL across the frequency range of 913Hz – 7303Hz bilaterally (Biologic Systems Corp., 2001). Reduced DPOAE amplitudes are evident at 913, 5477 and 7303Hz for DP1, DP2 and DP3 bilaterally. On visual inspection there appears to be good repeatability of DPOAEs across the frequency range bilaterally. At 3651Hz in the right ear, DP2 (22dB SPL) presents with a slightly improved mean amplitude as compared to DP1 (20dB SPL) and DP3 (19dB SPL). In the left ear at 913Hz and 2739Hz, DP3 presents with improved mean amplitudes as compared to DP1 and DP2. Furthermore, at 1826 and 3651Hz, DP2 and DP3 present with improved mean amplitudes as compared to DP1.

Thus, it is apparent that 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 for the monitoring of noise-induced cochlea changes over time for workers exposed to occupational noise in the beverage manufacturing industry. The results of the current study concurs with the findings of previous studies which indicate an overall high test-retest reliability of DPOAEs (Franklin et al., 1992; Zhao & Stephens, 1999, Beattie et al., 2003; Clark, 2005; Dreisbach et al., 2006; Wagner et al., 2008; Keppler et al., 2010). In the current study, a statistically significant difference was observed at 3651Hz in the right ear of Group C and further post hoc analysis revealed that that the difference was as a result of DP2 and DP3. Furthermore, a statistically significant difference was observed at 913Hz in the left ear of Group D and further post hoc analysis revealed that that the difference was as a result of DP2 and DP3. These results 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 (Zhao & Stephens, 1999, Beattie et al., 2003; Clark, 2005; Dreisbach et al., 2006; Wagner et al., 2008; Keppler et al., 2010).

Beattie et al. (2003) investigated the immediate and short-term test-retest reliability of DPOAEs at four test frequencies (550, 1000, 2000 and 4000Hz) on 25 normal hearing ears, over three time intervals, namely, immediate retest without repositioning the probe; repositioning of the probe and retest following 10-20 minutes; and lastly, retest 5-10 days after the initial test. The results of the study revealed poor test-retest reliability at 550Hz as compared to the higher frequencies. Standard errors were smaller for the immediate test-retest measures than for the DPOAE measurement done 10-20 minutes later. No test-retest reliability differences were found between the second (retest after 10-20 minutes) and the third (retest after 5-10 days) measurement. The results of this study indicated that probe removal and replacement was a major factor contributing to the increased variability of DPOAEs.

The results of a study conducted by Zhao & Stephens (1999) is in agreement with Beattie et al. (2003) as probe re-fitting and long term variance were significantly greater than short-term variability with no removal of the probe. However, the overall variance in the DPOAE measures was reasonably small at most frequencies greater than 1kHz. Franklin et al. (1992) also found that reliability testing at 1kHz across all measurements was least repeatable, whereas DPOAEs showed good repeatability at 2 to 8kHz. The authors attributed this to an increase in subject noise at 1kHz. Additionally, Keppler et al. (2010) found that the poorest test-retest reliability was found at 1, 1.4 and 8kHz. Wagner et al. (2008) further deduced that there was decreased DPOAE repeatability at frequencies below 1kHz, possibly attributed to the high susceptibility of internal noise in the lowest frequencies, and above 6kHz, possibly attributed to reduced DPOAE validity because of interference phenomena in the outer ear canal. This was observed in the current study as a significant difference was noted between DP2 and DP3 in the left ear of Group D at 913Hz. However, the finding of a significant difference between DP2 and DP3 in the right ear of Group C at 3651Hz is in contrast to that of previous studies and is possibly attributed to probe removal and reinsertion.

Keppler et al. (2010) conducted a short-term DPOAE test-retest reliability study on 14 females and 15 males over 5 sessions. The five sessions consisted of a baseline measurement, retest measurement without probe refitting, immediate retest measurement with probe refitting, retest measurement after 60 minutes, and lastly retest measurement after 7 days. The results of the study revealed highly significant between-subject variability with an overall good reliability of DPOAEs. It was noted that reliability decreased after probe fitting and with greater time intervals between DPOAE measurements. A higher reliability was noted for the primary tone level combination of L1/L2 = 75/70dB SPL as compared to L1/L2 = 65/55dB SPL.

This is in contrast to the results of Franklin et al. (1992) who found that varying primary tone levels from 55 to 75dB SPL had little influence on the test-retest reliability of DPOAEs. Dreisbach et al. (2006) agreed with the results of Franklin et al. (1992) as they found that at the frequencies <8kHz, repeated DPOAE level variations were within +/-10dB for 98.4 and 96% of young adult participants for the 70/55 and 60/50dB SPL stimulus level conditions, indicating that both combinations of primary tone levels are efficient. The current study utilized a primary level tone combination of L1/L2 = 65/55 dB SPL and resulted in overall good test-retest reliability of DPOAEs. There is general consensus that primary tone levels of >55dB SPL are preferable in obtaining reliable DPOAE results, however, there is little consensus regarding which primary tone level combination is most suitable for the measurement of repeatable DPOAEs.

Franklin et al. (1992) investigated the test–retest reliability of DPOAEs in 12 normal hearing participants (7 males and 5 females). The results of the study revealed a great inter-subject variability, similar to the findings of Keppler et al. (2010). However, the findings of a relatively heterogeneous population determined by the mean DPOAE amplitudes of various participants does not necessarily indicate that the overall test-retest reliability of DPOAEs will be poor (Franklin et al., 1992). Franklin et al. (1992) proved this by showing that test-retest reliability remained good across weeks as it did over days, and together, the calculated reliability values for the daily and weekly measures indicated that a high degree of correlation in DPOAE amplitudes

can be expected when this test is repeatedly administered to the same individual over time. The current study investigated the immediate test-retest reliability of DPOAEs. An investigation of DPOAE repeatability over time, namely, weeks or months, may have provided more information regarding the overall test-retest reliability of DPOAEs as a test for the monitoring of noise-induced cochlea changes for workers exposed to occupational noise in the beverage manufacturing setting.

Test-retest is expected to be highest when the retest immediately follows the initial test (Beattie et al., 2003). This is due to a minimization in the likelihood of changes in hearing, environmental or subject noise and probe tip position (Franklin et al., 1992; Zhao & Stephens, 1999, Beattie et al., 2003). Zhao & Stephens (1999) state that changing the position of the probe tip may affect the level of background noise in the ear canal, especially in the low frequencies; acoustic leakage; and the interaction of the ear canal resonance and the acoustic stimuli. For this reason, slightly poorer test-rest reliability is expected following a short break and/or removal or replacement of the probe tip (Beattie et al., 2003). Furthermore, this allows for more opportunities for changes in hearing, namely, environmental or subject noise, as well as swallowing or coughing which may alter middle ear pressure (Beattie et al., 2003). Although, a statistically significant difference was observed between DP2 and DP3 at two frequencies in the current study, overall test-retest reliability of DPOAEs was good and the removing and reinserting of the probe tip did not seem to affect the overall reliability of DPOAEs in the current study.

A review of the available literature suggests that DPOAE test-retest reliability decreases when the test probe is removed and replaced, when the retest time is increased from the same day to weeks, when the L2 level decreases from 75dB SPL to 55dB SPL, and lastly when f2 increases above 4000Hz (Franklin et al., 1992; Zhao & Stephens, 1999; Beattie et al., 2003; Dreisbach et al., 2006; Keppler et al., 2010). Another significant factor in the determination of DPOAE test-retest reliability is signal-to-noise ratio (SNR). Zhao & Stephens (1999) conducted DPOAE

testing in a double-walled, electrically shielded, sound-isolation chamber and were, therefore, able to use a SNR of >3dB SPL to accurately obtain DPOAE responses. Beattie et al. (2003) looked at the effects of SNR (3, 6 and 12dB) on the test-retest reliability of DPOAEs. The results showed that varying the SNR (3, 6 and 12dB) had no substantial effects on DPOAE reliability and this is possibly due to the fact that testing was conducted in a sound treated booth. Edwards et al. (2010) utilized a signal-to-noise ratio (SNR) of 10dB SPL as testing was conducted at different occupational health centers with varying ambient noise levels. The lower the SNR, the less reliable the results were and the greater the margin of error in recording the results (Edwards et al., 2010). SNR is directly related to the control of the ambient noise in the test environment as the quieter the environment, the easier it is for the recording equipment to distinguish between an emission and background noise (Edwards et al., 2010).

Edwards et al. (2010) found that the lowest (633Hz) and highest (6434Hz) frequencies did not reach a SNR of 10dB SPL, however, the level was still greater than 6dB SPL, a level still regarded as acceptable in clinical practice. Keppler et al. (2010) recommends the use of a SNR of 12dB as the relative influence of noise on the emission amplitude is smaller, reducing the variability of the emission amplitudes and decreasing the probability of false-positive responses. However, Wagner et al. (2008) states that the widely used minimum SNR of 6dB is a recommended criterion when considering measurement quality in a clinic setting and this is in agreement with Clark (2005). There appears to be poor consensus in the literature regarding the appropriate SNR to be used in the measurement of DPOAEs. The current study utilized a SNR of 6dB SPL. Ambient noise levels were controlled by conducting DPOAEs in a sound treated booth within a quiet room in a clinic setting. Furthermore, sound level measurements within the test environment were conducted once daily prior to testing to ensure that ambient noise levels were within the recommended level of 43dB(A) (Noise Control Reference, 2012).

It is evident that several factors may affect the test-retest reliability of DPOAEs. These include placement of the probe tip (Zhao & Stephens, 1999, Beattie et al., 2003; Clark, 2005; Dreisbach et al., 2006; Wagner et al., 2008; Keppler et al., 2010), ambient noise levels and biological noise

(Beattie et al., 2003; Wagner et al., 2008; Edwards et al., 2010); signal-to-noise ratio (Beattie et al., 2003; Edwards et al., 2010; Keppler et al., 2010); the combination of primary tone levels (Franklin et al., 1992; Dreisbach, 2006; Keppler et al., 2010) and the time intervals between testing (Wagner et al., 2008; Keppler et al., 2010). There appears to be a high inter-subject variability, with a good overall DPOAE test-retest reliability reported by numerous studies. A good test-retest reliability of DPOAEs was also found in the current study. Testing was conducted in a clinic setting at a manufacturing company, indicating that similar results would be obtained in other clinic settings with the use of appropriate test parameters and when ambient noise is sufficiently low. A good test-retest reliability further indicates the feasibility of DPOAEs in the annual medical surveillance test battery. Furthermore, to form part of the annual medical surveillance test battery, DPOAEs are required to be quick to conduct on many workers by trained personnel.

Several authors have stated that DPOAEs are a rapid and simple test to perform (Balatsouras et al., 2005) as well as a quick test (Attias et al., 2001; Johnson, 2002; Clark, 2005; Wagner et al., 2008). However, no studies could be found depicting the actual time taken to conduct DPOAE testing bilaterally. The current study, therefore, recorded the time taken to conduct DPOAE testing in order 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, this included the time taken to remove and reinsert the probe. Table 5.12 below illustrates the time taken to complete DPOAE testing bilaterally for each test group.

Table 5.12 Duration of time taken to administer DPOAEs for Group A, B, C and D

	Group A	Group B	Group C	Group D	Average
Duration					
(seconds)	86	90	81	86	86

In the beverage manufacturing company there were approximately 105 employees within the demarcated noise zones. Therefore, an additional time of only 86 seconds would be required for the occupational nurse to test each worker exposed to noise within these demarcated noise zones. The current study supports the notion that the DPOAE test is quick to administer as reported by previous authors (Attias et al., 2001; Johnson, 2002; Balatsouras et al., 2005; Clark, 2005; Wagner et al., 2008). These findings may also be applicable to other industrial settings where DPOAE testing is utilized in the monitoring of cochlea changes for workers exposed to occupational noise. Being a quick test to administer adds to the feasibility of including DPOAEs in the annual medical surveillance test battery.

5.5 CONCLUSION

The current study aimed to determine the feasibility of including DPOAEs in the annual medical surveillance test battery for the identification of NIHL in a group of employees in the beverage manufacturing industry in KwaZulu-Natal. The feasibility of the test was investigated by exploring the sensitivity and specificity of DPOAEs, the ability of DPOAEs to detect early subtle cochlea changes in a group of workers exposed to occupational noise, the test-retest reliability of DPOAEs and, lastly, the duration of time taken to conduct DPOAEs. A high sensitivity of DPOAEs was found in the current study, especially in the high frequency region of the audiogram, where noise-induced cochlea changes are most likely to occur and this is in agreement with previous studies (Kim et al., 1996; Attias et al., 2001, Balatsouras, et al., 2005; Jhetam et al., 2008; Edwards, et al., 2010; Swanepoel & Hall, 2010; Baradarnfar, et al., 2012).

Visual inspection of the DP-gram in the current study revealed a bilateral reduction in DPOAE amplitudes in the high frequency region of the DP-Gram, namely, 5477Hz and 7303Hz, in the absence of a statistically significant difference. This was evident for all test groups, indicating that subtle cochlea changes were observed, even for Group A, who were exposed to occupational noise for as little as 0-3 years. Pure tone audiometry was unable to detect NIHL in the group of

workers exposed to occupational noise for 0-3 years within the beverage manufacturing industry. However, noise notch configurations were evident for participants with a longer history of occupational noise exposure. This indicates that DPOAEs may be a feasible test to monitor early noise-induced cochlea changes. The findings of the current study are in agreement with several other studies (Attias et al., 2001; Balatsouras et al., 2005; Korres et al., 2009; Edwards et al., 2010; Hall & Swanepoel et al., 2010; Baradarnfar, 2012; Sampaio et al., 2012).

A good test-retest reliability obtained across the frequency range in the current study further suggests the feasibility of including DPOAEs in the annual medical surveillance test battery. These results are in agreement with numerous studies which have reported a good overall DPOAE test-retest reliability (Franklin et al., 1992; Zhao & Stephens, 1999, Beattie et al., 2003; Clark, 2005; Dreisbach et al., 2006; Wagner et al., 2008; Keppler et al., 2010). Although several factors may influence test-retest reliability, similar results may be obtained in other clinic settings with the use of appropriate test parameters, appropriately trained personnel and when ambient noise is sufficiently low. Lastly, an average of 86 seconds (1 minute, 26 seconds) was calculated to conduct the DPOAE test bilaterally. Therefore, the results of the current study is in agreement with previous authors (Attias et al., 2001; Johnson, 2002; Balatsouras et al., 2005; Clark, 2005; Wagner et al., 2008) who state that the DPOAE test is quick to administer. It is evident that it may be feasible to include DPOAEs as part of the annual medical surveillance test battery for the early identification of noise-induced cochlea changes for a group of workers in the beverage manufacturing industry.

CHAPTER SIX: CONCLUSION

6.1 INTRODUCTION

This chapter provides a conclusion of the significant findings of the study. Limitations of the

study and implications for future research are also discussed.

6.2 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 (Sliwinska-

Kowalska & Kotylo, 2001). This is commonly referred to as occupational noise-induced hearing

loss, which is a progressive, sensorineural hearing deficit resulting from irreversible damage to

the outer hair cells of the cochlea within the inner ear (Kurmis & Apps, 2007). A typical NIHL

presents as a noise notch between 3-6kHz on the pure tone audiogram (Attias et al., 2001;

Kurmis et al., 2007; Schmuziger et al., 2007). This pattern is said to be seen following exposure

to continuous noise, in which the earliest damage occurs between 3000 and 6000Hz (Sataloff et

al., 2011). Additionally, there is recent research to show that the effects of impulse noise on

hearing thresholds may affect a greater frequency range, between 1-8kHz, in the absence of a

noise notch (Tambs et al., 2006; Balatsouras et al., 2005; Edwards, van Coller & Badenhorst,

2010).

Workers in the beverage manufacturing industry are exposed to both continuous and impulse

noise due to the use of heavy machinery. These noise sources include truck offloading and the

use of forklifts, angle grinders, pneumatic wrenches, cut-off saws and grinders, can cutters and

bench grinders. In the current study, sound level measurements at a beverage manufacturing

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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.

There is evidence to show that attitudes to noise may be influenced by the perspective from which workers perceive it (Reddy et al., 2012). Furthermore, the perceived benefit and selfefficacy of use correlates strongly with the use of hearing protection devices and the compliance to hearing conservation programs (Kurmis & Apps, 2007). This implies that if workers are educated regarding the type of noise that they are exposed to and, as a result, if they are able to identify noise as a hazard, it will support the idea of the importance of using hearing protection devices to prevent NIHL (Reddy et al., 2012). This suggests a role for an educational approach to increase the awareness of workers regarding the prevention of NIHL, the importance of hearing protection devices and compliance with the South African guidelines and standards. Kurmis & Apps (2007) state that current standards should recommend good education, ear protection and information about how to preserve hearing and how to avoid NIHL when working in noisy environments. Although NIHL is permanent and irreversible, it is the most preventable type of hearing impairment and can be avoided by early detection and prevention (Atchariyasathian et al., 2008). Thus, the current standards should also ensure that an appropriate, adequate and feasible test battery is used for annual medical surveillance within a hearing conservation program for the early identification of noise-induced cochlea changes.

The South African National Standard (SANS): 10083 (2004) 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 (Korres et al., 2009; Attias et al., 2001; Clark & Bohl, 2005). Many employees incur their hearing losses during the first 5 to 10 years (Morata et al., 2005). 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 (Rosen et al., 2001). This means that whenever a referral threshold shift is recorded in a hearing conservation program, there is already significant damage to the inner ear (Korres et al., 2009). Several other studies have demonstrated the inadequacy of pure tone audiometry in the early identification of noise-induced hearing loss (Attias et al., 2001; Schmuziger et al., 2007; Edwards et al., 2010).

Vinck et al. (1999) suggested that OAE measurement might provide an interesting alternative to pure tone audiometry in monitoring cochlea changes in workers exposed to occupational noise. A decade later, there is more evidence to show that DPOAEs should be used in conjunction with pure tone audiometry in the monitoring of cochlea changes as a result of noise exposure (Korres et al., 2009; Edwards et al., 2010, Swanepoel & Hall; 2010) as it is a sensitive measure of cochlea function, with the potential for pre-clinical detection of damage (Engdahl & Tambs, 2002). This suggests that DPOAE testing should be included in the annual medical surveillance test battery for the identification and monitoring of noise-induced cochlea changes in noise exposed workers.

Therefore, the current study also investigated the feasibility of including DPOAEs in the annual medical surveillance test battery for the identification of NIHL in a group of employees in the beverage manufacturing industry in KwaZulu-Natal, South Africa. Feasibility was investigated by determining the sensitivity, specificity and predictive efficiency of DPOAEs, the ability of DPOAEs to detect subtle noise-induced cochlea changes, the test-retest reliability of DPOAEs and lastly, the duration of time taken to conduct the DPOAE test bilaterally. A high sensitivity and negative predictive value was reported in the current study, with good test-retest reliability. Visual inspection of the DP-gram in the current study for all test groups revealed a bilateral

reduction in DPOAE amplitudes in the high frequency region of the DP-Gram, namely, 5477Hz and 7303Hz, 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 history of noise exposure. This was not seen bilaterally as is typically expected with NIHL. Good test-retest reliability across the frequency range obtained in the current study further indicates the feasibility of including DPOAEs in the annual medical surveillance test battery. Additionally, the current study calculated an average of 86 seconds (1 minute 26 seconds) to conduct the DPOAE test bilaterally, confirming that DPOAEs are a quick test to administer.

Although DPOAEs are not intended to be a test of auditory function in isolation, 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 (Franklin et al., 1992). Two decades later, several more studies have reiterated the thoughts of Franklin et al. (1992) 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.

6.3 LIMITATIONS

- 6.3.1 The primary limitation of the study is that the findings are only relevant for noise-exposed workers within the beverage manufacturing industry and may not be generalized to other industries. This is due to the unique type of noise and sound levels found in this industry.
- 6.3.2 The study utilized a limited sample size. A larger sample size may allow for further inferences to be made regarding the feasibility of DPOAEs for inclusion in the annual medical surveillance test battery put forth by SANS (2004).
- 6.3.3 In the calculation of the sensitivity of DPOAEs, a specific formula was used, which resulted in zero as the denominator. This is a mathematical error and hence, sensitivity could not be calculated at certain frequencies. This may have affected the overall sensitivity of the DPOAEs in the current study.
- 6.3.4 A control group was not utilized in this study. A control group may have allowed for enhanced inspection of mean pure tone thresholds and mean DPOAE amplitudes to investigate early noise-induced cochlea changes.
- 6.3.5 Repeatability of DPOAEs was limited to immediate test-retest conditions. An investigation of DPOAE repeatability over time may have provided more information regarding the overall test-retest reliability of DPOAEs in the beverage manufacturing setting.
- 6.3.6 The current study did not control for non-disclosed infectious diseases (e.g. HIV/AIDS) and this could have impacted on the results of the study.
- 6.3.7 This study focused on test-retest reliability. The inclusion of inter-test reliability measures with the use of an occupational nurse may have provided more information regarding the reliability of DPOAEs. However, due to limited nursing staff at the beverage manufacturing company, this could not be done in the current study.

6.4 CLINICAL IMPLICATIONS

- 6.4.1 DPOAEs presented with a high sensitivity and negative predictive value, indicating that DPOAEs may be able to identify those who present with subtle cochlea changes as a result of exposure to occupational noise.
- 6.4.2 DPOAEs were reduced in the high frequency region of the DP-Gram for all test groups, including workers who have only been exposed to noise for 0-3 years, in the absence of corresponding findings on the pure tone audiogram for those workers exposed to noise for 0-3 years. This indicates that DPOAEs may be used to monitor subtle noise-induced cochlea changes for workers exposed to noise in the beverage manufacturing industry.
- 6.4.3 In addition, the results of this study suggest that DPOAEs may be used as a monitoring tool to evaluate the effectiveness of hearing conservation programs in the beverage manufacturing setting.
- 6.4.4 A good test-retest reliability of DPOAEs found in the current study suggests that DPOAEs may be used to monitor subtle noise-induced cochlea changes for workers exposed to noise in the beverage manufacturing industry.
- 6.4.5 The current study revealed that an average of 86 seconds is required complete the DPOAE test bilaterally. This confirms that DPOAEs are a quick test of cochlea function and could be included in the annual medical surveillance test battery without resulting in excessive testing time.
- 6.4.6 The findings of this study may have implications for a multidisciplinary team approach in hearing conservation as Audiologists may have a role in the training of occupational nurses for the identification and monitoring of noise-induced cochlea changes in this industry
- 6.4.7 The use of DPOAEs as an objective measure of cochlea function in the annual medical surveillance test battery would allow the occupational nurse/Audiologist to assess potential pseudohypacusis which is often prevalent in industry.

6.5 RESEARCH IMPLICATIONS

- 6.5.1 Participants accessed from other beverage manufacturing companies in South Africa would better represent the noise-induced cochlea changes in this population.
- 6.5.2 A longitudinal study to investigate the use of DPOAEs in the annual medical surveillance test battery would provide valuable information regarding long-term outcomes and feasibility of DPOAEs.
- 6.5.3 A study with a larger sample size across different types of industries and different types and intensities of noise may provide more information regarding the feasibility of including DPOAEs in the annual medical surveillance test battery.

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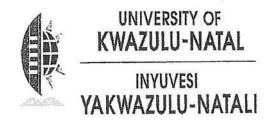
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APPENDIX A

04 June 2012

The CEO

Re: Feasibility of Conducting Research in Audiology at ABI

I am a student currently undertaking a Masters in Communication Pathology (Audiology) degree at the University of KwaZulu-Natal (Westville Campus).

Several studies have demonstrated the detrimental effects of occupational noise on hearing (Tambs, Hoffman, Borchgrevink, Holmen & Engdahl, 2006). The South African National Standard (2004) states that workers exposed to occupational noise at or above a noise rating limit of 85dBA are required to undergo medical surveillance, i.e. a baseline audiogram and periodic screening audiometry. This is to ensure that workers presenting with possible hearing loss are timeously referred for a diagnostic audiological evaluation and management thereafter. In addition to the screening tests outlined by the South African National Standard (2004), recent developments advocate the use of an objective test for the early identification of noise-induced hearing loss, known as Distortion Product Otoacoustic Emissions (DPOAEs). DPOAEs directly assess the function of the outer hair cells of the cochlea, which are specifically susceptible to the damaging effects of noise on hearing.

The purpose of this study will be to explore the possibility of DPOAEs being included in the periodic screening protocol of SANS (2004) for employees exposed to occupational noise at or above the noise rating limit of 85dBA. In order to achieve this, the study will investigate the sensitivity and specificity of DPOAEs as well as the effectiveness of DPOAEs in detecting mild hearing changes following minimal noise exposure. In order for this to be demonstrated, employees within this industry need to be assessed with DPOAEs.

It is for this reason that I am approaching Amalgamated Beverage Industries (ABI) to conduct the study at your Phoenix plant. I request permission to assess your employees hearing as part of their annual periodic screening test and to assess the feasibility of including DPOAEs in the periodic screening protocol. The actual testing procedure will include Otoscopy (inspection of the ear), Tympanometry (assessing the function of the middle part of the ear), Pure Tone Audiometry (finding the softest level at which the individuals can hear tones across different pitch level) and DPOAE testing (assessing the function of the cochlear). This will all take approximately 10 minutes per employee, over a period of approximately one to two weeks. Testing will be conducted daily, possibly between 02/07/2012 – 13/07/2012, at your convenience.

In order to complete the testing, I would require the following:

- 1. Access to invite employees to participate in the study.
- A list of employees working for particular time periods, i.e. 0-2 years, 2-5 years and >5 years.
- 3. Access to audiological equipment on the company premise.
- 4. Employees to complete a pre-test case history questionnaire.
- Employees to undergo periodic audiometric screening as per SANS 2004 and the additional test i.e DPOAE which is part of this study.

Once an employee is approached to participate in the study, they will be informed that their participation is voluntary and no employee will be obligated to participate. Informed consent will be obtained from all participants and they will be provided with written information documents to further enhance their knowledge of the study.

Furthermore, confidentiality will be maintained at all times. The personal details and periodic screening audiometry results of all participants will remain anonymous for the duration of the research study and thereafter. This will be achieved by assigning a numerical value to each participant. Additionally, the personal details and periodic audiometric screening results of all participants will be stored in a locked cupboard on the University of KwaZulu-Natal (Westville campus) premises. Only the researcher and two supervisors will have access to the data.

The results of all audiological test procedures will be carefully explained to each participant, with the use of visual aids, i.e. a diagram of the ear, the pure tone audiogram and the DPOAE results. If any of the participants require further audiological or medical management, they will be referred to the appropriate professional for further management (i.e. General Practitioner or Ear, nose and throat specialist). Moreover, the occupational hygienist/ nurse will be notified of the findings and the participants will thereafter be monitored via the company's existing management protocol.

The employees may benefit from their participation in the study as they will receive education and training regarding hearing, hearing loss, the importance of hearing protection and correct use of hearing protection. In addition, they will undergo free DPOAE testing which is regarded as a very specialized test procedure, which will provide reliable objective results. As a result of this study, it is hoped that employers in this industry will be able to remediate and implement hearing conservation programs to protect their employees. This will ensure that employees within this industry are productive as well as protected.

In terms of ethical clearance for this study, I have received provisional ethical clearance from the University of KwaZulu-Natal. Complete clearance will be granted pending a letter from the company at which I will conduct data collection. Should I receive permission to conduct research at ABI, the ethics board will be notified and the final ethical clearance letter will be forwarded to you.

Your assistance in my research project will be	
Yours sincerely	
Tarryn Marisca Reddy	
Audiologist	
4	
*	·
S. Panday	C. D. Govender
Supervisor	Supervisor



Ck 94/05783/23

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APPENDIX B

P. O. Box 273, Gillitts, 3603 No. 2 Gilro Park 34 Gillitts Road

Pinetown, 3610

Certificate of Sound Pressure Levels for Audiometric Booth /Room					
Company Name	& Address				
LIFE	0.14		Certifica	te no. 5114	32581
@ AS1	Prepare KD		94-	Pre- Calibration	Microphone
**********************	*************************		14-0	Post Calibration	Microphone
Type of Booth	LX A				
Frequency in Hertz	Screening Levels	Diagnostic Levels	With Fan	Without Fan	Average SPL
8000	35.5	35.5		~	14.9
4000	37.0	37.0			15.0
2000	31.0	31.0			15-3
1000	24.0	24.0			15.4
500	22.0	20.5			16.0
250	38.5	21.0			16· 7
125	52.0	29.0	L		15-7
Calibration Equipm	ent (G)		Calibration I	Equipment (P)	
Quest CRL224 Quest B&K 4153 AGO Toptronic	1800 Sound Level Meter OB-300 Octave Filter 1/2" Microphone CA 22 Calibrator Artificial Ear 7013 Microphone 11504 Multimeter 4930 Artificial Mastoid	HP2030920 HV1070028 900028 J1070023 1601611 11821 845v10 842289	Quest Quest Quest Artificial Ear B & K L & D Mutil-meter Toptronic B-71 Bone Vibrator 500c	1800 Sound Level Meter CA -12B Sound Calibrator OB 100 Octave Filter L & D AEC 101 4938 ½ "Microphone 2559 ½ "Pressure Microphone T1504 Medi PK 1A Artificial Ear Weight	HP1070017 U2030044 HW6120027 D189 2064317 32141 0520 52107A
Certificate numbers: (G) 2011-0721-22-20-19 & (P) 2011-0775-73-74					
Audiometric Booth has been checked in accordance with the SANS 10182-1:2004 and was found to be in agreement with the recommended limits. The certification of the calibration is valid for a period of one year (subject to the expectations given in SANS 10182-1:2004) While every endeavor is made to ensure this certificate is accurate, Stanyer Electroserve cc or its employees shall in no way be liable for any errors, whether in fact or opinion.					
Additional notes:			***************************************		
Calibration Date:	25-10		Calibration	Due;2.9	1-10-15
Calibrated by:	Mr. G.D. Stanye	er / Mr. P.T. Stanyer	Signature:		
(GDS) Certified in Noise Measurement and Calibration Department of Manpower Ref: 34/2/8/27/12 (PTS) Certified in Calibration and Tasting of Audio Equipment, Cape Peninsula University of Tachnology Ref: 208211926					
•		Member: Mr. G.D. Stanyer			

APPENDIX C

TEST ENVIRONMENT: MEASURED SOUND LEVELS

Date	LAI Max (dB)	LAI Min (dB)	Laeq (dBA)	LZpk (dB)
29.08.12	56.9	31.3	35.6	92
30.08.12	66.3	30	33.9	92.1
03.09.12	62.2	29.8	32.5	91.8
04.09.12	58.1	29.3	31.5	86.2
05.09.12	58.2	53.1	41	70.5
07.09.12	70.2	29.8	38.4	94.7
10.09.12	72.9	29.8	36.9	98.7
13.09.12	68.9	30.3	34	93.2
17.09.12	62.2	30.1	32.5	93.2
	64	32.6	35.1	90.3



4B 130

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CERTIFICATE OF CALIBRATION

CERTIFICATE NUMBER	2012-1202
ORGANISATION	UKZN-DISCIPLINE of AUDIOLOGY
ORGANISATION ADDRESS	PRIVATE BAG X 54001, DURBAN, 4000
CALIBRATION OF	INTEGRATING SOUND LEVEL METER with built-in %-OCTAVE/OCTAVE FILTER and %" MICROPHONE
CALIBRATED BY	M. NAUDĖ
MANUFACTURER	CEL
MODEL NUMBERS	450 and 485
SERIAL NUMBERS	468811 and 001414
DATE OF CALIBRATION	7 AUGUST 2012
RECOMMENDED DUE DATE	AUGUST 2013
PAGE NUMBER	PAGE 1 OF 4

This certificate is issued in accordance with the conditions of approval granted by the South African National Accreditation System (SANAS). This Certificate may not be reproduced without the written approval of SANAS and M and N Acoustic Services.

Calibrations performed by this laboratory are in terms of standards, the accuracies of which are traceable to national measuring standards as maintained by NMISA

The measurement results recorded in this certificate were correct at the time of calibration. The subsequent accuracy will depend on factors such as care, handling, frequency of use and the amount of different users. It is recommended that re-calibration should be performed at an interval, which will ensure that the instrument remains within the desired limits and/or manufacturer's specifications.

The South African National Accreditation System (SANAS) is member of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). This arrangement allows for mutual recognition of technical test and calibration data by member accreditation bodies worldwide. For more information on the arrangement please consult www.ilac.org

M.W. DE BEER (SANAS TECHNICAL SIGNATORY)

DATE OF ISSUE

1. PROCEDURE

The UUT was calibrated according to procedures 1002/P/003 to 1002/P/007 and to the SANS 656:2008, SANS 658:2008 and IEC 1260 specifications for Sound Level Meters, Integrating Sound Level Meters and Octave and 1/3-Octave Filters respectively as well as the manufacturer's specifications.

2. MEASURING EQUIPMENT

JFW	50BR-022	50 Ohm Step Attenuator	3157070043
Agilent	33220A	Function Generator	MY 44022646
Hang Chung	9205	Function Generator	920516183
Agilent	33220A	Function Generator	MY 44050084
Agilent	34410A	Digital Multimeter	MY 47016754
B&K	2610	Measuring Amplifier	145076
B&K	2645	1/2" Pre-Amplifier	1833489
B&K	4226	Multi-Function Acoustic Calibrator	2739549
B&K	UZ 0001	Barometer	LS-02

3. RESULTS

3.1 The following parameters of the Integrating Sound Level Meter were calibrated:

Parameter	Specification	Uncertainty of Measurement in dB
Input sensitivity	Manufacturer's specification	$\pm 0,23$
Amplitude Linearity (at 40 Hz, 1 kHz and 8 kHz	SANS 656: sections 9.9 & 9.10	± 0,27
from 40,0 dB to 120,0 dB)		
Weighting Network A (40 Hz to 20 kHz)	SANS 656: section 8.1	1 0,27
Weighting Network C (40 Hz to 20 kHz)	SANS 656; section 8.1	± 0,27
Linear (40 Hz to 20 kHz)	Manufacturer's Specification	± 0,27
Detector network (Fast, Slow and Impulse)	SANS 656: sections 9.2 & 9.3	± 0,27
Integrating (Time Averaging)	SANS 658: section 11.3.3	± 0.27
Integrating (Pulse Range)	SANS 658: section 11.3.5	± 0,33
Impulse Integrating (AI-weighted)	SANS 658: annex C	± 0.27
SEL (LAE)	Manufacturer's Specification	± 0.27
Peak Level	Manufacturer's Specification	$\pm 0,27$
Max. /Min. Level	Manufacturer's Specification	$\pm 0,27$
AC Output Level	Manufacturer's Specification	± 0,24

M.W. DE BEER (SANAS TECHNICAL SIGNATORY)

Only Member : Marianka Naude

Conclusion: The Integrating Sound Level Meter complied with the above-

specified clauses of the SANS 656:2008 and 658:2008

specifications, Type 2.

3.2 The following parameters of the 1/2" Microphone were calibrated:

Output sensitivity at 250 Hz Frequency response (125 Hz to 2 kHz)

Conclusion: The parameters measured for the 1/2" Microphone, complied

with the manufacturer's specification.

3.3 The following parameters of the built-in 1/3-Octave/Octave Filter was calibrated:

Octave Frequency response IEC 1260: sections 4.7 & 5.6

(63 Hz to 8 kHz)

1/2-Octave Frequency response IEC 1260: sections 4.7 & 5.6

(40 Hz to 12,5 kHz)

Conclusion: The built-in 1/2-Octave/Octave Filter complied with the above-

specified clauses of the IEC 1260 specification, Class 2.

4. REMARKS

4.1 The reported expanded uncertainties of measurements are based on a standard uncertainty multiplied by a coverage factor of k=2, providing a level of confidence of approximately 95,45 %, the uncertainties of measurements have been estimated in accordance with the principles defined in the GUM (Guide to Uncertainty of Measurement) ISO, Geneva, 1993

4.2 The environmental conditions were: Temperature: (23 ± 2) °C

Relative Humidity: (50 ± 15) %.

M.W. DE BEER (SANAS TECHNICAL SIGNATORY)

Only Member : Marlanka Naude

- 4.3 Calibration labels bearing cal date, due date (if requested), certificate number and serial number have been affixed to the instrument.
- 4.4 The uncertainties of the measurements were taken into account when the above statements of compliance to the relevant specifications are made.
- 4.5 Applicable only for South Africa: The SANS 656:2008 and SANS 658:2008 replace IEC 60651 and IEC 60804 Specifications for Sound Level Meters and Integrating Sound Level Meters respectively. Please note that these specified SANS specifications, the technical and prescriptive contents, is precisely the same as the abovementioned IEC Specifications. South Africa was forced to perform the name change exercise on the abovementioned IEC Specifications, due to the international superseding of the IEC 60651 and IEC 60804 Specifications by the IEC 61672 Specification parts 1, 2 and 3.
- 4.6 The total uncertainty of measurements was estimated as follows:

Integrating Sound Level Meter: $\pm 1.2 \text{ dB}$ ½" Microphone: $\pm 0.9 \text{ dB}$ Built-in ½-Octave/Octave Filter $\pm 0.5 \text{ dB}$

-----SECTION 4.6 THE END OF CERTIFICATE-----

UNIVERSITY OF KWA-ZULU NATAL DISCIPLINE OF AUDIOLOGY

CASE HISTORY QUESTIONNAIRE

Dear Participant

- This is a research project to determine if the feasibility of including distortion product otoacoustic emissions in the annual medical surveillance test battery for the identification of noise-induced hearing loss in a group of workers in the beverage industry.
- The researcher would like to assure you that all test results will remain confidential and that utmost care will be taken when conducting all test procedures.

INSTRUCTIONS TO THE PARTICIPANT

There are 5 sections to this questionnaire, please answer all questions with a cross and provide additional information where required.

SECTION A

BIOGRAPHICAL INFORMATION

	BIOGRAI III CALI IN ORMATION	
DATE OF BIRTH:	AGE: 18-25yrs 26-35yrs 36-45yrs	
GENDER:	DEPARTMENT:	
NUMBER OF YEARS WORKING IN A NOISY AREA:		
SECTION B		
FAMILY HISTORY		
1. Does any member of yo	our family have a hearing disorder and/ or wears a hearing aid?	
Yes	No	
If yes, please describe:		

SECTION C

MEDICAL HISTORY

1. Do you, or have you had any med etc.	lical co	ondition	s? For 6	exampl	e: German measles, meningitis
Yes		No			
If yes, please state the nature and du	ıration	of the c	onditio	n:	
2. Are you currently on any form of	medic	ation?			
Yes		No			
If yes, please state:					
a) The name of the drugs taken: b) Dosage taken:		_			
c) Frequency of consumption: 1	2	3	4	< 4	times a day
d) Duration of treatment: <1	2		<3 m	nonths	
3. Have you been hospitalized or recurrence surgical conditions?	ceived	treatme	nt for a	prolon	ged period for any medical or
Yes		No			
If yes, please describe:					
SECTION D					
<u>AUDIOLOGICAL HISTORY</u>					
1. Have you previously had your he	aring to	ested?			
Yes	No				
If yes, please answer the following:					
a) When was your hearing tested? _					
b) What were the results of the tests	?				

2. Do you experience difficulty hearing?
Yes No
If yes, please describe:
3. Do you experience pain in your ears?
Yes No
If yes, please describe:
4. Do you notice any discharge from your ears?
Yes No
If yes, please describe:
5. Do you experience difficulty listening in the presence of background noise? Yes No
If yes, please describe: 6. Do you experience dizzy spells?
Yes No
If yes, please describe:
7. Do you experience ringing or buzzing sounds in you ears?
Yes No
If yes, please describe:
8. Have you experienced any head or ear trauma? Yes No
If yes, please describe:

9. Do loud noises cause you any discomfort?			
Yes No			
If yes, please describe:			
10. Do you have difficulty listening to male or female voices?			
No Male Female			
SECTION E			
OCCUPATIONAL HISTORY			
1. How long have you worked in this particular type of industry?			
2. How many days a week do you work?			
3. How many hours a day do you work?			
4. How would you describe the noise level at work? Soft Comfortable Loud Very loud			
5. Does this noise level cause you any discomfort while at work?			
Yes No			
If yes, please describe:			
6. What type of equipment does your job require you to work with?			
7. Do you use ear protection at work?			
Yes No			

If yes, please answer the following:
a) Do you wear ear protection on a daily basis?
b) Do you wear ear protection whenever you are in a noisy environment?
c) On average, how many hours a day do you use the ear protection?
SECTION F
RECREATIONAL HISTORY
1. Do you participate in any hobbies or sports that involve exposure to very loud sounds?
Yes No
If yes, please describe:
2. How many months or years have you engaged in this hobby?
3. Do you use ear protection when engaging in this hobby/ sport?
No Yes
4. Do you frequently use walkmans, mp3s and/ or iPods?
No Yes
If yes, please answer the following:
a) On average, how many hours a day do you use it?
b) Would you describe the volume level to be?
Soft Moderately Loud Loud
5. Do you smoke?
No Yes

GENERAL

Please indicate any information that you may regard	as relevant but that has not been covered:
The researcher would like to inform you that the infand selected individuals will be required to undergo	
Thank you for your time and willingness to participa	te in this research project.
Tarryn Marisca Reddy	
Audiologist	
S. Panday Supervisor	C.D. Govender Supervisor

INYUVESI YEKWA-ZULU NATAL UPHIKO LWEZOKUCWANINGWA KWEZOKUZWA

NGEMISHINI AUDIOLOGY

IMIBUZO YEMINININGWANE NGOMLANDO WEMPILO YAKHO

Siyakubingelela Mhlanganyeli

- Lolu ucwaningo elokuthola ukuthi kunesidingo noma kubalulekile yini ukufakwa kwama (DPOAE) esetshenziswa ukuhlola isimo sokuzwa ko muntu, ohlweni lokuhlolwa kwesimo sempilo olwenziwa minyaka yonke. Lokhu kungenzelwa ukuhlola ukwehla kwezinga lokuzwa okwenziwa ukusebenza endaweni enomsindo kubasebenzi basembonini yeziphuzo.
- Umcwaningi uthanda ukukunikeza isiqiniseko sokuthi yonke imiphumela yocwaningo izakugcinwa iyimfihlo nokuthi luzokweziwa ngokucophelela nokunakekela okukhulu ukuphepha kuyo yonke imikhakha yocwaningo.

IMIYALELO KUMHLANGANYELI

Kunezigaba ezinhlanu kuleliphepha lemibuzo, uyacelwa ukuba uphendule yonke imibuzo ngokushaya uphawu lwesiphambano nokuba unikeze neminye imininingwane yokwengezelela lapho kunesidingo salokhu.

ISIGABA A

IMINININGWANE YOKUZALWA

USUKU LOKU	ZALWA:
IMINYAKA:	18-25yrs 26-35yrs 36-45yrs
UBULILI:	
UMNYANGO (OSEBENZA NGAPHANSI KWAWO:
IMINYAKA OY	ISEBENZILE ENDAWENI ENOMSINDO:

ISIGABA B

UMLANDO WOMNDENI

1. Kungabe ukhona yini emndenini wakho onenkinga yokuzwa noma osebenzisa izinsiz kuzwa ezifakwa ezindlebeni?
YEBO CHA
Uma yebo, sicela uchaze:
<u>ISIGABA C</u>
IMINININGWANE YOKUGULA
1. Kungabe uphethwe, noma wake waphathwa yilezi zifo? Njenge: Isifo sofuba – iTB, iGerma measles, isifo solwembu lobuchopho – imeningitis njl.
YEBO CHA
Uma yebo, sicela uchaze ubunjalo baso nesikhathi esisithathile sikugulisa:
2. Njengamanje kungabe kukhona yini imithi oyidlayo?
YEBO CHA
Uma yebo, sicela uchaze:
a) Igama lomuthi noma ngamaphilisi owadlayo
b) Uwuphuza isikalo esingakanani ngelanga :
c) Uphuzwa izikhathi ezingaki ngosuku: 1. 2. 3. 4 < 4 kane ngosuku
d) Isikhathi sokwelashwa singu: <1 2 <3 izinyanga
3. Uke walaliswa esibhedlela noma welashwa isikhathi eside ngokugula noma ngokuhlinzwa? YEBO CHA
Uma yebo, sicela uchaze:

ISIGABA D

<u>UMLANDO NGOKUCWANINGWA NGOKUZWA NGEMISHINI – AUDIOLOGY</u>

1. Uke wahlolwa ukuzwa ezindlebeni ngemishini phambilini?
YEBO CHA
Uma yebo, sicela uchaze lokhu okulandelayo:
a) Wahlolwa nini ukuzwa kwakho?
b) Yaba yini noma yathini imiphumela yalokhu kuhlolwa?
2. Kungabe kukhona izinkinga zokuzwa ohlangabezana nazo?
YEBO CHA
Uma yebo, sicela uchaze:
3. Kungabe kukhona ubuhlungu obuzwayo ezindlebeni zakho?
YEBO CHA
Uma yebo, sicela uchaze:
4. Lukhona yini uketshezi oye ulubone luphuma ezindlebeni zakho?
YEBO CHA
Uma yebo, sicela uchaze:
5. Kungabe ubanayo inkinga yokuzwa / yokulalela lapho kunomsindo?
YEBO CHA
Uma yebo, sicela uchaze:
6. Kungabe ubanazo izikhawu zokuzizwa unenzululwane na?
YEBO CHA
Uma yebo, sicela uchaze:
7. Kungabe kukhona imisindo yokukhala kwezinsimbi noma efana

neyezinyosi ezindizayo oyizwa ezindlebeni zakho?
YEBO CHA
Uma yebo, sicela uchaze:
8. Uke waba nokulimala okushaqisayo ekhanda noma yisendlebeni?
YEBO CHA
Uma yebo, sicela uchaze:
9. Kungabe imisindo emikhulu iyakuhlukumeza ikubangele ukungabi nakho ukunethezeka?
YEBO CHA
Uma yebo, sicela uchaze:
10. Kungabe ubanayo yini inkinga yokulalela amazwi abesilisa noma ngawabesifazane na?
Cha Abesilisa Abesifazane
<u>ISIGABA E</u>
IMINININGWANE ENGUMLANDO NGOKUSEBENZA KWAKHO
1. Usunesikhathi esingakanani usebenza kuloluhlobo lomsebenzi / lwenkampani?
2. Usebenza izinsuku ezingaki ngesonto?
3. Usebenza amahora / ama-awa amangaki ngosuku?
4. Ungalichaza uthi linjani izinga lomsindo emsebenzini wakho? Phansi Liyamukeleka Likhulu Likhulu Kakhulu
5. Kungabe lelizinga lomsindo likwenza ungakhululeki lapho usemsebenzini? YEBO CHA Uma yebo, sicela uchaze:

ukuba usebenze ngazo?
7. Kungabe uyakufaka okokuvikela izindlebe emsebenzini? YEBO CHA
Uma yebo, sicela uphendule lokhu okulandelayo:
a) Kungabe ukugqoka nsuku zonke okokuvikela izindlebe?
b) Kungabe uyakugqoka okokuvikela izindlebe lapho usendaweni enomsind
c) Ngokwesilinganiso, mangaki ama-awa ngosuku osebenzisa ngawo okokuviko izindlebe?
<u>ISIGABA F</u>
UMLANDO WAKHO NGEZOKUCHITHA ISIZUNGU NEZOKUZIVUSELELA
1. Kungabe kukhona ezikaqedisizungu noma ezemidlalo ozenzayo kumbe ohlanganyela ku ezikwenza ubesendaweni enomsindo omkhulu?
YEBO CHA
Uma yebo, sicela uchaze:
2. Usunezinyanga noma iminyaka emingaki uchitha isizungu ngalendlela?
3. Kungabe uyakufaka okokuvikela izindlebe lapho uchitha isizungu ngalokhu noma udlala lomdlalo?
YEBO CHA
4. Kungabe uyazisebenzisa ngokuvama lezi zidlala-mculo: walkmans, mp3s ne / noi iPods?
YEBO CHA
Uma yebo, sicela uphendule lokhu okulandelayo:
a) Ngokwesilinganiso, mangaki ama-awa ngosuku okusebenzisa ngawo?

b) Ungachaza isilinganiso sezinga lomsindo ukuthi liyaye libe?
Phansi / Pholile Umsindo oPhakathi nendawo OMkhulu
5. Ingaba uyabhema?
YEBO CHA
<u>OKWEJWAYELEKILE</u>
Uyacelwa ukuba uthasisele eminye imininingwane okholwa wukuthi ibalulekile kepha engabalulwanga lapha:
Umcwaningi uthanda ukukubikela ukuthi imininingwane oyinikezile izocwaningisiswa kuhlungwe ngayo labo okuzodingeka ukuba bakhethelwe ukuyohlolwa benziwe ucwaningo olugcwele ngemishini. Njengoba usukhombisile isifiso sakho sokuhlanganyela ohlelweni lwaloluhlobo kulolucwaningo, kuzoxhunyanwa nawe ngokuba uthintwe enombolweni oyinikeze ngenhla yocingo.
Siyabonga ngokusebenzisa isikhathi sakho nangokukhombisa ukuthanda ukuhlanganyela kuloluhlelo lwalolucwaningo.
Tarryn Marisca Reddy Umcwaningi ngemishini Audiologist
S. Panday Umphathi C.D. Govender Umphathi



APPENDIX G

Ear Institute, 1240 Webb Str. Queenswood Pretoria. Tel: (012) 333-3131 Fax: (012) 333-2298

H.A.S.S. Industrial (Pty) Ltd

Certificate of Calibration No. E SN644629/12

This certificate is issued in accordance with the conditions for calibration of the instrument as described by the manufacturer or the South African Bureau of Standards (SANS 10154-1; 10154-2). It is a correct record of measurements made. Copyright protected. This certificate may not be reproduced, except with the prior written approval of H.A.S.S. Industrial (Pty) Ltd.

Calibrated for:

University of Kwazulu Natal

Block E3, 6th Floor Room E3 616 University Road Westville

Calibration of:

AT235

Manufacturer:

Interacoustics

Serial Number:

SN644629

Calibration procedure:

Complete calibration: Tympanometer (AT235).

Complete probe, reflex and pressure calibration as described in the manufacturer's specification. Earphones (TDH 39 Right s/n C 334265;

Left s/n C334231)

Traceability:

The calibration was performed using instruments traceable to national

standards.

Date of Calibration:

2012-05-29

Cal. Due Date:

2013-05-29

Results:

The instrument complies with the requirements for use as specified by

the manufacturer.

Remarks:

None

Calibrated by:

Retief Roos

Signature

NOTE: The values in this certificate are correct at the time of calibration. Subsequently the accuracy will depend on such factors as the care exercised in the handling and use of the instrument and the frequency of use. Re-calibration should be performed annually to ensure that the instrument's accuracy remains within the desired limits.

LE

Participa	ant Number:			Date:	
0	toscopic Exam	ination:			
	NAD	Perforated	Impacted	Otitis	Other
		TM	Wax	Externa	
I	RE				

Tympanometry:											
	_			Middle							
	Type	Earcanal	Static	Ear	Comment/ Other						
		Volume	Compliance	Pressure							
RE											
LE											

Pure Tone Audiogram:											
	500Hz	1000Hz	2000Hz	3000Hz	4000Hz	6000Hz	8000Hz				
RE											
LE											

Duration of Test: ____min ____sec

DP-Gram I:										
	Test #	750Hz	1000Hz	2000Hz	3000Hz	4000Hz	6000Hz	8000Hz		
RE										
LE										

DP-G	ram II:							
	Test #	750Hz	1000Hz	2000Hz	3000Hz	4000Hz	6000Hz	8000Hz
RE								
LE								

DP-G	DP-Gram III:										
	Test #	750Hz	1000Hz	2000Hz	3000Hz	4000Hz	6000Hz	8000Hz			
RE											
LE											



Ck 94/05783/23

Tel: Fax:

031-7090710 031-7028778

Email:

info@stanyersa.com

Website:

www.stanyersa.com

APPENDIX I

P. O. Box 273, Gillitts, 3603 No. 2 Gilro Park 34 Gillitts Road Pinetown, 3610

Certificate of Air-Conduction Calibration

Company Name & Address	
LIEC 0.11	Certificate no. 511432541
8 BI ADOLOPIE DUE	Pre- Calibration Microphone
	୩५୦ Post Calibration Microphone

Frequ	uency	Li	nits	Actu	al Freq	uency	SPL	Tolerar	nce	Actual SPL			
in H	lertz	in b	lertz			at 70 dB		Į.	Left		Right		
2:	50	242	-258	-			94-100						
5(00	485	-515	500		8	80,5-86,5		33 : 1		81.9		
10	1000		970-1030		1000		74,5-80,5			~~~	1-6	7. {	ζ~ <u>ο</u>
20	00	1940	-2060		2000 76-82 79.6		76-82		0	79.4			
30	00	2910	-3090		3000 78,5-84,5 81-9		78,5-84,5		9	Q	1+4		
40	000 3880-412		3880-4120		ショウ		79-85			\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Li	ς;	2- 🤝
60	6000		-6180	6000		81-91			86.0		56 0		
8000		7760-8240		8000		80,5-90,5			86-1		ط دکا		
ATT.AT 4000 HZ	90	85	80	75	70	65	60	55	50	45	40	35	30
	1024	97-6	A7-5'	874	82.6	77-5	77-1	67.4	525	57-5	52.20	47-4	449

Calibration Equipment (G)

Calibration Equipment (P)

Quest Quest CRL224 Quest B&K 4153 ACO Toptronic B&K	1800 Sound Level Meter OB-300 Octave Filter 1/2" Microphone CA 22 Calibrator Artificial Ear 7013 Microphone T1504 Multimeter 4930 Artificial Mastoid	HP2030020 HV1070028 900028 J1070023 1601611 118221 845y10 842289	Quest Quest Quest Artificial Ear B & K L & D Multi-meter Toptronic B-71 Bone Vibrator 500g	1800 Sound Level Meter CA -12B Sound Calibrator OB 100 Octave Filter L & D AEC 101 4936 ½ "Microphone 2559 ½ "Pressure Microphone T1504 Medi PK 1A Artificial Ear Weight	HP1070017 U2030844 HW6120027 0189 2064317 32141 0520 52107A
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Certificate numbers: (G) 2011-0721-22-20-19 & (P) 2011-0775-73-74

The air conduction calibration of the above instrument has been checked in accordance with the SANS 10154-1:2004 and has found to be in agreement with the recommended limits. The Certification of the calibration is valid for a period of one year (subject to the expectations given in SANS 10154-1: 2004) While every endeavor is made to ensure this certificate is accurate, Stanyer Electroserve cc or its employees shall in no way be liable for any errors, whether in fact or opinion.

	Audiometer	Left Earphone	Right Earphone		
Make	INTERCONTROC	Telephonic	Telephonic		
Model	21524	TDH 39P	TDH 39P		
Serial no.	165 407	7-11-11	521915		

Calibration Date: 25-15-11.

Calibration Due:

21-10-12

Calibrated by Mr. G.D. Stanyer / Mr. P.T. Stanyer

Signature:

528

(GDS) Certified in Noise Measurement and Calibration Department of Manpower Ref: 34/2/8/27/12 (PTS) Certified in Calibration and Testing of Audio Equipment, Cape Peninsula University of Technology Ref: 208211926 Member: Mr. G.D. Stanyer



RESEARCH OFFICE
BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
Westville Campus
Govan Mbeki Building
Private Bag X 54001
Durban
4000

KwaZulu-Natal, SOUTH AFRICA Tel: 27 31 2604769 - Fax: 27 31 260-4609

Email: <u>BREC@ukzn.ac.za</u>
Website: http://research.ukzn.ac.za/ResearchEthics/BiomedicalResearchEthics.aspx

16 August 2011

Ms TM Reddy Discipline of Audiology, Westville Campus University of KwaZulu-Natal

Dear Ms Reddy

PROTOCOL: The feasibility of including distortion product otoacoustic emissions in annual medical surveillance for the identification of noise-induced hearing loss in a group of workers in the food and beverage industry. REF: BE181/11

EXPEDITED APPLICATION

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 16 September 2011.

The study was provisionally approved pending appropriate responses to queries raised. Your responses dated 13 August 2012 to queries raised on 25 October 2011have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval and may begin as from 16 August 2012.

This approval is valid for one year from 16 August 2012. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2004), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at http://research.ukzn.ac.za/Research-Ethics/Blomedical-Research-Ethics.aspx.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be RATIFIED by a full Committee at its next meeting taking place on 11 September 2012.

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

Professor D.R Wassenaar Chair: Biomedical Research Ethics Committee

APPENDIX K

28/07/2012

The Biomedical Research Ethics Committee

Westville Campus

Govan Mbeki Building

Private Bag X54001

Durban, 4000

Re: Permission to conduct research at ABI Premier and ABI Phoenix

Research to be conducted by Miss Tarryn M. Reddy, a post-graduate student at the University of KwaZulu-Natal (Westville Campus), which will include Distortion Product Otoacoustic Emissions in periodic hearing screening for the early identification of noise-induced hearing loss in a group of employees in the food and beverage manufacturing industry.

We are aware that Miss. Reddy intends to conduct her research by the following methods:

- Approaching our employees to participate voluntarily in the study.
- · Completion of a case history questionnaire by all participating employees.
- Administration of periodic audiometric screening (otoscopy, tympanometry and pure tone audiometry) as well as distortion product otoacoustic emissions.
- Periodic audiometric screening will be conducted during work hours.
- Presenting and explaining the results of all test findings and recommendations to the participating employees and our Occupational hygienist/nurse.

Permission are herewith granted to Miss Reddy to conduct the above mentioned research study at the premises as per above.

Should you have any queries or concerns, please feel free to contact my office.

Yours sincerely.

Chris Mathee

SC Risk Manager

 $031 - 508\ 2023$

083 263 3333

0866492919

CC Melissa O'Reilly

UNIVERSITY OF KWA-ZULU NATAL DISCIPLINE OF AUDIOLOGY

CONSENT TO PARTICIPATE IN THE RESEARCH STUDY

Dear Participant,

The focus of the study is to determine the feasibility of including distortion product otoacoustic emissions in the annual medical surveillance test battery for the identification of noise-induced hearing loss in a group of workers in the beverage manufacturing industry.

You have been asked to participate in the above mentioned research study. Your participation in this research study is voluntary and you are not obligated to participate. If you choose to participate in this study you will receive a hearing evaluation. You are required to fill out a case history questionnaire before testing begins. Your hearing evaluation will include the following procedures: Otoscopic examination to ensure that you do not have excessive wax in your outer ear or a hole in your eardrum, Tympanometry to ensure that your middle ear is free of infection, Pure Tone Audiometry to find the softest sound you can hear at different pitches, and Otoacoustic Emissions Testing to assess your inner ear structures. The whole testing procedure will not last longer than 15 minutes. If further hearing evaluations or management is required, the appropriate referrals will be made. Refusal to participate in this research study will not entail any adverse consequences.

You have been informed about the study by the researcher and are fully aware of the potential prospective outcomes of the study.

You may contact S. Panday at the University of KwaZulu-Natal, Audiology Department, on 031-2607438, should you have queries regarding the research study. You may contact the University of KwaZulu-Natal (Westville campus) biomedical research department on 031-260 1074, should you have queries regarding your rights as a research participant

Should you agree to participate in this research study, you will be required to sign this document as proof of your agreement to participate. Thereafter, you will receive an information document, which is a written summary of the research study.

The research study, including	the above information, has been described to me verbally.
I	agree to participate in the above mentioned research study. I
understand what my involven	nent in this study entails and I voluntarily agree to participate.
Signature of participant	Date

<u>IYUNIVESITHI YE KWAZULU – NATAL</u> <u>UPHIKO LWEZOKUZWA NGEMISHINI AUDIOLOGY</u>

IPHEPHA LEMVUME YOKUHLANGANYELA KULOLUCWANINGO

Mhlanganyeli Othandekayo,

Lolu ucwaningo elokuthola ukuthi kunesidingo noma kubalulekile yini ukufakwa kwama (DPOAE) esetshenziswa ukuhlola isimo sokuzwa ko muntu, ohlweni lokuhlolwa kwesimo sempilo olwenziwa minyaka yonke. Lokhu kungenzelwa ukuhlola ukwehla kwezinga lokuzwa okwenziwa ukusebenza endaweni enomsindo kubasebenzi basembonini yeziphuzo.

Uceliwe ukuhlanganyela kulolucwaningo olubalulwe ngenhla. Ukuhlanganyela kwakho kulo kungokuvolontiya kuphela kawuphoqelekile kukho. Ukwenqaba kwakho ukuhlanganyela kulo kakusoze kwakuholela ezimweni ezimbi noma ezinzima. Uma uvuma ukuhlanganyela kulolucwaningo uzothola ukuhlolwa mahhala ukusebenza nokuzwa kwezindlebe zakho. Uzakulindeleka ukuba ugcwalise ipheshana lemibuzo elingomlando wokuzwa kwakho ngaphambi kokuqalwa kocwaningo. Ukucwaningwa kwakho kuzakuhlanganisa nalenqubo elandelayo: Ukuhlolwa ngezipopolo ezindlebeni ukuqinisekisa ukuthi kawunazo izigonogono ngokweqile kwingaphandle lazo nokuthi kawunazimbobo ezidaleke kwingaphakathi lesitho sokuzwa sakho i-eardrum. Ucwaningo lokuzwa iTympanometry olwenzelwa ukuqinisekisa ukuthi ingaphakathi lendlebe yakho kalihlaselwe ngamagciwane asakhele kulo aze aliwohloze, Ucwaningo lokuzwa imisindo eYiyo iPure Tone Audiometry ukuthola umsindo omncane kakhulu nopholile izindlebe zakho ezingawuzwa emazingeni ehlukene omsindo, ne Otoacoustic Emissions Testing ukucwaninga ukusebenza kwezinhlaka zengaphakathi lezindlebe zakho. Inqubo yonke yalolucwaningo kayisoze ithathe` isikhathi esingaphezulu kwehora. Uma kunesidingo sokwenziwa olunye ucwaningo noma ukuphathwa, uyawube sewudluliselwa eminyangweni efanelekile ukwenziwa lokho kuyo.

Ubikelwe ngalo ngumcwaningi futhi unolwazi olugcwele ngemiphumela engabawusizo kuwe ngalo.

Ungathintana no S. Panday noma u C.D. Govender eYunivesithi ye KwaZulu – Natal, Audiology Department, ku 031 – 260 7438, uma unemibuzo ongathanda ukuyibuza ngocwaningo.

Ungaxhumana futhi neYunivesithi ye KwaZulu – Natal (Westville Campus) uphiko lomnyango wezokucwaninga ngokuhluma kwemithi <u>ibiomedical research department</u> ku 031 – 260 1074 lapho unemibuzo ngamalungelo akho okuba ngumhlanganyeli kulolucwaningo.

Uma uvuma ukuhlanganyela kulolucwaningo, kuzawudingeka ukuba usayine lelipheshana njengesiqinisekiso sakho sokuvuma ukuhlanganyela kulo. Ngemuva kwalokhu uyobe usunikezwa ibhuku lemininingwane, eliyingxenye yesamba sokulotshwe ngalolucwaningo.

Uphenyo locwaningo, kuhlangene nalemininingwa	nne engenhla, ngichazelwe ngakho ngomlomo.
Mina ngiyavum ngenhla. Ngiqonda ngokugcwele ukuthi lung kuzongilethelani futhi ngiyavuma ngokwami ukuv	
Kusayina uMhlanganyeli	Usuku
Kusayina uFakazi	Usuku

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INSTRUCTIONS TO PARTICIPANTS

Otoscopic Examination:

Please sit still and do not make any sudden movements as I will be placing the speculum into the ear. The reason for conducting an otoscopic examination is to identify any abnormalities of the outer ear and the surrounding areas.

<u>Tympanometry:</u>

Please sit still and do not make any sudden movements as it will affect the results obtained. Kindly refrain from chewing or swallowing during the test procedure. No physical response is required from you during the test.

Pure Tone Audiometry:

Kindly remove your earrings, glasses and hair ornaments, as well as switch of your cellphone. The objective of the test is to determine the softest sound that you are able to hear. Different tones will be heard in one ear at a time through the earphones, ranging from loud sounds to soft sounds. A physical response is required each time a sound is heard. The response must cease as soon as the tone is no longer heard.

<u>Distortion Product Otoacoustic Emission Testing:</u>

Kindly sit still and do not make any sudden movements as it will affect the results obtained. Kindly refrain from chewing or swallowing during the test procedure. Several different tones will be heard. No physical response is required from you during the test.

<u>IYUNIVESITHI YE KWAZULU – NATAL</u>

UPHIKO LWEZOKUHLOLWA UKUZWA NGEMISHINI AUDIOLOGY

IMIYALELO KUMHLANGANYELI

Uphenyo ngezipopolo, <u>Otoscopic examination</u>: Inhloso yophenyo ngezipopolo ukuthola noma yikuphi ukungakheki ngendlela kwengosi engaphezulu, i-auricle noma ingaphandle lomgudu wezokuzwa ukuthola izimpawu zokushaqeka noma ukuhlaselwa ngamagciwane kanye nokususa okuvimbile noma ukuthola ukufadalala komgudu wokuzwa (Gelfand, 1997).

Ucwaningo lokuzwa <u>iTympanometry</u>: lwenzelwa ukuphenya nokukala ukunyakaza kwengaphakathi lendlebe lapho ingcindezi yomoya ishintshwa kwingaphandle lomgudu wendlebe isuswa ku +200daPA iyiswe ku – 400daPA. Lusiza ukuphenya isimo sengaphakathi lendlebe nokukhombisa ubukhona benkinga. (Gelfand, 1997).

Uphenyo lwemisindo <u>i-Acoustic reflex testing</u>: Lolucwaningo luhlanganisa ukuphenywa kwesitho esingaphakathi kwendlebe ukusebenza kwaso lapho sihlangabezana nomsindo omkhulu. Kuchazwe ngokuthi kudingeka ukunyakaza okuncane ukwenza ukuba isitho sokuzwa sengaphakathi lendlebe sishwankane (Bess & Humes, 2003). Imiphumela yalolucwaningo isetshenziselwa ukuletha izinguquko ezitholakala ngobukhona, ukungabibikho noma isimo esikhushuliwe sokuphendula okutholwe ocwaningweni kungathathelwa ekutheni kuphuma ekusebenzeni kwengaphakathi lendlebe, ingaphakathi layo icochlea noma isimo sokusebenza kwezitho zayo iretro-cochlea pathology.

UMsindo oYiwo <u>iPure tone Audiometry</u>: Lokhu kwenzelwa ukuthola amazinga ehlukene ezokuzwa.

IZPZMMNKPZZ (<u>Distortion Product Otoacoustic Emissions</u>) iyakwenziwa ukuze kufinyelelwe futhi kutholakale nokusebenza kwengaphandle lezingcezu zezinwele.

UNIVERSITY OF KWA-ZULU NATAL DISCIPLINE OF AUDIOLOGY

INFORMATION DOCUMENT

To whom it may concern,

I, Tarryn M. Reddy, under the supervision of Ms. S. Panday and Mr. C.D. Govender, am conducting research on the effects of noise on hearing. The focus of the study is to assess the feasibility of including distortion product otoacoustic emissions in the annual medical surveillance test battery for the identification of noise-induced hearing loss in a group of workers in the beverage manufacturing industry.

I am asking if you are willing to participate in this research study. If you choose to participate in this study you will receive a hearing evaluation. You are required to fill out a case history questionnaire before testing begins. Your hearing evaluation will include the following procedures: Otoscopic examination to ensure that you do not have excessive wax in your outer ear or a hole in your eardrum, Tympanometry to ensure that your middle ear is free of infection, Pure Tone Audiometry to find the softest sound you can hear at different pitches, and Otoacoustic Emissions Testing to assess your inner ear structures. The whole testing procedure will not last longer than 15 minutes. If further hearing evaluations or management is required, the appropriate referrals will be made.

You can choose if you would like to take part in this study or not. You will not be required to pay for any services and can discontinue at any time you wish to. You are assured that this is a risk-free and harmless procedure as it consists of hearing test procedures that are used in everyday practice.

Your identity and results are strictly confidential and will be maintained during this study.

If you have any further enquiries, please feel free to contact the researcher.

Yours sincerely,	
Tarryn Reddy Audiologist	
S. Panday Supervisor	C. D. Govender Supervisor

<u>IYUNIVESITHI YE KWAZULU – NATAL</u>

<u>UPHIKO LWEZOKUHLOLWA UKUZWA NGEMISHINI AUDIOLOGY</u>

IBHUKWANA LEMINININGWANE

Kwebhekiswe kuye,

Mina, Tarryn M. Reddy, ngaphansi kokubhekelwa ngabaphathi bami oNksz S. Panday noMnuz C.D. Govender, ngenza ucwaningo ngomthelela womsindo ekuzweni. Lolu ucwaningo elokuthola ukuthi kunesidingo noma kubalulekile yini ukufakwa kwama (DPOAE) esetshenziswa ukuhlola isimo sokuzwa ko muntu, ohlweni lokuhlolwa kwesimo sempilo olwenziwa minyaka yonke. Lokhu kungenzelwa ukuhlola ukwehla kwezinga lokuzwa okwenziwa ukusebenza endaweni enomsindo kubasebenzi basembonini yeziphuzo.

Ngithanda ukwazi ukuthi uyathanda na ukuhlanganayela kulolucwaningo. Uma uvuma ukuhlanganyela kulolucwaningo uzothola ukuhlolwa mahhala ukusebenza nokuzwa kwezindlebe zakho. Uzakulindeleka ukuba ugcwalise ipheshana lemibuzo elingomlando wokuzwa kwakho ngaphambi kokuqalwa kocwaningo. Ukucwaningwa kwakho kuzakuhlanganisa nalenqubo elandelayo: Ukuhlolwa ngezipopolo ezindlebeni ukuqinisekisa ukuthi kawunazo izigonogono ngokweqile kwingaphandle lazo nokuthi kawunazimbobo ezidaleke kwingaphakathi lesitho sokuzwa sakho i-eardrum. Ucwaningo lokuzwa iTympanometry olwenzelwa ukuqinisekisa ukuthi ingaphakathi lendlebe yakho kalihlaselwe ngamagciwane asakhele kulo aze aliwohloze, Ucwaningo lokuzwa imisindo eYiyo iPure Tone Audiometry ukuthola umsindo omncane kakhulu nopholile izindlebe zakho ezingawuzwa emazingeni ehlukene omsindo, ne Otoacoustic Emissions Testing ukucwaninga ukusebenza kwezinhlaka zengaphakathi lezindlebe zakho. Inqubo yonke yalolucwaningo kayisoze ithathe` isikhathi esingaphezulu kwehora. Uma kunesidingo sokwenziwa olunye ucwaningo noma ukuphathwa, uyawube sewudluliselwa eminyangweni efanelekile ukwenziwa lokho kuyo. Ungazikhethela ngokwakho ukuthi uyafuna na ukuhlanganyela kulolucwaningo noma cha. Kawuzukukhokhiswa lutho ngokuzawukwenziwa kulo futhi ungashiya nganoma yisiphi isikhathi uma usufuna ukwenze njalo. Uyaqinisekiswa ukuthi lolucwaningo kalunabungozi nakancane njengoba lwenziwa ngengubo efanayo nelandelwa mihlayonke ezikhungweni zokwenza lomsebenzi eziphezulu.

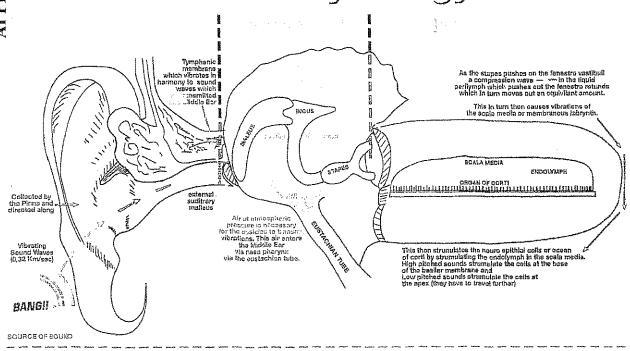
Ibizo, imininingwane yakho nemiphumela yalolucwaningo kuyakugcinwa kuyimfihlo futhi kuyakulondolozwa kulo lonke lolucwaningo.

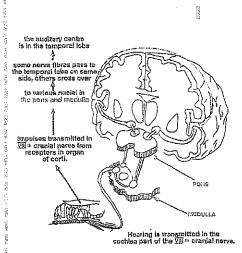
Uma kukhona eminye imibuzo ongathanda ukuyibuza, ukhululekile ukwenzenjalo ngokuxhumana nomcwaningi.

Ozithobayo,						
Tarryn Marisca Reddy	S. Panday	C.D.Govender				
Umcwaningi ngemishini	Umphathi	Umphathi				
Audiologist						

APPENDIX R

The Physiology of Hearing





According to the South African National Standard - At the lowest recorded intensity of 113d0A a parson should not be exposed for more than 1 minute without bearing protection

(HT)* VOVUESLA NOSSE LEVEL (131 dBA)

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SOUND	dB SPL
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Jet plane	140
Gunshot blast	130
Car horn	120
Pneumatic drill	110
Power tools	100
Subway	90
Nolsy restaurant	80
Busy traffic	75
Conversational speech	66
Average home	55
Library	40
Soft whisper	30

DISCIPLINE OF AUDIOLOGY SCHOOL OF HEALTH SCIENCES

Tel: 031 260 7438/8986 Fax: 031 260 7622

E-mail: sitholep2@ukzn.ac.za E-mail: naidoor1@ukzn.ac.za



Dear Dr. Joseph

APPENDIX S

Request to lend our Masters Student equipment for official usage

We would like to request for your permission to allow our Masters student, Ms. Tarryn Reddy to use the following equipment to conduct her research study. The equipment will be used at ABI in Phoenix from 29/08/2012 to 14/09/2012. She will take the equipment today and keep them at her home until her data collection is completed on 14/09/2012. She will be transporting the equipment between her home and ABI during the data collection.

1 X AT235 Impedance Audiometer Asset No: 237443

1 X Sound level Meter Asset No: 237697 1 X OAE Screener Asset No: 0004656 Extension cord with no Asset Number

Her Physical Address is:

9 First Avenue ISipingo Beach Durban 4110

We hope this request will receive your consideration

Yours sincerely,

Blessing Jili

Technician X7800

DR, L. Joseph

Mcademic Leader - Discipline of Audiology

X7625

28 August 2012